Journal of Pharmacology & Pharmaceutics

Review Article

Surgical Applications of In-House Additive Manufacturing (3D Printing)

Adam Major[1], Kevin Sneed[2] and Yashwant V Pathak[2,3]*

[1]*Judy Genshaft Honors College, University of South Florida, USA*

[2]*Taneja College of Pharmacy, University of South Florida, USA*

[3]*Faculty of Pharmacy, Airlangga University, Indonesia*

Abstract

Additive manufacturing (AM), also known as 3D printing, is an unconventional manufacturing method that is applied in many fields, including medicine. Although AM is not as efficient as subtractive manufacturing for mass production, its high degree of personalization, rapid manufacturing and design time, flexibility with regards to structural limitations and material choice, relatively lower skill ceiling, and lower cost for small-scale fabrication makes it an appealing option for in-house 3D printing. This article reviews previous applications of in-house small-scale AM and expands upon the reasons why 3D printing was adopted in each case. To date, in-house AM has been used to make common or specialized surgical instruments, surgical guides and templates, biologically active and passive implants, and postoperative supports such as splints for cranial, oral, maxillofacial, and orthopedic surgery. Customization was the most commonly enunciated reason for the adoption of AM for these applications, as the combination of AM with medical imaging allows for the comparatively simple manufacturing of high-quality patient-specific medical devices out of biocompatible materials such as titanium, which are difficult to subtractively manufacture with a high degree of precision. Cost, manufacturing speed, material choice, and favorable biological activity with implants are also cited as reasons for the selection of 3D printing in the reviewed cases. Small-scale surgical AM does also face regulatory, functional, and ethical challenges, along with a limited amount of valid data. These findings indicate that in-house AM permits the efficient manufacturing of superior medical devices. Significant growth is expected in the coming decade in the fields of bioprinting and AM-related tissue engineering for surgical applications.

Keywords: 3D printing; Additive manufacturing; Customized splints; Implants; Medical modeling; Personalized medicine; Surgical guides; Tissue engineering

Introduction

Additive Manufacturing (AM), known more colloquially as 3D printing, is a manufacturing process by which a part or device is built up in layers directly from a raw material [1]. Unlike other manufacturing processes like laser cutting and machining, where raw material is trimmed down from its original size and shape into the desired form, AM starts from nothing and additively builds up raw material into the desired form [1]. Although AM has its roots in the automotive, architectural, and packaging industries, it can be quite effectively applied to medicine, as it is easier to obtain a high degree of customization and complexity [2]. Certain fields in medicine, such as orthopedics and oral/maxillofacial surgery, require a very high level of customization for their devices and implants, and thus benefit greatly from AM [1]. 3D printing technologies help fulfil the demand for tailored devices that is only inefficiently satisfied with standard subtractive manufacturing techniques [3]. In order to make a part or device using AM, a 3-dimensional model of the device or part must first be made, either using a scan or computer-aided design [1,4,5]. Following the completion of the model, some software-guided pre-processing is also required before the part can be manufactured, and after the manufacturing process some post-processing is also necessary [1,5]. The specific AM process selected depends on the material used (polymer, ceramic, or metal), the required precision, and the desired cost. A large number of AM processes have been developed and some of these can be applied to medical applications: Stereolithography (SLA), Selective Laser Sintering (SLS), Electron Beam Melting (EBM), Direct Metal Laser Sintering (DMLS), Fused Deposition Modeling (FDM), and inkjet 3D printing [3]. SLA uses ultraviolet light to selectively harden liquid resin materials, and is one of the cheapest and most available polymer-based options. SLS is an AM process where a laser hardens the top layer of a bed of powder, and can be used to make parts in a variety of materials, including polymers, ceramics, and some metals [3]. EBM and DMLS work similarly to SLS except they are made more specifically for metals like titanium, which require more extreme conditions [3]. FDM is the most common commercially available type of 3D printer, and it functions by melting a polymer filament through the application of heat. Inkjet printing functions by depositing droplets of a fluid, and is commonly applied with heat-sensitive materials, such as with bioprinting [3,6]. The last ten years have seen a dramatic increase in attention to AM processes for medical purposes: for instance, the quantity of research published about AM with relation to pelvic surgery increased five-fold between 2015 and 2020 [7]. This trend in heightened awareness and usage of 3D printing technologies is also present in oral and maxillofacial surgery and orthopedics [3,8]. There are multiple reasons why AM has garnered attention in recent years. Firstly, AM is extremely conducive to customization, as there are little to no significant changes in the manufacturing process from one model to another [9]. This customization is made even easier when AM is used in concert with 3D medical

