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ORIGINAL RESEARCH

A New Approach to the Treatment of Sacroiliac Joint Pain and First Patient-Reported Outcomes Using a Novel Arthrodesis Technique for Sacroiliac Joint Fusion

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Purpose: To report the development of a new sacroiliac joint (SIJ) arthrodesis system that can be used for isolated fusion of the SIJ and, unlike known implant systems, in combination with lumbar instrumentation or as an alternative to existing sacropelvic fixation (SPF) methods, and the patient-reported outcomes in two cases.

Materials and Methods: After a comprehensive review of 207 pelvic computed tomography (CT) datasets, an implant body was designed. Its shape was modeled based on the SIJ recess. A screw anchored in the ilium secures the position of the implant and allows connection to lumbar instrumentation. Two patients with confirmed SIJ syndrome underwent surgery with the anatomically adapted implant. They were evaluated preoperatively, 6 months, and 12 months postoperatively. Visual Analogue Scale (VAS), Oswestry Disability Index (ODI), Million Visual Analogue Scale (MVAS), Roland Morris Score (RMS), reduction of SIJ/leg pain, and work status were assessed. Bony fusion of the SIJ was evaluated by radiographs and CT 12 months after the procedure.

Results: Analysis of pelvic CT data revealed a wedge-shaped implant body in four different sizes. In the two patients, VAS decreased from 88 to 33 points, ODI improved from 67 to 35%, MVAS decreased from 80 to 36%, and RMS decreased from 18 to 9 points 12 months after surgery. SIJ pain reduction was 80% and 90%, respectively. Follow-up CT and radiographs showed solid bony integration.

Conclusion: The implant used takes into account the unique anatomy of the SIJ and also meets the requirements of a true arthrodesis. Initial results in two patients are promising. Biomechanical and clinical studies will have to show whether the considerable theoretical advantages of the new implant system over existing SIJ implants – in particular the possibility of connection to a lumbar stabilization system - and SPFs can be put into practice.

Keywords: arthrodesis, sacroiliac joint fusion, sacropelvic fixation, Iliac screw, S2-alar-iliac screw, biokinemetrie

Introduction

Due to its anatomical position and joint surface geometry, the sacroiliac joint (SIJ) is difficult to access.[1,2] 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, primarily using a minimally invasive technique to transfix the SIJ laterally.[3] In addition to cannulated bone screws with large diameters, triangular plasma-sprayed titanium bolt implants with a porous surface (Figure 1a and b) are commonly used for this procedure. In addition to the anterior approach to the SIJ, which is difficult to perform for anatomical reasons, the dorsal approach via the recess seems to be more promising in terms of accessibility and the possibility of an arthrodesis of the SIJ.[3–5] The procedure involves resection of the interosseous ligaments between the sacrum and ilium, which have been injured due to trauma or degenerately altered and insufficient in the course of

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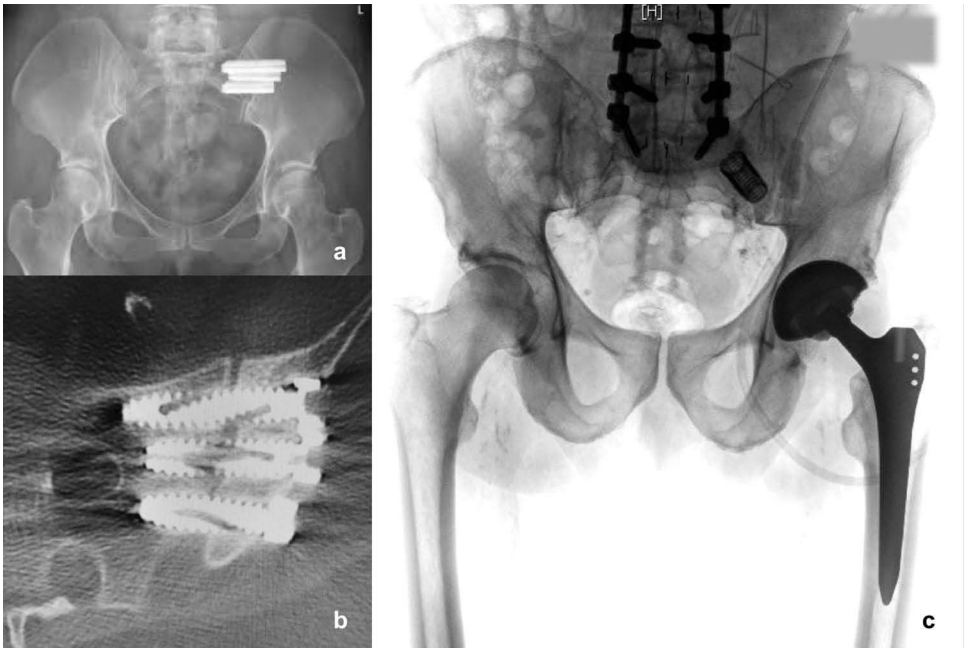

Figure 1 (**a**) Triangular plasma spray-coated titanium bolt implants with a porous surface, (**b**) cannulated bone screws with large diameters or (**c**) hollow screws as distraction interference arthrodesis are used for SIJ fusion.

osteoarthritis of the SIJ.[6] The exposed cortical surfaces provide sufficient space for placement of a hollow screw and insertion of bone graft (Figure 1c). Fusion is thus achieved indirectly through the recess of the SIJ.[3]

A major disadvantage of all SIJ implants on the market, regardless of the access route, is that none of them can be connected to existing, future or parallel lumbar instrumentation. Therefore, the goal was to develop an interbody cage-like implant with a large contact area between the sacrum and ilium, an optimal surface for bony integration, sufficient primary stability, and the ability to connect to a lumbosacral fusion or serve as a sacropelvic fusion (SPF) device as part of a multisegmental spinal fusion (Figure 2).

