

Four-year outcomes after minimally invasive transiliac sacroiliac joint fusion with triangular titanium implants

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Background: Increasing long-term evidence supports the safety and effectiveness of minimally invasive sacroiliac joint fusion (SIJF) for sacroiliac joint (SIJ) dysfunction, an important cause of chronic low-back/buttock pain.

Objective: To report 4-year follow-up in patients undergoing SIJF using triangular titanium implants (TTI) as part of two prospective trials.

Methods: We enrolled 103 subjects at 12 centers treated with TTI in two prospective clinical trials (NCT01640353 and NCT01681004) and followed them in the current study (NCT02270203), with clinic visits at 3, 4, and 5 years.

Results: At 4 years, mean SIJ pain scores (available in 91 subjects [88.3%]) had decreased by 54 points from baseline; disability (Oswestry Disability Index) scores decreased by 26 points; and quality of life (EuroQOL-5D) improved by 0.3 points (0–1 scale). Satisfaction rates were high and the proportion of subjects taking opioids decreased from 77% at baseline to 43% at 4-year follow-up.

Conclusion: Four-year follow-up showed continued excellent responses in patients with SIJ pain treated with SIJF using triangular titanium implants.

Keywords: sacroiliac joint fusion, chronic low back pain, multicenter prospective trial

Introduction

Approximately 15%–30% of all chronic low-back pain involves the sacroiliac joint (SIJ).^{1–5} Increasing evidence supports the safety and effectiveness of SIJ fusion in patients with chronic SIJ dysfunction, and several device systems are now available. The most commonly studied device – triangular titanium implants (iFuse Implant System, SI-BONE, Santa Clara, CA, USA) – is supported by prospective clinical trials^{6–8} as well as a pooled analysis of those trials⁹ and numerous case series.^{10–18} Herein, we report 4-year prospective follow-up, updating a previously published report of the same cohort at 3 years.¹⁹

Methods

As previously described, subjects in this study (LOIS, Long Term Outcomes from INSITE and SIFI, NCT02270203) were enrolled at 12 centers that participated in two feeder trials: INSITE (NCT01681004, a prospective, randomized controlled trial of SIJ fusion vs non-surgical management)⁶ or SIFI (NCT01640353, a prospective multicenter single-arm study).⁸ In both feeder studies, patients with SIJ pain – diagnosed by history, physical examination, and confirmatory diagnostic SIJ block with local anesthetic – underwent placement of triangular titanium implants in a lateral transiliac fashion during a brief (typically <1 hour) surgery. In the feeder studies, subjects had

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scheduled follow-up visits up to 2 years. The published 2-year reports showed marked, immediate, and sustained improvements in pain, disability, and quality of life.^{6,8}

Subjects at selected centers enrolled into the current study, which had similar study visits at years 3, 4, and 5 after initial surgery, with telephone visits at 2.5, 3.5, and 4.5 years to maintain contact with participants. At each clinic visit, subjects completed surveys to assess SIJ pain scores using a visual analog (0–100) scale, disability related to back pain as assessed by the Oswestry Disability Index (0 = no disability due to back pain to ≥ 60 = completely disabled),²⁰ using quality of life ([EuroQOL-5D]; on a 0 [death] to 1 [perfect health] scale),²¹ overall satisfaction with the procedure, and use of opioid medications for SIJ pain. Questionnaires were identical to those used in the two feeder studies and were administered by trained study research coordinators. Furthermore, study coordinators recorded all negative changes in health as adverse events. The relatedness of the reported event

to the index procedure or devices used during the procedure was assessed by the treating physician. All centers obtained institutional review board approval for study conduct.

Results

Of the 103 enrolled subjects, 93 (90.3%) completed 4-year follow-up. Marked improvements in pain (54 points), disability (26 points), and quality of life (0.3 points), previously observed at 3 years, were maintained at 4 years (Figure 1). Satisfaction rates remained high, except for a slight reduction in the proportion who were very satisfied. The proportion of subjects taking daily opioids decreased from 77% immediately prior to surgery to 43% at the 4-year follow-up.

In total, 114 adverse events were reported between years 3 and 4; however, none were rated as probably or definitely related to the study devices or index surgical procedure. Many events indicated underlying degenerative disease associated with age and osteoarthritis (eg, hip, knee, shoulder, neck, and

