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Clinical Study

Implant-Bone Interface of Sacroiliac Joint Fusion Using iFuse Implant System

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Introduction. Treatment of patients with SI joint pain is mostly limited to conservative care. However, in those with chronic pain and consequently prolonged mobilisation, internal fixation of the SI joint is often indicated. The aim of the present study was to assess stability and bone ingrowth of minimally invasive SI joint arthrodesis using a series of triangular, porous plasma coated implants (iFuse Implant System) using SPECT/CT. *Material.* We report ten cases of SI joint arthrodesis with a novel MIS SI joint fusion system. SPECT/CT was performed in all cases after a mean time of 5.8 months to evaluate bony ingrowth and stability within the SI joint. *Results.* In eight cases, no or only low tracer uptake could be visualized as an indicator of stability and bone ingrowth. Two patients have increased tracer uptake due to a second trauma-related ipsilateral sacral fracture and a low-grade infection. *Conclusion.* We could visualize satisfying osseous integration as well as stability within the SI joint after arthrodesis using iFuse Implant System. Therefore iFuse Implant System seems to be an effective treatment option in selected patients.

1. Introduction

Low back pain is a common disorder, affecting up to 70% of the population at some time point during their life span [1]. It is the most common cause for inability to work in patients younger than 45 years [1, 2]. In some cases low back pain is thought of as an idiopathic disorder. However, the sacroiliac (SI) joint can often be identified as source of pain [3–5]. In patients with low back pain, the prevalence of SI joint pain ranges between 15% and 30%, as has been established upon clinical evaluation and controlled fluoroscopy SI infiltration [3–5].

The identification of the SI joint as the source of pain is a significant diagnostic challenge. Most commonly, pain deriving from the SI joint manifests as discogenic or radicular low back pain. But it may present as hip, pelvic, gluteal, sacral, or groin pain as well [2, 6].

History and physical examinations still are the keystones to diagnostic work-up as in many cases no objective findings are present on X-ray, CT, and/or MRI. Furthermore, fluoroscopically guided SI infiltration can be helpful in cases were no objective findings were found.

Primary treatment options focus on physical therapy and medication optimization. Other options are infiltration with local anaesthetics.

In patients with chronic pain and consequently prolonged mobilisation, an internal fixation of the SI joint should be discussed. Such can be accomplished using lag screws, sacral bars, or plate fixation. Each fixation technique has its own advantages and disadvantages. Lag screws are tempted to loosen; furthermore, they primarily stabilize and do not fuse the joint [7]. Open plate fixation requires large incisions, carries a potential risk of injury to the lumbosacral nerve, and is associated with increased postoperative wound complications, a prolonged hospital stay, and a prolonged healing period including nonweight bearing for several months [8, 9].

To reduce these complications and to optimize the treatment, minimally invasive surgical approaches have been

Table 1: Patient demographics and results of SPECT/CT after SI fusion.

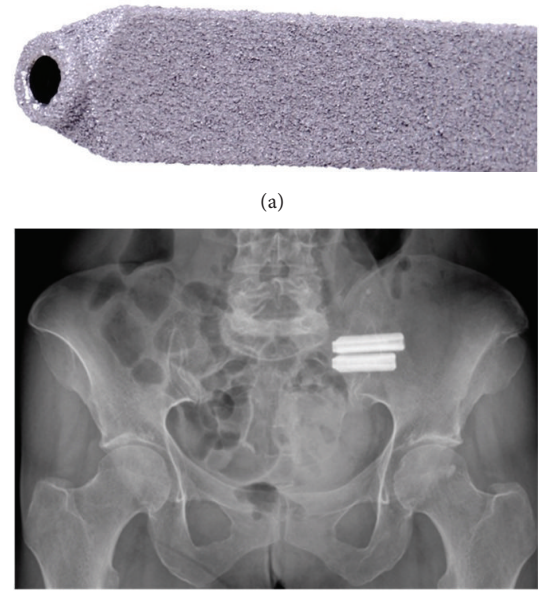
Case number	Age	Gender	Side	Time after surgery	Tracer uptake	Comments
1	59	f	Left	6	Low	No further uptake after ten months
2	60	f	Right	4	Low	Same patient like case 1
3	55	m	Right	6	Low	
4	90	f	Right	6	Low	
5	56	f	Right	7	High	Clinical suspicion of low grade infection
6	62	m	Right	2	High	Additional ipsilateral sacral fracture
7	50	m	Left	7	Low	Same patient like case 8
8	50	m	Right	7	No	Same patient like case 7
9	63	f	Right	7	Low	
10	44	f	Left	7	Low	

developed. In this context, recent efforts were made investigating the percutaneous placement of iliosacral (IS) screws or threaded cages [10, 11].

