Clinical Outcomes With Midline Cortical Bone Trajectory Pedicle Screws Versus Traditional Pedicle Screws in Moving Lumbar Fusions From Hospitals to Outpatient Surgery Centers

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Study Design: Level III.

Objective: To report on the outcomes of midline cortical bone trajectory (CBT) pedicle screw surgical technique for posterior lumbar fixation in the outpatient surgery center (OSC) compared with traditional pedicle screws in the hospital.

Summary of Background Data: Traditional pedicle screws have been the gold standard for posterior lumbar fusion. Advances in spine surgery, including less invasive procedures have propelled the design of instruments and implants to achieve greater posterior spinal fixation, with decreased tissue destruction and higher safety margins. Biomechanical studies have validated the superior pullout strength of cortical screws versus the traditional pedicle screws and represent an opportunity to perform safe lumbar fusions in OSCs with same day discharge.

Materials and Methods: The medical records of 60 patients with prospectively collected data were reviewed. Two matched cohort groups consisting of 30 patients each, CBT pedicle screws performed in OSC patients (group 1) was compared with traditional pedicle screws performed in hospital patients (group 2). Outcomes were assessed with self-reported Visual Analog Scale (VAS) scores, Oswestry Disability Index scores, and radiologic fusion rate.

Results: Totally, 33 males and 27 females, age range (28–75), average 58 ± 3 years. Average body mass index was 29 ± 1.15 kg/m^2. A total of 65% of surgeries were at L5–S1 level. Significant improvement noted in VAS back pain scores in the OSC group from 7.8 ± 0.5 to 2.5 ± 0.7, $P = 0.001$. Comparing intergroup VAS back pain scores and Oswestry Disability Index scores, OSC group demonstrated significant improvement, $P = 0.004$ and 0.027, respectively. Fusion rate at 2 years was similar, $P = 0.855$ between groups.

Conclusions: We successfully transitioned our lumbar fusions from hospitals to OSCs using a midline CBT pedicle screw technique. Although traditional pedicle screw placement is effective and may be viable in an OSC, we see more advantages to use midline cortical screws over traditional pedicle screws.

Key Words: less exposure surgery, traditional pedicle screws, cortical bone trajectory pedicle screws, lumbar fusion, hospital, outpatient surgery center

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Pedicle screw augmentation of the posterior lumbosacral spine has long been considered the gold standard for rigid 3-column fixation. Since the pioneering work of Roy-Camille et al,[1] several novel instruments and techniques have emerged which aid in a more reliable construct less tissue destruction and ultimately greater patient satisfaction.

Modern advances in spine surgery in conjunction with a growing desire for less invasive procedures are rapidly propelling the design of instruments and implants to achieve greater posterior spinal fixation, with decreased tissue destruction and higher safety margins.[2,3] Santoni et al[4] reported on a technique of insertion of pedicle screws using a cortical bone trajectory (CBT). This biomechanical study demonstrated equivalent pullout strength and toggle characteristics using this technique compared with traditional trajectory and can be used in poorer quality bone. The purpose of this study is to report on the clinical outcomes of CBT pedicle screws for posterior lumbar fixation in the outpatient surgery center (OSC) compared with traditional pedicle screws in a hospital. We also describe the surgical technique and advantages of the placement of CBT pedicle screws through a single 1.5-inch, midline incision.

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MATERIALS AND METHODS

A retrospective review of prospectively collected data from the medical records of 60 patients were conducted. Group 1 consisted of 30 patients who underwent CBT pedicle screws for posterior lumbar fixation in the outpatient setting. A comparison group, group 2 included 30 patients who had traditional pedicle screw fixation in the hospital setting. IRB approval was obtained for the study as part of a cohort group of patient undergoing lumbar fusion. All operations were performed by a single surgeon, who has experience in academic and private hospitals, before commencing in an outpatient setting. Patients were only considered for surgery after failed conservative management for at least 6 months. Indications for lumbar disk herniation, degenerative disk disease, spinal stenosis, chronic lower back pain with or without radiculopathy and spondylolisthesis (Figs. 1A, B). Exclusion criteria for this study included acute severe trauma, fractures, malignancy, infection, unstable chronic medical illnesses, prior lumbar fusions, and body mass index (BMI) > 42.[5] All patients were assessed preoperatively and narcotics were discontinued.[6] Patients with chronic but stable medical conditions, including hypertension, diabetes mellitus, asthma, hypercholesterolemia, and heart disease were medically cleared by their family practitioner and/or cardiologist where applicable.

