Carbon Fiber, Smart, and Antimicrobial Implants

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Disclosure
• Consultant and Implant design
  – Smith and Nephew

Why do we need to explore new technologies when what we have works?
“Metal works just fine”

- First metals used in orthopedics were stainless steel and cobalt-chrome-based alloys
- Offer benefits of strength, corrosion resistance, ease of machining, and low cost
- Titanium alloys have potential for osseointegration and modulus of elasticity that closely matches bone

Disadvantages of metal implants
- Fatigue failure
- Modulus of elasticity mismatch
- Wear debris
- Cold-welding
- Impair visualization of fracture reduction, healing, and tumor or infection progression or resolution

So Why Carbon Fiber?

- Composite material composed of layers of carbon fiber sheets, with fibers oriented in varying directions, embedded within polymer matrix of polyetheretherketone (PEEK)
- PEEK can be processed through various techniques, including injection molding, extrusion, or machining
So Why Carbon Fiber?

- PEEK has been shown to have excellent biocompatibility with minimal cellular response when studied in vitro and in vivo

So Why Carbon Fiber?

- Two main forms of carbon fiber incorporation are used for medical applications
  - Short CFR-PEEK consists of randomly aligned short carbon fibers, most less than 0.4 mm, which produce isotropic homogeneous material
  - Long CFR-PEEK consists of carbon fibers that essentially run entire width of implant. Tensile strength of long carbon fiber material is greater than 2000 megapascals (MPa), compared with 170 MPa for short carbon fiber material

So Why Carbon Fiber?

- Fatigue strength and modulus of elasticity make CFR-PEEK ideal implant material for plates and nails
- Carbon-fiber-reinforced implants can be engineered to have varying degree of strength and stiffness, based on orientation and number of carbon fiber layers
- 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
So Why Carbon Fiber?

- Modulus mismatch of metal implants can lead to altered loading, stress shielding, and detrimental periprosthetic bone remodeling
- Commercially available plates and nails have been tested to 1 million fatigue cycles without failure
- Average bending strength for 4.5-mm CFR-PEEK plate is 19.1 Nm (Newton meters)

So Why Carbon Fiber?

- Bending strength for 4.5-mm stainless steel locking compression plate is 16 Nm
- Average bending strength of commercially available 10-mm CFR-PEEK intramedullary tibial nail is 80.3 Nm, while bending strength of 11-mm titanium tibial nail is 43 Nm
- Wear debris testing has shown significantly lower wear debris volume with CFR-PEEK plates compared with titanium plates

So Why Carbon Fiber?

- Radiolucency and MRI compatibility of CFR-PEEK are beneficial
- Fracture reduction and healing can be assessed with x-rays
- Absence of artifact on both computed tomography (CT) and MRI
Why Not Carbon Fiber Implants?

- Can’t be contoured
- Too much flexibility can be disadvantageous, potentially leading to pseudarthrosis
- What if implant breaks?
- Radiopaque markers have been added to aid visualization of implant, including markers to identify intramedullary nail interlocking screw holes

Show me the Data?

Carbon Fiber Reinforced PEEK has a successful clinical history of more than 30 years

7. Li W, Gavrilis SA, Freeman CE, Nizzetto LC, Munford DS. Elbow prosthesis component. Proceeding...
Show me the Data?

- 23 studies included in review
- 20 were clinical and/or biomechanical studies and 3 were scientific reports
- 16 reported positive outcomes in favor of the use of CFR-PEEK as an implant material
- Three studies reported neutral outcomes


Show me the Data?

- One study found that using CFR-PEEK material in joint replacement therapy was suitable for hip arthroplasty, but not for knee arthroplasty

So Why Carbon Fiber?
Radiolucency
Improved Follow-Up: Clear visibility of the fracture line through the implant

Minimal Artifacts in CT & MRI
Allows improved pathology & soft tissue follow-up

Carbon Fibers Implants in cancer patients who undergo Radiotherapy
- No backscattering
- Precise pre radiation CT planning
Metal Allergy

Elasticity Modulus that Mimics Bone

Smart Implants?

