

Biomechanics of Joints and Orthopaedic Implants
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Lecture 38
Biomaterials and Design of Orthopaedic Implants

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The slide features a blue and white design with two logos at the top: the Indian Institute of Technology Kharagpur logo and the NPTEL logo. Below the logos, the text reads: "NPTEL ONLINE CERTIFICATION COURSES", "BIOMECHANICS OF JOINTS AND ORTHOPAEDIC IMPLANTS", "PROF. SANJAY GUPTA", "DEPARTMENT OF MECHANICAL ENGINEERING, IIT KHARAGPUR", "Module 07:", and "Lecture 05 : BIOMATERIALS AND DESIGN OF ORTHOPAEDIC IMPLANTS".

Good afternoon everybody, welcome to the fifth lecture of the seventh module on biomaterials and design of orthopedic implants.

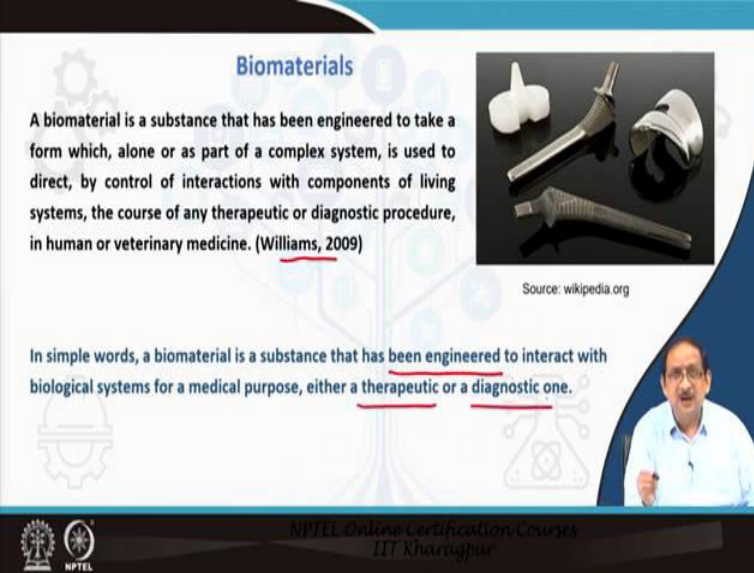
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The slide has a blue and white design with two logos at the top: the Indian Institute of Technology Kharagpur logo and the NPTEL logo. Below the logos, the text reads: "CONCEPTS COVERED", "➤ Biomaterials", and "➤ Overall Design Procedure of Orthopaedic Implants".

In this lecture, we will be discussing about biomaterials used for orthopedic implants and we will discuss about the overall design procedure of orthopedic implants.

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Biomaterials

A biomaterial is a substance that has been engineered to take a form which, alone or as part of a complex system, is used to direct, by control of interactions with components of living systems, the course of any therapeutic or diagnostic procedure, in human or veterinary medicine. (Williams, 2009)

Source: wikipedia.org

In simple words, a biomaterial is a substance that has been engineered to interact with biological systems for a medical purpose, either a therapeutic or a diagnostic one.

The slide features a blue header with the title 'Biomaterials'. Below the title is a definition of biomaterials, with the name '(Williams, 2009)' underlined. To the right of the text is a photograph of several orthopedic implants, including a white plastic component, a metal femoral head, a metal acetabular cup, and a metal femoral stem. Below the photograph is the source 'Source: wikipedia.org'. At the bottom of the slide, there is a simplified definition of biomaterials, with 'therapeutic or a diagnostic one' underlined. In the bottom right corner, there is a small inset video of a man in a light blue shirt speaking. At the very bottom of the slide, there are logos for NPTEL and IIT Khariagpur.

Now, the course is not complete unless we discuss the biomaterials used in implant materials. A biomaterial is a substance that has been engineered to take a form, which alone or as a as part of a complex system, is used to direct, by control of interactions with components of living systems, the course of any therapeutic or diagnostic procedure generally, in human and veterinary medicine. This is the definition of biomaterials suggested by T F Williams.

In simple words, a biomaterial is a substance that has been engineered to interact with the biological system for a medical purpose, either a therapeutic or a diagnostic one.

