Al_2O_3 against Al_2O_3 combination in hip endoprostheses. Histologic investigations with semiquantitative grading of revision and autopsy cases and abrasion measures

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For comparison of hip endoprostheses with Al_2O_3 combinations of the gliding surfaces with other material combinations, pseudocapsules and soft tissue membranes around hip endoprostheses retrieved at revision surgery or at autopsy were histologically investigated. In all tissue specimens around loosened prostheses, ceramic wear particles were found, in 50% of cases high-grade ceramic wear was seen. In contrast, only half of the autopsy cases revealed ceramic wear. Cases with Al_2O_3–Al_2O_3 combinations showed less villous transformation of the synovial tissue, a thinner synovial layer and reduced necroses in comparison to Al_2O_3–polyethylene and metal–polyethylene combinations. These differences appeared more pronounced in the autopsy cases. The result of this study confirm the hypothesis, that a high ceramic wear rate in loosened prostheses develops mainly as a consequence of loosening. For that reason, biologically fixation of implants with spongious structured surfaces and without bone cement fixation seems a logical consequence. Modular systems are necessary not only for stem and ball, but also for the acetabular component of the hip endoprostheses.

1. Introduction

Al_2O_3 on Al_2O_3 combinations as a bearing material for hip endoprostheses were introduced after tribological measurements had shown superior wear resistance and less friction between the gliding surfaces than in other material combinations [1–6]. Friction is markedly reduced in comparison to Al_2O_3 polyethylene combinations. The wear rate with alumina was found to be 500 times lower than in metal–polyethylene combinations [7].

2. Material and methods

From a total of 4882 hip joint endoprostheses inserted, 254 were with Al_2O_3 on Al_2O_3 combinations of weight bearing surfaces.

Tissue specimens of 14 cases with Al_2O_3–Al_2O_3 combinations, Al_2O_3–polyethylene combinations and metal–polyethylene combinations, obtained during revision surgery, were thoroughly histologically investigated including semiquantitative grading of the amount of wear particles and histologic alterations. In the same way pseudocapsules and soft tissue membranes at the bone–cement interface of six autopsy cases with lifetime functioning and stable protheses were investigated. For comparison, seven autopsy cases with Al_2O_3–polyethylene combinations and 17 cases with metal–polyethylene combinations (5 to 15 years *in situ*) were examined.

Loosening required revision of 13 cemented spherical sockets after 6–12 years. The revision case 14 (Table I) was a loosened cement-free Mittel-meier prosthesis 8 years after surgery.

In contrast to normal use it is remarkable that permanent load reduction (walking with crutches after poliomyelitis) results in solid size of a screwed conical socket without any sign of lossening after 14 years.

2.1. Microscopic evaluation

Tissue specimens of defined localizations were preserved during revision surgery or autopsy. About 600 sections of each localization were stained in HE-Goldner's trichrome and Prussian blue.

The following parameters were graded semiquantitatively: ceramic wear particles, bone cement wear particles, villous transformation of the synovial tissue, necroses and the extent of fibrosis. Grading of the

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TABLE I Ceramic and bone cement wear and ceramic abrasion of 14 revision cases; 1–13 socket cemented, 14 cementless

Patient	Years after surgery	Ceramic wear grade	Cement wear grade	Abrasion ball (μm)	Abrasion socket (μm)
1	7	2	9	15	5
2[a,b]	7	10	3	1300	3200
3[c]	12	10	4	260	200
4	8	6	8	10	5
5	8	2	9	5	2
6	8	9	6	–	–
7	7	4	2	–	–
8	9	5	8	–	–
9	8	10	2	–	–
10	8	10	8	–	–
11	9	5	6	–	–
12	8	1	9	–	–
13	6	8	0	–	–
14	8	8	–	25	8

[a] Socket protrusion and dislocation.
[b] Stem fracture.
[c] Figs 1, 2 and 4.

bone cement wear was performed by counting the zirconium oxide particles visible in HE-Sections.

The grading parameters (grade 1–10) were defined in the following manner:

1. Small granular foreign material (bone cement and Al_2O_3 wear particles)

Grade 1–2: Average amount of 100 particles per visual field (HPF) (HPF = high power field: diameter 0.45 mm)
Grade 3–4: 100–200 particles per HPF
Grade 5–6: 0.5–5 particles per histiocyte (average amount)
Grade 7–8: 6–10 particles per histiocyte
Grade 9–10: more than 10 particles per histiocyte

2. Villous transformation of the synovial tissue

Grade 1–2: Several villous structures at the synovial surface (max. 20%)
Grade 3–4: Villous transformation of 20–40% of the synovial surface
Grade 5–6: Villous transformation of 40–60% of the synovial surface
Grade 7–8: Villous transformation of 60–80% of the synovial surface
Grade 9–10: Nearly total villous transformation of the synovial surface

