Use of Carbon-Fiber-Reinforced Composite Implants in Orthopedic Surgery

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Abstract: Carbon-fiber-reinforced polyetheretherketone implants offer several benefits over traditional metal implants. Their radiolucent property permits improved, artifact-free radiographic imaging. Their lower modulus of elasticity better matches that of bone. Their fatigue strength is greater than most metal implants. This article reviews the use of these implants in orthopedic surgery, including treatment of conditions involving the spine, trauma, tumor, and infection. [Orthopedics. 2014;37(12):825-830.]

Metal has long been the foundation for orthopedic implants. Early pioneers in advancing orthopedic surgery often worked closely with similar pioneers in metallurgy. The first metals used in orthopedic applications were stainless steel and cobalt-chrome-based alloys. These materials offer the benefits of strength, corrosion resistance, ease of machining, and low cost. Additionally, stainless steel-based plates can be manually bent or contoured intraoperatively to fit individual fracture sites. In the past few decades, the use of titanium alloys has gained popularity, as this material has a potential for osseointegration and a modulus of elasticity that closely matches bone.

However, disadvantages of metal implants include limited fatigue life, mismatch of modulus of elasticity, potential for generation of wear debris, cold-welding seen with titanium locking screw constructs, corrosion, and radiodensity that can preclude accurate radiographic visualization of fracture reduction, healing, and tumor or infection progression or resolution.1-3

Although not new to the orthopedic literature, carbon-fiber-reinforced composite implants have gained more attention in the past few years. This trend, highlighted by more clinical articles on the use of carbon-fiber-reinforced composite implants and increased availability of implant options, is supported by good scientific laboratory data on the biomechanical properties of these implants. This article reviews the material properties of carbon-fiber-reinforced polyetheretherketone (CFR-PEEK) and summarizes some of the most interesting current clinical applications of CFR-PEEK implants.

Advantages and Disadvantages of CFR-PEEK Implants

Carbon-fiber-reinforced polyetheretherketone is a composite material composed of layers of carbon fiber sheets, with fibers oriented in varying directions, embedded within a polymer matrix of PEEK. The PEEK polymer can be processed through various techniques, including injection molding, extrusion, or machining. The PEEK polymer material has been shown to have excellent biocompatibility. Polyetheretherketone implants elicit minimal cellular response when studied in vitro and in vivo.4-7

The mechanical properties of the composite material are determined by the volume, length, and alignment of the carbon fibers. Two main forms of carbon fiber incorporation are used for medical applica-
tions. Short CFR-PEEK consists of randomly aligned short carbon fibers, most less than 0.4 mm, which produce an isotropic homogeneous material. Long CFR-PEEK consists of carbon fibers that essentially run the entire width of an implant. The tensile strength of the long carbon fiber material is greater than 2000 megapascals (MPa), compared with 170 MPa for the short carbon fiber material.8 Controlled alignment of the carbon fibers can provide a broad range of anisotropic properties that can be tailored for a specific application. Volume fraction of the carbon fibers also determines mechanical properties of CFR-PEEK.9 This material has several biomechanical advantages when compared with traditionally used metals such as titanium or stainless steel. Its fatigue strength and modulus of elasticity make CFR-PEEK an ideal implant material for plates and nails. Carbon-fiber-reinforced polyetheretherketone implants can be engineered to have a varying degree of strength and stiffness, based on the orientation and number of carbon fiber layers. This can permit manufacture of an implant that is more compliant than metal, better matching the modulus of elasticity of bone.

