1
Development Perspectives

Derek J.W. McMinn

Hip arthritis in its early stages involves the loss of a few millimeters of articular cartilage on the femoral head and acetabulum. From the pioneering hip resurfacing work of Charnley using double cups of Teflon (more correctly, polytetrafluoroethylene) in the 1950s right through to the end of the 1980s, surgeons were attracted to the resurfacing concept with replacement only of the worn-out parts. Over these 40 years, however, the major problem was excessive wear of the resurfacing materials, and the hip resurfacing operation fell into disrepute. I was able to witness the problem of wear of the bearing parts in my revision practice when large numbers of Wagner resurfacings had to be converted to total hip replacements (Figs. 1.1–1.3).

The particular problems with the Wagner were loosening of components and collapse of the femoral head. These extremely disappointing results in the hands of many surgeons encouraged the view that the concept of hip resurfacing arthroplasty was flawed. However, closer examination of the failure patterns show that this was a failure of materials rather than a failure of concept.

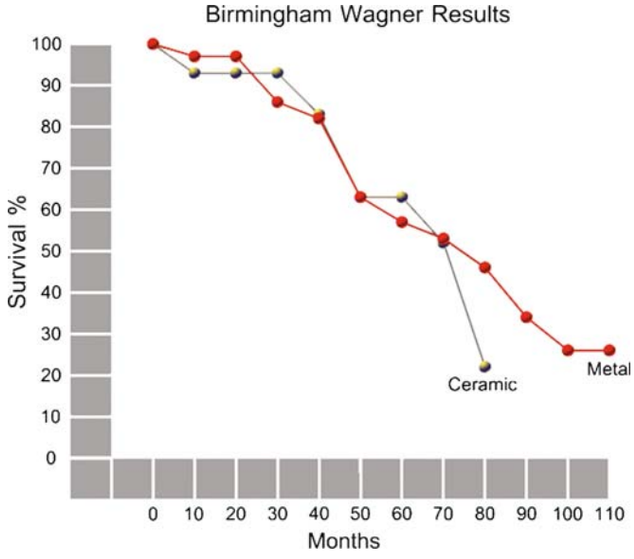


FIG. 1.1. Poor results on survivorship analysis with the ceramic on polyethylene and metal on polyethylene resurfacings performed in Birmingham.

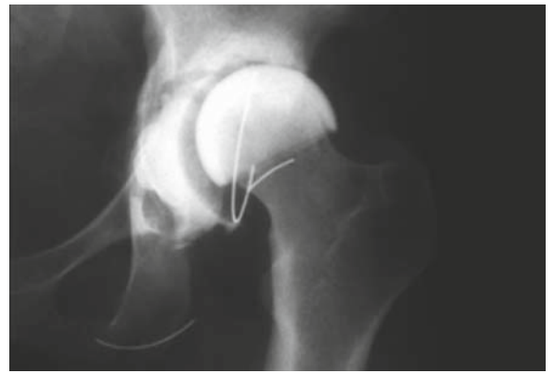


FIG. 1.2. Common form of failure in ceramic on polyethylene resurfacing. Linear osteolysis has loosened the acetabular component, which migrated into a vertical alignment. Severe wear of the acetabular component edge occurred with fracture of the peripheral metal cup marker.

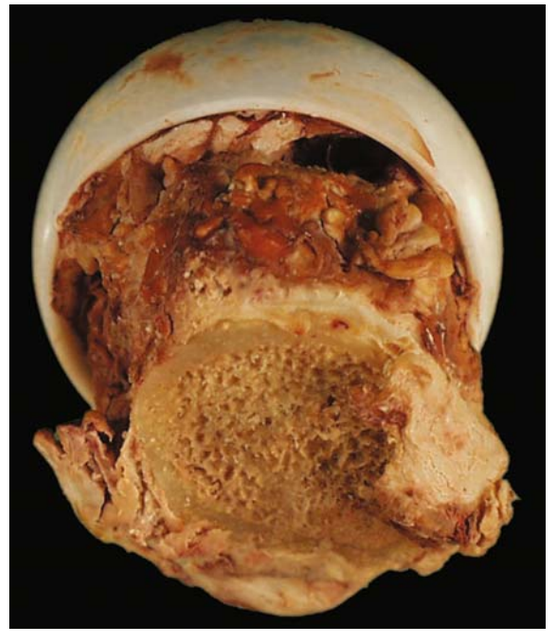


FIG. 1.3. Femoral head and neck removed at revision surgery with solidly fixed ceramic femoral component. Loose acetabular cup and acetabular osteolysis necessitated revision 9 years after implantation.

In this soundly fixed ceramic femoral component, the bone quality in the base of the femoral head looks excellent (Fig. 1.4). Although there are trabeculae streaming down from the tips of cement keyplugs, the concern is that large cavities are present in the polar aspect of this femoral head. Do these cavities represent avascular necrosis of the femoral head, stress shielding of the polar aspect of the femoral head, or osteolysis? The presence of a head-neck junction cavity starts to look like osteolysis (Fig. 1.5). Histology on the bone of this femoral head confirmed that the cavities were due to osteolysis from polyethylene debris (Figs. 1.6–1.8). Presumably, the intermittent high pressure in the hip joint cavity drove the polyethylene debris through the entry point at the femoral head-neck junction into the substance of the femoral head bone.

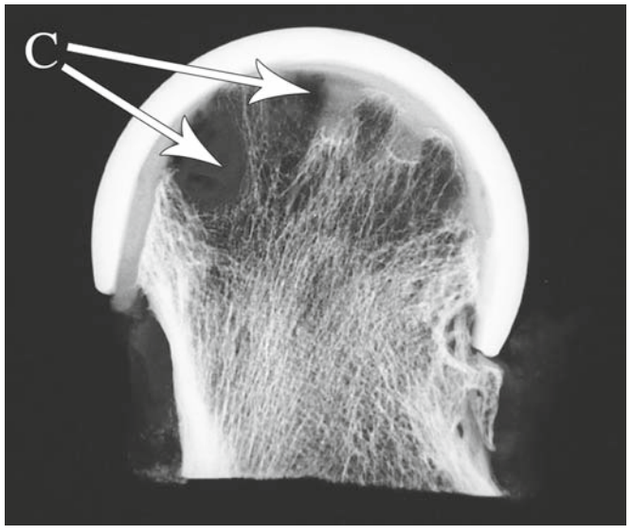


FIG. 1.4. Microradiograph of coronal slice of ceramic femoral component on femoral head and neck. Cavities (*C*) are present in femoral head.

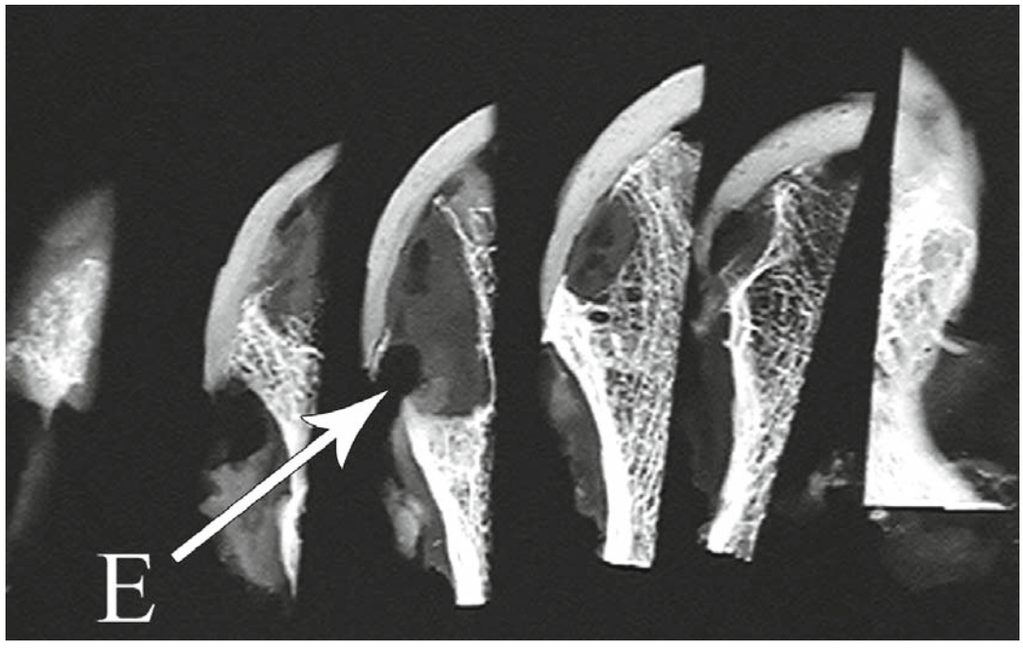


FIG. 1.5. Microradiograph of other femoral head slices showing cavities present including a cavity at the head-neck junction and what appears to be an entry point (*E*).

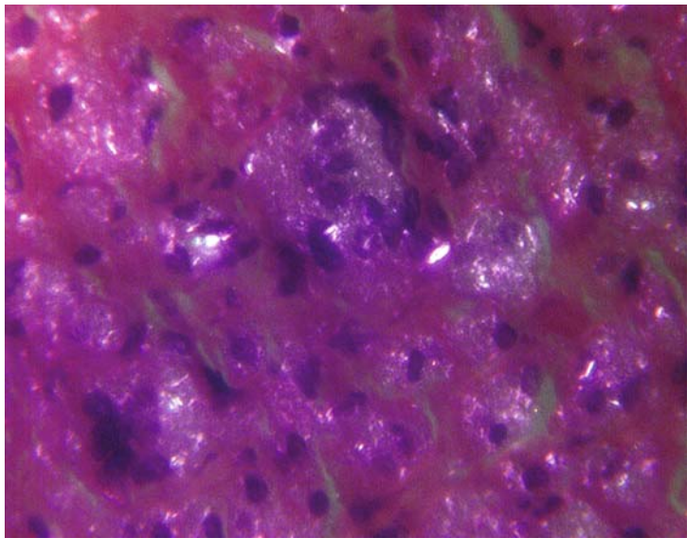


FIG. 1.6. Macrophages laden with polyethylene particles present in one section of the femoral head. This appearance was seen on every slice of the femoral head.

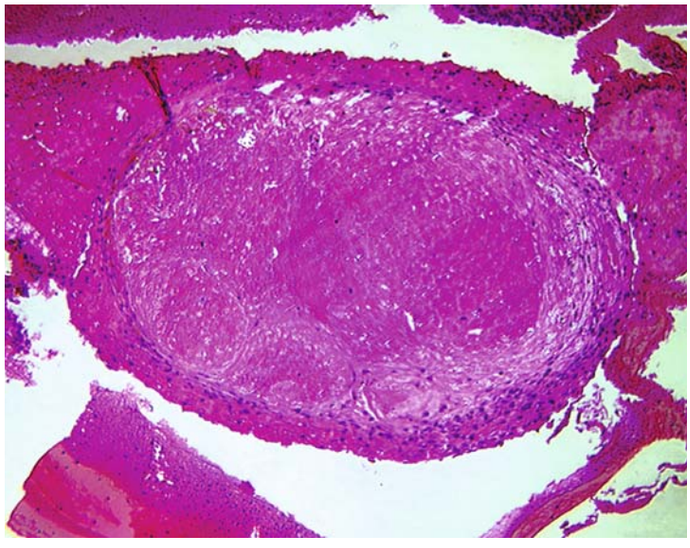


FIG. 1.7. Two-millimeter-diameter granuloma present on one section of femoral head. Granulomata were present on every slice of the femoral head.

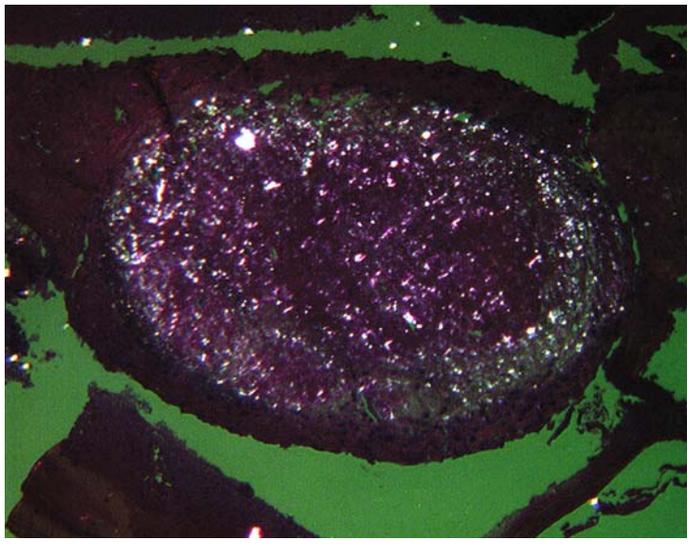
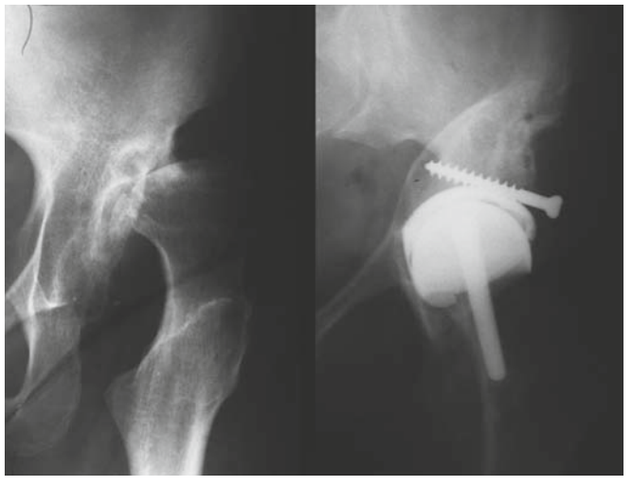


FIG. 1.8. Polarized light microscopy shows granuloma full of polyethylene debris.

With cemented polyethylene-containing hip resurfacing components, polyethylene particles gained access to the acetabular bone-cement interface, giving a predominately linear pattern of osteolysis and resulting in cup loosening. As can be seen from the above figures, even with cemented femoral resurfacing components, polyethylene debris gained access to the femoral head bone, and if acetabular loosening in these early resurfacings did not occur, then the system failed by femoral head collapse when femoral head destruction by osteolysis became severe enough. With cementless porous-ingrowth, acetabular components loosening was much less of a problem, but severe acetabular osteolysis occurred, often giving major problems at revision surgery (Figs. 1.9 and 1.10).

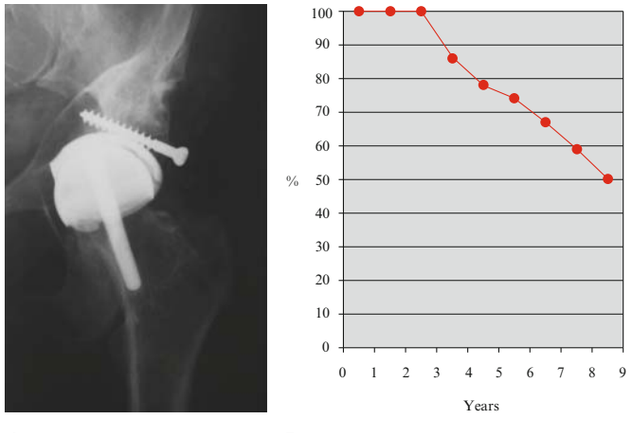
It was clear that polyethylene could not be used as the bearing material in hip resurfacing. First, the combined thickness of the polyethylene cup together with the thickness of the required acetabular cement mantle or cementless metal shell, plus the thickness of the femoral component and femoral cement mantle, led to a bulky implant that required excessive bone removal for implantation. The necessary use of a large femoral head size in the resurfacing arthroplasty led to excess polyethylene debris, osteolysis, loosening, and collapse of femoral heads. A bearing material had to be found that would be durable for use in young, active patients and would be durable when used with a large-diameter articulation. In addition, the bearing material had to be capable of manufacture as a thin component to avoid excessive resection of valuable bone stock in young patients. Ironically, such material had in fact been in successful clinical use for more than 30 years but had not been used in resurfacing arthroplasty in any significantly large study, or so we thought.

Maurice Muller performed 18 metal on metal hip resurfacings in the 1960s. He gave up using this implant when Sir John Charnley convinced him of the benefits of the metal on polyethylene articulation. Muller told me later that he very much regretted having given up metal on metal articulations either for resurfacing or total hip replacement. Gerard also performed a small series.



A B

FIG. 1.9. (A) Severe DDH treated with cementless Buechel-Pappas resurfacing and structural bone graft. (B) Early acetabular osteolysis 4 years postoperatively.



A B

FIG. 1.10. (A) Severe acetabular osteolysis 5 years postoperatively. (B) Buechel-Pappas survivorship analysis in Oswestry. This implant employed ethylene oxide–sterilized polyethylene in the bearing (Images courtesy Prof. James Richardson, MD, FRCS).

Metal on Metal Total Hip Replacement

Over the past 20 years, I have had the opportunity of following up patients who have had three different varieties of large-headed metal on metal total hip replacement (THR) performed by seven of my predecessors (Fig. 1.11). Most of these patients were seen for another problem and were surprised that I was interested in their well-functioning old metal on metal THRs. It is quite remarkable that most of these patients are clinically and radiographically excellent.

The biggest number of metal on metal THRs performed in Birmingham, United Kingdom, were of the Ring uncemented type. The surgeon who performed these (the late Robert Duke, FRCS) was allergic to bone cement (even wearing three pairs of gloves) and the uncemented Ring (Fig. 1.12) was his only THR. The acetabular component came in one size only and had an external surface of smooth cobalt chrome. The femoral component had three sizes, and again the stem surface was smooth cobalt chrome. Not surprisingly, in almost all instances, long-term x-rays show a radiolucent line at the implant-bone interface on both the acetabular and femoral sides. Despite interface access, I have never seen osteolysis associated with this implant.

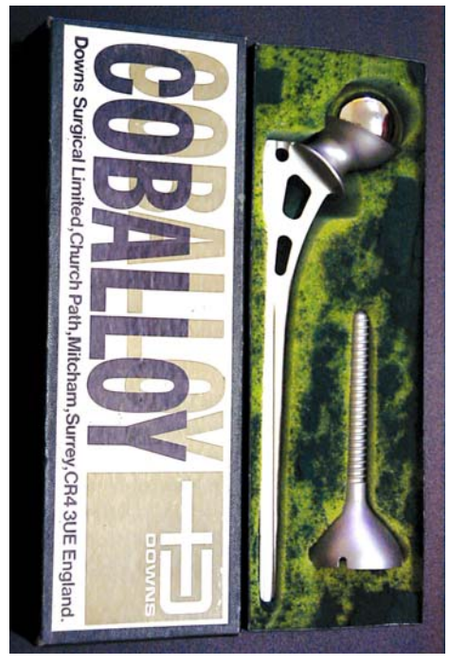


FIG. 1.12. Ring THR stem and cup in original, now rather faded, box.

