E1 Antioxidant Infused Technology:

The Revolutionary Second Generation, Vitamin E Infused Highly Crosslinked UHMWPE

Author: Biomet Biomaterials Laboratory, Warsaw, Indiana
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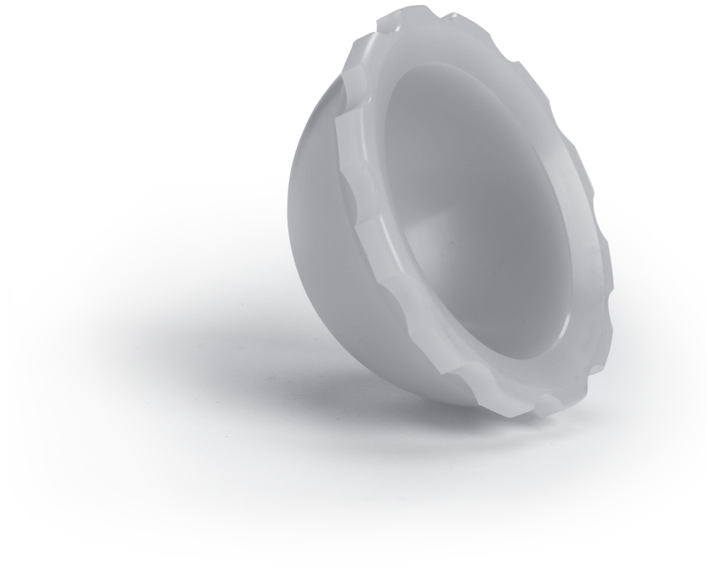
Introduction

A limiting factor in the longevity of total hip arthroplasty is osteolysis resulting from the biological reaction to polyethylene wear particles. In the late 90s, the orthopedic industry sought to address this concern by creating crosslinked polyethylenes. The presence of crosslinks between chains in the polyethylene increases wear resistance and may increase the life of the implant. Crosslinks are formed when the polyethylene is exposed to high-energy irradiation (i.e. gamma or e-beam), which also causes an increase in the amount of unpaired free electrons (or free radicals) present in the material after irradiation. If these free electrons are not stabilised or eliminated, they can react with oxygen and start a chain reaction that causes oxidative degradation over time.

Due to the limitations of the first generation highly crosslinked polyethylene (HXLPE), the industry continues to develop second generation crosslinked polyethylene materials that significantly reduce wear rate, maintain mechanical properties and prevent oxidative degradation. E1 Antioxidant Infused Technology, created by Biomet utilising technology invented by Massachusetts General Hospital, possesses a highly reduced wear rate, impressive oxidative stability and mechanical properties similar to that of ArCom polyethylene, the gold standard for polyethylene in the orthopedic industry.



Current Processing Methods

First generation crosslinked materials differ in the amount of crosslinking and the method used to counteract the decrease in oxidation resistance caused by residual free radicals remaining after irradiation.

Remelting

Some manufacturers attempt to reduce the oxidation potential of polyethylene after crosslinking by heating the material above its melt temperature. This remelting allows the free radicals left in the material to combine, which reduces the free-radical concentration below detectable levels. Although this process increases the oxidation resistance of the polyethylene, it detrimentally affects the material properties by reducing the tensile strength and the fatigue life of the polyethylene.[1-3] This reduction in mechanical properties can present clinically as cracking and fracture.[4-6]

Annealing

Another method used by manufacturers to reduce the concentration of free radicals involves annealing the polyethylene below the melt temperature after crosslinking. By staying below the melt temperature during processing, the polyethylene maintains its material properties. However, not all of the free radicals trapped in the crystalline regions of the material are able to combine and therefore remain in the material. Further, these materials are sterilised with gamma irradiation following the annealing process which significantly increases the quantity of non-stabilised free radicals. Due to these remaining free radicals, studies have shown that irradiated and annealed materials can oxidise *in vivo*.[7,9] Recently, this method of annealing was adapted and applied in a sequential process without terminal gamma sterilisation to create X3® polyethylene from Stryker Orthopaedics. X3® polyethylene has been shown to be more oxidatively stable than Crossfire® polyethylene from Stryker, which has shown oxidative degradation during *in vivo* use.[7, 8]

Vitamin E Stabilised Polyethylene

The E1 Antioxidant Infused Technology bearings, developed by Biomet, Inc. utilising technology invented at Massachusetts General Hospital, is processed below the melt temperature to maintain the strength of the crosslinked polyethylene and contains vitamin E to stabilise free radicals and prevent oxidative degradation.

Infusing vitamin E into irradiated polyethylene is a novel approach to reduce the oxidation potential of the material. As shown in Figure 1, the vitamin E molecule is made up of two ring structures and a carbon chain. The carbon chain makes the vitamin E molecule hydrophobic, which allows it to be readily infused into the polyethylene. When a molecule of vitamin E encounters a free electron in the polyethylene, it donates a hydrogen atom from the –OH group on the ring structure, which, in effect, transfers the free radical from the polyethylene chain to the vitamin E molecule.

