IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

BIOMEDICAL IMPLANTS AND ITS CAUSES OF FAILURE: A REVIEW

Dr. Vaibhav Trivedi[1], Dr. Anupam Srivastava[2], Mohammad Javed[3]

[1]Professor & Director,[2]Professor, [3]Assistant Professor

[1]Department Of Mechanical Engineering

IFTM University, Moradabad, India

ABSTRACT

As we know that the science and technology creates new records day by day and the inventions are very helpful for the human beings also. Many researches have been done in the field of medical industry and this process is continuing in the scenario. In medical devices mostly the biomaterial is used in terms of bone replacement and many other replacements of the parts in a human body and the biomaterial should have the capability to biocompatible with the human replaced parts. This paper gives an idea about the different studies in the field of biomedical implants and it also provide an overview about the material of the biomedical implant which have high success rate as compare to the other materials in terms of the comparative study. Also this paper gives an overview about the corrosion in biomedical implants and its causes of failure which is a major issue faced by many of the patients who are using the implants. The material should also have the property to work like the original part and not cause any adverse reactions in the body, they must be stable retaining their functional properties.

Keywords: Implant material, Biomedical implants, Biomaterial, Corrosion

1. INTRODUCTION

In the present scenario things are very easy and comfortable only, if we have lot of money to spend on the medical facilities. A person who got fracture in the hand or in the leg and the bone are totally crush then it will be replaced by the implant and after some time till the patient recover after the successful placing of the implant in the body at the place of the crushed bone, then the implant perform the same function of the bone. But when the procedure of bone replacement is in starting stage, it is necessary to select the best material of the implant which is biocompatible with the human body and not harm to the patient like swelling, itching a d many other problems. The selection of the implant material is based on the properties of the implant material. Such material must perform satisfactorily in the body environment without degrading till its intended use is over. Biomaterials can have a benign function, such as being used for a heart valve, or may be bioactive; used for a more interactive purpose such as hydroxy-apatite coated hip implants (the Furlong Hip, by Joint Replacement Instrumentation Ltd, Sheffield is one such example – such implants are lasting upwards of twenty years). Biomaterials are also used every day in dental applications, surgery, and drug delivery. [1]As our life style is changed rapidly, orthopaedic biomedical implants is being done in more young and active patients, than before. This necessitates the revision surgeries due to causes such as instability or dislocation of devices, corrosion and galling damage, abrasion and wear, etc. Studies have shown that corrosion products and metal ions which are released in the body due to metal dissolution from the implant surface lead to adverse tissue reactions. Adverse tissue reaction and other biological risks involved with metal ions release are formation of wear debris, accumulation of free metal ions, and inorganic metal salts or oxide formation [2].Although there are many studies reporting corrosion and mechanical damage of metallic implants in vivo, including detailed Scanning Electron Micrographs [3-6].The implant failure reported such mechanical properties like as: Wear corrosion, Fibrous encapsulation, Inflammation, Low fracture toughness, Low fatigue strength, Mismatch in modulus of elasticity between bone and implant [1].

2. IMPLANT MATERIALS

The prerequisite for any synthetic material to be implanted in a human body is its biocompatibility viz. the ability of a material to perform with an approximate host response in a specific application, i.e. it should not cause inflammatory, or generally adverse, tissue reaction. Additionally, an implant, which is an object made from nonliving material that is inserted into the human body where it is intended to remain for a significant period of time in order to perform a specific function, is expected to withstand loads (physiological, mechanical) without substantial detoriation or catastrophic event (reaction, fracture) or altering the environment. Also, the materials must not interact with blood so as to produce clotting or denaturing of plasma proteins [7].

The orthopaedic implants are therefore used for the:

1. Replacement of damaged or diseased part of the anatomy-e.g. total joint replacement.
2. To aid in healing of tissue-e.g. fracture plate.
3. To correct deformity-e.g. a plate used after osteotomy [8].

3. CLASSIFICATION OF IMPLANT MATERIAL

There are three groups of materials used for the implants: metals, alloys, polymers and ceramics.

