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MECHANICAL ENGINEERING

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PRODUCT DESIGN

MEE 510

PROJECT TITLE: COMPARATIVE ANALYSIS OF BIOMATERIAL PROPERTIES OF ZICORNIA AND ALUMINA CERAMICS.

1.0 PRODUCT AND PRODUCT DESIGN

WHAT ARE BIOMATERIALS?

Biomaterials can be defined as any substance that has been engineered to interact with biological systems for a medical purpose either a therapeutic or a diagnosis one. As a science, biomaterials are about 50 years old. The study of biomaterials is called biomaterial science or biomaterials engineering.

Examples of biomaterials are alumina, zicornia, titarium, niobium, and carbon. Bioactive this is the interaction between the implant and the bone tissue, interfering directly in the osteogenesis.

BACKGROUND TO STUDY

APPLICATION OF BIOMATERIALS

Biomaterials are the kind of materials that are introduced into the body as a medical device for medical purposes, biomaterials can be implanted to replace or repair missing tissues. Biomaterials such as bone substitutes and collagen membranes are used regularly in regenerative dentistry as well as for bone and cartilage regeneration in or orthopedics. These materials are having numerous medical applications such as cancer therapy, artificial ligaments and tendons, orthopedics for joint replacements, bone plates and ophthalmic. Applications in contact lenses, for wound healing in the form of surgical sutures, clips, nerve regeneration, in reproductive therapy as breast implants, etc. there's materials also have some non-medical applications such as to grow cells in culture medium, assay of blood proteins in laboratories etc.

Examples of biomaterials in study include: zirconia and alumina.

ZICORNIA

This had been known as a gem from ancient times. The name of the metal zirconium, comes from the Arabic argon (golden in color) weigh in turn comes from the two Persian words ZAR (gold) and gun. Zirconia the metal dioxide((ZrO2) was identified as such in 1989 by the German chemist Martin heinrich klaproth in the reaction product obtained after heating some gems, and was used for a long period.

Although low quality zirconia is used as an abrasive in huge quantities, tough, wear resistant refractory zirconia ceramics are used to manufacture parts operating in aggressive environments, like extrusion dyed, valves and port liners for combustion engines, low corrosion, thermal shock resistant refractory liners or valve parts in foundries. Zirconia blades are used to cut Kevlar magnetic tapes, cigarette filters (because of their reduced wear) high temperature ionic conductivity masked zirconia ceramics suitable as solid electrolytes in fuel cells and in oxygen sensors. Good chemical and dimensional stability mechanical strength Saabs toughness coupled with a young modulus in the same order of magnitude of stainless steel alloys was the origin of the interest in using zirconia as a ceramic biomaterial.

ALUMINA

Definition: alumina ceramics was sintered in air (Biolox). 1st generation was manufactured

until 1992, 2nd generation until 1995. Hiped alumina (Biolox Forte) was conforming to ISO

6747. 3rd generation manufacturing started in 1995 14 Despite the mentioned good properties of alumina, such as high mechanical strength, elastic modulus, high compression resistance, optimal chemical properties, its brittleness must not be forgotten: its fracture toughness is only ~4 MPa·m1/2 and it is also sensitive to slow crack propagation under a stress intensity factor KI lower than the critical value KIC. Ceramic materials are highly sensitive towards stress concentration, so uneven load distribution must be avoided. The design of the metal stems and tapers is important: Morse tapers must be properly designed for optimal load transfer, avoiding stress intensification in the ceramic-metal interface. The metal tapers have a specific surface roughness.

STATICS AND JOINT MECHANICS

Statics is the study of external effects of forces on bodies in equilibrium. The equilibrium or state of rest of a body is associated with a number of forces acting in various directions. The forces acting may be coplanar (lying in the same plane) or they may be in different planes, i.e non coplanar.

In various orthopedic procedures, physical therapy or rehabilitation procedures, the concerned people deal with the effects of forces. They may alter the force system by transferring a muscle by using an arch support or by performing osteotomy.

The analysis and correction of any musculoskeletal disorder is based on the understanding of the function of each of the member involved. This will call for knowledge of statics, dynamics and properties of materials.

A force is that which changes or tends to change the state of rest or motion of a body. The effect of force may be internal or external. The external effect causes motion of a body. The internal effects cause deformation and strain. Force is a vector quantity. To characterize a force, three definite parameters must be stated: its magnitude, direction and point of application. once the point of application and direction, including sense (i.e. the arrow head), is known, the force may be represented as a line within an arrow head. The length of the line is the magnitude of the force and the arrow head shows the direction.

MECHANICS OF THE HIPS

Anatomy

This joint allows a wide range of movement required for walking, sitting, squatting, sitting crossed legged and stair climbing. Such a joint should be precisely aligned and controlled. The acetabulum and femoral head forms a ball and socket joint. The concave component is covered with cartilage which thickens peripherally. This cavity face is obliquely forward outward and downward. The head of the femur is the convex part and forms two thirds of a full sphere lined with soft cartilage which is the thickest at the mid central surface and thinnest at the periphery. The joint reaction force usually acts on the superior quadrant. The neck shaft angle is usually 125^{o} and it is called coxa valga If it is more than that and coxa vera if less than 125^{o} . the range of this angle varies between 110^{o} and 150^{o}.

The articular movement between the spherical head of the femur and the acetabulum of the pelvis forms a pair of arthrodial joint which is a heavy load- bearing joint. The stability of the

hip joint is due to its nearly two third area coverage of the ball by the congruent socket type of configuration and its ligaments, and by the large and strong muscles crossing it. The femoral head fits well into the deep socket like cavity of the acetabulum. The ligaments of the hip joint, such as the transverse and teres femoris ligaments, support and hold the femoral head in the acetabulum as the femoral head moves. The construction of the hip joint is such that it is very stable and allows a wide range of movements including walking, stair climbing, sitting in chair or floor, squatting, skiing, dancing, running, etc. each posture is a marvel and could be analyzed if we can identify the muscles involved in such posture and their geometrical parameters, e.g cross sections. Points of insertions and origins.

BONY ARCHITECTURE

The head of the femur mostly consists of cancellous bone which is denser at the periphery. With the aging process the femur gradually undergoes degenerative changes wherein the cortical struts of the cancellous honey comb like structure gets thinned and the trabeculae gets resorbed.

