The Fabrication of Titanium Alloy Biomedical Implants using Additive Manufacturing: A Way Forward

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Abstract: A biomedical implant is a man-made transplanted device used to replace missing life structures and support damaged biological hard tissue. The primary goal of these structures is to preserve the anatomical fixation of the human body. Currently, advanced titanium alloys occupy almost half of the market share of implant products however, they still pose concerns such as decreasing osteogenesis during application. This paper presents a review of the role of additive manufacturing (AM) in providing innovative methods for fabricating metallic alloys toward Industrial Revolution 4.0. Initially, an overview of biomedical implants is discussed, followed by an examination of the ability of titanium alloys produced using AM methods. Mechanical properties and other issues relating to the functional application of these biomedical implants are promptly discovered. Further, the effect of bone-implant contact between implants and tissues, which can lead to failure, while advanced methods to improve osteointegration through surface modification of the AM fabricated titanium alloys are also scrutinised.

Keywords: Ti-6Al-4V, selective laser melting, additive manufacturing, osteointegration.

INTRODUCTION

Biomedical implants are medical devices manufactured to replace a missing biological structure and used to recover unfunctional hard tissue diseases. According to the U.S. Food and Drug Administration, this increasing number of fracture cases in clinical applications has increased the usage of biomedical implants in healthcare industries. They have been extensively used in open reduction internal fixation (ORIF) that practically stabilize in surgery and heal a broken bone [1]. In general, different implants and technologies have been engineered for various applications to meet the body's biological response to the devices and improve the quality of the recipients' lives. They can provide practical support like simple knee implants, artificial dentures and some of the advanced artificial organ transplants that enhance the functioning of human systems, such as synthetic blood vessels, artificial heart valves that contain electronic sensors [2].

Implant materials can be classified into two groups such organic and inorganic as shown in Figure **1**. Polymers as organic biomedical implants are much easier to fabricate yet, biopolymers are preferred due to their biocompatibility and ability to biodegrade in situ in the human body [3]. As an example, Polymethyl-methacrylate (PMMA) and Polytetrafluoroethylene (PTFE) are widely utilized in orthodontics retainer dentures, crowns, and vascular grafts to bypass obstructed blood vessels, while biopolymers polylactic acid (PLA) as cardiovascular implants applications. As can be seen from Figure 1, inorganic implants can be separated into ceramic and metal. Bioceramics such as zirconia and alumina are light material, highly resistant to wear, and compatible with blood suitably used for dental prosthetic tooth replacements [4, 5]. In addition, hydroxyapatite (HA) is a bioceramic coating commonly applied on the orthopaedic implant as its composition is similar to bone crystallinity. It is highly able to improve bone regeneration, nevertheless costly than the conventional implant [6].

As for fracture fixation and load-bearing capabilities in the human body, it is crucial to choose a permanent type of artificial device. Here inorganic metallic alloys like cobalt-chromium based alloys, 316L stainless steel and titanium are the most frequently used materials owing to outstanding performance such as excellent mechanical properties, and good tissue compatible drug delivery coating [1, 7, 8]. A superior mechanical behaviour of metallic alloys has proven that no relative motion between the contiguous bone and the implant during the patient's functional movements as reported by Saini *et al*. [9]. As far, the biocompatibility effect of these materials is the main process of osteointegration between the device and the periosteum without bacterial interference need to be a concern while designing a new biomedical implant. Increasing the

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E-ISSN: 2414-2115/21

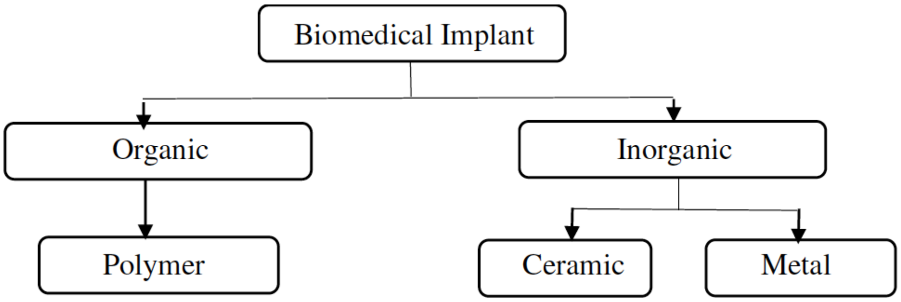

Figure 1: Classification of the biomedical implant [5].

bone growth and antibacterial performance of the implants could foster the bone remodelling process, leading to the formation of osteoblast and osteoclast growth cells surrounding the fracture site for successful osteointegration [5, 10]. Regarding these criteria, titanium alloys are widely chosen as inorganic materials for implantable medical devices.

