The Troubles of Zirconia
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A new ceramic material was introduced into clinical practice some 5 years ago with the expectation that it would improve performance and give better fracture toughness and wear resistance. In reality the reverse happened and far more failures have occurred. This article covers some of the details involved and asks whether there are any lessons to be learnt.

Over six years ago, I described in this column the phenomenon of transformation toughening in ceramics which had led to the use of a version of zirconia (zirconium oxide) in certain joint replacement prostheses[1]. The fundamental scientific argument was based on the use of a small amount of an additive such as yttria, which allowed the crystal structure to be far more resistant to the crack propagation that is an inherent feature of most structural ceramics. Several companies started to manufacture zirconia femoral heads because of the apparently good qualities, and many joint replacement manufacturers included zirconia – polyethylene bearing surface combinations in their product range. However, even as early as 1995, occasional reports of catastrophic fracture of the zirconia started to be published[2] and the last few years has seen very interesting developments in the performance of such devices. A major paper has just been published[3] that attempts to explain the current position in this now controversial area and some interesting points emerge in relation to the introduction of new materials into clinical practice. We may deal with this matter by first considering the clinical and commercial evidence and then the scientific facts, leading to a discussion of whether any lessons could be learnt.

The clinical evidence

It is interesting that production of zirconia heads goes back many years, starting with European use in 1985 with, it is claimed, some 400,000 cups being manufactured by one company alone. In fact over these nearly two decades of use, the majority of cups have been manufactured by one company, Saint-Gobain Desmarquest of France, who supplied these to many of the main medical device companies. It was recognized at an early stage that there was a theoretical chance that the zirconia could undergo changes over time, for reasons outlined below, and over a period of a few years in the mid-1990s there were a number of publications variously describing the advantages and disadvantages of the material. The company itself published work that showed no evidence of time-dependent changes[4], a conclusion supported by Shimizu et al[5] while other authors demonstrated good performance[6].

Several studies, however, were unable to demonstrate really significant advantages for zirconia over other materials[7]. Publications then started to appear challenging the superiority of zirconia as a bearing surface whilst it was clearly demonstrated that the crystal structure of the zirconia could change

under the conditions of total joint replacement[8]. Reports of poor clinical performance then started to appear. Allain et al[9] showed only a 37% survival at eight years of a titanium alloy stem, zirconia head and polyethylene cup. The combination of a zirconia head and a Hylamer cup resulted in a 67% failure rate at five years for 29 patients[10] whilst others have shown similar marked increases in failure rate through loosening associated with excessive wear.

The explanation for this quite sudden change in the performance appears to have two facets. The first, which is entirely scientific, is that the zirconia is indeed at risk for structural change over a period of time if a certain combination of circumstances arises. The second is that an unfortunate sequence of events during the manufacturing ensured that such a combination of circumstances arose in the zirconia cups in hip replacements.

The manufacture of the transformation toughened zirconia components involves a carefully controlled heat treatment during which the optimal crystal structure should be developed. Up until 1998 the company used a batch production process in which the ceramic heads were subjected to a complete heating and cooling cycle, which is necessary for the correct crystal structure to be generated. According to Clarke et al[3], only 28 fractures of the heads were reported from these products, a rate of 0.009%. The manufacturer then changed the production process, using a tunnel furnace which provided a continuous sintering operation as racks of the zirconia heads were conveyed through a tunnel shaped furnace. Within a short time, the orthopedic companies using these zirconia heads were receiving high numbers of reports of failures of these heads fabricated by this new method. In the first instance it appeared that one specific lot, produced in 1988, was at fault, but then breakages of devices using heads from four other batches were reported. Sales of the zirconia were suspended at that time and following collaboration between the Competent Authorities in France (AFSSAPS) and the UK (then the MDA), the latter issued an Alert Notice in 2001[11]. In their Alert Notice, the MDA confirmed that the failure rate was, at that time only 0.03% so that no elective revision surgery was recommended, and they noted that there was no predictive test to determine whether any particular hip would, in fact, fail. The FDA issued a similar alert in 2001.

The materials science issues

Although the overall rate of failure may not be very high it has become clear that the rate does vary and that the mechanisms of failure may be complex, depending on the precise heat cycle experienced by the ceramic head in question. The real quantitative parameter than judges this performance if the overall revision rate of the device over ten years. The benchmark is that quoted by the National Institute of Clinical Excellence[12]. Following an analysis of the performance of a range of products, the benchmark is effectively set at 90% survival of the hip replacement at ten years. One study has shown a survival rate of only 63% at 9 years[9]. The survival rate at 5 years in the study of Norton et al was only 32% [10]. The 'survival' in these cases will be determined by an absence of the critical failure mechanisms of ceramic head fracture and prosthesis loosening associated with the osteolysis caused by the release of wear debris from the ceramic-polyethylene interface. It is clear now that a zirconia heads that undergo a transformation to the monoclinic crystal structure may be susceptible to both failure mechanisms. A heat treatment that leaves a sub-optimal stability of the required tetragonal crystal phase will allow structural changes over a period of time, especially at the surface. These changes may involve the development of minor flaws that act as crack initiators and also volume changes that produce irregularities that affect the smooth sliding mechanism of the hip and an increase in the wear rate.

Observations

The resulting problems have clearly been significant from both the patients concerned

and the industry. It could be said that the instability of the zirconia could have been predicted, because a transformation toughened ceramic is indeed metastable, but there was every good reason to believe that the theory, the early experimental data and the initial clinical experience gave sufficient justification to proceed. It is difficult to see how technical progress could be made, that is the ability to achieve improvements to the advantage of patients, without using putatively important advantages in real medical devices. This is especially so when it would appear that the problem that eventually occurred happened because the material used in some of these patients was sub-optimal because of what appears to be a change to a manufacturing process. It would be a great pity if this example was to adversely affect the ability of medical technology to move forward on the basis of sound scientific advances.

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