A novel arthrodesis technique of the sacroiliac joint

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Technical advance

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Abstract

Purpose The aim of the study was to develop an implant for fusion of the sacroiliac joint (SIJ) which, in contrast to known implant systems, can be used for isolated fusion of the SIJ as well as in combination with a lumbar instrumentation procedure or as an alternative to existing sacropelvic fixation (SPF) methods.

Methods Following a comprehensive review of more than 200 high-resolution pelvic CT data sets, an implant body with high porosity and a large contact surface to the ilium and sacrum favoring integration was designed. Its shape was modeled based on the recess of the SIJ. A screw anchored in the ilium secures the position of the implant in the recess and allows connection to a lumbar instrumentation via an S1 screw. After receiving a detailed explanation and information about the novelty of the procedure, two patients with confirmed SIJ syndrome, who had undergone conservative treatment for more than 6 months without success, were operated on with a patient individual implant adapted to their anatomy.

Results There were no intraoperative or postoperative complications. The postoperative CT and pelvic X-rays showed a good form fit of the implant body in the respective recess as well as correct positioning of the inserted screws.

Conclusions The implant used first takes into account the special anatomy of the SIJ and also meets the requirements of a true arthrodesis of the joint. Clinical studies will now have to show whether the considerable theoretical advantages of the new implant system over existing SIJ implants and SPFs can be put into practice.

Introduction

The sacroiliac joint (SIJ) is difficult to access due to its anatomical position and joint surface geometry [1]. Arthrodesis with maximum cartilage removal from the joint surfaces, autologous or allogeneic bone graft and, in the given case, screw fixation is only possible with extensive soft tissue damage [2, 3]. In line with the surgical treatment of traumatic SIJ injuries, an increasing number of implant systems have been introduced to the market in recent years, which primarily use a minimally invasive procedure to transfix the SIJ laterally [4]. In addition to cannulated bone screws with large diameters, triangular plasma spray-coated titanium bolt implants with a porous surface are usually used for this procedure. The implants are inserted percutaneously through the ilium and ideally via the cartilage-bearing part of the SIJ press fit into the sacrum. Despite numerous studies on these implants, evidence of bone bridging between the ilium and sacrum has only been established in a minority of cases [5–7]. It therefore remains to be seen to what extent this transfixation of the joint with laterally inserted implants will last in the case of decreasing bone density with age, especially in the sacrum.

In addition to the anterior approach to the SIJ which is accompanied by many complications [3, 8], the dorsal approach via the recess of the SIJ seems more promising with regard to the possibility of an arthrodesis of the sacroiliac joint [9]. In this procedure, the interosseous ligaments between the sacrum

and ilium, which have already become degeneratively altered and insufficient in the course of arthrosis of the SIJ, are resected [10]. The cortical surfaces exposed as a result provide sufficient space to place an implant and insert bone graft. Fusion is thus carried out indirectly via the recess of the SIJ [4].

The weaknesses of currently available dorsal implant systems are the lack of primary stability, localized stress on the surrounding bones and the fact that the generously introduced bone allograft must first be converted into vital bone or has possibly already been resorbed before bony consolidation could take place [9].

A major disadvantage of all SIJ implants on the market, regardless of access route, is that none of them can be connected to an existing, future or parallel lumbar instrumentation. Therefore, the aim was to develop an implant together with a safe surgical technique, which has a large contact area between the sacrum and ilium, an optimal surface for bony integration, allows sufficient primary stability and can be connected to a lumbosacral fusion operation or serve as a replacement for known sacropelvic instrumentations as part of a multisegmental spinal fusion.

Materials And Methods

Implant development and design

In the first step, the size, shape and position of the posterior interosseous joint region of the sacroiliac joint were assessed retrospectively based on more than 200 high-resolution computed tomography (CT) data sets of the pelvis in patients with known SIJ symptoms.

After selecting the smallest, largest and eight additional representative posterior SIJ recesses, data were obtained morphometrically using Materialise Mimics version 17.0 (Mimics Innovation Suite 17.0, Materialise®, Germany) and reconstructed creating three-dimensional volumes. The geometries and sizes of the implants were then derived from this. Based on these measurements, it was found that a total of four sizes would be necessary. In addition, the flat surface on the iliac side was found to be different from the concave surface on the sacral side, thereby resulting in side dependence and the need for different implants for the right and left SIJ. Since the implant body was to be anchored in the recess with a screw at the S2 level in the ilium, the average angle formed between the recess and the body of the iliac bone in both the para-axial and para-sagittal CT reconstructions was determined. In general, a screw length of 5 cm (minimum of 4 cm), measured from the bottom of the recess or the exit point of the implant body, was necessary to reach the area of the ilium with the highest density (*Fig. 1*).. The larger the body of the four implants (*size 1*: 37 cm², *size 2*: 48 cm², *size 3*: 62 cm², *size 4*: 80 cm²), the larger the diameter used for the respective screw (*size 1*: 7 mm, *size 2*: 8 mm, *size 3*: 9 mm, *size 4*: 10 mm diameter). Another requirement was the use of self-cutting screw threads, which allow cement augmentation through a central cannulation in order to ensure adequate fixation even in the case of deficient bone stock.

