Coming to a Standstill?
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Executive Summary

We are entering a critical era for spine surgery – a confusing time of many major risks and opportunities. In recent years we have seen a renaissance in innovative technologies that promise to improve outcomes for spine patients. At the same time, global economic recession and long-term structural economic problems are obliging us to change our healthcare system, thus creating many major new opportunities. But most people in the field of spine are feeling somewhat disoriented by the amount and rapidity of the changes, as well as the accompanying overload of information, both in scientific research and in healthcare policy.

The purpose of the Mercury report on the recent SAS Conference in New Orleans is to provide greater clarity and insight into the current science and policy trends in spine surgery. Our company attended all 25 hours of conference presentations, met with representatives from nearly every company exhibiting in New Orleans, critically evaluated all 506 study abstracts as well as a variety of other written materials from the conference, and we spoke extensively with the SAS President, Staff, and Program Chairs. We have selected the best of this information for you, distilled it down into a quick and clear report, and provided our own commentary and insights into what it all means for the future of spine surgery.

Summarizing briefly, America is no longer able to sustain an opulent “taxis and limos” system of healthcare. The country is trying to shift to a “buses and taxis” system of healthcare. Thus although “motion preservation” technology has generally demonstrated excellent clinical outcomes for the majority of patients, reimbursement remains mostly blocked for now, due to a lack of cost-effectiveness studies, as well as regulatory hurdles. Meanwhile, minimally invasive surgery has emerged as the main road forward to improving healthcare outcomes through better technology and procedures. Across the field of spine surgery, further improvements in diagnostics, patient selection, safety, and cost-effectiveness would all help to advance the field. Finally, there are major opportunities in America and around the world for any spine clinic or spinal device company that can discover new ways to deliver the same level of high quality medical care at half the price.

Spine surgery has entered a disorienting period of critical changes. The Mercury reports will provide clarity and insight on the essential current research and healthcare reforms. Further information on subscriptions can be found at the end of this report.

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Introduction

For many years, arthroplasty, or “motion preservation technology”, has been enthusiastically promoted as the next generation of spine surgery treatment for degenerative conditions. Indeed, SAS grew up on the promotion of this new technology. But now arthroplasty is hitting a new economic situation, and is losing forward momentum. The recent global economic recession put the brakes on spending for most everything. Even long before then, healthcare spending was growing unsustainably, and healthcare reform was inevitable in America. Spine surgery in general has been on the defensive, due to its perceived high costs, and arthroplasty specifically has not been enthusiastically adopted by payors or policy makers. At SAS this year, there was a real sense of frustration and bewilderment with the loss of forward momentum that arthroplasty is encountering. And nearly a quarter of the conference was dedicated to discussing economic issues.

Summing up all the research and discussions, arthroplasty has demonstrated good clinical outcomes, but for the moment it remains stalled on reimbursement in the US and has not been as widely embraced as expected elsewhere. More economic research, as well as fine tuning of the patient selection criteria, would probably move arthroplasty forward to general acceptance. By contrast, posterior dynamic stabilization appears to have a dim future – safety concerns and lack of a clear rationale leave it difficult to envision any further growth in this area. Meanwhile, with improved clinical outcomes and continuing reimbursement, fusion is looking “not so bad after all”. Minimally invasive surgery is emerging as the clear way forward to improve upon fusion’s outcomes, especially in the US. Interspinous spacers remain an attractive option for indicated cases. New devices and procedures have led to improvements in diagnostics and in the treatment of deformity, fractures, and tissue repair. By contrast, biologics continue to raise safety concerns, and other biochemical treatments such as stem cells, although promising, remain mostly investigational for now. For many years, innovation in spine surgery has been driven by better engineering. While that is likely to remain true in some cases, spine surgery innovation in the coming decade is more likely to be driven by economics – finding ways to deliver the same level of high quality care... at half the price.

The purpose of this report is to provide an evaluative summary of the research studies and debates from the SAS conference. Although conferences only present a sampling of unfinished “research-in-progress”, they do serve as the earliest “warning system” of what is happening with specific devices and where the field as a whole is going. Regrettably, so much is communicated at conferences that it is difficult for anyone to take it all in, separate the gems from the junk, and stitch the best info back together into a coherent picture. The Mercury conference reports aim to provide the readers with the “Cliff Notes” summary of the most important information, and our own commentary on what the research and debates will mean for the future of spine. We hope you will find this report useful and welcome your feedback.
Health Care Economics

SAS had two high-level speakers give excellent talks about healthcare reform in America. Both speakers tried to impress upon the audience the inflexible economic realities that the country is confronting, and to provide a forecast of where things will be going.

Michael Leavitt – former governor of Utah, former CEO of a health insurance company, and former US Secretary of Health & Human Services – provided an executive-level view of the crisis that America is facing. He opened with an instructive historical account of how Argentina used to be one of the strong economies in the world but eventually sunk because over the half the population were either state-pensioners or state-employees who refused to accept changes to keep their economy competitive. He warned that America will need to make some painful changes or face the same kind of economic collapse that hit Argentina. He noted that America has painted itself into a corner on these issues. There will be 15-20 million Medicare patients, who will be the responsibility of the individual states, some of which are already financially challenged. There will be substantial downward pressure on reimbursements because of substantial downward pressure on the economy in general and because of America’s heavy load of debt. There will be fewer insurance companies, because many of them will simply redeploy their capital into completely other sectors. There will be a large group of people – the “strategically uninsured” – who will just pay the penalties for not purchasing insurance, because it is cheaper than paying for insurance and they are young and healthy anyway. Michael Leavitt affirmed that we are clearly moving toward more comparative effectiveness research, but he also predicted that future payment decisions will be linked very strongly to this CER, because Medicare already links to NIH research. He asserted that if MDs don’t get involved, payments will be determined by MBAs. He warned that history is replete with countries whose economies got out of balance and collapsed. He said that America must rebalance its economy and the only way to do this is to reduce healthcare costs. Many hospital CFOs are realizing that they will have to get by on Medicare rates. Michael Leavitt affirmed that this is substantial change for the country, but it’s not driven by 535 legislators in Washington DC. It is driven by global economies. China and Japan are no longer buying our debt at US bond sales. So, Michael Leavitt chided, we have to make real change and real sacrifice: we must change how we eat, how we exercise, and how we practice healthcare. He said that we are moving toward three types of insurance: Medicare/Medicaid, commercial carriers for large employers, and exchanges for individuals and small businesses. He said that it is like we are reforming the transportation system: most people will ride on buses even if it is slower and more crowded, while some people will themselves pay more to ride in taxis or limos. He asserted that we have a very opulent system – we have not made the hard decisions that the EU made to put limits on what they do and to let people wait in lines. But we cannot have a system where everyone rides around in a limo. So we are trying to create a system where at least everyone can get on the bus. If they want to pay for a taxi instead, that’s fine. He said that doctors must get involved and figure out how to measure the value of spine surgeries. If the MDs don’t, then the MBAs will. Michael Leavitt concluded by saying that in the past “innovation” has been defined as anything you could get reimbursement for. But in the future, “innovation” will be defined as something that demonstrates its cost-effective value. “Innovation” is going to have a new face – reaching the same health outcomes at half the cost.
The other keynote speaker this year was the world-renowned Healthcare Economist, Uwe Reinhardt from Princeton University. He began by explaining the three structural reasons why the US has been compelled to undergo healthcare reform. First, the rise in spending on healthcare is unsustainable. It is projected that healthcare spending would become 40% of GDP by 2050. Second, the lower middle class – the people who make the country run on a day-to-day basis – is being priced out of healthcare. He said that the median income in the lower middle class is $20-55K, but the median cost of health care is $16K. Third, there are growing doubts about the value obtained for the money spent. Even moderate business people feel that the US obtains 25% less value than Europe from its healthcare spending. Prof. Reinhardt then reviewed some of the issues that healthcare reform is supposed to address. Universal insurance coverage and reform of small policy insurance coverage were desired. More use of IT in healthcare is needed to reduce administrative inefficiency. Medical malpractice reform is needed – the tort system should be replaced with dispute resolution. There needs to be greater transparency of hospital costs and incentives for better physician performance. And the million dollar question facing the nation is whether we want to blow 40% of GDP on healthcare? Prof. Reinhardt wound down by saying that America needs to keep healthcare affordable for the blue-collar population but currently is pricing them out of it. He concluded that only doctors can do this, because they’re the ones who make the orders.

In his Presidential Address, Dr. Thomas Errico also emphasized the importance of increased economic research on spine surgery. He said, “Research is needed now to demonstrate the value of what we do. The recent global economic recession and healthcare reform means that everyone is looking at the price of everything and what they get for their money. There’s a lot of research showing that we deliver major clinical improvements. Privately, we know that spine surgery is a worthwhile investment in a patient’s long-term health, but we have not published enough on its cost-effectiveness. We need to increase our collaborations with professional healthcare economists to get this evidence and message out there to the public and policy makers.” Dr. Errico also stated that research is needed to “clean house”. To make room for the best new treatments, spine surgery needs to get rid of things that don’t work well. As examples, he expressed his doubts about EMGs and repeat epidural steroid injections. And then, foreshadowing Michael Leavitt’s comments above about buses and limos, Dr. Errico asked, “And what about all the brand-name narcotics, which are so expensive. Are they really any better than cheap generic narcotics, or is everyone riding around in a Rolls Royce these days? A lot of this stuff wastes money that could be better spent on the treatments that do work.”

Responding to the calls from Michael Leavitt, Uwe Reinhardt, and Thomas Errico for doctors to get involved in the economics of healthcare, SAS had a Symposium on “Defining Value in Spine Surgery”, (echoing the title of the Mercury report on NASS in San Francisco 2009).

Opening this symposium, Dr. Steve Glassman asked how value can be defined and measured in spine surgery. He said that everyone may have different views on what is valuable, but cost per “quality-adjusted lifeyear” (QALY) is the standard metric for value in medicine and healthcare economics, whereby treatments that cost about $50-100K / QALY are generally considered reasonably cost-effective. He said that comparative effectiveness research should not make people nervous, and that randomized controlled trials aren’t always the right way to get answers about something. He said that large patient registries are needed to answer these questions on the cost-effectiveness of treatments. And he concluded by remarking, as we also
have in past conference reports, that generating the evidence for spine surgery has become crucial at this historical moment.

Dr. Frank Phillips continued with a lucid talk on assessing the value of new spine technologies. He opened by citing the very recent paper of Deyo et al 2010 in JAMA as an example that spine surgeons are under attack because spine surgery is expensive. He noted that there are competing healthcare providers, such as radiologists, chiropractors, etc. He said that industry often comes up with overpriced new devices that adds to the problem. Yet he also stated that spine surgeons are often not innocent, because surgeons decide to use new technologies that are not cost-effective. Dr. Phillips asserted that new technology – and the high spending on it – may not always be worth it. It’s like the new 50” plasma-screen TV for $2000 vs. the old TV for $400. Is the plasma-screen TV really worth the extra money (or debt)? He added that the new technologies can make the old technologies more expensive because the old procedure is performed less often. He said that the cost/benefit ratio should be the main outcome for spine surgery studies, because that’s what payors care about – they don’t care about ROM. He reminded the audience that society must ration among different therapies for all people – society cannot purchase everything for everyone. He concluded by saying that payors and policy makers are demanding evidence, yet surgeons cannot focus only on cost, because the purpose of medicine is to improve health.

