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controversial topics in orthopaedics

The best bearing couple for hip arthroplasty

The McMinn Centre presents a well-researched, convincing case for metal-on-metal articulation. The tribological and clinical advantages of its use in the young active patient are highlighted.

Sandhu and Middleton argue that ceramics have superior biomechanical properties of low wear and friction. These characteristics are off-set by the cost, poor tolerance to implant malpositioning and dislocation that makes revision surgery challenging. These factors account for the relatively low usage in the UK.

The emphasis of Grover's article was the long history of good durable results of metal-on-polyethylene in patients over 65 years of age. Improvements in manufacturing, sterilisation and design of uncemented cups widen its application to a younger age group. The cost-effectiveness and long-term safety profile guarantees future usage in spite of its relatively poor wear resistance when compared with alternative couplings.

The consensus view is that metal-on-polyethylene is not the best bearing couple in the young, active patient and this would explain the ever-increasing popularity of metal-on-metal hip resurfacing in the UK. Concerns remain over the possible adverse long-term effects of raised blood metallic ion levels.

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Metal-on-metal

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The essential requirements of an ideal bearing couple in hip arthroplasty include excellent biocompatibility, adequate structural strength, low friction, low wear and high resistance to degradation/corrosion. Metal-on-metal bearings (M-M) were originally used in the 1960s and 1970s in total hip replacements (THRs) with limited success. Manufacturing and finishing techniques at the time were unsophisticated and tolerances were poor. As a result, there were several early failures. This and other reasons led to their withdrawal in favour of metal-on-ultra high molecular weight polyethylene (M-PE) bearings.

During the next 20 years, as modern arthroplasty procedures started restoring near-normal quality of life to arthritic patients, their usage was extended to younger patients as well. Sir John Charnley, who pioneered these bearings, cautioned against their use in young patients unless they had other restraining disabilities.[1] Just as Charnley had warned, these young active patients with conventional (M-PE) bearings experienced higher and earlier failures than older patients. Investigations into M-PE joint failures revealed that the limiting factor in their long-term survival was polyethylene-wear-debris induced osteolysis.[2] Polyethylene was, therefore, identified as the weak link and the search began for an alternate bearing.

Improvements are being made to polyethylene (PE) wear-resistance through techniques like cross-linking (XLPE), but these techniques have the potential to weaken the mechanical properties of PE. Furthermore, reduction in wear volume alone has not always been accompanied by a reduction in adverse functional biological activity. This was due to the fact that activity depends on the number of particles rather than wear volume. Most of the reduction in wear volume with XLPE is achieved through a reduction in particle size rather than number. The smaller particles are also more elongated, a shape that has a greater potential for adverse activity than the earlier rounded particles.

Ceramic components were introduced in the 1970s. A ceramic head PE combination reduces wear by 50%, but a phenomenal reduction in wear is achieved by hard-on-hard bearings including all-metal or all-ceramic bearings.

Modern metal-metal bearings

Some historic M-M bearings failed early while others showed excellent long-term survival.[3,4] In many long-term survivors, there was no evidence of osteolysis in spite of an extensive open bone-implant interface (Fig. 1). Retrieval studies on historic M-M bearings revealed extremely low *in vivo* wear rates.[5] Modern manufacturing technology and tight quality control led to the resurgence of much improved M-M bearings as a viable alternative option in arthroplasty. Advances in understanding the tribology of M-M bearings[6] also favoured their acceptance.

Advantages of metal-metal bearings

Wear

M-M bearings are known for their low wear rate. Volumetric wear rate is almost two orders of magnitude less than conventional bearings. *In vitro* studies have shown that both volumetric and linear wear rates in M-M bearings display an initial running-in phase during the first one million cycles (Mcyc). After this, the wear rate comes down

