



Triangular titanium implants for sacroiliac joint fusion

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Abstract

Background The sacroiliac joint (SIJ) is a common source of chronic low back pain. Published cohorts have reported favorable outcomes after SIJ fusion. We report the 12-month follow-up from SIJ fusion of the so far largest single-center and single-surgeon group.

Methods Over 15,000 outpatients were evaluated for chronic low back and leg pain, of whom 3,477 underwent SIJ blocks. 541 patients were stringently selected to undergo SIJ fusion with triangular titanium implants (TTI). 483 patients had a follow-up of 12 months. Patients were seen every 3 months and completed visual analog scale (VAS) and Oswestry Disability Index (ODI) ratings.

Results Mean age of all patients was 61 years, and the majority (65%) were women. 44% had undergone prior lumbar fusion and 10% had a spinal cord stimulator (SCS) in place at the time of SIJ surgery. 26% underwent non-simultaneous bilateral SIJ joint fusion. At 12 months, the proportion of patients with clinically important improvements in pain (≥ 2 points) was very high (100%). The proportion with substantial improvement (≥ 4 points) was 98%. Similarly, improvement in ODI was high, with nearly 99% having an improvement of ≥ 15 points by month 12. The proportions of patients with VAS ≤ 2 or ODI ≤ 15 was also high (92.8% and 48.9%).

Conclusions In our clinical practice, SIJ fusion with TTI produces significant improvement in pain and disability. The most important factor for achieving these clinical results may be the very stringent multistep selection of patients for surgery, which is described in detail, as well as the highly standardized and streamlined surgical procedure and the particular post-operative management.

Keywords Minimally invasive surgery · Sacroiliac joint dysfunction · Sacroiliac joint disruptions · Degenerative sacroiliitis · Sacroiliac joint arthrodesis · Spine surgery

Introduction

The sacroiliac joint (SIJ) is increasingly recognized as a common (15–30%) source of chronic low back pain [1, 12, 13, 19, 20]. SIJ pain can be debilitating and cause poor quality of life [2, 3]. Multiple devices are now commercially available for the surgical treatment of SIJ pain. These are

mostly metallic implants placed either across or within the joint. The former set of devices provide immediate fixation, and long-term fusion occurs most commonly by osteointegration and growth of bone within the SIJ [4]. The latter set of devices works via distraction arthrodesis.

A recent systematic review and meta-analysis provides support for both transiliac and interposition devices [22]. Therein, the most reported device was triangular titanium implants (TTI).

Previously, we reported our experience with lateral transiliac SIJ fusion, showing high levels of pain relief and disability improvement [17]. Herein, we report one of the largest clinical cohorts with lateral transiliac SIJ fusion using TTI, as provided by a single surgeon. One of the main goals of the study was to compare our clinical results with the published literature.

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Methods

From 2015 to 2023, 1,500–2,200 patients with chronic low back and leg pain were seen yearly at a single center in

Table 1 Number of patients seen per year with low back pain and number of SI joint injection procedures per year at author's surgical clinic

| Year | Patients with low back pain | Number (%) of SI joint injection procedures* | Number (%) of SI joint fusion procedures |
|--------------|-----------------------------|----------------------------------------------|------------------------------------------|
| 2015 | 359 | 52 (14.5%) | 7 (1.9%) |
| 2016 | 1550 | 235 (15.2%) | 43 (5.3%) |
| 2017 | 1720 | 345 (20.1%) | 91 (3.1%) |
| 2018 | 1940 | 398 (20.5%) | 60 (3.1%) |
| 2019 | 2010 | 576 (28.7%) | 62 (3.1%) |
| 2020 | 1680 | 230 (13.7%) | 64 (3.8%) |
| 2021 | 1890 | 376 (19.9%) | 82 (4.3%) |
| 2022 | 2140 | 590 (27.6%) | 94 (4.4%) |
| 2023 | 2260 | 675 (29.9%) | 38 (1.7%) |
| Total | 15,549 | 3,477 (22.3%) | 541 (3.5%) |

*Includes both diagnostic and therapeutic (corticosteroid) injections

Munich, Germany, of whom 15–30% underwent SIJ blocks (Table 1). Many of the patients, who were diagnosed with chronic SIJ pain as described below, underwent SIJ fusion using TTI (iFuse Implant System, SI-BONE, Inc., Santa Clara, CA, USA).

