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Cortical screw fixation using CT-navigation coupled with real-time electrophysiological monitoring of individual screw placement for unstable degenerative lumbar spondylolisthesis

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ABSTRACT

Introduction: Cortical screws offer a less invasive alternative compared to traditional pedicle screws. These screws are inserted in an inferomedial to superolateral trajectory achieving greater cortical bone purchase. Similar fusion rates, pain relief, and decreased surgical morbidity at 12-month follow-up have been documented when compared to traditional pedicle screws. Using intra-operative imaging, neuronavigation, and individual neurophysiological monitoring of each screw, we showed that this is a safe surgical approach.

Methods: Institutional review board (IRB) approved retrospective review of medical records for 173 patients to determine eligibility. Cases had to be elective one- or two-level fusion with surgical indication. Functional improvement was measured with Oswestry Disability Index (ODI) at pre and post-operative visits. Surgical morbidity data, individual screw thresholds, and radiographic evidence of stability was collected from electronic medical records (EMR).

Results: A total of 153 patients met criteria with mean age 66.60 ± 9.30 (range: 34–84) and mean BMI of 28.76 ± 4.47 kg/m². Of 558 screws inserted, no screws recorded <8 mA upon stimulation, thus no screw required repositioning. There were no pedicle or central canal breach related to screw insertion. ODI decreased from 44.83 ± 18.02 to 19.46 ± 19.52 at 3-months post-operative (p < 0.0001). A subset of 30 patients had 12-month post ODI, which showed a change from 41.22 ± 18.42 to 22.63 ± 22.01 at 12-months (p < 0.001).

Conclusions: Within, we discuss our approach for inserting cortical screws in posterior lumbar fusion for patients with unstable degenerative lumbar spondylolisthesis. Our study shows that the implementation of intraoperative imaging, neuronavigation, and neurophysiological monitoring of individual screws can provide a safe environment for cortical screw insertion. This approach allows for a less invasive approach and greater quality bone purchase while mitigating the associated risks.

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Posterior lumbar fusion
Cortical screw
Pedicle screw
Lumbar spine

1. Introduction

Spinal fusion utilizing pedicle screw fixation is the most commonly used technique for correcting a wide range of lumbosacral spinal degenerative disorders [1–3]. The insertion trajectory of traditional pedicle screws follows variable entry degrees throughout the spine, but are placed in a lateral-to-medial trajectory into the vertebral body [4]. Santoni et al. in 2009 described the cortical bone trajectory (CBT) for lumbar screw placement, which follows an inferomedial to superolateral trajectory [4]. This approach allows for greater cortical bone purchase...
throughout the entire screw length (Fig. 1). Studies using kinetic models have shown that the use of cortical screws provided up to a 30% increase in tensile strength of individual screws when compared to traditional pedicle screws, as well as equivalent multidirectional stress when combined with an interbody fusion device [4–6]. To our knowledge, studies focused on patients with degenerative lumbar spondylolisthesis have been limited, with only one article having a CBT treated sample size of 95 patients [7–16].

This study describes a less-invasive surgical technique of using cortical screws for posterior lumbar fusion in patients with degenerative lumbar spondylolisthesis combining 3D neuronavigation (Medtronic Inc. StealthStation S7 System, Memphis, TN USA) with intra-operative CT imaging (Medtronic Inc. O-arm Image Acquisition System, Memphis, TN USA) and intra-operative neurophysiological monitoring by triggered-electromyography (t-EMG) for each screw in an attempt to further mitigate risks associated with screw insertion. Considering the proposed benefits of using cortical screws for instrumented spinal fusion, the primary purpose of this study was to document the surgical morbidity and feasibility of such an approach in a consecutive series of patients operated for unstable lumbar degenerative spondylolisthesis.

2. Methods

This is an institutional review board (IRB) approved retrospective case series of 173 consecutive patients. Procedures were performed by a single neurosurgeon at a single institution from January 2012 to November 2016. Inclusion criteria required cases be elective and limited to one or two-level lumbar fusion with surgical indication of unstable degenerative spondylolisthesis refractory to conservative management. Cases with more than two-level fusions, non-degenerative pathology, scoliotic deformity, pars defect, surgical revision (prior failed surgery or compromised pedicle screw), and non-elective cases were excluded.