3. Necroses

Grade 1–2: Up to 15% necrotic tissue in the synovial section
Grade 3–4: 15–30% necrotic tissue in the synovial section
Grade 5–5: 30–45% necrotic tissue in the synovial section
Grade 7–8: 45–60% necrotic tissue in the synovial section
Grade 9–10: More than 60% necrotic tissue in the synovial section

4. Scar-like fibrosis

Grade 1–2: Up to 15% scar-like fibrosis in the synovial section
Grade 3–4: 15–30% scar-like fibrosis in the synovial section
Grade 5–6: 30–45% scar-like fibrosis in the synovial section
Grade 7–8: 45–60% scar-like fibrosis in the synovial section
Grade 9–10: More than 60% scar-like fibrosis in the synovial section

The thickness of synovial tissue was measured with an eye-piece graticule at 12 defined points per quadrant of the pseudocapsule.

The abrasion rates are measured at the Cerasive company, former Feldmühle AG, Plochingen.

3. Results

Ceramic wear particles were found in all of the newly formed joint capsules and soft tissue membranes around the loosened components. In 21% of cases we found small amounts of ceramic wear particles; in 29% moderate ceramic wear; and in 50%, high-grade ceramic wear.

In cemented protheses comparable amounts of bone cement wear were seen. Zirconium oxide particles (contrast medium of the bone cement), which served as a marker for the amount of bone cement wear, can be distinguished from ceramic wear particles by their round configuration and mainly smaller diameter (about 0.5 μm). Ceramic fragments appear as sharp-edged polygonal yellow-brown particles up to 5 μm diameter. All smaller granular wear particles are seen predominantly within the histologic appearance of the pseudocapsules, and soft tissue membranes at the bone–cement interface were characterized by infiltrates of histiocytes rich in cytoplasm. In cases with larger amounts of bone cement wear degenerative changes and single cell necroses were found.

TABLE II Ceramic and bone cement wear and ceramic abrasion of six autopsy cases with lifetime functioning implants

Patient	Years after surgery	Ceramic wear grade	Cement wear grade	Abrasion ball (μm)	Abrasion socket (μm)
1	7	0	2	–	3
2[a]	8	0	8	–	–
3	7	0	10	15	12
4	8	4	8	25	3
5	8	6	8	135	5
6[b]	9	8	2	–	–

[a] Fig. 4.
[b] Fig. 6.

TABLE III Autopsy specimens with prostheses > 5 years in situ

	Material combination		
	Cer–Cer 6 specimens	Cer–PE 7 specimens	Metal–PE 17 specimens
Synovial layer	2.1 mm	2.5 mm	3, 1 mm
Villous transformation graded	1, 5	3, 9	6, 0
Histiocytes graded	6, 0	6, 9	7, 4
Necroses graded	3, 3	8, 1	7, 5
Fibroses graded	7, 5	8, 0	7, 9

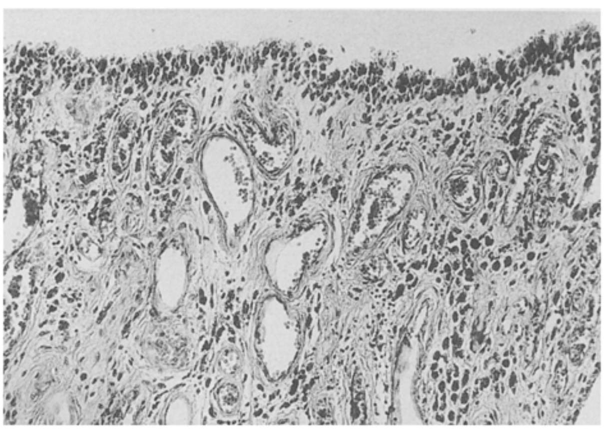

Figure 1 Revision case 2. Synovial tissue with high-grade ceramic and bone cement wear. Extended infiltrates of histiocytes, rich in cytoplasm (dark stained) containing wear particles. Top: proliferating synovial lining cells (HE: ×160).

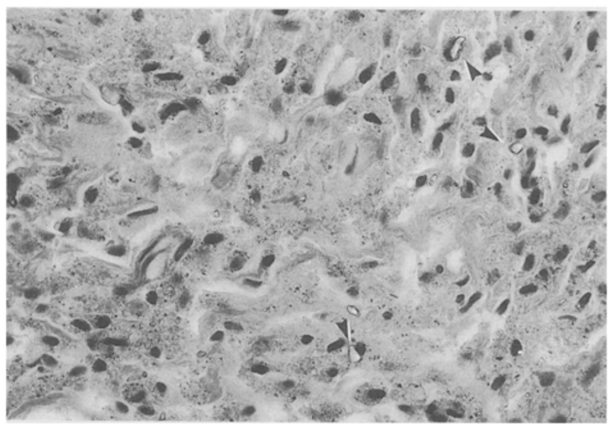

Figure 2 Revision case 2. Histiocytes with Al_2O_3 and zirconium oxide wear. Polygonal sharply edged, mainly larger, Al_2O_3 particles besides smaller round zirconium oxide particles (HE: ×470).