- Various systems have been used to classify these materials on the basis of their in-vivo tissue reactions are Bio tolerant, Bioactive, Bio inert and Biodegradable as shown in the following table with its examples.
- In general, a category of materials intended to perform medical and biotechnological functions are called biomaterials.
- In modern history, metals have been used as implants since more than 100 years ago when Lane first introduced metal plate for bone fracture fixation in 1895**.** In the early development, metal implants faced corrosion and insufficient strength problems [9].

Table 1. Classification of Biomaterials

Compatibility Degree	Bony Tissue Characteristics	Biomaterial's Example
Bio tolerant	Implants separated from adjacent bone by a soft tissue layer along most of the interface: distance osteogenesis.	Metallic biomaterials such as 316L, Co-Cr alloys, Ti and Ti Alloys, etc
Bio inert	Direct contact with bony tissue: contact osteogenesis	Bioceramics such as Al2o3, Zro2 and Tio2 etc.
Bio active	Bonding with the bony tissue: bonding osteogenesis	High temperature sintering Hap, Bioglass, etc
Bio degradable	Replaced by regenerating natural tissue, absorbed and released viametabolic process of the body.	Low temperature sintering Hap, TCP, etc.

4. Metals required for implants

4.1Biomaterials

The material which is used in medical industry and it is placed where the original part such as bone and other part of the body is damaged or crushed. The material which is used at the place of the replaced part should be biocompatible with the patient. If it is not biocompatible then the patient face many problems like pain, itching and many more after the surgery done to fix the implant in the body. These materials have their life and as per the specification an different properties the best implant is selected for the fitment in the human body. Let us take an example why we use implant? The answer of this question is here, If a person living its life happily and suddenly he got accidented and the whole bone of the leg is crushed so badly than there is no option other than implant. The implant is fitted at the place of the crushed bone and after sometime the implant perform the same function of the bone like the person can walk easily. The same thing will also happen for those person who have any bone disease and any other disease in which the part of the body is damaged. Vanadium steel was the first metal alloy used to manufacture bone fracture plates (Sherman plates) and screws. Sometimes those metallic elements, in naturally occurring forms, are essential in red blood cell functions (Fe) or synthesis of a vitamin B12 (Co), but cannot be tolerated in large amounts in the body. The most common metallic materials that are used in prosthetic implants are usually; cobalt based alloys, iron based alloys (stainless steels) and titanium alloys.A biomaterial is essentially a material that is used and adapted for a medical application.

Table 2. Implants division and type of metals used

Division	Example of implants	Type of metal
Cardiovascular	Stent Artificial valve	316L SS; CoCrMo; Ti; Ti6Al4V
Orthopaedic	Bone fixation (plate, screw, pin)Artificial joints	316L SS; Ti; Ti6Al4V; CoCrMo; Ti6Al4V;Ti6Al7Nb
Dentistry	Orthodontic wire Filling	316L SS; CoCrMo; TiNi; TiMo; AgSn(Cu) amalgam, Au
Craniofacial	Plate and screw	316L SS; CoCrMo; Ti; Ti6Al4V
Otorhinology	Artificial eardrum	316L SS

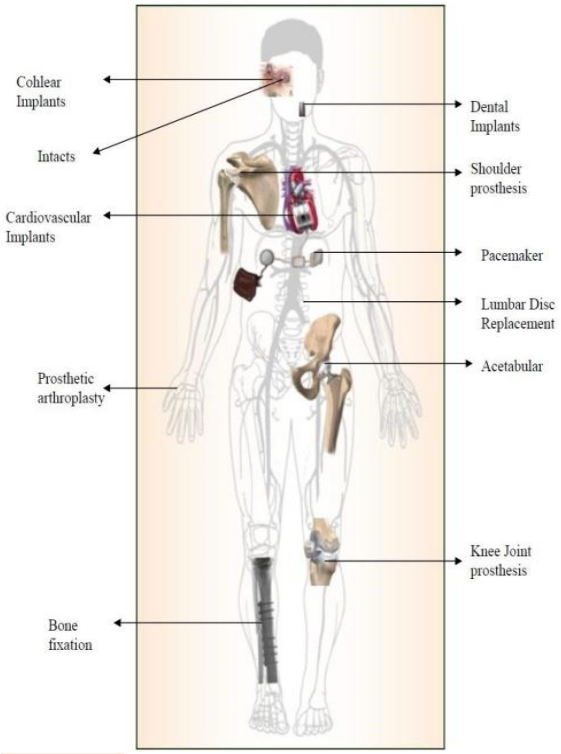

Figure 2.1 Implants for Human Anatomy Significance [10]