Materials and Methods

Using the so-called biokinemetrie software developed by the co-author, initial considerations for implant design were made. Biokinemetrie is a software program for comparative analysis of pathologically altered motion segments in the

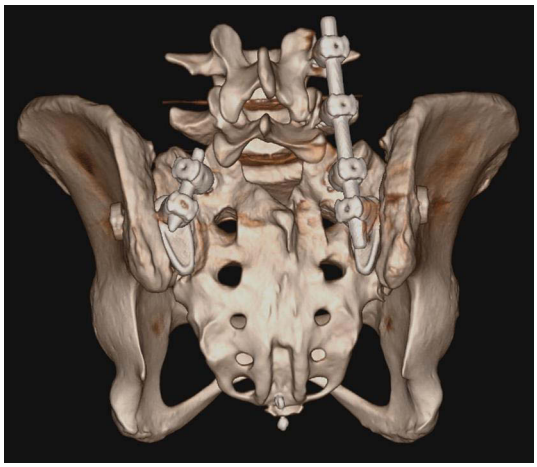

Figure 2 The custom implant (left) allows connection to a lumbar stabilization system (right).

spine to a pooled healthy cohort. This software allows the selection of the best possible implant to optimally treat the existing pathology and minimize the negative impact on the biomechanics of adjacent structures.[7]

After receiving the positive ethics vote (EC 24062016 and EC 249062016 – Ethics Committee of the Technical University of Dresden) for the biokinemetrie simulation software, the patient-specific care of the two patients was additionally endorsed by the local ethics committee (AMEOS Hospital Halberstadt) in its meeting on December 8th 2021.

In accordance with the Declaration of Helsinki, all biometric analyses of patient data and surgical interventions were performed with the informed consent of the patients.

Implant Development

The recess of the SIJ (implant negative) has the shape of a canyon (Figure 3a). Therefore, the resulting implant that can bridge this canyon should be shaped like a cone or wedge (Figure 3b and c). To achieve maximum primary stabilization of the SIJ – especially in flexion/extension and translation – a screw with a large diameter must be added, that passes through the implant body into the ilium (Figure 3b) and connects to an S1 pedicle screw via a rod to the sacrum (Figure 2). The implant body should be as large as possible, but should not exceed beyond the lower distal two-thirds of the recess, so that an S1 pedicle screw could be placed at the same time or the implant could be inserted with a preexisting S1 pedicle screw, leaving enough space to pack additional bone material into the recess cranial to the implant (Figure 2). Another requirement was the use of a self-cutting screw thread and a screw shaft allowing cement augmentation (Figures 4 and 5) through a central cannulation to ensure adequate fixation of the implant body in the case of deficient bone stock.

Therefore, the size, shape, and angulation of the posterior interosseous region of the SIJ were retrospectively evaluated using 207 high-resolution computed tomography (CT) scans of the pelvis in patients with known SIJ symptoms. 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 was determined in both the paraxial and parasagittal CT reconstructions (Figure 4).

After selecting the smallest, largest and eight additional representative posterior SIJ recesses, additional morphometric data was acquired using Materialise Mimics Version 17.0 (Mimics Innovation Suite 17.0, Materialise®, Germany). Three-dimensional volumes were created to derive the geometries and sizes of the individual implant bodies (Figure 6).

Based on the above considerations, computer-aided design (CAD) was used to create three-dimensional design models of each implant body and associated screws. The CAD files were then compared with the volumetric

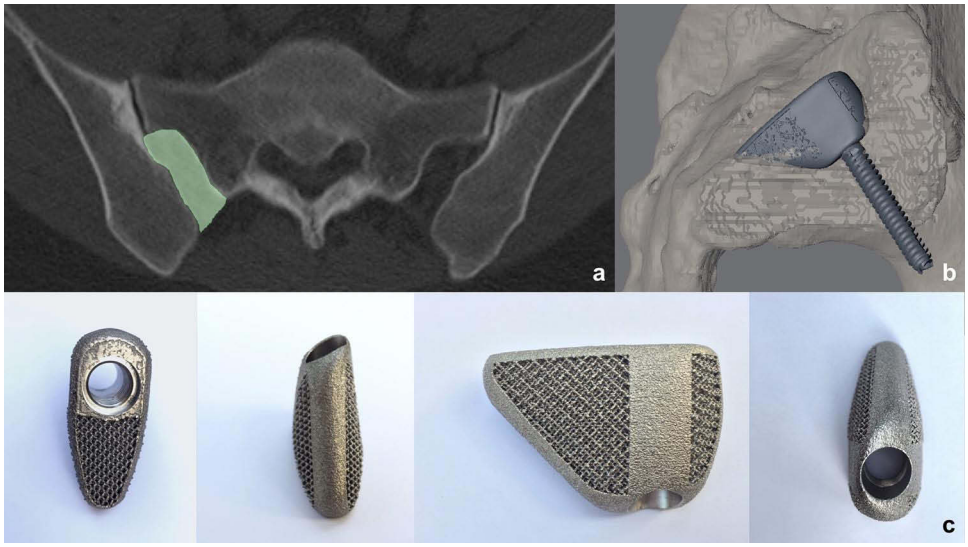

Figure 3 (**a**) The canyon shape of the recess (green), (**b** and **c**) determines the wedge shape of the custom implant.

