CHAPTER I
INTRODUCTION

Since the very beginning, human beings have always tried to explain the natural phenomena occurred every day, from the sunrise to the storms, and one of the most intriguing how our body works, in the old days our ancestors used to give the name of “gods” to everything that they did not understand, but it was not until years later when the first men of science studied the real why and how of the things, ending the era of the myth.

Biomechanics is the study of the structure and function of biological systems using the method of mechanics. It is one of the most important disciplines within the biomedical sciences. By applying scientific methods to biomedical research, this science provides quantitative, deterministic approach to biomedical research helping to understand more some other reactions on living beings. Mechanics is closely related to mathematical concepts that support biomechanics as essential. These include aspects of calculus and vector algebra. [6]

Biomechanics works in analytical and constructive ways, this means, analyzes the movement of living beings and constructs elements able to adapt to living bodies, and these elements require to be elaborated with very special materials that fulfill specific characteristics, these materials are called biomaterials.[43]

1.1 Biomaterials

Biomaterial can be defined as biological materials such as skin, wood, or any other element that replaces a function of tissues or organs of living beings. In other terms a biomaterial is a pharmacologically inert substance designed to be implanted or added inside the living system. It can also be any substance, element or combination of them, synthetic or natural that can be used to substitute partially or completely the function of some part of the living body.[58]

Since biomaterials restore functions inside the body, it is essential to understand the relations between properties, functions and structure of biological materials, which is why biomaterials are studied under three main points of view: biological materials, implant materials and the interaction existent between both inside the body. Artificial limbs, ear amplifiers and external prosthesis are not considered as implants.

The ultimate application of biomaterials has been the application to fracture fixation, restoring the structural integrity of the bone. In order to archive this objective it is needed to take into consideration some complex interplay of properties, device design and physiologic requirements; it is also important to consider the place and type of fracture, possible approaches and rapidity of bone healing.

So it is responsibility of the surgeon to know all the possibilities of materials and procedures to perform a successful medical intervention, and in the other hand, responsibility of the materials scientist to develop implants of optimum design that take advantage of the properties of the available materials.

The requirements for materials to be used in orthopedic fixation procedures are clinical, manufacturing and economic, in descending order of importance. Clinical requirements refers to use a material that has suitable mechanical properties, than make it able to accomplish its function of fixation and maintenance of fracture. As well as being a material that not degrades in response to the corrosive conditions of biologic environment.

Manufacturing requirements refers to have properties that permit an optimum fabrication and design, while cost requirements most be considered but, in human application these are not supposed to be a critical factor of decision. [45]

The most important nonmechanical requirement of an orthopedic biomaterial is the inertness; an ideal implant material should not degrade at all; this of course is impossible, but it is possible to get acceptable degree of degradation in biologic environment.

The corrosion of metals in biologic fluids is a reaction produced for the contact of the metal ions with and aqueous electrolyte surrounding. The alloys used for orthopedic implants are designed to prevent accelerated corrosion by a passivating oxide layer than acts like an electrical resistor to retard the anodic dissolution.

These alloys must be very strong, because they must not brake or bend under heavy loads; not too stiff since a very stiff device will stress shield the skeleton a lot; and biocompatible in order to be well tolerated by the bone tissue.

The most used materials for structural implants are metals since they own a superior strength. Many metals and alloys have been designed to have a very high resistance to corrosion. But the most metals are not suitable for implantation because of the poor tolerance of the body, only few metals have suitable biocompatibility. These materials are based on iron, cobalt, nickel, titanium, tantalum, zirconium, silver and gold.

Of these materials with acceptable biocompatibility, tantalum, gold and silver do not have the necessary mechanical properties for an implant; zirconium is too expensive, and from the four metals remained there have been developed six alloys described in table 1.1. [72]

Table 1.1 Biomedical alloys developed with suitable materials

COMPOSITION (% WEIGHT)	STAINLESS STEEL ASTM F55 OR F56 WROUGHT TYPE B	CO-CR ASTM F75 CAST	CO-CR ASTM F90 (VITALLIUM) WROUGHT
Tungsten	—	—	14–16
Cobalt	—	Bal (57.4–65)	Bal (46–53)
Chromium	17–20	27–30	19–21
Nickel	10–14	2.5 max	9–11
Molybdenum	2–4	5–7	—
Iron	Bal (59–70)	0.75 max	3.0 max
Carbon	0.03 max	0.35 max	0.05–0.15
Manganese	2.00 max	1.0 max	2.0 max
Phosphorus	0.03 max	—	—
Sulfur	0.03 max	—	—
Silicon	0.75 max	1.00 max	1.00 max

COMPOSITION (% WEIGHT)	STAINLESS STEEL ASTM A296 CAST	TITANIUM (PURE) ASTM F67 GRADE 4, FLAT PRODUCT CAST/WROUGHT	TITANIUM 6A1-4V ALLOY ASTM F136 CAST/WROUGHT
Cobalt	—	—	—
Chromium	16–18	—	—
Nickel	10–14	—	—
Molybdenum	2–3	—	—
Iron	Bal (62–72)	0.5 max	0.25 max
Aluminum	—	—	5.5–6.5
Vanadium	—	—	3.5–4.5
Titanium	—	Bal (99+)	Bal (88.5–92)
Carbon	0.06 max	0.10 max	0.08 max
Manganese	2.00 max	—	—
Phosphorus	0.045 max	—	—
Sulfur	0.030 max	—	—
Silicon	1.0 max	—	—
Oxygen	—	0.45 max	0.13 max
Nitrogen	—	0.07 max	0.05 max
Hydrogen	—	0.015 max	0.015 max

