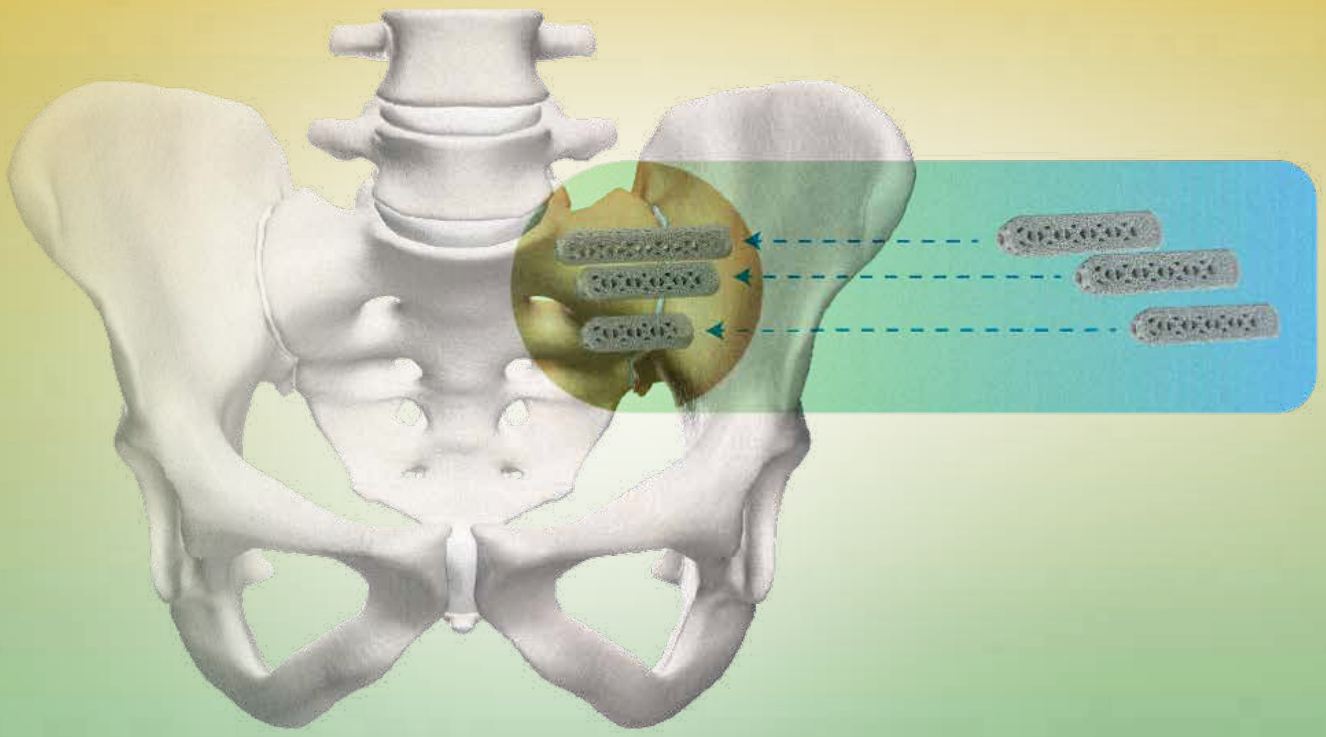

Imagery courtesy of SI Bone

SI Joint Dysfunction

How New Minimally Invasive Surgery Techniques and Triangular Titanium Implants Are Addressing an Unmet Need

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New surgical techniques and implant technology have increased the awareness of the unmet needs of patients suffering from sacroiliac (SI) joint dysfunction. The SI joint has historically been ignored as a pain generator or inappropriately grouped with other sources of lower back or pelvis pain.

Many sufferers of SI joint dysfunction have lived with chronic pain, or worse, endure procedures or surgeries including lumbar fusions that weren't necessary. Treating the incorrect diagnosis is costly and can leave the patient in worse shape.

Awareness and understanding of the SI joint as a pain generator are improving, however. Innovative minimally invasive surgical techniques are reducing operative morbidity and speeding patient recovery. Finally, advanced implant technology like interference fit, 3-D printed triangular titanium implants, has revolutionized SI joint fusion resulting in improved patient outcomes.

LEARNING OBJECTIVES

- Study the sacroiliac joint and its causes of pain
- Discuss the history of procedures for treating the SI joint
- Compare and contrast open SI joint fusion approaches
- Evaluate the products utilized to make SI joint fusion a success
- Review the minimally invasive surgical (MIS) techniques for treating SI pain

WHAT IS THE SACROILIAC JOINT AND WHY DOES IT HURT?

