

High Prevalence of SI Joint Pain in Patients Undergoing Thoracolumbar Fusion with Pelvic Fixation for Adult Spine Deformity:

Influence of a threaded implant design and manufacturing on osseointegration

Initial Results from a Multicenter Randomized Trial

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INTRODUCTION

Adult spine deformity (ASD) is characterized by degenerative changes that may cause neural compression, leading to low back pain, requiring spinal fusion¹. Pelvic fixation with bilateral S2AI screws is current standard practice in multilevel (≥ 4 levels) lumbar fusions.

- Pelvic fixation failure rates as high as 35% in ASD surgery, including²:
 - Set screw dissociation
 - Screw breakage / loosening

Fixation failures and sacroiliac (SI) joint pain are likely related to continued motion of the SI joint with use of single point of fixation. Thus, triangular titanium implants (TTI) have been designed to fuse the SI joint.

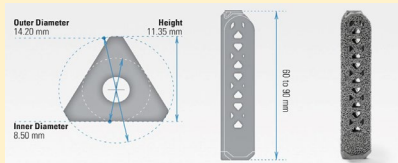
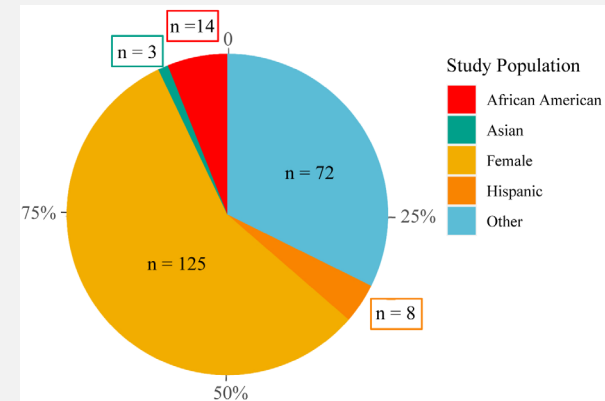


Figure 1. Triangular titanium implant designed to enhance osteointegration³.

METHODS

- Prospective, international, multicenter randomized controlled trial with follow up out to 2 years.
- Subjects were randomized 1:1 to receive either S2AI screws alone or S2AI + TTI. Baseline spinal deformity measures were read by an independent radiologist.
- Site-reported perioperative adverse events were reviewed by a clinical events committee.
- Quality of life questionnaires and other clinical outcomes are in process.



Subjects: Patients with ASD scheduled for multilevel spine fusion surgery with pelvic fixation, randomized to

- I. S2AI screws. (n = 113)
- II. S2AI + TTI placed cephalad to S2AI screws. (n = 109)

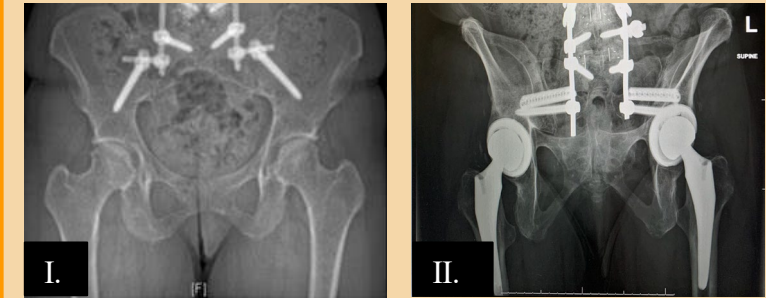


Figure 2. Anterior radiographic images of **I.** patient with ASD treated with S2AI screws and **II.** Patient with ASD treated with S2AI + TTI⁴.

OUTCOME MEASURES: Perioperative safety and incidence of pelvic fixation failures, and SI joint pain during long-term follow-up.

AIM: Determine the clinical benefit of simultaneous placement of TTI adjacent to S2AI screws during multilevel spine fusion surgery with pelvic fixation.

RESULTS

- No difference in overall rate of adverse event across treatment groups (Fisher test p=.4018).
- TTI placement was successful in 106 of 109 (98%) subjects assigned to TTI.
- 35/222 (16%) of all subjects had a history of SI joint pain or were diagnosed with SI joint pain during preoperative workup.

CONCLUSION: Sacroiliac (SI) joint pain is common in patients with adult spinal deformity. Concurrent placement of triangular titanium implants (TTI) cephalad to S2AI screws was feasible and associated with a low rate of adverse events.