3D Printing Prototypes for Healthcare Professionals: Creating a Reciprocating Syringe

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Abstract 3D printing (additive manufacturing) has been around since 1984, but interest in the technology has increased exponentially as it has become both accessible and inexpensive. The applications of the technology in healthcare are still being explored; however, initial forays have been encouraging. It has the potential to revolutionize the process of prototyping for healthcare professionals by democratizing the process and enhancing collaboration, making it cheaper to do iterative prototyping with little or no engineering experience. This case report details the creation of a multi-lumen reciprocating syringe with 3D printing. The product has been created and tested using a variety of publicly available resources. It provides a detailed overview of the approach and the framework required to create such a medical device. However, the implications of this report are much larger than this one product, and the fundamental ideas discussed here could be used for creating customized solutions for many healthcare problems.

Keywords Interventional radiology · 3D printing · Innovation

Background

Commercially available 3D printing allows for rapid prototyping of novel ideas to solve problems in the field of

medicine in an extremely cost-effective manner [1–5]. Resources, where users of varying skill levels can utilize 3D printing, are widely available. The goal of this case study is to detail the creation of a product using 3D printing technology. It is particularly useful for healthcare professionals as they would not need an in-depth knowledge of product engineering to contribute to the prototyping process.

There are two aspects of device design that one needs to keep in perspective to come up with a successful product: first is identification of a problem. However, devices do not exist in a vacuum and need to be useful in an ecosystem of healthcare professionals, which is where the second aspect of device design comes into play, a thorough understanding of the environment in which the device will be utilized.

The only way to truly understand the problems associated with any profession is through immersing oneself in it. Physicians have a nuanced understanding of where their equipment is failing them, or ways in which the equipment can be enhanced to make the process of using it more streamlined to serve the needs of the user. The product can be designed knowing exactly how it would be used in real life settings. The flaw in the current design and innovation process is that only a fraction of healthcare professionals play an active and integrated role in device prototyping, and engineers only have a limited understanding of the way the device is actually going to be used in the hands of medical professionals.

This case study will review the problems observed in the current image-guided aspiration technique. During ultrasound-guided aspiration of solid organ masses or fluid, it is difficult to generate a vacuum while maintaining syringe control (Fig. 1). The process involves holding the syringe while pulling the plunger simultaneously. Often, in order to generate an adequate level of vacuum, two hands are needed, which in turn, implies that an assistant is required to position the ultrasound probe for image guidance. Multiple needle

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Fig. 1 Variations of hand techniques

passes might be needed due to repeat sampling or needle control.

Having identified the issue, we have designed a multi-lumen reciprocating syringe which aims at increasing the efficiency of the technique. There on, we have outlined our design process to aid any healthcare professional looking for a guideline to exploring 3D printing technology to create innovative healthcare solutions.

Methods

In order to solve the problem of generating adequate force during ultrasound-guided aspiration, a rapid prototype was created using 3D printing. First, multiple hand-drawn solutions were drafted, and feedback was obtained from several colleagues to refine the design. The draft of the initial design was made on MS PowerPoint 2010 (Microsoft Corp., Redmond, WA), which is easily accessible and familiar to healthcare professionals. A background literature search was conducted along with an informal patent search using Google Patents (Google, Mountain View, CA) to analyze the current body of work in this space.

Due to lack of experience using 3D modeling software and product design on CAD, the design was submitted to a freelance CAD designer from FiverrTM, who generated a file suitable for 3D printing using the sketch in Fig. 2. The approximate cost of this service is \$20. Additional public resources available to the lay public are summarized in Table 1 [6]. The initial syringe design (Fig. 3) was manufactured by a third

party 3D printing company SD3D. Additional parts, including washers and plunger, were purchased from a local hardware store to complete the prototype.

The first iteration of the prototype gave insight into the manufacturing and design process. The second generation model is refined from the first iteration to increase functionality while using existing resources. For convenience, the inner lumen of the syringe was sized to fit the same plunger as a 20-cm³ syringe. This allowed for the utilization of the rubber stoppers that fit the existing syringes, streamlining the process of manufacturing by removing an unnecessary step. Then, the second design (Fig. 4) was printed by the University of

Fig. 2 PowerPoint sketch of initial prototype design

Table 1 Publicly available resources for 3D printing

3D marketplaces	Freelance CAD	Free software for beginners
Shapeways	Fiverr	Autodesk Fusion 360
Pinshape	Upwork	123D Sculpt
3D Marvels	Freelancer	123D Creature
3D Via	Craigslist	3D Slash
GrabCAD	Colleagues	Blender
Google 3D Warehouse	University Resources	Sculptira
Thingiverse	Industry	Leopoly

Maryland Department of Radiology 3D printing lab with an Ultimaker 2 fused deposition modeling (FDM) printer.

