

Six-month outcomes from a randomized controlled trial of minimally invasive SI joint fusion with triangular titanium implants vs conservative management

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Abstract

Purpose To compare the safety and effectiveness of minimally invasive sacroiliac joint fusion (SIJF) using triangular titanium implants vs conservative management (CM) in patients with chronic sacroiliac joint (SIJ) pain.

Methods 103 adults with chronic SIJ pain at nine sites in four European countries were randomly assigned to and underwent either minimally invasive SIJF using triangular titanium implants ($N = 52$) or CM ($N = 51$). CM was performed according to the European guidelines for the diagnosis and management of pelvic girdle pain and consisted of optimization of medical therapy, individualized physical therapy (PT) and adequate information and reassurance as part of a multifactorial treatment. The primary outcome was the difference in change in self-rated low back pain (LBP) at 6 months. Additional endpoints included quality of life using EQ-5D-3L, disability using

Oswestry Disability Index (ODI), SIJ function using active straight leg raise (ASLR) test and adverse events. NCT01741025.

Results At 6 months, mean LBP improved by 43.3 points in the SIJF group and 5.7 points in the CM group (difference of 38.1 points, $p < 0.0001$). Mean ODI improved by 26 points in the SIJF group and 6 points in the CM group ($p < 0.0001$). ASLR, EQ-5D-3L, walking distance and satisfaction were statistically superior in the SIJF group. The frequency of adverse events did not differ between groups. One case of postoperative nerve impingement occurred in the surgical group.

Conclusions In patients with chronic SIJ pain, minimally invasive SIJF using triangular titanium implants was safe and more effective than CM in relieving pain, reducing disability, improving patient function and quality of life.

Keywords Sacroiliac joint dysfunction · Pelvic girdle pain · Sacroiliac joint fusion · Titanium sacroiliac implant · Randomized controlled trial · Conservative management · iFuse Implant System

The members of iMIA Study Investigators/study coordinators are listed in “[Appendix](#)”.

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Introduction

Pain from the sacroiliac joint (SIJ) was first described in the 1800s [1]. Often described as a form of pelvic girdle pain (PGP), SIJ pain was believed to be the major source of low back pain (LBP) in the early twentieth century [2, 3]. The discovery of disc herniation in the 1930s [4] turned the focus from the SIJ to the intervertebral disc as a pain source. Since treatment of disc pathology does not always result in LBP relief, interest has resurfaced in the SIJ as potential source of LBP. Recently several reports estimate that 15–30 % of LBP is caused by the SIJ [5, 6]. The SIJ

may be an even more common pain source after lumbar fusion [7, 8].

LBP is an important socioeconomic problem, increasing the risk of early retirement and poverty in patients older than 45 years [9]. Although conservative management (CM) remains the first-line treatment for SIJ pain, a significant number of patients do not respond well, resulting in unremitting pain. The innervation, movement and elucidation of basic biomechanics [10–12] of the SIJ justify its treatment with sacroiliac joint fusion (SIJF). Approaches to SIJF were reported as early as the 1920s [13, 14] and case series of open SIJF report modest to good effectiveness [15–19]. However, open surgery is demanding for both the surgeon and patient since it results in substantial blood loss, pain and morbidity from soft tissue disruption, and a high frequency of non-union [16, 19, 20]. Therefore, minimally invasive techniques [21], which can also be performed percutaneously [22], were developed to reduce postoperative morbidity while maintaining or improving upon effectiveness. Some comparative studies suggest that minimally invasive strategies may be superior to open strategies [23–25]. Herein, we present the first prospective multicenter European study comparing the safety and effectiveness of minimally invasive SIJF using triangular titanium implants vs CM for patients with chronic SIJ pain.

Methods

iFuse Implant System Minimally Invasive Arthrodesis (iMIA, NCT01741025) is an ongoing prospective, open-label, multicenter randomized controlled trial. Enrollment took place between June 2013 and May 2015 at 9 spine care clinics in Europe. The clinical investigational plan was approved by all relevant ethics committees prior to first patient enrollment and all study data were 100 % source verified.

Patient population

The target patient population was adults with chronic, disabling SI joint pain unrelated to acute trauma or underlying inflammatory disease. Patients were between 21 and 70 years old, had LBP for >6 months (or >18 months for pregnancy-related pain), were diagnosed with the SI joint as the primary pain generator based on the following 3 criteria: (1) pain was present at or close to the posterior superior iliac spine (PSIS) and patient could point with a single finger to the location of pain (Fortin Finger Test [26]), (2) at least 3 positive findings on 5 provocative physical examination maneuvers for SIJ pain, and (3) at least 50 % pain reduction on fluoroscopically guided injection of local anesthetic into the joint (SIJ block).

Examples of physical examination maneuvers for SIJ pain are shown in Fig. 1. The predictive value of physical examination maneuvers for a positive SI joint block is fairly high, especially when multiple physical examination tests are positive [27].

Enrollment also required a baseline Oswestry Disability Index [28] (ODI) score of at least 30 %, a baseline LBP visual analog score (VAS) of at least 50 (0–100 scale) and signed consent form. Key exclusion criteria included: severe LBP due to other causes, autoimmune sacroiliitis, recent pelvic trauma, spine surgery in the last 12 months, diagnosed or suspected osteoporosis and allergy to titanium.

