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# Additive manufacturing of titanium alloys for biomedical applications: A systematic review

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ABSTRACT

This paper presents a systematic review of biomedical Ti alloys fabricated through additive manufacturing. It begins with an overview of the development of Ti metals and their applications in biomedical fields, particularly in orthopedic and dental implants. The review highlights recent advancements, such as the incorporation of porous structures. Key aspects of additive manufacturing for biomedical Ti alloys are explored, including material characteristics, preparation parameters, solidification behavior, and post-heat treatments, with emphasis on their effects on microstructure and material properties. This paper further summaries the current states of biomedical standards for Ti alloys, and concludes with a discussion of future trends, opportunities, and challenges in the additive manufacturing of biomedical Ti alloys, including advancements in material innovation, process optimization, and the integration of personalized implants. This review aims to provide valuable insights into the ongoing developments and future directions for additive manufacturing biomedical Ti alloys.

## 1. Introduction

Bio-metallic materials have gained widespread applications in medicine due to their exceptional specific strength, outstanding corrosion, fatigue resistance, and superior biocompatibility [1–3]. As advancements in medical technology continue and the global aging population grows, the demand for bio-metallic materials is poised to skyrocket. Representative practical metallic biomaterials can be broadly classified into three categories: stainless steels, cobalt (Co)-based alloys, and titanium alloys, accounting for about 40 % of the global biomaterials market share [4]. Ti alloys, in particular, are favored for their high strength, excellent biocompatibility, low density, and easy of processing, making them widely used in orthopedic implants. However, the functionality, biocompatibility, and longevity of traditional Ti alloys, such as pure Ti, Ti-6Al-4V, and Ti-6Al-7Nb, have increasingly been shown to be insufficient for modern clinical applications [5–7]. The inherent limitations of these materials often lead to complications, including the implant fracture due to inadequate mechanical properties, and non-healing from poor bone integration, causing considerable discomfort and distress for patients. To mitigate these issues, Ti alloys with improved mechanical properties that align with implant site requirements, coupled with enhanced bone integration, are expected to play a crucial role in the advancement of biomedical materials.

The development of biomedical Ti alloys has remained a prominent research focus, as illustrated in Fig. 1a. The number of publications on "biomedical Ti alloy" indexed in the Web of Science has steadily increased over the years, underscoring the growing interest in this field. Still, most Ti alloys are produced using traditional mechanical processing methods, which are costly, involving complex smelting and thermomechanical processes, and often failing to meet the rising demand for personalized treatments. Computer-assisted additive manufacturing (AM) technology has emerged as a promising solution for fabricating Ti alloys, enabling the customization and optimization of implants tailored to the specific needs of individual patients. This approach offers more precise and efficient production of personalized medical devices, paving the way for improved clinical outcomes and patient satisfaction. Since 2012, research on fabrication of biomedical Ti alloys using AM has gradually emerged, highlighting its significance and potential for sustainable development. As of November 2024, data from the World Intellectual Property Organization (WIPO) (Fig. 1b) reveals that countries such as the United States and those in Europe dominate in the number of patents related to biomedical Ti alloys, with a substantial portion of these patents focused on AM technology. In contrast, the number of patents from Asian countries remains relatively low.

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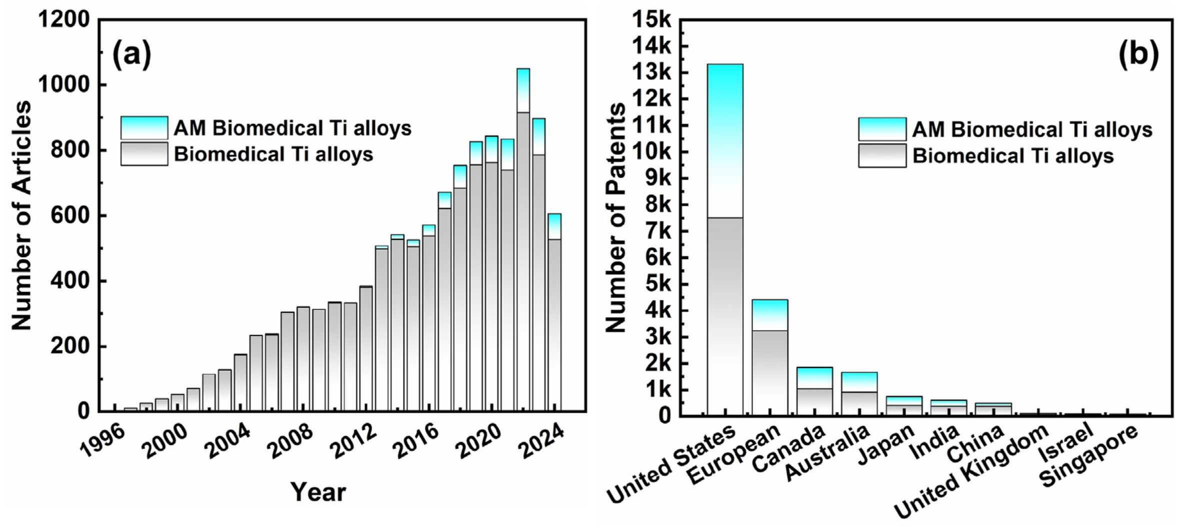


**Fig. 1.** Researches on biomedical Ti alloys. (a) The total number of publications indexed under the search term 'Biomedical Ti' and 'Additive manufacturing, Biomedical Ti' in the Web of Science database. (b) Number of patents related to "Biomedical Ti" in various countries as of November 2024, sourced from the WIPO.

This article provides a comprehensive review of the characteristics, applications, and advancements of AM technique for biomedical Ti alloys. It focuses on the solidification characteristics, defects generation, microstructural evolution, and the impact of post-processing treatments on the properties of biomedical Ti alloys. Additionally, the article discusses the current state of biomedical standards and the clinical adoption

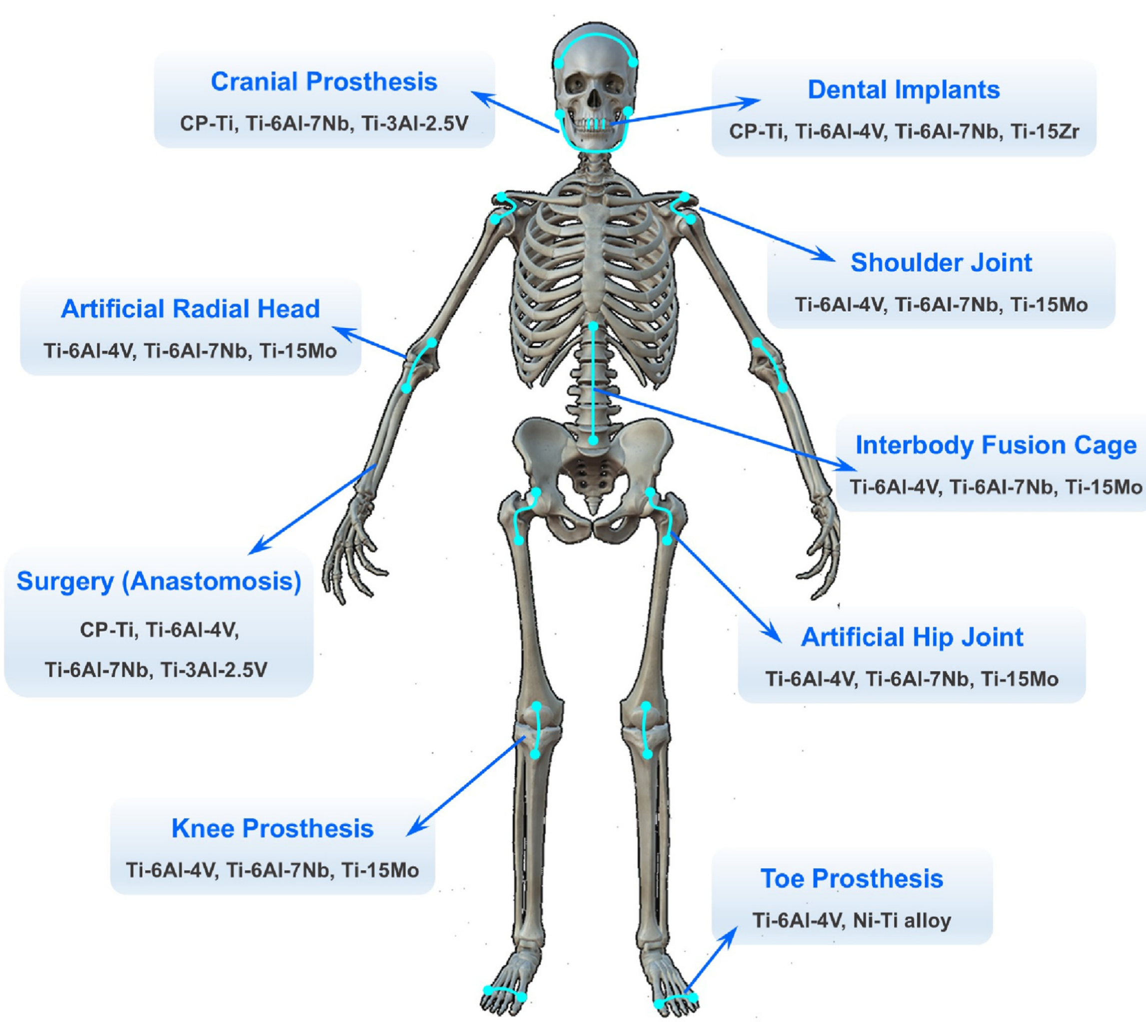


**Fig. 2.** Schematic diagram of biomedical Ti alloy for clinical applications.

of Ti alloys produced through AM. Furthermore, it highlights emerging trends, challenges, and future directions in the development and application of biomedical Ti alloys through AM technology, offering insights into potential innovations and improvements in the field.