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Primary Requirements of a Biomaterial

- **Biocompatibility (Bio-inert and non-toxic – must not react with body) – the ability of a material to perform with an appropriate host response in a specific application**
- Adequate mechanical strength in static and fatigue loading – tension, compression and shear
- Sufficient stiffness and hardness
- Reasonable ductility
- Resistance to corrosion – in presence of body fluids, singly or in combination with other materials
- Wear resistant materials with regard to articulating parts
- Long-term stability – both dimensional and chemical

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Now, there are certain primary requirements of a biomaterial. The first and foremost that comes as a primary requirement is biocompatibility. So, what is biocompatibility? Biocompatibility is the ability of a material to perform with an appropriate host response in a specific application. What do we mean by that? Biocompatibility means bio-inert and non-toxic, and the material must not react with the body.

Now, biomaterial should have adequate mechanical strength in static and fatigue loading in tension, compression, and shear mode. It should have sufficient stiffness and hardness. It should have reasonable ductility. It should have the property of resistance to corrosion in the presence of body fluids singly or in combination with other materials. It has to be wear-resistant materials with regard to articulating parts. And it should provide long-term stability both dimensionally and from chemical point of view.

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The slide features a central definition of biocompatibility: "Biocompatibility refers to the ability of a biomaterial to perform its desired function with respect to a medical therapy, without eliciting any undesirable local or systemic effects in the recipient or beneficiary of that therapy, but generating the most appropriate beneficial cellular or tissue response in that specific situation, and optimizing the clinically relevant performance of that therapy". (Williams, D.F, 2008). The slide is decorated with a stylized tree graphic in the background and icons of a hard hat and a flask. A video inset in the bottom right corner shows a man in a light blue shirt speaking. The footer includes the NPTEL logo and the text "NPTEL Online Certification Courses IIT Khariampur".

Now, let us discuss biocompatibility. Biocompatibility refers to the ability of a biomaterial to perform its desired function with respect to medical therapy, without evoking any undesirable local or systemic effects in the recipient or beneficiary of that therapy, but generating the most appropriate beneficial cellular or tissue response in that specific situation, as well as optimizing the clinically relevant performance of that therapy.

Now, a biomaterial can exhibit good biocompatibility with reference to bone replacement applications, but the same material may not be biocompatible in cardiovascular applications. Now, let us come to cytocompatibility. Cytocompatibility qualitatively describes how living cells are compatible with a synthetic, I mean non-living material substrate.

Biocompatibility can also be defined as the ability of biomaterials to be in contact with proliferating cells without producing any adverse effect in vitro. This is generally related to the behavior of biomaterials in the context of cell culture in vitro.

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Cytotoxicity
Cytotoxicity is the assessment of cytocompatibility to a device/implant related material and their leached out components.

Haemocompatibility
Haemocompatibility can be defined as an in vitro assessment of the blood compatibility of any material, surface, and their leached out components to change the clotting factors.

Osseointegration
Osseointegration is the stable anchorage of an implant achieved by direct bone-to-implant contact.
Osseointegration is also histologically defined as the direct anchorage of an implant by the formation of bony tissue around the implant, without the growth of fibrous tissue at the bone-implant interface.

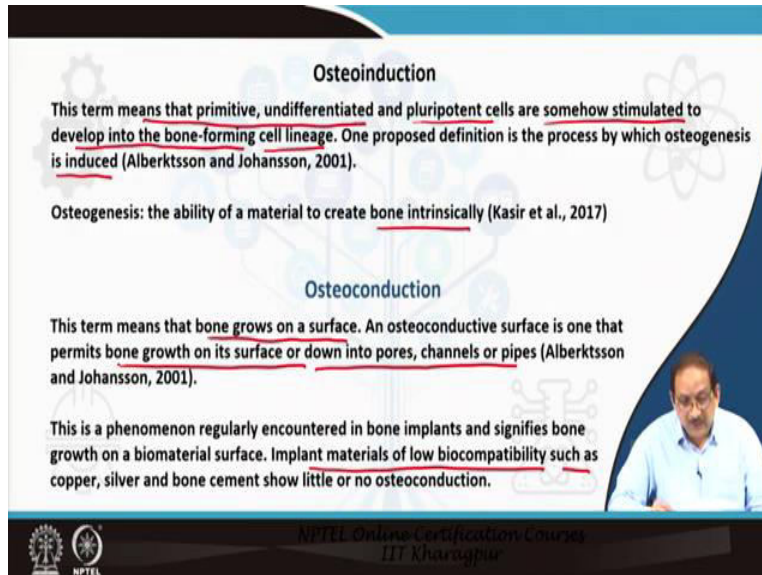
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Now, what is cytotoxicity? Cytotoxicity is the assessment of cytocompatibility to a device or implant-related material and its leached out components. Now, biomaterial should generally be pro healing and should not be pro-inflammatory. Haemocompatibility can be defined as an in vitro assessment of the blood compatibility of any material, surface, and their leached out components to change the clotting factors.

