

Review Article

A Review on Biomaterials in Orthopedic Bone Plate Application

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Accepted 20 July 2015, Available online 25 July 2015, Vol.5, No.4 (Aug 2015)

Abstract

This paper glances through the biomaterials used in the biomedical industry for a bone plate application. It has found among all biomaterials, currently titanium and stainless steel alloys are the most common in manufacturing of bone plates. The metallic bone plates have certain problems like metal incompatibility, corrosion, magnetism effect, anode-cathode reactions, including a decrease in bone mass, increase in bone porosity therefore composite materials for bone plates with higher strength and stiffness and more similarity to natural bone had started to develop. The main requirement for the choice of the biomaterial is its acceptability by the human body. The most common types of materials used as biomedical materials are Metals, Polymers, Ceramics, and Composite. This review touches on various aspects of biomaterials such as its biocompatibility, advantages and as well mechanical properties.

Keywords: Biomaterial, Orthopaedic bone plate, fracture fixation, composite, ceramics, Stiffness.

1. Introduction

Origins of biomaterials date back thousands of years, as archaeologists have found that metal dental implants have been used in 200 A.D. However they have been developed significantly after World War II (Dr A Thimmana Gouda, *et al*, 2014). Today, biomaterials are defined as “artificial or natural materials used in the manufacturing structures for replacing the lost or diseased biological structure to restore its form and function” (Javad Malekani, *et al*, 2011). Performance of biomaterials is controlled by two characteristics of bio functionality and biocompatibility. Bio functionality defines the ability of the device to perform the required function and refers to mechanical properties of the biomaterial, whereas biocompatibility determines the compatibility of the material with the body (Javad Malekani, *et al*, 2011).

Orthopaedic surgeons have been using metallic bone plates for the fixation of bone fractures. Recently, metallic prosthesis, which are generally made of stainless steel and titanium alloys, cause some problems like metal incompatibility, corrosion, magnetism effect, anode-cathode reactions, including a decrease in bone mass, increase in bone porosity (osteoporosis), and delay in fracture healing (callus formation, ossification) (stress shielding effect / stress protection atrophy) (Zheng-Ming Huang, *et al*, 2005). Due to insufficient bone growth, refractures after the removal of the prostheses are also widely reported.

It was also found that the difference in the elasticity of a metallic implant and bone may cause loosening of the implant (D. Chandramohan, *et al*, 2012). Natural fibres represent an environmentally friendly alternative by virtue of several attractive attributes that include lower density, lower cost, non-toxicity, ease of processing, renewability and recyclability (Dr A Thimmana Gouda, *et al*, 2014). Natural fibers present important advantages such as low density, appropriate stiffness and mechanical properties and high disposability and renewability. Moreover, they are recyclable and biodegradable (Dr A Thimmana Gouda, *et al*, 2014).

Polymeric composites are found to have fewer failures compared to other groups and are a better choice as alternative material which substitutes ceramic composites and metallic bone plates. They are variable and different in properties, performances and composition and found in different shapes and forms (Zahra S. Bagheri, *et al*, 2013). They can be also used as fillers and absorb some liquid material. Using polymeric composite material which has a lower modulus is popular (Zheng-Ming Huang, *et al*, 2005). The best choice would be reinforced polymeric material as composite material which has high strength and low modulus (Praveen Kumar A, *et al*, 2012). This paper aims to have a comprehensive review on developments and future advances in biomaterials for bone plates. Types of bone fractures observed in medical field and types of bone plates will be discussed at first.

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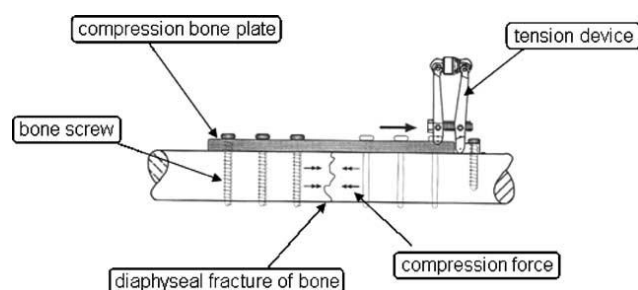
2. Bone fractures

The bone fractures are possible to repair in some different ways:

External fixation: In this procedure there is no need to open the tissue. The bone fracture is kept in some devices and material such as casts-splints. The casting material consists of composite material made of woven cotton and a calcium sulphate matrix and some reinforcement material such as glass fibers and polyesters.

Internal fixation: In this kind of fixation by using surgery techniques and implants the bone fracture is repaired. Depending on the bone fracture some different implants can be used such as wires, pins, screws, bone plates. Bone plates and screws are most common parts in internal fixation (Ghazal Hedjazi, 2009).

