A Review of Biocompatible Materials for Medical Implants Using Additive Manufacturing

Upendra Sharan Gupta[1], Ashok Patel[2], Vijay Gehlot[3], Jitendra jayant[4], Dr. M. L. Jain[5]

[1]*PhD Scholar, Dept. of Mech. Engineering, SGSITS, Indore, India*
[2]*PhD Scholar, Dept. of Mech. Engineering, SGSITS, Indore, India*
[3]*PhD Scholar, Dept. of Mech. Engineering, SGSITS, Indore, India*
[4]*PhD Scholar, Dept. of Mech. Engineering, SGSITS, Indore, India*
[5]*Professor & Head, Dept. of Mech. Engineering, SGSITS, Indore, India*

ABSTRACT

This review deals with the evaluation of biocompatibility and osseointegration of nanostructured biocompatible materials used for medical implants. Bulk material topography and surface modification of biocompatible materials are currently of intense research mainly due to the significant impact on biocompatibility and improvement of osseointegration of medical implants. The Clinical problems like risk of postoperative infection and increased incidence of pediatric trauma requiring surgical intervention raised the need for temporary medical implants that would resorb after the bone healing is complete. This would decrease high costs associated with repeated surgeries, minimize recovery times, decrease the risk of postoperative infections, and thus promote higher quality of life to each individual patient. The concept of biodegradation is already known in medical practice, resorbable sutures are successfully used in surgery. However, a bone implant that would resorb after the fracture healing is a completely new concept. Biomaterials used for implants can be metals, ceramics, polymers and composites. Metals have high impact strength, high wear resistance, high ductility and the capacity to absorb high strain energy compared to other materials. These properties make metals suitable candidates for maxilofacial and orthopedic load-bearing application and fixation devices such as joint replacement, bone plates and screws, as well as dental implants, pacer and suture wires, and coronary stents.

Keywords- Bio compatible materials, Bio-fabrication, Rapid Manufacturing, Medical Implants, Tissue Engineering.

I INTRODUCTION

The primary aim of medical intervention is to restore the human anatomy to its original state after it has undergone some form of physical trauma, disease or genetic defect. Biocompatibility and custom manufacturability are significant indicators of successful implant surgery. Biomaterials have emerged over the years through constant research and development and have permeated many fields of the medical profession. A biomaterial is classified as “any material used to manufacture devices that replace a part or a function of the

International Journal of Advance Research in Science and Engineering
Volume No.07, Special Issue No.05, April 2018
www.ijarse.com
IJARSE
ISSN: 2319-8354

body in a safe and reliable way". Owing to the increase in the average life expectancy of the general population, implants especially orthopaedic implants, are being installed on a more frequent basis. As patients become older, their joints degrade leading to decreased mobility and associated pain. This indicates the need for implant surgery in an increasing proportion of the population. This need has become one of the key drivers for research and development in medical implant and biomaterials technology. Therefore, it is essential that the application of biomaterials extends to as many regions of the body as possible. This will play an important part in creating a permanent solution to issues such as mobility and function. Although the range of experimental biomaterials is expanding, only approved biomaterials can be utilised for the manufacture of biomedical implants. Materials can only be classified as approved after extensive medical testing has been performed in order to ascertain the biocompatibility of the material with the human body. Problems such as bacterial infection, blood clots and tissue trauma are possible medical problems when a material is used in the design of a medical implant. Hence the material in question must undergo rigorous clinical trials to establish its biocompatibility and become FDA or equivalent compliant. A suitable surface coating may be applied to allow the implant to be fitted in vivo.