The discovery of titanium took place in 1791 when The Reverend William Gregor found a new black, magnetic, and sandy deposit in a stream in Cornwall, England [11]. In 2012, the cost of the global market for titanium orthopaedic implants, including joint replacement, spine and emergency cases, was estimated more than USD30.5 billion [12] rising to USD45.5 billion in 2014 [13]. Titanium alloys are superior to conventional alloys and low density (4.8gm/cm3), unfortunately, the risk of infection is still high (approximately 2-5%), which lead to an extra surgical revision [14, 15]. Figure **2** shows the x-ray images of titanium implants applied in ORIF fixation. Intramedullary nails are the most predominant use of Ti alloy in the small fragments fracture like subtalar fracture as illustrates in Figure **2(a)**. The length and thread of the nails depending on the fracture type. Ti alloys are preferable due to withstand of high load on the plantar side in comparison to other materials.

Distal radius fracture is a common nondisplaced fracture at the radius near the wrist breaks and can be treated using volar distal radius plates as shown in (Figure **2b**). This rigid Ti-alloy plate is employed for increasing carpal stabilization and reduce the risk of osteoarthritis in the radius anatomical region.

Figure **2c** shows a width of 3.5mm of Ti plate is placed at dorsal or volar for treatment of broken of the ulna and tighten using the compression screw. It can easily increase the contact area of the fracture gap and improved the callus formed around the implant. The number of holes and screws depending on the complexity of the fractures. Besides, in order to reduce the injuries associated with a high risk of periprosthetic fractures, a curve proximal tibia plate with fragments of 4.5mm is joined at the upper portion of the tibial bone as illustrated in Figure **2d**. If untreated, it can lead to osteoarthritis.

Since the mid-1980s, AM often called 3D printing able to manufacture bespoke metal, ceramic and polymer components without the need for moulding or

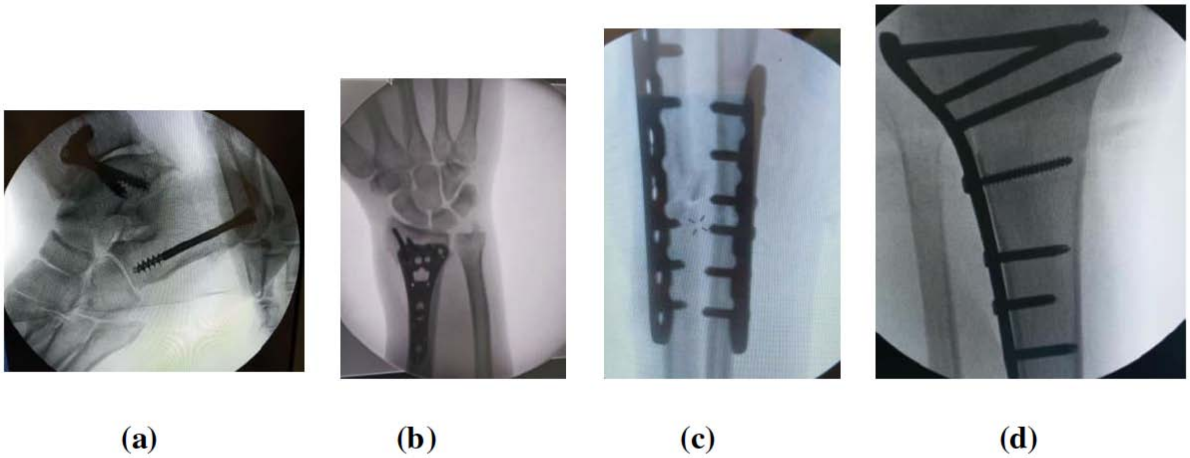

Figure 2: X-Ray imaging of ORIF fixations at (**a**) subtalar intramedullary nail (**b**) distal radius plate (**c**) midshaft radius and ulna plates and (**d**) proximal-distal tibia using titanium implants.

