Three-Dimensional Patient-Matched Template Guides Are Able to Increase Mean Diameter and Length and to Improve Accuracy of Cortical Bone Trajectory Screws: A 5-Year International Experience

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OBJECTIVE: **To analyze whether significant differences exist between free-hand three-dimensional (3D) planning—guided cortical bone trajectory (CBT) screw placement and 3D-printed template—guided CBT screw positioning in terms of accuracy, size of screws, and potential complications.**

METHODS: **In this retrospective study, data of adult patients in whom CBT screws were placed for lumbar degenerative pathologies were extracted from a prospectively collected database and analyzed. Patients in whom screws were placed using free-hand 3D planning—guided technique were compared with patients in whom screws were positioned using customized 3D-printed templates. Size of the screws, accuracy, clinical outcomes, and complications were analyzed.**

RESULTS: **The study evaluated 251 patients (1004 screws). The free-hand 3D planning—guided group included 158 patients (632 screws), and the 3D-printed template—guided group included 93 patients (372 screws). The 3D-printed template—guided group involved screws of larger size from L3 to S1. Differences between the 2 groups in terms of accuracy parameters reached statistical significance ($P \leq 0.05$).**

CONCLUSIONS: **With the use of 3D patient-matched template guides, mean diameter and length of CBT screws could be safely increased due to improved accuracy of screw placement. Based on previous evidence regarding CBT biomechanical properties, these advantages could allow increased fixation strength over traditional convergent pedicle screw trajectories. Further biomechanics studies are needed.**

INTRODUCTION

In recent years, great strides have been observed in all fields of spine surgery, with the continuous search for minimal invasiveness being one of the most important driving forces.[1-5] In this context, Santoni et al.[6] reported a cortical bone trajectory (CBT) for screw placement for the first time in 2009. The rationale for the original technique was the positioning of bicortical screws to increase the screw's purchase, especially for osteoporotic patients. The medial entry point and the need for less lateral dissection became the key point for further applications in the field of minimally invasive spine surgery techniques.[7,8]

Many strategies were then described to improve mechanical properties while preserving this reduced invasiveness.[9] The main authors reported a modified technique, based on the development of a personalized three-dimensional (3D) model, which was obtained with 3D reconstruction of a patient's preoperative computed tomography (CT) scan. This technique allowed

Key words
- 3D patient-matched template guides
- Cortical bone trajectory
- Degenerative disc disease
- Minimally invasive spine surgery
- Screw accuracy

Abbreviations and Acronyms
3D: Three-dimensional
CBT: Cortical bone trajectory
CT: Computed tomography
PG: Free-hand 3D planning—guided group
TG: 3D-printed template—guided group

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for tailored screw positioning, thus increasing the length of screws and, consequently, the overall biomechanical strength of the whole construct, enabling the safety of free-hand positioning.[10]

Starting from the 3D planned technique, the concept of tailored CBT screw placement while maximizing mechanical properties was further developed at the authors' institutions by using patient-matched 3D-printed templates.[11,12] These guides allowed us to define, first on the CT scan and then directly on the patient's vertebra, the best entry point and the best divergent screw trajectory. Thus, the maximal screw length together with a safe bicortical purchase was guaranteed. 3D-printed template guides were already adopted for spinal deformity surgery with notable results regarding accuracy of screws in rotated vertebrae.

To our knowledge, this article presents the largest series on CBT screws.[13]The aim of this study was to evaluate whether significant differences exist between free-hand 3D planning–guided CBT screw placement (free-hand 3D planning–guided [PG] group) and 3D-printed template–guided CBT screw placement (3D-printed template–guided [TG] group) in terms of accuracy, size of screws, and potential complications. Moreover, additional considerations regarding outcomes and lessons learned are provided.

MATERIALS AND METHODS

This was a retrospective study analyzing results from patients who underwent spine surgery for degenerative lumbosacral disease. Indications for surgery were discopathy, lumbar disc herniation, spinal stenosis, and spondylolisthesis. Surgery was performed at the authors' institutions. Patients matching all the inclusion criteria between 2015 and 2021 were analyzed.

