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

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

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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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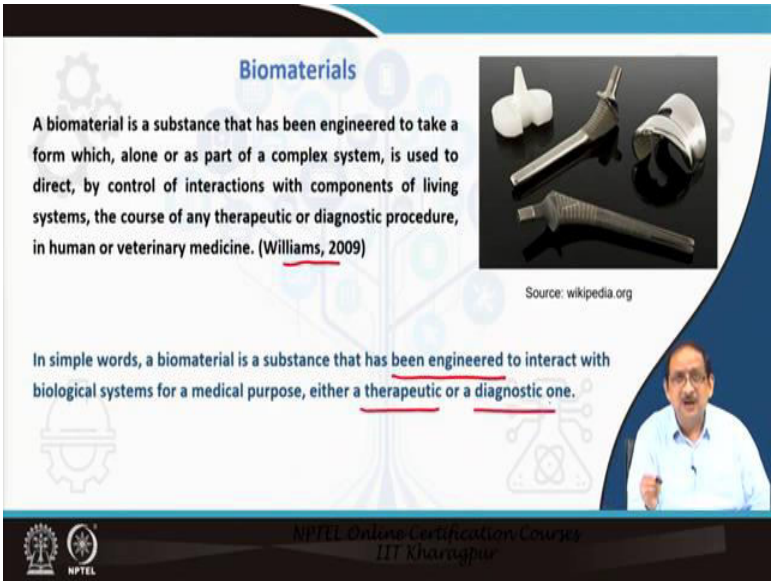


Now, the course is not complete unless we discuss the biomaterials used in implant materials. A biomaterial is a substance that has been engineered to take a form, which alone or as a as part of a complex system, is used to direct, by control of interactions with components of living systems, the course 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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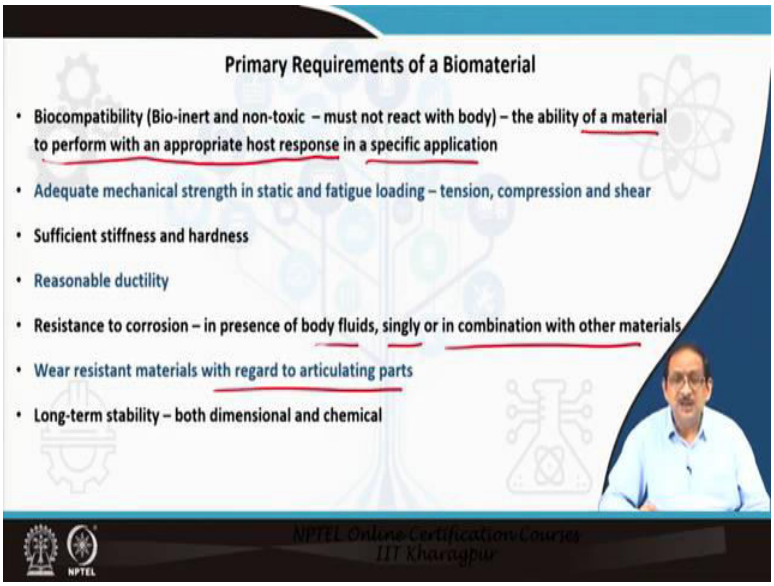


