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Original Article

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Comparison of Cortical Bone Trajectory to Pedicle-Based Dynamic Stabilization: An Analysis of 291 Patients

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Objective: Pedicle-based dynamic stabilization (DS) has gained popularity outside of America. Although pedicle screw (PS) loosening has always been a concern, it is reportedly innocuous. Cortical bone trajectory (CBT) screw is an emerging option with less invasiveness and similar effectiveness to PS in short-segment lumbar fusion. This study aimed to verify the use of CBT for DS by comparing the outcomes between pedicle- and CBT-based DS.
Methods: Consecutive patients with lumbar spondylosis or low-grade spondylolisthesis who underwent 1- or 2-level DS between L3–5 with a minimum follow-up of 24 months were reviewed. Screw loosening was determined by computed tomography and the incidences were compared.
Results: A total of 291 patients who underwent Dynesys DS (235 pedicle- and 56 CBT-based, respectively) were compared. The demographics and preoperative conditions were similar. All the clinical outcomes improved at 24-month postoperation, while the CBT-based group had less operation time and blood loss than the pedicle-based group. The rates of screw loosening were lower in the CBT-based (5.4% per screw and 12.5% per patient) than the pedicle-based group (9% per screw and 26.4% per patient). Furthermore, there were no differences in the clinical outcomes and complication profiles.
Conclusion: The CBT-based DS for 1- or 2-level lumbar degeneration demonstrated equivalent clinical improvement as the pedicle-based DS. The adaption of CBT-based screws for DS could be a less invasive approach (shorter operation time and less blood loss), with lower chances of screw loosening than the conventional PS-based DS.

Keywords: Pedicle screw-based, Dynamic stabilization, Screw loosening, Cortical bone trajectory

INTRODUCTION

Although lumbar fusion remains a standard surgical option for instability caused by spondylosis or spondylolisthesis, spinal arthrodesis inevitably would raise the concern of decreased segmental mobility and subsequent risks of adjacent segment disease (ASD). Therefore, there has been the emerging technology of dynamic stabilization (DS) as an alternative management, which has aimed at preservation of the segmental motion and mitigation of the risks of ASD.[1-15] In the past decade, reports have demonstrated satisfactory outcomes, including clinical improvements, low complication rates, and potential of motion preservation in the management of lumbar degenerative diseases of short-segments.[5,7,9,16,17] However, there are also adverse events reported with DS, including pedicle screw (PS) loosening and unintended facet arthrodesis.[18-21]

In the nonfusion construct of DS, which theoretically under long-term and repeated mechanical load, the PS reasonably may be subject to loosening or fatigue at the metal-to-bone interface.[22] In the literature regarding DS, the reported incidences of PS loosening varied among the series, ranging from 7% to 20%.[1,2,5,7-11,13,16,23,24] Interestingly, the PS loosening of DS is usually associated with little adverse clinical outcomes, and some of the recent series have attributed this to the unintended facet fusion after DS.[18,19,21] Furthermore, it is unclear whether the dynamic motility of lumbar segments after instrumentation is maintained for long or they are fused slowly.[19,21]

The recent innovation of cortical bone trajectory (CBT) screws, first reported in 2009 as an alternative to traditional PS,[25,26] assume a medial-to-lateral and caudal-to-cephalad direction to engage the dense cortical bone of pars interarticularis, pedicle, and lateral wall of the vertebrae (Fig. 1). The adaption of CBT has demonstrated feasibility and effectiveness in short-segment lumbar fusion surgery.[25,27-29] According to biomechanical studies, the CBT had up to a 30% increase of pullout strength compared to the conventional pedicle trajectory.[26,30] Since CBT potentially improves bone-to-screw osteointegration and reinforces the screw purchase to decrease screw loosening or breakage, it might be a reasonable innovation to adapt CBT for DS in the management of lumbar instability.[31] Moreover, CBT screws require less muscle dissection than the conventional PS, because the medial-to-lateral directions of CBT spare the need for exposure of the transverse-process-facet junction. Less extensive dissection of the soft tissues for CBT may also merit the rationale of motion preservation in DS. The authors have previously reported the safety and feasibility of CBT-based DS.[31]