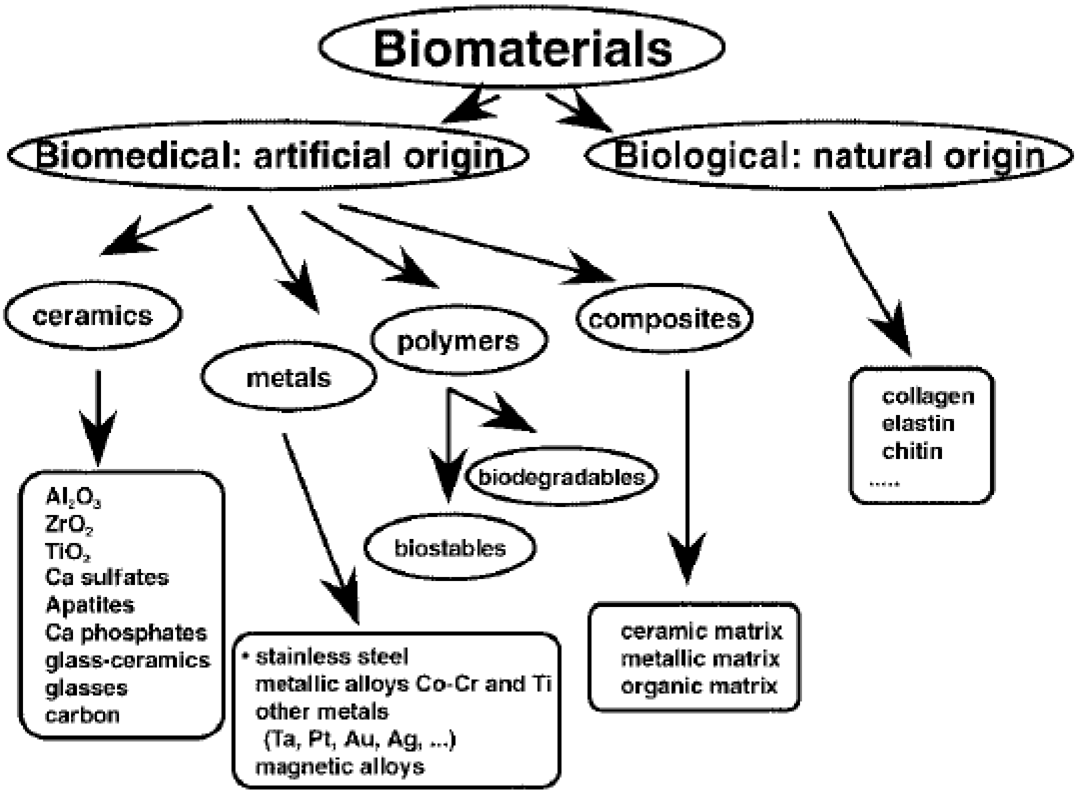

Figure 1 Classification of biomaterials. [2]

II BIOCOMPATIBILITY

"The biocompatibility of a long-term implantable medical device refers to the ability of the device to perform its intended function, with the desired degree of incorporation in the host, without eliciting any undesirable local or systemic effects in that host." [3]

III BIOMATERIAL APPLICATIONS

Examples are:

- Bone plates
- Heart valves
- Contact lenses
- Skin repair devices
- Blood vessel prostheses
- Dental implants
- Orthopaedic replacements
- Customised medical implants

Biomaterial Classification

Biomaterials can be classified into three main groups: metals, ceramics and polymers.

Metals	Ceramics	Polymers
316L stainless steel	Alumina(Al_2O_3)	Ultra high molecular weight polyethylene
Co-Cr Alloys	Zirconia	Polyurethane
Titanium	Carbon	
Ti6Al4V	Hydroxyapatite	

Figure 2 Categorized approved biomaterials. [4]

Metallic biomaterials are indicated for use in areas of high static or cyclic stress. Such activities include lifting, running, bending or chewing. All of these actions will transfer stresses to the implant, and metallic materials are best suited to these applications. Ceramic materials are designated where resistance to wear is of primary importance, and polymeric materials are used where stability, flexibility and controlled porosity are required. [5]

Careful selection of material is vital in ensuring that the implant:

a) Functions correctly

b) Is biocompatible

c) Is degradable or absorbable if required

If these fundamental selection criteria are satisfied this will increase the probability of a successful biomedical implant design. [6]

Biomaterial Applications

Metals:

(a) 316L Stainless Steel

This material demonstrates high strength, high corrosion resistance and improved biocompatibility when compared to other grades of stainless steel. This material is used for pins, plates and screws for locating and fixing. [7]

(b) Co-Cr Alloys

Cobalt chrome alloys have extensive industrial applications and are also used for medical implants. EBM is a process capable of producing such implants using CoCrMo ASTM 75. In terms of medical applications, this material is used for orthopaedic and dental implants. [8]

