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DEVELOPMENT IN ARTIFICIAL JOINTS MATERIALS, ANALYSIS AND MANUFACTURE TECHNIQUES

التطور في مواد وتحليل وطرق تصنيع المفصلات الصناعية

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خلاصة: منذ نهاية القرن الثامن عشر استخدمت المواد الهندسية في أشكال عديدة للزرع في الجسم البشرى. ولقد تطورت جراحات الزرع إلى مرحلة متقدمة حتى أصبحت المواد المستزرعة تستخدم في الكثير من فروع الطب نظرا لتطورها وخاصا جراحات العظام التي أصبحت من أكثر الفروع استخداما للمواد المستزرعة. لقد شهد القرن الأخير تطور كبير في المواد المستزرعة أدى إلى انخفاض نسب الانهيار الناتج من استخدام مواد ضعيفة وظهور مناطق تركيز إجهادات تؤدى إلى ظهور وانتشار الشروخ و انفصال الجزء المستزرع لسوء التثبيت أو عدم الالتصاق مع العظام أو المادة اللاصقة. لذا يقدم هذا البحث بيان بالتطورات الحادثة في العقد الأخير في المفصلات الصناعية من حيث المواد والتحليل وأساليب الإنتاج.

ABSTRACT: Engineering materials, in many forms have been implanted into the human body since the end of the eighteenth century. Implant surgery has developed to the extent that implants are now used in most branches of surgery and are becoming increasingly more sophisticated. Orthopaedic surgery uses more implants than any other branch of medicine. In the last decade, various joint replacements have been developed. However, many implants have failed in the past and even now there are occasional failures. Many of the failures are attributed to poorly chosen or badly used materials, high stress concentration leading to crack initiation and growth, loosening of the implant due to a poor fixation and/or a non-adequate adhesion between the implant/cement/bone interfaces. The present paper reviews the development in artificial implants during the last decade considering materials, analysis and manufacture processes.

1. HISTORICAL BACKGROUND

In the development of artificial joints, to be implanted in the human body, the idea of inserting interposing material is credited to Carnochan of New York in 1840 who used a block of wood between the raw bony surfaces after resection of the neck of the mandible in an ankylosed joint. In 1860, Vernenil of France, pioneered in the use of soft parts as interposing material, utilized muscle and then fat and fascia. More advances in arthroplasty of the hip had occurred in 1923 when Smith-Petersen first used a glass cup to cover the reshaped head of the femur. Glass was replaced by a celluloid material and later in 1933 by Pyrex, then by Bakelite in 1937 and finally by vitallium in 1938. In 1940, Bohlman of Baltimore and A.T. Moore of Columbia inserted stainless steel prosthesis for the replacement of the whole upper third of the shaft of the femur. However, Thomas Gluck performed the first total hip replacement in 1890, which consisted of an ivory ball and socket joint in which a cement type of material was used. Philip Wiles introduced the first metal-on-metal joint replacement for the hip in 1938, which was made of stainless steel, but two years later cobalt-chromium alloy was introduced in the US for the femoral head [1]. Metal-on-metal total joint replacements using either stainless steel or vitallium, developed rapidly

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since 1950 as well as the methyl-methacrylate used to fix the components in the bones. Identical metal materials were used to avoid corrosion problems but it represented unsound tribological practice and the high friction, which ensued, created severe fixation problems. In 1959, John Charnley introduced his metal-on-plastic total hip joint replacement (THR) in an attempt to reduce friction and alleviate the fixation problem. Polytetrafluroethylene (PTFE) acetabular cup was rubbing against the stainless steel ball of the femoral component. In 1964 Charnley turned from PTFE to ultra-high molecular weight polyethylene (UHMWPE) due to the rapid wear rate of PTFE (about 3 year life for the joint). UHMWPE against surgical grade stainless steel was been favored internationally for THR in the body since then and it now occupies about three-quarters of the market [2]. In 1964, Ring of England designed a socket with a long screw to be inserted into bone without cement. Muller M.E., of Switzerland in 1970 designed a variety of THR, the latest with a cobalt-chrome material. In general, efforts of engineers, surgeons and material scientists in the past two decades are reflected at present in new designs and new materials.