Only adult patients in whom CBT screws were placed for lumbar degenerative pathologies were considered for the analysis. Other inclusion criteria were a minimum follow-up of 12 months; the availability of preoperative screw planning and postoperative CT scans, which were essential for assessment of accuracy; and the complete availability of clinical and neurological data. Patients who underwent spinal fusion for ≥3 levels and/or patients treated only with posterior instrumentation (without intervertebral cages) were excluded from the study.

As 2 different techniques were used for screw positioning (see below), patients were divided into 2 groups. The PG group consisted of patients in whom screws were placed by using a free-hand 3D planning–guided technique; this technique has been described in a previous article.[10] In the TG group, screw positioning was accomplished by using a patient-specific 3D-printed guide.[11]

Data were extracted from a prospectively collected database, including age, sex, number of spine levels included in spine fusion, type of screw positioning technique, screw length, type of access for cage positioning, surgical time, evaluation of pain of back and legs based on a numerical rating scale, complications, screw misplacement, and the need for revision surgery. Clinical and radiological data were obtained at time of admission and at follow-up evaluation by fully trained surgeons. The introduction of 3D guides for CBT screw placement followed the use of the free-hand 3D planning technique; thus, patients for this study were not selected for one technique over the other but analyzed retrospectively.

Free-Hand 3D Planning–Guided versus 3D-Printed Template–Guided CBT Screw Positioning—Surgical Technique

Patients were divided into 2 groups according to different techniques adopted for CBT screw placement. Both techniques have been thoroughly described in previous articles by the main authors' group10,11, therefore, only a brief summary is provided below. A preoperative 0.625-mm-thickness CT scan was acquired for both techniques to define entry points and screw trajectories on a 3D reconstruction of the spine. This was obtained by using dedicated software (OsiriX [https://www.osirix-viewer.com/], Horos [https://horosproject.org/]) in the PG group, whereas it was sent to the manufacturer at least 10 days before surgery to allow for 3D-printed guide production in the TG group.

All patients underwent circumferential arthrodesis, with an interbody cage placed for each level included into the spinal fusion. Although interbody cage positioning is not part of the aim of this study, a brief description of the timing of cage positioning is provided. Specifically, interbody cages were usually positioned before screws when lateral approaches (lateral lumbar interbody fusion) were performed, while screws were placed before cages in patients undergoing posterior approaches (posterior lumbar interbody fusion and/or transforaminal interbody fusion).

Free-Hand 3D Planning–Guided Group. A preoperative multiplanar and 3D reconstruction of the patient's CT scan was obtained a few days before surgery. The surgeon defined the entry point of each screw on the axial and sagittal plane, taking care to place the entry point on the isthmus and to trace an ideal trajectory inside the pedicle, which allowed maximal divergency, maximal screw length, and bicortical purchase to be obtained. Specifically, the ideal trajectory was defined on the axial and sagittal plane as follows:

- Axial plane: a mediolateral line connecting the entry point with the more lateral available point on the vertebral anterior cortical bone without breaking the pedicle edge; usually, a safe divergency ranged from 3° to 7°
- Sagittal plane: a caudal-cranial line connecting the entry point with the point between the anterior one third and the posterior two thirds of the vertebral cranial end plate.

Subsequently, the entry points were defined on the 3D reconstruction, and the planning was carried into the operating room to help surgeons in screw positioning.

In the operating room, patients underwent general anesthesia and prone positioning. Due to the need for intraoperative neuromonitoring with free-running electromyography and triggered electromyography, anesthesia was performed without using muscle relaxants. A careful dissection was performed, taking care of cranial facet joint integrity and obtaining a clean exposure of the pertinent isthmi. With this technique, detailed exposure of the lateral edge of the isthmus and the caudal edge of the cranial facet joint was critical. At this point, surgeons checked the entry point on the 3D reconstruction and, identifying specific bony landmarks, defined the entry point with a 2-mm diamond drill. Then, the accuracy of the entry point and the caudal-cranial direction were checked under fluoroscopy by positioning a needle into the drilled entry point. Once the direction was defined, the isthmus cortical bone was broken by drilling about 10 mm of the planned trajectory. At this point, a neuromonitoring probe was used until 25 mm of the planned trajectory was reached (usually a safe length to overcome the pedicle and the lateral recess of the spinal canal). Then, after tapping of about 30 mm under neuromonitoring and checking for cortical bone integrity throughout the whole trajectory, a screw was placed under neuromonitoring of the screwdriver and with progressive fluoroscopy checking.

