Biomechanics of polyaryletherketone rod composites and titanium rods for posterior lumbosacral instrumentation

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Laboratory investigation

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Objective. Interest is increasing in the development of polyaryletherketone (PAEK) implants for posterior lumbar fusion. Due to their inherent physical properties, including radiolucency and the ability to customize stiffness with carbon fiber reinforcement, they may be more advantageous than traditional instrumentation materials. Customization of these materials may allow for the development of a system that is stiff enough to promote fusion, yet flexible enough to avoid instrumentation failure. To understand the feasibility of using such materials in posterior lumbosacral instrumentation, biomechanical performances were compared in pure moment and combined loadings between two different PAEK composite rods and titanium rods.

Methods. Four human cadaver L3–S1 segments were subjected to pure moment and combined (compression-flexion and compression-extension) loadings as intact specimens, and after L-4 laminectomy with complete L4–5 facetectomy. Pedicle screw/rod fixation constructs were placed from L-4 to S-1, and retested with titanium, pure poly(aryl-ether-ether-ketone) (PEEK), and carbon fiber reinforced PEEK (CFRP) rods. Reflective markers were fixed to each spinal segment. The range of motion data for the L3–S1 column and L4–5 surgical level were obtained using a digital 6-camera system. Four prewired strain gauges were glued to each rod at the level of the L-4 screw and were placed 90° apart along the axial plane of the rod to record local strain data in the combined loading mode. Biomechanical data were analyzed using the ANOVA techniques.

Results. In pure moment, when compared with intact specimens, each rod material similarly restricted motion in each mode of bending, except axial rotation (p < 0.05). When compared with postfacetectomy specimens, each rod material similarly restricted motion (p < 0.05) in all bending modes. In combined loading, rod stiffness was similar for each material. Rod strain was the least in the titanium construct, intermediate in the CFRP construct, and maximal in the pure PEEK construct.

Conclusions. Pure PEEK and CFRP rods confer equal stiffness and resistance to motion in lumbosacral instrumentation when compared with titanium constructs in single-cycle loading. The carbon fiber reinforcement reduces strain when compared with pure PEEK in single-cycle loading. These biomechanical responses, combined with its radiolucency, suggest that the CFRP may have an advantage over both titanium and pure PEEK rods as a material for use in posterior lumbosacral instrumentation. Benchtop fatigue testing of the CFRP constructs is needed for further examination of their responses under multicycle loading. (DOI: 10.3171/2010.5.SPINE09948)

Key Words • in vitro cadaver model • lumbosacral instrumentation • range of motion • stiffness • spinal stability

For more than 2 decades, implants composed of PAEKs have been promoted in the surgical treatment of spinal disorders. This family of thermoplastic polymers is radiolucent, has excellent biocompatibility, is stable at high temperatures, and is strongly resistant to chemical degradation and radiation damage. Due to its commercial availability, PEEK has been the dominant PAEK material for clinical applications. In addition to its desirable qualities as a biomaterial, pure PEEK can be reinforced with carbon fiber of various lengths and orientations while preserving biocompatibility and resistance to wear. Such composites allow for tailored modification of the elastic modulus of the material to match with cortical bone or titanium alloy. This article contains some figures that are displayed in color online but in black and white in the print edition.
variation allows for an unprecedented customization that
has the potential to allow for optimization of biomaterials
specific to the intended application. Despite the initial
interest in the use of PAEK biomaterials for orthopedic ap-
lications and trauma, most commercial applications of
PAEK compounds have been spine implants. The major-
ity of such implants are pure PEEK cages or carbon fiber
composite cages, and they are used to facilitate anterior
support in patients with spinal fusion.5,6 Such implants en-
joy wide application and have minimal implant-related
complications.3

One of the most active areas for the development
of PAEK implants is the posterior stabilization of the
lumbar spine. Although titanium rod and pedicle screw
constructs currently dominate clinical applications, there
has been an increasing interest in alternative materials to
facilitate fusion or stabilization. More flexible systems
may adequately offload anterior column stresses to treat
pain and simultaneously allow for sufficient limitation of
motion to promote fusion. At the same time, these con-
structs may reduce the incidence of accelerated adjacent-
segment degeneration and implant failure, both potential
risks of stiff instrumentation.8 Additionally, such implants
would allow for better visualization of fusion due to their
radiolucency. Despite the predicted advantages of more
flexible fixation systems, excessive flexibility may reduce
construct stability and may compromise the ability for
bone fusion, increasing the incidence of pseudarthrosis.
A balance, therefore, must be achieved to allow for opti-
mal stiffness to avoid complications associated with these
extremes. This has not yet been achieved.

