Via email

May 26, 2020

TO John Whitney, MD
Vice President Medical Policy and Clinical Pharmacy Policy
john.whitneymd@anthem.com

Dear Dr. Whitney:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), we wanted to thank you for your time to speak about minimally invasive surgical (MIS) sacroiliac (SI) joint fusion this week. As we discussed, there is ample rationale for Anthem to revise its current policy on this topic (SURG.00127), and to adopt a coverage policy that includes SI joint pain and dysfunction due to degenerative conditions not limited to patients with a history of direct trauma or injury to the pelvic girdle. With Level I and II evidence showing the immediate as well as long-term impact this important treatment option has had on a mostly degenerative sacroiliitis population, including more than 80 papers published in peer-reviewed journals with follow-up of 5 years prospectively, we believe there is sufficient rationale for Anthem's coverage with adequate pre-operative criteria.

The prevalence of SI joint pain in patients evaluated for chronic low back pain ranges from 15-30% (Figure 1).

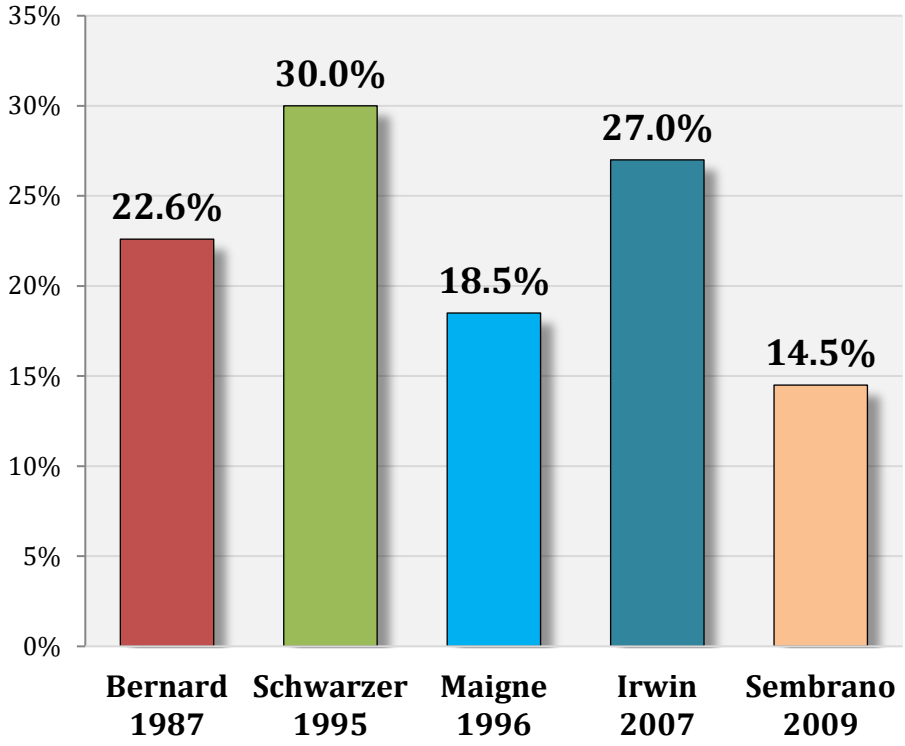


Figure 1. Prevalence of SI joint pain in patients evaluated for chronic low back pain.

The SI joint is an even more common (23-43%) cause of low back pain after lumbar fusion (need to add the references for this statement 5-8)
. Our study showed significant cross over with spine and hip pain patterns (Figure 2).

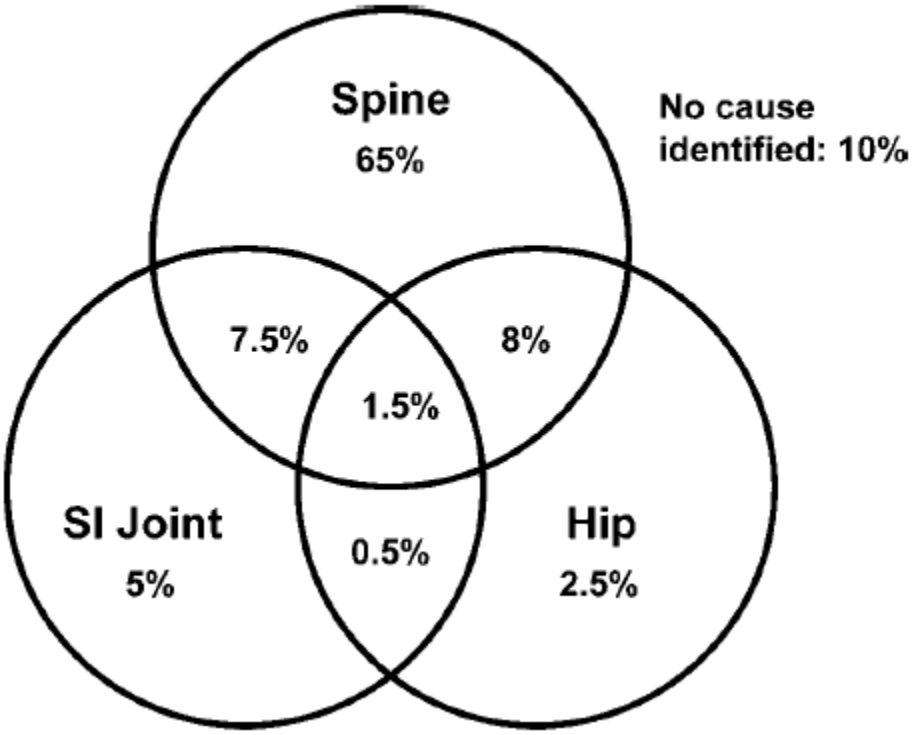


Figure 2. Venn diagram showing the distribution of pain generators (spine, hip joint, and SI joint) responsible for symptoms in 200 patients complaining of low back pain after diagnostic workup. Taken from Sembrano et al.

There are multiple potential causes of posterior pelvic pain. The following diagram is an excellent representation of the differential diagnosis.