3D-Printed Template—Guided Group. The 3D-printed guides are patient-specific devices intended to be used as anatomical guides to assist intraoperatively in screw positioning. The use of these guides requires surgical planning software (MySpine; Medacta International SA, Castel San Pietro, Switzerland). The surgeon can modify guide configuration and screw parameters, such as screw diameter and length and divergency in the sagittal, coronal, and axial planes. Principles of trajectory planning were the same as in the PG group on axial and sagittal planes to maximize the corridor, also aiming to maximize distal cortical purchase.

The 3D-printed guides are created using 2 lateral cylindrical guides (left and right) to perfectly match the patient-specific vertebral anatomy. They are furthermore designed to optimally support the insertion of the instruments necessary for screw placement.

After prone positioning, a linear midline skin incision of about 4 cm was performed. Dissection was performed carefully to preserve cranial facet joints, spinous processes, and laminae. Specific attention was paid to visualization of the caudal edge of the lamina of the vertebra due to its importance for template stability on the vertebra and thus for screw placement accuracy. Hence, guides were positioned on the corresponding vertebra, and the contact areas were checked to avoid any discrepancy. After this, the cortical bone on the isthmus was violated through the guide tubes with a high-speed drill. The drill itself had a stop mechanism provided by the guides. This mechanism ensured that the drilling could be safely performed up to the planned depth. Guidewires were then introduced into the pedicle and vertebral body. Undertapping was performed with a cannulated tapping instrument, and screws were positioned over Kirschner wires. Proper positioning of the implants was then verified on intraoperative fluoroscopy.

Intraoperative, Radiological, and Clinical Assessment

Diameter and length of all the implanted screws were registered and compared. A postoperative CT scan was available for all included patients to evaluate screw trajectory according to the Raley classification in terms of breaching of the wall of the pedicle ($\leq$2 mm or >2 mm), pedicle fracture, anterior breach, and neurological sequelae of the lateral/medial breach. Non-neurological complications due to any screw misplacement were included. The executed entry points were measured and compared with the planned entry point, and a mean deviation between them was calculated. A cone diverging no more than 2° calculated on the craniocaudal and mediolateral angles was built on the planned trajectory to verify the inclusion of the positioned screws, defining screw accuracy.[10] Postoperative back and leg pain according to a numerical rating scale at discharge was used also to assess any clinical implications related to screw malpositioning.

Statistical Analysis

Descriptive statistics were reported with mean and standard deviation for cardinal variables and with frequency and percentage for categorical variables. The χ^2 test was adopted to assess associations between nominal variables, while the Student t test was used to assess associations between scale variables. A binomial logistic regression model was used to assess correlation between nominal variables. Statistical significance was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Version 26.0 (IBM Corp., Armonk, New York, USA).

RESULTS

This study evaluated 251 patients (1004 screws). The PG group (Figure 1) included 158 patients (632 screws), and the TG group (Figure 2) included 93 patients (372 screws). Mean age of patients in both groups was 60.2 years, and there were 134 men and 117 women. The 2 groups appeared to be homogeneous in terms of treated levels (Table 1) with L4-L5 being most frequently involved. In the PG group, the mean entry point distance from the target was 1.5 mm (SD = 0.15 mm). In 562 screws (88.9%), the actual trajectory was included in the cone diverging $\leq$2° from the planned trajectory. In 7 patients with a total of 10 screws (1.6%), the length was changed, using a shorter size because of radiological or neuromonitoring alert. There were 54 screws (8.5%) that intercepted the cortical bone at Raley classification grade 1, while 7 screws were described as Raley grade 2 (1.1%). No misplaced screws required delayed surgical repositioning, and no new neurological deficit was recorded. Most used size and diameter of screws were 5.5 × 35 mm on S1 and 5.5 × 40 mm on L3, L4, and L5.

