3.8 Metal on Metal in Resurfacing Arthroplasty: Risks or Benefits?

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Introduction

At the beginning of hip endoprosthetics was the substitution of destroyed cartilage by biologigal or artificial materials. However, successful results were only achieved after the introduction of abrasion-resistant materials in combination with exactly matching differences of diameter (radial clearance) of head and socket. The cobalt-based alloy Vitallium[R] which had been introduced into medical therapy by dentists in 1932 was used by Smith-Petersen [1, 2] to create the world's first hemiprosthesis (1937) available on the market. The first total hip replacement was implanted by Wiles in London, who used a metal on metal joint made of stainless steel. In the course of the development of arthroplasty and after the introduction of bone cement, the successful period of THR began. Despite the excellent long-term results achieved for metal on metal prostheses (McKee-Farrar [10], Ring) which have been implanted since the sixties, hard on soft material configurations as specified by Charnley for his Low Friction Arthroplasty have been used at an increasing extent since the mid-seventies. The reasons for this were the excellent initial results obtained from the use of such prostheses. Apart from that, abrasion and loosening of acetabular cups due to equatorial jamming had occurred in some metal on metal prostheses in which the radial clearance provided for had been inappropriate. Moreover, there had been doubts in respect of possible allergic reactions and the possibility of carcinogenic effects of the metal particles at that time already [1]. The triumphant clinical advance of THRs using metal femoral heads and plastic acetabular cups continued until the problem of polyethylene abrasion and the destruction of bone induced by particle debris occurred and required new approaches to be developed [5]. This "particle disease" stopped, either, new attempts of resurfacing arthroplasty using a metal cap which was placed on the preserved bone of the femoral head, and a thin polyethylene cup, which had been rediscovered by Wagner and other authors.

For reintroduction of the metal on metal prostheses in 1988, the long-term results observed for McKee-Farrar and Ring prostheses which meanwhile had been published were referred to [10]. Weber propagated the use of a modular component system consisting of a 28mm femoral head and a corresponding metal cup [18], and after more than 150,000 implantations which had been carried out worldwide in more than 15 years it can be stated that the theoretical fears in respect of allergic or malignant effects have not been confirmed [4].
McMinn [12] caused the total resurfacing arthroplasty to be developed further and introduced it into clinical application as metal on metal bearing in 1991 (fig. 1 and 2). The results obtained seem to confirm his theory: the clinical results obtained have been excellent, the implant-specific risk is low, luxation safety is much higher than with smaller femoral heads, and there haven't been any side effects caused by stress shielding observed for resurfacing prostheses compared to stem-type prostheses. The preservation of the joint's natural biomechanics and

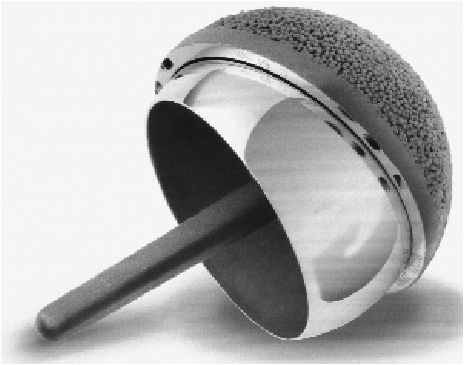

Figure 1:
Resurfacing prosthesis acc. to McMinn (picture supplied by manufacturer).

Figure 2:
Radiograph of a resurfacing prosthesis acc. to McMinn.

the proprioceptive functions of the proximal femur make this implant particularly suited for active patients [12, 13]. Apart from that, the resurfacing prosthesis according to McMinn and the variants thereof stand out for their comparably good reviseability in case of failure of the implantation.

Design conditions to be complied with by resurfacing prostheses

There are high demands placed on the structural design of double-cup prostheses: only materials featuring high hardness and resistance to abrasion must be used, and the production process must guarantee a high degree of sphericity including specified radial clearances for polar high conformity load transition. In this respect, the bioinert alumina-based ceramics would be suited perfectly. Wagner had used a ceramic femoral head before (fig. 3), but so far it has not been possible to manufacture suitable cups with corresponding rear surface design to enable the cup's integration into the acetabulum as was stated by leading ceramics manufacturers.

