ASPECTS OF ORTHOPEDIC IMPLANTS AND PROSTHESES. MATERIALS. PROCESSING TECHNOLOGIES

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Abstract. *The goal of this paper is to summarize and present the types of orthopaedic implants and hip prostheses, the biocompatible materials used and the conventional and unconventional processing technologies used to make them.*

Keywords: *implants / prostheses, biomaterials, conventional / unconventional processing technologies*

1. INTRODUCTION

Biological motion (life and locomotion of the living organisms) is a superior form of movement, which has special qualities and mechanisms that can not be explained solely by the application of mechanical movements or by the physical or chemical laws, which are considered lower forms [1].

In the understanding and interpretation of the biological motion, the application of mechanical, physics or chemistry laws fails to reproduce the whole complexity of the phenomena.

The application of these laws may render, schematic and mechanistic, only singular aspects of the complex biological process which is the animal or human locomotion. Mobility is a basic function of the human body and when this cannot be performed, a series of problems arises from the fact that the human being becomes socially dependent.

The research in the process of achieving an implant / orthopaedic hip prosthesis is based on the knowledge of the locomotor system, of the hip joint anatomy, the bone structure and its shape and on the study of the forces acting on the joint and bone, the knowledge and choice of the biocompatible material for implants / prosthesis and the best manufacturing technology.

The natural hip joint (Figure 1) is a "ball in cup"-shape joint. The "ball" is nothing but the head of the femur. The "Cup" is the acetabulum, a hip bone cavity.

Although continuous improvements are made on the implants' design, materials and fastening techniques, the ideal solution has not been found yet, and the basic concepts defined by Sir John Charnley (1911-1982), regarded as the father of modern prosthetic arthroplasty [2], are still valid. "The design of the single block "banana"-type tail stem with a 32 mm femoral head, which is between the 22.2 mm value proposed by Charnley and the 38+ mm value and above proposed by himself and by other authors, all coupled with a polyethylene cup, became an ideal implant standard great popularity in the '70s " [3], [4], [5], [6].

Figure 1 X-ray photograph of the normal joint morphology

2. IMPLANTS AND ORTHOPEDIC PROSTHESES

Vestiges and some documents prove some preoccupation for the construction of prostheses several hundred years ago. Real progress is evident in the sixteenth century.

Only in the twentieth century there were stated precise rules for the surgical treatment of fractures by means of metal devices. In 1907 A. Lambotte (Belgium) defines fixation: "My aim is mostly the bone suture study, or speaking more precisely, fixation" [7].

Immobilization or surgical fixation is done with screws, plates with screws, clasps, wire, bindings, stems or any other mechanical means of fixation, using compatible materials (austenitic steels, titanium and titanium alloys that do not corrode).

A. Lambotte performs internal fixation with plates and external clasps and in 1913 he publishes his work - "Operative Treatment of Fractures" which highlights the functional principles for the internal fixation of the fractures occurred inside joints. (Figure 2) [7].

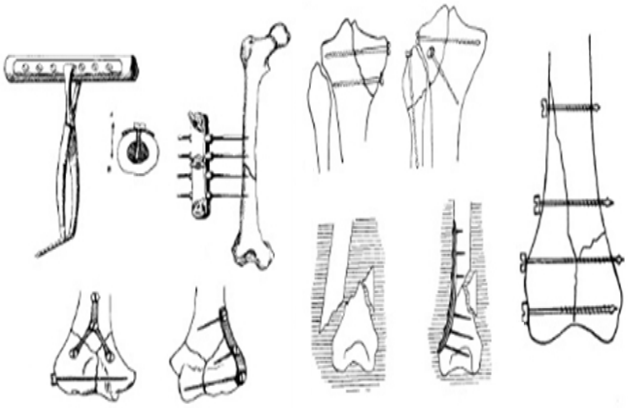

Figure 2 Fracture Fixation Methods, A. Lambotte

For fracture fixation there are used various devices in the form of wire rods, stems, screws, etc. These were the first metal implants, from the simplest to the most complex forms. There are several types and sizes of plates; pictures of osteosynthesis plates are shown in Figure 3.

Figure 3 Types of osteosynthesis plates

Figure 4 shows various models of femur osteosynthesis plates and their positioning.