ORTHOPEDIC IMPLANTS

An orthopedic implant is a medical device manufactured to replace a missing joint or bone or to support a damaged bone. The medical implant is mainly fabricated using stainless steel and titanium alloys for strength and the plastic coating that is done on it acts as an artificial cartilage. Internal fixation is an operation in orthopedics that involves the surgical implantation of implants for the purpose of repairing a bone. During the surgery of broken bones through internal fixation the bone fragments are first reduced into their normal alignment then they are held together with the help of internal fixators such as plates, screws, nails, pins and wires.

Orthopedic implants materials may have an important role in the fixation process. The choice of the implant material influences rigidity, corrosion, biocompatibility and tissue receptivity, while its surface morphology affects is stability within the skeleton or the surrounding cement mantle

WHAT IS THE IDEAL ORHOPEDIC IMPLANT MATERIAL?

The ideal implant material for orthopedics could be described as having the following characteristics:

- Chemically inert;
- Absolutely biocompatible;
- Great strength;
- High fatigue resistance;
- Low elastic modulus;
- Absolutely corrosion-proof;
- Good wear resistance;
- Inexpensive

Orthopedic implants manufacturers are constantly investing in R&D to improve existing materials and explore new ones to get closer to this description. The search is on

MANUFACTURED ORTHOPEDIC IMPLANTS MATERIALS

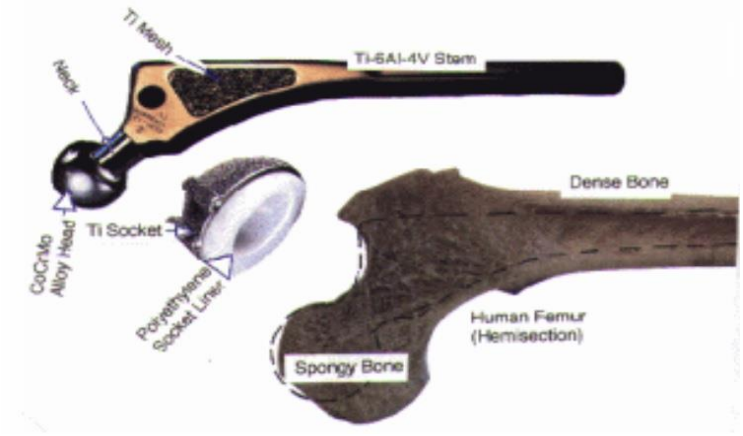
There are 3 categories of materials currently used in prostethic devices:

- Metals,
- Polymers,
- And ceramics

METALS

Metals used in orthopedic implants include surgical grade stainless steel (commonly 316L), cobalt-chromium (Co-Cr) alloys and pure commercial titanium (Ti) or titanium alloys.

Stainless steel is used for non-permanent implants, such as internal fixation devices, because of its poor fatique strength and liability to undergo plastic deformation. Before the use of titanium, cobalt-based alloys had largely replaced stainless steel as materials for permanent implants. These alloys are generally more corrosion resistant, owing to the formation of a durable chromium oxide surface layer. Despite the good corrosion resistance, ion release in vivo is a major concern, as chromium, nickel, and cobalt are known carcinogens.



Titanium use in orthopedic implants involves pure commercial titanium and titanium alloys, such as **Ti-6Al-4v**, for example. These metals have been demonstrated to be highly biocompatible. Nevertheless, some concern remains as to the effect of vanadium and aluminium. Titanium and its alloys are more corrosion resistan than Co-Cr alloys because of the formation of titanium oxide on the surface. This layer, however may be

porous and rather friable. Abrasion of this titanium oxide layer can lead to the release of particles into the surrounding tissues. Although titanium implants have been considered to be the most biocompatible, these debris particles may well cause an undesirable tissue response with eventual long term aseptic loosening of the implant.

POLYMERS

Polymers are formed by linking a large number of monomers through chemical reactions. In organic polymers, the monomer is an organic polymer, the monomer is an organic molecule with a central carbon atom.

The most used polymer. In an orthopedics, is ultra-high molecular-weight polyethylene (UHMWP) or high density polyethylene (HDP). Thus far polyethylene is the best material for articulating with metal or ceramic.

One major problem in polymers is the slow, temperature-dependent, deformation it suffers under load, commonly called “creep”. Another concern with the polyethylene is the progressive wear.

Carbon fibers has been used for reinforcement of the mechanical strength of polyethylene. although creep and tensile strength could be improved, resistance to surface wear was decreased.

In spite of the increasing implantation of cement-less devices, the use of self-curing bone cement, which is an acrylic polymer, remains widespread. Modern cementing techniques are responsible for the much improved clinical outcome of cemented prostethic implants. It should however be emphasized that cement does not act as a glue, but merely as a filler which allows mechanical anchoring of the implant and transfer of load from the prosthesis to the bone. Compared to cortical bone, polymethylmethacrylate (PMMA) is relatively weak with respect to nearly all mechanical properties. Its low modulus of elasticity appears to be an advantage in that it allows a gradual transfer of stress to bone.]

CERAMICS

The ceramics used in orthopedic implants include aluminium oxide and calcium phosphates. These ceramic materials are very resistant to compression, but weak under tension and shear, and brittle.

Aluminium oxide (Alumina) ceramics are formed by the simultaneous application of pressure and temperature to a powder. This process, called hot pressing, leads to a final product with high density, small grain size and good mechanical properties.

Ceramics have a high modulus compared to bone (330,000 MPa). This may result in fracture of bone or early loosening of ceramic acetabular sockets because of the high non complaint **elastic modulus.**
Although in vitro tests revealed excellent results as to tribology and wear for the combination of alumina-to-alumina (head and socket), unacceptable wear after some years of clinical use has been observed. Another reason for discontinuation of its use is the low resilience of this ceramic. This property may adversely influence impact crack initiation and propagation. Instead, ceramic to HDP articulating surfaces are being used.
Calcium phosphate ceramics are particularly attractive as implants coatings because of their high biocompatibility and reactivity. Titanium and titanium alloys are coated with hydroxyapatite (HA) using several methods. These calcium phosphate implant coatings have been shown to result in strong early bone ingrowth.
Other ceramic materials are commonly used, such as zicornium oxide (zicornia) and silicon oxide (silica).

