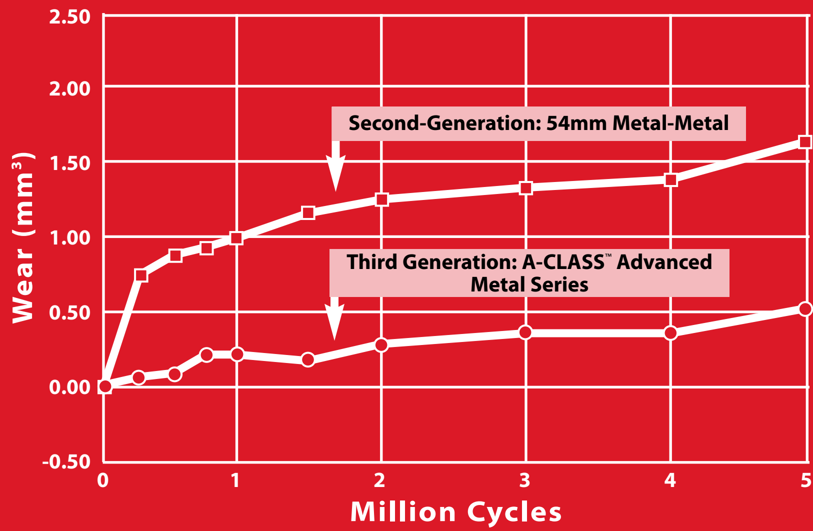
h i p   s o l u t i o n s

CONSERVE® Total A-CLASS™ ADVANCED METAL WITH BFH™ TECHNOLOGY HIP SYSTEM

TECHNICAL MONOGRAPH

WRIGHT®



Graphical results of the reduced wear of A-CLASS™ Advanced Metal with BFH™ Technology compared to the current BFH™ Technology.[1]

1. Data on file at WMT

CONSERVE® Total

A-CLASS™ ADVANCED METAL WITH BFH™ TECHNOLOGY HIP SYSTEM

PERFORMANCE CHARACTERISTICS

technical monograph

as described by Irina Timmerman

CONSERVE® Total

A-CLASS™ ADVANCED METAL WITH BFH™ TECHNOLOGY **HIP SYSTEM**

THIRD GENERATION OF METAL-ON-METAL ARTICULATION: SUBSTANTIAL WEAR REDUCTION THROUGH ADVANCED BEARING SURFACES

introduction

After fifteen years of experience and two generations of metal-on-metal bearings, the orthopaedic devices currently available have accumulated sufficient information to identify the most critical factors that affect wear behavior.

CLEARANCE BETWEEN ARTICULATING SURFACES

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 there is a sharp increase in wear rates.[7,12]

CARBON CONTENT

Carbon concentration also plays a critical role in wear behavior. Alloys with carbon content between 0.20% and 0.30%, called "high carbon" alloys have lower wear rates than "low carbon" alloys, those with less than 0.05% carbon content.[8,11,13,14]

SURFACE FINISH

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 Wright's metal-on-metal 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.

HEAD SIZE

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 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.[17,18]

The larger the articulating diameter, the larger the H_{min} value.

$$H_{min} = 1.64D(ńÚ/ED)^{0.65}(w/ED^{2})^{-0.21}$$

Where: H_{min} is the minimum film thickness
D is the head diameter
Ú is the entraining velocity

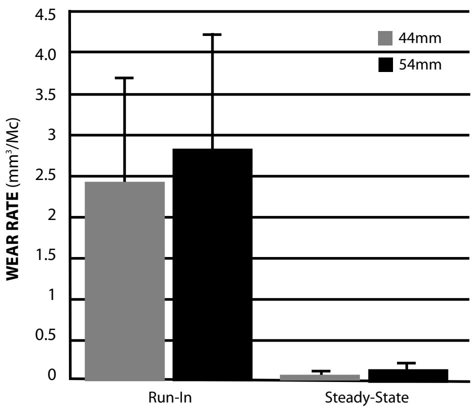


FIGURE 1 | Metal-on-Metal Wear 44mm and 54mm Bearing Couples

A thicker fluid film means less contact between hard surfaces during motion and, presumably, less wear. Numerous laboratory studies validate this theory. Nolan *et al*[18] 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[19] and determined that wear decreases with increasing head diameter for values 28mm and larger.

