Biomechanical Advantages of EXPEDIUM™ PEEK Rods

Finite Element Analysis
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Cadaveric and Mechanical Testing
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EXPEDIUM PEEK RODS

Polyetheretherketone (PEEK) material has a long history in spinal instrumentation. For over fifteen years PEEK has been used within the interbody disc space to support anterior column loads. Its mechanical properties have been well characterized and its biocompatibility confirmed through numerous published studies.[2,4,5]

PEEK material has recently attracted consideration as a material to provide lower rigidity posterior column instrumentation. EXPEDIUM PEEK Rods were designed to support fusion success within the anterior column by reducing the stiffness of posterior column instrumentation. With approximately one-fifth of the bending stiffness of titanium rods of equivalent size, PEEK provides two distinct advantages while maintaining appropriate strength and stability:

1. Greater load sharing with the anterior column.
2. Reduced stress at the bone screw interface.

Several investigations were performed to characterize EXPEDIUM PEEK Rods. First, computational modeling analyses were used to predict the load sharing and stress at the bone screw interface in an L1-S1 lumbar spine model. Second, the ranges of motion of cadaver spines fixed with PEEK Rods were compared to those fixed with titanium rods. Mechanical testing was also conducted to evaluate the strength and durability of PEEK Rods in a corpectomy model. Lastly, titanium and PEEK Rods imaging capabilities were compared.

FINITE ELEMENT ANALYSIS

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Finite Element Analysis (FEA) was conducted to quantify the benefits associated with 5.5 mm and 6.35 mm PEEK Rods as compared to a traditional 5.5 mm titanium rod. A validated model of the spine from L1-S1 was used, including ligamentous structures and a 400N follower load to simulate the effect of the muscles (Figure 1). Pedicle screws and either 5.5 mm Titanium, 5.5 mm PEEK or 6.35 mm PEEK Rods were implanted at the L4-L5 level while an interbody device was implanted at the L4-L5 disc. A displacement of 14° of flexion and 8° of extension was applied to the model while the forces in the anterior column, the screw bone interface and either the PEEK or titanium rods were calculated.

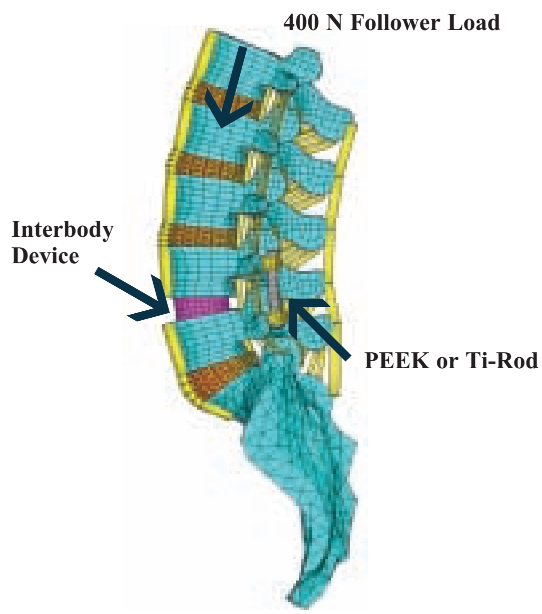

Figure 1: L1-S1 validated FEA model.

Load Sharing

As shown in Figure 2, the PEEK 5.5mm and 6.35mm Rods shifted 14% and 15% (respectively) of the total axial load from the posterior instrumentation to the anterior column. This shift increased the loading on the anterior column by approximately 21% and reduced the loading on the posterior instrumentation by approximately 50% compared to the titanium 5.5mm rods.

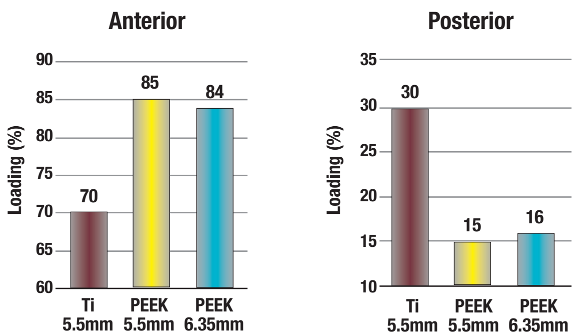

Figure 2: Percent load on the anterior and posterior column.