At our hospital, we are using a novel minimally invasive arthrodesis system (iFuse Implant System, SI-BONE Inc., San Jose, CA). The surgical procedure involves the percutaneous placement of a series of triangular-shaped, porous plasma spray-coated titanium implants across the SI joint without bone apposition within the SI joint. The aim of this procedure is to bridge the SI joint and hence stabilize it by iliac and sacral bone ingrowth onto the porous plasma spray-coated titanium implant. Recent investigations of this minimally invasive arthrodesis system exist and have shown excellent results [12–15].

The novel hybrid imaging modality SPECT/CT allows both for a visualisation and semiquantitative analysis of bone turnover and for a morphological assessment of the bone [16]. Using this imaging modality, it is not only possible to evaluate stability of the SI joint but also possible to assess for signs of bony ingrowth on the titanium implant. Furthermore, possible reactive changes within the surrounding soft tissue can be visualized.

The purpose of the present study was to evaluate stability within the SI joint after fusion and to assess signs of bone ingrowth on the titanium implants.



(a)

(b)

Figure 1: (a) Triangular, porous plasma spray-coated titanium implant (iFuse Implant System, SI-BONE Inc., San Jose, CA). (b) Plain radiograph of the pelvis after arthrodesis of the left SI joint using two iFuse implants.

2. Methods

Over a period of one year, eight consecutive patients (ten SI joints) at our hospital were deemed to undergo SI joint fusion (Table 1). To confirm the diagnosis, a fluoroscopy-guided intra-articular injection with local anaesthetics (Lidocaine) and corticosteroids (Triamcinolone) was performed during their diagnostic work-up.

Minimally invasive SI-joint fusion using the iFuse Implant System (SI-Bone Inc., San Jose, CA) was performed (Figure 1). One orthopedic surgeon carried out all surgeries.

To evaluate the bony ingrowth, all patients underwent SPECT/CT imaging within a mean time of 5.8 months (range of 2–7 months) after surgery. SPECT/CT was performed on a hybrid SPECT/CT system with a built-in CT component (Discovery NM/CT 670, GE Healthcare, Waukesha, WI) after injection of a standardized activity of an average 650 MBq ^{99m}Tc-DPD (technetium-99^{m}-3,3-diphosphono-1,2-propanedicarboxylic acid, Teceos, IBA Molecular, Louvain-la-Neuve, Belgium).

Planar perfusion and early-phase (blood pool) and late-phase spot images, as well as a SPECT and a CT dataset, were acquired. Perfusion images were carried out directly after the injection during three minutes (36 images, 5 seconds per image, matrix 128 × 128 mm, FOV 40 cm). Early-phase images were then performed during approximately seven minutes for 500 kilo counts (matrix 256 × 256 mm, FOV 40 cm). After four hours, late-phase images (same protocol as early-phase images), SPECT (matrix 512 × 512 mm, axial range 40 cm, collimators adapted to body contour), and CT

images (matrix 512 × 512 mm, FOV 50 cm, 120 kV, 100–440 mAs (automated dose modulation), 0.5 s rotation time, slice thickness 1.25 mm) were acquired.

SPECT and CT images were reconstructed iteratively with AsIR (Adaptive statistical Iterative Reconstruction, GE Healthcare). CT images were reconstructed with a slice thickness of 1.25 mm in all three planes. SPECT and CT images were fused by an automated software algorithm on a dedicated diagnostic workstation (Advantage Workstation 4.5, GE Healthcare).

Uptake on SPECT/CT was graded semiquantitatively. No uptake was defined as scintigraphic signal intensity being not higher than background signal. Normal uptake was defined as scintigraphic signal intensity equal to the physiological signal intensity of neighbouring normal bone tissue. Low uptake was defined as signal intensity equal to or slightly higher than the physiological bone marrow signal intensity in the anterior superior iliac spine. High uptake was defined as markedly increased signal intensity compared with the physiological bone marrow signal intensity in the anterior superior iliac spine.

During the postoperative clinical follow-up examinations, patients were asked about the subjective reduction of pain. Further clinical investigations were not provided, since this was not the primary objective of this investigation.