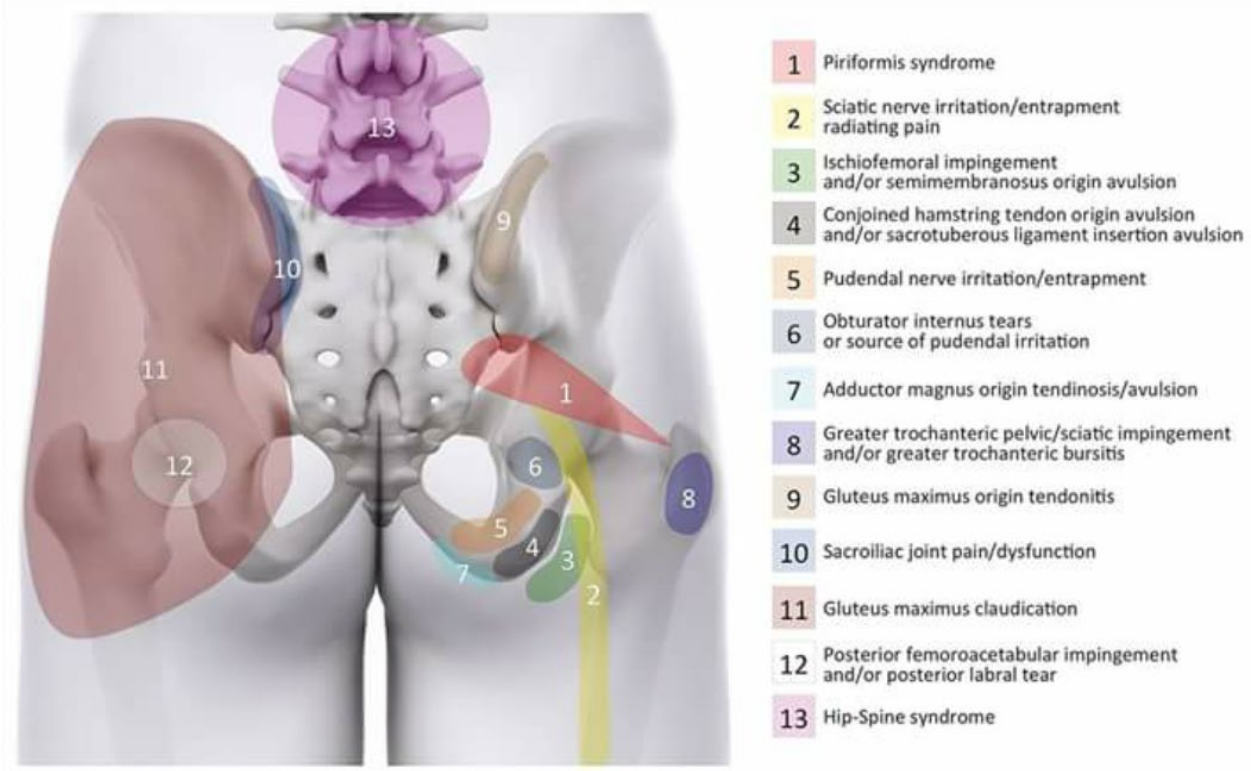
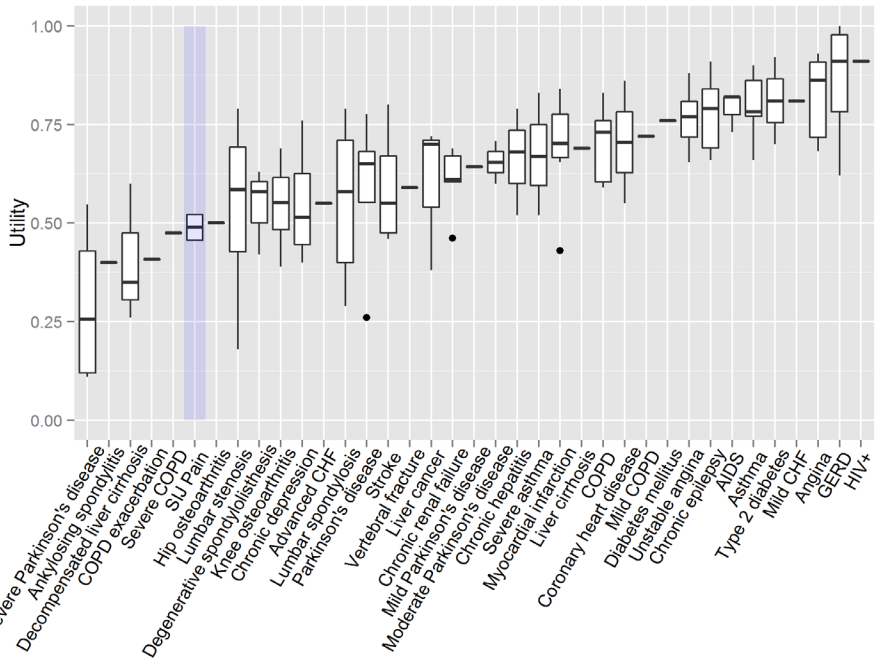


Figure 3. Potential causes of chronic pelvic pain. Figure courtesy of Dr. Baronio, Lombardia, Italy.

Patients with SI joint pain are severely disabled, with a high burden of disease (Figure 4).