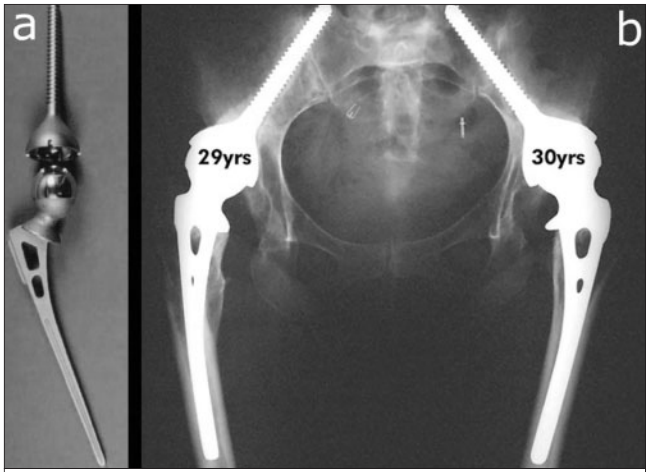

Figure 1. (a) A metal-on-metal (Ring) total hip replacement revised 23.5 years after implantation. It showed a femoral head linear wear of 10 μm (0.43 μm/year) and socket wear of 8 μm (0.35 μm/year). (b) X-rays of a patient with two well-functioning Ring THRs, 29 and 30 years after operation, respectively.

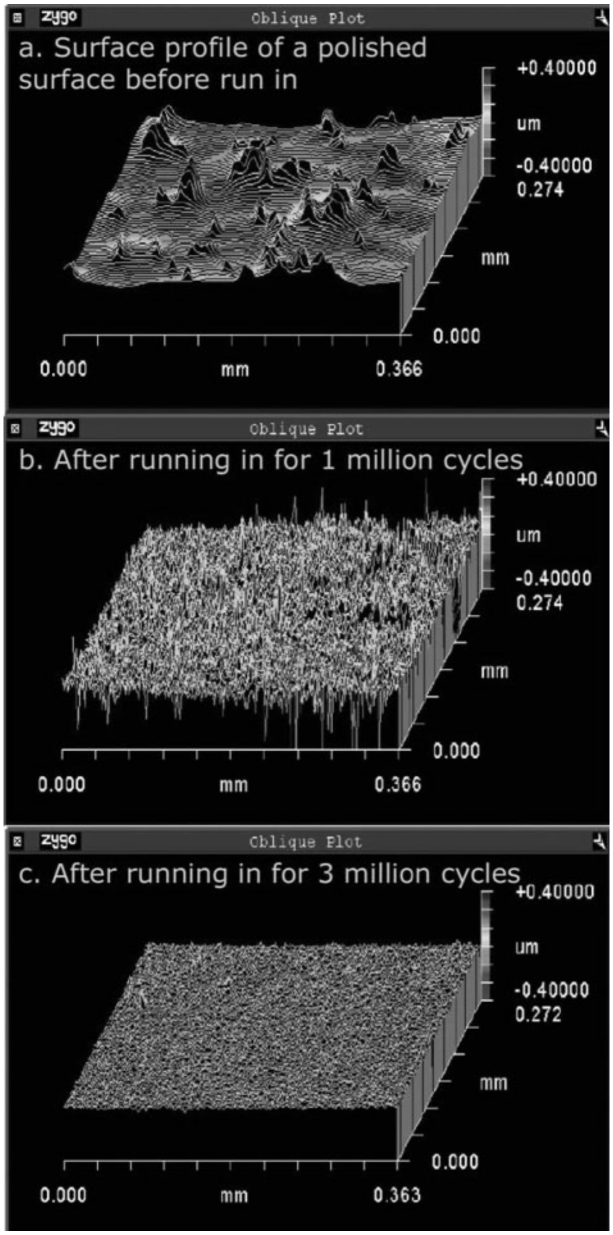

Figure 2. Surface profile of a Birmingham Hip Resurfacing (metal-metal bearing) before and after running-in in a hip simulator for one and three million cycles. The asperities seen protruding beyond the surface before run-in (a) are removed through wear making the surface progressively smoother (b,c). The surface also assumes a negative profile with troughs which are known to fill with lubricant and assist lubrication. (from Prof. Tony Unsworth, University of Durham, UK).

to under 1 μm/Mcyc. *In vivo* studies have confirmed a low wear rate in both historic and modern M-M bearings.

