

# Chapter 1

## Overview of Metal-on-Metal Implants

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Since the introduction of orthopaedic devices, the selection of biomaterials has played a primary role in the ultimate success of the implant. This is especially true for the materials used for the articulating surfaces of joint replacement prostheses. A number of different materials have been used for articulating surfaces with differing eventual outcomes (Table 1.1). While metal-on-polyethylene articulations have been the most widely used in the modern era of joint replacement, hard-on-hard bearings have also provided an alternative bearing surface. Metal-on-metal (MoM) was first introduced in the 1950s for total hip replacement by Drs. McKee and Farrar (Table 1.2). Their early results were unsatisfactory with two of three being removed at one year for loosening (both stainless steel alloy) and the third removed (cobalt-chromium alloy) for fracture of the femoral component [1]. After further modification of the design of the prosthesis, the outcomes improved and longer implantation times were achieved. The reported outcome for the McKee-Farrar total hip replacement has been as high as 77 % survivorship at 20 years [2], and case reports for the Ring [3] and Sivash [4] have also indicated the potential for long-term survival. The results for these early MoM designs, however, were diminished by a high rate of loosening of the

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**Table 1.1** Types of bearing surfaces

1881	Gluck [45]	Ivory on ivory
1938	Wiles [40, 42–44]	Stainless steel ball on stainless steel socket
1951	George K. McKee and J. Watson-Farrar [40]	Stainless steel on stainless steel socket
1953	G.K. McKee and J. Watson-Farrar [1]	Cast CoCr on cast Co-Cr
1953	Haboush [44]	Double cup
1958	Charnley [42, 43, 45]	CoCr on polytetrafluoroethylene
1959	Sivash [5, 40]	CoCr alloy femoral head and acetabular liner with titanium alloy (Ti-6Al-4V0) acetabular shell and femoral stem
1960	Charnley [42, 44]	PTFE on PTFE double cup
1960	Townley [44, 46]	Double cup arthroplasty; metal on polyurethane; metal on polyethylene
1962–1986	Charnley [41, 43, 47–49]	SS on UHMWPE (1960s); Co-Cr on UHMWPE (1960s); Ceramic head on UHMWPE (1970s)
1960s	Judet [50, 51]	Long stem femoral stem with snap-cup acetabulum; also a premounted femoral head in an UHMWPE cup
1960s	Smith [52]	CoCr; Austin-Moore prosthesis to a Gaenslen acetabular component
1964–1965	Ring [53]	CoCr on CoCr
1968	Weber-Huggler [54]	Polyoxymethylene polyacetal femoral head on metallic femur on cast Co-Cr cup (Teflon spacers)
1968	Muller [46]	Metal double cup
1963–1971	Stanmore [55]	Cast CoCr on cast CoCr
1969	Christiansen [56]	CoCr alloy on polyacetyl resin (also plastic trunnion sleeve)
1970	Exeter [57]	SS on UHMWPE
1970, 1972	Boutin [41, 43, 58, 59]	Alumina on alumina; alumina on UHMWPE; all ceramic femur
1970s	Gerard [60, 61]	Metal double cup; metal on UHMWPE double cup; metal-backed poly cup
1971	Oonishi et al. [62]	Crosslinked UHMWPE ( $\gamma$ -irradiated) on stainless steel monoblock stem
1973	Griss [59]	Alumina on alumina
1973	Mittelmeier [59]	Autophor; ceramic ball on ceramic socket
1975	Amstutz [63]	Total hip articular replacement using internal eccentric shells
1975	Sarmiento [64]	Titanium on UHMWPE
1977	Sedel/Ceraver [59]	Alumina on alumina
1980	Bousquet [65]	Ceramic on UHMWPE on Titanium or stainless steel (dual mobility)
1983	Amstutz [66]	Porous surface replacement (PSR) UHMWPE liner and CoCr head, then Alumina head
1984	Mallory Head [67]	Titanium alloy ball on UHMWPE
1986	Lord [59, 68]	Zirconia ceramic ball on HDP liner
1989	Several companies [69]	Ceramic on UHMWPE (US approval)
1990	DePuy Orthopaedics [70]	Metal on HyLamer (Extended Chain Recrystallized UHMWPE)

**Table 1.1** (continued)

1990s	Wagner [66]	CoCrMo metal-on-metal resurfacing
1990s	McMinn/Birmingham [66]	CoCrMo metal-on-metal resurfacing
1991	Weber [41, 76]	Metasul metal-on-metal
1993	Conserve® Plus [66]	CoCrMo metal-on-metal resurfacing
1998	Several companies [71]	Metal on first generation highly crosslinked UHMWPE
2003	Smith and Nephew [72]	Oxinium/zirconium on UHMWPE
2004	ASR hip [73]	CoCrMo metal-on-metal resurfacing
Late 2000s and early 2010s	Several companies [74]	Metal on second generation highly crosslinked UHMWPE
2011	DePuy [75]	Ceramic on metal