In the TG group, the mean entry point distance from the target was 0.5 mm (SD = 0.5 mm). A total of 357 screws (96%) were included into the cone defining the accuracy of the trajectory. Screw length was modified and reduced during surgery in only 2 cases, but in both patients the planning showed an alert of distal breaching while the surgeon tried to maximize screw length because of severe osteoporosis. There were 19 screws (5.1%) that intercepted the cortical bone at Raley grade 1; no cases of Raley grades 2, 3, or 4 were described. Most used size and diameter of screws were 5 × 40 mm on S1, 6 × 40 mm on L5, and 6 × 45 on L3 and L4. No misplaced screws or complications following misplacement were recorded. Differences between the 2 groups concerning Raley classification, average entry point distance from the target, standard deviations, cone inclusion of the actual trajectory, and screw size for each level reached statistical significance ($P \leq 0.05$). The TG group had a shorter surgical time and lower x-ray dose. Clinical outcomes were satisfactory in both groups at the last follow-up (mean 26.2 months) (Table 2).

DISCUSSION

The results of this study clearly showed that the diameter and length of CBT screws could be maximized with the use of 3D

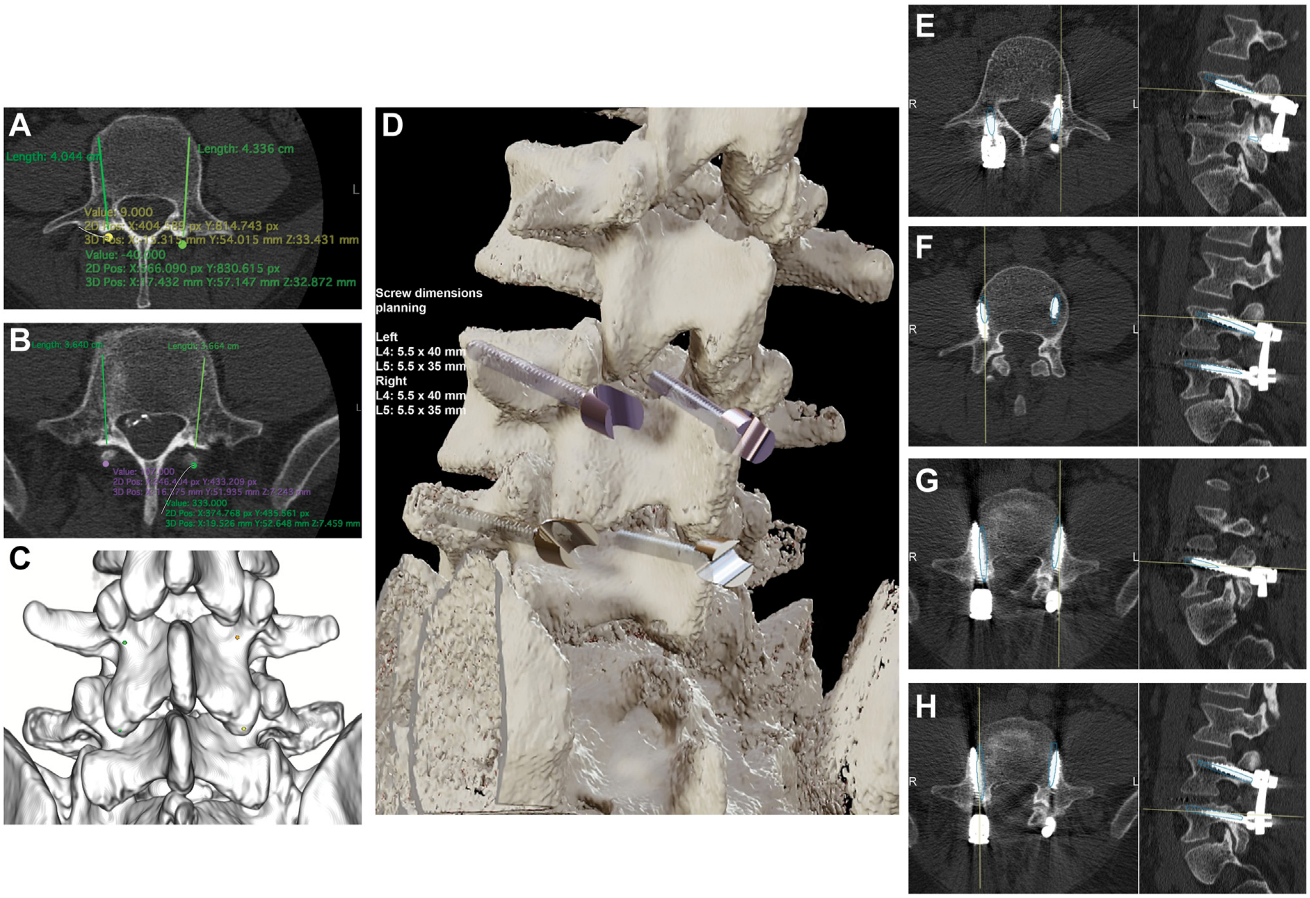

Figure 1. Illustrative case of free-hand three-dimensional planning–guided technique. The preoperative computed tomography scan was used to draw the best screw trajectories, their length (**A** and **B**), and the respective entry points on three-dimensional planning (**C**) using Horos software. Brainlab spine software (Brainlab AG, Munich, Germany) was used to reproduce the preoperative planning (trajectories and screw dimensions) (**D**) and to visually compare preoperative planning with postoperative results. Axial and sagittal images of each screw were obtained (**E**–**H**) and compared with the preoperative planned trajectory (represented as blue cylinder).

