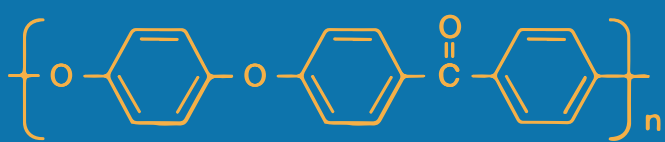
CONFERENCE PROGRAM

3RD International PEEK Meeting



WASHINGTON, D.C.

April 27-28

2017

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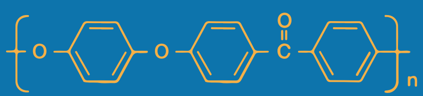
3RD International PEEK Meeting



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Dear Participant,

The purpose of the conference is to bring together engineers, scientists, regulators and clinicians from academia, industry and government agencies. Leading edge research on advancements in medical grade polyaryletherketone (PAEK) polymer technology and clinical applications will be presented:

- Additive manufacturing of PEEK and its composites
- Innovations in orthopedic bearings
- Bioactive PEEK composites
- Spinal rods and artificial disc applications
- Formulations for dental, trauma and arthroscopic implants
- Structural composites and woven fiber applications
- Biologic aspects of wear debris

Abstracts were evaluated by the Scientific Committee for inclusion in the program, either as a podium presentation or a poster.

Scientific Committee

Steven Kurtz, Ph.D.
CONFERENCE ORGANIZER
Implant Research Center, Drexel University & Exponent, Inc.

Joanne Tipper, Ph.D.
University of Leeds

Kate Kavlock, Ph.D.
US FDA CDRH (Center for Devices and Radiological Health)

John Bowsher, Ph.D.
US FDA CDRH

3RD INTERNATIONAL PEEK MEETING AGENDA

Thursday Morning, April 27

WELCOME

8:00 am	On-site Registration Opens	
9:00 am	Welcome, Opening Remarks & Advances Since 2015	*Steve Kurtz, Ph.D.*

SESSION I: Additive Manufacturing of PAEK
Moderators: Matthew Di Prima, Ph.D., FDA, and Steve Kurtz, Ph.D.

9:15 am	**Invited Talk 1:** Aromatic PAEKs in Additive Manufacturing using SLS: Understanding Process, Structure and Property	*Manuel Garcia-Leiner, Ph.D.*
9:35 am	**Podium Talk 1:** Design Based Considerations and Part Quality Intended Predictive Tool for a 3D Printer Conditioned for High Temperature Polymeric Materials	*Uwe Popp*
9:50 am	**Podium Talk 2:** Creating Lattice Structures with Polyetheretherketone via Additive Extrusion Processes	*Vinzenz Neinhaus*
10:05 am	**Podium Talk 3:** Tribological Performance of Additive Manufactured Poly Ether Ketone (PEK) Component	*Saurabh Lal, Ph.D.*
10:20 am	**Coffee Break**	

SESSION II: Processing and Properties of PAEK and PAEK Composites
Moderators: Kate Kavlock, Ph.D., FDA, and Manuel Garcia-Leiner, Ph.D.

10:50 am	**Invited Talk 2:** FDA Guidance for Additive Manufactured Medical Devices	*Matthew DiPrima, Ph.D.*
11:10 am	**Podium Talk 4:** Increasing the Toughness of PEEK-hydroxyapatite composites	*Anuj Bellare, Ph.D.*
11:25 am	**Podium Talk 5:** Failure of Carbon Fibre PEEK Laminated Composites	*Ellen Gallagher*
11:40 am	**Podium Talk 6:** Is Locking Screw Fixation in Carbon Fiber Composite Plates Mechanically Equivalent to Stainless Steel Plates?	*David Hak, M.D.*
11:55 am	**FDA Round Table:** What Are Unanswered Regulatory Science Questions in Advanced Manufacturing of PAEK, PAEK Composite Implants, and their Coatings?	*Matthew DiPrima, Ph.D., John Bowsher, Ph.D., Kate Kavlock, Ph.D., FDA*
12:25 pm	**Lunch & Poster Session 1**	

3RD INTERNATIONAL PEEK MEETING AGENDA

Thursday Afternoon, April 27

SESSION III: PEEK Knee

Co-Moderators: John Bowsher, Ph.D., FDA and Joanne Tipper, Ph.D.

2:00 pm	**Invited Talk 3:** Update on Biologic Response of PAEK Wear Debris	*Joanne Tipper, Ph.D.*
2:20 pm	**Podium Talk 7:** A Polymeric Total Knee Replacement: Pre-Clinical Review and Clinical Preview	*Adam Briscoe, Ph.D.* *Asit Shah, M.D., Ph.D.*
2:40 pm	**Podium Talk 8:** Pre-clinical Biomechanical Evaluation of Fixation of a Cemented PEEK Femoral Component in TKA	*Dennis Jannsen, Ph.D.*
2:55 pm	**Podium Talk 9:** The Wear of an All-Polymer Knee Replacement Under Different Environmental Conditions	*Raelene Cowie, Ph.D.*
3:10 pm	**Podium Talk 10:** Comparative Knee Simulator Study: PEEK and CoCr Femoral Components vs. Standard UHMWPE and Vitamin E Stabilised HXLPE	*Reto Lerf, Ph.D.*

3:25 pm Afternoon Coffee Break

SESSION IV: Novel Orthopaedic Applications and Biological Issues

Co-Moderators: John Bowsher, Ph.D., FDA and Joanne Tipper, Ph.D.

3:45 pm	**Podium Talk 11:** CFR-PEEK on CoCrMo Articulations in the Atlas Knee System	*David Lowe.*
4:00 pm	**Podium Talk 12:** Cartilage Function-Mimetic Hydrated Interface with Phospholipid Polymer for a Metal Free Bearing	*Masayuki Kyomoto, Ph.D.*
4:15 pm	**Podium Talk 13:** Fretting Corrosion Performance of Modular Tapers Fitted with Self-Reinforced Composite PEEK Gaskets	*Eric Ouluette, Ph.D.*

6:15 pm Day 1 Meeting Adjourns

Drexel Transportation – Transition to Reception and Dinner

6:30 pm Reception and Dinner Begins

3RD INTERNATIONAL PEEK MEETING AGENDA

Friday Morning, April 28

8:00 am	On-site Registration Opens, Breakfast	

PAPER SESSION V: Engineering PEEK Bioactivity

Session Chairpersons: Hany Demian, FDA, and Clare Rimnac, Ph.D.

9:00 am	**Extended Podium Talk 14:** In Vivo Models of the Bone-Implant Interface	*Bill Walsh, Ph.D.*
9:20 am	**Podium Talk 15:** Porous PEEK Versus Plasma-Sprayed Titanium Coating on PEEK: In Vitro and In Vivo Analysis	*Brennan Torstrick*
9:35 am	**Podium Talk 16:** PEEK *Staphylococcus Aureus* Biofilms: Effects of Media	*Noreen Hickok, Ph.D.*
9:50 am	**Podium Talk 17:** Characterization of In Vivo Osteoconductive and In Vitro Antibiofilm Properties of PEEK-Sliver Zeolite Composite in the Spine	*Boyle Cheng, Ph.D.*
10:05 am	**Podium Talk 18:** Do Antibacterial Coatings to PEEK Influence Bone Ongrowth	*Bill Walsh, Ph.D.*

10:20 am Morning Coffee Break

PAPER SESSION VI: Novel Clinical Applications of PEEK

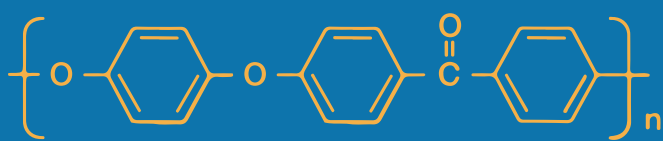
Session Chairpersons: John Bowsher, Ph.D., FDA, Steve Kurtz, Ph.D.

10:45 am	**Invited Talk 4:** Development of Novel Post-Market Surveillance Network for Implanted Medical Devices in the US	*Danica Marina-Dabic, Ph.D.*
11:05 am	**Podium Talk 19:** Clinical Evaluation of a Radiolucent Carbon/PEEK Pedicle Screw System - Early Experience in Degenerative Cases with 12 months follow up	*Thomas Nydegger*
11:20 am	**Podium Talk 20:** Preclinical and Clinical Evaluation of an all PEEK Total Facet Arthroplasty	*Ryan Siskey*
11:35 am	**Podium Talk 21:** Porous PEEK Cervical Interbody Fusion Device: Initial Radiographic Results	*David Safranski, Ph.D.*
11:50 am	**Podium Talk 22:** Randomised Controlled Clinical Trial Investigating PEEK versus Cobalt-Chromium Removable Partial Dentures on Periodontal Health, Chewing Ability and Oral Health Related Quality of Life	*Ali Zaid*
12:05 pm	**Podium Talk 23:** Feasibility of Radiostereometry for Assessment of Healing of Proximal Humeral Fractures	*M. Downing, M.D.*

12:20 pm Meeting Adjourn

ABSTRACTS

3RD International PEEK Meeting



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Invited Talk 4	Development of Novel Post-Market Surveillance Network for Implanted Medical Devices in the US	*Marina-Dabic*	–
SPINE			
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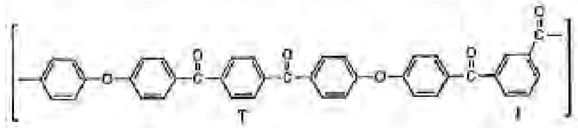
Poly(aryletherketone) (PAEK) Polymers in Additive Manufacturing: Understanding Process, Structure and Property.

Garcia-Leiner, M[1]
[1]Exponent, Bowie, MD, USA
mgarcia-leiner@exponent.com

Introduction: Additive Manufacturing (AM), otherwise known as three-dimensional (3D) printing, is a growing technology area comprised of a spectrum of processes that allow production of 3D solid objects of virtually any shape using information obtained from a digital object file. These days, AM processes are driving innovations in multiple areas, including engineering, manufacturing, art, education and medicine. In its broadest sense, AM processes use additive approaches to produce a final part where materials are applied in successive layers, differing from traditional subtractive manufacturing techniques that rely on methods such as cutting or milling where material is removed to produce the final part. AM processes are not necessarily new. In fact, they were introduced commercially in the early 90's for the manufacture of complex metal parts and have almost a 30-year history in the plastic industry, mainly due to prototyping efforts that drove the development of multiple commercial products using techniques, ranging from stereo-lithography to laser assisted powder-bed fusion processes.

A growing number of polymeric resins have become available in recent times due to developments of new processes and technological advancements in AM. High-performance thermoplastics are perhaps the most promising material candidates for the adoption of AM into the production of parts for demanding engineering applications. Among these, polymers such as poly(aryletherketone)s (PAEKs), could revolutionize and facilitate the adoption of polymers in AM. Understanding the fundamentals of existing AM process, and their potential effects on the structure of PAEKs in relation to their performance in critical environments is crucial for the success of these new technologies and materials in complex and demanding applications.

Methods and Materials: Polyetherketoneketone (PEKK) resins used in this study were manufactured and supplied by Arkema. In particular, OXPEKK-SP and resins from the KEPSTAN™ 6000 family were employed in this study. As shown in Figure 1, these resins are characterized by a terephthalic- and isophthalic- monomer content (T/I ratio) of 60/40.



Terephthalic (T) Isophthalic (I)

Figure 1 Overall chemical structure of PEKK resins used in this study (T/I = 60/40)

Thermal Characterization. Thermal properties of PEKK powders and pellets of this study were analyzed using Differential Scanning Calorimetry (DSC). DSC experiments were performed using a TA Instruments thermal analyst model 2920 DSC equipped with a liquid nitrogen cooling system. Materials were subjected to 10°C/min cycles from 25 to 400°C under nitrogen. The enthalpy of fusion (ΔH_f) and characteristic thermal transitions, including the glass transition temperature (T_g), melting temperature (T_m), and crystallization temperature (T_c), were measured in accordance with ASTM D3418.

Diffraction. Crystal structure and crystallinity were characterized in these materials using wide-angle X-ray diffraction (WAXD). WAXD experiments were conducted using a horizontal Rigaku Geigerflex RU-200B diffractometer with nickel-filtered Cu Kα radiation (λ 1.542 Å) generated at 40 kV and 40 mA. X-ray patterns were collected over 5 to 70° two-theta with a step size of 0.02° and step time of 1 s. Percent crystallinity and crystallite size were estimated from diffraction patterns using established methods described in detail elsewhere.

Results: As depicted in Figure 1, commercially available PEKK materials vary in terms of their structure according to their monomer (T/I) ratio, allowing for the production of highly crystalline, linear, and structurally robust resins with melting points as high as 360°C (T/I=80/20), as well as easier to process materials, with a significantly reduced melting temperature (300°C) and lower degrees of crystallinity (T/I=60/40).

The conditions used in existing AM processes will have a definite effect on the structure and the properties of additively manufactured plastic parts, including those made of PEKK. In powder-bed fusion processes, such as Selective Laser Sintering (SLS), a bed of powder is preheated in a chamber to a specific temperature and then distributed as a thin layer where a laser is used to precisely heat specific regions of the bed, and to selectively sinter the polymer powder in a predetermined pattern. The process is repeated multiple times, and the material is re-heated and selectively sintered in a specific pattern based on the morphological features of the part. Successive layering and sintering can then produce a 3D object that is finally removed from the un-sintered powder bed after manufacturing. Temperature, time and powder properties will play a significant role in these processes.

Similarly, extrusion-based AM processes, such as Fused Deposition Modeling (FDM), often involve the use of previously produced filament materials that are used as raw materials to feed a precisely heated die nozzle, which is capable of extruding polymer melt in a very accurate way, according to the 3D features of the final part. Extrusion temperatures, die design, residence times and the viscoelastic properties of the polymer melt, among other characteristics determine the effectiveness of these processes.

Understanding the effects of AM process conditions on the properties of AM parts produced with PAEK thermoplastics is essential to predict their performance in critical environments and high demanding applications, as well as for the development of new technologies and complex processing techniques. In this study, the crystal structure and crystallinity, in addition to the thermal and mechanical properties have been characterized for a series of PEKK resins processed using SLS and FDM at various conditions.

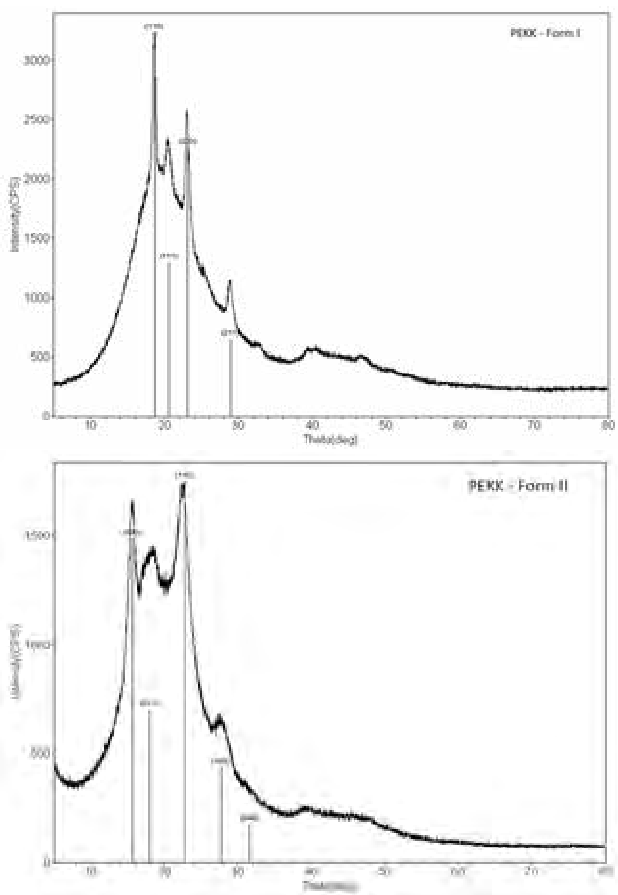


Figure 2 WAXD patterns for PEKK crystalline polymorphs (Form I and Form II). Below are some representative reflections for each crystal form:

Form I		*Form II*	
(hkl)	2θ (deg)	(hkl)	2θ (deg)
(110)	18.65	(020)	15.62
(111)	20.64	(021)	17.93
(200)	23.17	(110)	22.70

WAXD results allowed for the precise quantification of the crystal composition of PEKK systems. Figure 1 compares the WAXD patterns of both polymorphs in PEKK (Forms I and II). As shown here, distinct reflections are obtained for each crystal phase facilitating their quantification. Results suggest that heat treatment at elevated temperatures, observed for example during AM processing, has a direct effect in the overall degree of crystallinity, as well as in the crystal structure and polymorphism of PEKK. An example of this is shown below in Table 1 for the case of PEKK powders, where the presence of distinct crystal forms is controlled and affected by the specific heat treatment imposed during SLS processing. At elevated temperatures, the polymorphic nature in PEKK facilitates further nucleation through a combination of annealing with crystal-crystal transformations. As the temperature is increased, the more thermodynamically stable crystal form (Form I) predominates, leading to potential variations in the mechanical properties and overall performance of parts produced at different conditions.

Table 1 WAXD results showing the polymorphic behavior observed in PEKK powders (T/I = 60/40) when subjected to various processing conditions.

Heat Treatment		**Polymorph**	**% Form I (110)**	**Crystallinity (%)**
Time	**Temp.**			
Control	N/A	II only	0	27.8
1 h	200ºC	II + trace I	2.0	32.6
2 h	200ºC	II + trace I	2.7	32.3
8 h	200ºC	II + trace I	2.8	33.4
16 h	200ºC	II + trace I	2.8	33.7
1 h	250ºC	II major + I	12.3	33.6
2 h	250ºC	II major + I	11.9	33.1
8 h	250ºC	II major + I	11.5	32.8
16 h	250ºC	II major + I	11.9	31.6
1 h	285ºC	I only	100.0	19.7
2 h	285ºC	I only	100.0	22.2
8 h	285ºC	I only	100.0	22.9
16 h	285ºC	I only	100.0	23.6

Discussion: Under conditions often encountered in common AM processes, dramatic changes in the crystal structure can occur in PEKK systems, promoting the development of polymorphism. In particular, thermal and crystallographic studies in this study revealed that AM parts produced through various methods and conditions will display different crystalline characteristics that will consequently affect their mechanical properties. Since PAEKs are one of the most versatile series of high-temperature engineering thermoplastics, the understanding of their morphological changes during AM processing is critical for the success of these new technologies, and the introduction of these novel materials into high demanding applications.

Design based considerations and part quality intended predictive tool for a 3D printer conditioned for high temperature polymeric materials

Popp, UW[1] Okolo, BC[1,2]
[1]Indmatec GmbH, Karlsruhe, Germany
[2]*brando.okolo@indmatec.com*

Introduction: A typical pathway for the design and construction of 3D printers is the full consideration for the mechanical performance of the machine. To guarantee mechanical performance special focus is given to precision of gears, motors, drive system and the power delivered by the machine. Whilst this approach holds its merit in traditional machine construction guidelines, it fails to give due attention to the science governing the processibility of materials. The fused filament fabrication (FFF) 3D printing technology is without a doubt the most applied in the family of 3D printing technologies. This technology is designed for the processing of thermoplastic materials where melting and solidification behaviour determines the basic property of the material. Because the open-source (RepRap) community has massively contributed to the development of the FFF technology, with intense focus on the processing of commodity grade thermoplastic materials such as PLA and ABS, the incentive to explore highly thermo-mechanically demanding polymeric materials has been lacking. There are challenges inherently rooted in the processing of polymeric materials namely crystallinity, melting temperature, glass transition temperature, temperature range of the softening zone, solidification rate, viscosity as well as other rheology based attributes. These challenges become pronounced in the case of high-performance high-temperature polymeric materials requiring that they are handled or resolved already at the conceptual and design stages of 3D printer development. Thus for the processing of high temperature thermoplastic materials such as PEEK, PEI or PPSU, there are some key hardware features which need to be included in the machine.

The aim of this presentation is to highlight the underlying science behind the design and construction of a 3D printer suitable for processing high temperature polymeric materials. Model based descriptions of the influential role of some printing process parameters for polymers will be presented within the context of indicators for printed part quality.

Methods and Materials:

- Fused Filament Fabrication 3D printer equipped with: (i) a HotEnd capable of heating up to 410 deg. C. (ii) a print bed capable of heating up to 150 deg. C (iii) a build chamber to prevent the flow of atmospheric air across the depositing material

- A high melting point semi-crystalline thermoplastic material such as PEEK in filament form (Ø 1.75 mm; +/- 0.04 mm)

- Parametric studies which allows for the monitoring of influence of the printed part quality by various parameters namely (i) print bed temperature, (ii) chamber temperature, (iii) printing temperature, (iv) printing speed. This way it will be possible to develop a mathematical model which serves as both a predictive tool for part quality as well as process control tool. The model is generated by mathematically describing the print parameter's influences on part quality indices such as (i) yield strength, (ii) total strain, (iii) ultimate tensile strength, (iv) surface roughness, (v) dimensional parameter such as length or edge radius. The sets of equations (linear or polynomial functions) describing these correlations are then regressed (multiple) to a single equation which makes it possible to predict or produce specific properties in FFF 3D printed parts. The accuracy of this predictive tool or quality assurance tool is markedly dependent on the machine's (printer) ability to control the material behaviour during the printing process as it transforms from the fully melt amorphous phase to a solid state semi-crystalline phase.

Results: By managing the process of phase transformation during 3D printing of high temperature thermoplastic materials like PEEK, it would be possible to print parts with properties which compare well with those manufactured by conventional methods such as CNC milling or injection molding. With this thermal management in grip it is then possible to establish a realistic correlation between process parameter and part quality. Determining this correlation requires a large amount of sampling and data analysis. This is one way of creating a quality assurance tool in 3D printing processing.

Discussion: There is a need to begin gathering experimentally driven data for 3D printing processes. This way it becomes easier for industry to develop confidence in 3D printing as a truly manufacturing tool. Such a tool makes it possible to:

- Describe the material printing process

- Predict the material printing process

- Confirm / validate the material printing process

- Determine key material properties

Creating lattice structures with Polyetheretherketone via additive extrusion processes

Nienhaus, Vinzenz[1]; Spiehl, Dieter[1]; Dörsam, Edgar[1]
[1]Institute of Printing Science and Technology, Technical University Darmstadt, Germany
nienhaus@idd.tu-darmstadt.de, spiehl@idd.tu-darmstadt.de, doersam@idd.tu-darmstadt.de

Introduction: Extrusion based printers are present everywhere from home use and food printing to industrial applications and the medical sector. Despite the advantages of additive extrusion processes, like low investment cost, great control over porosity distribution and no powder inside of the voids, there is still a lack of research about processing equipment and toolchains especially with focus on Polyetheretherketone (PEEK).

In contrast to Laser Sintering, which has been around for some time and is commercially available [1], there are still very few extrusion based machines available which can process PEEK in an appropriate manner [2,3]. First investigations were made in 2013 with a custom printer [4]. In 2015 a syringe based and a custom filament based extruder head assembly was investigated [5].

In this work we describe how we managed to print PEEK filament on a commercially available printer. We modified parts of the printer so even printing using small nozzles with down to 0.2 mm orifice diameter is possible. With small lattice structures in mind, in former works we looked at the toolchain and identified major problems in the current workflow regarding the slicer software, which divides the geometry into printable layers. For processing of the CAD surface based geometry in STL format the open source software *slic3r* was used [6]. First the lattice structure was created in CAD software and transferred to the slicer software in STL format. As pointed out in [7] this comes with major drawbacks due to uncontrollable porosity and artifacts in the machine code. Full machine control was achieved by a direct machine code generator, which was implemented in *Matlab R2015b* [8]. The script could be easily extended by a multimodular modeling approach which can be used for modeling bone like structures.

Methods and Materials: The experimental setup is based on a Hyrel System 30M modular printer [9]. The machine provides the Cartesian kinematics and an extrusion head (MK400) which can reach temperatures up to 410°C. The extrusion head features the filament drive and cooling section (cold end), as well as the hot end. The schematic can be seen in figure 1. Because the heated build plate can only reach temperatures of 65°C, it was substituted with a hotplate with a maximum of 500°C. On top of the hotplate an appropriate buildplate was used (*MTplus-Dauerdruckplatte* [10]). It showes good adhesion to PEEK from 60°C on and very good adhesion at 250°C without thermal decomposition. This brings platform temperature above the glass transition temperature of 143°C. This helps to transform PEEK from amorphous to high strength semicrystalline state and reduces thermal deflection of the parts (warping) for the first layers. The amorphous state can be easily observed due to its transparency. Test samples printed on a hotplate at a

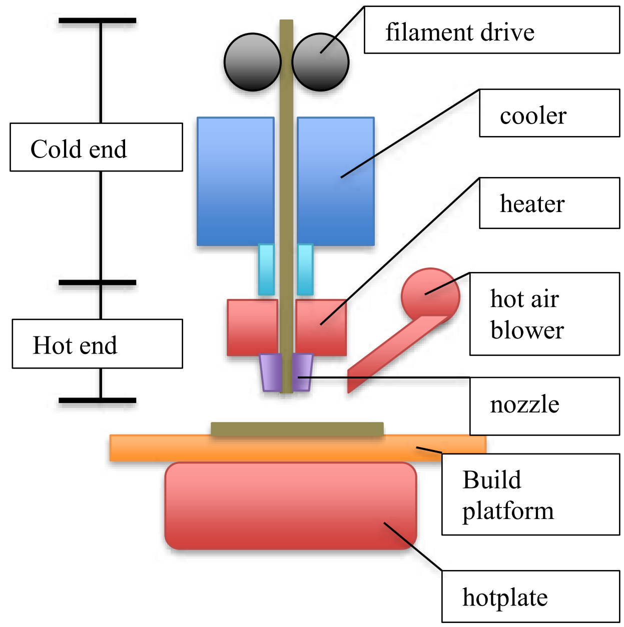


Figure 1: Schematic of the printer divided into cold end, hot end and build plate with attached hotplate.

temperature of 250°C showed constant semicrystalline state. The printer also lacks a heated build chamber which is mandatory for processing PEEK because it creates strong bonds between the layers. Therefore a hot air blower at a temperature of about 320°C was used. The use of the hotplate and hot air blower exhibits good results with constant color (figure 2).

Figure 2: Thin walled test sample printed with Indmatec PEEK Filament (390°C print temperature, 0.5 mm nozzle orifice diameter, 15 mm/s print speed, 320°C hot air, 250°C build plate temperature) showing semicrystalline state without color or transparency change.

Material in form of filament with a diameter of 1.75 mm was produced by *Indmatec GmbH*. It consists of *Victrex 450G*, which has a comparable molecular weight as *PEEK-OPTIMA LT1* from *Invibio* [5].

