Hydroxyapetite-Coated Bio-metal Based Fracture Plate and Tooth Implant

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***Abstract*- This study deals with the development of a unique alloy combining common metals generally categorized as "bio-metals". The ultimate product developed serves to be an effective fracture plate and/or tooth implant, replacing the ones in use (made with the traditional alloys), owing to the highly superior mechanical and biocompatible properties. The novelty of the product is that the bio-metal alloy, which could otherwise be rendered as toxic to internal tissues of the human body when implanted, has been successfully alleviated from its toxicity by coating it with a very biocompatible powder material (synthesized from a totally biological waste material) thus safeguarding the patient body from reacting or rejecting the implant as a whole or even developing any related immune response which could otherwise be fatal.**

Keywords-Bio-metal, Alloy, Fracture plate, Tooth Implant, Biocompatible.

I. INTRODUCTION

For Humans, by definition, an implant is a medical device used to replace a missing biological part or tissue, support such an entity or enhance them.

The surface of the implant that interacts with the human tissue is made of biocompatible materials, the choice of which depends on what is most functional.

Based on applications, implants are of Sensory and Neurological, Cardiovascular, Orthopaedic, Electric, Cosmetic, Other Organ and System types. The process of implantation of medical devices is subjected to the same complications that other invasive medical procedures can have during or after surgery. Common complications include infection, inflammation, and pain. Other complications that can occur include risk of rejection from implant-induced coagulation and allergic foreign body response. Depending on the type of implant, the complications may vary and thus in the course of all of it, a major aspect that remains the centre of all discussion is biocompatibility which refers to the ability of a material to perform with an appropriate host response in a specific situation. It reflects the ongoing development of insights into how biomaterials interact with the human body and eventually how those interactions determine the clinical success of a medical device (such as pacemaker, hip replacement or stent). Modern medical devices and prostheses are often made of more than one material so it might not always be sufficient to talk about the biocompatibility of a specific material.

Specifically with respect to metals, once metals are questioned to be implanted into a patient's body, based on the type of behaviour induced by the metal-tissue interactions, metals are Bio-inert, Bio-active and Bio-resorbable.

From time immemorial, implant biomaterials has always been the major concerning issue when related studies have been carried out. Amongst metals, titanium has a good record of being used successfully as an implant material and this success with titanium implants is credited to its excellent biocompatibility due to the formation of stable oxide layer on its surface [1,2]. Titanium reacts with several other elements for eg: silver, Al, Ar, Cu, Fe, Ur, Va and Zn to form alloys. Titanium alloys exists in three forms alpha, beta and α-β [3]. These types originate when pure titanium is heated with elements Al, Va in certain concentrations and cooled, these type originate [4].

The major disadvantage of titanium is that there is esthetic issue due to gray color of titanium and this is more pronounced when soft tissue situation is not optimal and the dark color shines through the thin mucosa.

Ceramics were used for surgical implant devices because of their inert behavior and good strength and physical properties such as minimum thermal and electrical conductivity. Certain properties of ceramics like low ductility and brittleness has limited the use of ceramics [5].

Root form or endosteal plate form, and pin-type dental implants are generally made from High ceramics from aluminum, titanium and zirconium oxides. The compressive, tensile and bending strengths exceed the strength of compact bone by 3 to 5 times. These properties combined with high moduli of elasticity and especially with fatigue and fracture strength have resulted in specialized design requirements for this class of biomaterials [6].

In all these years, a number of notable research activities have been carried out concentrating on analysis methods of biocompatibility of biomaterials.

In case a medical biomaterial is exposed to an environment including extremely strong energy that Magnetic Resonance Imaging (MRI) device generates, undesirable results in terms of human health may occur. Especially metalliferous biomaterials in the body interact with strong static magnetic field, gradient magnetic field and radiofrequency (RF) electromagnetic pulses which are used during MRI. In this study, by researching

possible physical effects of MRI device on biomaterials used as body support equipments, MRI compatibility and safety in terms of biomaterials was evaluated [7].