## 2. Biomedical applications of Ti alloys

Ti and its alloys are extensively utilized in various biomedical applications [8–10], including bone plates, joint prostheses, intramedullary nails, craniofacial and dental implants, artificial heart shells, cardiovascular stents, ultrasonic scalpels, and others, as illustrated in Fig. 2. As material intended for long-term implantation, they must meet the following key requirements [11,12]: (1) *Biocompatibility:* Implant materials should be compatible with the human body, eliciting minimal biological reactions. Ideal biomedical Ti alloys should be non-toxic, non-carcinogenic and non-allergenic etc. as required by ISO-10993. (2) *Mechanical properties:* The material should possess high strength, low elastic modulus, good plasticity, high fatigue resistance, ensuring optimal biomechanical compatibility with surrounding tissues. (3) *Chemical stability:* The material must maintain chemical integrity and resist degradation in the biological environment, ensuring long-term stability and safety. (4) *Processability:* The material should be easy to process, shape, and cost-effective, facilitating manufacturing and widespread clinical use. (5) *Corrosion resistance:* Corrosion can degrade mechanical properties, leading to the products fracture or the release of harmful by-products. Medical Ti alloys used in the human body must resist the corrosive effects of bodily fluids (e.g., blood, bone fluid), and withstand local corrosion, including stress corrosion cracking, pitting, and other forms of degradation.

The most commonly used alloys are commercially pure Ti (CP-Ti), Ti-6Al-4V, and Ti-6Al-7Nb. Despite the successful application in high-end medical devices, such as orthopedic hard tissue repair and soft tissue minimally invasive interventions, several long-term efficacy challenges have emerged [13,14]. These challenges have prompted continuous efforts to optimize traditional Ti alloys, while also driving the development of advanced Ti alloys.

### 2.1. *Alloy development of biomedical Ti alloys*

Research on biomedical Ti alloys began with Bothe's demonstration of the excellent biocompatibility of pure Ti, marking a key milestone in biomedicine [15,16]. By the 1970s, countries such as the United States, Japan, and the United Kingdom had begun to adopt traditional CP-Ti (α-type) and Ti-6Al-4V (α+β type) alloys in medical applications, particularly for implants such as bone plates and dental prostheses. Despite Ti alloys exhibit an elastic modulus of approximately 110 GPa, which is lower than that of stainless steel and Co-Cr alloys, it remains higher than the modulus of human bone [17] (ranging from 0.3 to 20 GPa). This disparity in stiffness leads to the phenomenon known as “stress shielding”, where the implant bears a disproportionate share of the load, causing surrounding bone tissue to undergo reduced mechanical stimulation. Over time, this can lead to bone resorption and secondary fractures. Furthermore, some Ti alloys, particularly Ti-6Al-4V, release potentially toxic elements such as Al and V into the body during use, raising concerns about their long-term safety and limiting their clinical acceptance.

To mitigate these challenges of mismatch in mechanical properties and the release of toxic elements, a global surge in research and development, aimed at designing new generations of medical Ti alloys to replace the CP-Ti and Ti-6Al-4V alloy. The mechanical properties of these Ti alloys are summarized in Table 1. The development of second-generation biomedical Ti alloys focuses on replacing the toxic element V with biocompatible elements like Nb and Fe, leading to the creation of new α+β type alloys such as Ti-6Al-7Nb and Ti-5Al-2.5Fe, in efforts to eliminate harmful substances. In parallel, researchers in the United States and Japan have focused on the development of low modulus β type Ti alloys, such as Ti-15Mo, Ti-12Mo-6Zr-2Fe (TMZF), and Ti-13Nb-13Zr from the U.S.A., as well as Ti-15Mo-5Zr-3Al and Ti-29Nb-13Ta-4.6Zr (TNTZ) from Japan. In 2003, Saito et al. [18] developed a multifunctional Gum metal composite by incorporating O element, with a typical composition of Ti-35Nb-2Ta-3Zr-0.3O (wt%) and a minimum elastic modulus of 55 GPa. The role of oxygen doping in achieving low modulus and high strength is increasingly recognized. However, despite the promising properties of Gum metals, not all oxygen-doped alloys [19] that adhere to its design principles demonstrate comparable performance. The absence of complex mechanisms [20,21] related to interstitial O element limits their broader applications. In China, the Northwest Institute for Non-Ferrous Metal Research developed two novels β type medical Ti alloys, Ti-5Zr-5Mo-15Nb (TLE) and Ti-5Zr-3Sn-5Mo-25Nb (TLM) with an elastic modulus lower than 80 GPa. The Institute of Metal Research, Chinese Academy of Sciences, developed the Ti-24Nb-4Zr-7.9Sn (Ti-2448) alloy, demonstrating an ultra-low elastic modulus of 42 GPa.

The development of low modulus biomedical Ti alloys has made

**Table 1**
Mechanical properties of selected Ti alloys for biomedical applications.

| Structures | Alloys | Young's modulus (GPa) | Yield strength (MPa) | Tensile strength (MPa) | Elongation (%) |
|---|---|---|---|---|---|
| | Cortical Bone [22] | 7~30 | 120~160 | | 0.55–0.94 |
| | Cancellous Bone [22] | 0.3–4 | 1.75 | | 0.78 |
| | Dental Enamel | 12~19 | | 48~105 | |
| | Dentin | 46~130 | | 10~40 | |
| α | CP-Ti (Grade 1–4) [23] | 103~107 | 170~485 | 240~550 | 15~24 |
| α | Ti-3Al-2.5V | 100 | 585 | 690 | 15 |
| α | Ti-3Al-2Mo-2Zr | 115 | 635 | 968 | 17 |
| α+β | Ti-6Al-4V | 110~114 | 820~870 | 900~930 | 6~10 |
| α+β | Ti-6Al-4V ELI [1] | 110 | 875 | 965 | 10~15 |
| α+β | Ti-6Al-7Nb [11] | 110 | 800 | 900 | 10 |
| α+β | Ti-5Al-2.5Fe [11] | 112 | 895 | 1020 | 15 |
| β | Ti-13Nb-13Zr [5] | 79~84 | 840~920 | 970~1040 | 10~16 |
| β | Ti-12Mo-6Zr-2Fe (TMZF) | 74~85 | 1000~1060 | 1060~1100 | 18~22 |
| β | Ti-15Mo [24] | 78 | 655 | 800 | 22 |
| β | Ti-15Mo-5Zr-3Al | 75~88 | 870~970 | 880~980 | 17~20 |
| β | Ti-29Nb-13Ta-4.6Zr (TNTZ) [25] | 55~66 | 800 | 830 | 20 |
| β | Ti-35Nb-2Ta-3Zr-0.3O (Gum metal) [18] | 55 | 1100 | 1160 | 13 |
| β | Ti-36Nb-1Ta-3Zr-0.6O [26] | 66 | 876 | 910 | 14 |
| β | Ti-15Nb-5Zr-4Sn-1Fe [27,28] | 61 | 912 | 972 | 18 |
| β | Ti-24Zr-4Nb-8Sn (Ti-2448) [29] | 46 | 700 | 830 | 15 |
| β | Ti-3Zr-2Sn-3Mo-25Nb (TLM) [30] | 45~81 | 610~950 | 685~1050 | 17~23 |
| β | Ti-5Zr-5Mo-15Nb (TLE) [31] | 60~84 | 560~1020 | 700~1060 | 15~22 |
| β | Ti-10Mo-6Zr-4Sn-3Nb [32] | 81~95 | 960~1130 | 1000~1210 | 9~15 |

significant strides. Numerous innovative alloys have been introduced, but only a few alloys have been successfully incorporated into clinical practice. While these alloys show promise, their elastic modulus remain relatively high compared to human bone, and their yield strengths generally fall below 1000 MPa. These limitations in their elastic properties mean that they are not yet ideal candidates for some orthopedic applications.

Additionally, processing techniques such as heat treatment and large plastic deformation can significantly enhance the strength while reduce the modulus. Hanada et al. [33] induced the formation of substantial α″ martensite in Ti-35Nb-4Sn alloy by employing a cold rolling deformation of 89 %, which led to a significant reduction in the elastic modulus to 42 GPa, while simultaneously enhancing the strength to 650 MPa. Liu et al. [34] and Guo et al. [35] confirmed that α" martensite induced by cold rolling significantly increases in the strength of Ti-15Nb-9Zr and Ti-10Nb-2Mo-4Sn alloys with low β-stability, while maintaining low elastic modulus of 39 GPa and 41 GPa, respectively. Recently, our research team [36,37] utilized cold rolling to modulate the martensitic transformation of the Ti-15Nb-5Zr-4Sn-1Fe alloy, achieving an optimal combination of low elastic modulus (45 GPa) and high strength (1093 MPa), with a large near-linear elasticity of 2.34 %. Moreover, grain refinement can effectively balance high strength and low modulus. Inoue et al. [38] achieved significant grain size reduction in Ti-18Nb-17Zr to approximately 5 nm through large deformation, resulting in an elastic modulus of 55 GPa and a tensile strength of 1100 MPa. Yu et al. [39] utilized the accumulative roll bonding (ARB) method to refine the grain size of TLM alloy, which led to an elastic modulus range of 62∼70 GPa and tensile strength of 995∼1050 MPa. Current research suggests that Ti alloys can be developed through optimized composition design and preparation methods, offering a promising approach to achieving the desired combination of mechanical properties and biocompatibility for biomedical applications.