2. DEVELOPMENTS IN ARTIFICIAL JOINT MATERIALS

2.1 CURRENTLY USED MATERIALS FOR PROSTHESES

Both articular surfaces of the prosthesis could be made of metal, one metal and the other non-metallic substance, or both could be composed of non-metallic materials. Three metallic alloys are sufficiently inert to be implanted surgically as a femoral component:

- Cast Cobalt-Chrome-Molubdenum alloy (Co-Cr-Mo) [3], known as Vitallium, is quite resistant to fatigue and to cracking caused by corrosion.
- Iron chromium nickel alloy, know as Stainless Steel [4], has a low content of impurities and high percentage of chromium and is passivated finish. However, if the thin protective layer of chromium oxide at the surface is abraded, corrosion may take place leading to prosthetic failure.
- Titaniun and titanium-based alloys (Ti-6Al-4V) [5-9] have an excellent resistance to fatigue failure and four times higher strength than cobalt-chrome alloy and the surface layer may be porous to encourage bone ingrowth for better fixation of the stem. Titunium protective surface is highly inert but it worn rapidly if rubbed against a hard counterface. Therefore, the combination of titanium on titanium is not encounterly used for the femoral articulating surfaces. A titunium stem with a spigot for the attachment of metallic or ceramic ball head is the satisfactory solution for this problem. For the acetabular cup, titanium fixed shell encloses the polyethylene liner. Fig. 1 illustrates a photographic view for a Ti-6Al-4V alloy stem (Allopro) [9] with a spigot for ball head attachment while Fig. 2 demonstrates another stem and shell made of the same alloy with a stainless steel head and UHMWPE liner [6].

The non-metallic materials are generally used for acetabular cup components in the THR. UHMWPE, a viscoelastic material of smooth molecular profile, is still widely used due to its superior tribological properties compared to other polymers [10-12] in many body implants including the hip [13], the knee [14], the ankle, the shoulder, the vertebral discs and the heart valves.. Other polymeric materials have also been used in limited cases. These include Polytetrafluroethylene (PTFE), which demonstrated insufficient wear resistance and polyformaldehyde, which cannot be regarded as being totally biologically inert and Derlin 150 [15]. However, due to the low strength and creep phenomena of UHMWPE, efforts have been made to increase its mechanical properties while keeping its superior tribological performance. This

was accomplished by reinforced the polyethylene matrix thus forming self-lubricated polymer composites of higher strength [16-19].

Concerning the lubricant which may be encountered between the articulating surfaces in an artificial joints, many authors have investigated the sliding of the different implanted materials either under dry conditions or in the presence of lubricant as distilled water [20], physiological saline solution and serum to duplicate the human body fluids. These investigations were conducted to elucidate the role of these lubricants upon the tribological performance of the artificial joint materials [21]. Human or bovine synovial fluids were also used as lubricant when testing orthopaedic materials for short duration of time due to the rapid degradation of the synovial fluid when exposed to atmospheric conditions [22].

In the last fifteen years, a considerable amount of work has been carried out in France and Germany on the development of ceramic bone and joint replacements, particularly on the high alumina type. This work has led to the clinical trials to use ceramic of chemical composition: aluminium oxide ($Al_2 O_3$) not less than 99.5%, silica ($Si O_2$) and alkali metal oxides not more than 0.1% with average grain size not more than 7 μm in total hip replacement. This high alumina, high-density ceramic offers a better tolerance to the biological environment and secure more readily the bone by encouraging bony ingrowth. The combination of ceramic and UHMWPE appears to have a more reduced wear rate compared to other combinations of materials [23-26]. Fig.3 illustrates a view for the ceramic head of the femoral component. Up to now, many research works have been devoted to the study of the tribological characteristics of the ceramic material as it represents a very promising material to be used in normal engineering, bioengineering and space applications [27-31]. Ceramic failure due to sub-critical crack formation and growth is still under investigations to overcome this problem encountered with ceramic material [32]. Table 1 illustrates some types of prosthesis and the combination of material used to fabricate them.

Table 1. Some Combination of Materials Used for Prostheses

Combination of Materials	*Types of Prostheses*
Metal on Metal	Ring, Mckee-Farrar-Stanmor
Metal on Polyethylene	Charnley, Muller, Amstutz, Harris, Aufrane-Turner, Matchett-Brown
Bipolar-Universal	Giliberty, Bateman
Resurfacing Procedures	Amstutz, Freeman, Wagner
Press Fit (Non-cemented)	Judet, Sivash

Fig. 1. View for the Ti-6Al-4V alloy cemented stem (The Allopro Design) [9]

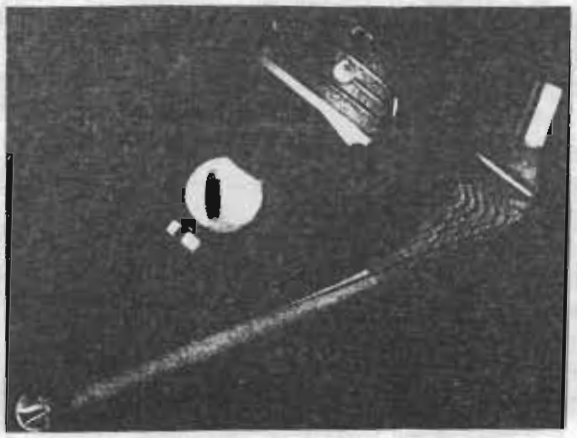

Fig. 2. A view for the "Premier-Total Hip Design", the stem and shell are made of Ti-alloy, the head from stainless steel and a liner from UHMWPE.