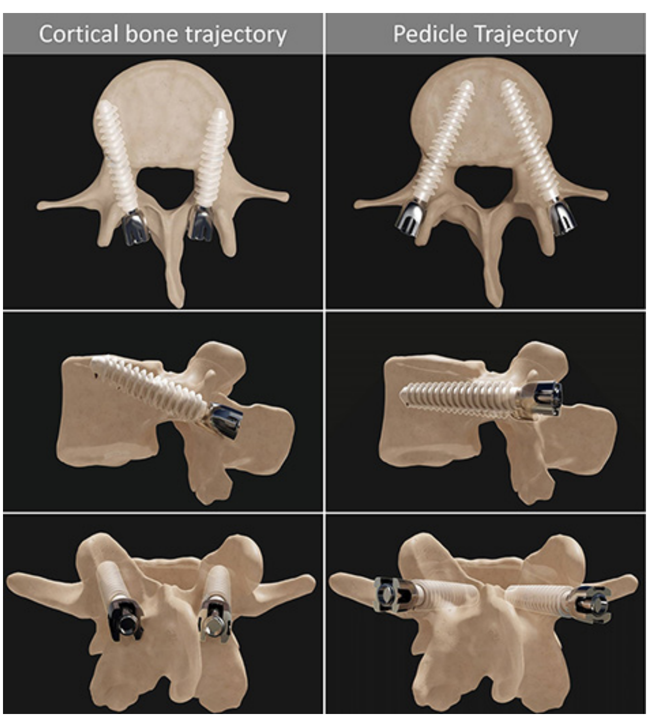

Fig. 1. Comparison of cortical bone trajectory and pedicle trajectory.

In this study, an attempt was made to compare the innovative CBT-based DS to standard pedicle-based DS. Clinical and radiological evaluations, including screw loosening, over more than 2 years of follow-up are demonstrated.

MATERIALS AND METHODS

1. Study Design and Patient Inclusion

This was a single center, retrospective comparison study that included consecutive patients with degenerative disease between L3 to L5 who underwent DS. The DS was indicated in patients who had degenerative spondylosis included symptomatic lumbar spinal stenosis without instability, recurrent disc herniation with or without previous discectomy, degenerative disc disease with discogenic pain, intractable radicular pain, back pain, or neurologic claudication that were refractory to conservative treatment for more than 4 months. The DS was also indicated in patients who had spondylolisthesis no more than Meyerding grade I (percentage of vertebrae slip between 0% to 25%). Exclusion criteria were patients who did not complete the 24-month follow-up, had involved levels of disease other than at L3-4-5, spondylolisthesis more than Meyerding grade I, lytic spondylolisthesis, or thoracolumbar deformity indicated by screening standing radiographs. All methods were carried out in accordance with STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines and regulations. The study protocol had been approved by the Institutional Review Board (IRB) of Taipei Veterans General Hospital (IRB No. 2019-12-001AC) and informed consent from each patient was obtained.

All patients used the same system of instrumentation, Dynesys DS (Zimmer Biomet, Warsaw, IN, USA) featured with screws, polycarbonate urethan spacers, and polyester cords to achieve DS. Since mid-2017, all patients who underwent DS adopted the CBT screws in the authors' service and were compared to previous patients who used the PS in DS. Thus, patients were grouped into two: the PS-based and the CBT-based groups by the timing of surgery. All the perioperative management and follow-ups were constant in the series.