TRADE NAME	TYPE	MANUFACTURER
Alivium	Co-Cr	Zimmer Orthopaedic Ltd., London, England
CoCroMo	Co-Cr	Orthopaedic Equipment Co., Bourbon, Indiana
Francobal	Co-Cr	s.a. Benoist Girard & Cie, Heronville, France
Orthochrome	Co-Cr	DePuy, Warsaw, Indiana
Protosul-2	Co-Cr	Protek & Sulzer, Zurich, Switzerland
Tivanium	Ti-6A1-4V	Zimmer USA, Warsaw, Indiana
Vinertia	Co-Cr	Deloro Surgical Ltd., Stratton St., Margaret, England
Vitallium	Co-Cr	Howmedica, Rutherford, New Jersey
Zimaloy	Co-Cr	Zimmer USA, Warsaw, Indiana

(Black J.: Biomaterials for internal fixation. In Heppenstall B (ed): Fracture Treatment and Healing. Philadelphia, WB Saunders, 1980)

1.1.1 Cobalt Chrome Alloy

Cobalt chrome alloy is very compatible with human body. As a result of this compatibility, it is commonly used as implants and fixations. In comparison with other materials used in orthopedic fixations, cobalt chrome alloys have a greater biocompatibility than stainless steel but lower than titanium.

These alloys are highly resistant to corrosion and especially to attack by chloride within crevice. As in all highly alloyed metals in the body environment, galvanic corrosion can occur, but to a lesser extent than in the iron based alloys. Cobalt – chrome alloys are highly resistant to fatigue and to cracking caused by corrosion, are not brittle since they have a minimum 8% of elongation. [38]

The molybdenum presented in this alloy decreases the grain size of the alloy, yielding improved mechanical properties. Chromium oxide forms on the surface of the cobalt-chromium-molybdenum alloy, providing resistance to corrosion. Nickel can be added to improve resistance to corrosion, but according to specifications of the samples it is not the case for them.

The crystal size of the alloy must be uniform to obtain optimum mechanical properties; the structure must be free of voids and shall not contain any impurities. Since it is very difficult to prevent some of these cases in cast materials, the manufacturers use mechanical working to close the voids between individual crystals and to expel impurities by a method called Hot Isostatic.

In this process, the components are subjected to high pressure of at least 1000 atm. and at temperatures of at least 1100^{o}C, but below the melting point of the alloy, in an oxygen free zone. The most commonly used atmosphere is argon. This process is very suitable to improve mechanical properties of cast cobalt – chrome. The result of this process is a stronger alloy but also with a different microstructure. The carbides present in the solid solution are driven out of the finished product. This may change some properties of the material such as wear resistance. [60]

1.1.1.1 Biocompatibility

According to a study made in July 2003, by a medical research corporate in Santa Clara, CA, USA. Cr-Co-Mo alloy was tested in accordance with two general regulations and guidance documents: [71]

- The Federal Good Laboratory Practices Regulations (2 1 CFR 0 58)
- International Standards IS0 10993-1 Part 1 : 1997 *(Biological Evaluation of Medical Devices)*

And the results are shown in table 1.2.

Table 1.2. Results of Biocompatibility tests

BIOCOMPATIBILITY TEST	***MEANING AND RESULT***
Carcinogenicity Test	Literature Reference – carcinogenicity testing not necessary
Cytotoxicity Test	Non-cytotoxic – PASS
Hemolysis Test	Non-hemolytic – PASS
Systemic Injection Test	Non-toxic – PASS
Intracutaneous Test	Non-irritating – PASS
Intramuscular Test	Non-toxic – PASS
Ames Mutagenicity Test	Non-mutagenic – PASS
Sensitization Test	Non-sensitizing – PASS
Subchronic Test	Non-toxic – PASS
Rabbit Pyrogen Test	Non-pyrogenic – PASS
LAL Pyrogen Test	Non-pyrogenic - PASS
Coagulation Prothrombin Time	No adverse effect on coagulation prothrombin time - PASS
Unactivated Partial Thromboplastin Time (UPTT) Assay	No adverse effect on UPTT – PASS

1.1.2 Comparison of different biomaterials

At the present, there is no material that can reproduce perfectly the mechanical properties of bone. Metals have sufficient strength and fracture toughness but relatively high stiffness, which can lead to weight shielding problems. Ceramics are very hard materials, strong in compression, but exhibit low fracture resistance. Polymers have low stiffness values, medium fracture toughness but poor strength.

Chrome Cobalt alloy is stronger than stainless steel. The first presents a strenght range between 430 and 1028 MPa, compared to the 230 and 1160 MPa for 316L Stainless Steel. Chrome Cobalt is also more corrosion resistant and has a higher Young’s Modulus.

Studies have revealed that Chrome Cobalt alloys are more compatible with human body than stainless steel. The only disadvantage is that stress shielding is a risk.

Mechanical properties of stainless steels are considered as good relatively to other implant alloys, but to maintain the austenitic microstructure, the normal hardening and heat treatments can not be performed. Hardening can only be achieved by a cold-working process; it increases 40% the ultimate strength, but in addition decreases ductility in 80%. Stainless steel alloys are the cheapest and most easily fabricated. [16]

Titanium alloy presents similar mechanical properties to cold-worked stainless steel, with excellent corrosion resistance. It is more weldable and machineable than pure titanium. It is used for patients with hypersensitivity reactions of some constituents of stainless steel or cobalt – chromium alloys.

Table 1.3. Characteristics of Biomaterials.

Characteristics	***S-Steel***	***Vitallium***	***Ti-6Al-4V***
Stiffness	High	Medium	Low
Strength	Medium	Medium	High
Corrosion Resistance	Low	Medium	High
Biocompatibility	Low	Medium	High

Finally, cobalt – chromium alloys display a useful balance between mechanical properties and biocompatibility; being superior to stainless steel in strength and corrosion, but more expensive to manufacture.