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Additively manufactured patient specific implants: A review

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Medical applications of additive manufacturing have seen a significant growth in recent years due to availability of advanced medical imaging and design software and wide range of materials. The range of additively manufactured medical implants is growing rapidly and surgeons need to keep themselves updated with state-of-the-art of the technology. This article reviews several articles related to medical implants to help surgeons and researchers to stay up-to-date on recent developments in the domain. Additively manufactured medical implants are reviewed in five categories: orthopedic implants, dental implants, cranioplasty implants, scaffold implants for tissue engineering and other medical implants including chest wall reconstructive implants, anti-migration enhanced tracheal stents, and buccopharyngeal stents. The additive manufacturing process and the material for fabrication of each type of implant are highlighted in the study. It has been observed that titanium alloy is a suitable material for cementless arthroplasty. Porosity in the implants supports bone ingrowth, which results in a significant reduction in stress shielding. Additive manufacturing has a very attractive future in medical implant fabrication due to its capability to produce complex and customized implants. The AM provides freedom to researcher to explore the complex design of medical implants for better bone regeneration and improved osseointegration.

1. Introduction

An implant is a special device, tissue or organ, intentionally kept inside or on the surface of the body to replace, support or enhance the functionality of an existing

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biological structure. Implants may be permanent or temporary. For example, pace makers, stent or knee implants are permanent in nature; on the other hand, fixation plates or chemotherapy ports are removed once desired outcome is achieved. Most of the implants are available in standard sizes in the market. However, due to variation in anatomical shape and size, these implants are tailored at the operation table. Due to the lack of shape conformity and fitting they may cause certain problems sometime after implantation, e.g., loosening, stress shielding, infection, etc. These problems may be reduced considerably by using a customized or a patient specific implant.

Additive manufacturing technology, invented in 1980s as rapid prototyping, has been utilized to provide a variety of solutions to medical arena [1, 2]. The major medical applications of AM include: 1) anatomical models for planning and simulation of complex surgeries, 2) customized implants, prosthetics and orthotics, 3) customized drug delivery doses, 4) patient-specific external aids, 5) surgical guides and instruments, 6) tissue engineering scaffolds, 7) organ printing, etc. [3]. There are several AM technologies, such as stereolithography (SLA), fused deposition modelling (FDM), selective laser sintering (SLS), binder jetting (BJ) selective laser melting (SLM), laser engineered net shaping (LENS) and direct metal deposition (DMD) available nowadays that can fabricate customized implants in polymer, ceramic or metal [4–6].

The article comprises review of 160 papers to present state-of-the-art in additively manufactured implants. Additively manufactured medical implants have been reviewed in five categories: orthopedic implants, dental implants, cranioplasty implants, scaffold implants for tissue engineering and other medical implants. The current advancement in medical applications and the factors affecting the accuracy

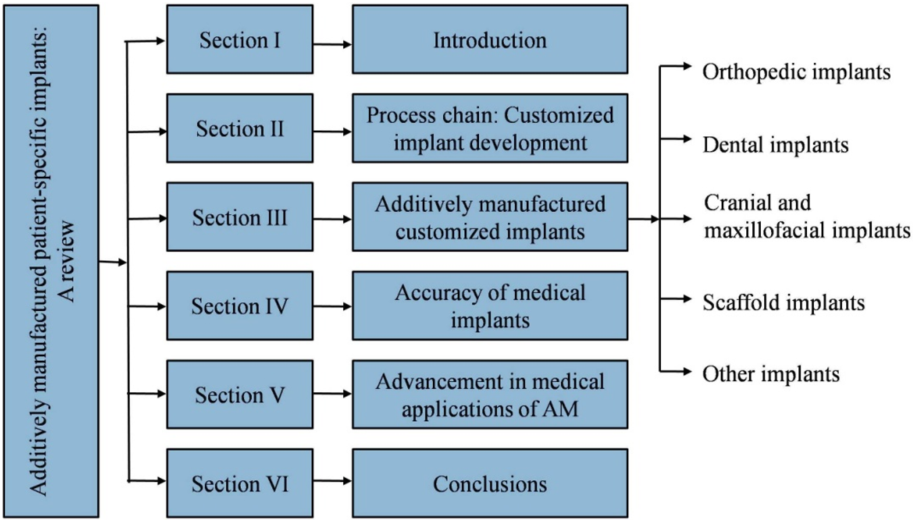


Fig. 1. Taxonomy of additively fabricated customized implants

of the additively fabricated implant have also been discussed. The objective of this review work is to report the state-of-the-art, discuss current advancements, and find future directions of research in additive fabrication of customized implants and scaffold printing for tissue engineering. The taxonomy of additively fabricated implants is shown in Fig. 1.

2. Process chain: customized implant development

The advancement in computer-aided designing and digital manufacturing increased their applications in medical areas, starting from 3D visualization of patient's affected body part to fabrication of customized implant, prosthetic, devices, etc. Additive manufacturing has emerged as a promising technology to fabricate patient-specific implants in recent years. The process of customized medical implant development starts with diagnosis of the patient's problem. Medical experts identify the problem and take digital imaging to explore the problem. Digital imaging is performed using magnetic resonance imaging (MRI), computed tomography (CT) scan or 3D laser scanning [1]. The MRI/CT scanning is used to capture image of internal organs or tissues; whereas, 3D scanning is usually used to capture images of external body parts. MRI/CT scanning involves capturing a huge number of two-dimensional images of the affected body part. This data is stored in digital imaging and communication in medicine (DICOM) file format. The set of DICOM images is exported to a volume rendering medical software for 3D reconstruction of the scanned body part. Several kinds of open-source and subscription-based 3D rendering software like 3DSlicer, InVesalius, DeVIDE, MIMICS, etc., are available for reconstruction, segmentation and implant design. Once 3D reconstruction is done, it is saved into an STL file format. The STL file is employed for additive manufacturing of the customized implant. The final implant may be obtained in two ways: 1) direct fabrication of the end-use implant, 2) indirect fabrication of the end-use implant via rapid tooling approach. In the former case, an implant is manufactured using sophisticated AM machines such as SLA, FDM, SLS, SLM, DMD, etc.; whereas, in the latter case, a pattern is first created using any low-end 3D printer like FDM printer, which is then used to make a mold/die to fabricate the final implant [7, 8].