Design consideration
Clinical results

Several aspects of any artificial bone design must be considered before implementing the design into a patient. Artificial bone implants that are an ill fit inside a patient due to events such as leaving the recipient bone unfixed can cause redness and swelling at the recipient region. Ill fit implants may also be caused by sintering, which can cause dimensional contraction of an implant by up to 27%. Osteoconductivity is another important consideration for artificial bone design. Sintered materials increase the crystallinity of calcium phosphate in certain artificial bones,

which leads to poor resorption by osteoclasts and compromised biodegradability. One study avoided this by creating Inkjet-Printed Custom made Artificial Bones that utilized α-tricalcium phosphate (TCP), a material that converts to hydroxyapatite and solidifies the implant without the use of sintering.In addition, α-TCP is biocompatible and helps form new bone, which is better for patients in the long term.Artificial bone designs must be biocompatible, have osteoconductivity, and last for long periods of time inside a patient in order to be a viable solution compared to autologous and allogeneic bone implants.

CHALLENGES

Surface properties

Artificial grafts maintain comparable compressive strength, but occasionally lack similarity to human bone in response to lateral or frictional forces. In particular, the topographyof artificial bone is inaccurate compared to its natural counterpart. In Grant et al., artificial bone grafts produced by fused deposition had on average a 20% lower coefficient of friction compared to real bone. While CT scans and subsequent bone models are highly indicative of real bone for internal composition, the final product relies on the resolution of the printer. In cases where printer defects occur, the most likely issue is a decrease in compressive strength due to unintentional voids. After implantation, decreased cellular proliferation and differentiation is evident as patients increase with age. This prolongs the integration of grafts and hinders the formation of bone tissue. In animal models, the incorporation of allografts causes teratoma formation. Whether or not the probability of this event is significantly increased remains to be seen.Thus, scaffolding with other biological agents is necessary to mimic the framework of the body. Type I collagen, which constitutes a significant portion of the organic mass of bone, is a frequently used scaffolding agent. Alternatively, the polymer chitosan possesses similar biological response, namely the promotion of osteogenesis in vivo.[2]

Fabrication limitations

More modern fabrication techniques include inkjet printing.First, a bone model is created by means of reconstruction of CT images obtained from a human patient. In one study, a 3D inkjet printer produced autograft implants for the lower jaw of 10 patients. The hydroxyapatite implant was produced from tricalcium phosphate powder which hardened after hydration.The surgical procedure was conducted for both aesthetic and function. All patients indicated satisfaction with the bone product. In another study, which examined replicate goat femurs, hydroxyapatite nanocrystals were produced and mixed on-site before loading a 3D printer. The study noted a slight decrease in compressive strength of the femurs, which could be attributed to imperfect printing and an increased ratio of cancellous bone. In general, 3D printing techniques produce implants with few adverse effects in patients. Host cells of varying classifications, such as lymphocytes and erythrocytes, displayed minimal immunological response to artificial grafts. Only in the case of improper sterilization or previous predisposition to infection did any significant complications occur. The speed of printing is the primary rate-limiting step in artificial bone production. Depending on the type of bone implant, printing time can range from an hour to several. As printers produce higher resolution grafts, the duration of printing increases proportionally.

Biological response

Research on artificial bone materials has revealed that bioactive and resorbable silicate glasses (bioglass), glass-ceramics, and calcium phosphates exhibit mechanical properties that similar to human bone. Similar mechanical property does not assure biocompatibility. The body's biological response to those materials depends on many parameters including chemical composition, topography, porosity, and grain size. If the material is metal, there is a risk of corrosion and infection. If the material is ceramic, it is difficult to form the desired shape, and bone can't reabsorb or replace it due to its high crystallinity. Hydroxyapatite, on the other hand, has shown excellent properties in supporting the adhesion, differentiation, and proliferation of osteogenesis cell since it is both thermodynamically stable and bioactive. Artificial bones using hydroxyapatite combine with collagen tissue helps to form new bones in pores, and have a strong affinity to biological tissues while maintaining uniformity with adjacent bone tissue. Despite its excellent performance in interacting with bone tissue, hydroxyapatite has the same problem as ceramic in reabsorption due to its high crystallinity. And since hydroxyapatite is processed in high temperature.

AIMS AND OBJECTIVES

- The aim of this work is to study and compare the biomaterials zirconia and alumina.
- analysis of mechanical biocompatibility of zirconia and alumina for internal fixator.
- To carry out tests on zirconia and alumina.
- To determine which biomaterial is more compatible.

2.0 MATERIAL SELECTION

❖ CERAMICS FOR BIOMEDICAL APPLICATIONS

Ceramics have a great potential in the biomedical field, thanks to their compatibility with the physiological environment, their strength and wear resistance. Ceramics are also very attractive for dental applications, because of their chemical inertness and their aesthetics. Thus, bioceramics are mainly used in the musculo-skeletal system, for orthopaedic and dental devices: the main applications include replacement for hip, knee, teeth, as bone gaps filler. A first distinction can be made between bioinert (as alumina or zirconia), bioactive (as hydroxyapatite, bioactive glasses, glass-ceramics), resorbable (as tricalcium phosphate) 2
.

This distinction is based on the interaction between the material and the living tissue. In the first case the material is biologically inactive, having a minimal interaction with the surrounding tissue, and a nonadherent fibrous capsule of variable thickness is formed at the interface with the device. Movement at the bioinert material-tissue interface can occur, often leading to aseptic implant loosening. Instead, bioactivity refers to a material, which, being placed in the human body interacts with the surrounding bone through an ion exchange reaction between the implant and the surrounding body fluids. This leads to the formation of a biologically active carbonate apatite layer on the implant surface. This phenomenon is exploited in microporous ceramics, thought to promote ingrowth of living tissue into the porosity of implant materials, in order to obtain a “biological fixation”; thanks to the ability to elicit a specific biological response which results in a bond between the tissue and the material. Good results are also achieved using bioactive ceramics such as hydroxyapatite coating on a metal surface 3. Finally, resorbable bioceramics are able to degrade gradually, being replaced by the natural tissue. For resorbable bioceramics, the difficulties are the maintenance of strength and stability of interface during the dissolution and replacement period, and the matching between the resorption and repair rates, that depends on several variables, such as health and age of the patient.

This broad spectrum of biological interaction, from inactivity to biodegradation, leads to a corresponding range of engineering design strategies. In fact, bioactive materials such as tricalcium phosphate and hydroxyapatite have poor mechanical properties, so them

applicability is confined to implants which do not have to sustain significant loading, and the main requirement is to provide favorable surfaces for biological bonding and bone ingrowth. Otherwise, the harsh conditions in joint replacement restrict the materials choice to the harder and stronger ones, such as alumina or zirconia, thanks to the good strength and wear resistance, even if they are not able to create a bone-material interface, and they cannot be successfully used as bone filler. Besides, bioceramics are characterized by brittleness and low crack resistance, thus, in some applications they cannot compete with metals or composites.