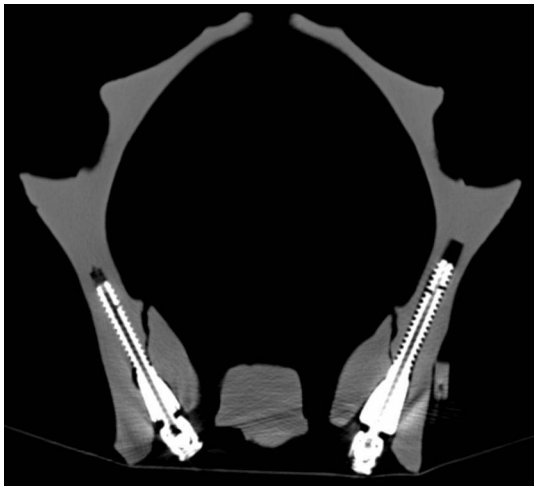

Figure 4 Iliac screws with a screw length of 40 mm (left side) or 50 mm (right side) fix the patient-specific implants on both sides. The anatomical conditions with a flat surface on the iliac side and a concave surface on the sacral side determine the chirality of the customized implants (solid plastic model).

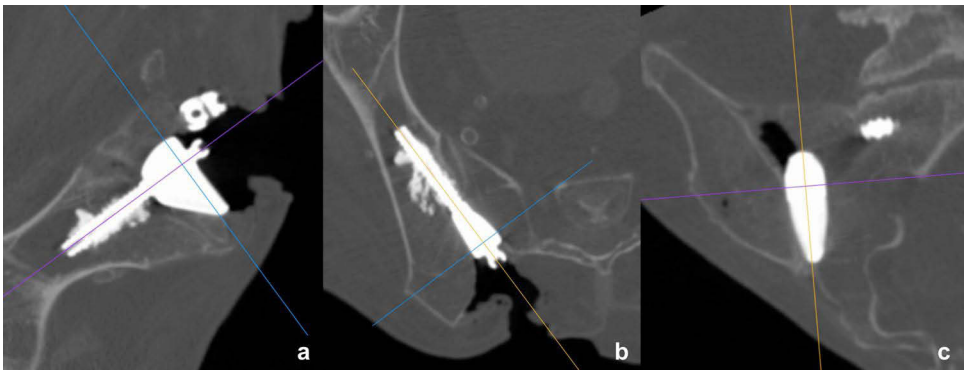

Figure 5 (**a** and **b**) Cement augmentation of the iliac screw. Since the implant body is to be anchored in the recess with a screw at the S2 level in the ilium, the average angle formed between the recess and the body of the iliac bone was determined in both (**a**) the parasagittal (**b**) and paraxial CT reconstructions; (**c**) paracoronal reconstruction (cadaver model).

representations (Figure 6), and patient-specific devices were fabricated by electron beam melting (EBM) of titanium powder (Ti6Al4V according to ISO 5832–3/ASTM F1472). The resulting implants were tested on models (Figure 7) and human specimens (Figures 8 and 5). Additional testing included cleaning validation (Ortek AG, Merenschwand, Switzerland) and mechanical acceptance testing for certification (SpineServ GmbH & Co. KG, Ulm, Germany).

Study Design

After the implant was designed, tested and manufactured, two patients with SIJ pain lasting more than 6 months were selected for surgery. Conservative treatment options had been exhausted.

The study design was questionnaire-based, with pre- and post-operative data collected at 6 and 12 months. Preoperative imaging included magnetic resonance imaging (MRI) of the lumbar spine as well as plain radiography and CT of the pelvis to rule out competing pathologies in these regions and to identify variations in SIJ morphology. In addition, pelvic plain radiographs and CT scans were performed to assess the correct positioning of the implants postoperatively. Pelvic imaging was scheduled for a 12-month follow-up.

Exclusion criteria include 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.

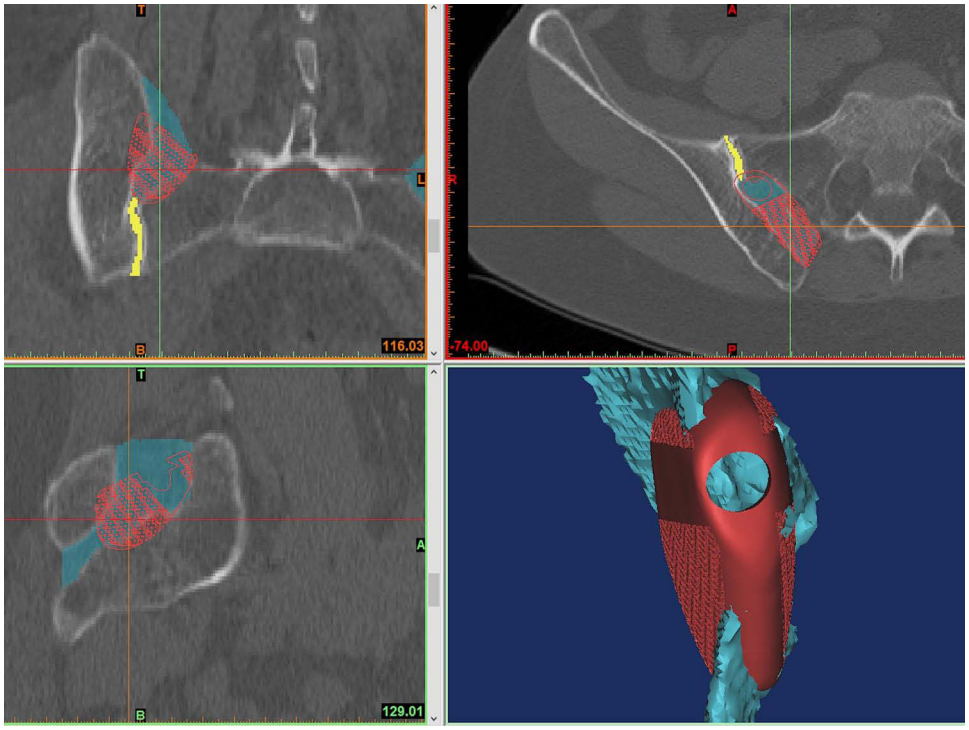

Figure 6 Three-dimensional volumes of the recess (turquoise) and SIJ (yellow) are created to derive the geometries and sizes of the individual implant bodies (red).

