

INTRODUCTION

This chapter provides a comprehensive introduction to biomedical implants and their classifications, with a particular emphasis on load-bearing applications such as orthopedic and dental implants. It discusses the physiological conditions that influence implant performance and outlines the essential characteristics of an ideal biomaterial for such applications. Furthermore, the chapter addresses the economic aspects of biomedical implants in the global market and concludes with the aim of the present study.

1.1 Biomedical implant

Joint pain, bone loss, bone fractures, and tooth loss are common conditions caused by trauma, disease, aging, or congenital defects. These conditions often result in significant discomfort, restricted mobility, and a reduced quality of life. In such cases, biomedical implants offer the most effective solution to restore function, alleviate pain, and prevent further deterioration [1,2]. Biomedical implants are devices or tissues engineered to be placed inside or on the surface of the human body to replace, support, or enhance the function of a biological structure [3]. Figure 1.1 shows the schematic images of different types of biomedical implants. These implants range from joint replacements and dental implants to more complex devices like cardiac pacemakers and cochlear implants. These implants are manufactured using biocompatible materials, including metals, ceramics, polymers, and composites, and are specifically engineered to function safely within the human body [4]. The use of biomedical implants has revolutionized modern medicine, offering life-saving and life-enhancing solutions for conditions once considered untreatable. They have significantly improved the quality of life for millions, enabling individuals to regain mobility, restore sensory functions, and more

effectively manage chronic health conditions [5]. Ongoing research and development continue to expand possibilities, leading to more biocompatible, durable, and functional implants that better mimic the properties of natural tissues.

