

C R O S S L I N K E D P O L Y E T H Y L E N E

Longevity



SOLVING THE
WEAR PUZZLE



Longevity

WEAR RESISTANT POLYETHYLENE

Crosslinking has been shown to reduce the wear rate of polyethylene by up to 89% in laboratory studies.¹ Clinical experience with highly crosslinked polyethylenes has also demonstrated a substantial reduction in the rate of wear.^{2,3} This remarkable process creates a three-dimensional structure that is more resistant to abrasion.^{4,5} Longevity Crosslinked Polyethylene was developed to address the issue of wear in total hip arthroplasty. To help ensure optimal wear resistance, Zimmer employs a proprietary process based in part on patents licensed from Massachusetts General Hospital and Massachusetts Institute of Technology. Using high-dose electron-beam radiation, this process fully crosslinks broken molecular

chains, leaving virtually no free radicals to promote oxidation. The process produces a ten-fold wear rate reduction – an average 89% reduction of debris generated – compared to standard polyethylene control samples.*¹ The material also meets all of the mechanical property requirements of the ASTM and ISO standards. Longevity Crosslinked Polyethylene is available with the Trilogy[®] Acetabular System, which is based on the long Zimmer tradition of clinical success with the Harris/Galante and HGP II porous cups. The Trilogy System also includes new features designed to help further reduce polyethylene wear.

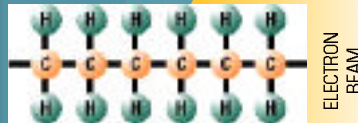


* Wear reduction of 90 and 88 percent for 22mm and 32mm femoral heads, respectively, when compared to standard Zimmer polyethylene. The results of in vitro tests have not been shown to correlate with clinical wear mechanisms. Further research is required to determine performance of highly crosslinked polyethylene in total knee applications.

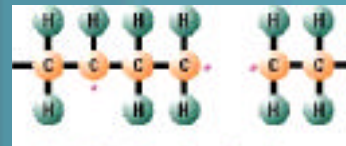
OXIDATIVE CHAIN SCISSION

Polyethylene crosslinking requires exposure to radiation energy. Crosslinking is one of three possible outcomes of the irradiation process. The other two outcomes are recombination and oxidative chain scission. All of these are illustrated below.

Polyethylene chains, made up of carbon and hydrogen atoms, are exposed to high dose electron-beam radiation energy.

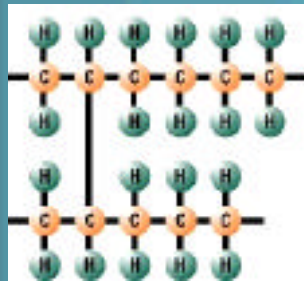


This breaks the chains and creates free radicals from the broken carbon-carbon and carbon-hydrogen bonds. The free radicals react in one of three ways.



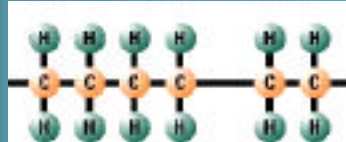
Reaction 1: Crosslinking

Chemical bonds are created between adjacent molecular chains, resulting in a three-dimensional structure that is more resistant to abrasive wear. This is the preferred outcome of the irradiation process and is achieved by using the Zimmer proprietary process.



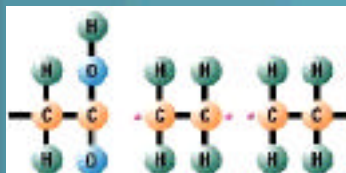
Reaction 2: Recombination

Free radicals recombine at their original breaking points to form stable bonds. There is no net effect on the polyethylene.