4.2 Applications of Biomaterials [1]

- Joint replacements
- Bone plates
- Bone cement
- Artificial ligaments and tendons
- Dental implants for tooth fixation
- Blood vessel prostheses
- Heart valves
- Skin repair devices
- Cochlear replacements

5. Review of related work

5.1 Renato Altobelli Antunes et.al [11]

Premature mechanical failure of metallic biomaterials is frequently linked to cyclic loads. Many studies have been conducted on the complicated relationship between fatigue and corrosion in the physiological environment. Microstructure, heat treatments, plastic deformation, surface finishing, and coatings all have a significant impact on fatigue fracture nucleation and growth in this setting.Wear is also a common occurrence that contributes to the process. Despite all of the effort put into understanding the mechanisms that regulate corrosion fatigue in biomedical alloys, failures still happen. The literature on corrosion-fatigue phenomena in Ti alloys, surgical stainless steels, Co–Cr–Mo, and Mg alloys is reviewed in this study.The correlation between structural and surface aspects of these materials and the onset of fatigue in the highly saline environment of the human body was discussed.

5.2 Mehdi MazarAtabakiet al [12]

Because of its corrosion resistance, mechanical qualities, and extremely low cost, Mehdi Mazar's research indicated that stainless steel 316L is commonly utilised for implantation purposes in orthopaedic surgery. He also looked into the use of a coating procedure on the stainless steel implant to form a thin film barrier in order to extend the life of the implantation. The implant material's surface is protected by a hydroxyapatite (HA) covering. Because of its low cost and ease of manufacture, the dip Sol-gel process is used to generate HA coating on stainless steel.This method has a number of advantages in terms of microstructure control and coating thickness control. At 900 °C sintering temperature in vacuum atmosphere, observations revealed that the coating film is uniform. Mechanical properties of the films are also investigated, such as tensile strength and hardness. At 900 °C of sintering temperature, the greatest tensile test and hardness value is achieved. The coatings are dense and strongly adhered to the substrates, with a strength of 45.9 MPa on average.

5.3 Amilcar C. Freitaset .al [13]

The goal of this study is to use step-stress accelerated life testing to assess the failure and reliability modes of anterior single unit repair in internal conical interface (ICI) implants (SSALT). The 42 ICI implants were distributed in two groups (n = 21 each): group AT–OsseoSpeedTM TX (Astra Tech, Waltham, MA, USA); group SV–Duocon System Line, Morse Taper (Astra Tech, Waltham, MA, USA) (SignoVinces Ltda., Campo Largo, PR, Brazil). The abutments were screwed to the implants, and standardised maxillary central incisor metal crowns were cemented and SSALT'd in water.Probability of using a certain level For a mission of 50,000 cycles at 200 N, Weibull curves and dependability were estimated. Kruskal– Wallis tests were used to analyse

differences between groups, as well as Bonferroni's post-hoc testing. For failure analysis, polarised light and scanning electron microscopes were utilised.

5.4 Maria Burbano et al [14]

Due to high failure rates and severe local tissue reactivity, the usage of metal-on-metal complete hip implants has declined (ALTR). The release of wear metal particles from the CoCr bearing surface may augment delayed hypersensitive reactions, according to a hypothesis proposed. The purpose of this research is to determine the features of implant bearing surfaces at the microscopic level. ALTR findings led to a revision. For characterization of the surface features, multiple microscopy techniques are employed to examine each head and cup of the bearing surface. The prevalence of significant mechanical scratching is a common trait reported in all studied implants. In this particular set of retrieved implants, the mechanical factors seemed to be the prevalent failure mode related to the appearance of ALTR.