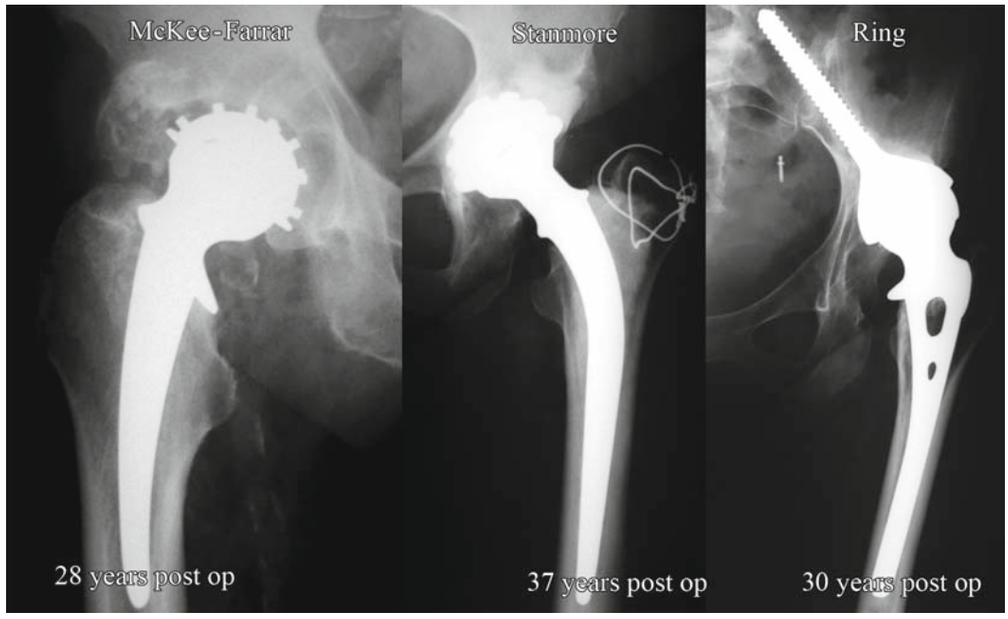


FIG. 1.11. Excellent outcomes after McKee-Farrar at 28 years follow-up, Stanmore at 37 years follow-up, and Ring at 30 years follow-up. No osteolysis. Note radiolucent cement has been used on McKee-Farrar.

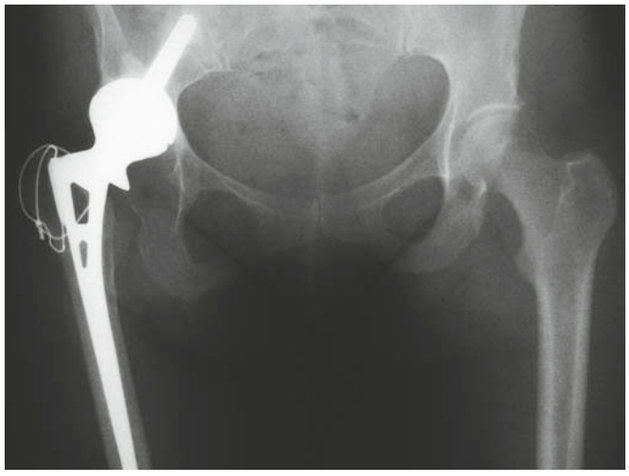


FIG. 1.13. A 56-year-old woman with pain after Ring THR 23.5 years before.

FIG. 1.14. Wear and clearance measurements of the components removed from the patient of Fig. 1.13.

It is remarkable how well patients performed clinically with this Ring THR. With good-quality radiographs, it could be seen that most patients developed an implant-bone radiolucent line, yet the vast majority of patients had no pain associated with this. However, I have had the opportunity of revising a small number of patients with Ring THR implants where loosening was associated with pain.

This woman had a Ring THR performed by Peter Ring at the age of 32 years (Fig. 1.13). Her diagnosis was developmental dysplasia of the hip (DDH), and the cup was inserted with a high hip center. She always had a degree of discomfort after surgery, but this did not stop her being active. After her THR, she had children, led an active life, and had a full-time occupation. Her pain gradually increased over the years, and approximately 5 years before the radiograph taken in Fig. 1.13, Peter Ring's successor made an attempt at revising her THR through a trochanteric osteotomy approach. Her components could not be removed, the greater trochanter was wired in position, and she continued to have discomfort on walking. She eventually tracked down Peter Ring who had retired, and he advised her to consult with me regarding revision surgery. At surgery, the acetabular component was loose with a thin film of soft tissue between the implant and bone. The femoral component was removed after division of the bone bridges growing through the upper femoral component fenestrations. There was no metallosis or osteolysis.

In this patient, who was known to be active, remarkably little wear of the bearing parts has occurred with only 10-µm wear on the femoral head and 8-µm wear on the acetabular component. This represents 0.43 µm per year wear on the femoral head component and 0.35 µm per year wear on the acetabular component (Fig. 1.14). The diametral clearance on this bearing was 272 µm, and with the current state of knowledge this would be regarded as a large clearance. The lack of osteolysis around the acetabular component in this patient with proven acetabular component loosening gives support to the view that normal low wear from these metal on metal bearings does not cause osteolysis (Fig. 1.15).

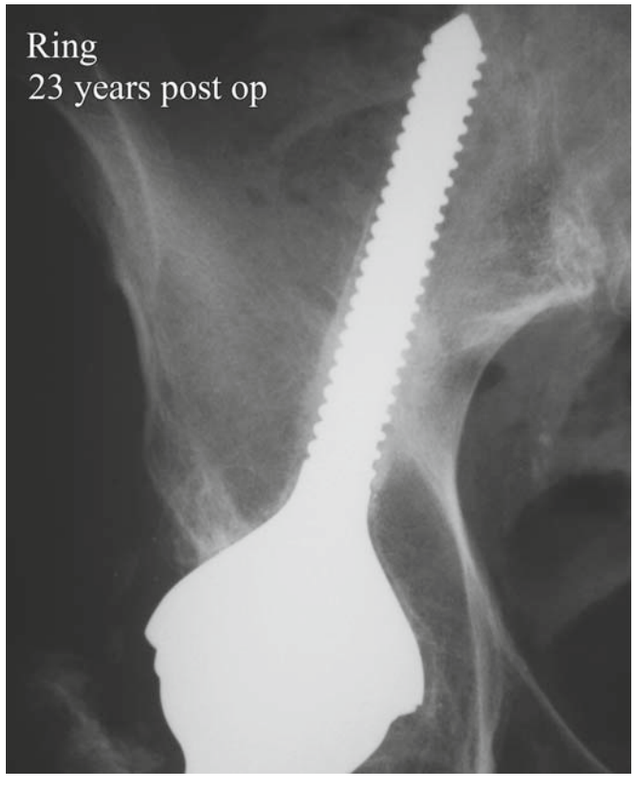


FIG. 1.15. Radiolucent line around smooth Ring cup. Another patient with interface access but no osteolysis.

I have some examples where I have had to revise a cemented metal on metal THR for osteolysis. In the revision of the patient below, the bearing looked pristine and bone cement was firmly adherent to the McKee-Farrar cup (Fig. 1.16). However, loosening at the cement-bone interface had abraded large volumes of cement debris. The femoral component was solidly fixed, and there was no metallosis (Fig. 1.17). In order to minimize the size of the operation in this elderly patient, the acetabulum was bone grafted, metal reinforcement was used, and the original McKee-Farrar cup was recemented with a good outcome.

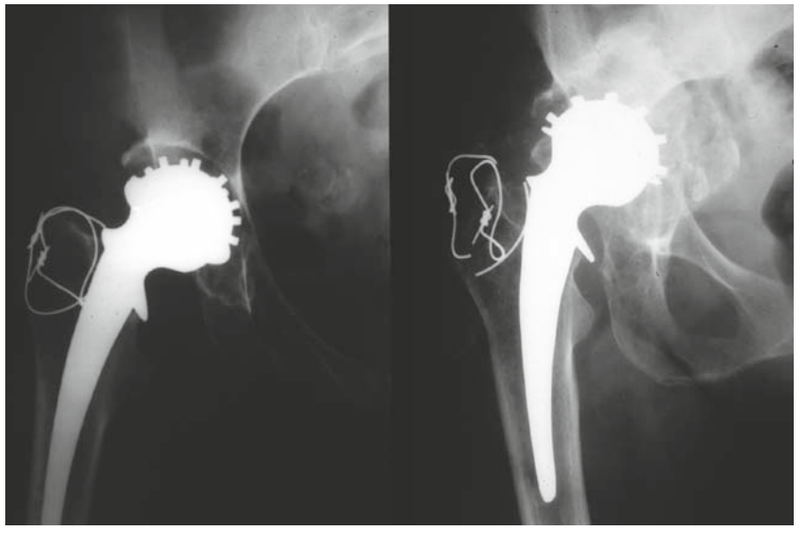


FIG. 1.16. McKee-Farrar postoperatively and after 20 years with severe pelvic osteolysis. At revision, no metallosis but massive production of cement debris.

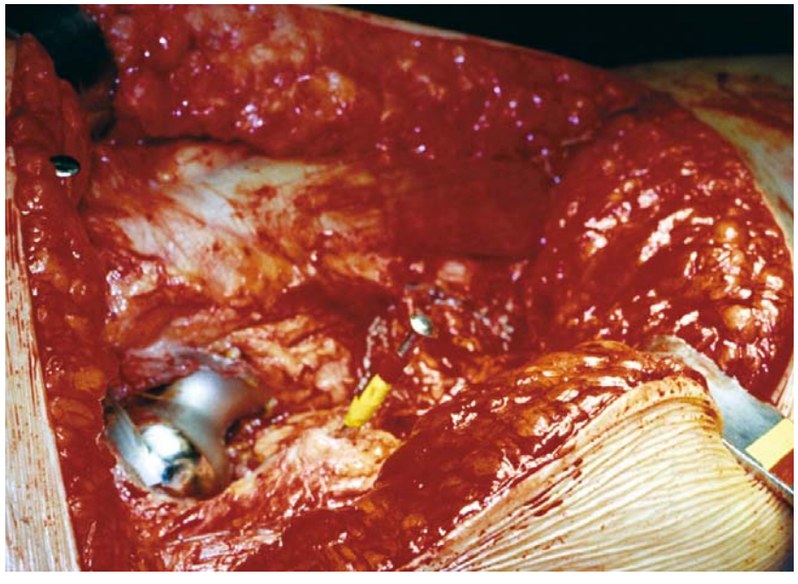


FIG. 1.17. Intraoperative photograph of patient of Fig. 1.16 during revision. Note absence of metallosis.

I also have some patients with less severe osteolysis after loosening of their cemented metal on metal THRs. For example, the following patient had acetabular cup loosening and moderate osteolysis 28 years after a McKee-Farrar THR that had been cemented with radiolucent cement (Fig. 1.18).

Before her THR, she had undergone a femoral osteotomy with a poor outcome. At operation, the femoral component was solidly fixed, the bearing showed no visible wear, and there was no metallosis. The patient was a frail 79-year-old and in order to minimize the extent of revision surgery, the femoral component was left *in situ*, the acetabular floor was bone grafted, and the cup was recemented with a good outcome.

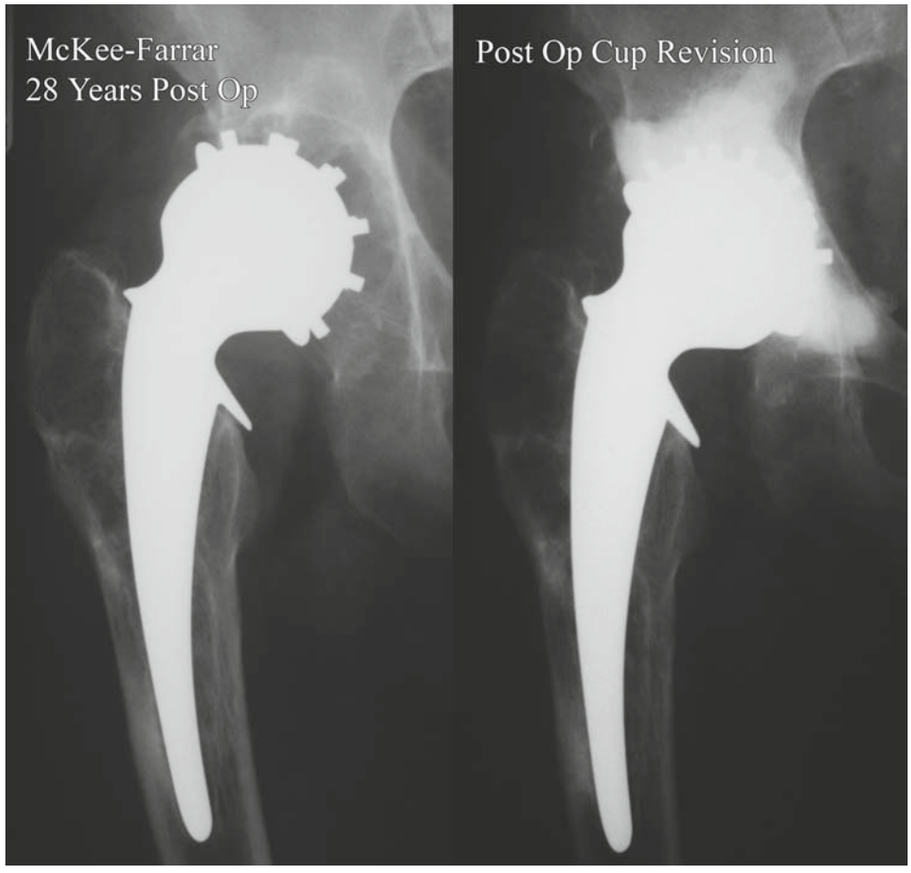


FIG. 1.18. Cup loosening and acetabular osteolysis 28 years after a McKee-Farrar THR. Acetabulum bone grafted and cup recemented. Note radiolucent cement used at original operation.

I also have some examples of osteolysis of the femur with loosening of the cemented femoral component of metal on metal THRs. The loosening and micromovement was usually at the implant-cement interface with osteolysis produced at an area of defective cement mantle (Fig. 1.19).

We had good evidence that metal on metal bearings exhibited low wear and in the absence of other debris did not cause osteolysis. The metal on metal bearings could be manufactured in different sizes and the components could be kept thin without reducing implant strength and risking fracture. Metal on metal bearings therefore seemed ideal to resurrect hip resurfacing.

There remained only the problem of convincing other surgeons and an implant manufacturer that combining two unattractive ideas would make an attractive implant (Fig. 1.20)!

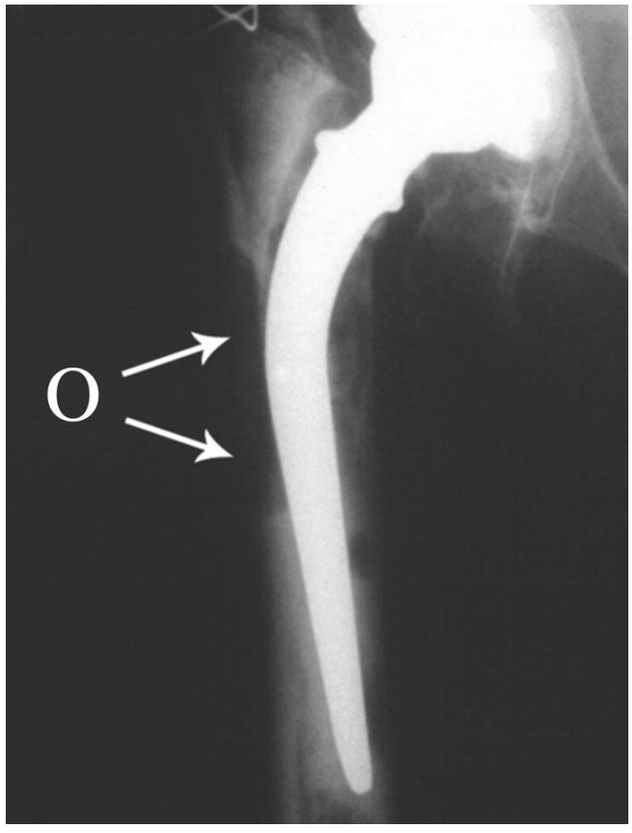


FIG. 1.19. Severe femoral focal osteolysis (O) in a patient with loose femoral component of Stanmore metal on metal THR with micromotion and cement generation at stem-cement interface 23 years postoperatively.

FIG. 1.20. Combining metal on metal bearings with Charnley's hip resurfacing concept proved a hard sell.

Why Were Metal on Metal Prostheses Abandoned?

Why, when the metal on metal implants were behaving well, were they abandoned in favor of metal on polyethylene articulations?

Difficulty with Manufacture of Cobalt Chrome

Cast cobalt chrome is very hard and difficult to manufacture. To give surgeons an idea how hard this material is to cut, one needs to attempt to saw through the material with a hacksaw from a hardware store. Certainly an impression can be made on the metal, but the teeth soon start to wear off the saw.

In implant manufacture, the teeth of cutting tools are much harder than those of a hacksaw, but wear of tools is a major issue and presents difficulty maintaining accuracy as wear of the cutting tools occurs. This difficulty translates into long machining times, frequent sharpening, replacement of tools, and increased man hours and cost. It was recognized at the time that a high degree of sphericity and a defined clearance with a polar bearing articulation were important for success, and with relatively unsophisticated machines available at the time, increased reliance was placed on the skill of the machinist again adding cost to the implant.

Ease of Manufacture of Polyethylene

By comparison with as-cast cobalt chrome, polyethylene was easy to manufacture. Charnley manufactured polyethylene cups himself in his workshop in 1962, and in 1963 a machine was built at Wrightington that could manufacture polyethylene cups in 4 or 5 minutes. The cost advantage over a metal on metal bearing is obvious.

Good Initial Results of Metal on Polyethylene Prostheses

The early results achieved by Charnley with polyethylene cups were outstanding. Neither Charnley nor Thackrays patented polyethylene as part of the bearing couple of joint replacements, and indeed Charnley encouraged other innovators like Bucholz and Muller to use the same bearing material.

This meant that a number of different manufacturers were able to make their own joint replacements without having to have the same expertise or production costs required in the manufacture of metal on metal couples. This opened up a whole new era of surgeons and engineers designing their own joint replacements with an increasingly large number of manufacturers eager to oblige to their own and the designer's financial advantage. Disappointingly, the greatest innovator of them all, Sir John Charnley, did not benefit financially in the same way as did a mass of lesser lights who followed.

In the midst of this bonanza for designers and corporations, there was no appetite to return to an expensive and difficult bearing couple like metal on metal.