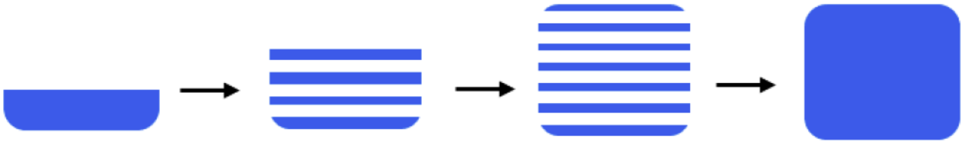

Figure 3: The layer-by-layer principle used in AM [16].

tooling. It is a fully digital computer-controlled process that creates three-dimensional objects by depositing the powder, in the layer-by-layer with a thickness of approximately 0.001 to 0.1 inches as shown in Figure 3 [17, 18]. In this process, powder materials are initially melted using a source of energy introduced by the laser through an electron beam or electric arc and become a densely packed metallic component after solidified [19]. In general, this end-product of AM is suited for biomedical implants and this process is more cost-effective than the conventional implant [20].

Therefore, this review summarised the Ti-6Al-4V implant fabricated using additive manufacturing for orthopaedic biocompatible application. Initially, an investigation of Ti alloy in the biomedical application is discussed, followed by the analysis of the effects of AM parameters on the surface topology of Ti implant. Then, the mechanical properties of this alloy as a comparison to bone and soft tissues are finally discovered.

TITANIUM ALLOYS IN BIOMEDICAL APPLICATIONS

Titanium and its alloys have commonly utilised as medical bioimplants since the beginning of the 1970s [21]. The Ti-6Al-4V alloy was originally designed for structural aerospace applications in the 1950s since it can minimise weight in highly stressed structures [1, 20]. For biomedical parts, the design of Ti alloy implant depends on external or macroscale of bone structure and type of fractures intended for fixations. This may positively influence tissue regeneration and integration between the tissue and skeletal systems after implantation [1, 4, 22].

Titanium alloys are available in three forms as shown in Table **1**. They are Alpha (α) alloys, Alpha-Beta (α+β) alloys and Beta (β) alloys. At moderate temperature levels (650–1340 K) all these alloys are heat-treated, weldable and provide high strength to weight ratio [4, 11]. In the α -type Ti alloy group, the pure titanium (CP-Ti) was the pioneer of biomedical implants fabricated from the 1950s to the 1990s as it manifested a successful bone osteointegration.

MANUFACTURING BIOMEDICAL IMPLANTS USING ADDITIVE MANUFACTURING

According to Schwab [23], IR 4.0 is a technical breakthrough in areas of robotics, the Internet of Things (IoT), artificial intelligence (AI), driverless vehicles, 3D printing (3DP), nanotechnology and quantum computing. These innovations can revolutionise computer-guided fabrication for both complicated objects and products using multipurpose materials [24]. With the development of AM, fields from medicine and science to engineering and robotics can be decentralised.

Biomedical devices could be enhanced by the flexibility offered by AM to manufacture devices with various shapes to tailors the complex shapes of bones

Table 1: Classification of Major Types of Titanium Alloys

Type/Material	α and near α	Near β and β	α+β	Ref
α stabilising elements	Al, Sn, Ga, Zr, C, O, N			[1, 16, 26]
β stabilising elements		V, Mo, Nb, Ta, Cr		[16, 26, 28, 29]
Common Material	Commercially pure Ti	Ti—5Al—2.5Fe	Ti—3Al—8V–6Cr–4Mo–4Z	[1, 11, 16, 29]
	Ti–5Al–2.5Sn	Ti–5Al–2Mo–2Fe	Ti–4.5Al–3V–2Mo–2Fe	
	Ti–5Al–6Sn–2Zr–1Mo	Ti–6Al–7Nb	Ti–5Al–2Sn–2Zr–4Mo–4Cr	
	Ti–6Al–2Sn–4Zr–2Mo	Ti–6Al–4V	Ti–6Al–6Fe–3Al	
	Ti–8Al–1Mo–1V	Ti–6Al–6V–2Sn	Ti–6Al–6Fe–3Al	
			Ti–10V–2Fe–3Al	

and advanced functionality than the market manufactured implants [20, 22]. AM Ti alloys able to influence the level of quality and morphology of the manufactured product, which may positively influence tissue regeneration and osteointegration of medical implants as it provides a high vascularisation and bone ingrowth [6, 22, 25]. Patient-specific implants which are tailored to fit a specific patient's anatomy or other specifications are one of the core aspects for the medical evaluation of AM methods [22]. Recent advances in AM techniques have made it possible to achieve exceptionally high precision in the manufacture of medical devices [1, 11, 22, 26]. Dr Jules Poukens and his team pioneered the world's first additive-engineered entire lower jaw implant for a patient in Belgium in 2012. The patient’s specific implant integrates multiple functions, including cavities to promote muscle attachment, and sleeves for mandible nerves [6].