guides, providing sizes comparable to those of traditional convergent pedicle screws. The length and diameter most used with 3D guides were 5 × 40 mm on S1, 6 × 40 mm on L5, and 6 × 45 mm on L3 and L4, and data showed a safer profile of accuracy exploiting the divergent track. Main authors' group previously provided a detailed description of the use of 3D planning CBT screw positioning[10] and highlighted the safety and clinical efficacy of this technique and the achieved results.[14,15] Nevertheless, the safe use of longer screws should not be underestimated considering the trend of biomechanical studies investigating the comparison between CBT and traditional convergent pedicle screws.[5]

In scientific literature, biomechanical properties were primarily evaluated mainly with computational analysis or specimen investigations, whereas few in vivo evaluations have been performed and described. In the first study of Santoni et al.[6] describing the CBT technique, a human cadaveric biomechanical study showed equivalent pull-out and toggle characteristics compared with the traditional convergent pedicle track. Subsequent articles[16,17] described equivalent findings, while other authors, such as Baluch et al.,[18] found no differences in axial pull-out strength between the 2 techniques but showed superior resistance in toggling of CBT screws. CBT screws having a notoriously smaller diameter showed no differences in mechanical testing against traditional convergent screws, mainly confirming the superior quality of intercepted bones,[19,20] as underlined by many radiological studies.[21-23] Perez-Orribo et al.,[24] in a nondestructive flexibility test comparing CBT versus classical pedicle screws, confirmed the same stability of the construct with or without an interbody support. Matsukawa et al.[25] first described in an in vivo study that CBT screws were able to provide a higher insertional torque. Other studies using finite element analysis showed a more pronounced fixation strength for CBT screws[26] as well as higher resistance to flexion and