Dr. David Wong talked about comparative effectiveness. He started by saying that Comparative Effectiveness Research received $1.1 billion of funding at the start of President Obama’s term, divided among NIH, CMS, and AHRQ. He told the audience that in the worst case CER becomes cost-containment, and they had to watch out for that. Dr. Wong reported that the director of AHRQ said they would look at public policy (e.g. should we fund fusion), systems (e.g. where should it be done), and clinical policy (e.g. who should get it). He concluded by pointing out that a bill saying that CER could not be used to deny coverage was voted down.

Talking about the European experience, Dr. Rudolf Bertagnoli noted that it is more accepted in Europe to have the government assess treatments, because the government is the one who pays for nearly all healthcare.

Dr. Todd Albert applied these questions of value to cervical TDR vs. ACDF. He started by defining value as the outcome per dollar – the “bang for the buck”. He then asserted that there isn’t much difference in outcome between cervical TDR and ACDF. There isn’t much difference in adjacent segment disease. There isn’t much difference between Bryan and ACDF for cost. Using Markov modeling, there isn’t much difference in clinical outcomes or complications for TDR vs. ACDF. He concluded that cervical TDR really isn’t cost-effective unless it reduces the long-term reoperation rates.

During the Q & A session, the CEO of one of the major spinal device companies said that in the EU his company is putting all its money into motion preservation, while in the US they are putting all their money into minimally-invasive fusion.

Another audience member remarked that vendors have reduced their prices because hospitals have become cost-conscious.

One of the symposium panel member remarked that data is going to drive things, so surgeons need to contribute to that research. Payors don’t want FDA IDE data, he said. They want real-world data on real-world patients.

In the opening “Arthroplasty Around the World” symposium, several speakers touched
on economic issues. Dr. Rudolf Bertagnoli, presenting the European perspective, opened by stating that in the EU, low back pain is the #1 cause of healthcare expenses, doctor visits, lost days of work, and worker’s comp. It costs Germany 24 billion Euros per year, 70% of which is indirect expenses. Later he remarked that in 2001 everyone expected TDR to take over fusion, but apparently it has lagged behind. Three of the seven reasons he gave for this were economic: surgeons get less payment than for fusion, industry has a stake in the old technology they have, and payors are wary of new technology.

The outgoing SAS President, Dr. Chun-Kun Park, presenting the Asian experience with TDR, had a cautionary tale. He said that Korea was one of the first Asian nations to use TDR. Many surgeons who were not properly trained for TDR were allowed to do it. There were many complications, and the patients went to other hospitals. TDR acquired a bad reputation in Korea, and its use declined dramatically. When the US FDA approved Charité for only single-level use, the Korean Health Agency also decided to sharply restrict the use of TDR. He later remarked that the second generation cervical discs don’t have a good educational program in Asia. They just launch and sell. They have good market share, but the future is unstable. He concluded that proper surgeon training is critical for the success of a disc.

Dr. Scott-Young gave a cogent overview of the healthcare realities that are facing Australia. He opened by remarking that Australia is a democracy, so they have to pay for their healthcare too. They are confronting the same issues: physician autonomy, litigation systems, prevention of obesity, etc. He pointed out that 60% of healthcare costs are incurred in the last years of people’s lives and asked if that was ethical or effective. He then went on to remark that a quarter of Australia’s doctors are from other countries, Australia unlike New Zealand has a rigid litigation system, and Australia has many racial, socioeconomic, and geographic disparities in its healthcare system. Dr. Scott-Young then asked rhetorically what all this has to do with total disc replacement. To answer this he reminded the audience that Australia has a nationwide healthcare system and TDR is just one tiny slice of that. So government is trying to manage a whole set of complex healthcare issues much bigger than TDR, and they use the scientific evidence available to reach quick decisions about what is most worth funding when.

In a symposium on cervical TDR, Dr. Frank Phillips talking about the Future of TDR also addressed mostly economic issues. He opened by saying that the spine surgery community has to show benefit to society as they compete for scarce resources. He noted that insurers care about pain and quality-of-life, not radiographic ROM. He said that pricing is an issue because TDR costs 1.5x what ACDF does. He told the audience that they have to show it’s worth the cost if they want people to pay for it. After further comments on disc design and clinical results, he conclude by saying that the spine surgery community needs to produce new kinds of research: long-term data, analysis of patient subsets, and cost-effectiveness studies.

One study evaluated the cost-effectiveness of lumbar TDR vs. fusion, examining all direct costs of treatment over 18 months in the Austrian healthcare system, with clinical data drawn from other recent studies. They reported that the cost per 1 point of ODI improvement was 954 Euros in the fusion group vs. 645 Euros in the arthroplasty group. They concluded that TDR is more cost-effective than fusion. [504]

One interesting study from the Texas Back Institute compared the costs of 8 patients receiving TDR to 8 patients who had been denied coverage for TDR and received fusion instead. There
were 5 single-level and 3 double-level patients in each group. TDR was significantly less expensive both in terms of the total billed ($66K vs. $99K) and the total paid ($37K vs. $55K). They said that one reason fusion was more expensive was the longer OP time and longer hospital stay. This suggests that minimally invasive fusion might be more cost-competitive. [56]

During a symposium, Richard Longland, the founder of a patient advocacy group (Arthroplasty Patient Foundation) mentioned that they had conducted an online survey of patients. He said they found that the average cost of TDR was $45,000, with average out-of-pocket costs of $19,000. He also said that 45% of patients flew abroad for TDR, 25% to Germany.

At least one other speaker also asserted that patients are shopping around internationally for their spine surgery. Given that the costs of most procedures dwarf the costs of an airline ticket, it is surprising that medical tourism is not already more widespread.

One oral poster reviewed data from 1030 patients treated at an ambulatory spine surgery center: 377 lumbar microdiscectomies & decompressions, 298 PLFs or TLIFs, 193 ACFs, and 83 lumbar TDRs. A total of 6 patients returned to the OR, 5 were transferred to the hospital, and 2 were transferred to a rehab unit. The patient satisfaction rate was 97% (at an unspecified timepoint). The poster reported that outside insurance audits indicated a 60% cost-savings compared to standard hospital settings. They implied that quality spine surgery can be provided at lower costs at an ambulatory surgery center. [115]

Finally, an insightful and promising poster reported on the first stage of a study assessing the feasibility of delivering treatment with X-stop in areas of the developing world with minimal medical resources. X-stop, an FDA-approved treatment for lumbar stenosis, is implanted under local anesthesia and requires minimal post-operative care. They retrospectively reviewed patient records at one clinic in San Francisco, and found that only 12 of 397 patients presenting with neurogenic intermittent claudication were counterindicated for X-stop, and the other 385 were treated. They noted that the symptoms predictably came from L3/L4 or L4/L5 in 92% of the cases. They anticipate that X-stop could be used in rural parts of developing nations, with or without x-rays, despite the scarcity of medical resources there. As the next stage of their pilot project, they are conducting screening interviews among rice farmers in Myanmar. [223]

[See also study 164 in “Minimally Invasive Surgery for a cost comparison of XLIF to PLIF.”]

The US and EU economies are unlikely to experience major expansion any time soon. Healthcare reform is also unlikely to fade away during this decade. Thus we anticipate that economic debates will remain active around spine surgery for many years to come. Indeed, it is not difficult to envision a future where the selection of which spine surgery procedures are performed or not is driven largely by reimbursement decisions. But currently, the field of spine surgery seems poorly prepared to address these economic debates. Spine surgeons and spinal device companies routinely collaborate with engineers for example but almost never with healthcare economists. And until recently, most spine surgery journals rarely published even one economics paper per issue. Yet insurance companies and even government agencies are full of economists, MBAs, and accountants. In our opinion, the field of spine surgery needs to substantially increase its collaborations with healthcare economists, in order to begin analyzing spine surgery from a financial perspective.
Overview

This quote is taken from the presentations by Dr. Kenneth Pettine, the inventor of the Maverick disc, who hit the bullseye on the general sentiment about arthroplasty at SAS this year. After each of his research talks, he said he’d added one more slide just last week to express how he’s been feeling lately. “We’ve got great level-1 data, but so what? Coverage remains impossible. And physician reimbursement is abysmal.” This supports our point above that the near future of spine surgery might be determined more by economics than by clinical effectiveness. At the very least, economic decisions will be driven by economic data, which so far is mostly lacking in the spine surgery literature.

In the opening symposium on arthroplasty, Dr. Scott Blumenthal echoed these sentiments. After reviewing all the US FDA IDE trials on arthroplasty, he said, “people say they need to see more data, but with several level-1 studies, what more do they need to see?” It is hard to understand, but the hidden answer is surely “economic data”. In reply, one expert surgeon expressed the opinion that payors are not covering arthroplasty because they know there are a lot of patients who would not have fusion for their back pain but would have TDR, and the insurers don’t want to pay for all those additional surgeries. On the surface this sounds plausible, but upon further scrutiny seems unlikely. Only a slim fraction of fusion patients could also be indicated for arthroplasty – in fact one published study reported that less than 1% of their patients receiving fusion for DDD met all the inclusion and exclusion criteria for TDR. Second, although American patients might go to Europe or delay surgery a few months in order to have TDR instead of fusion, it is unlikely that many patients would stubbornly refuse to have any surgery at all – remaining in pain and disability – just because they could not have TDR. To my awareness, there is no patient survey data to support this claim that many people are refusing surgery altogether merely because TDR is not covered. Although some patients did withdraw from TDR RCTs when they found they were assigned to the fusion control group, it cannot be assumed that they never had surgery later somewhere else. Finally, although insurance companies do have to manage the finite amount of finances they have available, it is difficult to presume that they are so nefarious that they would deny coverage on a new, more effective, less expensive treatment, simply because there are some additional patients who would only accept that new better treatment but not the old one. Thus the more plausible explanation is simply that payors want to review a very comprehensive body of clinical and economic data before granting approval, because it is much harder to reverse a coverage decision later. Or they are simply not yet convinced that TDR is cost-effective.

On the last day, an audience member echoed Dr. Pettine’s sentiment in a question to another panel. Dr. Rick Guyer responded more optimistically. As virtually the final remarks to the whole conference, he said that the spine surgery community just needs to keep reporting its data, and he felt that the insurers would eventually give in, do the right thing, and cover it. No mere overoptimism, this viewpoint seems correct. Insurance companies may continue to stall for up to a few years, but eventually they will cover arthroplasty. More studies on the cost-effectiveness of arthroplasty versus fusion would surely speed this process. The clinical outcomes and safety are already known and generally convincing. Studies to improve patient selection and sharpen the indications and counterindications would probably also be helpful, as this would improve the rates of success and the cost-effectiveness. So what is the most recent data on TDR, as reported this year at SAS?
Lumbar

Historically, lumbar arthroplasty has been viewed as much weaker and less convincing than cervical arthroplasty. But the studies at SAS this year showed generally strong and convincing outcomes. Major clinical studies were presented on ProDisc and Maverick. Several comparative trials elucidated the relevance of various disc design features. Several studies also shed light on the important differences of L4/L5 vs. L5/S1. Finally, some studies presented new experimental discs. Altogether, the studies at SAS this year suggest that lumbar arthroplasty has a more promising future than it seemed in the past.