Local ethics committee approval was gained. Data were acquired retrospectively.

3. Results

Patients demographic and results are listed in Table 1. The mean age at the time of surgery was 60 years (range from 50 to 90 years). Five patients were female and three were male. Six subjects had a history of prior trauma with a fracture of the posterior elements of the pelvic ring. All of them were classified as lateral compression fracture type II according the classification system by Young et al. [17]. At the time point of surgery, all fractures were healed. In six patients, additional pathologies of the lumbar spine coexisted, such as facet joint osteoarthritis (four patients), fracture of the fourth lumbar vertebra (one patient), and lumbar disc herniation (one patient). All the aforementioned were ruled out as sources of pain prior to surgery using clinical examination and fluoroscopy-guided intra-articular injection of the SI joint. In two patients, fusion of both SI joints was performed, thereof in one patient simultaneously and in the second patient one year after the first procedure. A SPECT/CT covering both SI joints was acquired in all cases after a mean time of 5.8 months after surgery. During follow-up, one patient underwent a second SPECT/CT due to the subsequent contralateral fusion.

In two cases, no increased tracer uptake could be visualized after seven and ten months, respectively (Figure 2). In seven SI joints, tracer uptake was hardly recognisable after a mean time of 6.1 months (range from 4 to 7 months) (Figure 3). One patient sustained a second trauma-related ipsilateral sacral fracture during the healing process with consequently increased tracer uptake within the fractured bone. In another case of an obese patient, no signs of consolidation but increased tracer uptake and lytic zones were detectable and the implants were then removed due to suspected loosening (Figure 4). Loosening could be confirmed by intraoperative findings. During the further course suspicion of Bechterew's disease was made in this patient.

4. Discussion

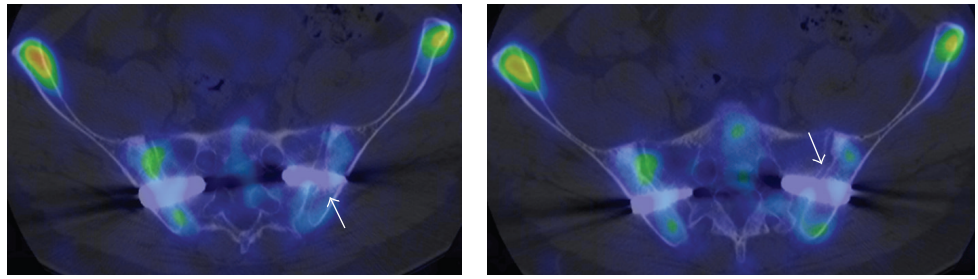
Low back pain is a common problem, affecting approximately 70% of the population during life time [1]. Although it is often assumed to be idiopathic, a specific source of pain can be identified in approximately 75% of patients. As facet joint osteoarthritis and disc herniations have a high prevalence among the population, they are frequently seen and diagnosed on MR imaging. Consequently, they are often held responsible as cause of low back pain, while the SI joint is often missed as a possible cause of pain. The main reason might be that most clinical tests for SI joint disorders have a good specificity, but poor sensitivity. In this context, novel tests such as the posterior superior iliac spine distraction test showed both a high specificity (89%) and sensitivity (100%) [18]. However, controlled fluoroscopy-guided diagnostic joint infiltrations, as performed in the present investigation in every subject, are the gold standard for diagnosis. With this diagnostic tool, SI joints have been found to be the origin of pain in 13% to 30% of patients with low back irritations [5].

Although the basis of treatment of SI joint disorders is noninvasive, there remains a small subset of patients that fail attempts at conservative management. In these cases, arthrodesis has been described as a possible treatment modality. Prior to surgery, the diagnosis of SI joint dysfunction has to be confirmed and other causes must be ruled out. Due to limitations of the physical examination and imaging modalities, many authors recommend fluoroscopy-guided intra-articular injection with local anaesthetics and corticosteroids as reference test to confirm the diagnosis [4, 11, 19]. More than 75% of pain relief on an analogue scale within thirty minutes after the procedure and lasting at least for 2 hours are the common utilized guidelines.

Once the SI joint has been confirmed as source of pain, several different surgical techniques for arthrodesis have been described [8, 11, 20–22]. Open techniques may result in pain relief and functional improvements, but the procedure is invasive and is frequently associated with complications such as wound infections, which hence leads to a high revision rate [8, 9].