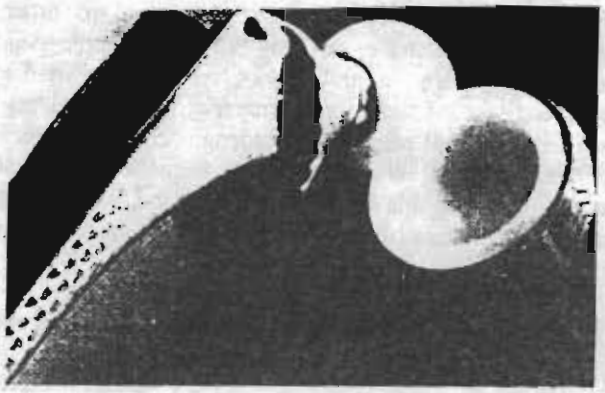

Fig.3. A view for prosthesis with a ceramic ball head.

2.2 RECENT MATERIALS FOR PROSTHESES

A new generation of artificial hip implants has emerged since 1970 when cementless fixation of hip prostheses to bone has been under aggressive development as an alternative to the conventional cemented fixation. Most contemporary cementless implants were coated over some portion of the implant surface. Coating materials include porous layers (beads or mesh), plasma-sprayed metals, hydroxyapatite, and tricalcium-phosphate. The primary objective of these coatings is to produce a lifelong biologic bond between the implant and bone thus eliminating the loosening problem encountered with cemented implants [33]. Fig. 4 demonstrates a comparison between scanning electron microscopic views for the human cancellous bone, the cancellous structured titanium coating with 530 μm average pore size, the spherical bead coating with 250 μm average pore size, the spherical bead coating with 425 μm average pore size and the fiber mesh coating with 300 μm average pore size. The porous full-coated cementless prosthesis was developed first together with press-fit surgical technique aiming at firm fixation with the bone, by bone ingrowth into the

pores. However, this prosthesis provoked severe bone absorption along the stem due to stress shielding. Thus, prosthesis models with partial porous coating over only the proximal part of the stem with either beads or mesh metal were developed. Figs. 5 and 6 demonstrate two different designs for prosthesis coated partially on the proximal part with cancellous structured titanium [5,7]. However, bone ingrowth into the porous surface did not take place to the extent that is sufficient to prevent loosening in about 10 years. Thus, hip prosthesis made of high-tech materials was introduced [34]. This prosthesis consisted of HDP socket and a socket back of new titanium alloy while the femoral component consisted of a femoral head made of zirconia ceramic and a femoral stem made of new titanium alloy. This new titanium is a vanadiumless titanium alloy known as KOMLLOY-3 and is characterized by higher compressive and bending strength and lower elastic modulus than Ti-6Al-4V. The bone-bonding process is accelerated by AW glass-ceramic bottom coating added over the Ti plasma spray coating over a small area of the stem which brings about earlier and stronger osseointegration than the hydroxyapatite coating. Zirconia ceramic was selected, as it is mechanically stronger than alumina ceramic used in previous models. Experiments have shown that zirconia head against HDP socket exhibits no wear after 100 hours of sliding in 37°C in saline solution and under a pressure of 2.5 MPa. It is worth noting that the problem of plasticity of porous and particulate materials, used at present in many artificial joint implants to encourage bone ingrowth into the artificial joint surface, has received considerable attention over the last few years [35].

Another trend in using new materials for prostheses has been revealed in the last seven years. As the stiffness of femoral stem decreases from the central core to the outside, new-layered stiffness in the form of prosthesis made of polyethylene-hydroxyapatite was introduced. This composite material, with layered stiffness, has good bone compatibility. To overcome the low stiffness of the matrix, carbon fiber reinforcement was incorporated resulting in maximum stiffness at the core and lower stiffness at the bone-implant interface [36]. Wintermantel et al. [37] also designed a new anisotropic carbon fiber reinforced uncemented hip endoprosthesis using a thick HT carbon fiber/polyether ether ketone (PEEK) laminate. This model was tested under a cyclic load of 2800 N peak-load and 300 N basic-load and was compared with a titanium standard prosthesis. Obtained theoretical results have indicated that the new model was

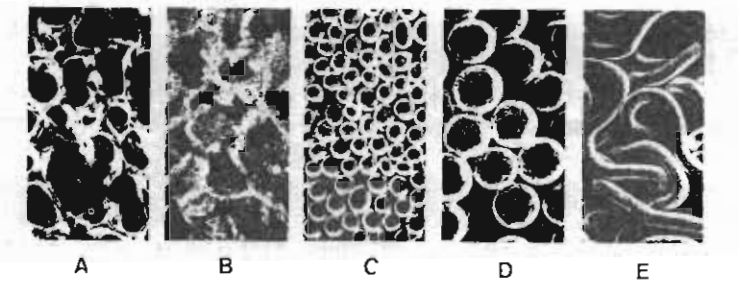

Fig. 4. Scanning electron microscopic views for: A) Human cancellous bone, B) Cancellous structured Titanium (530 μm average pore size), C) Spherical bead coating (250 μm average pore size), D) Spherical bead coating (425 μm average pore size), E) Fiber mesh coating (300 μm average pore size)