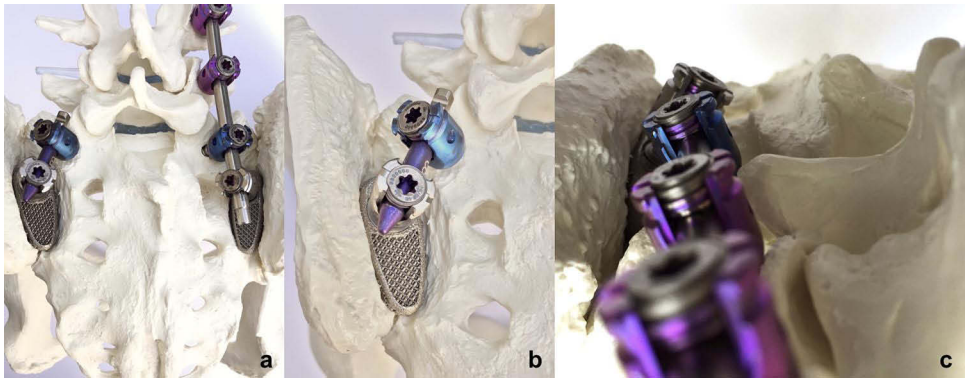

Figure 7 Trials of the printed titanium implants with diamond lattice structure on a solid plastic model. (**a**) On the left side, the patient-matched implant is used as a SIJF. On the right side, it contributes to the primary stabilization of the lumbar spine, sacrum and pelvis because it is fully integrated into the stabilization system. (**b**) Enlarged view of the application as a SIJF. (**c**) Pedicle screw heads in line with the implant screw tulip. The anatomy favors this patient-specific stabilization system.

Indication for Surgery

An SIJ syndrome can occur alone or as a consequence of lumbar stabilization in terms of adjacent degeneration (Box 1). SIJ surgery is to be performed only on patients with therapy-refractory SIJ pain following unsuccessful conservative therapy (physiotherapy, manual therapy, therapeutic ultrasound, SIJ orthoses), two peri- and intraarticular steroid injections, ≥3 positive diagnostic tests of the SIJ (FABER test, thigh thrust test, compression test, distraction test, Gaenslen test, sacral thrust test), and sitting intolerance.[8–12] The site of the pain had to be in the lumbosacral transition (positive Fortin finger test).[13] In addition, we decided that at least two of the four SIJ infiltrations must result in significant pain relief (>75%) for several days as part of the diagnostic criteria.[14]

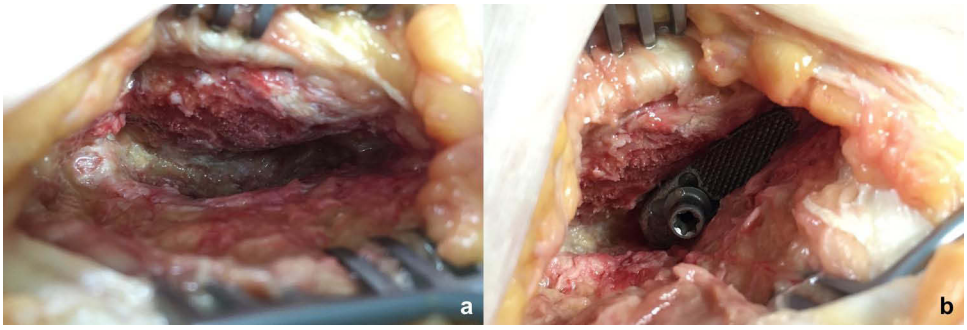

Figure 8 (**a**) The canyon-like recess is prepared to receive (**b**) the patient-specific implant, which is shaped to ensure a large titanium-bone interface.

Surgical Technique

Surgery was performed under general anesthesia. A midline dorsal incision of approximately 6 cm in length was made, centered at the superior border 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 medial to the PSIS before the spinal erectors were bluntly retracted medially, thereby exposing the posterior sacroiliac ligaments. After careful incision of the ligaments at the level of the SIJ recess, the interosseous sacroiliac ligaments were resected.

Subsequently, a K-wire at the S2 level was placed into the center of the iliac column (Figure 9 top row). The K-wire served as a guide for the bone rasps, corresponding to the different implant sizes, which were successively introduced down to the bottom of the recess until the appropriate size was reached. The selected implant was then inserted to 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 with a screw of the appropriate diameter and length (Figures 9 bottom row, 8b). The next step was to graft autologous or allograft bone, which was packed into the upper part of the recess. In the event of deficient bone stock, the screw could be augmented with cement (Figure 5).

In addition, the iliac screw was equipped with a tulip head, allowing the construct to be mounted on a bicortical S1 pedicle screw and a rod from any commercial implant provider (Figures 2 and 7). This could be done using the same skin incision.

For intraoperative radiologic determination of the correct K-wire and iliac screw orientation, an image intensifier was used in three pre-defined planes (Figure 9) to achieve an ideal implant fit (Figure 10).

