Posterior Spinal Fusion Using Pedicle Screws

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Abstract

Few clinical studies have reported polyetheretherketone (PEEK) rod pedicle screw spinal instrumentation systems (CD-Horizon Legacy PEEK rods; Medtronic, Minneapolis, Minnesota). This article describes a clinical series of 52 patients who underwent posterior spinal fusion using the PEEK Rod System between 2007 and 2010. Of the 52 patients, 25 had degenerative disk disease, 10 had lateral recess stenosis, 6 had degenerative spondylolisthesis, 6 had lumbar spine vertebral fracture, 4 had combined lateral recess stenosis and degenerative spondylolisthesis, and 1 had an L5 giant cell tumor. Ten patients had 1-segment fusion, 29 had 2-segment fusion, and 13 had 3-segment fusion. Mean follow-up was 3 years (range, 1.5-4 years); no patient was lost to follow-up. Clinical evaluation was performed using the Oswestry Disability Index and a low back and leg visual analog pain scale. Imaging evaluation of fusion was performed with standard and dynamic radiographs. Complications were recorded. Mean Oswestry Disability Index scores improved from 76% preoperatively (range, 52%-90%) to 48% at 6 weeks postoperatively, and to 34%, 28%, and 30% at 3, 6, and 12 months postoperatively, respectively. Mean low back and leg pain improved from 8 and 9 points preoperatively, respectively, to 6 and 5 points immediately postoperatively, respectively, and to 2 points each thereafter. Imaging union of the arthrodesis was observed in 50 (96%) patients by 1-year follow-up. Two patients sustained screw breakage: 1 had painful loss of sagittal alignment of the lumbar spine and underwent revision spinal surgery with pedicle screws and titanium rods and the other had superficial wound infection and was treated with wound dressing changes and antibiotics for 6 weeks. No adjacent segment degeneration was observed in any patient until the time of this writing.

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Figure: Lateral flexion (A) and anteroposterior (B) radiographs of a 65-year-old woman with L5-S1 degenerative disk disease of the lumbar spine at 1 year follow-up showing spinal stability. The patient was asymptomatic.
The ideal spine fixation system should provide sufficient stability without excessive rigidity to allow for bone graft loading and optimum fusion while maintaining natural posturing and alignment to minimize adjacent-level stress. Titanium rods have traditionally been used for lumbar spine pedicle screw fixation because they offer sufficient strength and construct stiffness, closer biomechanical properties to bone compared with stainless steel, improved biocompatibility, and reduced magnetic resonance artifacts. However, although fixation with titanium rods leads to high fusion rates, the increased stiffness of titanium constructs may also contribute to stress shielding and adjacent segment degeneration ranging from 2.5% to 28.4% at 1 year postoperatively and from 11% to 100% at 10 years postoperatively. This degeneration occurs because abnormal forces and motion are created at adjacent segments even though the global motion of the spine is largely unchanged. Once this occurs, it may lead to the recurrence of symptoms and may necessitate revision spinal surgery with extension of instrumented fusion.

Current technological advances have provided alternative solutions to fusion with rigid rods, including dynamic or flexible instrumentations such as the Dynesys system (Centerpulse Ltd, Zurich, Switzerland). Compared with rigid instrumentation, dynamic systems for the spine restore functional stability while maintaining some of the intersegmental motion and allow better stress distribution to all of the columns of the spinal segments, thus decreasing the load to the adjacent disks and to the bone-screw interface. However, the complication rate, which includes complications such as screw loosening, infection, back and leg pain, and endplate vertebral fracture with dynamic stabilization systems, can be as high as 25%, and reoperations are common.

These observations have led to the hypothesis that more compliant materials might restore normal kinematic behavior and allow optimal load sharing while maintaining enough rigidity to stabilize the spine and prevent pathologic motion at the instrumented segments. In this setting, semi-rigid instrumentation systems using rods made from synthetic polymers, such as the polyetheretherketone (PEEK) rod pedicle screw system (PEEK, CD-Horizon Legacy PEEK rods; Medtronic, Minneapolis, Minnesota), have been introduced as an alternative biomaterial for spinal applications. Polyetheretherketone is a fully biocompatible and inert semi-crystalline thermoplastic polymer with minimal toxicity; it has a modulus of elasticity between that of cortical and cancellous bone and a significantly lower modulus of elasticity than titanium (3.2 vs 114 GPa of titanium, respectively).