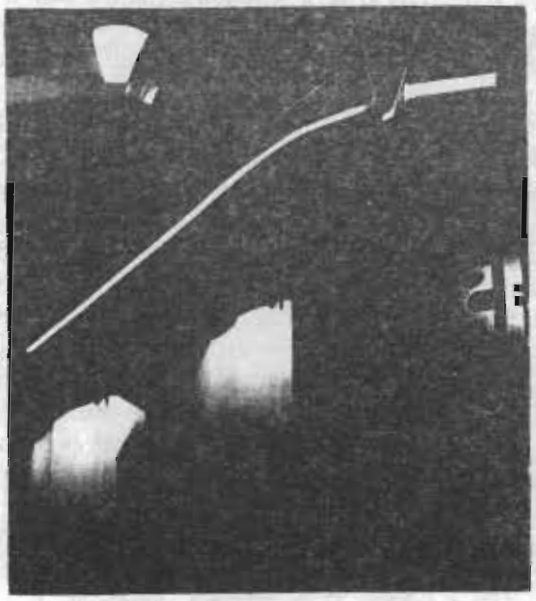

Fig. 5. View for a stem and shell coated partially, an UHMWPE liner and a stainless steel head [7].

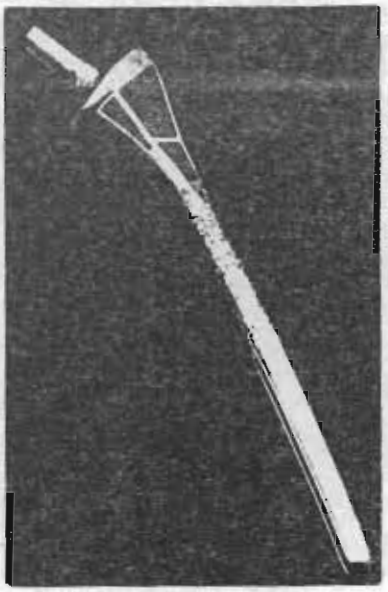

Fig.6 Hip prosthesis coated partially on the proximal stem part with cancellous structured titanium.

Fig. 7 The CF/PEEK prosthesis produced by injection moulding compared to a titanium-alloy prosthesis.

satisfactory and should be tested in vivo conditions. Fig. 7 illustrates a view for the CF/PEEK prosthesis produced by injection moulding and the titanium-alloy prosthesis. Akay and Aslan [38] examined the fatigue life of this combination of materials while Bazant et al. examined the fracture behavior of these composite laminates [39].

New bearing materials for artificial implants were also developed in the last few years. Compliant layered surfaces have been proposed as an alternative to UHMWPE for the bearing surface in total artificial joints. This type of bearing has been termed a "cushion form bearing" [40-41]. Non-permeable medical grade polyurethane elastomers have been used as the compliant bearing surface in artificial hip joint integrally bonded to a rigid polyethersulphone substrate. Although a continuous lubricating film has been developed in a simulator under physiological waking conditions, but problems were encountered when the fluid broke down under adverse lubrication conditions. Therefore, an alternative material, permeable hydrogel has

been proposed as a new cushion forms bearing [42-43]. This permeable hydrogel cushion resulted in a large reduction in the coefficient of friction. Large proportion of the load is carried by a hydrostatic stress field compared to the non-permeable hydrogel in particular at the start-up of the artificial joint motion after prolonged loading.

3. DEVELOPMENT IN ANALYSIS FOR IMPLANT JOINTS

Although the design and materials for artificial implants have rapidly developed during the last twenty years [44], clinical problems of fracture and loosening of the implants were frequently encountered for metallic stem prosthesis with spherical head. These failures were due to mechanical or biological reasons [45]. The mechanical failures include fracture [46] and/or loosening of the femoral stem [47], loosening of the acetabular component, dislocation of the femoral from the acetabular component and to fracture or collapse of the acetabulum [48]. These problems of fracture and loosening have focused attention on the mechanism of load transfer and stresses between the implanted components and the bone [49-50] and on cement (PMMA cement) as the weakest link in the system [51]. Many researchers suggest that the main reason for the stem loosening is "stress shielding" caused by the elasticity mismatch of the bone and the metallic prosthesis, which creates a sharp change in the strain field and causes stress concentration zones, which are the main generators of bone absorption. In order to overcome this problem, isoelastic prostheses were introduced which have a modulus of elasticity close to that of the bone and are, at the same time, strong enough to support the high loads without breaking. These materials being composite were mainly developed for aerospace industry. One of the major advantages of composite materials is the ability to tailor its structure to a specific need. To overcome the problem of loosening, some work was concerned with the reinforcement of the bone cement by incorporating a pre-coated wire coil inside the cement [52] while others have developed the cementless technique for artificial joint fixation into the bone.

