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Clinical study

Cortical bone trajectory technique's outcomes and procedures for posterior lumbar fusion: A retrospective study

Salvatore Petrone *, Nicola Marengo, Marco Ajello, Andrea Lavorato, Federica Penner, Fabio Cofano, Francesco Zenga, Diego Garbossa

Department of Neuroscience, Neurosurgery, University of Turin, Turin, Italy

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ABSTRACT

Cortical Bone Trajectory screws allow a limited soft tissue dissection with mechanical properties comparable to traditional pedicle screws. However, clinical results are still reported on limited samples.

The study aimed to evaluate perioperative and mid-term follow up outcomes, clinical results and complications in 238 consecutive patients underwent CBT fusion for degenerative lumbosacral disease.

Pre- and intraoperative data, clinical outcomes and complications were collected. The patients were stratified in three groups. The original technique was performed in the first 43 cases without a preoperative CT scan planning. The second group includes the patients who underwent preoperative CT scan for entry point and screw trajectory planning (158 patients). Surgical procedures in the last group were performed with patient-matched 3D printed guide (37 patients). The accuracy in screws positioning was evaluated on postoperative CT scan.

The mean follow-up was 32.3 months. Mean ODI and VAS index improved with statistical significance. Mean procedural time was 187, 142 and 124 min in the three subgroups. The total amount of recorded complications was 4.2% (16.3%, 3.8% and 0.0% respectively). Screws entirely within the cortex of the pedicle were 78.9%, 90.5% and 93.9% in the three groups. Fusion was obtained in 92.4% of cases.

The CBT technique is a safe procedure, especially with an accurate preoperative CT scan-based planning. This seems more evident with the 3D template patient-matched guide. More studies are needed to directly compare traditional pedicle screws and CBT screws on long-term outcomes.

1. Introduction

Surgery for treatment of lumbar degenerative disease is increasingly seeking muscle-sparing solutions. Minimally-invasive techniques have been developed to reduce the morbidity associated with the posterior approach [1].

The technique of positioning cortical bone trajectory screws was created with the aim of reaching the higher density bone of the vertebra in patients with osteoporosis [2]. The mechanical purpose met the minimally invasive aim. The divergent trajectory of the CBT screws allows a limited soft tissue dissection. Indeed, the convergent trajectory of pedicle screws (PS) requires a wide muscular dissection to expose the entry point located at the junction of the superior articular facet with the transverse process [3].

Several studies confirmed the comparable mechanical properties of the CBT screws compared to traditional pedicle screws [4].

The first aim of the study is to report perioperative and mid-term follow up outcomes, clinical results, complications and learning curve in a series of 238 patients who underwent posterior lumbar arthrodesis with CBT screws technique. The second aim is to investigate which surgical technique allows the highest screw positioning accuracy and to report the results of our learning curve comparing the original technique, the one with a preoperative CT-scan planning and the most recent 3D template patient-matched guide technique.

2. Materials and methods

A retrospective cohort study was conducted. Eligible patients were all adults (older than 18-year-old) undergone lumbar fusion with posterior pedicle screw instrumentation using the cortical bone trajectory and interbody fusion, performed in two institutions (Molinette and CTO Hospitals, Turin, Italy) from April 29th, 2014 to March 29th, 2019. The surgical procedures were performed by two senior surgeons and two junior surgeons.

* Corresponding author.
E-mail address: svt.petrone@gmail.com (S. Petrone).

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Inclusion criteria were degenerative lumbar spine disorder, no evidence of spinal tumor or infection, availability of clinical chart, surgical report and a postoperative lumbar CT scan. Exclusion criteria were: cases in which interbody fusion was not performed, patients who needed fusion at more than 3 motion levels, lytic spondylolisthesis, degenerative spondylolisthesis with slippage more than 25% and not availability of postoperative CT scan. In 4 patients the screw path was preoperatively changed after CT scan planning because of anatomical features. They underwent traditional pedicle screw procedure, so they were excluded from this study.