**Table 1.2** Metal-on-metal articulations

I. Total hip prostheses

Wiles	
McKee-Farrar	Down Brothers Ltd. / Hunton Engineering
Stanmore	Zimmer to 1984 / Biomet from 1984
Ring	Downs Surgical Ltd.
Müeller	
Huggler	
Sivash	U.S. Surgical / Joint Medical Products
ASR THR	DePuy
Metasul	Sulzer/Zimmer
M2a and M2a Magnum	Biomet
Pinnacle Ultimet	DePuy/J&J
S-ROM	Johnson & Johnson
Summit	DePuy/J&J
Zweymüller-Plus total hip arthroplasty system	Smith and Nephew Orthopaedics (Rotkreuz, Switzerland)

II. Hip resurfacing prostheses

McMinn Birmingham Hip Resurfacing (BHR)	Midland Medical Technologies/Smith & Nephew Orthopaedics Ltd., Memphis, Tennessee
ConservePlus	Wright Medical Technology Inc., Arlington, Tennessee
CormetTM	Corin Ltd., Cirencester, Gloucestershire
Durom	Zimmer Inc., Warsaw, Indiana
ReCap	Biomet Orthopedics, Warsaw, Indiana
Articular Surface Replacement (ASR)	Depuy International Ltd., Leeds, Yorkshire
ACCIS	Van Straten Medical, Netherlands
BS	ESKA Implants, Lübeck, Germany
ADEPT	Finsbury Orthopaedics Ltd., Leatherhead, UK
ICON	IO International Orthopaedics Holding, Geisinger, Germany
MRS Modular	Lima LTO, Italy
MIHR International	Comis Orthopaedics Ltd., UK
MITCH	Finsbury for Stryker
ROMAX	Medacta Australia
DynaMoM	Tornier, Netherlands

components—primarily a consequence of imprecise manufacturing tolerances and implant design [5]. However, one striking feature of retrieved implants from this generation of MoM implants was that there was little evidence of significant wear [5–7].

In the wake of the numerous reports documenting the adverse tissue response to polyethylene wear debris for metal-on-polyethylene prostheses in the 1980s and 1990s, alternative bearing surfaces were again explored. Metal-on-metal articulating surfaces were reintroduced in the early 2000s for both total hip and resurfacing arthroplasty procedures [8, 9]. The rationale for MoM bearings included (1) improved metallurgy and fabrication with the ability to manufacture components with controlled surface roughness, sphericity, inclusions, and clearances, (2) improved implant designs, (3) improved surgical technique, (4) substantially lower wear rates than seen for metal-on-polyethylene, and (5) the availability of larger-diameter femoral head sizes [10, 11]. In 2009, Bozic et al. estimated that 35 % of all total hip replacements incorporated MoM bearings [12]. Also, increased numbers of metal-on-metal resurfacing hip devices were seen in the 2000s, peaking in 2006–2007 as outlined in a study by Tucker et al. [13].

Initial reports of short-to-midterm outcomes for the current generation of MoM total hip and resurfacing hip surgeries were favorable [14–16]. However, more ominous findings on clinical outcomes were slowly appearing in the medical literature. In the early 2000's there were several reports of elevated serum metal ion levels in patients with MoM implants [17–19]. In 2003, Jacobs and colleagues warned that there was evidence of elevated serum and urine cobalt and chromium in patients with MoM bearings and that vigilance was required in following these patients for evidence of delayed type IV hypersensitivity reactions and, potentially, carcinogenic effects [20]. The first awareness of increased rates of revision was based on the Australian Orthopaedic Association National Joint Replacement Registry (AOA NJRR) in 2008 [21]. At about the same time, reports of inflammatory soft tissue masses associated with MoM implants began to surface [22–24]. Increasing awareness was intensified by increasing numbers of publications in the medical literature as well as by increasing awareness of the public fueled by implant recalls and numerous newspaper articles.

A number of regulatory and orthopaedic societies have weighed in on the subject of MoM total and resurfacing hip implants. In 2010, the British Orthopaedic Association issued a medical device alert regarding MoM hip replacement and hip resurfacing arthroplasty, the incidence of serious soft tissue reactions, and elevated levels of cobalt and chromium ions [25]. In 2011, the American Society for Testing and Materials (ASTM) International held a workshop on MoM to discuss the current state of MoM hip replacement and the need for better standards [9]. In the same year, the American Academy of Orthopaedic Surgeons published a systematic review of the published literature regarding the use of “modern” MoM hip implants as a technology overview of the prevalence of adverse responses, the revision rates, and the likely risk factors [26]. The Food and Drug Administration (FDA) has also issued their report on the “Concerns about Metal-on-Metal Hip Implants” [27], which followed

in a call for premarket approval (PMA) applications to appreciate the outcomes of contemporary MoM hip devices. However, a European multidisciplinary study group of 21 experts concluded that “Despite various national recommendations, efforts to achieve international harmonization of specific evidence-based recommendations for best practice are still lacking” [28].

