Can cortical bone trajectory screws replace traditional trajectory screws in osteoporotic lumbar spine fusion?

Mohamed A. Moussa[a], Kamal M.A. Meguid[a], Haytham A.-M. Abdel-Ati[a], Mahmoud Abdou[a], Ihab M. Emran[b]

[a]Orthopedic Department, Faculty of Medicine, Fayoum University, Fayoum, [b]Orthopedic Department, Faculty of Medicine, Cairo University, Cairo, Egypt

Correspondence to Mohamed A. Moussa, MD, Orthopedic Department, Faculty of Medicine, Fayoum University, Fayoum 63511, Egypt
Tel: +20 105 010 0247/01090377753;
fax: + 0846302350;
e-mail: mam21@fayoum.edu.eg

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Background
Osteoporosis is a challenging condition for spine surgeons. So, improving the instrumentation techniques is mandatory. Cortical trajectory screws, in comparison to pedicle screws, take the most cortical path, which is less affected by osteoporosis, so in this study, we aim to compare the clinical and radiological outcome of cortical bone trajectory screws (CBTS) to traditional trajectory screws (TTS) in osteoporotic patients.

Patients and methods
A randomized clinical trial study was done on 59 osteoporotic patients indicated for lumbar spine fusion: 27 patients in group A were treated using CBTS, and 32 patients in group B were treated with TTS. Patients were followed for at least 1 year clinically and radiologically. Dynamic radiographs and computed tomography to assess fusion and visual analog scale and Oswestry disability index for clinical assessment.

Results
In terms of fusion rate, implant failure, operational time, incisional length, hospital stay, the incidence of complications, and clinical outcome, there was no significant difference between the two study groups (visual analog scale, Oswestry disability index). It was accompanied by decreased intraoperative blood loss than the TTS group (P=0.012) but with greater radiation exposure (P<0.001).

Conclusion
In osteoporotic patients receiving short lumbar fusion surgery, CBTS revealed comparable clinical and radiological outcomes to TTS. So, CBTS could safely replace TTS in short-structure spine fusion surgery in osteoporotic patients.

Keywords:
cortical bone trajectory screws, lumbar spine fusion, traditional trajectory screws

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Introduction

Pedicle screws are the basis of lumbar spinal instrumentation and are used to treat several spinal disorders. Pedicle screws receive the majority of their acquisition in the pedicle's trabecular and subcortical bone rather than the dense cortical bone that is significantly impacted by osteoporosis [1].

Loosening of the screws is one of the major complications leading to loss of stability of the surgical construct [2,3], especially in osteoporotic patients [4,5]. Hence, the development of novel techniques improving bone-to-screw purchase is critical to achieving essential construct integrity [3].

Cortical bone trajectory screws (CBTS) have recently been developed as an alternative to traditional trajectory screws (TTS) lumbar spine fixation. CBTS, as compared to TTS, follows a caudal to cephalad and medial to lateral trajectory that takes the most cortical path while also avoiding the midline neural components. Its more medial insertion site than conventional screws reduces the soft-tissue dissection and surgical retraction, potentially limiting perioperative problems [6] and shortening the recovery period [7].

Despite the proven biomechanical advantages of CBTS over TTS in the osteoporotic spine, as well as the fact that it is less invasive, there are not enough prospective studies comparing CBTS and TTS in the osteoporotic spine. So, we tried to compare the clinical and radiological outcomes of CBTS to ordinary pedicle screws in osteoporotic patients in short-structure fusion surgeries.

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Patients and methods

The current study is a double-blinded randomised controlled trial. Sample size calculation was carried out using G*Power 3 software [8]. A calculated minimum sample of 50 patients with degenerative lumbar diseases were randomly assigned (via closed-label technique) into one of two equal groups (1: 1 design) [group I (*n*=25); fixed with CBTSs and group II (*n*=25)]; fixed with conventional pedicle screws, would have 80% power to detect an absolute difference of 0.4 [9] in the fusion rate and, at significance level of 0.05. To compensate for an anticipated dropout rate of 30%, 75 patients were required (flow chart). Only patients with degenerative lumbar diseases, documented osteoporosis by dual energy X-ray absorptiometry (DEXA), and failed conservative management for 6 months were included in our study. Cases with infection, tumors, congenitally small pedicles, congenital pars defects, and a lack of cortical bone at the pars were excluded from our study. Ethical approval was waived by the local ethics committee of our university in view of the retrospective nature of the study, and all the procedures being performed were part of the routine care.

Preoperative visual analog scale (VAS) and Oswestry disability index (ODI) questionnaires were used. Detailed neurological examinations were performed. Plain radiographs, MRI, computed tomography (CT), and DEXA scans were ordered for all patients. CT is important for the detection of pedicle morphology. Too small a pedicle and defective bars are contraindications of CT scan use [8]. In group A, 27 patients were fixed with CBTSs. In group B, 32 patients were fixed with conventional pedicle screws. All patients were followed for 24 months. All patients received antiresorptive therapy (bisphosphonate) in addition to vitamin D and calcium. Bisphosphonate was initiated 2 weeks postoperatively, weekly, until the end of the follow-up period, with a drug holiday every 6 months.

