Novel Technique for Sacral-Alar-Iliac Screw Placement Using Three-Dimensional Patient-Specific Template Guide

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Abstract:

Introduction: The sacral-alar-iliac (SAI) screw technique is becoming popular for sacropelvic fixation. However, appropriately placing SAI screws is technically demanding because of a narrow safe corridor and the risk of neurovascular/visceral injuries. Recently, a three-dimensional patient-specific template guiding technique for pedicle screw placement has been considered a promising method to improve accuracy and safety. The objective of the present study was to investigate the accuracy of SAI screw placement with a patient-specific template guide using cadaveric and prospective clinical pilot studies.

Methods: Three-dimensional planning of SAI screw placement, including entry point, screw trajectory, length, and diameter, was performed using a computer simulation software. Then, three-dimensional printed patient-specific template guides were created based on the plan. Firstly, a total of 12 SAI screws were placed for 6 cadaveric specimens using the guides. Next, in a prospective clinical trial, a total of 20 SAI screws were placed for 10 consecutively enrolled patients. The safety and accuracy of screw placement were analyzed using postoperative computed tomography by the evaluation of any cortical breach and measurement of screw deviations between the planned and actual screw positions.

Results: All the screws showed no perforation. In the cadaveric study, the mean horizontal and vertical deviations from the planned screw position at the entry point were 1.40±1.21 mm and 1.34±1.09 mm, respectively. The mean angular deviations in the sagittal and transverse planes were 1.68°±1.24° and 1.53°±1.06°, respectively. The results of the clinical study showed comparable accuracy with those of the cadaveric study, except for the vertical deviation at the entry point (p= 0.048).

Conclusions: This is the first study to evaluate the feasibility and accuracy of using a patient-specific template guide for SAI screw placement. This technique could become an effective solution to achieve accurate screw placement.

Keywords:
sacral-alar-iliac screw, accuracy, patient-specific template guide, radiation exposure, complications

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Introduction

Spinopelvic fixation is necessary for long fusion to the sacrum for the management of complex spinal pathologies, including fracture, infection, osteoporosis, tumors, and spinal deformities. The lumbosacral junction is one of the challenging spinal regions to undergo a solid fusion using pelvic anchors during posterior spinal arthrodesis because of poor sacral bone quality, complex anatomy, proximity to major neurovascular structures, and significant mechanical force, often leading to pseudoarthrosis and instrumentation failure[1]. Surgeons need to achieve a satisfactory distal foundation at the pelvis to resist considerable cantilever force generated by the long lever arm of multiple spinal constructs. In the literature, several supplemental pelvic fixation techniques have been reported, such as the Galveston technique[2], Jackson technique[3], S2 alar screws[4], iliac screws[5], and the four-rod fixation technique[6].

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Over the last decade, the sacral-alar-iliac (SAI) screw technique has been accepted for reliable sacropelvic fixation[7-9]. The rationale for SAI screw insertion is a medialized entry point that does not require wide dissection of the sacral paraspinal muscles, and it aligns with the cranial screws, eliminating the need for additional offset connectors and complicated rod bending for rod assembly. The SAI pathway crosses the sacroiliac (SI) joint and travels between the inner iliac cortices through the sciatic notch toward the anterior inferior iliac spine, allowing for the placement of longer and larger screws[10]. Biomechanical studies have demonstrated superior performance of SAI screws over iliac screws because of a higher level of cortical bone purchase[11,12]. These advantages are associated with lower rates of surgical infection, symptomatic screw prominence, pseudoarthrosis, and reoperation[13,14].

This innovative instrumentation technique can achieve both minimal invasiveness and strong anchoring; however, appropriately placing the SAI screws is sometimes challenging because of a narrow safe corridor and the risk of neurovascular or visceral injuries, necessitating high-level surgical skill to enhance accuracy. A variety of attempts have been proposed to secure screw placement, such as the free-hand curved gearshift-guided technique[15], fluoroscopic teardrop-view technique[9], inertial measurement units-guided technique[16], intraoperative three-dimensional (3D) navigation technique[17,18], and robotic guidance technique[19,20].

