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ORIGINAL ARTICLE

Cortical bone trajectory screws for circumferential arthrodesis in lumbar degenerative spine: clinical and radiological outcomes of 101 cases

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Abstract

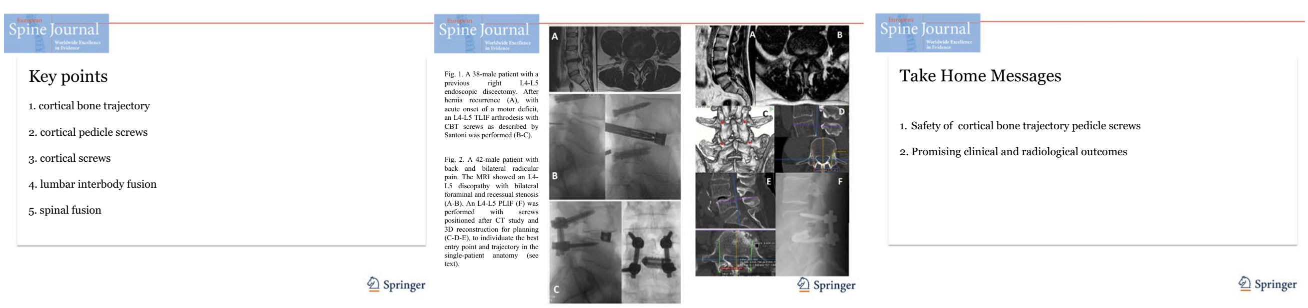
Purpose The use of cortical bone trajectory (CBT) pedicle screws for circumferential interbody fusion represents a viable alternative for single-level procedure with reduced invasiveness and less tissue destruction than the traditional technique. In addition, CBT screws have a potentially stronger pullout strength because of the greater amount of cortical bone intercepted. Only few series exist evaluating clinical and radiological outcomes of CBT screws.

Methods This is a retrospective cohort study. All patients that underwent circumferential lumbar interbody fusion with CBT screws in our institution from 2014 to 2017 were reviewed. Patient demographics, clinical outcome with visual analogue scale (VAS) and Oswestry Disability Index (ODI), radiological data such as fusion, lordosis and muscle trauma, operative blood loss, hospital stay and use of fluoroscopy were evaluated.

Results A total of 101 patients undergoing CBT-arthrodesis for degenerative lumbo-sacral disease were reviewed. Mean procedural time was 187 min. The mean operative blood loss and X-ray dose per procedure was 383 ml and 1.60 mg cm^2, respectively. The mean hospital stay was 3.47 days. The mean follow-up was 18.23 months. Mean lordosis increment at the treated level was 4.2°. When the follow-up was longer than 12 months (53% of patients), fusion was obtained in 94% of cases. Mean ODI and VAS index improved with statistical significance.

Conclusions This is to our knowledge that the largest available study regarding CBT for circumferential arthrodesis. Results underlined the safety of this technique and the promising clinical and radiological outcomes that will need a longer follow-up.

Graphical abstract These slides can be retrieved under Electronic Supplementary material.



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Keywords Cortical bone trajectory · Cortical pedicle screws · Cortical screws · Lumbar interbody fusion · Spinal fusion · Spinal fixation

Introduction

Pedicle screw (PS) instrumentation is considered a standard procedure in lumbar spinal fusion to provide the stability needed to achieve bony union [1]. Moreover, many studies have described the relevance of lumbar fusion to help restore global as well as local sagittal balance and ultimately improve the patients' function, pain and health-related quality of life [2, 3].

Minimally-invasive techniques have been developed to reduce the morbidity associated with the posterior approach [1]. Santoni et al. in 2009 described the cortical bone trajectory (CBT) with the aim of maximizing the pullout resistance in osteoporotic bone [4]. The divergent trajectory of the CBT screws (opposed to the convergent trajectory of standard pedicle screws) allows for comfortable implantation of the screws with a limited soft tissue dissection. Indeed, the convergent trajectory of pedicle screws requires an extensive muscular dissection to expose the entry point located at the junction of the ascending facet with the transverse process. As a result, CBT screws offer a less invasive technique that maintains similar mechanical properties as traditional pedicle screw instrumentation [5, 6]. Additionally, the entry point for the cortical screws requires a smaller incision, a reduced rate of facet joint violation [5] and a reduced manipulation of the muscular tissues [7]. Less soft tissue dissection could be associated with reduced post-operative pain and shorter hospitalization than in patients treated with classic pedicle screws [7].

