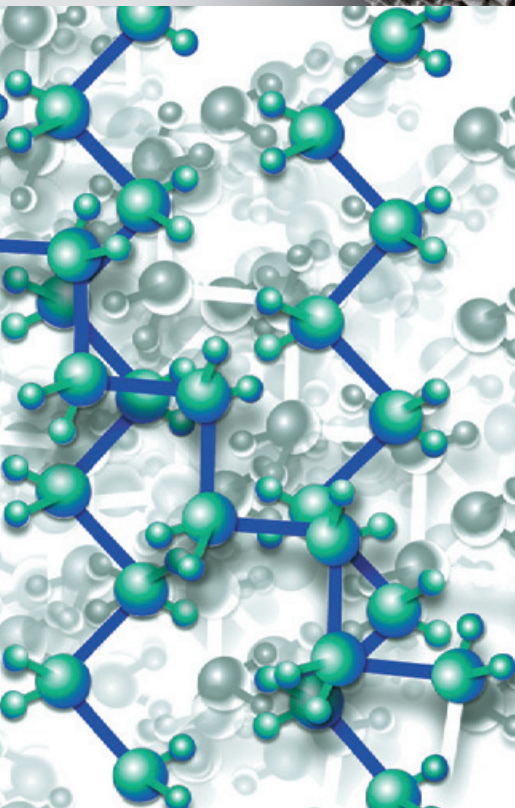




# Durasul® Highly Crosslinked Polyethylene

Scientific Information



Resistant to Wear and Aging



UHMWPE powder, rod and blank processed from slab material

## Scientific Information about Durasul

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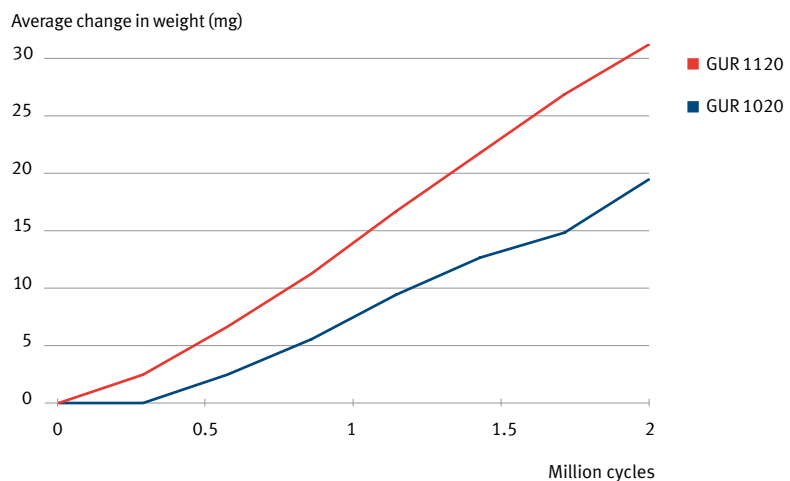
## Why a Highly Crosslinked Polyethylene?

### Material Development as a Chance for the Future

Various combinations of materials with plastics have played a key role since the very early days of the development of suitable articulations for artificial joints. However, there was little encouragement to be found in the initial results. After these initial setbacks, in 1962 Sir John Charnley used an ultra-high molecular weight polyethylene or UHMWPE that brought about a worldwide breakthrough with this material. Due to its good material properties, polyethylene was used successfully in both hip

and knee endoprosthesis. Yet ten years later, Prof. H. G. Willert was the first to describe osteolysis resulting from polyethylene wear<sup>1</sup>. He proved that foreign body reactions in the joint can lead to activity causing the breakdown of bone when the wear debris can no longer be removed by the lymphatic system. These findings were confirmed by Prof. W. H. Harris in 1976<sup>2</sup>. Subsequently, important advances were made in the wear debris and aging characteristics of UHMWPE used to manufacture joint prostheses as a result of further research and development.

### Comparison of Wear Values



In 1985, Sulzer (today Zimmer GmbH) introduced a polyethylene without calcium stearate. Studies in the hip simulator under physiological conditions showed that this much more homogeneous material was less subject to wear<sup>3</sup>. (GUR 1120: polyethylene containing calcium stearate. GUR 1020: polyethylene with no calcium stearate)

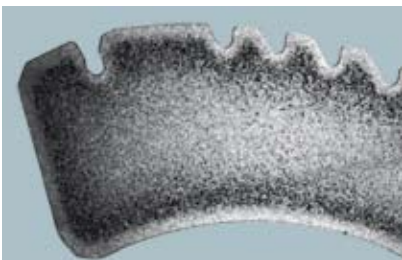
In the past, the majority of UHMWPE components were gamma-sterilized in air with a dose of 2.5 to 4 Mrad (or 25–40 kGy). In addition to sterilization, this resulted in partial crosslinking of the polyethylene chains. Various studies have shown that crosslinking is in fact an effective means of improving wear resistance<sup>4</sup>. At the same time, it must be considered that a secondary effect of gamma sterilization in air is oxidation<sup>5, 6</sup>. This has a negative effect over time on the material properties and wear of polyethylene.

Sulzer (today Zimmer GmbH) recognized this problem and began in 1986 to package components under an inert (nitrogen) atmosphere prior to gamma sterilization. This improvement in the production process prevents undesirable aging due to oxidation during manufacture and later during storage of the implants.

The quantity of wear debris depends not only on the quality of the material, but also on the design of the prosthesis and the patient activity. High levels of activity lead to a greater load on the artificial joint and consequently to greater wear debris<sup>7</sup>. In addition to that, increased polyethylene wear appears to have the direct effect of decreased service life for a prosthesis<sup>8</sup>. This makes the following clear:

**The goal of material development must be to minimize both wear and oxidative aging of the polyethylene without adversely affecting the outstanding mechanical properties of this material. The new highly crosslinked polyethylene Durasul meets this requirement to a high degree.**

Thin sections of acetabular cups after 10 years of storage, with and without traces of oxidation.



Gamma sterilization in air.



Gamma sterilization in nitrogen.

## Manufacture of Highly Crosslinked Polyethylene

The manufacture of *Durasul* can be divided into three key phases of production: the raw material manufacturing, then crosslinking with subsequent heat treatment and finally machining and sterilization of the components. Very specific process work-flows must be followed to ensure that the final *Durasul* product indeed has the desired characteristic properties.