In group A 'CBT screws fixation' a standard midline posterior subperiosteal dissection was performed bilaterally to the medial facet, exposing the lateral lamina and the pars interarticularis. Starting point on the pars interarticularis, 2 mm medial and caudal to the superior articulating process. The initial hole was made by the pedicle awl. Then under C-arm guidance, the trajectory of the screw was 5°–15° from medial to lateral in the coronal plane and 25° caudo-cranial in the sagittal plane. Then, interbody fusion was performed using polyetheretherketone cages with autologous bone graft.

Group B 'traditional trajectory pedicular screws fixation'

The midline posterior subperiosteal dissection was performed bilaterally till the base of the transverse process, exposing the lateral lamina with the whole facet. Pedicle screws were inserted, followed by decompression and interbody fusion with polyetheretherketone cages and autologous bone graft, with no posterolateral fusion.

Immediate postoperative radiograph and CT scan were done. All patients underwent a follow-up period of up to 24 months postoperatively (including different checkpoints: 3, 6, 12, and 24 months). Patients were assessed radiographically and clinically. Clinical assessment was done using the VAS and ODI. Surgical morbidity includes operating time, incision length, estimated blood loss, and drainage volume. The incidence of intraoperative complications (nerve-root injury, durotomy, and screw malposition) and postoperative complications (infection, cage displacement, screw loosening, and revision surgery) were all assessed.

Results

Fifty-nine patients who matched our inclusion criteria and follow-up were recruited in our study: group A: CBTS (27 patients) and group B: TTS (32 patients). There were no significant differences between both groups regarding age, sex, BMI, comorbidities, smoking status, pathology, DEXA scan *t* score, or the number of fused levels (Tables 1, 2).

In group A, there were 17 cases with degenerative spinal canal stenosis, eight cases with degenerative spondylolisthesis, and two cases with adjacent segment disease, while in group B, there were 21 cases with degenerative spinal canal stenosis, 10 cases with degenerative spondylolisthesis, one adjacent segment disease there was no statistical difference between both groups; *P* value=0.757 (Table 2).

All cases were assessed by dynamic radiographs and CT after 6, 12, 18, and 24 months, respectively. Fusion at 2 years postsurgery was achieved in 25 (92.6%) of 27 patients in group A and 31 (96.9%) of 32 patients in group B. The fusion rate did not differ significantly between the two groups (*P*=0.435) (Tables 3–5).

Clinical outcome

VAS and ODI scores were obtained for both groups preoperatively, at discharge, 3, 6 months, and 1 year postoperatively. Postoperative results were significantly better compared with the preoperative results. However, there was no significant difference between both groups. There was no significant difference between both groups regarding the ODI scores.

Table 1 Sociodemographic data in both studied groups

Variables	Group A (CBTS) (*N*=27)	Group B (TTS) (*N*=32)	*P*
Age (years) (mean±SD)	70.52±10.19	74.75±6.69	0.061*
Sex [*n* (%)]			
Female	20 (74.1)	25 (78.1)	0.716**
Male	7 (25.9)	7 (21.9)	
BMI (mean±SD)	28.59±2.36	29.63±1.96	0.101*
Diabetes mellitus [*n* (%)]	4 (14.8)	7 (21.9)	0.488*
Hypertension	8 (29.6)	11 (34.4)	0.698*
Smoker	6 (22.2)	9 (28.1)	0.604**
DEXA	−2.63	−2.73	0.101*

CBTS, cortical bone trajectory screws; DEXA, dual energy X-ray absorptiometry; TTS, traditional trajectory screws.
*Independent sample *t* test was used to compare the mean between groups.
**χ^2 test was used to compare frequency between groups.
P value less than or equal to 0.05 (statistically significant).

Table 2 Diagnoses and intervention strategies according to treatment group

Variables	Group A (CBTS) (*N*=27)	Group B (TTS) (*N*=32)	*P*
Diagnosis [*n* (%)]			0.757*
Spinal canal stenosis	17 (63)	21 (65.6)	
Degenerative spondylolisthesis	8 (29.6)	10 (31.3)	
Foraminal stenosis	2 (7.4)	1 (3.1)	
Fused spine level (PLIF)			0.447*
Single level	24	25	
Double level	3	6	
Three level	0	1	

CBTS, cortical bone trajectory screws; PLIF, posterior lumbar interbody fusion; TTS, traditional trajectory screws.
*χ^2 test was used to compare frequency between groups.

Table 3 Fusion rate

Variables	Group A (CBTS) (*N*=27) [*n* (%)]	Group B (TTS) (*N*=32) [*n* (%)]	*P*
Fusion rate	25 (92.6)	31 (96.9)	0.435*

CBTS, cortical bone trajectory screws; TTS, traditional trajectory screws.
*χ^2 test was used to compare frequency between groups.
P value less than or equal to 0.05 (statistically significant).

No statistically significant difference between groups according to operative time (*P*=0.839) or incision length (*P*=0.056). The mean intraoperative blood loss was 449.63±148.08 ml for group A and 576.56±216.27 ml for group B with a statistically significant difference between groups according to intraoperative blood loss (*P*=0.012).

The mean intraoperative blood transfusion for group A was 27.78±80.06 ml, and for group B was 117.19±228.82 ml which was statistically significant (*P*=0.130). The mean intraoperative radiation exposure for group A was 57.15±15.68 sc, and for group B it was 37.78±9.09 s which was statistically significant (*P*<0.001) (Table 6).