Figure **4** shows the International Organization for Standardization (ISO)/American Society for Testing and Materials (ASTM) 52900:2015 classifies AM processes into seven groups into seven categories pros standard classify standard, Powder-based AM methods such as Directed Energy Deposition (DED), Binder Jet (BJ), Electron Beam Melting (EBM) and Selective Laser Melting (SLM) are often used in the development of packed metallic products [20].

Figure **5(a)** shows a series of DED methods that melt and bind materials fed in powder or wire form using focused thermal energy and improve the high deposition rates. This results in faster build rates of parts, however, the structure of the implants has a low surface quality that may require additional machining [27].

In addition, BJ commonly uses as a combination of two materials of ceramic and alloy, but BJ involves several post-processing parts for quality improvement such as curing, sintering and annealing as illustrated in Figure **5(b)**. This post-processing leads to shrinkage of material due to repetitive cooling and solidification causes by internal stresses in the structure. Therefore, the massive void content of parts from the BJ process is not suitable for high mechanical strength in load-bearing applications. Currently, EBM (Figure **5(c)**) and SLM (Figure **5(d)**) have been promoted to manufacture Ti alloy biomedical implants which suit to fabricate different fracture types and irregular structures of the skeletal system [1, 34]. Those use powdered bed molten techniques and liquefy specific powder layers to produce dense parts. EBM has significantly offered parts with a rougher surface value of approximately 20-50 μm, which differ from the SLM product (5-20 μm) [35]. Ginestra et al. [36] found that the EBM sampled showed non-flattening on the surface due to the partially melted powder, and this is caused by the sintered particles that occur during the preheating in EBM.

This led to Ti alloy fabricated using EBM not favourable for in vivo cell adhesion and proliferation compared to the SLM sample. As for the surface

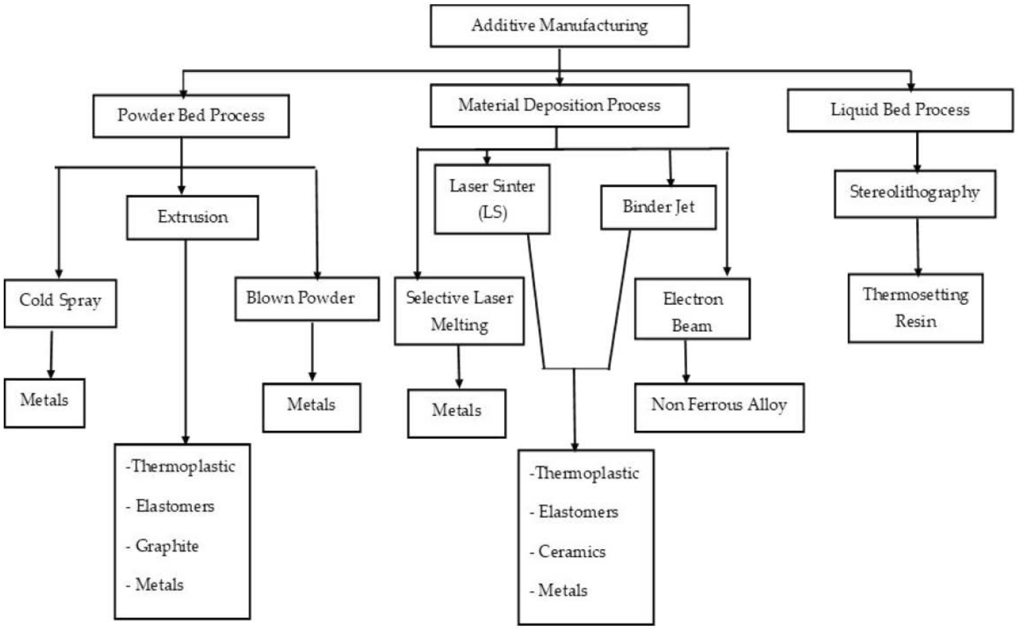

Figure 4: Branches of additive manufacturing [18].

