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Assessment of 3D Printing for Surgical Instrument Manufacturing

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Abstract – Three-dimensional (3D) printing has emerged as a method for rapid prototyping and manufacturing of tools. In low-resource settings or field settings, the ability to perform surgeries is often limited by a lack of surgical instruments. On-demand manufacture of surgical instruments via 3D printing may offer a low-cost, reliable, convenient solution for provision of necessary care, particularly during trauma or emergency situations. The global coronavirus-19 disease pandemic has emphasized the need for rapid manufacturing of surgical instruments at the point of care, as the pandemic has often limited patient access to hospitals, due to measures to minimize the spread of infectious disease. Moreover, the ability to 3D print surgical instruments is a priority for enabling surgery during space missions. Recent progress has been made on 3D printing of commonly used surgical instruments from plastics. Important surgical tools such as forceps, scalpel handles, needle drivers, Army/Navy retractors, and hemostats have all been 3D printed, with typical print times on the order of hours. This paper assesses the current status of 3D printing of surgical instruments. The review will include 3D printing methods, raw materials, design times, print times, sterilization methods, and the types of surgical instruments that have been successfully printed. In addition, the results of mechanical testing and simulated surgical testing of 3D printed surgical instruments will be described. Finally, avenues for future work will be identified, including the need for faster print times, and the necessity for producing more intricate instruments via 3D printing.

***Keywords*: 3D printing, surgical instruments, space medicine, prototyping

1. Introduction

Currently, a large amount of money is spent on medical devices worldwide, and much of that money is spent on transporting materials and supplies to remote treatment facilities. Three-dimensional printing offers a possible solution to this dilemma, as 3D printing enables on-site manufacturing of medical tools and supplies. The method relies on layer-by-layer deposition of thermoplastic material in a defined pattern, to create a desired three-dimensional tool (Fig. 1). Fused deposition modeling, for example, delivers materials through a single nozzle (Fig. 2) or multiple nozzles (Fig. 3).

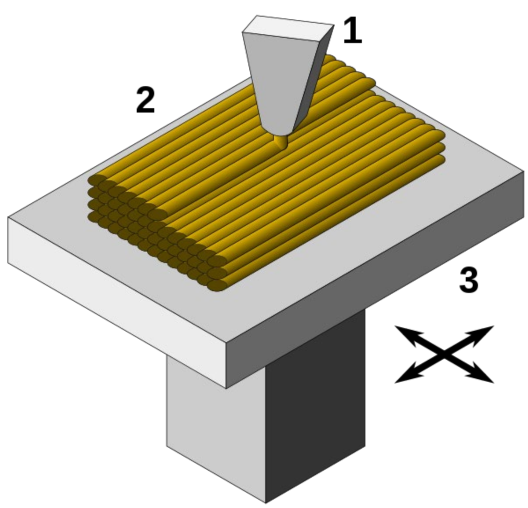

Fig. 1. Method of 3D printing (Gringer, Creative Commons CC0 1.0 Universal Public Domain).

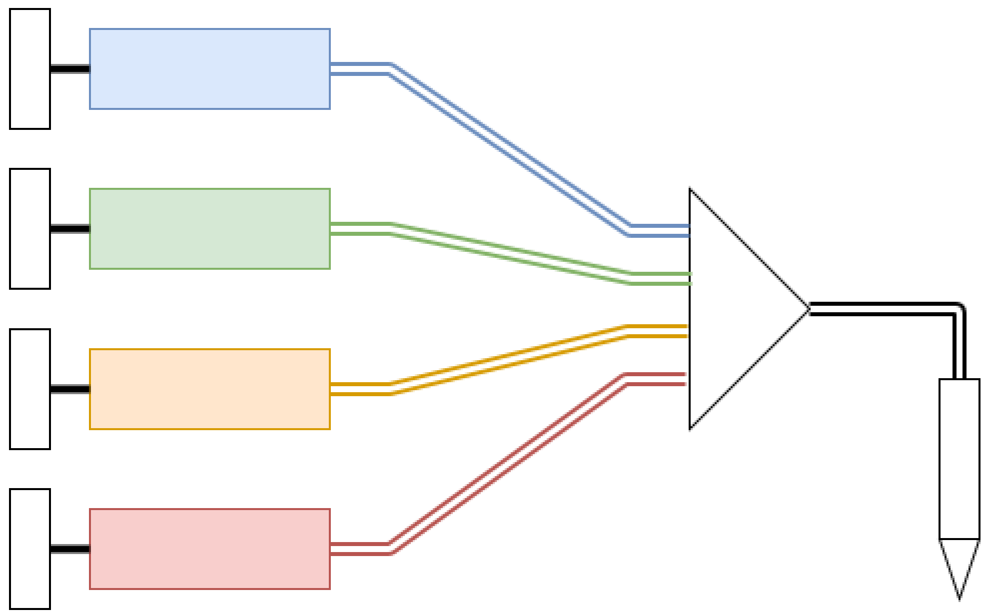

Fig. 2. Single-nozzle fused deposition modeling (Florian Kohn, Creative Commons Attribution Share-Alike 4.0 International).