Pain emanating from the SI joint was described by Hippocrates in ancient Greece. The SI joints (left and right) are part of the bony pelvic

ring, linking the ilium to the sacrum. The SI joints provide a balance between movement and stability of the pelvis and facilitate transfer of force from the torso to the lower extremities. They are the largest joints in the body. They have an upper ligamentous portion and the lower portion is a true synovial joint,[1–3] with articular (hyaline) cartilage on both joint surfaces, surrounded by a joint capsule with a synovial lining. The cartilage of the SI joint is subject to the same internal and external processes that can damage the cartilage of other joints.

The SI joint is highly innervated receiving nerve supply from dorsal nerve roots (L5-S3) and ventral nerve roots (S1-S4).[4–9] Various pain fibers supply the SI joint including free nerve endings, C fibers, and substance P and CGRP fibers.[5,10,11] Pain fibers have been identified in the joint capsule, the cartilage, the subchondral bone, and the ligaments and muscles supporting the joint.

The SI joint moves (about 2-4 degrees) with normal daily activities[12–15] and may be damaged from acute or repetitive trauma. The ligaments and soft tissues supporting the joint may be damaged leading to abnormal force/load transfer. The joint may be affected by autoimmune, inflammatory, and/or infectious processes.[16] It is also subject to degeneration secondary to de novo osteoarthritis or increased stress at the joint (i.e., adjacent segment disorder) after lumbar fusion.[17–20] SI joint ligament stiffness and SI joint function can change secondary to trauma, pregnancy, and normal aging.[21–25] The ability of the SI joint to accommodate load can be diminished in these cases. Asymmetry of SI joint ligament function is predictive of SI joint pain.[26]

Pregnancy is a common cause of SI joint dysfunction. About 50% of women have pelvic girdle (frequently SI joint) pain during pregnancy and 25% experience pain after pregnancy.[27] The ligaments supporting the SI joint are affected by the hormone relaxin which softens the ligaments allowing the SI joints to widen to facilitate parturition.[28] Often, the ligaments do not regain their pre-pregnancy stiffness and function.[24,25]

Fusion of the lumbar spine results in stress transfer to the motion segments above and below the fusion. This stress can lead to damage at these levels and is described as adjacent segment degeneration. This is a recognized cause of SI joint dysfunction. In patients with continued or new onset pain after lumbar fusion, 32-43% have the SI joint as a source of their pain.[17–19,29] In a prospective study, 78% of patients with a lumbar fusion had radiographic evidence of SI joint degenerative changes at five years later compared with 38% of age- and gender-matched controls without a fusion.[20] Studies have shown that the more spinal levels fused, the greater the incidence of post-fusion SI joint pain.[30]

TREATING THE SI JOINT

Non-surgical options including physical therapy, steroid injections and radio frequency nerve ablation, remain front-line treatments for patients suffering from SI joint dysfunction. Other treatments including prolotherapy and stem cell treatments also have been utilized. There is little high-quality published evidence that any non-surgical procedure provides long-term pain and disability relief for patients with SIJ dysfunction.

> The goal of any SI joint fusion procedure is acute joint stabilization often with hardware and long-term stabilization via biological bone fusion. Stabilization and fusion of the SI joint allows more effective load transfer from the torso to the lower extremities, which can improve pain and contribute to improved overall health status.

SURGICAL TREATMENT

The first SIJ fusion was reported in 1908,[31] with additional reports in the 1920s[32–34] and sporadic reports over the next 80 years. Various techniques for open SI joint fusion have been reported,[35] but no comparative studies have shown one surgical approach for open SI joint fusion to be superior than another. Since 2009, minimally invasive approaches to SIJ fusion have become available and are now the preferred method for fusion in patients with chronic SI joint dysfunction.[36]

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OPEN SI JOINT FUSION APPROACHES

Analogous to surgical approaches to the lumbar spine, there are three surgical approaches for SI joint fusion (anterior, posterior and lateral). Historically, case series describing these three approaches have reported modest results and all are associated with significant morbidity.

The anterior approach to the SI joint is the preferred approach of pelvic trauma surgeons for treating acute and post-acute SI joint trauma. Trauma surgeons typically utilize a subiliacus anterior approach.[37–39] Several elective series have been reported in spine literature. Murakami has described a retroperitoneal approach that is more familiar to spinal surgeons.[40,41] Complications of anterior SI joint surgery include injury to vascular structures, the lumbar plexus and sympathetic trunk, injury to the lateral femoral cutaneous nerve (sensory nerve to the thigh), as well as damage to the iliacus muscle. There is limited safe area for application of stabilizing hardware with the anterior approach.

