Title:

The Case for Ceramic on Polyethylene as the Preferred Bearing for a Young Adult Hip Replacement

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Abstract

Total hip replacement is amongst the most prevalent and clinically successful operations of the past few decades with around 70, 000 procedures performed in England and Wales alone.[1] Early metal on metal and ceramic designs were associated with rapid loosening and implant failure due to manufacturing problems and therefore the hard on soft bearing coupling has since become the gold standard for the majority of surgeons in both Europe and the United States.[1-3]

Since Charnley first introduced the metal on polyethylene low-frictional torque arthroplasty to clinical practice in the 1960s, both prospective and retrospective studies at a number of centres have achieved follow-up periods of up to forty years[4,5]. Excellent pain and function scores have been consistently demonstrated with a revision rate of around 12% at thirty years.

More recently, however, the indications for total hip replacement have been extended to include the younger and the more active patients in whom at least one revision surgery, perhaps two can be expected in their lifetime. Whilst polyethylene has remained popular amongst surgeons due to its ease and familiarity of usage and its versatility with regards to the size of the head and rim offset, concern regarding polyethylene has traditionally centred on the macrophage induced osteolytic wear process and the effect it has on the surrounding bone. There has, therefore, been a resurgence in interest regarding the utilisation of innovative bearing surfaces, particularly hard on hard bearings to address the requirements of longevity of the prosthesis, low wear rates and adequate bone stock at revision surgery.

The early part of the last decade saw renewed interest in the metal-on-metal (MOM) coupling. Proponents of all metal bearings cited decreased osteolysis and wear rates due to smaller particle size and reduced friction due to the smooth component surface finish.

During 2006-2008, MOM prosthesis accounted for 10% of all THRs in the UK and around 50% in those aged younger than fifty.

Earlier studies regarding MOM showed satisfactory short and mid-term survival.[6] However subsequent investigations have demonstrated significant concerns. Firstly, the lymphocyte induced Adverse Reaction to Metal Debris (ARMD) has resulted in significant soft tissue destruction around a proportion of MOM hips[7] leading to pain, component loosening and high rates of revision. Secondly, wear particles in the form of cobalt and chromium ions have been detected throughout the body.[8] Although granulomata have been found in both the liver and spleen[9] and increased chromosomal translocation has been found within lymphocytes, [10] there is currently no hard evidence that this leads to neoplasia.[11] However, these concerns have led the British Orthopaedic Association (BOA) to issue guidance on MOM hips and the current advice is to avoid usage of the large head diameter MOM hip replacements except in exceptional circumstances.[12]

A second area of interest over the past decade has been the ceramic on ceramic (COC) coupling. From just 5% of hip replacements in 2003, the usage of COC has increased to almost 1 in 4 procedures in 2011.[1] Potential benefits include lower wear rates, [13] increased wettability and excellent biocompatibility. However, the brittleness of ceramic predisposes it to fracture. Although rare, ceramic fracture can be a devastating complication, affecting revision surgery by means of third body wear from ceramic debris. The ceramic acetabular component is also vulnerable to failure when mal-positioned. Despite much discussion regarding accuracy of acetabular orientation, many single centre studies have shown that around 20% of the acetabular components are placed outside the presumed safe zone[14] with particular difficulties regarding the accurate version of the acetabular component.

When compared with polyethylene, imbalanced loading of ceramic liners can result in higher, more variable, and localised surface strains.[15] This edge loading of the ceramic liner directly predisposes to ceramic chipping[16] and audible squeaking.[17] Earlier studies documenting rates of femoral head fracture in COC hips utilising the first generation alumina showed a tenfold decrease when the ceramic head was coupled with a polyethylene liner.[18]

A further potential issue with all hard-on-hard bearings is stress shielding of the pelvic bone due to the stiffness of the acetabular component. Whilst this is often cited in the literature, there are no current studies demonstrating a deleterious effect the same on bone stock at revision surgery.

Due to these concerns, a number of surgeons remain advocates of the hard on soft bearings. It is well documented that macrophage induced osteolysis in total hip replacements is exponentially proportional to polyethylene wear rate.[19, 20] Therefore a further option regarding bearing surfaces is to couple the polyethylene acetabular lining with a ceramic femoral head. Potentially this keeps the advantages of the softer, less rigid polyethylene surface and utilises the advantages of the smooth, hard ceramic surface. Ceramic on polyethylene (COP) as a bearing couple, currently accounts for around 1 in 7 hip replacements in the UK[1], however there is a relative lack of literature investigating outcomes compared with the extensively documented MOM, COC and metal on polyethylene bearings. The aim of this review is to present the evolution of ceramic and polyethylene and secondarily to critically review the biomechanical, in-vivo and clinical studies related to its use.