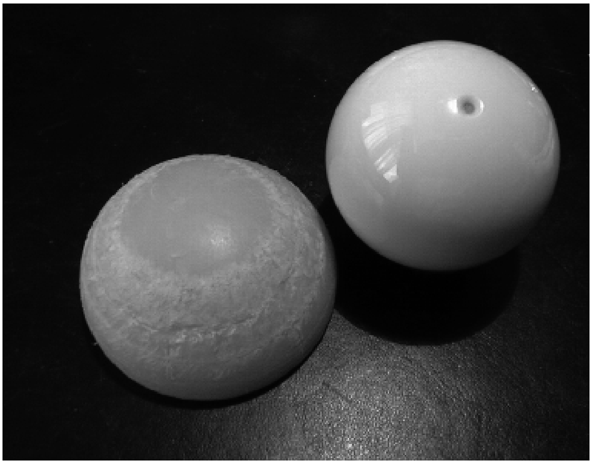

Figure 3:
Explanted resurfacing prosthesis acc. to Wagner with ceramic component.

The use of cobalt-based alloys with a carbide content of more than 3% ensures low surface wear under the geometric conditions mentioned above [3]. The relatively low speed of motion of the corresponding implant surfaces will not allow for reliable lubricating fluid-films to establish on the hydrophobe metal surfaces, and hence strain-related metal abrasion especially in the run-in phase cannot be eliminated.

Resurfacing prostheses are made of a cobalt-based alloy (residual), chromium (26.5 – 30%), molybdenum (4.5 – 7.0%), nickel (2.5%) and minor quantities of iron (<1%), manganese (<1%) and silicon (<1%), and in addition contain carbon at a rate of approx. 0.25 - 0.35% to enhance the material's hardness (alloy type HS 21). After the casting process, hard block carbides consisting of molybdenum, chromium and carbon are produced during congelation as a result of the carbon content, the total formula of which is $M_{23}C_6$ (fig. 4 from [15]). Although it is possible to enhance the material's strength by way of secondary thermal treatment and/or forging processes, this will also cause changes in the structure of the carbides (more refined distribution, smaller grain size of different structure (M_7C_3)).

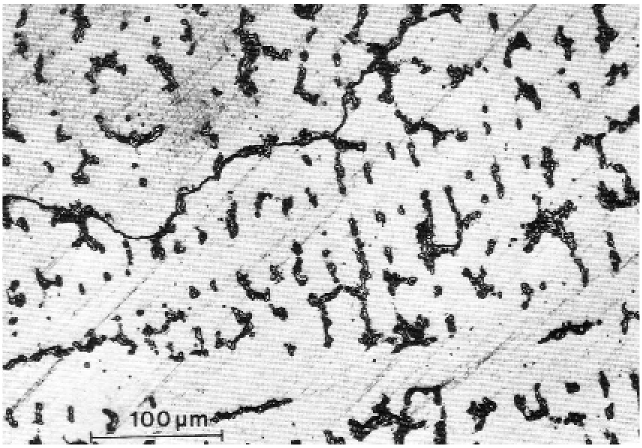

Figure 4:
"As cast" surface structure of the cast alloy HS21 from [15].

The majority of manufacturers of metal on metal resurfacing prostheses use strength-enhancing processes such as solution treatment, hot isostatic pressing or forging while others restrain from any kind of heat treatment for the sake of preservation of the block carbides [12, 16]. The author shall not go into detail on this discussion since so far there haven't been sufficient quantities of independent comparative data available.

However, all of the products mentioned before have one thing in common: fretting corrosion and loss of material will be incurred especially in the run-in phase as a result of insufficient establishment of lubricating fluid films. As a result, the carbide peaks break and the grain tear out will be available in the organism as abrasion particles (fretting). The material's high resistance to abrasion will then be ensured by the flattened block carbides which are located slightly above the surface. The quantity of metal particles is determined either as abrasion thickness or by way of volumetric measurement. For Metasul[R] for instance, an abrasion rate of 25 µm/year is reported by the manufacturer for the run-in phase, and of approx. 5 µm/year for the time after the run-in phase [4] (values determined by way of simulator testing), whereas an abrasion rate of approx. 3 to 6 µm/year is indicated for the large surfaces of resurfacing prostheses for which correspondingly higher speeds of motion are incurred and hence the establishment of lubricating films is improved [3]. In the run-in phase, a temporary "squeaking noise" is sometimes reported by the patients for instance when they climb up stairs slowly. In the aggressive body environment, abrasion is subject to chemical reactions (contact corrosion) as far as there is no possibility of repassivation of the surfaces.