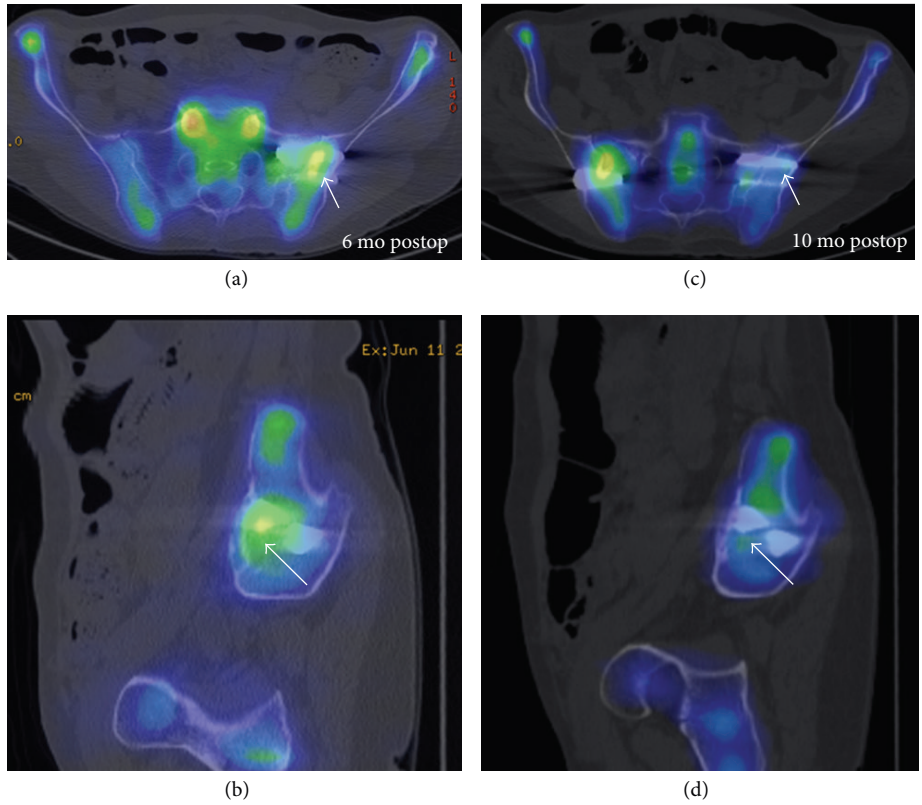
Minimally invasive methods were improved during the last years and reduced the perioperative complications. Advantages include a small incision, bone and ligament preservation, minimal blood loss, and a comparably short period of rehabilitation. Using percutaneously inserted fusion cages filled with bone morphogenic protein, Wise and Dall achieved fusions rates of 89% and a significant reduction of pain without any infections or neurovascular injuries [11]. Other investigations are in line with these results [10, 23].

The minimally invasive method used in our patients involves placing a series of triangular-shaped, porous plasma spray-coated titanium implants across the SI joint.



(a) (b)

Figure 2: The two images show the SI joints at different levels at the same time point. SPECT/CT visualized no tracer uptake along the implant in the left SI joint with no signs of instability of the fused joint (arrows). Along the right SI joint, persisting tracer uptake is visible as a sign of yet incomplete ingrowth.



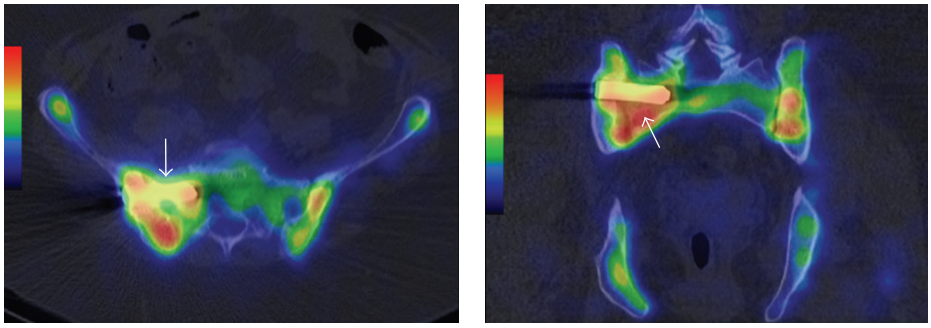
(a) (c)

(b) (d)

Figure 3: Low tracer uptake around the implant after arthrodesis of the left SI joint ((a) SPECT/CT axial, (b) SPECT/CT sagittal). Ten months after the first operation and four months after additional SI joint fusion on the right side, no more elevated tracer uptake could be visualized along the left SI joint, while low tracer uptake is seen along the more recent implant in the right SI joint ((c) SPECT/CT axial, (d) SPECT/CT sagittal).