Results: The printed lines were created at a hot end temperature of 390°C to 400°C which is about the same temperature used in previous investigations [4, 5]. The problem is, that the extrusion temperature cannot be directly compared to other extruders, because the sensor only measures heater block temperature at some point next to the heating element. Material extrusion temperature seems to be slightly lower [11].
A temperature much higher than the melt temperature is needed to reduce viscosity of the material. The viscosity is directly related to driving forces by the material laws which set shear rates and viscosity in proportion to pressure in the hot end [12]. So smaller nozzle orifice diameters result in a higher pressure in the hot end, demanding higher drive forces on the filament. Drive forces are limited by the drive mechanism. So print temperatures reasonably higher than melt temperature (343°C) were used. At temperatures of 410°C thermal degradation in form of small black particles in the extruded lines is observed. For the here shown setup an extrusion temperature of 405°C is the limit. At this temperature the plastic could be extruded through an nozzle orifice diameter of 0.3 mm at a speed of 15 mm/s. With a nozzle of 0.2 mm diameter the drive is blocked. The speed was reduced to 5 mm/s and a second drive was installed, which allowed printing with a 0.2 mm diameter.
The printed lines, shown in figure 3, range from 190-220 µm. The diameters of the lines get wider when they approach the perimeters and are constant in the middle region. Micro bubbles, as seen with other print setups [4], were not observed.
The distance between the printed lines was fixed at 300µm and showed a variation of 270-310µm. This can be explained by limits of the mechanical precision of the kinematics.

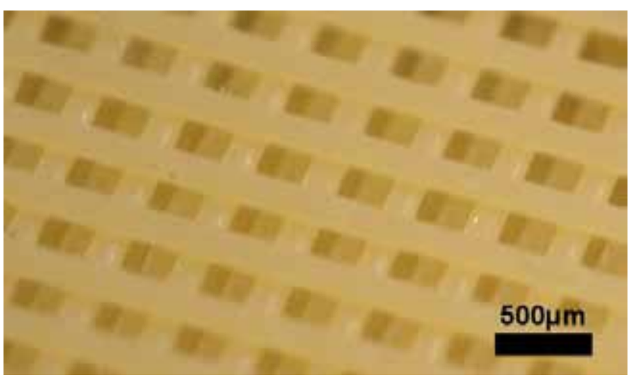


Figure 3: Isometric view on printed PEEK lattice with regular structure. Printing parameters: Nozzle orifice diameter 0.2 mm, print speed 5mm/s, print temperature 400°C.

Discussion: In this work the possibility of printing commercially available PEEK filament on a slightly modified standard printer with nozzle orifice diameters down to 0.2 mm is presented. Although standard PEEK is used, results can be transferred to medical grade PEEK due to the comparable material properties.
Smaller diameters could be achieved by more investigation on filament drive or better understanding of pressure drop in the hot end.

References:

[1] T. Wholers, T. Caffrey, Wholers report, 2013, Wholers Associates Inc. (2013), p. 280

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Tribological Performance of Additive Manufactured Poly Ether Ketone (PEK) Components

Lal, S[1], Berretta, S[2], Ghita, OR[2], Tipper, JL[1].
[1]Institute of Medical & Biological Engineering, University of Leeds, UK;
[2]Centre for Additive Layer Manufacturing (CALM), College of Engineering, Mathematics and Physical Science, University of Exeter, UK
J.L.Tipper@leeds.ac.uk

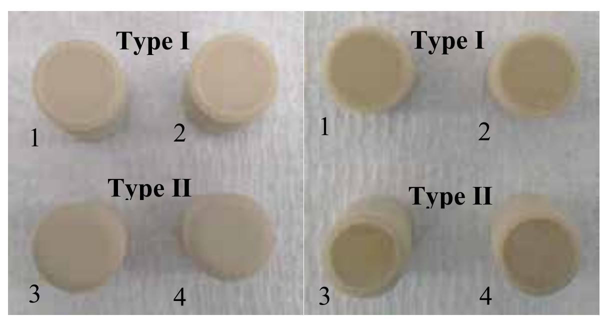
Introduction: There is currently much interest in Additive manufacturing (AM) in the medical sector as a prospective manufacturing method for implants. The design freedom, patient customization for low volumes and high value products are important criteria. Amongst the AM technologies available, laser sintering is one of the most robust methods for fabrication of polymeric parts layer by layer. However, over the years, the technology has mainly focused on the fabrication of porous structures such as scaffolds, as the materials available were limited in range and not strong enough for use in 3D printed implants for load bearing applications. This is no longer the case, and laser sintering of PAEKs is now possible [1, 2], although unexplored in terms of its suitability for load bearing implants including aspects such as surface finish, wear and fixation. AM would allow manufacture of one piece components with complex geometries e.g. femoral total knee replacements (TKR) components, in shorter time frames, with no machining, and in the future the manufacture of components with hydroxyapatite (HA) coatings will remove the need for cement fixation. This may improve the reliability of such implants and allow more flexible responsive manufacturing of devices at potentially similar or lower cost. AM technology also allows multiple component sizes to be manufactured within a single batch, improving lead times for patient specific implants, increasing efficiency, and providing patients with a better service, reducing the risk of cancelled operations and mantaining the reputation of the manufacturer in the market. The aim of this study was to investigate the feasibility of using AM to produce load bearing components for tribological assessment using simple configuration wear simulation.

Methods and Materials:
An EOSINT P800 system was used for manufacture of the PAEK pins. HP3 PEK powder was used for manufacturing of the specimens. The pins were manufactured in two opposite configurations in respect with the z direction. As a result of the build configuration, the specimens exhibited different levels of definition of the contact face edges and they are referred to as Type 1 (with sharp edge) and Type 2 (with smooth edge), see Figure 1.
AM PEK pins were manufactured with a diameter of 12 mm and a flat contact face 10 mm. Prior to testing and at the end of the test, the surface roughness of the AM PEK pins was measured using non-contacting profilometry (Talysurf PGI800, Taylor Hobson). Two traces were measured at 90 degrees to each other. PEK pins were soaked in deionised water for at least 3m prior to testing to stabilize their moisture content. AM PEK pins were assessed gravimetrically and then tested using a six-station simple configuration wear simulator against smooth (Ra 0.01 µm) cobalt chromium plates for a total of 100,000 cycles using 25% (v/v) bovine serum as a lubricant [3]. At the end of the test, pins were cleaned by sonication and assessed gravimetrically in order to calculate wear factors. PEK wear debris was isolated from the simulator lubricants using an acid digestion protocol described in ISO 17853 [4]. Isolated particles were then filtered onto polycarbonate filters and imaged using a cold field emission scanning electron microscope (SU8230, Hitachi). The particle size and shape analysis followed the same method as Lal *et al.* [5].

Results: The initial pin surfaces were rougher than optimal implant surfaces (0.01 µm) (Table 1), However, all pins were tested without further polishing in these initial tests. After the test, the pin surfaces were visibly more polished (Figure 1).

Table 1. Surface roughness of AM PEK pins prior to testing

	Ra (µm) Before	Ra (µm) After
Pin 1 Type I	8.0285	0.0143
Pin 2 Type I	9.4616	0.2533
Pin 3 Type II	9.2070	0.0164
Pin 4 Type II	9.9928	0.0170



BEFORE AFTER

Figure 1. AM PEK pin surfaces before and after testing. There is a noticeable polishing affect after testing.

Wear rates were generally high compared to traditional compression moulded PEEK components (Figure 2). However, where pins had sharp contact face edges (Type I), wear factors were lower and of the same order of magnitude to moulded PEEK Optima pins (tested against CoCr plates) [6].

Wear debris generated during the test was mostly submicron in size with large elongated and small granular wear debris (Table 2 and Figure 3).

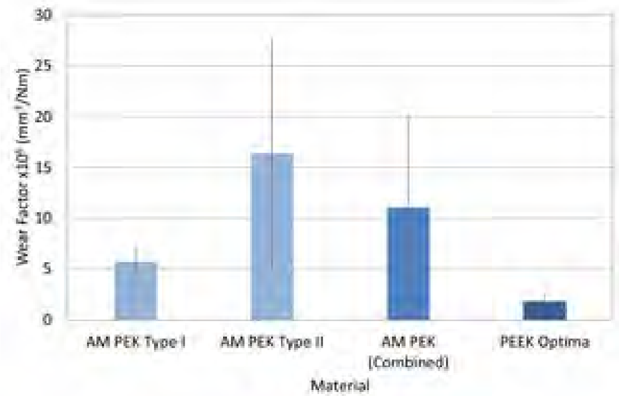


Figure 2. Wear Factors of AM PEK pins against smooth (Ra 0.01 µm) CoCr plates after 100,000 cycles of testing. PEEK Optima compression moulded pins are included for comparison.

Table 2. Size and shape characteristics of PEK wear debris.

PEEK Type	Feret's Dia. (µm)	Aspect Ratio	Roundness
Type I	0.337±0.292	1.92±0.61	0.42±0.13
Type II	0.220±0.197	1.72±0.53	0.48±0.12
Average	**0.268±0.247**	**1.81±0.57**	**0.45±0.13**

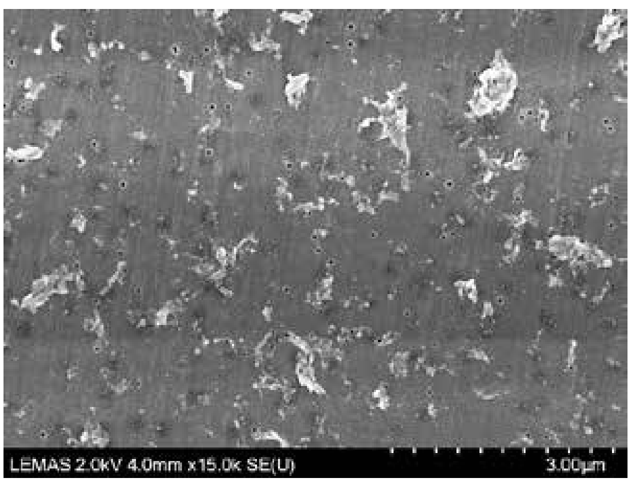


Figure 3. Scanning electron micrograph of the PEK wear debris.

Discussion: Additive manufacturing of PEK components for load bearing applications has been shown to have potential in this study. Whilst wear rates were 3 – 5 fold higher compared to traditional compression moulded components, in the present study no post treatment (e.g. polishing or chemical treatment) was performed on the AM pins. Wear particles generated by AM PEK components were similar in size and morphology to UHMWPE particles generated in previous studies [7]. Current work is investigating wear of polished AM PEK pins against CoCr counterfaces and also wear of UHMWPE pins against AM PEK plates to investigate the potential of using AM in an all polymer TKA system.

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Increasing the Toughness of PEEK-Hydroxyapatite Composites

Bellare, A[1], Jasty, N[1], Spiegelberg S[2]
[1]Brigham & Women's Hospital, Harvard Medical School, Boston, MA; [2]De Novo Materials, Boston, MA
anuj@alum.mit.edu

Introduction: Poly(ether ether ketone) (PEEK) is a high performance polymer used in spinal cages due to its bioinertness, high strength and wear resistance. However, proper fixation of spinal cages to adjacent vertebral bodies makes it desirable for PEEK to be bioactive. While surface modification methods can enhance fixation, they may wear away, making it more desirable for bulk modification using a bioactive compound so that there is a continuous supply of the bioactive compound. Hydroxyapatite (HA) is a common additive for enhanced osseointegration but blending of hard HA particles into PEEK can make it brittle. In this study, we hypothesized that HA nanoparticles would better preserve toughness of PEEK than conventional micrometer size HA powder. We characterized the dispersion of HA using small angle x-ray scattering and measured tensile properties of the PEEK-HA composites

Methods and Materials: PEEK pellets of Ketaspire 880 (Solvay Specialty Polymers) were melt-blended with 3 and 10 volume %, respectively of conventional HA powder (mHA) (Sigma-Aldrich) or 50nm nanoparticles of HA (nHA) (American Elements) using a microcompounder operating at 400˚C. Control, unfilled PEEK and PEEK-HA composites were thereafter injection molded into ISO 527 tensile specimens using a microinjector and subjected to tensile tests using a universal tensile tester operating at a crosshead speed of 10mm/min. Modulus, ultimate tensile stress (UTS), maximum strain and work-of-fracture (WOF) were measured. Sheets of PEEK-HA composites were subjected to small angle x-ray scattering (SAXS) using a SAXSLAB scattering system operating in extreme-SAXS mode. Scattering intensity, I, was measured as a function of scattering vector, $q = (4\pi/\lambda)\sin\theta$, where λ=x-ray wavelength=1.54 Å and θ is one-half the scattering angle. Porod analysis was conducted to measure specific surface area of HA aggregates in the blend. Porod's law is defined by $I=K/q^4$ at large q where $K=2\pi\Delta\rho^2S$, $\Delta\rho$ is the electron density difference between scatterer (HA) and matrix (PEEK) and S is the mean surface area of HA.

Results and Discussion: Tensile tests showed that the modulus of PEEK increased upon addition of HA (see Table 1), with the largest increase observed in PEEK containing 10 volume % HA compared to control PEEK ($p<0.05$, ANOVA). The UTS also increased with tensile modulus, again with 10% nHA showing the highest UTS. There was a remarkable decrease in maximum strain upon addition of mHA at both 3 and 10 volume %, which was largely responsible for a vast decrease in WOF, which is a measure of toughness (see Figure 1). This was also the case for 10 volume % nHA. However, at 3 volume %, nHA showed only a 29% lower WOF than control PEEK whereas 3% mHA had a WOF that was 37-fold lower, 10% mHA was 31-fold lower and 10% nHA was 21-fold lower, probably due to agglomeration at such high loading. SAXS Porod analysis showed a slope in a range of 3.2-3.5, lower than 4.0 for sharp interfaces, indicating rough interfaces of surface fractal dimensions ranging from 2.8-2.5 (see Figure 2). Additionally, the surface area ratio of only 1.4 between nHA and mHA indicates agglomeration of nHA particles, but the agglomeration is not sufficient to decrease WOF substantially at 3 volume % unlike 10 volume %. In summary, this study showed that PEEK-HA nanocomposite containing 50nm HA particles better preserved WOF, a measure of toughness, at 3 volume % (approximately 10 weight %), which was a remarkable 26-fold improvement in WOF over the same loading of conventional HA.

Table 1. Selected tensile Properties of various PEEK-HAs

Sample ID	Vol %	Modulus [GPa]	UTS [MPa]	Max strain [mm/mm]
Control	0	1.37 ± 0.18	90.6 ± 9.4	1.97± 0.30
mHA	3	1.65 ± 0.04	89.7 ± 1.6	0.14± 0.01
nHA		1.55 ± 0.02	85.9 ± 1.4	1.36± 0.31
mHA	10	1.98 ± 0.04	93.6 ± 0.9	0.07± 0.01
nHA		2.50 ± 0.05	122.5±1.1	0.08± 0.01

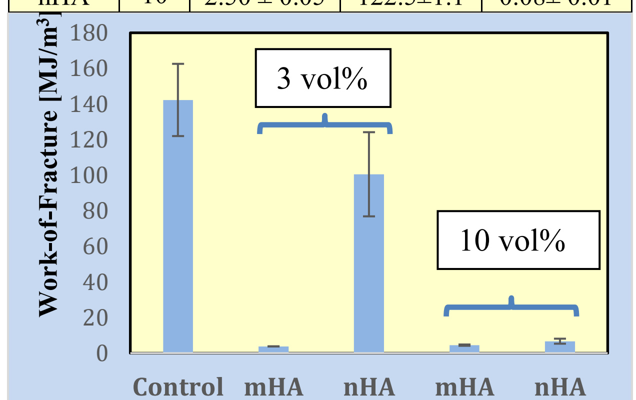

Figure 1. Work-of-fracture of various PEEK-HAs

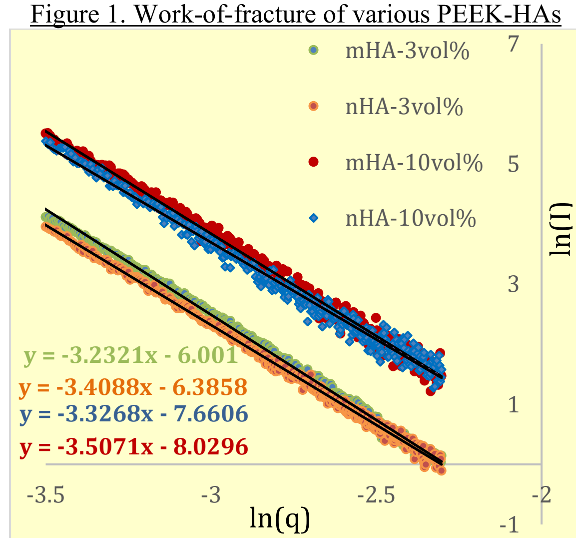

Figure 2. SAXS plot of ln(I) versus ln(q) for PEEK-HA composites and corresponding linear fits (lower left).

Failure of Carbon Fibre PEEK laminated composites

E.A Gallagher[1], **S. Lamorinière[2]**, **J.P. McGarry[1]**

[1]Dept. of Biomedical Engineering, National University of Ireland Galway, Ireland
[2]Invibio Ltd. Biomaterials Solutions, United Kingdom

Introduction

Previous studies have shown that continuous carbon fibre reinforced PEEK (CF/PEEK) laminates can be designed to withstand the loading conditions of the distal radius, while generating levels of interfragmentary micro-motion that induce improved rates of fracture healing compared to rigid metallic implants [1].

In the current study experimental tests are carried out to analyse the mechanical response of CF/PEEK laminates to flexure tests. The experiments are modelled computationally using the extended finite element method (XFEM) to simulate intra-ply failure in the laminate [2-3]. XFEM is computational method for modelling crack initiation and propagation without the requirement of pre-defining the propagation of a crack. The ability to accurately predict the failure mechanisms in CF/PEEK laminates through computational methods is an essential design tool for the development of laminated composite orthopaedic implants.

Methods

To manufacture the experimental test specimens unidirectional tape is assembled into laminates and consolidated in a compression press heated to 375°c under a specific pressure of 0.7MPa. Test specimens are cut to size using an automated laminate saw and finished in accordance with ISO test standards.

Four-point-bend flexure tests are carried out on 0° laminates on an INSTRON 4467. All samples are tested to failure. The laminates are made up of 10 plies and have dimensions specified in ISO 14125. The results are presented as mean values ± standard deviation.

An XFEM damage model is created to simulate the experimental flexure tests and predict the intra-ply crack propagation in the laminate. Damage is initiated through a user defined damage initiation (UDMGINI) subroutine which implements Hashin-type failure criteria.

Results

The load displacement curves for the four-point bend tests carried out on the laminate are displayed in Fig. 1A (dashed black lines). The measured flexure failure load is 0.981±0.037 kN at an applied displacement of 7.61±0.31 mm. An image of the laminate after fracture is shown in Fig. 1B. Cracks are observed on the tensile surface of the specimen under the loading points. Fast crack propagation in the vertical direction results in sudden and catastrophic failure of the specimen. Buckling delamination is also observed on the compressive surface in the region near the loading points.

The computed force-displacement curve is also shown in Fig. 1A. The predicted failure load of 0.911kN at a displacement of 7.38mm is in good agreement with experimental observations. Computed patterns of crack propagation are shown in Fig. 1C. The user defined XFEM damage model provides an accurate prediction of failure location and the vertical crack propagation on the tensile surface of the specimen. Sub-critical levels of compressive damage are computed in the regions where compressive buckling is observed experimentally.

The computed flexural modulus of the C/PEEK laminate with fibre aligned in the 0° is 130.65 GPa, which is in good agreement with the literature [4].

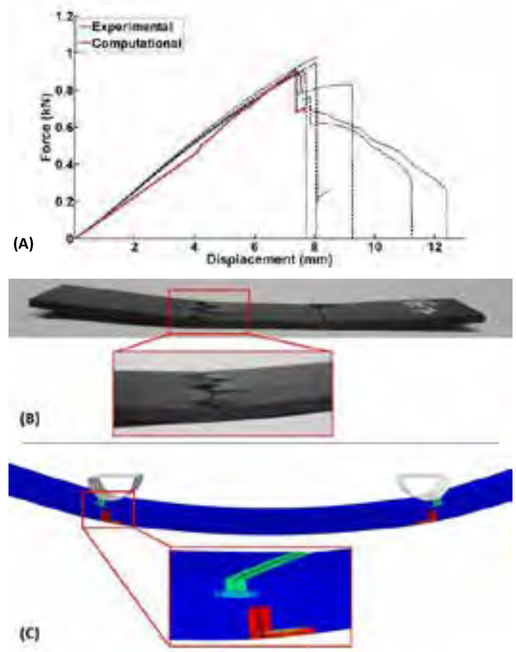

*Fig. 1: **A)** Load displacement curve for four-point flexure tests of the CF/PEEK laminates; **B)** Images of a 0° laminates after fracture; **C)** Crack prediction in the computational simulation of the flexure test (fully cracked elements show in red and undamaged elements are shown in blue)*

Discussion

This study presents the first experimental-computational study of biomedical grade CF/PEEK. The experimentally observed failure strength of the material suggests that this composite material will be suitable for a range of orthopaedic applications [1&5].The computed 0° flexural modulus is of a similar magnitude to medical grade titanium (113GP) [6]. However, as titanium is homogeneous its modulus cannot be altered, while the flexural modulus of a CF/PEEK laminate can be modified to match to the specific loading requirements of the implant. Experiments also uncover the modes of failure of the material. Fibre failure and fast crack propagation occurs in tensile regions, while interlaminar buckling delamination occurs in compressive regions. The computational methodology proposed in the current study provides accurate prediction of the failure load, in addition to correct prediction of crack propagation patterns. However, in order to compute buckling delamination a mixed-mode cohesive zone formulation will be implemented in future studies. Development of a computation framework for material damage based on extensive experimental characterisation is critical for the design of composite orthopaedic implants given the complex multi-axial loading conditions experienced in-vivo.

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Is locking screw fixation in carbon fiber composite plates mechanically equivalent to stainless steel plates?

David J. Hak, MD, MBA, FACS[1]
[1]University of Colorado / Denver Health Medical Center
david.hak@dhha.org

Introduction: Carbon-fiber-reinforced polyetherether-ketone (CFR-PEEK) is a composite biomaterial that is gaining popularity for certain orthopedic implant indications due to its high fatigue strength, favorable modulus of elasticity, and radiolucency. The purpose of this study was to compare the mechanical stability of locking screws used in CFR-PEEK plates with those used in stainless steel (SS) plates.

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Methods and Materials: CFR-PEEK proximal humerus locking plates (CarboFix Orthopedics, Inc., Collierville, TN) and stainless steel proximal humerus locking plates (Synthes, Paoli, PA) were studied. Screws were inserted and tightened to a maximum torque of 1.5 Nm per manufacturer recommendations. Screws inserted into the proximal and diaphyseal portion of the plates were analyzed independently. Stiffness and load to failure (defined as collapse of the screw/plate interface, screw pull-out, or 2 mm of screw displacement) were tested for three experimental conditions: (1) CFR-PEEK vs. stainless steel plate with on-axis trajectory of locking screw insertion, (2) CFR-PEEK plate in which the screw was inserted, removed and re-inserted in an on-axis trajectory, and (3) CFR-PEEK plate with screw insertion at 10-degrees off axis trajectory performed using a custom jig. Specimens were affixed to an Instron servo-hydraulic test machine and a perpendicular force was applied to the screws at a rate of 1 mm/min using a 6.35 mm diameter steel rod. T-test was used to compare mean differences in stiffness and load to failure between groups with statistical significance for all comparisons set at $p < 0.05$.

Results: Load to failure of diaphyseal locking screws was significantly greater in CFR-PEEK locking plates compared to stainless steel locking plates (746.4 ± 89.7 N vs 596.5 ± 32.6 N, respectively; $p < 0.001$), despite comparable stiffness of the two implants. In contrast, there were no significant differences in stiffness or load to failure of the proximal screws. Among CFR-PEEK locking plates, stiffness of distal locking screws in the diaphyseal holes was significantly greater when inserted on-axis (361 ± 63.6 N/mm) compared to 10-degrees off-axis (150.5 ± 36.2 N/mm), as was load to failure (746.4 ± 89.7 N vs 324 ± 60.5 N; $p < 0.001$). Stiffness and load to failure did not vary significantly according to number of screw re-insertions (Tables 1 & 2).

Table 1. Mean Load to Failure (N) of CFR-PEEK vs. Stainless Steel Locking Plates

Plate Type	Proximal Holes	Proximal Holes, 2 insertions	Diaphyseal holes	Diaphyseal holes, 10 ° off axis
CFR-PEEK	421.4 (98.8)	394.0 (150.2)	746.4 (89.7) *	324.0 (60.5) *
Stainless Steel	347.6 (59.1)		596.5 (32.6) *	

* Statistically significant, $p \leq 0.05$
All variables are represented as mean (SD)

Table 2. Mean Implant Stiffness (N/mm) of CFR-PEEK vs. Stainless Steel Locking Plates

Plate Type	Proximal Holes	Proximal Holes, 2 insertions	Diaphyseal holes	Diaphyseal holes, 10 ° off axis
CFR-PEEK	198.2 (50.8)	161.2 (75.8)	361.0 (63.6)	150.5 (36.2) *
Stainless Steel	239.5 (45.6)		436.6 (152.7)	

* Statistically significant, $p \leq 0.05$
All variables are represented as mean (SD)

Discussion: Compared to traditional stainless steel locking proximal humerus plates, the locking screws in CFR-PEEK locking plates tolerate a significantly greater load to failure. Mechanical stability of the CFR-PEEK implant does not appear to be significantly compromised by reinserting the screw a second time. However, off axis screw insertion significantly decreased the mechanical stability of the locking screw in the diaphyseal holes of the CFR-PEEK plates.

Conclusion: CFR-PEEK locking plates provide comparable or superior locking screw fixation strength compared to traditional stainless steel locking plates.

FATIGUE BEHAVIOR OF HYDROXYAPATITE COATED POLYETHER-ETHER-KETONE DERIVED FROM DYNAMIC MECHANICAL ANALYSIS

Thiago Patrício de Oliveira*, José Alexandrino de Sousa
Materials Engineering Department, Universidade Federal de Sao Carlos, Sao Carlos, Brazil
patricio@osteomedimplantes.com

Introduction: Novel developments of biomaterials for surgical implants indicate PEEK thermoplastic as one of the most suitable for orthopedic and spinal applications, due to its elastic modulus compatibility with that of the human bone, excellent mechanical fatigue properties and biocompatibility. As PEEK osteointegration in these applications is slow, gas plasma spray surface coating technique can be used to enhance its bioactivity using hydroxyapatite (HA) powder. However, as the high temperatures related to the plasma process may impair significantly PEEK's mechanical performance, this study aims to investigate the influence of the plasma spray process on the mechanical fatigue behavior of HA-coated PEEK injection moldings. Considering that the plasma process should influence mainly the PEEK molding surface properties, flexural test specimens with three distinct conditions: (i) PEEK "as molded", (ii) PEEK exposed to the plasma thermal process only and (iii) HA plasma coated PEEK were submitted to deformation-controlled three-point bending fatigue tests. The related stress decay rate of PEEK monitored up to 10^6 cycles was correlated to the storage modulus and mechanical damping (tan delta) properties of PEEK, determined through dynamic mechanical thermal analysis (DMTA), prior and after cycling. Thus, these correlations are used to elucidate the influence of the plasma spray process on the fatigue behavior of PEEK under the above mentioned conditions.

