Three-Year Clinical Outcomes after Minimally Invasive Sacroiliac Joint Arthrodesis Using Triangular Implants in Japan: A Pilot Study of Five Cases

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Abstract:

Introduction: Sacroiliac joint (SIJ) arthrodesis using a minimally invasive technique, particularly the triangular implant system, is performed in patients with SIJ dysfunction in the United States and Europe. We report three-year clinical outcomes of the first minimally invasive SIJ arthrodesis procedures using the implants performed in Japan.

Methods: Five patients (one man and four women; age: 56.4±16.9 years) with SIJ pain who underwent SIJ arthrodesis using a triangular implant system in 2017 were included. In addition to operation time and blood loss, pain intensity (visual analog scale [VAS]) and functional impairment (Oswestry disability index [ODI]) were assessed preoperatively and at a 36-month follow-up. Implant loosening and osseous bridging across the joint were evaluated using computed tomography images, and patients' satisfaction with the surgery was also assessed at 12 and 36 months.

Results: The surgical time was 67.7±13.1 minutes, and blood loss was 7.4±6.9 mL. The mean VAS value improved significantly from 88.0±8.4 mm to 33.6±31.9 mm at 3 months and was maintained at 46.4±30.9 mm at 36 months ($P<0.05$). The mean ODI improved significantly from 76.4%±3.8% to 46.2%±21.9% at 6 months postoperatively ($P<0.05$) but had no significant improvements thereafter: 46.94±23.7% (12 months) and 66.4±8.6% (36 months). Three of five patients presented with at least one implant loosening on the sacrum side. No patient had osseous bridging across the joint. A total of 80% (4/5) of patients reported satisfaction with the surgery at 12 months and 60% (3/5) at 36 months.

Conclusions: The mean VAS value and ODI significantly improved until 6 months after the surgery. However, the mean ODI was reaggravated at 36 months after the surgery. Osseous bridging across the joint was not observed in all patients. We should carefully keep an eye on further long-term results to evaluate the implant.

Keywords:

Sacroiliac joint, pain, minimally invasive surgery

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Introduction

Pain in the lower back and buttocks in 15%-30% of patients is caused by sacroiliac joint (SIJ) dysfunction[1,2)], and conservative treatments such as SIJ injections, radiofrequency neurotomy, pelvic belt, and physical therapy such as mobilization and manipulation[3)] are effective options. Patients with SIJ dysfunction should be first treated conservatively to ensure recovery of movement and restoration of the shock-absorbing function of the SIJ, which is important for human bipedal walking[4)]. However, when such conservative treatments cannot reduce pain significantly, SIJ arthrodesis, which has been performed since the 1920s[5)], is the last resort for patients.

There are three approaches for SIJ arthrodesis: anterior[6-8)], posterior[9)], and lateral[10)]. The number of patients who undergo surgery is not very large. Currently, various types of SIJ arthrodesis with minimally invasive techniques, particularly using the lateral approach, are performed in patients in the United States and Europe[11)]. Many surgeons have real-

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ized that dealing with SIJ problems could become part of their duties, and excellent surgical outcomes are reportedly achieved with new products[11-13].

SIJ arthrodesis through the anterior approach has been performed previously in Japan, and its surgical outcomes were found to be desirable[6]. However, it is relatively invasive and challenging in obese patients. Triangular implant systems are used worldwide as a minimally invasive technique for SIJ arthrodesis thorough the lateral approach[11]. With developing technology, an increase in the performance of less invasive surgery is expected in Japan. However, indications for SIJ arthrodesis have not been established, and they differ in each country as the human physique differs between people in Asia and those in the United States and Europe. The effectiveness of the triangular implant system[11,12] remains unknown for patients in Japan.

Until now, SIJ arthrodesis using triangular implant systems have not been performed in Japan. Thus, we report on the first five surgical cases in this pilot study and their 3-year clinical outcomes after minimum invasive SIJ arthrodesis using a triangular implant system under our current surgical indications.