As loosening and fracture of the stem are related to mechanical stresses in the joint, investigators have conducted stress analysis on the artificial implants which helped to reduce the surgical use of mechanically unsound implant constructions and improved the design of previously existing prostheses. Both experimental and theoretical means were used to evaluate the stresses in the stem in order to improve the stem design of many design concepts for the prosthesis. Among the techniques used to estimate or measure the critical stresses responsible for failure and their locations, the stress-coat technique [53-54], the electrical resistance strain gauges [55] and the photoelastic technique were initially used, but these suffered from different drawbacks. However, with the development of computers and software, finite element analysis has proved to be the only efficient technique and the powerful tool for analyzing mechanical behavior and determining the state of the stress and strain in the bone and the complex shape implant after joint replacement [56-57].

Analytical or experimental studies have generally focused on the implant surface stress distribution and the effects of changing the dimensions and shape of the femoral component (stem length, stem cross-section area, stem back curvature, neck inclination,...etc.), the prosthesis stem stiffness distribution, the stem elastic modulus, the variation of cement elastic modulus and the existence or absence of contact between a prosthesis flange and the calcar femoral (collar-calcar), fixed or adjustable

collar, either for cemented or cementless implants, upon the stress values and stress distribution [58-63].

For artificial implant analysis, researchers using finite element technique, utilized models which ranged from simple straight composite tubes to complex three-dimensional finite element assemblies [64-69]. Intermediate to these have been different two-dimensional models [70], which resulted in almost similar stresses to those obtained in the three-dimensional studies due to the constant thickness of the stem. Fig. 8 illustrates a 3D finite element model for the artificial hip joint. Efforts have contributed to the knowledge of the behavior of the implant systems in one way or another leading to improved design implants. At present, combinations of Finite Element Analysis (FEA) and numerical optimization techniques have been used to improve the implant design until an optimal design is reached [71-74]. It is worth mentioning that from June 1998, in accordance with European Standards, all orthopaedic implants would be required by law to carry the so-called "CE-mark" to ensure safety and quality of the implants [75].

Recently, some investigators have found that not only the stresses of the artificial implants are the main source of failure and loosening, but also the fatigue notch factor, which is the ratio between the fatigue strength of a specimen with no stress concentration to the fatigue strength with a stress concentration, plays an important role in the failure process [72-73, 76].

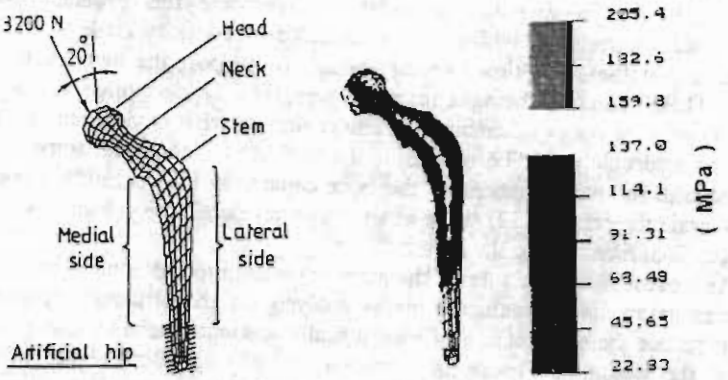

Fig. 8. A 3D finite element model for a femoral component shows the shear stress distribution for the model.

4. DEVELOPMENTS IN JOINT MANUFACTURE

Modern surgical implants are highly sophisticated devices. Wide range of techniques is employed in their manufacture. The overall manufacturing procedure can be subdivided into four general areas: basic forming processes, machining and finishing or roughing processes, material treatments and quality control procedures.

4.1 BASIC FORMING PROCESSES

4.1.1 Forging

In the basic forging processes, a piece of preheated material (billet) is deformed by means of single or multiple impact blows or by a heavy squeezing action. Impact forging is usually made by impact or drop forging in shaped dies for the preheated material thus producing forging with excellent mechanical properties.

4.1.2 Moulding

A similar process to forging can be applied to UHMWPE. This process is a hot solid phase compression moulding. A billet of preheated UHMWPE is squeezed between shaped dies in a hydraulic press, and allowed to cool, while the polymer takes the shape of the die. It has been reported that high-pressure moulding changes the properties of HMWPE markedly. Percentage crystallization rises from about 50% at low moulding pressure to as high as 80-90% at pressures in the region of 5 kbar. These changes have the effect of increasing the density of the moulded material and changing its mechanical properties. Polyethylene moulded at higher pressures becomes harder and more brittle, factors that one would expect to affect wear. Therefore, the use of lower moulding temperatures (below 200 ^{O}C) than those recommended (220 ^{O}C) confers a definite improvement in wear rate by a factor of 2-2.5. Furthermore, it has been shown that the reduction of Santonox (an antioxidant) from 0.25% level to a lower level of 0.025 improved the wear properties [77].

