Chapter-2

Literature Review

2.1 Background

Biomaterials for Orthopedic applications have grown multifaceted and advanced due to technological and scientific developments in orthopedic surgery. Over the past few decades, these materials have significantly improved the standard of living for millions of people. Orthopedic implants are crucial for healing, correcting deformities, and restoring lost functions in the skeletal system. Several important material characteristics are required for orthopedic implants, especially those used for load-bearing applications. These include superior corrosion resistance within the body, high strength, suitable wear resistance and fatigue, low elastic modulus, high elasticity, and no cytotoxicity. The choice of biomaterial is vital for ensuring the implant's proper functioning and long-term success. Specific properties are necessary for permanent orthopedic devices (load-bearing) like knees, hips, and shoulders and trauma fixation products such as screws and intramedullary nails. **First,** the prosthesis must be biocompatible with the human body, meaning it should not cause adverse reactions or toxicity. **Secondly,** it should possess a balanced combination of physical and mechanical properties to meet the desired performance requirements. Lastly, the material should be relatively easy to fabricate, ensuring reproducibility and conforming to biological and technical needs. Cost-effectiveness is also one of the important factors in choosing suitable materials for orthopedic implants **[49]**.

Among the austenitic stainless steels, 316L is commonly used for biomedical applications. The "L" in the designation stands for "low-carbon," indicating that this steel has a reduced carbon content. Carbon is typically kept low in austenitic grades, usually below 0.08%. In the case of

316L, the carbon content is further reduced to around 0.03%. The lower carbon content helps minimize the precipitation of carbides (Cr-C compounds) at the grain boundaries, which can lead to localized corrosion in vivo **[50]**. However, metals are often suitable for load-bearing applications in total arthroplasty and fracture fixation. The choice of material depends on the implant's intended application and anatomical location, with metals commonly used for load-bearing orthopedic devices **[51]**.

The application of steel alloys in orthopedics was a significant advancement in biomaterials. Steel alloys were first used in the biomedical area in the nineteenth century to make plates and screws to repair shattered bones. However, early steel alloys had several drawbacks, including fatigue failures and significant corrosion problems. A stainless-steel alloy comprising 18% chromium (Cr) and 8% nickel (Ni) was introduced for surgical implant applications in 1926. The resulting alloy surpassed Sherman's earlier vanadium (V) steel for fracture-fixation plates regarding resistance to body fluids and strength **[52]**. In the current classification, the 18-8 alloy, known as type AISI 304, was further enhanced by adding molybdenum (Mo) to improve corrosion resistance. This improved alloy found extensive use in manufacturing fracture-fixation devices and an early version of total hip replacements developed by Philips **[53]**.

316L stainless steel has become the most often implanted stainless steel, primarily for producing fracture-fixation products and stents. In response to patient concerns about nickel sensitivity, a new generation of implantable stainless steels with minimal nickel concentration was developed. Low-nickel alloys had more manganese and nitrogen to maintain the required austenitic phase while reducing nickel concentration. In particular, fracture fixations and total arthroplasty procedures have extensively used AISI 316L stainless steel. It is frequently used for aneurysm clips, intramedullary nails and pins, femoral fixation devices, bone plates and screws, and joints

for the ankles, elbows, fingers, knees, hips, shoulders, and wrists. The Zimmer-made intramedullary nail (M/DN intramedullary femoral/recon nail) is used for stainless steel implants. AISI 316L stainless steel maintains an austenitic structure even at room temperature. Its elemental composition resembles SUS304 stainless steel (Fe-18% Cr-8% Ni). Adding molybdenum enhances the alloy's corrosion resistance while reducing the carbon content helps minimize chromium carbide precipitation ($Cr_{23}C_6$) at grain boundaries, further improving corrosion resistance. This alloy is also called ASTM F138 by the American Society for Testing and Materials (ASTM) and ISO 5832-1 by the International Organization for Standardization (ISO). These designations provide standardized specifications and requirements for the material's composition, properties, and performance in biomedical applications.

2.1.1 Criteria for ideal bone implant

According to Bauer and Muschler **[54],** the ideal bone implant material should be viable for osteointegration, osteoinductive, and osteoconductive. Furthermore, biocompatibility and mechanical compatibility are essential for implant performance. Additionally, implant waste shouldn't adversely affect the body once it has degraded. The ability of an implant to promote osteogenesis is known as osteoinduction, whereas Osteoconduction is the process by which bone is made to conform to the surface of a substance. Undifferentiated cells will become preosteoblasts when an inductive substance stimulates them. Branemark **[55]** describes osteointegration as the attachment and proliferation of bone cells and surrounding tissues into the implant, resulting in long-lasting, appropriate clinical functioning without triggering rejection mechanisms. According to Geetha **[56]** and Ratner **[57],** biocompatibility is an aspect of an implant that prevents any inflammatory, toxic, or allergic reactions in the body. The periprosthetic tissue decreases if the implant material is harmful **[58]**. A fibrous tissue can form if the substance is inert, bio-tolerant,

non-toxic, and biologically inert. Rejection is the end effect if no complete integration into the implant exists. However, interfacial bone development occurs when a substance is physiologically active and non-toxic (bioactive), resulting in osteointegration and implantation.

Fig. 2.1 depicts Ideal Bone Implant Criteria. Osteoblasts (bone-forming cells), osteoclasts (cells that degrade or resorb bone), and osteocytes (mature bone cells) are the components involved in the formation of bone. They control homeostasis, which includes bone formation, development, healing, and remodelling **[59]**. Osteogenesis or ossification are other terms for the process of bone production. Collagen, glycoproteins, and proteoglycan, which are the organic components of bone, are produced by osteoblasts **[58]**. Additionally, osteoblasts move from connective tissue to the membranes to create mature osteocytes and deposit bone matrices there **[60]**. The long-term service life of an implant is determined by the early proliferation and maturation of immature cells **[61]**. The post-implantation bone healing process is biological and involves cells, a signal transduction system, hormones, and growth factors. These factors have all been extensively discussed in the literature **[58, 62-65]**. Modulus of elasticity is a crucial mechanical feature of an artificial device in addition to great mechanical strength when developing materials for bone implant applications. High wear resistance, good fatigue qualities when utilized under cyclic loading, minimal unfavourable tissue reactions, and strong corrosion resistance are vital requirements for the ideal orthopedic implant.