Materials and Methods

Study design

Approval of this study was granted by the Institutional Review Board of our hospitals. The use of implants has not been approved by the Ministry of Health, Labor, and Welfare in Japan. Implant costs were covered by the product company (SI-Bone Inc., CA, USA). The company did not provide any funding to the physicians/surgeons or hospitals who performed the procedure. Patients signed a written informed consent form to authorize the use of their data.

Patients

A total of five patients (one man and four women; mean age at surgery, 56.4±16.9 [range, 32-79] years) experiencing SIJ pain underwent SIJ fixation using a triangular implant system between July 2017 and December 2017 in two hospitals.

Definitive diagnosis of SIJ pain

All patients identified using their index finger (one-finger test)[14] the posterior superior iliac spine (PSIS) as the main location of pain and scored more than four points on the SIJ scoring system[15]. These patients were considered to have SIJ-related symptoms. The scoring system consists of six items: one-finger test, groin pain, pain while sitting on a chair, SIJ shear test, tenderness of the PSIS, and tenderness of the sacrotuberous ligament. The sum scores range from 0 to 9 points. The definitive diagnosis of SIJ pain was confirmed by ≥70% pain relief in the region of the SIJ after SIJ fluoroscopy-guided injection[16]. Injection efficacy was evaluated using the pain relief scale[17]. All patients were instructed to report the post-injection pain intensity based on the assumption that the pain score before injection was 10. The remaining pain was recorded 15 minutes post injection. Higher than 70% pain improvement was assumed if the patients reported a post injection remaining pain intensity score ≤3. We considered that the patient had an isolated condition with only SIJ pain when any other injection, except for those specific to SIJ, was not effective. Patients with a history of infection, tumors in the lumbar and pelvic regions, recent lumbar spine and pelvic fractures, and obvious ankylosing spondylitis were excluded. All patients had a history of other injections, including selective nerve root infiltration and/or lumbar disc block, and those injections elicited a negative response.

Indications for surgical treatment

The indications for SIJ arthrodesis were insufficient responsiveness to conservative treatments for ≥6 months, difficulty in working, and marked restrictions in the activity of daily living due to recurrence of severe SIJ pain, even after undergoing repeated injections and substantial physical therapies as inpatients[6]. We performed surgery only when there was an urgent requirement to operate. For this pilot study, we informed patients of the benefits and risks of conventional and new minimally invasive methods based on previous surgical results in our hospital and results of new methods in the literature; we had more than 5 years of follow-up data that included good surgical outcomes with a high rate of bony union using the conventional method. Several patients complained of femoral neuralgia due to this surgical approach, and pubic symphysis pain after bilateral SIJ arthrodesis may occur. SIJ pain can be relieved in a less invasive manner using this new implant system, but there are no data for surgical results in our country or Asian countries. The patients were allowed to choose among different methods. In this study, five consecutive patients chose the new method.

Surgical technique

Three triangular implants, namely the iFuse system (SI-Bone Inc.), were used. Each patient was placed in the prone position under general anesthesia. A 3 cm longitudinal skin incision was made between the iliac crest and the trochanter major under intra-operative lateral fluoroscopic imaging. Then, a guide pin was inserted across the SIJ. After placement of a soft tissue protector, the gluteus maximus and gluteus medius muscles were bluntly divided to reach the iliac bone, a hole was drilled, the cortical bone of the lateral ilium was disrupted using a sharp triangular broach through the guide pin, and a triangular implant was inserted. The other two implants were inserted using the same procedures parallel to the first implant, and two caudal implants were placed on the level of the S1 and S2 foramina (Fig. 1). The attending surgeons ensured that the implant did not protrude into the pelvic cavity in lateral, inlet, and outlet views.