Unlike the remelted material, E1 Antioxidant Infused Technology, still has detectable levels of free radicals, but the key to this technology is the location of those free radicals. After the infusion process, the free radicals detected in the polyethylene are likely associated with the ring structures on the vitamin E molecule, not the polyethylene molecule. Therefore, if oxygen was introduced into the system, the oxygen molecules would only react with the vitamin E molecules, leaving the polyethylene molecules untouched. In addition, the free radicals associated with the vitamin E molecules are part of the electron field of the ring structures, making it more difficult for oxygen to react with the free radicals.

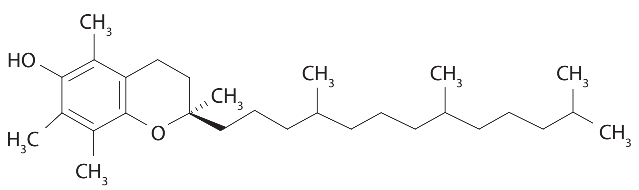


Figure 1: Vitamin E Molecule

After the infusion process, the E1 liners are gamma sterilised. First generation remelted crosslinked polyethylenes are sterilised by non-energetic methods to prevent additional free radicals from being introduced during the sterilisation process. The vitamin E molecules present in E1 liners stabilise any free radicals that are formed, allowing for the material to be gamma irradiated without increasing the risk of oxidative degradation.

Wear Performance

High Contact Stress

Small diameter femoral heads have a smaller contact area in small diameter polyethylene liners than larger diameter components.

Materials and Methods

Biomet Biomaterials Laboratory

To test the worst-case scenario for contact stress, the smallest, thinnest E1 liners were tested. Size 22 liners with a 28mm inside diameter and a nominal wall thickness of 4.8mm were tested on an orbital hip simulator. The simulator utilized a standard walking curve with a peak load of 2400N for 5 million cycles and a serum protein concentration of 20 g/L. The parts were tested under clean conditions against CoCr modular heads, and gravimetric measurements were taken every 500,000 cycles. Results were gathered for the average volumetric wear rates of E1 Antioxidant Infused Technology acetabular bearings, run on an orbital simulator and for ArCom and ArComXL liners run on an equivalent orbital simulator in a previous study.[10]

Results

- Average volumetric wear rate of 28mm E1 liners was more than 99 percent lower than those of ArCom and ArComXL liners. (Figure 2)

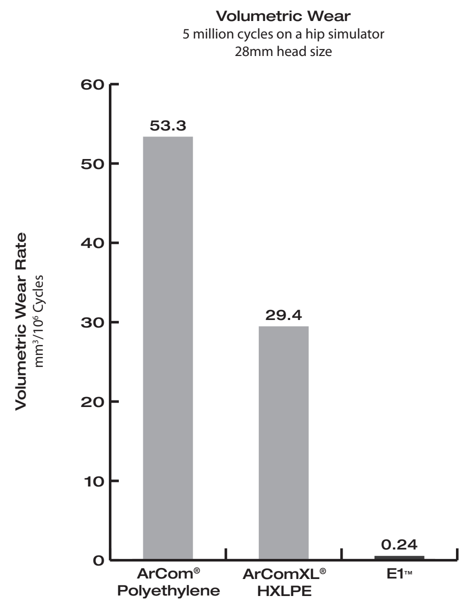


Figure 2: Volumetric Wear Rates for 28mm Acetabular Liners

High Contact Area

Large diameter femoral heads have a larger contact area in polyethylene liners than small diameter heads. As a result, they have the potential to produce more wear debris and have higher wear rates when coupled with polyethylene liners than smaller diameter components.

Materials and Methods

Biomet Biomaterials Laboratory

To test the worst-case scenario for wear, the largest, thinnest E1 liners were tested. Size 25 liners with a 40mm inside diameter and a nominal thickness of 4.8mm were tested, and they were coupled with CoCr-Mo modular heads.* The components were tested on an AMTI hip simulator with anatomical motion for 5 million cycles. The study was carried out per ISO 14242-1. Load soaks were used to account for fluid uptake during testing. Bovine calf serum with a protein concentration of 20 g/L was used as the lubricant. Gravimetric measurements were taken every 500,000 cycles.

Half of the liners were tested under clean conditions and the other half were tested under accelerated aged and abrasive conditions. The accelerated aging was completed in a pressure vessel for two weeks at 70 degrees Celsius and 5 atm of oxygen. The abrasive conditions were simulated by roughening the femoral heads with 600 grit sandpaper prior to testing to achieve a nominal Ra surface roughness of 100nm.

Results

- Average volumetric wear rates for 40mm E1 liners were 95 percent less than those of the 36mm ArCom liners under clean conditions and 88 percent less under abrasive conditions (Figure 3).