In the surgery field, patients with fractures are generally treated using compression bone plates made of stainless-steel, Cr-Co and Ti alloys as shown in Fig. 1. Although exhibiting reasonable fatigue strength, the stiffness of these metals (in between 110 and 220 GPa) is much higher than that of human cortical bone (around 20 GPa) (Zheng-Ming Huang, *et al*, 2005). As a result, the majority of the load is carried by the plate rather than by the underlying bone. Callus formation, ossification, and bone union at fractured part are refrained after the implant operation, and the whole bone structure, not only at the fractured part, becomes osteoporosis. The bone mass can be decreased by 20% and in some cases the bone re-fracture due to stress concentration around the bone screws can be induced after the removal of the plate. These phenomena are widely recognized as “stress shielding” effect, which is a main drawback for the use of metal bone plates (Zheng-Ming Huang, *et al*, 2005).



A compression plate is attached on tensile side of the fragmented bone. Tension device is pulling a compression plate and compression force is accordingly generated at the damaged bones (Zheng-Ming Huang, *et al*, 2005)

Fig.1 Schematic of a compression bone plate with a tension device

2.1 Materials choice for Bone Plates

The recent developments and future trends of the biomaterials of orthopedic bone plates are reviewed in the following sessions. It will cover the biomaterials, polymers and biocomposites.

Biomaterials used in orthopedics are inorganic metallic biomaterials. Biomaterials used in bone plate are neither bioactive nor biodegradable. However, they are the most common biomaterials for manufacturing medical devices such as hip joints, bone plates and dental implants (Dr A Thimmana Gouda, *et al*, 2014). Among biomaterials, stainless steel, cobalt alloys and titanium alloys have the most applications in orthopedics.

A. Stainless steel

Stainless steel is the most common biomaterial in manufacturing bone plates due to its advantages such as mechanical strength, cost, manufacturing implants, and deformation of implant during surgery. In practice, Stainless steel AISI 316L (ASTM F138 & F139) has the mostly used in biomedical applications because of its better fatigue strength, more ductility and better machinability (Dr A Thimmana Gouda, *et al*, 2014). However, it contains Nickel which has the potential for toxicity, sensitization and allergy. Therefore, Ni-free stainless steels have been recently developed for use in orthopedic field. In general, stainless steel is suitable in temporary implant devices such as fracture plates, screws and hip nails (Javad Malekani, *et al*, 2011).

B. Cobalt-Chromium Alloys

ASTM has recommended four types of cobalt-chromium (Co-Cr) alloys for surgical implant applications including cast Co-Cr-Mo alloy (F75), wrought Co-Cr-W-Ni alloy (F90), wrought Co-Ni-Cr-Mo alloy (F562) and wrought Co-Ni-Cr-Mo-W-Fe alloy (F563) (Javad Malekani, *et al*, 2012). While in all highly alloyed metals in body environment, galvanic corrosion can occur, cobalt based alloys are highly resistant to corrosion and especially to attack by chloride within crevices. Although cobalt based alloys are highly resistant to fatigue and cracking caused by corrosion they may fail because of fatigue fracture. It is also observed that cobalt alloys have lower biocompatibility and higher mechanical resistance compared with titanium alloys. In general, poor fabricability and high costs mean that Co-based alloys are currently unsuitable for broad use in bone plates (U Kamachi Mudali, *et al*, 2003).

C. Titanium alloys

Attempts to use titanium for manufacturing implants date to late 1930s and has been industrially used since 1950s (Soumya Nag, *et al*, 2012). Mechanical properties of implants are made by commercially pure titanium (cpTi) mostly depend on manufacturing method and amount of trace elements present. Also, apart from low mechanical strength, porous coated titanium alloy implants show 50-75% lower fatigue strength in compare with the equivalent fully dense materials. Only four grades of cpTi are distinguished for medical applications (ISO 5832-2) depending on

the amount of nitrogen, carbon, hydrogen, iron and oxygen (ISO 5832-2). However, cpTi (ASTM F67) and Ti-6Al-4V ELI alloy (ASTM F136) are mainly used for biomedical applications (Soumya Nag, *et al*, 2012).

Shape memory alloys (SMA) possess certain original properties, particularly their ability to return to their memorized shape by a simple change of temperature. SMAs have been considered for medical applications because of their capabilities of recovering the original shape after large deformations induced by mechanical load and maintaining the deformed shape up to heat induced recovery of the original shape. In spite of disadvantages of nickel, Ni-Ti (Nitinol) and Ti-Ni-Ag alloys have been mainly studied for orthopedics and it has been shown that it does not make toxicity and sensitization problems (Javad Malekani, *et al*, 2011).

