



Additive manufacturing-based design approaches and challenges for orthopaedic bone screws: a state-of-the-art review

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Abstract

Bone screws are used in almost every orthopaedic surgery to treat and fix fractured parts of the bone. In this new era, the ongoing revolution on manufacturing of bone screw uses innovative techniques of new generation such as the adaptation of additive manufacturing technology, intelligent technology automation and Industry 4.0. Additive manufacturing (AM) technology has been gaining much attention in fabricating orthopaedic bone screws. Moreover, the recent advancement in the materials and technologies used to manufacture the bone screw utilizing AM technology may reduce bone-screw-related complications. This review article presents a comprehensive and up-to-date review of various AM techniques used to fabricate metallic orthopaedic bone screws. Additionally, this article summarizes the characteristics, merits and demerits of the prominent biomaterials explored to fabricate orthopaedic bone screws until the twenty-first century. This state-of-the-art review is helpful for medical surgeons, researchers and design engineers to understand the complicated relationship among various parameters. Finally, this holistic review paper identifies significant challenges that need to be overcome before realizing the real potential of AM technology for fabrication of orthopaedic bone screws.

Keywords Additive manufacturing · Bio-absorbable · Biomaterial · Magnesium · Orthopaedic bone screw · Bone-screw-related complications

Abbreviations

AM	Additive manufacturing	PEEK	Polyether–ether–ketone
AI	Artificial intelligence	PEG	Polyethylene glycol
AO	Arbeitsgemeinschaft für Osteosynthesefragen	PGA	Poly-glycolic acid
ASIF	Association for the Study of Internal Fixation	PHB	Poly-hydroxyl–butyrate
CAD	Computer-aided design	PLA	Poly-lactic acid
CT	Computed tomography	PLGA	Poly-lactic–glycolic acid
FEM	Finite element method	PMMA	Poly-methyl–methacrylate
FDA	Food and Drug Administration	PPF	Polypropylene fumarate
FDM	Fused deposition modelling	SEM	Scanning electron microscope
3D	Three-dimensional	SLM	Selective laser melting
EBM	Electron beam melting	STL	Standard Tessellation Language
DMLS	Direct metal laser sintering	UV	Ultraviolet
ML	Machine learning		
PCL	Polycaprolactone		

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1 Introduction

Bone fracture is commonly faced due to ageing, accidents and stress fracture. A bone fracture can be fixed with stable internal fixation (through exposing the skin) for an excellent functional outcome as this technique precisely repairs and restores the bone [1]. Early mobilization and early union of fracture are the primary goals of the internal fixation [2]. Following the sequence of Arbeitsgemeinschaft für

Osteosynthese (AO) principles, stable internal fixation can be achieved. AO principle includes four significant sequence of pillars for successful fracture healing, as depicted in Fig. 1. Following the AO principles, some other factors responsible for implant failure that may cause revision surgery are low insertion torque, immediate loading at the implant site, bone chip coagulation, lack of initial implant stability and insignificant bone volume [1, 3–8]. Internal fixation can be achieved using devices such as orthopaedic bone screws, fixation plates, pins, wires, spinal fixation devices, intramedullary rods and nails [9–11]. Out of these devices, orthopaedic bone screws (Fig. 2) are most commonly used for accelerating the healing and mobility of injured tissues in almost every fractured bone [9, 10, 12–14]. The recovery of fractured parts majorly depends upon the selection of suitable implant and bone screws. It has been reported that nearly one-third of the treated fractures with locking plate have complications; 11% have screw-related complications [15]. The reported rate of screw misplacement in pedicle screw fixation ranges from 21 to 40% [16]. Moreover, the fixation stability is affected by bone–screw interface holding power, type of screw used, screw purchase strength, the number of screws implanted, the orientation of screws and bone mineral density [6, 7, 17–21]. In addition, as illustrated in Fig. 3a, there are various bone screws available commercially that are used for fixing different types of fractured human bones (Fig. 3b) [15, 22–25].

From ancient civilization to the twenty-first century, material properties and design parameters of bone screws have been modified to reduce bone-screw-related complications, such as stress shielding effect, pullout strength of bone screw, screw perforation and screw purchase failure.

The stress shielding effect occurs due to the incongruity of elastic moduli between screw and bone [4]. Pullout strength is defined as the force required for pulling a screw out of its foundation in bone [26]. Lower pullout strength [26] of the bone screw is the primary reason for bone loss during healing [4] and screw loosening [27]. Screw perforation is the failure at the bone–screw interface that leads to screw tip penetration through the subchondral bone into the joint [15]. Screw purchase failure occurs at the bone–screw interface without macro-displacement of bone segment or screw [15]. Screw perforation [15] and screw purchase failure [28–30] of the articular cartilage (observed in almost 11.6% of all the humeral fractures) may lead to problems such as avascular necrosis, mal-union, delayed union, lower bone–screw interface holding strength and non-union [4, 15, 26]. These problems cause unbearable pain and may increase the chances of revision surgery. Another major complication is the excessive load at the fracture site which mainly affects the bone screw and causes breakage of the bone screw leading to a revision surgery [30, 31]. All the discussed bone screw complications are summarized in Fig. 4.

Majorly, the bone screws are made of metallic biomaterials such as stainless steel, titanium alloys and cobalt alloys [32, 33]. The materials used in biomedical applications are known as biomaterials. Every biomaterial should have the properties such as biocompatible [34], biodegradable [35], mechanical stability [36] and sufficient mechanical strength for load-bearing structure [34–36]. Generally used biomaterials are metals [36], polymers [35, 36] and ceramics [34–36]. Metallic biomaterials are strong [37], ductile [38], fatigue resistance [37] and highly biocompatible [36]. However, due to high stiffness and high strength

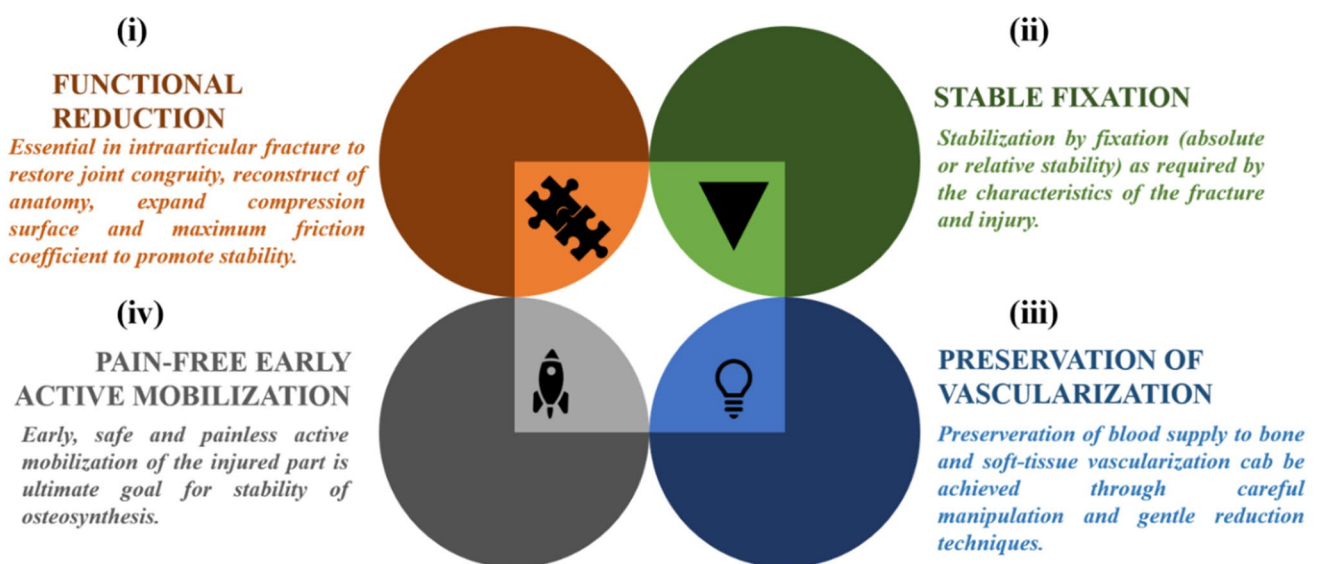


Fig. 1 Sequence of AO principle for contribution to successful fracture healing

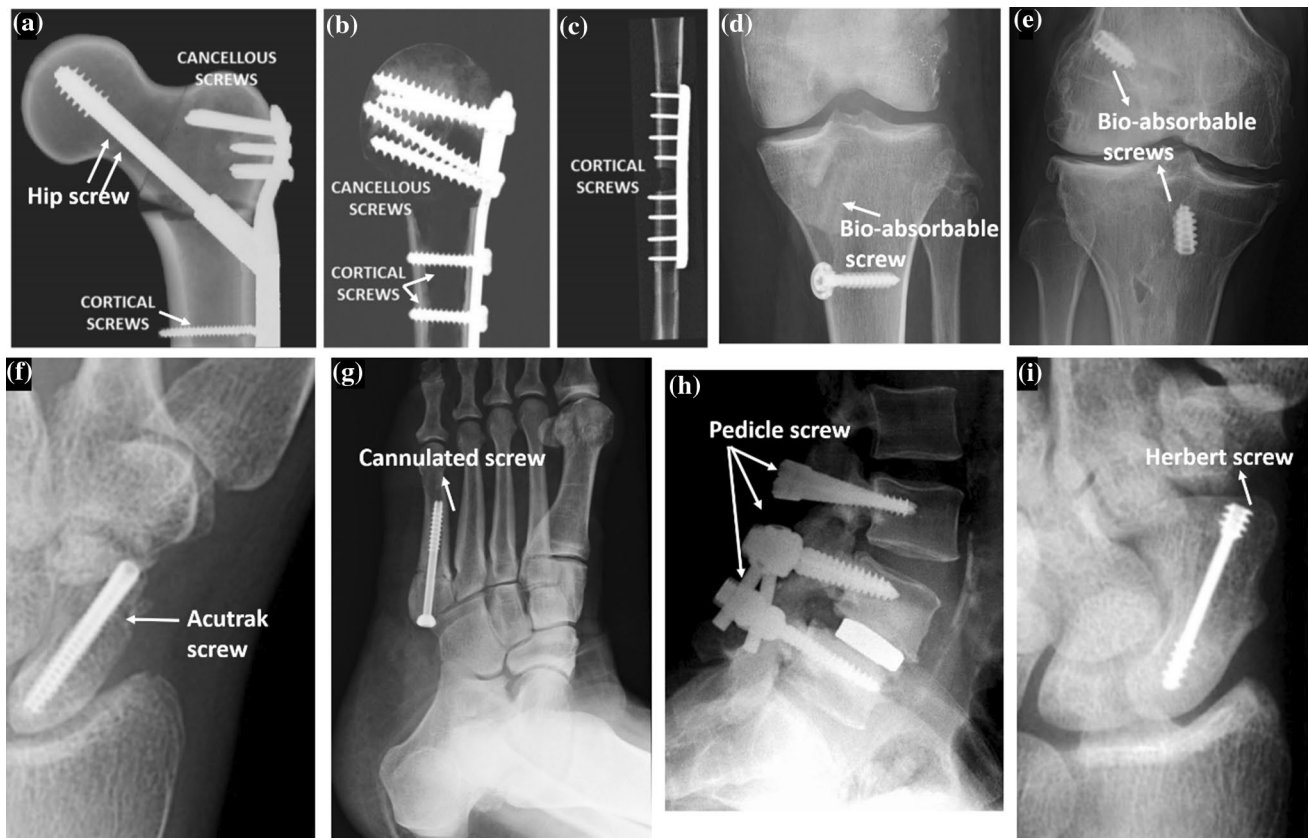


Fig. 2 Various types of bone screws: **a** cortical screw, **b** cancellous screw, **c** hip screw [9], **d**, **e** bio-absorbable screw [10], **f** Acutrak screw [12], **g** cannulated screw [13], **h** pedicle screw [14], **i** Herbert screw [12] (all the images are reprinted with permission from Elsevier [9, 10, 12–14])

of metallic nature, they cause wearing in surrounding bony tissues [38], notch sensitivity [23], bone resorption [39] and stress shielding [40]. Bio-absorbable screws are also used in the orthopaedic industry to fix the implants [25, 41]. They have the advantage of reducing the stress-shielding effect as they degrade and absorb in the body after a period that also diminishes the post-operative surgery to remove the implanted screw [4, 25, 39]. The absorption rate of the screw depends on factors such as copolymer ratio, porosity, crystallinity, molecular weight, purity, temperature, pH, morphology, moisture, shear stress and implantation site [4, 41–43].