238 consecutive patients met the inclusion criteria. Demographic and preoperative clinical data, intraoperative data (time of surgery, blood loss, number of fused levels, type of interbody cages), clinical outcomes (VAS and ODI) and complications (intraoperative and postoperative general and surgical complications and revisions) were collected from the clinical charts.

Table 1
Sample description.

Sex	Male 58.8% (n = 140), female 41.2% (n = 98)
Mean Age	54.8 y (32–71 y)
Prior lumbar surgery	37.8% (95.8% microdiscectomy, 4.2% interspinous device)
Symptoms	Pain (100%):
	Pure discogenic (9.7%)
	Pure radicular pain (25.2%)
	Both low back and radicular pain (65.1%)
	Sensory involvement (66.8%)
	Weakness (29.1%)
	Incontinence/impotence (2.5%)

Table 2
Treated levels and type of arthrodesis.

Number of levels	Single-level 92% (n = 219)
	L2-L3 1.8%
	L3-L4 3.2%
	L4-L5 46.6%
	L5-S1 48.4%
	Two-levels 6.7% (n = 16)
	Three-levels 1.3% (n = 3)
Type of arthrodesis	CBT-TLIF 87.8%
	CBT-PLIF 10.5%
	CBT-LLIF 1.7%

The patients were stratified in three groups. The first 43 cases were performed without a preoperative CT scan planning. The second group includes the patients who underwent preoperative CT scan for entry point and screw trajectory planning. The last group of 37 cases were performed with patient-matched 3D printed guide based on preoperative CT scan.

Preoperative surgical plannings were performed through 3D and Multi Planar Reconstruction (MPR) using Osirix® or Horos® softwares. For the third group, the preoperative surgical plannings were made using Mimics® (Materialise, Leuven, Belgium).

A comparison between the three groups was conducted in terms of intraoperative data, accuracy of screw positioning and complications.

Signs of fusion or non-union were collected from radiographs. Fusion was assessed only in patient with longer than 24-month follow-up using flexion–extension radiographs or CT scan (n = 127). The treated segments were considered fused if the difference of segmental lordosis was<2 degrees on flexion–extension X-ray or bony bridging was found on CT scan.

T-student and Chi-squared were used for the statistical analysis.

The CBT screws used in this study were MASPLIF ™ or MASTLIF™ (Nuvasive, San Diego, CA, USA) and MUST ™ (Medacta International SA). The interbody cages were MASPLIF™ and MASTLIF™ (Nuvasive, San Diego, CA, USA), T-PAL™ (DePuy Synthes, Oberdorf, CH) and Coroent™ (Nuvasive, San Diego, CA, USA).

3. Results

A total of 238 patients underwent circumferential arthrodesis with CBT screws. The selected patients suffered from degenerative lumbar disease.

The majority of patients were male (n = 140, 58.8%) (Table 1). Mean age was 54.8 years. Ninety patients (37.8%) had received prior lumbar surgery (microdiscectomy in 95.8% and interspinous device placement in 4.2%). Pre-operative symptoms were pain (100%)—either only in the lower back (9.7%), only radicular (25.2%) or both (65,1%); sensory involvement (66,8%); weakness (29,1%); incontinence / impotence (2.5%). 92% of patients underwent a single-level instrumented fusion (48.7% in L5–S1, 46.7% in L4–L5, 2.9% in L3–L4 and 1.7% in L2–L3). Almost all of the cages were inserted from a posterior approach (Table 2): transforaminal 87.8%, posterior 10.5%, lateral *trans*-psoas 1.7%.

Table 3
Clinical outcomes.

	Preop (VAS/ODI)	1-month FU (VAS/ODI)	Last FU (VAS/ODI)	Mean time FU (months)	p
All series	8.2/59.6	3.8/27.4	2.7/16.7	32.3	<0.01
Patients with greater than 2-y FU (n = 127)	8/57.5	3.9/27.8	2.7/15.4	38.7	<0.01

Table 4
Comparison between the three groups.

