Traducción simultánea:
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Inglés-Español-Inglés
durante las sesiones del
Sábado 15 de Septiembre

final program

3rd UHMWPE INTERNATIONAL MEETING

"Polyethylene in total joint replacement systems: Concerns and solutions"

Madrid - Spain
14 - 15 September 2007

Facultad de Medicina
Universidad Autónoma de Madrid

UHMWPE
ultra-high molecular weight polyethylene

with the acknowledge

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INDEX

WELCOME ADDRESS

Dear friends,

Ultra high molecular weight polyethylene (UHMWPE) is the key material to facilitate excellent long-term results in total joint arthroplasties. In spite of significant research and development in the previous years, new aspects are still controversial and clinical use of recent improvements is limited. This situation fosters new research while spreading UHMWPE updated knowledge to the orthopaedic community.

This meeting is planned in two main parts: one basic research module, open for papers and oriented to gather cutting-edge research on UHMWPE; and a second part oriented to clinical aspects and discussion.

Furthermore, a meeting of the Orthopaedic group of the 537 COST-Action, from the European Science Foundation, gathering representatives from 13 European countries, will be combined to our meeting. Scientific sessions that will occur in the afternoon of Saturday the 15th will be opened to researchers participating in this meeting and interested in retrieval analysis of orthopaedic implants. Again, from the basic science into the clinical use, many interesting topics will be covered in two exciting days to update research on UHMWPE.

Welcome to Madrid.

J.A. Puértolas | L. Munuera | E. Gómez-Barrena



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GENERAL INFORMATION

VENUE
Facultad de Medicina
Universidad Autónoma de Madrid
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Simultaneous translation: There will be simultaneous translation English-Spanish-English on Saturday September 15th

Traducción simultánea: se establecerá un servicio de traducción simultánea Inglés-Español-Inglés durante las sesiones del Sábado 15 de Septiembre



SCIENTIFIC PROGRAM

Friday, 14th September

08:45 Meeting Presentation

09:00 **Invited lecture: on Oxidation and stabilisation of UHMWPE**
L. Costa
U. Torino-Italy

Session I: Oxidation and microstructure

L. Costa
U. Torino, Italy
B. del Prever
U. Torino, Italy

09:30 A 15-years experience in analyses of UHMWPE prosthetic components: state of the art and future perspectives
P. Bracco
U. Torino-Italy

09:45 Analyses of oxygen-induced radicals UHMWPE
M.S. Jahan
Memphis University-USA

10:00 Ageing of gamma-sterilized UHMWPE: influence of the oxygen concentration on the oxidation and the oxidative potential
D. Yvo
Plus Orthopedics AG-Switzerland

10:15 Spectroscopy and nanoidentation study of in vivo degradation in total knee arthroplasty components
F.J. Medel
Drexel University-USA

SCIENTIFIC PROGRAM

10:30 *Coffee Break*

Session II: Antioxidant strategies

S. Kurtz
Exponent Inc., Drexel Univ-USA
A. Wang
Stryker Orthopaedics, USA

11:00 Practical considerations in the scale-up for converting of anti-oxidant UHMWPE blends for orthopaedics
L. Matrisciano Jr
Meditech Medical Polymers-USA

11:15 On the novel use of nitroxides and alpha-tocopherol as radiolytically-produced free radical scavengerin UHMWPE
M. Chumakov
University of Maryland-USA

11:30 Trace concentrations of vitamin E protect radiation crosslinked UHMWPE from oxidative degradation
S. Kurtz
Exponent Inc., Drexel Univ-USA

11:45 Oxidation and morphologics of tocopherol doped UHMWPE under large tensile deformation
N. Shibata
Japan N.I. Occupational Safety and Health-Japan

SCIENTIFIC PROGRAM

12:00 **Poster session**

- Modelling of fracture phenomena in ultra high molecular weight polyethylene using the discontinuous Galerkin finite element method
  F. Stan
  Duranea de Jos University-Romania
- Ultra height molecular weight polyethylene wear particles in failed total hip replacement
  M. Figurska
  Polish Academic of Sciences-Poland
- Friction and wear behaviors of UHMWPE against Co-Cr alloy under the physiological conditions in total joint replacement
  Kwon-Yong Lee
  Sejong University-Korea
- Wear analysis of UHMWPE tibial component on three different total knee joint prosthesis designs
  C. Ávila
  Instituto Biomecánica Valencia-Spain
- 3D scanning and CNC Milling of the glenoid fossa for mandibular reconstruction
  L. Sabadin
  Universiade Federal do Rio Grande do Sul-Brasil
- A quantifiable and validated model of local polymer particle delivery
  S. Goodman
  Stanford University medical Center-USA
- Polyethylene and Co-Cr-Mo particles elicit a different immune response in vitro
  E. Stefan
  Orthopedic and Trauma Surgery Olsberg-Germany
- Bacterial adhesion on UHMWPE: effect of surfaces roughness and sterilization procedure on adherence of S. Aurus and S. Epidermidis
  T. Kinnari
  U. Autónoma Madrid-Spain
- A study on the kinetics of free radial decay of gamma ray irradiated UHMWPE used in total joint arthroplaty and its applications in material improvement
  R.Y. Tsay
  Nacional Yang-Ming University-Taiwan
- Numerical simulation of injection molding of ultra high molecular weight polyethylene
  C. Fetecau
  Duranea de Jos Univ. Galaty-Romania

SCIENTIFIC PROGRAM

- Modification of surface morphology of UHMWPE for biomedical implants
  M. Yenigul
  Ege University-Turkey
- Processing and properties of carbon nanofiber composites with UHMWPE using twin-screw extrusion
  K. Zhong
  North Dakota State University-USA

13:00 *Lunch*

14:00 **Invited lecture:**
Advances in oxidation resistance of 2nd generation UHMWPEs
O. Muratoglu
U. Mass General Hospital-USA

Session III: Wear and wear debris

O. Muratoglu
Mass General Hosp-USA
C. Rieker
Zimmer, Switzerland

14:30 Determination of wear in total knee replacement components using CMM
P. Bills
University of Huddersfield-UK

14:45 Rheology and wear of crosslinking UHMWPE for total joint replacements
Z. Horak
Inst. Macromol Chemistry-Czech Republic

15:00 Wear resistance of highly crosslinked and remelted polyethylenes after ion implantation and accelerated aging
F. Medel
U. Zaragoza-Spain

SCIENTIFIC PROGRAM

15:15 Nano-scale modification with 2-methacryloyloxyethyl phosphorylcholine polymer brings to ultra-longevity for orthopaedic bearing
M. Kyomoto
The University of Tokyo-Japan

15:30 Influence of centrifugation on morphology of UHMWPE wear particles
M. Lapcikova
Institute Macromolecular Chemistry-Czeh Republic

15:45 UHMWPE wear particles in different zones around total hip replacements
M. Slouf
Institute Macromolecular Chemistry-Czeh Republic

16:00 *Coffee Break*

16:15 **Invited lecture: on mechanical properties of UHMWPE**
C. Rimnac
Case Western Reserve University-USA

Sesion IV: Material and manufacture improvements

C. Rimnac
Case Western Reserve University-USA
J. Puértolas
Universidad de Zaragoza-Spain

16:45 Comparison of sequential and single-dose irradiation effects on the mechanical, physical, and oxidative properties of UHMWPE
M. Morrison
Smith & Nephew Orthopaedics. Memphis-USA

17:00 The monotonic and cyclic fatigue behaviors of a conventional and a sequentially annealed highly crosslinked UHMWPE in a notch-induced triaxial stress-state
M. Sobieraj
Case Western Reserve University-USA



SCIENTIFIC PROGRAM

17:15 Mechanical properties of UHMWPE/MWCNT composites used for orthopaedic applications
K. Subramani
University of Aveiro-Portugal

17:30 Ultra high molecular weight polyethylene and polyether urethane nano-composite as acetabular cup material
M. Taghi Khorasani
Iran Polymer and Petrochemical Institute-Iran

17:45 *End of the Session*

20:30 *Meeting dinner*



SCIENTIFIC PROGRAM

Saturday, 15th September

1st Round table presentation: The state-of-the-art in UHMWPE research
Y. Konttinen
Biomedicum Helsinki-Finland

09:00 Advances in oxidation and future directions
L. Costa
U. Torino-Italy

09:15 Advances in wear resistance and future directions
O. Muratoglu
Mass General Hospital-USA

09:30 Advances in mechanical properties and future directions
C. Rimnac
Case Wester Reserve Univ-USA

09:45 Discussion

10:00 **Invited lecture: In vivo oxidation and retrieval analysis data**
S. Kurtz
Drexel University - USA

10:30 *Coffee break*

2nd Round table presentation: Advances in UHMWPE: from the bench to the market
E. Gómez Barrena
Universidad Autónoma de Madrid

11:00 Remelting advancements
C. Rieker
Centerpulse Laboratory-Switzerland



SCIENTIFIC PROGRAM

11:15 Sequential annealed polyethylene
A. Wang
Biomechanics Laboratory-USA

11:45 Discussion

3rd Round table presentation: Clinical selection and results

L. Munuera
Universidad Autónoma de Madrid

12:00 Long term results and selection at the hip
S. Goodman
Stanford University-USA

12:15 1st generation results at the hip. Prediction for 2nd generation
B. Grimm
Atrium Medisch Centrum-Düsseldorf

12:30 Are highly cross-linked polyethylenes useful at the knee?
S. Li
Hospital for Special Surgery-USA

12:45 Discussion

13:15 *Adjournment*

SCIENTIFIC INFORMATION

GENERAL RULES

- The Scientific Committee has made their selection on the basis of the abstracts' scientific content. The Scientific Committee reserves its right to require additional information on any text submitted. The Committee may also decide that certain papers should be presented as posters.
- The first author should be registered as a participant in the Congress.

RULES FOR ORAL PRESENTATIONS

- Speakers will be allowed 12 minutes for their presentations, plus 3 minutes for comments and discussion.
- The Chairman of each session shall hand authors their certificates at the end of each presentation.
- Presentations must be supported by PowerPoint PC software. A CD or USB device containing the presentation should be handed in to the audiovisual staff at least two hours before the beginning of each session. Presentation slides cannot be submitted on a laptop computer.

RULES FOR POSTER PRESENTATIONS

- Posters should be no larger than 110 cm tall by 90 cm wide and they must necessarily include the bibliographical references. Authors are advised to include an e-mail address so that participants can send them their questions.
- Poster presenters should stand by their posters during the poster session, that will be followed by buffet lunch.

ORAL PAPERS

Friday, 14th September **09.30 – 10.30 h.**

SESSION I: Oxidation and microstructure

Chair:

L. Costa
U. Torino, Italy
Brach del Prever
U. Torino, Italy

O-1

A 15-YEARS EXPERIENCE IN ANALYSES OF UHMWPE PROSTHETIC COMPONENTS: STATE OF THE ART AND FUTURE PERSPECTIVES.

P. Bracco, E.M. Brach del Prever*, V. Brunella, M. Zanetti, L. Costa
Dipartimento di Chimica IFM and NIS Centre of Excellence
*Dipartimento di Ortopedia, Traumatologia e Medicina del Lavoro
Università di Torino, ITALY

During the last 15 years we have had the opportunity of analysing more than 700 UHMWPE prosthetic components (hip, knee and shoulder). Among them, about 500 were retrieved during revision surgery, while the remaining were new, ready-to implant, variably shelf-aged samples.
The analysis of such a large, representative sample provided several important insights into the variables which influence the behaviour of UHMWPE in vivo; moreover, a long period of observation gave us the opportunity to follow changes and improvements in the field over time.
All samples dated back to the nineties or before and sterilized with high energy radiation, either shelf-aged or retrieved, showed variable, but generally high, oxidation levels. Starting from the observation of these samples and with the aid of specimens irradiated on purpose under controlled conditions, some improvement has been achieved in the knowledge of radiation-induced oxidation process. The importance of the determination of hydroperoxides on the oxidation potential has been highlighted and the influence of variables such as sterilisation atmosphere, packaging, temperature and dose rate on the oxidation process have been clarified. The need for a suitable stabilizer to minimize oxidation arises during these studies.
We also had the opportunity of analysing a large number of EtO-sterilised samples, both new and retrieved. A small amount of them, all manufactured in the nineties, showed some bulk-oxidation which has been related to the presence of calcium stearate into the pristine resin. None of the newly produced, calcium stearate-free samples showed any oxidation and this group allowed to explore the behaviour of undegraded UHMWPE in vivo and in the shelf. Diffusion of polar compounds from the synovial fluid into polyethylene was observed in the majority of the retrieved samples. The nature of these products have been investigated along with their possible influence on the mechanical properties of the polymer.

ORAL PAPERS

In the last five years, we had the opportunity to study a significant number of crosslinked polyethylenes, both new and retrieved. The results of this study indicate that the variables of the crosslinking process can greatly influence final material properties and that not all crosslinked polyethylenes are the same.

O-2

ANALYSES OF OXYGEN-INDUCED RADICALS IN UHMWPE

Muhammad Shah Vahan Jahan, Marlon D. Ridley, Muhammad Fuzal, Benjamin M. Walters
Department of Physics. The University of Memphis. USA

Degradation or failure of ultra-high molecular weight polyethylene (UHMWPE) components of total hip or knee prostheses is reportedly caused by the reaction of free radicals with oxygen molecules [1]. To combat such oxidation, repairing or quenching of radicals is performed by annealing the joint components or bulk materials at elevated temperature following radiation sterilization or cross-linking [2]. Anti-oxidant such as vitamin E (Tocopherol T), for example) is also being added to UHMWPE to reduce free-radical-induced oxidation [3].

In this report we conducted free radical measurements on UHMWPE following sterilization with gamma rays (Co-60) at room temperature in open air, vacuum, nitrogen, or argon and subsequently aged at room temperature, C or C for approximately 10 years. Measurements made on vitamin E-mixed UHMWPE powder as well as compression-molded bulk materials are also presented. Additionally, this report includes data obtained from measurements on retrieved acetabular cups and tibial inserts. All free radical measurements were conducted using X-band (~9 GHz) electron spin resonance (ESR) technique.

