PEEK Materials in Sports Medicine

Arthrex[®] Research and Development

Objective

Polyetheretherketone (PEEK) pronounced (poly-ether-ether-ketone) is an exceptionally strong thermoplastic polymer. Implantable-grade PEEK is an advanced thermoplastic material that is extremely well suited for both short- and long-term implantation. Arthrex PEEK devices have been cleared by the FDA and are CE marked. To date, uses of PEEK include spinal cages and spacers, replacement heart valves, pulmonary artery bands, dental appliances, and orthopedic devices such as pins, screws, anchors, ligament fixation washers and bone plate devices. The mechanical and nonmechanical properties of PEEK make it an ideal material for use in orthopedic implants like suture anchors, unlike absorbable or metallic materials which may elicit a tissue response or interfere with diagnostic imaging studies.

Mechanical Properties

Superior match to cortical bone

- Tensile yield strength
- Shear strength
- Modulus

In-vitro testing, excellent performance

- Fatigue
- Wear resistance
- Low coefficient of friction = "sick"

Another significant advantage of the material is its resistance to heat, therefore, special handling requirements are not necessary when distributing and transporting the material.

Mechanical Advantages

In orthopedic devices, a mismatch of mechanical properties between host bone and the orthopedic implant material is a concern. If an implant material is much stronger or has a higher modulus than the host bone, stress shielding can occur resulting in bone loss. This bone loss leads to implant loosening and subsequent biological failure of the implant. If an implant material is too weak or has a substantially lower modulus, the implant itself may fail mechanically. The mechanical properties of PEEK has advantages for various orthopedic applications.

The tensile yield strength and shear strength of PEEK are superior matches to cortical bone; especially when compared to titanium materials (Figures 1 and 2). PEEK is an excellent choice for orthopedic suture anchors due to the similarity between its modulus and that of cortical bone (Figure 3). In-vitro testing also demonstrates excellent performance in fatigue strength, wear-resistance fatigue resistance. PEEK also has a low coefficient of friction, making it a "slick" material easing insertion into host bone.

No significant effect on mechanical properties

- Gamma irradiation
 - Little or no cross-linking
- Stream sterilization
- -Little or no hydrolysis
- Oxidation
- -Little or no change in brittleness

PEEK mechanical properties retain their advantages in the clinical environment. Neither repeated gamma sterilization or oxidation (aka, aging) cause a significant deterioration of mechanical properties.¹ Unlike ultra-high-molecular-weight polyethylene (UHMWPE), PEEK does not undergo crosslinking or polymer chain breakage when subjected to gamma irradiation and therefore PEEK does not experience the weakening and increased brittleness often seen in other polymeric materials. There is no evidence to suggest that any of the material properties deteriorate as a result of gamma sterilization (Figure 4). Nor do material properties deteriorate after steam sterilization; PEEK is extremely resistant to hydrolysis (aka, water absorption) even at elevated temperatures. Oxidation testing results, simulating in-vivo aging, are also favorable to PEEK.¹ While UHMWPE is commonly understood to experience a significant decrease in strength after oxidation, oxidation has little or no effect on PEEK (Figure 5).

Clinical Benefits

- Biocompatibility
- Biostability
- Permanent implant with ability to be revised easily
- No scatter on MRI
- Radiolucent on X-ray

Due to its polymeric nature, PEEK orthopedic devices are easily revised. If revision surgery is needed in the future, PEEK devices are easily drilled or sawn through.

Nonmechanical Advantages

There are 2 behavior characteristics that are critical for any implantable biomaterial:

- (1) **Biocompatibility**, defined as the suitability of a material for exposure to the body or body fluids, and
- (2) **Biostability**, defined as the ability of a material to maintain its physical and chemical integrity after implantation into living tissue.

A third characteristic important to the clinician is a material's imaging capability. PEEK has excellent performance in all 3 of these areas.

