

RESEARCH ARTICLE

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Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients

John Cummings Jr¹ and Robyn A Capobianco^{2*}

Abstract

Background: Sacroiliac joint (SI) pain is an often-overlooked cause of low back pain due, in part, to lack of specific findings on radiographs and symptoms mimicking other back-related disorders. We report our experience with minimally invasive (MIS) SI joint arthrodesis using a series of triangular, titanium plasma spray (TPS) coated implants in patients refractory to conservative care.

Methods: We report outcomes from 18 patients with 12 months of postoperative follow-up. Demographics, complications, and clinical outcomes using visual analog scale (VAS) for pain, Oswestry Disability Index (ODI) for back function and SF-12 for quality of life were collected preoperatively and at 3, 6 and 12 months post-operatively.

Results: Mean age was 64 years and 67% of patients were female. There were no intraoperative complications and one explant at three months for malposition.

All patient-reported outcomes showed both clinically and statistically significant improvement at 12 months ($p < 0.001$ for each of the following): VAS improved by 6.6 points, ODI scores improved by -37.5 points. One year SF-12 physical and mental component (PCS, MCS) scores approximated population normal scores for both physical and mental functioning. Patient satisfaction with outcomes was high at 95%; 89% said would have the same surgery again.

Conclusions: MIS SI joint fusion using a series of triangular porous TPS coated titanium implants is a safe and effective procedure for patients with SI joint disorders who have failed conservative care.

Keywords: Minimally invasive surgery, Sacroiliac joint, Arthrodesis, Previous spine surgery

Background

Sacroiliac (SI) joint pain is an often-overlooked cause of low back pain. This may be due in part to the lack of visible abnormalities on plain radiographs and the fact that SI joint pain may mimic hip, lumbar radicular disorders or pain of discogenic origin [1,2]. Patients with SI joint problems may present with low back, groin, gluteal, and/or radicular pain leading to the potential for inaccurate diagnosis and treatment [3-5].

Historically, though the sacroiliac joint was a prominent initial focus of attention in the early 1900s as a significant generator of low back pain (LBP), as more reliably diagnosed conditions such as herniated discs and facet arthropathy became better understood, less

focus was placed on the SI joint [6]. A large study conducted by Bernard and Kirkaldy-Willis found that 22.5% of patients diagnosed with nonspecific LBP actually had SI joint problems [1]. A more recent study reported a prevalence rate between 15-30% of patients presenting with low back pain [2]. Several studies investigating the affect of lumbar fusion on SI joint disorders have shown an SI joint pain prevalence rate of up to 61% after lumbosacral fusion and significant radiographic SI joint degeneration in up to 75% of post-lumbar fusion patients at 5 years [7-9].

Open arthrodesis of the SI joint was commonly performed in the early 1900s. However, open SI joint fusion is less common now as it requires relatively large incisions, significant bone harvesting, and lengthy hospital stays; moreover, patients must avoid weight-bearing for several months postoperatively [10-13].

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Minimally invasive SI joint fusion has become available with various devices. Recent reports of a minimally invasive arthrodesis system have shown promising outcomes [14,15]. The surgical procedure involves the placement of three triangular implants across the SI joint (Figure 1). Second site bone harvesting or graft is not required as the porous titanium plasma spray (TPS) coating on the implants results in biological fixation of the implant in bone. Herein we report safety and effectiveness outcomes of patients undergoing MIS SI joint fusion with a series of triangular titanium, porous TPS coated implants (iFuse Implant System, SI-BONE, Inc., San Jose, CA) in a single surgeon's private practice.

Methods

A medical chart review was undertaken to identify patients who underwent MIS SI joint fusion surgery at a community based spine practice more than 12 months ago. Patients were excluded if concomitant spine procedures were performed and if no preoperative or follow up outcomes were available. A total of 34 patients were identified: 24 had one year follow up, 18 underwent unilateral surgery and are included in our analysis. All patients were treated between September 2011 and April



Figure 1 Triangular porous plasma coated implants (iFuse® Implant System, SI-BONE Inc, San Jose, CA).