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Citation: Major A, Sneed K, Pathak YV. Surgical Applications of In-House Additive Manufacturing (3D Printing). J Pharmacol Pharm. 2024; 1(1): 1002.

Publisher Name: MedClinics Journals

Received: May 06, 2024; **Accepted:** May 28, 2024; **Published:** May 31, 2024

***Corresponding author:** Yashwant Pathak, Taneja College of Pharmacy, University of South Florida, Tampa FL 33612, USA, Faculty of Pharmacy, Airlangga University, Surabaya, Indonesia, E-mail: ypathak1@usf.edu

imaging, since the 3D model used for the AM is already patient specific from the CT or MRI scan [10]. Cost is also a commonly-cited reason for using AM. As 3D printed materials are often cheap and disposable, AM decreases the requirement for unnecessary sterilization or the expense of expensive personalized instruments from conventional manufacturers [9]. A third reason that many physicians are looking into AM is its status as a rapid prototyping technology. 3D printing offers a faster fabrication process than conventional manufacturing, usually to less than 24 hours, thereby decreasing the amount of time between prototypes of a device and shortening the design process significantly [2,9]. AM is also used because it can manufacture parts in a variety of materials, most notably MRI-compatible and biocompatible materials like Polylactic Acid (PLA) and polyamide 12 (PA2200), making additively manufactured implants an attractive proposition [3,6,9,11-14]. Some other reasons for 3D printing's popularity in the medical field include its ability to increase accessibility to healthcare in remote areas, the possibility to easily test prototypes, and difficulties with conventional fabrication of certain devices [9].

In surgical settings, in-house 3D printing is used for manufacturing four primary classes of medical instruments: surgical tools, guides and templates, implants, and splints [1]. In addition, the field of tissue engineering can be readily applied to AM, allowing for the printing of biologically active substrates, from drugs and naturally derived materials to stem cells [2,4-6,14-16]. Surgical tools are instruments used directly by a surgeon, such as forceps or scalpels. Templates are 3D printed parts that are used to simulate the surgical site before surgery and plan out the procedure in advance, whilst guides are similar parts except, they are meant to guide the surgeon during the surgery and ensure successful placement of implants or incisions. Additively manufactured implants are 3D printed devices or parts that are meant to stay in the patient's body permanently or semi-permanently after the surgery. Splints are known under different names, such as "casts", "braces", or "covers", based on the type of procedure and the part of the body that was operated on. In all of these cases, they are 3D printed parts that are meant to temporarily isolate and/or immobilize a surgical site after surgery. In this document, each of these will be discussed, with a special focus on their applications to oral and maxillofacial surgery and orthopedics, followed by a review of some of the recent advances in the fields of tissue engineering and bioprinting and their implications for surgery in the future.