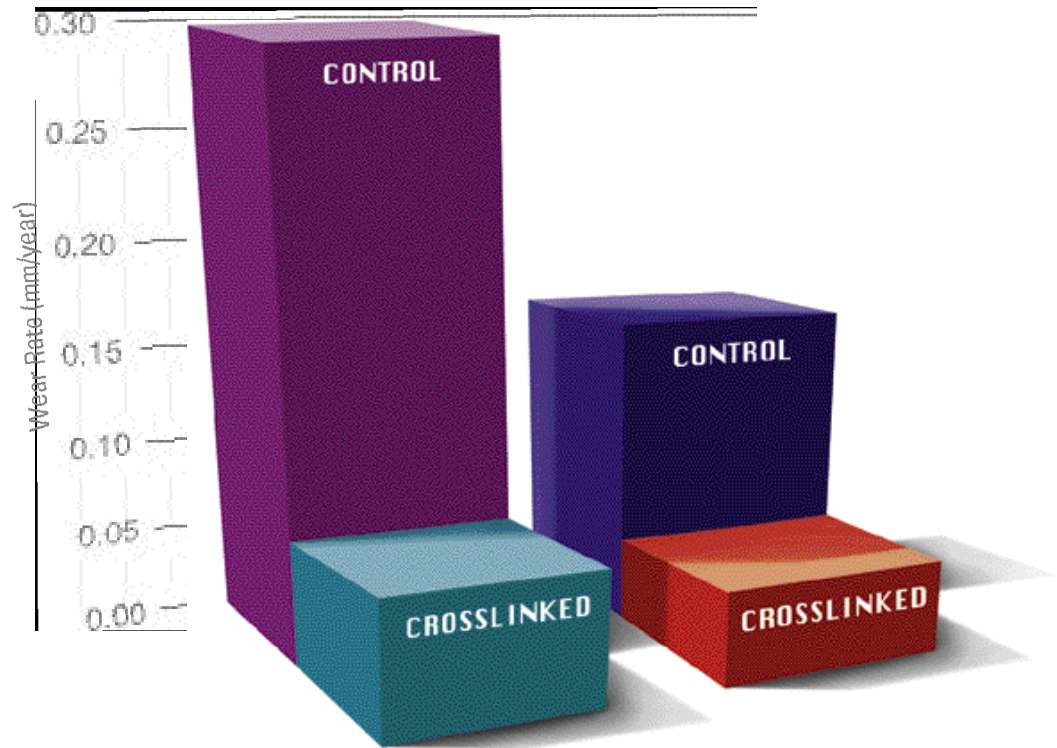


Reaction 3: Oxidative Chain Scission

Free radicals combine with oxygen causing oxidative chain scission. The result is a polyethylene with a lower molecular weight. Zimmer employs proprietary processing techniques that fully crosslink broken molecular chains, leaving virtually no residual free radicals to promote oxidation.



Clinical Experience with Crosslinked Polyethylenes



Oonishi Clinical Study: 79% Wear Reduction

In a comparative clinical study by Oonishi et al, ultra-high molecular-weight polyethylene (UHMWPE) acetabular cups were gamma irradiated at 100MRad (up to 40 times standard gamma sterilization dose) in an inert environment to promote high level crosslinking. These crosslinked components were then implanted in 62 patients. Non-irradiated components were used as a control. A radiographic follow-up showed that the steady state wear rate was 0.06mm/year in the cross-linked components, and 0.29mm/year in the control.² The mean follow-up period was 17.3 years, with an average wear reduction of 79%.

Wroblewski Clinical Study: 75% Wear Reduction

In a comparative clinical study by Wroblewski et al, crosslinked all-polyethylene cups were implanted and followed up at 10 years. The average wear rate for the crosslinked hips was 0.04mm/year compared to 0.16mm/year for a control group using non-crosslinked cups. The crosslinked polyethylene demonstrated a 75% reduction in wear.³

Wear

A MEANINGFUL REDUCTION

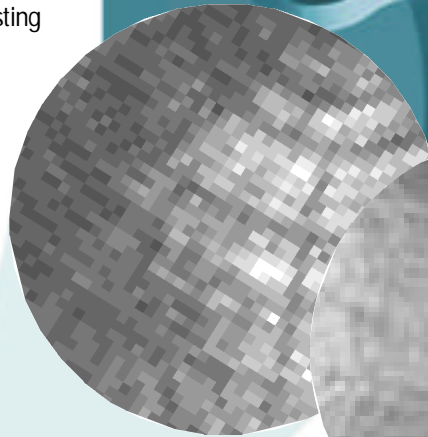
Extensive hip simulator wear testing has demonstrated the benefits of crosslinking with Longevity Polyethylene. The tests show an average wear reduction of 89% compared to standard polyethylene.¹ This improvement is made to Zimmer polyethylene that has a successful clinical history of more than 20 years.