Instability was assessed using standing flexion and extension X-rays while the patient held a 10 lb. weight in each hand. Radiologic instability was defined as abnormal motion >3 mm of translation [17] and was independently confirmed by neuroradiology colleagues at the time of imaging. The operating neurosurgeon assessed each patient in clinic to assess and inform on treatment options. Patients provided informed, written consent for the procedure and completed a baseline Oswestry Disability Index (ODI) assessment.

2.1. Operative technique

Prior to procedure start, the neurosurgeon developed an optimal treatment plan based on the patient’s presentation including entry point, screw dimensions, angle, and direction. Patients underwent general endotracheal anesthesia and placement of intraoperative neuro-monitoring leads prior to positioning on a Jackson frame. Once the patient was appropriately positioned and pressure points were padded, lumbar radiographs were obtained to confirm operative level. Standard 5–7 cm midline incision with sub-periosteal dissection to expose the lamina and lateral aspect of bilateral facet joints was performed. Bilateral partial laminectomies and foraminotomies were performed to ensure optimal decompression of the thecal sac and exiting nerve roots.

The remainder of the central canal decompression along with foraminotomies were performed using microscope magnification. The bone fragments removed were preserved for inclusion in bone fusion construct. Following decompression, the STEALTH navigation (Medtronic Inc. StealthStation S7 System, Memphis, TN USA) reference frame was attached to the spinous process one level above the operative levels. Intraoperative CT scan (Medtronic Inc. O-arm Image Acquisition System, Medtronic Inc., Minneapolis, MN) was obtained and images were merged with navigation software (Supplementary Fig. 1A). Precision and accuracy of the system was confirmed with a navigation probe used against the reference frame and observable anatomy. With the use of navigation guidance and real-time electrophysiological monitoring the cortical-screw trajectory was tunneled using the Powerrease drill bit (Medtronic Inc., Memphis, TN USA). Entry point was inferomedial to the pedicle and continued towards the superolateral border to forge the desired trajectory. Once all pedicles were “tapped,” appropriately sized screws were chosen and inserted with the use of STEALTH navigation. Simultaneous t-EMG was used to assess for proper screw position and assess its proximity to neural elements. Each inserted screw was stimulated for 0.2 ms at 0.8 Hz. Spacers (Capstone PTC Spacer, Medtronic Inc., Memphis, TN USA) were inserted under STEALTH navigation guidance, packed with autograft bone, and confirmed with fluoroscopic imaging. Each screw was re-stimulated to ensure proper position. A second O-arm spin was then used to confirm optimal screw position (Supplementary Fig. 1B). Once the screws were verified, the intervertebral cage (Capstone PTC, Medtronic Inc., Memphis, TN USA) was placed and appropriately expanded using fluoroscopic verification. Bilateral rods (CD Horizon Solera, Medtronic Inc., Memphis, TN USA) were then placed and secured to cortical screws using set screws (Supplementary Fig. 1C–E). Final hemostasis was obtained. Fusion was performed using a combination of bone autograft with Grafton paste and demineralized bone matrix (Grafton Biografts and Mastergraft, Medtronic Inc., Minneapolis, MN USA). Vancomycin powder (1 g) was applied liberally over exposed soft tissues and lateral instrumentation with care taken to not apply over dura. Subfascial drain was left in the operative field. Closure was achieved using standard fashion. Skin edges were approximated with subcuticular stitches and steri-strips.

2.2. Post-operative follow-up

Lumbar stability was evaluated at 3-months post-operative with standing flexion and extension radiographs, which were read and reported by the attending neuroradiologist at the time of imaging. Post-operative functional status was assessed with neurologic physical exam and patient-reported ODI at 3- and 12-month post-operative visits. As long-term follow-up outcomes were not a component of our study, length of follow-up was determined based on latest completed ODI.

