Motion in Miami
GLOBAL SYMPOSIUM ON
Motion Preservation Technology 8th Annual Meeting
MAY 6 - 9, 2008 • MIAMI BEACH, FL USA
NINTH ANNUAL GLOBAL SYMPOSIUM ON

Motion Preservation Technology

APRIL 28 - MAY 1, 2009 | LONDON, ENGLAND

WWW.SPINEARTHROPLASTY.ORG | EXCEL LONDON | THE INTERNATIONAL EXHIBITION AND CONFERENCE CENTER
# Table of Contents

## SAS Information
- Welcome Message from SAS President 4
- Message from the Incoming SAS President 5
- Letter from Program Committee Chair 6
- Welcome to Miami from Local Host SAS8 6
- SAS Board of Directors 7
- SAS8 Program Committees 8
- SAS Meeting Locations 9
- About SAS 10
- SAS Committees 11
- SAS Membership 13

## Meeting Highlights
- Presidential Guest Speaker 14
- Educational Information 15
- Industry Innovations Program / Taped Live Surgeries 19

## Meeting-At-A-Glance
- Meeting-At-A-Glance 21

## Exhibit Information
- SAS8 Partners 25
- Exhibit Hall Floor Plan 26
- SAS8 Exhibitor List 28
- SAS8 Exhibitor Directory 30
- Exhibitor Ads 40
- Industry Workshops 57

## Hotels, Transportation and Tours
- Hotels, Transportation and Tours 60

## Official Scientific Program Schedule
- Official Scientific Program Schedule 66

## Abstract Papers
- Tuesday, May 6th 83
- Wednesday, May 7th 88
- Thursday, May 8th 106
- Friday, May 9th 129

## Disclosure Information
- Disclosure Information 147

## Posters
- Poster Presentations 150

## Author’s Index
- Author’s Index 167
Dear Colleagues,

Welcome to Miami!

This has been an exciting year of growth for the SAS. We now have chapters in Korea and China and we hope to see our next chapter form in South and Central America. We have entered into an agreement with AOSpine. Our membership continues to grow, we have applied to participate in the AMA House of Delegates, the SAS Journal is offering new and exciting issues and the SAS8 is going to break all attendance records.

The SAS has not held a meeting in the U.S. since 2005. With the new devices on the market, the continual movement of emerging technologies and the current FDA and CMS issues looming over our heads this will be the most important SAS meeting in our history.

The Program Committee of 46 members from around the world headed by Henry Halm, MD, PhD, Overall Program Chair; Hans-Joachim Wilke, MD, PhD, Basic Science Chair; and Rick Guyer, MD, Clinical Science Chair was guided by incoming president Karin Büttner-Janz, MD, PhD has developed a strong academic program to include new technologies, biologics, biomechanics and MIS procedures—just to mention a few. We offer opportunities for open exchange and debates of scientific experiences as well as workshops and lectures led by the leading pioneers in the field of motion preservation. And, we have the largest number of exhibiting companies and posters available for your review in the exhibit hall.

Make sure to attend the Indications Symposium, Tuesday afternoon from 2-3:15 p.m. followed by the MIS papers. This debate format will be covering: Is There Sufficient Biomechanical Evidence That Artificial Disc Replacement Adjacent Segment Disease; Myth or Truth?; Hybrid or Two-Level TDR vs Two Level Fusion; Three Level TDR vs Dynamic Stabilization for a 25-year-old and Why Give Up Single Level ACF vs ADR? Also of great interest will be the Wednesday afternoon session titled Basic Problems and Provocative Solutions.

Miami, America’s southernmost resort city is one of the most popular domestic and international destinations in the world. It is the gateway to Central and South America as well as the rest of the world. Miami caters to multinational visitors; it is the perfect city to host the International Society for the Advancement of Spine Surgery. I am sure you will depart Miami having gained from this experience.

Hansen A. Yuan, M.D.
President
Spine Arthroplasty Society
The International Society for the Advancement of Spine Surgery
To include motion preservation, new technologies, biologics and MIS procedures.
Dear Spine Community:

As Incoming President of the SAS, I sincerely welcome you to the Spine Arthroplasty Society 8th Annual Global Symposium on Motion Preservation Technology.

I thank all who have contributed to this meeting. The Program Committee was challenged to review over 400 papers submitted from 27 countries, half of them about lumbar and cervical TDR. Program Chair Henry Halm, MD, PhD led a team of experts that included Clinical Committee Chair Rick Guyer, MD and Basic Science Chair Hans-Joachim Wilke, MD, PhD in developing this very well thought out scientific and educational program. Each abstract was scored by 5 of the 46 members of the program committee; after settlement of the sessions the best papers were listed in the program. We were challenged to ensure that each presenter would not appear at the podium more than two times and that we would have representation from around the world. These tasks were very important to us as we tried to capture the greatest interests of spine surgeons globally. On the last day of the meeting we will award the best presentations; your attendance would be greatly appreciated.

We have added something long missing from our meetings - a Members Business Meeting which will be held on Tuesday, May 6th at 12:30 p.m. following the Taped Live Surgery Session. I invite all SAS members to attend this important meeting to understand the direction of the SAS and to contribute with your own thoughts. During this meeting we plan an e-vote survey to further advance our society.

It is a great pleasure for me to personally thank those companies who have partnered with us in this meeting: Platinum Level Partners Interventional Spine, and Synthes Spine; Gold Partners Stryker, DePuy Spine, Medtronic and Zimmer Spine; and Silver Partners Paradigm Spine, SpinalMotion, B. Braun Aesculap and NuVasive.

It is most important that we are grateful to all involved companies for their support and recognition of the importance of this meeting. The Technical Exhibits have grown from last year with now over 68 booths - which will demonstrate basic implants and procedures for functional stabilization of the spine as well as the latest innovations in the field of spine care. The development of new devices, materials and procedures and significant improvements of common devices have gone very fast. Please take all the opportunity to visit industry exhibition and to take part in their interesting workshops - 30 industry workshops in all.

On Wednesday, May 7th I will take over the role of SAS President, after a very successful year of Dr. Hansen Yuan’s SAS leadership, in corporation with the Board of Directors, supported by the SAS administration. I hope you will attend the 9:45 a.m. session to hear my thoughts and direction for the coming year. I take this role most seriously and want each SAS8 attendee including industry people to be aware of my plans. The Guest Speaker will surprise you with a field which is becoming more and more important for our life.

On behalf of the Board of Directors, I thank every one of you for your time and all the energy you spent to prepare the SAS8 Global Symposium. I hope you enjoy memorable scientific presentations and impressive events in a sunny Miami.

Thank you,

Karin Büttner-Janz MD, PhD
Incoming SAS President
Dear Colleague,

I am honored to welcome each of you to the SAS8 Conference. It has been my pleasure and big responsibility to hold the position of Overall Program Chair this year. The Committee Chairs, Hans-Joachim Wilke, PhD and Richard Gayer, M.D. each contributed greatly to the direction of the program. I would also like to thank Karin Büttner-Janz MD, PhD for her guidance in developing the final program. This program is the result of great teamwork.

The SAS8 Program Chairs and Program Committee reviewed each and every abstract submitted for the Global Symposium in Miami. It was a challenging task but we feel we have selected the best papers that will interest all those attending the conference. All abstracts went through a blinded review process to avoid any bias. Also, it was our goal to expand to more presenters, and to avoid redundancy, thus we limited each presenter to only present 2 oral presentations. We also took note to include a nice representation of papers from around the world to ensure different points of view were offered. We continued the plan of the SAS7 Program Chairs of selecting a program that was different from those conferences of the past.

We have included a debate session on Tuesday which is different from previous years. Debates on both lumbar and cervical techniques will be of great interest to all. Please plan to attend these important sessions. Each session throughout the conference will offer handheld devices for feedback and questions. We feel this will make the SAS8 more interesting, interactive and give all a chance to add to each session. Each session throughout the conference will offer insights to all, you should not miss one session.

We are confident that you will depart Miami having gained from all those who have dedicated their work to improvements in motion preservation technology.

Henry Halm

Henry Halm, MD, PhD
SAS8 Overall Program Chair
THE SAS BOARD OF DIRECTORS

The Board of Directors provides leadership for SAS by:

- Upholding SAS’s vision, purpose and values;
- Setting the broad policies, direction and priorities of the organization;
- Ensuring that SAS has highly effective leadership;
- Providing fiduciary oversight; and
- Maintaining the integrity of SAS services and products developed for the benefit of SAS members.

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2007 - 2008 BOARD OF DIRECTORS

SAS thanks the following Board members for their leadership and guidance throughout the year:

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Professor Henry Halm, MD, PhD
Overall Program Chair

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Christopher Yeung, MD
THE SAS 2009 ANNUAL MEETING LOCATION AND DATES

9TH ANNUAL
SAS GLOBAL SYMPOSIUM ON MOTION PRESERVATION TECHNOLOGY
APRIL 28 - MAY 1, 2009, LONDON, ENGLAND

SAS ANNUAL MEETING LOCATIONS AND DATES

8TH ANNUAL
SAS GLOBAL SYMPOSIUM ON MOTION PRESERVATION TECHNOLOGY
MAY 6 - 9, 2008, MIAMI BEACH, FLORIDA

7TH ANNUAL
SAS GLOBAL SYMPOSIUM ON MOTION PRESERVATION TECHNOLOGY
MAY 5 – 7, 2007, BERLIN, GERMANY

6TH ANNUAL
SAS GLOBAL SYMPOSIUM ON MOTION PRESERVATION TECHNOLOGY
MAY 9 – 13, 2006, MONTREAL, CANADA

5TH ANNUAL
SAS GLOBAL SYMPOSIUM ON MOTION PRESERVATION TECHNOLOGY
MAY 3 – 6, 2005, NEW YORK, NEW YORK

4TH ANNUAL
SAS GLOBAL SYMPOSIUM ON MOTION PRESERVATION TECHNOLOGY
MAY 4 – 7, 2004, VIENNA, AUSTRIA

3RD ANNUAL
SAS GLOBAL SYMPOSIUM ON MOTION PRESERVATION TECHNOLOGY
APRIL 30 – MAY 2, 2003, PHOENIX, ARIZONA

2ND ANNUAL
SAS GLOBAL SYMPOSIUM ON MOTION PRESERVATION TECHNOLOGY
MAY 6 – 8, 2002, MONTPELLIER, FRANCE

1ST ANNUAL
SAS GLOBAL SYMPOSIUM ON MOTION PRESERVATION TECHNOLOGY
MAY 2001, MUNICH, GERMANY

REGIONAL MEETING LOCATIONS AND DATES

2ND ANNUAL ASIA PACIFIC CONFERENCE
LOCATION AND DATES TO BE CONFIRMED FOR JANUARY 2010

1ST ANNUAL ASIA PACIFIC CONFERENCE
SEOUL, KOREA JANUARY 16 – 18, 2008
The Spine Arthroplasty Society is a special interest group of medical and associated specialists devoted to the field of clinical and structural amelioration and restoration of the joints of the spinal column.

The Society’s focus is on restoration, or replacement and potential return to normal function lost by degenerative conditions of spinal joints, especially where prostheses or orthoses may be required to accomplish these goals.

While spine fusion may be the most widespread option for treating low back pain conditions today, in the near future, the options associated with Spine Arthroplasty will be available alternatives in treating spinal problems. The Spine Arthroplasty Society (SAS) was established on this platform and the Society’s focus will be on all advances in spinal treatment with a baseline credo of promoting “the science” and not “the product”.

The Society’s goal will be to promote the ethical exchange of knowledge, research and education to restore function and comfort to degenerative conditions of spinal joints, especially the intervertebral disc. The Society will advance the philosophy of natural spinal mobility through dissemination of educational materials to spinal surgeons, the medical community and the lay public.

Reflecting globalization, the Society will not be “regionalized” but be a contemporary and open forum for educating specialists throughout the world. Reflecting on the availability of the Internet as a communications resource the Society will extensively use its web site: www.spinearthroplasty.org in addition to staging of more traditional meetings and publications.
**IT Committee**
The members of this committee work to enhance the SAS website to ensure that current and relevant matters are addressed. The IT committee in conjunction with the Executive Director guide and direct the appointed webmaster to make necessary changes and upgrades to ensure member needs are met.

**Chairman:**
Chun-Kun Park, MD, PhD
Dilip Sengupta, MD, PhD
Hyun-Chul Shim, MD, PhD
Heather Howard and Michele Boylstein  
*SAS Staff Representatives*

**Publications Committee**
The design, text, layout and editing of the newsletter, hard copy and online books and instructional course material test books all fall under the realm of this Committee. They develop standards and guidelines to ensure all items published by the SAS or with SAS endorsement meet the requirements set up by the Committee. The committee monitors and approves all such materials with that goal in mind. They assist in the appointment of editors, associate editors and editorial boards as well as offer advice and content ideas.

**Chairman:**
Jeff Goldstein, MD
Chris Bono, MD
Federico Girardi, MD
James Yue, MD
Choll Kim, MD
Jean-Charles LeHuec, MD, PhD
Kristy Radcliffe, *SAS Staff Representative*

**CME Committee**
Discusses and provides interpretations of the ACCME guidelines regarding accreditation policies and decisions. Also concentrates on evaluating the effectiveness of the society’s system of accreditation, including the accreditation requirements and its processes for funding and support. This committee also forwards actions regarding accreditation decisions to the full Board of Directors for ratification. The CME Committee will work in the development and adherence of all CME rules and regulations. They will review all SAS sponsored programs to make sure that the SAS provides continuing education programs on substantive, practice-related subjects.

**Chairman:**
Jean-Jacques Abitbol, MD
Ken Burkus, MD
Heather Howard, *SAS Staff Representative*

**CME Provider:**
Medical Education Resources

**Membership Committee**
Responsible for increasing the number of individual and institutional members worldwide and to ensure members’ needs are met. This includes recommending ways for increasing the SAS membership base, formulating coordinating and implementing plans for membership recruitment, ways to acknowledge and welcome new members’ and encourage their participation in SAS committees and SAS sponsored activities. They will work with the Executive Director in the development of a renewal of membership program. This committee will be charged with developing a SAS membership directory and coordinating with the IT committee for membership access via the website. This committee will also work to identify members’ and non-members’ needs and perceptions, analyzing them and making recommendations to the Board of Directors.

**Chairman:**
Karin Büttner-Janz, MD, PhD
Chun-Kun Park, MD, PhD
Heather Howard, *SAS Staff Representative*

**Industry Relations Committee**
The members of this Committee will solicit exhibitors for meetings, recommend policies, and recommend policies governing and concerning exhibitors. They will advise on all aspects of the exhibit space and charges. They will monitor matters concerning exhibitors, the exhibits, the exhibit space and security of the exhibit space. They will provide input into location of meetings, policies and service providers and shall make recommendations to the board concerning policy and financial matters relative to exhibitors.

**Chairman:**
Gunnar Andersson, MD
Rich Toselli, MD
Gary Lowery, MD, PhD
Mike Janssen, MD
Hal Matthews, MD
Frank Phillips, MD
Pat Miles
Kristy Radcliffe, *SAS Staff Representative*
SAS COMMITTEES

Finance Committee
The Committee will assess the financial condition of the society on a quarterly basis. The role of this Committee is to review proposed budgets and present recommendations and findings to the full Board of Directors for approval. They will track the income and expenses and make recommendations as necessary. The group will advise the Board of Directors and provide guidance and direction to the Executive Director on all matters relating to financial management. This committee serves as the watchdog for the financial stability of the organization, reviewing banking and investment options and establishing procedures for investigating and making recommendations for large expenditures.

Treasurer:
Tom Errico, MD
Bart Sachs, MD
Kristy Radcliffe, SAS Staff Representative

Education Committee
The Education Committee is charged with devising goals and guidelines for the coordinating efforts of the Society to satisfy the changing needs of its membership in the field of continuing education. They will work closely with the CME committee to ensure the SAS educational programs meet all guidelines and requirements. It is the goal of SAS to be the leader in providing education and training opportunities through short courses, workshops, CD-ROM publications, seminars and conferences. This committee will regularly explore cost-effective training opportunities applicable to spine surgeons worldwide. They will develop new programs for those who cannot attend SAS sponsored seminars, such as short courses, distance learning programs and sanctioned educational opportunities. The main goal of this committee is to educate and promote medical excellence in the care of spine.

Chairmen:
Michael Janssen, MD/ Larry Khoo, MD
Amir Fayyazi, MD
Ken Yonemura, MD
Jean-Charles LeHuec, MD, PhD
Frank Phillips, MD
Chong Suh Lee, MD
Heather Howard, SAS Staff Representative

Public Policy Committee
This Committee could deal with some of the issues coming from FDA approvals and the CMS. The Public Policy Review Committee would serve in an advisory capacity and provide guidance in identifying experts to speak at FDA, government or congressional briefings, assist in crafting public policy/position statements that reflect the concerns of SAS, surgeons and the spine care industry.

Chairman:
Stephen Hochschuler, MD
Chris Bono, MD
Charles Ray, MD
Isador Lieberman, MD
Vincent Traynelis, MD
Kristy Radcliffe, SAS Staff Representative

Long Range Planning
This Committee reviews the current state of the SAS, determines whether the Society has met its goals and decides what changes to make within the Society in light of the needs of its members and changes in the medical profession. In order to serve its purpose, the committee develops a strategic plan to be reviewed annually which lays out the SAS objectives in areas such as governance and administration, membership, member services, public services and it determines what steps to take to fulfill those objectives.

Chairman:
Stephen Hochschuler, MD
Thierry Marnay, MD
Rudolph Bertagnoli, MD
Charles Ray, MD
Kristy Radcliffe, SAS Staff Representative

International Committee
The purpose of this committee is to ensure the society enlists the views from an international perspective. To address all international issues and make sure there is a collaborative exchange of information.

Chairman:
Thierry Marnay, MD
Karin Büttner-Janz, MD, PhD
Luis Pimenta, MD
Chun Kun Park, MD, PhD
Massimo Balsano, MD
Dewei Zou, MD, PhD
Henry Halm, MD, PhD
Alejandro Reyes-Sanchez, PhD
Alexander Hadjipavlou, MD
SAS Membership

Membership is open to all spinal specialists, groups or organizations, including government and industry, whose common cause is the advancement of spine arthroplasty. Membership categories are as follows: Full/Regular Membership which includes Physicians, Researcher and Industry as sub categories under it, and Allied Health Professionals which includes Residents, Fellow, Physician Assistants, Nurses, Student, and Retired as sub categories. The Society has been duly constituted under law with officers, directors and committees as defined in its bylaws.

Why join the Spine Arthroplasty Society?

We believe that our society is unique in its specific focus to become a global organization that concentrates on the newest techniques in artificial disc and nucleus replacement. It is our intent to complement existing organizations by presenting information that may not be available in the depth or breadth that will be provided by SAS. With the field of spine surgery changing so rapidly because of the myriad of new products and advancements, we believe it appropriate to provide a distinct voice to the new techniques. As a member, you will gain ready access to this information, receive discounts on conferences and symposiums and be associated with a global organization that recognizes what we believe to be a significant change in the treatment and resolution of degenerative disc disease.

What are the benefits of Membership?

The Spine Arthroplasty Society was organized to provide a venue on the benefits of non-fusion technology in providing for spinal stabilization because of trauma, deformities as well as degenerative diseases of the spine. Spine Arthroplasty is seen as the next evolutionary step to provide restoration of the original structure and in course, restoration of pain-free "natural" mobility of the spine. The purpose of the society is to educate and exchange information on Spine Arthroplasty technology.

- Association with a global organization that will promote the free exchange of information on the science of spine arthroplasty;
- Special discounted registration fees for all SAS sponsored programs including the annual congress scheduled for an internationally renowned venue;
- On-Line access to up-to-the-minute news on spine arthroplasty and related products;
- Members-only participation and access to on-line presentations and discussion groups;
- Access to SAS papers, presentations, research and membership directory;
- E-mail subscription to the SAS Newsletter and ‘breaking news’ issued by the society;
- CD Rom’s from previous meetings at a reduced fee
- Complimentary subscription to the SAS Journal
- On-Line membership renewal and ability to update your member profile information
- Doctors database search
- Additional benefits that are being negotiated for the future – affiliation with AOSpine and The Society for Minimally Invasive Spine Surgery, Access to the Pearl Diver research tool.

What is the value of Membership?

Consistent with our intent, we believe that the science of Spine Arthroplasty contains important developments that must be considered as an interim step to current fusion technology for restoring pain-free natural mobility in the relief of debilitating, discogenic back pain. We will provide education and exchange of information using the most modern means of communication. Through your membership support the Spine Arthroplasty Society will become a forum to:

- Provide research grants;
- Fund traveling fellowship programs;
- Support surgical Centers of Excellence;
- Establish educational certification;
- Organize conferences and symposia;
- Develop web-enabled forums;
- Raise worldwide awareness of Spine Arthroplasty

SAS Membership

For more information about becoming a SAS member or to request a membership application, please visit the membership booth in the Registration area or see page 175 in this program book for the membership application.
As incoming President of SAS, Karin Büttner-Janz, MD, PhD selected the European Space Agency to speak to the SAS audience as her Presidential Guest Speaker.

“There is a common tie between space research and spine surgeons. Both require courage, necessity of high accuracy and the responsibility for a good result. Spine surgeons seek a positive outcome in their patients while a successful space operation requires astronauts to return to earth, healthy and with data from their explorations. Astronauts and space research will continue to provide our world with new technologies and advancements in science. The same holds true with spine surgeons as more information is learned from our research in the motion retaining of the spine.

We are not yet where the spine community has to go but we do believe that those of us in the field can learn from astronauts much more than navigation…but also the education, reevaluation, personal adequacy and many other things that show the continued progress in explorations.

We will reach new heights and now know that the sky is not the limit!”

-- Dr. Karin Büttner-Janz, MD, PhD

Pictures have been provided to SAS and our members, with kind approval of the European Space Agency
EDUCATIONAL OBJECTIVES

Upon completion of the CME accredited portions of this program, participants should be better able to:

- Identify and describe the results of new research in spinal arthroplasty/surgical approach and clinical results for the management of conditions requiring treatment.
- Discuss practical clinical information aimed at improving diagnostic skills.
- Identify key aspects of the latest devices available for preserving the motion of the spine.
- Evaluate and determine a wider range of treatment and surgical options for patients with degenerative disc disease.
- Describe, compare and contrast innovative methods in both assessment and treatment options in spinal arthroplasty.

MEETING PURPOSE

The purpose of the eighth Annual Global Symposium on Motion Preservation Technology is to provide continuing medical education for practicing neurosurgeons and orthopedic spine surgeons, residents in training, post-graduate fellows as well as allied health professionals including nurses and physician assistants.

This education will be provided in many forms:

- Taped Surgeries
- Lectures
- Symposia
- Panel discussions to provide in depth coverage of selected topics
- Exhibits demonstrating the newest devices and technologies
- Industry Workshops
- Paper and Poster abstracts to provide the most current information regarding clinical and basic science advances in spine surgery

MISSION STATEMENT

The Spine Arthroplasty Society (SAS), The International Society for the Advancement of Spine Surgery, is a global, scientific society organized to provide an independent venue to address and discuss the issues involved with all aspects of basic and clinical science of motion preservation, biologics, innovative new technologies and minimally invasive spine surgery. SAS is dedicated to advancing a major evolutionary step in spine surgery – restoring pain-free mobility.

CME/COURSE EVALUATION FORM

The course evaluation form MUST be completed and returned to the box located at the back of the General Session room, in order to process your certificate. The CME certificates of attendance will be mailed approximately six weeks after the meeting.

FDA STATEMENT

Some drugs or medical devices demonstrated at the SAS8 Symposium have not been cleared by the FDA or have been cleared by the FDA for specific purposes only for use in the United States. The FDA has stated that it is the responsibility of the physician to determine the FDA status of each drug or device he or she wishes to use in clinical practice and to use the products in compliance with applicable law.

SAS policy provides that “off label” uses of a drug or medical device may be described in the SAS8 CME activities so long as the “off label” use of the drug or medical device is also specifically disclosed. The SAS8 Proceedings book indicated faculty presentations in which the FDA has not cleared the drug and/or medical device for the use described (i.e. the drug or medical device is being discussed for an “off label” use).

PHYSICIAN ACCREDITATION

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Medical Education Resources and the Spine Arthroplasty Society. Medical Education Resources is accredited by the ACCME to provide continuing medical education for physicians.

CREDIT DESIGNATION

Medical Education Resources designates this educational activity for a maximum of 23 AMA PRA Category 1 credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.
PHYSICIAN ASSISTANT ACCREDITATION
American Academy of Physician Assistants (AAPA) accepts category 1 CME approval from organizations accredited by the ACCME to grant Category 1 Credits to the PRA.

NURSING ACCREDITATION
Medical Education Resources is an approved provider of continuing education by the Colorado Nurses Association, an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation.

This CE activity provides 23 contact hours. Provider approval expires July 31, 2010. Provider approved by the California Board of Registered Nursing, Provider #CEP 12299, for 23 contact hours.

DISCLAIMER
The material presented at the SAS8 Symposium has been made available by the Spine Arthroplasty Society for educational purposes only. This material is not intended to represent the only, nor necessarily the best method of procedure appropriate for the medical situations discussed but rather it is intended to present an approach, view, statement or opinion of the faculty which may be helpful to others who face similar situations.

The SAS disclaims any and all liability for injury or other damages resulting to any individuals attending a session for all claim, which may arise out of the use of techniques demonstrated therein by such individuals, whether these claims be asserted by a physician or any other person.

No reproductions of any kind, including audiotape and videotape or photo may be made of the presentations at the SAS8 Symposium. The SAS reserves all of its rights to such material, and commercial reproduction is specifically prohibited.

The content and views presented in this educational program are those of the presenters/authors and do not necessarily reflect those of Medical Education Resources. The authors will disclose if any unlabeled use of products are mentioned in their presentations. Before prescribing any medicine, primary references and full prescribing information should be consulted.

DISCLOSURE
It is the policy of Medical Education Resources (MER) to ensure balance, independence, objectivity, and scientific rigor in all its educational activities. Each participant in the SAS8 Symposium has been asked to disclose if he or she has received something of value from a commercial company or institution, which relates directly to the subject of their presentation. The society has identified the options to disclose as follows:

- Grant/Research or institution support has been received
- Miscellaneous non-income support (i.e. equipment or services), commercially derived honoraria or other non-research related funding (i.e. paid travel).
- Royalties
- Stock Options
- Consultant or Employee
- Speaker’s Bureau
- Nothing of value disclosed

All indication of the participant’s disclosure will appear after his or her names as does the commercial company institution that provided that support. A full complete listing is noted in this SAS8 Program book on pages.

The SAS does not view the existence of these disclosed interests or commitments as necessarily implying bias or decreasing in the value of the author’s participation in the Symposium.
SPEAKER READY ROOM

Paper and Symposia Presenters, trained audiovisual staff will be available for any audiovisual needs.

It is REQUIRED that each presenter visit the Speaker Ready Room, located in Hall B, 2nd Level, Room B213, at least three (3) hours prior to the scheduled session start time to submit their presentation materials and convey last-minute requests.

Speaker Ready Room hours are:
- Tuesday, May 6: 7:00 a.m. - 7:00 p.m.
- Wednesday, May 7: 7:00 a.m. - 5:00 p.m.
- Thursday, May 8: 7:00 a.m. - 5:00 p.m.
- Friday, May 9: 7:00 a.m. - 3:00 p.m.

POSTER INFORMATION

The poster viewing hours in the Exhibit Hall are:

- Wednesday, May 7: 9:00 a.m. - 5:00 p.m.
- Thursday, May 8: 9:00 a.m. - 5:00 p.m.
- Friday, May 9: 9:00 a.m. - 4:00 p.m.

AWARDS PRESENTATIONS

The Spine Arthroplasty Society’s Eighth Annual Global Symposium on Motion Preservation Technology will offer four awards:

- The SAS Leon Wiltse Award for Best Overall Paper (sponsored by Dr. and Mrs. Hansen A. Yuan)
- Best Basic Science Paper Presentation
- Best Clinical Research Paper Presentation
- Best Poster

The purpose of these awards is to stimulate fundamental research in arthroplasty and motion preservation technologies. Each award will consist of $2,000. It is an honor for the society to recognize and award these presenters for original, outstanding research in motion preservation and independence of thoughts, originality of approach, clarity and excellence of data presentation.

ATTENDEE RESOURCES

SAS CYBER CAFE

Keep in touch with your home or office while at the SAS8 Conference. Visit the SAS Cyber Cafe located in the lounge area of the Exhibition Hall. Several computers will be available with internet access to check your e-mail. The cafe’s hours will be the same as the exhibit hall hours.

SAS HOUSING BUREAU BOOTH

Please visit the SAS Housing Bureau desk for information and to ask questions regarding housing and hotels in Miami Beach.

INFORMATION BOOTH

Do you need suggestions on dining, shopping, tours or getting around Miami Beach? Please stop by the Information Booth in the Registration area, Hall B, to visit with an information specialist and pick up literature about Miami Beach.

LONDON BOOTH

London, the location of the 2009 SAS Annual Meeting, is a city that encompasses the best that the world has to offer - in the arts and culture, business and commerce, sports and events, cuisine, entertainment and accessibility. London is a city able to motivate and inspire like no other.

Whether you’re a first time visitor or have been to London before, there’s always something new and exciting just waiting to be discovered. There has never been a better time to taste London for yourself and share it with colleagues, peers, friends and family. London has never been easier to get to, do business in, and come back to, time and again.

Why not combine attending the 2009 SAS Annual Meeting with taking in the sites from Trafalgar Square to St. Paul’s Cathedral, Big Ben, the Houses of Parliament and the Tower of London, Madame Tussaud’s and Piccadilly Circus. Or experience some of the worlds finest galleries and museums. National Gallery, the two Tate Galleries (Tate Britain and Tate Modern), the British Museum and the V&A. London is also a shopper’s paradise, whether in Knightsbridge, Regent Street, Piccadilly or Bond Street, or in 300 markets including Portobello Road.

Come by the London booth to learn more and plan your visit next year!
SPECIAL EVENTS

MEMBERS’ BUSINESS MEETING

All SAS Members are cordially invited to the Member’s Business Meeting on Tuesday, May 6, 2008 at 12:30 p.m. in the Miami Beach Convention Center, Room B214 - B218, second level.

Visit with your fellow members and meet some of our Board members as they share the mission and goals of the SAS. The Membership Department staff will be available to discuss the many benefits of SAS membership.

WELCOME RECEPTION

All attendees, exhibitors and guests are invited to the Opening Reception in the Exhibit Hall at the Miami Beach Convention Center, Hall B on Tuesday, May 6, 2008 from 5:00 p.m. to 7:00 p.m. Participation is included in the registration fee.

REGISTRATION INFORMATION

REGISTRATION

All delegates must check-in at the Registration Desk located inside the entrance of Hall B.

Badges are required and controlled for entrance to the General Sessions, Exhibit Hall, Breakout Sessions, Opening Ceremony and all social events.

Exhibitors must present a personalized business card for each person requiring a badge for their company.

REGISTRATION HOURS*

Tuesday, May 6, 2008  7:00 a.m. - 7:00 p.m.
Wednesday, May 7, 2008  7:00 a.m. - 5:30 p.m.
Thursday, May 8, 2008  7:00 a.m. - 5:30 p.m.
Friday, May 9, 2008  7:00 a.m. - 3:30 p.m.

*kindly note these registration hours are subject to change

BADGES

All congress badges will be marked to indicate the different categories of participation.

A $50.00 fee will be charged for lost badges and/or name changes on pre-registered badges and can be replaced at the registration desk.

LEAD RETRIEVAL DATA

If you wish to have exhibitors follow up with you or send you information on their products and/or services after the annual meeting, they will do so if you allow them to scan the bar code on your attendee badge.
You will not want to miss one of our newest additions to the SAS Meeting Program, for this year, Taped Live Surgeries in our Industry Innovations Program.

These will be held on Tuesday, May 6, 2008 between 9:30 am – 12:30 pm in the General Session Room (B214-B218), 2nd level. The moderators will be Tom Errico, MD and Michael Janssen, MD.

The schedule for the day will include:

**9:40 a.m. – 11:15 a.m.**

**Industry Innovations**  
**Moderator:** Tom Errico, MD

**9:40 am – 10:00 am**  
**Ellman Innovations (now Elliquence, LLC)**  
**Physician:** Laurence E. Mermelstein, MD

Dr. Mermelstein is Board Certified Orthopaedic Surgeon whose clinical practice places an emphasis on minimally invasive surgical techniques. As the first surgeon on Long Island to perform the Posterolateral Endoscopic Discectomy procedure, he continues to be on the forefront of surgical technology.

Elliquence, LLC; formally Ellman Innovations is the designer and manufacturer of Disc-FX™ a minimally invasive discectomy system with a multi-functional access system for maximum treatment options and enhances patient outcome. The Disc-FX™ system includes the patented, navigational Trigger-Flex® Bipolar System used extensively in endoscopic spine surgery. Disc-FX™ is an accessory for the patented Surgi-Max® Radiowave energy source that has been clinically proven to provide maximum precision, versatility and safety. Surgi-Max® advanced technology includes two proprietary Bipolar waveforms for nucleus ablation and annulus modulation.

**10:05 a.m. – 10:25 a.m.**  
**nuVasive**  
**Physician:** Mark Peterson, MD  
Southern Oregon Orthopedics, Medford, OR  
**XLIF™ Surgical Technique**

Surgical footage shows the eXtreme Lateral Interbody Fusion approach to the lumbar spine in step-by-step detail: targeting, retroperitoneal finger dissection, NeuroVision™ EMG guidance through the psoas muscle, exposure of the disc space through the MaXcess™ retractor, complete disc preparation, and interbody device placement. Corresponding fluoroscopic views demonstrate proper access and implant placement to achieve exceptional disc height and sagittal and coronal alignment restoration. The XLIF™ approach has been successfully to affect a minimally invasive correction of many thoracolumbar degenerative conditions including DDD, spondylolisthesis, scoliosis, adjacent segment disease, and revision surgeries.

**10:30 a.m. – 10:50 a.m.**  
**Interventional Spine**  
**Physician:** Dan Cohen, MD  
South Florida Spine

The PERPOS(TM) PLS System is the first and only PERCUTANEOUS transfacet-pedicular compression system for posterior stabilization during a fusion procedure of the lower spine. It is possible with the PERPOS(TM) PLS System to perform posterior lumbar stabilization to achieve lumbar fusion (at single or multiple levels) without cumbersome rod-and-screw technology.

**10:55 a.m. – 11:15 a.m.**  
**Hydrocision**  
**Physician:** Mitchell Hardenbrook, MD  
Boston Spine Group

Dr. Hardenbrook will present and discuss an innovative technique for performing microdiscectomy using the SpineJet MicroResector Hydrosurgery System. The technique, which utilizes a standard or minimally invasive approach with a hemilaminectomy, makes use of a small diameter (4mm) cannula to introduce a high velocity fluidjet instrument to cut and aspirate disc nucleus tissue to decompress disc herniations. The new technique addresses the two most significant long-term outcome concerns for microdiscectomy – reherniation and recurrent radicular pain. The risk of reherniation is reduced by the smaller than conventional annulotomy, and the risk of recurrent radicular pain secondary to neural fibrosis is decreased through the reduction of nerve root manipulation provided by the use of the cannula and elimination of the need to repeatedly pass instruments in and out of the disc space.

The biomechanical and biological advantages of lumbar interbody fusion depend on the ability to prepare the disc space for a solid intradiscal fusion. The SpineJet® XL Fusion Preparation System allows surgeons to more effectively prepare disc spaces for graft implantation during open or minimally invasive lumbar interbody fusion procedures. This fluidjet powered tool combines the power of fluidjet technology with a unique curette design permitting
surgeons to simultaneously cut, ablate, and remove hard or soft tissue – such as disc nucleus and endplate cartilage – quickly, safely and effectively, significantly reducing the need for additional instruments. When compared to conventional instruments, the SpineJet XL Fusion System has been shown to result in 65% fewer instrument passes, remove 95% more posterior contralateral nucleus, and reduce disc preparation time by 50%. Designed to work in conjunction with all currently available minimally invasive access systems, it is ideal for open or minimally invasive posterior fusion procedures.

Presented by the foundation of AOSpine International, this hour long segment will feature topics such as disc replacement procedures in the cervical and the lumbar spine, anterior lumbar demonstration techniques for access and fusions, cervical myelopathy decompressions and reconstructions.
Tuesday, May 6

7:00 A.M. - 7:00 P.M.
Registration
Exhibit Hall B

8:00 A.M. - 9:00 A.M.
Committee Meetings

9:00 A.M. - 9:30 A.M.
Coffee Break
Exhibit Hall B (lounge and poster area)

9:30 A.M. - 12:30 P.M.
Taped Live Surgeries
General Session Room: B214 - B218

12:30 P.M. - 1:45 P.M.
SAS Business Meeting
(for members only)

2:00 P.M. - 2:15 P.M.
Opening Ceremony
General Session Room: B214 - B218

2:15 P.M. - 3:15 P.M.
Symposium I - Indications Lumbar
(debate format)
General Session Room: B214 - B218

3:15 P.M. - 3:45 P.M.
Symposium II - Indications Cervical
(debate format)
General Session Room: B214-B218

3:45 P.M. - 4:56 P.M.
Session I - MIS
General Session Room: B214-B218

5:00 P.M. - 7:00 P.M.
Opening Reception/Opening of Exhibits
Exhibit Hall B
MEETING-AT-A-GLANCE

WEDNESDAY, MAY 7

7:00 A.M. - 5:00 P.M.
Registration
Exhibit Hall B

8:00 A.M. - 9:40 A.M.
Session I - Cervical TDR
General Session Room: B214-B218

9:00 A.M. - 5:00 P.M.
Exhibit Hall Open/ Posters Open for Viewing
Exhibit Hall B

9:45 A.M. - 10:30 A.M.
Transfer of SAS Presidency*/Presidential Guest Speaker*
*Exhibit Hall B will close

10:30 A.M. - 11:00 A.M.
Coffee Break, Viewing of Posters, Industry Exhibition
Exhibit Hall B

11:00 A.M. - 12:00 Noon
Session II - Cervical TDR
General Session Room: B214-B218

12:00 Noon - 2:00 P.M.
Industry Workshops
- Abbott Spine
- Innovative Spinal Technologies
- Interventional Spine
- Paradigm Spine
- Orthofix/Blackstone
- Rayamedica
- Stryker
- Synthes Spine
- Spinal Kinetics
- Zimmer Spine

2:00 P.M. - 3:00 P.M.
Session III - Cervical TDR
General Session Room: B214-B218

3:00 P.M. - 3:45 P.M.
Coffee Break, Viewing of Posters, Industry Exhibition
Exhibit Hall B

3:45 P.M. - 4:54 P.M.
Session IV - Basic Problems and Provocative Solutions
General Session Room: B214-B218
THURSDAY, MAY 8

7:00 A.M. - 5:00 P.M.
Registration
Exhibit Hall B

8:00 A.M. - 10:43 A.M.
Session I - Lumbar TDR
General Session Room: B214-B218

9:00 A.M. - 5:00 P.M.
Exhibit Hall Open/ Posters Open for Viewing
Exhibit Hall B

10:45 A.M. - 11:00 A.M.
Coffee Break, Viewing of Posters, Industry Exhibition

11:00 A.M. - 12:00 Noon
Session II - Lumbar TDR
General Session Room: B214-B218

12:00 Noon - 2:00 P.M.
Industry Workshop
  • Anulex
  • DePuy Spine
  • Globus Medical
  • Innovative Spinal Technologies
  • LDR
  • Medtronic
  • Paradigm Spine
  • Trans1
  • W.L. Gore
  • Zimmer Spine

2:00 P.M. - 3:00 P.M.
Session III - Lumbar TDR and Fusion Session
General Session Room: B214-B218

3:00 P.M. - 3:45 P.M.
Coffee Break

3:45 P.M. - 5:25 P.M.
Session IV - Nucleus Replacement and Other
General Session Room: B214-B218
FRIDAY, MAY 9

7:00 A.M. - 3:30 P.M.
Registration
Exhibit Hall B

8:00 A.M. - 10:12 A.M.
Session I - Posterior Dynamic Stabilization
General Session Room: B214-B218

9:00 A.M. - 4:00 P.M.
Exhibit Hall Open/ Posters Open for Viewing

10:15 A.M. - 10:30 A.M.
Awards Ceremony

10:45 A.M. - 11:00 A.M.
Coffee Break, Viewing of Posters, Industry Exhibition

11:00 A.M. - 12:00 Noon
Session II - Posterior Dynamic Stabilization and Lumbar Facet
General Session Room: B214-B218

12:00 Noon - 2:00 P.M.
Industry Workshops

• Disc Motion Technologies
• INION
• Medtronic
• Medtronic
• NuVasive
• Paradigm Spine
• Spine Frontier
• Spine Vision
• Stryker
• Synthes Spine

2:00 P.M. - 3:30 P.M.
Session III - Innovative Technologies
General Session Room: B214-B218

3:30 P.M.
SAS8 Meeting Adjourns
The Spine Arthroplasty Society would like to thank the following partners for their generous contributions and support:

Additional Partnership Contributions:

- Orthofix/Blackstone: Meeting Bags
- K2M, NuVasive: Hotel Key Cards
- Globus Medical: Lanyards
- Paradigm Spine: Writing Pad and Pen
- Covidien: Coffee Breaks
- Raymedica: Water Bottles, Gourmet Coffee Cart
- Abbott Spine: Luggage Tags
SAS8 EXHIBITOR LIST

A
Abbott Spine  116
Alphatec Spine  813
Altiva Corporation  825
Amedica  217
Anulex Technologies  415
Applied Spine Technologies, INC  413
Archus Orthopedics  918
ArthroCare Spine  621
Aspen Medical Products  1008

B
B. Braun Aesculap  607
Biomet Spine  125
BrainLAB  311

C
Cervitech  718
CoreSpine Technologies  327
Covidien  513

D
Depuy Spine  100
Disc Dynamics Inc  620
Disc Motion Technologies  419

E
Eden Spine LLC  330
Ellman Innovations  518
Exponent  624

F
Facet Solutions, Inc  809
Flagship Surgical LLC  820
FzioMed, Inc  524

G
Globus Medical  108
Gore & Associates  425

H
HydroCision, Inc  721

I
iMDs  919
Inion  824
Innovative Spinal Technologies  401
Interventional Spine Inc  303
Intrinsic Therapeutics  126
Invuity Inc  924

J
Joomax, Inc  519

K
K2M  407

L
Lanx  724
LDR  117
Life Spine  913

M
Medtronic  101
<table>
<thead>
<tr>
<th>Company</th>
<th>Booth #</th>
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<tbody>
<tr>
<td>Nexgen Spine</td>
<td>124</td>
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<td>1006</td>
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<td>Seaspine Inc</td>
<td>712</td>
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<td>Showa Ika</td>
<td>231</td>
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<tr>
<td>Signus Medical</td>
<td>321</td>
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<tr>
<td>Sintea Biotech, Inc</td>
<td>525</td>
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<tr>
<td>Spinal Elements</td>
<td>315</td>
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<td>Spinal Kinetics</td>
<td>310</td>
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<tr>
<td>SpinalMotion</td>
<td>507</td>
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<td>Spine Frontier</td>
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<td>Spine Wave</td>
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<td>SpineVision</td>
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<td>Stryker</td>
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<td>Synthes Spine</td>
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Abbott Spine was built on a foundation of innovation. Today, we continue our commitment to providing expertise to the surgical community. In addition to the enhancement and diversification of its spinal fusion product line, Abbott Spine is working to develop therapies that are less invasive and intervene earlier in the continuum of care. Abbott Spine. Expertise at your side.

Alphatec Spine is a medical device company focused on the design, development, manufacturing and marketing of products for the surgical treatment of spine disorders. We offer a broad range of products including a variety of spinal implant products and systems comprised of components such as spine screws, spinal spacers, and plates. As an alternative to metal and synthetic materials, we also distribute allograft spacers to be used in spine fusion.

Altiva Corporation will feature these comprehensive spinal systems and related products: HydraLok® Polyaxial Pedicle Screw System Opteryx® Cervical Plating system ALTESä Anterior Buttress Plating System Altiva DBM Altiva PEEK VBR Stop by and see us at booth #619 today!

Amedica Corporation is an emerging orthopedic implant company focused on using its silicon nitride ceramic technologies to develop and commercialize a broad range of innovative, high-performance spine and joint implants for the growing orthopedic device market. Its products under development include both spinal implants and reconstructive hip and knee implants that may represent new standards of care based on superior durability, performance and safety.

Anulex Technologies, Inc. specializes in the development and manufacture of new and innovative technologies used for the repair of soft tissue. Featured products include the Inclose™ Surgical Mesh System and the Xclose™ Tissue Repair System.

Applied Spine Technologies developed the Stablimax NZ®, a pedicle screw-based Dynamic Spine Stabilization System based on the biomechanical principles and Neutral Zone Hypothesis established by Manohar Panjabi, PhD. The Stablimax NZ works to preserve the Neutral Zone while maintaining physiologic motion. The Stablimax NZ IDE Clinical Trial is underway at selected sites around the US.
Archus Orthopedics
8624 154th Ave NE
Reddmond WA  98052
Phone: 425-284-3681
Fax: 425-882-2137
www.archususa.com

Archus is the global leader in facet replacement technology and works with leading spine surgeons to develop and design a complete suite of facet replacement products. Presently our products facilitate treatment of lumbar stenosis and are used with or after implantation of various interbody motion preservation devices such as artificial discs and nucleus replacements.

ArthroCare Spine
680 Vaqueros Ave
Sunnyvale CA  94085
Phone: 408-735-6496
Fax: 408-736-2973
www.arthrocare.com

ArthroCare Spine is dedicated to improving patient outcomes, creating innovative products for less traumatic spinal procedures. Our patented Coblation technology is the foundation for spinal disc decompression and soft tissue removal procedures. Solutions range from interventional to surgical treatments including discography, plasma disc decompression, fracture reduction, and vertebroplasty.

Aspen Medical Products
6481 Oak Canyon
Irvine, CA 92618
Phone: 949-681-0200
Fax: 949-681-0300
www.aspenmp.com

Aspen Medical Products is a leader in the development of innovative spinal bracing for post-trauma stabilization, pre- and-post surgical stabilization, pain management and long-term patient care. Aspen Medical Products offers multiple orthotic options that provide unsurpassed motion restriction, superior comfort and an economic advantage, encouraging better patient compliance.

B. Braun Aesculap
Am Aesculap Platz
Tuttlingen  78532
Germany
Phone: 0049-7461-95-0
Fax: 0049-7461-95-2600
www.asculapeusa.com

Aesculap Spine, a Division of B. Braun Group, developing spinal concepts since early 80s. In close collaboration with clinical authors, implants and special instruments are designed. Aesculap combines its core competence in surgical instruments with innovative engineering for high quality spine systems. Disc prostheses like activ L and activ C are the latest spine generation.

Biomet Spine
100 Interpace Parkway
Parsippany NJ  07054
Phone: 973-299-9300-3031
Fax: 973-334-4865
www.biometspine.com

Biomet Spine products meet or exceed physician expectations in Thoracolumbar, Cervical, Deformity, Spacers, Interbody, Trauma/Tumor, Minimally Invasive, Vertebroplasty, Osteobiologics, Spine Fusion Stimulation, and Bracing.

BrainLAB
3 Westbrook Street, Suite 400
Westchester IL  60154
Phone: 800-784-7700
Fax: 708-409-1619
www.brainlab.com

BrainLAB develops, manufactures and markets software-driven medical technology enabling more precise, less invasive, and less expensive procedures. Our image-guided systems provide highly accurate, real-time information for surgical navigation. BrainLAB solutions allow for expansion from one system to operating suites to digitally integrated hospitals covering neurosurgery, orthopedics, ENT, CMF, spine & trauma, and oncology. For more information, please visit www.brainlab.com.

Cervitech
300 Roundhill Drive
Rockaway NJ  07866
Phone: 703-754-4227
Fax: 973-625-4445
www.cervitech.com

With the PCM® - Artificial Cervical Disc - a metal-on-poly surface replacement type design - Cervitech has developed a motion retaining cervical intervertebral disc prosthesis, which is based on decades of experience in join and disc replacement. Utilizing clinical well-proven materials such as Cobalt Chrome and UHMW polyethylene in combination with latest coating techniques for fast bone integration, the PCM® features a simple surgical technique for motion-retaining cervical disc replacement utilizing a simple step-by-step instrumentation.
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<th>Fax</th>
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<tr>
<td>CoreSpine Technologies</td>
<td>#327</td>
<td>5909 Baker Road, Suite 550</td>
<td>612-759-2600</td>
<td>952-979-9343</td>
<td><a href="http://www.corespinetech.com">www.corespinetech.com</a></td>
</tr>
<tr>
<td>Covidien</td>
<td>#513</td>
<td>101 A First Ave</td>
<td>781-839-1700</td>
<td>781-839-1731</td>
<td><a href="http://www.confluentsurgical.com">www.confluentsurgical.com</a></td>
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<tr>
<td>Depuy Spine</td>
<td>#100</td>
<td>325 Paramount Dr</td>
<td>508-828-3253</td>
<td></td>
<td><a href="http://www.depuyspine.com">www.depuyspine.com</a></td>
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<tr>
<td>Disc Dynamics Inc</td>
<td>#620</td>
<td>9600 West 76th Street</td>
<td>952-345-2986</td>
<td>952-345-2990</td>
<td><a href="http://www.discdyn.com">www.discdyn.com</a></td>
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<tr>
<td>Disc Motion Technologies</td>
<td>#419</td>
<td>1900 Corporate Blvd., 400 E</td>
<td>561-988-6846</td>
<td>561-988-6847</td>
<td><a href="http://www.discardmotion.com">www.discardmotion.com</a></td>
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CoreSpine Technologies’ first products will set the standard for preparing the spinal disc for implantation of artificial disc nucleus devices and minimally invasive interbody fusion devices.

Covidien is dedicated to working with medical professionals to improve patient outcomes. Its portfolio of leading brands includes: DuraSeal, Autosuture, Kendall, Mallinckrodt, Nellcor, Puritan Bennett, Syneture and Valleylab.

Continuously arrives to be the leading company offering solutions for the treatment of spine disorders via proven and innovative high quality products, the provision of professional education and full customer support services.

Disc Dynamics, Inc. was established to provide patients and physicians with a minimally invasive surgical alternative for treating low back pain. To achieve this goal DDI developed the DASCOR® Disc Arthroplasty System. The DASCOR™ Disc Arthroplasty System is currently CE marked and is undergoing an IDE clinical trial in the United States.

Disc Motion Technologies is excited to attend its first Spine Arthroplasty Society meeting. Spine surgeons will appreciate the opportunity to see the first, posteriorly implanted, total, lumbar spinal joint replacement system. The True Total Spinal Motion Segment (TSMS) implant consists of two paired, posterior lumbar discs and a set of synchronous, posterior dynamic stabilizers. The TSMS is implanted via a PLIF surgical approach, but allows the surgeon to correct all pain generators. The TrueDyne Posterior Dynamic Stabilizer (PDS) is also the first PDS to offer an adjustable range of curved motion for more physiologic dynamic stabilization of the lumbar spine.

Eden Spine is a privately held spinal organization based in Florida. As a developer of motion preservation technologies, the Eden Spine Group is dedicated to turning imaginative ideas into leading spinal solutions. Eden Spine’s core values reflect the energy and spirit of a company with solid moral foundations articulated around a code of behavior that guides us with integrity and passion.

Elliquence, LLC; formally Ellman Innovations manufactures patented Radiowave technology with innovative delivery systems for minimally invasive spine procedures. Disc-FX® represents an innovative, 4-in-1 procedure for minimally invasive lumbar discectomy. Patented Radiowave device and Trigger-Flex® Bipolar navigational delivery system permit targeted, versatile tissue effects including, annulus modulation and nucleus ablation resulting in enhanced patient outcomes.
Exponent
3401 Market Street  suite 300
Philadelphia  PA  19104
Phone: 215-594-8851
Fax: 215-594-8899
www.exponent.com

Exponent (www.exponent.com) is an international research consulting firm, headquartered in California and with offices in the United States, Europe, and China. Exponent provides services in preclinical testing, finite element analysis, biomaterials and biologics characterization, drug delivery, cryopreservation, retrieval analysis, intellectual property, and clinical outcomes research for orthopedic and spinal applications.

Facet Solutions, Inc
124 South 600 West
Logan UT  84321
Phone: 435-753-1671-123
Fax: 435-753-3996
www.facetsolutions.com

The Anatomic Facet Replacement System AFRS™ is a joint reconstruction device that ideally matches the size and shape of the facet joint and is designed to provide patients with pain relief, normal motion, and stability. The Facet Solutions AFRS™ implants utilize conventional pedicle screw fixation and are placed with great precision utilizing reproducible instrumentation

Flagship Surgical LLC
16 Mt Bethel Road  Suite 313
Warren NJ  07059
Phone: 888-633-5843
Fax: 732-560-0936
www.flagshipsurgical.com

Flagship Surgical prides itself on providing comfortable, safe and economical products engineered to ensure a more focused and pleasant surgical experience for surgeons, nurses and OR technicians. The Surgical Mat™ and The Mini Mat™ are the only patented, easy to use disposable surgical mats addressing 3 important operating room issues: surgical comfort, fluid management and OR safety. Please visit our booth and discover why the innovative features of The Surgical Mat™ and The Mini Mat™ make them a necessity in every Operating Room.

FzioMed, Inc
231 Bonetti Drive
San Luis Obispo CA  93401
Phone: 805-546-0571
Fax: 805-549-7227
www.fziomed.com

FzioMed specializes in absorbable biomaterial medical devices based on the company’s patented polymer science. FzioMed products include Oxiplex Gel, the leading adhesion barrier for spine surgery, with over 100,000 patients treated worldwide.

Globus Medical
2560 General Armistead Ave
Audubon PA  19403
Phone: 610-415-9000-1618
www.globusmedical.com

Globus Medical, the world’s largest privately held spinal company, is driving significant technological advancements across the complete suite of spinal products including Fusion, MIS (minimally invasive surgery), Motion Preservation and Biomaterials. Since its founding in 2003 by an accomplished team of spine professionals with a shared passion for developing new technologies to improve patient outcomes, Globus’ single-minded focus on advancing spinal surgery has made it the fastest growing company in the history of orthopedics. Today, Globus is one of the world’s preeminent spine companies, with proven technology and innovation across the spectrum of spine surgery products

HydroCision, Inc
32 Linnell Circle  Suite 102
Billerica MA  01821
Phone: 978-289-1310
Fax: 978-600-5058
www.hydrocision.com

HydroCision’s SpineJet™ HydroSurgery System has been designed for application in both Fusion (open & MIS) and Discectomy procedures. The SpineJet XL has been clinically proven to optimize disc preparation, while the MicroResector combines the clinical advantages of a microdiscectomy procedure with the economic and patient advantages of a minimally invasive discectomy procedure.
iMDs
180 S 600 W
Logan UT 84321
Phone: 970-310-5974
Fax: 435-753-7698
www.medicine-lodge.com

iMDs is the leading innovator in full-service contract medical device development and manufacturing. iMDs offers customized sourcing services to provide exceptional responsiveness at every stage of the product life cycle – from idea to sale.

Inion
2800 Glads Circle
Weston FL 33327
Phone: 954-659-9224
Fax: 954-659-7997
Email: scott.pravda@inion.com
www.inion.com

Inion has developed novel next generation biodegradable polymer implants to be used in cervical spine fusion.

Innovative Spinal Technologies
111 Forbes Blvd
Mansfield MA 02048
Phone: 508-452-3554
Fax: 508-452-3600
www.istspine.com

Learn about a breakthrough in Dynamic Stabilization functionality and design. Experience first-hand how motion and control become one during this hands-on Workshop featuring the AXIENT Dynamic Fixation System.

Interventional Spine Inc
13700 Alton Parkway Suite 160
Irvine CA 92618
Phone: 949-472-0006
Fax: 949-472-0016
i-spineinc.com

Interventional Spine, Inc. is a very unique medical device company exclusively focused on the development and marketing of patented PERCUTANEOUS system to treat lower back pain.

Intrinsic Therapeutics
30 Commerce Way
Woburn MA 01801
Phone: 508-655-3037
Fax: 508-655-3027
www.intrinsic-therapeutics.com

Intrinsic Therapeutics, INC. has pioneered the “Anular Reconstruction” procedure based on years of feedback from leading orthopedic and neurosurgeons from around the world. Surgeons have tried for years and have been unsuccessful in repairing the anulus following a lumbar disc herniation. Intrinsic has developed a novel system which provides the surgeon with the results and confidence that has eluded them for years.

Invuity Inc
39 Stillman Street
San Francisco CA 94107
Phone: 415-847-2337
Fax: 415-778-0810
www.invuity.com

Invuity™ offers a line of advanced spinal retractors incorporating complex optical structures that provide flawless light to the surgical field, allowing surgeons to achieve an unparalleled level of visualization during less invasive surgery.

Joimax, Inc
275 E Hacienda
Campbell CA 95008
Phone: 408-370-3005
Fax: 408-370-3015
www.joimax.com

Joimax is introducing a complete ENDOSCOPIC Lateral Recess Stenosis and Central Stenosis instrumentation system. This system compliments it’s existing TESSYS system which is for the ENDOSCOPIC treatment of herniated discs.

K2M
751 Miller Drive SE Suite F1
Leesburg VA 20175
Phone: 703-777-3155
Fax: 703-777-4338
www.k2m.com

K2M will strive to be at the frontier of technological innovation, and through physician involvement from industry leaders, the Company will develop the highest quality products for surgeons with the ultimate purpose of promoting the well-being of patients with spinal disorders.
Lanx  #724
390 Interlocken Crescent
Broomfield CO 80021
Phone: 303-501-8434
Fax: 303-443-7501
www.lanx.us

Lanx specializes in systems and implants for all segments of spinal surgery. Integrating leading technology, intellectual property and state-of-the-art engineering, each product is designed to simplify surgery and improve patient outcomes.

LDR  #117
4030 W Braker Lane  #360
Austin TX 78759
Phone: 512-344-3325
Fax: 512-344-3350
www.ldrspine.com

LDR creates innovative fusion and non-fusion spinal technologies for surgeons and patients in 26 countries. The founders of LDR built the company with one focus: Spine. All the resources of LDR are dedicated to this highly specialized segment of orthopaedic and neurological markets, which enables us to be strong players in a quickly changing high-tech field. LDR is passionate about improving patients’ lives. Partnering with surgeons and sales people, LDR provides spinal systems and instrumentation that make spine surgery reproducible, easier to perform, and restores optimum stability and mobility to patients. We have A Passion for Innovation!

Life Spine  #913
2401 Hassell Road, Suite 1535
Hoffman Estates IL 60169
Phone: 847-884-6117
Fax: 847-884-6118
www.lifespine.com

Life Spine is a full line spine company which develops and markets spinal implants and instruments. Life Spine is dedicated to improving the quality of life for spinal patients by increasing procedural efficacy through innovative design and uncompromising quality standards.

Medtronic  #101
2600 Sofamor Danek Drive
Memphis TN 38132
Phone: 901-344-0801
www.medtronic.com

Medtronic is the market leader in the development and distribution of products that treat spinal disorders. Emphasizing minimal access spine surgery, biologic materials, and non-fusion technologies, we are committed to providing surgeons with the next generation of technology that will revolutionize the future of spine care.

Nexgen Spine  #124
9 Whippany Road Suite 11
Whippany NJ 07981
Phone: 973-386-1800-315
Fax: 973-386-5656
www.nexgenspine.com

Nexgen Spine is a leading developer of implants for the functional restoration of the spine. These implants relieve pain and restore physiologic motion in degenerated discs. The products use proprietary elastomeric polyurethane technology enabling shock absorption and wear prevention. Nexgen Spine has developed artificial disc replacements for the lumbar, Physio-L, and cervical, Physio-C spine.

NuVasive  #900
4545 Towne Centre Ct.
San Diego CA 92121
Phone: 858-909-1832
Fax: 858-909-2032
www.nuvasive.com

NuVasive’s Maximum Access Surgery (MAS™) platform features the MaXcess® retractor system, and specialized implants for minimally disruptive spine surgery. NuVasive’s XLIF® procedure integrates several of these proprietary technologies.

Orthofix/Blackstone  #711
90 Brookdale Dr.
Springfield MA 01104
Phone: 413-726-2551

Blackstone Medical, an Orthofix company, showcases its motion preservation line of products which includes the Advent(TM) Cervical Disc and the InSWing(TM) Interspinous Spacer. The Advent Cervical Disc has just entered its clinical trial stage in the United States while the InSWing device will be marketed overseas. The company will also be displaying its “breakthrough” ProView(TM) (MAP) System for MIS procedures to the spinal community.
Paradigm BioDevices
800 Hingham St  Suite 102N
Rockland MA 02370
Phone: 781-982-9950
Fax: 781-982-9008
www.paradigmbiodevices.com

Paradigm BioDevices, Inc. specializes in novel spinal technologies including STALIF-Single Incision 360, a system based solution to simple and complex spinal care.

Paradigm Spine
505 Park Avenue  14th Floor
New York NY 10022
Phone: 212-583-9700
Fax: 212-826-9509
www.paradigmspine.com

Paradigm Spine is a provider of non fusion spinal implant solutions that serves to address the unmet clinical needs of spine surgeons and their patients. Starting with the coflex™ interspinous implant technology Paradigm Spine develops a full non fusion product portfolio of motion preserving tissue sparing technologies.

The company proudly introduces three new products at SAS 8: The DCI™ implant for cervical dynamic stabilization, the DSS™ implant for lumbar dynamic stabilization and the coflex-F™ implant as a minimally invasive solution as an adjunct to fusion.

Pioneer Surgical Technology
375 River Park Circle
Marquette MI 49855
Phone: 906-226-9909
Fax: 906-226-4455
www.pioneersurgical.com

Pioneer Surgical Technology is a full service ISO 13485 certified medical device firm dedicated to researching, developing, manufacturing, marketing and distributing specialized orthopaedic and spinal implants and instruments.

Ranier Technology LTD
Greenhouse Park Innovation Centre
Newmarket Road
Cambridge CB5 8AA
United Kingdom
Phone: 4412-23505-045
www.ranier.com

Ranier Technology is an EN 13485 certified device developer & manufacturer focused on motion preserving spinal implants. Ranier’s lead product, CAdisc - L, is an entirely polyurethane, shock absorbing, total replacement lumbar disc which mimics the functionality & biomechanics of the natural disc and offers long term durability and full MRI compatibility to the clinician treating Degenerative Disc Disease. Ranier also has a range of spinal implants under development including its cervical disc, CAdisc – C.

Raymedica, LLC
9401 James Ave South  Suite 120
Minneapolis MN 55431
Phone: 952-885-0500
Fax: 952-885-0200
www.raymedica.com

Raymedica®, the pioneer and market leader of Nucleus Arthroplasty™ products, develops, manufactures & markets non-fusion, spinal nucleus arthroplasty devices for early Degenerative Disc Disease via less-invasive surgical techniques. Company products are available worldwide, but limited to investigational use only within the USA. Raymedica is located in Minneapolis, Minnesota. www.raymedica.com

Richard Wolf Medical Instruments Corp
353 Corporate Woods Parkway
Vernon Hills IL 60061
Phone: 847-913-1113-607
Fax: 847-913-6959
www.richardwolfusa.com

Richard Wolf features endoscopic spine systems which can be used for both posterolateral (foraminal) and interlaminar approaches to the disc, for discectomy, fragmentectomy, and foraminoplasty. High resolution endoscope optics, and radiofrequency, burring and debriding capabilities, provide strong alternatives for the spinal endoscopist.

Scient’X
1015 Maitland Center Commons Blvd 106A
Maitland FL 32817
Phone: 407-571-2550-219
Fax: 407-660-1129
www.scientx.com

Scient’x is a developer and manufacturer of Innovative Spinal Devices and has become a key player in Dynamic Stabilization with the Isobar Dynamic TTL-Rod. The Scient’x portfolio also includes the PCB Evolution cervical plate-cage, an Ultra Low Profile Cervical Plate, and a range of PEEK spacer systems.
Seaspine Inc  #712
2302 La Mirada Drive
Vista CA 92081
Phone: 760-727-8399-211
Fax: 760-727-8891
www.seaspine.com

Based in Southern California, SeaSpine is focused on providing high quality, competitive products for the spine fusion market and developing next generation non-fusion products.

Showa Ika  #231
8-7 Haneinishi -mach
Toyohashi Aichi 441 8026
Japan
Phone: 81-532-32-1543
Fax: 81-532-32-1106
www.showaika.com

SHOWA IKA is a Japanese medical device company which has a history of more than 30 years. We are fully dedicated to coordinate the development, design, manufacturing and global distribution of spinal devices as the assistance for better surgery.

Signus Medical  #321
18888 Lake Drive East
Chanhassen MN 55317
Phone: 952-294-8701
Fax: 952-975-0465
www.signusmedical.com

Signus Medical, LLC develops, markets & sells creative & unique spinal implants which provide surgical solutions & simplicity of implantation meeting the needs of any surgeon or patient. Signus has the most complete & comprehensive line of PEEK Optima® implants in the spinal market. Signus is introducing a new & revolutionary material for VBRs & cervical plating--ECF-PEEK®. Come see it!

Sintea Biotech, Inc  #525
407 Lincoln Rd suite 10L
Miami Beach FL 33139
Phone: 305-924-0626
Fax: 305-673-3312
www.sinteabiotech.com

Sintea Biotech one of the leaders in advanced product projecting and development in the orthopaedic and neuro-surgical fields. Sintea Biotech has focused its efforts on new material science to answer surgeons needs by offering them different solutions. Product included: Pedicle Screws, Expandible VBR, Interspinous stabilization and more others.

Spinal Elements  #315
2744 Loker Ave W Suite 100
Carlsbad CA 92010
Phone: 760-607-0121-208
Fax: 760-607-0125
www.spinalelements.com

Spinal Elements develops and markets innovative technologies for spinal fusion and arthroplasty. The product line includes: Mosaic™ Spinal Implant System; Atomic® Anterior Cervical Plate System; Crystal®, Lucent®, and Lucent Magnum™ intervertebral body devices; and Mercury™ Spinal System. Spinal Elements is also developing the Zyre™ facet implant system.*

Spinal Kinetics  #310
595 N Pastoria Dr
Sunnyvale CA 94085
Phone: 408-636-2500
Fax: 408-636-2599
www.spinalkinetics.com

Spinal Kinetics is a privately-held medical device company focused on partnering with spine surgeons to develop innovative and practical motion preservation systems for treating degenerative diseases of the spine. The company’s M6 artificial cervical disc is the only artificial disc that replicates the anatomic structure of a natural disc by incorporating an artificial nucleus and annulus.

SpinalMotion  #507
201 San Antonio Circle Suite 115
Mountain View CA 94040
Phone: 650-947-3472-10
www.spinalmotion.com

SpinalMotion is focused exclusively on spinal disc arthroplasty, developing innovative technology designed to further enhance options for patients suffering from degenerative disc disease. SpinalMotion was founded in June 2003. The company is located in Mountain View, California. To learn more, visit our website at www.spinalmotion.com.

Spine Frontier  #618
100 Cummings Centre Suite 240C
Beverly MA 01915
Phone: 443-610-9904
Fax: 978-232-3991
www.spinefrontier.com

Spine Frontier is growing from the ground up by surgeons to develop disruptive innovative technologies.
Our company is driven by surgeon ingenuity that will improve patients’ quality of life. Conceived by practicing surgeons, SpineFrontier comes to market with an innovative suite of MIS products.

**Spine Wave**

Two Enterprise Drive Suite 302
Shelton CT 06484
Phone: 203-944-9494
Fax: 203-944-9493
www.spinewave.com

Spine Wave develops and markets clinical solutions for several market segments including: nuclear replacement and augmentation, vertebral compression fracture repair and spinal fusion. The company’s portfolio includes the NuCore® Injectable Nucleus, the StaXx® FX Structural Kyphoplasty, the StaXx® XD Expandable Device, the CapSure™ PS Spine System and several additional products in development.

**SpineVision**

301 Howard Street Suite 970
San Francisco CA 94105
Phone: 415-512-2500
Fax: 415-512-8004
www.spinevision.com

SpineVision designs and markets innovative spine implants and instruments developed in close collaboration with leading neuro/orthopaedic surgeons. SpineVision’s portfolio includes PediGuard™, the only FDA-cleared Class II device for real-time detection of possible vertebral cortex perforation, the P.L.U.S.® posterior universal system, the UNI-Thread™ system for lumbar degenerative and its spondylolisthesis reduction extension, UNI-Thread™ SPL, the C3® anterior cervical plate, and Spacevision™ PEEK cages. SpineVision’s future innovations will offer unique solutions for dynamic stabilization and MIS.

**Stryker**

2 Pearl Court
Allendale NJ 07401
Phone: 201-760-8059
Fax: 201-760-8195
www.stryker.com

Back pain is becoming a more prevalent problem, affecting hundreds of thousands of people annually. To offer their patients relief from debilitating pain, surgeons in increasing numbers are choosing Stryker spinal implants. Stryker uses leading edge technology to design, manufacture, and service a full range of spinal implant products. With spinal systems designed specifically for thoracolumbar, cervical, interbody, bone substitute, and motion preservation applications, Stryker can offer our neurosurgeon and orthopedic surgeon customers a comprehensive range of procedural solutions.

**Synthes Spine**

1302 Wrights Lane East
West Chester PA 19380
Phone: 610-719-5674
Fax: 610-719-5100
www.synthes.com

Synthes Spine develops, manufactures, and is the sole authorized distributor of AO/ASIF instruments and implants used in the spine. Synthes Spine, in conjunction with the AO/ASIF, coordinates the most comprehensive postgraduate continuing education programs available to spine surgeons and operating room personnel.

**Thompson Surgical**

10170 E Cherrybend Rd
Travers City MI 49684
Phone: 231-922-0177
Fax: 231-220-0174
www.thompsonsurgical.com

Thompson Surgical is the original manufacturer of table-mounted retractors. Evolution, based on surgeon feedback, has made the original even better. Stop by our booth so you can see the new innovations that make our retractors easier, quicker and more versatile while providing best exposure for you! Sign up for a free trial to see for yourself.

**Trans1**

411 Landmark Drive
Wilmington NC 28412
Phone: 910-332-1700
Fax: 910-332-1701
www.TranS1.com

Trans1® is pioneering an innovative, trans-sacral approach to lumbar surgery. A percutaneous access and fusion system enables lumbar fusion to be performed with complete preservation of the annulus and all paraspinous soft tissue structures.