Titanium Alloy Ti6Al4V contains properties that are desirable for medical implants, these are:

a. High strength

b. Bio-compatibility

c. Low density

d. Good corrosion resistance

This material can be used in conjunction with the EBM or SLM process to produce good quality accurate medical implants such as cranial plates and acetabular implants. [9]

(c) Ceramics:

Ceramic materials are typically solid inert compounds; they offer many advantages in the manufacture of medical implants, including: They are bioactive, inert and absorbable Surfaces can be polished to a high degree High rigidity, required in certain applications Improved cell and tissue bonding [10]

Examples of ceramics currently used for medical implants are:

(i) Alumina (AL2O3)

This material is mainly used for orthopaedic and dental implants. Alumina can be polished to a high degree having a low average roughness value (Ra) with a high hardness value. Due to these properties, Alumina is used in load bearing applications such as total hiparthroplasties as the femoral head. [11]

(ii) Zirconia

Biomedical grade zirconia was first used in the 1980s to solve the problem of alumina brittleness and ultimately the failure of medical implants. Although this material is extremely hard it is susceptible to age hardening when in contact with water which leads to crack propagation and failure. In 2001 approximately 400 zirconia Prozyr femoral heads failed in application. This had a catastrophic effect on this material as an approved biomaterial. Since then detailed R&D has been undertaken which shows that the failure of these femoral heads was due to two factors:

a) Accelerated ageing of the ceramic

b) A change in the heating process technique

Tests carried out have concluded that zirconia with a grain size above 0.6 microns reduces the ageing dramatically. One solution was to add yttria as a dopant which increased the toughness and reduced the signs of aging in the implant. Zirconia toughened alumina may be another alternative as the addition of alumina to zirconia reduces the effect of ageing dramatically. For the immediate future, alumina and zirconia composites appear to be the solution and are currently been introduced to the area of dental implants. [12]

(d) Hydroxyapatite (HA)

HA is a naturally occurring mineral form of calcium apatite also found in bone and teeth. Medical applications include the replacement of amputated bone and bone growth promotion (osseoconductivity) in prosthetic implants. SLS is capable of producing medical implants from this material because the powders are subjected to low compression forces which naturally produce porous components. This is a key characteristic for some in vivo medical implants such as drug delivery devices. HA has been used in several in vivo applications such as dense sintered ceramics for middle ear implants, alveolar ridge reconstructions and augmentation, orbit implants for orbital floor fractures and general volume augmentation. HA is also used as a biocompatible surface coating for metals. [13]

(e) Polymers:

Medical grade polymers are used in various medical applications including tissue repair, drug delivery devices, wound healing and medical implants. Polymers have an extensive range of controllable structural properties including molecular weight, entanglement density, degree of crystallinity, and degree of crosslinking. In general polymers exhibit time-dependent mechanical behavior and are said to be viscoelastic. When polymers are subjected to sustained loads this can result in time-dependent strain or creep. Time dependent material properties make the prediction of in vivo performance difficult, especially when the loading conditions become complex. During use, load bearing medical devices may subject their polymer components to their fatigue, fracture and wear limits. [14]

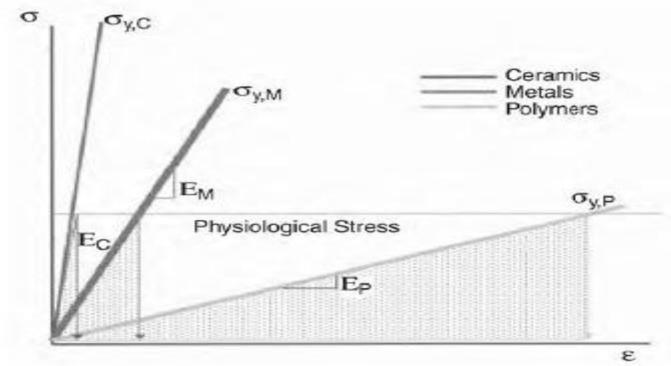

Figure 3 Compares strain on a ceramic, metal and polymer implant subjected to a given physiological stress. [15]

(i) Ultra High Molecular Weight Polyethylene (UHMWPE)

UHMWPE is a material better known as high performance polyethylene which is a thermoplastic polyethylene. Owing to its long chain like structure it can distribute loads more efficiently helping to reduce wear and increase stability. It has a high resistance to chemical attack and absorbs only minute amounts of moisture. In terms of medical applications, UHMWPE is the preferred material when performing arthroplasty procedure for spine and orthopaedic implants. [16]