When annealing is performed at C in inert environments, PE free radical number is reduced significantly (~98%). However, the residual radicals (remaining 2%, approximately) produce oxygen-induced radical (OIR) upon subsequent exposure to oxygen (open air). OIRs are also detected in acetabular cups and knee-joint plateaus retrieved 6-8 years following implantation. Two groups of vitamin-E samples were investigated. In one group, samples were prepared from blends of -T and UHMWPE powder (T-P), and in the second group, from compression molded blocks (-T-B). In each group, samples were gamma-irradiated in sealed packages filled with N2, or in open air, and free radicals were measured in open air environment as a function of time. PE radicals were found to be quenched by T in presence of oxygen (open air) but not in packages containing N2. Furthermore, like in control, OIR were formed in N2-packaged T-P as well as in T-B.

Acknowledgements: Work was supported in part by funds from the NSF Industry/University Center for Biosurfaces and the University of Memphis.

ORAL PAPERS

References
1. M.S. Jahan, C. Wang, G. Schwartz, J.A. Davidson, J. Biomet. Mater. Res.,25, 1991.
2. D. S. Sun and C. Stark, U. S. Patent No. 414,049, May 1995.
3. Oral, E et al. Biomaterials 2004; 25:5515-22.

O-3

AGEING OF GAMMA-STERILIZED UHMWPE: INFLUENCE OF THE OXYGEN CONCENTRATION ON THE OXIDATION AND THE OXIDATIVE POTENTIAL.

Dirix Yvo, Y. Dürr (Früh Verpackungstechnik AG) **D. Zurbrügg** (Niutec AG) **H. Schmotzer** (Plus Orthopedics AG) Plus Orthopedics AG

The oxidation index for gamma-sterilized UHMWPE quantifies the amount of carbonyl groups formed in a cascade of reactions between free radicals and oxygen. A high oxidation index has been shown to correlate with an increased fatigue wear which finally can lead to mechanical failure of the implant (for example knees). In the reaction chain, a precursor molecule (hydroperoxide) is formed prior to the carbonyl groups. This precursor is not directly quantified by the oxidation index but it represents an oxidative potential of the material; species that did not react yet, but can react in a chain reaction leading to a long-term oxidation.

The goal of this study is to measure the oxidation index and the oxidative potential for gamma sterilized UHMWPE as a function of the oxygen concentration present in the primary packaging at irradiation and afterwards during shelf ageing.

The oxygen concentration is varied by using a nitrogen flush and selecting packaging with variable diffusion rates, i.e., using 0, 1, 2 or 3 barrier films. The ageing is done at 55°C which corresponds to a ten-fold thermal acceleration for the packaging (ASTM F1980). After several time intervals, the local oxygen concentration and the oxidation index was determined. The oxidation potential was quantified by measuring the oxidation index of the UHMWPE after a second oxidative challenge under severe conditions according to ASTM 2003 (5 Atm O2 pressure / 70°C). The thermal decomposition of the hydroperoxides results in an oxidation which simulates the real-time ageing.

A higher oxygen concentration in the packaging resulted in a higher oxidation index although the differences were relatively small. This is in contrast to the oxidative potential of the material which strongly varied with the amount of oxygen present. Small differences in the oxygen concentration resulted in huge differences in the oxidative potentials. Consequently, the oxidation index alone for an implant is an incomplete indicator for the status of UHMWPE. This also explains why high clinical failure rates for gamma-air sterilized knees after shelf ageing despite the fact that the oxidation index itself was relatively low when taken out of the package.

ORAL PAPERS

O-4

SPECTROSCOPIC AND NANOINDENTATION STUDY OF IN VIVO DEGRADATION IN TOTAL KNEE ARTHROPLASTY COMPONENTS

Francisco J Medel Rezusta, Alexis Cohen*, Hina Patel*, Steven Kurtz*
*Implant Research Center, School of Biomedical Engineering, Science, and Health Systems. Drexel University, Philadelphia, PA. USA
+ Exponent, Inc. Philadelphia, PA. USA

Currently, FTIR spectroscopy is routinely used to assess oxidation (carbonyl, hydroperoxide and transvinylene contents) in acetabular and tibial UHMWPE components. On the other hand, Raman spectroscopy and nanoindentation have proven to be useful to characterize crystallinity and mechanical properties of hip and knee components, although they are not commonly used as routine techniques. In the present study, FTIR and Raman spectroscopies, as well as nanoindentation were chosen to characterize oxidative, microstructure, and mechanical changes undergone by a group of 8 radiation-sterilized total knee arthroplasty components (average shelf life 0.61y, and implantation time 11.5y). FTIR analysis of oxidation (OI; 1718 cm-1 band) and transvynilene index (TVI; 965 cm-1 band), which was carried out on 200-mm slices cut by microtome from the components, confirmed the occurrence of in vivo degradation (OI ranging 1.5-7.4; subsurface maxima ~1mm). In addition, the degree of crystallinity results calculated from FTIR spectra according to Costa et al., revealed in vivo oxidation highly increased this property (up to 75-90%; subsurface maxima at ~1mm). Raman spectra performed on surface, subsurface and bulk regions were used to calculate the crystalline content according to Strobl and Hagedorn. High crystallinity contents, ranging 65-90%, distinguished subsurface regions that previously exhibited a high OI, whereas surface and bulk regions displayed lower crystallinity, 45-60%. Furthermore, Raman 1415cm-1/(1440cm-1+1460cm-1) and 1415cm-1/1295 cm-1 intensity ratios provided information about the presence of monoclinic phase and the occurrence of a potential phase transformation in the oxidized polymer. It is worth mentioning that bulk regions showed crystallinity contents similar to the surface, "non-oxidized", regions, but the intensity ratios were generally lower for the former, suggesting bulk regions could develop some monoclinic or interfacial phase. Regarding nanoindentation results, hardness and elastic modulus in-depth profiles revealed typical subsurface maxima (~1mm) in both properties, which correlated accurately with OI, TVI and crystallinity results. This study corroborates in vivo oxidation as the underlying phenomenon responsible for the chemical and microstructure changes, as well as mechanical degradation, in tibial components for total knee replacement.

ORAL PAPERS

Friday, 14th September **11.00 – 11.45 h.**

SESSION II: Antioxidant strategies

Chair:

S. Kutz
Exponent Inc., Drexel Univ-USA
A. Wang
Stryker Orthopaedics, USA

O-5

ON THE NOVEL USE OF NITROXIDES AND ALPHA-TOCOPHEROL AS RADIOLYTICALLY-PRODUCED FREE RADICAL SCAVENGERS IN UHMWPE

Marina Chumakov, Michael Kasser (b), Joseph Silverman (b), Mohamad Al-Sheikhly (b)
University of Maryland, College Park
a- Fischell Department of Bioengineering
b- Department of Materials Science & Engineering

Gamma radiation and high energy electron beam are conventional sterilization methods for ultra-high molecular weight polyethylene (UHMWPE) for total joint arthroplasty. Radiolysis of UHMWPE produces alkyl free radicals which undergo various reactions. At high dose rates, bimolecular cross-linking reactions of alkyl radicals are enhanced. At low dose rates, alkyl radicals predominantly react with molecular oxygen present in the amorphous regions as well as at the amorphous-crystalline interface, to rapidly form the corresponding peroxyl free radicals. Peroxyl radicals can abstract a hydrogen atom from the polymer chain producing hydroperoxides and more carbon-centered free radicals. These reactions lead to oxidative degradation and premature aging of the material. As an alternative to post-irradiation annealing, antioxidants were infused into the UHMWPE to act as radical scavengers. The more commonly used hydrogen-transfer antioxidant alpha-tocopherol (Vitamin E) is compared to the proposed use of nitroxides as electron-transfer radical scavengers. Nitroxides (RRNO) are stable organic compounds that are able to reduce to hydroxylamines and oxidize to oxoammonium cations. These reactions are reversible and can be exploited to yield a novel radical scavenger in UHMWPE. It is proposed that these nitroxides will react with carbon-centered free radicals in the polymer. The product of this reaction can then react with a peroxyl radical to reform a nitroxide. In comparison, hydrogen abstraction by peroxyl radicals from the -OH on the chroman ring of alpha-tocopherol forms the tocopheryl radical, which can combine with more peroxyl radicals. These reaction mechanisms and kinetics of antioxidant diffusion into UHMWPE of various crystallinities will be discussed. Fourier Transform Infrared (FTIR) Spectroscopy was used to measure oxidation indices and antioxidant concentrations. Electron Paramagnetic Resonance (EPR) Spectroscopy was used to measure the yield of radiation-induced free radicals in spins per gram, transition of primary carbon-centered to peroxyl free radical peaks and radical scavenging by the antioxidants. The effect of dose rates on crosslinking in the presence of antioxidants will also be demonstrated.



ORAL PAPERS

O-6

TRACE CONCENTRATIONS OF VITAMIN E PROTECT RADIATION CROSSLINKED UHMWPE FROM OXIDATIVE DEGRADATION

Steven M. Kurtz, R.S. Siskey, J. Dumbleton,, M. Manley, A. Wang,
Exponent, Inc. and Drexel University

Vitamin E has been shown to effectively stabilize medical grade UHMWPE from oxidation. Our objective was to determine the minimum Vitamin E concentration necessary to protect conventional and highly crosslinked UHMWPE from a severe, in vitro oxidative challenge. Trace concentrations (0-500 ppm)of -tocopherol (Vitamin E) were blended with GUR 1020 and 1050 resins and compression molded into sheets. 10 mm-thick blocks were divided into three groups: (1) no irradiation (control); 30 kGy of gamma irradiation in nitrogen; and (3) 75 kGy of gamma irradiation in air. Three blocks of each condition were subjected to three aging protocols: (a) no aging (control); (b) two weeks and (c) four weeks of accelerated aging in accordance with ASTM F 2003. Mechanical behavior was assessed before and after aging was determined by the small punch test. The oxidation levels were measured using FTIR.

Aging of unirradiated materials resulted in a trend of reduced ultimate load in the small punch test. The addition of only 125 ppm of Vitamin E to unirradiated material brought the ultimate load back to baseline levels. 30 kGy-irradiated specimens exhibited severe oxidation when challenged by accelerated aging for 4 weeks in the absence of Vitamin E. Again, the addition of trace levels of Vitamin E reduced the effects of accelerated aging. The addition of any amount (125 ppm+) of Vitamin E protected the mechanical properties of the material for two weeks. 75 kGy-irradiated specimens also became severely oxidized when challenged by accelerated aging for 4 weeks in the absence of Vitamin E. For this group, the addition of 500 ppm Vitamin E was necessary to maintain baseline mechanical and chemical properties after four weeks.

The minimum concentration of Vitamin E needed to stabilize UHMWPE during our accelerated tests depended upon the method of radiation processing. For the 30 and 75 kGy irradiated materials, the addition of 125 ppm or more vitamin E was sufficient to maintain baseline mechanical and chemical properties through two weeks of accelerated aging. For these groups, the addition of 375 ppm or 500 ppm, respectively, was necessary to maintain baseline mechanical and chemical properties throughout the four-week accelerated aging period.

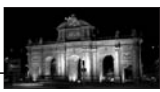
ORAL PAPERS

O-7

OXIDATION AND MORPHOLOGIC STABILITY OF TOCOPHEROL DOPED UHMWPE UNDER LARGE TENSILE DEFORMATION

Nobuyuki Shibata, Naohide Tomita
Japan National Institute of Occupational Safety and Health

Tocopherol-doped UHMWPE has been proposed as a novel joint bearing component. Previous researches have elucidated the anti-oxidative effect of -tocopherol on the oxidation stability and hence the improvement of the long term wears and fatigue performance in the conventional -irradiated UHMWPE. This study addressed effects of the addition of -tocopherol into UHMWPE on changes in macro-molecular structures of UHMWPE and oxidation stability under large deformation. Medical-grade UHMWPE powders prepared were GUR1050 (Hoechst-Ticona Inc., Texas, USA), which fulfills the requirements for medical grade UHMWPE powder and forms regulated in ISO 5834 Parts 1 and 2. Four types of UHMWPE plates, virgin, 0.3wt % -tocopherol doped, -irradiated, and -irradiated with 0.3 wt % -tocopherol doped were prepared in this study. Dog-bone shaped small tensile specimens were punched out from thin sections (thickness: 150 m) obtained by microtoming the UHMWPE plates. Each tensile specimen was fixed using two chucks of a custom-made portable tension-testing machine. The tensile tests were conducted at a crosshead speed of 1.0mm/sec. For the four types of UHMWPE samples, the transmission spectra were collected with an aperture size of 50m_50m. The infrared spectra obtained were analyzed to evaluate crystallinity and an oxidation level. Irradiated UHMWPE samples showed a steep decrease in crystallinity compared to other types, as an increase in the nominal tensile strain of the UHMWPE samples. Few decreases in crystallinity were observed at a nominal tensile strain of 0.22 in tocopherol doped UHMWPE samples with and without irradiation. Oxidation indices of all types of UHMWPE samples increased as an increase in the nominal tensile strain. The tocopherol doped UHMWPE samples and those followed by-irradiation exhibited extremely low oxidation level throughout the entire tensile deformation process. Incorporation of tocopherol into UHMWPE hampers a decrease in crystallinity under large tensile deformation. Particularly the stability of crystallinity change observed under relatively small plastic deformation supports the excellent wear and fatigue performance of tocopherol doped UHMWPE. The incorporation of tocopherol into UHMWPE demonstrates promise for the stabilization of morphologic change in the high-order molecular structure of UHMWPE as well as oxidation stability under large deformation.



ORAL PAPERS

Friday, 14th September **14.30 – 15.45 h.**

SESSION III: Wear and wear debris

Chair:

O. Muratoglu
Mass General Hosp-USA
C. Rieker
Zimmer, Switzerland

O-8

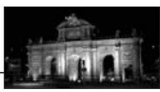
DETERMINATION OF WEAR IN TOTAL KNEE REPLACEMENT COMPONENTS USING CMM TECHNIQUES

Paul Bills, Costas Pantelis*, Professor Liam Blunt*, Gautum Chakrabarty**
* University of Huddersfield, Huddersfield, UK
** West Riding Knee Unit, Huddersfield Royal Infirmary, Huddersfield, UK
Centre For Precision Technologies, School of Computing & Engineering, University of Huddersfield

There are an estimated 1.5 million total joint replacement procedures performed annually worldwide, of these around 500,000 are total knee replacements (TKR). A total knee replacement system is currently expected to function for 10-15 years; however, there are constant demands to improve the life cycle of primary TKRs due to an increase in life expectancy, and a greater call for knee replacement due to increased activity levels. This in turn leads to improved function and offers longer term improved quality of life for patients.