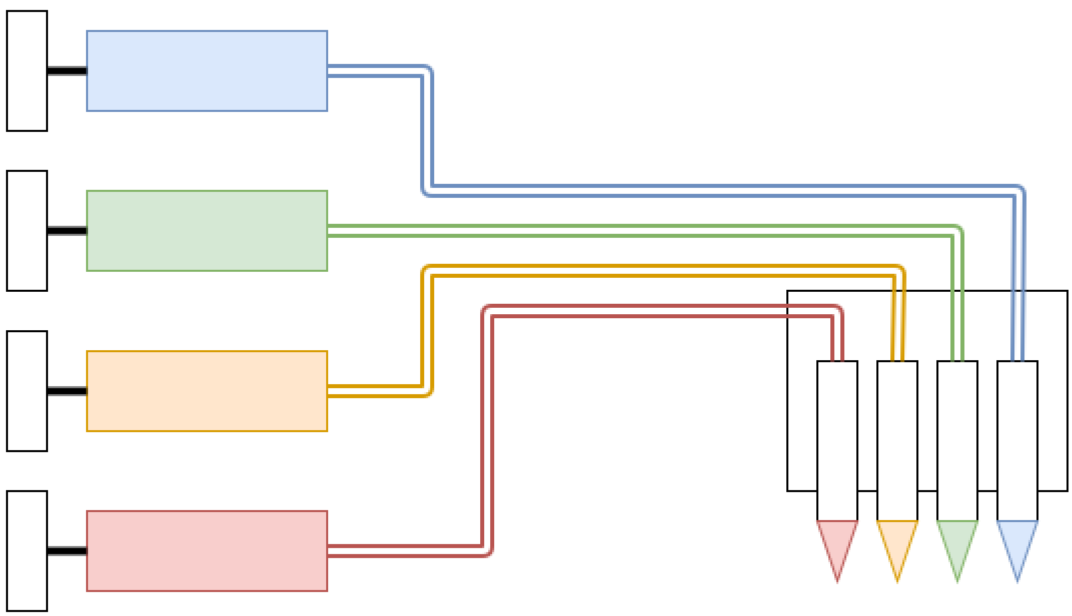

Fig. 3. Multi-nozzle fused deposition modeling (Florian Kohn, Creative Commons Attribution Share-Alike 4.0 International).

Manufacturing of surgical instruments via 3D printing can increase access to surgical care, especially in low-resource settings, emergency situations, and even in space. This paper summarizes the current status of 3D printing technology for surgical instruments.

2. Current Medical Uses of 3D Printing

Currently, 3D printing has found wide use in surgical planning, across several surgical specialties [1]. Models of organs and structures can be created via 3D printing, and are critical for both surgical strategy and patient education. In cardiac surgery, doctors were able to print a model of a 70 year old patient's heart based on computed tomography (CT) images; the 3D printed structure helped the surgeons plan an approach for stenting an aortic aneurysm, a very high risk procedure. In neurosurgery, models of the brain help surgeons and can improve communication with patients. In general surgery, 3D printed models of the liver were created to help surgeons plan for the treatment of two patients with multiple liver metastases from rectal cancer. Limitations of this approach were that a 70% scaled liver model took 18 hours to print and cost $420. For plastic surgery, models allow for hands-on planning and are more precise than 2D images.

In medical education, 3D printed models allow students to understand normal and abnormal anatomy; healthy and diseased conditions of organs and tissues; and anatomical variation. In addition, 3D printing has been leveraged for creation of customized implants. Printing implants allows for implants to be appropriately sized to a patient, and this method can reduce operating time. An example is that a special printing system called "inkjet-printed custom-made artificial bone" (IPCAB) helped with reconstructing facial structures. In the future, 3D printing could potentially be used to manufacture organs made with the patient's cells to reduce reliance on organ transplants. Surgical instruments, models, and certain reconstructive implants are printable in the near future; printing of complete organs will require further technology development.

Research into these clinical applications of 3D printing is continuing, and can dramatically advance the medical field. One drawback of 3D printing is that it could lead to fake instruments and devices being bought and sold; careful regulatory policy and oversight will be required to prevent the production of counterfeit medical materials. In conclusion, 3D printing has demonstrated clinical use in manufacturing implants and prosthetics, planning and training for surgeries, and medical education.