Polyetheretherketone was initially used in spinal surgery in the form of interbody cages; PEEK rods in posterior spinal fusion were introduced in 2007. Biomechanical studies have shown improved durability, stability, strength, and overall biomechanical profile of PEEK rods compared with metallic rod systems. However, few clinical studies have been reported on PEEK rod pedicle screw spinal instrumentation systems, and those that were reported had small sample sizes and short-term follow-ups. In addition, the reported results are conflicting; some studies reported good or excellent results with a low complication rate with PEEK rod systems, whereas others reported a high reoperation rate with this system in patients with lumbar degenerative spine disease with no improved benefit over all-metal instrumented fusions. To enhance the literature, the current article describes the authors’ clinical results with the use of PEEK rods for posterior spinal fusion. The aim of this article was to evaluate the outcomes of the patients, the fusions, and complication rates with this system.

**Materials and Methods**

This study was approved by the institutional review board and ethics committee of the authors’ institution. The authors retrospectively studied the medical files of 52 patients treated at their institution with posterior lumbar spine fusion (L3-S1) with the PEEK rod pedicle screw system between November 2007 and April 2010. Twenty-three men and 29 women with a mean age of 55.4 years (range, 35-71 years) were included. Indications for fusion were degenerative disk disease (n=25), lateral recess stenosis (n=10), combined lateral recess stenosis and degenerative spondylolisthesis (n=4), degenerative spondylolisthesis (n=6), lumbar spine vertebral fracture (n=6), and an L5 giant cell tumor (n=1). At the time of this study, only short PEEK rods were available for 1- or 2-segment spinal fusion. Ten patients underwent 1-segment fusion and 29 underwent 2-segment fusion; 13 women with a short body height (mean height, 165 cm) had 3-segment fusion with the available longer PEEK rods. The authors did not use the PEEK rod pedicle screw system in tall patients requiring more than 2-segment fusion or in patients with a short body height requiring more than 3-segment fusion because no longer rods were available during this study. Mean follow-up was 3 years (range, 1.5-4 years), and no patient was lost to follow-up. All patients gave written informed consent for their data to be included in this study.

All surgeries were performed by the same team (M.A., A.F.M., G.T., S.K., S.G.P.) through the midline posterior approach to the lumbar spine. All patients underwent primary lumbar spine surgery. Titanium pedicle screws were inserted, and laminectomy or hemilaminectomy was performed. Five patients with degenerative disk disease and 4 patients with combined lateral recess stenosis and degenerative spondylolisthesis as confirmed by preoperative flexion and extension lateral radiographs of the lumbar spine in all
patients with spondylolisthesis received a PEEK intervertebral cage inserted at the affected level using a transforaminal approach because of spinal instability. The PEEK rods were positioned and connected to the pedicle screws with distraction on the affected levels; no distraction was performed in patients who received a cage. The instrumentation in all patients was augmented with local bone graft from the lamina and demineralized bone matrix placed along the lateral gutters following bone decortication.

Postoperatively, all patients were mobilized on postoperative day 1 using a lumbar corset and were discharged with instructions to begin abdominal and back muscle strengthening exercises at 3 weeks and to avoid lumbar flexion for 12 weeks. Routine postoperatively clinical and imaging follow-up were performed at 6 weeks, 3, 6, and 12 months, and annually thereafter. Clinical follow-up included examination for low back and leg pain using a 0- to 10-point visual analog scale and function using the Greek translation (version 1.0) of the Oswestry Disability Index Questionnaire. Follow-up imaging included anteroposterior and lateral radiographs at each follow-up and flexion-extension lateral radiographs annually. Radiographs were evaluated for new bone formation at the lateral gutter, maturation or remodeling of the bone graft or trabeculation between the graft and host bone, lucent areas around the pedicle screws, less than 3° of intersegment position change on lateral flexion-extension radiographs, and visible bone formation in the interbody cage.

Computed tomography (CT) scans were not routinely obtained to reduce cost and radiation exposure. Instead, CT scans were obtained for patients with persistent clinical symptoms and when radiographs did not allow for accurate assessment of fusion, as occurred with 11 patients in this series. The postoperative and follow-up imaging were evaluated by all authors.

RESULTS

Mean Oswestry Disability Index improved from 76% preoperatively (range, 52%-90%) to 48% at 6 weeks postoperatively and to 34%, 28%, and 30% at 3, 6, and 12 months postoperatively, respectively. Mean low back and leg pain improved from 8 and 9 points preoperatively, respectively, to 6 and 5 points immediately postoperatively, respectively, and to 2 points each thereafter.

