ORIGINAL PAPER
PŮVODNÍ PRÁCE

Serum-Cobalt Levels with Metal-on-Metal Bearings in the Cement-Free Total Hip Arthroplasty Results Covering Two Years; Prospective Study

Sérové hladiny kobaltu u bezcementových totálních náhrad kyčelního kloubu s párováním kov-kov; výsledky dvouleté prospektivní studie

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ABSTRACT

PURPOSE OF THE STUDY

Total hip arthroplasty increases the use of alternate bearings to prevent polyethylene wear as the number of younger and more active patients has drastically risen.

We carried out a prospective randomized study, to assess and compare clinical results and radiological changes, serum-cobalt- and serum-aluminium-levels when metal-on-metal and ceramic-on-ceramic bearings are applicated.

MATERIAL AND METHODS

After giving informed consent 80 consecutive patients were included in this prospective randomized study. They were randomly assigned to receive either a metal-on-metal or a ceramic-on-ceramic bearing in their total hip replacement. Eligible were patients with a primary coxarthrosis or an avascular necrosis of the head of femur. Of the 80 patients 54 were females and 26 males. 42 patients were randomized to a metal-on-metal bearing and 38 patients were randomized to a ceramic-on-ceramic bearing. The average patient-age was 65,8 years and the mean body mass index was 27,7 at the time of operation. Surgery was performed through a transgluteal approach in supine position under general or spinal anaesthesia. A forged conical threaded acetabular component made of titanium-aluminium-niobium alloy was used in all patients. The metal inlays and the 28 mm metal heads were made of Co-28Cr-6Mo alloy with a carbon content of 0,2%. The ceramic inlays and the 28 mm ceramic heads are Al2O3 implants. We used as femoral component a conical rectangular stem of a titanium-aluminium-niobium alloy. Cup and stem werde implanted cementfree.

Clinical data werde obtained at a follow up at a minimum of two years after implantation.

Patients were assessed with the Harris Hip Score and the University of California at Los Angeles activity scale. 72 of the 80 patients could be explored clinically and radiologically.

RESULTS

The 2 year follow up check showed clinically and radiologically no difference between the two groups. The median Harris HipScore was above 90 points and the UCLA score was about 7 points. The medium serum-cobalt level was in the metal-on-metal group about 1.2µg/L and in the ceramic-on-ceramic group below the detection limit. The medium serum aluminium level showed values of 1.2 respectively 1.3 µg/L. The luminescencies in the metal-on-metal group were increased, but all components of the prosthesis could be regarded as stable.

DISCUSSION

It was the goal of our prospective study to compare clinical and radiological results of hip arthroplasty in metal-on-metal and ceramic-on-ceramic bearings and assess the serum-cobalt and the serum-aluminium levels. The socalled “biocorrosion” is still a high risk element for loosening of implants because of aseptic osteolysis. A higher release of polyethylene and metal particles is triggered, which leads to a slow but continuous process of inflammation.

Apart from the debris also metal ions in a higher concentration are released, so that we could detect after some years in patients with artificial implants a higher level of metal in blood and urine. So far we did not recognize any carcinogenity or the appearance of renal disorders, or other mutagene effects in our patients. We could also not observe any fractures in ceramic implants. We are convinced that short time and intermediate reports are necessary, although final judgement can only be based on long term data.

CONCLUSION

Our prospective randomized study showed after two years no difference clinically between the two groups of metal-on-metal and ceramic-on-ceramic bearings with total endoprostheses of the hip. Although medium serum-cobalt level in the metal-on-metal group with 1,2µ/L is a significant higher value, whereas it lies in the ceramic-on-ceramic group below the detectable limit.

Key words: total endoprosthesis of the hip, metal-on-metal bearing, serum-cobalt level, metallosis

INTRODUCTION

Total hip arthroplasty is without doubt one of the most successful methods in modern medicine. Excellent survival rates have been reported of cemented as well as cement-free implants. But the most important statement made in all these publications is that of the rather low rate of revision of the stem after an average of 10 years post operation (13, 14, 15, 16, 36, 37).

