Biomaterials and their requirements

1/Introduction

Biomaterials represent one of the major therapeutic advances of the last forty years. Defined as materials working under biological stress, destined to replace a function or an organ, they are present in many therapeutic strategies.

The choice of material is often a critical task in the process of developing a biomedical device whose performance is largely determined by that of the material used.

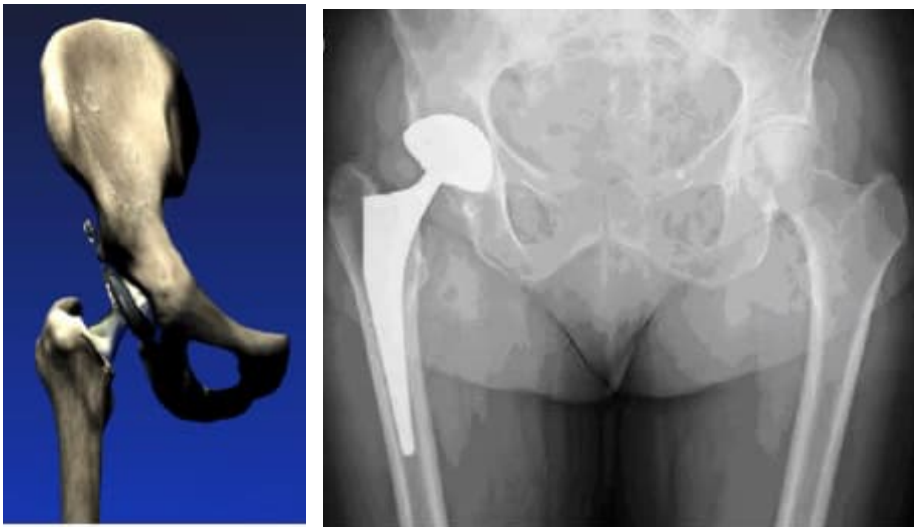

Fig.1 Orthopaedic implants

2/Categories of biomaterials

The nature (metals, biological grafts, ceramics, etc.), the biomedical applications (prostheses, prosthetic coatings, fillings of bone defects, etc.) and the properties of the biomaterials (long-term stability of the implant, controlled degradation, etc.) are very diverse. There is therefore a great diversity of biomaterials which can be classified into four broad categories according to their nature:

- **Metallic** biomaterials: Steels, Chrome, Cobalt, NiTi...
- **Ceramic** biomaterials: Alumina, Zirconia, Tricalcium phosphates, Glasses..
- **Biomaterials based on synthetic** polymers: **Teflon, Polyethylenes**, Polyurethanes, Silicones
- **Biomaterials of natural origin: collagen**, coral, mother of pearl, modified bones...