Patients Patients were assessed using an algorithm for diagnosis of SIJ pain (Fig. 1). SIJ pain was suspected based on self-reported non-axial buttock pain below L5 (with possible radiation into the legs), groin pain, and difficulty sitting on the affected side or on both sides. Careful history-taking was performed to evaluate for the presence of competing diagnoses.

If SIJ pain was suspected, the patient underwent a structured physical examination consisting of the following tests: (1) compression test, (2) Gaenslen test, (3) thigh thrust, (4) Patrick's test and (5) distraction test. Finding ≥ 3 positive physical examination tests has reasonable specificity for performing a SIJ anesthetic block [21]. An additional important physical examination finding was Fortin's test [10]. Additional physical exams were carried out to rule out other causes of pain (e.g. disc herniation, etc.).

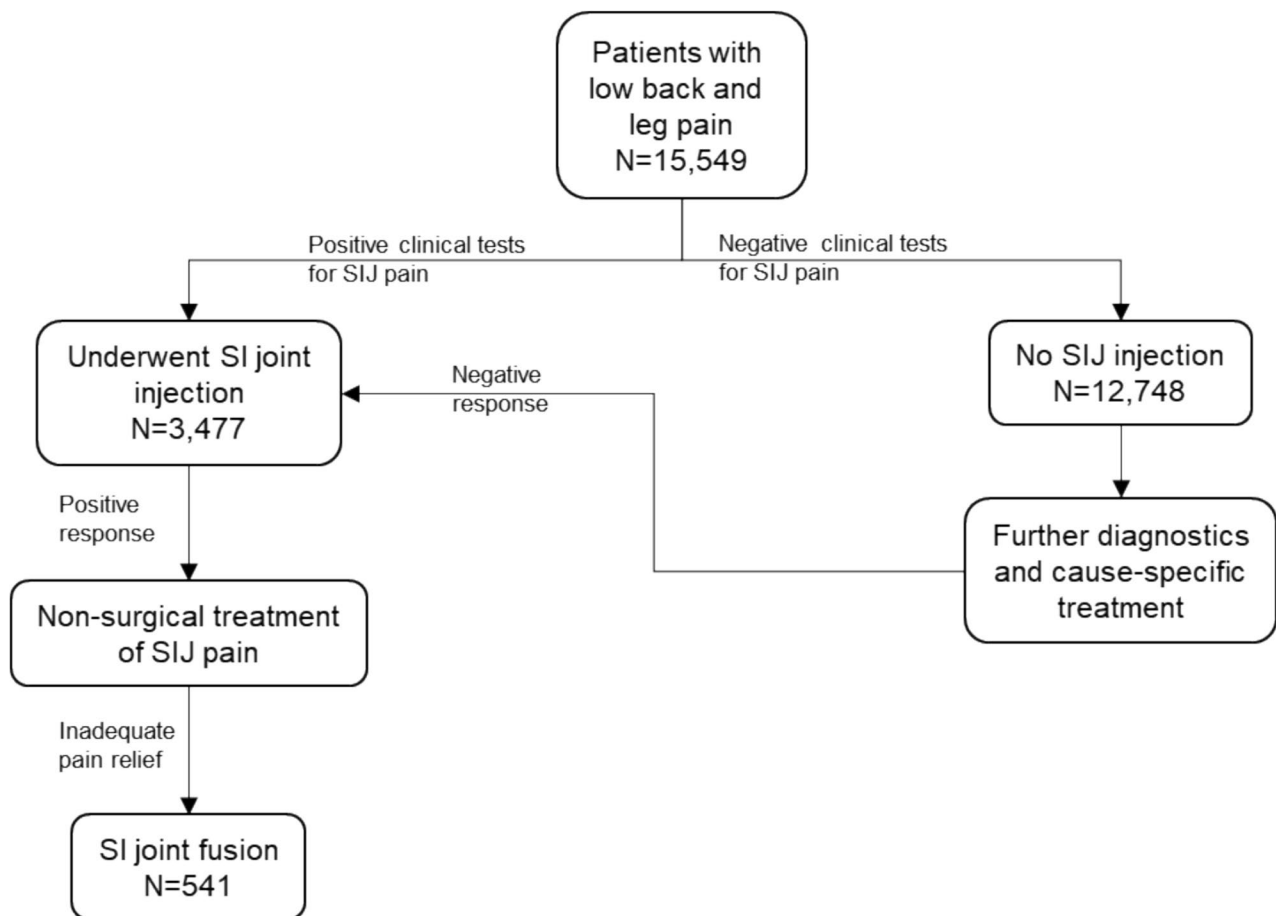


Fig. 1 Management of patients with SI joint pain during study period

Patients with a corresponding history and ≥ 3 positive physical examination tests underwent fluoroscopy- or CT-guided blocks using 3–5 ml of 7.5% mepivacaine plus 40 mg of triamcinolone, injected via the SIJ caudal pole. An arthrogram was performed with 0.5 ml of an iodine contrast agent to ensure adequate injection. A SIJ block was considered positive if reduction in the pain was $\geq 50\%$ within the first 6 h after injection. The block was considered negative in the absence of marked acute pain relief. Patients also underwent radiographic evaluation using MRI and CT to access the lumbar spine, in addition to the SIJ, and to point out possible sources of pain other than the SIJ.

Patients were seen in clinic, evaluated, and if indicated tested, in a multistep procedure by a team of experienced neurosurgeons and orthopedic surgeons. The final indication for a surgical procedure at the SIJ was approved in all cases by the performing surgeon (NGR).

To be diagnosed with bilateral SIJ pain, patients had to have history and physical examination findings suggestive of bilateral pain as well as positive bilateral SIJ anesthetic blocks.

All patients diagnosed with SIJ pain were treated non-surgically according to a pre-specified clinical pathway. Non-surgical treatment included physical therapy, non-steroidal anti-inflammatory drugs, and use of a SIJ orthosis (Sacroluc, Bauerfeind GmbH). Patients with an insufficient response after ≥ 3 months of non-surgical treatment were offered SIJ fusion.

Procedure SIJ fusion was performed as described previously [17]. All surgical procedures were performed by the senior author (NGR).