Now, there are certain primary requirements of a biomaterial. The first and foremost that comes as a primary requirement is biocompatibility. So, what is biocompatibility? Biocompatibility is the ability of a material to perform with an appropriate host response in a specific application. What do we 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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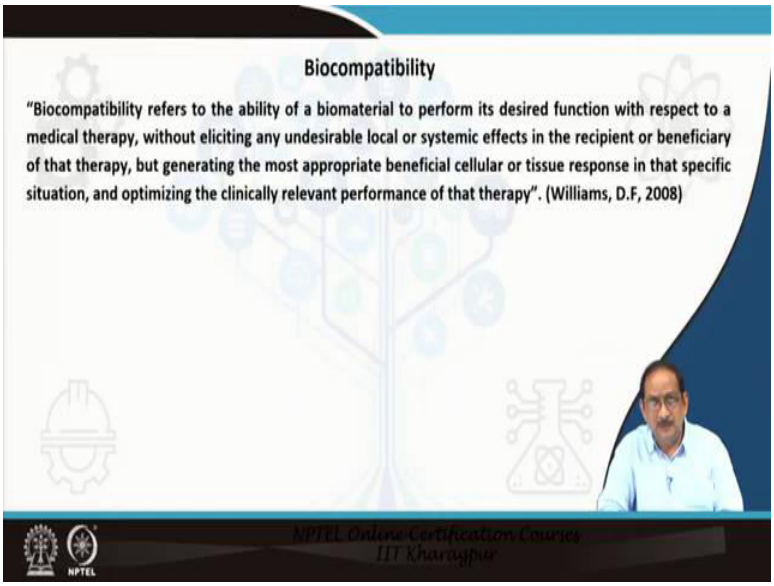


Now, let us discuss biocompatibility. Biocompatibility refers to the ability of a biomaterial to perform its desired function with respect to medical therapy, without evoking any undesirable local or systemic effects in the recipient or beneficiary of that therapy, but generating the most appropriate 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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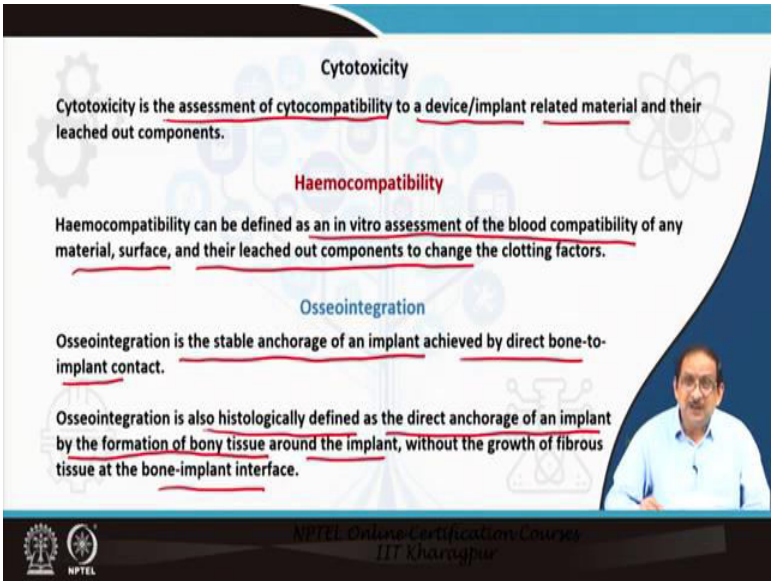


Now, what is cytotoxicity? Cytotoxicity is the assessment of cytocompatibility to a device or implant-related material and it's leached out components. Now, biomaterial should generally be pro healing and should not be pro-inflammatory. Haemocompatibility can be defined as an in vitro assessment of the 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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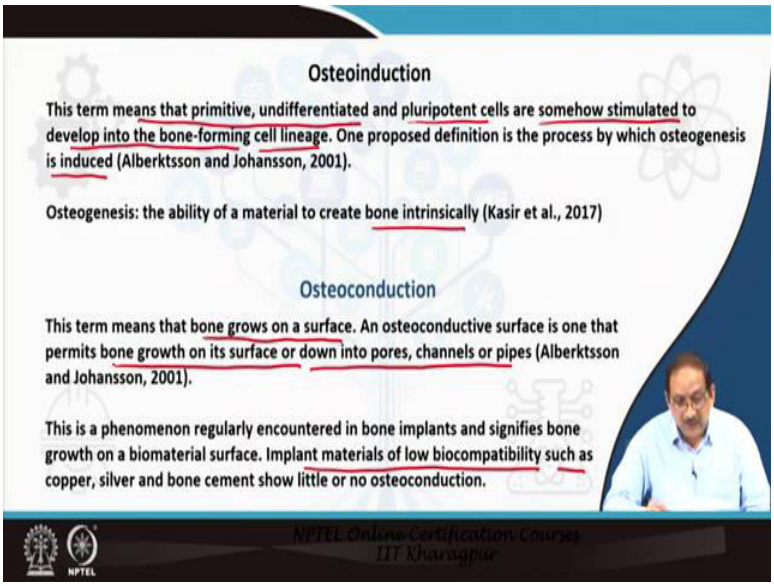