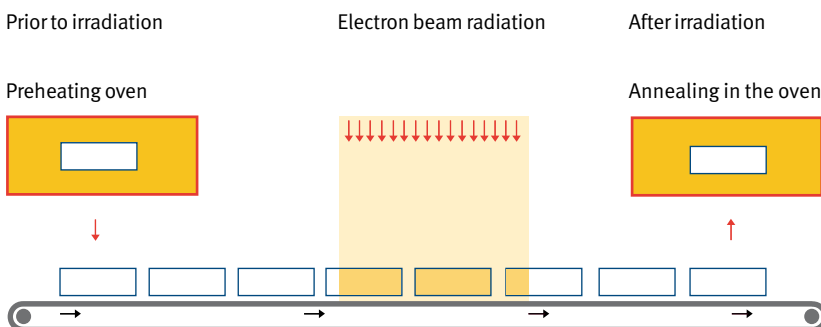
### Raw Material Manufacturing

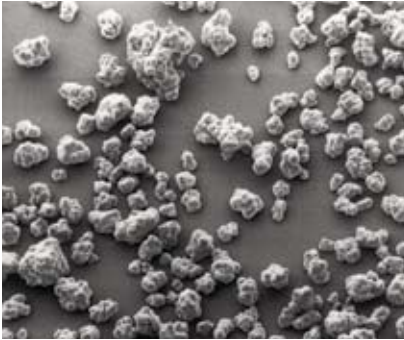
In the manufacturing process for *Durasul*, UHMWPE is synthesized from ethylene by low pressure polymerization. This produces a powdered starting material with a very low proportion of impurities<sup>9</sup>. After that in the clean room, heat and pressure are applied to the polyethylene powder to produce a homogeneous solid slab in a compression molding process. In this process, polyethylene powder is filled in a compression mold and gradually heated to the melting point. Slow cooling of the melted material and subsequent tempering yields a semi-finished material with a very homogeneous microstructure and the lowest degree of residual stress<sup>10</sup>. The minimum target material properties are precisely specified in detailed international standards<sup>11, 12</sup>.

### Crosslinking and Subsequent Heat Treatment

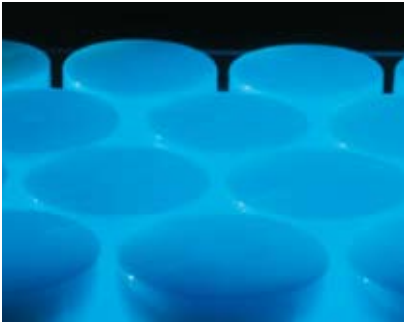
With conventional polyethylene, the untreated raw material is machined into finished components. Only afterward during radiation sterilization does partial crosslinking take place. Things are different with *Durasul*: Prewarmed blanks that are machined from the slab material are processed to produce a highly crosslinked network<sup>13</sup>. This involves a patented procedure using electron beam radiation<sup>14</sup>. Electron beam radiation has the advantage of high energy density versus gamma radiation. Because of this, the irradiation time can be significantly reduced while delivering the same radiation energy. The selected radiation dose of 9.5 Mrad for *Durasul* ensures optimal crosslink density and with it the wear resistance critical for clinical success. The subsequent heat treatment above the melting temperature enables residual free radicals to engage in additional cross-linking. This also eliminates later oxidation and aging in vivo.

### Crosslinking and Subsequent Heat Treatment

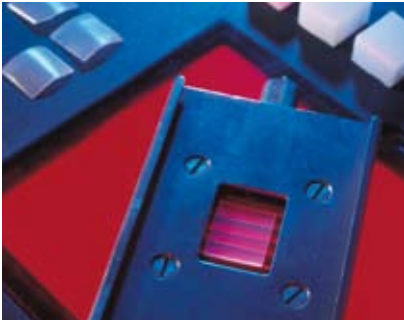




UHMWPE powder



Electron beam radiation



Process control



Machining

### Mechanical Finishing and Sterilization of the Components

The highly crosslinked blank is now machined to its final form as an implant. There are various basic options available for the sterilization. Three processes are applied for polyethylene: gamma radiation, ethylene oxide gas (EtO) and gas plasma sterilization<sup>15</sup>. Due to its penetrating effect, radiation sterilization is the method most frequently used for conventional polyethylene.

However, this process also has the undesirable secondary effect of producing free radicals. For just this reason gamma sterilization is unsuitable for *Durasul*, because the highly crosslinked, wear-resistant structure would be compromised by the free radicals. Therefore EtO sterilization, which has been in common use for many years with plastics and is clinically proven, was chosen for *Durasul*.

**Summary of the four key factors for the characteristic quality of Durasul with its high crosslink density:**

- Use of compression molded slab material
- High crosslinking density achieved by electron beam irradiation of pre-warmed blanks
- Postradiation heat treatment above the melting temperature to saturate residual free radicals
- Gentle sterilization with ethylene oxide gas to protect the wear-resistant crosslinked structure

## Significant Reduction of Wear

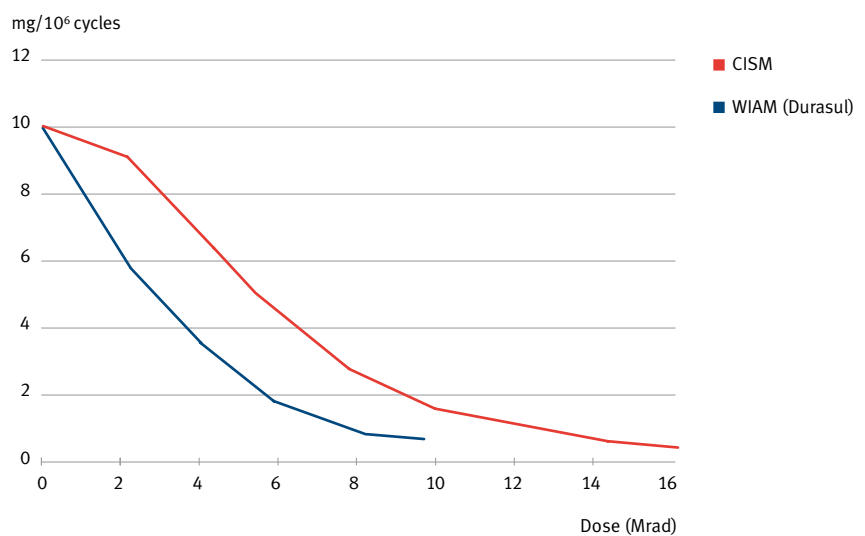
### Pin-on-Disk Testing

Failures of hip joint replacements associated with polyethylene wear have challenged manufacturers of orthopedic implants to search for new ways to optimize wear characteristics. At the same time as material development progressed, new test methods continued to be developed to determine the wear properties of newly developed tribological pairs prior to their clinical introduction. The pin-on-disk test is one such method.

In the early stages it was performed only with a unidirectional motion and yielded wear values that were far too low compared with explant studies. In fact, the test arrangement lacked the shearing motion to simulate the bidirectional pattern of movement present in vivo. Modern pin-on-disk testing equipment works bidirectionally. The physiological selected load, speed, lubrication and temperature simulate the conditions present in vivo. There has been a recognized ASTM standard<sup>16</sup> for this test method since 2000, facilitating reliable design-independent testing of new tribological pairs. The wear properties of *Durasul* were tested in three different laboratories. All pin-on-disk studies gave comparable results. Results from Massachusetts General Hospital (MGH)<sup>17</sup> in Boston (USA) are shown below as a representative example.

Highly crosslinked polyethylene should reduce the wear caused by load and movement of the joint to a minimum. The curve in the chart shows the trend of the wear rate in milligrams (mg) per million cycles relative to the radiation dose applied to the plastic material. *Durasul* was irradiated with a dose of 9.5 Mrad. This resulted in excellent wear resistance.