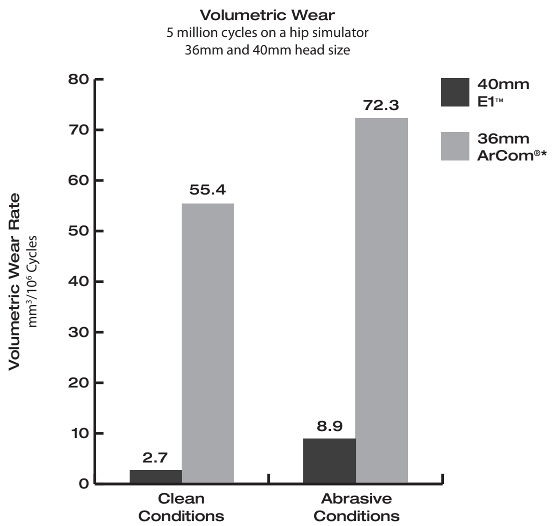


Figure 3: Volumetric Wear Rates for Large Diameter E1 and ArCom Liners

Wear Particle Analysis

Materials and Methods

Loma Linda University Medical Center

Wear particle analysis was conducted using serum samples collected from the large diameter wear study under clean conditions. The particles were processed using a hydrochloric acid digestion method.[11] The collected E1 and ArCom particles were analyzed for the equivalent circular diameter, aspect ratio and circular shape factor (Table 1).

Parameters	Statistic	ArCom [10] N=363 Particles	E1 N=867 Particles
Equivalent Circular Diameter (microns)	Mean +/- St. Deviation	0.409 ± 0.591	0.340 ± 0.214
	Median	0.263	0.274
	Minimum – Maximum	0.053 – 3.547	0.100 – 2.28
Aspect Ratio	Mean +/- St. Deviation	1.547 ± 0.532	1.64 ± 0.63
	Median	1.42	1.50
	Minimum – Maximum	1.00 – 7.31	0.100 – 9.58
Circular Shape Factor	Mean +/- St. Deviation	0.860 ± 0.128	0.847 ± 0.105
	Median	0.880	0.872
	Minimum – Maximum	0.170 – 1.220	0.180 – 0.997

Table 1: Particle Analysis Results for E1 and ArCom Materials

Results

- Wear particle morphology of E1 material is similar to that of the ArCom material and within parameters for wear particles seen in polyethylene currently in clinical use.[12,13]

*40mm liners are not currently available.

Oxidative Stability

Environmental Stress Cracking Study[14]

For polyethylene acetabular liners, cyclic loading, combined with the *in vivo* environment, may potentially induce cracks in polyethylene. This phenomenon is referred to as environmental stress cracking (ESC). ESC in polyethylene is related to the amount of non-stabilised free radicals in the material, the number of free radicals induced during loading and the ability for those free radicals to react with oxygen.

Materials and Methods

Massachusetts General Hospital

E1 material, conventional polyethylene (gamma-inert sterilised and removed from packaging) and sequentially crosslinked and annealed samples* were tested to determine their resistance to ESC. The ESC resistance was evaluated by cyclically loading test samples on an MTS system in an environmental chamber kept at 80 degrees Celsius for five weeks or until the samples failed. Failure of a sample was defined as the visible appearance of cracks in the surface of the triangular neck region or a complete shear fracture of the neck (Figure 4). Four specimens from each group were tested, and an additional three specimens were kept in the chamber at 80 degrees Celsius during the test without applying any load so that the effect of loading could be determined.

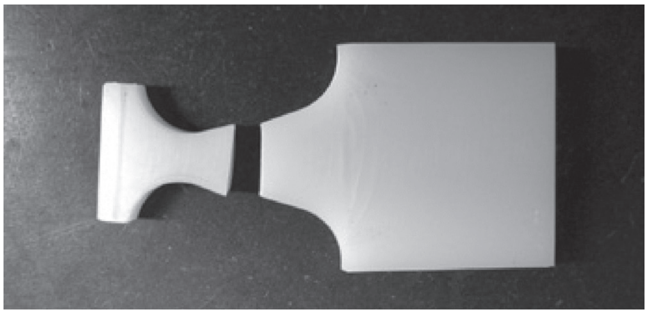


Figure 4: Sheared Sequentially Annealed Specimen

Sample Number	Failed Prior to 5 Weeks?	Cycles Completed
Conventional UHMWPE (gamma inert, removed from packaging)		
A1	Yes *(ESC observed)*	1,410,000 cycles
A2	Yes *(ESC observed)*	1,410,000 cycles
A3	Yes *(ESC observed)*	1,080,000 cycles
A4	Yes *(ESC observed)*	907,200 cycles
Sequentially Crosslinked and Annealed UHMWPE		
X1	No	1,530,000 cycles
X2	No	1,530,000 cycles
X3	Yes *(Sheared in half)*	1,500,000 cycles
X4	Yes *(Sheared in half)*	1,140,600 cycles
E1		
H1	No	1,530,000 cycles
H2	No	1,530,000 cycles
H3	No	1,530,000 cycles
H4	No	1,530,000 cycles

Table 2: Total number of cycles completed by the individual samples. If the samples failed less than five weeks into the test, the method of failure (ESC observed) is noted.

Upon specimen failure or the conclusion of five weeks of cyclic loading (whichever came first), the samples were analyzed by Fourier Transform Infrared Spectroscopy (FTIR, Bio-Rad FTS2000, Natick MA) to quantify the oxidation within the constant stress triangular region. Oxidation levels were expressed as an oxidation index.