Recently, with the development and practical application of 3D printing technology, a patient-specific drill guide technique for the successful placement of pedicle screws has been considered as a promising method to improve accuracy and safety[21,22], with a deviation accuracy of <1 mm and < 2°[23,24]. A randomized cadaveric study has shown superior screw placement using a patient-specific template guide technique in terms of reduced instrumentation time, greater accuracy, and lower radiation exposure compared with using the free-hand fluoroscopy-assisted technique[25]. However, to the best of our knowledge, there has been no report on the feasibility of a SAI screw guide. The objectives of the present study were as follows: (1) to investigate the accuracy of SAI screw placement with a patient-specific drill guide using a cadaveric study and (2) to evaluate the initial screw accuracy in a case series.

Materials and Methods

Cadaveric study

Lumbosacral segments were obtained from 6 freshly frozen Caucasian cadaveric specimens (2 males and 4 females, with an average age of 70.0±14.2 years) without fractures, infection, or metastatic spinal lesions. A total of 12 SAI screws were inserted using the patient-specific guide technology (MySpine MC®, Medacta International, Switzerland).

Preoperative planning

A 3D model of the sacropelvic segments was virtually reconstructed using preoperative computed tomography (CT) data with a slice thickness of 0.5 mm using Mimics® (Materialise, Leuven, Belgium). Then, 3D planning of SAI screw placement, including entry point, screw trajectory, length, and diameter, was performed by a surgeon using Solidworks® (Dassault Sysètmes, Vélizy-Villacoublay, France) (Fig. 1). The starting point of the SAI screw was 1 mm inferior and 1 mm lateral to the S1 dorsal foramen, and the trajectory was directed so as to penetrate the SI joint toward the anterior inferior iliac spine[8]. Based on the planning of the implant position, a 3D-printed patient-specific drill guide and sacral mold that reproduced the posterior anatomy of bone surface were manufactured using medical-grade polyamide and used after steam sterilization, similar to other implants (Fig. 2). The guides were equipped with drill sleeve structures for bilateral S1 screws and a unilateral SAI screw, but no additional surgical exposure was needed for guide-setting.

Surgical procedure

Through a midline skin incision, the paraspinal muscles were dissected to expose the entry points of the SAI screw. After meticulous posterior bone surface exposure, the guide was set on the sacral bone's surface (Fig. 3A). Once proper fitting of the guide was achieved, the surgeon could not feel any movement of the guide on applying a slight digital pressure. Then, the surgeon pushed the guide firmly to the posterior bone surface to secure stable positioning and drilled pilot holes (2.7 mm in diameter) through the guide tubes up to the same depth as the planned screw's length (Fig. 3B). Following jig removal and guidewire placement in the initial screw hole (Fig. 3C), the screw paths were prepared using cannulated taps. Lastly, cannulated screws of preoperatively determined sizes (MUST®, Medacta International, Switzerland) were placed (Fig. 3D). All the procedures were completed without fluoroscopic assistance.

Evaluation of screw position

Postoperative CT was performed with a slice thickness of 0.5 mm to check for any cortical breach outside the confines of the pelvis. Then, the pre- and postoperative reconstructed bone structures were superimposed, and deviations between the planned and actual screw positions were computationally analyzed: (1) screw position at the entry point, (2) caudal angle of the trajectory in the sagittal plane, and (3) lateral angle of the trajectory in the transverse plane. All radiologic measurements were computationally performed by an independent expert who was blinded to the study.

Clinical study

This was a retrospective study of prospectively enrolled patients using a guide for SAI screw placement following approval from our institutional ethics committee. The sub-