Figure 4 A complete hip replacement using UHMWPE as the acetabular cup with Co-Cr femur head.[17]

(ii) Poly(methyl methacrylate) (PMMA)

PMMA is a material that is highly biocompatible and is commonly used in the production of intraocular lenses. This material is better known as Vitroflex, Acrlyex or Perspex. This material can be used in RP to produce medical implants such as scaffolds and bioactive implants in conjunction with the SLS process. In orthopaedic surgery, PMMA is used as bone cement to locate and fix implants and to remodel and replace damaged or lost bone. PMMA is also used in the production of dentures and in cosmetic surgery to reduce the appearance of visible scar tissue. [18]

IV. PERFORMANCE OF POLYMER IMPLANTS

For a medical implant or device to function correctly, it is important that the following factors are discussed and analysed prior to material selection.

Factors are:

- Implant design
- Structural Requirements
- Clinical Issues
- Processing Treatments
- Material Selection

IJARSE
ISSN: 2319-8354

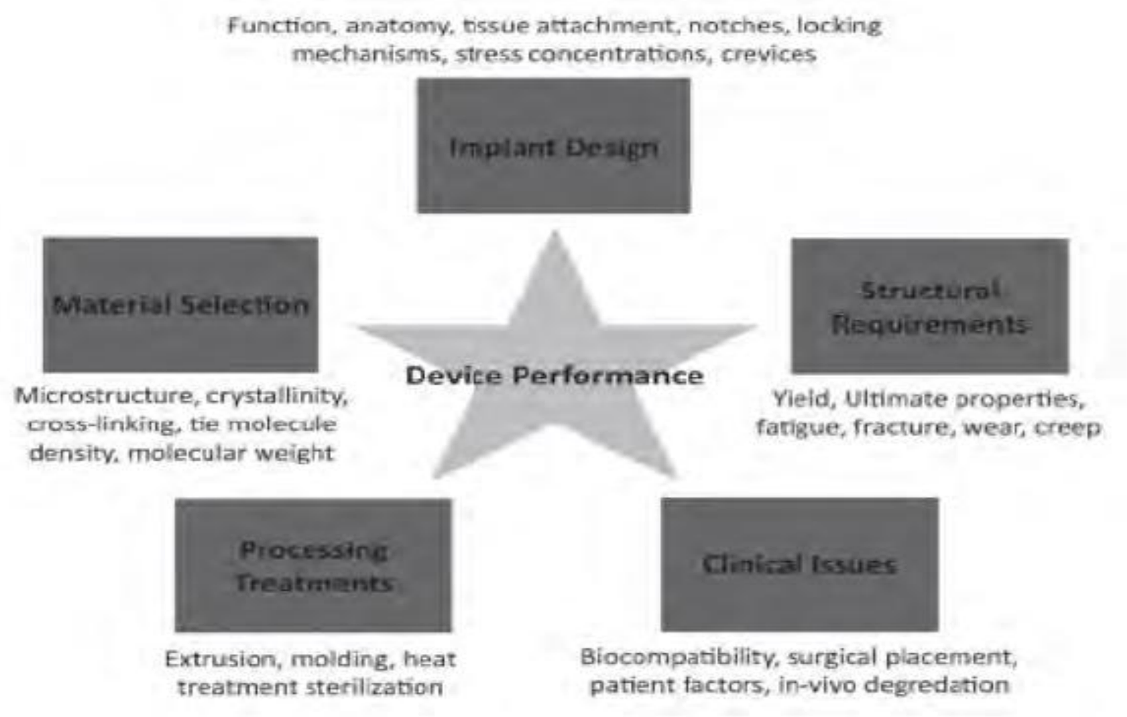

Figure 5 Key factors influencing the performance of a polymer in a medical device or implant. [19]

RP Biomedical materials

In terms of RP, there are several processes that can produce medical implants. These are:

i. SLS
ii. SLA
iii. EBM (Electron Beam Melting)
iv. SLM
v. LENS (Laser Net Shaping)
vi. SLS and SLA normally focus on polymers and ceramics whereas EBM, SLM and LENS deal with producing metal implants.

