EMERGING TRENDS IN DESIGN FOR MUSCULOSKELETAL MEDICINE (S GOLDCHMIT AND M QUEIROZ, SECTION EDITORS)



Three-Dimensional Printing in Orthopedics: from the Basics to Surgical Applications

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Published online: 7 January 2021

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Abstract

Purpose of Review Additive manufacturing (AM) is a rapidly evolving field traditionally utilized in non-medical industries. Recently, the medical use of AM is expanding, especially in orthopedics. The goal of this article is presenting the principles of AM and its main applications in orthopedics.

Recent Findings The main indications for AM in orthopedics are education, orthotics, surgical planning, surgical guides, and custom-made implants. Three-dimensional (3D) digital models can be obtained from tomographic scans using available free software. Then, it can be used to create a physical model, plan surgeries, or develop surgical guides which can aid the orthopedic surgeon during complex cases. Recent studies demonstrated the benefits of using printed models in educating patients and medical residents. Custom-made implants also have been evaluated with promising clinical outcomes.

Summary Using 3D technology has become a reality in orthopedics. Surgeons should expect exponential growth of its applications in the upcoming years. It is paramount that orthopedists get familiar with this disruptive technology.

Keywords Orthopedics · Three-dimensional printing · Surgery · Surgical guides · Three-dimensional models · Anatomic models

This article is part of the Topical Collection on *Emerging Trends in* Design for Musculoskeletal Medicine

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Introduction

Additive manufacturing (AM), popularly known as threedimensional (3D) printing, is the process of joining materials to create objects from a 3D digital model, layer-by-layer [1]. AM has been used in many industries for applications such as manufacturing of turbine blades, jewelry designs, mold making, tissue engineering, and several other applications [1]. Chuck Hall is considered the father of AM being the first one to develop stereolithography (STL) back in 1984 [2]. From then on, AM has become increasingly more popular for its versatility, relative ease of use, precise control of the fabrication process, and the possibility to make complex shapes and structures. Therefore, printed models can intentionally have properties highly sought after for biomedical applications [1]. Some examples are in the creation of personalized medical instruments, drug delivery systems, engineered tissues, scaffolds for bone regeneration, prosthetic sockets, orthotics, or surgical guides and implants [3...]. In the past decade, a trend of mass customization business models and advances in technology have brought down the costs and expertise required to exploit AM [4]. There is now a plethora of free software as well as many relatively low-cost 3D printers

available, which shows us that this technology is no longer an exotic and expensive tool limited to highly specific situations [4]. Even if the physician does not have access to a 3D printer, the use of a 3D digital model can already open many possibilities.

In this article, the AM process and its possible uses in orthopedics will be described.

3D Technologies

Data Acquisition Technologies

The process of using computer software to aid the creation, modification, analysis, or optimization of design is called "computer-aided design" (CAD) [5]. There are different techniques for measuring and modeling existing objects (including the human body) to create digital models that we can work on using CAD software. The most used methods include computer tomography (CT) and 3D scanning [3••].

CT is a powerful tool for diagnostics and surgical planning [3••]. Most modern tomographs enable high-resolution 3D reconstructions from the raw DICOM files using free software. Several denoising methods are available to enhance the quality of CT images. However, there is always a tradeoff between noise reduction and data preservation. Reducing noise without losing important features such as edges, contrast, or sharpness is challenging but doable with appropriate software [6]. Before image acquisition, inputs that can improve image quality by reducing noise are increasing the tube current (mA), increasing the duration of each measurement of X-ray detection (scan time), increasing the slice thickness, and increasing the kilovoltage [6]. Recently, deep learning algorithms using hierarchical network concepts are used in various image denoising concepts [7].