One abstract reported on the 5-year outcomes from the ProDisc FDA IDE study for 237 two-level patients randomized 2:1. The mean ODI improvement at 5-years was better for ProDisc (57% vs. 43%). VAS back pain remained the same from 2 years to 5. At 5 years, 93% of ProDisc patients and 89% of fusion patients said they would do it again. They concluded that the good two-year clinical outcomes of 2-level ProDisc patients are maintained out to 5 years. [90]

A prospective study on 506 patients receiving ProDisc, mostly at 1 or 2 levels, intended to report on the 5-8 year outcomes, which would have been valuable information. Regrettably, long-term numerical data was not actually presented; the study only vaguely stated that the 3-month clinical outcomes were maintained and that motion was preserved (in what percent of the devices?). [195]

One abstract reported on the 5-year outcomes from the FDA IDE study for 405 Maverick vs. 172 fusions. Maverick demonstrated statistically superior improvements over fusion for ODI, SF-36 PCS, and patient satisfaction at 5-years. The mean 5-year ODI improvement of 35 points in the Maverick group surpassed previous mean ODI improvement reported from other arthroplasty FDA trials. At five years, 87% of Maverick patients said they would do it again, and over 70% were working. The reoperation rate from year 2 to year 5 for Maverick was half that for the fusion control. The authors concluded here that Maverick has outstanding 5-year outcomes. [132]

However, Maverick is not currently available for sale in the US, because a US District Court ruled that its keel infringes on the patent of ProDisc. Considering that most other investigational lumbar discs have been designed with keels, Medtronic’s appeal of this case to a higher court will surely be of great interest in the arthroplasty community, yet seems unlikely to win a reversal. However, Medtronic could move its production of Maverick to Europe and continue sales there. Considering the total price of arthroplasty, the additional costs of medical tourism are negligible, but then the procedure might not be covered by some insurers.

One abstract reported on 66 single-level patients receiving the Charité disc as the comparison group in the Kineflex FDA IDE study, from a surgeon who was not in the Charité FDA study, has no financial ties to Depuy, and emphasized that if anything he would be biased against Charité, because he was the inventor of Maverick. Considering that Maverick is blocked from US sales by ProDisc, support of ProDisc’s only US competitor is not so surprising, but the motivation of this report seems to be to support arthroplasty generally, by counterbalancing the poor outcomes of Charité in its own FDA trial. Regardless of the motives, mean ODI dropped from 64 at pre-op to 21 at 2-years, and mean VAS back pain dropped from 85 at pre-op to 34 at
2-years. At the 2-year follow-up, about 30% of patients were essentially pain-free (VAS<20) and functioning normally (ODI<10). Three patients (5%) underwent reoperation due to device movement. FDA clinical success was achieved in 84% of patients, yet patient satisfaction was 92%. The investigator concluded that Charité is clinically effective and the results were better than in the Charité FDA trial. The full multicenter outcomes from the Kineflex (vs. Charité) trial are eagerly anticipated. [120]

President Obama has allocated $1.1 billion for comparative effectiveness research. The SAS President, Dr. Thomas Errico, commented that, by comparing different arthroplasty devices against each other, comparative effectiveness research could help to shed light on the relevance of certain design features for all discs. Several reports at SAS did just that this year.

One study compared three-year outcomes for 35 Kineflex, 31 Charité, and 25 Maverick patients from one site in the FDA IDE trials. FDA clinical success was met in 91% of Kineflex patients, 90% of Maverick patients, and 84% of Charité patients. About two-thirds of the Maverick patients, half the Kineflex patients, and one-third of the Charité patients were essentially pain-free and functioning normally at 3-year follow-up. There was 1 reoperation in each the Kineflex and Maverick groups, but 3 reoperations in Charité, due to implant complications. Patient satisfaction at 3-years was 96% for Maverick, 91% for Kineflex, and 84% for Charité. This study shows that arthroplasty can achieve good clinical outcomes regardless of implant type, though some discs do somewhat better than others. [114]

The sum of clinical studies seems to suggest that discs designed with a keel for initial fixation do better than those using some other form of fixation. One panel expert obliquely suggested that the keel provides firmer initial fixation, thus preventing micromotion and promoting better bony ongrowth. Without this, he felt the discs did not work as well.

Another interesting comparative research study examined the influence of disc design and operative level on the change in disc height, by comparing an unconstrained disc (Charité), a semi-constrained disc (Activ-L), and a constrained disc (ProDisc), among 87 single-level patients from 2 sites in a prospective RCT. The mean increase of disc height was 5.4 mm, with significantly greater height gain in Charité vs. ProDisc, and in L5/S1 vs. L4/L5. Regrettably, it seems that the statistical analysis was too simplistic to control for confounding factors. [287]

One interesting study on TDR opened by pointing out that the goal of TDR is to restore physiological motion, but L4/L5 and L5/S1 have different kinematics, so any one prosthesis may not be able to mimic the motion equally at both levels. They then compared 108 L5/S1 patients to 31 L4/L5 patients receiving Mobidisc TDR with 2-year follow-up. They claimed that VAS and ODI improved more in L5/S1 patients without quantifying it. At 2-year follow-up, 42% of L4-L5 patients and 55% of L5/S1 patients had stopped using analgesics. ROM increased 4.8 at L4/L5 and 3.4 at L5/S1. Patient willingness to undergo the procedure again was much higher in L5/S1 patients (93% vs. 69%). This study raises interesting research questions about the optimal disc design and kinematics for different spinal levels. It suggests that some discs may be better suited for L5/S1 while others are better suited for other lumbar levels, based on differences in the disc kinematics, due to differing designs. [471]
Another study also compared TDR in 24 L5/S1 patients vs. 12 L4/L5 patients and found that L4/L5 patients had a significantly higher rate of complications, but they did not specify what complications; the results were otherwise vague, and the study sample was small. [479]

One study used a highly accurate method of analyzing x-rays to assess motion in 80 TDR patients (equally Charité, ProDisc, and Maverick). They reported that about 90% of discs were mobile at the 2-year outcome, with the majority of non-mobile TDR at L5-S1. Yet they also claimed that mobility of the disc did not correlate with clinical outcomes. This last finding that mobility does not correlate with clinical outcomes might perhaps suggest that when other trials find marginally better clinical outcomes for TDR over fusion, the small difference represents the placebo effect of TDR patients doing a bit better than fusion only because they believe TDR is superior to fusion, not because motion preservation biophysically causes better outcomes. [69]

One interesting study examined the role of annular defects in 98 ProDisc and 19 Activ-L patients with mean follow-up of 3 years. The prevalence of annular defects was 58%. Compared to patients without annular tears, patients with central or paracentral tears had much higher VAS leg pain scores that did not improve. Patients with paracentral tears also had much high ODI scores that did not improve as much and remained high at post-op. And patients with lateral tears had higher pre-op VAS back pain and lower VAS leg pain yet comparable improvement on both. Patients with paracentral tears had a higher incidence of post-op radicular pain. They concluded that patients with paracentral annular defects benefit less from TDR and should be studied further. [307]

A vague study on ProDisc II in 221 patients reported that at a mean follow-up of 30 months, patients who had had a previous surgery for disc herniation had a significantly higher follow-up ODI than patients in whom this was their first surgery. It was impossible to draw any implications from these vague and unsurprising results. [76]

Studies were also presented on several new experimental discs with innovative designs.

One study on 48 FlexiCore and 20 fusion patients at 4 of 23 sites in the FDA trial reported on the 3-year secondary outcomes with economic relevance to payors. The use of pain medication was not statistically different between the groups at any given timepoint, but there was a greater reduction in the percent of patients using pain medication in the FlexiCore group (27% vs. 12%). At three years, most patients were able to work (80% FlexiCore, 74% fusion, difference not significant). The authors rightly concluded that data from the full multicenter sample is still needed. [221]

An original study examined wear debris in whole blood samples from 40 patients with single-level FlexiCore discs, with 2-year follow-up for 35 patients and 3-year follow-up for 21. Mean cobalt ion levels remained below the lower level of detection; mean chromium ion levels appeared to show only random fluctuation; mean molybdenum ion levels increased from 1.4ppb at baseline to about 2 ppb at follow-up. Clinical effects were not reported. This study provided useful information, but was limited by the fact that it reported mean ion levels, when the real question for patient safety is the percent of patients showing elevated levels of metal wear debris. [95]
The Freedom lumbar disc makes an interesting advance in disc design. Its two spiked metal endplates are joined by a viscoelastic core that allows motion in all directions including shock absorption. Its prefabricated one-piece design facilitates easy surgical insertion. AxioMed has received the CE Mark for Freedom. A European multicenter study reported on 50 patients (mean age 40) receiving the Freedom disc at 1 level L4-S1. At the 2-year follow-up, mean VAS had dropped from 71 to 27 and mean ODI from 48 to 23. Furthermore, over half the patients had VAS < 5, and over half had ODI < 15. These initial results appear promising, so results from the recently initiated FDA trial should be of interest. [161]

Other discs also using a polycarbonate polyurethane core to provide motion in all directions, such as Physio-L and CAdisc-L, are also currently under testing, but no studies were presented on them this year at SAS. Comparative studies will eventually be needed to determine whether motion in all directions has any noticeable influence on clinical outcomes, though this seems doubtful.

[See also study 504 in “Health Care Economics” for a cost-effectiveness study of TDR in Austria.]

[See also study 56 in “Health Care Economics” for a comparison of the cost of TDR to fusion.]

[See also study 58 in “Complications” for a report on adjacent level degeneration after TDR.]

[See also studies 306 and 309 in “Basic Science & Biomechanics” for a comparison of 3 kinds of disc fixation design.]

[See also study 82 in “Basic Science & Biomechanics” for a lab test of wear debris from ProDisc.]

[See also study 165 in the “Basic Science and Biomechanics” section for a cadaver study on the effect of TDR on facet joint loading.]

Cervical

The clinical outcomes of cervical arthroplasty have always been excellent, as they are for ACDF as well. Major clinical studies were presented on ProDisc-C and Kineflex-C. A few metatrials combining data from several discs examined various interesting clinical questions. Yet several studies reported on high rates of heterotopic ossification, which can effectively convert a TDR to a fusion. Given that ACDF already attains excellent clinical outcomes, there is much less room for cervical TDR to represent an improvement, thus probably increasing the pressure to be more cost-effective.