Biocompatible materials and medical applications

Material

Medical Application

Low density polyethylene (LDPE) Tubing , Shunts, Catheters

High density polyethylene (HDPE)

Plastic surgery implants

Ultrahigh molecular weight polyethylene (UHMWPE)

Acetabulum in total hip prostheses, artificial knee prostheses

Polypropylene

Heart valve structures

Polyvinylchloride (PVC)

Catheters, Maxillofacial prostheses

Polytetrafluoroethylene (PTFE)

Catheter coatings, facial prostheses, heart valves

Polydimethylsiloxane

Shunts, Maxillofacial prostheses heart valve structures

Poly(methyl methacrylate) (PMMA)

Bone cement, Middle Ear Prosthesis, intraocular lenses

Figure 6 Biocompatible polymers used in biomedical applications.

In terms of degradable polymeric biomaterials, typical applications include sutures, drug delivery devices, orthopaedic fixation devices, temporary vascular graphs and tissue engineering for guided tissue regeneration scaffolds. [20]

Material

Medical Application

Stainless Steel

AISI316Llvm, 319L

Customised medical implants

Stainless Steel F745 (Cast stainless steel)

Location and fixing devices, screws and pins

Co-Cr-Mo F75 (Vitallium)

Dental implants

Co-Cr-Mo F799 (Forged Co-Cr-Mo)

Coatings on artificial joints

Co-Cr-W-Ni F90

Surgical fixation wires

Co-Ni-Cr-Mo-Ti F562

Customised medical implants

Pure Ti, grade 4 F67

Spinal fixation devices, femoral components

Ti-6Al-4V ELI F136-79

Orthopaedic Implants and prosthesis

Figure 7 Biocompatible metals used in biomedical applications.

IJARSE
ISSN: 2319-8354

Ceramics

Medical Application

Alumina (AL2O3)

Total hip arthroplasties (Femoral Head)

Zirconia

Dental implants and crowns

Hydroxyapatite (HA)

Middle ear implant

Alveolar ridge reconstruction

Orbit implants for orbital floor fractures

Figure 8 Biocompatible ceramics used in biomedical applications. [21]

Ethical issues in the development of new biomaterials

(a) Biocompatibility

Materials specified for implant production must be biocompatible. Non-biocompatible materials can cause infections, create toxins which cause illness and in certain cases be fatal.

(b) Osseointegration

This is the direct relationship between osseo or calcium tissue e.g. bone and the surface of a biomaterial used in a medical implant. Two biomaterials that demonstrate osseointegration are hydroxyapatite and titanium. This material characteristic helps to increase the rigidity of the recovery site and promotes bone growth in the affected area therefore reducing the recovery time and improving the integration of the implant. [22]

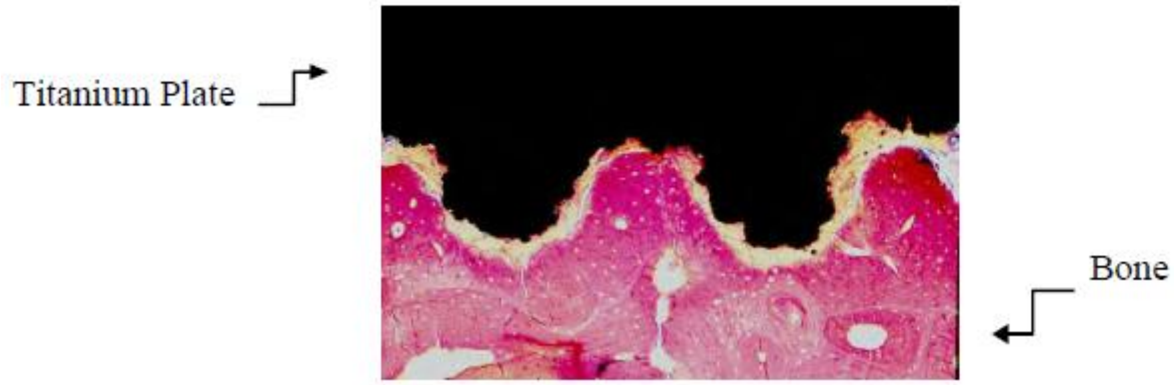

Figure.9 A titanium implant (black) integrated into bone shown in red. [23]

