Product Information

Durasul® Highly Crosslinked Polyethylene
Advanced Tribology for Total Knee and Hip Arthroplasty that Resists Wear and Aging

zimmer

Durasul Highly Crosslinked Polyethylene

Advanced Tribology for Total Knee and Hip Arthroplasty

Highly crosslinked polyethylene acetabular components enhance the surgeon's ability to provide patients with a long-term solution.

Durasul Natural-Knee® tibial and patellar components were tested extensively under both normal and adverse conditions.

A breakthrough in total joint replacement, Durasul highly crosslinked polyethylene directly addresses the problem of wear that can lead to osteolysis and implant loosening.

Durasul's properties are stable over time, as demonstrated by testing after accelerated aging. Thus, Durasul has the potential to extend the implant's durability, providing a long-term solution for joint replacement.

Why compromise?

The three key requirements for polyethylene in joint replacement include:

- resistance to wear,
- resistance to aging, and
- device-suitable mechanical properties.[1]

Durasul was designed and tested to fulfill all three.

A Leader in Innovation

1998 In collaboration with Dr. William Harris at Massachusetts General Hospital (MGH) and MIT, we developed Durasul highly crosslinked polyethylene.

First Durasul acetabular component implanted in Sweden.

1999 Durasul is the 1st highly crosslinked acetabular system available in U.S. market.

Market surveillance studies begin at over 300 centers worldwide.

2000 Durasul enables introduction of the 1st Large Diameter Head System.

2001 Durasul tibial inserts introduced to Natural-Knee® System - 1st knee system to use highly crosslinked polyethylene.

2002 Another 1st: Durasul patella introduced.

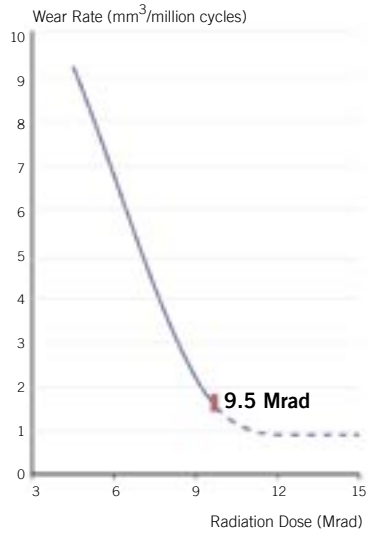
The results of in-vitro testing have not been shown to correlate with clinical wear mechanisms.

1 Muratoglu OK, Bragdon CR, O'Connor DO, Jasty M, Harris WH. A novel method of cross-linking ultra-high-molecular-weight polyethylene to improve wear, reduce oxidation, and retain mechanical properties. *Journal of Arthroplasty.* 2001; 16(2):149-60

Durasul Highly Crosslinked Polyethylene

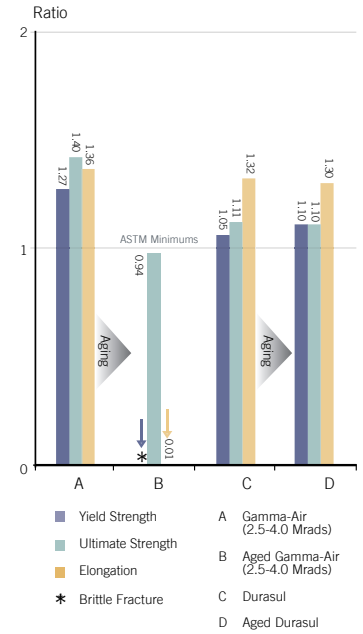
Resistant to Wear and Aging without Compromising Mechanical Properties

Wear Rate vs. Radiation Dose



Bi-directional pin-on-disk wear test. Durasul is irradiated at 9.5 Mrad to maximize wear benefits[5] and maintain mechanical properties.

Aging Effect on Mechanical Properties[8,9]



Unlike conventional polyethylene, Durasul meets ASTM and ISO minimums in both the aged and unaged conditions.

Durasul is highly crosslinked to resist wear.

Crosslinking is the formation of chemical bonds between adjacent molecular chains, making them more difficult to separate and improving wear properties. This has been demonstrated clinically[2,3], as well as through simulator testing.[1,4]

Free radicals removed to prevent aging.