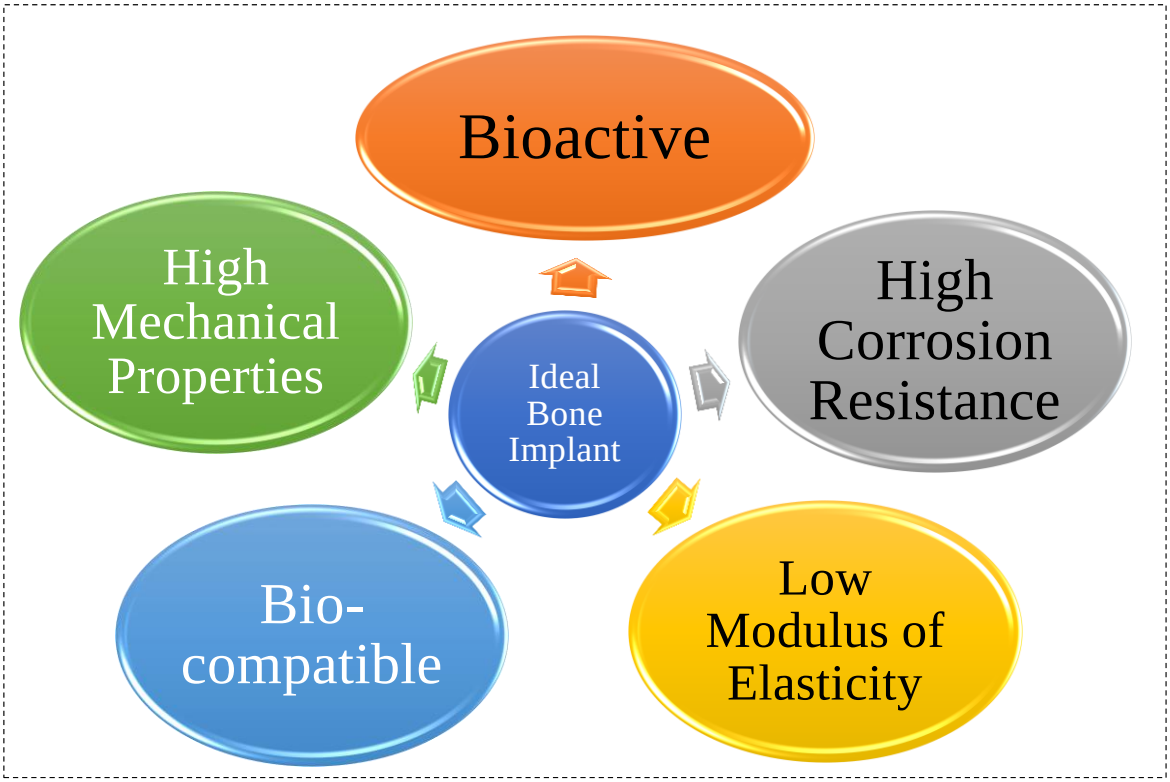

Fig. 2.1 Ideal Bone Implant Criteria

2.1.2 Current implant materials

Polymeric, metallic, ceramic, and composite materials are the four primary biomaterials categories **[57, 65]**. Even if each material has particular benefits for a given application, they have specific drawbacks that make them unsuitable. The current biomaterials utilized in bioimplants are listed in **Table 2.1,** while **Table 2.2** lists the benefits and drawbacks of the most popular biomaterials. Ceramics with excellent bioactivity, osteoconductive, and biocompatible properties, including calcium phosphate and bioactive glass, have been researched as bone transplant scaffolds. These ceramics are unsuitable for bone implant use due to their brittleness, impact resistance, low strength, inelasticity, and toughness **[66]**. A favourable environment for cell adhesion, proliferation, and differentiation, porous polymers are also desirable for implant usage. Due to their history of clinical success, studies of polyesters as biomaterials for bone regeneration

applications are growing **[67]**. However, their mechanical strength and bioactivity make them unsuitable for load-bearing applications.

High mechanical strength is commonly observed in metals and their alloys, including titanium, stainless steel, and chromium cobalt, making them appropriate for load-bearing bone substitutes, as explained in **Chapter 1.**

The mechanical characteristics of bone and bone implant materials are summarized in **Table 2.3**. Furthermore, metallic-based biomaterials have excellent tensile strength, which polymers and ceramics do not have, making them suitable for load-bearing applications. However, metal alloys are inert to human tissues because there is no direct chemical connection between the substance and the host tissue after implantation.

Table 2.1 An overview of biomaterials used in biomedical applications **[57-58]**.

Implant	Material
Skeletal system Joint replacements (e.g., knee, hip, Bony defect repair, Bone cement, dental implant, the bone plate for fracture fixation)	Titanium (Ti), Ti-6%Al-4%V (Ti6Al4V) alloy, 316 L, PMMA, HA, PE, Cobalt-chromium (Co-Cr) alloy, Calcium phosphate, and polyethylene
Cardiovascular system Blood vessel prosthesis Heart valve Catheter	Silicone rubber, Teflon, polyurethane, Carbon, Reprocessed tissue, Stainless steel, Polyurethane, Dacron, Teflon
Senses Corneal bandage Cochlear replacement Contact lens	Collagen, Hydrogel Platinum electrodes Hydrogel, Silicone-acrylate
Organs Artificial kidney (hemodialysis) Heart-Lung machine Artificial Heart Skin repair template	Hydrogel, e.g., Cellulose, polyacrylonitrile Silicone rubber Polyurethane Silicone-collagen composite

Table 2.2 The benefits and drawbacks of biomedical materials **[66]**.

Material	Benefits	Drawbacks
Metals Titanium and its alloys, Stainless Steel (SS), Cobalt Chromium (Co-Cr), Tantalum (Ta), and Magnesium (Mg)	Cytocompatibility Biocompatible Ductile High corrosion resistance (Ti and Ta) Excellent mechanical strength suitable for load-bearing Biodegradable (Mg)	No direct bonding to tissue High elastic modulus Low corrosion resistance (Mg)
Ceramics Hydroxyapatite, Bioglass, and Aluminum Oxide	Biocompatible Bioactive Strong in compression	Low Mechanical Properties Brittle nature. Weak in tension Low impact resistance
Polymers PMMA, PLLA, PUL PEG Polyester	Light Weight Ductile Easy to Fabricate Biodegradable	Bioinert Mechanical strength is too Low.

Table 2.3: Mechanical properties of the bone and bone implant materials **[69]**.

Material	**Elastic Modulus (GPa)**	**Tensile Strength (10^{-3}) (GPa)**
Co-Cr-Mo alloys	230	500
Stainless steel	200	700
Ti-6Al-4V	110	950
Titanium	110	500
Glass-ceramics	30	200[a]
Hydroxyapatite ceramics	20	100[a]
PMMA	3	80
Cortical bone	20	150
Cancellous bone	3	5

a = Bend strength

The implant may loosen in the case of titanium due to the considerable difference in the elastic modulus of titanium and native bone, which produces stress shielding **[68]**. Ti alloy (Ti-6Al-4V) has an elastic modulus in the 55-110 GPa region, much more significant than natural bone (Legeros and Craig, 1993). Another disadvantage of Ti-6Al-4V is the discharge of Al and V ions into the body, which may create long-term health concerns. The metals' failure to biodegrade necessitates extra surgery. As a result, these factors prompted the creation of novel Ti alloys or surface modifications to Ti-6Al-4V orthopedic implant materials.

2.1.3 Implant Failure

Failure is one of the essential aspects of implant material behavior and directly impacts the selection of materials and manufacturing processes. Implant failure analysis is a challenging field of research because of the many factors involved. Components fail despite being carefully designed, installed, operated, and machined. Due to the enormous number of implants, failure is widespread, even if only a small percentage of implants fail, making failure analysis a crucial topic. Establishing the reasons for failures can help designers, operators, and component users make better designs and use of components. Misuse, assembly or implantation challenges, defects in design, inappropriate material selection, corrosion, wear, and biomedical fitness are some of the primary causes of implant material failure.

After a femoral component neck fracture, Gilbert et al. **[65]** evaluated two modular hip implants with a cobalt alloy head and a cobalt-alloy stem. The fracture was caused by intergranular corrosive assault and cyclic fatigue stress of the stem, according to the findings. Chaodi et al. established a numerical approach (finite element) to anticipate the gradual failure of a thick, laminated composite femoral component for total hip arthroplasty under in vivo stress conditions.

Jaffe and Scott **[70]** studied the relationship between wear and the hydroxyapatite layer's thickness. The remaining tension induced during plasma spray coating has been associated with fracture initiation and propagation, demonstrated the biological effects of cobalt-chromium in animal cells and recommended comparing the findings from in vitro and in vivo research with results from human studies. Stainless steel sliding hip screw plates surgically removed had significant wear, corrosion, and damage to the tissue. Implant alloys, including titanium and 316L steel, have had similar results **[71]**.