Randomization and masking

Subjects were assigned at random in a 1:1 ratio after eligibility and baseline assessments by study coordinators using a password-protected web site. Randomization sequences were computer-generated using a random number generator. We used a stratified randomization process that was stratified by both site and pregnancy as a cause of SIJ pain. Subjects and researchers were not blinded to treatment.

Interventions

Conservative management was designed according to the European guidelines for the diagnosis and management of pelvic girdle pain [29]. CM consisted of (1) optimization of medical therapy, (2) individualized physical therapy (PT) that focused on mobilization and stabilization exercises for control and stability, and (3) adequate information and reassurance of the patient as part of a multifactorial treatment. CM subjects were asked to undergo PT sessions at least twice per week for up to 8 weeks. The protocol allowed cognitive behavioral therapy (CBT) as part of CM, but this was not available at all sites and no high quality evidence suggests that it is effective in chronic SIJ pain. The protocol specifically noted that interventional procedures (e.g., SI joint steroid injections, radiofrequency ablation of lateral branches of sacral nerve roots) are not part of CM.

Minimally invasive SIJF was performed using iFuse Implant System[®] (SI-BONE, Inc., San Jose, CA, USA) as described previously [30]. The device system is CE marked for SIJF. Subjects requiring treatment of both SI joints could undergo staged procedures. To reduce SI joint micromotion or rotation after surgery, the implant is designed in a triangular shape for interference fit and immediate joint stabilization. For the first 3 weeks after surgery patients were kept at heel-toe touchdown weight-bearing which was then increased until patients were fully ambulatory.

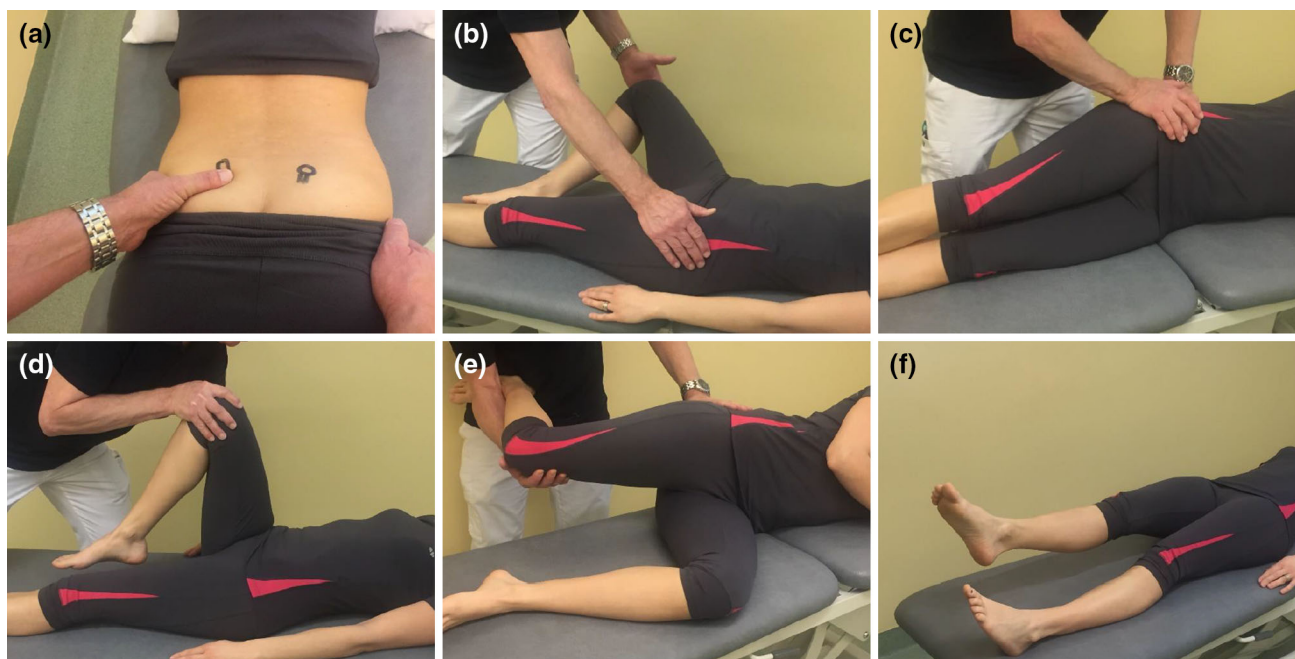


Fig. 1 Physical examination tests for SI joint pain. **a** Long ligament test, **b** FABER, **c** compression, **d** Östgaard test (thigh thrust), **e** Gaenslen's test, **f** active straight leg raise test

Follow-up

Subjects underwent in-clinic follow-up visits at 1, 3 and 6 months (study visits continue to 2 years after treatment initiations). Follow-up assessments consisted of LBP VAS, ODI, active straight leg raise test (ASLR) [31], EQ-5D [32], and self-rated assessments of satisfaction, desirability of having the same intervention again, overall pain levels and walking distance, and a review of adverse events (per ISO 14155:2011). According to the study protocol, subjects assigned to CM were allowed to cross over from CM to surgical care after the month 6 visit was complete.