Recent in vivo studies have demonstrated that pure
PEEK rods may be comparable to titanium rods with
regard to the stability of the spine under physiological
loads.16 However, CFRP rods have not been similarly
studied. The stiffer biomaterial more closely approxi-
mates the elastic modulus of the cortical bone and may
better approximate the normal biomechanics of the spine.
This may also allow for optimal stiffness for stabilizing
constructs to promote fusion, while minimizing the as-
associated pitfalls and complications inherent to alternative
materials. The CFRP rod is comparable to PEEK or ti-
nium constructs with regard to stability. The material
properties of CFRP may be advantageous for long-term
applications. The purpose of our investigation was to de-
termin the in vitro biomechanical responses, comparing
the traditional titanium rod constructs for posterior lum-
bar stabilization with PEEK and CFRP rod constructs.

Methods

Specimen Preparation and Surgical Technique

Four fresh human cadaver segments spanning from
L-3 to the sacrum (1 male and 3 females; 48–64 years of
age) were prepared for pure moment and combined load-
ing studies. Medical records and postmortem radiographs
were reviewed to ensure that the specimens were free of
neoplasm, significant degenerative changes, osteophytes,
prior surgical procedures, or spinal trauma. In addition,
after the test, the specimens were macroscopically exa-
mined to ensure that the discs had a normal appearance.
All specimens were stored at −20°C in sealed plastic bags
and thawed at room temperature for 24 hours prior to
testing.23 Specimens were cleaned of muscle tissue, and
all intervertebral discs, ligaments, and facet joint capsules
were kept intact prior to surgical manipulation.

The superior and inferior ends of the specimens were
embedded in PMMA blocks. Specimens were aligned such
that the superior and inferior PMMA blocks and the midplane of the L3–4 disc were parallel with the horizon. To normalize the sagittal orientation, the center
of the L-3 vertebral body was aligned with the center of the
superior and inferior blocks. To ensure that the infe-
rior end of the prepared specimen did not interfere with
the loading process, a clear gap was maintained during
the PMMA fixation process and during the experimental
loading process, and continuous monitoring was made
via load cell data.

After initial pure moment and combined biome-
chanical loading (which are described later) of intact
specimens, L-4 laminectomy with complete L4–5 facet-
ectomy was performed on each specimen. Laminectomy
and facetectomy were accomplished in a typical surgical
manner. A Woodson dissector was used to separate the
lamina from the ligament; Leksell rongeurs and Kerrison
punches were used to remove the lamina piecemeal. The
ligamentum flavum was teased free of the dura mater and
removed. Facet joints were thinned with a single-action
Adson rongeur and then resected with rongeurs anterior
to the level of the pedicle. Subsequent to the loading of
intact and postlaminectomy specimens, pedicle screw
instrumentation was performed on each specimen bilat-
erally from L-4 to S-1 by using standard surgical tech-
niques. The cephalad and caudal margins of the pedicle
were identified laterally by gently inserting a probe on
both sides of the transverse process. This site was decorti-
cated, and a chuck containing a Steinmann pin was intro-
duced into the vertebral body via the pedicle. The pin was
angled to correspond to the orientation of the pedicle, and
pin locations were verified with anteroposterior and lat-
teral radiographs. Rods made with either PEEK, CFRP, or
aluminum alloy were then individually fixed to the screws
for further study. After the instrumentation, the speci-
mens underwent pure moment and combined loading.

Implanted constructs included titanium 6×45-mm pedicle screws (EXPEDIUM, DePuy Spine) coupled
with either 5.5-mm titanium rods, 5.5-mm PEEK rods,
or 5.5-mm CFRP rods. The rods were placed within the
polyaxial screw heads and fixed into place with locking
caps supplied in the provided system. The locking caps
were secured to a torque of 80 in-lbs for titanium rods,
60 in-lbs for PEEK rods, and lower torque (< 60 in-lbs,
because at greater torque levels CFRP rods break). Figure
1 shows the instrumentation.

Biomechanical Loading

For pure moment loading, equal and opposite forces
were applied to the superior vertebra by using a loading
frame that allowed for independent flexion-extension,
right and left lateral bending, and right and left axial ro-
tation (Fig. 2). All specimens were attached to a 6-axis
load cell (model 3803; Denton, Inc.) placed beneath the
distal end of the preparation. The load cell was capable of
recording forces and moments along the 3 axes. For preconditioning, specimens were loaded to 8 Nm three times in each mode. Data were acquired after preconditioning. Specimens were allowed to relax for 30 seconds before measurements were recorded at load increments from 0.0 to 8.0 Nm. The order of modes tested was random. During loading, the purity of the applied moment was electronically monitored to ensure that the off-axis moments as recorded by the load cell were negligible (less than 5% of the intended on-axis moment). Three reflective markers were fixed to each spinal segment. A 6-camera optoelectronic digital motion detection system (Vicon Corp., Oxford Metrics Group) was used to obtain the ROM.

