


Patient-specific 3D-printed surgical guides for pedicle screw insertion: comparison of different guide design approaches

Aida Ribera-Navarro^{1,2}, Ravikiran Shenoy², Gregory Cunningham², Vejay Vakharia³, Alexander Gibson², Mehran Moazen⁴ & Deepak M Kalaskar^{*,1,2}

¹UCL Institute of Orthopaedic & Musculoskeletal Science, Division of Surgery & Interventional Science, University College London, Royal National Orthopaedic Hospital, Stanmore, London, HA7 4LP, UK

²Spinal Surgery Unit, Royal National Orthopaedic Hospital NHS Trust, Stanmore, London, HA7 4LP, UK

³UCL Queen Square Institute of Neurology & National Hospital for Neurology & Neurosurgery, University College London, London, WC1N 3BG, UK

⁴UCL Department of Mechanical Engineering, University College London, London, WC1E 7JE, UK

*Author for correspondence: d.kalaskar@ucl.ac.uk

Aim: Patient-specific 3D-printed guides for pedicle screw insertion in spinal deformity surgery offer an alternative to image-guided, robotic and free-hand methods. Different design features can impact their accuracy and clinical applicability. The aim of this study was to compare the performance of three different guide designs with the nonguided free-hand technique. **Materials & methods:** 3D-printed guides were design and tested using anatomical models of human spines and porcine cadaveric specimens. Three different guided groups (low, medium and full contact) and one nonguided group was formed. **Results & conclusion:** The design approach affected level of accuracy of screw placement. A variability in terms of accuracy of screw insertion between surgeon's experience using nonguided/guided techniques was also observed, suggesting benefit for junior surgeons in improving surgical accuracy.

First draft submitted: 19 January 2021; Accepted for publication: TBC; Published online: 2 July 2021

Keywords: 3D printing • cadaver • medio-lateral alignment • patient specific • pedicle screws • sagittal alignment • spinal fusion • surgical guides

Spinal fusion is used to treat a range of conditions associated with spinal column such as intervertebral disc degeneration and scoliosis [1]. It is an effective procedure in that it provides an almost immediate stabilization of the spine [2–5]. In this procedure accurate placement of pedicle screws is crucial to ensure both rigid fixation of the spine and associated implants (i.e., plates and rods) as well as minimizing the risk of neurological injuries [6,7]. Aside from the traditional free-hand (FH) techniques, a number of new approaches based on live imaging and 3D printing templates have been developed to increase the accuracy of the pedicle screw insertion while screw misplacements still occur.

Different techniques have shown different screw misplacement rates. For example, for the FH technique this seems to be as high as 40% [8–10], while for the robotic and image-guided techniques the misplacement rate has been reported to be in the range of 3–11% [11–15]. Recently 3D-printed patient-specific guides have gained increased popularity, but they also show a misplacement rate of 2–9%, in other words, similar to the robotic and image guided systems [16–20].

While image-guided and robotic-assisted systems may offer increased accuracy, there is also a higher radiation exposure associated with these systems. This is a concern especially for pediatric patients who are regularly exposed to radiation during their follow-up care/treatments [21–23]. Similarly, the high rate of complications and revision surgeries associated with scoliotic patients, has meant that these groups of patients are also at high risk of over radiation exposure [24–26]. Hence, patient-specific 3D-printed surgical guides for pedicle screw insertion have the potential to offer a cost-effective alternative without increasing intrasurgical radiation exposure and making complex surgeries much safer. Nevertheless, a wide variety of surgical guides have been developed, mainly based on their level of contact with the vertebra, with no clear consensus on the optimum design. To the best of our knowledge,

Table 1. First and second experiments overview of the screw insertions performed by the surgeons and the method of screw insertion.

First experiment	Surgeon 1	Surgeon 2	Surgeon 3
L2	FH	FH	FH
L2	FC	FC	FC
L2	MC	MC	MC
L2	LC	LC	LC
Total screws inserted	40	40	40
Second experiment	Surgeon 4		
T12	FH	FH	FH
L1	MC	MC	MC
L2	LC	LC	LC
L3	FH	MC	FH
L4	MC	LC	MC
L5	LC	FH	LC
Total screws inserted	12	12	12

FC: Full contact; FH: Free hand; LC: Low contact; MC: Medium contact.

no previous study has analyzed the reproducibility and repeatability of specific designs and nor has established a direct comparison between them.

The overall aims of this study were to evaluate and compare the accuracy of screw insertion between three 3D-printed surgical guides focusing on the level of contact. The specific aims were: to assess the reproducibility, repeatability and accuracy of screw insertion on 3D-printed model of a human vertebra; and to investigate the effect of soft tissue on the accuracy of screw insertion in cadaveric porcine specimen. The aforementioned two specific aims were addressed in two experiments detailed below.

Materials & methods

Experiment design

In the first experiment (repeatability and reproducibility), three different surgical guides for pedicle screw insertion were developed based on a model of human vertebrae. The guides were different based on their level of contact to the vertebra, in other words, full contact (FC), medium contact (MC) and low contact (LC). These were 3D-printed and used for screw insertion into the 3D-printed model of the same human vertebrae (L2). A FH group was also included where screws were inserted without 3D-printed guides. The FH insertion was performed using presurgical computed tomography (CT) 2D slices and no fluoroscopic guidance. Screw insertions were performed by four surgeons, surgeon 1 (2 years as spinal registrar, 1 year neurosurgery and 8 years in orthopedics), surgeon 2 (2 years as registrar in orthopedics, 5 years as spinal fellow and 10 years as spinal consultant), surgeon 3 (1 year in orthopedics and 2 years as spinal fellow) and surgeon 4 (8 years as neurosurgeon registrar from which 5 years doing spinal fixations). First screws were inserted based on the FH method follow by the 3D-printed guides. Following screw insertion, specimens were CT scanned and screw alignment were quantified and compared across the groups. This experiment enabled us to test the repeatability and reproducibility of screw insertion using the aforementioned techniques. In the second experiment (role of soft tissue), MC and LC 3D-printed guides were developed for a series of porcine cadavers (based on pre-op CT scans). These were used along sides a FH technique for screw insertions on the same porcine cadaveric specimens. These specimens were also CT scanned following screw insertion and characterized in the same way as the first experiment. This experiment enabled us to assess the effect of soft tissues on the screw insertion using the aforementioned guides. Note, in the first experiment a total of ten screws per technique and per surgeon were inserted. In the second experiment a total of four screws per technique and per surgeon were inserted. See Table 1 for detail break down of screw insertions across the two experiments.