Utility
1.00
0.75
0.50
0.25
0.00
Severe Parkinson's disease
Ankylosing spondylitis
Decompensated liver cirrhosis
COPD exacerbation
Severe COPD
SIJ Pain
Hip osteoarthritis
Lumbar stenosis
Degenerative spondylolisthesis
Knee osteoarthritis
Chronic depression
Advanced CHF
Lumbar spondylosis
Parkinson's disease
Stroke
Vertebral fracture
Liver cancer
Chronic renal failure
Mild Parkinson's disease
Moderate Parkinson's disease
Chronic hepatitis
Severe asthma
Myocardial infarction
Liver cirrhosis
COPD
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Unstable angina
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AIDS
Asthma
Type 2 diabetes
Mild CHF
Angina
GERD
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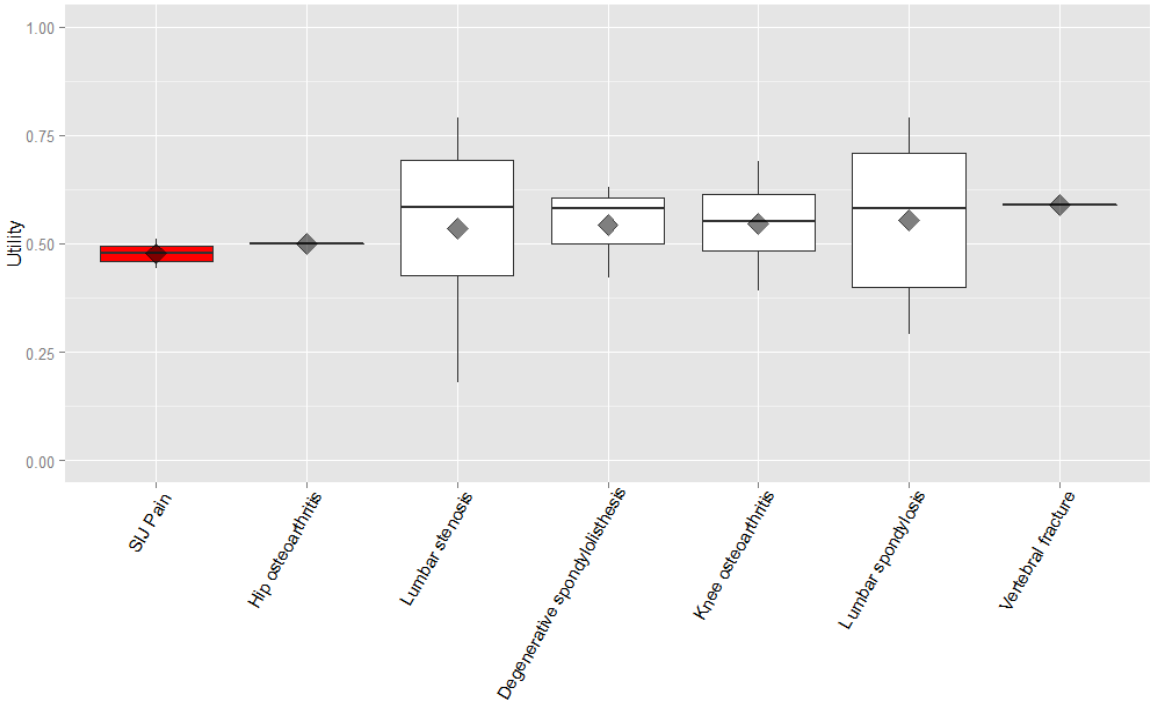
Utility
1.00
0.75
0.50
0.25
0.00
SIJ Pain
Hip osteoarthritis
Lumbar stenosis
Degenerative spondylolisthesis
Knee osteoarthritis
Lumbar spondylosis
Vertebral fracture

Figure 4. Health state utility from various health conditions (top). SI joint pain is highlighted in blue. Health state utility for orthopedic conditions commonly treated surgically (bottom, SI joint pain highlighted in red). Health state utility for SI joint pain (shaded region) taken from patients participating in two prospective clinical trials.

There are several available non-surgical and surgical treatments for chronic SI joint pain, with variable support from the published literature. While commonly prescribed, there is no evidence to support rest or physical therapy for the treatment of chronic SI joint pain associated with osteoarthritis (joint degeneration), probably the most common underlying etiology for SI joint pain. Two blinded randomized trials by a single author group support the use of periarticular corticosteroids for short-term (1-month) pain relief.[10,11] However, no high-quality evidence supports the more commonly used practice of intraarticular corticosteroid injections. Non-operative treatment for SI joint pain has been documented in both randomized trials[12,13] (6-month time frame) and a long-term (6-year) cohort study (Figure 5).

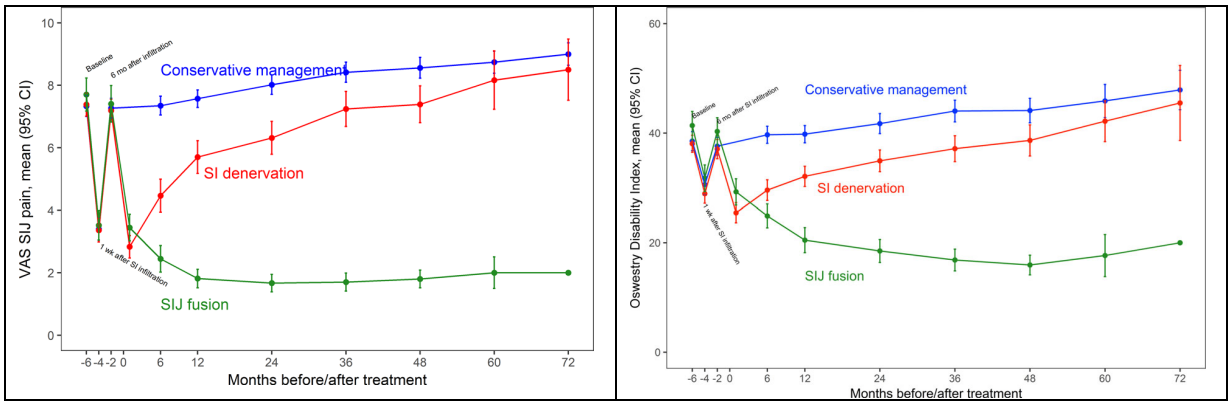

Figure 5. Cohort study showing no improvement in pain (left) or Oswestry Disability Index (ODI, right) in patients with chronic SI joint pain (blue lines).[14] ODI is a patient-reported outcome quantifying disability due to back pain. Values >40 indicate severe disability. Opioid use increased over time in the conservative group.