Until now, conventional machining operations such as turning, shaping, drilling, milling, sawing, grinding and broaching have been preferred to manufacture orthopaedic bone screws [33]. However, in the last few years, additive manufacturing (AM) technologies have been attracting the attention of researchers in the biomedical domain due to their unique advantages. AM techniques can provide incredible customizability, speed and accuracy. The recent AM technology gives the freedom to design any part easily and computer-aided design (CAD) design based on imagination. The core concept of AM technology involves layer-by-layer

deposition of material guided by the computer-generated model in 3D space [44, 45]. AM can print any complex geometry using various materials such as polymers, metals and ceramics that have been used in this modern technology for biomedical applications [46, 47]. These materials have specific mechanical properties, material composition, chemical and thermal properties, different processing methods and cell–material interactions that require Food and Drug Administration (FDA) approval [34, 48]. Each material is processed with different techniques with its applications and limits for producing a prototype model. These biomaterials can be processed with AM technology to develop biomimetic devices that can reduce the stress shielding effect caused due to mechanical mismatch properties between bone and implant.

The application of AM technology in the biomedical domain has been implemented for various surgeries, as presented in Fig. 5. Recently, the use of AM technologies has been explored to fabricate various biomedical instruments [20, 49], hydrogels [20, 50, 51], scaffolds [52], vascularized soft tissues [46, 53, 54], implanted strain sensors [55] and bone implants [47, 56–58]. Currently, AM technology is used in almost all sub-specialities in

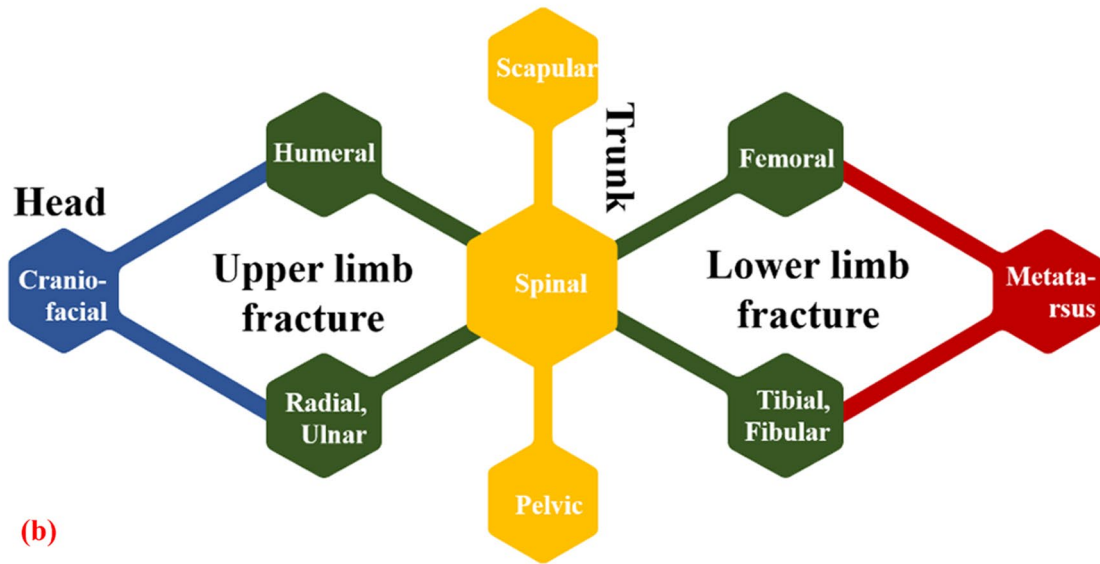
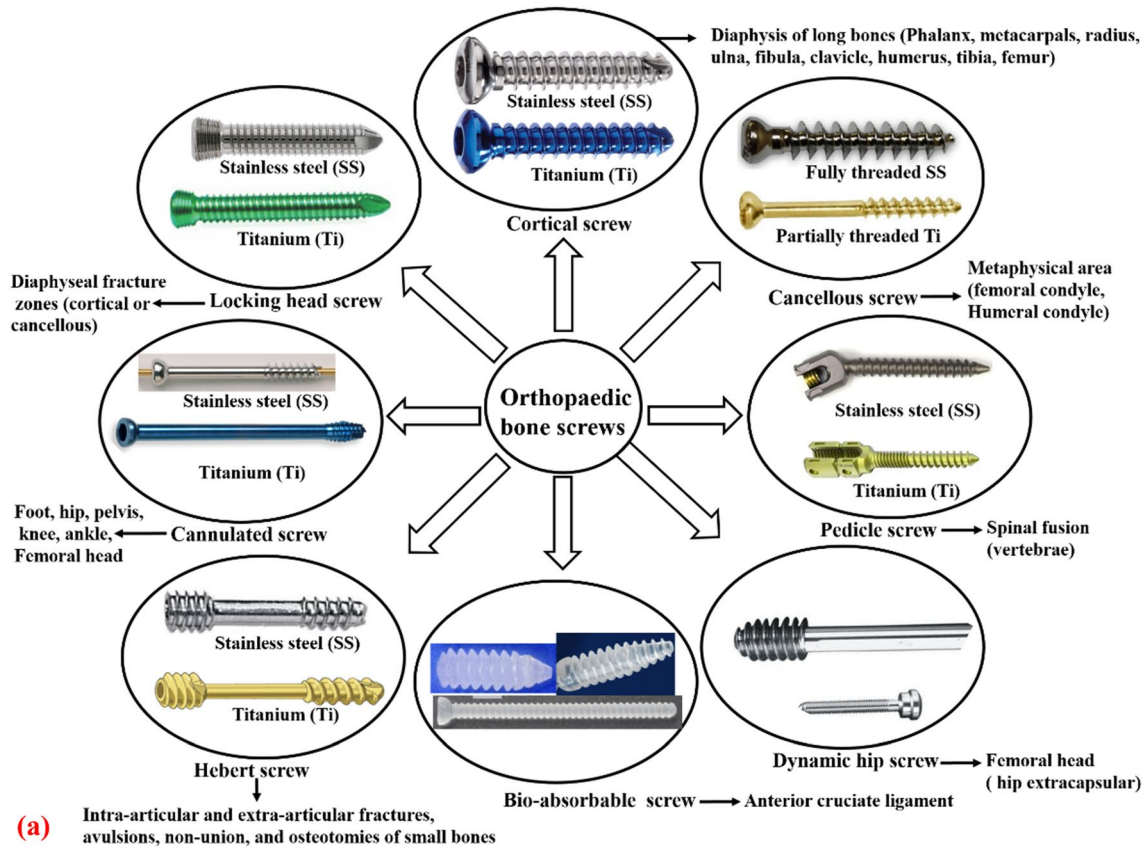


Fig. 3 **a** Various types of bone screws used for different applications within the human body, **b** application of bone screw in various body parts

orthopaedics, such as the joint, spine, trauma, bone oncology, paediatric orthopaedics, hand, foot, ankle, sports medicine, repair and reconstruction [34, 46]. The recent development of AM techniques is to fabricate patient-specific bone implants and orthopaedic bone screws [59–62].

Several articles have been published related to the design and fabrication of bone screws regarding the type of materials to be used, the manufacturing process to be considered and refining the screw geometry for enhancing pullout strength of bone screws. However, to the best

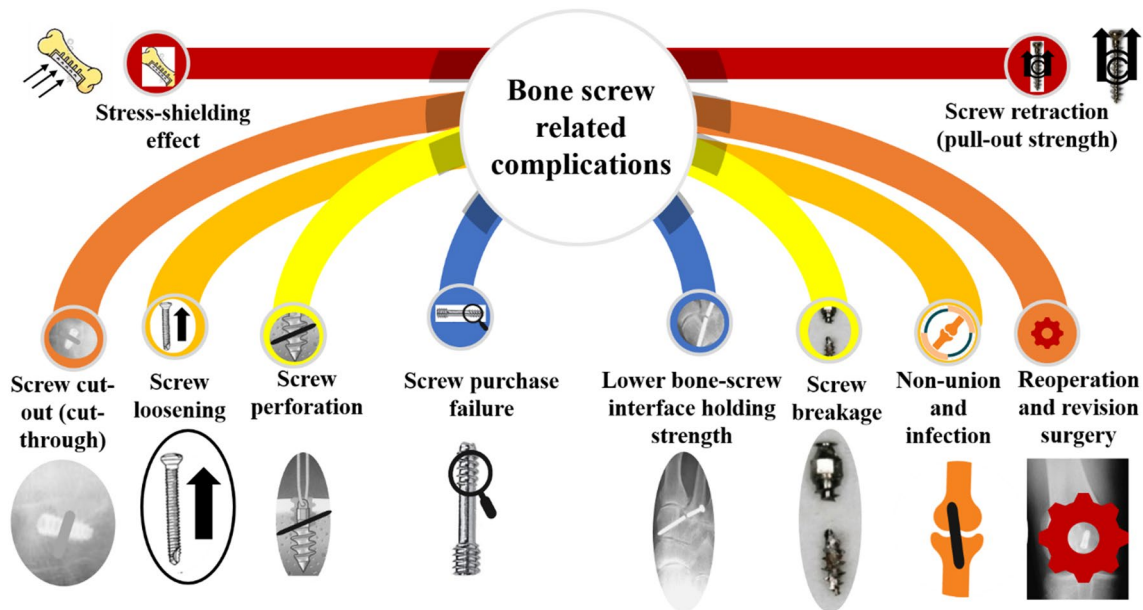


Fig. 4 Bone-screw-related complications observed in the literature



Fig. 5 Application of additive manufacturing technologies in the biomedical domain

of the author’s knowledge, a comprehensive review article devoted to understand the material properties and behaviour of different AM techniques-based bone screw fabrication has not been reported in the literature. Subsequently, no single study was noted summarising the performance and properties of currently used biomaterials (metallic or polymeric) for orthopaedic bone screw fabrication. Moreover, this review provides a comprehensive framework of various AM technologies used to fabricate metallic orthopaedic bone screws. In addition, this article identifies the major bone-screw-related complications and attempts to present viable

solutions. This holistic review would be helpful for medical surgeons, researchers and design engineers to understand the potential of AM technology and comparison of various metal-based AM techniques. The significant contributions of this work have been listed as:

- This current review article presents a comprehensive and up-to-date review of the different AM techniques used for orthopaedic bone screws fabrication. Various metal-based AM techniques have been reviewed from both theory and application perspectives to aid research-

ers and medical practitioners to select the appropriate technique based on their application and usage for their work.