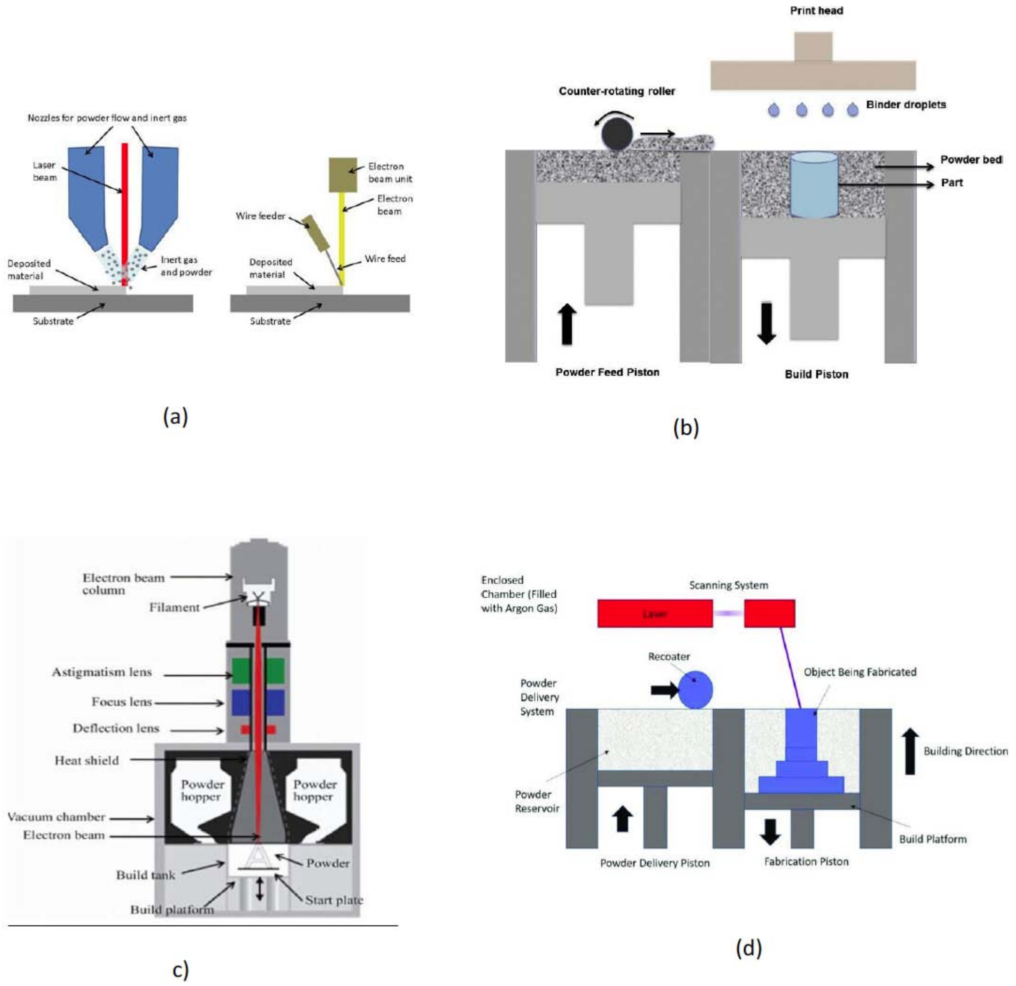

Figure 5: Schematic illustration of current AM Processes (**a**) directed energy deposition [30] (**b**) binder jetting [31] (**c**) electron beam melting [32] (**d**) selective laser melting [33].

roughness of the biomedical implant, 1-2 µm range has been proposed to be effective for the biomechanical anchorage for bone-implant contact [37-39].

Biomedical devices could be enhanced by the flexibility offered by AM to manufacture devices with various shapes to tailors the complex shapes of bones and advanced functionality than the market manufactured implants [20, 22]. Ti alloys fabricated using AM method able to influence the level of quality and morphology of the manufactured product, which may positively influence tissue regeneration and osteointegration of medical implants as it provides a high vascularisation and bone ingrowth [6, 22, 25]. Patient-specific implants which are tailored to fit a specific patient's anatomy or other specifications are one of the core aspects for the medical evaluation of AM methods [22]. Recent advances in AM techniques have made it possible to achieve exceptionally high precision in the manufacture of medical devices [1, 11, 22, 26]. Dr Jules Poukens and his team pioneered the world's first additive-engineered entire lower jaw implant for a patient in Belgium in 2012. The patient’s specific implant integrates multiple functions, including cavities to promote muscle attachment, and sleeves for mandible nerves [6].

