MINIMALLY INVASIVE SACROILIAC JOINT FUSION WITH RIALTO™ SI FUSION SYSTEM

Max W. Cohen, MD
Spine and Scoliosis Specialist
Greensboro, North Carolina, USA

Medtronic

BACKGROUND

Patients with SI joint pain typically report pain in the low back and buttocks, sometimes with radiation into the groin or upper legs. An algorithm, consisting of medical history, physical examination, imaging studies, and confirmatory intra-articular joint injections is typically used to diagnose SI joint disorders.[1] After failed conservative care, the standard of care for SI joint pain is sacroiliac joint fusion with SI joint fusion devices (e.g., iFuse Implant System, hollow modular anchorage screws, or long threaded screws).[1-2] Minimally invasive fusion of the SI joint has been reported with several types of implants, including triangular, titanium plasma spray coated implants, hollow modular screws, and allograft dowels.

The Rialto™ SI Fusion System (Medtronic, plc, Memphis, TN) consists of cannulated, fenestrated, threaded devices used to provide stabilization for sacroiliac joint fusion. For fusion of the SI joint, one, two, or three devices may be placed at a surgeon's discretion for unilateral or bilateral fixation. The device is placed across the SI Joint using a novel posterior oblique approach.

The purpose of this retrospective case series is to evaluate low back pain and narcotic medication usage changes in patients that underwent sacroiliac joint fusion with Rialto™ threaded devices. The study reports on the clinical outcomes of the procedure 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, if there was a history of recent significant trauma, if they had bilateral SI joint fusion procedures, and if no preoperative or follow up outcomes were available. A total of 14 patients were identified who met this criteria. All patients had surgery between August 12, 2013 and August 31, 2015. Data collected included patient demographics, medical history, and complications of surgery. Clinical outcomes were collected preoperatively and at 4 weeks, 3 months, 6 months, and 12 months postoperatively.

Diagnosis

The diagnosis of SI joint pain was made using a combination of detailed history, clinical exam, imaging, and positive diagnostic injections. All patients were diagnosed with either degenerative sacroiliiitis 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 Gaenslen'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. 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. When clinical, physical, and imaging findings were congruent, patients were sent for at least two image-guided diagnostic injections of the SI joint with confirmatory arthrogram. A positive result was defined as a 90% reduction in pain immediately following each injection of local anesthetic. Conservative treatment consisting of medication optimization, physical therapy, SI joint belt, and therapeutic SI joint injections with steroids was prescribed for a course of at least 6 months before offering the patient surgery.

Technique

Surgery was performed in each case by a single fellowship trained orthopedic spine surgeon in private practice. The procedure involves placing two implants across the SI joint using a novel posterior oblique approach (shown in Figure 1) with the assistance of 3-dimensional stereotactic imaging (O- Arm™ imaging system). The patient is positioned prone on a Wilson frame. After general endotracheal anesthesia the patient is prepped in the normal sterile fashion. A 3-dimensional stereotactic reference arc is placed in the contralateral posterior superior iliac spine using a percutaneous pin. The O-arm™ is brought into the field and 3-dimensional images are obtained and sent to the StealthStation™ System for navigation. Utilizing the 3-dimensional stereotactic navigation, a virtual plan is created for placement of two Rialto™ devices through a 2-3 cm skin incision, which is located just lateral to the posterior superior iliac spine and generally between the S1 and S2 neuroforamen (Figure 2). The skin incision is confirmed using stereotactic navigation. The tissue is split longitudinally down to the iliac crest. Navigated instruments are used to first drill, and then tap, across the sacroiliac joint in a posterior oblique fashion. The trajectory of the posterior oblique approach is generally parallel to the S1 endplate or pointed toward the sacral promontory. The appropriate length Rialto™ device (e.g., 40mm, 50mm, or 60mm) is chosen and can be packed with autograft and/or allograft. The Rialto™ device is inserted into the pilot hole and left flush with the lateral cortex of the iliac crest.

