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ORIGINAL ARTICLE

Distraction arthrodesis of the sacroiliac joint: 2-year results of a descriptive prospective multi-center cohort study in 171 patients

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Abstract
Purpose The aim of the given study was to evaluate the long-term outcomes of patients undergoing sacroiliac joint (SIJ) distraction arthrodesis to treat SIJ-related pain.
Methods Descriptive prospective multi-center cohort study involving 20 hospitals in Germany. Between January 2011 and June 2012, 171 patients with chronic SIJ pain underwent indirect arthrodesis of the SIJ using a distraction implant. The patients were questioned prior to surgery, 6-weeks, and 3-, 6-, 12- and 24-months postoperatively. Overall patient satisfaction was surveyed along with pain medication intake, the Million Visual Analogue Scale (MVAS), Oswestry Disability Index (ODI), Short-form McGill Pain Questionnaire (SF-MPQ), 12-Item Short-Form Health Survey (SF-12), Visual Analogue Scale (VAS) and a pain drawing. Bony fusion of the SIJ was evaluated using X-ray and computed tomography (CT).
Results A majority of patients (73%) reported to feel better or much better 24 months post-surgery, 49% of the patients reduced their pain medication intake. The MVAS dropped from 63 to 36%, the ODI improved from 51 to 33%, the SF-MPQ decreased from 50 to 31%, the SF-12 physical component summary rose from 22 to 41%, the mental component summary increased from 40 to 55%, and pain as measured by the VAS decreased from 74 to 37 points (all comparisons $p < 0.001$). In the follow-up CT scans 31% of the patients showed SIJ fusion.
Conclusions SIJ distraction arthrodesis has shown satisfactory outcomes in patients with SIJ-related pain for all scores reported in the surveys, accompanied by increased functionality.

Keywords Sacroiliac joint fusion · Sacroiliac joint arthrodesis · DIANA implant · Distraction interference arthrodesis with neurovascular anticipation · Pain drawing

Introduction

Lower lumbar and lumbosacral pain originating from the sacroiliac joint (SIJ) rather than from the lumbar spine has been described in the context of outpatient care with incidences of 13–30% [1–6]. It has been reported that the incidence of SIJ-triggered pain increases up to 32–43% as a consequence of lumbar spinal fusion, in particular including the L5–S1 segment [7–10]. Despite a range of adequate conservative treatment options, a certain percentage of patients continue to have a considerably reduced quality of life due to persistent SIJ pain [6]. These patients' pain symptoms are comparable to those with other musculoskeletal disorders, such as spinal canal stenosis and osteoarthritis of the hip joint [11, 12].

As a consequence of the lack of limited-open and low-complication surgical techniques to the SIJ, patients with SIJ-related pain are often referred to pain therapy as a final treatment option.

In late 2009, a new surgical procedure for the fusion of the painful SIJ was introduced in Germany, the so-called distraction interference arthrodesis with neurovascular anticipation (DIANA®, SIGNUS Medizintechnik GmbH, Germany). The initial outcomes of this were promising, leading to the decision to set up a multi-center observational

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study. The given study aimed to quantify if patients in a large multi-center cohort with chronic SIJ pain benefitted from SIJ arthrodesis under distraction over a 24-month observation period. The second aim was to analyze if participants with a typical preoperative pain pattern of the SIJ had a different outcome than those patients with an atypical pain distribution.

Materials and methods

Study design

Patients with chronic SIJ pain were included from 20 German hospitals in this descriptive prospective multi-center cohort study, with pain persisting for 6 months or more. Only patients with exhausted options of conservative treatment (≥ 6 months) were included, such as physiotherapy, manual therapy, therapeutic ultrasound, SIJ orthoses, peri- and intra-articular infiltration and SIJ denervation. The inclusion period was from January 2011 to June 2012. The study design was questionnaire based, surveying on preoperative and postoperative data at 6 weeks and 3, 6, 12 and 24 months. The patients themselves completed all postoperative questionnaires free from external influence at home. Besides magnetic resonance imaging (MRI) and X-rays of the lumbar spine preoperative imaging diagnostics included X-ray and computed tomography (CT) scans of the pelvis. A corresponding imaging of the pelvis was scheduled to be obtained immediately following the surgery and in a 6-month follow-up. The exclusion criteria included the presence of a tumor or bacterial infection, multiple prior surgical procedures to the SIJ, sacral insufficiency fractures and bony defects in the area of the recess of the ilium and sacrum following bone graft harvesting. Patients with ongoing pension claims or on disability leave were also excluded. Preoperative RF neurotomy was no precondition for the patients to be included in our study. No age-related exclusion criteria were defined. All relevant ethics committees approved the study. All patients gave their informed and written consent.

Indication for surgery

The patients had to present their maximum pain below the lumbosacral level and around the posterior superior iliac spine (PSIS). A combination of provocation tests of the SIJ (distraction test, compression test, thigh thrust test, FABER test, Gaenslen test and sacral thrust test) was used [5, 13, 14] for physical examination of the patients. Either peri- or intra-articular SIJ injections were performed additionally, considered positive with a pain reduction of 50% or more. X-rays of the pelvis together with CT scans of both SIJs were indicated to diagnose secondary osteoarthritis consistent with adjacent segment degeneration after lumbar/lumbosacral fusion, accessory joints (false joints of unknown etiology located in the recess of the sacroiliac joint either between the S2 or more rarely between the S1 transverse process of the sacrum against the ilium on one or both sides; Fig. 1) [15, 16], dysplasia, post-partum arthritis, post-traumatic arthritis, axial spondyloarthritis and primary arthritis of the SIJ.

However, it was not mandatory for all of the above-mentioned criteria to be fulfilled completely to enroll eligible patients in this study. The decision was made by the surgeon on basis of a conclusive combination of medical history, clinical tests, SIJ injections, X-ray and CT scan.