Study endpoints, cohorts and statistical analysis

The study's primary endpoint was the change in LBP VAS score at 6 months after the most recent SIJF (to accommodate subjects with staged bilateral surgery) or start of CM. A modified intent-to-treat cohort was used for statistical analysis, which includes all enrolled subjects who underwent the assigned study treatment. A sample size of 40 subjects per group had 80 % power to detect a difference of 20 points in VAS SIJ pain assuming a standard deviation (SD) of 35 points. The sample size was inflated to 50 subjects per group to account for potential loss to follow-up. There were no interim stopping plans. The primary analysis used a general linear model that adjusted for pregnancy-relatedness as a randomizing stratification variable. According to the statistical analysis plan, missing data for the primary endpoint were to be imputed using

regression methods if the missing data rate exceeded 5 %. Additional analyses, including multivariate analyses, were used to examine center-level effects and the effect of potential confounders. Poolability was assessed by comparing treatment effects across sites. No changes to the statistical analysis plan were made post hoc.

Secondary endpoints included change from baseline in the following: LBP VAS at other time points, ASLR for the affected side, ODI, and EQ-5D, walking distance, and adverse events. Age and sex norms for EQ-5D were taken from König et al. [33] and values in the current trial were compared with those from the Swedish Spine Registry [34]. Continuous endpoints were compared using methods similar to the primary endpoint using all available data. Ordinal endpoints were examined using logistic or proportional odds logistic regression. Analysis of procedure-related variables focused on the index (first side) procedure only. We used Poisson regression to examine the number of adverse events per subject. No adjustment for multiplicity was performed. All statistical analyses were performed using *R* [35].

Results

Enrollment

109 subjects were enrolled in 4 countries (31 from Belgium, 45 from Germany, 21 from Italy and 12 from Sweden) between June 2013 and May 2015, of whom 6 (4

assigned to CM, 2 to SIJF) withdrew prior to receiving any intervention. 4 subjects (all at one site) were enrolled despite having inadequate acute pain relief after SIJ block. As these subjects underwent study treatment, they were included in all analyses.

Table 1 shows demographic characteristics of the 103 participating subjects. Mean age was 48.1 years and 75 subjects (72.8 %) were women. 39 (37.9 %) were current smokers. Most subjects experienced SIJ pain during various activities (Table 1) and mean duration of SIJ pain was 4.7 years. Most (72.8 %) had undergone prior SI joint steroid injections and 16.5 % had had prior radiofrequency ablation of the sacral nerve root lateral branches. 37 (35.9 %) had undergone prior lumbar fusion.

Patient flow

To date, two subjects exited the study after receiving treatment but prior to completion, both in the CM group, 1 due to inability to tolerate physical therapy (Fig. 2). The six-month follow-up rate was 49/51 (96 %) in the CM group and 52/52 (100 %) in the SIJF group. No subject assigned to CM crossed over early. All subjects assigned to SIJF underwent the procedure.

SIJ fusion

All subjects assigned to SIJF underwent the procedure soon after assignment (median days to surgery: 18). 18 SIJF subjects were diagnosed at baseline with bilateral SIJ pain meeting study eligibility criteria; however, only 7 (39 %) underwent bilateral SIJF, the remaining 11 patients receiving only unilateral treatment. Mean procedure time was 57 min (range 19–107 min). Fluoroscopy time, which was not collected routinely at one center, averaged 2.3 min (range 1–4 min). In one case, four implants were placed; in the remaining cases, three implants were placed. Median hospital length of stay was 3 days (range 1–28). The long length of stay was due to acute postoperative glaucoma causing severe diminution of vision and requiring two eye surgeries.

Conservative management

For subjects assigned to CM, the mean number of PT sessions was 26.5 and 37 (72.5 %) underwent at least 15 sessions of PT (Table 3). One subject withdrew due to inability to tolerate PT.

Primary endpoint

At baseline mean VAS LBP was slightly higher in the SIJF group vs the CM group (77.7 vs 73.0, $p = 0.0606$). In the CM group, mean LBP VAS decreased to 67.8 at 6 months

[mean (SD) improvement of 5.7 (24.4) points, $p = 0.1105$]. In the SIJF group, LBP VAS decreased to 34.4 [mean improvement of 43.3 (25.0) points, $p < 0.0001$, Fig. 3]. The difference in VAS LBP improvement was 37.6 points higher in the SIJF group; controlling for underlying condition, the difference was 38.1 points (both $p < 0.0001$). A random effects model (with study site as a random effect) showed a similar difference in pain improvement across groups (37.8 points). By month 6, 78.8 % of subjects in the SIJF group had an improvement in LBP VAS by at least 20 points (minimal clinically important difference) compared to only 22.4 % in the CM group (Fisher $p < 0.0001$ for comparison). Preplanned subgroup analysis for the primary endpoint, which included pain related to pregnancy or not, history of prior lumbar fusion or not and unilateral vs bilateral SIJ pain at baseline, showed similar responses in subgroups. Additional subgroup analysis, including gender, sex, age (by quartiles), BMI category, pain duration (by quartiles), and whether taking strong opioids at baseline, also showed no differences in responses between SIJF and CM within subgroups. However, subjects who underwent bilateral SIJF had smaller improvements in back pain compared to those who underwent unilateral SIJF (analysis of variance $p = 0.0110$). Combining all postoperative time points, back pain improved by 37.8 points more in the SIJF (repeated measures analysis of variance, $p < 0.0001$).