The modulus of elasticity of CFR-PEEK is 3.5 gigapascals (GPa), compared with 230 GPa for stainless steel, 210 GPa for cobalt chrome, 106 to 155 GPa for titanium alloy, 12 to 20 GPa for cortical bone, and 1 GPa for cancellous bone.10 Modulus mismatch of metal implants can lead to altered loading, stress shielding, and detrimental peri-prosthetic bone remodeling.11 Commercially available plates and nails have been tested to 1 million fatigue cycles without failure.12 The average bending strength for a 4.5-mm CFR-PEEK plate is 19.1 Nm (Newton meters), while the bending strength for a similar 4.5-mm stainless steel locking compression plate is 16.7 Nm. The average bending strength of a commercially available 10-mm CFR-PEEK intramedullary tibial nail is 80.3 Nm, while the bending strength of an 11-mm titanium tibial nail is 43 Nm.12 Wear debris testing has shown significantly lower wear debris volume with CFR-PEEK plates compared with titanium plates.12

Finally, the radiolucency and magnetic resonance imaging (MRI) compatibility of CFR-PEEK are 2 additional characteristics that make this material beneficial. Fracture reduction and healing can be readily assessed with standard radiographs. The absence of artifact on both computed tomography (CT) and MRI means that CFR-PEEK has applications for the spine, for infection, and for oncologic cases.13 Although there are many advantages to using CFR-PEEK, there are also specific disadvantages. Carbon-fiber-reinforced polyetheretherketone implants cannot be contoured, so their use in fracture fixation is limited to straight diaphyseal fractures or requires an anatomically designed plate with a locking screw technique. Although decreased stiffness may be beneficial, too much flexibility can be disadvantageous, potentially leading to pseudarthrosis. Whereas the increased fatigue strength of the material decreases the risk of fatigue failure, the radiolucent nature of the material precludes directly visualizing this radiographically. Radiopaque markers have been added to aid visualization of the implant, including markers to identify intramedullary nail interlocking screw holes.

**USE IN SPINE SURGERY**

Carbon-fiber-reinforced materials have been used for spinal application for more than 2 decades.8 The earliest use consisted of lumbar interbody fusion cages that provided the benefit of radiolucency to better evaluate interbody fusion.14 The use of carbon-fiber-reinforced composite cages was subsequently expanded to the cervical spine.15,16 The use of PEEK rods in pedicle-based posterior spinal fusion was introduced in 2007.5,17 Additionally, a carbon-fiber composite anterior cervical plating system has been introduced in Europe.

The 2 attributes of PEEK implants making them attractive as a biomaterial for spinal fusion are their radiolucency and their elastic modulus. Improved assessment of union can be achieved with radiographs and CT scans. Follow-up MRI, when required, can also be performed without artifact.

Various PEEK interbody fusion cages are available and have been successfully used with both bone graft and bone morphogenetic protein.18 Successful fusion was reported in a series of 39 patients who underwent a combined single-stage anterior and posterior approach using interbody PEEK cages and posterior pedicle screw fixation.19

Concern was raised regarding a high pseudarthrosis rate in a series of 95 patients with degenerative disk disease treated with an anterior interbody lumbar fusion (21 double-level, 74 single-level) using a standalone PEEK cage. In this series, 23 patients (18 single-level, 5 double-level) required reoperation for a symptomatic pseudarthrosis. The surgeons cautioned that the absence of posterior fixation in combination with lower stiffness of the PEEK cage probably leads to insufficient initial stability, creating suboptimal conditions for bony bridging, and thus solid fusion.20 In contrast, in a prospective randomized study of 80 patients with cervical spondylotic myopathy, standalone PEEK cages were found to be superior to titanium cages in maintenance of intervertebral height and cervical lordosis, resulting in better clinical outcomes during long-term follow-up.21 Fusion was observed in all patients of 2 groups at the final follow-up, which averaged more than 7 years. The cage subsidence rate was 34.5% in the titanium group, compared with 5.4% in the PEEK group.

The increased stiffness of titanium rods used in pedicle-based posterior spinal fusion constructs is thought to con-
tigate the high tibial osteotomy studies of the canine femur and ovine tibia. The polymer used in these studies was epoxide resin rather than PEEK. Encouraged by these preclinical results, investigators performed a small clinical study of 20 closed displaced transverse and short oblique mid-diaphyseal tibial fractures. The initial clinical plate design was modified to increase plate stiffness, and all fractures treated with the modified plate healed.