Rationale and surgical technique

Several studies demonstrated that applying a pelvic belt or a Hoffmann–Slätis frame over the wing of the ilium might increase the force closure of the SIJ [17–20]. A distraction arthrodesis over the recess is hypothesized to have similar effects, but is placed on the short lever side of the ilium via a posterior approach to the SIJ [21]. Inserting an interference screw in the joint recess between the sacrum and ilium at the level of S2 brings about distraction near the joint and as a result of the accompanying ligamentotaxis, causing a repositioning of the joint surfaces. The distraction enables primary stabilization of the SIJ culminating in fusion (Fig. 2a, b).

The surgery was performed under general anesthesia. A dorsal 4–6-cm-long midline approach was used, with the center of the skin incision corresponding to the upper border of the sacrum. The incision was then extended to the thoracolumbar fascia, continuing laterally to the posterior superior iliac spine (PSIS). A lengthwise fascia incision was made 1.5 cm medial to the PSIS and somewhat further caudally than the skin incision but at the same length. After blunt retraction of the spinal erectors towards medial, the posterior sacroiliac ligaments were exposed and resected over the recess of the SIJ between the S1 and S2 transverse

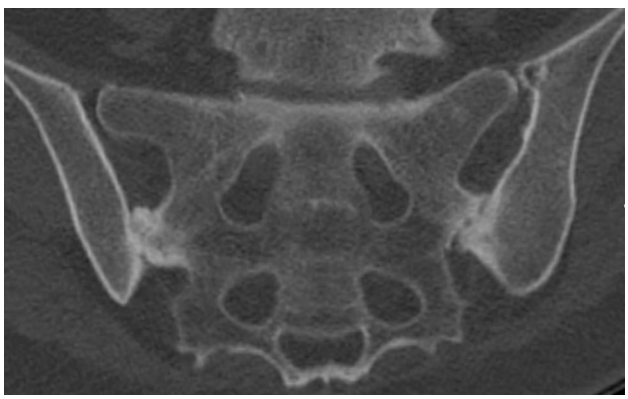

Fig. 1 Severe arthritis of both accessory joints between S2 transverse process of the sacrum and ilium

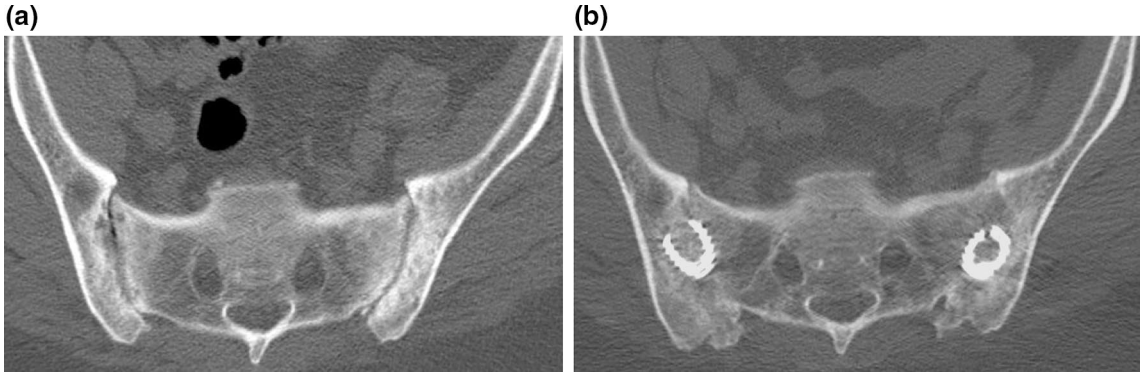

Fig. 2 **a** Severe arthritis of both SIJs with subluxation. **b** CT scan of the same patient 20 months postoperatively showing complete reposition and fusion

processes of the sacrum. In a next step, the interosseous ligaments were removed and the cortical surfaces of the ilium and sacrum exposed, along with the posterior joint space opening at the floor of the recess. A drill was used to open the iliac and sacral cortical bone. A guidewire was positioned along the weight-bearing axis of the ilium using an image intensifier in three predefined planes. The individual width of the recess together with additional possible distraction between the ilium and the sacrum were acquired with a distraction instrument used to determine the size of the required implant (hollow, tapered titanium screw with large fenestrations; implant diameter 13 mm/15 mm/17 mm or 19 mm; length 30 mm). While maintaining distraction between ilium and sacrum the interference screw was inserted in the recess. A large quantity of allograft or bone substitute material (30–45 cc) according to the size of the recess was deposited in and around the implant until the recess and the implant was filled completely (Figs. 3, 4a–c, 5a, b).

Follow-up treatment

Post-surgery the patients were mobilized for 6–8 weeks with a partial weight bearing (20 kg) on the operated side not to lose the achieved intraoperative distraction and ligamentotaxis. Vitamin D supplement therapy was carried out for 3 months postoperatively to promote bone metabolism [22, 23]. Patients undergoing surgery of both SIJs underwent two separate procedures. However, the second side was not operated on until full bearing was achieved on the side operated first.

Outcome measures

Preoperative data collection took place at the respective hospital of surgery. The postoperative surveys were mailed to the participants and completed by the patients independently. The questionnaires included: Million Visual Analogue Scale (MVAS), Oswestry Disability Index (ODI), Short-form McGill Pain Questionnaire (SF-MPQ), 12-Item Short-Form Health Survey (SF-12), and a pain drawing (PD). The postoperative questionnaires also contained questions about patient satisfaction.

A preoperative pain drawing was assessed as ‘typical’ (Fig. 6a) if the PD covered a region corresponding to the ‘Fortin area’ [24, 25]. If the patient additionally indicated referred pain in the leg on the same side or the inguinal region of the affected SIJ, the PD was also classified as ‘typical’ [26, 27]. Drawings that primarily showed pain over the midline at the level of L5 and further cranial or in the lower abdomen or hypoesthesia of the lower extremities or multiple pain locations in the entire body were classified as ‘atypical’ (Fig. 6b).