Michael Freeman, MD, FRCS: His Part in the Downfall of Metal on Metal

For the three orthopedic surgeons in the world who do not know him, Mike Freeman is one of the brightest and most articulate investigators one will ever meet. He has been a formidable debater at international conferences over the years, usually destroying the case of his opponent. Like a top-quality defense attorney, his use of words and clarity of thought could get his client away with blatant murder. He is, however, not shy about criticizing his own efforts. I helped organize a conference a few years ago, and we had invited Freeman to speak about ankle replacement. He started: "Gentlemen, my ankle replacement is the worst thing that ever hit the human frame. I shall now proceed to discuss salvage of the failed ankle replacement." If Freeman's ankle replacement was the worst thing to hit the human frame, then his Imperial College London hip (ICLH) hip resurfacing was the second worst thing. When he persuaded Peter Ring to abandon metal on metal articulations, the new Ring press-fit uncemented polyethylene cup was equipped with the Freeman osseous peg; this implant was a disaster and probably the third worst thing to hit the human frame (Fig. 1.21).

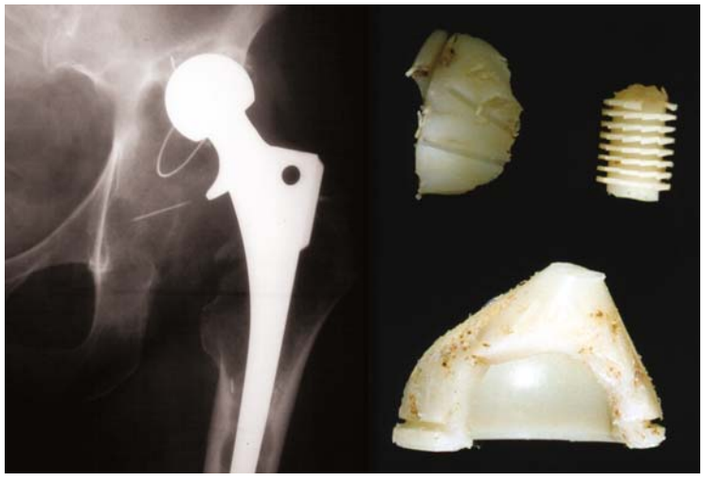


FIG. 1.21. Gross acetabular and femoral osteolysis with failed Ring metal on polyethylene THR. On the right is a disintegrated Ring, uncemented, polyethylene cup.

For metal on metal bearings, it was regrettable that Freeman was leading the case for the opposition. It is more helpful to have the Johnnie Cochran types on your side. Freeman clearly disliked cobalt chrome on cobalt chrome bearings and produced several pieces of work that were extremely damaging. Together with his colleagues Swanson and Heath [1], Freeman designed a joint simulator machine and reported the testing of several joint types including the McKee and Charnley hips.

For the Charnley hip, they ran the simulator to 4 million cycles and reported that *no* wear particles had been produced during the test, which they estimated to represent 4 years of use in the normal human. This needs to be viewed against a backdrop statement by Wilson and Scales in 1970 [2] (designers of the Stanmore metal on metal THR) "… if the wear products of polyethylene do not produce an undesirable tissue response; neither adjacent nor in tissues remote from the implant, then metal on metal bearings will be discarded." We now know, but it was not known in 1970, that polyethylene debris–associated osteolysis turned out to be the major problem with hip arthroplasty. No polyethylene wear particles on Freeman's simulator; this was just the encouragement that the new wave of Charnley surgeons wanted to hear and was another nail in the coffin of the decreasing band of metal on metal users. This proved to be the first of a string of totally misleading results from hip simulator machines, as we shall see later. In contrast, the McKee metal on metal prostheses produced "visible quantities" of metal debris on the simulator machine—hardly encouraging news for the followers of McKee.

Freeman produced two pieces of work relating to the frictional torque of metal on metal bearings compared with metal on polyethylene bearings [1,3]. Together with his colleagues, Anderson and Swanson, Freeman reported that the frictional torques of metal on metal bearings were higher than those of metal on polyethylene articulations. However, the maximum torques from the metal on metal articulations were 4 to 20 times lower than the torque required to loosen cups cemented into the acetabulum. Not deterred by this finding, Freeman still recommended metal on polyethylene on the grounds that the heat produced by curing bone cement might cause thermal damage to bone thus weakening the fixation and arguing that the lower torque of the metal on polyethylene bearings might allow the acetabular fixation to survive. As we will see later, the friction factor with a "run-in" Birmingham Hip Resurfacing (BHR) is as low as a 28-mm metal on polyethylene articulation. However, that is recent information, and the frictional torque issue in the 1970s was a concern for surgeons who wished to continue with metal on metal bearings.

Freeman produced two pieces of work relating to malignancy from metal wear particles [1,4]. In his 1973 *Journal of Bone and Joint Surgery* paper, Freeman and colleagues showed that injection of "massive doses" of cobalt chrome particles into the muscle of rats produced a variety of malignant tumors.

Local and distant site tumor potential weighed heavily on the minds of metal on metal surgeons. Freeman, many years later, is reported to have said, "I now know that even a nylon suture can cause tumors in rats—so I was wrong!" Happily, he does seem to have been wrong, at least in relation to local site tumors adjacent to metal on metal implants.

Perhaps the most devastating piece of work from Freeman was in relation to metal sensitivity and metal on metal joints [5]. Evans, Freeman et al. performed skin sensitivity tests on 14 patients with failed metal implants. Nine patients had positive tests; the suggested hypothesis was that these patients had a delayed hypersensitivity reaction to the released metal ions that caused vascular occlusion, bone necrosis, and implant loosening. Completely contrary and better evidence came later from the Hospital for Special Surgery, New York [6], unfortunately too late to save metal on metal implants. The paper of Evans, Freeman et al. was accompanied in the same issue of the *Journal of Bone and Joint Surgery* by an editorial [7] that gave no comfort to potential users of metal on metal joints. To a variable degree, concern around this issue still persists today. Metal hypersensitivity in a large population of BHR patients out to 10 years follow-up is discussed later. Happily, it seems to represent a very small clinical problem. As we shall see later in this book, cobalt, chromium, and molybdenum are the main constituents of the alloy used for metal on metal joints, and they are all essential elements. These three elements are all present in the diet, are in body tissues, and are essential for life. It is hard to see how a patient could be allergic to one of these elements and still survive. Surely that would be just as serious as a patient developing an allergy to oxygen. As we will see later, there are many trace elements also present in the cobalt chrome alloy, and the potential exists for allergy to some of these nonessential trace elements.

It is ironic that after so much work to help kill off the historic era of metal on metal joints, when the BHR was developed by Midland Medical Technologies (MMT), Finsbury Instruments was engaged to carry out a major part of the manufacturing, and Mike Freeman was a shareholder in that company. Mike Freeman has been nothing but helpful to me personally. The comments above should not be seen in any way as detracting from the contribution of one of the greatest innovators in the field of joint replacement alive today.

Sir John Charnley's Influence

During the late 1960s and early 1970s, surgeons across the world experienced initial success with all varieties of THR and attention then focused on which type of THR would prove more durable. Charnley concentrated on the issue of frictional torque. He built a pendulum comparator to demonstrate the superiority of the 22-mm metal on polyethylene Charnley joint over all other varieties of bearing couple (Fig. 1.22). Thanks to the generosity of Prof. Mike Wroblewski, I have had the opportunity to visit the Wrightington museum and to use and videotape the Charnley pendulum comparator. My senior colleagues had warned me that they believed the McKee joint was run on Charnley's pendulum without lubrication, so I went to Wrightington armed with a small bottle of fresh human synovial fluid. I liberally bathed the McKee-Farrar articulation in human synovial fluid before inserting the ball into the cup. The maximum load that the technician would allow me to apply to the apparatus was 80 lb (36 kg). When the pendulum bobs were released, the metal on metal couple came to a juddering halt after 3 half swings and made a screeching noise. The Charnley joint kept on swinging smoothly for 10 half swings. I thought there might be some grit or other foreign body in the articulation. The metal on metal couple was duly carefully cleaned and the experiment repeated several times with an equally dismal result (Fig. 1.23).

With the 36 kg of air pressure applied to the stationary metal on metal articulation, I tried to move the pendulum arm back and forth, and although movement could be obtained, the resistance to such movement was very high. Video footage of the Charnley pendulum comparator in action can be seen on the DVD accompanying this book. I understood clearly at that time why so many thousands of orthopedic surgeons who had visited Wrightington in the years before myself were completely convinced of the superiority of the metal on polyethylene articulation, and I could easily understand why none of them would ever insert a metal on metal articulation again. I found myself unconsciously looking toward the heavens in order to get a reply from Charnley on how he had managed to set up this awful rig that showed metal on metal in such an appalling light. No reply was forthcoming, and I left Wrightington that day devastated.

FIG. 1.22. Charnley pendulum comparator.

FIG. 1.23. The McKee-Farrar metal on metal couple (nearest) came to a juddering halt despite the application of human synovial fluid, and the Charnley metal on polyethylene couple (farthest) kept on swinging.

I have no definite answers on why the Charnley pendulum comparator is so awful for a metal on metal articulation. The first terrible thought was that as the metal on metal bearing behaved so badly at 36 kg, surely at loads up to 500 kg experienced in the hip of a sportsman the metal on metal bearing would be completely jammed. Charnley wrote an interesting section in his book [8] on this very subject. He described the situation whereby a patient could still function normally with bilateral intermittently jamming McKee-Farrar hips. I have seen many patients with excellent outcomes after 20 years of use of a metal on metal articulation, and I found it very hard to accept that their joints could intermittently jam each time the joint was loaded without loosening the components over those 20 years. The design of a metal on metal joint is critical to its performance, and in particular it is known that equatorial bearings perform worst when loaded, acting as a clutch mechanism. The best design for a metal on metal joint is a polar bearing. The McKee-Farrar joint that Charnley used, he claimed, was an annular bearing, which is suboptimal. An annular bearing is halfway between a polar bearing and an equatorial bearing. Like equatorial bearings, annular bearings have high frictional torque under load.

The design of the pendulum comparator is complex, and it does require that the center of articulation of the bearing couple under test is lined up with the center of rotation of the two outer roller bearings. The direction of load on this pendulum comparator is distinctly odd and quite different to the loading in the normal hip as Charnley's own work showed. In the pendulum comparator, the load is directed through the femoral component with the head-cup contact area moving in an arc described by the amplitude of the pendulum. This would give a multidirectional cup wear pattern, and Charnley knew that this did not occur in the human hip.

In a high-wearing polymer, such as the Teflon cup used by Charnley from 1958–1961, the direction of loading and wear can easily be appreciated (Fig. 1.24). The loading is in one direction, unlike Charnley's pendulum comparator where the loading is multidirectional. This may have implications for the lubrication and performance of metal on metal bearings.

We built a small pendulum that performed much better with metal on metal joints than did Charnley's apparatus. However, I could not rest until I had a pendulum apparatus constructed that loaded the hip joint in a more satisfactory fashion than did Charnley's pendulum comparator and also did not have the hazards of Charnley's two roller bearings incorporated in the apparatus. The pendulum furthermore had to load the hip joint to 500 kg, and the metal on metal articulation under test would have to be manufactured to modern standards (Fig. 1.25).

FIG. 1.24. Total wear-through of a Charnley Teflon cup after 3 years showing vertical direction of wear track. (Reproduced with permission from Springer).

FIG. 1.25. Author standing beside 500-kg concrete-filled steel bob. This weight was necessary to give realistic high loading on prosthetic hip joints.

Under the guidance of structural engineers, a large building was steel reinforced in order to prevent collapse of the building by a swinging half-tonne pendulum. When testing a bearing with this apparatus, the pendulum is started at a fixed point, and the number of swings taken for the pendulum to come to a standstill is recorded. A number of runs are then performed on each bearing. It is appreciated that peak loads in the hip of an active person can reach six to nine times body weight, which means that a sportsman engaged in high-level sport will generate a load across the hip joint in the region of 500 kg and above.

Until we started building this pendulum, I had not fully appreciated what a massive load 500 kg is. In addition, observing this monster pendulum swinging makes one appreciate how clever the normal hip joint design is to cope with these huge loads (Figs. 1.26–1.28).

FIG. 1.26. Big Ben in action. Happily, the calculations of the structural engineers were correct, and the pendulum did not cause collapse of the building.

FIG. 1.27. Loading area for test hip joint prostheses high in roof space. When stationary, a hydraulic ram is attached to distract the apparatus and load a new joint for testing.

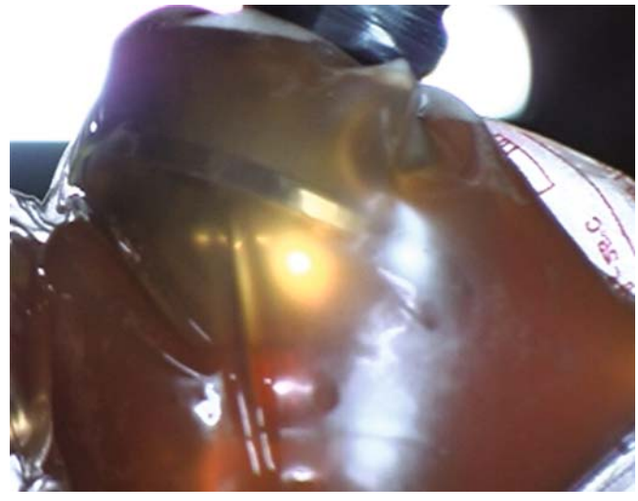


FIG. 1.28. This shows metal on metal couple with the acetabular component on top. Outside the prosthesis is a membrane containing serum and hyaluronic acid.

Results Obtained Using 500-kg Pendulum

When the metal on polyethylene bearings are considered, it can be seen that the 22-, 28-, and 32-mm bearings decrease the number of swings per run and then come to a plateau. The different-sized metal on metal bearings have been tested in serum and hyaluronic acid (HUA) (substitute for synovial fluid) and blood. Of course, these metal on metal bearings in patients are initially bathed in blood and later in synovial fluid.

Unlike the results from Sir John Charnley's pendulum comparator, it can clearly be seen that the frictional torque of these different-head-sized metal on metal bearings are not very different from a range of metal on polyethylene bearings in common clinical use (Fig. 1.29). It can be concluded, therefore, that frictional torque with these metal on metal bearings is not the issue that Sir John Charnley thought it would be. This relatively low frictional torque from the metal on metal bearings is entirely consistent with the clinical experience of historic metal on metal joints having lasted 30 years or more.

We made some other interesting observations using this apparatus. I tried running both the metal on polyethylene and metal on metal articulations dry and in lubrication fluid. With the metal on polyethylene joints, the number of swings to a standstill when run dry was slightly greater than when run in lubricating fluid, so all further tests with metal on polyethylene were run dry. The situation was completely different with the metal on metal articulations. When these were run dry, there was a loud screeching noise, and the bearings were destroyed after one run. The metal on metal bearings performed much better with a lubricant, and I tried calf serum, serum and hyaluronic acid, blood, and finally engine oil. The serum with added hyaluronic acid was marginally better than serum alone, but with both lubricants the metal on metal bearings emitted a low-grade grinding noise on movement. In addition, occasional squeaks could be heard. With blood as the lubricant, all noise ceased, and the number of swings to a standstill with each bearing size was improved compared with the same bearing with serum and hyaluronic acid as the lubricant. It should be noted that in the early weeks after implantation of a metal on metal bearing, these joints are bathed in blood. I also ran some metal on metal joints with engine oil as the lubricant. Interestingly, blood was just as efficient a lubricant as engine oil.

I was interested in attempting to investigate the effect of diametral clearance between the head and cup on the frictional torque. An electrical circuit was set up to detect when the head and cup were no longer in electrical contact. For this experiment, serum with added hyaluronic acid was used as the lubricant. In these newly manufactured metal on metal joints, no effect of reducing clearance was seen until the diametral clearance was reduced to 25 µm at which time electrical contact between the head and cup was broken. The relevance of all this will be seen in later parts of this book, suffice to say now that metal on metal joints exhibit the phenomenon of "run-in" with increasing usage. The surface profile of a newly manufactured metal on metal joint is distinctly inferior to the surface profile of a run-in joint, and as we shall see, this has implications for the lubrication of newly manufactured and run-in metal on metal joints.

Another interesting observation related to the metal on metal couples when subjected to 500 kg of static load. In Sir John Charnley's pendulum comparator with 36 kg of static load, the metal on metal articulation was virtually locked. In my pendulum with 500 kg of static load, the cup and the whole pendulum apparatus can be easily rotated on the prosthetic head using only little finger pressure. See Big Ben in action on the DVD that accompanies this book.

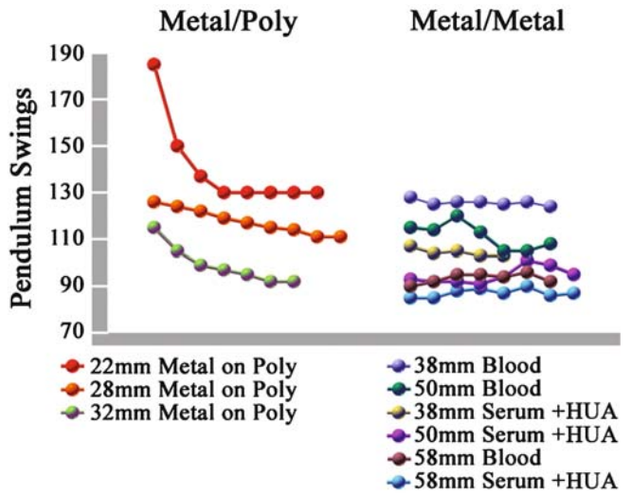


FIG. 1.29. With the 22-mm metal on polyethylene articulation, it can be seen that the number of swings to a standstill on each run decreased down to a plateau. Across the range of sizes, the metal on polyethylene frictional torque is broadly similar to the metal on metal frictional torque.

Development of My Metal on Metal Hip Resurfacing

I made good progress during 1988 with Ian Brown and his team at Zimmer UK, Swindon. We had agreed on the design for the femoral and acetabular components. I had used the Harris-Galante I acetabular cup and eventually ended up performing more than 1000 implants. I have not had cause to revise a single case for loosening but like many others have had my fair share of problems such as dislocation, infection, a handful of tine fractures with liner breakout, and rather too many cases of late pelvic osteolysis.

Fixation, however, has never been a problem with this implant. One of my patients developed recurrent dislocation and ended up being revised elsewhere by a surgeon who believed that uncemented fixation was not very powerful. An attempt was made to remove the cup shell without first breaking down the implant-bone interface. The surgeon extracted the cup but also removed the rest of the acetabulum, which he discovered was very powerfully attached (Fig. 1.30).

