

Very low wear of non-remelted highly cross-linked polyethylene cups

An RSA study lasting up to 6 years

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Background and purpose Highly cross-linked polyethylenes (PEs) all appear to reduce wear dramatically in laboratory studies, although there is substantial variation in this respect between manufacturers. Non-remelted cross-linked PE is almost as tough as unirradiated PE, but is not completely stable and can oxidize in vivo, as has been shown in recent retrievals studies.

We had reported low wear and good clinical performance after 2 years for 10 non-remelted highly cross-linked PE cups compared to 16 conventional PE cups sterilized by gamma-in-air.

Method Because of possible degradation by free radicals, we followed up both cohorts for 5 years (conventional PE) and 6 years (highly cross-linked PE).

Result Mean (CI) proximal head penetration over the observation time was linear and measured 0.08 (0.02–0.13) mm for cross-linked PE and 0.42 (0.23–0.62) mm for conventional PE, and total penetration was 0.23 (0.1–0.35) mm and 0.75 (0.05–1.4) mm respectively. After subtracting creep, the annual wear for non-remelted highly cross-linked PE was below 6 µm. The cups had equally low migration and few radiolucencies.

Interpretation The theoretical possibility of oxidation in non-remelted highly cross-linked PE may not show clinically. However, it may be that cemented cups with their thicker PE are more forgiving than metal-backed cups with thin PE moving in the locking mechanism. So far, we can conclude that the Crossfire highly cross-linked polyethylene cups performed very well clinically, with extremely low wear even after almost 6 years. This is reassuring, but care should be taken in extrapolating

these results to other cross-linked PEs or uncemented cups where toughness of PE is more of an issue. ■

Wear particles from joint articulations are considered to be the major cause of implant loosening and osteolysis. This problem has been addressed by the use of hard-on-hard bearings and highly cross-linked polyethylene (PE), which has shown excellent wear behavior in hip simulators (McKellop et al. 2000, Muratoglu 2001, Kurtz et al. 2002) and promising short-term clinical results (Digas et al. 2003, 2004, Martell et al. 2003, Heisel et al. 2004, Rothman et al. 2004, Dorr et al. 2005, Krushell et al. 2005, Manning et al. 2005, Engh et al. 2006).

Despite the encouraging short-term outcome, concerns still remain about the long-term effects of changes in the mechanical properties of polyethylene (Pruit 2005, Kurtz et al. 2006) and the free radicals that are trapped in the polyethylene during the cross-linking process (Wannomae et al. 2006). These free radicals could be quenched by remelting the polyethylene. As remelting also reduces the crystallinity and thereby the toughness of the PE (Puertolas et al. 2006), the submelt-annealing process is regarded as an advantage because it preserves the mechanical strength of PE (Wang et al. 2004). This results in an initially tougher PE since the grain structure is unchanged, but it still contains free radicals and can later oxidize in vivo—result-

Table 1. Characteristics of the 2 groups, median (range)

	Gamma in air (n = 20)	Highly cross-linked (n = 10)
Age (years)	70 (61–81)	58 (49–79)
Weight (kg)	75 (45–98)	72 (60–87)
Male / female	12 / 8	6 / 4
Side (right/left)	8 / 2	14 / 7
Charnley G 1 / 2 / 3	10 / 9 / 1	6 / 4 / 0
Cup size (mm)	52 (48–56)	52 (48–56)
Preoperative pain score	10 (0–20)	20 (10–30)
Preoperative Harris hip score	43 (26–56)	47 (23–76)
Inclination (°)	50 (34–67)	51 (28–64)

ing in less toughness, fractures and deterioration in wear characteristics. In a retrieval study, non-remelted highly cross-linked PE cups (Crossfire) showed high oxidation levels and an excessive amount of wear in the hip simulator (Wannomae et al. 2006). These findings are of some concern, as PE has been used in a large number of patients since the late 1990s and new highly cross-linked PEs based on the annealing technology have been launched on the market recently (Dumbleton et al. 2006).

Our hypothesis was that if oxidative degradation does occur after implantation of the non-remelted highly cross-linked PE cups, the wear rate will accelerate after a certain period of time. Thus, we considered it important to update our previous 2-year report on non-remelted cross-linked polyethylene (Rohrl et al. 2005) with 6-year data on wear and performance for Crossfire polyethylene.

Patients and methods

20 hips (20 patients) and 10 hips (10 patients) were operated consecutively with conventional and highly cross-linked polyethylene (Table 1). The former were followed for up to 5 years and the latter for up to 6 years. We refer to Rohrl et al. (2005) for further information regarding the surgical technique and the RSA method we used in these patients.