3D scanning is the most practical and comfortable solution to capture topography. There are plenty of affordable hardware and software available, the training requirement is minimal, and it can be very efficient [8]. It uses light to determine the 3D position of the surface points of the object, which can then be digitally reconstructed [3..]. Acquisition time and spatial resolution widely differ among 3D scanners, ranging from a few to several minutes, and from 0.1 mm to a few millimeters [9, 10]. The most commonly used systems are laser techniques and structured light methods. The laser technique utilizes a hand-held device to project a laser beam on the surface, and a sensor measures the distance to the projector. Structured light methods project pre-defined light patterns on the object, which are then captured by a camera. Data is more precise and less noisy than the laser scan [3...]. Laser scanning, however, seems to be the most suitable method in terms of cost, resolution, speed, accuracy, patient safety, and overall efficiency [3..]. Processing time for both techniques for 3D scanning is significantly lower compared to CT, as well as data files sizes [8]. Additionally, the model created with 3D scanning can have texture and color, differently from models created from CT. Limitations of 3D scanning include difficult readings of shinning or reflexive materials and the overlooking of the interior of the object [8].

Additive Manufacturing Technologies

As mentioned before, the combination of CAD and AM is an increasing approach in the biomedical field. The AM process requires five steps: (I) 3D scanning of the anatomic structure or surface, (II) 3D digital reconstruction, (III) CAD modeling, (IV) conversion to stereolithography format (STL), and, finally, (V) the printing process itself [3••]. The first step, i.e., data acquisition, was addressed in the previous section. The digital reconstruction, CAD modeling, and conversion to the STL format are done with appropriate software, and there are several free alternatives available [11, 12].

We will now focus on the printing process itself. After modeling the desired part through CAD, it is converted to an STL file format, which is standard for this application. The desired AM object is built of layers with sub-millimetric thickness of a substrate material, which can be liquid base (i.e., SLA, stereolithography), solid base (i.e., LOM, laminated object manufacturing; or FDM, fused deposition modeling), or powder base (SLS, selective laser sintering, 3DP, inkjet head 3D printing; and EBM, electron beam melting) [3••]. The most common processes for resin objects are SLS, 3DP, and FDM, and for metal objects, the most common processes are SLM (selective laser melting, a subcategory of SLS) and EBM.

In the SLS process, the powder is first deposited on the build platform. Then a CO_2 laser beam delineates the crosssectional shape of the object on that layer [3••]. The effect of the CO_2 laser beam in the material is called "sinterization," which ultimately solidifies it. Each layer thickness is between 0.05 and 0.2 mm depending on the accuracy required, and the progress of the printing process is made by lowering the build platform by the corresponding layer height [4]. Then another layer of substrate material is laid down, and this process is repeated for the required number of layers until the object is fully built. Polymers frequently used are thermoplastics, like polyamide 12 (PA). Also, different materials can be mixed to form composites. EBM works essentially in the same way, but instead of a laser beam, it uses an electron beam. The most commonly used metal is titanium.

3DP refers to "powder bed and inkjet head 3D printing," but it is often called simply "three-dimensional printing," which can create a terminology confusion. It is similar to the SLS process, but the solid layers are made by sticking powder with a viscous adhesive material. Firstly, a powder layer is deposited on the build platform, the same way as in the SLS process. Then, an adhesive liquid binder is deposited by an inkjet head. Once the layer is finished, the platform lowers, and the process starts again. It is less accurate than SLS, but cheaper and quicker, which led 3DP to have a predominant role in the prototyping industry [3••].

In the FDM process, a semi-molten material is extruded through the printer head to create each two-dimensional (2D) layer of the object [3••]. The most commonly used materials for FDM are thermoplastics such as polycarbonate (PC), acrylonitrile butadiene styrene (ABS), and polyethylene terephthalate glycol (PETG). Other possibilities include the use of polymers or nylon-based materials [3••]. Struts may need to be included in the project to allow overhanging parts of the object to be built, which will, by the end, be trimmed off the final printed part [4]. Typically, in each layer, the material is firstly extruded in the external perimeter, and then this delimited zone is filled by following a pre-defined pattern.

These methods enable manufacturing of very intricate, geometrically complex objects with a sub-millimetric resolution with relative ease and speed. One of the advantages of AM is that the overall cost per printed part generally does not increase with its complexity, only with its volume. Additionally, when several copies or even different objects are being fabricated on the build platform in each "run", the build time per object may decrease, which translates into cost savings [4].