2. Surgical Technique

1) Decompression

After general anesthesia, patients were put in a prone position on the Wilson frame with neutral lumbar lordosis. A midline incision was made and deepened for subperiosteal muscular dissection. The lamina was removed as well as the thickened ligamentum flavum. The medial part of the facet joints was removed up to the pedicles to decompress the lateral recess. If needed, foraminotomy was performed by removing bone spur and flavum ligament with curette and Kerrison rongeur to enlarge the foramen. Nerve roots were palpated along the exiting path with a Woodson dissector to ensure adequate decompression of the neuroforamen. Typically, the surgery required no discectomy since the lateral recesses were always decompressed thoroughly. However, removal of sequestrated disc fragments was performed on those patients who had ruptured intervertebral discs. Care was taken to avoid violation of the facets more than the medial-third.

2) Pedicle-based DS

From the midline wound, bilateral fascia dissections were then made for entering the intermuscular plane (Wiltse plane) under the guidance of intraoperative fluoroscopy. The Dynesys screws were placed in a transpedicular trajectory via the insertion point at the base of the transverse process without additional facet destruction. The length and diameter of the screws were determined by preoperative computed tomography (CT) scans and confirmed intraoperatively. The diameter of the most commonly used screws in pedicle-based DS was 6.4 mm. The polycarbonate urethan spacers were tailored for only slight distraction of the facet joints. The spacers were then inserted together with the polyester cord, following the standard procedures.[3,4,12,20] (Fig. 2. Please see https://sketchfab.com/TaroYen/models for interactive 3-dimensional images and an enhanced version of Fig. 2).

3) CBT-based DS

The entry points of the CBT screws were generally over the cephalad lateral part of the pars interarticularis, slightly caudal to the sulcus of the facet complex. A high-speed drill was used to break through the cortex. The trajectory was confirmed by intraoperative fluoroscopy, which allowed the screw to course through the dense cortical bone with the screw tip barely penetrating the cortex of the vertebral body laterally. According to biomechanical studies, the proper size of CBT screws was 5.0 to 5.5 mm in diameter and 35 to 40 mm in length.[32] Therefore, the most commonly used screws were 5.2 mm × 35 mm in CBT-based DS. A 5.2-mm cannulated tap was used to create the screw tract. The Dynesys screws were subsequently placed. The polycarbonate urethan spacer and polyethylene-terephthalate cord were subsequently assembled[31] (Fig. 2).

4) Clinical evaluation

The clinical data were prospectively collected and retrospectively reviewed. Clinical outcomes, including visual analogue scale (VAS) for back and leg pain and the Oswestry Disability Index (ODI) scores, were assessed pre-operatively and at 6 weeks and at 3, 6, 12, 18, and 24 months postoperatively.

5) Radiographical evaluation

Every patient underwent preoperative lumbar images, including anteroposterior and lateral radiography, lateral dynamic radiography, magnetic resonance imaging and CT scans. Fol-

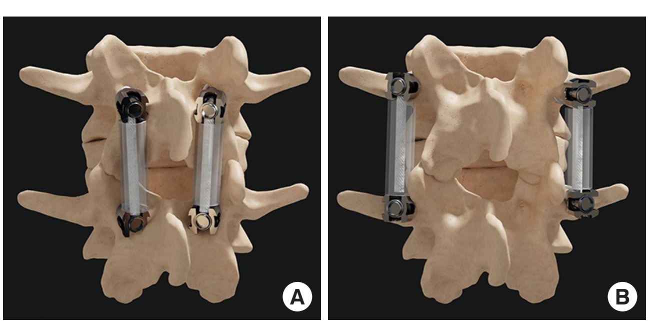

Fig. 2. Illustration of cortical bone trajectory (A) and pedicle-based dynamic stabilization (B). Copyright Shao-Yen Huang. Published with permission. Please see https://sketchfab.com/TaroYen/models for interactive 3-dimensional images and an enhanced version of Fig. 2.