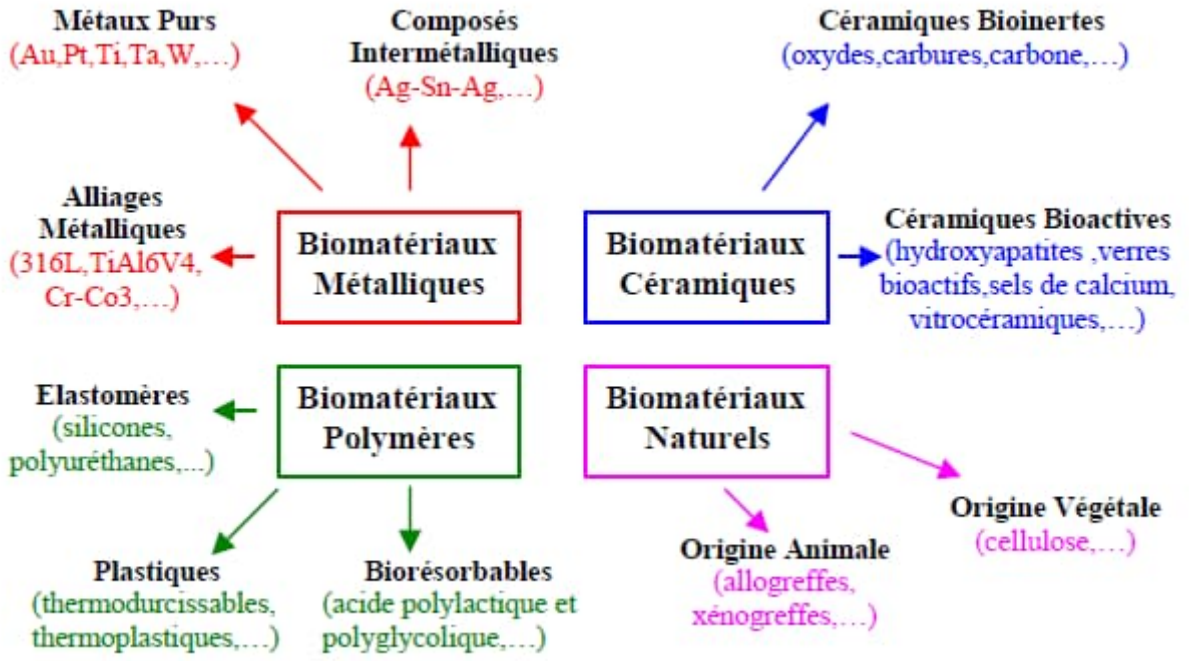

FIG. 2 Classification of biomaterials

3/Requirements forbiomaterial

3.1 Common requirements

Biocompatibility ~~Biological~~ tolerance

- ✓ To the product
- ✓ constituents
- ✓ A its degradation products

⇒

- ➢ **"Negative" biocompatibility: The** material must not have an inflammatory reaction or toxicity.....
- ➢ **"Expanded"** biocompatibility: The ability of a material to be used with an appropriate host response in a specific application
- ➢ **Biofunctionality:** Performing the function for which it is intended

3.1.1 Definition of Biocompatibility

All the phenomena involved in a physiological environment such that the material is not toxic to the organism and the organism itself does not degrade the implanted device

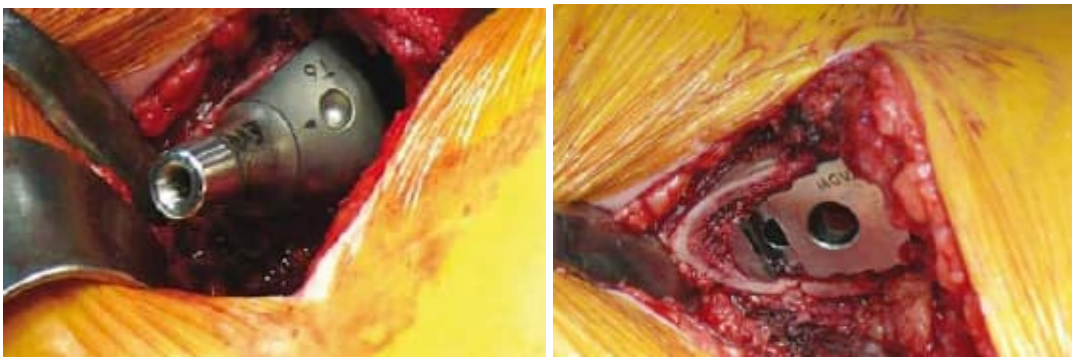

FIG. 2 Biocompatibility

3.2 Requirements for certain mechanical properties

Depending on the nature of the product, we cite some requirements such as:

- Tensile strength
- Wear resistance
- Fatigue resistance
- Creep resistance
- Impact resistance

3.2.1 What should not be forgotten during the selection of the biomaterial and consider that:

- **<u>Biomaterial will deteriorate</u>**
  - Corrosion of metals
  - Ageing of plastics
  - Mechanical deterioration:
    - ✓ Rubbish
    - ✓ Cracks
    - ✓ Fractures
- **<u>The biomaterial will change</u>**
  - Positive: tissue adaptation at the level regime of constraints
  - <u>Negatively</u>:
    - ✓ Inflammatory reactions
    - ✓ Cell death
    - ✓ Local or general toxicity

FIG. 3 Degradation of biomaterials

The figure above clearly shows:

- ✓ Mechanical stresses (tribology and wear) = wear debris
- ✓ Biocompatibility issues and???

4/Tools for choosing biomaterials

4.1 Calculations and simulations

- Pressures
- Distortions
- Interfaces
- Simulation of living environments

4.2 Mechanical tests

- Fracture tests
- Test benches: wear, flow
- Articular, vascular simulators...

4.3 Biological

- Cell cultures
- Fibroblasts, osteoblasts, endothelial cells....
- Animal models
- Studies in humans: clinical follow-up, radiological...

5/One real security

- Implantation in humans

- Long-term monitoring
- Data collection
- Results
- Chess
- Survival
- Comparison with an older equivalent product.

6/Specification forbiomaterial

- Sterilizable
- No risk of transmission of infectious or parasitic disease
- No immune response
- No toxicity of the original product and its degradation products
- Easy manufacturing and storage
- Lower cost

7/Economic and societal challenges

- In France 3.2 million people carrybiomaterial
    - ✓ 1.6 million people with implanted orthopaedic devices
    - ✓ 200 to 300 000 osteosynthesis per year
    - ✓ 80,000 hip prostheses per year
    - ✓ 30,000 knee prostheses
    - ✓ And we in Algeria???
- global market estimated at 30 billion Euros
- cost for health expenditure
- major additional cost in the event of failure

8/Legislative aspects

All biomaterials must be marked (Biomaterials **CE Marking) via**notifiedthe surgeon must be informed, the manufacturer must provide the information (part):

- Test benches, in vitro, in vivo

- Then transition to man according to a very strict protocol
- Then marketing
- Quality procedure
- Follow-up procedure

9/Conclusion

- Biomaterials are an expanding field of study
- High-tech field
- High responsibility
- Multidisciplinary field: surgeons, clinicians, mechanics, biologists, biochemists
- Need for collaboration of researchers - surgeons