CLINICAL ARTICLE

Patient Reported Clinical Outcomes of Minimally Invasive Sacroiliac Joint Arthrodesis

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Objective: To report patient-reported outcomes of minimally invasive sacroiliac (SI) joint fusion as a case series.

Methods: This study was a retrospective cohort study of patients 18 years of age and older who underwent a minimally invasive SI joint fusion by a single surgeon between 1 January 2013 and 31 December 2015. Routine demographic data, characteristics, and relevant surgical and clinical data were all collected for this group. In addition, patients completed preoperative and postoperative visual analog scale (VAS) and Short Form 36 (SF-36) questionnaires to assess outcomes. Patient selection for SI fusion was based on short-term resolution of symptoms (80% or greater relief) with an image-guided intra-articular injection of local anesthetic. Routine statistical analysis was performed using the Wilcoxon signed rank test, Fisher's exact test, or χ^2 analysis as appropriate.

Results: This study included 19 patients comprising 24 SI fusions, with a mean follow-up of 58 months. The average patient age was 50 years and the average surgical blood loss was 25 cc. Men comprised 79% of the cohort. The VAS score improved from 7 to 3 ($P = 0.0001$). SF-36 physical function, role limitations due to physical health, and role limitations due to emotional health improved to a statistically significant extent. General health was not significantly changed. Every patient showed improvement in their SF-36 physical function scores (mean 40 preoperatively to 55 at final follow up) and 18 of 19 showed improvement in the VAS score (mean 7 preoperatively to 3 at final follow-up).

Conclusion: In appropriately selected patients, minimally invasive SI joint fusion results in decreased pain and improved physical functioning of patients, which is sustained for more than 4 years post-procedure.

Key words: Sacroiliac joint; SI fusion; Minimally invasive surgery; Low back pain; Sacroiliac arthrodesis

Introduction

The sacroiliac (SI) joint has been implicated to be involved in 15% to 30% of patients with lower back pain[1,2]. The etiology of SI joint pain can be varied and include degenerative, post-traumatic, iatrogenic, infectious, inflammatory, neoplastic, and idiopathic causes. Many options for nonoperative management of SI joint-related pain exist. Anti-inflammatory medications, physical therapy, analgesics, bracing, prolotherapy, intra-articular injection, and radiofrequency ablation are all widely used nonoperative treatment options for pain emanating from the SI joint[3]. The amount of high-quality literature on successful conservative treatment of the SI joint remains limited. Despite this, many people suffering from SI joint dysfunction can be successfully treated with conservative means. However, a portion of patients fail conservative care and then proceed to SI fusion. This study analyzes the outcomes of such patients.

Open arthrodesis was previously used for the treatment of SI-related pathology *via* an anterior or posterior approach[4]. While the literature does report improvement in medical outcomes with open approaches, resulting complications are noted as well. Previously used open approaches involved direct surgical exposure of the SI joint most commonly *via* a posterior approach. Sometimes plating and

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hardware were applied across the joint in combination with grafting to facilitate the fusion. These open posterior approaches carried significant morbidity with associated wound problems. Local pain from damage to cluneal nerves and other local structures was common with open posterior approaches to the SI joint.

Newer approaches to SI fusion have evolved to include percutaneous minimally invasive placement of implants spanning the SI joint with less surgical exposure involved and, therefore, less concomitant disruption of surrounding soft tissues[5]. Some minimally invasive SI fusion techniques require the use of bone graft and others rely on transarthrodial healing of bone to implants to eliminate motion at the joint itself. The existing literature suggests improvement in patient outcomes with minimally invasive SI fusion[6,7]. A recent publication reported on the 5-year outcomes of this procedure with favorable results[8]. The present study was undertaken to report the experience a single surgeon performing this procedure in routine clinical practice. While initially skeptical regarding the efficacy of this procedure, the senior author (GLS) noted early in his experience several patients who returned after a unilateral SI fusion requesting that the other side be surgically treated as well. Thus, the impetus for objectively reporting the results of this case series was initiated and is presented herein. This study is presented to: (i) report the clinical patient outcomes and surgical data of the initial experience of a single surgeon using this technique for SI fusion; and (ii) to thereby assess the durability of this procedure beyond the expected timeframe for fusion to the implants to have occurred.

