

MIS SI Joint fusion using a lateral transfixing procedure

Early outcomes from the prospective, multicenter STACI study

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Introduction

Minimally invasive SIJ fusion using metallic implants via a lateral trans-iliac approach has shown significant outcome improvements. Initially performed by surgeons due to neurovascular risks, interventional pain management (IPM) physicians are now performing these fusions, though outcomes remain unpublished.

STACI (iFuse TORQ for the treatment of sacroiliac joint dysfunction) (NCT 05870488) is a prospective, multicenter study that will enroll 110 subjects across 15 Interventional Pain Management sites in the US and will follow them for 2 years. Herein we present an interim analysis of three-month outcomes.

Primary Endpoint: The change from baseline in SIJ pain on NRS at 6 months.

Secondary Endpoints: Changes in pain, function, quality of life, device or procedure-related adverse events, and evidence of fusion as observed on a CT scan obtained at 2 years.

Methods

Brief eligibility criteria include:

- Confirmed diagnosis of SIJD refractory to 6 months of conservative care
- Baseline ODI > 30% and SIJ pain score >5 on a 10 pt scale.
- No previous SIJ surgeries on index side or recent history of pelvic trauma.

Collected at 1, 3, 6, 12, and 24 months after surgery:

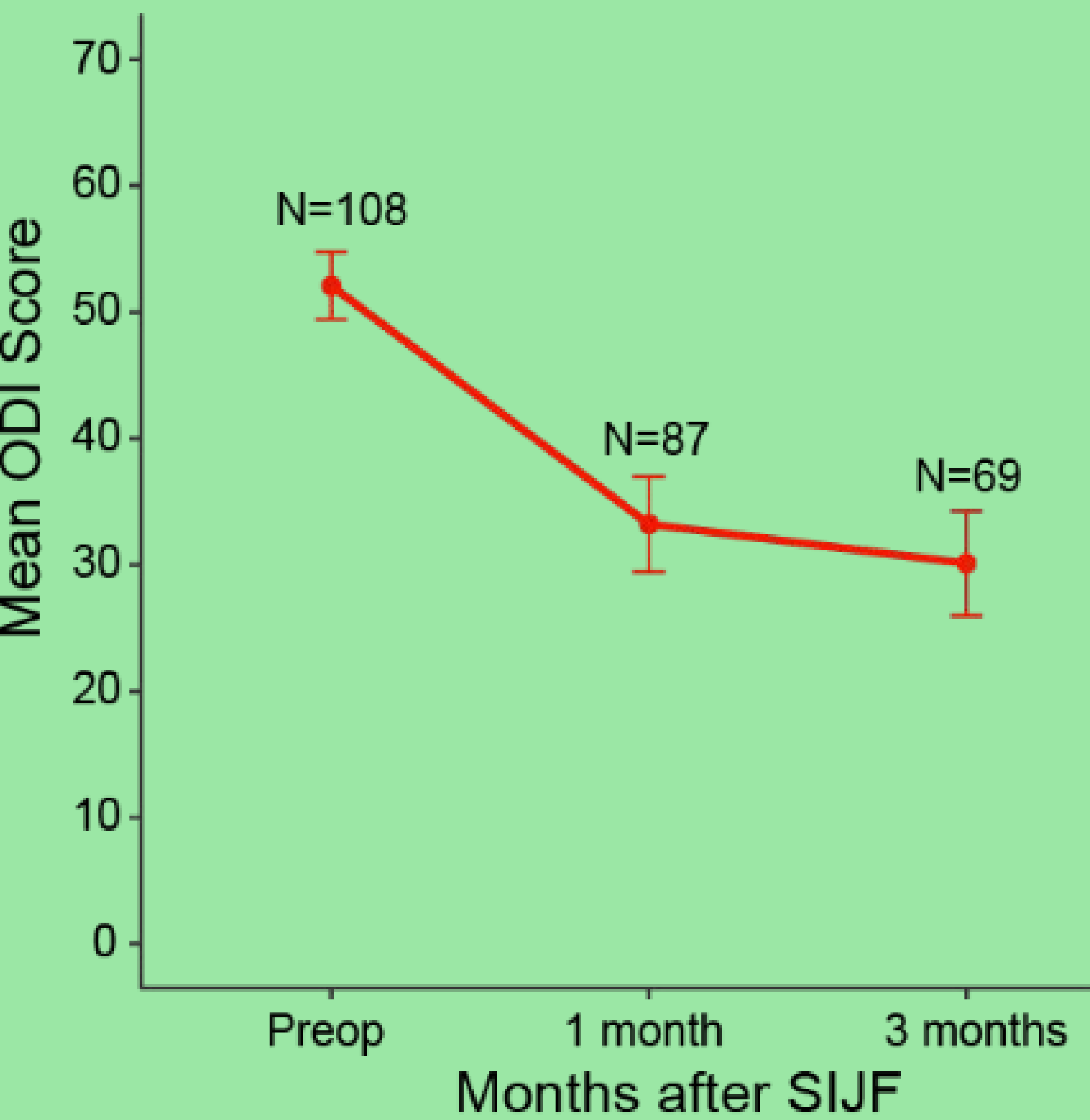
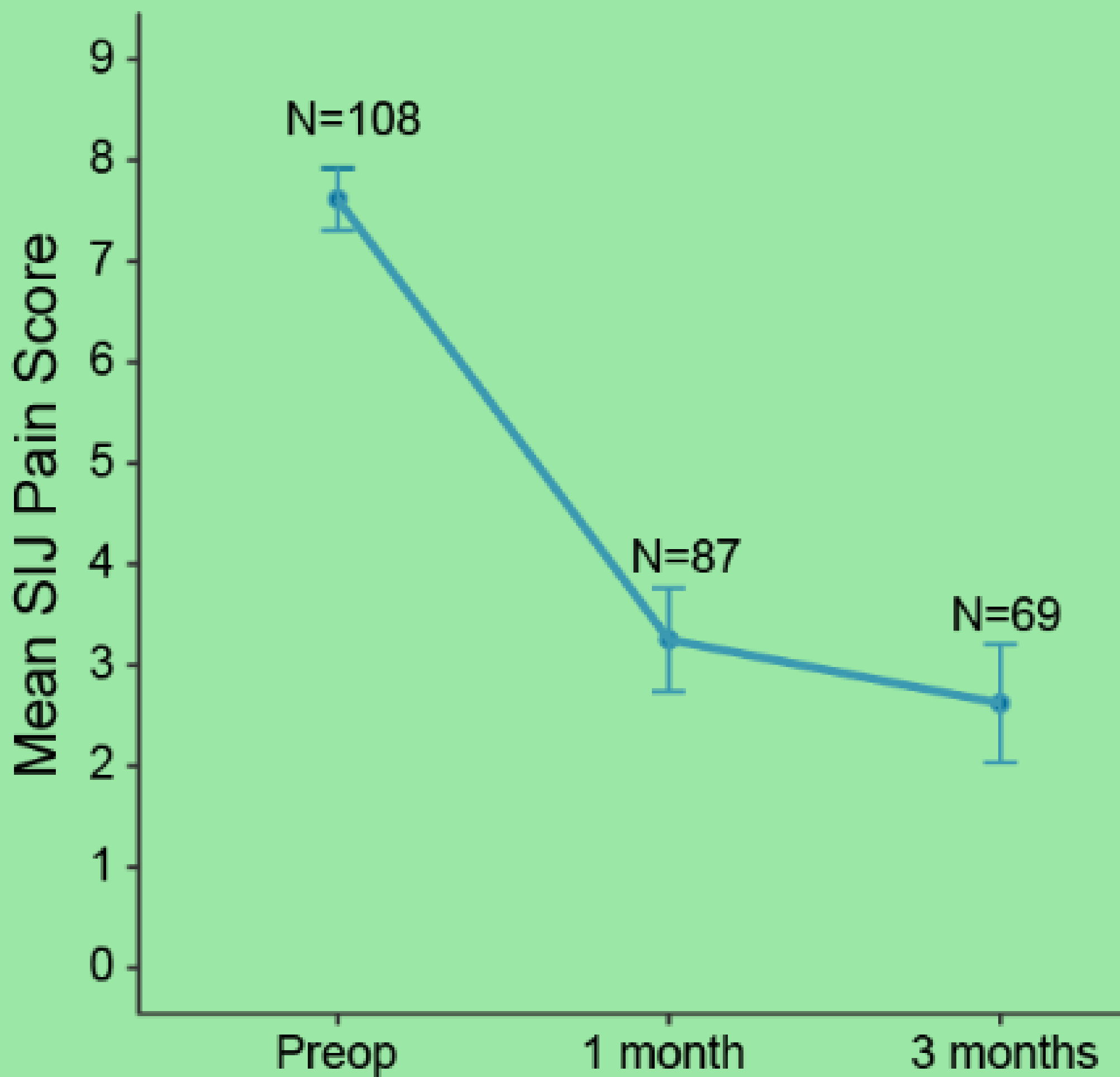
- NRS, ODI, PROMIS-29
- Device or procedure related adverse events

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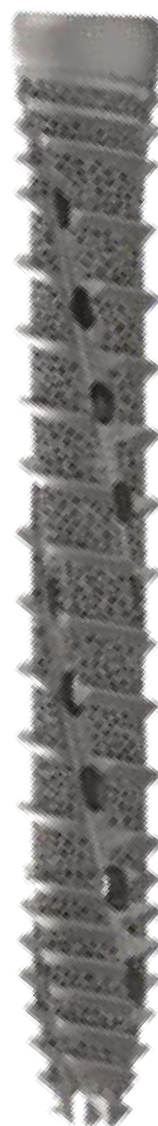
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The interim results of this prospective trial strongly confirm the safety and efficacy of lateral SI joint fusion.



