



**2016- 2017
ISASS BOARD OF DIRECTORS**

President

Hee Kit Wong, MD Singapore

Incoming President, Treasurer

Jeffrey Goldstein, MD, FACS, USA

Michael Ogon, MD, Austria

Marek Szpalski, MD, Belgium

Jack Zigler, MD, USA

Frank Phillips, MD, USA

Domojog Coric, MD, USA

Immediate Past President

Gunnar Andersson, MD, PhD, USA

ISASS Past Presidents

Luiz Pimenta, MD, PhD, Brazil

Steven Garfin, MD, USA

Jean-Charles LeHuec, MD, France

Thomas Errico, MD, USA

Chun-Kun Park, MD, PhD, South Korea

Karin Büttner-Janz, MD, PhD, Germany

Hansen A. Yuan, MD, USA

Stephen Hochschuler, MD, USA

Founding Member

Thierry Marnay, MD, France

Founding Member

Rudolf Bertagnoli, MD, Germany

Founding Member

(the late) Charles Ray, MD, USA

Founding Member

March 24, 2017

Mr. Phil Denniston

President

Work Loss Data Institute - Official Disability Guidelines

169 Saxony Rd., Suite 101

Encinitas, CA 92024

RE: Update to Official Disability Guidelines for Sacroiliac Joint

Dear Mr. Denniston:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am requesting that you update the Official Disability Guidelines (ODG) to account for pain arising from the sacroiliac joint. ISASS is a global, scientific, and educational society of spinal surgeons and scientists organized to provide an independent venue to discuss and address the issues involved with surgical aspects of the basic and clinical science of spinal care. Additionally, ISASS is a member of the AMA House of Delegates.

The current ODG (attached excerpted guidelines) are outdated and should be revised. Below is the rationale for a proposed update revision.

Incomplete Review

The ODG have ignored a second published randomized clinical trial on minimally invasive SIJ fusion.¹ 12-month results from this trial are now in press. In light of two positive randomized trials, the ODG conclusions are contrary to the weight of evidence.

SIJ Pain Diagnosis

The ODG state that research has been confusing and use non-standard diagnostic techniques. This is patently false. All published studies have used a very similar diagnostic algorithm based on a combination of medical history, physical examination and confirmatory diagnostic SI joint block. The fact that most studies of minimally invasive SIJ fusion have reported successful decreases in SIJ pain and pain-related disability, including two

prospective randomized trials against non-surgical treatment, itself validates the diagnostic algorithm.

The ODG dismiss the current SIJ pain diagnostic algorithm as insufficient as to sensitivity and specificity. If this were true, we would expect massive misdiagnosis to have plagued SIJ fusion studies, with attendant poor responses to surgery and little difference between surgery and non-surgical treatment. As noted below, this is patently contrary to published evidence in two prospective randomized controlled trials.^{1,2} The response to surgery was, by any standard, huge.

The guidelines state that no studies have connected post-fusion low back pain with SIJ pain. This is untrue. Depalma showed that approximately 40% of patients with post-lumbar fusion pain have pain attributable to the SIJ.³ When the SIJ is ignored, patients may undergo the wrong surgery, which has marked negative public health impact.

Role of Imaging

ODG expresses the desire for imaging-based diagnosis and focus heavily on the role of imaging. The guidelines include a statement that “the SIJ is notoriously difficult to read accurately.” We agree that current technology does not permit imaging to be used to diagnose (or rule out) SIJ pain as a cause of low back pain. While imaging may play an important role in other diagnoses (though false positive findings are very common⁴), it does not play an important role in ruling in SI joint pain. This has been noted by several authors.^{5,6} In the context of well-done clinical research showing that the current diagnostic methods (relying on history, physical exam and diagnostic SIJ block) identify patients populations with high response rates, the lack of correlation of clinical syndromes and radiographic findings is not of concern. Overreliance on radiographic findings may actually lead to poor outcomes. Imaging of the SIJ pain may be challenging because the SIJ is narrow and tortuous; imaging technology may be insufficiently developed to detect relevant changes. The major role of imaging is to rule out other conditions that can cause pain symptoms similar to SIJ pain, including L5-S1 disc degeneration and hip osteoarthritis. The lack of imaging technology to specifically diagnose SIJ pain is not a valid reason for ignoring positive results from prospective clinical trials. Such an attitude is contrary to public health.