- **ZICORNIA & ALUMINA AS BIOMATERIALS**

ZICORNIA AS A BIOMATERIAL

Zirconia ceramics have several advantages over other ceramic materials, due to the transformation toughening mechanisms operating in their microstructure that can give to components made out of them, very interesting mechanical properties. The research on the use of zirconia ceramics as biomaterials started about twenty years ago, and now zirconia (Y-YZP) is in clinical use in THR, but developments are in progress for application in other medical devices. Recent developments have concentrated on the chemistry of precursors, in forming and sintering processes, and on surface finish of components. Today's main applications of zirconia ceramics is in THR ball heads. This review takes into account the main results achieved up to now, and is focused on the role that microstructural characteristics play on the TZP ceramics behaviour in ball heads, namely mechanical properties and their stability, wear of the UHMWPE paired to TZP, and their influence on biocompatibility.

INTRODUCTION

Zircon has been known as a gem from ancient times. The name of the metal, zirconium, comes from the Arabic *Zargon* (golden in colour) which in turn comes from the two Persian words *Zar* (Gold) and *Gun* (Colour). Zirconia, the metal dioxide (ZrO_2), was identified as such in 1789 by the German chemist Martin Heinrich Klaproth in the reaction product obtained after heating some gems, and was used for a long time blended with rare earth oxides as pigment for ceramics. Although low-quality zirconia is used as an abrasive in huge quantities, tough, wear resistant, refractory zirconia ceramics are used to manufacture parts operating in aggressive environments, like extrusion dyes, valves and port liners for combustion engines, low corrosion, thermal shock resistant refractory liners or valve parts in foundries. Zirconia blades are used to cut Kevlar, magnetic tapes, cigarette filters (because of their reducedwear). High temperature ionic conductivity makes zirconia ceramics suitable as solid electrolytes in fuel cells and in oxygen sensors. Good chemical and dimensional stability, mechanical strength and toughness, coupled with a Young's modulus in the same order of magnitude of stainless steel alloys was the origin of the interest in using zirconia as a ceramic biomaterial. The R&D on zirconia as a biomaterial was started in the late sixties. The first paper concerning biomedical application of zirconia was published in 1969 by Helmer and Driskell [1], while the first paper concerning the use of zirconia to manufacture ball heads for Total Hip replacements (THR), which is the current main application of this ceramic biomaterial, was introduced by Christel et

al. In the early stages of the development, several solid solutions (ZrO_2—MgO, ZrO_2—CaO, ZrO_2—Y_2O_3) were tested for biomedical applications (Table 1). But in the following years the research efforts appeared to be more focused on zirconia—yttria ceramics, characterised by fine grained microstructures known as Tetragonal Zirconia Polycrystals (TZP).
Nowadays, TZP ceramics, whose minimal requirements as implants for surgery are now described by the standard ISO 13356 [3], are the materials selected by almost all the manufacturers that are introducing into the market zirconia ball heads (Table 2). More than 300 000 TZP ball heads has been implanted, and only two failures were reported up to now.

MECHANICAL PROPERTIES

There is no doubt that zirconia ceramics have mechanical properties better than other ceramic biomaterials, i.e. alumina, as shown in Table 1. Comparison among Young's moduli, strength and hardness of some biomaterials, including ceramics.
3.1. Results of compression tests on TZP ball heads Ultimate Compressive Load (UCL) of ball heads is tested following the ISO 7206-5 standard. The test procedure consists of the application of static loads to the ball head inserted in a metallic spigot until fracture, and
it may be considered a useful tool to compare different designs. It can be observed from UCL tests that using TZP ceramics, ball heads of 022.22 mm can withstand static loads ranging several times the physiologic ones. Ball heads UCL depends on design and material characteristics both of the ball head and of the metallic spigot: the angle mismatch between bore and taper, and the surface roughness controls the magnitude and position of maximum stress in the ceramic ball head. Finite elements analysis on different designs of ceramic ball
heads has shown that two main stress concentrations are localized in the inner surface of the ceramic bore, one (bending stress) at the top of the cavity, and one (hoop stress) at the ceramic—metal taper interface. The magnitude of such stresses is dependent on the position, the metal—ceramic contact area, the roughness of the surfaces and the friction coefficient of the two counter faces. Tests performed on TZP ball heads show that to minimize the concentration of stresses it is necessary to maintain a gap.

ALUMINA AS A BIOMATERIAL

Alumina as an alternative to metal-UHMWPE bearing system was first introduced in the 1970s, but early clinical applications showed a high fracture rate of 13% 13. Failure in this first generation of ceramics was due to the fact that they could not be processed to full final density. A second improved generation of ceramics, developed in the late 1980s, resulted in higher density and smaller grains. The fracture rate associated to the second generation of alumina decreased to less than 5%. Finally, today a third generation of ceramic components is available, characterized by high purity, full density and finer microstructure, mainly thanks to the doping with MgO to control the grain growth and to the full sintering by hot isostatic pressing at about 1250°C. For this new alumina bearing, a lower fracture rate of about 0.004-0.015% is reported. Considering the data in Table I, supplied by the producer of Biolox alumina 14, the influence of the material characteristics on the mechanical properties is clearly

stated: the mechanical strength is closely related to density, that must be maximized, to the mean grain size, kept small, as well as to the presence of glassy phase at the grain boundaries, that must be avoided by using a high-purity alumina. The flexural strength is higher than 550 MPa, and the Vickers Hardness is 1800-2000 HV, about four times the hardness of common orthopedic metals such as Co-Cr or Ti alloys 4. As mentioned before, the high hardness of alumina, and of ceramics in general, provides a minimum wear of the femoral heads and of the cups, also because it allows a superior surface quality. Besides, the capability of adsorbing polar molecules (as water, body fluid) promotes the formation of a liquid film which provides the lubrication between the ceramic head and the socket.

❖ MECHANICAL PROPERTIES OF BIOMATERIAL

TENSILE TEST

Background

A tensile test, also known as tension test, is probably the most fundamental type ofmechanical test you can perform on material to recognize its strength and its mechanical behavior.

