Tips on Using Carbon Fiber PEEK in Orthopaedic Trauma

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Historically, metal titanium or stainless steel implants have been used for fracture fixation. While other materials, including bone, have been tried their limitations have precluded their mainstream use. Carbon fiber has been used in non-medical industries for decades and had excellent performance in high demand applications in the automotive and aerospace industries. In orthopaedics, they have been introduced several years ago but their pricing and lack of familiarity has been a barrier to entry into that specific market. Recently, improvements in manufacturing and an excellent clinical track record has made them more familiar and accessible in the orthopaedic fracture market.

The main benefit for Carbon Fiber PEEK** implants in the treatment of trauma is their modulus of elasticity, which is between that of bone and titanium. Because of the flexibility in the manufacturing process, the elasticity of any specific implant can be tailored to the application. Invibio Biomaterial Solutions has developed a technology specifically for layering the fibers within the PEEK-OPTIMA™ Natural matrix, such that the direction of the flexural modulus can be adjusted. In this way, there can be implants that are flexible in bending, but not when in torsion; and alternatively, by layering the fibers a different way, the result could be flexibility in torsion, but not in bending. Thus, manufacturing can be adjusted to suit the application which makes this technology extremely attractive for fracture fixation.

Furthermore, fatigue tests have demonstrated that carbon fiber composites are almost indefatigable in certain configurations and can easily exceed 1 million cycles as compared to fatigue failure of metal which commonly occurs at around 100,000 cycles.[1] As a perspective, 1 million physiologic cycles is approximately one year of gait activity. This feature is another attractive quality for the fracture application, and recent experience and publications are validating this finding.

Radiographic Advantages

Another extremely attractive feature of carbon fiber implant technology is when advanced imaging or therapeutic radiation is needed. With metallic implants, the scatter of diagnostic radiation makes interpretation of adjacent structures difficult, even with advance subtraction software technology. In the therapeutic application, the scatter of high dose radiation results in damage to adjacent tissues. With a carbon fiber implant, there is little scatter and the ability to diagnose and treat without issue becomes possible.

As demonstrated in the case below, when ligament injuries are encountered during retrograde femoral nailing, a Carbon Fiber PEEK implant allows excellent visualization of peri-articular knee pathology (Figure 1).

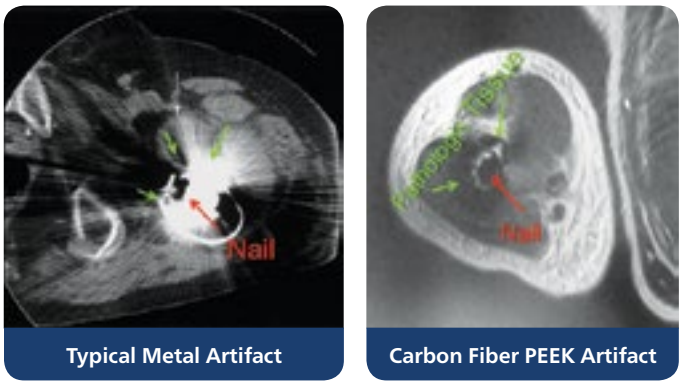

Figure 1: Radiolucency: Improved visualization with CT and MRI.+

Better Callus Faster

In the author's personal anecdotal experience, the best description of the results obtained when using Carbon Fiber PEEK implants is *Better callus faster.* The resulting callus appears more robust, most likely due to the lower modulus of elasticity of the implant (Figure 2). It is likely that the callus forms faster because as the patient begins weight bearing, the lower mechanical processes suitable to the healing cascade may experience an accelerated timeline. Perhaps one day in the future, we will have the radiographic capability to measure the calcium density of the callus, which would then probably prove the assumption – *Better callus faster.*

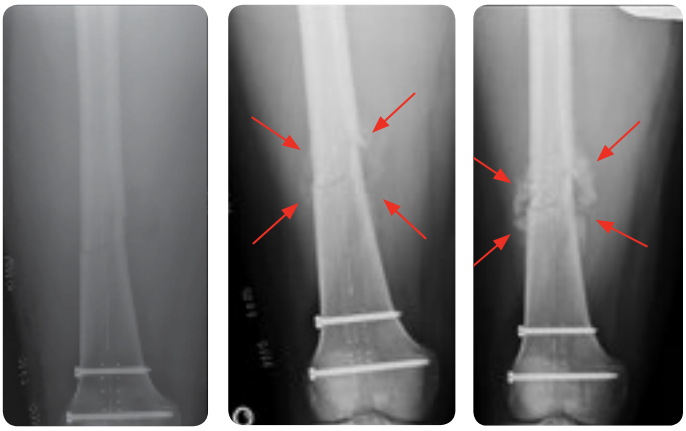

Figure 2: Potential effect on healing: Lower modulus may enhance callus formation. Immediate post-op (left), 2 weeks post-op (middle), 4 weeks post-op (right).+

Clinical Cases: Carbon Fiber PEEK in Action

Proximal Humerus Fracture

In this case, a female patient had a remote cuff repair, following a level fall. A Carbon Fiber PEEK plate was implanted. While the treatment is fairly standard, the ability to utilize MRI in the future if the rotator cuff pathology recurs is very attractive. In this case, the healing proceeded very nicely without incident (Figure 3).