The shapes of the cemented all-polyethylene cups were identical. The study group received an Osteonics (Stryker) cup made of Crossfire polyethylene. This is a highly cross-linked GUR 1050

irradiated with 7.5 Mrad, heat-annealed below melt temperature (120°C) and finally sterilized with 2.5 Mrad, all in an inert atmosphere. The control group received an Exeter cup (Stryker) made of GUR 1050 sterilized with 2.5 Mrad γ -irradiation in air. Identical Exeter femoral stems with 28-mm metal heads were used in both groups. The groups were well matched (except for age), with the Exeter group being slightly older ($p = 0.02$) (Table 1).

The study patients (highly cross-linked PE) were examined at 2 months, 1, 2, 3, 4, and 5 years, and also after 6 years, whereas the hips in the control group were followed postoperatively, at 2 months, 1 year, 2 years, and 5 years. Analyses of wear and migration were done with the UmRSA system (RSA Biomedical). Initial creep and wear-in was eliminated by subtracting the early (2-month) measurement from the last (6-year) one in each patient. The precision in this particular study according to the RSA standard (Valstar et al. 2005) was calculated from 99 double investigations of the patients in different positions, and found to be 0.08 mm for longitudinal wear (95% CI) and 0.16 mm for 3-dimensional (3D) wear. 3D wear is a vectorial value of the femoral head penetration along the 3 axes (x, y, and z) of the coordinate system. It is interpreted as the total or 3-dimensional wear.

Patients were assessed with Harris hip scores before surgery, at 2 years, and at the last visit. Conventional radiographs were taken postoperatively, at 2 years, and at 5 years. At the 6-year control, only RSA radiographs were taken to keep the radiation dose at a minimum. The percentage of the cup interface covered by a radiolucent line (RLL) more than 1 mm wide was assessed in addition to inclination and position of the cup.

At the last follow-up, 2 patients from the control group and 1 from the study group had died from causes unrelated to the arthroplasty—all with their implants unrevised. Thus, 27 patients (9 in the study group and 18 in the control group) could be evaluated clinically and 21 patients (9 in the study group and 12 in the control group) could be evaluated by RSA after 6 additional patients were excluded from the RSA evaluation because the RSA radiographs proved to be of insufficient quality.

Statistics

The study was approved by the ethics commit-

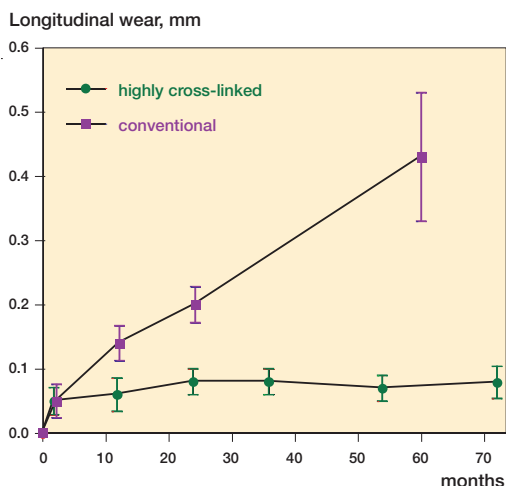


Figure 1. Longitudinal wear for gamma in air and non-remelted highly cross-linked cups (mean, SEM).

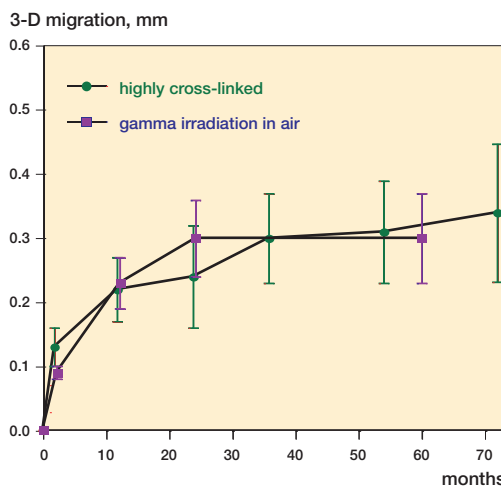


Figure 3. 3-dimensional migration for both groups, suggesting stable fixation (mean, SEM).