Osseointegration is important in craniofacial, ear, nose and orbital prosthesis in increasing rigidity and is especially useful for bone anchored hearing aids which rely on the transmission of vibration to hear

V. CLINICAL TRIALS

Clinical trials are performed to ascertain the safety and efficacy data required for biomaterials and medical devices. These trials can only be performed when satisfactory data has been collated and trials are in compliance with FDA or similar medical regulatory bodies. Clinical trials are mandatory and must be conclusive before materials are allowed to be used as approved biomaterials. Clinical trials are put in place to achieve a number of outcomes. Some of these are:

a) Assess the safety and biocompatibility of the material

b) Assess the risk of infection

c) Assess the long-term stability of the material in terms of mechanical properties e.g. age hardening in zirconia. [24]

Once the clinical trials are successful, and meet the specifications required the material can be categorised as an approved biomaterial.

VI SUMMARY

Surgical implant materials that have been used in recent times include cobalt chromium (Co–Cr) alloys, 316L stainless steel (316L SS), unalloyed tantalum, Zr-Nb alloys and titanium and its alloys. On the other hand elements namely Ni, Cr and Co are found to be released from the stainless steel and Co–Cr alloys because of corrosion in the body environment. In addition, both 316L SS and Co–Cr alloys possess much higher modulus than bone, leading to insufficient stress transfer to bone leading to bone resorption and loosening of implant after some years of implantation. But, titanium alloys are prominent as medical implants because of their high strength to weight ratio, lesser elastic modulus, brilliant corrosion resistance and better biocompatibility. Based on microstructures that can be produced by alloying, titanium alloys are grouped as α, $(\alpha + \beta)$ and β alloys. α and $(\alpha + \beta)$ alloys have been used medical implant applications. β Ti alloys are supposed to be the right choice material for medical implant applications since they have better mechanical strength, easily shapeable, and lesser elastic modulus though not very cost effective. Modern surgery needs chemically inert and sufficiently high mechanical strength materials. Titanium and titanium alloys are better candidates in this aspect. They satisfy almost all the requirements of implant materials and show no allergic reaction with the surrounding tissue or no thrombotic reaction with the blood of the human body. Ion substituted hydroxyapatite (HA) coatings such as Sr-HA, Mg-HA and Co-HA were cathodically deposited on Titanium oxide nanotubes formed on commercially pure titanium. Hydroxyapatite (HA) coatings on TiO_2 nanotubes (TNT) provide osteoconduction and hence promote bone healing and apposition, leading to the rapid biological fixation of implants. In the current study, TNT surfaces were formed by electrochemical anodization technique and Cu and Zn were simultaneously substituted in HA coating so as to form a coating with antibacterial properties with good osteoconductive surface. ZnHA showed higher adhesion strength as compared to other coatings. Moreover hydrophilicity and surface roughness of ZnHA was higher than CuHA coating. Having better mechanical, surface roughness, hydrophilic and biological properties, ZnHA is most suitable as a bioimplant surface as compared to HA or CuHA coating that can have better cell activities.

VII SCOPE FOR FUTURE WORKS

The development of a new generation of novel functional biomaterials and coatings with accelerated (or suppressed) bone growth on the charged surface of polarised bioceramics and an understanding of the role of surface charge in enhancing bone growth on medical implants.. The efficacy of the synthesized material depends on the material used and the methodology adopted which in turn determines the release profile of the doped element. In addition, all this affects the behavior of osteoblasts and osteoclasts in vitro, as well as the in vivo bone formation and remodeling. It was found from our review that there are effects of dopant elements on properties and efficiency of the existing medical implants. However, since the methodologies adopted were all different, it is hard to compare the effects of dopant elements based on assessment of biological performance and hence general conclusions cannot be drawn. This problem is not only associated with the materials discussed here, but it holds for the whole field of biomaterials research. We therefore believe that standardized, high throughput methods of investigating the behavior of materials in vitro to predict their performance in vivo, are required in order to obtain true directions for how to improve the existing bone implants. Further work focuses on developing true high-throughput systems using micro fluidics, in which gradients of additives and their combinations can be established to investigate the effect of large number of concentrations as well as combinations of additives at varying concentration in a controlled and systematic manner.

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