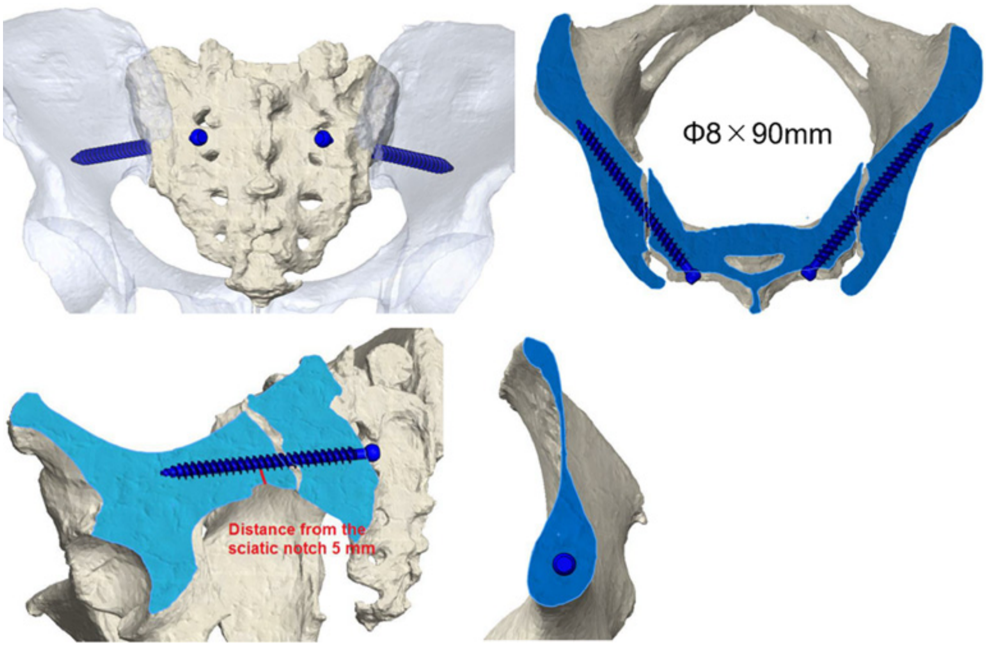

Figure 1. Example of preoperative planning for SAI screw placement.

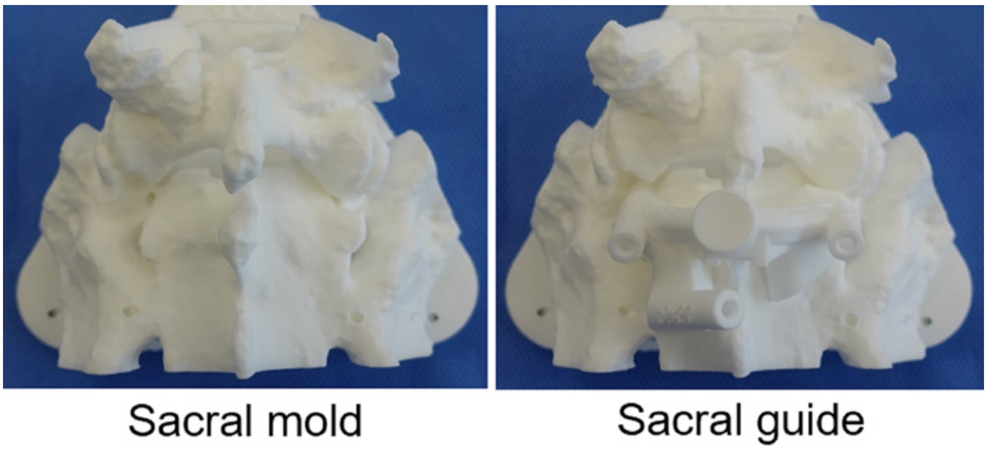

Figure 2. Design of the guide.
A 3D printed patient-specific template guide and sacral mold that reproduces the posterior anatomy of the bone's surface. The guide is equipped with drill sleeve structures for bilateral S1 screws and a unilateral SAI screw.

jects comprised 10 consecutively enrolled patients (1 male and 9 females, with an average age of 72.1±6.0 years) who underwent lumbosacral spinal fusion. There were 8 patients with degenerative scoliosis and 2 with degenerative kyphosis. The surgical procedure was essentially the same as mentioned previously with Hall frame. After initial screw hole creation by drilling through the guide tube up to 50 mm to penetrate the SI joint, a probe was used to develop the rest of the screw path using a manual technique. Once the holes were confirmed to be intraosseous using a pedicle feeler, the depth was measured and cannulated screws inserted over a guidewire. If necessary, the surgeons verified the accuracy of the final screw position based on a pelvic inlet view and lateral view using intraoperative fluoroscopy[26]. No patient required repositioning of the SAI screws after the intraoperative confirmation of screw placement. Postoperative CT was performed within a week after surgery, and deviation accuracy was evaluated by superimposing the pre- and postoperative CT images.

Statistical analysis

All results are shown as mean±standard deviation. The Mann-Whitney nonparametric test was performed to compare the accuracy between the cadaveric and clinical studies. JMP® version 12 (SAS, Cary, NC, USA) was used for all the analyses, with the level of significance set as $p < 0.05$.