- The current review article summarizes the characteristics, merits and demerits of the prominent biomaterials used to fabricate orthopaedic bone screws. The core idea is to systematically compare various available biomaterials (metallic and polymeric) to aid the selection of suitable biomaterials.
- The current review paper identifies significant challenges that need to be overcome before realizing the real potential of AM-based fabrication of orthopaedic bone screws. The key idea is to provide a framework hierarchy for reducing the bone-screw-related complications and address the input parameters relationship with the output parameters.

This review paper is structured as follows: Sect. 2 discusses the short history of orthopaedic bone screws. Section 3 reviews the specification and material properties of various biomaterials (metallic and polymeric) used in the fabrication of bone screws along with comparison of different metal-based AM technologies. Finally, in Sect. 4, the challenges and prospects in the area of AM-based fabrication of orthopaedic bone screws are detailed discussed and concluded.

2 History of bone screws

Orthopaedic bone screws have been used for the internal fixation of bone fractures for more than 100 years. In 1912, William O. Sherman [63] introduced orthopaedic screw as the most dependable and efficient means of securing and retaining the accurate position of fracture parts. In 1949, Robert Danis [64] designed the compressive plate and modified the machined screw by reducing thread surface, altering

thread diameter and introducing buttress thread design to improve the pullout strength of the screw. In 1958, Maurice Muller [64, 65] and a group of Swiss surgeons established the Association for the Study of Internal Fixation (ASIF) to study the effect of internal fixation and bone healing. In the same year, Bagby and Janes [65] designed impacting bone plate with oval-shaped holes that allowed eccentric screw placement for intra-fragmentary compression through tightening. This design, with slight modification, remains in use till today. From introducing stainless steel in 1926 to testing on titanium alloys introduced in 1970 [64], innovation and research continued to modify the material properties and design parameters of orthopaedic bone screws for better stability and holding capacity of screw.

In the following decades, screw geometry based on the number of threads, pitch, shape, diameter variations, etc., was optimized for a variety of bone types, quantities and pathologies [65]. As a result, the modification in bone screws has attracted more attention from academic researches to clinical applications. As presented in Fig. 6, with the participation of modern technology for the fabrication of bone screws, the research and innovation related to orthopaedic bone screws is constantly growing and evolving. The milestones of evolution in orthopaedic bone screws are illustrated in Fig. 6. The most recently developed orthopaedic bone screws are being manufactured via AM techniques.

3 Review of AM techniques and biomaterials used for bone screw fabrication

The role of AM technologies for fabrication of orthopaedic bone screws is becoming vital and popular as this technology provides incredible customizability, efficient speed, high accuracy and freedom to design anything using CAD models. With the advancement in the AM technique,

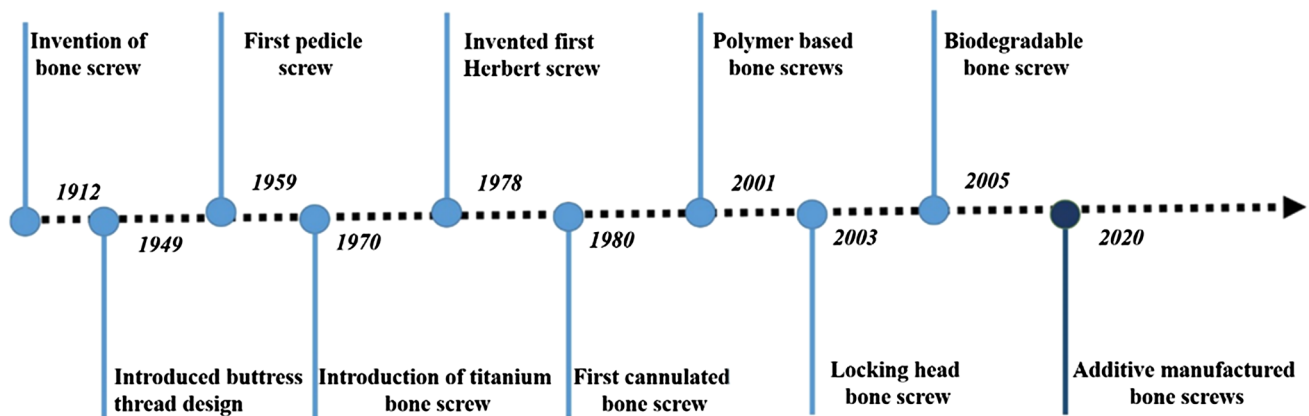


Fig. 6 Evolution of research in orthopaedic bone screws

patient-specific customized orthopaedic bone screws can be fabricated. AM technology can provide the porous auxetic structure to the surface of the bone screw to enhance the bone ingrowth through the screw body that improves the bone-healing contact and improve the process of osseointegration. The biomechanical performance of bone screws can be improved with the help of a porous structure. The open-pore design has superior bone-to-implant contact and higher pullout strength as compared to a solid system. AM-fabricated bone screws can produce rough and irregular geometry to the screw surface that may influence bone regeneration.

As AM technology provides high accuracy, safety, great customizability and less wastage in by-products. The recent development in the bone screw fabricated via AM technology is presented in Table 1. The AM-fabricated bone screws have the advantage of higher bone–screw contact, more excellent implant stability, capability to provide porous auxetic structure in the screw body to promote osseointegration and vascularization over traditional manufacturing of bone screws. The porosity in orthopaedic bone screw produced with AM technology could improve tibia graft fixation and enhance the biomechanical performance of the bone–tendon–screw interface [60]. The literature based on AM-fabricated orthopaedic bone screws is presented in Table 1.

3.1 Review of biomaterials in orthopaedic bone screw fabrication

3.1.1 Metallic biomaterials

Metals are the primarily used biomaterials in orthopaedic, dental and joint replacement surgeries due to their excellent strength, high fracture toughness, hardness and biocompatibility [37, 40]. The gold-standard metallic biomaterials for fabrication of orthopaedic implants (bone screws) are titanium-, stainless steel- and cobalt-based alloys [73]. It has been observed that titanium-based biomaterials have excellent biocompatibility and ductility, although titanium-based implants are fatigue resistance with poor wear characteristics [21, 38]. Moreover, cobalt-based alloys are highly considered due to their superior strength and property resistance [74]. Tables 2 and 3 provide a comprehensive detailed mechanical properties, specifications, indigent percentage of metals, advantages, disadvantages and application of metallic biomaterials in orthopaedics. Table 2 provides a summarized mechanical properties of metallic biomaterials currently used in orthopaedic bone screw fabrication. Moreover, the detailed comparison of different metallic biomaterials is presented in Table 3. This table could be helpful for selecting suitable biomaterials based on the application and usage of metallic biomaterials.

Titanium is highly reported in the literature as suitable biomaterial for bone screw fabrication utilizing different

AM techniques. Huang et al. [60] fabricated porous titanium screws with AM technology. The bioactive surface modification of porous titanium was observed with preservation in simulated body fluid for seven days. The surface-modified bone screws were implanted in rabbits to monitor the ultimate pullout strength. It was observed that ultimate pullout load failure was significantly higher in AM screw. Lee et al. [59] used AM technology to fabricate titanium ELI screws and performed an in vivo study on rabbits. It was witnessed that AM-fabricated screw has higher bonding strength and shows higher bone to implant contact, indicating a higher osseointegration rate than the conventionally machined screw. Active osteogenesis and new bone formation were significantly higher in AM-fabricated titanium bone screws. Recently, Yao et al. [72] enhanced the geometry of titanium pedicle screw by providing auxetic structure with the help of AM technology to resist the loosening of the pedicle screw. The better auxeticity of bone screw results in the better anti-pullout performance of pedicle screw with excellent screw–bone fixation.

3.1.2 Polymeric biomaterials

Polymers are highly considered as biomaterials for implant fabrication due to their superb processability and are the first material to be used by AM techniques. Polymers consist of the replication of multiple units of a basic sequence (monomer). They are divided into two categories: natural and synthetic polymers. Natural polymers such as collagen, chitosan, cellulose and starch have been studied for different applications in modern medicine [76, 77]. Synthetic polymers are widely reported for biomedical applications because of their thermomechanical and chemical properties. Poly-methyl-methacrylate (PMMA) as bone cement for prosthesis fixation is widely used as a void filler [78, 79]. Synthetic polymers such as polyether-ether-ketone (PEEK) have similar mechanical properties to the bone, excellent radiolucency and chemical resistance [80, 81]. Polycaprolactone (PCL) [68, 82], polylactic acid (PLA) [62, 81, 83, 84], poly-L-lactic acid (PLLA) [51, 62, 81–83] and polyglycolic acid (PGA) [32, 84–86] are the most used synthetic polymer in the field of orthopaedic as biodegradable materials. Various other polymers such as polyethylene glycol (PEG), poly-lactic–glycolic acid (PLGA), poly-hydroxyl–butyrate (PHB) and polypropylene fumarate (PPF) are used in the orthopaedic and dental field for fabricating the scaffolds, vascular tissues and hydrogels [36, 81, 87]. These polymers have different chemical structures, diverse degradation time interval and specific thermal and mechanical properties as depicted in Table 4 [42, 87–97]. The contribution of Table 4 provides brief details of the thermomechanical properties of polymeric biomaterials, along with their chemical structure and reported degradation time.

Table 1 Recent development for the fabrication of bone screw via AM technology

Publication	Year	Process used	Screw type	Material properties			Remarks
				Metallic screws	Bio-absorbable	Porous structure	
[66]	2017	–	Cortical	✓	✓		Metal screw provides higher fixation strength than the bio-absorbable screw
[67]	2018	Metal powder bed fusion	–	✓	✓		AM can influence the internal fixation of implants. The open pores can increase flexibility and can improve screw-level fixation
[29]	2019	–	Pedicle	✓			Double dual-threaded screws exhibited better pullout biomechanics in osteoporotic bone with bi-cortical bone
[68]	2019	Custom designed mould	Bone screw		✓		The highest mechanical strength properties were obtained with 10% MgO and 20% silk composite over PCL
[20]	2019	FDM	Screws, pins, plates		✓		Hybrid fabrication for adsorbing during osseous fixation devices can be achieved using AM
[69]	2020	EBM	Eli	✓			Higher bonding force and higher bone-implant contact with 3D-printed bone screw
[61]	2020	AM	Cancellous Screw	✓		✓	Different auxetic structures have additional tensile stiffness and strength
[60]	2020	AM	Cortical	✓		✓	Bioactive surface modification in 3D-printed screw improved bone ingrowth and enhanced biomechanical performance
[70]	2020	SLM and EBM	–	✓			The milling group presents a higher screw loosening value than AM group
[62]	2020	FDM	Cortical		✓	✓	The porous screws have better interaction and increased vascularization as compared to solid screws
[71]	2020	EBM	Bone screw	✓		✓	10 and 100 µg/ml of Ti6Al4V particles may improve osteogenic differentiation. Low concentration may improve osteogenesis in rats
[72]	2021	SLM	Pedicle	✓		✓	Auxetic pedicle screw can improve the bone-screw fixation by radial expansion of the screw body under tensile force to resist pulling out through the re-entrant unit cell pores