Patients used crutches after surgery to reduce weight on the operated side, and were discharged mostly on day 3 after the procedure. Patients progressively bore weight on the affected side as tolerated. Postoperative rehabilitation started generally after week 4 post-surgery.

Some patients had bilateral SIJ pain. These patients underwent second side SIJ fusion as dictated by the level of pain, but no earlier than 4 weeks after first side surgery.

Follow-up All patients were asked to return to clinic every 3 months for up to one year. They reported pain scores using a visual analog scale (VAS) and completed an Oswestry Disability Index [11] (ODI) questionnaire. During the COVID-19 pandemic, patients were interviewed by phone and sent paperwork by mail. Patients underwent CT scan of the lumbar spine and bilateral SIJ at 12 months. Patients who underwent contralateral SIJ fusion were followed up for at least 12 months after the second (contralateral) SIJ fusion surgery.

Statistical analysis All patients who had a 12-months follow-up were included in the statistical analysis. Data

were entered into an Excel spreadsheet and analyzed using R [16] on the RStudio platform. Baseline characteristics were reported. Improvement in continuous measures (VAS and ODI) were analyzed using Student's t-test or repeated measures analysis of variance. Proportions and confidence intervals were calculated using exact binomial tests. Subgroups of interest included: (1) spinal cord stimulator (SCS) in place, (2) sex, (3) history of prior lumbar fusion, (4) undergoing unilateral vs. bilateral fusion. The proportions of patients with VAS pain ratings improving by ≥ 2 or more points and the portion of patients with ODI improvement of 15 or more points were compared using Fisher tests.

Results

Between 2015 and 2023, over 15,000 patients with chronic low back and leg pain were seen, of whom 3,477 underwent SIJ blocks (Fig. 1). During this period, 541 patients (15.7% of all tested cases) were diagnosed with SIJ dysfunction unresponsive to non-surgical treatment and subsequently underwent SIJ fusion, of whom 483 had at least 12 months of follow-up. These 483 cases (89.3% of all fusion cases) constituted the dataset analyzed herein.

Mean age was 61 years (Table 2) and the majority (65%) were women. 44% had undergone prior lumbar fusion and approximately 10% had an SCS at the time of SIJ fusion surgery. 26% underwent bilateral SIJ fusion. Contralateral SIJ fusion procedures were more commonly performed in patients with a history of SCS (44.7% vs. 23.4%, $p = .002$) and less common in those with a history of prior lumbar fusion (20.3% vs. 29.5%, $p = .02$). Patients undergoing second surgeries were younger than those not undergoing a second surgery (mean age 55.4 vs. 62.8 years, $p < .0001$).