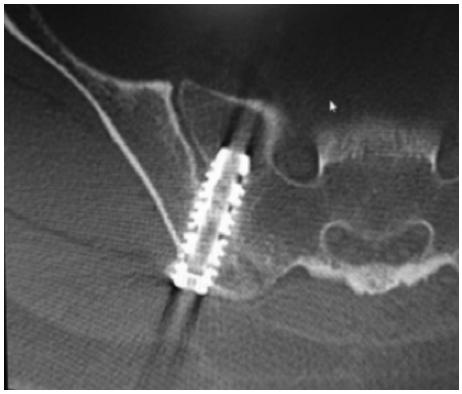


Figure 1a. Axial view of implant placed with posterior oblique approach.

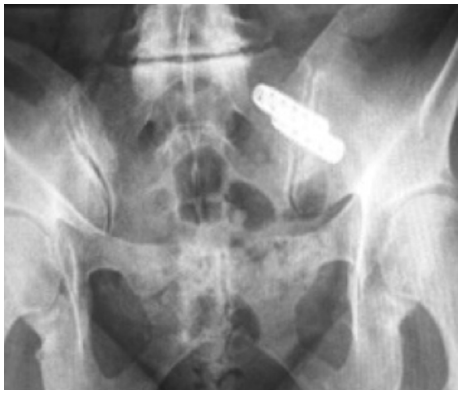


Figure 1b. Postoperative AP view of two implants.

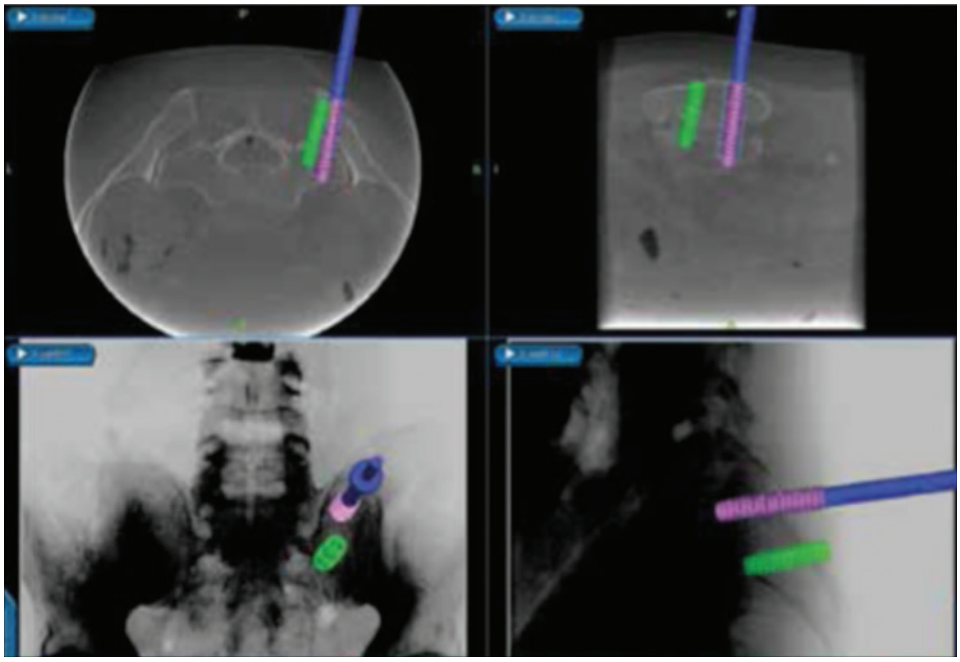


Figure 2. Navigated placement of implants.

Outcomes

Patient reported clinical outcomes were collected prospectively, prior to surgery, to establish baseline values and at 4 weeks, 3 months, 6 months, and 12 months postoperatively. The following assessments were used: visual analog scale (VAS) for pain and morphine milligram equivalent (MME) to assess narcotic usage. Data was obtained regarding the history of previous lumbar fusion, estimated blood loss (EBL), operative time, time to discharge from hospital, and complications.

Statistical Methods

Linear mixed effects models were fit using SAS v. 9.0 to determine if there was a significant change in VAS and MME scores over time. Post-hoc comparisons were assessed using a Bonferroni correction for multiple comparisons.