Osteoinduction means that primitive undifferentiated and pluripotent cells are somehow stimulated to develop into bone-forming cell lineage. One proposed definition is the process by which osteogenesis is induced. Now, osteogenesis is the ability of a material to create bone intrinsically. The bone healing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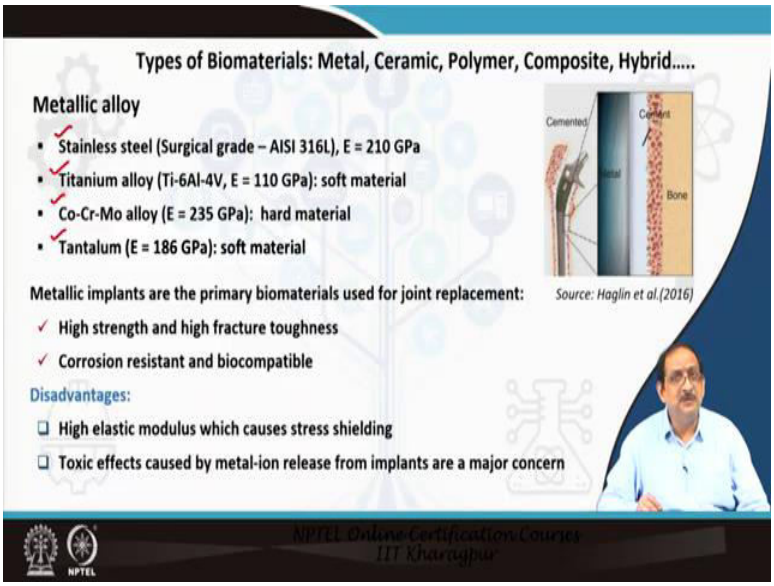


Let us now discuss different biomaterials, like metal, ceramic, polymer, polymer composites, and hybrid, used for orthopedic implants. Now, metallic alloy, if you consider metallic alloy, stainless steel surgical grade, titanium alloy (Ti-6Al-4V), cobalt-chromium-molybdenum alloy, these are the most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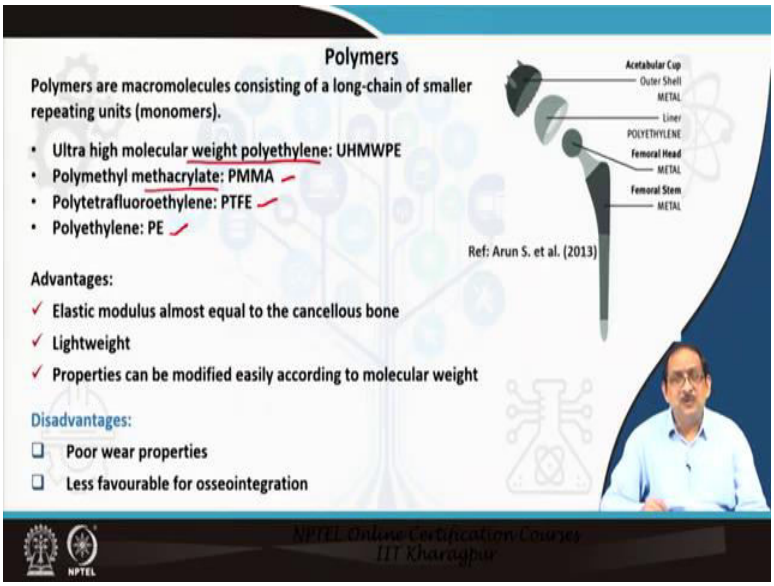