Postoperative Management

Initial postoperative pain management included 20 mg oxycodone (1-0-1), 500 mg novaminsulfon (2-2-2-2) and 600 mg ibuprofen (1-1-1) per day. Both patients were mobilized under partial weight bearing (20 kg) on the first postoperative day.

Outcome Measures

Pre- and post-operative data collection was performed at the hospital of surgery. The surveys were completed by the patients without medical supervision. The questionnaires included: Visual Analogue Scale (VAS), Oswestry Disability Index (ODI), Million Visual Analogue Scale (MVAS), Roland Morris Score (RMS), SIJ-/leg pain reduction and work status.

Box 1 Indications for SIJ Fusion

- Secondary osteoarthritis after lumbar/lumbosacral fusion
- post-traumatic arthritis
- post-partum arthritis
- accessory joints
- dysplasia
- axial spondyloarthritis
- primary arthritis

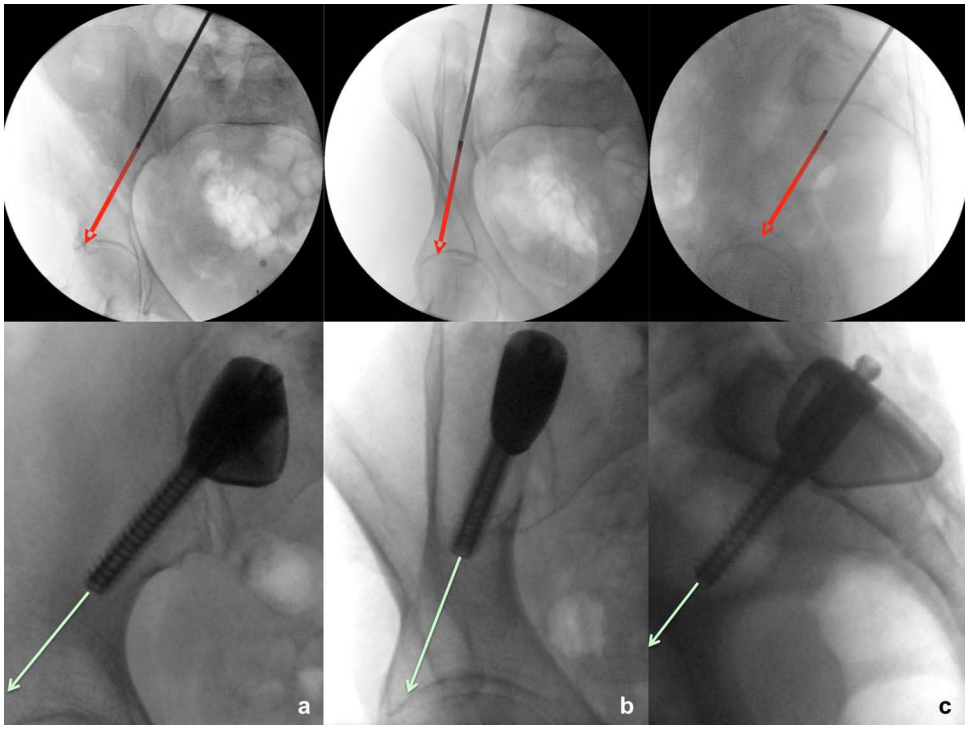

Figure 9 Intraoperative radiographs showing the K-wire in the center of the iliac column (top row) and the iliac screw path (red arrows) in three directions for proper placement of the custom implant (bottom row); (**a**) a.p., (**b**) oblique, and (**c**) lateral views.

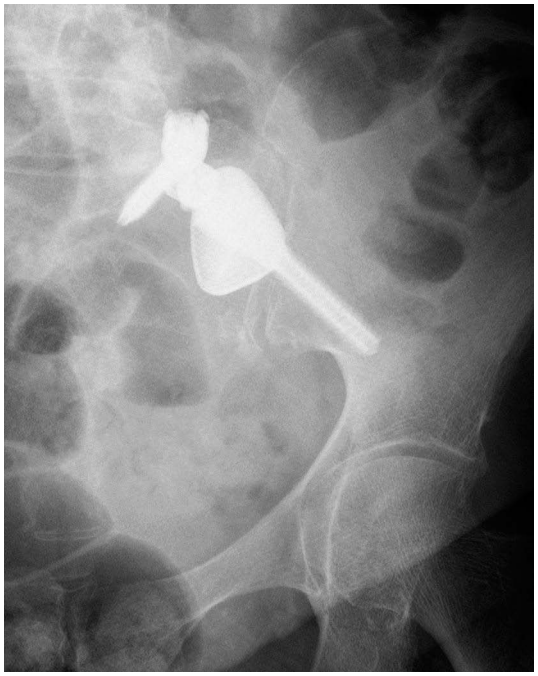

Figure 10 Postoperative radiologic result a.p. after implantation of the implant.

Two radiologists familiar with the surgical procedure evaluated both X-ray and CT datasets independently and blinded to each other's rating.

Results

Resultant Implant Specifications

Based on the biometric analysis, a total of four implant sizes were shown to be sufficient to theoretically treat all of the sacroiliac joints in the 207 CT datasets examined. 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 (Figure 4). In general, a screw length of 50 mm (minimum of 40 mm), 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. The larger the body and surface area of the four implants (size 1: 37 cm^2, size 2: 48 cm^2, size 3: 62 cm^2, size 4: 80 cm^2), the larger the possible diameter used for the respective screw (size 1: 7 mm, size 2: 8 mm, size 3: 9 mm, size 4: 10 mm diameter).