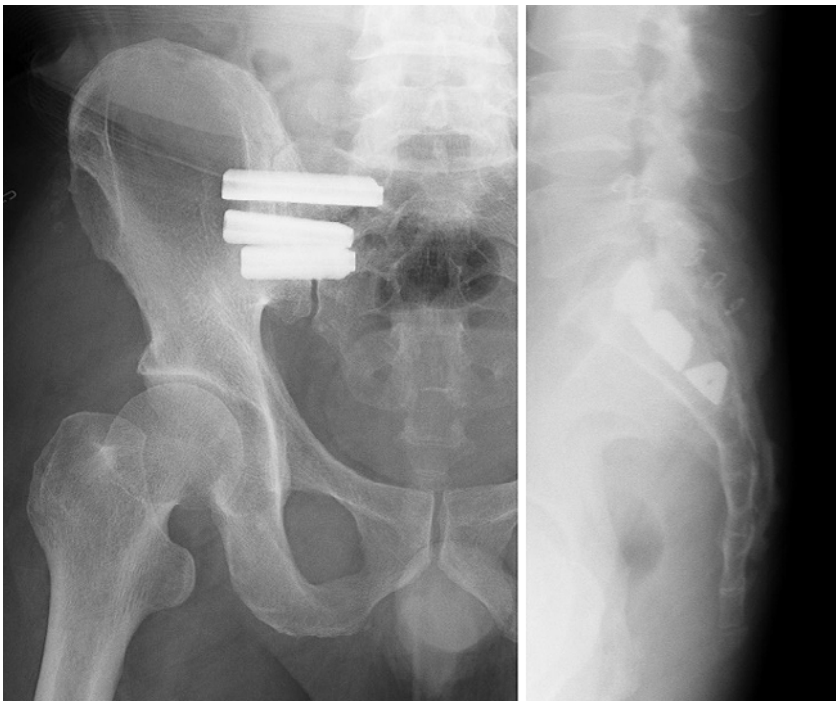

Figure 1. Post-surgical images.
Three triangular implants are inserted through the lateral approach.

Data collection

The following items were investigated in all patients:

1. pre-surgical physical findings: total sacroiliac joint score[15] and results of provocation tests[18]; Fabere test, Gaenslen's test, thigh thrust test, distraction test, and compression test;
2. effectiveness of SIJ injections measured on a pain relief scale[16];
3. time between confirmed definite diagnosis of SIJ pain and surgical treatment;
4. prior spine or hip surgeries;
5. imaging findings of the SIJ based on computed tomography (CT) and/or bone single-photon-emission computed tomography/CT (SPECT/CT)[19];
6. operation time, blood loss, and duration to full weight bearing;
7. pain intensity (visual analog scale [VAS]) and functional impairment were evaluated using the Oswestry disability index [ODI] prior to surgery and 3 months, 6 months, 12 months, and 36 months thereafter;
8. CT image-based evaluation of implant loosening and osseous bridging across the joint[20], 12 and 36 months after the surgery; and
9. postoperative satisfaction at 12 months and 36 months.

Statistics

A pre-post comparison of VAS and ODI was conducted using the Wilcoxon test. The significance level set to p= 0.05. The statistical analysis was performed using JMP® 14.2 software (SAS Institute Inc., Cary, NC, USA).

Results

All patients scored full points on the SIJ scoring system. In all the patients, at least four out of five provocation tests were positive. Furthermore, all patients experienced more than 70% pain relief temporally after SIJ injections were administered (Table 1). The average period between confirmed definite diagnosis of SIJ pain and surgical treatment was 2.9 ±2.4 (range, 1-7) years. Three of five patients underwent prior spine surgeries, but there was no prior hip surgery. Four out of five patients had slight osteoarthropathic changes of the SIJ on CT, whereas one patient had a normal CT scan. SPECT/CT was performed on four patients, of whom three patients had greater accumulation on the affected side of the SIJ.

Operation time averaged 67.7±13.1 (range, 52-87) minutes, and the average blood loss was 7.4±6.9 (range, 0-14) mL, and the average duration to full weight bearing was 12.4±11.7 (range, 3-32) days (Table 2).

