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Technical Review

Biomechanical evaluation and comparison of polyetheretherketone rod system to traditional titanium rod fixation

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Abstract

BACKGROUND CONTEXT: Polyetheretherketone (PEEK) has been increasingly used as a biomaterial for spinal implants. PEEK lumbar fusion rods have recently become available for use in posterior lumbar fusion procedures.

PURPOSE: To compare Polyetheretherketone Rod System to traditional titanium rod fixation in a cadaveric model and provide mechanical test data for the PEEK system.

STUDY DESIGN: Biomechanical testing.

METHODS: Cadaveric biomechanical testing was conducted to compare Expedium 5.5 mm PEEK rods to titanium rods of equivalent diameter. Biomaterials testing was performed to determine static and dynamic performance of Expedium 5.5 mm PEEK rods with 6% BaSo4 in compressive bending and torsion.

RESULTS: Cadaveric testing demonstrated that PEEK rods can significantly reduce the range of motion of a destabilized segment. The testing showed no significant difference in the stability provided by PEEK and titanium rods in posterolateral fusion (PLF) or posterior lumbar interbody fusion (PLIF) constructs. PEEK static compressive bending tests showed 67 degrees displacement without fracture of the rod. Torsion testing showed 30 degrees of rotation without yield or plastic deformation. Dynamic compression testing revealed two fatigue runouts at 23 degrees.

CONCLUSIONS: PEEK rods provide comparable stability to titanium rods of equivalent diameter in cadaveric testing. Mechanical testing suggests PEEK rods can withstand far beyond the angular displacements suggested by cadaveric testing and that of normal physiologic range of motion. Potential advantages to PEEK rods include better anterior column load sharing, reduced stress at bone-to-screw interface, and reduced computed tomography and magnetic resonance imaging scatter and artifact.

Keywords: PEEK; Polyetheretherketone; Lumbar; Instrumentation; Fusion; Biomechanics

Introduction

The use of lumbar pedicle screw instrumentation to augment interbody and posterolateral fusion (PLF) rates has been well established [1–5]. Traditional instrumentation consisting of stainless steel constructs eventually evolved into titanium implants as a result of closer biomechanical properties to bone, improved biocompatibility, and reduced magnetic resonance imaging (MRI) artifact. Titanium offers sufficient strength under physiologic loads and construct stiffness closer to the modulus of elasticity of cortical bone, thus improving the stress shielding characteristics of lumbar pedicle instrumentation [3,4,6–8].

Recent advancements in posterior spinal fixation has centered on the concept of dynamic stabilization [9–13]. Often used as a nonfusion alternative, dynamic stabilization has a theoretical advantage to traditional stiff fixation of minimizing adjacent segment disc degeneration. When applied to fusion, a more dynamic stabilization may provide

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additional load sharing onto the anterior column and reduce stresses at the bone screw interface. In the common case of an undersized graft or graft subsidence, these advantages may be amplified as a system of lower stiffness may flex to appropriately load the interbody device. However, inherent to reduced fixation stability is the risk of pseudarthrosis. The ideal fixation system would maximize fusion rates by providing sufficient stability without excessive rigidity to allow for bone graft loading, while maintaining natural posturing and alignment to minimize adjacent level stress.

Polyetheretherketone (PEEK) has been increasingly used as a biomaterial for trauma, orthopedic, and spinal implants [7,14]. PEEK is a thermoplastic polymer whose chemical structure maintains stability at temperatures exceeding 300°C, resists chemical and radiation damage, exhibits greater strength per mass than many metals, and offers compatibility with many reinforcing agents. PEEK as a biomaterial is fully biocompatible, with numerous studies documenting minimal systemic, intracutaneous, and intramuscular toxicity [7,14,15]. Furthermore, PEEK is considered to be relatively inert biologically with no evidence of inflammatory reaction to wear debris. Rivard et al. concluded after an in vivo biocompatibility study on New Zealand White rabbits that PEEK polymer is harmless to the spinal cord and it may be used safely as a component of spinal implants [16].

The purpose of this study was to compare the biomechanical performance of PEEK rods to titanium rods in a cadaveric study when used as posterior spinal instrumentation.