Disability

Disability, as measured by Oswestry Disability Index (ODI) score, was high at baseline (mean 56.6). In the CM group, ODI improved slightly from baseline (mean improvement 5.8 points, $p = 0.0114$, Fig. 3c). In the SIJF group, ODI improved by 25.5 points ($p < 0.0001$). The difference in 6 month ODI improvement across groups was 19.8 points, $p < 0.0001$, Fig. 3. All individual components of ODI showed more improvements in the SIJF group vs CM group (maximum p value 0.0002). The proportion of subjects with a 15-point 6-month improvement in ODI from baseline was 71.2 vs 24.5 % ($p < 0.0001$). Subgroup analysis showed no factor that predicted change in ODI except that changes were larger for subjects who underwent unilateral SIJF ($p = 0.0134$). Self-reported walking distance was significantly increased after SIJF (Fig. 4a) but only minimally after CM (proportional odds logistic regression, $p = 0.0111$).

SIJ functionality

SIJ functionality was also assessed using the ASLR. Mean (median) ASLR ratings decreased, expressed on the 0–6 scale, improved from 4.0 (4) to 2.0 (2) in the SIJF group and from 3.8 (4) to 3.7 (4) in the CM group. Mean

Table 1 Baseline characteristics of enrolled/randomized subjects

	CM (<i>n</i> = 51)	SIJ Fusion (<i>n</i> = 52)	<i>p</i> value**
Age, mean (SD) [range]	46.7 [23–69]	49.4 [27–70]	0.2104
Female, <i>N</i> (%)	37 (72.5)	38 (73.1)	1.0000
Pain duration, mean (SD) [range]	4.5 [0.45–23]	4.9 [0.58–44]	0.7765
Body mass index, mean (SD) [range]	27.6 [16–44]	26.5 [18–42]	0.3545
Smoking, <i>N</i> (%)			
Current	16 (31.4)	23 (44.2)	0.0444
Former	8 (15.7)	14 (26.9)	
Never	27 (52.9)	15 (28.8)	
Pain syndrome			
Pain began in peripartum period	3 (5.9 %)	6 (11.5 %)	0.4878
Radiates down leg	40 (78.4 %)	42 (80.8 %)	0.8107
Pain in groin	36 (70.6 %)	31 (59.6 %)	0.3027
Pain sitting	38 (74.5 %)	42 (80.8 %)	0.4856
Pain rising	40 (78.4 %)	48 (92.3 %)	0.0546
Pain walking	42 (82.4 %)	43 (82.7 %)	1.0000
Pain climbing stairs	41 (80.4 %)	41 (78.8 %)	1.0000
Pain descending stairs	29 (56.9 %)	33 (63.5 %)	0.5491
Prior treatment			
Prior physical therapy	27 (52.9 %)	32 (61.5 %)	0.4287
Prior prolotherapy	0 (0 %)	0 (0 %)	1.0000
Prior steroid SIJ injections	38 (74.5 %)	37 (71.2 %)	0.8253
Prior radiofrequency ablation ^a	6 (11.8 %)	11 (21.2 %)	0.2888
Work status			
Working normal hours/type	3 (5.9 %)	5 (9.6 %)	0.7918
Working with limitations	12 (23.5 %)	13 (25.0 %)	
Not working due to lower back pain	27 (52.9 %)	23 (44.2 %)	
Not working due to other reason	2 (3.9 %)	1 (1.9 %)	
Retired	7 (13.7 %)	10 (19.2 %)	
Ambulatory status			
Ambulatory without assistance	46 (90.2 %)	42 (80.8 %)	0.2945
Ambulatory with assistance	3 (5.9 %)	8 (15.4 %)	
Cannot walk	2 (3.9 %)	2 (3.8 %)	
History of prior lumbar fusion	19 (37.3 %)	18 (34.6 %)	0.8388

** Fisher test for nominal variables; *t* test for continuous variables^a Radiofrequency ablation of lateral branches of sacral nerve root

reductions were 2.0 points in the SIJF group and 0.2 points in the CM group ($p < 0.0001$). The proportion of subjects who could raise the affected leg with no or minimal difficulty at 6 months was 71.1 % in the SIJF group and 32.0 % in the CM group ($p = 0.0002$).