One study reported on the 5-year outcomes from the ProDisc-C FDA IDE trial on 236 patients. They asserted that NDI functioning, VAS pain, and SF-36 quality-of-life were improved for both groups equally at 6 weeks and maintained out to 5-years, but no quantification was provided in the abstract of how much improvement was seen. There were no significant differences between the two study groups on these clinical outcomes. The rate of second surgeries was much lower for ProDisc (0.2% vs. 8.8%). [106]

One abstract reported on the Kineflex-C FDA trial, with 135 Kineflex patients and 134 patients receiving anterior fusion with allograft and plate. Mean NDI dropped from about 60 at pre-op to about 20 at 1-year follow-up in both groups. In the 153 patients with 2-year follow-up, mean
neck pain dropped from 76 to 23 in both groups. This study demonstrates that Kineflex is equivalent to ACDF for the main short-term clinical outcomes. [74]

A prospective multicenter study on 532 Mobi-C discs in 382 patients reported that (only) 86% of the discs were still mobile by the 2-year follow-up and that heterotopic ossification had led to fusion in 27/158 levels (17%) by 3-years. They also reported that 10% of the patients had adjacent-level disease already by the 2-year follow-up. These results raise questions about the rationale for cervical TDR – to preserve motion and prevent adjacent segment disease. [496]

A metatrial reported the 2-year outcomes for 53 TDR patients (Bryan, Kineflex-C, or Discover) vs. 37 ACDF patients treated at one site in three FDA trials. A composite outcome of clinical success was significantly higher in TDR (85% vs. 70%). The criteria of >20% NDI improvement was met in 96% of Bryan patients, 87% of Discover patients, and 85% of Kineflex-C patients. The TDR group had a 6% incidence of “bridging heterotopic ossification” (i.e. fusion). The reoperation rate was 8% in both TDR and ACDF. They concluded that TDR provides better clinical outcomes than ACDF. [356]

Another metatrial reported on 66 TDR patients and 34 ACF patients pooled from 5 FDA trials at one site (Texas Back Institute). Mean NDI improved substantially in both groups with no significant difference between them. The rate of second operations was lower in the TDR group (1/66 vs. 3/34), but they concluded that a larger sample size is needed to determine if TDR has a lower reoperation rate. [55]

One clinical study on 187 Prestige-LP discs in 130 patients examined the relation between sagittal balance and clinical outcome at a mean follow-up of 28 months. They found correlations that were statistically significant but mild between post-operative Cobb angle on the one hand and improvements pre-op to follow-up of NDI, VAS neck pain, hospital depression score, and ROM flexion. This study suggests that restoration of sagittal balance may be as important (or more important) than restoration of motion, when treating cervical degenerative disease. [66]

Another metatrial combining data from two FDA trials at one site, compared the efficacy of arthroplasty in 37 patients with predominantly axial neck pain versus 50 patients with radiculopathy/myelopathy. Axial neck pain patients had significantly higher mean NDI scores at pre-op. Both groups seemed to experience comparable clinical benefits from arthroplasty, but regrettably the abstract was only rapidly and summarily presented in the lightning round at the very end of the meeting and was truncated in the printed program. [425]

One study reported on the 2-year outcomes for 21 CerviCore vs. 21 ACDF patients at 5 sites in the FDA trial. There were no statistically significant differences between the two groups on the outcomes reported. There was a mean improvement of 38 points on NDI and 52 points on VAS neck pain, and the percent of patients using pain medications dropped by 43. The authors rightly concluded that data from the full multicenter sample is still needed. [299]

Another study aimed to report on the 2-year outcomes for 97 two-level Prestige-LP patients vs. 83 patients receiving two-level fusion with spacers and the Atlantis plate at 6 sites in the FDA trial. They asserted that the Prestige-LP group showed greater improvements in NDI, VAS, and
SF-36 PCS at the two-year follow-up, but admitted that <30% of the patients had actually reached that follow-up visit. Thus it is premature to draw any conclusions; the full 2-year follow-up from all study sites is still needed. [302]

A radiographic study examined the effect of disc height of 186 Prestige-devices in 130 patients, but they found that disc height (5, 6, or 7 mm) had no effect on the ROM, the disc height of the adjacent level, or the cervical lordosis. [294]

Finally, a prospective study compared 40 patients receiving arthroplasty, 39 patients receiving fusion, and 14 patients with hybrid surgery, all for 2-level cervical degenerative disease. At a follow-up range of 1-5 years, they reported strong improvement for VAS neck pain in the arthroplasty and fusion groups, with arthroplasty doing significantly better (from 8.6 to 1.7 vs. from 8.3 to 2.5). The hybrid group did not seem to be successful as often as the arthroplasty group according to Odom’s criteria (9/14 vs. 34/39 rated as good or excellent). [322]

During the Q&A period after a session on cervical TDR, it was remarked that the two-level patients in the Discover FDA trial were not coming out well, and Discover had low ROM. The study went on hold, and then came back as a trial only for single-level patients.

During the symposium on cervical TDR, Dr. Jeffrey Goldstein reminded the audience that the center of rotation is different at each vertebral level. He said the ideal disc design is probably different for each level. Given the wide array of cervical discs available, some attempt to determine which discs are better for which specific levels and conditions would be useful.

[See also study 315 in “Complications” for a very good study on heterotopic ossification after Bryan, Mobi-C, and ProDisc-C arthroplasty.]

[See also study 300 in “Complications” for a report on heterotopic ossification in ProDisc and Mobi-C.]

[See also study 244 in “Complications” for a comparison of heterotopic ossification in cervical arthroplasty vs. fusion.]

Wrap-Up Remark

Over the past many years, the spine surgery community has become euphoric in its promotion of “motion preservation”. But the real issue isn’t “motion preservation”; the real issue is “health preservation”. (Indeed, in some patients, motion is the problem.) This issue of health preservation is not merely about individual patients with back pain; instead, this issue takes place at the level of all medical condition for the entire population. If spinal arthroplasty can contribute to the health of the nation effectively and cost-effectively – as it seems it can – then it is destined to become part of the healthcare system, sooner or later. Publishing more of the highest quality research could make this happen more “sooner” than “later”.

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Posterior Dynamic Stabilization: Under Safety Surveillance

When Mercury first reported on dynamic stabilization after NASS Austin in Fall 2007, we stated that the rationale and science behind dynamic stabilization was foggy for most surgeons, according to both conference polls and opinion leader pronouncements. Although this has improved with time and growing familiarity, fundamental problems remain with the concept and science of this class of devices, and we have continued to underline these problems ever since our report on NASS Austin. Although the technology behind all these “dynamic stabilization” devices may be no worse than traditional fusion or recent “motion preservation”, we believe that these devices have a bleak future in spine care. As the oxymoron of “dynamic stabilization” implies, these devices occupy a difficult conceptual space, being somewhere between fusion and motion preservation, but really neither one nor the other, with no clear identity of their own. Initially, they tried to ride the marketing wave of “motion preservation”, but biomechanically, they really are much closer to fusion than any kind of motion preservation, and they should be thought of as “slightly flexible fusion”. Consistent with our early assessment of these devices as conceptually confusing, the FDA mandated post-marketing surveillance for all these devices due to safety concerns about devices mixing motion and stability. The studies presented at SAS this year reflected this uncertainty about this class of devices.

Preliminary 3-year follow-up was glumly reported from the Dynesis FDA trial. Mean VAS leg pain had dropped from 80 to 25; mean ODI from 55 to 25. Neurological success was better in Dynesis than fusion (92% vs. 86%). The revision rate was about 10% in both groups, but there was 1 major complication in each group, despite twice as many patients randomized to Dynesis. The rate of screw failure for Dynesis was 5.5%. The FDA definition of success was reached by 72% of the Dynesis group (miraculously improved from the rate of 53% overall success reported from the same study at NASS Toronto 2008), but the FDA nonetheless denied approval for wider use (besides as an adjunct to fusion) because, as Dr. Reggie Davis put it, the FDA had a strong concern about “stable screws in a dynamic system”. This illustrates how the mere conceptual confusion inherent to the “dynamic stabilization” class of devices undermines their future in spine surgery. Indeed one panel member remarked that Dynesis has a “schizophrenic” background: it was studied as a non-fusion device but then cleared by the FDA only as a fusion device like any other pedicle screw system. [255]

However, in a symposium on “Avoiding Complications”, Dr. Paul McAfee had a somewhat more candid assessment of Dynesis and the FDA. After noting that many dynamic stabilization systems have been having problems because of unintended forward shear and stating that Dynesis was too stiff, Dr. McAfee stated that the FDA disapproved Dynesis 5:1 after spending 20-30 million dollars, so we need to understand why. He then rattled off some reasons. The study group was poorly defined because 40 patients were randomized but never treated. The indications were too vague. The control group only had a 40% success rate, making them a poor threshold of “success”. And at the 24-month outcome, there was no difference in ROM between Dynesis and fusion. Dr. McAfee’s remarks may be one of the rare instances when a spine surgeon at the podium has clearly repudiated an experimental device, rather than saying more research is needed or remaining politely quiet. In the present era of budget cutbacks, the spine surgery community needs to vigorously and proactively weed out its weakest treatments, so they retain credibility with payors and policy makers when it’s time to discuss their best new devices.
An oral poster stratified the Dynesis FDA IDE 2-year outcomes by indication and found that Dynesis was better than fusion for instability or lateral stenosis, while fusion was slightly better for central stenosis. [180]

One study gave reason to the FDA. Ten PET cords and eight PCU spacers were retrieved from 3/18 patients with a Dynesis dynamic stabilization system in an established multinational monitoring study when the patients presented for pain and pedicle screw loosening at 0.7, 2.4, and 5.4 years post-op. The PET cords had frayed and the PCU spacers evidenced wear and deformation. The speaker pointed out that PET cords are also used in other dynamic stabilization systems, including Graf and Wallis. [353]

Better news was heard from a study reporting on 106 patients receiving the ACADIA system at 18 centers in various trials worldwide. At 12 month follow-up, mean VAS back pain had dropped from 63 to 16, and mean ODI had dropped 44 points. There were no device-related complications or reoperations, though there was a 15% rate of dural tears and a 4% rate of wound infections. This large global metatrial shows good short-term clinical outcomes for ACADIA, and as the authors concluded, long-term follow-up is still needed to monitor safety and to determine if this system reduces the incidence of adjacent segment degeneration. [155]

One abstract reported on 21 patients receiving the Stabilimax posterior dynamic stabilization system at 2 sites in the FDA trial. There seemed to be meaningful improvement of VAS and ODI at the 1-year follow-up, but the published figures were too small to really read. They reported four asymptomatic patients harboring fractured screws under observation, and one other patient who had a second-look operation. Although no safety problems have been experienced yet, this high rate of observational signs (5 of 21 patients) lends credence to the FDA’s call for increased surveillance of posterior dynamic stabilization systems. [358]

[See study 289 in “Complications” for a study on Stabilimax demonstrating by example that the FDA has been quite sensible to insist on increased monitoring of stable screws in any dynamic system.]

A radiographic study of 49 single-level patients from the Stabilimax FDA trial reported that ROM and interpedicular travel of the adjacent levels remained unchanged (as it should) at the one-year follow-up. [301]

One study reported the 2-4 year outcomes of 52 patients receiving the SSCS system for various degenerative conditions. Mean JOA increased from 14 to 26, while mean ROM decreased from 9.6° to 2.0°. Three patients developed adjacent segment disorder, one of whom was treated with PLF. There were 2 cases of asymptomatic screw problems. The authors rightly concluded that the short-term outcomes seem good, but long-term follow-up is needed. [251]

One small but mid-term study compared 23 patients receiving decompression and interspinous ligamentoplasty to 18 patients receiving only bilateral laminotomy, at minimum 5-year follow-up. The ligamentoplasty group showed significantly greater improvement in ODI (29% vs. 17%) and less frequent symptomatic instability (4% vs. 28%). [452]

[See also study 172 in “Complications” for a report about an unspecified posterior dynamic stabilization system.]
“Dynamic stabilization” indeed appears to be a technology on its way to the Museum of Medical History. The indications are much narrower than for fusion. Clinically, none of these devices appear to achieve better short-term outcomes than traditional fusion, and the long-term outcomes are mostly unknown. The FDA’s post-approval safety surveillance on all dynamic stabilization systems is likely to lead to at least a few being removed from the market sooner or later, either because of real safety problems or manufacturer strategy. Also, it seems unlikely that payors will view dynamic stabilization any more favorably than motion preservation, in fact probably less favorably. Finally, dynamic stabilization involves a lot of clunky hardware and lacks the elegant simplicity of TDR, interspinous spacers, or even basic fusion. Although some of these devices will survive awhile as usable treatments, we find it hard to imagine dynamic stabilization becoming a part of the future of spine care.
Fusion: Back to the Future?