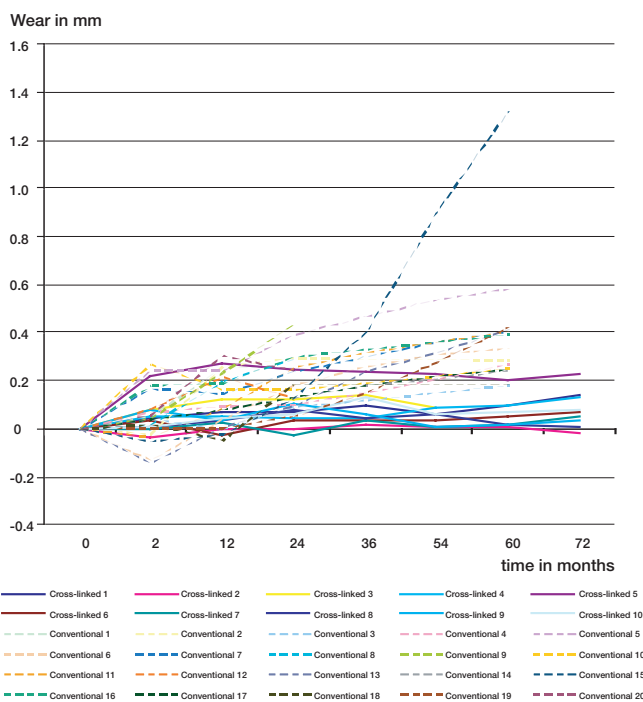


Figure 2. Longitudinal wear for each subject with conventional (gamma in air) and non-remelted highly cross-linked cups.

tee of Umeå University, Sweden. Statistical comparison was done with the Mann-Whitney U-test (comparing the two groups), or Wilcoxon signed rank test (comparing longitudinal changes within

a group). We calculated the effect of age, weight, sex, cup size, and inclination on the polyethylene wear and clinical outcome (Harris hip score) with multiple regression analysis.

Results

The mean (CI) proximal head penetration for highly cross-linked PE and conventional γ -irradiated PE over the full time of follow-up was 0.08 (0.02–0.13) mm and 0.42 (0.23–0.62) mm, respectively (Figure 1 and 2), whereas the mean 3D wear was 0.23 (0.1–0.35) mm and 0.75 (0.05–1.4) mm. After subtracting the head penetration during the first 2 months, proximal wear was 0.035 (0.001–0.068) mm for cross-linked PE and 0.36 (0.16–0.56) mm for conventional γ -irradiated PE, and 3D wear was 0.19 (0.03) mm and 0.56 (–0.1–1.2) mm, respectively. This corresponds to a proximal annual wear for cross-linked PE and conventional PE of less than 6 μ m and 72 μ m, respectively, and 3D wear of 33 μ m and 112 μ m.

There were no apparent differences in overall (3-dimensional) migration (Figure 3); the cups were

Table 2. Mean migration (95% CI) of the cup relative to the acetabulum (mm or degrees)

	Conventional ^a (n = 12)	Highly cross-linked ^b (n = 9)
Medial migration	-0.13 (-2.4– -0.20) ^c	0.04 (-0.80–0.17)
Superior migration	0.12 (0.02–0.22)	0.22 (-0.07–0.50)
Anterior migration	-0.11 (-0.80–0.10)	-0.01 (-0.90–0.06)
Forward rotation	-0.02 (-0.32–0.28)	0.11 (-0.14–0.37)
Incr. anteversion	-0.14 (-0.37–0.11)	-0.18 (-0.56–0.18)
Incr. inclination	-0.36 (-0.80–0.07)	-0.06 (-0.26–0.13)

^a Control group, 5 years.

^b Study group, 6 years.

equally stable in all the cardinal directions (Table 2). There were no differences in radiolucencies (RLs) between the groups, and none were progressive ($p = 0.5$) (Table 2). In the conventional PE group, 7 cups showed an RL of grade 1 in Charnley zone 1 and 1 cup had grade 4 in zone 1 with grade 3 in zone 2. 1 highly cross-linked cup showed radiolucency located in Charnley zone 1.

At the last follow-up, the pain score (min-max) was 44 (40–44) for Crossfire (at 6 years) and 35 (30–40) for conventional (at 5 years) ($p = 0.001$). The overall Harris hip score was 98 (94–100) for Crossfire and 82 (63–100) for conventional ($p = 0.001$). No cups were revised. Clinically, all patients were very satisfied.

Stepwise multiple regression analysis showed that none of the parameters age, sex, weight, cup size, or inclination were sufficient to explain the cup wear (adjusted $r^2 < 0.1$, $p = 0.5$, 95% CI for regression coefficients: -0.77 to 0.15)

Discussion

Our results with highly cross-linked PE show extremely low annual wear of less than 5 μm , even after 6 years and without any notable disadvantages. This is 10 times less wear than in the control group with conventional PE, γ -irradiated in air. Also, another of our studies involving 50 patients with highly cross-linked UHMWPE has shown almost negligible annual wear (0.009 μm) after the so-called wear-in period (Zhou et al. 2006). These values correspond well with the results of laboratory studies, but they are less than was reported for

Crossfire by Martell et al. (2003) as measured by another method. Several authors have also reported a drastic but different reduction in wear for remelted highly cross-linked polyethylene after short and medium-term follow-up (Digas et al. 2004, Heisel et al. 2004, Dorr et al. 2005, Manning et al. 2005, Engh et al. 2006). One reason for the differences may certainly be the difference in cohorts, but in some studies creep and early wear-in is also included in the wear. 6 μm of annual wear is far below the “safety limit” as suggested by Dumbleton et al. (2002). This,

of course is promising, but whether it is absolutely safe in the long term is unknown. Cross-linked particles are smaller than particles from conventional PE (Ries et al. 2001) and show an increased bioactivity in in vitro studies (Fisher et al. 2004, Ingram et al. 2004). However, so far we have not been able to detect an increased or alarming amount of osteolysis on conventional radiographs.

