Chapter 3

Polyethylene wear in metal-backed cups. A retrospective analysis of 200 uncemented prostheses.

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Introduction

Uncemented total hip prostheses were introduced some 40 years ago, after disappointing results with cemented hip prostheses in young and active patients.[4,8,10,56] In orthopedic literature, research on uncemented hip prostheses has focused on the survival of the uncemented femoral stem, and in general, excellent results were reported.[1,35,37,42] Although the femoral component showed excellent performance, recent in vivo studies have reported increased wear of the polyethylene (PE) liner of the uncemented acetabular cup.[6,18,25,32] This PE wear results in PE particles being distributed in the tissue surrounding the prosthesis, with macrophages being activated by these particles. These activated macrophages induce osteolysis (Figure 3.1) which in the end results in aseptic loosening of the prosthesis.[19,27,29,46,54,60]

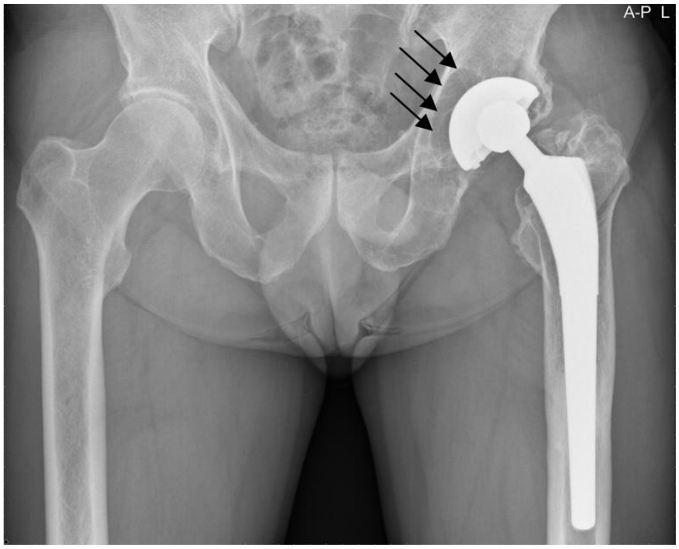

Figure 3.1, Osteolysis.

Although uncemented hip prostheses vary greatly in design, they all have a metal-backed acetabular cup (Figure 3.2). This metal-backing is needed since direct contact between bone and PE results in osteolysis.[23,29,51] Metal-backed cups are made more biocompatible by applying coatings which stimulate bone ingrowth. These coatings are either porous or hydroxyapatite (HA) coatings. When metal-backed cups were developed, a better force distribution with less peak forces was expected along the bone-prostheses interface.

Recent studies however stated there was less stress shielding with cemented cups than with uncemented cups.[14,44] Another possible disadvantage from metal-backed cups is the dislocation or rotation of the PE liner from the metal-backing, resulting in additional wear and an increased number of released PE particles. This type of wear is known as “backside” wear.[3,31]

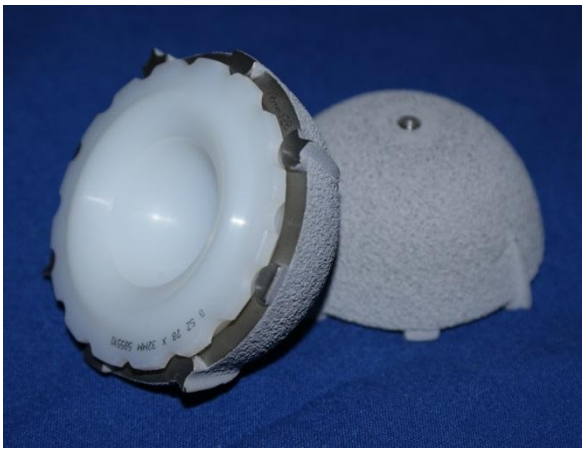

Figure 3.1, Metal-backed acetabular cup.