Now, polymers have found huge applications in the joint replacement sector. Polymers are macromolecules consisting of a long chain of smaller repeating units known as monomers. Now, the specific polymers that have been popularly used in joint replacement are Ultra-high molecular weight polyethylene,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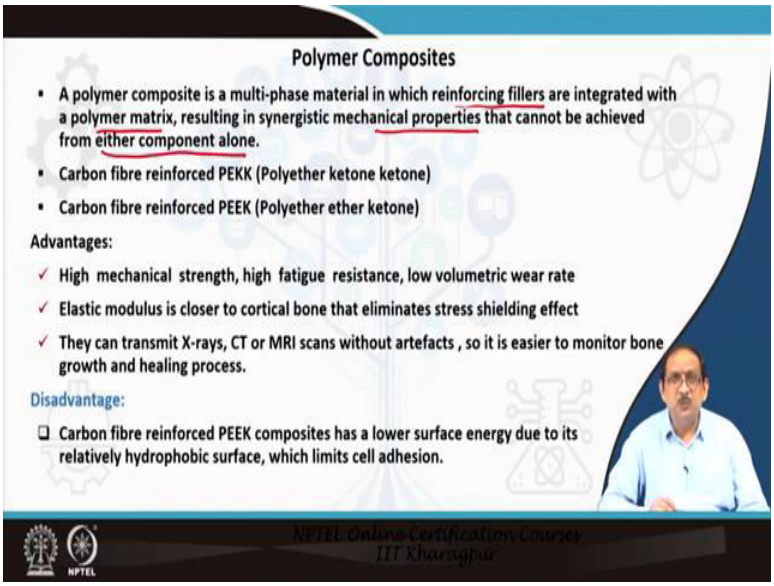


Now, polymer composites are a multiphase material in which reinforcing fillers are integrated with a polymer matrix, resulting in synergistic mechanical properties that cannot be achieved from either component alone. So, examples are carbon fiber reinforced PEKK, that is, polyether ketone ketone. And 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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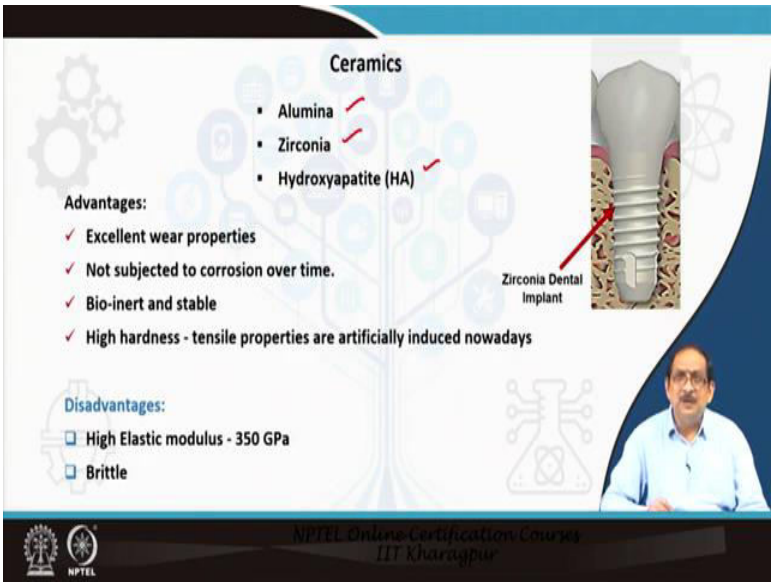