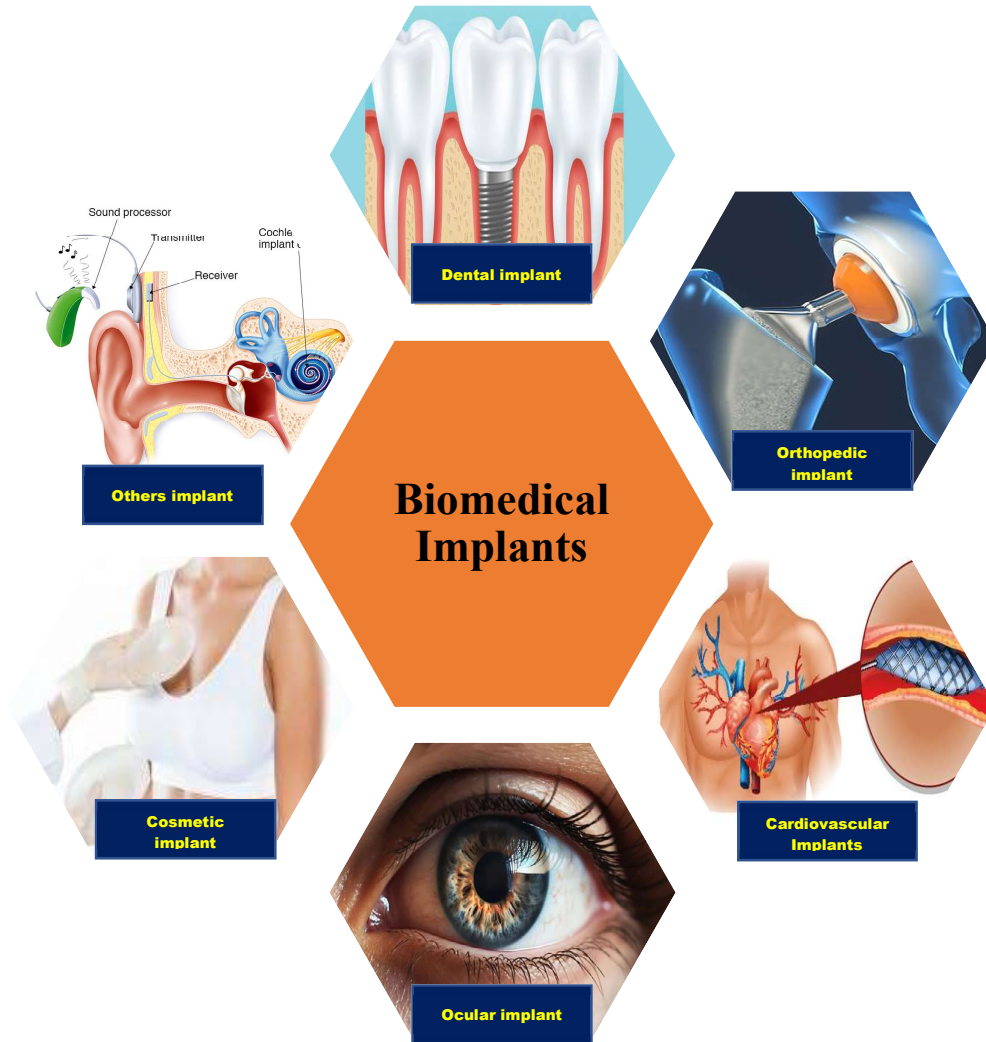


Fig. 1.1: Schematic classification of biomedical implants

1.2 Classification of biomedical implants

Biomedical implants can be classified into various categories based on different criteria, such as application and material. A brief description of each classification is given below.

1.2.1 Based on application

i. Orthopedic implants

Orthopedic implants are medical device designed to support or replace damaged bones and joints, facilitating the healing and restoration of musculoskeletal function. Typically made from metals, ceramics, or polymers, these implants are used in various orthopedic procedures, including fracture fixation, joint replacement, and spinal surgery. They are engineered to provide structural stability, promote bone integration, and withstand mechanical loads, thus aiding in the recovery and improvement of patient's mobility and quality of life [6].

ii. Cardiovascular implants

Cardiovascular implants are medical devices designed to support or enhance the function of the cardiovascular system. These implants include a range of devices such as stents, heart valves, pacemakers, and artificial vessels, each tailored to address specific cardiovascular conditions or deficiencies. By integrating advanced materials and technologies, cardiovascular implants aim to restore normal blood flow, regulate heart rhythms, or replace damaged heart structures, ultimately improving patient outcomes and quality of life [7].

iii. Dental implants

Dental implants are prosthetic devices used to replace missing teeth by anchoring into the jawbone to provide a stable foundation for artificial teeth. Typically made from biocompatible materials such as titanium or zirconia, these implants are surgically placed into the jawbone, where they integrate with the bone through a process called osseointegration. Once integrated, they serve as a durable base for attaching crowns, bridges, or dentures, restoring both the functionality and aesthetics of natural teeth [8].

iv. Ocular implants

Ocular implants are medical devices designed to restore or enhance the function of the eye by replacing or supporting damaged visual structures. Common types include intraocular lenses (IOLs) used in cataract surgery to substitute the eye's natural lens, retinal implants developed to assist patients with degenerative retinal conditions, and orbital implants for cosmetic restoration following enucleation. These devices are typically fabricated from biocompatible materials such as silicone, acrylic, or medical-grade polymers, and are engineered to integrate seamlessly with ocular tissues, effectively restoring visual function or cosmetic appearance [9].

v. Neurological implants

Neurological implants are medical devices designed to restore, enhance, or monitor neural functions by interfacing with the nervous system. Common types include deep brain stimulators for neurological disorders, cochlear implants for hearing restoration, and brain-computer interfaces enabling direct brain-to-device communication. These implants are typically made from biocompatible materials such as titanium for structural components and silicone for insulation and flexible interfaces. They are engineered to integrate with neural tissues to provide therapeutic benefits or facilitate monitoring and control of neural activity [10].

vi. Soft tissue implants

Soft tissue implants are medical devices designed to repair or replace damaged or missing soft tissues, such as skin, muscle, or fat. These implants are typically fabricated from synthetic polymers, biological tissues, or combinations thereof, differing from metallic or ceramic implants commonly used for hard tissue repair. Soft tissue implants are widely employed in procedures such as breast reconstruction, hernia repair, and cosmetic enhancements, where they restore both functional and aesthetic qualities by

mimicking the mechanical and biological properties of natural tissues. Their primary roles include providing structural support, facilitating tissue healing, and improving the form and function of the affected area [11,12].