Increased PE wear is most likely a multifactorial process influenced by, for example, the manner in which PE is produced and sterilized, the time between production and implantation (known as “shelf life”), the inclination angle of the cup, and the activity levels of the patient. Since we had concerns on the frequency of observed wear in our patient population, we retrospectively reviewed our first 200 uncemented hip prostheses using the Mallory-Head design (Biomet Inc., Warsaw, USA). The long-term survival of the femoral component of this particular prosthesis is well documented and has excellent results. Only a few studies report on acetabular wear and survival using this design. Yamamota et al found a mean liner wear of 0.3 mm after 3 years, 0.55 mm after 5 years, and increasing to 0.7 mm after almost 7 years of follow-up.[61] Kurtz concluded that the threshold for osteolysis is a head penetration rate of >0.1 mm per year. He also reported that osteolysis could not be detected with a head penetration rate of <0.05 mm per year.[32] Other studies reported an osteolysis threshold at a head penetration rate of 0.1–0.2 mm per year.[15,16,33,53,55] We therefore used a head penetration rate of >0.2 mm per year to classify any case as excessive wear. The primary objective of our study was to evaluate how many of the 200 implanted prostheses showed a

liner wear of more than 0.2 mm per year. The frequency of any osteolysis and implant survival was also evaluated.

Patients and Methods

Our first consecutive 200 uncemented total hip prostheses (Mallory-Head), implanted between November 1997 and September 2002, were retrospectively analysed (Table 3.1).

Table 3.1, *Patient demographics*	
Male (n)	98 (49%)
Female (n)	102 (51%)
Age (years)	54.6 (range: 29-69)
BMI (kg/m^2)	26.9 (range: 17.6-37.5)
Bilateral (n)	36 (18%)
Diagnosis: OA	187 (93.5%)
AVN	11 (5.5%)
FC	2 (1%)

*OA: osteoarthritis; AVN: Avascular Necrosis; FC: fractured collum

In all cases, an uncemented porous-coated femoral stem was used with a 28-mm ceramic head and a porous-coated ringloc acetabular cup. The liner was made of conventional ultra-high molecular weight polyethylene (UHMWPE) (ArCom®, Biomet Inc., Warsaw), manufactured with compression molding and sterilized with gamma radiation in argon gas. Liner thickness ranged from 4.8 (cup size 48) to 11.8 mm (cup size 62). Mean shelf life was four months (range: 0 to 41). All prostheses were implanted through the posterolateral approach. All patients were asked to return for clinical follow-up including a standard anteroposterior (AP) radiograph. Medical file data were collected on primary diagnosis, BMI, complications and details of the used components. Of all patients, 89% completed a Duke Activity Index[26] to measure current activity levels. There were 36 patients lost to follow-up (37 prostheses): 9 were deceased, 16 were revised, and we were unable to contact 10 patients. This left us with 163 prostheses (81.5%) available for analysis of PE wear. Liner wear was evaluated by measuring the two-dimensional displacement of the femoral head relatively to the cup position using software (Pro 3D software, Draftware Inc. Vevay, USA). We used the most recent AP radiograph (Figure 3.3). To check for interobserver reliability, a sample of ten

radiographs was measured by an experienced evaluator of Draftware Inc., and all PE wear measurements were 100% identical.

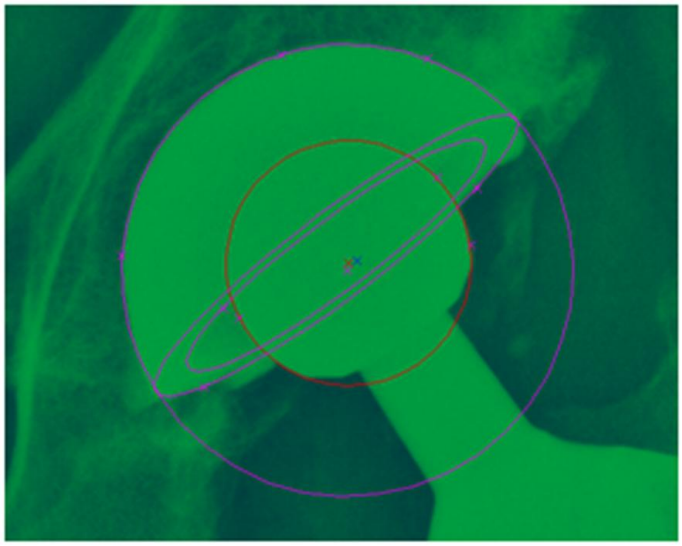

Figure 3.2, Measurements on AP radiograph

This is possible by using edge-detection features in the software, limiting the observer input on the obtained measurements. Besides the use of software, we retrospectively checked medical files if PE wear was noted by the orthopedic surgeon. We set the threshold for acceptable wear at <0.2 mm per year. A sensitivity analysis with a threshold of 0.1 mm per year was also calculated. We calculated the correlation between wear and the following subgroups: age, BMI, activity level, cup inclination angle, acetabular component size, liner thickness, and shelf life. Differences in wear between male and female patients were tested using an unpaired Student's t-test. Implant survival was calculated using the Kaplan-Meier (KM) method. All statistics were performed using SPSS software (SPSS Statistics, version 17.0, IBM Corporation, Somers, USA). The most recent AP radiograph was screened for any radiolucency or osteolysis according to the zones described by DeLee and Charnley for the acetabular component and the zones described by Gruen for the femoral component.[13,24]