Statistical Analysis

Values are expressed as counts or means ± SE as appropriate. Intergroup comparisons were made using *t* test. Data were analyzed using the SPSS statistical software version 22 (IBM Corp, New York, NY). Power analysis performed based on mean Visual Analog Scale (VAS) scores, to obtain a statistical power of 80% and confidence interval of 5% a sample size of 40 is required.[7] Tests were considered significant if $P < 0.05$.

SUMMARY OF OPERATIVE TECHNIQUE

The patient is placed prone on a Wilson frame and prepped and draped in the standard sterile surgical manner (Fig. 2).

Step 1: Access/Exposure

Using standard surgical landmarks, the pedicles are identified and the position is confirmed using a 22 G needle[8] and anteroposterior (AP) and lateral intraoperative fluoroscopy. An approximately 1.5 inch midline incision is made at the target level over the spinous process, with dissection from the cephalad facet to the caudal facet. A retractor is then used to expose the lamina by retracting the tissue to the approximate midpoint of the inferior facet of the superior level. A partial medial facetectomy is performed bilaterally. The disk space is then exposed and discectomy performed followed by placement of posterior lumbar interbody fusion cages.

Step 2: AP Fluoroscopic Target and Lateral Trajectory

The AP target is identified using fluoroscopy, at the intersection of the inferior aspect of the transverse process and the approximate midline of the inferior facet of the superior vertebral level's midline. The starting point should also be just lateral to the medial border of the pedicle on fluoroscopy. The trajectory is approximately 10 degrees medial to lateral (Fig. 3A).

Step 3: Lateral Fluoroscopic Target and Cranial Trajectory

Using a lateral fluoroscopic view of the cephalad level, a starting point caudal at the level of the pars interarticularis is obtained. A caudal to cephalad angle of approximately 30 to 45 degrees crossing just superior to the inferior border of the pedicle and terminating near the superior endplate is obtained (Fig. 3B). We prefer to start the cephalad level as caudal as possible on the pars and

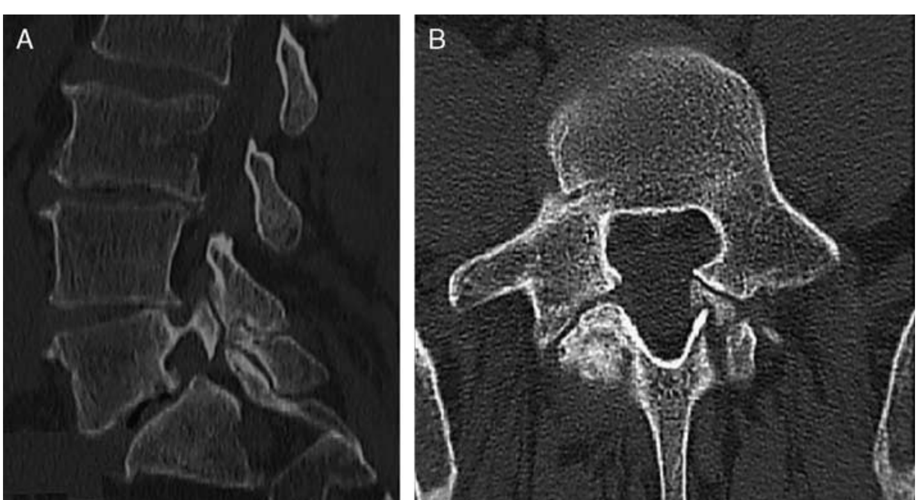

FIGURE 1. Preoperative computed tomographic scan showing spondylolisthesis at L5–S1 and pars fractures at L5. A, Sagittal view. B, Axial view.

