Orthopaedic Surgery & Aerospace Materials: Can a Hip Implant Fly?

Paul Wooley, PhD
Chief Scientific Officer, CIBOR
KBA Eminent Scholar of Biomaterials
Director, Orthopedic Research Institute
Professor of Biology, WSU
Professor of Orthopaedic Surgery, KUMS- W
OMTEC Chicago, June 2012
Disclosures

• Paid Consultant
  – Depuy
• Unpaid Consultant
  – Stryker Bearing Panel
• Research Funding
  – Synthes, Smith & Nephew, Stryker
• Boards & Committees
  – Orthopaedic Research Society
  – National Science Standards Group
DePuy Orthopaedics Launches the Never Stop Moving™

DePuy Orthopaedics, Inc. is pleased to announce the launch of a national, integrated direct-to-patient campaign, Never Stop Moving™, in conjunction with the 2008 Olympics.

This campaign features Mike “Coach K” Krzyzewski, a DePuy hip patient and coach of the 2008 U.S. Olympic Team of Men’s Basketball and Duke University Basketball. Coach K is a hands-on leader. Not one to sit on the sidelines, he likes to get on the court with his team. But when he developed severe hip arthritis, he just couldn’t. As his condition worsened, the pain became so severe that he had to coach from a chair. That’s when his orthopaedic surgeon recommended a hip replacement from DePuy Orthopaedics.

“My life’s all about movement. So when arthritis pain nearly ended my career nine years ago, I had to do something about it. I want other patients to see that I have gone from coaching from a chair to coaching the 2008 U.S. Olympic Team of Men’s Basketball and think about what they can accomplish!” said Coach K.

The goal of the Never Stop Moving campaign is to motivate osteoarthritis sufferers to learn more about hip and knee replacement and seek the care of an orthopaedic surgeon. Many of these patients are waiting too long or failing to seek help. We believe awareness and education can make a difference for these patients.

- Patients are receiving implants at a younger age and requiring high performance materials

- 30% of Patients in their fifties and 55% of Patients <50 will require revision ~15 years after surgery*

  - * Keener et al, JBJS 2003
  - Utting et al, JBJS 2008
Avoiding the cost of revisions\textsuperscript{1}

- The operative cost of revision surgical procedures are 41% higher than primary surgery.
- Hospitals stays are 2 days longer, and rehabilitation is significantly slower.
- The complication rate (particularly infections) is 32% higher than primary surgery.
- Patient pain, suffering and restoration of function.

\textsuperscript{1}Bozic et al, JBJS 2005
Potential for Improvement

• Potential Improvements with current devices come in 1 of 3 areas:

1. Reduce Cost
   • Implants & instruments

2. Reduce Time
   • Central processing, OR time

3. Improve Outcomes
   • Both short- and long-term outcomes
Intersection of composites & orthopedics

• Where can composites make these improvements?
  • Hips and knees
  • Spine
  • Trauma
Hips and Knees

- Cost
- Time
- Outcomes
  - Wear
  - Stress shielding
  - Material Sensitivity
Wear associated Osteolysis

Particles from the metal and plastic cause inflammation leading to bone loss and failure of the implant.
Bearing Surfaces

- Polyethylene
  - Conventional
  - Highly Crosslinked
- Metals
  - Stainless steel (316s)
  - Cobalt chrome
  - Titanium
- Ceramics
  - Alumina
  - Zirconia

Preferred combinations are metal or ceramic on poly
Has HXLPE ‘fixed’ Poly Wear?

- Claims of 70% to 90% volumetric wear reduction.
- Wear morphology has resulted in a reduction in particle size.
- Actual wear debris particle numbers has not altered.
- Does the ‘new wear’ constitute a novel biological problem?
Comparison of Conventional and HX-UHMWPE

Figure 1

Conventional UHMWPE

HX-UHMWPE

Histogram

Not sure what I’m looking at here…captions needed
Stress Shielding

- Stress shielding – BMD loss of 20-50%\(^1\)
  - Peri-prosthetic fracture rate implications?
    - 1% post-op fracture rate in primaries, 4% in revisions\(^2\)
  - Poor quality bone makes revision surgery more challenging
    - 21% intra-op fracture rate with cementless revisions\(^2\)
  - Makes bone-implant interface more susceptible to wear debris penetration and lysis?

Hips – Stress Shielding

• Composite Hips have demonstrated reduced stress shielding

Knees – Stress Shielding

• Stress shielding – BMD loss of 19-44% at 1 year¹

  – Peri-prosthetic fracture rate implications
    • 0.3-2.5% post-op fracture rate in primaries,
      1.6-38% in revisions²

  – Poor quality bone makes revision surgery more challenging

  – Makes bone-implant interface more susceptible to wear debris penetration and lysis?

