Correlation of wear debris-induced osteolysis and revision with volumetric wear-rates of polyethylene

A survey of 8 reports in the literature

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Submitted 99-12-14. Accepted 00-08-07

ABSTRACT – This survey focused on clinical reports of polyethylene wear and osteolysis in total hip replacements. With regard to documentation of clinical wear-rates, 57 publications were reduced to an analysis of 8 reports of THR series, including the incidence of osteolysis. A direct correlation was found among volumetric wear-rates, incidence of osteolysis and revision rates in THR concepts of the 1983–1987 era. As volumetric wear rate increased, the incidence of osteolysis and revision rates increased. With regard to our grading system for volumetric wear, with follow-up in the 4–15 year range, osteolysis was rare in group A (wear = 0–80 mm^3/year), ranging from 6% to 31% in group B (wear 40–80 mm^3/year) and from 21% to 100% in group C (wear > 140 mm^3/year). With regard to cup design, the optimal low-wear group had mainly cemented polyethylene cups with 22 and 28 mm head sizes. The mid-wear group B had metal-backed cemented and uncemented cups, with 28 mm head size, and the high-risk group C had only uncemented, metal-backed cups, with the highest wear in the 32 mm head size. Less than 10 years of follow-up did not distinguish adequately between different designs of THR, except in a few cases which had early failures due to material or design deficiencies. Overall, the cemented all-polyethylene cup combined with the smaller ball head proved to be better.

An understanding of the mechanism(s), pattern and degree of osteolysis and their relation to failure is complicated by the multi-factorial complexity of clinical THR studies (Sutherland et al. 1982, Schmalzried et al. 1992, Zicat et al. 1995, Aspenberg and Herbertsson 1996). Biological mechanisms triggered by polyethylene (PE) wear-debris were obviously involved in the loosening of acetabular cups (Charnley 1974, Sutherland et al. 1982, Wroblewski 1986, Livermore and Morrey 1990, Amstutz et al. 1992, Schmalzried et al. 1992, Bankston et al. 1993, Owen et al. 1994, Ritter 1995, Zicat et al. 1995, Aspenberg and Herbertsson 1996, Schmalzried et al. 1998). Such wear-related mechanisms appeared to take many years to cause the lesions seen radiographically or to develop as clinically apparent symptoms (Wroblewski 1986, Callaghan et al. 1998, Sochart 1999). Clearly, THR patients with minimal formation of wear-debris, such as rheumatoid patients with low-demand for loading (Griffith et al. 1978, Sochart and Porter 1997) or in ceramic-ceramic THR (Yoon et al. 1998), had little, if any, bone loss during long-term follow-ups. However, patients showing above-normal PE wear appeared to have much more bone loss and needed revision sooner (Sedel et al. 1990, Zichner and Willert 1992, Bono et al. 1994, Sedel et al. 1994, Sochart et al. 1997). Sochart (1999) showed the effects of increased PE wear in young patients with Charnley THR (average age 32 years). They divided the cases into 4 groups of PE wear-rates—i.e., 39, 58, 78 and 97 mm^3/year of volumetric wear. The cases

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Table 1. Inclusion criteria for review of THR wear and osteolysis based on our survey of journal articles (column A) and those quantifying wear-rates and incidence of osteolysis with regard to implant design (column B)

Level	Parameter	A	B
I	Randomized prospective	6	2
II	Osteolysis and wear	51	6
III	Minimum follow-up 4 years	53	6
IV	Minimum follow-up 2 years	4	2

with higher volumetric-wear also had a higher incidence of osteolysis and higher rates of implant migration and revision.