The harsh operating conditions that surgical implants are subjected to include corrosion, wear, and mechanical loading (both static and dynamic). Premature failure is a possibility and is impacted by factors such as material choice, manufacturing technique, medical installation techniques, postoperative complications, and patient usage **[72]**. The systematic analysis of surgical implants removed from patients advances knowledge of clinical implant performance, indicates interactions between implants and the body, establishes the foundation for creating biocompatible implant materials, promotes design improvement, and contributes to research into medical devices. According to a metallurgical assessment, 42% of failures were caused by corrosion and erosion-corrosion, 16.5% by inclusions and stress gaps that could be associated with fatigue, 16.5% by traces of production contaminants, and 25% by fatigue via ductile-type failures. Weight, age between 45 and 75, male sex, and avascular necrosis appear to be significant risk factors for prosthesis failure.71, 72 (BMI appears less predictive, as weight is closer to physiological load). According to the analysis of various implant materials, the primary causes of failure are corrosive attack, manufacturing faults, and nonstandard induced failures. Biocompatible inorganic materials, such as hydroxyapatite covering specific binders, would make metal ion dissolution harder, possibly delaying corrosion and wear while reducing implant loosening from the bone.

2.1.4 Biological Interactions on metallic biomaterial surfaces

The physicochemical reactivity of a biomaterial's surface plays a crucial role in its suitability for use in a physiological environment. When implanted in vivo, a biomaterial directly interacts with body fluids. Body fluid is an aqueous medium that contains a variety of ions, chemicals, proteins, polysaccharides, enzymes, and different cell types. The corrosive nature of body fluid and its composition can significantly influence the performance and longevity of an implant. According to Planell et al. **[73],** the early events that occur on the surface of a biomaterial upon implantation are of great importance. These initial processes can have a profound impact on the overall performance and lifespan of the implant.

Metallic biomaterials, in particular, are highly sensitive to their surface characteristics, which can influence the interactions with the surrounding environment. When a biomaterial is inserted into the body, water molecules are the first to come into contact with its surface. The surface properties of the biomaterial affect the interaction and binding of water molecules, which, in turn, can impact the subsequent interactions with proteins and other molecules that arrive later **[74]**. A water-coating layer forms on the material's surface within a few nanoseconds. The implantation site of a biomaterial can vary depending on its intended use. For example, in the case of prosthetic joints, bone fixation tools, and dental implants, the implanted biomaterial interfaces with both hard and soft tissues **[75]**. The material's surface interacts and adheres to these tissues, forming a connection that determines the stability and functionality of the implant.

The host response to implants is a complex biological reaction that involves various factors and processes. Several factors can influence the host's response to an implant, including the anatomical location where the implant is placed, the shape and size of the implant, the surgical procedure used

for implantation, the modality and direction of loading applied to the implant, biological fluids present in the surrounding environment, the age and gender of the host, and importantly, the surface characteristics of the implant. The host response to implants is primarily an inflammatory reaction that occurs as long as a foreign body is present. This inflammatory response is a natural defence mechanism of the body in response to the presence of foreign material. The host's immune system recognizes the implant as foreign and initiates an immune response to remove or isolate it.

Various immune cells, such as neutrophils and monocytes/macrophages, are used at the implantation site through chemotactic factors like cytokines during the inflammatory response. Neutrophils and monocytes/macrophages play crucial roles in the immune response. Neutrophils are responsible for phagocytosing cellular debris and foreign substances present at the site of implantation. After completing their task, neutrophils gradually disappear, and macrophages take over during the later stages of the inflammatory response. Macrophages play a vital role in the persistent inflammatory response associated with most implants. They continue phagocytosing debris and foreign materials and release signalling molecules that can influence tissue remodelling and healing processes. The macrophagic response is a common characteristic of the host response to implants and indicates the ongoing inflammatory process. As the host response to implants progresses, macrophages play a significant role in forming multinucleated or foreign body giant cells. The ECM forms a fibrous capsule that surrounds and encapsulates the implanted material. The thickness of this fibrous capsule can vary depending on the movement of the implanted device and other factors, and it physically separates the material from the host tissue **[73]**.

For a long time, fibrous connective tissue encapsulation was considered the only potential interface between living bone tissue and a foreign object, as observed around orthopedic and dental implants that have been clinically successful **[76]**. The fibrous capsule is a part of the host's response to the

implant and represents an attempt by the body to isolate foreign material from the surrounding tissue. It's worth noting that these responses, such as fibrous encapsulation, bacterial adherence, and inflammation, can be traced back to the initial interactions between the implantable device and the biological interface. The properties and characteristics of the implant's surface and its interactions with the surrounding tissue are crucial in determining the nature and extent of these unfavourable responses. The presence of macrophages leads to the formation of multinucleated giant cells, and fibroblasts become the dominant cell type in the host response to implants. Fibroblasts secrete an extracellular matrix, forming a fibrous capsule encapsulating the implanted material. This fibrous capsule serves to separate the material from the host tissue physically. Understanding and managing the initial bio-interfacial interactions are essential for mitigating unfavourable responses associated with implantable devices, such as fibrous encapsulation, bacterial adherence, and inflammation. **Fig. 2.2** shows the Biological interactions on metallic biomaterial surfaces.

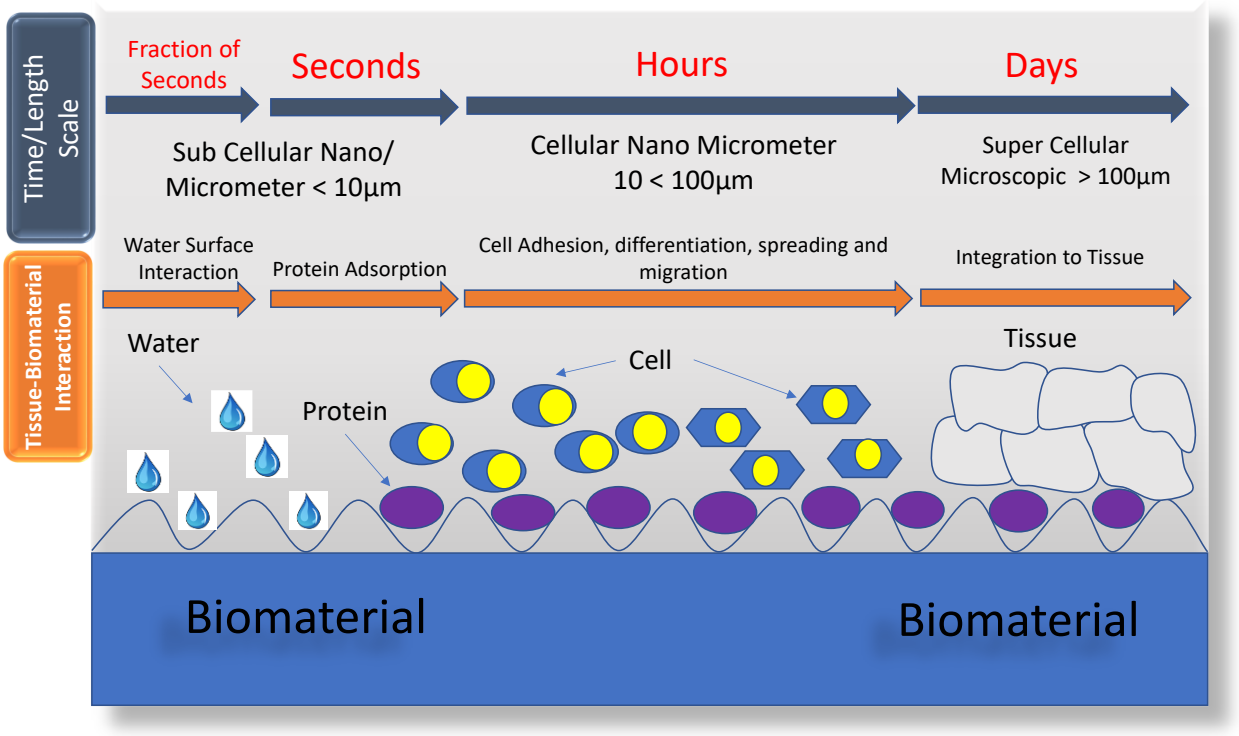

Fig. 2.2 Biological interactions on metallic biomaterial surfaces [**73**]

