

## BIOMECHANICS

# In Vivo Analysis of Insertional Torque During Pedicle Screwing Using Cortical Bone Trajectory Technique

Keitaro Matsukawa, MD,\* Yoshiyuki Yato, MD,\* Takashi Kato, MD,\* Hideaki Imabayashi, MD,\*  
Takashi Asazuma, MD,† and Koichi Nemoto, MD\*

**Study Design.** The insertional torque of pedicle screws using the cortical bone trajectory (CBT) was measured *in vivo*.

**Objective.** To investigate the effectiveness of the CBT technique by measurement of the insertional torque.

**Summary of Background Data.** The CBT follows a mediolateral and caudocephalad directed path, engaging with cortical bone maximally from the pedicle to the vertebral body. Some biomechanical studies have demonstrated favorable characteristics of the CBT technique in cadaveric lumbar spine. However, no *in vivo* study has been reported on the mechanical behavior of this new trajectory.

**Methods.** The insertional torque of pedicle screws using CBT and traditional techniques were measured intraoperatively in 48 consecutive patients. A total of 162 screws using the CBT technique and 36 screws using the traditional technique were compared. In 8 of 48 patients, the side-by-side comparison of 2 different insertional techniques for each vertebra were performed, which formed the H group. In addition, the insertional torque was correlated with bone mineral density.

**Results.** The mean maximum insertional torque of CBT screws and traditional screws were  $2.49 \pm 0.99$  Nm and  $1.24 \pm 0.54$  Nm, respectively. The CBT screws showed 2.01 times higher torque and the difference was significant between the 2 techniques ( $P < 0.01$ ). In the H group, the insertional torque were  $2.71 \pm 1.36$  Nm in the CBT screws and  $1.58 \pm 0.44$  Nm in the traditional screws. The CBT screws demonstrated 1.71 times higher torque and statistical

significance was achieved ( $P < 0.01$ ). Positive linear correlations between maximum insertional torque and bone mineral density were found in both technique, the correlation coefficient of traditional screws ( $r = 0.63$ ,  $P < 0.01$ ) was higher than that of the CBT screws ( $r = 0.59$ ,  $P < 0.01$ ).

**Conclusion.** The insertional torque using the CBT technique is about 1.7 times higher than the traditional technique.

**Key words:** cortical bone trajectory, insertional torque, pedicle screw, bone mineral density, screw stability.

**Level of Evidence:** 2

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A cortical bone trajectory (CBT) is a novel lumbar pedicle screw trajectory.<sup>1</sup> A starting point of the trajectory is located in the lateral part of the pars interarticularis and the trajectory follows a caudocephalad and laterally directed path through the pedicle. The traditional pedicle screws are inserted through the anatomic pedicle axis and anchored mainly in cancellous bone from the pedicle to the vertebral body. In contrast, the CBT screws maximize the thread contact with the cortical bone surface, providing enhanced screw purchase. Biomechanical study of CBT revealed a 30% increase in uniaxial yield pull-out load and equivalent characteristics of the screw-rod construct compared with the traditional trajectory in cadaveric lumbar spine.<sup>1,2</sup> However, no *in vivo* biomechanical study has been reported on the mechanical behavior of this new trajectory. The purpose of this study was to investigate the torque during pedicle screw insertion using CBT and traditional techniques.

## MATERIALS AND METHODS

Between July 2012 and March 2013, the insertional torque of pedicle screws using CBT and traditional techniques were measured intraoperatively in 48 consecutive patients (including 25 males and 23 females, age range: 25–87 yr, mean  $\pm$  standard deviation:  $63.3 \pm 15.6$  yr). Disorders were divided into degenerative spondylolisthesis (29 patients), degenerative disc disease (6 patients), and others (13 patients). A total of 202 screws excluding 26 screws for the sacrum were observed. Two groups of screws were compared: 164 screws

From the \*Department of Orthopaedic Surgery, National Defense Medical College, Tokorozawa, Saitama, Japan; and †Department of Orthopaedic Surgery, National Hospital Organization, Murayama Medical Center, Tokyo, Japan.