The triangular shape with an interference fit avoids rotation and micromotion of the implants. Previous investigations have already demonstrated good clinical outcomes in large case series, with more than 80% of patients declaring a significant benefit after surgery [12–15]. Complications were rare, mostly of a minor nature and comparable to other minimally invasive techniques described in literature [12].

The aim of this investigation was to evaluate stability of the SI joint fusion as well as the osseous integration of the implant using SPECT/CT. Usually the question of implant loosening is addressed with plain radiographs or CT scans. Despite recent developments regarding new sequences for metal suppression, MRI still often leads to inconclusive results due to metal artefacts [24]. Nuclear medicine techniques such as SPECT provide a valuable alternative since the visualized bone turnover is altered by metal to a comparably small degree and can be compensated for by attenuation correction using CT [25–27]. In cases of persistent SI joint instability due to insufficient stabilization or lack of integration of the implants, increased tracer uptake



(a) (b)

Figure 4: Increased tracer uptake with no signs of bone ingrowth in one case with suspicion of low-grade infection ((a) SPECT/CT axial, (b) SPECT/CT coronal).

can be visualized due to an increase in local bone turnover by activated osteoblasts.

In our cohort of patients undergoing minimally invasive SI joint fusion, the position of the iFuse implants was unchanged in all patients after a mean time of six months after surgery. Furthermore, we were able to demonstrate faint or no tracer uptake within six months in six patients, indicating no sign of instability of the fused SI joint and complete integration of the implants into the surrounding bone. Additionally, in one patient a second SPECT/CT acquired ten months after the initial SI joint fusion, corresponding to four months after the second contralateral SI joint fusion, showed no elevated tracer uptake on the initially fused side anymore. This indicates that the time for complete integration of the implant is presumably slightly longer than 6 months. Serial investigations at defined time points during follow-up are needed to confirm this suspicion. However, sufficient stability within the SI joint was obviously achieved. This is supported by the fact that all patients with faint or no tracer uptake reported significant reduced pain to the time of investigation.

With regard to the debatable association of decreased tracer uptake with integration of the implants, the observation of significant reduced pain in cases with decreased uptake confirms the relationship between both.

In two cases, increased tracer uptake was visualized on the surgery side due to a recent ipsilateral second sacral fracture and implant loosening, respectively. Both patients had intense pain at the time of follow-up examination. This observation confirms the abovementioned relationship between tracer uptake and stability as well as integration of the implants, too.

To our knowledge, this is the first case series on SI joint fusion in the literature that proved the integration of this novel implant using SPECT/CT. Using this imaging modality, the visualization of the osseous integration as well as the assessment of stability of the fused SI joint was clinically very satisfying. Despite our small sample size, the results of the minimally invasive SI joint fusion using the iFuse Implant System were promising. However, after a mean time of six months, persisting minor tracer uptake as a sign of progressive healing process could be visualized in seven cases. Therefore it seems possible that the time until complete integration is longer than the adopted six months. This assumption is supported by the observation of no more tracer uptake on the initially fused side after 10 months in one case with a second SPECT/CT due to second, contralateral fusion. Further investigations with a SPECT/CT at regular intervals are needed to confirm this assumption.

In conclusion, minimally invasive SI joint fusion with iFuse Implant System is a very effective treatment option in patients where conservative measures failed. Using SPECT/CT visualization of the osseous ingrowth could be confirmed after a mean time of six months with no remaining signs of instability within the SI joint in most of the cases.

Disclosure

P. Veit-Haibach received IIS grants from Bayer Healthcare and Siemens Healthcare and speaker fees from GE Healthcare.

Conflict of Interests

The authors declare that they have no other conflict of interests.

Authors' Contribution

M. J. Scheyerer contributed to the study conception and design, acquisition of data, analysis and interpretation of data, and drafting of the paper. M. W. Hüllner contributed to the analysis and interpretation of data and critical revision of the paper. C. Pietsch contributed to the analysis and interpretation of data and critical revision of the paper. P. Veit-Haibach helped in the study conception and design, analysis and interpretation of data, and critical revision of the paper. C. M. L. Werner contributed to the study conception and design, analysis and interpretation of data, and critical revision of the paper.

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