It has long been recognised that wear analysis of total joint replacements is an important tool for accurately determining failure mechanisms and improving longevity of these devices. The standardised method for assessing wear volumes in such joints is through gravimetric means and indeed it has been shown to be a useful tool for assessing simulated wear volumes. Gravimetric measurement is relatively simple and quick but it can introduce significant errors to the measurement of wear in a number of circumstances, such as when there is material transfer from the metal component to the plastic component or when trying to consider the effects of fluid uptake into the ultra high molecular weight polyethylene (UHMWPE) counterface. This method is also of little value when considering the case of a clinically explanted bearing surface for which, by definition, there is no 'pre-wear' data. As a result it is important to have an alternative measurement method that accounts for these factors. The most obvious answer to this conundrum is to physically measure the component, and this study looks at development of co-ordinate measurement techniques to this end.

This study shows the effectiveness of the CMM technique for assessing volumetric material loss during simulated life testing of a replacement knee joint. Furthermore a method is outlined for using these geometrical methods to measure component wear when there was no pre-wear data taken.



ORAL PAPERS

O-9

RHEOLOGY AND WEAR OF CROSSLINKED UHMWPE FOR TOTAL JOINT REPLACEMENTS

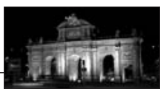
Zdenek Horak, Jana Mikesova, Miroslav Slouf, Jaroslav Fencl
Institute of Macromolecular Chemistry-Czech Republic

(Highly) crosslinked UHMWPE is considered as the best material for bearing parts of total joint replacements (TJR) because of its good wear resistance and balanced end-use properties. A lot of information about preparation, structure and properties of this polymer has been published since early nineties of the last century. Intensive research resulted in several efficient modification procedures of UHMWPE which were commercialized in replacements manufacturing. Surprisingly, no information on rheology of the polymer practically exists. In fact, rheological data are not necessary for present manufacture technologies or product quality testing. On the other hand, knowledge of UHMWPE rheological properties can contribute to explanation of structural changes associated with formation of polymer network due to irradiation and determination of crosslinked extent. Moreover, rheological characteristics are desired for direct compression molding of TJR parts.

To analyze modification effect on crosslinking process in UHMWPE a rheological study has been made. Set of UHMWPE samples prepared by current two-step modification process (irradiation + thermal treatment) under various conditions was measured with help of rotation rheometer using original anti-slipping plates. Complex viscosity G' and G'' moduli were determined from oscillatory measurements at C in the region of linear elasticity. The characteristics obtained were correlated with wear rate measured by multidirectional "pin on disc" tester of own construction.

Correlation proved the direct proportionality between complex viscosity and wear rate and so crosslinking extent and wear resistance. Moreover, the results showed that the same wear resistance can be attained using different radiation dose under different modification conditions. A concept of "variable optimal radiation dose" has been proposed.

Acknowledgement: financial support through grant MSMT 2B06096 (Ministry of Education, Youth and Sports of the Czech Republic) is gratefully acknowledged.



ORAL PAPERS

O-10

WEAR RESISTANCE OF HIGHLY CROSSLINKED AND REMELTED POLYETHYLENES AFTER ION IMPLANTATION AND ACCELERATED AGING

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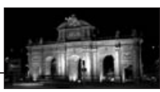
Departamento de Ciencia y Tecnologia de Materiales. CPS Ingenieros. Universidad de Zaragoza

Long-term osteolysis remains as the main problem in total joint replacements, as a consequence of the physiological reactions triggered by polyethylene wear particles. To address this concern, highly crosslinked and remelted polyethylenes, which are materials currently used as soft components in present artificial joints, were implanted with N and He ions at different ion fluences within the range of 5-20x1015 ionscm-2. Mechanical and tribological properties under distilled water lubrication at body temperature were assessed after ion implantation by means of microhardness and pin-on-disk tests respectively. Thus, the influence of the ionic species, and implantation dose on surface hardness, friction coefficient and wear factor were fully characterized. Furthermore, the tribological behavior was evaluated after an accelerated aging protocol (120 °C for 36 hours) as well. After ion implantation, specimens showed a color change from white to yellowish or even brownish, depending on the ion species and implantantion dose (lighter in the case of He ions and/or low dose). Besides, microhardness testing proved ion implantation to cause a surface hardness increase in a very surface layer (~1 mm-thick), which was thicker with higher implantation dose. The tribological tests showed that non-implanted specimens had the lowest friction coefficient values under distilled water lubrication, and the evolution of friction coefficient with sliding time was clearly different in the case of the implanted samples in comparison to the untreated ones. In addition, an influence of implantation dose on the steady friction coefficient was also present. Finally, all artificially aged materials showed a worse wear behavior, but polyethylenes implanted either with N or He ions at the highest doses kept a relatively good wear factor in comparison with the aged non-implanted material (7 times better). These improved features may assure a significant decrease in osteolysis related-problems, and guarantee an excellent in vivo performance.



ORAL PAPERS

O-11

NANO-SCALE MODIFICATION WITH 2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE POLYMER BRINGS TO ULTRA-LONGEVITY FOR ORTHOPAEDIC BEARINGS

Masayuki Kyomoto, Toru Moro, Fumiaki Miyaji, Masami Hashimoto, Hiroshi Kawaguchi, Yoshio Takatori, Kozo Nakamura, Kazuhiko Ishihara
Research Department, Japan Medical Materials Corporation.
Department of Materials Engineering, School of Engineering and Center for NanoBio Integration, The University of Tokyo

Introduction: Osteolysis caused by wear particles from polyethylene in the artificial hip joints is a serious issue. We have used photo-induced radical polymerization to graft 2-methacryloyloxyethyl phosphorylcholine (MPC) polymer onto the surface of cross-linked polyethylene (CLPE-g-MPC) in order to reduce friction and wear at the orthopedic bearing surface. The present study investigated the properties of the poly (MPC) layer formed on the CLPE surface by photo-induced radical graft polymerization, and the wear-resistant properties of the CLPE-g-MPC will be discussed in terms of the characteristics of the poly (MPC) nano-layer.

Methods: Surface chemical properties of the untreated CLPE and CLPE-g-MPC were examined by Fourier-transform infrared spectroscopy (FT-IR) and X-ray photoelectron spectroscopy (XPS). A cross-section of the MPC polymer layer on the CLPE-g-MPC surface was observed by TEM. The in vitro wear test was performed using an MTS hip joint simulator. In the hip simulator test, the acetabular cup (26 mm inner diameter and 52 mm outer diameter) was used with a Co-Cr-Mo alloy femoral head. The testing was continued until a total of 5.0 million cycles were completed.

Results: After grafting, the peaks ascribed to MPC unit were clearly observed in both FT-IR and XPS spectra. Various grafted poly (MPC) layers 10 to 200 nm thick were clearly observed on the surface of the CLPE substrate. Even after 5.0 million cycles in the hip joint simulator test, no wear of MPC-g-CLPE cups with a poly (MPC) layer 10 nm thick was observed. Discussion: It was confirmed from the hip joint simulator test that the wear rate was much lower in the CLPE-g-MPC cups than in the untreated CLPE cups. Since MPC is a highly hydrophilic compound, the water-wettability of the CLPE-g-MPC surface was greater than that of the untreated CLPE surface because of the poly (MPC) nano-layer. The orthopedic bearing with a CLPE-g-MPC surface had high lubricity as long as it has a poly (MPC) layer 10 nm thick. Such poly (MPC) layer 10 nm thick is assumed to be responsible for the improved wear resistance. We concluded that the nano-scale modification of poly (MPC) could bring to ultra-longevity for orthopedic bearings.

ORAL PAPERS

O-12

INFLUENCE OF CENTRIFUGATION ON MORPHOLOGY OF UHMWPE WEAR PARTICLES

Monika Lapcikova, Miroslav Slouf, Zlata Fejfarkova, Eva Zotolaravova, Gustav Entlicher, David Pokorny, Antonin Sosn
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Osteolysis in total joint replacements has been linked to ultrahigh molecular weight polyethylene (UHMWPE) wear particles [1]. It is known, that the particles with equivalent diameters between 0.1-10 _m exhibit the highest biological activity. The biological response to the UHMWPE particles depends on their number, size and morphology. As a result, number of studies dealing with isolation of wear particles and correlating their morphology with their biological activity exists. Centrifugation is routinely used in most of the isolation procedures described in the literature. It has been proposed that centrifugation at high speeds might influence the shape of the particles [2].
In this study, UHMWPE wear particles were isolated by our own procedure, which is based on nitric acid digestion [3].
In the final step, the wear particles were separated by flotation or centrifugation. Three different conditions of centrifugation were selected: (i) 2 min at 500g, (ii) 5 min at 16000g and (iii) 30 min at 105000g. The morphology of the particles was obtained by image analysis of SEM micrographs. Equivalent diameter (ED), circularity (CR) and elongation factors (EF) were determined for both flotated and centrifuged particles. The fraction of elongated particles was approximately the same in all cases and all the parameters (ED, CR, EF) were almost constant. This proves that even the highest centrifugation speed and time did not influence particle shapes.

Acknowledgement: Financial support through grant MSMT 2B06096 (Ministry of Education, Youth and Sports of the Czech Republic) is gratefully acknowledged.

References:

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[2] Visentin M. et al. (2004). A new method for isolation of polyethylene wears debris from tissue and synovial fluid.
Biomaterials 25:5531-5537
[3] Slouf M et al. (2006). Isolation, Characterization and Quantification of Polyethylene Wear Debris from Periprosthetic Tissues around Total Joint Replacements. Wear, in press.

ORAL PAPERS

O-13

UHMWPE WEAR PARTICLES IN DIFFERENT ZONES AROUND TOTAL HIP REPLACEMENTS

Miroslav Slouf, David Pokorny, Gustav Entlicher, Zlata Fejfarkova, Hana Synkova, Monika Lapcikova, Filip Vesely, Antonin Sosna
Institute of Macromolecular Chemistry-Czech Republic

Ultra-high molecular weight polyethylene (UHMWPE) has been used as a bearing material in total joint replacements (TJR) for more than four decades. Although UHMWPE is regarded as a golden standard in this field due to its excellent biocompatibility and high wear resistance, still some microscopic wear particles are released from the polymer causing damage of surrounding tissues. Surprisingly enough, there are almost no studies in the available literature correlating the amount of wear particles and the extent of tissue damage in particular zones around total joint replacements.
To show a relationship between the tissue damage and amount of wear debris around TJRs, high numbers of samples have to be processed. The samples of damaged tissues are obtained during the revision surgery of TJRs, and for every patient the samples from several well defined zones around TJR have to be taken. Such a high number of samples requires fast and reliable technique for isolation and quantification of polyethylene wear debris. Therefore, we have developed an IRc method, which determines total volume of UHMWPE wear particles in particular zone around TJR from a single infrared spectrum of wear particles isolated on a polycarbonate membrane.
The IRc results correspond very well to the results obtained by an independent method, which is based on (semi)automated image analysis of scanning electron micrographs showing the wear particles on a polycarbonate membrane. The IRc results were also confronted with radiographic images and with the reports coming from total hip replacements (THR) revision surgery. Again, very good correlation was found, indicating that the extent of tissue damage in a particular zone around THR is proportional to the volume of UHMWPE wear debris in the zone. The comparison of IRc results, radiographic images and other clinical data has been made for 22 patients so far. The results confirm that the UHMWPE wear particles are the main reason for THR failures in most studied cases.
Acknowledgement: Financial support through grant MSMT 2B06096 (Ministry of Education, Youth and Sports of the CzechRepublic) is gratefully acknowledged.

ORAL PAPERS

Friday, 14th September **16.45 – 18.00 h.**

SESSION IV: Material and manufacture improvements

Chair:

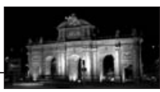
C. Rimnac
Case Western Reserve Univ-USA
J. Puértolas
Univ. Zaragoza-Spain

O-14

COMPARISON OF SEQUENTIAL AND SINGLE-DOSE IRRADIATION EFFECTS ON THE MECHANICAL, PHYSICAL, AND OXIDATIVE PROPERTIES OF UHMWPE

Mark Morrison, Jani Shilesh
Smith & Nephew Orthopaedics. Memphis-USA

Recently, sequential irradiation and annealing of UHMWPE has been suggested as a solution to increasing wear resistance without compromising the mechanical properties. The purpose of this study was to compare crosslinked UHMWPE produced by single dose irradiation to material that was irradiated by sequential cumulative doses. Compression-molded GUR 1020 rods from the same resin and production lots were gamma-irradiated to total doses of 9 Mrad by either (a) single dose (XL), or (b) three sequences of 3 Mrad (SQXL). The single-dose XL materials were annealed at either 130°C for 8 hours (XL-130) or 147°C for 2 hours (XL-147). The SQXL material was annealed at 130°C for 8 hours after each irradiation sequence. Unirradiated GUR 1020 (CPE) from the same resin lot served as the control. Tensile, Izod impact and small-punch tests were conducted to characterize the mechanical properties. The thermophysical properties and lamellar thickness distributions were measured by differential scanning calorimetry, and the free-radical concentration (FRC) in each material was determined by an electron spin resonance (ESR) spectrometer. The oxidation potential was evaluated through accelerated aging and subsequent determination of oxidation indices by Fourier-transform infrared (FTIR) spectroscopy.
Sequential irradiation of UHMWPE (SQXL) did not result in statistically significant differences in any of the properties evaluated in this study, as compared to material from the same lot that was irradiated with a single dose (XL-130). This study confirms that irradiation always results in decreases in tensile strength, elongation, and impact strength, compared to virgin UHMWPE. Although sub-melt annealing (XL-130) resulted in higher crystallinity, as compared to re-melted UHMWPE (XL-147), the impact strength and oxidation potential were negatively affected.