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Address correspondence and reprint requests to Keitaro Matsukawa, MD, Department of Orthopaedic Surgery, National Defense Medical College, 3-2 Namiki, Tokorozawa, Saitama 359-8513, Japan; E-mail: keitaro197897@hotmail.com

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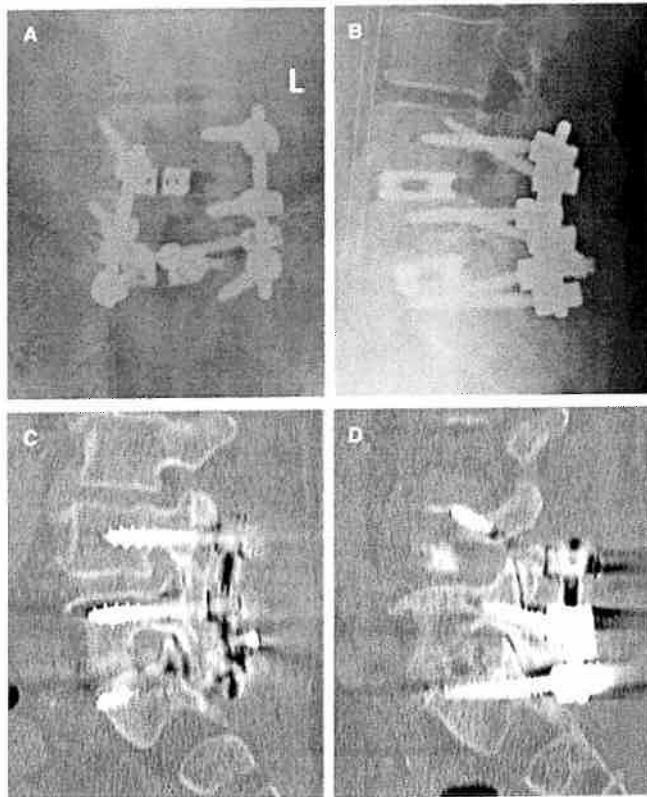
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using the CBT technique and 38 screws using the traditional technique. In 8 of the 48 patients (including 4 males and 4 females, mean  $\pm$  standard deviation:  $68.8 \pm 8.3$  yr), hybrid surgical technical procedures were performed, which formed the H group (Figure 1 A–D). In this group each vertebra was instrumented with the CBT screw on one pedicle side and the traditional screw on the contralateral side, and a side-by-side comparison was performed. The operative indication of the H group was lumbar foraminal stenosis. They required extensive facetectomy to decompress the exiting nerve root and thus lost the ideal starting point of CBT in many cases. Therefore, we selected the traditional insertional technique in place of the CBT technique for one side.

Through a midline incision, a spinous process splitting approach was performed. For each case, anteroposterior and lateral fluoroscopy was used to verify the correct screw trajectory. The starting point of the CBT technique screw was located in the lateral point of the pars interarticularis projecting in the 5-o'clock orientation in the left pedicle and the 7-o'clock orientation in the right pedicle under fluoroscopic imaging. Using a 2-mm high-speed round burr drill, the entry point was made and then the drill was aimed in a lateral and cephalad direction to make an approximately 10-mm starting

hole. In our previous morphometric study of the CBT, the lateral angle was  $8^\circ$  to  $9^\circ$  and the cephalad angle was  $25^\circ$  to  $26^\circ$ .<sup>3</sup> The hole was dilated by increasing the probe diameter gradually from 2.5 mm to 3.5 mm and was tapped to the size of the planned screw. The traditional technique screw was inserted through an anatomical pedicle axis with a starting point at the junction of the transverse process and lateral wall of the facet. The entry point was prepared in the same way and the pilot hole was made using a probe 3.5 mm in diameter. After 1-mm under-size tapping, screw insertion was carried out.