Two radiologists familiar with the surgical procedure evaluated all X-ray and CT datasets independently and blinded to each other’s ratings. This evaluation included the position of the implant, the ossification between the sacrum and the ilium in the area of the recess and the interference screw, as well as the vacuum phenomenon in the SIJ (Fig. 7a, b). If the results of the two radiologists diverged, the principal investigator additionally evaluated the case.

Statistical analysis

Group comparisons were performed using the Mann–Whitney *U* test, Wilcoxon signed-ranks test, Chi-square test and McNemar test. For multiple testing, confidence levels were adjusted using the Holm–Bonferroni-method. All calculations and visualizations were implemented in the Python programming language using community managed open source libraries of scientific tools (NumPy, SciPy, StatsModels, pandas, Matplotlib). For the scoring of the 12-Item Short-Form Survey (SF12), physical and mental component summaries (PCS/MCS) were calculated by

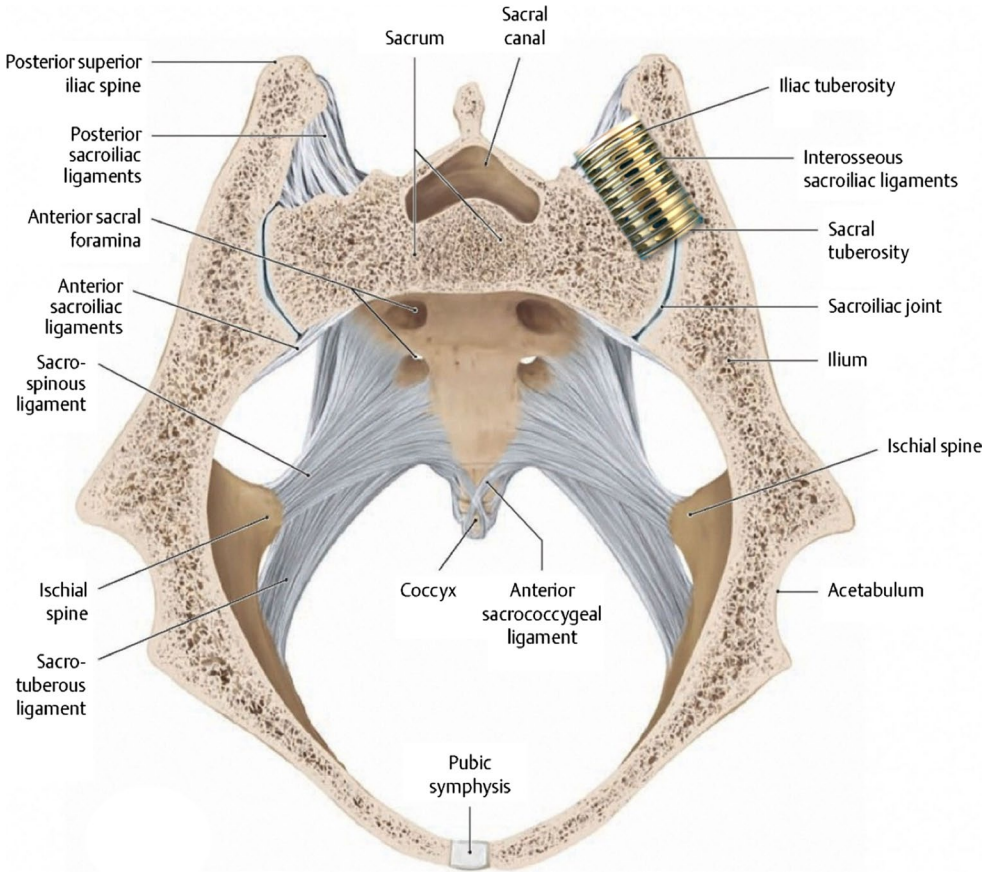

Fig. 3 DIANA implant located in the recess of the SIJ between sacrum and ilium; the cartilaginous part of the SIJ is almost not addressed with the implant (modified picture of Schuenke et al. Thieme Atlas of Anatomy, General Anatomy Musculoskeletal System, pp. 116–117; © Thieme 2007)

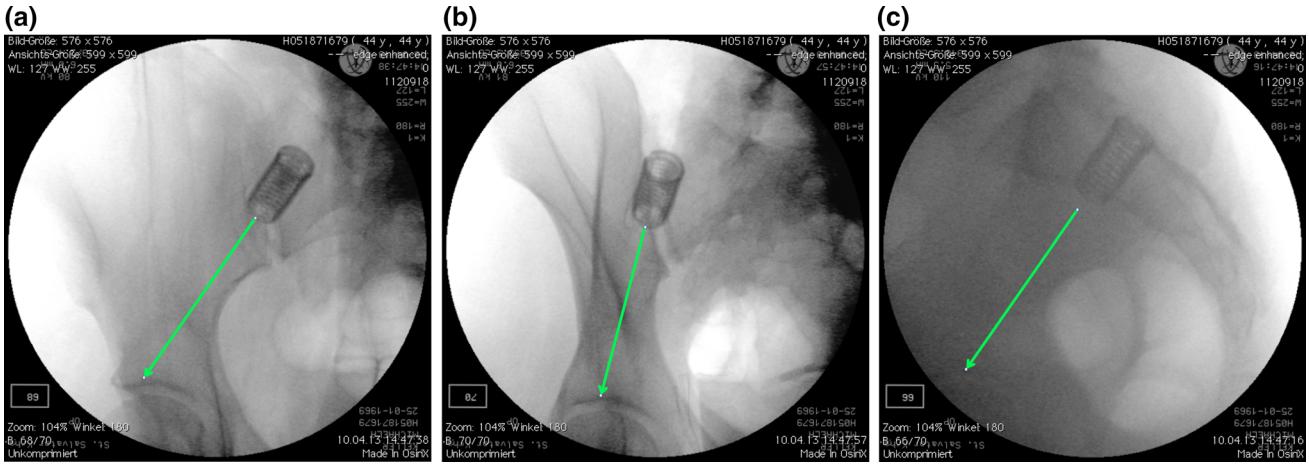

Fig. 4 Fluoroscopic views of correct intraoperative implant position. **a** a.p. view, **b** oblique view, **c** lateral view

reversing items 1, 8, 9, and 10. Scores were then calculated as a percentage ranging from the minimal (0%) to the maximal (100%) possible sum of all items (PCS: items 1–5 and 8; MCS: remaining items). Patients treated on both sides were considered as independent data sets regarding each operation.