Hence the cobalt and chromium levels in the blood are especially high during the run-in phase but also later on depending on the strain level. Jacobs [8] reported an increase of the chromium level in the serum by factor 9, while the cobalt level ranged below the detection limit. The cobalt and chromium levels available in the whole blood after implantation of 28 mm metal femoral heads in combination with corresponding metal cups were investigated by Lhotka et al. [9] who in the follow-up examinations found that the blood levels of both metals were increased significantly by up to factor 10, with the whole-blood examinations also considering the particles stored in the intracellular space.

However, one of the substantial demands placed on implants is that "the tissue and organs of the implant recipient must not be damaged in any way by either the implant material as such, nor by any particles which may be released from it" (Ungethüm 1984 [15]).

Potential hazards caused by metal abrasion

Carcinogenic effects have been detected for a multitude of substances. Tumours were for instance provoqued in rodents by the implantation of solid bodies or dust particles of gold, silver, platinum, nickel, titanium and also of cobalt-based alloys [7,11]. Since the carcinogenic effect of cobalt and of chromium as a result of vapour inhalation has been detected in man, the undesirable side effects of such implant materials have been discussed permanently since the sixties.

Cobalt is considered an essential trace element and is also contained in vitamin B_{12}. It is stored mainly in the liver and discharged via the kidneys or the intestines. Nutritional over dosage has been observed in beer drinkers and was found to cause cardiomyopathy. Hence the use of cobalt salts as foam stabilizers in beer production was prohibited. There hasn't been any carcinogenic effect detected as a result of oral uptake of cobalt compounds. So far, it has not been possible to define any limits for cobalt levels in the blood for reasons of the data available [6, 7].

Natural chromium compounds usually are trivalent and do not have any significant biological effect. The hexavalent chromium compounds seem to be much more questionable but usually are observed in connection with technical production processes only (metal vapours in foundries). Intoxications are extremely rare. In the animal experiments, mutagenic effects were detected as a result of administration of hexavalent chromium salts [6, 7]. However, any possible oxidation processes of chromium-containing corrosion particles in the body will involve the relatively harmless trivalent compounds only.

Nickel was found to provoque malignant tumours in rodents as a result of parenteral administration. Such effect has not been observed for alloys with low nickel content [7]. There aren't any relevant toxicological data available for molybdenum, iron or any other residual elements [7].

It is hard to assess the problem of allergological effects since the epicutan tests do not allow for conclusions to be made automatically as far as the reactions in the joint area are concerned. On the other hand, any surgical tools used in operations will leave behind undesired metal traces (which can be detected either histochemically or as foreign bodies/susceptibility artefacts in nuclear magnetic tomography).

Assessment of the risks posed by surgical implants made of cobalt-based materials:

The linear abrasion rate exhibited by metal on metal prostheses is lower than the one observed for ceramic or metal on polyethylene systems by the power of ten, but is almost twice as high as the one offered by ceramics on ceramics systems. Apart from that, metal abrasion will not cause osteolysis like PE debris, and hence this combination seems to be perfectly suited for use in arthroplasty. However, metal abrasion particles are frequently discussed in connection with the occurrence of allergic reactions and the risk of cancer. In the beginning, high abrasion levels usually will be detected, which even after lapse of the run-in phase cause increased chromium concentrations in the serum and increased chromium and cobalt discharge rates. The things which seem to be more alarming are the results obtained from whole-blood measurements and the detection of metal particles in tissues located far away from the prosthesis. It can be concluded from the published data so far that particles are released from the alloys as a result of fretting corrosion, and that such particles remain stable for reasons of the alloy's position in the electrochemical series. Only a minor fraction will be susceptible to contact corrosion as a result of which it will enter into chemical reactions. The measurements did not yield any significant increase in serum cobalt concentrations. Apart from that, cobalt represents an indispensable element of the human metabolism. Although the chromium levels in the serum were found to have increased, there weren't any toxic levels observed.