However, the reliability of this type of screw trajectory is supported by a limited number of clinical studies [8]. This study could potentially increase the clinical knowledge about posterior lumbar instrumentation after past technical contributions [3, 8].

The aim of the study is to report on the operative outcomes, clinical results and complications in a homogeneous series of patients who underwent posterior lumbar fixation and interbody fusion performed at a single institution.

Materials and methods

This is a retrospective cohort study.

Eligible patients were all adults (older than 18-year-old) undergoing lumbar fusion with posterior pedicle screw instrumentation using the cortical bone trajectory technique and implants [7] and interbody fusion at a single institution from April 29th, 2014 to August 18th, 2017. Inclusion criteria were: degenerative lumbar spine disorder, no diagnosis of spinal tumor or infection, availability of clinical chart, surgical report and a full set of front and lateral lumbar spine X-ray films both preoperatively and at the end of follow-up. Exclusion criteria were: patients where interbody fusion was not performed and patients who needed fusion at more than 3 motion levels.

105 patients were eligible and 101 met the inclusion criteria.

Demographic and preoperative clinical data, intra-operative data (time of surgery, blood loss, number of levels fused, number and type of inter-body cages), clinical outcomes [visual analog scale (VAS) for back pain and leg pain, Oswestry Disability Index (ODI) to assess loss of function] and complications (intra-operative general and surgical complications, post-operative general and surgical complications, mortality and revision) were collected from the clinical charts. The following complications were sought for in the clinical records: surgical site hematoma, infection, hemorrhage, seroma, neurological impairment, incidental durotomy and fistulas, failure of hardware, mobilization of implants, misplacements, thromboembolic complications, cardiac, pulmonary or renal complications.

Additional variables were collected from radiographs: screws and cages positioning, segmental lordosis, signs of fusion or non-union.

Fusion was assessed only in patient with longer than 12-month follow-up using flexion–extension radiographs or CT scan. The treated segments were considered fused if the difference of segmental lordosis was less than 2 degrees on flexion–extension X-ray or bony bridging was found on CT scan.

Multifidus cross sectional area—MFCSA—was measured on T2 weighted MRI axial views at the disk level for each segment of motion fused both preoperatively and 12 months postoperatively, thus excluding patients with less than 12-month follow-up, to quantify muscle damage due to surgery [9].

Then the difference of the area was expressed in percentage indicating the reduction of muscular tissue.

Time to last follow-up was defined as the time from the procedure to the last clinical evaluation performed by a clinician. All the patients had the last follow-up evaluation in November 2017.

Surgical technique of CBT pedicle screws fixation

Previous reports have described the surgical technique [3, 8]. In the present series, the surgical planning included evaluation of the pedicle anatomy with re-slicing of patients' CT to plan the best possible trajectory for each screw. For a single-level fusion, a 5–7 cm posterior midline incision is made centered on the target level with the assistance of fluoroscopy. The subperiosteal dissection of paraspinal muscles in medial to lateral direction is limited to the exposure of the pars interarticularis of the cranial and the caudal vertebrae [10], and the lateral edge of the facet joints of interest [10]. The entry point for the cortical screws is localized in the lateral portion of the pars at the junction between the midpoint of the superior articular process and the horizontal line passing 1 mm caudal to the inferior edge of the transverse process [1]. The starting point is checked with fluoroscopy [10]. The trajectory of the cortical screw is directed approximately 10° laterally and 25° cranially through the pedicle to maximize thread contact with the cortical bone surface [11], targeting the anterior third of the upper vertebral plate.