**Vertebral Technologies**

5909 Baker Road, Suite 550
Minnetonka MN 55345
Phone: 952-912-5400
www.vti-spine.com

Guiding the Future of Minimally Invasive Fusion.
VertiFlex
1351 Calle Avanzado
San Clemente CA 92673
Phone: 949-940-1400
Fax: 949-940-1450
www.vertiflexspine.com

VertiFlexTM is committed to transforming patient outcomes to through the creation, development, and marketing of minimally invasive and non-fusion technologies. Our platform of anatomically driven products offers surgeons the ability to treat a broad range of clinical indications with reduced operating times and minimal trauma to patients.

Vexim
10 Avenue Hermes
Toulouse 31240
France
Phone: 330-561-4886-63
Fax: 330-561-4895-19
www.vexim.fr

Vexim is a European based company dedicated to bringing clinically and scientifically proven solutions to minimally invasive treatment of patients suffering from spinal trauma disorders.

W.L. Gore
1505 N Fourth Street
Flagstaff AZ 86004
Phone: 800-437-8181
Fax: 800-742-5315
www.goremedical.com

The Gore Medical Products Division has provided creative therapeutic solutions to complex medical problems for three decades. During that time, more than 23 million innovative Gore Medical Devices have been implanted, saving and improving the quality of lives worldwide.

X-Spine Systems Inc
452 Alexandersville Rd.
Miamisburg OH 45342
Phone: 800-903-0640
Fax: 937-847-8410
www.x-spine.com

X-spine is a next-generation spinal implant company. We are dedicated to advancing spinal implant technologies that improve surgery outcomes and optimize surgeon experience.

Zimmer Spine
7375 Bush Lake Road
Minneapolis MN 55439
Phone: 952-857-5682
Fax: 952-857-5985
www.zimmerspine.com

Zimmer Spine develops, produces and markets the highest quality spine products and services that repair, replace and regenerate spine health. Zimmer Spine facilitates surgeon-to-surgeon training and provides continuous access to relevant information to improve patient outcomes. With continuous technological advancement, Zimmer constructs superior fusion and non-fusion spine systems, instrumentation systems, cervical plates, allograft bone filler and trabecular metal. Through the hands of skilled surgeons, Zimmer enhances patient quality of life.
In the U.S., the safety and efficacy of this device for the indication of spinal stabilization without fusion has not been established.
Visit us at Booth #310 to learn more about the M6 technology.

**WARNING:** This device is not cleared by the FDA for distribution in the United States.

**CAUTION:** Investigational Device. Limited by Federal law to investigational use.

**Artificial Nucleus/ Axial Compression**

**Artificial Annulus/ Controlled Range of Motion**

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**M6 ARTIFICIAL LUMBAR DISC**  
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**M6 ARTIFICIAL CERVICAL DISC**  
**CAUTION:** Investigational Device. Limited by Federal law to investigational use.
As pioneers in spine surgery, our comprehensive range of products have been the most trusted and respected in the world for years. Yet our experience shows that what matters goes far beyond the technologies we produce.

Today, DePuy Spine leads the way into the future of spine surgery with programs and details that matter to you. Conducting clinical trials to characterize the effectiveness and safety of our products so you can make more evidence-based decisions. Leading initiatives to improve access for more patients. And advancing spinal technology, research, and education by partnering with those who care most about taking spine care to the next level.

DePuy Spine is more than a spine implant company. We're here to help you provide the best care possible.

www.depuyspine.com
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Be a part of it.

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The PERPOS™ PLS System is the first and only PERCUTANEOUS transfacet-pedicular compression system for posterior stabilization during a fusion procedure of the lower spine.

PercuDyn™ System

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Visit us at SAS ‘08 Booth #303
to Discover the Pathway to PERCUTANEOUS Spine Therapy!

www.i-spineinc.com

Interventional Spine® Inc.
13700 Alton Parkway, Suite 160
Irvine, CA 92618
949.472.0006
800.497.0484

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Interventional Spine®, Inc. is certified to IS EN ISO 13485:2003. The products have been assessed in conjunction with the Notified Body as applicable, and are considered to meet the Essential Requirements and so bear the CE Marking of Conformity. As of date of print, Interventional Spine has several issued and pending U.S. patents. The PercuDyn™ System is not available for sale in the United States.

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Arthroplasty Solutions

**FlexiCore®**
- One-piece no-keel design for easy implantation
- Multiple fixation points
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- Intuitive procedure for easy implantation
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Replicating the mobility, load, and stability of the cervical spine is distinctly unique from that of the lumbar spine. Our technology platform of mobile bearing products consists of the next generation of cervical and lumbar disc prostheses distinctly adapted for each use.

Caution: The Mobi-C artificial disc is an Investigational Device and is limited to investigational use in the United States. The Mobi-L (Mobidisc®) is not available in the United States.

One implant design will not work for both Cervical and Lumbar.
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Ceramic articulation and titanium endplates allow the Discocerv® cervical artificial disc replacement to restore motion without compromising stability.

**Not approved for sale or distribution in the United States.**
For more information, visit Booth #225 or go to www.ScientX.com
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is indicated as a cover for vessels following anterior vertebral surgery to reduce the risk of potential vessel damage during a revision surgery by providing a plane of dissection.

- **Reduces Risk of Vessel Damage** – Provides a permanent and visible plane of dissection to facilitate anterior revision surgery of the spine.

- **Minimal Vascular Tissue Attachment to the Device** – Tight ePTFE microstructure provides a vessel-friendly interface while preventing penetration of fibroblasts.

- **Proven Performance** – Gore ePTFE technology is safe and effective with more than 30 million clinical implants. Surgeon feedback from an ongoing GORE PRECLUDE® Vessel Guard Revision Registry documents a permanent plane of dissection, providing vessel protection and facilitating re-operations.¹

- **Preserves Future Treatment Options** – A permanent and identifiable plane of dissection may facilitate anterior re-operations: adjacent level treatment, hardware removal, subsequent trauma treatment, and open vascular treatment.

- **Easy to Use** – Elastomeric inner layer minimizes impingement and provides stiffness for placement. Material may be trimmed and tailored without fraying.

¹ Data on file and available upon request.

W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004
800.437.8181 • 928.779.2771
For additional product information, visit goremedical.com/vesselguard

Product(s) listed may not be available in all markets pending regulatory clearance.
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Achieving segmental stability in fusion is a given. But how can you provide that stability while also offering your patients a controlled range of motion? With the Axient™ Dynamic Fixation System from IST, intended to provide controlled physiological motion. The articulating semi-constrained device is designed to allow for segmental movement, with integral stops to avoid excessive motion in flexion, extension and sagittal translation. And like all IST systems, the Axient Dynamic Fixation System features elegant, uncompromising design and engineering. Form and function become one. For more information, visit us at Booth #401 at SAS08, contact Innovative Spinal Technologies at 888.IST.SPINE, or visit istspine.com.
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To learn more about Medtronic’s Spinal and Biologics Business, visit us at www.medtronicspinal.com.
Get patients back on their feet faster. See how in Miami Beach.

NuVasive® complete portfolio of spine solutions at SAS8

NuVasive is an innovative spine surgeon-focused organization featuring specialized cervical and thoracolumbar systems and innovative solutions in surgeon-driven neurophysiology, lateral access surgery, and motion preservation. Visit Booth #900 in Miami Beach and see for yourself.

Visit us during the SAS 8th Annual Meeting, May 6–9, 2008, Booth #900, Miami Beach Convention Center.
Wednesday, May 7th
12:00 p.m. - 2:00 p.m.

**HALL B MEETING ROOMS, 1ST LEVEL**

**ABBOTT SPINE**
“Worldwide Experience with the Wallis Implant”
Dr. Nick Boeree and Dr. Kenneth Pettine
*Room: B112*

**STRYKER**
Disc Replacement versus Fusion for Lumbar Degenerative Disc Disease: State-of-the-Research and Overall Treatment Success Results
Speakers: Thomas Errico, MD (NYU Hospital for Joint Diseases, New York, New York, USA), George Miz, MD (Ingalls Memorial Hospital, Harvey, Illinois, USA), Rick Sasso, MD (Indiana Spine Group, Indianapolis, Indiana, USA), Jim Zucherman, MD (St. Mary’s Center, San Francisco, California, USA)
*Room: B113*

**SPINAL KINETICS**
The M6™ Artificial Disc Advancements in Cervical & Lumbar Disc Arthroplasty
*Room: B114*

**INNOVATIVE SPINAL TECHNOLOGIES**
Dynamic Fixation
Ali Araghi, MD
Michael Hisey, MD
Lisa Ferrara D.Eng
*Room: B115*

**SYNTHESES SPINE**
New Concepts in Posterior Stabilization
*Room: B116*

**ZIMMER SPINE**
To Be Announced On-Site
*Room: B117*

**HALL B MEETING ROOMS, 2ND LEVEL**

**PARADIGM SPINE**
Interlaminar Stabilization Concepts: coflex™ - a Functionally Dynamic Implant for the Treatment of Degenerative Spinal Stenosis and coflex-F™ as Adjunct to Interbody Fusion
Moderator: Dieter Adelt, MD
*Room: B210*

**RAYMEDICA**
Nucleus Arthroplasty™ Technology
Don’t miss this opportunity to learn about our Nucleus Arthroplasty™ Technology, a revolution in early DDD treatment.
*Room: B211*

**INTERVENTIONAL SPINE**
PERCUTANEOUS Lumbar Intervention, the Future of Spine Surgery: A Leadership Panel Discussion.
Dr. Khoo
*Room: B212*

**HALL A, MEETING ROOMS, 1ST LEVEL**

**ORTHOFIX/BLACKSTONE**
InSWing™ Interspinous Spacer
Marek Szpalski, MD
Robert Gunzberg, MD
*Room: A109*
Thursday, May 8th
12:00 p.m. - 2:00 p.m.

**HALL B, MEETING ROOMS, 1ST LEVEL**

**GLOBUS MEDICAL**
Clinical Experiences with New Technologies
Rooms: B112 - B113

**TRANS1**
AxiaLIF: 48 Month Experience in DDD, Instability and Adult Degenerative Scoliosis
Room: B114

**INNOVATIVE SPINAL TECHNOLOGIES**
Dynamic Fixation
Ali Araghi, MD
Michael Hisey, MD
Lisa Ferrara D.Eng
Room: B115

**LDR**
Screwless Anchoring Technology
Clinical Results for Motion Preservation and Fusion Technologies
Room: B116

**ZIMMER SPINE**
Room: B117

**DEPUY SPINE**
Moving Beyond The Basics: Advancing Lumbar Arthroplasty to the Next Level
Room: B211

**MEDTRONIC**
OUS Only
Overview of IPD Technologies: X-Stop, DIAM, and APERIUS
Room: B212

**HALL A, MEETING ROOMS, 1ST LEVEL**

**W.L. GORE**
Anterior Spinal Access: Strategies and Revision Considerations - A Vascular Surgeon's Perspective
Dr Sal Brau
Room: A106

**ANULEX**
New Surgical Advances in Anular Repair
Room: A109

**HALL B, MEETING ROOMS, 2ND LEVEL**

**PARADIGM SPINE**
Motion Control in the Treatment of the Degenerative Spine: Cervical and Lumbar Dynamic Stabilization with DCI™ and DSS™
Moderator: Reginald Davis, MD
Room: B210
Friday, May 9th

12:00 p.m. - 2:00 p.m.

HALL B, MEETING ROOMS, 1ST LEVEL

**SPINE FRONTIER**

MIS Lumbar Facet Fixation
Dr. Kingsley Chin, Dr. Warren Yu, Dr. Carl Bruce, and Dr. Josue Gabriel
Room: B112

**stryker**

Disc Replacement versus Fusion for Cervical Nerve Root Compression: Clinical and Radiographic Outcomes and Pain Management
Speakers: Rolando Garcia, MD (Aventura Hospital & Medical Center, Aventura, Florida, USA), Jim Youssef, MD (Durango Orthopedic Associates, P.C. / SpineColorado, Durango, Colorado, USA)
Room: B113

**MEDTRONIC**

OUs ONLY
Prestige LP - Update of Clinical Results
Room: B114

**DISC MOTION TECHNOLOGIES**

Posterior Lumbar Arthroplasty
Room: B115

**SYNTHEs SPINE**

Cervical and Lumbar Arthroplasty Solutions
Room: B116

**SPINE VISION**

“PediGuard*: a solution for the Challenges of Pedicle Screw Placement
Room: B117

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**HALL B, MEETING ROOMS, 2ND LEVEL**

**PARIAdigm SPine**

Non-Fusion Solutions for the Continuum of Care in Pediatric Scoliosis
Moderator: Thomas J. Errico, MD
Room: B210

**NUVASIVE**

XLIF® Approach - a Strategy for Degenerative Conditions and Safer TDR Revision
Luiz Pimenta, MD, Andrew Cappuccino, MD, Frank Phillips, MD
Room: B211

**MEDTRONIC**

US ONLY
Prestige St - Clinical Results, Cases, etc.
Room: B212

**HALL A, MEETING ROOMS, 1ST LEVEL**

**INION**

Next Generation Polymer Fixation in the Use of Cervical Spine Fusion
Room: A109
TRANSPORTATION INFORMATION

TAXI SERVICES
Taxi service from Miami International Airport to Miami Beach Convention Center - Fare: Approximately $35 (one way)

AIRPORT SHUTTLE - SUPER SHUTTLE
Upon arrival at the airport, please follow signs from baggage claim to the SuperShuttle ticket counter. No reservation is necessary. Please call 305-871-2000 with any questions. SuperShuttle accepts cash and credit cards for payment.
Fare: $20 Subject to change (one way)

PUBLIC TRANSPORTATION
Miami-Dade Transit
Specific Route Information: 305-770-3131
Fare: Approximately $1.50
Transfer: Approximately $0.50

HOTEL SHUTTLE SCHEDULE
*Please refer to the SAS sponsored shuttle schedule flyer included with your registration materials. Additional shuttle service flyers and appropriate signage will be posted at all hotels and the Convention Center lobby.

Tuesday, May 6, 2008
7:30 a.m. - 7:30 p.m. (Every 24-30 minutes)
Welcome Reception - (5:00 p.m. - 7:00 p.m.)
(at Convention Center)

Wednesday, May 7, 2008
7:30 a.m. - 10:30 a.m. (Every 12-15 minutes)
10:30 a.m. - 3:00 p.m. (Every 24-30 minutes)
3:00 p.m. - 6:00 p.m. (Every 12-15 minutes)

Thursday, May 8, 2008
7:30 a.m. - 10:30 a.m. (Every 12-15 minutes)
10:30 a.m. - 3:00 p.m. (Every 24-30 minutes)
3:00 p.m. - 6:00 p.m. (Every 12-15 minutes)

Friday, May 9, 2008
7:30 a.m. - 10:30 a.m. (Every 12-15 minutes)
10:30 a.m. - 4:00 p.m. (Service as needed)

HOTELS, ROUTES & PICKUP LOCATIONS
Route A - Pink
Fountainebleau Resort – Curbside on Collin Avenue
Miami Beach Resort and Spa – Curbside on Collins Avenue

Route B - Green
Loews Miami Beach – Curbside on Collins Avenue
Ritz Carlton – Curbside on Collins Avenue at Lincoln

*Subject to change and traffic conditions

TOUR INFORMATION
With countless sightseeing and professional tour choices available, visitors who want to get up close and personal with Greater Miami and the Beaches will have no trouble doing so. From the wide ocean beaches in the east to the Everglades swamps in the west, discover a dazzling variety of Miami tour and sightseeing options arranged by experienced, friendly professionals. From city tours of multifaceted Miami to shopping excursions or eco-treks and outdoor adventures, there are tours to match every taste and special interest. Find out what makes the Magic City so enchanting. No matter which way you prefer to tour Miami - by air, water or land - you will be introduced to a wonderful world of natural and man-made delights.

Tour and Activity programs are subject to change/cancel due to local conditions and/or minimum person requirement.
MIAMI CITY TOUR

Today guests travel around Miami and the surrounding areas learning about its rich history and exciting tales. The tour begins with a drive past South Beach's Art Deco district, where the world's largest collection of Art Deco architecture and a unique mix of natural and cosmopolitan settings abound.


Guests then make their way over to Little Havana or Calle Ocho, the vibrant neighborhood with a distinct Latin flavor which includes signs and billboards en Español and music to match. Everything is authentic from the fruit stands and cigar factories to the eat-at windows of the cafeterias. Guests make a brief stop to discover the tastes of Little Havana or to visit the quaint shops. Guests can sample a Cuban coffee or pastry, watch cigars being hand rolled, or find embroidered Guayabera shirts.

The next neighborhood guests discover is Coral Gables with its wide, tree-lined boulevards, winding roadways and green space. Coral Gables has been called “The City Beautiful.” Planned on a grand scale in the late 1920s, the city’s design blends color and detail with Mediterranean Revival style. The most notable building is the historic Biltmore Hotel.

Guests make their final stop in Coconut Grove and hear about such pioneers as Commodore Ralph Munroe and millionaire James Deering. Guests travel past Deering's estate, Villa Vizcaya Museum and Gardens, the Italian Renaissance-style villa built in 1916. The tour makes a one-hour stop for guests to explore the heart of Coconut Grove on their own before returning to the hotel.

Suggested Itinerary:
- 12:30 PM Depart hotel
- 12:45 PM Tour begins
- 1:30 PM Stop at Little Havana,
- 1:45 PM Depart Little Havana, Tour continues
- 2:30 PM Stop in Coconut Grove,
- 3:30 PM Depart Coconut Grove
- 4:30 PM Return to hotel

**Date:** Monday, May 5, thru Friday, May 9, 2008  
**Time:** (4) hours  
**Price:** $55.00 per person

THE THRILLER MIAMI POWERBOAT

The Thriller Miami Powerboat Tour departs from Bayside Marketplace South Pavillion in Miami, Florida. The tour provides the ultimate sightseeing experience on the waters of Biscayne Bay - Key Biscayne - Coconut Grove - Fisher Island and the Miami Gold Coast. The sightseeing cruise will cover three times the area as compared to other tour vessels. Guests enjoy this premier sightseeing adventure in true “Miami -Vice Style”.

**Program Details**

**Itinerary:**
- 10:00 AM Depart from your Hotel lobby
- 10:30 AM Arrive at Bayside Marina for departure
- 11:00 AM Tour Starts
- 11:45 AM Tour Ends
- 12:05 PM Tour Bayside Shops/ Lunch on own
- 1:30 PM Depart from Bayside to hotel
- 2:00 PM Arrive to Hotel

**Dates:** Monday, May 5, thru Friday, May 9, 2008  
**Time:** 45 minutes boat ride – shared tour  
**Price:** $82.00 per person

KENTUCKY DERBY MIAMI STYLE!

There is nothing more thrilling than standing at the rail at Calder Race Course as the horses come charging around the turn. Guest's senses are assaulted at once - eyes focus on the colorful silks, ears are strained to hear the announcer’s call over the thunder of hoofs and screams of the crowd and the swirling aromas of the racetrack fill the air.

Guests are greeted by a Calder Race Course customer service team-member who introduces them to the exciting world of Thoroughbred racing, leading the way to the upscale Turf Club located on the fifth floor to enjoy a delicious lunch buffet. After lunch, the race can be viewed from the air-conditioned reserved seating area overlooking the spectacularly landscaped courses.

**Program Details**

**Itinerary:**
- 11:00 AM Depart from Hotel
- 11: 45 AM Arrive at Calder Race Course
- 11:45 AM Buffet Lunch begins in the Turf Club
- 12:00 PM Free time to observe and bet on the races
- 3:00 PM Depart Calder Race Course
- 3:45 PM return to Hotel

**Dates:** Monday, May 5, and Tuesday, May 6, 2008  
**Time:** (5) hours  
**Price:** $105.00 per person
**MIAMI’S MAGIC SKYFLY**

Take an exciting overhead tour of Miami, flying high in the sky! Fly over the wonderful and exhilarating world of Miami and its fabulous beaches and see Miami’s Magic Skyline. As guests fly, they have an opportunity to view Virginia Key and South Florida’s famous Parrot Jungle. Fly a little further and guests view the vibrant buildings of South Beach, Miami Beach, and then the famous islands called Fisher, Hibiscus, Star, Venetian, and Palm, where the rich and famous live.

Next, the tour heads south for a bird’s-eye view of the luxurious cruise ships docked at the Port of Miami, Millionaire Road, Government Cut, and the Bayside area of the city. Sights not to be missed include Vizcaya Museum and Gardens and Coconut Grove. Guests fly over downtown Miami, the Miami River entrance, and the remarkable Brickell Avenue. Miami’s Magic Skyline is sure to astound guests!

**Program Details**

**Itinerary:**
- 10:30 AM Depart Hotel
- 10:45 AM Arrive at the helicopter landing/take-off platform
- 11:00 AM Helicopter tour begins
- 11:30 AM Helicopter tour ends
- 11:45 AM Depart the helicopter landing/take-off platform
- 12:00 PM Return to Hotel

**Date:** Tuesday, May 6 thru Friday, May 9, 2008
**Time:** (1½) hours
**Price:** $360.00 per person

**SAWGRASS RECREATION PARK**

Sawgrass Recreation Park offers the opportunity to see the unique ecosystem of the Everglades in its natural state. It has long been a favorite destination to visit. Guided airboat tours at Sawgrass Recreation Park allow guests to take a scenic beauty of the “River of Grass” while observing birds and animals in their natural habitat. The park also has a live Alligator and Reptile Exhibit and a Wildlife Exhibit, which in collaboration with the Vanishing Species, a non-profit organization, allows visitors to view endangered animals, including the Florida panther. The park also has a replica of an 18th century Seminole Indian Village.

**Program Details**

**Itinerary:**
- 7:30 AM Depart hotel
- 8:00 AM Arrive at marina
- 12:00 PM Return to marina
- 12:30 PM Return to hotel

**Date:** Monday, May 5 thru Friday, May 9, 2008
**Time:** (5) hours
**Price:** $375.00 per person

**Includes:**
- Airboat Tour, approximately (30) minutes
- Alligator and Reptile Exhibit, approximately (30) minutes
- Vanishing Exhibit, approximately (30) minutes
- Free time to walk and visit the Seminole Village, approximately (30) minutes
- (1) Colorful safari bandana
- (1) Bottled water
- Deluxe Transportation

**DEEP SEA FISHING IN MIAMI**

Today guests fish the Waters off Miami for Sailfish, Dolphin, Marlin, Shark, Tuna and other species. All boats are air-conditioned, tournament rigged, contain sophisticated electronics and have the most experienced captains and mates.

Enjoy the same fast paced action for tuna, billfish and other pelagic species that Ernest Hemingway made famous. Nothing beats the exhilaration of battling a really big fish in the Gulf Stream. Lying in wait are kingfish, Wahoo and tuna (January to March): sailfish, dolphin and marlin (April to June): marlin, Wahoo and dolphin (July to September): shark, snapper, Snook, yellowtail, grouper, spearfish and many others to add to the challenge.

**Program Details**

**Itinerary:**
- 7:30 AM Depart hotel
- 8:00 AM Arrive at marina
- 12:00 PM Return to marina
- 12:30 PM Return to hotel

**Date:** Monday, May 5 thru Friday, May 9th, 2008
**Time:** (5) hours
**Price:** $375.00 per person

**Includes:**
- Half-day private excursion aboard a deluxe 6-passenger, Coast Guard certified fishing boat from boat’s home port, based on (4) hours
- Captain and deck-hand(s) onboard to assist guests with fishing
- Bait and tackle for each guest
- Deep Sea fishing rod and reel for each guest
- Temporary Florida fishing license for each guest
- Beverages (sodas, water, and assorted beer)
- Deluxe van transportation
- All applicable taxes and gratuities
“COME SAIL AWAY”
OCEAN SNORKEL CRUISE
An unforgettable excursion awaits guests aboard a state of the art catamaran(s). Sit back while we set sail to the Atlantic Ocean. Our exclusive catamaran(s) pick guests up at the dock and set sail to a reef destination. On the way to the reef, dive masters instruct guests on the art of snorkeling and brief guests on the tropical reef. Once at the reef, guests can sip a cool beverage, soak up the sun and enjoy an adventurous snorkel tour. Guests have the opportunity to see close up coral formations, exotic marine life and colorful tropical fish on this exciting journey.

PROGRAM DETAILS
Date: Monday, May 5, thru Friday, May 9, 2008
Time: (4) hours (3-hour private cruise)
Price: $140.00 per person
Includes:
- 3-Hour Ocean Sail Cruise / Snorkel and Swim Cruise
- Private Charter of a 49-passerenger catamaran (minimum 3-hour exclusive charter) to include:
  - Snorkel Equipment and Instruction
  - Beer, Wine and Soft Drinks, based on (3) hours
  - Dry Snacks
  - Time at the reef destination, approximately (1) hour
  - Deluxe transportation

COOKING DEMONSTRATION WITH CHEF JEAN PIerre
Enjoy a Sensational cooking experience with famously acclaimed Chef Jean Pierre who has appeared on the “Today Show” many times in the past three years. Chef Jean-Pierre has also appeared on Larry King Live, the Lifetime Channel’s, and “Crook& Chase”. You will find that learning to cook is an impressive art and you do not need to be a professional cook to have healthy and delicious meals need. Chef Jean Pierre will show you the right way to cook so that you understand what you’re doing, why you’re doing it, and how to make the most of your ingredients so that your dishes will become incredible! And, you’ll have so much fun making these recipes, and even exploring and creating your own masterpieces. Come and join Chef Jean Pierre on a delicious meal that you will prepare!!

PROGRAM DETAILS
Suggested Itinerary:
10:00 AM Depart designated Hotel
10:45 AM Arrive at Chef Jean Pierre Cooking School
11:00 AM Start Cooking Class
12:00 PM Lunch
12:30 PM Depart Chef Jean Pierre Cooking School
1:15 PM Return to designated Hotel

Date: Monday, May 5, thru Friday, May 9, 2008
Time: (3) hours
Price: $180.00 per person
Includes:
- Cooking class
- Lunch
- Deluxe transportation
- All applicable taxes and gratuities

SHOPPER’S HEAVEN AT THE AVENTURA
“SHOPPING EXTRAVAGANZA”
The Village of Merrick Park is a place where fashion and style come to life in a quaint Village brimming with fountains, lush tropical foliage and a serene garden to relax and enjoy the sunshine. A stroll through the gardens at the Village leads guests to such world-class boutiques as Artefacto, CH Carolina Herrera, Cheeky, Hugo Boss, Robert Cavalli, La Perla, and many more shops guests know and love.

The Palm restaurant (near the Park) is famous for its caricature-filled walls and beloved for its large portions of prime meats and jumbo Nova Scotia lobsters. The Palm is a classic and elegant steakhouse, serving a fusion of all things Latin (i.e. Peruvian, Brazilian, etc), comes an oasis of old-fashioned Americana.

The Palm Restaurant are both a fitting end to a glamorous day of shopping and wine tasting!

PROGRAM DETAILS
Itinerary:
10:00 AM Depart hotel
10:30 AM Arrive at the Village of Merrick Park
1:30 PM free time to shop begins
1:30 PM Depa the Village of Merrick Park
2:00 PM Return to the hotel

Date: Monday, May 5, thru Friday, May 9, 2008
Time: (4) hours
Price: $60.00 per person
Includes:
- Free time to enjoy the shops at the Village of Merrick Park, approximately (3) hours
- Deluxe transportation
SHOP, AND GAMBLE, AT THE SEMINOLE HARD ROCK CASINO

Escape to the South Florida getaway that tops the charts. This 86-acre resort near Miami and Ft. Lauderdale is pure paradise featuring a colossal 130,000-square-foot casino, a lush 4-acre lagoon tropical pool area with a thrilling theme-park-style water slide, relaxing authentic Seminole Chickee poolside cabanas. In addition, the resort offers a legendary Hard Rock Cafe, a sensational European-style spa and fitness center.

Seminole Paradise at the Seminole Hard Rock Hotel & Casino is South Florida’s hottest retail, restaurant and live entertainment district. Stroll along Mediterranean streets with lush landscaping, dramatic fountains, all set against magnificent 12-acre Lake Paradise and enjoy more than nine restaurants, 10 nightclubs, over 22 specialty retail shops and the region’s top live performance venues.

**Program Details**

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<thead>
<tr>
<th>Date:</th>
<th>Monday, May 5, thru Friday, May 9, 2008</th>
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<tbody>
<tr>
<td>Time:</td>
<td>TBD</td>
</tr>
<tr>
<td>Price:</td>
<td>$60.00 per person</td>
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**Includes:**

- Free time to enjoy the Seminole Hard Rock Casino and Seminole Paradise, approximately (4) hours
- Deluxe Transportation

**Please Note:**

Tour and Activity programs are subject to change/cancel due to local conditions and/or minimum person requirement.
OFFICIAL HOTELS

1. Loews Miami Beach Hotel
   1601 Collins Avenue
   Miami Beach, FL 33139

2. Ritz Carlton, South Beach
   One Lincoln Road
   Miami Beach, FL 33139

3. Fontaine Bleau
   4441 Collins Avenue
   Miami Beach, FL 33140

4. Miami Beach Resort & Spa
   4833 Collins Avenue
   Miami Beach, FL 38141
Absolutely no audio, digital or video devices of any kind are allowed in any session room. All presentations will be available after the meeting to all attendees. Thank you for your assistance.

7:00 a.m. - 7:00 p.m.
Registration
Hall B

8:00 a.m. - 9:00 a.m.
Committee Meetings

9:00 a.m. - 9:30 a.m.
Coffee Break

9:30 a.m. - 12:30 p.m.
Taped Live Surgeries
Moderators: Tom Errico, MD
 Michael Janssen, MD

9:30 a.m. - 9:40 a.m.
Welcome/Instructions

9:40 a.m. - 11:15 a.m.
Industry Innovations
Moderator: Tom Errico, MD

9:40 a.m. - 10:00 a.m.
Ellman Innovations
(now Eliqueonce, LLC)
Laurence Mermelstein, MD

10:05 a.m. - 10:25 a.m.
NuVasive
Mark Peterson, MD

10:55 a.m. - 11:15 a.m.
Hydrocision
Mitchell Hardenbrook, MD

11:15 a.m. - 11:30 a.m.
Break

11:30 a.m. - 12:30 p.m.
Tips and Techniques from AOSpine
Moderator: Michael Janssen, MD

12:30 p.m. - 1:45 p.m.
SAS Business Meeting
(for members only)

2:00 p.m. - 2:15 p.m.
Opening Ceremony

2:15 p.m. - 3:15 p.m.
Symposium I - Indications Lumbar
(debate format)
Moderators: Karin Büttner-Janz, MD, PhD
 Rick Guyer, MD

• Is There Sufficient Biomechanical Evidence that Artificial Disc Replacement Prevents Adjacent Segment Disease; Myth or Truth?
  For: A. Patwardhan — Against: V. Goel

• For DDD at L5S1 and L4L5, is Two Level TDR better than Hybrid Surgery
  For: L. Pimenta — Against: J.C. LeHuex

• For Three Level DDD, is TDR better than Dynamic Stabilization for a 25 year old patient
  For: R. Bertagnoli — Against: R. Davis

3:15 p.m. - 3:45 p.m.
Symposium II - Indications Cervical
(debate format)
Moderators: Rick Guyer, MD
 Karin Büttner-Janz, MD, PhD

• Why Give up Single Level ACF for TDR?
  For: H. Halm — Against: J. Heller

3:45 p.m. - 5:00 p.m.
Session I - MIS
Moderators: Choll Kim, MD
 Frank Phillips, MD

3:45 p.m. - 3:50 p.m.
1. Experience in 150 Cases with the TranS1 Minimally Invasive Fusion Technique at L5-S1
   W. Tobler
   R. Bohinski
   Mayfield Clinic, University of Cincinnati Department of Neurosurgery, Cincinnati, OH, United States of America
3:51 p.m. - 3:56 p.m.

2. 2 Year Clinical Results of X STOP Interspinous Distraction Device in the Management of Symptomatic Lumbar Canal Stenosis
D. Wardlaw¹ N. Bilolikar¹
¹Woodend Hospital, Orthopaedics, Aberdeen, United Kingdom

3:57 p.m. - 4:02 p.m.

3. A Randomized Trial of Balloon Kyphoplasty and Nonsurgical Care for Patients with Acute Vertebral Compression Fractures: One Year Results
J.K. Van Meirhaeghe¹, L. Bastian², D. Wardlaw³, S. Boonen³, FREE Study Investigators
¹AZ Sint-Jan Brugge, Dienst Orthopedie en Traumatologie, Brugge, Belgium, ²Klinikum Leverkusen, Leverkusen, Germany, ³Woodend Hospital, Aberdeen, United Kingdom, ⁴Katholieke Universiteit Leuven, Leuven University Center for Metabolic Bone Diseases and Division of Geriatric Medicine, Leuven, Belgium

4:03 p.m. - 4:08 p.m.

4. Long-Term Outcomes of Minimally Invasive versus Open Transforaminal Lumbar Interbody Fusion: Surgical Results and Outcomes in a Series of 128 Patients
L. Khoo¹, N.F. Chen¹, H. Sheikh¹, S. Armin¹
¹UCLA, Neurosurgery, Santa Monica, CA, United States of America

4:09 p.m. - 4:14 p.m.

5. The Multiple Causes of Atypical Preoperative Sciatica and Post-Operative Dysesthesia: An Anatomic and Approach Related Risk of the Paramedian and Foraminal Approach to the Lumbar Spine
A. Yeung¹
¹Desert Institute for Spine Care, University of California San Diego School of Medicine, Department of Orthopedics, Phoenix, AZ, United States of America

4:15 p.m. - 4:20 p.m.

L. Khoo¹, S. Armin¹, F. Asgarzadie³, N.F. Chen¹, H. Sheikh¹
¹UCLA, Neurosurgery, Santa Monica, CA, United States of America, ³UCLA, Santa Monica, CA, United States of America

4:21 p.m. - 4:26 p.m.

C. Kim¹, S. Ward¹, R. Lieber¹, S. Garfin¹
¹University of California, San Diego, Orthopaedic Surgery, San Diego, CA, United States of America

4:27 p.m. - 4:32 p.m.

8. Failed Fusion Surgery Treated by Endoscopic Lumbar Decompression & Foraminoplasty (ELDF) - A 3-Year Review
M. Knight¹
¹The Spinal Foundation, Congleton, United Kingdom

4:33 p.m. - 4:56 p.m.
Discussion

5:00 p.m. - 7:00 p.m.
Opening Reception
Exhibit Hall B
7:00 a.m. - 5:00 p.m.
Registration
Hall B

8:00 a.m. - 9:40 a.m.
Session I - Cervical TDR

8:00 a.m. - 8:51 a.m.
Session I (A) - Cervical TDR
Moderators: Steve Garfin, MD
Rick Sasso, MD
Alternate: Courtney Brown, MD

8:00 a.m. - 8:07 a.m.
9. Results of the Prospective, Randomized, Multi-Center Food and Drug Administration Investigational Device Exemption Study of the ProDisc®-C Total Disc Replacement vs. Anterior Discectomy and Fusion for the Treatment of 1-Level Symptomatic Cervical Disc Disease
M. Janssen, D. Murrey, R. Delamarter, J. Goldstein, J. Zigler, B. Tay, B. Darden
1OrthoCarolina Spine Center, Charlotte, NC, United States of America, 2Spine Education and Research Institute, Thornton, CO, United States of America, 3The Spine Institute at Saint John’s Health Center, Santa Monica, CA, United States of America, 4New York University Medical Center/Hospital for Joint Diseases Spine Center, New York, NY, United States of America, 5Texas Back Institute/Texas Health Research Institute, Plano, TX, United States of America, 6University of California at San Francisco, San Francisco, CA, United States of America

8:08 a.m. - 8:14 a.m.
10. Comparison of BRYAN Cervical Disc Arthroplasty with Anterior Cervical Decompression and Fusion: Clinical Results of a Randomized Controlled Clinical Trial
R. Sasso, J. Heller, P. Anderson, S. Papadopoulos, R. Fessler
1Indiana Spine Group, Indianapolis, IN, United States of America, 2Emory, Atlanta, GA, United States of America, 3University of Wisconsin, Madison, WI, United States of America, 4Barrow Neurosurgical Group, Phoenix, AZ, United States of America, 5University of Chicago, Chicago, IL, United States of America

8:15 a.m. - 8:21 a.m.
11. Cervical Spine Arthroplasty for the Treatment of Cervical Spondylotic Myelopathy and Clinical Outcome
Y. Sun
1Peking University Third Hospital, Orthopaedics, Beijing, China

8:22 a.m. - 8:28 a.m.
12. Cervical Facet Degeneration after Total Disc Replacement 272 Levels in 158 Patients. 4-Year Follow-Up
L. Pimenta, C. Arias, L. Oliveira, J. Lhamby, E. Coutinho
1Santa Rita Hospital, Minimally Invasive Spine Surgery, Sao Paulo, Brazil

8:29 a.m. - 8:35 a.m.
13. Factors Affecting Re-Operations after ACDT Within and Outside of an FDA IDE Cervical TDR Trial
1Rush University Medical Center, Orthopaedic Surgery, Chicago, IL, United States of America, 2Rush University Medical Center, Chicago, IL, United States of America

8:36 a.m. - 8:51 a.m.
Discussion

8:52 a.m. - 9:40 a.m.
Session I (B) - Cervical TDR
Moderators: Luiz Pimenta, MD
Paul Anderson, MD

8:52 a.m. - 8:58 a.m.
14. Serum Metal Levels in Patients with Stainless Steel Metal-on-Metal Cervical Disc Replacements
M. Gornet, J. Burkus, K. Kattner, A. Skipor, J. Jacobs
1The Hughston Clinic, Columbus, GA, United States of America, 2The Orthopedic Center of St. Louis, Chesterfield, MO, United States of America, 3Central Illinois Neuroscience Center, Bloomington, IL, United States of America, 4Rush University Medical Center, Chicago, IL, United States of America
8:59 a.m. - 9:04 a.m.

15. Comparison of Secondary Operations between Arthroplasty and Anterior Cervical Fusion
P. Anderson¹, D. Riew², R. Sasso³
¹University of Wisconsin, Orthopaedics, Madison, WI, United States of America, ²Washington University, Orthopaedics, St Louis, MO, United States of America, ³Indiana Spine Group, Indianapolis, IN, United States of America

9:05 - 9:11 a.m.

16. Heterotopic Bone Formation and Secondary Fusion after Cervical TDR with over 24 Months Follow-up
P. Bernard¹, L. Aubourg², T. Dufour³, J. Vital⁴, J. Huppert⁵, J. Beaurnains⁶, J. Steib⁷
¹Clinique Saint Martin, Centre Aquitain du Dos, Pessac, France, ²LDR Medical, Troyes, France, ³Centre Hospitalier Régional, NeuroSurgery Department, Orléans, France, ⁴Centre Hospitalier Régional, Spine Unit, Bordeaux, France, ⁵Clinique du Parc, Saint Priest en Jarez, France, ⁶Centre Hospitalier Régional, NeuroSurgery Department, Dijon, France, ⁷Centre Hospitalier Régional, Orthopaedic Department, Strasbourg, France

9:12 a.m. - 9:18 a.m.

17. Bryan Cervical Disc Prosthesis: 5 Years Follow-up
S. Sola¹, R. Hebecker¹, S. Mann¹
¹University Rostock, Neurosurgery, Rostock, Germany

9:19 a.m. - 9:24 a.m.

18. Consequences of Athletic Activity in the Lumbar and Cervical Total Disc Replacement Patient: A Multi-Center Non-Randomized Prospective Study
J. Yue¹, M. Scott-Young², R. Bertagnoli³, J. Jaramillo⁴, M. McRae⁵
¹Yale University, Orthopaedic Surgery, New Haven, CT, United States of America, ²Pacific Private Clinic, Southport Queensland, Australia, ³ProSpine Center, Orthopaedic Surgery, Straubing, Germany, ⁴Yale University, Spine Surgery, New Haven, CT, United States of America

9:25 a.m. - 9:40 a.m.

Discussion

9:45 a.m. - 10:00 a.m.

Transfer of SAS Presidency*
*Exhibit Hall will close

10:01 a.m. - 10:30 a.m.

Presidential Guest Speaker*
*Exhibit Hall will close

10:30 a.m. - 11:00 a.m.

Coffee Break, Posters, Open for Viewing
11:00 a.m. - 12:00 Noon

**Session II - Cervical TDR**

*Moderators: Rudolf Bertagnoli, MD
Paul McAfee, MD*

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11:00 a.m. - 11:06 a.m.

19. **Results of a Prospective, Randomized, Multi-Center Clinical Trial of PCM Cervical Disc Replacement: Two Year Clinical Outcomes**

J. Regan¹, F. Phillips², A. Cappuccino³, J. DeVine⁴, J. Ahrens⁵, P. McAfee⁶

¹Pacific Coast Spine Institute, Beverly Hills, CA, United States of America, ²Midwest Orthopaedics at Rush, Department of Orthopaedic Surgery, Chicago, IL, United States of America, ³Buffalo Spine Surgery, Lockport, NY, United States of America, ⁴Madigan Army Medical Center, Tacoma, WA, United States of America, ⁵Pivotal Research Solutions, Allen, TX, United States of America, ⁶Towson Orthopedic Associates, Towson, MD, United States of America

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11:07 a.m. - 11:13 a.m.

20. **Absence of Bias between Non-Randomized and Randomized Cases in Three Prospective Randomized FDA Studies of Cervical Disk Replacement - 788 Cases**

P. McAfee¹, B. Cunningham¹, F. Geisler², C. Laurysen¹, S. Ruskin²

¹Spine and Scoliosis Center, Towson, MD, United States of America, ²Neurosurgery, Aurora, IL, United States of America, ³Cedars Sinai, Los Angeles, CA, United States of America, ⁴University of Pennsylvania, Philadelphia, PA, United States of America

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11:14 a.m. - 11:20 a.m.

21. **Heterotopic Ossification at the Index Level after ProDisc-C Surgery: What is the Clinical Relevance?**

R. Bertagnoli¹

¹ProSpine, Straubing, Germany

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11:21 a.m. - 11:27 a.m.

22. **Finite Element Analysis of Cervical Spine Following Bilevel Fusion, Bilevel Total Disc Replacement and Fusion plus Total Disc Replacement at Adjacent Levels**

A. Faizan¹, V. Goel¹, N. Kulkarni¹, A. Biyani², S. Garfin¹, C. Bono³, P. Maguire⁴, H. Serhan⁵

¹University of Toledo, Bioengineering, Toledo, OH, United States of America, ²University of Toledo, Orthopedics, Toledo, OH, United States of America, ³University of California, San Diego, Orthopedics, San Diego, CA, United States of America, ⁴Boston Medical Center, Orthopedics, Boston, MA, United States of America, ⁵Deuply Spine, Raynhem, MA, United States of America

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11:28 a.m. - 11:34 a.m.

23. **Kinematics of Cervical Total Disc Replacement Adjacent to a Two-Level, Straight vs. Lordotic Fusion**

S. Martin¹, A. Ghanyem¹, M. Tzermiadinos², R. Havey³, S. Renner³, G. Carandang³, C. Abjornson³, A. Patwardhan²

¹Loyala University Medical Center, Orthopaedic Surgery, Maywood, IL, United States of America, ²Edward Hines, Jr. VA Hospital, Spine Biomechanics Lab, Hines, IL, United States of America, ³Synthes Spine, West Chester, PA, United States of America

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11:35 a.m. - 11:41 a.m.

24. **Consequences of Whiplash Injury Following ProDisc-C Total Disc Replacement: Evaluation of Cervical Kinematics During Low Speed Rear-End Impact**

C. Demetropoulos¹, S. Sundararajan¹, S. Bikhu¹, W. Hardy², K. Yang², J. Bishop³, C. Abjornson³, M. Bey³, H. Herkowitz³, S. Bartol⁷

¹William Beaumont Hospital, Orthopaedic Research, Royal Oak, MI, United States of America, ²Wayne State University, Bioengineering Center, Detroit, MI, United States of America, ³Wayne State University, Bioengineering Center, Royal Oak, MI, United States of America, ⁴Henry Ford Hospital, Bone and Joint Center, Detroit, MI, United States of America, ⁵Synthes Spine, Research, West Chester, PA, United States of America, ⁶William Beaumont Hospital, Orthopaedic Surgery, Royal Oak, MI, United States of America, ⁷Henry Ford Hospital, Orthopaedic Surgery, Detroit, MI, United States of America
2:21 p.m. - 2:27 p.m.
28. The X-Ray and MRI Assessment of Upper and Lower Adjacent Level Degeneration after Minimal 2 Years Single Level Bryan Disc Replacement
Y. Sun1
1Peking University Third Hospital, Orthopaedics, Beijing, China

2:28 p.m. - 2:34 p.m.
29. Clinical Outcomes and Radiological Analysis Following TCDR with ProDisc C at the 24 Months Follow-Up
C. Mehren1, F. Mackel1, F. Grochulla1, A. Korge1, M. Mayer1
1Orthozentrum München, SpineCenter, München, Germany

2:35 p.m. - 2:41 p.m.
30. Validation of ISO Total Disc Wear Testing Using Retrieved Metal-on-Metal Cervical Disc Replacements
R. Siskey1, S. Kurtz1, P. Shah1, L. Ciccarelli1, M. Harper2, F. Chan1
1Exponent, Philadelphia, PA, United States of America, 2Medtronic Spinal and Biologics, Memphis, TN, United States of America

2:42 p.m. - 3:00 p.m.
Discussion

3:00 p.m. - 3:45 p.m.
Coffee Break

3:45 pm - 5:00 pm
Session IV - Basic Problems and Provocative Solutions
Moderators: Stephen Hochschuler, MD
Antonius Rohlmann, MD
Alternate: Harvinder Sandhu, MD

3:45 p.m. - 3:51 p.m.
31. The Reliability of CT and MRI Grading of Lumbar Facet Arthropathy in TDR Patients
J. Bendo1, M. Quirno1, M. Cunningham1, J. Spivak1, J. Stieber1
1NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States of America
3:52 p.m. - 3:58 p.m.
32. Incidence of Dysphagia Comparing Cervical Arthroplasty and ACDF with Internal Fixation
M. Janssen¹, J. Datta², B. Darden³, A. Rhyne³, F. Siddiqui³, R. Beckham³, C. Ponce³, S. Odum³
¹Spine Education and Research Institute, Denver, CO, United States of America, ²Sonoran Spine Center, Mesa, AZ, United States of America, ³OrthoCarolina, Charlotte, NC, United States of America

3:59 p.m. - 4:05 p.m.
33. The Loss of Water Content within the Intervertebral Disc through an Accumulation of Advanced Glycated Endproducts
A. Sharan¹, S. Tang¹, D. Vashishth²
¹Montefiore Medical Center/Albert Einstein College of Medicine, Orthopaedic Surgery, Bronx, NY, United States of America, ²Rensselaer Polytechnic Institute, Biomedical Engineering, Troy, NY, United States of America

4:06 p.m. - 4:12 p.m.
34. Analysis of Postoperative Pain Patterns Following Total Lumbar Disc Replacement
C. Siepe¹, F. Grochulla¹, A. Korge¹, H. Mayer¹
¹OrthoCenter Munich, Spine Center, Munich, Germany

4:13 p.m. - 4:19 p.m.
35. A Finite Element Study to Evaluate the Biomechanical Effects of the Artificial Disc Components’ Shape on the Cervical Spine
A. Faizan¹, V. Goel¹, A. Biyani², S. Garfin¹, C. Bono¹, P. Maguire³, H. Serhan⁵
¹University of Toledo, Bioengineering, Toledo, OH, United States of America, ²University of Toledo, Orthopedics, Toledo, OH, United States of America, ³University of California, San Diego, Orthopedics, San Diego, CA, United States of America, ⁴Boston Medical Center, Orthopedics, Boston, MA, United States of America, ⁵Depuy Spine, Raynham, MA, United States of America

4:20 p.m. - 4:26 p.m.
36. Does Placement of the Axis of Rotation of the Cervical Spine Affect Motion Segment Mechanics During Flexion and Extension?
D. DiAngelo¹, H. Bonin¹, B. Kelly¹
¹The University of Tennessee Health Science Center, Department of Biomedical Engineering and Imaging, Memphis, TN, United States of America

4:27 p.m. - 4:33 p.m.
37. Cervical Hybrid Constructs: A Reliable and Effective Option in the Treatment of Multilevel Degenerative Disc Disease
G. Barbagallo¹, R. Assietti², L. Corbino³, G. Olindo³, N. Platania³, P. Foti³, V. Russo³, V. Albanese³
¹Policlinico University Hospital, Department of Neurosurgery, Catania, Italy, ²Fatebenefratelli and Ophtalmic Hospital, Department of Neurosurgery, Milan, Italy

4:34 p.m. -4:54 p.m.
Discussion
THURSDAY, MAY 8

7:00 a.m. - 5:00 p.m.
Registration
Hall B

8:00 a.m. - 10:43 a.m.
Session I - Lumbar TDR

8:00 a.m. - 9:18 a.m.
Session I (A) - Lumbar TDR
Moderators: Chun-Kun Park, MD, PhD
Jack Zigler, MD
Alternate: Alex Vaccarao, MD

8:08 a.m. - 8:15 a.m.
38. F.D.A. I.D.E. Prospective Randomized Comparison of Three Lumbar Artificial Disc Replacements (A.D.R.) with Minimum Two-Year Follow-Up
K. Pettine1, E. Donner1
1Rocky Mountain Spine Arthroplasty Specialists, Loveland, CO, United States of America

8:16 a.m. - 8:23 a.m.
40. Interaction between Finite Helical Axes and Facet Joint Forces under Combined Loading
H. Wilke1, H. Schmidt1, F. Heuer1
1University of Ulm, Institute of Orthopaedic Research and Biomechanics, Ulm, Germany

8:24 a.m. - 8:32 a.m.
41. Prodisc-L Prosthesis Height: What Effect Does Increasing Height Have on Lumbar Spine Kinematics and Foraminal Size?
J. Gaffey1, A. Ghanayem1, L. Voronov2, R. Havey1, M. Sartori3, G. Carandang1, C. Abjornson4, A. Patwardhan1
1Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, United States of America, 2Loyola University Chicago, Stritch School of Medicine, Maywood, IL, United States of America, 3Edward Hines Jr. VA Hospital, Hines, IL, United States of America, 4Our Lady of the Lake Medical Center, Baton Rouge, LA, United States of America

8:33 a.m. - 8:40 a.m.
42. TDR Oxidative Properties following Gamma Sterilization in Air and First-Generation Barrier Packaging
S. Kurtz1, D. MacDonald1, A. Ianuzzi1, A. Van Ooij1, J. Isaza1, R. Ross4
1Drexel University and Exponent, Inc, Philadelphia, PA, United States of America, 2University Hospital of Maastricht, Maastricht, Netherlands, 3Our Lady of the Lake Medical Center, Baton Rouge, LA, United States of America, 4Hope Hospital, Salford, United Kingdom

8:41 a.m. - 8:48 a.m.
43. Polyethylene Particle Load in TDR and THR Retrieval Tissue using Polarized Light Microscopy
S. Kurtz1, R. Baxter1, M. Steinbeck1, A. Ianuzzi2, A. Van Ooij1, R. Ross4, J. Isaza4
1Drexel University, Philadelphia, PA, United States of America, 2Exponent Inc, Philadelphia, PA, United States of America, 3University Hospital of Maastricht, Maastricht, Netherlands, 4Hope Hospital, Salford, United Kingdom, 5Our Lady of the Lake Medical Center, Baton Rouge, LA, United States of America

Cities Orthopedics, Edina, MN, United States of America, 16LA Spine Surgery Institute, Los Angeles, CA, United States of America, 15SUNY Syracuse, Syracuse, NY, United States of America, 16William Beaumont Hospital, Royal Oak, IL, United States of America
44. Assessment of Motion Quality Following Lumbar Total Disc Arthroplasty and Lumbar Discectomy
A. Fayyazi¹, S. Park¹, N. Ordway¹, B. Fredrickson¹, H. Yuan¹
¹SUNY Upstate Medical University, Department of Orthopedic Surgery, Syracuse, NY, United States of America

8:57 a.m. - 9:18 a.m.
Discussion

9:19 a.m. - 10:43 a.m.
Session I (B) - Lumbar TDR
Moderators: John Regan, MD
Vijay Goel, PhD
Alternate: Hee-Kit Wong, MD

45. 5-Year Results of the Prospective, Randomized, Multicenter FDA IDE ProDisc®-L Trial
R. Delamarter¹, J. Zigler², J. Spivak³, R. Linovitz⁴, G. Danielson⁵, T. Haider⁶, F. Cammina⁷, J. Zucherman⁸, R. Balderston⁹, S. Kitchel¹⁰, K. Foley¹¹, R. Watkins¹², J. Yue¹³, H. Yuan¹⁴, H. Herkowitz¹⁵, D. Geiger¹⁶, J. Goldstein¹⁷
¹The Spine Institute at Saint John's Health Center, Santa Monica, CA, United States of America, ²Texas Back Institute/Texas Health Research Institute, Plano, TX, United States of America, ³NYU/Hospital for Joint Diseases, New York, NY, United States of America, ⁴CORE Orthopaedic Medical Center, Encinitas, CA, United States of America, ⁵Texas Spine and Joint Hospital, Tyler, TX, United States of America, ⁶Haider Spine Center Medical Clinic, Inc, Riverside, CA, United States of America, ⁷Hospital for Special Surgery, New York, NY, United States of America, ⁸St Mary’s Spine Center, San Francisco, CA, United States of America, ⁹Pennsylvania Hospital, Philadelphia, PA, United States of America, ¹⁰Orthopedic Spine Associates, LLC, Eugene, OR, United States of America, ¹¹Semmes-Murphy Neurological and Spine Institute, Neuro, Memphis, TN, United States of America, ¹²LA Spine Surgery Institute, Los Angeles, CA, United States of America, ¹³Yale Physicians Bldg, New Haven, CT, United States of America, ¹⁴SUNY Syracuse, Syracuse, NY, United States of America, ¹⁵William Beaumont Hospital, Royal Oak, MI, United States of America, ¹⁶Michigan Brain & Spine Institute PC/Michigan Orthopaedic Center, Ypsilanti, MI, United States of America, ¹⁷New York University Medical Center/Hospital for Joint Diseases Spine Center, New York, NY, United States of America

46. Clinical Results of Two-Level Lumbar Arthroplasty vs. Combined Arthroplasty & Fusion (Hybrid Procedure)
M. Scott-Young¹, C. Magno², D. Nielsen³
¹Bond University, Department of Health Sciences & Medicine, Gold Coast Queensland, Australia, ²Pacific Private Clinic, Southport, Australia

47. Evaluation of the Influence of TDR Positioning on Subsidence and Facet Arthrosis
S. Rundell¹, J. Auerbach², R. Balderston³, S. Kurtz³
¹Exponent, Inc, Philadelphia, PA, United States of America, ²University of Pennsylvania, Department of Orthopaedic Surgery, Philadelphia, PA, United States of America, ³Booth, Bartolozzi, Balderston Orthopaedics, Pennsylvania Hospital, Philadelphia, PA, United States of America

48. Prospective, Randomized, Multicenter FDA IDE Study of CHARITÉ Artificial Disc vs. Lumbar Fusion: Effect at 5-Year Follow-Up of Prior Discectomy on Clinical Outcomes Following Lumbar Arthroplasty
F. Geisler¹, R. Banco², S. Blumenthal³, R. Guyer⁴, P. McAfee⁵, R. Holt⁶, M. Majd⁷, J. Regan⁸
¹Illinois Neuro-Spine Center, Aurora, IL, United States of America, ²Boston Spine Group, Boston, MA, United States of America, ³Texas Back Institute, Plano, TX, United States of America, ⁴Orthopaedics Associates, O’Dea Medical Arts Building, Suite 104, Towson, MD, United States of America, ⁵Spine Surgery PSC, Louisville, KY, United States of America, ⁶Spine Source, Beverly Hills, CA, United States of America

49. Medico-Economical Evaluation of Total Disc Replacement Based on French National Health Care (Sécurité Sociale) Data’s
N. Bronsard¹, I. Hovorka², P. Paquis³, S. Litrico⁴, G. Daideri⁵, B. Gastaud⁶, J. Greffeville⁷, P. Boileau¹
¹University of Nice, Orthopaedic Department and Spine Surgery, Nice, France, ²University of Nice, Neurosurgery, Nice, France, ³University of Nice, Department d’Informatique Médical, Nice, France, ⁴Sécurité Sociale, Service Médical auprès de la Caisse Primaire d’Assurance Maladie des Alpes Maritimes, Nice, France, ⁵Sécurité Sociale, Caisse Primaire d’Assurance Maladie des Alpes Maritimes, Nice, France
9:56 a.m. - 10:02 a.m.
50. The Effect of Adverse Events on Clinical Outcome: Analysis of Data from an FDA IDE Trial
D. Ohnmeiss¹, W. Bodemer¹, J. Zigler²
¹Texas Back Institute Research Foundation, Plano, TX, United States of America, ²Texas Back Institute, Plano, TX, United States of America

10:03 a.m. - 10:10 a.m.
51. A Prospective Randomized Comparison of Two Lumbar Total Disc Replacement Devices
R. Guyer¹, A. Cappuccino², S. Blumenthal¹
¹Texas Back Institute, Plano, TX, United States of America, ²Buffalo Spine Surgery, Lockport, NY, United States of America

10:11 a.m. - 10:18 a.m.
52. Wear Testing of Metal-On-Metal Total Disc Replacement Component
M. Bushelow¹, W. Nechtow¹, J. Walker², M. Hinter³, A. Ochs³, C. Kaddick³
¹Synthes Spine, Mechanical Test Laboratory, West Chester, PA, United States of America, ²Synthes Spine, Product Development, West Chester, PA, United States of America, ³EndoLab Mechanical Engineering GmbH, Rosenheim, Germany

10:19 a.m. - 10:43 a.m.
Discussion

9:00 a.m. - 5:00 p.m.
Exhibit Hall Open / Posters Open for Viewing

10:45 a.m. - 11:00 a.m.
Coffee Break, Posters, Industry Exhibition

11:00 a.m. - 12:00 Noon
Session II - Lumbar TDR
Moderators: Hans-Joachim Wilke, MD, PhD
Scott Blumenthal, MD

11:00 a.m. - 11:06 a.m.
53. Is Preoperative Disc Height a Predictive Factor to Lumbar Total Disc Arthroplasty Results?
J. Allain¹, O. Kettani², J. Delecroix², J. Beaurain³, J.P. Steib⁴, H. Chataigner⁵, T. Dufour⁶, M. Ameil⁷, L. Aubourg¹
¹Paris XII University Hospital, Orthopedic, Creteil, France, ²Nantes University Hospital, Orthopedic, Nantes, France, ³University Hospital, Neurochirurgie, Dijon, France, ⁴University Hospital, Orthopedic, Strasbourg, France, ⁵Clinique de Besancon, Orthopedic, Besancon, France, ⁶Hôpital de la Source, Neurochirurgie, Orleans, France, ⁷Clinique de Reims, Orthopedic, Reims, France

11:07 a.m. - 11:13 a.m.
54. Minimally Invasive Lateral Lumbar TDR: 24 Months Follow-Up
L. Pimenta¹, C. Arias Pesantez¹, L. Oliveira¹, J. Lhamby², T. Schaffä, E. Coutinho²
¹Santa Rita Hospital, Minimally Invasive and Arthroplasty Spine Surgery, Sao Paulo, Brazil, ²Santa Rita Hospital, Spine Surgery, Sao Paulo, Brazil

11:14 a.m. - 11:20 a.m.
55. Comparison of Total Disc Replacement with Lumbar Fusion Surgery: A Randomized, Controlled Trial with Two-Year Follow-Up
S. Berg¹, H. Tropp²
¹Stockholm Spine Center, Stockholm, Sweden, ²University Hospital Linköping, Orthopedic Clinic, Linköping, Sweden

11:21 a.m. - 11:27 a.m.
56. TRIUMPH™Posterolateral Artificial Disc Biomechanics: The Effect of Posterior Tethering
P. McAfee¹, D. Sengupta¹, N. Anand³, G. Deol⁴, N. Khanna², D. Tyndall¹, R. Balderston⁴, A. Ingahahalikar⁷
¹Towson Orthopaedic Associates, P.A. - Scoliosis and Spine Center, Towson, MD, United States of America, ²Dartmouth-Hitchcock Medical Center, Hanover, NH, United States of America, ³Cedars Sinai Institute for Spinal Disorders, Los Angeles, CA, United States of America, ⁴M & M Orthopaedics, Naperville, IL, United States of America, ⁵Orthopaedic Specialists, Munster, IN, United States of America, ⁶Pennsylvania Hospital, Philadelphia, PA, United States of America, ⁷Globus Medical, Inc., Audubon, PA, United States of America
11:28 a.m. - 11:34 a.m.

57. Does Chronic Rim Impingement Influence Dome Wear in Mobile Bearing TDRs?
S. Kurtz¹, D. MacDonald¹, A. Ianuzzi¹
¹Drexel University and Exponent, Inc, Philadelphia, PA, United States of America

11:35 a.m. - 11:41 a.m.

58. Prospective, Randomized, Multicenter FDA IDE Study of CHARITÉ Artificial Disc vs. Lumbar Fusion: Effect at 5-year Follow-Up of Age on Clinical Outcomes Following Lumbar Arthroplasty
R. Banco¹, F. Geisler², R. Guyer¹, B. Hetzell¹, R. Holt¹, M. Majd³
¹Boston Spine Group, Boston, MA, United States of America, ²Illinois Neuro-Spine Center, Aurora, IL, United States of America, ³Texas Back Institute, Plano, TX, United States of America, ⁴Stat Tech Services, Chapel Hill, NC, United States of America, ⁵Spine Surgery PSC, Louisville, KY, United States of America

11:42 a.m. - Noon
Discussion

12:00 p.m. - 2:00 p.m.
Industry Workshops

2:00 p.m. - 3:00 p.m.
Session III - Lumbar TDR and Fusion Session

Moderators: Henry Halm, MD, PhD
Matthew Scott-Young, MD
Alternate: William Hutton, PhD

2:00 p.m. - 2:06 p.m.

59. Effect of Intervertebral Disc Degeneration on Spinal Stability - Relevance for Dynamic Stabilization
H. Wilke¹, A. Kettler¹, F. Rohlmann², C. Ring², C. Mack¹
¹University of Ulm, Institute for Orthopaedic Research and Biomechanics, Ulm, Germany, ²University of Ulm, Department of Biometry and Medical Documentation, Ulm, Germany

2:07 p.m. - 2:13 p.m.

60. Variability Among 10 Production Lots of a Single Demineralized Bone Matrix (DBM) Product
H. Bae¹, L. Zhao¹, Z. Dagny¹, L. Kanim¹, L. Thai¹, G. Mehta¹, J. Wang², B. Pradhan³, R. Delamarter¹
¹The Spine Institute, Spine Research Foundation, Santa Monica, CA, United States of America, ²UCLA, Dept. Orthopaedic Surgery, Santa Monica, CA, United States of America

2:14 p.m. - 2:20 p.m.

61. Revision Problems in Anterior Lumbar Surgery
S. Brau¹
¹Spine Access Surgery Associates, Los Angeles, CA, California, United States of America

2:21 p.m. - 2:27 p.m.

62. Serum Metal Levels in Patients with Cobalt-Alloy Metal-on-Metal Lumbar Disc Replacements
M. Gornet¹, J. Burkus², A. Skipor³, J. Jacobs⁴
¹The Orthopedic Center of St. Louis, St. Louis, MO, United States of America, ²The Hugheston Clinic P.C., Columbus, OH, United States of America, ³Rush University Medical Center, Chicago, IL, United States of America

2:28 p.m. - 2:34 p.m.

63. Total Disc Arthroplasty: An Effective Operative Treatment of Degenerative Disc Disease in Patients with Previous Surgical Discectomy
J. Allain¹, J. Beaurain², J. Delecroix³, J. Steib⁴, H. Chataigner⁵, M. Amell⁶, T. Dufour⁷, L. Aubourg⁸
¹Paris XII University Hospital, Orthopedic, Creteil Cedex, France, ²University Hospital, Neurosurgery, Dijon, France, ³University Hospital, Orthopedic, Nantes, France, ⁴University Hospital, Orthopedic, Strasbourg, France, ⁵Clinique de Besançon, Orthopedic, Besançon, France, ⁶Clinique de Reims, Orthopedic, Reims, France, ⁷University Hospital de la Source, Neurosurgery, Orleans, France, ⁸Paris XII University Hospital, Orthopedic, Creteil, France
2:35 p.m. - 2:41 p.m.

64. **Prospective, Randomized Trial of Lumbar Metal on Metal Total Disc Replacement: Initial Treatment of Degenerative Disc**

T. Errico5, R. Tibbs1, R. Sasso2, G. Miz3, C. Theofilos4, M. Quirno5  
1Oklahoma Spine Hospital, Oklahoma City, OK, United States of America, 2Indiana Spine Group, Indianapolis, IN, United States of America, 3Bone and Joint Physicians, Oak Lawn, IL, United States of America, 4Spine Center, Palm Beach Gdns, FL, United States of America, 5NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States of America

3:52 p.m. - 3:58 p.m.

66. **A Comprehensive Wear Assessment of NUBAC**

T. Brown1, Q. Bao1, T. Kilpela1, T. Schwenke2, M. Wimmer2  
1Pioneer Surgical Technology, Marquette, MI, United States of America, 2RUSH University Medical Center, Chicago, IL, United States of America

3:59 p.m. - 4:05 p.m.

67. **Nucleus Pulposus Replacement Material Stiffness Properties Affect Vertebral Body Strains and Remodeling Response**

S. Rundell1, H. Guerin1, J. Auerbach2, S. Kurtz1  
1Exponent, Inc., Philadelphia, PA, United States of America, 2The University of Pennsylvania, Department of Orthopaedic Surgery, Philadelphia, PA, United States of America

4:06 p.m. - 4:12 p.m.

68. **Motion Segment Stiffness and Subsidence with Hydrated and Dehydrated Nucleus Arthroplasty Devices**

B. Beaubien1, A. Freeman1, S. Seme2  
1Gustilo Medical Education Center/Midwest Orthopaedic Research Foundation, Minneapolis, MN, United States of America, 2Raymedica, Inc., Minneapolis, MN, United States of America

4:13 p.m. - 4:19 p.m.

69. **Clinical Experience with NUBAC™ Disc Arthroplasty**

D. Coric1, H. Yuan2, M. Songer3, K. Davenport3, L. Pimenta4, A. Reyes-Sanchez5, D. Werner6, M. Balsamo7, U. Agrillo8, A. Bucciero9, D. Zou10  
1Carolina Neurosurgery and Spine, Charlotte, NC, United States of America, 2Suny Upstate Medical University, Syracuse, NY, United States of America, 3Marquette General Hospital, Marquette, MN, United States of America, 4Santa Rita Hospital, Sao Paulo, Brazil, 5Instituto De Ortopedia, Mexico City, Mexico, 6Arkade Private Hospital, Breitungen, Germany, 7Ospedale Di Thiene, Thiene, Italy, 8San Pietro hospital, Rome, Italy, 9Pineta Grande, Castel Volturno, Italy, 10306 Hospital, Beijing, China
70. Hybrid Treatment of DDD with the PDN-SOLO Device Combined with Suture Anchorage and Interspinous Ligamentoplasty
A. Reyes-Sanchez
1 Instituto Nacional de Rehabilitación, Orthopaedics, Mexico D.F., Mexico

71. Effect of Lumbar Nucleus Arthroplasty on Adjacent Segment Degeneration; Report of 240 Cases with 2 to 10 Year Follow-up
M. Myers1, T. Myers2, M. Madison2
1 Center for Diagnostic Imaging, Twin Cities, MN, United States of America, 2 St. Paul Radiology, St. Paul, MN, United States of America

72. Identifying Appropriate Interventional Timepoints for Nucleus Pulposus Replacements: Impact of Degeneration-Dependent Mechanical Properties of the Cartilaginous Endplate
H. Guerin1, J. Heinly1, J. Auerbach1, R. Siskey3, B. Lonner1, M. Villarraga1, S. Kurtz1
1 Exponent, Inc., Biomechanics Practice, Philadelphia, PA, United States of America, 2 University of Pennsylvania, Philadelphia, PA, United States of America, 3 NYU/Hospital for Joint Diseases, New York, NY, United States of America

73. Endplate Geometry in the Lumbar Spine; A Potential Predictor in Success or Failure for Nucleus Arthroplasty
M. Myers1, T. Myers2
1 Center for Diagnostic Imaging, Twin Cities, MN, United States of America, 2 St. Paul Radiology, St. Paul, MN, United States of America

74. A Finite Element Study of L5-S1 Spinal Biomechanics Comparing Different Surgical Therapies
G. Loughran1, B. Wessman1, B. Beaubien1, S. Ainsworth1
1 TranS1, Inc, Wilmington, NC, United States of America, 2 Gustilo Medical Education Center, Minneapolis, MN, United States of America
7:00 a.m. - 3:00 p.m.
Registration
Hall B

8:00 am - 10:12 am
Session I - Posterior Dynamic Stabilization

8:00 a.m. - 9:02 a.m.
Session I (A) - Posterior Dynamic Stabilization
Moderators: Thierry Marnay, MD
John Sherman, MD
Alternate: Chris Yeung, MD

8:00 a.m. - 8:05 a.m.
75. Lumbar Decompression Followed by Coflex™ Interlaminar Implant vs. Pedicle Screw Posterior Lateral Fusion for Treatment of Stenosis
K. Pettine1, T. Errico2, J. Thalgott3, A. Yeung4, C. Yeung5
1Rocky Mountain Spine Arthroplasty Specialists, Loveland, CO, United States of America, 2NYU Hospital for Joint Diseases, New York, NY, United States of America, 3Center for Diseases and Surgery of the Spine, Las Vegas, NV, United States of America, 4Arizona Institute for Minimally Invasive Spine Care, Phoenix, AZ, United States of America

8:06 a.m. - 8:11 a.m.
76. 24-Month Results from a Prospective, Randomized IDE Study of the Dynesys® Dynamic Stabilization System
R. Davis1, J. Sherman2, R. Delamarter3, J. Maxwell4, W. Welch5, J. Wingate6
1Greater Baltimore Medical Center, Baltimore, MD, United States of America, 2Twin Cities Orthopedics, Minneapolis, MN, United States of America, 3The Spine Institute, Santa Monica, CA, United States of America, 4Scottsdale Spine Care, Scottsdale, AZ, United States of America, 5University of Pennsylvania Health System, Philadelphia, PA, United States of America, 6Spine, Warren, MI, United States of America

8:18 a.m. - 8:23 a.m.
78. In Vivo Deformation, Surface Damage, and Biostability of Polycarbonate-Urethane Spacers from Retrieved Dynesys Systems
A. Ianuzzi1, S. Kurtz2, A. Van Ooj3, R. Bindal4, R. Ross5, R. Bohinski6, W. Kane1, R. Siskey1, P. Shah1, M. Villarraga1
1Exponent, Inc. and Drexel University, Philadelphia, PA, United States of America, 2University Hospital Maastricht, Maastricht, Netherlands, 3Methodist Hospital, Houston, United States of America, 4Hope Hospital, Manchester, United Kingdom, 5Christ Hospital MOB, Cincinnati, OH, United States of America

8:24 a.m. - 8:29 a.m.
79. A Quantitative Radiographic Analysis of a Posterior Dynamic Stabilization System: Dynamic Parameters and Maintenance of Segmental Disc Height and Lordosis
R. Davis1, W. Welch1, J. Sherman3, R. Delamarter4, J. Wingate5, B. Cheng6, J. Maxwell7
1University of Pennsylvania Health System, Philadelphia, PA, United States of America, 2Greater Baltimore Medical Center, Baltimore, MD, United States of America, 3Twin Cities Orthopedics, Minneapolis, MN, United States of America, 4The Spine Institute, Santa Monica, CA, United States of America, 5Spine, Warren, MI, United States of America, 6University of Pittsburgh Medical Center, Pittsburgh, PA, United States of America, 7Scottsdale Spine Care, Scottsdale, AZ, United States of America

8:30 a.m. - 8:35 a.m.
80. Assessment of Lumbar Segmental Range of Motion Following Dynamic Stabilization in Comparison to Lumbar Discectomy and to Posterior Fusion with Pedicle Instrumentation
N. Ordway1, S. Park1, A. Fayyazi1, B. Fredrickson1, H. Yuan1
1SUNY Upstate Medical University, Department of Orthopedic Surgery, Syracuse, NY, United States of America

8:12 a.m. - 8:17 a.m.
77. Long Term Follow Up of Spinous Process Failure According to Bone Mineral Density in Coflex® Insertion for Lumbar Spinal Stenosis
K. Cho1, S. Lee2, P. Huh1, D. Yoo3, S. Kang1, D. Kim1, C. Park2
1Uijongbu St. Mary’s Hospital, The Catholic Univ. of Korea, Dept. of Neurosurgery, Seoul, Korea, Republic of, 2Kangnam St. Mary’s Hosp. The Catholic Univ. of Korea, Neurosurgery, Seoul, Korea, Republic of

8:12 a.m. - 8:17 a.m.