2.2 Corrosion Assessment of Orthopedic Implants

Generally, metallic implant systems have a moderate corrosion rate of approximately **2.5 x 10^{-4}** mm/yr or 0.01 mils/yr **[77]. Table 2.4 (a)** represents an overview of a few kinds of literature on the electrochemical corrosion behaviour of **uncoated** 316L stainless steel. This corrosion rate is acceptable to ensure the implants' longevity and functionality. However, it's important to note that the specific modest corrosion rate may vary depending on the type of implant and its intended application. Various forms of corrosion can occur in metallic implants, including uniform corrosion, intergranular corrosion, galvanic corrosion, stress corrosion cracking, pitting corrosion, and fatigue corrosion. Two key factors influencing implant corrosion are the thermodynamic forces that drive corrosion reactions (such as oxidation or reduction reactions) and a kinetic barrier, such as a surface oxide layer, that physically inhibits or slows down the corrosion reactions **[78]**.

The surface oxide layer serves as a protective barrier that can enhance the corrosion resistance of the implant material. By considering these thermodynamic and kinetic factors, researchers and engineers can develop strategies to optimize implant materials and surface modifications to improve corrosion resistance, enhance biocompatibility, and extend the lifespan of metallic implant systems. Ongoing research in this area aims to develop advanced materials and surface treatments that minimize corrosion and maximize the long-term performance of implants in the human body.

The study conducted by Aksakal et al. **[79]** investigated the failure of titanium alloy Ti-6Al-4V and 316L SS implants that were removed from patients. The researchers focused on understanding the underlying causes of implant failure and identified several mechanisms leading to the inability of different biomedical implants. The analysis of femoral titanium plates revealed that corrosion fatigue was the primary reason for their failure. Corrosion fatigue is a phenomenon where the repetitive cyclic loading of material and the corrosive environment leads to cracks and, ultimately, failure. Intense localized corrosion and intergranular cracking promote corrosion fatigue in these titanium plates. Similarly, the study found that corrosion fatigue and fretting corrosion were observed in bone plates and screws of modular hip implants. The interfaces between different implant components, such as the bone-stem and stem-cement interfaces, were particularly susceptible to these forms of corrosion. Fretting corrosion occurs when two surfaces experience small repetitive relative motions, causing material loss and leading to corrosion fatigue.

Consequently, these complications can ultimately lead to implant disintegration. To mitigate these issues, it has been found that the dissolution of metal ions can be reduced by applying suitable biocompatible inorganic coatings. One such coating is hydroxyapatite (HAP) with appropriate binders. The use of such coatings can delay corrosion and wear, as well as minimize the loosening

of implants from the bone. In summary, the study suggests that selecting higher-quality materials and applying appropriate coatings is the key to impeding corrosion in biomedical implants. This approach can help improve the longevity and performance of such implants.

Farzad et al. **[80]** conducted studies on stainless-steel implants that fractured in patients' thighs, yielding exciting findings. The investigations revealed several damage mechanisms associated with the failed implants. Among the observed damage mechanisms, crevice corrosion, pitting, initiation of cracks from these pits, intergranular surface cracking within the crevice, and stress corrosion cracking (SCC)-like branched cracks were identified. However, the primary failure mechanism identified in these cases was corrosion fatigue, assisted by crevice corrosion. This implies that the cyclic loading experienced by the implants and the corrosive environment within the crevices contributed to the development and propagation of fatigue cracks, ultimately leading to implant failure. These findings highlight the significance of addressing corrosion and fatigue issues when designing and selecting materials for stainless-steel implants. Strategies to mitigate crevice corrosion and enhance resistance to corrosion fatigue would be crucial in improving the longevity and performance of such implants.

The survey and examination of **50 failed** indigenous stainless steel implants retrieved from various patients in India over four years provided insights into the implant failures based on their anatomical location. The study **[50]** revealed that most failures, accounting for 74%, occurred in the femoral region. Other failure locations included the knee (8%), tibia (4%), humerus (2%), and radius and ulna (6%). An important finding from the study was that over 90% of the SS 316L implant devices failed due to substantially localized corrosion attacks, specifically pitting and crevice corrosion. Pitting corrosion refers to the formation of small holes or pits on the surface of a metal due to localized electrochemical reactions. In contrast, crevice corrosion occurs in narrow

gaps or crevices where stagnant electrolytes can accumulate. The severity of the corrosion attacks increased with the duration of implantation, indicating a cumulative effect over time. Pit-induced fatigue failure was observed in the compression bone plate, suggesting that the corrosion-induced pits acted as stress concentrators, leading to fatigue cracks and eventual implant failure. In the case of the intramedullary nail, severe pitting was observed along the edges, and most of the cracks were associated with these pits. This suggests that pit-induced stress corrosion cracking, which occurs due to the combined action of mechanical stress and corrosion, contributed to the failure of the intramedullary nail. These findings highlight the significance of localized corrosion attacks, particularly pitting and crevice corrosion, in the failure of SS 316L implants. The duration of implantation and the implant's anatomical location were identified as factors influencing the severity of corrosion attacks. Understanding these failure mechanisms is crucial for improving stainless-steel implants' design, materials, and corrosion resistance, ultimately enhancing their performance and longevity **[47-51]**. These observations highlight the prevalence of corrosion-related failures in SS implants, with pitting and crevice corrosion as significant factors contributing to implant deterioration. The study emphasizes the importance of addressing these corrosion mechanisms and improving the corrosion resistance of SS implants, particularly in high-stress areas such as the femoral region. Enhancements in implant design, material selection, and surface treatments can help mitigate corrosion-related failures and improve SS implants' overall performance and longevity.

Corrosion of metallic biomaterials in the body environment can have several negative consequences on human health and the performance of implants. The release of undesirable metal ions and corrosion products can cause adverse biological reactions and affect the biocompatibility of the implant, which can lead to inflammation, tissue damage, and even implant failure. Various

standard methods and guidelines are available to evaluate the corrosion performance of metallic biomaterials. ASTM G 61-86 and ASTM G 5-94 are mentioned as examples. These ASTM standards provide procedures for conducting corrosion tests on metallic materials and assessing their corrosion resistance. Corrosion testing methods typically involve exposing the metallic biomaterial to simulated body fluid or other corrosive environments and monitoring the corrosion rate and behavior. The choice of test method depends on the specific requirements and characteristics of the biomaterial being evaluated. It is essential to understand the corrosion behavior of metallic biomaterials to ensure their long-term stability and functionality within the human body. The study by U.W. Bischoff in 1994 **[81-82]** observed the concentration of metallic species in body fluids after 10-13 years of residence of 20 stainless steel Charnley hip arthroplasties. The study reported significantly higher concentrations of specific metal ions than those observed in individuals without implants. Nickel (Ni) concentration in blood, plasma, and urine is approximately 0.51, 0.26, and 2.24 µg/L, respectively, and Chromium (Cr) level in plasma is approximately 0.19 µg/L. The levels observed highlight the potential for metal ions to enter the systemic circulation and be detected in various body fluids. It's important to note that the concentration of metal ions can vary depending on the type of implant material, implant design, patient characteristics, and the duration of implant residence. Monitoring the concentration of metal ions in body fluids is one way to assess the extent of corrosion and potential systemic effects caused by releasing these ions. Ongoing research and advancements in biomaterial science aim to minimize the release of metal ions and improve the long-term performance and safety of metallic implants in the human body. **Table 2.4 (b)** represents an overview of the few kinds of literature on the electrochemical corrosion behavior of different types of **coated** stainless steel (Grade-316L) published in the recent decade **(2023-2013)**