Table 4 Visual analog scale score

Variables	Group A (CBTS) (*N*=27) (mean±SD)	Group B (TTS) (*N*=32) (mean±SD)	*P*
VAS score pre	7.59±1.47	7.59±1.14	0.963**
VAS score post	4.81±0.786	4.94±0.759	0.524**
VAS score 3 months	3.78±0.801	3.94±0.716	0.459**
VAS score 6 months	2.56±0.801	2.78±0.792	0.300**
VAS score 12 months	1.45±0.51	1.8±0.62	0.058**

CBTS, cortical bone trajectory screws; TTS, traditional trajectory screws; VAS, visual analog score.
*Independent sample *t* test was used to compare the mean between groups.
P value less than or equal to 0.05 (statistically significant).

Intraoperative and postoperative complications

No patients in either group developed an infection, hematoma formation, and neurological deficits. Two cases in CBTS associated with malposition screws with no significance (*P*=0.205). There was one case in the CBTS group and two cases in the TTS group in which a dural tear was present. It was repaired primarily with no postoperative cerebrospinal fluid leak. There were two cases of pseudoarthrosis and instability in the CBTS group and only one case of implant failure in the TTS group, but there was no significant difference between the two groups (*P*=0.435). Two cases of ASD developed in the CBTS group after 18 and 20 months, respectively, compared to one case in the pedicle group after 16 months with no significance (*P*=0.435) (Table 7, Figs 1–5).

Discussion

Surgeries on osteoporotic spines are always associated with a high risk of complications like screw loosening (it may reach 60%), implant failure, pseudoarthrosis, or adjacent level disease [2,5,10].

Table 5 Oswestry disability index score

Variables	Group A (CBTS) (*N*=27) (mean±SD)	Group B (TTS) (*N*=32) (mean±SD)	*P*
ODI score pre	52.07±26.72	54.75±27.18	0.742**
ODI score post	23.63±3.09	23.63±2.98	0.901**
ODI score 3 months	18.74±2.80	18.63±2.80	0.686**
ODI score 6 months	15.26±2.55	15.00±2.54	0.888**
ODI score 12 months	11.3±2.36	12.7±2.27	0.449**

CBTS, cortical bone trajectory screws; ODI, Oswestry disability index; TTS, traditional trajectory screws.
**Independent sample *t* test was used to compare the mean between groups.
P value less than or equal to 0.05 (statistically significant).

Table 6 Surgical procedural data according to treatment group

Variables	Group A (CBTS) (*N*=27) (mean±SD)	Group B (TTS) (*N*=32) (mean±SD)	*P*
Operative time (min)	123.67±17.32	124.56±16.29	0.839**
Incision length (cm)	5.44±0.974	6.41±1.86	0.056**
Intraoperative blood loss (ml)	449.63±148.08	576.56±216.27	0.012**
Intraoperative blood loss (ml)	27.78±80.06	117.19±228.82	0.130**
Intraoperative radiation exposure (s	57.15±15.68	37.78±9.09	<0.001**
Postoperative drain amount	588.52±292.40	732.97±227.39	0.052**
Hospital stay (days)	4.07±0.781	4±0.803	0.722**

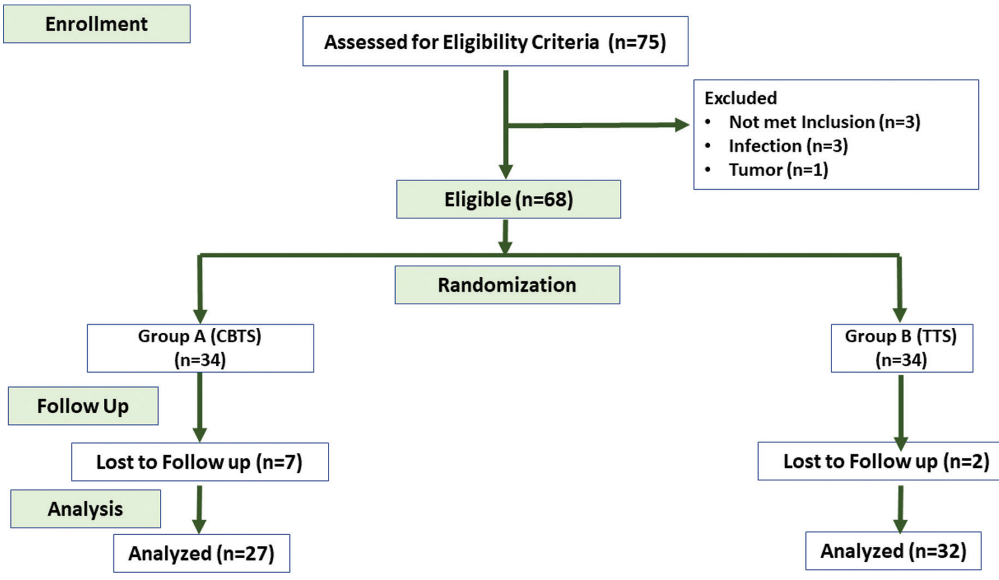
CBTS, cortical bone trajectory screws; SD, standard deviation; TTS, traditional trajectory screws.
**Independent sample *t* test was used to compare the mean between groups.
P value less than or equal to 0.05 (statistically significant).