2012. Data collected included patient demographics, medical history, and complications of surgery. Clinical outcomes were collected prospectively preoperatively and at 6 weeks, 3 months, 6 and 12 months postoperatively. Institutional Review Board Approval (Community Health Network) was obtained before beginning this study.

Diagnosis

Using a combination of detailed history, clinical exam, imaging and positive diagnostic injections, all patients were diagnosed with either degenerative sacroiliitis or sacroiliac joint disruption. A thorough physical and clinical exam was performed in order to establish the pain generator as accurately as possible in this complex population. A positive result on 3 or more pain provocation tests such as Gaenselen's, flexion abduction external rotation (FABER), compression, distraction and thigh thrust, was used as criteria for further testing to confirm the SI joint as the pain generator [16-19]. Diagnostic imaging studies such as x-ray, CT and MRI, while not sensitive in diagnosing disorders of the SI joint, are helpful in ruling out pathology in the lumbar spine and hip [17]. When clinical, physical and imaging findings were congruent, patients were sent for image-guided diagnostic injections of the SI joint. A positive result was defined as a 75% reduction in pain immediately following injection of local anesthetic [20]. Conservative treatment consisting of medication optimization, physical therapy and SI joint injections was prescribed for a course of at least 6 months before offering the patient surgery.

Technique overview

Minimally invasive SI joint fusion surgery was performed in all cases by a single neurosurgeon in private practice. This procedure involves fixation of the SI joint by placing a series (typically three) of triangular, titanium porous TPS coated implants across the SI joint. No second site bone harvesting is required due to the biological fixation properties of the porous TPS coating. The patient is placed in the prone position on a radiolucent table to facilitate the use of intraoperative fluoroscopy. After general endotracheal anesthesia is administered, the patient is prepped in the normal sterile fashion. A 3 cm lateral incision is made into the buttock region and the gluteal fascia is bluntly dissected to reach the outer table of the ilium. A Steinmann pin is passed through the ilium across the SI joint to the center of the sacrum (lateral to the neural foramen). After a soft tissue protector is passed over the pin, a hand drill is used to create a pathway and decorticate the bone. Finally, a triangular broach is used to further decorticate the bone and prepare the pathway to receive the first implant. Using a pin guidance system, a total of three implants

are placed. The most cephalad implant is seated within the sacral ala. The second implant is generally located above or adjacent to the S1 foramen and the third between the S1 and S2 foramen (Figure 2). The incision is then irrigated and the tissue layers are sequentially closed. Patients begin physical therapy on day 1 postop and are instructed to ambulate with the assistance of a walker or crutch for the first 3 weeks. During the 3–6 week postoperative period, patients progress to full weight bearing with a regimen of flexibility and strengthening exercises. After 6 weeks of gradual return to full weight bearing, patients are back to unrestricted activity and are encouraged to continue core stabilization exercises as well as weight and cardiovascular training.

Clinical outcome assessments

Patient reported clinical outcomes were collected prospectively prior to surgery to establish baseline values and at 6 weeks, 3, 6 and 12 months post-operatively. The following instruments were used: visual analog scale (VAS) for pain, Oswestry Disability Index (ODI) (version 2.1) for back related function, and Short Form 12 (SF-12) for quality of life [21,22]. Satisfaction at 12 months was assessed by asking the patient 2 questions: “describe your satisfaction with this surgical outcome” and “would you elect to have the same surgery again?” Possible responses were “very, somewhat, or not really” for question 1 and “definitely, likely, or definitely not” for question 2.

Statistical analysis

Baseline demographic variables were summarized with mean, standard deviation and frequency tables. Changes in clinical outcomes variables (VAS, ODI, SF-12 PCS

and MCS) were evaluated using a paired *t*-test. Analysis of variance (ANOVA) was used to evaluate differences in outcomes across subgroups. Subgroup variables analyzed were history of prior lumbar fusion, hypertension, body mass index (BMI) by category, age (> or < 65 years) and sex. BMI categories were defined using World Health Organization (WHO) standards: <25 normal, 25–30 overweight, >30 obese. All analysis was performed using SAS (version 9.0, Cary, NC).