Results

Wear and Osteolysis

The mean-measured PE wear was 0.2 mm per year (range: 0.07 to 0.5), after a mean follow-up of 8.3 years. In 53.4% of all cases, the PE wear was 0.2 mm per year (Figure 3.4), and if the threshold for acceptable wear was set at 0.1 mm per year, 96.3% of all liners showed excessive PE wear.

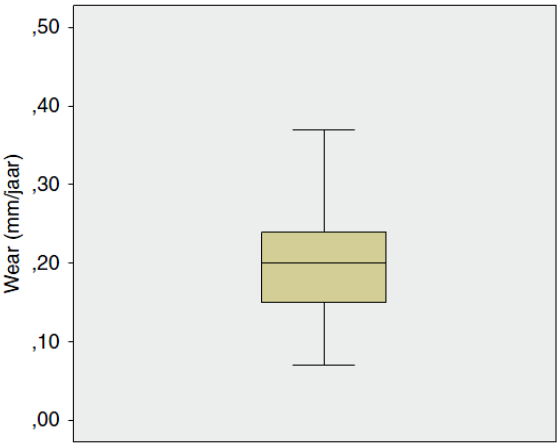

Figure 3.4, Boxplot of wear rate per year.

There was a significant correlation between PE wear and cup inclination angle and between PE wear and component size (Table 3.2). Mean PE wear was significantly higher in male patients than in female patients (respectively, 0.22 mm per year versus 0.19 mm per year, p = 0.02). On average, 24.3% of the original liner thickness was lost to PE wear (range: 10.7 to 42.7%). In 41 cases, PE wear was observed during routine clinical follow-up and noted in the medical file (24.8%), with a mean of 93 months after index surgery (range: 40 to 120). Osteolysis was observed in five cases (Table 3.3). The measured PE wear in these five patients had a mean of 0.22 mm per year (range: 0.19 to 0.26).

Table 3.2, *Sub analyses PE wear*		
	Correlation	**p-value**
Age	- 0.4	0.61
BMI	0.056	0.48
Activity level	0.166	0.053
Acetabular inclination	0.236	0.002*
Shell size	0.156	0.046*
Shelf life	0.065	0.41

Table 3.3, *Osteolysis*		
	N	**%**
Femoral component		
- None	160	98.2
- Gruen zone 1 or 7	3	1.8
- Gruen zone 2 – 6	0	0
Acetabular component		
- None	158	96.9
- DeLee & Charnley zone 1	2	1.2
- DeLee & Charnley zone 2	2	1.2
- DeLee & Charnley zone 3	1	0.6

Implant Failure

Of the 200 prostheses, 16 were revised, and one was scheduled for revision. Most frequent reason for revision was PE liner wear (N=10), see tables 3.4 and 3.5. Of the ten patients revised for liner wear, a straightforward cup exchange was done in nine cases. In two cases, the liner was detached from the metal-backing, and in one of these two cases, metallosis was observed. In the other case, a fibrous tissue layer was observed between the PE liner and the metal-backing. Four cases needed bone impaction grafting for an acetabular cyst. Mean time to revision was 108 months (range: 77 to 144), and the mean observed wear in the revised patients was 0.28 mm per year (range: 0.21 to 0.45). The KM probability estimate of survival, with revision for any reason as end point, was 90.7% after 12 years of follow-up (95%–CI: 85.6–94.2). With only revision cases due to wear as end point, the KM survival estimate was 93.1% after 12 years follow-up (95%–CI: 79.9–100), see figure 3.5.