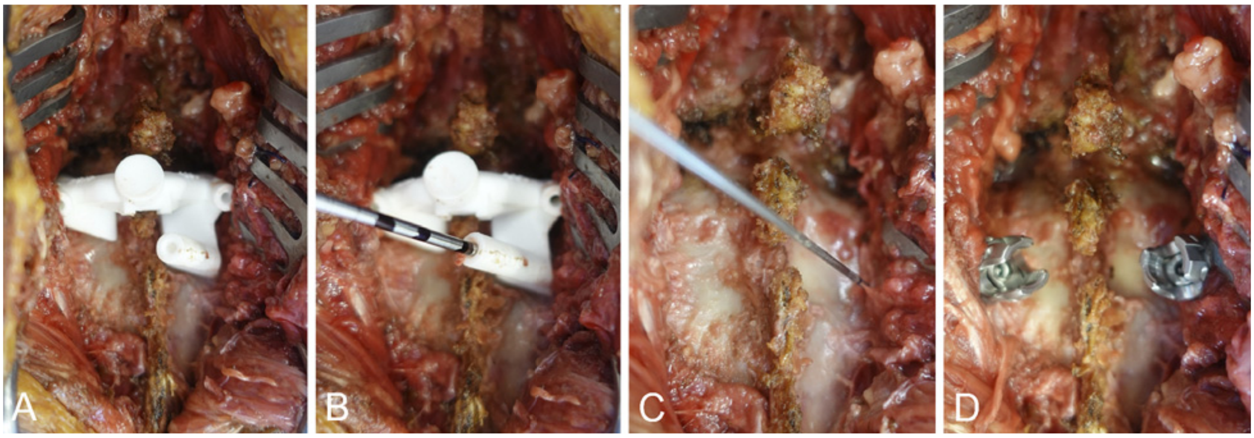

Figure 3. Intraoperative images using a patient-specific template guide for SAI screw placement.
A. Exposure and placement of the guide
B. Screw hole creation by drilling (2.7 mm in diameter)
C. Jig removal and guidewire placement
D. After-implant placement

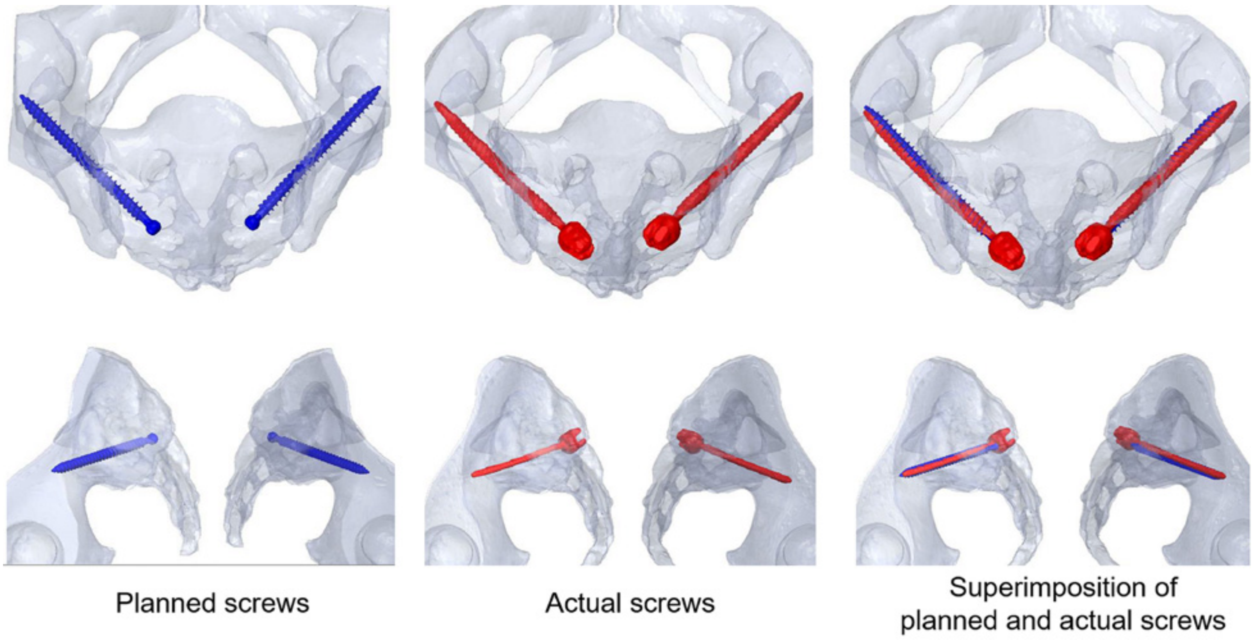

Figure 4 Superimposition of the planned and postoperative 3D reconstructed CT images.
The superimposed image demonstrates accurate SAI screw placement.