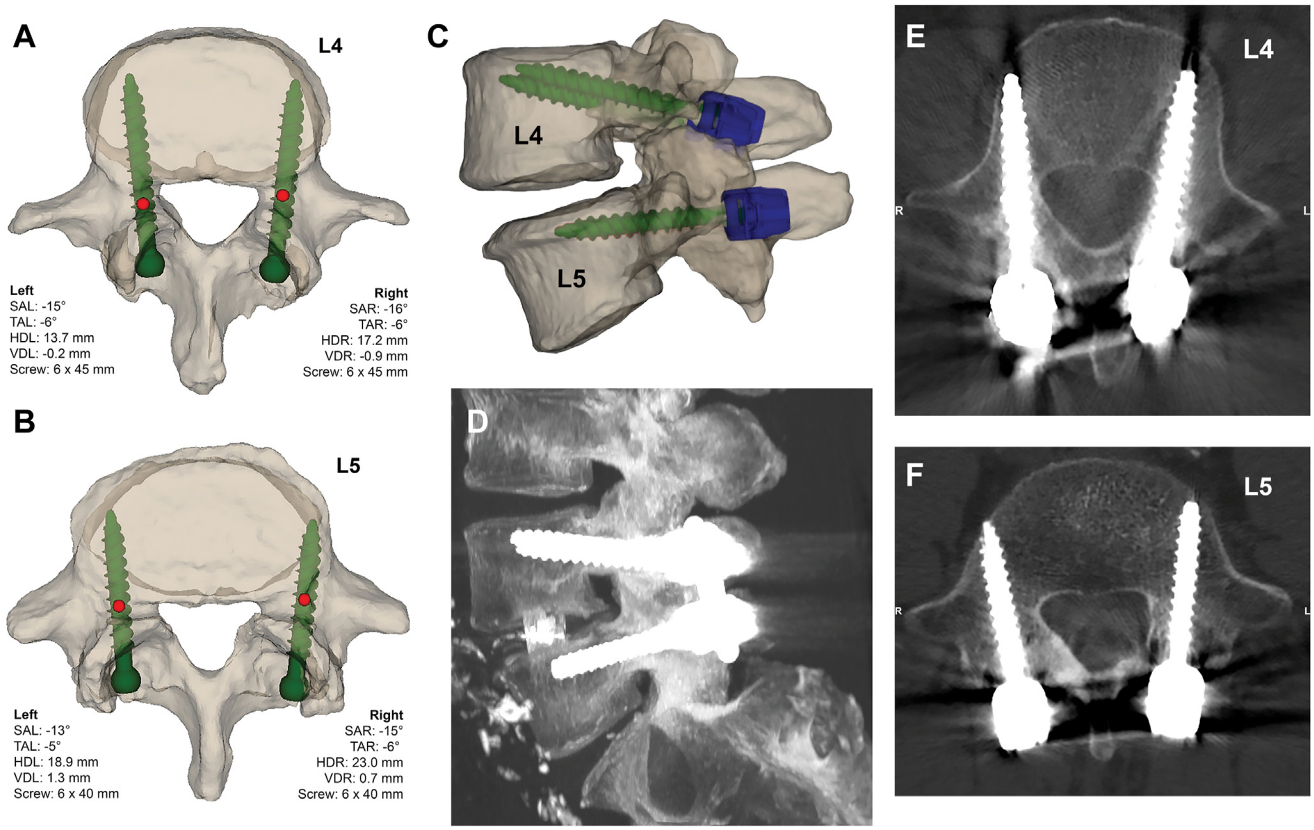

Figure 2. Illustrative case of customized three-dimensional-printed template–guided technique. Axial representation of screw planning (**A** and **B**) reporting characteristics for left and right screws, respectively. Preoperative three-dimensional planning and postoperative computed tomography scan reconstruction (maximum intensity projection) was compared (**C** and **D**) as well as the axial postoperative computed tomography scan of the fixed levels (**E** and **F**). SAL, sagittal angle left screw; TAL, transverse plane angle left screw; HDL, horizontal distance left screw; VDL, vertical distance left screw; SAR, sagittal angle right screw; TAR, transverse plane angle right screw; HDR, horizontal distance right screw; VDR, vertical distance right screw.

extension loading. Only lateral bending and axial rotation showed lower resistance. Year by year, it appeared progressively clear that mechanical data varied, mainly depending on technical factors and bone quality,[27] but, above all, screw size and length.[28] This was later confirmed in other cadaveric tests.[29,30] The use of longer screws with bigger sizes was associated with improved biomechanical properties compared with traditional convergent screws.[25,26]

To further improve biomechanical properties for fixation strength, some investigators described modified trajectories while preserving the main criteria of the technique.[31-33] Other studies evaluated the biomechanics of CBT screws in spondylolisthesis, namely, overt degenerative instability. No differences were observed considering the range of motion after fixation of lumbar cadaveric spines[34] as well as in radiological reduction investigation[35] in low-grade spondylolisthesis between classical and CBT screws.

The general consensus, as confirmed by an earlier review published by main authors' group,[5] is that CBT fixation seems to have at least equal biomechanical properties compared with classical fixation strength of convergent screws. The denser bone intercepted is one of the main factors able to justify these results, even when smaller screws are used because of the shorter corridor. Most probably, screw size plays a pivotal role in providing a real advantage over classical technique and accounts for many conflicting results of biomechanical tests. It is our opinion that the use of CBT screws with a size similar as in traditional convergent screw placement could empower further biomechanical properties highlighting the value of main cortical bone intercepted.

This is why the 3D-printed customized guides could be considered a real game changer for this technique: The use of 3D planning allowed for safer and tailored free-hand positioning, but guides enabled a further step to achieve the best profile of safety and efficacy around screw positioning also from a biomechanical point of view.