Materials and Methods: The PEEK used in this work was an injection molding medical grade OPTIMA LT1, supplied by Invibio. Medical grade HA was supplied by JHS Biomaterials, with particle size of 200 mesh. Flexural test specimens (ASTM D790) were injection molded on an ENGEL e-MAX 80/50 electric molding machine using the supplier recommended molding parameters. As specified in the introduction, some of the test specimens were subjected to HA surface coating applied on one side of the specimen with a Sulzer-Metco 9MB Ar/H_2 gas plasma gun using state-of-art process parameters (condition III), whilst other specimens were submitted to the same plasma thermal exposure process without the HA coating (condition II). Short-term 3-point bending tests were carried out on coated and uncoated specimens to determine the flexural strength (at 5% tensile deformation) and a specific deformation value (85% of 0.2% yield curve) to be used as a parameter for the flexural fatigue testing. For both these tests, the coated surfaces of test specimens were positioned in a way to submit these faces to a tensile stress. Differential scanning calorimetry (DSC) was used to determine the crystallinity content of the plasma spray thermally exposed PEEK surface samples to evaluate the influence of the plasma treatment under the above mentioned three conditions. The deformation-controlled flexural fatigue tests were carried in a one way three-point bending testing device on a MTS Bionix machine, using a 5 Hz sinusoidal waveform and periodically monitoring the maximum stress up to 10^6 cycles to obtain the stress relaxation curve for each of the three conditions. A high average deformation value (3.4%, ie. 85% of 0.2% yield deformation determined from static flexural test for the ""as molded"" test specimens) was used and ondulated between 80% and 90% of this static yield deformation value (±5%). Pristine and fatigued (up to 10^6 cycles) flexural test specimens were submitted to dynamic-mechanical thermal analysis (DMTA - model DMTA 800 from TA Instruments) and using identical one way three-point bending geometry at 1 Hz frequency and scanned in a temperature interval from room temperature up to 250 ºC. Other characterization techniques, such as X-Ray diffraction (XRD) and Scanning Electronic Microscopy (SEM) were used to assess the quality of the HA coating obtained. SEM was also used to analyze the PEEK bulk microstructure before and after fatigue testing.

Results and discussion: XRD patterns and SEM micrographs (data not shown here) indicated that the quality of the HA coating deposited on PEEK specimens were similar as presented in literature [Ref. 1, 2] and, therefore, considered adequate. DSC analysis on surface extracted PEEK samples indicated a slight increase in the crystallinity content (aprox. 2.5 %, as presented in Table 1) of samples exposed to the plasma thermal process (conditions ii and iii, w.r.t. ""as molded"" samples). Apparently, this crystallinity increase contributes directly to an increase in the short term flexural strength values of the same test samples, as shown in Table 1. The higher value for the HA-coated sample (condition iii) is most likely due to the physical presence of the high elastic modulus HA particles embedded on the coated surface. The deformation-controlled flexural fatigue test results allowed the determination of PEEK's stress relaxation rate, monitored continuously at the maximum stress point in the range of 10^3 to 10^6 cycles. Thus, the slope of these stress relaxation curves can be used as a parameter of the fatigue stress resistance of the PEEK specimens under the above specified three plasma thermal exposure conditions. From the data presented in Table 1, the percentage fatigue stress decay rate occurred in the following order: PEEK "as molded" (10.4%), PEEK HA-coated (7.2%) and PEEK-plasma treated (5.9%). Considering that all of the fatigued specimens indicated no visual surface defects after tested up to 10^6 cycles, it appears that the plasma thermal exposure contributed towards a slight improvement in the fatigue resistance of PEEK.

Table 1 – Crystallinity content, flexural monotonic short-term and fatigue and DMTA tests properties of PEEK samples under three thermal conditions.

PEEK Sample Conditions	Crystallinity Content (%)	Flexural Strength (MPa)	Fatigue Stress Decay rate (10^3-10^6 cycles) (%)	Storage Modulus E′ (GPa) at 50ºC	Tan Delta Intensity at Tg Peak
"as molded"*[1] (cond. i)	28.1 ± 0.2	140.0 ±4.9	-	3.14	0.194
Plasma-Treated*[1] (cond. ii)	31.4 ± 0.3	148,2±2.4	-	3.36	0.223
HA coated*[1] (cond. iii)	30.4 ± 0.1	151.3±0.7	-	3.37	0.183
"as molded"*[2] (cond. i)	-	-	10.4	2.77	0.185
Plasma-treated*[2] (cond. ii)	-	-	5.9	3.03	0.207
HA coated*[2] (cond. iii)	-	-	7.2	2.95	0.205

*Test specimens tested before and after fatigued up to 10^6 cycles

This reduced fatigue stress decay rate can be attributed to the verified increase in the crystallinity content and probably also due to the "frozen-in" stresses relaxation of the PEEK specimen molding's surface when exposed to the plasma thermal process.

The dynamic storage modulus (E′) data of the specified three conditions of pristine PEEK specimens, determined from DMTA analysis at 50 ºC, presented values compatible with the elastic modulus values obtained from static flexural test at room temperature (data not shown here). After fatigued up to 10^6 cycles, these same three distinct PEEK specimens presented reduced E′ values, with the "as molded" PEEK specimen presenting the lowest value. However, distinct behavior was observed for the damping tan δ values at the glass transition (Tg) peak temperatures. The pristine PEEK "as molded" and HA-coated specimens presented much smaller tan δ values, respectively, 0.194 and 0.183 in comparison to the plasma exposed PEEK specimen (0.223). Considering that the intensity of tan δ at Tg peak is inversely proportional to the degree of crystallinity of the polymer, the increase in tan δ value of the plasma exposed PEEK specimen, despite its higher crystallinity level w.r.t. "as molded" PEEK, is probably due to the "frozen-in" stresses relaxation of the PEEK specimen molding's surface, arising from the plasma thermal exposure. This relaxation effect was previously reported M. Berer et al from real time dynamic tan δ measurements during high tensile stress fatigue cycling for "as received" and annealed PEEK moldings [Ref. 3]. However, this "frozen-in" stresses relaxation process appears to be masked by the stiffening effect of high modulus particles embedded on the surface of the HA-coated PEEK specimen.

Post-fatigued "as molded" and plasma exposed PEEK specimens presented a decrease in its damping tan δ values, w.r.t. pristine specimens (respectively, 0.185 and 0.207), due to the "strain hardening" effect of PEEK polymer chains in the polymer's amorphous phase induced by the mechanical cycling history, as previously reported by M. Berer et al [Ref. 3]. This "strain hardening" effect was corroborated by the SEM micrographs (data not shown here) of "freeze fractured" fatigued PEEK specimens due to the fibrillar nature verified for all three conditions. However, the increase in the tan δ value for the HA-coated PEEK specimen (0.205) after the fatigue cycling suggests a possible debonding of the HA coating.

Conclusions: The assessment of the deformation controlled flexural fatigue behavior up to one million cycles of injection molded PEEK coated with HA indicated that the plasma spray process had a minor influence on the fatigue stress decay rate. Apparently, there is a slight reduction in the stress relaxation rate for the plasma exposed specimens. This reduction may be attributed to the slight increase in the crystallinity content and the "frozen-in" stresses relaxation of the PEEK specimen molding's surface, due to the plasma thermal exposure. Dynamic storage modulus (E′) and mechanical damping (tan δ) values determined from DMTA were useful to correlate the fatigue behavior of PEEK for all three thermal conditions assessed. Finally, the tan δ values of HA-coated PEEK specimen indicates a possible debonding effect of the coating after fatigued up to one million cycles.

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Conductive Coated Polyether Ether Ketone (PEEK) Filament for Functional Applications in Thermoplastic Composites

Foisal, A. B. M.
Southeast University, Dhaka, Bangladesh
foisal_text@yahoo.com

Introduction: Electrically conductive fibers, yarns and textile structures are highly desirable as industrial materials for applications such as filters, electrostatic discharge, electromagnetic interference shielding, dust and germ-free clothing and data transfer in clothing. Apart from such new application areas for functional textiles, the demand of additional function integration in textile reinforced composites is also increasing. Though textile-reinforced composites are preferentially manufactured based on a thermoset matrix, thermoplastic matrix-based composites are being developed due to some distinctive advantages over thermoset composites, such as lower density, unlimited storage, recyclability, improved shock/impact behaviour and a better environmental impact. However, due to the requirements of high temperature and high pressure during consolidation (for example, temperature required to manufacture a thermoplastic composite of glass fiber/poly propylene (GF/PP) is 220°C), the integration of functional components into the thermoplastic composites is challenging compared to thermoset composites.

The aim of this work is to develop electric conductivity on inert Polyether ether ketone (PEEK) filament surface by applying silver metallic layers by wet chemical procedure. To ensure good adhesion properties of the silver layer, the PEEK monofilament surface is treated with an atmospheric pressure plasma process and a subsequent coating of a polyamine based adhesion promoter. The wettability of plasma treated PEEK is investigated by means of contact angle and surface free energy measurement. Surface roughness and silver particles on the coated PEEK are observed using scanning electron microscopy (SEM). Measurements of electrical resistance and electromechanical properties of silver coated PEEK mono filaments with various amounts of silver coating are performed before and after their integration into the textile reinforced thermoplastic composite.

In this work, conductive silver coating of PEEK filament yarn is reported. PEEK is a high performance thermoplastic polymer possessing a service temperature from -250°C to +300°C, tensile strength of 90 to 120 MPa and elongation at break of 16% to 80% and is therefore gaining significant interest in aerospace and automotive industries. Taking the advantage of its high temperature resistance and good elongation properties, the silver coated PEEK filament yarn can be used apart from thermoset composites especially in textile reinforced thermoplastic composites as a functional component. The possible uses of such silver coated PEEK include sensory applications like an interphase strain sensor, heat generation and electrical signal transfer.

Methods and Materials: The plasma treatment is carried out using atmospheric pressure plasma system “Corona pretreatment system-AS Coating star (ASCS)”, Ahlbrandt, Germany. PEEK mono-filament is modified by varying the plasma discharge power. The characterization of the modified PEEK filament is done by contact angle measurement and SEM image analysis. The plasma modified PEEK filament is coated by cationic silver using aliphatic amines. After the chemical reduction, the cationic silver turns into metallic silver particles on the surface of PEEK filament. The amount of silver layer on the PEEK filament is varied by using different percentage of silver in the coating solution. The coated PEEK filaments are characterized by electrical resistance measurement and SEM image analysis. The silver coated PEEK filaments are then integrated into textile reinforced GF/PP thermoplastic composite, to investigate the effect of consolidation on their electrical resistance.

Results: The results of contact angle measurement and surface free energy of surface modified PEEK filament show that due to plasma treatment, polar parts can be increased significantly, which is most important for the wettability of PEEK in wet chemical method of silvering. From the SEM images, the difference between original PEEK and plasma treated PEEK can be clearly observed. The electrical resistance of silver coated PEEK filament shows that with the increased amount of silver on the PEEK surface, electrical resistance decreases. A pronounced linear dependence of resistance on the yarn length can be also observed. SEM analysis of coated PEEK shows that the size distribution of the silver particles is quite homogeneous with 80 % between 100 and 200 nm. These particles are uniformly distributed on the PEEK surface. Furthermore, the PEEK monofilament with an high amount of coated silver on the surface (4.39%) shows that it can withstand the consolidation temperature and pressure required to produce the GF/PP composite. Figure shows the silver coated PEEK monofilament.

Figure: silver coated monofilament

Discussion: The ultimate target of this work is to create an electrically conductive coating of silver particles on the surface of PEEK filaments having a good chemical and mechanical stability. Considering above results, this target has been achieved by a tailored plasma treatment modification of the PEEK filaments, which can be integrated into GF/PP thermoplastic composites for different functional applications.

High-efficiency grafting of biocompatible polymer on PEEK by photoinduced and self-initiated graft polymerization in the presence of inorganic salts

Ishihara, K[1], Shiojima, T[1], Inoue, Y[1], and Kyomoto M[1,2]
[1]The University of Tokyo, Tokyo, Japan, and [2]KYOCERA Medical Co, Osaka, Japan
ishihara@mpc.t.u-tokyo.ac.jp

Introduction: In order to obtain excellent resistance to infection of PEEK implants, we used 2-methacryloyloxyethyl phosphorylcholine (MPC), which bearing a phospholipid polar group in the side chain, as the monomer for photoinduced and self-initiated graft polymerization from the surface of the PEEK [1]. The surface requires a poly(MPC) (PMPC) layer of approximately 100-nm-thick for sufficient functionality. In this study, as this photoinduced and self-initiated graft polymerization is one of the free-radical polymerization processes, we hypothesize that the rate of graft polymer formation is dependent on the two important parameters, i.e., monomer concentration and initiator concentration. The concentration of the initiator may be limited by UV light intensity. Also, when the monomer concentration increased, spontaneously polymerization is occurred in the solution and sometime the gelation is observed. Therefore, we should consider alternative methodologies to increase the monomer concentration in the feed solution. Thus, we examined the effects of inorganic salt additives on the surface characteristics of the PMPC-grafted PEEK. Inorganic salts dissolve in an aqueous medium with ionic hydration. The formation of a hydration layer surrounding the ions prevents the dissolution of any chemical compounds; the addition of inorganic salts into the medium may reduce the active amounts of solvent. That is, the concentration of monomer may increase even the total volume of the solvent in the feed solution is the same. To investigate this hypothesis, we evaluated (1) the effect of inorganic salt additives in the polymerization solution on the structure and characteristics of PMPC-grafted PEEK, and (2) the effects of NaCl concentration on the photoinduced grafting of MPC on PEEK [2].

Methods and Materials: The PEEK specimens were prepared by cutting of original sheet. MPC and inorganic salts such as NaCl, LiCl, KCl, and NaBr in a particular molar ratio were dissolved into degassed purified water in glass tubing to obtain the MPC aqueous solutions with various inorganic salt additives. A mixture of 0.50 mol/L MPC and 2.5 mol/L inorganic salt was used as the feed solution. Furthermore, mixtures of 0.50 mol/L MPC and 0.0–4.0 mol/L NaCl were used. Ar gas was bubbled into the MPC/saline solution for 10 min to remove dissolved oxygen. Then the PEEK specimen was immersed into the MPC aqueous solution after which, Ar gas was re-bubbled through for further 10 min. Following this, the glass tubing was sealed. The glass tubing was placed in a water bath at 60°C and photoirradiation was carried out by using an ultra-high pressure mercury lamp (wavelength: 350 ± 50 nm) with an UV light intensity of 20 mW/cm^2 for 5–90 min. After photoirradiation, the glass tubing was opened and the PEEK specimen was removed from the reaction solution, rinsed with pure water and ethanol to remove unreacted monomer and non-grafted polymer, and then dried in in N_2 gas.

Results and Discussions: We considered that enhancement of the polymerization efficiency would shorten the polymerization time, and make the process more suitable for industrial-scale synthesis. We paid attention to the effects of inorganic salt, such as NaCl, on the polymerization rate and efficiency. The PMPC-grafted PEEK specimen obtained with a 90-min photoirradiation without NaCl additives in feed solution had an 80 nm-thick PMPC grafted layer. However, when photoirradiation at a power density of 20 mW/cm^2 was performed to induce polymerization, we obtained a PMPC layer with a thickness of only 100 nm, similar to the PMPC layer obtained by photoirradiation with a power density of 5 mW/cm^2 in the previous study. On the other hand, the thickness of the PMPC layer increased with increasing NaCl concentration. When the NaCl concentrations were greater than 2.5 mol/L, the PMPC layer was thicker than 120 nm, and increased to 180 nm with 4.0 mol/L NaCl. The rate of polymerization without NaCl is 1.25 mol/L·s, but increases to 5.00 mol/L·s with 2.5 mol/L NaCl in the feed. This significant phenomenon could be explained by a specific interaction between the ions and the MPC units. However, NaCl has no effect on the conformation of the polymer chains. Although it cannot make clear discussion in the present time, we are considering that the hydration effects of Na^+ and Cl^- ions in the feed solution. The ionic hydration is very stable and many water molecules affect in this order in the solution. Therefore, the addition of an inorganic salt in the MPC solution appears to decrease the amount of water that dissolves MPC and therefore increases the apparent MPC concentration. For conventional radical polymerization, the polymerization rate and molecular weight of the polymer are proportional to the monomer concentration.

In the present study, the concentration of MPC in the feed solution is one of the parameters that determine the polymerization rate. Addition of NaCl into the feed solution increases the thickness of the PMPC graft layer on the PEEK surface. The PMPC-grafted PEEK shows excellent biomedical characteristics, that is, reduced bioresponse and high lubrication in living circumstances.

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CRYOGENIC MACHINING OF PEEK IN COMMERCIAL CNC APPLICATIONS

Reference: Knopf, Jeffery A and Ghosh Ranajit, Air Products and Chemicals, Inc.: Cryogenic Machining of PEEK – an overview of the ICEFLY® cryogen delivery system and its application to the machining of PEEK

Keywords: Cryogenic machining, PEEK, ICEFLY® cryogenic delivery system, VMC – Vertical Machining Center, Swiss-Style Lathe, LIN, liquid nitrogen, GAN, gaseous nitrogen, programmable nozzle, polymer machining, medical polymers

Abstract:

The machining of PEEK, either turning or milling, presents challenges in a production CNC (Computerized Numerical Control) machine. It has been demonstrated in an R&D environment (lab conditions) that keeping the actual machining temperature of PEEK within the Cold Flow section of the Tg will result in minimizing burr formation. Reproducing this inside a production CNC machine has presented many challenges. The primary challenge has been to position the delivery nozzle tip to within 100mm – 125mm (4-5 inches) from the PEEK/Cutting Tool interface.

In a multi-axis CNC milling machine the LIN/GAN cooling stream needs to be focused on the cutting edge of the tool and the PEEK simultaneously. This serves two functions. One is to keep the cutting tools cool which keeps the tool sharper for a longer time and might allow for increasing the speed, feed and depth of cut. Second, the area of the PEEK being machined is spot chilled to increase its stiffness allowing it to be cut more freely resulting in less burr formation. In most cases the actual machining process needs to incorporate cutting tools of various lengths and the need for a direct positioning nozzle design becomes necessary. We have designed a cryogenic programmable LIN/GAN delivery nozzle. The cryogenic programmable nozzle allows the CNC machine to position the temperature controlled LIN/GAN stream precisely at the tool/PEEK cutting interface to maximize the cooling efficiency of the ICEFLY ® delivery system. The positioning of the LIN/GAN stream is easily “taught” to the programmable nozzle by the operator by first positioning it manually to the exact spot and then pressing the enter button to record the length for correct tool number. This is repeated for all the tools

Turning and machining in a CNC Swiss-style lathe has presented a different set of challenges to focus the LIN/GAN stream of cooling directly on the PEEK material. Due to the compact design and method of operation on a Swiss-style lathe the PEEK material will remain in a determined location directly in front of the sliding bushing. Since most parts are within the 25mm diameter by 25mm length we can focus the LIN/GAN stream in this spot and set our fixed nozzle distance to 100mm – 125mm from the material. In this case we will focus the cooling primarily on the PEEK and not the tool. In the turning of PEEK parts the part tends to heat up disproportionally to the tool

so we need to focus on cooling the part rather than the tool. When the PEEK part is actually being turned or machined the cutting tool will benefit from the LIN/GAN spray as it will enter the focal zone. Since CNC Swiss-style lathes can have as many as 48 tools on fixed sliding tool-posts as well as "live" drilling and milling spindles it is impossible to rout the LIN/GAN lines to each individual tool. Many of the medical PEEK parts have small intricate features and dimensions that necessitate the use of very small cutting tools. Some of these tools can be end mills in the .012" (.3mm) diameter and drills in the .008" (.2mm) diameter and need to run at 40,000-60,000 rpm to reach effective feeds, speeds, and chip load. At these higher feeds and speeds heat is generated, burrs are formed and tools will become prematurely dull. Many times unless the part and tool are kept cold these tools will need to be run much slower and the part will have a longer cycle time. Running cold [-75°C to -125°C (-103°F to -193°F)] cannot be achieved with shop air and can only be achieved with ICEFLY® cryogen delivery technology. Keeping the part at these cold temperatures will allow optimum machining conditions to exist.

In either the vertical machining center or Swiss-lathe scenario the medical PEEK part needs to be kept at a temperature range of -75°C to -125°C. The thermal properties of PEEK make it ideal as a medical implant polymer. These properties also make it thermally stable to a range of cold temperatures without contracting or changing its dimensional size. When machining a part heat will cause parts to expand thus necessitating the need for offsets to be made to the cutting tools to hold an accurate size on the machined piece. Since we are cooling the part the need for continual offset adjustments are minimized. The temperature of our LIN/GAN stream is controlled by our proprietary nozzle design. The LIN and GAN are obtained from a 240L High Pressure Dewer. The LIN then flows through a special Helitran® vacuum jacketed line to the ICEFLY® low flow nitrogen distribution system. Then another Helitran® vacuum jacketed line is used to bring the purified liquid nitrogen to a control box (manually or M-code operated on/off) and then to an operator manually controlled needle valve. The GAN line also goes to the control box and then to an additional operator manually controlled needle valve. The adjusted LIN and GAN flow controlled lines are then hard piped towards the final nozzle location. By controlling the proportions of LIN to GAN we control the temperature at the desired focal point. We can make it warmer for polymers with a higher Tg and colder for a polymer with a lower Tg. Thus we can dial in the best temperature for maximizing the cutting conditions for individual polymers.

In this presentation we will discuss actual installations on CNC Swiss machines and Vertical Machining Centers. We will discuss the actual machining of parts with and without the use of nitrogen as a cooling substance for PEEK machining.

A Polymeric Total Knee Replacement: Pre-Clinical Review and Clinical Preview

Briscoe, A[1] and Shah, A[2]
[1]Invibio Ltd., Thornton-Cleveleys, UK
abriscoe@invibio.com
[2]Englewood Hospital and Medical Center, Englewood, NJ

Introduction: The design characteristics of modern total knee arthroplasty (TKA) started with the introduction of the total condylar knee in the early 1970's using a metallic femoral component mated to polymer tibial component. The success of modern TKA's, have led to design changes on the femoral, tibial, and patellar components as well as the bearing surfaces. All modifications were aimed at improving the longevity and functional outcome of the implant. Until recently, few investigations have reported on changing the base biomaterial of the femoral component. We introduce here the pre-clinical trial review of a metal free TKA using a polymeric femoral component. The idea of a polymeric TKR is not novel, having been proposed and trialled approximately 30 years ago in the UK [1, 2]. While the trial was halted due to some manufacturing issues, it was a clear demonstration that the concept has merit and can provide a robust TKR solution.

Figure 1 - Maxx Freedom CoCr and PEEK-OPTIMA™ femoral components.

For the past 4 years Invibio Knees Ltd. and Maxx Orthopaedics have been developing a range of femoral component to complement the existing Freedom® Total Knee Replacement System. This component is to be manufactured from PEEK-OPTIMA™ and is based on the existing design of CoCr femoral component so as to be entirely compatible within the system.
The programme is now at a stage of readying for introduction to clinical usage. This will be through a controlled clinical study to establish the safety of the device before regulatory approval can be sought in appropriate geographies.
This paper gives a summary of the pre-clinical testing, some of the challenges and how these have been overcome and an overview of the design of the clinical trial.

Pre-Clinical Testing:
Wear: The tribological testing of the new PEEK-OPTIMA™ on Ultra High Molecular Weight Polyethylene (UHMWPE) has been carried out at the University of Leeds, UK [3].
From initial Pin on Plate (PoP) screening tests through to full knee simulation, results have demonstrated no statistically significant difference in wear of the tibial component produced by a PEEK component when compared with wear produced by a CoCr device. At all stages the measured wear rates were lower than other devices tested under the same conditions [4]. Additionally, analysis of the particulate produced showed no increase in the quantity of biologically impactful polyethylene particles produced.

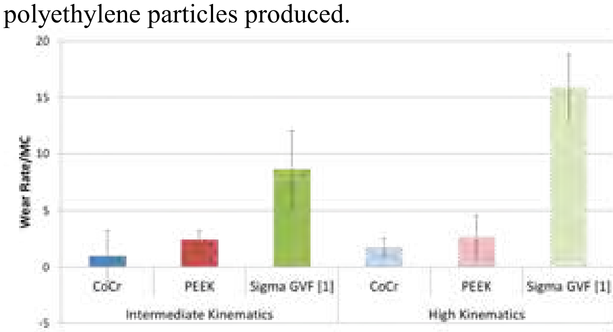

Figure 2 - Comparison of wear rates under intermediate or high kinematics. Incumbent device compared with PEEK femoral component and literature data point of Sigma GVF.

Fixation: An early challenge was fixating the PEEK-OPTIMA™ device to the bone. A surface which could be moulded on the PEEK component and would produce sufficient mechanical interlock with the cement mantle to was needed to adequately fix the device to the distal femur.
Testing conducted at the University of Southampton, UK and Radboud University Medical Centre, Netherlands showed that a combination of a micro texture and much larger ribs would provide the required fixation strength [5].
Cam Strength: The post CAM mechanism posed a potential weak point for fracture of the PEAK OPTIMA Cam when subjected to mechanical loading during gait. A specific area of concern was the bars that connect the posterior stabilizing cam on this variant of the device. This area of the component is not supported by underlying bone and is of only a few millimetres in diameter.
Testing consisted of an anterior draw test, pushing the cam against the tibial post until failure occurs. Results
conclusion, PEEK might be the new resource required for future denture material.

Imaging: Many of the medical applications substituting PEEK for metallic devices have benefitted from enhanced imaging capabilities due to the radiolucency of the material. The femoral TKR component is no different and cadaveric imaging tests have shown that MRI and CT images are capable of viewing all of the anatomical architecture without artefacts produced by the metallic scattering of x-rays or interruption of the magnetic field in MR.

Risk Analysis: Through a risk based approach these and many other areas of the design of this new component have been assessed and any risks have been reduced as far as is possible. It is now considered that the potential benefits of the clinical use of this device outweighs the residual risks. It is therefore to be submitted for clinical trial.

Benefits: It is anticipated that the use of PEEK-OPTIMA™ as a femoral component material will lead to a number of benefits in clinical use, though many of these cannot be established in pre-clinical testing. The elastic modulus, density and thermal characteristics of PEEK are very similar to the material being replaced. As such, the weight and feel of the replaced joint is expected to more closely replicate the natural joint. Additionally, the stiffness match is expected to reduce the propensity for stress shielding related osteopenia.