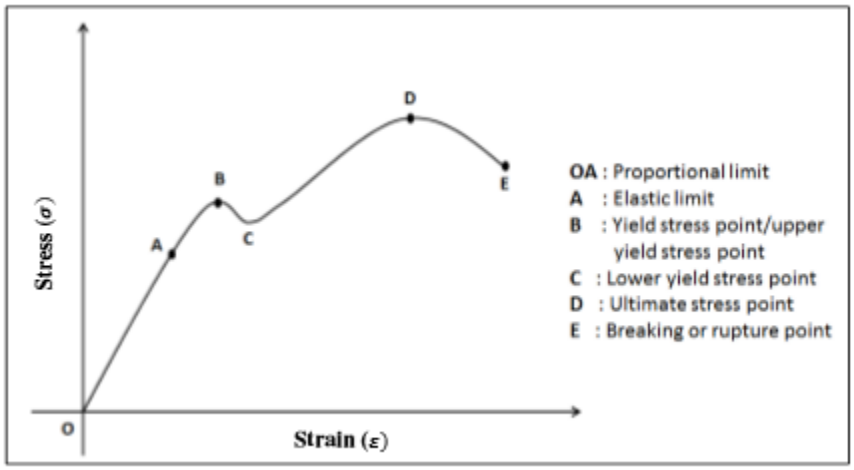
Tension test, in which a strip or cylinder of the material, having length L and cross-sectional area A, is anchored at one end and subjected to an axial load P – a load acting along the specimen's long axis – at the other. As the load is increased gradually, the axial deflection δ of the loaded end will increase also. Eventually the test specimen breaks or does something else catastrophic, often fracturing suddenly into two or more pieces.

The strain resulting from the stress applied is proportional to the stress and is directly related to it with a proportionality constant called the Elastic Modulus/ Young's Modulus. This constant is material dependent and only applies in what is called the "elastic region" of a material's behavior through the following equation:

$$\delta = E\, c$$

Where (δ) is the Stress in Pascal, (ε) is the Strain and (E) is the Elastic Modulus or Young's Modulus

A typical stress-strain curve is shown in the figure below:



Stress versus Strain Curve

Fig: stress versus strain curve

Note that stress - strain proportionality only applies in the elastic region (up to the yield stress point), also note that this curve assumes a constant cross-sectional area and does not take into consideration the Poisson's Ratio. The Poisson's Ratio(ν) is the ratio of transverse contraction strain to longitudinal extension strain in the direction of stretching force and is approximated to be 1/3 for isotropic metals and ½ for anisotropic polymers.

Definitions

• Gauge Length (L) - length of the test specimen on which elongation is measured at any moment during the test [m]

• Original Gauge Length (L0) - gauge length before application of load [m]

• Final Gauge Length (Lu) - gauge length after rupture of the test specimen [m]

• Elongation - increase in the original gauge length at the end of the test

• Stress (σ)- load at any moment during the test divided by the original cross-sectional area of the test specimen [Pa/ (N/m2)]

• Strain- It is the ratio of change in length to the original length ($\varepsilon = \frac{\Delta L}{Lo}$)

• Elastic Modulus-a measure of the stiffness of the material, but it only applies in the linear region of the stress – strain curve ($E = \frac{\delta}{\varepsilon}$) , [Pa]

• Yield Stress (σy)-when the material exhibits a yield phenomenon, a point is reached during the test at which plastic deformation occurs without any increase in the load [Pa/(N/m2)]

• Ultimate Tensile Stress (σu)-the maximum load the specimen sustains during the test [Pa/(N/m2).

3.0 FACTORS CONSIDERED IN CHOOSING THE MATERIALS

MICROSTRUCTURAL PROPERTIES

Zirconia is a well-known polymorph that occurs in three forms: monoclinic (M), cubic (C) and tetragonal (T). Pure Zirconia is monoclinic at room temperature. This phase is stable up to 1170^{o}C. above this temperature it transforms into tetragonal and then into cubic phase at 2370^{o} C. During cooling, a T M transformation takes place in a temperature range of about 100^{o}C below 1070^{o}C. The phase transformation taking place while cooling is associated with a volume expansion of approximately 3 4%. Stresses generated by the expansion originate cracks in pure Zirconia ceramics that, after sintering in the range 1500 1700^{o}C, break into pieces at room temperature. It was in 1929 that Ruff and coworkers showed the feasibility of the stabilization of C-phase to room temperature by adding to Zirconia small amounts of CaO.

The addition of stabilizing oxides, like CaO, MgO, CeO_2, Y_2O_3, to pure zirconia allows to generate multi-phase materials known as partially stabilized Zirconia (PSZ) whose microstructure at room temperature generally consists of cubic Zicornia as the major phase, with monoclinic and tetragonal Zicornia precipitates as the minor phase. These precipitates may exist at grain boundaries or within the cubic matrix grains, In 1972 Garvie and Nicholsen showed that the mechanical strength of PSZ was improved by an homogenous and fine distribution of the monoclinic phase within the cubic matrix. The development of zicornia as an engineering material was marked by Garvie et al. whoin their paper ceramic steel? Showed how to make the best of T-M phase transformation in PSZ improving mechanical strength and toughness of zicornia ceramics. They observed that tetragonal metastable precipitates finely dispersed within the cubic matrix were able to be transformed into the monoclinic phase when the constraint exerted on them by the matrix was relieved, i.e. by a crack advancing in the material. In that case, the stress field associated with expansion due to the phase transformation acts in opposition to the stress field that promotes the propagation of the crack. An enhancement in toughness is obtained, because the energy associated with crack propagation of the crack. An enhancement in toughness is obtained, because the energy associated with crack propagation is dissipated both in the T M transformation and in overcoming the compression stresses due to the volume expansion. A schematic representation of this phenomenon. The development of such tetragonal metashable precipitates may be obtained by the addition of some 8% mol of MgO to ZrO_2. This allows the formation a fully cubic microstructure at 1800^{o}C, and the nucleation within the matrix of a tetragonal metashable phase, during controlled cooling and ageing.

PSZ can also be obtained in the ZrO_2 Y_2O_3 system. However, in this system it is also possible to obtain ceramics formed at room temperature with a tetragonal phase only, called TZP. This result was reported first by Reith et al and by Gupta et al.

TZP materials, containing approximately 2.3% mol Y_2O_3 are completely constituted by tetragonal grains with sizes at the order of hundreds of nanometers. The fraction of T-phase retained at room temperature is dependent on the size of grains, on the yttria content, on the grade of constraint exerted on them by the matrix. Mechanical properties of TZP ceramics depend on such parameters.

It is very important to consider the metastable nature of the tetragonal grains. A critical grain size exists, linked to the yttria concentration, above which spontaneous F M transformation of grains takes place, whereas this transformation would be inhibited in a too fine grained structure.