On the basis of these findings, a total of eight implant bodies and eight screws (four diameters and two lengths each) were custom-made based on CAD files. The prints of the implant body were realized in a diamond lattice structure with a porosity of 82% for the best possible bone integration.

Patient-Related Outcome

The prefabricated individualized implants were used in two female patients (Table 1). Patient 1 had already undergone a contralateral SIJ fusion (SIJF) in 2010 with a common dorsal fusion device. Neither patient had a previous history of any other spinal surgery.

After 12 months, the patients reported SIJ pain reduction of 80% and 90%, respectively. Pain measured by the VAS decreased from 88 to 33 points 12 months after surgery, the ODI improved from 67 to 35%, the MVAS dropped from 80 to 36% and the RMS decreased from 18 to 9 points. Patient 1 returned back to work, Patient 2 was already retired (Table 2).

Surgery time was 120 and 130 minutes, and intraoperative blood loss was 350 and 300 mL for patients 1 and 2, respectively.

Imaging

The preoperative clinical imaging revealed vacuum phenomena and subchondral sclerosis in the affected SIJs, 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.

In both patients, the postoperative CT showed an adequate form fit of the implant within the SIJ recess and correct screw placement. The preoperative vacuum phenomenon of the SIJ was no longer detectable in either patient.

At the 12-month follow-up both CT scans showed solid fusion with the porous portions of the implant body, a distracted SIJ, a bony bridged recess, and no lucency around the iliac or sacral screw. In addition, the preoperative vacuum phenomenon in the SIJ space had not reappeared (Figure 11).

Table 1 Characteristics of the Enrolled Patients

Patient	1	2
Gender	Female	Female
Age	54	78
BMI	31	24
Smoker	No	No

Table 2 Outcomes and Work Status at Baseline, 6-Month and 12-Month Follow-Up Visits

Patient 1	**Preop**	**6 mth Postop**	**12 mth Postop**	**Difference (%)**
VAS (0–100)	95	26	29	69
ODI (0–100%)	60	44	34	43
MVAS (0–100%)	79	40	28	65
RMS (0–24)	19	10	10	47
Reduction SIJ pain (%)		70	80	
Reduction leg pain (%)		90	90	
Work status	Sick leave	Sick leave	Back at work	
Patient 2	**Preop**	**6 mth Postop**	**12 mth Postop**	**Difference (%)**
VAS (0–100)	82	55	38	54
ODI (0–100%)	74	33	37	50
MVAS (0–100%)	81	58	44	46
RMS (0–24)	18	11	8	56
Reduction SIJ pain (%)		60	90	
Reduction leg pain (%)	No pain	–	–	

Complications

During the operation, the instruments developed for implantation proved to be easy to handle and there were no problems when inserting the implant or connecting it to the S1 pedicle screw.

Neither patient experienced any adverse events during the operation or during the 12-month follow-up period.

Discussion

The percentage of lumbar back pain with symptoms originating from the SIJ is reported in the literature to be 13–30%.[10,15–19] In fact, this percentage is higher if surgical interventions on the lumbar spine or lumbosacral junction are preconditions, accounting for 15.8% and 32.9% of cases, respectively.[20]

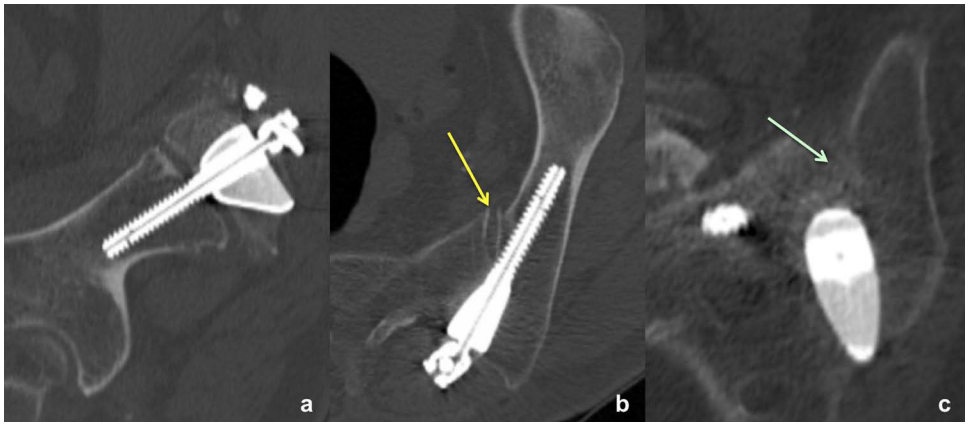

Figure 11 The 12-month follow-up CT scan shows (**a**) solid fusion with the porous portions of the implant body, (**b**, yellow arrow) absence of the preoperative vacuum phenomenon in the distracted SIJ, (**c**, green arrow) a bony bridged recess, and no lucency around the (**a** and **b**) iliac or (**c**) sacral screws.

