HOW LONG HAS METAL-ON-METAL ARTICULATION BEEN IN USE?
George McKee of Norwich, England was the first to use metal-on-metal with modified Thompson stems and a one-piece cobalt chrome socket combination in THR in 1953 | FIGURE 1. The design was primitive but many lasted for more than 7 years. Although metal wear was detected in devices that were revised, McKee did not observe any undesirable effects of that debris on the soft tissues or the bone1. The early history of M/M devices, including the Dr. Amstutz’ experience with the McKee device in New York, has been previously published2,3,4.

WHAT IS THE OPTIMUM MATERIAL FOR METAL-ON-METAL ARTICULATION?
Metal-on-metal articulation is typically associated with the cobalt chromium molybdenum alloy. Typically these alloys are divided into two categories: high carbon, where the C content is above 0.20%; and low carbon, where the C content is less than 0.05%. Several studies comparing both groups have been conducted | FIGURE 2. Earlier studies presented inconclusive results5. By comparison, later studies isolated the contribution of factors such as surface finish, clearance, sphericity and carbon content. There is now general consensus in the industry that the high carbon alloy has much better wear resistance than the low carbon type6.

CoCr alloy preferred for self-bearing applications because of high hardness and “self-healing” capacity.

At least three types of CoCr alloys are candidates for m-m implants.

Description of ASTM Grades of CoCr

F1537-94
- Low Carbon (<0.05%C)
- Forged
- Grain Size <10 µm

F1537-94
- High Carbon (>0.20%C)
- Forged
- Grain Size <10 µm

F75-92
- High Carbon
- Cast
- 30 µm < Grain Size <1000µm

CoCr alloy preferred for self-bearing applications because of high hardness and “self-healing” capacity.

At least three types of CoCr alloys are candidates for m-m implants.

Scanning electron (SE) micrograph (3300x) of low carbon, forged alloy showing indistinct, small grains (<10 µm)

SE micrograph (3300x) of high carbon, forged alloy showing small grain sizes (<10 µm) and small carbides at the grain boundaries

SE micrograph (70x) of high carbon, cast alloy showing larger grain sizes (30-100 µm) and larger carbides at the grain boundaries

FIGURE 1 | McKee-Farrar (left), Huggler (middle), and Müller (right) m-m hip prostheses (1950’s and 1960’s)

FIGURE 2 | Implant Materials
In addition, there are two types of processes used in manufacturing the cobalt chrome molybdenum components. One method is casting the components (used by Wright for the CONSERVE® Plus and CONSERVE® Total implants) and the other is forging the material. Although the chemical composition can be exactly the same between the two materials, there is a structural difference. The grain size of the forged alloy is typically less than 10 microns, whereas the grain size for the cast material ranges from 30 to 1000 microns | FIGURE 3. There is also a marked difference in the appearance of the carbides, in that the carbide regions tend to be smaller in the forged material. Metal liners and femoral heads have been produced at Wright with both types of material. A limited number of couples were tested in a hip wear simulator. The test showed less wear with cast high carbon alloy than the forged alloy. Due to the limited number of samples, the difference had low statistical reliability. This study was the basis for Wright’s decision for choosing case cobalt chrome alloy as the material of choice for their metal-on-metal components.

DOES THE CLEARANCE BETWEEN ARTICULATING COMPONENTS PLAY A ROLE IN WEAR DEBRIS GENERATION?

Absolutely! This is probably the most influential factor in wear behavior. The proper clearance is essential for entrapping the synovial fluid between the articulating surfaces. This fluid is largely responsible for separating the surfaces while the joint is in motion and, thereby, reducing wear. If the gap between components is too small or too large you will see a sharp increase in wear rates | FIGURE 4.

A study conducted by Isaac, Dowson and others (DePuy International, Leeds, UK) compared wrought and as-cast components with various clearances between those two groups. The results of the hip simulator study strongly indicated that clearance plays a major role in wear rates, and that "wear appears to be relatively insensitive to changes in materials that have similar chemical compositions but different microstructures."16
DOES THE CONSERVE® PLUS ACETABULAR SHELL WITH THE BIG FEMORAL HEAD USE THE SAME CLEARANCE FOR ALL SIZES?