Specimens, imaging & 3D reconstruction

For the first experiment, retrospective CT scan images of a female patient were obtained. The images were acquired using a T/L spine protocol. Slice thickness was 1 mm, spacing between slices was 0.5 mm and an in-plane resolution

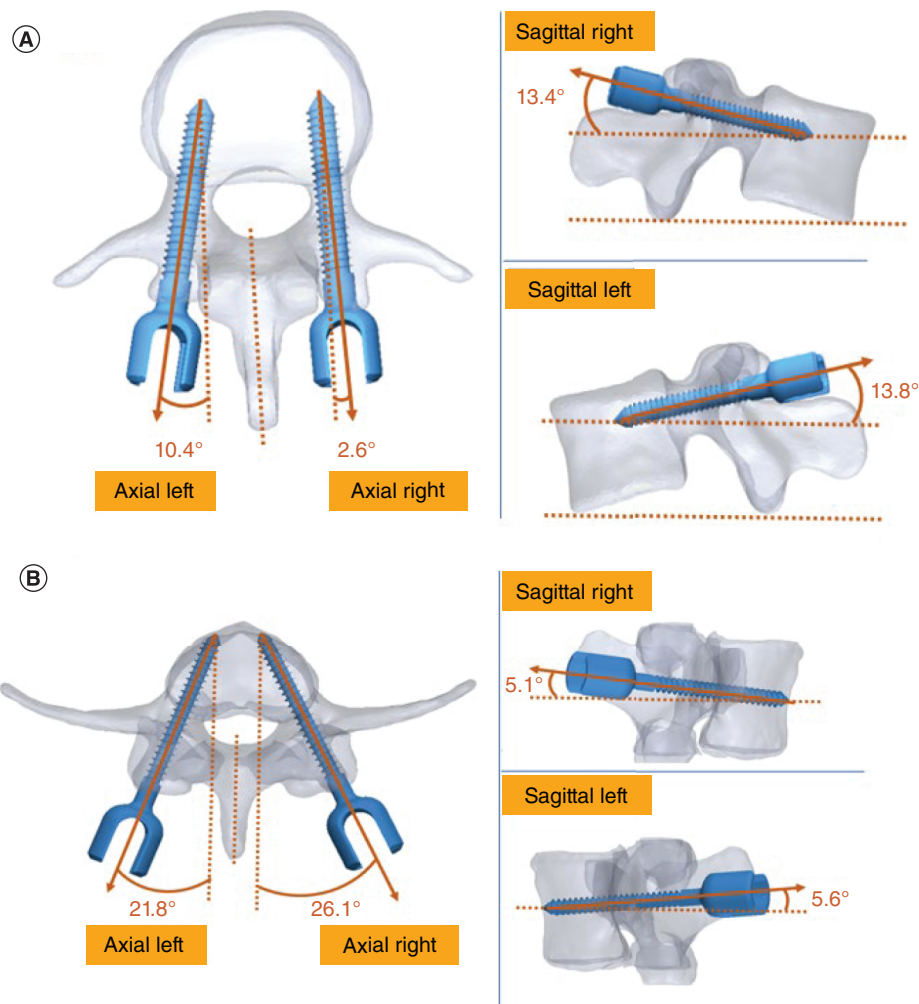


Figure 1. Virtual surgical planning to identify ‘ideal’ screw positioning. (A) First experiment. (B) Second experiment.

was 0.625 mm. The CT scanner used was the Ingenuity Core 128 (Philips, Amsterdam, The Netherlands). The L2 vertebra from this patient was segmented using ScanIP image processing software (Synopsys, CA, USA) to generate the 3D model of the L2 vertebrae. A threshold of 230HU for lower value and 3020HU for upper value was used to generate the bone mask a Gaussian filter of 1 px radius to smooth the surface. The following parameters were used to simulate the cancellous bone: minimum shell thickness, 1 mm; inner shell triangulation, three; fit small cavities, 0.5 mm; unit cell type, Schoen gyroid; target volume fraction, 15%; and unit cell size, 4 mm. The segmented model was then 3D printed. For the second experiment, porcine cadaver tissues were obtained from a specialized medical meat supplier. Same CT scanner and same segmentation protocols as the first experiment were used to develop 3D models of the vertebra for the virtual planning and characterization studies detailed below.

Virtual surgical planning

Virtual surgical planning was performed in a computer aided design package (SolidWorks, Dassault Systems, Vélizy-Villacoublay, France) to identify the ‘ideal’ or ‘planned’ screw insertion position in relation to various anatomical features in the axial and sagittal planes. These were quantified as a series of angle measurements and the deviation from these angles, in other words, ‘ideal’ screw insertion position, were then quantified across various groups (see Figure 1). For the first experiment, we followed the traditional surgical planning for the lumbar levels: entry point in between the ‘pars articularis’ and ‘laminae’ and sagittal trajectory parallel to the upper plate (AO Foundation). Two points were used to define this trajectory: centroid of the minimal cross-sectional area and entry point given by the anatomical references (see Figure 1A). For the second experiment in the cadaveric porcine specimens, an

Table 2. 3D printing parameters used to manufacture different components based on their material properties.

Material	Layer height (mm)	Infill (%)	Print speed (mm/s)	Extrusion temperature (°C)	Bed temperature (°C)
PolyWood™ (Polymaker)	0.18	Gyroid (100)	35	225	55
ABS (Flashforge)	0.12	Hexagonal (15)	50	205	105

ABS: Acrylonitrile butadiene styrene.

alternative trajectory with entry point on a flat surface was suggested. The entry point was placed on the flat area of the ‘laminae’ to avoid the drill bit slippage and angled according to the porcine pedicle anatomy. Trajectories were more laterally angled and slightly caudal in the sagittal plane (Figure 1B). In the case of the pig cadaveric specimen, every vertebra had its corresponding virtual surgically planned angles including the FH group.