Clinical Evaluation:

A device of this nature and novelty requires evaluation before general market release can be considered. To this end a prospective, international, multi-centre controlled safety study has been designed and is entering the submission phase for consideration by the regulators.

The trial is designed to evaluate the clinical and radiological outcomes and the reliability of the freedom total knee system with a new PEEK OPTIMA femoral component. Cemented total knee arthroplasty will be performed on approximately 126 patients (110-126 knees) at several hospital sites across 3-5 countries. Clinical and radiological evaluations will be performed preoperatively and postoperatively at 2, 6, 12, and 24 month follow-ups, using the KSS, WOMAC, SF-36 scores and standardized xrays and MRI evaluation at 2 and 12 months.

Conclusion

In summary, this is the first modern day clinical trial proposed to understand the tribiology of a completely metal free TKA. We believe the risks have been mitigated and the advantages are significant enough to warrant implantation in human subjects. Considerable investigative precautions and regulations are being engineered into the trial to ensure safety of the subjects. We anticipate a successful trial and look forward to submitting early outcome data.

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Pre-clinical biomechanical evaluation of fixation of a cemented PEEK Femoral Component in TKA

Janssen, D[1], de Ruiter, L[1], Rankin[2], K, Briscoe, A[3], Verdonschot, N[1,4]
[1]Orthopaedic Research Lab, Radboud University Medical Centre, Nijmegen, The Netherlands; [2]Bioengineering Science Research Group, University of Southampton, Southampton, UK [3]Invibio Ltd, Lancashire, UK; [4]Institute of Biomedical Technology, University of Twente, Enschede, The Netherlands
Dennis.Janssen@radboudumc.nl

Introduction: Polyetheretherketone (PEEK) has been proposed as an implant material for femoral total knee arthroplasty (TKA) components. PEEK is 50 times more compliant than cobalt chrome alloys that are commonly used for femoral TKA components. A potential benefit of PEEK implants therefore is the reduced stress shielding of the peri-prosthetic femoral bone. Conversely, the lower stiffness of the PEEK component also has implications for the load transfer from the implant to the cemented fixation. To minimize the risk for our patients, it is therefore of vital importance to extensively evaluate these mechanical implications in a pre-clinical phase.
For this purpose, the influence of adopting the more compliant PEEK as implant material on the biomechanics of the fixation of a femoral TKA component was studied. The objectives of these analyses were (1) to evaluate implant fixation, and (2) to determine the potential for reduced stress shielding associated with the use of a PEEK femoral TKA component.

Methods and Materials: A combination of experimental and computational analyses was adopted to evaluate the biomechanical response of the femoral knee components shown in figure 1.

Figure 1 Left: Freedom Knee, Maxx Orthopedics Inc., Plymouth Meeting, PA, USA; Right: PEEK-OPTIMA™ femoral knee component, collaboration partners Maxx Orthopedics Inc. and Invibio Knee Ltd, Thornton-Cleveleys, UK

In the initial experimental tests the fixation strength of CoCr and PEEK femoral components was evaluated in simple pull-off tests of cemented reconstructions made using cellular polyurethane foam blocks (Sawbones, Vashon Island, WA). Subsequent experimental testing investigated the cemented fixation in more detail, using cadaveric distal femurs. In these experiments the reconstructions were subjected to 500,000 cycles of the peak load occurring during a standardized gait cycle (ISO 14243-1).
In the computational analyses the effect of changing the implant material from CoCr to PEEK on implant fixation was investigated. In the analyses, the focus was on the stress distributions in the cement, implant, and the cement-implant interface. To explore a range of loading configurations, the reconstructions were analyzed both when subjected to the standardized gait load and a more demanding squat load.
To investigate the potential for reduced stress shielding when using a PEEK femoral TKA component, additional experimental tests were performed with paired cadaveric femurs. The intact femurs were first subjected to the standardized gait load, while measuring the local bone strains using digital image correlation (DIC). Subsequently, the left and right femurs were implanted with a CoCr and a PEEK implant, respectively. The reconstructions were then again subjected to the standardized gait load, while measuring the strain patterns using DIC. Finally, to verify the validity of the computational methodology, the intact and reconstructed femurs were replicated in FEA models, based on computed tomography scans.

Results: The initial pull-off experiments indicated the need for modifications to the PEEK design to increase the fixation strength of the reconstruction. For this purpose, additional features were included in the cement pockets, which substantially improved the fixation strength of the reconstructions.
The PEEK implants with the featured cement pockets were subsequently tested in the cadaveric experiments. These experiments revealed minimal migration for both the CoCr and PEEK components, although after sectioning of the reconstructions, loosening at the implant-cement interface was observed for the PEEK implants.
The FEA simulations indicated that under more physiological loading conditions, such as walking or squatting, the PEEK component did not increase the risk of loss of fixation as compared to the CoCr component.
Finally, the DIC experiments and the FEA simulations confirmed that a reconstruction using a PEEK femoral component more closely resembles the bone strain distribution in the pre-operative situation.

Discussion: The biomechanical consequences of changing implant material from conventional CoCr to PEEK on implant fixation was studied extensively, using both experimental and computational testing of cemented reconstructions. The results of these analyses indicate that, although changes occur in the implant fixation, the PEEK component has a fixation strength comparable to that of CoCr. Moreover, it offers advantages in terms of bone preservation on the long term, as the more compliant PEEK implant is able to more closely resemble physiological loads occurring in the intact femur.

The Wear of an All-Polymer Knee Replacement under Different Environmental Conditions

Cowie RM[1], Briscoe A[2], Fisher J[1], Jennings LM[1]
[1]Institute of Medical and Biological Engineering, University of Leeds, UK. [2]Invibio Ltd, Thornton Cleveleys, UK
r.cowie@leeds.ac.uk

Introduction: PEEK has been considered for use as an alternative arthroplasty bearing material due to its potentially low wear rates and the low biological activity of its wear debris [1]. In this study, PEEK-OPTIMA™ was considered as an alternative to cobalt chrome in the femoral component of total knee replacements. When coupled with an all-polyethylene tibial component, this combination gives the potential for a metal-free knee implant. To fully assess the safety of the device prior to implantation, it is important to test the implant was under a range of clinically relevant conditions in line with our SAFER® approach [2]. Experimental wear simulation was carried out under both room temperature and elevated temperature conditions and the wear of the all-polymer knee was compared to that of a conventional metal-on-polyethylene implant.

Methods and Materials: Six right mid-size, cruciate retaining PEEK-OPTIMA™ knee implants (collaboration partners Maxx Orthopedics Inc., Plymouth Meeting, PA, USA and Invibio Knee Ltd, Thornton-Cleveleys, UK) and six cobalt chrome femoral components (MAXX Orthopedics Inc.) of similar initial surface topography and geometry were tested against GUR1020 all-polyethylene tibial components (conventional, EO sterile). Experimental wear simulation was carried out using ProSim electropneumatic knee simulators (Simulation Solutions, UK) running Leeds high kinematics conditions [3] with a maximum anterior posterior displacement of 10mm. Three of each implant type were tested under room temperature conditions as per standard practice at Leeds [3], for 5 million cycles; and three implants tested under elevated temperature conditions for 10 million cycles. The lubricant used was 25% bovine serum with 0.03% sodium azide and in the elevated temperature test, the environment temperature was raised using a heater system to give a bulk lubricant temperature of ~33°C. The wear of the UHMWPE tibial components was assessed by their loss in mass measured by gravimetric analysis with two unloaded soak controls used to compensate for uptake of moisture. Statistical analysis carried out using ANOVA, significance taken at $p<0.05$.

Results: The wear of the UHMWPE tibial components (Figure 1) against the different femoral component materials was low for both environmental conditions ($<5mm^3$/MC). At room temperature, there was no significant difference ($p>0.05$) in the wear rate of UHMWPE tested against either PEEK-OPTIMA™ or cobalt chrome; testing at elevated temperature lowered the wear rate of UHMWPE against both femoral component materials. A high density of linear scratching was observed on the surface of the PEEK-OPTIMA™ femoral components following wear simulation (Figure 2) however, this did not influence the wear rate which remained linear for the duration of both studies.

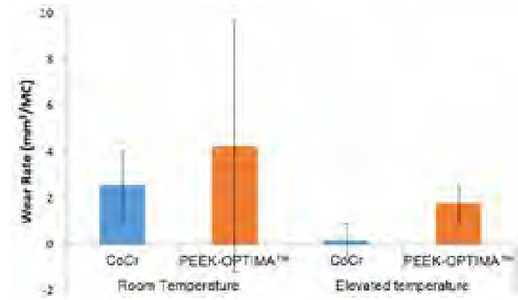

Figure 1: Mean wear rate (±95% CL) of UHMWPE tibial components articulating against PEEK-OPTIMA™ and cobalt chrome femoral components at room and elevated temperature (n=3).

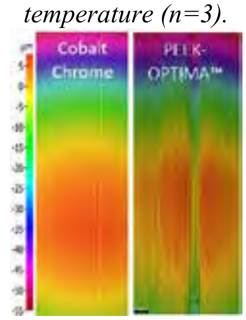

Figure 2: The surface of the femoral components following 5MC wear simulation at room temperature.

Discussion: Low wear rates ($<5mm^3$/MC) of UHMWPE against PEEK-OPTIMA™ and cobalt chrome femoral components of similar initial surface topography and geometry were observed in this study. Measuring low wear rates ($<5mm^3$/MC) can be difficult and there is a loss of reliability on the measurement technique which makes differentiation between the variables being studies and random errors in the system difficult especially in a small sample size [4]. Testing at elevated temperature however, introduced a test artefact, which lowered the wear rate of UHMWPE against both femoral component materials. This may have been a result of protein from the lubricant being deposited onto and artificially protecting the surfaces [5].

This study shows that in terms of its wear performance, PEEK-OPTIMA™ has potential for use as an alternative bearing material to cobalt chrome for the femoral component of total knee replacements; and that environmental conditions such as lubricant temperature can influence wear performance in experimental simulation.

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Comparative Knee Simulator Study:
PEEK and CoCr Femoral Components vs. Standard UHMWPE and Vitamin E Stabilised HXLPE

Reto Lerf[1], Daniel Delfosse[1]
[1]: Mathys Ltd Bettlach, Bettlach, Switzerland
reto.lerf@mathysmedical.com

Introduction: In 1980, Prof Freeman started a clinical trial with an all polymer total knee replacement comprising a femoral component made from POM (Delrin®) in the same design as an existing CoCr implant and a tibial component made form UHMWPE. After ten years, no Delrin® component had failed mechanically or due to wear [1]. Aim of the present study was to compare the wear rate generated by a commercial femoral component made from CoCr to that of a PEEK component of the same design.

Methods and Materials: The knee simulator studies were performed by Endolab GmbH, Thansau/Rosenheim, Germany, on their own simulators. Commercial balanSys® BICON femur components, size XS, were run against commercial balanSys® UHMWPE Inlays CR, size 62/8 and vitamys® inlays (highly cross-linked, vitamin E stabilised UHMWPE) of the same size (all Mathys Ltd Bettlach, Switzerland). The PEEK femur components were γ-sterilised samples of the same balanSys® design produced by Invibio from their PEEK Optima (Invibio Ltd, Thornton Cleveleys, UK). The test parameters were selected according to ISO14243-1, i.e. max. force 2600 N at 1 Hz up to 5 million cycles (Mc), in diluted calf serum at 37 °C. Three pairings were tested simultaneously, a 4th was used as "soak control". Wear of the inlays were measured gravimetrically according ISO 14243-2 and wear pattern assessed after 0.5, 1.0, 2.0, 3.0, 4.0 and 5.0 Mc on a high precision scale Sartorius BP211D. Additionally, the PEEK femoral components were weighed before and after testing.

Results: The cumulative wear curves rates of all three pairings were similar, showing a long run-in period with a steady state wear from 2 Mc. The wear rates were thus calculated using the data between 2 and 5 Mc. As expected, CoCr exhibits a significantly higher linear wear rate vs. UHMWPE compared to vitamys® (Table 1). The wear rates of the two different femur components (CoCr and PEEK) vs. vitamys® are nearly identical.

Pairing	Linear wear rate [mg/Mc]	StdDev [mg/Mc]
CoCr vs. UHMWPE	3.50	0.42
CoCr vs. vitamys®	2.45	0.54
PEEK vs. vitamys®	2.42	0.36

Table 1. Polyethylene wear rates of the knee simulator study, calculated after run-in, i.e. 2 to 5 Mc.

Comparing the wear pattern on the two sets of vitamys® inlays, the worn zone in the pairing against PEEK is more concentrated on the posterior zones for both condyles whereas in the coupling against CoCr the worn zone covers the whole length of the medial compartment after 2 Mc. All CoCr femur components showed slight scratching in flexion-extension, on both medial and lateral condyles. On the PEEK components, a worn zone could be clearly distinguished (Figure 2). A quantitative analysis of the PEEK wear has proven difficult because fluid absorption of the "soak control" PEEK component was 3.4 mg/Mc, i.e. higher than all measured wear rates. A crude estimation of the PEEK wear rate revealed that it may be as high as half of the PE wear.

Figure 1. Transition worn zone (top) unworn area (bottom) of a PEEK femur component after 5 Mc.

Discussion: While the PE wear rates are low and similar, the PEEK component wears visibly contrary to CoCr, which is only slightly scratched. One limitation of the study is the missing analysis of the wear particles. There is no information about the ratio of PE to PEEK particles. There are more limitations. We are aware that PEEK as well as PE have low thermal conductivity but we did not monitor temperature during the simulator test. Finally, the knee simulator is designed in a way that the femoral component is fixed to a massive steel shank, stiffening the femur side of the test set-up. This effect is more noticeable for components made of PEEK than CoCr.

Conclusion: The wear rate of a highly cross-linked, vitamin E stabilised UHMWPE was low and similar when tested in a knee simulator against two different femoral components, made from CoCr or PEEK.

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Acknowledgement: Many thanks go to Martin Hintner from Endolab for managing the simulator studies. The preparation and supply of the PEEK femur components by Invibio is acknowledged.

CFR-PEEK on CoCrMo Articulations in the Atlas™ Knee System

Lowe DL[1], Clifford AG[1], Saravia HE[1]
[1]Moximed Inc. Hayward, CA, USA
dlowe@moximed.com

Introduction: The Atlas™ Knee System (Figure 1) is a CE-marked second-generation implantable joint unloader for patients with medial knee osteoarthritis. The device, a load sharing system, is implanted extra-capsularly to the medial knee providing joint load reduction without joint alteration [1, 2]. Clinical investigations of the Atlas system have shown significant symptom improvement in a high demand population [3].

Figure 1. Atlas™ Knee System

The implant features two small diameter articulating ball-socket joints fixed on the femur and tibia, respectively, and a compliant polycarbonate urethane load absorber between the joints designed to share joint loads during stance phase of gait.

Each ball-and-socket articulation features a PAN-based carbon fiber reinforced polyetheretherketone (CFR-PEEK) on CoCrMo bearing surfaces. The purpose of this study was to assess the wear behavior of this novel ball socket coupling and report on gravimetric and morphological changes as a result of 10 million *in-vitro* cycles.

Methods and Materials: Five Atlas Knee System implants were tested on a custom designed multi-station knee simulator (Figure 2) out to 10 million cycles (Mc).

Figure 2. Multi-station knee simulator

The femoral ball and socket design of the Atlas implant features a 7 mm diameter CFR-PEEK ball (machined from Invibio's PEEK-OPTIMA Reinforced extruded plate) articulating within a wrought low-carbon CoCrMo alloy socket. In contrast, the tibial design features a 6.3 mm diameter low-carbon CoCrMo ball articulating within a CFR-PEEK socket.

Implants were tested in bovine serum diluted to 25% (v/v) with deionized water maintained at 37±5°C. Test fluid was supplemented with antibiotics and antimycotics to resist bacterial and fungal growth. Devices were tested at a cyclic test frequency of 2.5 Hz through 0° to 68° flexion/extension cycles representing the range of motion during the stance phase of gait.

Gravimetric assessment was performed at baseline, 2, 5, and 10 Mc. Two unloaded soak controls were used to compensate for weight change due to fluid absorption.

Scanning electron microscopy (SEM) and inspection on a coordinate measuring machine (CMM) of the articulating bearing surfaces were conducted at baseline and 10 Mc.

Results & Discussion: Of the two ball-socket interfaces, the femoral ball-socket surfaces exhibited more evidence of wear. This is attributed to the greater range of motion experienced at that joint and is consistent with observations from implant retrievals from previous generations [4].

Gravimetric: Using mass loss measurements at the three time points wear was found to be linear with the femoral CFR-PEEK ball and femoral CoCrMo socket losing 1.22 mg and 2.09 mg, respectively, after 10 Mc.

SEM: High powered microscopy was unremarkable after 10 Mc showing a general smoothening of surfaces and no evidence of scratching or notable tribological findings on either CRF-PEEK or CoCrMo surfaces. Refer to Figure 3.

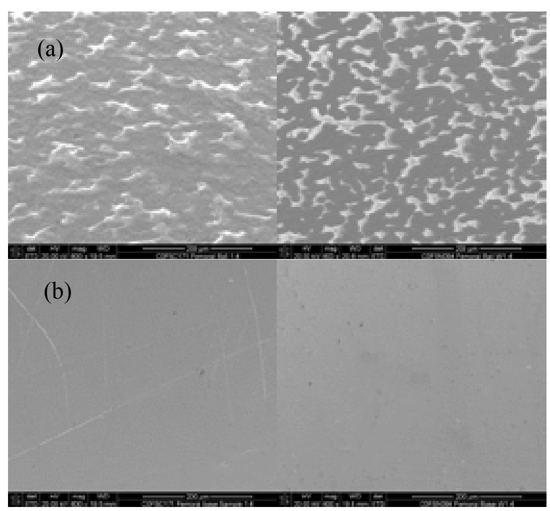

Figure 3. Representative SEM micrographs taken at 600x magnification of the femoral (a) CFR-PEEK ball and (b) CoCrMo socket surface at baseline (left) and after 10 Mc (right)

CMM: The measured deviation of the femoral ball and socket surfaces with respect to a nominal CAD model was determined at baseline and after 10 Mc (Figure 4). There was less than a .0001” dimensional change detectable within the apparent wear zone on the CFR-PEEK balls and the dimensional change on the CoCrMo socket surfaces was essentially undetectable.

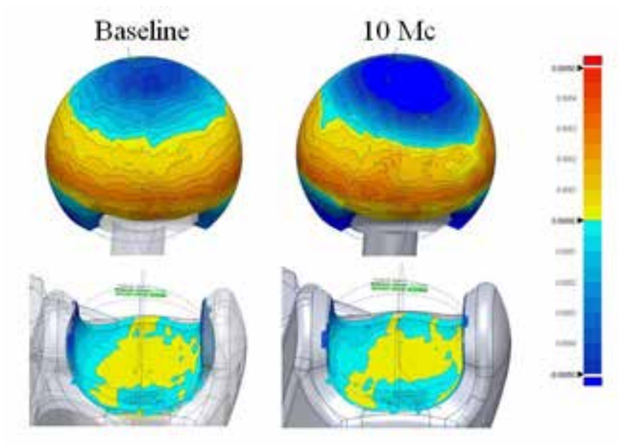

Figure 4. Representative plots showing the measured deviation at baseline and after 10 Mc of the femoral ball and socket surfaces with respect to the nominal CAD model

Conclusion: Wear performance of this novel ball-socket design and material combination demonstrated low mass loss and minor morphological changes after 10 million simulated-use cycles.

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Cartilage function-mimetic hydrated interface with phospholipid polymer for a metal-free bearing

Kyomoto M[1,2], Moro T[1], Yamane S[1,2], Saiga K[1,2], Watanabe K[1,2], and Ishihara K[1]
[1]The University of Tokyo, Tokyo, Japan, and [2]KYOCERA Medical Corporation, Osaka, Japan
kyomoto@mpc.t.u-tokyo.ac.jp

Introduction: The careful consideration of not only wear resistance but also metal ion release is very important for bearing couples or interfaces in total hip arthroplasty (THA). Several studies have shown that poly(ether-ether-ketone) (PEEK) might be useful as an alternative bearing material. However, conventional PEEK cannot satisfy some requirements, e.g., wear resistance in artificial joint fabrication. The articular cartilage surface is assumed to have a hydrogel-like layer with a brush-like structure: a part of the proteoglycan aggregate brush is bonded with the collagen network on the cartilage surface. The hydrogel-like layer, which is essential for the smooth motion of joints, provides hydrophilicity and works as an effective boundary lubricant. Here, we propose a new and safer methodology for constructing a nanometer-scale modified surface layer of poly(2-methacryloyloxyethyl phosphorylcholine [MPC]) (PMPC) on the PEEK substrates by self-initiated photoinduced graft polymerization [1,2], and a polymeric interface between PEEK and cross-linked polyethylene (CLPE), which is expected to make a metal-free bearing for artificial joints to prevent metal hypersensitivity reactions. The nanometer-scale PMPC layer was formed on PEEK or CLPE surface to better reproduce the ideal hydrophilicity and lubricity of the physiological joint surface, based on the concept of cartilage function-mimetic hydrated interface. In this study, we investigated the corrosion and wear resistance of the polymeric bearing interface between PEEK–CLPE to propose a better alternative.

Methods and Materials: PEEK (450G; Victrex PLC) specimens were fabricated without the use of stabilizers. The CLPE (GUR1020 resin, 50 kGy gamma-ray irradiation, and annealing) specimens were coated with benzophenone as a photo-initiator. Photoinduced graft polymerization was carried out on the PEEK or CLPE surface in a 0.5-mol/L MPC (NOF Corp.) aqueous solution for 90 min at 60°C under UV irradiation at the intensity of 5 mW/cm^2. The galvanic corrosion between the Co–28Cr–6Mo (Co–Cr–Mo) alloy or PEEK and Ti–6Al–4V alloy in a mixture of 27 vol% fetal bovine serum (FBS) at 37°C was evaluated for 7 days by using a built-in zero-resistance ammeter of the potentiostat according to ASTM G71-81. The friction test was performed using a pin-on-plate machine. The wear test of the Co–Cr–Mo alloy, PEEK, or PMPC-PEEK femoral head (size: 32 mm) against CLPE or PMPC-CLPE liner was performed using a 12-station hip simulator (MTS Systems Corp.) according to ISO14242-3. A mixture of 25 vol% FBS was used as the lubricant.

Results and Discussions: The galvanic current densities of galvanic interface of Ti–6Al–4V alloy against Co–Cr–Mo alloy or PEEK were significantly difference ($p < 0.01$), and their extremely low values (means ± 95% confidence intervals) were 0.28 ± 0.20 and 2.5 ± 0.5 nA/cm^2, respectively. On the other hand, taper corrosion at the head–stem neck junction in the modular THA has recently been recognized to be an important issue with multiple reports of adverse local tissue reactions in patients with even metal-on-polyethylene bearings, and has been considered a potential limiting factor for lifetime of THA. The dynamic friction coefficient of Co–Cr–Mo alloy, PEEK, or PMPC-PEEK against PMPC-CLPE was extremely lower than that of Co–Cr–Mo against CLPE; the values reached to 0.009–0.014. When restoring cartilage functions, it is important that the same level of lubrication is achieved artificially as was previously presented naturally. In the hip simulator test, it was also observed that the gravimetric wear in the Co–Cr–Mo alloy, PEEK, or PMPC-PEEK femoral head against PMPC-CLPE liner was significantly lower than that in the Co–Cr–Mo alloy femoral head against CLPE liner; the wear amount did not differ significantly, regardless of femoral head materials (Fig. 1). For ensuring a long-term cartilage function-mimetic interface, the PMPC layer and elastic polymer substrate were very suitable; especially the hydrated PMPC layers brought a stable hydration lubrication mechanism at the polymeric bearing interface. In conclusion, the metal-free bearing interface of PEEK against PMPC-CLPE is suitable candidate for THA. Such investigations are of great importance for the design of lifelong THA and obtaining a better understanding of the limitations resulting from the use of this material.

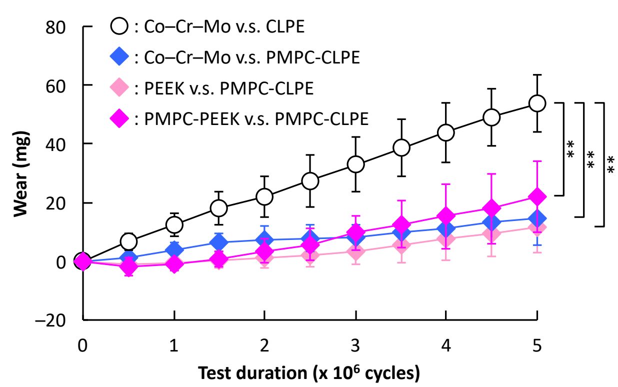

Fig. 1. Wear resistances of polymeric bearing interfaces in the hip joint simulation test. ** indicates $p < 0.01$.

References: [1] Kyomoto M., et al. Biomaterials. 2010:31;1017-1024; [2] Kyomoto M., et al. Biomaterials. 2013:34;7829-7839.

Acknowledgments: *This research was supported by the S-innovation Research Program, Japan Agency for Medical Research and Development (AMED).*

Fretting Corrosion Performance of Modular Tapers Fitted with Self-Reinforced Composite PEEK Gaskets

Eric S. Ouellette, Ph.D.[1,2,3]*, Jeremy L. Gilbert, Ph.D.[2, 3]

1. Exponent, Inc.
2. Department of Biomedical and Chemical Engineering, Syracuse University, Syracuse, NY 13244
3. Syracuse Biomaterials Institute, Syracuse, NY, 13244

*Work performed at Syracuse University

Background: Mechanically assisted crevice corrosion (MACC) of modular taper connections in medical devices is an area of significant clinical interest. While the benefits of modularity in orthopaedic design are clear, concern has been raised over the last two decades about the implications of corrosion and MACC on the clinical outcome of modular devices for patients.[1,2,3] Recent efforts have shown that self-reinforced composite PEEK (SRC-PEEK) has the ability to inhibit the onset of fretting and corrosion at metallic interfaces in pin on disk fretting corrosion testing.[4] This work aims to incorporate the same thin film SRC-PEEK materials in the junctions of modular tapers, and investigate the electrochemical and micromechanical performance of assembled head-neck tapers fitted with an interposing SRC-PEEK thin-film gasket.

Materials and Methods: PEEK fibers were hot compacted in a method previously described.[5] The resulting films were then fit around a Ti-6Al-4V trunnion and CoCrMo head, with design characteristics which promoted initiation of fretting corrosion in previous studies.[6] A control group of the same modular tapers with no SRC-PEEK was also employed in testing, with N=3 samples in the SRC-PEEK group, and N=6 metal-metal taper samples. Following an axial seating load of 4,000 N, the samples were then subjected to an incremental cyclic fretting corrosion (ICFC) test, where the currents and micromotion of the taper junction were measured simultaneously through incrementally increasing cyclic loads up to 4000N[6]. Following the short-term ICFC test, the same samples underwent 10^6 loading cycles while measuring current and micromotion. The tapers were then disassembled (with pull-off load recorded) and inspected for damage using digitial optical and scanning electron microscopy (Hirox, NJ and Jeol, Japan).

