

Articles of Interest: Metal-on-Metal Articulation



This literature piece is meant to provide you and your surgeons with a comprehensive summary of eight articles written over the last 10 years on metal/metal THR devices. This summary includes articles from MDs, PhDs, Immunologists and other leading orthopedic experts. It covers a broad spectrum of products from many different manufacturers including Wright Medical Technology Inc, Depuy, Sulzer and Midland Medical Technologies. For full article reprints please contact your distributor.

SKIPOR, ANASTASIA, PAT CAMPBELL *et al*,

Metal Ion Levels in Patients with Metal on Metal Hip Replacements,

Society for Biomaterials 28th meeting transactions, 2002. (Wright Medical Technology Inc.)

- 16 patients with metal on metal total hip replacements (Perfecta® stems and Transcend® metal on metal acetabular system)
- 22 patients received total surface arthroplasty components
- In both groups the post-op metal ions count increased in both serum and urine from pre-op assessments
- 16-fold higher for surface arthroplasties and 23-fold higher for THA's
- The head size of the Surface replacements is 50% larger than the THA's but only one variable (serum chromium) had a significant increase in measurable amount of metal ions
- This means that even though you increased the surface area contact metal ion levels did not increase significantly
CONSERVE® PLUS is for investigational use only in the U.S.

JOSH JACOBS *et al*,

Cobalt and Chromium Concentrations in Patients with Metal on Metal Total hip replacements. *Clin Orthop*, S256-S263, 1996

(McMinn Surface Replacements and McKee-Farrar Metal on Metal THR)

- Primarily talks about the increased levels of Chromium and Cobalt concentrations found in patient's with McMinn surface replacements and McKee-Farrar metal on metal THA.
- 8 patients were tracked (followed) for 25 years on average
- McKee Farrar had 9-fold elevations in serum chromium, 35-fold increase in urine chromium and 3-fold increase in serum cobalt
- Surface replacements had 3-fold increase in serum chromium, 4-fold increase in urine chromium and 4-fold increase in serum cobalt.
- McKee-Farrar devices used 39 and 41mm heads
- There was no correlation between head size and serum Co, serum Cr, urinary Cr or total urinary Cr
- Michel *et al* reported serum Co levels in 10 patients with UHMWPE/CoCr (traditional implants) THR were comparable to the McKee-Farrar at 90 days

JOSH JACOBS *et al*,

Metal Release in Patient's who have had a Primary THA, *JBJS*, vol. 80-A October 1998. (Zimmer THA)

- Non randomized patients were selected according to surgeon preference
- Patients received Zimmer THR, with standard metal on poly articulating surfaces
- All prostheses were inserted between 1989-1993
- Patients with a well functioning titanium-alloy hip without cement had a 3.4-fold increase in the titanium alloy serum concentration. (36 months)
- The above finding was in contrast to the previous study by the authors in which only loose components showed a higher titanium concentration in the serum
- Patients in one Group (3) had a 4.5-fold increase in chromium levels in the serum at 36 months
- In summary, even patients without metal on metal articulating surfaces have higher metal ion counts

CHAN, FRANK W *et al*,

Wear and Lubrication of Metal-on-Metal Hip Implants, *Clin Orthop* Number 369, pp. 10-24, 1999. (OTTO AUFRANC AWARD)

(Depuy Metal on Metal THR)

- Hip simulator testing at Depuy/J&J.
 - 22 CoCr heads and liners
 - Accelerated wear occurred within the first 1 million cycles, followed by a marked decrease in wear
 - Volumetric wear at 3 million cycles was small, ranging from .15 to 2.56mm³
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- All 22 metal-on-metal implants had significantly less wear than the conventional metal-on-poly
- Study shows that the head-cup clearance is a very important factor with regards to wear
- Reduction in head-cup clearance may reduce wear (This is why Superfinishing is so important to Wright Medical Technology, Inc.)
- Average wear for 28mm heads examined by Medley *et al*, was 3.71mm^3 , which is 3 to 8 times greater than those examined in this study (The heads in the current study were Superfinished with greater tolerances-the heads in the Medley study were hand finished)

KARAMAT, L. *et al*,

Blood analysis for Trace Metals in Metal-on-Metal and Ceramic-on-Ceramic Bearings in Total Hip Arthroplasty

(Sulzer METASUL® Metal on Metal THA)

- 50 patients with cementless THA with titanium stems
- Patients received either ceramic on ceramic-Group A (CERASUL®) or metal on metal- Group B (METASUL®) implants
- All hips were implanted between 1997-1999
- Cobalt levels in Group A were .19 ng/ml, and .84ng/ml for Group B
- Chromium levels in Group A were .19ng/ml and .77ng/ml for Group B
- Quote from the authors, " All reported blood-cobalt levels in patients with metal on metal THA's are far below the cytotoxic level of 100,000 ug."

SCHMALZRIED, THOMAS P *et al*,

The Risk of Cancer Following Total Hip or Knee Arthroplasty, JBJS 2001.

- 25 total cases of malignant disease occurring in association with a total hip or knee prosthesis have been reported in English-language literature
- Based on this small number, there is no apparent relationship between total joint replacements and cancer
- The most important finding in this data search was the limitations of the available data. (We need more future studies)

WILLERT, H.G. *et al*, Histopathological Changes in Tissues Surrounding Metal/Metal Joints - Signs of Delayed Type

Hypersensitivity? (DTH) *World Tribology Forum in Arthroplasty*, 2002. (Sulzer Medica)

- Study looked at 14 different hip endoprotheses (2 cemented, 12 uncemented) - all metal on metal
- 3 Zweymuller stems with Ceramic heads and poly cups were the control group
- The study sought to determine what if any immunological reactions of metals (CoCr, Titanium) occurs near the implants
- It looked for specific antibodies, humoral responses, or a cell-mediated immunization.
- The periprosthetic tissues from the metal/metal joints showed only a mild foreign body reaction to the wear debris generated particles.
- The periprosthetic tissues with implants without cobalt, chromium or nickel contained large amounts of poly debris, therefore, the foreign body reaction was much more severe. There were extended granulomas, large numbers of giant cells, and a tendency for necrosis.
- A correlation between morphological signs of a hypersensitivity reaction and the necessity for a revision hip surgery could not be shown yet.

FARRAR, R. *et al*, Effect of Head Size and Diametrical Clearance on Wear Production of a New Metal-on-Metal Hip Prosthesis. (J&J-Depuy)

- The theory of joint lubrication suggests that the potential fluid film thickness increases as the clearance between the surfaces is reduced and as head size increases.
- As fluid film thickness increases, the lubrication tends towards full fluid film so that the contact and therefore wear, between the articulating surfaces should be reduced.
- 12-station hip simulator was utilized at a frequency of 1.1 Hz.
- Heads were sizes 22, 28 and 35mm in diameter
- Total wear between the three heads sizes was not statistically significant at 2 million cycles
- Below .03mm of diametrical clearance the study began to see an increase in wear, which is thought to be due to geometrical errors, (i.e. deviations from a perfect sphere) which begin to take effect when clearances are small.



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