In a survey of eleven surgically retrieved stainless steel implants, failure was observed primarily due to aseptic cup loosening and stem cement debonding. These failures can be attributed to the corrosive effects of the bio environment on the implant materials, leading to mechanical instability and subsequent loss. Variations in the electrochemical conditions, such as obstruction or removal of the passive film, can significantly impact the fatigue strength of stainless-steel implants [**36, 44**]. To address these issues, researchers and engineers continue developing strategies to enhance the corrosion resistance of stainless-steel implants. Surface modifications, such as coatings or treatments, can improve the passive film's stability and protect the underlying stainless steel from corrosion. The corrosion of stainless steel, particularly SS316L, in the bio-environment has been extensively studied, focusing on releasing metallic ions into the surrounding tissues of the implants. Researchers have conducted both in vitro and in vivo experiments to investigate the release of metal ions and their harmful effects on tissue functions.

Orthodontic appliances made from stainless steel, such as SS304 and SS316, have also been investigated for metal ion release. These appliances have been found to release small amounts of nickel (Ni), chromium (Cr), and copper (Cu). However, the quantities released are typically low enough not to pose serious health hazards **[19]**. Temperature and pH are two crucial factors that significantly influence the corrosion behavior of materials, including metallic biomaterials in the human body. In the context of implants, body fluids typically maintain a constant temperature of 37°C, considered the normal physiological temperature. Therefore, the constant temperature of 37°C throughout the lifespan of an implant allows for a consistent environment for corrosion processes to occur. In addition to temperature, pH plays a critical role in corrosion behavior. The pH of body fluids, such as blood or interstitial fluid, is carefully regulated within a narrow range to maintain proper physiological functioning. pH affects the electrochemical reactions occurring

at the material's surface and can influence the stability of passive films or promote the breakdown of protective layers. Considering temperature, pH, and electrochemical reactions, one can better understand the corrosion mechanisms, design more corrosion-resistant biomaterials, and improve implants' long-term performance and biocompatibility.

Thermally grown amorphous oxide surface layers on SS316L have been subjected to corrosion characterization in Ringer's solution. The results have shown that the oxide layer provides more excellent resistance to corrosion compared to bare SS316L and other types of oxide layers **[33]**. The interaction between the host tissue or cells and the bio-metal surface can influence the formation and characteristics of the oxide layer. Conversely, the composition and thickness of the oxide layer can impact the biological response to the implant.

Table 2.4 (a) An overview of a few kinds of literature on the electrochemical corrosion behavior of **uncoated** 316L stainless steel

S. No.	Alloy	Medium	Experimental Conditions			Methods	Findings				References
			Temp.	pH	Others		Biocompatibility	Mechanical Properties	Corrosion Resistance	Others	
1.	316L, 316LN, 317L and 317LN	SBF	37°C	7.0	-	Potentiodynamic anodic polarization	↑	↓	↑	-	**[83]**
2.	316L, porous Ni-free HNS	SBF	37°C	7.4	-	Electrochemical methods, Cytotoxicity	↓	↓	↑	-	**[84]**
3.	316 SS	Hank, 22% NaCl	RT	7.1 - 7.4	-	OCP, PDP	↓	↑	↓	-	**[85]**
4.	316L SS	0.5M NaCl	RT	-	-	Potentiodynamic methods	↓	↑	↓	-	**[80]**
5.	316L, 316LN SS	0.1M Na2SO4 & 0.1M NaCl	RT	-	Deaerated Condition	PD, PSP, AES	↓	↓	↑	N may promote the enrichment of Cr within the passive film.	**[10]**

*SBF = Simulated Body Fluid, HNS = High Nitrogen Steel, RT = Room Temperature, OCP = Open Circuit Potential, PD = Potentiodynamic Polarization, PSP = Potentiostatic Polarization, AES = Atomic Emission Spectroscopy.

Table 2.4 (b) An overview of the few kinds of literature on the electrochemical corrosion behavior of different types of **coated** stainless steel (Grade-316L) published in the recent decade **(2023-2013)**

S.No.	Coating Material	Alloy	Medium	Experimental Condition		Methods	Findings & Drawbacks	References
				Temperature	pH			
1.	Zn, Cu, and Ag	316L SS	20% NaCl	RT	-	Electrodeposition, OCP, EIS, and PD	Effective antimicrobial properties can be achieved, but mechanical properties decrease.	**[56]**
2.	Ag/AgTa2O5 [t = 4.7-6.4 µm]	316L SS	-	-	-	Thermal treatment, AFM, scratch and wettability	Increased the crystallinity and adhesion strength, but the surface is hydrophobic (102.5°)	**[57]**
3.	TaC [0-30%]	316L SS	Ringer Solution	33°C	-	OCP, EIS, and PD	Ta20% has the best corrosion resistance and mechanical properties performance, while biocompatibility decreased.	**[58]**
4.	Ta/TaN [t = 15-8nm]	316L SS	SBF	37°C	7.4	OCP, EIS, and PD	Ta/TaN has higher corrosion resistance than a single layer of Ta.	**[58]**
5.	TiO2/Al2O3 [50nm]	316L SS	SBF	37°C±1	7.3	ALD, OCP, EIS, and PD	Al2O3 coating is better than TiO_2, but TiO_2	**[59]**

							has less toxicity than Al_2O_3.	
6.	ZrN/Cu [67/33 nm]	316L SS	SBF	RT	-	OCP, EIS, and PD	ZrN/Cu increases the Corrosion resistance, but mechanical properties decrease.	**[60]**
7	TaN [t = 960-300nm]	316L SS	0.5M H2SO4+ 2ppm Hf	RT	-	OCP, EIS, and PD	The corrosion resistance of TaC films correlates with roughness and porosity index.	**[61]**
8.	TiZrN [350 nm]	316L SS	Artificial Blood Plasma	RT	7.41	OCP, EIS, and PD	Better haemocompatibility nature and superior corrosion resistance but low mechanical properties.	**[60]**
9.	HAP	316L SS	0.9% NaCl % Ringer Solution	RT	-	OCP, EIS, and PD	Polarization resistance has been increased, but mechanical properties decreased.	**[62]**

*RT = Room Temperature, ALD = Atomic Layer Deposition, t = thickness of Coating

2.3 Mechanical Behavior of Orthopedic Implants

The 316L stainless steel is an essential material widely used in various industries, including biomedical and healthcare applications, due to its excellent mechanical properties. **Table 2.5** depicts the mechanical properties of 316L Stainless steel as per ASTM A240. When selecting an implant material, it's crucial to consider the specific requirements of the application, including the expected mechanical loads and wear conditions, to ensure optimal performance and durability; De Oliveira et al. **[84]** mentioned the limitation of using AISI 316L SS in cases requiring high hardness and wear resistance. Their study likely explored alternatives or identified shortcomings of AISI 316L SS regarding wear and hardness. Bills et al. **[85]** identified aseptic loosening as the leading cause of failure in joint replacements, initiated by the tissue reaction to wear debris. The wear rate of the joint is directly associated with reduced functionality and premature failure. Serra et al. **[86] investigated the reliability of total joint replacements** in medical devices. Various factors, including wear, inhibit their long-term performance.