Results: Introduction of SRC-PEEK films in the modular taper junction allowed for significantly larger subsidence to occur during seating than with metal-metal control samples (844.5 µm vs. 90.3 µm, $p < 0.05$, Figure 1). In short-term ICFC testing, SRC-PEEK-sleeved tapers showed no onset of fretting current across all cyclic loads, whereas a subset of metal-metal control samples had significantly higher fretting currents at the 4000 N cyclic load than SRC-PEEK samples (26.3 µA vs. 0.4 µA, $p < 0.05$, Figure 2), and fretting initiated at low cyclic loads (ca. 1200 N). Both the total head subsidence (Figure 3) and amplitude of micromotion of the femoral heads during ICFC testing were not distinguishable between SRC-PEEK and metal-metal test groups. In long-term testing, SRC-PEEK showed consistently lower fretting currents than the subset of metal-metal samples that experienced a high fretting corrosion current response. SRC-PEEK samples exhibited wide variability in head subsidence, but were not found to be significantly different than the head subsidence of metal-metal tapers. Pull-off testing following testing showed no differences between SRC-PEEK samples and metal-metal samples. Inspection of the films after testing showed signs of minor damage but no identifiable areas where the film had worn through.

Discussion: The use of SRC-PEEK in pin-on-disk fretting corrosion studies has previously shown the ability to prevent the onset of fretting corrosion. The introduction of the SRC-PEEK material into modular tapers showed similar electrochemical results, with fretting currents being completely inhibited. This is likely due to the combination of a soft and non-conducting polymer layer that cannot disrupt the oxide film and may inhibit fluid penetration due to its hydrophobic character. A subset of metal-metal tapers performed similarly to SRC-PEEK tapers, but another group of the same metal-metal tapers had significantly higher fretting currents than SRC-PEEK samples, indicating that SRC-PEEK sample perform similarly to otherwise well-performing metal-metal tapers, but significantly better than tapers that become pre-disposed to high fretting currents. Long-term testing indicated similar results, and importantly, SRC-PEEK tapers did not exhibit electrochemical signs of break-through or failure. Mechanically, tapers fitted with SRC-PEEK performed similarly to metal-metal samples, which is an important clinical considering in order to achieve proper head locking and resist complications such as head dissociation. The electrochemical and micromechanical evaluation presented here show that thin film SRC-PEEK may be a suitable candidate for a materials-based innovation to prevent the onset of fretting corrosion in modular taper systems.

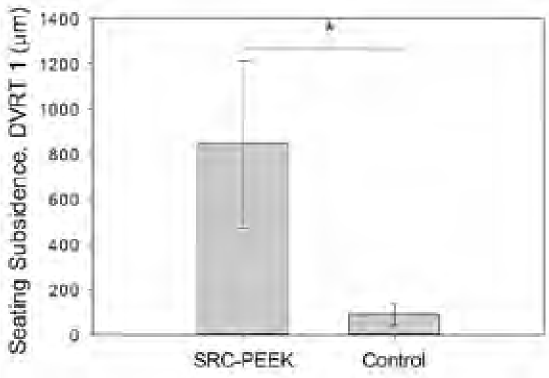

Figure 1 Average seating subsidence as measured for SRC-PEEK-sleeved tapers and metal-metal tapers.

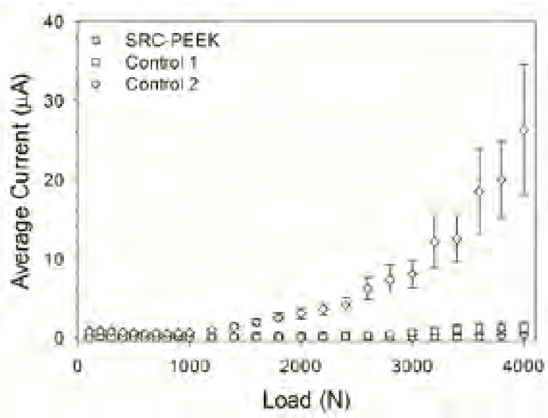

Figure 2 Average fretting current vs. load for SRC-PEEK-sleeved tapers and two subsets of identical metal-metal tapers: those which experienced elevated fretting currents, and those that did not. No significant fretting corrosion was seen with SRC-PEEK samples.

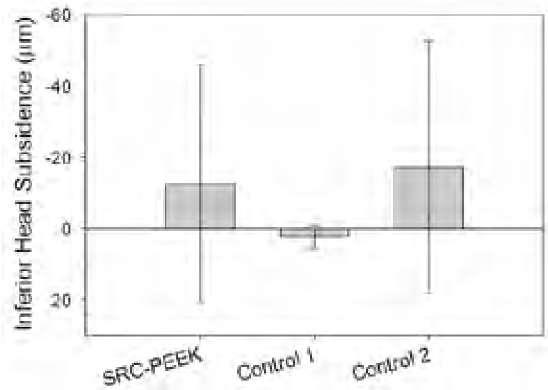

Figure 3 Head subsidence measured during short-term ICFC testing. Overall migration of heads fitted with SRC-PEEK was not different from metal-metal samples.

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Preclinical and Clinical Evaluation of an all PEEK Total Facet Arthroplasty

[1,2]Siskey, RL; [1,2]Toner, G; [3]Dahl, M
[1]Exponent Inc., Philadelphia, PA, [2]Drexel University, Philadelphia, PA, [3]Zyga Technology Inc., Minnetonka, MN
Corresponding author rsiskey@exponent.com

Introduction

The zygapophyseal, or facet, joints of the spine are a commonly treated source of back pain, and rates of percutaneous facet joint procedures in older adults have quadrupled since 2002 [1]. Osteoarthritis of the facet is a common cause of pain, and when conservative treatments fail, patients are left with few options for treatment. The facet is a synovial joint and can be resurfaced or augmented with articulating prostheses similar to other orthopedic devices. Polyetheretherketone (PEEK) may provide the durability and compliance needed to perform under the activities of daily living experienced by the facet. To assess this viability, a combination of a previously reported biomechanical evaluation, wear testing, and an ongoing clinical study have been used to assess the Glyder® Facet Restoration System.

Biomechanical testing was used to quantify the effect of facet arthroplasty on segmental range of motion (ROM) and to compare it to the intact condition [1]. Wear testing was used to challenge the facet arthroplasty to 10 MC of simulated wear conditions and to assess wear rate and mechanism, penetration and particle size and morphology. Finally, a prospective multi-center feasibility study was used to assess the clinical performance and safety of the device [2].

Materials and Methods

Twelve intact and implanted cadaveric functional spinal units (L2–L3 and L5–S1) were evaluated to 7.5 Nm of flexion-extension, lateral bending, and torsion. Specimens were also then subjected to 10,000 cycles of worst-case multi-axis loading, and the ROM testing was repeated. Torque versus angular displacement data and fluoroscopic data were analyzed to determine ROM and to evaluate device position during cyclic testing.

For wear testing, the facet loads and motions were identified from published data in literature [3, 4]. The facet joint has an average displacement of 4 mm (2 mm standard deviation) at full flexion [4]. According to published data on the normal in vivo forces applied to the facet joint, loads may reach 150 N, but typical loading during normal daily activity is approximately 50 N [5]. Therefore, a normal load of 200 ± 50 N was used for testing to ensure the devices experienced worst case loading. A combination of ± 5° of rotation and ± 2 mm of translation was used for the duty cycle. All motions were applied at 1.0 Hz for 10 MC using the six-station tester shown in Figure 2. The samples were held in place using molded fixtures that held the device in curved configuration with a bend radius of 10 mm. The test was stopped at least every 0.5 million cycles for fluid exchange and interval analysis. The interval analysis consisted of mass measurements and photo documentation. The bovine serum, with a protein content of 5 g/L, was also subjected to particle analysis per ASTM F1877. Two sets of load soak samples were subjected to only axial load and used to correct for fluid absorption throughout the test. The devices were imaged using a µCT 80 (Scanco Medical AG, Switzerland) at a voxel resolution of 10µm at 0, 5, and 10MC. Penetration measurements were taken at 9 locations on the device as seen in Figure 1.

The clinical study enrolled patients with confirmed lumbar facetogenic joint pain at 1 or 2 levels who underwent at least 6 months of unsuccessful non-operative care. Main outcomes included back pain severity using a visual analogue scale, back-specific disability using the Oswestry Disability Index (ODI), and adverse events adjudicated by an independent Clinical Events Committee.

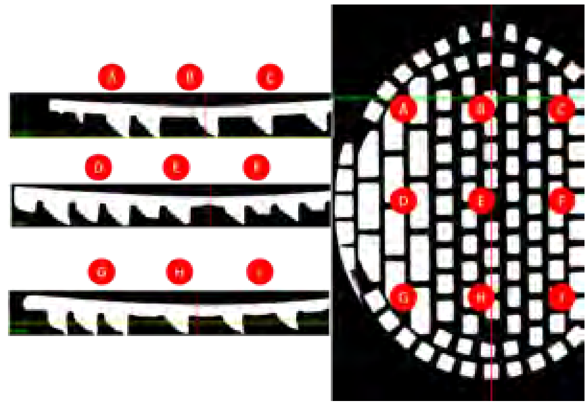

Figure 1. Representative microCT rendering of a tested sample with penetration measurement locations indicated.

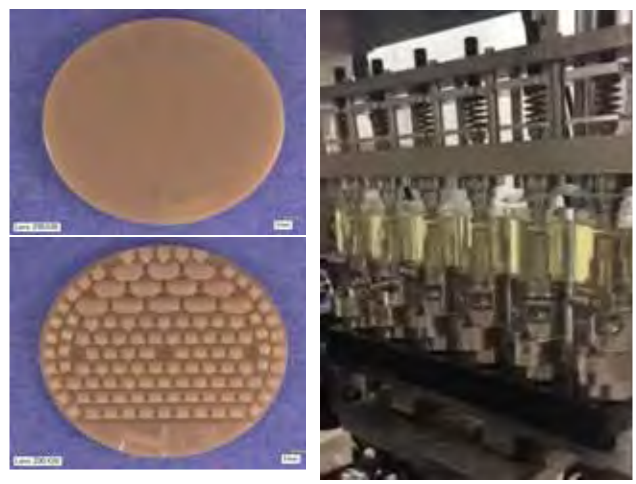

Figure 2. Representative images of the articulating (top left) and backside (bottom left) surface of an unworn Glyder ® samples. Six station custom facet wear tester (right).

Results

Range of motion post-implantation decreased versus intact and then was restored post cyclic-testing. Of the tested devices, 6.5% displayed slight movement (0.5–2 mm), all from tight L2– L3 facet joints with misplaced devices or insufficient cartilage. No damage was observed on the devices, and wear patterns were primarily linear.

The average mass loss for the Glyder® samples that reached 10 MC was 39.1 ± 5.8 mg, which represents 19.9 ± 3.0 % of the mass of the untested samples. Overall, the superior and inferior sample couples, by station, demonstrated an average total mass loss rate of 4.4 ± 1.0 mg/MC. This mass wear rate corresponds to a volumetric wear rate of 3.4 ± 0.8 mm^3/MC (Fig. 3). At 8 MC, two samples were irreversibly overloaded during setup. Therefore, the wear rates for those samples are based on 8 MC cycles of test data. Inspection of the samples found the wear mechanisms between the PEEK counterfaces was primarily abrasive. The articulating surfaces of the device demonstrated a mild burnished appearance along with linear and elliptical scratches indicative of abrasive and third body wear mechanisms, respectively. The particle analysis found the particles to range between 0.01 and 37.4 µm. The ASTM F1877 parameters were consistent with the spheroidal smooth particles observed under SEM. EDS confirmed the majority of these particles to be polymeric in nature. Penetration rate was measured to be 0.02 ± 0.01 mm/MC as calculated from the microCT analysis.

Of 40 enrolled patients, 37 patients received the facet restoration implant, and 34 patients had complete 1-year follow-up data available. Over the 1-year follow-up period, back pain severity decreased 41%, and ODI decreased 34%, on average. Freedom from a device- or procedure-related serious adverse event through 1 year was 84%. Implant migration was observed in 3 patients, and implant expulsion from the facet joint occurred in 3 patients. In total, 2 (5.4%) patients underwent implant removal through 1-year post-treatment. This study is ongoing, and 2-year follow-up data will be available in early 2017.

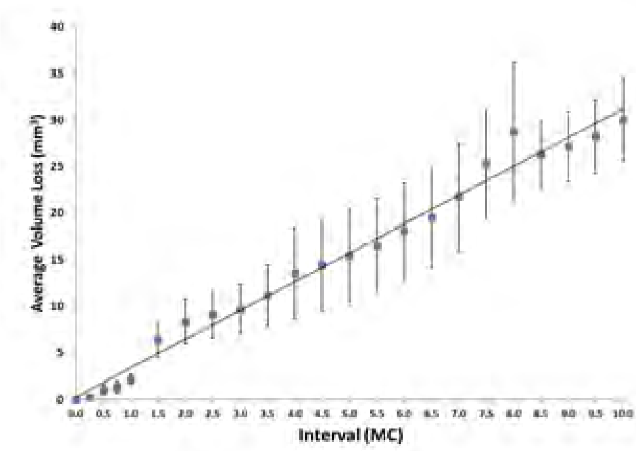

Figure 3. - Average total volumetric loss (mm^3) for 10 MC of testing. Error bars represent ± one standard deviation. Average volumetric wear rate is 3.4 ± 0.8 mm^3/MC, $R^2 = 0.98$.

Discussion

The results from the in situ cadaveric biomechanics and cyclic fatigue study demonstrate that a low-profile, PEEK-on-PEEK facet arthroplasty devices can maintain position and facet functionality post implantation and through 10,000 complex loading cycles. Wear testing revealed the Glyder® samples exhibited burnishing when subjected to loads and motions expected at the facet joint. The PEEK material demonstrated a wear mechanism consistent with other previously published PEEK tribological studies for spinal devices [6-8]. These studies found volumetric wear rates for PEEK articulations to range from 0.21 ± 0.01 to 2.1 ± 0.5 mm^3/MC. While the wear rate for the Glyder is higher than these rates, it is important to note the loads and motions used in the study may not be directly comparable to the loads and motions used in cervical total disc wear testing. Lastly, based on the clinical study data available at this time, a minimally invasive facet restoration implant appears to be a promising treatment option. The 1-year follow-up data suggests that in select patients with chronic lumbar zygapophysial pain who have exhausted nonsurgical treatments, this device demonstrates a therapeutic benefit. Two-year data will be collected to determine if these trends persist.

Acknowledgements

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In Vivo Models of the Bone-Implant Interface

Walsh, WR[1], Christou, C[1], Woods B[1], Pelletier, MH[1], Wang, T[1], Lovric, V[1], Oliver, RA[1]

[1]UNSW Australia, Prince of Wales Clinical School, Sydney, Australia
w.walsh@unsw.edu.au

Introduction: The in vivo response and clinical outcome of any implanted material is largely a reflection of interfacial reactions with the host that arises due to the boundary conditions. A complex combination of variables influence the boundary conditions including material properties, implant design, sterilization, surgical preparation, fixation, biomechanical loading coupled with the biological pathways of healing.

In vitro studies provide insight into the cellular reactions between cells and materials, however they fail to recreate the complex environment required robustly to evaluate a material or implant prior to human clinical use. Pre-clinical animal models allow further insight on the in vivo performance of materials and implanted devices prior to use in humans with limitations. This paper considers the in vivo response of PEEK and modified PEEKs at the bone-implant interface using idealized dowels in cortical and cancellous bone, interbody cervical and lumbar fusions, anterior cruciate ligament reconstruction and rotator cuff repair using various sheep models. PEEK Optima, PEEK Optima HA Enhanced, PEEK Optima coated with titanium were examined along with a large number of titanium, cobalt chrome or resorbable polymers in the models.

Methods and Materials: UNSW Australia institutional ethical clearance for the use of animals and the procedures performed was obtained prior to commencement. The unique surgical and clinical aspects of the human scenario for the use of the PEEK implant was taken into account regarding the animal age, surgical site, procedure, instrumentation, implant size and fixation for each model. The idealized bone dowel model, which has been used by our laboratory for two decades, used skeletally mature sheep as did the ACL reconstruction and rotator cuff while the spinal models utilized older sheep to more closely reflect clinical scenarios. Time points ranging from 4 weeks to 52 weeks allowed for a wide range of comparisons to consider from a healing point of view. While PEEK implants were often the topic of examination, they were also used as a method to fix different type of graft materials or used as the implants of choice considering the current state of the art.

The experimental endpoints common to all studies included radiography (routine and Faxitron radiographs), and micro-computed tomography allowed for a detailed examination of the implant – bone interface. Hard tissue (PMMA) histology was used to evaluate the PEEK – host interface. Samples were dehydrated, embedded in PMMA, sectioned using a rotary microtome (Leica SP1600) and stained with methylene blue – basic fuschin for analysis, in a blinded manner, under light microscopy. Specialized model specific biomechanical testing ranging from push out testing to assess shear strength to anteroposterior drawer using servohydraulic testing materials to functional range of motion in lateral bending, flexion-extension and axial rotation using a robot was performed to assess the functional aspects.

Results: Common to all studies was the lack of any adverse reactions detectable at the PEEK – bone interface radiographically. Adverse reactions attributed to the PEEK devices regardless of the surgical site or model was also not found when using more detailed micro computed tomography scans. Micro computed tomography did however demonstrate how differences in loading conditions can influence the presentation of the PEEK-bone interface. Histology provided the ultimate assessment of any positive or negative local tissue reactions. The inert nature of PEEK and its excellent biocompatibility was seen across all models and implantations sites. Modifications to PEEK such as incorporating hydroxyapatite in the bulk or titanium coating results in direct bone ongrowth to surface of the PEEK devices. Biomechanically, all PEEK devices met the requirements needed again regardless of model.

Discussion: The results of all pre-clinical experiments need to be carefully considered as they remain models designed to represent the human scenario. Input from specialist veterinary and human surgeons as part of the model development, anatomy, surgical techniques and post-operative husbandry allows a fuller appreciation of the strengths and weakness of the models. Well established and reproducible techniques from radiography, micro computed tomography, histology and biomechanical testing applied across the models allows insight into the performance of materials under different scenarios. Appreciation of the model limitations combined with an understanding of the human clinical scenario needs to be considered when evaluating and interpreting the results.

The diversity of PEEK implants across all surgical sub-specialties and the clinical success provides a firm foundation for the development of new devices using this material. Nevertheless, continued improvements in design and in materials such as PEEK Optima HA enhanced can influence the bone-implant interface with the aim of improving clinical performance. Pre-clinical models provide an important stage not only in material development but in the understanding of the role of devices in the biology and biomechanics.

Porous PEEK versus plasma-sprayed titanium coating on PEEK: *in vitro* and *in vivo* analyses

F. Brennan Torstrick[1], Angela S.P. Lin[1], Ken Gall[2], Robert E. Guldberg[1]
[1]Georgia Institute of Technology, Atlanta, GA, [2]Duke University, Durham, NC
brennan@gatech.edu

Introduction: Despite PEEK's widespread use in spinal applications due to its high strength, radiolucency and similar stiffness to bone; recent reports associating current smooth-surfaced PEEK implants with fibrous encapsulation and migration have stimulated development of alternative surface technologies. This study aims to directly compare the *in vitro* and *in vivo* bone response to two clinically available PEEK alternatives: porous PEEK and plasma-sprayed titanium coatings on PEEK.

Methods and Materials: Porous PEEK (Porous) was made as described previously [1]. The resulting porous architecture is 60-70% porous with a pore size of approximately 350µm [2]. Plasma-sprayed titanium coating of PEEK samples (TiPEEK) was performed by APS Materials, Inc. (Dayton, OH). Each surface was imaged and measured for roughness using laser confocal microscopy (LEXT, Olympus). MC3T3 cells were grown on smooth injection-molded PEEK (Smooth), Porous, and TiPEEK discs for 14 days in osteogenic media (n=5). Osteocalcin content of cell lysates was measured using an ELISA and normalized to DNA measured using a Picogreen dsDNA assay. Calcium content of parallel cultures was determined by a colorimetric Arsenazo III reagent assay. Cylindrical implants were implanted into the proximal tibial metaphyses of skeletally mature male Sprague Dawley rats (Fig 2). At 8 weeks, animals were euthanized and each bone-implant interface was subjected to µCT scanning and biomechanical pullout testing (n=3-5). All data were reported as mean±SE. Comparisons between groups were calculated using a 1-way ANOVA followed by a Tukey multiple comparisons test.

Results: The surface roughness, S_a, of TiPEEK surfaces (7.02±0.33µm) was greater than both Smooth (0.01±0.002µm) and Porous surfaces (0.45±0.06µm) ($p<0.01$). Cell cultures on Porous surfaces produced greater amounts of calcium and osteocalcin compared to Smooth and TiPEEK cultures ($p<0.01$). µCT scans from the animal study revealed a thin layer of mineralized tissue near the bottom face of Smooth implants and substantial mineralized tissue within the porous architecture of Porous implants. µCT evaluation of TiPEEK implants was obscured by imaging artifact. Porous implants exhibited greater failure loads (36.8±5.0N) compared to Smooth (15.9±2.8N) and TiPEEK (21.1±1.5N) implants ($p<0.05$).

Discussion: The current study investigated the *in vitro* and *in vivo* bone response to TiPEEK and porous PEEK as two clinically available alternatives to current smooth PEEK implants. Overall, porous PEEK was associated with a more differentiated bone cell phenotype *in vitro* and greater implant fixation *in vivo* compared to smooth PEEK and TiPEEK. Comparing the results from smooth and porous PEEK provides evidence that not all PEEK implants inherently generate a fibrous response, as has been stated in the literature [4]. Instead, the data seem to suggest that surface topography plays a larger role than implant composition, with macro-porous features exhibiting improved osseointegration compared to smooth surfaces. Comparing porous PEEK and TiPEEK provides further evidence that macro-scale porous features improve osseointegration compared to smaller micro-scale features. Surprisingly, TiPEEK and smooth PEEK performed similarly, which is in contrast to previous reports that rough titanium surfaces induce a greater osteogenic response compared to smooth PEEK [5]. One limitation of this study is that TiPEEK and porous PEEK possess different surface chemistry and different topography. Thus, conclusions regarding the relative importance of chemistry and topography cannot yet be made. Future work is focused on systematically altering these variables to investigate the contributions of each factor.

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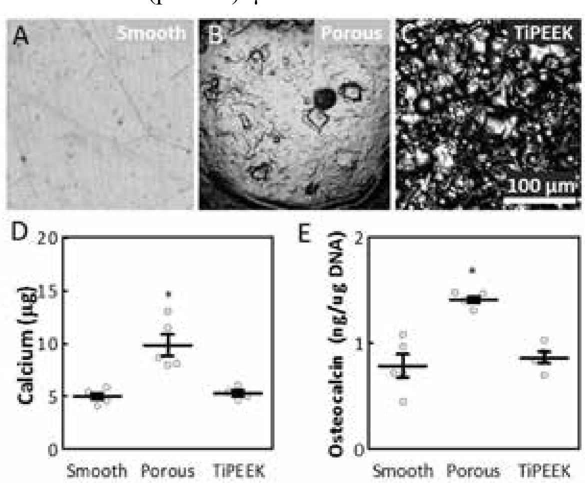

Fig1: (A-C) Photomicrographs of each surface at the micro-scale. (B) shows the topography of a pore wall. (D) Calcium and (E) osteocalcin content of MC3T3 cultures at 14 days in osteogenic media. *p<0.01, 1-way ANOVA, Tukey.

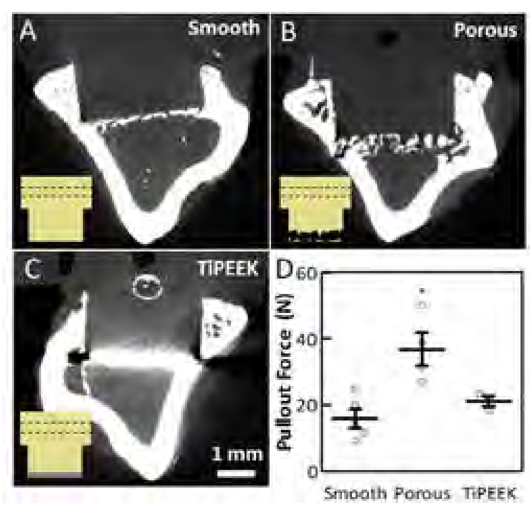

Fig2: µCT sections of (A) smooth, (B) porous and (C) TiPEEK implants at 8 weeks. (D) Pullout failure loads of implants at 8 weeks post-implantation. *p<0.05, 1-way ANOVA, Tukey.

PEEK *Staphylococcus aureus* biofilms: effects of media

Keith Fitzgerald[1], Christopher Kepler[1], Lauren Jablonowski[2], John Eisenbrey[2], Flemming Forsberg[2], Steven Kurtz[3], and Noreen Hickok[1]
[1]Dept of Orthopaedic Surgery and [2]Dept of Radiology, Sidney Kimmel Medical College of Thomas Jefferson University, Philadelphia, PA 19107 and [3]Implant Research Center, Drexel University, Philadelphia, PA 19104
Noreen.Hickok@jefferson.edu

Introduction: Orthopaedic joint infections are notoriously difficult and expensive to treat. In 2010, infection of artificial joints cost ~$785 million, with a projected cost of $1.62 billion by 2020(1,2). Furthermore, the incidence of antibiotic-resistant joint infections continues to increase, especially among those with risk factors, such as rheumatoid arthritis, age, obesity, and diabetes. It thus becomes imperative to create appropriate models to study the genesis of these infections, *in vitro*.

Periprosthetic infections are thought to arise from implant-associated biofilms, where surface properties and composition affect the extent of bacterial colonization. The purpose of this study is to ask two related questions important for the development of antibiofilm therapies, *in vitro*. First, we ask how medical grade PEEK compares with other biomaterials in the establishment of bacterial colonization. Secondly, we ask if experimental media used in the laboratory reasonably reproduces biofilm structure, *in vivo*. Our data suggest that composition of the surface is only moderately important whereas media composition affects not only the production of biofilm matrix, but also the formation of protein structures that facilitate biofilm formation.

Methods and Materials: 5mm diameter, 1mm thick disk specimens were machined from a 25mm extruded rod of PEEK-OPTIMA Natural (Invibio). Control materials were PLA, as machined Ti6Al4V (AM-Ti), and tissue culture-treated polystyrene (TCP, Falcon) (~5 mm diameter by 1 mm). PLA specimens were 3D printed using a FDM process (Ultimaker 2+). As machined Ti6Al4V were disks cut from stock rods of metal without further polishing. Prior to use, they had been washed and passivated with HCl/Methanol (50:50) for 1 hour. All materials were rinsed with sterile saline 3X, and sterilized by UV irradiation, 30 min.