In the bone tissue engineering, the new bone tissue regeneration is managed by these bone cells under tightly controlled microenvironment including both chemical and mechanical stimuli. In this specific study, an overview of published studies had been summarized on the understandings of the cells' response to environmental stimuli. Specific attention has been focused on the effect of biomaterial's chemical and physical properties on the bone cell functions [8].

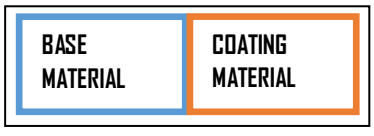
In this specific study, a microsensor implant (MSI) comprising microsensors was introduced for dissolved oxygen, pH and electrical impedance to monitor ingrowth behavior of biomaterial coatings into tissue. The chorioallantoic membrane (CAM) of ex ovo transferred avian embryos served as a physiological tissue environment. Here, different signal progressions during ingrowth could be observed in a time period of 3-4 days. Biodegradable poly(DL-lactide-co-glycolide) and biostable plasma-polymerized coatings compared to an uncoated MSI were tested [9].

The aim of a particular study was to synthesize the biocompatible acemannan scaffold for biomedical application by chemical-crosslinked method. Adipic acid and CDI were employed as a crosslinker and a coupling agent, respectively. The three dimensional porous structure was constructed by the salt leaching method and then with freeze-dried process [10].

Having gone through all the above studies along with a few other dealing with the employability of metal alloys in implants and other implantable biomaterials, it is seen that most of the studies have been a bit ambiguous in specifying the type of metal used in implants when talking of their biocompatibility. On the other hand, this study deals with the development of a new metal alloy employable as a tooth and bone implant (incl. fracture plates), covered with an extremely inexpensive biocompatible material which in turn cuts off any kind of bio-toxicity that would have been arising otherwise. The economic aspect of the product also is such that the base material consisting of readily available metals don't contribute to the fact of the product being costly by any chance and similarly, the coating material, having been made from biological waste material, has no cost at all.

II. IMPLANT DESIGN

The design of the implant consists of two major sections- the base material part, and the coating material part.



The base material part consists of an alloy made of three principal metals- Aluminium, Copper and Zinc. The coating material consists of Hydroxyapetite, which is derived from a biological waste material- wasted eggshells.

III. INITIAL IMPLANT SYNTHESIS AND EXPERIMENTATION

A. *Base Material*

The whole procedure of the synthesis of base material follows the following steps:

- Selection of Raw Materials
- Documentation of Alloy Charges
- Sand Moulding
- Alloy Synthesis
- Moulding of Alloy
- Demoulding of Alloy

A.I. *Selection of Raw Materials*

Aluminium, Copper and Zinc as raw materials were taken.

A.II. *Documentation of Alloy Charges*

First, in an attempt to determine the best fit, 10 samples employing different proportions of the raw materials were documented in order to decide the number of roll-over synthesis and the number of fresh synthesis of alloys, all in view of the employed crucible capacity of 4kg.

- 90:5:5
- 80:15:5
- 70:20:10
- 60:20:20
- 60:10:30
- 50:20:30
- 50:15:35
- 40:25:35
- 40:20:40
- 30:25:45

A.III. *Sand Moulding*

A metal frame with the required wooden channel pieces were taken in which sufficient amount of white stand was stuffed. Then, CO_2 gas was passed through this sand-packing in order to make the sand stiff. This way the mould gets packed and ready.

