

# Lateral Transiliac MIS SI Joint Fusion: 1-Year Follow-Up Results from the Prospective Multicenter STACI Trial

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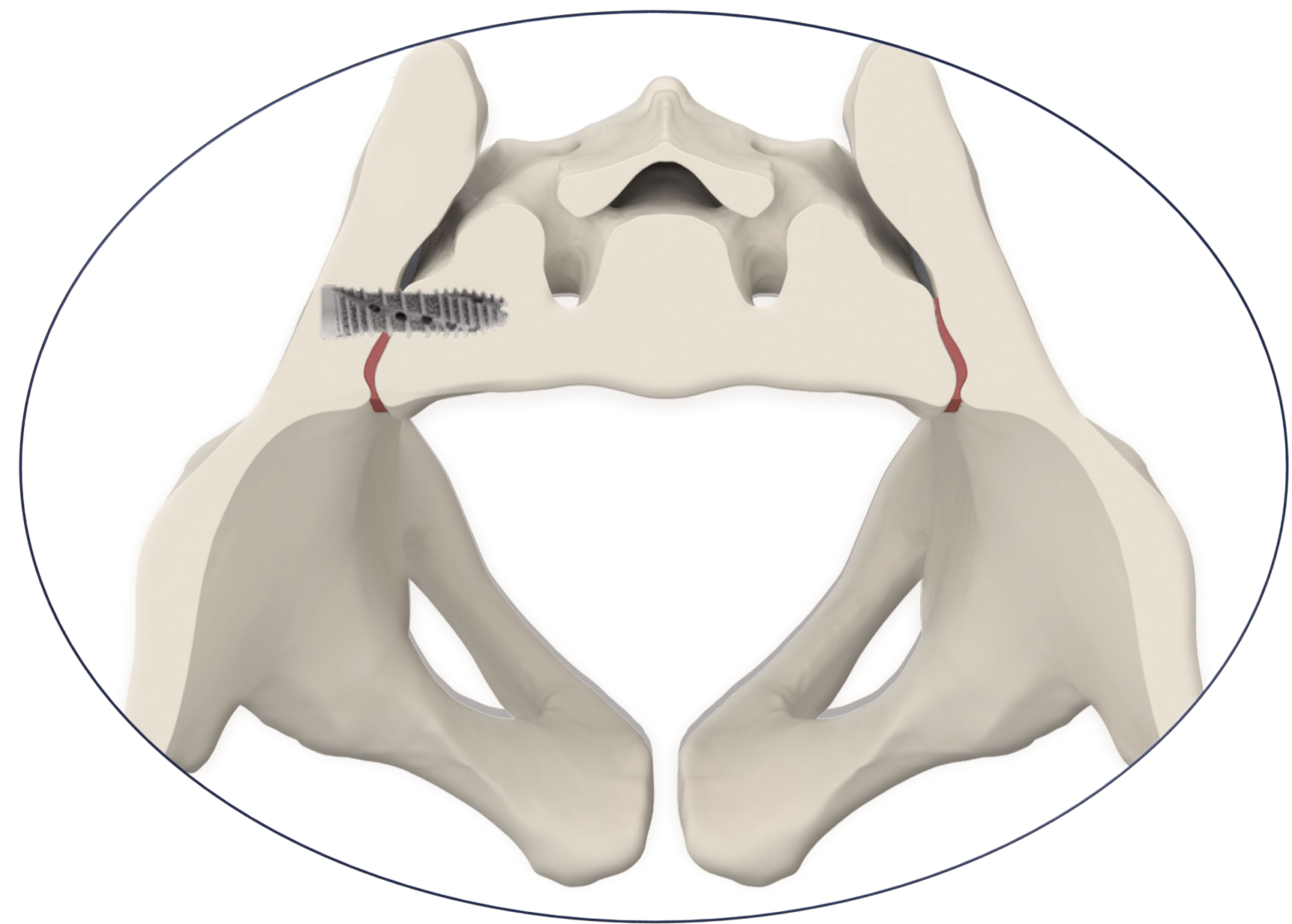


## INTRODUCTION

**Objective:** Evaluate outcomes with lateral SIJ fusion when the procedure is performed by IPM physicians

**Background:** Sacroiliac joint (SIJ) dysfunction is responsible for 15-30% of persistent lower back pain. Minimally invasive SIJ fusion using metallic implants in a lateral transiliac trajectory is supported by significant improvements in pain, disability, and quality-of-life parameters. Historically performed by surgeons, interventional pain management (IPM) physicians are now performing these fusions, though outcomes remain unpublished.