Excessive polyethylene wear compromises the longevity of total endoprostheses and is the main reason for revision. Some reports even mention a socalled "Polyethylene-disease" accounting for up to 40% of all reoperations (14, 26, 36, 37). Increase of life expectancy and also of the number of total endoprostheses of the hip joint in younger and more active patients call for the reduction of wear. Quantification of polyethylene wear and dissemination of polyethylene particles into the periprosthetic tissue of the hip joint have been described by some renowned authors (26, 28, 31, 36). Some providers have therefore in the last years next to their Standard-Polyethylene also produced a highly gauzed Polyethylene in order to minimize wear. Other alternate bearings like metal-on-metal and ceramic-on-ceramic could also prevent polyethylene wear.

Explanted metal-on-metal articulations made of cobalt-chromium-molybdenum alloy have been shown to have extremely low wear rates (29), same as the ceramic-in-ceramic bearings (8). Metal-on-metal articulations in total hip arthroplasty were reintroduced in 1988 to reduce wear and osteolysis (35). Excellent intermediate and long-term results have been reported with such devices. The volumetric wear of metal-on-metal bearings is considerably less than that with polyethylene-on-ceramic (4, 16, 17).

When metal inlays and metal heads are used, a greater number of smaller particles are produced and an elevated concentration of metal ions in the serum of patients can be detected. Metal dissemination from such articulations has been related to carcinogensis (7, 33) and autoimmune and connective tissue diseases (30). Also a certain mutagenicity (10) and the cause of hypersensivities (7, 38) are discussed. 1970 the first ceramic-on-ceramic bearing was implanted in France (3). The results of a prospective randomized study comparing ceramic-ploethylene and cobalt-chromium-polyethylene in clinical checks showed no difference between both combinations.

Our study was conducted to compare the clinical outcome, radiographic appearance and serum cobalt and aluminium serum concentrations of hip patients, when metal-on-metal or ceramic-on-ceramic bearings were used.

The prospective randomized procedure should analyze probable differences between these two implant bearings.

MATERIAL AND METHODS

After giving informed consent 80 consecutive patients were included in this prospective randomized study. Approval of our ethics committee had been obtained. They were randomly assigned to receive either a metal-on-metal or a ceramic-on-ceramic bearing in their total hip replacement. Only patients with primary osteoarthritis or avascular necrosis of the femoral head were eligible for inclusion. Patients with other metal implants were excluded from the study. Of the 80 patients 54 were females and 26 males. 42 patients were randomized to a metal-on-metal bearing. 38 patients were randomized to a ceramic-on-ceramic bearing.

There were 14 males and 28 females in the metal-on-metal and 12 males and 26 females in the ceramic-on-ceramic group respectively. The preoperative diagnosis was coxarthrosis in 71 and avascular necrosis of the femoral head in 9 cases. The diagnoses were distributed in the metal-on-metal and the ceramic-on-ceramic group. The average patient-age was 65,8 years (range 34,3 to 81,8 years) and the mean body mass index was 27,7 (19,6 to 37,3) at the time of operation (Tab. 1). Surgery was performed through a transgluteal approach in supine position under general or spinal anaesthesia. A forged conical threaded acetabular component made of titanium-aluminium-niobium alloy (CSF-Gamma, Protasul® 100; Zimmer, Winterthur, Switzerland) was used in all patients. The cup was designed to accommodate either a metal inlay (Fig. 1) or a ceramic inlay without a polyethylene layer.

The metal inserts and 28 mm ball heads were made of Co-28Cr-6Mo alloy (Metasul; Zimmer) with a carbon content of 0.2%. The ceramic inserts and 28 mm ball heads were made of Al_2O_3 implants (Cerasul; CeramTec, Plochingen, Germany) with a grain size of 1.8 mm and a density of 3.98 g/cm^3. To ensure correct positioning of the cup an intraoperative x-ray was taken on a routine basis. We used as femoral component

Tab. 1. Groups, diagnoses, demographic data

	Metal-on-Metal n=42	**Ceramic-on Ceramic n=38**
Osteoarthritis	37	34
Avascular necrosis femoral head	5	4
Median patient age (range)	68.5 (34,3-77,9)	64.8 (44,1-81,8)
Median patient body mass index (range)	28.1 (19,6-37,3)	27.4 (21,6-36,7)

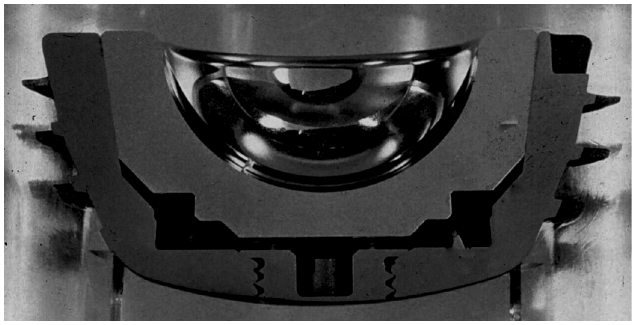


Fig. 1. Titanium cup with metal inlay.

