

Long-Term Prospective Clinical and Radiographic Outcomes After Minimally Invasive Lateral Transiliac Sacroiliac Joint Fusion Using Triangular Titanium Implants

Whang PG, Darr E, Meyer SC, Kovalsky D, Frank C, Lockstadt H,
Limoni R, Redmond A, Ploska P, Oh M, Chowdhary A, Cher D, Hillen T.
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KEY POINTS

- 5-year follow-up of 93 subjects (90%) from 103 patients at 12 sites enrolled and treated with iFuse in the prospective, multicenter trial **LOIS** (Long Term Outcomes from INSITE and SIFI, [NCT02270203](#))
- **Sustained, clinically important 5-year outcomes:**
(All results $p < 0.0001$, baseline to 60 months)

| | Mean 5-year Improvement | 5-year Clinically Important Notes |
|---|-------------------------|--|
| SI Joint Pain (VAS SI joint) | 54 points | 82% of subjects met primary efficacy composite endpoint (Endpoint Criteria: 20-point improvement, no severe device-related AE, no neurologic AE, and no revision surgery) |
| Back Function (Oswestry Disability Index) | 26 points | 69% of subjects had at least 15-point improvement |
| Quality of Life (EQ-5D Time Trade-off) | 0.29 points | 64% improvement from baseline |

• High Patient Satisfaction

- 95% of patients were very or somewhat satisfied at 5 years.
- Satisfaction correlated with improvement in SI joint pain and disability (ODI).

• Opioid Use Reduction

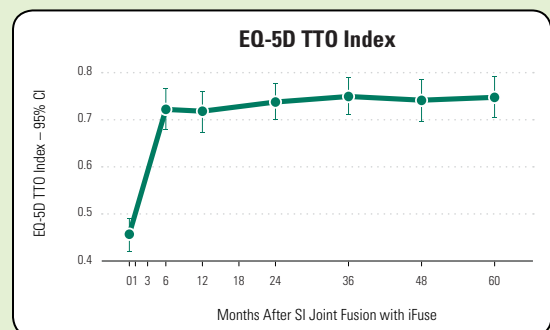
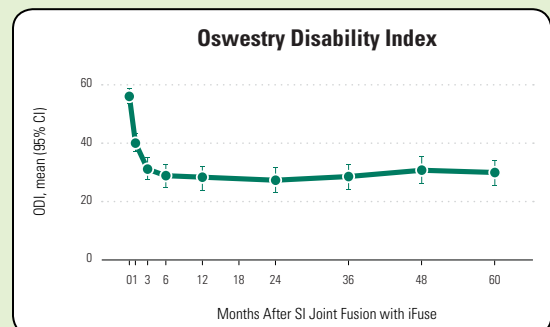
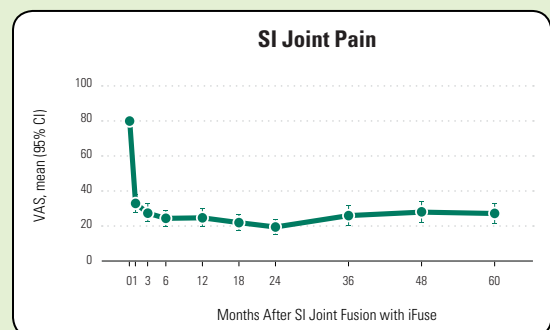
- Percentage of patients using opioids decreased progressively after the procedure from 77% at baseline to 41% at year 5.

• Safety

- 1 device-related adverse event.
- 1 procedure-related serious adverse event.
- 3 subjects (3%) had SI joint revision surgery by year 5.

• Radiographic Outcomes at 5-years

- 88% of subjects had bridging bone within the SI joint.
- 5% (only 6 treated sides) showed radiolucencies in sacral bone suggesting failure of implant integration.



PUBLISHED ABSTRACT

Background: Accumulating evidence supports the long-term safety and effectiveness of minimally invasive sacroiliac joint fusion (SIJF) for sacroiliac joint dysfunction.

Objective: To report 5-year clinical and radiographic follow-up in patients undergoing SIJF using triangular titanium implants (TTI).

Methods: One hundred and three subjects at 12 centers treated with SIJF using TTI in two prospective clinical trials (NCT01640353 and NCT01681004) were enrolled and followed in the current study (NCT02270203) with clinic visits at 3, 4 and 5 years. CT scans performed at 5 years were compared to prior CT scans (at 1 or 2 years) by an independent radiologist.

Results: Compared to baseline scores, SIJ pain scores at 5 years decreased by a mean of 54 points, disability scores (Oswestry Disability Index) decreased by 26 points, and quality of life scores (EuroQOL-5D time trade-off index) increased by 0.29 points (0–1 scale) (all $p < 0.0001$). Satisfaction rates were high and the proportion of subjects taking opioids decreased from 77% at baseline to 41% at 5-year follow-up. Independent radiographic analysis showed a high rate (98%) of bone apposition to implants on both the sacral and iliac sides of the SI joint, with a high rate of bony bridging (88%) and a low rate of radiolucencies suggestive of loosening (5%).

Conclusion: A 5-year follow-up showed continued excellent clinical responses in patients with SIJ pain treated with SIJF using triangular titanium implants along with a high rate (88%) of joint fusion.

Level of evidence: Level II.

Keywords: sacroiliac joint pain; sacroiliac joint degeneration; arthrodesis; sacroiliac joint fusion

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