The mean VAS value and ODI improved significantly from 88.0±8.4 mm to 33.6±31.9 mm and from 76.4±3.8% to 41.4±10.3%, respectively, 3 months after surgery ($p< 0.05$). The mean VAS value significantly decreased in comparison to the initial preoperative data until 36 months after the surgery: 34.0±30.7 mm (6 months), 26.0±22.2 mm (12 months), and 46.4±30.9 mm (36 months) ($P<0.05$). The mean ODI significantly improved to 46.2%±21.9% until 6 months after the surgery ($P<0.05$) but did not have significant improvement after this period: 46.94±23.7% (12 months) and 66.4±8.6 (36 months) (Fig. 2). Four out of five patients had dramatic improvement on VAS up to 12

Table 1. Pre-surgical States of Five Patients.

No.	Age (years)/sex	Painful side	SIJ score	Number of positive provocation tests	Effect of SIJ injections (Pain relief scale)	Time between diagnosis and surgical treatment (years)	Prior surgery
1	79 F	Rt.	9/9	4/5	From 10 to 0	7	None
2	52 F	Lt.	9/9	5/5	From 10 to 3	2	None
3	60 M	Rt.	9/9	5/5	From 10 to 2	1	Anterior cervical fusion
4	32 F	Rt.	9/9	5/5	From 10 to 2	1.5	Lumbar fusion: L5-S1
5	59 F	Lt.	9/9	5/5	From 10 to 3	3	Lumbar fusion: L3-5

SIJ, sacroiliac joint; F, female; M, male; Rt., right; Lt., left

Table 2. Surgical Procedure Time, Blood Loss, and Duration to Full Weight Bearing.

No.	Age (years)/sex	Operation time (min)	Blood loss (mL)	Duration to full weight bearing (days)
1	79 F	73	10	11
2	52 F	63	0	12
3	60 M	63	13	3
4	32 F	87	14	32
5	59 F	52	0	4

F, female; M, male

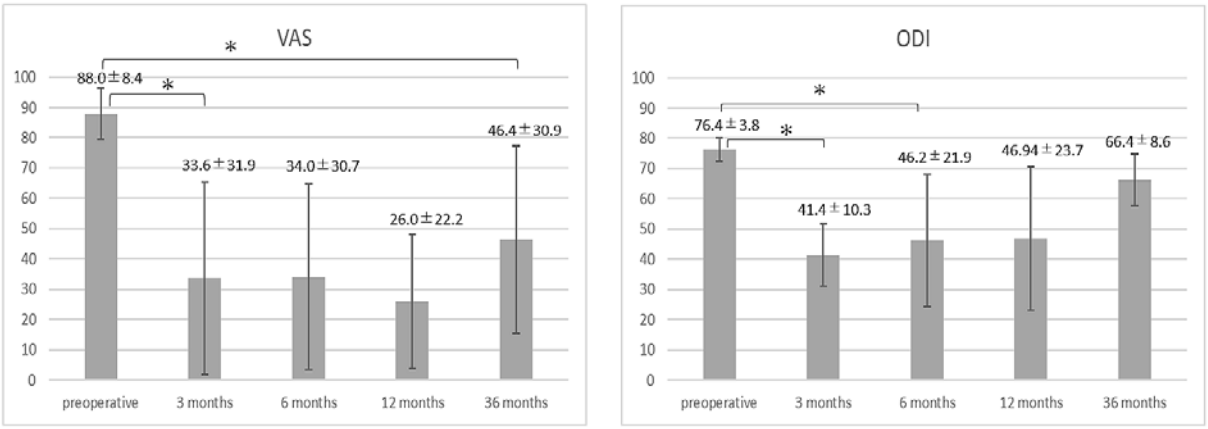

Figure 2. Mean VAS and ODI values at each follow-up period.
VAS, visual analog scale; ODI, Oswestry Disability Index
Significant differences (P<0.05) are marked with *.

months; however, one patient (Case 4), who was highly obese (body mass index: 35.93), had a slight improvement in VAS score after the first surgery (Fig. 3). This patient underwent revision surgery because the third implants, which should have been inserted in the most caudal portion, could not be inserted during the first surgery due to overheating of the C-arm. The second surgery was performed 4 months after the first surgery; two small implants were added; and the bone was grafted for bone defects in and around the joint cavity (Fig. 4). The revision surgery took 133 minutes, and blood loss was 30 mL. However, after revision surgery, the patient did not have improvements in either VAS or ODI.