Methods

This is a single center retrospective cohort study of patients aged 18 years and older, who underwent a minimally invasive SI joint fusion by the primary author from 1 January 2013 to 31 December 2015. The study was conducted in accordance with approval from the Allegheny Health Network Institutional Review Board. The study represents all patients who underwent this procedure by the primary author during the abovementioned period of time.

Inclusion Criteria for Surgery

Selection criteria for surgical candidates were patients aged 18–80 who experienced strict short-term resolution of symptoms (80% or greater relief) with image-guided diagnostic intra-articular injection of the involved SI joint. This level of relief was chosen as is used by the majority of insurers as a basis for procedure coverage. This is consistent with the coverage recommendation of the North American Spine Society, which states "at least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on two separate occasions"[9]. All patients were thereby diagnosed with sacroiliitis or SI dysfunction based on their response to local anesthetic. Patients had been sent for block based on multiple positive provocative maneuvers stressing the SI joint (at least 3/5 positive of thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, and posterior provocation test).

PICO Model

Patients in this study were consecutive patients who underwent minimally invasive SI fusion by the primary author between 1 January 2013 and 31 December 2015. The *intervention* was an SI fusion using cannulated triangular titanium-coated implants manufactured by SI Bone. *Comparison* was done between preoperative scores and scores at final follow-up for each individual patient. *Outcomes* are described in the results section as reported by patients using the visual analog score (VAS) and Short Form 36 (SF-36) scales.

Data Collection

Patients were identified and charts were reviewed for demographics, characteristics, relevant surgical and clinical data, and pre-surgery VAS and SF-36 scores as standard of care. Routine clinical follow up was performed on all patients. Eligible patients were contacted for final follow up first *via* mail at a minimum of 2 years after surgery. If they did not respond, three attempts were then made *via* telephone for a post-surgical follow-up survey *via* direct communication. Verbal consent was obtained for each patient, and VAS and SF-36 surveys were repeated.

Visual Analog Scale

The VAS is a well described pain scale whereby patients report their pain from 0 to 10. A score of 0 would indicate no pain and 10 would indicate the worst pain. The VAS allows patients a simple method of relaying their experience regarding how painful their condition is. Patients are asked to rate their pain on a 0-10 scale. The clinical significance of this is that it allows patients to compare their own pain based on their perception of their own previous pain. It also objectifies the pain level to allow for quantitative analysis. Patients are generally more functional with less pain.

Short Form 36

The SF-36 is a set of generic, coherent, and easily administered quality-of-life measures developed by the RAND Corporation. These measures rely upon patient self-reporting and are now widely used by managed care organizations and by Medicare for routine monitoring and assessment of care outcomes in adult patients. Patients completed handwritten responses to this survey. Assistance was available if needed. The clinical significance of the SF-36 is that it allows for quantitative analysis.

Surgical Technique

Patients were taken to the operating room and placed under general anesthesia prone over bolsters on a flat-top Jackson table. A single C-arm was used to obtain a perfect lateral view of the sacrum as well as pelvic inlet and outlet views. A standard 1.5-inch incision was made over the lateral gluteal

region along the posterior sacral line 1–2 inches from the intersection with the sacral alar line. Dissection was bluntly performed through the subcutaneous tissue and the gluteal fascia was sharply incised. Blunt dissection was then performed on the lateral ilium. Three sharp guide pins were placed across the SI joint under fluoroscopy with care taken to avoid the sacral foramina. A parallel pin guide was used to assist placement of the second and third pins after free-hand placement of the first wire. Measurements for appropriate length implants were taken. A cannulated one-step broach was impacted over the guide wires such that one to two teeth of the broach crossed the joint. The implants were then impacted over the guide wires under fluoroscopy to an appropriate position, leaving them 1–2 mm proud laterally. The wound was finally copiously irrigated and then closed in layers to include the fascia, subcutaneous tissue, and skin after obtaining meticulous hemostasis. Every attempt was made to obliterate dead space in the surgical wound. A compressive dressing was applied.

Postoperative Management

Patients were kept overnight in the hospital to allow for recovery from anesthesia. They were mobilized with physical therapy immediately while maintaining a strict touchdown weight-bearing status on the operative side (for 30 days). Patients were discharged to home the following morning with crutches or a walker based on patient preference and performance in physical therapy. They were maintained on Ecotrin 325 mg twice per day for deep venous thrombosis prophylaxis and encouraged to mobilize while maintaining weight-bearing restrictions.

