FUNDAMENTALS OF ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE

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INTRODUCTION

One of the greatest advances in Orthopaedic Surgery in the twentieth century is surely total joint replacement. Millions and millions of patients, crippled by arthritis, have been afforded relief of pain and restoration of mobility through this innovative rehabilitative procedure.

Nevertheless, there remain concerns, within the orthopaedic community, about the longevity of total joint replacement, beyond the 10 year time frame, becarse of possible loosening of the implant following erosion of the supporting bone due to wear debris induced osteolysis.

Wear debris, from any source, can induce the cascade of events that ultimately leads to the erosive, and aggressive removal of bone from around an implant. Although large particulates can illicit a osteolysis response, current research suggests that the main culprits are the very small, micron and sub-micron sized particles, often generated by the millions with every step. In this regard, UHMW Polyethylene is a major source of such particles. Accordingly, the properties of this key orthopaedic material have been subject to renewed interest in recent years.

HISTORICAL PERSPECTIVE

It is sometimes helpful to review the historical perspectives of an issue in order to mtintain a sense of balance. As worrisome as UHMW Polyethylene wear debirs is, this material has a remarkable record as a biological implant.

Sir John Charnley, the pioneer of total hip replacement (THR), first tried Teflon as a bearing material for his THR since Teflon exhibited an extremely low coefficient of friction. However, all of the Teflon cups failed rather quickly, due to excessive wear and the formulation of massive wear debris induced granulomas around the implants. Sir John Charnley next turned to RCH-1000, an industrial grade of UHMW Polyethylene. This material proved to meet his needs precisely.

RCH-1000 was an industrial grade of UHMW Polyethylene for which precise controls on such features as voids, contaminants. fusion defects, molecular weight variations were not implemented. Sterilization was accomplished with both gamma irradiation and EtO as well as, occasionally, other methods.

Nevertheless, we are now able to read reports of Sir John's patients, some of whom continue to do well after 25 years of service. This material, to be sure sub-standard by present day standards,has withstood the test of time remarkably well. Thus, even though substantial efforts are underway to improve this materials, it is well to remember that UHMW Polyethylene has served Orthopaedics well over the past 2 decades, and we can expect this remarkable material to continue this record of service, even as improvements in its manufacture and in its material properties continue.

WHAT IS UHMW POLYETHYLENE ?

Polyethylene is among the most widely used thermoplastics in the world today. It is available in multiple grades. Ultra-High Molecular Weight Polyethylene is defined as a grade with a molecular weight greater than 3 million Daltons. It is has high toughness and impact resistance, and a low coefficent of friction, a property that Sir John Charnley particularly sought. The material has an exceptional chemical inertness, which explains the biocompatibiligy of UHMW Polyethylene. In bulk form, it is oftern used as a negative control in biocompatibility tests. Finally, the material has exceptional abrasion resistance, which gives it excellent wear properties.

Polyethylene is manufactured using the Ziegler-Natta Catalyst method in a low pressure reaction where ethylene monomer is continuously linked to form a very long, linear homopolymer. On solidifying, the homopolymer molecule tends to fold upon itself to form crystalline area with a regular molecular pattern, but between these crystalline areas, the molecule forms a tangled mass, and amorphous, zone. The combination of both these regions in the UHMW Polyethylene micro structure accounts for its unique properties.

Where as UHMW Polyethylene in defined, by ASTM and ISO standards as a material with a molecular weight of greater that 3 million

Daltons, most currently used grades have molecular weights approaching or exceeding 5 million Daltons. Some representative, commercially available grades of UHMW Polyethylene include :

Hoechst GUR 412	4.4 million Daltons
Hoechst GUR 415	5.3 million Daltons
Hoechst GUR 4150 HP	4.8 million Daltons
Himont 1900	3.5 million Daltons

UHMW Polyethylene is supplied by the material manufacturers as a powder like material called flake. The flake has a broad distribution of particle sizes, but the majority fall in the 100 micrometer size range, with very few particles being smaller than 40 micrometers of larger than 500 micrometers. Since the vast majority of the world's supply of UHMW Polyethylene is consumed for industrial use, medical grade flake is created by carefully sorting production batches for contaminants, and molecular weight variability.