a conical rectangular stem of titanium-aluminium-niobium alloy (Zweymüller-Alloclassic®, Protasul 100, Zimmer). Acetabular and femoral components were implanted cement free (Fig. 2, 3). Routine prophylaxis against heterotopic bone formation and routine antibiotic prophylaxis with cephalosporines was administered.

Clinical data were obtained at a follow up at a minimum of 2 years after implantation. Patients were assessed with the Harris Hip Score (21) and the University of California at Los Angeles activity scale (1). None of the 80 patients had died in the meantime, but 7 (5.6%) were lost to the follow up after two years. One patient could not be followed due to a stroke 22 months post operation, leaving 72 patients for clinical and radiological exploration.

Anteroposterior and lateral x-rays of the hip were taken at the follow up visit and analyzed for osteolytic lesions and building of seams on the implant-bone border (Gruen's zones and DeLee classification) (11, 18). The lateral opening of the acetabular component was measured in all implants. Pararticular ossifications were graded by the classification of Brooker (6).

Blood was drawn and transported using cobalt-free Vacutainer® needles and Vacutainer® glass tubes (Becton, Dickinson and Company, Franklin Lakes, NJ) without additives before surgery and then again 12 and 24 months after the operation. Serum-cobalt and serum-aluminium levels were determined using a 5100-ZK atomic absorption spectrometer (Perkin Elmer, Shelton, CT) at wavelengths of 242.5 respectively 309.3 nanometre. The detection limit for cobalt in serum was 0.3 µg/L and for aluminium 0.5 µg/L in our laboratory. The laboratory technician was always blinded to the analyses and has randomizedly analyzed.

Concentrations below the detection limit were defined as 0.15 µg/L for cobalt and 0.25 µg/L for aluminium to permit statistical evaluation.

RESULTS

The clinical outcome did not show differences between the groups at 2 years follow up. The median Harris Hip Score improved from 50.3 (range, 10.3-75.1 points) to 92 (range, 66.9-100 points) in the metal group and from 52.2 (range, 24.4-82.4 points) to 91.5% (range, 48.7-100 points) in the ceramic group (p=0.75). The UCLA activity score was 7 of 10 points in both groups.

Radiographically no differences were found as far as stability was concerned. After x-rays 69 patients, 37 in the metal group and 32 in the ceramic group were available for screening at minimum 2 years. In the metal-on-metal group radiolucent lines were seen in zone 1 (4x), 2 (1x), 8 (2x) and 14 (3x). In one particular case, graded at high risk the radiolucencies extended to zones 6 and 7. Two x-rays showed osteolytic lesions. One lesion in zone 1 and one in zone 4 (DeLee). In the ceramic group radiolucent lines were seen in zones 2 (1x), 8 (1x) and 14 (1x). In one case the radiolucent lines extended to zones 9 and 13. We recorded one osteolytic lesion in zone 8 (Gruen). The radiolucencies were double as high in the metal-on-metal group, although the stability of prostheses components were the same in both groups. Heterotope ossifications were identified in 21 of 69 x-rays, 11 cases in the metal-on-metal group and 10 cases in the ceramic-on-ceramic group. In 9 cases ossifications grade I were recorded, in further 9 cases ossifications grade II and in 2 cases grade III and in one case grade IV (Brooker). The median angle of cup abduction was 45º (range, 34.7°–54°) in the metal group and 42º (range, 34.5°-54°) in the ceramic group.

Fig. 2. Titanium prosthesis with metal inlay and metal head.

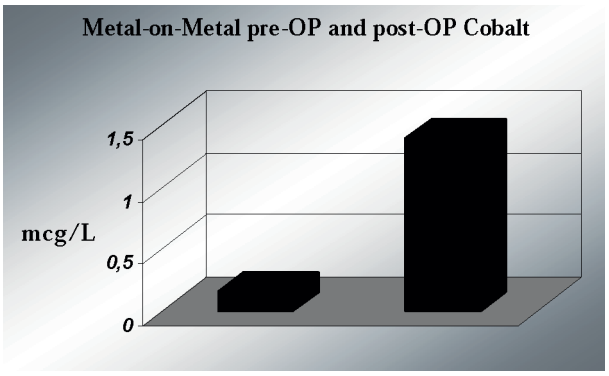
Fig. 3. Titanium hip with ceramic inlay and ceramic head.