No. The clearance between components is size-dependent. The larger the diameter, the larger the gap between the components. The range for the entire family of sizes is from 90 to 200 microns of diametral clearance, each bearing size having an optimized gap for maximum fluid film thickness | FIGURE 5.
I’VE HEARD A LOT ABOUT HEAT-TREATED COBALT CHROME COMPONENTS VERSUS “AS CAST” COMPONENTS. WHAT ARE THEY TALKING ABOUT AND IS THERE A DIFFERENCE?

Cobalt Chrome Molybdenum components that are cast usually go through the hot isostatic pressing (HIP) and solution annealing processes to remove microporosities often found in castings, and to improve the ductility and homogeneity of the material. The microstructure of this type of heat-treated material looks different from that of the original casting. It is important to note that even though heat treated material looks different it doesn’t affect wear.

Two global metal-on-metal resurfacing manufacturers use the heat-treated process for the castings (Corin, LTD. and WMT, Inc.). Midland Medical, the producer of the Birmingham Hip Resurfacing (BHR) implant, leaves the castings untreated. The BHR product champion, Derek McMinn, MD claims that heat treatment can lead to carbide depletion and, in turn, it can adversely affect wear rates. One “pin on disk” type test suggests that “as cast” material wears slightly less than “HIP” cast material, however, the data shows so much scatter that the results are inconclusive.

Bowsher, et al conducted a hip simulator wear study in which 40mm diameter metal-on-metal bearings, either “as cast” or heat treated, were compared side-by-side. Wear rates were compared for the running-in state (first 1 million cycles), steady state, and also fast jogging. In all three conditions, there was no difference between wear rates of the two forms of the alloy. The authors concluded that HIPing and solution annealing do not adversely affect the wear rates of large diameter metal-on-metal articulations. Furthermore, one additional study was presented at the recent June, 2003 Conference on Metal-on-Metal Devices in Montreal that corroborate the Bowsher study.
WHAT IS THE "STEADY-STATE" WEAR?

Typically, metal-on-metal couples in the hip simulators go through the "run-in" or "wear-in" period where the weight loss due to wear increases linearly. At some point, usually between 500,000 and 1 million cycles, the wear increase drops dramatically or stops altogether. It is then said that the metal-on-metal couple reached the "steady-state" of wear. Both "wear-in" and "steady-state" are demonstrated in FIGURE 8.

DOES THE SURFACE FINISH AFFECT WEAR RATES?

Surface finish has a definite effect on wear rates. The rougher the surface finish, the higher the peaks of material that eventually will be removed. Typical surface finish for the CONSERVE® resurfacing components is 0.008 microns (micrometers). This is an order-of-magnitude smoother than the finish on typical metal femoral heads articulating with polyethylene inserts used for THR.

DO LARGER HEADS WEAR LESS THAN SMALLER HEADS?

Theoretically, if the metal couple is dry, larger heads should wear more than smaller heads due to their longer sliding distance per step. However, in the presence of the fluid the opposite is true, larger diameter heads should wear less because of their greater sliding velocity. Calculations show that larger diameter wear couples can form a thicker synovial fluid film between components.\(^7\)

\[
H_{min} = 1.64D(_D/ED)^{0.65(W/ED)^2}^{-0.21}
\]

WHERE:  
- \(H_{min}\) is the minimum film thickness  
- \(D\) is the head diameter  
- \(\dot{U}\) is the entraining velocity

According to the formula above, the larger the articulating diameter, the larger the \(H_{min}\) value. A thicker fluid film means less contact between hard surfaces during motion and, presumably, less wear. Does this theory prove itself? The study cited above compared 22mm, 26mm, and 35mm diameter metal-on-metal articulations and found no difference between the three. Isaac compared 16mm, 22mm, 28mm, 36mm, and 54.5mm diameter couples\(^{15}\) and, for diameters 28mm and larger, it was determined that wear decreases with increasing head diameter.
In the study of the 54mm articulating couple (the largest size currently available in the BFH™ product line) conducted at WMT, the wear rates were found to be very similar to the wear rates for the 44mm CONSERVE® Plus articulating couple performed at another institution | FIGURE 9.

These numbers are in agreement with other experimental data obtained with hip simulators.