Table 7 Complications

Variables	Group A (CBTS) (*N*=27) [*n* (%)]	Group B (TTS) (*N*=32) [*n* (%)]	*P*
Infection	0	0	–
Wound complication	1 (3.7)	1 (3.1)	0.710*
Dural tear	2 (7.4)	1 (3.1)	0.565*
Malposition	2 (7.4)	0	0.205*
Misplacement	0	0	–
Hematoma formation	0	0	–
Neurological deficit	0	0	–
Pseudoarthrosis and implant failure	2 (7.4)	1 (3.1)	0.435*
ASD	2 (7.4)	1 (3.1)	0.435*

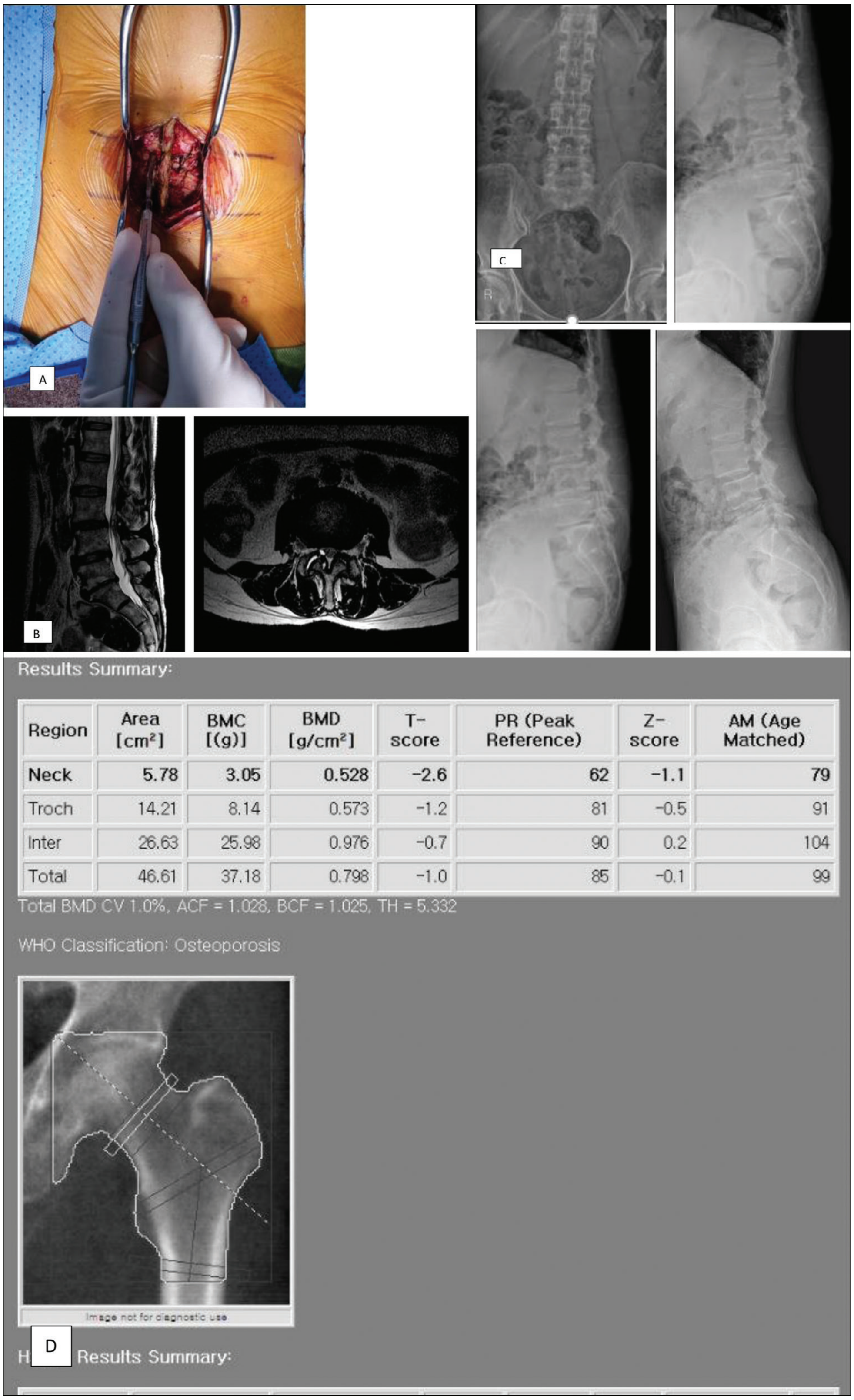
ASD, adjacent segment disease; CBTS, cortical bone trajectory screws; TTS, traditional trajectory screws.
*χ^2 test was used to compare frequency between groups.
P value less than or equal to 0.05 (statistically significant).

Figure 1



Flow diagram of the study selection.