Results

Cadaveric study

A total of 12 screws showed no cortical breach outside the ilium. In terms of the screw position's accuracy (Fig. 4), the mean horizontal deviation between the planned and actual screw positions at the entry point was 1.40±1.21 mm, whereas the mean vertical deviation was 1.34±1.09 mm (Table 1). The mean angular deviations between the planned and actual screw positions in the sagittal and transverse planes were 1.68°±1.24° and 1.53°±1.06°, respectively.

Table 1. Mean Deviation Between Planned and Actual Screw Positions.

Parameters	Cadaveric study	Clinical study	P-value
Horizontal (mm)	1.40±1.21	1.50±0.85	0.456
Vertical (mm)	1.34±1.09	2.39±1.89	0.048*
Sagittal plane (°)	1.68±1.24	2.64±1.77	0.192
Transverse plane (°)	1.53±1.06	2.45±1.59	0.193

*: p<0.05

Clinical study

The mean actual screw size was 8.50±0.51 mm in diameter and 83.16±4.78 mm in length. Among a total of 20 screws inserted for 10 patients using the SAI guide, the postoperative CT showed that all the screws were in correct positions, without any cortical breach, and there was no incidence of neurovascular injuries. The mean horizontal and vertical deviations between the planned and actual screw positions at the entry point were 1.50±0.85 mm and 2.39±1.89 mm, respectively. The mean angular deviations between the planned and actual screw positions in the sagittal and transverse planes were 2.64°±1.77° and 2.45°±1.59°, respectively. The results of the clinical study showed comparable accuracy with those of the cadaveric study, except for the vertical deviation (p=0.048).

Table 2. Perforation Incidence of Sacral-alar-iliac Screw.

Year	Author	Technique	Rate
2009	O'Brien et al.[8]	Fluoroscopy	15%
2010	Nottmeier et al.[17]	Navigation	15.6%
2013	Ray et al.[18]	Navigation	2.8%
2016	Jost et al.[16]	Inertial measurement unit	5.6%
2017	Park et al.[28]	Free-hand	20%
2018	Shillingford et al.[29]	Free-hand	8%
2018	Shillingford et al.[20]	Robotic	2.2%
Present study	Matsukawa et al.	Patient-specific guide	0%

Discussion

The present study is the first to investigate accuracy during SAI screw placement using a patient-specific template guide system. The results of the cadaveric accuracy study and initial clinical experience showed no perforation, with favorable reproducibility between the planned and actual screw positions.

The narrow safety range of SAI screw placement may cause an incidental cortical breach, potentially leading to fixation failure and an injury to adjacent pelvic structures[27]. Especially, anterior and inferior screw perforations cause risks of major vessel injuries, which can result in catastrophic complications. During the initial phases of introduction of the SAI screw technique, O'Brien et al. performed a cadaveric study and reported a 15% rate of cortical perforation of the ilium using the free-hand fluoroscopic technique[8] (Table 2)[28,29]. Appropriate screw placement needs both surgical experience and appropriate fluoroscopic support; however, optimizing the fluoroscopic setting is sometimes challenging because of complex and overlapping sacropelvic bone anatomy, poor imaging quality, and problems with a radiotransparent surgical table. To enhance SAI screw accuracy, several modern techniques have been introduced, such as the intraoperative computer-based navigation technique and robotic guidance technique, resulting in a 2.2%-15.6% rate of screw perforation[17,18,20]. Although these innovative technologies have been increasingly used in spine surgery because of their high reproducibility of screw placement and safety, the problems associated with these modalities include great expense, need for extra personnel and large space for equipment, and need for additional intraoperative radiation exposure for registration and planning; therefore, the availability of these techniques is still limited. On the contrary, the in situ patient-specific template guide technique is simple and relatively low-cost, with screw-placement accuracy comparable to that of the robotic and computer-based navigation techniques. In this study, we confirmed that all the screws were without any cortical violation of the ilium; however, higher deviations were observed in the clinical study compared to those in the cadaveric study. The depth of the pilot holes created by drilling (cadaveric study, full-length drilling up to the same length as the planned screw; clinical study, partial drilling up to 50 mm and the rest of the screw path developed by manual probing) might affect the differences in the deviations.