Figure 4 Femur osteosynthesis plates and their positioning

Fracture fixation plates are devices commonly used in the healing of broken bones.

For fixing fractures along the bone there are used intramedullary devices that are inserted in the intramedullary cavity.

In comparison with plate fixation, intramedullary devices can position the bone so as to respond better to the bending and they are better also for the central-axial fixation. However twisting resistance is lower than in the plate fixation's case, which is why these devices are used on a small scale [8]. Figure 5 shows a screw-plate fixation device, and Figure 6 shows various examples of nail-plate fixation systems.

Figure 5 Screw-plate fixation device

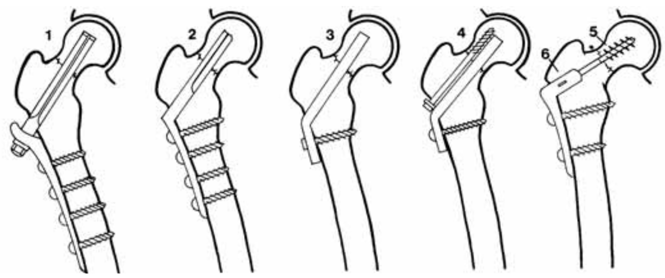

Figure 6 Examples of fixation using a nail-plate, blade-plate or screw-plate system used in the femoral neck fracture fixation

1 - McLaughlin nail-plate;

2 - STAC nail-plate, blade-plate;

3 - simple plate-nail;

4 - Additional anti-rotational screw;

5 and 6 - DKP (STAC) or DHS (AO) screw-plate where a compression screw (5) fastened in the proximal fragment slips in the distal part of the material (6) which is fixed to the shaft with 1-2 screws [9].

Another type of fixation, with centromedullary plugging stem, is shown in Figure 7.

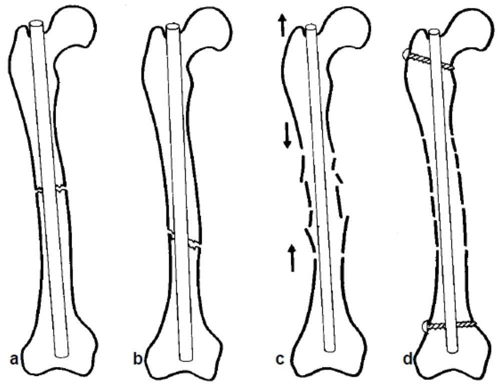

Figure 7 Osteosynthesis by stem plugging:

a, b, c – conventional type (Küntscher stem) for femur fracture, d - the modern version, with static locking [9].

Centromedullary rods are used when the plates are difficult to apply or when bone stability cannot be reached by other methods [8].

In the hip prosthesis procedure, the hip joint is replaced with a set of articulated implants (Figure 8) that allow natural movements of the hip.

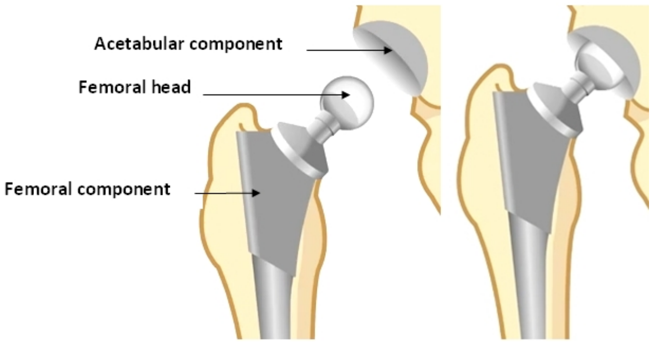

Figure 8 Total hip endoprosthesis, components

The types of prostheses and implants are varied, so as to cover the entire range of clinical indications.

The first short stem femoral prostheses made of Vitallium (1939-1940 Hohlman, 1946 Judet, 1950 Thompson), are shown in Figure 9 [10].

Figure 9 Short stem prostheses

Long-stem femoral prosthesis (unipolar, cervico-cephalic), made of stainless steel (Austin-Moore 1951, Thompson 1954), Figure 10 [10].

Figure 10 Long stem prostheses

To highlight the development of the implants' and orthopedic prostheses' typologies I will present several models of hip prostheses from two manufacturing companies: Stryker Howmedica Osteonics (Figure 11) and Zimmer (Figure 12).