<table>
<thead>
<tr>
<th>Source</th>
<th>Couple Size (mm3/Mc)</th>
<th>Run-In Wear Rate (mm3/Mc)</th>
<th>Steady-State Wear Rate</th>
<th>Sponsored By</th>
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<tr>
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<td>.084</td>
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<td>WMT⁶</td>
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<td>.956</td>
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<td>2.3</td>
<td>.48</td>
<td>Corin</td>
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</tbody>
</table>


⁶ On file at Wright Medical Technology, ER03-0049.


⁹ Bowershe et al. 49th Annual Meeting of the Orthopaedic Research Society, Poster #1398.

TABLE 1 | Hip Simulator Data
WHAT DO THEY MEAN WHEN THEY SAY THAT COBALT CHROME IS “SELF-HEALING”?
A cobalt chrome articulation has the ability to polish out the scratches from abrasive damage such as third-body wear. In retrieval studies, the deep scratches have often been partially or entirely polished out of the main contact zones.

WHAT IS THE AVERAGE PARTICLE SIZE FOR METAL WEAR DEBRIS?
In one study, the cobalt chrome particles from a McKee-Farrar metal-on-metal articulation were in the range of 6 to 744 nm (nanometers), with an average size of 42 nm\(^1\). By comparison, polyethylene particles range from 0.05 to 5 micrometers (50 to 5000 nm).

CAN A METAL-ON-METAL ARTICULATION PREVENT OSTEOLYSIS?
Since a metal-on-metal articulation does not eliminate wear entirely, there is always the potential for an osteolytic reaction. There are reports of isolated cases of osteolysis with metal-on-metal joints\(^2\). However, these are mostly limited to the first-generation metal-on-metal components. Those were implanted with acrylic cement, which can fragment and generate third-body abrasive particles. It is believed that the metal debris is too small, in comparison to the polyethylene particles, to initiate an osteolytic reaction.
A study of several metal-on-metal components (Metasul\textsuperscript{TM} total hip replacements and McMinn surface replacements) investigated the bone and tissue reactions to the metal debris\(^3\). It was noted that metallosis (a grey-black appearance of the soft tissue) was present with the surface replacements and the total hip replacements. Macrophages filled with metallic particles were found in all tissues, but in larger amounts in those with metallosis. Giant cells and small areas of histiocytic granulomas were also present. The authors noted that there were fewer macrophages and giant cells than typically seen in tissues around metal-polyethylene joints, and although an inflammatory response to the metal particles was present, this was not as severe as the response to the cement particles. The authors concluded that the long-term response to these very small CoCr particles should be monitored. There has been no observed occurrence of metallosis in connection with CONSERVE\textsuperscript{®} Plus or CONSERVE\textsuperscript{®} Total implants.

WHAT ABOUT METAL ION RELEASE?
Metal ions find their way into the tissues through wear particles or through corrosion mechanisms. These ions then travel into the bloodstream and eventually expel in the urine. The topic of metal ion release will be discussed in greater detail in a separate technical monograph.
CONCLUSIONS:

Many factors affect metal-on-metal wear behavior. Some of them are more significant than others. Surface finish, appropriate radial clearance and high carbon content have been shown to play the greatest role in reducing wear rates.

The microstructure of the alloy does not play a key role in wear behavior. While “as cast” and heat treated alloys were directly compared in hip simulators by the scientists from Corin, DePuy, Centerpulse, and in some independent laboratories, proponents of “no heat treatment” regimes have not provided us with laboratory or clinical data to date. McMinn’s claim of better metallurgy with the “as cast” components is based primarily on “pin-on-disk” type testing. The “pin-on-plate” or “pin-on-disk” type experiment can compare the wear of different materials as a flat surface, but the mechanism of these tests has nothing in common with the motion of the hip joint.

Hip simulators offer the most reliable way to assess wear in the laboratory, but keep in mind that the outcome greatly depends on the method, testing equipment, and measuring equipment. Since we are dealing with tiny amounts of debris, test results may vary greatly from one hip simulator study to another. Take that into account when comparing data between two tests conducted by different people and with different equipment.

And finally, the best proof of a good design is in the clinical outcome. To date, there have been no published reports of the clinical performance of the BHR device. The CONSERVE® Plus metal-on-metal articulation has a good clinical history with over 6 years and over 600 patients. The paper presenting the clinical results of the first 400 CONSERVE® Plus hip resurfacing cases performed at the JRI has been accepted for publication by the Journal of Bone and Joint Surgery.
REFERENCES


