Retrieval analyses of highly cross-linked polyethylene acetabular liners four and five years after implantation

K. Knahr, M. Pospischill, P. Köttig, W. Schneider, H. Plenk Jr
From the Orthopaedic Hospital, Vienna, Austria

Two Durasul highly crosslinked polyethylene liners were exchanged during revision surgery four and five years after implantation, respectively. The retrieved liners were evaluated macroscopically and surface analysis was performed using optical and electron microscopy. A sample of each liner was used to determine the oxidation of the material by Fourier transform infrared spectroscopy. Samples of the capsule were examined histologically.

The annual wear rate was found to be 0.010 and 0.015 mm/year, respectively. Surface analysis showed very little loss of material caused by wear. Histological evaluation revealed a continuous neosynovial lining with single multinucleated foreign-body giant cells. Our findings showed no unexpected patterns of wear on the articulating surfaces up to five years after implantation and no obvious failure of material.

In most designs of implant for total hip replacement (THR) the main threat to long-term fixation is osteolysis resulting from wear particles. One source of debris is ultra-high-molecular-weight polyethylene (UHMWPE). In vitro studies have shown that irradiation cross-linking of UHMWPE can improve its wear resistance. Durasul highly cross-linked polyethylene (Zimmer GmbH, Winterthur, Switzerland) was introduced for clinical use in 1999. A radiostereophotogrammetric analysis (RSA) of this implant at a follow-up of three years showed wear resistance which was better than that of conventional UHMWPE. We have performed retrieval analysis of two Durasul liners providing further evidence of the in vivo behaviour of highly-cross-linked polyethylene.

Patients and Methods

Durasul liners are manufactured from compression-moulded GUR 1050 (Granular UHMWPE Ruhr-Chemie, Bochum/Gelsenkirchen, Germany) which is irradiated with 95 kGy at approximately 120˚C and then melted. They are sterilised and packaged in an ethylene-oxide environment. In our report, the two Durasul liners were sizes II/28 and NN/28 and were retrieved during revision surgery at four and five years, respectively. They were used in combination with an uncemented replacement system (Alloclassic Variall; Zimmer GmbH), which consisted of a commercially pure titanium threaded acetabular component and a tapered straight stem made of wrought TiAlNb alloy. The head used in both cases was 28 mm in diameter and made of wrought CoCrMo alloy with a carbon content of 0.05% to 0.08%.

Case 1. A 43-year-old woman weighing 62 kg and 1.71 m tall underwent a THR for osteoarthritis (OA) secondary to congenital dysplasia (Fig. 1a). Post-operatively, her level of activity was grade 2 according to Devane et al6 because of increasing pain caused by heterotopic ossification (Brooker grade III) for which she underwent revision surgery four years after implantation. At surgery, the heterotopic ossification was removed and neocapsular samples were retrieved for histomorphological evaluation.

Case 2. A 68-year-old man weighing 77 kg and 1.82 m tall underwent THR for OA of his right hip. Post-operatively, he remained very active (Devane et al7 activity level of grade 4) but after a fall, he sustained a peri-prosthetic fracture (Fig. 2a). At revision surgery, the heterotopic ossification was removed and neocapsular samples were retrieved for histomorphological evaluation.

The acetabular shell and the stem were found to be well fixed and therefore only the liner and head were exchanged.

Visual and tribological evaluation. Immediately after retrieval, the extracted liners were decon-
taminated at room temperature by placement in a 4% disinfec-
tive solution (Deconex 53 plus; Borer Chemie AG, Zuchwill, Switzerland) for 30 minutes, and then rinsed with
tap water before soaking in industrial ethyl alcohol (96%) for
one hour. They were macroscopically inspected and
photographed.

The reconstruction of the sphericity of the original articular
surface of a retrieved acetabular polyethylene liner is possible
when areas which have not been affected by loading forces are
used as reference. The linear penetration resulting from wear
(material loss) and deformation (material displacement) can
then be determined. Linear penetration is defined as the max-
imum local deviation from the original sphericity. The geome-
try of the articular area of the implant was evaluated using a
co-ordinate measuring machine (CMM5; SIP, Geneva, Swit-
zerland) as described by Sieber, Rieker and Köttig. The tribo-
logical analyses were carried out at the laboratory of Zimmer
GmbH.