Regarding CT imaging findings, three of five patients showed at least one implant loosening at the sacrum side (Fig. 5 , Table 3). One patient (Case 1) complained of complete pain recurrence at the fixed side 18 months postoperatively due to implant loosening. No patient had osseous bridging across the joint.

Case 3 complained of contra-lateral SIJ pain 2 years postoperatively and had a lower ODI at 36 months. Case 5 had an accident that twisted the pelvis and triggered recurrence of pain in the SIJ region; both VAS and ODI were reduced at 36 months postoperatively (Fig. 3).

Satisfaction rates were 80% (4/5) at 12 months and 60% (3/5) at 36 months. The proportion of patients who would definitely undergo the surgery again was 60% at the 36-month follow-up.

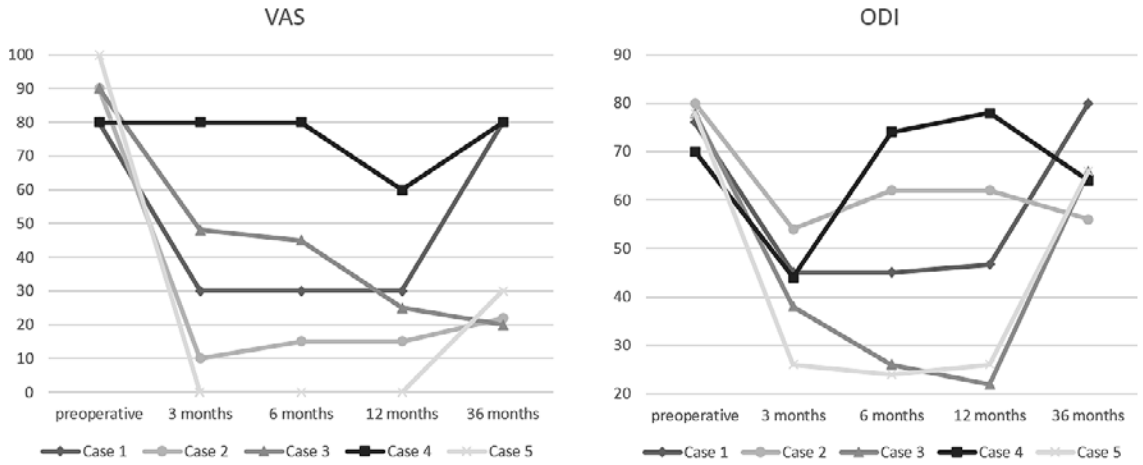

Figure 3. VAS and ODI values in each patient.
VAS, visual analog scale; ODI, Oswestry Disability Index