Procedure characteristics All surgeries were performed in a highly standardized manner by the senior author. At first SIJ fusion surgery, 2 implants were used in 396 cases (82%), and 3 implants in 86 cases (17.8%).

Table 2 Demographic and clinical characteristics of patients undergoing SI joint fusion

| Characteristic | Value* |
|-----------------------------------------------|---------------------|
| Age | 60.9 (13.2) [20–90] |
| Female sex | 314 (65%) |
| Presence of instrumented lumbar fusion | 212 (43.9%) |
| Presence of spinal cord stimulator | 47 (9.7%) |
| Previous SIJ implant removed prior to surgery | 4 (0.8%) |
| Underwent bilateral SI joint fusion | 123 (25.5%) |

*Continuous values reported as mean (SD) [range]; proportions reported as n (%)

For patients undergoing second side surgery, 2 implants were used in 108 cases (87.1%) and 3 implants in 16 (12.9%). In those undergoing second surgeries, younger age predicted fewer days between first and second surgeries; there was no other predictive factor.

Complications There were no permanent complications. We observed 3 cases of older patients with distended soft tissues to develop painful, but self-limiting hematomas in the surgical path of approach. This complication occurred within the first 25 cases of the cohort and was virtually eradicated after routinely applying compression to the surgical site using a layered elastic bandage for 24–48 h. In the follow-up period after discharge from hospital, there were no postoperative wound infections, no implant revisions, and no TTI migrations.

Mean (\pm SD) SIJ pain improved from 7.9 (0.7) at baseline to 3.7 (0.9) at 3 months, 2.3 (0.8) at 6 months, and 1.7 (0.7) at 12 months. The ODI improved from 41.1 (2.9) at baseline to 29.3 (5.9) at 3 months, 22.3 (5.0) at 6 months and 15.8 (3.8) at 12 months. Twelve-month improvement in VAS and ODI were 6.2 (0.8) and 25.3 (3.7) points (both $p < .0001$).

By month 3 and thereafter, all (100%) patients had an improvement in VAS by at least 2 points (a common

threshold for minimally clinically important difference [MCID] in chronic back pain [5]). By month 12, all but 2 had an improvement of ≥ 4 points and 98.3% had an improvement of ≥ 5 points. For ODI, all but 1 patient had an improvement of ≥ 10 points; 98.8% had an improvement of ≥ 15 points (a commonly accepted MCID), and 95% had an improvement of ≥ 20 points. No patient reported worsening of VAS or ODI compared to baseline.

Subgroup analysis was done on 6 factors (Fig. 2): time, sex, age ($< 65 >$ years), bilateral vs. unilateral SIJ fusion, presence/absence of SCS and prior lumbar fusion. Improvement in ODI was larger in patients under 65 years, patients undergoing contralateral SIJ fusion and those with an SCS in place. However, the differences were minor, not statistically significant and also of unclear clinical significance.

No important differences in VAS change were observed across subgroups. Across the same subgroups, the proportion of patients reporting low VAS (≤ 2 points) or low ODI (≤ 15 points) scores was 89–93% and 39–52%, respectively (Fig. 3).

Twelve-month post-placement CT scans were performed in all patients from 2015 until 2019. These patients received an earlier, non-3D-printed version of TTI, which has a porous surface but does not have a reticular internal structure. A total of 208 scans were available for review.