I wanted fibermesh on the acetabular resurfacing cup that we were designing, but we could not decide whether to go with commercially pure titanium or cobalt chrome fibermesh. Titanium fibermesh, of course, was used on the H-G1 cup, but we worried about dissimilar metals when diffusion-bonding it to cobalt chrome with the potential for galvanic corrosion. Cobalt chrome fibermesh was a possibility, but some of the Zimmer team worried that it might not be as friendly for bone ingrowth as titanium. Zimmer US had an extensive experience developing fibermesh, and I hoped to get some guidance from the United States. However, Jorge Galante turned the idea of a metal on metal resurfacing down flat. Sadly, the hip resurfacing project with Zimmer ended.

The Corin Years

Peter Gibson, Corin, and Mike Tuke, Finsbury, were instrumental in getting the metal on metal hip resurfacing project started. However, it was George Cremore, with his metal on metal manufacturing know-how, who was the key player once the decision had been made to proceed with the project (Fig. 1.31). I supplied George with new and used McKee-Farrar and Ring implants in the expectation that he would reproduce the excellent bearing characteristics of these implants.

We eventually agreed that there would be three component sizes. Corin wanted to use the Freeman superolateral fins (SLF) cup castings as these were readily available to them, leaving just three new femoral castings to be manufactured. Michael Freeman agreed to his cup design being used. I brought up the subject of porous coating on the acetabular cup, but this was rejected. I was very taken with a statement from Michael Freeman that he used to justify his design of nonporous coated acetabular cup: "To get bone ingrowth into a porous surface you need stability, but if you have stability who needs porous ingrowth."

FIG. 1.30. Harris-Galante I cup shell together with osseointegrated acetabulum removed at revision surgery.

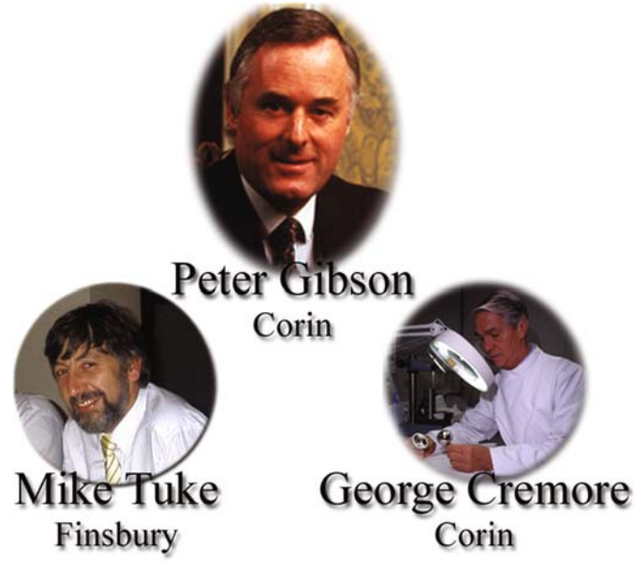


FIG. 1.31. Three key players.

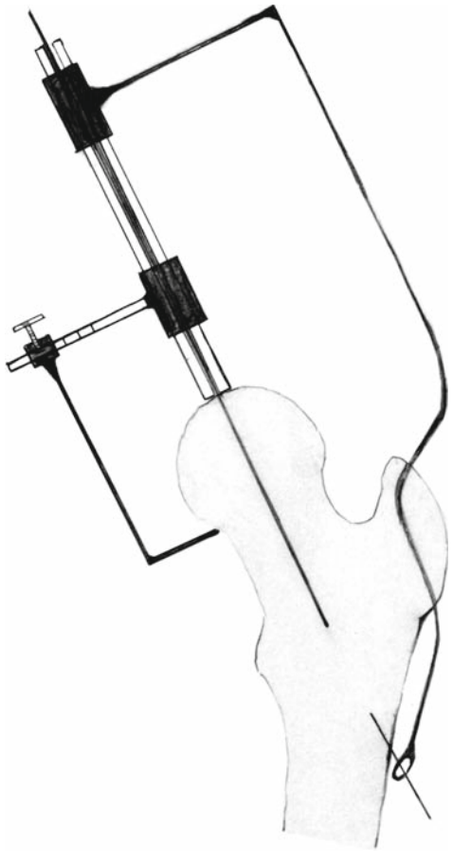


FIG. 1.32. Author's original drawing of femoral jig supplied to Corin.

FIG. 1.33. Prof. Heinz Wagner (1929–2001).

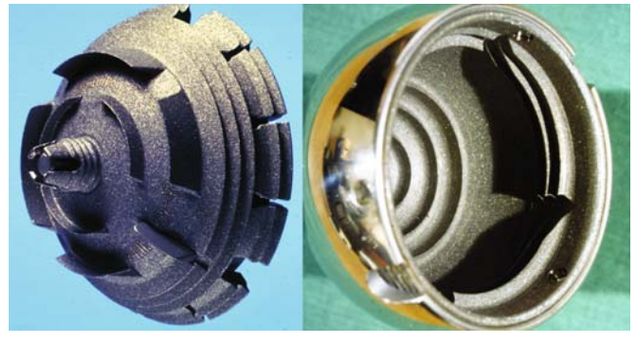


FIG. 1.34. Initial variety of cementless metal on metal resurfacing. Cup and head had porous titanium ingrowth surfaces with cobalt chrome articular surfaces. Femoral component was of a "screw-on" type.

FIG. 1.35. Second variety of cementless implant with femoral component changed to impacted press-fit type. (Images courtesy Prof. Michael Wagner, MD, PhD.).

This sounded like a logical argument to me at the time, and we applied this also to the femoral component, aiming for a design that would achieve stability as a press fit without worrying about a porous ingrowth surface. I set about designing a set of instruments; most of these were obvious adaptations of what had gone before, but the jig to place the femoral guide wire was new and turned out to be very useful (Fig. 1.32).

By February 1991, we were ready to insert the first metal on metal resurfacing. Unknown to me, Prof. Heinz Wagner had also been developing his metal on metal resurfacing, and he too inserted his first model in February 1991 (Fig. 1.33).

Heinz and Michael Wagner inserted two varieties of metal on metal resurfacing and reported their results in 1996 [9] (Figs. 1.34 and 1.35). Heinz and Michael Wagner eventually abandoned hip resurfacing due to fixation problems.

Pilot Series

Seventy implants of my press-fit design were inserted between February 1991 and February 1992 (Fig. 1.36).

In our publication in 1996 [10], we reported an 8.6% aseptic revision rate at 44 to 54 months follow-up. At revision of these loose press-fit components, both components were confirmed to be loose at reoperation. There was no macroscopic metallosis, and the femoral heads were viable on visual inspection and on histology. There was no osteolysis, but a thin soft tissue membrane was present at the interface in all cases.

The survivorship graph shows the disappointing outcome with these press-fit devices (Fig. 1.37). However, a number of these patients still continue to perform well (Fig. 1.38).

At the end of 1 year, I was not happy. I had a meeting with Michael Freeman and told him about the troubles I was having with the press-fit implant. I reminded him about his advice related to stability and porous ingrowth, and quick as a flash he told me that the SLF press-fit cups with a metal on polythylene total hip replacement were fine and my problems must be due to the metal on metal bearing. I said I could not carry on doing this operation with such a high failure rate, but to my surprise he said something along the lines of "now that you have started you have got to perfect it," and his concluding words were "slap a bit of cement on my son."

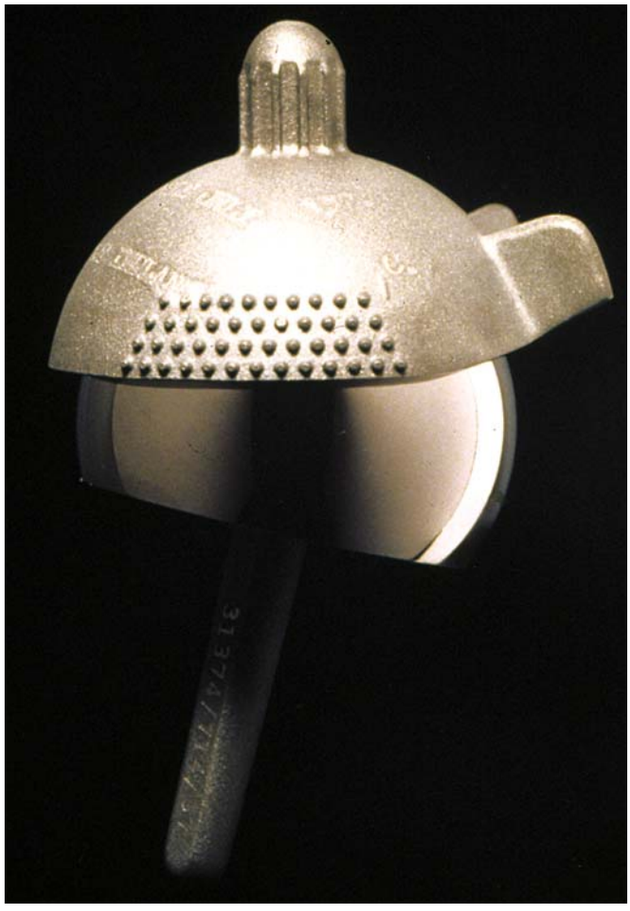


FIG. 1.36. Nonporous, non–HA-coated, uncemented, press-fit components. Note superolateral fins (SLF) Freeman cup design.

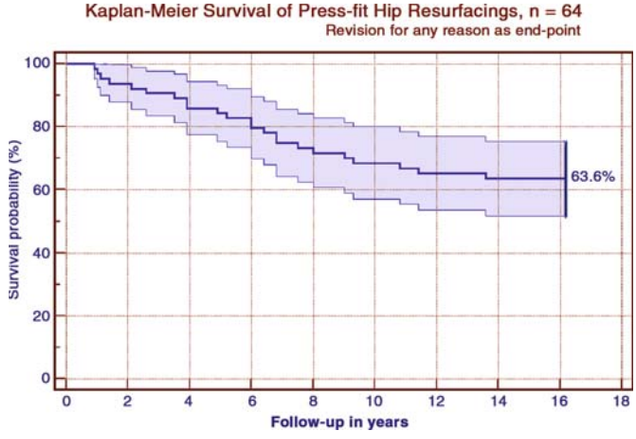


FIG. 1.37. Poor results with press-fit resurfacing.

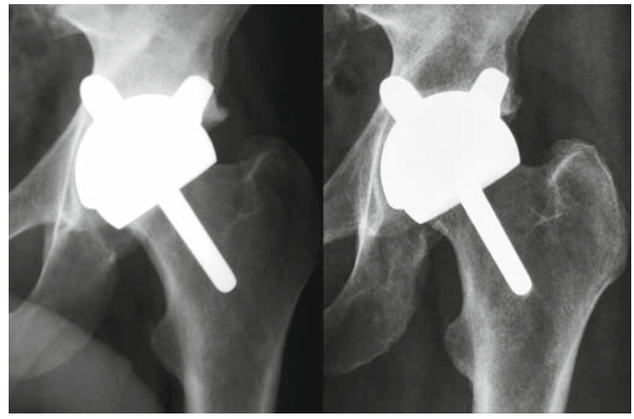


FIG. 1.38. Satisfactory clinical and radiologic outcome 1 year and 16 years after press-fit resurfacing.

I had similar advice from Prof. Mike Wroblewski who told me that I needed to get a large team around me and "make this device work." I decided to alter the implant and go with cemented fixation on both the acetabular and femoral components, but in the mean time we had a number of patients who were agitating to have their hips resurfaced. As a stop-gap measure, we decided to have the acetabular and femoral components HA-coated (Fig. 1.39).

The early results with the HA-coated implants were excellent. A survivorship curve on this tiny number of patients (six) is hardly very meaningful, but two patients have had to be revised for femoral loosening (Fig. 1.40).

I was nervous about carrying out cementless fixation of femoral components, and I restricted myself to patients with good-quality bone in the main.

FIG. 1.39. HA-coated head and cup.

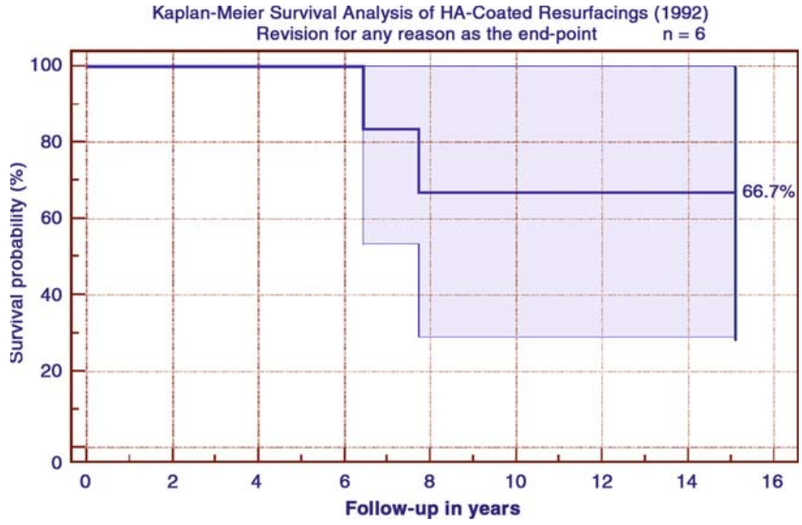


FIG. 1.40. Poor results with HA-coated components due to femoral loosening.

The implant was modified for cemented fixation, and I carried out 43 procedures between March 1992 and December 1993 (Fig. 1.41).

Cemented femoral components solved the femoral loosening problem, and I have not had a femoral loosening since I started the cemented femoral series in March 1992. However, the cemented acetabular cup fixation was terrible. At the time when we reported our early results in 1996, one patient had undergone revision surgery for infection and three patients had undergone revision for cup breakout from the cement mantle. These three patients with early breakout had been revised to an HA-coated acetabular component with a good outcome. The radiology of the cemented acetabular components was poor; at 1 year, 11% had a complete three-zone radiolucent line at the cement bone interface.

At 2 years, 22% had a complete radiolucent line, and at 3 years 67% had a complete radiolucent line. Not surprisingly, these progressive radiolucent lines turned into later cup loosening requiring revision surgery. The survivorship curve shows that this was the worst hip implant I have ever personally performed (Fig. 1.42).

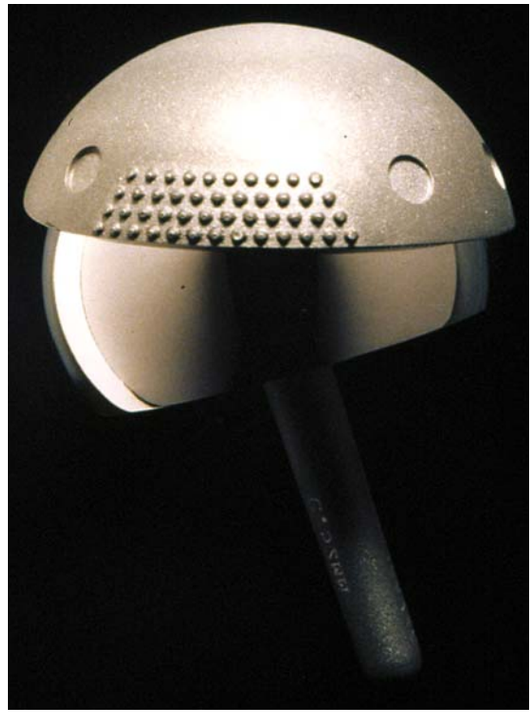


FIG. 1.41. Cemented cup and femoral components. Recesses in cup for cement fixation.

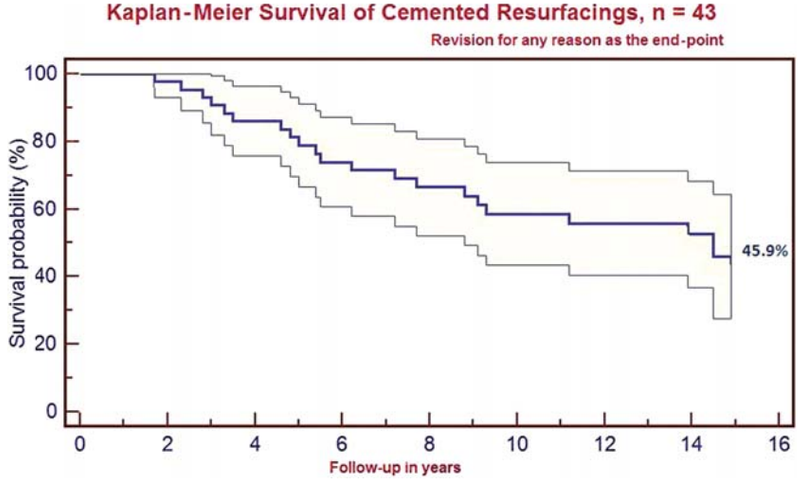


FIG. 1.42. Very poor results with cemented cup, cemented head resurfacings due to acetabular failure.

In some patients, cemented cup resurfacing lasted a good number of years. However, I have come to realize that this cemented cup resurfacing design was so bad that the patients would have been better off if their implant had failed sooner. When late de-bonding occurred between the implant and cement, a tremendous amount of cement debris was generated, and this caused osteolysis (Fig. 1.43). X-ray gives an overoptimistic picture. At revision, one is faced with a mess from massive amounts of cement debris (see the DVD that accompanies this book).

With loosening at the cement-bone interface (Fig. 1.44), cement debris production and osteolysis was not as severe. Revision of these failed cemented cup resurfacings to THR gave us the opportunity of examining femoral head viability in these femoral heads with securely fixed femoral components. Histologic examination of these femoral heads showed normal hemopoietic marrow (Fig. 1.45).

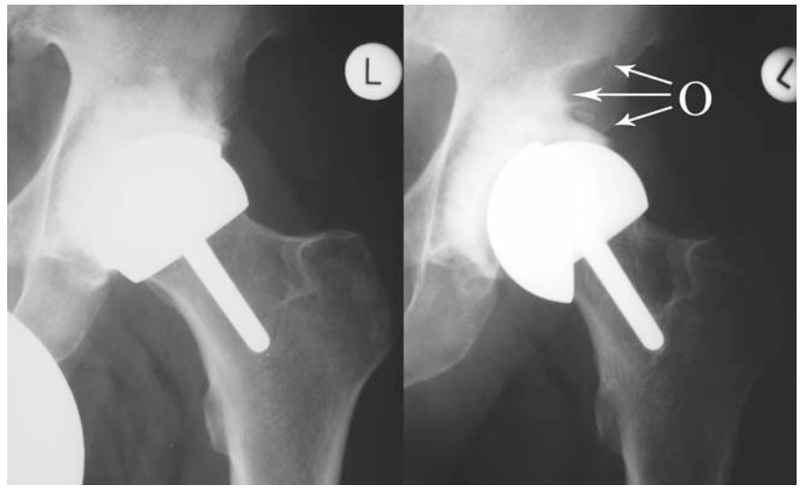


FIG. 1.43. Satisfactory appearances of cemented cup resurfacing at 1 year. Severe osteolysis (*O*) in pelvis at 13 years caused by cement generation at de-bonded implant-cement interface.