Imaging evidence of new bone formation was observed in 50 (96%) patients by 1-year follow-up; 2 patients developed no imaging signs of union during follow-up. One of the 2 patients remained asymptomatic and had received no treatment at the time of this writing (Figure 1). The second patient sustained breakage of both L5 screws at the head-screw interface and painful loss of sagittal alignment of the lumbar spine (Figure 2) and underwent revision spinal surgery with pedicle screws and titanium rods.

One patient sustained breakage of an S1 screw at the head-screw interface (Figure 3). The patient was pain free during follow-up; no reoperation was performed and imaging evidence of fusion was observed at 2-year follow-up. Another patient sustained a superficial wound infection with wound dressing changes and antibiotics for 6 weeks, with uneventful wound healing and imaging evidence of union at last follow-up 2 years postoperatively. No adjacent segment degeneration was observed in any patient until the time of this writing.

DISCUSSION

The concept of semi-rigid fixation has driven the development of spinal implants that use nonmetallic materials and novel rod geometries to promote fusion via a balance of stability, intra- and interlevel load sharing, and durability. Dynamic or flexible spine instrumentation systems, such as the Dynesys system, and semi-rigid systems, such as the PEEK rod pedicle screw system, have been manufactured. Polyetheretherketone systems could allow some motion of the spinal segment, potentially decreasing construct failure and adjacent segment degeneration. However, clinical studies on the outcomes of patients who underwent spinal fusion with the PEEK rod pedicle screw system are limited, and their results are conflicting. Therefore, the purpose of the current study was to evaluate the clinical and imaging outcomes of patients who underwent spinal fusion with the PEEK rod pedicle screw system until the time of this writing.
in the related literature supports this study. Second, no control group of patients treated with another instrumentation system was included. Comparison with other spinal instrumentations was avoided because of the relatively short follow-up in the current series compared with the longer follow-up of patients who had all-metal instrumented fusion. The short-term follow-up in the current series probably led to biased results with regard to fusion and reoperation rates compared with all-metal implants. Third, no cost analysis was performed to compare the PEEK rod with all-metal instrumented fusions. Although the authors did not perform a formal analysis, PEEK rods are more expensive than titanium implants. However, not using crosslinks probably lessens the cost of the PEEK rod pedicle screw systems. Fourth, imaging follow-up was performed using radiographs that were evaluated by the authors. Surgical exploration remains the reference standard for evaluating fusion. The disadvantages of radiographs are that measurement accuracy largely depends on obtaining true lateral views; they do not usually provide detailed appreciation of bony bridging and have significant intra- and interobserver variability. Dynamic radiographs have traditionally been used to monitor the progression of spinal fusion; however, no clinical consensus currently exists regarding their value for that purpose. Computed tomography is the preferred method for accurate evaluation of spinal fusion; it is rapid, offers the potential for high-quality reformatted images in the coronal and sagittal planes, and provides exquisite bone detail, such as solid bony bridging across the disk space in a successful fusion. Computed tomography can often identify device fixation failure, nonunion, and when arthrodesis has occurred. Instrumentation artifacts and patient movement can compromise the quality of CT images; however, titanium and radiolucent fusion devices result in less pronounced degradation by artifact compared with earlier stainless steel implants. In addition, novel high-speed multidetector CT technology and multiplanar reformation results in higher-quality images that are more useful clinically than axial images. However, the radiation exposure of patients undergoing imaging with novel high-speed multidetector CT and multiplanar reformation may be significantly increased. Magnetic resonance imaging and ultrasonography is unacceptable for monitoring the progress of an arthrodesis. Bone scans may be performed to assess fusion; no radioisotope uptake should be observed at the fused segment after 6 to 12 months postoperatively.

The use of PEEK rods in posterior spinal fusion was introduced in 2007. Biomechanical studies showed that PEEK rods reduced the range of motion of a destabilized spinal segment with no significant difference in stability compared with titanium.

Figure 3: Anteroposterior (A) and lateral (B) radiographs of a 45-year-old man with an L4 vertebral fracture at 3-month follow-up showing breakage of the right L5 screw. Anteroposterior (C) and lateral (D) radiographs at 6-month follow-up showing breakage of both L5 screws. The patient underwent reoperation with titanium rods.

Figure 4: Anteroposterior (A) and lateral (B) radiographs of a 60-year-old woman with lateral recess stenosis and L5-S1 degenerative spondylolisthesis at 6-month follow-up showing breakage of an S1 screw. The patient was asymptomatic.