4.1.3 Casting

The basic casting process involves the pouring of molten metal into a prepared mould, which has the shape of the required component. There are four primary casting techniques: sand casting, die-casting, shell moulded casting and investment casting or "lost wax process". Sand casting is not suitable for use on implant components due to the risk of sand inclusions and material defects common to this process. Die-casting is also not suitable for implants because the metal dies are not able to withstand the high temperatures of molten implant alloys. The shell moulding process could be used for implant work but the product is inferior to that resulting by the investment process in terms of surface finish and accuracy of size. Therefore, the investment process universally produces surgical implant castings, although it is an expensive casting procedure. The first stage in the process is to make a pattern or master, i.e. a model of the required component. This pattern is then used to make one or more master moulds "female patterns". The master moulds are used to make wax patterns identical to the master pattern. A number of wax patterns are then assembled to a central wax stem "gate" and the whole is coated with a smooth refractory substance by dipping or spraying. Successive coats are applied until a strong shell is formed. The next stage involves heating the invested wax assembly so that the wax melts and runs out leaving a hollow shell. The shell is then subjected to a vacuum process to remove any residual wax. Molten metal is poured into the shell under very clean conditions or under vacuum to ensure that no gas bubbles will be present in the finished castings. The final stage is the removal of the shell and the separation of individual castings from the gate.

4.1.4 Welding

For bioengineering purposes, a high degree of control over the fusion of the metals and over the environment during and immediately after fusion is required. Generally, fusion is brought about by either electric means as in arc welding or by gas blow-torch or by high energy stream of electrons as in electron beam welding. This latter process is still under development but has much to offer in the surgical implant field as it is a very clean, closely controlled process, producing excellent welds with minimum metallurgical disturbance.

4.2 MACHINING AND FINISHING PROCESSES

This group included all those processes, which change the shape, size or surface finish of the basic formed implant. In engineering field, there are many types of machining, but only those widely used in the implant production are: turning, milling, grinding, honing, lapping, polishing and fitting.

4.3 MATERIAL TREATMENTS

Of the wide range of treatments to which a material may be subjected in modern technology, only few are applicable to the implant manufacture.

4.3.1 Heat Treatment

During the manufacture of an implant, there are several stages where some form of heat treatment is applied to the material. Heat treatment is used to refine the metallurgical structure after any particular operation as forging or welding or it may be used to improve the mechanical properties of the component. Four basic heat treatments are used: annealing, normalizing, hardening and tempering.

4.3.2 Surface Chemical Treatment

Metallic implant materials have an inherent resistance to corrosion, which depends upon the formation of a protective oxide film on the material surface. For stainless steel, the surface oxide layer is artificially improved by passivation.

4.3.3 Surface Finishing Treatments

Various techniques are used to finish the non-articulating surfaces of implants. Among these techniques, bead blasting process, in which small glass beads are blasted against the surface of the implant. For plastic components a similar blasting process is used but the blasting medium is longeared corn to eliminate the unduly damage. In some cases, barrelling process is used to finish the non-sliding surfaces of the implants. In this process, a large number of components are loaded into hexagonal drum which rotates on a horizontal axis. The inside components roll in a random manner, rubbing against each other's. Sometimes a further abrasive medium such as steel-shot, is placed in the drum with the components. This process removes all sharp corners and machining burrs and improves the surface properties by work hardening.

4.4 QUALITY CONTROL PROCEDURES

The quality control procedures are essential in ensuring that the product entirely meets its specifications and is fully fitted for its application. It is applied at all stages of manufacture from basic raw material supply to the packaging of the finished product.

4.4.1 Quality Control of Raw Materials

Metallic raw materials are checked by means of chemical analysis, spectrographic analysis, radiography and microscopy. In spectographic analysis, a sample of the material under test is used as one of a pair of electrodes, through which an electric current is passed, causing an arc between two electrodes. The radiation from this arc is passed through a prism and disperses according to their wavelengths. Each constituent of an alloy has its own characteristic wavelength, thus a photographic record of the dispersions can be used to determine the quantities of these constituents. Raw materials are also subjected to standard mechanical tests.

4.4.2 Quality Control of Machining Operations

Machining operations are checked by a variety of measuring techniques, which indicate the accuracy of size or geometry and the quality of surface finish. The instruments used for the measurement of size range from simple micrometers to highly sophisticated comparators in which the part to be measured is compared to a known standard. Standards may be in the form of slip gauges, length bars...etc.

