3.3 Highly Cross-linked Polyethylene – A New Option in Tribology of THA

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Introduction

Highly cross-linked polyethylene Durasul was introduced at our hospital in March 1999. In vitro results regarding wear behaviour from different laboratories are very encouraging. Durasul polyethylene inlays showed after 27 million cycles no measurable wear in an AMTI hip simulator study. The ultra-low wear was masked by the minute fluid uptake from the serum. To date, only few in vivo results exist and show a tendency that Durasul resists to wear better than conventional polyethylene [1]. Thus, there is still a demand for investigations using early wear detection methods in order to expose a minimum number of patients to the risk of material failure.

We conducted two Durasul clinical investigations:

1. a prospective clinical study aiming measurements of femoral head penetration into polyethylene liners using PolyWare edge detection algorithm [2].
2. a retrieval study aiming the following analysis in each explanted liner made of Durasul Polyethylene:
    a) Surface analysis with light and electron scan microscope.
    b) Histological investigation of periprosthetic tissue.

Materials and method

1. Prospective investigation of penetration

Investigation about the performance of Durasul was designed as an ongoing prospective study. The study comprises 295 patients. A group of 10 patients with total hip arthroplasty using conventional polyethylene was used as control.

The implants used in this study are cemented anatomical stems (Optan) in combination with a 28 mm CoCr metal head, a press-fit titanium cup (Fitmore) with a highly cross-linked polyethylene liner (Durasul). In the control group, the same implants were used, except for the liner where a conventional UHMWPE was used. The follow-ups were done at 3 months post-operative, 1 year, 2 years, and each year after.

To measure and track penetration of the femoral head into the polyethylene liner, we used the PolyWare algorithm. This 3D technique uses digitized x–rays of a standard A/P view (Fig. 1a) and a shoot–through lateral view (Fig. 1b), which is taken in an angled position of 90 degrees in comparison to the standard A/P view. All x–rays were scanned at 100% magnification with a resolution of 250 dpi. The software reconstructs in 3D the center of the ball head and the cup, and calculates the relative displacement of the two centers in all directions. The accuracy of this method is ± 0.15 mm.

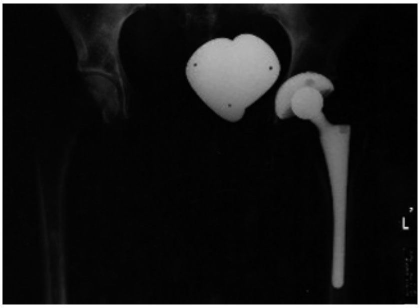

Figure 1a:
Standard a/p –view with the beam centered on the symphysis.

Figure 1b:
Shoot-through lateral.

2. Retrieval study

To date, we reviewed and documented 8 retrieved Durasul liners that were explanted after periods ranging from 3 to 43 months (Table 1):
Two cases due to a trauma after 3 and 5 months, three due to infection after 5, 14 and 26 months, one due to loosening of the cup as a result of an intra-operative technical problem after 10 months, one revision because of periarticular ossifications after 15 months and one following recurrent luxation after 43 months.

In all cases, the periprosthetic tissue was histologically analyzed in collaboration with Prof. H.G. Willert.

Table 1:
Overview of analyzed explants.

	Reason for Revision	**Time in vivo**
Case 1	Fracture posttraumatic	3 months
Case 2	Fracture posttraumatic	5 months
Case 3	Infection	5 months
Case 4	Fracture, loosening	10 months
Case 5	Infection	14 months
Case 6	Ossification	15 months
Case 7	Infection	26 months
Case 8	Luxation posttraumatic	43 months

All explants' articulating surfaces were investigated using light microscopy, and some of them were also investigated by scanning electron microscopy.

Due to the anticipated ultra low amount of wear and hence ultra low material loss, accumulation of surface changes (i.e. scratches) was expected on the articulating surfaces.

By means of remelting experiments (e.g. exposition of polyethylene to heat above the crystalline melting point which initiates the memory effect of UHMWPE [3, 4]), it is possible to distinguish surface changes due to wear from surface changes due to other mechanisms. Hence, surface investigations with light microscopy were performed before and after melting.

Results

Measurements of penetration using PolyWare

The penetration of the ball head into the polyethylene liner was measured as described above.

Due to the well-described bedding-in and creep phenomena, which take place first few years after implantation, the results in terms of penetration do not differ significantly between highly cross-linked polyethylene Durasul and the conventional polyethylene. A trend, however, shows that Durasul penetration values are getting smaller than penetrations in conventional polyethylene. The steady state is being settled, after which penetration will be interpreted as wear.

Retrieval study

In general, all histological examinations of periprosthetic tissue revealed extremely low deposition of Durasul polyethylene particles (Figure 2). In comparison with histological findings in conventional polyethylene, the amount of Durasul polyethylene wear particles observed was extremely little. In all cases, there were no signs of any biological reaction.

Case 4 was a special one: this patient has undergone his second revision surgery and before implanting a Durasul liner (2nd revision), the patient had a conventional polyethylene liner in place. In this case, more polyethylene particles were observed. Case 2 showed also extremely low deposition of Durasul polyethylene particles. However, the particles were very large (about 50 mm). This is due to a typical impingement after a proximal femoral fracture.