Dhandapani et al. [62] used PLA polymer to fabricate porous biodegradable cortical screws with the help of AM technology. PLA screw incubated in simulated body fluid

solution shows osteoblast-like cells in the form of calcium. PLA-based solid and porous screws were implanted in rats to observe mineralization and vascularization. It was observed

Table 2 Specifications of metals used in orthopaedic screw fabrication [21, 33, 37, 40]

Material	Young's modulus (GPa)	Elastic modulus (GPa)	Density (g/cm ³)	Yield strength (MPa)	Ultimate tensile strength (MPa)	Elongation (%)	Fatigue strength (MPa)
ASTM 316L Stainless steel	195–200	202	8	250 (hf) 310 (cw)	550 (hf) 655 (cw)	40–50	379–414 (cf) 414–448 (cw)
ASTM 22–13-5 Stainless steel	193–200	200	7.88	827 (hf) 993 (cw)	1069 (hf) 1262 (cw)	35	414 (hf) 483 (cw)
Titanium alloy Ti–6Al–4V	113	110–114	4.4	795–895	985	12	520
Cobalt chrome F5262	230–240	220	8.5	950–1000	1200	10–30	207

cf cold forging, *cw* cold worked, *hf* hot forged

that PLA porous screws fabricated by AM technology show higher human mesenchymal stem cell adhesion, mineralized matrix synthesis, enhanced mineralization and vascularization than solid PLA screw. As the PLA polymer has lesser mechanical strength, Suryavanshi et al. [68] used composite biomaterial (PCL–MgO–silk fibre) to fabricate biodegradable bone screws to apply bone–soft tissue fixation. These composite bone screws were implanted in rats to monitor cell viability and tissue adhesion. It was witnessed that composite biomaterials have excellent cell viability, tissue adhesion and hemocompatibility. The MgO nanoparticles contribute to enhancing the tensile strength of the bone screw, whereas silk fibre provides higher stability, modulus and imparting a synergistic effect on the mechanical performance of the bone screw. Composite biomaterial provides $1.7\times$ better tensile strength and $7.5\times$ tensile modulus as compared to PCL screw. Singh et al. [98] enhanced the shear strength and morphological features of PLA material, by 3D-printing almond skin powder-reinforced matrix of PLA biomaterial. The various depths of insertion of the cancellous screw were observed in different infill patterns. It was witnessed that the honeycomb printing infill pattern and 100% insertion of the cancellous screw have maximum shear strength. In contrast, maximum modulus of toughness was observed in the rectilinear infill pattern and 100% insertion of the cancellous screw. Figure 7 provides a recent development in biodegradable (polymeric) implants fabricated with the help of AM technique. Only PLA and PCL polymers have been explored with the AM technology for orthopaedic bone screw fabrication. However, future research can explore other biocompatible, biodegradable polymers with AM technology for orthopaedic bone screw fabrication.

3.2 AM technologies

3.2.1 Electron beam melting (EBM) technique

EBM is AM technology majorly used for metal parts. The build plate is coated with a layer of metal powder placed

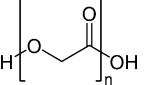
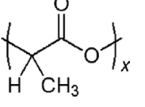
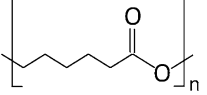
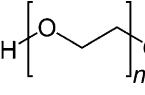
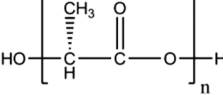
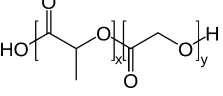
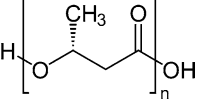
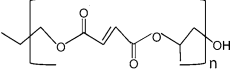
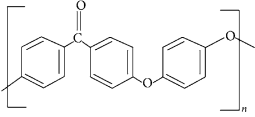
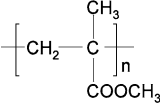
under a high vacuum (1×10^{-4} Torr) and fused using melting of material by electron beam (heat source) controlled by electromagnetic coils [56]. The maximum build part can be fabricated of dimension $350\times 350\times 380\text{mm}^3$ with the tolerance of ± 0.2 mm and minimum layer thickness of 0.5 mm [51, 99]. The EBM machine reads the 3D CAD model and then successfully lays down powdered material layers. After one layer is complete, the build platform is moved down and continues the process for the next layer [100]. The semi-sintered powder is removed for post-processing to get the fabricated metal part [101, 102]. Currently, EBM uses materials such as copper, bulk metallic glass, stainless steel, pure titanium, Ti6Al4V, CoCr and Inconel [71, 101, 103]. EBM technology has a faster printing speed due to electron beam, which is more potent than laser. EBM is ideal for manufacturing lightweight, durable, high-quality metal parts with high density (99.9%) and high strength of dense end parts [70, 100, 104]. This technology has an edge for building complex geometric structures to achieve a weight reduction of fabricated parts and a low risk of deformation with good mechanical properties. EBM offers minimal waste, as the unused powder can be recycled and reused [105]. This technology is used in biomedical applications for implants, acetabular cups, prostheses and bone screw fabrication [52, 70, 100, 103]. Due to its high energy density and scanning method, this technology has a unique build rate compared to other metal printing technologies such as DMLS and SLM. However, it has a little less accuracy than SLM [99]. EBM technology is a costly process and uses expensive materials that only suit industrial applications [106].

The recent development in EBM technology is to fabricate ELI bone screws and compared with conventional machined screw, as depicted in Fig. 8. EBM-machined bone screw and conventional screw were implanted in rabbit tibia for two weeks and then pushed out. The strained histological analysis, SEM micrographs and elemental analysis were conducted on the pushed out screws. It was observed that EBM-fabricated bone screw has higher adhered bone

Table 3 Gold-standard metallic biomaterials for orthopaedic bone implants

Metal	Type	Ingredients percentage	Advantages	Disadvantages	Usage
Stainless steel (SS)	316L SS (3% molybdenum, 16% nickel and L= lower carbon content)	Iron (59.8–68.97%)	Biocompatible [40]	Susceptibility to crevice and stress corrosion [37]	Used in plates, screws, intramedullary (IM) nails, external fixators, etc. [37, 40]
		Chromium (16–18%)	Strong [37]	Stress shielding effect [40]	
		Nickel (10–16%)	Relatively ductile [21]		
		Molybdenum (2–3%)	Relatively cheap [37]		
Titanium (Ti) alloys	Titanium 64 (Ti–6Al–4V)	Nitrogen (0.1%)	Reasonable corrosion resistance [74]	Poor wear resistance [74]	Used in internal fixators, screws, plates, vertebral spacers, halos, IM nails, etc. [37, 40, 74]
		Carbon (0.03%)		High Young's modulus (200 G Pascal) [21, 40]	
		Titanium (89%)	Excellent biocompatibility [73]	Poor wear characteristics [38]	
		Aluminium (6%)	MR scan compatible [21]	Relatively expensive [40]	
		Vanadium (4%)	Corrosion resistant [74]	Notch sensitivity [37]	
		Others (1%)	Ductile [74]	Systemic toxicity—vanadium [74]	
Cobalt chrome alloys	Co–Cr		Fatigue resistance [37]	Can be brittle (less ductile) + more metal debris generation than cobalt alloys [21, 37]	Usually used for bearing surfaces, artificial joints including knee and hip joints, arthroplasty implants, dental implants and orthopaedic implants [37, 40, 74]
			High osseointegration [73]		
			Low Young's modulus [37]		
			Excellent long-term biocompatibility with soft tissues and blood [75]	Risk of stress shielding [74]	
			High osteo-integration [37]		
			Incredible strong strength [74]		
		Chromium (20–30%)	High wear resistance [74]	Nickel sensitivity [74]	Very high Young's modulus [37]
		Molybdenum (5–7%)	High osteo-integration [37]	Expensive [37]	
		Elements such as 1% iron, manganese, tungsten, nitrogen and phosphorus	Excellent resistance to corrosion compared to SS and Ti alloys that reduce complications with surrounding tissues [21, 74]		
			Excellent castability and toughness [40]	Workability and plasticity are low as compared to SS and Ti alloys [40]	

Table 4 Specifications of various polymers used in orthopaedic screw fabrication

Material	Chemical structure*	Melting point (°C)	Density (g cm ⁻³)	Glass transit temperature (°C)	Ultimate tensile strength (MPa)	Tensile modulus (GPa)	Degradation time
PGA		220–230	1.53	34–40	57	6–7	6–12 months
PLA		170–180	1.210–1.430	55–60	53	3.5	2–5 years
PCL		59–64	1.11–1.15	– 60	10.5–16.1	0.4	> 2–3 years
PEG		62.2	1.12	– 63	61	2	> 1 year
PLLA		170–180	1.25	60	61–70	3.6	24 months
PLGA		240–280	1.3	37	4.3–12.9	1.31	5–6 months
PHB		170–180	1.25	5–14.85	40	3.5	1 month
PPF		171	0.89–0.92	31.9	15	1–1.4	–
PEEK		343	1.31	143	110	4.5	–
PMMA		160	1.18–1.2	110	71	1.7	–

**x*, *y*, *n* indicate the number of times each unit repeats

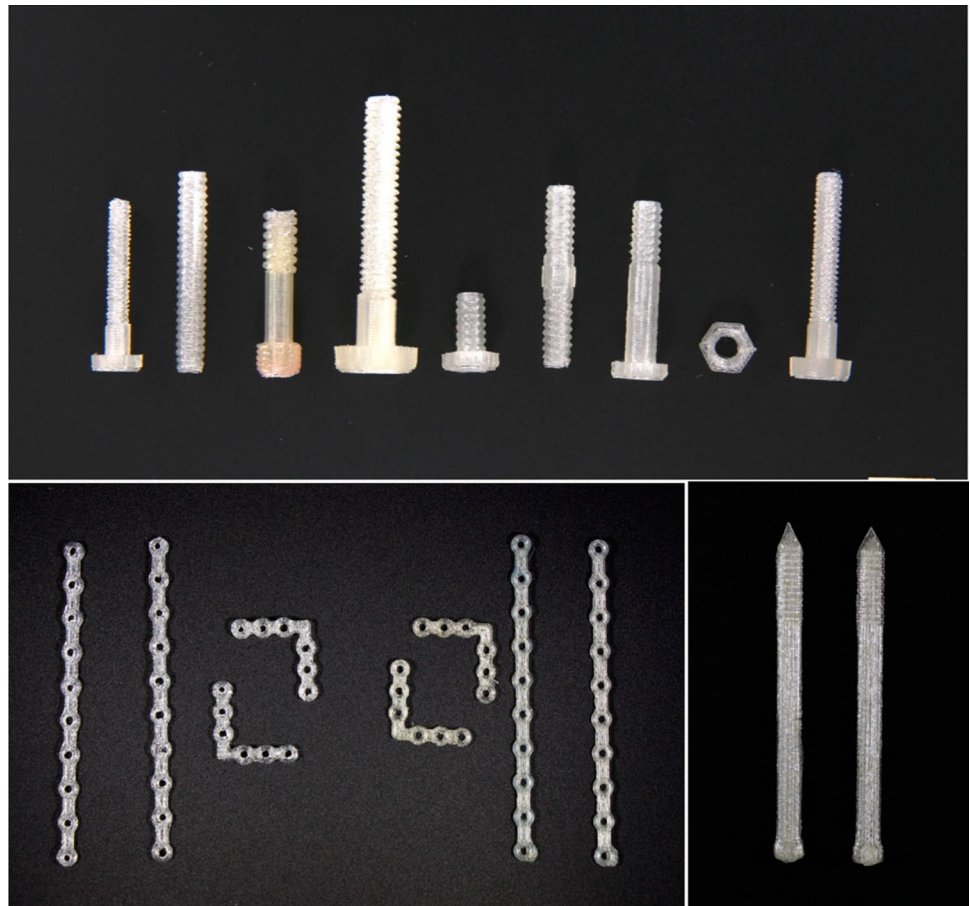
in the surface of screw as depicted in Fig. 8a compared to negligible bone attached in conventional bone screw. The result revealed higher bone-to-implant contact interaction and higher push-out strength of EBM-fabricated ELI screw than conventionally machined screw [69].

