Evaluation of Efficacy of Cortical Bone Trajectory Screw versus Traditional Pedicle Screw in Fixation of Lumbar Spine (Comparative Study)

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ABSTRACT

Lumbar cortical bone trajectory (CBT) screws constructs offer an alternate means of lumbar spine fixation to pedicle screws (PS). In the sagittal plane, it has an inferior to superior pathway, and in the transverse plane, it has a medial to lateral pathway. To evaluate efficacy of CBT as compared to traditional PS in lumbar spine fixation as regards clinical, radiological, surgical outcomes, fusion rate and complications. In total, 30 patients with lumbar spine pathology requiring fixation were enrolled in this prospective study and divided into 2 groups: group A (15 patients) has been fixed using CBTs, and group B (15 patients) has been fixed using PS. Clinical (ODI) and (VAS) scores, radiological, surgical outcomes, fusion rate and complications findings were evaluated and compared prospectively. According to our study, the CBT method in lumbar fusion surgery provided comparable clinical results (VAS, ODI), fusion rates, intraoperative and postoperative complications, operation time, and hospital stay to the pedicle screw method. The CBT technique, on the other hand, offers the added advantage of decreased blood loss but has the drawback of more radiation exposure. CBTs are reasonable alternative to PS in lumbar spine fusion in degenerative lumbar spine disease. Additional studies should be performed with larger sample sizes especially on lumbar spine trauma to have more solid results and recommendations.

Keywords: Cortical bone trajectory screw technique, traditional pedicle screw technique, clinical outcome, radiological outcome, fusion rates, lumbar degenerative disorders

Introduction

The classic way of pedicle screw insertion is from lateral to medial, having the starting point at the intersection of the vertebral's transverse process and the lateral wall of the facets. A number of complications may occur with traditional trajectory screw fixation, such as misplacement and loosening of screws, and loss of stability, especially in old patients with osteoporosis [1,2].

Recently, an alternative pathway for fixation of PS have been developed which aim to increase the PS purchase in the higher bone density regions of vertebrae. The cortical bony trajectory screw (CBTS) was described for the first time by Santoni et al. [1]

This recent trajectory enables the PS to engage the lamina and the pedicle through the cortical bone, increases the biomechanical stability, increases the pull-out strength of CBTS, and decreases the screw loosening incidence[3].
PATIENTS AND METHODS

The current study was held in orthopedic department (spine unit), Kasr AlAiny hospital, in the period from 2018 to 2020, a comparative study that includes 30 patients indicated for lumbar spine fixation. Patients were divided into two groups: Group A (6 males and 9 females), where fixed by cortical bone trajectory screws. Group B (8 males and 7 females), were fixed by conventional pedicular screws. In group A, there were 10 cases with degenerative spine diseases and 5 cases with fracture lumbar spine while in group B; there were 7 cases with degenerative spine diseases and 8 cases with a fractured lumbar spine. Preoperative evaluation included a patient's history and physical examination. Plain radiographs should be used in all patients' radiographic assessments to assess trauma cases, detect instability, and rule out abnormalities. Magnetic resonance imaging (MRI) is used when there is a suspicion of neural element compression. Computed tomography (CT) is important in delineating pathological conditions, especially in trauma cases.

The Operative procedure
CBT screws fixation

All patients were positioned in prone position using general anesthesia on a radiolucent table. Careful positioning of the limbs to avoid nerve entrapments and careful padding of the pressure areas of the body is insured. Skin incision was leveled and fashioned using the C-arm. After adequate draping, a standard midline posterior approach of the posterior elements was performed bilaterally to the medial facet. Subperiosteally, the paraspinal muscles on both sides of the spinous processes have been exposed, revealing the lateral lamina and the medial border structure of the articular process.

Figure (1) Diagram showing difference in dissection between cortical bone trajectory and Traditional trajectory.