These alterations were not seen within the tissues surrounding non-cemented prostheses. This difference could be an expression of the superior biocompatibility of the ceramic wear particles in comparison to bone cement and metallic wear, as Al_2O_3 wear particles release no toxic substances.

Other tissue changes in the form of marked villous transformation of the pseudocapsule, extended necroses and scar-like fibrosis, fibrin exsudates, scattered lymphocytic infiltrates and microhaemorrhages were found in nearly all cases.

In contrast to the findings in revision cases the tissue specimens from autopsy cases with lifetime stable prostheses revealed in only half of the cases ceramic wear; in two cases moderate and in one case high-grade ceramic wear was found (Table II, Figs 3 and 5).

Macroscopically as well as histogically the synovial tissue showed less villous transformation in comparison to prostheses with other material combinations. The synovial layer appeared thinner. Necroses and villous transformations are reduced significantly in the Al_2O_3–Al_2O_3 cases. The differences appeared more pronounced in the autopsy cases. However, a smoother surface and thinner newly formed capsule was seen macroscopically during revision surgery too.

With respect to bone cement wear and other histological alterations, no differences between Al_2O_3–Al_2O_3 combinations and Al_2O_3– polyethylene combinations were found. The greater reactive inflammatory changes in cases with Al_2O_3–polyethylene combinations, and especially in metal–polyethylene combinations, are mainly due to foreign body reactions around polyethylene wear particles, which appeared in all pseudocapsules including the autopsy cases with life-

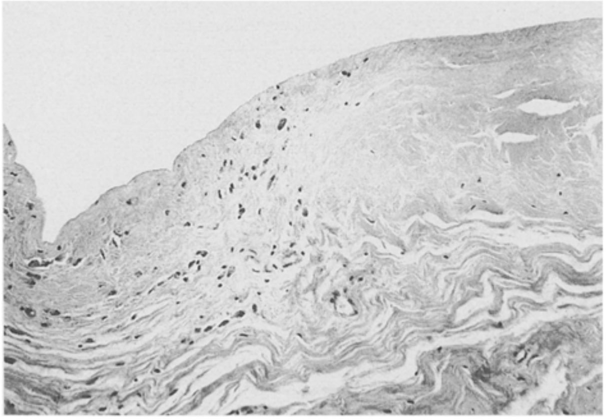

Figure 3 Autopsy case 2. Pseudocapsule with synovial tissue. Right: Degene rated hyalinized connective tissue, no ceramic wear (HE: × 150).

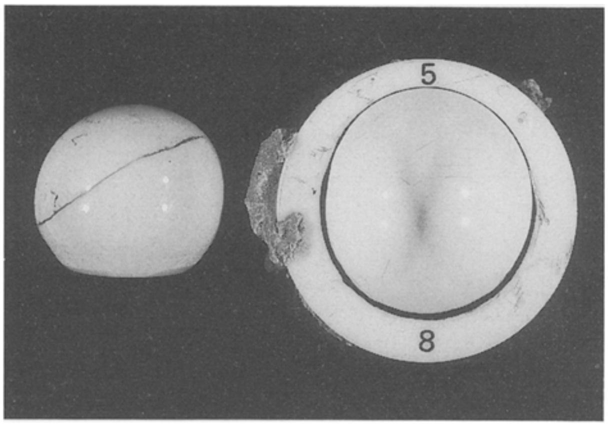

Figure 4 Revision case 2, 8 years *in situ*, dislocated and loosened; shows the greatest ceramic wear in the revision group (Table I). The width of the socket rim is segmentally reduced from 8 mm to 5 mm.

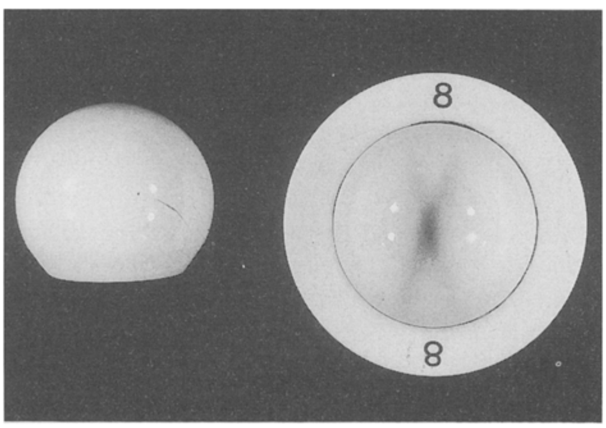

Figure 5 Autopsy case 6, 9 years (lifetime) without loosening *in situ*; shows the most ceramic wear in the autopsy group (Table II).

time stable prostheses. Ceramic wear was never seen in Al_2O_3–polyethylene combinations. Especially high polyethylene wear rates can be provoked by larger bone cement particles, if they get between the gliding surfaces.

