

# Level-based analysis of screw loosening with cortical bone trajectory screws in patients with lumbar degenerative disease

Chao-Hsuan Chen, MD<sup>a</sup>, Der-Cherng Chen, MD, PhD<sup>a</sup>, Hsiang-Ming Huang, MD<sup>c</sup>, Hao-Yu Chuang, MD, PhD<sup>b</sup>, Wei-Lin Hsu, MD<sup>b</sup>, Der-Yang Cho, MD, PhD<sup>a</sup>, Han-Chung Lee, MD, PhD<sup>a,\*</sup>, Da-Tian Bau, PhD<sup>d,e,f,\*</sup>

## Abstract

This study aimed to verify the relationship between the number of fusion level and the risk of screw loosening by using cortical bone trajectory (CBT) screws in patients with lumbar degenerative disease.

We retrospectively reviewed the serial plain radiograph images of lumbar degenerative disease patients who had undergone posterior fixation and fusion surgery with CBT from 2014. All included patients should have been followed-up with computed tomography scan or plain radiograph for at least 6 months after operation. We individually evaluated the prevalence of screw loosening according to each vertebral level. We also determined whether the number of screw fixation affected the prevalence of screw loosening and whether S1 fixation increased the risk of screw loosening.

The screw-loosening rates were high at the S1 level. Moreover, although fixation involved to S1, the loosening rates evidently increased (Fisher exact test,  $P = .002^{**}$ ). The screw-loosening rate was 6.56% in 2 level fusion. However, it increased with the number of fusion levels (3 level: 25.00%, 4 level: 51.16%, and 5 level: 62.50%). To investigate if the number of fusion level affected the S1 screw loosening, we classified the cohort of patients into either involving S1 (S1+ group) or not (S1- group) according to different fusion levels (Table 3). The screw loosening between 2 group in 2 (5.56% vs 6.98%) and 3 fusion level (26.32% vs 22.73%) did not exhibit any significant difference. Interestingly, significantly high screw loosening was found in 4 fusion level (60.00% vs 15.38%), indicating that the higher fusion level (4 level) can directly increase the risk of S1 screw loosening.

Our data confirmed that the screw-loosening rate increases rate when long segment CBT fixation involves to S1. Therefore, in case of long-segment fixation by using CBT screw, surgeons should be aware of the fusion level of S1.

**Abbreviations:** CBT = cortical bone trajectory, EPS = endplate penetration screw, LDD = lumbar degenerative disease, MIDLF = midline interbody lumbar fusion, TPS = traditional pedicle screws.

**Keywords:** adjacent segment degeneration, cortical bone trajectory, degenerative disc disease, screw loosening

## 1. Introduction

Lumbar interbody fusion is a standard instrument treatment for lumbar degenerative disease (LDD) that can cause spinal stenosis and instability.<sup>[1–4]</sup> Traditionally, posterior arthrodesis is a golden standard fixative procedure that uses traditional pedicle screws (TPS).<sup>[5]</sup> Recently, cortical bone trajectory (CBT)

screw fixation has emerged as an alternative surgical procedure due to its advantages, such as increased pullout resistance and decreased tissue dissection. Since CBT screw placement was first described by Santoni et al in 2009,<sup>[6]</sup> surgeons have exerted efforts to advance this minimally invasive technique. In the previous study, starting from minimally invasive surgery of the transforaminal lumbar interbody fusion<sup>[7]</sup> to the midline

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<sup>a</sup> Department of Neurosurgery, China Medical University Hospital, China Medical University, Taichung, <sup>b</sup> Department of Neurosurgery, Tainan Municipal An-Nan Hospital, China Medical University, Tainan, <sup>c</sup> Department of Neurosurgery, China Medical University Hsinchu Hospital, Hsinchu, <sup>d</sup> Graduate Institute of Biomedical Sciences, China Medical University, <sup>e</sup> Terry Fox Cancer Research Laboratory, Department of Medical Research, China Medical University Hospital, <sup>f</sup> Department of Bioinformatics and Medical Engineering, Asia University, Taichung, Taiwan, R.O.C.

\* Correspondence: Han-Chung Lee, Department of Neurosurgery, No.2 Yude Rd, North District, Taichung 40447, Taiwan (e-mail: braintumorgbm@gmail.com), Da-Tian Bau, No. 91 Hsueh-Shih Rd, North District, Taichung, 40402, Taiwan (e-mail: dtbau@mail.cmu.edu.tw).