5.5 A.F. Mavrogenis et al [15]

"Osseointegration" is defined as "a direct structural and functional connection between organised, living bone and the surface of a load-bearing implant," according to Mavrogenis. If there is no progressive relative movement between the implant and the bone, the implant is now considered osseointegrated. A lack of a local or systemic biological response to that surface may be indicated by direct bone contact as shown histologically. As a result, it is suggested that osseointegration is the result of the lack of a negative tissue response rather than an advantageous biological tissue response. The focus of the presentation is on the biology of osseointegration and the factors that influence osseous healing surrounding implants.

6. CONCEPT OF JOINT REPLACEMENT

In the vast majority of cases, however, the illness that demands THA only affects the femoral head and ace tabular regions, resulting in a significant amount of healthy bone and tissue being removed. As a result, it's critical to create a system that preserves healthy bone stock while also appropriately distributing loads on the proximal femur. There is a risk of bone resorption across broad areas of the proximal femur if loading patterns are insufficient, as Wolff [16] originally quantified.

The removal of substantial volumes of healthy bone and tissue also creates space for device-related debris to migrate into. Spaces and inclusions must therefore be reduced during the design phase using appropriate design and fastening procedures. Failure to eliminate such factors can lead to particle-induced osteolysis, which can be treated with a revision treatment that is less effective than THA.

7. CAUSES OF FAILURE OF IMPLANTS

7.1Implant Corrosion

Corrosion is defined as the chemical or electrochemical reaction with the environment that causes a metal to corrode. Corrosion is not the term for degradation caused by physical or mechanical activities; erosion, galling, or wear are used instead. When metals and alloys are utilised as implants in the body, corrosion is one of the key processes that causes issues. A deeper grasp of some of the underlying principles involved in the corrosion degradative process is essential to minimise these issues. Electrochemical reactions cause implant corrosion in the aqueous medium of body fluids, thus it's important to appreciate and understand the electrochemical concepts that are most pertinent to corrosion processes. The electrochemical reactions on the surgically implanted alloy's surface are identical to those seen when exposed to seawater (namely, aerated sodium chloride). The dissolved oxygen is reduced to hydroxyl ions, and the alloy's metallic components are oxidised to their ionic forms. The overall rates of oxidation and reduction reactions, also known as electron generation and electron consumption, must be equal during the corrosion process. The slower of these two processes is in charge of controlling the total reaction rate.

The presence of a protective surface passive film on metals and alloys used as surgical implants gives them passivity. This coating suppresses corrosion and limits current flow and corrosion product release to a minimum, i.e., all implantable materials corrode at some finite rate due to the body's complex corrosive environment while in operation. Pitting, crevice, galvanic, intergranular, stress-corrosion cracking, corrosion fatigue, and fretting corrosion are the forms of corrosion that are relevant to today's alloys.

8. TYPES OF CORROSION

8.1 General Corrosion

A chemical or electrochemical response that occurs uniformly over a whole exposed surface characterises general or uniform corrosion. Uniform corrosion of metals is regarded to be the most common type of corrosion, accounting for the majority of metal loss on a tonnage basis. [17].

8.2 Pitting Corrosion

Pitting is a type of corrosion that is particularly localised and resulting in pitting on the metallic surface. Pitting is one of the most destructive and challenging types of corrosion to anticipate, frequently resulting in system failure with minimal material mass loss. Pitting corrosion occurs on metals that rely on the production of a protective oxide coating for their technical utility. A corrosion pit, often known as a 'autocatalytic' anodic process, is a unique sort of anodic process. This is owing to the presence of meta stable phases, which contribute to the construction of an active pit over time. [17].

Due to the establishment of an aggressive environment capable of supporting dissolution, an active pit frequently develops a pit geometry and chemistry capable of sustaining dissolution of the alloy.

For example: Pitting was frequently observed in older stainless steel fracture fixation hardware, e.g., on the underside of screw heads [17].