	Group 1 (n = 43)	Group 2 (n = 158)	Group 3 (n = 37)	p
Age	47.5 y	58.6 y	57.9 y	0.023
Procedural time	187 min	142 min	124 min	0.038
X-ray dose	1.60 mGy/cm^2	1.24 mGy/cm^2	1.07 mGy/cm^2	0.085
Hospital stay	3.5 days	2.7 days	2.2 days	0.057
Complications	16.3% (7)	3.8% (6)	0.0% (0)	0.022
Raley pedicle break classification				
Screws (total)	204	644	148	
Grade 0	161 (78.9%)	583 (90.5%)	139 (93.9%)	
Grade I	26 (12.7%)	54 (8.4%)	9 (6.0%)	
Grade II	13 (6.4%)	7 (1.1%)	0 (0.0%)	
Grade III	4 (2.0%)	0 (0.0%)	0 (0.0%)	

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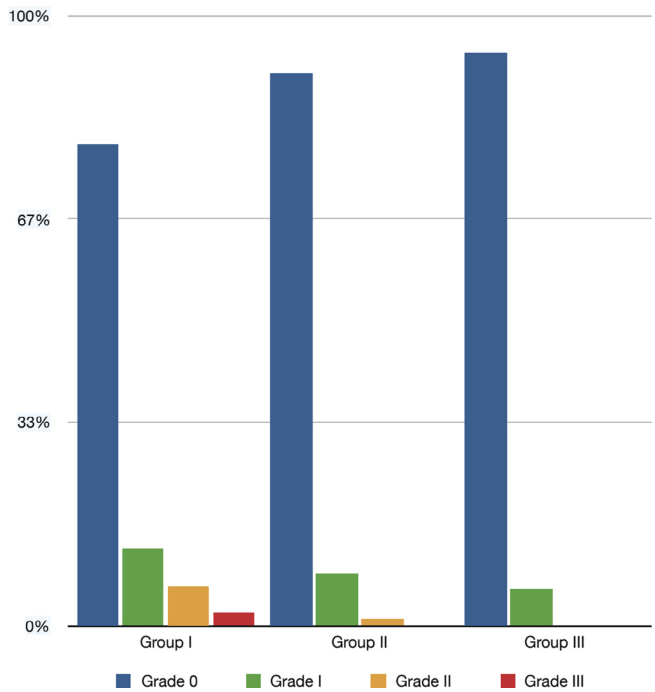

Fig. 1. Screw placement accuracy. Comparison between the three groups according to the Raley pedicle break classification.

Clinical outcomes are shown in detail in Table 3. The mean follow-up was 32.3 months (range 1–42 months). Mean preoperative ODI was 59.6. The mean ODI at 1-month follow-up was 27.4, and 16.7 at the last follow-up. Mean preoperative VAS was 8.2. Mean VAS at 1-month follow-up was 3.8 and 2.7 at the last follow-up. In patients with a follow-up longer than 24 months (53.4% of patients), fusion was obtained in 92.4% of cases.

A comparison between the three groups was performed (Table 4). Mean ages of patients were 47.5 (range 35–64), 58.6 (range 32–71) and 57.9 (range 39–68) respectively. Mean procedural time was 187 (range 157–223), 142 (range 117–207) and 124 (range 98–210) minutes and the mean hospital stay was 3.47 (range 2–7), 2.7 (range 1–5) and 2.2 (range 1–3) days in the three subgroups, respectively.

The total amount of recorded complications was 4.2% (n = 10/238). In the first group, complications were equal to 16.3% (n = 7): 4 misplaced screws that required delayed surgical repositioning; 1 cage dislocation that required surgical repositioning; 1 wound infection managed successfully with oral antibiotics; 1 pseudomeningocele after incidental durotomy was managed successfully with bed rest for 7 days. In the second group, complications were 3.8% (n = 6): 3 superficial infection successfully managed with oral antibiotics and 1 deep infection of the intersomatic cage that required surgical revision; 2 incidental durotomy. Neither screw misplacements nor neurologic deficits were recorded. In the third group, no complications were recorded.

