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ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion

Morgan P. Lorio[1], Ralph Rashbaum[2]

[1]Neuro-Spine Solutions, Bristol, TN [2]Texas Back Institute, Plano, TX

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Background

The sacroiliac (SI) joints are paired diarthrodial articulations of the sacrum and ilium and serve as the connection between the spine and pelvis. The small amount of motion in the joint (2-4 degrees) occurs primarily through nutation and counternutation of the sacrum.[1] There are no muscles that cross solely the SI joint, thus there are no prime movers. Instead, movement is dependent on the articulations and movement within the lumbopelvic hip complex (e.g. flexion at the hip results in diminished lumbar lordosis and counternutation of the sacrum, extension of the lumbar spine results in nutation of the sacrum).[2] The subchondral bone, capsule, and surrounding ligaments of the SI joint are rich in nociceptive pain fibers.[3] Though the specific segments responsible are a subject of debate, it is generally accepted that the posterior primary rami of the lower lumbar and upper sacral segments innervate the joint.[1]

The SI joint is a well-known cause of pain in the lumbopelvic hip complex.[1,4-6] There are many possible etiologies including, but not limited to, degenerative sacroiliitis, primary osteoarthritis, post-traumatic osteoarthritis or incongruence, adjacent joint degeneration as a result of lumbar spinal conditions and procedures, and idiopathic causes.

Low back pain (LBP) is a worldwide epidemic and one of the top 3 causes of health related chronic pain in developed countries.[7] LBP is not limited to industrial countries, however, Lin et al. report devastating effects of LBP in aboriginal population of Australia[8] and Hoy et al. reported that 20% of villagers in rural Tibet have substantial functional disability due to low back pain.[9] Louw et al. report a 62% lifetime prevalence of LBP in Africa.[10] Furthermore, low back pain is associated with increased risk of falling,[11] which in an elderly population, can result in hip and/or spinal fractures. The annual expenditures for chronic back pain are astounding and exceed $100 billion in the U.S. alone.[12]

While lumbar spinal structures are important factors in to consider in patients who presented with low back pain, substantial evidence suggests that the SI joint may be the pain generator in many of these patients.[4,5,13,14] In patients who fail to improve after successful lumbar spinal arthrodesis, SI joint pain may explain the delayed onset of

postoperative pain or failure to improve as a result of possible misdiagnosis or presence of other pain generators.[15-18] Ha et al. report radiographic evidence of SI degeneration in up to 75% of patients treated with lumbar spinal fusion.[19] DePalma et al. determined the SI joint as the pain generator in 43% of patients complaining of persistent pain after lumbar spinal fusion.[20]

A recent study by Cher et al. reported the significance of the burden created by SI joint pain.[21] The impact of SI joint pain on pain and function is commensurate with other common orthopedic conditions, such as hip and knee osteoarthritis, spinal stenosis and degenerative spondylolisthesis, all of which are treated surgically. The cost of conservative care in the patients diagnosed with SI joint disorders is substantial. Ackerman et al., using the MarketScan Commercial Claims and Encounters database, estimated an approximate cost of $1.6billion per 100,000 covered lives (including Medicare and private insurance) for conservative treatment. Furthermore, if we assume that 15% of the $100B spent on LBP should be directed at treating SI joint pain, a conservative estimate of the cost of SI joint pain is upwards of $15B in the US alone. It is paramount that correctly elucidating the primary pain generator in LBP patients is crucial for adequate treatment and return to function.

Diagnosing the sacroiliac joint

SI joint pain can be difficult to diagnose as the pain syndrome may present similarly to other lumbar spinal conditions. Patients with SI joint pain typically report pain in the low back and buttocks, sometimes with radiation into the groin or upper legs. An algorithm consisting of medical history, physical examination, imaging studies and confirmatory intra-articular joint injections is typically used to diagnose SI joint disorders.

SI joint pain primary affects women over the age of 40.[21] History may include mild trauma, pain during single leg stance on the affected side, difficulty sleeping, pain in the peri- or post-partum period or pain after lumbar spinal fusion. Specific physical examination tests that stress the SI joint (e.g., distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver, sacral sulcus tenderness) are performed in the physician's office. In combination, these tests are thought to be predictive of SI joint pain.[22] Apart from ankylosing spondylitis, in which the diagnosis can be made based on imaging of the SI joint typically does not provide valuable diagnostic information.[23] Rather, imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SI joint pain (e.g., hip osteoarthritis, occasionally L5/S1 spine degeneration).