The steps to develop a patient-specific cranial implant are shown in Fig. 2. The CT scan data of a patient having a cranial cavity is exported to the medical image processing software for 3D reconstruction. 3D reconstruction and segmentation is a very crucial step in implant design and usually requires assistance of an experienced radiologist. In 3D reconstruction, a solid model of the bony skeleton of the scanned area is created by applying a suitable threshold range. The segmentation of the region of interest (ROI) is done to separate the ROI from the rest of the reconstructed entities. The segmented item serves as a template for the tailored implant's design. After segmentation, the shape and size of the implant are almost clear, therefore the implant is designed and analyzed for an optimum design using the software.

The 3D image of the implant is converted into the STL file format and sent to an additive manufacturing system for 3D printing. After post-processing, the concerned surgeon or the medical personnel checks for any possible error before implanting it into the patient's body.

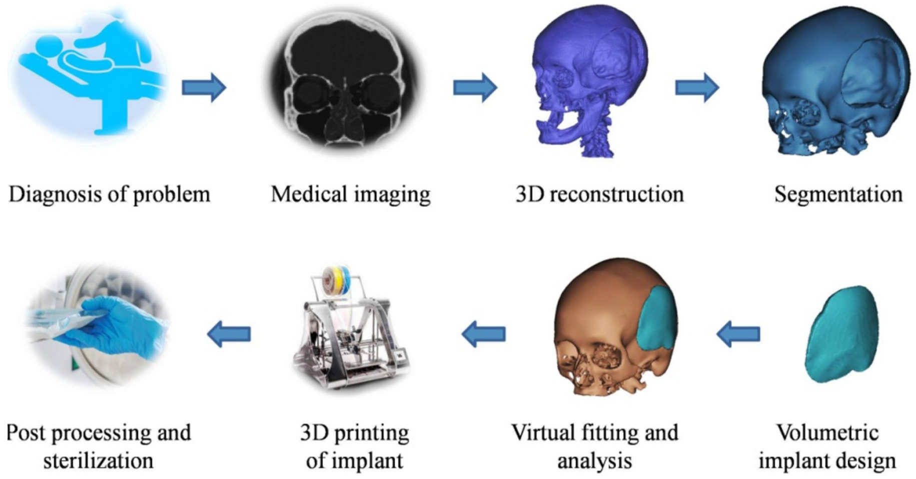


Fig. 2. Process chain of medical implant development

3. Additively manufactured customized implants

A significant growth in additive manufacturing of customized implant has been observed recently. Additive manufacturing is being extensively used to fabricate various kinds of implants, like orthopedic, dental, cranioplasty, arthroplasty, and tissue engineering implants [9]. In fact, some implants are only possible to fabricate using additive manufacturing technologies. Implants need to be conforming to anatomical shape, which generally contain freeform surfaces. Customized implants are frequently needed when the standard implants are not available or the standard implant does not fit properly to a patient. A customized shape has a potential to prolong the lifespan of the implant and concurrently augment the patient's quality of life. Due to additive nature, AM can fabricate freeform surfaces easily, quickly with very good accuracy. The fabrication of knee implants using additive manufacturing can save up to 80% of material as compared to the conventional methods of knee implant fabrication [10]. AM has been used by the researchers as an effective tool to fabricate variety of customized implants, such as cranial implants, a mandibular implant for mandibular reconstruction, dental implants, orthopedic implants like titanium femoral head acetabulum cup for total hip joint replacement, knee implants and customized prosthetics, as shown in Fig. 3. There is a variety of biocompatible materials available for additive manufacturing of these implants at present.

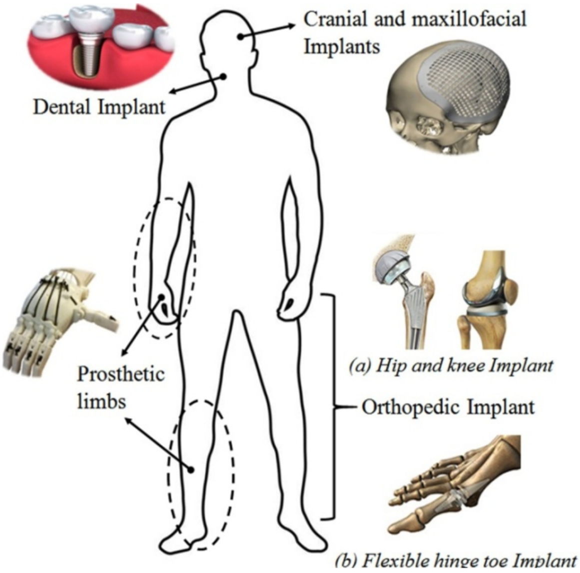


Fig. 3. Additively manufactured medical implants and prostheses for human body

3.1. Orthopedic implants

According to Abate et al. (2021) [11], the porous structure of biomaterials is suitable for orthopedic implants due to better cell proliferation and osseointegration. This study showed that the hip implant fabricated with porous structure results in a significant reduction of stress shielding, and also allows bone tissue ingrowth. Though the porous hip implant showed 62% lower stiffness and 50% lower weight in comparison to the solid hip implant, the porosity in the implant improved osseointegration. The authors concluded that the implants with porosities of 56% and 58% could be used to improve osseointegration for the size of pores and the distribution of pores used by them. Both hip joint and knee joint replacements were done using additively fabricated titanium implants. Excellent clinical results were observed by Narra et al. (2019) [12].