Surgical Tools

3D printing can firstly be used to cheaply and rapidly make standard surgical instruments, including forceps, scalpels, hemostats, or retractors [9]. Due to the simple shape and function of such tools, a more inexpensive and imperfect type of 3D printer, such as an FDM or SLA can be used to efficiently and rapidly make disposable surgery kits at a nonprohibitive cost. The use of more sophisticated AM technologies, such as SLS, can be an alternative to ordering permanent medical instruments [9]. A mechanical testing study performed by Lewandowski and Seifi demonstrated that, for mechanical properties tested, metal 3D printed parts usually meet or exceed the properties expected of standard subtractive manufacturing processes [17]. Therefore, access to a SLS, EBM, DMLS, or other metal-substrate 3D printer allows for the manufacturing of standard surgical instruments of a quality on par with externally sourced instruments. Additionally, 3D models for such common tools are now commonplace online, and can be bought inexpensively from companies such as Sketchfab and TurboSquid, if there is no expert in computer-aided design in the surgical setting. Multiple types of AM can also be combined to make a single instrument. For example, Băilă used a combination of DMLS and SLA to make a dental elevator: DMLS was used to make the beak of the elevator, and SLA was used to make the handle [18,19]. A more exclusive benefit in the use of AM for the manufacturing of surgical tools is the extension of existing surgery tools or design of novel surgery instruments. Different extensions for a more complex tool can be easily manufactured to improve the performance of the instrument in specific situations [9]. For example, a variety of caps for a conventional gastroscope can be additively manufactured to allow the surgeon to more easily perform different types of biopsies [9]. The nature of computer-aided design makes it relatively simple to design new instruments, and the high speed at which AM operates allows for rapid prototyping. Most AM processes have a far more rapid fabrication process than conventional manufacturing [9]. This allows for a dramatic reduction in turnover time between design iterations as the results of each design phase are apparent almost immediately. One example of an instrument designed using AM is a tool that estimates the probe size necessary for a lumpectomy, a breast cancer removal procedure, in order to limit the amount of probes that are unnecessarily desterilized through trial and error [9]. The nature of AM has also allowed for the advent of completely new devices that would be nearly impossible to fabricate by conventional methods [9]. The most promising and prevalent class of AM-specific surgical instruments are those known as steerable devices [9,20]. In recent years, there has been much attention drawn to the side effects caused by invasive surgery, such as heightened risk of infection and hemorrhage, lengthened hospitalization time, and increased pain for the patient [20]. The solution to limiting these side effects is Minimally Invasive Surgery (MIS), where instruments are inserted through two to three small incisions between 5 and 10 mm [20]. However, this strategy limits the surgeon's ability to visualize the operation site and move the instruments freely by limiting the amount of degrees of freedom [20]. Steerable instruments help solve this problem by allowing for complex flexion along the length of the instrument, thus increasing the degrees of freedom available to the surgeon [9,20]. Such devices are almost impossible to make by conventional fabrication methods, and require AM to be effectively created [9,20]. These 3D printed instruments can be personalized based on the surgeon's hand size and the procedure to be executed [9,20]. They have been shown to lead to shorter execution times and improved hand-eye coordination for surgeons [20]. Overall, AM is very useful for the fabrication of standard, personalized, and steerable medical devices.

Medical Modeling

Some instruments, like the surgical tools mentioned above, incorporate little to no information about specific patients in their fabrication. However, the majority of tools made with AM are personalized for the benefit of each patient, and thus require more precise physical measurements from patients to be effective. Medical modeling is the factor that bridges the gap between the patient and the additively manufactured instrument [3,21,22]. The combination of medical imaging technologies, including Computed Tomography (CT) and Magnetic Resonance Imaging (MRI), and additive manufacturing results in parts that are uniquely suited to each patient [21,23]. Medical imaging provides a large amount of spatial information on the treatment area for the patient in a suitable format for stereolithographic reproduction [11,21,24]. The medical models that result from this reproduction can then be leveraged with AM techniques to make an extensive variety of models, templates, guides, implants, and splints [1,3,22]. In order to make a medical model, a CT or MRI scan must be obtained of the patient, encompassing the treatment area [22,23]. The file obtained is then stored digitally as a Digital Imaging and Communication in Medicine file, or DICOM file [22,25]. Firstly, this file must be filtered to separate the tissue of interest from other tissues [26]. Next, the filtered file must be converted from an image format to a 3D model [26]. DICOM files cannot be processed directly by a Computer-Aided Design (CAD) software, because CAD software's can only modify and aid visualization of 3D models, which DICOM files are not [26]. These two steps are resolved together through a process known as segmentation [1,24,26]. Segmentation can be performed by a number of softwares dependent on the tissue and application of interest, including but not limited to 3D Slicer, Mimics, Magics, 3D Doctor, OsiriX Imaging Software, and InVesalius [13,24,26,27]. Following this process, the DICOM file obtained will be converted into a 3D model file, often in Standard Tessellation Language (STL) format, [22]. This 3D model can then be manipulated within the CAD software to make personalized parts for AM. One of the simplest ways this model can be useful is through 3D printing templates for educational purposes or mock surgery planning [11,24,28]. Physical models of large areas, such as models of an entire organ, can be used to aid patient visualization of conditions and procedures [24]. Smaller models with more limited scope can be used to help engineers and developers in their design process [11]. Surgeons can also benefit from patient-specific anatomical models to more effectively visualize and anticipate challenges for more unconventional or technically difficult surgeries, such as those present in hand surgery [28]. For example, a 3D printed model can accurately show joint dislocations and fragmentations in bone structures and give the surgeon a better understanding of that patient's anatomy [3]. Another use of these 3D models, especially in the field of orthopedics, is the ability to make patient-specific instruments [22]. For some surgeries, it can be quite helpful to have tools that conform precisely to the bone anatomy of the patient in order to more effectively and accurately execute complex surgeries, such as difficult osteotomies [22]. These custom tools can facilitate the accurate alignment of parts, thereby improving operating efficiency [3]. To sum up, medical imaging makes an effective synthesis with AM technology to allow for maximal leverage of medical models.