Haemocompatibility is also considered important in bone tissue engineering, as every implant is expected to interact with blood upon implantation. Osseointegration is defined as the stable anchorage of an implant achieved by direct bone-to-implant contact. The word osseointegration means integration of the implant with the host bone.

So, osseointegration is also histologically defined as the direct anchorage of an implant by the formation of bone tissue around the implant, without the growth of fibrous tissue at the implant-bone interface. Osseointegration is a time-dependent healing process and is critical for implant stability.

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Osteoinduction

This term means that primitive, undifferentiated and pluripotent cells are somehow stimulated to develop into the bone-forming cell lineage. One proposed definition is the process by which osteogenesis is induced (Alberktsson and Johansson, 2001).

Osteogenesis: the ability of a material to create bone intrinsically (Kasir et al., 2017)

Osteoconduction

This term means that bone grows on a surface. An osteoconductive surface is one that permits bone growth on its surface or down into pores, channels or pipes (Alberktsson and Johansson, 2001).

This is a phenomenon regularly encountered in bone implants and signifies bone growth on a biomaterial surface. Implant materials of low biocompatibility such as copper, silver and bone cement show little or no osteoconduction.

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Osteoinduction means that primitive undifferentiated and pluripotent cells are somehow stimulated to develop into bone-forming cell lineage. One proposed definition is the process by which osteogenesis is induced. Now, osteogenesis is the ability of a material to create bone intrinsically. The bone healing process, as in the case of fractures, is primarily dependent on osteoinduction.

Now, osteoconduction means that bone grows on a surface. An osteoconductive surface is one that permits bone growth on its surface or down into the pores, channels, or pipes. It is a phenomenon regularly encountered in bone implants and signifies bone growth on a biomaterial surface. Implant materials of low biocompatibility, such as copper, silver, and bone cement, show little or no osteoconduction.

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Types of Biomaterials: Metal, Ceramic, Polymer, Composite, Hybrid.....

Metallic alloy

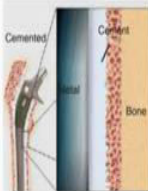
- ✓ Stainless steel (Surgical grade – AISI 316L), $E = 210 \text{ GPa}$
- ✓ Titanium alloy (Ti-6Al-4V, $E = 110 \text{ GPa}$): soft material
- ✓ Co-Cr-Mo alloy ($E = 235 \text{ GPa}$): hard material
- ✓ Tantalum ($E = 186 \text{ GPa}$): soft material

Metallic implants are the primary biomaterials used for joint replacement:


- ✓ High strength and high fracture toughness
- ✓ Corrosion resistant and biocompatible

Disadvantages:

- High elastic modulus which causes stress shielding
- Toxic effects caused by metal-ion release from implants are a major concern



Source: Haglin et al. (2016)



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Let us now discuss different biomaterials, like metal, ceramic, polymer, polymer composites, and hybrid, used for orthopedic implants. Now, metallic alloy, if you consider metallic alloy, stainless steel surgical grade, titanium alloy (Ti-6Al-4V), cobalt-chromium-molybdenum alloy, these are the most popular, apart from that, we have tantalum.

Metallic implants are the primary biomaterials used for joint replacement because it has high strength and high fracture toughness. It is also corrosion-resistant and bio-compatible. The disadvantages of the metallic alloy implants are high elastic modulus, which may cause stress-strain shielding, and toxic effects caused by metal ion release from implants are also a major concern.

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Polymers

Polymers are macromolecules consisting of a long-chain of smaller repeating units (monomers).