The investigators concluded that they clearly showed the desirability of movement at the fracture site, since an external bridging callus appeared in all cases and this went on to produce a fairly rapid union in all patients except one. The carbon fiber and epoxy resin plate was also studied in a series of 19 more complicated cases that involved either infection, nonunion, comminution, or contamination. Radiological union with satisfactory clinical results was achieved in 18 of 19 patients within 40 weeks.

Despite the initial clinical results, the use of carbon-fiber plate fixation did not catch on in orthopedic trauma. One area of concern related to the relatively high infection rate. Tayton et al reported 3 deep infections in their clinical study of 20 patients with closed tibial shaft fractures, which all went on to heal despite infection. The inability to manually contour the plates also limited their use outside of the diaphysis. Additionally, the cost of these implants was prohibitively high compared with stainless steel. During the time of these initial studies, the formation of a callus was not desired following internal fixation. There was a reliance on direct anatomic reduction, which often required manual plate contouring—something not possible with the carbon-fiber plates. At that time, locking screw technology was not available to permit indirect reduction and bridging fixation with a non-contourable plate.

In 2004, Baker et al reported on the use of an 11- or 14-hole carbon-fiber plate in the treatment of 12 elderly patients (mean age, 76 years; range, 57-94 years) with periprosthetic femoral shaft fractures. Proximal fixation was achieved with 6.5-mm cancellous screws, distal fixation was achieved with 4.5-mm cortical screws, and cables were used for supplemental fixation in the area of the prosthesis. Eleven of the 12 cases healed, with an average time to union of 4 months (range, 3-6 months). The 1 failure occurred by pulling off of an intact plate, and this was converted to a longstem revision arthroplasty.

Carbon-fiber intramedullary nails for treatment of humerus, tibia, and femur fractures are currently commercially available (Figures 1-2). Anatomy-specific carbon-fiber locking plates for treatment of proximal humerus, distal radius, and fibula fractures are commercially available (Figures 3-5). In addition, a straight diaphyseal plate that includes a compression-style hole that accepts both 4.5-mm nonlocking and 4.0-mm locking screws is also available for diaphyseal fractures. A CFR-PEEK high tibial osteotomy.

Use in Orthopedic Trauma and High Tibial Osteotomy

Carbon-fiber-reinforced composite plates for fracture fixation were originally investigated in the 1980s, including in preclinical osteotomy studies of the canine femur and ovine tibia. The polymer used in these studies was epoxide resin rather than PEEK.

Commercially available carbon-fiber-reinforced polyetheretherketone intramedullary nails. (Image courtesy of Carbofix, Herzliya, Israel.)

Figure 1: Commercially available carbon-fiber-reinforced polyetheretherketone intramedullary nails. (Image courtesy of Carbofix, Herzliya, Israel.)

Figure 2: Tantalum markers embedded in the implant are oriented to define the interlocking hole location.

Figure 3: Commercially available carbon-fiber-reinforced polyetheretherketone intramedullary nails. (Image courtesy of Carbofix, Herzliya, Israel.)
osteotomy plate is also available. Typically, either titanium locking or nonlocking screws are used to secure these CFR-PEEK plates. One disadvantage of CFR composite plates is that they cannot be bent or contoured.

Tarallo et al\textsuperscript{29} reported on 10 intra-articular distal radius fractures treated with a CFR-PEEK volar locking plate. They reported favorable overall preliminary experience with this new plate. Radiographic union was present at an average of 6 weeks (range, 5 to 8 weeks), and they observed no loss of position or alignment of fixed-angle locking screws or plate breakage.