As the standard workhorse form of treatment in spine surgery for over a 100 years, fusion has never been a very sexy or exciting topic at conferences. Mostly it just takes the role of the dumb ugly control group treatment in studies on other exciting new technologies. But coming back to reality for a minute, fusion has a few key advantages these days over most any new technology:

1) fusion is generally covered by all insurance companies for everyone,
2) it is already approved by the FDA, and widely established in medical practice,
3) the outcomes are very well-known, even into the ultralong-term.

In fact, the evidence base for fusion completely dwarfs what is known on any other technology in spine surgery. The outcomes may not always be better for fusion, but there’s no guesswork what they really are. Almost every controlled clinical trial presented at SAS this year presented data on fusion as the control group. Although the focus was rarely the fusion group, the data is still just as valid. Altogether it adds up to an enormous mountain of knowledge about fusion. And in most studies, the outcomes for fusion are often just as good as for other new technologies, and almost never dramatically worse. A few studies reported specifically on fusion or put the emphasis more on fusion than the other treatment group.

One non-randomized study on degenerative stenosis compared 39 patients receiving fusion to 27 patients receiving the Coflex interspinous spacer, according to patient choice. Surgery time, blood loss, and hospital stay were almost half in the Coflex group. At minimum one-year follow-up there was no difference between groups on VAS and ODI (scores not reported) and the satisfaction rate was 91% in each group. Possibly the most important point of this study is that high patient satisfaction can be achieved with either method when patients are allowed to choose the treatment they want. [452]

One oral poster reviewed the rates of clinical success and reoperation of ACDF in five FDA IDE trials. They found that the reported clinical success ranged from 68% to 73%, and the two-year reoperation rates covered a wide span depending on device: 4% (Bryan’s fusion control), 9% (ProDisc’s fusion control and Affinity cage), 12% (BAK-C), 18% (BAK-C and Affinity allograft control groups without plating), 20% (Prestige’s fusion control). [119]

A small but good quality prospective poster compared 32 patients with spondylolisthesis – half treated with PLF, half with ALIF – with a mean (range) follow-up of 3 (2-5) years. Fusion was obtained faster and more often with ALIF. Complete pain relief was obtained in 11/16 PLIF cases but 14/16 ALIF cases. These results suggest that ALIF is more effective than PLF for treating spondylolisthesis.

[See study 244 in the “Complications” section for a comparison of heterotopic ossification in cervical arthroplasty vs. fusion.]

[For further evidence on fusion, see also almost any other controlled clinical trial in this report, as well as many of the studies in the next section on Minimally Invasive Surgery.]
Minimally Invasive Surgery: Improving upon Tradition

While the speakers in the motion preservation sessions bemoaned its fate with payors and the FDA, minimally invasive surgery was the quietly blossoming success at the conference. Many MIS studies reported equivalent or superior outcomes to open surgery and touted various advantages for patient recovery and cost-reduction. Although MIS is hardly new, there was an air at SAS that MIS is the next wave forward for improving spine surgery. But due to scheduling, you had to be at SAS on Tuesday (or read this report) to catch everything on MIS.

During the Tuesday Symposium on MIS, Dr. Anthony Yeung made a particularly interesting presentation on Advanced Endoscopy procedures. He began by asserting that the endoscope allows the surgeon to see the pain generator (in DDD) and to treat it, noting that it is most suited for discogenic pain or stenosis. Stroking controversy, he noted that most surgeons think that IDET does not work, and then continued by saying, “Well, if you don’t do it right, it won’t work. But if you do it right, to remove the pain generator, it will work.” In the past, some experts have disputed that there is a simple localizable pain generator, so this statement went to the crux of the issue. He continued by saying that Osman & Panjabi showed that better decompression can be achieved by a lateral approach rather than medial. Interestingly, Dr. Yeung asserted that the surgeon can see the space better with an endoscope, but it is seen differently, just as a submarine sees a boat differently than an airplane does. He concluded that if a surgeon spends the time to learn, he can treat most conditions with endoscopic technique, and the endoscope opens the door to new treatment options.

Also during the Symposium, Dr. Isador Lieberman discussed complications during MIS. He began by noting that MIS is not just one device; it’s a philosophy of treatment. The goal is to target the exact pain generator and minimize collateral damage. He continued by emphasizing that the complications are still the same, because it’s still spine surgery, even if the rates are different. He cautioned that even though the surgery is minimally invasive, major complications are still seen and it still carries the same risks as the rest of spine surgery. He wrapped up by saying that imaging is crucial and explaining how he uses 2 C-arms, so he can see both A/P and lateral simultaneously. Yet he warned about blind spots and parallax effects, and cautioned against replacing excellent 3D open surgery with mediocre 2D MIS.

Dr. Kern Singh also emphasized that the most important part of any MIS procedure is accurate visualization on the skin marking and fluoroscopy.

Dr. Joseph Riina discussed the use of an MIS lateral approach for treatment of scoliosis. He said that this is for adults, especially for supplemental correction, but it is not for L5-S1, because there are better approaches to that level.

And at the MIS World Café, Dr. Luis Pimenta made a case presentation on treating degenerative scoliosis with XLIF. He also remarked that they have developed wider cages for XLIF to reduce the rate of subsidence. He said it’s like walking on snow – if you wear snowshoes, you won’t sink into the snow. A poster he presented supported this assertion. [297]

[See studies 413, 175, 329, and 390 in the “Deformity” section for reports on MIS correction of degenerative scoliosis.]

A retrospective comparison of 117 two-level XLIFs to 109 two-level PLIFs reported that the reoperation rate was better for XLIF (8% vs. 19%). Considering the substantial costs of reoperation, this is a meaningful finding in a sufficiently sized study. Indeed, at the podium, the speaker switched to a cost study, and concluded that the MIS XLIF had a cost savings of about
10% / $2500 per patient compared to the open surgery PLIFs. [164]

A prospective study on 2-level DDD compared 78 patients treated with percutaneous TLIF, 37 with open TLIF, and 54 with PLIF at a mean 2-year follow-up. The mean improvement of VAS and ODI was substantial in all groups, but slightly more in percutaneous TLIF. [193]

In support of his symposium talk, Dr. Yeung had a poster on radiofrequency lesioning of the nerves underlying facet joint back pain, via an endoscopic MIS approach in 50 patients. They seemed to say that VAS dropped from 62 to 25 and ODI from 48 to 28, at an unspecified time post-op, with no patients getting worse. [142]

Another innovative poster reported on the use of plasma energy discoplasty as an alternative to open decompression, in 30 cervical radiculopathy patients and 20 axial neck pain patients. The majority of patients in both groups showed substantial improvement in mean VAS scores. They concluded that plasma energy discoplasty is a beneficial MIS alternative to TDR or ACDF, which does not preclude later revision to these. [131]

A retrospective review of 164 cases receiving lateral transpsoatic interbody fusion (i.e. XLIF, DLIF, etc.) with a mini-open approach reported descriptively on complications. At the podium the speaker reported that about 30% of patients experience thigh weakness post-operatively. Regrettably, the study was severely limited by its lack of quantitative results and the fact that conclusions about safety cannot be drawn from studies of this small magnitude. [473]

[See also study 224 in “Surgical Procedures” for a report on XLIF as revision strategy for failed TDR.]

The AxiaLIF system is an attractive procedure for fusion of L5/S1, accessing the space through a minimally invasive transsacral approach, which is a relatively avascular fatty space. A prospective multicenter study on 178 patients receiving AxiaLIF mostly for discogenic pain reported a mean reduction of VAS by 71% (from 77 pre-op to 22 at 2-years) and ODI by 51% (scores not specified), suggesting very good clinical outcomes for L5-S1 fusion with AxiaLIF. The fusion rate was 93% and the complication rate was just under 3%. [457]

A poster on 41 patients receiving AxiaLIF and MIS pedicle screws reported that VAS dropped from 68 to 41 and ODI from 55 to 29 at mean 22 month follow-up. Two patients did not fuse and one patient had device removal due to a rectal tear. [53]

Another poster reported on the new two-level AxiaLIF in 8 patients L4-S1, plus pedicle or facet screws. At one year follow-up, mean VAS improved substantially (70 to 33), but oddly mean ODI did not (35 to 34). All levels showed continuous bridging bone but also radiolucency. [506]

[See also study 337 in “Complications” for a report on complications in AxiaLIF.]

Finally, one speaker remarked that minimally-invasive surgery is exciting but the learning curve is steep. And later Dr. Kern Singh also affirmed that there’s a learning curve to MIS. He said that most of his complications occurred in his first 200 or 300 cases of 1400 cases total. He advised the audience to work their way up the learning curve and to always have a back-up plan.
Interspinous Spacers: Reversible Motion Restriction

Interspinous spacers remain an attractive class of devices because of their relative simplicity and because they are easily revisable later to other more aggressive treatments if necessary. A few studies on interspinous spacers were reported at SAS this year, continuing to support the usefulness of this class of devices.

A well-done study examined the survivorship of 154 DIAM interspinous spacers in 150 consecutive patients with stenosis (n=96) or disc herniation (n=54), with a mean (range) follow-up of 2 (0-4) years. They reported that 5% of the patients needed a revision surgery during this time, and that Kaplan-Meier analysis predicted this would reach 8% by the full 4-year follow-up for all patients. Cox regression found that DIAMs implanted at L5/S1 or in 2-level patients were each about 10 times as likely to require revision surgery. This study implies that DIAM is best reserved for single-level L4/L5 patients. This may or may not be true of other interspinous spacers as well and deserves further analysis. [9]

One study on 52 patients receiving the DIAM spacer for mild but painful DDD reported that mean pain dropped from 60 at pre-op to 23 at 5-year follow-up and concluded that DIAM is useful treatment for mild DDD. [2]

One study reported on 182 Coflex spacers implanted in 143 patients with stenosis. Mean VAS pain dropped from 79 pre-op to 45 at 1-year; there were only 2 revisions to fusion; and 87% of patients were satisfied with the procedure. This study suggests that Coflex offers good clinical benefit for stenosis. [253]

A poster compared the outcomes for 35 Coflex spacers in 17 patients vs. 15 fusion procedures in 12 patients from four sites in the FDA IDE trial. At an unspecified short-term follow-up, Coflex showed better improvement of mean VAS (from 74 to 15 vs. from 74 to 34) and mean ODI (from 55 to 11 vs. from 59 to 39). There were no reoperations. [116]

[See also study 452 in the section on Fusion for a comparative study on Coflex.]

A poster reported on 150 patients treated with X-stop for low-grade degenerative spondylolisthesis. At one-year follow-up, they reported a mean improvement of 17 on ODI and 19 on VAS. The actual pre-op and follow-up scores were not reported, making it difficult to judge how sufficient this amount of improvement would be, but patient satisfaction was 74%. Nine patients had revision surgery. [327]

[See also study 223 in “Health Care Economics” for a review of plans to use X-stop in the developing world.]

Altogether, interspinous spacers appear to have a secure future in spine surgery.
Deformity

Historically, SAS has been focused on arthroplasty. Although SAS has in principle broadened out to cover all of spine surgery, the main focus remains on TDR and degenerative disc disease. Aside from a few studies on MIS treatment of degenerative scoliosis, there was not much discussion of deformity. There was however an interesting debate session on Friday about whether or not low back pain due to degenerative scoliosis should be treated surgically.