The CBT technique screw diameter was 5.5 mm and the length was in the range from 30 to 35 mm; the traditional technique screw was the same shape, with a diameter ranging from 6.5 to 7.5 mm and a length of 40 mm. In this study, SOLERA Spinal System screws (Medtronic, Memphis, TN) were used. A screwdriver connected with a torque meter (HTG2-5N; Imada, Toyohashi, Japan) was used to insert the screws and to determine the torque generated during screw insertion (Figure 2). Each screw was placed at a depth that was not connected to the entry point cortex with the screw head. This was because the insertional torque increased rapidly when the screw head made contact with the near cortex during the last phase. In addition, bone mineral density (BMD) of the femoral neck was assessed by dual-energy x-ray absorptiometric (DXA) scans and correlated with the insertional torque. We did not apply lumbar BMD in this study because elderly patients had osteophyte formation and articular facet hypertrophy that could influence the lumbar BMD results, especially in the patients with osteoporosis. The study received ethics committee approval of our institution and all patients gave signed informed consent. The results are presented as mean  $\pm$  standard deviation. Statistical analyses



**Figure 1.** A 70-year-old female with degenerative spondylolisthesis in L4 and left-side foraminal stenosis at the L5–S1 level. **A** and **B**, Radiograms obtained just after the operation. **C**, The traditional screws were applied in the left pedicle. **D**, The CBT screws were inserted in the right pedicle. CBT indicates cortical bone trajectory.



**Figure 2.** Photograph of a torque measurement device. During the screw insertion, the real-time torque was recorded with a frequency of every 0.05 seconds.

were performed using Student *t* test and 1-way analysis of variance for comparison of the torque and Pearson correlation coefficient to analyze BMD data and the torque for both insertional techniques. Significance was defined as  $P \leq 0.01$ .

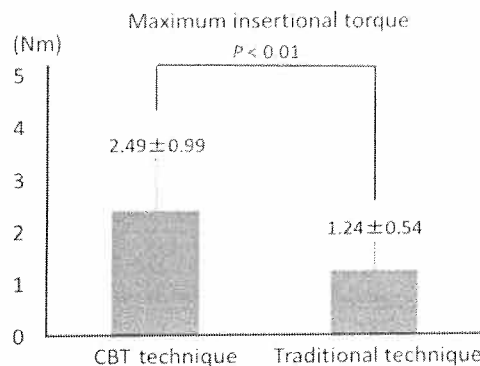
**RESULTS**

Four screws (2 CBT screws and 2 traditional screws) with perforation through the pedicle evaluated by postoperative CT were excluded; therefore, 198 screws (162 CBT screws and 36 traditional screws) in 48 patients were available for this study. There were no significant differences between the CBT screw group and the traditional screw group in terms of the mean age and mean BMD (Table 1). The mean maximum insertional torque of CBT screws and traditional screws were  $2.49 \pm 0.99$  Nm and  $1.24 \pm 0.54$  Nm, respectively (Figure 3). The CBT screws showed 2.01 times higher torque and the difference was significant between the 2 techniques ( $P < 0.01$ ). There were no significant differences in each technique of the insertional torque between right and left side, and each lumbar level. In the H group (mean BMD:  $0.80 \pm 0.19$  g/cm<sup>2</sup>), in which each vertebra was subjected to both CBT and traditional techniques, the mean maximum insertional torque were  $2.71 \pm 1.36$  Nm in the CBT screws and  $1.58 \pm 0.44$  Nm in the traditional screws (Figure 4). The CBT screws demonstrated 1.71 times higher insertional torque and statistical significance was achieved ( $P < 0.01$ ).

An evaluation of BMD was possible in 41 of 48 patients. Positive linear correlations between maximum insertional torque and BMD were found in both techniques (Figure 5); the correlation coefficient of traditional screws ( $r = 0.63$ ,  $P < 0.01$ ) was higher than that of the CBT screws ( $r = 0.59$ ,  $P < 0.01$ ).