The shape of the implant body was carefully adapted to not exceed the lower two-thirds of the recess so that an S1 screw could be placed simultaneously or the implant could be inserted with a preexisting S1

screw in place and also leave enough space to pack additional bone material cranially of the implant into the recess.

Based on these considerations, a total of eight implant bodies (four for each joint side) and eight screws (four diameters and two lengths each) were custom made based on computer-assisted design (CAD) files. The CAD files were then compared to the volumetric representations (*Fig. 2*). After that, prototypes were manufactured by electron beam melting (EBM) of titanium powder (Ti6Al4V according to ISO 5832–3/ASTM F1472). The prints were realized in a diamond lattice structure and a porosity of 82% before the resulting implants were trialed on models (*Figs. 4–7*) and human specimen. Further trials involved a cleaning validation (Ortek AG, Merenschwand, Switzerland) and mechanical tests (SpineServ GmbH & Co. KG, Ulm, Germany).

Indication for surgery

SIJ surgery was to be performed only on those patients with therapy-refractory SIJ syndrome following unsuccessful conservative therapy (i.e. physiotherapy, manual therapy, therapeutic ultrasound, SIJ orthoses), two peri- and intraarticular steroid injections [11–12], ≥ 3 positive diagnostic tests of the SIJ (FABER test, thigh thrust test, compression test, distraction test, Gaenslen test, sacral thrust test) and sitting intolerance [13–15]. The site of the pain had to be in the lumbosacral transition close to the PSIS (positive Fortin finger test) [16]. In addition, at least two of the four infiltrations of the SIJ should have resulted in significant pain relief ($>75\%$) over several days as part of the diagnostic criteria [17]. 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, dysplasia, post-partum arthritis, post-traumatic arthritis, axial spondyloarthritis and primary arthritis of the SIJ.

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.

All patients gave their informed and written consent to the surgery including a statement that a patient individual non-CE certified implant would be used for which no clinical data was available at this stage. All patients were provided with detailed information about possible nonsurgical and surgical alternatives to the given implant and technique.

Pre- and postoperative imaging

Preoperative imaging diagnostics included magnetic resonance imaging of the lumbar spine as well as a plain X-ray and CT of the pelvis to rule out competing pathologies in those regions and identify variations in SIJ morphology. In addition, a plain X-ray and CT were taken of the pelvis to assess the correct positioning of the implants following surgery.

Surgical technique

Surgery was performed under general anesthesia. A midline dorsal incision measuring approximately 6 cm in length was made with the center at the upper boundary of the sacrum. Once the thoracolumbar fascia was reached, the epifascial exposure was extended laterally to the posterior superior iliac spine (PSIS) on the affected side. The fascia was then opened 1.5 cm medially to the PSIS before the spinal erectors were bluntly retracted medially, thereby exposing the posterior sacroiliac ligaments. After incising the ligaments carefully at the level of the SIJ recess, the interosseous sacroiliac ligaments were resected. The opposing cortical surfaces of the ilium and sacrum were then partially removed using a high-speed burr until the cancellous bone was exposed. Subsequently, a K-wire at the S2 level was placed into the center of the iliac column under strict fluoroscopic guidance (*Fig. 8a–c*). The K-wire served as a guide for the four bone rasps (*Fig. 9a–b*), corresponding to the four implant sizes that were successively introduced down to the bottom of the recess up to the appropriate size (*Fig. 9c*). The next step included the grafting of autologous or allogeneic bone, which was packed into the upper part of the recess. Afterwards, the implant was inserted to reach the maximum depth of the recess, using the K-wire as a guide. The size of the implant matched the largest bone rasp used. The implant was then fixed to the ilium using a screw length of 4 to 5 cm (*Fig. 10a–c*). In the event of deficient bone stock, the screw can be augmented with cement.

In addition, the ilium screw was equipped with a tulip head, which allows the construct to be mounted on a bicortical S1 pedicle screw and a rod with a length of 25 to 35 mm from any commercial implant provider (*Fig. 11*). This can be accomplished using the same skin incision. Finally, a drain was placed before wound closure.