Posterior approaches also have been described. Surgical access to the articular SI joint from a dorsal approach requires removal of a portion of the overlying posterior iliac crest,[42] as well as excision of the dorsal SI joint ligaments, and the interosseous SIJ ligament. These soft tissues are important stabilizing structures. Removal of these structures may compromise immediate and long-term stability. Placement of stabilizing hardware may require additional surgical dissection of the paraspinal musculature.

In the lateral transiliac approach, the SIJ is approached from a lateral to medial direction. This approach spares the crucial supporting ligamentous structures of the SIJ dorsally and avoids the neurovascular and pelvic structures ventrally. The open lateral approach requires elevation of the gluteus musculature, creation of a window through the ilium into and across the SI joint. There is significant morbidity associated with this approach including potential involvement of the cluneal nerves.

MODERN MINIMALLY INVASIVE SURGERY

With the evolution of surgical practice, minimally invasive surgical (MIS) techniques have been developed and are now considered standard of care. Multiple health technology assessment organizations have validated the safety and effectiveness of MIS SI joint fusion with laterally placed devices, such as ECRI, Evicore, AIM,[43–45] and the UK's NICE.[46] Two medical specialty societies NASS and ISASS[47,48] have published positive coverage recommendations. Minimally invasive techniques are much less traumatic with reduced blood loss, tissue damage, and recovery time. However, clinical results shown for TTIs placed from a lateral approach are likely not generalizable to other surgical approaches or other SI joint fusion devices.

MIS anterior approach. An MIS anterior retroperitoneal approach with placement of fusion cages has been described.[49] As with the open anterior-approach, risks include injury to the great vessels, lumbar nerve plexus and important abdominal/pelvic structures (colon, bladder, etc.). No prospective studies support the safety or effectiveness of this approach. Surgical anatomy of the anterior SI joint limits the size of hardware that can be placed through this approach. No publications have reported biomechanical stability after device placement. No devices have been cleared for use with this approach.

MIS dorsal approach. Placement of fusion cages into the dorsal ligamentous portion of the SI joint is common in Europe, however, these devices are not FDA cleared.[50,51] Clinical results and bone fusion is improved with use of BMP which is off label for use in this area.[52,53] It has been suggested that SI joint stability can be achieved with this approach via capsular distraction and ligamentotaxis similar to the once popular BAK spinal fusion cage.[54,55] The ligamentous portion of the joint may be disadvantageous for fusion from both a biomechanical and a biologic perspective.[48] The bone in the ligamentous portion of the joint is under tension (attachment of the interosseous ligament) and is thinner and less dense compared with the bone in the articular portion of the joint, which is under compression (beneath the articular cartilage) and is thicker and more dense.[56,57] Thinner, less dense bone will not support devices as well as thicker, more dense bone. Published two-year clinical results report modest improvements[50,51] in pain and function.

MIS lateral transiliac approach. This is by far the most studied approach for SI joint fusion with placement of transfixing devices. Fusion devices are placed across the SI joint from lateral to medial under fluoroscopic guidance or navigational control. Devices are placed using standard muscle sparing minimally invasive surgical techniques which require only a small (1-2 inches) skin incision and spreading of the gluteus muscle fibers. This approach is an adaptation of the Smith-Petersen techniques.[32] Over two dozen devices are FDA-cleared for lateral transiliac MIS SI joint fusion.

EVIDENCE SUPPORTS THE LATERAL MIS APPROACH, USING TRIANGULAR TITANIUM IMPLANTS (TTIS)

The safety and effectiveness of MIS SI joint fusion with laterally placed transfixing devices, as described by AMA CPT® code 27279 has been well established. The vast majority of the published clinical evidence describes the use of TTIs including, two randomized controlled trials (RCTs)[58,59] one large multicenter prospective trial,[60] several comparative studies,[61–66] many case series[67–73] as well as several systematic reviews and meta-analyses.[74–78] Other publications including studies out to five and six years have demonstrated the durability of the procedure and the high rate of long-term fusion.[60,62,72] In addition to the clinical evidence base supporting TTIs, additional publications have addressed the biomechanical aspects of fusing the SI joint with TTIs. Publications have addressed the immediate stability provided by the implants,[60,72] number and location of implants, effects of implant placements on adjacent segments showing minimal stress transfer to the contralateral SIJ,[79–81] the spine[82] or the hip.[83] In addition, there are publications showing the cost effectiveness of the product/procedure.