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interbody lumbar fusion (MIDLF),<sup>[8]</sup> we also introduced minimal invasive surgery-MIDLF for less tissue damage to patients and reduction in the radiation exposure of surgeons.<sup>[9]</sup>

In addition to well-known altered bone quality contributing to screw loosening, length of fixation correlates with the rate of screw loosening.<sup>[10]</sup> Nearly half of the S1 screw loosening occurred at 3–4 fusion levels in patients with TPS fixation.<sup>[11]</sup> Theoretically, CBT screw placement provides better biomechanical strength and decreases the possibility of screw loosening than TPS fixation. Nevertheless, the screw loosening occurred even in patients with CBT screw placement, which can be caused by chronic infection,<sup>[12]</sup> loss of fixation, and non-union,<sup>[13]</sup> particularly in patients with osteoporosis. Therefore, reduction of such incidence and the factors related to screw loosening have become important issues. To our knowledge, only a few available studies have examined the postoperative outcome of screw loosening in a large patient population,<sup>[14]</sup> and no study elucidated the relationship between the number of surgical level and the risk of screw loosening by using CBT screw placement.<sup>[15]</sup> In the present study, we tried to investigate individually the prevalence of screw loosening according to each vertebral level. We also validated whether the number of screw fixation affects the prevalence of screw loosening and whether S1 fixation increases the risk of screw loosening.

## 2. Methods

### 2.1. Patient selection and characteristics

The study was performed at China Medical University Hospital and was approved by the local Institutional Review Board. Since November 2014, we began performing MIDLF with CBT fixation in our institute for LDD without traumatic vertebral column fracture, infection, or tumor invasion. A total of consecutive 172 patients who underwent posterior fixation and fusion surgery by using CBT screws for LDD were enrolled from 2014 to 2019. The follow-up period was at least more than 6 months. The patients' demographic data are shown in Table 1.

**Table 1**  
Patient's demographics.

Characteristics		
Age, yr		
Range	26–87	
Mean ± SD	59.89 ± 13.18	
Gender, no. (%)		
Male	69 (40.12%)	
Female	103 (59.88%)	
Follow-up period (mo)		
Range	5–39	
Mean ± SD	13.56 ± 8.07	
Fusion area, no. (%)		Loosening in patient/screw no. (%)
T11	1 (0.20%)	0
T12	1 (0.20%)	0
L1	3 (0.58%)	0
L2	29 (18.29%)	1/1 (2.13%/1.22%)
L3	83 (18.29%)	2/4 (4.26%/4.88%)
L4	147 (28.60%)	0
L5	156 (30.35%)	5/7 (8.51%/7.32%)
S1	94 (18.29%)	40/70 (85.11%/86.59%)

SD = standard deviation.

### 2.2. Surgical procedure

Instead of traditional mini-open MIDLF with CBT, we used the minimally invasive MIDLF surgical procedure described previously to achieve smaller wound incision, less muscular damage, and less radiation exposure.<sup>[9]</sup> The wound incision was made between the entry points of the fusion level with minimized muscular dissection to the medial pars interarticularis. The guiding pins were inserted under anteroposterior view in fluoroscopy followed by mediolateral and caudocephalad directions. However, the entry point of the caudal level was on the articular surface of the superior articular process, and the trajectory took a mediolateral path parallel to the endplate to minimize caudal muscular dissection. Then, decompression with cage interbody fusion was performed using a microscope. At last, the screws were inserted through the pilot tract or guide pins.

### 2.3. Radiographic evaluation

According to the research by Sanden in 2004, a radiolucent zone is a good indicator of the loosening of a pedicle screw,<sup>[16]</sup> either a halo sign appeared at a screw–bone interface on anteroposterior plain radiograph or evidence of screw motion on dynamic images in the present study was defined as screw loosening. All patients were followed with anteroposterior and dynamic lateral plain radiograph at least 1, 2, 3, and 6 months post-operation. The serial images were reviewed by 2 neurosurgeons familiar to CBT, and cases were excluded if the 2 neurosurgeons do not agree on the results.