4.4.3 Quality Control of Surface Finish

A machine "Talysurf", which measures the deviation from a true path of a stylus as it is drawn across the surface, assesses surface finish. For very smooth surface finishes a similar machine called "Talystep" is used. The accurate control of geometry in implant work is usually concerned with roundness and sphericity. A machine called "Talyrond" measures the roundness. Sphericity is measured indirectly by roundness measurements taken in a large number of planes forming the spherical part.

4.5 MANUFACTURE OF CEMENTED CHARNLEY HIP PROSTHESIS

To illustrate the degree of effort, which goes into the manufacture of an implant, a summary of the production process for a Charnley hip prosthesis is given. Although this example is based on a stainless steel femoral component and an UHMWPE cup, but the general procedure is valid for other alloy materials.

4.5.1 Femoral Component

The material used for the femoral component is a fully austenitic stainless steel produced from double vacuum re-melted ingots.

Stage 1 is the metallurgical inspection of the ingot by chemical and spectrographic analysis of sample drillings taken from various places in the ingot.

Stage 2 is a further metallurgical examination of material after it has been reduced in size by forming to billet form. Transverse sections of the billet are taken and examined by microscopy for structure and inclusions.

Stage 3 involves a further reduction and heat treatment of the billets into bar form and the centreless grinding of the bars prior to forging. At this stage the bars are in the fully softened condition.

Stage 4 is the forging of the implant along with further heat treatment to obtain the desired mechanical properties. One sample forging from each batch (about 250) is examined metallurgically for microstructure and also subjected to a variety of mechanical tests to determine the ultimate tensile strength, the 0.2% proof stress and the elongation.

Stage 5 is the delivery of forgings to the implant manufacturer and the 100% inspection of forgings for straightness, excessive flash on the forging die line, mismatch of the upper and lower halves of the forging and surface defects.

Stage 6 is the total machining and finishing program which is divided into several operations:

Operation 1. The parallel sides of the tang are milled to remove the forged surface and to provide location faces for following operations. Inspection is made by random selection followed by 100% inspection. Tolerances are maintained at 0.125 mm.

Operation 2. The outer profile of the tang is milled to remove the forged surface. Inspection and accuracy are similar to operation 1.

Operation 3. The inner profile is milled, with similar inspection and accuracies.

Operation 4. The femoral component is held in special fixtures mounted in purpose-adapted lathes, and the neck and head are rough and finished turned. Tolerance of +0.075 mm is maintained on the neck and a tolerance of + 0.050 mm, minus zero, is kept on the head diameter while sphericity is kept at accuracy of 0.005 mm. Inspection by random followed by 100% inspection of the batch is done again. The batch is 50.

Operation 5. This is a fitting operation necessary to blend certain difficult radii to the body of the prosthesis. Visual inspection and gauge checks are performed.

Operation 6. The tang is polished to remove machining marks and to give slight taper to the parallel sides. A surface finish of 1 μm R_a is achieved and inspection is 100%.

Operation 7. The implant is subjected to surface treatments such as bead blasting to produce the desired surface texture.

Operation 8. Manufacturer's codes and internationally accepted implant material quality symbols are engraved on the component.

Operation 9. The femoral head of the prosthesis is lapped to size. Accuracies of order + 0.0125 mm on the diameter and 0.0025 mm on the sphericity are maintained. 100% inspection of the lapping, surface texture and engraving is applied. Inspection of the head size is carried out using pneumatic comparators.

Operation 10. Using special purpose machines, the head is polished to a surface finish of better than 0.025 μm R_a. The polishing media and applicators are discarded after each prosthesis.

Operation 11. The implants are then passivated by soaking in a 30% nitric acid and water mixture by volume at 85 °C for a prescribed time.

4.5.2 Acetabular Cup

A similar process is followed in the manufacture of the polyethylene acetabular cup with similar material controls and certification. There are seven machining or fitting operations to complete the cup, which is then washed in a six-part process. The cups should then be handle by operators wearing disposable sterile gloves.

The final operation brings together the individual components of the prosthesis for packaging and sterilization. Packaging is carried out in a clean zone and the double packaging process is checked by a vacuum test. Sterilization is done by gamma irradiation with a dose of 2.5 Mrad.

4.6 MANUFACTURE OF CEMENTLESS PROSTHESES

Different types of uncemented hip endoprosthesis shaft has been developed resulting in different manufacture procedures followed for production. For carbon fiber/PEEK laminate hip endoprosthesis, Wintermantel et al. [37] used a five-axis machining center with the following machining parameters to manufacture the femoral component:

1) Dry milling is used in order to avoid contamination of the shaft with bio-incompatible lubricating substances.

2) Optimal milling speed is found to be 350 m/min. using axial feed.

3) Forward feed lower than 800 mm/min. results in melting of the surface-forming matrix, while a higher forward feed results in delamination.