The diagnosis of SI joint pain is confirmed by performing a fluoroscopy guided intra-articular SI joint block with local anesthetic (e.g., lidocaine). Pain using a VAS scale of 0-10 scale is assessed both prior to and within 4 hours after the block. The response time is dependent upon and is usually consistent with a short vs. long acting anesthetic and the inclusion/exclusion of epinephrine. An acute reduction in pain of at least 75% using a visual analog scale is considered a positive result and indicates that the injected joint is likely the pain generator based on published studies.[24,25] SI joint blocks have been validated by a blinded study of patients who were injected with either saline or local anesthetic.[26] It is important to note that one or more pathologic processes can coexist with SI joint pain. In order to confirm that SI joint pain is the primary (or only) diagnosis, the

physician should rule out other possible causes of pelvic or lower back pain. Examples of alternative diagnoses include pelvic fracture, tumor, infection, skeletal deformity, hip arthritis, and degenerative spine conditions.

Non-surgical treatment

Non-surgical treatments available for patients suffering from SI joint pain include pain medications (e.g., non-steroid anti-inflammatory agents, opioids), physical therapy,[27] a pelvic compression belt,[28] and manipulative therapy. If these initial treatments are unsuccessful, patients may be sent for interventional treatments such as intra-articular anesthetic and steroid injections[29] and where appropriate, radio frequency (RF) ablation.[30,31] Injections may provide temporary relief and in most cases will need to be repeated on a regular basis. The anesthetic phase is typically diagnostic only. A biphase approach that includes immediate relief post-anesthestic injection, followed by recurrent pain with a subsequent steroid injection may also be used. Despite positive initial results with RF ablation, recrudescence of symptoms within one year is common for many patients as a result of nerve regeneration; the SI joint is never truly denervated, it is only desensitized.

While a percentage of patients will respond well to these non-surgical measures, many of them will not experience adequate symptom relief and may be functionally disabled. Patients with a diagnosis of SI joint pain who experience pain for a minimum of six months and who do not respond to an adequate course of non-surgical treatment may be considered for SI joint fusion.

Open and Minimally Invasive SI joint Fusion

Open surgical approaches to arthrodesis of the SI joint have been available since the 1920's and can provide pain relief, but recovery times are long and the complication rate is high.[32-36] Multiple incisions, damage to muscle tissue and significant intraoperative bleeding are common. Furthermore, open surgical SI joint arthrodesis requires a prolonged course of postoperative rehabilitation. Therefore, open fusion of the SI joint is commonly reserved for pelvic ring fractures in the setting of trauma.[37]

Minimally invasive fusion of the SI joint was first reported in the literature in 2004 and has been performed with several types of implants, including triangular, titanium plasma spray coated implants,[38-43] hollow modular screws,[44-46] titanium cages,[47] allograft[32] dowels, and autograft iliac bone plugs[48] (Table 1). These devices are placed either inside (posteroanterior approach) or across (lateral approach) the SI joint through relatively small incisions under fluoroscopic guidance. It is hypothesized that SI joint fusion provides acute pain relief by stabilizing the painful SI joint with subsequent fusion of the device to the sacrum and ilium, and in some cases an actual joint fusion via creeping substitution.

Table 1.

Author, Year	N	Study design	Demographics	Implant description	Results	Complications

Rudolf, 2012	50	Retrospective case series	Age: 54 years Sex: 34F/16M Prior lumbar fusion: 44% Follow up: 40mo (range 24-56)	iFuse Implant System	VAS: 7.6 pre-op, 2.0 at f/u Mean VAS improvement: -4.3 pts 82% reached MCID 82% patient satisfaction OR time: 65 ± 26min	Superficial cellulitis: 3 Deep wound infection:1 Hematoma: 2 Reoperation: 3
Sachs, 2013	40	Retrospective case series	Age: 58 years Sex: 30F/10M Prior lumbar fusion: 30% Follow up: 12 months	iFuse Implant System	VAS: 8.7 pre-op, 0.9 at f/u Mean VAS improvement:-7.8pts 98% reached MCID 100% patient satisfaction	Piriformis syndrome: 1 New LBP: 1 Facet joint pain: 8 Trochanteric bursitis: 2
Cummings, 2013	18	Retrospective case series	Age: 64 years Sex: 12F/6M Prior lumbar fusion: 61% Follow up: 12mo	iFuse Implant System	VAS: 9.0 pre-op, 2.3 at f/u 90% reached MCID Mean improvement: VAS -6.6pts, ODI -37.5pts, SF-12PCS 11.2, SF-12MCS 20.4 94% very or somewhat satisfied	Trochanteric bursitis: 3 Hematoma: 1 Fluid retention:1 Toe numbness: 1 Implant malposition: 1
Gaetani, 2013	12	Retrospective case series	Age: 53 years Sex: 12F Prior lumbar fusion: 1 Follow up: 10mo	iFuse Implant System	VAS: 7.7 pre-op, 3.0 f/u ODI: 31.4 pre-op, 12.0 f/u 100% patient satisfaction 3mth CT scans show initial fusion OR time: 65min EBL: <45cc	2 local hematoma
Schroeder, 2013	6	Retrospective case series	Age: 50 years Sex: 6F/0M Prior lumbar fusion: 100% (deformity correction) Follow up: 10mo	iFuse Implant System	VAS: 7.8 pre-op, 2.7 at f/u ODI: 44.2 pre-op, 21 f/u	None reported
Graham-Smith, 2013	114	Retrospective multicenter, comparative cohort study	Age: 57 years Sex: 82F/32M Prior lumbar fusion: 47% Follow up: 24 mo	iFuse Implant System	VAS: 8.3 pre-op, 2.3 at 12mo, 1.7 at 24mo 86% reached MCID at 12mo, 82% at 24mo OR time: 70min EBL: 33cc Hospital stay: 1.3 days	3.5% reoperation due to nerve root impingement, facet pain (4), fall (4), piriformis syndrome (2), cellulitis (3), trochanteric bursitis (2)