Surgical Guides

Surgical guides were one of the first applications of AM technology because they naturally lend themselves to the easily personalizable and rapid 3D printing process. Many orthopedic and orthognathic surgeries require very precise placements of cuts and burr holes in hard tissue, primarily bone tissue [28-30]. In addition, these precise cuts or drill holes often must be made in hard-to-reach areas with low visibility and hindered degrees of freedom. For orthognathic surgeries, cosmetic concerns with regards to visible facial scarring severely limits the angle at which the mandible and maxilla can be viewed and accessed, strongly incentivizing virtual surgical planning with digitized 3D models and the implementation of surgical guides to ensure screw placement and the accuracy of sectional planes [21,29,30]. Optimal section locations and angles for osteotomies or tumor resections are often difficult to visualize while orthopedic surgery is in progress due to the nondescript appearance of pathological bony tissue and hindered visibility from anatomical limitations [25,28]. In orthognathic surgeries, guides are often used in order to correctly space drill holes for screw placement in the jaw and to ensure sections are at the right location and angle for each particular patient [21,29,30]. One example of guide usage in maxillofacial surgery is for dental implant placement. Kumar developed a surgical template to plan implant placement for a patient with completely missing mandibular teeth, which doubled as a surgical guide to ensure that the implants were aligned with the hardest bone in the jaw during surgery [21]. They used data from a CT scan of the patient to determine the locations with the strongest bone, then developed a complementary guide with holes above those locations using CAD software [21]. Another study on orthognathic guides and implants by Sembronio indicated that the use of additively manufactured patient-specific guides helped ensure the accurate positioning of Temporo-Mandibular Joint (TMJ) implants [30]. Although randomized control study data is lacking, current clinical evidence suggests that surgical guides made using AM can effectively promote good alignment for sections and screws in maxillofacial surgery [29]. This suggests that AM is an effective method of making patient-specific guides for various types of craniofacial and dental surgery. In orthopedic surgery, AM has been used to make Surgical Cutting Guides (SCG) for the facilitation of pelvic surgery [25]. A digital chain methodology for making such additively manufactured SCGs has been devised by Biscaccianti for any pelvic tumor resections from a CT or MRI image of the patient's treatment area [25]. These SCGs helped surgeons align their cutting implements at the correct location and angle to more precisely and rapidly resect tumors in simulations of each major type and presentation of pelvic tumor [25]. The data and workflow presented by this study suggests that it would be possible to make additively manufactured surgical guides to improve efficacy and reliability of other orthopedic surgical procedures as well, as AM can match the anatomy of any part of the patient with reasonable accuracy [22]. For example, additively manufactured guides are beginning to be used to aid hand surgeons reliably perform more difficult surgeries, such as corrective malunions and osteosynthesis of scaphoid fractures [28]. However, like with orthognathic surgery, there is a lack of rigorous data to confirm the effectiveness of orthopedic surgical guides, and the results of studies using such guides are primarily qualitative in nature [28].