### 2.4. Statistical analysis

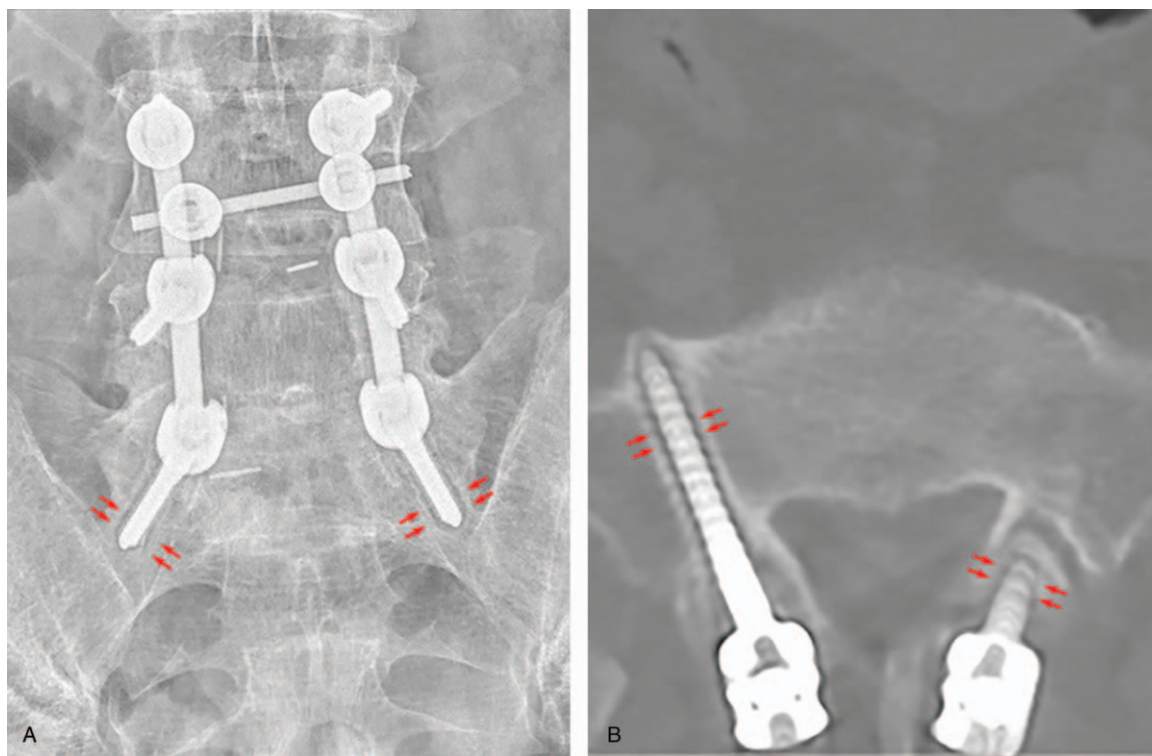
Data plotting and analysis were performed using GraphPad Prism. Data were represented as mean ± standard deviation. All categorical data are presented as a percentage or number. The results among groups were compared using unpaired *t* test, and Fisher exact probability test. Significance was set at  $P < .05$ .

## 3. Results

All patients that suffered from LDD were enrolled from 2014 to 2019. A total of 172 patients underwent MIDLF with CBT screw fixation. The average follow-up period was 13.56 months (5–39 months). The mean age was 59.89 years (26–87 years). A total of 69 males (40.12%) and 103 females (59.88%) were included (Table 1).

The halo phenomenon was evaluated by plain films (Fig. 1). Based on the location of instruments, the intended fusion levels were classified into T11 to S1 initially. We observed that the screw-loosening rates were higher especially in the S1 level, indicating that such level is prone to screw loosening compared with the other levels (Table 2). Moreover, whereas fixation involved to S1, the loosening rates were evidently increased (Fisher exact test,  $P = .002^{**}$ ).

Similar to a previous study in TPS fixation,<sup>[10]</sup> the number of fusion level correlates with the rate of screw loosening in CBT fixation (Table 2). The screw-loosening rate was 6.56% in 2 fusion level. However, the screw-loosening rates increased with the fusion level (3 level: 25.00%, 4 level: 51.16%, 5 level: 62.50%). To investigate whether the number of fusion level affects the S1 screw loosening, we classified the cohort of patients into either involving to S1 (S1+ group) or not (S1– group) according to the different fusion levels (Table 3). No evident



**Figure 1.** Under (A) plain radiograph, and (B) computed tomography, the halo phenomenon around the CBT screw (red arrows) was defined screw loosening. CBT = cortical bone trajectory.

differences were observed in the screw loosening between the 2 groups in 2 (5.56% vs 6.98%) and 3 fusion level (26.32% vs 22.73%). Interestingly, the significantly higher screw loosening was found in 4 fusion level (60.00% vs 15.38%), indicating that the greater number of fusion level (4 level) can directly increase the risk of S1 screw loosening. Moreover, the long-segment screw loosening is not related to age-dependent or follow-up time length in S1+ group (Table 4). Therefore, in case of long-segment fixation by using CBT screw, the surgeons should be aware of the fusion level involving to S1.