In prospective trials, investigators used specific criteria (leakage, widening, joint sclerosis, osteophytes, subchondral cysts, vacuum phenomenon) to characterize the underlying cause of SIJ pain (disruption or degeneration). These were not used for SIJ pain diagnosis, which relies solely on medical history, physical exam and confirmatory SI joint block, but rather etiology of SIJ disruption. There was no difference in response rates or effect sizes between those diagnosed with SIJ disruption and degenerative sacroiliitis. The relevance of ODG comments in regards to underlying cause of SIJ pain are not relevant.

Randomized Trial Follow-Up

Oddly, the guidelines criticize the published US clinical trial for short follow-up.² The trial reported outcomes at 2 years, which is considered standard. The trial allowed crossover from non-surgical to surgical treatment. Crossover was demanded by investigators at the time of trial design due to: 1) their familiarity with poor response of the condition to non-surgical treatment, and 2) their need to care for patient participants in the trial who did not respond to non-surgical

treatment. They believed that it would be unethical to withhold surgical treatment from such patients. In retrospect, this decision was entirely correct, in that response to non-surgical treatment in the US randomized trial was clinically negligible, and most patients responded after crossover to surgical treatment, as documented in the INSITE 12-month publication.⁷

Small Effect Size?

The guidelines suggest that the effect size was small. This is patently false. The difference in ODI treatment effect between surgery and non-surgical treatment was 26 points, which is substantially larger than the accepted 15-point value for minimally clinically important difference. At 12 months, 72% of fusion subjects had a 15-point improvement in ODI, compared with <10% of subjects who underwent non-surgical treatment. This is, by any standard, a huge treatment effect.

A pooled analysis of all 3 prospective clinical trials (2 RCTs and one multicenter prospective single-arm study, encompassing >320 SIJ fusion subjects and nearly 100 non-surgically treated subjects) is in press in the journal *Spine*.⁸ The effects size calculated across all 3 trials are nearly identical to those reviewed above.

Opioid Use

Published studies have shown moderate decreases in opioid use after SIJ fusion. It should be noted that the studies had no structured behavioral or structural program to reduce opioid use. To focus on opioid use ignores the large benefits seen in pain, disability and quality of life. The reader should note that even FDA allows the manufacturer to make claims about improvement in pain, disability and quality of life.

An article in press in the journal *Neurosurgery* examined pain, disability, work status and opioid use in a cohort of 137 patients with chronic SI joint pain.⁹ Of these, 27 underwent minimally invasive SIJF, 47 underwent RF ablation of the lateral branches of the SI joint and 63 (because of insurance denials) were forced to undergo continued conservative management (CM). In the CM group, the proportion using opioids increased from 49% at baseline to 84% at least follow-up (approximately 6 years). In contrast, the proportion using opioids decreased in the SIJ fusion group from 63% to 7% over a 6-year period. Lack of access to SIJ fusion is likely to increase opioid use, with its attendant medical and social problems.

Fusion Surgery vs. Conservative Therapy

The guidelines suggest that bone growth onto the iFuse implant is not documented. This is untrue. Independent analysis from a core laboratory showed binding of bone to implants in nearly 100% of cases.¹⁰ The surface's device design is similar to other orthopedic implants (e.g., hip implants) where bone binding has been shown. A 5-year study shows bridging bone across the SI joint in 87% of cases.¹¹

Kube and Muir demonstrated an analogous fusion rate of 88% bridging bone at 1 year using Zyga Symmetry, a screw based technology.¹² The bulk of the published data on MIS SIJ fusion is through a lateral approach using triangular titanium implants (iFuse Implant System, SI-Bone, Inc.). The ISASS Policy does not endorse any specific MIS SIJ system as numerous devices have received FDA 510(k) clearance. The instrumentation utilized in a MIS SIJ procedure is the purview of the surgeon.

