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Is Anodised Aluminium A Suitable Alternative to Stainless Steel and Titanium Alloys for Use in Orthopedic Implants?

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Abstract
Biomaterials used need to satisfy two main criteria: Bio-functionality and Biocompatibility. Titanium alloys and Stainless steels are the two most widely used materials for medical implants due to their biocompatibility. But Titanium alloys are expensive and Stainless steels present possible metal toxicity due to high Chromium and Nickel content. Aluminium offers a suitable alternative to both the aforementioned materials as it is cheaper, easily available and has a number of alloys with varying strengths to suit particular needs. Aluminium was believed to be responsible for neurodegenerative diseases such as Alzheimer's but research has yet to prove a causal relationship. Pure Aluminium is susceptible to corrosion and hence Anodised Aluminium is explored as a potential material for orthopaedic implants.

Keywords: *Biomaterials, titanium, stainless steel, aluminium alloy, anodising*

1. Introduction

Aluminium is the most abundant metal on earth, its low density, ductility and malleability offer a range of uses for it and its alloys. Yet, when it comes to use as an implant biomaterial, aluminium has not been preferred. Biomaterials used need to satisfy two main criteria: Bio-functionality and Biocompatibility. Most metals and their alloys used for implants satisfy Bio-functionality due to their higher strength compared to human bone. But the bio-compatibility of Aluminium is poorer when compared to the already used materials namely Titanium alloys and Stainless Steel. Yet, alumina(aluminium oxide) membranes have been shown to be bio inert and ceramic alumina is used as a material for dental implants and is bio inert.

Aluminium is a metal which readily forms a an oxide layer on its surface when exposed to air containing oxygen, but for implant usage increasing the depth is suggested to improve its biocompatibility. Thus anodising process is used to increase the depth of oxide layer. Now we shall explore the properties and possible benefits of using anodised aluminium alloys for orthopaedic implants.

2. Literature Survey

2.1 Biomaterials

David F. Williams in The Williams Dictionary of Biomaterials[1] defines a Biomaterial as a synthetic material used to replace part of a living system or to function in intimate contact with living tissue. He further classifies Biomaterials into three categories:

a) Bio-Inert biomaterial
b) Bio-Active biomaterial
c) Bio-Resorbable biomaterial

Bio-inert biomaterials are any materials that are placed in a human body will have minimal interaction with the surrounding tissues. e.g., Stainless steel, Titanium and Titanium alloys, Alumina (Al_2O_3), Zirconia (ZrO_2), Cobalt-Chromium alloys, etc.
Bio-Active biomaterials are any materials that placed in a human body interact with the surrounding tissues, e.g., Glass ceramics and Bio glass.
Bio-Resorbable biomaterials are any materials when placed in the human body start to dissolve and are slowly replaced by advancing tissues. e.g., Bone, Hydroxyapatite.

2.2 Mechanical Properties of Human Cortical Bone

The mechanical properties of cortical bone were determined from literature as follows:

Table 1: Mechanical properties of human cortical bone

Sl No.	*Property*	*Value*
1	Tensile strength	50-151 MPa
2	Compressive strength	100-180 MPa
3	Young's modulus	7-30 GPa
4	Density	0.5 g cm^{-3}
5	Impact energy	$0.18*10^5$J m^{-2}
6	Bending strength	103-238 MPa
7	Brinell hardness number	5.5-9.1 BHN

2.3 Disadvantages Of Titanium Alloy and Stainless Steel Alloy

One of the Aseptic failure theories applicable to metallic implants is Stress Shielding [9]. Insertion of an implant in the knee or hip leads to remodeling of the bone as a result of the new loading conditions imposed by the implant. This can lead to bone loss around the implant in areas not subjected to loading, and is usually referred to as stress shielding. The balance between loading conditions and bone remodeling is called Wolff's Law: "Every change in the form and function of a bone or of their function alone is followed by certain changes in their internal architecture and equally definite secondary alteration in their external conformation, in accordance with mathematical laws". This implies that bone remodeling adapts the bone tissue depending on loading conditions i.e. when an implant is inserted. Stress shielding leads to bone loss, which is not a result of osteolysis but of bone remodeling.

Chromium toxicity has reference to the fact that chromium is toxic. Water-insoluble Chromium-III compounds and chromium metal do not pose any health hazard, but the toxicity and carcinogenic properties of Chromium-VI have been known for a long time. High concentrations of Chromium-III in the cell can lead to DNA damage is indicated by in vitro studies. [16]

Health effects of chromium compounds can vary with type of exposure, with certain effects more specific for the portal of entry. Oral and dermal exposures, and gastrointestinal effects are primarily associated with oral exposure. However, the description shows that effects of chromium are not limited to the portal of entry but also haematological, immunological, and reproductive systems also identified as targets for chromium. In addition to non-cancer health effects, occupational exposure studies and chronic-duration animal studies have results that indicate inhalation and oral exposures to Chromium-VI compounds are associated with respiratory and gastrointestinal system cancers, respectively.

