

CHAPTER 2

Biomaterials and Biomedical Applications: Development and Characterization for Medical Devices, Implants, and Tissue Engineering

Mahendra H. Janrao,^{1*} Dilip D. Thorat,¹ Pratap M. Zalake¹ and Namdeo T. Dhokale²

¹ *VPMK's Art's Commerce and Science college Kinhalvali Tal. Shahapur Dist. Thane 4214032 Maharashtra, India*

² *K.J. Somaiya College of Arts, Science and Commerce, Mohinirajnagar, Kopargaon, Dist. Ahmednagar 423601 Maharashtra, India*

Corresponding author Email: mhj.vpmkchem@gmail.com

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Abstract: Biomaterials play an important role in the development of novel tissue regeneration, replacement, and repair techniques in the field of biomedical engineering. The design, creation, and characterisation of biomaterials for use in implants, medical devices, and tissue engineering are the main topics of this review. Incorporating vital characteristics like as biocompatibility, mechanical strength, degradability, and biological usefulness is a crucial part of designing biomaterials. Numerous medical applications, including orthopaedic, dental, cardiovascular, and ophthalmic devices, use a variety of

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biomaterials, including metals, polymers, ceramics, and composites. Because of their distinct qualities, different kinds of biomaterials are appropriate for particular uses. The properties of biomaterials are characterized and assessed using a variety of methods, such as mechanical testing, thermal analysis, X-ray diffraction, biological assays, and scanning electron microscopy. These methods offer important new information about the physicochemical, biocompatible, and structural characteristics of biomaterials. Replicating functioning tissues using biomaterials, stem cells, and bioactive compounds is known as tissue engineering, and it is a quickly expanding subject. New developments in the field of biomaterials, including AI-driven material design, 4D bioprinting, and stimuli-responsive biomaterials, are revolutionizing the industry and opening up new avenues for customized medicine. An interdisciplinary approach incorporating knowledge from materials science, biology, medicine, and engineering is necessary for the development of biomaterials. Researchers can create novel approaches for a variety of medical applications by creating biomaterials that can easily interact with human biology.

Keywords: Biomaterials, Biomedical applications, Medical implants, Tissue engineering, Characterization techniques, Biocompatibility.

1. Introduction

Biomaterials have transformed medicine by offering novel approaches to tissue regeneration, replacement, and repair. In order to guarantee biocompatibility, mechanical integrity, and functional interaction with live tissues, these materials are made to integrate with biological systems. To develop biomaterials, a multidisciplinary strategy integrating chemistry, materials science, bioengineering, and medical sciences is necessary. Applications include drug delivery systems, scaffolds for tissue engineering, implants, and medical devices. X-ray diffraction and scanning electron microscopy are two characterization methods used to assess the characteristics of biomaterials. Understanding the characteristics and uses of biomaterials enables researchers to create novel medical applications, revolutionizing the medical field.

2. Classification of Biomaterials

In order to choose appropriate materials for certain medical applications, biomaterials are classified according to criteria including composition, origin, biological reaction, and functioning. Biomaterials are divided into metals, polymers, ceramics, and composites according to their composition. Orthopaedic and dental implants benefit greatly from the mechanical strength and corrosion resistance of metals like titanium and stainless steel. Sutures, scaffolds, and drug delivery devices all use polymers with biodegradability and flexibility, such as polyethylene and polylactic acid. Because of their hardness and biocompatibility, ceramics like hydroxyapatite are appropriate for applications involving bones. Multiple-material composites can replicate the characteristics of genuine bone. Biomaterials can also be categorized by their place of origin. These include synthetic biomaterials, such as PEG and PLGA, which provide precise control over mechanical and degrading properties, and natural biomaterials, such as collagen and

chitosan, which are obtained from biological sources. Comprehending these categories is essential for directing the choice of materials in biomedical engineering and tissue regeneration techniques.