The acceptable results of the present study has practical implications because the high-level accuracy of SAI screw placement using template guides can lead to marked benefits with regard to both safety and strong fixation. Similar to the intraoperative 3D navigation technique, one of the rationales for the use of a patient-specific guide is that surgeons can perform preoperative 3D planning following the ideal trajectory, which engages dense bone and maximizes the screw length and diameter, potentially leading to rigid fixation with improved fusion rates. Furthermore, this technique provides 2 major advantages in addition to its marked reproducibility. First, simple and high operability using the guide contributes to reduced operative time. This template guide is designed to achieve sufficiently large and specific contact with the posterior bone surface to provide stable fitting. Contrary to a convergent screw trajectory that necessitates extensive dissection for guide installation, SAI guides, using a divergent drill tube, can be easily installed and obviate the need for additional surgical exposure in comparison with the conventional SAI technique. Accordingly, intraoperative preparation, such as positioning of the guide and subsequential hole creation, becomes a quick and automatic process. Second, the guide technique can reduce the amount of radiation exposure for accurate screw insertion compared with a CT-based navigation technique. Intraoperative radiation exposure is still a critical problem for surgeons, medical staff, and patients during spine surgery. Because the patient-specific template guide system is based on the patient's spinal CT commonly taken prior to instrumentation surgery to obtain osseous information, no additional radiation exposure is needed for surgical planning and production of the guides. For clinical use, it is not desirable to completely omit intraoperative radiation exposure to confirm its correctness; however, the need for fluoroscopic assistance is significantly reduced and required only once after final screw placement, without sacrificing its accuracy.

There are some cautions to be exercised when using a guide. First, clean preparation of the bone surface, such as meticulous removal of soft tissue and preservation of the bone structure where the guide is to be attached, is essential to achieve stable fitting. Second, high cost (200 USD total for one segment) and time expenditures (2-week period until shipment) are needed for preoperative planning and production of the guides. A limitation of this study is the small number of cases and lack of a control group comparing the instrumentation time and radiation exposure dose for SAI screw placement. Additionally, there is still a slight learning curve using the guide that we did not examine. Further clinical study of a large number of patients is necessary to elucidate the potential benefits as well as reproducibility and safety of using a guide.

In conclusion, to the best of our knowledge, this is the first study to evaluate the feasibility and accuracy of a patient-specific template guide for SAI screw placement. This technique is simple and highly accurate and can become an effective solution for achieving both correct screw placement and a reduced incidence of complications.

Conflicts of Interest: The authors are consultants for Medacta.

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Ethical Approval: This study was performed after obtaining approval from our institutional review board the Research Ethics Committee of Murayama Medical Center (ID: 12-10).

Informed Consent: Informed consent was obtained from all individual participants included in the study.