ORAL PAPERS

O-15

THE MONOTONIC AND CYCLIC FATIGUE BEHAVIORS OF A CONVENTIONAL AND A SEQUENTIALLY ANNEALED HIGHLY CROSSLINKED UHMWPE IN A NOTCH-INDUCED TRIAXIAL STRESS STATE

Michael Sobieraj, Steve M. Kurtz*, Aiguo Wang,, Michael Manley**, Clare M. Rimnac*****
Exponent Inc, Philadelphia PA*,
Stryker Orthopaedics, Mahwah, NJ**
Musculoskeletal Mechanics and Materials Laboratories, Departments of Mechanical and Aerospace Engineering and Orthopaedics***
Case Western Reserve University Department of Mechanical and Aerospace Engineering and the School of Medicine

The objectives of this study are to examine the effect of a notch-induced triaxial stress state on the monotonic and cyclic tensile true stress-strain behavior of two UHMWPE materials: a conventional (30kGy; packaged in N_2 and gamma irradiated to 30 kGy) and a second-generation crosslinked UHMWPE (SA; X3™ process: irradiated to 30 kGy and then annealed at 130 ºC for 8 hours 3 times sequentially for a cumulative dose of 90 kGy).
Both materials were prepared from GUR 1050 extruded barstock. Two geometries of cylindrical dog-bone tensile specimens, smooth (O.D.=8mm) and notched (circumferential U-shaped groove, kt=2.7, O.D.=8mm, I.D.=6mm), were tested to failure. For the monotonic tests, specimens were soaked for 6 weeks in 37ºC PBS bath and tested at two extension rates (30 and 150 mm/min) in 37ºC air. Engineering strains were found using non-contacting video extensometry methods.
The effects of material, notching, and rate on the true yield and ultimate stresses and strains and notch strengthening and hardening ratios were examined using ANOVA analyses (a=0.05) in which first order interactions were included.
Both the 30kGy and the SA materials showed a significant reduction in ultimate true stress (Material, Notch, Material:Notch significant) and true strain (Material, Notch, Material:Notch significant) upon notching and an elevation of true axial yield stress (Material, Notch, Rate significant) and yield strain (Notch, Rate significant). Both materials showed notch strengthening of stress (Notch, Rate significant) and strain (Notch significant) at both extension rates. The materials showed stress hardening (all terms but Notch:Rate significant) and strain hardening (all terms significant) in the smooth and notched conditions at both extension rates. The smooth specimens exhibited the most stress and strain hardening.
Fractographic analysis showed a difference in the fracture micromechanism of the notched 30kGy and SA materials at both rates. All the notched 30kGy 30mm/min and 8/14 of the notched 30kGy 150mm/min specimens showed 2 fracture zones whereas none of the notched SA (30 or 150mm/min) showed 2 different fracture zones.
Companion S-N type fatigue tests are currently underway and the findings of these studies will also be presented.

ORAL PAPERS

O-16

MECHANICAL PROPERTIES OF UHMWPE/MWCNT COMPOSITES USED FOR ORTHOPAEDIC APPLICATIONS

Kanagaraj Subramani, Fonseca A, Ferreira J.M.F, Mónica Oliveira, José Simões
University of Aveiro. Portugal

Ultra high molecular weight polyethylene (UHMWPE) has been the material of choice for the acetabular cup. But, it has been found that loosening and failure in total hip replacements are induced by very fine UHMWPE particles. Thus, an attempt has been made to enhance the characteristics of UHMWPE as a bearing material for the acetabular cup by adding multiwalled carbon nanotubes (MWCNT). The chemically treated MWCNT was homogeneously mixed with required quantity of UHMWPE using a ball miller. This UHMWPE-MWCNT mixture was compressed in a mould to prepare a plate specimen where tensile specimens were cut to study their mechanical properties. The composite samples were prepared with different weight percentages of MWCNT. An experimental setup using a small punch technique has been developed to study the elastic modulus, ultimate strength, ultimate displacement and load at failure of MWCNT/UHMWPE composites, which involves deforming a disc-shaped specimen under multiaxial loading conditions. The results are compared and the optimum value of weight fraction of MWCNT has been suggested in such way that material will have the lowest volumetric wear rate which is determined from the toughness of the materials. It is concluded that the small punch technique is suitable for evaluating the mechanical behavior of the MWCNT/UHMWPE composites along with wear rate of materials.

O-17

ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE (UHMWPE) AND POLYETHER URETHANE NANO-COMPOSITE AS ACETABULAR CUP MATERIAL

Mohammad Taghi Khorasani
Iran polymer and Petrochemical Institute. Tehran, Iran.

An acetabular cup implant is formed from a composite of polymeric materials. The cup consists of 2 zones such as the articulating surface of the implant is 100 % of UHMWPE and shock absorber of the cup contains of PU – UHMWPE composite. This material consists of UHMWPE and PU, which in one side adhere to UHMWPE and in other side is in contact with body. In this study an attempt was made to blending of micro – porous UHMWPE with PU in a solution casting process. SEM photomicrographs show that PU not only covers the surface of the porous film but also after molding in hot press, inter-diffused between UHMWPE lamella. It seems that lamella reinforced with PU and this phenomenon consequently increases mechanical properties drastically. Results of tensile modulus (also tensile strength) show that tensile modulus of composite increase 50 and 4 times in comparison to pure PU and UHMWPE respectively. In vitro L-929 cell culture results noticed that L-929 cells attach and growth on composite surface as like as UHMWPE and there are not fond any toxicity and cell inflammations.

POSTERS

P-1

MODELING OF FRACTURE PHENOMENA IN ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE USING THE DISCONTINUOUS GALERKIN FINITE ELEMENT METHOD

Felicia Stan
Dunarea de Jos University of Galati, Faculty of Mechanical Engineering. Romania

Ultra-high molecular weight polyethylene (UHMWPE) is widely used for bearing surface in hip and knee joint implants because of its excellent mechanical properties and biocompatibility. From mechanical point of view, the major factors that affect the stability of joint implants are: fracture of the implants, wear of the material implants and failure of the interface between the cement and UHMWPE.
In this paper, we present a class of discontinuous Galerkin (dG) methods for predicting the various fracture phenomena in UHMWPE components. The dG method is a finite element method, which uses discontinuous, piecewise polynomial spaces for the numerical solution and the test functions. Thus, dG methods offer an elegant and rigorous possibility to handle problems with discontinuous displacements as arise in fracture.
The formulation also allows for discontinuities in the displacement field across the grain boundaries. The microcracking along the grain boundaries is modeled using the cohesive-zone concept, and the difference between inter-granular and intra-granular mechanical characteristics is taking into account. Several numerical examples are presented that illustrate the performance of the dG method in complex geometries with a wide range of boundary conditions.

P-2

ULTRA HEIGHT MOLECULAR WEIGHT POLYETHYLENE WEAR PARTICLES IN FAILED TOTAL HIP REPLACEMENTS

Malgorzata Figurska, Ingrid Milo_ev, Eligiusz Wajnryb
Polish Academy of Sciences, Warsaw, Poland b Jo_ef Stefan Institute, Ljubljana, Slovenia c Orthopedic Hospital Valdoltra, Ankaran, Slovenia

Ultra height molecular weight polyethylene (UHMWE) is widely used in orthopedics as a bearing material in artificial joints. Despite the success of arthroplasty the UHMWPE has finite lifespan. The intensive wear process of polyethylene is one of the most important factors limiting implant longevity. The biological response to wear particles can evoke chronic inflammation, what can lead to aseptic loosening of the implant and subsequently to revision arthroplasty.
The aim of this study was to compare the size of polyethylene particles prevalent in fibrous periprosthetic tissues with roughness measurements of the femoral heads and histological response of those tissues in two groups of total hip replacements.
In the examined cases the self-locking stems were made of Ti6Al4V alloy and were cemented; the polyethylene cups were used in both groups. The two groups differ in the material of femoral head, which was either metal or ceramic (Al_2O_3).



POSTERS

The correlation of the particle size and roughness of femoral head was observed. Low roughness of ceramic heads caused the formation of the smaller particles. The surfaces of metal femoral heads revealed higher roughness properties, what contributes to the generation of the big diversity of the size of polyethylene particles during friction against polyethylene cup. No significant difference in cellular reaction between the two groups was found. However, the amount of giant cells that surround big polyethylene particles was different among groups.

P-3

FRICTION AND WEAR BEHAVIORS OF UHMWPE AGAINST CO-CR ALLOY UNDER THE PHYSIOLOGICAL CONDITIONS IN TOTAL JOINT REPLACEMENT

Kwon-Yong, Lee, Dong Wook Kim, Dept. of Mechanical Engineering, Sejong University, Seoul, Korea; **Sung Jae Lee**, Dept. of Biomedical Engineering, Inje University, Gimhae, Korea; **Sung Soo Kim**, Biomaterials Lab., Korea Research Institute of Chemical Technology, Daejon, Korea; **Yong Sik Kim**, Dept. of Orthopaedic Surgery, Kangnam St. Mary's Hospital, Catholic University Medical College, Seoul, Korea; **Doo Hoon Sun**, Corentec Inc., Seoul, Korea Sejong University. Department of Mechnical Engineering. Bioengineering Resear Center. Korea

Objectives: Friction and wear between UHMWPE and C0-Cr alloy components in total hip and knee replacements affects the clinical performance. The purpose of this study is to understand friction and wear behaviors of these components under the physiological conditions in TJR.
Methods: For friction tests, UHMWPE pin and Co-Cr alloy disc (Ra =0.002) were relatively slid in the dry, fully immersed, and rarely bovine serum-lubricated (dropping of 0.05ml on disc per minute) conditions under the contact pressures of 10, 20, 30, and 40Mpa. All tests were performed in a repeat pass sliding motion of 60rpm speed and frictional coefficients were determined. For wear tests, UHMWPE pin and Co-Cr alloy disc (Ra =0.002) were relatively slid in a fully immersed bovine serum-lubricated condition under the contact pressures of 20, 40, and 60Mpa. All tests were performed in a linear reciprocal sliding motion of 60rpm speed up to the one million cycles. The weight changes of UHMWPE pins were measured using a microbalance. Wear track on the Co-Cr alloy disk specimens were observed with a microscope.
Results and Discussion: Coefficient of friction varied in the range of 0.07~0.25 in the dry condition. Coefficient of friction in the rarely and fully immersed bovine serum-lubricated conditions were 0.025~0.04 in a steady state. Coefficient of friction decreased as the contact pressure increased.
Wear almost linearly increased as a number of sliding cycles increased. And also wear increased as the contact pressure increased. The average wear rates for the 20, 40, and 60Mpa were 1.71x10-10 g/cycle, 2.2x10-10 g/cycle, and 2.5x10-10 g/cycle, respectively. Under the high pressure, some scratches and transfer film of UHMWPE were observed on the sliding track.
Acknowledgements: This study was supported by a grant of Components and Materials Technology Development Program from the Korea Ministry of Commerce, Industry, and Energy (10025570).

POSTERS

P-4

WEAR ANALYSIS OF UWMWPE TIBIAL COMPONENT ON THREE DIFFERENT TOTAL KNEE JOINT PROSTHESIS DESIGNS. STUDY IN A NEW KNEE SIMULATOR

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Instituto de Biomecánica de Valencia. Spain

Introduction: Wear of polyethylene tibial component is one of the major causes of failure of total knee joint replacements. Apart from mechanical damage of the bearing surfaces, wear generates polyethylene debris which can induce osteolitic reactions that produce implant loosening and lead to the subsequent need of implant revision.

Some of the aspects affecting wear in total knee joint prostheses are: type of materials (especially the UHMWPE of the tibial insert), manufacturing and finishing of the bearing surfaces and knee prosthesis design.

Some published studies have shown the important influence of bearing surfaces design in wear of total knee joint prostheses. Design of bearing surfaces determines the kinematic behaviour of knee prostheses (ranges of anterior-posterior and medial-lateral displacements and different rotations) and contact pressures as well. Wear is directly related to both issues. The aim of this study is to have a better knowledge about influence on wear of total knee joint prostheses design.

Material and Methods: Three different knee prosthesis designs are being tested on a new Biopuls Dual-Station Knee Simulator (INSTRON) in accordance with ISO 14243-1 standard in force control mode during 5 million cycles. This system applies physiological load and motion profiles, including flexion-extension, anterior-posterior shear, interior-exterior torque and axial load on the test specimen while it is soaked in a bovine serum solution at 37°C.

All of the tested designs are fixed bearing knee joint prostheses: one posterior cruciate ligament retaining (ANAKINE CR – LAFITT), one posterior stabilized (ANAKINE PS – LAFITT) and one ultracongruent knee with cruciate substitution (NATURAL KNEE II® –ZIMMER).

Gravimetric wear measurements are taken at different time periods according to the ISO 14242-2 standard. Wear debris analysis, including number, size and particles' morphology, is performed at three time periods during the test.

Results: Differences in wear behaviour among these designs will be checked by comparing results of wear debris analysis and gravimetric wear. Moreover, differences in kinematic behaviour will be evaluated as well. Tests are being performed at this moment, so results and conclusions will be presented at the meeting.

POSTERS

P-5

3D SCANNING AND CNC MILLING OF THE GLENOID FOSSA FOR MANDIBULAR RECONSTRUCTION

Liciane Sabadin Bertol, Faller, Roberto da Rosa, Luis Alberto Santos, Wilson Kindlein Júnior
Universidade Federal do Rio Grande do Sul

There is a great interest, in many areas of applied science (like Engineering and Medicine) in producing parts of complex geometry using different materials. In Medicine, in special, materials with particular properties are used currently to substitute organs, tissues and functions of the human body. The selection of the material, however, cannot be done independently of the selection of the manufacture process and the geometry of the part.
The most widely accepted configuration for implants includes a metallic component (normally titanium) articulated against a polymeric component (normally Ultra High Molecular Weight Polyethylene, UHMWPE). Parts made with UHMWPE, however, can't be produced through the traditional methods of polymer manufacturing processes. Implantations produced in such material demand hot pressing or machining.
The conventional development of products, that demands CAD data, is normally not viable when talking about organic forms. In this case it is necessary to apply the non conventional method: the reverse engineering. This technique allows capturing the geometry of the part or prototype, and then, the generation of a model to be used in CAE CAM systems. The aim of this study was to develop a method to manufacture a component of a mandibular prosthesis, the glenoid fossa. It is necessary, so that the titanium, used to reproduce de condyle, does not damage the osseous structure against which it is articulated. For this, a stereolithography biomodel of the patient skull was used. The glenoid fossa region was isolated, and manually, was recovered by a resin. After the time of the cure of the resin, a model of the implant to be manufactured was obtained. To get a virtual model of the implant to be machined, a three dimensional laser scanning of the physical model was made.
Using the virtual model, the implant could be manufactured in UHMWPE through a CNC milling process, acquiring the desired forms, being apt for implantation in the patient that needed a total mandible reconstruction.