- Ultra high molecular weight polyethylene: UHMWPE
- Polymethyl methacrylate: PMMA ✓
- Polytetrafluoroethylene: PTFE ✓
- Polyethylene: PE ✓

Advantages:

- ✓ Elastic modulus almost equal to the cancellous bone
- ✓ Lightweight
- ✓ Properties can be modified easily according to molecular weight

Disadvantages:

- Poor wear properties
- Less favourable for osseointegration

Ref: Arun S. et al. (2013)

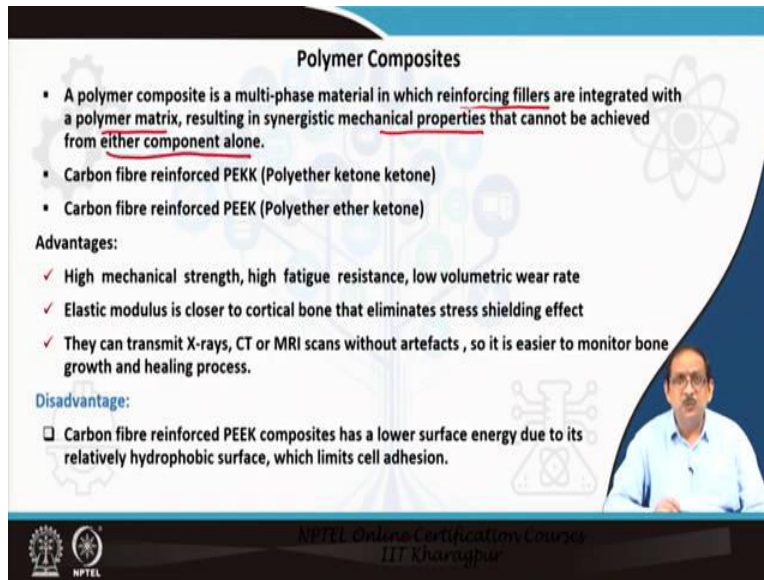
Acetabular Cup
Outer Shell METAL
Liner POLYETHYLENE
Femoral Head METAL
Femoral Stem METAL

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Now, polymers have found huge applications in the joint replacement sector. Polymers are macromolecules consisting of a long chain of smaller repeating units known as monomers. Now, the specific polymers that have been popularly used in joint replacement are Ultra-high molecular weight polyethylene, polymethyl methacrylate, PMMA, which is bone cement, PTFE, and polyethylene.

The advantages of the polymers are elastic modulus almost equal to the cancellous bone. It is lightweight, and the properties can be modified easily according to the molecular weight. The disadvantages are poor wear properties and less favorable for osseointegration.

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Polymer Composites

- A polymer composite is a multi-phase material in which reinforcing fillers are integrated with a polymer matrix, resulting in synergistic mechanical properties that cannot be achieved from either component alone.
- Carbon fibre reinforced PEKK (Polyether ketone ketone)
- Carbon fibre reinforced PEEK (Polyether ether ketone)

Advantages:

- ✓ High mechanical strength, high fatigue resistance, low volumetric wear rate
- ✓ Elastic modulus is closer to cortical bone that eliminates stress shielding effect
- ✓ They can transmit X-rays, CT or MRI scans without artefacts, so it is easier to monitor bone growth and healing process.

Disadvantage:

- ❑ Carbon fibre reinforced PEEK composites has a lower surface energy due to its relatively hydrophobic surface, which limits cell adhesion.

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Now, polymer composites are a multiphase material in which reinforcing fillers are integrated with a polymer matrix, resulting in synergistic mechanical properties that cannot be achieved from either component alone. So, examples are carbon fiber reinforced PEKK, that is, polyether ketone ketone. And there is another polymer composite, which is very popular nowadays, that is the carbon fiber reinforced PEEK, polyether ether ketone, both these polymer composites are actually thermoplastic material.

The advantages are high mechanical strength, high fatigue strength, and low volumetric wear rate. The elastic modulus of these materials is closer to the cortical bone, which eliminates stress shielding effect, or reduces stress shielding effect to a great extent. They can transmit X-ray, CT, or MRI scans without artefacts. So, it is easier to monitor bone growth and the healing process. The disadvantage is carbon fiber reinforced PEEK composites have lower surface energy due to its relatively hydrophobic surface, which limits cell adhesion.