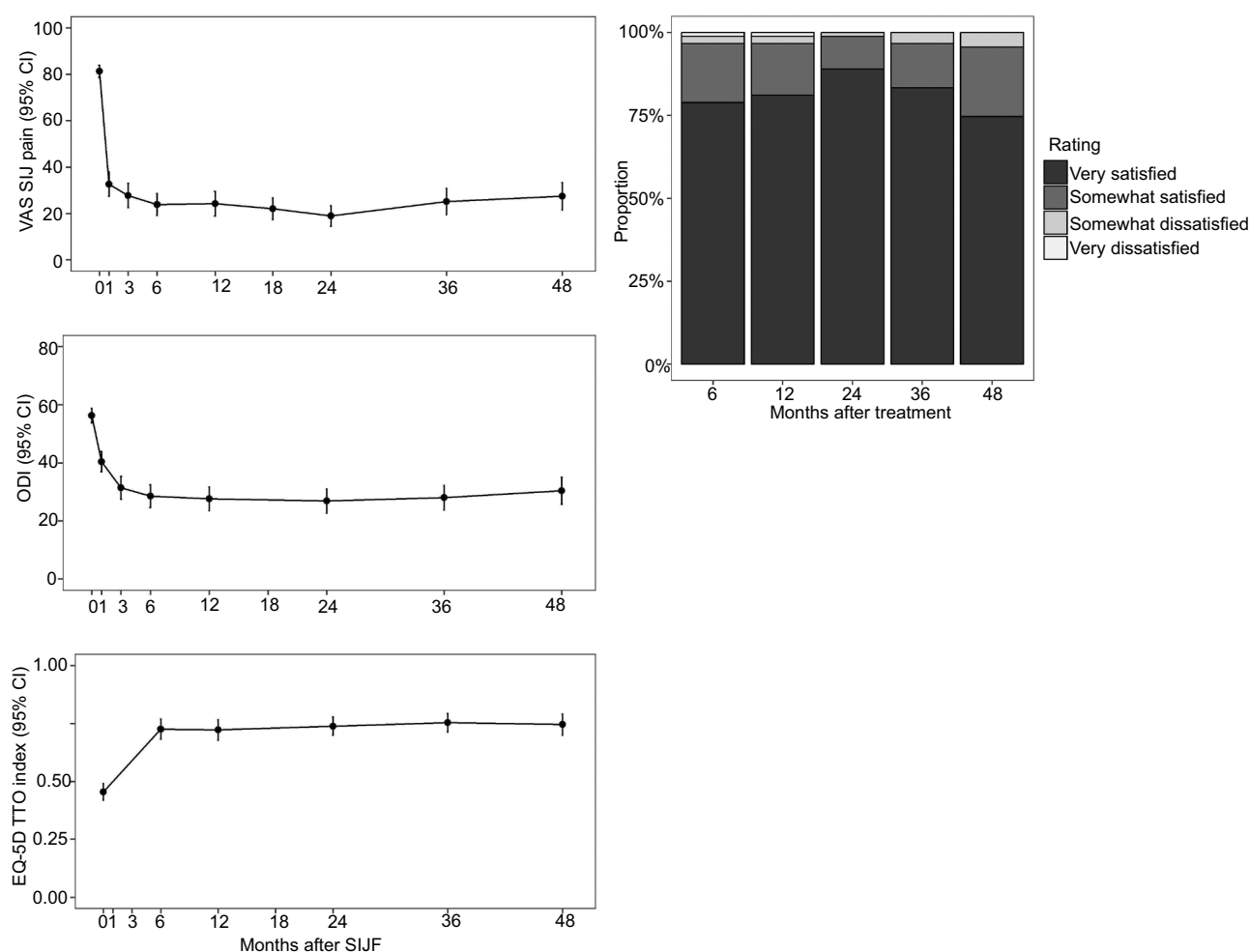


Figure 1 Left: Improvement in SIJ pain (top), dysfunction due to pain (ODI, middle), and quality of life (EQ5D-TTO, bottom). Right: patient satisfaction levels.

Abbreviations: SIJ, sacroiliac joint; SIJF, sacroiliac joint fusion; ODI, Oswestry Disability Index; EuroQOL-5D, quality of life; EQ5D-TTO, EuroQOL-5D time trade-off index.

lumbar spine osteoarthritic degeneration). Other than one previously reported subject who underwent surgical revision of the target SIJ at 3.8 years, no other subjects underwent revision procedures between years 3 and 4.

Discussion

In the past, surgeons overlooked the SIJ as a cause of chronic low-back pain, probably because no feasible surgical treatment was available. Our data, reporting the longest prospective follow-up to date, show that SIJ fusion with triangular titanium implants can provide marked and sustained relief of pain, disability, and quality of life in patients for whom no other treatment had provided clinically important relief. Observed improvements were as large as those seen in other commonly conducted spine surgeries. Our data stand in marked contrast to non-surgical treatments, which have shown poor rates of pain relief and increased opioid use.²²

Summary

In two prospective clinical trials, 103 subjects with sacroiliac joint dysfunction underwent SIJ fusion with triangular titanium implants. At 4-year follow-up, clinical outcomes were preserved, with no new adverse events related to the index procedure or devices.

Acknowledgment

SI-BONE sponsored this clinical trial.

Disclosure

Emily Darr conducts clinical research as part of prospective trials sponsored by SI-BONE. Daniel Cher is an employee of SI-BONE. The authors report no other conflict of interest in this study.

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