Can Extremities Plates Be Made Thinner, and Still Maintain their Strength?

AUTHOR: SHERRI GAMBILL - INVIBIO BIOMATERIAL SOLUTIONS™

The Clinical Challenges

Minimizing soft tissue irritation in the extremities is critically important due to the minimal amount of soft tissue coverage, especially in the foot and ankle. Surgeons are routinely faced with hardware challenges such as, "I have a reoperation rate of about 10-15%...mostly for hardware prominence" and "I use the lowest profile plate that is still strong. A thinner plate that is equal in strength could be a win."[1]

Medical device manufacturers aim to address this concern with low-profile plates, often manufactured from commercially pure titanium and titanium alloys.[2-6] Invibio's PEEK-OPTIMA™ Ultra-Reinforced polymer has the potential to provide medical device manufacturers and surgeons with an option of a thinner plate that could meet the necessary performance requirements.

The Unique Attributes of a PEEK Composite Biomaterial

Invibio's PEEK-OPTIMA Ultra-Reinforced, a carbon fiber reinforced PEEK (CFR-PEEK) polymer, has been used clinically since 2009.[7] Comparative studies for trauma fixation plates, manufactured from CFR-PEEK, have demonstrated earlier healing, fewer non-unions, and fewer hardware failures than metallic devices[8-10] which may be attributed to the material's modulus closer to bone and fatigue resistance.

PEEK-OPTIMA Ultra-Reinforced combines the high-performance material properties of PEEK-OPTIMA™ Natural polymer with the strength imparted by continuous carbon fibers. When manufactured into a fracture fixation plate, the stiffness and strength originate from both the plate geometry and the orientation of the carbon fibers throughout the plate. Layers of pre-impregnated tape are stacked, compression molded into a blank, and then machined into the plate as depicted in Figure 1. The carbon fibers in each layer can be oriented in varying directions with the intent of achieving the desired mechanical properties.

Figure 1: Layers of carbon-fiber reinforced tape are the precursor to a fully finished fracture fixation component. This illustration is a simple schematic. Orientation of fibers and quantity of layers vary depending on application and mechanical requirements.

A specific feature of this material is revealed when changing the orientation of the carbon fibers, the mechanical properties can be altered without changing the geometry of the device. This can give engineers freedom to tailor the properties of the implant to the specific application. In direct like-for-like biomechanical testing, PEEK-OPTIMA Ultra-Reinforced plates were 17% stronger than similar titanium alloy plates and 174% stronger than similar commercially pure titanium plates.[1] This testing was performed on one orientation of fibers. Revising the fiber orientation even further could provide medical device manufacturers with the potential to design plates that are thinner than metallic plates while maintaining strength requirements.

Biomechanical Testing

Materials and Methods

For the testing, representative fracture fixation plates were manufactured from PEEK-OPTIMA Ultra-Reinforced, Ti6Al4V, and commercially pure titanium grade 2 with Type II anodization, based on materials typically used to manufacture foot plates. The plates were 56mm long, 7mm wide, and 2mm thick with holes sized typical of those accepting 2.4mm diameter screws (Figure 2). The plates were then tested in 4-point bending per ASTM F382.

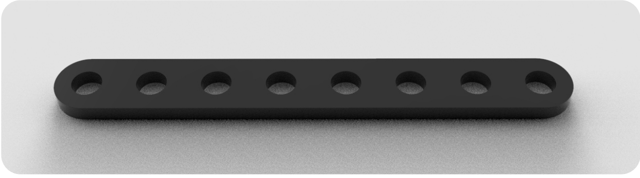
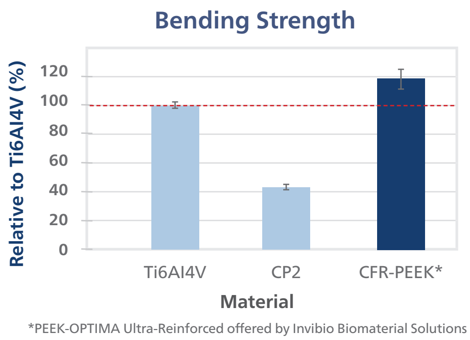


Figure 2: Representative fracture fixation plate design for biomechanical testing.

Results

In the test, the bending strength of the PEEK-OPTIMA Ultra-Reinforced plate was 17% greater than the Ti6Al4V plate and 174% greater than commercially pure titanium (CP-Ti) grade 2 with a Type II anodize. The bending stiffness of the PEEK-OPTIMA Ultra-Reinforced plate was 35% lower than Ti6Al4V and 24% lower than CP-Ti grade 2 (Figure 3).



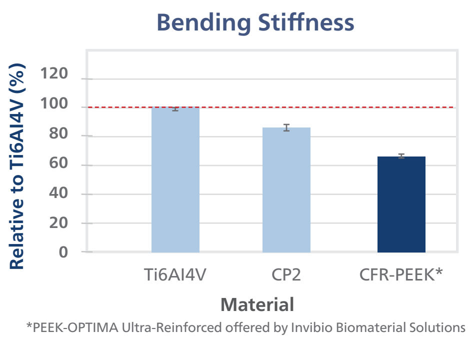


Figure 3: Results of 4-point bend testing relative to performance of Ti6Al4V. In the test, PEEK-OPTIMA Ultra-Reinforced demonstrated greater bending strength and lower bending stiffness.