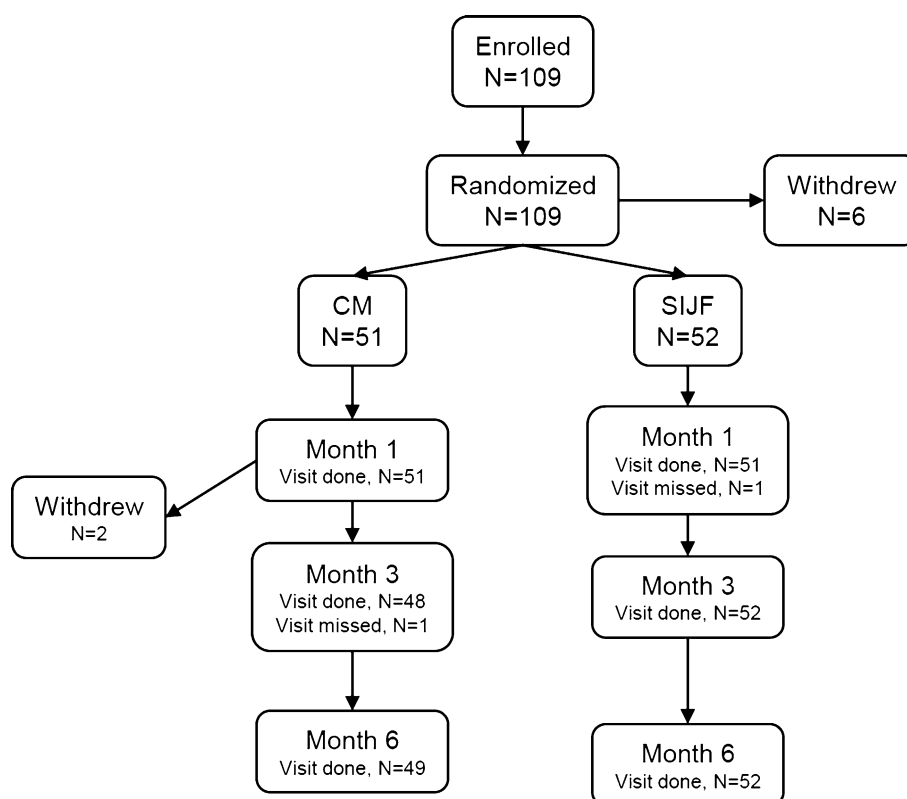
Quality of life

Mean (SD) EQ-5D TTO index and visual analog scale (EQ-5D VAS) were markedly depressed in both groups at baseline compared to age- and sex-matched population norms (Fig. 4e, f). EQ-5D TTO improved more in the SIJF group compared to the CM group [change of 0.37 points

($p < 0.0001$) in SIJF group change of 0.11 points in CM group ($p = 0.0189$), 0.21 point difference, $p < 0.0001$]. Similarly, EQ-5D VAS improved more in the SIJF group (20.2 points more improvement, $p < 0.0001$).

Additional effectiveness outcomes

Satisfaction levels were higher at months 3 and 6 in the SIJF group compared to the CM group (Table 4, Fig. 4c, $p < 0.0001$ by proportional odds logistic regression) as were the proportion of patients reporting that they would have the assigned intervention again (Fig. 4d, $p = 0.0001$). A larger proportion of SIJF subjects reported they were improved

Fig. 2 Patient flow

overall compared to baseline (Fig. 4d, $p < 0.0001$). Self-reported walking distance and global comparison to baseline were also higher for the SIJF group (Fig. 4a and b).

Adverse events

Within 180 days of initial treatment, there were 24 reported adverse events: 10 events in 9 SIJF subjects and 14 events in 13 CM subjects. The mean (median) number of events per subject prior to 180 days was slightly smaller in the SIJF group compared to CM: 0.19 (0) vs 0.27 (0), $p = 0.0918$. There were 18 severe adverse events prior to month 6, 8 in the SIJF group and 10 in the CM group. Adverse event severity was distributed equally across groups (Wilcoxon p value 0.7868). Of the 8 severe adverse events in the SIJF group, none were related to the device and 2 were related to the procedure (postoperative hematoma and postoperative neural impingement related to incorrect device placement). The two procedure-related severe adverse events in the SIJF group were both reversible and within the spectrum of possible surgical complications known from comparable spine procedures.

Device- and procedure-related events

One subject had postoperative radicular pain resulting from implant protrusion into the sacral neural foramen. Pain

resolved when the implant was pulled back a few mm. Two additional subjects had postoperative hematomas; one resulted in gluteal pain and required surgical evacuation and one was treated conservatively. No subject has undergone late revision of implants.

Discussion

In our trial of patients with chronic SIJ pain, improvements in LBP, disability scores, physical function and quality of life were superior in subjects receiving minimally invasive SIJF using triangular titanium implants compared to CM. Differences in these outcomes occurred soon after treatment initiation and were statistically significant between the two groups at all postoperative time points.

Our findings both replicate and extend previous studies. In previously published case series [36–39], systematic reviews [40, 41], a prospective multicenter clinical trial [42], and a recently published randomized clinical trial of similar design conducted in the USA [43], similar improvements in SIJ pain, self-rated limitations in activities due to pain (Oswestry Disability Index) and quality of life were observed in participants undergoing SIJF. Our study provides an additional, independent confirmation that the improvements after surgery are clinically important and statistically superior to those seen with continued