8:36 a.m. - 8:41 a.m.

81. Complications and Adverse Events Observed When Using Dynesys as a Dynamic Stabilization Device
M. Majdi1, R. Kube1, R. Holt1, J. Mahan1
1Spine Surgery PSC, Louisville, KY, United States of America

8:42 a.m. - 9:02 a.m.
Discussion

9:03 a.m. - 10:12 a.m.
Session I (B) - Posterior Dynamic Stabilization
Moderators: J.D. Auerbach, MD
Reggie Davis, MD

9:03 a.m. - 9:09 a.m.

82. The Surgical Outcome of Coflex® Interspinous Device in Lumbar Degenerative Disease: Comparative Study between the Conventional and a Modified Surgical Technique
K. Ryu1, H.Y. Heo1, C. Park1
1The Catholic University of Korea, Neurosurgery, Seoul, Korea, Republic of

9:10 a.m. - 9:16 a.m.

83. The Potential Impact of New Technologies on Spine Surgery
W. Yu1, D. Goodwin1, J. O’Brien1, J. Gabriel2, K. Chin1
1The George Washington University, Orthopaedic Surgery, Washington DC, United States of America,
2The Ohio State University, Orthopaedic Surgery, Columbus, OH, United States of America

9:17 a.m. - 9:23 a.m.

84. Clinical Outcome and Survivorship Analysis after X STOP Implantation
A. Tuschel1, A. Chavanne2, S. Becker2, M. Ogon2
1Orthopaedic Hospital Speising, Spine Unit, Vienna, Austria, 2Orthopaedic Hospital Vienna Speising, Spine Unit, Vienna, Austria

9:24 a.m. - 9:30 a.m.

85. Does an Interspinous Device (COFLEX®) Improve the Outcome of Decompressive Surgery in Lumbar Spinal Stenosis (LSS)? A Prospective Comparison Analysis of 60 Patients
A. Richter1, C. Schütz1, H. Halm1
1Klinikum Neustadt, Klinik für Wirbelsäulenchirurgie, Neustadt in Holstein, Germany

9:31 a.m. - 9:37 a.m.

86. Long Term Effect of the Intervertebral Dynamic Stabilization as a Protective Technique for Adjacent Levels
G. Perrin1, A. Cristini1
1CHU-Lyon, Hôpital Neurologique P. Wertheimer, Department of Neurosurgery, Lyon, France

9:38 a.m. - 9:44 a.m.

87. Spinous Process Strength Varies with Axial Loading Direction: Implications for Interspinous Device Design
M. Tufaga1, G. Ortiz1, J. Buckley1, J. Lotz1
1University of California, San Francisco, Orthopaedic Surgery, San Francisco, United States of America

9:45 a.m. - 9:51 a.m.

88. One-Year Follow Up after Insertion of a Minimally Invasive Self Locking Interspinous Implant. Clinical Results and CT Measurements of Foramen Size
M. Szpalski1, J. Pienazek2, R. Gunzburg3, L. Ciupik4
1Iris South Teaching Hospitals, Orthopedics, Brussels, Belgium, 2Silesian Medical Academy, Neurosurgery, Bytom, Poland, 3Cavell Clinic, Orthopedics, Brussels, Belgium, 4Society for Study and Treatment of Spine, Zielona Gora, Poland

9:52 a.m. - 10:12 a.m.
Discussion

9:00 a.m. - 3:00 p.m.
Exhibit Hall Open / Posters Open for Viewing

10:15 a.m. - 10:30 a.m.
Awards*
*Exhibit Hall will be closed

10:30 a.m. - 11:00 a.m.
Coffee Break, Posters, Industry Exhibition
11:00 am - 12:00 noon
Session II - Posterior Dynamic Stabilization and Lumbar Facet

Moderators: Dilip Sengupta, MD
James Yue, MD

11:00 a.m. - 11:06 a.m.
89. Kinematics of Facet Arthroplasty: A Comparison of L5-S1 and L3-L4 Levels
L. Voronov1, R. Havey1, D. Rosler2, S. Sjovold2, S. Rogers3, G. Carandang1, J. Ochoa2, A. Patwardhan1
1Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, United States of America,
2Archus Orthopedics, Inc., Redmond, WA, United States of America,
3Kwanghye Hospital, Seoul, Korea, Democratic People’s Republic of

11:07 a.m. - 11:13 a.m.
90. Biomechanical In Vitro Study of a Novel Minimally Invasive Interspinous Spacer
B. Lazaro1, L. Brasiliense1, A. Brantley1, P. Reyes1, N. Theodore1, V. Sonntag1, N. Crawford1
1Barrow Neurological Institute, Spinal Biomechanics, Phoenix, AZ, United States of America

11:14 a.m. - 11:20 a.m.
91. The Total Facet Arthroplasty System® (Tfas®) in the Treatment of Lumbar Stenosis. Medium Term Clinical Results on 20 Cases
R. Prejbeanu1, I. Branea1, D. Vermesan1, H. Vermesan1, D. Poenaru1, S. Webb2
1Spitalul Clinic Judetean De Urgenta Timisoara, Timisoara, Romania, 2Florida Spine Institute, Clearwater, FL, United States of America

11:21 a.m. - 11:27 a.m.
92. Indirect Decompression (X-Stop) versus Conventional Decompressive Surgery for Lumbar Spinal Claudication - A Prospective Randomized Trial
B. Stromqvist1, S. Berg1, P. Gerdhem1, R. Johnsson1, A. Muller1, T. Sahlstrand1, T. Tullberg2
1Lunds University Hospital, Dept of Orthopedics, Lund, Sweden, 2Stockholm Spine Center, 3Dept of Orthopedics, Upplands Vasby, Sweden, 3Malmö University Hospital, Dept of Orthopedics, Malmö, Sweden

11:28 a.m. - 11:34 a.m.
93. Load-Sharing Property of a Posterior Dynamic Stabilization (PDS) Device as Assessed by Disc Pressure Profilometry - A Biomechanical Study in Cadaver Spine
H. Fan1, D. Sengupta1, J. Park2
1Dartmouth-Hitchcock Medical Center, Orthopedics, Lebanon, NH, United States of America, 2Kwanghye Hospital, Seoul, Korea

11:35 a.m. - 11:41 a.m.
94. A Biomechanical Comparison of Different Spinal Implants: Motion Preventing (Fusion), Motion Preserving (Anatomic Facet Replacement) and Dynamic Stabilization (Dynesys)
V. Goel1, A. Kiapour1, A. Mehta1, B. Hoy2, A. Fauth2
1The University of Toledo, Departments of Bioengineering and Orthopaedic Surgery, Toledo, OH, United States of America, 2Facet Solutions, Logan, OH, United States of America

11:42 a.m. - Noon
Discussion

12:00 p.m. - 2:00 p.m.
Industry Workshops

2:00 p.m. - 3:30 p.m.
Session III - Innovative Technologies

2:00 p.m. - 2:44 p.m.
Session III (A) - Innovative Technologies

Moderators: Neel Anand, MD
Donna Ohnmeiss, PhD
Alternate: Hulin Yang, MD

2:00 p.m. - 2:05 p.m.
95. Novel DNA Test for Severe Adolescent Idiopathic Scoliosis- Presymptomatic Prognostic Test Identifies Patients Who Might Benefit from Early Application of Non-Fusion Implants
J. Ogilvie1, K. Ward1, L. Nelson1
1Axial Biotech, Inc., Salt Lake City, UT, United States of America
2:06 p.m. - 2:11 p.m.
96. A Novel Quantitative Measure of Facet Joint Integrity Using T1rho MRI
J. Auerbach\textsuperscript{1}, C. Wang\textsuperscript{1}, A. Milby\textsuperscript{1}, H. Guerin\textsuperscript{1}, J. Heinly\textsuperscript{1}, B. Lonner\textsuperscript{1}, D. Elliott\textsuperscript{1}, A. Borthakur\textsuperscript{1}
\textsuperscript{1}The University of Pennsylvania, Orthopaedic Surgery, Philadelphia, PA, United States of America,
\textsuperscript{2}The University of Pennsylvania, Department of Radiology, Philadelphia, PA, United States of America,
\textsuperscript{3}The University of Pennsylvania School of Medicine, Philadelphia, PA, United States of America,
\textsuperscript{4}Exponent, Inc., Biomechanics Practice, Philadelphia, PA, United States of America,
\textsuperscript{5}New York University-Hospital for Joint Diseases, Department of Orthopaedic Surgery, New York, NY, United States of America,
\textsuperscript{6}McKay Orthopaedic Laboratories, Department of Orthopaedic Surgery, The University of Pennsylvania, Philadelphia, PA, United States of America

2:12 p.m. - 2:17 p.m.
97. Adipose-Derived Regenerative Cell Transplantation: Evaluating Intervertebral Disc Repair in a Canine Model
H. Meisel\textsuperscript{1}, T. Ganey\textsuperscript{2}, W. Hutton\textsuperscript{1}, R. Schreiber\textsuperscript{1}, M. Hedrick\textsuperscript{1}
\textsuperscript{1}BG Clinic Bergmannstrost, Department of Neurosurgery, Halle, Germany,
\textsuperscript{2}Atlanta Medical Center, Atlanta, GA, United States of America,
\textsuperscript{3}VA Medical Center, Atlanta, GA, United States of America,
\textsuperscript{4}Cytori Therapeutics, San Diego, CA, United States of America

2:18 p.m. - 2:23 p.m.
98. Prospective, Randomized, Controlled Study of Plasma Disc Decompression Compared to Conservative Care for Treating Symptomatic Contained Cervical Disc Protrusion
A. Cesaroni\textsuperscript{1}, P. Nardi\textsuperscript{1}
\textsuperscript{1}Policlínico Casillín, U.O.C. Neurochirurgia, Roma, Italy

2:24 p.m. - 2:29 p.m.
99. Two Levels Presacral Axial Lumbar Interbody Fusion (AxiaLIF). A Prospective 12 Months Follow-Up: Clinical And Radiological Results
L. Pimenta\textsuperscript{1}, C. Arias Pesantez\textsuperscript{1}, J. Lhamby\textsuperscript{2}, L. Oliveira\textsuperscript{1}, T. Schaffa\textsuperscript{1}, E. Coutinho\textsuperscript{1}
\textsuperscript{1}Santa Rita Hospital, Minimally Invasive and Arthroplasty Spine Surgery, Sao Paulo, Brazil,
\textsuperscript{2}Santa Rita Hospital, Spine Surgery, Sao Paulo, Brazil

2:30 p.m. - 2:44 p.m.
Discussion

2:45 p.m. - 3:29 p.m.
Session III (B) - Innovative Technologies
\textbf{Moderators:} Rolando Garcia, MD
Srdjan Mirkovic, MD
\textbf{Alternate:} Nate Ordway, MD

2:45 p.m. - 2:50 p.m.
100. Navigation-Assisted Fluoroscopy in Minimally Invasive Direct Lateral Interbody Fusion: A Cadaveric Study
J. Webb\textsuperscript{1}, G. Regev\textsuperscript{1}, L. Gottschalk\textsuperscript{1}, Y. Lee\textsuperscript{1}, C. Kim\textsuperscript{1}
\textsuperscript{1}University of California, San Diego, Department of Orthopaedic Surgery, San Diego, CA, United States of America

2:51 p.m. - 2:56 p.m.
101. Development of an Elastomeric Disc Prosthesis
C. Lee\textsuperscript{1}, G. Makris\textsuperscript{1}, W. Ogilvie\textsuperscript{1}, S. Roth\textsuperscript{1}, E. Ho\textsuperscript{1}
\textsuperscript{1}Nexgen Spine, Whippany, NJ, United States of America

2:57 p.m. - 3:02 p.m.
102. Oxiplex Intraoperative Surgical Gel: An Adjuvant to Lumbar Disc Surgery for the Reduction of Post Surgical Pain
S. Blumenthal\textsuperscript{1}, Oxiplex Study Group
\textsuperscript{1}Texas Back Institute, Plano, TX, United States of America

3:03 p.m. - 3:08 p.m.
103. Novel Minimally Invasive Percutaneous Multilevel 360 Degree Fusion for Lumbar Degenerative Scoliosis - Feasibility, Technique and Early Results
N. Anand\textsuperscript{1}, E. Baron\textsuperscript{1}, T. Thaiyananthan\textsuperscript{1}
\textsuperscript{1}Cedars Sinai Medical Center, Institute for Spinal Disorders, Los Angeles, CA, United States of America

3:09 p.m. - 3:14 p.m.
104. Initial Cadaver Evaluation of a Mechanical Nucleus Removal Device
J. Sherman\textsuperscript{1}, C. Horton\textsuperscript{2}, B. Norton\textsuperscript{2}
\textsuperscript{1}Twin Cities Orthopedics, Orthopedic Consultants Division, Edina, MN, United States of America,
\textsuperscript{2}CoreSpine Technologies, LLC, Minneapolis, MN, United States of America

3:15 p.m. - 3:29 p.m.
Discussion

3:30 p.m. - Close
SAS8 Meeting Adjourns
MIS

1. Experience in 150 Cases with the TranS1 Minimally Invasive Fusion Technique at L5-S1

W. Tobler¹, R. Bohinski¹
¹Mayfield Clinic, University of Cincinnati Department of Neurosurgery, Cincinnati, OH, United States of America

Objectives: The TranS1 technique (axiaLIF) of access to the L5-S1 interspace is a new and unique approach for surgical treatment of degenerative disc disease at the L5-S1 level. Access is through a small incision (<20mm) at the tip of the coccyx. A cannula is passed through the pre-sacral fat pad in the midline. This space is void of neural and major vascular elements. A 10 mm channel is created through an entry point in the anterior sacrum at the S1-S2 level to gain entry into the central portion of the disc space. The annulus is not violated and its integrity is preserved in this approach.

Methods: This is a report of 150 consecutive patients, age range from 19 to 71, treated with the TranS1 technique at the Mayfield Clinic from June 2005 to September of 2007. All patients underwent a pre-operative MRI evaluation of the pre-sacral space to rule out any aberrant vessels and to determine that there were no sacral anomalies to prevent an appropriate trajectory into the disc space. A pre-operative bowel prep was routinely prescribed. The entire procedure was performed with bi-planar fluoroscopy and air was injected into the rectum in all but a few cases to outline the bowel during the procedure. The arthrodesis was accomplished with placement of autograft from the sacral channel, BMP and allograft extenders. The majority of cases were treated with posterior fixation with percutaneous pedicle screws, and more recently percutaneously placed facet screws. A small number of patients were treated with a standalone interbody fusion (an off-label use of the device). A more recent approach, in 18 patients, is a trend to treat in the outpatient setting.

Results: Surgery was successfully completed in every patient as planned. There were no intra-operative complications identified at the time of surgery. One patient did suffer a bowel laceration, not identified at the time of surgery, that presented with a fever and pre-sacral abscess on post-op day four. Air was not injected into the bowel in this case. This was successfully treated with open drainage and diversionary colostomy that was reversed in 90 days. The disc space never became infected. Occasionally a pre-sacral hematoma has been identified on post-operative CT scans. However there were no symptomatic hematomas and none was surgically explored in this group. There were no device related complications or failures and none of the TranS1 screws have been removed. In the first 50 patients in this cohort who have reached a one year follow-up evaluation, 3 cases of pseudarthrosis were identified on thin section multi-planar CT. Only one was surgically treated with a posterior revision of the inter-transverse fusion.

Conclusions: The TranS1 approach to the L5-S1 interspace has been a safe and easily re-producible operation in 150 consecutive cases at the Mayfield Clinic. It has been safely performed in the outpatient setting. The axiaLIF procedure is an effective, minimally invasive procedure for L5-S1 arthrodesis. This approach offers intriguing possibilities for an outpatient L5-S1 motion preservation procedure that does not compromise the annulus.

2. 2 Year Clinical Results of X STOP Interspinous Distraction Device in the Management of Symptomatic Lumbar Canal Stenosis

D. Wardlaw¹, N. Bilolikar¹
¹Woodend Hospital, Orthopaedics, Aberdeen, United Kingdom

Aim: To measure the clinical effectiveness of Xstop interspinous distraction device in patients with neurogenic claudication due to lumbar canal stenosis. X stop is a dynamic interspinous distraction device which maintains the spinal segment in flexion thus increases the spinal canal area and foraminal area without causing any significant effect on the kinematics of the spine.

Methods: Forty one patients with unilateral or bilateral leg pain due to lumbar canal stenosis, who had significant relief from sitting or flexing the lumbar spine have now completed 2 year follow up. Clinical outcome was assessed by Zurich Claudication Questionnaire (ZCQ), visual analogue score, Oswestery Disability index and SF36 questionnaires preoperatively and at 2 years. ZCQ has three components Symptom severity, physical function and patient satisfaction. ZCQ is considered most precise, reliable and condition specific questionnaire for lumbar spine stenosis with neurogenic claudication (Pratt. et.al Spine Volume 27, Number 1, pp 84-91).

Results: Out of 41 patients 1 patient died due to unrelated causes, 3 patients withdrew from study leaving 37 patients in the study. Thirty five, 33 & 30 patients completed ZCQ, ODI, and SF36 respectively. M:F ratio 18: 23. The mean age was 71(53-94). Xstop device was inserted at double levels in 21(51%) and single level in 20 (49%) patients. By 24 months 77% reported improvement in symptom severity, 62% in physical function, 71% were satisfied with the procedure. The overall 51% made a clinically significant improvement. The mean VAS improved by 1.2 from 5.3 to 4.1. The average improvement in Oswestery Disability Index was noted by 12 points from 43 to 31. Average hospital stay for the procedure was 1.6 days. One patient stayed for 10 days for investigation unrelated to the procedure. The results are almost same as the 1 year results previously reported. None of the patients had any major complications.
Conclusions: The results of our study shows that Xstop remains clinically effective by the end of 2 years. Xstop is relatively less invasive procedure which can be performed as a day case procedure without any major complications.

3. A Randomized Trial of Balloon Kyphoplasty and Nonsurgical Care for Patients with Acute Vertebral Compression Fractures: One Year Results

J. Van Meirhaeghe1, L. Bastian2, D. Wardlaw3, S. Boonen4, FREE Study Investigators
1AZ Sint-Jan Brugge, Dienst Orthopedie en Traumatologie, Brugge, Belgium, 2Klinikum Leverkusen, Leverkusen, Germany, 3Woodend Hospital, Aberdeen, United Kingdom, 4Katholieke Universiteit Leuven, Leuven University Center for Metabolic Bone Diseases and Division of Geriatric Medicine, Leuven, Belgium

Background: Balloon kyphoplasty is a minimally invasive treatment for acute vertebral fractures that aims to reduce and correct vertebral deformity by inserting expandable balloon tamps and then stabilize the body by filling it with bone cement. The effect of balloon kyphoplasty on quality of life has not been tested in a randomized trial.

Methods: Patients with up to 3 non-traumatic acute vertebral compression fractures were enrolled within 3 months of diagnosis and randomly assigned to receive either balloon kyphoplasty (N=149) or usual nonsurgical care (N=151). Measurements of quality of life, back pain and function, and days of disability and bed rest and spine radiographs were assessed through 12 months of follow-up.

Results: Compared with those assigned to nonsurgical care, participants assigned to balloon kyphoplasty had 5.2 points (95% CI, 2.9 to 7.4; p<0.0001) greater improvement in the physical component of the SF-36 quality of life questionnaire at one month and 1.5 points (95% CI, -0.8 to 3.8; p=0.2) at twelve months. Those in the balloon kyphoplasty group also had greater improvement in quality of life by the EuroQol questionnaire at one (0.18 points; 95% CI, 0.08 to 0.28; p=0.0003) and twelve months (0.12 points; 95% CI, 0.01 to 0.22; p=0.025) and improved disability by the Roland-Morris scale at one month (4.0 points; 95% CI, 2.6 to 5.5; p<0.0001) and twelve months (2.6 points; 95% CI, 1.0 to 4.1; p=0.0012). Balloon kyphoplasty patients had less back pain on a 0 to 10-point numeric rating scale at seven days (2.2 points; 95% CI, 1.6 to 2.8; p<0.0001) and twelve months (0.9 points; 95% CI, 0.3 to 1.5; p=0.0034) and reported fewer days of limited activity at one month (2.9 days per 2 weeks; 95% CI, 1.3 to 4.6; p=0.0004) and twelve months (1.6; 95% CI, -0.1 to 3.3; p=0.068). Fewer patients assigned to balloon kyphoplasty took pain medications or used walking aids during follow-up. There was no significant difference in the number of patients with adverse events or serious adverse events in the kyphoplasty and nonsurgical groups. New radiographically detected vertebral fractures occurred in 41.8% of subjects in the balloon kyphoplasty and 37.8% in the nonsurgical group (4% difference; 95% CI -7.5 to 15.6; p=0.5) and were not statistically different.

Conclusion: Compared to nonsurgical treatment, balloon kyphoplasty safely improved quality of life and reduced back pain, disability and the use of pain medications and walking aids. Significant improvements in multiple measurements of quality of life, pain and disability continue for at least 1 year. Balloon kyphoplasty did not increase adverse events including the risk of vertebral fractures.

4. Long-Term Outcomes of Minimally Invasive versus Open Transforaminal Lumbar Interbody Fusion: Surgical Results and Outcomes in a Series of 128 Patients

L. Khoo1, N. Chen1, H. Sheikh1, S. Armin1
1UCLA, Neurosurgery, Santa Monica, CA, United States of America

Objectives: Minimally invasive interbody and pedicle screw instrumentation techniques have become increasingly applied. The purpose of this study is to serve as one of the only comparative surgical, functional, and fusion long term outcome data from patients treated by minimally invasive unilateral transforaminal interbody fusion (MIS-TLIF) versus that of matched group of open TLIF patients.

Methods: This is a nonrandomized, prospective series of patients treated with open or MIS TLIF by a single surgical group, for diagnoses of spondylolisthesis, disc herniations with radiculopathy and/or back pain, and degenerative disc disease in a group with mean age of 48 years. For each MIS procedure, a minimally invasive ipsilateral hemilaminectomy and total facetectomy was performed through a 20mm tubular access for decompression followed by discectomy and oblique interbody graft placement and a single interbody cage placement through the same portal under microscopic, fluoroscopic and electromagnetic surveillance, along with percutaneous segmental pedicle screw instrumentation. Open procedures were done through standard wide dorsal exposure and open instrumentation and cages placement.

Results: There were 34 open and 96 minimally invasive cases of single and two level TLIFs. The average MIS surgical data were as follows: 105 cc/level blood loss, 156 minutes/level surgical time, and total hospital stay of 2.9 days. The open surgical data were respectively 275 cc/ level, 206 min/level and 4.2 days stay. On postoperative CT imaging, all but 2 TLIF cages (96% accuracy) crossed midline with pedicle accuracies of grade 0-58%, grade 1-42%, grade 2-8%, grade 3-2%. Accuracies were similar for open cases. Complication rates were 65% higher in the open surgeries with three times more infections, incidence of medical complication and transfusion rate. Mean Oswestry scores were preoperatively 54.7, at 3 months postoperative follow-up 39.5, at 6 months 32.8, at 9months 29.5, and at12months 24.2. Mean back pain scores were preoperatively 16.1, and 9, 8.5, and 8 at 3, 6, and 12 months postoperatively respectively. ODI and VAS scores were similar for open surgery although VAS and ODI scores were superior at 6 and 12 weeks in the MIS group (p<.01). Of those able to return to full-time work, 58% of the MIS and 40% of the open group are working at the
time of publication. Of patients at more than 1 year, 93% demonstrate rigid fusion radiographically.

**Conclusions:** This is one of the first studies to prospectively demonstrate that MI-TLIF can be performed safely with superior surgical and functional outcomes as compared to open TLIF while still attaining nearly identical radiographic fusion rates in the hands of an experienced minimally invasive surgical group.

**5. The Multiple Causes of Atypical Pre-operative Sciatica and Post-operative Dysesthesia: An Anatomic and Approach Related Risk of the Paramedian and Foraminal Approach to the Lumbar Spine**

A. Yeung1

1Desert Institute for Spine Care, University of California San Diego School of Medicine, Department of Orthopedics, Phoenix, AZ, United States of America

**Purpose:** The paramedian and lateral trans-foraminal approach to the lumbar spine has known pitfalls from operating near the dorsal root ganglion. With foraminal endoscopic surgery, however, documentation and visualization of patho-anatomy has identified additional, but lesser known causes of sciatica and post-operative dysesthesia.

**Method:** Pre-operative and Post-operative dysesthesia in patients undergoing endoscopic decompression for painful degenerative conditions of the lumbar spine are prospectively studied and retrospectively reviewed. Inflammatory conditions and patho-anatomy identified with the endoscope recorded in vivo serves as the data base for study. Discogenic pain, identified through intra-operative chromo discography was correlated intra-operatively by evocative chromo discography performed as an integral part of the endoscopic transforaminal decompression procedure. Indigocarmine dye, mixed 1:10 with Isovue 300, stains degenerative nucleus and foraminal structures in the path of the transforaminal needle. The dye pattern helps differentiate foraminal and intradiscal anatomy. Findings: Post-operative dysesthesia occurred 5-15% of the time in a review of over 1000 consecutive procedures for herniated lumbar discs and painful degenerative conditions of the lumbar spine. The most common pathologic endoscopic finding was inflammatory tissue in the foramen, annulus, and disc. The presence of inflammation in normal tissue denotes pain. This endoscopic finding correlated well with severe back pain and sciatica produced by low pressure low volume discography. Its severity is post-operatively correlated with the extent of thermal annuloplasty and the presence of anomalous and furcal nerves in the foramen. These “anomalous” nerves in the foraminal zone identified pain generators in-vivo that has not been emphasized in the literature. Foraminal branches of either the traversing or exiting nerve (furcal nerves) contribute to the pre-and post-operative symptom complex. Furcal nerves may be difficult to differentiate from a conjoined nerve. Autonomic nerves confirmed by endoscopic excisional biopsy, have also been identified.

**Discussion:** Working near the Dorsal Root Ganglion is a risk by itself, a known risk factor in all transforaminal surgery. Ablation or removal of nerves in the inflammatory membrane results in decreased axial back pain and sciatica, but may also produce a side effect of dysesthesia of varied severity. Furcal nerves, when identified, but are correlated with temporary dysesthesia if ablated. Dysesthesia is usually mild, self limited, and temporary, but a major concern to patients who get it post-operately. Permanent residuals are rare, but may result in residual numbness and extremity weakness. Post-operative dysesthesia responds well to Lyrica or Neurontin, foraminal nerve blocks, and lumbar sympathetic blocks. Co-morbidities such as peripheral neuropathy, and seizure disorders are additional risk factors.

**Conclusion:** Post Operative neuropathic pain staying the same or worsening may not be able to be completely eliminated, and is a risk of the endoscopic procedure. Pre-operative Consent should include neuropathic pain, usually transient, but with a possibility of permanent numbness or weakness. A thorough discussion of the risks associated with foraminal endoscopic surgery must be explained to any patient undergoing open or endoscopic foraminal surgery. Knowledge of the effect of foraminal epidural injections intra-operatively, post-operatively, and in the management of post-operative dysesthesia will decrease this adverse side effect of foraminal surgery. The overall risks and surgical morbidity are still less than posterior trans-canal surgery.


L. Khoo1, S. Armin1, F. Asgarzadie2, N. Chen1, H. Sheikh1

1UCLA, Neurosurgery, Santa Monica, CA, United States of America, 2UCLA, Santa Monica, CA, United States of America

**Objectives:** Open trans-thoracic approaches, considered the standard in treating thoracic disc herniation (TDH), are associated with significant co-morbidities. We describe a minimally-invasive lateral-extracavitary tubular based approach for discectomy and fusion (MI-ECTDF) to treat TDH.

**Methods:** In 13 myelopathic patients (5 men, 8 women, mean age: 51.8 years) with 15 non-calcified TDHs, a far-lateral trajectory was achieved by dilating percutaneously to a 20-mm working portal docked on the transverse process-facet junction which then provided a corridor for near total discectomy, bilateral laminotomies, and interbody arthrodesis with minimal cord retraction. A cohort of 11 demographically comparable patients treated via transthoracic approaches was used as control.

**Results:** Preoperative Frankel grades were B:1, C:4, D:5, and E:3 patients, while at mean of 10 months postop, 11 were grade E, and 2 were grade D. Mean surgical metrics were OR time: 86.5min, blood loss: 33cc, and hospital
86

C. Kim1, S. Ward1, R. Lieber1, S. Garfin1
1University of California, San Diego, Orthopaedic Surgery, San Diego, CA, United States of America

Introduction: Dynamic instability is an important but often unrecognized contributor to chronic low back pain. Although the multifidus muscle is considered clinically important as a lumbar stabilizer, its architectural properties are not completely understood. Detailed cadaveric and in vivo architectural studies show that the human multifidus muscle is designed to produce unusually high forces over short distances. This design is unique compared to other paraspinal muscles, supporting the hypothesis that the multifidus is the most important dynamic stabilizer of the lumbar spine.

Materials and methods: Cadaveric Study-Whole spines (T12 to sacrum) from eight cadaveric specimens were excised en bloc, dissected free of skin and superficial subcutaneous tissues covering the deep spinal muscles, and immersion-fixed. Multifidus muscles were isolated from each vertebral level, permitting measurements of muscle length (Lm), muscle mass and raw muscle fascicle length (Lfraw). Laser diffraction was used to measure fascicle sarcomere length (Ls) thus permitting calculation of normalized fiber length (Lfn), physiological cross-sectional area (PCSA), and the ratio Lfn/Lm. One-way repeated measures ANOVAs were used to compare Lfn and Ls among segmental levels of origin. In Vivo Study-Intraoperative biopsies obtained during spinal surgery were used to determine sarcomere lengths. The position of the spine at the time of biopsy was compared with lumbar spine range of motion obtained from preoperative flexion-extension radiographs to determine their position on the sarcomere length-tension curve.

Results: Cadaveric studies showed that average raw Lf for the lumbar multifidus was 4.79 ± 1.01 cm, average Ls was 2.20 ± 0.06 μm, yielding an average normalized Lfn of 5.84 ± 1.07 cm. Average muscle mass was 149.2 ± 11.4 g, average PCSA was 24.8 ± 4.53 cm², and average Lfn/Lm was 0.17 ± 0.8. These architectural data demonstrate that the multifidus muscle is, by a factor of two, the strongest muscle in the lumbar spine. In vivo sarcomere length measurements obtained during spinal surgery ranged from 1.98 ± 0.15 μm in extension/neutral to 2.56 ± 0.10 μm in flexion demonstrating that the multifidus muscle becomes progressively stronger as the spine is flexed forward.

Discussion: The architectural design of the human multifidus muscle is to create large forces over short distances. This design is best suited to provide a stabilizer function. This corresponds well its anatomic position on the lumbar spine where it is placed centrally and in direct apposition to the posterior spinal elements. Furthermore, in vivo sarcomere length measurements suggest that the multifidus muscle becomes stronger as the spine is flexed. The forward-flexed posture is known to produce high intradiscal pressures and cause increased low back pain in patients with degenerative disk disease. These results suggest that the multifidus muscle is a major dynamic stabilizer of the human lumbar spine, exerting its maximal effect when the lumbar spine is in its most vulnerable position.

8. Failed Fusion Surgery treated by Endoscopic Lumbar Decompression & Foraminoplasty (ELDF) - A 3 Year Review
M. Knight1
1The Spinal Foundation, Congleton, United Kingdom

Background: Recent randomised controlled clinical trials of fusion surgery have demonstrated an inadequate outcome in approximately 30% of interventions. Consequently many require ongoing pain management and Cognitive Behavioural Therapy. Endoscopic Foraminoplasty has been shown to bring benefit in cases of Failed Back Surgery.

Purpose: To examine whether Endoscopic Lumbar Decompression and Foraminoplasty (ELDF) can benefit patients with Failed Fusion Surgery (FFS).

Study design: A prospective study of “ambulatory” Endoscopic Lumbar Decompression and Foraminoplasty.

Patient sample: During 2000, ELDF was performed on 37 males, and 28 females with FFS and a mean age of 58 years (Range: 42-81, SD: 10.4) and reviewed at 12, 24 and 36 months. The average preoperative duration of symptoms was 9.2 years (Range: 5-27, SD: 4.2). Patients had undergone 153 previous open operations (Range 1-7, mean 2.4). 10 patients had undergone a caged ALIF, 16 an ALIF and instrumented Pedicle Fixation, 20 an instrumented PLIF with intervertebral caging or mesh, 12 instrumented Pedicle Fixation alone & 7 uninstrumented posterolateral bone grafting. Further open surgery had been deemed unlikely to be of benefit in their treating centre. 35 had had a multi-level fusion. In all cases Flexion / Extension radiography failed to detect intervertebral micromovement.

Outcome measures: A 50% or greater reduction in back AND leg pain and the Oswestry Disability score deemed the
threshold for a good clinical impact (GCI).

Methods: Patients completed a questionnaire containing the Oswestry Disability Questionnaire and a Visual Analogue Pain Score prior to ELDF and at yearly intervals. A single level ELDF was selected by the production of concordant symptoms during Spinal Probing and Discography.

Results: The mean pre-operative pain score of 8.6 (SD: 1.4) was reduced to 3.0, 3.2, & 3.3 over subsequent years. Cohort integrity was 100%, 98% & 92% annually which included 2 deaths. Concordant symptoms were produced by spinal probing & discography at a non operated level in 13 patients. The percentage gain was 63%, 50% & 60% annually. Consequently a “GCI” was recorded in 56 patients at year 1, 50 at year 2 and 44 at year 3. By year 3, 2 ELDFs had had to be revised, 1 patient required ELDF for causalgic symptoms and 1 at a level additional within the fusion and 3 at an additional level adjacent to the original fusion. There were no post-operative infections. 7 patients had a flare of symptoms lasting 3 - 8 weeks manifest as back pain and 4 had a transient paraesthesia lasting up to 12 weeks.

Conclusions: Transforaminal ELDF allows many patients deemed inoperable to be offered amelioration over a sustained period. Aware state Spinal Probing and Discography allows the definition of post fusion pain sources and ELGF outcomes demonstrate the importance of foraminal extradiscal pathology in the causation of lumbar axial and referred pain.
Background: Cervical total disc replacement (TDR) is intended to address discogenic pain and preserve functional motion between two vertebral bodies in patients with symptomatic cervical disc disease (SCDD). TDR may thus prevent long-term subsequent accelerated degeneration at adjacent disc levels. **Purpose:** The purpose of this trial is to compare the safety and efficacy of the TDR, ProDisc®-C (Synthes Spine Company, L.P., West Chester, PA) to anterior cervical discectomy and fusion (ACDF) surgery for the treatment of one level disease between C3-C7.

**Study design/setting:** The study was conducted at 13 sites. A non-inferiority design with a 1:1 randomization was utilized.

**Patient sample:** Two hundred nine patients were randomized (106 ACDF; 103 ProDisc®-C).

**Outcome measures:** Visual Analog Scale (VAS) Pain and Intensity (Neck and Arm), VAS Satisfaction, Neck Disability Index (NDI), neurological exam, device success, adverse event occurrence, and SF-36 standardized questionnaires.

**Methods:** A prospective, randomized, controlled clinical trial was performed. Patients were enrolled and treated in accordance with the FDA approved protocol. Patients were assessed pre-operatively and post-operatively at prior to discharge, 6 weeks, 3, 6, 12, 18 and 24 months.

**Results:** Demographics were similar between the two patient groups (ProDisc®-C: 42.1 ± 8.4 years, 44.7% males; Fusion: 43.5 ± 7.1 years, 46.2% males). The most commonly treated level was C5-C6 (ProDisc®-C = 56.3%; Fusion = 57.5%). NDI and SF-36 scores were significantly less compared to pre-surgery scores at all follow-up visits for both treatment groups (p < 0.0001). VAS neck pain intensity and frequency as well as VAS arm pain intensity and frequency were statistically lower at all follow-up time points compared to pre-operative levels (p < 0.0001) but were not different between treatments. Neurologic success (improvement or maintainence) was achieved at 24 months in 90.9% of ProDisc®-C and 88.0% of Fusion patients (p = 0.638). Results show that at 24 months post-operatively, 84.4% of ProDisc®-C patients achieved ≥ 4 degrees of motion or maintained motion relative to pre-operative baseline at the operated level. There was a significant difference in the number of secondary surgeries with 8.5% of Fusion patients needing a re-operation, revision, or supplemental fixation within the 24 month post-operative period in comparison to 1.8% of ProDisc®-C patients (p = 0.033). At 24 months, there was a significant difference in medication usage with 89.9% of ProDisc®-C patients not on strong narcotics or muscle relaxants, compared to 81.5% of Fusion patients.

**Conclusions:** The results of this clinical trial clearly demonstrate that ProDisc®-C is a safe and effective surgical treatment for patients with disabling cervical radiculopathy due to single level disease. By all measures evaluated, clinical outcomes after ProDisc®-C implantation were equivalent or superior to those same clinical outcomes after Fusion.

10. Comparison of BRYAN Cervical Disc Arthroplasty with Anterior Cervical Decompression and Fusion: Clinical Results of a Randomized Controlled Clinical Trial

R. Sasso1, J. Heller2, P. Anderson3, S. Papadopoulos4, R. Fessler5

1Indiana Spine Group, Indianapolis, IN, United States of America, 2Emory, Atlanta, GA, United States of America, 3University of Wisconsin, Madison, WI, United States of America, 4Barrow Neurosurgical Group, Phoenix, AZ, United States of America, 5University of Chicago, Chicago, IL, United States of America

We conducted a randomized controlled multicenter clinical trial involving 463 patients with cervical radiculopathy or myelopathy who met the study’s enrollment criteria. Of these patients, 242 were assigned to the investigational group, which received the BRYAN® Cervical Disc, and 221 patients were assigned to the control group, which underwent a single-level anterior cervical discectomy, decompression and fusion with allograft bone and a cervical locking plate. Patients completed clinical and radiographic follow-up examinations at regular intervals for 2 years after surgery. Analysis of 12- and 24-month postoperative data showed improvement in all clinical outcome measures for both groups; however, at 24 months after surgery, the investigational group patients treated with the artificial disc had a statistically superior improvement in Neck Disability Index scores than the control group (P=0.030). They also had a significantly higher rate of overall success (P=0.012). With regard to implant or implant/surgical procedure-associated serious adverse events, the investigational group had a rate of 1.7% and the control group, 3.2%. There was no statistical difference between the 2 groups with regard to the rate of secondary surgical procedures performed subsequent to the index procedure. Patients
Background: cervical spine arthroplasty for the treatment of degenerated disc disorders (DDD) has been performed in many spine centers. The early and midterm clinical outcome and radiological evidence reported in the literature is satisfactory. The majority cases of cervical spine arthroplasty presented in the literature is cervical radiculopathy due to soft disc protrusion. Some authors suggested that the cervical spondylotic myelopathy (CSM) should be a contraindication for the total disc replacement (TDR).

Objective: To study the clinical and radiological outcome of CSM treated with cervical spine arthroplasty.

Method: 121 cases of CSM were treated with cervical spine arthroplasty during the period of Dec.2003 to Jun. 2007. Patient's age was range 22-62 years old. 99 cases had prosthesis of Bryan Disc and 31 cases had Prodisc-C. There were 103 cases of single-level, 16 cases of double-level and 2 cases of three-level TDR with total 141 disc replaced in this series. Clinical outcome was assessed with JOA 17 score scale and Odom's criteria. Radiological assessment including range of motion and heterotopic ossification of operated level were recorded.

Result: (1) Pathology: There were 54 discs had only soft disc protrusion compressed on the spinal cord with posterior longitudinal ligament intact and 45 discs ruptured causing severe spinal cord compression. There were 42 discs protrusion complicated with osteophyte formation causing spinal cord compression. 23 cases had developmental stenosis of cervical spinal canal (on X-ray) but only had anterior spinal cord compression (on MRI). There was no case of ligamentum flavum impingement into spinal canal. (2) Clinical outcome: 89 out of 99 cases with Bryan Disc prosthesis obtained follow-up ranged 12 to 40 months. 26 out of 31 cases with Prodisc-C prosthesis obtained follow-up ranged 6 to 12 months. Pre-operative JOA score was 8.5 and post-operative one was 15.5 on average. According to the Odom's criteria 75 cases had an excellent outcome, 32 good, 8 fair, and no case of poor result in total 115 cases at final follow up. Patients were discharged 4 days (2 to 6 days) with soft collar protection for 8 days (5-12 days) after the operation. There was no subsidence of implant and no worsening of pre-operative symptoms. (3) Radiological result: Motion was observed at operated level in most of cases at final follow up. The heterotopic ossification (HO) around the prosthesis was observed in 7 cases and only 1 case lost movement in single-level Bryan Disc replacement. There were 3 HO cases found in double-level Bryan Disc replacement and only 1 case lost movement. There was no HO case found in three-level Bryan Disc replacement and Prodisc-C replacement. 23 patients who had developmental stenosis of cervical spinal canal on X-ray had no more spinal cord compression on MRI after the surgery.

Conclusion: Cervical spine arthroplasty for the treatment of CSM will offer a satisfied clinical and radiological outcome. The heterotopic ossification may relatively easily occur in the cases with Bryan Disc prosthesis.
proposed classification, the majority of patients belong to grade I and II. We didn’t find relationship between the MRI facet degeneration and clinical results in these stages, except in grade III and IV that outcomes scales had a worsening.

13. Factors Affecting Re-Operations after ACDF within and outside of an FDA IDE Cervical TDR Trial


1Rush University Medical Center, Orthopaedic Surgery, Chicago, IL, United States of America, 2Rush University Medical Center, Chicago, IL, United States of America

Introduction: Anterior cervical discectomy and fusion (ACDF) has been considered standard treatment for symptomatic cervical spondylosis. More recently cervical total disc replacement (TDR) has been performed with proponents claiming that maintained motion at the operated level will reduce the incidence of adjacent level degeneration and improve clinical outcomes compared to ACDF. The excellent clinical results of the USA FDA trial for the first approved cervical TDR (Prestige, Medtronic) have been published. In this prospective, randomized study, superiority of TDR was claimed with 12.1% of control ACDF patients requiring additional related cervical surgery within 2 years vs. 2.9% receiving the Prestige TDR. This rate of re-operation within 2 years after ACDF seems alarmingly high. The goal of the current study was to assess the rate of re-operation within 2 years of ACDF in a cohort of patients receiving the fusion as part of their customary care and therefore not enrolled in an IDE study.

Methods: At our institution, 193 patients with spondylotic radiculopathy or myelopathy underwent ACDF by 3 surgeons between 2001 and 2005. All patients had at least 2 years of follow-up with final follow-up within 6 months of completion of this study. Review of medical records was completed to determine the number of patients who had undergone a revision cervical procedure at the same or adjacent level.

Results: At final follow-up, complete data was available for 176 ACDF patients. Of the 64 patients who underwent single-level ACDF at the authors’ institution and would have met criteria for inclusion in the Prestige IDE TDR study, two patients (3.1%) required additional surgery within 2 years (duration of follow-up of Prestige study) with both patients requiring adjacent level fusion. Of the 176 patients who received single or multi-level ACDF’s, at a mean follow-up of 3.5 years, twelve patients (6.8%) had undergone revision cervical surgery with three patients (1.7%) undergoing same-level revisions (posterior fusion) and nine patients (5.1%) undergoing adjacent anterior level fusions. Patients who underwent revision same level surgery typically had the intervention within the first year (mean: 11 months) whereas those requiring adjacent level fusions typically had surgery later (mean: 29 months).

Conclusions: The current study identifies a 3.1% rate of repeat surgery within 2 years of a single-level ACDF performed during routine clinical practice which is substantially lower than that reported in the control ACDF arm of the Prestige FDA trial (12.1%). Even with longer follow-up of more complex (multi-level) cases, our re-operation rate (6.8%) compared favorably to the IDE rate. This discrepancy may reflect different thresholds for re-operation in the control arm of a device IDE study when compared to routine clinical practice. Additionally, patients enrolled in the single-level only FDA trial may have in fact received multi-level procedures outside of the study. This discrepancy may result in a higher rate of short-term, adjacent level fusions. These data suggest that we need to better understand factors driving treatment and in particular decisions to re-operate in the context of an FDA device trial.

14. Serum Metal Levels in Patients with Stainless Steel Metal-on-Metal Cervical Disc Replacements

M. Gornet1, J. Burkus1, K. Kattner2, A. Skipor4, J. Jacobs4

1The Hughston Clinic, Columbus, GA, United States of America, 2The Orthopedic Center of St. Louis, Chesterfield, MO, United States of America, 3Central Illinois Neuroscience Center, Bloomington, IL, United States of America, 4Rush University Medical Center, Chicago, IL, United States of America

Introduction: Total disc arthroplasty is a recent alternative treatment to fusion for degenerative disc disease. All joint replacement implants will generate some degree of wear particles in vivo. For example, in metal-on-metal total hip replacements, corrosion and wear results in elevated levels of cobalt and chromium in the serum, erythrocytes, and urine [1,2]. This study examines the serum chromium (Cr) and nickel (Ni) levels in patients with stainless steel (SS) metal-on-metal cervical disc replacements.

Methods: This is a prospective, longitudinal study consisting of a group of twenty-five patients implanted with the PRESTIGE® Cervical Disc (Medtronic, Memphis, TN). This system consists of a 316L stainless steel (ASTM F138) metal-on-metal ball-in-trough articulation. Serum samples were collected pre-operatively and at 3, 6, and 12-months post-operatively. Serum was assayed for Cr and Ni using a high-resolution inductively-coupled plasma-mass spectrometer (Element2, Finnigan MAT, Germany). The detection limits were 0.015 ng/mL for Cr and 0.17 ng/mL for Ni. Values below the detection limits were assigned a value of half the detection limit. Longitudinal statistical comparisons were made using the Friedman test.

Results: The median serum Cr levels at pre-op, 3, 6, and 12 months were 0.075, 0.11, 0.13, and 0.17 ng/mL, respectively. The median serum Ni levels were 0.085, 0.18, 0.22, and 0.18 ng/mL at the same time points. For Cr, the difference was statistically higher (p<0.01) between serum levels at the 3, 6, and 12-month time periods compared with pre-op levels.
In addition, the 6-month Cr levels were statistically higher (p<0.01) than the 3-month levels and the 12-month levels were statistically higher (p<0.01) than the 6-month levels. For Ni, the serum levels were statistically higher (p<0.02) at 6-months than at 3-months; differences between Ni levels at other time points were not statistically significant. Generally, the values for Ni were low with many samples having levels below the detection limit (13, 12, 8, and 12 samples at pre-op, 3, 6, and 12 months, respectively). It is interesting to note that the median serum Cr values were an order of magnitude lower than those from a group of patients with cobalt-chromium (CoCr) alloy metal-on-metal surface replacements of the hip and total hip replacements at comparable time intervals [1]. This is consistent with the lower service loads and sliding distances of the cervical spine compared with the hip and the different Cr concentrations between SS (>18% Cr) and CoCr alloy (>30% Cr). Compared with reported metal ion data for patients with posterior spinal arthrodesis with stainless steel instrumentation [3,4], the cervical disc cohort showed up to an order of magnitude lower Ni and Cr metal ion levels.

**Conclusions:** These results indicated that short-term metal levels are lower than those observed in SS posterior spinal instrumentation and CoCr alloy metal-on-metal hips. Continued surveillance of this patient cohort is ongoing and will provide longer-term follow-up data for this cervical disc replacement system.

**References:**
[1] Skipor et al, ORS, 2004;

15. **Comparison of Secondary Operations between Arthroplasty and Anterior Cervical Fusion**

**P. Anderson**, **D. Riew**, **R. Sasso**

1University of Wisconsin, Orthopaedics, Madison, WI, United States of America, 2Washington University, Orthopaedics, St Louis, MO, United States of America, 3Indiana Spine Group, Indianapolis, IN, United States of America

**Introduction:** Secondary operations after anterior cervical discectomy and fusion often result in prolonged disability and increased costs. One of the theoretical advantages of cervical arthroplasty over arthrodesis is that preservation of motion decreases stress on the adjacent levels which should result in fewer re-operations at other cervical levels. If adjacent segment degeneration is decreased by arthroplasty then fewer surgeries at adjacent levels will be necessary. Furthermore, avoiding arthrodesis eliminates reoperations for pseudarthrosis and other complications related to bone graft and instrumentation. For these reasons we hypothesize that secondary cervical spine procedures occur less frequently in patients treated with cervical arthroplasty. The aims of this investigation are to compare rates of additional cervical spine procedures in patients with single-level radiculopathy or myelopathy who were randomized to decompression with arthrodesis or decompression with arthroplasty from a large prospective multi-center investigation.

**Methods:** Two prospective randomized controlled trials were performed to evaluate the safety and efficacy of the Bryan and Prestige cervical disc replacements compared to fusion. All patients who underwent a cervical re-operation, either at the index level or at another level for whatever reason, were included in this study. The number of re-operations for both groups were tabulated, and the reasons for the re-operations as well as the time from the index operation, was noted.

**Results:** No statistically significant differences in demographics or disease state between control and investigational groups were present at baseline. Significantly more re-operations occurred in the arthrodesis group as compared to the arthroplasty group, 48 (8.8%) compared to 25 (5.0%), p<0.0001. In the fusion group, a total of 29 patients had 32 operations at the index level, while in the arthroplasty group, 18 patients had 18 operations. The difference was highly statistically significant (p<0.001). At the adjacent level, 19 fusion patients had 20 operations while 9 arthroplasty patients had 10 operations. This difference too was highly statistically significant (p<0.001).

**Discussion:** The purported advantages of cervical arthroplasty over arthrodesis include preservation of motion, and the potential for decreased adjacent segment degeneration. While arthroplasty has been shown to preserve motion in a number of studies, there are few studies that have demonstrated that arthroplasty results in fewer operations at the adjacent segment as compared to arthrodesis. We undertook this study to compare re-operation rates following arthroplasty versus arthrodesis in a large group of patients who were part of two prospective, randomized, controlled, multi-center studies with a minimum two-year follow-up. To our knowledge, this is the first such study.

We found definite evidence that arthroplasty reduces the need for additional operations both at the index and the adjacent levels.

16. **Heterotopic Bone Formation and Secondary Fusion after Cervical TDR with over 24 Months Follow-Up**


1Clinique Saint Martin, Centre Aquitain du Dos, Pessac, France, 2LDR Medical, Troyes, France, 3Centre Hospitalier Régional, Neurosurgery Department, Orléans, France, 4Centre Hospitalier Régional, Spine Unit, Bordeaux, France, 5Clinique du Parc, Saint Priest en Jarez, France, 6Centre Hospitalier Régional, Neurosurgery Department, Dijon, France, 7Centre Hospitalier Régional, Orthopaedic Department, Strasbourg, France
Purpose: The Mobi-C® cervical disc prosthesis is a second generation, three-piece, non-constrained device, designed to replicate the normal disc motion. The purpose of this study is to assess the safety and efficacy of Mobi-C® and to evaluate the onset of segmental heterotopic ossification (mobile) or fusion (non mobile).

Methods: 35 patients, included in a prospective study on Mobi-C® across 8 sites in France, have achieved their 24 months follow-up control. Indications were disc herniation and/or neurologic compression causing radiculopathy and/or myelopathy at one or several levels between C3 and C7. Efficacy was assessed by auto-evaluation, including Neck Disability Index (NDI) and SF-36 scores, Visual Analog Scale for cervical and arm pain, and Satisfaction Index. Complications, analgesic requirements, employment status were also documented. X-rays and Ranges of Motion (ROM) from flexion/extension views were analyzed.

Results: Average age of patients was 44 years (23-66), with 43% of men. Single-level implantation concerned 30 patients and 5 patients were operated on at two levels. Mean VAS for cervical pain decreased from 61.3pts to 21.5pts after 2 years (p<0.05). Arm pain also decreased significantly (70.9pts pre-operatively vs 25.2pts post-operatively, p<0.05). Functional improvement was relevant, with NDI score decreasing from 49.9% pre-operatively to 26.6% after 2 years (p<0.05). Consistent with pain decrease and functional improvement, SF-36 quality of life score showed significant improvement with mean PCS increasing from 37.3% pre-operatively to 48.5% after 2 years and mean MCS increasing from 35.2% to 48.2%. Finally, 64% of the patients experienced an improvement of the NDI score of at least 15pts compared to pre-operative value, and 78% had an improvement of the VAS cervical pain of at least 20pts. 85% and 76% of patients declared satisfaction regarding cervical and arm pain respectively, and 96.6% would undergo the surgery again. Mean duration of sick leave after surgery was 2.8 months. Only 7% of patients were on sick leave one year after surgery, vs 53% pre-operatively. 97% of the population was under analgesic treatment before the surgery vs 18% after 2 years. There was no migration, no subsidence and no subluxation of the implant. Mean ROM was 8.8° (range 0-25) post-operatively, with 93.6% and 88.9% of the prostheses having a ROM superior or equal to 2° and 5° respectively. Heterotopic ossifications have been reported on 11/40 implanted levels (8 patients): 8/40 calcified segments are still mobile (20%), and 3/40 are fused (7.5%).

Conclusion: The study demonstrates an excellent safety profile with no reported device-related complications. Both the pain decrease and functional improvements occurred within 1 month and were maintained over 2 years. The Mobi-C® prosthesis is a very promising device with a simple implantation technique. The absence of keels or screws allows both single and multi-level implantation, achieving excellent stability of the implant. Radiological evaluation has shown in most cases a long-lasting restoration of the segmental motion. Though secondary fusions are to deplore at latest follow-up, the fusion rate is often related to inaccurate implant sizing or positioning, and should decrease with surgical experience.

17. Bryan Cervical Disc Prosthesis: 5 Years Follow-Up
S. Sola1, R. Hebecker1, S. Mann1
1University Rostock, Neurosurgery, Rostock, Germany

Purpose: The replacement of moderately degenerated cervical discs by mobile artificial prostheses, instead of interbody fusion, is supposed to maintain segment motion and to prevent increased stress on the adjacent segments. The aim of the study was to evaluate retrospectively the efficacy of the Bryan cervical disc prosthesis using radiological and clinical parameters.

Methods: In 2001 and 2002 20 patients with 26 symptomatic cervical disc herniations were selected for artificial disc replacement surgery. All segments showed significant motion. The series included 13 male and 7 female patients with an age range between 37 and 64 years. All patients received nonsteroidal anti-inflammatory medication for at least 10 days and underwent routine follow-up with ap, lateral, flexion and extension x-rays, which were analyzed for size and position of the implant and for heterotopic ossification, fusion and motion of the segment and evidence of adjacent segment degeneration. The clinical outcome was monitored with the Neck Disability Index and VAS.

Results: 5 segments were not suitable for implanting the Bryan artificial disc: 3 due to poor bone quality with loosening of the scaffolds anchor pins, 1 with insufficient x-ray conditions and 1 with iatrogenic instability. Artificial discs were implanted in single level (9), two segments (2), three segments (2) and in combination with adjacent fusion (2). All implants were in proper position. No subsidence or dislocation occurred. The size was adequate, except of three segments with a larger diameter than the biggest available implant (18mm). 1 patient died after the 3 year follow-up from oesophageal cancer. At that time he showed grade III ossification. 4 patients had subsequent cervical spine surgery: 2 revision and fusion, 1 revision and fusion + adjacent segments, 1 decompressive laminoplasty because of posterior osteophytes and adjacent segment degeneration. The 5 reoperated segments had grade IV ossification at the time of surgery. At the 5 year follow-up frequent heterotopic ossification was observed: grade 0: 2 segments, grade I: 0, grade II: 1, grade III: 3, grade IV: 9. 3 segments are in a severe kyphotic position. Mean Neck Disability Index improved to 32, VAS for neck-pain to 35. No significant correlation between clinical outcome and ossification was observed. Patient’s self-assessment provides a very good result in 2, a good in 4, an average in 4 and a bad result in 6 cases.

Conclusion: The results indicate that the Bryan artificial cervical disc can maintain motion only in a limited number of cases. Probably the surgical technique for the preparation of the implant-bed with bone-drilling might be a
cause for the high fusion-rate compared to other cervical prostheses. The potential benefit of motion-preservation must be confronted with the high revision-rate and the disadvantages of the more invasive approach and the increased implant cost compared to interbody fusion.

18. Consequences of Athletic Activity in the Lumbar and Cervical Total Disc Replacement Patient: A Multi-Center Non-Randomized Prospective Study

J. Yue1, M. Scott-Young2, R. Bertagnoli3, J. Jaramillo4, M. McRae5

1Yale University, Orthopaedic Surgery, New Haven, CT, United States of America, 2Pacific Private Clinic, Southport Queensland, Australia, 3ProSpine Center, Orthopaedic Surgery, Straubing, Germany, 4Yale University, Spine Surgery, New Haven, CT, United States of America

Study design: Prospective, non randomized, longitudinal, multi-center, minimum 2 year follow-up
Objective: To evaluate the consequences of differing levels of athletic activity on the clinical and radiographic outcomes of lumbar and cervical disc arthroplasty.
Background: The influence of athletic activity on the clinical and radiographic outcomes of lumbar disc arthroplasty has not been evaluated to the best of our knowledge.
Methods: The prospective records of 3 major arthroplasty centers in 3 continents (North America, Europe, and Australia) were analyzed for the pre-operative and post-operative athletic activities of lumbar and cervical total disc replacement (TDR) patients. Athletic activities prior to the onset of spinal injury, after the onset of spinal injury, and post-TDR surgery were assessed. Activities were classified professional vs. amateur as well as into contact/vigorous, moderate, and light in terms of effect on involved spinal segments. Complications were assessed both radiographically as well as clinically.
Results: Lumbar. A total of 1003 lumbar patients full-filled all follow-up criteria including 2 year follow-up. There were 255 Charite and 748 Prodisc prostheses. Of the Charite discs 56 participated in sports prior to spine injury. Following TDR, 48/56 participated in athletic activities (22 contact/vigorous, 11 moderate, and 15 light). Five were professional and 43 were amateur. There were no implant complications. Five patients complained of radiculopathy symptoms during participation. No implant related complications occurred during any type of activity. Of the Prodisc cases 172 participated in sports prior to spine injury. Following TDR, 158/172 participated in athletic activities (34 contact/vigorous, 27 moderate, and 97 light). Eight were professional and 150 were amateur. Seven patients complained of radiculopathy symptoms during participation. Three L5/S1 subluxations occurred with heavy weight lifting and 1 implant loosening occurred after a bike injury.

Results: Cervical. A total of 210 cervical patients full-filled all follow-up criteria including 2 year follow-up. There were 45 PCM discs and 167 Prodiscs. Of the PCM discs 18 participated in sports prior to spine injury. Following TDR, 8/18 participated in athletic activities (3 contact/vigorous, 5 moderate, and 0 light). Three were professional and 5 were amateur. There were no implant complications. No implant related complications occurred during any type of activity. Of the Prodisc cases 138 participated in sports prior to spine injury. Following TDR, 87/138 participated in athletic activities (16 contact/vigorous, 47 moderate, and 24 light). None were professional. No implant complications occurred.

Conclusions: Athletic activities of varying degrees appear to be well tolerated following both cervical and lumbar TDR surgery in single and multi-level cases. Contact-vigorous athletic activities do not appear to result in high levels of clinical or radiographic complications in the lumbar TDR patients except for heavy weight lifting activities in patients who have undergone L5/S1 Prodisc surgery in which we experienced 3 PE subluxations. In our limited number of cervical TDR patients who were involved with contact-vigorous activities, no implant complications occurred in either implant type. Further biomechanical and clinical studies are necessary before general recommendations can be made.

Session II - Cervical TDR

19. Results of a Prospective, Randomized, Multi-Center Clinical Trial of PCM Cervical Disc Replacement: Two Year Clinical Outcomes

J. Regan1, F. Phillips2, A. Cappuccino3, J. DeVine4, J. Ahrens5, P. McAfee6

1Pacific Coast Spine Institute, Beverly Hills, CA, United States of America, 2Midwest Orthopaedics at Rush, Department of Orthopaedic Surgery, Chicago, IL, United States of America, 3Buffalo Spine Surgery, Lockport, NY, United States of America, 4Madigan Army Medical Center, Tacoma, WA, United States of America, 5Pivotal Research Solutions, Allen, TX, United States of America, 6Towson Orthopedic Associates, Towson, MD, United States of America

Purpose: The use of Cervical Disc Replacement for surgical treatment of cervical radiculopathy or myelopathy, particularly adjacent to previous cervical fusion, has become a promising alternative to anterior cervical discectomy and fusion (ACDF). Preliminary results are reported from five sites in a prospective randomized study comparing PCM and PCM-V disc replacement to ACDF for the treatment of symptomatic cervical spondylosis, including in “training” cases, myelopathy and at levels adjacent to previous fusion.
Methods: Study inclusion criteria identified patients between 18 and 65 years old with single-level symptomatic
cervical radiculopathy and/or myelopathy unresponsive to at least 6 weeks of non-surgical therapy, or experiencing progressive neurological symptoms. Patients may have had a successful previous single level ACDF. Each site was entitled to enroll up to four initial non-randomized “training” PCM cases. Thereafter, enrolled patients were randomized to receive either PCM/PCM-V disc replacement or ACDF using structural allograft and plating, and were blinded to their assignment until after surgery. At the five centers, 226 patients were enrolled. Of these, 18 training, 65 PCM, and 36 control patients and five training, 18 PCM, and eight control patients have completed one- and two-year follow up visits respectively. Neck VAS, arm VAS, and Neck Disability Index (NDI) scores, as well as all complications and adverse events were recorded at various follow up intervals.

Results: Analysis revealed no significant differences in patient demographics between the PCM “training”, PCM, or control groups. Clinical outcomes for each group are as follows:

Clinical Outcomes (Preoperative/6wk/12wk/26wk/1yr/2yr):
NDI: Training: 28/15/14/11/13/12, PCM/PCM-V: 28/16/13/12/10/12, Control: 28/20/16/14/15/18
Arm VAS: Training: 70/21/22/19/28/28, PCM/PCM-V: 72/27/26/24/24/39, Control: 75/29/33/32/29/37

Subsequent surgery was performed in 1/19 (5.2%) of the “training”, 3/117 (2.6%) of the PCM/PCM-V, and 2/90 (2.2%) of the control group patients. Implant migration occurred in 1/136 (0.7%) disc replacement cases. The duration of surgery differed significantly (p=0.001) for the randomized and randomized cases respectively. Duration of surgery is longer, within the first 6 weeks of surgery and lower NDI scores at 20. absence of bias between Non-randomized and Randomized Cases in three prospective randomized FDA studies of cervical disk replacement-788 cases.

Methods: The complete to date data (788 patients) from three prospective randomized FDA IDE studies on cervical arthroplasty (Kineflex-C, PCM, Secure-C) was analyzed [non-randomized (N=214) and randomized subjects (N= 574)].

Results: The age, gender, and vertebral levels of surgery were similar between the groups. Height= 100% (98.5% to 101.5%); weight = 101.2% (97.7% to 104.9%); BMI = 102% (99.2% to 104.9%); Baseline NDI= 100.7% (97.0% to 104.4%) and Baseline VAS = 100.8% (90.2% to 112.6%). The mean baseline VAS was (71.8±19.94 and 71.0±20.82), and the NDI (60±12.57 and 59.5±12.12), for the non-randomized and randomized cases respectively. A learning/experience effect was observed: surgery time improved from 106 minutes ±40.8 from the early non-randomized cases to 84.3 minutes ±34.4 (p < .0001) for the randomized cases and EBL improved from 61.3 cc ±50 to 50.6 cc ±39.9 (p = .02) consistent with surgeon experience in all new procedures.

Conclusions: Such uniform consistency is rarely encountered to this degree in prospective randomized trials. The “intent to treat” analysis of the entire study for validated clinical scales and complications can be performed on the pooled non-randomized and the randomized “new” device patients. This analysis can then be compared against the reference group, even though for regulatory purposes only the randomized subset of data was planned to test the non-validated FDA scale. The concept of an initial set of non-randomized (training) cases should be considered as not being inherently biased and can be pooled with the randomized group of the “new” device for the safety and validated clinical scale outcome analysis. This statistical approach is useful in prospective randomized clinical surgical trials to decrease the total number of patients entered. The analysis maximizes the use of a larger number of patients to get a more accurate picture of the true device related complication rate.

Introduction: This is the largest prospective randomized analysis of cervical arthroplasty (Kineflex-C, PCM, Secure-C) ever compiled -Level I Study = 788 total subjects. These were the only three IDE studies on cervical arthroplasty which had both 1) utilized training cases and 2) completed enrollment so there was no study selection involved. The goal was to perform the appropriate “intent to treat” analysis in a randomized prospective FDA IDE trial with non-randomized initial (training) cases followed by randomized cases when both clinically validated and non-validated regulatory outcome measures are collected. Enrollment differences or bias between 1) the initial non-randomized and 2) the randomized portion of clinical study groups could potentially prevent the pooling of these two “new” technique groups prespecified in the randomization scheme of the study.

20. Absence of Bias between Non-Randomized and Randomized Cases in Three Prospective Randomized FDA Studies of Cervical Disk Replacement-788 Cases

P. McAfee, B. Cunningham, F. Geisler, C. Lauressan, S. Ruskin

1Spine and Scoliosis Center, Towson, MD, United States of America, 2Neurosurgery, Aurora, IL, United States of America, 3Cedars Sinai, Los Angeles, CA, United States of America, 4University of Pennsylvania, Philadelphia, PA, United States of America
21. Heterotopic Ossification at the Index Level after ProDisc®-C Surgery: What Is the Clinical Relevance?

R. Bertagnoli¹
¹ProSpine, Straubing, Germany

Introduction: Heterotopic ossification (HO) has been defined as the abnormal formation of new bone at joints and within soft tissue. HO is a multi-factorial bodily response. It has been reported after trauma, surgery, and peripheral events. Causal theories of HO include genetic predisposition, muscle and tissue damage, surgical implantation technique, and peri-operative measures. The incidence of HO following cervical total disc replacement (TDR) should be interpreted based on a classification system of clinical and motion relevance (as proposed below) rather than the current radiograph based system. The authors retrospectively investigated the clinical relevance of HO in patients treated with the ProDisc®-C TDR.

Methods: 117 patients treated with the ProDisc®-C TDR were retrospectively evaluated at 2-5 years post-surgery. Radiography determined the presence of anterior ossification. Patients can be classified without a CT scan or MRI. HO was assessed according to a clinical classification system: C0 - ossification present but not clinically relevant; C1 - ossification present and clinically relevant, based on no improvement in Neck Disability Index (NDI) scores; M0 - ossification present but not motion relevant; M1 - ossification present and motion relevant, based on Range of Motion (ROM). Patients were rated using a combination of these four classifications. Those patients classified as having C1 ossification had significant clinical consequences.

Results: At 2-5 years post-surgery, radiographic evaluation of ProDisc®-C patients identified 9.4% as having HO. The mean flexion/extension (F/E) ROM for HO patients was comparable to the mean F/E ROM for the entire group of patients. Of these HO patients, none were classified as C1 based on their NDI scores. Although HO may exist on radiographs, the clinical relevance of such findings in and of themselves is inconsequential. Patients not classified as C1 were not experiencing greater pain associated with HO, nor was there a statistically different range of motion as a result of the HO formation in comparison to the remaining patient population.

Conclusions: HO formation following cervical TDR appears to be a result of surgical technique. HO may be prevented by peri-operative interventions, including: using pharmacological agents such as NSAIDS, Indomethacin, or Diphosphonates; rinsing the surgical site to remove bone fragments; reducing retraction forces on the lungus colli muscle to lessen soft tissue trauma; reducing bone surface by using the largest appropriate device footprint, cutting off the rim of the vertebral body, and using bone wax to seal surfaces; and by positioning the center of rotation at least to the 50% margin (area of equilibrium).

22. Finite Element Analysis of Cervical Spine Following Bilevel Fusion, Bilevel Total Disc Replacement and Fusion plus Total Disc Replacement at Adjacent Levels

A. Faizan¹, V. Goel¹, N. Kulkami¹, A. Biyani², S. Garfin³, C. Bono⁴, P. Maguire⁵, H. Serhan⁶
¹University of Toledo, Bioengineering, Toledo, OH, United States of America, ²University of Toledo, Orthopedics, Toledo, OH, United States of America, ³University of California, San Diego, Orthopedics, San Diego, CA, United States of America, ⁴Boston Medical Center, Orthopedics, Boston, MA, United States of America, ⁵Deupuy Spine, Raynham, MA, United States of America

Introduction: Motion preservation devices such as artificial discs are being pursued because of the aim to preserve physiological motion of the cervical spine. As TDRs gain popularity, different combinations of TDR and fusion will possibly be performed in patients. For example, one patient may have bi-level TDR (BTDR) while another may have fusion plus TDR (F+TDR) at adjacent levels. The aim of the present study is to investigate the biomechanical differences among the above surgical procedures using a ball and socket type disc implant.