Orthotics

In the biomedical field, the use of AM technology is increasing rapidly, and it is especially widespread in the fabrication of orthoses—by definition, devices applied externally to support the neuromuscular and skeletal system by modifying its structural and functional characteristics. However, it is still a relatively new approach—orthoses began to be 3D-printed less than a decade ago. The manufacturing of orthoses and prostheses is still mostly manual, and thus the end result is completely crafter-dependent [3••].

Advantages of orthoses made by AM include lower cost, easier modification, and, once the designing process is over, faster fabrication. Patients usually feel more comfortable with prosthetic sockets made with AM machines than the traditional handmade ones [3••, 13]. AM technology has been used to aid orthotic fabrication in several situations: spinal braces, knee orthosis, ankle-foot orthosis, wrist and hand orthosis, foot orthotics, for chronic pain relief, or for peripheral nerve injuries (Fig. 1).

Choosing a specific material is vital to the success of the designed device. A material with inadequate elasticity or hardness, for instance (not to mention a poor design), may result in a painful or biomechanically useless, or even harmful orthotic device. The most used materials to manufacture orthotic



Fig. 1 3D-printed custom-made orthosis (Hefesto Medtech, São Paulo, Brazil) used in developmental hip dysplasia

devices through AM are thermoplastics, composites, and foams [14, 15], especially ABS and PLA. They have relatively low elasticity, so structures will be rigid or semi-rigid. Specific sections of the devices that need to be soft are made with foamed materials. Materials used in FDM have similar properties to thermoplastic materials used for injection molding. PC and ABS or their combinations, nylon-based materials, and other polymers are generally used and are frequently cheaper. Combinations of different types can modify the material properties [3••]. Another advantage is the possibility to modify the internal structure of the object or orthosis to obtain different characteristics in elasticity/hardness in the same object.

Customized foot and ankle orthosis has been made by AM for over a decade with satisfactory effectiveness [16–19]. Designed from a 3D surface scan of the patient's feet, the precision is such that it is possible to specify angles and linear dimensions consistently within 1°/1 mm, which would not be possible with usual techniques [17, 18, 20]. Artioli et al. [21] concluded that the use of CT scan and AM produces differences of only 0.1% between the manufactured prosthesis and the digital model. Since the first step of AM is a 3D computer model, there is the opportunity to use finite element analysis or other computational modeling techniques (computer-aided engineering (CAE)) to measure and potentially optimize the stiffness of the device prior to its manufacture, which would be difficult if not impossible to recreate using traditional manufacturing methods [4]. This technology has also been applied for producing personalized insoles for sports footwear [22, 23], for plantar fasciitis [24], or for diabetic foot [25–27]. Pressure and tissue strain on the plantar foot were significantly reduced with the customized insoles [26]. Customized transtibial prosthetic sockets were one of the first orthotic devices ever made using CT to obtain the morphology of the patient's stump [28], but much longer manufacturing times were needed.

Personalized wrist orthoses, either for chronic wrist pain [29] or for splinting a healing fractured bone, can be made by AM. A recent study evaluated a 3D-printed wrist brace for Colles fracture [30]; wrist radiographs were taken periodically to observe the palmar inclination angle, ulnar deviation angle, and radius height. All these parameters were significantly better in the experimental group than in the control group (conventional splint). The authors concluded that not only the 3D printing braces better kept reduction during healing time, but they also stressed the cosmetic benefits—the customized orthotics are light, breathable, comfortable, beautiful, and convenient for dressing. Despite taking longer to prepare (when compared to the traditional manual method), the subjects were more satisfied with the fit, esthetics, and comfort of the 3D-printed orthoses [31].

Among the papers about this subject, it is a very frequent statement that the process is still time-consuming, often taking longer than the traditional methods. Thus, the creation of an automated process that is less operator-dependent might be the missing link for better integration of AM technology in the clinics [31].