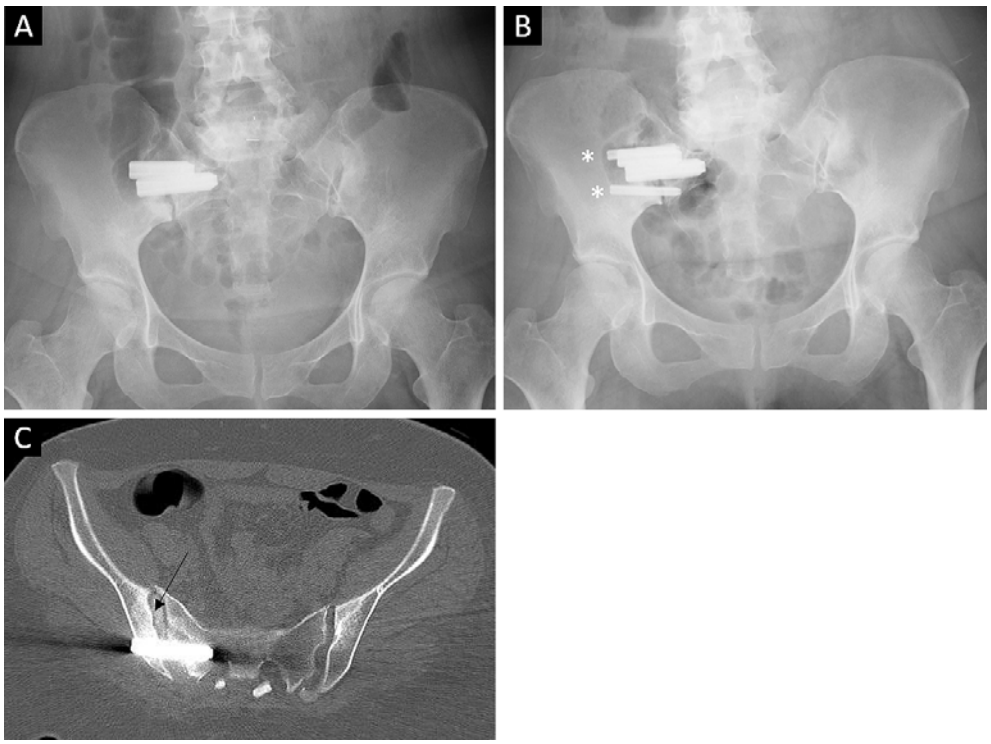

Figure 4. Revision surgery.
A. Post-surgical image of the first surgery.
B. Post-surgical image of the second surgery; two small implants are added (*).
C. CT image of bone grafting in the joint (arrow).
CT, computed tomography

Discussion

In this Japanese pilot trial for minimally invasive SIJ arthrodesis, three out of five patients had good results after a long-term follow-up of three years. Previous studies on SIJ arthrodesis using conventional open techniques have demonstrated that approximately 75% of patients obtain good results[6-8,21]. By contrast, most industry-supported studies have described that recent minimally invasive techniques yielded significantly superior surgical results (mean 84% of patients satisfied with the surgery)[21,22]. There are few reports of independent studies that indicate that the surgical outcomes are somewhat lower[23]. In fact, two of five patients indicated inadequate long-term efficacy in this study.

The iFUSE implant has a large porous surface area that allows for bony ingrowth, which could lead to fusion of the joint. Regarding bone union, a previous paper reported intra-articular osseous bridging in 87% of patients after a 5-year