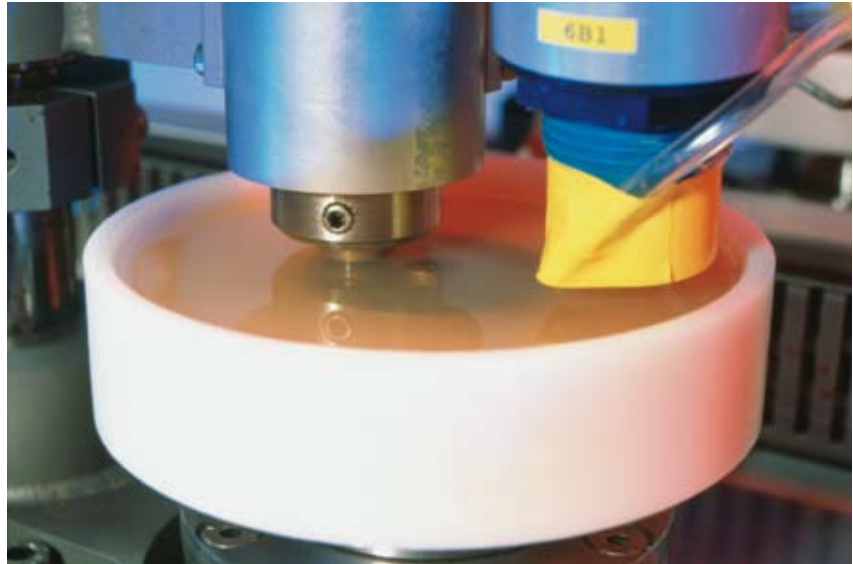
### Wear Rate Versus Radiation Dose<sup>17</sup>



Wear rate from bidirectional pin-on-disk testing of polyethylene crosslinked with electron beam radiation. (CISM: radiation of unheated samples with subsequent melting. WIAM: radiation of preheated samples with subsequent melting.) *Durasul* is irradiated with 9.5 Mrad to maximize its wear resistance.

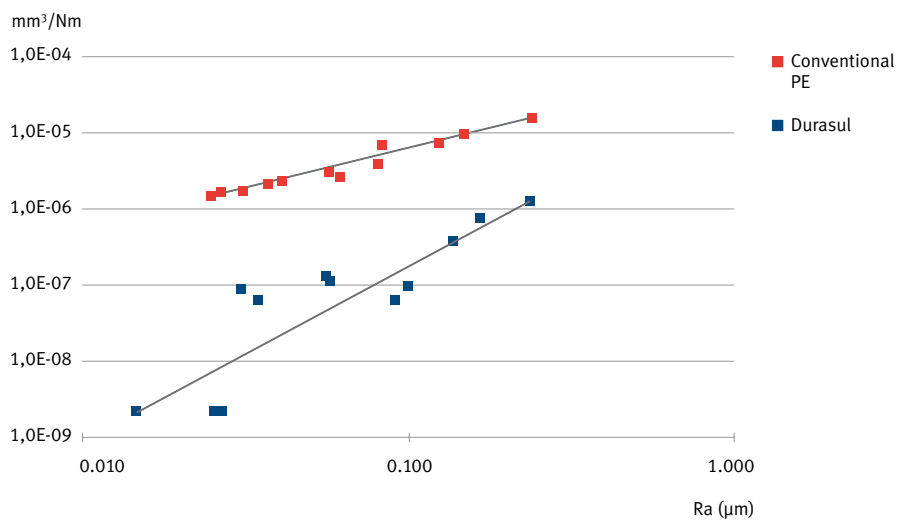


However, it should be considered that the joint replacement is often subject to an abrasive three body wear in vivo. This leads on one hand to a significant roughening of the femoral head or the femoral component and on the other to increased wear of the polyethylene component. Repetition of the experiment with friction surfaces comparable to explants with varying degrees of roughness, which ranged from 0.014  $\mu\text{m}$  (a finely polished surface) to 0.24  $\mu\text{m}$  (extremely scratched surface), showed a clear difference in wear rate between conventional and highly crosslinked polyethylene under all conditions. The highly crosslinked polyethylene *Durasul* showed significantly lower wear than the conventional material in all tests<sup>18</sup>.



Pin-on-disk test

**Wear Factor k (Pin-on-Disk Test)<sup>18</sup>**



Wear factor (path- and load-dependent) of Durasul and conventional polyethylene as a function of roughness of the metallic articulation partner.

### Hip Simulator Testing

Modern pin-on-disk testing equipment yields material property measurement values and characteristic data that are not influenced by the design. Therefore, in order to obtain more clinically relevant data it is essential to perform additional tests with hip components in the finished design – using hip simulator, for example. The following questions can be investigated this way, for example:

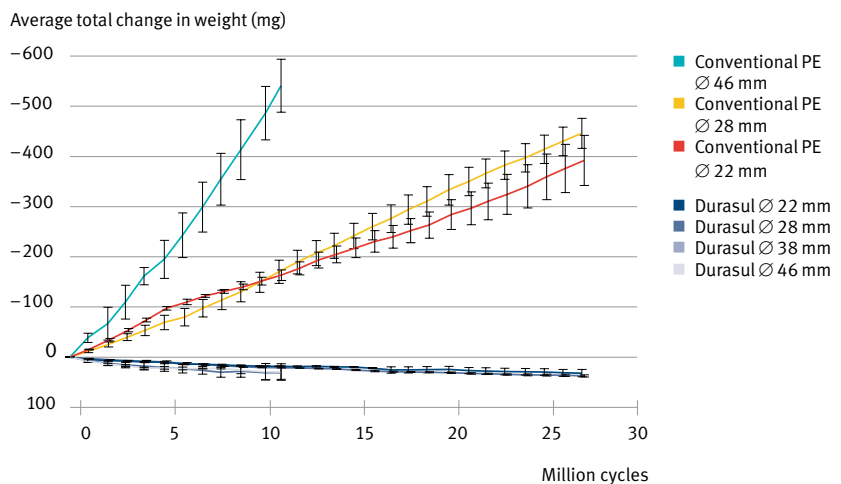


Hip simulator

### How Is the Wear Resistance Influenced by Various Head Diameters in Hip Joints?

*Durasul* inserts with 22, 28, 38 and 46 mm head sizes showed scarcely measurable wear. Control implants made of conventional polyethylene (gamma sterilized under nitrogen) show increasing wear with greater head size<sup>19</sup>. The increase in weight found for *Durasul* is due to fluid absorption during the tests. This also occurs with conventional polyethylene, but the trend is not apparent due to the larger amount of wear.