It is apparent that more questions than answers have been raised by the scientific community surrounding MoM implants. However, as the use of MoM prostheses is ongoing, the need for answers is immediate and not just a philosophical debate. There are two major issues that the orthopaedic surgeon must evaluate: (1) Are MoM bearings a viable alternative to other articulating bearings and (2) what is the best action plan for taking care of patients with existing MoM implants? On the one hand, the answers to these questions need to be based on an understanding of the basic principles of biology, materials science, and biomechanics. On the other hand, the answers need to be based on the clinical evidence.

As discussed in this practicum, the nature of articulating orthopaedic implants is that they eventually wear. How much depends on the materials in the bearing couple, the demands placed on the joint, and the implant design and implantation. Modular connections introduce additional sources for debris and metal ion release including head–neck, stem–neck, and midstem tapers [29–33] which have the potential to evoke systemic and local tissue responses [33, 34]. While wear from metal-on-polyethylene and ceramic-based implants appear to evoke a nonspecific, nonantigenic response, metal wear and the associated metal ions have the capacity to incite both nonspecific and specific immune responses [35–38]. The potential mechanisms involved are introduced by Goodman (Chap. 2) but are a recurring theme throughout this practicum.

A discussion of the clinical experience of MoM hip arthroplasty implants is considered from several points of view including an evaluation of the results from established implant registries, reports from clinical series, as well as examination of the tissues interfacing with compromised implants. The eventual outcome of MoM arthroplasty procedures, as discussed by Mont and Pivec (Chap. 3), may range from stable interfaces to severe osteolysis requiring revision. The higher failure rates experienced with some designs of MoM implants at earlier time points than reported for metal-on-polyethylene implants is a major concern. But what is happening at the implant–tissue interface? Are the cells in the periprosthetic tissues mostly macrophages or lymphocytes? Are the cells activated? Are they responding to metal particles (nanoparticles and microparticles) and/or metal ions? A review of the pathology can give us some understanding of what is happening at this microscopic level, as described by Grammatopoulos et al. (Chap. 4) and Bauer (Chap. 9). Is there a threshold, as suggested by Langton (Chap. 5)? Are low levels of metal ions “reassuring” or an enigma? Who is at risk? There has been considerable discussion about the type of patient but evidence shows that adverse tissue responses are not limited to one patient cohort. Is there a way to objectively measure whether a patient is at risk for an adverse tissue response and, if so, what laboratory tests should be obtained? We can measure serum levels of metal ions, but this measure in and of itself does not tell us how an individual patient will respond. The debate has surrounded

the use of skin patch testing versus lymphocyte transformation testing; an excellent description of the strengths and weaknesses of these tests have been provided by Hallab and Wooley (Chap. 6) and Thomas et al. (Chap. 10).

In trying to comprehend the characteristics of what has been labeled as a pseudotumour, it is important for us to understand the biological principles of wound healing, acute and chronic inflammation, and the immune response. Dee et al. [39] stated:

A crucial concept to understand about the tissue–biomaterial interface is that a lot of things happen there! The environment inside the body is chemically, electrically, and mechanically active, and the interface between an implanted material and the body is the location of a variety of dynamic biochemical processes and reactions.

This understanding is even truer for the microenvironment surrounding wear debris. Laboratory and clinical studies have reported differing responses to different types of materials and sizes of debris. As discussed by Wooley and Hallab (Chap. 7), while a biological threshold is likely to play a significant role as a trigger to an adverse tissue response, the length of continuous exposure is also likely to play a role. While we are debating over whether the findings of pseudotumors are Type IV hypersensitivity reactions or not, Cooper and Jacobs (Chap. 8) suggest that more than one instigator may be involved ranging from inorganic metal salts and oxides to the presence of metal wear nanoparticles. In fact, these different metal-based stimuli are likely to be present simultaneously as time of implantation and use increase creating an unstoppable chain of reactions. However, Bauer encourages us to recognize that there is a diversity of adverse tissue responses. That these differences may be related to differences between the source of the stimulus as well as patient-related factors is a reasonable premise.

Is there a future for MoM implants? It is important to recognize that there are several currently implanted MoM prostheses that have successful outcomes with mid- to long-term follow-up. In determining the factors that differentiate between success and failure, Pourzal, Urban, and Wimmer (Chap. 11) note that we need to evaluate the implant itself: the materials, the design, and the kinematics of the resurfaced joint. Metal-on-metal implants are usually made of alloy of cobalt and chromium, and the presence of higher yields of carbides may influence the behavior of the material. As discussed by Thomas et al. (Chap. 10), a number of design and surgical factors may contribute to increased wear and corrosion including whether there is an increased risk of impingement and the use of modular implants. A better understanding of tribology and tribocorrosion is also very important in future evaluations and assessments for all types of articulating surfaces involving metal–metal interfaces.

The answers to the questions raised in the ensuing chapters of the practicum should be based on the evidence—which would require sifting through hundreds of articles, white papers, and government documents. The goal of this book is to provide the reader with an overview of the issues surrounding the use of MoM hip prostheses from the experts in the field. However, the reader is strongly encouraged to investigate further.

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