Austenitic stainless steel exhibits significant wear during sliding and tribological behavior influenced by load, sliding speed, distance, surface hardness, and working environment. Despite being appropriate for high temperature and corrosion resistance applications, 316L stainless steels lose their reliability due to severe metallic wear and high friction **[87].** As a result, there is significant potential for reducing wear by avoiding direct metal-to-metal contact. Thus, surface modification technique, including surface coating, was attempted to improve the tribological properties of 316L SS to decrease and prevent wear and corrosion.

D. Siva Rama Krishna and Y. Sun **[88],** researched applying thin film coatings to the 316L SS surface to investigate eliminating adhesive wear. Coatings such as TiN, TiCN, and TiC were used

to result in high wear resistance and low coefficient of friction. Huang **[89],** reported the successful application of TiN, TiCN, and TiC coatings, which exhibited high wear resistance and low coefficient of friction. These coatings were effective in reducing adhesive wear on the 316L SS surface. However, Saravanan **[90]** reported that the TiN coating did not show a significant increase in wear resistance despite having a low coefficient of friction. This suggests that while the TiN coating reduced friction, it did not effectively enhance wear resistance on the 316L SS surface. Ni-Al Coatings: They exhibit excellent uniformity and homogeneity, suggesting a consistent composition throughout the coating. The coatings have low oxide content and porosity, indicating good quality and reduced vulnerability to oxidation and corrosion.

Many scientists have investigated the performance of tungsten nitride thin films produced by the magnetron sputtering method, mainly concentrating on their structural characteristics. Nevertheless, only a few research studies have been done to increase wear resistance **[91].** The hardness of the coated steel was found to be 124.2% greater than the hardness of the ordinary AISI 1020 steel by studying the characterization of tungsten carbide coating applied to AISI 1020 steel by thermal spraying **[92].** A few studies have been published using Radio Frequency (RF) magnetron sputtering to deposit thin tungsten carbide coatings on stainless steel. The scratch test is commonly used to evaluate coatings' adhesion and mechanical properties. By subjecting the coatings to progressively increasing load, the researchers observed the response of the coatings and recorded their deformation behavior. The HA coating exhibited trackside cracking as the initial failure mode and trackside delamination as tensile stresses built up behind the indenter. Eventually, steady delamination occurred as the crack width remained constant, which suggests that the failure of the HA coating was primarily due to cohesive and adhesive failures. It's worth noting that various factors, including deposition parameters, coating thickness, adhesion test parameters, and

composition of the coatings, can influence the deformation behaviour and failure modes of coatings. In this case, adding silicon (Si) to the HA coating composition resulted in a different deformation behavior than pure HA coating.

Table 2.5 Mechanical Properties of 316L Stainless Steel as per **ASTM A240**

Material	Properties	
316L SS	Density	8.027 g/cm^3
	Melting Point	1390 to 1440°C
	Modulus of Elasticity	200 GPa
	Modulus of Shear	82 GPa
	Thermal Conductivity (20-100°C)	14.6 W/m. K
	Yield Strength 0.2 offset	170 MPa
	Ultimate Tensile Strength	485 MPa
	Elongation	40 %
	Hardness (RB)	95

Table 2.6 represents the summary of the wear behavior of different types of coating over 316L stainless steel (**2023-2012**). Higher contact pressures or sliding speeds can accelerate wear in terms of sliding conditions. Repetitive or cyclic loading can also lead to fatigue wear, causing surface damage and wear over time. Wear can significantly limit the durability of austenitic stainless-steel implants, including grade 316L. However, wear can occur when the implant is subjected to repetitive or continuous mechanical loading. The wear mechanisms that affect austenitic stainless-steel implants include adhesive wear, abrasive wear, and fretting wear. Several strategies, like surface modifications, material selection, design optimization, and lubrication, can be employed to mitigate wear-related issues in austenitic stainless-steel implants. It's worth noting that research and development efforts are continuously being undertaken to improve the wear resistance of stainless steel implants.

Table 2.6 Summary of the Wear behavior of different types of coating over 316L Stainless steel (2023-2012)

S.No.	Coating Material	Alloy	Medium	Experimental Condition		Major Findings and Drawbacks	References
				Load (N)	COF		
1.	ZrSiN/ZrSi (N, O) [t= 1µm]	316L SS	Ringer 0.9% NaCl	27	0.47 (Bare 316L) 0.20/0.23 ZrSiN/ZrSi (N, O)	Better mechanical properties (i.e. hardness and adhesion strength); however, wear rate is maximum.	**[104]**
2.	VC-Cr_7C_3	316L SS	Dry	20	1.4/1.2	The primary wear mechanism transfers from adhesion wear to abrasive wear.	**[105]**
3.	MA	316L SS	SBF	40	0.35/0.36	Hardness increases as MA-time increases.	**[106]**
4.	TaZrN/TaZr (7LC and 11 LC) [t = 3.09 & 3.38 µm]	316L SS	Dry	0.5, 1, 2	0.9-0.95	The thicknesses of 7LC and 11LC are quite similar; at 2N, the 11LC was removed due to fracture and spallation of coating.	**[107]**
5.	TaC-Au Hf C-Au [t = 20 nm]	316L SS	Ringer	3	0.4	The thick coating allows a protective barrier against the abrasive wear phenomena.	**[108]**
6.	Ta/Ta_xN [t = 500nm]	316L SS	Dry	-	-	Ta_xN interlayer increases the plasticity of subsequent Ta thin film up to 91% due to a decrease in hardness and Young's modulus.	**[109]**
7	DLC [t = 2.2 µm]	316L CoCrMo Ti6Al4V	PBS	0-30 (Prog)	0.5-0.6	DLC coating is most feasible for Ti6Al4V only; DLC-316L shows high coating spallation and the worst adhesion strength due to the weak carbide-forming ability of Cr and ion.	**[110]**
8.	WC-DLC [t = 2.8 µm]	316L	Dry	200, 400	0.3	The stresses were too high to be absorbed/released by the coating and consequently caused circular cracks, which penetrated the whole coating and also caused saw-teeth-like deformation in the substrate.	**[66]**

*MA= Mechanical Alloying, VC = Vanadium-Carbide, DLC = Diamond like Carbon, WC = Tungsten Carbide, LC = layers' coating.

2.4 Biological Evaluation of different types of Coated 316L for the orthopedic application

Biocompatibility results decided to accept non-living materials in a live body (human or mammal) from a biological perspective. A proposed biomaterial aims to achieve three key elements of biocompatibility across various aspects, including blood vessels, bone, and the eye. Biomaterials must be non-toxic, non-irritating, non-allergic, non-carcinogenic, and biochemically compatible. Additionally, they must be in harmony biomechanically with the neighbouring tissues. The materials must then make bio-adhesive contact with live tissues. The biocompatibility depends on the application location, which needs to be emphasized. For instance, a specific substance might be biocompatible for bone replacement but not for applications involving direct contact with blood. The ISO-10993 specification divides implants into three categories based on their ability to interact with the body: brief exposure (up to 24 hours), sustained exposure (24 hours to 30 days), and permanent contact (more than 30 days). The duration and nature of the device-tissue connection affect the selected device compatibility test.

(A) In Vitro Studies:

To harmonize the current recommendations, ISO created the guideline document 'Biological Testing of Medical Devices — Part 1: Guidance on Test Selection' (ISO 10933 - 1), including all national and international documents. ISO 10993 standards for long-term tissue/bone implants necessitate a variety of biological tests, the most important of which are the following in vitro testing: Cytotoxicity, Genotoxicity, and Hemocompatibility.