CHALLENGES AND A WAY FORWARD

Table **2** shows the differences of Young’s modulus, tensile strength and elongation of break of various long bones as compared with Ti alloy. In general, the skeletal system has a higher tendency to fracture in the pressurised event, such as a direct blow or fall beyond their tensile strength and fracture strain [45]. In recent years, titanium has been widely used in orthopaedics, however, there are some cases of titanium implant loosening.

As can be seen from the table, an elastic modulus of Ti6Al4V alloy implants (50 – 120 GPa) significantly

Table 2: Mechanical Properties of Ti-6Al-4V Human Bone and Tissues

Type of Material	Composition	AM Technique	Tensile strength (MPa)	Young Modulus (GPa)	Elongation at break (%)	Reference
Ti-6 alloy	(α+β)-Ti alloys Ti-6AL-4V	SLM, EBM	895-930	50 - 120	6-10	[1, 11, 40, 41
Human Tissue	nanoparticle or of collagen fibers and non-organic materials, hydroxyapatite	SLM	150	30		[11, 37, 42]
Long Bones (Humerus, Femur,Tibia, Fibula)	50-70% Hydroxyapatite 90% Collagen, 5-10% water	3D Bioink Printing	149-151	15.6-16.1	1.90-2.2	[1, 43, 44]
			134-141	~15.0	1.8-2	
			100-150	17.0-23.0	1.5-3.0	
			80-100	15-19	1-2	

higher than long bone (15 to 23 GPa), and this modulus mismatch has been identified as one of the major contributions for "stress shielding effect" of bone [1, 6, 16]. Many attempts have been made to reduce the stress shielding effect of the metal implants by replacing them with polymers material. Bose et al. [42] used polyglycolic acid (PGA) and polylactic acid (PLA) to fabricate the femur long bone via 3D bio-ink printing. In contrast, it found that these implants produced a poor acidic environment that caused inflammation in the human body.

Also, biopolymer orthopaedic materials are unstable to withstand substantial loads and show degradation when autoclaving sterilised at high temperature before implantation. To combat this issue, the porous titanium implant with the high structural complexity of the bone fractures and a patient-customisable insert fabricating using additive manufacturing (AM) has been promoted. For the AM implants to be fabricated, it is found that the porosity of the implantable decrease its Young's Modulus. Bandyopadhyay et al. [46] reported that AM structures containing 25% porosity showed modulus equivalent to human cortical bone, reducing the stress shielding effect. It showed that the Ca^{2+} massively accumulated around the implant, indicating successful osseointegration. In particular, bone structure's porous properties are considered a crucial factor in manufacturing AM orthopaedic implants [47].

In general, in fabricating the Ti alloy, the laser energy density, (E), that provided by the beam during the process is described by Equation (1)

$$E = \frac{P}{vht} \tag{1}$$

where laser power(P), scan speed(v), hatch spacing(h) and layer thickness(t). The energy density (E) is a critical aspect of SLM as it impacts the components' performance as the primary objective in the SLM process is to obtain parts with full density and free of defects [48]. The size and defects might occur depending on the laser energy input, as it directly