Guide design

Three and two different screw insertion guides were designed for the first and second experiments, respectively. The designs were different based on the level of contact to the posterior vertebrae anatomy, in other words, FC, MC and LC (Figure 2). This was based on Azimifar *et al.* classification, low and medium invasiveness surgical guides [27]. In brief, the FC guides were designed based on the posterior surface topography of the vertebra (negative shape) where a perfect match could be achieved between the guide and the vertebra. The MC guides were designed to ensure contact can be achieved at several selected areas (superior articular process and spinous process (negative shape) and base of spinous process and transverse process (flat supports). This approach ensured minimizing the screw insertion error that can occur due to an inefficient soft tissue removal. The LC guides were designed using a limited contact area across (spinous process (negative shape), superior articular process, base of spinous process and transverse process (pointed supports) (Figure 3).

Two tools were used within each surgical technique and therefore two-step guiding system was designed: pilot hole drilling with a pedicle probe in the first experiment and a drill in the second experiment; and pedicle screw insertion with the screwdriver. For the first experiment multistep guides were designed (Figure 2A). For the second experiment we used one step screwdriver guide with an added drilling sleeve inserted on the screwdriver guide to ensure pilot hole and screw insertion trajectories were concentric. Spinous process support orientation was also changed from the previous design because it did allow to fit the guides in consecutive spinal segments (Figure 2B). The same tolerance was applied for the two tool-guide interfaces. We used a tolerance of 0.24 mm for the probe/drill guide and 0.2 mm for the screwdriver guide.

3D printing

Filament fused fabrication methodology employed in Dreamer Dual extruder 3D printer (Zhejiang Flashforge 3D Technology Co., Ltd, Jinhua, China) was used to manufacture the vertebrae in the first experiment and all guides used throughout the study. The vertebrae anatomical model and the patient-specific surgical guides were manufactured using wood filament (Polywood™, Polymaker, Utrecht, The Netherlands) and acrylonitrile butadiene styrene (Flashforge), respectively. The printer was used in its standard configuration, equipped with a nozzle of 0.4 mm diameter. 3D printing parameters were adjusted for the different materials based on supplier advice (see Table 2 for details).

Analysis

Following the screw insertion in all groups, all the 3D-printed L2 vertebrae and the porcine cadaveric specimens were CT scanned to assess the screw insertion accuracy. The CT images were reconstructed, and various angles as detailed in ‘virtual surgical planning’ (Figure 2) were measured. The difference between the implanted screw angles obtained from the postoperative CTs and the initial angles based on the pre-operative ‘virtual surgical planning’ were then calculated across all cases.

Two limitations of the aforementioned angle measurement (detailed above) are: a misplaced screw can be parallel to the planned surgical trajectory and cortical breaching can occur despite accurate screw placement. To address aforementioned limitations: detail qualitative visual inspection of all postoperative CT images was carried out, and Gertzbein–Robbins extended screw misplacement classifications was used [28]. In brief, this classification, uses a grading system to comment on the extend of cortical breaching where: grade A refers to a that has not breached the cortical layer of the pedicle in the axial plane; grade B refers to a screw that has breaches the cortical

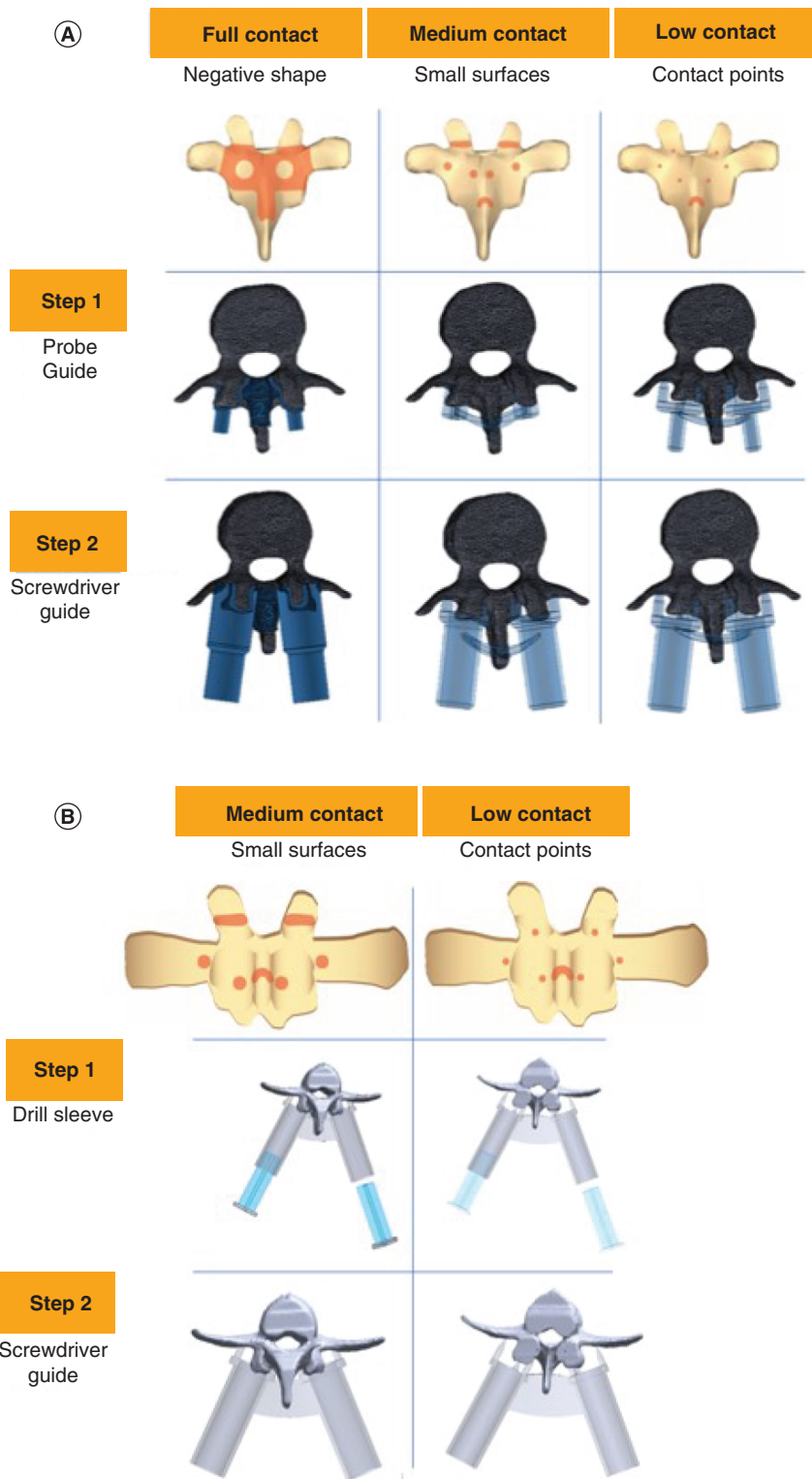


Figure 2. The guide designed, and the surgical techniques used. (A) First experiment. (B) Second experiment.