Dr. Frank Schwab, presenting the “Yes” answer to this debate, opened by pointing out that surgeons are seeing more and more of these cases due to the ageing demographics of the population. He reminded the audience that although surgeons think a lot about medical and radiographic parameters, what these patients think about is pain, a listing walk, and their physical appearance. He asserted that these patients do not get better with non-operative care, so that is a waste of time and money. Thus surgeons need to know which radiographic parameters actually correlate with patient-centered outcomes: namely SVA, T1 tilt, pelvic tilt, and the lumbar lordosis / pelvic incidence match. He asserted that these are the parameters that surgeons need to get right; by contrast, Cobb angle for example does not correlate much with patient outcomes. Dr. Schwab emphasized that it doesn’t matter so much which techniques surgeons use for deformity correction, but they need to do the pre-op planning to get all these parameters right. They can’t simply straighten out the patient’s spine.

Dr. Scott Kitchel, representing the “No” answer to this debate on whether degenerative scoliosis patients should be operated on, argued that there is insufficient scientific evidence to support surgery for these patients. He began by asserting that a PubMed search only turns up 97 articles on low back pain in scoliosis. (And even this may be too generous – a search of “degenerative scoliosis” in the title/abstract field, limited to clinical trials, RCTs, and meta-analysis, yields only 24 hits, many of which are not about main clinical outcomes.) Dr. Kitchel then continued by citing several well-known review papers that either criticized the lack of evidence and/or reported on the high rate of complications and cost (Mirza & Deyo 2007, Glassman et al 2009, Daubs et al. 2007, Deyo et al 2010). He concluded that the case for not operating on patients with degenerative scoliosis is that there is a lack of level-1 evidence to support surgery in this population and no cost-effectiveness studies to show it’s worth it.

Considering the general pressure for more evidence in medicine and the very large costs of deformity correction surgery, more research reports will clearly be needed. Development of better surgical planning guidelines, based on sound engineering analysis of the relevant radiographic parameters, will help ensure that clinical studies obtain the best results possible.

A few other studies presented at SAS are contributing to the evidence about MIS surgical treatment of degenerative scoliosis.

One study retrospectively reported on the MIS treatment of degenerative or idiopathic scoliosis in 32 adults (mean age 67). The patients received lateral transpsoas interbody fusion (LTIF), AxialLIF when indicated, percutaneous pedicle screw fixation with Medtronic CD Horizon, rh-BMP2, and DBM. At 1-3 year follow up, mean VAS decreased from 7 to 3 and mean ODI from 56 to 7. They concluded that the combination of these 3 MIS techniques allows good correction of scoliosis in elderly patients. [413]

A poster from the same study sample presented the radiographic outcomes. [449]

A prospective multicenter study reported on the use of XLIF in 107 patients with degenerative
scoliosis (mean age 68), frequently combined with posterior fixation. By the 1-year follow-up, mean VAS back pain improved from 73 to 37, mean ODI from 48 to 27, mean SRS-22 from 2.7 to 4.3, and mean scoliosis curvature from 24° to 16°. They concluded that XLIF allows for meaningful clinical improvement in elderly scoliotic patients who may have been considered too risky for open surgery. [175]

The Brazilian group reported on the prospective use of XLIF with autograft to treat 48 patients (mean age 63) with degenerative scoliosis at a mean (range) of 2 (1-4) lumbar levels. They reported that patients were typically discharged the next day. Mean VAS dropped from 8.7 at pre-op to 4.1 at 2 years, and mean ODI dropped from 56 at pre-op to 24 at 2 years. Scoliotic deformity improved from 26° to 12° and lumbar lordosis from 31° to 38°. They concluded that XLIF provides good clinical improvement and alignment correction, with less immediate post-op morbidity. [329]

Similarly, the Brazilian group reported on the use of XLIF to treat 14 patients (mean age 70) with degenerative scoliosis at 4-7 levels, T10-L5. The procedures were performed in an average of 2 hours without complications. At the two year follow-up, VAS had improved from 83 to 32, ODI from 51 to 27, Cobb angle from 16.4° to 7.8°, and lordosis from 17.1° to 37.4°. They concluded that XLIF was able to treat long thoracolumbar deformities with good pain relief and reasonable curvature correction. [390]

Finally, one very useful oral poster reported that upright MRI is a reliable radiation-free alternative to x-rays for measuring Cobb angles (and presumably other parameters?) in deformity patients. [169]
Fractures

Osteoporotic vertebral compression fractures are a very painful and debilitating event, commonly occurring in the elderly population. They have generally shown good clinical response to treatment with vertebroplasty or kyphoplasty. Given the ageing demographics of the population, an increasing number of cases can be anticipated in the coming years. But treatment of osteoporotic fractures has become a hot topic of debate in the recent medical literature. Two RCTs published in the NEJM showing no benefit of vertebroplasty over sham surgery have generated much controversy and discussion. Furthermore, a professional task force has advised Medicare that kyphoplasty should not be reimbursed at a higher level than vertebroplasty, because there is no evidence yet that it confers additional benefits to justify higher costs. Nonetheless, various new approaches to kyphoplasty are currently moving into clinical trials. Several reports appeared this year at SAS.

Radiofrequency kyphoplasty is a novel approach to treating vertebral compression fractures by injection of ultrahigh viscosity cement. A prospective clinical trial compared radiofrequency kyphoplasty for 80 vertebral fractures in 52 patients versus standard vertebroplasty for 38 fractures in 28 patients. VAS Pain and ODI functioning were improved in both groups at 3-month follow-up, and height gain was reported for kyphoplasty. The cement leakage rate was lower for kyphoplasty (5% vs. 60%). This new technique seems promising but, depending on pricing, will probably encounter the same coverage difficulties as balloon kyphoplasty, given the clinically comparable but much cheaper traditional treatment of vertebroplasty. [86]

An oral poster reported on 50 osteoporotic fractures in 44 patients from one site in a prospective clinical trial of vertebroplasty with Cortoss or PMMA cements. At 6 month follow-up, mean VAS had dropped from 67 to 24 and mean ODI had dropped from 32 to 15. One third of all patients had a subsequent fracture within 3 years post-op. [235]

One study compared 4 surgical treatment modalities in 98 patients with thoracolumbar burst fractures and found that patients receiving vertebral augmentation and screw reinforcement had better radiographic outcomes than those that did not. [188]

A poster reported on an unnamed structural kyphoplasty procedure with an expandable titanium intravertebral implant and cement that was used to treat 42 vertebral compression fractures in 38 patients. They claimed 82% reduction of pain at 6-month follow-up, without stating the actual scores. Minor asymptomatic cement leakages were found on CT in 45% of the vertebrae. [366]

The Brazilian group also had a poster reporting on 14 patients with osteoporotic compression fractures, 10 treated with StaXx structural kyphoplasty, 4 treated with the Benvenue system (“Kiva”?/), both apparently used without any cement (?). There was one case of failure of the surgical gun grip, resulting in expulsion of one wafer into the retroperitoneal space with damage of an iliac vein. They claimed short-term improvement of VAS and ODI, but did not quantify it. By one year, nearly half the patients had new osteoporotic fractures and consequent pain. This illustrates the challenge of treating this medically frail population. [280]
Tissue Repair

Several studies reported on annulus repair, which appears to be a promising little procedure.

One study investigated whether the rate of reherniation after lumbar microdiscectomy could be reduced by repairing the annulus with the Xclose device, after discectomy. Patients were randomized 2:1 to discectomy + annulus repair vs. discectomy alone. At SAS, a preliminary data analysis was presented, excluding patients in whom annulus repair was not anatomically possible and patients from sites where the surgeon had done less than 5 cases, still leaving 458 Xclose patients and 235 controls. They reported that the reherniation rate was reduced by 57% with Xclose, but they did not state the absolute number of reherniations, making conclusions difficult to draw. Clinical outcomes and AEs were comparable. This preliminary report suggests that annular repair is a beneficial extra step after microdiscectomy, so the full study outcomes should be of interest. [219]

An oral poster presented a randomized study on 44 patients receiving microdiscectomy plus annular repair with Xclose vs. 16 patients receiving only microdiscectomy. At a mean one-year follow-up, 2/16 control patients had reoperations for true reherniation, while 4/44 annular repair patients had reoperations: 2 for true reherniation, 1 for a new herniation remote from the original, and 1 had fusion for DDD. This suggests that annular repair is beneficial for reducing the short-term rate of reoperation. The full long-term follow-up is eagerly anticipated. [208]

An oral poster from one surgeon retrospectively compared 45 microdiscectomies followed by Xclose annular repair to 61 microdiscectomies without, and found that the reoperation rate was 2.2% with annular repair vs. 6.6% without. However, this non-randomized study was not designed to prevent a patient selection bias, and the follow-up period (mean 1.3 months) is too short, leaving open the possibility that annular repair does not reduce the reoperations, but only delays them until a later timepoint. [197]

Another oral poster from an ongoing prospective multicenter randomized trial compared 221 sciatica patients receiving microdiscectomy plus annular repair vs. 75 control patients and found that all clinical outcomes were the same (e.g. VAS from ca. 8 to 2), but the reoperation rate was half in the annular repair group (4% vs. 8%). [285]

One pilot study assessed the efficacy of intradiscal injection of the “Biostat Biologx” fibrin sealant in 15 patients with chronic low back pain refractory to conservative, pharmacological, and epidural injection therapies. Mean VAS dropped from 72 at baseline to 32 at 6-month follow-up, and at 1-year 7 patients had VAS improvement >50% from baseline. This pilot study suggests that this fibrin sealant may be a beneficial treatment for discogenic low back pain, but a large, randomized, double-blind, placebo-controlled study is needed to confirm whether the clinical benefit is due to the fibrin sealant. [248]

[See also the lab study 406 in the “Basic Science” section for a possible explanation of these effects from fibrin sealant.]
Biologics

Interestingly, there appeared to be no presentations or oral posters primarily about biologics at SAS this year. Instead, there were only a half dozen posters, almost all from the same research team. The general lack of studies on biologics would seem to indicate a waning interest among the spine surgery research community.

One poster reported on the use of demineralized bone matrix in 139 patients receiving instrumented 2-level ACDF and found a 1-year fusion rate greater than 97%. [257]

Another poster on beta-tricalcium phosphate / hydroxyapatite used with XLIF on 64 levels in 57 patients obtained a 93% fusion rate at 1-year. [173]

A poster reported on two cases of a rare but serious complication resulting from the use of rhBMP-2 in lumbar fusion, presumably related to an early inflammatory response to rh-BMP-2. One patient had progressive quadriceps weakening and became wheelchair-bound by 3-months post-op; the other patient developed new severe radicular pain at 6-months post-op and had to be reoperated for removal of extensive ectopic bone formation. [273]

Finally, one poster compared the fusion rate in 46 smokers vs. 61 non-smokers receiving 2-level PLIF with demineralized bone matrix, bone marrow aspirate, and local bone. At 1-year follow-up, the fusion rate was in the 90-95% range for both groups, without a significant difference between them. The poster vaguely implied that smoking is not a contributing factor to pseudoarthrosis, but conclusions cannot be drawn, since the study did not compare the fusion rate in smokers vs. non-smokers without the use of any biologics, (which are used precisely because smokers have lower fusion rates than non-smokers). [261]
Diagnostics

One of the main reasons that lumbar surgery for DDD does not have higher success rates is the difficulty of accurately identifying which patients’ back pain is actually due to disc degeneration versus due to something else. Imaging is helpful but limited, because many healthy people have degenerated discs without pain, while many back patients have pain due to other physical, neurological, and psychiatric causes. Until recently, discography was the only diagnostic tool available to help clarify whether back pain was due to disc degeneration or not. But discography has always been controversial, and recent studies from Carragee and others have shown that discography will actually cause disc degeneration, thus making its continued use highly problematic. Indeed, one speaker even called the past 10 years “the decade of Carragee” because of his dozen article showing that discography is unreliable and causes harm.