In addition, mechanical testing is provided that characterizes the properties of 5.5 mm PEEK lumbar rods.

Methods

Cadaveric testing

Four fresh human cadaveric lumbar spines from L1 to S1 were harvested and used for this experiment after screening for abnormal anatomy using anteroposterior and lateral fluoroscopy. The specimens were stored in double plastic bags at −20°C until preparation and testing. Both L1 and sacrum were rigidly fixed and potted into custom cups using wood screws and a urethane compound (SmoothCast [Smooth-On Inc., Easton, PA]) such that the specimen was in neutral posture with the L3–L4 disc oriented horizontally. Follower load was not used in this experiment to maximize the effects of segmental destabilization. Motion measuring flags, made of three noncollinear infrared light-emitting diodes mounted on light copper plates, were affixed to each vertebra and the two mounts. L2–L3 and L4–L5 of each specimen were used in this experiment making the total number of instrumented segments eight across four cadaveric spines.

Instrumentation constructs consisted of Expedium 5.5 mm pedicle screws (DePuy Spine, Raynham, MA), standard 5.5 mm titanium Expedium rods or 5.5 mm Expedium PEEK rods, and Saber interbody fusion cages (DePuy Spine, Raynham, MA). Titanium rods were clamped to 100 in lb (135.6 Nm) torque, whereas PEEK rods were fixed with 60 in lb (81.36 Nm).

All spines were tested using a standard flexibility protocol to apply pure moments in flexion/extension, lateral bending, and axial rotation using test methods and fixtures that were published by Spenciner et al. [17]. The custom-built test frame was designed to apply continuous pure moment around each of the 3three traditional orthogonal axes, without constraining the remaining degrees of freedom (Fig. 1). With a turnstile arrangement, the specimen was remounted in the Instron test frame for each of the loading conditions, such that the mounted specimen was subjected to pure bending moments. The nondestructive, unconstrained, three-dimensional testing was performed in room temperature (22°C) with a maximum moment of ±6 Nm [18–20].

Moments were applied sinusoidally at a frequency of 0.1 Hz. The three-dimensional segmental motions of L2–L3 and L4–L5 were measured using an optoelectronic motion measuring system (Optotrak, Northern Digital Inc., Waterloo, Ontario, Canada). After testing in the intact and destabilized conditions (laminectomy with medial facetectomy), Titanium pedicle screw constructs were implanted at both the L2–L3 and L4–L5 segments and randomized for PEEK and Titanium rods (ie, PEEK for L2–L3 and titanium for L4–L5). These levels were instrumented to simulate the use of PEEK or Titanium rods in PLF applications. After testing, the PEEK and titanium rods were alternated at the same L2–L3 and L4–L5 and testing was repeated. Subsequently, a posterior lumbar interbody fusion (PLIF) procedure was performed at the same levels with either PEEK or Titanium rods (Table 1). By skipping the L3–L4 level and with the use of pure moments, it was assumed that each level was subjected to 6 Nm and can therefore be treated independently. This resulted in a sample size of n = 8 for the PEEK and n = 8

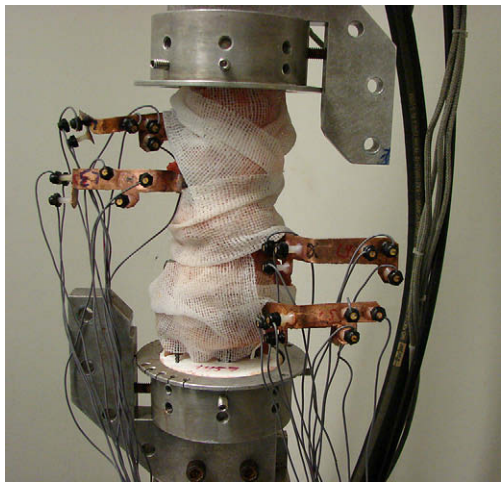

Fig. 1. Biomechanical testing construct.