Table 3.4, *Overview of revision cases*	
Reason for revision	**N (%)**
A-septic loosening	1 (0.5)
Liner exchange	9 (4.5)
Dislocation	4 (2)
Wound infection	1 (0.5)
Breakage ceramic head	1 (0.5)
Total	**16 (8)**

Table 3.5, *Wear related revision*		
Casus	**Months to revision**	**Details**
1	77	Liner exchange, components well fixed
2	104	Liner exchange, components well fixed
3	107	Liner exchange, components well fixed
4	107	Liner exchange, components well fixed
5	109	Liner exchange, components well fixed
6	109	Liner exchange, components well fixed
7	110	Liner exchange, components well fixed
8	144	A-septic cup loosening
9	Unknown	Revised in other hospital, patient deceased
10	Planned	Wear observed

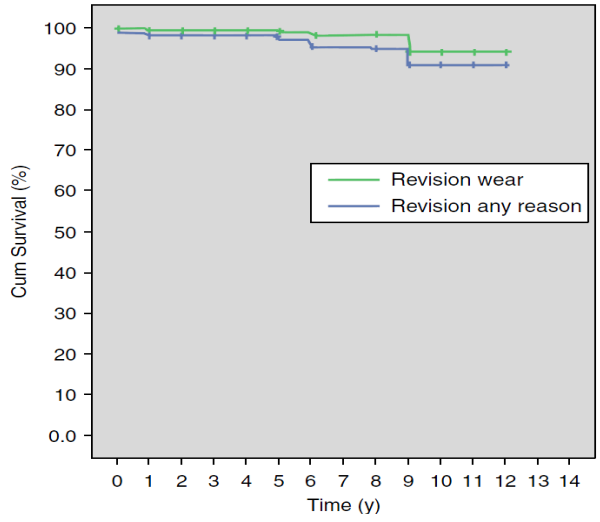

Figure 3.5, Kaplan-Meier survival probability estimate.

Discussion

In our study, we report a high proportion (53.4%) of UHMWPE liners with a wear rate of 0.2 mm per year, after a mean follow-up of 8.3 years. In contrast, implant survival after 12 years is acceptable (KM 90.1%). However, it is disturbing that in literature the liner wear rate is reported to be nonlinear, with an increase in PE wear 7 to 8 years after index surgery.[26,63] These findings suggest that we have to expect an increasing number of revisions within the next few years of follow-up. Parvizi conducted a study with longer mean follow-up than our study and found a revision rate of 20% after 11 years of follow-up.[47] And McLaughlin reported a revision rate of 65% after 16 years.[41] A possible explanation for the measured amount of wear can be found in the type of PE used. Free radicals, formed during the sterilization process, negatively influence the characteristics of conventional UHMWPE. Before and after implantation, these free radicals react to oxygen. This oxidation leads to accelerated wear rates. Wear can be reduced by using highly cross-linked polyethylene (HXLPE). Compared to conventional PE, HXLPE shows a significant reduction of the head penetration rate in several clinical studies.[30,40,43,50] Currently, we do not know if in the long term, free radicals are released from HXLPE and can still cause oxidation. A recent method to prevent this happening is the infusion of vitamin E into (highly cross-linked) PE to scavenger any free radicals. This method is too new for clinical studies to be available. Alternatively, other bearing materials may be used such as metal or ceramics. Although there are some benefits of Metal-on-Metal (MoM) bearings such as low dislocation rates (due to the large diameter) and very low wear rates reported in in vitro studies[2,9,11,21] these benefits are outweighed by the occurrence of serious complications due to an adverse reaction to metal debris (ARMD), as reported in recent clinical studies.[12,34,36] In general, recent clinical studies using MoM bearings report higher revision rates than expected with the introduction of these bearings.[49] Clinical studies with ceramic bearings have good long-term results, but the use of ceramics is limited by high cost, “squeaking,” and difficult revision after liner fractures.[7,45,48,58,59] The choice of material for the femoral head does not influence the PE wear rate significantly; only small differences in liner wear were observed between different materials for the femoral head.[57] Wear is not only dependent on the used materials but indeed multifactorial. In our study cohort, more wear was observed in cups with a steeper inclination angle and in male patients. This corresponds with earlier publications.[5,20,61] In contrast to