Implants

Biomedical implants, especially musculoskeletal ones, are the most common application of AM to surgery. Implants benefit from nearly all of the perks of AM. They require a relatively rapid fabrication process for the implantation surgery to proceed in a timely manner, which can be an issue with conventional manufacturing [2,9]. Implants benefit from being composed of only one part as opposed to as assembly of conventional manufactured parts as it contributes to their mechanical process in the long term [3,9]. The scale of AM is appropriate to many types of musculoskeletal surgical implants [13]. Implants can come in a large variety of shapes and sizes depending on the specific location and application of the implant, making standardized production inefficient [28,31]. Most importantly, implants often inherently require a high level of patient specificity, which is the greatest advantage AM has over subtractive manufacturing [1,3,10,21,24]. Musculoskeletal implants are generally made of metal alloys for hardness, stiffness, long-term durability, and biocompatibility [3,12,13,27,29]. The most common type of alloy used is titanium for its mechanical strength, formability, corrosion resistance, biocompatibility, and low leaching rate [13,27]. Titanium alloys also make few MRI artifacts for postoperative scans and future procedures [27]. Titanium and its alloys are difficult to machine because of their high tensile strength and low ductility, but those very attributes make them excellent materials for AM, as the starting feedstock is the metal in powder form, not solid form [13]. Due to this, titanium-alloy implants made from conventional manufacturing can be cosmetically more unfavorable, less conducive to proper wound closure, and surgically more difficult to implement compared to additively manufactured titanium implants due to less precise tissue interfaces [27]. Other materials used for implants include Cobalt-chromium alloys and high-performance polymers such as Polyether Ether Ketone (PEEK) and Ultra-High Molecular Weight Polyethylene (UHMWPE), which have similar properties [11,32]. One common type of 3D printed implant is a Temporo-Mandibular Joint (TMJ) prosthesis. These implants replace the joint between the jaw and the skull that allows for the opening and closing of the mandible [29,32]. When the bone at the end of the jaw (mandibular condyle) becomes eroded or the jaw is damaged, such as from a bone tumor in the mandible, an implant is necessary to restore normal jaw mobility [29,32]. Due to the large amount of use the TMJ undergoes on a daily basis from eating and speaking, it is essential that any implant to replace the TMJ is stably attached to the bones on both ends and durable enough to last years of constant use [29]. TMJ implants are often additively manufactured for cost and time efficiency as well as to ensure that the interface of the implant with the bones is as form-fitting as possible [29,31]. A CT scan is usually taken preoperatively in order to ensure the model for the TMJ implant complements the bone structure of the jaw and skull [29]. Ideally, TMJ implants are made of titanium alloys for maximum durability, but some models for TMJ implants are made with cobalt-chromium alloys and/or UHMWPE [32]. AM is also used to make cranial implants. In cases with cranial deformities, such as those caused by vehicular accidents, it is necessary to add an implant to replace missing or deformed bone tissue in the skull or ensure proper bone healing after cranial fractures [10,27]. Previously, custom implants made of titanium mesh or bone cement (Polymethyl Methacrylate, PMMA) were used to fill in the bone defect [27]. However, the machined titanium mesh is cosmetically unfavorable and negatively impacts wound closure, while the bone cement had a 50% infection rate following implantation, making additively manufactured titanium implants a more attractive option as it allows for the superior shape of the bone cement with the mechanical and anti-infectious properties of titanium [27]. For AM, a model of a damaged or deformed skull is developed through medical imaging and segmentation, which can then be used to determine the precise shape and size of the missing or deformed piece and make an implant to complement the intact section of the cranium [26]. This implant can then be additively manufactured with SLS or DMLS [26,27]. These implants, if properly designed, can be significantly more form-fitting than conventional implants [26]. Implants can be manufactured in mesh form as well to ensure proper fracture healing, such as orbital plate fractures, while maintaining sufficient mechanical properties [13]. Other implants made with AM include dental implants and various types of orthopedic implants. A study by Bae comparing conventionally casted and additively manufactured dental prostheses demonstrated that 3D printed Cobalt-Chromium implants and crowns are reliably within the margin of error applied to conventional implants [33]. A stochastic model developed by Zahan and previous experiences with additively manufactured hip replacement implants suggests that AM could be a cost-effective and durable alternative for standard hip implants [13,31]. Lastly, 3D printed implants to restore mobility and function to areas with bone defects, such as in the hand and other joints [22,28].