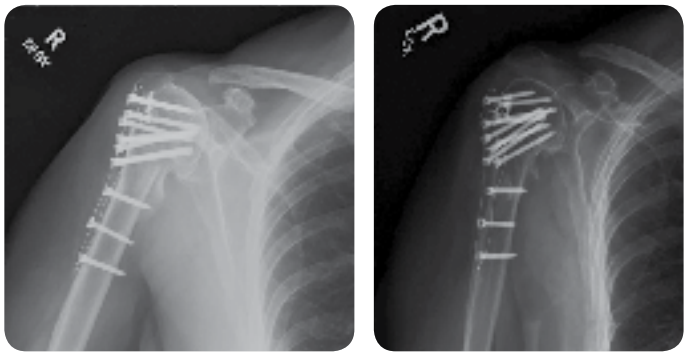

Figure 3: Post-operative scans demonstrating robust callus: 6 weeks (left), 2 years (right).[+]

A Bilateral Fracture of the Femur, in a 20-Year Old

You would expect a bilateral fracture of the femur (in a 20-year old) to heal quite quickly, but even so, callus in two weeks is not normally observed. It is commonly accepted that X-ray images *lag* behind what's really happening *in-situ*. Regardless, the amount and timing of callus in this case appears impressive and accelerated. At 12 weeks the callus appeared more mature and robust which again is not typical for metallic implants (Figure 4).

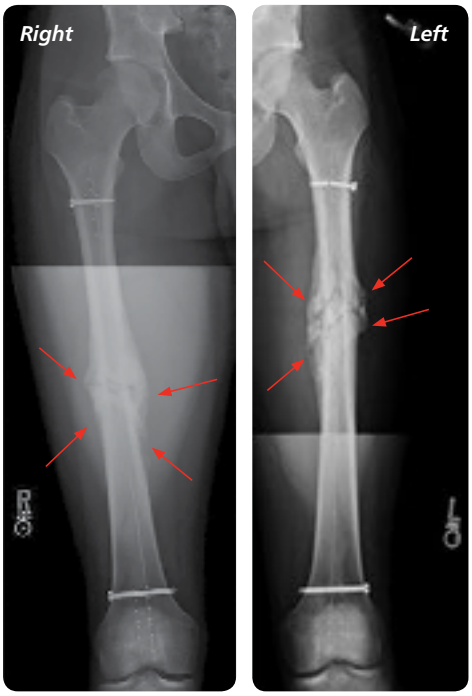

Figure 4: Bilateral fracture of the femur 12 weeks post-op callus formation with smooth edges.[+]

The Pivotal Case

A 35-year old male experienced a femur fracture (Figure 5) and underwent retrograde nailing (Figure 6). Knee instability was apparent after fixation and an MRI was ordered. The MRI imaging (Figure 7) is very clear and demonstrates complete absence of cruciate ligament image which represents a complete cruciate ligament tear. A normal metallic implant would not provide such clear imaging and expeditious diagnosis and treatment.

Figure 5: 35-year old male with femur fracture.[+]

Figure 6: 35-year old male, AP view of femur fracture with retrograde nailing.[+]