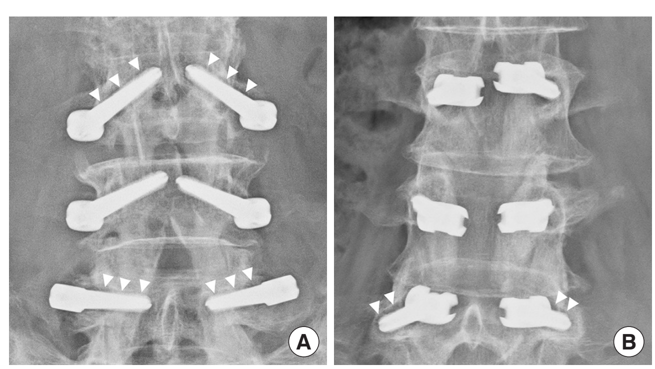

Fig. 3. Radiographs of (A) a 73-year-old male who underwent Pedicle-based dynamic stabilization at L3-4-5, (B) a 68-year-old female who underwent cortical bone trajectory dynamic stabilization at L3-4-5. Loosened screws are documented (arrowhead).

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low-up images included standard anteroposterior, lateral and flexion-extension radiography immediately postoperative, and at 6 weeks, and at 3, 6, 12, 18, and 24 months after surgery. An initial halo sign (a radiolucent line around the implant > 1 mm wide) followed by a double halo sign on anteroposterior radiographs or CT scans was defined as screw loosening[2-4,12,20] (Fig. 3). The measurement was performed using quantitative measurement analysis software (SmartIris, Taiwan Electronic Data Processing Co.) For any ambiguity, the CT scan was reviewed with radiologists for the final determination of a halo sign.

3. Statistics

Medcalc (Ostend, Belgium) was used for statistical analysis. Descriptive statistics were reported as means and standard deviations, and as frequencies and percentages where appropriate. Continuous variables were compared using an unpaired Student t-test, and categorical variables were compared using Pearson chi-square test. Probability values were 2-tailed and an alpha of 0.05 was considered statistically significant.

RESULTS

1. Demographics

A total of 291 consecutive patients were included in this study. The first 235 patients received pedicle-based DS and the later 56 patients underwent CBT-based DS. The mean age was 61.7 ± 10.9 versus 62.5 ± 10.4, p = 0.61. There were 117 male patients (49.7%) in the pedicle-based group compared to 27 (48.2%) in the CBT-based group (p = 0.83). Medical comorbidities were similar between the 2 groups, as the incidence rates of hypertension and diabetes mellitus were similar (42.6% vs. 37.5% and 21.7% vs. 16.1%, p = 0.49 and 0.35, respectively) in both groups. There was no difference in the body mass index (BMI) between the 2 groups (25.8 ± 3.8 kg/m^2 vs. 25.7 ± 2.4 kg/m^2, p = 0.92). The pathologies and distribution of levels were also similar in both groups (p = 0.82 and 0.87, respectively). The pedicle-based group had an average longer follow-up than the CBT-based group (61.8 ± 34.9 months vs. 31.2 ± 6.1 months, p < 0.001) (Table 1).

Table 1. Demographics

Variable	Pedicle-based DS	CBT-based DS	p-value
No. of patients	235	56	
Mean age (yr)	61.7 ± 10.9	62.5 ± 10.4	0.61
Sex, male:female	117:118	27:29	0.83
Hypertension	100	21	0.49
Diabetes mellitus	51	9	0.35
Body mass index (kg/m^2)	25.8 ± 3.8	25.7 ± 2.4	0.92
Level			0.82
L3/4	14	4	
L4/5	93	24	
L3/4/5	128	28	
Pathology			0.87
Spondylosis	116	27	
Spondylolisthesis	119	29	
Follow-up (mo)	61.8 ± 34.9	31.2 ± 6.1	< 0.001*

Values are presented as mean ± standard deviation or number.
DS, dynamic stabilization; CBT, cortical bone trajectory.
*p < 0.05.