3.2.2 Direct metal laser sintering (DMLS) technique

DMLS is a laser-based technology that utilizes a high-powered laser as a power source to sinter and fuse layers of metallic powder together by pointing the laser and outlining the object in a layer-by-layer format to build up the design

of a 3D cad model [46, 56]. Parts are printed in an enclosed build chamber with argon gas. The maximum part resolution of 250 mm × 250 mm × 300 mm with a layer thickness of 0.02 mm to 0.06 mm and tolerance of ± 0.1 mm can be achieved [14, 38, 82, 85]. When the build finishes, the post-processing requires an initial brushing to remove the slack powder, and part is removed. The materials used in DMLS technology are aluminium (AlSi10Mg), stainless steel (316L or 17–4), titanium (Ti64), cobalt chrome (Co28Cr6Mo), copper (CuNi2SiCr) and nickel alloy 625 [21, 44, 46, 56, 106]. Titanium-based implants fabricated using DMLS technology have a survival rate of 97% biological complications

Fig. 7 AM-fabricated biodegradable implants (screws, pins, plates) using PLA biomaterial (no permission is required according to the journal policy [20])



of 7% [21]. DMLS technology prints durable, lightweight and precise, detailed metal parts with excellent quality, high accuracy, strong mechanical strength, creep resistance and fatigue characteristics pretty much the same as products machined from comparable wrought, forged or cast material [57, 105, 107]. This technology creates complex structures, intricate detailing and delicate features [57].

The recent development of DMLS technology was to fabricate different biomimetic dental implants that significantly incorporate bone in the porous scaffolds. The CAD models of external portion of implants are presented in Fig. 9a. The micrographs of morphology of DMLS titanium dental implants and different DMLS-fabricated dental implants are presented in Fig. 9b, c, respectively. The non-porous dental implants have the highest mean torque and higher pullout strength of implant, as depicted in Fig. 9d, g.

3.2.3 Selective laser melting (SLM) technique

SLM is a metal printing (powder bed fusion) technology that utilizes metallic powder and a high-intensity laser as an energy source that fuses high-temperature metallic powder in a layer-by-layer format based on 3D CAD model [57]. The layers are continuous to be combined and deposited

one over the other until the completion of the part. The most commonly used metallic powders for the SLM process are titanium, ferrous alloys, cobalt-chrome, aluminium, copper, magnesium, zinc and tungsten [38, 44, 57]. The significant advantage of SLM technology is to fabricate any complex lattice structured metallic implants with high fracture toughness and mechanical strength that may promote bone ingrowth, vascularization and the process of osseointegration [38, 45, 108]. The manufacturing of critical structures, customized metallic design with high-dimensional precision and good surface integrity, is the key advantage of this technology [44]. The only limitation of SLM technology is that the conduction and diffusion of laser heat cause unwanted fusion of neighbouring powder particles, limiting the resolution of final features [109].

Most recently, SLM technology was used to fabricate an anti-pullout auxetic-structured pedicle screw, as depicted in Fig. 10. The pedicle screws were manufactured with SLM technology with different re-entrant angles and auxetic units, as presented in Fig. 10a. These various re-entrant angles and wall thickness of fabricated pedicle screws are morphologically monitored by micrographs as shown in Fig. 10b. The tensile strength and pullout strength of the screw were monitored with a FEM and experimentally using sawbones

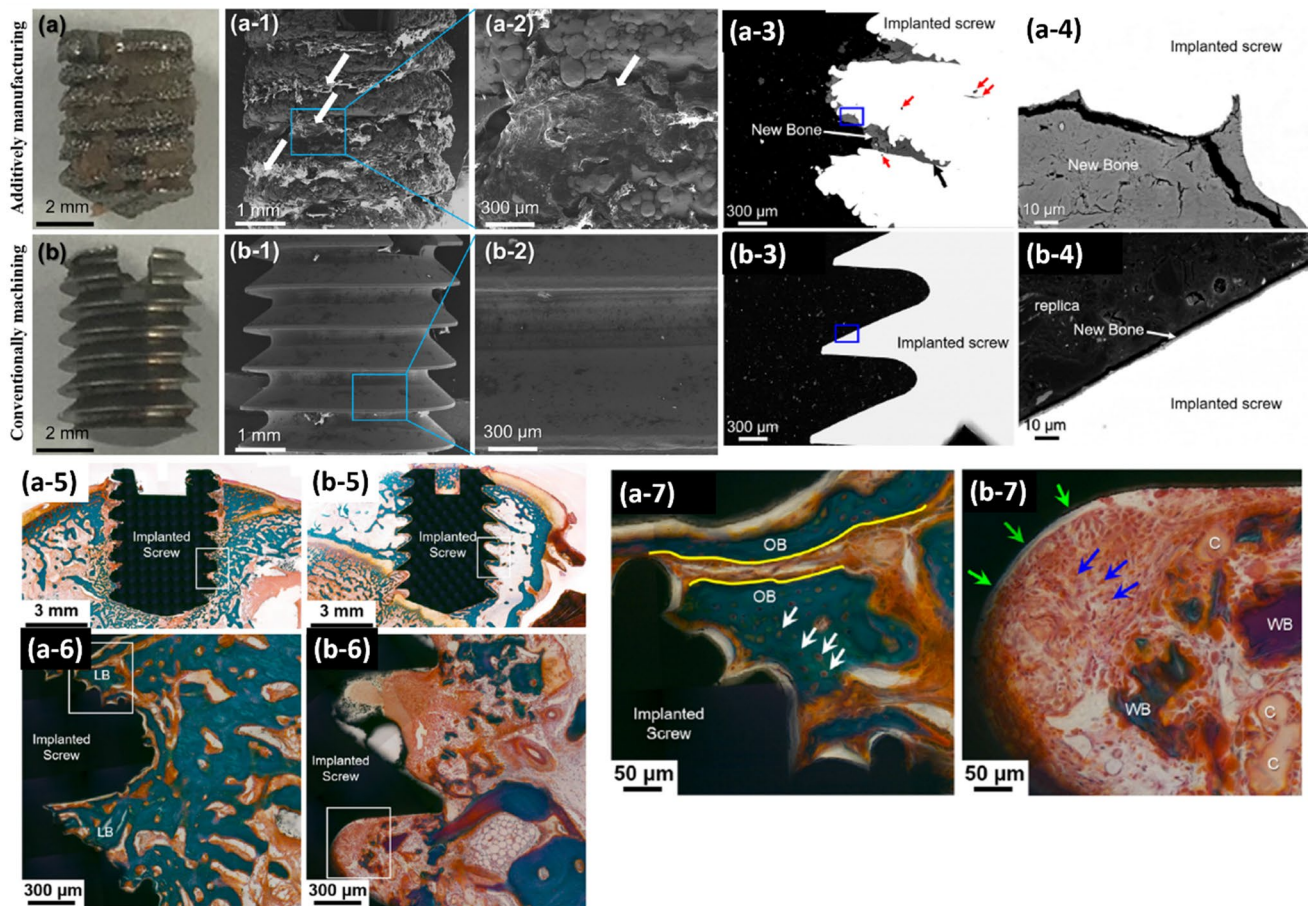


Fig. 8 Comparison of after push-out of **a** EBM-fabricated Ti6Al4V ELI screw with **b** conventional screw, SEM images of bone screw **a1–a4** EBM ELI screw with **b1–b4** conventional screw, histologi-

cal images of **a5–a7** EBM screw with **b5–b7** conventional screw (Reprinted with permission from Elsevier [69])

as depicted in Fig. 10c, d, respectively. It was concluded that varying the wall thickness and re-entrant angles of auxetic structure may support the pullout strength of pedicle screws, as presented in Fig. 10e [72].

3.3 Analytical graphs and data analysis

The recent advancement in the metal-based AM technologies for fabrication of orthopaedic bone screws has been progressively advancing and evolving. The advantages of AM-fabricated orthopaedic bone screws over conventional bone screw have been monitored based on bone growth, biodegradability, bone–implant contact, pullout strength, tensile stiffness, bone surface density and bone volume fraction in the literature. In a study [60], the AM-fabricated screw was compared with controlled screw to monitor the bone formation, bone surface density and bone volume fraction. The screws were implanted in rabbit animals for 6 months and was monitored at different time intervals (after 1 month, 3 months and 6 months). The micro-CT

examination of implanted control screw and AM screw is presented in Fig. 11a, b, respectively. The tissue volume and bone volume fraction were quantified using micro-CT analysis. The histological analysis of bone screw was conducted for monitoring bone ingrowth as depicted in Fig. 11c, d. The AM-fabricated screw has rough surface that quickly promotes bone ingrowth. After 6 months of implantation, bone screw construct was monitored. It was witnessed that AM screw healed higher woven bone and wider gap at interface as compared to controlled screw as illustrated in Fig. 11e, f, respectively.

The analytical data charts for evaluation of bone volume fraction, bone surface density, on-growth and ingrowth bone volume fraction of control screw and AM screw are illustrated in Fig. 12. It was witnessed that the AM-fabricated interference screw has significantly higher bone volume fraction, surface density, on-growth and ingrowth bone volume fraction as compared to controlled bone screw as presented in Fig. 12. Therefore, the AM-fabricated bone screw is preferred over the control screw. As AM-fabricated screw has the potential of