In contrast to others (Digas et al. 2003), we believe that it has been shown clearly that the time period for creep is short (2–3 months) (Penmetsa et al. 2005). In addition, we have seen similar “early creep” behavior in other RSA results with highly cross-linked PE (Zhou et al. 2006), and using in vitro tests Deng et al. (1998) found that creep occurs in the early time period following the application of load. Creep and true wear might in fact be different for the new highly cross-linked PEs manufactured by different methods.

A drawback of our study is of course the small sample size, and that the study was not randomized. However, with the small SDs and the repeatedly found linear (conventional) and low (highly cross-linked) wear, we still consider our findings to be close to the true values in a larger group—and therefore of interest.

Wannomae et al. (2006) found free radicals, oxidation, and white bands in retrieved Crossfire polyethylene. When these cups were tested in a hip simulator they performed poorly, with high wear and also fractures, which has raised concerns as to possible clinical failures with this PE. Thus, the authors concluded that remelting is superior to annealing. This is, however, still debatable because contrary to the latter findings, Gencur et al. (2006)

found that annealing as a post-irradiation treatment may be somewhat less detrimental to the fatigue crack propagation resistance of PE than remelting.

Firstly, it is still questionable whether free radicals really cause clinical failures. None of the cross-linked PEs used in the 3 classical long-term reports by Oonishi et al. (1998), Wroblewski et al. (1999), and Grobbelar et al. (1999) was annealed or remelt-stabilized. They contained free radicals and oxidized, but still seemed to perform well clinically over a long period of time. Sugano et al. (2004) reported no clinical deterioration regarding a retrieved gamma-irradiated cup that was cross-linked with 10 times the irradiation dose (100 kGy) compared to modern highly cross-linked cups. In our study, there was no acceleration of wear from 2 years to 6 years in the non-remelted highly cross-linked PE, which might have been the case if further oxidative degradation of the PE would lead to clinical failure. Kurtz et al. (2006) found that oxidation mainly occurs on the acetabular ring because the pressure from the femoral head protects the articulation area from oxidation. They speculated that oxidation will therefore not show clinically before 10 years. Thus, 6 years may still be regarded as an early stage, and our findings substantiate the idea that further oxidation of the remaining free radicals is not a significant issue in the short to medium term.

Secondly, oxidation occurs with a peak of about 1–3 mm below the surface of the polyethylene. This implies that an increase of wear due to oxidation might not happen for a number of years. Until the ball has penetrated the oxidized sub-surface region, the cross-linked cup will perform well clinically. However, delamination-type wear is also a risk in the case of sub-surface oxidation, and before wear reaches the deeper layer. Thus, the effect of further oxidation of free radicals must be monitored in the longer term.

Thirdly, fractures have been reported for remelted highly cross-linked PE (Bradford et al. 2004). This complication did not occur in our series. One reason might be that the annealed highly cross-linked PE is mechanically tougher than remelted PEs, but it might also be caused by the fixation method—which was cement. Cemented cups are more forgiving and tolerant of stress. A thin PE liner squeezed between a metal head and shell held

only by a locking mechanism is a different story. In such cases, reduced toughness of oxidized PE might lead to failure.

Fourthly, in remelted PE the effects of different durations of the remelting process (2h, 6h, 24h) (Santavirta et al. 2003) are not known, and to our knowledge they have been insufficiently documented in the literature.

Apart from the issue of wear, patient satisfaction, stability, and development of osteolysis are just as important in helping prediction of a possible failure scenario for THA. None of our cups showed worrisome migration in any direction, and they were as stable as the conventional cups. This confirms our earlier results and the findings are in agreement with those of other authors (Hopper et al. 2003, Martell et al. 2003, Digas 2005). The higher HHS score in the group with cross-linked PE than in the group with conventional PE may be attributed to the younger age of the former.

In summary, highly cross-linked cemented Crossfire polyethylene cups performed well even after almost 6 years in vivo, and showed a very low wear rate and good clinical performance. There was no acceleration of wear rate after the initial 2 years. This is reassuring, but care should be taken when extrapolating these results to other cross-linked PEs and uncemented cups where PE toughness might be more of an issue.

Contributions of authors

BN: initiated the study. SMR, KGN and MGL: collected the data and performed the analysis. SMR: wrote the manuscript. All authors critically reviewed and contributed to the final paper.

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