Standard Polyethylene Before Testing

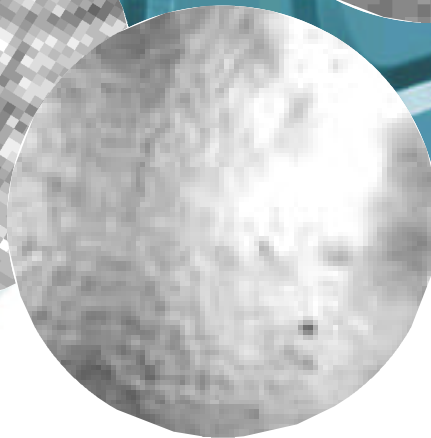
Machining lines are clearly visible at 24x magnification, and appear as parallel arcs.

Standard polyethylene liner and section under magnification.



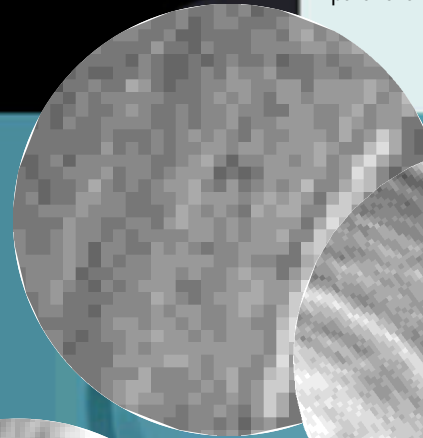
Standard Polyethylene After 5 Million Cycles

Machining lines have been worn away and are no longer visible at 24x magnification.



Longevity Polyethylene Before Testing

Machining lines are clearly visible at 24x magnification, and appear as parallel arcs.



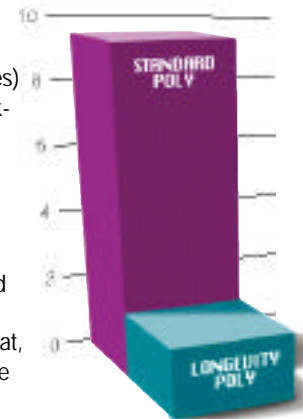
Longevity Liner and section under magnification.

Longevity Polyethylene After 5 Million Cycles

Machining lines are still evident at 24x magnification.

Wear Testing

using a hip simulator (5 million cycles) demonstrated the effect of crosslinking on the amount of wear in both aged and unaged polyethylene. Longevity Crosslinked Polyethylene showed an average wear reduction of 89% in the unaged condition and 88% in the aged condition compared to standard polyethylene. Additional testing (3 million cycles) revealed that, even in an abrasive environment, the crosslinked polyethylene performed significantly better, reducing wear by approximately 96%.¹



Effect of Crosslinking
Wear Rate (mg/million cycles) of
Longevity polyethylene and standar

