Metal-on-metal total hip arthroplasty
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Men moet niet alles zeggen wat men weet, maar wèl alles weten wat men zegt.
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SUMMARY

Total hip arthroplasty (THA) is a very successful treatment for alleviating end-stage osteoarthritis of the hip. The rate of hip replacement surgery is increasing worldwide. Initially designed for elderly patients with crippling osteoarthritis, the procedure is now performed in young patients hoping to regain quality of life and physically demanding activities. With these young patients in mind, so-called alternative bearing materials were designed, for example ceramic-on-ceramic and metal-on-metal. These alternative bearings aim to increase the longevity of the prosthesis by reducing wear debris, osteolysis and aseptic loosening.

This thesis focuses on one of the alternative bearings above, namely metal-on-metal total hip arthroplasty. General aim of this thesis is to determine the clinical outcome and bone implications of metal-on-metal total hip arthroplasty. We formulated four research objectives.

1. To determine the mid and long term clinical outcome of cemented 28mm metal-on-metal THA in comparison with metal-on-polyethylene THA

We studied the clinical outcome of a cemented 28mm metal-on-metal THA. We performed a prospective randomized trial and used a cemented 28mm metal-on-polyethylene THA as a comparison. We found that both prostheses led to significant clinical improvements. At both 5-year (Chapter 3) and 10-year follow-up (Chapter 4), the clinical results did not differ between the two groups, nor did the radiological results. Five-year prosthetic survival was 97% for the metal-on-metal articulation and 99% for the metal-on-polyethylene articulation, with no significant difference. Ten-year survival was 96% and 97% respectively, with no statistically significant difference. Ten-year median serum cobalt and chromium ion levels were higher in the metal-on-metal group (1.1 resp. 1.0 μg/L, versus 0.5 resp. 0.5 μg/L).

Our clinical results and survival are comparable to, or even better than other cemented metal-on-metal THA series. Based on clinical results, radiological performance and prosthetic survival, the cemented 28mm metal-on-metal THA in our series performed well. We did not find any specific metal-on-metal bearing related adverse events, apart from one patient. To the existing literature, our study has added the only published randomized trial on metal-on-metal THA with 10 years follow-up.
2. To determine the short term clinical outcome and periprosthetic bone implications of cementless large femoral head metal-on-metal THA in comparison with metal-on-polyethylene THA

We designed a randomized clinical trial to assess clinical outcome and periprosthetic bone density changes around the acetabular component of a cementless large femoral head metal-on-metal THA (Chapter 5). We used a cementless 28mm metal-on-polyethylene THA as a comparison. At one year postoperatively, the clinical results were comparable. We further found retained acetabular bone density with the large head metal-on-metal THA (Chapter 6). Bone density had decreased over the year in 3 of 4 regions of interest in the metal-on-polyethylene patients, but was retained in all regions in the metal-on-metal patients. Bone density preservation was most pronounced superior to the cup. Although a follow-up of one year is very short, the finding of preservation of acetabular bone with a large head hard-on-hard bearing is novel, as far as we know. It will be essential to see what happens to the acetabular bone density after 5 or 10 years, when the effects of metal wear particles and ions start to take effect.

Bone density was not related to serum metal ion levels, in spite of elevated cobalt and chromium levels with the metal-on-metal bearings (1.7, resp. 2.1 μg/L). The ion levels were in line with the literature and maximum values were less than those mentioned as a risk for metallosis. A major task for future research is to establish predictive cut-offs for cobalt and chromium ion levels indicating possible future prosthetic failure.

3. To assess the effect of large femoral head THA on range of motion and to study heterotopic ossification as a factor that can compromise range of motion

We studied clinical range of motion (ROM) after large femoral head metal-on-metal THA (Chapter 7). Again, we used a 28mm metal-on-polyethylene THA for comparison, in a randomized trial. Hip simulator and biomechanical studies suggest that large femoral heads can prevent dislocation and lead to greater ROM, but the latter had not been shown clinically so far. We found that improvement in endorotation was greater after large (48mm) femoral head total hip arthroplasty, compared to 28mm THA (14 versus 7°). However, no differences in absolute postoperative endorotation or other ROM measures (flexion, extension, abduction or adduction) were found. Whether this small difference in endorotation improvement (7°) is clinically relevant is open to discussion. We estimate our measurement error to be around 4° based on our clinical method of ROM measurements.
Severe heterotopic ossifications (HO) may compromise hip range of motion. We studied the incidence of HO after cementless THA, with and without peroperative pulsed lavage (Chapter 8). We performed a matched-control study and found that the incidence of severe heterotopic ossification was lower in the patients treated with pulsed lavage (3% vs 17%).

4. To study the effects of cobalt and chromium ions on osteoblast cells in-vitro.

We investigated the effects of cobalt and chromium ions on osteoblast cells in-vitro (Chapter 9). We used clinically relevant concentrations of 1, 10 and 100 μg/L, and assessed cytotoxicity (cell number and cellular activity), oxidative stress, and the influence on the expression of bone turnover regulatory proteins receptor activator of nuclear factor kappaB ligand (RANKL) and osteoprotegerin (OPG). We found that higher ion concentrations were more toxic for osteoblasts, especially in the first 24 hours. Chromium was more toxic than cobalt, but both ions combined yielded greatest cell reduction. Cell activity decreased when chromium ion concentration increased.

Our results support available studies describing the detrimental influence of cobalt and chromium ions on osteoblasts. It was not known however, whether RANKL and OPG were involved in the effects of cobalt and chromium ions on osteoblasts. RANKL and OPG regulate the interplay between osteoblasts and osteoclasts and are key factors in periprosthetic osteolysis. Our results show reduced OPG to RANKL ratio’s at 72 hours and beyond, indicating net bone loss starting from Co 10 μg/L, Cr 1 μg/L and Co+Cr 1 μg/L. The oxidative stress response visible after 96 hours further strengthens these findings. On the other hand, high ion concentrations were not more osteolytic than low concentrations based on the OPG to RANKL ratios.

In conclusion, the main findings of our in-vitro study are that cobalt and chromium ions, in clinically relevant concentrations, reduce human osteoblast activity, lead to oxidative stress and reduce the OPG to RANKL ratio suggesting osteolysis. For clinical practice, this suggests that even in well functioning metal-on-metal implants local periprosthetic osteolytic reactions may be expected.
CONCLUSIONS

1. Cemented 28mm metal-on-metal THA is clinically not better, nor worse than cemented 28mm metal-on-polyethylene THA, at 5 and 10 years follow-up. Metal-on-metal THA induces elevated serum cobalt and chromium ion levels. These elevated levels do not necessarily lead to clinical consequences, but carry potential biological risks.

2. Cementless large femoral head metal-on-metal THA is clinically comparable to cementless 28mm metal-on-polyethylene THA, at 1 year follow-up. The large femoral head metal-on-metal THA can however preserve periprosthetic acetabular bone density.

3. Large femoral head THA has no clinically relevant benefits over 28mm THA in terms of range of motion. Peroperative pulsed lavage can prevent severe heterotopic ossifications after cementless THA.

4. Cobalt and chromium ions, in clinically relevant concentrations, reduce osteoblast activity in-vitro, lead to oxidative stress and alter the balance between receptor activator of nuclear factor kappaB ligand and osteoprotegerin consistent with osteolysis.