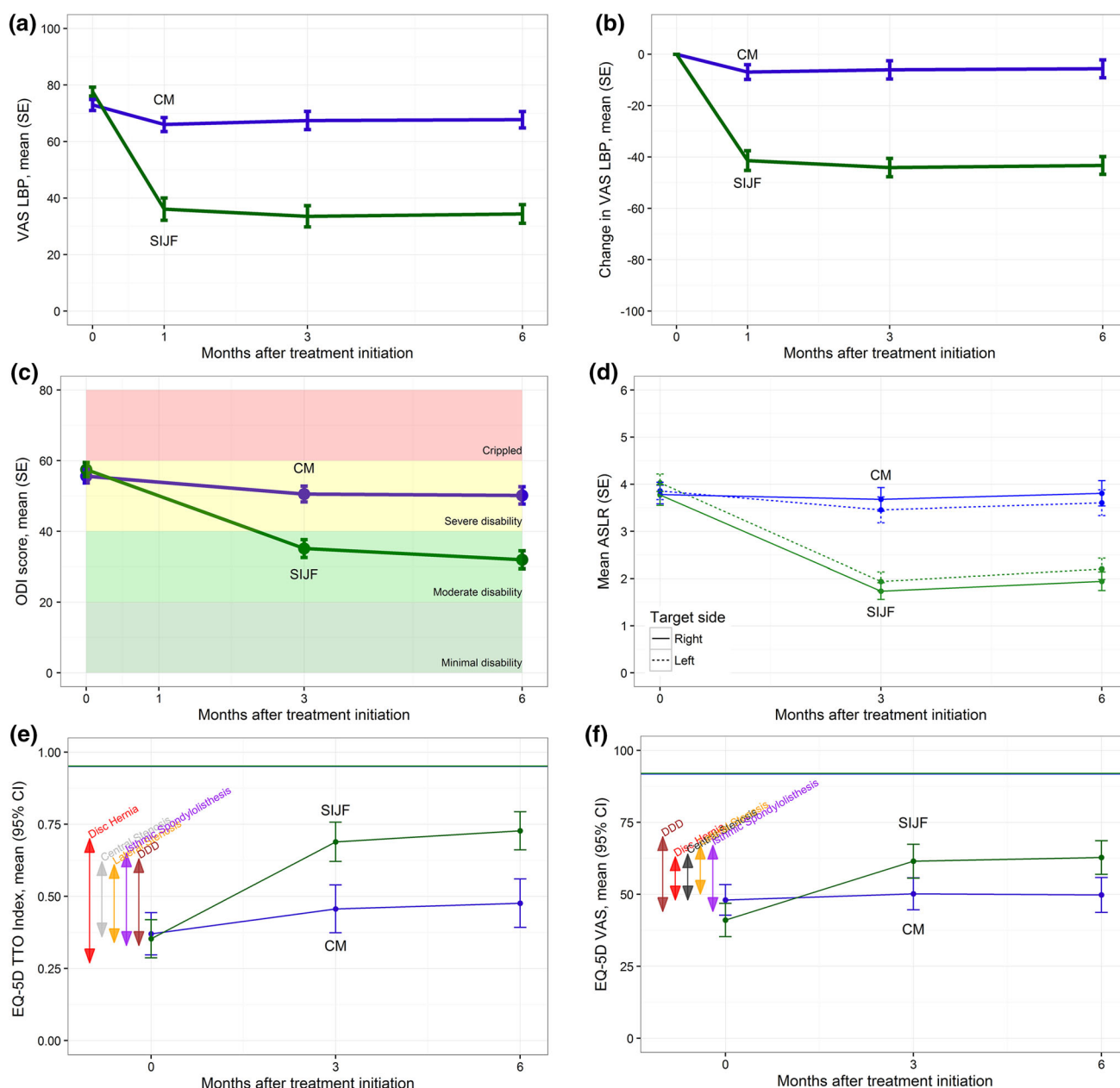


Fig. 3 Improvement in VAS low back pain (a) and change from baseline (b), Oswestry Disability Index (c), active straight leg raise test (d), EQ-5D time trade-off (TTO) index (e), and EQ-5D visual analog scale. For all plots, green lines show SIJF and blue lines show

CM. For e and f, green and blue horizontal lines indicate age- and sex-matched German population norms and arrows represent baseline (bottom of arrow) and 12-month findings (top of arrow) from the most recent Swedish Spine Registry data [34]

conservative care. Similar to previous studies, preplanned subgroup analyses revealed no predictors of poor responses after surgical fusion.

Our randomized trial differed in design and intervention compared to a US randomized trial; in the US study, non-surgical management included intraarticular SIJ steroid injections and radiofrequency (RF) ablation. Instead, our trial included only PT and adequate information and reassurance, consistent with European guidelines for pelvic

girdle pain [29]. We note that although SIJ steroid injections and RF ablation are not commonly delivered in Europe, many trial participants had already undergone such treatments.