Methods: Three different finite element models were created by modifying the current experimentally validated C3-C7 model to incorporate all three surgical procedures. In the first model, to simulate the blevel fusion (BLFu), bone grafts were placed at the C4-C5 and C5-C6 disc spaces following the removal of intervertebral discs at the respective levels. The bone grafts consist of a cancellous core which is surrounded by a cortical layer. In the F+TDR model, the bone graft at C5-C6 level was replaced by a ball and socket type disc implant (DMT, Inc, Florida) while the bone graft at the C4-C5 level was retained. For the third model, both the bone grafts at C4-C5 and C5-C6 levels were replaced by disc implants, simulating BTDR scenario. The intact model was loaded with 75N of follower load using a set of springs. A moment of 1.5 Nm was also applied to simulate physiologically relevant flexion and extension motions of the intact spine. However, for the BLF, BTDR and F+TDR models, a hybrid protocol (displacement control protocol) was employed for load application.

Results: BLFu model required 4.1 Nm of extension moment to achieve the same C3-C7 motion as predicted for the intact spine. For F+TDR and BTDR models, these moment values were 1.05Nm and 0.8Nm, respectively. Compared to the intact spine, the C3-C4 and C6-C7 extension motions increased by more than 100% in the BLFu model. The corresponding motion changes in the F+TDR model were only -1% and -9%, respectively. However, for the BTDR model, the corresponding changes were -40% and -37%, respectively. BLFu, F+TDR and BTDR models required 3.4Nm, 1.2Nm and 1.5Nm of flexion moments, respectively.
to achieve the flexion intact motion. C3-C4 and C6-C7 flexion motions increased by approximately 100% in the BLFu model, as compared to an intact model. Corresponding motion changes in F+TDR model were 36% and 22%, respectively, as compared to intact. In the BTDR model the corresponding motion changes were 5% and -6%, respectively.

**Discussion:** The BLFu restricts the motion at fused levels while significantly increasing the motion at adjacent levels. BTDR preserves the motion by redistributing it over all the segments. BTDR can potentially prevent the excessive adjacent level degeneration by mimicking the kinematics similar to intact spine. F+TDR model also reduces the higher adjacent level motion by yielding greater motion at the TDR implanted level. BTDR and F+TDR models provide biomechanics closer to intact spine for ball and socket type TDR.

23. Kinematics of Cervical Total Disc Replacement Adjacent to a Two-Level, Straight vs. Lordotic Fusion

**S. Martin**¹, A. Ghanayem¹, M. Tzermiadianos², R. Havey², S. Renner², G. Carandang², C. Abjornson², A. Patwardhan²

¹Loyola University Medical Center, Orthopaedic Surgery, Maywood, IL, United States of America, ²Edward Hines Jr. VA Hospital, Spine Biomechanics Lab, Hines, IL, United States of America, ³Synthes Spine, West Chester, PA, United States of America

**Purpose:** Anterior cervical discectomy and fusion (ACDF) is considered the gold standard for treatment of symptomatic cervical degenerative disc disease. However, fusion of cervical segments may result in progressive degeneration of adjacent levels in the cervical spine. Cervical total disc replacement (TDR) may be a promising alternative to fusion of a symptomatic adjacent level after prior cervical fusion. However, little is known about the behavior of a TDR in this setting. The aims of this study are to characterize the response of a cervical TDR above a 2-level fusion, and to study the effect of fusion alignment on the response of the TDR.

**Methods:** Eight fresh-frozen human cadaveric cervical spine specimens (C2-T1, age: 59±8.6) were tested (i) first intact, (ii) after a simulated 2-level fusion at C4-C6 first in lordotic alignment (3.5 degrees more than neutral posture) and then in straight alignment (3.5 degrees less than neutral posture), and (iii) after insertion of a Pro-Disc C implant at C3-C4. Fusion was performed using an external fixator-styled stabilization apparatus that allowed easy adjustment of C4-C6 lordosis, as well as restoration of intact mobility. This allowed testing of TDR alone, fusion alone and TDR above fusion of different alignments, using a combination of load-control (±1.5N/m) and displacement-control protocols. Segmental range of motion (ROM) was measured at all levels using optoelectronic instrumentation and monitored using digital fluoroscopy.

**Results:** C3-C4 flexion-extension ROM significantly decreased with the TDR compared to the intact spine from 10.7 to 8.5 degrees (p=0.008). Both flexion and extension moments needed to bring the spine to similar endpoints significantly increased for TDR above a lordotic fusion compared to TDR alone (1.52 vs. 0.70 Nm, p<0.001; -1.44 vs. -1.03 Nm, p=0.002). There was no significant difference in segmental ROM at C3-C4 between TDR above straight or lordotic fusion (8.9 vs. 9.0 degrees, p=0.204). Interestingly, the flexion moment to reach the same endpoints was significantly increased for TDR above a lordotic fusion compared to the straight fusion (1.52 vs. 1.11, p<0.001), while the extension moment was significantly increased for the TDR above the straight fusion compared to the TDR above a lordotic fusion (-2.20 vs. -1.44, p<0.001).

**Discussion:** Although there was no significant difference in segmental ROM of the TDR at C3-C4 between the two fusion alignments, the corresponding flexion and extension moments to reach the same displacement endpoints were significantly different. This suggests that more force is required to bring the spine with a TDR into extension when the spine is fused in a straight alignment and conversely more force is required to bring the spine into flexion when fused in a lordotic alignment. Increased loading may adversely affect the survivorship of the TDR. Refinements in cervical disc replacement design criteria may become necessary as we contemplate performing an arthroplasty adjacent to fusions with differing sagittal alignments. Further clinical studies are required to determine the long-term implications of increased loading of the TDR above a fusion.

24. Consequences of Whiplash Injury Following ProDisc-C Total Disc Replacement: Evaluation of Cervical Kinematics During Low Speed Rear-end Impact

**C. Demetropoulos**¹, S. Sundararajan¹, S. Bilku₁, W. Hardy², K. Yang³, J. Bishop⁴, C. Abjornson⁵, M. Bey⁴, H. Herkowitz⁵, S. Bartol⁷

¹William Beaumont Hospital, Orthopaedic Research, Royal Oak, MI, United States of America, ²Wayne State University, Bioengineering Center, Detroit, MI, United States of America, ³Wayne State University, Bioengineering Center, Royal Oak, MI, United States of America, ⁴Henry Ford Hospital, Bone and Joint Center, Detroit, MI, United States of America, ⁵Synthes Spine, Research, West Chester, PA, United States of America, ⁶William Beaumont Hospital, Orthopaedic Surgery, Royal Oak, MI, United States of America, ⁷Henry Ford Hospital, Orthopaedic Surgery, Detroit, MI, United States of America

**Introduction:** Whiplash injuries are very common
following low speed rear-end automotive impacts. The potential for harm following such accidents for cervical total disc replacement patients is yet unknown. As this procedure nears FDA approval and widespread implantation becomes reality, questions of occupant safety must be addressed. This study is the first to test full body post mortem human subjects (PMHS) under low speed rear-end impacts for cervical response in the orthopedic literature, per the authors’ knowledge. The purpose of this study is to evaluate the biomechanical response of the cervical spine following ProDisc-C implantation in low speed rear-end impact. 

Methods: 8 PMHS specimens had 3.2 mm diameter lead markers implanted from C1 through C7 (Figure 1). Markers were placed in the vertebral body and spinous process of each vertebra percutaneously under fluoroscopic guidance. Previous studies have tested the isolated head neck complex. Such work does not consider compressive loads developed in the spinal column by straightening of spinal curvature or occupant-seat interactions, thus resulting in altered kinematics and kinetics. Each PMHS was positioned in a standard car seat. A crash sled imparted a peak acceleration of 14 g and a peak velocity of 14 kph. Planar high speed fluoroscopy, at 1000 frames per second, captured head and cervical spine motion. Motion of the vertebrae during impact and segmental range of motion were assessed. Each PMHS was first tested in the intact state as a control and then retested after the implantation of a ProDisc-C at C5-6. Two specimens were tested with the headrest in the bottom position, two were tested with the headrest raised (to make initial contact at or above the center of gravity of the head), two were tested with the headrest raised while the body was placed in a forward prone position, and two were tested with the headrest removed. 

Results: None of the ProDisc-C disc replacements implanted in the PMHS specimens demonstrated any signs of loosening, subsidence, motion with respect to the endplate or failure of the ProDisc-C prosthesis. Post-test implant retrieval analysis demonstrated no signs of damage or wear. 

Conclusions: Whiplash injuries frequently result from low speed rear-end impacts. These experiments demonstrate that the ProDisc-C prosthesis is stable in the event of such an automotive impact. While not even under the most severe testing condition without a headrest was the implant affected, a substantial decrease in loading was observed when the headrest was in place and properly positioned. The results of this study address the safety of occupants in a low speed rear-end impact following ProDisc-C total disc replacement in the most critical post-operative period.
endpoints of >20% improvement in NDI was calculated. Statistical analyses were performed for data within and between treatment groups.

Results: A total of 57 patients were enrolled (32 Kineflex|C, 25 ACDF). Six Kineflex|C training cases are included. At one year, mean NDI decreased from 64 to 27 (58%, p<0.001) for Kineflex and from 66 to 28 (57%, p<0.001) for ACDF. Mean VAS decreased from 74 to 32 (58%, p<0.001) for Kineflex and from 78 to 34 (56%, p<0.001) for ACDF at one year. There was no significant difference in postoperative improvement in NDI or VAS between groups. NDI decreased by at least 20% in 93% of Kineflex|C and 76% of ACDF at one year (p<0.05). Operative time, estimated blood loss and hospitalization did not differ between groups. Mean ROM for Kineflex|C versus ACDF differed significantly (8.7 vs. 1.5 degrees, p<0.001). Range of motion was greater than 3 degrees for 83% of Kineflex|C. Post-operative disc height was greater for Kineflex|C vs. ACDF (5.7 mm vs. 4.8 mm, p=0.013) while there was no preoperative difference (3.0 mm vs. 3.1 mm). Ninety-one percent of patients were very satisfied or satisfied. There were no major device related adverse events: no implant subsidence, extrusions or revisions. Adverse events were similar between groups.

Conclusions: These preliminary results suggest Kineflex|C is at least equivalent to ACDF in clinical outcome. Kineflex|C may be superior in percent of patients achieving the primary outcome measure of at least 20% NDI improvement. The outcomes for Kineflex|C were achieved while maintaining significantly greater range of motion than ACDF. The pooled multi-center data may reveal further significant differences between groups. Long term data is needed to determine if TDR will decrease the incidence of adjacent level disease.

26. Biomechanics of Multilevel Cervical Arthroplasty and Combined Arthrodesis and Arthroplasty

N. Crawford1, S. Safavi-Abbasi1, S. Baek1, P. Reyes1, M. Senoglu1, V. Sonntag1

1Barrow Neurological Institute, Spinal Biomechanics, Phoenix, AZ, United States of America

Introduction: Little research exists on the biomechanics of combined cervical arthroplasty/arthrodesis and multilevel arthroplasty. Simply studying the range of motion of these conditions in vitro provides little useful information. Therefore, a new experimental protocol was used to investigate how these conditions affect posture and distribution of segmental angles under physiologic loads.

Methods: Seven human cadaveric C3-T1 specimens were studied (age 32-67 years). After completing normal tests, C4-C5, C5-C6 and C6-C7 discs were replaced with ProDisc-C (Synthes Spine, Paoli, PA). Then, using a rigid screw-rod system fixated at 3 points per vertebra, various combinations of fusion (“F”) adjacent to arthroplasty (“A”) were simulated at C4-C5, C5-C6 and C6-C7 respectively: fAA, AfA, AaF, fAf, AfA, ffF, C3-C4 and C7-T1 were left intact during all tests. A compressive belt apparatus simulated normal muscle co-contraction and gravitational preload. This apparatus controlled the angle of C3 relative to T1 but did not interface with intermediate levels. All motion segments (C3-C4, C4-C5, C5-C6, C6-C7 and C7-T1) were individually monitored using a 3D optical tracking system. Parameters studied were segmental compensation to restore the original neutral postural balance, tendency for buckling while maintaining global neutral postural balance, and shift in sagittal plane axis of rotation.

Results: During all 7 conditions in which one or more ProDisc-C levels were mobile, the arthroplasty levels preferentially moved toward upright posture more easily than the normal intact levels. This difference was significant in the AAA, fAA, fAf, ffA configurations (p<0.05, paired Student’s t-tests). To keep a global, upright posture of 0°, the buckling tendency for worse buckling to occur with greater shifts in IAR location was related to buckling—anterior IAR shift resulted in flexion. Although there was a tendency for worse buckling to occur with greater shifts in the axis of rotation, this correlation did not reach significance (p=0.112).

Conclusions: Arthroplasty levels provide the “path of least resistance,” through which the initial motion is more likely to occur than normal levels. This phenomenon may in part explain focal kyphosis observed clinically with cervical arthroplasty. The tendency for specimens to buckle under vertical compression became greater as more arthroplasty levels were introduced. Buckling appeared more severe with arthroplasty more caudal. Malpositioning of the arthroplasty device would be expected to cause shifts in IAR and therefore more buckling. Buckling only moderately correlated to shifts in IAR, meaning slight malpositioning of the devices would not necessarily predispose the patient to buckling.
27. Comparison of Adverse Events between the Bryan Artificial Cervical Disc and Anterior Cervical Arthrodesis

P. Anderson1, D. Riew2, R. Sasso3, R. Trehane4
1University of Wisconsin, Orthopaedics, Madison, WI, United States of America, 2Washington University, Orthopaedics, St Louis, MO, United States of America, 3Indiana Spine Group, Indianapolis, IN, United States of America, 4University of Tennessee, Memphis, TN, United States of America

Objectives: Cervical disc arthroplasty as a substitute for fusion has been developed to maintain motion and, theoretically, prevent adjacent segment degeneration. Currently, cervical arthroplasty devices are undergoing clinical testing for safety and efficacy. The evaluation of safety is performed by critical analysis of all adverse occurrences following surgery to determine if the new device has a beneficial risk profile for the patient. The objective of this study is to compare the rates of adverse events associated with disc arthroplasty versus those of anterior cervical disectomy and arthrodesis with allograft and plate.

Methods: Adverse events associated with Bryan Disc arthroplasty and arthrodesis were compared in a prospective randomized study. Four hundred sixty-three (463) patients having cervical radiculopathy and or myelopathy at a single level were treated at 31 sites. A total of 242 patients received the disc and 221 patients had anterior cervical disectomies and arthrodesis (ACDF). All patients were evaluated preoperatively and at 1.5, 3, 6, 12, and 24 months post-operatively. Adverse events were recorded concurrently and categorized by severity and as medically or surgically related.

Results: No differences in overall medical events occurred between groups. Surgically related events occurred more frequently in the investigational group secondary to more complaints of postoperative dysphagia and late medical events occurred more frequently in the investigational patients. However, the more severe WHO grade 3 and 4 events occurred more frequently in the arthrodesis patients related to treatment of pseudoarthrosis and persistent symptoms. Significantly, more cervical spine re-operations occurred in the fusion group. Only one spinal cord injury occurred and it was in the arthrodesis group and no patients had deep infection or death related to either procedure.

Conclusion: Bryan cervical disc replacement and anterior cervical fusion are both safe procedures with a low incidence of significant adverse events related to the procedure. Statistically, more serious adverse events and re-operations occurred in the fusion group while a greater number of less serious surgical related events were seen in the investigational group.

28. The X-ray and MRI Assessment of Upper and Lower Adjacent Level Degeneration after Minimal 2 Years Single Level Bryan Disc Replacement

Y. Sun1
1Peking University Third Hospital, Orthopaedics, Beijing, China

Object: To assess the degenerative process on the adjacent segments by means of X-ray and MRI after single level Bryan disc replacement. The clinical outcome and the motion of operated level were reviewed.

Method: From Dec.2003 to Aug.2005, 51 patients received single level Bryan disc replacement. 26 cases including 18 of myelopathy and 8 of radiculopathy obtained minimal 2 years follow up (average 29.5 months, range from 24 to 40 months). The pre-operative and post-operative X-ray and MRI scan were evaluated by two independent observers. Following measurement on X-ray films were recorded: the height ratio of disc space and vertebral body (DS/VB) at upper and lower adjacent level; the range of movement (ROM) of operated level; the heterotropic ossification (HO) around prosthesis. The disc degeneration of superior adjacent segment (SAS) and inferior adjacent segment (IAS) on MRI was recorded according to Pfirrmann’s classification. The invasion ratio of disc protrusion and ligamentum flavum budge to the duro sac of SAS and IAS were measured and recorded respectively on MRI T2 weighted image. The clinical outcome was recorded according to JOA score scale and Odom’s grade.

Result: (1) On X-ray: The DS/VB at upper adjacent level was 0.442 before surgery and 0.430(P>0.05) after surgery. The DS/VB at lower adjacent level was 0.457 before surgery and 0.451(P>0.05) after surgery. The ROM of operated level was 6.9 degrees (range from 2 to 12 degrees) pre-operatively and 7.8 degrees (range from 1 to 14 degrees) post-operatively (P>0.05). There were 7 cases of HO seen around the implant but only one case lost movement (1 degree flexion/extension movement) recorded as spontaneous fusion. (2) On MRI scan: Two orthopaedic surgeons assessed the adjacent disc degeneration independently according to Pfirrmann’s classification and there was no statistic difference between observers (P>0.05). The majority adjacent discs remained same grade on final follow up. There was one disc changed from grade 1 to grade 2 and two discs changed from grade 2 to grade 3 on the SAS, respectively. For the IAS, there was one disc changed from grade 2 to grade 3 and one disc changed from grade 3 to grade 4, respectively. The invasion ratio of disc protrusion changed from17.9% to 19.1% (P<0.05) on SAS and from 18.4% to 19.5% (P<0.05) on IAS after the operation. The invasion ratio of ligamentum flavum increased from 8.9% to 9.4% (P<0.05) on SAS and from 11.5% to 11.8% (P>0.05) on IAS after the operation. (3) The JOA score was increased from 8.5 before surgery up to 16 on final follow-up in the cases of myelopathy with 86% average improvement rate. All symptoms disappeared in the cases of radiculopathy. 15 patients were in excellent result, 7 in good and 4 in fair according to Odom’s grade.

Conclusion: The adjacent segment degenerative process
was not aggravated after Bryan disc replacement. This technology has offered an excellent clinical outcome for the treatment of cervical disc disorders. Radiographic evidence supports the effect of motion preservation of the target segment.

29. Clinical Outcome and Radiological Analysis Following TCDR with ProDisc C at the 24 Months Follow-Up

C. Mehren1, F. Mackel1, F. Grochulla1, A. Korge1, M. Mayer1

1Orthozentrum München, SpineCenter, München, Germany

Introduction: Dynamic reconstruction of a degenerative “functional spinal unit” is a rapidly growing field in spinal surgery. Due to the implantation of a total disc prosthesis the concerned segment should be kept mobile to decrease the load for the adjacent levels. Aim of the study is to prove the function of the implanted prosthesis and the registration of radiological changes after total cervical disc replacement.

Methods: This clinical/radiological study was enrolled in one center (Munich) as part of a prospective European multi-center study with ProDisc C. The X-Rays (active flexion and extension preoperatively 3,6,12 and 24 months after surgery) of 45 patients (in total 66 implanted prosthesis) were analysed 24 months after TCDR with a ProDisc C prosthesis (Spine Solution, Tuttlingen). The measurement to determine the ROM of the implanted prosthesis was done electronically with MedImage V5.0 (Vepro AG, Pfungstadt, Germany). We classified the heterotopic ossifications (HO) in 5 grades. For clinical parameters the Visual Analog Scale (VAS) and the Neck Disability Index (NDI) were evaluated preop and 1 year postoperative. Findings: The clinical parameters improved significantly. The NDI improved in average from preoperatively 20.5 points out of 50 to 9.5 points. In the VAS the patients improved from 6.3 (VAS arm) and 6.3 (VAS neck) to 1.6 resp. 1.8 two years postoperatively in average.

The preoperative ROM of the treated segment was in average 8.4 degrees. It increased in the 2 years control up to 9.7 degrees in average, excluded the 5 cases of solid fusion due to heterotopic ossification (included 8.7 degrees in average). 24.2% (n=16) of the treated segments didn’t show any signs of HO. Grade I HO appeared in 15.2% (n=10), Grade II in 33.3% (n=22) and Grade III in 19.7% (n=13).

Discussion: In most cases we could prove a satisfactory maintained mobility of the treated segment. The clinical parameters improved significantly. The rate of high-grade heterotopic ossifications makes us expect an high fusion rate in the future.

So far the TCDR fulfill the requirements as expected, but the rate of spontaneous fusions will decide the fate of total cervical disc replacement. A very important issue is to develop strategies to avoid the origin of HO.

30. Validation of ISO Total Disc Wear Testing Using Retrieved Metal-on-Metal Cervical Disc Replacements

R. Siskey1, S. Kurtz1, P. Shah1, L. Ciccarelli1, M. Harper2, F. Chan2

1Exponent, Philadelphia, PA, United States of America, 2Medtronic Spinal and Biologics, Memphis, TN, United States of America

The short-term in vivo wear performance of metal-on-metal cervical total disc replacements (TDRs) has been characterized. However, it remains unknown how many cycles of in vitro wear testing correspond to the duration of implants in vivo. The Prestige® cervical TDR (Medtronic, Memphis, TN) consists of a superior ball articulating against an inferior trough. Previous wear tests employed a custom test sequence producing similar wear mechanisms as retrievals, however the abrasion was more severe than what was observed in vivo. Because our current retrieval collection consists of all short-term retrievals, a study to characterize the short-term wear response within the first 1.0 MCycles was conducted. The objective of this study was to test the hypothesis that wear patterns and surface morphology produced by an in vitro test protocol replicate those exhibited by retrievals.

Three 316L stainless steel TDRs (Prestige® ST) were tested at 2.0Hz on a six-degree-of-freedom MTS Spine Wear Simulator (MTS, Eden Prairie, MN) in accordance with the cervical loading and motion profiles prescribed by ISO/FDIS 18192. To evaluate the short-term in vitro wear behavior, the simulator was stopped after 0.05, 0.1, 0.2, 0.3, 0.4, 0.5 and 1.0 MCycles and interval analyses performed. These analyses consisted of photogrammetry and white light interferometry. The results from each interval analysis were compared to a Prestige® ST retrieval collection analyzed from nine patients ranging from 0.7 to 3.3 years in vivo.

After 0.1 MCycles all components exhibited a faint wear scar, produced by abrasive wear. This wear mechanism was consistent with short-term explants. The average surface roughness of the worn regions for both the retrievals and in vitro tested components was measured to be 0.12 ± 0.08µm and 0.16 ± 0.07µm, respectively. Furthermore, the photogrammetry data showed that the average percentage of total worn area for both the retrievals and in vitro tested components was 46.8 ± 21.3% and 65.4 ± 15.7%, respectively. The surface roughness and worn area percentages were compared using an ANOVA (JMP, SAS, Cary, NC) and found not significantly different (p=0.69 and p=0.21, respectively).

The results of this study suggest that the ISO/FDIS 18192 standard test method replicates the short-term in vivo wear patterns in TDRs within the first MCycles of testing. The same mechanism of abrasive wear is occurring at the
bearing surface of both the retrievals and wear-tested components, although the greater worn surface area in the wear-tested components may indicate that the ranges of motion are more extensive than those experienced by TDRs in vivo. Overall, the study suggests that shorter-term test durations may generate surface morphology consistent with short-term in situ wear. Previous studies have suggested that a patient may undergo as few as 100,000 cervical loading cycles per year. Similarly, comparing the ISO simulator testing to the collection of short-term retrievals, one can begin to see similar wear patterns as early as 100,000 to 200,000 cycles of wear testing for this ball-in-trough articulation.


Session IV - Basic Problems and Provocative Solutions

31. The Reliability of CT and MRI Grading of Lumbar Facet Arthropathy in TDR Patients

J. Bendo¹, M. Quirno¹, M. Cunningham¹, J. Spivak¹, J. Stieber¹
¹NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States of America

Introduction: With the advent of motion preservation technologies for treatment of lumbar spine disorders, new interest has arisen in evaluation of the lumbar facet joints and their degree of arthropathy. Devices have been introduced including mechanical total disc replacements, nuclear replacements, and non-fusion posterior stabilization systems, with the success of all considerably dependent upon the degree of facet joint disease. Both Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) are commonly utilized to evaluate facet arthropathy, and grading systems have been devised for both imaging modalities. This study compares the interrater and intrarater reliability of MRI and CT for grading of facet arthropathy among spine surgeons in a clinical setting as well as the interrater and intrarater reliability of MRI and CT for grading of facet arthropathy as a contraindication to Total Disc Replacement (TDR).

Method: Ten fellowship-trained orthopaedic spine surgeons and three orthopaedic spine fellows concurrently evaluated 50 spinal levels from L3-4 through L5-S1 on parallel axial MRI (T1 and T2) and CT images. The degree of osteoarthritis was graded on the same four-point scale (Fujiwara (MRI) :Pathria (CT)) according to previously published criteria for grading of facet joint osteoarthritis on CT, and adapted and validated for MRI. Surgeons also were asked to evaluate whether the degree of facet disease represented a contraindication to treatment at that level with a mechanical disc replacement given no other contraindications. Images were obtained from the files of surgical patients and were of representative quality used in an academic clinical practice for surgical decision-making. Grading was repeated during an identical second session 3 weeks later. Weighted kappa statistics were used to describe interobserver and intraobserver agreement.

Results: The inter-observer reliability for MRI was 0.21 and 0.07 (fair to slight agreement) among attending surgeons and fellows, respectively. Inter-observer reliability for CT was 0.33 and 0.27 (fair agreement), respectively. The mean intraobserver reliability for MRI was fair, 0.36 (attendings) and 0.26 (fellows). The mean intraobserver reliability for CT was moderate, 0.52 (attendings) and 0.51 (fellows). After looking at the facets as a possible TDR contraindication, the inter-observer reliability for MRI was 0.22 and 0.01 (fair to slight agreement) among attending surgeons and fellows, respectively. Inter-observer reliability for CT was 0.33 and 0.45 (fair agreement), respectively. The mean intraobserver reliability for MRI was fair, 0.36 (attendings) and 0.26 (fellows). The mean intraobserver reliability for CT was moderate, 0.52 (attendings) and 0.51 (fellows).

Conclusions: The existing grading system for facet arthropathy has only fair agreement. CT is slightly more reliable for grading lumbar facet arthropathy. Intraobserver reliability was only fair for MRI and moderate when employing CT. When evaluating potential surgical levels on cross-sectional imaging, only limited agreement existed between surgeons as to the extent of facet disease that would pose a contraindication to treatment with lumbar total disc replacement.

32. Incidence of Dysphagia Comparing Cervical Arthroplasty and ACDF with Internal Fixation

M. Janssen¹, J. Datta², B. Darden³, A. Rhyne³, F. Siddiqui³, R. Beckham¹, C. Ponce¹, S. Odum³
¹Spine Education and Research Institute, Denver, CO, United States of America, ²Sonoran Spine Center, Mesa, AZ, United States of America, ³OrthoCarolina, Charlotte, NC, United States of America

Introduction: Dysphagia after anterior cervical discectomy and fusion with plating is a well known complication. It appears that approximately 80% of these patients have resolution of their symptoms at 12 months leaving 12.5-20% with persistent dysphagic symptoms. These symptoms include difficulty swallowing and dysphonia. The etiology of this complication is unknown in a majority of patients. Vocal fold paresis is only identified in 1.3% of patients and adhesions to the plate or just irritation of the soft tissues of the anterior neck are felt to contribute to dysphagia. When dysphagia is severe enough plate removal and adhesion lysis can be attempted if the vocal folds appear to be functioning appropriately. Reports show improvement of symptoms to little or none in 87% of patients treated in this manner. There has been concern that the rates of dysphagia may be higher with arthroplasty procedures because of the amount soft tissue mobilization to place the prosthesis in
33. The Loss of Water Content within the Intervertebral Disc through an Accumulation of Advanced Glycated Endproducts

A. Sharan¹, S. Tang², D. Vashishth²

¹Montefiore Medical Center/Albert Einstein College of Medicine, Orthopaedic Surgery, Bronx, NY, United States of America, ²Rensselaer Polytechnic Institute, Biomedical Engineering, Troy, NY, United States of America

**Introduction:** Advanced glycated endproducts (AGEs) are compounds that form through a nonenzymatic interaction between collagen and glucose. The accumulation of AGEs within the extracellular matrix has been implicated in the degeneration of cartilage and other soft tissue structures. The effect of AGEs on the intervertebral disc has not been well characterized. It is hypothesized that the accumulation of AGEs within the nucleus pulposus (NP) competitively inhibits the binding of water to the proteoglycans within the intervertebral disc (IVD) and thus leads to an accelerated dehydrated state.

**Materials and methods:** Twenty lumbar and thoracic intervertebral discs were removed from two sheep spines. 40 strips of dog-bone shaped tissue samples approximating 10mm x 5mm x 1mm were taken from the nucleus pulposus (NP) and from the annulus fibrosis (AP). Using a previously established in vitro ribosylation procedure, the tissues were grouped by disc location to undergo a 0, 2, 4, 6, 8 day incubation period in a ribose-rich solution. The samples were then stored in PBS with enzymatic inhibitors. After the incubation process, the tissues were mounted and tested in tension under stress relaxation using an Enduratec ELF 3200 desktop system. An instantaneous 10% strain was applied to the tissues, and the tissues were allowed to relax over a 120 second period. The tissues were first massed under hydrated conditions, and then massed again after a 48-hour desiccation period at 50°C to determine the percentage water content. The tissues were subsequently digested in 6N HCl at 60°C for 24 hours, and the extent of autofluorescence of the hydrolysates were determined at 370nm excitation and 440nm emission. Collagen content was quantified from the lysates using a colormetric assay. The AGEs measure was then normalized by collagen content of the tissues. One-way ANOVA was used to determine the effects of incubation period due to NEG on water content, AGEs accumulation as indicated by tissue-fluorescence, and mechanical behavior of the tissues. Multiple regression analyses were used to determine relationships between AGEs and water content; and between AGEs and mechanical behavior.

**Results:** Fluorescence per collagen increased significantly in a dose-dependent manner with incubation time in both the AF (p<0.001) and NP (p<0.001) tissues. In addition, water content in both tissue types decreased significantly with incubation time in both the AF (p<0.001) and NP (p<0.001) tissues. Regression analyses show a significant inverse relationship between decreasing water content and increasing AGEs; furthermore, the decrease in water content in the NP tissue is more susceptible to increases in AGEs than in AF tissues.

**Discussion:** In this study an increase in AGE was correlated with a loss of water content within both the NP and AF. This effect was noted to have a stronger correlation within the nucleus pulposus than the annulus fibrous. This study suggests that the accumulation of AGEs may competitively inhibit the binding of proteoglycans to water and thus result in an accelerated dehydrated state within the IVD. Future strategies to regenerate the IVD through rehydration may require consideration of compounds that can breakdown these AGEs.

34. Analysis of Postoperative Pain Patterns Following Total Lumbar Disc Replacement

C. Siepe¹, F. Grochulla¹, A. Korge¹, H.M. Mayer¹

¹OrthoCenter Munich, Spine Center, Munich, Germany

**Introduction:** Although a variety of biomechanical laboratory investigations and radiological studies have highlighted potential problems associated with total lumbar disc
replacement (TDR), no previous study has performed a clinical failure analysis and systematically investigated postoperative pain patterns. The objectives of this study were therefore to perform a failure analysis following TDR, identify postoperative pain sources, establish the incidence of postoperative pain patterns and investigate the effect on clinical outcome.

**Methods:** The study design is an analysis of postoperative pain patterns following total lumbar disc replacement with ProDisc II. The results from fluoroscopically guided spine infiltrations were correlated with the postoperative outcome from patients of an ongoing prospective study. Patients that reported unsatisfactory results at any one of the FU-examinations received fluoroscopically guided spine infiltrations as part of an intensified diagnostic and conservative treatment program. Pain sources were identified in patients with a reproducible (≥ 2x) significant (50%-75%) or highly significant (75%-100%) pain relief upon the infiltrations. Results were correlated with outcome parameters Visual-Analogue-Scale (VAS), Oswestry-Disability-Index (ODI) and the subjective patient satisfaction rates.

**Results:** 175 patients were included with a mean FU of 29,3 months (range 12,2-74,9 months). N=342 infiltrations were performed in n=58 patients (33,1%) overall. Facet joint pain, predominantly at the index level (86,4%), was identified in n=22 patients (12,6%). The sacroiliac joint was a similarly frequent cause (86,4%), was identified in n=22 patients (12,6%). The sacroiliac joint was a similarly frequent cause (75%-100%) pain relief upon the infiltrations. Results were correlated with outcome parameters Visual-Analogue-Scale (VAS), Oswestry-Disability-Index (ODI) and the subjective patient satisfaction rates.

**Conclusion:** Reported problems associated with TDR include postoperative hyperlordosis with subluxation of the facet joints, increased segmental (rotational) instability, up to 2,5x increased load on posterior structures and abnormal stress distribution patterns with sudden rather than gradual load increase. All of these factors could potentially impair postoperative outcome. In contrast to lumbar fusion procedures, however, no previous clinical study has performed a systematic failure analysis following TDR. As the results from this study show, pain from the lumbar facet- and sacroiliac joints are a frequent and currently underestimated source of postoperative pain and the most common reason for unsatisfactory results following TDR. In the light of rapidly increasing market volumes of TDR worldwide further failure-analysis studies are required and adequate salvage treatment options need to be established with respect to the underlying pathology of postoperative pain.

Future studies will have to investigate if TDR compromises the index-segment in an attempt to avoid adjacent segment degeneration. Whether TDR will reduce the incidence of posterior joint pain, previously attributed to lumbar fusion procedures, remains unknown.

### 35. A Finite Element Study to Evaluate the Biomechanical Effects of the Artificial Disc Components’ Shape on the Cervical Spine

**A. Faizan**1, **V. Goel**1, **A. Biyani**2, **S. Garfin**3, **C. Bono**4, **P. Maguire**3, **H. Serhan**4

1University of Toledo, Bioengineering, Toledo, OH, United States of America, 2University of Toledo, Orthopedics, Toledo, OH, United States of America, 3University of California, San Diego, Orthopedics, San Diego, CA, United States of America, 4Boston Medical Center, Orthopedics, Boston, MA, United States of America, 5Depuy Spine, Raynham, MA, United States of America

**Introduction:** The articulation between the ball and socket components of the artificial disc may use a hemispherical ball rolling over a curved surface. Other variations of the spherical design, such as an oval shape, are also feasible. The main purpose of the present study is to understand the biomechanics of the cervical spine following implantation of two different B&S type artificial discs. These discs use hemispherical and oval shaped ball components rolling over curved surfaces of socket components.

**Methods:** An experimentally validated, three dimensional, ligamentous, finite element (FE) model of C3 -C7 cervical spine segments was modified to create four different models to accommodate the TDR in various configurations. In the first model an oval shaped ball component rolls over the inferior socket component (OSB), while in the second model, the ball and socket components were switched, so the socket component rolls over the inferior oval ball component (OBB). Corresponding models were also created with a hemispherical ball type disc. These models had a spherical socket at the bottom (SSB) or a spherical ball at the bottom (SBB). The artificial disc implants were placed at the C5-C6 level following the removal of the anterior longitudinal ligaments, the nucleus and part of the annulus. All of the models were loaded with 75N of follower load using a set of springs. Once activated, these springs applied a constant load of 75N throughout the simulation. A moment of 1.5 Nm was also applied to simulate physiologically relevant flexion and extension motions.

**Results:** The extension motion at the implanted C5-C6 level for SSB, SBB, OSB and OBB models were 15.2, 12.1, 14.7, 15.8 degrees, respectively as compared to 8.0 degrees in the intact spine. The corresponding flexion motions were 6.9, 7.2, 5.5, 8.5 degrees as compared to 6.4 degrees in the intact spine. With all four types of implants, the motions at the adjacent levels were close to the corresponding intact motion values.

Facet loads on the C5-C6 left facet for intact, SSB, SBB, OSB and OBB models were 54N, 62N, 88N, 70N and 67N,
ORAL ABSTRACT SESSIONS

respectively. The corresponding facet loads on the C5-C6 right facets were 41N, 94N, 106N, 112N and 125N, respectively.

Discussion: The biomechanical response of the cervical spine varies with variations in the shapes and configurations of B&I type implant. Out of the four configurations studied, the design with a spherical ball at the bottom (SBB) yielded motion closer to the intact spine. Nevertheless, as compared to intact, a 50% increase in extension motion and a 13% increase in flexion motion at the implanted level were observed for this design as well. For the other designs, corresponding increase in extension motion ranged from 85%-95% and the increase in flexion motion ranged from 10%-35% at the implanted level. The designs of ball and socket components and their placements are relevant variables that may affect the above results. We are studying the effects of these variables.

36. Does Placement of the Axis of Rotation of the Cervical Spine Affect Motion Segment Mechanics During Flexion and Extension? D. DiAngelo1, H. Bonin¹, B. Kelly1

¹The University Of Tennessee Health Science Center, Department of Biomedical Engineering and Imaging, Memphis, TN, United States of America

Objective: Different paradigms exist in the design of nucleus or disc arthroplasty devices that may constrain motion to pure rotation, as in a ball and socket device, or may use a less constrained mobile or compliant design in an attempt to emulate the coupled (translation and rotation) movements of the healthy human spine. Motion segment unit (MSU) mechanics may also be sensitive to not only anterior-posterior (A-P) device placement but also cephalad-caudal location of the center of rotation (CoR) inherent with a device design. The objective of this research was to investigate the effects of placement of the CoR of the cervical spine on segmental mechanics. The null hypothesis tested was forcing a fixed CoR on subaxial cervical spinal motion segments that did not coincide with the motion segment’s real CoR would not expose the tissue to unnatural (unphysiological) excessive loads throughout normal flexion or extension movement.

Methods: Six fresh human cadaveric cervical MSUs were procured and mounted in a custom designed spine robot. The spine robot was programmed to rotate the specimen about selected points of rotation: three upper points located along the plane of the disc in the A-P direction at 1) the mid-point of the disc (C1), 2) half way between the mid-point and anterior aspect of the disc (A1), 3) and half way between the mid-point and posterior aspect of the disc (P1). The three remaining lower points were located 4mm below the upper points (A2,C2,P2) in the subjacent body. The MSUs were rotated about the six designated points until a target moment of 3.0Nm of flexion or extension was reached or stopped if the shear or compressive forces exceeded 250N. For all test conditions, the MSU tension/compression and A-P shear forces across the MSU, and sagittal bending moment were measured and compared using a one-way ANOVA (P=0.05).

Results: At common end limits of applied load (+/-2.5Nm) significantly more motion occurred in flexion than extension at all fixed points of rotation. Significantly more flexion occurred at the midpoints and more extension at the posterior points. Further in both flexion and extension, significantly more motion occurred at the mid-points compared to the anterior or posterior points and at the posterior points compared to the anterior points.

Conclusion: A new testing protocol was developed that prescribed a given motion pattern to cervical spine motion segment units and measured the load response to accommodate the motion. Flexion about a posterior point was limited by excessive compression of the anterior aspect of the intervertebral disc, whereas flexion about an anterior point was limited by tension in the posterior ligaments. Extension about midline and anterior points resulted in excessive compression across the facets. These findings suggest that the rotational axis of the cervical spine varies between flexion and extension. In this study the facets remained active throughout the movement and contributed to the loading response. If a spinal device was designed to eliminate or minimize facet involvement, the loading mechanics would likely differ from our findings.

37. Cervical Hybrid Constructs: A Reliable and Effective Option in the Treatment of Multilevel Degenerative Disc Disease

G. Barbagallo1, R. Assietti2, L. Corbino1, G. Olindo1, N. Platania1, P. Foti1, V. Russo1, V. Albanese1

1Policlinico University Hospital, Department of Neurosurgery, Catania, Italy, 2Fatebenefratelli and Ophthalmic Hospital, Department of Neurosurgery, Milan, Italy

Purpose: To analyse the clinical and radiological results of a prospective, multicentre, study, with 7 to 35 months follow-up, on the safety and effectiveness of an hybrid technique combining arthroplasty and arthrodesis during the same surgical procedure in the treatment of symptomatic, multilevel degenerative disc disease (DDD).

Materials and methods: Between November 2004 and March 2007 24 patients (15 males), mean age 46.7 years, affected by neck pain and myeloradiculopathy secondary to multilevel DDD, either soft disc hernia or spondylosis, with different stages of degeneration per each level, underwent a single-stage combination of intervertebral cages and artificial discs.

SF-36 and Neck Disability Index (NDI) questionnaires and radiographs, with flexion and extension views, CT and MR scans were performed before and after surgery for clinical and radiological evaluation.

CFRP and Cornerstone CFC cages were used for ACDF and either ProDisc-C, Prestige LP or Bryan disc for arthroplasty. Treated disc levels were C3-C7. Fifteen patients underwent a two-level procedure, seven patients a three-level and two a four-level implant, respectively.
Prestige LP prostheses were used in two patients, Prodisc-C in 17 cases and Bryan discs in 5. A total of 59 devices (19 Prodisc-C, 3 Prestige LP, 5 Bryan, 27 CFRP cages and 5 Cornerstone cages) have been used. The TDR/fusion ratio at different disc levels is as follows: C3-C4: 4/4; C4/C5: 10/2; C5/C6: 11/12; C6/C7: 2/14. Rationale for choosing arthroplasty or ACDF is based on an algorithm, developed to decide which technique is most suitable at each level. Type and degree of DDD per segment, segmental range of motion (ROM), residual ROM evaluated by intra-operative fluoroscopy after neural decompression, presence of adjacent degenerated levels not operated and degree of uncoarthrosis were analysed.

 Patients were assessed at 1, 3, 6, 12, 18, 24 months and at regular intervals after surgery using the same parameters. A radiologist, blinded to the clinical outcome, independently analysed imaging studies to assess either ROM or changes in the sagittal alignment, particularly with regard to lordosis, or presence of heterotopic ossification.

 Results: Mean NDI score decreased from 31.5% to 13.3% after surgery. Mean preoperative SF-36 (PCS and MCS) values were, respectively, 38.7% and 48.2%; postoperative values changed to 53.2% and 56%, respectively. All scores are statistically significant (p < 0.05). Follow-up flexion-extension x-rays demonstrated a 3° to 18° ROM. In all cases fusion was shown through cages; McAfee grade 2 ossification was found in two patients. No complications related to the devices (dislocations, subsidence, loosening) or to the technique were registered. None of the patients required surgery for persisting or recurrent symptoms.

 Conclusions: This is the study on cervical hybrid constructs with the longest available follow-up in Italy. The proposed hybrid, single-stage, fusion-non fusion technique (HSSFNFT) is a safe, reliable and effective surgical strategy. It can relieve symptoms and preserve segmental motion, while achieving fusion in severely degenerated levels, preventing raised stress on adjacent segments, a recognised possible cause of further degeneration, and avoiding iatrogenic instability or painful conditions secondary to induced mobilization of markedly degenerated segments.
Session I - Lumbar TDR

38. F.D.A. I.D.E. Prospective Randomized Comparison of Three Lumbar Artificial Disc Replacements (A.D.R.) with Minimum Two-year Follow-Up

**K. Pettine¹, E. Donner¹**

¹Rocky Mountain Spine Arthroplasty Specialists, Loveland, CO, United States of America

**Purpose:** To establish safety, efficacy, and possible clinical superiority between the Maverick™ (M), Charité™ (C), and Kineflex™ (K) A.D.R.’s.

**Method:** Three A.D.R.’s performed by two surgeons at one I.D.E. site were compared in a prospective randomized minimum two-year follow up. All of the A.D.R.’s were one level at L4-L5 or L5-S1. There were 25 Maverick, 31 Charité, and 35 Kineflex patients. Average age was 42.5 in each group. B.M.I. averaged 25. The majority of A.D.R.’s were performed at L5-S1 vs. L4-L5 (M) 19 to 6, (C) 19 to 12 and (K) 28 to 7. Inclusion/exclusion criteria will be discussed. All results are based on audited F.D.A. I.D.E. study forms.

**Results:** O.R. time was similar (M) 99 min. (C) 84 min. (K) 84 min. Blood loss averaged 30 cc. Hospital stay averaged 24 hours. Re-operations included: (M) 1 infection (eighteen months post ADR), (C) 3 implant complications (all within eight weeks ADR), (K) 1 implant complication (one day post ADR). These cases will be presented.

ODI results for all groups: Pre-op = (M) 57.6, (C) 63.8, and (K) 61.1; One-year post-op = (M) 16.3, (C) 27.3, and (K) 20.4; Two-year post-op = (M) 14.6 (p<0.001), (C) 20.5 (p<0.001), and (K) 19.3 (p<0.001)

VAS results for all groups: Pre-op = (M) 74.1, (C) 85, (K) 83.9; One year post-op = (M) 27.9, (C) 31.4, and (K) 27.3; Two-year post-op = (M) 20.5 (p<0.001), (C) 33.8 (p<0.001), and (K) 26.9 (p<0.001)

All A.D.R. had statistically significant improvement from pre-op to two-year follow-up on ODI and VAS. F.D.A. clinical success was met in (M) 90%, (C) 83.5%, and (K) 90.5% of patients. Patients basically “pain free” (VAS less than 2) (M) 68%, (C) 29%, (K) 47%. Patients with basically “normal” function (ODI less than 10) occurred in (M) 67% (C) 33%, (K) 52%.

Patient satisfaction with their A.D.R. at two-year follow up was (M) 96%, (C) 84%, and (K) 91%.

The clinical results of Maverick were statistically superior to Charité and Kineflex in terms of ODI improvement (p<0.05) and the Charite in VAS (p<0.05) improvement.

**Conclusions:** All three A.D.R.’s demonstrated safety with a trend to more device related complications with (C) 3 compared to (M) 1 and (K) 1. They all showed efficacy with a statistically significant improvement in ODI and VAS at two year follow-up (p<0.001). F.D.A. clinical success was (M) 90%, (C) 83.8%, (K) 90.5%.

The Maverick demonstrated statistical superiority in ODI measurements compared to the Charité and Kineflex and VAS compared to Charite.

39. Results of the Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc®-L Total Disc Replacement versus Circumferential Fusion for the Treatment of 2-Level Degenerative Disc Disease

**R. Delamarter¹, J. Zigler², R. Balderston³, J. Spivak⁴, R. Linovitz², J. Zucherman⁵, J. Yue⁶, T. Haider⁶, S. Kitchel⁷, F. Cammisa⁸, G.O. Danielson⁹, D. Geiger¹², J.E. Sherman¹³, R. Watkins¹⁴, H. Yuan¹⁵, H. Herkowitz¹⁶**

¹The Spine Institute at St John’s Health Center, Santa Monica, CA, United States of America, ²Texas Back Institute/Texas Health Research Institute, Plano, TX, United States of America, ³Pennsylvania Hospital, Philadelphia, PA, United States of America, ⁴NYU/Hospital for Joint Diseases, New York, NY, United States of America, ⁵CORE Orthopaedic Medical Center, Encinitas, CA, United States of America, ⁶St Mary’s Spine Center, San Francisco, CA, United States of America, ⁷Yale Physicians Bldg, New Haven, CT, United States of America, ⁸Haider Spine Center Medical Clinic, Inc, Riverside, CA, United States of America, ⁹Orthopedic Spine Associates, LLC, Eugene, OR, United States of America, ¹⁰Hospital for Special Surgery, New York, NY, United States of America, ¹¹Texas Spine and Joint Hospital, Tyler, TX, United States of America, ¹²Michigan Brain & Spine Institute PC/Michigan Orthopaedic Center, Ypsilanti, MI, United States of America, ¹³Twin Cities Orthopedics, Edina, MN, United States of America, ¹⁴LA Spine Surgery Institute, Los Angeles, CA, United States of America, ¹⁵SUNY Syracuse, Syracuse, NY, United States of America, ¹⁶William Beaumont Hospital, Royal Oak, IL, United States of America

**Study Design:** A prospective, randomized, multicenter, Food and Drug Administration-regulated Investigational Device Exemption (IDE) clinical trial.

**Objective:** To evaluate the safety and effectiveness of the ProDisc®-L (Synthes Spine Company, L.P., West Chester, PA) lumbar total disc replacement (TDR) compared to circumferential spinal fusion for the treatment of discogenic pain at two vertebral levels between L3-S1.

**Methods:** Two hundred thirty-seven (237) patients were treated on protocol, randomized in a 2:1 ratio (ProDisc®-L: fusion). Patients were evaluated pre-operatively and post-operatively, at 6 weeks, 3, 6, 12, 18, and 24 months. Evaluation at each visit included patient self-assessments, physical and neurological examinations, and radiographic evaluation.

**Results:** Overall patient demographics showed no statistically significant differences between treatment groups in age, gender, race, smoking status, height, weight, body mass index (BMI), baseline Oswestry Low Back Pain Disability Questionnaire (Oswestry Disability Index (ODI)).
or prior surgical treatment. Intra-operative/peri-operative data showed the investigational group was significantly lower, both statistically and clinically relevant, with regard to intra-operative time, estimated blood loss, and hospital stay (p = 0.0001, p = 0.0006, p < 0.0001, respectively). At 24 months, 90.0% of investigational and 86.7% of control patients reported improvement in ODI from pre-operative levels and 73.3% of investigational and 55.9% of control patients met the > 15 point ODI improvement criteria. Overall neurological success in the investigational group was superior to the control group (89.2% - investigational, 77.9% - control; p = 0.0260). At all follow-up time points, the ProDisc®-L patients recorded SF-36 scores significantly higher than the control group (p = 0.0523). The visual analog scale (VAS) pain assessment showed statistically significant improvement from pre-operative scores regardless of treatment (p < 0.0001). At 24 months, the investigational group showed significantly higher pain reduction than the control group (p = 0.0466). VAS patient satisfaction at 24 months showed a statistically significant difference favoring investigational patients over the control group (p = 0.002). Radiographic range of motion was maintained within a normal functional range.

Conclusions: ProDisc®-L has been found to be effective for the treatment of discogenic pain at two vertebral levels. In properly chosen patients, ProDisc®-L has been shown to be superior to circumferential fusion at two levels by multiple clinical criteria.

40. Interaction between Finite Helical Axes and Facet Joint Forces under Combined Loading

H. Wilke1, H. Schmidt1, F. Heuer1

1University of Ulm, Institute of Orthopaedic Research and Biomechanics, Ulm, Germany

Finite helical axes (FHA) in a functional spinal unit can indicate mechanical disorders and are relevant for the development of new arthroplasty techniques. The facet joints protect the intervertebral discs from excessive movements. The relationship between the FHAs and facet joint forces is not well understood, since previous studies have separated both, spinal motion and facet forces.

A finite element model of a lumbar spinal segment L4-5 was utilized to simulate axial compression load of 500 N together with moments starting from zero to 7.5 Nm in single anatomical main-planes. Load combinations of 7.5 Nm were generated by changing the load direction in steps of 15° between each pair of the three anatomical main-planes. For single axes loading, the FHAs were found to be in the center of the disc under small moments, independently from load directions. The facet joints were only slightly loaded. Higher moments increased the forces in facet joints up to 105 N in axial rotation, followed by extension (50 N) and lateral bending (36 N). Combined moments did not essentially increase the facet forces compared to the same moment applied in an anatomical main direction. High facet forces might have directed the FHAs to migrate posteriorly, especially for axial rotation. This situation resulted in FHAs outside the disc towards the compressed facet joint. Results of this study suggest that axial rotation alone tend to maximal facet forces. These high facet forces caused the FHA to migrate posteriorly, outside the disc. A previous study showed that axial rotation or axial rotation in combination with other load applications, especially with lateral bending or flexion generated the largest fiber and shear strains in the annulus fibrosus. This means that axial rotation alone or in combination with other directions can lead to the highest risk of injuries in a spinal segment. For clinical practice, this would mean that patients immediately after an operation as well as patients with pathological changes of facet joints should reduce or avoid these complex motions.

41. Prodisc-L Prosthesis Height: What Effect Does Increasing Height Have on Lumbar Spine Kinematics and Foraminal Size?

J. Gaffey1, A. Ghanayem1, M. Voronov2, R. Havey1, M. Sartori3, G. Carandang3, C. Abjomson4, A. Patwardhan1

1Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, United States of America, 2Loyola University Chicago, Stritch School of Medicine, Maywood, IL, United States of America, 3Edward Hines Jr. VA Hospital, Hines, IL, United States of America, 4Synthes Spine, West Chester, PA, United States of America

Purpose of the study: To evaluate the effect of lumbar artificial disc height on the kinematics of the implanted segment and the size of the neural foramina.

Methods: Seven fresh-frozen human lumbar spines (age: 54.4±11.4, L1-sacrum) were tested. The spines had no serious bone pathology or bridging osteophytes and had no previous spinal surgery. The spines were tested intact and after discectomy at L4-5 and sequential insertion of ProDisc-L implants of increasing heights. All available implant heights (10, 12, and 14mm) were tested. The specimens were tested in flexion (8Nm) and extension (-6Nm) with a 400N compressive follower preload. They were then tested in lateral bending (LB, ±6Nm) and axial rotation (AR, ±5Nm) without preload. An optoelectronic motion measurement system was used to measure the three-dimensional motion of each lumbar vertebra relative to the sacrum. Finely graded cylindrical probes were used to assess the smallest foraminal width at L4-L5 for the intact spine and after each implantation. Multiple comparisons were made with Bonferroni correction between specimens implanted with the 10mm and 12mm inserts, the 10mm and 14mm inserts, and the 12mm and 14mm inserts.

Results: With increasing implant height, the amount of flexion-extension (F-E) and LB motions significantly decreased compared to the ROM with the smallest height implant. In F-E using a 10mm Prodisc-L implant at L4-5, the
specimens averaged 9.2±1.9 degrees of motion compared to 7.7±2.0 degrees with a 12mm implant (p<0.05) and 5.8±2.4 degrees with a 14mm implant (p<0.05). The difference in F-E motion between the 12mm and 14mm implants was also significant (p<0.05). In lateral bending with a 10mm implant at L4-5, the specimens averaged 5.7±2.8 degrees of motion compared to 4.6±2.6 degrees with a 12mm implant (p<0.05) and 3.6±1.7 degrees with a 14mm implant (p<0.05). In axial rotation with a 10mm implant at L4-5, the specimens averaged 3.9±1.9 degrees of motion compared to 3.2±2.0 degrees with a 12mm implant (p<0.05) and 3.0±2.2 degrees with a 14mm implant (p>0.05). Foraminal width also significantly increased as the implant height increased. Foraminal width with a 10mm implant at L4-5 averaged 9.4±1.3mm, compared to 9.7±1.3mm with a 12mm implant (p<0.05) and 9.9±1.4mm with a 14mm implant (p<0.05).

Conclusions: Implanting a relatively larger prosthesis into the lumbar disc space adversely affected the range of motion (ROM) of the L4-L5 segment. Increasing implant height significantly decreased ROM in flexion-extension by up to 37±21%, in lateral bending by up to 33±18%, and in axial rotation by up to 29±28%. The increase in foraminal size, while significant, was only 4.6±3.2%. A possible explanation for the relatively small increase in the foraminal width with increasing implant height is that increasing implant height also increased segmental lordosis, thus minimizing the effects of disc space distraction. These results suggest that a smaller implant height should be used to optimize the ROM of the implanted segment. In addition, neuroforaminal decompression should be performed via direct decompression rather than distraction with a larger implant.

42. TDR Oxidative Properties Following Gamma Sterilization in Air and First-Generation Barrier Packaging
S. Kurtz1, D. MacDonald1, A. Ianuzzi2, A. Van Ooij2, J. Isaza3, R. Ross4
1Drexel University and Exponent, Inc, Philadelphia, PA, United States of America, 2University Hospital of Maastricht, Maastricht, Netherlands, 3Our Lady of the Lake Medical Center, Baton Rouge, LA, United States of America, 4Hope Hospital, Salford, United Kingdom

Introduction: The clinical significance of in vivo oxidation of polyethylene in the spine following gamma sterilization in an air or inert environment remains unclear. We previously conducted a pilot study of polyethylene oxidation in total disc replacement (TDR), finding significantly higher oxidation in the rim as opposed to the dome. The Charité TDR was sterilized in air prior to 1997, after which a first-generation, polymeric barrier package was used that was permeable to air. The Charité is currently produced by DePuy Spine (Raynham, MA), and the polyethylene is gamma sterilized in an impermeable metal foil-based package. This study’s aim was to extend our previous research to a larger collection of retrievals and to investigate the oxidation potential of the polyethylene in the context of the sterilization environment. Our main hypothesis was that the rim region would exhibit greater oxidation and oxidation potential than the dome.

Methods: We analyzed polyethylene oxidation, oxidation potential, and dome penetration of 40 Charité (SBIII) implants from 34 patients (74% female). The cores were implanted for 7.2 y (range: 1.8 - 16.1 y). 12/40 of the TDRs (30%) were gamma sterilized in air. 5/40 (13%) were identified as sterilized in a polymeric barrier packaging. The sterilization method was not traceable in 23/40 retrievals. The oxidation index was calculated in accordance with ASTM F2102. Sections were then exposed to NO for >16 hours to convert hydroperoxides to nitrates. Hydroperoxide content represents the oxidation potential for polyethylene in the long-term. The maximum oxidation and hydroperoxide indices at the rim and the dome were compared within the same core (paired t-test), as well as between the same regions in the controls (ANOVA with Dunnett’s Test).

Results: First-generation barrier packaging exhibited similar oxidation magnitudes as those that were gamma sterilized in air. The control TDRs had comparable levels of oxidation and oxidation potential at the rim and the dome. Moderate oxidation (OI > 1) was detected at the dome in 6/40 retrievals (ave dome OI: 0.64), and at the rim in 29/40 cases (ave rim OI: 2.9). The average dome hydroperoxide index was 0.36 while at the rim it was 0.57. Oxidation and hydroperoxide index was significantly higher at the rim, as compared with the dome of the cores (p < 0.0001).

Discussion: This is the first study to compare the in vivo oxidation and oxidation potential of polyethylene in TDRs following gamma sterilization in historical and first generation barrier packaging. Our data support our hypothesis that, for the two types of historical packaging methods employed by Link, oxidation and oxidation potential were significantly higher at the rim as opposed to the dome. Because variations were not apparent in the never-implanted controls, we can infer that the rim oxidation occurred in vivo. These findings are consistent with previous observations from acetabular components from total hip replacement, which showed elevated oxidation at the rim. Our findings have clinical significance in cases of chronic impingement, when the rim has to support repeated loading for the lifetime of the implant.

43. Polyethylene Particle Load in TDR and THR Retrieval Tissue Using Polarized Light Microscopy
S. Kurtz1, R. Baxter1, M. Steinbeck1, A. Ianuzzi2, A. van Ooij2, R. Ross4, J. Isaza5
1Drexel University, Philadelphia, PA, United States of America, 2Exponent Inc, Philadelphia, PA, United States of America, 3University Hospital of Maastricht, Maastricht, Netherlands, 4Hope Hospital, Salford, United Kingdom, 5Our Lady of the Lake Medical Center, Baton Rouge, LA, United States of America
**Introduction:** Advances in polymeric bearing surfaces have revolutionized total joint arthroplasty. However, material wear remains a major long-term concern. Particulate wear can cause foreign body reactions in periprosthetic tissue, which can activate the production of cytokines and contribute to osteolysis and loosening. The purpose of this study was to compare polyethylene (PE) wear particle load of periprosthetic tissue from total disc replacement (TDR) with results from total hip replacement (THR) at the time of revision surgeries.

**Methods:** Periprosthetic tissue samples were collected from eight patients during revision surgery of Charité disc prostheses. This device is currently produced by Depuy Spine (Raynham USA). TDR implants were revised after an average of 8.1y (range: 2.2-16.2y). One patient exhibited sacral osteolysis underneath the prosthesis. Tissue samples were collected from four THA revisions of uncemented PE hip components, whose average implantation time was 14.2y (range: 9.6-18.9y). The implants were revised for osteolysis, wear, and/or aseptic loosening. Tissue samples were fixed in formalin, dehydrated, and embedded in paraffin. Paraffin-embedded tissue samples were sectioned into 6 micron-thick slices, mounted onto glass slides, and stained with hematoxylin and eosin. Slides were imaged by brightfield and polarized light microscopy. PE particles have been shown to exhibit birefringence when viewed by polarized light microscopy [1]. PE in TDR changed in 1997, from gamma sterilization in air to gamma sterilization in a first-generation polymeric barrier package. Therefore, TDR tissue samples were separated into pre- and post-1998 groups.

Five images of each tissue were acquired at 40x objective magnification and scored from 0 to 3. A score of 0 was assigned to fields of view with no visible particles; 1 for small isolated groupings of particles (n<10); 2 for moderate particle load (10<n<100); 3 for elevated particle load (n>100). Image scores were summed for all five fields. Summed scores of polyethylene particle load were displayed as an average for tissue samples from Pre-1998 TDR (n=4), Post-1998 TDR (n=4), and Pre-1998 THR (n=4) implant cohorts.

**Results:** PE particles were present in all tissues, however PE particle load for pre-1998 TDR tissue was significantly greater as compared to post-1998 TDR components (Student’s t-test, t < 0.001). Periprosthetic tissue from historical TDR and THR exhibited elevated numbers of polyethylene particles; these long-term implant tissues exhibited similar numbers of micron-sized particles. Image analysis and implementation of scoring criteria were shown to be repeatable for multiple observers.

**Conclusions:** Our findings are the first to demonstrate a particle load comparison between TDR and THR periprosthetic tissue from historical and current implant cohorts. Polyethylene particle load for historical TDR implants was comparable to historical THR and statistically greater than the post-1998 gamma sterilized TDR components. Acknowledgements: Supported by NIH R01 AR47904, Depuy Spine, and Medtronic.

**References:**

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**44. Assessment of Motion Quality Following Lumbar Total Disc Arthroplasty and Lumbar Discectomy**

S. Park1, A. Fayyazi1, N. Ordway1, B. Fredrickson1, H. Yuan1
1 SUNY Upstate Medical University, Department of Orthopedic Surgery, Syracuse, NY, United States of America

**Introduction:** The maintenance of motion following lumbar total disc arthroplasty (TDA) has been well established and quantified. Unfortunately, there has so far been very little attention of the quality of this motion in the clinical setting. The kinematics of a spinal segment is quite complex, in addition to the intended motion, paradoxical and coupled motions do occur and can have adverse effects on the motion segment and the facet joint. Paradoxical motion is defined as a motion opposite of intended motion, whereas a coupled motion is defined as a motion in planes perpendicular to the intended motion. This study was designed to evaluate the quality of motion by measuring the paradoxical and coupled motions seen following lumbar TDA in comparison to lumbar discectomy.

**Methods:** Ten patients (14 levels, 6 males & 4 females, 47±7yrs) with lumbar disc degeneration at L2/3, L4/5 and/or L5/S1 that were treated with Prodisc™-L (Synthes, Inc.) TDA and eight patients (8 levels, 4 males & 4 females, 41±6 yrs) with lumbar disc herniation at either L4/5 or L5/S1 that were treated using lumbar microdiscectomy were followed postoperatively at 1 month, 1 year and 2 years. Standard surgical technique was followed and tantalum beads were placed into the vertebral bodies intraoperatively. At each post-operative follow-up, biplanar standing-neutral, flexion and extension radiographs were obtained and 3D segmental rotations were measured for each sagittal motion in both groups using the Radiostereometric Analysis (RSA). The coupled motions following each sagittal plane motion and the frequency of paradoxical motion were statistically analyzed over the follow-up period.

**Results:** The sagittal motions did not significantly change over the follow-up times in both groups. The flexion and overall sagittal ROM were measured at 1.8±3.3°, 3.5±2.4° in the TDA and 2.8±2.6°, 4.7±2.2° in the discectomy groups, respectively. The differences between the two groups were not significant. The extension ROM was significantly smaller in the TDA when compared to the discectomy group (-0.6±1.1° vs. -2.2±1.6°, p=0.004). There were no significant differences in coupled motions over the 2 year follow-up (Figure 1). TDA exhibited significantly higher rate of paradoxical motion when compared to the discectomy group (26.4% vs. 6.7%, p<0.001). In the TDA group, the rate of paradoxical motion at 1 month (40%) was significantly higher than at 1 year (21.1%, p=0.001) and at 2 years (25.0%, p=0.001). The presence of paradoxical motion was
45. 5-year Results of the Prospective, Randomized, Multicenter FDA IDE ProDisc®-L Trial


1The Spine Institute at Saint John’s Health Center, Santa Monica, CA, United States of America, 2Texas Back Institute/Texas Health Research Institute, Plano, TX, United States of America, 3NYU/Hospital for Joint Diseases, New York, NY, United States of America, 4CORE Orthopaedic Medical Center, Encinitas, CA, United States of America, 5Texas Spine and Joint Hospital, Tyler, TX, United States of America, 6Haider Spine Center Medical Clinic, Inc, Riverside, CA, United States of America, 7Hospital for Special Surgery, New York, NY, United States of America, 8St Mary’s Spine Center, San Francisco, CA, United States of America, 9Pennsylvania Hospital, Philadelphia, PA, United States of America, 10Orthopedic Spine Associates, LLC, Eugene, OR, United States of America, 11Semmes-Murphy Neurological and Spine Institute, Neuro, Memphis, TN, United States of America, 12LA Spine Surgery Institute, Los Angeles, CA, United States of America, 13Yale Physicians Bldg, New Haven, CT, United States of America, 14SUNY Syracuse, Syracuse, NY, United States of America, 15William Beaumont Hospital, Royal Oak, MI, United States of America, 16Michigan Brain & Spine Institute PC/Michigan Orthopaedic Center, Ypsilanti, MI, United States of America, 17New York University Medical Center/Hospital for Joint Diseases Spine Center, New York, NY, United States of America

Background: Previously, the IDE clinical trial results of lumbar total disc replacement with the ProDisc®-L were reported with 2 year follow-up. With continued follow-up of the same patient population, the primary objective of this study was to evaluate the safety and effectiveness of the ProDisc®-L (Synthes Spine, West Chester, PA) lumbar total disc replacement compared to spinal fusion surgery for the treatment of discogenic pain unresponsive to non-operative treatment at one vertebral level between L3 and S1 with 5 year follow-up.

Methods: Two hundred thirty-six patients had surgery at one of 17 investigational sites across the United States in the randomized portion of the trial. The randomization was weighted in a 2:1 ratio to receive either ProDisc®-L (investigational) or circumferential fusion (control). The clinical status of each patient was evaluated pre-operatively and post-operatively at 6 weeks, 3, 6, 12, 18, and 24 months. Evaluation at each visit included patient self-assessments, e.g., Oswestry Low Back Pain Disability Questionnaire (ODI), SF-36 Health Survey, Visual Analog Scale (VAS) for Pain and Satisfaction; physical and neurological examination, and radiographic evaluation.

Results: Patients in both groups improved significantly following surgery. Baseline preoperative ODI values were not different (investigational: 63.4±12.6, control: 62.7±10.3, p = 0.6125). At 24 months, ProDisc®-L patients trended toward significance (p = 0.0551) over control patients. At 24 months, the mean score in the investigational group was 34.5±24.8 points for an average improvement from baseline of 28.9 points (46.1%), and the mean score in the control group was 39.8±24.3 for an average improvement from baseline of 22.9 points (36.0%). Average improvement stayed consistent out to five years with no statistical difference in mean score between 24 to 60 months in either treatment group. The VAS pain assessment showed statistically significant improvement from pre-operative levels regardless of treatment (p < 0.0001). At 24 months, the scores trended toward a significant improvement in the investigational group compared to the control group (p = 0.08). At 60 months, VAS pain remained consistent to 24 month values showing no deterioration over time. At 24 months, there was a statistically significant difference in the VAS satisfaction score improvement in the ProDisc®-L patients (p = 0.015) and satisfaction remain constant out to 60 months. The radiographic range of motion outcome in which the normal range had to be maintained at the operative level was achieved by 93.7% of the ProDisc®-L patients.

Conclusions: This is the first reported five year IDE prospective, randomized, multi-center study following lumbar total disc replacement with the ProDisc®-L. The data shows that significant clinical improvement was achieved and maintained in the ProDisc®-L out to 5 years with no deterioration of outcomes from 2 year levels. These results support earlier reports in the literature that total disc replacement with the ProDisc®-L is a safe and effective surgical treatment of discogenic pain in patients who met the patient selection criteria.

46. Clinical Results of Two-Level Lumbar Arthroplasty vs. Combined Arthroplasty & Fusion (Hybrid Procedure)

M. Scott-Young1, C. Magno2, D. Nielsen2

1Bond University, Department of Health Sciences & Medicine, Gold Coast Queensland, Australia, 2Pacific Private Clinic, Southport, Australia

Objectives: The surgical treatment of multilevel lumbar
Degenerative disc disease (DDD) requires a precise diagnosis. The pathology at each spinal motion segment dictates what technology can be applied to that level. This paper compares two-level lumbar total disc replacement (2TDR) with a hybrid procedure, combining 2TDR with fusion (HYB).

**Methods:** A prospective case cohort study involving 227 patients with multilevel DDD, who underwent either a 2TDR or HYB with a minimum one year follow-up. 143 males and 84 females. 120 patients had a 2TDR and 107 had a HYB. The average age for the 2TDR group was 45.5yrs (range = 26-66yrs) and 51.0yrs for the HYB group (range = 32-69yrs). The mean follow-up was 38.0 months (range = 13mos-9.2yrs). The primary indications for 2TDR was proven 2 level discogenic back pain and failed conservative management. HYB is considered over 2TDR when the posterior structures contra-indicate 2TDR (facet arthritis, spondylolisthesis, previous laminectomy, and deformity). A precision diagnosis was obtained by the use of clinical history, MRI, electrophysiological studies, and discography. A standardised surgical technique was employed.

Clinical outcomes were measured using Visual Analogue Back and Leg (VAS), Oswestry Disability Index (ODI) questionnaire, Roland-Morris Disability questionnaire (RMDQ), and SF-36. Patients were assessed preoperatively and at 3, 6, and 12 months postoperatively; and annually thereafter.