Results

Demographic and surgery-related data

The implant and surgical technique were trialed in two female patients. Both individuals suffered from chronic therapy-refractory SIJ pain and fulfilled the above-mentioned inclusion criteria, thereby making them eligible for SIJ fusion. Patient 1 had already undergone a successful contralateral SIJ fusion in 2010 with a different implant system. Neither patient had a previous history of any other spinal surgery. Further information on both patients, including the preoperative scores (Visual Analogue Scale [VAS], Oswestry Disability Index [ODI], Million Visual Analog Scale [MVAS] and the Roland Morris Score [RMS]), is summarized in *Table 1*.

In the preoperative clinical imaging of both patients, vacuum phenomena and subchondral sclerosis were seen on the affected SIJs, which is indicative of arthrosis of the painful joint. In patient 1, additional subchondral bone cysts were found on the sacral side. Furthermore, unspecific degenerative changes were observed in the lumbar spine.

Surgery time was 120 and 130 minutes and intraoperative blood loss was 350 and 300 ml for patients 1 and 2, respectively. No intraoperative complications occurred at the time of surgery.

Postoperative management and imaging

Postoperative pain management included 20 mg of oxycodone (1–0–1), 500 mg novaminsulfon (4x2) and 600 mg ibuprofen (1–1–1) per day. The drains were removed and both patients were mobilized under partial weight bearing (20 kg) on the first postoperative day.

In both cases, the postoperative CT showed adequate form closure of the implant with the SIJ recess and correct placement of the screws (*Figs. 12a–c, Figs. 13a–c*). In patient 1, the iliac screw appeared to be positioned quite caudally (*Fig. 14*), but had not perforated the cortical bone. The vacuum phenomenon of the SIJ was no longer detectable in either patient. Wound healing completed without complications.

Discussion

Lumbar back pain with symptoms originating from the SIJ is reported to be 13–30% in the literature [18–23]. In fact, these numbers are much higher if surgeries to the lumbar spine or lumbosacral junction are preconditions, accounting for 32–43% of cases [24–27]. In particular, if multisegment fusion surgery to the spine is performed, sacropelvic fixation methods are increasingly used. Often, S2-alar-iliac (S2AI) or ilium screws are used to help minimize the risk of both L5-S1 pseudarthrosis and also symptomatic SIJ arthrosis [28, 29]. A number of possible indications exist for surgical fusion of the SIJ other than secondary arthrosis, such as primary, post-traumatic or post-partum arthrosis, accessory joints, dysplasia and axial spondylarthropathy [9]. Therefore, during the course of a lifetime, either an isolated SIJ fusion or an SIJ fusion following lumbar spondylodesis in the sense of an adjacent segment degeneration [30], or a combination of both SIJ fusion and lumbar spondylodesis may be required. Existing devices on the market, however, are unable to fully address these surgical needs. Neither implants for lateral placement nor those for posterior placement offer the possibility of being connected to lumbar instrumentations. Consequently, these devices may even hamper SPF since they are placed in the area of the surgical exposure of S2AI or ilium screws [31].

In addition, lateral approaches to the SIJ carry significant surgical site morbidity and revision risk. Lesions of the superior gluteal nerve and artery have been observed in up to 18% of cases [32]. Furthermore, sacral nerve root irritation may occur in cases where implants are malpositioned or if the chosen implant length is too long. The surgeon is presented with another difficult scenario in the case of bony ingrowth of the implants in the ilium but not the sacrum. Here, recovery of the implant(s) is only possible by overdrilling.

In the case of long fusions, SPF has the advantage of significantly reducing peak stresses at the S1 segment, and thus the rate of L5-S1 pseudarthrosis [33]. Since in the case of S2AI screws, the SIJ is only

transfixed and in case of ilium screws it is only fixed, screw loosening or breakage may also occur depending on the preoperative extent of SIJ mobility [34, 35]. Another disadvantage of S2AI screws is the difficulty in placing the implant exactly within the sacral bone stock without it failing laterally towards the recess of the SIJ [36]. Furthermore, the high stresses placed on the screw shaft at the level of the SIJ may increase the risk of screw failure [37] and the interface between screw head and tulip may also become disconnected [37, 38]. The disadvantages of ilium screws include greater soft tissue damage and the marked prominence of the head of the screw [39], with higher wound infection rates and soft tissue irritations as a consequence [40]. Also, the peak stresses to the necessary offset connectors may result in disconnections or breakage [37, 41]. Neither the S2AI screw nor the ilium screw is on the same level as the S1 screw. The head of the S2AI screw is positioned more medially, whereas the head of the ilium screw is placed much more laterally than the S1 screw [42, 43]. Very long S2AI or iliac screws may interfere with a total hip arthroplasty, should it be required in the future.