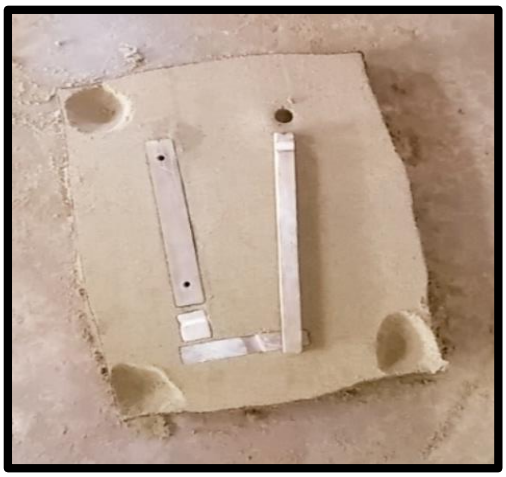


Fig. 1. Sand Moulding

A.IV. *Synthesis of Alloy*

Employing the Fusion Method of Alloy Synthesis, for every fresh or carry-over charge of metal alloy, first we put the aluminium metal as the formation of Aluminium Oxide on combustion, is a purely exothermic reaction which in turn makes the environment conducive for copper to melt as well and thus, following aluminium, copper, after being subjected to indirect heat (to avoid thermal shock), is put to melt along with aluminium. Lastly, zinc is taken and pushed with the help of a punch, to the bottom of the crucible.

After the proper mixing of all the materials, a certain amount of slag remover is put in order to remove the slag that might have formed.

Fig.2. Synthesis of Alloy in Crucible

A.V. *Moulding of Alloy*

The liquid metal alloy as formed above is then poured into the sand-packed mould and left to solidify under atmospheric temperature conditions. While the liquid metal alloy solidifies, it attains the shape as pre-determined by the channels in the sand-packed mould.

Fig.3. Moulding of Alloy

A.VI. *De-moulding of Alloy*

After the liquid metal alloy has solidified, the sand packed mould is physically beaten for the sand to loosen up and break off, in return of which we obtain the final structure known as the test bars, which are then subjected to the desired experimentation procedures.

Fig.4. All the ten sample Test Bars

B. *Coating Material*

The whole procedure of the synthesis of coating material- Hydroxyapetite (synthesized from wasted eggshells) follows the Wet Chemical Method of Synthesis and has the following steps:

- Selection and Rinsing of Eggshells
- Calcination of Eggshells
- Hydration of Eggshells
- Acidification
- Precipitation
- Dehydration of Precipitate
- Final Product

B.I. *Selection and Rinsing of Eggshells*

A set of wasted eggshells are taken, rinsed thoroughly with distilled water and then crushed into small pieces.

Fig.5. Raw Eggshells

B.II. *Calcination of Eggshells*

The crushed eggshells are stuffed in mini-crucibles and then calcined in a muffle-furnace at 900C for 2 hours for the constituent $CaCO_3$ to be converted to CaO.

Fig.6. Crushed Eggshells in Mini-Crucibles

Fig.7. Calcination of Eggshells

B.III. *Hydration of Eggshells*

The newly formed CaO is subjected to simple hydration using distilled water where the Cao gets converted to $Ca(OH)_2$.

Fig.8. Hydration of Calcined Eggshells

B.IV. *Acidification*

Following the above, 0.6M Orthophosphoric Acid is poured dropwise in order for the whole thing to clump up as a precipitate.

$10\ Ca(OH)_2 + 6H_3PO_4 \rightarrow Ca_{10}(PO_4)_6(OH)_2 + 18H_2O$

B.V. *Precipitation*

As soon as the Orthophosphoric Acid is poured, the $Ca(OH)_2$ gets precipitated into a dark clumped entity which is left as it is for a period of 24 hours.

Fig.9. Acidified Precipitate

B.VI. *Dehydration of Precipitate*

After 24 hours, the precipitate is first put in a Magnetic Stirrer for 30 minutes after which again the whole thing is left alone for another period of 24 hours.

After this particular 24 hours, the precipitate is then again stuffed into mini-crucibles and put in a muffle furnace at 900C for 2 hours.

Fig.10. Preparation for Dehydrating Acidified Precipitate

B.VII. *Final Product*

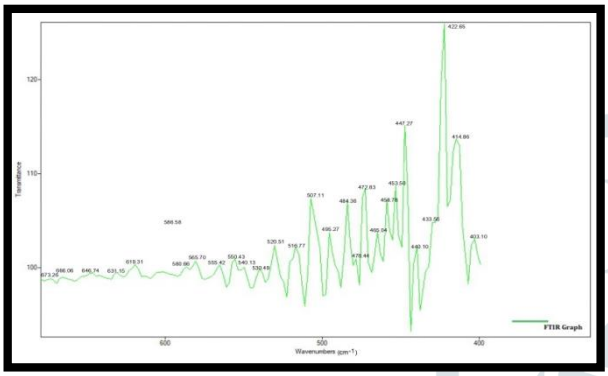
After the above mentioned step of dehydration is completed, what we get is a fine white powder known as Hydroxyapetite.