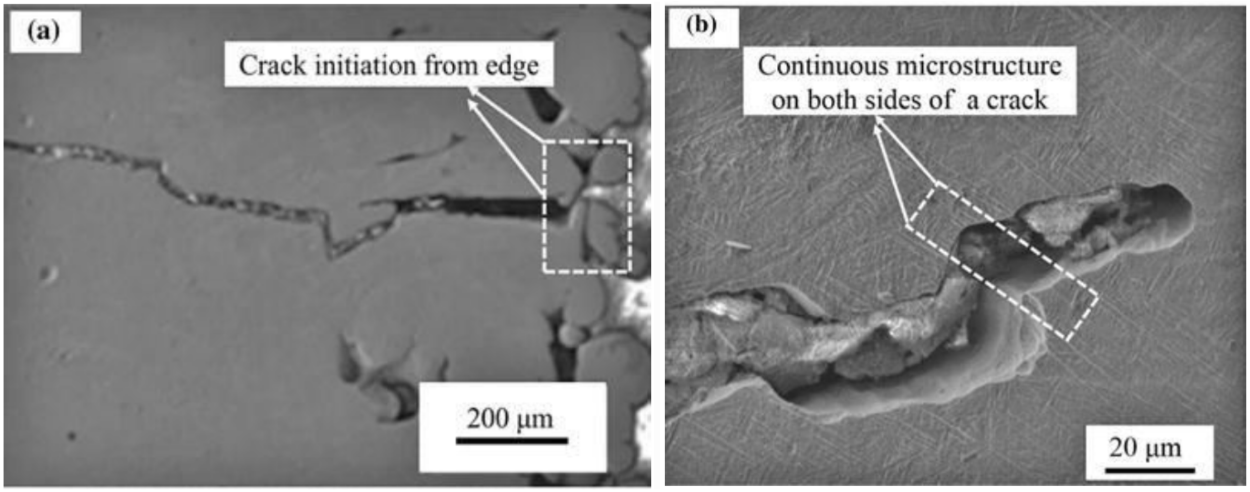

Figure 6: SEM representations from the cross-section of the Ti6Al4V SLM part (**a**) crack morphology (**b**) microstructure across both side of the crack [51].

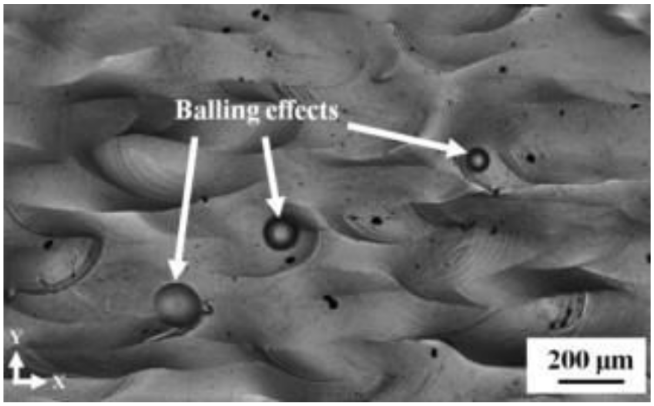

Figure 7: Balling effect on the surface of SLM fabricated Ti-alloy [56].

determines the melt condition of metal powders and the flow of molten metal during fabrication [49]. Zhao et al. [50] reported that low scan speed and high laser power led to porosities, resulting in stress concentration points and fatigue crack initiation as shown in Figure **6(a)**. This defect resulted from more powders that melted at a raised temperature and caused by the trapped gas originated from the raw material powders in the SLM process [51]. The continuous crack eventually causes continued deterioration on both sides of the Ti-6Al-4V samples (Figure **6(b)).** This type of defect unfavourable for enhancing cell growth attachment as the osteocytes' scale is about 10-50 µm for callus formation [52]. Osteoblast favours wider pores (100-200 µm) to mineralise bone regeneration after implantation. Fuduka et al. [53] mentioned that osteoinduction of Ti-6 alloy significantly improved when the pore sizes obtaining between 500 and 600 µm. In addition, these porous Ti implants were also effective in vivo bone replacements after undergone surface treatment to improve tissue regeneration and combat infection to the patients. Marsell et al. [54] obtained the gap between fracture bone and implant must be less than 800 µm to 1 mm to increase the longitudinal revascularized osteons. It shown the implant carrying osteoprogenitor cells and produce lamellar bone on each surface. Figure **7** illustrates a balling effect that occurred due to the volatility of the molten pool which standard the SLM method and balling effect able to be prevented by improving the length/width ratio of the melt pool or raising the contact width when fabricating Ti6Al4V [26, 34]. Balling effect may cause the formation of weak bonding between the implant and the fracture site.

The roughness of the SLM surface encourages the differentiation and development of bone-forming cells [55]. In addition, the surface abnormalities of the EBM samples were more noticeable than those observed in the SLM samples [35]. As an established AM process, emerging modern technologies like SLM allow complex-shaped components to be generated highly efficiently and show great potential as an implant used for orthopaedic fixation [26].