### 2.2. Biomedical Ti alloys for orthopedics and dental implants

The human skeleton is composed of 206 bones, varying in shape and size, each performing critical functions such as protection of internal organs, structural support, and facilitating movement. In clinical practice, metal orthopedic implants are primarily classified into three major categories: trauma implants (e.g., bone plate, hollow nail, screw, and intramedullary nail), spinal implants (e.g., fusion devices, non-fusion treatment devices, and vertebral fracture treatment), and joint implants (e.g., hip, knee, ankle, and shoulder replacements). These implants are used for bone fixation, reconstruction, and replacement to treat various musculoskeletal disorders. Bones possess an inherent ability to self-repair. Researchers [40,41] have shown that materials with low elastic modulus and high strength, which more closely mimic the mechanical properties of natural bone, can significantly enhance the speed and efficacy of bone regeneration around metal implants.

Implants for general fractures typically feature simple shapes and structures, making them amenable to fabrication using conventional manufacturing methods. However, with advancements in medical technology, there is growing demand for implants with more complex geometries, customized designs, and enhanced functionality. This shift may necessitate the adoption of advanced manufacturing methods, such as AM or advanced machining, to better address specific needs and improve clinical outcomes. The Delta TT porous Ti alloy acetabular cup (Fig. 3b), developed by Lima, an Italian orthopedic company, using selective electron beam melting (SEBM) technology, has received market approval from relevant authorities. Similarly, Depuy-Synthes (Johnson-Johnson Medical's) 3D-printed spinal fusion device portfolio, CONDUIT (Fig. 3c), with an elastic modulus similar to that of trabecular bone, received Food and Drug Administration (FDA) approval in 2017. The NEST 3D-printed fusion device from Joimax (Germany) features a porous central structure and solid edges (Fig. 3d), promoting bone growth and biological fixation, with a modulus of approximately 3 GPa. In 2015, Beijing Aikang Medical's porous acetabular cup, produced using AM technology, was

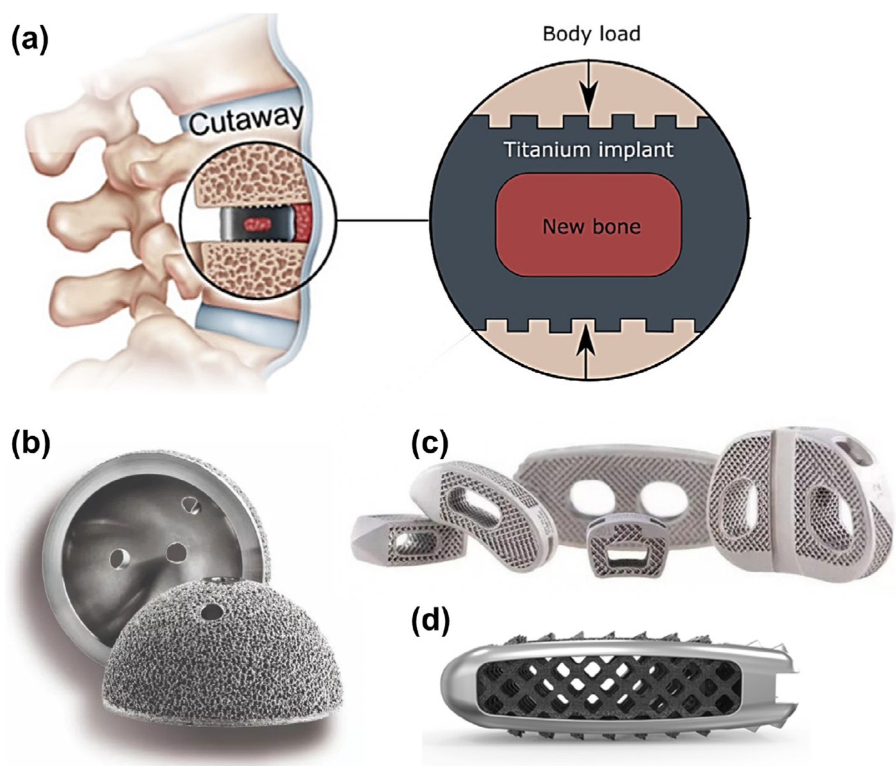


**Fig. 3.** Application of AM Ti alloy. (a) Schematic diagram implant material [42]. (b) Ti-6Al-4V acetabular cup. (c) Ti-6Al-4V spinal fusion cages (Conduit™ Interbody Platform (aofoundation.org)). (d) Ti alloy spinal fusion cages (NEST-Product-BIOMECH-Total Spine solution (paonan.com.tw)).

approved for market release. In parallel, Double Medical leveraged AM technology to develop varied porous Ti products, including hip and knee joints, spinal fusion devices, and implants. Thus, metal orthopedic implants prepared by AM offer personalized macroscopic and microscopic structures with high forming quality, demonstrating significant clinical potential.

Ti alloys are commonly used in dental implants, where they serve as artificial tooth roots, providing a stable and durable foundation for both individual teeth and full dental arches [43]. Currently, CP-Ti, Ti-6Al-4V are the commonly utilized Ti materials in surgical and dental applications. However, these alloys do not fully meet all clinical requirements, particularly regarding long-term mechanical performance and corrosion resistance. Adell et al. [44] reported that after the implantation of CP-Ti dental implants for 5–9 years, the retention rates of the upper and lower jaws were 81 % and 91 %, respectively. Furthermore, Ti-6Al-4V implants showed premature fracture after 6 months of implantation in the oral cavity [45,46]. While the overall success rate of dental implant surgeries exceeds 95 %, revision surgeries due to prosthesis failure remain around 5 %. This has prompted ongoing research into alternative Ti alloys to better addressing the evolving needs of dental and surgical treatments.

Kobayashi [47] first incorporated bio-friendly Zr element into Ti alloys, introducing Ti-Zr alloys as a promising material for medical dental implants. Gottlow et al. [48] found that after implanting Ti-Zr (13–17 wt %) alloy and CP-Ti implants in the mandibles of mini pigs for a period of 4 weeks, Ti-Zr implants exhibited stronger bone tissue responses compared to CP-Ti. Aritza et al. [49] measured the modulus of the Ti-15Zr alloy to be approximately 103 GPa through ultrasonic testing. In *in vivo* studies with 12 adult rabbits, the Ti-15Zr implant showed a higher bone-implant contact (BIC) percentage than Ti-6Al-4V at both 3 and 6 weeks, indicating superior biocompatibility. Up to date, Ti-Zr alloy implant products, such as SLA® Implant, are widely used in dentistry. It is estimated that hundreds of thousands of Ti-15Zr implants may be required for global implantation annually. Moreover, Ti-Nb alloy is also considered to be an ideal material for dental implants. Fojt et al. [50] and de Andrade et al. [51] reported that Ti-39Nb and Ti-35Nb alloys showed superior biocompatibility comparable to CP-Ti and Ti-6Al-4V alloys in physiological saline. Moreover, porous Ti-35Nb alloys were found to be more favorable for the proliferation and differentiation of osteoblasts, as well as for promoting the formation of extracellular matrix [52]. While these materials show considerable promise, research remains in its early stages, and further clinical trials are needed to evaluate their practical applications and long-term outcomes.

### 2.3. Porous biomedical Ti alloys

As mentioned above, porous Ti alloys have increasingly been recognized as the most suitable materials for the clinical repair and replacement of hard tissues. The porous structure of Ti alloys closely resembles the microarchitecture of human bone, creating an environment conducive to cell adhesion, diffusion, and differentiation [53,54]. The mechanical properties of porous materials are closely related to their unit mesh characteristics. By adjusting the pore size, shape, and porosity distribution, the modulus, strength, and deformation behavior can be customized to align with the mechanical properties of the bone tissue being repaired or replaced. Liu et al. [55] fabricated porous Ti-24Nb-4Zr-8Sn scaffolds using SLM and EBM, obtaining an elastic