Figure 4: Anteroposterior (A) and lateral (B) radiographs of a 60-year-old woman with lateral recess stenosis and L5-S1 degenerative spondylolisthesis at 6-month follow-up showing breakage of an S1 screw. The patient was asymptomatic.
Segments instrumented with PEEK more closely mimicked intact physiologic loading in the subadjacent level, which may reduce the likelihood of adjacent level disease.\textsuperscript{47} Moreover, the more flexible posterior rods should bear less of the construct load, which transfers more load to the anterior column.\textsuperscript{5,47} The improved anterior column support and load sharing and reduced stress at the bone-screw interface is believed to potentially lower the possibility of implant failure, such as screw loosening or pullout and pseudarthrosis,\textsuperscript{1,5,25} especially in osteoporotic bone.\textsuperscript{1,7,26,46,48}

Although not marketed as dynamic stabilization devices, PEEK rods have a less rigid profile than all-metal systems, and, therefore, create a less rigid construct in the posterior lumbar spine.\textsuperscript{14} Compared with dynamic systems, the rigidity of the PEEK construct may prevent screw loosening,\textsuperscript{14} which is a risk with the motion of a dynamic device.\textsuperscript{20,21} Compared with titanium, PEEK implants provide similar stability while allowing greater angular displacements and more physiologic anteriorposterior column load sharing,\textsuperscript{1,24,26} are associated with a substantial reduction in stress-shielding characteristics that reduce the strain to the pedicle screws and may decrease the risk of failure, especially in osteoporotic bone,\textsuperscript{7,25} have similar bone-forming capacity as measured by human osteoblast response,\textsuperscript{23} have less wear debris,\textsuperscript{22} and are radiolucent, which facilitates evaluation of fusion by reduced imaging artifacts. A potential disadvantage associated with PEEK rods is the increased theoretical risk of pseudarthrosis due to decreased rigidity and rod breakage. The radiolucent properties of PEEK rods may alter perceptions of clinical outcomes in the setting of failed spinal implants; to improve imaging, some PEEK rods use a contrast agent.\textsuperscript{49} Because of PEEK rods’ radiolucency, postoperative imaging may fail to identify breakage. It is possible that PEEK rod breakage occurred in patients in the current series. However, this cannot be proven because surgical exploration is the only definitive method to document breakage of radiolucent implants. In patients who underwent revision surgery for the management of other complications, PEEK rod breakage was not observed. The remaining patients were asymptomatic; therefore, revision surgery was not performed to document possible PEEK rod breakage.

Fusion rates for instrumented lumbar spinal fusion using variable instrumentation systems augmented with autograft and different types of allograft range from 52% to 96%.\textsuperscript{31,50,51} Small case series using PEEK rod constructs for lumbar fusion reported that patients performed well and had a low risk of mechanical failure and reoperation at 18-month follow-up.\textsuperscript{16,27} A recent study reported a fusion rate of 89.3% and a reoperation rate of 19.1% with PEEK rods in lumbar degenerative spine disease.\textsuperscript{14} These authors postulated that PEEK rods may not provide an improved benefit over instrumented fusions with all-metal implants.\textsuperscript{14} In the current series, the PEEK rod pedicle screw system was a reliable system for lumbar pedicle screw fixation: Oswestry Disability Index and pain improved, fusion rate was 96% (n=50), and implant failure occurred in 4% (n=2); reoperation was necessary in 1 patient who sustained screw breakage and a painful loss of sagittal alignment of the lumbar spine. No adjacent segment degeneration was observed in any patient at the time of this writing. The improvement in the Oswestry Disability Index and pain scale is well above the minimum acceptable improvement for lumbar spine fusion\textsuperscript{52} and is comparable with the clinical outcome following fusion with rigid rod pedicle screw systems.\textsuperscript{31} The excellent clinical outcome and the absence of adjacent level degeneration should be attributed to the biomechanical properties of PEEK rod constructs that do not transfer higher stresses on the adjacent disk spaces when compared with the intact spine. This effect could slow the development of adjacent level degeneration.\textsuperscript{24,48} Even if no anterior load-sharing device was used in the majority of the current patients, anterior column support should increase interbody fusion.\textsuperscript{25} However, because of the similar modulus of elasticity of PEEK rods with bone and the load-sharing biomechanical properties, the anterior spinal column should be intact. Therefore, when using a PEEK rod pedicle screw system, an anterior column load-sharing device is recommended in patients in whom no anterior column support exists, such as patients with fractures with at least 2-column involvement, to avoid complications, such as loss of sagittal alignment and subsequent implant failure.

**CONCLUSION**

The PEEK rod pedicle screw system has shown excellent early clinical results with high fusion rates, minimum complications, and absence of adjacent segment degeneration. Anterior column support is recommended to avoid a loss of sagittal alignment and implant failure in patients with insufficient mechanical integrity of the anterior column, such as patients with vertebral fractures.

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