Minimally Invasive Sacroiliac Joint Fusion with Cylindrical Threaded Implants Using Intraoperative Stereotactic Navigation

Sharad Rajpal and Sigita Burneikiene

BACKGROUND: **Significant progress in hardware and surgical techniques for sacroiliac joint (SIJ) fusion surgeries has facilitated safer and more efficacious procedures for patients. Triangular-shaped implants for SIJ fusions are the most-studied devices and have demonstrated good short-term and long-term clinical outcomes. Reports on cylindrical threaded implants are very limited. Owing to biomechanical differences in the implants and the surgical techniques required for their placement, previously reported results may not be applicable to cylindrical threaded implants. The aim of this study was to report preliminary clinical experience with minimally invasive SIJ fusion using intraoperative stereotactic navigation and the Rialto SI Fusion System.**

METHODS: **We retrospectively reviewed 24 patients who underwent SIJ fusions between May 2015 and October 2017 performed by a single surgeon.**

RESULTS: **Mean total satisfaction score was 89.0% ± 27.6%. A statistically significant reduction ($P = 0.0028$) in low back pain scores was noted from an average baseline score of 6.6 ± 2.4 to 3.7 ± 3.3 postoperatively. Leg pain scores decreased from 4.8 ± 3.8 to 1.5 ± 2.9 ($P = 0.0034$). Mean surgical time was 53.0 ± 13.9 minutes. It took significantly longer ($P = 0.0089$) to perform the initial 13 cases (59.9 ± 15.2 minutes) compared with subsequent cases (45.4 ± 7.3 minutes). Estimated blood loss was minimal (10.4 ± 5.2 mL).**

CONCLUSIONS: **Minimally invasive SI joint fusion using cylindrical threaded implants can be safely performed with minimal morbidity and good clinical outcomes.**

INTRODUCTION

Significant improvement in hardware and surgical techniques for sacroiliac joint (SIJ) fusion surgeries over the last decade has facilitated safer and more efficacious procedures for patients experiencing SIJ pain. Several devices are currently approved for clinical use in the United States for minimally invasive SIJ fusion, including iFuse Implant System (SI-BONE, Inc., Santa Clara, California, USA); SI-LOK Sacroiliac Joint Fixation System (Globus Medical, Inc., Audubon, Pennsylvania, USA); SambaScrew SI Fixation System (Orthofix, Lewisville, Texas, USA); Silex Sacroiliac Joint Fusion System (Xtant Medical, Belgrade, Montana, USA); Simmetry Sacroiliac Joint Fusion System (Zyga Technology, Inc., Minnetonka, Minnesota, USA); and, the most recent addition, Rialto SI Fusion System (Medtronic, Minneapolis, Minnesota, USA). The iFuse Implant System is the most-studied device and has demonstrated good short-term and long-term clinical outcomes.[1-6] The iFuse Implant System is based on the placement of 3 triangular implants; however, reports on outcomes from the placement of cylindrical threaded implants are very limited.[7-12] Owing to the biomechanical differences of the implants and the surgical techniques used for their placement, previously reported results may not be applicable to cylindrical threaded implants.[3] The purpose of this study was to report our preliminary clinical experience with minimally invasive SIJ fusion using intraoperative stereotactic navigation and the Rialto SI Fusion System.

MATERIALS AND METHODS

We retrospectively reviewed 24 patients who underwent SIJ fusion between May 2015 and October 2017 performed by a single surgeon (S.R.). SIJ disruption or sacroiliitis was diagnosed in all patients, and the patients underwent at least 6 months of conservative treatment. Clinical diagnosis was established based on extensive physical examination, provocative SIJ pain tests, imaging studies, and confirmation via diagnostic SIJ injections performed using fluoroscopic guidance.

Key words
- Arthrodesis
- Minimally invasive surgery
- Sacroiliac joint
- SI joint fusion

Abbreviations and Acronyms
EBL: Estimated blood loss
SIJ: Sacroiliac joint

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Table 1. Self-Reported Patient Satisfaction Survey Questions and Scores

Question	Scores				
How satisfied are you with the outcomes of your surgery?	Very satisfied	Somewhat satisfied	Don't know	Somewhat dissatisfied	Dissatisfied
How is your pain or condition that you had surgery for now compared with before surgery?	Much better	Better	Same	Worse	Much worse
Would you have surgery again for the same condition?	Definitely yes	Probably yes	Don't know	Probably no	Definitely no
Satisfaction score	100%	75%	50%	25%	0%