Fig. 1. Inferomedial to superolateral cortical bone trajectory for cortical screws (black dotted arrows) and traditional pedicle screw trajectory (grey dotted arrows). Sagittal view (A), axial view (B), and posterior coronal (C) shown. PS = pedicle screws; CS = cortical screws.
2.3. Data collection

Age, sex, body mass index, Meyerding spondylolisthesis grade [18],
total number of levels instrumented, exact levels of fixation, and initial
presenting symptoms were acquired from the electronic medical record
(EMR) as approved by the IRB. Coding with assignment of sequential
study identification numbers was used to avoid breach of personal
identifying information.

Surgical morbidity was measured by collecting the estimated blood
loss (EBL) from anesthesia operative reports, length of stay (LOS) from
nursing discharge reports, skin-to-skin operative time from anesthesia
reports and wound or instrumentation infection rate from nursing and
medical staff notes. Neurophysiological monitoring data for each screw
inserted was collected from the intraoperative t-EMG reports. Pedicle
breach data were collected from operative reports and intra-operative
computed tomography (CT) scan (O-arm) images and durotomy from
operative reports. Secondary outcomes such as functional status and
post-operative lumbar stability were collected from pre- and post-
operative reports and represented by ODI and post-operative radio-
graph reports, respectively.

Study data were collected and managed using REDCap electronic
data capture tools hosted at Baptist Health South Florida [19,20].
REDCap (Research Electronic Data Capture, Vanderbilt University,
Nashville, TN USA) is a secure, web-based software platform designed to
support data capture for research studies.

2.4. Statistical analysis

Statistical analysis of quantitative data was conducted using a two-
tailed paired t-test to compare pre-operative ODI and 3-month post-
operative ODI. Repeated measures one-way analysis of variance
(ANOVA) with Geisser-Greenhouse’s correction and post-hoc Tukey
analysis was used to compare pre-operative ODI with post-operative 3-
and 12-month ODI.

Statistical significance for all analyses were set at p-value < 0.05.
Statistical analyses and corresponding figures were completed using
GraphPad Prism (version 8.0.0) (for Windows, GraphPad Software, La
Jolla, CA USA, www.graphpad.com).

3. Results

3.1. Patient demographics

Data were collected for all cases that met eligibility criteria (n = 153); twenty cases were excluded. Cases were excluded for the following reasons: in-situ fusion (n = 2), diagnosis other than unstable spondylolisthesis (n = 6), three-level fusion (n = 1), cervical fusion (n = 1), revision surgery (n = 2), insufficient medical history on charts (n = 4), and no fusion decided intraoperatively (n = 4). Intra-operative decision to not pursue fusion (n = 4) were made regarding safety due to thecal sac distortion (n = 1) and extensive blood loss during exposure (n = 3). Demographics showed 60.1% (n = 92) were female, the mean age was 66.60 ± 9.30 (range: 34–84), and a mean BMI of 28.76 ± 4.47 (Table 1).

The most common presenting symptoms were neurogenic claudication
with or without mechanical back pain 96.1% (n = 147) and radiculopathy
in 88.2% (n = 135) (Table 1). Reduced walking distance and bowel
or bladder incontinence were reported by 39.2% (n = 60) and 7.8% (n =
12) respectively.

Additionally, 83.7% (n = 128) were single level fusions at L3–L4,
L4–L5 or L5–S1 (n = 9, n = 106, n = 13, respectively) (Table 1, Fig. 2).
Two level fusions occurred in 16.3% (n = 25) of cases at L3–L5 (n = 19) and L4–S1 (n = 6).

3.2. Intra-operative monitoring and surgical morbidity

More than 90% of screws inserted were 4.5 mm in width by 35 mm in
length. Of 622 screws placed, electrophysiological screw monitoring
threshold reports were available for 558 screws (n = 138) (Table 2). Of
these, 539 (96.6%) screws had thresholds ≥ 14 mA on testing. The 19
remaining screws had thresholds lower than 14 mA, but none lower than
8 mA, thus no screw required intraoperative reposition [21]. To confirm
lack of pedicle breach, 121 cases received a second O-arm spin to
evaluate pedicle integrity. Successful screw and interspace placement in
100% of the first 121 consecutive patients provided the necessary pru-
ence to eliminate the 2nd O-arm spin in the remaining cases to decrease
patient and staff exposure to radiation. There was no pedicle breach in
any patient (n = 153) as determined by a second O-arm spin; post-operative
electrophysiological monitoring, or post-operative imaging
(Table 3). The mean ± SD EBL was 148.9 ± 101.28 mL with 5 patients
experiencing ≥ 400 mL EBL unrelated to screw placement (Table 3).
Durotomy not associated with screw placement occurred in two patients
with prompt repair intraoperatively. Surgical site infection not related to
screw placement occurred in one patient and was successfully treated
with intravenous vancomycin, surgical debridement, and care by the
infectious disease service. The mean ± SD length of stay was 2.75 ±
1.49 days, with the majority of patients (53.6%) staying two days or less.