**Results:** Mean follow-up was 37.8 months (range = 13mos-9.2yrs). Results at latest follow-up vs. baseline were compared. For the 2TDR group, the ODI score was reduced from 48.2 (14-90) at baseline to 17.0 (0-64) at follow-up (-64.7%). For the HYB group the ODI score was reduced from 47.5 (10-82) to 17.2 (0-71). At follow-up (-63.9%) the VAS back score decreased from 77.2 (17-100) to 23.4 (0-98) in the 2TDR group (-69.7%) and from 76.4 (0-100) to 20.8 (0-84) in the HYB group (-72.7%). The VAS leg score decreased from 52.4 (0-100) to 16.5 (0-9.8) in the 2TDR group (-68.6%) and from 60.8 (0-100) to 16.5 (0-98) in the HYB group (-72.9%). For the RMDQ score, there was a decrease from 16.5 (4-24) to 4.8 (0-22) in the 2TDR group (-71.2%), and a decrease of 16.8 (2-48) to 4.6 (0-22) in the HYB group (-72.5%). For the SF-36 scores, the PCS score increased from 27.5 (0-47) to 46.2 (16-66) in the 2TDR group (+40.5%) and from 29.2 (15-53) to 46.1 (24-63) in the HYB group (+36.8%). The MCS score increased from 34.6 (0-64) to 51.3 (16-65) in the 2TDR group (+32.5%), and from 41.2 (0-69) to 52.8 (10-65) in the HYB group (+22.0%).

**Conclusions:** The principle is to match the appropriate technology with a particular pathology at each individual motion segment. There is no statistical difference between the results, however, a larger proportion of hybrid patients received a greater than 75% improvement on VAS back, when compared to 2TDR. The clinical benefits of both procedures are supported by the data, with documented significant relief of pain and improvement in functional scores. The outcomes reflect a precision diagnosis, appropriate patient selection, and a standardised surgical technique.
segments with TDR may be the result of increased loading from greater joint mobility regardless of implant positioning. Anterior placement of the TDR resulted in a reduced area of high strain around the posterior edge of the device in flexion. This coincided with increased FCFs, suggesting that vertebral body loading in extension is reduced when the facets participate in resisting the load. Areas of high strain were also documented along the anterior edge of the TDR in flexion, suggesting that implant subsidence and anterior migration may be the result of activities that place the spine in flexion.

48. Prospective, Randomized, Multicenter FDA IDE Study of CHARITÉ Artificial Disc vs. Lumbar Fusion: Effect at 5-year Follow-up of Prior Discectomy on Clinical Outcomes Following Lumbar Arthroplasty

F. Geisler1, R. Banco2, S. Blumenthal2, R. Guyer3, P. McAfee4, R. Holt5, M. Majd6, J. Regan6

1Illinois Neuro-Spine Center, Aurora, IL, United States of America, 2Boston Spine Group, Boston, MA, United States of America, 3Texas Back Institute, Plano, TX, United States of America, 4Orthopaedics Associates, O’Dea Medical Arts Building, Suite 104, Towson, MD, United States of America, 5Spine Surgery PSC, Louisville, KY, United States of America, 6Spine Source, Beverly Hills, CA United States of America

Purpose: To evaluate the clinical outcomes at 5-year follow-up of lumbar arthroplasty and arthrodesis on patients with prior discectomy.

Methods: All patients included in the randomized controlled multicenter 5-year CHARITÉ IDE study were analyzed herein. Fusion and arthroplasty patients were further divided into 2 groups: Fusion patients with prior discectomy (FPD) vs. fusion patients without prior discectomy (FNPD), and arthroplasty patients with prior discectomy (APD) vs. arthroplasty patients without prior discectomy (ANPD). Demographic, surgical and clinical data were analyzed for both groups.

Results: In the 90-patient CHARITÉ cohort, 21 had prior discectomy. In the 43-patient BAK cohort, 6 had prior discectomy.

For the fusion groups, surgical outcomes indicated small non-statistical trends towards less surgical time (95.6±29.42min for PD vs. 112.0±49.50min for NPD, p=0.3010) and less blood loss (145.2±124.64cc for PD vs. 232.8±258.39 for NPD, p=0.2846) for the PD group. There were no differences in duration of hospitalization between both groups.

For the fusion groups, less surgical time (81.8±29.14min for FPD vs. 128.6±68.51min for FNPD, p=0.0539) but comparable blood loss was observed between FPD and FNPD groups. A trend towards longer hospitalization was observed in the FNPD group (3.5±0.55days for FPD vs. 4.4±1.88days for FNPD, p=0.1613).

Pain and disability were further analyzed for all groups. For the arthroplasty groups, changes in VAS scores were comparable with -36.5mm improvement for the PD group and -39.4mm improvement for the NPD group (p=0.7468). Changes in ODI indicated a small, non-statistical trend towards greater improvements in the NPD vs. the PD group (changes in ODI: -17.6 points for PD vs. -26.0 points for NPD, p=0.1677). This trend was not observed on SF-36 PCS scores, for which both groups averaged similar improvements (12.4 points for PD vs. 12.6 points for NPD, p=0.9705).

For the fusion groups, changes in VAS scores showed trends towards improved VAS scores in the FNPD group (-26.7 for FPD vs. -42.2 for FNPD, p=0.3499). A greater trend was also noted in ODI scores, where FPD group (change in ODI: -10.7) experienced far less improvement than the FNPD group (change in ODI: -30.2; p=0.0515). These differences were reflected as well in SF-36 PCS changes: FPD group showed a mean SF-36 PCS of 4.3 points whereas FNPD group showed a mean SF-36 PCS improvement of 13.6 (p=0.1188).

Conclusions: All CHARITÉ patient groups, with or without prior discectomy, experienced significant clinical improvements from preoperative to the 5-year postoperative time point, as seen in VAS, ODI and SF-36 changes. However, BAK patients with prior discectomy showed trends towards reduced clinical outcomes. This analysis provides evidence that the CHARITÉ can be utilized after a prior discectomy with similar results as expected from patient without prior discectomy.

49. Medico-economical Evaluation of Total Disc Replacement Based on French National Health Care (Sécurité Sociale) Data’s

N. Bronsard1, I. Hovorka1, P. Paquis2, S. Litrico2, G. Daider3, B. Gastaud4, J. Greffeuille5, P. Boileau1

1University of Nice, Orthopaedic Department and Spine Surgery, Nice, France, 2University of Nice, Neurosurgery, Nice, France, 3University of Nice, Departement d’Informatique Medical, Nice, France, 4Sécurité Sociale, Service Medical auprés de la Caisse Primaire d’Assurance Maladie des Alpes Maritimes, Nice, France, 5Sécurité Sociale, Caisse Primaire d’Assurance Maladie des Alpes Maritimes, Nice, France

Background: Disc prosthesis exists since 1984 but it still can’t get it paid for by French National Health Care. Few data are available on medicoecominal background in France. Our objective was to evaluate the clinical and radiological outcomes, and also the medical cost before and after operation.

Methods: We present a prospective, descriptive study of the first 20 patients treated by a total disc replacement in two centers. Operations were realized on 16 women and 4 men with mean age of 41 years (24-57), using SB CHARITE(9), MOBIDISC(6), MAVERICK (3), PRODISC(2) prosthesis on L4L5 (8) and L5S1 (12) levels. Only patients less than 60 years old with single level
Disc pathology were included without sagittal or frontal deformity. Patients with workers' compensation were excluded.

Clinical outcome was evaluated with VAS, Oswestry disability index, MOS SF 36, and the ability to return to work.

The placement accuracy of prosthesis was determined by computed analysis. We evaluate the medical cost with help of French National Health Care by consulting their own bill's archives for each patient (in France it represents the all cost). Statistical analysis was based on Kruskall Wallis, Wilcoxon, and Mann Whitney tests for mean comparison and Spearman test for correlations between clinical and economical parameters.

Results: One complication with peroperative endplate fracture needed a revision surgery. The mean follow up is 15 month before operation and 24 month after for the 20 patients. The VAS for back pain decreased from 7.6 to 3.9 at 3 month postoperatively and maintained at 3.9 at 2 years of follow up.

The ODI score and global SF36 score decreased respectively from 46.3 and 33.1 to 28.8 and 64.5 at 3 month postoperatively and maintained at 29.6 and 62.7 at 2 years of follow up.

75% of patients was satisfied and very satisfied at the last follow up and 65% returned to work at the same or less level.

The radiographic study showed 70% of disc space occupation on coronal and 83% on sagittal view. The disc height reconstruction was at 134% compared to superior level. The mean mobility in flexion extension was 8° of range and most of the time < 5° in lateral bending. The economic study showed 455 122 € of bill for 20 patients on 39 month of follow up. A significant reduction of mean cost compared before (846.46 € +/-567.86) to after operation (590.3 € +/-750.27) (p=0.03) was found. A statistic correlation was found between Vas (p=0.05, r= 0.53), ODI (p=0.03, r= 0.6), SF36 (p=0.03 r=-0.6) and the global cost. It was the same for satisfaction (1187.2 € +/-1187.7 with non satisfied against 391.3 € +/-437.3 for satisfied p=0.04).

Discussion: This is the first French report on economical cost of total disc replacement with the help of French National Health Care. We found good short-term clinical results and reduced economical outcomes after total disc replacement with patients who complain about chronic low back pain.

50. The Effect of Adverse Events on Clinical Outcome: Analysis of Data from an FDA IDE Trial

D. Ohnmeiss1, W. Bodemer1, J. Zigler2

1Texas Back Institute Research Foundation, Plano, TX, United States of America, 2Texas Back Institute, Plano, TX, United States of America

Objectives: Comorbidities have been reported to be related to lumbar spine surgery outcome. Adverse events (AE, any change in the medical condition of a patient occurring during the course of a study, may or may not be related to the study device or the surgery) include a wide variety of problems including injury due to vehicular accidents, cancer, hand surgery, initiation of asthma treatment, etc. In some respects, adverse events recorded in clinical trials may be viewed as "transient comorbidities", that is, during the study, these events may be active or may have resolved. At any follow-up period during the study, a patient may have none or more than one active AE. The AE may or may not resolve by the next follow-up visit and may or may not be related to the study procedure. The purpose of this study was to determine if the presence of active adverse events have an impact on clinical outcome in an FDA IDE trial.

Methods: The study group was 220 patients enrolled in the ProDisc-L FDA IDE trial, randomized and continued access arms, at a single site. Per study protocol at each visit, adverse events were assessed including date of onset, severity (mild, moderate, severe), relationship to the study procedure (related, unrelated or inconclusive), and date of resolution vs. ongoing status was recorded. Clinical outcome was determined based on the percentage improvement on visual analog scales (VAS) assessing pain and Oswestry scores from pre-operative to the various follow-up visits. For this abstract, the 24-month follow-up data were reported. The mean improvement in VAS and Oswestry scores at each study follow-up visit were compared using ANOVA analysis across the severity and relationship categories, as well as across the number of active AEs within a patient at the time of the follow-up visit.

Results: There was a significant relationship between the presence of active AEs and clinical outcome. Among patients with no AEs present the mean improvement in the VAS pain score was 74.2%, compared to 58.9% in patients with one AE, 30.0% with two AEs and 40.6% among patients with three or more active AEs (p<0.01). Oswestry scores were also significantly related to the number of active AEs (p<0.01). With respect to AE severity, patients with no AEs improved statistically significantly more on VAS scores than did patients with moderate or severe AEs (74.2% vs. 43.1% and 42.3%). Patients with mild AEs (mean improvement 54.3%) did not differ significantly from those with no AEs. Patients with AEs related to the surgery had less favorable VAS scores than patients with no AEs or unrelated AEs.

Conclusions: This study represents the first investigation of the impact of adverse events on clinical outcome in a spine clinical trial. We found that the presence of active AEs significantly influenced clinical outcome. Rigorous recording of AEs appears to be important not only for assessing the safety of a device but also explain part of the variance in post-operative results.
51. A Prospective Randomized Comparison of Two Lumbar Total Disc Replacement Devices

Objective: Total disc replacement (TDR) has been available for many years in Europe. After completion of the FDA trials, these implants are gaining acceptance in the United States. Previous randomized studies have compared TDR to anterior lumbar interbody fusion or combined anterior/posterior instrumented fusion. In these studies, TDR results were as good as fusion, and better on some outcome measures. To date, there has not been a prospective, randomized study comparing two TDR devices. The purpose of this ongoing study was to compare the results of TDR using Charité to Kinflex.

Methods: A total of 85 patients from two centers participating in the FDA-regulated trial were randomized in a 1:1 ratio to receive Kinflex or Charité total disc replacement. All patients were treated for single-level symptomatic disc degeneration at either the L4-5 or L5-1 level. The majority of surgeries were performed at L5-1. Data collection included peri-operative data, 12-month clinical outcomes based on the Oswestry and visual analog scales assessing pain, adverse events and re-operations, and radiograph evaluation assessing disc height and range of motion.

Results: The mean operative time was very similar in the two TDR groups, almost 59 minutes in each. The length of hospitalization was 2.4 days in the Kinflex group and 2.7 days in the Charité group. Estimated blood loss was higher in the Kinflex group (113.9 vs. 64.1 cc). Clinically, both groups improved significantly with respect to VAS scores assessing pain and Oswestry scores assessing function. VAS scores in the Kinflex group improved from 83.0 to 19.0 at 12 month follow-up and the Charité group improved from 81.7 to 30.3. The mean pre-operative Oswestry score in both groups was about 57. In the Kinflex group, it improved to 20.6 at 12 month follow-up and to 23.4 in the Charité group. The incidence and types of adverse events in the two groups were very similar. Radiographic assessment data was available through 6 month follow-up. In both groups, disc height increased after TDR (Kinflex: 8.1 to 14.6 mm; Charité: 8.4 to 15.7 mm). The pattern of change in range of motion at the implanted level, as measured from flexion/extension radiographs, was similar in the two groups. Pre-operatively, the mean range of motion in the Kinflex group was 4.9 degree at 6 months was 4.0 degrees. In the Charité group, the range of motion was 5.2 degrees pre-operatively and 5.0 degrees at 6 months post-operative.

Conclusions: This study provides preliminary data for two sites participating in the FDA-regulated trial evaluating the Kinflex artificial disc by comparing it to the Charité disc.
ISO standard. In this study, a current MoM TDR under IDE investigation and a prototype MoM TDR were tested. Prototype TDR design parameters were based upon a literature review of successful THA designs. Previously, Mathews has reported a wear rate of 1.2 to 1.4mm\(^3\)/Mc for the Maverick TDR. It is not possible to compare our results in that specifics of their test method were not reported. Pare has recently reported steady state wear rates for Maverick components on the order of 0.33 to 0.43mm\(^3\)/M. Their results are based upon the ASTM guideline for wear testing which tests at a significantly lower load than the ISO test. Additionally, the Mavericks tested had clearances of 38±7\(\mu\)m, which are considerably less than the clearances of the off-the-shelf Mavericks tested in this study. The wear rate determined in this study is considerably greater than those previously reported. Additionally, it is at least 15 times greater than the steady state wear rates reported for THA MoM designs. This study suggests that MOM TDR implant parameters thought to affect wear (diameter, material, clearance, surface finish, etc.) must be optimized in order to achieve MOM wear improvements similar to those seen in THA.

Lumbar TDR - Session II

53. Is Preoperative Disc Height a Predictive Factor to Lumbar Total Disc Arthroplasty Results?

J. Allain\(^1\), O. Kettani\(^1\), J. Delecrin\(^2\), J. Beaurain\(^3\), J. Steib\(^4\), H. Chataigner\(^5\), T. Dufour\(^6\), M. Ameil\(^7\), L. Aubourg\(^1\)

\(^1\)Paris XII University Hospital, Orthopedic, Creteil, France, \(^2\)Nantes University Hospital, Orthopedic, Nantes, France, \(^3\)University Hospital, Neurochirurgie, Dijon, France, \(^4\)University Hospital, Orthopedic, Strasbourg, France, \(^5\)Clinique de Besançon, Orthopedic, Besançon, France, \(^6\)Hôpital de la Source, Neurochirurgie, Orleans, France, \(^7\)Clinique de Reims, Orthopedic, Reims, France

**Introduction:** Criteria to determine the best indications for disc arthroplasty include clinical and radiological endpoints. Degenerative Disc Disease (DDD) and Modic classification at the MRI, and discogenic pain during discography are usually used to define the best surgical procedure. For some surgeons, preoperative narrowing of the disc height is also necessary to purpose Total Disc Arthroplasty. We report a prospective study result comparing the outcomes of lumbar disc arthroplasty according to the preoperative disc height at the operative level.

**Methods:** 51 consecutive patients who received Mobidisc prostheses (disc prosthesis designed with a mobile nucleus) implanted at L3L4, L4L5 or L5S1 levels have been followed-up prospectively for 12 months. 30 disc prostheses have been implanted for degenerative disc disease with disc height narrowing (Group 1) and 21 for degenerative disc disease with no disc height narrowing (Group 2). Clinical evaluation included VAS (0-10 scale) for back and leg pain, Oswestry Disability Index (ODI) and radiological assessment included Range of Motion (ROM) measurement from dynamic x-rays.

**Results:** The mean age in Group 1 was 40 years vs. 36 in Group 2. 50% were female in Group 1 vs 36% in Group 2. Mean lumbar VAS scores decreased significantly compared to pre-operative values from 6.5 to 2.5 (Group 1) and from 6.2 to 2.4 (Group 2). Mean leg VAS scores decreased significantly compared to pre-operative values from 6.7 to 2.5 (Group 1) and from 7.0 to 4.0 (Group 2). Average ODI score decreased significantly compared to pre-operative values from 51% to 23% (Group 1) and from 46% to 19% (Group 2). Finally, 79% of the patients in both groups were satisfied or very satisfied regarding the surgical procedure. Mean Range of Motion at the operated level was 10\(^\circ\) in both groups at follow up.

**Conclusion:** According to Oswestry score and back pain, functional results at one year are similar between both groups of patients. The decrease of leg VAS score is better in case of preoperative disc narrowing than not (4.2 pts vs 3 pts). Nevertheless, disc arthroplasty statistically improves leg pain, back pain and Oswestry scores even without preoperative disc height narrowing. This study demonstrates that Total Disc Arthroplasty is an effective surgical procedure to treat degenerative disc disease even without narrowing of disc height at the operative level with equivalent satisfaction index of the patients towards the surgical procedure in both groups.

54. Minimally Invasive Lateral Lumbar TDR: 24 Months Follow-Up

L. Pimenta\(^1\), C. Arias Pesántez\(^1\), L. Oliveira\(^2\), J. Lhamby\(^2\), T. Schaffa\(^2\), E. Coutinho\(^2\)

\(^1\)Santa Rita Hospital, Minimally Invasive and Arthroplasty Spine Surgery, Sao Paulo, Brazil, \(^2\)Santa Rita Hospital, Spine Surgery, Sao Paulo, Brazil

**Purpose:** Current lumbar total disc replacement (TDR) devices require an anterior approach for implantation. The anterior approach to place lumbar TDR devices has inherent limitations, including risks to abdominal structures, and resection of the anterior longitudinal ligament (ALL). Placement of a TDR device from a true lateral (XLIF) approach allows for easier, less invasive access to the disc space, as has been shown in reports of XLIF for fusion procedures. Lateral implantation of TDR also preserves the stabilizing ligaments, which are a natural restraint to excessive rotations and translations, and thereby help to minimize facet stresses. Importantly, implantation from a lateral approach leaves greater opportunity for safer revision surgery, if necessary, by avoiding scarring of anterior vasculature. Additionally, the footprint of the lateral TDR device capitalizes on the biomechanical support of the ring apophysis.

**Methods:** A TDR device designed for implantation through
ORAL ABSTRACT SESSIONS

A true lateral, retroperitoneal, transpsoas approach (XLIF) was implanted in 25 patients with discography-confirmed 1- or 2-level DDD. Clinical and radiographic outcomes assessments were prospectively collected.

Results: Patients included 12 males and 13 females, average age 43 yrs (24-60). Surgeries included 8 1-level, 3 2-level, and 14 hybrid TDR/ALIF cases. The surgery is performed through a 4cm lateral incision in an average of 134 minutes (90-300) and with an average 58cc blood loss (30-150). There have been no intra-op or post-op complications. Postoperative x-rays show good device placement, with restoration of disc height, foraminal volume, and sagittal balance. All patients were up and walking within 12 hours of surgery and all but 9 were discharged the next day (7/9 were hybrid TDR/ALIF cases). 5/36 patients (13.8%) had psoas weakness and 3/36 (8.3%) had anterior thigh numbness postoperatively, both resolving within 2 wks. 4/36 (11%) had postoperative facet joint pain, all in hybrid cases. VAS pain scores improved from an average of 9.3 at pre-op to 2.4 immediately post-op, 3.2 at 6 wks, 1.9 at 3 mos, 2.6 at 6 mos, 2.4 at 1 yr and 2.2 at two years. Oswestry Disability Index improved from an average of 57 at pre-op to 31 at 6 wks, 23 at 3 mos, 21 at 6 mos, 15 at 1 yr and 12 at 2 years. Average postoperative ROM remains steady, not significantly different from preoperative values.

Conclusion: Mid-term results of a laterally placed TDR device demonstrate maintenance of pain relief and functional improvement. The benefits of this technique — minimal morbidity, avoiding mobilization of the great vessels, preserving the anterior longitudinal ligament, biomechanically stable orientation, and broader revision options—suggest a promising new direction for TDR procedures.

55. Comparison of Total Disc Replacement with Lumbar Fusion Surgery: A Randomized, Controlled Trial with Two-Year Follow-Up

S. Berg¹, H. Tropp²

¹Stockholm Spine Center, Stockholm, Sweden, ²University Hospital Linköping, Orthopedic Clinic, Linköping, Sweden

Aims: In patients with chronic low back pain (LBP) that is discogenic and unresponsive to conservative treatment, lumbar fusion is considered the “gold standard” of surgical treatment. Total disc replacement (TDR) has been introduced as an alternative treatment. The purpose of this study was to compare TDR and lumbar fusion in terms of clinical outcome.

Methods: The study design was a prospective, randomized, controlled comparison (RCT) between TDR and instrumented lumbar fusion. All included patients had failed a conservative treatment program. LBP was the predominant symptom. Diagnosis was made on the basis of clinical examination, radiographs, MRI, and in some cases, diagnostic injections. Clinical outcome was determined by means of The Swedish Spine Registry and included Visual Analogue Scale (VAS; back and leg), Oswestry questionnaire, SF-36, Euroqol, and the patient’s global assessment of back and leg pain.

Results: A total of 152 patients were included. Eighty underwent TDR, and 72 had instrumented fusion. The mean age was 40±8 years (range 21-55), and 59% of the patients were female. The follow-up rate was 100% at one year and so far 78% have completed two-year follow-up. All main clinical outcome parameters improved for both groups. After one year the TDR group had a larger improvement with regard to pain (VAS), Oswestry Disability Index, Euroql, and global assessment than the fusion group. In the TDR group, 29% of the patients reported total relief with regard to back pain compared to 10% in the fusion group (p<0.01). There was no change in results between one and two years, however we can not show all the significance differences between groups due to lower follow-up rate so far.

Conclusions: The superiority of TDR compared to fusion in clinical outcome at one year seems to stay on at two-year follow-up. Even so, a new treatment option needs a longer term perspective, so these patients will again be checked and compared at 5 and 10 years from surgery.

56. TRIUMPH™ Posteriorlateral Artificial Disc Biomechanics: The Effect of Posterior Tethering

P. Mcafee¹, D. Sengupta², N. Anand³, G. Deol³, N. Khanna⁴, D. Tyndall⁵, R. Balderston⁶, A. Ingalhalikar⁷

¹Townson Orthopaedic Associates, P.A. - Scoliosis and Spine Center, Towson, MD, United States of America, ²Dartmouth-Hitchcock Medical Center, Hanover, NH, United States of America, ³Cedars Sinai Institute for Spinal Disorders, Los Angeles, CA, United States of America, ⁴M & M Orthopaedics, Naperville, IL, United States of America, ⁵Orthopaedic Specialists, Munster, IN, United States of America, ⁶Pennsylvania Hospital, Philadelphia, PA, United States of America, ⁷Globus Medical, Inc., Audubon, PA, United States of America

Objectives: Posterior Total Disc Arthroplasty may involve resection of the facet joints depending on the amount of decompression required and implant design. A dynamic stabilization device may be used as a posterior tether to stabilize the implanted level. The aim of this study was to evaluate the in vitro biomechanical characteristics of a posterior dynamic stabilization device (PDS) adjunct to a posterolateral total disc arthroplasty (PL-TDA) for reconstruction of the lumbar spine. The primary objective was to quantify the change in kinematics of the 3 joint complex due to posterior intervention and subsequent dynamic stabilization.

Methods: Seven cadaver lumbar sacral spines (L1-S1) were tested in a six-degree of freedom spine tester in the following sequences: (1) Intact specimen, (2) bilateral facetectomy at L4-L5; (3) PL-TDA at L4-L5 (4). PL-TDA (TRIUMPH™) + PDS (TRANSITION™). A hybrid test protocol was used for flexibility testing with moments of ±8Nm used for flexion-extension, lateral bending and
Conclusions:

106.3±9.2, and 99.6±22.7% while L5-S1 experienced IDPs of 108.5±33.4%, and 49.3±58% respectively for the three constructs, extension, IDPs at L3-L4 were 99.5±44%, 94.86±61% with PL-TDA and 148.3±25.8% with PL-TDA+PDS). In direction (123.2±21.8% with facetectomy, 67.4±28.8% adjacent segment (L5-S1), the IDP changed in a similar again after addition of PDS (169.6±34.6%) The inferior after PL-TDA alone (65.1±52.46%) and increased following bilateral facetectomy (114.2±48.4%), reduced adjacent segment (L3-L4) in flexion was increased close to intact (108.82±21.6%). IDP in the proximal + PL-TDA further stabilized ROM to 34.4±39.2% in flexion and 41.5±43.11% in extension. Lateral bending was minimally affected with bilateral facetectomy (106.1±15.7%) and also, with PL-TDA (104.7±7.9%). Addition of PDS further reduced ROM to 38.4±14%. Axial rotation was significantly increased after bilateral facetectomy (175.3±13.6%) which was not corrected with the insertion of PL-TDA alone (180.82±21.6%). Addition of PDS to this construct restored the motion close to intact (108.82±21.6%). IDP in the proximal adjacent segment (L3-L4) in flexion was increased following bilateral facetectomy (114.2±48.4%), reduced after PL-TDA alone (65.1±52.46%) and increased again after addition of PDS (169.6±34.6%). The inferior adjacent segment (L5-S1), the IDP changed in a similar direction (123.2±21.8% with facetectomy, 67.4±28.8% with PL-TDA and 148.3±25.8% with PL-TDA+PDS). In extension, IDPs at L3-L4 were 99.5±44%, 94.86±61% and 49.3±58% respectively for the three constructs, while L5-S1 experienced IDPs of 108.5±33.4%, 106.3±9.2, and 99.6±22.7%

Conclusions: The results indicate that PL-TDA reconstruction after bilateral facetectomy increased operative level ROM in all three physiologic planes compared to the intact; more specifically in axial rotation than in other directions. Posterior tethering with PDS stabilized the spine and reduced ROM in all directions and particularly restored axial rotation close to intact. This study provides a biomechanical foundation for posterior tethering a PL-TDA device using a PDS system when bilateral facetectomy is required for decompression.

Results: In flexion and extension, bilateral facetectomy increased L4-L5 ROM to 110.3±16.14% and 128.6±41.3% respectively. Insertion of PL-TDA restored ROM restored ROM closer to intact (103.09±3.71% in flexion and 113.37±39.1% in extension). The PDS + PL-TDA further stabilized ROM to 34.4±39.2% in flexion and 41.5±43.11% in extension. Lateral bending was minimally affected with bilateral facetectomy (106.1±15.7%) and also, with PL-TDA (104.7±7.9%). Addition of PDS further reduced ROM to 38.4±14%. Axial rotation was significantly increased after bilateral facetectomy (175.3±13.6%) which was not corrected with the insertion of PL-TDA alone (180.82±21.6%). Addition of PDS to this construct restored the motion close to intact (108.82±21.6%). IDP in the proximal adjacent segment (L3-L4) in flexion was increased following bilateral facectomely (114.2±48.4%), reduced after PL-TDA alone (65.1±52.46%) and increased again after addition of PDS (169.6±34.6%). The inferior adjacent segment (L5-S1), the IDP changed in a similar direction (123.2±21.8% with facectomy, 67.4±28.8% with PL-TDA and 148.3±25.8% with PL-TDA+PDS). In extension, IDPs at L3-L4 were 99.5±44%, 94.86±61% and 49.3±58% respectively for the three constructs, while L5-S1 experienced IDPs of 108.5±33.4%, 106.3±9.2, and 99.6±22.7%.

Discussion: The results of this study did not support our hypothesis, that chronic rim impingement would be associated with greater dome penetration. We estimate that the power of our analysis to detect a 50% decrease in wear rate is <80%, therefore a greater number of retrievals is necessary to definitively refute our hypothesis. However, at present our findings would suggest that dome wear and

**57. Does Chronic Rim Impingement Influence Dome Wear in Mobile Bearing TDRs?**

*S. Kurtz*, *D. MacDonald*, *A. Ianuzzi*

Drexel University and Exponent, Inc. Philadelphia, PA, United States of America

Introduction: Impingement has been observed in retrieved TDRs, however the clinical consequences of chronic rim impingement remain poorly understood. In total hip replacements, rim impingement has previously been associated with elevated liner shell-relative motion and backside wear. We evaluated our retrieval collection of polyethylene mobile bearing TDRs to determine whether rim impingement adversely affected dome penetration.

Methods: We analyzed the motion patterns and dome penetration of 40 Charité (SBIII, manufactured by Link) implants from 34 patients (74% female) from the United States and Europe. All of the TDRs were revised for intractable back pain. 28/40 (70%) cores, implanted for 2-16 years (7.9y ave), were classified as exhibiting chronic rim impingement based on observations of plastic deformation, burnishing, and/or fracture of the rim. In addition to pain, chronically impinged cores were also revised for subsidence (n=10), anterior migration (n=3), core dislocation (n=2), lateral subluxation, endplate loosening, and osteolysis (n=1). 10/40 (25%) of the cores, implanted for 2-10 years (5.1y ave), showed evidence of mild or negligible rim contact, and one case was revised for loosening. For 2 cores the impingement pattern could not be determined. Dome and rim penetration was measured using a calibrated micrometer in all but one case. Linear regression and multivariate analysis of variance were used to explore relationships between implantation time, dome and rim penetration, and chronic impingement.

Results: Dome penetration was comparable in chronically impinged cores (ave: 0.3, range: 0.1 to 0.9 mm) as compared with non-impinging cores (ave: 0.3, range: 0.1 to 0.5 mm). Rim penetration was significantly greater in chronically impinged cores (p<0.05). Using linear regression, the dome penetration rate for cores with negligible impingement (0.036 mm/y, 95% CI: 0.012 to 0.061 mm/y) appeared slightly higher than in cores with chronic impingement (0.021 mm/y, 95% CI: 0.005 to 0.038 mm/y), however the difference was not significant. The average dome penetration rate for all the components in our study was 0.022 mm/y (95% CI: 0.009 to 0.036 mm/y).

Discussion: The results of this study did not support our hypothesis, that chronic rim impingement would be associated with greater dome penetration. We estimate that the power of our analysis to detect a 50% decrease in wear rate is <80%, therefore a greater number of retrievals is necessary to definitively refute our hypothesis. However, at present our findings would suggest that dome wear and
impingement are effectively decoupled phenomena, and may be studied independently of each other. Although the majority of retrievals in our collection (70%) showed signs of chronic rim impingement, the findings from revisions represent clinical failures and are not necessarily representative of the prevalence of impingement in patients with well functioning TDRs.

58. Prospective, Randomized, Multicenter FDA IDE Study of CHARITÉ Artificial Disc vs. Lumbar Fusion: Effect at 5-year Follow-up of Age on Clinical Outcomes Following Lumbar Arthroplasty

**Objectives:** To evaluate the effect of age on 5-year clinical outcomes, for patients implanted with the CHARITÉ Artificial Disc.

**Methods:** All arthroplasty patients included in the randomized controlled multicenter 5-year CHARITÉ IDE study were analyzed herein. Patients were divided into 2 groups by age at implantation (18-45 and 46 to 60). Demographic and surgical data was recorded for both groups separately. Clinical outcomes evaluated herein included VAS, ODI, SF36, patient satisfaction and work status.

**Results:** Of the total 90 CHARITÉ patients, 67 were included in the 18-45 year-old group (referred below as the “18-45 group”), and the remaining 23, in the 46-60 year-old group (referred below as the “46-60 group”). There was no statistical difference in gender (46% female and 54% male in 18-45 group vs. 48% male in 46-60 group, p=0.6381) or body mass index (26.2±4.44 in 18-45 group and 26.9±3.06 in 46-60 group) between groups. A majority of implanted levels were at L5-S1 for both groups (69% for 18-45 group and 78% for 46-60 group, p=0.4364). Although not statistically significant, a trend of increased operating time was observed in the 46-60 group (101.9±39.87min for the 18-45 group and 126.3±57.66 for the 46-60 group, p=0.1485). Similarly a small trend of increased blood loss was observed in the older group (185.3±181.43cc for 18-45 group and 289.1±342.69cc for 46-60 group, p=0.1265). Duration of hospitalization was similar between groups.

Pain and disability scores both showed a slight, non-statistical trend of increased improvement in the 46-60 group as compared to the younger cohort. From baseline to 5-year post-operative, changes in VAS scores reached -36.8mm for the 18-45 group and -44.1mm for the 46-60 group (p=0.2080). Changes in ODI scores reached -21.9 points for the 18-45 group and -30.2 points for the 46-60 group (p=0.1474). Changes in SF-36 PCS scores were also non-statistically greater in the older group: 11.8 points in the 18-45 group and 14.7 points in the 46-60 group (p=0.2853).

Patient satisfaction was similar across groups (89% “satisfied” or “somewhat satisfied” in the 18-45 group and 96% “satisfied” or “somewhat satisfied” in the 46-60 group). A slight, non-statistical difference was also observed in everyday activity levels: 42% of the 18-45 group had “definitely more everyday activity” as compared to 61% in the 46-60 group. Employment figures were also similar between groups: 74% of 18-45 group and 65% of the 46-60 group were employed part- or full-time.

**Conclusions:** Overall both patient age groups demonstrated significant pain and disability improvements. Patient age divided at 45 (range 18-60) did not statistically affect clinical outcomes by the 5-year follow-up time point.

Session III - Lumbar TDR and Fusion Session

59. Effect of Intervertebral Disc Degeneration on Spinal Stability - Relevance for Dynamic Stabilisation

**Purpose of the study:** Intervertebral disc degeneration is known to affect the stability of the spine. According to Kirkaldy-Willis and Farfan (1982) lumbar disc degeneration may be divided into three stages: (1) temporary dysfunction, (2) unstable phase and (3) stabilisation. Based on this classification, mild or moderate intervertebral disc degeneration could be one of the clinical indications for dynamic stabilisation devices. These devices are intended to restabilise unstable segments but still allow some movements in order to prevent the progression of adjacent level diseases. However, in the literature, there are also data reported, which indicate the opposite: stability continuously increases from the lowest towards the highest degree of degeneration. Thus, it is still not known whether mild or moderate intervertebral disc degeneration is always equivalent to instability, and, thus could be treated with dynamic stabilisation devices. The aim of the present study therefore was to correlate the degree of intervertebral disc degeneration with the segmental flexibility based on data from a large in vitro database and to discuss the impact of the results on dynamic stabilisation.

**Methods:** The flexibility data from all spine specimens
tested in our institute so far were collected in a large in vitro database. From this database, all lumbar spine specimens were selected, which had been tested for flexibility in flexion/extension, lateral bending and axial rotation under pure moment loads of ±7.5Nm and for which radiographs were accessible. 203 segments from 111 donors with an age of 19 to 99 years (median 56 years) met these criteria. Their radiographic degree of disc degeneration was determined on a scale from 0 (no degeneration) to 3 (severe degeneration). For this purpose, three criteria were rated: height loss, osteophytes and sclerosis. The overall degrees of degeneration were then correlated to the respective range of motion and neutral zone. Since the different lumbar levels differ in flexibility, a statistical model was created which allowed to pool them together.

**Results:** The statistical model predicted a continuous decrease of the range of motion from grade 0 to 3 in flexion/extension, lateral bending and axial rotation. This decrease was 3.1° in magnitude in flexion/extension and 3.4° in lateral bending (p<0.05). Only in axial rotation the range of motion tended to increase, however not only from grade 0 to 1 but continuously towards grade 3 (by 0.2°; p>0.05). The neutral zone was affected by the degree of degeneration in a similar way but to a smaller degree. Thus, an unstable phase, as described by Krikaldi-Willis and Farfan was not found.

**Conclusion:** The results of this study indicated that early stages of intervertebral disc degeneration do not necessarily cause instability. In contrast, the results showed that stability continuously increased in flexion/extension and lateral bending. Only in axial rotation stability tended to decrease. From these results it may be concluded that dynamic stabilisation devices should mainly stabilise in axial rotation and may be suitable not only in mild but in all degrees of degeneration.

60. **Variability among 10 Production Lots of a Single Demineralized Bone Matrix (DBM) Product**

_H. Bae\(^1\), L. Zhao\(^1\), Z. Dagny\(^1\), L. Kanim\(^1\), L. Thai\(^1\), G. Mehta\(^1\), J. Wang\(^2\), B. Pradhan\(^1\), R. Delamarter\(^1\)\(^1\)

\(^1\)The Spine Institute, Spine Research Foundation, Santa Monica, CA, United States of America, \(^2\)UCLA, Dept. Orthopaedic Surgery, Santa Monica, CA, United States of America

**Introduction:** There are over 17 demineralized bone matrix based products (DBMs) commercially available as bone graft extenders for fusion procedures. Few of these “off-shelf” DBMs have been evaluated for reliability and fusion efficacy. Recent studies have shown both intra-product variability (due to production lots) and inter-product variability (product formulations) \(^1\). The purpose of this study was to assess lot-to-lot variability of one DBM product (intra-variability) using both in vitro and in vivo assays. In particular, can BMP-2, BMP-7 and/or alkaline phosphatase (AP) assays accurately predict the in vivo osteoinductive potential of individual DBM lots from a single vendor? The inconsistency of fusion outcomes from previous DBM studies \(^5\) warrants the development of a screening method for ensuring optimal osteoinductivity in clinical settings. Materials and

**Methods:** 10 individual production lots of a commercially available DBM putty. In vitro methods: 1) BMP-2 and BMP-7 concentrations in each of 10 DBM lots were measured using ELISA. 2) Mouse myoblasts were incubated with each DBM lot, and the extent of subsequent osteoblast differentiation was detected using an AP assay.

In vivo osteoinductive potential: 40 mature athymic nude female rats were used (170g, Harlan Sprague Dawley, IN). L4-L5 posterolateral intertransverse process fusion was performed with decortication of only the L4 and L5 transverse processes (lamina and facet joints were left intact without decortication). Wounds were irrigated. An aliquot from each of 10 DBM lots (0.3 cc per side) was implanted into 4 rats (n = 4 rats / each 10 lots, n = 40 rats). Rats were sacrificed at 8 weeks. Radiographs and histology were done. Explanted segments were manually tested for intersegmental motion.

**Results:**

**In vivo study:** 96% of the rats showed de novo bone formation on high resolution radiographs of explanted lumbar spines after sacrifice at 8 weeks (example radiographs, Fig 1). There was significant manual fusion variability across lots (p<0.04) where 23% of the rats were completely manually fused at 8 weeks. While 2 lots almost always promoted fusions, 5 lots consistently failed.

![Example radiographs Not fused fused](image)

[Figure1]

**In vitro study:** From lowest to highest, there was a five-fold difference in amounts of BMP-2 and a three-fold difference for BMP-7 revealing lot-to-lot variability among the aliquots. There was a positive correlation between amount of BMP-2 and BMP-7 in lots of DBMs (r = 0.77, p<0.0001). Most notably, BMP-2 and BMP-7 concentrations positively predicted the rate of successful manual fusions across lots of DBM (BMP-2 p < 0.01; BMP-7 p<0.009), Fig 3. The same 2 lots that induced the highest fusion rate (75%) also contained the highest concentrations of both BMP-2 and BMP-7.

**Conclusion:** There is significant lot-to-lot variability in BMP levels, extent of AP induction, and in vivo fusion rates. This is the first of a series of studies to test in vitro predictors of in vivo lot-to-lot variability in one product of DBM in one study.
61. Revision Problems in Anterior Lumbar Surgery

S. Braun

1Spine Access Surgery Associates, Los Angeles, CA, United States of America

Background: Anterior lumbar surgery revisions remain a most challenging problem facing spine surgeons. This study presents results, management issues and complications in a consecutive series of revisions performed by the author.

Methods: 62 patients had surgery between February 2000 and September 2007. 34 were females and 28 were males. BMI ranged from 22 to 40 and age from 21 to 67. 23 patients had the same level re-exposed for removal or repositioning of the prior device. Of these, 7 had a failed total disc replacement (TDR) and 16 had pseudoarthrosis after anterior lumbar interbody fusion (ALIF). Of the failed TDR’s, 6 were at L5-S1 and 1 at L4-5. Two patients with devices removed at L5-S1 also needed fusion of L4-5 and the one removed at L4-5 required fusion of L5-S1. 3 of the 23 were re-explored within 1 to 10 days while the rest were approached after that (6 weeks to 23 months). 39 patients had adjacent level degeneration. 6 of these had an artificial disc deployed at L3-4 after L4 to S1 anterior surgery. Of the remaining 32, 9 had L5-S1 fused after fusion above, 6 had L4-5 fused after L5-S1 and 3 after L3-4. 6 had L3-4 fusions after prior L4 to S1 ALIF. The remainder had L2-3 and/or L1-2 fused after lower level fusions. In all patients left ureteral catheters were placed (bilaterally for L5-S1 revisions), the cell saver was used and groins were prepped in expectation of endo-vascular repairs. A venogram was done for an anteriorly extruded core at L4-5. Proximal and distal control of major vessels was not obtained in any case. The retroperitoneal approach was used in all but 3 patients. Opposite side for L5-S1 and antero lateral for L4-5 and above.

Results: There were 3 venous injuries (4.8%), 3 arterial injuries (4.8%) and 1 ureteral injury (1.6%). All were treated successfully with no deaths or major sequelae. One revision for pseudoarthrosis at L5-S1 was aborted after the vein injury was repaired. Another venous injury occurred while removing an artificial disc from L5-S1 and required ligation of the vena cava and both common iliac veins after completion of the arthrodesis. This patient recovered and had a posterior instrumentation 2 weeks later. The three arterial injuries occurred while doing a TDR at L3-4 after prior L4 to S1 surgery. All three devices were deployed successfully and the arterial problem treated with good resolution. One intimal disruption was repaired with endovascular stents after thrombectomy via groin approach and the one ureteral injury was identified by the ureteral catheter. 1of 2 males revised at L5-S1 reported retrograde ejaculation. There were no other complications.

Conclusions: Although revisions remain extremely challenging, especially returning to L4-5 and exposing L3-4 after L4-5, the success rate can be high with relatively low complication rates. Careful planning is mandatory with precautionary measures, such as ureteral catheters and groin preps. Surgeon’s experience is key to good results. Minimum 5 years with 200+ cases is recommended.

62. Serum Metal Levels in Patients with Cobalt-Alloy Metal-on-Metal Lumbar Disc Replacements

M. Gornet1, J. Burkus2, A. Skipor3, J. Jacobs2

1The Orthopedic Center of St. Louis, St. Louis, MO, United States of America, 2The Hughston Clinic P.C., Columbus, OH, United States of America, 3Rush University Medical Center, Chicago, IL, United States of America

Objectives: Total disc replacement is a recent alternative treatment for degenerative disc disease. Corrosion of metallic wear particles can lead to increased metal ion release in the body. This study examines the serum chromium (Cr) and cobalt (Co) levels in patients with cobalt-chromium (CoCr) alloy metal-on-metal (MOM) lumbar disc replacements out to 12 months.

Methods: A prospective longitudinal study was performed consisting of a group of patients implanted with the MAVERICK® Lumbar Disc (Medtronic, Memphis, TN). This system consists of a MOM CoCr alloy (ASTM F1537) articulation. Serum samples were collected pre-operatively (n = 24) and at 3 (n = 24), 6 (n = 24), and 12 (n = 23) months post-operatively. Serum was assayed for Cr and Co using high-resolution inductively-coupled plasma-mass spectrometry (Element2, Finnigan MAT, Bremen, Germany). The detection limits were 0.015 ng/mL for Cr and 0.04 ng/mL for Co. Values below the detection limits were assigned a value of half the detection limit. Longitudinal statistical comparisons were made using the Friedman test.

Results: The median serum Co levels at pre-op, 3, 6, and 12-months post-op were 0.10, 1.03, 0.96, and 0.98 ng/mL, respectively. The median serum Cr levels at pre-op, 3, 6, and 12-months post-op were 0.06, 0.49, 0.65, and 0.43 ng/mL, respectively. Co levels were statistically higher (p < 0.01) at the 3, 6, and 12-month time periods compared with pre-op levels. Cr levels were statistically higher (p < 0.01) at the 3, 6, and 12-month time periods compared with pre-op levels. The median serum Co levels at 12 months post-op appear to be equivalent to Co serum levels in a group of CoCr alloy MOM surface replacements of the hip and CoCr MOM total hip replacements [1]. The median serum Cr levels in this lumbar disc replacement cohort appear to be lower than those reported in a group of CoCr alloy MOM surface replacements of the hip and CoCr MOM total hip replacements at the 12-month post-op time period [1]. Additionally, when compared with reported Cr metal ion data for patients with posterior spinal arthrodesis with stainless steel instrumentation [2,3], this lumbar disc cohort reported lower Cr metal ion levels.

Conclusions: In general, these results indicated that short-term metal ion levels are of the same order of magnitude as those observed in well-functioning metal-on-metal hips and lower than those observed in posterior spinal arthrodesis. Continued surveillance of this patient cohort is ongoing and will provide longer-term follow-up data for this lumbar disc replacement system.
63. **Total Disc Arthroplasty: An Effective Operative Treatment of Degenerative Disc Disease in Patients with Previous Surgical Discectomy**

**J. Allain**¹, J. Beaurain², J. Delecrin³, J. Steib⁴, H. Chataigner⁵, M. Ameil⁶, T. Dufour⁷, L. Aubourg⁸

¹Paris XII University Hospital, Orthopedic, Creteil Cedex, France, ²University Hospital, Neurosurgery, Dijon, France, ³University Hospital, Orthopedic, Nantes, France, ⁴University Hospital, Orthopedic, Strasbourg, France, ⁵Clinique de Besançon, Orthopedic, Besançon, France, ⁶Clinique de Reims, Orthopedic, Reims, France, ⁷University Hospital de la Source, Neurosurgery, Orleans, France, ⁸Paris XII University Hospital, Orthopedic, Creteil, France

**Introduction:** In some cases, surgical discectomy fails to treat back or leg pain. In some others, after post-operative healing, degenerative disc disease appears and leads to recurrent back or leg pain. Options for iterative surgery include re-discectomy with or without fusion; usually with poor results. We report multi-center prospective study results comparing the outcomes of disc arthroplasty following discectomy to no previous surgery.

**Methods:** 130 consecutive patients who received Mobidisc prostheses (disc prosthesis designed with a mobile nucleus) have been followed-up prospectively for 12 months. 35 disc prostheses have been implanted after discectomy due to disc herniation (Group 1) and from 49% to 19% (Group 2). A decreasing trend in the proportion of patients who reported improvement in pain and function was observed. 36% (Group 1) and 86% (Group 2) of the patients were satisfied or very satisfied about the surgical procedure. 90% should undergo this surgery again. Lordosis at the operated level increased from 4.5° (preoperatively) to 11.5° (at follow-up) in Group 1 and from 7° to 13° in Group 2. Preoperative and follow-up Mean Range of Motion at the operated level was similar in both groups: respectively 4° (0-18°) and 7° (0-17°).

**Conclusion:** Disc arthroplasty statistically improves leg pain, back pain and Oswestry scores even with previous surgical discectomy which represents 27% of its indications. According to Oswestry score and leg pain, functional results at one year seem to be better in the group of patients with no previous surgery. Nevertheless, this study demonstrates that disc arthroplasty is an effective alternative solution to treat degenerative disc disease following discectomy due to disc herniation. In these cases, disc arthroplasty seems to be the best surgical procedure.

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64. **Prospective, Randomized Trial of Lumbar Metal on Metal Total Disc Replacement: Initial Treatment of Degenerative Disc**

**T. Errico**², R. Tibbs¹, R. Sassó², G. Miz³, C. Theofilos⁴, M. Quirno², ⁵Oklahoma Spine Hospital, Oklahoma, OK, United States of America, ⁶Indiana Spine Group, Indianapolis, IN, United States of America, ⁷Bone and Joint Physicians, Oak Lawn, IL, United States of America, ⁸Spine Center, Palm Beach Dnts, FL, United States of America, ⁹NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States of America

**Introduction:** The FlexiCore® Intervertebral Disc (Stryker, Allendale, NJ) is a lumbar metal on metal total disc replacement device currently being studied for the treatment of degenerative disc disease (DDD) under an investigational device exemption (IDE) granted by the United States Food and Drug Administration. This study examines the outcomes of the FlexiCore® as compared to traditional circumferential fusion for the treatment of single level DDD.

**Methods:** 111 patients from four of the study sites were randomized in a 2:1 fashion (FlexiCore®:Fusion). 71 patients were treated with the FlexiCore® (F) and 40 patients were treated with fusion (C). Disability and pain were assessed using the Oswestry Disability Index (ODI) and the Visual Analog Scale (VAS). Prospective data was collected preoperatively and postoperatively at 6 weeks and 3, 6, 12, and 24 months.

**Results:** The mean ODI scores were 61(F) and 60(C) preoperatively, 37(F) and 48(C) at 6 weeks, 30(F) and 34(C) at 3 months, 28(F) and 31(C) at 6 months, 26(F), 31(C) at 12 months, and 23(F) and 22(C) at 24 months. The FlexiCore® had significantly better ODI scores at the 6 week follow-up (p=0.006) when compared to fusion.(Graph 1).

**References:**

[1] Skipor et al, ORS 0124, 2004;
The mean VAS scores were 87 (F) and 83 (C) preoperatively, 37 (F) and 31 (C) at 6 weeks, 36 (F) and 28 (C) at 3 months, 36 (F) and 31 (C) at 6 months, 30 (F) and 33 (C) at 12 months, and 32 (F) and 34 (C) at 24 months. There was no significant difference in VAS scores between fusion and the FlexiCore® Graph 2.

The average operative time was 82 minutes for the FlexiCore® and 170 minutes for fusion. The average estimated blood loss was 76cc for the FlexiCore® and 99cc for fusion. The average hospital stay was 2.5 days for the FlexiCore® and 3.3 days for fusion.

Discussion: These results represent 111 of the 400 patients randomized under an IDE protocol for the treatment of symptomatic lumbar single level DDD. These initial results from four study sites show that the FlexiCore® compares favorably to circumferential fusion in such treatment.

Session IV - Nucleus Replacement and Other

65. Two Year Interim European Clinical Results of Nucleus Replacement Using an In Situ Cured, Balloon Contained, Injectable Polyurethane Device

J. Sherman1, P. Donkersloot2, F. Martens3, M. Ahrens4, H. Halm5, A. Tzantrizos6, H. Yuan7, J. Le Huec7

1Twin Cities Orthopedics, Edina, MN, United States of America, 2Virga Jesse Hospital, Neurosurgery, Hasselt, Belgium, 3OLV Ziekenhuis Hospital, Neurosurgery, Aalst, Belgium, 4Clinic for Spine Surgery & Scoliosis Center, University of Luebeck, Neustadt, Germany, 5Disc Dynamics Inc, Eden Prairie, MN, United States of America, 6Upstate Medical University, Orthopaedic Surgery, Syracuse, United States of America, 7Victor Segalen University, Orthopaedics, Bordeaux, France

Introduction: Nucleus replacement has received renewed interest as a treatment alternative to alleviate discogenic pain. The DASCOR® device is a two-part in situ cured nucleus replacement device designed to alleviate discogenic pain and restore/maintain disc height and segmental mobility in the mild to moderate stages of degenerative disc disease (DDD). The device is made from a two-part in situ cured polyurethane core and an expandable balloon. The liquid polyurethane is implanted under controlled pressure in the expandable balloon using a minimally invasive procedure. The device is a CE Mark approved product. A post-market European study is currently underway. The purpose of this European multi-center prospective, non-randomized, clinical study was to evaluate the interim two-year safety and effectiveness of the DASCOR® device in patients.

Methods: Eight-four eligible patients with mild-moderate single-level DDD, concordant provocation discography, significant back pain, six-month failed non-operative care and no prior fusion surgery were enrolled in the study. A standardized retroperitoneal anterolateral or lateral approach was used for nucleus removal and device implantation. Outcome parameters such as the Oswestry Disability Index (ODI), visual analog scale (VAS), analgesic medication use, and plain film or MRI radiographic assessments were collected preoperatively and throughout the duration of follow-ups. Clinical success was defined as at least a 2 and 15 point decrease in VAS and ODI scores, respectively. A repeated measures ANOVA was used to statistically compare outcomes across follow-up timepoints.

Results: Of the patients implanted (mean age: 39±8yrs; 45 male, 39 female), 67, 50 and 18 patients were followed for 6, 12 and 24 months, respectively with 98% of expected patient visits completed. Eight, 36 and 40 patients were implanted at the L3/4, L4/5, and L5/S1 levels, respectively. Mean operating time and blood loss was 88.6 minutes and 42.0cc, respectively. Mean pre-operative VAS (7.6) and ODI scores (58) improved significantly after 6 weeks (4.0 & 36) and throughout the 2 years (3.1 & 19). Although most patients met the clinical success criteria, patients implanted at the L5/S1 level, compared to those at the L4/5 or L3/4, experienced a more significant decrease in ODI and VAS within the first year. Analgesic medication use decreased dramatically over time, with patients eliminating the use of narcotic analgesics after six weeks and almost all anti-inflammatory drugs after one year. Radiographic results demonstrated, at a minimum, preservation of disc height, lordosis and range of motion, with no significant Modic changes beyond Type I, nor any expulsion.

Conclusions: The two-year clinical experience using the nucleus replacement device demonstrated high clinical-radiographic safety based on significant postoperative pain reduction, functional improvement, and low complication rate. The ability to implant the device using a small annulotomy along with the large contact area for axial load transmission provided by the device is believed to be responsible for the positive results of this study.
66. A Comprehensive Wear Assessment of NUBAC

T. Brown¹, Q. Bao¹, T. Kilpela¹, T. Schwenke², M. Wimmer²

¹Pioneer Surgical Technology, Marquette, MI, United States of America, ²RUSH University Medical Center, Chicago, IL, United States of America

Objective: To provide a comprehensive wear assessment of NUBAC under different motion profiles and environmental conditions.

Methods: Four groups (n=6) of NUBAC devices manufactured from PEEK-OPTIMA (PEEK) were tested on a spine simulator. The implants were submersed in newborn calf serum (20g/l) at 37°±2°C. Group 1 consisted of ±7.5° flexion/extension to 10 million cycles (Mc) followed by ±7.5° lateral-bending to 10 Mc. This sequence was alternated to 40 Mc. Groups 2-4 consisted of ISO/DIS 18192-1 to 10 Mc, except that group 3 incorporated frequency shifting to insure a non-repetitive load and motion profile. Groups 1-3 were exposed to 30 kGy gamma sterilization in air. Group 4 was exposed to the combined effects of 200 kGy followed by simulated aging. The simulated aging process was similar to ASTM F2003-02, which was developed to measure accelerated ageing in UHMWPE packaged in air, except that the aging time was extended from 14 days to 40 days. All studies incorporated a load magnitude of 225-1024 N. The average wear rates were determined using linear regression analysis with significant differences between groups (p<0.05) determined via one-way ANOVA.

Results: Groups 2-3 displayed a wear-in period from 0-1 Mc and groups 2-4 displayed a bimodal wear rate (Figure 1). Therefore, wear rates were calculated from 1-5 Mc and from 5-10 Mc (R²>0.97). For group 1, the wear rate remained consistent at 0.28 mg/Mc from 10-40 Mc. From 1-10 Mc, the wear rate for group 1 was significantly less than all groups with groups 2-4 not significantly different from each other. Except for group 1, all wear rates were seen to decrease after 5 Mc.

Conclusion: The lack of accelerated wear from 10-40 Mc for group 1 suggests that self-mating PEEK does not undergo strain hardening during unidirectional motion. This is different for UHMWPE, which undergoes strain hardening with a significant increase in wear after perpendicular motion². In addition, for metal on UHMWPE it has been reported that frequency shifting can increase the wear several orders of magnitude¹, and accelerated aging of UHMWPE from chain scission via oxidative processes can result in a significant increase in wear⁴. Groups 3 and 4 did not incur a significant increase in their wear rates as compared to group 2, suggesting that self-mating PEEK is insensitive to these wear increasing parameters. The higher wear rates for groups 2-4 as compared to group 1 are expected due to the additional degree of freedom introduced in the motion profile generating longer motion trajectories. Overall, the results of this study suggest that PEEK can be a durable material for the intended application.

References:
3. Nechtow W. 52nd ORS, 0118;

67. Nucleus Pulposus Replacement Material Stiffness Properties Affect Vertebral Body Strains and Remodeling Response

S. Rundell¹, H. Guerin¹, J. Auerbach², S. Kurtz¹

¹Exponent, Inc., Philadelphia, PA, United States of America, ²The University of Pennsylvania, Department of Orthopaedic Surgery, Philadelphia, PA, United States of America

Introduction: Nucleus pulposus replacements (NPRs) are interventional therapies that restore stiffness and height to mildly degenerated intervertebral discs (IVDs). A stiff NPR may induce implant subsidence from overloading of the vertebral body (VB). A less stiff device might unload the central portion of the VB, resulting in alterations in IVD load bearing. The objective of this study was to use a validated finite element (FE) model of a single functional spinal unit (FSU) to evaluate the effects of a range of NPR stiffnesses. We hypothesized that an optimum NPR stiffness would minimize the likelihood of implant subsidence, but also minimize the potential for bony resorption.

Methods: A FE model of an L3-L4 FSU was generated from cadaveric QCT data with bone mineral density-dependent orthotropic material properties. Material properties for the IVD and ligaments were based on published data. Specifically, incompressible fluid elements with a bulk modulus of 1667 MPa were used to simulate the nucleus pulposus (NP). An “intact” model with normal IVD properties was validated against published disc pressures, endplate and cortical strains, and kinematics. The NPR simulations were created by replacing the NP of the intact model with a range of NPR stiffnesses. The NPRs were modeled as linear elastic and nearly incompressible with Young’s moduli of 0.1, 1, 4, and 100 MPa and a Poisson’s ratio of 0.48.
1240 N of axial compression was applied. VB strains and bony remodeling stimulus were reported.

**Results:** L4 VB strains for the physiologic nucleus were under 1%. NPRs with moduli of 0.1 and 1 MPa generated strains above 1% adjacent to the AF. A 4 MPa NPR demonstrated no strains above 1% and was most similar to the physiologic NP. The 100 MPa NPR showed a large region of strains above 1% directly adjacent to the NPR, and a decrease in strains adjacent to the AF as compared to the intact model. Remodeling analysis indicated that a 0.2 MPa NPR would result in bony resorption adjacent to the NPR in the central VB. This was not true for the 1 MPa scenario, but both the 1 MPa and 0.1 MPa NPRs indicated bone growth adjacent to the AF. The 4 MPa NPR showed some bone growth under the NPR while the 100 MPa NPR indicated bone growth throughout the entire central VB with bone resorption at the edges.

**Discussion:** Our results indicate that a modulus of 4 MPa for a nearly incompressible material provides a physiologic response in terms of VB strains. Very soft material resulted in central VB bone resorption, which could lead to implant subsidence and an increase in strains adjacent to the AF. This suggests a transfer of load to the AF, which could hasten DDD. Stiffer materials, while providing load transfer to initiate bone growth under the implant, resulted in higher VB strains, indicating a higher likelihood of implant subsidence from overloading. Thus, NPR material properties have important consequences not only for mechanical device cooperation with surrounding tissues, but also for the remodeling response of those tissues.

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**68. Motion Segment Stiffness and Subsidence with Hydrated and Dehydrated Nucleus Arthroplasty Devices**

_B. Beaubien_¹, _A. Freeman_¹, _S. Seme_²

¹Gustilo Medical Education Center/Midwest Orthopaedic Research Foundation, Minneapolis, MN, United States of America, ²Raymedica, Inc., Minneapolis, MN, United States of America

**Objective:** Hydrogel-based devices represent one type of nucleus arthroplasty (NA) option. Generally, these devices are inserted dehydrated and hydrate over time in vivo. As with any interbody construct, NA devices may introduce the risk for device subsidence. A previous study evaluated isolated endplate-device interface subsidence using hydrated hydrogel-based NA devices ([1] Beaubien, SAS, 2008). The objective of the current study was to assess subsidence of dehydrated NA, hydrated NA (HydraFlex) and interbody (PEEK) devices using an unconstrained spinal motion segment model.

**Methods:** DEXA scans were obtained for nine cadaveric motion segments. Specimens were tested in the intact and denucleated states using a compressive load of 1600 N with flexion/extension and AP translation unconstrained. Motion segments were randomized for implantation of a dehydrated Hydraflex, hydrated Hydraflex or PEEK spacer and testing was repeated. All specimens were then tested to failure in compression using load increments of 200N. Failure testing was performed under fluoroscopic visualization to identify the onset of endplate failure and subsequent catastrophic failure. Load-displacement data was used to calculate the change in disc height at 20N and 1600N.

**Results:** During nucleotomy, an overall median of 3.4cc of material was removed with a corresponding median unloaded loss in disc height of 1.7mm and 2.6mm, for NA and PEEK devices, respectively. Following implantation, the unloaded disc height was restored to within 0.5mm of the intact for the PEEK spacer and hydrated Hydraflex groups; dehydrated devices had the least restoration (Fig.1). Conversely, at 1600N, the compliant hydrated devices showed the least restoration. Fluoroscopy revealed more FSU flexion with increasing compressive load in the NA groups (induced flexion’). On average, the hydrated NA device group had higher subsidence initiation loads, while dehydrated NA device and PEEK spacer groups were generally similar (Table 1).

<table>
<thead>
<tr>
<th>Level Group</th>
<th>DEKA (T Score)</th>
<th>Failure (b)</th>
<th>Failure (b)</th>
<th>Constant Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 L4 PEEK</td>
<td>2.9</td>
<td>3000</td>
<td>5000</td>
<td>Same VR Ir f;</td>
</tr>
<tr>
<td>2 L4 PEEK</td>
<td>3.2</td>
<td>3000</td>
<td>5000</td>
<td>Same VR Ir f;</td>
</tr>
<tr>
<td>3 L4 PEEK</td>
<td>0.9</td>
<td>3500</td>
<td>4500</td>
<td>Inf subsidence;</td>
</tr>
<tr>
<td>4 L4 Hydra</td>
<td>-3.7</td>
<td>3000</td>
<td>3600</td>
<td>Inf subsidence;</td>
</tr>
<tr>
<td>5 L4 Hydra</td>
<td>-0.8</td>
<td>6400</td>
<td>6600</td>
<td>Inf subsidence;</td>
</tr>
<tr>
<td>6 L4 Hydra</td>
<td>0.3</td>
<td>4200°</td>
<td>4400°</td>
<td>VB Fr (Endplate intact to 7th);</td>
</tr>
<tr>
<td>7 L3 Dehydr</td>
<td>-0.5</td>
<td>3400°</td>
<td>460°</td>
<td>VB Fr (Endplate intact to 6th);</td>
</tr>
<tr>
<td>8 L3 Dehydr</td>
<td>1.6</td>
<td>4000</td>
<td>5000</td>
<td>Inf subsidence;</td>
</tr>
<tr>
<td>9 L3 Dehydr</td>
<td>-2.0</td>
<td>2600°</td>
<td>3400°</td>
<td>Inf subsidence;</td>
</tr>
</tbody>
</table>

**Discussion:** Appropriately sized PEEK spacers and hydrated Hydraflex devices approximately restored unloaded disc height whereas dehydrated devices did not. Hydrated Hydraflex devices were compliant under load, which may have allowed high failure loads in spite of low bone density and central positioning. The similarities in device failure load between the PEEK spacer and dehydrated NA device may be related to the clinical intent: PEEK spacers are intended to immediately distract the disc.
space to restore height, while dehydrated NA devices are intended to maintain height at insertion, thereby sharing load with the surrounding annulus [1]. Overall, the dehydrated NA devices showed a subsidence risk similar to the PEEK spacers.

69. Clinical Experience with NUBAC™ Disc Arthroplasty

D. Coric1, H. Yuan2, M. Songer3, K. Davenport4, L. Pimenta4, A. Reyes-Sanchez5, D. Werner6, M. Balsano7, U. Agrillo8, A. Bucciero9, D. Zou10

1Carolina Neurosurgery and Spine, Charlotte, NC, United States of America, 2SUNY Upstate Medical University, Syracuse, NY, United States of America, 3Marquette General Hospital, Marquette, MN, United States of America, 4Santa Rita Hospital, Sao Paulo, Brazil, 5Instituto de Ortopedia, Mexico City, Mexico, 6Arkade Private Hospital, Breitungen, Germany, 7Ospedale di Thiene, Thiene, Italy, 8San Petrini Hospital, Rome, Italy, 9Pineta Grande, Castel Volturno, Italy, 10306 Hospital, Beijing, China

Purpose: While most patients with degenerative disc disease (DDD) can be successfully treated conservatively, patients with disabling low back pain often seek surgery. NUBAC™, a two-piece design with an inner ball and socket articulating joint, manufactured from polyetheretherketone (PEEK), was designed to treat symptomatic discogenic back pain with mild to moderate DDD. This is a prospective, non-randomized study evaluating the worldwide clinical experience with NUBAC using all three surgical approaches; lateral, anterolateral, and posterior.

Methods: NUBAC is indicated for back pain with or without leg pain caused by DDD in patients who have failed conservative care for at least 6 months. Patient pathology and surgeon preference determined which of the three surgical approaches was used to implant NUBAC. A small annulotomy window provides access to the disc followed by a complete nucleotomy and implantation of NUBAC. In this series, the patients were followed at 6 weeks, 3, 6, 12 and 24 months postoperatively. VAS, ODI, SF36 and radiographs were collected at each visit. The data from the patients enrolled between December 2004 and October 2007 are presented.

Results: The NUBAC has been implanted in the lumbar spine of 131 patients with near even distribution between the gender at 135 levels from L2-S1 with more than 90% at L4/5 and L5/S1. Mean age is 40.7 years (21-70). No major intra-operative neurological or vascular complications occurred. The average operating time was 96 minutes and the average EBL was 60 cc. Most patients were discharged from the hospital 1-2 days after the surgery. The clinical results showed that good pain relief was established and maintained from six weeks through 2 years (VAS 78 at baseline to 30, 30, 26, 26 and 23 at 6 weeks, 3, 6 months and 1 and 2 years, respectively). Function using the Oswestry Disability Index questionnaire showed continuous improvement at all visits (53 at baseline to 31, 26, 23 and 10 at 6 weeks, 3, 6 months and 1 and 2 years, respectively). Radiographic examination showed that the index disc height was maintained when comparing the last follow-up disc height to the pre-op disc height.

Conclusions: The data demonstrate that NUBAC is capable of relieving the symptoms of discogenic back pain. This series demonstrated that NUBAC is clinically viable for all three major surgical approaches. The pain relief, improvement in function, lack of intra-operative and postoperative neurological complications and maintenance of the disc height suggested that NUBAC is an alternative to fusion and total disc replacement surgery. From the average OR time, EBL, patient hospital discharge time, and nature of the procedure which does not require large amount of tissue dissection, the NUBAC appears to be less invasive and less bridge-burning than total disc replacement.

70. Hybrid Treatment of DDD with the PDN-SOLO Device Combined with Suture Anchorage and Interspinous Ligamentoplasty

A. Reyes-Sanchez

1Instituto Nacional de Rehabilitación, Orthopaedics, Mexico D.F., Mexico

Objectives: One of the clinical goals of nucleus replacement is the prevention of post discectomy disc collapse with subsequent pain. The PDN-SOLO device was developed with these goals in mind but suffered an approximate 10% incidence of device migration. Taking into consideration total column support, the use of an interspinous ligamentoplasty was used for posterior column stability. However, imaging out to 7 years using ligamentoplasty alone indicates an overall disc height loss of approximately 50%. We hoped to positively affect these events with the addition of suture anchorage and ligamentoplasty. This study was undertaken to use this combined approach to address both anterior and posterior column support in an effort to improve segmental stability and restore disc function. With the addition of these two modalities the PDN-SOLO device migration rate is null.

Material and methods: Nineteen patients with degenerative disc disease were selected from the population of the National Rehabilitation Institute. All patients meeting the inclusion criteria have completed a minimum of 24 month follow-up. Using suture anchors (Smith & Nephew, London, UK), all patients had suture placed through the lateral edges of the device jacket taking care not to damage it. With the aid of fluoroscopy, the screw anchor was positioned 1 cm from the anterior portion of the cephalad vertebra, with a penetration depth of 5 mm into the endplate. Additionally, an interspinous ligamentoplasty composed of a knitted polyester band (Dallous Prosthesis, Tricomed, S.A., Lodz, Poland) was placed between the spinous processes of the affected disc space. All patients were evaluated using the Oswestry Disability Index (ODI), serial plain x-rays and Magnetic Resonance imaging. Statistical analysis was made using the
72. Identifying Appropriate Interventional Timepoints for Nuclear Pulposus Replacements: Impact of Degeneration-Dependent Mechanical Properties of the Cartilaginous Endplate

H. Guerin\(^1\), J. Heinly\(^1\), J. Auerbach\(^2\), R. Siskey\(^1\), B. Lonner\(^3\), M. Villarraga\(^1\), S. Kurtz\(^1\)

\(^1\)Exponent, Inc., Biomechanics Practice, Philadelphia, PA, United States of America, \(^2\)University of Pennsylvania, Philadelphia, PA, United States of America, \(^3\)NYU/Hospital for Joint Diseases, New York, NY, United States of America

**Objectives:** Appropriate interventional timepoints for nuclear pulposus replacements depend on the mechanical properties of retained tissues and the effect of degeneration on those properties. For instance, understanding endplate (EP) tensile mechanical behavior may help prevent implant subsidence. The EP is loaded in compression as the intervertebral disc (IVD) is compressed, and is likely also to be loaded in direct tension. The fibers of the annulus fibrosus (AF) anchor directly into cartilaginous EP, and are subjected to tension as the IVD is loaded. The AF fibers thus may transfer a tensile stress component directly to the EP. The objective of this study was to measure tensile mechanical properties of human IVD cartilaginous EP and to evaluate the effects of disc degeneration and direction dependence.

**Methods:** Human lumbar spines were obtained under an IRB approved protocol and imaged with MR. Degenerative grade was determined from MR and gross images by two clinicians. Ten samples (n=5 radial and n=5 circumferential) were taken from superior EPs and tested in stress-relaxation using a Bose Enduratec LM1 in a PBS bath at 37±4°C. Strain was applied in 2% increments to 16%, or failure. Equilibrium toe- and linear-region moduli (Etoe and Elin) and transition strain (e*) were calculated from equilibrium stresses and strains. Pearson’s correlation coefficients were calculated between IVD grade and mechanical properties. Paired t-tests assessed the effect of sample orientation (sig. at p<0.05).