There is difference in the morphology of particles as well. It is hypothesised that the size of polyethylene particles (micrometre/submicrometre range), which is similar to the size of a bacterium, is partly responsible for triggering macrophage activity. The smaller sized metal-wear particles are less likely to induce macrophage stimulation and initiate the osteolytic cascade.

Friction

It is possible to achieve much higher precision in terms of roundness and surface roughness with metal components as compared to PE components. The combination of low surface roughness and increased bearing diameter in modern M-M joints favours the formation of a fluid film separating the articulating surfaces.[6] This has the potential to reduce friction and wear drastically. Furthermore, M-M bearings are known to self-polish with usage, a phenomenon unique to these bearings (Fig. 2). In simulator studies, it is found that as the bearing runs in, friction factor decreases to a range that predicts full fluid film lubrication. In a run-in M-M bearing, friction factor is lower than that in M-PE and is almost as low as in ceramic-ceramic.

Ceramic-ceramic bearings have been shown to have lower wear rates than M-M bearings. However, ceramic bearings have several other problems.[7] They are less forgiving towards variations in component positioning and alignment. Microseparation during normal walking cycle and stripe-wear (from edge loading) lead to higher than predicted wear rates *in vivo*.[8] High wear at modular junction cones are a serious cause for concern with ceramics. Ceramic impingement on the femoral component neck can lead to wear debris and neck damage. Zirconia ceramics are known to degrade with time and produce excessive wear.

Mechanical strength

Metal components have much greater mechanical strength and ductility compared to ceramic components. The low structural mechanical strength of ceramics reduces the number of possible neck-length and liner options and, worse still, it is almost impossible to use them as resurfacing components.

Osteo-integration

Metal components can be directly osteo-integrated. Bone growth can occur directly onto and into an appropriately roughened metal surface providing excellent biological fixation. PE and ceramic components need either bone cement or a metal-back carriage for fixation. This has the undesirable effect of either increasing acetabular bone loss or reducing the bearing diameter.

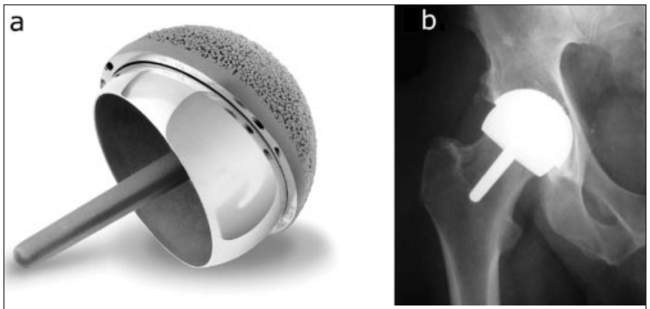

Figure 3. (a) Birmingham Hip Resurfacing components. (b) 7-year follow-up X-rays of a patient aged 45 years at operation.

Resurfacing option

Hard-hard bearings including M-M have the potential to generate a fluid film while in motion. The greater the film thickness, the lower is the bearing wear and friction. Film thickness increases with increasing bearing diameter. Hence, in M-M joints, larger diameters reduce wear while in M-PE bearings, they increase wear. Therefore, M-M bearings are suitable for use as resurfacing components while M-PE bearings are not.

The greatest benefit from metal-metal bearings comes from this possibility to use them as thin, less invasive resurfacing components[9] thereby reducing bone loss (Fig. 3). This conservative option is especially useful in younger patients who have the potential to outlast any arthroplasty device. Revising a resurfacing device is much easier and gives a better outcome than revising a stemmed device.

Revision options

The problems of using a ceramic device are multiplied when it comes to revision. High trunion wear makes it inadvisable to use a ceramic head a second time on the stem. Although better manufacturing has brought ceramic component fracture rates down, every such fracture can be a revision surgeon's nightmare because the particulate debris is very abrasive and detrimental to the outcome of the revision. A ceramic device should only ever be revised to another ceramic device to prevent runaway wear from the dispersed particles. In contrast, revision of a metal-metal device leaves the full range of revision bearing options open.