Clinical improvement was defined using minimum clinically important difference (MCID) and substantial clinical benefit (SCB) values available in the literature. Currently there are no reported MCID or SCB values for SI joint fusion. We chose MCID thresholds for VAS pain and ODI improvement reported in the Spine Patient Outcomes Research Trial (SPORT): ≥ 2 points for VAS pain and ≥ 12.8 for ODI [23]. MCID values for SF-12 PCS and MCS (8.8 and 9.3 points respectively) were acquired from a study on lumbar spine surgery for adjacent segment disease, since the majority of the patients in our cohort had a history of previous lumbar spine fusion [24]. Substantial clinical benefit (SCB) values were chosen using criteria by Glassman et al. for patients undergoing lumbar spine arthrodesis [25]. SCB for ODI is defined as an 18.8-point improvement or final score of <31.3 points. SCB for SF-36 PCS is defined as 6.2-point improvement or final score of ≥ 35.1 and SCB for pain is 2.5-point decrease or raw score of < 3.5.

ODI scores may be described in terms of degree of disability. A score of 0–20% represents minimal disability, 21–40% moderate disability, 41–60% severe disability and 61–80% crippled (Table 1). Scores greater than 81% were not seen in our population and are described as “either bed bound or exaggerating their symptoms.”



Figure 2 Postoperative radiograph demonstrating placement of three implants across the SI joint.

Table 1 Score interpretation of the Oswestry disability questionnaire [21] for low back pain

0% to 20%: minimal disability:	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise.
21%-40%: moderate disability:	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means.
41%-60%: severe disability:	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
61%-80%: crippled:	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81%-100%:	These patients are either bed-bound or exaggerating their symptoms.

Table 2 Patient demographics

N	18
Age	64 (range 39–81) (12.2 SD)
Sex	67% (12) F, 33% (6) M
Race	83% (15) Caucasian 17% (3) African American
BMI mean	31
Obese (>30)	61% (11)
Overweight (25–30)	28% (5)
Normal (<25)	11% (2)
Diabetes	21% (4)
Smoking status	2 current, 5 former
Hypertension	44% (8)
Prior lumbar spine surgery	83% (15): 2 microdiscectomy 11 fusion 2 decompression
Side treated	11 L (61%), 7R (39%)

Results

Eighteen patients underwent unilateral MIS SI joint fusion and had 1-year follow-up. No patient had a concomitant procedure. No intraoperative complications were observed and blood loss was minimal (<50 cc) in all cases. Mean age was 64 years (range 39–81) (Table 2). Patients were primarily white (83%) and female (67%). The large majority (89%) of patients in this cohort were obese (BMI > 30) or overweight (BMI 25–30), and 44% were hypertensive. Most patients (83%) had a history of previous lumbar spine surgery that included: fusion at one or more levels (73%), decompression (13%), and discectomy (13%).

VAS pain scores improved clinically and statistically at all postoperative time points (Table 3). Mean (SD) scores improved from 8.9 (±1.9) at baseline to 2.3 (2.1) at 12 months with a mean change of -6.56 points (p < .0001) for this time period (Table 4). A clinically significant benefit, defined as ≥2 point change from baseline, was observed in 90% of patients [23].

Back-related function measured on ODI improved clinically and statistically. Improvement was observed as early as the 6-week post-operative visit. Mean (SD) scores

decreased from 52.7 (18.8) at baseline to 13.2 (12.6) at 12 months with a mean change of -37.5 points (p < .0001). Baseline ODI scores categorized 61% of patients as “severely disabled,” 17% as “crippled,” and 2% each as “moderately” and “minimally disabled.” At the 12 month visit, 89% of patients were classified into the “minimal disability category” and the remaining 2 patients scored into the “moderate disability” category [21]. Both of these patients were considered as “severely disabled” at baseline with multiple back pain complaints. Substantial clinical benefit was achieved for 89% of patients.