An interesting characteristics of transformation toughened zirconia ceramics is the formation of compressive layers on their surface. Surface tetragonal grains are not constrained by the matrix, and can transform to monoclinic spontaneously or due to abrasive processes that can induce compressive stresses at a depth of several microns under the surface.

The surface phase transition and the consequent surface hardening may have a relevant role in improving the mechanical and wear properties of Zirconia parts, the thickness of the transformed layer being one of the limit conditions. Progresses in T-M surface transformation may originate surface cracking, followed by ejection of grains from the surface with catastrophic effects on mechanical behavior and joint wear.

Several PSZ were tested as ceramic biomaterials, especially Mg- PSZ, which was extensively tested with favourable results. But R&D on this material for biomedical applications appears to have to be stopped in the early 1990s. several reasons can account for this fact: Mg-PSZ are characterized by a residual porosity as is normal in materials with grain sizes in the range 30-40 μm. this can influence negatively the wear rate of UHMWPE sockets that are currently coupled with zircornia ball heads. Also technological aspects may have been taken into account. Mg PSZ sinter at higher temperatures than TZP (1800^{o}C vs. 1400^{o}C), implying the need of special furnaces. The precipitation and development of the metastable tetragonal precipitates, that occurs during cooling, requires a strict control of the cooling cycle in terms of temperature and time, especially in the ageing step that takes place at about 1100^{o}C, during which the precipitation of T-phase occurs.

Difficulties in obtaining Mg PSZ precursors free of SiO_2, Al_2O_3 and other impurities, increase in SiO_2 contents due to the wear of milling media during powder processing before firing. May have contributed to shift the interest of ball head manufactures towards TZP materials. In ceramics containing MgO, magnesia silicates like enstatite ($MgSiO_3$) and forsterite (Mg_2SiO_4) may form at grain boundaries, lowering the MgO contents in the grains and promoting the formation of the monoclinic phase, reducing the mechanical properties of the material and its stability in a wet environment. Nevertheless, Mg PSZ ball heads were used in the USA and Australia. Also TZP precursors can contain silica, which is sometimes used as a liquid phase forming additive to achieve full density at temperatures lower than 1500^{O}C limiting grain growth. Observed that aluminosilicate glasses in the grain boundaries scavenge yttrium ions from TZP grains, leading to a loss of stability of the tetragonal phase. Moreover, mullite ($3Al_2O_3.2SiO_2$) pockets were detected in the alumino silicate glass, which leads to a loss of stability of the material in a wet environment. The use of such additives is hence to be avoided in TZP as ceramic biomaterials.

IMPACT TESTS

Impact test constitutes a useful assay to evaluate the ability of a component to dissipate shock energy, i.e its toughness. There is very limited information in this field: up to now the only results presented on this topic are due to Tateishi and Yunoki. Bodies growing in weight were dropped from a 0.5m height onto a ball head inserted in its spigot. Ø22mm TZP ball heads (on Ti alloy spigot) failed under an impact of some 78J, while Ø28mm alumina ball heads (on CoCr spigot) failed under some 15J impact. The role exerted by the spigot material due to the differences in elastic properties of the two alloys and its differences in elastic properties of the two alloys and its influence on the results reported was not clarified.

FATIQUE RESISTANCE

Tests in Pseudo Extra Cellular Fluid (PECF) and in saline solution, with loads cycled from 1 to 12 Kn and from 5 to 10Kn at 30Hz are reported by Tateishi. Tests were performed up to 10 million cycles on Ø22.2 mm TZP ball heads without failure. More interesting results are reported by Cales. The number of cycles-to-rupture increase as the maximum load decreases from 15 to 90Kn, and shows a tendency to increase to infinity for loads less than 28Kn. It was observed experimentally that TZP Ø22.2mm ball heads can withstand up to 50 million cycles with load cycled from 2.8 to 28Kn.

WEAR

ZICORNIA ON ZICORNIA

There is a clear experimental evidence that the wear rate of the couple zirconia/zirconia is too high to use this ceramic couple in prosthetic joints. Early studies performed by Murakami and Ohtsuki, Sudanese, show the disastrous amounts of wear of this ceramic couple, up to 5000 times the wear of the alumina/alumina one. Recently TZP/TZP wear was the object of new interest, probably due to the improvements in TZP ceramics processing (reported after the previous studies). The TZP/TZP couple was investigated taking into account the effects of environment, sliding speed, and load on wear properties, using the ball on ring (pin on disk) method, by the ring on disk test in conformity of the standard ISO6474, and on hip simulator. These authors confirmed the results obtained previously.

Sliding of a pair made of low thermal conductivity materials leads to an increase in surface temperature. For zirconia/zirconia pair the temperature may raise up to more than 100^{o}C, enhancing the T-M phase transition in wet environment. This process may lead to cracking grain pullout and catastrophe abrasive wear. Nevertheless, the work recently published by chevalier opens again the research in this field. In pin-on-disc tests performed using water as a lubricant, they observed zirconia/zirconia or zirconia/alumina wear rates one order of magnitude lower than the wear rate of alumina/alumina pair. These results were not replicated using bovine serum as lubricant.

MATERIAL	DENSITY	COMPRESSIVE STRENGHT	ELASTIC MODULUS	TENSILE STRENGHT	ELONGATION AT FAILURE	FRACTURE TOUGHNESS
NATURAL BONE	1.8-2.1	130-180	3-20	80-150	1-7	3-6

4.0 DESIGN SPECIFICATION

KINEMATICS AND FORCES

This joints allows movement in all three planes: sagittal, frontal and transverse. In sagittal plane it allows 0-140^o flexion and extension of 0-15^o ; in frontal plane, abduction of 30^o and adduction of 25^o . in transverse plane external rotation is 0-90^o and internal rotation is 0-70^o. hip joint is maximally flexed during gait in the late swing phase as the limb moves forward for heel strike. As the body moves forward at the beginning of the stance phase, the hip joint extends. The maximum extension is reached at heel off. The joint reverses into flexion during the swing phase again and reaches maximal flexion 35-40^o prior to heel strike.

The articulation surfaces of the femoral head and the acetabulum are lined with hyaline cartilage. Degenerative osteoarthritis and autoimmune diseases like rheumatoid arthritis may cause derangements of the hip which can produce altered force distributions in the joint cartilage. These diseases degenerate the cartilage and synovium, leading to severe pain and altered range of movements and joint forces.