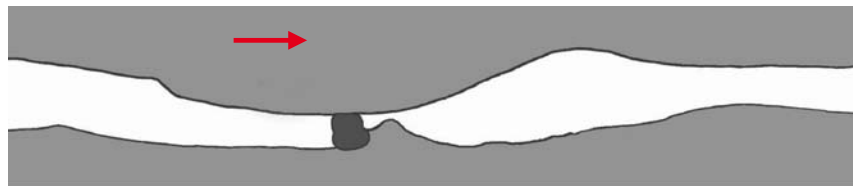
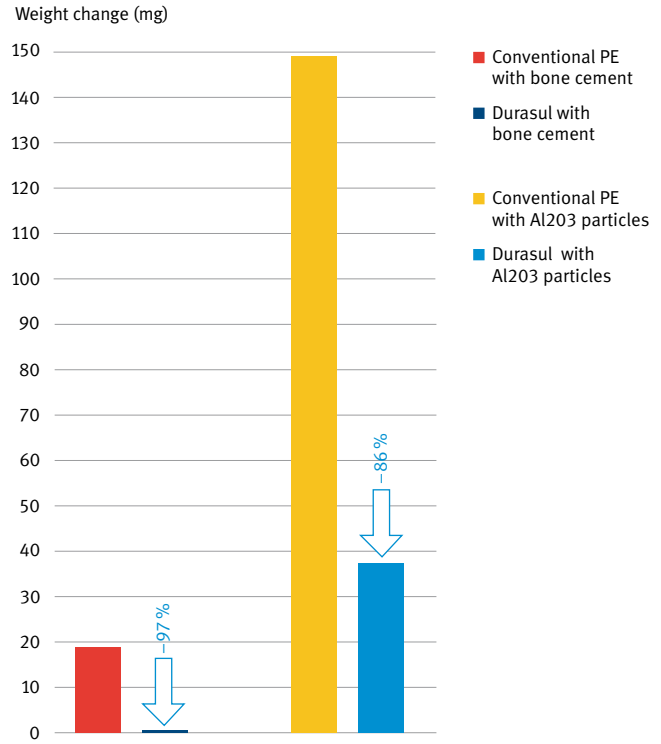
### Wear Results for the Hip Simulator



**How Does the Wear Resistance Change if the Hip Joint Is Subject to Abrasive Three Body Wear?**

The wear rate for *Durasul* under rigorous conditions with three body wear was significantly lower than the rate for conventional polyethylene. In the presence of bone cement and aluminum oxide particles, *Durasul* showed 97% and 86% less wear than conventional polyethylene<sup>20</sup>.

**Three Body Wear Results for the Hip Simulator**

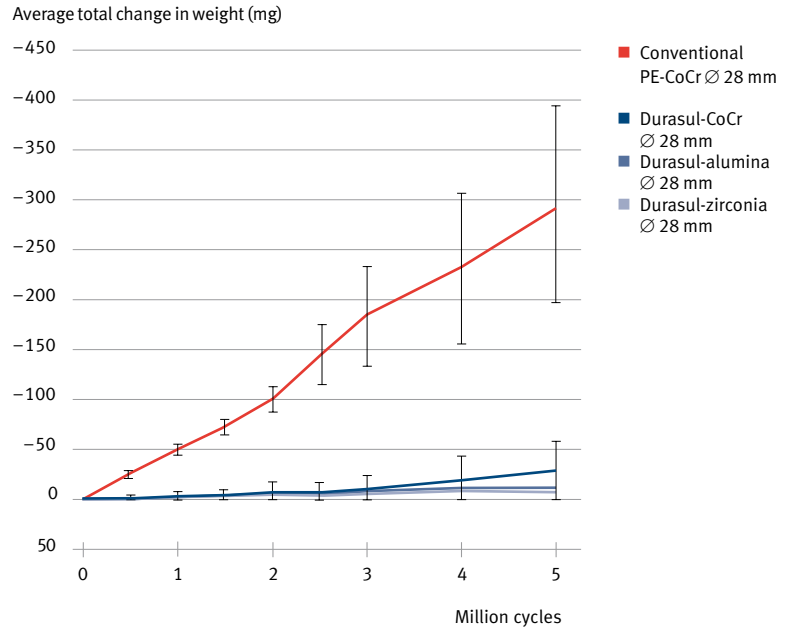


Abrasive three body wear

### How Is the Wear Resistance Affected by Various Femoral Head Materials?

Gravimetric wear measurements for 28-mm bearings of *Durasul* with a CoCr femoral head as well as *Durasul* with two different ceramic materials showed no statistically significant difference. However, all three material combinations showed significantly lower wear values than the pairing of conventional polyethylene with a CoCr femoral head. In the test arrangement in the PM-MED hip simulator, the femoral head is positioned above the cup. This non-physiological test configuration produces higher wear values than those from the AMTI hip simulator.

### Wear Results for the PM-MED Hip Simulator



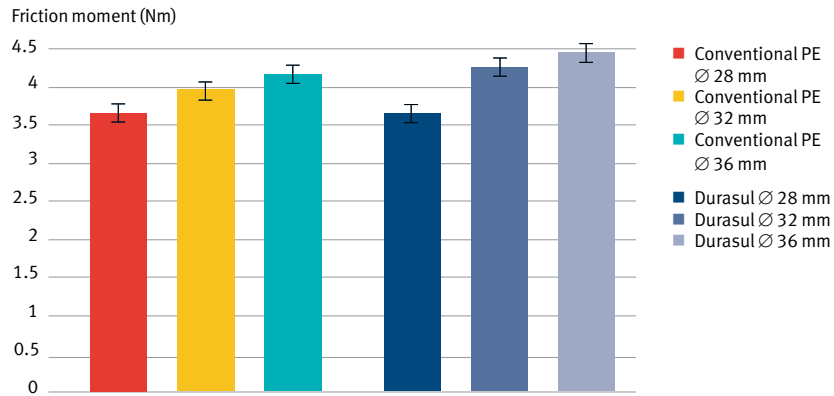
### Friction Characteristics

In addition to the wear resistance, the friction between the femoral head and the acetabular component is of interest for the hip joint replacement. The influence of high crosslinking density was investigated using a pendulum test involving acetabular cups and various inserts. The test facilitates a direct comparison between conventional polyethylene and *Durasul* for various articulation diameters.



Pendulum test

### Pendulum Test: Conventional PE Versus Durasul



The test results for Durasul show a slight increase in friction moment with increasing head diameter. Based on the small difference with respect to clinically proven 28 mm and 32 mm articulation using conventional polyethylene, no negative effect on the in-vivo situation is expected.

**The wear resistance as well as the friction characteristics of Durasul have been confirmed in various laboratory tests that were performed independently of one another. These tests included methods which took into account the physical influences to which a prosthesis is subject in vivo.**

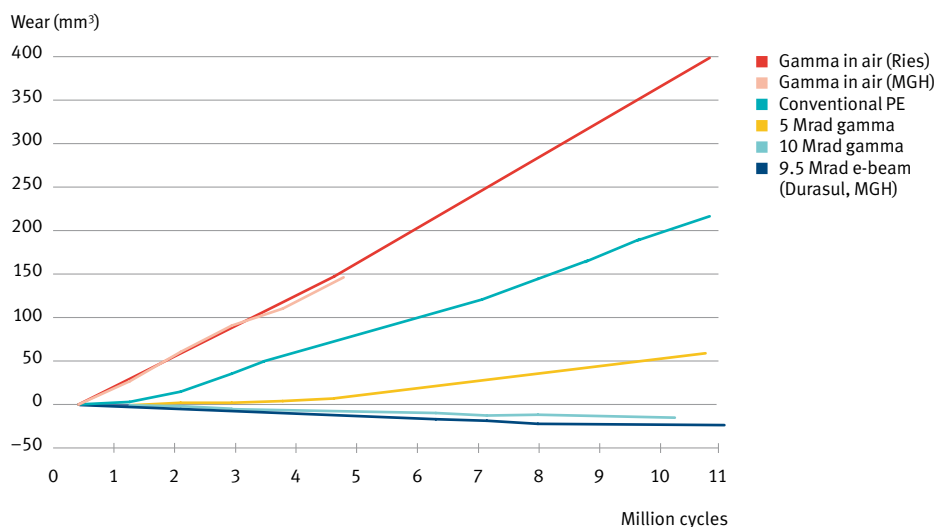
## Keeping Undesirable Biological Reactions at Bay

### Minimal Wear Reduces the Risk of Particle-induced Osteolysis

The goal of every implant is to replace the natural joint successfully and long-term. However, over time complications can occur which require revision surgery of the joint<sup>21</sup>. For the hip joint, locally limited or erosive bone resorption (osteolysis) is a common indication for revision surgery. Possible causes include increased hydrodynamic pressure and wear debris<sup>22</sup>. Thus wear is a decisive factor for the survival rate of total hip replacements.