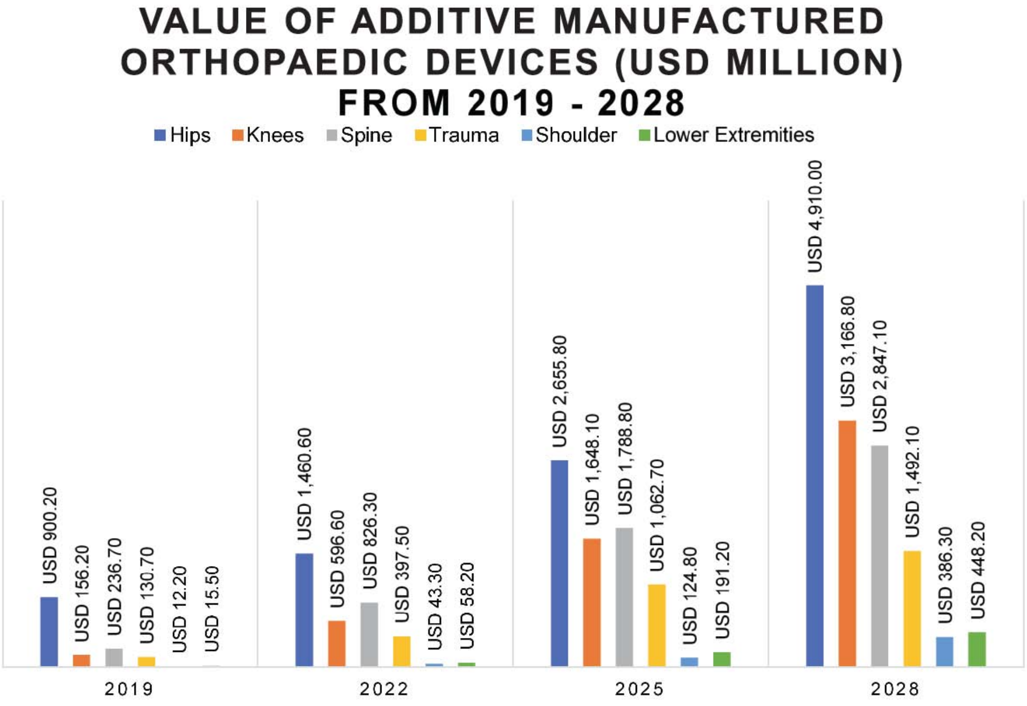

Figure 8: The value of AM orthopaedic devices from 2019-2028 [57].

Figure **8** illustrates the current and predicted sale values of the orthopaedic market from 2019 to 2028. It can be seen that a tenfold increase in sales volume in 2028 compared with 2019 and will continue to evolve. The AM industry can become one of the potential future capabilities to bring additive orthopaedic implant applications. This, at the same time, reducing the cost and feedstock produced in the orthopaedic market

CONCLUSIONS

In the biomedical field, ceramic, polymers, and metallic materials are commonly used for various clinical applications. For the orthopaedic fracture fixation, Ti alloy, a bioinert material is preferable as it can withstand the pressure in load-bearing applications. However, due to its difference in moduli between the bone, it can cause a biomedical incompatibility known as the “stress shielding effect”. As going to IR 4.0, AM has gained attention to be used in the medical field for its minimal machining and capability of fabricating complexly shapes tailored to the orthopaedic application. SLM which an AM method is an attractive alternative to produce Ti implants complex shapes and may widen its potential in the load-bearing application and cure bone diseases. This review summarizes the Ti-6Al-4V implants manufactured by SLM on their mechanical properties, surface roughness, porous structure, and optimum parameters in reducing Young’s modulus for biomedical applications. It was found that mechanical properties of the SLM fabricated implant show superior features in comparison to other AM methods and a brief introduction to unfavourable concerns of SLM Ti implants such as cracks and balling effects were also presented. For future recommendation, surface modification and coating of the SLM fabricated can be studied to improve the surface roughness, pore size and its biocompatibility are interesting to discover.

ACKNOWLEDGEMENT

The authors wish to thank Universiti Teknologi Malaysia for its extensive support to complete the course of this research project granted through FRGS/1/2020/TKO/UTM/02/59. This work was also funded by Universiti Teknologi Malaysia throughout the “Geran Universiti Penyelidik’ UTMFR Q.K.130000.2656.21H13 scheme and “UTM R&D Fund R R.K130000.7756.4J507.

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Received on 05-06-2021 Accepted on 23-06-2021 Published on 15-07-2021

DOI: https://doi.org/10.31437/2414-2115.2021.07.5