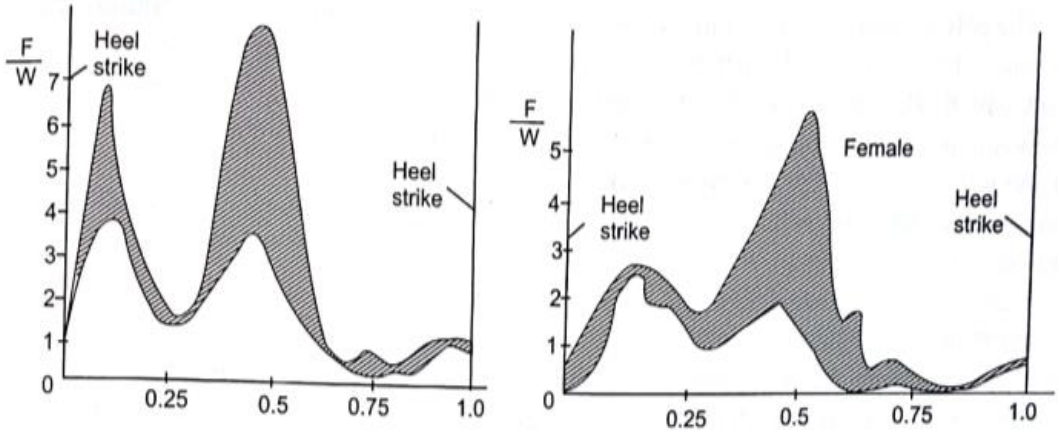


FIG: VARIATION IN HIP JOINT FORCE PROFILE FROM SUBJECT TO SUBJECT FOR MEN AND WOMEN

Bergmann et al of biomechanics laboratory, Benjamin franklin school of medicine, free university of berlin measured the hip contact force in vivo using hip prosthesis with integrated load sensors and telemetry, and they recorded contact forces and muscle forces during gait analysis of human patients. It is available in a compact disc, and interested readers may look into the reference.

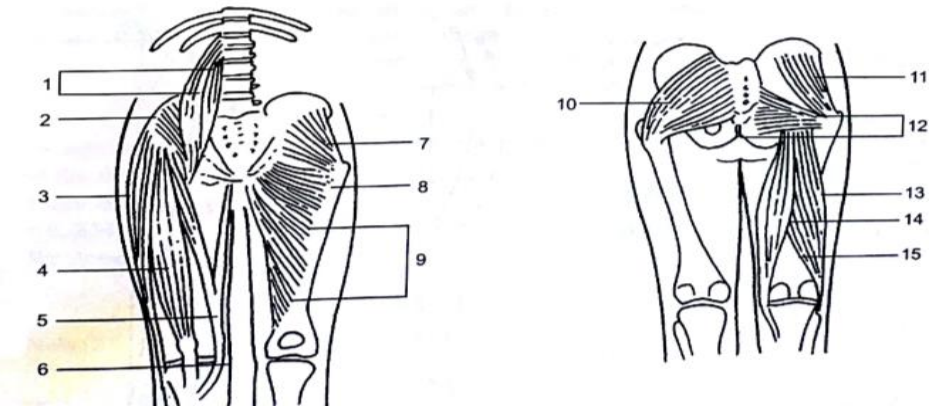


FIGURE: MUSCLES OF THE HIP: (a) ANTERIOR VIEW (b) POSTERIOR VIEW (1) PSOAS (2) ILICUS (3) TENSOR (4) RECTUS FEMORIS (5) SARTORIUS (6) GRACILIS (7) GLUTEUS MINIMIS (8) PECTINEUS (9) ADDUCTORS (10,11) GLUTEUS MAXIMUS AND MEDIUS (12) LATERAL ROTATORS (13) BICEPS FEMORIS (14) SEMITENDINOSUS AND (15) SEMIMEMBRANOSUS.

The pelvis consists of the ilium, ischium, pubis bones and sacrum. At birth and during growth, the bones of the pelvis are distinct. In adult the bones of the pelvis are fused and form synarthrodial joints which allow no movement. The pelvis is located between the spine and the two femurs. The position of the pelvis makes it relatively less stable. Movements of the pelvis occur primarily for the purpose of facilitating the movements of the spine or the femurs. There are no special muscles that move the pelvis. Movement of the pelvis are caused by the muscles of the trunk and the hip.

Based on their primary actions, the muscles of the hip joint may be divided into several groups. The psoas, iliacus, rectus femoris, pectineus and tensor fascia latae are the primary hip flexors. They are also used to carry out activities such as running or kicking. The gluteus Maximus and the hamstring muscles (the biceps femoris, semitendinosus and semimembranosus) are hip extensors. The hamstring muscles also function as knee flexors. The gluteus minimus are hip abductor muscles providing for the inward rotation of the femur. The gluteus medius is also the primary muscle group stabilizing the pelvis in the frontal plane. The adductor longus, adductor brevis, adductor magnus and gracilis muscles are hip adductors. There are also small deeply placed muscles (outward rotators) which provide for the outward rotation of the femur.

The hip muscles predominantly suffer stress and strains in the pelvis region.

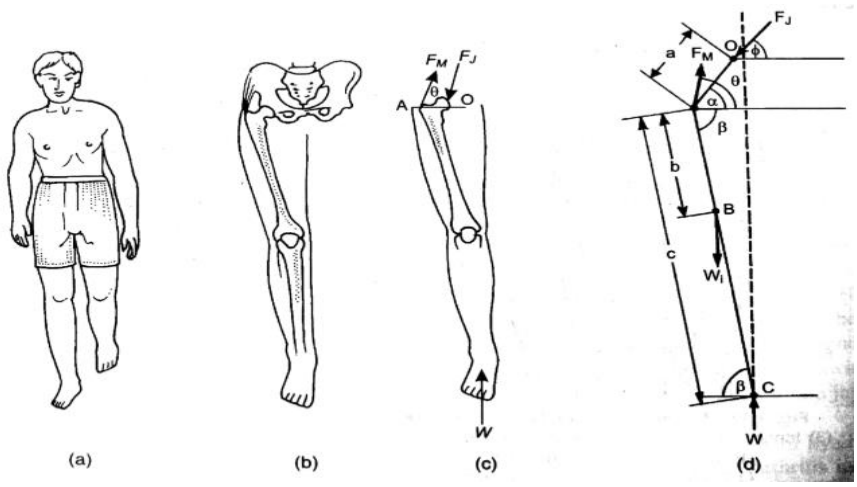


FIGURE. (a) single-legged stance phase of GAIT. (b) Anatomical model of the hip joint, (C) Biomedical model of the hip showing the simplified force system acting while standing on one leg, (d) Mechanical model of the hip ready for the application of the laws of 2D, statics.