(B) In Vivo Studies:

Some of the various in vivo testing are:

• **Sensitization:** This is an in vivo test in which materials are kept in the subcutaneous region of an animal, and the results include a change in skin colour, an allergic reaction, or other irritations.

• **Implantation:** An in-vivo test in which a sample with a predetermined shape is put into the long bone of a mouse or rabbit. The tissues around the specimens are examined histopathologically to determine whether the materials respond in vivo after a predetermined time. Tests for short-term implantation can take up to 12 weeks, and long-term implantation can last up to 78 weeks. Because they are sacrificed, few animals are used, considering the perspective of animal health.

• **Carcinogenicity:** A long-term in vivo experiment is called a carcinogenicity test used to assess a substance's potential to cause cancer in cells. Pb, Sn, and other elements are materials that might cause cancer.

The biological properties of tantalum-coated surgical-grade stainless steel have been studied. Regarding chemical composition and resistance to severe acidic environments, the examined tantalum-coated parts had attributes similar to surgical-grade bulk tantalum. The tantalum layer's adhesion was demonstrated to be excellent. No layer separation is detected when stainless steel specimens are subjected to the fatigue test till fracture. As a result, the coated materials act similarly to uniform materials. By applying tantalum coating, the biocompatibility was increased to a much higher level in 316L SS than that of commercial pure titanium (CpTi) **[93].** These outcomes provide potentially novel possibilities for the implant and other medical device designs. An additional benefit is the ability to use substrate materials that are easier to machine than conventional implant materials because the (substrate) materials can be tantalum coated after

shaping to achieve the required biocompatibility. Because the tantalum surface regulates the tissue response, the substrate material can be selected depending on mechanical qualities, processing, and cost. **[93].**

The results of platelet, endothelial cell (EC), and smooth muscle cell (SMC) interactions with different compositions of Ir/Ti-oxide coated surfaces were presented. These metal-oxide surfaces demonstrated lower thrombogenicity than the 316L stainless steel (SS) control surface. Notably, metal-oxide coatings containing 20% and 40% Ir showed minimal platelet interaction. The metal-oxide-coated surfaces exhibited enhanced blood compatibility, with higher EC attachment and reduced affinity of SMCs for proliferation. This indicates improved biocompatibility and reduced potential for cell proliferation, which are desirable characteristics for implantable devices.

Radiopacity is crucial for visualizing the stent in medical imaging and facilitating proper placement and assessment of the device. Thus, the Ir 0.4Ti0.6-oxide coating offers better visibility than the currently used 316L-SS stent surfaces **[94].**

The technique of dopamine polymerization was employed to generate a functional adherent amine-rich coating. The procedure involved immersing the substrates in a single-step aqueous solution containing dopamine and HD (hydroxylamine hydrochloride). Using the PDAM/HD coating process, a high density of amine groups, approximately 30 nmol cm^2, was achieved on the surface of the substrate. This coating method allowed for the incorporation of a substantial amount of amine functional groups on the substrate. The PDAM/HD adherent coating exhibited favourable mechanical properties, indicating good adhesion to the substrate and stability over time. The coating demonstrated biocompatibility with human umbilical vein endothelial cells (HUVEC), suggesting that it supported the growth and interaction of these cells. This biocompatibility

assessment indicates that the coating is suitable for promoting a positive tissue response when applied to 316L stainless steel **[95].**

Tantalum is an excellent choice for orthopedic implants because of its superior mechanical properties, resistance to corrosion, and high biocompatibility. By altering the deposition method and processing parameters, tantalum coatings with microscale and nanoscale surface topographies were developed. Tantalum coatings stimulate cell interaction and proliferation, according to a biological study utilizing human bone marrow-derived mesenchymal stem cells. Furthermore, with improved cell attachment on sub-micrometre and micrometre-sized surface topographies compared to hybrid nano-/microstructures, hBMSC adhesion to tantalum coatings is surface feature dependent. To improve the surface coating features of metals that stimulate osteogenesis and enhance the osseointegration of tantalum-based orthopedic implants. **[81].**

The MC3T3-E1 mouse osteoblast-like cells were used to study the cell activities on self-organized nanopores created by anodic polarization of type 316L stainless steel. Compared to samples with mirror finishes, those with nanopores had higher cell densities. The sample with the nanopores that were the smallest in diameter (26 nm) had the highest cell density. The sample with the smallest nanopores also displayed more ALP activity than the others. While cells grown on nanopore samples displayed spreading of the lupoid and extension of their cell bodies, cells grown on mirror-finished surfaces tended to be more rounded. These findings showed that Type 316L stainless steel with the smallest nanopores (26 nm) produced on its enhanced cell activity **[75].**

The 316L SS has sustained long-lasting antibacterial action due to the antibacterial-passivated treatment in a physiologically-inspired environment. The zebrafish test shows that the improved 316L SS has outstanding in vivo biocompatibility and good application performance **[96].**

Developing and accessing 316L SS composites coated in Nb_2O_5 with Ce integrated has shown promise as a new biomaterial composite. Cerium concentration in the Ce-integrated Nb_2O_5 coatings changed the 316L SS's surface properties and nanostructured surface morphology **[97].** Using the EPD process, a nanocomposite was effectively deposited onto the 316L stainless steel samples. Studies on in vitro cell culture showed that nanocomposite coatings permit greater cell viability and increased cell proliferation compared to uncoated cells. As a result, the investigated composite-coated 316L SS might extend an implant's lifespan and be used in bone applications **[98].**

2.5 Need for the metallic coatings and Significance of Tantalum (Ta)

Over the last few decades, innovations and advances have been implemented to accomplish tremendous and sustainable progress in biomaterials development, leading to refined medical devices and implants **[99].** Future implants are expected to provide long-term clinical performance with no revision surgery. Revision surgery is unfavourably related to the physical, social, and economic consequences, and it is sometimes more complicated than the first surgery. Poor osteointegration at the implant-bone contact, aseptic loosening, and infections are the most common reasons for revision surgery. The biomechanical mismatch between the implant and the surrounding tissues and the formation of fibrous tissue, which causes implant movements, are the leading causes of aseptic loosening following long-term implantation. One strategy for resolving the biomechanical mismatch is to decrease the elastic modulus of the biomaterials by creating new substances or modifying their surface. Surface modification of biomaterials has attracted considerable attention in recent years because of the importance of the material's surface when an implant or other biomaterial comes into contact with the biological environment. Protein

adsorption, cell adhesion, proliferation, and differentiation are processes/reactions that occur at these material surfaces rather than the bulk material. A changed surface helps the bone to form and locks the artificial implant for increased attachment due to many binding interactions caused by surface chemistry and topography. Coating techniques changed the surface by altering the surface chemistry or varying the surface topography. Material surface texturing enhances surface roughness, which promotes cell adhesion and proliferation due to increased surface area. The biomaterial's surface coating, known as bioactive coating, solves the problem of inadequate osteointegration from the coating material by obtaining more effective mechanical properties from the metal base **[100].**

Tantalum (Ta) has received attention as a promising material in recent years because, in contrast to titanium (Ti), it is bioactive and has intriguing chemical valences that encourage more significant biomineralization kinetics and improve osseointegration **[101].** Tantalum pentoxide (Ta_2O_5) is associated with Ta coating as per the literature survey, Ta_2O_5 is intrinsically associated with tantalum (Ta) coating due to its inherent chemical composition. Tantalum forms a stable oxide layer, Ta_2O_5, when exposed to oxygen. This oxide layer acts as a protective coating, exhibiting high dielectric constant and exceptional stability. Consequently, It is a favored material for thin film coatings, particularly in the realm of biomedical applications. The symbiotic relationship between tantalum and its oxide underscores their integral role in coating technologies, where the unique properties of Ta_2O_5 contribute to the performance and longevity of tantalum coatings. **Table 2.7** shows the overview of tantalum (Ta) properties as per ASTM B 365 and ASTM B 708. A hydroxyapatite layer was quickly produced on a Ta surface submerged in a simulated body fluid (SBF). This demonstrates a strong chemical connection because Ta has a higher surface energy than CP Ti, according to Balla et al. **[99].** Ta has the most significant melting point of any metal

(>2000°C) and excellent hardness, density, strength, and resistance to wear and corrosion (compared to tungsten (W), molybdenum (Mo), niobium (Nb), and rhenium (Re).