Results

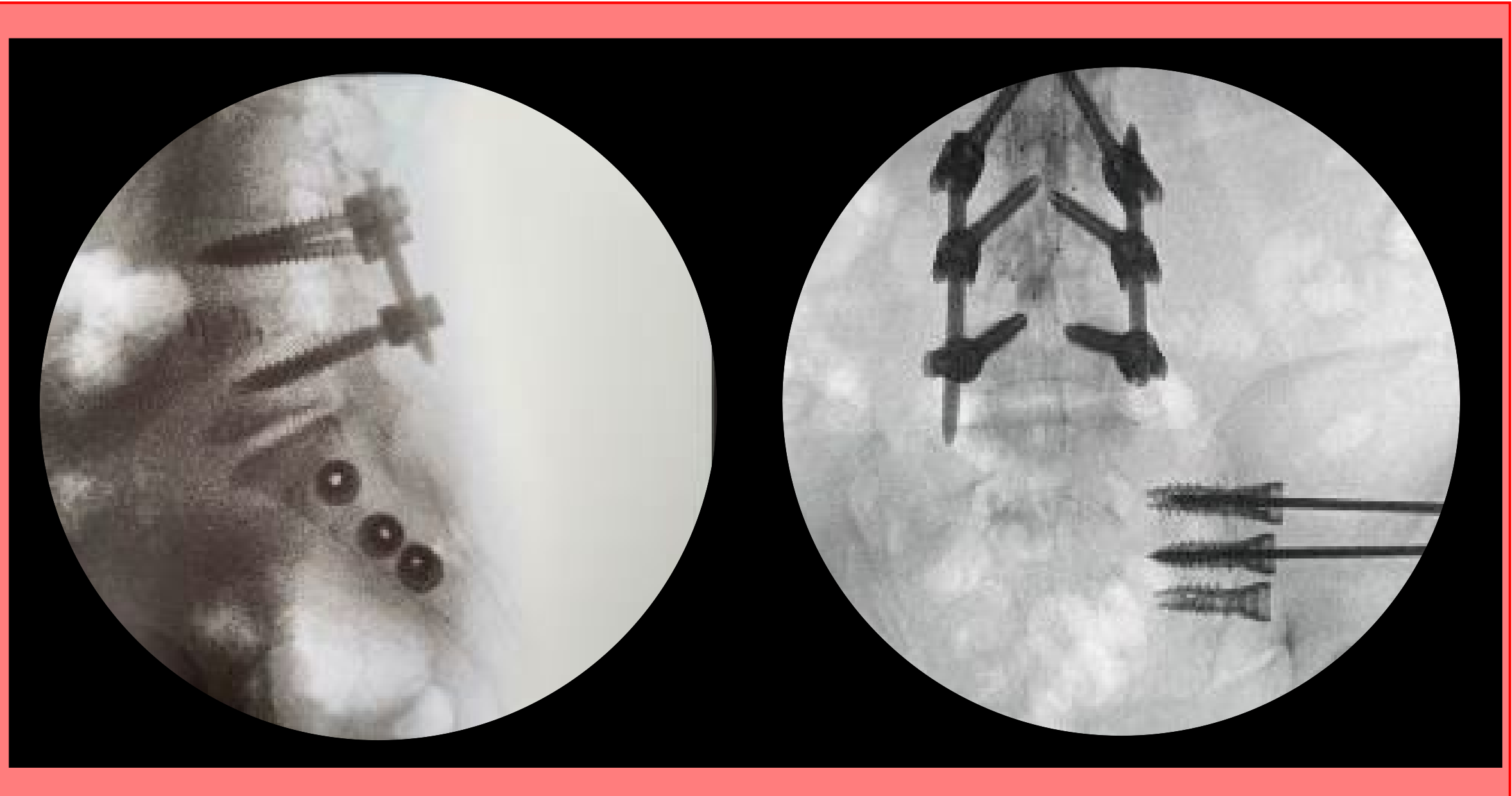


Baseline Characteristics

Subjects treated , n	108
Mean age (SD)	63.5 yrs (14)
Mean BMI (SD)	29.1 (5.2)
Female	67.6%
Prior spine fusion	44.3%

Procedural Metrics (n = 108)

Mean OR time (SD)	44.7 min (16.1)
Est. blood loss (SD)	13.8 cc (15.7)
Procedure Location	63.9% ASC 36.1% HOPD
Device-related AE	0
Serious Adverse Events	0



Fluoroscopy images of metal implants placed using a lateral transiliac trajectory.

Primary endpoint results at 6-months are expected at the end of 2024, with final study results, including 2-yr CT scan, expected by the end of 2026.