The general population has exposure to nickel via inhalation, oral, and dermal routes. Based on occupational exposure studies, reports of allergic contact dermatitis and animal exposure studies, the primary targets of toxicity appear to be the respiratory tract from inhalation exposure, the immune system from inhalation, oral, or dermal exposure, and possibly the reproductive system and the developing organism from oral exposure. [17]

Humans and animals exposure to nickel compounds at concentrations much higher than typically found in the environment will have adverse respiratory effects. Limited data is available on noncancerous respiratory effects in humans. Exposure to nickel in nickel workers, did not result in increases in the risk of death from non-malignant respiratory system disease. Consistent results have not been found from studies examining potential nonlethal respiratory effects. Animal data provides strong evidence that lung inflammation is the predominant effect of nickel as a respiratory toxicant. Evidence of lung inflammation in rats has been observed following acute-, intermediate-, and chronic-duration exposure to nickel sulphate, nickel sub sulphide, or nickel oxide. According to human and animal data, lung cancer can be induced due to inhalation exposure to some nickel compounds .

2.4 Benefits Of Anodised Aluminium

Kristen E. La Flamme et al [18] investigated the biocompatibility of nanoporous Aluminium oxide (alumina) formed by anodising process on aluminium tubes. It has been shown previously that nanoporous alumina biocapsules can act effectively as immunoisolation devices, and support the viability and functionality of encapsulated β cells. The aim of this investigation was to assess the biocompatibility of the material with host tissue. The cytotoxicity of the capsule, as well as its ability to activate complement and inflammation was studied. Their study has shown that the device (alumina membrane) is non-toxic.

A U.S. Patent was granted to William W. Cimino [19] for the use and method of making aluminium ultrasonic surgical applicator. According to William W.Cimino, aluminium oxide is a brittle ceramic. Normally if aluminium oxide was used in or on an ultrasonic applicator, crack would be easily formed as the applicator extends and contracts during vibration, which results in a decrease in fatigue strength and increase of the potential for fracture of the applicator. He found that, the requisites for an acceptable applicator can be achieved if an applicator for an ultrasonic surgical device is fabricated with a core of aluminium alloy and a thin coating of aluminium oxide and the thickness of the aluminium oxide coating is properly controlled. Specifically, when the coating is "clear," i.e., having no dye or colour additives, the thickness of the aluminium oxide coating should be about 0.0001 and 0.0003 inch, more favourable between 0.0001 and 0.0002 inch. Coatings less than about 0.0001 inch does not provide sufficient biocompatibility. Coatings thicker than about 0.0005 inch will have an increased tendency to crack and thereby decreases the fatigue strength and increases the potential for fracture.

Table 2: Material properties

	Stainless Steel	***Titanium***	***Aluminium***	***Cortical bone***
Density ($g\ cm^{-3}$)	8	4	2.7	0.5
Young's Modulus (GPa)	193	144	70	7-30

3. Materials and Methods

This chapter details the various materials used in the study, the methods used for process designing and evaluation of various mechanical properties like ultimate tensile strength, hardness, compressive strength, wear resistance, bending strength, impact resistance and corrosion. The method used for anodising Aluminium specimens is also described.

3.1 Selection of Materials Used in the Study

Two materials Aluminium and Stainless Steel are selected for the study. Aluminium is selected for its strength and light weight having a density of 2.7 g/cm^3. Stainless Steel 316L is chosen as it is already used for orthopaedic implants. The aim of the study is to evaluate the possibility of replacing Titanium and Stainless Steel implants with anodised Aluminium implants.

Table 3: Chemical composition of materials

Stainless Steel 316L								
Fe	C	Cr	Mn	Mo	Ni	P	Si	S
72	0.02	18	2	3	14	0.045	1	0.03

Aluminium 6061							
Al	Cu	Cr	Mn	Mg	Fe	Zn	Si
98.1	0.2	0.05	0.05	0.6	0.15	0.05	0.6

Above values are maximum possible percentages of total mass

3.2 Anodising

Aluminium anodising is an electrochemical process in which an oxide (anodic) layer is chemically built on the surface of the metal. The anodic oxide structure originates from the aluminium substrate and is composed entirely of aluminium oxide. This aluminium oxide is not applied to the surface like paint or plating, but is fully integrated with the underlying aluminium substrate, so it cannot chip or peel. It has a highly ordered, porous structure that allows for secondary processes such as colouring and sealing. Anodising is accomplished by immersing the aluminium into an acid electrolyte bath and passing an electric current through the medium. A cathode is mounted to the inside of the anodising tank; the aluminium acts as an anode, so that oxygen ions are released from the electrolyte to combine with the aluminium atoms at the surface of the part being anodised. Anodising is hence a matter of highly controlled oxidation-the enhancement of a naturally occurring phenomenon. The coating thickness and surface characteristics are tightly controlled to meet end product specifications. Sealing process closes the pores in the anodic film, giving a surface resistant to staining, abrasion and colour degradation.