Duhon, 2013	32, 94	Prospective, multi-center	Age: 50 years Sex: 21F/11M Prior lumbar fusion: 69% Follow-up: 6 months	iFuse Implant System	VAS: 76.2 pre-op, 29.3 f/u ODI: 55.3 pre-op, 38.9 f/u SF-36PCS: 30.7 pre-op, 37 f/u 88.5% success rate 85% somewhat or very satisfied, OR time: 48min EBL: 59cc Hospital stay: 0.8 days	No implant revision or removal, 6 AEs probably or definitely related to study procedure (1 nausea, 2 wound infections, 1 cellulitis, 1 buttock pain)
Sachs, 2014	144	Retrospective, multi-center	Age: 58 years Sex: 30F/10M Prior lumbar fusion: 62% Follow-up: 16mo	iFuse Implant System	VAS: 8.6 pre-op, 2.7 f/u 91% Very or somewhat satisfied 91.7% would have surgery again OR time: 73min EBL: minimal Hospital stay: 0.8 days	Implant revision (1), fall (5), trochanteric bursitis (4), piriformis syndrome (3), facet pain (3)
Al-Khayer 2008	9	Retrospective case series	Age: 42 years Sex: 9F Follow-up: 40 mo	Hollow modular anchorage screw packed with demineralized bone matrix	VAS decreased: 8.1 to 4.6 ODI decreased: 59 to 45 Satisfaction: 6.8 (out of 10) Blood loss: <50 ml Hospital stay: 6.9 days Return to work: 4/9	1 deep wound infection Complication rate: 11%
Khurana, 2009	15	Retrospective case series	Age: 48.7 years Sex: 11F/4M Prior lumbar fusion: 40% Follow-up: 17 months	Hollow modular anchorage screw packed with demineralized bone matrix	SF-36 PF: 37 pre-op, 80 f/u Majeed's: 37 pre-op, 79 f/u Good to excellent results: 13/15 Blood loss: < 50 ml Hospital stay: 2.7 days	None reported
Mason, 2013	55	Retrospective case series	Age: 57 years Sex: 46F/9M Prior lumbar fusion: 40% Follow up: 36mo	Hollow modular anchorage screw packed with demineralized bone matrix	VAS: 8.1 pre-op, 4.5 f/u SF-36, PCS: 26.6 pre-op, 43 f/u Majeed scoring: 36.9 pre-op, 64.8 f/u	2 cases of post-op nerve pain requiring reoperation
Wise, 2008	13	Retrospective case series	Age: 53 years Sex: 12F/1M Prior lumbar fusion: 8/13 Follow-up: 29.5mo	2 Titanium cages packed with BMP	VAS improved by 4.9 pts Leg VAS improved by 2.4 pts Blood loss: < 100 ml Hospital stay: 1.7 days	Reoperation (nonunion): 1 Complication and Revision rate: 8%

McGuire, 2012	37	Retrospective case series	Age: 42.5 years Sex: 34F/3M Follow up: 40mo	Fibular allograft dowels	Baseline VAS: 9.1 Final VAS: 3.4	Nonunion requiring revision: 4 (10.5%)
Giannikas, 2004	5	Retrospective case series	Age: 30.6 years Sex: 3F/2M Follow up: 29mo	Autograft iliac bone plugs	Complete pain relief: 4/5 Partial pain relief: 1/5 *Patient kept non weight bearing for at least 3 months	None reported