The cortical bone at the entry point is entered using a high-speed drill till about 10 mm depth and then a hand drill is used to complete the trajectory. A fine ball-tipped probe is used to palpate the pathway for breaches and to measure screw length [10]. Tapping is performed and the screw is inserted by hand [10]. The tactile sensation during screw insertion is an important feedback about the screw purchase in the bone [10]. The CBT screws used in this study (MASPLIF™ or MASTLIF™, Nuvasive, San Diego, CA, USA) are inserted without tulips to allow surgeons to easily perform decompression and insert posterior cages, without the bulk of the tulip screw heads (only when performing CBT–PLIF or TLIF).

The interbody fusion was obtained using cages inserted through the same posterior approach (MASPLIF™ and MASTLIF™ Nuvasive, San Diego, CA, USA; T-PAL™ DePuy Synthes, Oberdorf, CH) or through a trans-psoas direct lateral approach (Coroent™ Nuvasive, San Diego, CA, USA).

Allogenic bone graft substitute was placed inside all the implanted cages and around them to fill the inter-body space as much as possible (Attrax ™ Nuvasive, San Diego, CA, USA).

The ideal screw size for CBT should be larger than 5.5 mm in diameter, longer than 35 mm and the screw should be placed deep into the vertebral body [12]. Still, one study has shown equivalent mechanical purchase between smaller screws with cortical trajectory and long pedicle screws placed in traditional pedicle trajectory [13].

Regarding the S1 CBT screw, the starting point differs, due to anatomical differences with the other lumbar vertebrae. It is located at the junction of the center of the superior articular process of the S1 and approximately 3 mm inferior to the most inferior border of the inferior articular process of the L5. The trajectory is directed straight in the axial plane without divergence, angulated cranially in the sagittal plane to reach the anterior third of the endplate. Matsukawa described the penetration of the middle end of the sacral endplate [14] to increase purchase.

During each procedure neuro-monitoring with triggered EMG (electromyography) was performed to provide additional nerve root safety [15].

Results

During the study period, 101 patients underwent circumferential arthrodesis with CBT screws. Every patient considered in this study suffered from degenerative lumbar disease. The decision to perform arthrodesis with CBT screws instead of classical pedicle screws was made before the procedure considering various factors including: (1) patient spinal surgery history, excluding cases of previous laminar decompression with a large amount of bony removal. (2) Number of levels to fuse, preferring patients with only a single-level to be treated. (3) Sagittal balance, excluding patients in which lumbar lordosis restoration was the target of surgery. (4) Bony degeneration, excluding patients with severe osteoarthritis and bony anatomy distortion. After successful surgical learning curve accomplishment, a progressive degree of arthrosis and bony alterations was accepted for placing CBT screws. Increasing familiarity with the technique and improving pre-operative imaging study—using 3D reconstruction and trajectory planning with Osirix © or Horos © softwares—made surgical placement safer even in largely degenerated lumbar vertebras.

The majority of patients were male ($n = 58$, 57.4%) (Table 1). Mean age was 47.6 years.

Thirty-two patients (31.6%) had received prior lumbar surgery (microdiscectomy in 92% and interspinous device placement in 8%).

History of smoking was found in 41%. The most common preoperative comorbidities are shown in Table 1. Pre-operative symptoms were pain (100%)—either only in the lower back (27%), only radicular (48%) or both (25%); sensory involvement (61%); weakness (35%); incontinence/impotence (5%).

94% of patients underwent a single-level instrumented fusion (48.5% in L5–S1, 44.5% in L4–L5, 5% in L3–L4 and 2% in L2–L3). Almost all of the cages were inserted from a posterior approach (Table 2): transforaminal 53.5%, Posterior 44.5%, Lateral trans-psoas 2%.