Several health technology appraisal organizations have published positive reviews of lateral MIS SI joint fusion with transfixing devices. Several of these reviews have been product (iFuse TTI) specific[43–46] based upon the results of the randomized controlled trials, the totality of the published clinical literature and the unique features of the TTIs, notably the triangular cross section, the porous surface and the fact that the implants are impacted into place. Most health plans including all the Medicare MACs, Tricare, most Medicaid programs and most commercial health plans now cover MIS SI joint fusion. Several of these plans have exclusive coverage for TTIs, again based upon the published clinical evidence.

- **3-D printed triangular titanium implants (TTIs)** are FDA-cleared implants (FDA 510(k) K080398), (FDA 510(k) K162733), that are triangular in cross-section with a porous surface. The implants do not have threads and are impacted into position rather than rotated or screwed into position. A triangular implant is six times more resistant to rotation than a threaded implant of similar diameter.[84] Typically, three implants are placed across the joint. The use of three implants results in immediate stabilization of the SI joint.[85] TTI implants have a porous surface, similar to other implants commonly used in orthopedic and spine surgery such hip and knee arthroplasty, spinal fusion cages and the surfaces of disk arthroplasty devices. The implants' porous surface allows bone to grow into and onto and (when fenestrated) through the implant, resulting in integration of bone into the implant on the both the sacral and iliac sides of the joint.[86] An independent radiographic analysis of five-year high resolution CT scans in patients participating in two prospective multicenter clinical trials of SI joint fusion with TTIs was recently published, and bridging bone across the SI joint adjacent to the implant was seen in 85% of treated SI joints.[60]
- **Titanium screws.**[87–89] These are titanium screws FDA-cleared for SI joint fusion. Typically, two implants are placed across the joint after decorticating the joint using a proprietary instrument. Whether decortication is beneficial is not known; decortication may result in damage to the subchondral bone on both sides of the joint which may affect joint or device stability. These types of implants do not have specialized surface characteristics that promote bone integration. Two prospective and one retrospective published study describe outcomes with this device type. The first prospective study with 19 patients found favorable fusion results at 12 and 24 months, and bone growth was observed, but no data nor comparisons with other studies could show decortication played a role. It was also noted that the low number of subjects did not allow for a comparison of radiographic fusion and clinical outcomes.[87,88] A study by Kube and Muir with 18 patients showed positive results with a drop in pain scores and a fusion rate of 88% at one year, but also noted that long-term radiographic and fusion data were limited.[90] When considering short-term results, it's worth noting that screw loosening is also common in orthopedics. A comparative case series suggests that screw loosening is very

common in SI joint fixation and far more common than with TTI implants.[63]

- **Hydroxyapatite (HA) coated screws**.[91] These are FDA-cleared titanium screws with a roughened surface and HA coating. The original screw surface was not porous. A second-generation product does have some porous surface features. HA coatings are eventually reabsorbed by the body during the physiologic process of creeping substitution, so the value of HA is not clear. HA does not result in bony integration with the device as the original device did not have a porous surface. In hip arthroplasty, HA-coated implants have not shown superior results.[92,93] While these devices contain fenestrations where bone graft may be placed, this SI joint fusion strategy remains unproven. One prospective study with two-year follow up reports good improvement in pain and disability.[91] Mechanical stability (defined as absence of screw loosening and radiolucent gaps at the bone-screw interface and improvement in symptoms) occurred in 93%; joint fusion itself was unreported.[91] No published study has evaluated the biomechanics of this system.
- **Threaded cylindrical fusion cages**.[94–96] These FDA cleared devices are placed across the joint from postero-lateral to antero-medial. The fusion cages contain fenestrations for bone graft (as noted above, an unproven fusion strategy). The trajectory of the cages results in placement at an angle that is oblique to the axis of rotation. This implant placement is less biomechanically stable than placing implants from a transarticular approach that are parallel to the axis of rotation.[96] The fusion cage is also placed across the ligamentous portion of the SI joint which may be biomechanically and biologically disadvantaged compared to placement across the articular portion of the SI joint.[97]

There are at least 20 other devices that have been FDA-cleared for SI joint fusion. Several of these devices are also available in the EU and UK. These devices are typically threaded implants (screws) with or without fenestrations. None of the devices has a porous surface with proven biologic integration, bone ingrowth/bone ongrowth. Moreover, there are few clinical publications that document the safety, effectiveness, durability, economic benefit, or radiographic fusion results of any of these other devices.

> The SI joints provide a balance between movement and stability of the pelvis and facilitate transfer of force from the torso to the lower extremities. They are the largest joints in the body.