2. Perioperative Parameters and Clinical Improvement

In this study, patients of the CBT-based group used significantly less operation time for both 1-level and 2-level surgery (163.2 ± 26.6 minutes vs. 196.9 ± 62.1 minutes, p = 0.005 and 227.1 ± 43.1 minutes vs. 257.7 ± 75.3 minutes, p = 0.04, respectively) than the pedicle-based group. The CBT-based group also had significantly less blood loss for 1-level and 2-level surgery (173.2 ± 157.2 mL vs. 399.1 ± 303.3 mL, p < 0.001 and 353.7 ± 248.8 mL vs. 816.8 ± 463.7 mL, p < 0.001, respectively) than the pedicle-based group (Table 2).

Both groups demonstrated significant improvement in VAS for back and leg pain, and ODI scores. Moreover, both groups demonstrated similar scores in VAS for back pain (2.3 ± 2.5 vs. 2.2 ± 2.5, p = 0.88), VAS for leg pain (2.1 ± 2.7 vs. 2.5 ± 2.5, p = 0.62), and ODI scores (19.6 ± 17.3 vs. 15.5 ± 10.8%, p = 0.43) at the final follow-up, 24 months after surgery (Fig. 4).

3. Screw Loosening, Fracture, and Other Complications

There was no breach of the screws that caused symptoms or

Table 2. Comparison of perioperative parameters

Variable	Pedicle-based DS	CBT-based DS	p-value
Operation time (min)			
1 Level	196.9 ± 62.1	163.2 ± 26.6	0.005*
2 Levels	257.7 ± 75.3	227.1 ± 43.1	0.04*
EBL (mL)			
1 Level	399.1 ± 303.3	173.2 ± 157.2	< 0.001*
2 Levels	816.8 ± 463.7	353.7 ± 248.8	< 0.001*

Values are presented as mean ± standard deviation.
DS, dynamic stabilization; CBT, cortical bone trajectory; EBL, estimated blood loss.
*p < 0.05.