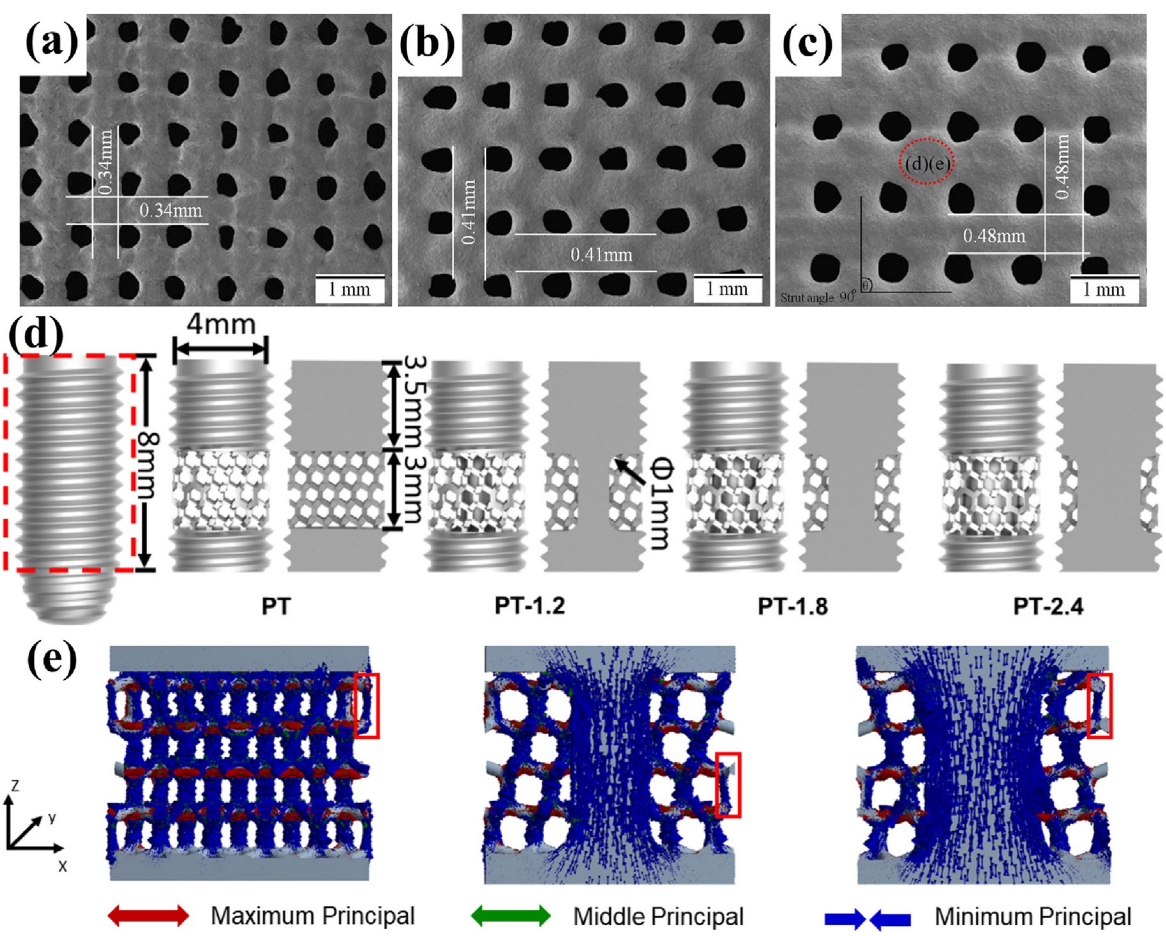


**Fig. 4.** Microstructure of the SLM-fabricated Ti-35Nb-2Ta-3Zr alloys: (a) 0.34 mm, (b) 0.41 mm, and (c) 0.48 mm [57]. Porous Ti alloys design: (d) Porous scaffolds with different geometries, (e) The vectors of principal stresses in the porous structures of each designed scaffold under compression [62].

modulus of 0.95 GPa and a compressive strength of 50 MPa for the SLM sample, and an elastic modulus of 1.34 GPa and a compressive strength of 45 MPa for the EBM sample. Yang et al. [56] performed finite element analysis on various hole geometries with different aperture size, and found that honeycomb holes had the highest elastic modulus, while square holes exhibited the lowest. For pore size range of 500 μm–800 μm, the elastic modulus varied between 15 GPa and 20 GPa, similar to the mechanical properties of the human femur. Hafeez et al. [57] demonstrated that in Ti-35Nb-2Ta-3Zr porous alloy (Fig. 4a–c), larger pore sizes result in increased elastic strain and a lower elastic modulus (about 3.1 GPa), resembling the properties of cancellous bone, while compressive strength decreases with the increasing pore size. Sun et al. [58] built a simplified model of porous structure to calculate maximum bearing capacity, and found that there is an exponential relationship between the experimental fracture load and the porosity of the porous structure. Although porous Ti alloys with varying geometric shapes and parameters exhibit significant variations in mechanical properties, a general trend emerges: compressive strength and elastic modulus are inversely proportional to porosity, both typically decreasing as porosity increases. Therefore, a porous structure is more conducive to achieving the desired mechanical properties.

In addition, orthopedic implants are subjected to cyclic stresses from the internal environment, requiring specific fatigue performance characteristics to ensure their reliability and longevity. According to the ASTM F382-17, Standard Specification and Test Method for Metallic Bone Plates, an implant is considered qualified if it can withstand one million stress cycles during the fatigue testing [59]. Ahmadi et al. [60] investigated the normalized fatigue strength of Ti-6Al-4V porous alloys fabricated using LPBF and found that it was lower than that of Co-Cr alloys and CP-Ti. Hrabe et al. [61] observed that the fatigue limit ratio of porous structures with pore sizes from 500 to 1500 μm was between 0.15 and 0.25, after $10^6$ cycles, significantly lower than the fatigue limit ratio of dense structures, ranging from 0.4 to 0.6. Xiong et al. [62] developed porous scaffolds with dense cores of varying diameter (Fig. 4d and e), which effectively enhanced their normalized fatigue strength (~0.5) while achieving a reduced Young's modulus of 23 GPa. While the inclusion of porosity in Ti alloys reduces the elastic modulus, thereby mitigating the stress shielding effect, it can also lead to reduced fatigue resistance. Nevertheless, the fatigue performance of porous structures can be significantly improved through strategic design modifications, such as optimizing pore size and distribution, or incorporating dense core regions, which strike a balance between mechanical strength, fatigue durability, and biomechanical compatibility.

## 3. Additive manufacturing of biomedical Ti alloys

### 3.1. Additive manufacturing techniques

The preparations of Ti alloys typically involve techniques such as casting, powder metallurgy, and mechanical processing. However, to address the growing demand for personalized medical treatment, AM is increasingly recognized as a key technological advancement [63]. This innovative technology, which builds parts layer by layer based on digital models, provides significant advantages, including high design flexibility, rapid production speeds, and superior part quality [64,65]. Metal AM technologies are generally classified according to their forming processes, including selective laser melting (SLM), direct energy deposition (DED), selective laser sintering (SLS), selective electron beam melting (SEBM), laser cladding (LC), and wire and arc additive manufacturing (WAAM). Among these, SLM and SEBM are the most commonly used methods for producing medical Ti alloys [66], owing to their relatively high precision.

SLM technology uses a laser beam to selectively melt pre-deposited metal powder, fusing each layer to build up the part. As illustrated in Fig. 5a, the process takes place in an inert gas environment, with the laser beam directed along a predetermined scanning path. After each layer is formed, a new layer of powder is applied, and the process repeats until the entire part is completed. SLM offers several advantages, including high material efficiency, as unused powder can often be recycled for future builds. Additionally, the process eliminates the need for complex support structures typically required in traditional manufacturing, enhancing flexibility and reducing material waste. The working principle of SEBM is similar to SLM, as shown in Fig. 5b, but instead of a laser, SEBM employs a high-energy electron beam as the heat source. The direction of the electron beam is controlled by an electromagnetic deflection coil to selectively melt the metal powder [67,68]. While both technologies are based on additive layer-by-layer processes, key differences exist in their performance characteristics. SLM generally offers higher molding accuracy than SEBM, making it well-suited for the rapid production of small, high-precision components. However, SLM is less efficient in terms of build speed, and parts produced through this method tend to exhibit higher residual stress, necessitating post-heat treatment to relieve these stresses. In contrast, while the dimensional accuracy of parts produced by SEBM is somewhat lower, it offers greater molding efficiency. The higher temperatures in the SEBM process help reduce residual stress, meaning that post-heat treatment is usually unnecessary.

Currently, Ti alloys produced through AM technology exhibit exceptional mechanical properties and formability. Fischer et al. [71] fabricated a binary Ti-40Nb alloy with less than 3 % porosity using SLM technology, which exhibited mechanical properties comparable to forged alloys, with no significant anisotropy and a uniform modulus of approximately 76 GPa. Yang et al. [72] employed the SLM method to create a Ti-24Nb-4Zr-8Sn alloy with a bimodal grain structure, which demonstrated a strength of 950 MPa and an elongation of 28 % superior to that of the alloy in its forged state. Hernandez et al. [73] utilized EBM to manufacture Ti-24Nb-4Zr-8Sn blocks with acicular α″ phases, achieving an average hardness of 2.5 GPa, higher than both the precursor powder (2.0 GPa) and the Ti-24Nb-4Zr-8Sn blocks produced by SLM (2.3 GPa). Our research team [74] developed a Ti-19Nb-0.6O alloy with low β stability using SLM technology, achieving a density of 99.8 %. After post-heat treatment, the alloy attains an ultra-low modulus of 42 MPa. Compared to the forged Ti-Nb-O alloy, Young's modulus decreased by 25 GPa, while maintaining a substantial elongation (15 %) and high strength (919 MPa).

The mechanical behavior of AM produced Ti alloys can differ significantly from conventionally processed ones, as illustrated in Fig. 6 and Table 2. AM technology enables the production of nearly fully dense metal parts and offers Ti alloys with superior mechanical properties. Moreover, AM technology enables highly personalized production with greater design flexibility, allowing the fabrication of implants with tailored shapes, structures, and sizes for better tissues integration [75]. These advantages are challenging to achieve with traditional casting or powder sintering techniques [76,77].

### 3.2. Defects of additive manufactured Ti alloys

The workability of alloys is closely associated with their internal defects. If the defects are not effectively addressed, they can lead to premature structural failure, potentially causing serious accidents. AM processes involve rapid heating, cooling, and solidification, which can easily induce microstructural defects such as lack of fusion, porosity, inclusions, and microcracks [93]. Additionally, macro-scale issues like warping and cracking of printed components can occur, significantly degrading the mechanical properties of the final product. The formation of these defects is closely tied to the solidification behavior, which is, in turn, influenced by various printing process parameters.