With transforaminal interbody fusion (TLIF) a 5° PEEK (polyetheretherketone) cage was used in almost all cases (99%) and a 12° titanium cage (Fig. 1) was inserted in only one patient. With posterior inter-body fusion (PLIF) 8° cages were used in 65% of patients, 4° cages in 25% and 12° cages in 10%. PEEK was used in 92% of patients,

Table 1 Pre-operative data

Sex	Male 57.4%, female 42.6%
Prior lumbar surgery	31.6% (92% microsurgical herniectomy, 8% interspinous device)
History of smoking	41%
Comorbidities	Hypertension (47%), hypercholesterolemia (21%), thyroid disease (17%), diabetes mellitus type 2 (7%)
Symptoms	Pain 100%:
	Pure discogenic (27%)
	Pure radicular (48%)
	Both (25%)
	Sensory involvement 61%
	Weakness 35%
	Incontinence/impotence 5%
Number of levels	Single-level 94%
	L5–S1 48.5%
	L4–L5 44%
	L3–L4 5%
	L2–L3 2%
	Two-levels 5%
	L4–S1 80%
	L3–L5 20%
	Three-levels 1%
	L2–L5

Of the 101 patients undergoing CBT-arthrodesis, 95 (94%) received a single-level instrumented fusion. In 32 cases (31.6%) there was a history of previous lumbar surgery

Table 2 Surgical parameters and complications of 101 patients treated with CBT-arthrodesis

Type of arthrodesis	CBT–TLIF 53.5%
	5° LC 99%
	12° LC 1%
	CBT–PLIF 44.5%
	8° LC 65%
	4° LC 25%
	12° LC 10%
	CBT–LLIF 2%
	8° LC
Mean procedural time	187 min (ds 0.80)
Mean hospital stay	3.47 days (ds 2.24)
Mean blood loss	383 ml (ds 0.9)
Mean X-ray dose per procedure	1.60 mg cm^2 (ds 1.9)
Complications	Screw misplacement needing repositioning 4/418 (0.95%)
	Wound infection 1%
	Pseudomeningocele 1%

Peri-operative outcomes were satisfactory. Four cases (0.95%) of screw misplacement needing repositioning were observed

CBT cortical bone trajectory, *TLIF* transforaminal lumbar interbody fusion, *PLIF* posterior lumbar interbody fusion, *LLIF* lateral lumbar interbody fusion, *LC* lordotic cage

titanium 8%. With lateral trans-psoas (LLIF) an 8° PEEK cage was used in 100% of patients (Fig. 2).

Mean procedural time was 187 min. The mean hospital stay was 3.47 days. The mean blood and X-ray dose were 383 ml and 1.60 mg cm^2, respectively.

Six complications were encountered in six patients (5.9%): 4 screws misplaced that required delayed surgical repositioning; 1 wound infection managed successfully with oral antibiotics; 1 pseudomeningocele after incidental durotomy was managed successfully with bed rest for 7 days.

Clinical outcomes are shown in detail in Table 3. The mean follow-up was 18.21 months (range 3–42 months). Mean pre-operative ODI was 50.24. The mean ODI at 1-month follow-up was 23.27, and 17.56 at the last follow-up. Mean pre-operative VAS was 7.96. Mean VAS at 1-month follow-up was 3.36 and 2.44 at the last follow-up. In patients with < 1-year follow-up clinical data showed early satisfactory outcomes. Posterior compression after screw and rod placement before locking the set screws was always obtained. Mean lordosis increment at the treated level was 4.2°. In patients with a longer than 12-month follow-up (52.5% of patients), fusion was obtained in 94% of cases and mean MF-CSA % change was 16% between the pre-op and the post-op. Fusion was assessed in 45 patients with a CT scan, in 56 patients with flexion–extension radiographs. No adjacent segment disease was observed at the last follow-up.