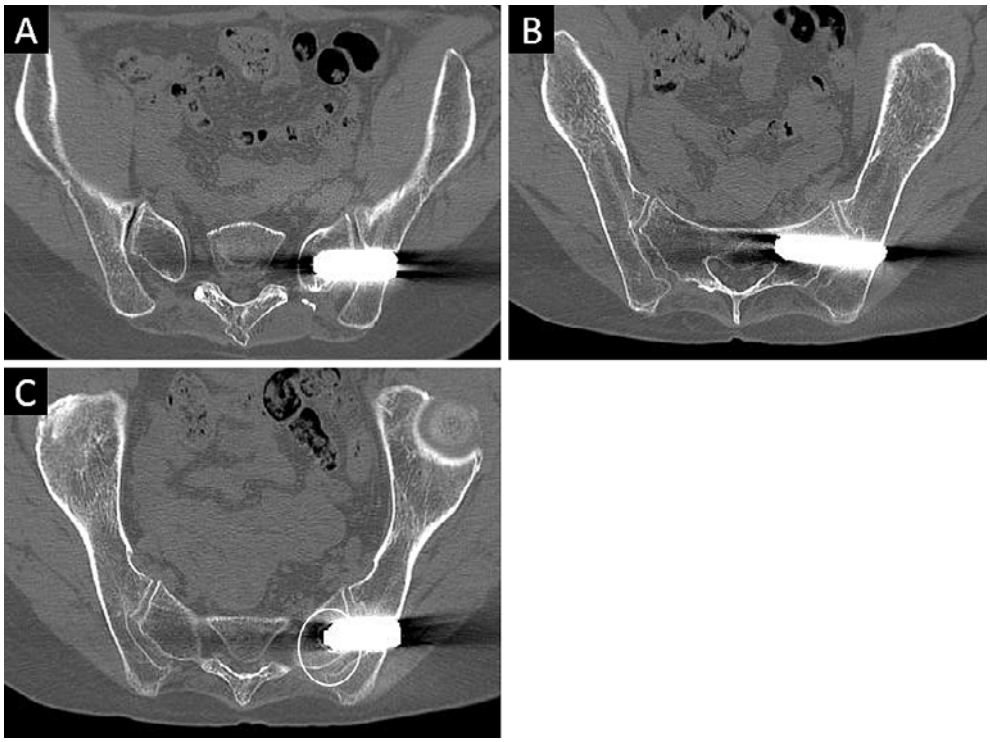

Figure 5. CT images 12 months after the surgery.
A. Upper region.
B. Middle region.
C. Caudal region; implant loosening is indicated on the sacrum side (white circle).
CT, computed tomography

Table 3. Implant Loosening on CT.

No.	Age (years)/sex	3 months	12 months	36 months
1.	79 F	-	+Caudal (Sacrum side)	+
2.	52 F	-	-	-
3.	60 M	-	-	-
4.	32 F	-	+Middle (Sacrum side)	+
5.	59 F	-	+Caudal (Sacrum side)	+

CT, computed tomography; F, female; M, male

follow-up[20]. By contrast, at least in the 3-year follow-up in our study, no patient had osseous bridging across the joint. The other 3-year follow-up study did not demonstrate radiographic outcomes regarding bone union[24]. Further long-term follow-up might be necessary to confirm fusion of the joint.

In the anterior open approach[6], a plate placed on the upper anterior part of the SIJ is thought to aid in effectively suppressing the rotation of the joint as a plane. However, this approach requires invasive procedures for this purpose. The triangular implant system is a minimally invasive procedure that is easier to perform. Therefore, it has been used worldwide[25]. The advantage of this implant is that the upper anterior portion of the SIJ can be fixed from the bone side in the horizontal plane of the triangular prism. The shape of this implant is suitable because it is better to hold this upper anterior portion of the SIJ than to use a conventional screw in the lateral approach[26,27].

In the United States, full weight bearing is allowed on the same day or the next day after surgery, and most patients stay in hospital overnight or are discharged the same day[11,28]. Manufacturers emphasize the advantages of minimally invasive techniques for reduction of medical costs[29-31]. This would provide a benefit for private insurance companies in the United States. In this study, the load was raised over a period of averaged 12 days, depending on post-surgical pain.

In general, the lateral approach has potential for serious complications such as pelvic vascular/ nerve injuries[10,25,32]. Of the three implants in the triangular implant system, the most cephalad one has a guideline for the safety entry point. However, the entry point of the other two caudal implants must be slightly anterior to the line of the anterior surface of the sacrum to pass through the articular surface (Fig. 6). Se-