During irradiation, some free radicals form crosslinks while others do not. The remaining free radicals may react with oxygen over time, leading to embrittlement, reduction in mechanical properties, and increased wear.[6,7] This change in properties over time is an example of "aging."

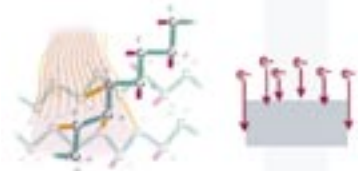
To remove the remaining free radicals, Durasul is heated above its melt temperature following crosslinking, allowing residual free radicals to recombine. This creates additional crosslinks while ensuring the stability of Durasul over time.

Device testing ensures appropriate mechanical properties for Durasul components.

Centerpulse Orthopedics, in conjunction with MGH, pioneered rigorous device-specific biomechanical and simulator tests for Durasul tibial, patellar, and acetabular components. In all cases, the Durasul components met or surpassed the performance of conventional polyethylene components.

A unique manufacturing process designed from the latest in materials technology

1. Preforms are machined from ultra-high molecular weight polyethylene, a network of long molecular chains composed of carbon and hydrogen.



2. Preforms are pre-heated then electron-beam irradiated. Molecular bonds are broken, resulting in the creation of free radicals. Many of the free radicals combine to form crosslinks, while others remain trapped in the crystalline regions.

3. Preforms are melt-annealed, eliminating the crystalline structure and increasing the mobility of the molecular chains. This allows all remaining free radicals to form additional crosslinks.

4. Preforms are then cooled at a controlled rate and machined to their final geometry.

5. Components are packaged and EtO sterilized.

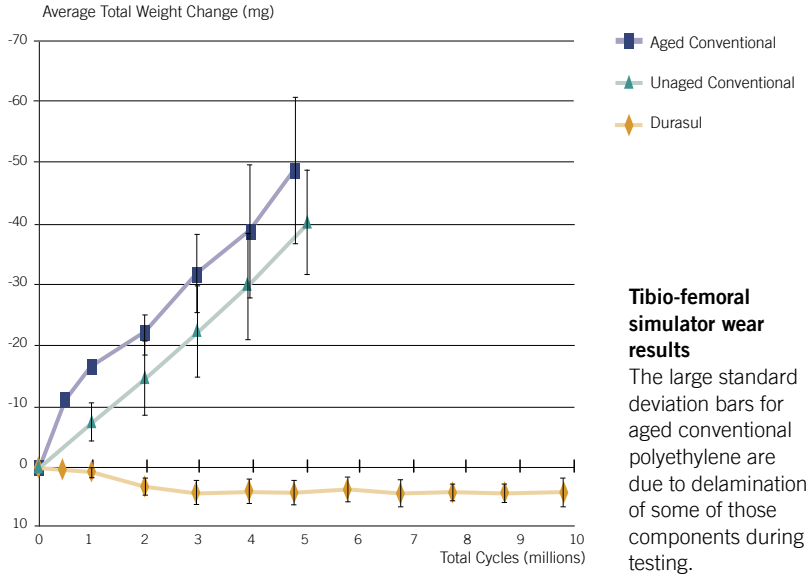
Free Radicals — Crosslinks

2 Oonishi H. Long term clinical results of THR: clinical results of THR of an alumina head with cross-linked UHMWPE cup. *Orthop Surg Traumatol.* 1995; 38:1225.
3 Wroblewski BM, Siney PD, Dowson D, Colling SN. Prospective clinical and joint simulator studies of a new total hip arthroplasty using alumina ceramic heads and cross-linked polyethylene cups. *Journal of Bone and Joint Surgery (Br).* 1996; 78:280.
4 McKellop H, Shen F, Lu B, Campbell P, Salovey R. Development of an extremely wear-resistant ultra high molecular weight polyethylene for total hip replacements. *Journal of Orthopaedic Research.* 1999; 17:157-67.
5 Muratoglu OK, Bragdon CR, O'Connor DO, Jasty M, Harris WH, Gul R, McGarry F. Unified wear model for highly crosslinked ultra-high molecular weight polyethylenes (UHMWPE). *Biomaterials.* 1999; 20(16):1463-70.
6 Fisher J, Reeves EA, Isaac GH, Saum KA, Sanford WM. Comparison of the wear of aged and non-aged ultrahigh molecular weight polyethylene sterilized by gamma irradiation and by gas plasma. *Journal of Material Science: Materials in Medicine.* 1997; 8(6): 375-8.
7 Bohl JR, Bohl WR, Postak PD, Greenwald AS. The Coventry Award. The effects of shelf life on clinical outcome for gamma sterilized polyethylene tibial components. *Clin Orthop.* 1999; Oct(367):28.
8 Muratoglu OK, Bragdon CR, O'Connor D, Perinchief RS, Estok DM, Jasty M, Harris WH. Larger Diameter Femoral Heads Used in Conjunction with a Highly Cross-linked Ultra-High Molecular Weight Polyethylene. *J Arthroplasty.* 2001; 16(8) Suppl 1:24-30.
9 DiMaio WG, Saum KA, Lily WB, Moore WC. Effect of Sterilization Type and Accelerated Aging on Physical Properties of UHMWPE. *24th Annual Meeting of the Society for Biomaterials.* San Diego, April 22-26, 1998.