Bone Screw Interface

Failure of a construct at the bone-screw interface is increasingly common in cases of osteopenia or osteoporosis. This can often lead to pseudoarthrosis and potential revision surgery. Using the FEA discussed above, the moments that contribute to such failures can be quantified (Figure 3).

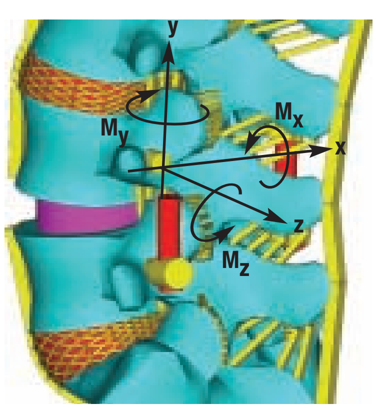

Figure 3: Bone screw interface with relevant moments labeled.

As shown in Figure 4, the moment acting on the bone screw interface is reduced by up to 70% in flexion when

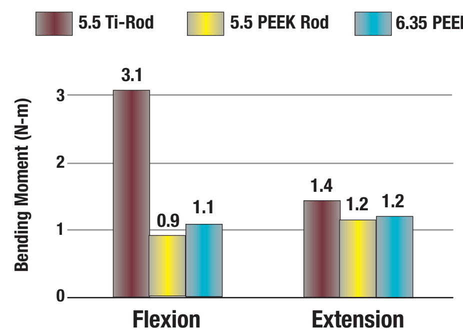

Figure 4: Bending moments at the bone-screw interface.

compared with a titanium rod.

STABILITY AND STRENGTH

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Cadaveric testing was conducted to characterize the ability of the PEEK Rods to re-stabilize a motion segment after laminectomy and medial facetectomy relative to that of titanium rods. Biomechanical testing was then performed to show the strength and resiliency of PEEK Rods to loads and motions above physiologic demands.

Cadaveric testing was performed on eight fresh human cadaveric lumbar functional spinal units harvested from L1-sacrum. Spines were tested to ±6 Nm in three mechanical test modes: flexion/extension, lateral bending, and axial rotation. Segmental motions in three dimensions were measured utilizing an optoelectronic motion tracking system. Each spine was tested under the following conditions:

1) Intact

2) Destabilized (laminectomy and medial facetectomy)

3) PLIF using PEEK or titanium rods (randomized)

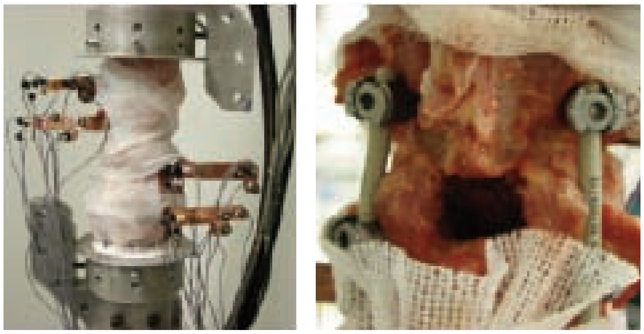

Figure 5: Instrumented lumbar spine (left) and destabilized motion segment with PEEK rods (right).

Results demonstrated that in all modalities both the titanium and PEEK rods significantly reduced the range of motion as compared to the intact and destabilized constructs. Data also showed no significant difference between PEEK and titanium PLIF constructs in flexion-extension (Figure 6).

While cadaveric testing provided an estimate of the rod performance in the spine, biomechanical benchtop testing was performed to evaluate the rods durability. Mechanical testing was conducted on corpectomy polyethylene block constructs in accordance with ASTM F1717 (Figure 7). Static testing to failure showed that the corpectomy constructs could flex 67°, approximately five times that of normal motion segments without rod fracture, screw slippage, or significant permanent set. Similarly, in static torsion, each construct reached 30° of rotation without any yield or deformation of the rod. In dynamic compression studies, five million cycles were consistently accomplished with 23° of flexion. These displacements are significantly greater than the physiological ranges of a normal spine reported in the literature.[1,3,6]

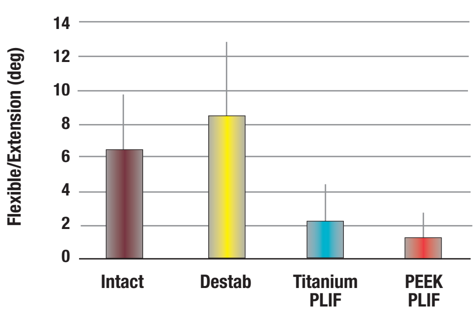

Figure 6: Flexion/Extension ROM data from cadaveric testing.