Figure 11 Stryker Howmedica Osteonics Manufacturer

Figure 12 ZIMMER Manufacturer

Currently there is a great variety of types of prostheses / implants categorized by:

-the prosthetic design (single block stems, modular prosthetic stems);

-the biomaterials that the prostheses / implants are made of;

-fastening methods: cemented, uncemented.

3. BIOCOMPATIBLE MATERIALS

To achieve implants and orthopedic prostheses, special materials, known as biomaterials, are used.

A biomaterial is an altered synthetic or biological biomaterial material that is used to make an implant.

A classification of biomaterials can be made on structural criteria, by the used material classes: metal, ceramic, polymeric, composite and natural origin [7], [11], [12].

Metallic biomaterials are the most used class of materials for implants, prostheses and medical devices, because of its very good mechanical properties, corrosion-resistance and acceptable biocompatibility.

Table 1 presents some characteristics of the metallic materials used as orthopedic implants.

Table 1 Orthopedic characteristics of some metallic materials [8].

Specification	Stainless steels	Cobalt alloys	Titanium and titanium alloys
International standards	ASTM F-138 316L (plastic processing)	ASTM F-75 ASTM F-799 ASTM F-1537 (cast and forged)	ASTM F-138 ASTM F-136 ASTM F-1295 (plastic processing)
The main alloying elements %	Cr = 17-20 Ni = 12-14 Mo = 2-4	Cr = 19-30 Ni = 0-37 Mo = 0-10	Al = 6 V = 4 Hb = 7 Mo = 5-15
Advantages	-low cost -simple processing	- resistance to wear -corrosion resistance -stamina	Biocompatibility -low elastic modulus -stamina
Disadvantages	-Short term use	-Modest biocompatibility	-low shear-strength
Uses	temporary devices	-dentistry -prosthetic rods	-femoral prosthesis components -permanent orthopedic devices.

The choice of material for manufacturing implant is aimed factors such as: type of interaction with the body - the host, duration of implantation, implant functionality.

4. MANUFACTURING TECHNOLOGIES

In terms of processing, not all metallic biomaterials used to make implants and orthopedic prostheses are cost effective. For example, Cobalt alloys are extremely difficult to machine when the desired implants / prostheses are complex in shape, and therefore these are achieved by casting or metal powder processing methods [13]. Titanium is relatively difficult to cast in complicated shapes so a Titanium ingot is processed mechanically.

Among the known processing technologies there are: the casting technology, the stamping technology, the material removal technology and, more recently, the rapid prototyping technology.

The processing technology by casting

The casting process consists mainly in filling a cavity (mould) with metal or a liquid alloy (Figure 13). The moulding-casting technological process includes the following operations:

-the casting technology engineering;

-producing the model of the part and the casting runner (the ledge);

-assembling the model and the casting gate;

-producing the mould;

-drying and assembling the shape;

-pouring the metal or the alloy in the shape (mould) [8].

Figure 13 Images from the casting of a hip prosthesis

To obtain metallic prosthetic components, high precision casting procedures are applied, in order that the cast part requires a small number of further processing. Casting procedures that provide accurate shapes and sizes to the parts, without the need for significant further processing, are: pouring in shell moulds with fusible models or thermo-active mixtures, and chilled casting.

The processing technology by stamping

The stamp (mould) is a tool with an internal cavity, made of one or more elements, which is used to give the material the desired shape by means of plastic deformation under pressure. For the stamping processing circular section semi-finished rolled bars are used.

The operations required by the processing by stamping are:

-designing and producing the mould (stamp);

-cutting the semi-finished rolled bar;

-heating the semi-finished bar to reach the plastic deformation temperature;

-hot-working in the mould;

-deburring and machining the prosthesis component (turning, drilling, etc.);

-performing the thermal treatment operations of annealing and temper hardening;

-final processing by grinding, marking, sterilization, packaging [8].

The processing technology by material removal

The processing technologies by material removal start from an amount of raw material and consist in removing the excess material by turning, milling, grinding etc. A modern method of processing by material removal is the one used by the CNC machine tools.

A CNC (computerized numerical control) machine tool is made up of the actual machine tool and the numerical control equipment (CNC).

During processing both the part and the tool can move.

Unconventional technologies by successive layer deposition

The Rapid prototyping manufacturing technology or Rapid Prototyping (RP) emerged in the '90s and is a technology based on adding material as much as needed and where necessary.