Comparison of the serum metal levels yielded the expected results. In the **metal group** the **medium level of cobalt** at median 24.3 months after surgery was **1.2µg/L** (25% quantile: 0.8µg/L, 75% quantile: 2.7µg/L). In the ceramic group the median level of cobalt was 0.15µg/L (25% quantile: 0.15µg/L, 75% quantile: 0.4µg/L) (p<0.0001). The medium aluminium level was 1,2µg/L (0,9µg/L, 1,8µg/L) in the metal group and 1.3µg/L (1.0µg/L, 1.9µg/L) in the ceramic group (p=0.74). No correlation of the body mass index with serum metal levels could be detected. (cobalt: r = 0.03; aluminium: r = -0.15). The lateral opening of the acetabular component could not be shown in correlation with the serum levels of cobalt (r = 0.14) or aluminium (r = 0.03) (Tab. 2-5).

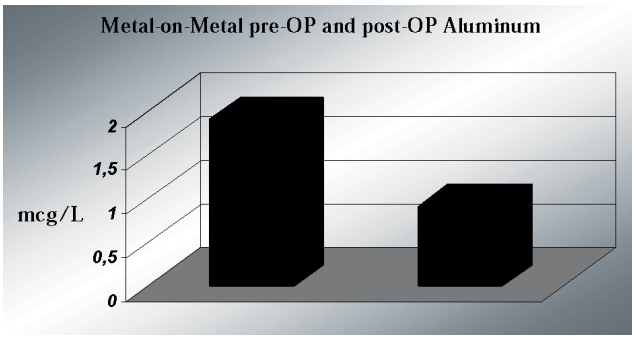
DISCUSSION

It was the aim of our prospective study to assess serum-cobalt und serum-aluminium levels with metal-on-metal and ceramic-on-ceramic bearings and to evaluate and compare clinicial and radiographic parameters. Although the quality of implants has improved largely nevertheless corrosion of osteosynthesis – and prosthesis implants in a physiological environment (biocorrosion) is still an element of high risk for the loosening of implants because of an aseptical osteolysis (7,

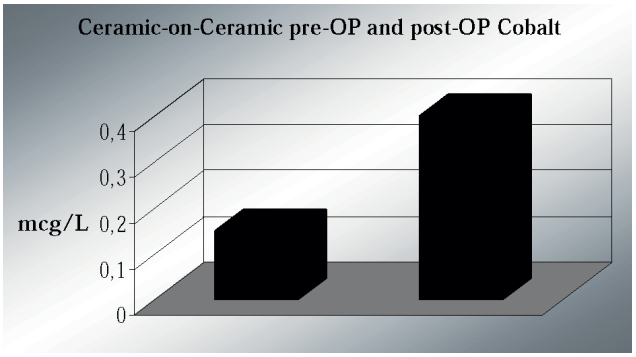
Tab. 2. Metal-on-metal pre-OP and post-OP cobalt



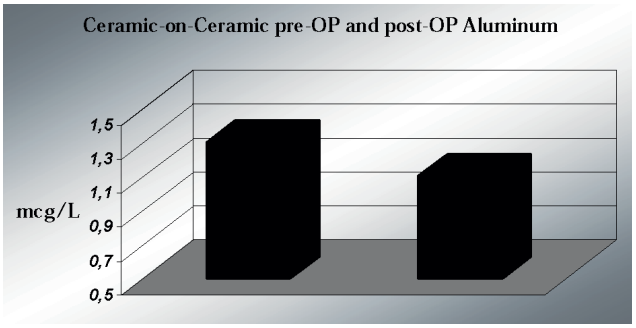
Tab. 3. Metal-on-metal pre-OP and post-OP aluminum



Tab. 4. Ceramic-on-ceramic pre-OP and post-OP cobalt



Tab. 5. Ceramic-on-ceramic pre-OP and post-OP aluminum



20). Through biocorrosion a greater number of polyethylene and metal-particles are released, which trigger a slow but continuous process of inflammation. This chronical inflammation leads to an increased osteolytical activity, the socalled "particle-disease". In addition these relea-sed metal-ions are a serious component of aseptical loosening of the prosthesis.