<table>
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<th>Table 1</th>
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<tr>
<td>Clinical characteristics and demographics for all included patients (n = 153).</td>
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<td>Including presenting symptoms, Spondylolisthesis grading, affected levels and levels treated.</td>
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<td><strong>Clinical Characteristics (n = 153)</strong></td>
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<td>Age</td>
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<td>Female</td>
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<td>Male</td>
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<td>BMI</td>
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<tr>
<td><strong>Presenting symptoms</strong></td>
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<tr>
<td>Neurogenic Claudication ± mechanical back pain</td>
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<tr>
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<td>Bladder/bowel incontinence</td>
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<td>Grade 1</td>
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<td>Grade 3–5</td>
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<td><strong>Levels fused</strong></td>
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<tr>
<td>One-level fusion</td>
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<td>L3–L4</td>
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<td>L4–S1</td>
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**Table 2**

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4 patients on 3-month post-operative radiographs, however, were not determined to be unstable by an experienced neuroradiologist at the time of imaging. No patients required revision surgery due to screw malposition or loosening during the time period followed, even for the four patients with persistent motion on 3-month post-operative radiographs.

Pre-operative and 3-month post-operative ODI were available for 80 patients (Table 4). For this group, mean ± SD ODI statistically significantly decreased from severely disabled pre-operative levels (44.83 ± 18.02) to minimally disabled (19.46 ± 19.52) at three months post-operative [t(79) = 10.34, p < 0.0001; Fig. 3]. Of those 80 patients, post-operative 12-month ODI was available for 30 patients. For this subset of 30 patients, mean ± SD ODI statistically significantly changed from severely disabled (41.22 ± 18.42) pre-operative to minimally disabled (17.89 ± 17.10) at three months post-operative to moderately disabled (22.63 ± 22.01) at twelve months post-operative [F(1,29, 37.47) = 23.91, p < 0.0001; Fig. 3].

Post-hoc analysis for the subset with both 3- and 12-month ODI showed a statistically significant mean difference of 23.33 (14.25 to 32.41, 95% CI) with adjusted p-value <0.0001 at 3-months post-operative and a mean difference of 18.59 (7.419–29.75, 95% CI) with p-value <0.001 at 12-months post-operatively (Fig. 4). The difference between 3- and 12-months post-operatively was not significant when compared to each other, p-value >0.05.

### Table 2

<table>
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<th>Neurophysiological Monitoring (n = 138)</th>
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<tr>
<td>Total # of screws</td>
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<td># of screws per patient</td>
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<tr>
<td># of O-arm spins per patient</td>
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<tr>
<td>IO EMG &lt; 8 mA (requiring reposition)</td>
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<tr>
<td>IO EMG 8 mA–14 mA</td>
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<td>IO EMG ≥ 14 mA</td>
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IO EMG = Intra-Operative electromyography; mA = milliamps; SD = standard deviation.

### Table 3

Surgical morbidity for all 153 included patients (n = 153). Including estimated blood loss, intra-operative time (IO), pedicle breach, durotomy, wound or instrumentation infection, and hospital length of stay.

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<tr>
<th>Surgical Morbidity (n = 153)</th>
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<tr>
<td>Estimated blood loss (mL)</td>
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<td>IO time (min)</td>
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<tr>
<td>Pedicle Breach</td>
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<tr>
<td>Durotomy</td>
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<tr>
<td>Infection of Wound or Instrumentation**</td>
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<tr>
<td>Hospital Length of Stay (Days)</td>
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IO time = Intra-operative skin-to-skin time; SD = standard deviation.

