

Retrospective Evaluation of Minimally Invasive Surgical (MIS) Method for Sacroiliac Joint Arthrodesis

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Summary

- Clinically significant results at 3, 6, and 12 months post-op vs. pre-op
- 90% of responding patients indicated they would have the procedure again
- The sacroiliac (SI) joint is a common symptom generator in patients with low back problems

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Introduction. Historically treatment focus in spine has centered on lumbar pathology. In published literature, 15-30% of individuals who presented with lower back complaints had sacroiliac (SI) joint problems.^{1,2} The incidence of SI joint degeneration is 75% in patients with previous lumbar fusions.³ A minimally invasive surgical (MIS) procedure may help to address this significant unmet clinical need.

Relevance. A triangular, titanium, MIS implant was developed that requires a minimal incision and fluoroscopic guidance (Fig.1). The implants are coated with a porous plasma spray creating an interference fit to decrease implant motion. The implant size, geometry, and metallurgy, provide immediate post-op fixation, accomplishing the goal of traditional open SI joint fusion.



Fig. 1

Diagnostic methods. SI joint diagnoses require appropriate interpretation of a patient's history, clinical exam, and imaging studies (often hip and lumbar pathology coexists with SI joint). Physical examination includes pain, palpable tenderness, provocative tests, and absence of neurologic deficits. CT or fluoroscopic guided injection provides confirmation of sacroiliac pathology. Some physicians repeat injections to reduce the chance of a false positive. When physical findings point to the SI joint, chronic, degenerative changes in the lumbar spine or bulging discs should not override a diagnosis of SI joint pathology.

Methods. This retrospective, post-market analysis covers 43 treated patients from a single center who completed pre-operative and post-operative questionnaires. To evaluate the procedure, radiologic studies were used to document implant position, fixation of implants and observe osseous integration. In addition, patient satisfaction questionnaires were utilized.

The MIS procedure is performed under general anesthesia in the prone position. 4.0mm or 7.0mm implants are inserted through a 2-3cm incision. The drills, broaches, and implants are cannulated to allow precise placement over a guide pin. This implant is marketed for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. As a rule, patients are implanted with three MIS implants across the SI joint. However, MIS implant numbers may vary based on the size of the patient. Post-operatively patients are kept partial-weight bearing for 3 weeks, depending on the patient's pain level. Routine activities are allowed 12 weeks after surgery.

Table 1 - Patient Demographics

Sex:	Etiology of SIJD:
32 female (75%)	Sports injury 4%
11 male (25%)	MVA 4%
Median age 55 yrs	Work accident 13%
	Post-partum 4%
	Progressive 40%
	Fall 13%
	Unknown 13%
	Other 7%
	Inflammatroy 2%

Results. Clinical significance was consistently good for those patients participating in assessments at 3, 6, and 12 months post-op vs. pre-op (follow-up range 3-12 months). Patients reported significant improvement at each time point for the questions below (Fig. 2- 8) and up to 90% of the patients would elect to have the procedure performed on the contralateral side (Fig. 9). Some patients exhibited evidence of bone at the bone-implant interface at 3 months post-op, as seen on the sagittal CT (Fig. 10).

Fig. 2 - How much pain are you in at this time? (1-10)

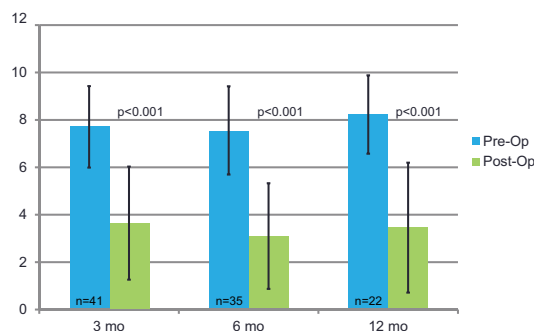


Fig. 3 - How well are you able to perform activities at this time? Light activities like walking a block or dressing yourself (1-10)

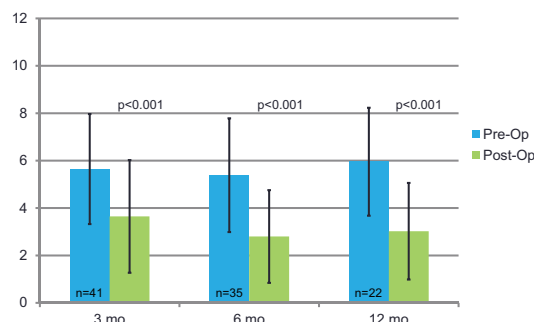
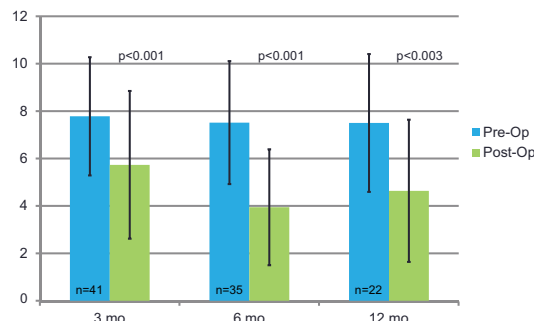


Fig. 4 - How well are you able to perform activities at this time? Moderate activities like playing golf, walking half a mile, or dancing (1-10)



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**Fig. 5 - How well are you able to perform activities at this time?
Vigorous activities like running or moving furniture (1-10)**

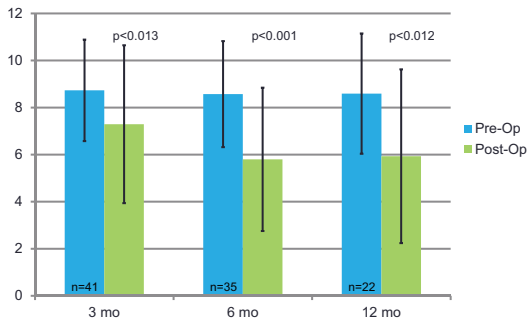


Fig. 6 - How would you assess your level of happiness at this time?

