Manufacturing Trauma Fracture Fixation Implants: Partnering with Invibio

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Overview

Metal implants have been used for over 50 years with generally good outcomes, but in some fractures, complications related to non-unions, delayed unions, and implant failure continue to be a challenge, with overly stiff constructs as a reported risk factor.[1,2] PEEK-OPTIMA™ Ultra-Reinforced is a composite material growing in popularity as an alternative to stainless steel and titanium for fracture fixation devices, and has seen clinical success in a variety of application areas.[3-6]

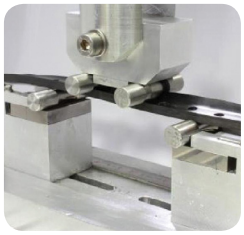
PEEK-OPTIMA Ultra-Reinforced combines the high performance material properties of PEEK-OPTIMA Polymer with the strength imparted by continuous carbon fibers. When manufactured into trauma devices, PEEK-OPTIMA Ultra-Reinforced enables semi-rigid fixation with improved fatigue and imaging properties over metal.[7] Unlike metals, the carbon fiber PEEK offers the ability to tailor the mechanical properties of the implant without altering the geometry, offering increased design flexibility to meet the device requirements.

Partnering with Invibio enables medical device companies to expand their trauma product offerings beyond metal technologies at a fraction of the time and investment it would take to translate from a metal to composite solution internally. Medical device manufacturers can leverage Invibio's expertise in composite technology, state-of-the-art tools, and dedicated manufacturing facility to bring new fracture management solutions to market.

Idea to Innovation – do more with fewer resources

Medical device manufacturers are experts in implant design, but converting those designs to composites requires time and money to build the knowledge, processing capabilities and supply chains internally. Invibio has invested heavily to build the capabilities required to deliver these components including: basic research, composite processing knowledge, and application-specific knowledge. A dedicated staff, assembled from the polymer/composite and medical device industries, works with partners from concept through production to overcome design and manufacturing challenges by offering comprehensive assistance, including design for manufacturing, prototyping, testing, and regulatory support. Invibio's state-of-the-art manufacturing facilities are operated under ISO 13485 certified quality management system and feature dedicated medical testing laboratories and a controlled manufacturing environment. These investments enable medical device companies to iterate quickly with low risk and decreased investment compared to developing on their own.

Design for Manufacturing



Prototyping and Testing

Components of any size and length can be produced, from small extremity plates to large distal femur plates. The process of plate creation is controlled by Invibio, from monomer through plate production. The process begins with the production of PEEK-OPTIMA Natural, which is then combined with carbon fibers into a tape. The tape is cut and compression molded into semi-finished components, and then finished to the customer's design specifications and inspected.

Continuous Carbon Fiber & PEEK-OPTIMA Polymer | *PEEK-OPTIMA Ultra-Reinforced Tape* | *Manufactured to Design Specifications* | *Finished Component*

Clinical Relevance – why change materials?

Locked plating is a significant advancement in fracture care resulting in improved patient outcomes for certain fractures.[8] However, early reports of clinical success were followed by reports of clinical failures, which suggested that in some applications, the plate and screw construct may be too rigid, inhibiting the interfragmentary micromotion necessary to permit secondary healing by callus formation.[9,10] Distal femur fractures are an often cited example where overly stiff locking plate constructs may lead to healing difficulties, with recent studies reporting non-union rates up to 20%[2,11-15]

Strategies have been developed for reducing construct stiffness in three areas: (1) modifications in the surgical technique for existing plates and screws, (2) new screw designs, and (3) material advancements. Focusing on material advancements, studies have shown that a material with a lower elastic modulus may improve outcomes. More flexible titanium plates produce more callus and have fewer non-unions than stainless steel plates.[2,9,14-16] PEEK-OPTIMA Ultra-Reinforced provides another alternative to the goal of more flexible fixation.

Testing demonstrates a plate produced from PEEK-OPTIMA Ultra-Reinforced can have reduced stiffness and greater fatigue strength than a titanium plate of the same geometry.[7]

Performance – Design Flexibility through Material

Carbon Fiber PEEK polymer plate stiffness and strength come not only from the plate geometry, but from the orientation of the carbon fibers throughout the plate, offering a huge array of choices to meet device specifications. This design flexibility is why carbon fiber devices have been adopted not only in medical devices, but in many advanced applications including the aerospace and automotive industries.

The plate geometry does not need to change in order to alter mechanical properties. In a 4-point bend test (per ASTM F382) of four identical generic distal femur plates, changes to the order of fiber orientation enabled a reduction in stiffness without a significant impact to the yield strength. In the example of Variant A to B, reducing stiffness by 12% resulted in a loss of yield strength of only 2% (ref. figure 1).[7]

Distal Femur Plate: 4-Point Bend Testing[7]

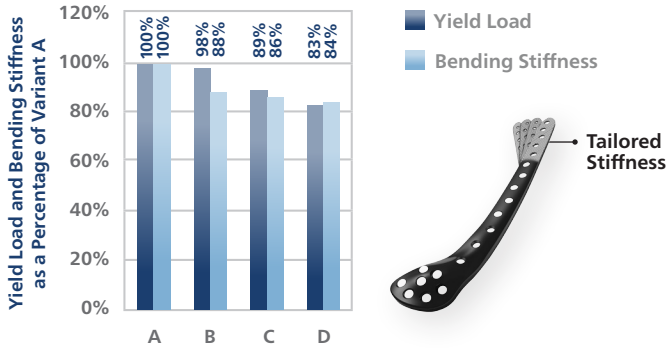


Figure 1

Conclusion

Invibio's investment in research and development, staff, and facilities to produce composite trauma plates enables medical device manufacturers to provide new options for treating traumatic injuries, with the potential for improved OR and point of care efficiencies, increased confidence to progress patients through recovery, and fewer and easier revisions.[7]

ABOUT THE AUTHOR

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Sherri (Wykosky) 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. 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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