Table 1
Cadaveric test conditions

1. Intact specimen.
2. Destabilized specimen (laminectomy with medial facetectomy).
3. PLF at L2–L3 and L4–L5. Randomized PEEK or Titanium (Ti) rods at either level (ie, Ti at L2–L3 and PEEK at L4–L5).
4. PLF at L2–L3 and L4–L5. Opposite of Step 3 (ie, PEEK at L2–L3 and Ti at L4–L5).
5. PLIF at L2–L3 and L4–L5. Randomized PEEK or Ti rods at either level (ie, Ti at L2–L3 and PEEK at L4–L5).
6. PLIF at L2–L3 and L4–L5. Reverse of Step 5 (ie, PEEK at L2–L3 and Ti at L4–L5).

PEEK = Polyetheretherketone; PLF = posterolateral fusion; PLIF = posterior lumbar interbody fusion.

for the Titanium constructs (Table 1: Cadaveric test conditions).

Synthetic model testing

Mechanical tests were performed following the guidelines of ASTM F1717-04 "*Static and Dynamic Test Method for Spinal Implant Assemblies in a Corpectomy Model*" to determine the mechanical characteristics of the 5.5 mm Expedium PEEK rod (DePuy Spine, Raynham, MA) under static and dynamic loading. The constructs consisted of two 5.5 mm Expedium PEEK spinal rods with 6% BaSO4 and four 4.35 mm Expedium titanium polyaxial screws mounted onto two parallel ultra high molecular weight polyethylene blocks spanning a measured and consistent gap between the blocks of 76 mm to simulate a two-level corpectomy construct (Fig. 2).

Static compression bending studies were conducted with an Instron 4204 electromechanical test machine on six constructs (Instron Corp., Canton, MA) with unconstrained fixtures (Fig. 2). They were performed in displacement control at a rate of 10 mm/min until failure occurred; failure was defined as either fracture of an implant or a noticeable reduction in stiffness. Load and displacement data were collected at 10 Hz, while the angle between the polyethylene blocks created by linear displacement of the crosshead was measured.

Static torsion studies were conducted with a MTS Mini-Bionix 858 servohydraulic testing machine on five constructs (MTS Systems Corp., Eden Praire, MN). Tests were performed under rotation control at a rate of 60 degrees/min until a rotational displacement of 30 degrees was reached or failure occurred. Torque and rotation data were again collected at 10 Hz.

Dynamic compression studies were conducted with a servohydraulic testing machine on six constructs consistent with that recommended for research and development testing suggested by ASTM E739-91. Tests were performed in sinusoidal displacement control using an R ratio equal to 10, where r = maximum displacement/minimum displacement (ie, tests run dynamically from 1 to 10 mm of displacement). Tests were run at a maximum frequency of 5 Hz and in ambient conditions. Each specimen was dynamically loaded until fracture of the implant occurred or five million cycles had occurred, at which point the specimen would be designated as a "runout." Samples were tested until two "runouts" were achieved to determine an endurance limit consistent with the aforementioned standards. A fatigue curve with 95% confidence intervals was generated based on sample size and results using a commercially available software package (TableCurve2D, Jandel Scientific, San Rafael, CA, USA).

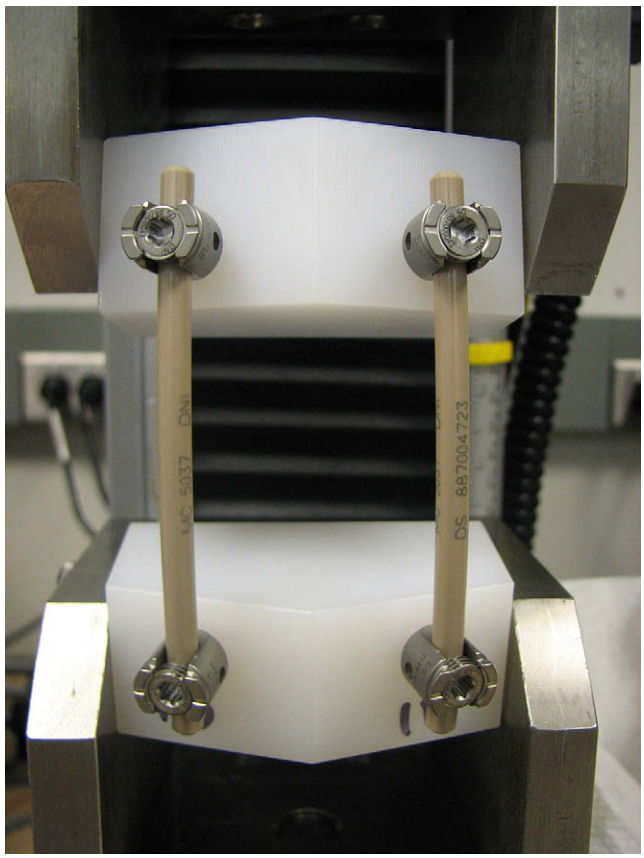

Fig. 2. Cadaveric testing apparatus and set-up.