**Monitored during hospital stay and follow-up visits.

### 3.3. Post-operative assessment

Lumbar stability was noted in 137 (97.2%) patients on standing flexion and extension radiographs at 3-month post-operative (Table 4). Post-operative 3-month imaging was not available for 12 patients. Persistent motion (<3 mm) at spondylolisthesis level was present in four (2.84%) patients on 3-month post-operative radiographs, however, were...
Overall, post-operative functional follow-up was for 7.2 ± 5.8 months (mean ± SD) (Table 4). No patient was found to have developed any neurological deficit on post-operative physical exams by the operating neurosurgeon during the follow-up period. Of those with ODI at 12-month follow-up (n = 30), none were documented as having developed adjacent segment disease.

4. Discussion

Santoni et al. introduced the CBT in 2009 describing its utility in instrumented spine fixation and showing comparable strength to traditional pedicle screw fixation [4]. The inferomedial to superolateral trajectory allows for a cortical bone only purchase as well as a smaller incision with less soft tissue dissection. Lee et al. in 2015 conducted a randomized controlled trial comparing CS to traditional PS instrumentation and reported similar fusion rates, pain relief, and improvement in functional outcome at 6- and 12-month follow-up, as well as decreased surgical morbidity [14]. These findings have been replicated in various studies, however, with limited sample sizes [8–10,12,14].

Cortical screws have been reported to serve as a reasonable alternative to traditional pedicle screws in various situations. Osteoporotic patients may benefit from fixation with CBT due to the greater purchase of higher quality cortical bone. The decreased amount of trabecular bone with subpar quality in osteoporosis commonly leads to screw loosening that ultimately precludes vertebral stability and adequate bony fusion [4,22–30]. Additionally, Mobbs has described a combined approach that uses traditional pedicle screws in the inferior affected vertebral level while using the CBT at the superior vertebral level to prevent superior facet damage introduced by aggressive dissection or screw placement in lumbar trauma cases [31]. Implementation of CBT for the treatment of adjacent segment disease has also been proposed, as a method that eliminates the need to expose or alter the preexisting instrumentation as an advantage of the different entry-point and trajectory [32]. To date, all studies on the use of CBT have been limited to one- and two-level vertebral disease with limited level I evidence [33].

The medialized trajectory of cortical screws can, however, increase the risk of central canal breach and pedicle fracture. Although intra-operative radiographs and palpation of bony architecture are implemented to ensure proper screw trajectory, they both have varying degrees of reliability [34,35]. Triggered electromyography (t-EMG) provides an additional method to detect malpositioned pedicle screws, providing information on possible medial breach without any radiation.

Fig. 3. Functional Assessment Pre-operative ODI compared to 3-month post-operative (n = 80) (A) and subset with 3- and 12-month post-operative (n = 30) (B). Mean ODI with standard deviation. **** = p < 0.0001; *** = p < 0.001; ns = not significant.

Fig. 4. Oswestry disability index score difference. Absolute difference with median and interquartile range for 3-month post-operative ODI score (n = 80) (A) and for patient subset with both 3- and 12-month post-operative scores (n = 30) (B).
Intraoperative fluoroscopy and 3-dimensional (3D) imaging such as the O-arm have been quintessential modalities in spine surgery as methods to decrease surgical morbidity [23–25,41,42]. Implementation of intraoperative 3D neuronavigation provides live anatomical guidance shown to result in 95.5% screw insertion accuracy, which can be particularly helpful for surgeons that are inexperienced using the CBT [43]. The use of 3D intraoperative neuronavigation has been shown to decrease the odds of a pedicle breach by 99% when compared to traditional fluoroscopic assisted screw insertion [44]. Furthermore, the limited dissection commonly employed in the CBT is one that can benefit from the assistance of intraoperative guidance to ensure preservation of the poorly visualized bony structures. We theorized, that the coupling of intraoperative 3D neuronavigation with real-time neurophysiological monitoring of individual cortical screws would provide immediate feedback to allow for screw re-positioning if need be.