Results

The final design (Fig. 3 and Fig. 4) created contains two concentric cylinders. Fluid flows from the needle tip through an outer lumen into the inner lumen, which is outfitted with a plunger. These two chambers are connected at the proximal end of the syringe. The inner lumen is outfitted with concentric rubber washers to create an airtight seal ensuring the effectiveness of the plunger. A metal dowel rod that fit the aperture size of the rubber washers serves as the plunger. On the most distal end of the plunger, another set of concentric washers creates a second airtight seal. As the plunger is depressed, the negative pressure generated in the inner lumen is transferred to the outer lumen via the proximal connection. This allows fluid to be drawn into the needle as the plunger is depressed.

Discussion

3D printing uses additive processes in which successive layers of material are assembled on top of one another to build the desired object [3, 7]. This process means that items can be

Fig. 4 CAD model of V2.0

assembled directly from a digital model. Since the process is based on addition rather than extraction of excess material, less raw material is wasted. Due to the recent advances in technology, 3D printing is relatively cost-effective to produce small-scale customized solutions [7, 8]. Although there are a variety of methods, the general steps involved to manufacture a product using 3D printing are

1. Identify a problem that can be solved by a customized 3D printed solution
2. List the resources available to translate the idea into a printable model
3. Print and test the prototype
4. Reiterate and perfect the prototype based on the feedback collected in the previous step

The design process is outlined in Fig. 5. In order to print a prototype, the blueprint of the object is first converted into a CAD file. The most commonly used file format is Standard Tessellation Language (.stl) or .stl formatted file. It is a file that encodes 3D designs as a collection of triangles, which are called facets. These facets interlock together like a jigsaw puzzle to make the 3D design [3]. Other 3D printing formats

Fig. 3 CAD model of V1.0

Fig. 5 Design theory for prototype generation

include Additive Manufacturing File Format (AMF), Virtual Reality Modeling Language (.vrl), and Form1 (.form). After a

file is created, a slicing software is used to create the 3D design into sequential slices. The type of slicing program used will depend on the type of printing hardware one plans to use. Resources required for creating and slicing a CAD file, as well as for printing a design, are described below.

Resource Identification

With the advent of affordable 3D printers, it is certainly possible to invest in one but it is not entirely necessary. It is not practical for novices to purchase a 3D printer or realistically become quickly proficient with 3D modeling software. Therefore, we have identified multiple affordable publically available resources and outlined ways to discover the resources available within one's network. It is helpful to identify

Table 2 Review of 3D printing hardware and techniques

Fused deposition modeling: printers that extrude a molten or semiliquid material				
Material extrusion	<i>Material</i>	<i>Cost</i>	<i>Speed</i>	<i>Summary</i>
	Polymers and plastics	\$	++	The most widely used consumer 3D printing method. It is also known as fused filament fabrication (FFF), thermoplastic extrusion, plastic jet printing, and fused filament method. The finish quality and resolution may be lower than other methods; however, the cost is significantly less. This technology utilizes a controlled extrusion head deposits layers of plastic or polymer on a build platform. The extrusion head heats the material, and the material hardens on cooling. There are now very large 3D printers that extrude thermoplastics.
Stereolithography: printers that solidify a photo curable resin				
Vat photopolymerization	<i>Material</i>	<i>Cost</i>	<i>Speed</i>	<i>Summary</i>
	Polymers and plastics	\$\$\$	++	This technology, which is also known as digital light processing, has three basic components: a high intensity light source, a vat of photo-curable resin, and a controlling system. 2D layers are sequentially created by exposing the liquid to a light source. The resin is solidified on light exposure. After this is complete, the model undergoes curing in a UV chamber. The post processing procedure for this type of printer involves a solvent rinse and manual removal of excess resin, which is labor intensive. The outcome is a product with excellent surface quality that may be relatively fragile.
Material jetting	Polymers and plastics	\$\$\$	+++	This technology may be thought of as similar to ink-jet printing. However, instead of jetting ink onto paper, these 3D printers jet a liquid photopolymer onto a build tray. The liquid polymer layers are then solidified by exposure to UV light. Mixing of materials can create models with variable flexibility. The result is a model with a high resolution. This technology has been applied in the creation of dental casts.
Powder deposition printing: printers that bind or fuse granules of powder				
Binder jetting	<i>Material</i>	<i>Cost</i>	<i>Speed</i>	<i>Summary</i>
	Metals, sands, and ceramics	\$\$	+++	This process also known as "inkjet 3D printing" uses jetting technology, similar to material jetting. However, in this process, a liquid binding agent is jetted to a bed of fine powder, which selectively binds the powder to create a layer of print. After all layers are complete, the unbound powder is removed and the product is cured in an oven. After curing, the product is infused with cyanoacrylate, wax, or resin, for structural support.
Powder bed fusion	Plastics and metals	\$\$	—	With this technology, a heat source is used to fuse small preheated particles of plastic, metal, ceramic, or glass powder in layers on the surface of a powder bed. Powder bed printers may use selective laser sintering, direct metal laser sintering, selective laser melting, or electron beam melting. This has been applied for printing of metal devices such as implants and fixations.
Directed energy deposition	Metals	\$	+++	In this process, the powder build material is deposited from a nozzle into a heat source beam that will fuse the powder into a solid metal. This process has had limited applications in medicine. One unique property of this technology is that it can add or repair an existing part.
Sheet lamination: printers that stick cut sheets of paper, plastic, or metal				
Sheet lamination	<i>Material</i>	<i>Cost</i>	<i>Speed</i>	<i>Summary</i>
	Paper, metals, or plastic	\$	—	Sheets or ribbons of paper, metal, or plastic are bonded together by the use of ultrasonic welding. This process may be inexpensive; however, the post processing may labor intensive, and the finish quality may vary, depending on the material used.

available resources prior to creating a CAD file for 3D printing so that the entire process can be completed smoothly.