In what was probably the most important study presented at SAS this year, Lotz et al. presented a new, highly accurate method for determining whether disc degeneration is causing back pain: magnetic resonance spectroscopy (MRS). They use spectroscopy to analyze the chemical signatures of magnetic resonance images of the patients’ discs, applying an algorithm to diagnose the patient as positive or negative for discogenic pain, based on the amount of lactic acid, proteoglycan, and alanine found in the MRI. In their SAS report, they analyzed MRIs for 25 discs from 12 patients who also had discography results, 13 discs from 5 patients without discography results, and 27 discs from 19 asymptomatic volunteers. Using appropriate sophisticated statistical analysis, they found that MRS had a sensitivity of 92% and a specificity of 97% in the total sample. MRS matched the clinical diagnosis in 50/52 patients. Among the patient subset with discography results, MRS matched the discography in 23/25 discs. [126]

MRS is based upon analysis of the MRI that most surgical candidates receive anyway. It avoids the serious potential iatrogenic harm of discography. A high degree of diagnostic accuracy is being reported. Because MRS does not involve an additional examination procedure, it is probably also more cost-effective. MRS should replace discography without delay.

A related study on 63 discs in 13 patients and 45 discs in 9 healthy control subjects demonstrated that the T1ρ time of the MRI has a significant strong correlation with both the grade of disc degeneration and the opening pressure of discography, thus suggesting that it is a reliable measure of disc degeneration and a viable alternative to discography. [201]

In a symposium on Avoiding Complications, Dr. Scott Blumenthal pointed out that we have an ageing population and that over half the people over age 50 are osteoporotic. He said a study showed that many spine surgeons are not routinely screening for osteoporosis. He conceded that Dexa scan is not a perfect test, but said it is easy to perform and inexpensive ($250-$500).

[See also study 169 in “Deformity” for a study on MRI imaging.]
Patient Selection

In past reports on other spine surgery conferences, Mercury has reported on the importance of better patient selection for improving clinical outcomes and reducing the rate of complications. These themes surfaced again this year at SAS.

In his Presidential Address, Dr. Thomas Errico asserted the importance of research to improve patient selection. He said, “We need new research to improve patient selection for some procedures. For example, among patients receiving fusion for degenerative disc disease, are there certain patient factors – age, smoking, Worker’s Comp, depression – that reliably predict lack of clinical improvement? We also need research to determine if some forms of treatment for a condition are better suited to specific subgroups of patients than others. These are questions we need to answer to better match the optimal treatments with the right patients.”

In the symposium on cervical TDR, Dr. Todd Albert also talked about the importance of patient selection. He opened by saying that both TDR and ACDF have great results because they remove the pathology and decompress the spine, but surgeons have to choose the right procedure for the right patient. He told the audience that they need to keep in mind the inclusion/exclusion criteria behind the TDR trials. He said that unstable patients or patients with osteophytes are not good candidates for TDR. Instead, TDR is best for single-level patients with soft disc and only mild spondylolisthesis.

Dr. Paul Anderson reinforced these points in his presentation in the same symposium. He said the best way to avoid complications is by good patient selection – surgeons must remember the counterindications. If the patient has instability, kyphosis, or hypermobility, then TDR should be avoided. He also asserted that spondylotic spines will not get much motion and will fuse spontaneously. Finally, he remarked that although metal allergies are hard to screen for, patients may know if they are allergic, especially women who avoid wearing jewelry.

In a talk on Avoiding Complications, Dr. Jean-Charles LeHuec echoed Dr. Anderson’s sentiment by stating that TDR failures are due to poor patient selection or poor surgical technique.

Interestingly, two panel members also commented on different days about the importance of setting realistic patient expectations. Dr. Matt Scott-Young said that surgeons must tell patients that the operation will improve their quality-of-life but not completely remove their pain; he said patients will be happier if they start with more realistic expectations. Dr. Scott Hodges said that patients should stay away from the internet; otherwise they start to daydream about a pain-free wonderful life after a mere band-aid.

During the Q&A period after a session on lumbar arthroplasty, one panel member remarked that to get to the next level, better patient selection is needed. He said the implants will be improved but this will make less difference than patient selection. Yet he remarked that surgeons have been struggling for decades with patient selection for fusion.

Despite the fact that several key opinion leaders emphasized the importance of better patient selection, there appeared to be no studies about it, nor even brief analyses of patient selection within clinical trials. One possible reason for this may be the lack of familiarity of many spine surgeon researchers with the kinds of statistical analysis (regression, ANOVA, etc.) that can be used to determine which patients do better than others. Another reason may be that most clinical studies lack pre-operative non-surgical diagnostic data, such as genetic tests or psychological screening questionnaires. Unless clinical studies improve these shortcomings, spine surgeons may continue to struggle with patient selection for many more decades.
Surgical Procedures

A randomized study compared unilateral vs. bilateral laminotomy for the treatment of degenerative stenosis at L4-L5 in 56 patients and found comparable clinical outcomes and complication rates in both groups at a mean 50 month follow-up. [467]

A retrospective study on 31 laminoplasty patients compared those whose C7 spinous process was preserved to those in whom it was removed. Axial neck pain was observed more often when the C7 spinous process was removed (87% vs. 56% at early follow-up, 73% vs. 13% at late follow-up). They recommended that the C7 spinous process be preserved in laminoplasty. [129]

The Brazilian group reported on use of XLIF as a successful MIS revision strategy to remove and replace 9 Charité discs, 3 Lateral discs, 2 Mavericks, 1 Physio-L, and 1 Triumph. Mean surgical time was just under 2 hours, and the only intraop complication was one case of iliac vein tear. [224]

Finally, one important occupational safety study measured the amount of radiation exposure a single surgeon received when wearing vs. not wearing lead gloves during fluoroscopy for 2 months in each condition. They found that wearing lead gloves cut the cumulative radiation dose in half and recommended that they be worn. [263]
Complications

In the opening symposium on arthroplasty around the world, Dr. Luis Pimenta remarked, “We learn more from our complications than from our successes.” So what was learned from complications this year at SAS? While wound infection rates was the main topic of discussion for complications last fall at NASS San Francisco, they barely received mention this spring at SAS. Instead, several studies reported disconcerting levels of heterotopic ossification at short-term follow-up after cervical arthroplasty.

One very good study examined the factors leading to heterotopic ossification after cervical arthroplasty in 81 patients receiving the Bryan disc, 61 patients receiving the Mobi-C disc, and 28 patients receiving ProDisc-C, with a minimum of 1 year follow-up, using appropriate statistical analysis. Unexpectedly, they found that the degree of pre-operative degeneration had no significant influence on the occurrence of heterotopic ossification. Instead, males were about twice as likely as females to have HO. Furthermore, compared to the Bryan disc patients and controlling for other factors, Pro-Disc patients were nearly 6x as likely to develop HO, and Mobi-C patients were over 14x as likely to develop HO. This study raises important concerns about the possible effects of particular disc designs on HO, which frequently eliminates motion of the disc, effectively converting TDR to an ACDF procedure. [315]

Another study tracked the rate of heterotopic ossification in 35 ProDisc-C patients and 31 Mobi-C patients. At one-year follow-up the rates were in the single digits, but by the two-year follow-up, 60% of the ProDisc patients and 81% of the Mobi-C patients showed heterotopic ossification. Less than 2° of motion was seen in 20% of ProDisc patients and 26% of Mobi-C patients, meaning that they had essentially converted to fusions. This study confirms important questions concerning the rationale for cervical arthroplasty (i.e. motion preservation). [300]

Another study compared the rate of heterotopic ossification for TDR (Bryan or ProDisc) at 39 levels in 37 patients vs. ACIF (Rabea stand-alone cage or Atlantis plate) at 42 levels in 33 patients. At a mean follow-up of 29 months, the rate of heterotopic ossification was three times higher in the TDR group than in the ACIF group (51% vs. 17%, p<0.05). There was no difference between Bryan and ProDisc, but Rabea cage showed HO three times as often as Atlantis plate (21% vs. 8%). This study again suggests that cervical motion leads to HO as a compensatory attempt to restore stability. [244]

[See also study 496 in “TDR, Cervical” for data on heterotopic ossification in Mobi-C.]

In a symposium’s case presentation on cervical arthroplasty, Dr. Rudolf Bertagnoli remarked that when the patient has instability, it’s important to use a constrained disc to prevent heterotopic ossification as the body’s natural reaction to instability. In another symposium on cervical TDR, Dr. Paul Anderson went even further simply saying that if there’s instability, TDR is counterindicated. He also added that heterotopic ossification occurs in 2-15% of patients. Similarly, in the same symposium, Dr. Todd Albert remarked that TDR is not a good choice for patients with osteophytes, because the osteophytes will grow back with motion.

A retrospective review of 1000 consecutive cases of TDR found that 21 had to undergo
reoperation for adjacent segment disease at a mean of 28 months and that many of them already had imaging evidence of adjacent level degeneration at initial presentation. Although interesting, the study was limited by not specifying the duration or completeness of follow-up, nor the number of patients with pre-op data on adjacent levels. [58]

Two surgeons reported the complications from use of AxiaLIF in 285 patients, including: 11 cases of pseudoarthrosis, 4 graft extrusions, 2 fractures of S1, 10 cases of wound mishealing/infection, and others. On the whole, the rates seemed low and complications sounded manageable, suggesting good safety for this implant. But although the sample was reasonably large, conclusions about safety can never be drawn reliably without long-term follow-up on over 10,000 patients from multiple sites. [337]

One study reported on 40 patients receiving limited microdiscectomy and an unspecified posterior dynamic stabilization at a single-level for disc herniation. At a mean follow-up of nearly 3 years, they had observed one case of each of the following: bladder retention requiring catheterization, superficial wound infection, and a malpositioned transpedicular screw requiring reoperation. [172]

[See also study 273 in “Biologics” for 2 case reports on rare but serious complications after use of rh-BMP-2.]

A very well-conducted poster study reported that the FDA IDE study of the Stabilimax posterior dynamic stabilization system was paused because of a 2.4% rate of screw fractures. Seemingly appropriate statistical analysis showed that two-level cases, high BMI, and previous microdiscectomy were significant risk factors for screw fracture. A literature review showed that grit-blasting reduces the fatigue strength of the screws. A second-generation screw was developed using peening rather than grit-blasting, and they claimed that fatigue testing showed a significant increase in longevity of this new screw. [289]

[See also study 95 for a report on whole blood metal ion levels in FlexiCore patients.]

[See also study 353 in the section on Dynamic Stabilization Systems for an analysis of retrieved worn-out Dynesis systems.]

[See also study 9 in the section on Interspinous Spacers for an excellent study on DIAM revision rates.]

[See also in “Minimally Invasive Surgery” the paragraph on Dr. Lieberman’s symposium presentation on complications in MIS.]

[See also studies 473 & 45 in “Minimally Invasive Surgery” for reports on complications after MIS lumbar fusion.]

[See also study 224 in “Surgical Procedures” for a report on XLIF as revision strategy for failed TDR.]