Postoperative CT scan was obtained for all patients to assess the accuracy in screws positioning. The results have been classified with the grading system proposed by Raley [5] (Table 4 and Fig. 1).

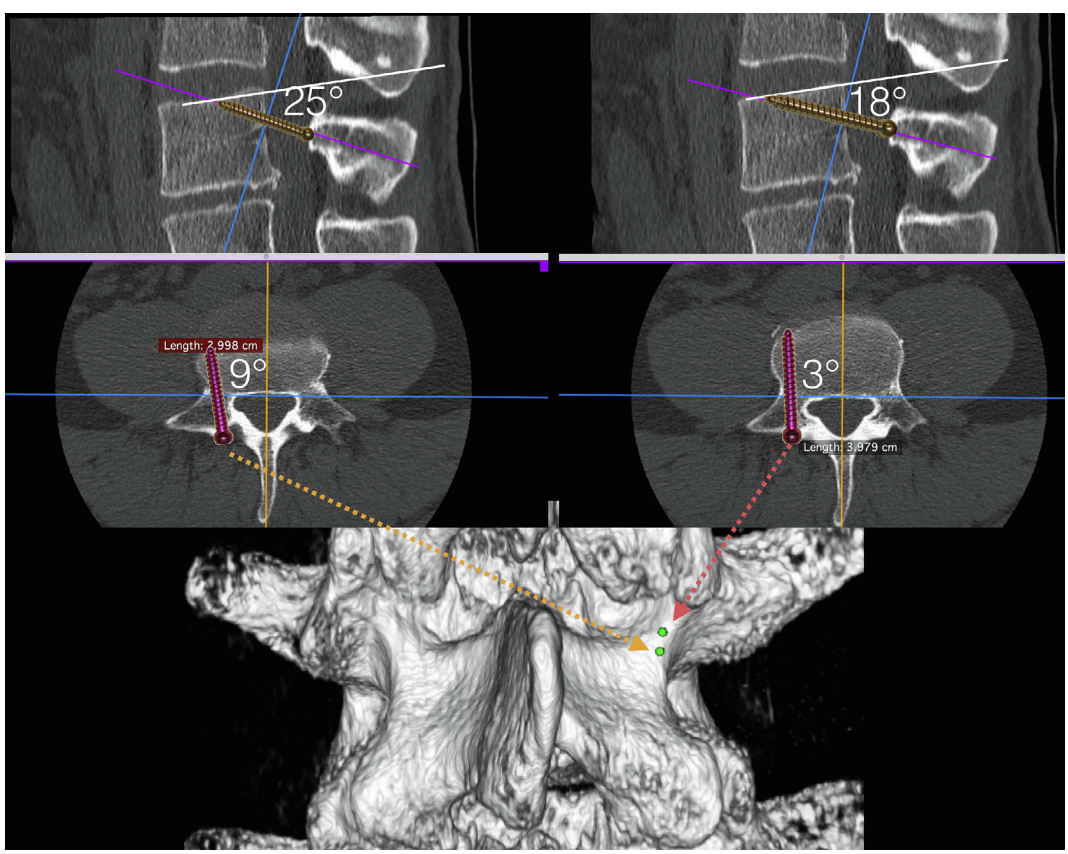

Fig. 2. Modified trajectory. A cortical trajectory targeting the anterior third of the upper plate of the vertebra allows to achieve the maximum length and size of the screw. As a consequence, the entry point will be modified.