Diagnosis of SI joint pain can be reliably made based upon a combination of history, physical examination tests that stress the SI joint (Figure 6) and confirmatory diagnostic block. A recent comprehensive review suggests that clinical examination for SI joint pain is amongst the most accurate of all tests for chronic low back pain.[15,16] If 3 or more of the 5 physical examination maneuvers shown in the figure are positive, there is an 85% chance that an image-guided diagnostic SI joint block will be positive (i.e., 85% positive predictive value). SI joint blocks are performed by injecting 1-2.5 cc of anesthetic into the joint under image guidance (fluoroscopy or CT).

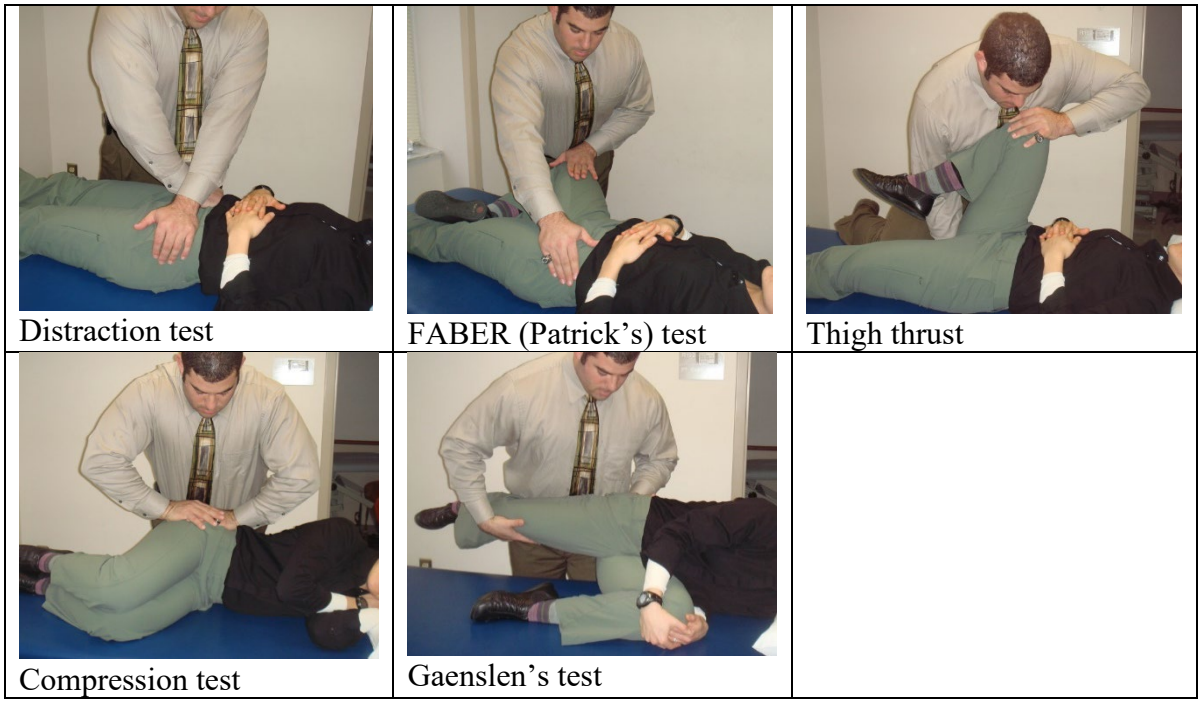

Figure 6. Physical examination maneuvers for SI joint pain. Each test puts stress on the SI joint. A positive test is one that elicits typical pain.

Several studies provide evidence to support the safety and effectiveness of SI joint fusion using triangular titanium implants (TTI). SIFI is a prospective open-label multicenter clinical trial of patients with chronic SI joint pain, all of whom underwent SI joint fusion using TTI. Observed were large improvements in pain and disability related to pain (Figure 7). (reference Duhon 17)

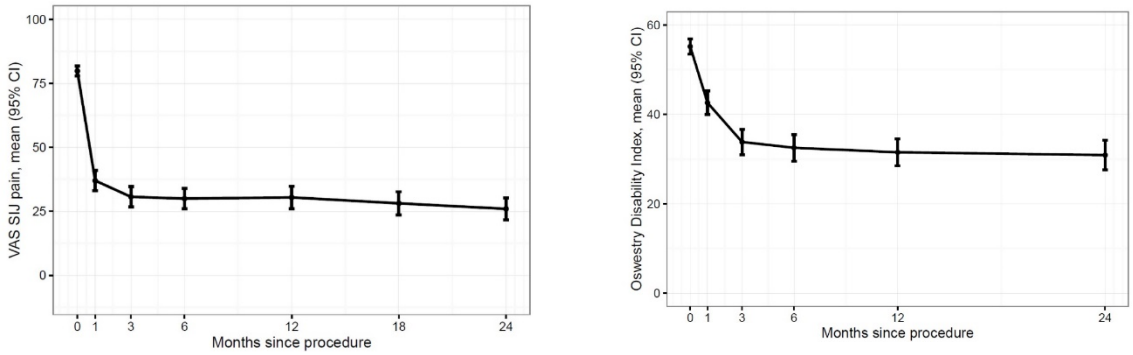

Figure 7. Improvement in SI joint pain (left) and disability (right) in patients with chronic SI joint pain participating in a prospective multicenter single-arm trial.[17]

Two prospective randomized controlled trials also demonstrated immediate, marked and sustained improvement in pain and disability after SI joint fusion with TTI (INSITE [Figure 8],

a US RCT (reference Polly 12), and iMIA[13] [Figure 9], a similarly designed European RCT). Both trials had concurrent randomized control subjects treated with best-available non-surgical care (interventions not well-supported by clinical science but commonly provided), which showed very little, if any, improvement in pain and disability. All improvements were statistically greater in the surgery vs. non-surgery groups. All change scores exceeded the minimally clinically important different (MCID, 20 points for VAS pain and 15 points for ODI). Both RCTs showed a decrease in opioid use, preserved work status, and improved physical activity (walking distance, Figure 10).