Also, the fear that metal implants may cause malignant tumours, which has been expressed time and again, has not been confirmed by long-term studies. The manufacturers of such implants are right in pointing out to their own investigations [4, 14]. An increase in the tumour risk as a result of metal abrasion from metal on metal THRs has not been confirmed neither by the data of the International Agency for Research on Cancer [7] nor by the studies conducted by Visuri et al. which covered a period of 15 years [17]. Also, there aren't any genetic defects to be expected as a result of the measured serum levels [6]. With today's state of knowledge, metal abrasion particles released from resurfacing prostheses made of cobalt-based alloys will not pose any special risk not even in younger patients (also including female patients capable of childbearing). On the other hand, there are excellent clinical results obtained from the implantation of resurfacing prostheses (fig. 5). Conservation of the proximal femur also offers long-term benefits particularly to younger patients since the possibility of revision offered by such prostheses in the case of complications is much better than the one offered by conventional stem-type prostheses. As long as there aren't any better materials available for the purpose of resurfacing, the theoretical risk posed by metal abrasion can be disregarded in view of the clinical benefits offered by resurfacing prostheses since there haven't been any harmful effects of metal abrasion detected so far.

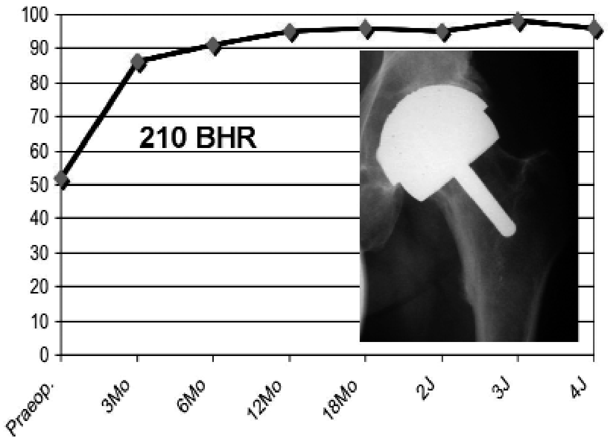

Figure 5:
Curve of the Harris-Hip-Score subsequent to implantation of a metal on metal resurfacing prosthesis.

References

1. Amstutz, HC, P Grigoris (1996) Metal on Metal Bearings in Hip Arthroplasty. Clin Orthop 329S, S11-S34
2. Anonym (o.J.) The Century in Orthopedics. www.slackinc.com/bone/ortoday/200001/time.pdf
3. Band T (2003) Microstructure and Metallurgy for Metal on Metal Bearings. The International Resurfacing Forum, June 13th –15th, Malaga
4. Centerpulse (o.J) MetasulR Metal Ion Studies. www.centerpulse.com
5. Elke R (2001) Partikelkrankheit. Orthopäde 30, 258 – 265
6. Expert Group on Vitamins and Minerals (2002) Review of Cobalt/Chromium www.foodstandards.gov.uk

7. International Agency for Research on Cancer (1999) IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Surgical Implants and other Foreign Bodies (Vol. 74) http://monographs.iarc.fr/htdocs/monographs/vol74/implants.html
8. Jacobs JJ, AK Doorn, et al. (1996) Cobalt and Chromium Concentrations in Patients with Metal-on-Metal total Hip Replacements. 5th World Biomaterial Congress, June 2, 1996, Toronto, 918
9. Lhotka C, J Steffan et al. (2000) Determination of Cobalt and Chromium Blood Concentrations in Patients with different Metal-Metal Pairings. AAOS Meeting Orlando, March 17, 2000
10. Jacobsson SA, D Krister, O Wahlström (1996) 20-Year Results of McKee-Farrar Versus Charnley Prosthesis. Cin Orthop 329S, S60-S68
11. Maltoni C, F Minardi,, JF Holland (o.J.) Physical Carcinogens. www.cancer.org
12. McMinn DJW (2003) Die Entwicklung des Metall/Metall-Hüftoberflächenersatzes. Hip International 13 (Suppl. 2)
13. National Institute for Clinical Excellence (2002) Guidance on the use of metal on metal hip resurfacing arthroplasty. Technology Appraisal Guidance No 44. www.nice.org.uk
14. SulzerMedica (1999) Research and Analysis News: Total Joint Replacement and Cancer. Firmenmitteilung
15. Ungethüm, M, W Winkler-Gnieweck (1984) Metallische Werkstoffe in der Orthopädie und Unfallchirurgie. Thieme, Stuttgart
16. Varano R, JD Bobyn, S Yue (2003) Does Alloy Heat Treatment Influence Metal-on-Metal Wear? Orthop Res Soc Poster #1399 49th Annual Meeting
17. Visuri T, et al. (1996) Cancer Risk After Metal on Metal and Polyethylene on Metal Total Hip Arthroplasty. Clin Orthop 329S, S280-9
18. Weber, BG (1992) Metall-Metall-Totalprothese des Hüftgelenkes: Zurück in die Zukunft. Z Orthop 130, 306-309