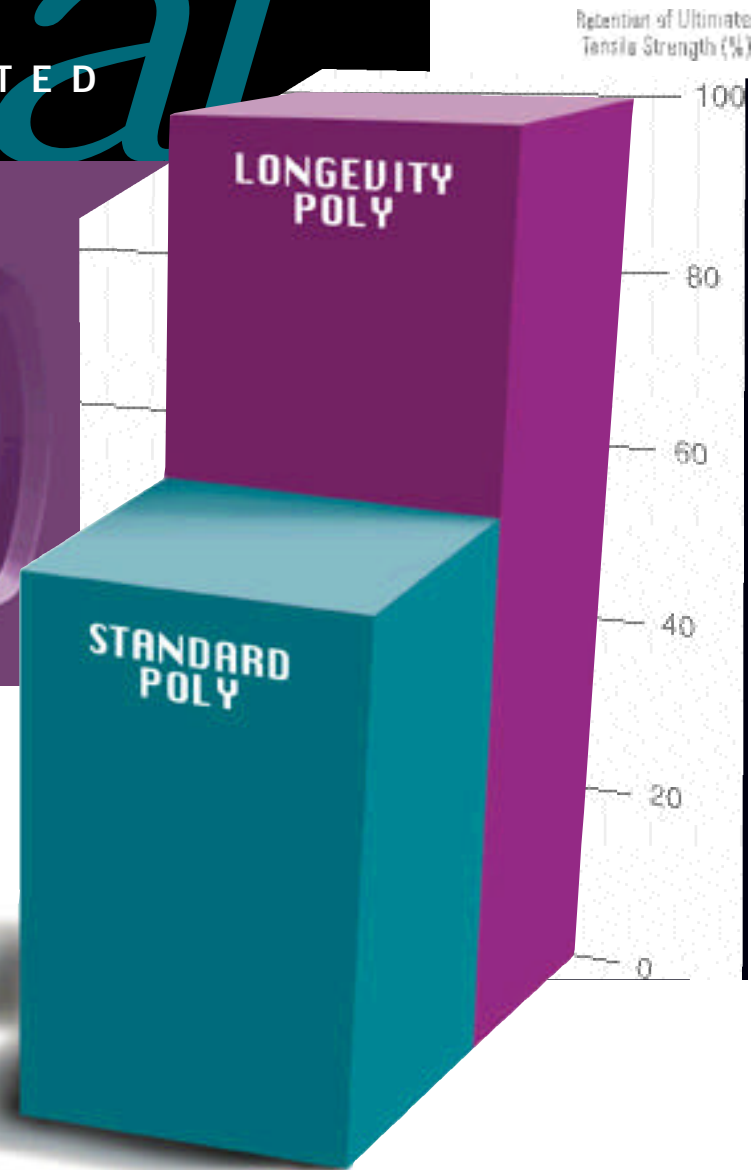
Material

FREE RADICALS
VIRTUALLY ELIMINATED

The crosslinking process used to produce Longevity Polyethylene virtually eliminates free-radicals. This greatly reduces the potential for oxidation. Like all Zimmer polyethylene, Longevity meets or exceeds industry standards.

Mechanical Properties

Longevity Polyethylene better maintains its mechanical properties after accelerated aging compared to standard polyethylene irradiated in a nitrogen environment.



Meets or Exceeds Industry Standard :

Standard	Longevity
ASTM (American Society for Testing and Materials)	✓
ISO (International Standards Organization)	✓

Tradition

PROVEN ACETABULAR DESIGN

Longevity Crosslinked Polyethylene is available with the Trilogy Acetabular System which builds on the success of the Harris/Galante Porous Acetabular Component and HGP II Acetabular Shell. The Trilogy Cup features full liner-to-shell congruency and innovative liner locking mechanisms to help reduce micromotion and wear.^{1,6} The hemispheric, fiber metal mesh design is clinically proven to maintain fixation.^{7,8}



Harris/Galante
Porous Acetabular
Component

HGP II
Acetabular
Component

Trilogy
Acetabular
System
Component



Standard

10-degree elevation

20-degree elevation

7mm offset

Removable Liners

Removable Longevity Polyethylene liners are available in standard, 10-degree and 20-degree elevations, and 7mm offsets, offering a range of options to assist the surgeon in optimizing femoral head coverage and restoring proper hip kinematics.



All the pieces fit

The combination of Zimmer compression-molded polyethylene with the design features of the Trilogy Acetabular System has already created a cup that minimizes micromotion and wear.⁶ With the addition of high level crosslinking, this wear resistance has been significantly improved. The proprietary Zimmer process minimizes the potential for oxidation and maintains compliance with industry standards.

While crosslinking has had a major impact on the wear performance of polyethylene;²⁵ the effectiveness of crosslinking is significant only if the polyethylene addresses the five key factors that have always been important to polyethylene performance: Material, Processing, Design, Sterilization, and Packaging.

Longevity . . . Trilogy . . . it's the perfect fit. For more information, contact your Zimmer representative or visit us at www.zimmer.com.

Longevity Crosslinked Polyethylene

Today's surgeon faces the increasing challenge of meeting the clinical needs of patients with cost-efficient solutions. The Longevity Crosslinked Polyethylene addresses these concerns through innovation, and a wide range of options to meet virtually all patient needs.

For more information regarding the Longevity Crosslinked Polyethylene, contact your Zimmer representative or visit us at www.zimmer.com.