earlier studies, we observed more wear with larger sizes of acetabular cups. We could not identify any possible explanation for this observation. We explored the hypothesis that larger cups would be more difficult to place, resulting in steeper cup placement. However, there was no significant difference in cup inclination angle between smaller (54 mm) and larger (56 mm) cup sizes. From our analysis on different subgroups, we could not detect any relation between age, BMI, shelf life or activity level, and the measured PE wear in our study cohort. This was unlike findings from other studies.[5,52,61] There is however a large heterogeneity in number and characteristics of the included patients, making it difficult to compare these results. In our study, shelf life was quite short with an average of four months. The measured wear in all patients revised because of liner wear was more than 0.2 mm per year. However, 82.5% of all our patients with a PE wear rate of >0.2 mm per year had no radiolucent zones, no cyst formation, or such clinical symptoms that revision surgery was indicated. This might be due to the genetic profile of these patients, which makes them resistant to osteolysis.[19,23] The observed wear in our study is comparable to other studies using metal-backed cups.[17,22,28,38] Considering this comparable high wear rate, the number of cases with aseptic loosening (0.5%) and the number of observed osteolysis (5.5%) in our series is low in comparison to other studies. Although, most of these other studies had longer follow-up the retrospective nature of our study which makes it more difficult to classify aseptic loosening. Another explanation might be that the osteointegration of the coating is so effective that the acetabular component appears to be well fixed in place during revision surgery. Even if only a small area is integrated into the bone tissue, the optimal treatment if wear is observed and the best timing to perform revision surgery are clinical issues described in a treatment algorithm by Goosen et al (Figure 3.6).[22] Strong points of our study are the large number of included prostheses, the use of a validated method to measure wear, and the analyses of multiple variables which might influence than our series. For example, Emms et al found a 17.1% osteolysis rate and a wear-related revision percentage of 20% after 11.5 years of follow-up.[18] The fact that we only used the most recent radiograph for PE wear evaluation, might explain we only observed osteolysis instead of any radiolucency. It is also striking that the number of cases with aseptic loosening in our study cohort is very low.

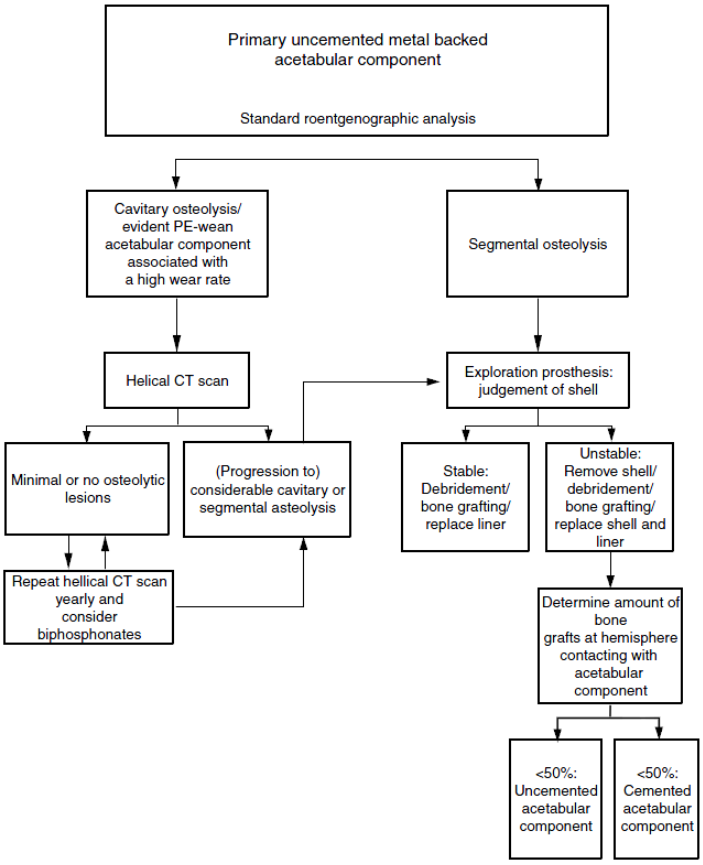

Figure 3.6, Treatment algorithm for uncemented metal-backed acetabular components by Goosen et al (reprinted with permission).[22]

This might either be because we revised patients early or by wear. Our study is limited by the retrospective design, the lack of a control group, the loss to follow-up, and the limited duration of the follow-up. Based on our results and the current literature, we strongly question the use of conventional UHMWPE in uncemented total hip prostheses with metal-backed cups. Detailed follow-up, especially in the long term, can prevent serious complications due to the use of conventional PE. Studies with longer follow-up, preferably more than 10 years, are necessary to validate the safety of conventional UHMWPE in uncemented total hip prostheses.

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