**Results:** Gross degenerative grade was 2.8±1.2 and MRI grade was 2.6±0.4. Circumferential properties were: Etoe=7.81±3.45MPa (n=4); Elin=33.3±9.15MPa (n=5); e*=0.04±0.02. Radial: Etoe=0.75±0.77MPa (n=4); Elin=4.11±1.37MPa (n=5); e*=0.05±0.02. The effect of sample orientation was significant for Etoe and Elin. Circumferential Elin decreased significantly with...
Tensile mechanical properties of the cartilaginous EP were degeneration- and direction-dependent. Radial moduli were an order of magnitude less than circumferential. As the fibers of the AF anchor directly into the cartilaginous EP, this direction-dependence may be influenced by AF anisotropy. AF tensile properties are less stiff than the EP properties reported here. Thus, the EP is important to distribution of loads across the bone-IVD interface.

Gross degenerative grade corresponds to a decrease in Elin, which may increase the likelihood of EP fractures. The fact that circumferential modulus decreases with degeneration, but radial modulus does not, indicates a decrease in tissue anisotropy with degeneration. This may affect the ability of the EP to transmit IVD loads, and also predispose it to fracture as degeneration progresses. Understanding EP mechanical property changes in the context of IVD degeneration is important for identifying appropriate interventional timepoints for the success of EP-retaining IVD degeneration therapies.

Acknowledgements: The authors thank Dawn M. Elliott, Ph.D. for her assistance, and Synthes Spine for research grant support.

**Conclusions:**

Etoe showed a similar trend (r=-0.44, ns; Fig. 1).

**Results:**

The grading system used is as follows: grade 0=flat endplate; grade 1=continuous concave slope; grade 2=posterior concavity; grade 3=anterior concavity. In the non-operative group, 410 patients were grade 0-1; 90 were grade 2-3 with 85% of the grade 2-3 changes occurring at L5. In the PDN-SOLO operative group 87 were grade 0-1; 13 were grade 2-3. In the subgroup of grade 2-3 endplate changes, evidence of device migration, subsidence or focal endplate damage was present in 10(76%) of patients. In grade 0-1 patients, device or endplate complications were identified in 5(6%) of patients.

**Conclusion:** Differences in endplate geometry can be categorized and occur naturally in the lumbar spine. Certain patterns particularly at the L5-S1 level may play a role in predicting surgical and clinical success when contemplating a nucleus arthroplasty type procedure.

74. A Finite Element Study of L5-S1 Spinal Biomechanics Comparing Different Surgical Therapies

**Methods:** A 3D nonlinear finite element model of the L5-S1 motion segment was developed. Tissue properties were sourced from the literature. In order to accommodate the nonuniform geometry and lordosis of the L5-S1 disc, fibers were modeled as reinforcement layers (rebars) in surface elements for three annular layers. Careful attention was paid to facet geometry to correctly model its role in segmental biomechanics. The model was validated against in vitro data (L5-S1 range of motion (ROM), center of rotation, facet motion) [Beaubien, SAS, 2007], and published values (intradiscal pressure, axial compressive stiffness, fiber mechanics) [Shirazi-Adl, Spine, 1984]. Surgical therapies were simulated by varying the nucleus space contents as follows: normal segment (fluid-filled), denucleated (empty), nucleus implant (in-situ formed with attention to endplates at L4-5 and L5-S1. A grading system was devised accounting for variations in endplate contour ranging from flat to significant concave deformity. Previously described congenital defects were recognized and excluded from this study. 100 patients implanted with the PDN-SOLO device were reviewed pre and two years post surgery. Outcomes were correlated with endplate geometry as a single variable.

**Results:** The grading system used is as follows: grade 0=flat endplate; grade 1=continuous concave slope; grade 2=posterior concavity; grade 3=anterior concavity. In the non-operative group, 410 patients were grade 0-1; 90 were grade 2-3 with 85% of the grade 2-3 changes occurring at L5. In the PDN-SOLO operative group 87 were grade 0-1; 13 were grade 2-3. In the subgroup of grade 2-3 endplate changes, evidence of device migration, subsidence or focal endplate damage was present in 10(76%) of patients. In grade 0-1 patients, device or endplate complications were identified in 5(6%) of patients.

**Conclusion:** Differences in endplate geometry can be categorized and occur naturally in the lumbar spine. Certain patterns particularly at the L5-S1 level may play a role in predicting surgical and clinical success when contemplating a nucleus arthroplasty type procedure.

**Acknowledgements:** The authors thank Dawn M. Elliott, Ph.D. for her assistance, and Synthes Spine for research grant support.

**73. Endplate Geometry in the Lumbar Spine; A Potential Predictor in Success or Failure for Nucleus Arthroplasty**

**M. Myers**¹, **T. Myers**²

¹Center for Diagnostic Imaging, Twin Cities, MN, United States of America, ²St. Paul Radiology, St. Paul, MN, United States of America

**Purpose:** Disc size and annular competency are important factors to consider when contemplating a nucleoplasty procedure. Little to no attention has been paid to endplate geometry. The purpose of this study is to analyze natural variations in curvature of the endplates at L4-5 and L5-S1 and to determine if any geometries are predictive of outcomes after a disc or nucleuse replacement procedure.

**Methods:** 750 Lumbar MRI’s in patients presenting with back and/or leg pain were retrospectively reviewed with attention to endplates at L4-5 and L5-S1. A grading system was devised accounting for variations in endplate contour ranging from flat to significant concave deformity. Previously described congenital defects were recognized and excluded from this study. 100 patients implanted with the PDN-SOLO device were reviewed pre and two years post surgery. Outcomes were correlated with endplate geometry as a single variable.

**Results:** The grading system used is as follows: grade 0=flat endplate; grade 1=continuous concave slope; grade 2=posterior concavity; grade 3=anterior concavity. In the non-operative group, 410 patients were grade 0-1; 90 were grade 2-3 with 85% of the grade 2-3 changes occurring at L5. In the PDN-SOLO operative group 87 were grade 0-1; 13 were grade 2-3. In the subgroup of grade 2-3 endplate changes, evidence of device migration, subsidence or focal endplate damage was present in 10(76%) of patients. In grade 0-1 patients, device or endplate complications were identified in 5(6%) of patients.

**Conclusion:** Differences in endplate geometry can be categorized and occur naturally in the lumbar spine. Certain patterns particularly at the L5-S1 level may play a role in predicting surgical and clinical success when contemplating a nucleus arthroplasty type procedure.

**Acknowledgements:** The authors thank Dawn M. Elliott, Ph.D. for her assistance, and Synthes Spine for research grant support.

**Figure 1**

74. A Finite Element Study of L5-S1 Spinal Biomechanics Comparing Different Surgical Therapies

**G. Loughran**, **B. Wessman**, **B. Beaubien**, **S. Ainsworth**

¹TranS1, Inc, Wilmington, NC, United States of America, ²Gustilo Medical Education Center, Minneapolis, MN, United States of America

**Objective:** Surgical therapies in the L5-S1 disc space vary in terms of their biomechanical effects. Many finite element models have been developed to help understand the biomechanics of the normal and treated lumbar spine, however few represent the L5-S1 segment due to its complex geometry.

This study evaluates the effect of various surgical therapies on the biomechanics of the L5-S1 spinal segment utilizing a finite element model.

**Methods:** A 3D nonlinear finite element model of the L5-S1 motion segment was developed. Tissue properties were sourced from the literature. In order to accommodate the nonuniform geometry and lordosis of the L5-S1 disc, fibers were modeled as reinforcement layers (rebars) in surface elements for three annular layers. Careful attention was paid to facet geometry to correctly model its role in segmental biomechanics. The model was validated against in vitro data (L5-S1 range of motion (ROM), center of rotation, facet motion) [Beaubien, SAS, 2007], and published values (intradiscal pressure, axial compressive stiffness, fiber mechanics) [Shirazi-Adl, Spine, 1984]. Surgical therapies were simulated by varying the nucleus space contents as follows: normal segment (fluid-filled), denucleated (empty), nucleus implant (in-situ formed with attention to endplates at L4-5 and L5-S1. A grading system was devised accounting for variations in endplate contour ranging from flat to significant concave deformity. Previously described congenital defects were recognized and excluded from this study. 100 patients implanted with the PDN-SOLO device were reviewed pre and two years post surgery. Outcomes were correlated with endplate geometry as a single variable.

**Results:** The grading system used is as follows: grade 0=flat endplate; grade 1=continuous concave slope; grade 2=posterior concavity; grade 3=anterior concavity. In the non-operative group, 410 patients were grade 0-1; 90 were grade 2-3 with 85% of the grade 2-3 changes occurring at L5. In the PDN-SOLO operative group 87 were grade 0-1; 13 were grade 2-3. In the subgroup of grade 2-3 endplate changes, evidence of device migration, subsidence or focal endplate damage was present in 10(76%) of patients. In grade 0-1 patients, device or endplate complications were identified in 5(6%) of patients.

**Conclusion:** Differences in endplate geometry can be categorized and occur naturally in the lumbar spine. Certain patterns particularly at the L5-S1 level may play a role in predicting surgical and clinical success when contemplating a nucleus arthroplasty type procedure.

**Acknowledgements:** The authors thank Dawn M. Elliott, Ph.D. for her assistance, and Synthes Spine for research grant support.

**Figure 1**

73. Endplate Geometry in the Lumbar Spine; A Potential Predictor in Success or Failure for Nucleus Arthroplasty

**M. Myers**, **T. Myers**

¹Center for Diagnostic Imaging, Twin Cities, MN, United States of America, ²St. Paul Radiology, St. Paul, MN, United States of America

**Purpose:** Disc size and annular competency are important factors to consider when contemplating a nucleoplasty procedure. Little to no attention has been paid to endplate geometry. The purpose of this study is to analyze natural variations in curvature of the endplates at L4-5 and L5-S1 and to determine if any geometries are predictive of outcomes after a disc or nucleus replacement procedure.

**Methods:** 750 Lumbar MRI’s in patients presenting with back and/or leg pain were retrospectively reviewed with attention to endplates at L4-5 and L5-S1. A grading system was devised accounting for variations in endplate contour ranging from flat to significant concave deformity. Previously described congenital defects were recognized and excluded from this study. 100 patients implanted with the PDN-SOLO device were reviewed pre and two years post surgery. Outcomes were correlated with endplate geometry as a single variable.

**Results:** The grading system used is as follows: grade 0=flat endplate; grade 1=continuous concave slope; grade 2=posterior concavity; grade 3=anterior concavity. In the non-operative group, 410 patients were grade 0-1; 90 were grade 2-3 with 85% of the grade 2-3 changes occurring at L5. In the PDN-SOLO operative group 87 were grade 0-1; 13 were grade 2-3. In the subgroup of grade 2-3 endplate changes, evidence of device migration, subsidence or focal endplate damage was present in 10(76%) of patients. In grade 0-1 patients, device or endplate complications were identified in 5(6%) of patients.

**Conclusion:** Differences in endplate geometry can be categorized and occur naturally in the lumbar spine. Certain patterns particularly at the L5-S1 level may play a role in predicting surgical and clinical success when contemplating a nucleus arthroplasty type procedure.

**Acknowledgements:** The authors thank Dawn M. Elliott, Ph.D. for her assistance, and Synthes Spine for research grant support.

**Figure 1**
silicone), and developing fusion (simulated cortical bone). All segments were subjected to ±7.5 Nm unconstrained flexion and extension with a 400N preload. Segmental ROM, facet contact stress, and stress distributions in disc tissues were analyzed.

**Results:** Segmental ROM did not change with denucleation compared to normal, slightly decreased with the nucleus implant (13%) and dramatically dropped with the developing fusion (75%). The changes in the maximum facet stresses compared to the normal segment are: 145% increase with denucleation, 32% decrease with developing fusion and 6% increase with the nucleus implant (Fig.1).

The stress distribution in the annulus and endplates indicates that after denucleation, inward annulus bulging provides the main support to the applied loading, creating high stresses in the annulus layers. With a developing fusion, segment stresses are concentrated on the underlying endplate. Nucleus implant placement restores the normal stresses in the annulus and the endplate (Fig.2).

**Conclusions:** In this finite element study, denucleation altered the L5-S1 disc mechanics and more than doubled facet stress compared to the normal disc. A simulated developing fusion resulted in a dramatic reduction in loading of the facet joints, high stresses on the endplates and minimal annulus stresses. The study also predicted that an in-situ formed nucleus implant restores normal stresses in the facet joints and disc tissues.
Session I - Posterior Dynamic Stabilization

75. Lumbar Decompression Followed by Coflex™ Interlaminar Implant vs. Pedicle Screw Posterior Lateral Fusion for Treatment of Stenosis

K. Pettine1, T. Errico2, J. Thalgott3, A. Yeung4, C. Yeung4
1Rocky Mountain Spine Arthroplasty Specialists, Loveland, CO, United States of America, 2NYU Hospital for Joint Diseases, New York, NY, United States of America, 3Center for Diseases and Surgery of the Spine, Las Vegas, NV, United States of America, 4Arizona Institute for Minimally Invasive Spine Care, Phoenix, AZ, United States of America

Purpose: To compare the clinical safety and efficacy of Coflex™ Interlaminar Fixation vs. instrumented fusion following standard decompression for lumbar stenosis.

Methods: A prospective randomized comparison of Coflex vs. fusion from four FDA IDE sites are reported. The study was a 2:1 randomization of Coflex vs. fusion. Every patient underwent a standard one or two level decompression (as determined by the treating surgeon) L2 to L5 followed by placement of a Coflex Interlaminar implant vs. pedicle screw fixation with posterior lateral bone graft. Major inclusion criteria included stenosis at one or two levels between L2 and L5. Leg and back pain longer than 6 months, ODI greater than 40, and VAS greater than 50 (on a 100mm scale). All patients failed conservative treatment including a lumbar E.S.I.. Major exclusion criteria included osteoporosis (T-Score of -1.0) or previous lumbar surgery of any type. FDA clinical success was based on Improvement of at least 15 points in the ODI at 24 months compared to baseline, no reoperations, revisions, removals or supplemental fixation and no major device-related complications. Follow up was completed at 6 weeks, 3 months, 6 months, and one year with physical exam, SF -12, VAS, ODI, and radiographic analysis.

Results: Patients ranged in age from 51-84 (average 64 years). Twenty-one patients were male and eighteen female. Seven of the patients were smokers. BMI ranged from 24-38 (average BMI 29). There were 28 one level surgeries (19 Coflex and 9 Fusion) and 11 two level surgeries (8 Coflex and 3 Fusion). Average pre-op ODI in the Coflex group was 55 (range 40 to 70). Average pre-op ODI in the fusion group was 59 (range 42-72). Post-op ODI in the Coflex group was 10.5 (range 0-40) a 81% improvement. Post-op ODI in the fusion group was 34.8 (range 14-56) a 41% improvement. Pre-op VAS in the Coflex group was 74.2 (range 56-94). Average pre-op VAS in the fusion group was 73.5 (range 64-90). Post-op VAS in the Coflex group was 15.2 (range 0-68) a 80% improvement. Post-op VAS in the fusion group was 34.2 (range 11-66) a 53% improvement.

Conclusion: Both the Coflex and the fusion groups demonstrated safety with no device related complications and no reoperations or revisions. Both groups showed efficacy with statistical improvement in ODI and VAS at follow up. The subjects randomized to Coflex demonstrated statistical superiority in all clinical measurements compared to fusion.

76. 24-Month Results from a Prospective, Randomized IDE Study of the Dynesys® Dynamic Stabilization System

R. Davis1, J. Sherman2, R. Delamarter3, J. Maxwell4, W. Welch5, J. Wingate6
1Greater Baltimore Medical Center, Baltimore, MD, United States of America, 2Twin Cities Orthopedics, Minneapolis, MN, United States of America, 3The Spine Institute, Santa Monica, CA, United States of America, 4Scottsdale Spine Care, Scottsdale, AZ, United States of America, 5University of Pennsylvania Health System, Philadelphia, PA, United States of America, 6Spine, Warren, MI, United States of America

Objectives: The results of a prospective, randomized IDE study examining dynamic stabilization with the Dynesys® Dynamic Stabilization System are being reported. This study reports the outcomes of 253 patients following dynamic stabilization (DS) and 114 patients treated with posterolateral fusion (PLF) at 28 centers.

Methods: Patients enrolled in this study exhibited lateral or central spinal stenosis, degenerative spondylolisthesis or retrolisthesis (up to Grade I), and were appropriate for instrumented fusion at 1-2 contiguous spinal levels (L1-S1). Participants randomly received treatment with DS or instrumented PLF (2:1 ratio) and were evaluated pre-operatively and post-operatively at 3-weeks, 3-, 6-, 12-, and 24-months.

Results: At 24M, the DS cohort reported 54.8mm improvement in leg pain scores, a reduction in ODI scores of 29.2, 24.8mm improvement in back pain, and 92% of subjects either improved or maintained their level of neurologic success compared to pre-op assessment. In the PLF cohort, leg pain scores improved by 45.8mm, ODI scores were reduced by 24.1, back pain scores improved by 18.8mm, and 84% of subjects reported improved or maintained neurologic success compared to pre-op evaluation. The improvement in leg pain scores reported at 24-months was significantly different between the study groups (p<0.05). Additionally, 24M data shows the SF-12 Physical Component increased significantly from 27.5 (pre-op) to 41.0 (24M) in the DS group and 27.4 to 37.2 in the PLF group (p<0.05). The SF-12 Mental Component increased from 43.7 (pre-op) to 50.4 (24M) in the DS cohort and 42.4 to 50.9 in the control group. In the DS cohort, 28 subjects (11.1%) required a revision surgery and 11 revision surgeries were reported in the PLF cohort (9.6%). Additionally, there were 39 reported intra-operative adverse events reported in the DS group, 34/39 were dural tears.
Conclusions: The 24M clinical shows positive outcomes for patients treated with dynamic stabilization. The subjects implanted with the Dynesys® system show an improvement in back pain, ODI, Neurological Success, and SF-12 scores and a significant improvement in leg pain and SF-12 Physical Component scores.

77. Long Term Follow up of Spinal Process Failure According to Bone Mineral Density in Coflex® Insertion for Lumbar Spinal Stenosis

K. Cho1, S. Lee1, P. Huh1, D. Yoo1, S. Kang1, D. Kim1, C. Park2

1Uijongbu St. Mary’s Hospital, The Catholic Univ.
of Korea, Dept. of Neurosurgery, Seoul, Korea, Republic of, 2Kangnam St.Mary’s Hosp. The Catholic Univ. of Korea, Neurosurgery, Seoul, Korea, Republic of

Introduction: An interspinous process implant has been developed to treat patients suffering from neurogenic intermittent claudication secondary to lumbar spinal stenosis. As most patients who suffer from spinal stenosis are over the age of 60 and may have weaker bones, it is imperative to know how bone mineral density (BMD) correlates with spinous process failure.

Material & methods: We performed 110 cases of Coflex® insertion into lumbar spinal stenosis patients for 3 years retrospectively. Two levels Coflex® insertion was done in 22 patients. Mean follow period was 3.5 years (24 months - 46 months). The small portion of spinous process cortex was removed for Coflex® insertion in our operative procedure. We divided the patients into two groups according to bone mineral density (BMD); BMD equal or more than -2.5 (Group I, N = 45) and less than -2.5 (Group II, N = 55, osteoporosis). Pre & Post-operative back pain VAS score, leg pain VAS score, X-ray, C-T were checked at post operative 6 months, 1 year and 2 years. The spinous process failure defined as in cases of dislodgement of Coflex® and more than 3 mm impaction into spinous process by Coflex® with back pain development at back motion.

Results: Back pain VAS scores were 7.9, 2.4, 2.3 & 2.5 in Group I and 7.8, 2.4, 5.6 & 6.3 in Group II in preoperative, postoperative 6 months, 1 year and 2 years. Leg pain VAS scores were 8.0, 2.4, 2.3 & 2.5 in Group I and 7.9, 2.4, 2.7, & 3.1 in Group II in preoperative, postoperative 6 months, 1 year and 2 years. There were spinous process failure rate 22.2% (10/45) in Group I and 65.5% (36/55) in Group II at postoperative 2 years. In two levels Coflex® insertion cases, spinous process failure rate were 50% (4/8) in Group I and 85.7% (12/14) in Group II at postoperative 2 years.

Conclusion: There was a significant relationship between the BMD and spinous process failure rate. The significant relationship between BMD and spinous process failure load suggests that patients with lower BMD must be approached with caution such as preservation of spinous process cortex during the implant insertion procedure.

Keywords: Spinous process, Lumbar spinal stenosis, Bone mineral density

78. In vivo Deformation, Surface Damage, and Biostability of Polycarbonate-Urethane Spacers from Retrieved Dynesys Systems

A. Ianuzzi1, S. Kurtz1, A. Van Ooij2, R. Bindal2, R. Ross4, R. Bohinski3, W. Kane1, R. Siskey1, P. Shah1, M. Villarraga2

1Exponent, Inc. and Drexel University, Philadelphia, PA, United States of America, 2University Hospital Maastricht, Maastricht, Netherlands, 3Methodist Hospital, Houston, United States of America, 4Hope Hospital, Manchester, United Kingdom, 5Christ Hospital MOB, Cincinnati, OH, United States of America

Introduction: The Dynesys® Dynamic Stabilization System (Zimmer Spine) consists of pedicle screws (Ti alloy), polycarbonate urethane (PCU) spacers, and a polyethylene terephthalate cord. Prior studies investigating in vivo degradation of spacer components demonstrated small changes in surface chemical composition after up to 5.5y implantation (e.g., Trommsdorff et al., SAS, 2004). The objective of the current study was to examine the deformation, wear, and biostability of retrieved PCU components of Dynesys systems.

Methods: Ten retrieved (mean implantation 1.8y, range: 0.7-4.2y; 44 spacers) and two exemplar implant systems were available. Implants from single (n=3) and multi-level (n=7) systems were examined (44 spacers). Reasons for revision were persistent pain (9/10) and screw loosening (7/10), with 1/10 complications of implant migration. PCU spacers are cut at the time of the index surgery, leaving one cut and one molded end. Changes in chemical structure on the cut and molded ends of all PCU spacers were evaluated using attenuated total reflectance (ATR) FTIR. In addition, regions identified as surface damage were examined in 32/44 components. Baseline-corrected peak areas from 1650-1800 cm⁻¹ were determined and normalized relative to the aromatic peak area (509 cm⁻¹). MicroCT (mCT80, Scanco) and scanning electron microscopy (SEM, JSM-6390LV, JEOL) images were obtained on select components for wear evaluations.

Results: Most of the retrieved spacer components exhibited permanent bending deformation (range 0.0-15.8°, mean 4.0°), which was significantly (p=.0014) but weakly (R²=.22) correlated to PCU spacer length. Other common modes of deformation included screw indentation on spacer ends (43/44 spacers) or cord imprints around the center opening (42/44 spacers). In vivo fracture or cracking of the spacers (confirmed with microCT and SEM) were rare damage modes (2/44 spacers) unrelated to clinical reason for device removal. A focal region of abrasive wear was observed along the length of 27/44 spacers (likely from impingement with surrounding bony structures). Significant (ANOVA, p<.05) decreases in ATR-FTIR peak areas were observed in damaged regions compared to cut and molded ends (1698 and 1740 cm⁻¹) and compared to exemplars (1698 cm⁻¹). However, increased peaks associated with degradation products of PCU (Christenson et al., J Biomed Mater
Res, 2004) were observed in only along the sides of two spacers from a single patient (4.2y implantation). **Discussion:** PCU spacers from retrieved Dynesys systems exhibited permanent deformation and, in some cases, focal regions of in vivo wear and surface damage. We found evidence of contact of the PCU spacer with the titanium screws, cord, and adjacent bone. In the current study, chemical changes associated with biodegradation of PCU were only detected on the side surface of 2/44 spacers, where the spacer would be in contact with tissue. All implants were revised for clinical reasons unrelated to wear, surface damage, or biostability. Thus, our observations after short-term revision were judged incidental and of limited clinical relevance for these retrievals. Longer-term retrievals are needed to provide greater context for the clinical implications of our short-term observations.

### 79. A Quantitative Radiographic Analysis of a Posterior Dynamic Stabilization System: Dynamic Parameters and Maintenance of Segmental Disc Height and Lordosis


1University of Pennsylvania Health System, Philadelphia, PA, United States of America, 2Greater Baltimore Medical Center, Baltimore, MD, United States of America, 3Twin Cities Orthopedics, Minneapolis, MN, United States of America, 4The Spine Institute, Santa Monica, CA, United States of America, 5Spine, Warren, MI, United States of America, 6University of Pittsburgh Medical Center, Pittsburgh, PA, United States of America, 7Scottsdale Spine Care, Scottsdale, AZ, United States of America

**Objectives:** Posterior dynamic stabilization has been used for segmental fixation without fusion. Favorable clinical results have been reported for stenosis, spondylolisthesis, and recurrent herniation. However, in vivo anatomical characteristics and in situ dynamic parameter characterization following posterior dynamic stabilization is lacking. Concerns have also been raised regarding concomitant changes in disc height, spondylolisthesis, and induction of kyphosis. The purpose of this study is to provide a rigorous, quantitative radiographic analysis of the dynamic parameters and static measurements following treatment with a posterior, dynamic-stabilization system (PDSS).

**Methods:** Radiographs (lateral, flexion/extension) were obtained pre-operatively and at 6-, 12-, and 24-months post-operatively from patients treated with the Dynesys® Dynamic Stabilization System (n=253) or with instrumented, posteriolateral fusion (PLF, n=114). Quantitative assessments of intervertebral rotation, translation, disc height, lordosis, and spondylolisthesis were produced using validated, computer-assisted methods. Analysis included 346 and 134 individual levels (Dynesys® and PLF) between L3-S1.

**Results:** Mean pre-operative rotation was 5.8° (PDSS) and 5.8° (control arm). At 24-months, mean rotation was 2.1° for the PDSS cohort and 1.3° for the PLF cohort across all levels. Relative to pre-operative values for the PDSS cohort, 28.1% to 47.1% of the rotational angle was maintained at 24-months. There was a significant decrease in rotation at all post-operative assessments. Mean pre-operative translation was 1.1mm for both the investigational and control arms across all levels. At 24-months, mean translation was 0.5mm for the PDSS cohort and 0.3mm in the PLF cohort. Pre-operative mean intervertebral lordosis was greater in the investigational arm (9.4°) than control (8.0°) arm and increased with descending segment. Mean lordotic angle was reduced to 8.4° (PDSS) and 6.8° (PLF) at 24-months. There was no instance of segmental kyphotic deformities and 65% of levels showed no change or an increase in lordosis. Mean disc height in the investigational arm was 7.8mm preoperatively and at 24-months. Similarly, mean anterior/posterior disc height changed less than 1mm after 24-months. The PLF arm showed comparable results. At 24-months, mean percent spondylolisthesis changed 1.5% in the PDSS (8.5% to 10.0%) and 0.5% in the PLF (9.6% to 9.1%) cohorts.

**Conclusions:** Preliminary 24-month results show the Dynesys® Dynamic Stabilization System controlled motion in both sagittal rotation and translation. A mean of 28.1% to 47.1% of the pre-operative angular rotation was maintained at 24-months. Translation was controlled in a similar manner. Furthermore, slight changes, if any, were observed in segmental lordosis, disc height, and spondylolisthesis for both cohorts at 24-month. Importantly, there were no kyphotic events in levels treated with the Dynesys® system. In conclusion, the spine segments treated with the Dynesys® Dynamic Stabilization System were successfully stabilized without the need for fusion.

### 80. Assessment of Lumbar Segmental Range of Motion Following Dynamic Stabilization in Comparison to Lumbar Discectomy and to Posterior Fusion with Pedicle Instrumentation

**N. Ordway, S. Park, A. Fayyazi, B. Fredrickson, H. Yuan**

1SUNY Upstate Medical University, Department of Orthopedic Surgery, Syracuse, NY, United States of America

**Introduction:** Lumbar spinal dynamic stabilization systems have been developed as the alternative to lumbar fusion. The proposed advantage of these devices includes the absence of pseudoarthrosis complications, bone graft complication, and the preservation of motion. Biomechanical studies have demonstrated that dynamic stabilization restores the neutral zone and stabilizes the motion segment. These devices decrease the range of motion of the operated segment. Unfortunately, there are limitations to clinical measurement of lumbar motion segment when using routine radiographs. Precise measurement of the lumbar motion segment can be achieved using Radiostereometric Analysis (RSA) which has been shown to be an accurate technique in examining spinal kinematics. The purpose of this study was to measure the sagittal range of motion following dynamic...
stabilization with RSA and compare it to the motion following posterior lumbar fusion and lumbar discectomy.

**Methods:** Following approval by the institutional review board, four patients with lumbar spondylosis at L3/L4, L4/L5 and/or L5/S1 who were treated decompression and dynamic stabilization (Dynesys® Dynamic Stabilization System, Zimmer Spine) were compared with four patients with similar diagnosis that were treated by posterior lumbar fusion and pedicle screw fixation (PLF) and eight patients that had undergone lumbar microdiscectomy for treatment of radiculopathy at either L4/5 or L5/S1. During the surgical procedure, 3 to 5 tantalum beads were placed into each of the operative segments. The patients were followed post-operatively at 1-month, 1-year and 2-year. At each follow up time point, segmental motions (flexion, extension, and total sagittal rotation) were measured using radiostereometric analysis.

**Results:** Flexion, extension, and sagittal rotation were measured at 0.9±0.9°, -1.5±1.3°, and 2.1±1.3° in the Dynesys group, 1.1±1.3°, -1.5±1.6°, and 2.4±1.3° in the PLF group, and 2.8±2.6°, -2.2±1.6°, and 4.7±2.2° in the discectomy group. A significant difference was not seen between the Dynesys and the PLF groups in flexion, extension or sagittal rotation (Figure 1). A significant difference was seen between the Dynesys/PLF groups and discectomy group in sagittal rotation (p=0.002, p=0.046) and between Dynesys and discectomy in flexion (p=0.031). There was no significant change in the range of motion of the groups over time.

**Conclusions:** In this study, a significantly lower amount of motion was seen following dynamic stabilization when compared to discectomy and much less than the normal 10-20 degrees noted in the literature for a normal lumbar segment motion. The average motion following dynamic stabilization was similar to the motion measured following posterior lateral fusion and is similar to the amount of motion seen in previously published biomechanical studies evaluating the segmental motion following dynamic stabilization. In the current study, the motion following dynamic stabilization during sagittal movements may support the premise of dynamic stabilization controlling abnormal motions, although the clinical significance is currently not yet known.

**Dynamic Stabilization Device**


1Spine Surgery PSC, Louisville, KY, United States of America

**Objectives:** Dynesys consists of titanium hydroxyappetite (HA) coated pedicle screws, flexible cord and polycarbonaturethane spacer and has been used off-label as a dynamic stabilizer of the lumbar spine. Biomechanical studies reveal motion at the level of Dynesys implantation. The theorized benefit of motion is improved outcomes, fewer returns to the operating room and decreased arthritic change at adjacent motion segments. To this point, no one has published postoperative complications observed when using Dynesys off-label as a motion preservation device. This study reviews the complications and adverse events that occurred in our series of 92 patients in the first 2 years following surgery.

**Methods:** Ninety-two patients underwent implantation of 538 screws from March, 2005 to March, 2007. Patients had 6 to 24 months of follow-up and were seen in the office at 2, 4, 6, 12 and 24 months after surgery. At each visit, AP/Lat lumbar radiographs were taken. Patients with suspicious radiographic findings or clinical symptoms underwent further imaging studies such as MRI, myelogram/CT or discogram. Further treatment was rendered as needed.

**Results:** 18 of the 92 patients (20%) had events leading to revision surgery in 15 patients (16%). Seven complications (39% of complications) were screw loosening seen on x-ray (screw halo sign) which was confirmed with a CT scan. All loose screws were non-HA coated and located at the cephalad or caudal aspect of the construct. There was also association of loosening with thoracolumbar junctional implantation, T score < -1 and implantation into motion segments with advanced (>50%) disc height collapse. Four of seven patients with screw loosening underwent revisions with larger diameter HA coated screws. All four demonstrated significant clinical improvement. One patient developed a screw fracture and required revision. One patient had a pars fracture which has not produced symptoms requiring further surgery. Two patients developed spinal stenosis cephalad to the level of implantation. Both patients had a normal spinal canal at the time of the index procedure and both underwent a decompression and extension of the implantation. Eight patients (44% of complications) underwent revisions and conversions to fusion due to continued low back and leg pain. Two of these patients and two of the seven patients with screw loosening (4% of total patients and 22% of total complications) had developed a deep wound infection and underwent irrigation and debridement with implant removal and conversion to fusion.

**Conclusions:** Posterior dynamic stabilization using the Dynesys system is an effective treatment for multiple degenerative lumbar pathologies. There are a significant number of complications (20% of patients) seen in the 6-24 months following surgery. About 40% of these complications were related to screw loosening. After correcting for loosening, the complication rate is about 12% overall which

![Figure 1](image)
Objective; The authors performed a comparative study of clinical and radiologic results between the conventional and modified surgical techniques for applying an interspinous stabilization device, Coflex®.

Methods: Since Coflex® was introduced in the clinical field, there have been two techniques used for inserting the device: the one, a conventional technique of removing ligaments structure (CT); the other, a modified technique of preserving ligaments and inserting the device far anteriorly (MT). The selection criteria for the procedure were degenerative spinal stenosis with or without mild degree of instability. We assessed the clinical and radiological differences between the two groups. The clinical outcome was assessed using visual analog pain scale (VAS) and Oswestry disability index (ODI). The disc and foraminal heights were measured pre- and postoperatively by observing follow-up radiological images. The rate of surgical complications was also compared.

Results: In CT group, there were 36 patients, in an average age of 66.9 years (range: 33-84). The follow-up period was ranged from 27 to 38 months (mean 32.1 months). In MT group, there were 13 patients, in an average age of 62.6 years (range: 51-81). The mean follow-up period was 12.4 months (range: 11-15). There was statistically significant improvement of back pain VAS, leg pain VAS and ODI score in both groups at the final follow-up. In both group, the mean disc height and the mean foraminal height was significantly increased postoperatively immediately, and MT group showed statistically more significant increase in the two parameters (11.7±4.2→17.4±2.9mm (P=0.042) and 17.4±2.9→22.6±3.4mm (P=0.003), respectively) than in CT group (11.9±3.1→13.8±2.9mm, 19.4±2.7→22.4±3.2mm). However, they returned to the preoperative values at the final follow up in both groups. With regard to the other radiological results at the last follow-up, in CT group the loosening of ISU was observed in 19 cases (46.3%). And the other various radiological abnormalities, such as newly developed or aggravated spondylolisthesis and collapsed disc were also observed at the index levels in 9 patients. However, there was no statistical relationship between the outcome and loosening of device or between the outcome and radiological aggravation (P=0.310). In the meantime, in MT group, the loosening of ISU was observed in 2 cases (15.4%) at the last follow-up. Newly developed spondylolisthesis was observed in only 1 patient. With regard to postoperative complication, a posterior stabilization effects and decrease various device-related complications when used in proper surgical techniques. Further long-term controlled study is needed.

Conclusion: Our results demonstrate that Coflex® may not have long-term effects on the widening of the intervertebral foramen by maintaining an artificial extension of the operated segment, regardless of the techniques used. However, based on our results that there was fewer occurrence of postoperative instability such as spondylolisthesis and surgical complications in MT group, Coflex® may have a posterior stabilization effects and decrease various device-related complications when used in proper surgical techniques. Further long-term controlled study is needed. Acknowledgements: This work was supported by grant No (RO1-2005-000-10116-0) from the Basic Research Program of the Korea Science & Engineering Foundation.
more contraindications for the device, and patients that were eligible for the device. A patient was deemed eligible to receive a device if that patient matched at least one indication and none of the contraindications for a device. Patients eligible to receive all three devices and patients ineligible to receive any of the three devices were also calculated.

**Results:** In patients undergoing lumbar surgery excluding fusion, the percentage of patient who had appropriate indications for an interspinous spacer, facet replacement or PDS was 47%, 48%, and 47% respectively. 33% of patients had one or more contraindications for an interspinous spacer, 28% of patients had at least one contraindication for a facet replacement, and 31% of patients had contraindications for PDS. The average number of contraindications for the interspinous device, facet replacement, and PDS was 1.27, 1.25, and 1.29 respectively. 25% of patients were eligible to receive an interspinous spacer, 26% were eligible to undergo facet replacement, and 27% were eligible to receive PDS. 25% of patients were eligible to receive all three devices while 73% were not eligible to receive any of the devices.

In patients undergoing lumbar fusions, the percentage of patient who had appropriate indications for an interspinous spacer, facet replacement, or PDS was 84%, 84%, and 89% respectively. 71% of patients had one or more contraindications for an interspinous spacer, 63% of patients had contraindications for a facet replacement, and 62% of patients had contraindications for PDS. The average number of contraindications for the interspinous device, facet replacement, and PDS was 1.51, 1.36, and 1.39 respectively. 22% of patients were eligible to receive an interspinous spacer, 30% were eligible to undergo facet replacement, and 34% were eligible to receive PDS. 23% were eligible to receive all three devices and 65% were not eligible to receive any of the devices.

**Conclusions:** A significant percentage of patients currently indicated for lumbar surgery are also potentially eligible for nonfusion posterior device implants at our institution. This data suggests that these devices will have a significant impact on spine surgery.

### 84. Clinical Outcome and Survivorship Analysis after X STOP Implantation

**A. Tuschel**\(^1\), **A. Chavanne**\(^2\), **S. Becker**\(^2\), **M. Ogon**\(^2\)

\(^1\)Orthopaedic Hospital Speising, Spine Unit, Vienna, Austria, \(^2\)Orthopaedic Hospital Vienna Speising, Spine Unit, Vienna, Austria

**Objectives:** To evaluate implant survivorship and patient-oriented outcome after implantation of the X-STOP interspinous device.

**Methods:** A total of 44 consecutive patients who underwent X-STOP implantation were asked to complete SF-36 and Oswestry Disability Index questionnaires and some additional outcome related questions after a minimum follow-up of 2 years. The data from 33 of these patients, who did not underwent revision surgery and of whom a complete pre- and postoperative dataset was available were analyzed. All 44 cases were used to perform a Kaplan-Meier survivorship analysis.

**Results:** Within the 2-year follow-up period, 9 of 44 (20%) patients required further surgical intervention. At follow-up, mean improvement for lumbar pain (VAS) was 2.6 (p=0.002) and 5.7 (p<0.001) for radiating leg pain. SF-36 PCS improved 11.9 (p<0.001), MCS 4.8 (p=0.17), the Oswestry Disability Index decreased 20.1 points (p<0.001). Mean walking distance increased from 200m to 2600m (p<0.001). All nine patients that required revision surgery showed lack of improvement at 6-week follow up compared to the other group of patients. Kaplan-Meier survivorship analysis predicted a survival probability of 79% for 18 months postoperatively.

**Conclusions:** The results of this study show a relatively high revision rate, the revision peak lies within the first year after surgery and implant survival after the first year correlates with an overall good outcome whereas lack of clinical improvement within 6 weeks postoperatively seems to be a predictor for revision surgery.

### 85. Does an Interspinous Device (COFLEX®) Improve the Outcome of Decompressive Surgery in Lumbar Spinal Stenosis (LSS)? A Prospective Comparison Analysis of 60 Patients

**A. Richter**\(^1\), **C. Schütz**\(^1\), **H. Halm**\(^1\)

\(^1\)Klinikum Neustadt, Klinik für Wirbelsäulenchirurgie, Neustadt in Holstein, Germany

**Objectives:** The uni- or bilateral undercutting decompression is a well established procedure in the operative treatment of a symptomatic LSS. The decompression of the spinal canal and additional implantation of an interspinous device is currently being investigated as a good alternative which might improve the clinical outcome. Clinical comparison trials (prospectiv, randomised) are still missing.

**Methods:** A prospective analysis was performed on 60 patients treated for a one or two level symptomatic LSS with decompressive surgery. Two groups were build. In Group one (UD) we treated 30 patients with decompression surgery alone and in group two (CO) 30 patients got an interspinous device (COFLEX®) additionally implantet. Pre- and postoperatively disability and pain scores were measured using the Oswestry Disability Index (ODI), the Rowland Morris Score (RMS), the Visual Analog Scale (VAS) and the pain free walking distance (WD). The ROM (flexion/extension) of the operated levels was analysed pre- and postoperatively. The patients underwent postoperative assessments 3, 6 and 12 month including the above mentioned scores as well as patient satisfaction. Minimum follow up one year.

**Results:** In the UD-Group the ODI improved from 39,4% to 19,9%, the RMS from 11,4 to 4,7, the VAS from 6,0 to 2,7, the WD raised from 550m to 2400m. Within the CO Group the ODI improved from 47,8% to 19,2%, the RMS from 13,2
to 5.1, the VAS from 6.4 to 2.6, and the WD raised from 280m to 2800m. We couldn’t find any statistic significant differences within both groups. In the CO group two cases had to be re-operated due to implant dislocation and one patient had to be fused. In the UD group one patient had to be fused.

**Conclusions:** In our trial we couldn’t see a benefit in implanting a interspinous device additionally to decompressive surgery in a symptomatic LSS. But limiting in this study is the short follow up of one year and the missing randomization of the patients.

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86. **Long Term Effect of the Intervertebral Dynamic Stabilization as a Protective Technique for Adjacent Levels**

**G. Perrin**, **A. Cristini**

1CHU-Lyon, Hôpital Neurologique P.Wertheimer, Department of Neurosurgery, Lyon, France

**Purpose:** Rigid fusion is often associated with adjacent segment degeneration (ASD). Dynamic stabilization devices have been recently designed to palliate this main drawback, by preventing mechanical failures and stress-shielding phenomena. However, there are few comparative studies available, regarding ASD after rigid fusion versus dynamic stabilization.

The purpose of the current study was to assess the long-term adjacent level degeneration after dynamic stabilization with a hybrid construct, i.e. semi-rigid fusion with dynamic component, and after rigid fusion in two comparable populations.

**Methods:** From 1991 to 1997, 60 consecutive patients underwent lumbar interbody vertebral fusion with posterior fixation for isthmic spondylolisthesis and adjacent pathological but non compressive disk:

- **Group1:** 36 (16 female/20 male) received rigid instrumentation.
- **Group2:** 24 (10 female/14 male) who underwent dynamic stabilization by means of a hybrid, i.e. rigid-and dynamic, construct (Isobar TTL®, Scient’X, France).

Mean age was 32 years [22,51] in Group1 and 29 years [23,47] in Group2. Minimum follow-up was 6 years in both populations (mean= 8.27 years, Max = 13years)

The evaluation criteria were:

- Fusion status (intervertebral bone bridges, absence of intervertebral motion on dynamic X-rays, no vertebral endplate subsidence, no fracture or dismantling of the fixation system)
- Radiological ADS (loss of disc height, loss of intervertebral motion, spontaneous facet fusion)
- Clinical outcome with occurrence of recurrent symptoms and requirement for second surgery with extension of the posterior fixation.

**Results:** No specific complications occurred per-operatively. Post-operative complications occurred in 2 patients with screws or plate breakage in Group 1 versus 0 in Group 2. More than five years after surgery (mean follow-up = 8.27 y.), solid fusion at the treated level was documented in 100% of patients in both groups according to the aforementioned criteria. Radiographic analysis showed ASD in 16 (44.4%) of patients in Group 1 and 1 (4.2%) patient in Group 2. Five patients (13.9%) underwent revision surgery for ASD in Group 1 and none in Group 2.

**Conclusion:** The results of this retrospective analysis show that dynamic stabilization is an efficient procedure for the assessment of lumbar degenerative diseases, while preserving adjacent levels from early degeneration. Indeed, the biomechanical concept of stabilization through load sharing prevents from excessive loading of adjacent segments, often leading to ADS. Besides, a better load sharing pattern results in less mechanical complications such as hardware breakage and bone fractures, mostly due to the neo-hinge phenomenon between a fused spinal segment and an adjacent overstressed and hypermobile intervertebral segment.

Our long term results after dynamic stabilization are most encouraging. However, our findings need to be confirmed through further prospective comparative studies.

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87. **Spinous Process Strength Varies with Axial Loading Direction: Implications for Interspinous Device Design**

**M. Tufaga**, **G. Ortiz**, **J. Buckley**, **J. Lotz**

1University of California, San Francisco, Orthopaedic Surgery, San Francisco, CA, United States of America

**Introduction:** Interspinous implants alter the mechanical demands placed on the spinous process (SP) in vivo. These devices consist of spacers and straps limit relative motion in extension and flexion, respectively, by applying bidirectional axial loading to the SP. Because there has been very little work done to understand the mechanical demands placed on the SP by these devices [Talwar 2007; Shepherd 2000], the goal of this study was to fully characterize the strength of the SP under loads meant to simulate current interspinous products. Our specific aims are to determine whether SP strength depends on 1) axial loading direction, and 2) vertebral bone mineral density (BMD).

**Methods:** Donor-matched pairs of adjacent human thoracolumbar vertebrae (N=4 pairs; T11-L1; 3 male; 48±3 y.o.; DEXA scanned) were harvested from fresh-frozen spines. The anterior portion of the vertebrae was potted in metal cups using bone cement (PMMA) such that transverse processes were completely submerged. One vertebra from each matched pair was potted with the inferior endplate facing the base of the cup, while the other was potted in the opposite orientation.

Specimens were attached to a metal test fixture and mounted beneath the LVDT-instrumented actuator of a hydraulic press (MTS 858) fitted with a tension clamp and a load cell (AMTI MC6-5000). A polyester strap was looped around the SP with the ends securely attached to the clamp. Specimens were preconditioned (10 cycles of 50-100N force at 0.1 Hz) to allow the specimen strap to settle onto the
Conclusions: The results of this study indicate that SP strength differs substantially depending on the direction of the axial loading. Superior-directed loading (extension with Wallis® and XStop® devices) is associated with lower strength than inferior loading (flexion with Wallis® device). This asymmetry may be attributed to the concavity on the inferior rim of the SP, which can act as a site of crack initiation under superior-directed axial loads. Our finding that SP strength does not correlate with BMD may be a result of the low sample size used in this study or it could reflect the fact that BMD is preferentially lost in the centrum relative to the posterior elements. Future work will expand the sample size used in this study, and these will be useful in evaluating the safety of current and proposed interspinous products.

88. 1 Year Follow-Up after Insertion of a Minimally Invasive Self Locking Interspinous Implant. Clinical Results and CT Measurements of Foramen Size

M. Szpalski1, J. Pienazek2, R. Guenzburg3, L. Ciupik4

Iris South Teaching Hospitals, Orthopedics, Brussels, Belgium, 2Silesian Medical Academy, Neurosurgery, Bytom, Poland, 3Cavell Clinic, Orthopedics, Brussels, Belgium, 4Society for Study and Treatment of Spine, Zielona Gora, Poland

Objectives: Spinal stenosis with neural claudication is a common pathology in the elderly. Studies have shown that the diameter of the spinal canal is further reduced during. Based on those findings interspinous implants that decrease unwanted extension have been proposed. Furthermore interspinous implants have been combined with a tension banding system achieving a stabilization effect with unloading of the disc and facets. Most of those implants require a bilateral approach with partial or total sacrifice of the supraspinous ligament, with a destabilizing effect. Objective of the present study is to evaluate clinical results of a novel interspinous implant inserted unilaterally with total preservation of the supraspinous ligament.

Methods: The implant, the InSwing, is automatically locked and kept in correct position thanks to a system of self opening and self locking wings. Those wings facilitate and guide introduction of the device in the interspinous space. The implant can be used alone as a stopper or with a tension band adding stabilizing effect. In this study implants were used with the added banding. 39 patients are included with a follow-up of at least 1 year. They presented with degenerative spinal disorders with persistent low back pain in 22 cases, associated with lumbar stenosis involving neurogenic claudication in 15. Average age was 62 and there were 24 men and 16 women. All patients had undergone CT scan and standard Xrays, and most MRI, prior to surgery. The 12 last patients did undergo a systematic control CT scan at 6 months in order to measure foramen surface, disc height and dural sac diameter compared to preoperative CTs. Results of foramen sizes are reported here.

Results: There were no clinical device related complications. One partial spinous process fracture was discovered on a control CT scan without complaints from the patient. No implant had to be removed. The back pain average VAS score were 6.4 (± 1.5) before surgery and 2.6 (SD ± 1.2) at 1 year (Student test: p=0.01). 12 patients out of the 15 with neurogenic claudication reported an increase of walking perimeter. 82% of patients had an improvement of at least 30% on VAS. Correct lordosis was maintained in most patients. The CT scans showed an average increase of the size of foramen of 16%. Diameter of the dural sac also showed increase.

Discussion: The real place of interspinous implants is still discussed and more control studies are needed to clarify the exact indications. However in a stenosis case with positional claudication, an interspinous implant seems to show a good efficacy. Its place in disc and facet disease is still to precise exactly but makes good biomechanical sense. Moreover, those procedures have low invasiveness, are fast and carry a low complication rate. Furthermore, the technique studied here does not “burn any bridges” by respecting a maximum of anatomical structures. Decompression, fusion or arthroplasty can be later performed, just as it would be in a “virgin” spine. Our results confirm other studies showing similar results to more aggressive techniques.

Session II - Posterior Dynamic Stabilization and Lumbar Facet

89. Kinematics of Facet Arthroplasty: A Comparison of L5-S1 and L3-L4 Levels

L. Voronov1, R. Havey1, D. Rosler2, S. Sjovold2, S. Rogers2, G. Carandang3, J. Ochoa3, A. Patwardhan1
1Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, United States of America, 2Archus Orthopedics, Inc., Redmond, WA, United States of America, 3Edward Hines, Jr. VA Hospital, Hines, IL, United States of America
Purpose of the study: Facet arthroplasty is a motion restoring procedure, suggested as an alternative to rigid fixation after facetectomy. While previous studies have reported successful results in reproducing near normal spine kinematics after facet replacement at L4-L5 and L3-L4, there are no data on the viability of facet replacement at the lumbosacral joint. The anatomy of posterior elements and the resulting kinematics at L5-S1 are distinctly different from those at proximal levels, making the task of facet replacement challenging. This study evaluated the kinematics of facet replacement at L5-S1 in comparison to the L3-L4 level.

Methods: Six human cadaveric lumbar spines (L1-S1, 46.7±13.0 years) were tested in the following sequence: (1) intact (L1-S1), (2) complete laminectomy and bilateral facetectomy at L5-S1, and (3) implantation of TFAS-LS™ (Archus Orthopedics) at L5-S1 using pedicle screws. Next, the L5-S1 level was fused using transpedicular rigid fixation and anterior plate and the specimens were retested in the following sequence: (4) L1-L5 (with L5-S1 fusion), (5) bilateral facetectomy of the superior L4 facets, and (6) TFAS-TL™ implantation at L3-L4 using translaminar anchors at L3 and pedicle screw anchors at L4. Specimens were tested in flexion (8Nm), extension (6Nm), lateral bending (LB, ±6Nm), and axial rotation (AR, ±5Nm). A 400N compressive follower preload was applied during the flexion-extension (F-E) tests.

Results: Laminoectomy-facetectomy at L5-S1 significantly increased the L5-S1 angular range of motion (ROM): F-E ROM increased from 15.3±2.9 to 18.7±3.5 degrees (p<0.05), LB from 8.2±1.8 to 9.3±1.6 degrees (p<0.05), and AR from 3.7±2.0 to 5.9±1.8 degrees (p<0.05). TFAS-LS significantly decreased ROM compared to the laminoectomy-facetectomy condition in all tested directions (p<0.05). TFAS-LS restored the L5-S1 ROM to its intact levels in LB and AR (p>0.05). F-E ROM after TFAS-LS implantation (10.1±2.2 degrees) was smaller than the intact value (p<0.05). Bilateral facetectomy of the superior L4 facet significantly increased the L3-L4 ROM in axial rotation from 3.1±1.7 to 6.7±3.1 degrees and in F-E from 9.9±1.6 to 10.6±1.3 (p<0.05), but not in LB (p>0.05). TFAS-TL™ significantly decreased the F-E and AR ROM values compared to the destabilized condition (p<0.05), restoring them to the intact (L3-L4) values (p>0.05). The ROM in LB (10.5±2.0 degrees) after TFAS-TL implantation was maintained at the intact level (p>0.05). The load-displacement curves after TFAS implantation at both operative levels (L3-L4 and L5-S1) were sigmoidal, demonstrating graded resistance to angular displacement in F-E, LB, and AR.

Conclusion: This is the first report on the kinematic assessment of facet arthroplasty at the lumbosacral joint. The TFAS-LS was able to restore stability to the lumbosacral segment after complete laminectomy and bilateral facetectomy, while allowing near normal motions in all planes. While F-E ROM after TFAS-LS implantation was smaller than the intact value, it was within the physiologic norms for L5-S1. Facet arthroplasty at L3-L4 also restored motions to intact values after bilateral facetectomy; this finding is consistent with previous studies. These results demonstrate that TFAS technology can be adapted to the lumbosacral joint and functions just as well as at proximal lumbar levels.

90. Biomechanical In vitro Study of a Novel Minimally Invasive Interspinous Spacer

B. Lazaro¹, L. Brasiliense¹, A. Brantley¹, P. Reyes¹, N. Theodore¹, V. Sonntag¹, N. Crawford¹
¹Barrow Neurological Institute, Spinal Biomechanics, Phoenix, AZ, United States of America

Objectives: The InSpace device (Synthes Spine, Paoli, PA) is a new minimally invasive interspinous spacer (ISS). We sought to evaluate how this device alters lumbar biomechanics through extensive in vitro testing.

Methods: Seven human cadaveric T12-L2 segments were studied (4 male, 3 female; age 36-64 years). Specimens were tested normal and again after inserting the ISS at the L1-L2 motion segment with no alteration to any soft tissues except the interspinous ligament where the device was inserted. Range of motion (ROM), lax zone (LZ), and stiff zone (SZ) were studied during flexion, extension, lateral bending and axial rotation induced using pure moments (7.5 Nm maximum). Instantaneous axis of rotation (helical axis of motion) was measured in 0.5-degree intervals from optical markers during flexion and extension with 400N preload. Foraminal area was measured by inserting quick-setting molding compound in the left neural foramen with the specimen in upright, flexed and extended postures while preloading the spine with 400N, then removing and measuring molds. Facet loads were measured from 8 strain gauges applied to the superior articular processes of L2.

Results: Angular ROM and SZ during extension were significantly reduced after ISS insertion (p less than 0.01); slight reduction also occurred during flexion (p=0.103), while little change was observed during lateral bending or axial rotation (Figure 1). The LZ decreased during flexion-extension, although not significantly; LZ increased during axial rotation after ISS insertion (p=0.012). Foraminal measurements showed a significant (20%) reduction in available area from flexion to extension (p=0.045) in both normal and ISS-implanted cases. However, there was no significant difference in foraminal area available between normal and ISS-implanted conditions (p greater than 0.25). Facet load measurements showed little difference between normal and ISS-implanted cases except during lateral bending. The position of the sagittal plane IAR after ISS implantation was less than 1 mm from the normal position (Figure 2). This displacement was not significant (p greater than 0.18).
Conclusions: The primary effect of the ISS on the natural biomechanics of the spine was reduction of extension. The ISS had little effect on motion in other directions and did not affect the facet loading, available foraminal area, or axis of rotation. This outcome reflects usage of spacers sized to fit snugly but not to distract the spinous processes in neutral posture.

91. The Total Facet Arthroplasty System® (TFAS®) in the Treatment of Lumbar Stenosis. Medium Term Clinical Results on 20 Cases
R. Prejbeanu¹, I. Branea¹, D. Vercesan¹, H. Vercesan¹, D. Poenaru¹, S. Webb²
¹Spitalul Clinic Judetean De Urgenta Timisoara, Timisoara, Romania, ²Florida Spine Institute, Clearwater, FL, United States of America

Purpose: The current standard of care in the surgical treatment of moderate to severe degenerative lumbar spinal stenosis is decompression and instrumented fusion. Non-union, iliac crest donor site morbidity and adjacent level degeneration due to load transfer are some of the potential complications that can result from fusion in these patients. The Total Facet Arthroplasty System (TFAS, Archus Orthopedics, Redmond, WA) is a motion-restoring articulating facet joint prosthesis designed to restore the spinal biomechanics and stabilize the motion segment after wide neural decompression and facetectomy. This report documents the results obtained after the first implantations.

Methods: Twenty patients were implanted with TFAS and followed in this prospective clinical trial. Surgery consisted of a standard midline approach, single or multiple level decompression and bilateral facetectomy at a single level chosen for stabilization with TFAS. The patients were followed prospectively at 1, 3, 6, 12, 24 and 30 months. Clinical evaluation included the Zurich Claudication Questionnaire (ZCQ) and Visual Analogic Scale (VAS). Radiographic evaluation consisted in AP, lateral, flexion and extension radiographs to evaluate device and ROM.

Results: The average age was 57.1, range 48-78. One patient expired due to pulmonary embolism at 14 days postoperatively. Follow-up was 24-30 months for 13 patients. The shortest follow up was 12 months, with the mean at 21.9 months. Device was intact in all patients at the end of follow-up with evident ROM. Seventeen patients had improved ZCQ symptom and function scores with significant improvement of more than 1.4 with at least 0.5 improvement in 16 patients. Leg pain VAS scores improved in all patients (mean 4.2 points). VAS back pain scores improved in 15 patients (mean 4.3 points). Two patients suffered deep infections which resolved after surgical debridement and antibiotic therapy.

Conclusion: The results obtained after a significant follow-up are very encouraging, with no device failures and significant improvement in pain status and function scores. The less expected decrease in back pain may be explained by the elimination of the pain generators at the facet joint level and to the motion restoring qualities of the TFAS device.

92. Indirect Decompression (X-Stop) versus Conventional Decompressive Surgery for Lumbar Spinal Claudication - A Prospective Randomized Trial
B. Strömqvist¹, S. Berg³, P. Gerdhem³, R. Johnsson¹, A. Möller², T. Sahldstrand³, T. Tullberg²
¹Lund University Hospital, Dept of Orthopedics, Lund, Sweden, ²Stockholm Spine Center, 3Dept of Orthopedics, Upplands Väsby, Sweden, ³Malmö University Hospital, Dept of Orthopedics, Malmö, Sweden
**Introduction:** Although generally successful, decompressive surgery for lumbar spinal claudication has its complications and requires hospitalization and rehabilitation. Zucherman et al have demonstrated X-Stop patients to fare better than patients given conservative treatment in an RCT.

**Aim of the study:** To compare the outcomes in terms of function, quality of life and re-operations after indirect decompression versus conventional decompression for LSC.

**Patients and methods:** Prospective randomized study including patients with central spinal stenosis according to MRI or CT, refractory to conservative treatment and accepting participation in an RCT. Outcome at 6, 12 and 24 months. 50 patients in each group using randomization by envelope. 54 males and 46 females, mean age 70 (45-89) years. Surgical treatment at three spine centres in Sweden. Outcome at 6, 12 and 24 months according to the Zürich Spinal Stenosis questionnaire, SF-36 and the national Swedish register. Registration of re-operations and complications.

**Results:** To date inclusion is complete and 80/100 have passed 6 months follow-up. When spine process fracture has been noted in the X-Stop group and these patients and 13 others have been re-operated in this group compared to 4 in the decompressive group. Follow-up (ITT) demonstrate 6 and 24 month outcomes regarding ZSQ and SF-36 to be similar and significantly improved compared with baseline.

**Conclusion:** Preliminary figures demonstrate that, when successful, X-Stop decompressive surgery may give similar results as decompressive surgery in terms of function and quality of life. An increased rate of secondary surgery is obvious and will be analyzed regarding cause when the follow-up is complete.

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**93. Load-sharing Property of a Posterior Dynamic Stabilization (PDS) Device as Assessed by Disc Pressure Profilometry - A Biomechanical Study in Cadaver Spine**

**H. Fan**, **D. Sengupta**, **J. Park**

1Dartmouth-Hitchcock Medical Center, Orthopedics, Lebanon, NH, United States of America, 2Kwanghye Hospital, Seoul, Korea, Democratic People’s Republic of Korea

**Introduction:** Chronic low back pain in degenerative disc disease of the lumbar spine is thought to be secondary to spinal instability leading to abnormal loading of the disc. The goal of Posterior Dynamic Stabilization (PDS) device is to share the load with the disc and facet joints, while preserving motion. The present study evaluates the load-sharing property of a novel PDS device, BioFlex™, made up of Nitinol or Titanium coil, by Disc Pressure Profilometry (DPP).

**Methods:** Five cadaver lumbar spines (L3-S1) were tested in a six-degrees-of-freedom spine tester. In the first test set-up, the intradiscal pressure (IDP) was recorded from the center of the disc space, by a miniature pressure transducer, during flexion-extension (FE), lateral bending (LB) and rotation (ROT) of the spine. In the second set-up the the pressure profile across the disc space (DPP) was measured using a needle mounted pressure transducer, drawn across the disc space from posterior to anterior direction, keeping the motion segment in fixed in a position of flexion, neutral and extension with axial load or 100N. The specimens were tested in both set-up in the following sequence, intact, following stabilization with PDS-Ni (Nitinol coils), and PDS-Ti (Titanium coils) applied through pedicle screws to the L4-5 motion segment. The data were normalized for comparison.

**Results:** In the first test set-up, the IDP was lowest in neutral position and did rise both in flexion (250±38 KPa) and extension (150±35 KPa), in all the three motion segments. A similar pressure rise was noted in a smaller magnitude in lateral bending (105±27 KPa) and rotation (65±17 KPa). Following stabilization with PDS-Ni, the pressure rise was normal (100%) in flexion, lateral bending and rotation, but ‘zero’ in extension in the stabilized segment. The distal adjacent segment showed normal pressure rise (100%), but in the proximal adjacent segment the pressure rise was much larger (flexion 120%, extension 116%, lateral bending 250%, and rotation 115%). The PDS-Ti, which is a 25% stiffer that the PDS-Ni, had similar effect.

In the second test set-up, the disc pressure profilometry from the intact specimen showed a uniform rise in pressure across the disc space (350±46 KPa). The pressure profile was little higher near posterior annulus in extension and minimal rise near anterior annulus in flexion. Stabilization with both the PDS-Ni and PDS-Ti device reduced the pressure profile across the index disc level in extension (45%) but little effect was noted in neutral and extension.

**Conclusion:** Both the IDP and pressure profile showed that the Posterior Dynamic Stabilization System unloads the disc at the index level, particularly in extension, which may significantly overload the proximal adjacent segment. The stiffness of the device may need to be adjusted, to prevent an extension block, causing excessive unloading in extension.

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**94. A Biomechanical Comparison of Different Spinal Implants: Motion Preventing (Fusion), Motion Preserving (Anatomic Facet Replacement) and Dynamic Stabilization (Dynesys)**


1The University of Toledo, Departments of Bioengineering and Orthopaedic Surgery, Toledo, OH, United States of America, 2Facet Solutions, Logan, OH, United States of America

**Introduction:** Facet arthroplasty, a pedicle screw-based stabilization following decompression, is a newly
developed technology designed for treatment of spinal stenosis and Spondylolisthesis which allows motion close to normal/intact. Unlike spinal fusion, facet arthroplasty is designed to reduce the risk of potential changes to biomechanics of adjacent level; however the literature on biomechanics of motion preservation and dynamic stabilization devices is sparse.

**Objective:** Biomechanics of a rigid posterior screw and rod system, dynamic stabilization with the Dynesys device (Zimmer Orthopedics, Warsaw, IN), and total facet arthroplasty with the Anatomic Facet Replacement System (AFRS™) (Facet Solutions, Inc., Logan, Utah) was compared.

**Methods:** A two part study was undertaken. First, the load-displacement behaviors of both intact spines and those having undergone facet arthroplasty were determined using fresh, ligamentous spines and well established in vitro testing protocols. Next, a finite element (FE) model of the L3-S1 segment was developed to understand the mechanics of facet replacement (Goel et al 2005). The predicted motions were compared with the in vitro cadaver data for both the intact and facet arthroplasty conditions for model validation. Additional models were then created in order to compare the facet arthroplasty condition with both dynamic stabilization and rigid fixation. To simulate facet arthroplasty (FA), the intact FEA model was modified to cause destabilization by removing the facets across the L4-L5, and the facets were replaced with the AFRSTM facet arthroplasty device. To simulate rigid fixation (RF) across the intact L4-L5 segment, a rigid pedicle screw and rod implant was added, bilaterally. Likewise, to simulate dynamic stabilization (DS) across the L4-L5 segment, the Dynesys system was modeled bilaterally.

**Results:** The predicted ROM from the simulation was in agreement with the cadaver data, both for the intact and FA model. All treatment conditions restored stability at the operated level, but in a significantly different manner. The RF and DS models showed significant reductions in ROM, while the ROM following FA was similar to the intact model predictions. IDP in the RF and DS models was decreased while the IDP for the FA model was similar to that of the intact spine (Figure 1).

**Conclusion:** These data have demonstrated that facet arthroplasty (AFRS) provides restoration of motion while maintaining normal disc pressures at the operated level, just like the intact motion segment, which may reduce the risk of altered biomechanics at adjacent spinal levels.

### Session III - Innovative Technologies

**95. Novel DNA Test for Severe Adolescent Idiopathic Scoliosis- Presymptomatic Prognostic Test Identifies Patients Who Might Benefit from Early Application of Non-Fusion Implants**

*J. Ogilvie*, K. Ward, L. Nelson

1Axial Biotech, Inc., Salt Lake City, UT, United States of America

**Background:** Adolescent idiopathic scoliosis (AIS) shows polygenic, multi-factorial inheritance. Causative gene(s) have not been identified, but using our unique genealogy and high-throughput, gene discovery resources, we have
discovered DNA markers useful for predicting curve progression in AIS.

**Method:** DNA samples and clinical data documenting the progression of scoliosis during adolescence were available for 600 adult AIS patients, collected from spine centers across the United States. 300 subjects had progression to a severe curve as defined using usual clinical criteria; the other 300 had mild or moderate curves at skeletal maturity. Genotypes were obtained for 20 DNA markers previously discovered by our group to have prognostic utility in scoliosis. Genotypes were weighted based on attributable risks derived through logistic regression on an independent sample set. Clinical risk scores (Lonstein/Carlson criteria; JBJS 1984) were estimated based on the subject’s first radiologic evaluation for scoliosis (blinded to the genetic data). Genetic risk scores for each patient were summed and various risk score cutoffs were considered to classify a patient at “HIGH” risk of progression.

**Results:** The DNA markers selected were able to discriminate surgical patients from the patients with mild or moderate scoliosis (p<0.001). The DNA markers were a better predictor of progression risk than the clinical predictors. Optimal test performance was obtained using a 12 marker subset which showed a specificity of 90% and sensitivity of 93%. Continued refinements in the algorithm are likely as additional markers are considered as components of the test panel.

**Conclusion:** The DNA marker panel derived through these experiments is superior to existing prognostic schema for AIS. Additional improvements are likely as we learn more about the genetic loci involved. Eventually, patients with low scores may avoid serial radiologic surveillance. Novel, preemptive care with minimally invasive, non-fusion implants may direct spinal growth in patients at high risk, lessening the need for extensive fusion procedures.

96. A Novel Quantitative Measure of Facet Joint Integrity Using $T_1$rho MRI

J. Auerbach1, C. Wang2, A. Milby3, H. Guerin4, J. Heinly4, B. Lonner5, D. Elliott6, A. Borthakur2

1The University of Pennsylvania, Orthopaedic Surgery, Philadelphia, PA, United States of America, 2The University of Pennsylvania, Department of Radiology, Philadelphia, PA, United States of America, 3The University of Pennsylvania School of Medicine, Philadelphia, PA, United States of America, 4Exponent, Inc., Biomechanics Practice, Philadelphia, PA, United States of America, 5New York University-Hospital for Joint Diseases, Department of Orthopaedic Surgery, New York, NY, United States of America, 6McKay Orthopaedic Laboratories, Department of Orthopaedic Surgery, The University of Pennsylvania, Philadelphia, PA, United States of America

**Introduction:** Advancements in diagnostic methods and biomarkers of facet arthrosis are needed as emerging motion-preserving technologies to treat degenerative spinal conditions continue to develop. Recent clinical and finite elemental model studies suggest that the facet joints experience increased contact forces following lumbar total disc replacement (TDR), and that progressive facet arthrosis may be a source of continued pain post-operatively. Currently there exists no imaging tool that facilitates a quantitative measure of facet articular cartilage integrity. We have recently validated $T_1$rho MRI as a noninvasive, quantitative, highly reproducible biomarker of nucleus pulposus proteoglycan loss and early degenerative disc disease (DDD). 1;2 The purpose of this study was to evaluate the feasibility of using $T_1$rho MRI in vitro to quantify facet arthrosis.

**Methods:** Twenty intact human lumbar facet joints were obtained from an IRB-approved source. First, conventional 1.5Tesla T2-weighted axial images were acquired (slice thickness: 3mm, TE/TR = 75ms/3000ms). Facet degeneration was graded using an integer-based grading scheme from 0 (normal facet joints) to 3 (severe facet arthrosis) by two clinicians using the Weishaupt classification system. 3 Second, multiple axial images were acquired using a $T_1$rho-prepped turbo spin-echo based imaging sequence with the following parameters: 3mm slice thickness, acquisition matrix 256x256, and TE/TR = 14ms/3,000ms with eleven echoes per TR. Spin-lock pulse durations ranged from 1 - 60ms. A single user manually segmented the facet cartilage from each $T_1$rho-weighted image, and the average signal intensity value of the segmentation is then fitted to a decaying exponential equation in order to determine the $T_1$rho value. Bivariate nonparametric correlations between $T_1$rho value and degenerative grade of facet arthrosis were performed. Finally, the inter- and intra-observer reliabilities for $T_1$rho measurements and facet degenerative grading using the Weishaupt scale were calculated.

**Results:** Correlation analysis revealed a significant linear relationship between $T_1$rho and MRI grade of facet degeneration (p=0.46, p=0.03). The intra-observer reliability in selecting the region of facet cartilage for calculating $T_1$rho values was high, with p=0.98, p=0.001. In contrast, the inter-observer reliability using the integer-based grading scale was moderate, with p=0.64, p=0.002, while the kappa values for intra-observer reliability was low, ranging from 0.13-0.19.