Stress shielding in a load-bearing bone occurs when a part of the load is taken by the implant or the prosthetic. The load is thus shielded from acting on the bone. For instance, when a stem with higher stiffness is implanted in the femur canal, the stem bears partial load thus sharing the load with the femur. The bone is subjected to a reduced stress and thus subjected to stress shielding. A bone adapts itself and develops a structure to withstand the load acting on it. The areas of the bone subjected to higher load respond by increasing the bone mass. The areas under lower load react by decreasing their bone mass. A decrease in bone mass is called bone resorption. This may cause the implant to become loosened or fail completely. Therefore, it is desirable in many cases to reduce stress shielding. A fully porous titanium femoral stem was studied and implanted to decrease stress shielding by Arabnejad et al. (2017) [13]. The stress shielding decreased by 75% compared to the conventional femoral stem. A comparative study of the hip stem was done by Cronskar et al. (2013) [14]. The customized hip stems 3D-printed by electron beam melting resulted in a significant cost reduction of 35% in comparison to CNC milled hip stems. The anteroposterior standing plain CT scan of a 15-year-old patient suffering from adolescent idiopathic scoliosis is shown in Fig. 4. Additive manufacturing was used to fabricate 3D-model of the patient's spinal column and intraoperative template for proper insertion of the pedicle screw to correct the spine curvature.

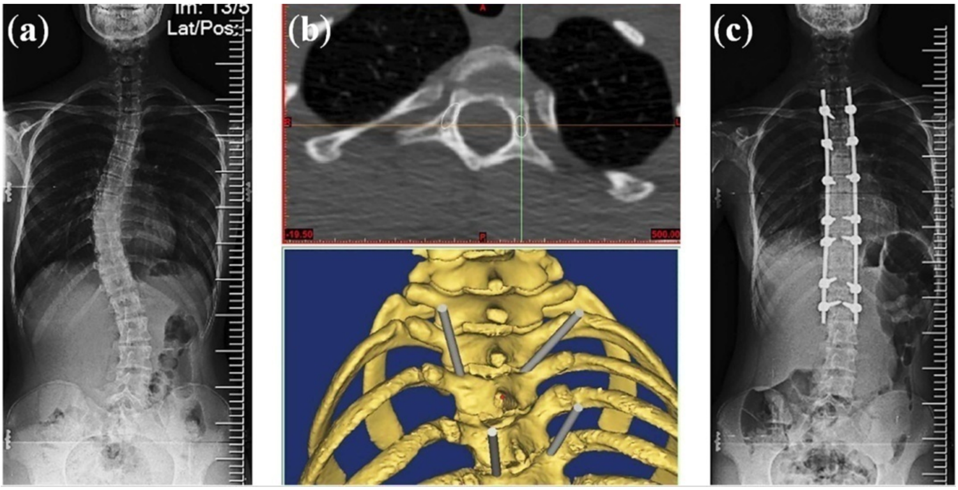


Fig. 4. (a) Anteroposterior standing plain CT scan of the patient; (b) 3D view of pedicle screw trajectory; (c) Postoperative CT scan of the patient showing corrected anteroposterior view [15]

A fracture fixation implant was designed and 3D printed using laser-based powder bed fusion (L-PBF) by Tilton et al. (2020) [16] for the treatment of proximal humerus fractures that were in a comminuted state. The powder of biocompatible, SS316L stainless steel (Cr – 17%, Ni – 12%, Mo – 2.5%, Si – 2.3%, C – 0.03%, Fe – balance) was used for the fabrication of a customized fixation plate. Finite Element Analysis (FEM) of patient-specific fracture fixation plate was done to reduce the common complications after surgery such as screw cut-out and varus collapse. A varus deformity is an excessive medial angulation of the distal segment of a bone. A medial angulation is an inward angulation of a bone or a joint and is toward the midline of the body. A valgus deformity is an outward angulation of a bone or a joint. Several biomechanical tests were performed to quantify the fracture gap displacement at different loading conditions. A patient-specific intervertebral disc implant (end-plate) was designed and fabricated by De Beer and Van Der Merwe (2013) [17] using the direct metal laser sintering (DMLS) process. They designed and fabricated the footprint profiles matching end-plate geometry of the intervertebral disc implant. An accuracy of 0.37 mm was achieved in this process. Three designs of knee implants were analyzed by Shuib et al. (2021) [18]. They performed the structural analysis at angles of flexion of 0°, 90°, 135°, and 165° and under different loading conditions. Von Mises stress, total deformation, and shear stress were analyzed in the FEA analysis.

Jain et al. (2009) [19] have presented a work for non-surgical treatment of club foot or congenital talipes equinovarus (CTEV) using additive manufacturing. They used an FDM system to fabricate biomodels to cure a baby patient. Ramos et al. (2009) [20] compared the dimensional parameters such as the standard, average, maximum and minimum deviations and surface roughness (Ra, Rt, and Rp) of the hip implant fabricated by CNC machining and room temperature vulcanizing (RTV) method. In order to conduct in-vitro tests, they used specific lost wax casting (LWC) technology to produce the models. They found that the RTV rubber vacuum casting method gives good dimensional stability to produce the small number of implants. Harrysson et al. (2003) [21] made a model for preoperative planning of deformities in a dog. A one-year-old dog was suffering from bilateral multifocal pelvic limb deformities. The MIMICS software package from Materialise was used for the solid model reconstruction. Stereolithography and RTV tooling methods were used for the fabrication of physical models. Bezuidenhout et al. (2015) [22] studied the drug delivery functionality incorporated in medical implants and prosthetics to cure postoperative infections. A design of patient-specific knee implants was proposed by Boorla and Prabeena (2019) [23] to replace the load-bearing surfaces so that joint pain can be alleviated. 3D printing was used to provide liners of poly lactic acid (PLA) material instead of poly (methyl methacrylate) (PMMA) antibiotic eluting spacer to cure the post-operative deep infections of joint arthroplasty [24]. A list of biomaterials and the suitable AM methods for manufacturing of orthopedic implants are summarized in Table 1.