The largest body of available literature describes the use of a series of triangular titanium implants (iFuse Implant System, SI-BONE, Inc.). In addition to publication of multiple retrospective case series,[38-41] published results from a prospective multicenter trial of minimally invasive SI joint fusion using triangular implants have substantiated high rates of pain relief, improvement in functional measures (SF-36, ODI and EQ-5D) and a low rate of both revisions (<5%) and serious adverse events.[43] In a multicenter retrospective comparative cohort review of 263 patients undergoing either open or minimally invasive SI joint fusion, the latter was associated with statistically significant and clinically marked decreases in operating room time (mean 163 minutes for open vs. 70 minutes for minimally invasive), decreased blood loss (mean 288 cc vs. 33 cc), and decreased hospital length of stay (5.1 vs. 1.3 days) as well as improved relief of pain (using 0-10 VAS) at 1- (-2.7 vs. -6.2 points, p<.001) and 2-year (-2.0 vs. -5.6 points, p<.001) follow-up.[42]

The complication rate for minimally invasive SI joint fusion is low. Importantly, the rate of removal or revision is less than 2%.[43-49] Revisions can be required in the immediate postoperative period or after many months. Early revisions may include the need to reposition an implant that is impinging on a sacral nerve or removal of an implant due to infection.

In cases of bilateral SI joint pain, bilateral SI joint fusion may occasionally be indicated and is usually performed serially to minimize the impact on rehabilitation (i.e., patients who undergo simultaneous bilateral fusion procedures may be wheelchair or bedbound for several weeks, slowing overall recovery). A frequent finding is that once the most painful side has healed (6 to 9 months), the contralateral side is often markedly improved making subsequent contralateral surgery unnecessary.

If bilateral fusion is performed at the same operative session, the surgeon must document both medical necessity and why serial fusion is not indicated in the patient. It is expected that a person would not undergo more than one SI joint fusion per side per lifetime except in the rare case that a revision is needed.

Indications for surgery

Patients who have all of the following criteria may be eligible for minimally invasive SI joint fusion:

- Significant SI joint pain (e.g., pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) or significant limitations in activities of daily living because of pain from the SI joint(s).
- SI joint pain confirmed with typical pain reproduction on at least 3 positive physical provocative examination maneuvers that stress the SI joint.22
- Confirmation of the SI joint as a pain generator with ≥ 75% acute decrease in pain immediately following fluoroscopically guided diagnostic intra-articular SI joint block using local anesthetic.24,25 This improvement is specifically accomplished in the immediate post-injection period whien the anesthetic agent is active (i.e., 4 hours dependent on the agent, dose level, and concentration.
- Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti- inflammatory drugs and/or opioids (if not contraindicated) and one or more of the following: rest, physical therapy, SI joint steroid injection or rhizotomy. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability.
- Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been clearly considered, investigated and ruled out.

Coding and coverage history

Minimally invasive SI joint fusion is coded using CPT code 0334T until January 1, 2015. CPT code 27280 may be recommended by payers at their individual discretion. When bilateral fusions are performed, use CPT code 0334T until January 1, 2015 on two line items with the RT (right side) and LT (left side) modifiers on each line item to indicate bilateral fusion.

Revision and/or removal of the SI joint implant is coded using 22899 (unlisted procedure, spine) or 27299 (unlisted procedure, pelvis or hip joint) depending on the type of approach and procedure performed, whether within the global period of the fusion, or not. ICD-9 codes that support medical necessity are shown in Table 2.

Table 2.

ICD-9 code	Description
720.2	Sacroiliitis not elsewhere classified; inflammation of sacroiliac joint NOS
721.3	Lumbosacral spondylosis without myelopathy
724.6	Disorders of sacrum
739.4	Nonallopathic lesions, not elsewhere classified in the sacral region; sacrococcygeal region or sacroiliac region
846.9	Sprains and strains of the sacroiliac region, unspecified site of sacroiliac region
847.3	Sprains and strains of sacrum

Conclusion

The prevalence of patients suffering from SI joint pain is not only high, but most likely underestimated due to improper diagnosis. Moreover, the burden of conservative care in this patient population is significant. In patients suffering from intractable SI joint pain after lumbar spinal fusion, MIS SI joint fusion is cost neutral compared to conservative care in the first year.[50]

Minimally invasive SI joint fusion is a safe and effective procedure for patients with unremitting pain due to SI joint disorders. Published literature consistently reports a low re-operation rate (<5%) along with highly favorable patient outcomes; 88% average reported rate of clinically significant reduction in pain. Furthermore, these outcomes are consistent, replicable and durable across surgeons and geographic regions.

This ISASS policy does not endorse any specific MIS SIJ System. There are numerous devices available that have received FDA 510 (k) clearance for use in minimally invasive/ percutaneous sacroiliac joint fusion/stabilization. The instrumentation utilized in a MIS SIJ procedure is the purview of surgeon preference.

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