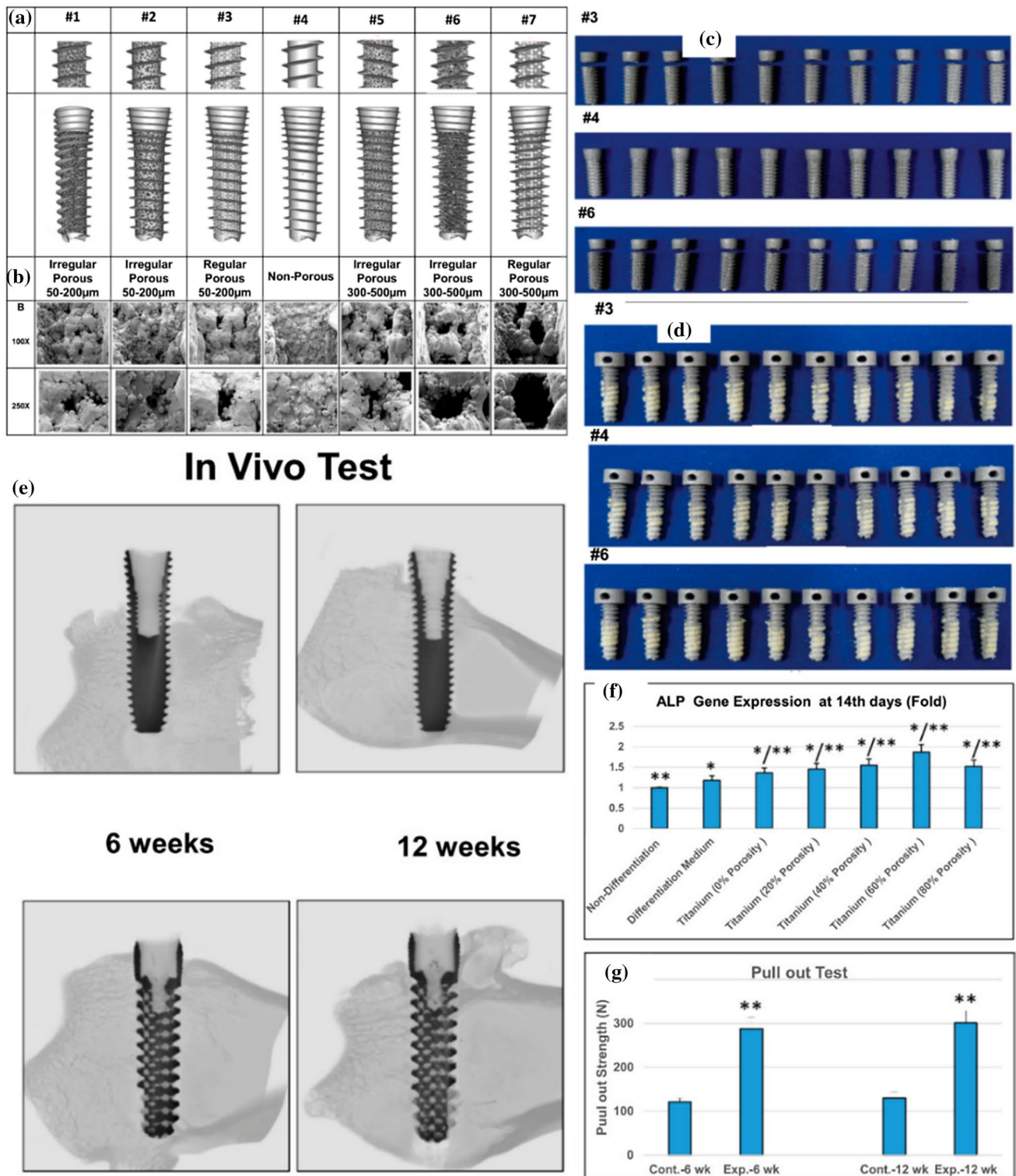


Fig. 9 a CAD models of seven dental implants, b SEM images show no inter-layers, c DMLS-fabricated dental implants, d after push-out images of implants, e in vivo study on rabbits, f in vitro biocompat-

ibility test of implants, g mechanical testing shows higher pullout strength of DMLS dental implant (no permission is required according to the journal policy [107])

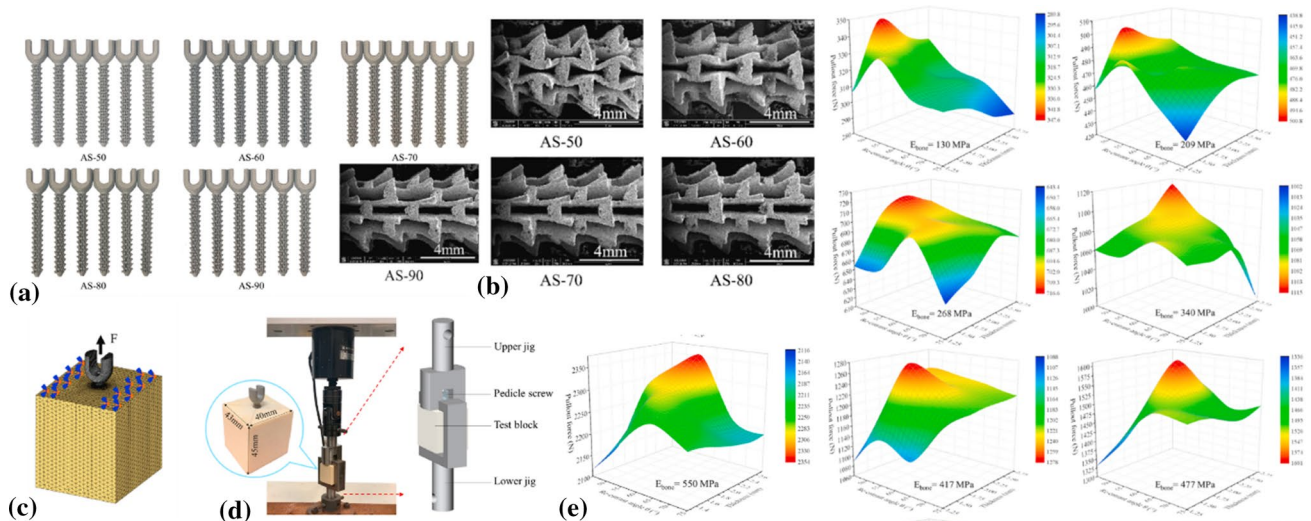


Fig. 10 **a** Pedicle screws by SLM technology with different re-entrant angles and auxetic units, **b** SEM images of screw bodies with auxetic units, **c** FEM and boundary conditions, **d** schematic of test specimen,

e maximum pullout force interactions with different designs of auxetic structures (Reprinted with permission from Elsevier [72])

surface modification, design customization and patient-specific screw over the conventional screw.

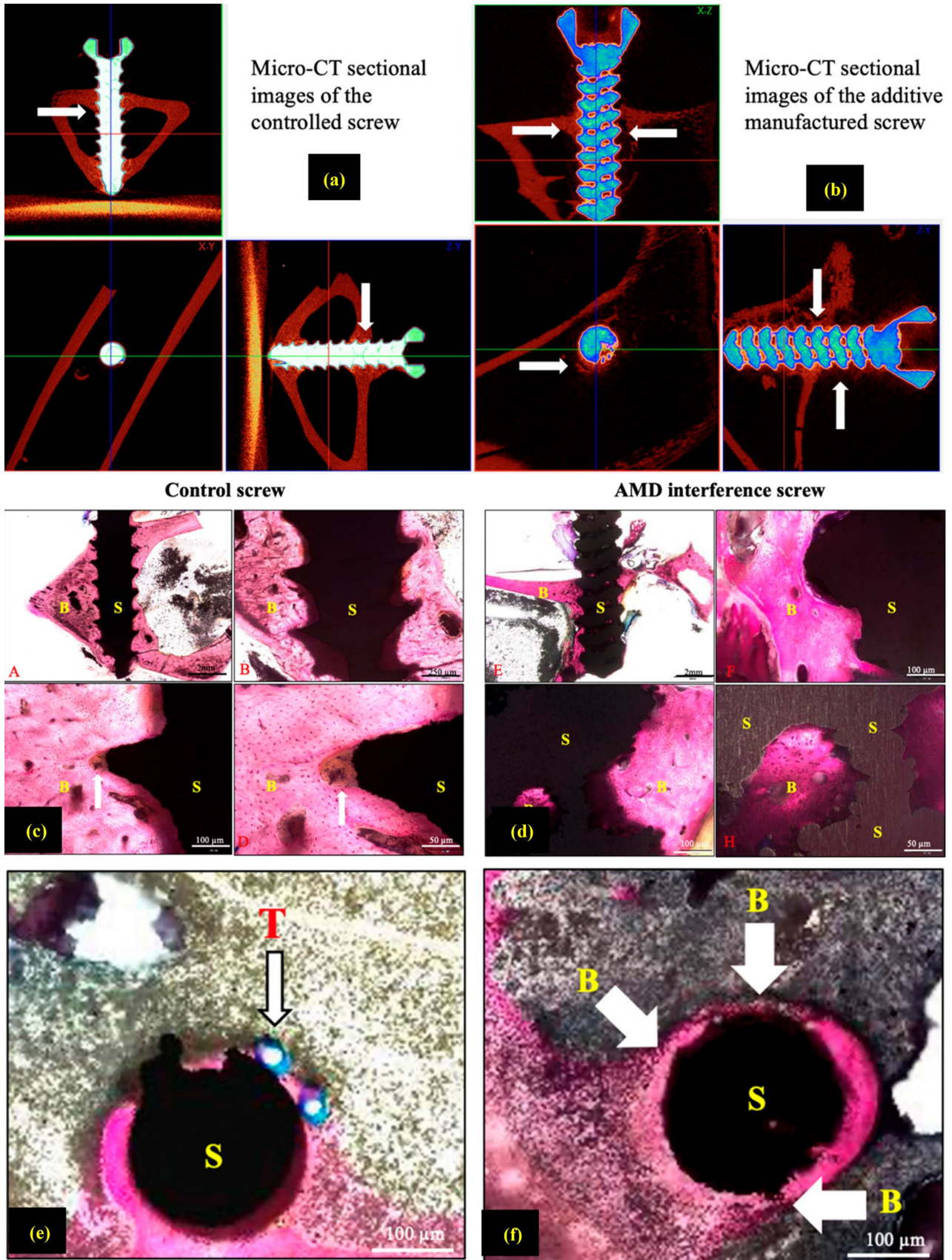
3.4 Comparing metal AM techniques

Metal-based AM techniques for fabrication of orthopaedic implants, including bone screws, are the new era of research trend of the present generation. Most metal-based AM techniques use powder bed fusion technology that employs either a laser or electron beam to fuse the metallic powder into a solid model. The most commonly used metallic AM techniques are electron beam melting, selective laser melting and direct metal laser sintering. Table 5 provides a concise summary and comparison of different metal-based AM techniques used in biomedical domain to fabricate metallic orthopaedic implants (bone screws). The comparative summary of different metal-based AM techniques is helpful for other researchers, medical practitioners and professionals to select the suitable AM technique based on their choice of material, resolution, part size and application.

The literature reports maximum utilization of titanium as promising metallic biomaterial for orthopaedic bone screw fabrication using different AM techniques. However, future research can explore stainless steel and cobalt chrome alloys with AM technology to fabricate orthopaedic implants.

4 Current state and challenges of AM technology

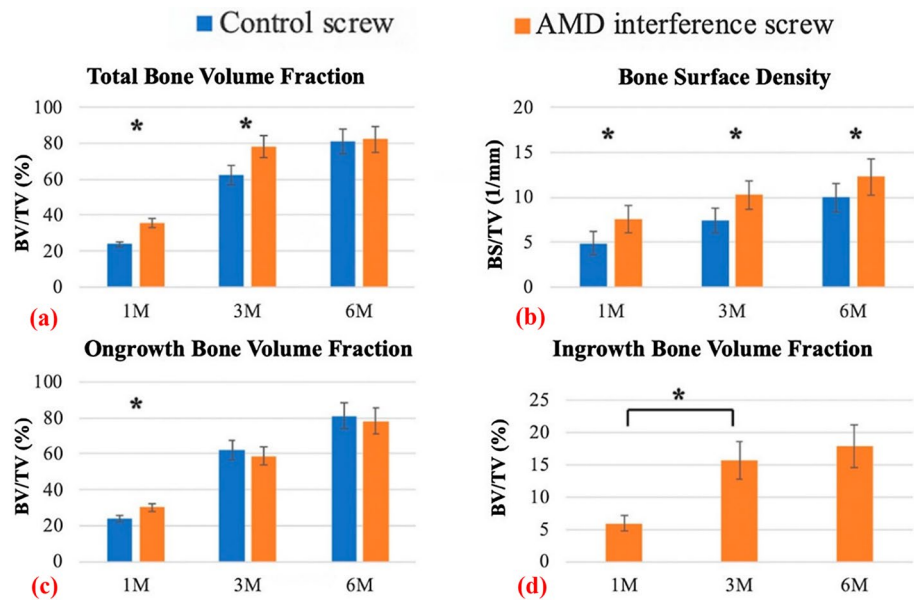
Bone screws have been the gold standard for fixation and an integral part of surgeries for internal fixation of the fractured bone. However, biodegradable bone screws have not received as much attention as they deserve. Biodegradability is an asset for bone screws as they have the advantage to dissolve or degrade with time and does not require complicated surgery for extraction. Most research focused on fabricating biodegradable bone screws with the help of AM technology and limited to biological behaviour and mechanical properties. The potential of AM technology to manufacture orthopaedic bone screws is becoming highly popular and advantageous for orthopaedic surgeons. This technology can change the manufacturing process of the bone screw and reduce material wastage. However, AM technology faces significant challenges and issues, as illustrated in Fig. 13. This current state of challenges must be overcome to maximize the utilization and reveal the full potential of AM technologies. These states of challenges are detailed, discussed and presented below in this section.