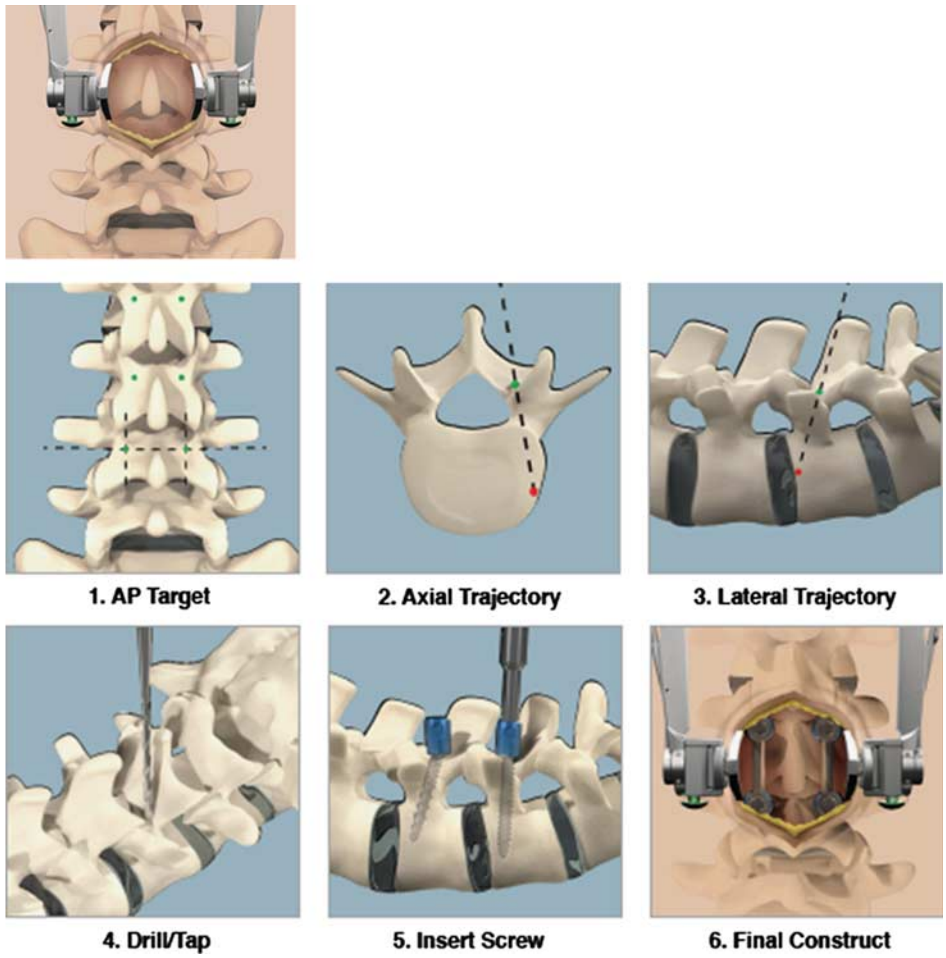

FIGURE 2. Summary of technique steps of placement of cortical midline pedicle screws. full color online

leave the screw 5 mm proud to avoid abutment of the inferior facet in extension. Note that due to the lordosis at L5–S1, the S1 trajectory is parallel to the endplate and not caudal to cephalad as with other lumbar levels.

Step 4: Preparing the Hole (Drill/Tap)

A pilot hole is created with the drill or high speed burr. The drill is advanced through the drill guide along the previously established trajectory using a tap drilling technique to provide tactile feedback that the drill is contained in the pedicle as well as when the cancellous bone of the vertebral body is encountered. The depth markings on the proximal end of the drill are used to select the appropriate length screw. The drill guide is then removed and the ratcheting t-handle is attached to the desired tap, which is inserted into the pilot hole and tapped to the desired depth (Fig. 3C). It is important to confirm the appropriate screw length and tap size to prevent inadvertent canal breach or pedicle fracture.