3. Development of Biomaterials

Materials science, chemistry, biology, and engineering are all involved in the intricate and multidisciplinary process of creating biomaterials for use in medicine. In order to replace, repair, or regenerate tissues or to serve as parts of medical devices, biomaterials are made to interact with biological systems. A thorough understanding of the biological context and clinical necessity in which the biomaterial will be employed is essential to the development process. To guarantee the material's success in medical applications, a number of crucial criteria must be considered when designing biomaterials. These factors include:

3.1 Biocompatibility

One essential prerequisite for biomaterials is biocompatibility. The substance shouldn't cause any harmful biological reactions, such immunological rejection, cytotoxicity, or persistent inflammation. Rather, it ought to facilitate cellular processes such as adhesion, differentiation, and proliferation. Surface characteristics, like roughness and chemical makeup, are frequently designed to improve compatibility and have a big impact on biological reactions.

3.2 Mechanical Characteristics

To guarantee functional integration, biomaterials' mechanical characteristics must coincide with those of the target tissue. This covers characteristics including fatigue resistance, compressive strength, and tensile strength. For instance, cardiovascular grafts require elasticity and compliance comparable to native vessels, but orthopaedic implants require a high load-bearing capacity and fatigue resistance.

3.3 Biodegradability

Biomaterials are made to break down in the physiological environment in certain applications. The rate of this disintegration should be regulated, ideally occurring concurrently with medication release or tissue repair. Degradation byproducts need to be safe for the body to metabolize or eliminate. Biodegradable applications frequently use polymers such as polylactic acid (PLA) and polyglycolic acid (PGA).

3.4 Stability of Chemicals

Long-term implanted devices must be chemically stable. The biomaterial must withstand long-term deterioration from oxidative stress, enzymatic activity, and body fluids. Because of their strong resistance to corrosion and ability to generate stable oxide layers, metals such as titanium and its alloys are preferred for permanent implantation.

3.5 Sterilization and Processability

Biomaterials need to work with manufacturing processes including 3D printing, electrospinning, and injection moulding. After going through sterilization processes, they must also maintain their structural and functional integrity.

3.6 Selection of Materials

Choosing the appropriate materials, such as metals, ceramics, polymers, or composites, is the first step in the development process. Every kind of material has special qualities suited to particular biomedical applications.

3.6.1 Metals

Stainless steel and titanium are two common metals utilized in structural applications such as dental and orthopaedic implants. They are perfect for load-bearing applications because of their high tensile strength, resistance to corrosion, and fatigue resilience.

3.6.2 Polymers

Both natural and manmade polymers provide a great deal of flexibility and degradability. Soft tissue engineering, wound dressings, and drug delivery systems all make use of materials like polylactic acid (PLA) and polyethylene glycol (PEG).

3.6.3 Ceramics

Because of their osteoconductivity and chemical resemblance to genuine bone mineral, ceramics like hydroxyapatite and tricalcium phosphate are preferred for bone restoration.

3.6.4 Combinations

The greatest qualities of two or more materials are combined in composites. For instance, polymer-ceramic blends are utilized in bone scaffolds, where the polymer offers flexibility and degradability while the ceramic component encourages bone growth.

3.7 Advanced Methods of Synthesis

Advanced synthesis techniques that enable exact control over material properties have greatly accelerated the development of biomaterials. These methods make it possible to produce biomaterials with specific structural and functional properties, which makes them appropriate for a variety of biomedical uses.

3.7.1 Processing with Sol-Gel

One method for creating bioactive glasses with regulated porosity and surface chemistry is sol-gel processing. This technique makes it possible to produce glasses that have the ability to communicate with biological processes, encouraging tissue healing and regeneration.

3.7.2 The process of electrospinning

Nanofibrous scaffolds that resemble the extracellular matrix may be made by electrospinning, which makes them perfect for soft tissue engineering. These scaffolds enable the development of functional tissue substitutes by offering a framework for tissue regeneration and cell proliferation.

3.7.3 Polymerization with Emulsion

Drug delivery vehicles and nanoparticles with adjustable release profiles can be created by the emulsion polymerization process. Particles that can release therapeutic substances in a regulated manner can be produced using this technique, which makes them appropriate for drug delivery applications.

3.7.4 Printing with 3D

3D printing, sometimes referred to as additive manufacturing, makes it possible to precisely fabricate intricate scaffold structures and implants tailored to each patient. By using this technology, it is possible to create implants that are tailored to the patient's anatomy, which lowers the chance of implant failure and enhances patient outcomes.