Numerous studies have led to the common, basic recognition that not merely quantitative wear, but rather the concentration of the wear debris in a critical particle size range of 0.2 to 0.8  $\mu\text{m}$  is important<sup>23,24</sup>. Particle-induced osteolysis is likely to occur only if both criteria (quantity and concentration) are met.

### Hip Simulator: Gamma Versus Electron Beam Irradiation



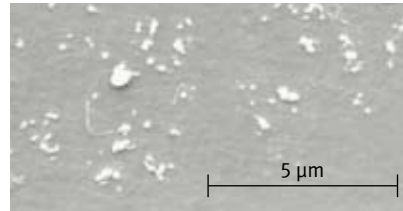
Comparison of the wear curves from various studies for polyethylenes irradiated by different methods, based on the common reference material treated with gamma radiation in air. The volume increase results from the conversion of gravimetric to volumetric wear values. (Sources: gamma-irradiated material = Ries<sup>25</sup>, electron-irradiated material = MGH<sup>14</sup>)

### Does the Particle Size Change for Highly Crosslinked Polyethylene?

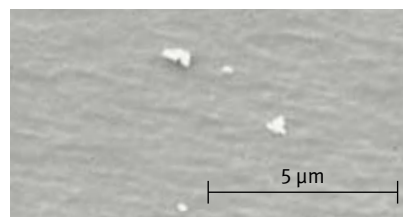
A study by M. D. Ries based on tests in the hip simulator shows that highly crosslinked PE greatly reduces the particle volume per cycle compared with conventional PE.<sup>25</sup> With a gamma irradiation dose of 10 Mrad, the diameter of most particles decreases to between 0.05 and 0.25  $\mu\text{m}$ . This size corresponds to the smaller particles known from conventional PE.

More recent studies by V. Saikko, on the other hand, show no significant size difference between wear debris particles from conventional polyethylene and the electron-beam irradiated, highly cross-linked polyethylene *Durasul*. In both cases the average diameter ranged between 0.20 and 0.30  $\mu\text{m}$ <sup>26, 27</sup>. However, all studies showed a sharp reduction in the quantity of wear debris particles. This minimizes the risk of a known biological reaction.

**The greatest reduction in the amount of wear and a particle size comparable to that of conventional polyethylene have been proven for electron beam irradiated, highly crosslinked Durasul. Therefore with Durasul the risk of osteolysis induced by wear debris is minimal.**

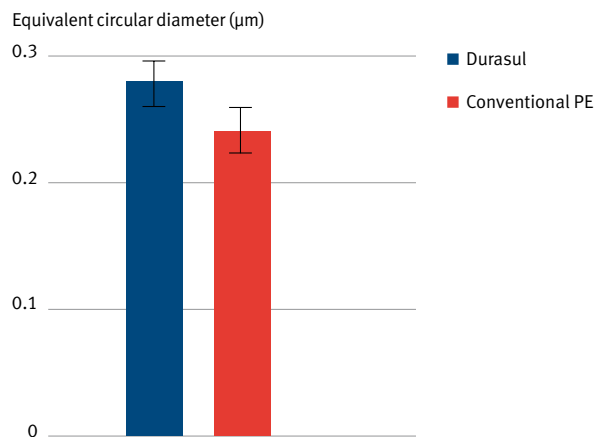


Conventional PE particles



Durasul particles

### Particle Size Analysis



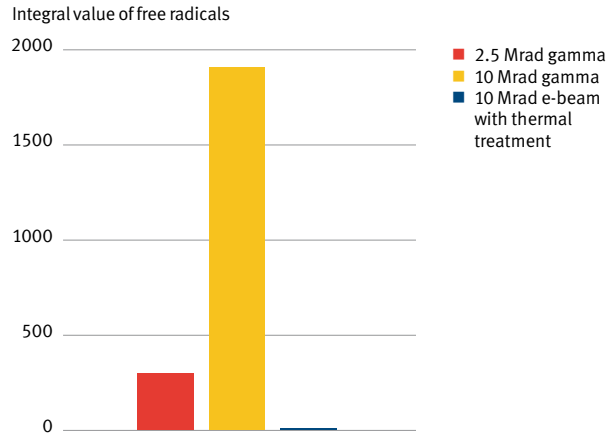
The particles were generated in a hip simulator at MGH and studied at the Technical University of Helsinki<sup>27</sup>.

## Oxidation Potential Successfully Eliminated

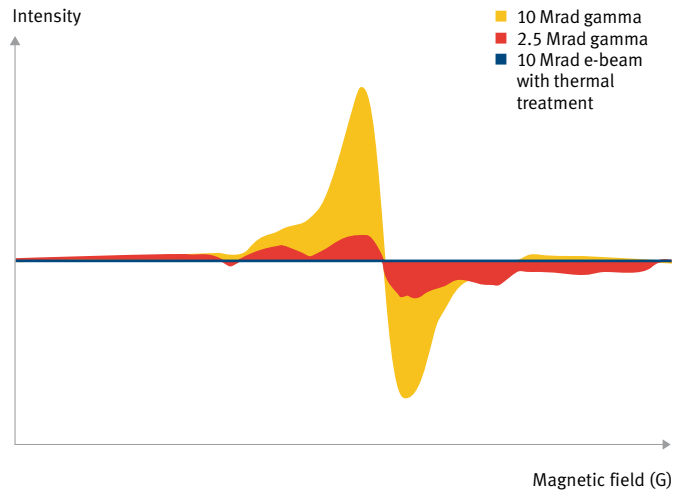
Aging of the material must be prevented in order to maintain the good mechanical properties of *Durasul* in the long term. Aging phenomena can occur as a consequence of oxidation of the material<sup>28, 29</sup>. These would not only adversely affect the mechanical properties by embrittlement of the material<sup>30</sup>, but also severely impact its outstanding wear characteristics.

For this reason, directly after the electron beam irradiation, the material undergoes thermal treatment to saturate the free radicals that cause oxidation. Subsequent electron spin resonance (ESR) studies showed that no more free radicals were detectable in the material matrix<sup>31</sup>. This proves the effectiveness of the saturation process.

### Free Radical Measurements (ESR)



### Residual Free Radicals (ESR)



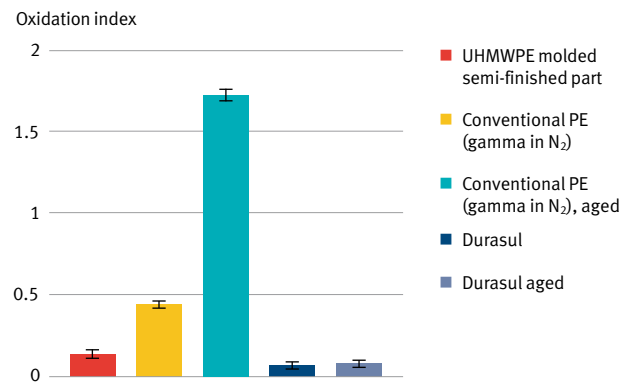
The oxidation potential in the polyethylene is determined by means of ESR measurement. The bar chart and the integrated areas under the curves show the content of free radicals in the polyethylene.