It is our hypothesis that the quality of the PE material and design of the cups may be the main significant factors (Charnley and Cupic 1973, Charnley 1974, Charnley and Halley 1975, Bankston et al. 1993, Rentfrow et al. 1996, Kesteris et al. 1996, Kadoya et al. 1998, Garellick et al. 1999), but other implant design features could be of equal importance (Beckenbaugh and Ilstrup 1978, Bloebaum and Dupont 1993, Mulliken et al. 1996, Barrack et al. 1997, Diwan and Drummond 1997, Hop et al. 1997, von Knoch et al. 1997, Malchau and Herberts 1998, Morscher et al. 1998). It seems evident that design features such as femoral head diameter, material and surface quality of the head, PE material, cup thickness, metal-backing and fixation-methods have all affected the generation and severity of osteolytic lesions (Harris and McGann 1986, Bankston et al. 1993, Kabo et al. 1993, Bono et al. 1994, Goetz et al. 1994, Bankston et al. 1995, Weidenhielm et al. 1995, Kesteris et al. 1996, Clarke et al. 1997, Devane et al. 1997, Jasty et al. 1997, Madey et al. 1997, Malchau et al. 1997, Okamoto et al. 1997, Elfick et al. 1998, Thanner et al. 1999). The various criteria for reporting clinical data may also play an important role in distinguishing between the performances of such THR designs. In this study, we describe a unifying concept which ranks the clinical success of various THR designs with regard to the extent of volumetric wear, to show which implant designs are at greatest risk for higher wear, increased incidence of osteolysis and higher revision rates.

Methods and material

Randomized and non-randomized clinical trials focusing on THR wear and osteolysis were selected from the MEDLINE, Cochrane and other databases (Cochrane 1999), as recommended by Dickersin et al. (1994). We found only 6 randomized studies (Table 1). The search was extended to include THR studies, with a minimum follow-up of 4 years or more and which described PE wear, osteolysis and related risk factors. Osteolysis is defined here as periprosthetic bone resorption with radiographic evidence of progressive bone loss not present on the initial radiographs (Wan and Dorr 1996). This search provided 51 articles (Table 1). In addition, 4 studies, with a minimum of 2 years' follow-up, were included when they also had longer-term results in the same series. Examination of these papers for PE wear-rates and incidence of osteolysis also left only 8 papers for analysis (Table 2). Some of these compared different design concepts in the same study and thereby provided data with different rankings.

The various implant types in the 8 studies were ranked in order of their average volumetric wear-rates (Table 2). These were graded into 3 categories with grade A having wear rates up to 80 mm^3/year, grade B from 80 to 140 mm^3/year and grade C over 140 mm^3/year. On inspection, there even seemed to be a grouping of osteolytic incidence—i.e., 0–20%, 17–31% and 21–100% in these grades.

When radiographic data alone were available for linear wear-predictions, the corresponding volumetric wear-rate was calculated (volume = $\pi \times R^2 \times x$, where R mm = radius of femoral head and x mm = linear wear). The published failure rates for Charnley, T28, Muller and MOSC hip joints were plotted with respect to duration of follow-up and we used linear regression analysis to determine their terminal failure rates from 5 years's duration or more (Figure 1). These data were taken from Ritter et al. (1995).

Results

As the ranking of PE volumetric-wear increased, the incidence of osteolysis also increased greatly