S. aureus ATCC25923 were added to the wells containing biomaterial disk specimens at 1 x 10^6 colony forming units (CFU)/ml in 1 ml of trypticase soy broth (TSB) ± 10 µg/ml cefazolin (CFZ, antibiotic) to test surface colonization. Surfaces were incubated at 37°C for 24; followed by recovery of bacteria from biofilm and enumeration by direct plating. In parallel, colonization was assessed at 24 hours, using scanning electron microscopy(3) (SEM). To test the importance of media, 1 ml of Mueller Hinton Broth (MHB), TSB, Brain Heart Infusion (BHI), fetal bovine serum (FBS), human Synovial Fluid (SF) ±100 µg/ml CFZ were inoculated with 10^5CFU/ml *S. aureus*, 37°C, 24 hrs. Biofilms formed on surfaces were visualized by SEM.

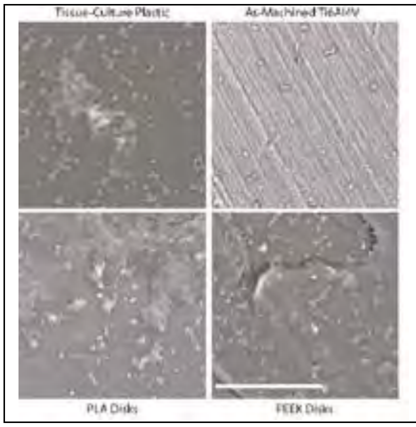

Figure 1: Comparison of *S. aureus* colonization on three commonly used orthopaedic materials with tissue culture polystyrene. *Magnification:* bar = 30 µm.

Results: Material composition may affect bacterial adhesion so we first examined the effect of four materials with smooth surfaces on colonization by *S. aureus* (Fig. 1). PEEK, Tissue culture polystyrene, and PLA all showed abundant colonization by *S. aureus*. Even after 24 hours, bacterial colonies encased in biofilm slime were apparent. In contrast, little colonization was observed on AM-Ti, with single bacteria apparently aligned in the machine grooves. We next examined the actual bacteria recovered from these surfaces (Fig. 2).

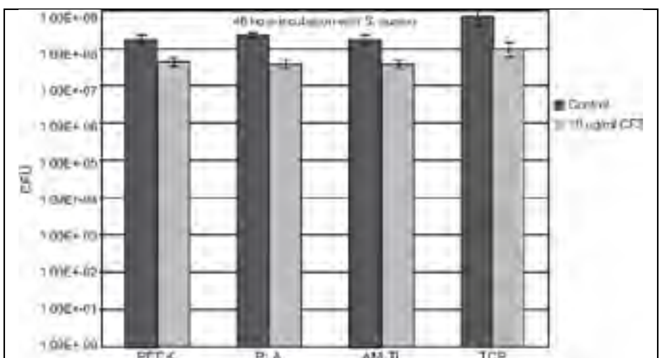

Figure 2. *S. aureus* colonization of different surfaces in the absence or presence or 10 µg/ml CFZ. Values shown are average ± S.D. for 4 independent samples in a representative experiment of four. Note log scale.

No significant differences were observed between the bacterial colonization on the four surfaces. Of note is that treatment with at least 10X the minimum inhibitory concentration of CFZ only caused a 0.5-1 log reduction in biofilm bacteria.

We next asked how the bathing medium affected biofilm formation on PEEK vs. tissue culture polystyrene (TCP). After 24 hours, adherent bacteria in the various media
toughness and impact strength, which are important for their application as load bearing implants.

in all media. In TSB, large colonies embedded in what appeared to be a thin biofilm matrix were apparent on TCP, whereas colonization on PEEK was more sparse and appeared to favor clusters that had already become encased in biofilm slime. In MHB, colonies on TCP were smaller, with individual bacteria readily apparent; this single colony morphology was more marked on PEEK. In BHI, large, indistinct colonies were encased in biofilm slime on TCP; these appeared thicker on PEEK. In 100% FBS, both PEEK and TCP showed only small 3D colonies and, again, these colonies appeared smaller on PEEK. In human SF, a fibrous matrix of bacteria was apparent on TCP; some of this fibrous character was seen on PEEK in much smaller aggregates, and in other cases, only typical biofilm encased colonies were seen (arrows) (Fig. 3). Importantly, we confirmed that bacterial aggregates from an infected joint showed localization to a fibrous matrix (Figure 4).

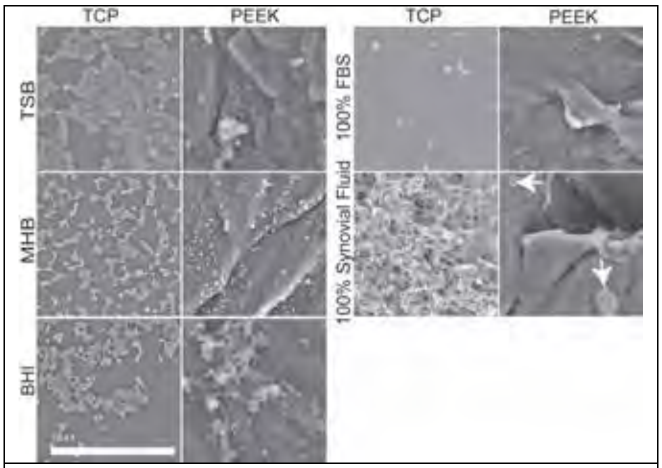

Figure 3: SEM of *S. aureus* biofilms grown in the media indicated for 24 hours on tissue culture plastic (TCP) or PEEK disks. Arrows show one normal and one fibrous biofilm formed on PEEK. Magnification: bar = 30 µm

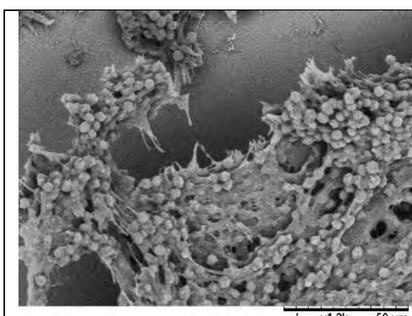

Figure 4: Aggregated *S. aureus* recovered from infected joint.

Discussion: The polymer materials, PEEK and PLA, have in our previous work shown only modest *S. aureus*. colonization. Our present work shows that colonization does not appreciably differ between these polymers and that the normal laboratory medium used for bacterial growth does not recapitulate the complicated structures observed in the physiological fluid, human synovial fluid, at least on PEEK.

Specifically, we directly compared PEEK with tissue culture plastic to determine if any inhibition of bacterial colonization can be attributed to the materials. Based on SEM images, only AM-Ti showed decreased colonization. Interestingly, the recovered counts do not suggest that the observed difference is important. We have observed that a loosely adherent biofilm is apparent over the surface of the AM-Ti, perhaps suggesting heterogenous areas of colonization.

Of particular importance in these studies is the change of biofilm character when bacterial medium is varied. The effects with PEEK are much less marked than on TCP. Our work[3,4] establishes that clumps such as those formed in human synovial fluid on TCP changes virulence factor production as well as antibiotic efficacy. The apparent underrepresentation of this structure on PEEK may suggest that because of hydrophobicity, bacterial colonization and virulence may result in different morphologies, and by implication, phenotypes, than those on TCP. Again, the two physiological media, however, suggest that protein presence may be critical. We suggest that studies of bacterial colonization of important biomaterials, like PEEK and PLA, should be performed in protein-rich physiological fluids.

Acknowledgements: Thanks to Jackie Schachtner and Daniel MacDonald, Drexel University, for assistance with preparing the PEEK and PLA specimens. The authors would also like to thank Invibio for providing the extruded rod of PEEK-OPTIMA Natural used in this study. The authors thank the NIH, NIAMS AR069119 for supporting this work.

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Characterization of the in vivo osteoconductive and in vitro antibiofilm properties of a PEEK-Silver Zeolite Composite in spine

Sankar, Sriram[1]; Crudden, Joseph[1]; Johns, W.Derrick[1]; Kraemer,Paul[2]
[1]DiFusion Technologies Inc., Georgetown, TX-USA [2] Indiana Spine Group, Indianapolis, IN 46256 .
sankar@difusiontech.com

Introduction: Polyether ether ketone (PEEK) demonstrates intrinsic inertness and hydrophobic properties, thereby resulting in an inherent susceptibility to bacterial infections and reduced fusion capacity within the intervertebral space due to fibrous encapsulation. CleanFuze™ (CF) is a bioactive PEEK- silver zeolite composite, which has recently received CE approval in Europe and is known to have infection resistive properties due to silver ions and osteoblast stimulative effects due to ceramic zeolite particles respectively.

Aim: Evaluate the efficacy of PEEK- silver zeolite in preventing in vitro biofilm formation in a biofilm bioreactor model and in promoting in vivo osseoconduction relative to PEEK in a critical sized defect.

Methods and Materials:

- **Flow Cell Biofilm Bioreactor Assay (Modified ASTM E2647).**

S.aureus (ATCC 6538) biofilm quantification was done using a Flow cell Bioreactor Model with low shear and continuous flow. Growth conditions as detailed in ASTM E2647 at 37°C were used to grow an initial inoculum dosage of $1.5*10^4$cfu's into biofilms on PEEK and CleanFuze coupons (dia=12.5mm) after 48 hrs. The quantification of biofilm/cm^2 was done via colony count technique.

- **Invivo critical sized rabbit femoral defect model:** A critical sized rabbit femoral defect model was utilized to evaluate in vivo osteoconductive properties of PEEK-Silver Zeolite (Group A) in comparison to PEEK (Group B) at 12 weeks. The study was carried out using mature nine month old New Zealand white female rabbits (n=6). A critical sized femoral defect was created in the metaphyseal region of both femurs in each animal by drilling a single unicortical hole (4.5mm diameter X 6mm deep) into the lateral distal femoral metaphysis. The two materials were implanted as dumbbell shaped implants into the defects in each femur of all 6 rabbits.Upon explantation after 12 weeks, all implants were imaged using micro-CT and un-decalcified histology(H&E and Goldner's Tri-Chrome staining)for new bone formation.

Results and Discussion:

Flow cell Biofilm Bioreactor assay:

Data at the end of 48 hrs, tabulated below, demonstrates that CleanFuze is actively anti-biofilm while PEEK is susceptible to colonization.

SPECIMEN	Initial Inoculum (CFU/cm2)	± SD	Colony Count -48 hrs (CFU/cm2)	± SD
CLEANFUZE	13274	328	752	125
PEEK	13274	328	2,831,858	38000

Invivo critical sized rabbit femoral defect model

After 12 weeks, Micro-CT imaging and H&E staining as shown in Fig.1 & Fig.2 respectively, demonstrated that PEEK Ag zeolite showed increased amount of immature new bone formation along the inner diameter of dumbbell shaped implant and increased spicule growth within the medullary canal while control PEEK implants showed minimal new bone formation within the inner diameter and displayed no distinct evidence of spicule formation along the medullary canal.

Conclusion: CleanFuze™ demonstrates enhanced invitro anti-biofilm activity and improved invivo osteointegrative properties relative to plain PEEK; thereby allowing for an alternative biomaterial in spine and orthopedics with improved characteristics.

Do Antibacterial Coatings to PEEK Influence Bone Ongrowth

Walsh WR[1], Oliver R[1], Moore S[2], Zimmerman C[2], Storey D[2], Pelletier, MH[1], Christou, C[1]

[1]UNSW Australia, Prince of Wales Clinical School, Sydney, Australia
[2]CHD Biosciences, Fort Collins, Colorado, USA
w.walsh@unsw.edu.au

Introduction: Infection following implantation of any surgical device remains a significant clinical problem. While prophylaxis to reduce infection (including use of local and systemic antibiotics) is effective, the risk of bacteria becoming increasingly resistant to the antibiotics has the potential to pose new threats to modern medicine. The World Health Organisation and other bodies worldwide have recognised that development of antibiotic resistance by microbes is one of the most important health issues facing the world. There is a clear clinical need to test the ability of new non-traditional antimicrobials to reduce infection without compromising healing at the implant – bone interface.

A novel antibacterial coating based on alpha-keto alkylperacids combined with a polymer that can be applied as a coating to implants was evaluated. This pilot study assessed if the compounds had any adverse reactions at the bone – implant interface or altered the response that has been well observed and reported with titanium PEEK.

Methods and Materials: A standardized bone ongrowth model was used, following ethical approval, to evaluate the effect of a novel antibacterial coating based on alpha-keto alkylperacids (VERIOX™) combined with a PEG polymer at the bone –implant interface. Two concentrations of VERIOX™ in PEG were coated on Titanium PEEK dowels. Titanium PEEK dowels coated with PEG alone and uncoated Titanium PEEK dowels served as negative controls. One sample from each group was randomly selected to evaluate using an environmental scanning electron microscope.

The sheep bone dowel model and endpoints have been used by our laboratory for two decades. Cylindrical dowels were implanted in the cortical bone of the tibia in a line-to-line manner (6 mm diameter implants and 6 mm hole) and cancellous bone of the distal femur in a press fit manner (6 mm diameter implants and 5.5 mm hole). Animals were euthanized at 4 weeks, radiographed and samples harvested and surgical sites carefully inspected prior to push out testing to evaluate the shear strength in the cortical bone implantation sites. Hard tissue (PMMA) histology was to evaluate the bone – implant interface in the cancellous sites as well as the cortical sites. Samples were dehydrated, embedded in PMMA, sectioned using a rotary microtome (Leica SP1600) and stained with methylene blue – basic fuschin for analysis, in a blinded manner, under light microscopy. The local tissue response at the bone – implant interface was evaluated in cortical (as well as inside the marrow cavity) and cancellous sites as per ISO 10993-6. Soft tissues overlying the implantation sites were harvested and processed for routine paraffin histology and stained with H&E. Shear stress data was analyzed using a 1-way ANOVA and a Games Howell post hoc test.

Results: The VERIOX™/PEG coating adhered to the titanium PEEK dowels and revealed a smooth surface when evaluated using an environment electron microscope.

All animals recovered uneventfully following surgery. No infections or adverse reactions were noted at the skin, subcutaneous tissues or at the bone implantation sites in cortical or cancellous bone at the time of harvest. Radiographs were uneventful and no adverse reactions were noted. Mechanical push out testing did not demonstrate any adverse reactions to the VERIOX™/PEG coating. Cortical bone histology at the bone – implant interface for all groups was normal in appearance at 4 weeks and did not present any evidence of adverse reactions from a cellular perspective. The newly formed bone on the surface of the titanium PEEK implant was intimate with the surface and no adverse reactions were observed at this interface or in the bone marrow present in the medullary canal. Similarly, cancellous bone histology as well as the soft tissues over the implantation sites was normal in appearance across all groups at 4 weeks. The VERIOX™/PEG coating was not detected histologically at 4 weeks.

Discussion: The presence of the PEG coating alone or in combination with either dose of VERIOX™ did not alter the bone – implant interface in any adverse manner based on radiographs, mechanical testing or histology. The coating appeared to resorb in vivo with no alteration in the normal healing patterns observed with this model in cortical or cancellous sites.

The work is a pilot study and is limited in terms of single time point and small sample size. The titanium coated PEEK implants provide an excellent substrate for the VERIOX™/PEG coating. The animal model did not challenge the antibacterial aspects of the VERIOX™ which could be evaluated in the future. The results support that non-traditional antimicrobials, such as those evaluated in this study, have great potential to provide a means to fight infection without risking developing superbugs.

Clinical Evaluation of a Radiolucent Carbon/PEEK Pedicle Screw System – Early Experience in Degenerative Cases with 12 months follow up

Nydegger, T[1], Klabunde, R[1], Dr. med. Markus Rühli[2] ,
[1] icotec ag, Altstätten, CH, [2] Hirslanden Klinik, Zürich, CH
thomas.nydegger@icotec.ch

Introduction: Imaging artefacts from metal spinal hardware often hamper the postoperative evaluation of the onset of spinal diseases. In particular, the exploration of the neural structures and implant position may be challenging when postoperative symptoms pertain. Preclinical studies have demonstrated that pedicle screws made of high strength, continuous carbon fiber reinforced PEEK (Carbon/PEEK) are effective in significantly reducing imaging artefacts in CT and MRI[1].
This study presents early clinical results of the first cases of transpedicular fusion with utilization of a pedicle screw system made from Carbon/PEEK.

Methods and Materials: The objective was to prospectively collect outcome information on ten consecutive patients suffering from symptomatic degenerative disc disease or degenerative spondylolisthesis requiring one or multi-level spinal fusion (mean age 72.1 yrs). Posterior stabilization was performed utilizing a pedicle screw system construct, where the screw shank and the rods are made from Carbon/PEEK (icotec, Switzerland). The pedicle screw system was combined with titanium coated Carbon/PEEK cages (icotec, Switzerland). Primary study endpoint was overall fusion rate and rate of complications as well as rate of subsequent surgical interventions were selected as secondary endpoints. Oswestry Low Back Pain Disability scores (ODI) and Visual Analogue Scale score (VAS) on low back, leg and buttock pain, the Core Outcome Measures Index (COMI) as well as patient's satisfaction scores (VAS) were collected for every patient.

Results: For the first ten consecutive patients, no pseudarthrosis was found at the six months follow up. Other complications were limited to asymptomatic screw loosening in two patients. Preoperative ODI was 54.7 (SD 13.7) which was reduced to 25.7 (SD 18.9) after six months and was at 20.4 (SD 16.5) after one year. VAS scores for low back pain was reduced from 75 (SD 32.9) to 17.5 (SD 19.9) after six months and to 9.8 (SD 12.6) after one year. VAS scores for leg and buttock pain decreased from 67.5 (SD 33.7) to 13.8 (SD 22.1) after six months and slightly increased at one year to 17.9 (SD 23.8). Overall patient satisfaction VAS lumbar score was 14.4 (SD 25.5) after six months and increased to 24.4 (SD 29.6) after twelve months. Preoperative COMI was 7.7 (SD 2.4) which was reduced to 3.1 (SD 2.9) after six months and to 2.2 (SD 2.1) after one year.

Discussion: Those early clinical outcome results compare well to other series reported in literature assessing instrumented spinal fusion outcomes[2,3,4]. The surgical technique did not differ from other standard pedicle screw systems. The use of Carbon/PEEK composite pedicle screws and rods reduced artifacts in CT and especially MR imaging. This facilitates a better postoperative evaluation of spinal structures, postoperative or late complications and assessing the onset of spinal disease. Due to the nonmetallic Carbon/PEEK material, screw positioning and potential screw loosening can be assessed in detail by MRI, therefore additional CT investigation in these cases may no longer be necessary. These promising preliminary results need to be confirmed in further multicentric trials.

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Porous PEEK Cervical Interbody Fusion Device: Initial Radiographic Results

Safranski DL[1], Lee CS[1], Smith KE[1], Gall K[2], Burkus JK[3]
[1]Vertera Spine, Atlanta, GA, [2]Duke University, Durham, NC, [3]The Hughston Clinic, Columbus, GA
david.safranski@verteraspine.com

Introduction: Degenerative disc disease affects more than 60% of individuals over the age of 40. It is typically treated by spinal fusion of the neighboring vertebrae with approximately half a million procedures performed domestically each year. Many interbody fusion devices (i.e. cages) are made from PEEK due to its high strength, radiolucency, and similar stiffness to bone. However, smooth-surfaced PEEK cages have been associated with fibrous encapsulation and implant migration, resulting in failed fusion rates as high as 11-15%. Therefore, a technology that can enhance bony tissue-in-growth into PEEK cages would address a significant unmet need for spinal fusion devices. Recently, the 1st porous all-PEEK cage with a continuous porous architecture on the superior and inferior surfaces was FDA 510(k) cleared. The purpose of this study is to evaluate the radiographic results from a series of cases using the porous PEEK cage (Cohere™).

Methods: Nineteen patients undergoing anterior cervical fusion surgery have been implanted with a porous PEEK cage (Cohere™) (Figure 1). In this series of patients, there are fourteen females and five males with an average age at surgery of 60 years (range 42 – 78 years). Seven patients (37%; 7/19) had single level fusions; twelve (63%; 12/19) had multi-level fusions. Nine patients had prior cervical fusion surgery. There have been no complications following the use of these implants.

Results: A 64-year-old female had undergone two prior cervical fusions in 1982 and 1997. She had developed adjacent segment degeneration at the C3-4 cervical level. Lateral radiograph shows disc space collapse, radial osteophyte formation and sagittal plane malalignment (retrolisthesis and kyphosis) at C3-4 (Figure 2). At three months following surgery, lateral radiograph shows restoration and maintenance of anatomic disc space height, segmental lordosis, and normal sagittal alignment (Figure 3). Importantly, there are no lucencies around the porous PEEK implant. An uninterrupted, continuous column of bone is seen through the central portion of the porous PEEK implant with complete integration of the bone graft to the bony endplates of the adjacent vertebra.

Discussion: These results indicate that radiographic fusion occurs as early as 3 months with the porous PEEK cage. Furthermore, this case illustrates the successful application of an interbody fusion device in a challenging healing environment because the surgical level was adjacent to a prior fusion in a female. Future studies will evaluate clinical and biomechanical metrics after fusion and at longer timepoints.

Figure 1: Porous PEEK cervical cage (Cohere™).

Figure 2: Lateral radiograph shows severe disc space narrowing adjacent to prior fusions with loss of segmental lordosis, retrolisthesis of C3 on C4.

Figure 3: Lateral radiograph shows complete incorporation of bone grafts with no lucencies around COHERE implant. Anatomic disc space height and sagittal alignment has been maintained by the interbody implant.

Clinical Experience with a Carbon/PEEK Pedicle Screw System for the Treatment of Spinal Tumors

Eicker, SO[1] , Nydegger, T[2] , Klabunde, R[2] , Süss, O[3] ,
[1] Hamburg-Eppendorf University Hospital, Hamburg, GER, [2]icotec ag, Altstätten, CH, [3] DRK Kliniken Berlin Westend, Berlin, GER
thomas.nydegger@icotec.ch

Introduction: The spinal column is the most common location for skeletal metastases with up to 40 % spinal metastasis in cancer patients (Singh et al.)[1]. In the decision for surgical treatment, decompression of neural structures and stabilization of the spinal column with dorsal and ventral implants is often required. For pain control and local tumor control, supplemental radiation therapy is often applied postoperatively. As radiation therapy planning is based on CT data, imaging artifacts from metal hardware present a major hurdle for accurate irradiation planning, appropriate dose delivery during radiotherapy as well as post-op tumor control in CT and MRI. Pedicle screws, made of carbon fiber reinforced Polyetheretherketone (Carbon/PEEK), present a clinical alternative.

Methods and Materials: In a series of 32 consecutive patients (treated between 2013 and 2016, mean FU 11.4 (SD 7.1) months) with metastatic thoracic and/or lumbar tumor disease, treated in two centers, all patients were instrumented with a Carbon/PEEK pedicle screw system (PSI, icotec ag, Switzerland). The Carbon/PEEK pedicle screw had a screw shank made from high-strength Carbon/PEEK with only the tulip and set screw being made from titanium. The screw can be combined with rods made of titanium or Carbon/PEEK.
In one center pathologic fractures and epidural tumor invasion was located between T4 and T11. After microsurgical decompression surgery with epidural tumor excision, a dorsal instrumentation including one to two levels above and below the target level was implanted. In all cases, titanium rods were used. In the second center the number of instrumented levels (between T5 and L1) was subdivided into a cohort limited to three consecutive spinal segments were high stiffness Carbon/PEEK rods were used and a cohort with longer constructs and titanium rods. Intraoperative handling, X-ray guidance during implantation and postoperative visualization of four regions (dural sac, neuroforamen with the exciting nerve roots, pedicle and vertebral body) was assessed. Diagnostic imaging quality was compared against titanium spinal hardware in five degenerative cases and five tumor cases. Imaging quality was graded into good, moderate or poor. CT and MRI scans as well as prospective clinical data collection were performed pre- and postoperatively. All tumor patients underwent subsequent radiotherapy.

Results: In both centers, intraoperative handling of the Carbon/PEEK screws (ø 5.5 and ø 6.5 x 35 - 55 mm) was identical to full titanium implants due to similar screw design/geometry and surgical implantation technique. Radiographic control during surgery required only a short learning curve of the “invisible” screws, as markers in the screw tip, the titanium tulip and the rods facilitate implant orientation. Radiolucency of the screw shank helped in identifying the implant position and evaluating the pedicle in lateral as well as in a-p X-rays.
The complication rate was generally low: screw breakage: 0%; radiologic signs of screw loosening: 3.75%, with need for surgical revision: 0%; deep wound infection: 1/32).
Postoperative CT scans demonstrated distinctive intracorporal radiolucency und sharp delineation at the screw thread and bone interface. This lead to an excellent visualization of anatomic details adjacent to the implants, with the exception of the posterior region around the titanium tulip of the screw. Evaluation confirmed a good visualization in all four regions except one case due to restlessness of the patient during the examination with corresponding artifacts. In MRI imaging no artifacts were detectable around the screws shanks. This allowed a thorough evaluation of all four diagnostically relevant regions. In a retrospective evaluation of ten cases treated with titanium screws a poor to moderate visualization quality of the same areas was found. In radiation therapy, irradiation foci and dose distribution (30-36Gy) were easier and more precise to specify in contrast to the planning with present metal artifacts (Mesbashi et al. and Son et al.)[2, 3].

Discussion: Titanium implants can cause considerable difficulties in irradiation planning and significant errors in proton dose calculation, for example in the treatment of spinal chordomas[4].
In the present study, the reduction of metal artifacts as a result of the use of Carbon/PEEK pedicle screws improved postoperative assessment of neural and anatomical structures close to the implants.
Less metal artifacts allowed accurate and rapid radiation therapy planning, and may have reduced beam scattering into surrounding tissue and organs. Moreover, the monitoring of recurrent disease may be facilitated in the ongoing follow up of the enrolled tumor patients.
Furthermore, the ultra-thin titanium coating in the pedicle anchoring area of the screw may be reason for good osseointegration as indicated in the present study. Our findings need to be statistically confirmed by further randomized multicenter studies.

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Feasibility of Radiostereometry for Assessment of Healing of Proximal Humeral Fractures

Martin Downing[1], Alan J Johnstone[2], G Patrick Ashcroft[1]
[1]Aberdeen University, Scotland. [2]Aberdeen Royal Infirmary, Scotland.
m.downing@abdn.ac.uk

Introduction: Sufficient early stability of proximal humeral fracture (PHF) is an important factor in outcome. In principle, fracture stability can be assessed using radiostereometric analysis (RSA). This is a stereo x-ray imaging technique used in orthopaedic research in which involves locating the three dimensional position of millimeter sized tantalum markers implanted during surgery into the bone segments. Relative movements of bone segments can then be determined with sub millimeter accuracy on subsequent examinations.
Our planned clinical study will follow patients who have received a plated fixation of a proximal humeral fracture using a PEEK implant. We will investigate whether there are changes in stability of the fracture during healing. In particular, we will assess the fracture and plate stability under the loading produced by patient rehabilitation exercises. In order to make these assessments the patient's humerus must be imaged at different positions. However, the accuracy of RSA may be affected by positional changes between images, by size of the fracture segments studied and by the visibility of the tantalum markers which may be occluded by metal plates and humeral plate.
The aim of this in-vitro study was to assess these errors so that we could determine whether the technique was feasible for use in a clinical study.