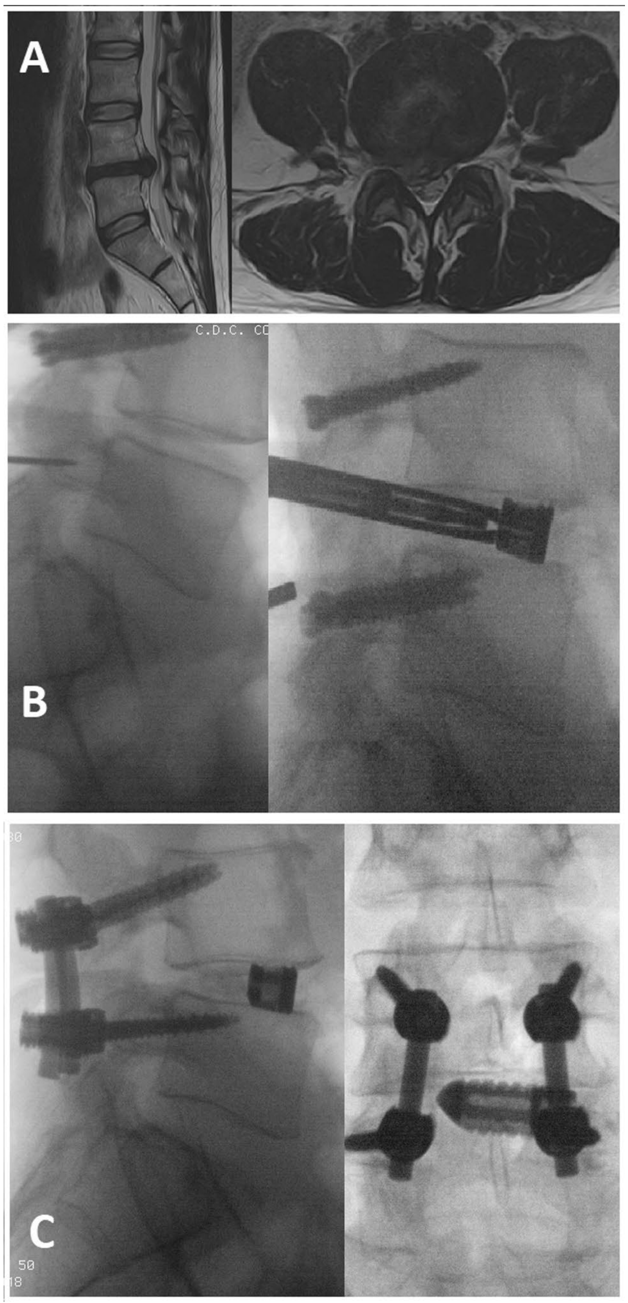

Fig. 1 A 38-male patient with a previous right L4-L5 endoscopic discectomy. After hernia recurrence (**a**), with acute onset of a motor deficit, an L4-L5 TLIF arthrodesis with CBT screws as described by Santoni was performed (b, **c**)

Discussion

Biomechanical basis

Biomechanical features of cortical screws were evaluated and compared with traditional screws both in cadaveric and in vivo studies. Santoni et al. [4] in 2009 showed an increase of about 30% in axial pullout load compared with that for traditional trajectory in the cadaveric lumbar spine. A CT scan study showed that cortical trajectory penetrates a vertebral region that is richer in cortical bone with a HU-derived index (Hounsfield units) almost four times higher compared with traditional trajectory [16]. It also been reported that CBT had a 27.8% stronger rigidity in cefalocaudal loading and a 140.2% in medio-lateral loading. Thus, cortical screws had more resistance to flexion and extension loading, but they had inferior resistance to lateral bending and axial rotation [17]. According to the study conducted by Perez-Orribo et al. the cortical screws combined with TLIF cages had a greater flexion and extension resistance, but less lateral and axial bending resistance than classic PS. There were no significant differences between the two trajectories regarding the type of interbody support [18]. Furthermore, in the literature there is contrasting data about the CTB's effects and resistance during stress tests (physiological loads repeated over time) compared to the traditional trajectory [19, 20].

Mechanical behavior of this new trajectory was studied in vivo and CBT screws had an insertion torque about 1.7 times higher than the traditional technique [21]. CBT screws appeared a suitable option for patients with severely degenerated vertebrae with some limitations in patients over 75-years-old with spondylolysis [22]. In the spondylolytic vertebrae, no statistically significant difference was observed for pullout strength between PS and CBT. However, the cortical trajectory screw showed lower vertebral fixation strength in flexion, extension, lateral bending and axial rotation compared with traditional trajectory screw [23]. Finally, there were no significant differences between the CBT and the classical pedicle screw technique concerning the range of motion in a cadaveric study [24].

It is therefore possible to consider that CBT screws ensure the durability of the construct at least equal to the traditional approach with pedicle screws, but with a reduced bony exposure and muscular dissection required.