Results

- Half of the sequentially annealed samples sheared in half close to the end of the test. (Table 2)
- E1 Antioxidant Infused Technology, samples showed no evidence of environmental stress cracking. (Table 2)
- Oxidation indices were higher for the conventional and sequentially crosslinked and annealed polyethylene test samples than those for the unloaded controls. (Figures 6 and 7)
- E1 Antioxidant Infused Technology, specimens showed little to no detectable oxidation in the loaded or unloaded samples. (Figure 5)

*33kGy gamma irradiated and annealed at 130 degrees Celsius for 5 hours, slow cooled and repeated twice more.

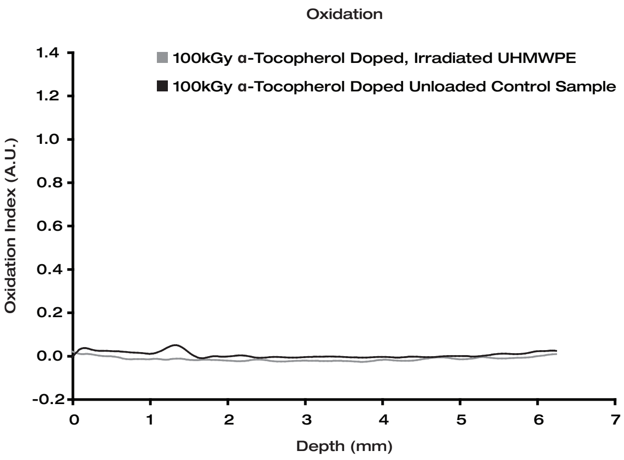


Figure 5: Oxidation Profiles of E1 Specimens

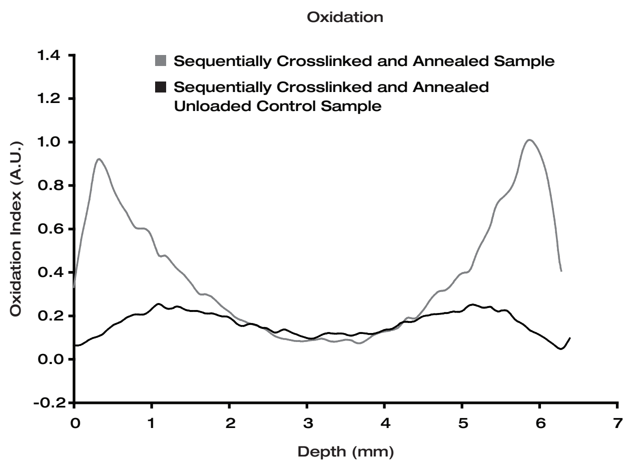


Figure 6: Oxidation Profile of Sequentially Crosslinked and Annealed Specimen

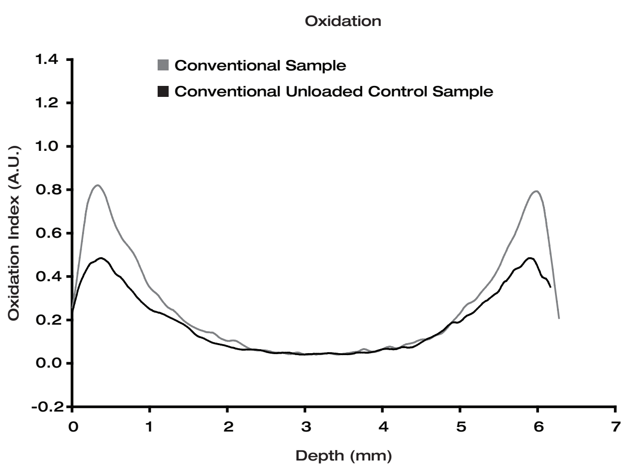


Figure 7: Oxidation Profile of Conventional Specimen

Small Punch Testing

Materials and Methods

Exponent

Small punch testing was completed per ASTM F2183-02 as recommended by ASTM F2565. Six aged and six unaged E1 material surface specimens were tested for peak load, ultimate load, ultimate displacement and work to failure. (Table 3)

Material Description	Peak Load (N)	Ultimate Load (N)	Ultimate Displace-ment (mm)	Energy to Failure (mJ)
ArCom Non-aged	72.2±1.8	75.4±5.3	3.96±0.15	223±12
Conventional Aged*	75.6±1.1	42.6±16.0	4.16±0.28	211±10
E1 Non-aged	74.3±2.4	105±5.5	3.4±0.20	209±24
E1 Aged	78.9±1.5	115±3.2	3.7±0.20	255±19

*Gamma-inert sterilised, removed from packaging.

Table 3: Small Punch Results for ArCom and E1 Materials Average Values of Mechanical Properties[10]

Results

- The peak loads and energies to failure were similar for all four material groups.
- Ultimate load of the E1 specimens was significantly higher than that of the ArCom material, especially under aged conditions.
- Ultimate displacements of the E1 material are slightly lower than those of the ArCom material because of the increase in crosslink density.
- Aging of the E1 specimens had no detrimental effects on the small punch mechanical properties of the material.