The polyethylene was divided into several segments, for
surface analysis using an optical microscope (Leica
DMRX; Leica Microsystem, Vienna, Austria). After the
initial examination, these segments were heated at over
150˚C for ten minutes and then cooled down when they
were re-examined. This memory test can differentiate wear
from plastic deformation.

Oxidation analyses. One piece from each liner was used to
evaluate the oxidation of the material using Fourier trans-
form infrared spectroscopy. The index which characterises
the oxidation of UHMWPE is determined by detecting
ketone and ester peaks (1650 cm⁻¹ to 1850 cm⁻¹) using the
carbon-hydrogen peak (1330 cm⁻¹ to 1396 cm⁻¹) as a refer-
ence. The measurement was taken according to the ASTM
F2102 protocol. The oxidation depth profile was mea-
sured by samples taken close to the pole of the liner.

The ability of UHMWPE to absorb particles of body flu-
dids in vivo can affect the oxidation measurements. Thus, in
order to evaluate their actual oxidation, the body-fluid
components were extracted using cyclohexane at 80˚C for
48 hours for the first case and for 96 hours for the second.
The extraction time directly depends on the quantity of the
absorbed human tissue. After preparation with cyclohex-
ane, the oxidation depth profiles of the liner segments were
measured again.

Histological evaluation. In the first case, the neocapsule was
hard to define because of the surrounding heterotopic ossi-
fication and the harvested samples included some calcified
tissue. In the second case, full-thickness capsular samples
were taken from multiple areas. All the specimens were
placed in neutral formalin, and representative samples from
the harvested tissue were placed in methylmethacrylate
resin. After decalcifying the tissue, small sections (5 μm
thick) were placed in Giemsa, Trichrome-Goldner and
toluidine Blue stain for microscopic evaluation under
transmitted and polarised light. One specimen, which had
signs of neosynovial covering, was divided into blocks
1 mm × 1 mm in size and postfixed in glutaraldehyde and
osmium tetroxide. The samples were then embedded in
epoxy resin and evaluated by transmission electron
microscopy.

Results
Visual and tribological evaluation. Macroscopic examination
of the liner in the first case, showed slight yellowing of the artic-
ulating surface (Fig. 3a). The weight-bearing area had a pol-
ished appearance with some smooth scratches in the loaded
area. There were no signs of delamination. The hole seen in
the loaded zone had been drilled for removal of the liner
The maximum linear penetration measured by the coordinate measuring machine was 0.043 mm. The drilled area was excluded from the calculation. This suggested an annual linear penetration rate of 0.010 mm/year. In the second case the liner showed a slight yellow pigmentation of the surface facing the metal shell. The entire articulating surface appeared to be polished, but some scratches and marks were visible. There were no signs during revision surgery. The maximum linear penetration measured by the coordinate measuring machine was 0.043 mm. The drilled area was excluded from the calculation. This suggested an annual linear penetration rate of 0.010 mm/year. In the second case the liner showed a slight yellow pigmentation of the surface facing the metal shell. The entire articulating surface appeared to be polished, but some scratches and marks were visible. There were no signs
of delamination. The maximum linear penetration was 0.075 mm, suggesting an annual linear penetration of 0.015 mm/year.

The results of the shape memory tests showed that in both liners most of the marks, except in parts of the weight-bearing area, recovered after heat treatment (Figs 3b and 3c) indicating that there was very little loss of material because of wear.

Oxidation analyses. The oxidation of UHMWPE after treatment in cyclohexane was below the detection limit of 0.05. The initial oxidation measurements of 0.3 to 0.4 in case 1 (Fig. 4a) and of 1.2 in case 2 (Fig. 4b) resulted from the absorption of body-fluid particles as described by Costa et al. It is known that because of diffusion, higher quantities of absorbed body fluid are found on the surface. There was no measurable oxidation in the centre of the UHMWPE in either of the retrieved liners.