AM and Tissue Engineering

Tissue engineering is an important emerging field when discussing AM in surgical settings. Unlike standard transplant or implant strategies developed up to date, tissue engineering attempts to fabricate functional constructs that incorporate more seamlessly with surrounding tissue in order to improve that tissue's function [14]. This is done through the use of various biomaterials and/or biologically active products in implants to improve their biocompatibility and bioactivity [14]. By definition, biomaterials are materials that interact with biological systems [14]. In practice, those biomaterials used are materials to which the human body reacts favorably, compared to other materials [14]. An example of a biomaterial described previously is titanium, due to its chemically inert and stable nature. However, many more biomaterials exist for different purposes, including other metals, ceramics, synthetic and biological polymers, and even human cells [38]. In tissue engineering, a combination of carefully structured biomaterials and embedded drugs help induce short and long-term incorporation of implants [2,15,16,34]. Porous biostructures are an important contribution of tissue engineering to surgery. AM can be used to fabricate not only solid implants, but also implants with complex internal structures [15,23,34]. These porous biostructures change the material properties of the implant, decreasing their rigidity and increasing their flexibility especially for metal implants, thereby decreasing their stress shielding and providing space for bone regeneration [34]. It is possible to make porous biostructures out of metals, including titanium alloys, Cobalt-Chromium alloys, and nitinol, and out of polymers and ceramics using AM without decreasing their material properties below the point of viability [34]. Porous biostructures additionally allow for incorporation of drugs for long-term release within the implant [16]. By adding antibiotics to the inside of a 3D printed porous implant, it is possible to inhibit the growth of bacteria on or around the site of implantation for days or weeks [16]. These antibiotics are occasionally added directly to the inner layers of the implant, but more common research suggests that incorporated drugs are more effective when applied as a coating to nanoparticles, which are in turn embedded in the implants [16]. In addition, the antibiotics are localized at the site of surgery, and may reduce or eliminate the need for systemic antibiotics in the future [16]. For example, a study by Manjunath of a porous biostructure proposed to improve stability in the mandible made of a Polycaprolactone (PCL) matrix embedded within a PLA matrix was demonstrated to have adequate rigidity and flexion parameters, low cytotoxicity, and the ability to perfuse drugs through the addition of the porous PCL matrix [15]. Biomaterials can also be selected and designed to allow cell perfusion and be degradable in the long term. By designing the internal structure of implants to mimic the extracellular matrix, these can encourage surrounding cells to invade the region [23]. These types of implants are often called 'scaffolds' [4,5,15,23,34]. The addition of growth factors to the scaffold or the pre-colonization of the scaffold with regenerative cells can also encourage the invasion of cells from the implantation site into the implant [23]. When using softer and more biodegradable biomaterials, like most biologically derived polymers, it is possible to plan for the partial or complete degradation of the scaffold as cells perfuse throughout it, especially when the surrounding tissue is relatively rigid, like cartilage or bone [4]. A study by Kilian developed a proof-of-concept project and workflow for additively manufacturing a biodegradable implant out of alginate-methylcellulose (algMC) blend and calcium phosphate cement to fill in osteochondral defects [4]. This article also discussed the possibility of incorporating bioprinting to seed regenerative cells into the implant in order to encourage rapid cell perfusion [4].

Bioprinting is AM using biological substrates, such as living cells [2]. Generally, these substrates are composed of a type of cell held in nutrient-rich hydrogel, a mixture known as a bioink [2]. The field of bioprinting as a whole transcends the scope of this article, but it is still worth elaborating upon some applications of bioprinting to surgical implants. Bioprinting has been used to make artificial bone, cartilage, and heart valves by seeding the patient's cells onto a neutral template or scaffold (as in, an AM support structure and not an implant specifically) [5]. One example of this is the seeding of human aortic valve interstitial cells onto a hybrid manufactured (AM and subtractive manufacturing combined) template valve [5]. Bioprinting has also been used to incorporate drugs and patient-derived cells into bioprinted implants made of collagen in order to further reduce inflammation and immune response from the body at implantation sites [2]. However, there are still a number of issues still to be resolved when considering bioprinting. The bioprinting process can exert shear of cells, increasing the risk of lysis, and the bioinks may contain toxic materials, among other drawbacks [2]. Overall, tissue engineering and bioprinting are important fields to pay attention to when considering the use of AM for surgical purposes.