Akay and Aslan [38] noted that carbon fiber reinforced PEEK is a difficult material to process by injection moulding in thick cross-sections. The differential solidification of the melt in the mould can cause voids in the core of the component, which weaken the mechanical performance. Therefore, in order to eliminate the voids, the sprue diameter was enlarged and the sprue bush was heated with electric cartridge heaters to higher temperature than the mould in order to delay the solidification and allow the packing of the melt into the cavity so that the shrinkage could be compensated.

In general, the manufacture procedure used for metallic cementless prosthesis is similar to that followed for metallic cemented prosthesis except for the final treatment of the surface. In order to obtain satisfactory fixation and bio-functionality of bio-tolerated and bio-inert materials, surface alterations such as threaded surface, grooved surface, pored surface and rough surface have been produced in order to promote tissue and bone ingrowth. Rough surfaces, in particular, have been widely used for cementless new metallic prosthesis. However, up to now, there is no report on suitable roughness to a specific metallic biomaterial but it is suggested that surface roughness in the range from 10 nm to 10 μm may influence the interface biology, since it is of the same order of size as cells and large bio-molecules. Small roughness of the order 10 nm may become important because microroughness on this scale length consists of material defects such as grain boundaries, steps, vacancies, etc. These features are well known to be active sites for adsorption, thus influence the way bio-molecules can bond to the implant surface [78]. The surface roughness can be obtained by mechanical or chemical treatments. Mechanical treatments such as mechanically polished, grind, hone, machine, etc. are seldom used due to the high variation of the structure of the surface area, the high divergence of roughness and the difficulty in obtaining the required roughness. The chemical treatments include electro-polishing [79], anodization or etching for smooth surfaces. On the other hand, rough surfaces, for implants surfaces, can be attained by four ways: (a) Sandblasting: Different surface microroughness can be obtained by changing the kind of sand grid, the size of sand grid (from 10 μm to 1000 μm), the pressure of sandblasting (from 1 bar to 10 bar), the time of sandblasting (several minutes to several hours). (b) Anodizing: different microroughness can be attained by controlling the kind and the concentration of anodized agent (e.g., 30% nitric acid, sulfuric acid, acetic acid, etc.), the voltage of anodizing (from 10 V to 200 V), the time of anodizing [80]. (c) Etching: different microroughness can be obtained by controlling the kind and concentration of the etched agent, the time of etching. (d) Coating: Such as sintering coating, electro-phoretic deposition, vapor deposition and high temperature vapor deposition, sputtering coating, immersion deposition, flame-spray coating and plasma spray coating. The techniques widely used in recent design of artificial joints for coating are the flame-spray coating [81] and the plasma spray coating [82]. Fig. 9 illustrates a titanium stem with titanium alloy plasma spray coating while the titanium shell component may be domed with porous coating or finned with plasma spray coating or grooved with the groove surface near the rim. Surface oxidation is also used to obtain rough surface for implants. In surface oxidation, four choices are available: (a) Aged, for example, boiling in distilled water for several hours. (b) Radio frequency plasma [83]. (c) H_2 O_2 in solution may increase the surface roughness. (d) Thermal heating in a furnace for one to three hours usually at 100 ^{O}C to 600 ^{O}C [83]. Investigators have found that the bone-implant bonding strength increases with the increase in surface roughness in the scale of microroughness [84] and that for the

microrought surfaces the bonding strength increases with time, reaching reliable bone-implant fixation after eight weeks of operation [85].

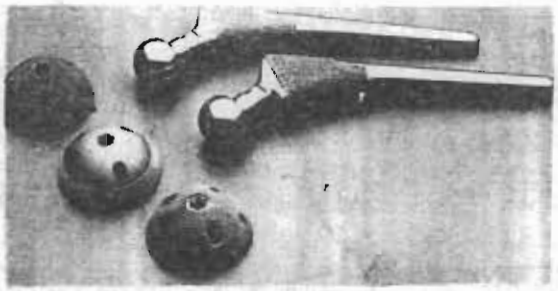

Fig. 9 The Perfecta stems, Standard and Reduced flare, and Domed, Finned and Grooved acetabular shells.

5. CONCLUSION

The load-bearing human joint is a self-acting, dynamically loaded bearing which employs a porous and elastic bearing material (the articular cartilage) and a highly non-Newtonian lubricant (the synovial fluid) enclosed in an elastic capsule. In engineering terms it is the perfect joint. One of the more dramatic developments in orthopaedic surgery in recent history has been the total joint prosthesis, which is frequently used to replace a diseased or injured joint. Two centuries of study and developments in artificial joints have not yet produced the perfect artificial joint. However, the utilization of composite technology and new materials for artificial implants, in particular the load-bearing joints during the past decade has opened up many new avenues for product and design improvements. These new designs and materials will provide one or more of the following benefits: weight reduction, cost savings, physical and/or mechanical property improvements and tribological improvements in artificial joints. At present, a considerable amount of work would be required to optimize the various designs and materials for implants to reach the perfect artificial joint.

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