In the study of 54mm articulating couples, which was conducted at Wright, wear rates were found to be lower for the run-in period and very similar for the steady-state period, when compared to the wear rates of 44mm articulating couples of similar design and metallurgy performed at another institution. **| FIGURE 1**

BIOLOGIC PERSPECTIVES

Despite the advantages that metal-on-metal articulation can offer, (strength, versatility, longevity, ability to use big heads and thin shells, etc.), the issues of the biological response to metallic wear debris have come under close scrutiny. Ironically, none of these issues are new in the joint replacement field. The cases of cell necrosis and apoptosis, hypersensitivity, and elevated metal ion levels have been reported with the traditional implants for THR, trauma, and intramedullary nails. The fact remains, however, that the levels of metal ions in patients with metal-on-metal articulation can be 5 to10 times higher than the levels in patients with traditional implants.[22]

THIRD GENERATION OF METAL-ON-METAL BEARINGS

From the clinical perspective, the future of the metal-on-metal articulation should be coupled with the effort to restore the anatomical size of the patient's femoral head and increase the usage of large diameter femoral heads. It has been shown that total hips with larger diameter femoral heads are more resistant to dislocations in primary THR.[20] Bearings with diameter 40mm and larger were also successfully used in revision applications in patients with a history of recurrent dislocations.[21]

The goals of reducing wear debris even further and, more importantly, reducing the levels of metal ions in patients, are driving companies to continue research of advanced metals. Coatings and "surface modifications", such as oxidizing the outer layers of metals in an effort to make them harder, have been proposed, investigated, reviewed, and evaluated. Unfortunately, coatings sometimes flake off and these very hard flakes create huge amounts of debris, so-called third-

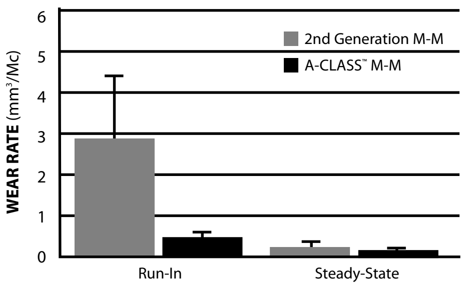


FIGURE 2 | Wear rates of second generation Metal-on-Metal and A-CLASS™ Metal-on-Metal bearing couples

body wear. Surface modifications are only several angstroms thick and may not last for the life of the implant. Another way to reduce wear is to create a bearing couple with two distinctly different surface properties. If these differences are carefully selected, the resulting couple acts in such a way as to minimize the effect on its bearing partner. In other ways, the cup is designed to be "good" to the femoral head, and the femoral head is designed to be "good" to the cup—a perfect marriage.

FIGURE 2 shows the comparison of wear rates for two groups of 54mm diameter bearings. The experiment was conducted on the orbital bearing hip wear simulator, manufactured by Shore Western Mfg., Inc. of Monrovia, CA. The bearings were tested in the anatomically inverted position with heads above and shell below, consistent with the methods used by McKellop.[15] A simulated gait profile with a minimum and maximum force of 200N and 2000N respectively was applied to the bearings. The **second generation** Metal-on-Metal group was produced from high carbon cast CoCrMo alloy, and the **A-CLASS**™ Metal-on- Metal group was a combination of two CoCrMo alloys with distinctly different material properties. The cumulative wear for the **A-CLASS**™ Metal-on-Metal couples was 0.47 mm^3 as compared to 1.49mm^3 for **second generation** Metal-on-Metal couples at 5 million cycles. The **second generation** Metal-on-Metal bearings demonstrated an average run-in (RI) wear rate of 2.8mm^3/Mc, followed by a low steady state(SS) wear rate of 0.11mm^3/Mc. The **A-CLASS**™ Metal-on-Metal bearings demonstrated an average run-in (RI) wear rate of 0.28mm^3/Mc, followed by a low steady state (SS) wear rate of 0.06mm^3/Mc. **The A-CLASS™ Metal-on-Metal bearings exhibited on an average 10x lower run-in wear rates and approximately 2x lower steady state wear and 3x lower cumulative volumetric wear rates than the second generation Metal-on-Metal bearing couples.** | **TABLE 1**