Data analysis and statistics

Two-sample *F* tests were used to test for equal variances ($p<.025$) followed by two-sample *t* tests assuming equal or unequal variances. Significance was achieved at $p<.05$.

Results

Cadaveric testing

Results demonstrated that the PLIF and PLF PEEK constructs significantly reduced the range of motion (ROM) as compared with both the intact and destabilized conditions ($p<.05$). Results demonstrated that there was no significant difference in the stability provided by a 5.5 mm PEEK construct and a 5.5 mm Titanium construct (Table 2). After destabilization, there was no significant difference ($p<.05$) in

Table 2
Cadaveric biomechanical test data averages

Condition	Flexion/extension (deg)	Lateral bending (deg)	Axial rotation (deg)
Intact	6.54 ± 3.29	6.13 ± 2.00	3.47 ± 1.95
Destabilized	8.49 ± 4.25	6.42 ± 2.54	4.23 ± 1.66
Titanium (Ti) PLF	2.30 ± 1.95	1.74 ± 1.29	1.97 ± 1.10
PEEK PLF	2.09 ± 1.32	1.91 ± 1.38	2.12 ± 1.90
Ti PLIF	2.31 ± 2.15	1.76 ± 1.18	1.68 ± 0.82
PEEK PLIF	1.22 ± 1.51	1.60 ± 0.60	1.71 ± 0.78

PEEK = Polyetheretherketone; PLF = posterolateral fusion; PLIF = posterior lumbar interbody fusion.

the percent reduction in ROM provided by Titanium PLF, PEEK PLF, Titanium PLIF, or PEEK PLIF for any of the three test modalities: flexion/extension, lateral bending, and axial rotation.

Biomechanical testing

In static bending studies, each of the six constructs reached 67 degrees of displacement without fracture or slippage. In static torsion studies, each construct reached 30 degrees of rotation without any yield or deformation of the rod. A significant rotation of the screws within the test blocks was noted for each test sample. In dynamic compression, constructs were tested at maximum displacements between 23 and 45 degrees (Table 3). Two runouts were achieved at 23 degrees of displacement. Notably, all failures occurred at the rod-screw interface. No weight loss of the rods was detected Fig. 3).

Discussion

PEEK rods have recently become available for use in posterior lumbar fusion procedures. To the best of our knowledge, there have been no published reports of the biomechanical properties of these devices. It has been suggested that stiffness of metallic spine implants/constructs may far exceed the requirements for successful fusion and predispose secondary adjacent level disc degeneration and failure [12].

The results from our cadaveric testing show that the PEEK rod construct significantly reduces the ROM of a destabilized construct and offers semirigid fixation comparable to that provided by 5.5 mm titanium constructs.

Mechanical testing showed that the rods could withstand static and fatigue angular displacements that were at least five times to that suggested by the cadaveric study and

Table 3
Dynamic compressive bending results

Angle (deg)	Cycles to failure
45	25,5021
39	33,1921
34	1.27 M
28	3.83 M
23	5 M (runout)
23	5 M (runout)

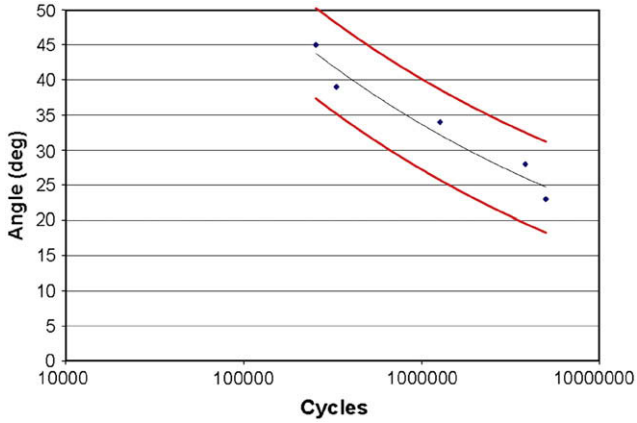

Fig. 3. Fatigue curve for dynamic compression bending results.

significantly more than that of 5.0 mm titanium rod constructs [21]. The angular displacements achieved without failure are also in excess of that expected for normal nonfused physiologic lumbar motion without any anterior column [22].