3.2. Dental implants

Additive manufacturing is also widely used in dentistry for the fabrication of complex dental implants, customized jaw fracture fixation plates, clear dental aligners, and other dental applications. Jindal et al. (2020) [44] performed a study on 3D printing and post-curing of clear dental aligners. Their study showed that the compressive strength of aligners depends on the temperature and time duration of post-curing. The conventional method of making aligners is a long process starting from taking the dentition of a patient to pouring the plaster of Paris in order to get a dental mold [45]. On the other hand, additive manufacturing can easily fabricate customized dental aligners. Ramakrishnaiah et al. (2017) [46] fabricated customized root-form dental implants for the replacement of missing teeth using the ARCAM A2TM electron beam melting system. Salm et al. (2013) [47] designed an occlusal splint using liquid photopolymer on a stereolithography (SLA) system. 3Data Expert and VisCAM RP software packages were used to design the occlusal

Table 1. List of biomaterials and AM methods for orthopedic implants

Biomaterial	AM methods	Description
Polymers [12, 25–29] • Polyether-ether-ketone (PEEK) • Polytetrafluoroethylene • Poly-caprolactone • Poly-lactic acid (PLA)	• Fused deposition modeling • Selective laser sintering • Plasma immersion ion deposition	• PEEK is widely recognized as the most frequently utilized polymer for additive manufacturing of orthopedic implants owing to its exceptional compatibility with cellular structures. The bulk elastic modulus of PEEK can be easily tailored similar to the cortical bone by changing chemical composition. • PTFE is a fluoropolymer known for its low friction, chemical resistance, and biocompatibility, making it suitable for orthopedic implants. • PCL is a biodegradable polyester with low melting point and good mechanical properties, making it suitable for orthopedic implants, particularly for temporary support or scaffolding. • PLA is a biodegradable polyester derived from renewable resources, offering good mechanical properties and biocompatibility for orthopedic implants. Its biodegradability makes it suitable for temporary implants or implants that need to degrade over time as new tissue forms, promoting natural healing processes.
Metals [30–40] • Titanium alloys (Ti6Al4V) • Tantalum alloys • Magnesium alloys • Cobalt alloys • Chromium alloys	• Selective laser melting • Electron beam melting • Laser-engineered net shaping • Selective laser sintering • Direct metal laser sintering	• Titanium alloy (Ti6Al4V) is the most commonly used biomaterial for additive fabrication of orthopedic implants. Hip implants, knee implants, bone fracture fixation plates, etc., are common metallic implants. SLM and EBM are the most utilized AM system to manufacture metallic implants. • Tantalum alloys, such as Ta-10%W, are utilized in orthopedic implants for their excellent biocompatibility, corrosion resistance, and radiopacity. Tantalum implants are commonly used in orthopedic applications such as hip and knee replacements, spinal fusion, and bone defect reconstructions. • Magnesium alloys exhibit biocompatibility and biodegradability, making them attractive for orthopedic implants intended to degrade over time as new tissue forms. • Cobalt-chromium (CoCr) alloys are commonly used in orthopedic implants for their excellent wear resistance, strength, and biocompatibility. • CoCr implants, such as CoCrMo, are particularly suitable for articulating surfaces in joint replacements and components requiring high strength and durability.

Table 1 [cont.]

Biomaterial	AM methods	Description
Ceramics [41–43] • Alumina • Zirconia • Calcium phosphate (CaP) • Hydroxyapatite (HA)	• Plasma spraying • Solution-based coatings • Vapor deposition techniques	• Ceramics in orthopedics implants are often used for the surface coating to provide high fatigue strength. The biomaterials of this group have excellent tribological properties. The coating of ceramics on metallic implants reduces the aseptic loosening of the implant. • Alumina (aluminum oxide) ceramics are known for their excellent mechanical properties, including high hardness, strength, and wear resistance. In orthopedic applications, alumina implants are commonly used for hip and knee replacements due to their biocompatibility and low wear rates. • Zirconia (zirconium dioxide) ceramics exhibit high strength, fracture toughness, and biocompatibility, making them suitable for orthopedic implants. • Calcium phosphate ceramics, including hydroxyapatite (HA) and tricalcium phosphate (TCP), closely resemble the mineral composition of natural bone, promoting osseointegration. In orthopedics, CaP ceramics are used as coatings on metal implants or as standalone bone graft substitutes to enhance bone regeneration. • HA coatings facilitate early bone formation and integration with the implant surface, reducing the risk of implant loosening and improving patient outcomes in orthopedic surgeries.

splint. The splint works for six months without any significant wear and tear. In another similar, the thin-wall dental coping was designed by Syam et al. (2012) [48]. The metal-ceramic thin wall dental coping was additively fabricated for crown restoration. The average hardness and thickness of coping achieved are 333.35 HV and 0.52 mm, respectively. Generally, metals are used for making dental implants and crown copings. Biomaterials and additive manufacturing methods for dentistry applications are listed in Table 2.

Wu et al. (2012) [49] used additive manufacturing to fabricate a mold using a sacrificial pattern. Chromium-cobalt alloy was then cast into the mold to make a removable partial denture framework. They used the LPS 600 SLA system. Fantini et al. (2015) [50] designed atrophic maxillary arches of titanium alloys using FDM and DMLS rapid prototyping systems. Two different approaches were used to fabricate titanium mesh to aid the prosthetically guided bone regeneration in two patients with atrophic maxillary arches. Sufficient bone regrowth was observed for dental implant placement. A patient-specific jaw implant of titanium alloy was additively fabricated layer wise, Leuven, Belgium, for the first time using the selective laser melting process [51]. Li et al. (2005) [52] optimized the dimensional parameters of laser-densified dental porcelain bodies for additive fabrication. For a 25-year-old patient with skeletal Class II occlusal characteristics, Wang et al. (2017) [53] developed a personalized dental mini-screw surgical template using CAD system and additive manufacturing. To provide controlled anterior retraction, two titanium double treaded mini-screw (diameter, 1.8 mm; length, 8 mm) were inserted using 3D printed polymeric surgical template at canine-second premolar space of both, right and left buccal sites, as shown in Fig. 5.