Ta's surface chemical characteristics led to a quicker rate of matrix mineralization (30%). After seven days of immersion in SBF, bioactivity assessments revealed the existence of calcium phosphates only in $Ta_{1-x}O_x$ samples. After 14 days of exposure, Ca/P ratio values of 1.57 and 1.73 were observed for Ta coatings, close to the hydroxyapatite value (Ca/P 1.67) **[100-101].**

Table 2.7 Overview of tantalum (Ta) properties per **ASTM B 365** and **708**.

Properties	**Tantalum (Ta)**
Density (g/cm3)	**16.6** (Bulk), **16.27-16.65** (α-Ta), and **16.9** (β-Ta)
Coefficient of thermal expansion (μm/m K at 20°C)	6.5
Hardness (HV)	80-100
Tensile Strength (N/mm^2)	280-330
Modulus of Elasticity (kN/mm^2)	186
Electrical resistivity (μΩcm)	**13** (Bulk), **13-60** (α-Ta), and **170-210** (β-Ta)
Electrical Conductivity (Sm/mm^2)	8
Thermal Conductivity 293 K at 20°C	74
Elongation (%)	20-35

Recent research has examined titanium oxide [**102**], diamond-like carbon [**103**], and amorphous hydrogenated carbon as prospective candidates for a thromboresistant coating of biomedical metals. At the same time, superior corrosion resistance is claimed for Ta, TaN, and TaC [**80**].

2.6 Research Gap

The use of metallic coatings on 316L stainless steel for orthopedic applications has shown promise in improving the performance and biocompatibility of implants. However, several research gaps

in this area require further investigation, including **Coating Selection and Optimization**: There is a need for research focused on selecting and optimizing the metallic coatings applied to 316L stainless steel for orthopedic implants. Comparative studies evaluating the performance of different coating materials on 316L stainless steel are necessary. **Coating Adhesion and Stability**: Ensuring strong and durable adhesion of the metallic coatings to 316L stainless steel is critical for the long-term performance of orthopedic implants. Research is needed to evaluate these coatings' adhesion strength and stability under realistic physiological conditions, including cyclic loading, corrosion, and wear. Understanding the mechanisms contributing to coating delamination or failure will help guide the development of more reliable coating techniques. **Biocompatibility and Tissue Response:** While metallic coatings can enhance the biocompatibility of 316L stainless steel implants, further research is necessary to comprehensively evaluate the biological response to these coated surfaces. This includes studying the interaction between the coating and surrounding tissues, assessing inflammatory reactions, evaluating cell adhesion, proliferation, and differentiation, and investigating long-term biocompatibility and potential toxic effects. Wear Resistance and Surface Integrity: Metallic coatings are expected to improve the wear resistance of 316L stainless steel implants, thereby reducing the generation of wear debris and minimizing adverse biological responses. However, it is necessary to focus on quantifying and comparing the wear resistance of different coating systems. Additionally, the impact of wear, such as delamination or degradation, on the surface integrity of the coatings should be investigated to ensure long-term functionality. **Clinical Performance and Long-Term Outcomes:** Despite the promising results in laboratory settings, clinical studies are scarcely evaluating the performance and long-term outcomes of metallic-coated 316L stainless steel implants in orthopedic applications. Prospective clinical trials comparing the clinical outcomes, implant survivorship,

revision rates, and patient-reported outcomes of coated implants to conventional uncoated implants will provide valuable insights into the effectiveness and reliability of metallic coatings. **Manufacturing and Scalability:** The development and implementation of metallic coatings on 316L stainless steel implants require considerations of manufacturing processes and scalability. Research is needed to explore efficient and cost-effective coating techniques that can be easily integrated into existing manufacturing processes [i.e., physical vapour deposition (PVD)]. Evaluating the feasibility and scalability of coating techniques will facilitate their translation into clinical practice.

In order to retard the release of the ions like Ni^{2+}, Cr^{3+} and other toxic and unwanted constituents from 316L stainless steel, the surface has been coated with the different types of Tantalum with different alloying elements-based coating like Ta_xN, TaZrN/TaZr, TaC has already done; however pure Tantalum (Ta) based coating is too scarce.

2.7 Research Motivation and Objective of the Present Thesis

Incorporating Tantalum (Ta) in orthopedic implant coatings can enhance adhesion and potentially prolong the service life of the implant. Tantalum is known for its excellent biocompatibility and mechanical properties, making it a suitable candidate for improving the adhesion of metallic coatings, which helps to prevent the detachment of the coating and reduces the risk of particle release at the implant-bone interface, which can lead to implant failure. In addition to enhancing adhesion, Ta incorporation can also provide other advantages. It has been reported to possess antibacterial properties, which can help reduce the risk of infection at the implant site. Furthermore, Ta coatings have shown improved wear and corrosion resistance, which can contribute to the overall longevity and performance of the implant. It's important to note that the

specific composition and characteristics of coating depend on various factors such as the coating method, processing parameters, and coating thicknesses. These parameters must be carefully optimized for the desired adhesion strength and coating performance.

Ta is known for its higher chemical stability, which can help retard the release of ions such as Cr^{2+} and Ni^{2+} from the underlying stainless-steel substrate. It is essential because releasing these ions can cause adverse effects on the surrounding tissue. When Ta is deposited on the stainless-steel surface, it forms an amorphous coating. This amorphous structure can further contribute to the suppression of ion release. By preventing the release of harmful ions, the Ta coating can help reduce the risk of adverse reactions and improve the biocompatibility of the implant.

Additionally, the surface texture of the implant plays a significant role in the interaction between the implant and the surrounding tissue. Surface characteristics such as surface area, roughness, topography, and wettability influence protein adsorption and cell adhesion. By carefully controlling these surface properties, the implant can be designed to enhance osteointegration, which is the process of bone formation and attachment to the implant. By combining the effects of Ta coating and surface texturing, the present study aims to improve the osteointegration of orthopedic implants. The ultimate goal is to create biomaterials that closely resemble bone properties, enhancing implant longevity and functionality.

Through this research, it is hoped that the findings will contribute to developing improved orthopedic implants that exhibit better biocompatibility, reduced ion release, and enhanced osteointegration, ultimately benefiting patients needing such implants.

The objectives of this study are as follows:

- Fabrication and characterization of Tantalum coating deposited on 316L Stainless steel using DC magnetron sputtering with different film thicknesses.
- To investigate the morphology, structure, surface roughness, wettability, and adhesion strength of the as-deposited coatings and the effects of post-deposition treatments.
- Study the Wear behavior of Tantalum coated 316L SS.
- To study the Electrochemical Corrosion behavior in Simulated Body Fluid.
- To Study the Biocompatibility evaluations (in vitro) on the Ta-coated 316L Stainless steel for Orthopedic applications.