The wear behavior of all the Metal-on-Metal bearing couples tested was similar to that of previously reported metal-metal bearings; i.e., run-in wear followed by steady state wear.

BEARING SYSTEM	VOLUMETRIC WEAR RATE (mm^3/Mc)	
	Run-In	Steady-State
Second Generation M-M	2.8 (1.52)	0.11(0.07)
A-CLASS™ Advanced Metal Series	.28 (.11)	.06 (.01)

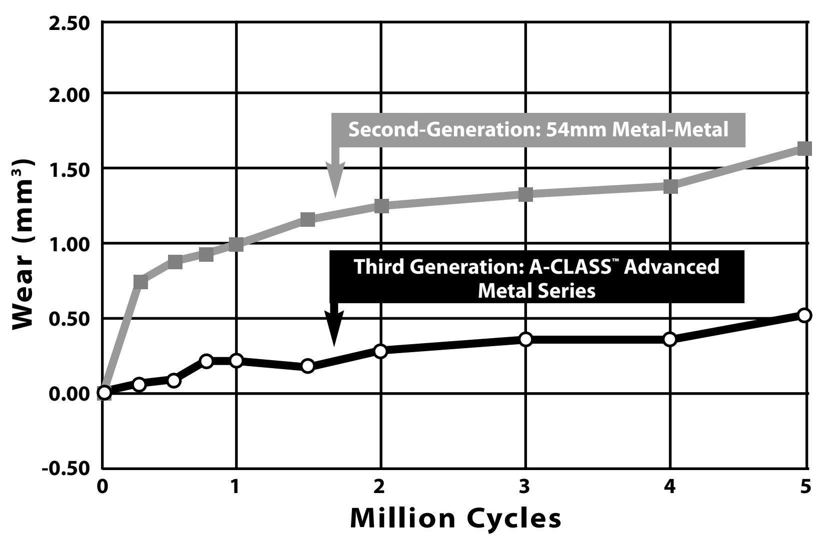
TABLE 1 | WEAR RATES OF SECOND GENERATION AND A-CLASS™ METAL-ON-METAL BEARING COUPLES

AHEAD OF ITS TIME?

The "big head" concept was introduced 44 years ago for THR and 37 years ago for resurfacing[16] because it made perfect sense. Unfortunately, some concessions had to be made in regards to the size of the femoral heads. The limiting qualities of polyethylene as a wear surface reduced the femoral head size to 22.25mm. The second generation of the Metal-on-Metal implants also began with the small heads. The desire to utilize the metal/polyethylene sandwich, Metasul, led to the introduction of 28mm and 32mm diameter heads. Just recently, head sizes larger than 36mm began to gain acceptance, mostly in total resurfacing applications. Tribology of large diameter Metal-on-Metal articulation remains controversial. Although in theory larger diameter heads should wear less than smaller diameters[17,18], and several laboratory studies validate this theory[11,19], comparison data of metal ion levels for large and small articulation is conflicting.[16]

CONCLUSION

Developing a large diameter articulation with the substantial reduction of wear debris should result in reduction of metal ion levels and provide all the benefits of the BFH™ Technology, which include reduced dislocation, increased range-of-motion, and increased jump distance.



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1. Data on file at WMT

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