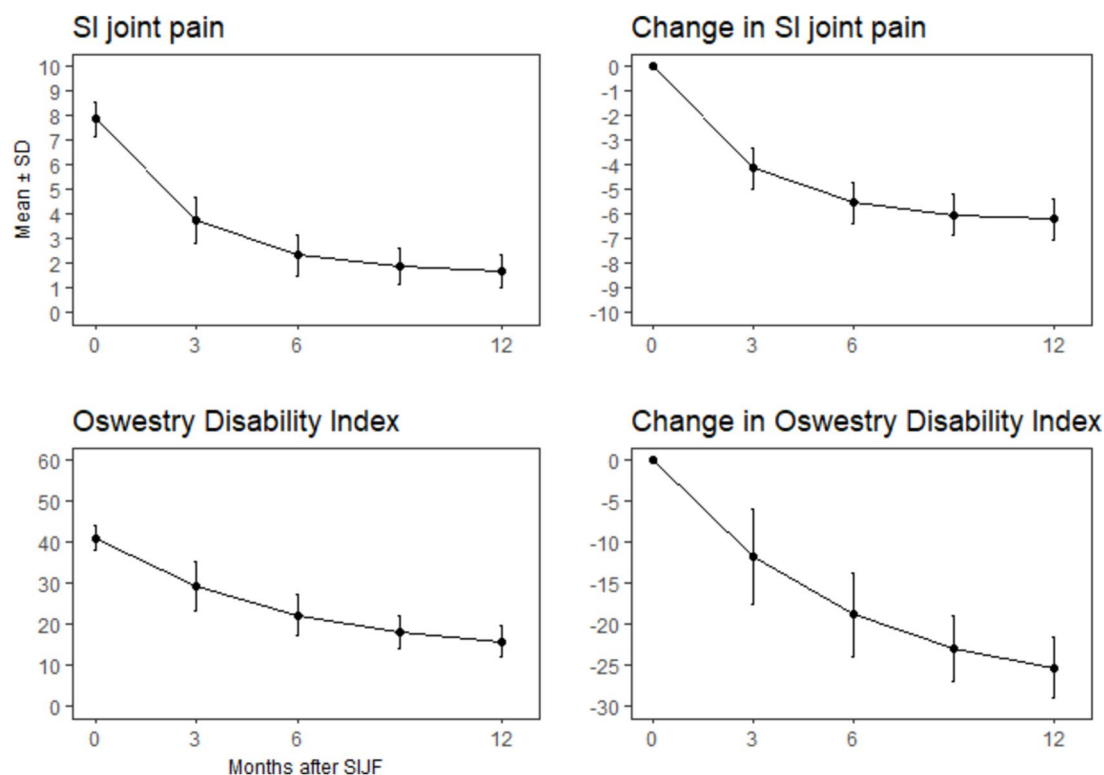


Fig. 2 Improvement in pain (top) and Oswestry Disability Index (bottom) over time. Left-hand panels show population means. Right-hand panels show improvement from baseline

Bone adherence to implants in both the sacrum and ilium was commonly observed (Fig. 4). When single-side surgery was done, evidence of reabsorption of bone around one or more implants was seen in 15 of 135 cases (11.1%). When a second-side surgery was done, evidence of reabsorption was seen in 9 of 73 (12.3%). There was no correlation between the observation of reabsorption around implants and any recurrent pain (Fig. 5).

Discussion

SIJ fusion is a clinically accepted procedure for chronic SIJ pain. Many techniques and devices are commercially available worldwide. Most reports involve TTI, the devices used in our cohort. Our cohort is unique in that it is the largest single-center clinical experience with TTI reported to date.

Like other studies, we reported significant improvements in VAS and ODI. At 12 months, the proportion of patients with clinically important VAS improvements was very high (100%). The proportion with substantial improvement was 98%. Similarly, improvement in ODI was very common, with nearly 99% having an improvement ≥ 15 points by month 12. The proportions of patients with low final scores (VAS ≤ 2 or ODI ≤ 15) was also high (92.8% and 48.9%). Our observation of larger improvements VAS compared to ODI is similar to other studies [8, 15].

Subgroup analysis was undertaken for 6 factors. We found little difference in response rates across these factors.

Patients who underwent bilateral SIJ fusion responded as well as those undergoing unilateral fusion. We also observed that some patients with bilateral pain, who underwent SIJ fusion using TTI of the most affected side, had sufficient pain relief and contralateral SIJ fusion was not required.

Lumbar fusion is a risk factor for SIJ pain. Several studies have reported that responses to SIJ fusion were similar between patients with a history of lumbar fusion vs. those who had not undergone prior lumbar fusion [7, 18]. We observed the same phenomenon. In our experience, some patients experience SIJ pain within weeks after lumbar fusion procedures; in others, it develops more slowly.

In our cohort, a substantial number of patients had undergone SCS placement for chronic neuropathic pain. We observed no difference in responses to SIJ fusion in those with prior SCS placement compared to those without. Additionally, we observed no statistical interaction between SCS or prior lumbar fusion on responses to SIJ fusion. Importantly, among SCS patients with SIJ pain, SIJ fusion appeared to produce an important improvement in VAS. Therefore, the presence of a SCS should not be considered an impediment to providing SIJ fusion.

Radiographic analysis in our cohort was limited to CT scans performed in the earlier portion of our

cohort. Evidence of some bone reabsorption was seen in 11–12% of those early cases [17]. No patients underwent surgical revision as a result of radiolucencies seen on CT scans.