STACI (iFuse T<sub>OR</sub>Q for the treatment of sacroiliac joint dysfunction) (NCT 05870488) is a prospective, multi-center, single-arm clinical trial of lateral SIJ fusion performed by IPM physicians using threaded titanium implants. 110 subjects were enrolled across 15 Interventional Pain Management sites in the US. Herein we present primary and secondary endpoint results.



Lateral SIJ Fusion

## METHODS

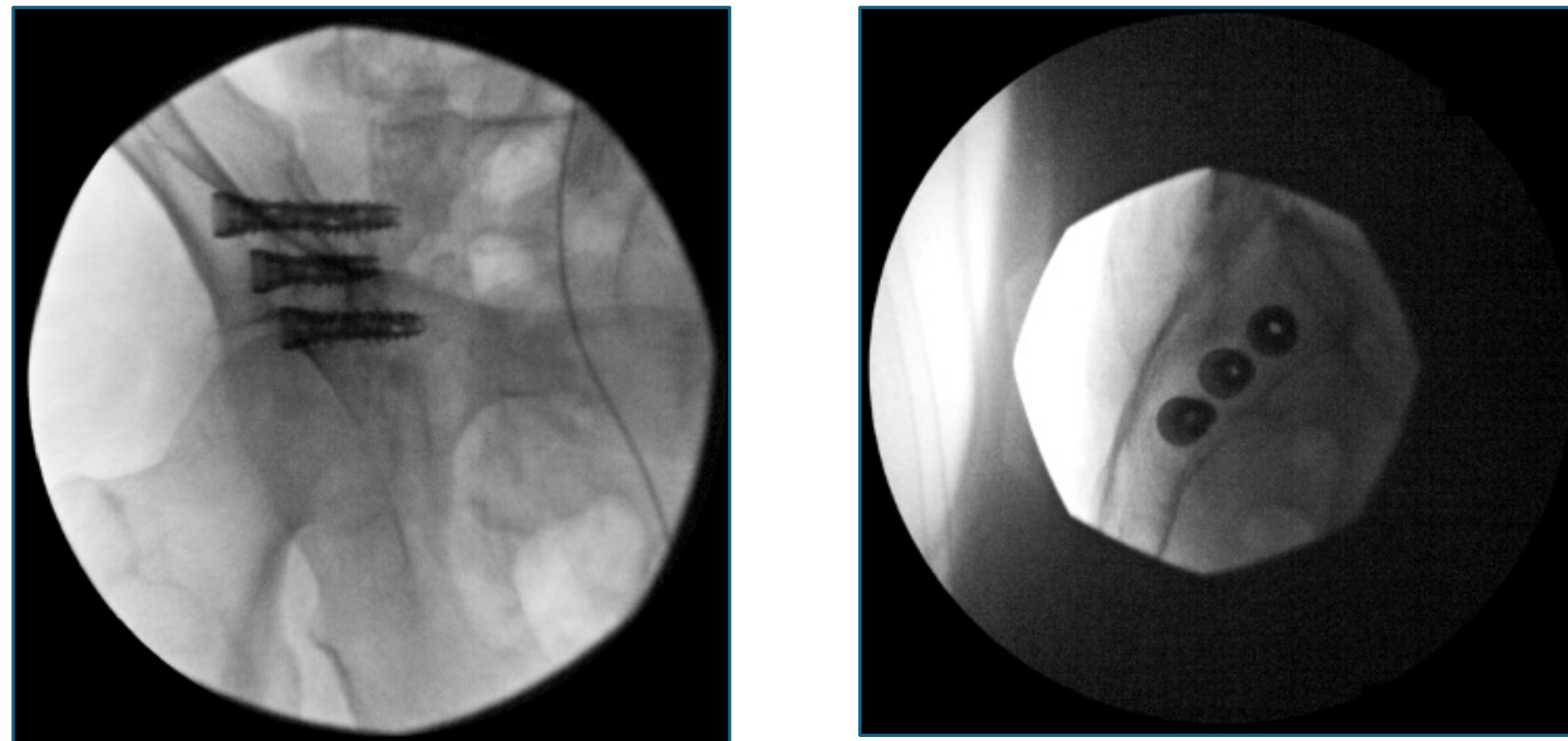
**Primary Endpoint:** The change from baseline in SIJ pain on NRS at 6 months.

**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.

- 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.