Durasul for the Knee
Addressing Delamination and Wear

These simulator studies have been correlated to implant retrievals to substantiate Durasul's superior wear performance over conventional polyethylene.[11,12]

Tibio-Femoral Simulator Wear Results[10]



Tibio-femoral simulator wear results
The large standard deviation bars for aged conventional polyethylene are due to delamination of some of those components during testing.

We pioneered new standards for tibio-femoral and patello-femoral testing where none previously existed.

Patello-Femoral Simulator Results

Retrieved conventional polyethylene, after 4.5 years ***in vivo***. Note severe delamination on the lateral edge.

Aged conventional polyethylene, after **1 million cycles** on simulator. Damage mode is similar to that in retrievals.

Aged Durasul, after **2 million cycles** on simulator. No delamination observed.

10 Muratoglu OK, O'Connor DO, Bragdon CR, Jasty M, Perinchief RS, Savadove T, Harris WH, Krevolin J, Shen M. Wear Evaluation of Tibial Inserts made from Conventional and Durasul UHMWPE through simulated Gait. *White paper #1001-01-042.* 2001.
11 Muratoglu OK, Burrough BR, O'Connor DO, Bragdon CR, Perinchief RS, Sargent MR, Krevolin J, Shen M, Estok II DM, Freiburg AA, Rubash HE, Jasty M, Harris WH. Comparison of Conventional and Durasul UHMWPE on a new In Vitro Patella simulator. *White paper #1001-01-048.* 2001.
12 Krevolin J, Shen M, Bailey A, Prybyla R, Muratoglu OK, Burroughs BR, Delozio K, Wyss U, Harris WH. Comparison of Conventional Versus Durasul UHMWPE for the Patella: A New In Vitro Simulation of Stair Climbing. *White paper #1001-01-050.* 2001.

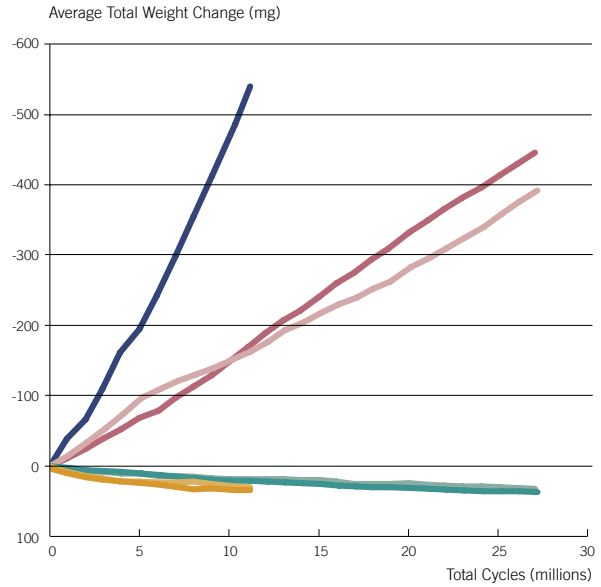
Durasul for the Hip
Larger Heads for Increased Stability

The unique combination of Durasul and large heads addresses the two most common complications following hip replacement: wear-induced osteolysis and postoperative dislocation of the hip.[13,14]

Durasul liners for use with the Converge® Acetabular System demonstrated immeasurable wear in hip simulator tests after 27 million cycles.[15] In fact, the wear of Durasul liners is independent of head size, while wear of conventional polyethylene liners increases dramatically as head size increases.[15] Thus, femoral heads with diameters up to 44 mm may be paired with Converge Durasul liners. Larger diameter heads more closely replicate the patient's anatomy, enhance stability, and increase ROM.