Dislocation rate

Early dislocation rate with M-M bearings is low. The rate was found to be 0.9% in a 28-mm M-M bearing compared to

6.2% in a 28-mm ceramic on polyethylene bearing in a matched series. This has been explained to be due to a possible 'suction-fit effect' in M-M bearings.[10]

Results

Around 400,000 modern M-M bearings have been used in the past 17 years as both replacements and resurfacings with excellent medium term results.[11,12] With the M-M hip resurfacings, it was found that the results are significantly better than those of conventional THRs in young and active patients – the very group in which THRs are known to fail early. In patients who are under the age of 55 years with primary osteoarthritis, it was found that patients with resurfacings could safely return to levels of activity, which would have been neither advisable nor possible with conventional hip replacement. Of all the patients in this study, 87% played sport. Amongst male patients with unilateral resurfacings, 92% played sport and 62% participated in impact sports. The survival rate in this group of 446 M-M hip resurfacings (379 patients) is 99.8% at 11 years (follow-up, 4–11.1 years; mean, 6.1 years).

In a DEXA (dual energy X-ray absorptiometry) scan study of proximal femoral bone mineral density (BMD),[13] it was found that there was a median increase of 11% in patients with modern M-M Birmingham Hip Resurfacings (BHRs) compared to a 17% BMD decrease in patients with an uncemented M-PE hip replacement at 2 years in the critical region of the calcar femorale. This leads to the conclusion that resurfacing, which is only possible with a M-M device, transfers load to the proximal femur in a more physiological manner than long-stem devices and that it prevents stress shielding and preserves the bone stock of the proximal femur.

Concerns

Since many of these M-M bearings are being used in younger patients, it raises concerns about the possible adverse effects of raised systemic metal ion levels in the long-term. Most modern M-M bearings are made of cobalt–chrome alloy. The constituent elements of the alloy happen to be essential elements and, therefore, the body is able to clear excess ions in the urine effectively.

Two specific concerns have been raised and they relate to the potential for: (i) carcinogenesis; and (ii) metal hypersensitivity. Delayed lymphocyte-mediated hypersensitivity has been reported in patients with failed M-M bearings, although the incidence is extremely low. It is not yet clearly understood whether pre-existent metal hypersensitivity in an individual leads to failure or whether the metal debris generated from a M-M bearing leads to hypersensitisation.

There have been very infrequent reports of local tumours in the vicinity of both M-M and M-PE bearings, but no causal relationship has been established. The best information on carcinogenicity is obtained from large population-based epidemiological studies based on the Scandinavian cancer registries. The longest of these studies[14] that tracks patients with historic M-M bearings involves a total of 9756 person-years at risk and no loss to follow-up (osteoarthritis as the primary diagnosis). This study showed that, although there were gender differences, there was no significant increase in either the all-site cancer rate or site-specific cancer rate amongst patients with M-M bearings (at a maximum follow-up of three decades) in comparison to the expected rates in the general population.

In one study of metal ion levels, a cohort of 16 patients with historic M-M THRs were compared with another cohort of 19 young active patients who were participating in high quality sport and had modern M-M resurfacings. It was found that the whole blood cobalt and chromium levels in the two groups were in the same range. This leads to the expectation that modern M-M bearings are likely to have the same benign long-term clinical history as the historic bearings.

Conclusions

The excellent low-friction, low-wear, high-biocompatibility properties of modern M-M joints make them the best bearing couple for hip arthroplasty. They can also be used as resurfacing components making them ideal for use in the young and active patient. The benign, long-term, clinical history of these bearings assures us that they are safe. However, there is a continuing need for long-term metal ion monitoring and large-scale epidemiological surveillance.

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Ceramic-on-ceramic

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Ceramic bearings in hip replacement are a source of debate among hip arthroplasty surgeons. Ceramics potentially have excellent bearing properties, but there are potential drawbacks. Half of all hip arthroplasties in central Europe use ceramic heads, with increasing numbers of ceramic acetabular inserts. There is much lower usage of ceramic bearings in the UK, probably reflecting both the concerns of use of ceramics as well as the expansion of hip resurfacing. In the US, the use of ceramic in hip arthroplasty is < 10%.