Results

Patient numbers and operations

Preoperative questionnaires were received from a total of 171 patients. An operation of the contralateral SIJ was performed in 7 patients (4.1%) in the 24-month

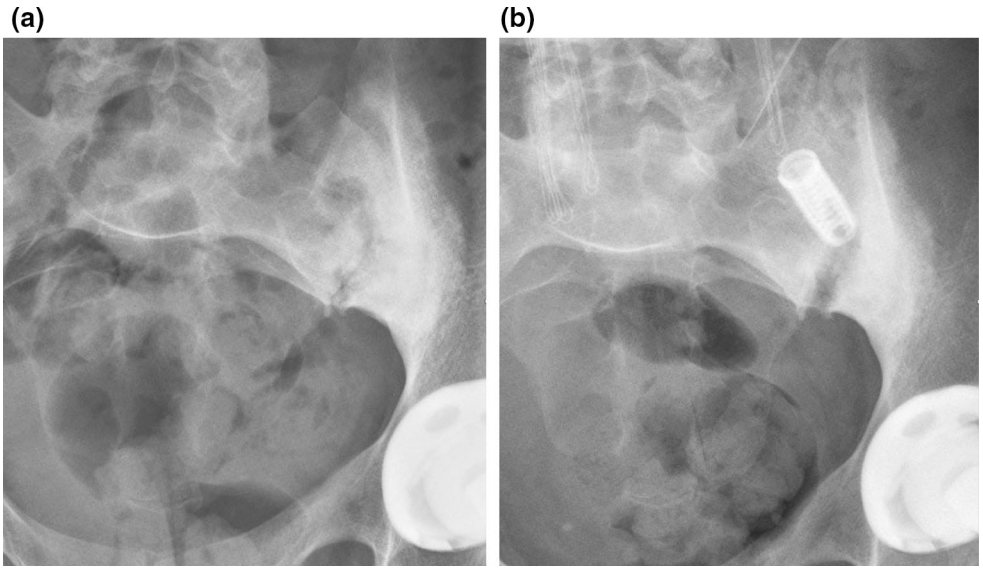

Fig. 5 **a** Preoperative X-ray of severe left SIJ arthritis. **b** Postoperative X-ray with DIANA implant and distraction of left SIJ

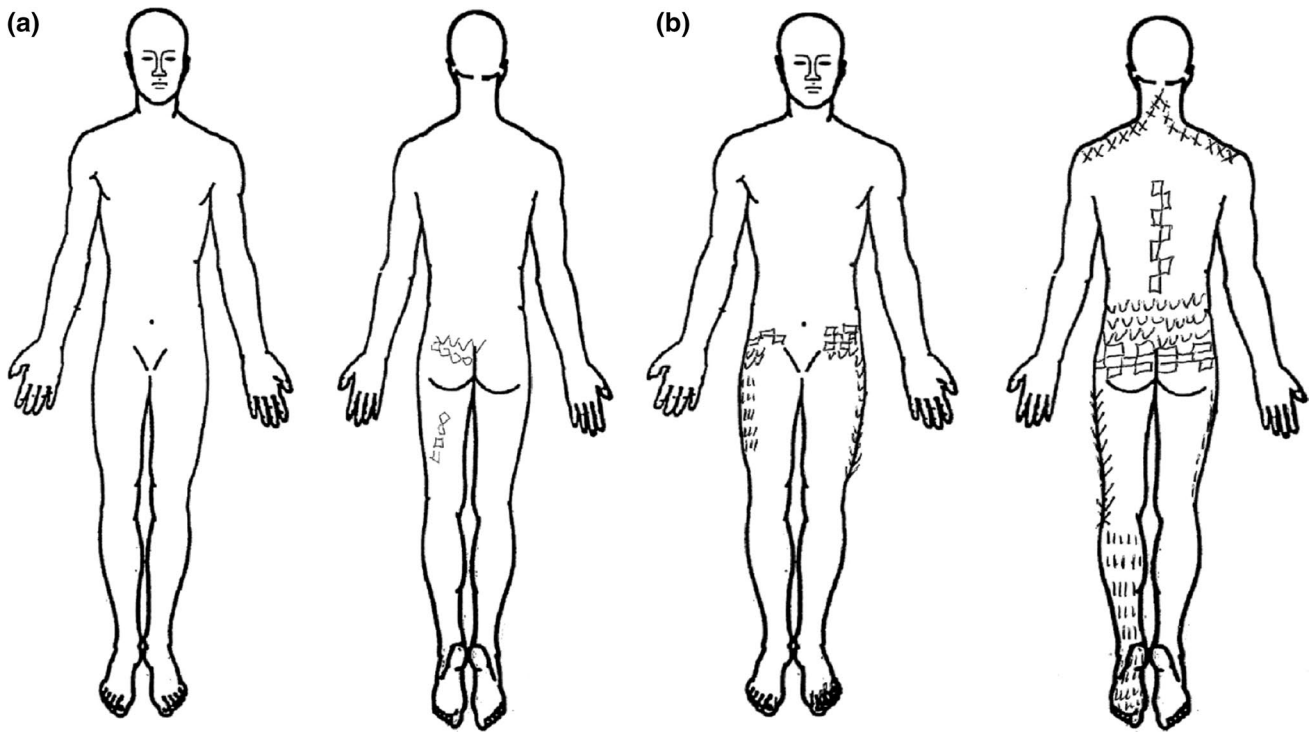

Fig. 6 **a** Typical pain drawing. **b** Untypical pain drawing

surveillance period. At the study endpoint (24 months post-surgery), 143 12-month datasets from 137 patients and 137 24-month datasets from 132 patients were available for evaluation (22.8% loss to follow-up at 24 months). Revisions due to misplacements of the implant or persistent pain were reported in six patients (4.3%) in the postoperative course. All of these patients were followed-up after revision surgery for a period of 12–24 months and were included in the evaluation.