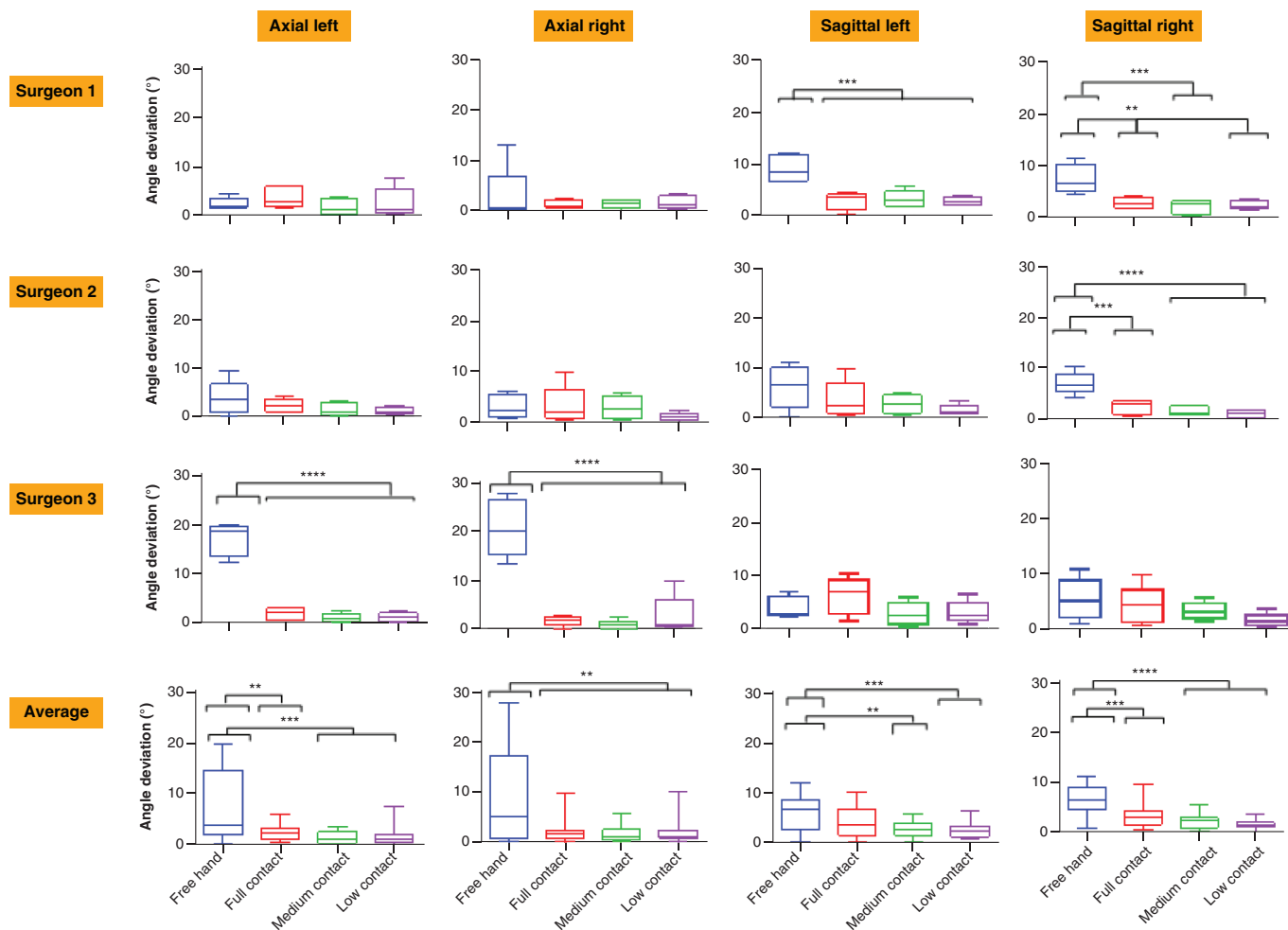


Figure 3. Summary of the differences between the planned screw position and the inserted screws in the first experiment. Results are presented by each surgeon and also the average of all three surgeons for all guides and the free-hand technique. The significance level was set at $p \leq 0.05$ where: $*p \leq 0.05$; $p \leq 0.01$; $***p \leq 0.001$; $****p \leq 0.0001$.**

layer of the pedicle but does not exceed it laterally by >2 mm; grade C and D refer to a screw that has penetrated into the cortical layer by <4 and 6 mm, respectively; and grade E refers to a screws that do not pass through the pedicle or that, at any given point in their intended intrapedicular course, breach the cortical layer of the pedicle in any direction by >6 mm. Grades A and B are considered clinically acceptable while grades C, D and E are not.

Statistical analysis was performed using GraphPad Prism 6.0 (GraphPad Software Inc., CA, USA). One-way ANOVA was carried out between all groups. The significance level was set at $p \leq 0.05$ where: $*p \leq 0.05$; $**p \leq 0.01$; $***p \leq 0.001$; $****p \leq 0.0001$.

Results

Experiment 1: repeatability & reproducibility

Postoperative surgical variability from the ‘planned’ screw insertion based on the first experiment is summarized in Figure 3. Deviations from the ‘planned’ screw insertion for surgeon 1 (Figure 3) between the guided groups (FC, MC and LC) and the nonguided (FH group) with a mean difference ranged between 4.5 to 6.2° from the planned trajectories. This was statistically significant for sagittal angles. A similar pattern was observed based on the screws that were implanted by surgeon 2, in other words, statistically significant difference was found between the guided and nonguided only for sagittal right angles, with a mean difference ranging from 4.6 to 6.0°. Results obtained from the surgeon 3 showed no difference in the sagittal angles across all groups; however, there was a significant difference between the guided and the nonguided (FH group) in the axial plane. The mean difference range of the

Table 3. Clinical accuracy according to the Gertzbein–Robbins classification of the pedicle screws inserted by surgeon 1–3 in both experiments.