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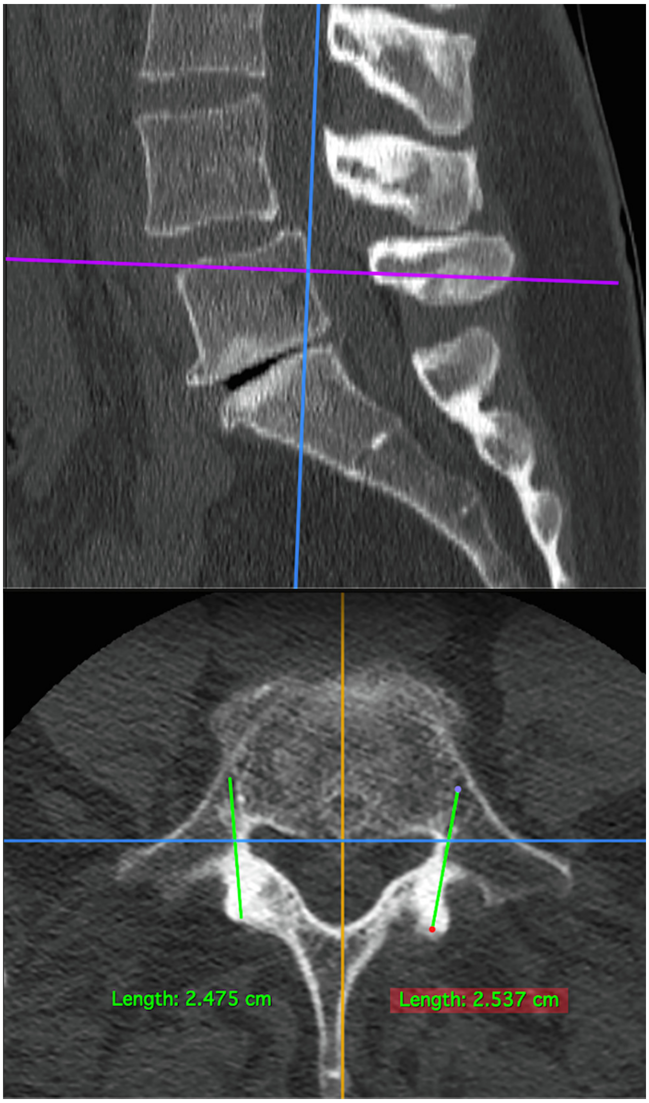

Fig. 3. Preoperative evaluation. A case of a short isthmus with a particularly wide lateral recess, identified on the preoperative CT scan. The divergent path is not safe-enough. In these cases, it is advisable to perform a traditional pedicle screws fusion.

4. Discussion

4.1. Effectiveness and learning curve of the CBT technique

The clinical and radiological outcomes confirmed that Cortical Bone Trajectory is a reliable alternative to the traditional pedicle screw technique: a more demanding procedure with remarkable advantages. Several studies corroborated the superiority of the CBT technique over the traditional pedicle screws in terms of blood loss, muscle damage, operative time, perioperative pain and length of hospital stay. Rates of bony fusion were similar between the two techniques [6–9].

The limited muscle damage is the main feature: several Authors have reported that CBT screws ensure a reduced multifidus damage [10,11].

The comparison between the three subgroups underlined the progressive reduction of overall complications. The reduction in procedural times and the improvement of the accuracy of screws placement could be explained by an actual learning curve performed by the surgeons and the support of a preoperative planning. The mean ages of the second and the third groups are significantly higher compared to those of the first one. This could reflect the increasing familiarity of the surgeons with the technique that allows to perform safe CBT procedures on elder patients, too. Noticeably, marked bony alterations in degenerated lumbar vertebrae frequently hide intraoperative landmarks and make the procedure more demanding. The combination of an accurate CT planning and a fair learning curve could be the key tool for a safe and accurate CBT screws positioning.

The impact of a learning curve on screws positioning has been already investigated by Dayani et al. [12]: after the first 52 screws positioning there was a reduction in the rate of complications, even if not statistically significant.

4.2. Evolution of the technique

The surgical technique has been well described in literature [13,14]. The trajectory of the cortical screw, as originally reported, is directed approximately 10 degrees laterally and 25 degrees cranially through the pedicle to maximize the contact with the cortical bone surface, targeting the posterior third of the upper vertebral plate [15].

Fig. 4. Patient-specific template guide. In order to obtain a perfect fitting with the bone surface, the surgeon have to perform an accurate exposition of the laminae and isthmus.