At an early stage of material development, PEEK underwent extensive biocompatibility testing and performed excellently.¹ There was no evidence of cytotoxicity, systemic toxicity, irritation, or macroscopic reaction. Using a rabbit model, irradiated and aged test samples of PEEK were implanted intramuscularly for 1 year; no cytotoxic substances were released.²

Using the same rabbit intramuscular model to test biostability, there was virtually no response 1 year after implantation. Only mild fibrosis or light fibrous capsule were noted.¹ No muscle degeneration, necrosis or other significant changes were observed in explanted tissues. Chemical analysis of the explanted tissues showed no new chemical species present.¹

The third, nonmechanical advantage to PEEK is its ability to be imaged using MRI or X-ray. There is no metal present and therefore no metallic scatter is seen on MRI scan and the material is radiolucent.

Summary

PEEK mechanical properties closely match the mechanical properties of bone: tensile yield strength, shear strength and modulus.¹ These properties are not significantly degraded by gamma irradiation, steam sterilization (water environments), or oxidation (aka, aging). The material is also resistant to heat and requires no special accommodations for shipping and handling.

PEEK is biocompatible and highly biostable. Additionally, PEEK implants do not produce scatter when viewed using MRI, and when used without additions they are radiolucent on X-ray, allowing for better visibility. Many implantable orthopedic devices are successfully made of PEEK such as cages, spacers, pins, screws, anchors, washers and plates.

Figure 1: Tensile Yield Strength [MPa]

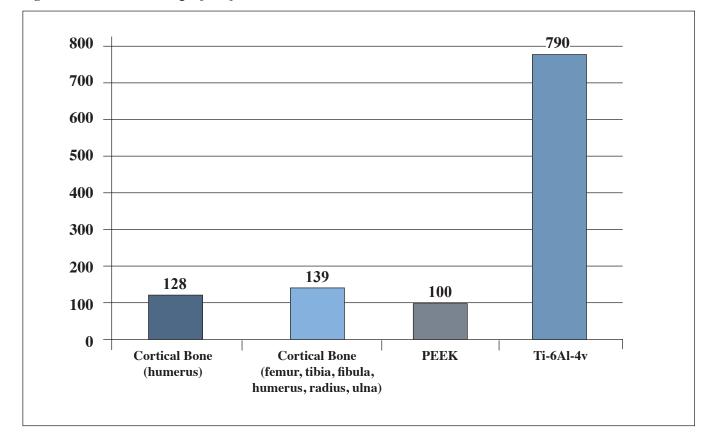


Figure 2: Shear Strength [MPa]

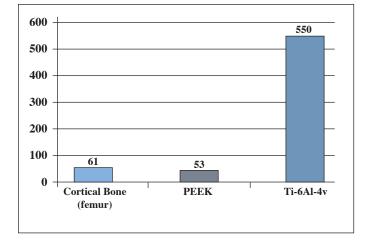


Figure 3: Tensile Yield Strength [MPa]

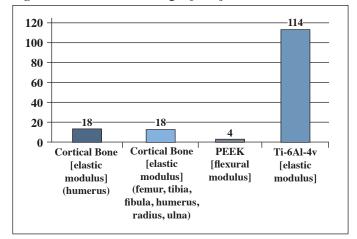


Figure 5: Effects of oxidation on tensile strength [MPa] for PEEK and UHMWPE; Ti-6A1-4V provided for comparison

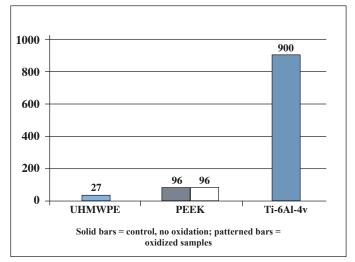
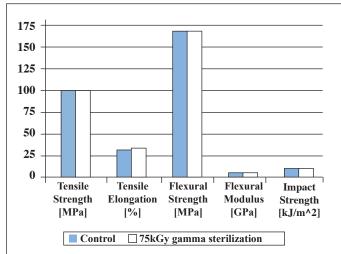


Figure 4: Influence of gamma sterilization on PEEK



Reference

- Kurtz SM, Devine JN. PEEK Biomaterials in Trauma, Orthopedic, and Spinal Implants. *Biomaterials*. 2007;28(32):4845-4869. doi:10.1016/j.biomaterials.2007.07.013
- Green S, Cartwright K. Polyetherethereketone polymer and compounds for surgical applications. Paper presented at: Medical Polymers 2003: 3rd International Conference focusing on Polymers used in the Medical Industry; April 2-3, 2003; Dublin, Ireland.