# IMAGE-GUIDED POSTERIOR SACROILIAC JOINT ARTHRODESIS USING THE RIALTO™ SI FUSION SYSTEM: A RETROSPECTIVE REVIEW

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## ABSTRACT

A retrospective review of 40 consecutive patients who underwent a navigated SI joint fusion using Rialto SI Fusion System implants was performed. There were 27 women and 13 males with an average age of 53±11.75 years old. The average length of symptoms prior to surgery was 3.2 years. Before surgery all patients underwent non-surgical management for an average of 2.2 years which included a combination of physical therapy, bracing, chiropractic care, and intra-articular steroid injections. All patients were indicated on the basis of strict inclusion criteria including: a failure of at least six months of nonsurgical management, greater than three of five provocation signs on examination, and a greater than 70% improvement in pain scores after two successive intra-articular anesthetic SI joint injections. 50% of the procedures were done as outpatient surgeries, while the rest required inpatient admissions based on insurance at two local hospitals. Mean intra-operative blood loss was 14.98 ±4.51 cc, and patients were immediate weight bearing after the surgical procedure. Patients' VAS pain scores decreased from 7.7±1.47 preoperatively to 0.78±1.23 at three months follow up. Narcotic usage also declined, and these trends persisted at the final follow-up. There was one intra-operative anesthetic complication in which a patient had a bradycardic episode, and there was one postoperative wound seroma. There were no other postoperative complications observed.


## INTRODUCTION

Patients with SI joint (SIJ) 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. After failed conservative care (for a minimum of six months), the standard of care for SIJ pain is sacroiliac joint fusion.[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 or long threaded screws, and allograft dowels. The Rialto SI Fusion System consists of cannulated, fenestrated devices designed to enhance SI joint fusion. The Rialto SI Fusion System procedure uses a posterior approach to the SI joint, which provides better visibility and minimal muscle disruption compared to a transgluteal approach, as the implants pass through less tissue and muscle during implantation.[3] Using the posterior approach for fusion of the SI joint, one, two, or three implants may be placed at the surgeon's discretion for unilateral or bilateral fixation. The device is intended for SI joint fusion for conditions including SI joint disruptions and degenerative sacroiliitis. Some of the risks associated with the use of the device include migration, loosening, or fracture of the implant, metal sensitivity, or allergic reaction to a foreign body, debris, corrosion products, including metallosis, staining, tumor formation, autoimmune disease, and decrease in bone density due to stress shielding.

The purpose of this retrospective case series is to evaluate Rialto SI Fusion System implants in the treatment of patients with symptomatic degeneration of the SI joint by assessing the performance of the posterior procedure in improving low back pain and/or disability. The study reports the outcomes of the procedure in a single surgeon's private practice.

## METHODS

We retrospectively reviewed 40 patients that underwent a minimally invasive posterior SI joint fusion procedure using Rialto SI Fusion System implants. Patient inclusion criteria were: Degenerative SI joint disease resulting in low back pain (including sacroiliac joint disruptions and degenerative sacroiliitis); unresponsive to conservative medical treatment; and confirmatory testing of SIJ diagnosis. Only patients with a complete dataset of pre- and postoperative assessments were included in the study. Patients with SIJ fusion due to acute trauma were excluded.

All patients were diagnosed and treated based on strict inclusion criteria including: a failure of at least six months of nonsurgical management, greater than three of five provocation signs on examination, and a greater than 70% improvement in pain scores after two successive intra-articular anesthetic SI joint injections. Provocation signs included the Fortin finger sign, FABER sign, compression sign, Gaenslen's sign, and the thigh thrust sign. All procedures were done as outpatient surgeries, unless otherwise required inpatient admission based on insurance. Patients were followed in the office at two weeks, three months, and six months postoperatively. To obtain 12-month assessments of pain scores and narcotic usage secondary to SI joint pain, all patients were contacted by phone.

Preoperative and postoperative visual analog scale (VAS) scores were recorded at baseline, two weeks, three months, six months, and up to 12 months post-operatively. Other outcomes reviewed were operating (OR) time, complications, change in narcotic use from preoperative to postoperative levels at six months and 12 months, and the mean time to return to work following surgery.

**Surgical Technique**

The surgical procedure was done with the patient in a prone position on a Jackson table. Implants were placed with the assistance of StealthStation™ Navigation

System and the O- arm™ Imaging System (Medtronic). After prepping and draping the patient, an appropriately-sized reference pin was inserted through a stab wound on the contralateral posterior iliac crest. The reference arc was then attached. A surgical spin of the O-arm was performed with all OR personal protected behind radio protective shields. A two to three-inch incision was made over the operative side. Soft tissue was cleared down the posterior iliac crest and a self-retaining retractor was placed. Under guidance, a 4.5mm drill was advanced to the anterior sacral cortex without penetrating the cortex. This was followed by a 11.7mm tap, after which the tracts were sounded with a guided ball probe.

Two Rialto SI Fusion System implants were used in all procedures except one. The implants were packed with allograft (demineralized bone fibers) and inserted using a powered surgical driver under image guidance. Depending on bone quality, tightening of the SI joint was tactilely felt as the implants set. The wounds were irrigated and closed in standard fashion. Repeat imaging (a final O-arm spin) was not performed in patients. Patients were allowed immediate weight bearing without assistive walking devices.