Subjects in our cohort had marked reduction in baseline quality of life compared to the general population, with EQ-5D scores substantially lower than population controls. At 3 and 6 months, minimally invasive SIJF resulted in improved EQ-5D scores (postoperative means

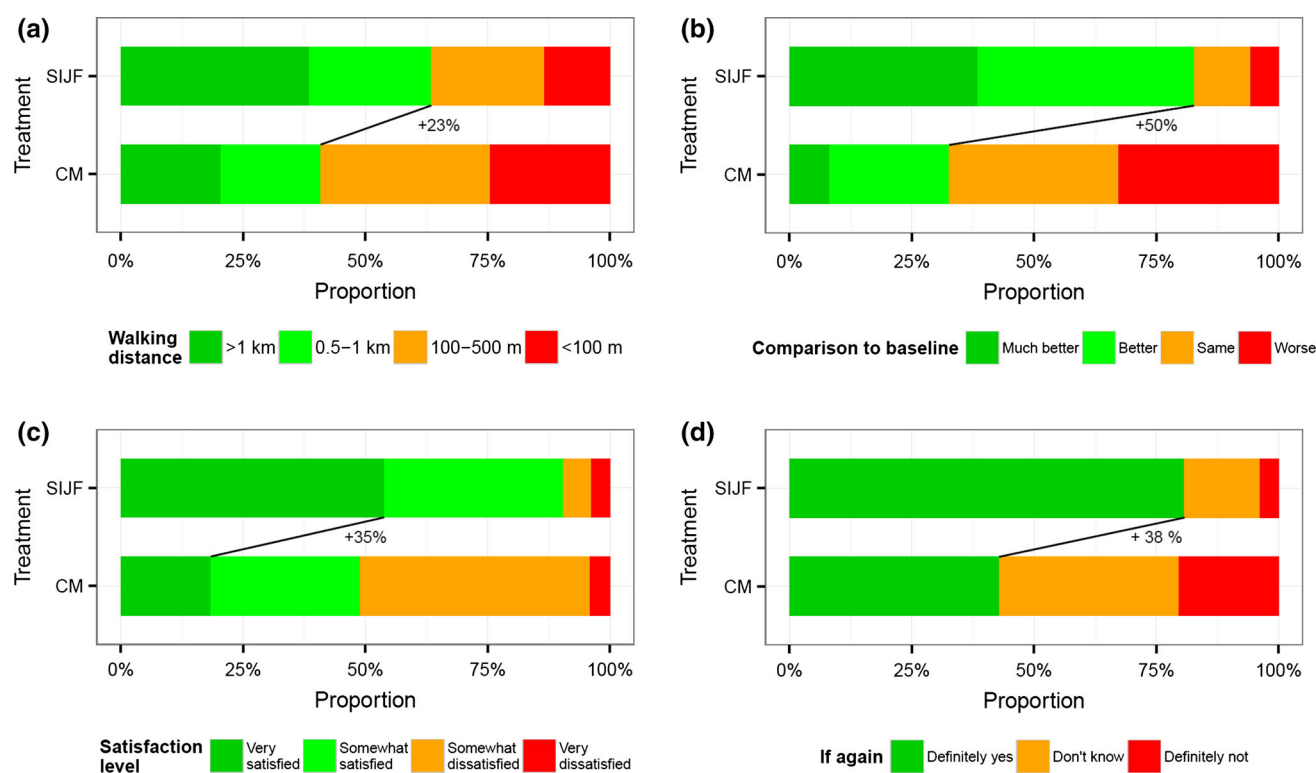


Fig. 4 Improvement in self-reported walking distance (a), global comparison to baseline (b), satisfaction level (c), and desirability of having surgery again (d) in subjects treated with SIJF or CM

Table 2 Characteristics of SIJ fusion

	SIJF (<i>n</i> = 52)
Days from enrollment to surgery, median (range)	18 (1–82)
Number of implants, <i>N</i> (%)	
Three	51 (98.1%)
Four	1 (1.9%)
Procedure duration (min), median (range)	54 (19–107)
Fluoroscopy time (min), median (range) ^a	2.1 (1.0–4.0)
Hospital length of stay (days), median (range)	3 (1–28)

^a Some sites did not record fluoroscopy time

of 0.69 and 0.74) that were similar to postoperative values observed for other low back pain surgical procedures [44]. In contrast, EQ-5D score improvements in the CM group were minimal. The improvements in quality of life seen in our study mirror those seen in a prior randomized trial [43]. Our study, combined with the prior randomized trial and 4- and 5-year outcomes from both European [39] and US [45] cohorts, suggest that minimally invasive SIJ fusion can be added to the portfolio of spine surgeries proven safe and effective that European surgeons can offer their patients.

Minimal clinically important differences (MCID) are often used to assess the clinical significance of study

findings as they may be distinct from statistical differences. Although they were developed for degenerative spinal conditions other than SIJ and the effects of SIJF, the MCID for improvement in chronic back pain is approximately 20 % when measured by VAS [46] and that for ODI is approximately 13–15 points [47]. For EQ-5D, the MCID is less well defined, with changes of 0.15–0.46 reported [44, 48]. Observed mean values in our study exceeded these MCID values for pain, ODI and EQ-5D, and response rates were markedly higher in the SIJF group compared to CM. Improvements in EQ-5D TTO and VAS in our study were similar to those seen in the Swedish spine registry for other spine surgeries [34].

Our results extend findings from prior studies in important ways. First, we included two functional assessments [walking distance and physical functioning (ASLR)], both of which have not been previously reported. Both measures showed improvement in the SIJF group but not in the CM group. Second, CM was provided per European treatment guidelines, meaning that the control group intervention may have been more standardized than prior trials. Our findings extend prior trials and serve to validate the procedure overall.