	First experiment		Second experiment	
	Grade A and B	Grade C, D and E	Grade A and B	Grade C, D and E
Surgeon 1				
Free hand	9 (90%)	1 (10%) E	2 (50%)	2 (50%) CC
Full contact	10 (100%)	0%	-	-
Medium contact	10 (100%)	0%	3 (75%)	1 (25%) C
Low contact	8 (80%)	2 (20%) EE	3 (75%)	1 (25%) D
Surgeons 2 and 4				
	Surgeon 2		Surgeon 4	
Free hand	9 (90%)	1 (10%) C	1(25%)	3 (75%) CCD
Full contact	8 (80%)	2 (20%) CC	-	-
Medium contact	10 (100%)	0%	1(25%)	3 (75%) CDD
Low contact	10 (100%)	0%	3 (75%)	1 (25%) D
Surgeon 3				
Free hand	7 (70%)	3 (30%) CCC	2 (50%)	2 (50%) DD
Full contact	10 (100%)	0%	-	-
Medium contact	10 (100%)	0%	2 (50%)	2 (50%) CC
Low contact	9 (90%)	1 (10%) C	4(100%)	0%
Total				
Free hand	25 (83.3%)	5 (16.67%)	7 (58.3%)	5 (41.6%)
Full contact	28 (93.3%)	2 (6.67%)	-	-
Medium contact	30 (100%)	0%	6 (50%)	6 (50%)
Low contact	27 (90%)	3 (10%)	10 (83.3%)	2 (16.6%)

nonguided group for axial angles was 14.9–19.8°. Overall based on the averaged data presented in Figure 3, there was a significant difference between the guided groups and the nonguided group while no statistically significant difference was found between the different guided groups, in other words, FC, MC and LCs.

Clinical grading based on Gertzbein–Robbins classification for the first experiment highlighted that all screws placed using the MC guides were grade A and B with 100% accuracy by all three surgeons. This was followed by the FC, LC, and then FH approach where the FH had the highest number of grade C, D and E, in other words, 5 screws out of 30 (see Table 3 for first experiment data).

Experiment 2: role of soft tissue

Postoperative surgical variability from the ‘ideal’ screw insertion based on the second experiment is summarized in Figure 4. Deviations from the ‘planned’ screw insertion for surgeon 1 showed a statistically significant difference in the sagittal left angles (Figure 4) between the MC and LC groups and also between the MC group and the FH technique. There was no statistical difference between the considered techniques based on the screws that were inserted by surgeon 4. However, there was a significant difference between all considered techniques in the axial left measurements based on the screws that were inserted by surgeon 3. Overall, the average data from all three surgeons did not show any statistically significant difference between the guided groups (MC and LC) and the nonguided group. Nonetheless, the FH group showed higher deviations from the ‘planned’ screw insertion path comparing to MC and LC groups in the axial plane and the sagittal left (see Figure 4 for the average data).

Clinical grading based on Gertzbein–Robbins classification for the second experiment highlighted that 83% of the screws inserted using the LC guides were classified as grade A and B. This was followed by 58% for the FH and 50% for the MC guides (see Table 3 for the second experiment data).

Qualitative observations

During the screw insertion in both experiments, several patterns were observed and found by the surgical team unanimously:

- FC guides were found to be more stable but hard to fit and remove from the vertebral body due to the soft tissue;