3. Progress on 3D Printing of Surgical Instruments

The technique of 3D printing has several possible advantages for surgical instruments [1]. Instruments can be printed to be specific to a patient, potentially improving patient outcomes. Moreover, 3D printed instruments can be cheaper than stainless steel instruments, thereby reducing costs. Additionally, 3D printing of surgical instruments could increase the availability of these tools in low-income and middle-income countries and war zones; one limitation is that many 3D printers are not currently available in low-income and middle-income settings, and this deficiency will need to be addressed.

Currently, 3D modeling is used for surgeries and dentistry, but there is research for 3D modeling and printing of biodegradable implants and stitches. Modeling and 3D printing are emerging for surgical instruments as well. In one study, researchers used a Fused Deposition Modeling (FDM) 3D printer to create Army/Navy retractors from polylactic acid (PLA), the chemical structure of which is shown in Fig. 1. The instruments were sterile right after being printed and had no polymerase chain reaction product, meaning that the instruments could potentially be used immediately after being printed [2]. Overall, the instrument took approximately 90 minutes to print, and its cost was 1/10 of that of a comparable metal retractor; the PLA Army/Navy retractor cost $0.46 for 16 grams of PLA. This technology could be used in underserved or less developed parts of the world to give access to much needed surgeries.

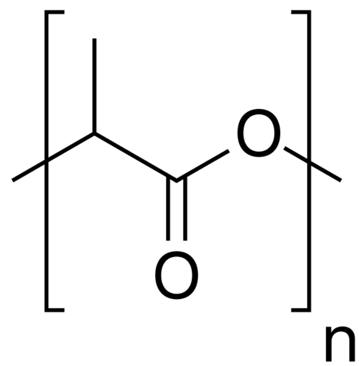

Fig. 1: Polylactic acid (PLA).

The Army/Navy Retractors that were being modeled and printed had to meet several technical specifications. The instruments had to be strong enough to retract human tissue, withstand multiple sterilizations, and not cause allergies in patients. Most of the sterilization methods studied did not affect the strength of the printed retractor but some left behind some harmful amounts of chemicals. To make the retractors, the researchers used Makerbot Makerware software, Makerbot slicer, and the Makerbot Replicator 2. The retractors were 17 cm x 1.5 cm x 4mm and were 75% infilled. The instruments were sterilized with FDA approved glutaraldehyde protocols, so that the instruments could be used in a surgical setting. Before and after sterilization, the instruments were able to withstand 13.6 kg of tangential force.

The time that it took to print a retractor was less than 90 minutes and was consistent with each print. The print time was mainly dependent on the g-code made by the slicer program and what printer was being used. Each retractor that was printed was accurate due to the design and the resolution of the printer. While the environment had bacterial gene products, the instruments that were collected immediately after being printed didn't have any. The retractor was able to withstand 11.3 + 0.57 kg of tangential force, started to visually deform at 13.6 + 0.68 kg of force, and finally broke at 15.9 + 0.8 kg of force. The cost of the 3D printer itself was $2199, and one kg of PLA cost $27.99 with shipping. Each retractor was 16 g, which means that 61 retractors could be made with one kg of PLA and equates to about ¢46 per retractor.

In the design process, there were some edits to the retractor to optimize the model for FDM printing. The overall force that the retractor could handle was more than enough for operating room use, making 3D printed retractors viable for surgeries. When the retractor did break, it was consistent in each retractor and was a clean break, so that retractor failure could be predicted.. The researchers used polymerase chain reaction (PCR) to test sterility, and glutaraldehyde sterilization was used to sterilize the retractors. In 92% of cases, the retractors were sterile after being printed and could be immediately used. PLA was chosen to print the instruments because it is unlikely to cause allergies.

This technology is easily accessible in developed countries but is also accessible internationally due to the small amount of electricity needed to power a 3D printer. The retractors are relatively easy to reproduce with other printers because one only needs the 3D model and printer settings to reproduce the tools. After printing 95 PLA retractors, a 3D printer would pay for itself, given the price of traditional stainless steel retractors. To add onto that, 3D printers are able to produce retractors for an extended period of time at lower costs. As better 3D printing technology is developed, more and more medical instruments will be accessible, but intricate instruments may still pose a problem to FDM printers.

In a broader study, researchers used a Selective Laser Sintering (SLS) 3D printer and DuraForm EX plastic to print five different surgical instruments: needle driver, hemostat, Army/Navy retractor, scalpel handle, and forceps [3]. Each of the printed instruments was tested on male cadavers. A set of five instruments (needle driver, hemostat, Army/Navy retractor, scalpel handle, and forceps) took 20 hours to fully print. On average, each instrument had four design cycles to reach a final design. The iterative process was to print the instrument, then test it, get feedback from surgeons, redesign the instrument based on the feedback, and repeat the cycle. For the needle driver, the overall design process took the most time out of all five instruments, with six hours. The reason is that the tips of the driver would always cross and drop the needle. Even after edits to the hinge, the driver would still drop the needle. The final design had the arms interlocked. The hemostat took five hours to design, and the edits to the model included editing the hinge to reduce the tips crossing, and thickening the tips to increase the visibility. The Army/Navy took two and a half hours to design and the main edit was increasing the strength of the retractor. The scalpel handle took three hours to design and was similar to a normal handle except the blade holder was strengthened. The forceps took three and a half hours to design and the edits were to make it easier to grip and increase the stiffness. The reason for the majority of the edits was the differences in mechanical properties between plastic and stainless steel.