The starting point is 2 mm medial and caudal to the superior articulating process, positioned on the pars interarticularis slightly medial to its lateral border and at the meeting of the pars interarticularis with the superior articulating process of the facet joint after the exposure was completed. Using a pedicle awl, we made the starting hole. The trajectory of the screw tilts 5° to 20° medial–lateral in the coronal plane, and 30°C to 10°C caudo-cranial in the sagittal plane. We used a straight pedicle probe for creating the screw passage guided by the C-arm. After investigating the integrities of the walls and the floor using a malleable pedicle feeler, we started tapping using 4 mm pedicle tap, then we reevaluated integrities of the walls. We used cancellous screws or double threaded conical screws with diameter 4.5 mm and length 30 – 35 mm. Rods are then inserted and anti-torque is applied to tighten screw cap to audible click.
Figure (2) Steps for cortical bone trajectory screw insertion
(a) Making initial hole using awl   (b) Creating passage using probe (c) Tapping (d) Screw insertion.

If decompression and fusion is indicated, after insertion of CBT screws, laminectomy was then performed. Then interbody fusion was performed as in classic PLIF surgery using cages and morselized autograft. Rods were then inserted and anti-torque is applied to tighten screw cap to audible click.

Final imaging confirms appropriate placement of the implants. Vancomycin powder is distributed over the instruments to achieve hemostasis. There is a suction drain installed. The deep muscle, fascia, subcutaneous tissue and skin were closed in layers.

Figure (3) Final imaging for L4-L5 decompression &fusion with CBTPS fixation.
(a) A-P view.                                (b) Lat view

Conventional pedicular screws fixation screws fixation
Midline posterior exposure of the posterior elements was performed bilaterally to base of transverse process. The lateral lamina and lateral border structure of the articular process, and
the base of the transverse process, were revealed by dissecting the paraspinal muscles on both sides of the spinous process subperiosteally.

An awl was used to make a starting point, and then a pedicle probe was inserted into the pedicle at roughly a 30° medial angle, being careful not to pierce the inner wall. A feeler was utilized to ensure the integrity of the pedicle walls and floor, then the pedicle was tapped for a screw and reevaluation using a pedicle feeler was done. Then a pedicle screw of appropriate length was inserted. Screws had a diameter of 6.0 or 7.0 mm and a length of 40 or 45 mm. Finally, the screws' length and cranio-caudal orientation have been verified under the c arm. rods were then inserted and anti-torque was applied to tighten screw cap to audible click. Decompression and fusion were done in the same way like group A.

**Figure (5)** Laminectomy, decompression with PS fixation and final images.

Immediate post-operative radiographs and CT scan were done to detect hardware malposition. Postoperative antibiotics were continued for two days postoperatively. Oral diet was started in the second day. All patients discharged from the hospital after drain is removed, analgesics and antiedematous medications. All patients were followed in the outpatient clinic as follows: After two weeks post op: for wound condition and removal of stitches. Patients were assessed radiographically and clinically at three, six, and twelve months after surgery. Clinical and functional outcomes were assessed using the visual analogue scale (VAS) [4] and the Oswestry Disability Index (ODI) [5]. Plain radiography and CT scans of the lumbosacral spine are used to evaluate fusion and stability, as well as to detect complications such as implant failure.

**RESULTS**

**Operative time per level:**
The mean operative time for group A was 122.5± 17.28 minutes ranging from 85 to 130 minutes, and for group B was 118±16.81 minutes ranging from 80 to 135 minutes with no statistically significant difference between groups according intraoperative time. (P value = 0.775)

**Intra-operative blood loss per level:**
The mean intra-operative blood loss for group A was 365± 66.62 ml ranging from 250 to 500 ml, and for group B was 475 ± 59.55 ml ranging from 300 to 550 ml with statistically significant difference between groups according to intra-operative blood loss. (P value < 0.001)

**Intra-operative radiation exposure per level:**
The mean intra-operative radiation exposure for group A was 66.95± 15.07 sec ranging from 45 to 100 sec, and for group B was 36.6 ± 6.68 sec ranging from 30 to 55 sec with
statistically significant difference between groups according to intra-operative radiation exposure. (P value < 0.001)

**Fusion rates:**
Fusion rates were assessed radiologically by X rays or CT-scan. Fusion has been achieved in 12 of 15 patients (80%) in group A and in 14 of 15 patients (93%) in group B at 1 year post-operation. The fusion showed no statistically significant difference between the 2 groups (P value = 1)

**Intra and post-operative complications:**
In group A, one patient (fracture L2) developed screws fracture 6 months post-operative and one patient in group B (fracture L1) had the same complication. The first case didn’t have significant pain or disability refused a second operation at the time. The second patient is scheduled for a second revision surgery not at the moment upon his request

Only one case of group A was non-fused at the 1-year follow-up versus 2 cases group B. Patients were clinically stable and there was no need for further intervention with no statistically significant difference between 2 groups.