Figure 2



Region	Area [cm²]	BMC [(g)]	BMD [g/cm²]	T-score	PR (Peak Reference)	Z-score	AM (Age Matched)
Neck	5.78	3.05	0.528	-2.6	62	-1.1	79
Troch	14.21	8.14	0.573	-1.2	81	-0.5	91
Inter	26.63	25.98	0.976	-0.7	90	0.2	104
Total	46.61	37.18	0.798	-1.0	85	-0.1	99

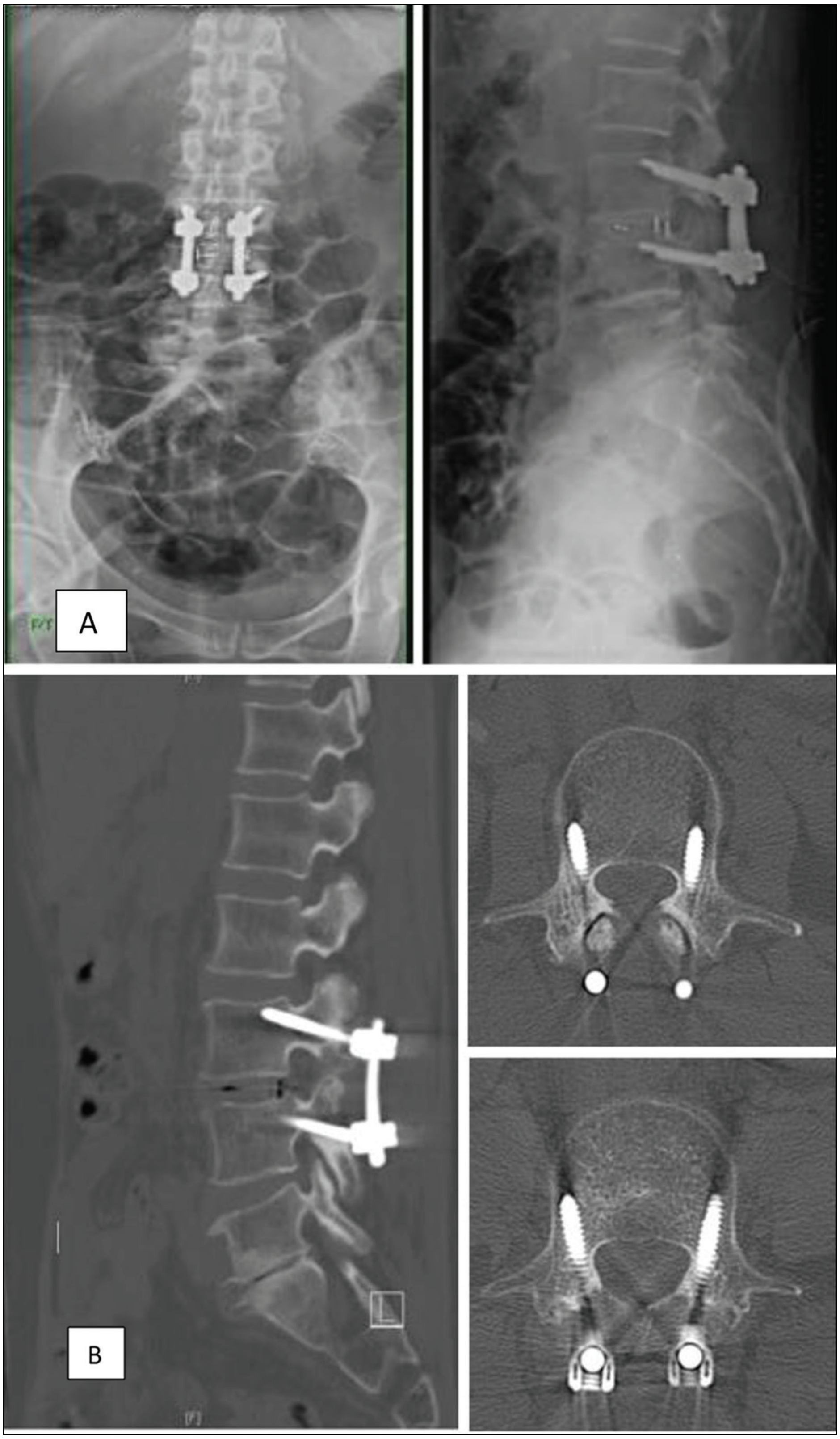
(a) Midline posterior dissection up to medial facets and exposure of the pars for screw entry. (b) MRI showing L3–L4 lumbar canal stenosis. (c) Preoperative radiographs showing L3–L4 degenerative spondylolisthesis. (d) DEXA scan of neck femur *t* score=–2.6. DEXA, dual energy X-ray absorptiometry.

CBT is a unique fixation technique that is based on thread contact with the cortical bone surface in the pedicle isthmus and the superior endplate [11–13].

Santoni and colleagues found that CBTS had a 30% increase in uniaxial yield pullout load compared to TTS, in addition to increased insertion torque in their cadaveric investigation [6,11,14–18]. It has been thought to be especially beneficial in osteoporotic individuals because the cortical bone was less impacted by osteoporosis than the cancellous bone [15,19].