Table 2. Severity of osteolysis correlates with increase in volumetric wear-rate

A	B		C	D	E	F	G	H	I
Bankston-i	T R-28 CoCr	(CE PE)	6–8	28	162	0.05	30.8	A	
Bankston-ii	T-28 SS	(CE PE)	6–8	28	307	0.06	36.9	A	
Sochart-i	Charnley SS	(CE PE)	6–30	22	117	<0.10	<38.9	A	6
Bankston-iii	MOSC Ti64	(CE PE)	6–8	28	99	0.08	49.2	A	
Cates et al.	MOSC Ti64	(CE PE)	3–10	28	99	0.08	49.2	A	
Sochart-ii	Charnley SS	(CE PE)	6 –30	22	36	<0.14	<58.3	A	13
Nashed-i	BIAS Ti64	(CE PE)	5–10	28	24	0.10	61.5	A	0
Bankston-iv	MOSC Ti64	(CE-MB)	6–8	28	134	0.11	67.7	A	
Cates et al.	MOSC Ti64	(NC-MB)	3–10	28	134	0.11	67.7	A	
Sochart-iii	Charnley SS	(CE PE)	6–30	22	40	<0.19	<77.7	A	20
Nashed-ii	BIAS Ti64	(CE-MB)	5–10	28	62	0.13	80.0	B	31
Thanner et al. [a]	PCA CoCr	(NC-MB)	7–9	28	84	0.15	92.3	B	6
Sochart-iv	Charnley SS	(CE PE)	6–30	22	22	<0.24	<97.2	B	18
Thanner et al. [a]	HGP Ti64	(NC-MB)	7–9	28	87	0.16	98.5	B	20
Nashed-iii	BIAS CoCr	(NC-MB)	5–10	28	74	0.17	104.6	B	24
Devane-i [a]	MH Ti64	(CE-MB)	4–6	28	12	0.20	123.7	B	17
Bono-i	AML+ CoCr	(NC-MB)	2–6	32	72	0.18	144.7	C	21
Nashed-iv	BIAS Ti64	(NC-MB)	5–10	28	15	0.25	153.9	C	87
Devane-ii [a]	MH Ti64	(NC-MB)	4–6	28	34	0.30	187.1	C	49
Kim-i	AML CoCr	(NC-MB)	7–11	32	29	0.30	241.2	C	100
Kim-ii	AML CoCr	(NC-MB)	7–11	32	16	0.53	426.0	C	75
Bono-ii	AML+ CoCr	(NC-MB)	2–6	32	15	0.77	619.0	C	100

[a] Randomized trials, CRG clinical wear grades, ACS anatomic cup system, AML anatomic medullary locking, BIAS biologic ungrowth anatomic system, CE cemented, CoCr cobalt chromium, HGP Harris Galante porous, MB metal back, MH mallory head, MOSC Miami orthopedic surgical consultant, NC uncemented, PCA porous-coated anatomic, PE polyethylene, T 28 trapezoidal, TR 28 trapezoidal-rectangular, Ti64 titanium alloy, Kim-i and ii: 7- and 10-year duration of follow-up (1999), Sochart-i to iv 4 groups of increasing wear-rates in Sochart's study (1999).
Notes on Grade C: the study by Bono et al. (1994) was an inferior ACS cup design with 32 mm head-size and rim-cracking; Kim et al. studied a high-activity patient group (average age 48 years.). Devane et al.'s study was complicated by variations in polyethylene resin content and by design modularity and fixation.

A Reference
B Design, material (fixation)
C Follow-up (years)
D Femoral head sizes (mm)
E No. of HIPS in study
F Wear-rate mm/year
G Vol. wear-rate (mm^3)/yr
H CW grade
  A <80 mm^3/year
  B 80–140 mm^3/year
  C >140 mm^3/year
I Osteolysis total (%)

(Table 2). In group A, osteolysis rarely developed and then only in studies with up to 30 years of follow-up. The THR in group A had only 22 and 28 mm femoral head diameters and mainly had cemented PE cups. The Charnley cases had also by far the longest follow-up. It was noted that the two implants that wore most in group A were metal-backed PE liners. It was also apparent that group A included stainless steel, CoCr and Ti6Al4V femoral heads, apparently with equally good results.

The THR in group B had an incidence of osteolysis, which ranged from 6 to 31%. With the exception of 1 Charnley study, the typical follow-up was 5–10 years. The ball diameters were still 22 and 28 mm and included a mixture of CoCr and Ti6Al4V heads. Metal-backed PE cups then predominated in group B and consisted of cemented and uncemented designs.

The THR in group C had an incidence of osteolysis rangin from 21 to 100%. The 32 mm ball diameters now predominated with a mixture of CoCr and Ti6Al4V heads. We noted that the highest wear-rate occurred in studies using CoCr heads (Table 2) and that uncemented, metal-backed PE cups were also common. The randomized study by Thanner et al. (1999) had two THR designs in group B. The other randomized study by Devane et al. (1997) had implants in groups B and C. In both studies, the incidence of osteolysis