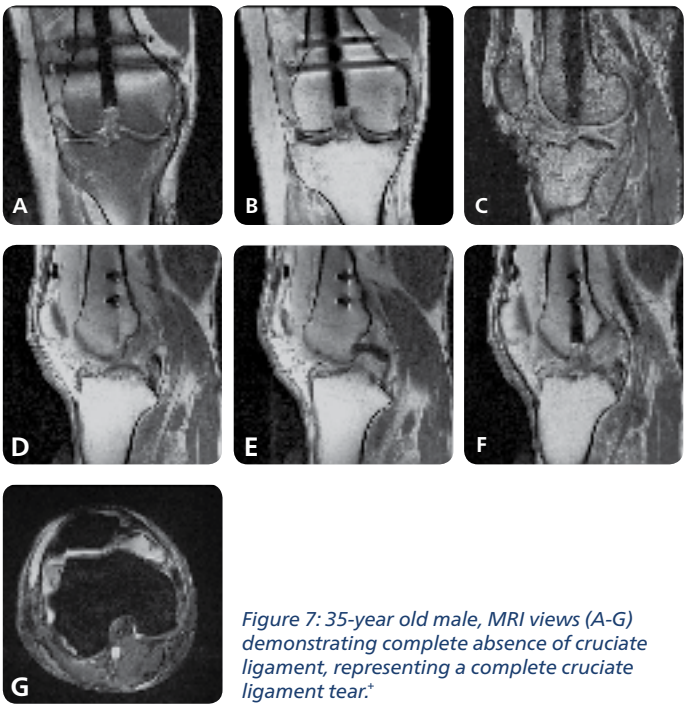

Figure 7: 35-year old male, MRI views (A-G) demonstrating complete absence of cruciate ligament, representing a complete cruciate ligament tear.[+]

Common Applications

One of the newer introductions of carbon fiber is for one of the most common fractures: the peri-trochanteric fractures. The implant can be used as a short nail or long nail. One concern with metallic nails for these injuries is the effect of stress risers in brittle osteopenic bone. Because of the lower modulus of elasticity, the use of short nails for such fractures theoretically reduces such a risk. It was commonly known that large diameter steel nails would result in a large step-off of modulus at the transition zone between implant tip and unprotected bone. With carbon fiber, there is less modulus change in the transition zone and thus, less risk for stress induced complications. In the case presented, the implant is used in standard fashion and its configuration and design is similar to commonly used metallic implants, making it more familiar to surgeons (Figure 8 and 9).

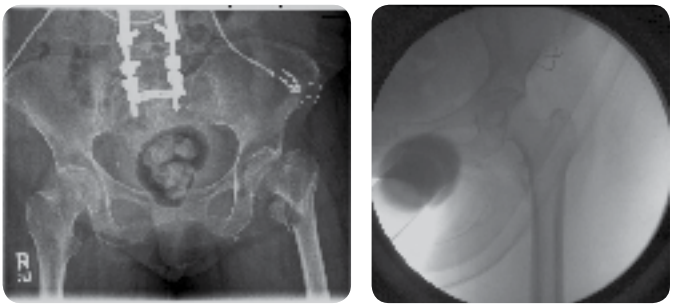

Figure 8: AP view of peri-trochanteric fracture (left), and reduction (right).[+]

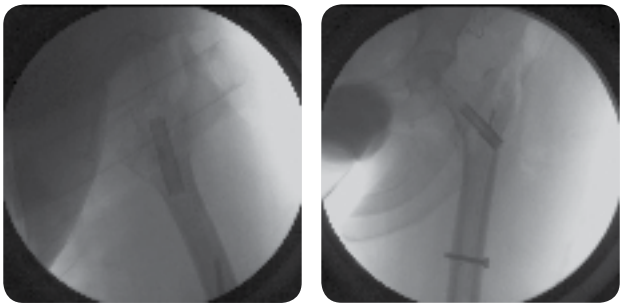

Figure 9: Peri-trochanteric fracture fixation, fluoro, lateral view (left), AP view (right).[+]

Newer Applications

New applications include the distal femoral plating system. It is pre-contoured with a targeting jig. In the case noted below, the standard technique was used to treat a (distal femur) fracture in a geriatric patient (Figure 10). One of the common user errors with metal technology is a construct that is *too stiff* which results in stress shielding of the fracture zone. While older non-locking technology might not result in such stiff constructs (as seen with locking technology), their failure mode was loosening of the non-locking screw-bone interface. With carbon fiber plates, the use of locking screws allows for stability of the construct, but the plate, and its lower modulus of elasticity, allow for a flexible fracture zone conducive to healing. In the case presented, we see an exuberant callus response at an early time period, which is not typically seen with metallic implants (Figures 11-13).

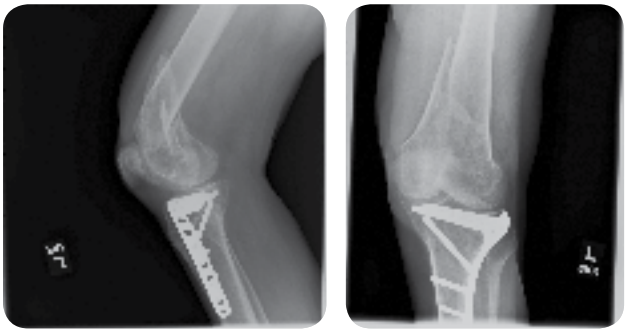

Figure 10: Distal Femur fracture, lateral view (left), AP view (right).[+]