Some research evidence suggests that higher molecular weight polythylene has greater wear resistance that the lower molecular weight variety. However, since wear of UHMW Polyethylene is a multi-factorial issue, special emphasis on high molecular weight alone may be misplaced.

FINAL PRODUCT MANUFACTURE

1. Raw Material

The UHMW Polyethylene flake is purchased from material suppliers and used to fabricate such products as implants by orthopaedic manufacturers. The flake is often sent to secondary vender to form the flake in long bars of sheets of solid UHMW Polyethylene. These bars or sheets can then be machined into their final implant form.

2. Manufacturing Defects

There have been a number of reports on the discovery of manufacturing defects in the UHMW Polyethylene of retrieved explants or in unused implants taken from the shelf. Such defects can include contaminants, shrinkage voids (where a very small hole or series of holes in the bulk material can be caused by uneven cooling of the bulk material), and fusion defects (where the original flake has failed to properly melt and solidify with the rest of the bulk material). These defects are within the control of the bulk material manufacturer and can be checked for by a rigorous quality assurance program. Whereas these defects are undesirable, and whereas some researchers have suggested that such defects can lead to accelerated wear, there is little solid evidence that such defects, in themselves, can lead to early failure of an implant. Nevertheless, since such defects are both unintended and controllable, there is no longer any good reason for tolerating such workmanship.

3. Material Sterilization And Oxidation

Recently, an area of considerable controversy is the method of sterilization for UHMW Polyethylene . Most manufacturers, in the past 20 years, have used gamma irradiation to sterilize their product. However, gamma irradiation has now been demonstrated to have some other unintended effects.

The UHMW Polyethylene molecules, under gamma irradiation, can suffer chain session of the carbon-carbon bonds, or formation of free radicals with the splitting off of a hydrogen ion. Afterwards, the chain can repair itself, but, other reactions can also occur. In the presence of free oxygen, the UHMW Polyethylene can become oxidized. Or, it neighboring chains are in cose proximity, cross-linking of the polymer chain can occur. In such cases, there can be a change and sometimes a degradation of the mechanical properties of the polymer. The current concern is that the material property changes could lead to a significant reduction in the wear resistance of the polyethylene and a consequent increase in the war rate.

In fact, Laboratory tests have shown that oxidized UHMW Polyethylene does wear at a greater rate than non-irradiated polyethylene.

There a several methods that can be used to avoid the oxidation of polyethylene during gamma sterilization. One, that several companies have chosen, is to use an alternate sterilization means such ethylene oxide sterilization or gas plasma sterilization. These methods have been shown to effectively sterilize UHMW Polyethylene without inducing oxidation of the material. Other firms have chosen to gamma irradiate their components, sealed in an oxygen free container. In this way, the polyethylene is not able to oxidize to any significant degree during the sterilization process of afterwards during shelf storage since they are in an inert atmosphere.

4. Cross-Linked Polyethylene

The wear properties of UHMW Polyethylene , sterilized with any of these new methods, have been demonstrated, through laboratory tests, to wear less than oxidized material. However, the most recent research shows that gamma irradiation had a very significant positive side effect. Cross-linked polyethylene has consistently shown excellent wear resistance, far better than non-cross linked polyethylene. In a recent study, polyethylene sterilized by non-cross lingking methods were compared with polyethylene irradiated in an inert atmosphere. The non-oxidized, cross-linked polyethylene was decidedly more wear resistant. Finally, research from centers in Boston, South Africa and Osaka, Japan has shown that hyper-cross linked polyethylene may be so resistant to wear, in total joint simulators, that the wear rates become difficult to measure. Thus, it appears that gamma irradiation of UHMW Polyethylene , stored in an inert atmosphere, may be the proferred method. Further research will be required before high does radiation sterilized UHMW Polyethylene is commercially available.