1.2.2 Based on material

i. Metallic implants

Metallic implants are widely used in orthopedic and dental applications due to their high strength, fatigue resistance, and ability to withstand physiological loads. Titanium and its alloys are particularly favored for their excellent biocompatibility and corrosion resistance [13]. However, conventional alloys like Ti-6Al-4V raise concerns due to the potential toxicity of aluminium and vanadium elements [14]. Additionally, their relatively high elastic modulus compared to natural bone can cause stress shielding, leading to bone resorption and implant loosening over time. Moreover, titanium alloys exhibit relatively poor wear resistance, which can limit their performance in articulating applications. This has led to the exploration novel titanium alloys and newer material systems with non-toxic alloying elements [15]. Recent advances in alloy design strategies and processing techniques are enabling the development of materials with improved mechanical compatibility and biological performance, which are essential for next-generation load-bearing implants [16].

ii. Ceramic implants

Ceramic implants such as alumina (Al_2O_3), zirconia (ZrO_2), and hydroxyapatite ($\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$) are widely used in dental prostheses, joint replacements, and bone grafts due to their excellent biocompatibility, wear resistance, and chemical stability [17,18]. Hydroxyapatite is particularly valued for its bioactivity and ability to enhance osseointegration [19]. However, ceramics are inherently brittle with low fracture toughness, which limits their application in load-bearing orthopedic implants subject to

dynamic stresses [20]. This brittleness increases the risk of catastrophic failure under impact or cyclic loading, making ceramics less reliable as standalone materials for structural implants [21]. Consequently, ceramics are often combined with metallic materials or used in non-load-bearing roles [20].

iii. Polymeric implants

Polymeric implants, primarily fabricated from synthetic polymers such as polymethylmethacrylate (PMMA), ultra-high-molecular-weight polyethylene (UHMWPE), polylactic acid (PLA), and polyglycolic acid (PGA), are employed in various biomedical applications including bone cement, craniofacial plates, and temporary fixation devices [22,23]. These materials offer notable advantages such as chemical inertness, biocompatibility, ease of processing, and controllable degradation rates, making them suitable for short-term or supportive clinical roles. However, their inherently low mechanical strength, poor wear resistance, and susceptibility to fatigue under physiological loading severely limit their use in orthopedic and dental load-bearing applications [2]. Consequently, polymeric materials are either combined with metallic components or restricted to applications where mechanical demands are minimal.

iv Composite implants

Composite implants are developed by combining two or more distinct biomaterials, such as metals, ceramics, or polymers, to achieve multifunctional performance not possible with single-phase materials. These systems are designed not only to enhance mechanical properties, but also to improve biological responses, control degradation rates, and optimize tissue integration, particularly in applications such as bone grafts, dental implants, and coating layers for orthopedic devices [24,25]. However, their application in load-bearing orthopedic and dental implants is often limited due to issues

such as poor interfacial bonding between constituents, mismatch in degradation rates, and reduced fatigue resistance compared to monolithic metallic systems [26,27].

1.3 Load bearing implants

Load-bearing implants are biomedical devices designed to replace or support skeletal structures subjected to significant mechanical loads during routine physiological activities such as walking, chewing, or lifting. These implants are essential in orthopedic and dental procedures, where they help restore mobility, maintain anatomical alignment, and ensure effective load transmission to surrounding tissues [28,29]. Their long-term success depends on biomechanical compatibility, precise anatomical fit, and functional integration with host tissues [30].

The detailed overview of the anatomical structure, functional role, and clinical relevance of dental and orthopedic load-bearing implants is presented in the following sections.