The new rapid prototyping technologies are able to produce high accuracy models and prototypes in a very short time, with the advantage of being directly functional.

Rapid prototyping technologies have been developed in several directions in the recent years, depending on the material used.

An example of rapid prototyping equipment is "ARCAM S12" (Figure 14), which uses metal powders (Cobalt-Chromium alloys, Titanium alloys, stainless steels, Aluminium, etc.), using an electron stream as melting source.

The accuracy achieved is + / - 0.1 mm, depending on the material, the thickness of the deposited layer and the powder grain. Parts such as the Osteosynthesis implants are made ready for use, requiring only sterilization.

Figure 14 „Arcam S12" Equipment

Another example is the "Titanium Version EOSINT M 270" equipment (Figure 15) [14].

Figure 15 „EOSINT M 270 Titanium Version" Equipment

Selective LASER sintering, known as SLS, uses various powder materials, from polyamide powders, metal powders, to Quartz or Zirconium based powders etc., which are melted in layers with a LASER beam of various powers. Based on the variation of the exposure intensity and the way the material layers are deposited, the hardness of the processed material may be controlled.

The working principle of LASER sintering is shown in Figure 16.

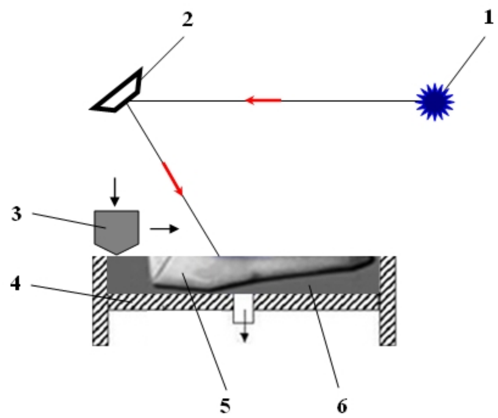

Figure 16 SLS Working principle

1 LASER system,
2 mirror system,
3 powder supply system,
4 mobile platform,
5 part
6 unsintered powder.

The LASER System (1) (Figure 15) generates a laser radiation which is redirected through a mirror system (2), towards the surface of the working platform (4). At the beginning of the working process, the platform (4) is in the highest position (at the top). A powder supply system (3) lays a thin layer of powder (a controlled amount) on the surface of platform. The LASER beam scans the surface of the platform following a path corresponding to the geometry of the first section through the implant to be processed (a 3D implant built in SolidWorks and saved as a .stl file. (Standard Tessellation Language) or resulting from 3D scanning data); after the scanning process, the LASER beam sinters the powder coating locally. After the scanning of first layer's surface, the working platform (4), lowers by a distance equal to the thickness of a new layer. The process is repeated until the implant / part (5) is completed. After the implant is complete, it is covered up by un-sintered powder (6), which substitutes the support and is removed only after the implant is cooled down.

The gauge of the part that can be made on rapid prototyping machine depends on the machine model, being thus limited by the size of the growth chamber.

The important feature of the RP process is the automatic translation of the 3D model to the physical model. An important impact of this aspect is the shortening of the period required by the new product to be released on the market.

The term RP used at first for material deposition technologies is replaced by more and more authors with the term SRP (Subtractive Rapid Prototyping), including milling in this category.

SRP is a geometric transformation of digital models into a physical object. The term "subtractive" suggests material removal during the process. This is what CNC rapid prototyping does.

5. CONCLUSIONS

Researches on different hip implants and orthopaedic prostheses prove that, although in the recent years the implant industry has developed quickly, ideal devices for replacement or repair of bone segments affected by trauma and diseases have not been made yet.

Neither in the biomaterial field has there been found the material able to eliminate all processes occurring at the interaction between biomaterial and the living organism without causing side effects, the human body representing a very aggressive medium in terms of corrosion for implant-used materials.

6. FUTURE DIRECTIONS FOR RESEARCH

Our future research will focus on delivering an implant / prosthesis achieved by means of conventional technologies by material removal and manufacturing the same implant / prosthesis with conventional technologies based on material deposition.

The comparative study of the results obtained in terms of mechanical strength, surface quality, productivity, and cost.

Conclusions on determining the technology to be used, depending on the nature of the implant to be made.

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