Statistical Analysis

Data are presented as mean (standard deviation) or median (interquartile range) for continuous variables and frequency (percentage) for categorical variables. Continuous variables were compared using a Wilcoxon signed rank test as appropriate. Categorical variables were compared using Fisher's exact test or χ^2 analysis as appropriate. The SAS Enterprise Guide 7.15 HF3 (SAS Institute, Cary, NC, USA) was used to conduct the statistical analysis. P-value <0.05 was set as the significance level where appropriate. Categorical variables collected included sex and laterality. Continuous variables collected included age, length of follow-up, estimated blood loss, VAS, and the SF-36 subsets of physical function, role limitations due to physical health, role limitations due to emotional health, energy fatigue, well-being, emotional well-being, social function, pain, and general health.

Surgical Devices

All SI fusions were performed using cannulated triangular titanium (T1 6AI4V ELI) implants with a porous surface made by SI bony (Clara, CA, USA). Relevant imaging of the procedure, preoperatively and postoperatively, is included for illustration purposes (see Fig 1). The first-generation triangular titanium-coated implants which were used in this study from SI Bone. Lengths are variable and widths include 4-mm or 7-mm diameter implants (Fig 2).

Results

Patient Cohort

A total of 19 patients met inclusion criteria, were contacted, and responded to the VAS and SF-36 surveys. They comprised 24 SI joint fusions (among which, 5 were staged bilateral procedures).

Demographic and Surgical Characteristics

The majority of the patient population were middle aged (median [interquartile range]: 50 [44–52] and male (frequency [%]: 15 [79%]) (Table 1). Ten of the fusions were on the right side (53%). Estimated blood loss for the procedure averaged 25 mL. The mean follow-up for the study was 58 months (± 8.4).

Patient Clinical Outcomes

All patients provided preoperative and postoperative VAS scores. Patients' VAS survey scores were significantly different from pre-surgery to follow up (7 [6–9] *vs* 3 [1–7], P-value = 0.0001 respectively). Nine patients completed preoperative SF-36 questionnaires and all patients completed SF-36 evaluation at final follow up. Physical function scores were significantly different between pre-surgical and follow-up surveys (40 [25–60] *vs* 55 [30–80], P-value = 0.016 respectively). Role limitations due to physical and emotional health scores were significantly different between pre-surgical and follow-up surveys (Table 2). All the other SF-36 domains (energy fatigue well-being, emotional well-being, social functioning, pain, and general health) were not significantly altered at follow-up.

Outlier

Only 1 of the 19 patients reported a worsened VAS score with SI fusion (by 1 point, from 6 to 7). However, every patient showed improvement in SF-36 physical function scores preoperatively compared to postoperatively. The one "non-responder" appeared to have good radiographic implant placement at all time periods and was felt to have secondary gain issues.

Discussion

This case series represents one surgeon's experience in the surgical management of SI joint pain with minimally invasive fusion using triangular titanium implants. In appropriately selected patients, the procedure resulted in significant improvements in pain, as evidenced by the VAS improvement noted here. These results appear persistent given our mean follow-up of 58 months (±8.4 months). From a clinical standpoint, it is unlikely that results would be expected to change (for better or worse) for any particular reason at such a lengthy duration out from surgery. At nearly 5 years out from surgery, the joint should have either