1.3.1 Dental implants

Dental implants restore the function and aesthetics of missing teeth by anchoring prosthetic components within the jawbone. As illustrated in Fig. 1.2, the dental implant system comprises three primary components: the implant (fixture) embedded in the jawbone, the abutment serving as a connector, and the prosthetic crown. Clinical success depends on stable osseointegration and the long-term structural integrity of these components. However, several failure modes compromise implant longevity. Peri-implantitis, an inflammatory response due to bacterial accumulation, causes progressive bone resorption and implant loosening [31]. Additionally, a mismatch in elastic modulus between implant and bone often induces stress shielding, reducing local bone density [32]. The physiological environment surrounding implants presents complex chemical and biological conditions, including fluctuating pH and enzymatic

activity, which can accelerate electrochemical corrosion, leading to ion release (e.g., Al, V) and potential local or systemic cytotoxicity [33,34]. Moreover, micromotion at interfaces causes mechanical wear, generating debris that triggers inflammatory responses and disrupts osseointegration [35,36].

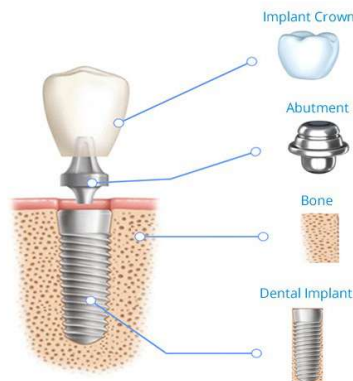


Fig. 1.2: Dental implant replacement [37]

1.3.2 Orthopedic implants

Orthopedic implants are used to restore the function of musculoskeletal tissues by replacing or supporting damaged bones and joints. They are widely applied in hip and knee joint replacements and fracture fixation. Similar to dental implants, the success of orthopedic devices depends on their mechanical durability, corrosion and wear resistance, and biocompatibility [1,38].

Hip implant

Hip implants typically consist of a femoral stem, femoral head, and acetabular cup. As illustrated in Fig. 1.3, the femoral stem is inserted into the medullary canal of the femur and is commonly fabricated from Ti-based alloys (e.g., Ti-6Al-4V) or Co–Cr alloys due to their high strength and corrosion resistance [39]. The femoral head, which articulates with the acetabular cup, is often made of ceramic materials (e.g., alumina, zirconia) or metals, while the acetabular cup typically comprises ultra-high-molecular-weight polyethylene (UHMWPE) or ceramics. During articulation, wear at the metal–polymer

or ceramic–polymer interfaces produce microscopic debris that may accumulate in surrounding tissues, potentially inducing osteolysis and implant loosening [40]. Furthermore, corrosion at modular junctions, such as the stem–head interface, can lead to metal ions release, raising concerns about local inflammatory responses and systemic toxicity [41].

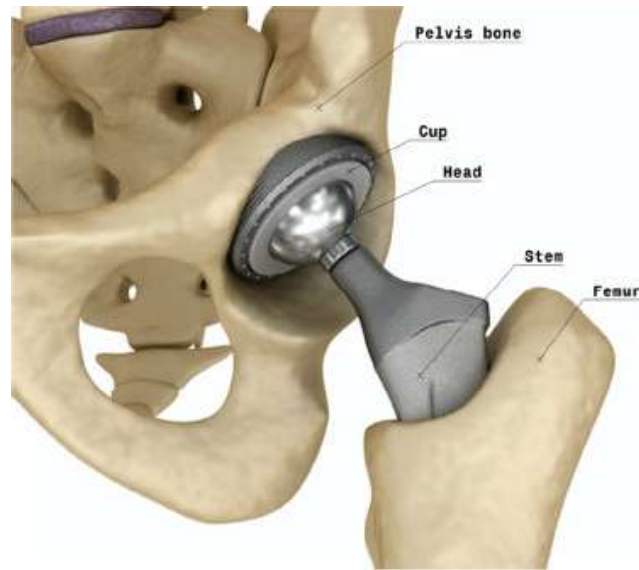


Fig. 1.3: Hip implant replacement [42]

Knee implant

Knee prostheses include femoral, tibial, and patellar components, as shown in Fig. 1.4. The femoral and tibial baseplates are typically made of cobalt–chromium (Co–Cr) or titanium (Ti) alloys, while the insert, which serves as the bearing surface, is often composed of ultra-high-molecular-weight polyethylene (UHMWPE). Tribological interactions between these components can result in the generation of polymer wear debris, which may trigger macrophage-mediated inflammatory responses and ultimately lead to aseptic loosening [43]. Therefore, careful material selection is essential to balance wear resistance, mechanical strength, and compatibility of elastic modulus to prevent stress shielding.