FIG. 1.44. Cemented cup removed for loosening.

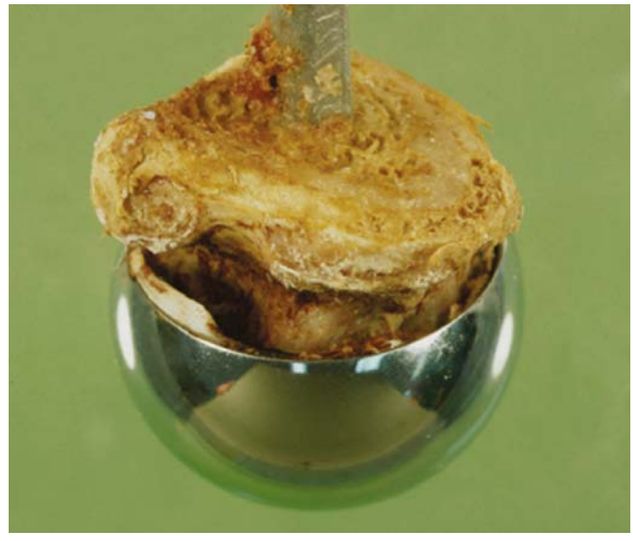


FIG. 1.45. Solidly fixed femoral component revised for cemented cup loosening.

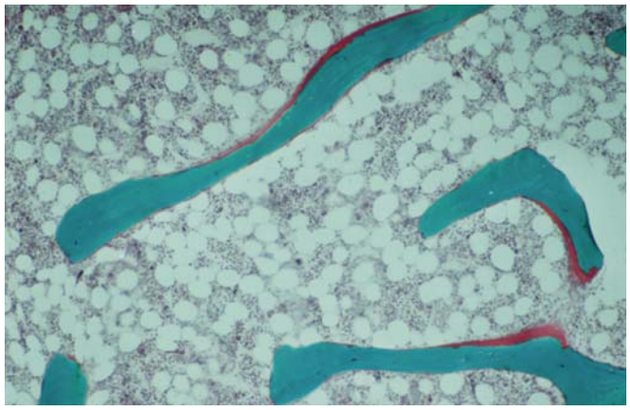


FIG. 1.46. Viable femoral head after resurfacing using a posterior surgical approach.

I had a number of femoral heads examined histologically by Prof. Archie Malcolm, and he considered that none of them showed any evidence of avascular necrosis. He did suggest, however, that we could go further and give the patients tetracycline 2 weeks before their revision surgery. Because we had a number of patients needing revision for their failed cemented cup resurfacing, we were able to do this (Fig. 1.46, Fig. 1.47).

These cemented femoral components were soundly fixed to the underlying bone. In order to obtain histology of the femoral heads, the implant with the contained bone had to be sectioned. Mr. Brian Mawhinney performed a number of these sections for me, and all of the samples we had examined by Prof. Malcolm showed viable femoral heads. Brian Mawhinney and Archie Malcolm left Newcastle, and I have not had further femoral head histology since then, as most histology labs seem incapable of sectioning through the femoral component.

I was becoming increasingly nervous about the cemented cup fixation in view of the progressive radiolucent lines, but two surgeons from abroad showed interest in using this device. Harlan Amstutz from Los Angeles was one of these. I told him about my early cup breakouts and the progressive radiolucent lines, and he believed that further features on the back of the acetabular cup would prevent breakouts. He also shocked me a little bit by telling me that the radiolucent lines were due to my poor acetabular cement technique! I did point out to him that I had carried out a lot of cemented polyethylene cups in the past without any of these problems, but he was undeterred. Corin made deeper grooves in the acetabular cup back and supplied him with the implant (Fig. 1.48). Harlan continued carrying out this cemented cup for 2 years after I had abandoned it. No doubt all the measurements being performed were useful in developing his own resurfacing, the Conserve Plus. Don Howie from Adelaide, unlike Harlan Amstutz, did come and see me performing these cemented cup resurfacings. I also told him that I had already decided to give this fixation method up and would move to an HA cup as soon as this became available. The day that Don Howie came to visit me, I did one resurfacing, and my senior registrar at the time, Eric Isbister, carried out two or three other cases. Don Howie watched them all. Despite our misgivings, he decided to start implanting the cemented cup and cemented femoral component device, and again Corin supplied this to him. I enquired of both of these surgeons a few years ago about their results, and I was interested to learn that their cemented cup results appeared to be at least as bad as my own.

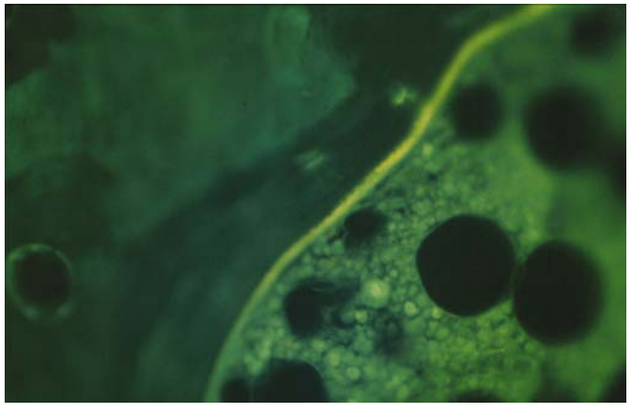


FIG. 1.47. Femoral head bone in a patient with a previous cemented femoral component that was solidly fixed. The resurfacing operation had been performed through a posterior surgical approach. Reason for revision: cup loosening. Under ultraviolet light, uptake of fluorescent tetracycline can be seen on a trabecula.

FIG. 1.48. Deeper fixation features for cemented cup provided for Dr. Amstutz.

About 14 years after the event, I was giving a talk abroad, and Michael Freeman was in the audience; I described the excellent results I had achieved with the cemented femoral component but the terrible carnage I had caused with the cemented acetabular component that had behaved worse than any cemented polyethylene cup I had ever inserted. The only polyethylene cup that I had experience revising that came close to being as bad as this implant was the cemented Exeter metal-backed cup. In that device, we also saw cup breakout from the cement mantle (Fig. 1.49) and accelerated cup loosening (Fig. 1.50).

I was amazed at the end of my talk when Michael Freeman stood up and asserted that he only meant me to cement the femoral component and not the acetabular component! Afterwards, I tried to think how I could possibly have known that, when I was seeing loosening with the press-fit acetabular component and his advice was "slap a bit of cement on my son." Perhaps Michael was worried about being associated also with the fourth worst implant to hit the human frame!

I had often wondered why my cemented resurfacing acetabular cup was so much worse than the cemented McKee-Farrar cup. I now think that the answer lies in the spikes on the outer surface of the McKee-Farrar cup (Fig. 1.51).

In my cemented resurfacing cups, the patients with thin cement mantles seemed to develop cup loosening. The patients with thick cement mantles seemed to be less prone to bone-cement interface loosening, but they developed late cup-cement de-bonding. The McKee-Farrar cup spikes guaranteed a thick cement mantle around the cup. I speculate that this reduced relative movement between the cement and bone. In addition, the spikes guaranteed that the cup could not break out from the cement mantle, either early or late.

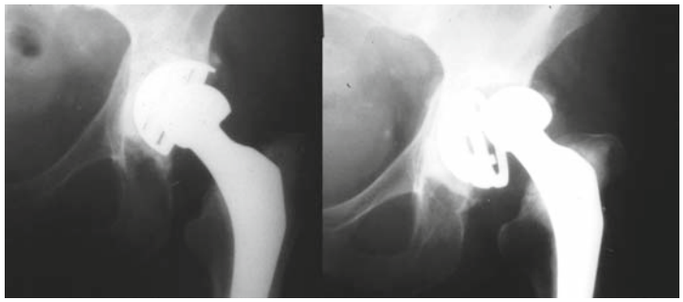


FIG. 1.49. Postoperative x-ray of Exeter metal-backed cemented cup and cup de-bonded from cement mantle.

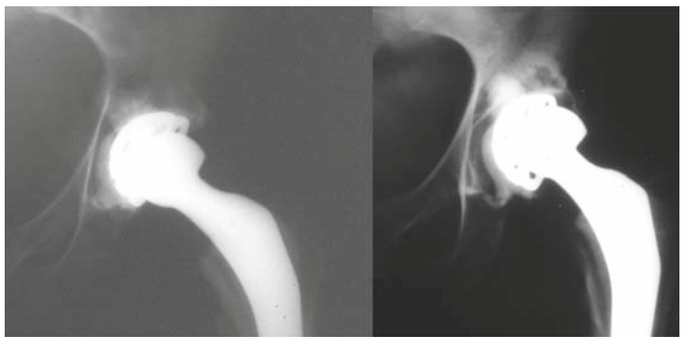


FIG. 1.50. Postoperative x-ray of Exeter metal-backed cemented cup and accelerated loosening at cement-bone interface.

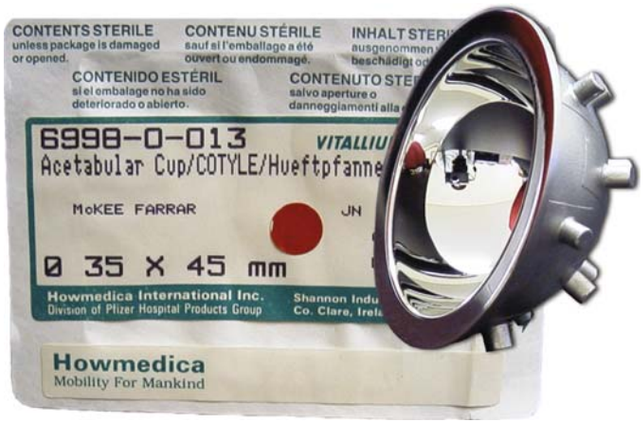


FIG. 1.51. Spikes on the back of McKee-Farrar cup with its original box.

The Hybrid Series

The best acetabular fixation I had seen with my resurfacings, even though the numbers were only tiny, was in the HA-coated cup device. I did not want to return to this device because I had been used to the Harris Galante cup filling the acetabular cavity; Michael Freeman's SLF cup was a cut-away device that just did not fill the acetabulum, at least it did not fill the arthritic acetabulum after it was reamed. It seemed to me that a device that took maximum surface area contact would do better with respect to fixation and impingement of the anterior and posterior acetabular walls, which regularly protruded and required trimming with the Freeman SLF cup. A new cup was designed for cementless HA-coated fixation that had a 180-degree outer sector angle to obtain maximum bony contact and support. The cup was made eccentric in thickness, and the inner sector angle was kept exactly the same as the SLF articular surface.

There was no cup introducer for the early SLF resurfacing cup design, and we just used a block of plastic to impact the cup. The new cup would have an introducer and antirotation flanges. In addition, I had modeling done. We decided that a peripherally expanded acetabular cup would be better than a hemispherical cup at getting a good initial press fit. I designed-in four sets of antirotation fins and eventually this was manufactured. We started inserting this device in March 1994. The first problem related to the antirotation fins. These were to be arranged so that one set bit into the pubis and another set into the ischium. However, the anterosuperior set of antirotation fins regularly hit against sclerotic bone in the anterosuperior acetabulum, and instead of biting into this bone, a common occurrence was that the fins caused the acetabular cup to stand away from the acetabulum in that region.

The posterosuperior set of fins created another problem. This region of the acetabulum is, of course, unsupported and relatively thin, and a regular occurrence on impacting the cup was that these posterosuperior fins split the acetabulum in a radial direction (Fig. 1.52). This problem was solved by removing the superior two sets of fins leaving only fins to bite into the soft bone of the pubis and ischium (Fig. 1.53). The peripherally expanded acetabular component caused me much trouble with insertion, and failure to fully bottom-out the cup was a common occurrence in my practice.

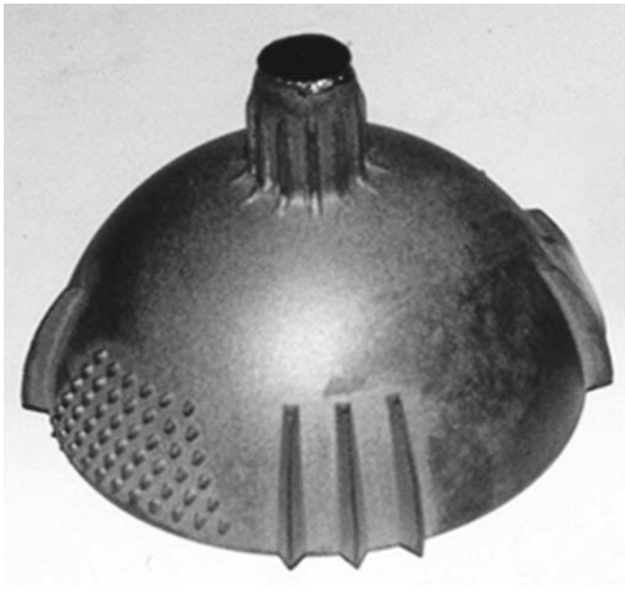


FIG. 1.52. New variety of cup before HA coating. Three of the four sets of antirotation fins can be seen.

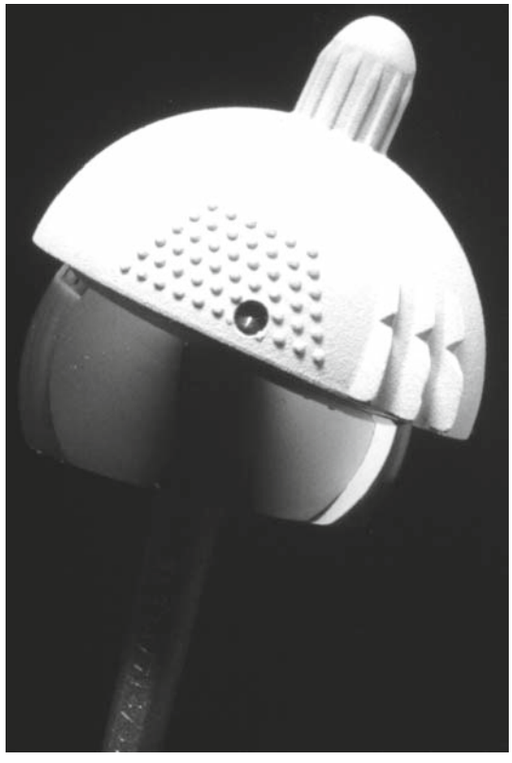


FIG. 1.53. McMinn Hybrid Resurfacing used from March 1994 to December 1996.

When others started using this device, there was much trouble with this design feature. I knew this had to go, but Peter Gibson and the Corin company had been very obliging in modifying the design of the resurfacing to try and get it to work for me. I could not bring myself to ask them to change it again after such a short time in use, so we worked around this problem basically by overreaming the acetabulum. A review of my cases by Dr. Christian de Cock showed that the early results with this device were very good but also showed that failure to seat the acetabular component was a common occurrence (Fig. 1.54). This did not, however, create any clinical problems and, unlike the press-fit, uncoated devices, patients made a rapid and excellent recovery after this hybrid fixed device.

On my postoperative radiographs, only 13 of the first 100 cases had no radiolucent lines in any zone (98 of the 100 were alive at 3 years for comparison). However, on the 3-year-plus radiographs, most of the radiolucent lines had gone with new bone filling the gaps. Seventy-four hips of the 98 had no radiolucent line in any zone at the 3-year-plus time period (Table 1.1).

Eighty hips were classified as Charnley category A or B. These patients had no built-in restraint from other conditions to their activity level. These patients had very good function from their hips (Table 1.2).

At last, I had a hip resurfacing design that gave a good early outcome in patients and, despite the difficulty with cup insertion and poor seating, the radiology at the interfaces improved with time. I started developing more confidence in the device and allowed my numbers to gradually increase. I was grateful to many colleagues in the United Kingdom for referring me young patients who they thought would be suitable for hip resurfacing. Most of these early hybrid designs continue to work well in patients (Fig. 1.55).

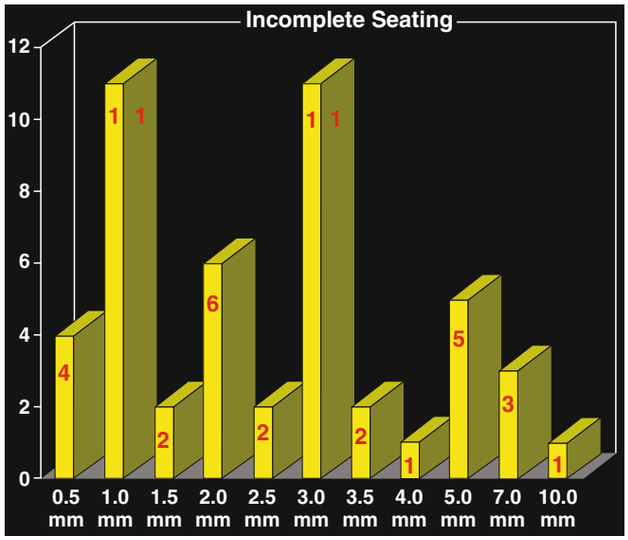


FIG. 1.54. Forty-eight of the first 100 cups were not fully seated. Incomplete seating varied from 0.5 mm to 10 mm.

TABLE 1.1. Cup radiolucent lines

Post-op		3+ years	
One Zone	13	One Zone	15
Two Zone	47	Two Zone	7
Three Zone	25	Three Zone	2
No Radioluency	13	No Radioluency	74

TABLE 1.2. Merle-D'Aubiginé scores in charnley A + B categories

	80 Hips	
Pain	➤	5.99
Walking	➤	5.95
Movement	➤	5.96

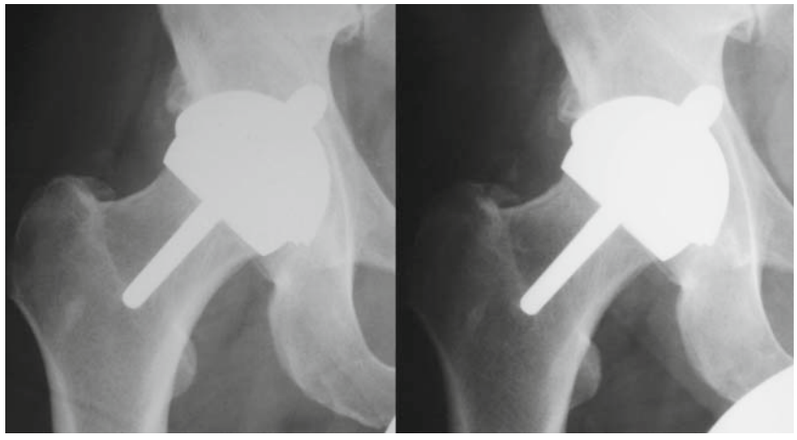


FIG. 1.55. Perfect radiographic outcome 2 years and 12.7 years after McMinn Hybrid Resurfacing performed in 1994. The patient is a keen golfer with a 6 handicap.