**DISCUSSION**

Pedicle screws have become the most popular and reliable instruments in treating a variety of spinal disorders, for early mobilization and simplifying the use of bracing. Problems of screw loosening, which may lead to a loss of correction and nonunion, have not been resolved in pedicle screw



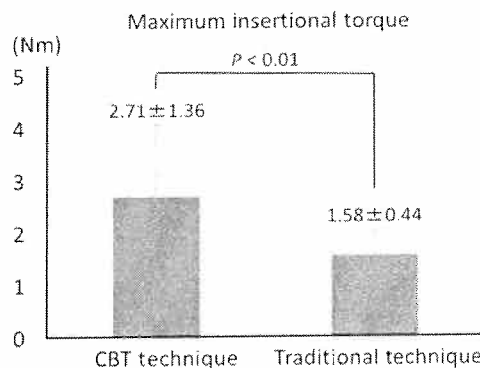
**Figure 3.** Means of the maximum insertional torque for CBT technique screws and traditional technique screws. The CBT screws showed 2.01 times higher torque and the difference was significant between the 2 techniques ( $P < 0.01$ ). CBT indicates cortical bone trajectory.

fixation. Thus, achieving solid implant fixation to osteoporotic bone presents a challenge to spinal surgeons. Several factors affecting the stability of pedicle screws, such as bone properties, screw mechanical properties, and the insertional technique, have been mentioned.<sup>4</sup> In particular, the effect of BMD on screw fixation strength has been elucidated by several authors. Yamagata *et al*<sup>5</sup> has shown, using DXA, that a 100 mg/cm<sup>2</sup> decrease in BMD caused a 10-kp decrease in pull-out force. Several other authors have also shown a high correlation between BMD and the stability of pedicle screws.<sup>6,7</sup> From the point of view of the screw characteristics, Skinner *et al*<sup>8</sup> reported that stability was achieved by an increase in the major diameter of the screw and was weakened by an increase in the pitch of the screw. Chao *et al*<sup>9</sup> also demonstrated that the pull-out strength increased with a tapered shape and a decrease in screw core diameter.

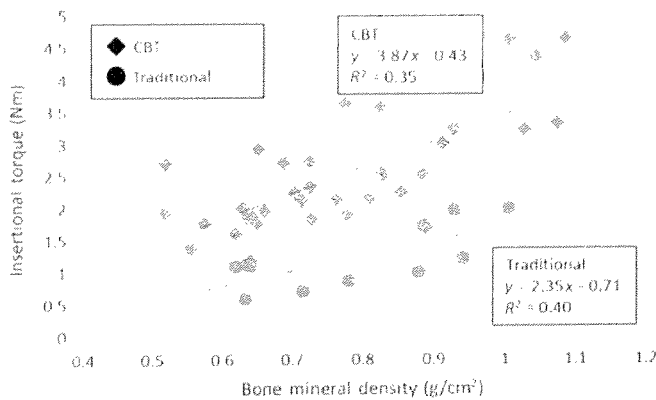
The CBT is a novel lumbar pedicle screw trajectory that was first advocated by Santoni *et al*<sup>1</sup> in 2009. The advantage associated with this modified technique is maximizing the thread contact with the higher-density bone surface. Biomechanical study revealed a 30% increase in uniaxial yield pull-

	CBT Technique	Traditional Technique
No. of screws	162	36
No. of patients	42	14
Male	22	7
Female	20	7
Age (yr)	62.5 ± 15.6	66.0 ± 8.1
BMD* (g/cm <sup>2</sup> )	0.77 ± 0.15	0.79 ± 0.13

\*An evaluation of BMD was possible in 38 of the 42 patients who underwent CBT technique and 12 of the 14 patients who underwent the traditional technique.  
BMD indicates bone mineral density; CBT, cortical bone trajectory.



**Figure 4.** Comparison of 2 technique screws in the H group. The CBT screws demonstrated 1.71 times higher insertional torque and statistical significance was achieved ( $P < 0.01$ ). CBT indicates cortical bone trajectory.



**Figure 5.** Comparison between CBT technique and traditional technique. The correlation between the mean insertional torque and BMD in each patient revealed the superiority of the CBT technique. CBT indicates cortical bone trajectory.

out load and equivalency in mixed loading compared with the traditional trajectory. It may be especially effective in poorly trabeculated osteoporotic bone.