Now, ceramics also find application in different orthopedic implants as well as dental implants. There are primarily three types of ceramics for different applications, one is the alumina ceramic, another is the zirconia ceramic, and the third one is the hydroxyapatite. The advantages are excellent wear 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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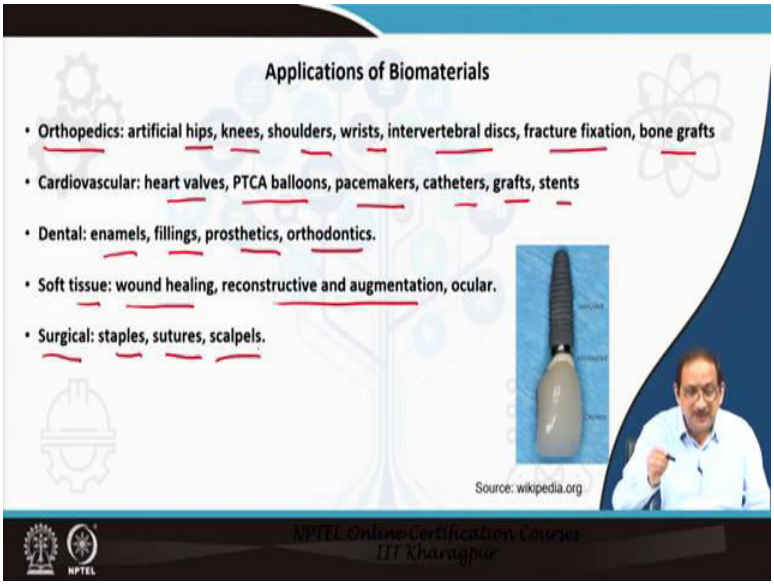

Now, the applications of biomaterials are many. So, I am just summarizing the applications in different areas, say, orthopedics: artificial hip, knee, shoulder, wrist, intervertebral discs, fracture fixation, and bone grafts. Apart from orthopedics, we have cardiovascular applications: heart valves,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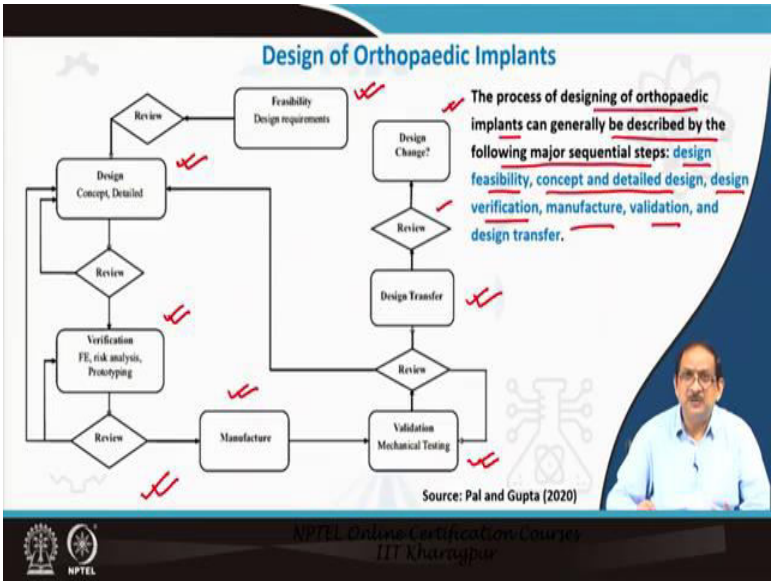