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Ceramics

- Alumina
- Zirconia
- Hydroxyapatite (HA)

Advantages:

- ✓ Excellent wear properties
- ✓ Not subjected to corrosion over time.
- ✓ Bio-inert and stable
- ✓ High hardness - tensile properties are artificially induced nowadays

Disadvantages:

- ❑ High Elastic modulus - 350 GPa
- ❑ Brittle

Zirconia Dental Implant

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Now, ceramics also find application in different orthopedic implants as well as dental implants. There are primarily three types of ceramics for different applications, one is the alumina ceramic, another is the zirconia ceramic, and the third one is the hydroxyapatite. The advantages are excellent wear properties, not being subjected to corrosion over time, it is bio-inert and stable, and high hardness- tensile properties are artificially into artificially induced nowadays. The disadvantages are high elastic modulus of about 350 GPa, and it is brittle in nature.

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Applications of Biomaterials

- Orthopedics: artificial hips, knees, shoulders, wrists, intervertebral discs, fracture fixation, bone grafts
- Cardiovascular: heart valves, PTCA balloons, pacemakers, catheters, grafts, stents
- Dental: enamels, fillings, prosthetics, orthodontics.
- Soft tissue: wound healing, reconstructive and augmentation, ocular.
- Surgical: staples, sutures, scalpels.

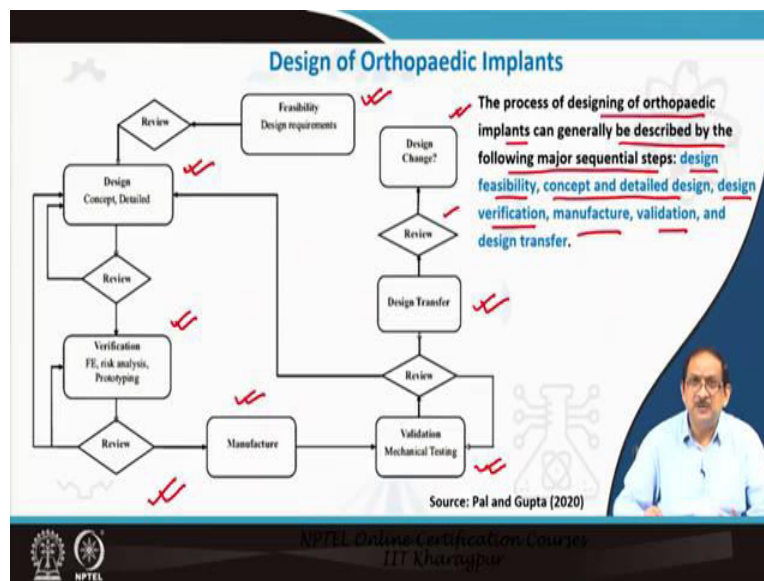
Source: wikipedia.org

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Now, the applications of biomaterials are many. So, I am just summarizing the applications in different areas, say, orthopedics: artificial hip, knee, shoulder, wrist, intervertebral discs, fracture fixation, and bone grafts. Apart from orthopedics, we have cardiovascular applications: heart valves, PTCA balloons, pacemakers, catheters, grafts, and stents.

For dental applications, you also find quite a few biomaterials used for enamels, fillings, prosthetics, and orthodontic. Apart part from these, there is also the application of biomaterials for soft tissue in the area of soft tissue: wound healing, reconstructive, and augmentation. It is also used in surgery for staples, sutures, and scalpels.

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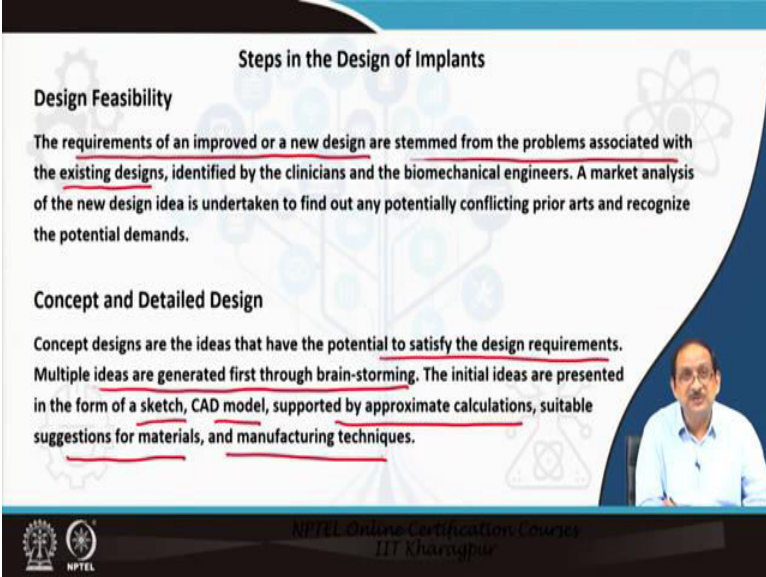