Steps 5 and 6: Insert Screws and Final Construct

A ball tip pedicle feeler is used to assess depth, confirm the trajectory, and confirm the anterior cortex is intact. The appropriately chosen screw is then placed into the pilot hole and advanced to a depth that allows for positioning of the tulip. AP and lateral fluoroscopic images are used to confirm the screw's final position.

Steps 1–6 were repeated for contralateral pedicle screw placement. The pedicle screws are secured with rods and set screws after Wilson frame is reduced to restore and improve segmental lordosis. Final AP and lateral fluoroscopic images were taken of the construct (Figs. 3D, E) as well as visualized through the incision (Figs. 4A, B). Incision length was measured at 1.5 inch (Fig. 4C).

DISCHARGE AND FOLLOW-UP

OSC patients were discharged within hours of completing surgery after being deemed oriented and neurologically intact by the anesthesiologist and operating surgeon.[5] Outpatient postoperative instructions were discussed with patients and caregivers with written copies provided.[5,9]

Postoperative radiographs were evaluated by the authors (K.R.C., F.J.R.P., and J.A.S.) in both groups at 6 weeks, 6 months, and at 2 year postoperative period. Fusion was defined as the absence of radiolucency's,

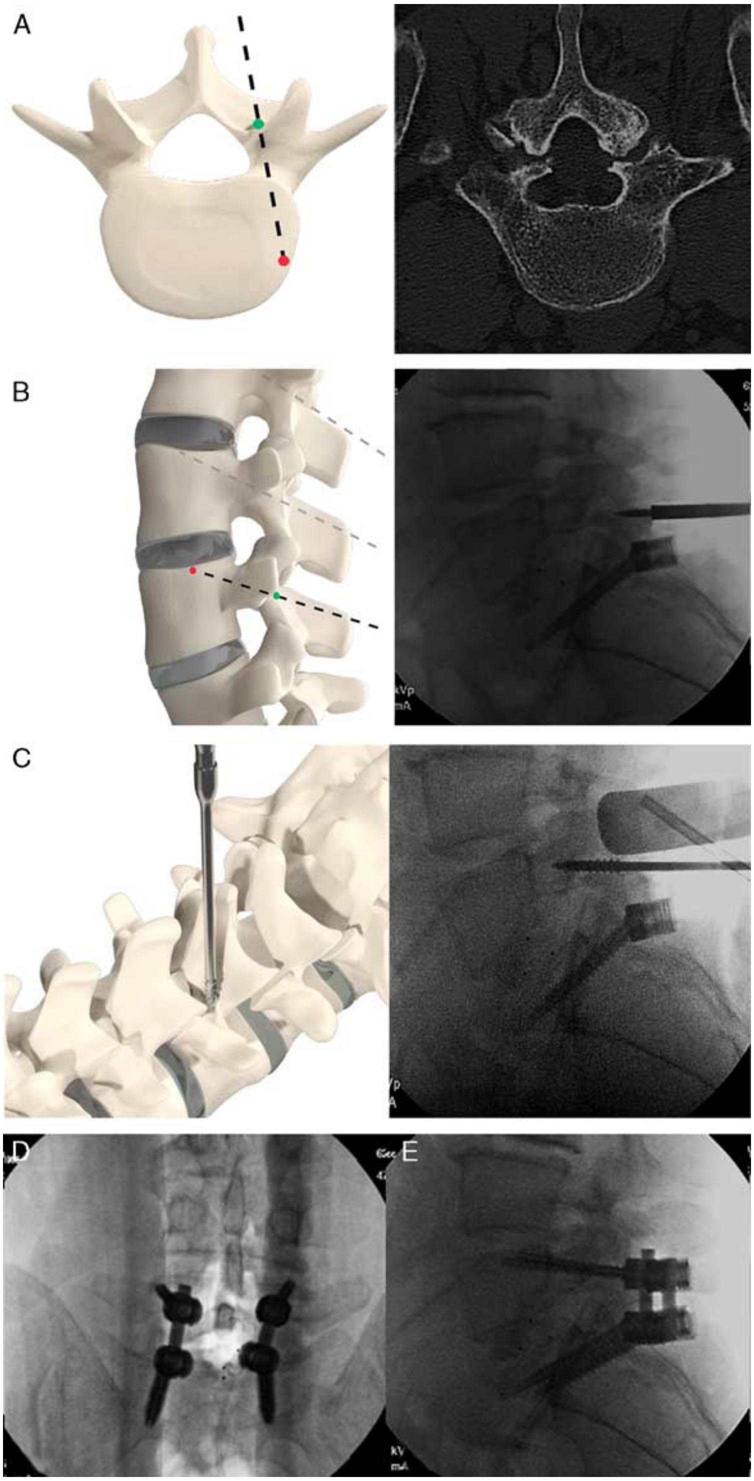

FIGURE 3. A, Axial trajectory displaying the approximately 20 degrees angle. B. Lateral trajectory displaying the approximately 30–45 degrees angle. C, Pilot hole creation illustration. Final postoperative anteroposterior (D) and lateral (E) fluoroscopic images. full color online

evidence of bridging trabecular bone within the fusion area, which was assessed in 2 years follow-up radiographs (Figs. 5A, B). At 2-year follow-up 56 (93%) patient radiographs were available. Fusion was achieved in all patient group 1 (29 patients) and group 2 (27 patients), $P = 0.855$. There was neither evidence of implant failure

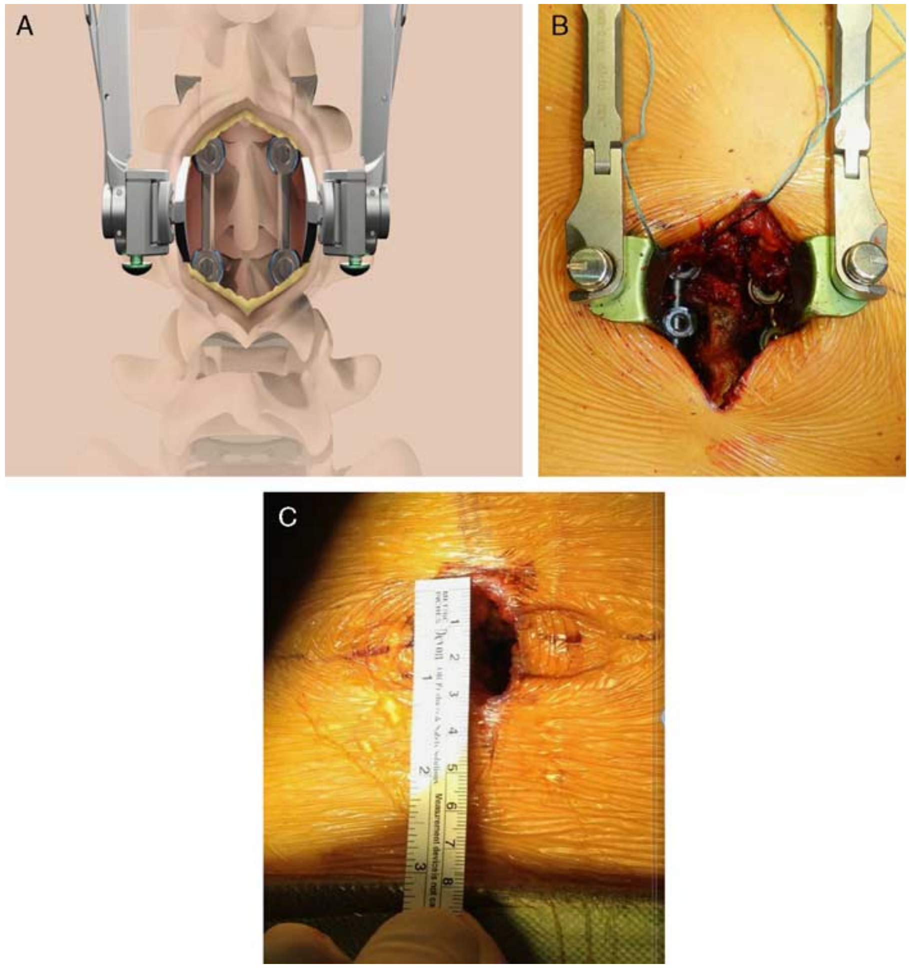

FIGURE 4. Final construct and midline incision. A, Image of final construct. B, Photograph of final construct. C, <1.5 inch skin incision measurement. full color online

nor signs of nonunion in the groups. No major complications were reported in our series and there were no unplanned postoperative admissions for pain, nausea or any other complaints.