We routinely saw increased bone density surrounding the implants in both the ilium and sacrum, which we attributed to bone loading and viewed positively. No patient had implant-related bone fractures.

We observed a very low rate of procedure-related adverse events in our cohort. Other studies have reported an approximate 1% incidence of implant malposition causing new onset radicular leg pain [4, 7]. In our cohort, during the hospital treatment there was only one surgical correction of an implant on the next day after the initial surgery. We have also observed no evidence of device migration or implant breakage over the whole study period.

Some have argued that injury to branches of the superior gluteal artery may occur in lateral transiliac procedures [6, 9], including patients with sacral dysmorphism [14]. In our cohort, we observed a small number of postoperative hematomas, but no case of significant vascular damage. In a recent meta-analysis, the rate of serious vascular injury was low (0.04%) [22].

To minimize postoperative hematomas, we routinely apply two layers of compression on the surgical site: a tissue tampon as the first layer and an elastic bandaging tape around the pelvis as the second layer.

Our findings are in agreement with those of a recent meta-analysis [22]. Specifically, the mean improvement in VAS in our cohort (6.2 points) was slightly larger than that reported in this meta-analysis (4.8 points for lateral transiliac procedure). The mean improvement in ODI in our cohort (25.3) was very similar to the meta-analysis (25.8 points) [22].

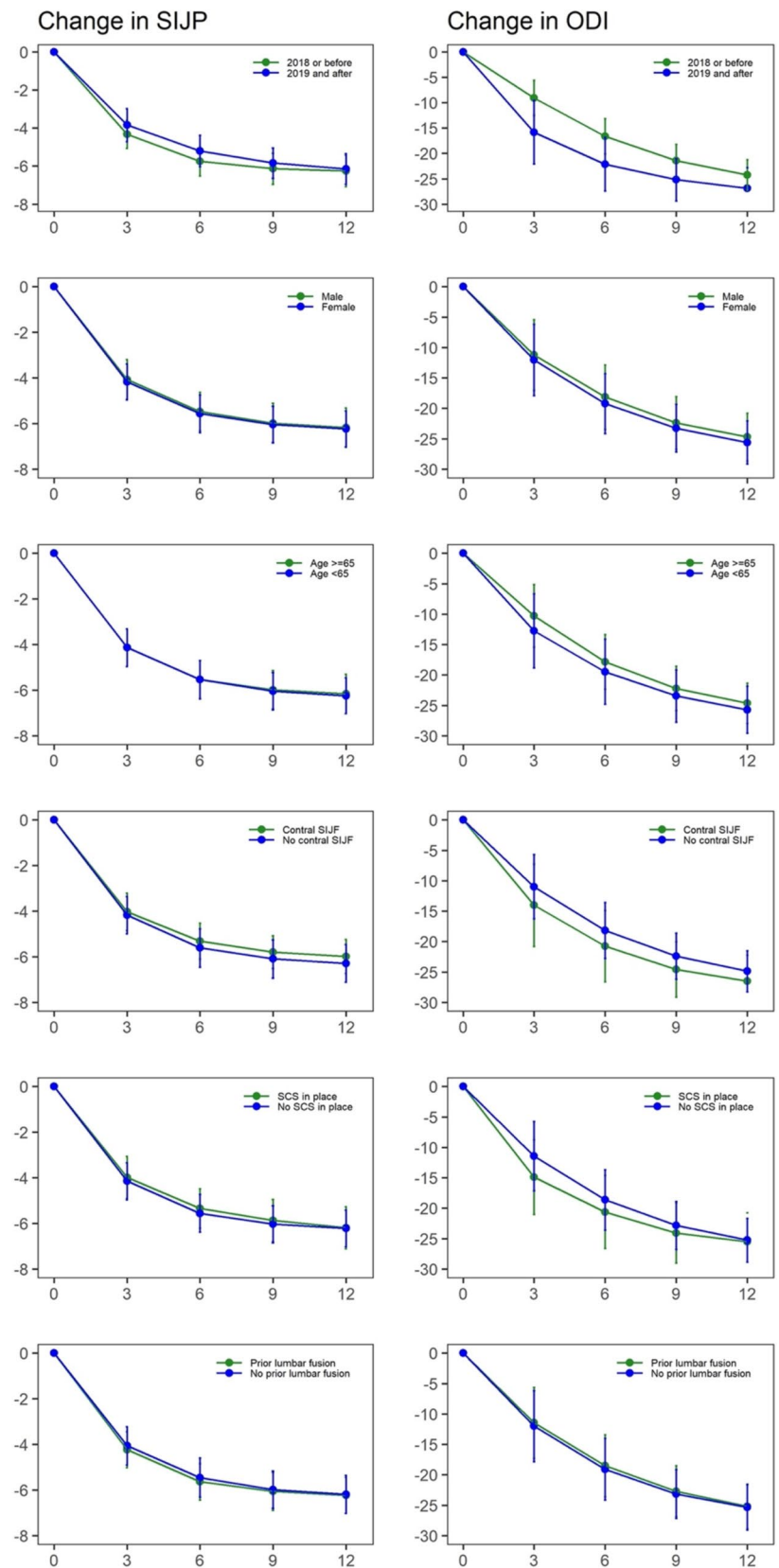
Reasons for a slightly larger improvement in VAS could include the following: 1) In our clinic, we carefully select patients for SIJ fusion. We perform at least 2 independent SIJ blocks to ascertain consistent results and to reduce false positive/negative findings.