Table 4: Standards Used

Sl.No.	Test carried out	Standards used
1.	Tensile Test	ASTM E-8
2.	Charpy Impact Test	ASTM E-23
3.	Brinell Hardness Test	ASTM 92
4.	Wear Test	ASTM G-99
5.	Compression Test	ASTM E-9
6.	Bending Test	ASTM D-790
7.	Corrosion Test	ASTM G-31

3.3 Corrosion Test

The specimens were immersed in a simulated biological solution (SBS). The SBS chosen was Phosphate-Buffer Saline (PBS) solution. The specimens were kept immersed for 8 days (192 hours), every 48 hours the specimens were taken out, dried and weighed to determine weight loss.

Table 5: Composition of PBS Solution

Salt	Concentration (g/liter)
NaCl	8.00
KCl	0.20
Na_2HPO_4	1.42
KH_2PO_4	0.24

4. Results and Discussions

4.1 Comparison of results with mechanicals properties of bone

Table 6: Comparison of mechanical properties of bone

	SS 316L	*Al 6061*	*Cortical Bone*
Tensile Strength (MPa)	543[6]#	235#	151[10]
Compressive Strength (MPa)	549[6]#	291#	180[10]
Impact Energy(Jm^{-2})	$1.7*10^6$[6]	$0.9*10^6$	$0.18*10^5$[13]
Bending Strength (MPa)	1744[6]#	417#	238[14]
Brinell Hardness Number	177[6]	93	9.1[15]

#indicates the strengths at elastic limit, since yielding is not favourable phenomenon

4.2 Experimental Results On Anodised Aluminium Alloy

1) Anodising the aluminium alloy does not affect the tensile strength, ultimate strength was experimentally found to be 265 MPa which remains within the normal range for Al6160 alloy (130 - 310 MPa). Elastic limit was determined to be 235 MPa from stress-strain curve.
2) The aluminium alloy being highly ductile in nature does not fracture under compressive load. The specimens were loaded up to 350 kN. Load versus deflection graphs were obtained from which stress - strain curve was plotted, elastic limit was determined from the graph.
3) In the Charpy impact test the angle of rise was 84 degree for anodised aluminium alloy. The impact energy was subsequently determined to be 0.9*10^6 J/m^2.

4) In 3-point bending test the stress at the elastic limit was found to be 490 MPa.
5) In Brinell hardness test the indentation diameter was 0.9mm in all trials, corresponding to a Brinell Hardness Number (BHN) of 93.
6) In both constant time and constant load pin on disc testing the wear rate of aluminium was far greater than that of stainless steel. The wear rate was 10 times greater.

4.3 Corrosion Test Results

The immersion corrosion test specimens were weighed after immersing it for above mentioned duration. Specimens were weighed at intervals of 48 hours. The test results show that the weight loss of the specimens is negligible. This negligible weight loss maybe due to the error in the weighing machine or due to the surrounding conditions where the specimens are being weighed. No changes on the surface of the specimens were observed.

Table 7: Corrosion test results

Material	**Sl No.**	**0 hours**	**48 hours**	**96 hours**	**144 hours**	**196 hours**
Al 6160	1	34.03	34.03	34.02	34.02	34.02
	2	34.18	34.18	34.17	34.17	34.16
	3	34.07	34.07	34.06	34.04	34.04
SS 316L	1	100.02	100.02	100.00	100.00	100.00
	2	99.93	99.92	99.91	99.91	99.91
	3	100.06	100.05	100.05	100.05	100.05

(Weight of specimen in gram)

5. Conclusion

Anodising the aluminium alloy does not adversely affect the mechanical strength properties of the material. The results of the experimental tests on anodised aluminium specimens were more than satisfactory barring that of wear. In most results the strength of aluminium alloy was close to 2 times higher than that of bone.
The corrosion resistance of the anodised specimens was on par with that of stainless steel specimens showing almost no weight loss while immersed in simulated biological solution over a period of 8 days. Also, the corrosion test carried out by immersion needs to be supplemented by electrochemical tests required for biomedical implants namely ASTM 746 and ASTM 2129
Given the poor wear results of anodised aluminium alloy 6160, testing of alloys with better wear properties or increasing the depth of oxide film developed by anodising process is suggested.
Based on the above we believe anodised aluminium alloys, especially 7000 series alloys present a attractive alternative to the biomaterials already in use for orthopaedic implants namely SS 316L and Titanium alloy (grade 5 & grade 23). As with any medical drug or device extensive clinical trials are required before it can be granted approval for use.

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