Metal implants for orthopaedics and accidential surgery are produced mainly from medicinical high grade steel or from pure titanium or titanium alloy. These implants contain furthermore trace elements like cobalt, chrome, aluminum, nickel and others.

Biocorrosion of orthopaedic implants is a rather slow process, taking various ways like mechanical wear, electrochemical reactions and cellular processes. Apart from the wear debris biocorrosion also increases the concentration of metal-ions, so that one finds increased metal levels in the blood and in urine of patients with artificial joints. Increased concentration of metal-ions are detected not only in blood and urine, but also in local tissue and in more distant organs (spleen, liver and lymphatic nodes) (24). Metal-ions play a central role in the complex cellular and molecular pathophysiological mechanism of aseptical loosening of titanium-implants. Metal-ions released by biocorrosion lead to preinflammatory reactions and differentiation and activation of osteolytical effective cells and cells of the peripheral immune system.

In our prospective randomized study we could after 2 years assess the serum cobalt and serum aluminium levels in 72 from a former total of 80 patients with ceramic-on-ceramic respectively metal-on-metal bearings. We are convinced that intermediate reports are necessary in order to identify early failure although a final judgement can only be based on long-term data. Very small particles released from metal-on-metal couplings and the biological response of the human body as well as increased concentrations of metal-ions in blood and urine continue to be a source of concern. Long-term follow up of contemporary metal-on-metal total hip replacement has been published recently (15, 16). Serum cobalt and serum aluminium levels did not differ from short and intermediate term follow up values (17). There was no evidence of an increase of malignancies or renal insufficiencies with our patients.

Ceramic-on-ceramic bearings have the clear advantage of the lowest wear rates of any bearing surface combinations and high biocompatibility (12). During the last years the thoughness of ceramic implants has considerably improved and the risk of fractures was minimized (19). There remains still a small risk of ceramic ruptures as in some publications recently reported (2, 9, 22, 25, 27, 31). Development of new ceramic implants, namely the socalled Bioloxdelta, will certainly help to prevent further ceramic ruptures. In a study covering 2.397 primary and 319 revisions of total endoprostheses of the hip joint (all with ceramic-on-ceramic bearing) the occurrence of squeaking has been reported in 17 cases. The authors believe that the reason for this lies is the inclination of the cup (5, 34). In another report this

squeaking phenomenon was explained with the breaking of one of the ceramic components (31). In our 2-year follow up we had no case of broken ceramic, the inclination of all our cups was registered with an angle of less than 55º.

Recently we reported about serum cobalt and serum aluminium levels with metal-on-metal and ceramic-on-ceramic total endoprostheses of the hip (17). The one-year results show no difference in serum aluminium levels in the metal-on-metal respectively the ceramic-on-ceramic group. But the serum cobalt level was significantly higher in the metal-on-metal group.

Our prospective randomized study showed in a follow up at average 2 years clinically no difference between the metal-on-metal and the ceramic-on-ceramic group. The serum aluminium level showed no difference in both groups, but the medium serum cobalt level was definitely increased for a value of 1.2 µg/L in the metal-on-metal group. Also the rate of radiolucencies was higher in the metal-on-metal group. There was no significant difference in the medium serum cobalt levels in the metal-on-metal group in a follow up after 2 years. No correlation between body mass index and increased serum metal levels could be found.

We have learned from many publications that long-term results with metal-on-metal bearings show a high percentage of metalloses (16, 32). In some distinct cases this aggressive metal debris may lead to catastrophic osteolyses and other systemic diseases (23).

CONCLUSION

We carried out a prospective randomized study with 80 patients, who had a total hip arthroplasty, in order to compare, after a time lapse of two years, the clinical and radiological results as well as the serum cobalt and serum aluminium levels in the metal-on-metal and the ceramic-on-ceramic groups.

Serum cobalt and serum aluminium levels werde defined by atomic-absorptions spectrometry. The medium Harris Hip Score of the 72 follow up patients read 96 points and the UCLA score 7 points. Clinically there was no difference between both groups. The medium **serum cobalt level** read **1,2µg/L** in the **metal-on-metal group** and was therefore significantly higher than in the other group. In the ceramic-on-ceramic group it was under the detection limit.

Within a given period we will present the 5-year results in order to evaluate intermediately the risks of the socalled metallosis with its typical signs of aseptic loosening.

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