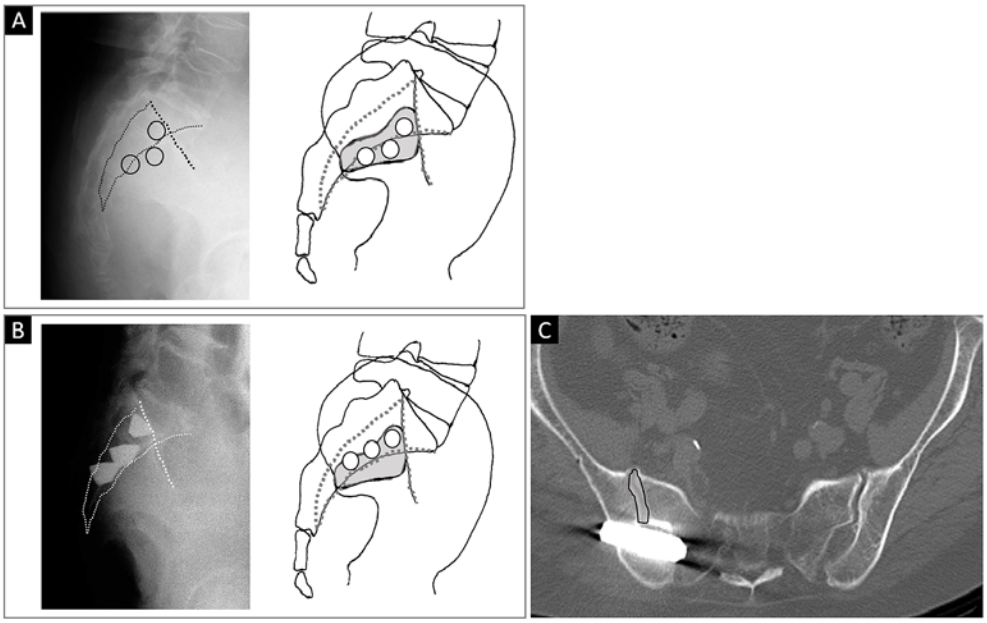

Figure 6. Implant insertion point in lateral view.
A. Ideal insertion point.
B. Caudal implants are often inserted at the posterior portion of the joint to avoid organ and blood damage to the pelvis.
C. The caudal implant does not pass through the articular surface.

rious complications may be avoided when we use an intraoperative navigation system. In the lateral approach, the tip of the implant is inserted into the cancellous bone of the sacrum. Implant loosening due to bone weakness on the sacral side[11,33,34] is a problem in older women who generally often present with bone weakness and vacuum phenomena in the SIJ cavity, which implies a few millimeters of articular separation[35]. Of the possible reasons for the poor long-term results, loosening of the implant may be one of the factors. In this study, a 32-year-old woman (Case 4), who did not have osteoporosis but was obese, also had implant loosening. Hence, not only osteoporosis but also obesity could cause implant loosening. When the implant loosens and symptoms recur, re-fixation with addition of an implant is challenging in the lateral approach because the SIJ articular region is not wide.

There were two key limitations to this study. First, the number of cases was very low. Second, there was a lack of a specific quantifiable indicator of the severity of the patients with SIJ dysfunction, which makes it impossible for one to simply compare the results with previous studies on minimally invasive surgery in SIJ surgery conducted in other countries. MIS procedures allow surgeons to perform SIJ arthrodesis with more peace of mind for both surgeons and patients. Therefore, surgery might be performed for patients with moderate or light SIJ pain. Surgical outcomes might be better when surgery is performed in mild cases. In addition, the data at 24 months postoperatively were missing because the follow-up was not conducted uniformly. However, to the best of our knowledge, this is the first case series in Asian subjects. Despite these limitations, we were able to obtain data that will serve as a basis for future studies.

Conclusions

Five patients in whom substantial conservative treatment failed underwent surgery using the triangular implant system. The mean VAS value and ODI significantly improved until 6 months after the surgery. However, the mean ODI was reaggravated at 36 months after the surgery. Osseous bridging across the joint was not observed in all patients. We should carefully keep an eye on further long-term results to evaluate the implant.

Conflicts of Interest: The authors declare that there are no relevant conflicts of interest.

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Author Contributions: Daisuke Kurosawa: conceptualization, methodology, investigation, and writing of the original draft, Eiichi Murakami: conceptualization, investigation, supervision, and writing of the original draft Hiroaki Koga: writing/review and editing and supervision, Hiroshi Ozawa: writing/review and editing and supervision.

Ethical Approval: This study was approved by the Institutional Review Board of JCHO Sendai Hospital (no. 2017-6) and Kikuno Hospital (no. 201705193).

Informed Consent: Patients provided written informed

consent for the use of their data in this study.

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