D. Other biometals

Several other metals have been studied for a variety of specialized implant applications. Tantalum (Ta) is known as an excellent biomaterial for bone plates because of excellent ductility, toughness, corrosion resistance, biocompatibility, bioactivity, cellular adherence, growth and differentiation with abundant extracellular matrix formation (Soumya Nag, *et al*, 2012). However, it has limited applications because of processing challenges, poor mechanical properties and high density. Platinum group metals (PGM) such as Platinum (Pt), Palladium (Pd), Rhodium (Rh), Iridium (Ir), Ruthenium (Ru), and Osmium (Os) are extremely corrosion resistant, but have poor mechanical properties (U Kamachi Mudali, *et al*, 2003). Therefore, currently they are not feasible for bone plate.

Magnesium is also very important for biological functions of the human body. Main disadvantage of most magnesium alloys is that they corrode too rapidly in physiological environments which produce hydrogen pockets near the implant and retard the healing process (Sebastian Bauer, *et al*, 2013). Studies on Mg-Zn alloys highlights that they have high tensile strength and have no adverse effect because of the zinc released. Similarly studies on Mg-Zn-Ca, Mg-Y-Zn, Mg-Ca, Mg-Dy acknowledge their high potential for using in fabrication of internal fixation implants (Sebastian Bauer, *et al*, 2013).

E. Composite Biomaterials

The idea of using composite in bone implant came since 1980. Considering the observed problems and failures from the previous materials, using composite materials with higher strength and stiffness and more similarity to natural bone had started to develop. In manufacturing of medical composites, bioactivity is a main factor that should be considered in choosing the material.

Polymeric composite material is stable in the body and in vivo condition without any change in strength

and stiffness. It can be made of thermoset or thermoplastic composite materials. In partially cured epoxy material are some toxic monomers reported (Ghazal Hedjazi, 2009). Thermoplastic CF/PMMA-CF/PP-CF/PS-CF/PE-CF/Nylon CF/PBT-CF/PEEK- (this material is biocompatible and difficult to hydrolyze) it is also stiff enough and fatigue resistant and a rejection of carbon fibers by tissue has not seen to be much. (PLA) or polylactic acid poly gesticolic acid (PGA) can be degraded in the body, this material gets weaker after a certain period (R.Sakthivel, *et al*, 2014).

Polymeric composites are found to have fewer failures compared to other groups and are a better choice as alternative material which substitutes ceramic composites. They are variable and different in properties, performances and composition and found in different shapes and forms (Praveen Kumar A, *et al*, 2012). They can be also used as fillers and absorb some liquid material. Using polymeric material which has a lower modulus is popular. The best choice would be reinforced polymeric material as composite material which has high strength and low modulus. (Zahra S. Bagheri, *et al*, 2013). Thermoplastic polymers form strong bonds; they are biocompatible and show resistance to wetting and moisture (due to strong bonds). Thermosetting polymers such as Epoxy resins, they are different and vary in biocompatibility and durability. They are not so good in orthopedic applications. But they have found to be attractive in fracture fixation. Their processing characterization is much better than thermoplastics (Praveen Kumar A, *et al*, 2012)

The hybrids composite has emerged and have the potential reinforcement material for composites and thus gain attraction by many researchers. This is mainly due to their applicable benefits have they offer low density, low cost, renewable, biodegradability and environmentally harmless and also comparable mechanical properties with synthetic fiber composites (R.Sakthivel, *et al*, 2014). In the case of using composite materials as bone plates, a hybrid composite may need to be used to have a combination of properties with acceptable performance in different directions which may not be achieved by one type of fiber. Many investigations have been done regarding hybrid composites, but few studies involve hybrid composites reinforced with natural fibers and carbon fibers, and no studies have considered hybrid composites with a "sandwich structure" for bone fracture plate applications (Zahra S. Bagheri, *et al*, 2013).