Methods: In order to simulate a rigidly fixed 3 to 4 part proximal humeral fracture, a phantom was constructed from a humeral orthopaedic bone model (Sawbones Washington USA). A carbon PEEK proximal humeral plate (Carbofix Orthopaedics) fixed to the model with titanium screws proximally and steel distally. Tantalum markers (0.8 and 1.0mm) were inserted into the Greater tuberosity 6, lesser tuberosity 3, head 7, and shaft 6. The model was imaged using an upright RSA protocol and moved through the imaging volume replicating the expected variability of an upright patient RSA exam with differing arm orientations used for the different rehabilitation loading (figure 1). The procedure was then repeated with small variations to the model and xray system position a number of times, which simulated the variation expected between imaging visits. The position of each proximal segment was compared to the reference shaft segment, any relative movement observed was taken to be error since the whole model was rigid. The relative movement of fracture segments were compared between 43 image pairs, giving 903 comparisons. These were grouped according to the extent of rotation between exams for statistical analysis. The measurements were compared for our system with standard calibration supplied by the manufacturer (RSA Biomedical AB, Sweden) and with a new calibration data which was determined previously.

Figure 1. Bone model held in a horizontal position in the upright patient stereo imaging setup.

AC	Tx	Ty	Tz	T	Rx	Ry	Rz	R
0	0	2	4	4	6	5	1	8
8	16	7	11	20	18	89	14	92
45	26	24	62	72	57	111	23	127
90	21	63	26	71	42	143	36	153

Table 1. Segment 12 errors grouped by angle between exams. AC is the average angle between the exams. T translational error (um) in x y z and total. R rotational error (thousandth of a degree) in x y z and total.

AC	Tx	Ty	Tz	T	Rx	Ry	Rz	R
0	0	1	4	4	6	5	1	8
8	16	9	16	25	23	89	16	93
45	42	84	37	101	103	77	41	135
90	53	138	36	152	104	122	65	173

Table 2. Segment 12 errors with original calibration data.

Results: Seven markers were placed in the shaft as the reference segment, within a volume of 10cm3, giving a spread condition number (CN) of 54. Seven markers were placed into the proximal head segment, within a volume of 20 cm3, giving a CN of 33. Six markers were placed in the greater tuberosity, within a volume of 4 cm3, giving a CN of 66. Finally three markers were placed in the lesser tuberosity with a linear spread of 2cm but a volume of only 0.1cm3, giving a CN of 508. Tables 1 and 2 show the errors for the movement of the head segment with reference to the shaft with increasing angular difference between compared exams. The error for both translation and rotation increases with comparison angle. However this is reduced by the recalibrated system (table 1) compared to the original

Randomised controlled clinical trial investigating PEEK versus Cobalt-Chromium Removable Partial Dentures on periodontal health, chewing ability and oral health related quality of life

Ali Z[1], Baker SR[1], Sereno N[2], Martin N[1]
[1]University of Sheffield, Sheffield, UK. [2]JUVORA Ltd, Thornton-Cleveleys, UK
ali.zaid283@gmail.com

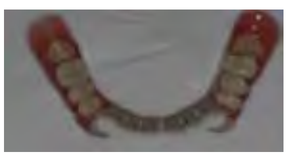
Introduction:

Patients with missing teeth have reduced chewing efficiency and have been shown to have negative impacts on their oral health-related quality of life (OHRQoL). Removable partial dentures (RPD) are used to restore oral function; chewing, speaking and smiling and have been shown to have a positive effect on OHRQoL. RPDs have supporting frameworks, which attach to teeth and are veneered with aesthetic materials for the tooth and gum replacement. Traditional materials for the fabrication of RPD frameworks include cast metals including Cobalt-Chromium (Co/Cr) and Titanium alloys.

A significant clinical concern in removable prosthodontics is plaque retention and impact on the periodontal health of supporting teeth[1]. This, if not adequately controlled by patient's oral hygiene can cause an exacerbation of gum disease to remaining teeth. This can cause pocketing, where crevices open in the gums around teeth. Signs of disease progression are pockets deeper than 3mm or bleeding. Measures of gum disease include probing pocket depths (PPD), Bleeding Index (BI) and Plaque Index (PI).

Milling allows the use super-polymer materials; poly-aryl-ether-ketones (PAEKs) in prosthodontics. The JUVORA Dental Disc™, a medical grade poly-ether-ether-ketone (PEEK) suitable for milling, has been introduced to the dental market[2].

We aimed to compare the effects of RPDs from PEEK, JUVORA™ Clasp Dentures, versus Co/Cr frameworks on OHRQoL, chewing ability and periodontal health.



Methods and Materials:

30 patients were invited to this randomised crossover-controlled clinical trial. Patients with extensive tooth decay and gum disease or symptomatic dental infections were excluded.

26 patients were provided with RPDs with PEEK and Co/Cr frameworks of same designs, optimized for the dental material, and were randomly allocated to wear one denture for 4 weeks. They returned for full assessment, full mouth cleaning and given the second denture for 4 weeks before final review when they selected preferred denture. Patients were then reviewed at 6-months and 12-months review periods.

At baseline and each review evaluations of gum health including PPD, BI and PI.

Patient questionnaires were used from the following validated Person Centred-Outcome Measures:

1. The McGill Denture Satisfaction Instrument to assess chewing ability.
2. The 20-item Oral Health Impact Profile (OHIP-20) to measure oral health-related quality of life (OHRQoL).

Both questionnaires were scored using a Likert Scale (0=Least Impact/Very Easy, 4=Highest Impact/Greatest Difficulty). The maximum score for OHIP-20 was 80-points representing worst OHRQoL, and minimum score of 0 representing best OHRQoL. The minimum change that patients can perceive as clinically meaningful (MCID) is 7-points[3]. The maximum score on chewing ability was 40-ponts representing worst ability and minimum score was 0-points representing maximum ability.

Results:

At 4 weeks 25 patients returned, 13 preferred the JUVORA™ Clasp Denture and 12 preferred the Co/Cr denture. 21 patients returned for 6-month evaluation. 12 preferred the JUVORA™ Clasp Denture against 9 preferring Co/Cr.

Mean OHIP-20 scores at 6-months evaluations were 16.22 points (SD=12.73) for Co/Cr, mean improvement from baseline 9.22 points (SD=14.46), and 11.67 points (SD=11.43) for JUVORA™ Clasp Dentures, mean improvement 15.17 points (SD=18.85).

Median scores for chewing ability were 13 points for both dentures at 4-week review. At 6-months, patients wearing JUVORA™ Clasp Dentures chewing score was 12-points (IQR 6-14.5 points). Patients wearing Co/Cr at 6-months scored 10-points (IQR 4-13 points) for chewing ability.

At 6-months, in patients wearing JUVORA™ Clasp Dentures: mean PPD was 1.44mm, mean BI was 5.78% and mean PI was 54.96% at 6-months. In patients wearing Co/Cr dentures: mean pocket depth was 1.68mm, mean BI was 12.57% and mean PI was 49.21%.

Discussion:

52% of participants preferred the JUVORA™ Clasp denture at 4 weeks and 57% preferring it at 6-months recall. At 6-month review, mean improvement in OHIP-20 scores from baseline was 6-points higher in the JUVORA™ Clasp denture group. This falls slightly short of the minimum clinically important difference (MCID) of 7-points. The mean improvement in OHIP-20 from baseline in both dentures met the MCID.

There was no difference between denture materials in terms of patient's chewing ability.

Markers of gum disease were similar in both dentures, JUVORA™ Clasp denture showing a slight reduction in BI and a slight increase in PI at 6-months. The difference in PPD 0.24mm, is too small to be clinically meaningful indicating the JUVORA™ Clasp Denture was no more detrimental on periodontal health than the Co/Cr framework RPDs.

The use of PAEK materials in fixed and removable prosthetic dentistry remains a novel introduction to clinicians' armamentarium and requires further, long-term clinical trial research.

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Total TMJ Prosthesis in PEEK

Genovesi, W[1]
[1]Nove de Julho Hospital, São Paulo, Brazil
Wladimir.genovesi@h9j.com.br

Abstract: The TMJ (temporo mandibular joint) is a complex joint, with distinct anatomical and functional characteristics of difficult treatment. Many authors, from the early twentieth century, reported techniques for TMJ reconstruction, aiming to return to their ideal shape and function. Many prototypes have been developed in search of the ideal prosthesis, which adheres to the principles of biomechanics and biocompatibility, with good long-term performance and lower cost. Based on 10 years of experience with 125 patients who underwent reconstruction using full custom TMJ prosthesis in gold (unilateral or bilateral) had been developed a new surgical technique less traumatic, with a prosthesis that features functional design and less recurrence. Because of the high cost of gold alloys, ensued in search of a suitable material, to follow the ideal characteristics. Among the new material, highlights the PEEK, a polymer derived from petroleum (Invibio, UK), thermoplastic, biocompatible, inert and high stability, resistance and compared with others materials, it is like a feather. Successfully used as a choice for orthopedic implants and column material, it presents coefficient aggregation fibrocytes very low on its surface. This study demonstrates the feasibility of a custom prosthesis PEEK, with protocol development for TMJ reconstruction.

Wear of Highly Crosslinked UHMWPE Against an Advanced Polymer to Prevent *In Vivo* Trunnion Corrosion

Wannomae, KK[1], Lozynsky, AJ[1], Konsin, ZB[1], Muratoglu, OK[1,2]
[1]Harris Orthopaedic Laboratory, Massachusetts General Hospital, Boston MA
[2]Harvard Medical School, Boston MA
omuratoglu@mgh.harvard.edu

Introduction: Corrosion of the femoral head-trunnion junction in modular hip components has become a concern as the corrosion products may lead to adverse local tissue reactions. A simple way to avoid trunnion corrosion is to manufacture the femoral head with a non-metallic material, such as ceramics that are widely. An alternative solution may lie in advanced polymers like polyaryletherketones (PAEKs). These thermoplastics have high mechanical strength necessary for use as femoral heads in hip arthroplasty, but they must be tested to ensure that they do not adversely affect the wear of the ultrahigh molecular weight polyethylene (UHMWPE) liner counterface. Pin-on-disc (POD) wear testing has been extensively used to evaluate the wear properties of UHMWPE prior to more extensive and costly analysis with joint simulators. We hypothesized that the wear of crosslinked UHMWPE would not be adversely affected in POD tests when articulated against an advanced thermoplastic counterface.

Methods and Materials: 0.1 wt.% vitamin E blended UHMWPE stock (VitE-PE) was e-beam irradiated to 100, 125, 140, 160, and 175 kGy and machined into cylindrical pins for testing. An additional group of 100 kGy e-beam irradiated and melted UHMWPE (with no vitamin E) was also machined and tested.

Three different counterface materials were tested (Figure 1): (1) Cobalt-chrome (CoCr) with a surface roughness (R_a) of <0.05 µm, (2) Biolox™ ceramic (CeramTec), and (3) Polyetheretherketone (PEEK), a member of the PAEK family.

Figure 1: A representative disc from each counterface material: PEEK (top), Biolox™ ceramic (middle), and polished CoCr (bottom). The hemispherical indentations on the ceramic disc were part of the fixation mechanism to hold the disc in the test basin; they were located far from the area of articulation so they should not have affected the wear of the UHMWPE pins. Note that machining marks can still be seen on the PEEK disc – the material was tested as-machined; the other two discs had highly polished surfaces.

A bidirectional POD wear tester [1] was used to measure the wear rate of UHMWPE specimens, where the specimens moved in a 10 mm × 5 mm rectangular pattern under a Paul-type load curve [2] synchronized with the motion. The peak load of the loading curve corresponded to a peak contact pressure of 5.1 MPa between each UHMWPE pin specimen and the counterface disc. Each test was conducted at 2 Hz in undiluted bovine serum stabilized with ethylenediamine tetraacetate (EDTA) and penicillin. The pins were cleaned and weighed daily, and a wear rate was calculated at the end of each week-long test by linear regression.

Results: As expected, higher radiation doses led to lower wear rates against all counterface materials (Table 1). The PEEK discs produced the lowest UHMWPE wear in each group and the CoCr discs produced the highest UHMWPE wear; however, the two UHMWPE groups with the lowest wear rates showed no difference between the three counterface materials.

Table 1: Calculated linear wear rates of the six different highly crosslinked UHMWPE formulations when articulated against the three counterface materials. A total of 3 pins of each UHMWPE formulation was tested against each counterface material.

	Wear Rate (mg per 10^6 cycles)		
	CoCr	Ceramic	PEEK
100 kGy VitE-PE	4.0 ± 0.4	3.1 ± 0.6	2.5 ± 0.4
125 kGy VitE-PE	3.1 ± 1.4	2.4 ± 0.2	1.9 ± 0.4
140 kGy VitE-PE	2.7 ± 0.5	1.8 ± 0.0	1.2 ± 0.3
160 kGy VitE-PE	1.7 ± 0.4	1.4 ± 0.0	1.0 ± 0.2
175 kGy VitE-PE	1.0 ± 0.2	0.9 ± 0.1	1.0 ± 0.2
CISM-100	1.3 ± 0.2	1.2 ± 0.7	0.8 ± 0.0

Discussion and Conclusion: Even though the PEEK discs had visible machining marks – that is they were not polished to an implant surface finish – they still yielded the lowest wear rates for UHMWPE articulating against them when compared to the highly polished and smooth CoCr and ceramic materials. Implementing further steps to better the surface roughness of the PEEK counterface may yield even better wear rates. Using PEEK in femoral heads may alleviate issues with trunnion corrosion without increasing the incidence of osteolysis or other wear related issues.

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Wear Properties of Poly-ether-ether-ketone Bearing Combinations under High Cross Sheer and Linear Sliding Environments

Kathryn Chamberlain[1], Kenny Rankin[1], Adam Briscoe[2], Philip Hyde[1]
[1]Newcastle University, Newcastle Upon Tyne, UK
[2]Invibio Biomaterial Solutions Thornton-Cleveleys, UK
Philip.Hyde@ncl.ac.uk

Introduction: PEEK-OPTIMA™ (Poly-ether-ether-ketone, produced by Invibio Ltd, hereafter referred to as PEEK) has shown good biocompatibility and wear properties in spinal applications. The behaviour of PEEK based bearings for other joints is less well known. It is well-documented that ultra-high molecular weight polyethylene (UHMWPE) exhibits a very large range of wear behaviour dependent upon the amount of cross shear (CS) present in the bearing motion. CS is defined as the amount of multi-directional sliding motion of the bearing surfaces, therefore, zero CS means purely linear sliding motion. The behaviour of PEEK bearing combinations under a range of CS conditions is much less understood compared to UHMWPE.

The aim of this study was to compare PEEK articulating on PEEK (PKoPK) and PEEK on highly polished metal (PKoM) bearings under two CS conditions: zero CS and high CS. A pin-on-plate (PoP) test rig was used to assess bearing wear of test pins and test plates.

Methods and Materials: PKoPK studies used PEEK-OPTIMA™ (Invibio Ltd) pins, with a contact diameter of 3 mm, and counter-bearing plates with a mean surface roughness (Ra) of 1.54 µm and 0.030 µm respectively. Soak controls were used to ensure accurate, soak-compensated wear data. For PKoM studies Stainless Steel 316 L metal plates were polished to a Ra < 0.05 µm.

All tests were conducted on a four station PoP test rig capable of uni- and multi-directional motion: reciprocation (1 Hz), rotation (0 or 1 Hz), 20 mm sliding distance and 33 % new born calf serum equating to 22 g/L protein concentration as the lubricant.

Prior to data collection, samples were cleaned using Virkon, iso-propanol and distilled water then left to air dry for 48 hours before being weighed. Gravimetric analysis was performed and the wear factor k (mm^3/Nm) calculated using the formula below, where; V is the volumetric wear (mm^3), L is the applied load (N) and D the total sliding distance (m).

$$k = \frac{V}{LD}$$

Statistical Analysis was performed using a one way ANOVA with 95 % confidence intervals and Tukey post hoc test. Statistical difference was defined as $p < 0.05$.

Results: Under multidirectional high CS conditions the wear factor for the PKoM pins recorded was (1.5 ± 0.76) x10^{-5} mm^3/Nm, which is in agreement to that reported previously [1] and significantly ($p < 0.05$) higher than for the PKoPK pins.

The total PEEK wear factor for PKoPK bearings subject to multidirectional high CS motion was (7.93 ± 2.62) x10^{-6} mm^3/Nm. This was significantly higher ($p < 0.05$) than that of the unidirectional zero CS wear factor of (3.38 ± 1.47) x10^{-6} mm^3/Nm and was visibly noticeable from the wear scars present.

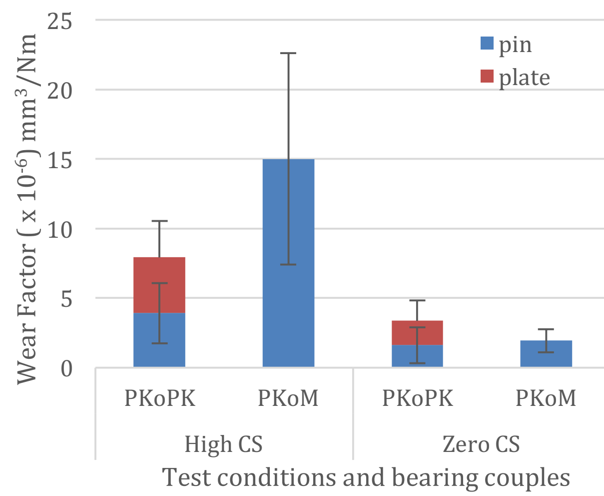

Figure 1: *Wear factors for PKoPK and PKoM bearing couples under high CS and zero CS conditions. Error bars are ± SD.*

Discussion: The effect of CS on the wear performance of PKoPK and PKoM bearing couples under identical test conditions was investigated. *Figure 1* highlights the drastic increase in wear of the PKoM pins when subject to high CS multidirectional motion, compared to the non-significant ($p > 0.05$) increase for PKoPK. However, the total PKoPK wear factor under high CS motion was higher than those reported for UHMWPE on polished metal under similar test conditions [2].

Comparing the total wear of each bearing couple, it appears preferable to use PKoM bearing couples under linear motion and PKoPK for high CS applications.

In conclusion, this study suggests that the wear rates of PEEK-OPTIMA™ are CS dependent when articulating on hard counter-bearings and less CS dependent when articulating on polymer counter-bearings.

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Tribological, Mechanical and Thermal Properties of Graphene/PEEK Composites

J. Morris[1*], R. Ríos[1], M. Castro[2], P. Castell[3], J.A. Puértolas[1]

[1]Instituto de Investigación en Ingeniería de Aragón, I3A, Zaragoza, Spain

[2]Instituto de Ciencia de Materiales de Aragón, ICMA, Zaragoza, Spain

[3]Centro Tecnológico AITIIP, Zaragoza, Spain.

754278@unizar.es

Introduction: Polyetheretherketone (PEEK) has gained much popularity as a biomaterial for trauma, spine, and orthopaedic applications due to its high mechanical performances, chemical stability, radiolucent properties, and good tribological properties. In order to enhance these properties, different reinforced composites have been developed, of which carbon-fiber has been most commonly implemented (CFR-PEEK) [1].

The use of graphene as a filler in polymers [2] can be attributed to its high intrinsic performance in stiffness and mechanical resistance, given by its high elastic modulus of 1 TPa and strength of 130 GPa. On the other hand, a greater surface area of graphene should provide more interfaces with the matrix, increasing the load transfer capability and strength of the composites. Concerning chemical stability, the presence of a network of conjugated double bonds provides a large electron donor–acceptor capacity with the ability to easily react with free radicals [3]. Finally, the two-dimensional structure of graphene, like other carbonaceous materials, points to the potential use of graphene as a high-performance solid lubricant or as an additive in liquid lubricants [4].

The aim of this work is to achieve graphene/PEEK composites with high stiffness and strength for devices to support higher loads, and with lower coefficients of friction and wear factors against standard counterparts capable of substituting metallic components in total joint replacement. Therefore, we will assess the influence of graphene reinforced PEEK composites concerning tribological, mechanical, and thermal properties.

Materials and Methods:

PEEK 150 P grade was provide in pellets by Victrex plc, UK.

Graphene nanoplatelets (GNP), avanPLAT-40® (Avanzare, Spain) were obtained by the mechanical exfoliation of graphite, with a lateral size of 40 µm, a thickness of 10 nm, and composed of approximately 30 layers.

Composite samples (GNP/PEEK) for each test were prepared by a GNP and PEEK powder blending in an extrusion-compounding machine Coperion ZSK 26, (Coperion GmbH, Germany) followed by an injection molding process using JSW 85 EL II injection machine (JSW Plastics Machinery Inc., USA). The final composites presented 0, 1, 3, 5, and 10 wt% of GNP.

Mechanical tests:

Uniaxial tensile tests were conducted according to ASTM D638M on an Instron machine (model 5565). From the stress-strain curves the following mechanical parameters were obtained: Young´s modulus, E, ultimate tensile strength, σ_{UTS}, deformation of fracture, $\varepsilon*$, and work of fracture, W. Three-point flexural testing on samples of 10x4x80mm were also performed at 2mm/min.

Tribological measurements:

A ball-on-disk tribometer (CSM instruments; Switzerland) allowed monitoring of the coefficient of friction (COF) for all the composites through 180 m of displacement. GNP/PEEK disks were immersed in deionized water, and an alumina ball of 6mm in diameter, with an average roughness, R_a= 0.05 ± 0.02 µm was used as a counterpart. The applied load was 5 N, the radius of the circular track 2 mm, and the temperature 37 ◦C.

Thermal experiments:

Thermograms were conducted by a Q2000 TA differential scanning calorimeter, DSC, (TA instruments, USA) at 10 ºC/min to obtain crystalline and amorphous contents. A heat of fusion of 130 J/g and a specific heat jump at the glass transition of 0.27 J/g K were considered for 100% of crystalline and amorphous phase, respectively. Thermal conductivity, k, data were performed at 19±1ºC along the thickness direction of the bending test sample using a TCi™ thermal conductivity analyzer (C-Therm Technologies, Canada).

Results and Discussion

Thermal results: DSC experiments reveal that the addition of GNP do not modify significantly T_m = 347-348 ºC or the crystallinity content, 38 % of the unfilled PEEK, although a minimum of this last parameter, 34 %, appears at composites with 3 wt% of GNP. However, glass transition shifts to higher temperatures with the addition of GNP, starting at 120 ºC for unfilled PEEK against 135 ºC for composites, which would indicate that the fillers hinder the segmental mobility of the polymer chains of the amorphous phase. The calculated content of this phase covers the range between 26 to 32 %. The rest of phase material, 31-39%, is attributed to a so-called rigid amorphous phase without a clear correlation with GNP weight fraction.

Thermal conductivity presents a value of 0.53 ± 0.02 W/mK for the unfilled polymer and a minimum around 0.44 W/mK for 3-5 wt% of GNP. The absence of an enhancement of the thermal conductivity with the GNP content could be related to a decrease in the degree of crystallinity and/or of orientation together with the lack of a good dispersion of the GNP, which avoid the formation of an effective thermally conductive network in the PEEK matrix.

Mechanical results: Tensile testing showed a positive correlation between the wt% GNP concentration and Young`s Modulus or flexural modulus. At 10 wt% these values were 2.5 and 3.7 GPa, respectively, corresponding to a 37 % and 17 % increase with respect to the unfilled PEEK values. Tensile strength, however, presented a slight decrease when increasing the GNP weight fraction, from 105 MPa for pure PEEK to 90 MPa at 10 wt% (Figure 1). However, the introduction of GNP produced a strong decrease in the elongation at break. This behavior is similar to that found by Yang et al [4]. The lack of a good dispersion between GNP and PEEK powder provokes the formation of GNP aggregates that act as stress concentrations, generating a premature fracture.

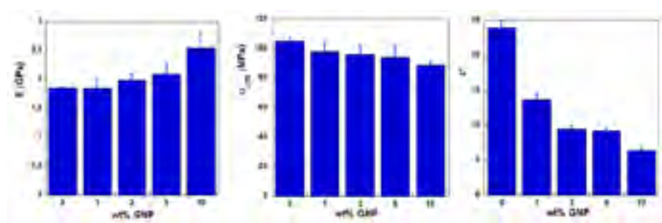

Fig 1. Mechancial properties of the unfilled PEEK and its GNP/PEEK composites.

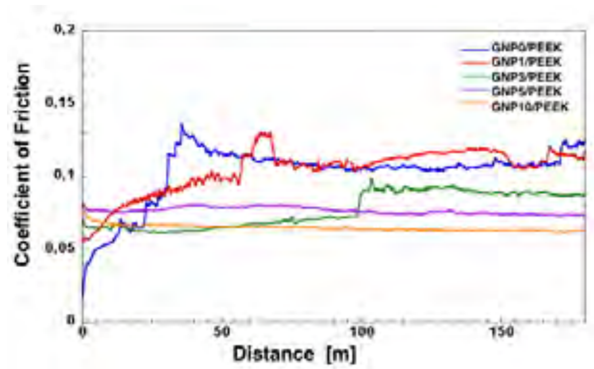

Fig 2. The evolution of the coefficient of friction in unfilled PEEK and its graphene-based (GNP/PEEK) composites.

Tribological results: The evolution of COF with the sliding distance reached, after the running regime, a plateau for all the materials. Tribometer testing showed a decrease in the coefficient of friction at this stationary regime as the percentage of graphene in the sample increased, from 0.11±0.02 for the unfilled PEEK to 0.065±0.003 for the 10 wt% of GNP composite. Some noise and instability are seen; however, even so, the correlation between friction coefficient and filler content is evident (Figure 2). This outcome confirms the lubrication capability of graphene. Besides, a higher number of layer in GNP (around 30 in our work) improve COF according to Kaway experiments [5]. General explanations of this behavior are based on a better interlayer sliding and in the out-of-plane elastic deformation generated by the displacement of the indenter on the graphene sheets, which is higher in thinner sheets, providing high resistance to the movement of the indenter.

Conclusion:

The incorporation of GNP in PEEK in amounts around 3-5 wt% can reduce strongly the frictional coefficient without altering the elastic modulus and strength, although new preparation methods (functionalization of graphene or the use of solvent) must be assessed in order to increase the toughness. In addition, wear measurements should be conducted to confirm these preliminary high tribological performances of graphene as a reinforcement of PEEK.