Elution Study

With any process where one material is infused into another, there is the risk that the infused material may elute out of the parent material over time. Biomet invested a great deal of time and energy into drastically reducing this risk by manipulating the proprietary process for manufacturing E1 liners.

Materials and Methods

Biomet Biomaterials Laboratory

To quantify the elution from the surface of the E1 liners, liners were placed in a water bath at 40 degrees Celsius for six months. From the baseline, time points were set at two weeks, two months, four months and six months. Three liners were pulled and sacrificed at each time point for FTIR analysis to determine the average surface concentration of vitamin E (Figure 8).[10] The surface layer was defined as the first 20 percent of the normalised thickness of each liner.

The baseline vitamin E indices were higher than those at other time points through the entire surface layer of the polyethylene, suggesting that the baseline liners had vitamin E profiles that were higher through the entire polyethylene thickness and therefore, the difference was not due to elution. If the difference was the result of elution of α-tocopherol, the indices would converge toward the other groups as the depth increased.

Results

- No detectable vitamin E elution from the surface of the liners.

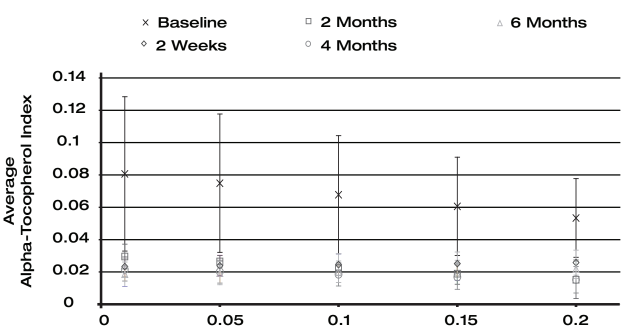


Figure 8: Six Month Elution Data for E1 Acetabular Liners

Mechanical Properties

Maintaining the tensile and fatigue properties after crosslinking polyethylene is vital to the integrity of locking mechanisms and extended lip liners when they are subjected to normal and adverse loading conditions *in vivo*. The strength of the polyethylene is also important when thinner liners are used to accommodate larger diameter modular heads.

Biomet has carried out extensive mechanical testing to prove that the E1 liners have similar mechanical properties to ArCom liners, which have 15 years of successful clinical history. The testing included tensile strength, crack propagation resistance, bending fatigue to test crack initiation, impact strength and rim impingement fatigue.

With the exception of the two device tests, accelerated aged specimens were tested in addition to the unaged specimens to provide further evidence of the oxidative stability of the E1 material. The accelerated aging was done in a pressure vessel at 70 degrees Celsius and 5 atm of oxygen for two weeks.

Tensile/Yield Strength

Materials and Methods

Bodycote Polymer, Broutman Laboratory

The tensile testing was carried out per ASTM standard D638. Type V dog bone specimens were processed using methods identical to those used for E1 Antioxidant Infused Technology material, acetabular liners. Half of the specimens underwent accelerated aging prior to testing. Five specimens were tested in each group to gather average ultimate tensile and yield strengths (Figures 9 and 10).

Results

- Ultimate tensile strength and yield strength of the E1 material are similar to those of the ArCom material and higher than those of the remelted materials.
- Accelerated aging did not detrimentally affect the E1 material.