Cotic et al\textsuperscript{30} reported on the use of a CFR-PEEK plate in 26 patients undergoing an opening wedge high tibial osteotomy. Four patients treated with the CFR-PEEK implant sustained implant-related complications. One patient suffered screw loosening with loss of correction following a fall, and 3 patients developed nonunion and were revised to a titanium implant. The timing of the nonunion formation was not described, but failure analysis revealed that all 3 patients were smokers; in 2 cases, there was a complete fracture through the lateral cortex during the surgical procedure. Compared with osteotomies fixed with a titanium implant, the authors reported a higher failure rate with the CFR-PEEK plate and recommended against using the current CFR-PEEK plate design in high tibial osteotomies.

**USE IN SPORTS MEDICINE**

Polyetheretherketone suture anchors, without carbon-fiber reinforcement, are widely used for rotator cuff and acetabular labral repairs.\textsuperscript{31,32} These anchors have gained popularity due to their radiolucency and mechanical strength. Polyetheretherketone interference screws are also available for anterior cruciate ligament fixation.\textsuperscript{33} The flexible nature of certain PEEK composites even allows these anchors to maintain one shape for insertion and then be transformed into another shape for secure fixation.\textsuperscript{34} Because the PEEK material is not capable of self-drilling, these all require pre-drilled holes or use of a metallic punch or anchor tip.

A PEEK suture anchor incorporating 30% short carbon fibers was introduced in 2010. The increased mechanical strength of CFR-PEEK, along with optimized anchor design, may address the challenges of insertion torque and permit future development of self-drilling and self-tapping CFR-PEEK suture anchors.\textsuperscript{9}

**USE IN MUSCULOSKELETAL ONCOLOGY**

The use of carbon-fiber implants may be beneficial in the treatment of certain musculoskeletal tumors. The radiolucent characteristic of this implant has the potential to permit improved assessment of bone healing.\textsuperscript{35} It also provides an option for obtaining artifact-free CT and MRI scans, which may be important for evaluating local recurrence. Finally, carbon-fiber implants have minimal perturbation effects on the radiotherapy dose distribution and may offer benefits for patients receiving postoperative external beam radiation treatment.\textsuperscript{36}

Although there are theoretical benefits to the use of CFR-PEEK implants in musculoskeletal oncology, there is currently a lack of published clinical studies examining this indication. The use of a carbon-fiber intramedullary humeral nail for treatment of metastatic malignant melanoma has been described.\textsuperscript{35} In addition to metastatic lesions and cases receiving postoperative external beam radiation, CFR-PEEK implants may also be appropriate for certain benign lesions,
such as fibrous dysplasia (Figure 6).

**USE IN MUSCULOSKELETAL INFECTIONS**

Antibiotic cement coating over a carbon-fiber intramedullary nailing has been successfully used for the management of infected tibial nonunions. Compared with similar antibiotic coating of a metallic nail, the radiolucent property of the carbon-fiber nail allows for improved radiographic visualization of fracture healing and permits follow-up, artifact-free MRI (Figure 7).

Compared with nonlocking antibiotic cement nails that can be fashioned using a metal guidewire, using the carbon-fiber nail permits proximal and distal interlocking. Interlocking increases the rotational and axial stability and expands potential indications to include infected metadiaphyseal nonunions.

**CONCLUSION**

Carbon-fiber-reinforced polyetheretherketone implants offer several benefits over traditional metal implants. Their mechanical properties, including high fatigue strength and low modulus of elasticity, are advantageous for use in orthopedic surgery. Their radiolucent property allows improved imaging, which is useful for assessing healing or in situations in which an artifact-free CT or MRI scan is required. Although commonly used as material for spinal interbody fusion implants, their use in other areas of orthopedics is now being explored. Future clinical studies will help define their usefulness and role in other areas of orthopedic surgery. Several unresolved issues remain. First, translational research is needed to confirm that the low Young’s modulus of CFR-PEEK improves callus formation and provides quicker time to union in fracture cases. Second, clarification is needed regarding the clinical benefits of using intramedullary nails coated with antibiotics in relation to the ability to monitor bone infection progression or regression via MRI. Third, clinical studies must be performed verifying the direct benefits of radiolucency of the material for the quality of fracture reduction.

**REFERENCES**


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