**Statistical Methods**

Standard descriptive statistics were used, and paired t-test was performed to determine any differences in baseline and postoperative assessments.

# RESULTS

40 consecutive patients underwent navigated, minimally invasive posterior SI joint arthrodesis with Rialto SI Fusion System implants. 39 patients (97.5%) received two implants and one patient was treated with one implant. There were 27 females and 13 males with an average age of 53±11.75 years old. The average length of symptoms prior to surgery was 3.2 years. All patients failed at least six months of non-surgical management and were indicated for surgery following strict inclusion criteria. Before surgery, the patients underwent non-surgical management for 2.2 years. The non-surgical management included a combination of physical therapy, bracing, chiropractic care, and intra-articular steroid injections. All patients were followed in the office for at least eight months and patients were contacted by phone for ≥ 12 months follow-up assessment. The mean follow-up was 25.7 months.

The mean OR time was 17.2 minutes, and the mean blood loss was 14.98 ±4.51 cc. All patients were immediate weight bearing after the procedure. 50% (20/40) of the patients underwent outpatient surgeries and were discharged the same day of surgery, with the remainder being kept overnight and discharged the following morning for insurance reasons. There was one intraoperative episode of bradycardia. This resolved with pharmacologic measures and there were no postoperative issues. There was one wound dehiscence postoperatively in an obese, diabetic patient which healed uneventfully with wet to dry dressing changes.

A significant improvement in VAS scores was observed from a preoperative mean of 7.7±1.47 to 1.28±1.50 ($p<0.001$) at the first postoperative follow up. As shown in Figure 1, a significant improvement was maintained at all subsequent postoperative visits ($p<0.001$). At three months follow-up, the mean VAS score was 0.78±1.23.

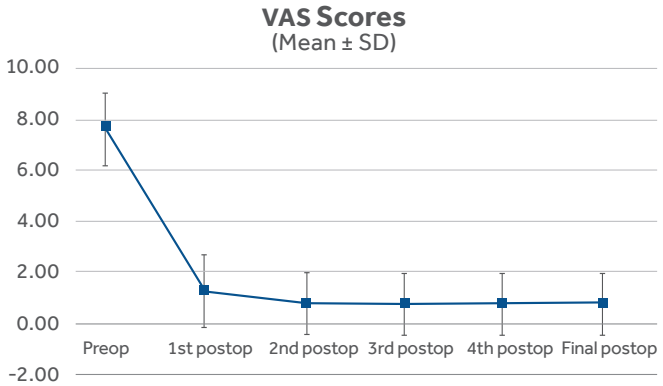


**Figure 1**

At baseline, all patients were taking prescribed narcotics for pain. By two weeks postoperatively, narcotic usage had declined in most of the patients. Nineteen of the 40 patients (47.5%) were still using narcotics. Approximately three months after surgery, 75% of patients were no longer taking prescribed narcotics for spinal pain, but continued usage was observed in 10 patients (25%). Of those patients, the mean MME (morphine milligram equivalent) declined from 28.42 ± 13.8 mg two weeks after surgery to 13.5±9.4 mg at final follow-up. Most patients were able to resume full activity by 4.2 weeks and the return to work averaged 4.4 weeks.

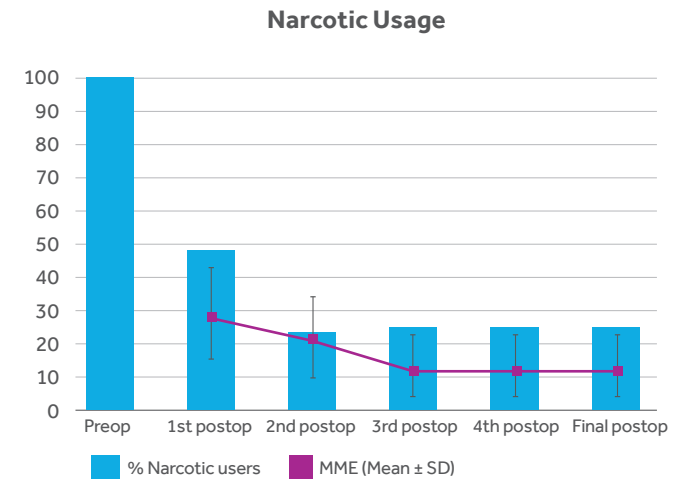


**Figure 2**

## CONCLUSION

This study describes the experience of a single, fellowship- trained orthopedic spine surgeon performing SI joint fusions using a novel, posterior approach in 40 consecutive patients. The Rialto SI Fusion System device and the posterior oblique approach allowed for a procedure with rapid mobilization of patients. All patients pain scores improved significantly over time. At an average of 25.7 months, there was continued improvement of pain scores in all patients. Besides the retrospective nature of the study, other study limitations include the less powerful statistical method for the VAS scores, which were not normally distributed.

## REFERENCES


1. Lorio, M.P., ISASS Policy 2016 Update - *Minimally Invasive Sacroiliac Joint Fusion*. Int J Spine Surg, 2016. 10: p. 26.
2. Zaidi, H.A., A.J. Montoure, and C.A. Dickman, *Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature*. J Neurosurg Spine, 2015. 23(1): p. 59-66.
3. Internal Data on File. Data was obtained through a survey of surgeons who had experience with both approaches.


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