The implant presented here theoretically has the potential to compensate for the aforementioned disadvantages for the following reasons: 1) In contrast to lateral exposure approaches to the SIJ, the surgical exposure approach is similar to conventional spine surgery. 2) No at-risk structures such as nerves and vessels are situated directly within the surgical corridor. 3) Due to the large areas of bone contact between implant and ilium and implant and sacrum, as well as the osseointegrative surface coating of the implant body itself, there is a high chance of bony integration with full arthrodesis. 4) The fixation of the implant body to the ilium by means of a screw with a maximum possible diameter and the direct connection with an S1 screw using a short rod increase the likelihood of stability of the construct. 5) Due to the expected higher primary stability of the implant compared to an isolated S2AI or ilium screw, the use of shorter screws in the ilium allows unrestricted treatment of pathologies of the hip joint. 6) The screw head of the implant is exactly in line with the S1 screw and sufficiently covered by soft tissue. 7) Following integration of the implant, material failure seems less likely since no further movement occurs in the SIJ. 8) The implant can be used for isolated SIJ fusion and for SIJ fusion as part of lumbar fusion surgery or as a treatment sequela after lumbar fusion (provided the S1 screw has been placed correctly). 9) In comparison to most devices for lateral implantation to the SIJ, this technique is an indirect but nevertheless true arthrodesis rather than a transfixation of the SIJ. 10) In the case of revision surgery, the expected access morbidity is similar to that of a primary intervention.

Conclusions

The preliminary experience following the first trials with this new implant system proves the concept of feasibility with promising results. Further prospective large-scale multicentric studies will need to assess the advantages and disadvantages of this new implant design in detail. To this end, a patient group with isolated fusion of the SIJ may need to be assessed as well as a patient group with multisegment fusion of the spine.

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Table 1

Table 1 - Characteristics of enrolled subjects

<i>Subject</i>	<i>No. 1</i>	<i>No. 2</i>
Gender	female	female
Age	54	78
BMI	31	24
Smoker	no	no
Work status	unable to work	pension
VAS (0-100)	95	82
ODI (0-100%)	60	74
MVAS (0-100%)	79	81
RMS (0-24)	19	18

Declarations

Abbreviations

SIJ: sacroiliac joint; SPF: sacropelvic fixation; SIJF: sacroiliac joint fusion; S2AI screw: S2-alar iliac screw; CT: computed tomography; CAD: computer assisted design; EBM: electron beam melting; VAS: Visual Analogue Scale; ODI: Oswestry Disability Index; MVAS: Million Visual Analogue Scale; RMS: Roland Morris Score

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Authors' contributions

VF invented the new implant system and performed the operations on both patients.

Funding

None

Availability

Not applicable

Ethics approval and consent to participate

Both patients gave their informed and written consent to the surgery including a statement that a patient individual non-CE certified implant would be used for which no clinical data was available at this stage.

Consent for publication

Both patients gave their informed and written consent for publication of their data.

Competing interest

None

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Figures

Figure 1

Illustration of the ideal screw length (5 cm) measured from the bottom of the recess. a) para-sagittal plane, b) para-axial plane

Figure 2

Bottom right: volumetric representation of the recess (turquoise) as well as the implant body (red); coronal (top left), sagittal (bottom left) and axial (top right) planes; SIJ space (yellow)

Figure 3

Implant body (example size 3, left). View from a) above, b) the longitudinal axis, c) the side and d) below

Figure 4

Sawbone model, dorsal view: SIJ fusion (left), SIJ fusion in combination with long lumbar instrumentation (right)

Figure 5

Sawbone model, dorsal view. a) detailed image of SIJ fusion, b) detailed image of position of screw heads in relation to each other in the case of long fusion

Figure 6

CT scan of sawbone model, 3D reconstruction, dorsal view

Figure 7

CT scan of sawbone model, para-axial plane (implant size: 2 (left), 1 (right); screw length: 50 mm (left), 40 mm (right))

Figure 8

Fluoroscopic views of correct guide pin position (pointing to the lateral third of the acetabulum). a) intraoperative a.p., b) oblique, c) lateral view

Figure 9

Bone rasps (example size 3, left). a) side, b) longitudinal and c) intraoperative lateral view

Figure 10

Implant body and iliac screw. a) intraoperative a.p., b) oblique, and c) lateral view

Figure 11

Fluoroscopic a.p. view of correct implant position

Figure 12

Patient 1 postoperative CT scan. a) para-sagittal, b) para-axial and c) para-coronal view (implant size 2, screw length 40 mm, screw diameter 8 mm)

Figure 13

Patient 2 postoperative CT scan. a) para-sagittal, b) para-axial and c) para-coronal view (implant size 3, screw length 50 mm, screw diameter 9 mm)

Figure 14

Patient 1 postoperative X-ray of the pelvis