A final point to remark about complications is the general lack of studies (especially with an adequate sample size) on most of the new devices being developed. Large-scale international patient registries should be developed to monitor the rates of complications, especially for implants that remain inside the patient indefinitely. This kind of Phase IV safety surveillance should be initiated by professional societies and/or government agencies, and far more scientific reports should be made about the actual rates of various complications for the many newly available devices. The current level of scientific publication in this area is rather low.
Laboratory Studies: Basic Science & Biomechanics

The laboratory plays a crucial role in spine surgery. Knowledge for new and better treatments of the future is first developed here, even if the intended applications are not often obvious from the outset. Similarly, lab testing of current devices and procedures can provide knowledge about the efficacy and safety of spinal treatments not easily obtainable in the clinic. In his Presidential Address, Dr. Thomas Errico highlighted the importance of basic research for the future of spine surgery. He said, “We need to look beyond the crisis issues of today, and make investments in the therapies of tomorrow. Spine surgery 20 years from now will be even better than spine surgery today, but how much better depends on us now. Recent major discoveries in the life sciences have led to promising new treatment concepts in spine surgery. Genetics opens up many opportunities, including personalized treatment, pre-symptomatic prevention, and new therapeutic interventions. Stem cells and tissue engineering hold the possibility to regrow damaged neural, bone, or soft tissue structures. We need to strengthen the basic and translational research that will create new spine treatments for our children and grandchildren.” Several scientists and engineers provided interesting reports at SAS this year.

Stem cells appear to be one of the most promising options for the future of spine surgery, though it is currently still mostly in a pre-clinical stage. One study injected mesenchymal stem cells from human umbilical cord blood into cultured explanted rabbit intervertebral discs. One month later, fluorescence microscopy and RT-PCR showed that the injected stem cells had survived and fully differentiated into various lineages. This lab study supports the concept that stem cells can be injected into intervertebral discs to replace lost or damaged tissues. [409]

An in vitro lab study reported that the “Biostat Biologx” fibrin sealant reduces the synthesis of several pro-inflammatory cytokines (TNFα, IL-1β, IL-6, IL-8) in constructs of human nucleus pulposus cells, suggesting that fibrin sealant may have an anti-inflammatory effect that is beneficial when injected into degenerated intervertebral discs. [406]

Discography, which has always been controversial, has recently become disreputable in the wake of Carragee’s reports that it causes disc degeneration. Dr. Howard An presented a laboratory study showing that the contrast agents and local anesthetics used in discography are cytotoxic for the annulus and nucleus. [407]

[See studies 126 and 201 in the “Diagnostics” section for excellent new alternatives to discography.]

Infections have always been a safety concern in spinal surgery, all the more so since Medicare declared them a “never event”. One team reported on the initial development of nanoscale fibers and coatings of TiO₂ with photoactive antimicrobial attributes. They vaguely stated that the density of E. coli colonies on these nanomaterials decreased when exposed to infrared radiation. It is conceptually interesting to use nanotechnology to reduce the incidence of infections, but the technology remains at the earliest stages of development. [472]

Wear debris has been a running topic in the development of arthroplasty devices. In an attempt to minimize the amount of potentially harmful wear debris, developers have turned to metal-on-metal, ceramic-on-ceramic, and other materials. But do these represent the ultimate wear-
resistant materials? Apparently not. The Dimicro company has developed a new prosthesis prototype made of diamond-on-diamond (polycrystalline diamond compact). They subjected 6 such 28mm total hip bearings to a battery of highly aggressive wear debris testing. They found virtually no wear debris in pin-on-plate studies and no wear debris in microseparation studies, which they characterized as “unprecedented”. They concluded that the extreme abrasion-resistance of this material would enable the design of prostheses with incongruent articulations that better approximate normal spinal kinematics. But given the difficult coverage acceptance of arthroplasty, reassuring clinical results about wear debris, and development of discs with elastomeric cores that also shed no debris, it is unclear whether there will be much need for this incredibly abrasion-immune material in spinal applications. [489]

[See also study 353 in the section on dynamic stabilization systems for an analysis of retrieved worn out Dynesis systems.]

One interesting study used fabricated models of arthroplasty discs to compare the fixation stability of three different disc endplate designs: a large central keel, a small central keel with a sawtooth profile, and a stepped dome. The dome design showed significantly greater initial anterior/posterior motion, suggesting that keel fixation provides better initial resistance to shearing motion. [306]

A similar study by the same group reported that the large keel design required less energy to achieve the desired loading condition, while the dome design showed a greater reduction in the rate of energy dissipation. The clinical implications remain unclear. [309]

A human cadaver study examined the effects of ProDisc TDR on loading of the facet joints. They found that axial rotation is the most demanding movement on intact spines, and that after TDR, both axial and lateral bending increase facet forces at the index level, while the superior level facet joints are unloaded by motion in any direction. [165]
Anatomical Studies

A few anatomical studies provided new information that may help surgeons improve the safety and effectiveness of certain operations.

A cadaver study on the transpsoas (i.e. lateral) surgical approach found that the “safe zone” was relative in size and recommended taking care to not place the femoral nerve under traction for long, in order to avoid causing post-operative thigh pain/weakness. [420]

A cadaver study found great variation of the branches of the dorsal ramus and suggested that this may explain the inconsistent clinical outcomes of radiofrequency lesioning of nerves to treat lumbar facet joint pain. [145]

A clinical poster on 159 patients undergoing anterior surgery at L4/L5 from one access surgeon reported that about three-fourths of patients had a single iliolumbar vein, while one-fourth had two or more iliolumbar veins. [202]
Other Innovative Technologies

Dr. Luis Pimenta presented his long-term experience with three different nucleus replacement devices. His team reported on 80 patients receiving PDN, 26 patients receiving PNR, and 19 patients receiving NUBAC. After a 9 year follow-up period, the retrieval rate was very high: 42% of NUBAC, 48% of PDN, and 58% of PNR. His team concluded that over time endplate reaction, subsidence, and device expulsion do occur frequently, and he said he has stopped using this class of devices, due to their poor durability and safety record. Dr. Pimenta also rejected the rationale that nucleus replacement can postpone other surgeries for a few years, because that only prolongs the patient’s suffering. This study underscores the importance of long-term follow-up in large patient samples to evaluate the safety of devices that are intended as permanent implants inside the patient’s body. [227]

One feasibility study reported on 20 patients receiving NUBAC nucleus replacement at L4/L5 for mild to moderate DDD. At the 6 week follow-up, there were substantial mean improvements in VAS (from 71 to 34) and ODI (from 54 to 31). Two-year outcomes were also reported but cannot be relied on, because less than half of the small sample had reached that timepoint. NUBAC has entered an FDA pivotal study; as the first such study for a nucleus replacement device, the results will surely be of interest. [458]

An oral poster presented the worldwide results on about 300 patients receiving NUBAC, the majority of whom did not have even 6-week follow-up. Among the ca. 100 patients who did have 6 month follow-up, the mean VAS had dropped from about 8 to 3 and ODI from about 55 to 15. However, due to the very low follow-up rate even at early timepoints, which may have introduced considerable patient selection bias at later follow-up, conclusions cannot be drawn. The presenter did remark that the annulus must still be in good condition to use NUBAC, but they don’t repair it. He also noted the NUBAC can be revised to TDR. The results of the FDA IDE pivotal study are eagerly anticipated. [483]

A similar study reported on 48 patients (mean age 40) receiving 49 NUBAC implants for disc herniation. At the 6 month follow-up, VAS back pain had dropped from 82 to 31, and ODI had dropped from 55 to 18. By a mean follow-up of 16 months, there was only 1 reoperation due to device migration after a traffic accident. As mentioned above, long-term follow-up will be essential. [250]

A poster compared the iO Flex set of flexible tools to traditional rigid tools for the decompression of lumbar stenosis at 28 levels in 7 cadaver specimens. They reported that the iO Flex tools obtained significantly greater increases in forminal width and area, with significantly less disruption of the facet joint. [304]

[See also study 86 under “Fractures” about Radiofrequency Kyphoplasty]

In this section on “Innovative Technologies”, we have reported on some of the various new devices, regardless of FDA status, that did not fit into any of the other chapters. Of course, many of the other devices in this report are equally innovative, and aside from fusion, almost none of the devices in this report could be considered “standard routine” treatment. SAS has always
been clearly focused on innovation technology.

Yet in this context it is worth repeating what Michael Leavitt – the former US Secretary of Health and Human Services – had to say about “innovation”. He concluded his talk by saying that in the past “innovation” has been defined as anything you could get reimbursement for. But in the future, “innovation” will be defined as something that demonstrates its cost-effective value. “Innovation” is going to have a new face – reaching the same health outcomes at half the cost. Regardless of whether anyone agrees that it should be that way, we would say that surely any spinal device company or any spine surgery clinic that can provide that kind of “Southwest Airlines” innovation – same outcomes at half the price – has a once-in-a-lifetime opportunity now to make a fortune from healthcare in America,… and the rest of the world as well.
Conclusions

Recall that the main sentiment at SAS was captured and expressed by Dr. Kenneth Pettine, the inventor of the Maverick disk: “We’ve got great level-1 data, but so what? Coverage remains impossible. And physician reimbursement is abysmal.” In a sense, the spine surgery community has over the past decade developed a fleet of excellent new taxis and limousines. The spine surgery community is saying, “These taxis and limos have shown great performance on the test track, are really comfortable, get good mileage, demonstrated a good safety profile, have many attractive new features, and have better performance for the cost than the cars we used to sell you in the past.” But government and payors are just shaking their heads, thinking to themselves, “We need to set up a public bus system, or maybe even a rent-a-bike system; we can’t buy any more taxis or limos, regardless of how good these new models are.” This is surely a tough disjuncture between providers and purchasers. For any spinal device company or spine surgery clinic that wants to set up a public bus system – there’s a fortune waiting to be made, by whoever can figure out first how to actually do that. For those who want to maintain a transportation system of taxis and limos, it is certainly possible, but there will be a much more difficult road ahead. This road will necessitate voluminous research, advocacy, and communication.

In his Presidential Address, Dr. Thomas Errico said, “The recent global economic recession and healthcare reform have brought spine surgery to a pivotal moment of defense. But good quality research can demonstrate the value of spine surgery to people who don’t see it day in and day out.” He then cited the example of spine surgery societies convincing Washington State to cover arthroplasty, by presenting the scientific literature to them. But he continued, “Much more research is still needed though to support our claims on the benefit, safety, and value of spine surgery to any doubters in government and the public. And we need that research now. If we wait another five years, it will be too late.” As an example, he mentioned a paper from the Medicare Coverage Advisory Committee warning that the evidence for fusion was unconvincing. Dr. Errico concluded his Address by saying, “Spine surgery is at a historic pivotal moment. Many breakthrough technologies are in the pipeline these days, and at the same time government is getting involved in healthcare like never before. We the spine surgery community need to proactively get research out there showing the benefits and value of our best available treatments.”

The SAS conference in New Orleans showed that a lot of good research is being done around the world, on arthroplasty, minimally invasive surgery, and many other promising new devices, though much of this research may not ever be moving beyond the conference hall and into publicly available journal publications. Furthermore, the largest source of clinical resource data – the actual day-to-day operations of practicing surgeons on routine patients – mostly vanishes, for lack of patient registries. And as many SAS speakers suggested, oftentimes the research is not addressing the right questions – the diagnostics, the patient selection, the safety, and above all at this moment – the cost-benefit ratios. Finally, even when the research is available, addresses the right questions, and gets published, it may still not be communicating effectively with non-specialist outside of spine surgery – the patients, the payors, and the policy makers. The evidence for the value of spine surgery is available. But it may now also require exceptional communication to convince people in an era of economization.

See you in October in Orlando and next April in Vegas.
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Thank you for your time and interest.