**Discussion:** Our previous studies have demonstrated the correlation between $T_1$rho and proteoglycan content in the nucleus, and the ability to use this technique as a noninvasive biomarker for early DDD. The current study demonstrates that $T_1$rho correlates well with clinician grading and suggests the feasibility of using $T_1$rho MRI to provide a quantitative measure of proteoglycan loss and early facet degeneration. Potential advantages of $T_1$rho MRI over ordinal grading scales using CT or T2-weighted MRI include its ability to provide quantitative, highly reproducible, continuous data over a broad dynamic range, and the ability to quantify early subtle changes. $T_1$rho MRI shows promise as a noninvasive, quantitative biomarker of facet joint integrity to study the effects on the facet joints that result from various motion-preserving technologies.

[1] Auerbach, Eur Spine J, 2006;
97. Adipose-Derived Regenerative Cell Transplantation: Evaluating Intervertebral Disc Repair in a Canine Model

H. Meisel1, T. Ganey2, W. Hutton3, R. Schreiber4, M. Hedrick4
1BG Clinic Bergmannstrost, Department of Neurosurgery, Halle, Germany, 2Atlanta Medical Center, Atlanta, GA, United States of America, 3VA Medical Center, Atlanta, GA, United States of America, 4Cytori Therapeutics, San Diego, CA, United States of America

Aims: Adipose tissue provides a source of regenerative cells that can differentiate into a nucleus pulposus-like phenotype when exposed to the appropriate environment (1). To assess the response of such cells to the postsurgical milieu, and to develop a clinical option for cell placement, adipose-derived cells were collected, concentrated, and transplanted, under fluoroscopic guidance, into a surgically damaged disc.

Methods: Following IACUC approval, adipose tissue was harvested from the super-scapular region of the neck (scruff) from 12 skeletally-mature dogs. Fom that tissue the cells were separated, collected, and labeled with DAPI. Three lumbar intervertebral disc levels in each of the 12 dogs underwent a partial nucleotomy. Each of the three levels in each dog then received one of the following interventions: 1) adipose-derived cells in hyaluronic acid (HA) carrier (HA plus Cells); 2) HA alone; 3) No Intervention. All deliveries of cellswere guided by fluoroscopy. Assessments during the course of the next 12 months were made using MRI and radiography. At the end of 12 months the dogs were euthanized and the harvested disc tissue was analyzed using microscopy, RT-PCR, and ELISA.

Results: The implanted cells from the disc tissue that was harvested from the lumbar spine in each dog were viable, at the time of harvest. Matrix composition was assessed; assays were performed for aggrecan, Types I and II collagen by both RT-PCR and ELISA. mRNA and protein from each level are presented with respect to normal values defined as the 100 percent expression (Table 1). Table 2 depicts the relative protein levels as measured by ELISA.

Conclusions: In the discs that received HA plus Cells the cells were viable at the time of harvest, disc morphology was maintained, intervertebral disc height was not lost, and the MRI signal remained similar to native control.

References:

Acknowledgements: Support for this project was made possible by Cytori Therapeutics, San Diego, the Atlanta Medical Center, Atlanta VA Medical Center, and Bergmannstrost Klinik.

98. Prospective, Randomized, Controlled Study of Plasma Disc Decompression Compared to Conservative Care for Treating Symptomatic Contained Cervical Disc Protrusion

A. Cesaroni1, P.V. Nardi1
1Policlinico Casilino, U.O.C. Neruochirurgia, Roma, Italy

Objectives: Spontaneous regression of symptoms associated with contained cervical disc protrusion is likely to occur with appropriate conservative care although patients are often reluctant to wait. A past case series study showed that plasma disc decompression may be an option but a controlled comparison to conservative care (CC) is required to assess its effectiveness. The purpose of this study is to determine whether plasma disc decompression (PDD) in patients presenting with symptomatic contained cervical disc protrusion is associated with significantly improved clinical outcomes during the 6 months following the procedure compared to conservative care (CC).

Methods: This was a prospective, randomized, controlled single-site clinical study. Patients considered for enrollment were 18-75 years old, herniation-related neck and arm pain, arm pain greater neck pain, reported neck or arm pain ≥50 as measured using a 100-point visual analogue scale (VAS) score, had failed 30 days of conservative care, and had symptomatic focal cervical disc protrusion confirmed by imaging. Patients (n=85) were randomly assigned to receive PDD or continued conservative care. The CC program included transcutaneous electrical stimulation, progressive mobilization of the neck with gradual reduction of collar use, postural rehabilitation, and non-steroidal anti-inflammatory drugs. The PDD was performed using a plasma ablation device (DC SpineWand; ArthroCare Corporation, Austin, TX). Clinical outcomes measures included VAS pain scores (neck/arm), analgesic use, Neck Disability Index (NDI), and quality of life (SF-36).
questionnaire. Outcomes were collected at 6 weeks, 3 and 6 months, and 1 year. To date, 120 patients have been enrolled; these interim results include 85 patients who have currently reached 1 year follow-up. Results for the complete cohort will be presented.

**Results:** Both groups had similar demographics and baseline pain, function, and quality of life scores.

At 6 weeks, PDD patients had significantly greater reduction of neck and arm pain than CC patients (PDD, 26.1±24; CC, 57.2±18; p<0.001); significantly more PDD patients than CC patients (49% vs. 16%; p<0.001) had ceased using analgesics. Improvement in SF-36 scores (role physical, p=0.008; bodily pain, p=0.000; physical component score, p=0.013) was significantly greater in PDD patients than CC patients. For NDI, 70% of PDD patients and 39% of CC patients were classified as having ‘no or mild disability’ (p=0.007). At 1 year, PDD patients had significantly greater reduction in pain (p<0.001) and NDI (p=0.04) scores. At 1 year, the proportion of patients with no pain and using no analgesics was 60% for PDD and 6% for CC (p<0.001). At 1 year, PDD patients had significantly better physical functioning (p<0.001), role physical (p=0.011), bodily pain, (p=0.039), general health (p=0.013), role emotional (p=0.036), and physical components (p=0.006) scores than CC patients.

**Conclusion:** Plasma disc decompression patients experienced earlier resolution of symptoms and functional improvement and had significantly greater pain relief at 1 year compared to patients continuing with a conservative care regimen.


### 99. Two Levels Presacral Axial Lumbar Interbody Fusion (AxiaLIF). A Prospective 12 Months Follow up: Clinical And Radiological Results

*L. Pimenta¹, C. Arias Pesantes², J. Lhamby³, L. Oliveira³, T. Schaffa², E. Coutinho²*

¹Santa Rita Hospital, Minimally Invasive and Arthroplasty Spine Surgery, Sao Paulo, Brazil, ²Santa Rita Hospital, Spine Surgery, Sao Paulo, Brazil

**Purpose:** Traditional surgical approaches to the lumbosacral spine involve direct exposure to anterior or posterior segments. Both approaches require muscle and ligament dissection, neural retraction, and annular disruption. A less invasive technique has been developed for axial lumbosacral surgery in two levels that preserves the integrity of the annulus. A clinical study was conducted to assess the safety, effectiveness and reproducibility of presacral percutaneous access to the anterior sacrum with insertion of an axially oriented stabilization construct.

**Methods:** A prospective single center clinical trial. 10 patients with a median age of 51.6 years (29-70 y/o) underwent for an axial lumbosacral surgery in two levels. Subjects were evaluated preoperatively and postoperatively at discharge, 1 and 6 weeks, and 3, 6, 12 and 18 months. Analyses consisted of measurement of disc height and fusion using X ray films and CT evaluations by an independent radiologist. Pain assessment was conducted by means of Visual Analog Scale (VAS), Oswestry Questionnaire responses, and through SF-36 Health Survey responses. Fixation of lumbosacral junction was performed through a 14 mm access cannula using an axial presacral approach. Treatment of the patients was facilitated by insertion of an axial interbody fusion construct coupled with osteogenic material and posterior minimally invasive pedicle screw instrumentation.

**Results:** 360 degree minimally invasive stabilization and fusion was accomplished through three small incisions. Mean surgical time was 130.7 minutes. There was minimal post-operative pain. The preoperative mean VAS of 9.2cm (Standard Deviation 0.90) decreased to 2.2cm (Standard Deviation 1.2) at 12 months and decreased 1.1cm ( Standard Deviation 0.8) at 18 months following implantation. The preoperative ODI was 63.3% (Standard Deviation 18.5), and decrease to an average of 17.6% (Standard Deviation 6.5) at 18 months follow up. All data were statistically significant (p<0.05). Six months after surgery the rate of fusion was 60% (6 patients) and at 12 months follow up, the fusion rate increased to 90% (9 patients), and before 18 months the fusion rate increased 100%. The overall satisfaction of patients was 100%.

**Conclusions:** The clinical data to date indicate that subjects being treated with the AxiaLIF two-level device and procedure have on average improved since their pre-treatment condition and that the fusion implant can be safely delivered utilizing the presacral access technique with a minimal blood loss and hospitalization time.

### 100. Navigation-Assisted Fluoroscopy in Minimally Invasive Direct Lateral Interbody Fusion: A Cadaveric Study

*J. Webb¹, G. Regev¹, L. Gottschalk¹, Y. Lee¹, C. Kim¹*

¹University of California, San Diego, CA, Department of Orthopaedic Surgery, San Diego, CA, United States of America

**Purpose:** Improved designs and instrumentation along with expanding experience has brought MIS surgery to the forefront of new spinal technology. Unfortunately, MIS is heavily dependent on intraoperative fluoroscopy for visualization and implant insertion. Increased use of radiation in the operating room significantly increases the surgeon’s exposure to radiation in comparison to other non-surgical procedures. Computer-assisted navigation (NAV) is a potential method of decreasing radiation exposure and improving operating room ergonomics by decreasing the
use of a C-arm and minimizing the need for protective equipment. The direct lateral interbody fusion (DLIF) technique is a new MIS method for MIS anterior lumbar interbody fusion. This study assesses the use of navigation for the DLIF procedure (NAV DLIF). Comparisons of radiation exposure and procedure time using navigation versus standard fluoroscopy were assessed. Accuracy of NAV DLIF using a reference frame mounted in the anterior superior iliac spine (ASIS) is also assessed.

**Methods:** Three fresh whole body cadavers underwent DLIF from T10-L5 using either navigation-assisted fluoroscopy (NAV) or standard fluoroscopy (FLUORO). Radiation exposure to the surgeon and times for specific surgical steps were recorded and compared between each group. One fresh whole body cadaver was used to evaluate the accuracy of the NAV DLIF procedure from L2-3 through L4-5. Accuracy was evaluated by measuring intraoperative deviation from a known marker placed in the vertebral bodies of the lumbar spine and comparing the error found at each level as the surgeon works further from the ASIS tracker.

**Results:** In comparing navigation with standard fluoroscopy for the DLIF procedure, statistically significant differences were obtained for the set-up, approach, diskectomy and total fluoroscopy times. Approach time for the FLUORO group (19.61±2.52 minutes) was higher when compared to the NAV group (15.91±4.08 minutes, p=0.024). Diskectomy time was also significantly longer for the FLUORO group when compared to the NAV group (8.43±1.99 vs 5.98±1.88 minutes, p=0.009). Total fluoroscopy times for the FLUORO group was nearly double times for the NAV group (43.7±16.6 vs 24.0±10.8 seconds, p=0.004). In contrast, the set-up time for the NAV group averaged 5.81±2.65 minutes, which was higher than the FLUORO group that averaged 3.01±0.84 minutes (p=0.005). There was no statistical significance obtained for cage insertion or total operating times. Radiation exposure of the surgeon for the NAV group was undetectable, unlike the radiation exposure for the FLUORO group (1.50±2.81 mREM per level). The accuracy of the NAV DLIF technique were: L2-3 (0.86±0.08 mm), L3-4 (0.97±0.12 mm), L4-5 (0.78±0.33 mm).

**Conclusion:** The use of navigation-assisted fluoroscopy for the minimally invasive DLIF procedure is feasible. Accuracy for this procedure is within 1-2 mm over the most common levels (L2-3 to L4-5) which is likely to be sufficient for safe clinical application. Although initial set-up time is longer with NAV, simultaneous AP and lateral imaging with NAV decreases the time for the approach, guide wire insertion and diskectomy, making overall surgery time similar to that of standard fluoroscopy. Navigation also minimizes radiation exposure to the surgical team and eliminates the need for cumbersome lead protective gear.
102. Oxiplex Intraoperative Surgical Gel: An Adjuvant to Lumbar Disc Surgery for the Reduction of Post Surgical Pain

S. Blumenthal1, Oxiplex Study Group
1Texas Back Institute, Plano, TX, United States of America

Purpose: Postoperative pain following standard lumbar discectomy can be a significant source of morbidity. We performed a prospective, randomized, blinded, parallel group clinical study of 352 patients (Oxiplex treated, N = 177 and surgery only, N = 175) to assess the safety and reduction of neurological sequelae using Oxiplex intraoperative surgical gel (FzioMed, San Luis Obispo, CA) to protect the nerve roots of patients undergoing their first single level laminotomy, laminectomy, or discectomy at L4-L5 or L5-S1.

Methods: Patients were randomly selected to receive surgery only or surgery plus Oxiplex placed on and around the nerve root prior to wound closure. The effectiveness of Oxiplex for the reduction of pain and associated symptoms following single level lumbar discectomy was assessed 6 months following surgery using 1) quality of life measure (Lumbar Spine Outcomes Questionnaire [LSOQ], BenDebba et. al., Spine J. 7:118-132), and 2) clinical evaluations.

Results: The demographics, surgical procedures, baseline LSOQ scores and baseline clinical evaluations were well balanced between the Oxiplex (N=177) and surgery-only (N=175) groups. There were no cases of CSF leaks associated with the Oxiplex treated group. There were no clinically significant differences in laboratory values or vital signs between groups. Subjects treated with Oxiplex were consistently shown to experience greater reductions in back pain and leg pain at 6 months compared to controls, especially in the challenging group with substantial back pain at baseline (statistically significant reduction of back pain \( P=0.0193 \) and leg pain \( P=0.0123 \) in the Oxiplex group compared to the control group). More subjects in the Oxiplex group were satisfied with the outcome of their surgical treatment than subjects in the control group \( P=0.0456 \). Subjects in the Oxiplex group had less hypoaesthesias, paraesthesias, and sensory loss compared to controls. Subjects in the Oxiplex group had fewer reoperations during the 6-month follow-up than subjects in the control group \( 1 \) vs. 6).

Conclusions: The results of this study demonstrate that coating the dura, nerve root and laminotomy site with Oxiplex following lumbar spine surgery is associated with a greater improvement in neurological function and less postoperative pain compared to patients undergoing surgery only. Taken together, these data demonstrate a consistent, clinically significant improvement in outcome with the use of Oxiplex gel in lumbar spine surgery.

103. Novel Minimally Invasive Percutaneous Multilevel 360 Degree Fusion for Lumbar Degenerative Scoliosis - Feasibility, Technique and Early Results

N. Anand1, E. Baron1, T. Thaiyananthan1
1Cedars Sinai Medical Center, Institute for Spinal Disorders, Los Angeles, CA, United States of America

Introduction: Age, co-morbidities and blood loss may be limiting factors when considering traditional surgical correction and fusion for Adult lumbar degenerative scoliosis. Minimally Invasive Spine Surgery has been reported to allow for less blood loss and morbidity. Operative results of Circumferential Minimally invasive spine surgery (MISS) for Adult lumbar degenerative scoliosis have not been reported to date. We study circumferential deformity correction and fusion using a combination of 3 novel MISS techniques.

Methods: 16 patients have had circumferential 360-degree instrumentation and fusion over two or more levels for adult degenerative scoliosis. We report on 12 consecutive patients with minimum 3-month follow-up. Mean number of levels operated was 4.2 (range: 2 - 8). Age range was 50 to 85 years (mean: 72.8 years) with 7 male and 5 females. All patients underwent direct lateral trans-psoas approach (XLIF/DLIF) for discectomy and fusion with PEEK cage and rh-BMP2. All fusions to the sacrum included L5-S1 fusion with the Trans1 AxialLIF technique. Posteriorly, multilevel percutaneous pedicle screws and rods were inserted using the CD Horizon Longitude system. All three of the above procedures were done percutaneously using fluoroscopic guidance. The anterior and posterior procedures were staged with three days in-between when three or more levels were fused. Radiographs, Visual Analog Scores (VAS), and Treatment Intensity Scores (TIS) were assessed preoperatively and at every follow-up visit. Operative times and estimated blood loss (EBL) were recorded.

Results: Mean EBL for anterior procedures (transpsoas discectomy/fusion) was 163.89 cc (SD 105.41) and for posterior percutaneous pedicle screw and rod fixation (and in some cases L5-S1 interbody fusion) was 93.33cc (SD 101.43). Mean surgical time for anterior procedures was 4.01 hours (SD 1.88) and for posterior procedures was 3.99 hours (SD 1.19). Mean Cobb angle preop was 18.93° (SD 10.48) and postop was 6.19° (SD 7.20). Mean preoperative VAS score was 6.8 and TIS score was 54.3. At mean follow-up of 7 months (range: 3 months to 1 year), mean VAS was 2.3; TIS was 22.9. There were no intraoperative complications. Three patients had transient groin pain that...
resolved completely. No patient needed admission to the ICU and no patient needed a blood transfusion. Fusion is progressing satisfactorily with the first five patients showing solid fusion on radiographs and/or CT Scan. Conclusions: A combination of novel minimally invasive techniques have allowed for Multi-segment surgical correction and fusion of Adult lumbar degenerative scoliosis. Our early results show less blood loss and morbidity with satisfactory correction and fusion. The results are very promising and we continue to follow our patients with regards to long-term outcome.

104. Initial Cadaver Evaluation of a Mechanical Nucleus Removal Device
J. Sherman1, C. Horton2, B. Norton2
1Twin Cities Orthopedics, Orthopedic Consultants Division, Edina, MN, United States of America, 2CoreSpine Technologies, LLC, Minneapolis, MN, United States of America

Purpose: A device has been designed for improved nucleus removal to aid in optimum placement and performance of nucleus replacements and other minimally invasive spinal implants. An evaluation of the device’s ability to remove nucleus tissue was performed.

Methods: The device incorporates a rotational shaver that can extend from an articulating tip that can bend over 90º, providing access to the entire nucleus cavity from even a unilateral posterior approach. The device uses a central lumen for aspiration of cut nucleus tissue. The cutting head geometry and related cutting parameters are designed to minimize damage to adjacent annulus and cartilaginous endplate tissue.

Five intervertebral discs (L3 - S1) from three cadaver lumbar spines (mean age = 59yr) were used to evaluate the ability of a prototype device to remove nucleus tissue. The spines were mounted in a frame for unilateral posterior access. Access to the discs was performed via a hemilaminectomy (preserving the facet) and a stab incision through the annulus the full height of the disc. A small amount of nucleus material was removed with an IVD rongeur to create an initial cavity for the prototype device. The prototype device was inserted into the disc space, activated, and manipulated in the nucleus cavity with aspiration for a maximum of 10 minutes. As the prototype device was not designed with an irrigation port, water was occasionally injected into the disc space to hydrate the nucleus and prevent adherence of the cut tissue within the evacuation lumen. The device was occasionally flushed with water to further clear the aspiration tubing. All cut tissue was collected in a filter trap.

The intact discs were dissected, photographed, and analyzed using a visual measurement method. The annulus/nucleus and enucleated cavity borders of each specimen were delineated, then measured with digital video measurement software (Universal Desktop Ruler, avpsoft.com) that converts video pixel count into area after calibration against a known scale. The enucleated cavity area was compared to the total nucleus cavity to calculate a percent of maximum nucleus removed. The results were compared to an earlier nucleus removal study using standard rongeurs in nine lumbar disc levels (Sherman, 2006).

Results: The cavity created by the prototype device averaged 68.2% of the total nucleus area compared to 45.7% using just rongeurs, statistically significant with p < 0.05. An analysis of the material remaining in the quadrant of the disc contralateral to the annulus access showed a 34.0% increase in the cavity with the prototype device compared to standard rongeurs (p = 0.05). Visual examination of the disc cavities enucleated with the prototype device showed no damage to the annulus in any of the specimens, and only minor removal of some the cartilage of the endplates (compared to significant damage to the endplates common in the study using rongeurs).

Conclusions: The prototype device created a larger nucleus cavity than with a rongeur, and damage to the annulus and endplates was minimized. These results will lead to refinements in the device design.
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Poster# Abstract#

P9/#175. Prospective, Randomized, Multicenter FDA IDE Study of CHARITÉ Artificial Disc vs. Lumbar Fusion: Effect at 5-year Follow-up of Prior Surgery on Clinical Outcomes Following Lumbar Arthroplasty
P. McAfee1, R. Banco2, S. Blumenthal3, F. Geisler4, R. Guyer5, R. Holt6, M. Majd5
1Orthopaedics Associates, O’Dea Medical Arts Building, Suite 104, Towsom, MD, United States of America, 2Boston Spine Group, Boston, MA, United States of America, 3Texas Back Institute, Plano, TX, United States of America, 4Illinois Neuro-Spine Center, Aurora, IL, United States of America, 5Spine Surgery PSC, Louisville, KY, United States of America

P10/#183. Prospective, Randomized, Multicenter FDA IDE Study of CHARITÉ Artificial Disc vs. Lumbar Fusion: Comparison of the Clinical Outcome of Patients Implanted at L4-L5 vs. L5-S1
J. Regan1, R. Banco2, S. Blumenthal3, F. Geisler4, R. Holt5, M. Majd5, B. Hetzell6
1Spine Source, Beverly Hills, CA, United States of America, 2Boston Spine Group, Boston, MA, United States of America, 3Texas Back Institute, Plano, TX, United States of America, 4Illinois Neuro-Spine Center, Aurora, IL, United States of America, 5Spine Surgery PSC, Louisville, KY, United States of America, 6Stat Tech Services, Chapel Hill, NC, United States of America

Poster Presentations

LUMBAR TDR

Poster# Abstract#

P1/#440. Why Lumbar Artificial Disc Replacements (A.D.R.) Fail (Home Run or Strike Out)
K. Pettine1, E. Donner1
1Rocky Mountain Spine Arthroplasty Specialists, Loveland, CO, United States of America

P2/#372. Subsidence Resistance Evaluation of Posterior Implanted Total Disc Replacements
F. Phillips1, C. Gordon2, D. Sengupta3, J. Gimbel4
1Rush University Medical Center, Chicago, IL, United States of America, 2Texas Spine & Joint Hospital, Tyler, TX, United States of America, 3Dartmouth-Hitchcock Medical Center, Lebanon, NH, United States of America, 4Orthopaedics Associates, O’Dea Medical Arts Building, Suite 104, Towsom, MD, United States of America

P3/#499. Effect of Previous Surgery on 2-level Surgery Comparing ProDisc-L vs Circumferential Fusion
J. Goldstein1
1NYU Hospital for Joint Diseases, Orthopaedics, New York, NY, United States of America

P4/#41. A Prospective Randomized Study Comparing Cervical Total Disc Replacement to Fusion
R. Guyer1, C. Lauryssen2, C. Idler3
1Texas Back Institute, Plano, TX, United States of America, 2Olympia Medical Center, Beverly Hills, CA, United States of America

P5/#35. Author withdrawn

P6/#338. Clinical Results of NUBAC™ Disc Arthroplasty - Experience with Focus on Posterior Approach
A. Bucciero1, M. Balsano1, U. Agrillo2
1Hospital of Thiene-Schio, Spinal Department, Thiene, Italy, 2Ospedale Sandro Pertini, Rome, Italy

P7/#527. Correlation between Preoperative Disk Height and Outcomes in Total Disk Replacement
M. Wildstein1, J. Zucherman1, K. Hsu1, C. Idler2, M. Hannibal1, D. Kondrashov1
1St Mary’s Spine Center, Spine, San Francisco, CA, United States of America, 2St Mary’s Medical Center, Spine, San Francisco, CA, United States of America

P8/#165. Prospective, Randomized, Multicenter FDA IDE Study of CHARITÉ Artificial Disc vs. Lumbar Fusion: Index- and Adjacent-Level Range of Motion at 5-year Follow-Up
L. Jenis1, R. Banco1, F. Geisler2, R. Holt3, M. Majd3, N. Wharton4
1Boston Spine Group, Boston, MA, United States of America, 2Illinois Neuro-Spine Center, Aurora, IL, United States of America, 3Spine Surgery PSC, Louisville, KY, United States of America, 4Medical Metrics, Houston, TX, United States of America

P11/#7. Analysis of Total Disc Replacement Outcomes When Applying MCID (Minimal Clinically Important Difference) Criteria
D. Ohnmeiss1, R. Guyer2, S. Blumenthal3, S. Hochschuler4
1Texas Back Institute Research Foundation, Plano, TX, United States of America, 2Olympia Medical Center, Beverly Hills, CA, United States of America, 3Texas Back Institute, Plano, TX, United States of America

B. Cunningham1, N. Hu1, J. Kikkawa1, P. McAfee1
1St. Joseph Medical Center, Scoliosis and Spine Center and Orthopaedic Spinal Research Laboratory, Towson, MD, United States of America

P13/#318. Can Preoperative Disc Height Predict Success with Lumbar Total Disc Replacement?
J. Auerbach1, A. Milby2, R. Balderston3
1The University of Pennsylvania, Orthopaedic Surgery, Philadelphia, PA, United States of America, 2The University of Pennsylvania School of Medicine, Philadelphia, PA, United States of America, 3B Orthopaedics, Department of Orthopaedic Surgery, Philadelphia, PA, United States of America
P22/#39. Analysis of Hybrid (Total Disc Replacement / Fusion Constructs) in the Lumbar Spine: A Comparison with Two-Level Total Disc Replacement
S. Blumenthal1, T. Roush2, R. Guyer2, D. Ohnmeiss1
1Texas Back Institute Research Foundation, Plano, TX, United States of America, 2Texas Back Institute, Plano, TX, United States of America

P23/#97. Lumbar Total Disc Replacement with SB Charite III Prosthesis: Chinese Experiences with More than Two Years Follow up
Y. Hai1, Q. Wang1, S. Lu1, Q. Su1, N. Kang1, J. Yang1, L. Guan1, X. Meng1, C. Zhang1
1Capital Medical University, Orthopedic Surgery, Chaoyang Hospital, Beijing, China

P24/#197. Migration of the Tantulum Marker of the Mobidisc: Report of Three Cases
C. Shim1, T. Jung1, G. Choi1, S. Lee1
1Wooridul Spine Hospital, Neurosurgery, Seoul, Korea, Republic of

P25/#377. Comparison of Cobb Technique and Radiostereometric Analysis in Measurement of Segmental Range of Motions Following Lumbar Total Disc Arthroplasty
S. Park1, N. Ordway1, A. Fayyazi1, B. Fredrickson1, H. Yuan1
1SUNY Upstate Medical University, Orthopedic Surgery, Syracuse, NY, United States of America

P26/#418. Mechanical Evaluation of Expulsion Forces for a Novel Polyurethane Spinal Disc Prosthesis in a Simulated Cancellous Bone Model
D. McNally1, M. Cable1, S. Johnson1, A. Roome1
1Ranier Technology Ltd., Cambridge, United Kingdom, 2University of Nottingham, Institute of Biomechanics, Nottingham, United Kingdom

P27/#513. Hybrid Fusion Construct for the Treatment of Symptomatic 2-Level Degenerated Disc Disease Involving the Lower Lumbar Spine
J. Le Huec1, R. Meyrat2, S. Aunoble1
1Bordeaux CHU Hopital Pellegrin Tripode, Spine Unit, Bordeaux, France, 2Methodist Health System, Section of Neurosurgery, Dallas, TX, United States of America

P28/#545. Facet Arthroplasty and Anterior Disc Replacement Combination Restores Normal Segmental Biomechanics and Addresses Several Clinical Issues
V. Goel1, A. Kiapour1, R. Hoy2, H. Chee3, F. Fellenz3
1The University of Toledo, Departments of Bioengineering and Orthopaedic Surgery, Toledo, OH, United States of America, 2Facet Solutions, Inc., Logan, UT, United States of America, 3SpinalKinetics, Sunnyvale, CA, United States of America

P322. Outcomes Analysis Hybrid Arthroplasty: Lumbar Arthroplasty with Stand Alone Lumbar Interbody Fusions
M. Quirino1, P. Pizzino1, R. Verma2, J. Regan3
1NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States, 2Beverly Spine Institute, Beverly Hills, CA, United States of America, 3Pacific Spine Institute, Spine, Beverly Hills, CA, United States of America

P21/#13. Clinically Used Artificial Discs Have a Similar Effect on Lumbar Spine Mechanics
A. Rohmann1, T. Zander1, G. Bergmann1
1Charité Campus Virchow-Klinikum, Biomechanics, Berlin, Germany

P42. Is There a “Euphoric Bias” Effecting the Outcomes of Randomized vs. Non-randomized Patients Enrolling in New Technology Trials?
J. Zigler1, D. Ohnmeiss2
1Texas Back Institute, Plano, TX, United States of America, 2Texas Back Institute Research Foundation, Plano, TX, United States of America

P17/#87. Results with the Charité Disc in Military Personnel
J. Petilon1, J. Roth1, M. Hardenbrook2
1Naval Medical Center, Orthopaedics, Portsmouth, ME, United States of America, 2New England Baptist Hospital, Orthopedics, Boston, MA, United States of America

K. Kafka/hsas1, M. Rauschmann1
1University Clinic Frankfurt, Orthopaedics-Spine Department, Frankfurt/Main, Germany

P16/#42. Is There a “Euphoric Bias” Effecting the Outcomes of Randomized vs. Non-randomized Patients Enrolling in New Technology Trials?
J. Zigler1, D. Ohnmeiss2
1Texas Back Institute, Plano, TX, United States of America, 2Texas Back Institute Research Foundation, Plano, TX, United States of America

P19/#396. Wear Performance of a Metal-On-Metal Lumbar Disc Implant under ASTM, ISO, and Conditions of Daily Living
P. Pare1, F. Chan1
1Medtronic, Memphis, TN, United States of America

P20/#473. Two-Level IDE ProDisc®-L Clinical Trial vs One-Level IDE ProDisc®-L Clinical Trial
J. Goldstein1, R. Delamarter2, J. Zigler3, R. Balderston4
1NYU Hospital for Joint Diseases Spine Center, New York, NY, United States of America, 2The Spine Institute, St John's Hospital, Santa Monica, CA, United States of America, 3Texas Back Institute/Texas Health Research Institute, Plano, TX, United States of America, 4Pennsylvania Hospital, Philadelphia, PA, United States of America, 5NYU/Hospital for Joint Diseases, New York, NY, United States of America

P21/#13. Clinically Used Artificial Discs Have a Similar Effect on Lumbar Spine Mechanics
A. Rohmann1, T. Zander1, G. Bergmann1
1Charité Campus Virchow-Klinikum, Biomechanics, Berlin, Germany

P28/#545. Facet Arthroplasty and Anterior Disc Replacement Combination Restores Normal Segmental Biomechanics and Addresses Several Clinical Issues
V. Goel1, A. Kiapour1, R. Hoy2, H. Chee3, F. Fellenz3
1The University of Toledo, Departments of Bioengineering and Orthopaedic Surgery, Toledo, OH, United States of America, 2Facet Solutions, Inc., Logan, UT, United States of America, 3SpinalKinetics, Sunnyvale, CA, United States of America

P29/#52. FlexiCore Disc Replacement vs. Fusion for Lumbar Degenerative Disc Disease: Pain Relief Results from Four Study Sites
R. Sasso1, M. Hisey2, C. Theoiflos3, A. Araghi4
1Indiana Spine Group, Indianapolis, IN, United States of America, 2Texas Back Institute, Denton, TX, United States of America, 3Jupiter Medical Center, Palm Beach Gardens, FL, United States of America, 4Texas Back Institute, Phoenix, AZ, United States of America
P30/#169. Comparison of Metal-on-Metal to Metal-on-Polyethylene Material Combinations for Lumbar Total Disc Arthroplasty
P. Pare1, M. Wimmer2, T. Schwenke1, F. Chan2
1Rush University Medical Center, Department of Orthopedics, Chicago, IL, United States of America, 2Medtronic, Memphis, TN, United States of America

P31/#188. Author Withdrawn

P32/#271. Changes in Center of Rotation and Facet Loads of the Lumbar Motion Segment Following Total Disc Replacement
S. Jun1, K. Lee2, C. Park3, S. Lee1
1Inje University, Department Of Biomedical Engineering, Gimhae-shi, Korea, Republic of, 2Sejong University, Department of Mechanical Engineering, Seoul, Korea, Republic of, 3Kangnam St.Mary’s Hospital, the Catholic University of Korea, Department of Neurosurgery, Seoul, Korea, Republic of

P33/#320. Outcomes Analysis of Hybrid Disc Arthroplasty
P. Pazmino1, R. Verma2, T. Lanman3, J. Regan4
1Beverly Spine Institute, Beverly Hills, CA, United States of America, 2Beverly Spine Institute, Beverly Hills, CA, United States of America, 3Todd Lanman INC, Beverly Hills, CA, United States of America, 4Pacific Spine Institute, Beverly Hills, CA, United States of America

P34/#337. Hybrid Procedures with Navigated O-MAV™ Artificial Disc Replacement and ALIF in Multi-segmental Osteochondrosis
O. Hausmann1, F. Sgier1
1Hirslanden Klinik St.Anna, Neurosurgery, Lucerne, Switzerland

P35/#385. Two-Level Interbody Fusion from a Less Invasive Lateral Approach (XLIF)
C. Cox1, W. Rodgers2, E. Gerber3
1Spine Midwest, Inc, Jefferson City, MO, United States of America

P36/#436. A Pose-Based Image Analysis Technique for Measuring Wear of Total Disc Replacements
T. D. Brown1, D. Pedersen1, S. Mendoza1, C. Siepe2, H. Mayer2
1University of Iowa, Orthopaedics and Rehabilitation, Iowa City, IA, United States of America, 2Spine Center Munich, Munich, Germany

P37/#484. Activ L vs. Prodisc L: A Comparison Study of Minimum 1-Year Follow-Up
J. Feil1, R. Garcia2, J. Yue3
1ATOS Clinic, Orthopaedic & Spine Surgery, Heidelberg, Germany, 2Orthopaedic Care Center, Spine Surgery, Aventura, FL, United States of America, 3Yale University School of Medicine, New Haven, CT, United States of America

P38/#388. eXtreme Lateral Interbody Fusion (XLIF) in Obese Patients
C. Cox1, W. Rodgers1, E. Gerber1
1Spine Midwest, Inc., Jefferson City, MO, United States of America

P. Pare1, R. Natarajan1, M. Wimmer1, J. Coleman2
1Rush University Medical Center, Department of Orthopedic Surgery, Chicago, IL, United States of America, 2Medtronic, Memphis, TN, United States of America

P40/#476. FlexiCore Disc Replacement vs. Fusion for Lumbar Degenerative Disc Disease: State-of-the-Research and Overall Treatment Success Results from Four Study Sites
T. Errico1, C. Theofilos2, A. Araghi3, J. Zucherman1, R. Sasso4
1NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States of America, 2Spine Center, Palm Beach Gardens, FL, United States of America, 3Surgical Specialty Hospital of Arizona, Phoenix, AZ, United States of America, 4St. Mary’s Center, San Francisco, CA, United States of America, 5Indiana Spine Group, Indianapolis, IN, United States of America

P41/#519. FlexiCore® Disc Replacement vs. Fusion for Lumbar Degenerative Disc Disease: Patient Outcomes from Four Study Sites in a Prospective, Randomized, Multi-center Trial
R. Sasso1, C. Theofilos2, M. Hisey3, A. Araghi4
1Indiana Spine Group, Indianapolis, IN, United States of America, 2University of Pennsylvania, Department of Orthopaedic Surgery, Philadelphia, PA, United States of America, 3Booth, Bartolozzi, Balderston Orthopaedics, Pennsylvania Hospital, Philadelphia, PA, United States of America, 4Texas Back Institute, Phoenix, AZ, United States of America

P42/#395. Effects of TDR Implantation and Positioning on Adjacent Level Facet Forces and Disc Pressures
S. Rundell1, J. Auerbach2, S. Balderston3, K. Kurtz4
1Exponent, Inc., Philadelphia, PA, United States of America, 2The University of Pennsylvania, Department of Orthopaedic Surgery, Philadelphia, PA, United States of America, 3Booth, Bartolozzi, Balderston Orthopaedics, Pennsylvania Hospital, Philadelphia, PA, United States of America

P43/#58. Blood Metal Ion Levels Following Implantation of the All-Metal FlexiCore® Lumbar Intervertebral Disc Replacement
J. Stieber1, T. Errico2, G. Miz3, T. Bauer4, C. Whitaker5, R. Sasso6
1St. Luke’s-Roosevelt Hospital Center, Orthopaedic Surgery, New York, NY, United States of America, 2New York University / Hospital for Joint Diseases, Division of Spine Surgery, Department of Orthopaedic Surgery, New York, NY, United States of America, 3Bone & Joint Orthopaedic Specialists, Oak Lawn, IL, United States of America, 4Cleveland Clinic, Cleveland, OH, United States of America, 5University of Kansas School of Medicine, Orthopaedic Surgery, Kansas City, KS, United States of America, 6Indiana Spine Group, Indianapolis, IN, United States of America
P44/#184. Return to Work and Pain Management after Artificial Disc Replacement vs. Fusion in Single Level Lumbar Disc Disease
R. Verma1, J. Regan2, P. Pazmiño3
1Century City Doctors, Los Angeles, CA, United States of America, 2Spine Source, Beverly Hills, CA, United States of America, 3Pacific Coast Spine Institute, Los Angeles, CA, United States of America

P45/#207. FlexiCore Disc Replacement vs. Fusion for Lumbar Degenerative Disc Disease: Cost-Related Outcomes at Four Study Sites in a Prospective, Randomized, Multicenter Trial
G. Mitz1, G. Tepper2, S. Wolf3, J. Zucherman4
1Bone & Joint Physicians, Oak Lawn, IL, United States of America, 2Miracle Mile Medical Center, Los Angeles, CA, United States of America, 3Orthopedics Institute of PA, Camp Hill, PA, United States of America, 4St. Mary’s Spine Center, San Francisco, CA, United States of America

P46/#347. Prospective Randomized U.S. Trial of Kineflex® vs. Charité® in Lumbar Total Disc Arthroplasty: Minimum One-Year Follow-Up
D. Musante1, D. Coric2, R. Liebelt1, P. Shadduck1, M. Henegar2, F. Finger III3, T. Dimmig4
1Triangle Orthopaedic Associates, Orthopaedic Surgery, Durham, NC, United States of America, 2Carolina Neurosurgery & Spine Associates, Neurological Surgery, Charlotte, NC, United States of America

P47/#398. Adjacent Level Disease in Lumbar Arthroplasty: Comparison between Anterior and Lateral TDR. 12 Months Follow up
L. Pimenta1, C. Arias Pesántez2, L. Oliveira3, L. Juliano3, T. Schaffa4, E. Coutinho5
1Santa Rita Hospital, Minimal Invasive and Arthroplasty Spine Surgery, Sao Paulo, Brazil, 2Santa Rita Hospital, Minimally Invasive and Arthroplasty Spine Surgery, Sao Paulo, Brazil, 3Santa Rita Hospital, Spine Surgery, Sao Paulo, Brazil

P48/#43. Analysis of the Height and Angulation of the L5-S1 Disc Space and the Relationship to Range of Motion and Clinical Outcome in Total Disc Replacement Patients
J. Zigler1, D. Ohnmeiss2
1Texas Back Institute, Plano, TX, United States of America, 2Texas Back Institute Research Foundation, Plano, TX, United States of America

P49/#352. Author withdrawn

P50/#404. Changes in Biomechanics of L3-S1 Spine Following a Novel Anterior Disc Replacement: A FEM Study
A. Kiapour1, V. Goel1, J. Aferzon2, J. Bash3, L. Ferrara4
1The University of Toledo, Bioengineering, Toledo, OH, United States of America, 2University of Connecticut, Department of Neurosurgery, Storrs, CT, United States of America, 3Connecticut Spine Institute, Hartford, CT, United States of America, 4OrthoKinetic Technologies, Southport, CT, United States of America

P51/#130. A New Registry for the Advancement of Arthroplasty: The Center for Arthroplasty Research and Education (CARES)
S. Blumenthal1, F. Bitan2, A. Cappuccino3, F. Geisler4, R. Geyer1, P. McAfee5
1Texas Back Institute, Plano, TX, United States of America, 2Manhattan Orthopaedics - Lenox Hill Hospital, New York, NY, United States of America, 3Buffalo Spine Group, Lockport, NY, United States of America, 4Illinois Neuro-Spine Center, Aurora, IL, United States of America, 5Orthopaedics Associates, Towson, MD, United States of America

1Ranier Technology Limited, Clinical and Regulatory, Cambridge, United Kingdom, 2McGill University, Montreal, Canada, 3University, Bern, Switzerland, 4Southwest Foundation for Biomedical Research, Texas, United States of America, 5University, Aberdeen, Scotland, United Kingdom, 6Ranier Technology Limited, Cambridge, United Kingdom

P53/#431. Finite Element Analysis of Total Disc Replacement Wear
T. D. Brown1, K. Mittelholtz1, D. Pedersen1, S. Mendoza2, H. Mayer1, C. Siepe1, R. Hall6
1University of Iowa, Orthopaedics & Rehabilitation and Biomedical Engineering, Iowa City, IA, United States of America, 2University of Iowa, Orthopaedics & Rehabilitation, Iowa City, IA, United States of America, 3Spine Center Munich, Munich, Germany, 4University of Leeds, School of Mechanical Engineering and School of Medicine, Leeds, United Kingdom

P54/#474. Wearless Total Disc Arthroplasty through Compliant Mechanism Design
P. Halverson1, A. Bowden1, L. Howell7
1Brigham Young University, Mechanical Engineering, Provo, Utah, United States of America

P55/#192. Potential Subsidence of an Artificial Disc Alters Segment Mechanics: A FEM Study
V. Goel1, A. Kiapour1, C.. Lee2, H. Serhan3, N. Ibrahim4, A. Biyani5, D. Mc Gowan4
1The University of Toledo, Departments of Bioengineering and Orthopaedic Surgery, Toledo,OH, United States of America, 2University of Medicine and Dentistry, Newark, NJ, Orthopaedic Surgery, Newark, NJ, United States of America, 3DePuy Spine, Departments of Bioengineering and Orthopaedic Surgery, Boston, MA, United States of America, 4Spine and Orthopedic Surgery Associates, Kearney, MA, United States of America

P56/#200. Artificial Lumbar Disc Replacement in 129 Patients: Early Results and Results of Outcome Analysis with a Mean Follow-Up of 16 M (Range 3 to 48 Months)
T. Kjaer1, L. Klingenberg1, M. Gehrchen1, 1Spine Center, Copenhagen, Hellerup, Denmark
Posters

P66/#59. A Considered Approach to Adhesion Strength Testing of Thin Calcium Phosphate Coatings for Compliant TDR Devices
D. Barnes1, S. Best1, R. Cameron1, S. Johnson2, S. Kimi3, R. Snell1
1University of Cambridge, Department of Materials Science and Metallurgy, Cambridge, United Kingdom
2Ranier Technology Limited, Cambridge, United Kingdom

P65/#355. Core Mobility of Semi-constrained Disc Prosthesis Affects Intervertebral Lumbar Kinematic - In vivo Comparison between Implanted and Untreated Levels
J. Delecrin1, J. Allain2, J.P. Steib3, J. Beaurain4, H. Chataignier5, T. Dufour5, L. Aubourg5, J. Hupert6
1CHU Nantes, Orthopaedic, Nantes, France, 2Henry Mondor, Orthopaedic, Creteil, France, 3CHRU, Spine, Strasbourg, France, 4CHU, Neurosurgery, Dijon, France, 5Clinique St Vincent, Orthopaedic, Besancon, France, 6Neurosurgery, Neurosurgery, Orleans, France, 7LDR Medical, Troyes, France, 8Clinique du Parc, Neurosurgery, St Etienne, France

P64/#351. Limiting TDA Subsidence by Moving the Centroid of the End Plate Closer to the COR
P. McCombe1
1Watkins Medical Centre, Brisbane, Australia

P63/#111. A Simplified Method for Comparing 3D Quality of Motion in vitro
M. Metzger1, O. O'Reilly2, J. Buckley1, F. Acosta3, J. Lotz1
1University of California at San Francisco, Orthopaedic Surgery, San Francisco, CA, United States of America, 2University of California at Berkeley, Mechanical Engineering, Berkeley, CA, United States of America, 3University of California at San Francisco, Neurosurgery, San Francisco, CA, United States of America

P62/#50. Is Degenerative Spondylolisthesis a Contra-Indication for Total Disc Replacement? Kineref Lumbar Disc in Seven Patients with 24 Months Follow-Up
U. Hählenle1, K. Sliwa2, M. De Villiers3, I. Weinberg4, G. Candy5
1University of the Witwatersrand, Orthopaedic Surgery, Johannesburg, South Africa, 2University of the Witwatersrand, Medicine, Johannesburg, South Africa, 3University of Potchefstroom, Mechanical Engineering, Potchefstroom, South Africa, 4Linksfeld Hospital, Neurosurgery, Johannesburg, South Africa, 5University of the Witwatersrand, Surgery, Johannesburg, South Africa

P61/#524. Lumbar Spine Biomechanics Following A Posterior Disc Replacement: A FEM Study
A. Kiapour1, V. Goel1, J. Gerchow2, L. Ferrara3, N. Alleyne4
1The University of Toledo, Departments of Bioengineering and Orthopaedic Surgery, Toledo, OH, United States of America, 2Smart Disc Inc., Allen Park, MI, United States of America, 3OrthoKinetic Technologies, LLC, Southport, NC, United States of America, 4Orthopedic Surgeon, Oceanside, CA, United States of America

P60/#515. Oblique Insertion of Mav Total Lumbar Disc Arthroplasty: Advantages in Avoiding Excessive Retraction of the Great Vessels while Maintaining Accurate Positioning
J. Le Huec1, S. Aunoble1, R. Meyrat2
1Bordeaux CHU Hospital Pellegrin Tripode, Spine Unit, Bordeaux, France, 2Methodist Health System, Section of Neurosurgery, Dallas, TX, United States of America

P59/#362. Biomechanical Analysis of a Disc Prosthesis Distal to a Scoliosis Model
M. Quira1, B. Yaszay1, M. Kang2, A. Valdevit3, T. Errico4
1NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States of America, 2NYU Medical Center, New York, NY, United States of America

P58/#356. Author withdrawn
CERVICAL TDR

**POSTER/# ABSTRACT#**

**P72/#63.** Lower Incidence of Dysphagia with Cervical Arthroplasty compared to ACDF in a Prospective Randomized Clinical Trial

P. McAfee1, B. Cunningham2, F. Phillips3, J. Devine4, A. Cappuccino5, J. Regan6
1St Joes Hospital, Towson, MD, United States of America, 2St Joes, Towson, MD, United States of America, 3Rush Presbyterian, Chicago, IL, United States of America, 4Madigan Army Base, Seattle, WA, United States of America, 5Buffalo Spine Institute, Buffalo, NY, United States of America, 6Cedars Sinai, Los Angeles, CA, United States of America

**P73/#298.** Effects of Total Disc Arthroplasty vs. Fusion on the Mechanics of the Cervical Spine

A. Patwardhan1, M. Lorenz1, M. Zindrick1, M. Tzermiadianos1, L. Voronov2, R. Havey1, G. Gerard2
1Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, United States of America, 2Edward Hines Jr. VA Hospital, Hines, IL, United States of America

**P74/#233.** Is there any Difference between Prodisc-C and Mobi-C Artificial Discs in a Range of Motion Change after Cervical Arthroplasty?: Preliminary Results 1 Year after Surgery

J. Shim1, C. Park1, D. Lee1, D. Kim1, J. Kim1, J. Hwang1
1The Leon Wiltse Memorial Hospital, Neurosurgery, Suwon, Korea, Republic of

**P75/#252.** Cervical Disc Arthroplasty Imparts a More Physiologic Segmental Contribution towards Total Cervical Range of Motion Compared with Fusion

J. Auerbach1, A. Milby2, R. Balderston3
1University of Pennsylvania, Orthopaedic Surgery, Philadelphia, PA, United States of America, 2The University of Pennsylvania School of Medicine, Philadelphia, PA, United States of America, 33B Orthopaedics, Department of Orthopaedic Surgery, Philadelphia, PA, United States of America

**P76/#291.** Are Currently Implanted Cervical TDRs Too Tall? A CT Study

F. Phillips1, L. Pimenta2, A. Ferree3, A. Asher4, B. Ferree3
1Rush University Medical Center, Orthopaedic Surgery, Chicago, IL, United States of America, 2Santa Rita Hospital, Neurosurgery, Sao Paulo, Brazil, 3Mercy Hospital, Cincinnati, OH, United States of America, 4Mercy Hospital, Radiology, Cincinnati, OH, United States of America, 5Mercy Hospital, Orthopaedic Surgery, Cincinnati, OH, United States of America

**POSTER/# ABSTRACT#**

**P77/#304.** Disc Replacement Adjacent to Previous Cervical Fusion: A Biomechanical Comparison of Hybrid Construct vs. Two-level Fusion

M. Lee1, M. Dumonski2, F. Phillips3, G. Carandang3, S. Renner1, R. Havey1, L. Voronov2, A. Patwardhan3
1University of Washington, Orthopaedics and Sports Medicine, Seattle, WA, United States of America, 2Rush University Medical Center, Chicago, IL, United States of America, 3Edward Hines JR VA Medical Center, Hines, IL, United States of America

**P78/#77.** Author withdrawn

**P79/#189.** Serum Metal Levels in Patients with a Titanium Ceramic Composite Metal-on-Metal Cervical Disc Replacements

M. Gornet1, W. Ceola2, A. Skipor2, J. Jacobs3
1The Orthopedic Center of St. Louis, St. Louis, MO, United States of America, 2Springfield Neurological and Spine Institute, Springfield, IL, United States of America, 3Rush University Medical Center, Chicago, IL, United States of America

**P80/#220.** Author withdrawn

**P81/#246.** Radiologically Documented Adjacent Segment Degeneration after Cervical Arthroplasty; Characteristics and Review of Cases

S. Yi1, D. Lee1, P. Ahn1, K. Kim1, H. Shin2, D. Yoon1
1Spine and Spinal Cord Institute, Yonsei University, College of Medicine, Neurosurgery, Seoul, Korea, Republic of, 2Kangbuk Samsung hospital, Neurosurgery, Seoul, Korea, Republic of

**P82/#444.** Author withdrawn

**P83/#494.** Evidence of Lower Adjacent Level Changes after ProDisc-C Compared to ACF

J. Zigler1, R. Delamarter2, M. Janssen3, D. Murrey4
1Texas Back Institute/Texas Health Research Institute, Plano, TX, United States of America, 2The Spine Institute, St John’s Hospital, Santa Monica, CA, United States of America, 3Spine Education and Research Institute, Thornton, CO, United States of America, 4OrthoCarolina Spine Center, Charlotte, NC, United States of America

**P84/#547.** Medical Imaging Characteristics of Silicon Nitride Ceramic: A New Material for Spinal Arthroplasty Implants

J. Bernero1, M. Anderson1, D. Brodke2
1Amedica, Salt Lake City, UT, United States of America, 2University of Utah Hospital and Clinics, Departments of Orthopaedics and Neurosurgery, Salt Lake City, UT, United States of America

**P85/#158.** Minimum 2-Year Follow-up of Postoperative Radiological Changes in Cervical Spine Arthroplasty: Bryan vs. ProDisc-C

C. Park1, K. Ryu1, H. Heo1, S. Lee2, K. Lee3
1The Catholic University of Korea, Neurosurgery, Seoul, Korea, Republic of, 2Inje University, Biomedical Engineering, Kimhaye, Korea, Republic of, 3Sejong University, Bioengineering Research Center, Seoul, Korea, Republic of
P86/#187. 2-Level Cervical Arthroplasty with the Prestige LP Cervical Disc: Early Clinical Results from 5 Centers in a Prospective Randomized IDE trial

T. Lanman1, J. Burkus2, M. Gornet3, B. Gunter4, I. Canavati5
1 California Spine Institute, Beverly Hills, CA, United States of America, 2Hugheston Clinic, Columbus, OH, United States of America, 3The Orthopedic Center of St. Louis, St. Louis, MO, United States of America, 4Columbia Neurosurgical Associates, Columbia, SC, United States of America, 5Fort Wayne Neurological Center, Fort Wayne, IN, United States of America

P87/#216. Author withdrawn

P88/#221. Prospective Randomized Clinical Trial to Compare the Clinical Outcomes of Total Disc Arthroplasty with ACDF in One-level Degenerative Disc Disease of Cervical Spine: Preliminary Results

P. Nunley1, C. Gordon2, A. Jawahar1, E. Kerr1, T. Raabe2, D. Cavanaugh1, M. Russell1, G. Danielson2
1 Spine Institute of Louisiana, Shreveport, LA, United States of America, 2Gordon Spine Associates, Tyler, TX, United States of America

P89/#224. Preliminary Results with Mobi-C Cervical Disc Replacement for One or Two-level Disc Disease from the US FDA Trial

J. Babbitz1, H. Bae1, K. Kim1, L. Kanim1, R. Delamarter1, E. Peng1, J. Spivak1, T. Friesem2, K. Kim3
1 UC Davis, Neurological Surgery, Sacramento, CA, United States of America, 2Spine Research Foundation, The Spine Institute at Saint John’s Health Center, Santa Monica, CA, United States of America

P90/#459. Effect of Intervertebral Disk Height on Post-operative Motion Following Prodisc-C Cervical Disk Replacement

J. Goldstein1, C. Peng1, M. Quirno1, J. Spivak1, J. Bendo1, T. Errico1
1 NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States of America

P91/#467. Analysis of Segmental Post-operative Motion Following Prodisc-C Cervical Disc Replacement

M. Quirno1, M. Cunningham1, J. Bendo1, J. Spivak1, T. Errico1, J. Goldstein1
1 NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States of America

P92/#487. Effect of Intervertebral Disk Height Following Prodisc-C Cervical Disk Replacement on Adjacent Level Post-operative Motion

M. Quirno1, C. Peng1, J. Spivak1, J. Bendo1, J. Goldstein1
1 NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States of America

P93/#74. Prospective Series of 84 Cervical Arthroplasties in 75 Patients Adjacent to Prior Fusions

P. McAfee1, L. Pimenta2, M. Scott Young3, A. Cappuccino4, B. Cunningham5
1 St Josephs Hospital, Towson, MD, United States of America, 2Santa Rita Hospital, Sao Paulo, Brazil, 3Gold Coast Orthopedics, Brisbane, Australia, 4Buffalo Spine, Buffalo, NY, United States of America, 5Spine and Scoliosis Center, Towson, MD, United States of America

P94/#303. Is the Anatomical Midline Marking Technique during Arthroplasty with Prodisc-C as Safe and Reliable as the Standard Fluoroscopically Guided Method? Analysis of Clinical and Radiological Results in a Consecutive Series of 70 Implants

G. Barbagallo1, L. Corbino1, G. Olindo1, N. Platania1, V. Russo1, V. Albanese1
1 Policlinico University Hospital, Department of Neurosurgery, Catania, Italy

P95/#328. Risk Factors for Heterotopic Ossification in Cervical Arthroplasty (Minimum 2-year Follow-up of Bryan Artificial Disc)

H. Shin1, P. Ahn2, D. Lee3, S. Yi3, K. Kim2, D. Yoon2
1 Kangbuk Samsung Hospital, SungkyunKwan University, Neurosurgery, Seoul, Korea, Republic of, 2Spine and Spinal Cord Institute, Yonsei University, College of Medicine, Neurosurgery, Seoul, Korea, Republic of

P96/#540. Placement of Artificial Disc Affects the Biomechanics of the Cervical Spine: A Finite Element Investigation

A. Faizan1, V. Goel1, M. Krishna2, T. Friesem2
1 University of Toledo, Bioengineering, Toledo, OH, United States of America, 2Spine and Scoliosis Center, Towson, MD, United States of America

P97/#103. Biomechanics of Adjacent Level Cervical Disc Arthroplasty and Subsequent Salvage Procedure

B. Santoni1, A. Lyons1, K. McGilvray1, A. Turner2, V. Patel1, C. Puttlitz1
1 Colorado State University, Department of Mechanical Engineering, Fort Collins, CO, United States of America, 2Colorado State University, Department of Clinical Sciences, Fort Collins, CO, United States of America, 3University of Colorado Health Sciences Center, The Spine Center, Aurora, CO, United States of America

P98/#178. The Effect of Prestige LP Cervical Disc Replacement on the Adjacent Level Movements. Functional and Radiological Outcome

A. Kasis1, R. Raju2, T. Friesem3
1 Spinal Unit, University Hospital of North Tees, Stockton-On-Tees, United Kingdom, 2Radiology Department, University Hospital of North Tees, Stockton-On-Tees, United Kingdom, 3Spinal Unit, University Hospital of North Tees, Stockton, United Kingdom
An Analysis of Factors Affecting Sagittal Alignment in Single Level and Multi-level Cervical Disc Arthroplasty
S. Kim1, M. Park1, J. Shin2, J. Arbatin2, K. Chang3, S. Kim4, S. Kwon5
1International Spine Center, Hangang Sacred Heart Hospital, College of Medicine, Hallym University, Department of Orthopaedic Surgery, Hangang Sacred Heart Hospital, College of Medicine, Hallym University, Seoul, Korea, Republic of; 2International Spine Center, Hangang Sacred Heart Hospital, College of Medicine, Hallym University, Seoul, Korea, Republic of; 3University of Toledo, Orthopaedic Surgery, Toledo, OH, United States of America, 4DePuy Spine Inc., Raynham, MA, United States of America, 5Cleveland Clinic Foundation, Neuroscience Institute, Center for Spine Health, Orthopaedic and Neurological Surgery, Cleveland, OH, United States of America

Motion Preservation Using the Discover Total Disc Replacement: Critical Considerations in Disc Sizing and Adjacent Level Surgery
C. Demetropoulos1, E. Francke2, A. Dooris3, H. Serhan4, J. Harm5, H. Herkowitz6
1William Beaumont Hospital, Orthopaedic Research, Royal Oak, MI, United States of America, 2William Beaumont Hospital, Orthopaedic Surgery, Royal Oak, MI, United States of America, 3DePuy Spine, Research and Technology, Raynham, MA, United States of America, 4Klinikum Karlsbad-Langensteinbach Orthopaedics and Spinal Column Surgery, Karlsbad, Germany

Clinical Outcomes from the SECURE-C Cervical Disc IDE: Single-site Experience
J. Marzluff1, J. Highsmith1
1Trident Medical Center, Charleston, SC, United States of America

Cervical Arthroplasty: A Systematic Review of the Literature
T. Mroz1, E. Klineberg2, M. Steinmetz3, I. Lieberman4, E. Benzel5, J. Wang6
1The George Washington University, Orthopaedic Surgery, Washington DC, United States of America, 2Cleveland Clinic Foundation, Neuroscience Institute, Center for Spine Health, Orthopaedic Surgery, Neurological Surgery, Cleveland, OH, United States of America, 3University of California, Davis, Orthopaedics Surgery, Spine Surgery, Sacramento, CA, United States of America, 4Cleveland Clinic Foundation, Neuroscience Institute, Center for Spine Health, Neurosurgery, Cleveland, OH, United States of America, 5Cleveland Clinic Foundation, Neuroscience Institute, Center for Spine Health, Neurological Surgery, Cleveland, OH, United States of America, 6Cleveland Clinical Foundation, Neuroscience Institute, Center for Spine Health, Neurological Surgery, Cleveland, OH, United States of America

Characterizing MRI Distortion Associated with Cervical Artificial Disc Replacement Devices made of Titanium and Cobalt Chrome
A. Biyani1, S. Chinthakunta2, M. Dennis3, V. Goel4, F. Ahmad5, A. Dooris6, H. Serhan7
1University of Toledo, Orthopaedic Surgery, Toledo, OH, United States of America, 2Engineering Center for Orthopaedic Research Excellence (E-CORE), Bioengineering, Toledo, OH, United States of America, 3University of Toledo, Radiology, Toledo, OH, United States of America, 4DePuy Spine Inc., Raynham, MA, United States of America

The Effect of Progressive Circumferential Bone and Ligament Resection (Decompression) in Conjunction with the Prodisc C Cervical Disc Arthroplasty in a Spondylic cervical Spine Model
R. Roberto1, T. McDonald1, C. Neu2, S. Curtiss3, F. Pennings4, K. Kim5
1University of California, Davis, Orthopedic Surgery, Sacramento, CA, United States of America, 2Orthopedic Spine Associates, Eugene, OR, United States of America, 3Spine Midwest, Orthopedics, Jefferson City, MO, United States of America, 4University of Toledo, Radiology, Toledo, OH, United States of America, 5Greater Chesapeake Orthopedic Associates, Baltimore, MD, United States of America

A Kinematic Classification System for Total Disc Replacements
W. Sears1, P. McCombe2, R. Sasso3
1Macquarie University, School of Advanced Medicine, Sydney, Australia, 2St Andrew’s War Memorial Hospital, Orthopaedics, Brisbane, Australia, 3Indiana Spine Group / Indiana University School of Medicine, Clinical Orthopaedic Surgery, Indianapolis, IN, United States of America
P110/#391. Radiographic Analysis of SECURE-C Cervical Disc Arthroplasty at One and Two Year Post-op
J. Highsmith1, J. Marzluff2, C. Tomaras3, T. Morrison4, K. Stevenson5, I. Volcan6, A. Goodrich7, P. Asdourian8, J. McConnell9
1Neurosurgical Associates, Charleston, SC, United States of America, 2Peachtree Neurosurgery, Atlanta, GA, United States of America, 3West Augusta Spine Specialists, Augusta, GA, United States of America, 4Greater Chesapeake Orthopedic Associates, Baltimore, MD, United States of America, 5Orthopedic Associates of Allentown, Allentown, PA, United States of America

P111/#47. Effects of Degenerative Disc Disease on the Segmental Cervical Spine Alignment
N. Duggal1, T. Mink1, D. Rabin2, R. Bertagnoli3
1University of Western Ontario, Department of Clinical Neurological Sciences, London, Canada, 2Spine Center St. Elizabeth Klinikum, Straubing, Germany

P112/#89. Early Functional Outcomes of Cervical Arthroplasty with the CerviCore® Intervertebral Disc
J. Youssef1, A. Paterson2, S. Webb3, K. Renkens4, E. Lehmer1, J. Grenoble1
1Durango Orthopedic Associates/Spine Colorado, Orthopedics, Durango, CO, United States of America, 2University of New Mexico, Orthopaedics, Albuquerque, NM, United States of America, 3Florida Spine Institute, Orthopedics, Safety Harbor, FL, United States of America, 4Indiana Spine Group, Orthopedics, Indianapolis, IN United States of America

P113/#127. Long-Term Radiographic Follow-up of Patients Treated with a Single Level Cervical Disc Replacement
J. Burkus1, T. Zdeblick2, V. Traynelis3
1The Hughston Clinic, Columbus, GA, United States of America, 2University of Wisconsin, Madison, WI, United States of America, 3University of Iowa, Iowa City, IA, United States of America

P114/#267. Cervical Disc Prosthesis: What Are The Limits Of The Indications? Do We Need to Systematically Open the Posterior Longitudinal Ligament? What Are The Limits of the Excision of the Uncinate Processes? Can We Reduce Secondary Calcifications and Fusion?
A. Jodaitis1
1CHU Tivoli, La Louviere, Neurosurgery, Morlanwelz, Belgium

P115/#391. Cervical Arthroplasty: A Solution for Pseudarthrosis?
T. Dufour1, J. Beaurain2, J. Steib3, L. Aubourg4
1CHR Orleans, Neurosurgery, Orleans, France, 2CHU, Neurosurgery, Dijon, France, 3CHU, Orthopaedic Spine Unit, Strasbourg, France, 4LDR Medical Research Unit, Troyes, France

P116/#532. Clinical Outcomes of Cervical Arthroplasty with the CerviCore® Disc Prosthesis
J. Abitbol1, J. Fischgrund2, N. Baldwin3
1Scripps Mercy Hospital, California Spine, San Diego, CA, United States of America, 2William Beaumont Hospital, Royal Oak, MI, United States of America, 3Covenant Hospital Covenant Surgicenter, Neurosurgical Associates, LLP, Lubbock, TX, United States of America

P117/#339. Comparison of Adjacent Level Changes after ACDF with Plate versus Bryan Disc Arthroplasty in Single and Multi Level Cases
S. Kim1, M. Park1, J. Shin1, J. Arbati1, K. Chang1, S. Kim1, S. Kwon1
1International Spine Center, Hangang Sacred Heart Hospital, College of Medicine Hallym University, Seoul, Korea, Republic of

P118/#405. Natural and Accelerated Post-Sterilization Aging of Polyurethanes in the BRYAN® Cervical Disc
S. Kurtz1, M. Ebert2, R. Sikey3, L. Ciccirelli4, M. Reitman1, M. Harper2, F. Chan3
1Exponent, Philadelphia, PA, United States of America, 2Medtronic Cardiac Rhythm Disease Management, Minneapolis, MN, United States of America, 3Medtronic Spinal and Biologics, Memphis, TN, United States of America

P119/#478. Kineflex Cervical Disc Prosthesis: Disc Development, Clinical and Radiological Results at 27 Months Follow up
U. Hahn1, H. Siwaw2, I. Weinberg3, M. De Villiers4
1University of the Witwatersrand, Saxonwold, South Africa, 2University of the Witwatersrand, Johannesburg, South Africa, 3Linksfield Hospital, Johannesburg, South Africa, 4University of Potchefstroom, Potchefstroom, South Africa

P120/#504. Bi-Level Cervical Arthroplasty Outcomes: Compare to Single Level Arthroplasty
K. Cho1, S. Lee2, P. Huh3, D. Yoo1, S. Kang1, D. Kim1, C. Park2
1Uijongbu St. Mary’s Hospital, The Catholic Univ. of Korea, Dept. of Neurosurgery, Seoul, Korea, Republic of, 2Kangnam St.Mary’s Hosp. The Catholic Univ. of Korea, Neurosurgery, Seoul, Korea, Republic of

P121/#109. DBM + Local Bone: 1-Year Follow-Up in 100 Two-Level ACDF Patients
C. Cox1, W. Rodgers2, K. Smith1, E. Gerber1
1Spine Midwest, Inc., Jefferson City, MO, United States of America, 2Exactech, Inc., Gainesville, FL, United States of America

P122/#241. Author withdrawn

P123/#251. “Discover” Prosthesis - Changes in Global/Segmental Lordosis and Range of Motion (ROM) - Short Term Results
K. Aretz1, J. Harms1
1Spine Surgery Centre, Karlsbad, Germany

P124/#477. Retrieval and Analysis of NeoDisc Cervical Total Disc Replacement Device
R. Dryer1, K. Rich2, T. Bauer1, G. Cornwall1, L. Eisermann1
1Central Texas Spine Institute, Austin, TX, United States of America, 2Capital Neurosurgery, Inc., Raleigh, NC, United States of America, 3The Cleveland Clinic, Cleveland, OH, United States of America, 4NuVasive, Inc., San Diego, CA, United States of America

P125/#538. Functional Spinal Unit Angle According to the Segment after Cervical Artificial Disc Replacement
K. Bak1, S. Oh2, J. Kim1, C. Kim1, J. Cheong1
1Hanyang University, Department of Neurosurgery, Kuri, Korea, Republic of, 2Hanyang University, Department of Neurosurgery, Seoul, Korea, Republic of
NUCLEUS REPLACEMENT

P126/#123. Early Experience with the Discover Cervical Disc Prosthesis - Results of the First 25 Cases
S. Nagel1, B. Al Sharef2, A. Richter3, H. Halm4
1Klinikum Neustadt, Spine Surgery, Neustadt, Germany

P127/#143. CerviCore® Disc Replacement vs. Fusion for Cervical Radiculopathy: Functional and Occupational Outcomes
J. Youssfi1, J. Abitol2, N. Baldwin3, N. Wright4
1Durango Orthopedic Associates/Spine Colorado, Orthopedics, Durango, CO United States of America, 2Scripps Mercy Hospital, California Spine Group, San Diego, CA, United States of America, 3Covenant Hospital Covenant Surgicenter, Neurosurgical Associates, Albuquerque, NM, United States of America, 4Washington University School of Medicine/Barnes-Jewish Hospital, Neurological and Orthopaedic Surgery, St. Louis, MO, United States of America

P128/#244. Clinical Outcome in Cervical Arthroplasty using the BagueraC SpineArt® Device. Short Term Results
R. Srou1, A. Kunzeanu1, D. Orenstein1, P. Otten2
1Hopital Pasteur, Colmar, France, 2Hopital Daler Spiatal, Fribourg, Switzerland

P129/#205. Prodisc-C Prospective Single Center Clinical Study. Intermediate Results after 2 Years from 1 Hospital in Czech Republic
J. Stulík1, P. Sebesta1, J. Kryl1, T. Vysokci1
1Faculty Hospital Prague - Motol, Prague, Czech Republic

P130/#299. CerviCore Disc Replacement vs. Fusion for Cervical Nerve Root Compression: Surgical and Clinical Outcomes from a Prospective, Randomized, Multicenter Trial
R. Garcia1, M. Gratch2, J. Fischgrund3, J. Wright4
1Orthopedic Care Center, Aventura, FL, United States of America, 2Orthopedic Specialty Center, Willow Grove, PA, United States of America, 3Weissman, Gitlin, Herkowitz, MD PC, Orthopedic Surgery, Southfield, MI, United States of America, 4Swedish Group, Neurosurgery, Seattle, WA, United States of America

P131/#147. Total Cervical Disc Replacement with the Discocerv® Cervidisc Evolution Cervical Prosthesis: Intermediate Results of a Prospective Multicenter Study
A. Ramadani1, O. Gillé2, G. Roualdes3, J. Auque4, G. Jacquet5, C. Mazel6, L. Nogues7

P132/#344. The Kinematic Conflict Vector
P. McCombe1, W. Sears2
1Watkins Medical Centre, Brisbane, Australia, 2Macquarie University, The School of Advanced Medicine, Sydney, Australia

P133/#505. Kinematic Demands of Nucleus Arthroplasty Technology
D. DiAngelo1, N. Zufelt1, E. Sander1, B. Kelly1
1The University of Tennessee Health Science Center, Department of Biomedical Engineering and Imaging, Memphis, TN, United States of America

P134/#506. Development of a Kinematics Based Testing Protocol to Study Lumbar Disc Dynamics
D. DiAngelo1, E. Sander1, N. Zufelt1, B. Kelly1
1The University of Tennessee Health Science Center, Department of Biomedical Engineering and Imaging, Memphis, TN, United States of America

P135/#509. Comparison of Compliant and Non-Compliant Nucleus Arthroplasty Devices
D. DiAngelo1, B. Kelly1, N. Zufelt1, E. Sander1
1The University of Tennessee Health Science Center, Department of Biomedical Engineering and Imaging, Memphis, TN, United States of America