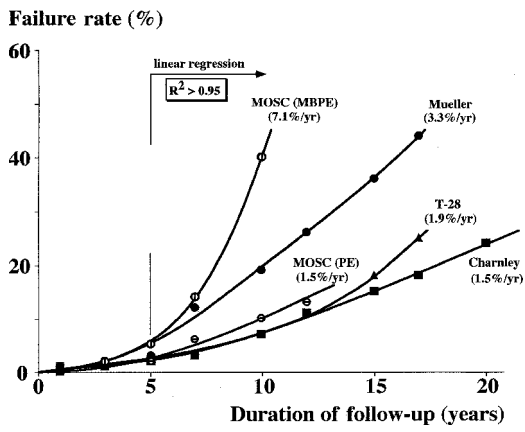

Figure 1. Failure rates for Charnley, T-28, Muller and MOSC THR were plotted with respect to duration of follow-up. These data were taken from Table 3 of Ritter (1995). The terminal failure rates were calculated by linear regression from 5 years to the end of the follow-up. Charnley = cemented PE cup with 22.2 mm stainless-steel head. MOSC = cemented PE cup with 28mm Ti6Al4V head. MOSC-MB = uncemented, metal-backed with 28mm Ti6Al4V head. Mueller = cemented PE cup with 32 mm CoCr head.

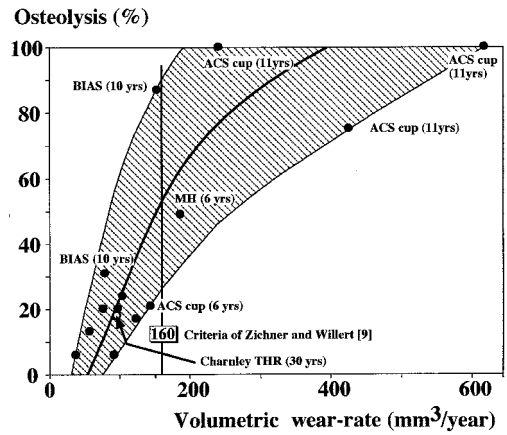

Figure 2. Osteolysis rates plotted with respect to wear-rates showed the dramatic effect of increased wear and the effects of THR design with different follow-ups. Zichner and Willert (1992) reported that wear-rates over 0.2 mm/year with 32 m heads caused significantly more revision problems. Their criterion was converted to volumetric wear of 160 mm^3/year.

increased with the rise in volumetric wear-rates.

Comparison of studies describing implants with various follow-ups showed major differences in failure rates due to THR design (Figure 1). In a comparison of the metal-backed cups to cemented PE cups of the MOSC design, we found the failure rates for the metal-backed PE cups were higher as early as 5 years and had increased significantly with a 10-year follow-up. Similarly, the cemented Muller design with 32 mm femoral head diameter was much worse than the Charnley design with 22 mm head size after 5 years and still worse after a 10-year follow-up. These data applied to both the femoral and acetabular component designs. At the 10-year follow-up, the MOSC-MB had a greatly increased failure rate while the MOSC-PE, T-28 and Charnley were not very different. In a comparison of the cemented T-28 and the Charnley designs, a follow-up of 15-17 years was required to show a clinical difference in revision rates (Figure 1). For follow-ups longer than 5 years, linear regression analysis estimated THR failure rates at 1.5%/year (Charnley; MOSC-PE) to 3.3% (Müller). The Muller and T-28 designs showed comparable rates after 15 years of follow-up. By 17 years, the T-28 and Muller had clinical failure rates of 25% and 47%, respectively, vs. the Charnley THRs 18%, a 1.4 to 2.4-fold difference. With the same Charnley cup design, Sochart (1999) noted no difference in survivorship between his 4 wear groups at 10 years (92–97% range) but after a 20-year follow-up, we saw a significant difference in survivorship (89% dropping to 47% with increased wear). It takes more than 10 years and possibly even 20 years to distinguish between performances of the various THR designs (Callaghan et al. 1995, Hamilton and Gorczyca 1995, Callaghan et al. 1998).

When the osteolysis data were plotted against wear rates (Table 2), it was apparent that there was a rapid increase with increased wear-rates (Figure 2). This also showed the interaction of follow-up periods with THR design. For example, the ACS cups had a 100% incidence of osteolysis within 11 years. This contrasted with the maximum osteolysis rates of 18% for the Charnley THR in studies with up to 3 times longer follow-up (Table 2).

