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Early Results of Minimally Invasive Sacroiliac Joint Fusion with Lateral Transfixing Technique: Insights from the STACI Study

Christopher Mallard, Michael Harned, Timothy Davis, Jacqueline Weisbein, Denis Patterson, Jack Smith, Anne Christopher, Dan Kloster, Jeff Foster, Dan Nguyen, Charles Simmons, John Hatheway, Douglas Beall, Caroline Harstroem, Andrew Trobridge, John Broadnax, Eric Anderson
University of Kentucky

Introduction

Minimally invasive sacroiliac joint (SIJ) fusion has become a mainstay treatment for chronic refractory sacroiliac joint dysfunction. Various techniques are now available, including transfixing methods where implants are positioned through lateral or posterolateral transiliac trajectories, and intra-articular techniques involving devices and/or allografts inserted via a dorsal approach.¹ The majority of the literature has been published by surgeons.

STACI (NCT 05870488) is a prospective, multicenter study that will evaluate the safety and efficacy of lateral SIJF when performed by interventional pain management physicians. 110 enrolled participants across 15 sites will be followed at regular intervals for 2 years. The primary endpoint is SIJ pain change from baseline at 6 months; secondary endpoints include improvements in pain, function, and quality of life at all time points, and CT evidence of fusion at 2 yrs. Herein we present interim three-month results.

Materials and Methods

STACI is an ongoing prospective, multicenter single-arm clinical trial. The study protocol (registered on clinicaltrials.gov [NCT 05870488]) was institutional review board (IRB) approved at each participating site prior to patient enrollment. The study is being conducted according to the Declaration of Helsinki and ISO 14155. Adults with a confirmed diagnosis of SIJ disorders using NASS criteria, refractory to non-operative care were screened for eligibility. Eligibility criteria include: SIJ pain score $\geq 5/10$, ODI score $\geq 30\%$, excluded are those with prior SIJF, severe non-SIJ back pain, interfering comorbidities, and worker's compensation. Those who agreed to participate in the study were enrolled by providing written informed consent.

Baseline and procedural characteristics, patient reported outcomes at 1- and 3-month follow-up, and adverse events are reported. Follow-up visits are conducted at 1-, 3-, 6-, 12-, and 24-months post-surgery to monitor for adverse events, usage of medications, and patient-reported outcomes.

Results/Case Report

To date, 89 enrolled participants have been treated, and 63 have completed the 3-month follow-up visit. Mean (SD) age is 64 years (14), BMI is 29 (5), 65% are female, 31% had prior lumbar or lumbosacral spine fusion, and 35% were on opioids at baseline. Mean (SD) operative time was 47 minutes (16) and EBL was 14 cc (14). All subjects were treated in either an ambulatory surgery center or hospital outpatient setting and 82% of procedures were done under

general anesthesia (GA). No intraoperative or device related adverse events have occurred.

At 3 months, mean (SD) SIJ pain, measured on 0-10 numerical rating scale, decreased from 7.6 (1) at baseline to 2.4 (2). Function as measured on ODI improved from 51.6 (14) to 28.1 (16) (Fig.1).

Discussion

The interim results of this prospective trial support the safety and efficacy of lateral SI joint fusion using a threaded implant when performed by interventional pain physicians. Patient-reported improvements in pain and function were commensurate with previous reports²⁻⁴. Full results of this multicenter trial are expected at the end of 2026.

References

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Disclosures

No

Tables / Images

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