POSTERS

P-6

A QUANTIFIABLE AND VALIDATED MODEL OF LOCAL POLYMER PARTICLE DELIVERY

Stuart B. Goodman, Steve Ortiz, Ting Ma, Harry Huang, Pei-Gen Ren, R. Lane Smith
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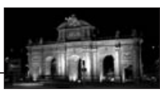
Polyethylene wear particles generated from prosthetic joints induce a chronic inflammatory reaction that may lead to periprosthetic osteolysis and implant loosening. In humans, particles are generated continuously. However, animal models exploring the effects of particles generally implant a single dose per primum, or use multiple bolus injections that are painful and could introduce infection. We validated and quantified a model of continuous polymer particle infusion in mice to more closely simulate the human scenario. This model is cost-effective and facilitates the use of genetically manipulated mice and sophisticated molecular techniques.
Methods: In the first proof-of-concept experiment, blue-dyed polystyrene particles (PS) (0.5±0.015 m) and UHMWPE particles (0.5±0.2m) suspended in mouse serum were loaded into Alzet mini-osmotic pumps (volume: 200 L; delivery rate: 0.25 L/h) connected to polyvinyl tubing and a hollow titanium rod (6 mm, 21 G). Particle suspensions of 6.0x109 - 3.0x1011 particles were loaded into the pumps. Assemblies were placed inside collection tubes with PBS and rocked at 37°C.
In the second experiment, hollow titanium rods were inserted retrograde into explanted mouse femora. Femora and pump assemblies containing particles were placed in organ culture for up to 4 weeks.
In the third experiment, the pump-rod assemblies were implanted in live mice.
Results: Using turbidity analysis, spectrophotometry and SEM, PS particles pumped at values ranging to 21% of the original particle load (2 weeks) and 46% (4 weeks). Higher particle suspensions pumped less efficiently. 19% (2 weeks) and 32% (4 weeks) of UHMWPE particles were pumped, with increasing efficiency at higher dose. Using the mouse femoral explants model, visual, microscopic and microCT analysis confirmed that particles could be pumped successfully. In vivo studies using PS and UHMWPE verified particle delivery to the distal femur.
Discussion: The present model, a variant of one previously described by our group and Kim et al, uses an infusion pump, tubing and a hollow intramedullary rod to deliver submicron polymer particles to the distal femur continuously. This novel murine model simulates the clinical scenario more closely and facilitates cellular and molecular studies in mechanistic experiments on particle-induced loosening and osteolysis.



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P-7

POLYETHYLENE AND COBALT-CHROMIUM MOLYBDENIUM PARTICLES ELICIT A DIFFERENT IMMUNE RESPONSE IN VITRO

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Periprosthetic osteolysis is a major clinical problem that limits the long-term survival of total joint arthroplasties. Particles of prosthetic material stimulate immunecompetent cells to release cytokines, which may cause bone loss and loosening of the prosthesis. This study examined the following hypothesis. Polyethylene and titanium particles elicit a different immune response in vitro. To test these hypotheses, we used the human bone marrow cell culture model that we have established and previously used to examine particle associated cytokine release. Ultra high molecular weight polyethylene (UHMW-PE) induced a proliferation of CD14 positive cells (monocytes/macrophages) whereas cobalt chromium molybdenium (CoCrMb) particles demonstrated an increased proliferation of CD66b positive cells (granulocytes). Light and scanning microscopic evaluation revealed that the UHMW-PE particles, which have built large clusters of particles, were mainly surrounded by the cells and less phagocytosed. On the other hand the smaller particles from CoCrMb have been phagocytosed by the cells. These results provide strong support for our hypothesis: that wear particles derived from prosthetic materials of different material can elicit significantly different biologic responses. In summary the results suggest that the" in vitro" response to wear particles of different biomaterials should be investigated by culture systems of various lineages of cells.

Keywords: wear particles; in vitro; biocompatibility; immune modulation

P-8

BACTERIAL ADHESION ON UHMWPE: EFFECT OF SURFACE ROUGHNES AND STERILISATION PROCEDURE ON ADHERENCE OF S. AUREUS AND S. EPIDERMIDIS

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INTRODUCTION: Bacterial adhesion on implant surface is a major reason for implant sequelaeand can eventually lead to implant removal. The adhesion process is a complex series of physical and chemical interactions between the substratum and microbe. Some physical biomaterial surface properties such as roughness are known to have effect on this process especially in metallic materials. The surface properties can be manipulated by surface treatments, including

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sterilisation. In this study we tested the bacterial adhesion on UHMWPE of three different roughnesses. Furthermore the effect on bacterial adhesion of two different sterilisation methods was tested.
METHODS: Staphylococcus aureus and Staphylococcus epidermidis were used in this experiment. The bacteria were suspended in PBS to yield the final concentration of 1 x 108 colony-forming units (CFU)/ml. The UHMWPE samples were incubated in bacterial suspension for 90 minutes at +37°C to allow bacterial adhesion and after washing with PBS sonicated in determined volume of PBS. The number of bacteria in each sonication product was quantified by plate counts. The samples of 0.3 µm, 0.7 µm and 2.0 µm roughnesses were sterilised by using gas plasma (GP) or ethylene oxide (EO).
RESULTS: The median number of S. aureus adhered on UHMWPE of three different roughness was following. Samples sterilized with GP: 5580 CFU/mm2 (SEM +/- 380) for material with roughness of 0.3 µm, 5510 CFU/mm2 (SEM +/- 440) for 0.7 µm and 5280 CFU/mm2 (SEM +/- 390) for 2.0 µm. Samples sterilized with OE: 3110 CFU/mm2 (SEM +/- 390) for material with roughness of 0.3 µm, 3990 CFU/mm2 (SEM +/- 520) for 0.7 µm and 3890 CFU/mm2 (SEM +/- 560) for 2.0 µm. Subsequently the adherence of S. epidermidis was following. Samples sterilized with GP: 6140 CFU/mm2 (SEM +/- 820) for material with roughness of 0.3 µm, 6350 CFU/mm2 (SEM +/- 430) for 0.7 µm and 5290 CFU/mm2 (SEM +/- 540) for 2.0 µm. Samples sterilized with OE: 2980 CFU/mm2 (SEM +/- 490) for material with roughness of 0.3 µm, 2850 CFU/mm2 (SEM +/- 460) for 0.7 µm and 3980 CFU/mm2 (SEM +/- 330) for 2.0 µm. With both bacteria in all three roughnesses the bacteria adhered significantly more to materials sterilized with GP. No significant differences appeared between the materials of different roughness.
DISCUSSION: The results show that the two different sterilisation methods tested may cause changes in surface characteristics that alter the bacterial adherence on UHMWPE surface. In all materials both S. aureus and S. epidermidis adhered more to the UHMWPE surfaces sterilized with GP. Although material roughness influences significantly the bacterial adhesion on metal surfaces such as titanium the results of this study show that surface roughness does not have such influence on the bacterial adhesion on UHMWPE.

P-9

A STUDY ON THE KINETICS OF FREE RADICAL DECAY OF GAMMA RAY IRRADIATED UHMWPE USED IN TOTAL JOINT ARTHROPLASTY AND ITS APPLICATIONS IN MATERIAL IMPROVEMENTS

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Wear of UHMWPE element remained to be one of the major problems in total joint arthroplasty. Numerous studies indicated that the oxidation reaction induced by gamma irradiation for sterilization is responsible for the wear of the material. It has also been shown that the wear

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problem can be substantially improved by cross-linking treatment, induced by high dose of gamma ray irradiation, of the UHMWPE material. However, relatively few works has been done to provide quantitative, instead of qualitative, data to describe the reaction mechanism of the free radical decay in a gamma ray irradiated UHMWPE material. Herein, the effects of gamma ray irradiation on the UHMWPE element were studied both theoretically and experimentally. The electron paramagnetic resonance (EPR) spectroscopy was applied to study the reaction kinetics of free radical decay in vacuum and in air. Theoretical analysis on the free radical decay curves obtained by EPR spectroscopy suggesting that the reaction kinetics in vacuum and in air can be well described by a modified second order and a typical second order reaction, respectively. This result was further implemented into a theoretical model, which integrates the effects of free radical generation, oxygen diffusion, free radical termination reaction, and oxidation reaction, to describe the oxidation behavior of a gamma irradiated UHMWPE element. Based this model, we were able to predict the evolving of the oxidation depth profiles of the UHMWPE elements kept under various environments and to design in vitro accelerated aging protocols for aging processes on shelf or in vivo.

P-10

NUMERICAL SIMULATION OF INJECTION MOLDING OF ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE

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Because of its unique combination of properties such as high abrasion resistance, low coefficient of friction, chemical inertness and stress crack resistance, ultra high molecular weight polyethylene (UHMWPE) is an excellent candidate for medical application especially for total joint replacements. Due to its high melt viscosity at the processing temperatures, the UHMWPE is commonly processed by compression molding and ram extrusion into semi-forms or net profile-formed through direct compression molding. A problem in applications of UHMWPE is the tendency for components to contain fusion defects, especially voids, arising during processing of the polymerized powder. These defects have been implicated previously in failures of UHMWPE implants. Building on the known benefits of UHMWPE as a material for implants, recently, Ticona offers two grades of UHMWPE in pellet form for injection molding. Injection molding of UHMWPE allows production of small, high-precision, more complex implants. Thus, the objective of this investigation is the evaluation of the influence of the different acetabular cup shapes on the injection molding process of the GUR EP 4221(UHMWPE) with the aim of predicting the potential manufacturing defects such as air traps, weld lines and cracks. The numerical simulations will be carried out using the Moldflow Plastics Insight software. The numerical results are further used to select the appropriate injection technology, investigate material processability, and to proper design the part and the mould for the acetabular cup implants.

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MOD_F_CAT_ON OF SURFACE MORPHOLOGY OF UHMWPE FOR B_OMED_CAL IMPLANTS

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An attempt was made to change the surface morphology of UHMWPE samples at nano scale by metal and metal+gas hybrid ion implantation (Ag, Ag+N, C+H, C+H+Ar, Ti+O) to obtain increased hardness and wear resistant surfaces. UHMWPE samples were metal and metal-gas hybrid ion implanted by using improved MEVVA ion implantation technique with an extraction voltage of 30 kV and fluence of 1017 ions/cm2. Characterizations of the implanted samples with ATR - FTIR, RBS and UV-Vis - NIR spectrum were compared with the un implanted ones. Implanted and unimplanted samples were also thermally characterized by TGA and DSC. XRD and DSC measurements showed an increas in polymer crystallinity. It is observed that C–H bond concentration decreased. The results indicated that he linear chain structure of UHMWPE are damaged and crosslink number was increased compared to unimplanted ones resulting in increased hardness. It is observed that nano size cracks (approx.10nm) are significantly disappeared after Ag implantation, which also has improved the antibacterial effect. Contact angle measurements showed that wettability of samples increased with ion implantation. Results showed that metal and metal+gas hybrid ion implantation could be an effective way to improve the surface properties of UHMWPE to be used in biomedical materials.

Key words: Surface modification, UHMWPE, Ion Implantation.

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PROCESSING AND PROPERTIES OF CARBON NANOFIBER COMPOSITES WITH UHMWPE USING TWIN-SCREW EXTRUSION

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Ultra high molecular weight polyethylene (UHMWPE) has many excellent properties, including high impact strength, low friction coefficient, good chemical resistance and biocompatibility. Modification of UHMWPE through adding nano-fillers to make it into nanocomposites can improve the strength and modulus as well as other properties, which may lead this type of material to greater applications. The carbon nanofibers (CNFs) are attractive fillers for composites due to their high mechanical, thermal and electrical properties. In particular, CNFs have layered graphene structures, which afford them good lubricant property. Therefore, CNF/UHMWPE composites have been paid great attention in recent years. Extrusion has been widely used in processing polymeric materials in industry. Our previous studies showed that twin-screw extrusion produced uniform particle dispersion by the shear force in polymers.

In this work, we studied the CNF-reinforced nanocomposites prepared by using a twin-screw extruder. Due to the high viscosity of UHMWPE, which made it initially difficult in processing by extrusion, a low density polyethylene (LDPE) was added to lower the viscosity of UHMWPE. A set of nanocomposite specimens with different loadings of CNFs in the polymer matrix (blend of UHMWPE/LDPE) were prepared by a twin-screw extruder. Morphology and properties of the nanocomposites were studied by differential scanning calorimetry (DSC), scanning electron microscopy (SEM), X-ray diffraction (XRD), tensile test and Thermogravimetrical analysis (TGA). Study results showed that the crystallization temperature rises with the increasing of CNF loading due to the effects of CNFs on the nuclear of crystallization. The enthalpy of melt and crystallization of nanocomposite are lower than the UHMWPE polymer blend. The morphology and extent of dispersion by SEM indicated that the dispersion of CNF!
s was uniform in the matrix. Mechanical properties and thermal stability of the nanocomposites were enhanced compared to that of the polymer matrix.

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Friday, 14th September

ON OXIDATION AND STABILISATION OF UHMWPE

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The orthopedic ultra high molecular weight polyethylene (UHMWPE) has been the material of choice for bearing components of total joint arthroplasty for the past 30 years. According to the ASTM regulation, the UHMWPE does not contain any stabiliser and therefore it can oxidise very easly.
The UHMWPE prosthetic components must be sterilised. The EtO process does not modified the UHMWPE. The irradiation process with high energy radiation as gamma radiation or e-beam produces, at the end of sterilization, an amount of macroradicals proportional to the absorbed dose and, in the presence of oxygen, the oxidation process start at low temperature. This process is called post-irradiation oxidation.
In the present work we have studied both the stability of macroradicals produced during irradiation under inert atmosphere and the thermal stability of hydroperoxides (ROOH) produced during irradiation in air.
The stability of alkyl macroradicals in the amorphous phase is around 10 hour, while the thermal stability of macro-hydroperoxides at 110°C is reported in fig. 1. From FTIR analyses, it is evident that two different kind of hydroperoxides are formed: bounded hydroperoxides, decomposing in 30 hour, and free hydroperoxides, more stable.

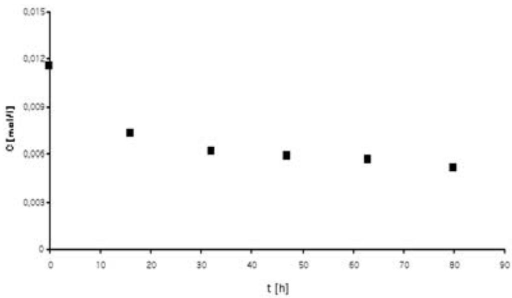

Figure 1: *Hydroperoxide decomposition in vacuum at 110°C*

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Irradiated UHMWPE was left at room temperature and the oxidation process was followed for long time in absence of hydroperoxides decomposition. In Figure 2 the carbonyl and hydroperoxides build-up and their rate of formation are reported.