Quality of life as measured on SF-12 using the aggregate physical and mental component summary (PCS and MCS) scores showed a clinically and statistically significant improvement (p < 0.005, p < 0.001 respectively). Mean PCS score rose from 32.3 (6.4) at baseline to 44.6 (10.5) at 12 months, representing an improvement in physical health by 11.2 points. MCS scores improved from 37.8 at baseline to 53.8 at 12 months, a mean improvement of 20.4 points. The SF-12 outcome measure scale of 0–100 was designed such that a mean score of 50 with a standard deviation of 10 represents average health status (United States population). The improvement gained in our patient population is commensurate with reported age category scores of the general US population suggesting a return of health to near normal levels. SCB and MCID were reached for 72% of patients on SF-12 PCS. MCID (no SCB was available) for SF-12 MCS was reached in 78% of patients.

More than half of patients were “very satisfied” with the surgical outcome only 1 patient (5.6%) was “not really” satisfied (Table 5). When asked if they would have the same surgery for the same result, 83% responded “definitely,” 5.6% answered “likely,” and 11% indicated “definitely not.”

Most (84%) patients had undergone previous lumbar spine surgery. A subgroup analysis of improvement in pain amongst those with and without a history of prior lumbar spine fusion showed no difference in clinical outcomes. Analysis of variance showed that other variables (history of hypertension, diabetes, smoking, age and gender) had no affect on pain (VAS), function (ODI), or quality of life (SF-12) improvements. Of interest, 89% of patients had a BMI of greater than 25 indicating they were overweight or obese. Although only a

Table 3 Clinical outcomes

	Baseline		6wk		3mo		6mo		12mo	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
VAS	18	8.9 (1.9)	12	3.1 (1.6)	13	3.0 (2.5)	10	4.4 (3.2)	18	2.3 (2.1)
ODI	18	52.7 (18.8)	5	22.8 (19.8)	10	16.8 (16.4)	3	29.0 (12.7)	18	13.2 (12.6)
SF-12 PCS	18	32.3 (6.4)	6	38.1 (10.1)	9	44.8 (10.2)	3	37.4 (1.9)	18	44.6 (10.5)
SF-12 MCS	18	37.6 (10.2)	6	42.6 (13.1)	9	51.2 (11.3)	3	36.1 (2.1)	18	53.8 (9.5)

Table 4 12 month clinical outcomes

	Baseline	12 mo	Change	p
VAS	8.9 (1.9)	2.3 (2.1)	-6.56	<0.001
ODI	52.6 (18.8)	13.2 (12.6)	-37.54	<0.001
SF-12 PCS	32.3 (6.4)	44.6 (10.5)	11.19	<0.005
SF-12 MCS	37.8 (10.4)	53.8 (9.5)	20.37	<0.001

small percentage of patients fell within the “normal” BMI range, subgroup analysis revealed no statistically significant effect of BMI on outcomes.

Complications

There were no intraoperative complications. Postoperatively, one patient had fluid retention, three patients experienced transient trochanteric bursitis treated with medical management and one patient had transient toe numbness of unclear relationship to SI joint fusion surgery (Table 6). One operative site hematoma occurred. In this same patient, a selective nerve root block was performed at S1 to alleviate pain from a resulting piriformis spasm. One patient experienced new radicular pain at the 3 month visit. CT scan revealed the most cephalad implant was seated just outside the anterior cortex, resulting in an irritation of the L5 nerve root. The implant was subsequently removed and the patient had a complete resolution of radicular symptoms. The resulting major complication rate as defined by Lebude et al. [26] for this cohort was 5%.

Discussion

SI joint symptoms can present as pain in the SI joint, low back, hip, groin, or buttock, and abnormalities are rarely seen on plain radiographs alone [1,17]. To accurately diagnose the SI joint as the pain generator in patients with low back pain symptoms requires a combination of detailed clinical history, physical exam maneuvers that stress the SI joint, and marked pain relief on diagnostic SI joint block [8,27].