Discussion

Overall, by ranking the THR studies with regard to average volumetric wear-rates, one might conclude that the very best results occurred with 22

and 28 mm heads and cemented PE cups (group A; osteolysis rare). The Charnley THR's osteolysis rates (Table 2) seemed to be worse than they really were, no doubt because their follow-ups were twice as long as any other series. Thus if comparison had been restricted to the 10–15-year duration, all Sochart groups (i-iv data) would probably be found at the lower levels in group A. In addition, the wear-ranking represented the upper-level of stratification in Sochart's 4 groups (Table 2), compared to the average wear-rates shown in the other studies. However, those with the highest wear in grade C (75%–100% osteolysis), mainly had 32 mm heads with uncemented, metal-backed cups. Various controversial design features further complicated these 4 publications. One study included the AML cup (ACS) with cylindrical PE-inserts from the 1988–1990 era. This design resulted in problems of rim-fracture and accelerated PE wear (Bono et al. 1994). Another AML study had potentially more active patients (< 60 years) with 32 mm heads (Kim et al. 1999). However, the average age of 48 years in this series (group C) was offset by the Charnley series wich had an average age of 32 years (group A).

Devane et al. (1997) compared cemented versus uncemented designs, but the PE-insert and cup design also included molded resin (H1900; non-modular metal-backed) and the extruded-machined PE (GUR1450; modular metal-backed). Thus there was a difference in PE material, cup design and fixation parameters. The 4 groups studied by Nashed et al. (1995) included cemented PE and metal-back cups with uncemented cups and included both Ti64 and CoCr femoral heads. In these groups, the Ti64-PE cemented THRs averaged 0.1 mm/year compared to 0.17 mm/year for CoCr-PE/metal-backed, uncemented types (Table 2), i.e., an increase of 70% in wear-rate with CoCr. In contrast, when Ti6A/4V heads were combined with uncemented metal-backed cups, the resulting PE wear-rates were 0.25 mm/year, corresponding to a wear volume of 154 mm^3/year. This was a 150% increase in volumetric wear-rate, compared to 61 mm^3/year for the same heads used with the cemented PE cups (Table 2).

It should be noted that 4 of the 8 studies done (Table 2) were published in 1993–95 and 4 in 1997–99. Thus in general, these data reflected THR designs of the 1983–1987 era or earlier. Certainly there is now an increased awareness of the deleterious wear-effects of thin PE liners combined with the larger femoral heads. It is hoped that the present designs of metal-backed PE cups will overcome the limitations of previous designs. However, we shall not know that until the follow-up times have been longer.

Therefore, on the basis of this survey of 8 publications on wear-rates and incidence of osteolysis with designs of the 1983–1987 era, the following conclusions can be drawn:

1. As volumetric wear-rate increased, the incidence of osteolysis and revision-rates also increased.
2. With regard to the grading system used for volumetric wear in this study, with follow-up in the 10–15-year range
   - osteolysis was rare in group A (wear rate = 0–80 mm^3/year),
   - osteolysis ranged from 6% to 31% in group B (wear-rate = 80–140 mm^3/year),
   - osteolysis ranged from 21% to 100% in group C (wear-rate = > 140 mm^3/year).
3. With regard to cup design
   - group A mainly had cemented polyethylene cups with 22 and 28 mm head-sizes,
   - group B had metal-backed cups, both cemented and uncemented, with 28 mm head-size,
   - group C had only uncemented, metal-backed cups, with the greatest wear in the 32 mm head-size.
4. Follow-up duration of less than 10 years was not enough to distinguish between various designs of THR unless these had unusually high wear-rates. Such disparities increased continually with follow-ups and were even evident 20 years later. In all such trends, the cemented all-polyethylene cup combined with the smaller ball head continued to give better results.

This study was partly supported by an educational grant from Biomet Inc (Warsaw IN) and by the Departments of Orthopaedics at Sahlgrenska University Hospital in Goteborg, Sweden, and Loma Linda University Medical Center, Loma Linda, CA. 92408.

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