5. Calcium Stearate

In the fabrication of UHMW Polyethylene bar or sheet, calcium stearate, a soapy lubricant is used to reduce wear and tear on the tool dies used to shape the final material. Although this material is benign, recently, calcium stearate has been detected as a contaminant in the UHMW Polyethylene . One particular brand of polyethylene, which is subject to a special post manufacturing process to further align the polymer molecules and increase the crystallinity of the polyethylene, has been shown to be particularly susceptible to calcium stearate entrapment. Moreover, although this brand of polyethylene has demonstrated superior mechanical properties such as hardness, recent clinical reports have suggested that the clinical wear performance of this material is significantly less than standard polyethylene. It may be that the calcium stearate permits rapid in vivo oxidation of the material, leading to accelerated wear rated. At any rate, the use of calcium stearate in the manufacture of UHMW Polyethylene bar or sheet stock is no longer recommended.

6. Direct Molding

Finally, at least 2 manufacturers have the technology to directly mold final shaped products from the polyethylene flake, rather than using the intermediate step of shaping the flake into a bar. Directly molding the polyethylene results in a material that is fully consolidated and exhibits very uniform properties. Direct molding does not require the use of calcium stearate. In addition, direct molding produces a product with almost no internal defects.

Recent retrieval studies on such implants has shown that these implants show remarkably low wear, even after 10 years of hard service. Even more remarkable, is that some of these directly molded components were made of a lower molecular weight polyethylene and were gamma sterilized in air. Apparently, molding an implant with very high integrity can overcome many other material deficits. The reasons for the surprising durabiligy of such implants is not yet clear, but may be related to the exceptional integrity of the material which prevents or limits the diffusion of free radical oxygen ions, in vivo, into the depths of the material, thus significantly limiting the rate of oxidation.

TEST METHODS

The final word on UHMW Polyethylene is not yet in. The wear of polyethylene is clearly a multi-factorial issue in which the effects of each of the key factors in not yet fully appreciated.

Reserchers use various laboratory test methods to evaluate the effects of various changes on the wear performance of UHMW polyethylene . Some tests are standard engineering wear tests that can be simply and easily run. Other tests, such as joint simulators, are much more complicated pieces of test machinery that are expensive to purchase, difficult ot use and very time consuming to run. A single hip simulator test, attempting to simulate 15 years of use, may take some 6 months or more to complete. Although the simple tests are useful as a quick screen, they do not simulate the actual clinical condition very well, and their results can be misleading. Simulator tests are best, but even these do not estimate actual clinical performance well. Accordingly, great caution should be used in comparing the wear performance of various types or grades of UHMW polyethylene . The type of wear test used can greatly influence the final result, and the wear test may not simulate the clinical situation very well, at all.

Although extremely time consuming, the very best way to evaluate the wear performance of polyethylene is via clinical use. Regrettably, published reports on the long - term clinical wear performance of UHMW polyethylene are few in number.

CONCLUSIONS

UHMW polyethylene has proven to be a remarkably durable and suitable bearing material for orthopaedic applications. There is no pressing need to change to a different material, if such a material is even available.

On the other hand, there a number of actions that can be taken to reduce, to an absolute minimum, the number of submicron sized particles that are shed from the polyethylene surface. These include the elimination of fusion and other defects in the bulk material manufacturing process, elimination of the use of calcium stearate, the use of very high molecular weight material, and the use of sterilization methods that avoid oxidation of the polyethylene .

Recent clinical studies suggest that directly molding polyethylene imparts significant advantages to the material in terms of wear resistance, advantages that can greatly compensate for other factors such as lower molecular weight or storage in an air containing package. In addition, current materials research suggests that cross-linking of the polyethylene by exposure to radiation also seems to toughen the material to a large degree. Experimentally fabricated polyethylene with hyper-cross-linking has demonstrated virtually no wear in both laboratory tests and in human clinical use over a 20 year period. If validated, such hyper-cross-linked polyethylene may be the material of choice for use in orthopaedic implants.

Finally, there are many other factors that can affect the wear rate of UHMW polyethylene . These include design of the implants, quality and hardness of the metal or ceramic counterface on the opposing implant component, and the amount of sliding and rolling between the two components. Thus, the wear of polyethylene cannot be examined in isolation, without regard to the rest of the implant system.

UHMW polyethylene is a remarkable material that has served Orthopaedics well in the past and promises to do even better in the future.

In choosing an implant material, orthopaedic surgeons should not hesitate to demand evidence from their suppliers regarding the factors considered in the manufacture of the supplier's implants.