3.3. Cranial and maxillofacial implants

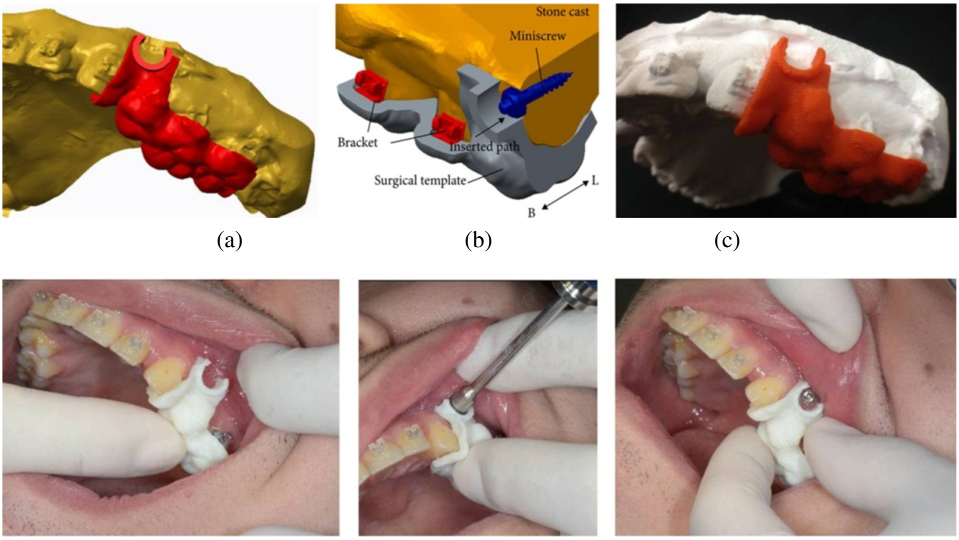
In cranioplasty, any deformity of the skull due to traumatic injury can be treated with surgery and the application of a suitable cranial or maxillofacial implant [77]. The benefits and technical efficacy of combining computer-aided design (CAD) and AM techniques for the production of maxillofacial implants and guides were explored by Peel and Eggbeer (2016) [78]. The fabrication time and cost were compared for three alternative additive fabrication workflows and implant designs. They found that a semi-digital approach results in the shortest duration and the lowest cost for the fabrication of such cranioplasty implants and guides. Yaxiong et al. (2003) [79] developed a patient-specific mandible substitute using reverse engineering and rapid prototyping techniques. The result showed that a customized mandible fits well and is time-saving to substitute in comparison to a conventional implant. Hieu et al. (2003) [80] suggested some design methods for additive fabrication of customized cranioplasty implants to cure all types of cranial defects. These methods include both types of data – solid bone models (in STL file format) and bone slice contours (in IGES and SSL file formats). Rukskul et al. (2019) [81] studied porous cranial implants fabricated by 3D printing technology

Table 2. List of biomaterials and AM technologies for dentistry applications

Biomaterial	AM methods	Description
Polymers [53–59] • Poly lactide • Poly caprolactone • Poly glycolide • Acrylate photopolymers • Acrylonitrile butadiene styrene (ABS) • Polyesters • Polypropylene • Polycarbonate	• Fused deposition modelling • Stereolithography • Electro hydrodynamic jetting	• PLA's compatibility with 3D printing technologies enables the fabrication of custom dental models, prosthetics, and orthodontic appliances, offering precision and efficiency in dental treatments. • PCL is a biodegradable polymer with low melting point and good mechanical properties. Its biocompatibility and biodegradability make it suitable for temporary dental implants, scaffolds for tissue regeneration, and drug delivery systems in dentistry. • PGA's ability to degrade into non-toxic byproducts makes it suitable for resorbable dental implants, sutures, and bone graft materials. While less commonly used in 3D printing compared to other polymers, PGA can be incorporated into composite materials for dental applications to enhance mechanical strength and degradation kinetics. • Acrylate photopolymers are UV-curable resins commonly used in stereolithography (SLA) and digital light processing (DLP) 3D printing technologies for dental applications. They offer high resolution, accuracy, and surface finish, making them suitable for fabricating dental models, crowns, bridges, and temporary restorations with fine details. • ABS is a thermoplastic polymer known for its toughness, impact resistance, and dimensional stability, commonly used in dentistry for manufacturing dental appliances and equipment. • Polyesters, Polypropylene, and Polycarbonate are less commonly used in 3D printing for direct dental applications due to its processing challenges.
Metals [60–67] • Titanium alloy • Aluminum alloy • Stainless steel • Cobalt-chromium alloy	• Selective laser sintering • Selective laser melting • Direct metal laser sintering • Direct metal deposition	• Metals are generally used for maxillofacial implants. Cobalt-chromium alloy is being used to fabricate the metal crown copings using the selective laser sintering method. • Titanium alloys are widely used in dentistry for their excellent biocompatibility, corrosion resistance, and mechanical properties. • Stainless steel alloys, such as 316L, are commonly used in dentistry for various applications, including orthodontic appliances, dental instruments, and temporary crowns. While not typically used for permanent dental implants due to its aesthetic limitations, stainless steel is valued for its affordability and versatility in dental practice. • Cobalt-chromium (CoCr) alloys are employed in dentistry for their high strength, wear resistance, and biocompatibility. CoCr alloys are commonly used in removable partial dentures, dental crowns, and dental bridges due to their durability and compatibility with oral environments.

Table 2 [cont.]