For combined loading, a lever arm was fixed to the superior end of the proximal end of the preparation (Fig. 3). Loading was applied using an electrohydraulic testing device (model 858 Mini Bionix system, MTS Systems). The piston of the testing device induced a flexion bending moment to the specimen by compressing the lever arm at 10 cm anterior to the center of the L-3 vertebral body. Specimens were loaded at a constant displacement of 4 mm/second, to the maximum force-controlled compression of 55 N. They were preconditioned via cycling three times before gathering force and deformation data. To obtain strain data in the rods, 4 prewired strain gauges (Omega Engineering) were glued to each rod at the level of the L-4 screw and placed 90° apart along the axial plane of the rod (Fig. 4). All strain data were acquired with a digital system (DTS, Inc.).

Statistical Analysis
The ANOVA techniques were used to perform statistical analyses. The analysis was conducted using the SAS statistical software (SAS Institute, Inc.). Repeated ANOVA measures were used to assess differences between constructs. Intraconstruct differences were tested using the Tukey-Kramer procedure to account for multiple tests. A p value of < 0.05 was defined as significant.

Results

Pure Moment Loading
The average ROM for the L3–S1 column and across the L4–5 surgically treated level is shown in Figs. 5 and 6. The postfacetectomy specimen did not significantly differ when compared with the intact specimen in all modes of bending. All 3 instrumented constructs, however, significantly and similarly limited ROM compared with intact specimens in all modes (p < 0.05), except axial rotation. When compared with the uninstrumented, surgically altered specimen (L-4 laminectomy), all 3 types of instrumentation significantly reduced ROM (p < 0.05) in all modes of loading. Table 1 includes a summary of ROM data.

Combined Loading
Force-deformation responses were obtained and stiffness was determined. All constructs demonstrated similar stiffness (Table 2). Strains were recorded during each trial. Titanium rods demonstrated compressive strains on the anterior and tensile strain on the posterior ends of the rods, whereas PAEK rods responded with tensile strains.
Comparison of PAEK and titanium rods in lumbosacral fixation

Discussion

Since their introduction to clinical use more than 2 decades ago, the use of PAEK polymer implants has grown. This growth has primarily been limited to anterior interbody applications in the spine. An increasing interest in alternatives to standard titanium alloy pedicle screw/rod constructs in the lumbar spine, however, has been slowly growing. A limited literature on these alternative constructs has emerged. Although the goals of such studies are to demonstrate anterior load distribution, less stress shielding, and a reduction in adjacent level-degeneration, no long-term data exist. Biomechanical studies of these alternative systems are even more limited. These studies have been confined to pure PEEK rod constructs with interbody grafting, and do not include isolated pedicle screw and rods in the absence of anterior column support, and also titanium screws are used in the majority of studies. To the best of our knowledge, biomechanical studies of CFRP rods do not exist. Theoretically, the inherent increased stiffness of CFRP versus pure PEEK may be advantageous for long-term implants, reducing the risk of instrumentation failure while still offering enough stiffness to allow for fusion. Given the equality of the safety profile of such compounds to pure PEEK and their safe use in anterior interbody applications, expanded use of these compounds deserves study.

In terms of efficacy, the in vitro biomechanical data in the current study demonstrate equivalency of CFRP to pure PEEK rods in stabilizing the postfacetectomy lumbar spine. More importantly, CFRP demonstrates the same limitation of ROM in pure moment studies as standard titanium alloy, which is the gold standard, in all modes of bending. These data compare favorably with the limited data on the ability of PEEK constructs to limit ROM in a posterior lumbar interbody fusion model. The pure moment data presented in our study is reinforced by combined loading studies indicating similar stiffness in single-cycle loading of CFRP constructs to both PEEK and titanium alloy constructs under physiological loads. Despite similarities in stiffness between constructs, the strain patterns were different. In the compression-flexion mode, titanium rods bent in the expected manner of a
metal alloy. The rods constructed of CFRP and PEEK, however, were simultaneously bent and stretched. One possible explanation is that the higher bending stiffness of the titanium rods may shift the center of rotation closer to the rod during loading. With the CFRP and PEEK rods, the center of rotation will be closer to the natural center of rotation (in the disc), thus causing the less stiff rods to undergo tension only during spine flexion. To determine the true effects of these different patterns of strain, multiple-cycle studies and finite element modeling may be necessary.