References

1. Kim YJ, Bridwell KH, Lenke LG, et al. Pseudarthrosis in long adult spinal deformity instrumentation and fusion to the sacrum: prevalence and risk factor analysis of 144 cases. Spine. 2006;31(20):2329-36.
2. Allen BL Jr, Ferguson RL. The Galveston technique for L rod instrumentation of the scoliotic spine. Spine. 1982;7(3):276-84.
3. Jackson RP, McManus AC. The iliac buttress. A computed tomographic study of sacral anatomy. Spine. 1993;18(10):1318-28.
4. Leong JC, Lu WW, Zheng Y, et al. Comparison of the strengths of lumbosacral fixation achieved with techniques using one and two triangulated sacral screws. Spine. 1998;23(21):2289-94.
5. Kuklo TR, Bridwell KH, Lewis SJ, et al. Minimum 2-year analysis of sacropelvic fixation and L5-S1 fusion using S1 and iliac screws. Spine. 2001;26(18):1976-83.
6. Shen FH, Harper M, Foster WC, et al. A novel "four-rod technique" for lumbo-pelvic reconstruction: theory and technical considerations. Spine. 2006;31(12):1395-401.
7. Chang TL, Sponseller PD, Kebaish KM, et al. Low profile pelvic fixation: anatomic parameters for sacral alar-iliac fixation versus traditional iliac fixation. Spine. 2009;34(5):436-40.
8. O'Brien JR, Yu WD, Bhatnagar R, et al. An anatomic study of the S2 iliac technique for lumbopelvic screw placement. Spine. 2009;34(12):E439-42.
9. Kebaish KM. Sacropelvic fixation: techniques and complications. Spine. 2010;35(25):2245-51.
10. Tavares Junior MCM, de Souza JPV, Araujo TPF, et al. Comparative tomographic study of the S2-alar-iliac screw versus the iliac screw. Eur Spine J. 2019;28(4):855-62.
11. O'Brien JR, Yu W, Kaufman BE, et al. Biomechanical evaluation of S2 alar-iliac screws: effect of length and quad-cortical purchase as compared with iliac fixation. Spine. 2013;38(20):E1250-5.
12. Cunningham BW, Sponseller PD, Murgatroyd AA, et al. A comprehensive biomechanical analysis of sacral alar iliac fixation: an in vitro human cadaveric model. J Neurosurg Spine. 2019;30(3):367-75.
13. Ilyas H, Place H, Puryear A. A comparison of early clinical and radiographic complications of iliac screw fixation versus S2 alar iliac (S2AI) fixation in the adult and pediatric populations. J Spinal Disord Tech. 2015;28(4):E199-205.
14. Elder BD, Ishida W, Lo SL, et al. Use of S2-alar-iliac screws associated with less complications than iliac screws in adult lumbosacropelvic fixation. Spine. 2017;42(3):E142-9.
15. Andrade NS, Okafor L, Neuman BJ. Novel technique for sacral alar-iliac (S2AI) fixation. Clin Spine Surg. 2018;31(9):373-6.
16. Jost GF, Walti J, Mariani L, et al. A novel approach to navigated implantation of S-2 alar iliac screws using inertial measurement units. J Neurosurg Spine. 2016;24(3):447-53.
17. Nottmeier EW, Pirris SM, Balseiro S, et al. Three-dimensional image-guided placement of S2 alar screws to adjunct or salvage lumbosacral fixation. Spine J. 2010;10(7):595-601.
18. Ray WZ, Ravindra VM, Schmidt MH, et al. Stereotactic navigation with the O-arm for placement of S-2 alar iliac screws in pelvic lumbar fixation. J Neurosurg Spine. 2013;18(5):490-5.
19. Bederman SS, Hahn P, Colin V, et al. Robotic guidance for S2-alar-iliac screws in spinal deformity correction. Clin Spine Surg. 2017;30(1):E49-53.
20. Shillingford JN, Laratta JL, Park PJ, et al. Human versus robot: a propensity-matched analysis of the accuracy of free hand versus robotic guidance for placement of S2 alar-iliac (S2AI) screws. Spine. 2018;43(21):E1297-304.
21. Radermacher K, Portheine F, Anton M, et al. Computer assisted orthopaedic surgery with image based individual templates. Clin Orthop. 1998;354(2-4):28-38.
22. Lu S, Xu YQ, Lu WW, et al. A novel patient-specific navigational template for cervical pedicle screw placement. Spine. 2009;34(26):E959-66.
23. Lamartina C, Cecchinato R, Fekete Z, et al. Pedicle screw placement accuracy in thoracic and lumbar spinal surgery with a patient-matched targeting guide: a cadaveric study. Eur Spine J. 2015;24(Suppl 7):937-41.
24. Matsukawa K, Kaito T, Abe Y. Accuracy of cortical bone trajectory screw placement using patient-specific template guide system. Neurosurg Rev. 2020;43(4):1135-42.
25. Farshad M, Betz M, Farshad-Amacker NA, et al. Accuracy of patient-specific template-guided vs. free-hand fluoroscopically controlled pedicle screw placement in the thoracic and lumbar spine: a randomized cadaveric study. Eur Spine J. 2017;26(3):738-49.
26. Yamada K, Abe Y, Satoh S. Safe insertion of S-2 alar iliac screws: radiological comparison between 2 insertion points using com-

puted tomography and 3D analysis software. J Neurosurg Spine. 2018;28(5):536-42.

27. Abdul-Jabbar A, Yilmaz E, Iwanaga J, et al. Neurovascular relationships of S2AI screw placement: anatomic study. World Neurosurg. 2018;116:E108-12.

28. Park YS, Hyun SJ, Park JH, et al. Radiographic and clinical results of freehand S2 alar-iliac screw placement for spinopelvic fixation: an analysis of 45 consecutive screws. Clin Spine Surg. 2017;30(7):E877-82.

29. Shillingford JN, Laratta JL, Tan LA, et al. The free-hand technique for S2-alar-iliac screw placement: a safe and effective method for sacropelvic fixation in adult spinal deformity. J Bone Joint Surg Am. 2018;100(4):334-42.