Education

Understanding the complex anatomy of the musculoskeletal system is challenging. Orthopedic surgeons struggle to teach normal anatomy to medical students and residents. Explaining altered anatomy in disease can be even more difficult. The possibility of creating virtual models or even printing anatomical structures can aid in education in various ways.

Traditionally, anatomy is taught using cadavers and plastic models. However, cadavers are limited to university settings, present ethical considerations, and cannot be easily utilized in a regular classroom or in a clinical setting. Anatomical plastic and foam models have been used to decrease the need for cadaveric models. However, these models are expensive and are difficult to develop.

The possibility of printing specific anatomical parts, especially in the setting of orthopedic disease, opens an opportunity for education. The authors already use 3D-printed models in their offices in order to explain diseases and surgical procedures to their patients (Fig. 2). In a comparative study, surgeons were more comfortable communicating with patients presenting with tibial fractures when they used a 3D-printed model to illustrate their explanation [32].

Resident education can also be enhanced with 3D printing. Montgomery et al. [33] evaluated how a 3D-printed model of a calcaneal fracture would impact the understanding of the fracture among orthopedic residents. A group of residents evaluated calcaneal fractures and classified them. Then, they were asked how confident they were in the classification. To half of them, a 3D-printed model was shown, and a 3D CT



Fig. 2 3D-printed model of a hip joint. The femur presents a cam deformity, typical of femoroacetabular impingement. This model was used to educate the patient about his disease and the correction procedure that would be performed. It also helped the surgeon to plan the correction

scan was shown to the other half. Residents' confidence and perceived accuracy were greater in cases with 3D-printed models. Li et al. [34•] performed a randomized study evaluating the effect of 3D printing in the understanding of a spinal fracture. Altogether, 120 medical students were randomized into 3 teaching module groups: 2D computed tomography images (CT), 3D CT images, and a 3D-printed model. Students were evaluated through a questionnaire. Those in the 3D image and 3D-printed model scored significantly better than those in the CT groups. Pleasure, assistance, effect, and confidence were more predominant in students in the 3D-printed model group.

We can extrapolate the knowledge of 3D modeling in education to other emerging technologies like virtual reality and mixed reality (MR). 3D-printed models can give the student the tactile feeling of the structures, and even its weight. By combining 3D printing with MR, the relationship of bones and joints with other anatomic structures such as nerves and arteries, which are not amenable to printing, can also be studied.

Surgical Planning

The importance of surgical planning in orthopedic surgery is well known to all in the field. It is paramount that the surgeon knows in advance what are his goals during surgery and has alternative plans in case something goes wrong. However, most of this planning is performed in a 2D way. For example, transparencies are positioned over X-rays to determine the size of implants in total hip replacement. This process has gone digital as special software was developed, but it is still frequently 2D.

Doctors are used to work with X-ray or 2D CT images or magnetic resonance (MRI) to evaluate the anatomy. Spatial 3D rendering was done only in doctors' minds. With emerging 3D renderings, the third dimension could be reproduced to improve the diagnostic of some pathologies and deformities, but it still lacks the tactile feeling. 3D-printed models can be used to study cases, test surgical procedures, and to teach students or patients. 3D printing can be used as a powerful tool for any bony surgery. Examples of 3D-printing applications for shoulder surgery are shown below.

Arthroplasties

Optimal functional recovery and implant longevity following both total shoulder arthroplasty (TSA) and reverse shoulder arthroplasty (RSA) depend, in large part, on proper placement of the glenoid component. Implants with improper technique have higher risk of dislocation, loosening, component wear, and more revision rates [35]. The same rationale is valid for hip and knee arthroplasty [36, 37].

Traditionally, glenoid component positioning has been done manually by the surgeons based on their review of preoperative films and knowledge of glenoid anatomy. Other joints like hip and knee follow the same paradigm. The main concern about these new implants is the correct position of the baseplate and glenosphere. Individual patient anatomy determines ideal placement; however, several guidelines for placement include inferior translation on the glenoid with neutral to inferior inclination [38]. However, the different anatomy in many revision surgeries, soft tissue contractures, and bone loss may lead to unreliable anatomical landmarks [39, 40].