The behaviour of hydroperoxides is very similar to that of ketones. Ketones and ROOH are accumulated during the post-irradiation process. The rate of ketones formation is high when the concentration of ROOH is minimum and the macroradicals concentration is high. Therefore, ketones and ROOH could form with a similar mechanism: a direct reaction between macroalkyl radicals and oxygen. In figure 2 two different oxidation process are evident. The first is due to the reaction between O2 and the alkyl macroradicals produced by e-beam in amorphous phase, while at the same time the macroradicals can decay. The second process, where the rate of oxidation is very low, is due to the alkyl macroradicals present in the crystalline phase that move to the amorphous phase or to the crystalline-amorphous interphase and react with the oxygen present there.

It is evident that the formation of ketone does not arise from the thermal decomposition of hydroperoxides for two different reasons: first, hydroperoxides are stable at room temperature, then, at the beginning of the oxidation process, the concentration of hydroperoxides is very low and the rate of formation of ketones is at a maximum.

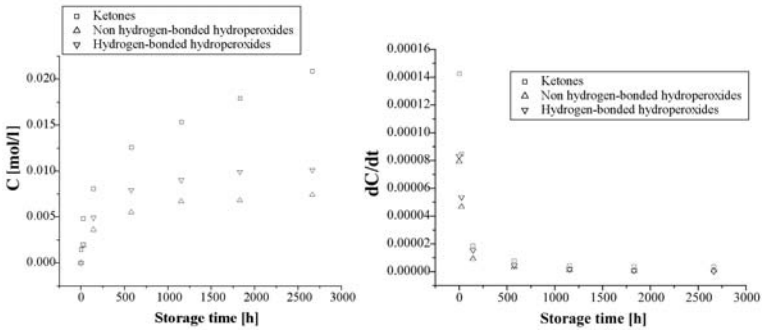

Figure 2: *(_)Formation of ketones as a function of ageing time at RT for films irradiated in air at 60 kGy; (_) Derivative of the ketones formation profile*

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At the beginning of the oxidation process, the concentration of alkyl and peroxy macroradicals is very high, therefore a reaction in which ketones are formed straight from the peroxy radicals must be hypothesized:

The enthalpy of this reaction is about -47 kJ/mol (calculated using the peroxy radical of isopropane as a model compound), thus it is an exothermic reaction that takes place with increase of entropy and therefore it occurs spontaneously at room temperature.
At this stage, a new mechanism of oxidation, which justifies the formation of ketones at room temperature, can be suggested:

$$R^{\circ} + O_2 \quad \_ \quad ROO^{\circ}$$
$$ROO^{\circ} \quad \_ \quad RCOR + HO^{\circ}$$
$$HO^{\circ} + PH \quad \_ \quad H_2O + P^{\circ}$$

We have compared the relative amount of the oxidation products - ketones and acids - produced during the thermal decomposition of the UHMWPE at 90°C, with or without induction of the e-beam irradiation, and we have found the same products obtained at room temperature. Therefore, the same reaction occurs at room temperature and at high temperature, also in the presence of the auto-acceleration effect due to the thermal decomposition of hydroperoxides. It is also proved that during the post-irradiation process acid groups are formed. We have also studied the oxidation process induced by e-beam of UHMWPE stabilized with Vitamin E. The OH group of Vitamin E is consumed during irradiation. During the post-irradiation period hydroperoxides, ketones and acid are formed. The stabilization effect is a function of the concentration of Vitamin E. These results will be considered in the stabilization process of oxidation of UHMWPE in presence of vitamin E.

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ADVANCES IN OXIDATION RESISTANCE OF 2ND GENERATION UHMWPE

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Part 1: Oxidative Stability of Highly Crosslinked UHMWPEs: Aggressive aging of First- and Second-Generation Highly Crosslinked UHMWPEs

Introduction: Radiation crosslinking has been shown to reduce the wear of UHMWPE used in total joint arthroplasty. In the first generation highly crosslinked UHMWPEs residual free radicals created by the irradiation were either eliminated by melting or reduced by annealing. The latter has been shown to result in compromised oxidative stability [1]. Sequential irradiation and annealing (X3) has been proposed as an alternative to the first generation irradiation and annealing for further reduction in residual free radicals in the former [2]. Another second generation radiation crosslinked UHMWPE is stabilized by Vitamin E (VitE-PE). Both X3 and VitE-PE have better mechanical properties than the first generation materials. In addition they both are expected to be oxidatively stable in the long-term based on accelerated aging studies that were standardized in mid- to late-90s to assess the stability of conventional polyethylene. With the reduction in the free radical concentration and increase in oxidative stability of later generation UHMWPEs, more aggressive aging protocols need to be utilized to differentiate the oxidative stability of UHMWPEs. We propose to increase the duration of the aging from 14 days to 27 days and longer to determine the difference in the oxidative stability between various highly cross-linked UHMWPEs.

Materials and Methods: All specimens used in this study were final components, prepared and packaged according to their manufacturers' specifications except for the VitE-PE. The six materials investigated in this study were:

Conventional UHMWPE: _-sterilized in inert tibial bearing, 20 mm thick (Trilogy, Zimmer, Inc., Warsaw IN)
X3™ UHMWPE: 90 kGy sequentially cross-linked and thermally annealed, terminally gas plasma sterilized acetabular liner, 18 mm thick (Stryker Inc., Mahwah NJ)
VitE-PE: 0.2 wt.% VitE blended GUR1050 UHMWPE stock, warm irradiated to 150 kGy, 10 mm thick (Zimmer, Inc.)

The samples were packed loosely inside the pressure vessel such that as much surface area of the components as possible was exposed. The vessel was purged with pure oxygen (Airgas, formerly BOC Gases, Hingham MA) for 10 minutes. After purging, the outlet valve was closed, and the vessel was pressurized to 5 atm. If no leak was detected, the vessel was placed into a convection oven set at 70°C. After 8 hours, the outlet valve on the vessel was slowly opened to lower the pressure back to 5 atm.

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At the end of the aging interval, the pressure vessel was removed from the convection oven and allowed to cool to room temperature. The vessel was then depressurized and disassembled. Pieces were cut from the specimens for oxidation analysis. The remainder of each specimen was placed back in the pressure vessel, for aging to continue. Samples were removed at the end of 14 days, 21 days, 23 days, 25 days, and 27 days, with the exception of VitE-PE, which was aged for 14 days, 21 days, and 28 days. All aged samples were analyzed within 2 weeks of removal.

FTIR (Bio-Rad FTS2000, Natick MA) was performed on thin (~150 _m) sections cut with a sledge microtome. Oxidation levels were quantified as a function of depth from an articular surface of the component. Oxidation levels were expressed as an oxidation index which was calculated by normalizing the absorbance over 1680 cm-1 – 1780 cm-1 to the absorbance over 1330 cm-1 – 1390 cm-1 per ASTM F2102. The surface oxidation indices (SOI) were calculated as the average of the oxidation indices over the first 3 mm of the sample.

Results and Discussion: The ASTM standard pressure vessel aging method (14 days) showed higher oxidation in X3 than in conventional UHMWPE (Fig 1a). This difference grew wider after 27 days of pressure vessel aging (Fig 1b). The oxidation of the X3 and conventional UHMWPE increased as a function of aging time (Fig 2). The VitE-PE showed no detectable oxidation even after 28 days of aging.

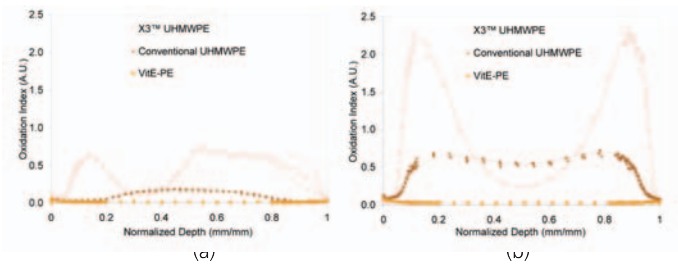

***Fig 1:** Oxidation profiles after (a) 14 days and (b) 27 or 28 days of pressure vessel aging (ASTM standard). Both the actual data (individual data points) and the splined average of the n=3 samples are given.*

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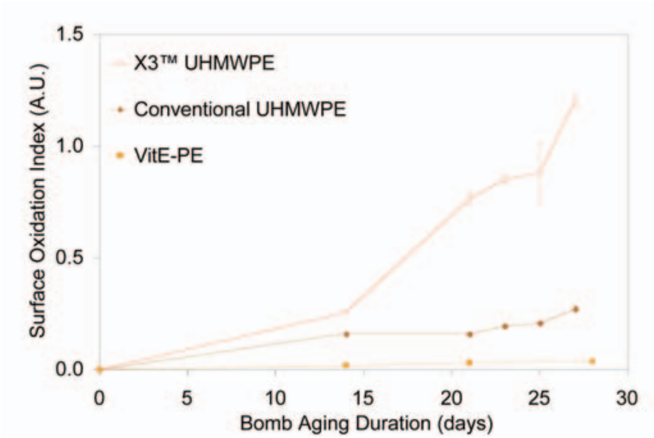

Fig 2: *The surface oxidation indices (SOI) after various durations of pressure vessel aging. The average and standard deviations of n=3 samples are given at each time interval.*

Two week accelerated aging at 70°C under 5atm oxygen pressure was standardized for gamma-in-air sterilized conventional UHMWPE. With the advent of more stable UHMWPE formulations, a more aggressive aging method is needed. We advance the use of longer duration aging under the same standard pressure vessel aging conditions to distinguish the oxidative stability of the more stable UHMWPE formulations. We also conclude that Vitamin E stabilization results in higher oxidative stability than the stability that can be achieved through sequential irradiation and annealing.

Acknowledgement: This study was funded by a research grant from Zimmer, Inc.
References:
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[2] Dumbleton JH, et. al. Clin Orthop Relat Res. 2006 Dec; 453: 265-71.

Part 2: Environmental Stress Cracking of Contemporary and _-Tocopherol Doped UHMWPEs

Introduction: Environmental stress cracking (ESC) is one of the mechanisms that could affect long-term stability and performance of total joints. Fatigue crack propagation resistance of UHMWPE is typically measured to predict long-term fatigue behavior of UHMWPE implants. Current fatigue crack propagation resistance tests start with a test sample, which has a crack

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induced. In almost all in vivo applications, cracks do not exist at the time of surgery and are initiated during in vivo service for fatigue type failure to occur. It is therefore important to determine the propensity of these cracks to form in UHMWPE. No standard methods of determining the environmental stress cracking resistance of UHMWPE exist for total joint applications. A method was developed to cyclically bend polyethylene specimens to a constant displacement at an elevated temperature. This simulated the potential adverse effects of oxidation of the test samples while they were simultaneously subjected to thermal aging and mechanical loading. The test duration was 5 weeks, unless failure occurred prior. Materials and Methods: All specimens were manufactured from compression molded GUR1050 UHMWPE stock (Ticona, Bishop TX). The four specimens from four different groups tested were: 1) Conventional UHMWPE, gamma sterilized; 2) Sequentially irradiated and annealed UHMWPE irradiated to 100kGy, gas plasma sterilized; 3) UHMWPE stock gamma irradiated to 85kGy and doped with _-tocopherol, gamma sterilized; 4) UHMWPE stock gamma irradiated to 100kGy and doped with _ -tocopherol, gamma sterilized.

Resistance to ESC was quantified by cyclical loading of the UHMWPE specimens. ESC samples were modeled after flexural fatigue samples described in ASTMD671. The body of the specimen was clamped into place and the head was impinged upon by load applicators due to upward and downward movement of the actuator.

The samples were centered vertically between the load applicators and displaced to generate a maximum stress of 10MPa in the neck region. The frequency of the load cycles was 0.5 Hz, which simulated the load frequencies encountered by total knee tibial components in vivo. Testing occurred in an environmentally insulated chamber. A heater and fans forced air to maintain the chamber temperature at 80°C.
The tests were conducted on an MTS (Eden Prarie, MN) hydraulic system. Failure of a sample was defined as the visible appearance of cracks in the surface of the triangular neck region. Upon failure, samples were removed from the chamber and analyzed along with a control sample removed at the same time.

Upon specimen failure or the or the conclusion of five weeks of cyclic loading (whichever came first), samples were analyzed by FTIR (Bio-Rad FTS2000, Natick MA) to quantify the oxidation within the neck region.

Results and Discussion: The total numbers of cycles completed by each individual specimen from all four sample groups are given in Table 1. 100% of the conventional UHMWPE specimens, 50% of the sequentially irradiated and annealed UHMWPE specimens, 0% of the 85kGy a-tocopherol doped, irradiated UHMWPE specimens, and 0% of the 100 kGy _-tocopherol doped, irradiated UHMWPE specimens failed prior to the completion of 1,530,000 cycles (5-week testing at 0.5 Hz).