Durasul acetabular liners performed well in biomechanical tests, including: fatigue[16], micromotion[17], push-out/lever-out[18], and contact stress analysis[19] with inserts down to 3 mm thick.

Hip Simulator Wear Results[15]



Wear of Durasul liners is independent of head size
Durasul liners with head sizes 22, 28, 38, and 46 mm demonstrated immeasurable wear. Control liners showed increased wear as head size increased. (Control was gamma-sterilized in N_2.)

Converge hemispherical acetabular cup with Durasul liner and 44-mm CoCr head on a Natural-Hip™ stem.

Tested under normal and adverse conditions
Durasul inserts are tested within their shells ensuring anatomical testing of specific design features.

13 Turner RS. Postoperative total hip prosthetic femoral head dislocations. Incidence, etiologic factors, and management. *Clinical Orthopedics.* 1994; 301:196-204.
14 McCollum DE, Gray WJ. Dislocation after total hip arthroplasty. Causes and prevention. *Clinical Orthopedics.* 1990; 261:159-70.
15 Muratoglu OK, Bragdon CR, O'Connor D, Perinchief RS, Estok DM, Jasty M, Harris WH. Larger Diameter Femoral Heads Used in Conjunction with a Highly Cross-linked Ultra-High Molecular Weight Polyethylene. *J Arthroplasty.* 2001; 16(8), Suppl 1:24-30.
16 Bailey A. Application of 3mm Durasul Polyethylene with the Inter-Op Acetabular System: Evaluation of Fatigue Performance Characteristics of the Size 41 x 28 mm Acetabular System Under Cyclic Physiological Loads and Torque. *Centerpulse Orthopedics Technical Report #99028G.* 2001.
17 Bailey A. Application of 3mm Durasul Polyethylene with the Inter-Op Acetabular System: Evaluation of Micromotion Performance Characteristics of the Size 41 x 28 mm Acetabular System Under Cyclic Physiological Loads and Torque. *Centerpulse Orthopedics Technical Report #99029G.* 2000.
18 Kralovic BJ. Evaluation of Shell-Insert Push-In, Push-Out, Lever-Out and Torque-Out of Converge Cluster-Hole 53 mm Shells and 28 x 54 mm Durasul Inserts. *Centerpulse Orthopedics Technical Report #01034G.* 2001.
19 Kurtz S, Giddings V. Stress analysis of the Inter-Op Durasul System. *Exponent Inc.* January 4, 2000.

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Knees

Apollo® Knee System
Classic condylar knee replacement system

Durasul® Tribological System
Highly crosslinked polyethylene that resists wear and aging

Natural-Knee® System
Anatomic design for superior clinical results

UniSpacer™ Knee System
No bone cuts. No compromises.

Severe Revision/Limb Salvage

MOST Options™ System
Modular knee and hip options for severe bone loss, trauma and revision

Hips

Alloclassic® (Zweymüller™) Hip
Classic proven design with superior clinical results

Allofit™ Acetabular Cup System
Unique Ridgelock™ surface designed for easy implantation and stability

Apollo® Hip System
Designed for optimal results with low-demand patients

APR® Anatomical Hip System
The anatomic solution for bone matching

CLS™ (Spotorno™) Hip System
The standard of proximal press-fit design

Converge® CSTi™ Porous Acetabular Cup System
Where technology and experience meet

Durasul® Tribological System
Highly crosslinked polyethylene that resists wear and aging

FracSure™ Hip System
A classic design for hip fractures

Metasul® Metal-on-Metal Acetabular System
Over 15 years of clinical results & 200,000 implantations worldwide

MS-30™ Hip
A highly polished cemented stem

Natural-Hip™ System
A comprehensive system with a natural approach

Precedent™ Revision Hip System
A better solution for revision hips

SL Revision™ Hip System
A stable revision design with extensive sizes

Upper Extremities

Anatomical™ Shoulder System
Multiple adjustments of inclination & retroversion with the potential for precisely restored anatomy

GSB® Elbow System
A nonconstrained design with 21 years of clinical results

Select® Shoulder System
TSA and fracture management with offset head options

zimmer
Confidence in your hands™

1001-00-013 Rev. 10/2003