- 1 Data on file at Zimmer, Inc.
- 2 Oonishi H, Saito M, Kadoya Y. Wear of high-dose gamma irradiated polyethylene in total joint replacement – long-term radiological evaluation. 44th Annual Meeting, Orthopaedic Research Society, March 16-19, 1998.
- 3 Wroblewski BM, Siney PD, Fleming PA. Low-friction arthroplasty of the hip using alumina ceramic and crosslinked polyethylene. *J Bone Joint Surg (Br)*. 1999;81-B:54-5.
- 4 Grobbelaar CJ, Du Plessis TA, Marais F. The radiation improvement of polyethylene prosthesis. *J Bone Joint Surg*. 1978;60-B(3):370-374.
- 5 Oonishi H, Kuno M, Ikada Y, et al. Super low wear crosslinked UHMWPE by heavy high-dose gamma-radiation. Proceedings from the 2nd Congress of Hip Section of Western Pacific Orthopaedic Assn. 1996;4.
- 6 Doehring TC, Saigal S, Shanbag AS, et al. Micromotion of acetabular liners: Measurements comparing the effectiveness of locking mechanisms. Orthopaedic Research Society, 42nd Annual Meeting, 1996.
- 7 Sporer SM, Callaghan JJ, Olejniczak JP, et al. Hybrid total hip arthroplasty in patients under the age of fifty: A five-to-ten year follow-up. *J Arthroplasty*. 1998;13(5):485-491.
- 8 Berger RA, Jacobs JJ, Quigley LR, et al. Primary cementless acetabular reconstruction in patients younger than 50 years old: 7-11 year results. *Clin Orthop Rel Res*. 1997;344:216-226.

† U.S. Patent 4,678,472

Polyethylene Liners

Liners are available in 2mm increments. Shell sizes 50, 52, and 54 use the same size liner.

Prod. No.	Description
Standard	
6305-36-22	Poly Liner 36x22
Through ↓	Through ↓
6305-80-22	Poly Liner 80x22
6305-42-26	Poly Liner 42x26
Through ↓	Through ↓
6305-80-26	Poly Liner 80x26
6305-44-28	Poly Liner 44x28
Through ↓	Through ↓
6305-80-28	Poly Liner 80x28
6305-48-32	Poly Liner 48x32
Through ↓	Through ↓
6305-80-32	Poly Liner 80x32
10° Elevated†	
6310-36-22	Elev Rim Liner 10° 36x22
Through ↓	Through ↓
6310-80-22	Elev Rim Liner 10° 80x22
6310-42-26	Elev Rim Liner 10° 42x26
Through ↓	Through ↓
6310-80-26	Elev Rim Liner 10° 80x26
6310-44-28	Elev Rim Liner 10° 44x28
Through ↓	Through ↓
6310-80-28	Elev Rim Liner 10° 80x28
6310-48-32	Elev Rim Liner 10° 48x32
Through ↓	Through ↓
6310-80-32	Elev Rim Liner 10° 80x32
20° Elevated†	
6320-36-22	Elev Rim Liner 20° 36x22
Through ↓	Through ↓
6320-80-22	Elev Rim Liner 20° 80x22
6320-42-26	Elev Rim Liner 20° 42x26
Through ↓	Through ↓
6320-80-26	Elev Rim Liner 20° 80x26
6320-44-28	Elev Rim Liner 20° 44x28
Through ↓	Through ↓
6320-80-28	Elev Rim Liner 20° 80x28
6320-48-32	Elev Rim Liner 20° 48x32
Through ↓	Through ↓
6320-80-32	Elev Rim Liner 20° 80x32

7mm Offset	
6341-40-22	7mm Offset 40x22
Through ↓	Through ↓
6341-70-22	7mm Offset 70x22
6341-42-26	7mm Offset 42x26
Through ↓	Through ↓
6341-70-26	7mm Offset 70x26
6341-44-28	7mm Offset 44x28
Through ↓	Through ↓
6341-70-28	7mm Offset 70x28
6341-48-32	7mm Offset 48x32
Through ↓	Through ↓
6341-70-32	7mm Offset 70x32

Liner Thickness

Shell OD (mm)	Poly Liner Thickness			
	22mm	26mm	28mm	32mm
38	5.1	—	—	—
40	6.1	—	—	—
42	6.1	5.3	—	—
44	7.1	6.2	5.2	—
46	8.2	6.3	6.3	—
48	9.1	7.3	6.2	5.3
50	10.1	8.2	7.2	6.3
52	10.1	8.2	7.2	6.3
54	10.1	8.2	7.2	6.3
56	11.2	9.3	8.3	6.4
58	12.2	10.3	9.3	7.3
60	13.2	11.3	10.3	8.4
62	14.2	12.3	11.3	9.3
64	15.2	13.3	12.3	10.3
66	16.2	14.3	13.3	11.4
68	17.2	15.4	14.3	12.4
70	18.2	16.3	15.3	13.3
72	19.2	17.3	16.3	14.4
74	20.2	18.4	17.3	15.4
76	21.2	19.3	18.3	16.3
78	22.2	20.3	19.3	17.3
80	23.2	21.3	20.3	18.3