Splints

AM can be used to make postoperative supporting structures or prosthetics as well as implants and guides. After surgery, it is often important to keep the surgery site immobile and/or isolated from the environment to avoid dislocation, ensure wound closure, and prevent infection [6,28,35-37]. AM techniques can be used in order to make effective supports for these purposes with more personalized and convenient structures than conventional manufacturing [28]. In some cases, it may be most beneficial to combine AM and conventional manufacturing in order to make the most cost-effective and clinically rigorous splints [1,37]. An example of this would be a 3D-printed polymer mold that is then filled with another material for increased rigidity or on-the-spot fitting [37]. The first type of postoperative support that can benefit from AM is skin wound bandages [6]. Most bandages only interact passively with the wounded tissue underneath, absorbing discharge and blood from the wound and isolating the site from the environment to prevent infections [6]. When considering acute or chronic wounds, however, passive bandages may not be sufficient to ensure rapid and effective wound closure [6]. AM can be used to make "smart" bandages made out of synthetic hydrogels, which interact actively with the wound [6]. These bandages can react to temperature, pH, electric and magnetic fields, light intensity, and biological molecules to promote swelling or collapse [6]. In addition, they mimic the cell micro-environment, are resistant to dehydration, and can be tissue-engineered to include drugs [6]. All of these factors contribute to synthetic-polymer-hydrogel-based bandages' ability to heal skin wounds more rapidly [6]. Using AM in fabricating these hydrogel dressings allows for rapid fabrication, facilitates drug incorporation within the hydrogel, creates porosity necessary for high water-uptake capacity, and grants the bandages improved antibacterial properties [6].

Another post-operative application of AM is in ensuring the immobilization of surgical sites. This is especially important in orthopedic surgery and hand surgery for the proper healing of bone fractures, such as wrist fractures [28,35-37]. The current solution for fractures in the forearm and wrist is most often the use of a fiberglass cast, called a splint, molded around the site [28,35-37]. This splint is often heavy, cosmetically unfavorable, uncomfortable, and malodorous [28,35,36]. Additively manufactured splints have been tested as an alternative to fiberglass casts in order to alleviate these negative attributes without increasing costs or compromising on clinical effectiveness and durability [28,35-37]. With the help of a 3D scanner or a CT scan along with a 3D modeling software, casts can be additively manufactured to be more breathable, comfortable, and approximately three times lighter, without compromising on clinical effectiveness [28,35,36]. Additionally, software algorithms have been developed to streamline the process for 3D modeling such casts [37]. A random control study demonstrated an overall higher level of patient comfort and satisfaction for 3D printed splints (using Digital Light Processing (DLP), a technique similar to SLA) as compared to fiberglass casts, along with a higher clinical effectiveness for the additively manufactured splints as compared to fiberglass [36]. A study by Hoggervorst compared the mechanical properties of an AM hand splint to a fiberglass hand splint and found no statistically significant or clinically relevant differences between the two models [35].