The use of neuronavigation can provide similar results, but the use of this technology is completely different in terms of costs, operating room setting, surgical experience, and availability and thus warrants different considerations that are beyond the main

Table 1. Population and Group Characteristics

	PG Group	TG Group	*P* Value	Total Population
Age, years, mean	60.1	61.3	NA	60.2
Sex				
Female	72	45	NA	117
Male	86	48		134
Number of patients	158	93	NA	251
Number of screws	632	372	NA	1004
Number of levels,%				
Single level	93	95.7	NA	NA
L3-L4	3.8	4.2		
L4-L5	49.2	48.1		
L5-S1	47	47.7		
Two level	7	4.3		
Screw length most used, mm				
L3	40	45	$\leq$ 0.05	NA
L4	40	45		
L5	40	40		
S1	35	40		
Screw diameters most used, mm				
L3	5.5	6	$\leq$ 0.05	NA
L4	5.5	6		
L5	5.5	6		
S1	5.5	5		
Entry point distance from target, mm, mean (SD)	1.5 (0.15)	0.5 (0.5)	$\leq$ 0.05	NA
Screw trajectory accuracy, %	88.9	96	$\leq$ 0.05	NA
Raley classification, number of screws				
Grade 0	571	353	$\leq$ 0.05	924
Grade 1	54	19		73
Grade 2	7	0		7
Grade 3	0	0		0

The χ^2 test was used for nominal variables, and the Student *t* test was used for scale variables.
PG, free-hand 3D planning—guided; TG, 3D-printed template—guided; NA, not applicable.

focus of this article. 3D guides, however, represent a very safe and accessible tool with a reduced learning curve that can be used even by unexperienced surgeons.

Other advantages of these tools concern the radiation dose for both the patient and the surgeon. Although the use of a guide does not completely eliminate the need for an intraoperative x-ray to check the correct positioning of the guide, it can significantly reduce the frequency of x-ray use during cortical bone screw insertion by eliminating above all the time required to make the pilot hole for the trajectory. Further research will be needed to determine how the use of templates could affect clinical outcomes.

Limitations

The main limitation of this study is its retrospective nature. However, the wide number of cases and the postoperative analysis of radiological assessment of accuracy, screw length, and bicortical purchase, which was the main goal of the study, allow for adequate statistical analysis. No comparison with

Table 2. Procedural and Clinical Data

	PG Group	TG Group
Procedural time, minutes	138	122
X-ray dose, mGy/cm^2	1.25	1.08
NRS leg Δ pre-/post-op	5.2	5.1
NRS back Δ pre-/post-op	4.3	4.4
Revision surgery	None	None
Complications following misplacement	None	None

PG, free-hand 3D planning—guided; TG, 3D-printed template—guided; NRS, numerical rating scale; pre-/post-op, preoperative/postoperative.

another technique to guide screw positioning is described, but, as specified in Discussion when mentioning neuronavigation, the goal of this article was to highlight the role of this handy tool in safely increasing the size of CBT screws in lumbar fixation. Costs are not mentioned because this analysis could vary among different countries and different health systems. Nevertheless, in our experience, the routine use of 3D guides did not demonstrate significant differences from the use of other standard equipment.

CONCLUSIONS

With the use of 3D patient-matched template guides, mean diameter and length of CBT screws could be safely increased due to improved accuracy of screw placement. Based on previous evidence regarding CBT biomechanical properties, these advantages could allow increased fixation strength over traditional convergent pedicle screw trajectories. Further biomechanics studies are needed.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Giuseppe Di Perna: Conceptualization, Methodology, Project administration, Formal analysis, Writing – original draft. **Nicola Marengo:** Conceptualization, Methodology, Data curation, Writing – original draft. **Keitaro Matsukawa:** Data curation, Writing – review & editing. **Geert Mahieu:** Data curation, Writing – review & editing. **Bianca Maria Baldassarre:** Investigation. **Salvatore Petrone:** Investigation. **Raffaele De Marco:** Data curation, Formal analysis, Writing – review & editing, Visualization. **Pietro Zeppa:** Investigation. **Marco Ajello:** Investigation. **Alessandro Fiumefreddo:** Investigation. **Francesco Zenga:** Writing – review & editing. **Diego Garbossa:** Data curation. **Fabio Cofano:** Project administration, Coordination of study group, Conceptualization, Methodology, Writing – original draft, Supervision.

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