Ceramic bearings were introduced as a potential solution to polyethylene wear by, amongst others in the 1970s, Pierre Boutin who, having operated on a vice president of a ceramic company, then worked with him to develop ceramic orthopaedic implants. During this time, Boutin actually implanted ceramic balls in himself. Ceramic bearings have now been widely used with over 150,000 components having been implanted in Europe. There are several European studies with good results justifying their use,[1] as well as there being a few North American and UK supporting studies.

The ceramics used in orthopaedics, either alumina (Al_2O_3) or zirconia (ZrO_2), exhibit properties which make them attractive potential bearing surfaces. They demonstrate excellent resistance to both wear and surface damage such as scratching by their high level of hardness. Also, they display a low coefficient of friction, with good lubrication. Both volumetric and linear wear is enormously reduced with ceramic-on-ceramic bearings, and even a ceramic-on-polyethylene bearing significantly reduces polyethylene wear debris as compared to a metal-on-polyethylene bearing.[2] These wear characteristics make the use of ceramic as a bearing material very attractive, especially in young patients in whom there are reports of the high rates of polyethylene wear debris with subsequent osteolysis and failure.[3] Present-day ceramics have seen very significant improvements in purity, smaller grain size, zero porosity, high strength and excellent fracture mechanics. The highly debated potential problems of raised metal ions, such as teratogenicity, from large metal-on-metal alternate bearings, are avoided with ceramic bearings.

Conversely, there are both resource implications and infrequent, but significant, drawbacks of using ceramic bearings. These have resulted in some surgeons strongly opposing their use.

The cost of orthopaedic implants is an important issue in both the present day NHS (especially with the introduction of 'Payment by Results') and the private health care sector. Ceramic implants are extremely expensive: the routine use of these may affect the economic competitiveness and even the viability of an orthopaedic unit. Hence, with the introduction of tariff prices for hip replacement, and the critical assessment of implant costs, can ceramic bearings be justified? As surgeons, we have a responsibility to offer the best possible care available to our patients: does the potential longevity offered by ceramics justify their use in young active patients, considering the reported poor outcomes from standard metal on polyethylene articulation? This dilemma will only increase with time in the present health economic environment.

Ceramic is very brittle and fracture of the bearing surfaces, with catastrophic failure such as the femoral head 'exploding', has been reported regularly. However, many of these reports are based upon first generation ceramic implants. Newer second and third generation ceramic implants with the improvements in strength and fracture mechanics have a much lower fracture rate, and indeed Willmann[4] has reported a fracture rate of only 0.004% in 500,000 ceramic total hip replacements. Hence, this risk of fracture, although highly pertinent, is probably overstated.

Revision hip arthroplasty following a primary hip replacement with ceramic bearings is potentially a very difficult problem. Allain *et al.*[5] reported a 5-year survival rate of 63% for revision following fracture of a ceramic femoral head. Any ceramic debris remaining, following a revision, acts to produce third body wear. If a standard metal-on-polyethylene bearing is used in such a revision, there will be very high levels of third body wear upon the less hard polyethylene with subsequent osteolysis. Even for metal-on-metal bearings there is concern regarding metallosis and raised metal ions. Some surgeons advocate only using ceramic-on-ceramic bearings in such revisions.

Prior to such a revision hip replacement, the Morse tapered neck of the femoral component is frequently damaged following articulation with fractured or damaged ceramic bearings, as well as damage to the acetabular shell to be retained. Implanting new ceramic bearings onto these retained components at the time of revision surgery will result in higher tensile stresses in these bearings which may result in future failure. Hence, a revision with the simple exchange of the bearing surfaces, for well-fixed components, will probably not be possible if ceramic bearings are to be used at the time of revision. The often difficult and time-consuming removal of well-fixed femoral and acetabular components will be required in such a revision situation.