Biomaterial	AM methods	Description
Ceramics [68–70] • Alumina • Zirconia	• Stereolithography • Selective laser sintering • Inkjet 3D printing • Thermoplastic printing • Multi-jet printing	• These are corrosion-resistant and bio-inert materials having the same color as the tooth. Commonly used for fabrication of dentures and crowns. • Alumina implants offer long-term stability and durability, making them a reliable choice for dentistry applications. • Zirconia implants are utilized in dental applications for crowns, bridges, and dental implants, and they are increasingly explored for orthopedic use.
Hydrogels [71–76] • Photo-cross-linkable gels • Reinforced-composite polymers • Low viscosity cell slurries • Polyacrylamide (PAM) • Polyethylene glycol (PEG) • Poly 2-hydroxyethyl methacrylate (PHEMA) • Poly (vinyl alcohol) (PVA)	• Stereolithography • Electro hydrodynamic jetting • Inkjet 3D printing	• Hydrogels are three-dimensional networks of hydrophilic polymer chains are capable of retaining large amounts of water within their structure. In dentistry, hydrogels are utilized for various applications, including tissue engineering, drug delivery, and dental restoration. • With advancements in 3D printing technologies, hydrogels can be precisely fabricated into complex shapes and structures, offering tailored solutions for dental needs. • These synthetic hydrogels are used to fabricate porous scaffolds for maxillo-facial grafting. The major use of hydrogels is in tissue engineering of dental and maxillofacial.



(a) (b) (c)

(d) (e) (f)

Fig. 5. 3D printed customized dental mini-screw surgical template (a-b); Solid model and assembly of the surgical template with dental arch (c); Surgical template fitted on the stone cast of the dental arch (d-f) the application of the polymeric surgical template to position the mini-screw with proper stability [53]

and evaluated their post-operative performance. A cranial reconstruction is done using a customized polyethylene implant. The post-operative aesthetics, safety, patient satisfaction, and reactions to the implant were found to be satisfactory. Bone ingrowth was also observed. A case study was conducted by Singare et al. (2005) [82] on the customized chin implant design and fabrication using rapid prototyping techniques. Another case study was done by Gopakumar (2004) [83] on cranial reconstructive surgery. He highlighted the advantages of pre-operative simulation of complex surgeries on medical models.

Park et al. (2020) [84] presented a case report of mandible reconstruction using the selective laser sintering method. A 3D printed titanium implant was used to restore a 53-year-old man's discontinuous mandible deformity. This was a novel approach to mandible reconstruction with pre-mounted dental implants (Fig. 6) to rehabilitate occlusion without postoperative infection until one-year follow-ups. According to Lewin et al. (2021) [85], a mesh-type patient-specific cranial implant made of titanium-reinforced calcium phosphate (CaP–Ti) showed good clinical results. This implant can be fabricated using both laser-beam based powder bed fusion (L-PBF) and electron-beam-based powder bed fusion (E-PBF) processes. However, E-PBF was found to be more time-efficient. Espalin et al. (2010) [86] designed and developed a craniofacial reconstructive implant. Their research looked into whether PMMA might be used to create porous freeform structures using the FDM process for orthopedic spacers and craniofacial repair.

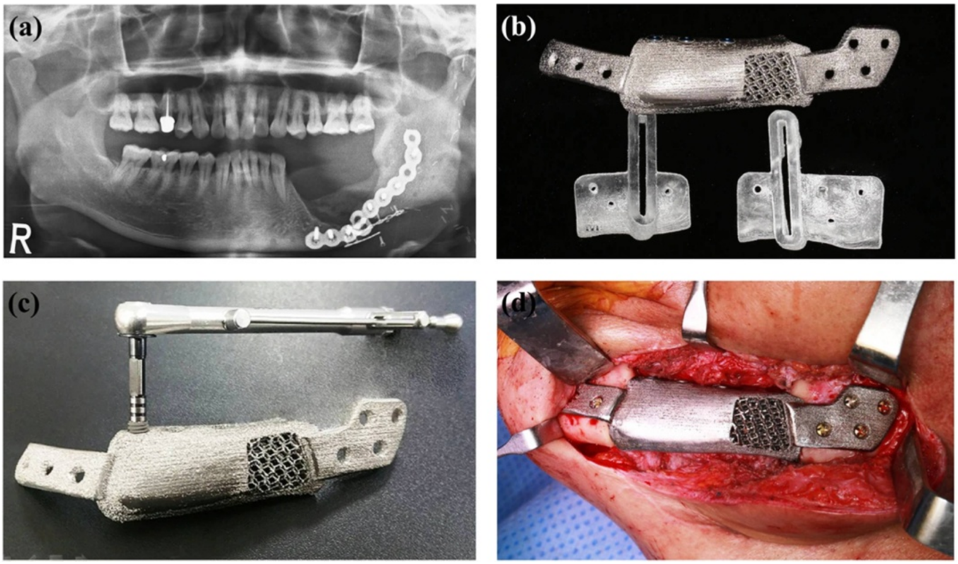


Fig. 6. Mandible reconstruction using 3D printed pre-mounted dental implants (a); Computed tomography image of patient showing pathologic fracture of the left mandibular body (b); 3D-printed titanium mandibular implant and resection guide (c); The titanium mandibular implant installed with dental implant fixtures (d) 3D printed titanium implant was implanted to the resected area of the left mandibular body [84]

A customized mandible implant of extra low interstitial titanium alloy was made by Nasr et al. (2017) [87] to correct a lower jaw fracture using the EBM system. They employed titanium alloy (Ti-6Al-4V) exceptionally low interstitial powder in the size range of 50–100 µm. Fantini et al. (2008) [88] additively fabricated an implant for restoring a defective medieval skull. The cranial implant was created using reverse engineering, CAD, and rapid prototyping methods. A customized maxillofacial implant was created by Singare and Yaxiong (2006) [89] utilizing CAD and AM methods. After creating a 3D reconstruction of the patient's skull using helical computed tomography (CT) data, a CAD model of the implant was created. The result showed that a very good fit, mandible stability, and symmetry were achieved by the customized implant and the time taken for surgery was also reduced. Singh et al. (2023) [90] performed cranial reconstruction for symmetric as well as asymmetric cranial cavities through mirror approach and subD modeling, respectively.