A REAL LIFE SCENERIO

During walking and jogging, we automatically put our body weight on one leg. The forces acting on the leg carrying the total body weight shown in the figure during a single legged stance, f_m is the resultant force exerted by the hip abductor muscles, f_j is joint reaction force applied by the pelvis on the femur, W_1 is the weight of the leg, and W is the total weight of the body applied as a normal reaction force by the ground on the leg. The angle between the resultant muscle force and the horizontal is Θ.

The point O is the joint center and also the instantaneous axis of rotation of the hip joint, A is the point where the hip abductor muscles are attached to the femur at an angle of Θ with horizontal, B is the center of gravity of the leg (upper and lower combined), and C is where the ground reaction force is acting on the foot. The distances between A and O, B and C are specified as a, b and c, respectively, α is the angle of inclination of the femoral neck to the horizontal, and β is the angle that the long axis of the femoral shaft makes with the horizontal. Therefore, α + β is approximately equal to the total neck-to-shaft angle of the femur.

5.0 BEME (BILL OF ENGINEERING MEASUREMENTS AND EVALUATION)

S/N	DESCRIPTION	QUANTITY	COST (N)
1	TOP BOND	2 MEDIUM SIZED TOP BOND	1,300
2	ZICORNIUM	128 GRMS	25,000
3.	ALUMINA	128 GRMS	25,000
4.	FLEXIBLE HOSE	Flexible hose 10mm long	700
		total	N 52,000

A PRACTICAL GUIDE TO ISO 1099312: SAMPLE PREPARATION AND REFERENCE MATERIALS

ISO 10993

Critical to all types of bio compatibility studies, the methods for preparing device materials for testing are covered in this standard. Note: this is the continuation of an ongoing series of articles on ISO 10993.

TEST MATERIAL SELECTION

To ensure patients safety, the biological evaluation of medical devices must go beyond the testing of constituents' materials. The goal of such testing programs is not only to confirm the safety of individual device materials but also to confirm that manufacturing steps will not compromise the biocompatibility of the device. Processing aids, mold release agents. Lubricants, and other additives, as well as cleaning agents and sterilants, can have adverse effects if they contact the body: therefore, the samples used for testing must be selected to take these factors into account.

The standard recommends testing medical devices in their final product form and condition whenever possible, except for selected tests (e.g., implantation) that may require that individual's materials be evaluated separately. If finished devices will not be available for testing, the evaluation of representative sub components of the device is acceptable in some cases. As a last option, representative's samples of the formulated materials that have been preconditioned by the same processing steps as the final product should be tested. If the device is too large or cannot be tested as a whole for some other reason, each individual material having the potential of coming in contact with body tissues should be represented in the same proportion in the test sample as it is in the final product. In all cases, the standard requires that the sample be handled in such a manner as to avoid contamination.

PREPARATION OF EXTRACTS OF TEST MATERIALS

Medical device materials present a unique challenge to toxicologists, whose experiments usually involve chemical substances that can be delivered to a biological test system such as a cell culture in a measurable dose. Because devices are made of plastics, metals e.t.c defining specific doses of the substances of interest is generally not possible. For more tests the preparation of fluid extracts of the device materials is the most appropriate technique to provide test samples for determining the biological reactivity of possible chemical leachable.

According to the standard, the fluid used for extraction and the extraction conditions should be appropriate to the final device and its end use. It is critical that the various extraction media selected for testing represent the environments in which the final product will be used. Physiological saline and vegetable oil are usually sufficient to provide polar and non-polar environments.

Extraction should be carried out at a temperature that are high enough to maximize the amount of extractable substances as well as to simulate the highest temperatures the device may be exposed to before or during use. However, extraction conditions should not cause deformation or degradation of the test or control articles. A number of specific acceptable extraction conditions are outlined in the standard.For most test materials, extractions are performed under the static

conditions. However, agitation may be deemed appropriate as an effort to more closely mimic an end use or to ensure that the extraction media come in contact with all relevant device components. In any case, when agitation is considered appropriate, the method used should be documented.

Thickness (mm)	Extraction ratio ±10%	Examples of materials
≤ 0.50	6 cm^2 / ml	Metal, synthetic polymer, ceramic, composite film, sheet, and tubing walls
> 0.5	3 cm^2/ ml	Metal, synthetic polymer, ceramic, composite tubing walls, slab, molded items.
≤ 1.0	3 cm^2/ ml	Natural elastomer
>1.0	1.25 cm^2/ ml	Natural elastomer
Irregular	0.1-0.2 g/ml, 6 cm^2/ ml	Pellets

The standard notes that there are no standardized methods available for testing absorbents and hydrocolloids and suggests the following protocol. Using 2g of the material as a test sample, determine the absorption capacity of the sample that is, the amount of extract ant absorbed by the material. The extract volume should then be 20 ml more than the samples absorption capacity.

REFERENCE MATERIAL

In nearly every biocompatibility test, reference materials are used to serve as experimental controls. Negative controls, in the form of blanks, are used in most biological evaluations where test article extracts are prepared. The use of these blanks provides the basis for a comparison of the effects of the test material extracts with a validated negative test result.

A number of materials have been used extensively in biological testing as negative or positive controls. High density polyethylene, obtained from US. PHARMACOPEIA, is a standard negative control. The non-reactive plastic can be implanted into living tissue and the results compared with those for a test material that has been similarly implanted. Likewise, a polyvinyl chloride formulation containing organotin additives serves as well as a positive control.

CONCLUSION

ISO 10993-12. ‘’sample preparation and reference materials’’ clearly indicates that it is preferable to evaluate medical devices in their final product form. The reasoning is simple – the biological testing must incorporate everything involved in making the device. Obviously the constituents’ materials must be safe for patient contact; equally important to device biocompatibility are the processes and materials used during manufacturing. For most devices, the use of fluid extracts of the test materials prepared in a fashion to mimic or exaggerate the expected clinical conditions is the most appropriate technique for determining the potential effects of chemical leachable. Extraction fluid selection, extraction conditions, and material to extractant ratios are all outlined in the standard. The selection and use o appropriate experimental control also is important in evaluating device materials for safety and is also covered in ISO10993-12.

REFERENCE:

WWW.WIKIPEDIA.COM

PROJECT REPORT

WWW.GOOGLE.COM