Although things were going well on the clinical front, changes occurred at Corin that were unsettling. Peter Gibson sold a large chunk of his shares in Corin, and the new investors brought in their own managing director. From that day I saw the culture of the company change with the dollar becoming the new God. Cost-cutting and increased profits seemed the overriding target. The animals were in charge of the zoo.

I spent my time training new surgeons who wished to take up the resurfacing method in several different countries. I was increasingly being invited to give talks at various meetings on hip resurfacing. It was an interesting fact that when my resurfacings were distinctly suboptimal in the pilot study years, I only had a modest amount of grief from surgeons around the world who objected to hip resurfacing. The opposition started to intensify when the hybrid devices were obviously working well. I had to endure sequential arguments with time, along the lines of:

Dealing with all these sceptics was no problem because when I came back from conferences, I was able to listen to patients who were absolutely delighted, and my wine cellar was looking distinctly healthy from the many gifts I had received. Everything was going well until the end of 1996 when a few of my patients started to report a screeching noise from their

hips in the immediate postoperative period. Other surgeons from around the world reported the same problem, and we think there were about 20 patients from different centers who reported this early noise from their hips.

It is relevant for me now to describe all the noises that a metal on metal hip resurfacing can make at different time periods. In the early postoperative period, it is common for patients to report a knocking or tapping noise. We have investigated this with standing and leg dangling x-rays of the hip and have observed 2 mm of distraction of the hip with dangling in patients who report a knocking noise. We think this is caused by a hip capsule full of blood, and pain inhibition of various muscles around the hip in the early postoperative period allowing the head to displace slightly out of the cup. When the leg is loaded, a relocation noise occurs. This noise is generally reported on the ward, and when the patient returns for their 2- to 3-month postoperative review, the noise has gone. Unlike the common early postoperative tapping noise, a screeching noise is very rare and to my knowledge has occurred in about 1 per 1000 cases in my series. I have of course had the same noise reported by other surgeons around the world. This noise occurs typically at around the 6-month postoperative stage. My patients who have developed this have been very careful in the early postoperative period and then around the 6-month stage they have gone mountain climbing. I have had a patient on top of a mountain telephone me, and holding their mobile phone beside their hip, I could hear a loud screeching noise with each hip movement. I believe that if we could magically place a hip resurfacing into a patient's hip without producing any bleeding, then I think every

patient would get noise from their hip in the early postoperative period. It is the blood after surgery that bathes the hip joint and acts as an excellent lubricant that allows the hip to "run in" without any noise. We know from retrievals that a small patch on the acetabular cup and a larger patch on the femoral head are run in. I speculate that the timid and careful patient runs in a smaller patch and at the 6-month stage when they go mountain climbing, a different and larger patch is required, particularly on the head, to accommodate walking with a flexed hip. The problem now is that they are "running in" a new patch without blood and instead have synovial fluid lubricating the hip joint and a noise is produced. I advised patients who had this noise to engage in intensive swimming, trying to reproduce the noise by various movements and running in their new patch. This noise disappears after about 3 weeks.

The noise reported from patients at the end of 1996 was different in timing to those just described. Corin could not account for this noise, and we all worried that something awful might have happened in the manufacturing process that could cause premature failure of these joints. An international recall was instigated, and a thorough investigation of recalled devices was started.

Investigations showed that the probable cause of the noise was a problem with the introducer. Apparently in the interests of efficient production, a change in the order of manufacturing had occurred whereby face polishing of the cup now occurred after drilling the holes for the introducer ("animals at work"). This meant that the holes for the introducer were too close to the cup face on occasions and the impact load was transferred through the holes of the cup instead of through the face of the cup. Small burrs could be raised at the articular edge of the cup holes, and this was thought to be the reason for the noise (Figs. 1.56 and 1.57).

The few patients of mine who reported this noise in the early postoperative period all did perfectly well, and the noise typically had gone by the time of their 2–month postoperative review.

There were a number of other problems discovered in the investigation after this recall. One of these was that the components in some cases were moderately out of specification on roundness. I knew that this had occurred right from the beginning because when Harlan Amstutz started to do my resurfacing, he had all these implants measured by Harry McKellop before the implants were inserted. On a regular basis, I received phone calls from Harlan Amstutz telling me that yet again they had found some of the McMinn implants were out of round. The problem was that Harlan could never remember that there was a time difference between Los Angeles and Birmingham, and I was regularly woken up at 3 AM to be told about this out-of-round problem. I reported all these conversations to Corin, and they kept telling me that the components were fine. Thanks to Harlan's phone calls, I knew for certain that the components had been manufactured out of round long before 1996. We later had 17 new and unused McKee-Farrar and Ring metal on metal THRs measured; they were out of round also by a similar amount to that consistently reported by Harlan. There were a number

FIG. 1.56. Cup introducer being attached to acetabular component. Two locking pins hold the cup on.

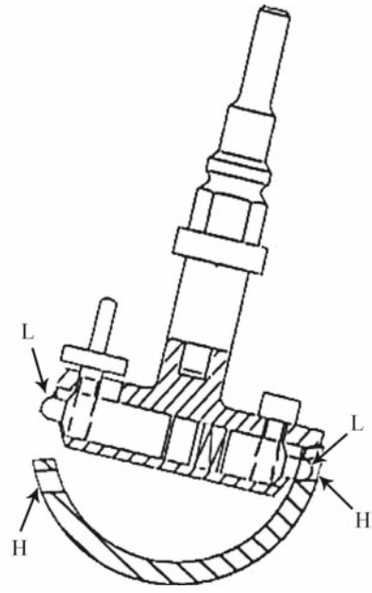


FIG. 1.57. Drawing of introducer and acetabular cup. If the holes in the cup (*H*) are too close to the cup face, then impact load will be transferred through the locking pins (*L*) to the cup hole edge, and a burr can be raised.

of other tiresome issues, but one stood out as being of potential significance. This concerned heat treatments of the metal castings; apparently there had been problems with porosity of the metal castings and a high factory scrap rate. It was described to me that a casting could look perfectly satisfactory, but when machined and polished, the articular surface would have a porosity defect and the casting would have to be scrapped. It seems that various post-casting heat treatments had been employed to attempt to get over these porosity problems. There seemed to be a certain randomness to the exact nature of the heat treatments but roughly speaking during 1994 and 1995, the implants were given single heat treatments of either hot isostatic pressing (HIP) or solution heat treatment (SHT). During 1996, the implants were given double heat treatment of both HIP and SHT. I am certain that if Peter Gibson had remained in charge, this problem would have been discussed with me given that my name was attached to the implant concerned. When I heard about this heat treatment, I looked at the literature; there were two published papers showing that heat treatment increased the wear of metal on metal bearings [11,12]. I met with Corin and insisted that these heat treatments be stopped and that instead the implant should be manufactured like the Ring and McKee-Farrar from an as-cast structure. They refused on the grounds that they already had a number of castings in their possession that had been heat treated and they refused to scrap these castings. I pointed out that I simply could not have a device with my name attached to it where the implant had been heat treated and the available literature showed that heat treatment damaged the wear properties of the bearing. I was receiving a royalty on sales from Corin, but despite the obvious financial disadvantage, we shook hands and went our separate ways. The McMinn resurfacing double heat treated castings were used to manufacture the Cormet 2000. This was launched in 1997 and remains, I understand, double heat treated to this day.

The McMinn Hybrid Resurfacing implant continued to work very well in the early years, but time has started to show some problems (Fig. 1.58).

The mode of failure in a vast majority of the 1996 series was metallosis, osteolysis, and acetabular component loosening (Figs. 1.59 and 1.60).

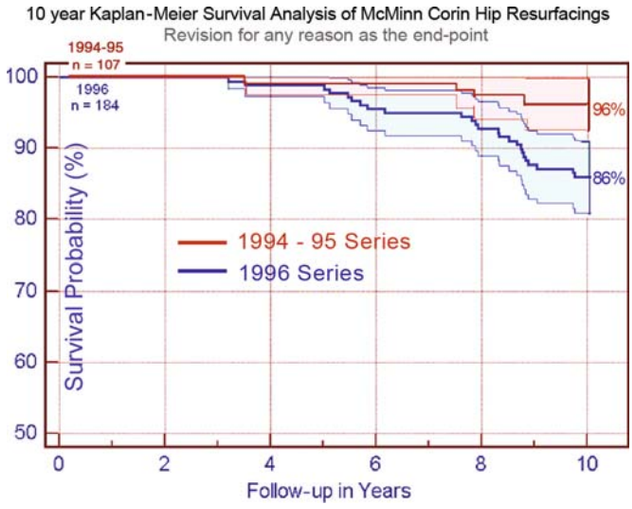


FIG. 1.58. Ten-year survival analysis showing 4% failure with single heat treated implants from 1994 and 1995 and 14% failure from double heat treated implants from 1996.

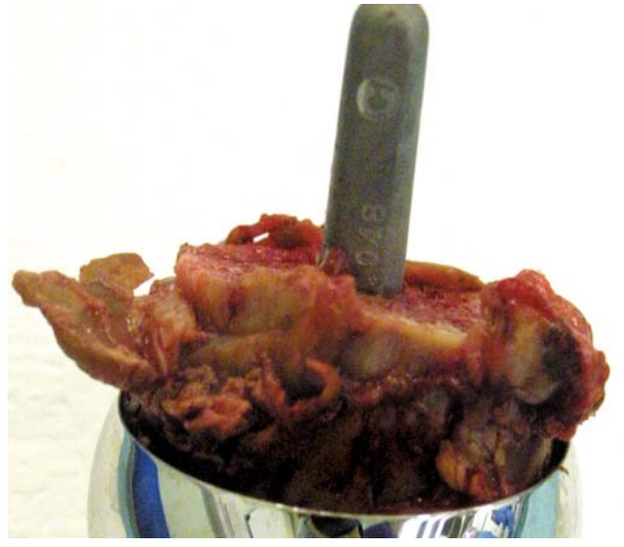


FIG. 1.59. Metallosis staining of soft tissue around femoral neck at revision of 1996 McMinn Hybrid Resurfacing. The patient had osteolysis and cup loosening.

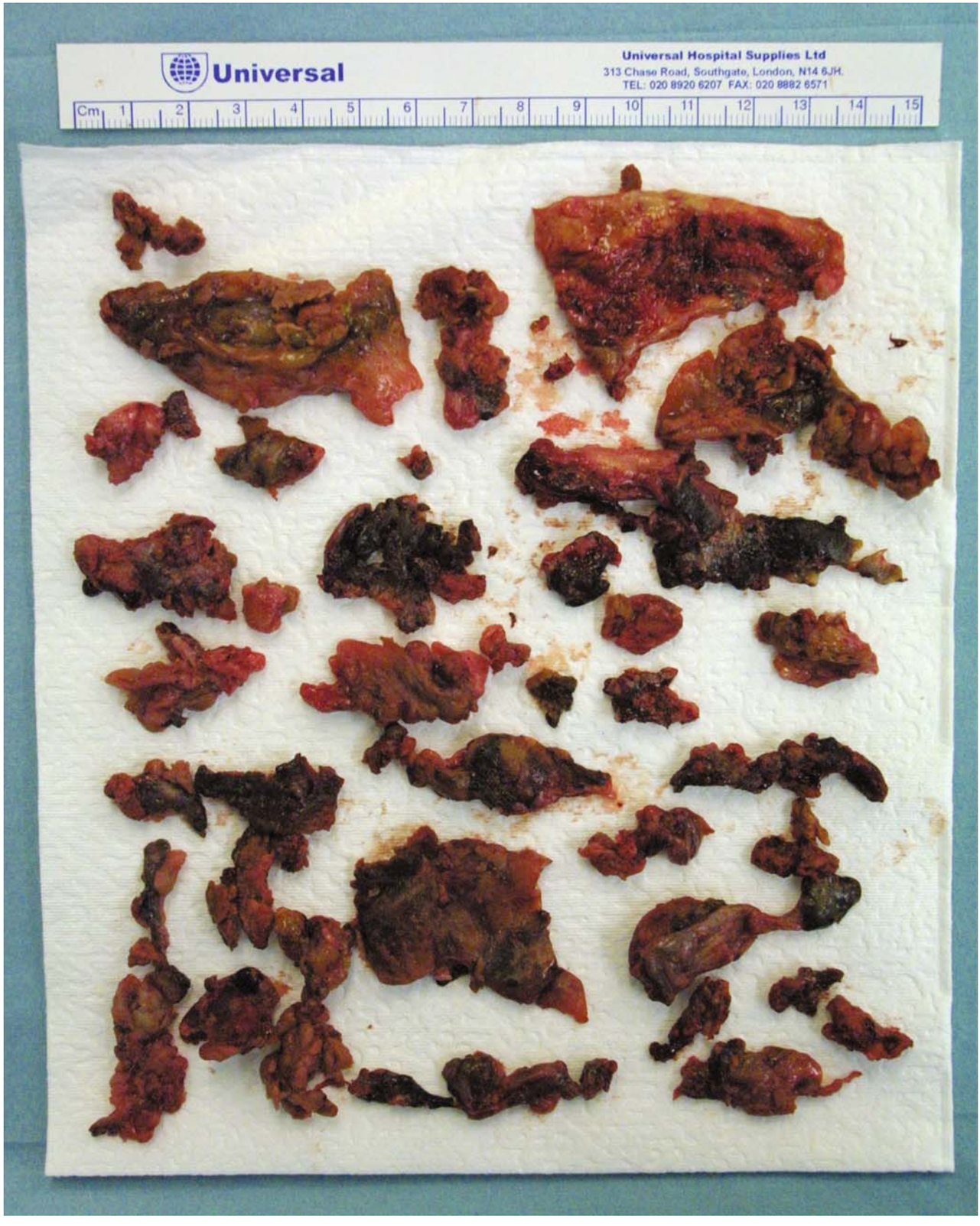


FIG. 1.60. Same patient as that of Fig. 1.56 showing the extent of metallosis in capsule and acetabular pseudomembrane.

A few patients from the 1996 series at the time of writing have still not been reviewed clinically or radiographically at 10 years even though we know that their implants are still *in situ*. At this stage, approximately 20% of the unrevised patients from the 1996 series have radiographic failure in the form of osteolysis and/or cup loosening (Fig. 1.61).

Although the divorce from Corin in 1996 was painful, I am now grateful that I did not perform more of these double heat treated implants. It should be noted on the survivorship graph of the 1996 series that failure did not become obvious until after 5.5 years. That means that if one was checking a national register or one's own results, failure of a double heat treated implant would not become obvious until after 5.5 years. On a worldwide basis, many thousands of defective implants could be inserted into patients before an obvious failure pattern was recognized. There are characteristics of the McMinn 1996 hybrid implant that could have caused earlier failure. We believe that hydroxyapatite on a substantially smooth surface is a relatively weak interface to be invaded by particulate debris like excess production of metal particles. Some of the newer implants on the market with porous coating of the acetabular component but double heat treated metal bearings may take longer before clinical failure occurs compared with my 1996 implants. However, I fear that the longevity of these implants will be at the expense of severe acetabular osteolysis.

I have heard many explanations from Corin as to why the wear of the 1996 series was so bad. They said at one stage that I had inserted the cups vertically in 1996. It would be odd for me to put in resurfacing cups satisfactorily from 1991 to 1995, then vertically during 1996, and then satisfactorily again in 1997.

The acetabular inclination angles from 1994 and 1995 to 1996 to 1997 did not change (Fig. 1.62).

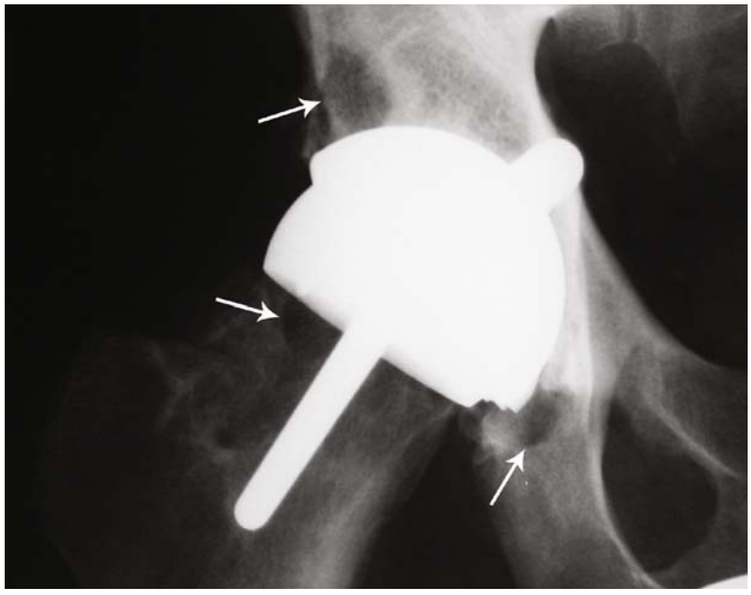


FIG. 1.61. A 35-year-old man with McMinn Hybrid Resurfacing performed in 1996. Very minor symptoms at 10-year follow-up, but radiographic osteolysis (arrows) present in pelvis and femoral neck.

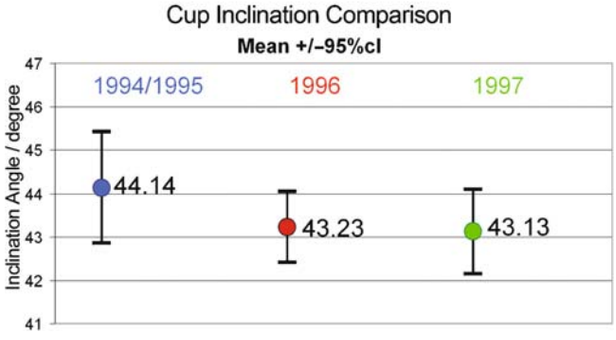


FIG. 1.62. Satisfactory cup inclination angles 1994–1995, 1996, and 1997.

In addition, a detailed wear analysis was carried out in 2002 of retrieved implants from 1996 (Fig. 1.63). Mike Tuke spent many hours carefully analyzing these implants using coordinate measuring machines (CMMs; see Chapter 3) and multiple roundness tracings. On the cups, the wear scars are colored in white, the deepest point in the wear scar is marked with a black dot, and the unworn areas are colored in black. It can be seen that in only 2 of the 9 cup explants does the wear scar extend to the cup edge (cup 2 and cup 4). However, it can be seen that the deepest point of the wear scar in all cup explants lay within the articular surface and not on the cup edge. We now know from many years of analyzing retrieved metal on metal implants that edge loading does indeed lead to marked wear of a metal on metal bearing. However, the cup wear on these edge-loaded implants is profound and localized, and the deepest point of the wear scar is right on the cup edge. The pattern of wear on these 9 cup retrievals from 1996 shows no evidence of edge loading as a cause of failure in this patient cohort.