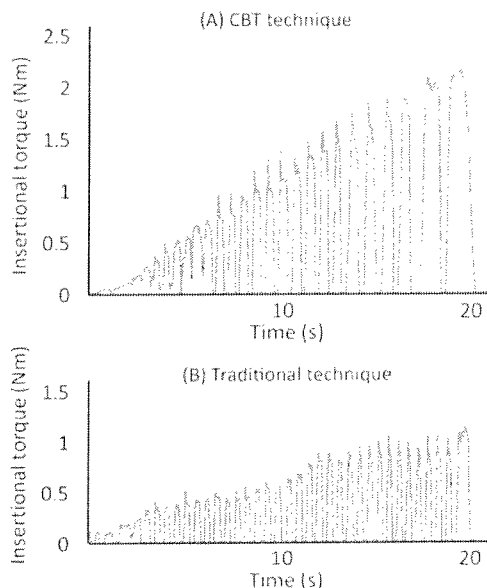
In this study, we measured the torque during screw insertion as an objective value concerning pedicle screw stability. The insertional torque of the screw, generated primarily by the shearing force and friction in the bone-screw interface, is defined as an angular moment of the force required to advance the screw into the bone.<sup>10</sup> Many studies have reported the relationship of initial screw stability and insertional torque.<sup>11-13</sup> Zdeblick *et al*<sup>13</sup> stated that the insertional torque of pedicle screws was highly correlated with the pull-out strength in a human cadaveric study.

With regard to the insertional torque using the traditional technique *in vivo*, it was  $1.45 \pm 0.35$  Nm (62 patients, mean age: 58 yr) reported by Okuyama *et al*<sup>10</sup> and  $1.29 \pm 0.56$  Nm (8 patients, mean age: 56.8 yr) reported by Bühler *et al*.<sup>14</sup> In addition, they showed significant positive linear correlations between insertional torque and BMD. The mean insertional torque using the traditional technique of  $1.24 \pm 0.54$  Nm in this study was similar to those in the above previous studies, and the CBT screw torque of  $2.49 \pm 0.99$  Nm was higher than any other results. This study is the first to investigate CBT screws stability *in vivo* by measuring insertional torque. Generally, it is not correct to compare pedicle screw stability by each insertional torque between differently designed screws.<sup>15</sup> We conducted torque measurement of 2 different insertion techniques using a single shape of screw and demonstrated greater stability of the CBT screws. What is particularly interesting is that the correlation between the insertional torque and BMD was higher in the traditional screw group than in the CBT screw group. This could be explained theoretically by the traditional screws being anchored mainly in cancellous bone and the CBT screws being in cortical bone. This is an important finding because osteoporosis has a far greater effect on cancellous bone than on cortical bone.

In addition, we performed the side-by-side comparison of 2 different insertional techniques using a single shape of screw for each vertebra in the H group. Although the H group has

the biomechanical potential induce an imbalance of the spinal construct, we have used a cross-linking connector for stabilizing the reconstruction, and have experienced no loosening or breakage with very satisfactory results. Between CBT and traditional techniques, there were 4 factors affecting the insertional torque besides its trajectory. First, the pull-out force of the screw decreased as the screw diameter decreased.<sup>7,16</sup> In this study, the diameter of the CBT screws (5.5 mm) was smaller than that of the traditional screws (6.5–7.5 mm). Because the CBT allows the screw to engage the denser regions, there is a potential risk of entrance point and pedicle fractures during screw insertion. Second, the screw stability increased as the screw length increased.<sup>17</sup> According to our previous morphometric study, we used CBT screws of 30 to 35 mm in length, which is shorter than the traditional screws of 40 mm.<sup>3</sup> Third, the size of the pilot hole relative to the screw diameter size is an important factor. Chatzistergos *et al*<sup>18</sup> and Steeves *et al*<sup>19</sup> concluded that using a pilot hole of smaller diameter increased the pull-out force significantly. In this study, the pilot holes were prepared using the same 3.5-mm-diameter probe in both techniques and the diameter of the CBT screws was smaller than that of traditional screws. Therefore, the size of the pilot hole was relatively larger in the CBT screws. Finally, under-tapping of a pilot hole can increase the pull-out strength of self-tapping screws.<sup>18,19</sup> Kuklo and Lehman<sup>20</sup> reported that under-tapping the pedicle by 1 mm increased the maximum insertional torque by 93% when compared with the same size tapping. In this study, tapping of the same size as the planned screw was carried out for the CBT screws and 1-mm under-size tapping was carried out for the traditional screws. For the 4 factors mentioned in the earlier text, the CBT technique had a theoretical disadvantage associated with measuring the insertional torque. However, the mean maximum torque of the CBT screws was about 1.7 times higher than that of the traditional screws. It is a very important result that there was strong screw stability using the CBT technique. None of the previous studies reported the biomechanical stability of CBT relative to the traditional screw *in vivo*.

