Bio-Medical Engineering: Report On Ceramic Total Hip Replacement

Abstract

This report will examine ceramic on ceramic total hip replacements and the work of engineers who are involved in the field.

Introduction

Bio-engineering is a very wide area of study. It can cover areas ranging from advanced experimental medical technology, refining existing medical technologies and areas through to the genetic modification of plant crops to enhance harvest quality and capacity and environmental management.

The aim of this report is to analyse a ceramic on ceramic total hip replacement and examine the work of engineers working in the field.

The analysis section of this report gives a description of the product and its function, a brief history and development of hip replacements, the effects the replacement has had on peoples lives, development of materials used in the product and the manufacturing procedure, environmental effects created by the product and producing it, ethical issues and innovations that are taking place in the product.

Analysis

A description of the product and its function.

Hip replacement prosthesis replaces the ball and socket hip joint which can relieve pain, restore function of the hip joint and allow the person to return to their daily activities and improve the quality of life.

A total hip replacement implant has three parts:

- The stem, which fits into the femur
- The ball which replaces the spherical head of the femur and
- The cup which replaces the worn out hip socket.

Ceramic on ceramic total hip implants have the femoral ball and the cup components made from medical grade alumina ceramic. These ceramic implants have been developed to decrease the wearing out of the hip implants as ceramics are very hard and smooth and reduce the need for hip implants to be replaced as often as metal or plastic ones.

History of the product

Ceramic on ceramic hip implants were developed to improve the length of time a hip replacement would last and to prevent wear particles that dissolve the bone called osteolysis that occurred with traditional hip implants made from metals or plastics.

The use of alumina ceramics in total hip implants began in Europe by Professor Pierre Boutin in France in 1970, where he replaced the traditional metal femoral head with alumina. There were many problems with the first ceramic total hip implants, but technological advancements were approved for use in the USA in 2003. Further technological advancements in the manufacture of the ceramic components led to more advanced medical grade alumina ceramics in 1994.

The effects these products have had on people’s lives

Ceramic on ceramic hip implants have enabled people to maintain active healthy lifestyles, free from pain and discomfort, especially young and active people. Due to the ceramic implants people have been able to increase their range of motion and reduce their dislocation rate. About 95% of people are able to return to their normal activities such as playing tennis or golf. Traditionally hip replacement implants tend to wear out faster in young active people making them unsuitable to have hip replacements due to the need to replace the device every 10 to 15 years. Ceramic on ceramic hip implants have superior abilities to withstand wearing overtime making them suitable for young active people. Ceramic on ceramic implants wear at a rate of about 0.0001millimeters per year. The medical profession expects the ceramic on ceramic hip implants to cause no inflammation, bone loss or systemic distribution of wear products in the body as previously found in traditional hip implants which can make following replacements or modification very difficult.

The area of bio-engineering that works with this type of product and training a typical career path for an engineer in this field.

People who wish to pursue a career in ceramic on ceramic hip implants would need to study at university to gain the necessary qualifications. Students may study a bachelor of biomedical science and gain skills to understand and investigate human biology and health. The course at Monash University is a 3 year full time and 6 year part time course. Graduands have a wide range of career opportunities including biotechnology research institutes, industries development and product technology, biomaterials and hospital biomedical engineering.

Students may also undertake a combined degree at the Monash universities such as bachelor of biomedical science/ bachelor of engineering specialising in for example material engineering. This course is a 5 year full time or 10 year part time course. Material engineers with training in the bio medical science area would work for example in the development of new materials and products such as ceramic on ceramic hip implants. There is a urgent need for biomedical engineers with a background in biomedical science and materials engineering. Australia has many biomedical companies to gain employment.

Development of materials used in the product

The first hip replacement was made from ivory in Germany. In the 1960’s hip replacement joints were made from metal such as titanium, stainless steel and cobalt, chrome and plastic

called polyethylene. The use of ceramics for hip implants was first used in France in 1970 which was made from pure medical grade alumina. Alumina is a white granular material called aluminium oxide. These very small and very pure crystals of aluminium oxide are compressed very close together and form the basis of medical grade ceramics.

Ceramics components have more ions (electrical charged particles) on their surface that help to introduce a layer of joint fluid between the components and decrease friction in an artificial joint. They are harder than their associated metals and plastics and produce less wear on the surfaces adjacent to them because they are more resistant to the development of surface scratches.

Ceramics were first introduced to hip replacement surgery to prevent wear particles that dissolve the bone called osteolysis and decrease the wearing out of the hip implants. Some researches believe that the bacteria staphacoccus epidermis adheres more strongly to polyethylene hip implants than to ceramic implants reducing the patient's risk of infection with the use of ceramic implants.

Advances in material quality and processing techniques of ceramics led to ceramic components that offered patients better wear performance and longer-lasting hip implants due to enhancements in purity, density and grain size of alumina. An innovative thermal treatment called hot isostatic pressing resulted in alumina ceramics producing with a dense fine grain. The alumina grain size is less than two microns. This process led to a strong ceramic implant. The newest ceramics combines small amounts of zirconium and yHrium with alumina to produce a even stronger material for hip implants. These ceramics contains 75% alumina and the rest zirconium and yHrium.

Materials used in hip implants that are available today for surgeons used in total hip replacements are mental on metal, metal and polyethylene, ceramic on polyethylene, and ceramic on ceramic.

With the development of these new materials the wear rate has been reduced from 200 microns per year on the metal on polyethylene to metal on metal which has a wear rate of 4.2 microns per year to the newest innovation ceramic on ceramic, which has less than 1 micron per year. (See appendix 5.2, page 2)

Manufacture of the product

The manufacturing of ceramic components for joint replacement implants is a very complex process consisting of a series of more then 60 manufacturing and quality assurance steps.