Another reason put forward was that the introducer used in 1996 caused failure in this cohort of patients. The same introducer was used in 1994, 1995, and 1996. It is true that a small number of patients had a problem with noise in the early postoperative period as already described at the end of 1996. None of these patients however had clinical failure. In addition, if burrs at the introducer holes were the reason for failure in this cohort, one would expect wear in the region of the introducer holes. Figure 1.58 shows that only 2 of the 18 introducer holes had the wear scar encroaching onto the area of the introducer holes. Furthermore, in these two examples the wear scar only just encroaches onto the introducer holes. There is no evidence that the introducer caused failures in the 1996 cohort.

The uncomfortable fact is that the one thing that changed in 1996 was the heat treatment regimen, with the 1996 implants being double heat treated. The reader can see in the basic science chapter that pin on disk and pin on plate tests show that the wear of heat-treated cobalt chrome is higher than that of as-cast cobalt chrome. These types of tests are a test of material with the lubricant playing a small part only. If one were to judge heat treatment on the basis of these tests, then heat-treated cobalt chrome would never be used as the bearing for a metal on metal implant. There is a tendency to think of hip simulators as producing a more clinically relevant result. Perhaps surgeons equate expense of the test with clinical relevance or perhaps the apparent complexity of the machines instills

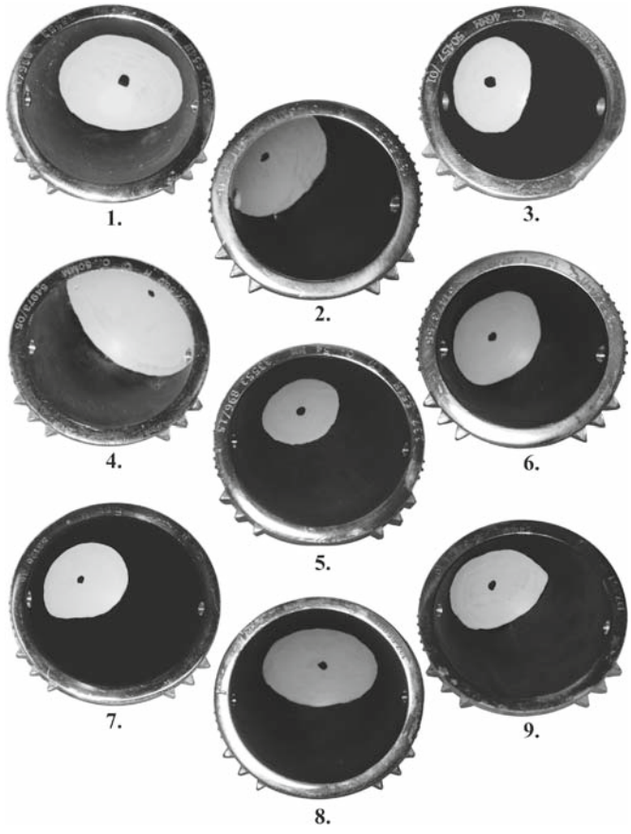


FIG. 1.63. Nine retrieved McMinn hybrid cups from revision surgery. Implants were all inserted in 1996. Wear patch is marked white, center of the wear patch is marked with a black dot, and unworn cup is black.

confidence. On hip simulators, heat-treated cobalt chrome wears no more than the as-cast material. However, one hip simulator study that purported to show no difference between as-cast and double heat treated cobalt chrome was particularly poorly controlled [13]. The mean diametral clearance of the as-cast group was 259.5 μm with the mean clearance of the double heat treated group 215 μm. The difference was highly significant ($p \leq 0.01$). This lower clearance gives the heat-treated couples a fluid film advantage on a hip simulator.

It will be seen in Chapter 4 that fluid film lubrication on certain hip simulators can protect the bearing material from wear. This has important implications when testing materials with poor wear characteristics such as heat-treated cobalt chrome. It should be understood that if the bearing couple is round enough, smooth enough, and has an acceptable clearance, then it will do well on a hip simulator no matter how poor the wear properties of the material. Look at the severe clinical problems caused by the use of high wearing, low carbon containing metal on metal couples. These joints performed very well on hip simulators [14]. Read this Otto Aufranc award paper and see if you too could have been misled by this science. A simple pin on disk test would have shown the high wear of this bearing couple in a matter of days, and many patients could have been spared unnecessary early failure and revision surgery. The real-life test of double heat treated metal on metal bearings was a miserable failure, despite satisfactory simulator tests. I was unwittingly the first surgeon in the world to insert double heat treated metal on metal bearings. My patients have already paid a heavy price for this mistake, and others will continue to pay a price for many years to come. Do you seriously think that I would now accept that these awful bearings are, after all, fine on the basis of hip simulator tests, and that I would ever insert a heat-treated bearing again?

The MMT Years

My colleague Ronan Treacy, FRCS, had been using the McMinn Hybrid Resurfacing since 1994. He had constant problems with supply of enough implants from Corin. In addition, he had quality problems. He routinely tested the implants before insertion and had to reject a number of implants because the head would not spin in the cup. His confidence in the manufacturing ability of Corin was starting to ebb. During 1996, he had decided to seek another source of resurfacing implants and had made moves toward setting up an independent company. When I departed from Corin, Ronan and I joined forces in this venture. The company was called Midland Medical Technologies (MMT). Now Ronan and I had to gather a large team of able-minded people around us to develop the best hip resurfacing the world had seen hitherto. We both had total confidence in the hip resurfacing principle and, in this cause, put our families' finances and our reputations on the line.

During 1996, I had started to take an interest in how the resurfacing was manufactured. With reports of manufacturing problems, I began to realize that I could not leave things to the engineers and hope that they would fix the problems. I made trips to factories and casting houses to learn how these implants were manufactured. By 1997, therefore, I had received a good education on what to do and even more information on what not to do in relation to metal on metal bearing manufacture.

We engaged Centaur Precision in Sheffield to cast the implants, Finsbury Instruments to machine and finish the implants, Plasma Coatings to carry out HA coating of the acetabular cup, Hunts to clean and pack the finished implants, and Swann Morton to carry out sterilization.

We were very clear that we did not want to start some new experiment with the metallurgy, having developed confidence in the material used by McKee and Ring, with a successful history going back to 1960. Tim Band at Centaur was a tireless source of energy and was a key person in getting the Birmingham Hip Resurfacing developed. He took on the role of identifying the methods of casting used to make the McKee and Ring implants. We supplied him with new and used Ring and McKee implants to reverse engineer. This felt like *déjà vu* as I had gone through the same exercise with Corin in 1989. This time, however, Tim Band was in charge. He did a thorough job and produced a huge dossier of results. He was assisted by Graham Dixon, metallurgist at Centaur, and John Metcalf and Jess Crawley, materials scientists at Sheffield Hallam University.

The results of this work were clear. The historic metal on metal implants were as-cast structures.

That meant that these implants were not heat treated. All these investigators were most accommodating with their time and teaching. Ronan did not carry the same baggage as myself, but having been let down by manufacturers on my resurfacing once, I was determined to learn as much as possible from these experts. I spent hours in Sheffield learning about cobalt chrome and the effect of heat treatment on its microstructure and mechanical and wear properties.

We all believed that the implant should be as-cast like the Ring and McKee, and no postcasting heat processes would be used. This threw up some problems. How would we prevent the porosity problems that set Corin off on the wrong track with the McMinn resurfacing implant?

The Sheffield team were confident that by a combination of good design of the waxes and metal feeds, together with vacuum casting, porosity would not be a problem. Time proved that they were right.

Ronan and I were both determined to have a porous ingrowth surface on the cup. We were, however, impressed by the ability of hydroxyapatite (HA) to encourage bone to grow toward it. We had seen the large gaps left by failure of full seating of the hybrid cup fill in beautifully. However, there was accumulating evidence that HA would eventually become resorbed, and this raised concern about late cup loosening. What we really wanted was HA on a porous surface. We discussed this with the experts in HA coating and the advice was to have a coarse, porous coating. With a fine

porous coating, the HA spraying can block the pores in the porous network thus removing the point of having the implant porous coated in the first place.

Also, when the pores are larger, the insides of the pores can be coated by the line-of-sight process that is involved in HA coating.

We tried various porous coatings. The BHR with sintered porous beads was investigated (Fig. 1.64). The microstructure of the cup was ruined by the sintering process, and this type of porous-coated BHR was never implanted into patients.

Interestingly, Wright have applied sintered beads to the Conserve Plus cup and DePuy have applied sintered beads to the ASR cup. We considered plasma-sprayed titanium but had two concerns. We were concerned that titanium coated onto the cobalt chrome substrate could suffer from galvanic corrosion. We were very worried about the plasma spray breaking off and entering the articulation as we had observed plasma-sprayed titanium fall off in its packaging box (Fig. 1.65). I had seen evidence of plasma-sprayed

FIG. 1.64. Sintered beaded BHR cup. Because of microstructural damage of the metal, this implant was never used clinically.

FIG. 1.65. Plasma-sprayed titanium particles in packaging box having fallen off the porous surface of an acetabular cup.

FIG. 1.66. Polyethylene liner removed at revision with embedded plasma-sprayed titanium particles. Plasma-sprayed acetabular shell was solidly fixed.

titanium coating migrate into the articulation in my revision practice (Fig. 1.66).

In view of the above, we dismissed plasma-sprayed titanium as a bad alternative for porous coating the cup. Interestingly, Corin decided to plasma spray the Cormet 2000 cup, initially with cobalt chrome and later with titanium, Biomet has plasma-sprayed titanium on the Recap resurfacing, and Zimmer has plasma sprayed titanium on the Durom cup. Elevation of blood titanium after insertion of the Durom resurfacing implant has been reported [15]. Whether this was due to galvanic corrosion on the back of the cup or particles of titanium getting into the articulation has not been clear until now (see Chapter 6). As can be seen in the retrievals section, titanium has been found ground into the articular surfaces of a retrieved Durom resurfacing. The effect of third-body titanium particles on a second-generation metal on metal bearing has been investigated in a hip simulator study. The titanium particles increased the metal on metal bearing wear by almost an order of magnitude [16].

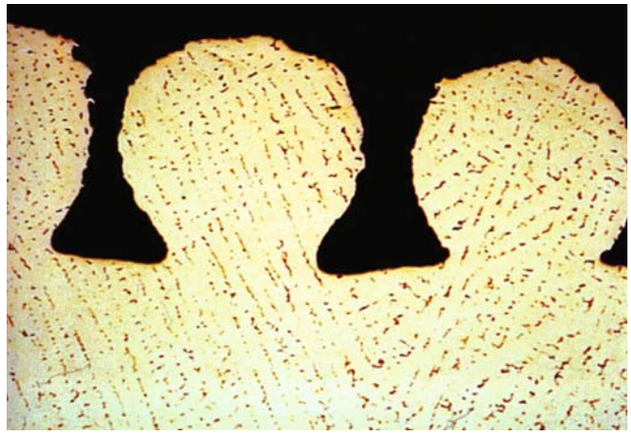


FIG. 1.67. Section through Porocast beads and cup substrate metal. Beads are integral with cup substrate metal. Carbides (dark dots) in microstructure can be seen.

It was decided that a cast-in porous surface would be best, and the Porocast ingrowth surface was developed (Fig. 1.67).

This was not an easy development. I landed Tim Band in trouble with the bigwigs at Centaur when I destroyed a £17,000 tank of ceramic during one of my less successful experiments. I rather liked the appearance of a tea leaf porous-coated cup, with a Harrods tea variety giving a perfect texture. Unfortunately, the tea leaves caused contamination during first dipping, destroying the tank of ceramic. Happily, success eventually followed with a much more reliable method.

Time has shown that the HA-coated Porocast BHR cup has worked very well. I have seen tremendous bone ongrowth (Fig. 1.68) and ingrowth into this cup (Fig. 1.69).

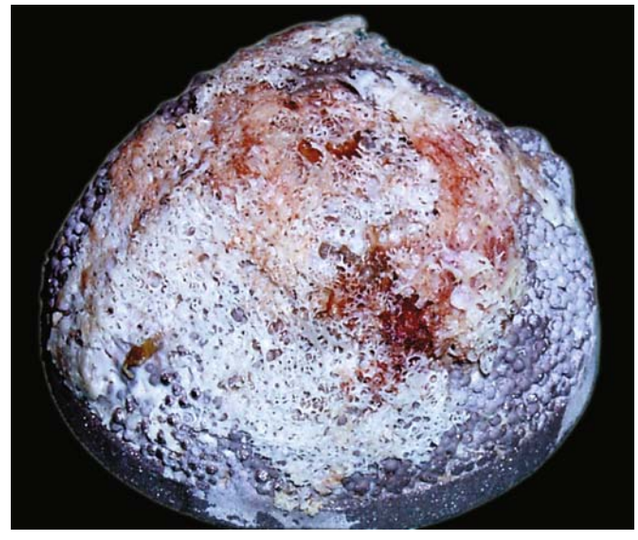


FIG. 1.68. Extensive bone on-growth. BHR cup removed at Girdlestone excision for hematogenous infection 3 years postoperatively

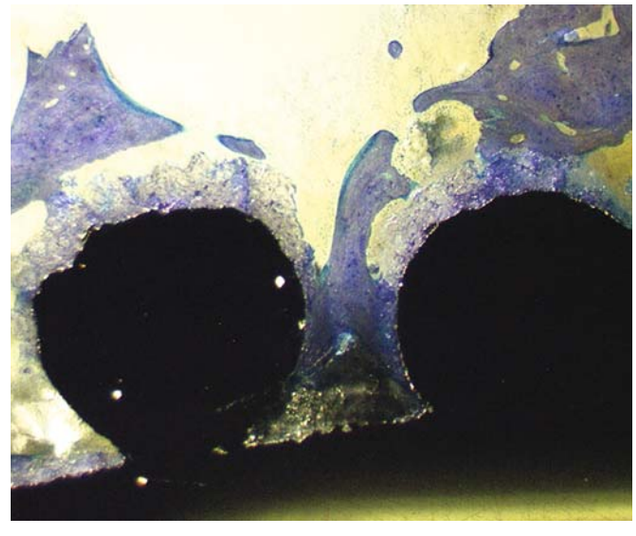


FIG. 1.69. Excellent bone ingrowth into HA on Porocast BHR surface at 6 months.

The introducer had been a problem with the McMinn Hybrid Resurfacing and a new introducer was developed with a grasping and tensioning mechanism in the introducer, locking onto cables that are prethreaded through wormholes in the cup edge (Fig. 1.70). This instrument had designed out, as far as possible, the opportunity for the introducer to damage the articulating surface of the cup.

We were not prepared to tolerate the out-of-roundness issues that kept on being brought up during the Corin years. Mike Tuke and his team at Finsbury did a great job by introducing precision manufacturing for the BHR. All the phone calls and concern about quality that existed during the Corin years disappeared at a stroke. What a joy to be able to trust your manufacturer. Clearance was another issue that had to be decided upon, and again we did not want to engage in any new experiments with patients, instead relying on the clearances used in the historic metal on metal devices (Fig. 1.71).

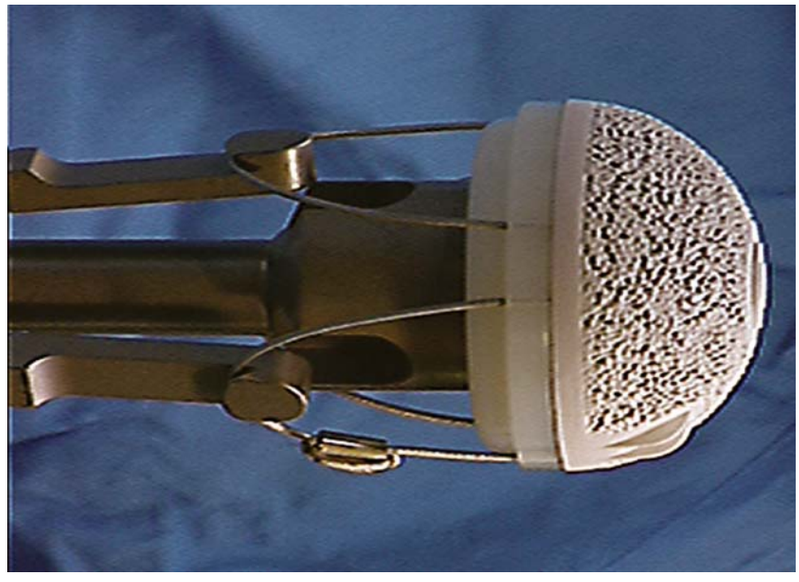


FIG. 1.70. BHR cup on introducer.

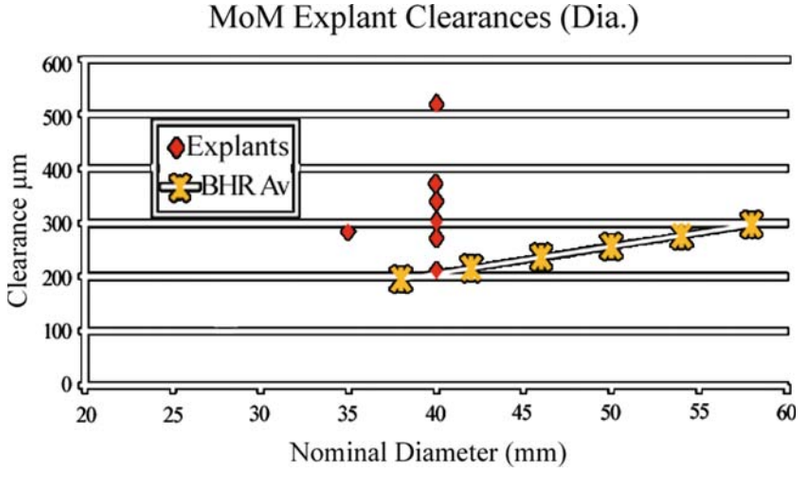


FIG. 1.71. Diametral clearances of long-term Ring and McKee-Farrar explants with measured low wear. Clearance of the BHR increases with increasing head size.

The range of clearances of the BHR was chosen from the lower end of the range of clearances from successful historic metal on metal devices.

Laboratory simulator experiments have shown that reducing the clearance reduces initial run-in wear. As already discussed, I am sceptical about laboratory simulators. Some years after the introduction of the BHR, we decided to get simulator experiments done as some of our surgeons were asking for these. A colleague and I went to see Prof. John Fisher in Leeds, and we had a tour of his laboratories. Afterwards in his office, he expressed surprise that we wanted simulator studies as the BHR device was obviously clinically successful. I explained that surgeons in some countries wanted results from these tests and hence my enquiry. He then shocked me by asking, "What do you want to show? Would you like the wear to be lower, the same or higher than other metal on metal devices? I can set the simulator to show whatever you want!" He reinforced his point by giving me a slide showing completely different wear results of the same metal on metal bearings on two different simulators. I later published this slide with his permission [17]. My colleague and I left Leeds that day rather confused about the value of hip simulators. Laboratory simulator studies will be presented later in this book for those who place reliance on these devices. My position is that if something looks good on a simulator, then it may be worthy of definitive testing in the clinical setting. I object when surgeons present suboptimal clinical results and then say; "Can't be anything to do with the bearing because the simulator results were fine!" The simulator results are a rough guide, on a good day, as to what might happen in the body. Clinical studies are reality. Conversely, if hip simulator studies produce poor results on a device that is known to work well clinically, then the hip simulator regimen needs to be examined to understand where the simulator study went wrong.