Let us now discuss the second topic of this lecture, the design procedure of orthopedic implants. The process of designing orthopedic implants can generally be described by the following major sequential steps, as presented in the flow chart here in the slide. So, it starts with design feasibility, and the design feasibility is based on the design requirements. It is followed by conceptual and detailed design, and thereafter we perform, we have to perform the verification, design verification.

After verification using finite element analysis, or risk analysis, or prototyping, we can move towards manufacturing. Manufacturing is followed by validation with the help of mechanical testing. And thereafter, we can actually transfer the design to a competent manufacturer. So, after

review, if there is any design change required for any specific application, we may repeat the whole procedure.

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Steps in the Design of Implants

Design Feasibility

The requirements of an improved or a new design are stemmed from the problems associated with the existing designs, identified by the clinicians and the biomechanical engineers. A market analysis of the new design idea is undertaken to find out any potentially conflicting prior arts and recognize the potential demands.

Concept and Detailed Design

Concept designs are the ideas that have the potential to satisfy the design requirements. Multiple ideas are generated first through brain-storming. The initial ideas are presented in the form of a sketch, CAD model, supported by approximate calculations, suitable suggestions for materials, and manufacturing techniques.

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We will now discuss these steps of the design of the procedure of the implants in a little bit more detail. So, let us first take the first step that is design feasibility. The requirements of an improved or a new design are stemmed from the problems associated with the existing designs, identified by the clinicians and the biomechanical engineers.

A market analysis of the new design idea is undertaken to find out any potentially conflicting prior arts and recognize the potential demands. Now, what is concept and detailed design. The concept designs are the ideas that have the potential to satisfy the design requirements. Multiple ideas are generated first through brain-storming. The initial ideas are presented in the form of a sketch, CAD model, supported by approximate calculations, suitable suggestions for materials and manufacturing techniques.

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Steps in the Design Of Implants

Design Verification

This activity examines whether an implant satisfies the prescribed design requirements or not. There are several methods of design verification including finite element analysis, risk analysis, and prototyping.

Manufacture

Selection of a repeatable and reliable manufacturing method is essential to manufacture the design. Several factors can influence the selection of the manufacturing method, including quantities required, desired surface finish, cleaning required post-fabrication, risk of contamination during manufacturing, packaging, and sterilization.

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Now, design verification is an activity that examines whether an implant satisfies the prescribed design requirements or not. There are several methods of design verification, including finite element analysis, risk analysis, and prototyping. Manufacturing is an important step in the design procedure. The selection of a repeatable and reliable manufacturing method is essential to manufacture the design.

Several factors can influence the selection of the manufacturing method, including quantities, required, desired surface finish, cleaning required post-fabrication, risk of contamination during manufacturing, packaging, and sterilization.

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The slide is titled "Steps in the Design Of Implants" and features a background with faint icons of gears, a tree, and a molecular structure. It is divided into two main sections: "Design Validation" and "Design Transfer".

Design Validation

This important step is aimed at investigating the behavior and performance of the design under scenarios that replicate the intended use of the implant as close as possible.

In vitro mechanical testing is commonly performed for pre-clinical investigation of the mechanical behavior of the design and its associated risk of failure, following guidelines prescribed in standards produced by several professional bodies.