Fig.11. Obtained Hydroxyapetite Powder

IV.RESULTS AND DETERMINATION OF BEST SAMPLE

Based on the results obtained from Mechanical Analysis, X-Ray Diffraction (XRD), Fourier Transform Infrared Spectroscopy (FTIR) and Scanning Electron Microscopy (SEM), we determined that Sample No. 8 which consisted of Aluminium, Copper and Zinc in the ratio of 50-20-30.

Tensile Strength	85 MPa
% Elongation under 50mm Gauge Length	2



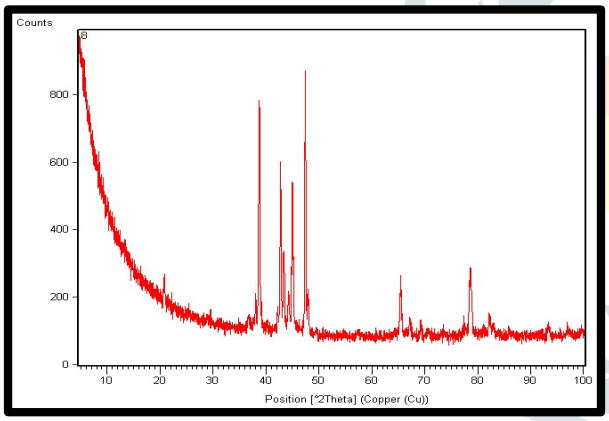


Fig.12. FTIR Plot of Sample No. 8

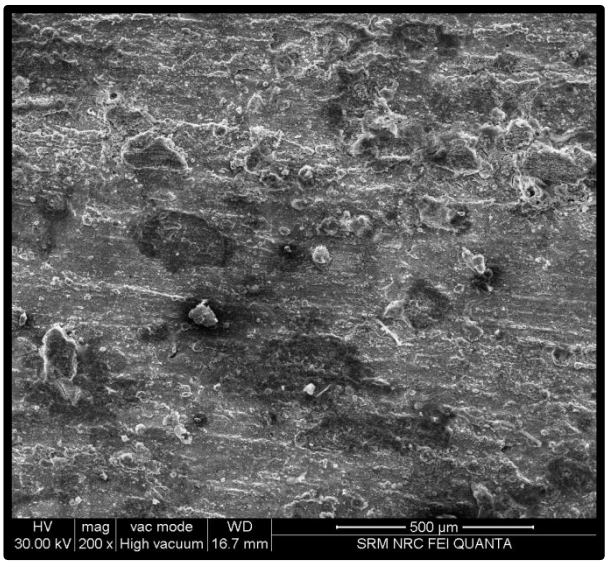


Fig.13. XRD Plot of Sample No. 8

Fig.14. SEM Image (Mag: 200X)

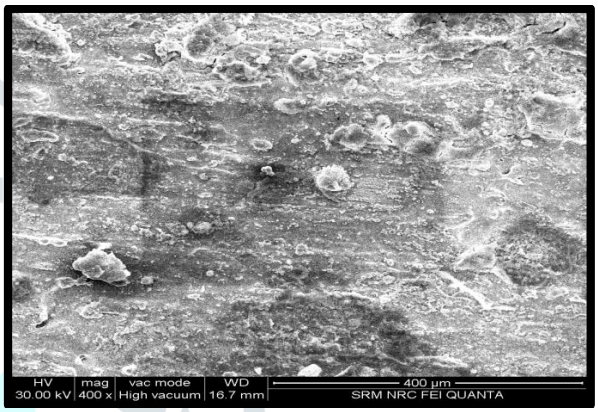


Fig.15. SEM Image (Mag: 400X)