The reader refers to a limitation in diagnosis if leakage occurs during a diagnostic SIJ block. While leakage could be associated with false positives, subjects in all prospective trials diagnosed with this method showed improvements, independent of underlying diagnosis

Irrelevant Resources

The ODG include review of some professional statements/guidelines that predate most of the literature on minimally invasive SIJ fusion. Such guidelines are irrelevant and should be removed.

Conclusions Reverse of Evidence

It is disappointing that the guidelines support SIJ fusion for conditions such as SIJ infection, tumor, spondyloarthropathy, conditions for which high-quality evidence supporting superiority over non-surgical treatment is completely lacking but the guidelines dismiss two high-quality randomized trials in patients with chronic SIJ dysfunction showing superiority over non-surgical treatment. The guidelines should be revised to better reflect the level of available evidence and follow standard scientific approaches to evidence interpretation. The recent ODG withdrawal from an AHRQ sponsored federal database (National Guideline Clearing House at www.Guideline.gov) speaks to this same concern voiced by ISASS.¹³

Thank you for your attention to this matter.

Sincerely,

Morgan P. Lorio, MD, FACS
Chair, Coding & Reimbursement Task Force
International Society for the Advancement of Spine Surgery

Citations

1. Stuesson, B. *et al.* Six-Month Outcomes from a Randomized Controlled Trial of Minimally Invasive SI Joint Fusion with Triangular Titanium Implants vs. Conservative Management. *Eur. Spine J.* (2016). doi:10.1007/s00586-016-4599-9
2. Polly, D. W. *et al.* Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs. Non-Surgical Management for Sacroiliac Joint Dysfunction. *Int. J. Spine Surg.* **10**, Article 28 (2016).
3. DePalma, M. J., Ketchum, J. M. & Saullo, T. R. Etiology of Chronic Low Back Pain in Patients Having Undergone Lumbar Fusion. *Pain Med.* **12**, 732–739 (2011).
4. Boden, S. D. The use of radiographic imaging studies in the evaluation of patients who have degenerative disorders of the lumbar spine. *J. Bone Joint Surg. Am.* **78**, 114–124 (1996).
5. Vleeming, A., Albert, H. B., Östgaard, H. C., Stuesson, B. & Stuge, B. European guidelines for the diagnosis and treatment of pelvic girdle pain. *Eur. Spine J.* **17**, 794–819 (2008).
6. Lorio, M. P. ISASS Policy 2016 Update - Minimally Invasive Sacroiliac Joint Fusion. *Int. J. Spine Surg.* **10**, 26 (2016).
7. Polly, D. W. *et al.* Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes. *Neurosurgery* **77**, 674–691 (2015).
8. Dengler, J. *et al.* Predictors of Outcome in Conservative and Minimally Invasive Surgical Management of Pain Originating from the Sacroiliac Joint – a Pooled Analysis. *Spine Accept. Pub Pending* (2017).
9. Vanaclocha-Vanaclocha, V., Herrera, J. M., Sáiz-Sapena, N., Rivera-Paz, M. & Verdú-López, F. Minimally Invasive Sacroiliac Joint Fusion, Radiofrequency Denervation and Conservative Management for Sacroiliac Joint Pain: Six Year Comparative Case Series. *Press Neurosurg.* (2017).
10. Duhon, B. S. *et al.* Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study. *Glob. Spine J.* **6**, 257–269 [Epub 2015 Aug 11] (2016).
11. Rudolf, L. & Capobianco, R. Five-year clinical and radiographic outcomes after minimally invasive sacroiliac joint fusion using triangular implants. *Open Orthop. J.* **8**, 375–383 (2014).
12. Kube, R. A. & Muir J. M. Sacroiliac Joint Fusion: One Year Clinical and Radiographic Results Following Minimally Invasive Sacroiliac Joint Fusion Surgery. *Open Orthop. J.* **10**, 679-689 (2016). doi: 10.2174/1874325001610010679
13. Goldberg, S. Well-known Comp Disability Guidelines Removed From Federal Data Base. <https://www.businessinsurance.com/article/20160629/NEWS08/160629773/odg-guidelines-workers-compensation-work-loss-data-institute>.