Fig. 1.4: Knee implant replacement [44]

Bone plates and screws

Bone plates and screws are commonly employed in fracture fixation to maintain proper alignment and provide mechanical stability throughout the healing process. Titanium and stainless steel are the primary materials of choice because of their excellent mechanical strength, corrosion resistance, and well-established clinical outcomes [45]. Recently, increasing interest has been directed toward biodegradable polymer-based implants, which offer the potential to reduce long-term complications and eliminate the need for secondary surgeries for implant removal [46]. The typical design and application of bone plates and screws are illustrated in Fig. 1.5.



Fig. 1.5: Bone plates and screws [47]

1.4 Physiological conditions for load bearing implants

Physiological conditions critically influence the clinical success, integration, and long-term performance of load-bearing biomedical implants. These implants interact with the biological environment and are subjected to complex mechanical, chemical, and

immunological factors. A detailed understanding of these conditions is essential for the development of advanced biomaterials to ensure optimal clinical outcomes. A few key physiological factors include:

Mechanical stress

Orthopedic implants, such as hip and knee prostheses, must withstand high mechanical loads generated during daily activities like walking or stair climbing. Typical peak loads can range from 2.5 to 5 times body weight for hip joints and 3 to 6 times body weight for knees [48,49]. Dental implants, although subjected to comparatively lower loads, experience occlusal forces during mastication typically ranging from 90 to 220 N, with occasional peak loads up to around 450 N [50].

Corrosive environment

Load-bearing implants are constantly exposed to physiological fluids such as blood plasma, lymph, and synovial fluid, which contain chloride ions at concentrations between 96 and 106 mEq/L [51]. Under healthy condition, these fluids maintain a near-neutral pH of approximately 7.4. However, during pathological states like inflammation or infection, the local pH can drop significantly, reaching value as low as 4.5 to 5.0 [52]. This acidic, chloride-rich environment can accelerate corrosion of metallic implants, resulting in the release of metal ions such as nickel (Ni), vanadium (V), and aluminium (Al), which have been linked to adverse biological effects including cytotoxicity and inflammation [53].

Body temperature

Load-bearing implants are exposed to physiological temperatures typically around 37°C, though these may vary slightly under certain conditions such as fever or inflammation. This thermal environment affects material behavior and corrosion kinetics during implant service life [54].

Biological interaction & immune response

Load-bearing implants interact continuously with surrounding biological tissues and fluids. Adverse immune reactions such as inflammation, allergic responses, or fibrosis may occur if the implant material is not biocompatible [55]. Integration with both bone and soft tissues influences implant stability and longevity. Inadequate tissue integration can result in implant loosening, chronic inflammation, and eventual implant failure, potentially necessitating revision surgery [56].

Wear and friction

Load-bearing implants, including orthopedic and dental implants, are continuously exposed to mechanical wear and friction due to repetitive joint articulation or mastication forces during normal physiological activity [57,58]. This repetitive motion generates wear particles that can provoke biological responses, such as inflammation and peri-implant bone loss, which may compromise implant stability [59]. The wear mechanisms are influenced by factors like load magnitude, motion type, and the biochemical environment surrounding the implant.

Microbial environment

Load-bearing implants are exposed to microbial challenges due to the presence of bacteria in surrounding tissues and the surgical environment. Bacterial colonization on implant surfaces can lead to the formation of biofilms, which are resistant to immune clearance and antibiotic treatment. Such infections may persist chronically and compromise implant functionality and longevity [60].