Surgical trauma: how minimally-invasive?

With the advancement of technology and increased anatomical knowledge, the principle of "minimally-invasive surgery" (MIS) arose in response to various problems related to traditional approaches. There is general agreement about the advantages of minimally-invasive spinal surgery, but a small number of studies from the literature compare the complications between MIS and classical open techniques. Then et al. [25] reported that MIS resulted in significantly fewer neurological and operative complications. Re-operation rates were similar and despite complications, the patients reported significant improvement in pain and function compared with the open technique. Patients in the MIS group also experienced shorter operative time and less blood loss.

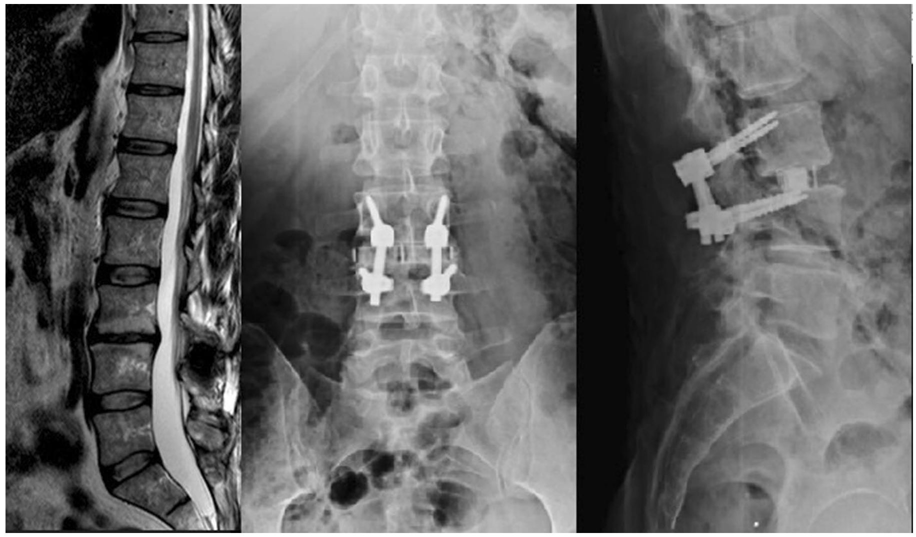

Fig. 2 A 46-female patient with resistant back pain. The MRI showed an L3–L4 discopathy. An L3–L4 LLIF arthrodesis with CBT screws as described by Santoni was performed

Table 3 Clinical outcomes in CBT-arthrodesis evaluated with the visual analogue scale (VAS) and the Oswestry Disability Index (ODI)

	Pre-op (ODI/VAS)	1 month FU (ODI/VAS)	Last FU (ODI/VAS)	Time FU in months (average/max/min)	*N*	*p*
All series	50.24/7.96	23.27/3.36	17.56/2.44	18.23/42/3	101	< 0.01
Patients with > 1 year FU	49.86/7.99	24.1/3.38	17.61/2.32	25.4/42/12	53	< 0.01
Patients with < 1 year FU	50.56/7.95	22.6/3.3	17.53/2.50	6.8/12/3	48	< 0.01

Results were collected considering all series (first line), patients with > 1-year follow-up (FU) (second line) and < 1-year follow-up (third line). A statistically significant clinical improvement was observed after surgery, both after 1 month from the procedure and at the time of the last follow-up

Despite the advances in reducing the surgical trauma obtained with percutaneous, anterior or lateral approaches, the role of the posterior approach in spinal surgery remains unquestionable in most cases. Direct decompression of nervous structures is often necessary and irreplaceable. With all the limits of a posterior arthrodesis, it may therefore be appropriate to consider that a solution to minimize muscle trauma and blood loss belongs to the category of minimally-invasive techniques.

Traditional PS requires wide muscular dissection to reach the entry point and to provide an appropriate convergent trajectory as well. This is often the reason for post-operative spasms, pain and need for narcotics, therefore, increasing hospitalization length and time to regain a normal mobilization [25, 26].

Muscular dissection for CBT screws does not need to expose the ascending facets and transverse processes, reducing soft tissue manipulation. Furthermore, the divergent trajectory minimizes the length of skin and fascia incision.