Let us now discuss the second topic of this lecture, the design procedure of orthopedic implants. The process of designing orthopedic implants can generally be described by the following major sequential steps, as presented in the flow chart here in the slide. So, it starts with design feasibility, and 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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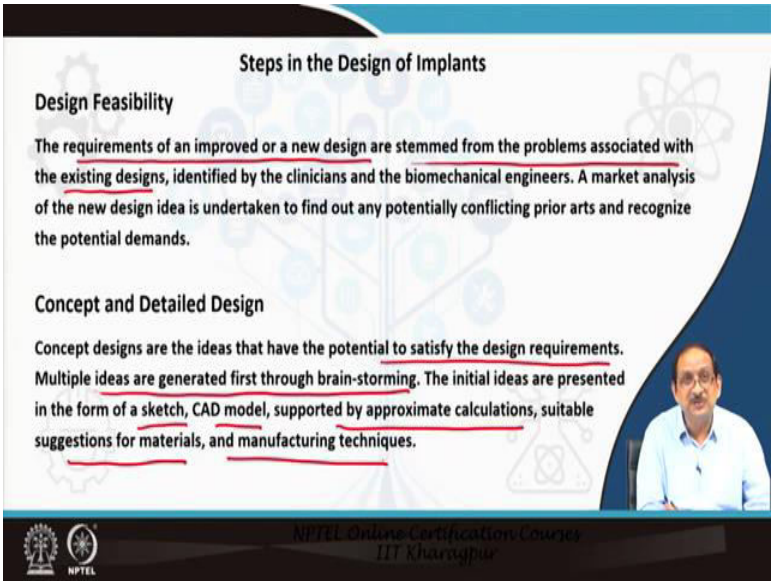


We will now discuss these steps of the design of the procedure of the implants in a little bit more detail. So, let us first take the first step that is design feasibility. The requirements of an improved or a new design are stemmed from the problems associated with the existing designs, identified by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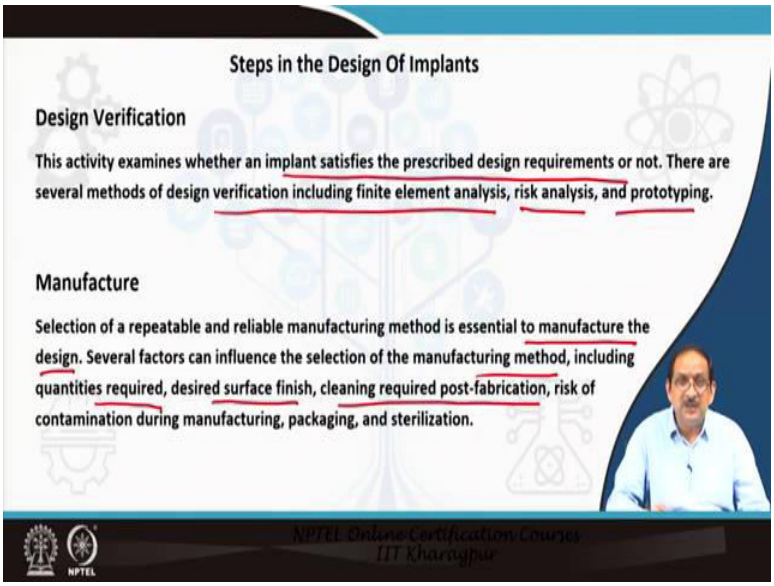


Now, design verification is an activity that examines whether an implant satisfies the prescribed design requirements or not. There are several methods of design verification, including finite element analysis, risk analysis, and prototyping. Manufacturing is an important step in the design procedure. 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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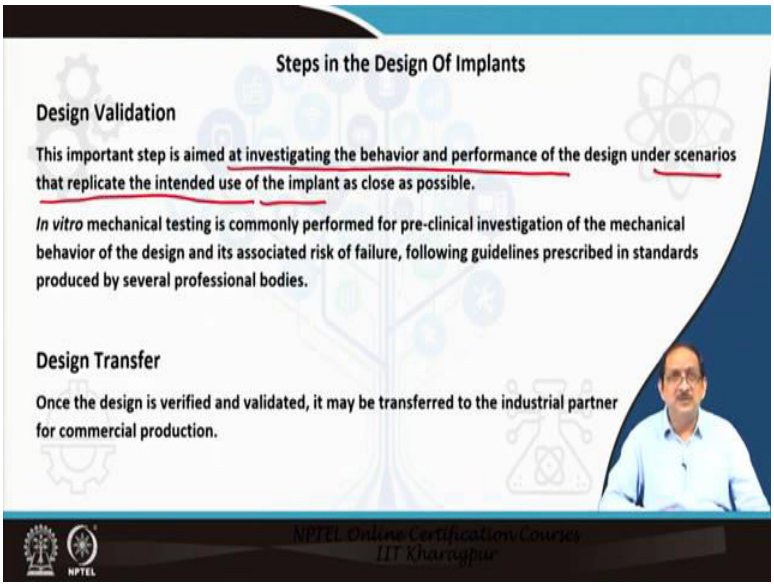