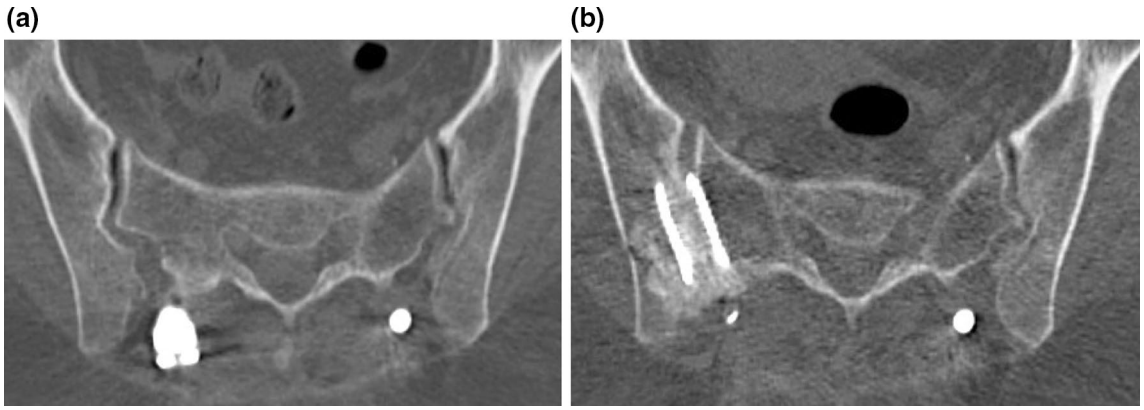

Fig. 7 **a** Preoperative vacuum phenomenon left and right SIJ. **b** Postoperative distraction and subsidence of vacuum phenomenon right SIJ (S1-pedicle screw removed)

Table 1 Characteristics of enrolled subjects (missing percentages = no response)

Characteristics	Value
Subjects (female)	67%
Age females, mean (range)	54 (21–82)
Age males, mean (range)	53 (28–78)
Years of pain, mean	4.5
Prior lumbar operation	45%
Pedicle screw L5/S1	27%
Work status at the time of operation	
Unable to work	31%
Pension	35%
Working	32%
Prior conservative treatment	
Physiotherapy	87%
Manual therapy	66%
Denervation	37%
Orthosis	12%

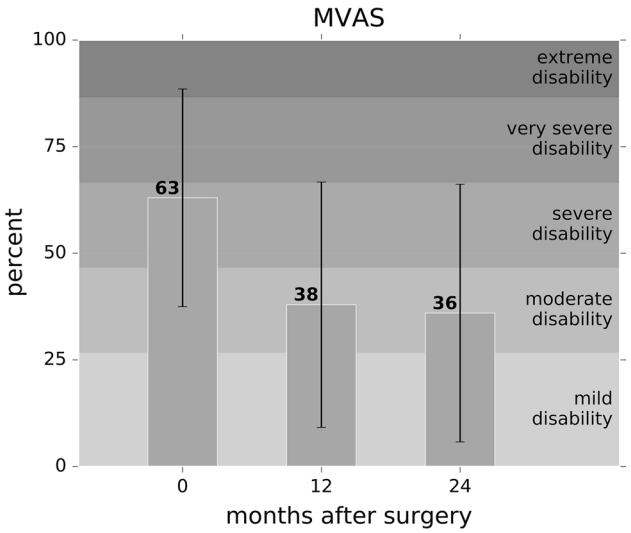

Fig. 8 MVAS preoperatively, 12 and 24 months postoperatively (all p values < 0.001)

Demographic and surgery-related data

Patients' characteristics are presented in Table 1. The surgery duration averaged 100 min (range 45–230 min), mean blood loss 187 ml (range 30–1000 ml). Longer operation times and greater blood loss in isolated cases were explained by the fact that revision surgeries of the DIANA implant were also included and that in some patients, a pre-existing lumbosacral instrumentation had to be removed because the S1 screw was located in the approach path of the DIANA instruments and the implant. Some surgeons also performed a re-instrumentation of the lumbosacral motion segment after inserting the interference screw in the recess. Allogenic bone grafts were used in 66% of the cases, Beta-tricalcium phosphate in 26%, others in 8%—in addition with Dibotermin alfa [Bone Morphogenic Protein-2 (BMP-2); Induct Os®, Medtronic Inc., USA] in 21%.

Clinical outcomes

There was a highly significant decrease in the MVAS (Fig. 8), from 63% preoperatively to 36% after 24 months ($p < 0.001$). The ODI (Fig. 9) decreased from a preoperative score of 51% to 33% after 24 months ($p < 0.001$). The SF-MPQ (see Table 2) of all patients improved from an average of 50% preoperatively to 31% after 24 months ($p < 0.001$). The physical component summary (PCS) increased from 22% preoperatively to 41% 24 months postoperatively ($p < 0.001$). The mental component summary (MCS) increased from 40% preoperatively to 55% 24 months postoperatively ($p < 0.001$). With regard to the development