Surgical Technique

The patient was positioned prone on a Jackson table with support under the chest, pelvis, and hips. The lower lumbar region, including the buttocks and pelvis, was prepared and draped in the usual sterile surgical fashion. A small incision was made over the contralateral posterior superior iliac spine, and a percutaneous reference frame was placed for the StealthStation navigation system (Medtronic). After confirmation anteroposterior and lateral localizing x-rays were obtained, a three-dimensional O-arm spin was performed with the information subsequently transferred to the StealthStation for navigation. Using navigation, the ideal entry points and trajectories for placement of 2 cylindrical threaded implants in a posterior-to-anterior and medial-to-lateral direction across the SIJ were selected. Navigation was then used to first drill and then tap 2 pilot holes across the SIJ via a minimally invasive incision. Two cylindrical threaded implants filled with allograft were placed across the ipsilateral SIJ using navigation. An additional intraoperative three-dimensional O-arm spin was performed to confirm placement of both implants. The wounds were closed in standard fashion.

Clinical Outcomes

The severity of low back and leg pain was evaluated using an 11-point visual analog scale. Patient functional outcomes were assessed using a self-reported patient satisfaction survey (Table 1). Answers were scored on a scale from 0 to 100: 100 = very satisfied/much better/definitely yes; 75 = somewhat satisfied/better/probably yes; 50 = don't know/same/don't know; 25 = somewhat dissatisfied/worse/probably no; 0 = dissatisfied/much worse/definitely no. A total score was calculated for each patient by averaging the scores from all 3 responses.

Data collection also included patient age, sex, previous surgeries, surgical time, estimated blood loss (EBL), length of stay, and complications. Plain radiographs (standing anteroposterior views) were used to assess fusion as an absence of lucency around the implant or screw fracture and migration. Pelvic computed tomography scans were performed only for symptomatic patients.

Statistical Analysis

A paired t test was performed to determine any differences in baseline and postoperative low back and leg visual analog scale scores.

RESULTS

The mean follow-up time was 19 months (range, 12–34 months). There were 21 female patients and 3 male patients with a mean age of 62.2 years (range, 33–79 years). The left SIJ was treated in 14 patients, and the right SIJ was treated in 8 patients. One patient underwent simultaneous bilateral SIJ fusion, and another patient had the contralateral side treated 5 months following the initial SIJ fusion procedure. Selected demographic, clinical, and surgical characteristics are presented in Table 2. Only 7 (29.2%) patients had no previous surgery, whereas 15 (62.5%) patients had prior lumbar spine fusions.

The paired t test revealed a statistically significant reduction ($P = 0.0028$) in low back pain scores from an average baseline score of 6.6 ± 2.4 to 3.7 ± 3.3 postoperatively. Leg pain scores decreased from 4.8 ± 3.8 to 1.5 ± 2.9 ($P = 0.0034$). Although similar improvement in leg pain scores was observed for patients who had previous surgeries (5.0 ± 3.7 to 1.9 ± 3.2; $P = 0.028$), the low back pain scores did not quite reach statistical significance (6.5 ± 2.4 to 4.4 ± 3.3; $P = 0.068$). The mean total satisfaction score was $79.0\% \pm 27.6\%$. The responses to the question about

Table 2. Selected Patient Demographic and Clinical Criteria

Variable	Value
Number of patients	24
Male/female	3/21
Age, years, mean (range)	62.2 (33–79)
Follow-up, months, mean (range)	19 (12–34)
Side fused	
Right	8 (33.3%)
Left	14 (58.3%)
Bilateral	2 (8.3%)
Previous surgeries	
No previous surgery	7 (29.2%)
Decompression	2 (8.3%)
Lumbar fusion 1–2 levels	7 (29.2%)
Lumbar fusion 3–5 levels	6 (25.0%)
Lumbar fusion >5 levels	2 (8.3%)
SCS	4 (16.7%)
SIJ fusion	2 (8.3%)
Hip replacement	1 (4.2%)

SCS, spinal cord stimulator; SIJ, sacroiliac joint.

having surgery again for the same condition were the most highly rated with an average score of 88.2% ± 24.1%, followed by the question about satisfaction with surgery outcomes with an average score of 76.3% ± 31.7%. Finally, the question about pain or condition compared with before surgery had an average score of 72.4% ± 42.4%.

The mean surgical time was 53.0 ± 13.9 minutes. It took significantly longer (Student t test, $P = 0.0089$) to perform the initial 13 cases (59.9 ± 15.2 minutes) compared with subsequent cases (45.4 ± 7.3 minutes). EBL was minimal at 10.4 ± 5.2 mL, and although the same tendency toward reduction was observed (12.1 ± 6.6 mL vs. 8.6 ± 2.3 mL), the difference was not statistically significant (Student t test, $P = 0.11$).