AM process involves various process parameters, with laser power, scanning speed, scanning strategy, scanning spacing, and powder layer thickness being the key influential factors [94,95]. Esmaeilizadeh et al. [96] demonstrated that laser scanning speed significantly affects the distribution and types of defects. Extremely high scanning speeds (>1300 mm/s) cause lack of fusion, while low scanning speeds (<550

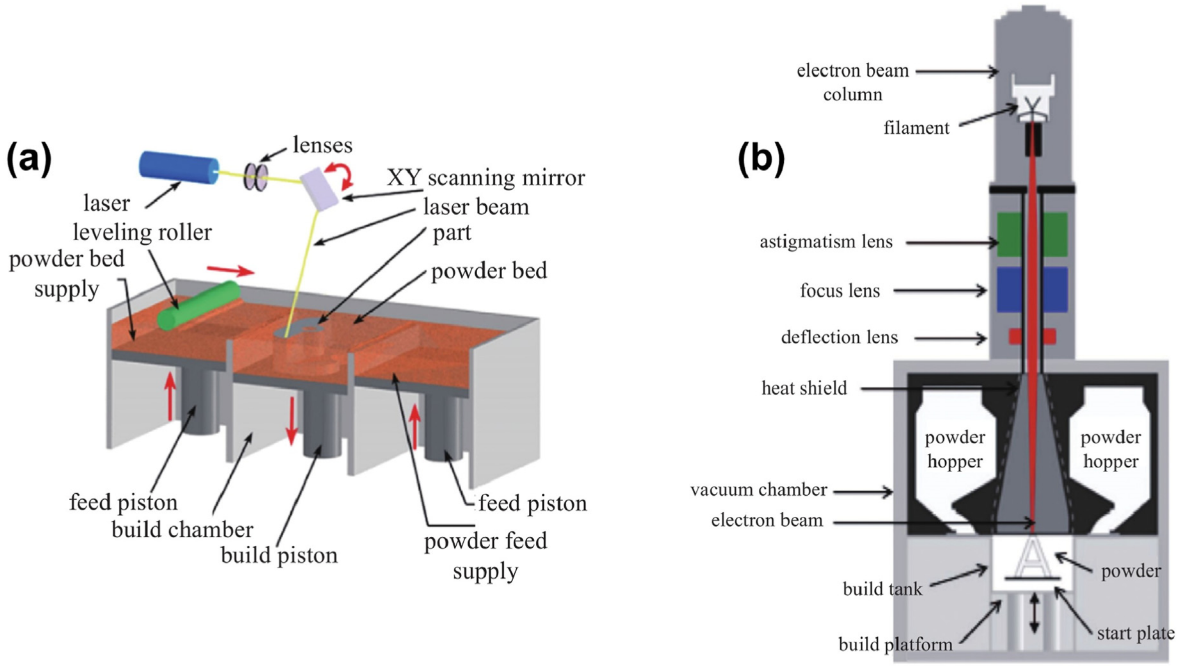


**Fig. 5.** Schematic diagram illustrating the forming principle of typical AM technology. (a) SLM technology [69]. (b) SEBM technology [70].

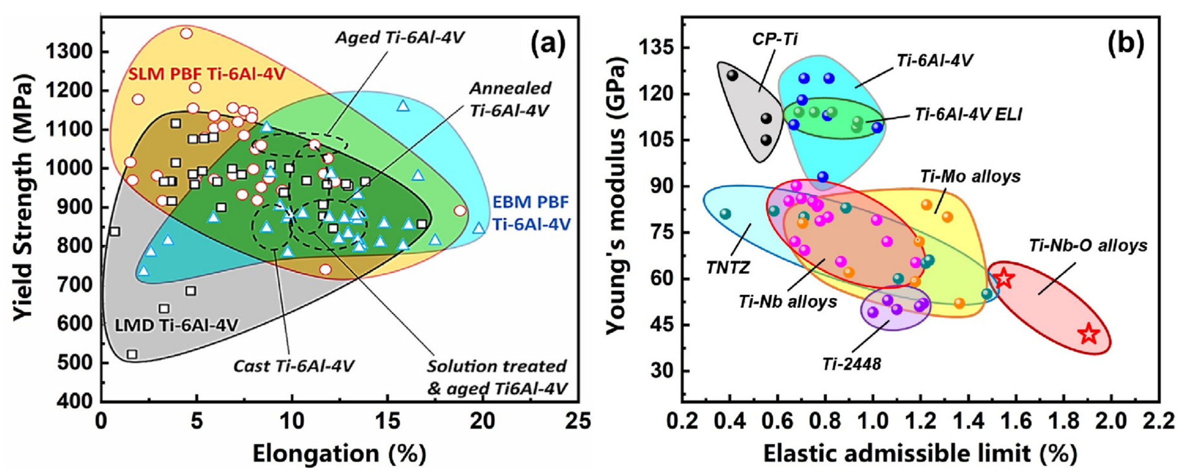


**Fig. 6.** Performance comparison of AM Ti alloys. (a) Mechanical property of additively manufactured Ti-6Al-4V alloys compared to conventionally manufactured ones [78]. (b) Relationship between Young's modulus and the elastic admissible limit for additive manufacturing Ti alloys [9,22,76,79–83]. YS: yield strength, UTS: ultimate tensile strength, EL: elongation.

mm/s) lead to keyhole defects. Liu et al. [55] fabricated porous Ti-24Zr-4Nb-8Sn alloy using SLM and EBM techniques, respectively (Fig. 7). The SLM sample exhibits a smoother surface than the EBM sample. Surface roughness is primarily influenced by the heat source spot size and layer thickness. The electron beam spot size (200 μm) is much larger than the laser spot size (40 μm), resulting in a larger melt pool, and consequently a rougher surface in EBM sample compared to the SLM. While the EBM sample has fewer defects, the compressive modulus of the SLM sample is significantly lower.

Pore defects are common in AM and typically occur when gas escapes from the melt at a slower rate than the solidification, trapping gas within the solidified structure. These defects are usually less than 100 μm in size and spherical. Pore defects can arise from three main sources [97]: (1) gas inclusions within the powder, (2) poor powder flowability during spreading or feeding, leading to gas adsorption or entrainment, and (3) the high energy density of the laser, which induces rapid metal vaporization in the molten pool. This vaporization generates back-pressure that forces the liquid metal downward, forming a narrow keyhole, as shown in Fig. 8. The laser beam undergoes multiple reflections inside the keyhole, increasing absorption and causing vaporization at the keyhole's bottom. The resulting bubbles collapse and become trapped in the molten pool, forming porosity as they are captured by the solidifying structure [98]. To reduce porosity, it is essential to select powders with high sphericity and excellent flowability. Additionally, optimizing processing parameters, controlling protective gas volume, and minimizing vaporization in the melt pool are key strategies for mitigating porosity formation [99–101].

### 3.3. Microstructural characteristics

Due to the inherent characteristics of AM, grains tend to grow epitaxially along the building direction, often resulting in columnar

**Table 2**
Mechanical properties of various biomedical Ti alloys fabricated by AM techniques.

| Alloys | E/GPa | YS/MPa | UTS/MPa | EL/% | Method |
|---|---|---|---|---|---|
| CP-Ti [84] | 112 | 620 | 703 | 5.2 | SLM |
| CP-Ti | 106 | 555 | 757 | 19.5 | SLM |
| CP-Ti | 126 | 518 | 640 | 29 | DED |
| Ti-6Al-4V [85] | 109 | 1110 | 1267 | 7.3 | SLM |
| Ti-6Al-4V | 125 | 1020 | 1100 | 8.0 | DED |
| Ti-6Al-4V ELI | 109 | 1015 | 1218 | 5.9 | L-PBF |
| Ti-6Al-4V ELI [82] | 114 | 945 | 1003 | 8.1 | DMLS |
| Ti-6Al-7Nb [86] | 105 | 900 | 1000 | 12 | SLM |
| Ti-13Nb-13Zr [87] | 65 | 794 | 996 | 5 | SLM |
| Ti-24Zr-4Nb-8Sn [29] | 53 | 563 | 665 | 13.8 | SLM |
| Ti-24Zr-4Nb-8Sn | 49 | 490 | 700 | 22 | SLM |
| Ti-42Nb [88] | 44 | 674 | | | L-PBF |
| Ti-40Nb [71] | 84 | | 748 | 19.9 | SLM |
| Ti-35Nb [89] | 72 | 485 | 645 | 23.5 | SLM |
| Ti-10Nb [76] | 72 | 763 | 855 | 21.6 | SLM |
| Ti-35Nb-5Ta-7Zr | 67 | 816 | 830 | 16.5 | SLM |
| Ti-35Nb-5Ta-7Zr | 55 | 813 | 834 | 19 | DED |
| Ti-35Nb-5Ta-7Zr [90] | 81 | 310 | 630 | 15 | SLM |
| Ti-25Nb-3Zr-3Mo-2Sn [91] | | 592 | | 37 | SLM |
| Ti-30Nb-5Ta-3Zr [92] | 60 | 664 | 680 | 15.3 | SLM |
| Ti-10V-2Fe-3Al [64] | | 828 | 853 | 17.2 | L-PBF |
| Ti-19Nb-0.6O [74] | 42 | 792 | 919 | 15 | SLM |

grains and an uneven microstructure [64,88,102,103], which is undesirable in biomedical applications. AM involves rapid melting and solidification, causing high undercooling in the micro-zone of the melt pool but insufficient undercooling at liquid-solid interface, leading to a significant reduction in spontaneous nucleation rate. The issue arises from the mismatch between kinetics and thermodynamics during solidification process. Therefore, controlling grain structure is essential for the broader adoption of AM technology. Ti alloys, with excellent formability in AM and broader processing window, allow for the adjustment and optimization of process parameters to control the morphology of solidified grains while maintaining their metallurgical quality [104].