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The insertional torque of the CBT technique is generally higher than that of PS [16]. Matsukawa conducted a finite element (FE) method study: each individual CBT screw compared to PS had a superior fixation strength (pullout strength, stiffness during cephalocaudal and mediolateral loading), superior resistance to flexion and extension loading, but inferior resistance to lateral bending and axial rotation [17].

Our first 43 cases were performed following the traditional CBT surgical technique described in literature. With this technique, identifying the entry points without the visualization of the facet joints and the transverse processes is very challenging, due to the lack of intraoperative landmarks. Moreover, the medio-lateral trajectory is hard to verify with the risk of nerve root damages. On average, the length of the screws was 25 mm.

Several studies underlined that a short CBT screw could cause an improper loads distribution, with consequent inferior resistance to torsional motion compared to PS [18–20]. It seems that the mechanical properties of CBT screws depend not only on the density of the bone reached [21] but on the length of the screw too. Several authors proposed modified trajectories to increase fixation strength [23–26]. Matsukawa et al. described the ideal cortical trajectory to reach at the same time the highest dense bone and the longest path in the vertebral body. The result was a reliable bone purchase and effective load transmission [22].

In order to achieve the maximum length and size of the screw, a less angulated trajectory on the sagittal plane compared to the original technique has been planned, targeting the anterior third of the upper plate of the vertebra (Fig. 2). A preoperative planning was based on patients' CT scan to achieve the best possible trajectory for each screw. The ideal screw size for CBT should be at least 5.5 mm in diameter and long at least 35 mm [22]. The support of a pre-operative planning combined with the intraoperative triggered EMG allows the surgeon to recognize and predict anatomical features to reduce nerve root damages, procedural time and use of fluoroscopy [27].

The preoperative CT scan allows the surgeon to identify unfavorable anatomical conditions in order to perform a safer CBT technique with longer CBT screws. In a few patients (n = 4/242) it was noticed that a short isthmus with a particularly wide lateral recess should have forced the positioning of too short screws (<25 mm) with a not safe-enough path (Fig. 3). The preoperative CT scan planning is one of the key tools to reach a high level of safety and accuracy in positioning CBT screws. In our experience, the average entry point distance from the planned target was 1.1 mm. The 91.8% of the CBT screws had a trajectory differing no more than 2 degrees from the planned one [27].

In agreement with the literature evidences, CBT technique should not be performed just free-hand, but it requires x-ray guidance or image-guided navigation [28]. Three-dimensional fluoroscopic- or CT-image navigation systems demonstrated a significantly high pedicle screw placement accuracy [29,30], but they require expensive devices not broadly available.

A good compromise between costs and reliability could be a patient-specific template guide system. Our last 37 cases were performed through this procedure. This technology ensures a patient-tailored entry point and trajectory of each screw with a high level of accuracy. Also, it is possible to use larger and longer screws with minimal need of fluoroscopy. Moreover, the evidences suggest a quick learning curve with a reduction of the procedural time. The first results with patient-matched 3D printed guides in thoracic and lumbar spine surgery are promising [31,32].

In our experience, we found the template guide system much beneficial in terms of accuracy, operating time and rate of complications (Table 4). The opportunity to reconstruct a 3D model of each vertebra and a template guide based on the preoperative CT scan arises from the collaboration between surgeons and engineers. These patient-matched guides ensure a minimal error risk, because the best entry points, trajectory and screws' parameters of length and diameter are strongly suggested by the planning and 3D printed guides themselves.

The correct use of customized guides requires an accurate exposition of the bony structures to obtain a perfect fitting with the bone surface (Fig. 4). Even minimal residual soft tissue could lead to an improper matching and unpredictable variation of screws' trajectory during their placement.

Once accomplished all these procedural steps, the surgeon is able to visualize the pre-planned entry points and screws trajectory directly in the surgical field, minimizing the accidental error of incongruence between preoperative planning measurements and their intraoperative application.