Overall, the risk of future re-revisions is increased. Ceramic debris limits the bearing options which may be used at revision and the use of ceramic bearings at the time of revision surgery may limit the implant options.

The modularity of ceramic bearings is limited, with reduced acetabular options in particular. Elevated rims, variable offset, eccentricity and constrained acetabular options are in the main unavailable, these may result in instability and dislocation, as well as leg length and offset problems. Dislocation (a phenomenon to be taken into consideration following hip replacement and revision surgery) is potentially very significant with ceramic bearings. Indeed, the dislocation rate with ceramic bearings is potentially higher, by comparison to standard polyethylene and metal bearings, with a cited rate of up to 4%. The high degree of hardness of the ceramic components leads to a point contact associated with very high contact stresses on dislocation and subluxation. This may lead to ceramic chipping or complete fracture. Such chips, if lodged between the articulating surfaces, may promote third body wear and osteolysis.

The surgeon requires exacting technique with ceramic bearings, particularly for component positioning. Malpositioning will result in impingement. Original first generation designs were prone to rim wear of the acetabular ceramic component, from impingement of the femoral neck with malpositioning. To avoid this, newer second generation designs have elevated metal rims peripherally with the ceramic insert recessed. However, with these newer designs there may be metal-on-metal impingement with metallosis, as well as a reduced range of motion present with malpositioning.

The surgeon has to be accurate when inserting the acetabular ceramic liner: this is often not straightforward. Malalignment of 5° may result in chipping and cracking of the ceramic. For minimally invasive surgery. this 5° of malalignment and chipping may be even more relevant. When reducing the hip, the surgeon must also ensure there is no point loading between the ceramic femoral head and acetabulum since this risks damage to the ceramic bearing

Controversies around use of ceramic bearings will continue to excite fixed opinions.

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Metal-on-polyethylene

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Over the last 30 years, total hip replacement has been one of the most cost effective and quality of life enhancing surgical procedures available. In the late 1960s, metal-on-metal bearings were relatively common but produced significant problems with early loosening and metallosis, thought to be from abrasive wear. Prior to this, Charnley had used Teflon for the acetabular component but it soon became clear that materials with a low coefficient of friction do not necessarily possess sufficient resistance to wear. The introduction of ultra high molecular weight polyethylene (UHMWPE) cups, allied to cobalt–chrome or stainless steel heads, so improved the intermediate term results that this became the standard bearing combination for the majority of hip replacements world-wide.[1]

Figure 4. X-ray of a Charnley THR at 12 years in active asymptomatic patient showing wear of polyethylene but with little osteolysis. The wear was possibly caused by excess shelf storage of a component packed in air or surface damage to the femoral head.

Improved cementing techniques, better understanding of the behaviour of acrylic cement[2] and the introduction of finer engineering tolerances all improved the longevity of the procedure such that wear of the bearing surfaces became an issue. Sound fixation of components began to be compromised by osteolysis secondary to production of specific debris from the UHMWPE surface of the bearing. As a consequence, the use of alternative materials became more popular. This condemnation of the polyethylene cup was unjustified and we have learnt much from these early failures.

All bearing surfaces wear, producing debris capable of inciting an inflammatory response leading to stimulation of osteoclasts with resultant osteolysis. Particle size is particularly important in the polyethylene/metal bearing. Larger particles are relatively inert but those of less than 5 µm are ingested by macrophages and giant cells, invoking release of prostaglandin PGE_2 and TRF, with subsequent stimulation of osteoclastic activity. However, there is no evidence of UHMWPE having local or distant toxicity, unlike metal-on-metal debris, the long-term effects of which are uncertain.[3]

Commercially available polyethylene has many applications and is produced either by ram extrusion or compression moulding, the latter producing a more uniform material with fewer fusion defects. Gamma irradiation is used for sterilisation, but this process breaks the polymer chains, reducing molecular weight and hence resistance to wear. If irradiated and stored in air, oxidation occurs and the wear characteristics are further compromised. Shelf-life of UHMWPE components is now strictly limited and they are packed in an inert gas. Natural oxidation *in vivo* also occurs, fortunately slowly.