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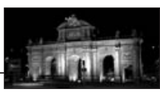
Table 1: *The number of cycles completed by each individual sample. If sample failed less than five weeks into test, method of failure is noted (ESC ovserved or specimen sheared in half) is noted.*

Sample Number	Failed Prior to 5 Weeks?	Cycles	Max. Oxidation (A.U)
Conventional UHMWPE			
A1	Yes (ESC observed)	1,410,000	.58
A2	Yes (ESC observed)	1,410,000	.81
A3	Yes (ESC observed)	1,080,000	1.18
A4	Yes (ESC observed)	907,200	1.10
Sequentially Irradiated and Annealed UHMWPE			
X1	No	1,530,000	.4
X2	No	1,530,000	.68
X3	Yes (Sheared in half)	1,500,000	.89
X4	Yes (Sheared in half)	1,140,600	1.04
85 kGy _-Tocopherol Doped, Irradiated UHMWPE			
E1	No	1,530,000	0.0
E2	No	1,530,000	0.0
E3	No	1,530,000	0.0
E4	No	1,530,000	0.0
Sample			
H1	No	1,530,000	0.0
H2	No	1,530,000	0.0
H3	No	1,530,000	0.0
H4	No	1,530,000	0.0



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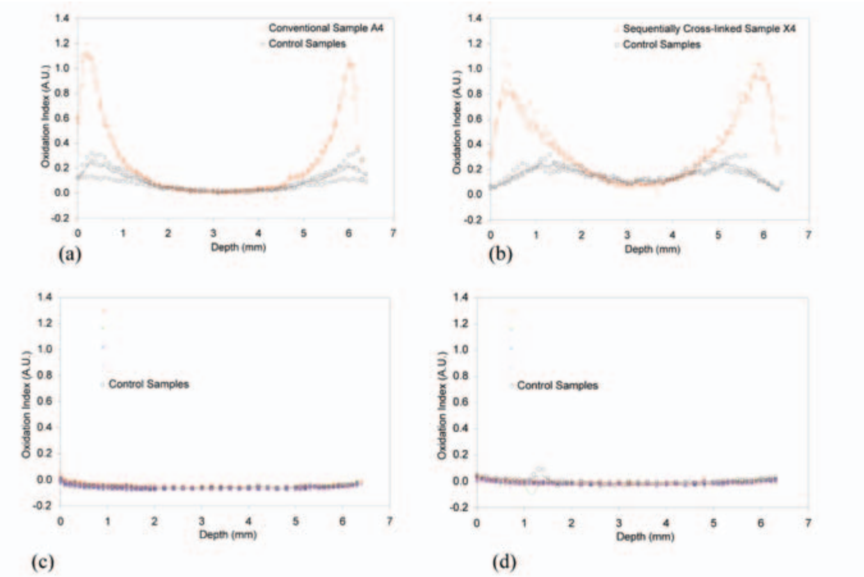

As seen in **Figure 1**, cyclic loading had an adverse effect on the oxidation of the conventional and the sequentially irradiated and annealed UHMWPE groups, both of which contained residual free radicals that made the samples prone to oxidation. Their peak oxidation levels were higher in the cyclically loaded samples as compared to the control samples which were not loaded. The increase in the peak oxidation levels when the samples were subjected to cyclic loading was likely due to an increase in chain scission induced by the mechanical load. We postulate that free radicals formed due to mechanical loading added to the free radical burden of the conventional UHMWPE and sequentially irradiated and annealed UHMWPE and accelerated the oxidation to the extent that it caused cracking and/or fracture in some of these samples.

Neither of the _-tocopherol doped, irradiated UHMWPE specimens exhibited any environmental stress cracking after 5 weeks of bending at 80°C. Furthermore, FTIR did not reveal detectable oxidation in neither the control samples nor the loaded samples from both _-tocopherol doped, irradiated UHMWPE groups. The _-tocopherol present in these samples protected them against oxidation during this aggressive environmental stress cracking test.

Acknowledgement: This study was funded by a research grant from Biomet, Inc.

LECTURES

ON MECHANICAL PROPERTIES OF UHMWPE

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Ultra high molecular weight polyethylene (UHMWPE) is a member of the polyethylene family of polymers. The International Standards Organization (ISO 11542) defines UHMWPE as having a molecular weight of at least 1 million g/mole and the American Society for Testing and Materials (ASTM D 4020) specifies that UHMPWE have an average molecular weight greater than 3.1 million. The UHMWPE formulations used in orthopaedic applications typically have a molecular weight between 2 to 6 million g/mole. UHMWPE is a linear (non-branching) semicrystalline polymer. It is initially manufactured as powder with a percent crystallinity on the order of 60-75%, depending on the resin. Orthopaedic components may be made by direct compression molding, or by machining from ram extruded rod or compression molded sheets.

The physical and mechanical properties of UHMWPE are influenced by resin variations and consolidation process. Native UHMWPE typically has a density of 0.930-0.945 g/ml, elastic modulus of 0.8-1.5 GPa, tensile yield strength of 19.3-23 MPa, elongation at fracture of 200-350%, and an ultimate stress of 30.4-48.6 MPa (1). As with any polymer, the mechanical properties are both rate and temperature dependent.

The physical and mechanical properties of UHMWPE are altered by ionizing radiation, such as may be used for sterilization or for the purposes of deliberate crosslinking (to improve wear resistance) (1,2). When UHMWPE is radiation sterilized in the presence of oxygen, chain scission predominates over crosslinking. Chain scission leads to a decrease in molecular weight and an alteration of mechanical properties. In addition to the immediate radiation effects, oxidative degradation of UHMWPE components radiation sterilized in air-permeable packaging will occur during shelf-storage prior to implantation and will continue to occur during in vivo use (1-3). Oxidation embrittles UHMWPE, leading to a decrease in the elongation to failure, an increase elastic modulus, and a decrease in fatigue crack propagation resistance. These changes in mechanical properties have resulted in the premature failure of some UHMWPE components in vivo.

Crosslinking improves the wear resistance of UHMWPE compared to conventional UHMWPE (non-crosslinked, or lightly crosslinked during radiation sterilization). In the United States, highly crosslinked UHMWPEs are produced using 50 to 105 kGy of either gamma or electron beam radiation, depending on the manufacturer and the process. In general, crosslinking adversely affects uniaxial ductility, fracture toughness, and fatigue crack propagation resistance (4-6). Radiation-induced crosslinked UHMWPE materials still contain free radicals that can lead to oxidative degradation; thus, post-processing to reduce or eliminate free radicals (remelting above the melt transition or annealing below the melt transition) is usually conducted. While effective at eliminating entrapped free radicals, heating above the melt temperature also leads to a reduction in crystal size, which leads to a reduction in yield stress and ultimate stress (1). In contrast, annealing preserves the original crystal structure and better retains mechanical

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properties, but reduces free radicals less effectively than remelting; thus, oxidation is possible. Methods to more effectively reduce free radicals without having to remelt the material (e.g, doping with vitamin E) have been explored as a means to maintain crystallinity, while simultaneously maintaing better mechanical properties of crosslinked UHMWPE (7). The combined effects of radiation-induced crosslinking followed by remelting or annealing on mechanical properties of UHMWPE can be complex. For example, using a crosslinking dose of 100 kGy, the elastic modulus, yield stress, and ultimate stress of a remelted material was significantly lower than an annealed material (4). However, though the estimated fracture toughness, KC, was found to decrease with increasing radiation dose, no significant difference in KC was found between the annealed and the remelted highly crosslinked materials (5). The crosslinked materials were also found to be more sensitive to notches under uniaxial tensile loading as compared with non-crosslinked UHMWPE, though, again, no pronounced difference was found between the remelted and annealed UHMWPE materials (8).

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Acknowledgements: NIH AR 47192, NIH AR 47904, NIH T 32 GM07250, Strkyer Orthopaedics, Zimmer, Inc., Sulzer, Wilbert J. Austin Chair.

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Saturday, 15th September

ADVANCES IN WEAR RESISTANCE AND FUTURE DIRECTIONS

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Part 1: A second generation highly crosslinked UHMWPE: Vitamin-E stabilization does not adversely affect the wear of irradiated acetabular liners

Introduction: Cross-linking by ionizing irradiation increases the wear resistance of ultra-high molecular weight polyethylene (UHMWPE) but also generates residual free radicals, which are the precursors of long-term oxidative embrittlement. To eliminate these residual free radicals, in the first-generation highly cross-linked UHMWPEs, oxidative stability was achieved by post-irradiation melting. While effective in increasing oxidative stability, melting reduces the crystallinity of polyethylene resulting in a decrease in the fatigue strength of the irradiated polymer.

An alternative second-generation highly crosslinked polyethylene that is irradiated and stabilized by Vitamin-E (-tocopherol) doping has been proposed [1]. Because Vitamin-E stabilization replaces melting, the crystallinity of the irradiated polyethylene is not decreased and hence mechanical properties and fatigue strength are preserved. We investigated the effect of vitamin E presence on the wear resistance of acetabular liners.

Materials and Methods: All specimens were manufactured from isostatically molded UHMWPE bar stock (Biomet Inc., Warsaw, IN). The UHMWPE resin utilized was GUR1050 (Ticona, Bishop TX).
Two different groups of test samples, an _-tocopherol doped, irradiated UHMWPE and conventional UHMWPE were compared. Both groups of test samples were terminally gamma sterilized in argon gas before testing. Conventional UHMWPE samples were machined from a GUR1050 UHMWPE stock, packaged in argon gas, and gamma sterilized. The _-tocopherol doped, irradiated UHMWPE samples were machined into their respective shapes from annealed GUR1050 UHMWPE stock below the melting point of UHMWPE. This annealing of bar stock materials was to reduce the thermal stresses in the UHMWPE stock resulting in greater dimensional stability of machined parts at elevated temperatures. These samples were packaged under argon gas with an oxygen scavenger (Fresh Pax, Multisorb Technologies Inc., Buffalo, NY), and the packages were gamma-irradiated to 85 kGy. Since gamma-irradiation is a lengthy process (several days for 85-100 kGy), the probability of samples coming into contact with oxygen even though they are in inert packaging is high. The purpose of the scavenger was to provide an extra measure to eliminate any oxygen present in the environment during irradiation. The irradiated samples were then doped with D,L-_-tocopherol (vitamin E, >98%, Fisher Scientific, Houston, TX) by immersion into _-tocopherol at 120 C and subsequently annealed at 120 C under argon flow for homogenization. The samples were then packaged in argon gas with an oxygen scavenger and gamma sterilized. Immersion in _-

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tocopherol and the subsequent homogenization durations were adjusted to obtain similar amounts of _-tocopherol in samples with different thicknesses (Table 1). Hip Simulator Testing: We used hip simulator wear testing to determine if the addition of _-tocopherol in highly cross-linked acetabular liners would adversely affect the adhesive and third body abrasive wear resistance of cross-linked UHMWPE.

We chose a worst-case geometry that would result in high contact stresses by using a liner thickness of 4.9 mm for both groups of liners. The conventional UHMWPE liners had an inner diameter of 28 mm. We tested the _-tocopherol doped, irradiated UHMWPE liners with both an inner diameter of 28 mm and 36 mm. The 28mm liners allowed comparison of the two groups of liners. Since larger femoral heads result in higher wear, we also tested the _-tocopherol doped, irradiated UHMWPE liners with a 36 mm femoral head.

All liners were coupled with the corresponding cobalt-chrome femoral head sizes for testing. Each group included 4 liners that were subjected to both motion and load and 2 load-soak liners that were only subjected to load without motion. The lubricant used for the study was 100% bovine serum, stabilized with 10.7 millimoles of ethylenediamine tetraacetate (EDTA, Fisher Scientific, Pittsburgh, PA) and 33 ml of penicillin-streptomycin solution (Sigma-Aldrich, St. Louis, MO) per 500 ml of serum.

All testing was performed on the AMTI 12-Station Hip Simulator (Watertown, MA). Testing was carried out at 2Hz for a total of 5 million-cycles (MC) in clean serum or at 1 Hz for a total of 3 MC for testing in serum with third-body bone cement particles. The kinematics used was a standard walking gait cycle with the peak load of 3000 N. All stations were temperature controlled at 37 °C with circulating bovine serum. The simulator was interrupted at approximately 500,000 cycle intervals for gravimetric assessment of wear.

For gravimetric measurements, the liners were cleaned by sonication in a soap solution for 10 minutes, followed by sonication in distilled water for 10 minutes, followed by an ethanol bath for 10 minutes and finally by drying in air for 10 minutes before weighing. The liners were weighed three times and then averaged using an A-250 balance (Denver Instrument Co., Arvada, CO). The articular surfaces were photographed at the dome and at 4 quadrants at about 3 to 4 mm from the dome using an Olympus SZX12 optical microscope and an Olympus DP11 camera at every gravimetric measurement.

Weight loss of each liner was used to calculate a wear rate before and after correction for fluid absorption. The correction for fluid absorption was done by subtracting the average weight gain of the load soak components from the weight change of the motion components. The actual wear rate was calculated by applying a linear regression. The slope of the linear regression is reported as the wear rate in milligrams per million cycles (mg/MC).

Results: Average wear rate corrected for fluid absorption of the 28 mm conventional liners were 9.54±0.73 mg/million-cycles after 5 million cycles of simulated gait with clean serum.

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The average wear rates for the 28 mm and 36 mm inner diameter _-tocopherol doped, irradiated UHMWPE acetabular liners were 0.78±0.28 and 0.97±0.49 mg/million-cycles, a 10-fold decrease with respect to the conventional UHMWPE (Fig 3). The wear rate of the _-tocopherol doped, irradiated UHMWPE was not affected by the larger femoral head size. Optical microscopy of the articular surfaces of the tested liners showed the presence of original machining lines after 5 million-cycles of simulated gait (Fig 4); while the conventional liners exhibited no machining marks throughout the loaded region of the articular surfaces (Fig 5).
Average wear rates corrected for fluid absorption of the 28 mm conventional liners were 20.55±0.50 mg/million-cycles after 3 million cycles of simulated gait with third body bone cement particles. The average wear rates for the 28 mm and 36 mm inner diameter _-tocopherol-doped, irradiated UHMWPE acetabular liners were 5.76±0.82 and 5.13±0.34 mg/million cycles (Fig 6). These values were 72 and 75% lower than that for the conventional UHMWPE. Optical microscopy of the articular surfaces of the tested liners showed the presence numerous scratching on all tested liners.

Scanning electron microscopy of the articular surfaces of the tested liners showed abundant formation of fibrils in the conventional liners that were tested in clean serum; whereas the _-tocopherol-doped, irradiated UHMWPE liners showed reduced fibril formation (Fig 7). All liners tested in serum with third-body bone cement particles exhibited extensive scratching of the articular surface.

Acknowledgements: This work was funded by NIH RO1 AR051142-01 and by a research grant from Biomet Inc. We acknowledge with thanks the assistance of Dave Schroeder and Jordan Freedman in sample preparation and lengthy discussions.

Part 2: Vitamin E Stabilized, Radiation Crosslinked UHMWPE for Cruciate Retaining Knee Components

Introduction: Radiation crosslinked ultra high molecular weight polyethylene (UHMWPE) is becoming the bearing material of choice for total knee arthroplasty for its improved wear resistance. Irradiation of UHMWPE also generates residual free radicals, which could compromise the long-term oxidative stability of the implants; today thermal methods are used to down regulate the residual free radicals. Another method of free radical stabilization is through impregnation of irradiated UHMWPE with _-tocopherol. The material, because of its higher mechanical properties and improved fatigue resistance [1,2], constitutes an alternative bearing surface for total knee applications.

The present investigation was designed to asses the wear, oxidation, and fatigue resistance of _-tocopherol stabilized irradiated UHMWPE for a cruciate retaining knee design.

Materials and Methods: GUR1050 was direct compression molded into Vanguard™ tibial bearings, size 10 mm _ 87/91 mm (Biomet, Inc., Warsaw IN). The bearings were vacuum-packaged and e-beam irradiated to 100 kGy. The irradiated bearings were doped with _-

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tocopherol for 7 hours at 120°C and subsequently homogenized for 144 hours at 120°C. The _-tocopherol doped, irradiated bearings were vacuum-packaged and gamma sterilized.