3.4. Scaffold implants

Tissue engineering has attracted the attention of researchers due to its vast potential to repair damaged tissue and organ [91]. In some medical applications, a porous mechanical structure is required to graft into the patient's body where further growth of tissue is required. This porous mechanical structure is known as scaffolds that provide the porous medium for tissue culture. The scaffolds may be non-biodegradable or biodegradable depending on application. Maher et al. (2009) [92] used a bioplotting technique to produce complex scaffolds for tissue engineering. They observed that by adjusting the viscosity, concentrations, and temperature of both the plotting media and the plotting material, the rate of hydrogel gelation may be sped up while being cross-linked. Chu et al. (2008) [93] created a scaffold-based drug delivery system (DDS) using a nano-composite deposition system (NCDS). They employed a biodegradable thermoplastic polymer as the matrix to construct the DDS. The polymer was combined with a bio-ceramic and an anti-cancer medication. Polymer, metal as well as ceramics are available for 3D printing of scaffolds (see Table 3). Collagen-based natural polymers are most widely used for making the scaffold for tissue engineering [94–96]. Pham et al. (2008) [97] developed a new bio-plotter using a rapid freeze prototyping (RFP) technique for the fabrication of tissue scaffolds. They found the RFP method suitable for temperature-sensitive polymers to fabricate macro and micro-porous scaffolds.

Scaffolds are also being used for the treatment of cardiovascular disease using the 3D printed vascular graft of inner diameter less than 6 mm [129]. Using the gelation method and crosslinking chemicals, Gurumurthy et al. (2021) [130] conducted a study to enhance the mechanical properties of collagen-based scaffolds. The key factors influencing the mechanical properties of collagen-based scaffolds, according to Gurumurthy et al., include the collagen source, gelation process, crosslinking methods, crosslinking agents, testing circumstances, and other scaffold additives. Complex wounds are being healed using flexible nano-fibrous scaffolds that can be 3D printed. The electrospinning technology is employed for these purposes to create aligned nanofiber scaffolds for the use in wound dressings [131]. Advances in topology optimization software, range of biodegradable metals and shape memory alloys caught attention of researchers towards additively manufactured metallic porous bone scaffolds. Porous metal scaffolds are implanted to repair critical sized bone defects. The metal scaffolds mostly serve as load-bearing devices. Various porous scaffolds in orthopedic have been developed using AM technologies so far, includes implants like cranial, mandible, hip, femur, knee, spine, etc. [132, 133].

3.5. Other implants

Agarwala et al. (2020) [134] fabricated a thin titanium implant for a patient suffering from a twisted spine. The abnormality led to severe debilitating scoliosis. For correction of this abnormality, the sixth and seventh ribs of the patient were resected. The result of the surgery was excellent except for the intermitted chronic pain that developed due to entrapment of the right scapular. The surgeons found a solution by introducing additive manufacturing to this treatment. A chest wall reconstructive implant of titanium mesh plate of 1 mm thickness was implanted below the ribs to protect the lungs and fill the gap in the chest wall. Several

Table 3. List of biomaterials for tissue engineering application

Nature of biomaterial	Name of biomaterial	Remarks
Natural biopolymer [98–108]	• Collagen • Starch-based polymer powders (cornstarch, dextran, and gelatin) • Chondroitin sulphate • Chitin • Chitosan	• Collagen is widely used as a scaffold material in tissue engineering due to its similarity to natural extracellular matrix. It can be processed into various forms, such as gels, sponges, and fibers, suitable for 3D printing. • Starch-based Polymer Powders are utilized as bioinks in 3D printing for tissue engineering applications due to their ability to form hydrogels, which mimic the extracellular matrix, providing a suitable microenvironment for cell growth and proliferation. • Chondroitin sulfate can be incorporated into scaffolds or hydrogels for cartilage tissue engineering applications, providing mechanical support and promoting chondrogenic differentiation of stem cells. • Selective laser sintering, stereolithography, fused deposition modeling, and direct metal laser sintering are being used for tissue engineering applications. • The microarchitecture of the tissue can be 3D printed via projection Stereolithography using Gelatin methacrylate natural biopolymer.
Synthetic biopolymer [109–118]	• Poly(-caprolactone) (PCL) • Poly(lactic acid) (PLA) • Poly(glycolic acid) (PGA) • Poly(lactic-co-glycolic acid) (PLGA) • Poly(L-lactide) (PLLA)	• Synthetic biopolymers can provide good control of their physicochemical properties. • PCL is commonly used in 3D printing for scaffolds due to its ability to provide structural support, promote cell adhesion, and facilitate tissue regeneration, particularly in bone and cartilage tissue engineering. • PLA is widely used in 3D printing for tissue engineering due to its versatility and ability to form porous scaffolds that support cell attachment, proliferation, and differentiation. • PGA is often used in combination with other polymers like PLA to form copolymers such as PLGA, offering tunable degradation rates and mechanical properties for 3D printed scaffolds in tissue engineering. • These polymers can easily be tailored to get the required specific molecular weight, chemical composition, and structure. • The biodegradation time of synthetic biopolymers is more favorable than natural biopolymers.

Table 3 [cont.]

Nature of biomaterial	Name of biomaterial	Remarks
Metal and alloys [119–123]	**Non-biodegradable** • Stainless steel 316L • Ti and its alloy • Co_Cr alloys • NiTi **Bio-degradable** • Fe, Mg, and Zn alloys	• Selective lase sintering, selective laser melting, electron beam melting, directed metal deposition are being used for preparing metallic porous implant scaffolds. • Non-biodegradable metals and alloys are generally used for making of customized porous cranial implant, femur bone, hip and knee implants. • AM of biodegradable metal and alloys are in their infancy till date. Researcher have tried making porous mandible, heel bone implant as well as porous scaffolds with various pore shape and sizes for bone tissue engineering.
Ceramics [124–128]	• Calcium silicate • calcium phosphate • hydroxyapatite • tricalcium phosphate (TCP) • mesoporous bioglass • Zirconia • Alumina	• Binder jetting, material jetting, fused deposition, SLA, SLS are being employed to print ceramic scaffolds. • Hydroxyapatite is very close to natural bone material and is researched for making of porous bone scaffolds. • Researchers are trying to make ceramic-ceramic and ceramic-polymer composites to impart mechanical strength matching with cortical bone. • Slow degradation rate is still an issue for ceramic scaffolds.

models of the ribs and the cavity were additively fabricated for pre-operative study and planning of surgery in order to make this treatment successful. Sisias et al. (2002) [135] suggested rapid prototyping techniques to replicate the reconstruction of cancellous bone samples.