Furthermore, we compared the real-time torque change during screw insertion as well as the maximum insertional torque (Figure 6). During the initial insertion of screws into the pedicle, the torque increased with contact area for both techniques. As the screw advanced more deeply, the insertional torque changed with gentle increases and plateaued for the traditional screws. On the contrary, the insertional torque continued to increase to the last phases for the CBT screws. This is because, as mentioned by Hirano *et al*,<sup>21</sup> the traditional pedicle screw stability depends on the pedicle rather than on the vertebral body and the CBT screws exhibit increased cortical bone contact with insertion. The insertional point of the CBT is located in the lateral part of the pars edge, which possesses favorable cortical bone. Ivanov *et al*<sup>22</sup> reported a gradual increase in pars interarticularis thickness from the medial to the lateral edge. In addition, according to a morphometric study of the lumbar pedicle isthmus using reformatted computed tomographic images by Li *et al*,<sup>23</sup> medial cortical pedicle wall was found to be thicker than that



**Figure 6.** Typical torque profile of a CBT technique screw (A) and a traditional technique screw (B). CBT indicates cortical bone trajectory.

of the lateral equivalent. We think that the CBT screws take better advantage of the vertebral/pedicle complex, obtaining a 4-point fit between the dorsal cortex at the site of insertion, the medially oriented posterior pedicle wall, the laterally oriented anterior pedicle wall, and the curvature of the vertebral body wall. These anatomical features seem to have a critical role in CBT screws' stability.

There are some limitations to this study that should be mentioned. This is the intraoperative *in vivo* study of the insertional torque. Many studies have reported that the insertional torque is highly correlated with the pull-out strength.<sup>11-13</sup> Meanwhile, screw loosening was caused mainly by cyclic caudocephalad toggling at the bone-screw interface.<sup>24</sup> Okuyama *et al*<sup>10</sup> have shown that the insertional torque cannot be used as an objective predictor of pedicle screw loosening or clinical outcome. However, other factors such as preoperative spinal instability, operative methods, or postoperative management may therefore play an important role in the development of clinical failure. Additional research including the postoperative radiographical changes with a large number of patients is needed to analyze regarding whether insertional torque could be an index for the strength of the long-term fixation stability. Another limitation is the method for BMD measurement. Because the presence of osteophytes, articular facet hypertrophy, or calcified aorta detected in DXA influences the measured lumbar BMD values especially in elderly patients, we used the femoral neck BMD. For the *in vivo* insertional torque measurement, Bühler *et al*<sup>14</sup> demonstrated a linear correlation between insertional torque and the femoral neck BMD, not lumbar BMD. They also noted that lumbar BMD measured by DXA must be used with caution in degenerative spine cases. Contrary to this, Myers *et al*<sup>12</sup> reported that regional BMD inside the pedicle measured by quantitative CT had a much higher correlation with insertional torque than

BMD determined by DXA. BMD measurements could be the topic of further consideration.

## CONCLUSION

The favorable stability of each individual CBT screw has been reported. However, not much has been done to clarify the biomechanical stability of CBT screws within a unit construct, so additional study is needed for complete elucidation of the biomechanical behavior of CBT.

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