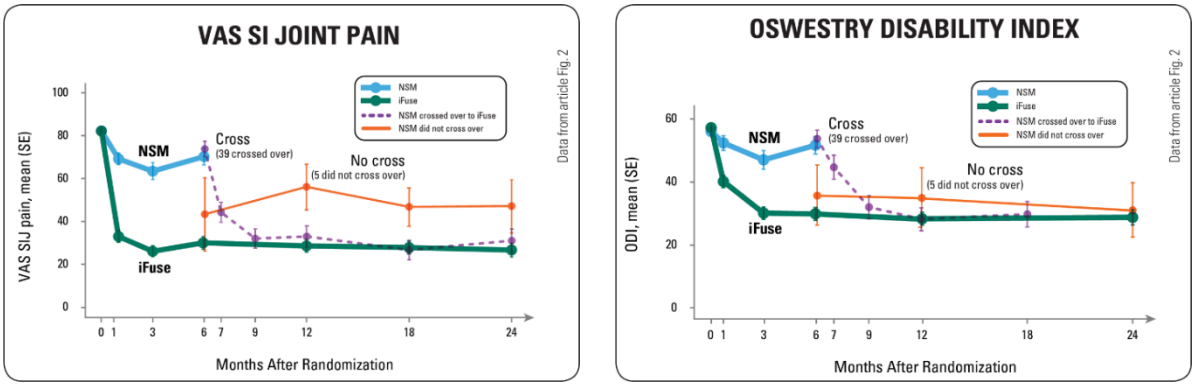

Figure 8. Improvement in SI joint pain (left) and Oswestry Disability Index (right) in patients with chronic SI joint pain randomized to either immediate SI joint fusion ("iFuse", green) or best-available non-surgical management (NSM, blue). NSM included medication optimization, physical therapy, SI joint corticosteroid injections and RF ablation of the lateral branches of the sacral nerve roots, as required for control of pain and disability. Subjects who crossed over from NSM to SI joint fusion (purple dotted lines) also showed marked improvement after crossover.

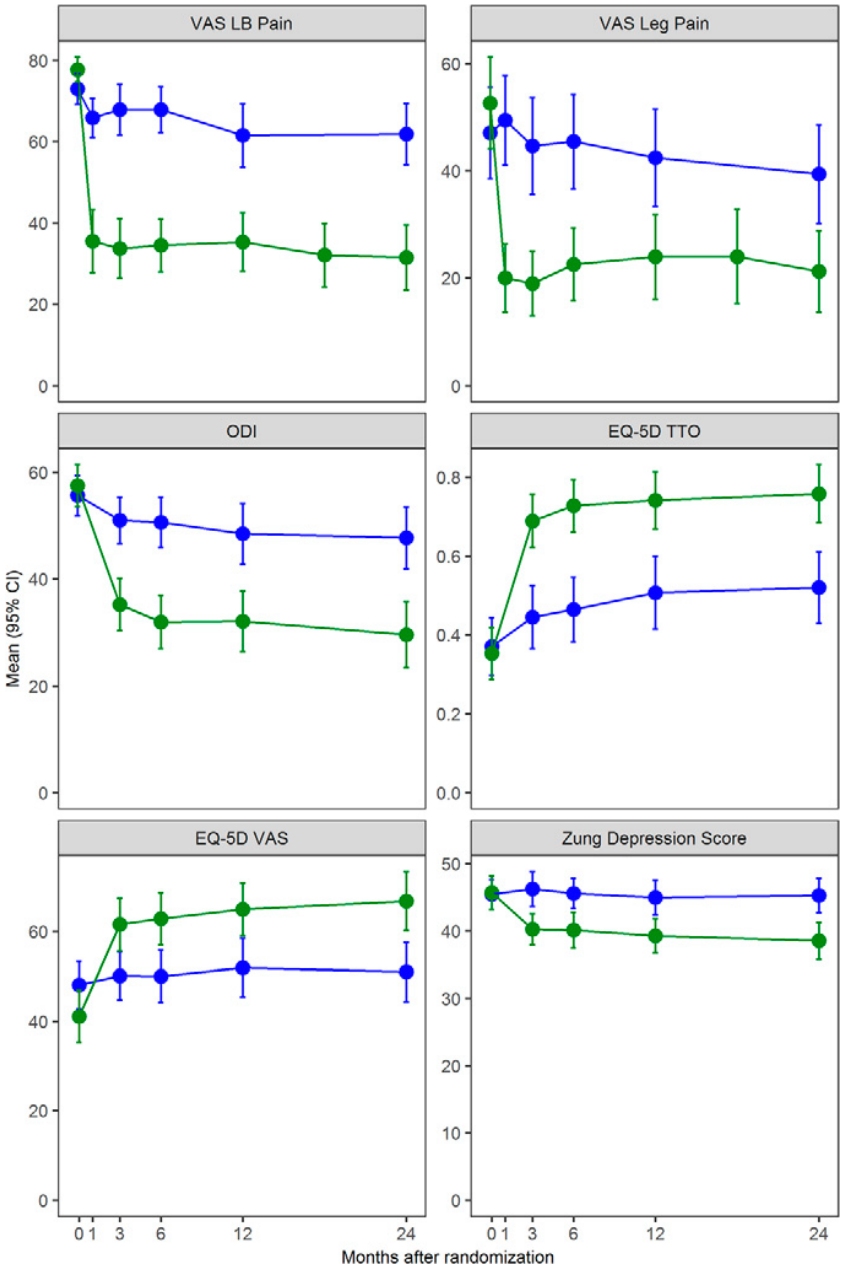

Figure 9. Improvement in low back (LB) pain, leg pain, Oswestry Disability Index, EuroQOL-5D time trade-off index (EQ-5D TTO) and visual analog scale (VAS) and Zung Depression Score in patients with chronic SI joint pain randomized to either immediate SI joint fusion using TTI (green) or conservative management (CM, blue).[13] CM consisted primarily of intensive physical therapy.