Thijs et al. [105] demonstrated that the orientation of elongated grains in Ti-6Al-4V fabricated by SLM is governed by local heat transfer conditions, which are in turn affected by the scanning strategy. Specifically, a cross-scanning strategy helps refine the columnar grain, leading to a more uniform microstructure and an increased Vickers hardness. Wang et al. [106] observed that increasing scanning speed reduces the laser's interaction time with the powder material, resulting in smaller melt pool sizes and limited grain growth in Ti-6Al-4V alloys. This smaller melt pool enhances heat transfer to the surrounding material, increasing the cooling rate, which promotes rapid grain nucleation and leads to finer average grain sizes. Ibrahim et al. [81] examined the effects of laser energy density $E_v = \frac{P}{v \times s \times n}$ on the melt pool shape and grain size, where $P$ is the laser power, $v$ is the scanning speed, and $s$ is the scanning spacing. As shown in Fig. 9, higher $E_v$ results in better melt pool overlap, fewer defects, and smaller grain size. Murr et al. [107] emphasized the impact of different fabrication methods on phase composition. Specifically, the Ti-6Al-4V alloy produced by SLM is primarily composed of acicular α′ martensite, whereas the alloy fabricated by EBM features a (α+β) basket structure. This difference is mainly attributed to the solidification rates: the rapid cooling rate of SLM (up to $10^6$ K/s) favors the formation of the α′ phase, while the slower cooling rate in EBM, with the processing chamber maintained at 650–700 °C, results in the development of the lath α phase.

AM is a highly complex, multi-parameter material processing technique, where precise control of process parameters is critical for developing high-performance Ti alloys. The solidification process significantly influences the microstructure and mechanical properties of the final product. However, optimizing process parameters alone offer limited control over these properties. To further enhance manufacturing quality, it is essential to implement additional strategies, such as alloying and the application of external fields (e.g. ultrasonic vibration-assisted, and micro-alloyed second phase particles. This approach enhances the mechanical properties of Ti alloys and enables the production of components with superior performance and reliability for demanding applications.

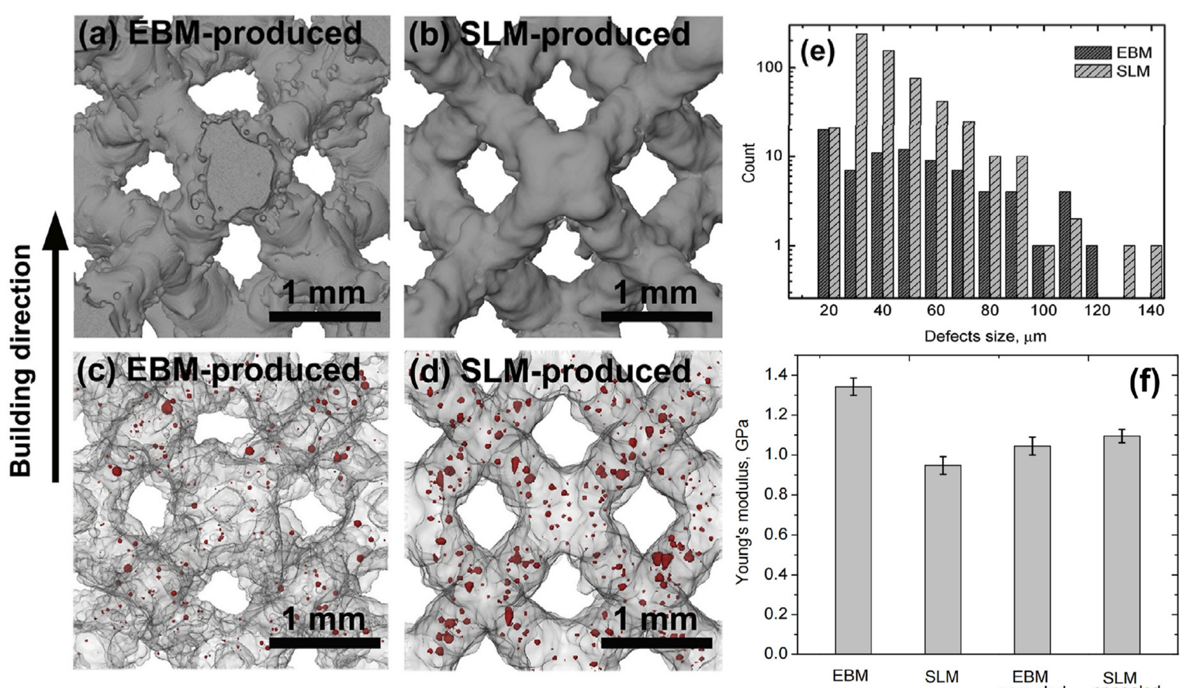


**Fig. 7.** Defects and mechanical properties of porous materials fabricated using different AM technologies. The micro-CT reconstructed images show the outer surface of the struts for (a) EBM and (b) SLM samples. The defects within the solid struts of (c) EBM and (d) SLM samples. (e) Distribution of defect size and count. (f) Young's Modulus of the samples [55].

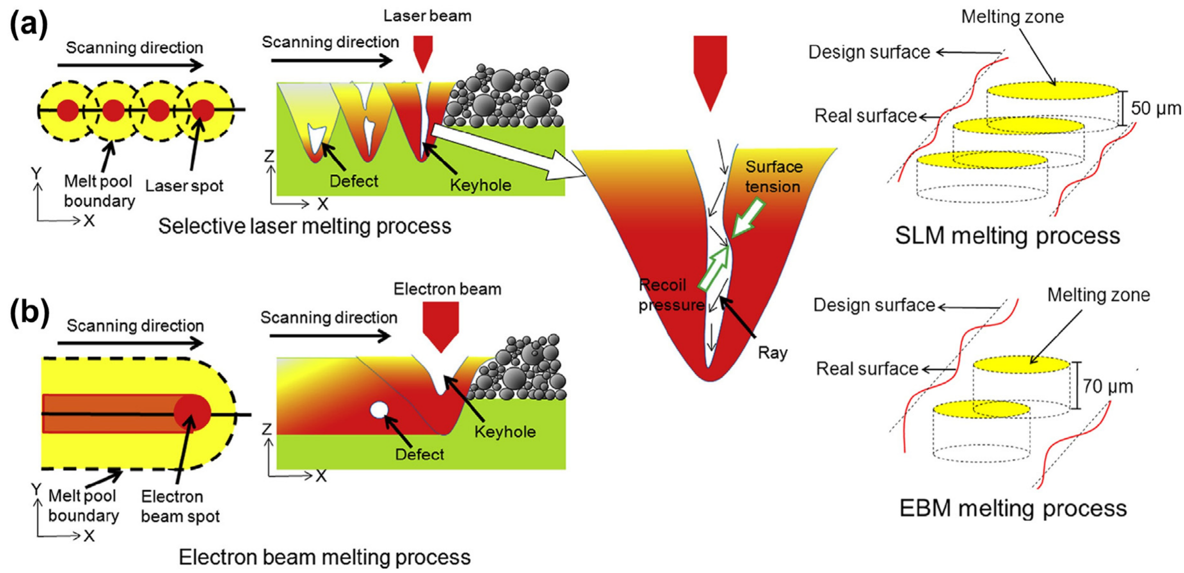


**Fig. 8.** Forming principles of SLM technology and EBM technology [55].

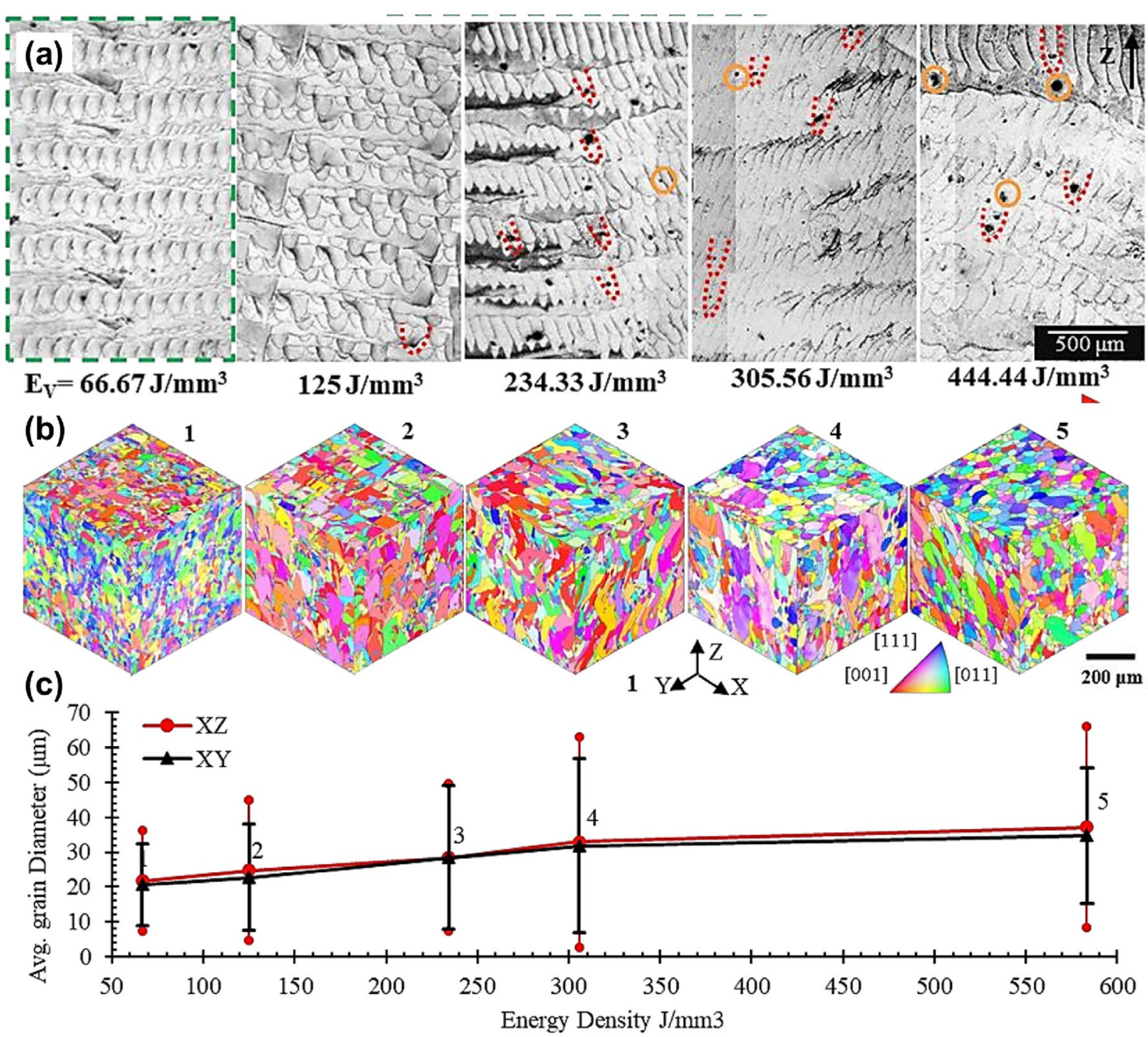


**Fig. 9.** The influence of printing parameters on the microstructure of Ti-34Nb-13Ta-5Zr-0.3O alloys. (a) OM of melt pools with different energy density. (b) EBSD maps. (c) Effect of energy density on grain size [81].