8.3 Galvanic Corrosion

As per Ohm's law, galvanic corrosion occurs when a potential difference exists between two electrically connected metals submerged in a corrosive or conductive fluid. This potential difference causes an electron flow between the metals, which causes the more sensitive alloy (anode) to corrode faster while the other alloy is protected (cathode). This is commonly used to predict which materials will corrode preferentially, with the anode in the couple being the alloy with the lowest electrode potential. The distance between the anode and the cathode, the anode to cathode area ratio, and the environment can all influence galvanic corrosion. [12]. For example: Inappropriate use of metals, e.g., a stainless steel cerclage wire in contact with a cobalt or titanium - alloy femoral stem, a cobalt - alloy femoral head in contact with a titanium - alloy femoral stem, and a titanium - alloy screw in contact with a stainless - steel plate [12].

9. Causes behind Implant Corrosion

Corrosive (oxidation and reduction) processes are caused by thermodynamic factors. The electrochemical series connects the normal electrode potentials of metals, usually in reference to hydrogen [13]. These forces correspond to the energy required or released during a process. Unfortunately, this series ignores the capacity of these metals to produce oxide films in any given electrolyte, therefore engineers should refer to the galvanic series, which ranks metals according to their relative reactivity in saline solutions. Corrosion kinetic barriers are variables that physically obstruct or inhibit corrosion reactions from taking place [13]. In orthopaedic implants, only metals with the ability to create a protective oxide layer against corrosion are permitted. Passive films must possess particular features in order to limit oxidation. They must be non-porous and completely cover the metal surface; they must have an atomic structure that prevents ions and electrons from migrating across the metal oxide-solution interface; and they must be able to stay on the material's surface even when subjected to mechanical stress or abrasion, as is common with orthopaedic devices. [14]

10. Clinical Impact of Corrosion

- Corrosion can significantly reduce the material's fatigue life and ultimate strength, resulting in implant mechanical failure.
- The release of corrosion products may cause a negative biological reaction in the host, and some authors have documented elevated amounts of local and systemic trace metals in conjunction with metal implants.
- In the absence of infection, corrosion products have been linked to the development of local discomfort and swelling around the implant. [15]
- The presence of particle corrosion and wear products in the tissue around the implant could set off a chain reaction that leads to periprosthetic bone loss [16].

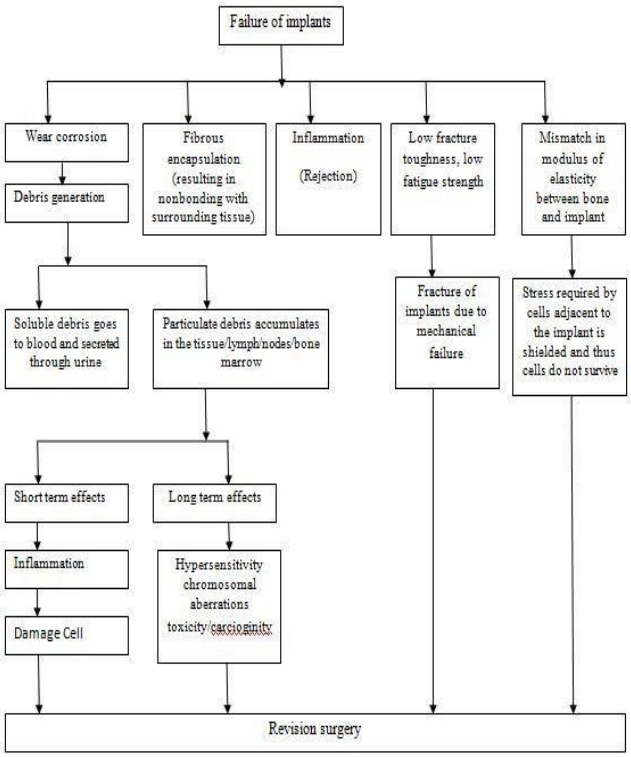

Figure 1.1: Flow Diagram for Reported Causes of Implants Failure [17]