The following data are collected at 1, 3, 6, 12, and 24 months after surgery:

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

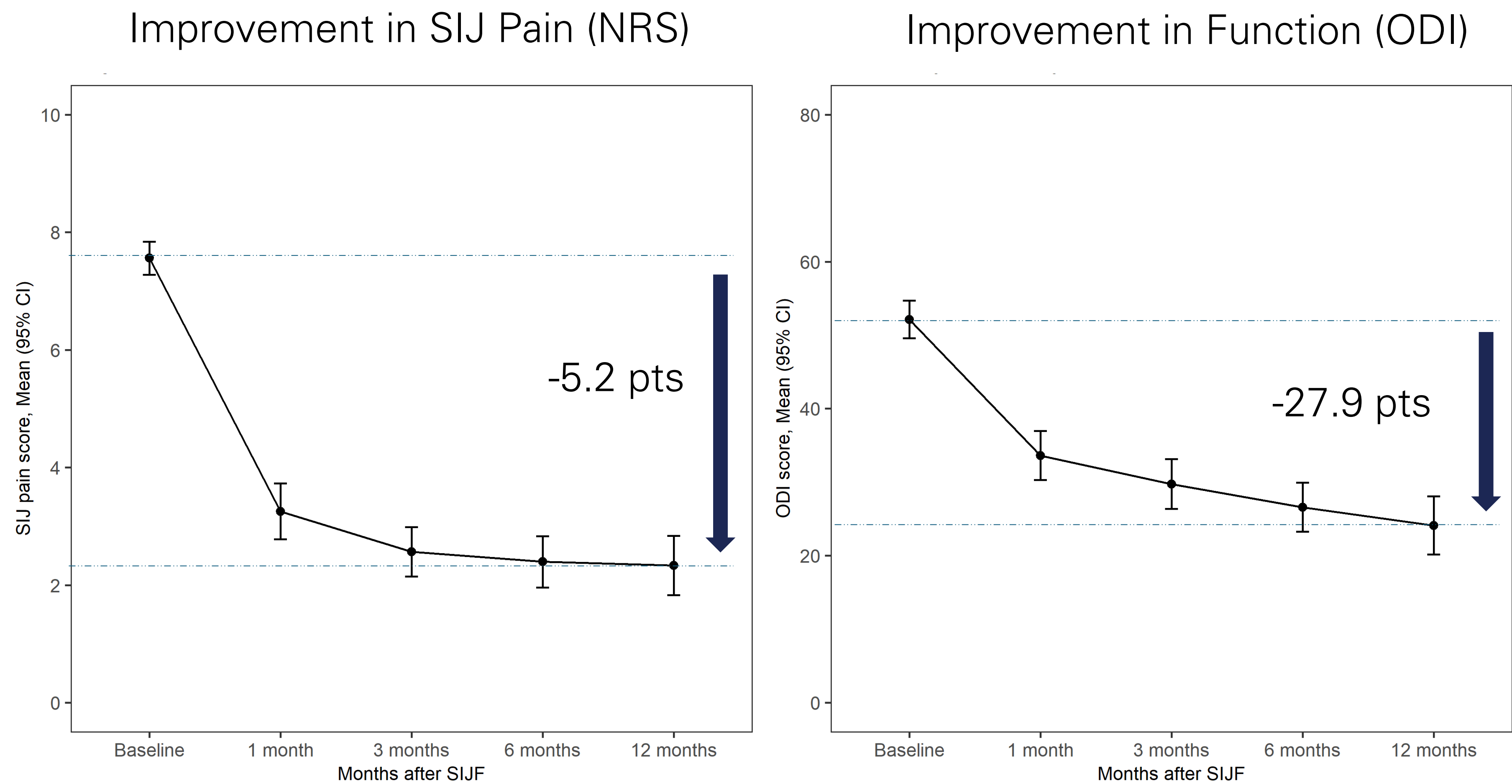


Fluoroscopy images of metal implants placed using a lateral transiliac trajectory.

## RESULTS

| Procedural Metrics                                                   |                 |
|----------------------------------------------------------------------|-----------------|
| Mean OR time (SD)                                                    | 44.3 min (15.8) |
| Est. blood loss (SD)                                                 | 12.5 cc (12.1)  |
| AEs possibly, probably or definitely related to procedure or implant | 4               |
| Serious Adverse Events                                               | 0               |

| Baseline Characteristics |                 |
|--------------------------|-----------------|
| Subjects treated, n      | 112             |
| Mean age (SD)            | 63.8 yrs (14.1) |
| Mean BMI (SD)            | 29.5 (5.1)      |
| Female                   | 67.9%           |
| On opioids               | 43.8%           |



**CONCLUSION:** Lateral SIJ fusion performed by IPM physicians is safe and effective, producing substantial and clinically meaningful improvements in pain and function at one year.