TIPS AND TRICKS

(1) When establishing the starting point, the high speed burr or drill provides more accurate starting points than an awl. Because of the angle of the screw trajectory and the lordotic nature of the lumbar spine, the awl will tend to walk and cause the starting point to be more cephalad than intended. In a patient with aggressive hemilaminotomy or narrow pars, the awl can cause a fracture.

(2) For the first few cases, we recommend advancing the drill on oscillate. This allows for increased tactile feedback and reassures the surgeon as the neural elements cannot become wrapped around the drill bit.

(3) The cephalad screw should be left 5 mm proud to prevent the cephalad inferior articular process from impinging on the screw tulip.

(4) We routinely place a more "straight screw" at the inferior level of the fused segment. The starting point is moved more cephalad to the tip of inferior articular process of the facet joint being fused. This decreases the amount of dissection needed, and allows for a less technically demanding insertion.

(5) In patients with lytic spondylolisthesis, the starting point is in the fibrous defect. After checking AP and lateral trajectories on fluoroscopy, the technique is the same as previously described.

RESULTS

The average age was 58 ± 3 years and the average BMI was 29 ± 1.15 kg/m^2. Group 1 mean age and BMI was 48 ± 3 years and 28.9 ± 1.3 kg/m^2, respectively, with 60% male patients. Group 2 mean age was 62 ± 3 years and BMI was 29.0 ± 1.0 kg/m^2 with 50% male patients. There is no statistical difference between groups age and BMI $P = 0.606$ and 0.486, respectively. Follow-up period was for 2 years.

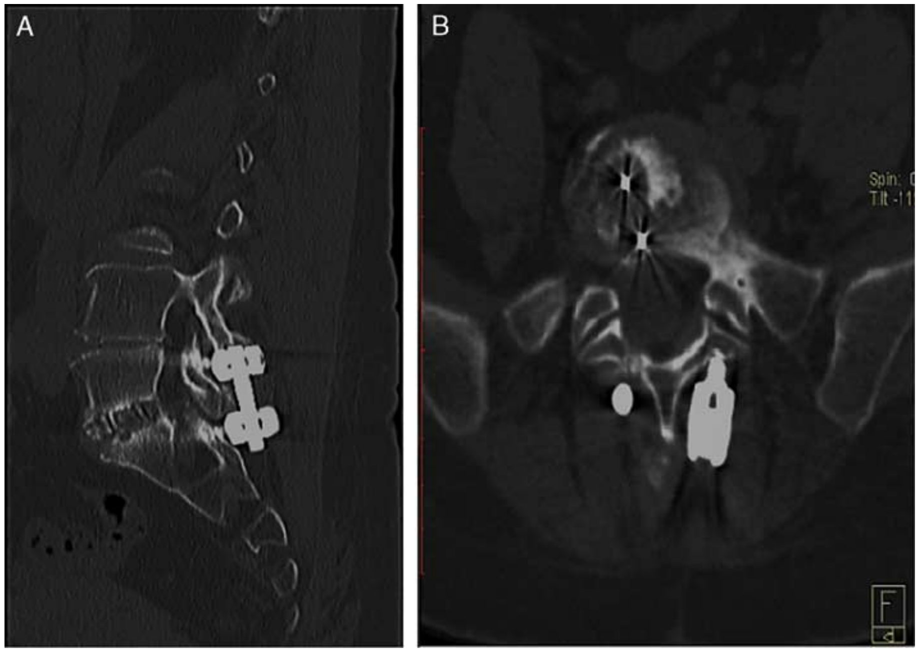

FIGURE 5. A, Postoperative sagittal computed tomography demonstrating fusion. B, Postoperative axial computed tomography demonstrating fusion. full color online

Operative levels included L4–L5 and L5–S1, with 65% of procedures at the L5–S1 level.