Patients with a reduced general condition not able to undergo endotracheal intubation and general anesthesia are not subjected to TTI implantation, but rather to SIJ denervation under local anesthesia. Such patients were included in the 3,477 cases tested with SIJ joint injections, but excluded from the 541 cases with surgical SIJ fusion. Therefore, a population with a very high degree of surgical responders was selected.

Surgery was performed by a single, very experienced neurosurgeon who has close to 1,000 TTI surgical procedures.

Our results were achieved by combining the most stringent selection of candidates with the highest level of surgical experience and lowest level of intraoperative complications.

Fig. 3 Subgroup analysis



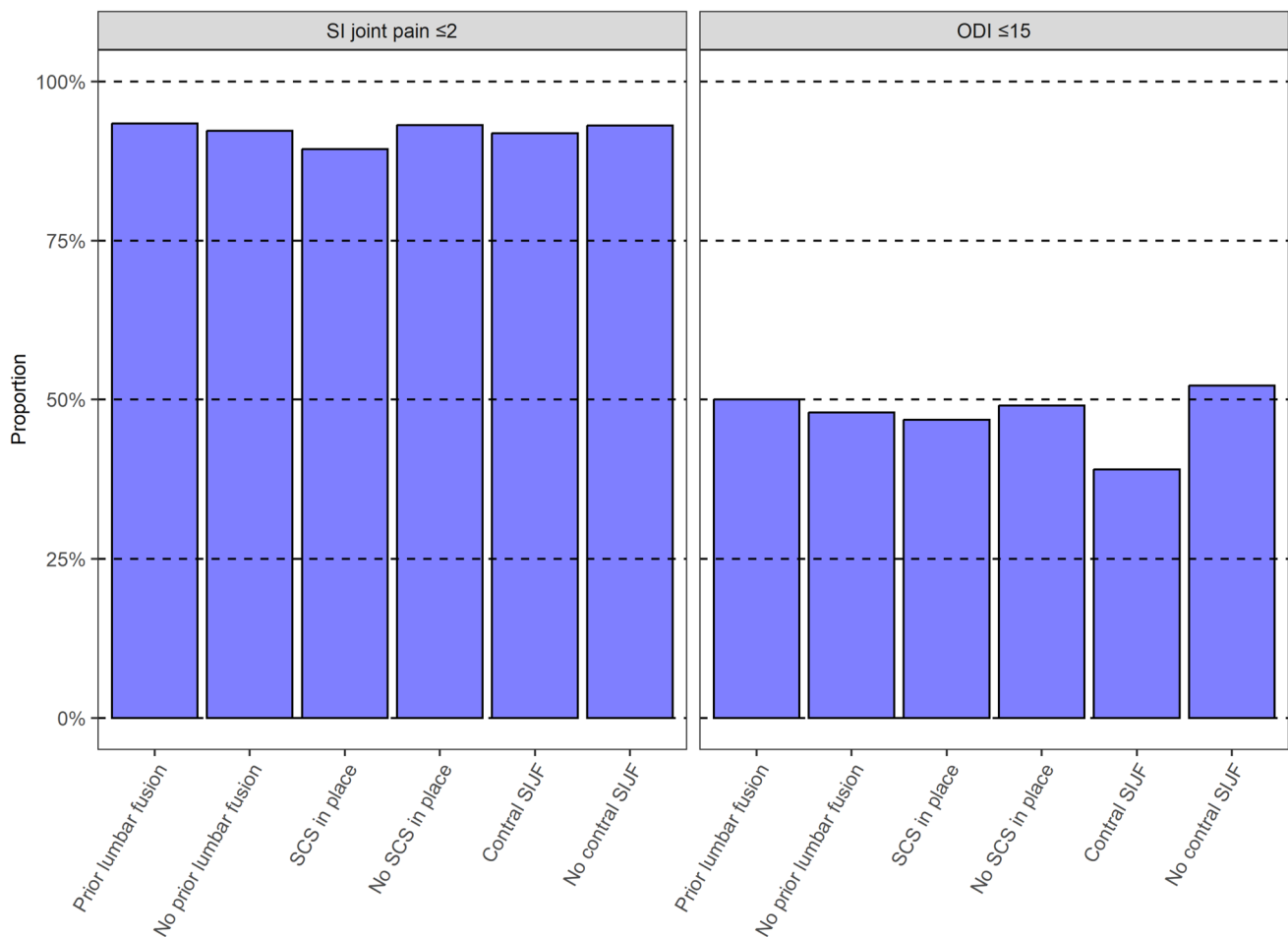
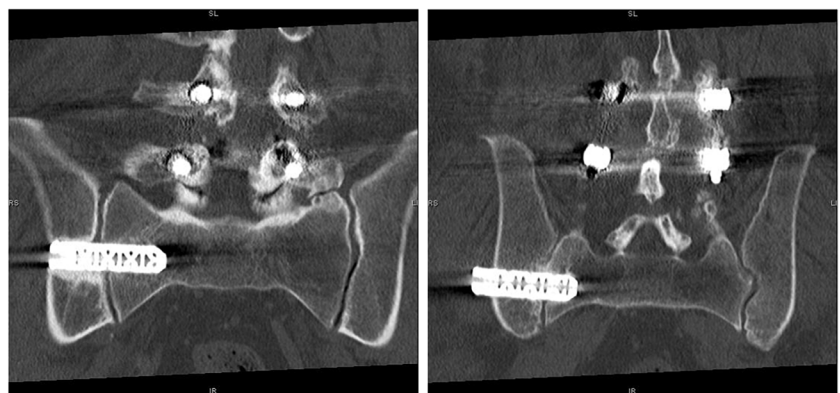