Evolution of Ceramic and Polyethylene

Ceramics are ionic compounds of oxidised metals characterised by their strength and hardness. As far back as 1930, a German patent was granted for ceramic use in joint replacement, however manufacturing difficulties meant it was another forty years before Boutin was able to introduce ceramic bearing surfaces into clinical practice.[21]

The first ceramic used was alumina (Al_2O_3) and compared to modern day standards had a coarse microstructure and was relatively weak due to its manufacturing process of sintering in air. Since then the mechanical properties of alumina have significantly improved with the development of hot isostatic pressing and the introduction of the alumina matrix compound with nano-particles added to reduce the grain size. This has resulted in a threefold increase in strength, reduced grain size, increased purity and increased smoothness of the material. These improvements have resulted in a decreased rate of a femoral head fracture. From a reported rate of 5-13% for a fracture of the femoral head in the pioneering studies of the 1980's, [22] more recent reviews have documented that the fracture rates have significantly dropped to around 0.01-0.1%. [23]

Zirconia (ZrO_2) was another ceramic compound originally popular due to its high strength, resistance to scratching and increased fracture toughness compared with alumina. Approved for use in 1985, zirconia originally produced good short-term results. However, phase transformation of the lattice occurring over a five to ten year period led to decreased long term wear characteristics and implant failure which led to zirconia femoral head withdrawal from the market in 2002.[24]

Polyethylene has also undergone a number of improvements following its introduction into clinical practice in the 1960s. The original Ultra High Molecular Weight polyethylene (UHMWPE) popularised by Charnley is synthesised from the monomer ethylene (C_2H_6) and contains around 250, 000 monomer units per molecule giving it a molecular weight of between two and six million. This produces a tough material with the highest strength of any thermoplastic currently manufactured. UHMWPE is, however, susceptible to both adhesive and abrasive wear.

Many unsuccessful attempts were made to improve the wear characteristics of UHMWPE by modifying the manufacturing process and by blending the material with carbon fibre but there were no major advancements until 1998 with the introduction of highly crosslinked UHMWPE. By gamma irradiating the material in an oxygen free environment, increased wear characteristics can be achieved without significantly interfering with the overall material properties. Highly-cross linked UHMWPE has consistently been shown to have decreased in-vivo wear compared to conventional UHMWPE[25,26]. This process has further been enhanced with the development of sequential radiation and annealing leading to the development of X3 polyethylene with excellent early results.[27,28]

Further development has involved addition of vitamin E to the polyethylene polymer to act as a free radical scavenger and improve oxidative resistance during the irradiation process. Biomechanical studies have demonstrated excellent wear characteristics[29] but clinical evidence is currently lacking.

Wear Characteristics of Ceramic on Polyethylene

Hip Simulator Studies

Hip simulator studies have produced variable results dependant on the lubricant used between the two surfaces. Saiko[30] showed around a fifty fold reduction in wear with a ceramic versus metal femoral head on a polyethylene liner, however these results have been brought into doubt as the saline used for the lubricant produces conditions which allow for virtually no polyethylene wear to occur. Subsequent studies have used serum as a lubricant at varying concentrations with Clarke[31] demonstrating an average 50% wear reduction with an alumina head with bovine serum used as the lubricant.

One further study[32] specifically evaluated changes in wear during edge loading and separation of components during the gait cycle. It was demonstrated that wear is reduced during eccentric acetabular loading when an alumina on UHMWPE coupling is used compared with alumina / alumina.

Retrieval Studies

There is relatively little evidence regarding implant retrieval as a means to measure ceramic on polyethylene wear. Bragdon[33] used a combination of fluid displacement of the polyethylene acetabular component and scanning electron microscopy of the femoral head. Only four hips were evaluated and at 3-6 years from primary surgery, there was no discernable difference between ceramic and metal head wear rates. Kusaba[34] however retrieved 159 prosthesis and found that the alumina heads, although worn, remained smoother than new cobalt chrome heads. A significant reduction of polyethylene wear when coupled with alumina was also demonstrated.

Clinical Studies

There have been a number of *in-vivo* studies evaluating wear rates of ceramic on polyethylene which fall into two broad groups – those purely evaluating wear and those making comparison with other bearings.

Of the former, Urban[35] achieved the longest follow-up of twenty-one years. Survival of the prostheses was 80% at twenty years with all but two demonstrating good or excellent clinical results. There was no osteolysis noted and linear wear rates were approximately 0.034mm per year, significantly lower than for metal on polyethylene bearings. Similar results were demonstrated by Wroblewski[36] with an average yearly linear wear of 0.03mm at fifteen years and Sugano[37] who demonstrated wear of 0.1mm per year with first generation ceramics. Tanaka[38] evaluated wear rates with different diameter ceramic heads. Again, linear wear rates were found to be 0.03-0.1mm per year with lower linear and volumetric wear with 26mm heads compared with those of a larger diameter. Kim[39] prospectively evaluated 73 hips in patients below the age of fifty years. Again, the wear rate was similar at 0.05mm per year with excellent patient reported outcomes and no loosening at eight years.