Design Transfer

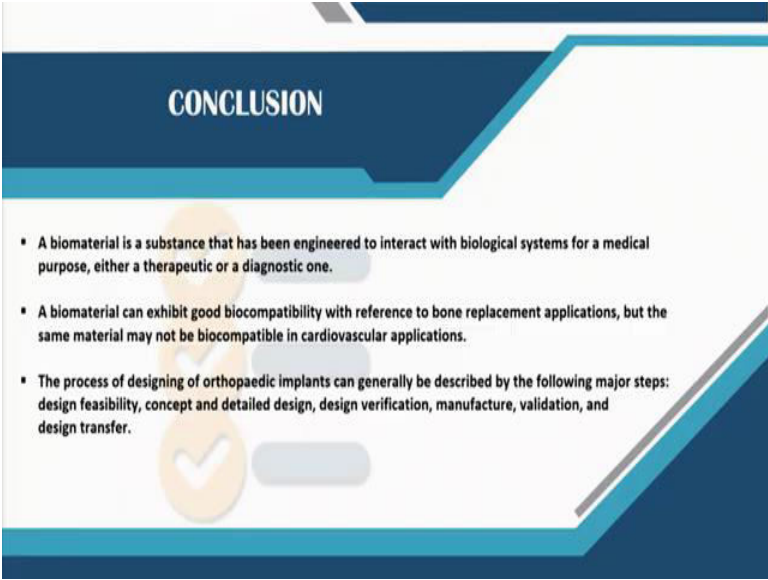
Once the design is verified and validated, it may be transferred to the industrial partner for commercial production.

A small inset video shows a man in a light blue shirt speaking. At the bottom of the slide, there are logos for NPTEL and IIT Kharygpur, along with the text "NPTEL Online Certification Courses IIT Kharygpur".

Now, design validation is another important step, which is aimed at investigating the behavior and performance of the design under scenarios that replicate the intended use of the implant as close as possible. *In vitro* mechanical testing is commonly performed for preclinical investigations of the mechanical behavior of the design and its associated risk of failure, following guidelines prescribed in standards produced by several professional bodies.

Now, once the design is verified and validated, it may be transferred to the industrial partner for commercial production.

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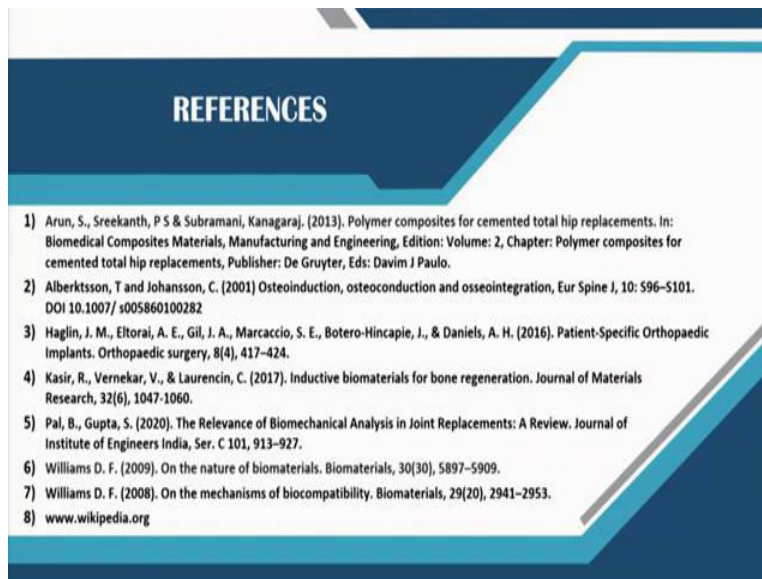
CONCLUSION

- A biomaterial is a substance that has been engineered to interact with biological systems for a medical purpose, either a therapeutic or a diagnostic one.
- A biomaterial can exhibit good biocompatibility with reference to bone replacement applications, but the same material may not be biocompatible in cardiovascular applications.
- The process of designing of orthopaedic implants can generally be described by the following major steps: design feasibility, concept and detailed design, design verification, manufacture, validation, and design transfer.

Let me now come to the conclusions of this study. A biomaterial is a substance that has been engineered to interact with biological systems for a medical purpose, either therapeutic or a diagnostic one. A biomaterial can exhibit good biocompatibility with reference to bone replacement applications.

But the same material may not be biocompatible in cardiovascular applications. The process of designing of orthopedic implants can generally be described by the following major steps: design feasibility, concept and detailed design, design verification, manufacture, validation, and finally design transfer.

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The list of references is presented in one slide and I thank you all for listening.