Fig. 4 Proportion of patients with ODI ≤ 15 or SI joint pain ≤ 2 at 12 months by subgroups of interest

Fig. 5 Sample appearance of implants on 12-month CT scan



The primary advantage of our study is its large size compared to other published cohorts. Our center sees large numbers of patients with chronic low back pain. The proportion of our patients with chronic low back pain who were evaluated with SIJ blocks (22%) is similar to the reported prevalence of the condition (15–30%) [1, 12, 13, 19, 20].

Since adopting SIJ fusion in 2015, we have followed all operated patients by regularly scheduled follow-up visits and assessments. The large sample size provided substantial statistical power for subgroup analyses.

Although we have performed many SIJ fusion procedures, the overall proportion of patients evaluated for chronic low

back pain who underwent the procedure is low (3.5%), suggesting that we are not overutilizing the procedure.

Our retrospective, single site/single surgeon study has inherent disadvantages due to its design. It reflects the clinical experience of a single surgeon who performs SIJ fusions regularly and in high numbers. The main outcomes of our study are VAS and ODI, i.e., subjective outcomes that could be subject to some bias. While no functional testing was performed, ODI scores improved and patients were observed to improve their motor skills with walking. While our study had no control group, previous randomized trials of SIJ fusion showed large differences between surgical and non-surgical treatment groups [8, 15].

Conclusions

Our data suggest that pain arising from the SIJ can be reliably identified by very careful and stringent clinical and functional diagnostic procedures, and effectively treated with minimally invasive implantation of TTI according to a highly standardized and streamlined surgical procedure.

Author contributions NR and RS collected and evaluated retrospective data, NR wrote the main manuscript text and DH prepared the figures and tables. All authors reviewed and approved the manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Ethical approval Reference number of study 2024 – 1019 with the Ethics Committee of the Bavarian State Chamber of Physicians: According to § 15 of the professional code of physicians of Bavaria retrospective reviews of anonymized patient data do not require ethical approval. For such studies a written Informed Consent from study participants is not required.

Competing interests The authors declare no competing interests.

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