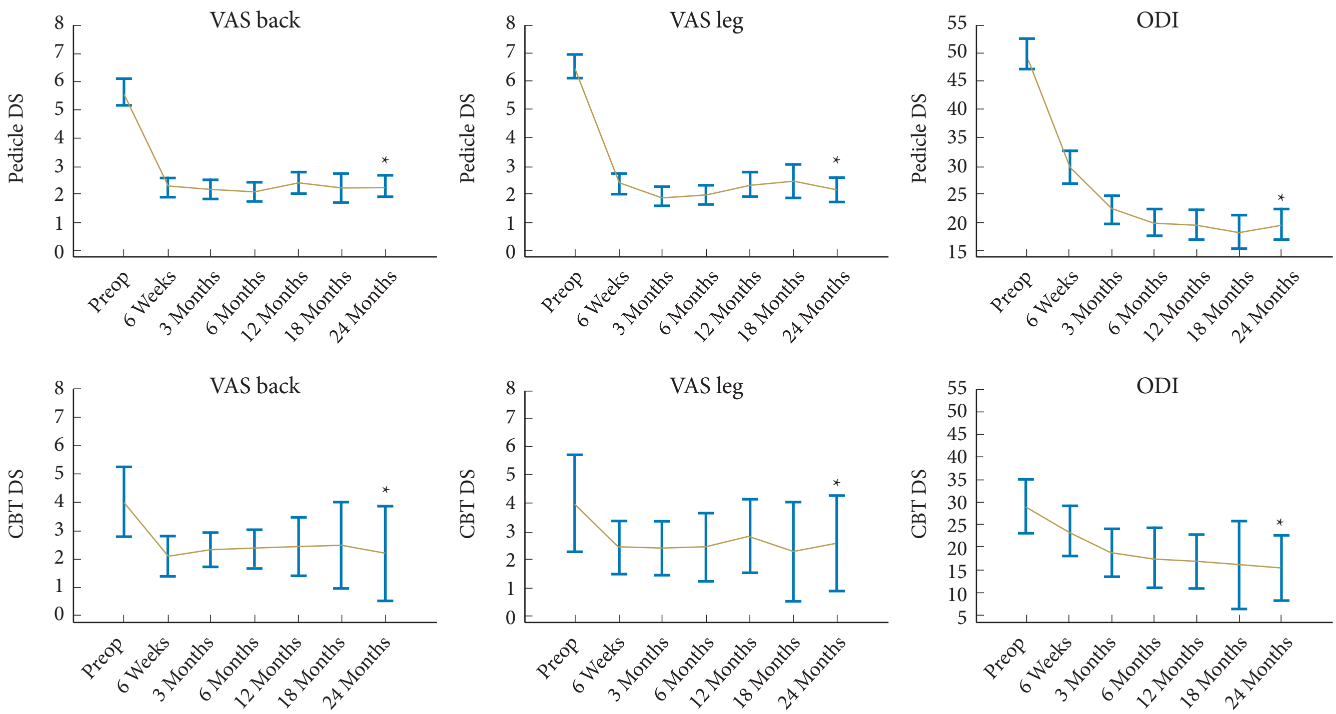

Fig. 4. The patient-reported outcomes demonstrated equivalent clinical improvements between the 2 groups. VAS, visual analogue scale; ODI, Oswestry Disability Index; DS, dynamic stabilization; CBT, cortical bone trajectory. *The score at 24 months after surgery was significantly lower than preoperation (preop).

required revision surgery in the entire series. In the pedicle-based group, there were 108 loosened screws (9%) in 62 patients (26.4%), which was significantly higher than that in the CBT-based group (15 screws [5.4%] in 7 patients [12.5%], p = 0.045 and 0.028, respectively). Moreover, there were 7 fractured screws (0.6%) in 5 patients (2.1%) in the pedicle-based group, while there were none in the CBT-based group (Table 3).

Other surgical complications (e.g., incidental durotomy, superficial or deep wound infections) were similarly low in both groups. There were 3 wound infections and 3 incidental durotomies in the CBT DS group. On the other hand, there were 13 incidental durotomies, 2 wound infections, and 1 epidural hematoma in the pedicle-based DS group. There was no newly-onset foot-drop or other lumbosacral radiculopathy causing weakness after surgery in both groups. In pedicle-based DS group, there were 38 patients had ASD. Among them, 6 patients had revision fusion surgery. Three patients had progressed spondylolisthesis over the index level. In CBT-based DS group, there were 2 patients had asymptomatic ASD. One patient had recurrent disc over the index level that revision fusion surgery was performed.

Table 3. Analysis of screw loosening

Variable	Pedicle-based DS	CBT-based DS	p-value
Loosen screw	108 (9.0)	15 (5.4)	0.045*
Nonloosen screw	1,088 (91)	265 (94.6)	
Patients with loosen screw	62 (26.4)	7 (12.5)	0.028*
Patients without loosen screw	173 (73.4)	49 (87.5)	
Fractured screw	7 (0.6)	0 (0)	0.19
Patients with fractured screw	5 (2.1)	0 (0)	0.27

Values are presented as number (%).
DS, dynamic stabilization; CBT, cortical bone trajectory.
*p < 0.05.

4. Effects of Screw Loosening

Comparisons were made between the intact and loosened screws in and between both the CBT-based and pedicle-based groups. In the CBT-based DS group, most of the demographic data demonstrated no differences, except that patients with screw loosening were older than those without. In the pedicle-based DS group, with or without screw loosening, there were no differences in patients' age, BMI, or bone density. However, there was a male predominance of screw loosening in pedicle-based DS for uncertain reasons. At 24-month postoperation, there were no differences between the subgroups of loosened and intact screws, within both the pedicle-based or CBT-based groups.