**Back pain visual analogue scale (VAS):**
The VAS scoring was measured for back pain preoperative, at discharge, 3 months and 6 months and at one year postoperative for both groups. Post-operative scores were significantly improved than pre-operative scores. In group A it decreased from 8.75±0.47 pre-operative to 4.85±0.99 post-operative to 3.05±0.66 at 3m post-operative to 2.75±0.78 at 6m post-operative to 1.55±0.41 at 1 year post-operative. In group B it decreased from 8.65±0.77 pre-operative to 5.65 ± 0.69 post-operative to 3.4 ± 0.6 at 3m post-operative to 4.15 ± 0.55 at 6m post-operative to 1.7 ± 0.52 at 1 year post-operative with no statistically significant difference between 2 groups.

**Oswestry Disability Index (ODI):**
The ODI was measured for evaluating the clinical outcome preoperative, at discharge, 3 months and 6 months and at one year postoperative for both groups. Post-operative ODI was significantly improved than pre-operative scores. In group A it decreased from 68.1±26.99 pre-operative to 24.1±2.76 post-operative to 17.1±2.53 at 3m post-operative to 13.9±2.65 at 6m post-operative to 10.3±3.47 at 1 year post-operative. In group B it decreased from 45.3±22.44 pre-operative to 23±4.11 post-operative to 18.1±2.96 at 3m post-operative to 16.2±2.56 at 6m post-operative to 13.7±2.27 at 1 year post-operative with no statistically significant difference between 2 groups.

**DISCUSSION**
The emergence of CBT screws, however, may help alleviate some of conventional pedicle screws drawbacks. The medial-to-lateral and caudal-to-cephalad path of CBT screws theoretically reduces the risk of nerve roots injury. CBT screws can also be used as a salvage technique in failed PS placement or in patients with a pedicle too small to hold a screw. The biomechanical evidence supporting their use is strong. When compared to PSs in cadaveric models, Santoni et al [1] noticed a 30% rise in uniaxial pullout load.

The fusion rate between the two groups in our study was not significantly different (P value = 1). Orita et al.[6] discovered that the fusion rates of CTB and PS were similar, with 91% in the CBTS group versus 91.5 % in the conventional pedicle screw group. Lee et al [7] discovered that the fusion rates in single-level PLIF were equal between CTB and PS at one year of follow-up,
and at two years of follow-up, the fusion rate was (91.4%) in the CBTS group versus (94.5%) in the conventional pedicle screw group.

In our study there was no significant difference as regarding the VAS scoring preoperative, at discharge, 3 months and 6 months and at one year postoperative for both groups. Post-operative scores were significantly improved than pre-operative scores. Liu et al. [8], Chin et al. [9], Orita et al.[6], Lee et al.[7], Ninomiya et al.[10] and Takenaka et al.[11] found no significant difference in presurgical leg or back pain (P>0.05) between their individuals.

In our study there was no significant difference as regarding the ODI at discharge, 3 months and 6 months and at one year postoperative for both groups. Post-operative ODI was significantly improved than pre-operative scores. Chin et al. [9] reported a significant reduction in ODI score in the CBTS group relative to the PS group following surgery (28.7 versus 32.5, P=0.027), which they justified due to the capacity to maintain anatomy, reduced operational time, intraoperative blood loss, reduced dissecting, and less postsurgical pain. Hung et al.[12] and Lee et al.[7] showed no significant difference as regarding the ODI. (p= 0.777), (p= 0.157) respectively.