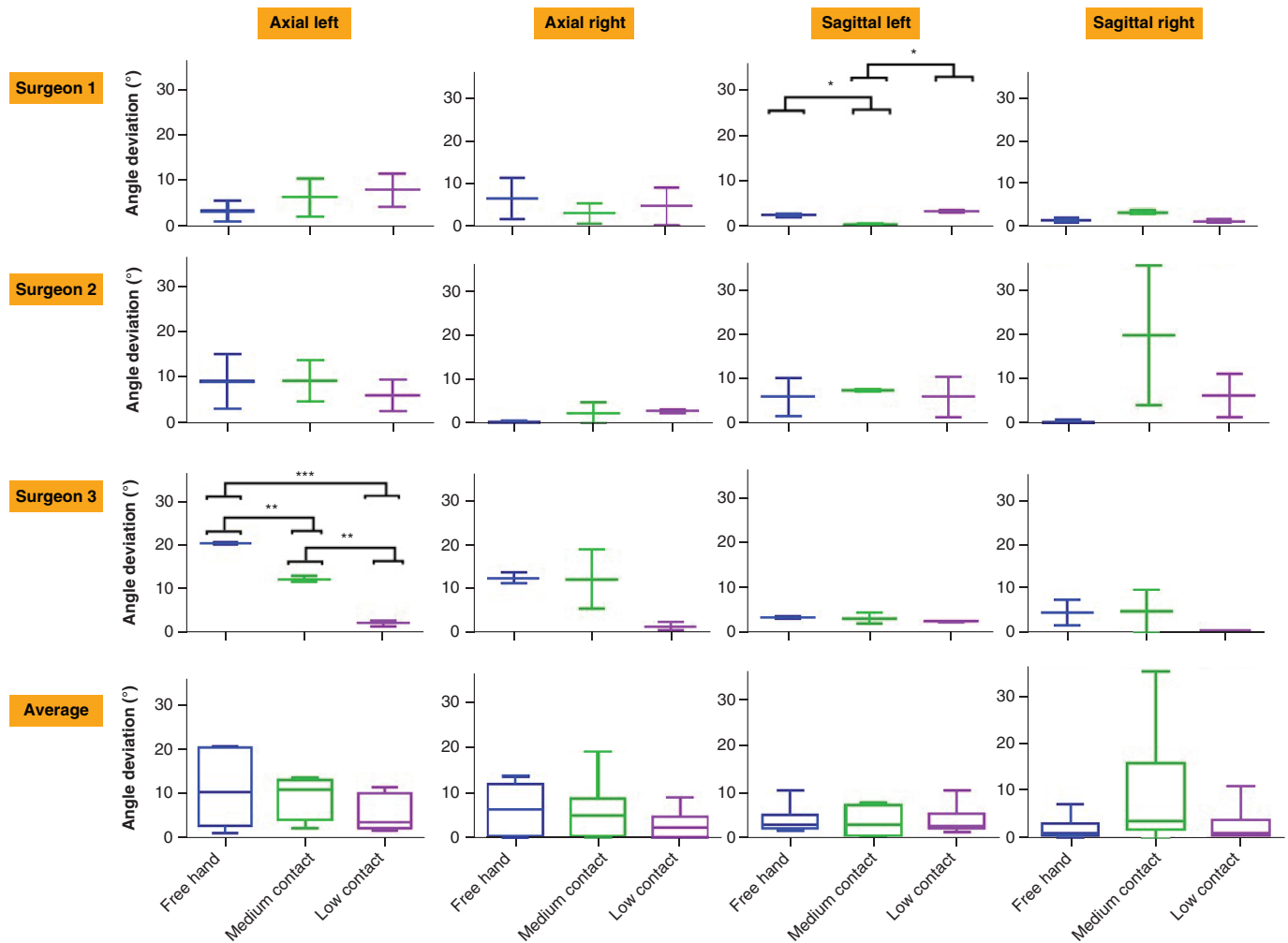


Figure 4. Summary of the differences between the planned screw position and the inserted screws in the second experiment. Results are presented by each surgeon and also the average of all three surgeons for all guides and the free-hand technique. The significance level was set at $p \leq 0.05$ where: * $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$; **** $p \leq 0.0001$.

- LC guides were least stable requiring more time to verify the correct guide positioning;
- MC guides had higher stability in compare to LC guides yet the surgical team appeared to prefer to work with the LC guides offering higher visibility of the entry point area;
- Three step guides, used in the first experiment on 3D-printed vertebrae, were found to be time consuming and with potential risk of non-concentric trajectories between the steps. Hence, a concentric drill sleeve and screwdriver sleeve guide was designed for the second experiment on porcine cadaveric specimens minimizing the number of steps and time as well spent placing the guides;
- Guiding the screwdriver for screw insertion makes guides significantly bigger, affecting the visibility of entry point. The pilot hole is a determining factor for a correct screw placement [29,30], therefore, screwdriver guidance is not a conclusive factor in screw accuracy. A drilling guide might significantly reduce the size of the guide;
- There is always possibility that deflection off trajectory or deflection forces can overwhelm the guide. This can be avoided by keeping entry point small and can lessen the potential for deflection and help maintain trajectory;
- Spinous process landmark despite being reported to add high rotational stability [31] and high reproducibility [32] it appeared not to be reliable in this study. The interspinous and supraspinous ligament could lead to excess of lack of soft-tissue removal like some authors reported [19,27,33–35]. Furthermore it contains cartilage tissue that has low reproducibility on CT imaging (around 10% error thickness) [36]. This suggests that cartilaginous landmarks are not advised in this type of surgical guide;

- The articular process joint has a similar issue;
- Laminae was found to be highly reproducible in CT imaging. It is typically exposed in FH technique, what makes it very convenient landmark for this guide;
- Guide fitting was found to be a sensible step in LC and MC guide designs. A 3D-printed anatomical model was used in the porcine cadaveric testing to check the guide fitting as proposed by other authors [16] to potentially avoid fluoroscopic shots to confirm guide trajectory;
- Strategies to increase the stability of guides are needed (i.e., supports, pin the guide, handle, multilevel guides);
- The use of the guides in long segment open spinal fusion cases can be favored given the amount of bone free of soft-tissue exposure.

Discussion

The aim of this study was to compare the reproducibility, repeatability and accuracy of pedicle screw insertion between guided and nonguided techniques. Three different guided groups (LC, MC and FC) were compared on a 3D-printed models of human vertebra (i.e., experiment 1). Based on the feedback from the clinical team involved in the insertion of the screws in the aforementioned experiment two guide designs, in other words, LC and MCs were then further tested on cadaveric porcine specimen (experiment 2) to assess the impact of soft tissue on the potential differences between the aforementioned guides and the FH technique.

Results of the first experiment highlighted that the guided techniques led to a more accurate and repeatable screw insertion compared with the nonguided (FH) technique. This was reflected in both comparison between the postoperative screw insertion and the planned screw position (Figure 3; note the lower standard deviations for the guided techniques in compare to the nonguided one) and the clinical classification results (Table 3; 83% of nonguided screws were grade A and B vs over 90% of guided screws were grade A and B). This finding was not statistically significant in the second experiment, nonetheless LC guides showed a higher clinical accuracy compared with the FH techniques (83.3 vs 58.3% grade A and B; Table 3).

On the other hand, we did not observe any statistically significant difference between the different guides that were considered in both experiments. Nonetheless, results of the first experiment highlighted that the medium guides were perhaps more repeatable and accurate than the FC and LC, in other words, Figure 3 showed overall lower standard deviation for this group compare to the other two guided techniques and Table 3 highlighted that all screws inserted using the MC guides had clinical score of grade A and B. While results of the second experiment highlighted the contrary where LC guides appeared to have higher accuracy than the MC guides (83.3 vs 50% grade A & B; Table 3).

The differences observed in the outcomes of the first and second experiments performed here can be due to several factors perhaps the most important ones are:

- Soft tissues – we were indeed interested to investigate if soft tissues alter the findings of the first experiments. Our results highlight the crucial role of the soft tissues when designing and developing patient-specific surgical guides;
- Surgical implantation technique – in the first experiment two-step guides were used while in the second experiment one-step screwdriver guide with an added drilling sleeve was used. This was due to the clinical team feedback during the first experiment also considering that that two-step guides can lead to a mismatch between the planned and final screw insertion trajectories. Nevertheless, Sugawara *et al.* used multistep guides to offer multiple confirmation of the trajectory using the FC approach [35];
- Number of inserted screws and anatomical differences – a higher number of screws were inserted in the first group as oppose to the second group (i.e., 120 vs 35 screws) which is indeed the main limitation of the study. Due to the cost and ethical implications current study compared use of pig cadaver tissue versus 3D-printed materials. Naturally, an ideal scenario would be to use human cadaver tissue. Nonetheless, considering the differences between the two experiments carried out here, it was interesting that both experiments found higher clinical accuracy for the screws that were inserted with a guide in compare to the FH inserted screws. This is indeed in line with recent clinical studies in this area (see e.g. [37–39]).