Strain patterns in the rods are important to investigate load sharing in different combinations of screw and rod materials; this in turn allows for further understanding of construct fidelity over time. In the current biomechanical analysis, CFRP rods demonstrated lower average strains than PEEK rods at the L-4 level (Table 2). Conclusions regarding this small difference may not be fully realized in single-cycle loading. However, a clinically relevant effect of these small differences may come to light over the lifetime of a construct undergoing multiple cycles of loading and motion. Therefore, over the clinical lifetime of an implant, this small difference may lead to less implant fatigue at strained interfaces. It is acknowledged

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**Fig. 5.** Bar graph showing the ROM of the entire L3–S1 column under pure moment loading. Loading modes are shown along the x axis. Error bars indicate the SDs. Deg = degrees.

**Fig. 6.** Bar graph showing the ROM at the surgically altered L4–5 level under pure moment loading. Loading modes are shown along the x axis. Error bars indicate the SDs.
Comparison of PAEK and titanium rods in lumbosacral fixation

that this advantage may not be clearly elucidated with the small number of specimens and loading cycles used in this study; detailed computer modeling may be needed to clarify such relationships and to quantify the internal responses of the spine and the construct. Similar studies have been advanced in other implants.6,10,21

Other limitations exist. In this study we used an in vitro cadaver model requiring the removal of the support musculature of the lumbar column prior to instrumentation. Although this experimental model does not replicate clinical applications, it allows for the standardization of techniques to draw conclusions between the various biomaterials, a methodology used in the present study. Similar protocols have been used to evaluate instrumentation systems in the human cervical and lumbar spines.5,11,12,14,15,19,24,25

The experimental design introduced different instrumentations to the same specimen. Although this process changed the local anatomical characteristics at the locations of screw/rod construct placement, they did not penetrate or directly affect the integrity of the disc and associated ligament complexes. In addition, because tests were conducted at low magnitudes of bending moments (subfailure levels), and sufficient time was allowed between runs to allow for viscoelastic effects to stabilize, the integrity of these soft-tissue structures was not violated due to pure moment load applications. To eliminate any potential effect, it would be necessary to increase the sample size, and this is contemplated as future research.

Dynamic or semirigid constructs are not without their reported problems. Short-term clinical outcomes with commercially available systems have demonstrated high rates of revision surgery.3,16 Although this may be restricted to the specific dynamic system, to the best of our knowledge, significant long-term studies are not available to draw general conclusions. In addition, the evaluation of constructs made entirely of CFRP, including the pedicle screws, would help further the understanding of possible advantages of the use of these materials, but such screws have yet to be produced. It should be noted that the potential for brittle fracture of CFRP rods during the operation securing them to the titanium pedicle screws makes them less attractive compared with pure PEEK.

Recognizing these limitations, our results show that CFRP constructs merit further study, because they may represent a compromise between stiff constructs, which may preclude proper anterior stress, preventing optimal fusion, and softer dynamic materials, which are likely to deform over time. Despite their theoretical advantages, titanium rod constructs dominate the current surgical practice for posterior lumbar instrumentation, and should be considered the gold standard to which alternative materials should be compared. The CFRP constructs may hold a true advantage over alternative materials, including titanium, for surgical implantation, because they have widely customizable biomechanical properties, such as stiffness, to best suit clinical applications. In addition to this customizability, CFRP constructs are radiolucent, conferring a significant advantage over titanium alloys for evaluation of the patients’ fusion status over time. Thus, independent of its application as a dynamic material for instrumentation, the biomaterial properties of CFRP may be ideal for any fixation.

Conclusions

We found that CFRP rods have similar stiffness to PEEK and titanium alloy constructs in single-cycle, in vitro, biomechanical loading in the human lumbar spine. Unlike titanium rods, CFRP rods are radiolucent and al-

<table>
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<tr>
<th>Construct</th>
<th>Stiffness (N/mm)</th>
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<tr>
<td>PEEK</td>
<td>10.64 ± 3.28</td>
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<tr>
<td>CFRP</td>
<td>10.70 ± 2.84</td>
</tr>
<tr>
<td>titanium</td>
<td>11.07 ± 2.80</td>
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TABLE 2: Summary of data from combined loading tests in 4 cadaveric spines

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low better evaluation of fusion after surgery. The CFRP constructs may also offer the advantage of better resistance to mechanical failure over time compared with titanium constructs. Multiple-cycle biomechanical testing of CFRP constructs is required to obtain additional information on the viability of CFRP instrumentation in the human lumbar spine.

Disclosure

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Author contributions to the study and manuscript preparation include the following. Conception and design: Maiman, Yoganandan, Pintar. Acquisition of data: Bruner, Guan, Yoganandan. Analysis and interpretation of data: Maiman, Bruner, Guan, Yoganandan, Pintar. Drafting the article: Maiman, Bruner, Yoganandan. Critically revising the article: Maiman, Yoganandan, Slivka. Reviewed final version of the manuscript and approved it for submission: all authors. Administrative/technical/material support: Maiman, Bruner, Yoganandan, Pintar. Study supervision: Maiman, Bruner, Pintar.

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