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Clinical Study

The comparison of pedicle screw and cortical screw in posterior lumbar interbody fusion: a prospective randomized noninferiority trial

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Abstract

BACKGROUND CONTEXT: Pedicle screws (PS) offer great benefits in posterior lumbar interbody fusion (PLIF), but several drawbacks of PS, including the risk of superior facet joint violation and muscle injury, have also pointed out. Recently, cortical screws (CS) were invented, which can be placed without the drawbacks associated with PS. However, whether CS in PLIF can provide similar or greater clinical and radiologic outcomes compared to those of PS has not been fully evaluated in clinical research studies.
PURPOSE: To evaluate whether the CS provides similar results to the PS in PLIF, in terms of fusion rate, clinical and surgical outcomes, and complications.
STUDY DESIGN: This is a prospective, randomized, noninferiority trial.
PATIENT SAMPLE: Seventy-nine eligible patients were randomly assigned to either Group A (39 patients), for which PS was used, or Group B (40 patients), for which CS was used.
OUTCOME MEASURES: The primary study end point was to measure fusion rate using dynamic radiographs and computed tomography scans. Secondary end points included intensity of low back pain and pain radiating to the leg using visual analog scales, and also, functional status using the Oswestry Disability Index, surgical morbidity, and additional outcomes such as pedicle fracture and mechanical failure.
METHODS: We compared baseline data in both groups. To evaluate the efficacy of CS in PLIF compared to PS, we compared fusion rates, clinical outcomes, and complications after surgery in both groups.
RESULTS: At the 6- and 12-month follow-up points, similar fusion rates were observed in both groups ($p=.81$ and 0.61, respectively). According to the clinical outcome, CS provided similar improvements in pain amelioration and functional status compared to PS, with no significant differences. Additionally, CS resulted in significantly less surgical morbidity, including shorter incision length, quicker operative time, and less blood loss, compared to PS.
CONCLUSIONS: CS in PLIF provides similar clinical and radiologic outcomes compared to PS in PLIF. On the basis of the present study, we suggest CS to be a reasonable alternative to PS in PLIF.

Keywords: Lumbar spinal stenosis; Posterior lumbar interbody fusion; Pedicle screw; Cortical screw; Fusion rate; Clinical outcome

FDA device/drug status: Approved (PEEK cages (CAPSTONE®, Medtronic, Memphis TN, USA), bilateral screw-rod systems (CD Horizon Legacy system, Medtronic, Memphis TN, USA), bilateral screw-rod system (MIDLFTM, Medtronic Sofamor Danek, Memphis TN, USA)).

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EVIDENCE & METHODS

Context
The authors maintain that spinal cortical screws have a more favorable entry point than conventional pedicle screws and may be technically easier to place. The authors also maintain that facet violation occurs at a lower rate with the use of cortical screws. Differences in clinical and radiographic outcomes between patients treated using cortical screws and pedicle screws have not been widely investigated. The authors present results of a small, prospective randomized noninferiority trial.

Contribution
This study involved 79 patients. No significant differences were encountered in terms of fusion rates and clinical outcomes between patients treated using cortical screws or pedicle screws. Patients in the cortical screw cohort had shorter incision lengths, reduced operative times and less blood loss.

Implications
As a noninferiority study, the work itself was not designed to demonstrate the superiority of cortical screws to pedicle screws, only that outcomes were not significantly worse. This seems to be the case with respect to the primary outcome measure (fusion rates). The power calculation was conducted around determining a sample size that could demonstrate differences in fusion rate only and the sample could be underpowered to detect differences in other outcomes. That said, given the small number of patients included in each cohort, the findings regarding incision length, operative time and blood loss may be more related to the technical facility of the surgeons involved in the study as opposed to direct effects of the cortical screw technique. Larger, prospective studies conducted across multiple centers are likely necessary before the advantages of cortical screw instrumentation can truly be quantified.

—The Editors

Introduction

Posterior lumbar interbody fusion (PLIF) surgery with pedicle screw (PS) has recently been widely used as an effective surgical method for certain lumbar pathologies such as spondylolisthesis [1–5]. PS has been recognized as an irreplaceable instrument in fusion surgery of the lumbar spine because of its advantages [3,6–11]. However, concerns regarding PS include the risk of superior facet joint violation during screw placement or dissection, the skin incision length, and the amount of lateral muscle dissection due to the entry point being lateral to the midline, near the lateral wall of facet joint. In spite of those drawbacks, there was little choice for spine surgeons but to use PS, resulting from the lack of alternatives.

Recently, cortical screws (CSs) using cortical screw trajectories in the lumbar spine were introduced for posterior stabilization [12–14]. Some experimental studies have demonstrated that CS provides similar strength compared to PS [12–14]. Perez-Orribo et al. [12] reported that the bilateral CS-rod fixation technique could provide similar stability in cadaveric experiments compared to PS-rod fixation, regardless of the presence of the interbody cages. Because of their favorable entry point (near the pars articularis) and favorable passage (through the pedicle superolaterally from the entry point), CSs are expected to reduce the rate of facet joint violation and to achieve better clinical and surgical outcomes. However, postoperative outcomes when using CS in PLIF have not been fully described.

To date, the therapeutic efficacy of CS in PLIF has yet to be fully described. Furthermore, to the best of our knowledge, outcomes using CS and PS for PLIF have not yet been compared in a prospective randomized study. Therefore, we analyzed and compared the clinical and radiologic outcomes of CS and PS in PLIF, using a prospective, randomized design via a noninferiority trial. We hypothesized that CS would result in comparable efficacy in terms of fusion rate and clinical and surgical outcomes, in comparison with PS in PLIF.

Methods

Participants

This study was approved by the institutional review board. Inclusion criteria were as follows. First, patients were diagnosed with certain lumbar pathologies, including lumbar spinal stenosis with severe foraminal stenosis and isthmic spondylolisthesis, using lumbar spine radiographs, computed tomography (CT) scans, and magnetic resonance images (MRI) that corresponded to clinical manifestations and physical examinations. Second, patients were required to have shown no improvement in clinical symptoms despite several conservative treatments (including medication, physical therapy, and injection treatment) over a period of 6 months or more. Third, patients were required to have undergone PLIF at a single level using screws (PS or CS) and interbody polyetheretherketone (PEEK) cages. Fourth, patients were aged between 40 and 60 years. Fifth, patients were volunteers for this study with their written consent. Finally, patients were required to complete a 1 year or longer follow-up period.

Exclusion criteria were as follows: fractures, infection or tumors in the lumbar spine; osteoporosis diagnosed by a T score less than -2.5 on dual-energy X-ray absorptiometry bone densitometry measurements, multilevel fusion surgery, hemorrhagic disorders, such as hemophilia and