3D Marketplaces

In the scenario that 3D printing resources are either not available within an institution or they do not fulfill the user's needs, one can consider using marketplaces for 3D printing. A few examples of these marketplaces are Shapeways, Pinshape, 3D Marvels, 3D Via, GrabCAD, Google 3D Warehouse, Ponoko Product Plans, and Thingiverse [6]. The services provided by these marketplaces can differ slightly, and some marketplaces, such as Shapeways, offer 3D printing services where they accept the CAD file of the prototype and mail the user the 3D print. Other marketplaces like Thingiverse offer the option to download CAD files for free or to purchase them for a relatively small monetary value. Finally, there are 3D marketplaces that integrate the services offered by the abovementioned two, such as MyMiniFactory.

Free Software for Beginners

Often providers are new to 3D printing, looking to experiment and gaining more experience with the technology to create personalized designs. There are numerous 3D modeling software options available which offer free version of their products.

Some examples of such products are

- Design Software: 123D Design, 123D Sculptr, 123D Creature, 3DSlash, 3DTin, Blender, Leopoldy, Sculptris, and SculptrGL
- Slicing Software: Ultimaker Cura, Craftware, and KISSlicer

We recommend Autodesk Fusion 360, because it is free to use and meets all industry standards.

Colleagues and Freelance Designers

Colleagues and freelance CAD designers could be a valuable resource if one does not have the time or expertise to become familiar with modeling software. The most cost-efficient way to build one's own 3D prototype is to find a colleague who is familiar with 3D modeling software. If that is not possible, then there are freelance services, such as Fiverr, Upwork, or Freelancer, which can connect one with engineers who can create and slice the file format necessary to 3D print a design. Nondisclosure agreements are available on these platforms to safeguard one's intellectual property. In addition to that, you can also hire or consult local hobbyists on Craigslist.

Institutional Resources

Most hospital departments, especially ones affiliated with academic institutions would in all likelihood, have a 3D printer available, for little or no cost involved. This should provide a good starting point for healthcare professionals looking to explore 3D printing. An academic environment can be ideal because of the easy availability of guidance from more experienced users of the technology. The only foreseeable limitation to using university resources is the limited variety of software and hardware available.

3D Printing Hardware Review

An understanding of the available 3D printing hardware is crucial before one creates a CAD file for the prototype design. The decision of which printer to use is influenced by several factors like availability, cost, color capabilities, sterilization capabilities, and materials [3]. A thorough understanding of the software and hardware available would streamline the process of prototype generation and would ensure that it remains cost-effective. The International Organization for Standardization (ISO) and the American Society for Testing and Materials (ASTM) have developed a standard nomenclature that defines seven 3D printing technologies [9]. These seven technologies fall into four categories and are summarized in Table 2 [3, 10].

Sterilization Considerations

Throughout the process of prototyping, sterilization should be considered depending on the application. If the goal is to create 3D printed surgical equipment, or other devices in which direct contact with a patient or animal is made, a sterilization plan is necessary. The four most common sterilization techniques are autoclave, ethylene oxide gas, hydrogen peroxide gas plasma, and gamma radiation. The standards and definitions of sterility and sterilization, as well as descriptions for each technique, can be found on the CDC website [11]. Recent tests have shown that most 3D printed material can withstand ethylene oxide gas, hydrogen peroxide gas plasma, and gamma radiation sterilization techniques; however, certain materials may be damaged when sterilized with autoclave methods [12]. If one plans to use autoclave as the method of sterilization, it is best to consider heat-resistant printing materials.

Conclusion

The advent of commercially available 3D printers greatly decreases the barrier to entry for healthcare providers. The process of prototype generation and design is no longer cost

intensive and can be accomplished with the help of readily available resources. The purpose of this study is to demonstrate through an example, the process of designing and generating a device prototype in a way that is cost-effective and does not require special expertise.

One can come up with possible solutions to everyday problems in medicine and customize these solutions to fit the existing healthcare ecosystem. Inexpensive 3D printing would also encourage rapid prototyping to have a closed feedback in the iterative process. Working prototypes can be assembled and tested using 3D printers commercially available to the public or within one's institution. The democratization of the process of prototype creation by 3D printers is remarkable. This approach can aid creative device design collaborations by encouraging healthcare professionals to lead the process of creating the next generation of medical innovations.

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