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Table 4. Comparison of loosened screw and intact group

Variable	Pedicle-based DS Screw loosening			CBT-based DS Screw loosening		
	Yes (n = 62)	No (n = 173)	p-value	Yes (n = 7)	No (n = 49)	p-value
Age (yr)	62.4 ± 11.3	61.5 ± 10.9	0.57	70.1 ± 5.8	61.5 ± 10.5	0.04*
Sex			0.03*			0.61
Male	38	79		4	23	
Female	24	94		3	26	
BMI (kg/m²)	26.1 ± 4.1	25.7 ± 3.7	0.63	25.4 ± 2.5	25.7 ± 2.3	0.71
Diabetes mellitus	13	38	0.87	2	7	0.34
DEXA T score	-0.36 ± 1.6	-0.56 ± 1.5	0.52	-0.98 ± 1.1	-0.56 ± 1.5	0.58
Preoperation						
VAS back	5.7 ± 3.1	5.6 ± 3.2	0.81	1.5 ± 1.0	3.7 ± 3.2	0.17
VAS leg	6.8 ± 2.4	6.3 ± 3.1	0.35	2.5 ± 3.7	5 ± 3.4	0.19
ODI	52.7 ± 16.1	48.7 ± 19.5	0.19	20.5 ± 8.6	28.1 ± 17.3	0.41
24-Month postoperation						
VAS back	2.1 ± 2.6	2.2 ± 2.4	0.83	2.5 ± 3.5	2.2 ± 2.2	0.87
VAS leg	1.7 ± 2.4	2.2 ± 2.7	0.4	2.5 ± 3.5	2.2 ± 2.8	0.89
ODI	17.6 ± 16.1	20.3 ± 17.7	0.39	18 ± 8.4	9.2 ± 10.1	0.27

Values are presented as mean ± standard deviation or number.
DS, dynamic stabilization; CBT, cortical bone trajectory; BMI, body mass index; DEXA, dual-energy x-ray absorptiometry; VAS, visual analogue scale; ODI, Oswestry Disability Index.
*$p < 0.05$.

The loosened screws had no adverse effects on the patient-reported outcomes (Table 4).

DISCUSSION

This series demonstrated that CBT is a feasible alternative to pedicle trajectory for DS, with less soft tissue dissection and higher strength of the screws. The novel CBT DS had less incidence of screw loosening in the current series compared to the conventional DS. The CBT was first described by Santoni et al.[26] in 2009 as a novel method for PS placement in lumbar surgery. Biomechanical studies demonstrated the superiority of the CBT, which could yield a 30% increase in pullout strength and a 71% increase in insertional torque.[26,32] Using CBT could theoretically enhance bony integration at the bone-screw interface and reduce the incidence of screw loosening. Because CBT uses an entry point at the pars interarticularis and a medial-to-lateral trajectory, it inherently allows avoidance of a wide exposure of the transverse process or muscle detachment at both index and cephalad facet joints. Minimizing muscle detachment from the facet joint could maintain structural integrity of the facet joint and would likely help to reduce future ASD. The features of CBT, less soft tissue violation, coincidentally matches the design rationale of screw-based DS to preserve motility by preservation of muscles. The invention of adapting CBT for DS was first attempted by the authors with a promising preliminary report.[31] Most of the series of CBT used cortical screws in lumbar fusion, and both the trajectory and design of the screws could have enhanced the purchase. Although the original design of screws of DS was similar to common PSs rather than cortical screws, the novel trajectory reportedly plays a more important role than the screw per se.[33]