Recent reports of MIS approaches to SI joint arthrodesis using hollow modular anchorage (HMA) screws packed with demineralized bone matrix show relatively good clinical results, but with room for improvement [28-30]. However, recent reports suggest that this technique may not be appropriate for patients with a history of instrumented spinal surgery. Mason et al. reported

Table 5 Satisfaction

Satisfaction with surgical outcomes	Would you have the same surgery for the same result?	
Very	10 (55.6%)	15 (83.3%)
Somewhat	7 (38.9%)	1 (5.6%)
Not really	1 (5.6%)	2 (11.1%)

Table 6 Complications

Complication	n
Trochanteric bursitis	3
Hematoma	1
Fluid retention	1
Toe numbness	1
Implant malposition	1

significantly worse outcomes after SI joint fusion using HMA screws in patients with a history of previous lumbar spine surgery [30]. In contrast, a recently published report of outcomes after SI joint fusion using the triangular implants reported herein (iFuse Implant System) showed clinically and statistically significant improvements in pain and function independent of a prior history of lumbar spine fusion [14]. Similarly, there was no difference in outcomes in the current study between patients with and without history of lumbar spinal fusion. Recent case series reports using the same technique described herein report favorable results with minimal complications and no suggestion of implant loosening [14,15,31,32].

Advantages of a MIS approach over standard open fusion include a small incision, minimal blood loss, bone and ligament preservation, and a relatively short period of immobilization. The triangular shape combined with an interference fit of the titanium implant used in this cohort was designed to minimize rotation and micro-motion in order to avoid the issues of loosening, backing out and implant protrusion that can be encountered with traditional screws [33]. Due to both the porous nature of the implant’s titanium plasma spray coating along with the implant versus cage design, iliac crest bone harvesting is not required.

Post-operative complications were minimal and the most common complaint was transient trochanteric bursitis. This is neither uncommon nor unexpected, and can be a result of altered gait pattern due to low back or hip pain, post-operative hip abductor weakness, increased activity levels and other trauma in the region [34]. One patient presented with pain in the L5 distribution 3 months after device placement. Impingement of the distal end of the most cephalad implant on the L5 nerve root was revealed on CT scan. After the implant was removed, the patient’s pain resolved completely. This patient had an otherwise excellent outcome with a 12-month pain score of 1, an ODI score of 6, and normal SF-12 PCS and MCS scores. This finding underscores the importance of accurate device placement during surgery.

Most patients in this cohort had a history of previous lumbar spine surgery with the most common procedure being instrumented fusion (75%). It is unclear whether

the degradation of the SI joint was a result of adjacent segment disease (ASD) or de novo degeneration. Using pre-determined thresholds (MCID or SCB where available) for clinically significant improvement, the success rates observed in our study were high: 90% of patients met this threshold for improvement in pain (VAS), 89% for back related function (ODI), 72% for physical quality of life (SF-12 PCS), 78% for mental quality of life (SF-12 MCS). Moreover, the presence of prior lumbar spine fusion did not seem to affect improvement of pain and functional scores.

Although the current study sample size is small, the results are very encouraging. Favorable outcomes in this cohort underscore the necessity to suspect the SI joint as a pain generator in patients with low back pain especially after lumbar spine surgery. Results for this reported procedure in patients with instrumented fusion are as favorable as in patients with no prior lumbar surgical history. This procedure has the potential to significantly benefit the elderly population, who are not candidates for other conventional techniques due to poor bone quality, delayed healing and reduced mobility. Half of the patients in this cohort are 65 years or older and a sub group analysis revealed no difference in outcomes at one year for patients < or > 65 years. This segment of the population is not likely to respond well to physical therapy alone in part because of the degenerative nature of SI joint disease. The MIS procedure described herein affords this segment of the population an opportunity to regain mobility, alleviate SI joint and low back pain caused by SI joint issues and experience an improved quality of life.

Conclusion

Minimally invasive SI joint fusion using a series of triangular porous TPS coated implants is effective in improving pain, function and quality of life in patients with disorders of the SI joint who have failed conservative treatment. The complication rate was low.

Competing interests

JC is a paid consultant for SI-BONE, Inc. RC is an employee of SI-BONE, Inc.

Authors' contributions

JC performed all surgeries, patient assessments, data collection, critical revision of the manuscript and gave final approval of the manuscript. RC performed data analysis, interpretation, and drafted the manuscript. Both authors read and approved the final manuscript.

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JC is a board certified neurosurgeon specializing in minimally invasive treatment of spinal disorders. RC is a clinical research professional and medical writer.

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