- Combination of technology, cloud computing, and traditional orthopaedic implants and instrumentation
- Sensor assisted technology in products intended to promote improved clinical outcomes and greater patient satisfaction by knowing “what is going on inside”

Carbofix Composite implants lower the risk for “stress risers” and secondary fractures
Smart Implants?

- What they are
  - Integrated circuits
  - Digital signal processors and RFIDs
  - Embedded biosensors

Smart Implants?

- VERASENSE, a disposable sensor-assisted technology for total knee replacement
- Embedded microelectronics placed in knee implants that wirelessly send patient information to healthcare professionals

Smart Implants?

- Receive real-time feedback regarding femoral contact point position and mediolateral intercompartmental loads
- Mediolateral imbalance in flexion, mid-flexion, and extension can be defined and corrected intraoperatively
Show me the Data?

- 3-year, multicenter study evaluating 500 patients who have received primary TKA with use of intraoperative sensors in order to correlate quantified ligament balance to clinical outcomes
- 7 centers, 215 patients

Show me the Data?

- Using intraoperative sensor for guidance, 82% (p<.01) of patients were released & confirmed to exhibit optimal joint balance at closure
- Both KSS and WOMAC showed significant improvement (p<.01) from pre-operative interval to 6-month follow-up interval

Show me the Data?

- Average increase for KSS at 6 months was 60 points
- 200% greater than historical data, obtained from existing literature, using traditional methods of TKA balancing

Smart Hip

- “Smart Hip” monitors real-time performance of bone implants, stimulates bone growth
- Network of capsules and measuring sensors that are placed on hip implant
- Activated by a computer connected to Bluetooth device and “Smart Hip” components send information that can help prevent eventual problems after surgery

Antimicrobial Implants

- Critical pathogenic event in process of biofilm formation is bacterial adhesion
- Two targets
  - Inhibition of biofilm formation
  - Minimizing local immune response suppression


Antimicrobial Implants

- Up to 2.5% of primary hip and knee arthroplasties and up to 20% of revision arthroplasties are complicated by periprosthetic joint
- Staphylococcus aureus is leading cause of both SSIs and PJIs, and MRSA SSI and PJI are increasing, especially in United States
Antimicrobial Implants

- Bacteria have ability to adhere and survive on virtually all natural and synthetic surfaces
- Adhesins for a wide range of biomaterial surface receptor sites
- Reservoir of receptors for bacterial adhesive ligands mediating adhesion of free-floating bacteria to surface

Antimicrobial Implants

- Complement and albumin are considered main components of conditional protein film
- Bacterial adhesion has two basic phases
  - Reversible
  - Irreversible

Antimicrobial Implants

- Reversible is mechanically and biologically less stable than irreversible
- At least four distinct classes of surface proteins have been identified to participate on firm adhesion of S. aureus micro-colonies to a biomaterial and to each other
- Adhesion phase is followed by gene expression for secretion of protective slime
Basic Concepts of Coatings

- Anti-adhesive properties
- Antimicrobial agents

Anti-adhesive properties

- Hydrophilic, highly hydrated, and non-charged surfaces could be a good choice
- These surfaces have been shown *in vitro* to prevent many bacterial species from biomaterial adhesion by limiting contact between bacterium and potential surface placement sites

Anti-adhesive properties

- These strategies can’t be used in setting of implants requiring bony ingrowth, but may be appropriate for non-fixation surfaces (plates, screws, or intramedullary nails)
Antimicrobial agents

- Contact Killing or
- Drug Eluting
- Some not suitable for surface treatment of orthopaedic implants due to problems with cytotoxicity, immunoreactivity, and genotoxicity

Antimicrobial agents

- Silver is most prevalent metal used in biomedical applications
- Dissolved silver cations are biochemically active agents that interfere with bacterial cell membrane permeability and cellular metabolism
- Silver also contributes to formation of reactive oxygen species and other mechanisms that potentially influence prokaryotic cells

Antimicrobial agents

- There is concern about toxicity of silver ions
- Even in minute levels silver can adversely affect surrounding cells and lead to potentially harmful accumulation in distant locations
So what is the Future of Implants?

• Multifunctional smart implants that help prevent implant infections while enhancing healing and restoration of patient function