1.5 Desirable characteristics of a load bearing implants

Load-bearing implants, particularly those used in orthopedic and dental applications, must meet stringent requirements to ensure long-term functionality, safety, and compatibility with the human body. The essential characteristics of such implants

include [61]:

Biocompatibility

The material must be non-toxic, non-carcinogenic, and biocompatible to prevent inflammation, rejection, or other adverse immune responses that could lead to implant failure.

Mechanical Strength and Fatigue Resistance

Load-bearing implants require a minimum yield strength above 500 MPa for orthopedic and 200-300 MPa for dental applications, along with fatigue strength over 200-400 MPa to endure cyclic loading. High tensile strength, fracture toughness, and long-term mechanical reliability are essential to prevent failure under physiological conditions.

Corrosion and Wear Resistance

Resistance to corrosion in physiological fluids and wear during movement is critical to ensure long-term performance and to avoid ion release or wear particle-induced inflammation.

Osteointegration

The implant surface should support bone ingrowth for secure anchorage. This biological integration can be enhanced by surface modifications such as roughening, porosity, or bioactive coatings.

Elastic Modulus Compatibility

A low elastic modulus, close to that of natural bone (~20-30 GPa), helps minimize stress shielding and promotes bone remodeling.

1.6 Economic perspective of biomedical implants

From an economic perspective, biomedical implants represent a rapidly growing segment of the global healthcare market. As population ages and the prevalence of

chronic diseases such as arthritis, osteoporosis, and cardiovascular conditions increase, the demand for implants, including hip, knee, dental, and cardiovascular devices, continues to rise. This sector is highly lucrative, driven by technological innovations, increased healthcare spending, and advancements in materials and biocompatibility, which extend the longevity and effectiveness of implants. The market is also shaped by regulatory requirements, research and development costs, and competitive pressures to reduce manufacturing costs while maintaining high standards of safety and efficacy. Although the upfront costs of developing and producing implants are high, the long-term benefits, such as reduced hospitalization and improved quality of life, lead to significant economic advantages for healthcare systems globally. Referring to the reports of market.us [62], the overall global implants market which includes orthopedic, dental, cardiovascular, spinal, breast, ophthalmic, and other implants was 106 billion USD in 2022 and is expected to reach up to 177 billion USD in 2032 at compound annual growth rate (CAGR) of 6.7%. Other reports also by market.us forecast the global market of the implant will grow from 111.4 billion USD in 2023 to 225.4 billion USD in 2033, at a CAGR of 7.3% [63]. From the materials perspective, the metallic materials are most widely used as compared to ceramic and other materials. Furthermore, the report from research and market shows, out of these orthopedic implant market in 2022 was 49.8 billion USD and is expected to reach 68.71 billion USD in 2028 at a CAGR of 5.5% [64]. While, the dental implant market was 3.86 billion USD in 2022 and can reach up to 8.6 billion USD in 2029, grows at a CAGR of 11.4% [65]. The Emergen Research described that among metallic implant, titanium, stainless steel, Co-Cr, other metals and its alloys are used. However, titanium shares the highest proportion to develop the medical implant compared to stainless steel, Co-Cr, and other alloys [66].

1.7 Aim of the study

The primary aim of this research is to develop novel titanium-based alloys via powder metallurgy, utilizing vacuum-sealing-assisted sintering, for potential application in load-bearing biomedical implants. The study focuses on the design of alloy systems incorporating biocompatible elements such as Ti, Nb, Zr, Mo, Sn, and Cu, selected for their ability to tailor the mechanical strength, elastic modulus, corrosion resistance, and tribological performance of the developed materials in accordance with the physiological requirements of orthopedic and dental implants. The research involves a comprehensive investigation of phase formation, microstructural evolution, and mechanical behavior, followed by electrochemical corrosion, wear, and tribocorrosion analysis under SBF conditions. This work aims to address the limitations associated with conventional implant materials such as commercially pure titanium (cpTi) and Ti-6Al-4V, and to explore the feasibility of advanced titanium-based alloy systems with improved performance for biomedical applications.