◀**Fig. 11** Micro-CT images of **a** controlled screw, **b** AM-fabricated bone screw; histological analysis of **c** control screw, **d** AM-fabricated screw, 6-month specimens for bone formation evaluation of **e** control screw, **f** AM-fabricated screw; *B* bone, *S* screw (no permission is required according to the journal policy [60])

- *Adaption of intelligent manufacturing* New informative technologies such as the Internet of things, cloud computing, big data, machine learning (ML) and artificial intelligence (AI) are deeply integrated into different industries for manufacturing. Embedding these intelligent technologies into traditional AM techniques may aid in developing centralized intelligent manufacturing models. Employing AI and ML in the AM techniques could improve processing defects and inconsistent quality of the fabricated part. The topological designs, performance of metamaterials, rate of powder spreading, data securities and acoustic-based monitoring can be assessed with the adoption of ML and AI in the AM technology. The adaptation of ML and AI in AM technology can be used for various applications such as optimization of design for AM, AM process and AM production, as illustrated in Fig. 14. The innovative and patient-specific implants can be fabricated with smart and hybrid AM technology using ML for digitally automated and robot-assisted processes. The combination of new informative technologies such as ML, AI and Industry 4.0 in traditional AM techniques may allow the customer to accelerate the adoption and productivity of AM in existing production environments.
- *Quality consistency* Quality of bone screw is highly influenced by key parameters of AM technique that includes build orientation, metal powder size, shrinkage, scanning speed, layer height, wall thickness, support material, resolutions, printing speed, proper alignment, printing time and manual post-processing. These initial process parameters are necessary to be optimized for the fabrication of orthopaedic bone screws. Inconsistent quality of fabricated part may result in lower quality of the bone screw, which may not be ideal for superior fixation output for medical usage. Orthopaedic bone screws fabricated with randomly selected process parameters are illustrated in Fig. 15. The quality of these bone screws can be improved by optimizing the printing process parameters with the adaptation of ML algorithms.
- *Scalability limitation* AM technology is not feasible enough for mass production compared to the traditional manufacturing of orthopaedic bone screws due to slow production speed and quality inconsistency. The scalability issue is the main challenge, as AM technique requires operational skills and knowledge to operate the machines [111]. Very few medical practitioners and design engineers working in orthopaedic bone screws fabrication have the domain knowledge to scale up AM technology commercially. The adaptation of AM technology for mass production, repeatability and consistency of fabricated orthopaedic bone screws is critical. The scalability and mass production of orthopaedic bone screws can be possible by adopting sensor-enabled, robot-assisted smart manufacturing and industrial automation to fabricate orthopaedic bone screws.
- *Narrow range and expensive biomaterials* The biomaterial used for orthopaedic bone screws should possess excellent biocompatibility, biodegradability and mechanical stability with sufficient mechanical strength for the load-bearing structure of fractured bone. Based on the high performance of biomaterials, very few biocompatible biomaterials have been explored to fabricate orthopaedic bone screws via AM technology. Few studies have used titanium in the literature for orthopaedic bone screws fabrication by AM techniques. Stainless steel and cobalt–chromium should also be explored with various AM techniques to fabricate orthopaedic bone screws. Moreover, biodegradable materials with good mechanical properties may also be suitable based on the application and load-bearing capacity of the fractured site.
- *Restriction of multi-material capabilities* The inability of AM techniques to produce parts in multiple materials is the major limitation of AM technology [111]. It is foreseeable that advancement in multi-material AM technologies may improve the composition for multi-functionalities of metallic biomaterial. The use of multi-material during bone–implant fabrication may develop long-term mechanical properties for permanent usage inside the body, biodegradation for temporary replacements and short-term mechanical integrity. Extrusion-based multi-material AM technique has the potential to fabricate multi-functional metallic biomaterials to flourish and inhibit biomedical adaption, especially for biocompatibility [111].
- *Lack of real-time manufacturing* The communication–connection gap between medical practitioners and design engineers may lead to a lack of real-time manufacturing of orthopaedic implants required at the time of surgery. This lack of real-time manufacturing may dramatically influence the life of a patient. The clinical application of real-time manufactured orthopaedic implants may be possible with the knowledge and adaptation of AM technology and respective designing software. Design software such as SolidWorks or Creo is used for the 3D CAD model. The design preparation, slicing and removing errors from the STL file of the model part require MIMICS and MAGIC software to optimize the requirements of AM-fabricated parts. The lack of knowledge of designing software in data preparation may not lead to the potential use of AM technology by doctors. There-

Fig. 12 Comparison of control screw and AM-fabricated screw in rabbit animal for (a) total bone-volume fraction, (b) bone surface density, (c) on-growth bone volume fraction, (d) in-growth bone volume fraction (no permission is required according to the journal policy [60])



fore, knowledge of design, slicing and error removing software forbids AM technology's maximum potential.

- *Use of magnesium for bone screw fabrication* Magnesium is an essential element present in human bones, blood serum and human blood. The daily magnesium intake in normal human beings is around 250–350 mg, enhancing the bone quality and activating enzymes [4]. Magnesium and its alloys are the most suitable biomaterials with good biocompatibility, osteopromotive property and natural degradability [112]. Moreover, the Young's modulus and density of magnesium are quite similar to human bones with sufficient metallic mechanical strength [112]. Very few research reports utilize magnesium as an appropriate biodegradable biomaterial for bone screw [112–115]. Until now, no study has been reported using magnesium powder ceramics as a biomaterial for orthopaedic bone screw fabrication with the AM techniques due to the specific particle size of powder. The advantages, applications, strategies to resist corrosion and fabrication methods of magnesium as prominent biomaterial for bone-implant fabrication are illustrated in Fig. 16. Therefore, magnesium powder for orthopaedic bone screw fabrication can be the future demand for biodegradable bone screw fabrication using AM technology.
- *Standardized geometry of bone screw* The same standard geometries of bone screws are used in almost all ages of fractured human bones. The bone densities vary with variation in the age of patients causing osteoporosis. As the density of human bone decreases, the holding strength between the bone-screw interface decreases that reduces the pullout strength at the bone and screw initial contact area. The traditional geometry of bone screws may lead

to bone-screw complications and loosening of the orthopaedic bone screw in higher-aged patients with less bone mineral density. The customized patient-specific bone screws can provide better stability and rigid internal fixation to the fractured site. These customized orthopaedic bone screws can be fabricated using AM technology.

5 Solutions and future directions

To overcome the challenges of AM technique and to see the full potential of AM technology, significant further research and development are required in terms of new biomaterials, new designs of orthopaedic bone screws, new techniques of AM technology, process control, bio-additives manufacturing and adaptation of intelligent manufacturing (Industry 4.0). Moreover, new informative technologies such as the Internet of things, cloud computing, big data, machine learning and artificial intelligence may improve the capabilities of AM technology for orthopaedic bone screws fabrication.

AM technology is currently used to fabricate orthopaedic bone screws such as pedicle screws and cortical screws; it is expected that this technology can also fabricate other bone screws and reduce bone-screw-related complications by manufacturing the biodegradable orthopaedic bone screws. A descriptive tree map is presented in Fig. 17 that details the advantages of biodegradable screws over conventional metallic screws. There are various unexplored biodegradable metallic biomaterials available in the market that can be consumed during AM technique to improve the capabilities of biodegradable orthopaedic bone screws.

Table 5 A comparison of metal-based additive manufacturing technology

AM technique	Biomaterial usage	Processing parameters	Advantages	Limitations
SLM	Ti alloys	Powder size (10–45 μm)	Complex lattice structure fabrication with ease	The conduction and diffusion of laser heat originate from the unwanted fusion of neighbouring powder particles and limit the resolution of final features
	Stainless steel	Laser sintering (intensity 100 W–1 kW)	Customized design with high accuracy	
	Aluminium, copper	Layer thickness (30–90 μm)	Diversity of printable metallic biomaterials	
	Ni–Ti alloy	Scanning strategy (unidirectional or bidirectional)	No requirement of support	Porous lattice structures require a post-printing process
	Cobalt–chromium	Nd–YAG laser (1.064 μm)/fibre-laser (1.09 μm)	High utilization (unsintered powder can be reused and removed)	Acute size restrictions
EBM	Ferrous alloy			
	Magnesium, zinc, tungsten	An inert environment	Good surface integrity	Expensive
	Ti alloys	High vacuum (1×10^{-4} Torr)	Range of printable metallic biomaterials	Slightly lesser accuracy compared to SLM
	Cobalt–chromium	Layer thickness (50–100 μm)	High accuracy (tolerance ± 0.2 mm)	Expensive powder materials
	Stainless steel	Freedom of size of build part ($350 \times 350 \times 380 \text{mm}^3$)	Low risk of deformation with decent mechanical strength	The cost of the printing process is significantly higher
DMLS	Bulk metallic glass	Scanning strategy (unidirectional or bidirectional)	The unsintered powder can be recycled (High utilization)	Porous structures require post-processing of fabricated parts
	Inconel, copper		High-quality metal parts with tuneable strength and density	
	Aluminium, Copper	High power laser (intensity 200 W–1000 W)	Range of printable metallic biomaterials	A fine range of layer thickness
	Ti alloys	Layer thickness (20–50 μm)	Low level of internal defects	Costly process
	Cobalt–chromium	Feature size ($250 \text{mm} \times 250 \text{mm} \times 300 \text{mm}$)	Strong mechanical strength	The quality of parts varies depending upon resolution and material
	316L Stainless steel		Complex structures with intricate detailing	
	Inconel	High accuracy (tolerance limit ± 0.1 – 0.2 mm)	High quality with great accuracy and detailed metal parts	Post-processing required for fabricated parts

6 Conclusions

We have recently witnessed a fast growth in the additive manufactured orthopaedic bone screws in clinical and research usage. Still, there exists the need for improvement in orthopaedic bone screws to understand the complete potential of AM technology. This technology can fabricate biodegradable orthopaedic bone screws that reduce the “stress shielding effect” caused by metallic screws and eliminate the need for post-operative surgery for screw extraction. The search of suitable biomaterials for superior safety, biocompatibility and bio-absorbance (degradability) with enough mechanical properties is ongoing. The composite materials with coating or nanoparticles additives can be

the future for manufacturing of orthopaedic implants using AM technology. Magnesium is found to be the most suitable and promising biomaterial for orthopaedic bone screw fabrication. As magnesium has inherent biodegradability, biocompatibility, osteopromotive and favourable mechanical properties. This concise, detailed review of properties of available metallic biomaterials and polymeric biomaterials, AM-fabricated orthopaedic bone screws and specifications of various metal-based AM techniques witnessed for manufacturing of metallic orthopaedic implants will be helpful for forthcoming researchers, professionals, design engineers and medical practitioners for selecting suitable AM technique and choosing promising biomaterial based on their usage and application.