**Table 2**

**Overview of screw loosening.**

	Patient no. of loosening (%)	No. of screw loosening
2 level	4/61 (6.56%)	4/264 (1.52%)
3 level	15/60 (25.00%)	21/360 (5.83%)
4 level	22/43 (51.16%)	26/344 (7.56%)
5 level	5/8 (62.50%)	14/80 (17.50%)

**Table 3**

**Screw loosening in patient with and without S1 screw.**

	S1 (+)			S1 (-)		
	Loosening (+)	Loosening (-)	(%)	Loosening (+)	Loosening (-)	(%)
2 level	1	17	5.56%	3	40	6.98%
3 level	10	28	26.32%	5	17	22.73%
4 level	18	12	60.00%	2	11	15.38%
5 level	5	3	62.50%	0	0	

**4. Discussion**

Among the patients who underwent lumbar arthrodesis with TPS fixation, including S1, the screw-loosening rate (24.4%, 2%–50%) increased with the extended number of fusion levels. The report indicated that the greater the number of fusion levels, the greater the risk of S1 screw loosening in TPS fixation.<sup>[11]</sup> Given that the sacrum primarily comprises cancellous bone and received greater mechanical load than other segments,<sup>[17]</sup> the unique anatomical features of the S1 pedicle, with a larger diameter and shorter length than lumbar pedicles, lead to the higher failure of sacral screw fixation.<sup>[18]</sup> Other factors contributing to instrumentation failure are inappropriate direction or depth of the screw insertion, osteoporotic bone quality, lack of true pedicles with cortical bone ring, and large cantilever bending moments loaded resulting from long-level instrumentation.<sup>[17,19,20]</sup>

Matzukawa et al reported that CBT technique has 1.71 times higher insertional torque compared with traditional technique.<sup>[21]</sup> Many studies also reported the biomechanical advantages of lumbar arthrodesis of CBT screws especially in osteoporotic bone.<sup>[22]</sup> However, the S1 loosening problem may occur in CBT



**Table 4**  
Loosening diagnosed and follow-up period in patient with S1 screw.

	S1 (+)				
	Loosening (+)		Loosening diagnosed (mo)	Loosening (-)	
	Follow-up period (mo)	Age, yr		Follow-up period (mo)	Age, yr
4 level	12.53±6.54 (6–30)	64.42±10.67 (37–83)	3.90±2.51 (2–11)	19.11±11.19 (8–36)	60.89±7.42 (50–74; <i>P</i> =.3757)
5 level	13.6±11.10 (6–33)	61.6±14.96 (39–79)	4.80±2.59 (2–9)	11.33±0.58 (11–12)	57.33±7.77 (51–66; <i>P</i> =.5714)

screw placement. To date, the large variation in CBT screw-loosening rate ranging from 0% to 62.5% must also be validated because of the limitation in cohort size and different evaluated methods.<sup>[8,14,23,24]</sup> Overall, we found that S1 exhibited a higher loosening rate (%) compared with other levels. Moreover, the significantly higher screw loosening was found at 4 and 5 fusion level (60.00% vs 62.50% in S1+ group). On the other hand, the screw-loosening rate in S1– group was 15.38% at 4 fusion level. These findings suggest that avoiding fusion involving to S1 may be a solution for screw loosening while performing long-segment fusion than 4 level. Although the CBT screw fixation is advocated for less than 4 levels,<sup>[25]</sup> the low screw-loosening rate in S1– group demonstrates that it is still recommended for long-segment fixation while necessary for the fixation of patients.

To avoid fusion involving to S1, strengthening the sacral screw fixation may be another solution to reduce screw-loosening rate with CBT fixation. Matsukawa et al has introduced an endplate penetration screw (EPS) technique that involves penetrating the endplate to obtain bicortical purchase. They reported the significantly higher insertion torque in EPS trajectory compared with that in unicortical trajectory.<sup>[26]</sup> A cadaveric biomechanical study also validated the EPS technique by providing higher pullout force and more stable strength against screw loosening, implicating an alternative for lowering screw-loosening rate.

This study has several limitations, namely, retrospective nature, lack of examination of bone density, and lack of evaluation on postoperative progression of adjacent segment degeneration. Importantly, the prospective comparative study between different S1 fixative techniques should be considered for further investigation.

## 5. Conclusions

Our data confirm the increased rate of screw loosening during long segment CBT fixation including S1. Therefore, in the case of long-segment fixation by using CBT screw, surgeons should be aware of the fusion level of S1.

## Author contributions

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