11. Biological Environment

11.1 Tissue Reaction to Implants of Different Metals

Due to the complex and corrosive environment of the human body, all medically inserted metallic materials, including the most corrosion resistant ones, undergo chemical or electrochemical dissolution at some finite rate. Water, complex molecules, dissolved oxygen, huge numbers of sodium (Na+) and chloride (Cl) ions, as well as other electrolytes like bicarbonate and minor amounts of potassium, calcium, magnesium, phosphate, sulphate, and amino acids, proteins, plasma, lymph, and so on, make up the bodily fluid. Ionic species also have a variety of activities, including maintaining the body's pH and participating in electron transfer reactions. The interior body environment is considerably altered during surgical implantation, including disruption of blood supply to the bones and changes in ionic balance.

11.2 Tissue–Implant Corrosion

The interactions between the substance and the tissues are crucial, especially given the implant's hostile environment and substantial burden. Corrosion/ionization of the implanted device occurs as a result of such interactions. Corrosion has two possible outcomes. The implant may first deteriorate, resulting in early failure. The tissue reaction, which causes the implant to produce corrosion products, is the second effect. Within living tissues, no metal is completely impervious to corrosion or ionisation. In vivo investigations have revealed that implanting devices made of most alloys raises the concentrations of different ions in the tissues.

12. Other Variables

Despite the fact that new metallurgical and technological breakthroughs have achieved significant progress in implant design and selection, failures still occur due to underlying causes. In every case of orthopaedic failure, the patient is subjected to the stress of multiple operations as well as significant agony during the implantation process. Furthermore, its replacement is costly and inconvenient for the patient. As a result, keeping the number of failures to a bare minimum is very desirable. The following section discusses the most common failures of stainless steel orthopaedic implant devices.

12.1 Direct Overloading

The purpose of utilising a fixation device is to keep the shattered bone's ends close together to encourage healing. The bone and the fixation device are designed to bear equal amounts of weight. Even if the weight is shared, the load on the afflicted bone must be kept to a minimum until it recovers. Excess load transmitted to the implant fixed on the fractured bone slit (because to the patient's inadequate mobility) causes the implant to fracture. As a result, deformation and overload fracture can occur when an orthopaedic fixation device, such as a bone plate or a hip nail, is subjected to a single overload or a series of overload cycles.

12.2 Fatigue Loading

Fatigue failure is defined as failure caused by dynamic and cyclic stress loading on the implant. It is not necessary for the implant to be loaded in the plastic deformation range for a fatigue crack to occur. Local stresses that arise during loading in the implant's elastic deformation range are sufficient to produce fatigue fractures on the implant's surface. Cracks are frequently initiated as a result of corrosion and propagated primarily through a fatigue process. Improper installation and the presence of a space between the shattered bone fragments after implantation can potentially cause fatigue failure. The tissue environment is disrupted during implantation, causing blood flow to the surrounding tissue and the implant to fail.

13. CONCLUSION

Implant failure is caused by fretting corrosion, crevice corrosion, pitting, and ploughing. In the presence of bodily fluids, any implant surface that encounters micro motion, such as a screw, may fret. The issue of corrosion resistance is the most essential difficulty to be addressed in developing novel implant materials in order to extend the life of the implant and avoid unfavourable bodily reactions and pain. If an implant is utilised for longer than its designated service period in vivo, it will show signs of corrosion and will eventually fail. According to the findings, the UHMWPE surface has been completely destroyed by steel-to-steel contact, resulting in severe adhesive wear and pitting corrosion of the steel ball surface.The appearance of discomfort and swelling happens as a result of unfavourable responses of wear debris and corrosion products with local tissues. When submerged in different solutions, the explanation for the maximum and minimum corrosion rates (weight loss) in both scenarios could be attributed to some micro and macro nutrients present in the solution that help the progression of corrosion through distinct kinetics. In-vitro, the corrosion rate (weight loss) of both 316L SS and Ti6Al4V implants coated with HAp-10 percent Al2O3 coating decreases when compared to uncoated 316L SS and Ti6Al4V implants, indicating that coated implants perform better. The decrease in corrosion rate indicates that coatings improve material corrosion resistance and, as a result, could extend the life of implants in vivo when compared to uncoated as a result, the odds of early implant failure are reduced.