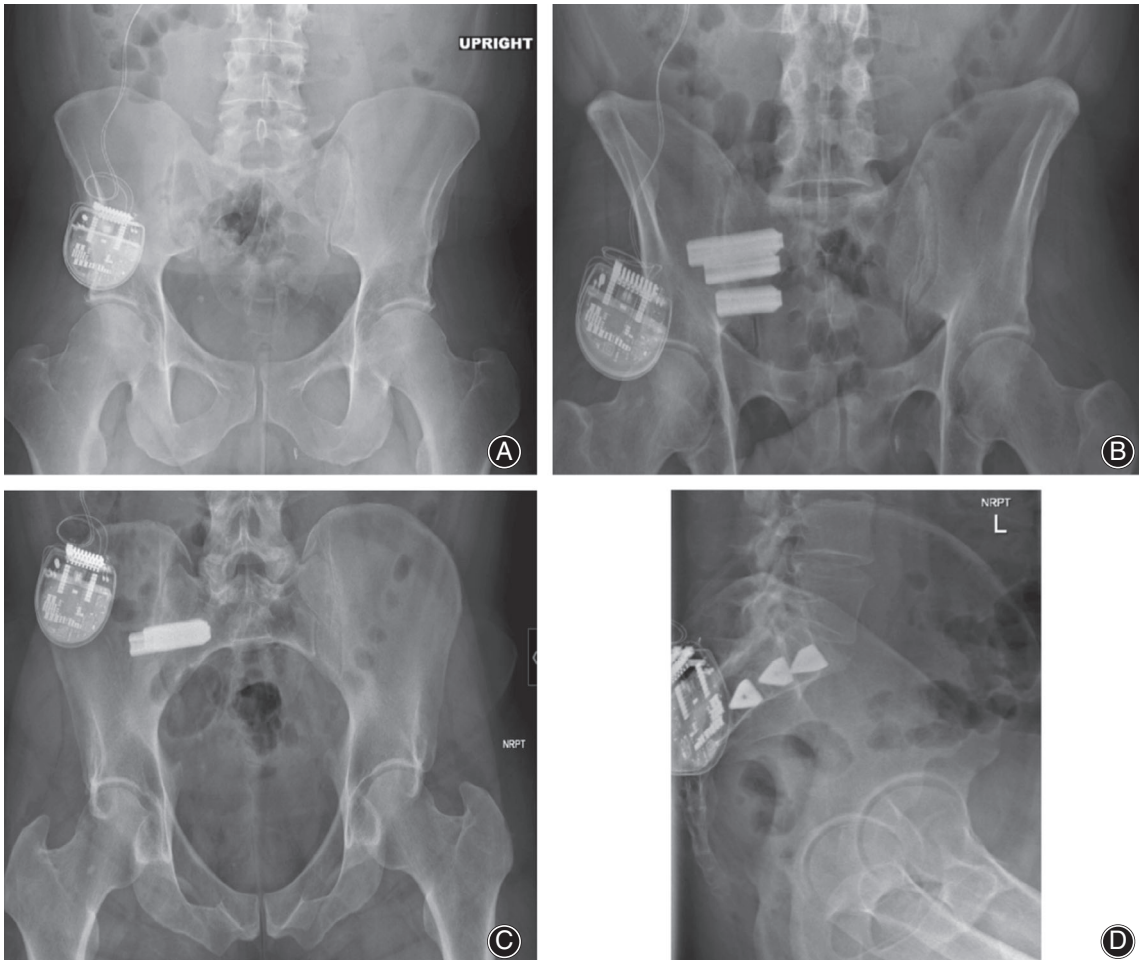

Fig 1 Radiographic studies of SI (SI) fusion. (A) Preoperative anteroposterior (AP) pelvis X-ray of a patient prior to right SI joint fusion shows evidence of sclerosis adjacent to the SI joint. Incidental impulse generator from spinal cord stimulator is also seen. A 53-year-old man with right SI pain improved >80% with diagnostic image-guided injection with local anesthetic. (B) Postoperative pelvic outlet view showing three implants traversing the right SI joint and sparing the sacral foramina. A 53-year-old man 6 weeks after right SI fusion. Note that the implant length is chosen intraoperatively so as to spare the sacral foramina and maximize the surface area for bony ingrowth. (C) Postoperative pelvic inlet view shows implants in appropriate AP position traversing the right SI joint contained within the bone. A 53-year-old man 6 weeks after right SI fusion. (D) Postoperative lateral view of the sacrum showing three implants in position after right SI joint fusion. A 53-year-old man 6 weeks after right SI fusion.

Fig 2 iFuse implant

TABLE 1 Table of patient characteristics/demographics

Variable	Data (*n* = 19)
Age, years	50 (44–52)
Sex, male	15 (79%)
Laterality, right	10 (53%)
Length of follow up, months	58 (8.4)
Estimated blood loss	25 (20–50)

Notes: Continuous variables: if normal then presented as mean (standard deviation), otherwise as the median (interquartile range). Categorical variables are presented as frequency (*n*) and percent of total within group (%).

osseously fused (to the implants at a minimum) and healed or one would expect the implants to have loosened and come to clinical attention. Thus far, to the author's knowledge, there has been zero need for revision surgeries in these patients. The significant improvements in role limitations due to physical health and emotional health seen in this series lend credence to this procedure making a meaningful difference in these patients' lives. A painful SI joint can cause significant problems in daily activities as even just ambulation and sitting can become painful[10].