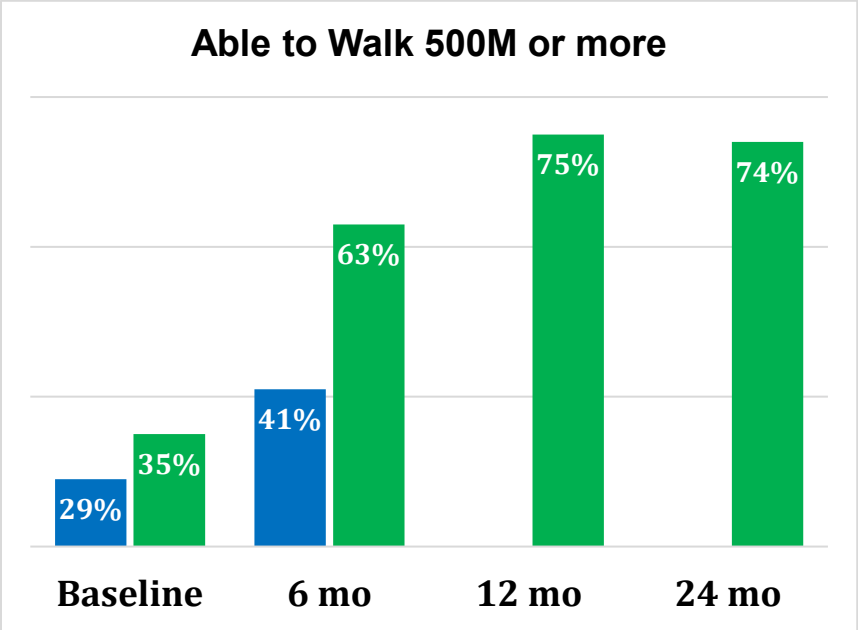

Figure 10. Self-reported walking distance after either conservative management (CM) or SI joint arthrodesis (fusion) with TTI.

The above trials have been criticized as they were not blinded. However, subjects completed the visual analog pain scale and the Oswestry Disability Index scores independent of study physicians. In my own practice (DWP), this is accomplished by a medical assistant or LPN as part of the rooming process prior to me seeing the patient. In the US trials, these patient reported outcomes were collected using handheld computers (iPads).

Despite different settings, the three trials showed marked consistency of effect size and direction (Figure 11). Results from prospective trials also agree with published retrospective case series (Figure 12).

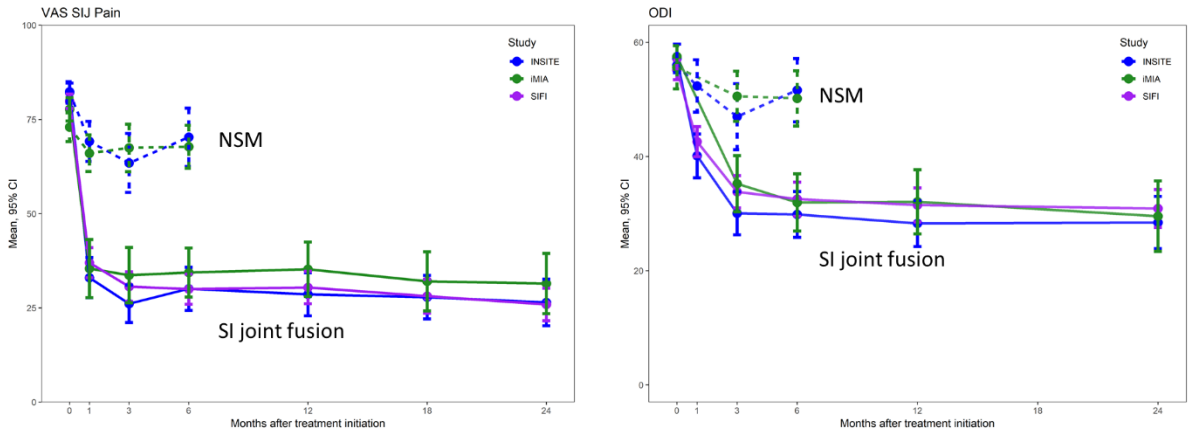

Figure 11. Improvement in SI joint pain and Oswestry Disability Index in 3 prospective TTI trials to date (2 RCTs and 1 prospective single-arm study).

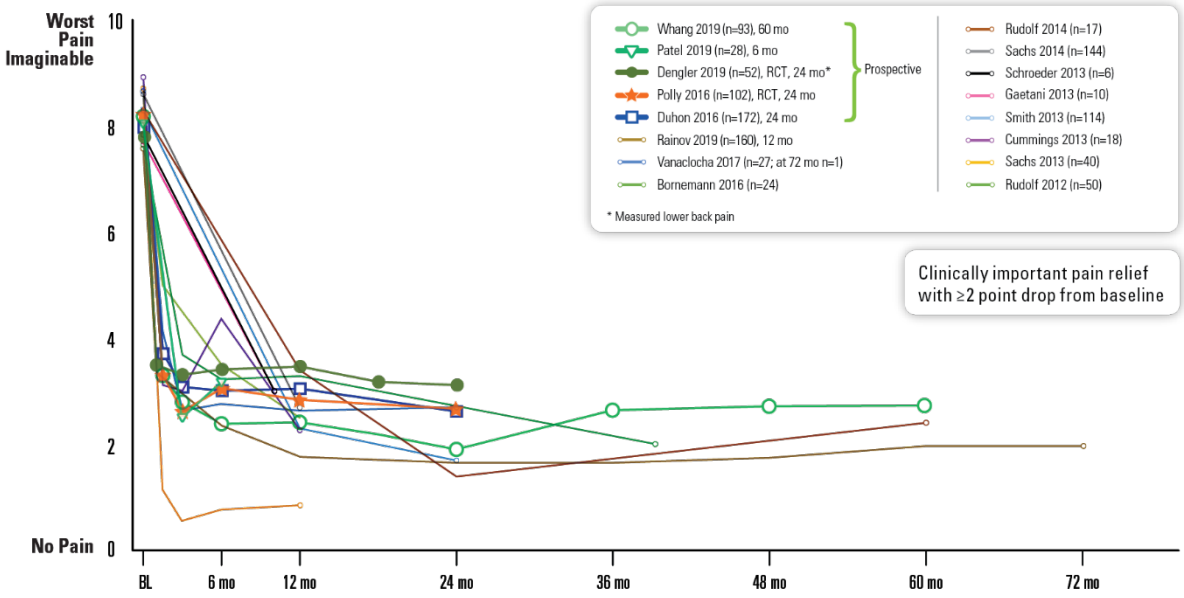

Figure 12. Improvement in prospective trials and retrospective case series. (0-100 VAS scale normalized to 0-10.)