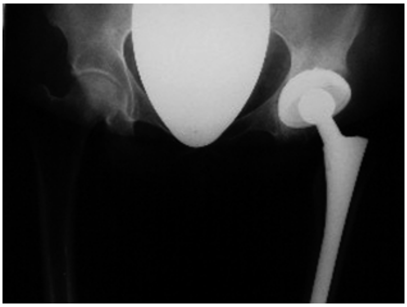

Figure 2a:
Post-op A/P x-ray of Case 3.

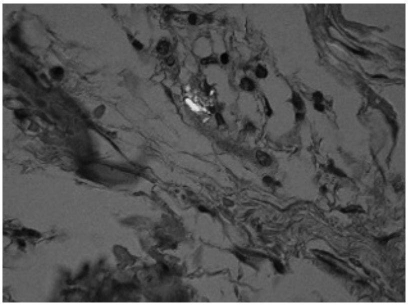

Figure 2b:
HE pol 100x Case 3
Extremely low deposition of polyethylene particles.

As wear is supposed to be extremely low with Durasul, more and stronger initial surface changes than with conventional polyethylene are visible (Figure 3).

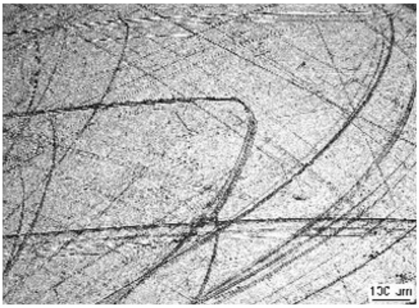

Figure 3a:
Polished (worn) conventional Liner after 6 months in vivo.

Figure 3b:
Scratched Durasul Liner after 15 months in vivo.

Due to the memory effect of highly cross-linked UHMWPE, exposition to heat above the crystalline melting point enables the reconfiguration of the molecular chains. Flattened machining marks reappear after melting. Scars and scratches disappear, as long as they constitute plastic deformation only without any loss of material (Figure 4).

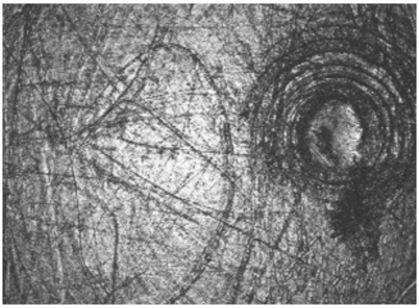

Figure 4a:
Durasul surface as retrieved after 10 months in vivo.

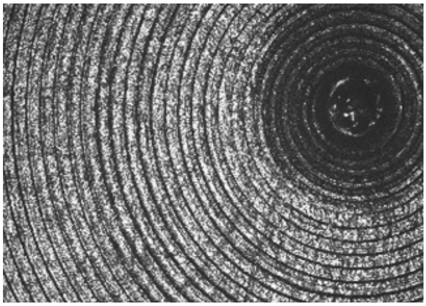

Figure 4b:
Durasul surface after melting.

Worn machining marks and scratches due to wear (i.e. loss of material) do not reappear after melting. In cases 7 and 8 where the retrievals were obtained after an implantation time of more than 2 years (26 and 43 months respectively), the articulating surfaces showed some signs of minute wear in the loaded area.

Discussion

In the 70's, H.G. Willert described the so-called particle disease, which lead to periprothetic osteolysis in total hip replacement [5].

Liberation of wear particles causes biological reactions, a so-called aggressive, inflammatory fibrous tissue response. Late aseptic implant loosening remains today the major problem in the lifespan of joint replacement. The consequence of evidence-based medicine must be to reduce wear. After 27 million cycles in vitro, Durasul, a highly cross-linked polyethylene, shows a drastic wear reduction. Wear was not measurable due to fluid uptake. This encouraging finding is predictable for an important reduction of in vivo wear and hence a substantial drop of osteolysis risks.

As the short-term (few first years post-op) penetration rate is the combination of bedding-in, creep and wear, the penetration results do not differ significantly between Durasul and conventional polyethylene. A trend is, however, observed and suggests that penetration in case of Durasul started leveling-off and reaching a steady state. This observed trend is in line with published information by the Gothenburg group in 2003 [1]. The 2-year wear as measured by RSA showed a significant lower value in Durasul as compared to conventional polyethylene in the standing position. In the supine position, a trend that Durasul wears less than conventional polyethylene was also observed. According to P. Devane, the penetration rate for conventional polyethylene levels-off to a steady state using his algorithm (PolyWare) around 5 years post-op.

The histological examinations confirm the excellent results known from AMTI hip simulator tests of the MGH in Boston. In all cases, we found an extremely low deposition of polyethylene particles and no biological reaction like macrophages or foreign body giant cells.

The remelting experiments are showing mainly plastic deformation without loss of polyethylene material. After two years or more in vivo and in the 2 cases where machining marks did not reappear following remelting, the first visible signs of wear in the loaded area suggest a yearly wear rate of about 5 mm, since the height of the machining marks is 3-7 μm. The findings confirm the very low amount of wear until 43 months in vivo. For comparison, a good conventional polyethylene should have 0.2 mm wear after two years in vivo.

These results encourage us to continue implanting highly cross-linked polyethylene. The retrieval investigations and radiological analysis will be continued.

References

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