P136/#263. Developing a Surrogate Annulus Fibrosus Model for Nucleus Pulposus Replacement Wear and Fatigue Characterization
R. Siskey1, M. Villarraga1, H. Guerin1, P. Shah1, S. Kurtz1
1Exponent, Philadelphia, PA, United States of America

P137/#85. Biomechanical Testing of a Novel Modular Nucleus Replacement System
B. Norton1, A. Dowling2, M. Dreissigacker3, Y. Kim2, J. Laubach2, S. Vaidya2, J. Felt1
1Vebral Technologies, Inc., Minneapolis, MN, United States of America, 2Stanford University, Biomechanical Engineering, Palo Alto, CA, United States of America

P138/#392. 1-Year Clinical Results of an in Situ Polymerising Protein Hydrogel Nuclear Replacement
D. Wardlaw1, N. Craig1, F. Smith2, V. Singh3
1Woodend Hospital, Orthopaedic Unit, Aberdeen, United Kingdom, 2University of Aberdeen, Department of Radiology, Aberdeen, United Kingdom

P139/#12. Regenerative Effects of Cell-free Polymer-based Constructs in a Rabbit Model of Disc Degeneration
C. Wojciechowski4, A. Abussh1, M. Endres2, M. Gaborja3, S. Kroppenstedt1, A. Lemke4, C. Kaps1
1Charité, Department of Neurosurgery, Berlin, Germany, 2Charité, Department of Rheumatology, Tissue Engineering Laboratory, Berlin, Germany, 3Charité, Neurosurgery, Berlin, Germany, 4Charité, Radiology, Berlin, Germany, 5Spine Center Berlin, Berlin, Germany

P140/#229. Clinical Evaluation of an Injectable, In-Situ Curing Nucleus Replacement: 24 Month Outcomes
U. Berlemann1, O. Schwarzenbach1
1Spine Center - Thun, Thun, Switzerland
POSTER DYNAMIC STABILIZATION

P143/#232. The Effects of a Novel Interspinous Spacer on the Foramen and Canal Dimensions of Instrumented Levels in the Lumbar Spine: An in vitro Analysis
A. Goyal1, V. Goel1, A. Mehta1, J. Jangra1, A. Ivanov1, A. Biyani1
1University of Toledo, Engineering Ctr. for Orthopedic Research Excellence, Toledo, OH, United States of America

P144/#181. The Effect of the Device for Inter-vertebral Assisted Motion (DIAM) on the Space Available for the Neural Elements in Elderly Patients with Spinal Stenosis
A. Kasis1, R. Raju1, T. Friesem1
1Spinal Unit, University Hospital of North Tees, Stockton-On-Tees, United Kingdom, 2Radiology Department, University Hospital of North Tees, Stockton-On-Tees, United Kingdom

P145/#518. The Effect of TRANSITION™ Posterior Dynamic Stabilization on Load Sharing in Segments Adjacent to Rigid Instrumentation
D. Sengupta1, J. Lindley2, A. Powers3, J. Isaza4, R. Haid5, A. Ingalhalikar6
1Dartmouth-Hitchcock Medical Center, Orthopedics, Lebanon, NJ, United States of America, 2Neurological Institute, Neurosurgery, Savannah, GA, United States of America, 3Washington Brain & Spine Institute, Neurosurgery, Bethesda, MD, United States of America, 4Surgical Specialty Centre, Baton Rouge, LA, United States of America, 5Atlanta Brain and Spine Care, Atlanta, GA, United States of America, 6Globus Medical, Inc., Audubon, PA, United States of America

P146/#526. In-Vitro Evaluation of a Novel Dynamic Stabilization System ‘Transition’™ in Motion Preservation
D. Sengupta1, A. Ingalhalikar2, P. McAfee3, A. Powers4, J. Lindley5, J. Isaza6, A. Lott7, R. Haid8
1Dartmouth-Hitchcock Medical Center, Orthopedics, Lebanon, United States of America, 2Globus Medical, Inc., Audubon, PA, United States of America, 3Scoliosis and Spine Center, Towson, MD, United States of America, 4Washington Brain & Spine Institute, Neurosurgery, Bethesda, MD, United States of America, 5Neurological Institute, Neurosurgery, Savannah, GA, United States of America, 6Surgical Specialty Centre, Baton Rouge, LA, United States of America, 7Atlanta Brain and Spine Care, Atlanta, GA, United States of America

A. Castelv1, D. Clabeaux2
1Florida Orthopaedic Institute, Tampa, FL, United States of America

P148/#435. Biomechanics of Novel Posterior Dynamic Stabilizing Device (InSpace)
L. Voronov1, R. Havey2, S. Renner2, G. Carandang2, C. Abjornson2, A. Patwardhan2
1Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, United States of America, 2Edward Hines Jr. VA Hospital, Hines, IL, United States of America, 3Synthes Spine, West Chester, PA, United States of America

P149/#55. The DIAM Interspinous Stabilization for Low Back Pain: 24 Months Follow-up
J. Buric1, L. Rigobello2
1cdc Villanova, Functional Unit for Spinal Surgery, Florence, Italy, 2University of Padua, Neurosurgery, Padua, Italy

P150/#323. DIAM for Stabilization of the Grade I Degenerative Spondylolisthesis: Preliminary Results
C. Shim1, N. Vasavada1, S. Lee1
1Wooridul Spine Hospital, Neurosurgery, Seoul, Korea, Republic of

P151/#349. Reduction in Spinal Mobility by Posterior Dynamic Stabilization Devices for the Treatment of Multiple Degenerative Disc Diseases
J. Lee1, Y. Ahn2, K. Park3, W. Chen4, S. Lee1
1Inje University, Biomedical Engineering, Gimhae, Korea, Republic of, 2Korea Orthopedics & Rehabilitation Engineering Center, Incheon, Korea, Republic of, 3Kwang-Hye Spine Center, Seoul, Korea, Republic of, 4Division of Bioengineering, National University of Singapore, Singapore, Korea, Republic of

P152/#450. Lumbar Spine Kinematics Following PDS and Isobar Posterior Dynamic Stabilizers Replacements vs Intact: A Cadaveric Study
A. Kiapour1, B. Parepalli1, V. Goel1, M. Krishna2, T. Friesem1
1The University of Toledo, Engineering Ctr. for Orthopedic Research Excellence, Toledo, OH, United States of America, 2The University Hospital of North Tees, Stockton-on-Tees, United Kingdom

P153/#28. The Effects of a Novel Interspinous Spacer on the Kinematics of Instrumented and Adjacent Levels in the Lumbar Spine: An in vitro Analysis
A. Goyal1, V. Goel1, A. Mehta1, A. Ivanov1, A. Biyani1, A. Khere1
1University of Toledo, Engineering Ctr. for Orthopedic Research Excellence, Toledo, OH, United States of America

P154/#66. The Effects of a Novel Titanium Interspinous Spacer on Intradiscal Pressure: An in vitro Analysis
A. Goyal1, V. Goel1, A. Mehta1, J. Jangra1, A. Ivanov1, A. Biyani1
1University of Toledo, Engineering Ctr. for Orthopedic Research Excellence, Toledo, OH, United States of America
P155/#134. A Finite Element Analysis to Predict Peak Bending and Shear Stresses on the NFlex™ Dynamic Stabilization Device and Comparison to Empirically Derived Fatigue Data
J. Yim1, B. Bowman1, J. Paganeli2, S. Rundell2, T.A. Jahng1, R. Watson1
1NSpine, R&D, San Diego, CA, United States of America
2Exponent, Biomechanics, Philadelphia, PA, United States of America
3Seoul National University, Seoul, Korea, Democratic People’s Republic of Korea

P156/#325. Author withdrawn

P157/#345. Posterior Dynamic Stabilization in the Treatment of Lumbar Degenerative Spondylolisthesis
T. Oktenoglu1, M. Sasani2, A.Ozer3, H. Bozkus3, A. Sanoglu2
1VKV-American Hospital, Neurosurgery Department, Nisantasi, Turkey
2VKV-American Hospital, Neurosurgery Department, Istanbul, Turkey

P158/#462. Posterior Non-fusion Stabilization of the Lumbar Spine for Degenerative Disc Disease - Minimum 2 year Clinical, Radiological and Functional Results for Back Pain
N. Anand1, J. Lim1
1NYU-Hospital for Joint Diseases, Orthopaedic Surgery, New York, NY, United States of America

P159/#394. The Effects of Motion and Intra Discal Pressure after Adding a Dynamic Stabilization Device to an Injured Spine: A Finite Element Based Study
B. Parepalli1, A. Kiapour2, V. Goel1, L. Ferrara1, A. Cylia1
1The University of Toledo, Bioengineering, Toledo, OH, United States of America
2The University of Toledo, Bioengineering, Toledo, OH, United States of America

P160/#426. Long-Term Clinical Outcome of Coflex™ Dynamic Stabilization Device
J. Kamerlink1, T. Errico1, M. Quirno1
1NYU-Hospital for Joint Diseases, Orthopaedic Surgery, New York, NY, United States of America

P161/#451. A Novel Lateral Percutaneous Interspinous System for the Treatment of Lumbar Stenosis: Early Clinical and Radiological Results up to One Year Follow up
J. Lhamby1, C. Arias Pesantez2, L. Oliveira1, L. Pimenta1
1Santa Rita Hospital, Spine Surgery, Sao Paulo, Brazil
2Santa Rita Hospital, Minimally Invasive and Arthroplasty Spine Surgery, Sao Paulo, Brazil

P162/#128. Biomechanical Study of In-Space Interspinous Device
J. Lim1, J. Park1
1Stanford University Medical Center, Neurosurgery, Palo Alto, CA, United States of America

P163/#507. Motion Characteristics of the NFlex™ Pedicle Screw Based Dynamic Stabilization System: A Human Cadaver Study
J. Yim1, N. Crawford2
1NSpine, R&D, San Diego, CA, United States of America
2Barrow Neurological Institute, Spine Biomechanics, Phoenix, AZ, United States of America

P164/#64. Hybrid Dynamic Stabilization with Posterior Spinal Fusion in the Lumbar Spine; Two Year Follow-up
A. Castelvi1, D. Clabeaux1
1Florida Orthopaedic Institute, Tampa, FL, United States of America

P165/#196. Is the Coflex-F Suitable to be Used as Adjunct Implant to a Lumbar Cage?
H. Wilke1, K. Werner1, E. Kast2
1University of Ulm, Institute of Orthopaedic Research and Biomechanics, Ulm, Germany
2Kantonsspital Winterthur, Neurosurgery, Winterthur, Switzerland

P166/#269. Biomechanical Strength of Facet Joints Following Implantation of a Novel Percutaneous Dynamic Stabilization System
R. Zaki1, B. Parepalli2, V. Goel1, A. Ivanov1, A. Khere1, B. Culbert1
1University of Toledo, Toledo, OH, United States of America
2Interventional Spine, Irvine, CA, United States of America

P167/#428. Long -Term Device Related Issues of Coflex™ Dynamic Stabilization Device
J. Kamerlink1, T. Errico1, M. Quirno1
1NYU-Hospital for Joint Diseases, Orthopaedic Surgery, New York, NY, United States of America

P168/#492. Early Clinical and Radiographic Results of the NFix™ II Posterior Dynamic Stabilization System
F. Acosta1, F. Christensen2, J. Doe3, T. Jahng4, S. Kitchel5, H. Meisel6, M. Schorning7, C. Wingo1, C. Ames8
1University of California, Neurological Surgery, San Francisco, CA, United States of America
2University Hospital of Aarhus, Aarhus, Denmark
3Silicon Valley Spine Institute, Los Gatos, CA, United States of America
4Seoul National University, Seoul, Korea, Republic of, 5Orthopaedic Spine Associates, Eugene, OR, United States of America
6BG-Clinic, Bergmannstrost Halle, Germany
7Tallahassee Orthopaedic Institute, Tallahassee, FL, United States of America
8University of California, San Francisco, CA, United States of America

P169/#199. New Method for Dynamic Neural Foraminotomy
B. Cheng1, Y. Zhang2, C. Oh2, J. Spehar1, J. Burgess2
1University of Pittsburgh, Neurological Surgery, Pittsburgh, PA, United States of America
2Carnegie Mellon University, Mechanical Engineering, Pittsburgh, PA, United States of America
3Allegheny General Hospital, Pittsburgh, PA, United States of America

P170/#206. Functional Dynamic Stabilization in Treatment of Lumbar Spinal Stenosis with COFLEX® Interspinous Implant - 2 Year Results
R. Bertagnoli1
1St.Elisabeth Hospital, Pro Spine First European Center for Spine Arthroplasty and Nonfusion Technologies, Straubing, Germany

P171/#516. Long Segment Posterior Dynamic Stabilization with Zimmer Dynesys
L. Abram1
1Florida Atlantic University, Biomedical Sciences, Boca Raton, FL, United States of America

P172/#379. Dynesys as a Dynamic Stabilization Device: Does it Preserve Lumbar Motion?
M. Maid1, R. Kube1, R. Holt1, J. Mahan1
1Spine Surgery PSC, Louisville, KY, United States of America
P175/#511. Dynamic Lumbar Stenosis: Restabilization with Agile after Decompression
J. Le Huec¹, S. Aunoble¹, F. Sibilla¹, R. Meyrat¹, F. Tonga¹
¹Bordeaux CHU Hospital Pellegrin Tripode, Spine Unit, Bordeaux, France

P177/#427. Early Results of Non-fusion Stabilisation of Degenerate Lumbar Spine with Cosmic Posterior Dynamic System
M. Rashid¹, N. Harland¹, K. Allerton¹
¹Frazerage Hospital, Spinal Surgery, Northallerton, United Kingdom

P178/#301. Seven Years Experience with Dynamic Interspinous Stabilization. DIaM Implant and Aperius Percutaneous Implant: A Series of 1450 Patients
A. Fabrizi¹, R. Maina¹
¹Villa Maria Pia Hospital, Neurosurgery, Torino, Italy

D. Gordon¹, F. Cammisa², P. Nunley³, K. Strauss⁴, B. Cunningham⁵, G. Miz⁶
¹NJ Spine Group LLC, Shrewsbury, MO, United States of America
²Hospital for Special Surgery, Garden City, KS, United States of America
³Spine Institute of Louisiana, Shreveport, LA, United States of America
⁴K2M, LLC, Leesburg, FL, United States of America
⁵St. Joseph Medical Center, Towson, MD, United States of America
⁶Bone & Joint Physicians, Oak Lawn, IL, United States of America

P180/#112. Diam Stabilisation: Experience with 500 Devices
P. D’Urso¹
¹Epworth Hospital, Department of Neurosurgery, Melbourne, Australia

P181/#115. Diam Dynamic Stabilisation: Expanded Indications
P. D’Urso¹
¹Epworth Hospital, Department of Neurosurgery, Melbourne, Australia

P182/#155. Dynamic Stabilization With Aladyn System In Lumbar Spinal Stenosis: Preliminary Data
E. Tessitore¹
¹University of Geneva, Neurosurgical Unit, Geneva, Switzerland

LUMBAR FACET REPLACEMENT
P183/#305. The Total Facet Arthroplasty System® (TFAS®) in the Treatment of Spinal Stenosis: Us IDE Experience with Longest Follow-up of 24 Months
S. Webb¹, B. L. Sachs², A. Castellvi³, C. Wingo⁴, M. Halperin⁴, D. Wiles⁴, P. Schwaegler⁴
¹Florida Spine Institute, Clearwater, FL, United States of America
²Texas Back Institute, Plano, TX, United States of America
³Texas Back Institute, Tampa, FL, United States of America
⁴Tallahassee Orthopedic Clinic, Tallahassee, FL, United States of America
⁵Norwich Orthopedic Group, Norwich, CT, United States of America
⁶Orthopedics International, Seattle, WA, United States of America

INNOVATIVE TECHNOLOGIES
P186/#104. The Emergence of Internet Based Collaboration in Surgical Decision Making and New Technology Training
J. Yousef¹, P. Slosar¹
¹SpineCare Medical Group/ San Francisco Spine Institute, Daly City, CA, United States of America
²Durango Orthopedics, Durango, CO, United States of America

P187/#282. In vivo Effects of a Novel ALL Reconstruction Device in Sheep
F. Phillips¹, L. Pimenta², D. Van Sickle³, H. Seim³, S. Turner⁴, B. Ferrere⁵
¹Rush University Medical Center, Orthopaedic Surgery, Chicago, IL, United States of America
²Santa Rita Hospital, Neurosurgery, Sao Paulo, Brazil
³Purdue University, Basic Medical Sciences, West Lafayette, IN, United States of America
⁴Colorado State University, Clinical Sciences, Ft. Collins, CO, United States of America
⁵Mercy Hospital, Orthopaedic Surgery, Cincinnati, OH, United States of America
P188/#399. Plasma Disc Decompression Compared to Selective Nerve Root Injections for the Treatment of Contained Disc Protrusions: Interim Results of a Prospective, Randomized, Controlled, Multi-center Study
1University of Pittsburgh Medical Center, Pittsburgh, PA, United States of America, 2OrthoCarolina, Charlotte, NC, United States of America, 3Innovative Spine Care, Little Rock, AK, United States of America, 4TRIA Orthopaedic, Bloomington, MN, United States of America, 5The Orthopedic Clinic Association, Scottsdale, AZ, United States of America, 6Western Pennsylvania Hospital, Pittsburgh, PA, United States of America, 7Fletcher Allen Health Care, Center for Pain Medicine, Burlington, VT, United States of America, 8Colorado Pain Management, Thornton, CO, United States of America, 9Medical Advanced Pain Specialists, Edina, MN, United States of America, 10Beth Israel Deaconess Medical Center, Boston, MA, United States of America, 11University of Michigan, The Spine Program, Ann Arbor, MI United States of America

P190/#93. Anterior Dynamic Stabilization via a Semi-Elastic Vertebral Body Prosthesis
G. Buttermann1, B. Beaubien2, A. Freeman2
1Rush University Medical Center, Orthopaedic Surgery, Chicago, IL, United States of America, 2Santa Rita Hospital, Neurosurgery, Sao Paulo, Brazil, 3Mercy Hospital, Cincinnati, OH, United States of America, 4Purdue University, Basic Medical Sciences, West Lafayette, IN, United States of America, 5Colorado State University, Clinical Sciences, Ft. Collins, CO, United States of America, 6Mercy Hospital, Orthopaedic Surgery, Cincinnati, OH United States of America

P191/#153. One-Year Follow Up of Discectomy Patients who Received a Novel Device that Re-Approximates the Anulus Fibrosus
G. Bajares1, A. Perez1, M. Diaz1, R. Rodriguez1
1Instituto de Columna, Caracas, Venezuela

P192/#237. One Year Outcomes of Minimally-Invasive Presacral Approach and Instrumentation Technique for Anterior Lumbosacral Intervertebral Discectomy and Fusion
L. Khoo1, F. Asgarzadie1, M. Cosar2, N. Marotta3, L. Pimenta4
1UCLA, Neurosurgery, Santa Monica, CA, United States of America, 2Ayyon Kocatepe University, Ayyonkarahisar, Turkey, 3Sapienza Hospital, Rome, Italy, 4Santa Rita Hospital, Sao Paolo, Brazil

P193/#293. Effects of Suture Orientation in the Anulus Fibrosus on Resistance to Pullout
F. Phillips1, A. Ferree2, D. Tompkins3, L. Pimenta4, D. Paller5, B. Ferree6
1Rush University Medical Center, Orthopaedic Surgery, Chicago, IL, United States of America, 2Mercy Hospital, Cincinnati, OH, United States of America, 3University of Cincinnati, Cincinnati, OH, United States of America, 4Santa Rita Hospital, Neurosurgery, Sao Paulo, Brazil, 5Brown University, Orthopaedic Surgery, Providence, RI, United States of America, 6Mercy Hospital, Orthopaedic Surgery, Cincinnati, OH, United States of America

P194/#49. Resolution of Radiculopathy in Patients Identified with Cytokine Biomarker Corresponds to Inflammatory Blockade in an Animal Model of Disc Herniation
G. Scuderi1, J. Cuellar2, V. Grabovsky2, M. Angst3, D. Yeomans3
1Private Practice, Jupiter, United States of America, 2Stanford Univ, Anesthesia, Palo Alto, CA, United States of America

P195/#118. Development of a Strong Polymer-Metal Interface for Spinal Prostheses
C. Lee1, A. Clemow1, S. Roth1, W. Ogilvie1, E. Ho1
1Nexgen Spine, Whippyary, NJ, United States of America

P196/#489. A Posterior Lumbar Total Joint Replacement: First Clinical Cases
S. Humphreys1, S. Hodges1, L. Nel, Jr.2, R. Fessler2
1Chattanooga Orthopedic Group, Chattanooga, TN, United States of America, 2Zuid-Afrikaanse Hospital, Pretoria, South Africa, 3Northwestern University Hospital, Dept of Neurosurgery, Chicago, IL, United States of America

P197/#510. Low Endurance Testing of a Novel Spinous Process Spacer under Coupled Loading Conditions
B. Kelly1, E. Sander1, N. Zufelt1, D. DiAngelo1
1The University of Tennessee Health Science Center, Department of Biomedical Engineering and Imaging, Memphis, TN, United States of America

P198/#311. Author withdrawn

P199/#433. Damage Control Spine Surgery - Motion vs. Fusion?
K. Poelstra1, S. Ludwig1
1University of Maryland - Shock Trauma, Orthopaedics, Baltimore, MD, United States of America

P. Benton1, T. Ganey1
1Atlanta Medical Center, Orthopaedics, Atlanta, GA, United States of America
P201/#148. Balloon Kyphoplasty using KyphOsTM FS(R) Calcium Phosphate Bone Substitute for the Treatment of Traumatic Vertebral Body Fractures
J. Van Meirhaeghe1, J. Hillmeier2, J. Meeder2, R. Gumpert2, P. Vanderschot2, F. Ortner3, BEST Study Investigators
1AZ Sint-Jan Brugge, Dienst Orthopedie en Traumatologie, Brugge, Belgium, 2St. Vincenz Krankenhaus, Limburg, Germany, 3Universität Heidelberg, Unfall-und Wiederherstellungs chirurgie, Heidelberg, Germany, 4Universitätsklinik für Unfallchirurgie, Graz, Austria, 5UZ KUL, Gasthuisberg, Traumatologie, Leuven, Belgium, 6A.Ö. Krankenhaus der Statutarstadt, Wiener Neustadt, Austria

P202/#407. Short Term Clinical Results Of An Elastomeric Lumbar Disc Prosthesis (Physio-L)
I. Pimenta1, C. Lee2
1Santa Rita Hospital, Minimally Invasive and Arthroplasty Spine Surgery, Sao Paulo, Brazil, 2Santa Rita Hospital, Orthopaedics, Whippany, NJ, United States of America

P203/#171. Biomechanical Evaluation of the B-twin Implant in Kyphoplasty of Induced Compression Fractures in Human Vertebral Bodies
1, 2Meir Hospital, Spine Unit, Kfar Saba, Israel, 2Meir Hospital, Orthopedic Department, Kfar Saba, Israel

P204/#520. P-15 Bone Putty - A Novel Bone Graft Substitute for Use in Cervical Spinal Fusion. Early Results of a Multi-center Randomized Controlled Trial in North America
R. Sasso1, M. Janssen2, M. Fehlings3
1Indiana Spine Group, Indianapolis, IN, United States of America, 2Center for Spinal Disorders, Denver, CO, United States of America, 3University of Toronto, Toronto, Canada

P205/#273. Percutaneous Access to the Canine Intervertebral Disc
1University of Pennsylvania School of Veterinary Medicine, Clinical Studies, Kennett Square, PA, United States of America

P206/#378. Vesseloplasty in the Treatment of Vertebral Compression Fractures (VCF) in Osteoporosis and Myeloma Vertebral Lesions
V. Paliotta1, B. Magliozzi1, G. Martelli1
1S. Eugenio Hospital, Orthopaedic, Roma, Italy

P207/#138. The Use of CT Angiography to Define the Prevertebral Vascular Anatomy Prior to Anterior Lumbar Procedures
N. Grisoni1, J. Datta2, R. Beckham1, C. Ponce1, M. Janssen1, 3
1Spine Education and Research Institute, Denver, CO, United States of America, 2Sonoran Spine Center, Mesa, AZ, United States of America

P208/#162. A Clinical Evaluation of Anular Repair Post Lumbar Discectomy
R. Guver1
1Texas Back Institute, Plano, TX, United States of America

MIS

P209/#266. Author withdrawn

P210/#276. Author withdrawn

C. Kim1, S. Ward2, R. Lieber1, S. Garfin1
1University of California, San Diego, Orthopaedic Surgery, San Diego, CA, United States of America

P212/#317. Cyclic Loading does not Compromise Functionality of Interspinous Spacers or any Damage to the Segment
A. Guyard1, V. Goel2, A. Mehta1, D. Dick1, A. Khere1, C. Abjornson2
1Engineering Center for Orthopaedic Research Excellence (E-CORE), University of Toledo, Toledo, OH, Bioengineering, Toledo, OH, United States of America, 2Synthes Spine, West Chester, PA, United States of America

P213/#331. Nonunion Osteoporotic Vertebral Fractures Treated by Balloon Kyphoplasty
H. Yang1, G. Wang1, J. Liu2, G. Niu3, T. Tang1, N. Ebraheim4
1The First Affiliated Hospital of Soochow University, Department of Orthopaedic Surgery, Suzhou City, China, 2University of Toledo, Toledo, American Samoa, 3The First Affiliated Hospital of Soochow University, Suzhou City, China

P214/#45. Minimally Invasive Trans-sacral Approach to L5-S1 Interbody Fusion: Technique and Clinical Results
1, 2University of California, Neurosurgery, San Francisco, CA, United States of America, 3University of California, Neurosurgery, Santa Monica, CA, United States of America

P215/#9. Author withdrawn

P216/#204. Mechanical Evaluation of a Compressed, Allograft, Intervertebral Implant with and without Flowable Ceramic Augmentation
B. Conrad1, M. Mac Millan1, J. Strickland1
1University of Florida, Department of Orthopaedics, Gainesville, FL, United States of America

P217/#227. Minimally Invasive Microsurgical Lumbar Decompression with Preservation of the Contralateral Outer Laminar Cortex and Spinous Process: 4-year Comparative Outcomes in One- and Two-level Spinal Stenosis
L. Khoo1, S. Lam1, N. Chen1
1UCLA, Neurosurgery, Santa Monica, CA, United States of America

P218/#60. Percutaneous Axial Lumbar Interbody Fusion (AxiaLIF) of the L5-S1 Segment: Initial Clinical and Radiographic Experience
C. Newman1, C. Ames2, H. Aryan3
1University of California, Neurosurgery, San Diego, CA, United States of America, 2University of California, Neurosurgery, San Francisco, CA, United States of America

P219/#113. Surgeon Perceptions of Minimally Invasive Spine Surgery
J. Webb1, C. Kim1, L. Gottschalk1, Y. Lee1
1University of California, San Diego, Department of Orthopaedic Surgery, San Diego, CA, United States of America
P220/#410. Minimally Invasive AxiaLIF L5-S1 Interbody Fusion for Anterior Column Support: Early Results
N. Anand1, R. Wuppperman1, E. Baron1
1Cedars Sinai Medical Center, Institute for Spinal Disorders, Los Angeles, CA, United States of America

P222/#539. Vesselplasty, A New Concept to Treat Vertebral Compression Fractures. 3 Year Follow-up Study
A. Darwono1
1Gading Pluit Hospital, Orthopaedic, Jakarta Utara, Indonesia

P223/#46. Comparison of Open vs. Minimally Invasive Surgical Techniques for Posterior Lumbar Fusion
A. Araghi1, M. Hisey2, J. Zigler3, R. Guiver3, B. Sachs2, R. Rashbaum2, D. Ohnmeiss4
1Texas Back Institute, Phoenix, AZ, United States of America, 2Texas Back Institute, Denton, TX, United States of America, 3Texas Back Institute, Plano, TX, United States of America, 4Texas Back Institute Research Foundation, Plano, TX, United States of America

P224/#88. Far Posterolateral Approach and Paramidline Approach Endoscopic Surgery for L5-S1 Level Disc Herniations
X. Zhang1, Y. Wang1, S. Xiao1, Z. Liu1, B. Liu1, Y. Zhang1, S. Zhu1, N. Lu1, K. Mao1, Z. Wang1
1General Hospital of PLA, Orthopedic Department, Beijing, China

P225/#231. A Novel Interspinous Spacer for the Treatment of Moderate Lumbar Spinal Stenosis
L. Nel1, C. Kieck2
1Zuid Afrikaans Hospital, Neurosurgery, Pretoria, South Africa, 2Vincent Pallotti Hospital, Neurosurgery, Pinelands, South Africa

P226/#310. Minimizing the MIS Learning Curve: Analysis of a 1-Day Training Program Comprised of a Standardized Technique Protocol, Synthetic Models, and a Low Trainee to Cadaver Ratio
C. Kim1, A. Choo1, G. Regev1
1University of California, San Diego, Dept. of Orthopaedic Surgery, San Diego, United States of America

P227/#380. Using MRI to Determine Painful Vertebrae Treated by Kyphoplasty in Multiple-level Vertebral Compression Fractures: A Prospective Study
H. Yang1, G. Wang1, G. Niu1, B. Meng1, X. Cai2, L. Chen1, T. Tang1
1The First Affiliated Hospital of Soochow University, Department of Orthopedics, Suzhou City, China

P228/#481. Author withdrawn

P229/#461. Mini-Open Lateral Approach for Thoracolumbar Pathologies: Lateral Corpectomies
W. Smith1, K. Malone2
1Western Regional Center for Brain and Spine Surgery, Las Vegas, NV, United States of America, 2Nevada Neurosciences Institute Research Foundation, Las Vegas, NV, United States of America

P230/#486. Author withdrawn

P231/#485. Author withdrawn

P232/#552. Endoscopic Rhizotomy of the Dorsal Ramus Targeting the Lateral and Medial Branch for Chronic Discogenic/Axial Back Pain
A. Yeung1
1Desert Institute for Spine Care, University of California San Diego School of Medicine, Department of Orthopedics, Phoenix, AZ United States of America

P233/#314. Can Discogram Identify a Painful Disc?
D. Sengupta1, R. Singh1, S. Behari2, A. Nene3
1Postgraduate Institute of Medical Sciences, Rohtak, Orthopedics, Rohtak, India, 2Sanjay Gandhi Postgraduate Institute of Medical Sciences, Neurosurgery, Lucknow, India, 3P. D. Hinduja Hospital, Orthopedics, Mumbai, India, 4Dartmouth-Hitchcock Medical Center, Orthopedics, Lebanon, NH, United States of America

P234/#194. A New Laser Scanning Technique for Imaging Intervertebral Disc Displacement and its Application to Modeling Nucleotomy
F. Heuer1, H. Schmidt1, L. Claes1, H. Wilke1
1Institute of Orthopaedic Research and Biomechanics, University of Ulm, Ulm, Germany

F. Girardi1, A. Sama1, F. Cammissa2, M. Urban2, L. Gaber3, M. Besculides4, S. Memtsoudis2
1Hospital for Special Surgery, Spinal Surgery, New York, NY, United States of America, 2Hospital for Special Surgery, Anesthesiology, New York, NY, United States of America, 3LKG Consulting, Plainsboro, NJ, United States of America, 4Mathematica Policy Research Inc, Princeton, NJ, United States of America

P236/#402. Evaluation of Pedicle Screw Loosening in a Combined Facet and Total Disc Replacement System
S. Rundell1, J. Gimbel2
1Exponent, Inc., Philadelphia, PA, United States of America, 2Flexuspine, Inc., Carnegie, PA, United States of America

P237/#212. Validation of a Numerical Method to Predict Post-Fusion Motion Compensation Using Load-Control Flexibility Test
A. Patwardhan1, G. Carandang2, R. Havey3
1Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, United States of America, 2Edward Hines Jr. VA Hospital, Hines, IL, United States of America

P238/#319. Validation of the Pure Moment Cable Pulley System for Spinal Biomechanics Testing
J. Equizabal1, M. Tufaga1, D. Wheeler1, J. Buckley1, C. Ames2, J. Lotz2
1University of California at San Francisco, Department of Orthopaedic Surgery, San Francisco, CA, United States of America, 2University of California at San Francisco, Department of Neurological Surgery, San Francisco, CA, United States of America

OTHER
P241/#182. Long Term XStop Interspinous Process Decompression Follow-up Comparing Pre- and Post-operative MRI Canal and Foramen Area

C. Idler1, J. Zucherman1, K. Hsu1, M. Hannibal1, D. Kondrashov1, B. Justice1, D. Lentz1
1St. Mary’s Spine Center, San Francisco, CA, United States of America

P242/#350. Lumbar Plexus Nerve Root Position within the Psoas Muscle: An Anatomic Study

C. Paulino1, N. Shanti2, M. Quirno1, N. Pathari2, J. Spivak1
1NYU Hospital for Joint Diseases, Division of Spine Surgery, New York, NY, United States of America
2SUNY Downstate Medical Center, New York, NY, United States of America

P243/#369. Adjacent Segment Mobility Evaluated by Radiostereometry before and Five Years after Fusion

B. Strömqvist1, P. Axelsson1, R. Johnson1
1Lund University Hospital, Dept of Orthopedics, Lund, Sweden

P244/#409. 2 Year Positional MRI Scan Results of Dural Sac Area and Foraminal Area Following X Stop

D. Wardlaw1, N. Biolikar1
1Woodend Hospital, Orthopaedics, Aberdeen, United Kingdom
2Woodend Hospital, Radiology, Aberdeen, United Kingdom

P245/#437. Silicon Matrix Calcium Phosphate as a Bone Substitute. Early Clinical and Radiological Results: A Prospective Study with Twelve Month Follow-Up

L. Pimenta1, C. Arias1, J. Lhamby1, L. Oliveira1, E. Coutinho1
1Santa Rita Hospital, Minimally Invasive Spine Surgery, São Paulo, Brazil

P246/#157. Adjacent Segment Stenosis and Instability after Lumbar Fusion Requiring Second Operation

K. Cho1, S. Lee1, P. Huh1, D. Yoo1, S. Kang1, D. Kim1, C. Park2
1Uijongbu St. Mary’s Hospital, The Catholic Univ. of Korea, Dept. of Neurosurgery, Seoul, Korea, Republic of
2Kangnam St.Mary’s Hosp. The Catholic Univ. of Korea, Neurosurgery, Seoul, Korea, Republic of

P247/#334. Immunohistochemical Analysis of Intervertebral Disc Innervation in the Dog

T. Schaer1, S. Tucker1
1University of Pennsylvania School of Veterinary Medicine, Clinical Studies, Kennett Square, PA, United States of America


A. Ramruttun1, H. Wong1, J. Goh1, J. Ruiz2
1National University of Singapore, Orthopaedic Surgery, Singapore, Singapore
2National University Hospital, Department of Orthopaedic Surgery, Division of Spinal Surgery, Singapore, Singapore

P249/#242. Anatomical Considerations for Cervical Pedicle Screw Insertion: The Use of Multiplanar Computerized Tomography Measurements in 102 Consecutive Clinical Cases

L. Khoo2, A. Onibokun1, S. Bistazzoni1, S. Armin2, N. Chen2, H. Sheikh2
1UCLA, Santa Monica, United States of America
2UCLA, Neurosurgery, Santa Monica, CA, United States of America

P250/#131. Histologic Changes after Vertebroplasty with Calcium-Phosphate Cement and Pmma in Experimental Animal Model

C. Doria1, L. Tidu1, F. Milia1
1University of Sassari, Orthopaedic, Sassari, Italy


C. Kim1, A. Choo1
1University of California, San Diego, Orthopaedic Surgery, San Diego, United States of America

P252/#201. Estimation of Back Bending Cycles of Elementary School Teachers and Office Workers

B. Zarda1, A. Dooris1, C. Bartish1, J. Fanger1
1DePuy Spine, a Johnson & Johnson Company, Raynham, MA, United States of America

P253/#333. Long -Term Outcomes of Lumbar Discectomy by Fenestration. a Follow-Up Study of More than 15 Years

H. Yang1, G. Wang1, J. Liu2, Y. Wang1, T. Tang1, N.A. Ebraheim2
1The First Affiliated Hospital of Soochow University, Suzhou City, China
2University of Toledo, Toledo, American Samoa

P254/#243. Anatomical Considerations for C2 Pedicle Screw Placement: The Use of Computerized Tomography Measurements

L. Khoo2, A. Onibokun1, S. Bistazzoni1, S. Armin2, N. Chen2, H. Sheikh2
1UCLA, Santa Monica, CA, United States of America
2UCLA, Neurosurgery, Santa Monica, CA, United States of America

P255/#132. Instrumented Lumbar Interbody Fusion: Experimental Study in Animal Model

C. Doria1, L. Tidu1, F. Milia1
1University of Sassari, Orthopaedic, Sassari, Italy

P256/#535. Intermediate Term Degenerative Changes in Segments Adjacent to X STOP Procedure

C. Idler1, J. Zucherman1, K. Hsu1, M. Hannibal1, D. Kondrashov1, B. Justice1, D. Lentz1
1St. Mary’s Spine Center, San Francisco, United States of America
SAS8 AUTHORS’ INDEX

A

Abitbol J.-J.: P116, P127
Abjornson C.: OR22, OR24, P148, P212
Abram L.: P171
Abusshi A.: P139
Acosta F.: P63, P168
Aebi M.: P52
Aferzon J.: P50
Agrillo U.: OR69, P6
Ahmad F.: P107
Ahn P.G.: P81, P95
Ahn Y.H.: P151
Ahrens M.: OR19, OR65
Ainsworth S.: OR74
Al Sharef B.: P126
Albanese V.: OR37, P94
Allain J.: OR53, OR63, P65
Allerton K.: P177
Alleyne N.: P61
Ameil M.: OR53, OR63
Ames C.: P168, P218, P238
An H.: OR13
Anand N.: OR56, OR103, P158, P174, P220
Anderson M.: P84
Anderson P.: OR10, OR15, OR27, P78, P80, P87
Andersson G.: OR13
Andrews G.: P52
Angst M.: P194
Araghı A.: P223, P29, P40, P41, P69
Arbatın J.: P117, P99
Aretz K.: P123
Arias C.: OR12, P245
Arias Pesántez C.F.: OR53, OR54, P47, P161
Armin S.: OR4, OR6, P249, P254
Armstrong I.: P174
Arnold B.: P174
Aryan H.: P218
Asdourian P.: P104, P110
Asgarzadie F.: OR6, P192
Asher A.: P76
Assietti R.: OR37
Aubourg L.: OR16, OR53, OR63, P115, P65
Auerbach J.D.: OR47, OR67, OR71, OR72, OR96, P13, P42, P75
Aunoble S.: P175, P27, P60
Auque J.: P131
Axelsson P.: P243

B

Babbitt J.D.: P89
Bae H.: OR60, P89
Baek S.: OR26, P105
Bajares G.: P191
Bak K.H.: P125
Balderston R.: OR39, OR45, OR47, OR56, P13, P42, P75
Baldwin N.: P116, P127
Balsamo M.: OR69, P6
Banco R.J.: OR48, OR58, P10, P8, P9
Bao Q.-B.: OR66
Barbagallo G.: OR37, P94
Barnes D.: P66
Baron E.: OR103, P158, P220
Bartish C.: P252
Bartol S.: OR24
Bash J.A.: P50
Bastian L.: OR3
Bauer T.: P124, P43
Baxter R.: OR43
Beaubien B.: OR68, OR74, P190
Beaurain J.: OR16, OR53, OR63, P115, P65
Becker S.: OR84, P57
Beckham R.: OR36, P207
Behari S.: P233, P240
Bento J.: OR31, P90, P91, P92
Benton P.: P200
Benzel E.C.: P102
Berg S.: OR55, OR92
Bergmann G.: P21
Berlemann U.G.: P140
Berlin J.: P142
Bernard P.: OR16
Bernero J.: P84
Bertagnoli R.: OR18 OR21, P111, P170
Besculides M.: P235
Best S.: P66
Bey M.: OR24
Bhagia S.: P188
Bhattacharya S.: P159
Bilkhu S.: OR24
Bilolikar N.: OR2, P244
Bindal R.K.: OR78
Bishop J.: OR24
Bistazzoni S.: P249, P254
Bitan F.D.: P51
Biyani A.: OR22, OR35, P103, P107, P143, P153, P154, P55
Blumenthal S.: OR48, OR51, OR102, P10, P51, P9
Bodemer W.: OR50
Bohinski R.: OR1, OR78
Boileau P.: OR49
Boltes M.: P82
Bonaldi M.: P205
Bonin H.: OR36
Bono C.: OR22, OR35, P31
Boonen S.: OR3
Borthakur A.: OR94
Bowden A.: P54
Bowman B.: P155
Bozkus H.: P157
Bradley W.D.: P214
Braithwaite G.: P142
Branea I.: OR91
Brantley A.: OR90
Brasiliense L.: OR90
Brau S.A.: OR61
Bray, Jr. R.: P158
SAS8 AUTHORS’ INDEX

Brodke D.: P84
Bronsard N.: OR49
Brown C.: P183
Brown T.: OR66
Brown T.D.: P36, P53
Bucciero A.: OR69, P6
Buckley J.: OR87, P238, P63
Burgess J.: P169
Buric J.: P149
Burkus J.K.: OR14, OR62, P113, P86
Bushelow M.: OR52
Butler J.: P141
Buttermann G.: P190
Byung-Ho J.: P156

Cable M.: P26
Cabraja M.: P139
Cai X.: P227
Cameron R.: P66
Cammissa F.: OR39, OR45, P179, P18, P235
Canavati I.: P86
Candy G.P.: P62
Cappuccino A.: OR19, OR51, P51, P72, P93
Carrandang G.: OR23, OR41, OR89, P148, P185, P237, P77
Casesnoves F.: P68
Castellvi A.: P147, P164, P183, P184
Cavanagh D.: P88
Ceola W.: P79
Cesaroni A.: OR98
Chan F.: OR30, P118, P19, P30
Chang K.-Y.: P117, P99
Chataigner H.: OR53, OR63
Chataignier H.: P65
Chavanne A.: OR84, P57
Chee H.: P28
Chen L.: P227
Chen N.F.: OR4, OR6, P217, P249, P254
Chen W.M.: P151
Cheng B.: OR79, P169
Cheong J.H.: P125
Chin K.: OR83
Chinthakunta S.R.: P103, P107
Cho K.-S.: OR77, P120, P246
Choi G.: P24
Choi J.-W.: P210
Choo A.: P226, P251
Christensen F.: P168
Ciccarelli L.: OR30, P118
Ciupik L.: OR88
Clabeaux D.: P147, P164
Claes L.: P234
Clemow A.: P195
Coleman J.C.: P39
Collignon F.: P176
Conrad B.: P216
Corbino L.: OR37, P94
Coric D.: OR25, OR69, P46, P82
Cornwall G.B.: P124
Cosar M.: P192

Coutinho E.: OR11, OR54, OR99, P245, P47
Covey C.: P188
Cox C.S.: P121, P35, P38
Craig N.: P138
Crawford N.: OR26, OR90, P105, P163
Cristini A.: OR86
Cuellar J.: P194
Culbert B.: P166
Cunningham B.: OR20, P12, P179, P72, P93
Cunningham M.: OR31, P91
Curtiss S.B.: P108

D
Dagny Z.: OR60
Daideri G.: OR49
Danielson G.: OR39, OR45, P88
Darden B.: OR9, OR32
Darwono A.B.: P222
Datta J.: OR36, P207
Davenport K.: OR69
Davis R.: OR76, OR79
De Villiers M.: P119, P62
Delamarre R.: OR9, OR39, OR45, OR60, OR76, OR79,
P20, P83, P89
Delecrin J.: OR53, OR63, P65
Demetrioupolos C.K.: OR24, P100
Dennis M.: P103, P107
Deol G.: OR56
DeVine J.: OR19, P72
Dhall S.: P221
DiAngelo D.: OR36, P133, P134, P135, P197
Diaz M.: P191
Dick D.: P212
Dimmig T.: OR25, P46
Doe J.: P168
Donald G.: P179
Dong-Kyu C.: P156
Donkersloot P.: OR65
Donner E.J.: OR38, P1
Doonk A.: P100, P103, P107, P252
Doria C.: P250, P255
Dowling A.: P137
Dreissigacker M.: P137
Dryer R.: P106, P124
Dufour T.: OR16, OR53, OR63
Duggal N.: P111
Dumonski M.: P77
D’Urso P.: P180, P181
Dykes D.: P239

E
Ebert M.: P118
Ebraheim N.A.: P213, P253
Eguizabal J.: P238
Eisermann L.: P124
Elliott D.M.: OR96
Endres M.: P139
Engel I.: P203
Errico T.: OR64, OR75, P40, P43, P59, P90, P91, P160, P167
Fabrizi A.P.: P178
Faizan A.: OR22, OR35, P96
Fan H.: OR93
Fanger J.: P252
Fantini G.: P18
Fauth A.R.: OR94
Fayyazi A.: OR44, OR80, P25
Fehlings M.: P204
Fell J.R.: P37
Fellenz F.: P28
Felt J.: P137, P141
Ferrara L.: P159, P50, P61
Ferree A.: P189, P193, P76
Ferree B.: P187, P189, P193, P76
Fessler R.: OR10, P78
Fessler R.G.: P196
Fenberg F.: P82
Finger F.: P46
Finger III F.: OR25, P46
Fink M.: P111
Fischgrund J.: P116, P130
Foley K.: OR45
Ford W.: P188
Foti P.: OR37
Franke E.: P100
Fransen P.: P176, P209
Fredrickson B.: OR44, OR80, P25
Freeman A.: OR88, P190
Friesem T.: P144, P152, P173, P96, P98

G
Gaber L.: P235
Gabriel J.: OR83
Gaffey J.L.: OR41
Ganey T.: OR97, P200
Garcia R.: P130, P37, P71
Garfin S.: OR7, OR22, OR35, P211
Gastaud B.: OR49
Gehrchen M.: P56
Geiger D.: OR39, OR45
Geisler F.H.: OR20, OR48, OR58, P10, P51, P8, P9
Gepstein R.: P203
Gerard G.: P73
Gerber E.J.: P121, P35, P38
Gerchow J.R.: P61
Gerdhem P.: OR92
Gerstner W.: P122
Gerszten P.: P188
Ghanayem A.: OR22, OR39
Gille O.: P131
Gimbel J.: P2, P236
Girardi F.: P18, P235
Goel V.: OR23, OR31, OR91, P28, P50, P55, P56, P103, P107, P143, P152, P153, P154, P159, P166, P212, P96
Goh J.C.H.: P248

Goldberg E.: OR12
Goldfarb N.: P31
Goldstein J.: OR17, OR43, P20, P3, P90, P91, P92
Goodrich A.: P104, P110
Goodwin D.: OR81
Gordon C.: P2, P88
Gornet M.: OR13, OR60, P86, P79
Gottschalk L.: OR98, P219
Goyal A.: P143, P153, P154, P212
Grabovsky V.: P194
Gratch M.: P130
Greffeuille J.-J.: OR48
Grenoble J.: P112
Grisoni, N.: P207
Grochulla F.: OR29, OR50
Guan L.: P23
Guerin H.: OR66, OR71, OR94, P136
Gumpert R.: P201
Gunter B.: P86
Gunzburg R.: OR86
Guyer R.: OR47, OR57, OR58, P9, P11, P51, P208, P22, P223, P4

H
Hahnle U.R.: P119
Hähnle U.R.: P62
Hai Y.: P23
Haid R.: P145, P146
Haider T.: OR39, OR45
Hall R.M.: P53
Halm H.: OR65, OR85, P126
Halperin M.: P183, P184
Halverson P.: P54
Han B.: P198
Hannibal M.: P241, P256, P7
Hardenbrook M.: P17
Hardy W.: OR24
Harland N.: P177
Harms J.: P100, P123
Harper M.: OR30, P118
Harrop J.: P31
Hausmann O.: P34
Havey R.: OR23, OR41, OR89, P148, P185, P237, P73, P77
Hebecker R.: OR17, P70
Hedman T.: P198
Hedrick M.: OR97
Heinly J.: OR72, OR96
Heller J.: OR10, P78
Henegar M.: OR25, P46
Heo H.-Y.: OR82, P85
Herkowitz H.: OR24, OR39, OR45, P100
Hetzell B.C.: OR58, P10
Heuer F.: OR40, P234
Highsmith J.: P101, P104, P110
Hillmeier J.: P201
Hinter M.: OR52, P5
Hisey M.: P214, P223, P29, P41
Ho E.: OR101, P195
Hochschuler S.: P11
SAS8 AUTHORS’ INDEX

Hodges S.D.: P196
Holly L.T.: P80
Holt R.: OR48, OR58, OR81, P10, P8, P9, P172
Horton C.: OR104
Hovorka I.: OR49
Howell L.: P54
Hoy B.: OR94
Hoy R.W.: P28
Hsu K.: P241, P256, P7
Hu N.: P12
Huh P.-W.: OR77, P120, P246
Humphreys S.C.: P196
Huppert J.: OR16, P65
Huston C.: P188
Hutton W.: OR97
Hwang J.H.: P74

I
Ianuzzi A.: OR42, OR43, OR57, OR78
Ibrahim N.: P55
Idler C.: P241, P256, P7
Ingalhalikar A.: OR56, P145, P146
Iott A.: P146
Isaza J.: OR42, OR43, P145, P146
Ivanov A.: P143, P153, P154, P166

J
Jabbour P.: P31
Jacobs J.J.: OR14, OR62, P79
Jacquet G.: P131
Jahng T.: P155, P168
Jangra J.: P143, P154
Janssen M.: OR9, OR32, P204, P207, P83
Jaramillo J.: OR18
Jawahar A.: P88
Jenis L.: P8, P10
Jodaitis A.: P114
Johnson S.: P26, P66
Johnsson R.: OR92, P243
Juliano L.: P47
Jun S.C.: P32
Jung T.-G.: P24
Justice B.: P241, P256

K
Kabazie J.: P188
Kaddick C.: OR 52, P5
Kafchitsas K.: P15
Kamerlink J.: P167, P160
Kane W.: OR78
Kang M.: P59
Kang N.: P23
Kang S.-G.: OR77, P120, P246
Kanim L.: OR60, P89
Kaps C.: P139
Kasis A.: P144, P173, P98
Kast E.: P165
Kattner K.A.: OR14
Kelly B.: OR36, P133, P134, P135, P197

Kerr E.: P88
Kettani O.: OR53
Kettler A.: OR59
Keun-Su K.: P156
Khanna N.: OR56
Khera A.: P153, P166, P212
Khoo L.: OR4, OR6, P192, P217, P249, P254
Ki Seok P.: P156
Kiaer T.: P56
Kiamil S.: P66
Kiapour A.: OR94, P152, P159, P28, P50, P55, P61
Kieck C.F.: P225
Kikkawa J.: P12
Kilpela T.: OR66
Kim C.: OR7, OR100, P211, P219, P226, P251, P125
Kim D.H.: P74
Kim D.-S.: OR77, P120, P246
Kim J.-H.: P210
Kim J.K.: P74
Kim J.M.: P125
Kim K.: P108, P89
Kim K.N.: P81, P95
Kim S.-B.: P117, P99
Kim S.-H.: P210
Kim S.W.: P117, P99
Kim Y.B.: P137
Kitchel S.: OR39, OR45, P106, P168
Klineberg E.O.: P102
Klingenberg L.: P56
Knight M.: OR8, P228, P230, P231
Kondrashov D.: P241, P256, P7
Korge A.: OR29, OR34
Krishna M.: P152, P96
Kroppenstedt S.: P139
Kryl J.: P129
Kube R.: OR81, P172
Kuklo T.R.: P87
Kulkarni N.: OR22
Kunzeanu A.: P128
Kurtz S.: OR47, OR67, OR78, OR30, OR42, OR43, OR57, OR72, P118, P136, P42
Kwon S.E.: P117, P99

L
Lam S.: P217
Landscheidt J.: P122
Lanman T.: P33, P86
Laubach J.: P137
Laurysen C.: OR20, P4
Lazaro B.: OR90
Le Huec J.: OR65, P27, P60, P175
Lee C.: OR101, P202, P195
Lee C.K.: P55
Lee D.C.: P74
Lee D.Y.: P81, P95
Lee J.-K.: P210
Lee J.W.: P151
Lee K.Y.: P32
Lee K.-Y.: P85
Lee M.: P77
Lee S.-B.: OR77, P120, P246
Lee S.-H.: P150, P24
Lee S.J.: P151, P32
Lee S.-J.: P85
Lee Y.-P.: OR100, P219
Lehmer E.: P112
Lemke A.: P139
Lentz D.: P241, P256
Lhamby J.: OR12, OR54, OR99, P161, P245
Liebelt R.: OR25, P46
Lieber R.L.: OR7, P211
Lieberman I.H.: P102
Lim J.: P162
Lindley J.: P145, P146
Linovitz R.: OR39, OR45
Litrico S.: OR49
Liu B.W.: OR25, P24
Liu J.: P213, P253
Liu Z.S.: P224
Lonner B.: OR72, OR96
Loree H.: P198
Lorenz M.: P73
Lotz J.: OR87, P238, P63
Loughran G.: OR74
Lu N.: P224
Lu S.: P23
Ludwig S.: P199
Lyons A.: P97

M
Mac Millan M.: P216
MacDonald D.: OR42, OR57
Mack C.: OR59
Mackel F.: OR29
Madison M.: OR71
Maglozzii B.: P206
Magno C.: OR46
Maguire P.: OR22, OR35
Mahan J.: OR81, P172
Maina R.: P178
Majd M.: OR48, OR58, OR81, P10, P8, P9, P172
Makris G.: OR101
Malone K.: P229
Maltenfort M.: P31
Mann S.: OR17, P70
Mao K.Y.: P224
Marawar S.: P18
Marotta N.: P192
Martelli G.: P206
Martens F.: OR65
Martin S.: OR23, P52
Marzluff J.: P101, P104, P110
Maxwell J.H.: OR76, OR79
Mayer H.M.: OR34, P36, P53
Mayer M.: OR29
Mazel C.: P131
Mc Gowan D.: P55
McAfee P.: OR19, OR20, OR48, OR56, P146, P72, P93, P12, P51, P9

McCombe P.: P109, P132, P64
McConnell J.: P104, P110
McDonald T.: P108
McGilvray K.: P97
Mclanahan M.: P82
McNally D.: P26, P67, P68
McRae M.: OR18
Meeder J.P.: P201
Mehren C.R.: OR29
Mehta A.: OR94, P143, P153, P154, P212
Mehta G.: OR60
Meisel H.: OR97, P168
Mentsoudis S.: P235
Mendoza S.: P36, P53
Meng B.: P227
Meng X.: P23
Metzger M.: P63
Meyrat R.: P175, P27, P60
Milby A.H.: OR96, P13, P75
Milla F.: P250, P255
Mittelholtz K.S.: P53
Miz G.: OR64, P179, P43, P45
Mocell C.: P188
Möller A.: OR88
Moon S.-J.: P210
Morgenstern R.: P215
Morrison T.: P104, P110
Mroz T.E.: P102
Mummaneni P.: OR7, P221
Murrey D.: OR9, P83
Musante D.B.: OR25, P46
Myers M.: OR71, OR73
Myers T.: OR71, OR73

N
Nagel S.: P126
Nardi P.V.: OR98
Natarajan R.N.: P39
Nechtow W.: OR52, P5
Nel L.: P225
Nel, Jr. L.J.: P196
Nelson L.: OR95
Nene A.: P233
Neu C.: P108
Newman C.B.: P218
Nielsen D.: OR46
Niu G.: P213, P227
Nogues L.: P131
Norton B.: OR104, P137
Novachek T.: P239
Nunley P.: P179, P88
Nyska M.: P203

O
O’Brien J.: OR83
Ochoa J.: OR89, P185
Ochs A.: OR52, P5
Odum S.: OR32
SAS8 AUTHORS’ INDEX

Ogilvie J.: OR95, OR101, P195
Ogon M.: OR84, P57
Oh C.: P169
Oh S.H.: P125
Ohnmeiss D.: OR50, P11, P16, P214, P22, P223, P48
Okenouglu T.: P157
Olindo G.: OR37, P94
Oliveira L.: OR12, OR54, OR99, P161, P245, P47
Onibokun A.: P249, P254
Ordway N.: OR44, OR80, P25
O’Reilly O.: P63
Orenstein D.: P128
Ortiz G.: OR87
Ortner F.: P201
Otten P.: P128
Oyola A.: P159
Ozer A.F.: P157

P
Paganelli J.: P155
Palotti V.: P206
Palissey V.: P67
Paller D.: P193
Papadopoulos S.: OR10, P78
Paquis P.: OR49
Pare P.: P30, P39, P19
Parepalli B.: P152, P159, P166
Park C.K.: OR77, OR82, P85, P120, P246, P32, P74
Park J.: OR93, P162
Park K.W.: P151
Park M.S.: P117, P99
Park S.-A.: OR44, OR80, P25
Patel V.: P97
Paterson A.: P112
Pathari N.: P242
Patwardhan A.: OR23, OR41, OR89, P148, P185, P237, P73, P77
Paulino C.: P242
Pazmismo P.: P14, P33, P44
Pedersen D.R.: P36, P53
Peng C.W.: P90, P92
Pennings F.: P108
Perez A.: P191
Perrin G.: OR86
Petition J.: P17
Petite K.: OR38, OR75, P1, P106
Phillips F.: OR13, OR19, P187, P189, P193, P2, P72, P76, P77
Piek J.: P70
Pienazek J.: OR88
Pimenta L.: OR12, OR54, OR69, OR99, P161, P187, P189, P192, P193, P202, P245, P47, P76, P93
Pinto M.: P141
Platania N.: OR37, P94
Poelstra K.: P199
Poenaru D.: OR91
Ponce C.: OR32, P207
Popovich J.: P198
Powers A.: P145, P146
Pradhan B.: OR60
Prejbeanu R.: OR91
Puttlicht C.: P97

Q
Quirno M.: OR31, OR64, P160, P167, P242, P59, P90, P91, P92

R
Raabe T.: P88
Rabin D.: P111
Raju R.: P144, P173, P98
Ramadan A.: P131
Ramruttun A.K.: P248
Rashbaum R.: P223
Rashid M.A.: P177
Rathmell J.: P188
Rauschmann M.-A.: P15
Regan J.: OR19, P14, P33, P72, OR48, P10, P44
Regev G.: OR100, P226
Reitman M.: P118
Renkens K.: P112
Renner S.: OR23, P148, P237, P77
Resnick D.K.: P87
Reusswig P.: P188
Reyes P.: OR26, OR90
Reyes-Sanchez A.: OR69, OR70
Rhyne A.: OR32
Rich K.: P124
Rich M.: P174
Richter A.: OR85, P126
Riew D.: OR15, OR27
Rigobello L.: P149
Riina J.: P80
Ring C.: OR59
Rivera D.: P141
Roberto R.F.: P108
Rodriguez W.: P106, P121, P35, P38
Rodriguez R.: P191
Rogers S.: OR89
Rohlmann A.: P21
Rohlmann F.: OR59
Roome A.: P26
Rosler D.: OR89, P185
Ross R.: OR42, OR43, OR78
Roth J.: P17
Roth S.: OR101, P195
Roualdes G.: P131
Roush T.: P214, P22
Rozumalski A.: P239
Ruiz J.N.: P248
Rundell S.: OR47, P155, P236, OR67, P42
Ruskin S.: OR20
Russell M.: P88
Russo V.: OR37, P94
Ryu K.-S.: OR82, P85

S
Sachs B.: P223, P183, P184
Safavi-Abbasi S.: OR26
Sahlstrand T.: OR92
Sama A.: P235
Sander E.: P133, P134, P135, P197
Santoni B.G.: P97
Sarioglu A.C.: P157
Sartori M.: OR41
Sasani M.: P157
Sasso R.: OR10, OR15, OR27, OR64, P109, P204, P29, P40, P41, P43, P69, P78
Schaer T.P.: P205, P247
Schaffa T.: OR54, OR99, P47
Schmidt C.: P52
Schmidt H.: OR40, P234
Schmering M.: P168
Schreiber R.: OR97
Schultz D.: P188
Schütz C.: OR85
Schwaegler P.: P183
Schwartz M.: P239
Schwarzenbach O.: P140
Schwenke T.: OR66, P30
Scott-Young M.: OR18, OR46, P93
Scuderi G.J.: P194
Sears W.: P109, P132
Sebesta P.: P129
Seim H.: P187, P189
Seme S.: OR68
Sengupta D.: OR56, OR93, P2, P233, P145, P146, P240
Senoglu M.: OR26
Serhan H.: OR22, OR35, P100, P103, P107, P55
Sgier F.: P34
Shadduck P.: P46
Shah J.: OR13
Shah P.: OR30, OR78, P136
Shanti N.: P242
Sharan A.: OR33
Sheikh H.: OR6, P249, P254, OR4
Sherman J.: OR103, OR76, OR79, OR104, P14, OR39
Shim C.S.: P150, P24
Shim J.H.: P74
Shin H.C.: P81, P95
Sibilla F.: P175
Siddiqui F.: OR32
Siepe C.: P36, P53, OR34
Simopoulos T.: P188
Singh K.: OR13
Singh R.: P233, P240
Singh V.: P138
Siskey R.: OR30, OR72, OR78, P118, P136
Sjovold S.: OR89
Skipor A.K.: OR14, OR62, P79
Sliwa K.: P119, P62
Slosar P.: P186
Smith F.: P138, P244, P52
Smith K.K.: P121
Smith W.: P229
Smuck M.: P188
Snell R.: P66
Sola S.: OR17, P70
Songer M.: OR69
Sonntag V.: OR26, OR90
Spehar J.: P169
Spine Study Group: P224
Spivak J.: OR31, OR39, OR45, P20, P242, P90, P91, P92
Srour R.: P128
Steffen T.: P52
Steib J.P.: OR16, OR53, OR61, P115, P65
Steinbeck M.: OR43
Steinmetz M.P.: P102
Stevenson K.: P104, P110
Stieber J.: OR31, P43
Strauss K.: P179
Strickland J.: P216
Strömqvist B.: OR92, P243
Stulik J.: P129
Su Q.: P23
Summerhayes K.: P52
Sun Y.: OR11, OR28
Sundararajan S.: OR24
Sung-Uk K.: P156
Swanson A.: P239
Szpalski M.: OR88

T
Tang S.: OR33
Tang T.: P213, P253
Tang T.-S.: P227
Tarver J.: P188
Tay B.: OR19
Taylor W.: P174
Tepper G.: P45
Tessitore E.: P182
Thai L.: OR60
Thaiyanaanthan T.: OR103
Thalgott J.: OR75
Theodore N.: OR90
Theofilos C.: OR64, P29, P40, P41, P69
Tibbs R.: OR64
Tidu L.: P250, P255
Tobler W.: OR1
Tomaras C.: P104, P110
Tompkins D.: P193
Tonga F.: P175
Traynevelis V.C.: P113
Treharne R.: OR27
Tropp H.: OR55
Tsantrizos A.: OR65
Tucker S.: P247
Tufaga M.: OR87, P238
Tullberg T.: OR92
Turner A.S.: P97
Turner S.: P187, P189
Tuschel A.: OR84, P57
Tyndall D.: OR56
Tzermiadianos M.: OR23, P237, P73

U
Urban M.: P235
SAS8 AUTHORS’ INDEX

V
Vaccaro A.: P31
Vaidya S.: P137
Valdevit A.: P59
Van Meirhaeghe J.K.: OR3, P201
van Ooij A.: OR42, OR43, OR76
Van Sickle D.: P187, P189
Vanderschot P.: P201
Vasavada N.B.: P150
Vashishth D.: OR33
Verma R.: P14, P33, P44
Vermesan D.: OR91
Vermesan H.: OR91
Villarraga M.: OR72, P136
Villarraga M.L.: OR78
Vital J.-M.: OR16
Volcan I.: P104, P110
Voronov L.: OR89, P148, P185, P73, P77, P237, OR41
Vorwald P.: P31
Vyskocil T.: P129

W
Walker J.: OR52, P5
Wang C.: OR96
Wang G.: P213, P227, P253
Wang J.: OR60
Wang J.C.: P102
Wang Q.: P23
Wang Y.: P224, P253
Wang Z.: P224
Ward K.: OR95
Ward S.R.: OR7, P211
Wardlaw D.: OR2, OR3, P138, P244
Watkins R.: OR39, OR45
Watson R.: P155
Webb J.: OR100, P219
Webb S.: OR91, P112, P183, P184
Weinberg I.: P62, P119
Welch W.C.: OR76, OR79
Werner D.W.: OR69
Werner K.: P165
Wervey R.: P239
Wessman B.: OR74
Wharton N.: P8
Wheeler D.: P238
Whitaker C.: P43
Wildstein M.: P7
Wiles D.: P183
Wilke H.-J.: OR40, OR59, P165, P234
Wimmer M.A.: OR2, OR3, P138, P244
Wingate J.K.: OR76, OR79
Wingo C.: P168, P183
Wociejchowsky C.: P139
Wolf S.: P45
Wong H.K.: P248
Wright J.: P130
Wright N.: P127, P141
Wupperman R.: P220

X
Xiao S.H.: P224

Y
Yang H.: P213, P227, P253
Yang J.: P23
Yang K.: OR24
Yapor W.: P141
Yaszay B.: P59
Yeomans D.: OR91
Yeung A.: OR75, OR5, P232
Yeung C.: OR75
Yi S.: P81, P95
Yim J.: P155, P163
Yong-Eun C.: P156
Yoo D.-S.: OR77, P120, P246
Yoon D.H.: P81, P95
Yoon K.: P49, P58
Young-Sul Y.: P156
Youssef J.: P106, P112, P127, P186, P31
Yu W.: OR83
Yuan H.: OR39, OR44, OR45, OR65, OR69, OR80, P25
Yue J.: OR39, OR45, OR18, P37

Z
Zaki R.: P166
Zander T.: P21
Zarda B.: P252
Zdeblick T.A.: P113
Zhang C.: P23
Zhang X.F.: P224
Zhang X.S.: P224
Zhang Y.: P169
Zhang Y.G.: P224
Zhao L.: OR60
Zhu S.R.: P224
Zigler J.: OR9, OR39, OR45, OR50
Zindrick M.: P73
Zou D.: OR69
Zucherman J.: OR39, OR45, P241, P256, P40, P45, P69, P7
Zufelt N.: P133, P134, P135, P197
# APPLICATION FOR MEMBERSHIP

**MEMBER INFORMATION**

*Please print clearly in BLOCK characters*

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<thead>
<tr>
<th>Salutation:</th>
<th>First Name:</th>
<th>Last Name:</th>
<th>Suffix (MD, PhD):</th>
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Do you have an administrative contact that will handle your membership? If yes, please enter the contact information:

<table>
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<tr>
<th>Admin Name:</th>
<th>Admin Telephone:</th>
<th>Admin Email:</th>
<th>Admin Fax:</th>
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Public information, if supplied, will appear in the public member search on the SpineArthroplasty.org website. Note that only basic contact information is provided to the public to promote your organization. To see the information provided to the public, please visit www.SpineArthroplasty.org home page and do a search.

<table>
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<th>Web Site URL:</th>
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<td>(Example: YourSite.com)</td>
<td>(Example: <a href="http://www.yoursite.com">http://www.yoursite.com</a>)</td>
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Please provide a brief description of your professional qualifications (for application purposes only – non-public):

Please provide us with a 6 digit character password that you will use to access the SAS members area. This password will also provide you with access to the SAS Online Journal:

Please provide a brief description (200 characters or less) for your profile:

Please provide us with a 6 digit character password that you will use to access the SAS members area. This password will also provide you with access to the SAS Online Journal:

### INDIVIDUAL MEMBERSHIP CATEGORIES (SELECT ONE FROM THE FOLLOWING):

#### REGULAR MEMBERSHIP

- **Physicians:** Those actively practicing spine surgery.
- **Industry:** Those actively involved in the spine surgery industry.

#### ALLIED HEALTH PROFESSIONALS

- **Resident:** Those in residency to become a practicing spine surgeon.
- **Fellow:** Graduates of orthopedic surgery residency training programs under the direction of a spinal surgeon.
- **Nurse:** Nurses practicing spine surgery.
- **Student/Researcher:** Students or researchers in spine surgery.
- **Retired:** Physicians no longer practicing medicine.

### INDIVIDUAL MEMBERSHIP FEES:

#### REGULAR MEMBERSHIP FEES:

- One Year $390
- Two Year $705 (Savings of $100)
- Five Year $1,725 (Savings of $250)
- Lifetime Member $2,500 (10 years)

#### ALLIED HEALTH PROFESSIONAL MEMBERSHIP FEES:

- One Year $250
- Two Year $425 (Savings of $100)
- Five Year $1,025 (Savings of $250)

*Note: There will be a one-time registration fee of $25 added to membership fee at time of membership*

In submitting this application for membership, I agree to the bylaws and the rules and regulations of the Spine Arthroplasty Society.

Membership dues for all categories, including board, advisory panels, committees, corporations, affiliated societies and government entities are USD $390 (three hundred ninety US dollars) for Regular memberships or $250 (two hundred fifty US dollars) for Allied Health Professionals payable on an individual annual basis. Dues may be paid in local currency contingent upon the payment option selected. An additional handling surcharge of $10 is required for all fax and mailed applications. All applications must include full payment to be processed.

**CHECK, MONEY ORDER, BANK DRAFT** - Local currency equivalent equal to above total. Make payable to: The Spine Arthroplasty Society. Mail with completed order form to: The Spine Arthroplasty Society, 2323 Cheshire Drive, Aurora, IL 60504 USA

**CREDIT CARD, DEBIT CARD** - Your signature below authorizes a charge for the total amount.

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<th>Signature:</th>
<th>Expiration Date:</th>
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**Fax to:** SAS Registrar - (817) 460-6200  **Mail to:** The Spine Arthroplasty Society, 2323 Cheshire Drive, Aurora, IL 60504 USA

**WIRE TRANSFER** - To pay the total amount by wire transfer, provide the following information to your sending financial institution: Chase JPMorgan Chase Bank, NA, Chicago, IL USA 60670 Routing/Transit No. 071000013 For credit to Spine Arthroplasty Society, Inc. Account No. 001026071000012 747302297 Chase JPMorgan Chase Bank’s website 1-800-741-1700

**QUESTIONS?** - Contact: Heather Howard, Director of Operations for Spine Arthroplasty Society; call (817) 460-5200; fax: 817-460-6200; email: heather@spinarthroplasty.org or visit the website at www.SpineArthroplasty.org  The Spine Arthroplasty Society, 2323 Cheshire Drive, Aurora, IL 60504 USA
The Spine Arthroplasty Society

Kristy Radcliffe, Executive Director
Tel: +1-630-375-1432, Fax: +1-630-375-1437, Email: kristy@spinearthroplasty.org

Heather Howard, Director of Operations
Tel: +1-817-460-5200, Fax: +1-817-460-6200, Email: heather@spinearthroplasty.org