---

Knees – Stress Shielding

- Composite knees have the potential to reduce stress shielding based on known material properties.
Material Sensitivity

Allergic-like reactions to orthopaedic metals and plastics can lead to bone loss and failure of the implant
Hips – Material Sensitivity

Toxic Cellular Reactions to Biomaterials

- PMMA
- UHMWPE
- Ti alloy
- Co-Cr alloy

Percent

0 5 10 15 20 25
Aerospace Material as Potential Solutions
## Scanning Electron Microscopy

<table>
<thead>
<tr>
<th></th>
<th>GRAFOAM® Carbon Foam (FPA-20)</th>
<th>Duocel® Reticulated Vitreous Carbon (RVC) Foam (80 ppi)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Density</strong></td>
<td>0.32 g/cc</td>
<td>0.048 g/cc</td>
</tr>
<tr>
<td><strong>Porosity</strong></td>
<td>80%</td>
<td>97%</td>
</tr>
</tbody>
</table>
Evaluation of Carbon Foam as a Bone scaffold

- **In Vitro Techniques**
  - Rapid evaluation of cell activation and cytokine profile

- **Short Term In Vivo Techniques**
  - Rodent air pouch model.
  - Inflammation and benign response discrimination.
  - Modification for bone assessment.

- **Longer Term Implantation Models**
  - Calvarial Plate and Critical defect models
Cellular Response to Carbon

Activation Index

PMMA | UHMWPE | Ti alloy | C powder | C milled | Con A

2.5
2.0
1.5
1.0
0.5
Brightfield Analysis of Cell Interactions with Debris
Air Pouch Model (BALB/c)
Murine Air Pouch
Image Analysis System
Carbon Foam *In Vivo*
GRAFOAM® Carbon Foam- Modification

Osteoblast viability and functionality

Mechanical Properties

Carbon foam

Carbon foam
GRAFOAM® Carbon Foam
(Femoral defect model in rats, 6 weeks)
GRAFOAM® Carbon Foam
(Femoral defect model of rats, 6 weeks)

Day 0 → Day 42

Carbon → Bone

Carbon
Rat Skull Defect Model
RVC foam (Rat calvarial defect model, 4 wks)

- MicroCT Data

0 Day

28 Days

Autograft  Negative control  Carbon only  Carbon + BMP-2  Carbon + Osteoblasts
Spine – IBF Devices

– Cost
  • Need for expensive BMP reduced?

– Time

– Outcomes
  • Time to fusion reduced
  • Reliability of fusion enhanced with fusion mass enlargement
  • Potentially reduced incidence of dysphagia with guided bone growth
Cervical and Lumbar Implants
Spine – Radiolucent Instruments

• Cost

• Time
  – Reduced OR time from fewer intra-op x-rays

• Outcomes
  – Improved implant placement and outcome from enhanced visibility
  – Potentially improved safety to patient (& staff) from reduced x-ray exposure
Spine – Radiolucent Instruments

- Radiolucent retractors made from non-metallic composite materials (carbon fiber/PPS resin)

- Ergonomic design
  - light weight
  - low glare

- 10 commonly used instruments

- Engineered to perform equivalently to stainless steel
  - Stiffness
  - Strength (bending and torsion, pre/post sterilization)
  - Biocompatibility (ISO 10993)
Spine – Radiolucent Instruments

Product Performance:

Fluoro image with 5mm carbon fiber/epoxy resin composite plate over specimen (metal pin as contrast element)

Anatomic structures clearly seen despite intervening material
Trauma – Radiolucent Instruments

- **Cost**
- **Time**
  - Reduced OR time from fewer intra-op x-rays
- **Outcomes**
  - Potentially improved safety to patient (& staff) from reduced x-ray exposure
About CIBOR
What is CIBOR?

Mission

*CIBOR, a not-for-profit company, was founded in 2009 to promote translational research of biomaterials for orthopaedic applications and develop an active medical device industry for the State of Kansas.*

Goals

- Develop medical devices using advanced materials, especially composite materials derived from aerospace technology
  - On our own
  - In partnership
- Improve the practice of orthopaedic medicine
What does CIBOR offer?

CONTRACT R&D FOR ORTHOPAEDIC MEDICAL DEVICES (TURN-KEY or INDIVIDUAL SERVICES)

MATERIAL SCIENCE & ENGINEERING EXPERTISE & EQUIPMENT

Design  Prototype  Test  Analyze  Mfg. Transfer

Turnkey Project Management

Composites  Metals  Polymers  Biologics

SPEED FROM EXPERIENCE

COMPETITIVE PRICING
Questions?