The stability shown through the cadaveric study combined with the static and fatigue properties exhibited in mechanical testing suggest PEEK rods may allow for more flexible stabilization of the motion segment without failure. Although the data included suggest that PEEK may be a viable alternative to traditional titanium rods, several potential advantages of PEEK are not easily determined through biomechanical testing but worth discussing based on basic principles of engineering and biomechanics.

Advantages

Load sharing

Traditional metallic pedicle screw/rod constructs shift physiologic loads more posteriorly, shielding the anterior column from normal compression forces [1,3,4]. More flexible rod systems may allow for greater contact between end plate and bone graft because of the greater compliance of the PEEK biomaterial in PLIF cases. The PEEK rod system may offer better anterior column load-sharing profile as a result of the PEEK rod modulus of elasticity [7]. Theoretically, the flexible rods should bend and transfer more physiologic load anteriorly to the interbody space, promoting interbody fusion in accordance with Wolffe's law [3]. This advantage will be amplified in the case of an undersized or partially subsided interbody graft where traditionally stiff rods might completely shield the graft from load. Additional cadaveric testing to analyze the loads within the disc space is needed to further quantify this advantage.

Bone screw interface

By shifting loads posteriorly, stiff constructs inherently place the bone screw interface at a higher stress. In cases of osteopenia or osteoporosis, this could lead to a failure resulting in fracture, pseudarthrosis, or potential revision

surgery. As a byproduct of maintaining appropriate anterior column support, the more flexible PEEK rods may reduce stress on the anchorage points and decrease risk of implant or construct failure while healing occurs.

Radiolucency

Finally, an additional notable feature of PEEK biomaterial for spine applications is radiolucency. The radiolucency of PEEK greatly facilitates radiographic assessment of fusions in vivo, thereby improving clinical assessment and accuracy. There is reduced computed tomography and MRI scatter or artifact. This feature allows for better fusion assessment and has been a very significant factor in the widespread adoption for spinal applications.

Potential disadvantages

Although PEEK as a biomaterial in spine implants is becoming increasingly popular, flexible fixation may not prove to be as reliable as traditional stiff constructs. Recent short-term clinical outcome studies on other comparable systems such as Dynesis (Zimmer Spine, Warsaw, IN) have shown high failure rates with early reoperations [9,10]. In addition, the improved dynamics of PEEK may be insufficient to foster a stable union leading to increased rates of pseudarthrosis. Given the favorable rod fatigue testing reported in this study, implant failure may be indefinitely delayed leading to aymptomatic nonunions; however, longevity and survivorship in those situations have yet to be determined.

Although dynamic stabilization in concept may address limitations of the current spine treatment options, new types of problems may be precipitated, possibly increasing reoperations and patient morbidity.

Conclusion

PEEK rods offer an alternative to traditional Titanium rod fixation. Biocompatibility studies, biomechanical evaluation, and cadaveric testing demonstrate that PEEK rods can provide stability under normal physiologic conditions. In addition, several notable benefits of PEEK in comparison to Titanium include increased anterior column load sharing, reduced stress at bone-to-screw interface, and reduced computed tomography and MRI scatter/artifact.

Further study is needed to evaluate the clinical benefits of flexible rod systems in terms of prevention of adjacent segment disc degeneration, effect on fusion rates, and survivorship. In addition, the long-term clinical benefit of a more flexible system and its effects on adjacent level problems would also be optimal to improve the current high rate of adjacent segment disease. Additional research is also required to ascertain the quantity of wear debris associated with PEEK and its in vivo effect on higher order animals and humans.

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