Orthopaedic Implants and Prostheses. Conventional and Unconventional Processing Technologies

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Abstract—The goal of this paper is to present the typology of hip implants and the processing technologies used in their implementation and to customize these technologies for some common types of implants.

Keywords—Implants, prostheses, manufacturing technologies.

I. INTRODUCTION

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.

Concerns for the construction of implants and prostheses date back several hundred years ago, as proved by certain remains and documents. 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" [1]. 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) Fig. 1.

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].

Fig. 1 Fracture Fixation Methods, A. Lambotte [1].

For fracture fixation there are used various devices (Fig. 2) in the form of wire rods, stems, screws, etc. These were the first metal implants, from the simplest to the most complex forms.

Fig. 2 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 [7].

Another type of fixation, with centromedullary plugging stem, is shown in Fig. 3.

![Fig. 3 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].

II. BIOMATERIALS

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

Concerning the prosthetics, relevant are the phenomenological analysis and the analysis of the internal prostheses (such as artificial joints, called endo-osseous, or dentures), which are inserted into the body, and not the external ones (such as artificial limb prostheses).

The interaction between the implant and the surrounding tissues must not induce, by means of corrosion or degradation, secondary changes in the body or any kind of implant instability. A determining role is held by the physical, mechanical, chemical, biological and the specific surface-developed processes. The human body is a highly aggressive environment in terms of corrosion to the materials used in implants because the tissue fluid in the human body contains water, dissolved oxygen, proteins and various ions [9], [10], [11], [12], [13], [14], [15].

A classification of biomaterials can be made on structural criteria, by the used material classes: metal, ceramic, polymeric, composite and natural origin [16], [17].

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.

Advantages, disadvantages and uses of the biocompatible metallic materials:

- stainless steels have the of the advantages of low cost and simple processing, the disadvantage consists in the short-term use, so stainless steels are used for temporary devices
- cobalt-based alloys are resistant to wear, corrosion and fatigue; the disadvantage consists in modest biocompatibility; cobalt alloys are used for prosthetic rods
- titanium and titanium alloys have the following advantages: good biocompatibility, low elastic modulus, fatigue strength; the disadvantage consists in low shear resistance; titanium and titanium alloys are used for femoral prosthesis components, for 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.

Titanium and titanium alloys are widely used in the development of biomedical devices and components, due to their properties like: relatively low elastic modulus, high strength, good fatigue strength, formability, machinability, corrosion resistance and biocompatibility. However, titanium and its alloys can not meet all the clinical requirements. Therefore, in order to improve the biological, chemical and mechanical properties, the surface modification is often performed [18].

In the long bones’ case (femur, tibia, humerus, radius, ulna), depending on the mechanical properties, there are two types of bone tissue: hard (cortical) tissues and soft (spongy) tissues. For the implants that will replace hard tissues, the Ti-6Al-4V alloy offers the best mechanical compatibility compared to other metallic materials [19].

III. MANUFACTURING TECHNOLOGIES

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

Not all metallic biomaterials are cost effective in terms of processing. Manufacturing technologies of medical devices are developing constantly to achieve lower prices and increase the quality and efficiency of the medical care.

The processing technology by casting

The casting process consists mainly in filling a cavity (mould) with metal or a liquid alloy.

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

The working principle of LASER sintering is shown in Fig. 4.

![Fig. 4 SLS Working principle](image)

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.

IV. Implants and Orthopedic Prostheses

In the hip prostheses procedure, the hip joint is replaced with a set of articulated implants (Fig. 5) that allow natural movements of the hip.

Joints connect the bone levers. Most joints are mobile, allowing movement in different directions: rotary motion or sliding (translation) motion [20].

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

![Fig. 5 Total hip endoprosthesis, components](image)

The femoral component has a neck and a rod (tail) and may be a sole piece (single block) or may be composed of two pieces, as in the case of the modular head components (Fig. 6).

![Fig. 6 Types of prostheses: a) -single block and b) - modular plus variants of metal and ceramic femoral head](image)

V. Stamping Operations included in the Technological Process of Orthopedic Hip Prosthesis Manufacturing

To achieve a single block femoral component hip prosthesis by drop forging the technological process consists in:

Step 1 drop forging

1.1 Forging phase 1 (mould 1)
1.2 Forging phase 2 (mould 2)
1.3 Deburring (burring mold)
Use a 100tf cam press
Step 2 Ball Processing (turning) on a 5-axes CNC machine.
Step 3 Ball Processing (polishing) on a polishing machine.
Step 4 Plating of the surface layer by sintering the prosthesis rod (there are several variants of plating: plasma jet superficial layering or SOL-GEL superficial layer deposition, which occurs at relatively low temperatures and does not require deposition installations or pressure switch).
Step 5 Technical Quality Control (dimensional control, dynamic bending and shear tests on testing facility).
Step 6 Packaging
Step 7 Sterilization (γ-rays).

The second element of the joint, the acetabular cup (Fig. 7) may be manufactured using metal or polymeric materials. On modern acetabular cups, the outside surface is covered by hydroxyapatite or ceramic layers for better fixation in hip bone cavity (acetabulum).

Fig. 7 Various versions of acetabular cup

Fig. 8 Types of osteosynthesis plates

Fig. 9 Various models of femur osteosynthesis plates and their positioning.

VI. TECHNOCAL PROCESS OPERATIONS FOR ACETABULAR CUP MANUFACTURING

The technological process for the acetabular component consists of:
Step 1 Stamping (eccentric press)
Step 2 Cupping (eccentric press)
Step 3 Inner and outer spherical processing (CNC machines)
Step 4 Deburring (CNC machine)
Step 5 Plating of the spherical surface on the outer side
Step 6 Writing (printing machine)
Step 7 Technical Quality Control
Step 8 Washing
Step 9 Packaging
Step 10 Sterilization (γ-rays).

There are several types and sizes of plates; pictures of osteosynthesis plates are shown in Fig. 8.

Fig. 8 Various versions of acetabular cup

Fig. 9 Types of osteosynthesis plates

Fig. 9 Various models of femur osteosynthesis plates and their positioning.

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].

Fig. 10 shows a screw-plate fixation device.

Fig. 10 Screw-plate fixation implant
VII. TECHNOLOGICAL PROCESS FOR A FIXATION IMPLANT

The technological process for the manufacturing of an implant fixation out of a bar-type blank consists of:

Step 1 Technical Quality Control of the bar-type blank
Step 2 Machining on CNC machine
Step 3 Bending (gradual bending device, device for determining the abatement)
Step 4 Heat Treatment
Step 5 Coverage (anodizing type)
Step 6 Writing
Step 7 Washing
Step 8 Technical Quality Control
Step 9 Packaging
Step 10 Sterilization (γ-rays).

VIII. 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.

Engineers and doctors altogether make efforts towards improving prosthetic devices by replacing the conventional technologies with the non-conventional ones.

My future research will focus on achieving a common type of implant, both by conventional and unconventional technology, followed by the comparative analysis of the two technologies in terms of mechanical strength, surface quality and cost effectiveness of the implant obtained.

A problem that occurs frequently with hip prostheses is the great friction between the acetabular cup and the femoral head. Currently the acetabular cup is made of high density polyethylene and the femoral head is made of porcelain. To eliminate problems arising from friction, tendencies are to use porcelain for the cup too, but porcelain is brittle and the risk for the cup to break is very high, although combining porcelain with porcelain has the great advantage of achieving a very low friction coefficient.

Therefore, one of my future concerns is to study new options in order to achieve low friction between the prosthetic head and acetabular cup.

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