TABLE 2 Results of visual analog score (VAS) and Short Form 36 (SF-36) in preoperative and postoperative groups

Variable	Data (*n* = 19)	*P*-value
VAS		
Preoperative	7 (6–9)	0.0001
Postoperative	3 (1–7)	
Physical function		
Preoperative	40 (25–60)	0.016
Postoperative	55 (30–80)	
Role limitations due to physical health		
Preoperative	0 (0–0)	0.016
Postoperative	50 (0–100)	
Role limitations due to emotional health		
Preoperative	0 (0–66)	0.0078
Postoperative	67 (33–100)	
Energy fatigue well-being		
Preoperative	56 (36–72)	0.84
Postoperative	30 (15–45)	
Emotional well-being		
Preoperative	56 (36–72)	0.44
Postoperative	60 (44–76)	
Social functioning		
Preoperative	50 (37–63)	0.078
Postoperative	50 (37–88)	
Pain		
Preoperative	45 (33–48)	0.79
Postoperative	45 (23–55)	
General health		
Preoperative	65 (30–65)	0.99
Postoperative	55 (30–65)	

Notes: Comparison of categorical variables using χ^2 or Fisher's exact test as appropriate. Comparison of continuous variables using Wilcoxon signed rank test. Continuous variables: if normal then presented as mean (standard deviation), otherwise median (interquartile range [IQR]).

The findings in this study are largely in line with the published medical literature. In 2019, Whang *et al.*[8] reported 5-year results for this procedure, revealing significant improvement in pain scores, improvement in quality of life with high satisfaction rates, and decreased opioid use. Kube and Muir[11] reported improvement in pain and decreased disability at 1 year postoperatively, with no major complications in their series. In comparing minimally invasive SI fusion to conservative management, Sturesson *et al.*[12] showed significantly better improvement in low back pain and disability in the surgical compared to the nonoperative group. They also reported that walking distance and satisfaction were higher in those patients treated with SI fusion. In the oldest published case series, Rudolf reported that clinical improvements in pain and disability observed at 12 months after surgery were maintained at 5 years postoperatively[7].

The present study adds to the published literature on intermediate to long-term outcomes of SI fusion. The durability of pain relief at 5 years seen here is consistent with the other limited data published to date. The consistency of all of this peer-reviewed published data should be used as evidence-based medicine for appropriate decision-making by all parties involved in the healthcare processes associated with treating patients afflicted by conditions of the SI joint. Further study of this procedure will elicit more detail regarding the precise role that this surgery will play moving forward in the algorithm of treatment for patients with low back pain. The financial independence of this series from industry bias is one of its strengths.

Study Limitations

The small number of patients involved in this case series is the biggest limitation of this study. The authors conjecture that with larger numbers likely more effects could have been seen on the various SF-36 subset scores. However, this series was presented for publication as an attempt to report the clinical course of patients seen in a routine spinal surgery practice. Certainly also, if more patients had completed the preoperative SF-36 evaluations, the data would have been more robust. Patient-reported outcomes are now being captured at every clinical visit in our practice for all conditions, but that was not the case in 2013. Other instruments (e.g. the Oswestry Disability Index) also could have been used to quantify the effects of this procedure on outcomes in back pain. Radiographic outcomes also could have been considered to be included in the study but were not embodied in the original institutional review board submission protocol and are felt to be less important clinically than patient-reported outcomes. Radiographic outcomes have been reported robustly in the published medical literature[7,11]. In summary, despite these limitations, the minimally invasive SI fusion procedure was shown to have significant positive effects on pain relief and role limitations as detailed earlier.

Conclusion

Minimally invasive SI joint fusion using triangular titanium implants was found to improve pain in appropriately selected patients at 58 months postoperatively. Role limitations due to physical and emotional health were significantly improved as well. The procedure had minimal morbidity (with mean estimated blood loss of 25 mL) and no patients required revision of their implants at final follow-up.

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