

Pelvic Fixation for Adult Spine Deformity: Two Year Results from an International, Multicenter, Randomized Trial

Joshua Paul Herzog, Gregory Michael Mundis, Jean-Christophe Leveque, Robert Kenneth Eastlack, Isador H Lieberman, Han Jo Kim, Ryan D Snowden, Jonathan N Sembrano, Benjamin D Elder, David W Polly

INTRODUCTION:

Pelvic fixation is used in multilevel fusion constructs to the sacrum to improve fusion of the lumbosacral junction, reduce mechanical failures, and maintain surgical correction of alignment. Pelvic fixation may also reduce incidence of postoperative sacroiliac joint (SIJ) pain, a complaint reported to occur in up to 30% of patients after fusion to the pelvis.

METHODS: A prospective, randomized trial was conducted at 29 centers in the US, EU, and AUS. 222 patients undergoing surgery for adult spinal deformity to the pelvis were enrolled and randomized to S2AI alone (control; n=113) or S2AI plus a triangular titanium fusion implant (TTI; n=109). Randomization was stratified based on planned upper instrumented level (UIV) and preoperative presence of SIJ pain. Patient reported outcomes (PROs), SIJ pain, and adverse events were assessed postoperatively at months 1, 6, 12 and 24. The study's primary clinical endpoint was onset of new SIJ pain by 2 years.

RESULTS: At baseline, 16% of patients were diagnosed with preoperative SI joint pain. No difference was seen in: demographic factors, planned UIV, or preoperative SIJ pain. No spinopelvic parameters were predictive of preoperative SIJ pain. On average, 8 (3.4 SD) levels were fused, 75% of patients received an interbody cage at L5/S1, and 48% had previous lumbar spinal fusion. At 2 years after surgery, new onset of SIJ pain was significantly higher in the control group (9.6% vs 1.0%, p=0.02) with no difference across groups on any other PROs. Overall incidence of L5-S1 rod fracture was low (4%) with no difference between groups. S2AI screw breakage was higher in the control group (1.8% v 0.9%, p=0.1). Tulip dislodgement was observed in 2 of 113 control patients (0.02%) and no TTI patients. A total of 35 revisions occurred in the control group and 45 in the TTI group. Of these, 14 revisions in the control group and 9 in the TTI group involved pelvic revisions.

DISCUSSION AND CONCLUSION: SIJ pain is present preoperatively in almost 1 in 5 patients with adult spinal deformity. Concurrent placement of TTI with S2AI screws during multilevel spine fusion surgery is safe and associated with a marked reduction in the incidence of new postoperative SIJ pain. TTI placement reduced the rate of S2AI screw breakage, tulip failure, and set screw dissociation.