Histological evaluation. In case 1, the removal of the calcified tissue meant that only small areas of neosynovium were found on the samples of the joint neocapsule. Around the vessels of the fibrous neocapsule, mononuclear macrophages and multinuclear foreign-body giant cells were seen. The acetabular bone had intact neocapsular insertions and appeared to have undergone remodelling, but without increased osteoclastic resorption.

Case 2. The multiple fibrous neocapsular samples were up to 3 mm thick in some areas and were lined by a thin neosynovial layer (Fig. 5), in which many mononuclear macrophages and multinuclear foreign-body giant cells were seen. The acetabular bone had intact neocapsular insertions and appeared to have undergone remodelling, but without increased osteoclastic resorption.

Discussion
The mean linear penetration for both liners was found to be about 0.015 mm/year. This was significantly lower than
the wear rates of 0.1 to 0.3 mm/year reported for conventional polyethylene in which particle-induced osteolysis had occurred.\textsuperscript{13-15} The recently published literature review by Dumbleton, Manley and Edidin\textsuperscript{16} suggested that osteolysis was rare if the wear rate was below 0.1 mm/year. The mean penetration rate for the Durasul liners was found to be seven times lower than this threshold. The RSA study by Digas et al\textsuperscript{15} measured at follow-up of three years a mean penetration of 0.07 mm for Durasul compared with 0.19 mm for the conventional polyethylene controls. A two-dimensional (2D) vector analysis of 109 hips with acetabular bearings of highly cross-linked polyethylene showed a wear rate of 0.08 mm/year. When compared with an age-matched group with a traditional UHMWPE implant it showed a wear reduction of 93\% \textit{in vivo}.\textsuperscript{17} In the same study, no correlation was found between the femoral head size used, gender, or body mass index, with the rate of wear. Since these rates of wear are calculated from the change in head penetration depth, or by deviation from the ideal spherical shape, the presence of deep scratches in the articulating surface is not always interpreted as loss of material.\textsuperscript{9} Such deep scratches in polyethylene liners could originate from third-body wear originating from the implant metal components, as seen in metal-on-metal articulations.\textsuperscript{18} The heat treatment examination as previously described verifies the actual wear of material. The reappearance of the machining marks after the heat treatment in both Durasul liners suggested that the actual wear was minimal. The marks which did not reappear were located at the loading surfaces of the implant, indicating loss of material because of wear and verifying the source of the traces of small wear particles responsible for the cellular reactions in the histological examination. Our long-term collaboration and experience with the Zimmer Laboratory in Winterthur allows us to believe that they offer us objective and non-biased data. Similar results have been reported by Muratoglu et al\textsuperscript{19} and confirm the reliability of our laboratory data. The yellow pigmentation seen in the articulating and back surfaces in both Durasul liners was attributed to the diffusion of absorbed body-fluid particles since the Fourier transform infrared spectroscopy data showed no measurable real oxidation of the polyethylene material.\textsuperscript{20}

The synovial layer preserved on the thick fibrous neocapsule in case 2 showed mild chronic inflammation and a distinct foreign-body response. The presence and distribution of mononuclear macrophages and multinucleated giant cells were typical of neocapsules around artificial joints. In addition, few polyethylene wear particles were detected in these cells by polarised light. With regard to the ‘empty vacuoles’ seen in the cells, it should be emphasised that even submicron size polyethylene particles are regarded as insoluble by the embedding media. Thus, only a few very small wear particles seem to be present after four to five years. In addition, no evidence of particle disease was found at the insertion zones of the neocapsule into the bone around the acetabulum in case 1.

In conclusion, our findings showed that there were no unexpected wear patterns on the articulating surfaces for up to five years, nor were there visible material failures. The mean rate of penetration was seven times lower than the threshold which is thought to cause osteolysis.\textsuperscript{18} Furthermore, the reappearance of most of the machining marks after heat treatment suggested that the improved wear resistance of highly cross-linked UHMWPE was comparable with that reported from \textit{in vitro} studies. The minimal material loss of the articulating surfaces located in the weight-bearing areas resulted in small amounts of polyethylene wear particles in the cells responding to foreign-body presence in the neocapsule, thus confirming the effectiveness of highly cross-linked polyethylene acetabular bearings in THR.
References