Conclusions and Future Trends

In-house additive manufacturing in all its forms can be effective as a solution to fabricate medical devices for surgery. Although AM is a less efficient manufacturing process for large-scale fabrication than the more traditional subtractive manufacturing, it presents notable advantages for small-scale medical manufacturing [1]. These strengths include rapid fabrication, structural flexibility, a wider range of available materials, a simpler design process for personalized parts, and the ability to modulate products' internal microstructures [1,3,9,34]. AM is a low-cost manufacturing solution for disposable surgical tools like scalpels and forceps, while also being an important catalyst of rapid prototyping for steerable and patient-specific instruments due to its high production speed and design flexibility [28]. Medical scans such as CT, MRI, and PET scans are convenient tools to make accurate patient-specific models which can be combined with computer-aided-design algorithms to facilitate the design process for additively manufactured devices [1,13,21,23,24]. 3D printed patient-specific surgical guides and templates can facilitate difficult surgical procedures by improving visualization of obstructed areas and ensuring accurate section planes [1,17,21,28-30]. Implants may be the family of devices that benefits the most from AM, as they benefit the most from the variety of available biocompatible materials and patient personalizability [1,13,26,27,29]. The ability to create porous internal microstructures via AM also allows for the fabrication of more mechanically biocompatible and/or drug-seeded implants [14,34]. Lastly, AM can be used to make patient-specific splints or biologically active bandages to improve postoperative patient satisfaction and clinical outcomes [6,28,35-37]. However, in-house surgical AM has yet to overcome several obstacles before it can be more widely adopted. The large majority of 3D printed parts, especially when it comes to implantation, are considered FDA Class III devices due to their patient-specific nature [13,16]. Due to this tight regulation, these parts must be rigorously approved and may not be marketed or made in large quantities, hindering the spread of this technology [13]. The physician or technician responsible for making these parts is also held responsible for defects in said parts, as AM devices are labeled “high-risk” [13]. As AM becomes better documented and understood, regulations can be expected to loosen or change in nature, encouraging the proper application of the technology without excessively disincentivizing its implementation. Additionally, ethical challenges become apparent when making bioprinted constructs, as it is difficult to design a double-blind control study [2] Bioprinting requires the patient’s own cells for transplantation, so it is difficult to determine what proportion of a favorable result, if any, is caused by the bioprinted transplant [2]. Until a formal means of quantifying outcomes from bioprinted implants is devised, it may be impossible to start clinical trials without trespassing upon ethical standards [2].

Other challenges include a lack of valid clinical data, inconsistent nomenclature, workflow design, and for the case of bioprinting, bioink toxicity. Although AM has been applied in surgical settings for over a decade, there is still a lack of complete, quantifiable, and valid clinical data on patient outcomes with AM technologies [1,29]. Most data is qualitative or a result of case studies, as opposed to a rigorous control study [29]. Also, there is no consistent nomenclature for AM parts, inhibiting effective communication between researchers [1]. For example, fused filament fabrication, Fused Deposition Modeling (FDM) and filament freeform fabrication all refer to the same process, and exist separately simply because FDM was trademarked and registered by Stratasys [1]. As interest in the field of medical AM grows, it is expected that the amount of valid in vitro, in vivo, and clinical studies on this topic will continue to grow in the coming years, naturally eliminating these obstacles [1,3,7,8]. Workflow design is also a significant concern for AM in surgery [1,4,28]. Most commonly for in-house AM, the physician is the person who initiates the use of AM for their surgeries, and therefore the expert for computer-aided-design and model processing [28]. However, this process is time-consuming and takes away from time that could be spent treating other patients, often increasing the effective personnel cost of AM to higher than conventional manufacturing [28]. One solution to this problem would be to hire a technician or train staff members with less qualifications to make the 3D models and perform model postprocessing, thereby decreasing workforce costs dramatically and increasing the workflow’s efficacy [28]. AM can be expected to expand in scope in the coming years, both in surgery domains and strategic application. Currently, AM’s applications are constrained primarily to cranial and oral-maxillofacial surgery, with limited applications in hand and pelvic surgery and the treatment of miscellaneous osteochondral defects [4,5,23,28,29,31]. The applications of additively manufactured implants and braces especially can relatively simply also be applied to other subfields in orthopedics. Techniques for manufacturing porous implants can also be applied more widely to different types of implants, splints, and surgical tools in order to increase their biocompatibility and/or favorably change their mechanical properties [34]. In addition, the advent of bioprinting as a new field within AM allows for the growth of AM into transplantation surgery. Bioprinting is expected to develop rapidly within the next decade, allowing for more varied types of implantable tissues in the five years, and likely even whole organs for transplantation within the next ten years [2]. This will cause AM to become relevant in transplant surgery, perhaps helping to resolve the shortage of kidneys, livers, hearts, and other organs for transplantation.

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