The resistance to aging can be tested with two recognized test methods<sup>32, 33</sup>. These methods are standardized and were calibrated using stored parts and explants<sup>53</sup>. The test sample components were subjected to pressure and temperature in an artificial thermal aging process for 15 to 30 days. This experimental period corresponds to an aging period of about 10 years. The result was that there were traces of oxidation in the material from the initial manufacturing stages which did not increase following irradiation. The oxidation index of the artificially aged test implants made of *Durasul* showed no significant change compared to non-aged *Durasul* test implants. This was in contrast to test implants made of conventional polyethylene which was affected by aging.

**The causes responsible for the aging process are successfully eliminated by the saturation of the free radicals immediately after electron beam irradiation in the manufacture of Durasul.**

#### Oxidative Aging (30 Days, 70°C, 5 bar O<sub>2</sub>)



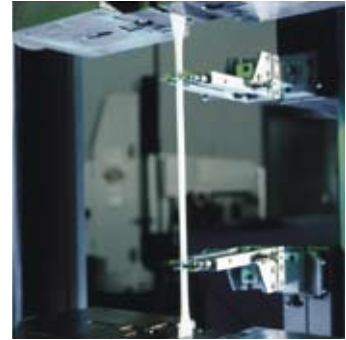
Comparison of oxidation for polyethylene with various treatments. In contrast to conventional PE, Durasul shows no significant change in the oxidation index.

## High Crosslinking Density and Mechanical Properties

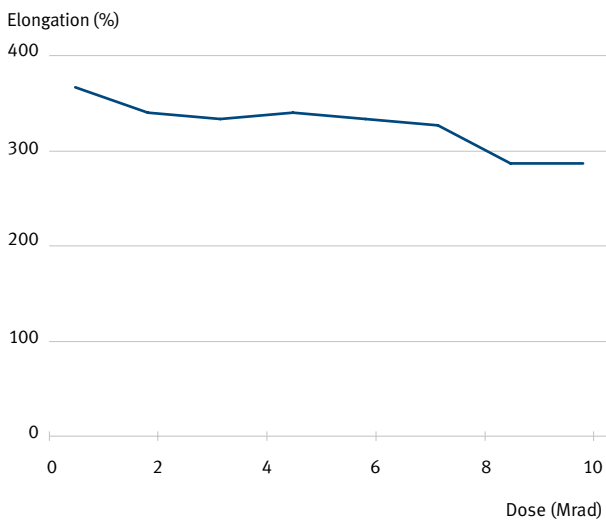
The determination of the radiation dose for crosslinking the polyethylene has the objective of achieving an optimal balance between tribological and other mechanical properties. Pin-on-disk studies show that the wear resistance approaches an asymptotic limit at about 10 Mrad<sup>17, 36</sup>. This achieved a reduction in wear of approximately 90% compared with untreated polyethylene. The essential mechanical properties of polyethylene are barely affected at this dose<sup>14, 37</sup>.



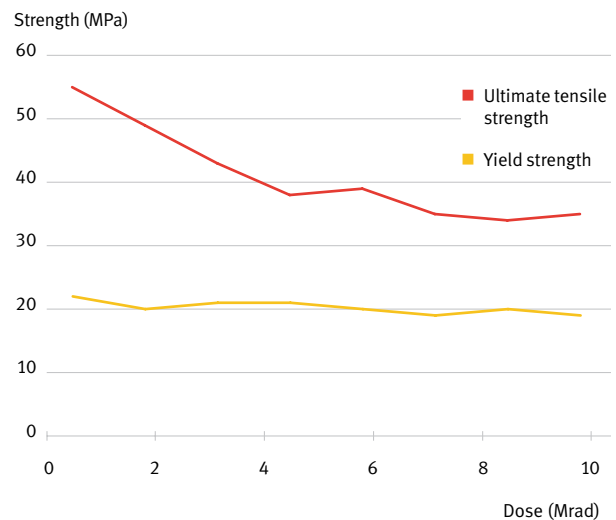
Tensile test



### Elongation at Break



### Yield Strength and Ultimate Tensile Strength



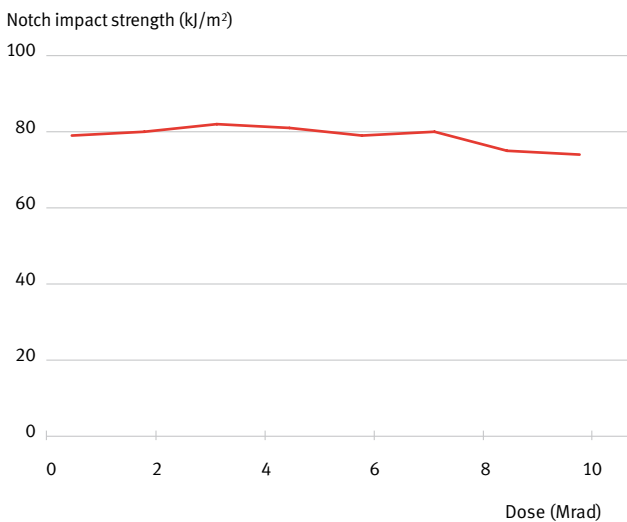
**Mechanical Properties**

The ISO 5834-2 and ASTM F648 standards define the test methods and limit values with which the mechanical properties can be determined. These are elongation at break, yield stress, notch impact strength and tensile strength. These material characteristics are used to define and monitor the production quality of polyethylene and do not correlate directly with specific clinical requirements for hip joint replacement. *Durasul* corresponds to the reference values defined in the standards. Since there are no more free radicals present in the highly crosslinked polyethylene, the mechanical properties remain stable over time in contrast to conventional polyethylene.

The suitability of a prosthesis for a specific clinical application depends not only on the material, but to a great extent on the design of the component as well. Thus it is no problem to compensate for the minor impairment of mechanical properties due to electron beam irradiation by the design of the implant system. In this regard, the creep and fatigue behavior of the material require particular consideration.