## 4. Post-heat treatment of biomedical Ti alloys

The microstructure, mechanical properties, and deformation mechanisms of biomedical Ti alloys are intricately linked to the control of processing and heat treatment. In AM, materials experience significant temperature gradients, leading to rapid cooling rates and the accumulation of thermal stresses. These thermal gradients can induce the chemical inhomogeneity and the formation of non-equilibrium microstructures [108], which often impair plasticity and reduce fatigue strength. Post-heat treatments are essential for addressing these issues and improving performance. Vrancken et al. [109] annealed Ti-6Al-4V alloy at 850 °C for 2 h followed by air cooling, resulting in an increase in elongation from 7.3 % to 12.8 % compare to the as-built condition. Chen et al. [110] investigated the effects of various annealing treatments on L-PBF Ti-6Al-4V alloy. As the annealing temperature increased, the acicular α′ martensite progressively transformed into lamellar α+β phases, which led to a reduction in strength and an enhancement in elongation, with the optimal combination of properties achieved at 800 °C for 2 h. Deformation behavior is governed by the evolution of phase structure stability, which typically involves slip deformation, martensitic transformation, and twinning. Understanding the interplay between these factors is crucial for optimizing the mechanical properties and performance of biomedical metallic materials.

### 4.1. Phase stability

Due to the presence of acicular α′ martensite and columnar prior β grains, SLM Ti-6Al-4V alloys typically exhibit low ductility and significant mechanical anisotropy. To enhance properties, post-heat treatment is commonly applied to decompose the α′ martensite into the equilibrium α+β phases. The precipitation of the α phase is closely related to the phase transformation kinetics, which can be manipulated through post-heat treatments. Specifically, the diffusion driven phase transformation from β to α alters the β matrix composition and enhances the phase structure stability, realizing the combination of low modulus and high strength [111].

Elastic modulus is a fundamental physical property that quantifies the strength of interatomic bonding forces within a crystal lattice, reflecting the atomic interactions. It is intrinsically linked to the atomic and electronic structure of the material. Empirical studies have identified a relationship between the elastic modulus of various phases in Ti alloys, typically expressed as $\beta \approx \alpha'' < \alpha' < \alpha < \omega$ [20,112,113]. Based on this understanding, the development of low-modulus Ti alloys primarily targets metastable β-Ti alloys. As widely recognized, Young's modulus of β-Ti alloys follows a "W-like" variation pattern [3], which is contingent upon the phase stability influenced by the content of β stabilizers and the average valence electron-to-atom ($e/a$) ratio of β phase, as illustrated in Fig. 10a. During the precipitation of the α phase, elements diffuse and redistribute between the two phases. The residual β phase typically undergoes an increase in β-stabilizing elements and a decrease in α-stabilizing elements, which affects the stability of the β matrix [114]. This redistribution suggests that the elastic modulus of the residual β phase could follow a "W-shaped" evolution as the volume fraction of the α phase increases.

Fu et al. [28] proposed a model that explains the fluctuation in elastic modulus associated with the precipitation of α phase. The model predicts that, as the α phase content increases, the modulus initially decreases, reaching a minimum value at around 50 vol% α phases. Beyond this point, the modulus begins to increase, reflecting the complex interplay between the phases as shown in Fig. 10b. Hariharan et al. [115] observed that the phase transition temperature of Ti-13Nb-13Zr fabricated by AM is 40 °C higher than that of the forged material. Following solution treatment and quenching, the alloy exhibited an increase in strength while maintaining ductility in the range of 9~12 %, and a low elastic modulus of 73 GPa. Pilz et al. [116] enhanced the yield strength of Ti-42Nb alloy fabricated by LPBF by 50 %, reaching 1060 MPa, through

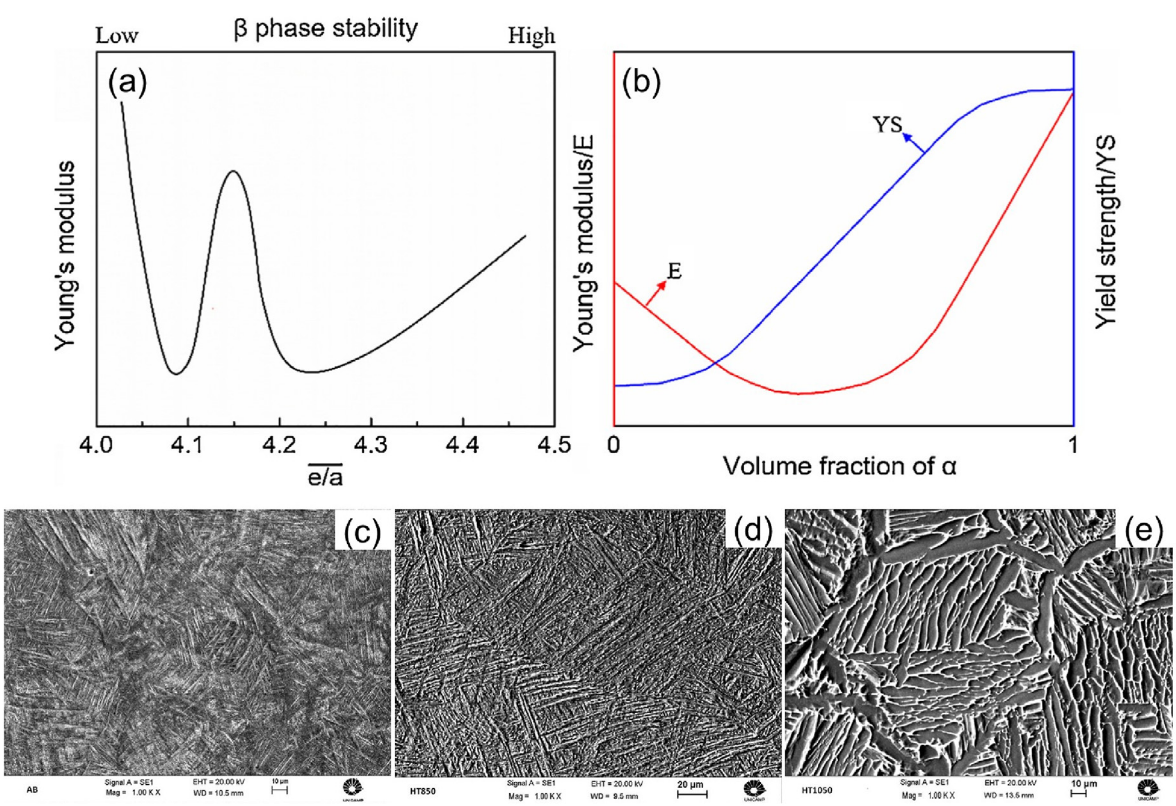


Fig. 10. The effect of heat treatments on modulus and microstructure. (a) Schematic evolution of Young's modulus of the Ti alloys. (b) Young's modulus and yield strength as a function of the volume fraction of α phase [28]. (c) The SEM images of as built Ti-6Al-4V ELI alloy and heat treated at (d) 850 °C and (e) 1050 °C [82].

post-treatment at 723 K, but accompanied by a 34 % increase in elastic modulus, reaching 87 GPa. Thus, by precisely controlling the heat treatment parameters to regulate the α phase content, the alloy's strength can be effectively enhanced while simultaneously reducing its elastic modulus. This strategy facilitates the optimization of mechanical properties, enabling a tailored balance of strength and modulus for specific applications.

### 4.2. Microstructure and mechanical changes after post-heat treatment

The mechanical properties of α+β dual phase Ti alloys are influenced not only by the volume fraction of the α phase but also by its morphology and distribution. Ti alloys fabricated through SLM typically exhibit lamellar intragranular αp and αs (α-WI) phases, along with the grain boundary α phase (α-GB) following post-heat treatment [117]. Precipitation of the lamellar α-WI phase is well known to enhance alloy strength, but often results in a reduction in plasticity due to the limited dislocation motion in the fine α phase. High-temperature annealing, which leads to the coarsening of lamellar microstructure, results in a less pronounced decrease in plasticity, but provides weaker strengthening effect, as the larger α phase lamellae provide fewer obstacles to dislocation movement. In contrast, low-temperature annealing yields fine lamellar structures that significantly improve strength by creating grain boundary and dislocation interactions, but evidently decrease plasticity [118]. Thus, the balance between strength and plasticity in α+β Ti alloys can be optimized by adjusting annealing conditions to control α phase size and distribution.