In this case series, mean blood loss per procedure was 383 ml and the mean hospital stay 3.47 days. Snyder et al. [1] reported similar results with 306.3 ml of mean blood loss and 3.5 days of hospitalization in a 79 patients series. Sakaura et al. also reported 495 ml with CBT screws fixation for 2-level degenerative lumbar spondylolisthesis [27]. Classical pedicle screws showed worse peri-operative outcomes: Rivet et al. [28] reported average blood loss of 507 ml in 1-level standard pedicle screw fusions and 800 ml in 2-level fusions, with a length of stay of 4.6 and 5.3 days, respectively. Furthermore, in the classical pedicle screw placement, the degree of disruption of the adjacent facet capsule upon exposure provides a theoretical increase in the likelihood of proximal junctional kyphosis [29]. With CBT technique this risk is theoretically reduced, considering that the exposure does not involve the superior facet capsule with respect of the junctional facet joints.

A decreased amount of exposure required and muscular trauma, justifies less blood loss and post-operative pain. This may lead to faster mobilization and discharge [6].

Achieving successful fusion

In this study CBT screws were used to obtain fusion (TLIF, PLIF, LLIF) with 1-year fusion rate of 94%, in line with classical techniques [30]. The cages positively impacted on local lordosis with a mean increase in the treated level of 4.2°, thus being able to re-establish a correct balance on the single-level. Patients where balance restoration was