4. Discussion

Whereas hip prostheses with Al_2O_3–Al_2O_3 combinations showed excellent laboratory results, clinical results seemed to be variable. Many investigations have shown predominantly good clinical results [8–14]. Some authors, however, reported a higher rate of ceramic components from postheses retrieved at revision surgery [15]; excessive wear is initiated when ceramic grains are torn from the high-gloss polished articular surfaces. Other authors have viewed this high wear rate as a consequence of loosening [9, 16].

5. Conclusions

The results of this study showed that in cases with lifetime stable prostheses, considerably less wear particles were found, confirming the hypothesis that high wear rate in loosened prostheses develops mainly as a consequence of loosening, sometimes with dislocation of the cup. Another precondition for the appearance of ceramic wear is malpositioning of the socket, steep position leading to dry friction of the socket rim [9, 16]. Further, fracture of the ceramic components and protrusion of the screwed conical socket are of importance.

Missed safety aspects in manufacturing and in the intraoperative handling of the fixation of ceramic balls on the conical metal stems, and poor design features are responsible for breakage of the balls [2, 3, 7].

To avoid the problems of the Al_2O_3–Al_2O_3 combination, we favour modular systems with cementless biologically fixation by spongious structured surfaces of the implants [18].

References

1. E. DÖRRE, H. BEUTLER and D. GEDLDIG, *Arch. Orthop. Trauma. Surg.* **83** (1975) 269.
2. G. HEIMKE, W. BEISLER, H. V. ANDRIAN-WERBURG, P. GRISS and B. KREMPIN, *Ber. Dtsch. Keram. Ges.* **50** (1973) 4.
3. G. HEIMKE, P. GRISS, H. V. ANDRIAN-WERBURG and B. KREMPIN, *Arch. Orthop. Unfallchir.* **78** (1974) 216.
4. J. HINTERBERG and M. UNGETHÜM, *ibid.* **116** (1978) 294.
5. M. SEMLITSCH, M. LEHMANNN, H. WEBER, E. DÖRRE and H. G. WILLERT, *Med. Orthop. Tech.* **5** (1976) 152.
6. M. SEMLITSCH, M. LEHMANN, H. WEBER, E. DÖRRE and H. G. WILLERT, *J. Biomed. Mater. Res.* **11** (1977) 537.
7. I. C. CLARKE, J. M. DORLOT, J. GRAHAM, D. J. LEVINE, H. OONISHI, J. RIEU, D. SCHWARTZ, L. SEDEL, A. TONI and J. ZITELLI, *Ann. Ny. Acad. Sci.* **523** (1988) 292.
8. P. GRISS and G. HEIMKE, *ibid.* **98** (1981) 157.
9. J. HEISEL and E. SCHMITT, *Z. Orthop.* **125** (1987) 480.
10. H. MITTELMEIER and G. HARMS, *ibid.* **117** (1979) 478.
11. H. MITTELMEIER and J. HARMS, *Mschr. Unfallheilk.* **83** (1979) 67.
12. E. B. RISKA, *Clin. Orthop.* **297** (1993) 87.
13. L. SEDEL, L. KERBOULL, P. CHIRSTEL, A. MEUNIER and J. WITVOET, *J. Bone Jt Surg.* **72B** (1990) 658.
14. D. STOCK, E. D. DIEZEMANN and J. GOTTSTEIN, *Arch. Orthop. Trauma. Surg.* **97** (1980) 7.

15. W. PLITZ, A. WALTER and M. JÄGER, *ibid.* **122** (1984) 299.
16. H. MITTELMEIER, W. SITZ and U. HANSER, *Z. Orthop.* **120** (1982), 487.
17. G. HEIMKE, in "Bioceramics", Vol. 6, Proceedings of the Sixth International Symposium on Ceramics in Medicine, Philadelphia, USA, November 1983, edited by P. Duchenne and D. Christiansen (Butterworth–Heinemann, Oxford, 1993) pp. 283–288.
18. O. SPRICK and P. DUFEK, *Z. Orthop.* **131** (1993) 524.
19. M. UNGETHÜM and H. J. REFIOR, *Arch. Orthop. Unfallchir.* **79** (1974) 97.