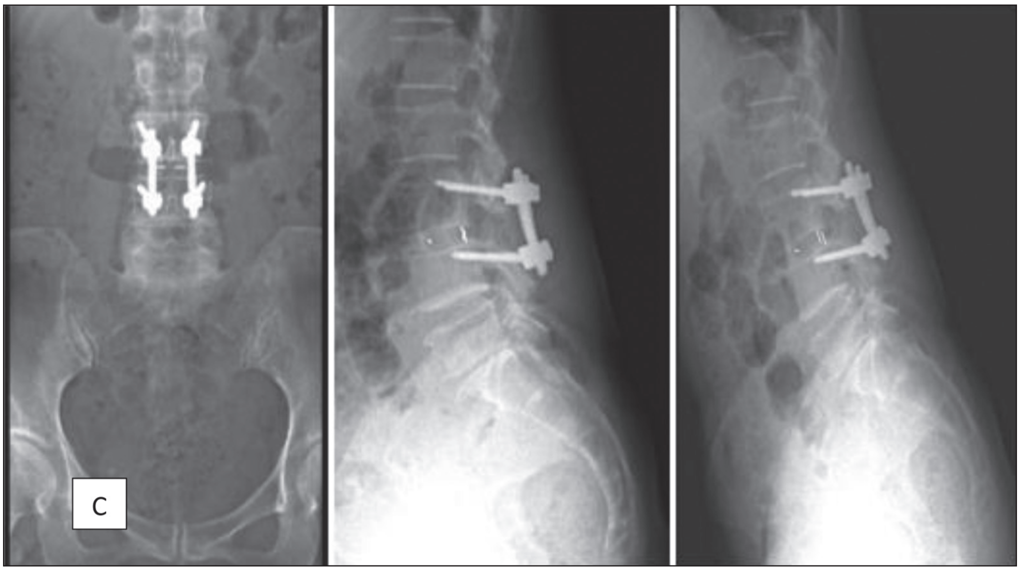
It also allows for a minimally invasive approach with less muscle dissection, meaning less postoperative pain. In addition to its cranio-lateral trajectory, it avoids the

Figure 3



(a) Immediate postoperative radiographs. (b) Sagittal and axial CT for CBTS showing good placement of screws. (c) Twenty-four months postoperative dynamic radiographs showing fair fusion. CBTS, cortical bone trajectory screws; CT, computed tomography.

Figure 3



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adjacent spinal cord, nerve roots, and vascular structure [6,11,20–22].

In our study

The fusion rate was the primary endpoint of our study. Fusion was achieved in 25 (92.6%) of 27 patients in the CBTS group and 31 (96.6%) of 32 patients in the TTS group. There was no significant difference between both groups (*P*=0.435), which was consistent with previous studies [23–25]. Clinical outcome and patient satisfaction were the second endpoints in our study. Although postoperative VAS scores were significantly better than preoperative, there was no statistically significant difference between the two groups in VAS scores. In Wang *et al.*'s [26] meta-analysis, he reported that the outcomes for VAS scores for back pain were better for the CBTS, but it could not reach significance. Also, Zhang and colleagues reported that there was no significant difference between both groups [23,24,27–31]. Only Lee *et al.* [9], observed improvement in back pain in the first week following surgery with the CBTS group. However, long-term pain was not significantly different. He explained that it could be because of the smaller skin incision, less muscle attachment disruption, and soft-tissue dissections [23]. Overall, it is clear that CBTS results in comparable or reduced postoperative pain when compared to the TTS technique. Second is ODI: in our study, there was no significant difference regarding the ODI during follow-up for both groups. However, it was consistent with previous studies' findings [23,32–34], Chin and colleagues, found that the CBTS group had a significantly lower postoperative ODI score than the TTS group (*P*=0.027), and Zhang *et al.* reported that the CBTS group had a significant improvement over the TTS group in his meta-analysis [29,30]. It may be related to decreased operative time, soft-tissue dissection, and less postoperative pain.