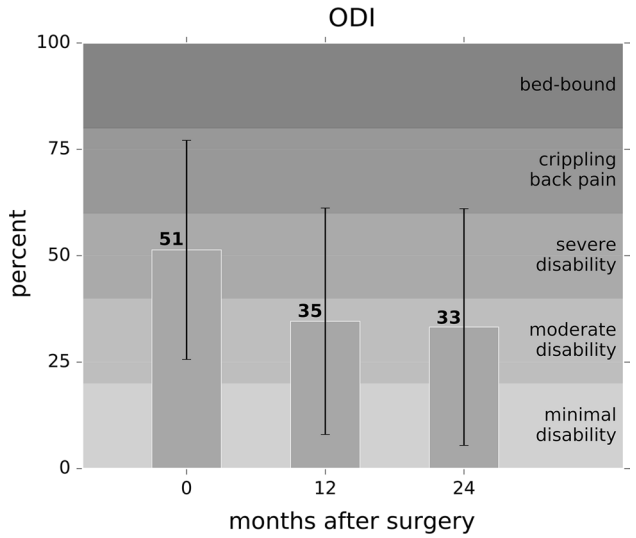

Fig. 9 ODI preoperatively, 12 and 24 months postoperatively (all p values < 0.001)

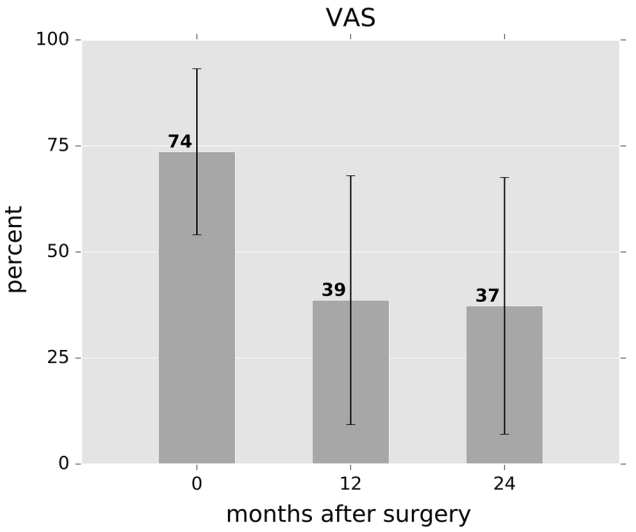

Fig. 10 VAS preoperatively, 12 and 24 months postoperatively (all p values < 0.001)

of pain symptoms in the course of the study, a decrease in pain was observed from 74 points on the VAS (Fig. 10) preoperatively to 37 points after 24 months ($p < 0.001$). When the patients were specifically asked about the decrease in leg pain, their responses yielded a decrease from 60 points on the VAS preoperatively to 32 points after 24 months ($p < 0.001$).

Patient satisfaction

When asked about their current level of satisfaction, 73.3% of all patients reported that they felt better or much better 24 months postoperatively than prior to surgery. In contrast, 13.7 and 13.0% of the patients reported that they felt the same or worse. After 12 months, 79.0% of the participants responded 'yes' to the question as to whether they would recommend the surgical method to a good friend and 78.5% responded with 'yes' after 24 months.

Pain drawing

In the preoperative PD, 57.0% of the patients showed a typical PD (Fig. 6a), 43.0% showed an untypical PD (Fig. 6b). Patients with a typical preoperative PD had highly significant better 24-month results for VAS, MVAS and ODI (Table 3).

Analgesic use

At the time of surgery, 90.9% of the patients were taking analgesics. Before the SIJ fusion, 49.3% of the patients used weak or strong opioids and after 24 months this was decreased to 30.3%. After 24 months, a total of 49.3% of the participants reduced their pain medication (Fig. 11). Although 15.1% of the patients reported to use more analgesics 24 months after the SIJ fusion, only three of these patients stated that they were feeling worse than before surgery. All three of them had a non-union in the follow-up CT scan because of a bad preparation and bone grafting of the

Table 2 Outcomes at baseline and after surgery (12 and 24 months); difference = 24 months − baseline value

	Baseline Mean (SD)	12 months Mean (SD)	24 months Mean (SD)	Difference	p value
MVAS	63 (26)	38 (29)	36 (30)	− 27	$p < 0.001$
ODI	51 (26)	35 (27)	33 (28)	− 18	$p < 0.001$
SF-MPQ	50 (16)	33 (23)	31 (25)	− 19	$p < 0.001$
VAS total	74 (20)	39 (29)	37 (30)	− 37	$p < 0.001$
VAS leg	60 (27)	33 (29)	32 (30)	− 28	$p < 0.001$
SF-12 (PCS)	22 (15)	40 (26)	41 (27)	19	$p < 0.001$
SF-12 (MCS)	40 (20)	54 (24)	55 (25)	15	$p < 0.001$

Table 3 Outcomes in patients with typical pain drawing vs. patients with atypical pain drawing at baseline and 24 months after surgery; difference = 24 months − baseline value

	Baseline Mean (SD)	24 months Mean (SD)	Difference	*p* value
Typical PD				
MVAS	63 (14)	28 (24)	−35	$p < 0.001$
ODI	51 (14)	27 (20)	−24	$p < 0.001$
SF-MPQ	49 (16)	23 (22)	−26	$p < 0.001$
VAS	73 (19)	29 (28)	−44	$p < 0.001$
Atypical PD				
MVAS	63 (16)	46 (25)	−17	$p < 0.001$
ODI	51 (16)	40 (19)	−11	$p < 0.001$
SF-MPQ	48 (17)	38 (24)	−10	$p = 0.011$
VAS	75 (18)	48 (29)	−27	$p < 0.001$

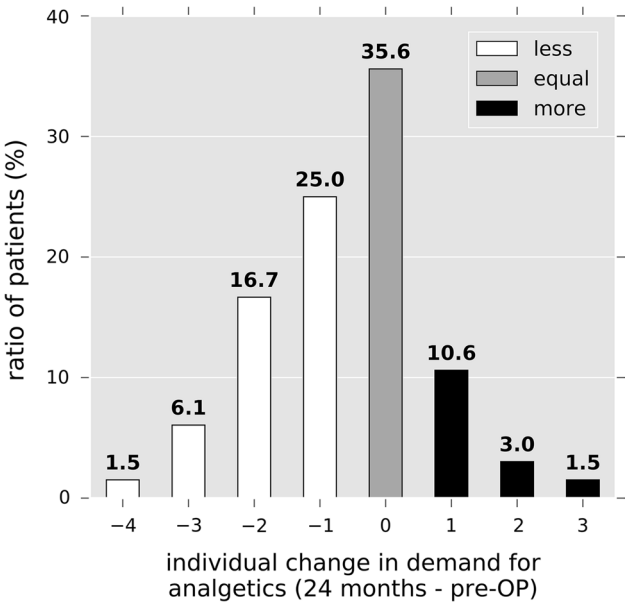

Fig. 11 Individual level change (24 months − preoperative) within the groups of analgesics (strong opioid, weak opioid, non-opioid, on-demand medication, no analgesic)

recess. None of them had a poor implant positioning. Two of them had an atypical pain drawing preoperatively.