Natural fibers present important advantages such as low density, appropriate stiffness and mechanical properties and high disposability and renewability (D. Chandramohan, *et al*, 2012). Moreover, they are recyclable and biodegradable. Natural fiber reinforced polymer composite materials which are less rigid than metals may be good alternatives because of properties closer to bone mechanical properties (D. Chandramohan, *et al*, 2012). It was found that they help to avoid stress shielding and increase bone

remodeling (Dr A Thimmana Gouda, *et al*, 2014). Orthopaedic surgeons have been using metallic bone plates for the fixation of bone fractures. Apparently, metallic prosthesis, which are generally made of stainless steel and titanium alloys, cause some problems like metal incompatibility, corrosion, magnetism effect, anode-cathode reactions, including a decrease in bone mass, increase in bone porosity, and delay in fracture healing (Dr A Thimmana Gouda, *et al*, 2014). Natural fiber reinforced polymer (NFRP) composite plate material can be coated with bone graft substitutes such as calcium phosphate and hydroxyl apatite and this plate material can be used for both inside fixation and external fixation of fractured human bone (D. Chandramohan, *et al*, 2012).

3. Mechanical aspects of implant materials

Biomechanical definition of bone fragility includes at least three components of strength, brittleness and work to failure, which are determined by the concepts of yield strength, Ultimate tensile/compression strength and toughness (Javad Malekani, *et al*, 2011). Orthopedic implants must reinforce the fractured-bone from these points of view (Javad Malekani, *et al*, 2011). These parameters not only define the processability of a material, but also are key to the rate of success and biocompatibility of an implant in the field of hard tissue replacement. A goal may be matching of Young's modulus of implants and bone, the latter for compact bone ranges 10–30 GPa(Zahra S. Bagheri, *et al*, 2013). If the Young's modulus for example of a hard tissue implant material is much higher than that of cortical bone, the load bearing is not ideal and the risk of stress shielding occurs (Zheng-Ming Huang, *et al*, 2005). In particular this may lead to a mechanical insulation of the synthetic material from the tissue, so that the typically observed balance of tension induced remodelling of bone is hampered, and as a direct result the loosening of the prosthetic device may occur (Sebastian Bauer, *et al*, 2013). Table 2-2 and Table 2-3 show that ceramic and metallic materials are 10-20 times higher in modulus than natural bones (Ghazal Hedjazi, 2009). This case itself can lead to some failures in using these materials. One of the problems in orthopedic has been arisen from this fact that the stiffness between metal or ceramic implants were not match with host bone tissue and this led to the less load bearing in bone compared to implant that is called "stress shielding" or stress protection (Zheng-Ming Huang, *et al*, 2005).

Table 1 Properties of emetallic and ceramic biomaterials (Ghazal Hedjazi, 2009)

Material	Modulus(Gpa)	Tensile strength (Mpa)
Stainless steel	190	586
Ti-alloy	116	965
Amalgam	30	58
Co-Cr alloy	210	1085

Ceramic material		
Alumina	380	300
Bioglass	35	42
Zirconia	220	820
Hydroxyapatite	92	50

Table 2 Mechanical properties of some bones (Ghazal Hedjazi, 2009)

Tissue	Modulus(Gpa)	Tensile strength (Mpa)
Cortical bone	17.7	133
Enamel	84.3	10
Cancellous bone	0.4	7.4
Dentine	11.0	39.3

Conclusions

Biomaterials play a prominent role in efficiency of bone plates because of their direct and indirect effects on healing process, and therefore numerous studies have been conducted in this field. As a result, biomaterials used in manufacturing bone plates have been significantly improved and their approach has been totally changed from bioinert stabilizers to bioactive and biodegradable healing facilitators. Also, many investigations have been performed to maximize their biocompatibility, bioactivity, biodegradability, and cellular interaction. However, currently specific classes of stainless steel and titanium alloys are mainly used in practice.

Additionally

- 1) The bone plate with low-stiffness material offers less stress-shielding to the bone, providing higher compressive stresses at the fractured interface to induce accelerated healing in comparison with Ti alloy and stainless-steel bone plate. Therefore, the bone plate with low-stiffness material may be recommended for treatment of long bone fractures.
- 2) We can compare the existing material (SS316L) with the natural fiber or hybrid polymer composite material and these properties can be comparing to orthopedic bone plates.
- 3) The polymer composite biomaterials are particularly attractive because of their manufacturing processes and properties comparable to those of the host tissues.
- 4) Innovation in the composite material design and fabrication processes are raising the possibility of realizing implants with improved performance.
- 5) Titanium alloy has high strength, when compared to other materials, the problem associated with its include: metal incompatibility, corrosion, magnetism effect, anode-cathode reaction, decrease in bone mass, increase in bone porosity and delay in fracture healing.

Although bioceramics are bioactive and biocompatible, they cannot be used independently in bone plates, which usually involves with loading. Despite having high potential for use as coating of inert biometals, they have some serious drawbacks such as cracks, porosities and delamination. Further studies should be conducted to solve these problems. After solving these problems they can be used as a suitable coating of bone plates.

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