Longhitano et al. [82] characterized the microstructure and properties of Ti-6Al-4V ELI alloy after heat treatment at 850 °C, 950 °C, and 1050 °C for 1 h, followed by furnace cooling (Fig. 10c–e). As the temperature increases, the α-WI phase grows significantly. Compared to the as-built alloy, elongation improves from 6 % to 8 % and 12 % after heat treatments at 850 °C and 1050 °C, respectively. Yield strength decreases from 1015 MPa to 945 MPa and 787 MPa, respectively, while the change in elastic modulus remains negligible. Zou et al. [119] refined and equiaxed the prion-β grains in SLM Ti-6Al-4V alloy through rapid heat treatment, increasing elongation from 5.2 % to 16.6 %, while reducing yield strength from 1123 MPa to 853 MPa. Sabban et al. [120] applied an innovative cyclic heat treatment to achieve a bimodal microstructure through repeated phase transformation, which provided an additional driving force for α lath spheroidization, significantly improving plasticity.

Additionally, throughout the relatively gradual cooling processing, alloying elements in the dual-phase Ti alloy tend to partition between the α and β phases, promoting the formation of the α-GB phase. Typically, α-GB preferentially nucleates and grows at the high-angle grain boundaries (HAGB) of the β phase [121], where the presence of continuous α-GB layers can significantly reduce fracture resistance. By adjusting the morphology of the α-GBs through a reduction in annealing temperature and diffusion time, the continuity of phase transformation at the grain boundaries can be altered without inducing interfacial roughening, leading to the formation of discontinuous α-GBs. The presence of discontinuous α-GBs mitigates strain accumulation at the β grain boundaries during deformation, thus impeding crack propagation along these boundaries. The discontinuous α-GBs are typically linked with variant selection during the α phase transition. Decreased cooling rate and abbreviated furnace cooling duration contribute to pronounced variant selection. Consequently, the resultant α-GB structure is discontinuous and finely equiaxed, facilitating a substantial enhancement in the alloy's plasticity [122].

Therefore, post-heat treatment and microstructure manipulation are crucial in the AM of Ti alloys. These factors influence mechanical properties such as strength, elastic modulus, and elongation, while also affecting microstructural stability and performance under service conditions. By adjusting heat treatment parameters (e.g., temperature, time, and cooling rate), it is possible to enhance the alloy's overall properties. Furthermore, post-heat treatment helps minimize residual stresses and reduce defects, improving fatigue resistance and corrosion performance, all of which are critical for ensuring the reliability, durability, and service life of the final product.

## 5. Biocompatibility evaluation of biomedical Ti alloys

Since the early 21st century, Ti alloys, as representative biomedical materials, have become essential in clinical applications due to their exceptional overall performance. They are emerging as a pivotal sector in the global materials industry and a major focus of innovation in the field of advanced biomaterials. Medical devices that directly interact with the human body, particularly those designed for implantation or therapeutic intervention, inherently carry certain risks, including potential adverse biological reactions and long-term performance issues. Therefore, a series of biological studies and evaluations are required prior to clinical use. These evaluations, as summarized in Table 3, typically encompass in vitro biological testing, animal testing, and rigorous clinical trials [13, 123].

The long-term biological safety and biomechanical performance of Ti alloys are critical for the design and development of high-performance medical devices and their clinical applications. Biomechanical compatibility should serve as the theoretical foundation for developing new surgical implant materials and devices. As medical Ti alloy evolves, novel alloys and processing techniques continue to emerge. While standards for additive manufacturing, such as ISO 17296:2021, ASTM 52900, GB/T 34508 and YS/T 1139, have been established, specific standards for AM in the biomedical field are lacking. The manufacturing processes, structural characteristics, and usage forms of AM materials and implantable medical devices differ significantly from those produced by traditional methods, complicating quality assessment and risk evaluation. These challenges hinder both the development of industry products and regulatory oversight, highlighting the need for updated and comprehensive standards for medical Ti alloys.

## 6. Summary and prospect

Ti and its alloys are extensively utilized in the biomedical field due to their exceptional performance. The ongoing advancement of Ti alloys not only fosters innovation in medical technologies but also significantly contributes to the development of functional and structured materials. As the public awareness of health issues increases, the demand for personalized medical devices has grown substantially. AM offers several advantages over traditional production methods, enabling greater design flexibility and customization. AM technique of biomedical Ti alloy has become a prominent research focus. However, despite significant progress, there remain several challenges that need to be addressed.

(1) Composition design of AM biomedical Ti alloys

The chemical composition directly impacts both mechanical properties and biocompatibility in biomedical Ti alloys. Elements such as V, Cr, Mn, Co, and Al may induce adverse biological effects, which should be minimized or replaced with more biocompatible alternative; however, most of the biocompatible elements, such as Zr, Nb, Ta, and Sn, exhibit lower β stability, requiring multi-alloying and high concentrations to achieve a low modulus, which may raise additional biocompatibility concerns. Furthermore, the rapid solidification and repeated re-melting between layers during AM process can cause the formation of columnar grains, thermal stress and phase transitions, resulting in the development of metastable phases and cracking that impact both formability and mechanical performance of the alloy. Thus, it is crucial to account for the unique solidification and printing behaviors of AM techniques when designing biomedical Ti alloys.

(2) Post-treatment and industrial production

**Table 3**
Biological evaluation relative standards of biomedical titanium alloy devices [13, 123].

| Biological evaluation | International standard |
|---|---|
| Animal welfare requirements | ISO 10993-2 |
| Tests for genotoxicity, carcinogenicity and reproductive toxicity | ISO 10993-3 |
| Selection of tests for interactions with blood | ISO 10993-4 |
| Tests for in vitro cytotoxicity | ISO 10993-5 |
| Tests for local effects after implantation | ISO 10993-6 |
| Ethylene oxide sterilization residuals | ISO 10993-7 |
| Framework for identification and quantification of potential degradation products | ISO 10993-9 |
| Tests for irritation and skin sensitization | ISO 10993-10 |
| Tests for systemic toxicity | ISO 10993-11 |
| Sample preparation and reference materials | ISO 10993-12 |
| Identification and quantification of degradation products from metals and alloys | ISO 10993-15 |
| Toxicokinetic study design for degradation products and leachable | ISO 10993-16 |
| Establishment of allowable limits for leachable substances | ISO 10993-17 |
| Chemical characterization of materials | ISO 10993-18 |
| Principles and methods for immunotoxicology testing of medical devices | ISO 10993-20 |
| Quality management systems-Requirements for regulatory purposes | ISO 13485 |
| Application of risk management to medical devices | ISO 14971 |
| Validation of software for medical device quality system | ISO/TR 80002-2 |
| Additive manufacturing-General Principles | ISO 17296:2021 |
| Additive manufacturing with TC4 alloys powder by bed electron beam melting | GB/T 34508:2017 |
| TC4 titanium alloy cellular structure parts by additive manufacturing | YS/T 1139:2016 |

Post-heat treatment is used to stabilize the product structure and to modify the phase composition of AM Ti alloys, enhancing their overall performance. However, brittle oxidation layers easily form on the Ti alloy surface when temperature exceeds 600 °C, which severely degrades both mechanical properties and surface integrity. Therefore, vacuum environment, atmosphere protection, protective coatings, or surface polishing are often adopted to mitigate this issue. Nevertheless, these methods increase manufacturing complexity and cost, limiting their feasibility for widespread commercial application. Rapid cooling from high temperature is commonly employed for metastable β-Ti alloys to achieve low modulus. Thus, developing advanced, user-friendly heat treatment techniques suitable for industrial-scale production is essential.

(3) Bio-mechanical properties

AM holds significant potential for customizing biomedical Ti alloys to meet individual patient needs. However, studies on the mechanical behavior of these alloys under realistic physiological conditions remain limited. Most research on Ti alloy's mechanical properties has been conducted under room temperature and in air, without fully considering the complex *in vivo* environment. Given the variability in biological conditions, such as pH, these factors can affect the long-term mechanical properties and biocompatibility. Additionally, individual differences in bone structure, movement patterns, and stress conditions should be considered. Standard implants often overlook dynamic factors, which can lead to discomfort or functional issues. Therefore, it is essential to consider high compatible implant design, material selection, and AM processing control comprehensively to develop optimized, burden-free implants.

(4) Standardization of biomedical Ti alloys industry

Establishing industry standards for biomedical Ti alloys and related products is essential to guarantee their safety, reliability, and clinical effectiveness, particularly for products yielded using emerging technologies, where standardized guidelines are currently insufficient. As AM technology continues to evolve, new fabrication methods, processing conditions, and material characteristics are being continuously innovated and refined, creating challenges for existing standards that struggle to keep pace with the rapid advancement in materials. For instance, differences in AM equipment, alloy component, printing parameters, and post-processing methods can contribute to discrepancies in the final product's performance. Therefore, it is crucial to develop comprehensive material standards, process guidelines, and equipment manufacturing specifications to address the varied structural and performance requirements of each body part. Such efforts will enhance the safety and efficacy of biomedical implants while fostering trust among healthcare providers and patients in the technologies employed.

In summary, the developments aim to enhance the performance, safety, and clinical success of biomedical Ti-based produced through additive manufacturing, ensuring they meet both the biological and mechanical demands of medical applications.

## CRediT authorship contribution statement

**Yue Gao:** Writing – original draft, Formal analysis. **Wentao Jiang:** Writing – review & editing, Investigation. **Da Zeng:** Resources, Funding acquisition. **Xiongwei Liang:** Supervision, Conceptualization. **Chaoli Ma:** Project administration, Methodology. **Wenlong Xiao:** Writing – review & editing, Methodology.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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