Studies comparing the outcomes of ceramic on polyethylene versus conventional metal on polyethylene have produced mixed results. Of those indicating no difference, the two largest studies[40, 41] showed equivalent wear rates in two hundred implanted hips at five and six years respectively. However, in the former study, a combination of zirconia and alumina heads were used. Similarly, Cohn[42] demonstrated no difference in wear between zirconia and cobalt chrome heads at four years and Stilling[43] no difference at five years. Hernigou[44] differentiated between the two ceramics and found equivalent volumetric wear rates at ten years between 28mm zirconia and 32mm cobalt chrome heads but a fifty present decrease in wear when a 32mm alumina head was used. Schuller[45] demonstrated a threefold decrease in linear wear with alumina compared with metal heads at 10 years however, there were demographic differences between the populations.

The most comprehensive study[46] comparing long term outcomes with alumina versus cobalt-chrome prospectively followed up 93 arthroplasties for twenty years with none lost to follow-up. Linear wear involving the alumina head was half that for the cobalt chrome resulting in significantly lower rates of osteolysis and revision surgery.

Studies comparing ceramic-polyethylene and ceramic-ceramic hips have generally found little clinical difference between the two. Two recent studies[47,48] looked at patient reported outcomes following randomisation to a bearing surface and found no differences in satisfaction or complications between the two. Amanatullah[49] compared wear rates between the two bearings and found that, although the polyethylene group had a higher penetration at two years, this did not result in differences in satisfaction or revision. Conversely, the rate of implant fracture (2.6%) and audible squeaking (3.1%) were significantly higher for the ceramic-ceramic group. Lewis[50] achieved a slightly longer average follow-up of eight years and demonstrated similar differences in wear rates, which, again, resulted in no significant differences in clinical outcomes.

One study, which demonstrated a difference, followed twenty-eight patients in whom a ceramic-ceramic and contralateral ceramic-polyethylene replacement was performed in the same sitting. Significantly lower rates of osteolysis and wear were found on the COC side, however the operative procedures took place between 1981 and 1985, utilising non-cross linked UHMWPE and early ceramics therefore it is uncertain whether these results, which differ from the more recent studies above, can be extrapolated to current bearing surface technology.

With regards to ceramic versus highly cross linked or standard polyethylene, Ise[51] has published a ten year follow-up demonstrating that by cross linking the polyethylene, acetabular wear rates were reduced by 50% and the rate of osteolysis was zero compared with 25% for the standard polyethylene. Kelly[52] has also demonstrated that highly crosslinked polyethylene shows very little wear at 5 million cycles even at thicknesses of 4mm also when it is eccentrically loaded.

Conclusion

The choice of bearing surfaces in total hip arthroplasty, particularly in the younger and more active patient, remains controversial and it is unlikely that a consensus will be reached in the near future. Studies evaluating ceramic and polyethylene clinical and radiological outcomes are heterogenous with regards to the mechanical properties of the implants. Ceramic manufacture has undergone significant improvements over the past twenty years and the introduction of highly cross linked and X3 polyethylene has yielded encouraging early biomechanical and clinical results.

Certainly, compared with standard metal on polyethylene implants, alumina femoral heads have been documented to induce lower rates of linear and volumetric wear *in vivo*. When discarding those studies which include the zirconia ceramic implants, the difference is more pronounced.

It is also apparent from the literature that ceramic on ceramic hips have lower wear rates compared with the ceramic on polyethylene hips, however, the midterm studies utilising newer alumina ceramic with newer polyethylenes show no difference in osteolysis or patient satisfaction at five years. Early results of large, multi-centre product specific clinical trials have been presented in recent years[53] but it may be many years until these reach fruition.

Callaghan(54) has made an attempt to quantify the cost-effectiveness of using an alumina rather than metallic head. By the authors' own admission, this is difficult to quantify without results on long-term outcomes. However, their overall conclusion on evaluating wear rates and extrapolating these to an estimated revision rate at twenty years is that the cost savings are likely to more than offset the increased cost of the alumina head.

Therefore, for the time being, the choice of acetabular bearing surface in hip arthroplasty remains largely related to surgeon preference. The good medium term outcomes with the newer polyethylenes and the alumina ceramic along with a reduced risk of catastrophic failure certainly allow ceramic on polyethylene to be given serious consideration especially in younger patients but longer-term studies with newer implant materials must be awaited.

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