- **Allograft Products.** Finally, there are several allograft products available and marketed for MIS SI joint fusion in the US. These products are not FDA-cleared through the 510(k) process and are unclassified products per FDA regulations. They are designated as CDRH biologics as Human Cell and Tissue Products (HCT/P). They do not have specific labeling and claims for SI joint fusion. These allograft products are placed into the inferior limb of the articular SI joint and into the dorsal portion, ligamentous area, of the SI joint. The products themselves do not cross or transfix the joint. There is limited published clinical evidence to support early, intermediate or long-term stabilization or long-term fusion using these products. It is unclear if placing an allograft bone product into the dorsal aspect of the SI joint will result in fusion. There is no published clinical evidence to support the safety, effectiveness, or durability of these products.

Among the three surgical approaches and multiple fusion devices, triangular titanium implants remain unique in that:

- TTIs are triangular in shape. Triangular shape limits rotational motion more than a screw (circular in cross section).
- Implants are impacted into position resulting in interference press fit.
- TTIs have a porous surface that promotes bone growth and joint fusion.

LITERATURE SUPPORT FOR SI JOINT FUSION IMPLANTS

An important distinction for the lateral approach and triangular implants is the large amount of published peer-reviewed literature demonstrating the safety, effectiveness, durability and cost effectiveness. Literature supporting

threaded implants and allograft products is limited.[63,72,98–100] The high-level evidence supporting TTIs includes two randomized controlled trials, and multiple comparative studies. There are demonstrated advantages of MIS lateral compared with open SI joint surgery.[36,48,65,66,96] There is additional clinical evidence supporting the durability[60,62] and economic benefits[101,102] of TTIs.

All surgical procedures have inherent risks. With TTIs, the major risks related to the procedure are of post-operative wound problems or hematoma, symptomatic malposition of an implant (<1%), pseudoarthrosis or failure to achieve fusion, and failure of the procedure to improve pain or function. The surgical revision rate reported in the clinical trials is approximately 3%.[58,59,103] Not all patients will benefit from the surgical procedure.

CONCLUSION

Increased awareness of the SI joint as a pain generator and improved understanding of the diagnostic algorithm has led to increased interest in the diagnosis and treatment of patients with SI joint dysfunction. Like the lumbar spine, there are three surgical approaches (anterior, posterior, and lateral) to the SI joint. MIS techniques have demonstrated less operative morbidity and early return to function. MIS SI joint fusion with devices that have novel features such as a triangular cross section and a porous surface have demonstrated improved patient outcomes, long-term durability, and economic benefit.

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SI Joint Dysfunction and New Minimally Invasive Surgery Techniques

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1. There are three surgical approaches for SI joint fusion. Which of the following is NOT one of them?
a. Posterior
b. Anterior
c. Lateral
d. Dorsal

2. The left and right SI joints are part of the _____.
a. Ilium
b. Sacrum
c. Pubic bone
d. Bony pelvic ring

3. How many degrees does the SI joint move from normal activities each day?
a. 2-4
b. 3-5
c. 4-5
d. 5-7

4. Pregnancy is a common cause of SI joint dysfunction. About ____ of women have pelvic girdle pain during pregnancy.
a. 40%
b. 50%
c. 60%
d. 70%

5. Which is the most studied approach for SI joint fusion with placement of transfixing devices?
a. MIS lateral transiliac approach
b. MIS anterior approach
c. MIS ventral approach
d. MIS dorsal approach

6. In the lateral transiliac approach, the SIJ is approached from lateral to which direction?
a. Anterior
b. Posterior
c. Medial
d. Ventral

7. How much more resistant to rotation is a triangular implant than a threaded implant of similar diameter?
a. 3
b. 4
c. 5
d. 6

8. How many triangular titanium implants are placed across the joint to result in immediate stabilization of the SI joint?
a. 2
b. 3
c. 4
d. 5

9. Which approach is favored by trauma surgeons for treating acute and post-acute SI joint trauma?
a. Dorsal approach
b. Retroperitoneal approach
c. Lateral transiliac approach
d. Subiliacus anterior approach

10. What year did minimally invasive approaches to SIJ become available?
a. 1908
b. 1920
c. 2009
d. 2015

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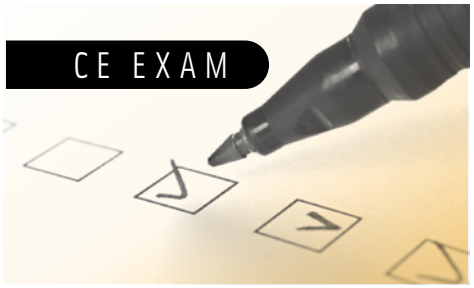

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