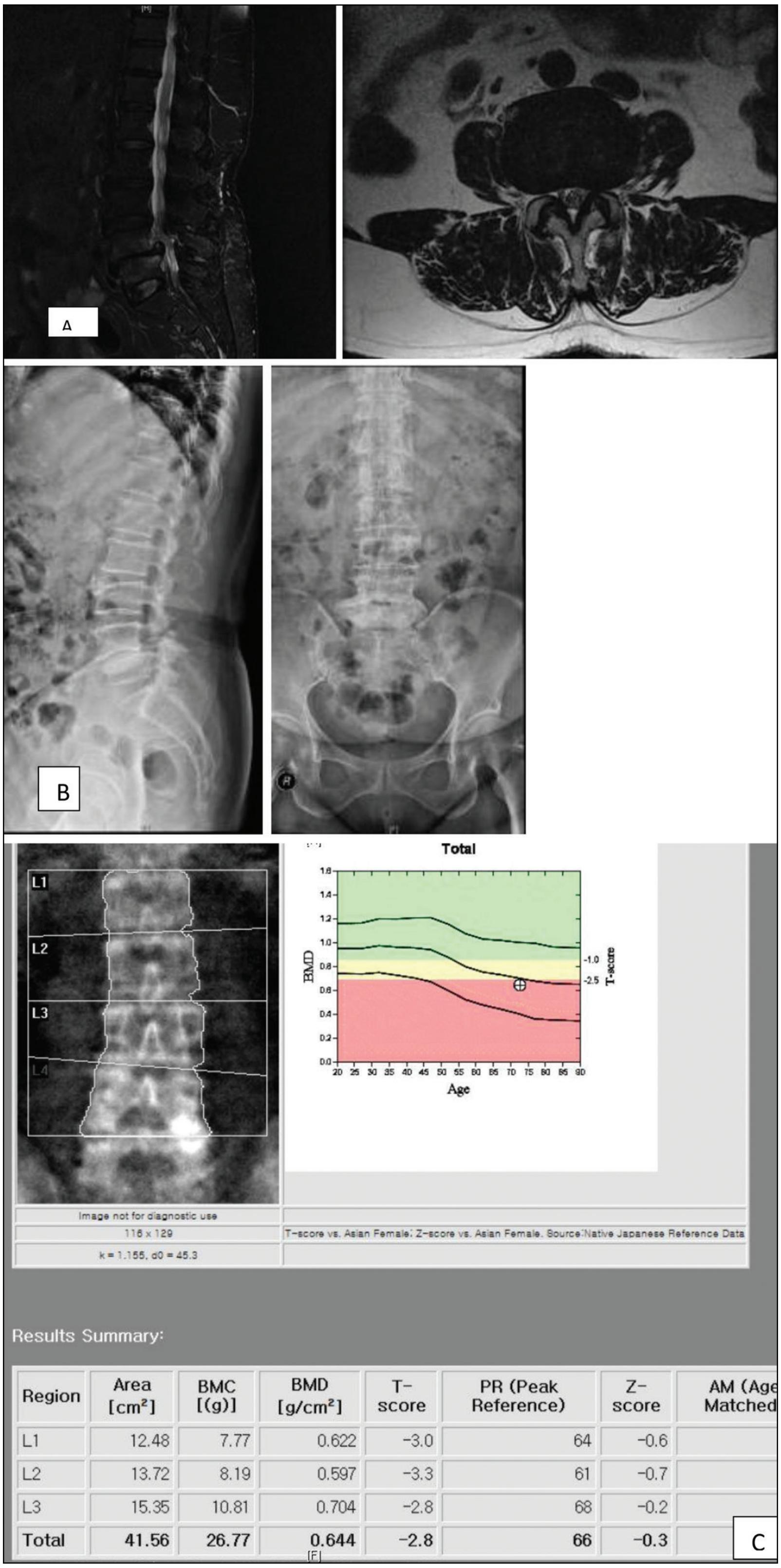
Regarding intraoperative blood loss, there was a significant reduction in intraoperative blood loss *(P value 0.012).*

In Wang *et al.*'s meta-analysis of 450 patients with CBTS and 460 patients with TTS, the overall results showed that the CBTS group was associated with less intraoperative estimated blood loss [26]. In addition, Zhang and colleagues meta-analysis of two randomised controlled trial studies and 10 cohort study of the pooled outcome confirmed that the CBTS technique was associated with less intraoperative blood loss [35].

Regarding radiation exposure: in our study, there was a statistically significant difference between groups according to intraoperative radiation exposure (*P*<0.001). However, in Marengo *et al.*'s [36] study, there was no significant difference between both groups (*P*=0.6913). We assume that it may be related to our learning curve, particularly in our late cases, where it was associated with less documented radiation exposure.

Complication assessment is critical in determining the clinical safety of the CBT group in comparison to the TTS group in the treatment of osteoporotic patients. Perioperative complications would have a significant