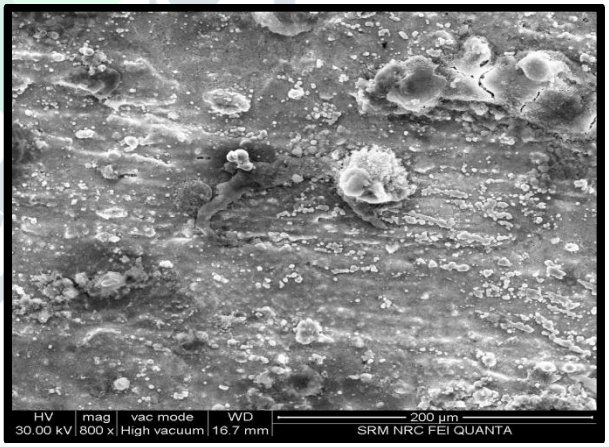


Fig.16. SEM Image (Mag: 800X)

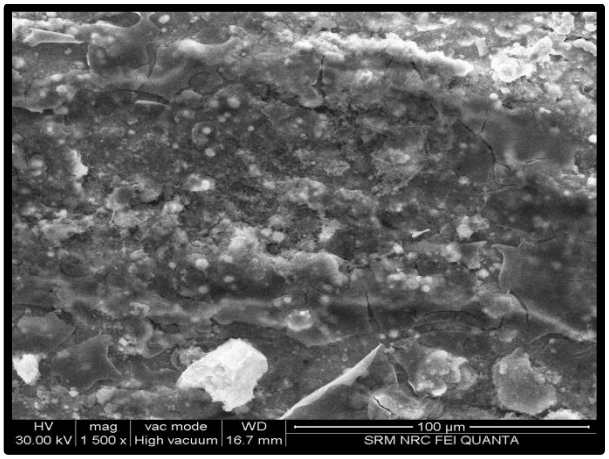


Fig.17. SEM Image (Mag: 1500X)

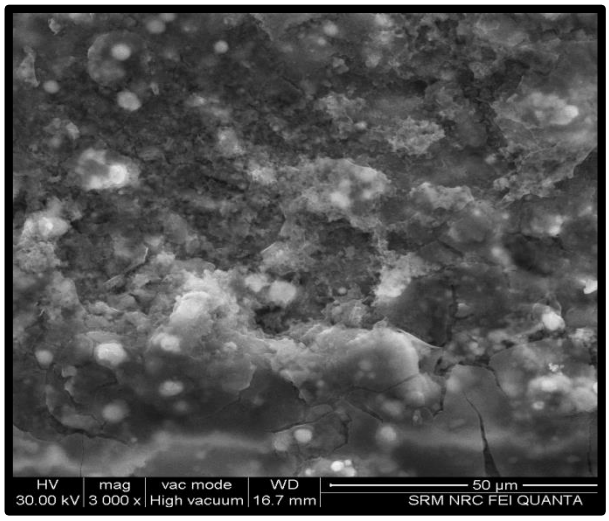


Fig.18. SEM Image (Mag: 3000X)

V. SYNTHESIS OF FINAL IMPLANT

After the best fit out of the 10 metal alloy samples is decided (Sample No.8), we reproduce that particular combination of metal alloy and this time hammer it into a 50mm x 100mm rectangle with a thickness of 3.5mm.

Following this, the Hydroxyapetite powder is taken and with the help of Metal Spraying technique, the powder is sprayed onto the metal piece up to a thickness of 2mm.

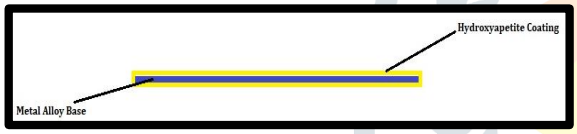


Fig.19. Final Implant Structure

VI. DISCUSSIONS

The study presented above clearly shows that when considering the scenario where the usage of the traditional alloy of Titanium is in question with respect to implant biomaterial, major issued in aesthetics, manufacturing difficulty, lack of novelty in metal alloy and the cost factor- all come into the scene whereas the product dealt with in this study beats all of the above disadvantages as well as employs a novel coating to nullify any possible metal toxicity as well as maintain an excellent biocompatible property along with being extremely cost effective.

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