The concept of preservation of motion in surgery for lumbar degeneration has gained popularity outside North America. Most of the reported series of DS came out of Europe and the Asia-Pacific region. Several reports demonstrated satisfactory and noninferior outcomes of DS compared to that of lumbar fusion surgery.[16,34] The historic concern that the DS screws were subject to loosening after repeated load challenge has been addressed with little clinically significant consequences.[21,35,36] Stoll et al.[10] reported 10 loose screws (3.6%) in 7 of 83 patients (8.4%) at a mean follow-up of 38.1 months. Grob et al.[23] reported on screw loosening in 4 of 31 patients (13%) at a 2-year follow-up, and all these patients underwent reoperation. Bothmann et al.[1] documented screw loosening in 7 of 40 patients (17.5%). Furthermore, they reported a case with screw breakage at 21 months after surgery. Schaeren et al.[8] reported 3 of 19 patients (15.7%) with screw loosening at a 4-year follow-up. Additionally, 1 of 19 patients (5.2%) experienced screw breakage. They also pointed out neither screw breakage nor screw loosening was related to the patients' satisfaction or back pain. Wu et al.[12] documented 31 cases (4.7%) of screw loosening in 25 of 126 patients (19.8%), with a mean follow-up of 37 months. Most of the rates reported for screw loosening range from 10% to 20% of the patients and seldom require revision surgery. This feature of DS is distinct from the arthrodesis series, in which screw loosening often causes pseudarthrosis warranting reoperation. The biggest difference between fusion surgery and DS is that the facet should be preserved as much as possible in DS to prevent iatrogenic instability. Once the screw loosening occurred in DS, the preserved facet joint could still provide enough support to prevent the progression of instability. This might be the reason why the revision surgery was seldom required in DS patients with screw loosening. Nonetheless, minimization of screw loosening and enhancement of osteointegration are certainly important for DS. In the present study, CBT-based DS demonstrated superior screw integrity, with lower rates of screw loosening than the pedicle trajectory (12.5% vs. 26.4%, $p = 0.028$). The subgroup analysis also demonstrated that the screw loosening rates were lower in the CBT-based group than the pedicle-based group in any of the subgroup analyses. Moreover, there was no screw breakage in the CBT-based group, compared with 7 screws (0.6%) broken in 5 patients (2.1%) in the pedicle-based group. In our experience, the utilization of the new trajectory yielded a lower screw loosening rate and breakage in DS. Furthermore, at 24-month postoperation, all the clinical outcomes, including the VAS for back and leg pain, and the ODI scores, demonstrated equally significant improvement in all subgroups, which were also compatible with the published series.

There were limitations to the study. This was a single institute, retrospective, nonrandomized, comparison study. The 2 cohorts were enrolled with the same indication but at different time points. There was study bias in that the pedicle-based cohort had a significantly longer follow-up which may have influenced the occurrence of screw loosening. However, all the complication profiles were analyzed with equal scrutiny, and the time point of screw loosening always occurred within 24 months after surgery. Since all patients in this study had a minimum of 2 years of follow-up, the influence of unequal follow-up on the occurrence of screw loosening would be minimal and omissible. Furthermore, the DS screws used in the 2 subgroups were slightly different. Not only the diameters but also the lengths of the screws for the CBT and PSs were different by design. The CBT-based group used shorter and smaller screws. However, this was compatible with all the published series of CBT screws that were used for fusion. Whether the differences of screw size and shape matter in DS as in fusion constructs remain elusive. Investigations with a longer follow-up and larger sample sizes are warranted to understand the long-term outcome of the novel strategy.

CONCLUSION

The CBT-based DS for 1- or 2-level lumbar degenerative disease demonstrated equivalent clinical improvements as the pedicle-based DS. The adoption of CBT-based screws for DS could be a less invasive approach (shorter operation time and less blood loss), with lower chances of screw loosening than the conventional PS-based DS.

NOTES

Conflict of Interest: The authors have nothing to disclose.

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Author Contribution: Conceptualization: CCC, THT, WCH, JCW; Data curation: CCC, HKC, CCK, CLW, YHK; Formal analysis: CCC, HKC, CCK, CLW, YHK; Methodology: CCC, HKC, CCK, CLW, YHK, THT, WCH, JCW; Project administration: THT, WCH, JCW; Writing - original draft: CCC; Writing - review & editing: CCC, THT, WCH, JCW.

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