To improve the longevity of the procedure further, fixation of the socket has to be enhanced and wear from the articulation reduced. Current cementing techniques using pressurisation and rim flanges have reduced the incidence of radiolucent lines and subsequent premature loosening.[4]

Abrasive wear is particularly relevant to polyethylene and the importance of avoiding surface damage to the femoral head and third body wear has now been recognised (Fig. 4).

Although modularity introduces another interface for potential failure, it enables the bearing surface of the femoral head to be protected such that the benefits of better engineering tolerances can be used to their full potential in reducing the serious effects of abrasive wear. Attention to surgical detail and the use of pulsed lavage also reduce the incidence of third body wear.

Having achieved better fixation and protected the bearing surface, the wear characteristics of polyethylene have been improved further by changing its structure by cross-linking. This is achieved by bonding adjacent molecules using ionising radiation or electron beam irradiation. Whilst increasing the molecular weight improves the resistance to wear, those particles generated tend to be small and, therefore, the most likely to induce osteolysis. Current thinking suggests that any reduction of particulate debris is likely to improve outcome – reduce wear and the replacement will last longer. Time will tell.

Where does this leave the surgeon in choosing the most appropriate bearing combination?

As the majority of early experience of hip arthroplasty has been with the use of metal-on-polyethylene bearings, the long-term follow up data for this choice are more extensive than for alternative materials. More has probably been published about the Charnley hip than any other cemented replacement.[5,6] As can be expected, single-surgeon series tend to produce the best results but excellent, long-term performance has been reported from many other units. Most series achieve survivorship of just over 90% at 10 years reducing to 80% at about 18 years. The Exeter group reported the results of their original series of cemented all-polyethylene cups with 95% survival at 10 years, 81% at 20 years and 72% at 30 years.[7] The Stanmore hip achieved 73% survival at 20 years in a series from Portsmouth.[8]

Results from widely differing units have repeatedly shown that a conventional cemented metal-on-plastic arthroplasty produces consistent intermediate and longer term results, so why consider changing?

The increasing success of the procedure has inevitably led to its use in the younger, high-demand, patient which has significant implications for the future in terms of need for revision surgery. Survivorship at 10 years for these patients is lower than cited earlier and due to failure of the acetabular side. As a result, uncemented metal-backed cups were adopted in the belief that this would prolong fixation. Unfortunately, this produced cups in which the thickness of the polyethylene liner was inadequate. Dramatic, early failures occurred because of high shear forces being generated within the liner effectively sandwiched between two hard metal-bearing surfaces. The phenomenon of backside wear also became recognised together with the importance of adequate locking mechanisms to retain the liner within the shell. Once these shortcomings were addressed, evidence accrued to suggest that, in the younger patient, a hybrid system might offer better survivorship than a cemented socket.[9]

In the very young patient, it is only right that alternative bearings be evaluated but wide-spread adoption seems unnecessary given the proven track record of the metal-on-polyethylene articulation and some of the uncertainties surrounding the use of new materials.

However, it is a fact of health care provision world-wide that costs are rising and have to be contained. Joint replacement is at risk of becoming a victim of its own success and it is inappropriate to use expensive bearings and prostheses in patients of an age that renders them unlikely to outlive a conventional, proven system.

Enough experience has been gained with the behaviour of a well executed, metal-on-polyethylene hip replacement, of proven track record, to suggest that its use in the substantial majority of patients be continued. Compelling arguments exist for reducing the future burden of revision surgery but alternatives for the primary need to be explored and critically assessed before release onto the wider market.[10]

For the present, in the average patient of 65 years or older, the metal-on-polyethylene couple represents a safe, predictable and cost-effective bearing for total hip arthroplasty. We can re-assure the patient undergoing surgery with evidence collected over almost 40 years, we know the warning signs of impending failure and we know when intervention is appropriate. The bearing may wear, but over one to two decades, it does not produce distant toxic effects, it cannot shatter and, with meticulous primary surgical technique, should outlive the typical patient for whom it is chosen.

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