**Notch Impact Strength**

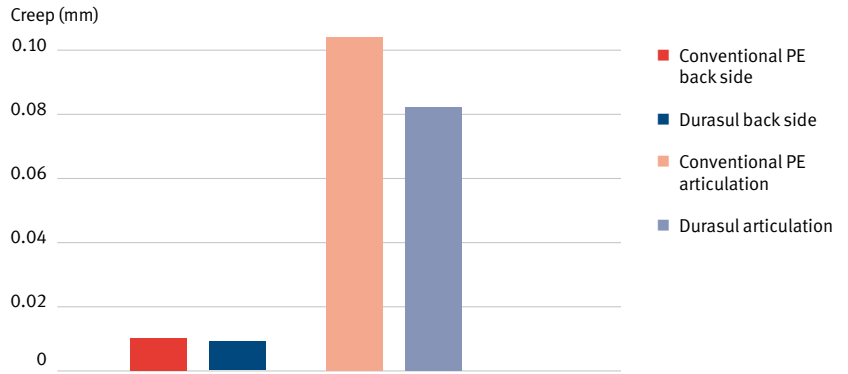


Notch impact test

### Creep Properties

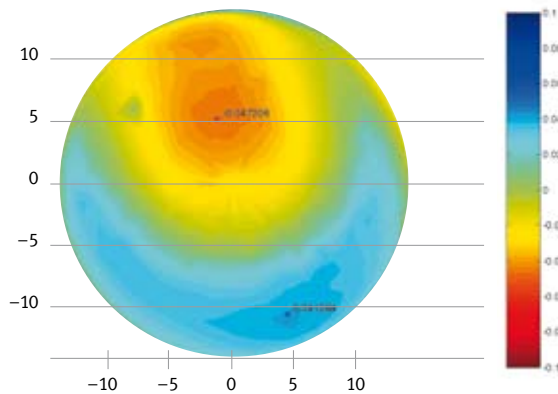
In pure material testing, highly cross-linked polyethylene exhibits a slightly higher susceptibility to creep than conventional polyethylene<sup>38</sup>. The reason for this is the greater proportion of amorphous phases that remain after crosslinking. Plastics such as polyethylene are two-phase materials with a crystalline phase and an amorphous phase. The respective proportions influence the material properties. In order to achieve a conclusive understanding of the creep behavior in clinical use, the implant system as a whole must be evaluated. The greater proportion of amorphous phases in the *Durasul* component increases the contact area with the metallic or ceramic counterface. This reduces the specific load and therefore the potential for creep<sup>39</sup>.

### Creep Behavior Measurements with Hip Simulator Components



Comparative measurement of changes due to creep. No differences were observed on the back side, and in the articulation Durasul exhibits lower susceptibility to creep.

### 3-D Measurement of the Creep Behavior on the Explant



Graphical representation of the slight change in shape due to creep in the area under load in the spherical calotte on a Durasul explant.

### Fatigue Strength

In the hip joint, each step is accompanied by load changes that are repeated constantly. Therefore it is important to have comprehensive information on the fatigue strength of the polyethylene. Various procedures are available for analyzing the fatigue characteristics. Reliable methods include material fatigue using standard test pieces (ASTM D671) and mechanical testing as well as hip simulators and pulsators. The FDA has defined a test arrangement for determining the fatigue limit. Using this, *Durasul* exhibits better fatigue characteristics with the same elongation in testing comparisons with conventional polyethylene<sup>40</sup>.

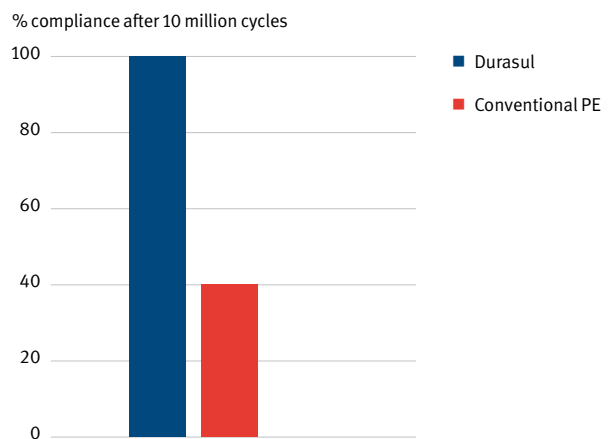
Pure material characteristic values based on standard test pieces have limited significance. Therefore, acetabular components made of *Durasul* were subjected to intensive testing related to the intended application, and in all cases they met or exceeded the specified requirements.

**The mechanical properties of Durasul completely satisfy all specifications. Due to its high crosslink density, Durasul even has specific advantages over conventional polyethylene in creep behavior and fatigue strength.**



Component testing on the mechanical test machine

### Fatigue Limit



Testing the fatigue limit of a test piece. After 10 million path-controlled load cycles, 60% of the conventional PE samples failed, whereas all Durasul samples were still intact.

## Examinations of Explants

No other analyses can reveal more about the *in vivo* wear characteristics than the examination of the articulation surface of explants<sup>41, 42</sup>. The characteristics observed on the surface of *Durasul* components can be classified as follows:

- Machining marks, scratches and impressions
- Flattening and leveling
- Microcracks, ripples, overlaps
- Discolorations

### Machining Marks, Scratches and Impressions

Machining leaves processing traces on the surface of a new polyethylene component that are 2 to 8  $\mu\text{m}$  deep. In a study of 26 *Durasul* explants, the material wear was found to be so low that the machining marks were still partially visible in the area under load after a period of use up to two years<sup>43</sup>. This indicates that the annual rate of wear is in the range of 2 to 8  $\mu\text{m}$ , which is confirmed by clinical results based on X ray image analyses<sup>44</sup>. Moreover, the surface of the explanted components showed clear evidence of scratches and impressions<sup>45</sup>.

This can be attributed to the three body wear which commonly occurs *in vivo*. Things are different with conventional polyethylene. After a comparable period the material wear is considerably higher (50 to 300  $\mu\text{m}/\text{year}$ ) and an accumulation of scratches is also observed. However, it is less apparent due to the higher wear.

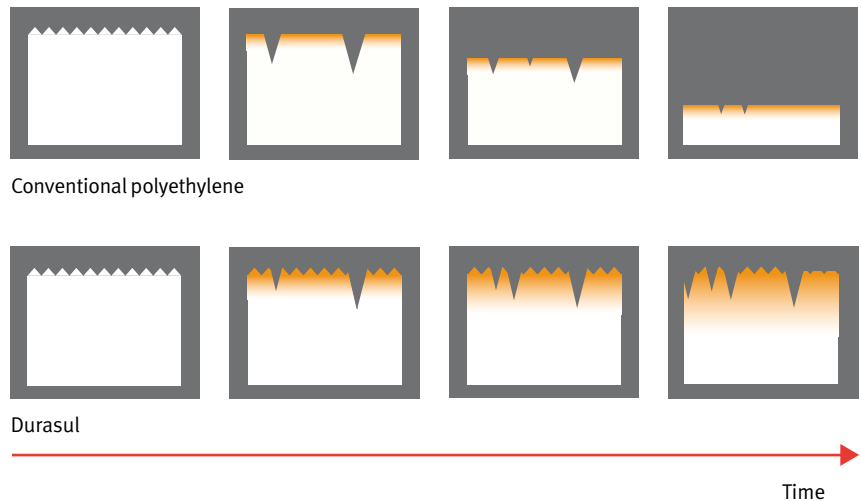


Durasul surface (15 months *in vivo*)



Surface of conventional polyethylene (6 months *in vivo*)

### Surface Modifications in Explants (Schematic Representation)



The individual surface changes cumulate as the implant period in the body increases. Furthermore, conventional polyethylene exhibits significantly higher material wear.

**Flattening and Leveling**

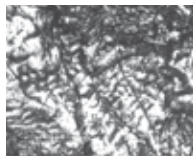
Explanted cup liners made of *Durasul* exhibited some flattened spots in the loaded articulation zone. Here the machining marks were evened out so far that they could no longer be recognized. The appearance was reminiscent of the polished surface of worn, conventional polyethylene. However, this was due to material creep, not wear. A special procedure proved this material behavior. Thermal treatment above the melting temperature can restore the original surface morphology<sup>45</sup>. This occurs because warming activates the material memory of the polyethylene.