RESULTS

There were 14 patients included in this study. The sample was 50% male (n = 7) with a mean age of 58.1 years (standard deviation (SD) = 8.7). Other characteristics are listed in Table 1. All of the patients were discharged within 23 hours after surgery and one patient had a postoperative hematoma that resolved without additional intervention. Patients were allowed to weight-bear as tolerated and were advised to avoid impact exercises for 3 months.

Table 1. Sample Characteristics

Gender	7 Female/7 Male
Worker's Compensation Patients	7 (50%)
Patients with Previous Fusion Surgery	10 (71.4%)
Mean OR time	54.3 ± 10.2 min
Mean EBL	51.8 ± 6.7 ml
Complications	1 (7.1%)
Patients discharged within 23 hours post-surgery	14 (100%)

Visual Analog Scale (VAS) Outcome

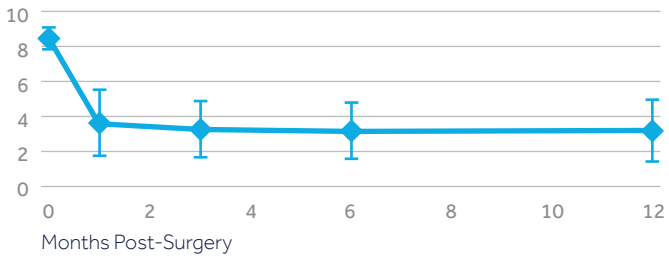
VAS scores were measured pre-surgery (baseline) and at 1, 3, 6, and 12 months post-surgery. The mean VAS scores at each time point are summarized in Table 2 and plotted in Figure 3.

Table 2: Mean VAS Scores

	Mean	SE	95% CI
Pre-Surgery (Baseline)	8.50	0.29	(7.87, 9.13)
1 Month Post-Surgery	3.68	0.88	(1.78, 5.58)
3 Month Post-Surgery	3.29	0.74	(1.68, 4.89)
6 Month Post-Surgery	3.21	0.76	(1.58, 4.85)
12 Month Post-Surgery	3.21	0.84	(1.40, 5.03)

SE = Standard Error, CI = Confidence Interval

Figure 3: Mean VAS Scores with 95% Confidence Intervals



There was a significant change in VAS scores from baseline through 12 months post-surgery ($F(4,10) = 17.8$, $p = 0.0002$). The trend was such that scores decreased significantly from baseline to 1 month post-surgery (8.5 to 3.7) and remained low (3.2 – 3.9). The estimated changes in VAS scores from baseline to each follow-up month are summarized in Table 3.

Table 3: Mean VAS Decrease from Baseline

Follow-Up	Decrease	SE	95% CI	p-value
1 Month	4.82	0.73	(3.25, 6.39)	< 0.0001
3 Month	5.21	0.59	(3.95, 6.48)	< 0.0001
6 Month	5.29	0.59	(4.02, 6.56)	< 0.0001
12 Month	5.29	0.65	(3.88, 6.69)	< 0.0001

SE = Standard Error, CI = Confidence Interval
Bonferroni corrected $\alpha = 0.05/4 = 0.0125$

Morphine Milligram Equivalent (MME) Outcome

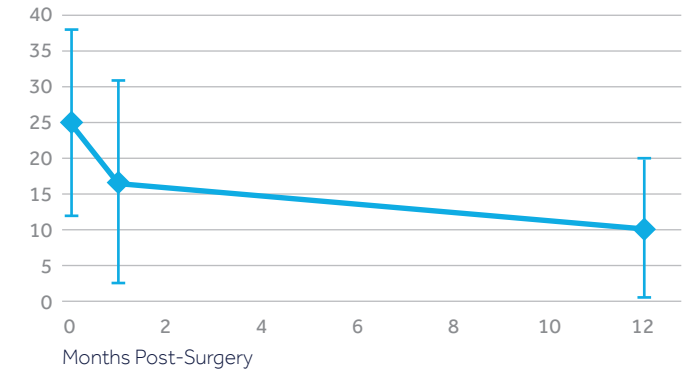
MME was measured pre-surgery, 1 month post-surgery, and 12 months post-surgery. The mean MME is summarized in Table 4 and plotted in Figure 4.