Now, design validation is another important step, which is aimed at investigating the behavior and performance of the design under scenarios that replicate the intended use of the implant as close as possible. In vitro mechanical testing is commonly performed for preclinical investigations of the mechanical 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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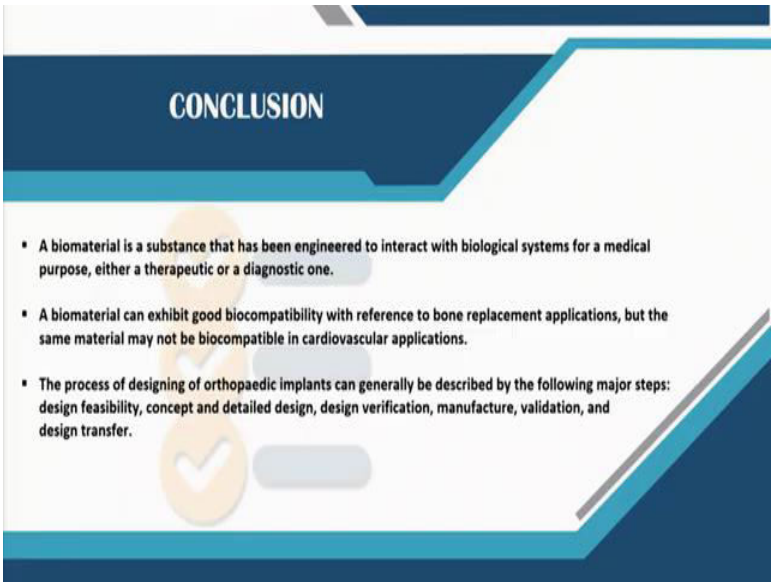


Let me now come to the conclusions of this study. A biomaterial is a substance that has been engineered to interact with biological systems for a medical purpose, either therapeutic or a diagnostic one. A biomaterial can exhibit good biocompatibility with reference to bone replacement applications.

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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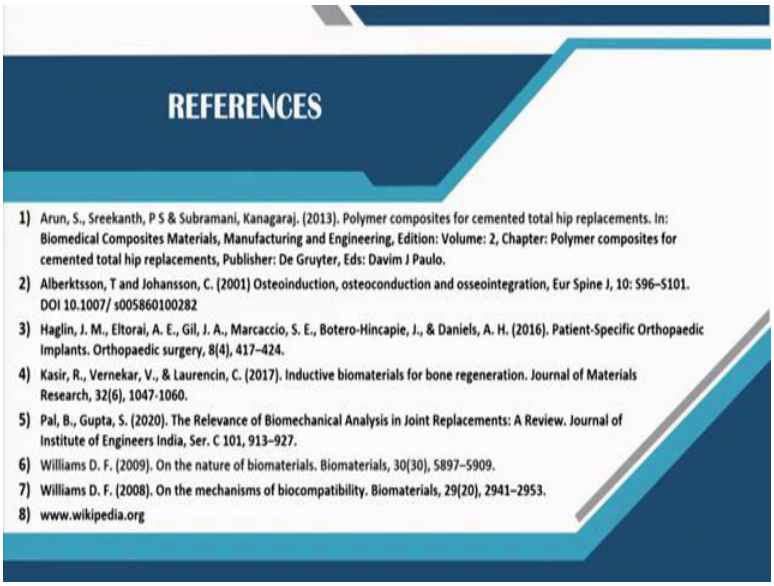


The list of references is presented in one slide and I thank you all for listening.