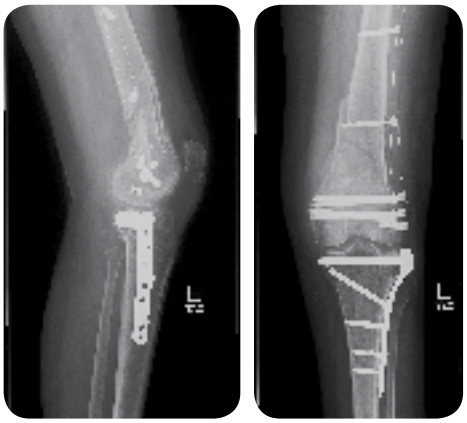

Figure 11: Distal Femur fracture, 1 month, early callus response, lateral view (left), AP view (right).[+]

Figure 12: 3 months flexion.[+]

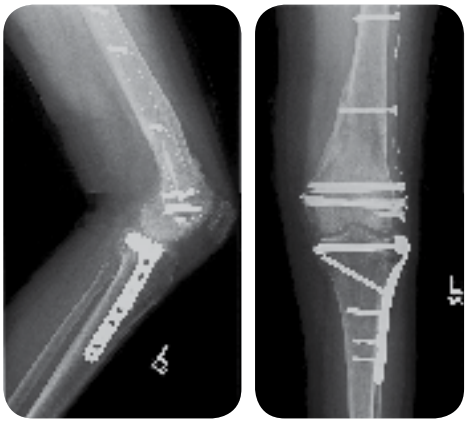

Figure 13: Distal Femur fracture, 4 months, lateral view (left), AP view (right).[+]

In Summary

- Longitudinal carbon fiber reinforced PEEK-OPTIMA™ Natural polymer.
- Radiolucent
- Minimal artifacts in CT and MRI
- Advantageous in radiation therapy
- Excellent fatigue strength
- Similar size plates and surgical technique, offered by CarboFix Orthopaedics, compared to metal
- FDA 510(k) cleared and CE mark approval ▲

ABOUT THE AUTHOR

Bruce H. Ziran, MD, FACS

Bruce H. Ziran, MD, FACS is a board certified orthopaedic surgeon and orthopaedic traumatologist at the Hughston Clinic at Gwinnett Medical Center, Atlanta, GA. He graduated from the Case Institute of Technology (BS Biomedical Engineering), and from Case Western Reserve University School of Medicine (MD) in Cleveland, Ohio. He completed his orthopaedic surgery residency at University Hospitals of Cleveland / Case Western Reserve University and then pursued orthopaedic traumatology at UC Davis in Sacramento California under Dr. Michael W. Chapman, and an additional AO International fellowship at Inselspital in Bern, Switzerland under Dr. Reinhold Ganz.

Prior to coming to the Hughston Clinic, Dr. Ziran was at the University of Pittsburgh from 1995-2003. He then worked as Director of Orthopaedic Trauma to help salvage the orthopaedic trauma program at St. Elizabeth Health Center in Ohio. He was then recruited to Atlanta Medical Center, Orthopaedic Residency for the same reasons before leaving to join the iconic Hughston Clinic. The Hughston Clinic Trauma program is a multi-site single specialty program that partners with hospitals around the country to provide a co-management service model that benefits patients and the institution. Dr. Ziran is currently the Chief Medical Officer of Hughston Orthopaedic Trauma and course chairman of the Atlanta Trauma Symposium in Atlanta, Georgia, which he started in 2010. He is engaged in implant design and consulting with industry, and is active in speaking and educational meetings. Dr. Ziran is an examiner for the American Board of Orthopaedic Surgery and was awarded the first American Fracture Association/Orthopaedic Trauma Association Community Fracture Surgeon award in 2017.

To listen to this presentation in its entirety, please visit www.invibio.com/trauma.

REFERENCES

1. Mechanical benchmark of PEEK-OPTIMA™ Ultra Reinforced vs. Ti6AL4V plates undergoing dynamic testing to ASTM F382-99 (2008). Data on file at Invibio Biomaterial Solutions.

* Bruce Ziran, MD provides ad hoc consultancy services for CarboFix Orthopedics.

* The case studies and testimonial presented have been provided by a practicing orthopedic surgeon. His view and experiences are his own and do not necessarily reflect those of others. "Invibio" disclaims any liabilities or loss in connection with the information herein.

** Carbon Fiber PEEK is a composite formed by the combination of carbon fibers and Polyetheretherketone (PEEK). In this article, carbon fiber composite and Carbon Fiber PEEK, reference PEEK-OPTIMA™ Ultra-Reinforced manufactured by Invibio Biomaterial Solutions.

+ Images of radiographic scans provided courtesy of Bruce Ziran, MD.

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