In shoulder arthroplasty, placing the glenoid baseplate and the central pin in optimal position with sufficient bone stock may pose as a difficult surgical task, especially because most surgeons rely on their memory and only a 2D analysis of the case, which sometimes is performed days or weeks prior to the surgery.

Planning or creating a guide for orthopedic surgery follows a protocol. A CT scan of the region of interest is obtained. The DICOM images are imported using specific software to create a 3D model of the patient. Planning the surgery depends on the type of procedure and implant of your choice. The main goal is to define the best location for the implant.

There are specific software created from each major implant manufacturer, but it is possible to plan and even create your own guide for any implant using regular CAD software available free. It is important to remember that these tools are still not validated as planning tools for surgery but can be used as a good reference for the surgeon.

Here we describe our preferred method for planning:

Transforming the CT (or MRI) to a 3D File This step is called segmentation. Open the DICOM files with a segmentation software (HorosTM (Horos Project, Annapolis, MD), InvesaliusTM (Centro de Tecnologia da Informação Renato Archer, Campinas, SP, Brazil), 3DSlicer TM (open-source, www.slicer.org)). Then select the desired structure using pixel density filters available in the software. For CT images, for instance, each tissue usually falls in a specific range of the Hounsfield scale: <1000 (air), ~ -500 (lungs), -100 to -50 (fat), 0 to 50 (muscle), 200–500 (medullary bone), and >1000 (thick cortical bone). Then you can create the 3D model and save it as a .STL file.

Adjusting Software—Cleaning and Preparing the Models

Open the .STL file with Meshmixer[™] (Autodesk, San Rafael, CA, USA) or Meshlab[™] (ISTI-CNR, Pisa, Italy), both available free. Remove anatomical parts that are not needed using selection tools or plane cut tool (Ex. the ribs and sternum in a shoulder CT). Then, verify and correct mesh errors that are common and could ruin your print. For that, you can use "analysis > inspector" in Meshmixer, or "filters > cleaning and repairing" in Meshlab.

CAD Software—Creating Guides, Implants, and Planning Surgeries

Use a CAD software like Windows 3D Builder (Microsoft, Redmond, WA, USA), Rhino[™] (Robert McNeel & Associates, Seattle, WA, USA), ThinkerCAD[™] (Autodesk, San Rafael, CA, USA), or Meshmixer[™] (Autodesk, San Rafael, CA) to plan the surgery. By visualizing the 3D structure and being able to rotate it in any axle, you can plan surgeries, implant positioning, osteotomy planes, or resections. Using solid-creation tools like cylinders, hexahedrons, and spheres, you can create your own instruments or guides, or even design a customized implant. It is also possible to import 3D files from your manufacturer's implant.

Slicing and Printer-Control Software

Open the 3D .STL file in your printer "slicer software" (Slic3rTM (open-source, www.slicer.org), CuraTM (Ultimaker, Utrecht, Netherlands)). Select the options as resolution and infill and hit print. A .GCODE file will be created. After this file is created, it is possible to print the created model in any available printer.

Surgical Guides

Patient-specific guides are low-cost surgical instruments that can be used for many surgeries, including fractures, osteotomies, and arthroplasties (Fig. 3). It allows the surgeon



Fig. 3 Surgical 3D-printed guide used to perform an iliac osteotomy during a complex tumor resection of the acetabulum

to better define the optimal location for the implant and accurately execute the preoperative plan at the time of surgery. It can also change the usual paradigm by using the plate to directly reduce the fracture (or the correction osteotomy) and decrease errors caused by plate malposition. Minimally invasive techniques can emerge from this new way to plan and fix fractures.

A proximal humerus fracture is considered a difficult procedure, thus we will use it as an example. One of the authors (BG) has experience in designing guides for surgeries like shoulder arthroplasties, Latarjet procedure, and for clavicle fractures. With 3D surgical planning, and the utilization of patient specific surgical guides, it is possible to decrease surgical time.