Table 4: Mean MME

	Mean	SE	95% CI
Pre-Surgery (Baseline)	25.00	6.00	(12.04, 37.96)
1 Month Post-Surgery	16.79	6.54	(2.66, 30.91)
12 Month Post-Surgery	10.36	4.55	(0.52, 20.19)

SE = Standard Error, CI = Confidence Interval

Figure 4: Mean MME with 95% Confidence Intervals



There was a significant change in MME from baseline through 12 months post-surgery ($F(2,12) = 11.46$, $p = 0.0016$). As shown in Table 5, there was a significant decrease in MME from baseline to 1 month post-surgery and a nominal (not significant after adjusting for multiple comparisons) decrease in MME from 1 month to 12 month post-surgery. The total decrease in MME from baseline to 12 months was 14.6 ($p = 0.0004$).

Table 5: Mean Changes in MME

Follow-Up	Decrease	SE	95% CI	p-value
Baseline – 1 month	8.21	2.07	(3.74, 12.69)	0.0016
1 month – 12 month	6.43	2.64	(0.72, 12.14)	0.0302
Baseline – 12 month	14.64	3.12	(7.90, 21.39)	0.0004

SE = Standard Error, CI = Confidence Interval
Bonferroni corrected $\alpha = 0.05/3 = 0.0167$

DISCUSSION

With the advent of MIS approaches to SI joint fusion, there has been increased awareness of the SI joint as a potential pain generator in patients with chronic back pain with or without a history of previous lumbar surgery. SI joint symptoms can present as pain in the SI joint, lower back, hip, groin, thigh, and buttocks. The diagnosis of SI joint as a pain generator in patients with low back pain requires a combination of detailed clinical history, physical exam, and provocative maneuvers. The gold standard of diagnosis is marked pain relief with diagnostic SI joint injections under fluoroscopic guidance with confirmatory arthrogram. The patients in this study were carefully selected utilizing the above criteria over a two-year period from a busy orthopedic spine practice. The results of this study show significant improvements in both VAS and MME, demonstrated at 1 month post-operatively and sustained at the 12 month follow-up. There was one minor complication of hematoma that resolved without further intervention. In the study, no patient required a return to the operating room.

The novel posterior oblique approach used for placement of the Rialto™ device is advantageous for several reasons. The patient can be positioned prone on a standard spinal frame which is familiar to the surgeon. The entry point, just lateral to the PSIS, requires minimal muscular dissection compared to a more lateral entry point through the gluteus medius musculature. Theoretically, the cluneal nerves may be at risk with this approach however there were no patients reporting symptoms postoperatively related to the cluneal nerve injury. The posterior oblique approach and the Rialto™ device are easily adaptable to the three-dimensional stereotactic navigation. The contralateral PSIS is an ideal point of fixation for the reference arc. The O-Arm™ System can easily and quickly be maneuvered over the anatomy of the pelvis without interference from the arms or anesthesia. The three-dimensional stereotactic navigation allows for confident positioning of the Rialto™ device in the complex anatomy of the pelvis. The trajectory of the posterior oblique approach reduces the potential of impingement on the neuroforamen of the sacrum. By utilizing the posterior oblique approach and the three-dimensional stereotactic navigation, there is more flexibility in positioning the implants around individual patient anatomy.

Although the current study sample size is small, the results are encouraging in this difficult cohort of patients with chronic back pain, history of previous lumbar fusion (71.4%), and Worker's Compensation claims (50%). The Rialto™ device and the posterior oblique approach allowed for a MIS technique with minimal blood loss, rapid mobilization of patients, and discharge home within 23 hours post surgery.

REFERENCES

1. Lorio MP. ISASS Policy 2016 Update - Minimally Invasive Sacroiliac Joint Fusion. *Int J Spine Surg*. 2016; 10:26.
2. Zaidi HA, Montoure AJ, Dickman CA. Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature. *J Neurosurg Spine*. 2015; 23(1):59-66.

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Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

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