Our study showed that the coupling of intra-operative CT imaging with neuronavigation, and neurophysiological monitoring provides a safe and reasonable alternative to traditional pedicle screws for the fixation of degenerative lumbar spondylolisthesis. There was no pedicle breach in any of the cases (n = 153) confirmed by intra-operative and post-operative imaging. Screw re-positioning was not necessary in any of the patients with a total of 558 screws inserted and all screws recorded >8 mA upon stimulation [21,37]. Our screw malposition rate of 0% is lower than all previously published literature that show a 2.1% and 3.7% cortical screw and traditional pedicle screw respective malposition rate, respectively [7]. Average EBL for all included cases (n = 153) of 148.86 mL (±101.28) is similar to those previously reported in CBT vs. PS case series [7,23,24]. Compared to the literature, our cohort had a LOS that was significantly shorter with an average less than 3-days [13,14,16,45]. Overall complication rate of 1.96% (n = 3) is similar if not lower than those reported in prior literature, with rates as high as 8.9% reported in one prior article [7,8,10,45]. Our cortical screw fixed patients showed surgical morbidity that was comparable, if not superior to those previously published.

Post-operative functional improvement was collected and measured using patient-completed ODI that showed a statistically significant improvement at 3-month (n = 80) and 12-month post-operative visits (n = 30), with p-value <0.0001 and p-value <0.0001, respectively. The average post-operative ODI at 3-months and at 12-months both met the “acceptable” symptomatology threshold with an absolute score decrease of 20 or more points [46]. In addition, the 12-month average ODI score decrease of 19.54 points meets the minimal clinically important difference (MCID) of a 14.3 or greater point decrease as established by Asher et al. [47]. At the individual patient level, however, 12 patients did not achieve a 14.3-point reduction at their 12-month post-operative ODI, of which eight patients showed an increased ODI. Further review of these eight cases did not elucidate a pattern that can explain worsening disability at 12-months. The vast majority of patients with ODI data available showed post-operative improvement in their disability.

To our knowledge our study is the first to highlight the use of cortical screws coupled with intraoperative image-guided navigation and electrophysiological monitoring. We showed that implementing multiple modalities for cortical screw placement may mitigate the risks of neural or bony structural damage. Overall, we showcased a safe and feasible alternative with a potentially less invasive approach that may serve as positive groundwork for future studies.

4.1. Study limitations

As this is a single-institution, single surgeon case series, there were limitations to the study such the fact that efficacy could not be compared to a control group. Functional outcome was limited to 3-months and 12-months post-operatively, as health records after this time point were lost to follow up and our patient population included a large number of international patients. Longer imaging follow-up, particularly with CT imaging would have allowed for better documentation of long-term cortical screw performance and bony fusion. Additionally, as this study was conducted to document the overall surgical morbidity and feasibility of using our multimodal approach, data on comorbidities such as, diabetes, chronic steroid use, and smoking were not documented. Future randomized studies should compare cortical screw outcomes to a traditional pedicle screw group across multiple institutions.

5. Conclusions

These findings of low surgical morbidity with improved post-operative function in patients with posterior lumbar fixation using cortical screws are similar to those previously reported in the literature. The implementation of intraoperative imaging, neuronavigation, and neurophysiological monitoring of individual screws can provide a safe environment for cortical screw insertion. Although we cannot conclude that following a cortical screw approach is superior to using traditional pedicle screws, we provide an alternative approach that incorporates a higher quality bone purchase. Cortical screws are a reasonable method for posterior lumbar fusion in the treatment of unstable degenerative spondylolisthesis.

CRediT authorship contribution statement

Reinier Alvarez: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing - original draft, Visualization. Angel V. Chinea: Conceptualization, Methodology, Investigation, Writing - original draft, Writing - review & editing. Alexander E. Braley: Conceptualization, Methodology, Investigation, Writing - original draft, Writing - review & editing. Sonia Majid: Conceptualization, Methodology, Investigation, Writing - original draft, Writing - review & editing. Kunal Patel: Writing - review & editing, Resources, Methodology. Daniel Segui: Writing - review & editing, Resources, Validation, Conceptualization, Methodology. Amy K. Starosciak: Project administration, Supervision, Writing - original draft, Writing - review & editing, Resources, Validation, Conceptualization, Methodology. Sergio Gonzalez-Arias: Project administration, Supervision, Writing - original draft, Writing - review & editing, Resources, Validation, Conceptualization, Methodology.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.inact.2021.101051.

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