Thirteen (54%) patients were discharged home the same day, and the remaining patients stayed overnight and were discharged the following day. The following complications were encountered: 2 patients had symptomatic subcutaneous hematomas, which resolved spontaneously, and 2 patients had superficial wound infections treated with antibiotics. One patient developed an osteophyte on the lateral aspect of the implant. Because of symptomatic pain localized to that area, an osteophytectomy was performed 1 year after the index surgery with an improvement in patient symptoms. No other hardware or revision surgeries were required, and no hardware failures were observed in patients.

At the time of the last follow-up, all patients were perceived to have achieved a fusion based on pelvic x-rays. Two patients had questionable periprosthetic lucencies seen on pelvic x-rays, but no further imaging was pursued because both patients were asymptomatic and the decision was made to follow them clinically. There was no correlation between radiographic evidence of nonunion and inferior clinical outcomes.

DISCUSSION

It has been estimated that in 15% of patients presenting with low back pain, the pain can be attributed to the SIJ.[13] This number is much higher in patients with prior instrumented lumbar fusion, as up to 75%[14,15] of patients develop SIJ symptomatic conditions, which could potentially increase to 100%[15] when the lumbosacral levels are fused. Patients with SIJ symptoms often receive a misdiagnosis, with their pain attributed to other causes, including failed back surgery syndrome.[16] In properly selected patients and when all conservative treatment methods fail to provide relief, minimally invasive SIJ arthrodesis seems a feasible option.

Minimally invasive SIJ fusion techniques are gaining popularity because they seem to provide a significant reduction of pain with improvements in functional outcomes. With open SIJ fusion procedures, however, up to 44% of treatment failures were reported, and patients required removal of spinal implants.[17] Worse clinical outcomes were reported when bilateral arthrodesis procedures were performed: 82% of patients had unacceptable results, and 65% required reoperation.[18] Smith et al.[17] retrospectively compared open and minimally invasive techniques in a study that included 263 patients and reported significantly greater pain relief, lower EBL, shorter operating room time, and shorter length of hospitalization in minimally invasive surgeries.

The Rialto SI Fusion system was implanted via a posterior oblique approach, which allows for disruption of fewer muscles and tissues during implantation compared with a lateral transgluteal approach that most other systems use. Although this approach is muscle sparing and the risk of vascular structure injury and a possibility of impingement on the sacral neural foramina are reduced, the disruption of stabilizing ligaments remains a concern. Therefore, care should be taken to preserve all major pelvic ligaments during implant placement.

All of our patients received 2 cylindrical implants per side, but according to a study on fixation biomechanics, 1 implant inserted farther and more parallel to the sacroiliac rotation axis may provide the same level of SIJ stability.[19] On the contrary, finite element modeling of triangular implants demonstrated a greater motion reduction provided by 3 implants compared with any combination of 2 implants.[20] When assessing surgical invasiveness, it took on average of 46.6–65.0 minutes[2-4] to insert the 3 triangular implants with reported EBL of 31–51 to mL.[3,21] This compares favorably with the results reported in our study: the average time to implant the Rialto SI Fusion System was 53.0 minutes with 10.4 mL EBL for unilateral procedures. A slight learning curve was observed, as surgery time decreased from the mean of 59.9 minutes to 45.4 minutes.

Most authors have reported minimally invasive SIJ fusion techniques under fluoroscopic navigation.[3,12,22] Lee et al.[23] previously described a percutaneous technique for SIJ fusion using O-arm multidimensional surgical imaging with navigation. The authors noted that this technique allows for more precise implant placement, and the learning curve could be less steep than using fluoroscopic image guidance. Most importantly, correct implant position could be verified before leaving the operating room.

The evaluation of clinical outcomes is challenging in this patient population. In our cohort, 62.5% of patients had prior lumbar fusion surgeries, including multilevel fusions, or were given a diagnosis of failed back surgery syndrome. This could potentially confound patients' ability to differentiate between multiple pain generators, thus reducing improvement obtained from SIJ fusion, as clinical outcomes are evaluated and reported using the same measurement tools. We observed similar statistically significant improvement in leg pain scores for patients with previous lumbar fusion history, but low back pain score reduction was not quite significant. Similarly, Rudolf[24] acknowledged that the co-occurrence of symptomatic lumbar spine pathology potentially confounds the treatment effect, and these patients tend to have a lower reduction in pain scores. The author still reported a highly statistically significant decrease in pain scores for patients with previous fusion surgeries, but no differentiation was made between low back and leg pain scores. On the contrary, Polly et al.[22] did not find that a history of lumbar fusion predicted pain improvement.

CONCLUSIONS

Minimally invasive SI joint fusion using cylindrical threaded implants can be safely performed with minimal morbidity and good clinical outcomes.

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