14.REFERENCES

[1] Amogh Tathe, Mangesh Ghodke and Anna Pratima Nikalje (2010), A brief review: biomaterials and their apllication, International Journal of Pharmacy and Pharmaceutical Sciences, ISSN- 0975-1491,Vol 2, Suppl 4, 2010

[2] Rodrigues, D.C., Urban, R.M., Jacobs, J.J. and Gilbert, J.L. (2009) *In Vivo* Severe Corrosion and Hydrogen Embrittlement of Retrieved Modular Body Titanium Alloy Hip-Implants. *Journal of Biomedical Materials Research Part B*: *Applied Biomaterials*, 88, pp: 206-219.

[3] Suito, H., Iwawaki, Y., Goto, T., Tomotake, Y. and Ichikawa, T. (2013) Oral Factors Affecting Titanium Elution and Corrosion: An *in Vitro* Study Using Simulated Body Fluid. *PLoS ONE*, 8

[4] D.F. Williams. J. black and P.J. Dohetry, "second consensus conference of definitions in biomaterials", advances in biomaterials 10pp.525-533 elsevier, Tokyo, 1992.

[5] G.Heimkei, 'The aspects and modes of fixation of bone replacements- in osteointegerated implants', pp. 1-29, CRC press, Boca Raton, F.L., 1990.

[6] A.Kocija, I.Milosev, B.Pihlar, Colbalt-based alloys for orthopeadic applications studied by electrochemical and XPS analysis. Journal of Materials Science: Materials in Medicine 2004;15, pp 643-650.

[7] Lees S. and Devidson, C. L. (1977). The role of collagen in elastic properties of calcified tissues, J. Biomech., Vol. 10(8), pp. 473-486.

[8] Memmone, J. F. and Hudson, S. M. (1993). Micromechanics of bone strength and fracture, J. Biomech, Vol. 26(4-5), pp. 439-446

[9] J.Williams, Engineering Tribology, 2 ed: Cambridge University Press, 1994.

[10] http://training.seer.cancer.gov/module_anatomy/unit3_3_bone_growth.html.

[11] Mehdi MazarAtabakiRabi'atuladawiyahJafar "SOL–GEL BIOACTIVE GLASS COATING FOR IMPROVEMENT OF BIOCOMPATIBLE HUMAN BODY IMPLANT" Association of Metallurgical Engineers of Serbia

[12] Amilcar C. Freitas-Junior, Erika O. Almeida,Estevam A. Bonfante,Nelson ,R.F.A.,Silva, Paulo G. Coelho "Reliability and failure modes of internal conical dental implant connections" Clin. Oral Impl. Res. 0, 2012 / 1–6

[13] Maria Burbano, Robert Russell, Michael Huo, Robert Welch,Danieli C. Rodrigues, Diana Roy "Surface Characterization of Retrieved Metal-on-Metal Total Hip Implants from Patients with Adverse Reaction to Metal Debris" *Materials* 2014, *7*,1866-1879; doi:10.3390/ma7031866

[14] A.F. Mavrogenis, R. Dimitriou, J. Parvizi, G.C. Babis "Biology of implant osseointegration" J Musculoskelet Neuronal Interact 2009; 9(2):61-71

[15] J Wolff, The Law of Bone Remodeling: Berlin Heidelberg New York: Springer, 1986.

[16] Fossati, A., Borgioli, F., Galvanetto, E. and Bacci, T. (2006) Glow Discharge Nitriding of AISI 316L Austenitic Stainless Steel: Influence of Treatment Time. *Surface & Coatings Technology*, 200,pp: 3511-3517.

[17] Mohamed A. Hussein Abdul Samad Mohammed, and Naser Al-Aqeeli Wear Characteristics of Metallic Biomaterials: A Review *Materials* 2015, *8*, pp: 2749-2768