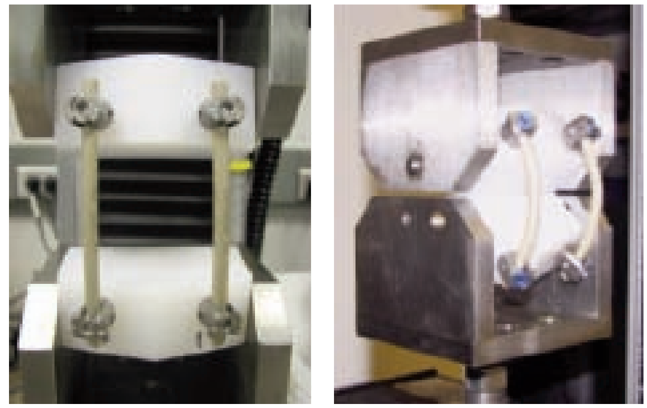

Figure 7: Corpectomy construct used for mechanical testing in neutral position (left) and in fully compressed position (right).

Finally, another notable feature of PEEK biomaterial for spine applications is radiolucency. PEEK's radiolucency greatly facilitates radiographic assessment of fusions *in vivo*, potentially improving clinical assessment and accuracy. There is reduced or no CT and MRI scatter or artifact. This feature allows for fusion assessment and has been a very significant factor in the widespread adoption for spinal applications elsewhere. Figure 8 shows a titanium rod and an EXPEDIUM PEEK Rod with 6% barium sulfate added in bilateral pedicle instrumentation. The EXPEDIUM PEEK rod allows visualization without the obstruction seen with the titanium rod.

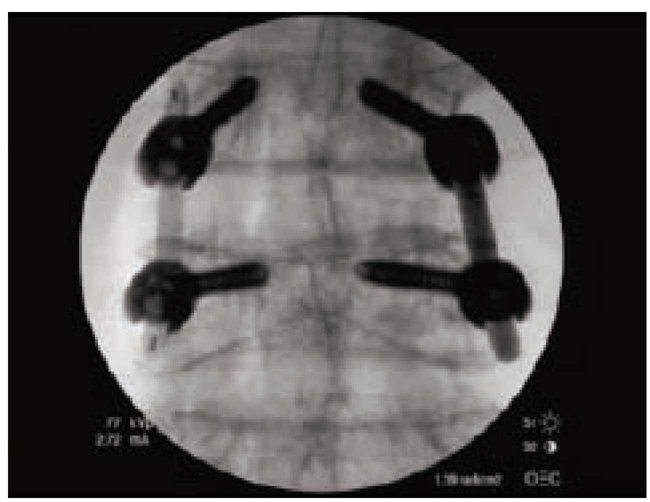

Figure 8: PEEK Rod (left) and titanium rod (right).

CONCLUSION

The EXPEDIUM PEEK rods offer an alternative to traditional titanium rod fixation. EXPEDIUM PEEK Rods offer a lower stiffness construct with two key advantages.

- FEA shows PEEK rods provide 22% greater load in the anterior column than titanium.
- FEA showed the bending moment on the bone-screw interface for PEEK was reduced by 70% as compared to Titanium. This is critical for osteopenia/osteoporosis.
- Unlike the stiffer titanium 5.5mm rods, PEEK Rods improve the load sharing pattern between the anterior and posterior elements in a manner that closely replicates the normal load distributions in the human spine. PEEK Rods may support the fusion process by increasing loads on the anterior column bone graft while reducing loads on the bone screw interface.

Test data shows that PEEK has the mechanical properties necessary to withstand static and fatigue *in vivo* demands.

- Cadaveric testing showed that PEEK Rods provide equivalent stability to that of titanium rods in PLIF constructs.
- Mechanical testing showed the PEEK Rods can withstand significantly higher angular displacements than what is reported in the literature. In addition, several notable benefits of PEEK in comparison to titanium include closer modulus of elasticity to bone, reduced stress at bone-to-screw interface, improved anterior load sharing, reduced CT and MRI scatter and artifact.
- Further study is needed to evaluate the clinical benefits of flexible rod systems in terms of increasing fusion rates and/or accelerating fusion and prevention of adjacent segment disc degeneration.

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