Group 1 (OSC patients) mean preoperative VAS scores for back pain improved from 7.8 ± 0.5 to 2.5 ± 0.7 at 2-year follow-up, $P = 0.001$. A reduction in VAS scores for leg pain was achieved from 4.2 to 0.2 ± 0.2, $P = 0.0025$. Preoperative Oswestry Disability Index (ODI) scores improved from 40.8 ± 3.3 to 28.7 ± 1.8 at 2-year follow-up, $P = 0.002$. Looking at group 2 (hospital patients) preoperative VAS scores for back pain improved from 7.2 ± 0.6 to 5.9 ± 0.8 postoperatively at 2-year follow-up, $P = 0.462$. Preoperative VAS scores for leg pain decreased from 5.0 ± 1.7 to 1.9 ± 1.1, $P = 0.259$. Preoperative ODI scores improved from 44.6 ± 4.1 to 32.5 ± 2.1, $P = 0.01$. Comparison of groups 1 and 2 revealed a statistical improvement of VAS scores for back pain in group 1, $P = 0.004$ and no significance between mean single leg VAS scores, $P = 0.169$. Comparing ODI scores between groups 1 and 2 there was no significance in preoperative ODI scores, $P = 0.053$, however there was significance between postoperative scores, $P = 0.027$. The mean estimated blood loss and surgeon time for group 1 was 152 ± 28 mL and 138 ± 10 minutes, respectively, compared with group 2, estimated blood loss 319 ± 87 mL and surgeon time 254 ± 24 minutes with a P-value of 0.025 and 0.084, respectively.

DISCUSSION

The combined use of interbody cages and pedicle screw rod construct has been shown to increase spinal stability in all directions.[10,11] The benefits of CBT pedicle screws over traditional pedicle screws include the ability to preserve more of the patient's anatomy through a less extensive dissection; this translates into potentially less intraoperative blood loss, reduced operative time, less postoperative pain, and reduced risk of catastrophic intraoperative complications such as entering the spinal canal with a lateral to medial trajectory.[11]

In addition, these advantages can be clinically relevant in obese patients, to limit extensive paraspinal dissection, and also in cases where more cortical bone purchase is desirable as in osteoporotic patients. Both static and dynamic biomechanical studies have validated the superior pullout strength of cortical screws versus the traditional pedicle screws.[11–13] Limitations of this approach include the possibility of disrupting the medial pedicular wall, however, with careful screw placement and appropriate image guidance the anecdotal incidence of this occurrence is extremely low. In fact, the cortical path provided by this mediolateral trajectory may potentially be protective against inadvertent canal breach as opposed to the medially directed traditional pedicle screw trajectory.[10,14,15] Several clinical and radiologic studies have evaluated CBT of pedicle screw placement with good results demonstrating safety, ease of placement, and higher cortical bone contact.[16,17] Limiting tissue destruction and patient morbidity, while improving the clinical outcome of patients through the successful use of new devices, instruments and techniques are a collective desire of most, if not all spine surgeons.

Discussion of Results

Our results demonstrate a significant reduction in mean VAS back scores and ODI scores in patients with CBT pedicle screws performed in the outpatient setting. This can be attributed to decreased pull out strength as noted by previous biomechanical studies[4,13] as well as decreased operative time. As demonstrated by Lee et al[18] clinical and radiologic outcomes were similar in patients with pedicle screw and cortical screw. Fusion was achieved in patients after 2 years follow-up period in this study concurring with results from previous studies.[18]

The strengths of this study include adequate sample size, detail outline of procedure for clinical study, and single surgeon mitigating surgeon variability. The main limitation is a retrospective review of prospectively collected data.

CONCLUSIONS

In this study demonstration of successful transition of lumbar fusion in the inpatient setting to the outpatient setting. The use of a less exposure surgery technique of placing pedicle screws by a CBT has shown better outcomes with equivalent fusion rates to the traditional trajectory.

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