Our data recorded in the last 37 cases confirm the promising advantages of this technique that allows to perform a patient-tailored surgery with a high level of accuracy in screws' placement (Figs. 1 and 5).

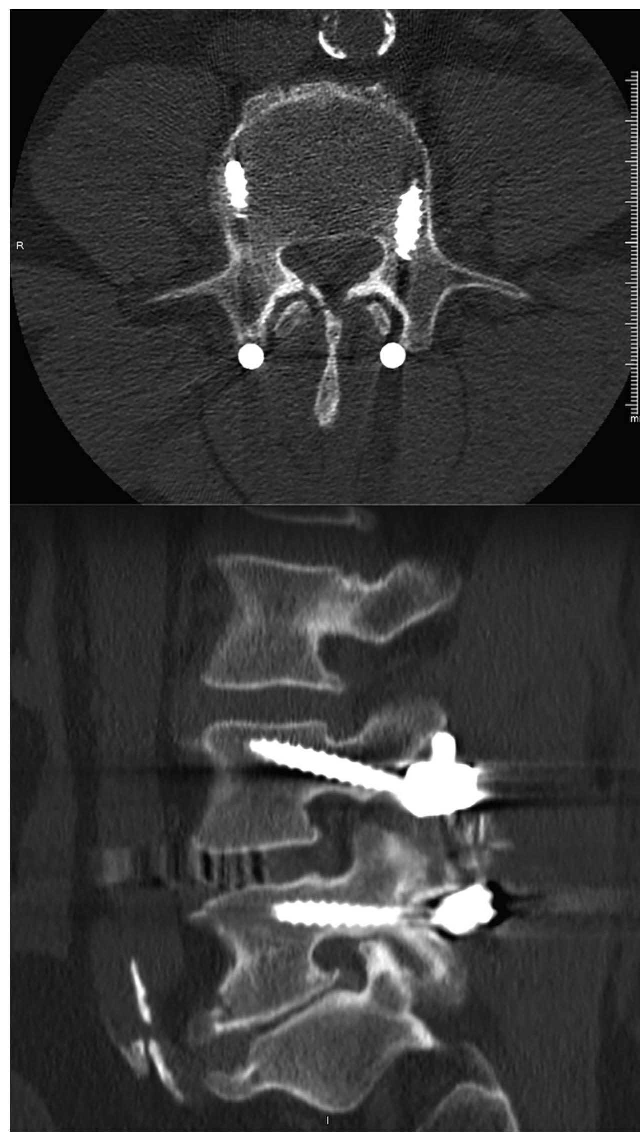

Fig. 5. A case of L4-L5 CBT circumferential arthrodesis. The postoperative CT scan showed on axial and sagittal planes the high level of accuracy in screws positioning using the template guide. In a patient-tailored procedure, the implanted screws have the maximum length and size.

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5. Study limitations

The retrospective nature of this study limits the significance level of our results.

It would be necessary to collect further data about patient-matched 3D printed guide to properly compare more homogeneous subgroups in terms of sample size.

Using different type of interbody cages (T-PAL, MASTLIF, MAS-PLIF, Coroent) represents a further confounding factor that limits the statistical meaning of the results.

No conclusions can be made about adjacent segment disease, global balance, junctional kyphosis and other long-term outcomes. No direct comparison of clinical and radiological outcomes has been made with traditional technique.

6. Conclusion

The research for minimally invasive procedures is leading more and more interest towards the CBT screw technique. Despite the advances in reducing the surgical trauma obtained with percutaneous, anterior or lateral approaches, the role of the posterior approach with direct decompression in spinal surgery remains mandatory in most cases. Our data confirm that CBT technique is a safe and reliable procedure. The high-level surgical skill can be overcome by an accurate preoperative CT scan-based planning and a proper learning curve. These advantages are even more evident with the most recent 3D template patient-matched guide technique. More studies are needed to directly compare traditional pedicle screw and CBT screw on long-term outcomes.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jocn.2020.04.070.

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