The results of the present study also highlight the variability that exists in terms of accuracy of screw insertion between different surgeons using either guided or nonguided techniques. In the first experiment surgeons 1 and 3 had lower clinical experience compare to surgeon 2. In the second experiment all three surgeons were junior.

Regarding the FH trajectory preferred, in the first experiment surgeons 1 and 2 used the traditional trajectory while surgeon 3 was more lateral to achieve higher screw pullout resistance. This was to some extent reflected in both experiments. For example, in the first experiment the FH screws inserted by surgeon 1 had higher misplacement grade E (i.e., 10%) and surgeon 3 had lower grade A and B but higher number of misplaced screws (i.e., 70%) compare to surgeons 2 and 4 (i.e., >90%; see Table 3) with grade C misplacement. Also, both Figures 3 and 4 showed higher deviation from the planned screw position in the axial left and right for surgeon 3 comparing to surgeons 1 and 2. Interestingly, it appears that the 3D-printed guides help surgeon 3 more than surgeons 1 and 2 to achieve a closer match to the planned screw trajectories (see Figures 3 & 4) and higher-grade A and B scores (see Table 3) across both experiments performed in this study. While this observation is based on limited number of surgeons ($n = 3$), it highlights that perhaps the screw guides have a much more important role in the clinical outcome of junior surgeons than the more senior surgeons while the guides are clearly benefiting all surgeons regardless of their experience.

In summary, we believe that patient-specific guides can reduce the risk of screw misalignment that can be high especially in case of patients with spinal deformities without increasing intra surgical radiation. The current FH technique heavily relies on the surgical team experience and various anatomical landmarks. While patient-specific guides naturally advance our understanding of the patient anatomy preoperatively, leading to higher screw insertion accuracy and potentially reducing the time of surgery and risk of future complications.

Conclusion

Patient-specific 3D-printed guides regardless of their design features improve the accuracy and consistency of screw insertions in compare to nonguided FH technique regardless of surgeon's level of experience. Nonetheless perhaps junior surgeons will benefit even more than senior surgeons. While our results did not find a conclusive difference between the FC, MC and LC designs that were considered in this study, it highlighted that perhaps MC and LC guides and smaller guide approaches for better visualization of the anatomy can be considered in future cadaveric human studies. A drilling guide could significantly reduce the size of the guide and offer a better visibility of the entry point. It is necessary to find the correct combination of landmarks with good CT scan reproducibility and easily to expose in the surgical practice to ensure a good guide design.

Summary points

- Patient-specific 3D-printed guides for pedicle screw insertion in spinal deformity surgery offer an alternative to image-guided, robotic and free-hand (FH) methods. The aim of this study was to compare the performance of three different guides designs based on their level of contact to the vertebra (guided) versus the FH (non guided) approach.
- For the first experiment a 3D-printed anatomical model of a L2 of a female patient was used to assess the repeatability and variability of the screws inserted using these devices.
- For the second experimental, lumbar spine of porcine cadaveric specimens were used to assess the role of soft tissues. An 'ideal' screw position was planned pre-operatively and the postoperative deviations from the planned screw alignment were quantified. Further screw positions were graded according to Gertzbein–Robbins classification. Statistical analysis was carried out on the quantified data.
- The first experiment highlighted that the guided techniques led to a more accurate and repeatable screw insertion compared with the nonguided technique ($p \leq 0.05$).
- This finding was not statistically significant in the second experiment, nonetheless low contact guides showed a higher clinical accuracy compared with medium contact and the FH technique. A variability in terms of accuracy of screw insertion between different surgeons using nonguided/guided techniques was also observed.

Financial & competing interests disclosure

The authors thank the Orthopaedic Research UK (ORUK) for financially supporting of Ribera-Navarro's PhD studentship. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

Images were obtained with informed consent under NHS ethics London – Stanmore Research Ethics Committee (IRAS project ID: 271231).