The steps for creating fracture guides are similar to arthroplasty guides. However, in fractures there is a need to segment each major bone fragment. For a proximal humeral fracture, we create one 3D file for the diaphysis and one for the head and import them to a regular CAD software (e.g., Windows 3D Builder[™] (Microsoft, Redmond, WA, USA), or Rhino [™] (Robert McNeel & Associates, Seattle, WA, USA). Then, reduction and alignment of the fragments to an anatomical position is obtained (3D virtual reducing the fracture). Subsequently, a 3D model of the chosen implant (proximal humerus locking plate) is also imported and placed in the best fitting position to achieve adequate bone fixation.

The next step is the creation of the guides. Two guides are usually needed, one for each major part (proximal and distal fragments). The two proximal locked screws are used as a reference for the proximal guide creation, and two distal screws (one locked and one cortical) for the distal segment. When selecting the anatomical references for the guides, it is crucial to have the soft tissue anatomy in mind.

At the time of surgery, after the proper bone exposure, we position the proximal guide according to the humeral head anatomical reference (lesser or greater tuberosity) and drill the two proximal holes. Then, we position the distal guide and drill the two distal holes. Now, with the fracture still displaced, we fix the plate in the pre-drilled head holes, and by manipulating the arm, we match the plate holes to the predrilled diaphysis and fix the plate distally. The fracture is automatically reduced as planned without using fluoroscopy and temporary fixation. We acknowledge that this is a timeconsuming process, but it pays off in the intra-operative procedure.

3D-Printed Implants

Traditionally, orthopedic implants are ready to be implanted off the shelf. Surgeons have at their disposal a selection of sizes and variations, and they have to adapt these pre-made devices to their patients' anatomy. This technique works in most cases; however in more complex cases, it may not be ideal. Failed arthroplasties and tumor cases are specially challenging to reconstruct because the bone defect created by these conditions creates very unique patterns (Fig. 4).

After the development of industrial metal 3D printers, it became possible to design specific implants to specific needs. The process starts with a CT scan. It may be necessary to process the image in order to erase previous implants and artifacts. Then, the implant is designed to fill the bone defect and achieve adequate stability and fixation. It is paramount that the surgeon works in conjunction with the engineer. The correct understanding of the anatomy and specific technique which will be used in the operation are essential to the correct development of the implant. Using the "normal side" or even the normal anatomy from a matching individual, the surgeon can understand the deformity and plan the corrections that a patient-specific implant can achieve. With better comprehension of the anatomy, biomechanics, and finite element analysis, it is possible to match the individual anatomy and bony defect. It is even possible to predict implant failures and the post-operative range of motion.

This kind of solution is increasingly available. Kieser et al. [41••], for example, reported clinical outcomes of 46 consecutive patients submitted to revision hip arthroplasty presenting



Fig. 4 Custom-made implant used in the same case from Fig. 3. The whole acetabulum needed to be resected, and an acetabular component was designed to reconstruct the hip. A perfect fit with a 3D model of the patient's pelvis is observed

severe bone loss. Reconstruction was performed using a custom 3D-printed acetabular implant. In all patients, the hip center of rotation was restored. One patient presented early migration of the implant, but was managed non-operatively; all other patients presented implant integration. The authors considered the technique encouraging. Publications regarding customized implants (case reports, case series) are escalating in the literature.

Conclusion

AM applications in orthopedics are expanding rapidly with increasing benefits to surgeons and patients alike. Main uses today include education, orthotics, surgical planning, surgical guides, and 3D-printed implants. As any new technique, it requires time and education. With 3D printers widely available, new generations of young orthopedic surgeons born in the era of computer and mobile tech will use this naturally for their learning and diagnosis. Therefore, it is important that all orthopedic surgeons understand this technology.

Compliance with Ethical Standards

Conflict of Interest The authors declare no conflict of interests.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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