3.8 Surface Engineering and Functionalization

A crucial first step in improving the biological performance of biomaterials is surface modification. To enhance cell adhesion, guide tissue response, or prevent bacterial colonization, methods such as chemical grafting, plasma therapy, and biomolecule immobilization are used.

Hydroxyapatite Coatings: By offering a surface that encourages bone formation, hydroxyapatite coatings on metal implants support osteointegration and bone repair. **Heparin-Functionalized Surfaces:** Heparin-functionalized surfaces on stents and vascular grafts improve hemocompatibility and reduce thrombogenicity, which lowers the risk of blood clotting and increases vascular graft patency. **Surfaces with nanopatterns:** In neurological and musculoskeletal applications, nanopatterns can improve tissue regeneration results by influencing cell orientation and differentiation.

3.9 Preclinical Verification and Enhancement

Before being used in clinical settings, biomaterials must pass stringent preclinical testing. This includes testing for hemocompatibility, cytotoxicity assays, mechanical and chemical characterization, and in vivo assessment using animal models. These tests aid in spotting possible problems and direct iterative improvements in architecture, composition, and material design.

Scalability, cost control, regulatory compliance, and reproducibility are some of the difficulties that arise during the transition from laboratory invention to clinical application. For biomaterials to be safe, scalable, and effective for general usage, close cooperation between scientists, doctors, regulatory bodies, and industry partners is necessary.

4. Biomaterials Characterization Techniques

One of the most important steps in making sure biomaterials are suitable for medical uses is their characterisation. To satisfy the exacting requirements of tissue engineering applications, implants, and medical devices, a thorough assessment of their structural, functional, and biological qualities is necessary.

4.1 Structural and morphological characteristics

The structural and morphological characteristics of biomaterials are described using a variety of methods. A strong tool for obtaining fine-grained pictures of the surface morphology of biomaterials is SEM. It makes it possible to observe characteristics including fibre orientation, surface roughness, and porosity. When assessing materials for tissue engineering or implant applications, where surface roughness might affect cell adherence and proliferation, this is very crucial. Transmission electron microscopy (TEM) can be used to analyse the interior microstructure of materials at the nanoscale. TEM, which shows the material's internal organization by guiding electrons through minuscule slices of the material, can be a huge help in comprehending properties like crystallinity and the distribution of phases inside the biomaterial. X-Ray Diffraction (XRD) can be used to determine the phase composition and crystallinity of biomaterials. This technique is essential for identifying the phases present in ceramic biomaterials like hydroxyapatite or titanium alloys. It provides information about the substance's crystal structure and can influence decisions regarding the mechanical properties of the material, such as strength and stability. The chemical groups and bonding interactions found in biomaterials are identified using Infrared Fourier-Transform Spectroscopy (FTIR). Understanding the chemical interactions between the biomaterial and biological tissues requires knowledge of functional groups like hydroxyl, amine, or carbonyl groups, which are obtained by FTIR analysis of the infrared absorption spectra.

4.2 Mechanical Properties

4.2.1 Compressive and Tensile Testing

These tests establish the ultimate tensile strength, yield strength, and elasticity of the material. Knowing these mechanical characteristics is essential for biomaterials used in implants or prostheses to make sure they can sustain physiological pressures without failing. Biomaterials' viscoelastic behaviour is evaluated by dynamic mechanical analysis (DMA), which provides important details about their stiffness, damping properties, and temperature dependence. For polymers and elastomers utilized in soft tissue applications, where mechanical resilience and flexibility are essential, this is particularly significant.

4.2.2 Hardness and Wear Resistance Testing

Biomaterials, especially those utilized in joint replacements or dental implants, are frequently subjected to repetitive mechanical pressures. Hardness testing determines the material's resistance to deformation, whereas wear resistance testing assesses its capacity to endure abrasion and mechanical wear. These qualities are crucial to maintaining the implants' durability and performance.

4.3 Thermal Analysis

Differential Scanning Calorimetry (DSC) determines a material's thermal transitions, such as melting point and glass transition temperature. This information aids in evaluating the material's thermal stability and suitability for a variety of therapeutic situations, including temperature variations in the human body.

Thermogravimetric Analysis (TGA) determines the material's weight loss as a function of temperature, revealing information about its thermal stability and degradation behavior. This is critical for assessing the long-term performance of biomaterials, especially those designed for biodegradable implants.