Control tibial bearings of conventional UHMWPE and of the same design were fabricated by direct compression molding GUR1050, vacuum packaging followed by gamma sterilization.

Both the _-tocopherol doped, irradiated bearings and the conventional tibial bearings were mated with their respective tibial trays and femoral components and were subjected to simulated normal gait on a 6-station knee simulator (AMTI, Watertown MA). The simulated gait adhered to ISO standard 14243-3. The tibial bearings were subjected to 5 million cycles (MC) of simulated gait. At the completion of 5MC of testing, the inserts were accelerated aged in an oxygen bomb according to ASTM F2003 and subjected to an additional 3 million cycles of gait. Wear was determined gravimetrically approximately every 1 million cycles.

In addition to tibial bearings, GUR1050 was direct compression molded into cylindrical pucks with a diameter of 82.5 mm and a height of 35 mm. Bending fatigue resistance specimens were machined from this stock material. These specimens were vacuum-packaged and e-beam irradiated to 100 kGy. The irradiated specimens were doped with _-tocopherol for 5 hours at 120°C and subsequently homogenized for 64 hours at 120°C. The _-tocopherol doped, irradiated specimens were vacuum-packaged and gamma sterilized.

Conventional UHMWPE bending specimens were also prepared in the following manner: GUR1050 was direct compression molded into cylindrical pucks with the dimensions given above from which bending specimens were machined, vacuum-packaged and gamma sterilized.

Fatigue crack initiation resistance was quantified by cyclically loading the post of the UHMWPE bending specimen. Testing was carried out on an MTS Bionix 858 system in an aqueous chamber maintained at 40°C. Load was applied on the UHMWPE post as a sinusoidal waveform with a frequency of 0.5 Hz. Failure was defined as a sudden increase in displacement for a given load; in most cases, the post sheared off and separated from the base within 10 cycles of failure. Bending specimens were tested both before and after accelerated aging (ASTM F2003).

Results and Discussion: The _-tocopherol doped, irradiated UHMWPE exhibited a 91% and a 94% reduction in wear before and after accelerated aging, respectively, over conventional DCM UHMWPE. The _-tocopherol doped, irradiated UHMWPE tibial bearings were unaffected by accelerated aging, as there was no significant difference in wear after accelerated aging. The conventional UHMWPE tibial bearings exhibited a 52% increase in wear after accelerated aging. The reason for subjecting the tibial inserts to accelerated aging after 5MC of testing was to determine if the extent of _-tocopherol elution out of the tibial inserts would have compromised the oxidative stability of the _-tocopherol stabilized tibial inserts. Because there was no change in the wear behavior of the _-tocopherol impregnated inserts after aging, we postulate that the extent of _-tocopherol elution was not large enough to adversely affect the oxidative stability of these implants.

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Table 1: *Wear properties of conventional and _-tocopherol doped, irradiated UHMWPE tibial bearings before and after accelerated aging*

Sample Group	Linear Wear Rate (mg/million-cycles)
Unaged – during the 1st 5MC	
_-Tocopherol Doped, Irradiated UHMWPE	- 2.40 ± 0.50
Conventional DCM UHMWPE	-26.94 ± 3.54
Accelerated aged (after the 1st 5MC) – during the subsequent 3MC	
_-Tocopherol Doped, Irradiated UHMWPE	- 2.46 ± 0.78
Conventional DCM UHMWPE	- 40.78 ± 3.00

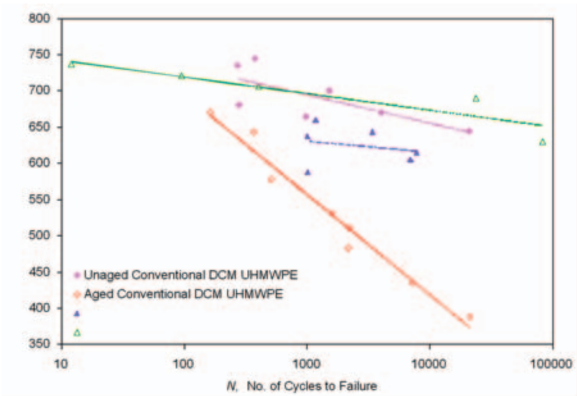

Fig 1: *S-N bending fatigue curves for the UHMWPE variants studied. The bending force plotted on the y-axis is the peak bending force applied during the cyclic bending load cycles.*

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POLYETHYLENE -THE HIP: LONG-TERM RESULTS

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The major problem limiting the longevity of total hip replacements is polyethylene wear and the biological effects of wear particles generated at the articulation. As patients live longer and are more physically active, the demand for increased durability of total hip replacements is increasing. Conventional polyethylene was traditionally sterilized with gamma irradiation in air and therefore only moderately cross-linked. This lead to increased oxidation and wear of the plastic, especially in young active patients. The introduction of highly cross-linked polyethylene has attempted to solve the problem of increased wear. Volumetric wear of conventional polyethylene is about 30-120 mm3/year. Volumetric wear of highly cross-linked polyethylene is significantly less, about 17 mm3/year. Short-term clinical studies have substantiated these findings. Most recent clinical studies show a decrease in linear wear by about 45%-60% at 4-5 years post-operatively. These findings have prompted the use of larger femoral heads that may decrease linear wear and the dislocation rate, but are associated with an increase in volumetric wear. Furthermore, highly cross-linked polyethylene is generally more expensive than conventional polyethylene. Long-term clinical follow-up is needed to establish the durability of highly cross-linked polyethylene, and determine a viable cost-benefit analysis, especially in conjunction with larger diameter femoral heads so as to guide use.

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IN VIVO OXIDATION AND OXIDATION POTENTIAL OF HISTORICAL, CONVENTIONAL, AND HIGHLY CROSSLINKED UHMWPE: LESSONS FROM ANALYSIS OF RETRIEVED ACETABULAR LINERS AND TIBIAL INSERTS

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Introduction: Highly crosslinked polyethylenes were developed to reduce wear and are thermally processed by remelting or annealing. Second generation polyethylenes were recently introduced to improve the mechanical behavior and oxidation resistance of first-generation materials, however limited information is available about their in vivo performance. The aim of our ongoing multi-center retrieval study is to compare the oxidative properties of contemporary and historical polyethylenes with first- and second-generation highly crosslinked polyethylenes both in the hip and knee. In addition to measuring oxidation, we also evaluate the hydroperoxide content in the retrieved polyethylenes. Hydroperoxides are the precursors to carbonyl formation, and thus represent the oxidation potential of polyethylene. Our main hypothesis was that highly crosslinked polyethylene formulations would have lower oxidation, oxidation potential, and lower head penetration than historical gamma-air and conventional gamma-inert sterilized components for the hip and knee.

Materials and methods

Retrieved Acetabular Liners

139 acetabular components produced from 3 different manufacturers were collected and stored in a subzero freezer after revision surgery. The processing route, sterilization method, shelf life, and implantation time were traced using the lot history in all the implants. 31 of the retrieved components were historical gamma sterilized in air (Air), 17 conventional gamma sterilized in nitrogen (Inert), 43 highly crosslinked and annealed (Annealed), 41 highly crosslinked and remelted (Remelted), and 7 highly crosslinked and annealed in three sequential steps (SA). The hips were classified into 6 categories (Air 1-2, Inert, Annealed, Remelted, and SA), according to the resin type, conversion method, processing route, and sterilization method. For acetabular inserts, 200 micron-thick sections were obtained using a microtome from the superior/inferior axis. The UHMWPE sections were boiled in heptane for 6 hours to extract absorbed lipids. The extracted sections were scanned at 0.1 mm increments through the thickness using a micro-FTIR spectrometer. Maximum oxidation indexes were obtained from the FTIR spectra in accordance with ASTM F2102-01. The study of the hydroperoxide levels required the exposure of the sections to NO for at least 16 hours to convert hydroperoxides to nitrates, which are easily detected by FTIR spectroscopy [1]. The bearing, backside, and rim face surfaces in both superior and inferior portions of the acetabular component were measured. Head penetration was assessed directly using a micrometer (0.001 accuracy) for liners implanted for more than 1 year [2]. Penetration rate was calculated by dividing the penetration by implantation time.

Retrieved Tibial Inserts

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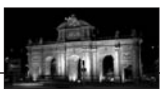
133 tibial inserts produced from 3 different manufacturers were collected and stored in a subzero freezer after revision surgery. 28 of the retrieved PE components were historical gamma sterilized in air (Air), 99 conventional gamma sterilized in nitrogen (Inert), 4 gamma-inert sterilized and annealed (Annealed), and 2 highly crosslinked and remelted inserts (Remelted). The knee retrievals were classified into 8 categories (Air1-3, Inert1-3, Annealed and Remelted), according to the resin type, conversion method, processing route, and sterilization method. 200 micron-thick sections were obtained using a microtome from the sagittal plane at two locations: medial condyle and unloaded central spine. Oxidation and hydroperoxide analysis was conducted using the same protocols as used for the acetabular liners. The anterior-posterior faces, bearing and inferior surfaces, as well as the post region where present were measured. Statistical analysis of the oxidation, hydroperoxide, and penetration results was performed using JMP software. Differences between material types were assessed by means of t-tests, whereas paired t-tests were used to evaluate regional variations ($p<0.05$ for significance).

Results: The 91 highly crosslinked liners (both first- and second-generation) were revised for reasons unrelated to wear or osteolysis, such as instability, mechanical loosening, or infection. Penetration measurements were significantly lower in the highly crosslinked groups. Penetration rates were comparable in the highly crosslinked groups (0.06 mm/yr in the Annealed and Remelted groups) and significantly lower than the Inert and Air 2 groups ($p < 0.05$). All SA liners were implanted for less than one year and therefore not evaluated for penetration. Regional variations in oxidation were observed in all groups except for the Remelted and SA groups (Tables 2 & 3, $p < 0.05$). Elevated rim oxidation was observed in the Air 1-2 and Annealed groups, but was incidental and not related to the reason for revision. Oxidation and hydroperoxide levels were significantly lower in the Inert, SA, and Remelted groups ($p < 0.05$). The Annealed group exhibited elevated oxidation levels at the rim, but not at the bearing surface ($p < 0.05$), consistent with the low penetration rates for this material. All the material groups for the tibial inserts studied appeared to oxidize, regardless of the processing route or sterilization method, except for the short-term Annealed and Remelted retrievals. Oxidation and hydroperoxide levels in historical gamma-air sterilized knee inserts (Air 1-3) were severe and significantly higher ($p < 0.05$) than in the gamma-inert (Inert 1-3), Annealed, and Remelted groups, regardless of the resin type. However, the Air 1-3 groups showed comparable oxidation and hydroperoxide indexes results among them. On the other hand, the Inert 1&3 groups exhibited significantly greater oxidation in comparison with the Inert 2 group, especially at the AP faces and bearing surfaces ($p<0.05$). Hydroperoxide levels were similar for all gamma-inert retrievals, except in the articulating surface where the Inert 1 group had a significantly higher index than Inert 2. All of the gamma sterilized and Annealed knee components had comparable TVI levels (0.02) consistent with exposure to a standard sterilization dose of 25-40 kGy. The Remelted inserts had higher trans-vinylene levels (0.04), consistent with the higher dose of e-beam radiation used for crosslinking (65 kGy).



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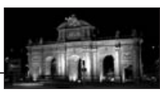
Discussion: The results of this retrieval study support the hypothesis that highly crosslinked polyethylene reduces in vivo wear in THA, however the oxidation resistance was formulation-dependent. Specifically, the Annealed liners had significantly higher levels of rim oxidation and oxidation potential than the Inert, Remelted, and SA groups. However, the highly crosslinked groups, including the Annealed liners, all had low levels of oxidation at the bearing surface, and lower wear than historical controls. Even though the Remelted and SA liners had zero-to-low levels of oxidation following a brief in vivo period, they exhibited measurable oxidation potential. The long term clinical significance of these hydroperoxides, if any, remains unknown at the present time. This study represents, to the authors' knowledge, the largest comparison of fully traced historical, conventional, and highly crosslinked acetabular components and provides an important context with which to compare new formulations such as those produced by sequential annealing. Because validated methods do not exist to predict the long-term resistance of biomaterials to in vivo oxidation, retrieval analysis is essential to verify the performance of new polyethylene formations after their clinical introduction. Longer-term retrieval studies also needed for the Annealed liners to continue to monitor the clinical significance (if any) of the elevated rim oxidation.

Regardless of their resin and conversion method, gamma-air tibial inserts suffered from much more severe oxidation and higher hydroperoxide indexes than the gamma-inert and Annealed inserts. Substantial regional variations were observed in both oxidation and hydroperoxide levels for the Gamma Air 1-3 groups, whereas gamma-inert, Annealed and Remelted inserts showed more homogeneous patterns. Shelf life seemed to be a minor contributor to oxidation in this study, as shelf lives were relatively short and not significantly different between the 8 groups. The Annealed and Remelted tibial inserts in this study exhibited measurable oxidation potential, but very low levels of oxidation. Even though the Annealed and Remelted components showed zero-to-low oxidation following a short in vivo period, measurable oxidation potential could be still detected. The long-term clinical significance of these low initial levels of hydroperoxides, if any, remains unknown for thermally stabilized UHMWPE materials at the present time. Our current data do not support the hypothesis that resin type, conversion techniques, and radiation environment substantially influence the in vivo oxidative resistance of tibial inserts. After sterilization, either in air or in an inert atmosphere, oxidation was influenced only by the implantation time as mentioned before. Lower molecular weight resins, 1900H & GUR 1020, showed slightly lower, but not significantly different, oxidation and hydroperoxide indexes than GUR 1050. In summary, changing UHMWPE resin, conversion method, or inert irradiation atmospheres alone may not be sufficient to protect UHMWPE components from long-term in vivo oxidation.

Acknowledgements: Supported in part by NIH R01 AR47904, Stryker Orthopedics, Inc., Sulzer, and Zimmer, Inc. We are grateful to the support of the surgeons who made this research possible by collaborating and providing the explants for analysis: W. Hozack, P. Sharkey, J. Parvisi, M. Austin, J. Purtill, R. Rothman, V. Goldberg, M. Kraay, J. Garino, B. Stulberg, G. Klein, M. Hartzband, and H. Levine. Special thanks are also due to Dan MacDonald, Eric Brenner, Francisco Medel, Lauren Ciccarelli, and Rebecca Lehman for their assistance.



LOCATION MAP



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