Clearance, therefore, was an issue that I considered worthy of clinical investigation. Twenty-six low-clearance BHRs were manufactured for my study. The mean diametral clearance in these implants was 98 µm, with a range 94 to 109 µm. The study was designed to remove confounding variables, and only 50-mm bearings were manufactured with this low clearance Men with unilateral hip arthritis, no other metallic devices in their bodies, and a willingness to participate in this long-term study after informed consent were regarded as suitable patients.

As will be seen in the section later in this book on metal ions, cobalt is an ion that is rapidly excreted from the body in the urine. A timed urine collection with a 24-hour measurement of cobalt excretion is labor intensive but gives an excellent measurement of daily production of metal from wear and corrosion. The graphs of Fig. 1.72 show the daily production of cobalt by the low-clearance BHRs compared with the regular-clearance BHRs.

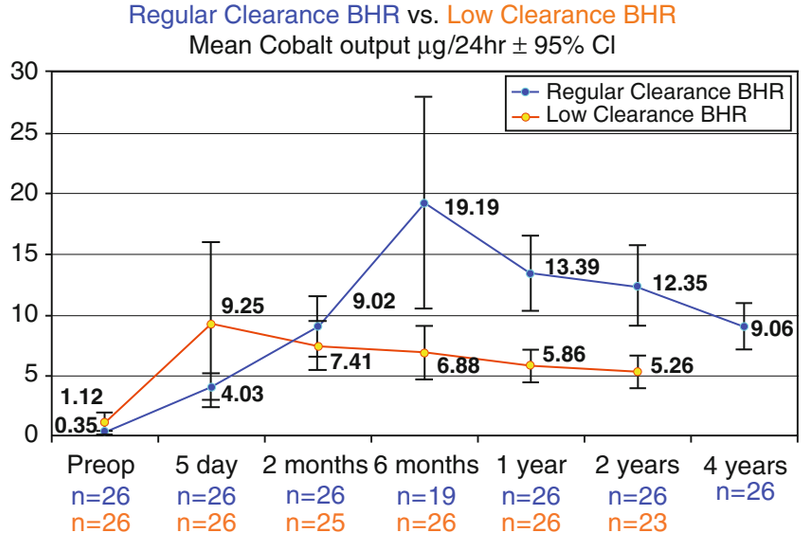


FIG. 1.72. Daily output of cobalt from regular-clearance and low-clearance BHR.

This appears to give a clear result, with the clinical study agreeing with previous hip simulator studies showing that low-clearance bearings reduce run-in wear. Interestingly, the peak production of cobalt in the regular clearance group is at 6 months with a slow decline in production to 4 years. The peak production of cobalt in the low-clearance group is at 5 days with a slower decline in production out to 2 years. It will be interesting to see when these two lines meet, if they do indeed meet, indicating an equal steady-state wear in these different clearance joints.

It might be wondered, therefore, why we have not reduced the clearance of the 50-mm-diameter bearing BHR from around 250 μm down to around 100 μm. This can easily be done from a manufacturing viewpoint. Unfortunately, there is a catch. Three patients out of the 26 low-clearance BHRs in the study have developed radiolucent lines around their cups (Fig. 1.73). This is an unusual finding for the BHR cup. An independent study of 230 BHRs with 210 complete sets of radiographs showed no radiolucent lines around the acetabular component [18]. We think that these radiolucent lines may be related to intraoperative cup deformation. A discussion of intraoperative cup deformation will be seen in later chapters; suffice it to say here that it is now known that intraoperative deformation of acetabular cups does occur. The line of deformation is from the anterior inferior iliac spine to the ischium (Fig. 1.74).

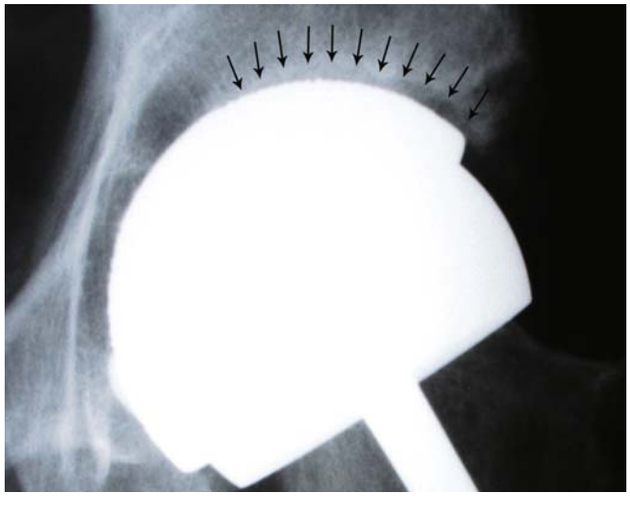


FIG. 1.73. Zone 1 and 2 radiolucent line (arrows) in low-clearance BHR cup 2 years postoperatively.

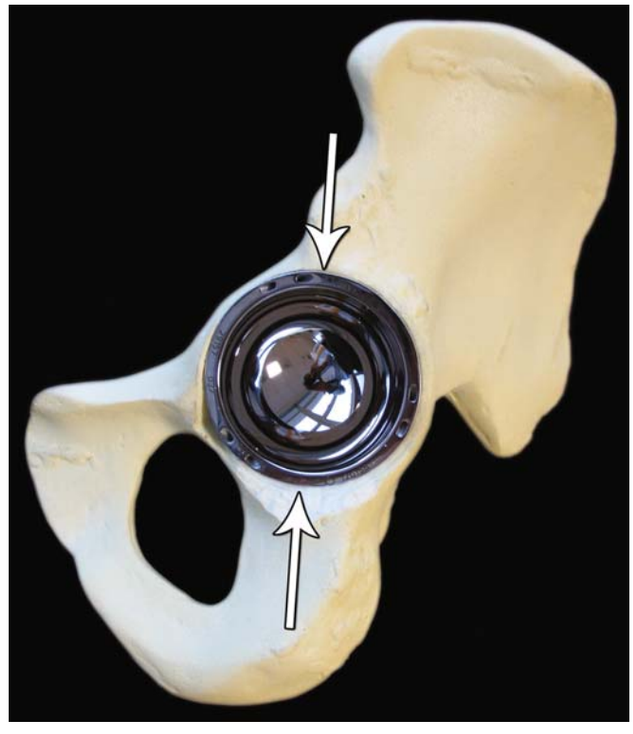


FIG. 1.74. With press-fit cementless cups, compression occurs between anterior inferior spine and ischium (arrows).

We have been able to measure intraoperative cup deformation with a special instrument and have observed cup deformation measurements of more than 100 µm (Fig. 1.75). Intraoperative deformation of acetabular THR cup shells has been measured between 10 and 455 µm [19]. We speculate that the radiolucent lines in the three patients from the low-clearance group were due to cup deformation greater than the clearance, thus causing gripping of the head by the deformed cup periphery. The extent of cup deformation relates to the quality of the patient's acetabular bone stock, the amount of acetabular underreaming and extent of press-fit achieved, and the deformation characteristics of the component. Only the latter of these is under the control of the implant designers. Excessively low clearance of a resurfacing metal on metal device is considered dangerous. To put this in perspective, as the BHR ball sits in the cup, the argument is about whether to have the gap between the ball and the cup one hair's breadth or two hairs' breadth. Two hairs' breadth gap is safer.

Thus, the ingredients for the cake were assembled, and the first BHR was inserted in July 1997. This patient continues to do well clinically and radiographically at the 10-year postoperative stage (Fig 1.76).

FIG. 1.75. Equipment for measurement of intraoperative cup deformation.

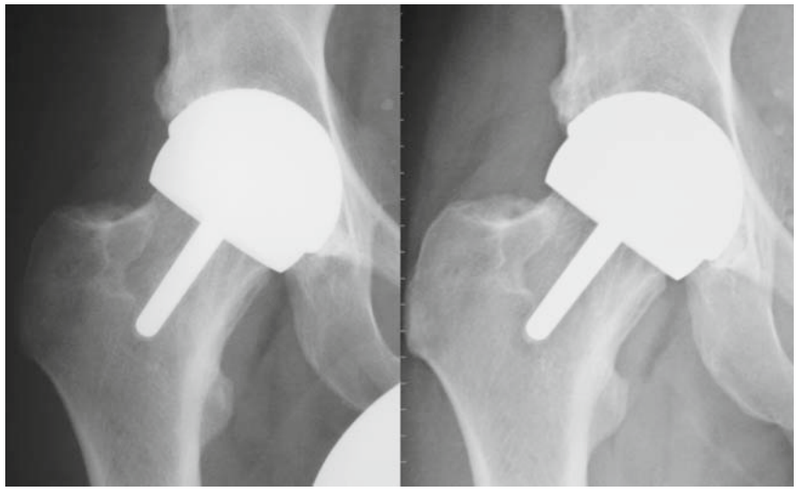


FIG. 1.76. Five-year and 10-year postoperative radiographs of first BHR patient.

Because Ronan and I were financially linked to the BHR, we were concerned that our reporting of our own results would be seen as biased. We knew very well that our results would not be biased, but it was the perception of others that mattered. We decided that an outside group should review our results; the question was who? We had an excellent research center at the Royal Orthopaedic Hospital run by Prof. Paul Pynsent, and there was an expectation that we would engage that group to carry out the independent patient follow-up. I was bothered that the Birmingham-based research group would also be seen as being our friends, and I sought another group who would definitely not be seen as our friends. For more than 100 years, the Robert Jones and Agnes Hunt Orthopaedic Hospital in Oswestry and the Royal Orthopaedic Hospital in Birmingham have competed for funding and staff and view each other as local rivals. I came to the view that the Oswestry Outcome Centre could never be regarded as our friends and that they were the perfect group to carry out an independent review of our cases. Prof. James Richardson and his group were engaged to carry out follow-up not only on Ronan's and my cases but also on the first 5000 BHRs from around the world. This decision was not popular in Birmingham and gained me some enemies, but I think in the end it was seen as an honest attempt at getting truly independent data.

More than 70,000 BHRs have been inserted in a number of countries since, with several publications showing good outcomes and investigations.

Life was never boring at MMT. Eric Isbister, Ronan Treacy, and myself carried out the BHR for 6 months before the implant was released to a wider group. We trained the company representatives properly. Every representative spent time in the operating room with Ronan and myself, and the best ones came back on multiple occasions and scrubbed in with us. We had a fantastic group of representatives who were high-quality people to start with, and the training that they received made them a valuable resource for our new surgeons performing their first few cases. When fully released, the uptake of the BHR was greater than we had ever thought likely. We had no effective competition in the early days and were able to choose the best hip surgeons across the world to take on this implant. The vast majority of these surgeons came to Birmingham for training. We discovered that the better the surgeon, the more likely they were to come for training. Really good surgeons hate failure, and any tips they can pick up to avoid problems are sought, even if it involves the inconvenience of traveling to Birmingham. We have grown to mistrust the know-all types who believe that they do not need training. Experience has shown that their results are soon found wanting, but they will always try and blame the instruments or the implant! Australia was the second biggest market outside the United Kingdom, and Harry Revelas, a BHR surgeon from South Africa, moved to Sydney to become our Australian distributor. He and his team did a wonderful job training surgeons and getting the BHR off to a successful start in Australia. We had one troublesome time when an employee had been secretly abusing company funds. We discovered very late that MMT was the owner of a luxury yacht and other items that were a diversion from our purpose. With around 60% growth per annum, every penny the company made in the early days was ploughed back into purchase of instruments, surgeon training, and more implant stocks. With this silly diversion of funds, stocks were low and there were unhappy surgeons for several weeks until the situation was resolved. At the time of this problem, Mike Tuke temporarily assumed a management role in MMT to try and get things back on track. Finsbury and MMT had been separate companies, and I suggested to Mike that the two companies should merge. I offered a 50–50 split of shares between MMT and Finsbury, but my offer was rejected and the two companies continued to run separately. Our two nonexecutive directors, Simon Hunt and Graham Silk, spent a lot of their time guiding this happy bunch of enthusiastic amateurs in the ways of management, and now we had missed blatant misuse of funds! Simon and Graham searched out John Hatton who was appointed as the managing director of MMT. He used all his financial and people management skills to grow the company fast but at the same time taking no shortcuts that could degrade the quality of our products or services. John was a huge success, and he guided MMT into a stronger position than Ronan and I could ever have imagined. Data started to accumulate showing good results with the BHR in the hands of many surgeons. The new messages from the former malcontents at conferences were particularly amusing:

Tim Band succumbed to our offer to move from Centaur to become a director of MMT, and Brendan McGrath, Tony Alleeson, and Roger Ashton also joined as directors. We outgrew the space available at the Birmingham University Research Park and moved to new premises on the outskirts of Birmingham.

The Birmingham Mid Head Resection (BMHR) implant was developed and an a radiostereometric analysis (RSA) study was started. A cemented-stem THR was developed with Richard Field, and development of a cementless THR stem with Peter Walker and Sarah Muirhead-Allwood was begun.

We started to get offers from larger companies to buy MMT. These were rejected. One major market still eluded us. We had started work to try and gain access to the United States. We hired M Squared from Washington run by Marie Marlow who were expert at building a case and putting it to the Food and Drug Administration (FDA). We discussed distribution deals with different companies in the United States, but then two offers were made to buy MMT that we could not ignore. After a lot of consideration with our agents, Kimbells[LLP], we decided to accept the offer of Smith & Nephew Ltd. The sale was completed on March 12, 2004, and announced at the San Francisco meeting of the American Academy. I gave a talk from the Smith & Nephew stand on the BHR, and the interest was so great that there was standing room only. I was asked to participate in a live Webcast to city financiers with members of the Smith & Nephew team chaired by Sir Chris O'Donnell, chief executive officer. Ronan and I were asked to stay on for 5 years to help with the transition and also to help in gaining FDA approval. It was sad to say goodbye to Simon Hunt, Graham Silk, and John Hatton who had all done so much to ensure the success of MMT.

Smith & Nephew backed the efforts of Marie Marlow and her team with input from their regulatory affairs department. My staff at the McMinn Centre worked tirelessly to have a 100% audit of our notes and x-rays by M Squared and then make ourselves ready for a week-long audit by the FDA. The Outcome Centre in Oswestry also had the same work to prepare for audits. Smith & Nephew added 2-mm increment heads, each with two matching regular cups and each having a matching dysplasia cup. New instruments were also designed and manufactured. The BHR was now the most comprehensive resurfacing system available (Fig. 1.77).

FIG. 1.77. Two-millimeter-increment Birmingham Hip Resurfacing sizing chart.

On May 9, 2006, the Birmingham Hip Resurfacing was given clearance for sale in the United States by the FDA. We all drank a toast to Marie Marlow on that day.

References

1. Swanson SAV, Freeman MAR, Heath JC. Laboratory tests on total joint replacement prostheses. J Bone Joint Surg Br 1973;55:759–773.
2. Wilson JN, Scales JT. Loosening of total hip replacements with cement fixation, clinical findings and laboratory studies. Clin Orthop 1970;72:145–160.
3. Andersson GB, Freeman MA, Swanson SA. Loosening of the cemented acetabular cup in total hip replacement. J Bone Joint Surg Br 1972;54:590–599
4. Heath JC, Freeman MA, Swanson SA. Carcinogenic properties of wear particles from prostheses made in cobalt-chromium alloy. Lancet 1971;1:564–566.
5. Mervyn Evans E, Freeman MAR, Miller AJ, Vernon-Roberts B. Metal sensitivity as a cause of bone necrosis and loosening of the prosthesis in total joint replacement. J Bone Joint Surg Br 1974;56:626–642.
6. Brown GC, Lockshin, MD, Salvati, EA, Bullough PG. Sensitivity to metal as a possible cause to sterile loosening after cobalt-chromium total hip replacement arthroplasty. J Bone Joint Surg Am 1977;59:164–168.
7. Sweetnam R. Metal sensitivity. J Bone Joint Surg Br 1974;56: 601–602.
8. Charnley J. Low Friction Arthroplasty of the Hip. Berlin, Heidelberg, New York: Springer-Verlag, 1979.
9. Wagner M, Wagner H. Preliminary results of uncemented metal on metal stemmed and resurfacing hip replacement arthroplasty. Clin Orthop 1996;329S:S78–S88.
10. McMinn D, Treacy R, Lin K, Pynsent P. Metal on metal surface replacement of the hip. Clin Orthop 1996;329S:S89–S98.
11. Ahier S, Ginsburg K. Influence of carbide distribution on the wera and friction of Vitallium. Proc Inst Mech Eng 1966;181: 137–139.
12. Clemow AJT, Daniell BL. The influence of microstructure on the adhesive wear resistance of Co-Cr-Mo alloy. Wear 1980;61: 219–231.
13. Bowsher JG, Hussain A, Williams PA, Shelton JC. Metal-on-metal hip simulator study of increased wear particle surface area due to 'severe' patient activity. Proc Inst Mech Eng [H] 2006;220:279–287.
14. Chan FW, Bobyn JD, Medley JB, Krygier JJ, Tanzer M. The Otto Aufranc Award. Wear and lubrication of metal-on-metal hip implants. Clin Orthop Relat Res 1999;369:10–24.
15. Lavigne M, Vendittoli P-A, Roy AG. Early results of an RCT comparing conventional and resurfacing total hip arthroplasty. Presented at: International Symposium on Resurfacing of the Hip Joint, Zurich, April 2–22, 2005.
16. Lu B, Marti A, McKellop H. Wear of second generation metal on metal hip replacement. Effect of third body abrasive particles. Transactions of the Sixth World Biomaterial Congress, Kamuela, Hawaii, May 15-29, 2000, abstract 183.
17. McMinn DJW. Development of metal/metal hip resurfacing. Hip Int 2003;13:41–53.
18. Back DL, Dalziel R, Young D, Shimmin A. Early results of primary Birmingham hip resurfacings: an independent prospective study of the first 230 hips. J Bone Joint Surg Br 2005;87B:324–329.
19. Peindl RD, Squire M, Griffin WL, Mason JB, Odum S. Acetabular component deformations and press-fit loads in total hip arthroplasty. Presented at: ORS 2006, Carolinas Medical Center, Charlotte NC, OrthoCarolina, Charlotte NC, Poster 487, 2006.