Comparative effectiveness studies comparing open to minimally invasive SI fusion all favor the minimally invasive approach. Differences include superior pain relief, decreased blood loss and decreased OR time in the minimally invasive approach. One comparative effectiveness study (reference Vanacloacha 14) reported outcomes of 3 treatments: 1) conservative management, 2) RF ablation of the lateral branches of the sacral nerve roots) and 3) SI joint fusion using TTI. Patient's insurance coverage guided treatment choice; in many cases insurance did not cover SI joint fusion, and patients were forced to undergo continued conservative management. Of interest: Conservative management resulted in no improvement (and possible worsening) of pain and ODI scores (Figure 5). Opioid use increased. RF ablation showed marked but transient improvements in pain and ODI. By 1 year, pain and disability returned. Opioid use was intermediate.
SI joint fusion showed marked, clinically important, immediate and sustained (to 6 years) improvement in pain and disability, with a large reduction in opioid use.

Prospective long-term follow-up is available in two studies.

Rudolf reports 5-year follow-up in patients undergoing the earliest procedures (2009 -2010 time frame); pain improvement was sustained and there was a high rate of radiographic fusion of the SI joint.
Patients participating in the surgical arms of two US clinical trials (SIFI [multicenter single-arm study] and INSITE [prospective RCT]) enrolled in a long-term follow-up study. At year 5, improvement in pain, disability (ODI) and quality of life (EuroQOL-5D TTO index) were sustained (Figure 13). (references Rudolf 20 and Whang 21)

These findings are very similar to those observed in retrospective long-term cohorts.

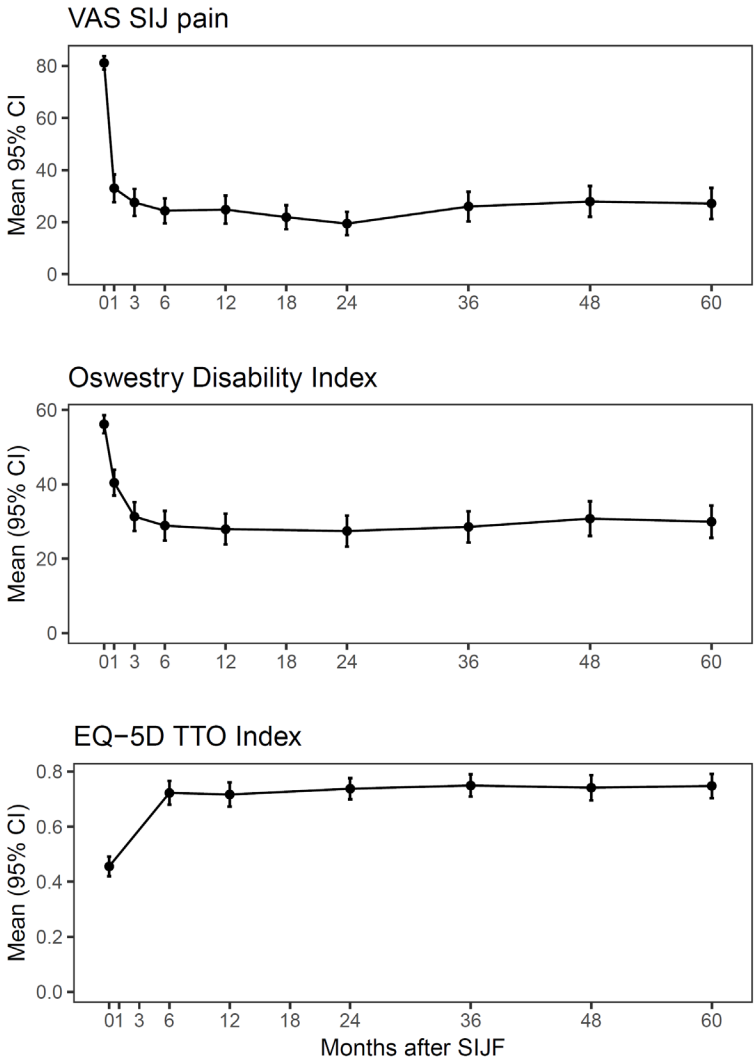

Figure 13. Improvement in pain (top), disability (middle) and quality of life (bottom) in patients participating in long-term follow-up after SI joint fusion.

Revision surgery after SI joint fusion surgery occasionally occurs. In approximately 1% of cases, implants are placed into the sacral foramen, resulting in irritation of nerve roots and newly appearing postoperative radiating leg pain. In almost all cases, this pain resolves on repositioning the offending implant. The rate of device malposition may be reduced with more advanced imaging techniques. Causes of late revision including pain never decreasing (some patients desire to have implants removed) or return of pain after a period of pain relief. The latter is sometimes associated with implant loosening apparent within the sacrum on imaging. The rate of revision surgery is low and decreased over time (Figure 14) (reference Cher 22). The rate of revision surgery with the latest iteration of the TTI is even lower (Figure 15) (reference Cher 23). Revision rates are lower than many other spine procedures and may be similar to those observed for hip replacement.