Imaging

A complete series of CT scans (pre-/postoperatively/6 months or more) was available for 115 operations. The radiologists' assessments on fusion and vacuum phenomena diverged in four of the cases (3.5%). 36 operations (31.3%) were assessed as unequivocally fused, with a considerably higher fusion rate of 67% when BMP-2 was used compared to a fusion rate of 19% when no BMP-2 was used ($p < 0.001$). In terms of operations with no observed vacuum phenomenon (preoperative vacuum phenomenon in SIJ space, no longer present in the last follow-up CT), the fusion rate amounted to 83% in contrast to a fusion rate of 13% for operations showing a vacuum phenomenon ($p < 0.001$). In 33% of the cases a poor implant position (implant inserted too far into the ilium or the sacrum) was observed. Overdistraction of the SIJ as an indirect sign of a rupture of the surrounding sacroiliac ligaments was not found in any of the cases. Statistics showed no significant correlation regarding fusion against all scores (ODI, MVAS, SF-MPQ, VAS) or the reported improvements of back or leg pain by the patient.

Complications

Intraoperative and implant-associated postoperative complications occurred in one case, where a sensory L5-radiculitis was caused by too liberally applied bone substitute. After surgical revision and removal of the bone substitute, symptom relief was achieved in 5 days.

Discussion

This study is the first prospective multi-center study to report on 2-year findings after posterior SIJ arthrodesis using the DIANA technique in patients with SIJ-related pain.

Compared to the most common lateral transarticular approach [21], the DIANA SIJ fusion technique has several advantages. First, decortication of the ilium and sacrum, bone grafting and fixation follows orthopedic principals concerning bone to bone fusion. Laterally based techniques rely mostly on transfixation of the ilium against the sacrum. Second, distracting the ilium against the sacrum can achieve a reposition of a subluxated SIJ into anatomic position again. Lateral techniques might transfixate the SIJ in an unphysiological position. Third, using the recess for SIJ fusion is a safe approach because no major nerves or vessels are at risk. Lateral approaches might harm the superior gluteal neurovascular bundle or the S1 or S2 nerve root in case of a too deep implant positioning or narrow bony corridors in between the neuroforamen of the sacrum [28]. Fourth, the dorsal approach offers the opportunity to remove accessory joints in the recess of the SIJ. Lateral approaches are not able to address this pathology directly. Finally, in case of a pseudarthrosis the distraction implant is easy to revise through the same approach going again for decortication, grafting and fixation with a larger implant. Lateral-based implants coming loose in the soft bone of the sacrum but being well integrated in the ilium or vice versa might be hard to remove without collateral damage.

The preoperative quality of life of the patients included in the given study was as strongly compromised, comparable to

Table 4 Comparison of study results Fuchs et al. and Sturesson et al.

	Follow-up (months)	VAS	ODI	Procedure again (%)
Fuchs et al. (DIANA)	24	37	33	78
Sturesson et al. (iFuse)	6	34	32	80

patients with lumbar spine pathology [12]. Although patients suffered from pain for 4.5 years on average, had exhausted the options for conservative treatment and in many cases already undergone spinal surgery, the study outcomes showed a clear and sustainable decrease in SIJ-related pain in a 2-year interval. The vast pain decrease is also reflected by the overall decrease in the use of pain medication. In those patients who reported an increase in the need for analgesics 24 months after the operation, only 13.6% reported that they felt worse than before surgery. Because of those findings, we can only speculate that the higher demand of analgesics in most of those patients might be due to a different reason than ongoing SIJ pain.