4.4 Biological Characterization

Biological characterization of biomaterials is an important stage in determining their safety and efficacy for use in medical applications. It entails a variety of studies to analyse their interaction with biological systems. Cytotoxicity assays, such as MTT and Live/Dead assays, examine cell viability and potential toxicity, with the MTT assay employing a colorimetric approach to quantify metabolic activity and the Live/Dead assay visualizing live and dead cells. Hemocompatibility testing is also required, especially for materials used in vascular or cardiac applications, to assess the material's interactions with blood components such as blood coagulation, platelet adhesion, and haemolysis.

Furthermore, biodegradable materials must be evaluated for degradation rate and nature of breakdown products using in vitro and in vivo research to ensure the material operates as intended throughout its lifespan in the body. Furthermore, histology investigations in animal models investigate the tissue response to biomaterials, shedding light on biocompatibility and integration with neighbouring tissues, as well as how the material effects cell proliferation, vascularization, and tissue remodelling. By integrating these tests, researchers can acquire a thorough understanding of a biomaterial's biological features and possible applications, which will eventually inform the design and development of safe and effective biomaterials for medical use. Biomaterials must be thoroughly evaluated using biological characterisation techniques to ensure their safety and efficacy in medical applications and to advance the field of biomaterials research and development.

5. Applications in Medical Devices and Implants

Biomaterials are crucial in the creation and performance of medical devices and implants because they are designed to interact with biological systems while retaining functionality, mechanical strength, and biocompatibility. The selection of biomaterials is determined by the application, with specific materials chosen to fulfil the mechanical, biological, and chemical needs of the target tissue or organ. Biomaterials such as titanium and its alloys are commonly utilized in orthopaedic implants due to their high strength, corrosion resistance, and biocompatibility, and they are frequently augmented with surface treatments or coatings such as hydroxyapatite to facilitate bone bonding and osseointegration. Common applications include joint replacements, bone plates and screws, and spinal implants. In cardiovascular devices, biomaterials must have great hemocompatibility, fatigue resistance, and flexibility, utilizing materials like

polyurethane and expanded polytetrafluoroethylene (ePTFE) are extensively used. Nitric oxide-releasing polymers and bioabsorbable stents are also being researched to increase hemocompatibility and lower long-term problems. Dental biomaterials, such as titanium and zirconia, must withstand mechanical loads from chewing while being biocompatible with oral tissues. They are used in dental implants, bone grafting, and restorative dentistry. In ophthalmology, biomaterials are chosen for their optical clarity, softness, and biocompatibility and are utilized in devices such as intraocular lenses, contact lenses, and synthetic corneas. Soft contact lenses are made from hydrogels, specifically poly(2-hydroxyethyl methacrylate) (pHEMA), because of its water content, oxygen permeability, and comfort.

Tissue engineering is an interdisciplinary field that seeks to restore, replace, or regenerate damaged tissues and organs through the use of scaffolds, cells, and signalling molecules. Scaffolds must be carefully designed to provide a supportive environment for cell growth and tissue development. Tissue engineering, which combines biomaterials, cells, and signalling molecules, has the potential to improve the treatment of a wide range of diseases and injuries. Overall, biomaterials play an important role in the creation of medical devices and implants, and their uses are expanding to new areas such as tissue engineering and regenerative medicine. As biomaterials research & development progresses, we may anticipate to see new and novel applications in medical devices and implants, which will improve patient outcomes and overall quality of life. Furthermore, the use of biomaterials in medical devices and implants has enhanced the quality of life for millions of people throughout the world, and it will continue to play an important part in the advancement of new medical technology. Understanding the properties and applications of biomaterials allows researchers and clinicians to create and develop innovative medical devices and implants that address patients' specific needs while also improving their overall health and well-being.