However, it should be remembered that degenerative changes of the SIJ visible on CT, such as vacuum phenomenon, joint space narrowing, subchondral sclerosis/cysts, osteophytes and erosions up to ankylosis, can occur in asymptomatic patients in 65–83% of cases.[21,22] Bone marrow edema and erosions, as well as fat infiltrations, can also be seen on MRI in up to 24% of healthy subjects and in 27% of subjects with nonspecific back pain.[23,24]

On the other hand, the question must be asked as to why many patients with clear clinical signs of SIJ pathology initially show no changes on CT or MRI. If one assumes that repetitive microtrauma or an accident initially results in damage to the interosseous ligaments of the SIJ and that this only triggers radiologically visible changes in the synovial part of the SIJ much later due to the resulting instability of the pelvic ring, this would be a possible explanation. This assumption is supported by the fact that single-photon emission computed tomography (SPECT) in combination with CT showed an increased uptake of the tracer in the area of the interosseous ligaments in 95–100% of affected SIJs and that affected patients benefit far more frequently from a periarticular injection into the recess of the SIJ (81%) than from an intraarticular SIJ injection (19%).[25–27]

Even spontaneous fusion patterns during SIJ degeneration are still poorly understood. Spontaneous ankylosis of the SIJ has been described in up to 24% of patients, irrespective of previous lumbar surgery. In the majority of cases, anterior (69.4%), followed by combined (16.3%), posterior (8.2%) and medial (6.1%) ankylosis was recognized.[28]

In this respect, physicians should be careful not to overestimate visible changes in the SIJ on CT or MRI scans with regard to possible surgical treatment of the SIJ.

Currently, there is no standard treatment or surgical indication for SIJ pain. When patients do not respond well to nonsurgical treatment, SIJF seems to be effective in reducing pain and disability in patients with SIJ dysfunction.[29]

From an economic point of view SIJF and multilevel lumbar fusion with SPF appear to be cost-effective in this patient population and cost saving in the long term.[30,31]

Open arthrodesis, as described by Smith-Petersen in 1921, with maximum cartilage removal from the joint surfaces and bone grafting, is only possible in combination with extensive soft tissue damage.[2,32]

More recently, minimally invasive SIJF has been shown to reduce morbidity and recovery time compared to the traditional open approach.[33–36] Minimally invasive approaches have also been associated with shorter hospital stays and improved functional and quality of life outcomes compared to open surgical techniques.[33,37,38] The primary surgical goal of all minimally invasive SIJF procedures is to provide immediate fixation and stabilization across the joint space to support bony consolidation and the development of a mechanically stable arthrodesis. This can be achieved through several different surgical approaches (anterior, lateral, posterior oblique, and posterior approach).

There are two minimally invasive techniques that are mainly used to achieve this goal: the posterior approach and the lateral approach. In the posterior approach, an implant is placed in a posterior-to-anterior trajectory within the ligamentous portion of the joint. In the lateral approach, implants are placed across the cartilaginous part of the joint from lateral to medial.

In the lateral approach, 2 or 3 implants, either cannulated screws with a large diameter or, even more frequently, triangular implants with a porous surface are inserted percutaneously through the ilium and ideally via the cartilage-bearing part of the SIJ into the sacrum. This approach provides immediate fixation of the joint while avoiding the disruption of the SIJ ligaments.

Despite numerous studies on triangular implants, evidence of bone bridging between the ilium and sacrum has only been established in a minority of cases.[39–42] It therefore remains to be seen to what extent this transfixation of the joint will last in the case of decreasing bone density with age, especially in the sacrum. However, lateral implants with additional partial joint decortication achieved significantly higher radiographic fusion rates.[43]

In particular, lateral approaches to the SIJ carry significant surgical site morbidity and revision risk. The difficulty in instrumentation is further complicated by the sacral morphology. Lesions of the superior gluteal nerve and artery have been observed in up to 18% of cases.[44] Sacral nerve root irritation can occur if implants are malpositioned or if the implant length chosen is too long.[45] Bony ingrowth of the implants in the ilium but not in the sacrum is another challenging scenario for the surgeon. In this case, the only way to recover the implant(s) is by overdrilling.

Unlike lateral exposure approaches to the SIJ, the dorsal approach is similar to conventional spine surgery. There are no at-risk structures such as nerves and vessels situated directly within the surgical corridor. Degenerately altered

interosseous ligaments between the sacrum and ilium are resected and the cortical surfaces forming the recess are exposed to provide space for a hollow screw, dowel or rectangular-shaped allograft.[6] Advancing the implants into the cavity causes distraction and repositioning of the subluxated joint surfaces, resulting in pain relief due to reduced stress on the articular cartilage and anterior neural structures.[3]

The weaknesses of currently available dorsal implant systems are the lack of durable primary stability, localized stress on the surrounding bone and the fact that the implant itself or generously placed bone allograft in and around the implant must first be converted to vital bone or may have already been resorbed before bony consolidation can occur.[5]

Cadaver studies evaluating SIJ motion reduction have shown no significant differences between posterior and transarticular placement techniques.[46–48]

Neither lateral nor posterior implants offer the ability to connect to lumbar instrumentation. As a result, some of these devices may actually interfere with SPF because they are placed in the area of surgical exposure for S2-alar-iliac (S2AI) or iliac screws.[49]

The loads transmitted through the SIJ may be increased by surgical fixation of the thoracolumbar spine, where the application of large flexion moments due to high spinal stiffness may further increase the risk of developing SIJ arthrosis. Postoperative SIJ pain has been reported in approximately one-third of patients undergoing multilevel spinal fusion including the sacrum without pelvic fixation.[20,50,51] SPF methods are increasingly being used to provide an important point of stability in multilevel spinal fusion procedures. S2-Alar-Iliac (S2AI) or iliac screws can minimize the risk of both symptomatic L5/S1 pseudarthrosis and SIJ osteoarthritis.[52–54]