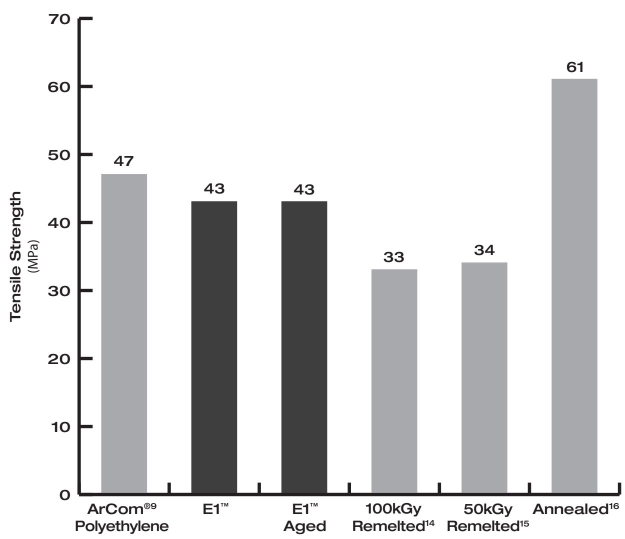


Figure 9: Ultimate Tensile Strength of Multiple Polyethylenes

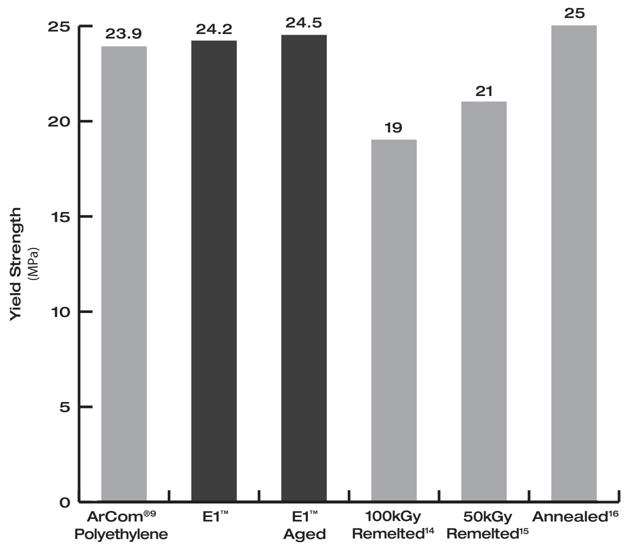


Figure 10: Yield Strength of Multiple Polyethylenes

Crack Propagation

Materials and Methods

Case Western Reserve University

Fatigue crack propagation testing is used to evaluate the fatigue performance of a material once a crack has initiated. The fatigue crack propagation testing was carried out per ASTM standard E647. Circular C(T) specimens were processed using methods identical to those used for E1 acetabular liners. Half of the specimens underwent accelerated aging prior to testing. Four specimens were tested for each of the two E1 material groups. Values were recorded for ΔK inception, or the minimum stress intensity factor at which a crack will propagate (Table 4).

Results

- ΔK inception for the two E1 material groups was slightly lower than that of the ArCom polyethylene control due to the increased crosslinking in the E1 material.
- It requires more stress to propagate a crack through E1 material, which is processed below melt temperature and has a higher ΔK inception than remelted materials.

Material	ΔK Inception (MPa·√m)
ArCom Polyethylene[10]	1.8
ArComXL Polyethylene[10]	1.4
E1	1.1
E1 Aged	1.1
100kGy Remelted[18]	0.9
100kGy Annealed[18]	1.1

Table 4: ΔK Inception of Different Materials

Bending Fatigue

Although understanding how a crack propagates through a material is necessary, it is also important to understand the material's level of resistance to crack formation.

Materials and Methods

Massachusetts General Hospital

The crack initiation behavior of the E1 material was quantified by cyclically loading the post of the UHMWPE bending specimen (Figure 11). The post had a rectangular cross section and was impinged upon by load applicators due to the upward and downward movement of the actuator. This motion created regions of alternating stress states (compression and tension) that caused cracks to initiate. The number of cycles it took to initiate a crack varied with load.

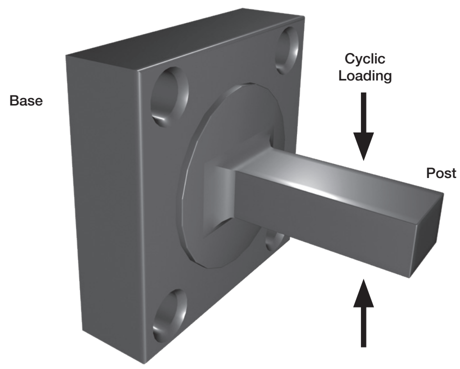


Figure 11: Bending Fatigue Specimen

This study was conducted on an MTS system in an aqueous environment at 40 degrees Celsius to simulate *in vivo* conditions. The displacement corresponding to the maximum and minimum loads for each load cycle was recorded. Failure initiation was defined as a sudden increase in displacement, and in most cases, the post sheared off and separated from the base within 50–100 cycles of failure initiation. The E1 and ArCom specimens tested were compared on an S-N curve (Figure 12).[10]

Results

- Aged and unaged E1 material groups showed an equivalent resistance to bending fatigue as the clinically proven ArCom material.

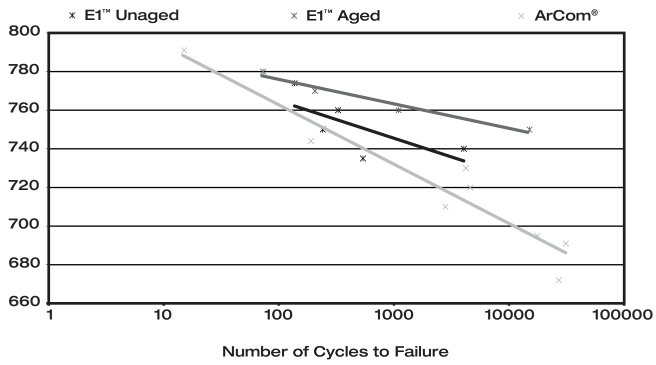


Figure 12: Bending Fatigue Resistance

Rim Impingement Testing

Rim impingement loading can occur *in vivo* as a result of misalignment or patient movements that require a large range of motion. The worst case for this type of loading is a small, thin hi-wall liner where the point of impact is the top of the wall.

Materials and Methods

Biomet Biomaterials Laboratory

To simulate this loading condition, a fatigue test was used, where the trunion was in contact with the rim of the acetabular liner when load was applied (Figure 13). Loading at this point allowed deflection of the polyethylene and produced a higher load at the base of the wall due to the moment arm. The smallest thinnest liners provided less support for the loaded portion of the liner and were theoretically more susceptible to fracture than larger liner designs. The E1 liners were compared to ArCom liners of the same size.