In our study we calculated the operative time per level not collectively as we included different pathologies with different levels of fixation and fusion. There is no statistically significant difference between groups according intraoperative time per level. Only Sakaura et al. [13] noticed a significant difference in the duration of PS results (145±33 min) versus lumbar fusions conducted through CBT (123±16 min) (P<0.01). There was no difference in surgery time between the techniques according to Chin et al. [9] (P=0.084) and Takenaka et al.[11] (P=0.672).

In our study there is statistically significant difference between groups according intra-operative blood loss per level (P value < 0.001). According to Chin et al. [9], CBT led to less loss of blood (152 mL) than PS (219 mL) (P<0.05). Likewise, Takenaka et al.[11] discovered that CBT (120 mL) caused lower loss of blood than PS (201 mL) (P<0.001).

On the whole, our results imply that the CBT technique could result in less loss of blood than PS techniques, which could be an important element to consider when selecting a surgical technique for high-risk operating candidates. [14]

In our study there is statistically significant difference between groups according intra-operative radiation exposure per level (P value < 0.001). The mean intra-operative radiation exposure for group A was 38.15± 5.16 second for group B was 24.06 ± 3.28 sec. Marengo et al.[15] showed no statistically significant difference between 2 groups regarding radiation exposure (p=0.6913). This difference between our result and Marengo et al. maybe justified by our learning curve and lack of familiarity with this new technique.

In our study there is no statistically significant difference between groups according hospital stay (P value = 0.062). Marengo et al. showed statistically significant difference between 2 groups regarding hospital stay (p= 0.0413). The mean hospital stay for CBTs group was 2.9± 1.37 days and for group PS group was 3.8± 1.32 days. Lee et al.[7] showed significant difference between both groups according hospital stay(p=0.04).The mean for cortical screws group was 4.5±1.1days and 6.9±0.9 days for conventional pedicle screws group. This difference may be due to increased muscle damage during traditional pedicle screws spine surgery which is correlated with longer hospital stay.

In our study there was no significant difference as regarding post-operative complications like implant failure, infection, dural tear ,misplacement ,hematoma formation, neurological deficit, wound complications , non-union and pseudoarthrosis (p=1).In group A , there was 1 case of implant failure , 1 case of dural tear and 1 case of pseudoarthrosis. In group B there
was 1 case of implant failure, 1 case of dural tear and 2 cases of pseudoarthrosis. There were no significant differences in screw misplacement between the two groups, according to Sakaura et al. [13] and Takenaka et al.[11] They also discovered no significant differences between the CBT and PS groups in dural tears, symptomatic hematomas, deeper or superficial wound infections. The PS group had a higher rate of dural tears than the other groups. This was not, though, shown to be statistically significant. Takenaka et al.[11] found a greater frequency of symptomatic hematoma in the CBT group (2.4% versus 0%), whereas Sakaura et al.[13] found comparable occurrences in both groups (1.1% versus 1.2%). However, Sakaura et al. [13] did find a greater frequency of infection of superficial wounds in the CBT group (2.1% versus 0%), and both articles found a high rate of infection of deeper wounds in the PS group. Hegde et al. [16] support the idea that infection rates are linked to the length and complexity of surgical operations. This outcome could be explained by factors such as increased surgical length, dissection, and postsurgical dead space.

CONCLUSION

The aim of this research was to compare the efficacy of CBT to traditional PS in lumbar spine fixation and fusion through a prospective comparative design. When compared to the PS approach in lumbar fusion operations, the CBT method gave equivalent clinical results (VAS, ODI), fusion rates, complications (intraoperative and postoperative), surgery time, and hospital stay. The CBT technique, on the other hand, offers the added benefit of decreased blood loss but has the drawback of more radiation exposure. We believe that CBT screws will deliver comparable results to PS in fixation and fusion of the lumbar spine in degenerative spine diseases. Thus; CBTs are reasonable alternative to PS in lumbar fixation and fusion in these cases. But it has inferior results to PS in cases of fracture lumbar spine regarding maintenance of correction achieved on the follow up period. Further research, especially on trauma cases, ought to be done with larger sampling sizes and longer follow-up durations to give more solid results and recommendations.

REFERENCES