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New biotribological experiment for joint replacement materials

Štefan, J[1], Daniel, M[2], Fulín, P[1], Heřt, J[1], Popelka, S[1], Jahoda, D[1] , Pokorný, D[1]
[1]1st Department of Orthopaedics, 1st Faculty of Medicine, Charles University in Prague and Motol University Hospital, Prague, CZE [2]CTU in Prague, Fac. of Mechanical Eng. Dept. of Mechanics, Biomechanics and Mechatronics, Prague, CZE
jan.stefan@lf1.cuni.cz

Introduction: Average lifetime of artificial joint replacements has continuously increased during the last few decades, but the wear of articulating surfaces is still a major limiting factor. A joint replacement is not usually destroyed directly by the loading of articulating components. The crucial problem is connected with wear particles, which are produced by wear. The mechanism of wear of a typical joint replacement is a combination of adhesion, abrasion by roughness or second-body action (particles from metal component or bone cement), fatigue and corrosion. Deposition of wear particles between bone and joint replacement stem causes inflammation of surrounding tissue and aseptic loosening. Many different materials were tested over the years, but UHMWPE has remained to be the gold standard for decades. However, even after many of its improvements were introduced over time, it is still far from perfect and great effort was put into brand new material research. PEEK is one of new materials already being used in orthopaedics that may surpass its older rival. There are PEEK modifications with superior structural strength, enabling use of thinner portions of material; which is beneficial for example for hip replacements, where thinner cap insert means a possibility of use of a larger head and therefore better implant stability. However, further research of new PEEK variants and modifications has to be done. In vitro experiments are necessary for prediction of the wear rate of material pairs and thus lifetime of replacement. Two methods exist today to experimentally assess the wear rate. The first one is represented by experiments using standard tribological devices (pin-on-disc, ring-on-disc, 3 balls test, etc.). These experiments are usually simple, quick and cheap, making them a natural first step. The second is actual replacement testing using special loading simulator, which mimics mechanical and physical conditions during daily activities so results are much more precise, but these realistic tests are naturally more expensive and time consuming. This poster deals with the new concept, which is a compromise between two approaches mentioned above. Geometry of testing samples is still very simple and their relative movement and loading involves wear phenomena that are present in implanted joint replacements as cross-shear and combination of rolling and sliding. One can say that this universal test can simulate both wear of ball-shaped joint replacement (hip, shoulder, toe, etc.) and wear on/under knee joint condyles.

Methods and Materials:

New biotribological wear experiment was proposed. An articulating pair consists of spherical head (R=8mm) and cup (R=16) articulating each other. They perform two relative rotations (IE=±18°, FE=±15°) and relative sliding (AP=±1mm). Theoretical contact point orbits a “flattened eight curve”. The constant axial force was set at 200N. Utilized simulator controls movements using accurate step motors and it controls loading force using hydraulic piston with proportional valve. Each tested pair underwent 250,000 loading cycles at frequency 0,5Hz (two “eight curves” per second). Two lubricant liquids, kept at a constant temperature 37±0,5C°, were tested: 1) distilled water and 2) bovine serum solution. Two materials of cups: pure UHMWPE (n=24) and pure PEEK (n=4) and many material variations of heads (CoCrMo, Ti grade 5 and βTi alloys variously technologically treated with and without DLC coatings) were used. The wear of all cups was identified with their volume lost. The geometry of cups were scanned after loading test using optical 3D coordinate measuring machine RedLux (accuracy=1µm). Articulating surfaces of the cups were scanned at 7200 points. Two ways of wear evaluating were used. In the first, worn sub-area was manually identified and removed and the Gaussian best-fit sphere was generated to the rest of points. Then the map of radial deviations between scan and reference best-fit sphere was computed. Three characteristic dimensions of worn scares were measured manually: a) length of a scar (in the direction of sliding), b) width of the scar (perpendicular to the direction of sliding) and c) the maximum depth under fitted sphere (the maximal radial deviation). The fitted sphere should represent original geometry of the cup. Freeware GOM Inspect V7.5 was used for this analysis. In the second, in-house Matlab software was used. We found that the radius and center position of reference sphere strongly affect values of wear, so this script precisely and automatically identifies worn and unworn sub-area and finds reference sphere position and radius. The outputs of the script are mainly total volume loss (mm3), 2D map of linear wear (mm) and total scanned area. The average linear wear was easily calculated as total volume lost divided by total scanned area. Finite element (FE) analysis was performed to asses stress distribution in sample pairs and distribution of contact pressure within contact area during one testing cycle. Abaqus/CAE 6.12 was used. Combination of head from βTi alloy and cup from UHMWPE was chosen as a representative pair. Material parameters were used according to the tab. 1. Friction between surfaces while sliding was defined using friction coefficient f=0,1. Kinematic and loading of model mimic real experiment. Mapped mesh from linear brick-elements was generated. The whole mesh consist of about 46000 (cup) and 34000 (head) elements. Mises stress inside both of parts and contact pressure on the articulating surfaces were analysed during one loading cycle. FE analysis of maximal contact pressure was compared by simple analytical calculation based on Hertz theory of elastic contact.

Results: The wear of metallic heads was negligible in comparison with wear of plastic cup. All five evaluated parameters of wear show better wear resistance of pure UHMWPE than of pure PEEK. For example the depth of scar in pure UHMWE and pure PEEK cups after loading were averaged as (0.80±0.57) mm and (0.16±0.05) mm. Both maximum linear wear and volumetric wear were about 2.5 times higher in the case of pure PEEK cups than in the case of pure UHMWPE cups in average. No significant changes between tests in distilled water and in bovine serum were observed. Also material or technology treatment of heads had no impact on wear of cups. FE model of the experiment showed, that the peak Mises stress under contact in the cup is about 32MPa and appears just under head surface. Maximum contact pressure is about 53MPa. Maximum contact pressure counted analytically using material and geometrical parameters corresponding to our test is 51.1 MPa. When only pairs tested in bovine serum with UHMWPE cups are analysed, the influence of material and/or coating of cups on total wear can be studied. According to this comparison, the best counterpart (head) material seems to be conventional CoCrMo alloy, followed by all modifications of βTi alloys. But this result has not credible statistical significance.

Discussion: The new wear experiment was proposed. It is a compromise between standard tribo-tests and testing of real joint endoprosthesis like knee joint testing according to ISO 14243, hip joint testing according to ISO 14242, or other sophisticated tests with real endoprosthesis. The wear test was proposed with aim to mimic important mechanisms of wear, mainly cross-shear and combination of rolling and sliding. The values of contact pressure roughly correspond to real situation within real implants. This test is appropriate for pilot study of new material combination or new surface treatment without the necessity to manufacture expensive testing samples. The geometry of samples for the new test is very simple. Contact pressure in the interface head-cup roughly corresponds to contact pressure under condyles of knee joint replacement during normal gait. The pilot study with thirty testing couples (plastic head and metal head) pointed to several outcomes: All ways of wear evaluating showed that pure UHMWPE has better tribological properties than pure PEEK. This result corresponds with some other experimental works. The plan is now to test several known PEEK and UHMWPE modifications, especially CFR-PEEK and cross-linked UHMWPE, to confirm this accordance. Ultimate goal is then to test as many newly developed PEEK variants and modifications as possible. The proposed experimental procedure gives primary results and the wear test of actual joint replacements on special ISO-standardised joint simulator is still necessary as the next step. However, this method could become an acceptable indicator, helping researchers to detect the best candidates for it.

Compressive and Wear Behavior of Surface Porous PEEK

Safranski DL[1], Lee CS[1], Evans NT[2], Torstrick FB[2], Guldberg RE[2], Gall K[3],
[1]Vertera Spine, Atlanta, GA, [2]Georgia Institute of Technology, Atlanta, GA, [3]Duke University, Durham, NC
david.safranski@verteraspine.com

Introduction: Porous poly(ether-ether-ketone) (PEEK) has recently emerged as a candidate material for load-bearing in orthopedic applications due to its favorable bulk mechanical properties, imaging compatibility, and promising in vitro and in vivo results [1,2]. Prior studies have investigated the tensile and fatigue properties of PEEK containing a porous architecture, but the local deformation response of the porous region itself has not been previously explored. The evaluation of the local compressive properties and wear behavior of porous PEEK is important as most implants are subject to loading in vivo. The overall focus of this work is to study the mechanics of the porous architecture relevant to orthopedic applications. In situ microcomputed tomography scans (μCT) of the porous architecture were used to understand the pore architecture deformation mechanisms.

Methods and Materials: Porous PEEK was made by extruding Zeniva® PEEK (Solvay) through the spacing of NaCl crystals under heat and pressure, followed by leaching as described previously [1]. The resulting porous architecture is 60-70% porous with a pore size of approximately 350μm [2]. To control the pore architecture depth, the PEEK was extruded through the sodium chloride either 0.65 mm or 1.5 mm to create "thin" and "thick" samples, respectively. Compression tests were utilized to determine the compressive stress– strain behavior of surface porous PEEK. The tests were performed using an Instron machine with a 5 kN load cell at room temperature (Instron; Norwood, MA). The samples were compressed past yield of the solid component using a displacement controlled test at a rate of 1.3 mm/min according to ASTM D695-10. A Scanco Medical Compression/Tension Device was used with a Scanco Medical μCT 50. Samples were placed under a small preload (2 N, 0% strain condition) to prevent rotation during scanning and then were scanned at 10 μm voxel resolution with a voltage of 55 kVp and a current of 200 μA (n = 3/group). The compression device was then used to compress the sample to 5% strain. The samples were then rescanned and compressed to another 5% strain of the original height. This process was continued in 10% strain increments until the sample was compressed to 70% of the original height. A global threshold was applied to segment PEEK from pore space for all evaluations. Pore architecture morphometric parameters were evaluated using direct distance transformation methods as described previously [3].
The abrasion resistance of the porous architecture was characterized according to ASTM-F1978. Samples 10 cm x 10 cm x 4 mm thick with a 6.4 mm hole were placed on a Taber Rotary Abraser Model 5135 with H22 Calibrade wheels and a load of 250g. The samples were abraded for 2, 5, 10, and 100 cycles with the vacuum on. Between each abrasion cycle the samples were cleaned in an ultrasonic cleaner for at least 20 minutes, dried in a vacuum oven at 100°C for 1 hour and then cooled at room temperature for 10 minutes. The samples were then weighed 3 times. The clean, dry, and weigh cycle was repeated until the change in weight was ≤ 0.01g and the mass loss is the measure of abrasive wear to the specimen. Comparisons between groups were determined using a 1-way ANOVA and Tukey post hoc analysis. All data reported as mean ± standard deviation.

Results: For unloaded samples, the porosity was 71.3±0.89% and 75.4±2.9% for the thin and thick samples, respectively. The pore architecture depth was 1.10±0.23mm and 2.00±0.56mm for the thin and thick samples, respectively. No difference in pore sizes or strut spacing were measured from those reported previously [2]. The thin samples had a significantly higher moduli compared to the thick samples (109±18MPa vs 61±6.8MPa, $p<0.01$), and significantly higher yield stress than the thick samples (8.72±1.68MPa vs 4.33±0.63MPa, $p<0.01$). Figure 1 shows μCT reconstructions of representative thick and thin samples at various strains. The in situ μCT testing revealed that the average percent porosity decreased as a function of strain (Figure 2) and was inversely related to the applied stress. Porosity was evaluated for various regions of a representative thick pore architecture. The measured mass loss after 100 cycles of abrasion was 39±18mg for the injection molded and 27.6 ±12.3mg for the porous PEEK samples. μCT comparing the pore structure before and after abrasion revealed a slight densification of the pore network and flattening of the top pore architecture. No change in porosity and architecture depth was found between abraded and non-abraded porous PEEK samples.

Discussion: μCT analysis demonstrated three stages of deformation – linear elastic, plastic, and densification – regardless of architecture depth, and this is characteristic of foams. In the initial regime of deformation, the cell wall 'struts' undergo elastic deformation and uniaxially bend below 5% strain. With increasing deformation up to 50% strain, the struts buckle and the material experiences plastic deformation. The variation in strength and stiffness with architecture depth is likely due to the increased porosity of the thicker pore architectures. Importantly, the μCT compression data reveals that the sample can deform up to 40% of its original size and still offer high porosity for ingrowth (over 50% porous, or ~70% of the original open space). The stress at 50% strain is around 14 MPa. This indicates that in an application such as lumbar spinal fusion, where the average cage is between 90 and 330 mm2, a surface porous PEEK device could withstand a minimum of 1260 N and as much as 4620 N of load while still offering high porosity for ingrowth. These loads are above those commonly placed on the spine during daily activities [4]. Thus, porous PEEK can withstand physiologically relevant loads while still maintaining a high degree of porosity available for bone-ingrowth. There was no observed increase in mass loss during abrasion on surface porous samples; abraded surface porous samples showed slight densification of the pore network. The normal mechanism of wear in this test setup is particle shedding. However, an additional wear mechanism for the surface porous groups – pore architecture collapse and slight densification of the pores – also occurs in surface porous groups.

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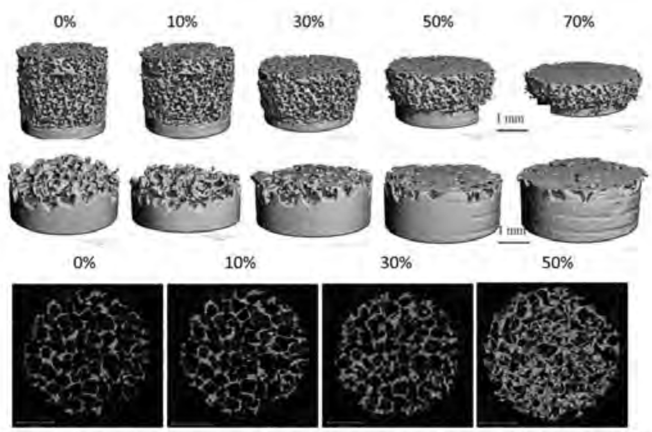

Figure 1. *In situ* μCT reconstruction at varying strains for (top) thick and (middle) thin sample. (Bottom) Cross-sections at varying strains of thick sample.

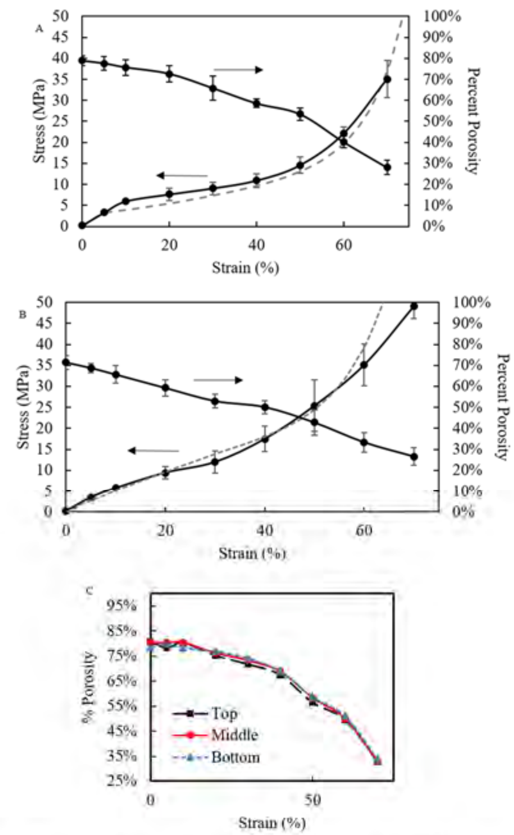

Figure 2. *In situ* μCT compressive response of (A) thick samples, (B) thin samples. Dashed line represents monotonic compression test. (C) Characterization of porosity as a function of strain for three regions of thick sample: top 1/3, middle 1/3, bottom 1/3.

Figure 3. Representative μCT reconstructions of surfaces before and after abrasion. (A) Cross-section pre-abrasion. (B) Cross-section post-abrasion.

The Influence of Environmental Conditions on the Tribology of PEEK-OPTIMA™-on-UHMWPE

Cowie RM[1], Briscoe A[2], Fisher J[1], Jennings LM[1]
[1]Institute of Medical and Biological Engineering, University of Leeds, UK. [2]Invibio Ltd, Thornton Cleveleys, UK
r.cowie@leeds.ac.uk

Introduction: PEEK-OPTIMA™ (Invibio Ltd, Thornton Cleveleys, UK) has been considered as an alternative arthroplasty bearing material to cobalt chrome in the femoral component of total knee replacements [1]. The aim of this study was to investigate the wear and friction of PEEK-OPTIMA™-on-UHMWPE under different lubricant protein concentrations at room and elevated temperature in a series of tribological tests. When testing novel material combinations such as PEEK-OPTIMA™-on-UHMWPE, to better understand the tribology, it is important to test under a wide range of experimental conditions in line with our SAFER® approach [2]. Studies were carried out in a simple geometry configuration with PEEK-OPTIMA™-on-UHMWPE compared to cobalt chrome-on-UHMWPE.

Methods and Materials: The pins used were GUR 1020 UHMWPE (conventional, non-sterile) and the plate material was either highly polished cobalt chrome (initial mean surface roughness (Ra) <0.01µm) or PEEK-OPTIMA™ (Invibio Ltd, UK), Ra ~0.03µm. Wear simulation was carried out for 1 million cycles using a multi-axial pin-on-plate rig using a contact pressure and cross shear to reflect the conditions in total knee replacement. The protein concentrations tested were 0, 2, 5, 25 and 90% bovine serum and tests were run at either room temperature as per standard practice at Leeds [3] or at elevated temperature (~36°C) as in the ISO standard [4]. The wear of the UHMWPE pins was assessed by gravimetric analysis. The uniaxial pin-on-plate friction rig study reflected the contact pressure used in the wear simulation (3.18MPa). Tests were carried out at room temperature in 0, 2, 5, 25 and 90% bovine serum and the coefficient of friction (COF) was measured using a piezoelectric sensor. At least 3 repeats were carried out for each test condition, statistical analysis was carried out with ANOVA with significance taken at $p<0.05$.

Results: Without protein in the lubricant, the wear of UHMWPE pins (Figure 1) was very low and polymer transfer was observed on the plates. Testing in low serum concentrations (2 and 5%) increased the wear of UHMWPE under all conditions but polymer transfer was still apparent. In 25 and 90% protein, at elevated temperature, the wear of UHMWPE followed similar trends against both plate materials. At room temperature, the trend in wear of UHMWPE was not consistent against the different materials and in 90% serum, protein deposition was visible in the wear area of the cobalt chrome plates which led to a higher rate of wear in the metal-on-polyethylene combination. This was the only condition where there was a significant ($p>0.05$) difference in wear between the two materials. In 90% serum at elevated temperature, protein precipitation was evident on the cobalt chrome plates. Under all protein concentrations, the COF was higher in the all-polymer couple compared to the metal-on-polyethylene materials (Figure 2), only when protein was in the lubricant, was this difference significant ($p<0.05$). For both material combinations, there was a trend of decreasing COF with increasing protein concentration however, this was not significant for either material.

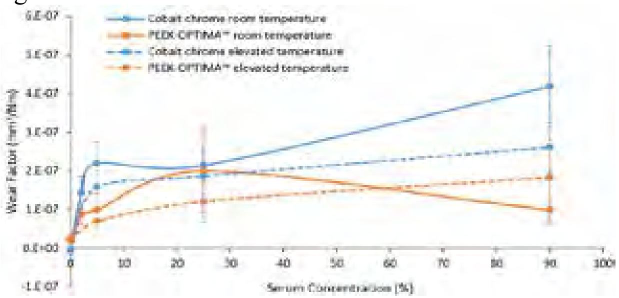

Figure 1: Mean wear factor (±95% CL) of UHMWPE pins against PEEK-OPTIMA™ and cobalt chrome plates.

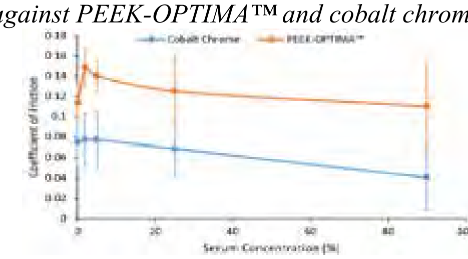

Figure 2: Mean COF (±95% CL) of PEEK-OPTIMA™-on-UHMWPE and cobalt chrome-on-UHMWPE.

Discussion: The polymer transfer observed on the plates tested in 0, 2 and 5% serum suggests insufficient boundary lubrication and a non-clinically relevant wear mechanism. In 25 and 90% protein, at elevated temperature, the wear mechanism was dominated by a factor independent of the material of interest perhaps protein deposition or lubrication; at room temperature, the wear of the all-polymer couple and the metal-on-polyethylene couple did not follow the same trend. The higher COF of the PEEK-OPTIMA™-on-UHMWPE bearing couple may have caused frictional heating of the lubricant which could have contributed to differing wear mechanism and lubrication regime between the different bearing materials. Testing in 25% bovine serum at room temperature minimised test artefacts such as protein precipitation, protein deposition and polymer transfer. Under these conditions, the wear of PEEK-OPTIMA™-on-UHMWPE was equivalent to metal-on-polyethylene. This study shows that environmental conditions influence the tribology of materials and should be considered when testing novel bearing combinations.

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Influence of Third Body Damage with PMMA Cement Particles on the Wear of PEEK-OPTIMA™-on-UHMWPE

Cowie RM[1], Briscoe A[2], Fisher J[1], Jennings LM[1]
[1]Institute of Medical and Biological Engineering, University of Leeds, UK. [2]Invibio Ltd, Thornton Cleveleys, UK
r.cowie@leeds.ac.uk

Introduction: Preliminary studies have shown the potential for PEEK-OPTIMA™ to be used as an alternative bearing material to cobalt chrome as the femoral component in total knee arthroplasty [1]. In this study, the influence of third body damage with PMMA cement particles on the wear of PEEK-OPTIMA™-on UHMWPE was investigated in a simple geometrical configuration. Pre-clinical testing beyond the current ISO standard was carried out in line with our SAFER® approach [2] to further assess the efficacy and safety of the device prior to implantation. To compare the performance of PEEK-OPTIMA™ with that of a more conventional knee replacement material, tests were carried out in parallel against cobalt chrome counterfaces.

Methods and Materials: The study was split into two phases. In Phase 1, third body damage with PMMA cement particles was simulated. In Phase 2, wear tests were carried out against the damaged counterfaces. Third body damage simulation was carried out using a bespoke rig. Particles of polymerised Palacos R&G bone cement (size range 500-1000μm) were trapped between an UHMWPE pin (flat 3mm contact face) and either a cobalt chrome (initial Ra~0.01μm) or PEEK-OPTIMA™ (Invibio Ltd, Thornton Cleveleys, UK) plate (Ra~0.03μm). A 120N load was applied axially through the pin and the plate pulled beneath the pin at 8mm/min to create the damage using an Instron materials testing machine [3]. The trapped particles were passed over the plate five times in each region of damage and 5 regions of damage were created. Following damage simulation, the surface topography of the plates were analysed using contacting profilometry (Taylor Hobson, UK) with traces taken perpendicular to the damage simulation. In Phase 2, wear tests of GUR 1020 UHMWPE pins were carried out against the plates perpendicular to the direction of damage simulation in a 6 station multi axial pin on plate reciprocating rig. The tests were carried out for 1 million cycles (MC) at 1Hz with a 20mm stroke length, 20° rotation, and a constant 160N load giving a nominal contact pressure of 3.18MPa. The lubricant used was 25% bovine serum and the wear of UHMWPE against the damaged plates was compared to the wear against control plates which had not undergone damage simulation. At the conclusion of the study, the wear of the UHMWPE pins was assessed by their loss in mass measured by gravimetric analysis and the surface topography of the plates was re-analysed. All data is presented as mean ± 95% confidence limits, statistical analysis was carried out using ANOVA with significance taken at $p<0.05$. N=3 (minimum) was completed for each condition.

Results: Following damage simulation, scratches were visible on the surface of the PEEK-OPTIMA™ plates. Compared to pre-test measurements, there was a significant increase ($p<0.05$) in the surface roughness (overall roughness, Ra and lip height, Rp) of the PEEK-OPTIMA™ plates compared to pre-test values (Table 1); the surface roughness of the cobalt chrome plates was similar to pre-test measurements. Following 1MC of wear testing, there was no significant difference ($p>0.05$) in the wear of the UHMWPE pins against negative control plates or those damaged with third body particles for either PEEK-OPTIMA™ or cobalt chrome (Figure 1). However, following wear simulation, in the wear area on the PEEK-OPTIMA™ plates, there was a region where the scratches had been polished out and the surface roughness was significantly ($p<0.05$) lower than that measured following the damage simulation (Table 1).

Table 1: Mean (±95% CL) Ra and Rp of plates, pre-test, after damage simulation (Phase 1) and following 1MC of wear testing (Phase 2).

Parameters	Cobalt chrome			PEEK-OPTIMA™		
	Pre-test	Phase 1	Phase 2	Pre-test	Phase 1	Phase 2
Ra (μm)	0.011 ± 0.014	0.012 ± 0.015	0.011 ± 0.009	0.006 ± 0.002	0.054 ± 0.006	0.018 ± 0.008
Rp (μm)	0.058 ± 0.094	0.062 ± 0.088	0.053 ± 0.066	0.030 ± 0.013	0.245 ± 0.037	0.057 ± 0.018

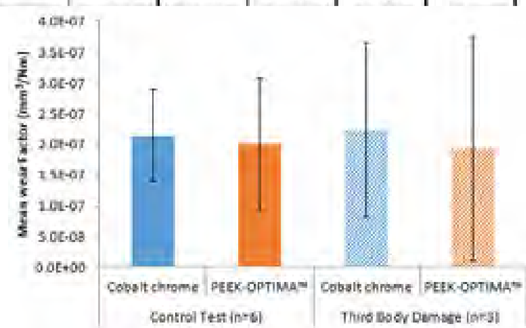

Figure 1: Mean wear factor (±95% CL) of UHMWPE pins against PEEK-OPTIMA™ and cobalt chrome plates

Discussion: Damage to metal counterfaces resulting in a lip height (Rp) of similar magnitude to that measured on the PEEK-OPTIMA™ plates following damage simulation has previously been shown to influence the wear rate of UHMWPE [4]. However, during wear simulation, a polishing effect of the UHMWPE pin against the damaged region of the PEEK-OPTIMA™ was seen and the third body damage had no influence on the wear rate of UHMWPE. In this simple geometry study, although third body damage with PMMA particles caused scratches of the PEEK-OPTIMA™, there was no influence on the wear rate of UHMWPE.

[1] Cowie, R.M. et al. 2015. ISB, Glasgow, UK. AS-0340. [2] Jennings, L.M. 2012 Orthopedics and Trauma; 26(4):246-252. [3] Cowie, R.M. et al. 2016. ProcIMechE-Part H; 230(8):775-783. [4] Minakawa, H. 1998. JBJS(Br); 80-B:894-9

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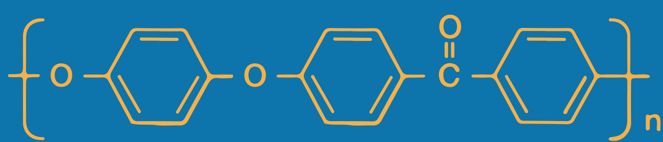

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