This study was run at 5 Hz for 2 million cycles using size 22x28mm hi-wall acetabular liners. A diagram of the experimental setup is included as Figure 13. The liners were locked in place using the standard RingLoc® locking mechanism. The trunion was loaded such that the moment at the center of the modular head was 100 in-lbs.[21] To reach this moment, the trunion was loaded from 10 to 100 lbs. At 500,000 cycle intervals, the test was stopped and liners were photographed and visually inspected for signs of fatigue failure. The area of impingement was outlined using permanent marker. At the end of the 2 million cycles, the liners were removed from the fixture by shrinking them with exposure to liquid nitrogen to bypass the locking mechanism. The backsides of the liners were also visually inspected for signs of damage.

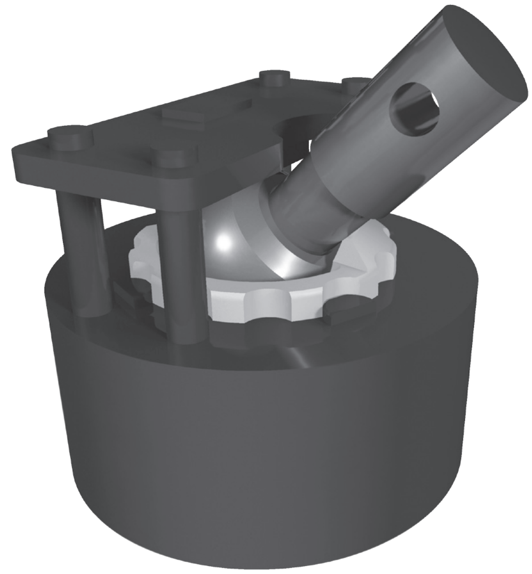
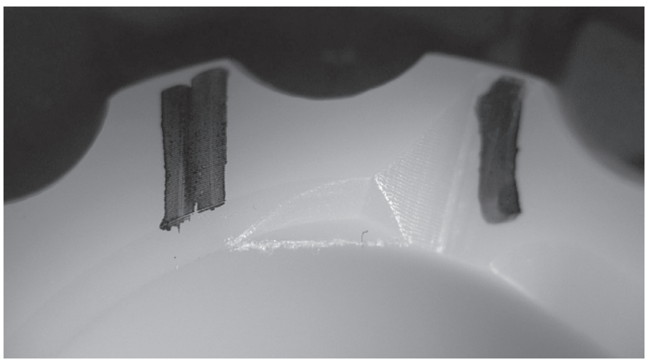


Figure 13: Experimental Setup for Rim Impingement Loading

Results

- Impingement region for the 100kGy liners was very similar to that for the ArCom liners (representative pictures included in Figure 14).[10]
- Regions appeared larger at each time point for both materials, which was likely the result of creep.
- Visual liner inspection showed no cracking, pitting or other gross damage to the ID or OD of the E1 liner or the clinically proven ArCom polyethylene liners.

A



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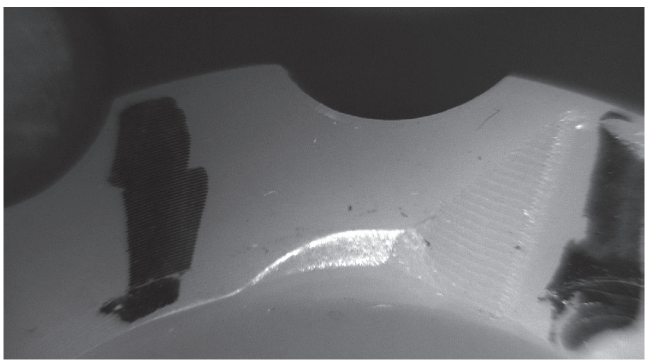

Figure 14: E1 Liner (A) ArCom Liner at 2 Million Cycles (B)

Impact Strength

Materials and Methods

Biomet Biomaterials Laboratory

Impact strength was measured using the technique presented in ASTM standard F648. Half of the E1 specimens were accelerated aged at 5 atm of oxygen and 70 degrees Celsius for two weeks. The aged and unaged E1 materials had average impact strengths of 49.0±0.6 and 36.5 ± 0.7 kJ/m^2 respectively.[10] The average impact strength of 100kGy irradiated and remelted polyethylene was reported in the literature as 30.6 kJ/m.[2,17]

Results

- Impact strength of the E1 material is higher than that of the irradiated and remelted material that is currently on the market.

Biocompatibility Testing

In addition to the elution study, Massachusetts General Hospital conducted two biocompatibility studies that looked at the tissue response to vitamin E doped UHMWPE.

Study One[19]

Materials and Methods

Massachusetts General Hospital

In the first study, small plugs of crosslinked and vitamin E infused UHMWPE were implanted in the mid-back region of multiple rabbits. The control material used was a gamma sterilised UHMWPE plug with the same geometry as the test plug. The rabbits were sacrificed at 2 weeks and 12 weeks and the fibrous tissue sacks were harvested and examined by a pathologist.