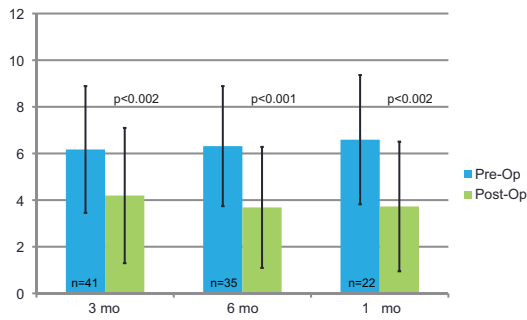


Fig. 7 - How much is your sleep disturbed by pain at this time? (1-10)

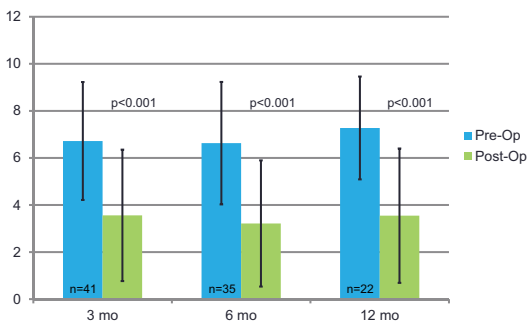


Fig. 8 - Because of pain, how much is your socializing limited at this time? (1-10)

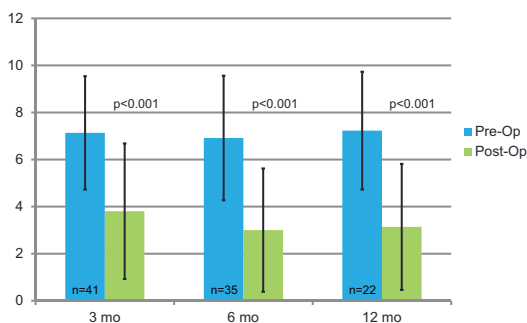
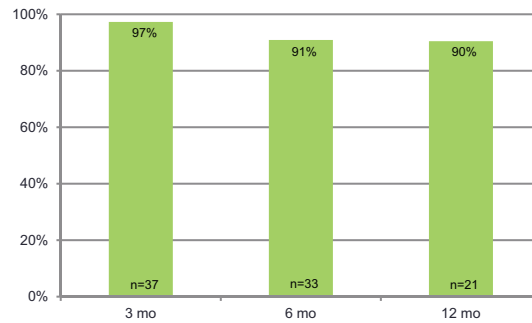


Fig. 9 - Would you choose to have this procedure for the other side if needed? (Y/N)



Conclusions. This retrospective study reinforces the need for awareness that SI joint problems are common symptom generators. Traditional treatments (e.g., continued SI joint injections and open fusion) have shown limited efficacy. In some patients with residual symptoms after hip arthroplasty or lumbar spine procedures, it may be the SI joint that is the symptom generator. With the advent of this MIS procedure, surgeons may avoid further, unnecessary surgery for failed lumbar fusion patients by looking at the SI joint. Multicenter prospective studies are ongoing.

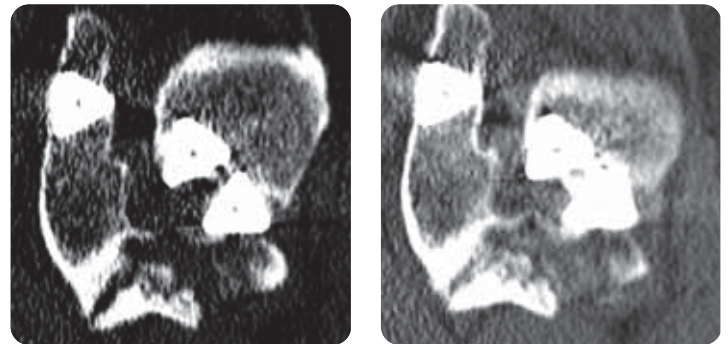


Fig. 10 - Reactive intra-articular bone at 3 months. Mature bone forming at 3 months

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References

1. Schwarzer AC, Aprill CN, Bogduk N. The sacroiliac joint in chronic low back pain. Spine. 1995; 20(1):31-37.
2. Sembrano JN, Polly DW Jr. How often is low back pain not coming from the back? Spine. 2009; 34(1):E27-32.
3. Ha, et al. Degeneration of Sacroiliac Joint After Instrumented Lumbar or Lumbosacral Fusion. Spine. 2008; 33 (11): 1192-1198

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