Fatigue testing was also performed on these plates. The Ti6Al4V plate failed at an average of 65,000 cycles, while the PEEK-OPTIMA Ultra-Reinforced plate ran out to beyond 3 million cycles.

Discussion

In a like-for-like design, based on the above tests, the CFR-PEEK composite plate outperformed both titanium versions in terms of bending strength and fatigue performance, meaning a thinner plate could potentially outperform a predicate metallic plate, especially if the predicate plate were manufactured from commercially pure titanium. A thinner plate could potentially improve patient comfort by reducing soft tissue irritation and therefore improve patient satisfaction and possibly reduce reoperation rates. The data above is only one lay-up of composite tape layers. Multiple lay-ups can achieve the same plate thickness, so the properties can be further tailored if required.

The testing demonstrated the bending stiffness of the PEEK-OPTIMA Ultra-Reinforced plate was less than that of both titanium plates. A construct that is less stiff, yet strong enough to withstand loads may help promote secondary fracture healing.[11-12] Looking specifically at extremity fixation, a review paper of locking plate technology in foot and ankle surgery comments, "constructs that are too stiff can 'lock in a gap,' which combined with a stiff construct can lead to lack of micromotion and eventual nonunion."[13] Smith et al[14] suggest a high failure rate (11/15 nonunions) in tibiocalcaneal arthrodesis may be due to excessive plate rigidity, while Simons et al[15] suggest a less rigid and more forgiving plantar medial column fusion plate may reduce screw cut-out rates.

It is worth noting the bending performance isn't the only requirement of fracture or fusion fixation plates. Previous testing on a variety of other plates demonstrates 2.4mm, 3.5mm, and 5.0mm screws of various designs can be inserted into the plate at required insertion torque values.[1]

Beyond mechanical requirements, PEEK-OPTIMA Ultra-Reinforced is radiolucent, which can provide 360° visibility of fracture or fusion sites as seen in Figure 4. The improved visualization may enable easier assessment of healing and surgeons can potentially identify nonunions or delayed unions earlier and begin interventions sooner.

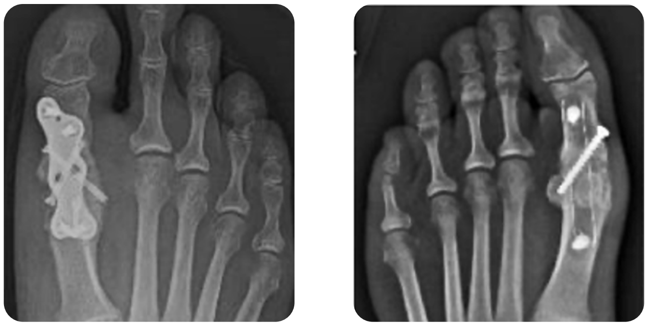


Figure 4: Radiograph of metallic fusion plate (left) and CFR-PEEK composite fusion plate (CarboFIx Orthopaedics) (right) for 1st metatarsophalangeal joint fusion. The CFR-PEEK composite plate offers increased visibility of the fusion site perioperatively and postoperatively.[16]

Conclusion

PEEK-OPTIMA Ultra-Reinforced can meet the strength and durability requirements of fracture or fusion fixation. By nature of the manufacturing process, the properties can potentially be tailored to meet the requirements of a specific application. Mechanical experiments in this study demonstrated improved performance over incumbent metallic materials in bending strength and fatigue performance in similar designs, which gives the potential to push plates even thinner and improve patient outcomes.

ABOUT THE AUTHOR

Sherri Gambill

Sherri Gambill is currently Trauma Technology Manager at Invibio Biomaterial Solutions™ where she is responsible for product development. Previously, as Business Development Associate she maintained relationships across client organizations as they adopted new biomaterials. Prior to Invibio, Sherri was a Product Development Engineer at DePuy Synthes and BD Opthalmic Systems, where she designed and developed implants and instrumentation for orthopaedic trauma and glaucoma treatment, respectively. In 2006, Sherri received a Bachelor of Science (BS) degree in Bioengineering at the University of Pennsylvania in Philadelphia, PA USA.

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Invibio
BIOMATERIAL SOLUTIONS

Invibio Ltd.
Victrex Technology Centre
Hillhouse International
Thornton-Cleveleys
Lancashire
FY5 4QD, UK

Tel: +44 (0) 1253 898 000
FAX: +44 (0) 1253 898 001

Invibio Inc.
300 Conshohocken State Road
West Conshohocken, PA
19428
USA

Toll Free: 866-INVIBIO (468-4246)
Tel: (484) 342-6004
Fax: (484) 342-6005

For further information please email us at info@invibio.com or visit our website at:

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