This is due to the relaxation of orientations and stresses induced in the polyethylene through use. If the material were actually worn, the machining marks could not reappear. In this experiment, the scratch-like structures and impressions were reduced to shadowy phenomena. Thus with *Durasul* after an implant period of up to 43 months, only a few micrometers of wear could be determined despite significant changes in the surface morphology.

**Memory Effect Method**



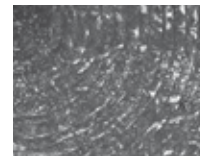
Remove the sample from the explant



Surface morphology (before)



Relaxation during the remelting process



Surface morphology (after)

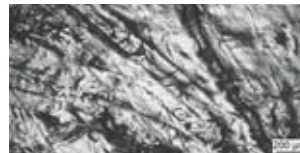
**Results of the Remelting Experiment**

Explant after 15 months in situ

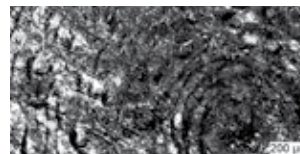
**Sampling**



**Condition prior to remelting**



**Condition after remelting**



Sample 1

Sample 2

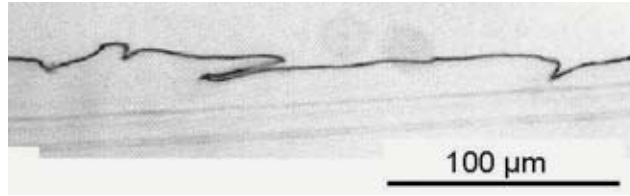
Sample 3

### Microcracks, Ripples, Overlaps

Scanning electron microscopy studies have revealed uneven structures in simulator parts and explants made of polyethylene, which look like microcracks and ripples. Further analyses using polarization and transmission electron microscopy have shown that these are in fact mostly overlaps, which are only a few micrometers deep<sup>46</sup>. This is a familiar phenomenon described in the literature for conventional polyethylene as far back as 1978<sup>47, 48</sup> and it can also be reproduced in laboratory experiments. A special cup-on-ball test was used to show that overlaps already form after the first 100,000 load cycles and continue to develop up to the first quarter million cycles. Measurements after a million cycles have shown only an insignificant increase of these structures. However, these structures remain visible because of the low degree of wear. The same phenomenon and its development can also be recognized during a test with the hip simulator. Even after 27 million cycles, no change occurs in the overlaps, which are no more than 5  $\mu\text{m}$  deep<sup>49</sup>.



Ripples and overlaps on the Durasul explant



Transverse section of the Durasul explant

**The surface of an explanted prosthesis provides reliable information about the wear characteristics of the material. With Durasul, the machining marks left on the surface during the manufacture of an implant component as well as scratches produced in vivo remain recognizable for longer periods of time. The fact that these traces are still present is conclusive evidence of the resistance to wear.**



## Clinical Results with Durasul

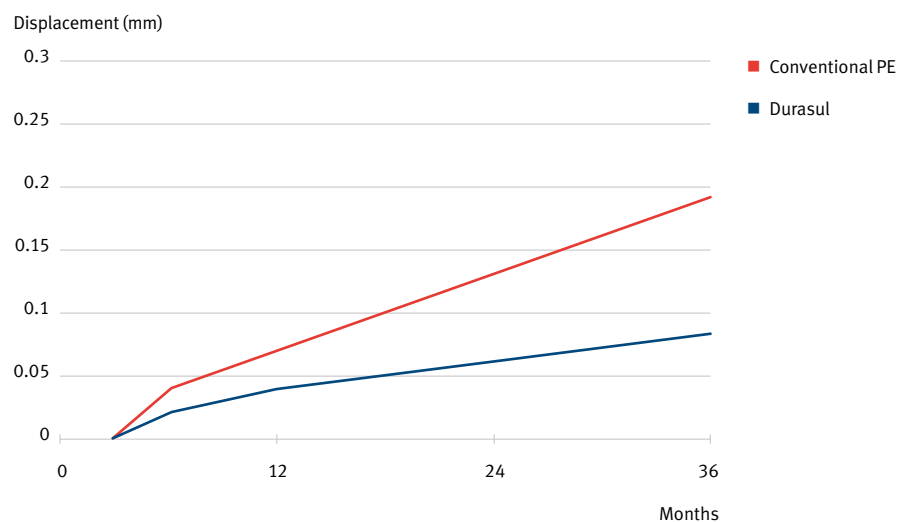
The latest in vivo data for the use of *Durasul* are convincing. Three recently published clinical studies confirm the high wear resistance of this highly crosslinked polyethylene<sup>50, 51, 54</sup>.

Data from Sahlgrenska University Hospital in Göteborg, Sweden with the cemented Weber cup are presented below as a representative example.

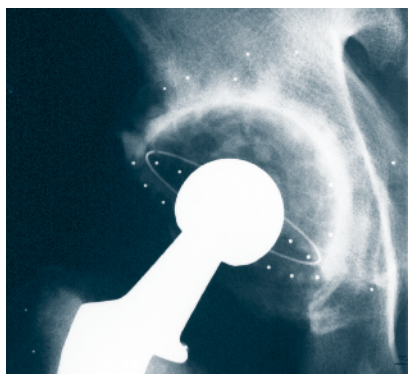
In a randomized in vivo radiostereometry study of 60 patients with an average age of 55 (35–70 years) and an average weight of 82 kg (47–120 kg), 61 hips were implanted with either a component made of highly crosslinked *Durasul* or conventional polyethylene. After a follow-up period of three years, the penetration of the femoral head into the highly crosslinked polyethylene was significantly lower than with conventional polyethylene. Initially, the penetration measured for the femoral head in vivo for both materials is dominated by embedding, creep and cold flow. Later actual wear predominates.

During the follow-up examination on standing patients, the average head penetration was altogether significantly lower in the group with highly crosslinked polyethylene. After the first year, further penetration of the head into highly crosslinked polyethylene was 90% lower than for polyethylene gamma sterilized under nitrogen<sup>44</sup>.

### Penetration of the Femoral Head<sup>50</sup>



This chart shows the proximal femoral head penetration into the cemented acetabular component in 18 patients with highly crosslinked *Durasul* and 25 patients with conventional polyethylene. The examination was performed with the patient in the standing position.



Radiostereometry analysis (RSA) allows precise three-dimensional measurements of the femoral head penetration based on X ray images.

Another confirmation of the excellent performance of *Durasul* in vivo comes from explanted components and histology.

Histological tissue analyses from eight revision surgeries showed a significantly lower concentration of particles with highly crosslinked polyethylene ( $1.2 \times 10^{-5}$ ) than the typical concentration measured with conventional polyethylene ( $1.1 \times 10^{-3}$ )<sup>52</sup>. These results document the lower amount of wear found with highly crosslinked *Durasul* and the consequently likely reduction of undesired biological reaction to the wear compared to conventional polyethylene.

**After a three- to five-year follow-up period, the highly crosslinked Durasul exhibited significantly better wear resistance clinically than conventional polyethylene. Another confirmation of the excellent performance of Durasul in vivo comes from explanted implant components and histology.**

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