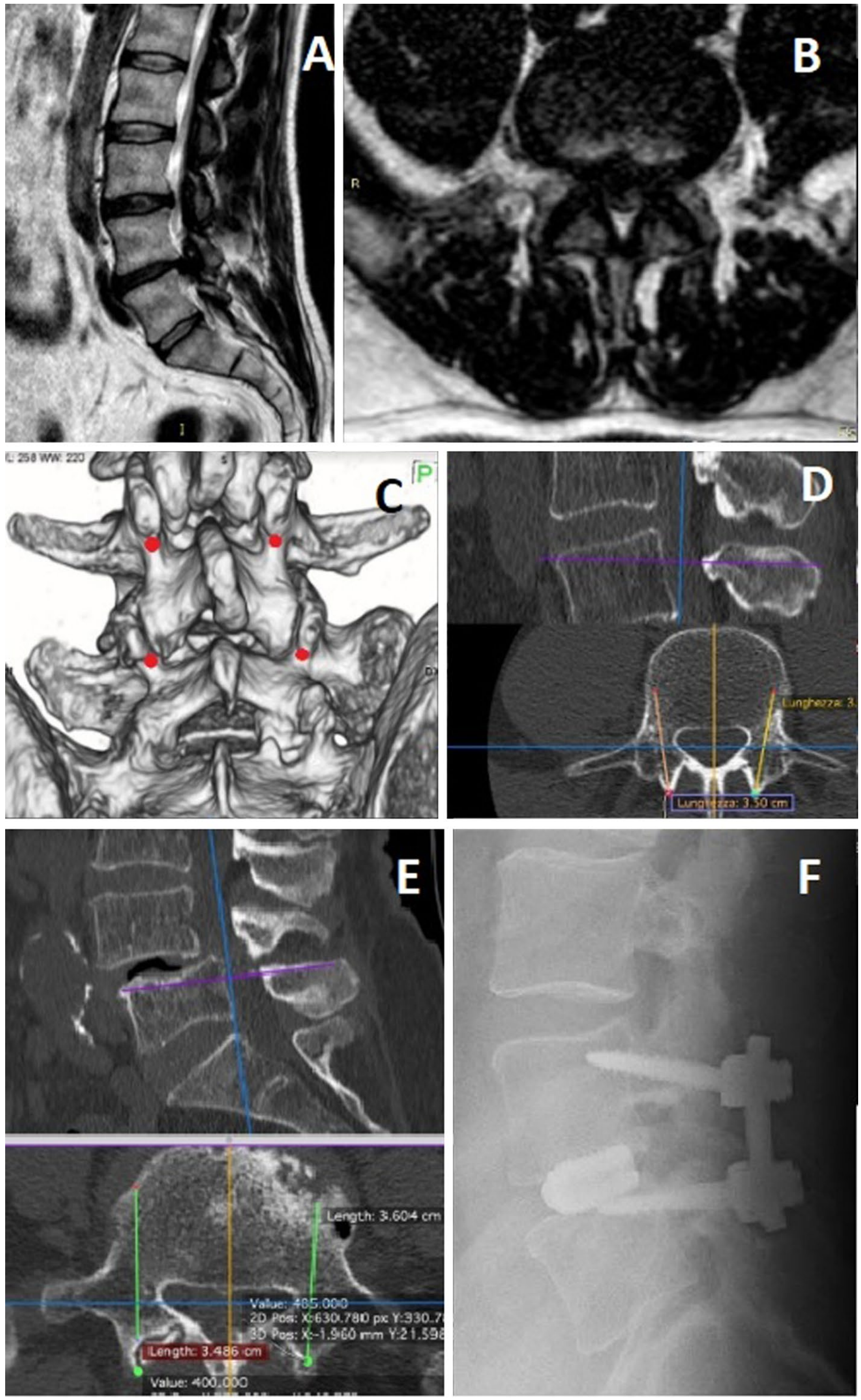

Fig. 3 A 42-male patient with back and bilateral radicular pain. The MRI showed an L4–L5 discopathy with bilateral foraminal and recessual stenosis (**a**, **b**). An L4–L5 PLIF (**f**) was performed with screws positioned after CT study and 3D reconstruction for planning (**c**–**e**), to individuate the best entry point and trajectory in the single-patient anatomy (see text)

the goal of surgery underwent arthrodesis with classical pedicle screws. However, there are no contraindications using CBT screws for sagittal corrections, considering their resistance to flexion and extension loading [17], the possibility to use lordotic cages with every approach and to perform posterior compression. Clinical outcomes were satisfactory compared to the pre-op, with an ODI score of 17.56 and a VAS score of 2.44, respectively, at the last follow-up ($p < 0.01$). In this study no adjacent segment diseases were observed at the last follow-up.

Screw placement: a tailored surgery

Among the complications recorded there were 4 misplaced screws that required delayed repositioning (0.9%). The literature reported rates ranging from 3 to 55% of freehand pedicle screw malpositioning [31].

Gaining familiarity with the technique, pre-operative planning with digital softwares (Osirix © or Horos ©) has concretely helped improving accuracy of screw placement and reduced complications. Multiplanar view and 3D reconstruction of every single-patient anatomy has been essential to locate the best entry point and the right trajectory during the procedure. That is why a progressively greater degree of arthrosis and bony alterations has been accepted during patient selection for placing CBT screws: the importance of recognizing, during surgery, the standard anatomical entry point at the pars interarticularis has been replaced by the importance of recognizing the best entry point for the anatomy of every single-patient, as planned in the pre-op (Fig. 3). All cases of misplacements, indeed, occurred at the beginning of the experience.

This technique benefits, without any doubt, from the importance of using intra-operative neuro-monitoring, since it allows us to evaluate positioning error or root damage in real time [15]. In this case triggered EMG is essential to exploit the potential of this trajectory and to reduce the need for fluoroscopy (mean X-rays dose per procedure was 1.60 mg cm^2). In these patients no nerve roots were injured. However, there was only one case of incidental durotomy that occurred during decompression for cage insertion.

Study limitations

No conclusions can be made about adjacent segment disease, global balance, junctional kyphosis and other long term complications with a mean follow-up of 18.23 months. No direct comparison of clinical and radiological outcomes has been made with traditional technique.

Conclusions

This is, to our best knowledge, the largest available study regarding CBT for circumferential arthrodesis in lumbar degenerative disease. Results underlined the safety of this technique and the promising clinical and radiological outcomes that will need a longer follow-up.

Conflict of interest PB Honorarium for surgeon's education: Nuvasive, Medacta, Depuy Synthes. Grants for research: Nuvasive, Medacta, Depuy Synthes, K2M. No conflicts of interest were declared by the other authors.

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