A customized tracheal stent was additively fabricated by Melgoza et al. (2014) [136] using fused deposition modeling (FDM) machines and medical-grade silicone. Swann et al. (1996) [137] investigated the connection between MRI data and stereolithography to produce models of human anatomy. Soni et al. (2018) performed finite element analysis of human knee joint for additive manufacturing of the knee implant [138]. Modi and Khare (2022) [139] fabricated a customized wrist splint using polyamide material via reverse engineering and selective laser sintering process. Chen et al. (2004) [140] fabricated an artificial bioactive bone using an additive manufacturing technique. They proposed a method to additively fabricate a mold of artificial bone. Bibb et al. (2009) [141] reported the application of SLM to the manufacturing of surgical guides made of stainless steel. Increased wear resistance, enhanced rigidity, and easier sterilization are some critical properties of the material that should be present in the surgical guides. The SLM was successfully used by them to fabricate the surgical guides for four different case studies on maxillofacial surgery. They used 316L stainless steel to fabricate the surgical guides. Many researchers analyze the additively fabricated customized foot orthoses for individuals with flatfoot [142].

4. Accuracy of medical implants

A rapid growth in the demand for the customized implant has been observed in past couple of years. Additive manufacturing is successfully being applied to fabricate the complex geometry of the patient-specific implant. Although, the AM is a very accurate, versatile, and cost-effective technique, final quality of the fabricated implant is dependent on several factors, such as quality of image captured, 3D reconstruction of virtual model, selection of STL file parameters, etc. Van Eijnatten et al. (2017) [143] studied the effect of various CT scan parameters on the accuracy of the STL model. They assessed the image quality taken by different CT scanners and the accuracy of STL models of human skulls. Kwon et al. (2020) [144] discussed the accuracy of additively printed guides for an orbital implant to reduce post-operative complications during the treatment of the orbital fracture. They used the Bland-Altman plot to perform statistical evaluation. Mallepree et al. (2009) [145] generated facsimiled rapid prototyping models for medical analysis. They found that the accuracy of a medical model can be significantly enhanced by editing the CT images during 3D reconstruction. The circular shape like spheres, cylinders, and holes is less accurate when fabricated by the FDM method. The parts fabricated by the FDM method exceed the tolerance limit of (±0.127 mm) [146]. The accuracy of additively fabricated aligners using the SLA process is independent of print orientations and post-curing duration also has no significant effect on the accuracy of aligners [147]. The range of thresholds used for reconstruction affects the accuracy of the implant. Some tools like 'smoothening' and 'wrapping' can be used to enhance the accuracy of the implant.

5. Advancement in medical applications of additive manufacturing

Additive manufacturing has become a giant pillar to help the medical field with its potential to fabricate complex prototypes easily. Nowadays, several medical practitioners are using additive manufacturing for creating surgical tools and templates, customized implants and prostheses, and for preoperative surgical planning [148]. Many researchers are working on the development of customized prostheses to help patients with missing body parts. Ige et al (2022) [149] have 3D printed the patient-specific smart hand prosthetic. The electroencephalogram (EEG) signals were recorded from the scalp and used to make the prosthetic limb smart [149]. Wei Peng et al. (2020) [150] used a novel treatment strategy to cure patients with pelvic tumors using 3D-printed anatomically conforming pelvic prostheses.

Additive manufacturing is very successfully being used in tissue engineering. Many researchers are using additive manufacturing in cardiovascular tissue engineering to fabricate porous vascular grafts or scaffolds [151, 152]. Great advancement has been seen in the field of four-dimensional (4D) bio-printing. Many researchers are working to develop multifunctional smart materials for bio-applications of additive manufacturing. The dynamic scaffold is also being developed to get the morphological changes in the cultured tissue. 4D printing is a promising and powerful technique for the development of bio-functional tissue printing [153–159]. Macromolecular crowding (MMC) controlled extracellular matrix (ECM) accumulation in a bio-printed human rhabdomyosarcoma model was an aspect of a study by D'Agostino et al. [160].

6. Conclusions

Additive manufacturing has emerged as a promising tool for fabricating customized medical implants due to its capability to fabricate structures of complex external shapes and intricate internal architectures. Availability of topology optimization software further paves the path of producing strong yet light customized metallic implants. Major findings from this literature review are summarized below:

- AM has a very good potential for fabrication of medical implants due to its capability to produce complex and customized implants. It has been observed that titanium alloy is a suitable material for cementless arthroplasty.
- Some orthopedic and arthroplasty implants require porosity for better bone regrowth to reduce stress shielding. A designed porosity with the required pore size and distribution of pores can be provided in the implant by AM systems.

- It has been observed that the accuracy of additively manufactured implant depends on CT scan, method of 3d reconstruction, and 3D printing process. A careful selection of relevant parameters is inevitable for obtaining geometrically accurate implant.
- AM provides geometric freedom to researchers for exploring the complex design of an implant for better bone regeneration. The ability of AM to fabricate patient-specific implants allows surgeons to explore alternative methods for treating the patients.
- AM in tissue engineering has a huge potential for further research and development of smart biomaterials to repair tissue and/or organ. Cardiovascular tissue engineering has recognized AM as a great tool to fabricate customized vascular grafts.

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