Surgical revision is an important clinical outcome. To date, only one trial subject has undergone revision surgery after SIJF; in this case, the implant was placed too close to

Table 3 Characteristics of CM

	CM (<i>n</i> = 51)
Physical therapy sessions, <i>N</i> (%)	
1	1 (2.0)
2–5	2 (3.9)
6–10	1 (2.0)
11–15	9 (17.6)
>15	37 (72.5)
Cognitive behavioral therapy sessions, <i>N</i> (%)	
0	27 (52.9)
1	1 (2.0)
2–5	7 (13.7)
6–10	10 (19.6)
11–15	3 (5.9)
>15	3 (5.9)

the sacral nerve root, a known risk, and this subject's new radicular pain improved on repositioning the implant. The risk of early revision of this implant is approximately 1 % and the risk of revision at 4 years is approximately 3.6 % [49], a revision rate that is low compared to standard open surgical procedures in the spine [50, 51]. No unanticipated adverse events occurred.

Our study has several limitations. Because the intervention was not blinded, we cannot rule out the possibility that knowledge of the treatment assignment might have influenced patient responses to questions, which could have contributed to the greater improvements seen in the SIJF group. However, other potential biases—e.g., the fact that 11 of the 18 patients in the SIJF group diagnosed with bilateral pain received only unilateral SIJF, might have decreased the improvements in the SIJF group due to under treatment. Moreover, blinding is not done in standard clinical settings, so our results may be more generalizable

Table 4 Other outcomes at 6 months

	CM	SIJF	<i>p</i> value
Walking distance			
<100 m	12 (24.5 %)	6 (11.8 %)	0.0111
100–500 m	17 (34.7 %)	12 (23.5 %)	
0.5–1 km	10 (20.4 %)	13 (25.5 %)	
>1 km	10 (20.4 %)	20 (39.2 %)	
Work status			
Not working due to lower back pain	28 (57.1 %)	20 (39.2 %)	0.0711
Not working due to other reason	0 (0.0 %)	2 (3.9 %)	
Retired	5 (10.2 %)	11 (21.6 %)	
Working with limitations	10 (20.4 %)	6 (11.8 %)	
Working normal hours/type	6 (12.2 %)	12 (23.5 %)	
Walking status			
Ambulatory without assistance	45 (91.8 %)	46 (90.2 %)	1.0000
Ambulatory with assistance	2 (4.1 %)	5 (9.8 %)	
Cannot walk	2 (4.1 %)	0 (0.0 %)	
Level of satisfaction			
Very satisfied	9 (18.4 %)	28 (54.9 %)	<0.0001
Somewhat satisfied	15 (30.6 %)	19 (37.3 %)	
Somewhat dissatisfied	23 (46.9 %)	2 (3.9 %)	
Very dissatisfied	2 (4.1 %)	2 (3.9 %)	
Desirability of having assigned treatment again			
Definitely not	10 (20.4 %)	2 (3.9 %)	0.0001
Don't know	18 (36.7 %)	8 (15.7 %)	
Definitely yes	21 (42.9 %)	41 (80.4 %)	
Global comparison to baseline			
Worse	16 (32.7 %)	3 (5.9 %)	<0.0001
Same	17 (34.7 %)	6 (11.8 %)	
Better	12 (24.5 %)	22 (43.1 %)	
Much better	4 (8.2 %)	20 (39.2 %)	

to what can be expected in standard practice compared to a blinded trial.

While we included patients for whom the SIJ had been identified as the primary cause of LBP, we cannot exclude that patients with other contributory sources of LBP, e.g., facet arthropathy or degenerative disc disease, have been enrolled. In these patients the LBP due to the SIJ pathology might have been reduced; however, the other causes of the LBP might not have been addressed adequately. It is reasonable to suppose that both arms of the study are equally affected by this potential problem.

Second, although CM was patterned after European guidelines for pelvic girdle pain, which recommend treatment individualized to patient needs, non-surgical care provided to patients in our trial may have varied across centers. Physical therapy may be helpful in post-partum pelvic girdle pain [45], most of which is likely to emanate from the SIJ, but the target population in our study differs from the cited study. Finally, our report includes 6-month data only; the study continues to 24 months of planned follow-up. However, one-year data from other prospective trials of the same device/patient population [42, 43], as well as longer-term data from retrospective cohorts [39, 45] suggest sustained effectiveness.

In summary, 6-month data from a randomized surgery vs non-surgical clinical trial show that minimally invasive SIJF using triangular titanium implants provided superior pain, disability, function and quality of life outcomes compared to CM (Figs. 3, 4, Table 4). Combined with previous evidence, minimally invasive SIJF is a reasonable surgical option for patients with SIJ pain not responsive to non-surgical care for at least 6 months.

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Compliance with ethical standards

Conflict of interest Bengt Sturesson, Julius Dengler, Djaya Kools, Robert Pflugmacher, Domenico Prestamburgo and Alessandro Gasbarrini are investigators in SI-BONE clinical trials. Bengt Sturesson, Djaya Kools and Robert Pflugmacher are paid consultants to SI-BONE. The trial reported herein was funded by SI-BONE.

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Appendix

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