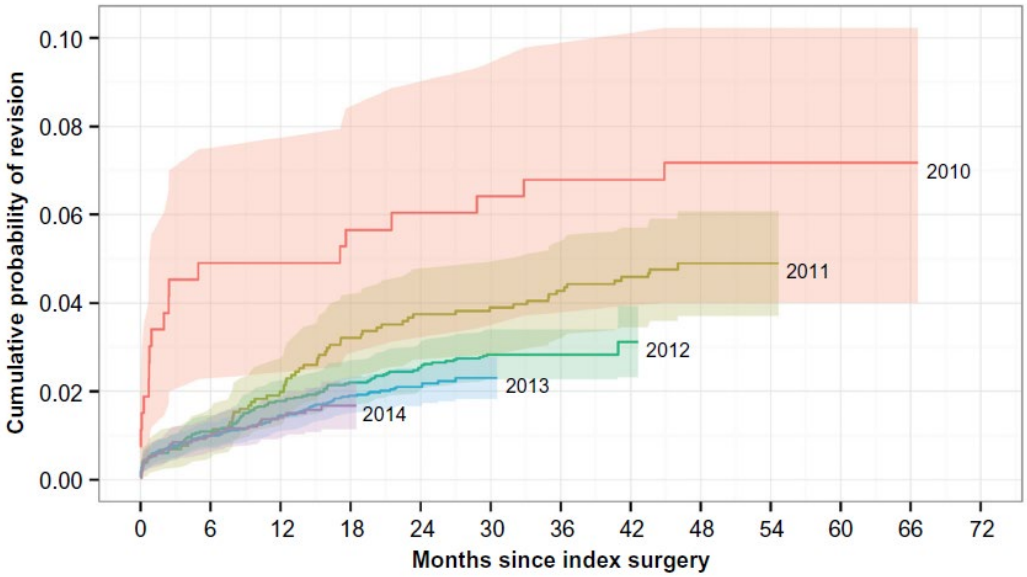

Figure 14. Cumulative rate of revision surgery after SI joint fusion using TTI. In the most recent time periods in this 2014 report, the 2-year revision rate was approximately 2%.

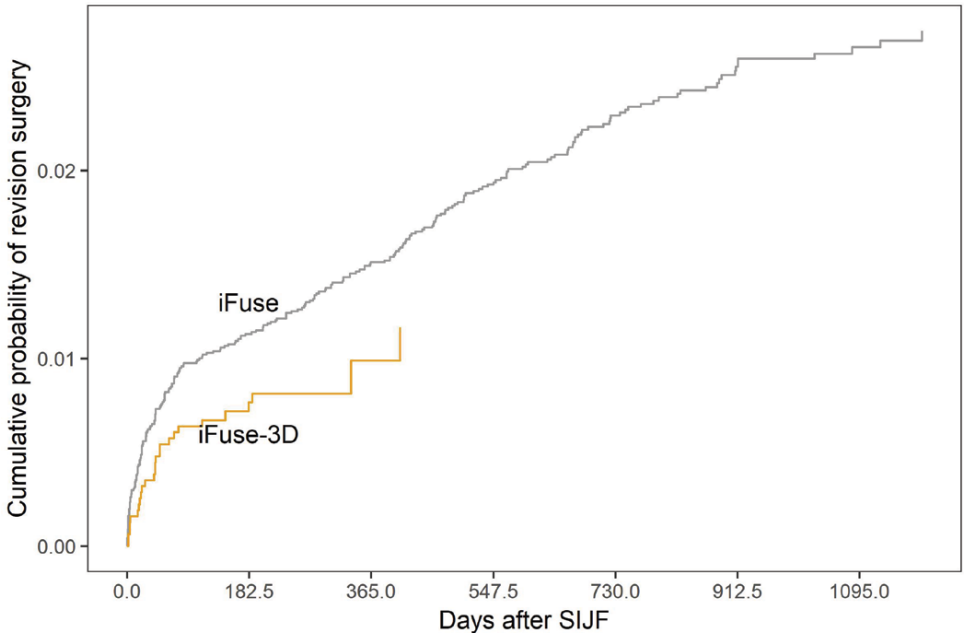

Figure 15. Cumulative rate of revision surgery after SI joint fusion using TTI or 3D-printed TTI. Index surgeries were performed between 2015 and 2018.

Washington HCA Committee Meeting

In 2018, the Washington Health Care Authority (HCA) conducted a comprehensive review of the literature on this topic. The report finalized in December 2018 following this review was favorable for SI joint fusion, yet when the Washington HCA committee meeting was convened on this topic on January 18, 2019, the committee decided against its broader application for conditions other than trauma. Certain committee members questioned the complications resulting from this procedure, characterizing them as significant, and occurring with significant frequency. No references were provided in support of these statements, certainly none as strong as those supporting the broader population of mostly degenerative sacroiliitis patients. Also, they argued the procedure was not easily revisable when in fact the procedure is revisable as we believe the references and tables above amply demonstrate. This point was understood by the initial policy review which was favorable before commenters provided unsubstantiated statements regarding revision.

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Another issue raised in our May 18th meeting another discussion point was around sham surgery as a control group for randomized controlled trials. Although there are situations where sham may be appropriate and beneficial, in the case of an interventional procedure for patients in acute pain, such as SI joint disorders, ISASS regards sham surgery as unethical and unlikely

to be approved by IRBs/ethics committees (reference 24). Moreover, the patient population that might participate in a sham surgery study would likely be different from those in standard practice, greatly limiting the generalizability of such a study (if it could be done).
ISASS also recognizes that there are multiple devices used in MIS SI Joint Fusion surgery, not just iFuse, and while iFuse has primarily been discussed, ISASS regards coverage as applicable to all device types and does not endorse any specific devices.
In summary this is a relatively common problem. It is significantly disabling. There is limited evidence of benefit of non-operative treatment and no evidence of spontaneous recovery. The condition can be reliably diagnosed on physical examination. It can then be confirmed by image guided diagnostic injections. Surgical treatment provides clinically significant improvement. This improvement is durable through 5 years. The revision surgery rate is low and has decreased over time. Finally, we believe the above points provide compelling evidence to support coverage of this cost effective and clinically efficacious treatment for long lasting back pain relief.

We would be delighted to answer any further questions.

Sincerely,

David W. Polly, Jr., MD
James W. Ogilvie Professor and Chief of Spine Surgery
Catherine Mills Davis endowed Professor
Department of Orthopaedic Surgery
Professor (w) of Neurosurgery
University of Minnesota
Past President, Scoliosis Research Society 2015-2016

Morgan Lorio, MD
Chair, ISASS Coding and
Reimbursement Task Force