One of the ways of producing the ceramics in total hip implant is a procedure called Hot Isostatic Pressing (HIP) technology. The aluminium oxide crystals are very small, very closely packed together, and the impurities make up less then 0.5% of the volume of the ceramic.

The close packing of aluminium oxide crystals is achieved through the HIPing process. The ceramic component is reheated and then subject to enormous symmetric pressures. The HIPing process extrudes impurities out of the material and packs the crystals very close together.

The HIP process is often combined with solution heat treatment of materials. This involves applying heat, very high gas pressures (up to 200 MPa) and the control of cooling rates. Pressure is applied inside a vessel by compressing a gas such as argon or nitrogen. As this is happening the heat is supplied through a resistance heated furnace. The temperature and pressure are monitored and controlled using a computer providing exact temperatures and pressures.

Each ccomponent is individually stress tested and the alumina ceramic ball is very strong structure, stronger than the metallic stem on which it is placed on, and even more then the natural thighbone. The alumina ceramic ball must sustain 60 times the average patient's weight, the metallic femoral stem 15 times the average patient's weight and the thighbone also 15 times the average patient's weight.

The grain size of these materials has been reduced from a high of 4.2 micrometers in 1984 to 1.8 micrometers in 1995.

A consequent result of the reduction in grain size is the burst strength, which has increased from 46kN in 1984 to 65kN in 1995. this means that the ceramic balls will sustain 85 times the average weight of a person (average weight is 77kg). Where as the older model could only sustain 60 times the average weight.

Environmental effects created by this product or from materials used in this product.

The production and manufacturing of medical grade ceramics consume large quantities of energy and water and also release pollution to the air, ground and aquatic environments. Landfill, erosion and loss of biodiversity from mining can also occur.

Ethical issues concerning this product

Animal experimentation is essential during the development of the implant to show their effectiveness and safety before being used in humans. Biomedical scientists must follow strict ethnical guidelines and avoid unnecessary animal experimentation and clinical trials. Animal welfare including nonexplorative practices and humane treatment of the animal must be considered when using animals in medical research. Clinical trials using human experimentation must be done to strict ethnical guidelines to protect the human subject.

In this ever cost driven society many questions are asked when dealing with aged care the right to be comfortable in old age and the use of expensive products to sustain or maintain an aged persons life or lifestyle. It has been shown that one of the greatest ethical issues in regard to total hip replacement is what constitutes appropriate medical care on an individual who has a limited life expectancy or does a person's age or ability give the medical industry the right to se or withhold ceramic hip replacements. The cost of ceramic hip joints is astronomical for the health budget in Australia and last year alone an individual requiring a total hip replacement would cost up to $17000. This cost varies from public to private yet in Australia in 2007 to 2008 about 40,000 people went through this procedure with over 50% of these being greater than 70 years old.

Some hospitals due to the high cost of ceramic hip implants restrict the surgeon's choice or use even in younger patients. Many older people these days are in good health live very active lives and expect to live a long life. Shouldn't all people deserve a high quality hip replacement that will serve them well for the rest of their lives? This has become one of the greatest modern biomedical ethical issues in medicine today.

Innovations that are happening in the product

A major challenge for material engineers is developing high-performance biocompatible materials to be used in implant surgery. The first ceramics used in hip implants was a pure medical-grade alumina in 1971. Advancements in material quality and processing techniques and designs of ceramic implants led to the introduction of alumna components that offered patients better wear performance and longer-lasting hip implants.

In 1992 the first use of better quality alumina powder with a finer granulometry ("the measurement of the size distribution in a collection of grains"

http://en.wikipedia.org/wiki/Granulometry) and a higher degree of purity was used in ceramic hip implants.

The newest ceramic used combines small amounts of zirconia and yHrium with 75% alumina to produce a even stronger material.

An innovative thermal treatment called Hot Isostatic Pressing is being used. This process treatment removes porosity and other micro-defects and impurities, refines the grain structure and carbide distribution and density ceramic powders to obtain optimal strength, wear and fatigue properties.

The Australian nuclear science and technology organisation have equipment and expertise for Hot Isostatic pressing for manufacture of ceramic implants for orthopaedics.

Scientific research is continuing on new ceramic material to improve the performance for hip replacement joints. Due to the research, companies hope to introduce in the future a ceramic material for hip implants that is extremely hard and low wearing as well as having excellent mechanical properties.

A porous coating of alumina ceramics for the femoral stems in hip implants to encourage bone growth around the implant is being trailed in both human and animals.

Ceramic hip implants require exact surgical technique so they will not chip or break the implant. In 2004 a new invention at St Vincent Hospital in Melbourne was used where surgeons used computers to guide them whilst performing the hip replacement to reduce chipping and breaking the ceramic implant and help the surgeon to have a perfect surgical technique.

Conclusion

Ceramic on ceramic total hip replacements have given many people a better quality of life, and freedom to continue to live an active life. There is also a need for qualified engineers in the field

of bioengineering and many different areas for an individual to pursue.

As more research is done the better the quality of the replacement becomes. And in a few years there may be a new development in the ceramics that will be even better than the current ones. As time goes on there may also be innovations in the techniques used to make the replacements, making them stronger and smoother.

References

1. Kerrie Wood (Stryker joint replacements)
2. Stryker joint replacements
3. Welding technology institute of Australia
4. http://en.wikipedia.org/wiki/Granulometry
5. www.medicineatmichigan.org
6. www.novamedical.co.nz
7. www.evertsmith.com/innovations/ceramic-on-ceramic/
8. www.pennhealth.com
9. www.wmt.com/ceramic
10. www.bonesmart.org
11. www.activejoints.com/ceramic-hip.html
12. www.totaljoints.info
13. www.eng.monash.edu.au
14. www.alcoa.com/alumina.en