Results

- Two weeks: the membrane around both control and vitamin E impregnated polyethylene contained numerous macrophages and fibroblasts, which, presumably, represented a response to the surgical procedure (Figure 15 A).
- Twelve weeks: the encapsulating membrane consisted of a thin layer of fibrous tissue lined by several layers of synoviocyte-like cells (Figure 15 B).
- No significant inflammatory infiltrate or foreign body reaction associated with either type of plug.

- No discernible difference in the tissue response to the control polyethylene or the vitamin E impregnated implants at either 2 or 12 weeks after implantation.
- This subcutaneous implant study indicated no deleterious tissue reaction to vitamin E impregnated polyethylene when it was in direct intimate contact with the surrounding tissue, indicating that it will be well tolerated as an implanted material.

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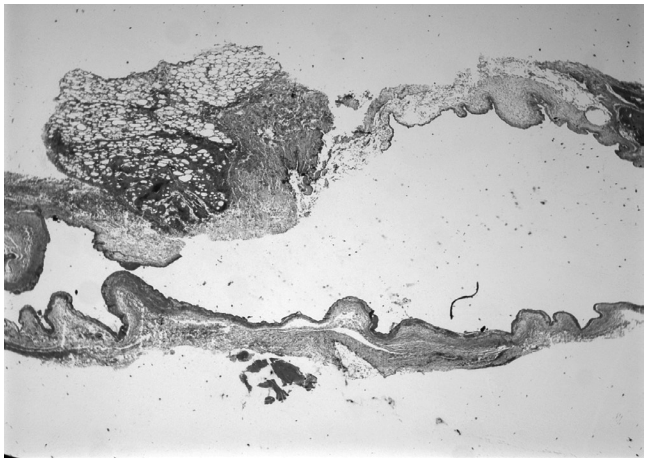

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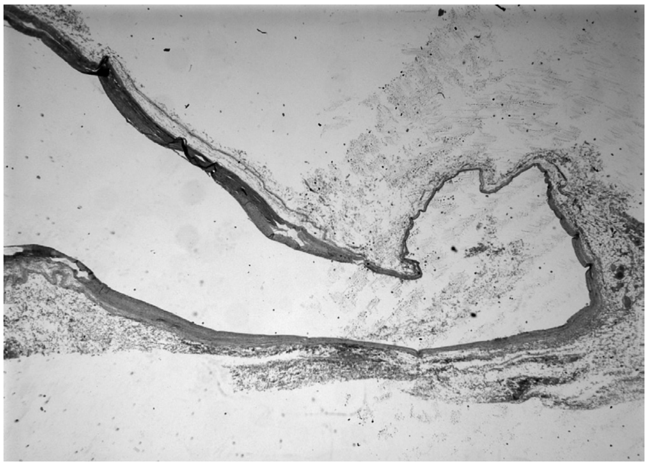

Figure 15: While there was evidence of acute inflammation and tissue repair at two weeks (A) around both vitamin E impregnated and control polyethylene implants, by twelve weeks (B) there was a stable synovial-like membrane around all plugs with no signs of inflammation or foreign body reaction.

Study Two[20]

Materials and Methods

Massachusetts General Hospital

The second study used a canine model where a complete hip system was implanted in each dog. The acetabular liner was a highly-crosslinked, vitamin E infused UHMWPE coupled with a CoCr head. The control liners were highly crosslinked and remelted UHMWPE. The animals were sacrificed at 12 weeks and histology sections were taken and analyzed by a pathologist.

Results

- No discernible difference in the local tissue response surrounding the control or the vitamin E doped polyethylene components.
- Noted variations in histological observations were not unique to either group and appear to represent normal variations in the tissue healing response.
- Vitamin E doped polyethylene acetabular components were well-tolerated in the study with no adverse tissue reaction.

Conclusion

Biomet's materials and engineering expertise and Massachusetts General Hospital's cutting edge science have produced highly crosslinked acetabular liners that utilize the novel method of infusing crosslinked polyethylene with vitamin E to neutralize free radicals that can cause oxidative degradation (as demonstrated in the above mechanical and device testing). The E1 acetabular liners have good mechanical strength, superior wear performance (95–99 percent over the proven ArCom high-performance material under clean conditions[10]) and excellent resistance to oxidation (as shown in ESC testing[14]).

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Contributing Authors

Jordan Freedman
Dave Schroeder

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Verantwortlicher Hersteller
Biomet UK Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA
Tel: +44 [0] 1656 655221
Fax: +44 [0] 1656 645454

Vertrieb Deutschland
Biomet Deutschland GmbH
Gustav-Krone-Str. 2
D-14167 Berlin
Tel.: +49 / 30 / 845 81-0
Fax: +49 / 30 / 845 81-110
www.biomet.de

Vertrieb Österreich
Biomet Austria GmbH
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A-5303 Thalgau
Tel.: +43 / 62 35 / 200 33-0
Fax: +43 / 62 35 / 200 33-9
www.biomet.at

Vertrieb Schweiz
Biomet Orthopaedics Switzerland GmbH
Riedstr. 6
CH-8983 Dietikon
Tel.: +41 / 44 / 200 76 00
Fax: +41 / 44 / 200 76 01
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