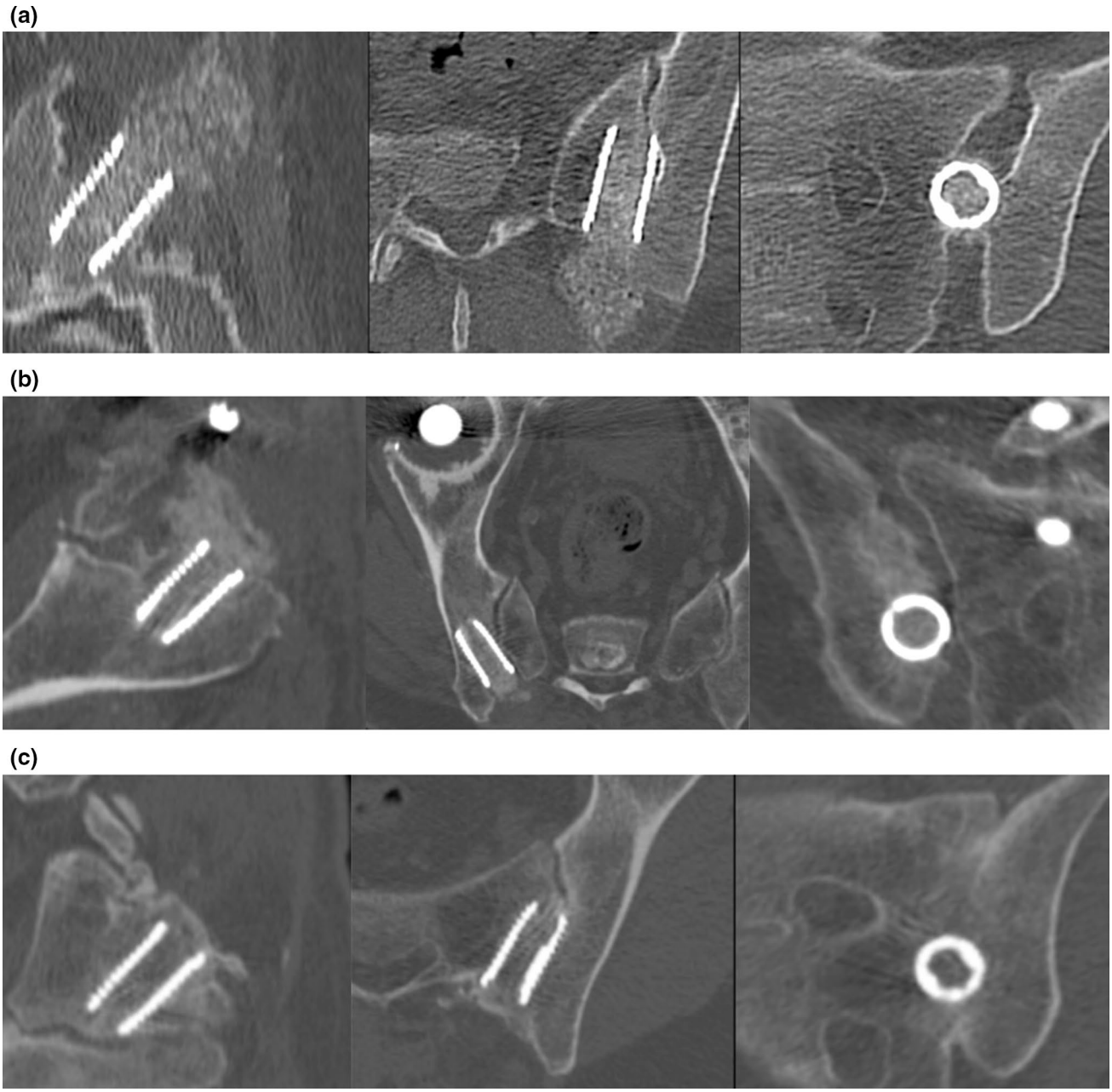

Fig. 12 **a** Insufficient preparation and bone apposition in the recess around the implant. **b** Inadequate position of the implant (in the example shown here, too far inside the ilium). **c** Solid fusion of the SIJ

The patient population in our study showed an average decrease on the VAS of 37 points 24 months after distraction arthrodesis of the SIJ was performed, reaching far beyond the minimum clinically important difference (MCID) [29, 30]. Literature reports varying MCID values for the ODI [29, 31–33]. If the frequently used threshold of 15% is used, the average decrease of 18% provides evidence for the clinical relevance in our patient population in this area as well. If the end values for VAS and ODI 24 months following posterior fusion were compared with the results recently published by Sturesson et al. [34] 6 months after lateral percutaneous stabilization, comparable values are yielded (Table 4). According to Grafton [35], the minimum detectable change in the overall score of the SF-MPQ is 8.7%, which was reached here at an observed decrease of 19% in the values after a 24-month observation period. The patients' quality of life clearly improved in the postoperative course, equally corresponding to the SF-12. It can be assumed that the pain drawings we used to diagnose SIJ pain are a good instrument for the use in preoperative diagnostics. Typical preoperative PDs resulted in highly significant better results in all scores 24-month postoperatively.

In the postoperative CT scans, bony fusion was observed in only 31.3% of all joints undergoing surgery. There might be a number of reasons for this: First, the follow-up CT scans were conducted at a comparably early stage after surgery, and bony fusion might not have completed by then. This presumption is supported by bone progression in those patients who had had further CT scans of their pelvis. Second, in a large percentage of the patients, the postoperative CT scan showed inadequate preparation of the recess or inadequate deposit of bone (substitute) material (Fig. 12a). Third, a poor positioning of the implant (Fig. 12b) or a severe osteoporosis could be a potential reason for non-union. Surprisingly, there was no statistically significant correlation between the clinical findings and fusion rates. It may be possible for delayed bone union in the area of the recess or rigid scar tissue to achieve acceptable SIJ stability. It is certain that in the case of proper implant insertion, conscientious preparation and bone apposition (possibly with the use of BMP-2), solid SIJ fusion can be achieved on one or both sides (Figs. 12c, 2b) also in the presence of a lumbar or lumbosacral fusion.

The positive aspects of the given study include that it is a prospective multi-center study independent of the initial describer of the procedure [21]. Furthermore, all of the patients were able to complete their postoperative questionnaires at any time without any influence by third parties.

This study, however, has a few limitations. Most importantly, a corresponding conservative control group is missing. This concept was discarded for two reasons: First, it was difficult to standardize a corresponding control group at the given level of quality. Second, the participants were for the most part, patients who had exhausted all options for conservative treatment and at the time of the study were hoping to solve their problem as a result of the surgery. Furthermore, the data presented were certainly negatively influenced by the large number of patients who already undergone previous surgery and chronic pain patients who had pain for many years in various parts of their body. Moreover, among the participating physicians, due to the nature of the surgical technique, there was a certain level of uncertainty with regard to their indications of the procedure. Also, the learning curve for the novices needs to be acknowledged, which for most of the surgeons was included in the results presented here in nearly its entirety.

Conclusion

This prospective multi-center study demonstrated that patients with long-lasting and severe SIJ pain, that were treated with distraction arthrodesis of the SIJ, had reduced pain and disability and increased quality of life after 24 months. The absence of permanent nerve and vascular injuries is evidence that distraction arthrodesis is a safe and gentle surgical procedure.

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Compliance with ethical standards

Conflict of interest Volker Fuchs is a primary investigator in SIGNUS clinical trials. He is a paid consultant of SIGNUS. The surveillance study was funded by SIGNUS Medizintechnik GmbH.

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