6. Tissue Engineering and Regenerative Medicine

Tissue engineering and regenerative medicine are fast expanding fields that combine biology, materials science, and engineering to develop functioning tissue constructs capable of restoring, replacing, or regenerating damaged tissues and organs. Scaffolds are essential in tissue engineering, serving as temporary three-dimensional scaffolds that direct cell adhesion, proliferation, and differentiation. An ideal scaffold should be biocompatible, biodegradable, and have suitable mechanical strength for the target tissue, as well as porosity to allow for nutrient transfer, waste elimination, and cell penetration. Natural polymers, such as collagen and alginate, are often employed because of their inherent bioactivity and resemblance to native extracellular matrix (ECM). While synthetic polymers such as poly(lactic-co-glycolic acid) (PLGA) and polycaprolactone (PCL) have adjustable breakdown rates and mechanical qualities. Hybrid scaffolds combine synthetic strength with biological cues found in natural materials, resulting in an optimal milieu for tissue regeneration. Various fabrication techniques, such as electrospinning, 3D bioprinting, and freeze-drying, are used to create scaffolds with specific architectures. Tissue engineering applications include bone tissue engineering, where scaffolds made of hydroxyapatite (HA) or tricalcium phosphate (TCP) are used to promote osteointegration and bone regeneration; cartilage

regeneration, where hydrogels like chitosan and agarose serve as matrices for chondrocyte proliferation and extracellular matrix production; skin substitutes, where bilayered scaffolds mimic the structural complexity of dermis and epidermis; and neural tissue electrical signal transmission. Tissue engineering, which combines biomaterials, cells, and signaling molecules, has the potential to improve the treatment of a wide range of diseases and injuries. The area of tissue engineering and regenerative medicine is quickly evolving, with novel biomaterials and fabrication processes emerging to improve the design and functionality of tissue constructions. As research advances, we should expect to see new and innovative applications of tissue engineering in the treatment of many diseases and injuries, which will improve patient outcomes and quality of life. Furthermore, by offering alternatives to conventional surgical procedures and lowering the need for donor tissues and organs, tissue engineering and regenerative medicine have the potential to lower healthcare costs and enhance patient care. All things considered, tissue engineering and regenerative medicine are exciting fields with enormous promise to enhance human health and well-being.

7. Future Trends and Smart Biomaterials

The science of biomaterials is fast moving toward the development of smart and adaptive systems that can interact dynamically with biological settings, resulting in better therapeutic outcomes and patient care. Smart biomaterials can detect and respond to environmental changes such as pH, temperature, and enzyme activity. They are intended to adapt to external stimuli, interact with digital technologies, and facilitate personalised medical treatments. Smart biomaterials include stimulus-responsive hydrogels, shape-memory polymers, and self-healing materials, which can swell, shrink, or release pharmaceuticals in response to certain triggers, restore their previous shape when exposed to certain stimuli, and repair micro-damage autonomously. Advanced fabrication techniques, such as 4D printing and bioprinting, are changing the way biomaterials are planned and executed, allowing for the construction of complex, personalized geometries and patient-specific implants. Artificial intelligence (AI) and machine learning are also being used to accelerate biomaterial development, anticipate material behaviour, optimize scaffold design, and assess biocompatibility. These advancements hint to a future in which biomaterials are intelligent, flexible, and personalized to the specific demands of each patient, resulting in superior therapeutic outcomes and lower healthcare expenditures. The usage of biomaterials in medical applications is predicted to increase, with smart biomaterials playing an important part in the advancement of personalized medicine and precision healthcare. Researchers can use AI and machine learning to design and manufacture biomaterials that are tailored to the specific needs of individual patients, increasing patient outcomes and quality of life. Furthermore, the development of smart biomaterials and advanced fabrication techniques is expected to transform the field of biomaterials, allowing for the creation of complex, tailored biomaterials that can interact dynamically with biological environments and support personalized medical treatments. Overall, the future of biomaterials seems bright, with smart biomaterials and sophisticated fabrication techniques projected to play a significant role in enhancing patient care and outcomes.

8. Conclusion

Biomaterials have transformed healthcare by allowing the creation of innovative medical devices, implants, and tissue engineering scaffolds. With ongoing advancements in materials science, additive manufacturing, and biotechnology, the area is set to address more complicated clinical difficulties, ranging from organ regeneration to intelligent medicinal delivery. The future lies in interdisciplinary integration, where personalized medicine, smart biomaterials, and regenerative methods come together to provide patient-specific, minimally invasive, and highly successful treatments. Robust development and extensive characterization are critical for guaranteeing safety, efficacy, and long-term success in biomedical applications.

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