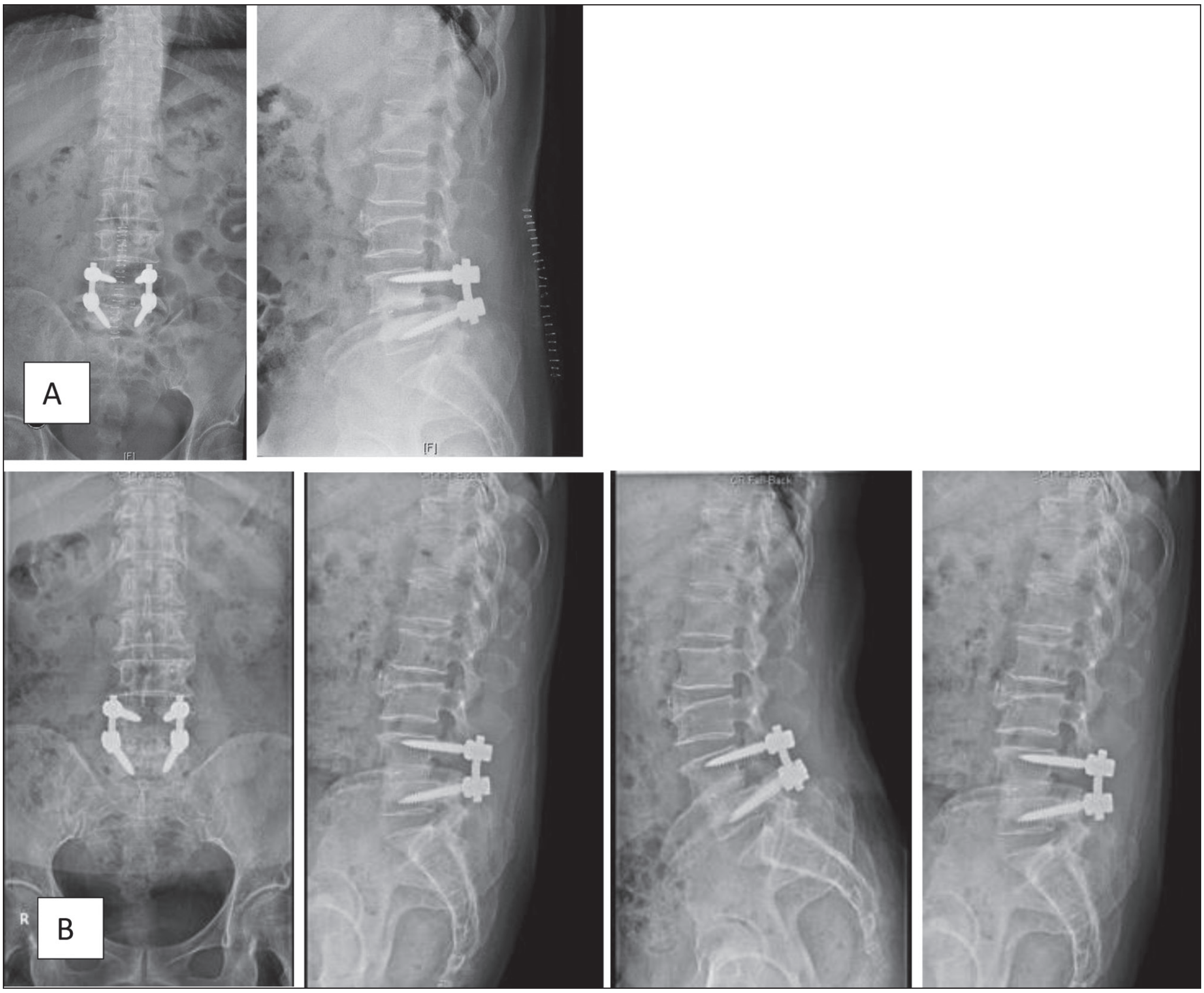
Figure 4



(a) MRI showing L4–L5 lumbar canal stenosis. (b) Preoperative radiographs showing L4–L5 degenerative spondylolisthesis. (c) DEXA scan of lumbar spine=−2.8. DEXA, dual energy X-ray absorptiometry.

impact on clinical outcomes and patient satisfaction [37]. First, mal-positioning of screws is a very crucial issue. The lower cranial and higher lateral directions of CBTS, according to Lee *et al.* [9], are associated with a high incidence of loosening and, thus, a less favorable clinical outcome. However, there were two cases with screw mal-positioning; by the end of the follow-up, solid bony fusion had occurred in both cases in the CBTS group, with good

Figure 5



(a) Immediate postoperative radiographs. (b) Twenty-four months postoperative dynamic radiographs showing fair fusion.

functional outcomes and no mechanical instrumentation failure. Also, we assume the high incidence of bony fusion despite osteoporosis may be attributed to the addition of interbody fusion with enormous bony grafts in both study groups. For the late postoperative complications, besides its biomechanical strength, CBTS provides the advantage of minimal soft-tissue dissection, particularly lateral to the proximal facet, which theoretically decreases the incidence of adjacent segment disease [6,20,21,35,36,38,39].

As reported by Matsukawa *et al.* [35], the incidence of cranial facet joint violation by CBTS was 11.8% with no intra-articular violation compared to 15–100% with the TTS. As a result, it was expected to reduce the occurrence of adjacent segment disease. However, in our study, two cases developed adjacent segment disease with cortical screws (after 12 and 20 months of follow-up) and only one case with pedicle screws (after 16 months of follow-up), but this finding was not statistically significant (P=0.435).

In Sakaura and colleagues, study, two cases from the CBTS group and four cases from TTS developed ASD. Only two cases of TTS patients required revision surgery, while the CBTS patients were managed conservatively with good results. Despite the incidence of ASD being doubled with TTS, Sakaura *et al.* [33] could not reach significance. The same author, in a recent study, confirmed that the radiological findings exceed the clinical ones [40,41]. However, our results are not consistent with those of previous studies. We suppose that it might be related to an increase in construct stiffness. Furthermore, we believe a larger study group and a longer period of follow-up are required to achieve significance.

Limitations

Our study has some limitations. The sample size was small; however, we aimed to make the study population homogenous. A longer follow-up period is required for a better assessment of functional outcomes and late postoperative complications. Furthermore, more studies assessing long-segment fusion using CBTS are required, particularly in osteoporotic patients.

Conclusion

CBTS showed comparable results to TTS regarding fusion rate, operative time, incisional length, hospital stay, the incidence of complications, and clinical outcome (VAS, ODI). Moreover, it was associated with less intraoperative blood loss than the TTS group, but it may be accompanied by more radiation exposure. So, CBTS could safely replace TTS in short-structure spine fusion surgery in osteoporotic patients.

Authors' contribution statement

Mahmoud A. Moussa: conceptualization, design of methodology, investigation, data collection, writing-original draft preparation, agree to be accountable for the work, and approval of the final version of the manuscript. Kamal M.A. Meguid: investigation, curation of data, data collection, writing the original draft of the manuscript, agreeing to be accountable for the work, and approval of the final version of the manuscript. Haytham A.-M. Abdel-Ati: curation, analysis, and interpretation of data, data collection, writing the original draft of the manuscript, agreeing to be accountable for the work, and approval of the final version of the manuscript. Ihab M. Emran: investigation, data analysis, data collection, interpretation and writing of the original draft of the manuscript, agree to be accountable for the work and approval of the final version of the manuscript. Mohamed A. Moussa: managing the work, supervision, data collection, revision of the final manuscript, writing-original draft preparation, agreeing to be accountable for the work, and approval of the final version of the manuscript.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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