References

- Hsu KZJ, White. Internal fixation with pedicle screws. In: *Lumbar Spine Surgery*. White AH, Rothman RH, Ray CD (Eds). CV Mosby, St Louis, USA, 322–327 (1987).
- Negrini S, Donzelli S, Aulisa AG *et al*. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. *Scoliosis Spinal Disord*. 13, 3 (2018).
- Liljenqvist UR, Halm HF, Link TM. Pedicle screw instrumentation of the thoracic spine in idiopathic scoliosis. *Spine (Phila Pa 1976)* 22(19), 2239–2245 (1997).
- Cinotti G, Gumina S, Ripani M, Postacchini F. Pedicle instrumentation in the thoracic spine. A morphometric and cadaveric study for placement of screws. *Spine (Phila Pa 1976)* 24(2), 114–119 (1999).
- Wood KB, Wentorf FA, Ogilvie JW, Kim KT. Torsional rigidity of scoliosis constructs. *Spine (Phila Pa 1976)* 25(15), 1893–1898 (2000).
- Hadjipavlou A, Enker P, Dupuis P, Katzman S, Silver J. The causes of failure of lumbar transpedicular spinal instrumentation and fusion: a prospective study. *Int. Orthop*. 20(1), 35–42 (1996).
- Katonis P, Christoforakis J, Kontakis G *et al*. Complications and problems related to pedicle screw fixation of the spine. *Clin. Orthop. Relat. Res*. June(411), 86–94 (2003).
- Sugawara R, Tsuji T, Saito T *et al*. Medially misplaced pedicle screws in patients without neurological deficits following scoliosis surgery: to observe or to remove? *Eur. Spine J*. 24(7), 1450–1456 (2015).
- Kim YJ, Lenke LG, Bridwell KH, Cho YS, Riew KD. Free hand pedicle screw placement in the thoracic spine: is it safe? *Spine (Phila Pa 1976)* 29(3), 333–342 discussion 342 (2004).
- Molliqaj G, Schatlo B, Alaid A *et al*. Accuracy of robot-guided versus freehand fluoroscopy-assisted pedicle screw insertion in thoracolumbar spinal surgery. *Neurosurg. Focus* 42(5), E14 (2017).
- Abul-Kasim K, Ohlin A. The rate of screw misplacement in segmental pedicle screw fixation in adolescent idiopathic scoliosis. *Acta Orthop*. 82(1), 50–55 (2011).
- Kochanski RB, Lombardi JM, Laratta JL, Lehman RA, O’toole JE. Image-guided navigation and robotics in spine surgery. *Neurosurgery*(2019).
- Lonjon N, Chan-Seng E, Costalat V *et al*. Robot-assisted spine surgery: feasibility study through a prospective case-matched analysis. *Eur. Spine J*. 25(3), 947–955 (2016).
- Moldes JM, De Badiola FI, Vagni RL *et al*. Pediatric robotic surgery in South America: advantages and difficulties in program implementation. *Front. Pediatr*. 7, 7 (2019). <https://www.frontiersin.org/articles/10.3389/fped.2019.00094/full>
- Yu L, Chen X, Margalit A *et al*. Robot-assisted vs freehand pedicle screw fixation in spine surgery: a systematic review and a meta-analysis of comparative studies. *Int. J. Med. Robot*. 14(3), e1892 (2018).
- 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*. 24(Suppl. 7), 937–941 (2015).
- Kaneyama S, Sugawara T, Sumi M *et al*. A novel screw guiding method with a screw guide template system for posterior C-2 fixation: clinical article. *J. Neurosurg. Spine* 21(2), 231–238 (2014).
- Sugawara T, Higashiyama N, Kaneyama S *et al*. Multistep pedicle screw insertion procedure with patient-specific lamina fit-and-lock templates for the thoracic spine: clinical article. *J. Neurosurg. Spine* 19(2), 185–190 (2013).
- Sugawara T, Higashiyama N, Kaneyama S, Sumi M. Accurate and simple screw insertion procedure with patient-specific screw guide templates for posterior C1-C2 fixation. *Spine (Phila Pa 1976)* 42(6), E340–E346 (2017).
- De Vega B, Ribera-Navarro A, Gibson A, Kalaskar DM. Accuracy of pedicle screw placement methods in pediatrics and adolescents spinal surgery: a systematic review and meta-analysis. *Global Spine J*. doi:10.1177/21925682211003552 21925682211003552 (2021) (Epub ahead of print).
- Simony A, Hansen EJ, Christensen SB, Carreon LY, Andersen MO. Incidence of cancer in adolescent idiopathic scoliosis patients treated 25 years previously. *Eur. Spine J*. 25(10), 3366–3370 (2016).
- Doody MM, Lonstein JE, Stovall M *et al*. Breast cancer mortality after diagnostic radiography: findings from the U.S. Scoliosis Cohort Study. *Spine (Phila Pa 1976)* 25(16), 2052–2063 (2000).
- Hoffman DA, Lonstein JE, Morin MM *et al*. Breast cancer in women with scoliosis exposed to multiple diagnostic x rays. *J. Natl Cancer Inst*. 81(17), 1307–1312 (1989).
- Levy AR, Goldberg MS, Hanley JA, Mayo NE, Poitras B. Projecting the lifetime risk of cancer from exposure to diagnostic ionizing radiation for adolescent idiopathic scoliosis. *Health Phys*. 66(6), 621–633 (1994).

25. Law M, Ma WK, Lau D *et al.* Cumulative radiation exposure and associated cancer risk estimates for scoliosis patients: impact of repetitive full spine radiography. *Eur. J. Radiol.* 85(3), 625–628 (2016).
26. Presciutti SM, Karukanda T, Lee M. Management decisions for adolescent idiopathic scoliosis significantly affect patient radiation exposure. *Spine J.* 14(9), 1984–1990 (2014).
27. Azimifar F, Hassani K, Saveh AH, Ghomsheh FT. A medium invasiveness multi-level patient's specific template for pedicle screw placement in the scoliosis surgery. *Biomed. Eng. Online* 16(1), 130 (2017).
28. Gertzbein SD, Robbins SE. accuracy of pedicular screw placement in vivo. *Spine* 15(1), 11–14 (1990).
29. Erkan S, Hsu B, Wu C *et al.* Alignment of pedicle screws with pilot holes: can tapping improve screw trajectory in thoracic spines? *Eur. Spine J.* 19(1), 71–77 (2010).
30. Defino HLA, Rosa RC, Silva P *et al.* The effect of repetitive pilot-hole use on the insertion torque and pullout strength of vertebral system screws. *Spine* 34(9), 871–876 (2009).
31. Berry E, Cuppone M, Porada S *et al.* Personalised image-based templates for intra-operative guidance. *Proc. Inst. Mech. Eng. H* 219(2), 111–118 (2005).
32. Takemoto M, Fujibayashi S, Ota E *et al.* Additive-manufactured patient-specific titanium templates for thoracic pedicle screw placement: novel design with reduced contact area. *Eur. Spine J.* 25(6), 1698–1705 (2016).
33. Fang J-J, Kuo T-H, Lin R-M, Ho C-Y. Guiding templates for pedicle screws insertion: a preliminary study. *Biomed. Eng. Appl. Basis Commun.* 24(06), 495–501 (2012).
34. Farshad M, Betz M, Farshad-Amacker NA, Moser M. 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.* 26(3), 738–749 (2017).
35. Sugawara T, Kaneyama S, Higashiyama N *et al.* Prospective multicenter study of a multistep screw insertion technique using patient-specific screw guide templates for the cervical and thoracic spine. *Spine (Phila Pa 1976)* 43(23), 1685–1694 (2018).
36. Anderson AE, Ellis BJ, Peters CL, Weiss JA. Cartilage thickness: factors influencing multidetector CT measurements in a phantom study. *Radiology* 246(1), 133–141 (2008).
37. Cecchinato R, Berjano P, Zerbi A *et al.* Pedicle screw insertion with patient-specific 3D-printed guides based on low-dose CT scan is more accurate than free-hand technique in spine deformity patients: a prospective, randomized clinical trial. *Eur. Spine J.* 28(7), 1712–1723 (2019).
38. Garg B, Gupta M, Singh M, Kalyanasundaram D. Outcome and safety analysis of 3D-printed patient-specific pedicle screw jigs for complex spinal deformities: a comparative study. *Spine J.* 19(1), 56–64 (2019).
39. Senkoylu A, Cetinkaya M, Daldal I *et al.* Personalized three-dimensional printing pedicle screw guide innovation for the surgical management of patients with adolescent idiopathic scoliosis. *World Neurosurg.* 144, e513–e522 (2020).