SPF has the advantage of significantly reducing peak stresses at the L5/S1 segment.[55] However, because the SIJ is only transfixed with S2AI screws and only fixed with iliac screws, screw/rod breakage or screw loosening may occur depending on the preoperative extent of SIJ mobility.[56,57] Another disadvantage of S2AI screws is the difficulty in accurately placing the implant within the sacral bone stock without it failing laterally into the SIJ recess.[58] In addition, the high stresses on the screw may increase the risk of screw failure at the level of the SIJ or separation of the screw head and tulip interface.[59,60] Disadvantages of iliac screws include greater soft tissue damage and significant prominence of the screw head, resulting in higher rates of wound infection and soft tissue irritation.[61,62] In addition, the peak stresses on the required offset connectors can cause disconnection or breakage.[59,63] Neither the S2AI screw nor the iliac screw are at the same level as the S1 pedicle screw. The head of the S2AI screw is positioned more medially, while the head of the iliac screw is positioned much more laterally than the S1 pedicle screw.[64,65]

Over the course of a lifetime, either isolated SIJF, SIJF following lumbar spondylodesis for adjacent segment degeneration, or a combination of both SIJF and lumbar spinal fusion may be required.[66] Currently available implants for SIJF cannot be connected to lumbar stabilization systems. The aim was therefore to develop an implant for fusion of the SIJ that can be inserted via a safe dorsal approach with high primary stability using the largest possible space in the recess with distraction of the SIJ even under soft bone conditions and, if necessary, connected with lumbar instrumentation (Figures 2 and 7a).

The large areas of bone contact between the implant and the ilium and the implant and the sacrum, as well as the diamond lattice structure of the implant body itself, induce bony integration. By inserting this wedge down to the bottom of the recess, the ilium is repositioned and stabilized against the sacrum by distracting the SIJ, ie, Distraction Interference Arthrodesis (DIA). Fixation of the implant body to the ilium with the largest possible diameter screw and direct connection to an S1 pedicle screw increases primary stability. This surgical technique provides stabilization of the SIJ until bony bridging of the recess can occur, which is one of the natural ankylosis patterns of this joint (Figure 12). It also serves as a DIA in weak bony conditions by providing the largest possible bony-titanium interface within the recess (Figures 4 and 5). The cage within the SIJ recess acts as an augmentation for the screw crossing into the ilium, potentially providing more stability than a single S2AI or iliac screw. Another major advantage is that the head of the implant screw is exactly in line with the S1 pedicle screw and is adequately covered by soft tissue (Figures 2, 7a and c). The implant can be used for isolated SIJF or as an alternative to existing SPF methods and as a follow-up treatment after lumbar fusion. After integration of the implant, material failure appears to be less likely as there is no further movement in the SIJ. In the case of revision surgery, the expected access morbidity is similar to that of primary intervention.

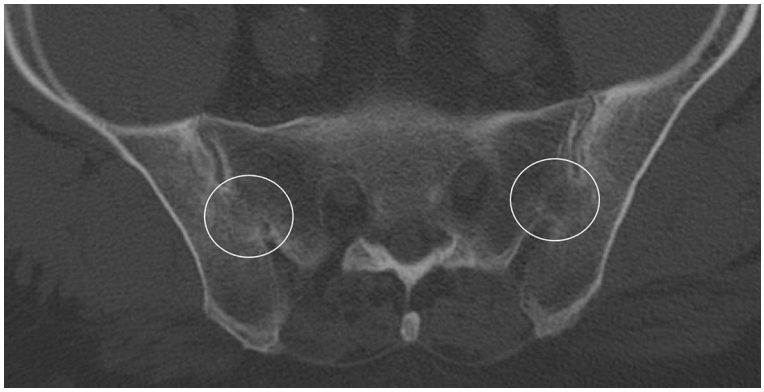

Figure 12 Natural ossification of the SIJs occurring first in the recesses (white circles), corresponding to fusion from a DIA.

It remains to be seen whether it makes a difference whether the arthrodesis is performed in the extra- or intra-articular portion of the SIJ and whether the innervated articular cartilage remains a pain generator.[67] Critical voices will certainly be raised regarding the stated duration of the operation. On the one hand, it must be said that the two patients described are the first to have been treated with the instruments and implants developed and, on the other hand, that a treatment with an iliac or S2AI screw cannot be compared with an SIJ arthrodesis. This would be similar to comparing a percutaneous stabilization of the lumbar spine with a 360° fusion. Furthermore, finite element and cadaver studies must show whether the screw length calculated in the CT examinations is sufficient or whether longer screws may be necessary to achieve even greater stability.

The results achieved by the first two patients are encouraging. They experienced an 80% and 90% reduction in SIJ pain at 12 months, respectively. All the recorded scores (VAS, ODI, MVAS and RMS) changed far beyond the minimally clinically important difference (MCID). These good results are substantiated by the follow-up CT scans showing solid bone ingrowth into the porous part of the cage, no lucency around the screws or screw breakage, and the absence of a vacuum phenomenon inside the SIJ after one year.

The study has considerable limitations. Although the implant presented corresponds in principle to a screw-retained cage, the obvious advantages derived from it compared to the implants currently on the market are largely hypothetical and must first be proven. In addition, the implant was only used in two patients in the context of osteoarthritis of the SIJ and not for SPF. Although these results are encouraging and expected, it remains to be seen whether they can be reproduced in a larger cohort of patients.

Conclusion

The implant designed on the basis of the evaluation of CT data sets and the associated instruments proved their worth when used on patients. The implant sizes and shapes produced showed a very good fit in the recess and correct alignment of the iliac screw required for secure anchoring. The planned connection to an S1 pedicle screw was possible without any problems.

First results in two patients are promising. Whether the significant theoretical advantages of the new implant system over existing SIJ implants – in particular the ability to be connected to a lumbar stabilization system - and SPFs can be realized in practice will now need to be demonstrated in biomechanical and clinical studies.

Disclosure

Dr Volker Fuchs is the inventor of the implant that is used in this study. The authors report no other conflicts of interest in this work.

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