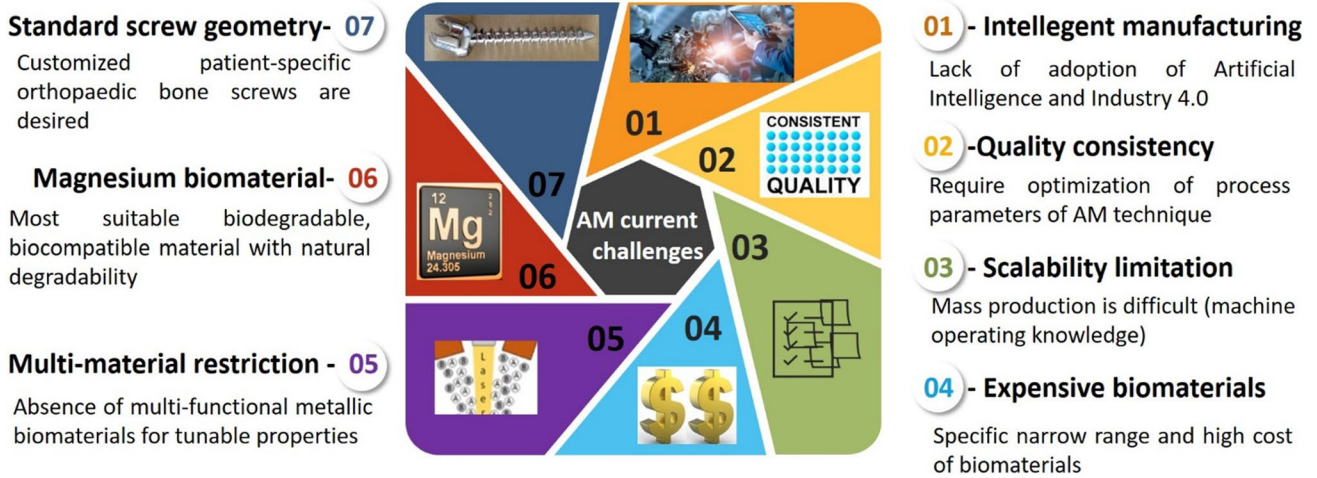
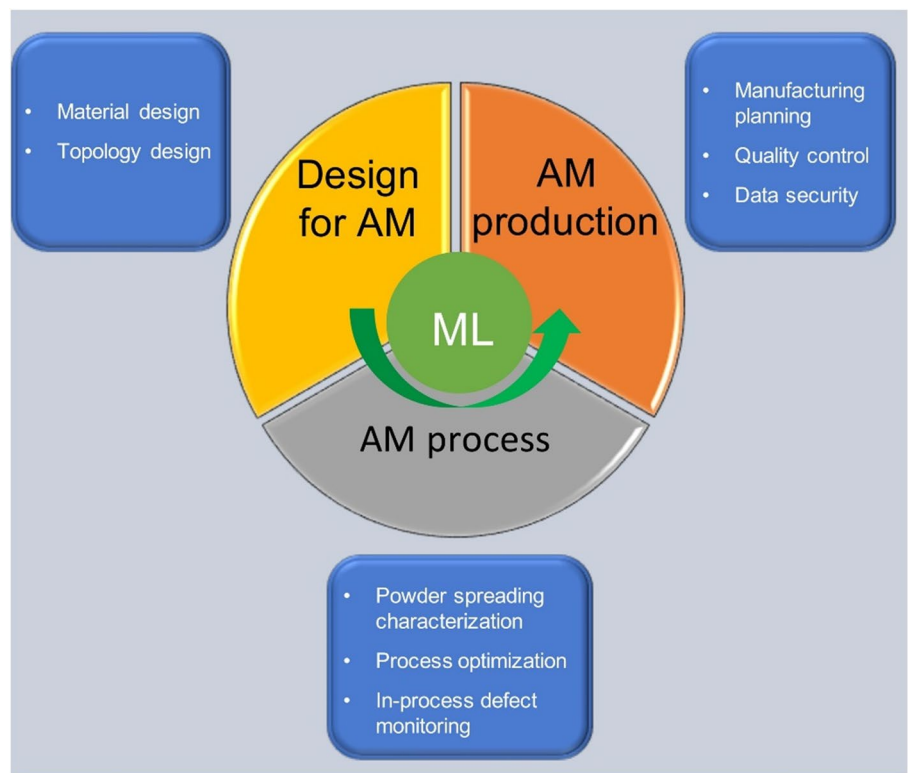


Fig. 13 Pictorial representation of current state and challenges of AM technology

Fig. 14 Application of AI and ML for different domains of AM research work (Reprinted with permission from Elsevier [110])



AM technology is a game-changing and better alternative than conventional fabrication methods in the field of orthopaedics. This technology enables the fabrication of orthopaedic bone implants. It allows the easier fabrication of complex parts, porous lattice structure, precise shape,

biodegradable screws and fine-tuning of topography with sufficient strength and suitable mechanical properties. However, with the current rate of development in orthopaedic implants utilizing AM technology, it is exciting and motivating to see what the near future holds.

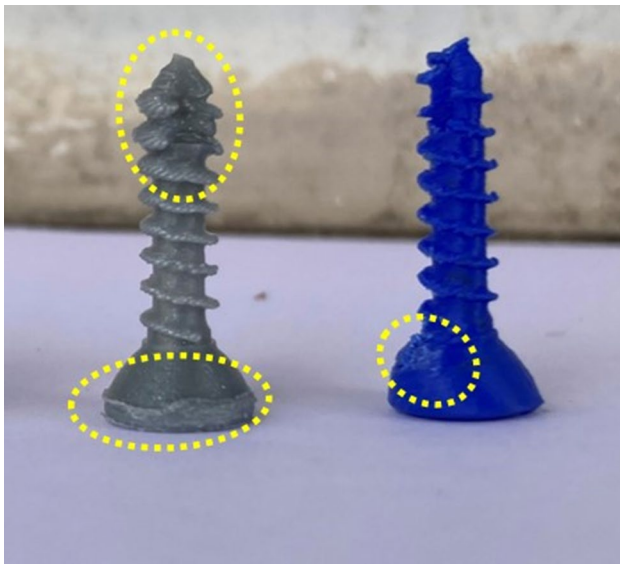


Fig. 15 Quality inconsistency of bone screw with random process parameters

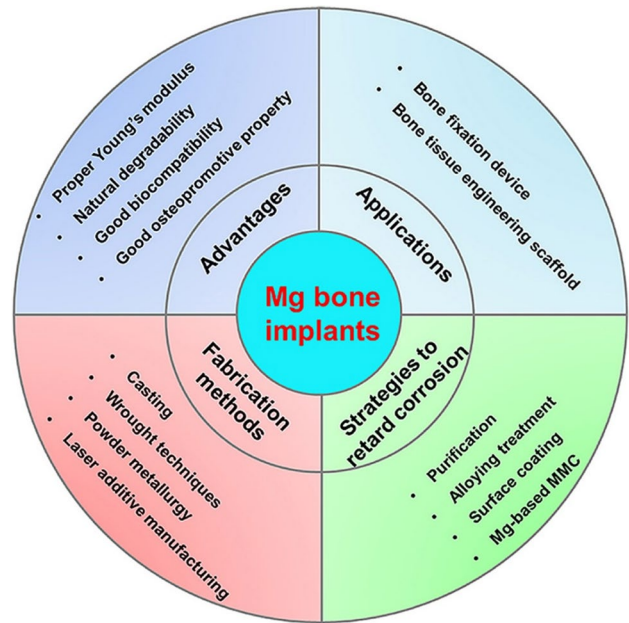


Fig. 16 Advantages, applications, methods of fabrication and strategies to retard corrosion of magnesium-based bone implants (no permission is required according to the journal policy [112])

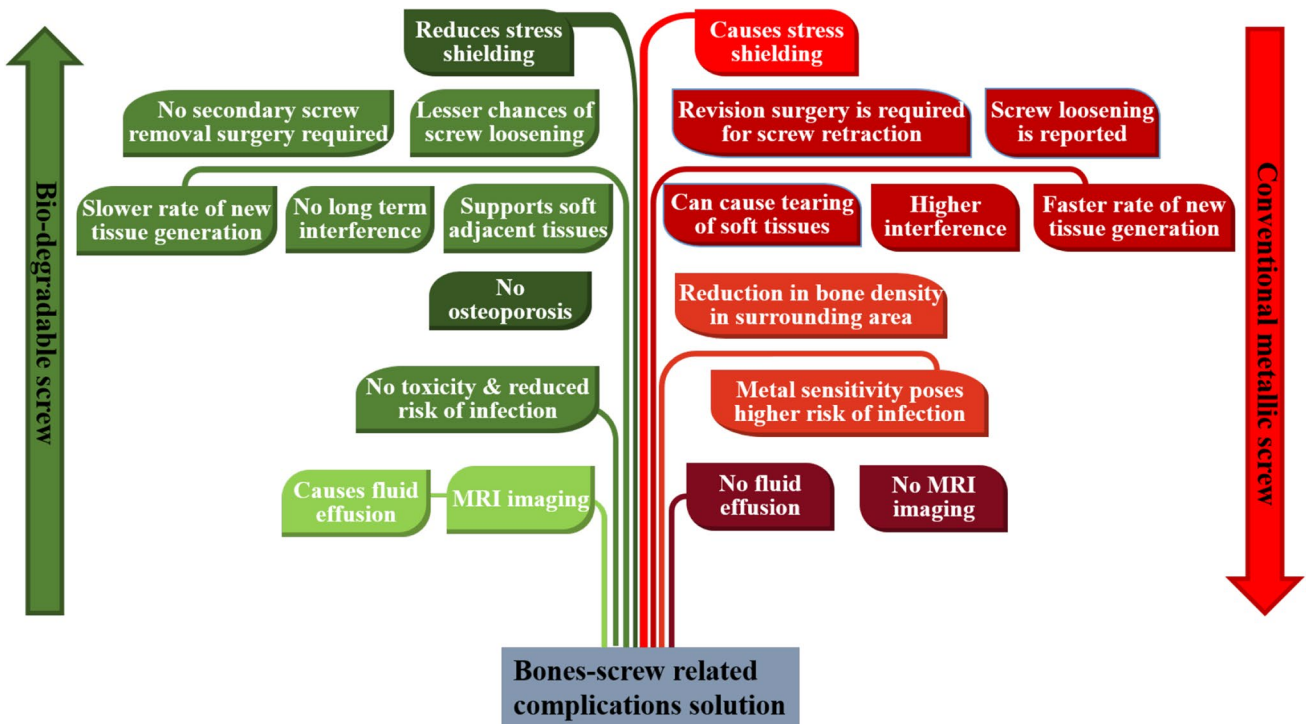


Fig. 17 Descriptive tree map showing advantages of the biodegradable screw (green colour) over metallic screw (red colour) (colour figure online)

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

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