4. Production of 3D Printed Surgical Instruments for Space Missions

In long duration space missions, it is predicted that surgeries are going to occur. Due to many factors (mass, volume, skills, ancillary services, and cost constraints and uncertainties regarding which surgical disorders may occur), it is impossible to be prepared for a full surgery, so 3D printing could be used in these situations to produce the tools needed for a surgery. The main use for 3D printing during/in-space missions is to be able to print tools on site.

A recent study evaluated whether crew members of a simulated Mars mission, who had no surgical experience, could use acrylonitrile butadiene styrene (ABS) printed instruments [4]. The result was that there were no differences between the control instruments and the 3D printed sponge stick, towel clamp, scalpel handle, and Adson toothed forceps. The individuals who tested these instruments were from the Hawai'i Space Exploration Analog and Simulation 2 (HI-SEAS 2) mission; the team was composed of two men and three women. None of the crew members had any surgical experience (medical school, residency, or surgical practice or skills). The crew completed 16 sets of 4 timed simulated tasks from April 2014 - July 2014 using these printed instruments.

The models of the sponge stick, towel clamp, scalpel, and Adson toothed forceps were made using SolidWorks 3D CAD 2012 on Windows 7. The instruments were chosen because they are used for prepping, draping, incising, and suturing. The models were based off of their traditional metal versions. The printer that was used was a Dimension Elite 3D printer with Stratasys Catalyst EX 4.0.1 3D software. ABSplus-P430 was used as the instrument material and P400 SR Soluble Support Material was used as support. After printing, the support material was manually removed and dissolved in a heated alkaline bath (Stratasys WaterWorks Soluble Concentrate P400SC).

The first task the members had to complete was to prep an area with 10% povidone-iodine solution, the second task was to clamp a cloth surgical towel, the third task was to make a cut with a surgical blade on a handle, and the fourth was to suture on a suture pad. Crew members completed tasks with both 3D printed instruments and conventional metal instruments. The order in which control or printed instruments were used was randomized. All of the tasks were completed by the team and showed no substantial difference in the time of completion between control and printed instruments.

One limitation of the study is that there could be bias from the testers if they knew that they were using a printed or control instrument. The result could also have changed if experts were using the printed instruments. In space, the outcomes of the instruments could be altered as well, making the instruments different from what it is on Earth. However, overall these results support further research on 3D printed surgical instruments. If approved, 3D printed instruments could be used to perform surgeries that otherwise might have failed or been impossible in space.

Another study explored FDM printer capabilities in microgravity and the resulting ABS surgical instrument performance on Earth [5]. The researchers tested the ABS printed tools, applied the findings to the design and printing process, noted the printing time, and assessed whether the printed tools could be used based on 13 surgeons' feedback. Printed instruments were stress tested to compare the difference between FDM printed and industrially manufactured ABS tools. To test the performance of the instruments in a surgical setting, 13 surgeons were tasked with prepping, draping, incising, and suturing using printed and conventional instruments. The surgeons were then asked to rate each instrument on a five-point Likert scale.

To create the surgical instruments, the researchers used SolidWorks 3D Computer Assisted Design 2012 software in Microsoft Windows 7 Workstation to create models of towel clamp, sponge stick, scalpel handle, straight hemostat, curved hemostat, Adson's toothed forceps, Debakey tissue forceps, smooth forceps, Allis tissue clamp, and right angle clamp. These instruments were modeled due to their uses in many types of surgeries. The models were based and influenced by stainless steel and MRI safe plastic instruments. Some changes were made to accommodate the difference in material.

To test if 3D printed ABS would be weaker than solid conventional ABS, the researchers printed small pieces of ABS with thicknesses of 1.588 mm, 3.175 mm, and 6.35 mm to test their strength. These pieces were printed on a Stratasys

Dimension Elite 3D printer in different orientations. All of the pieces were tested using a MTS 858 hydraulic load frame with a 13,000-N load cell. The data from the stress test was then analyzed with a custom MATLAB program to find yield strength and linear region stiffness. The findings were then used to influence how the instruments would be modeled and printed.

The data showed that printed ABS objects were weaker than conventional ABS objects. Horizontally printed objects were stronger as the thickness increased, but vertically printed objects had little effect on the strength of the object. However, vertically printed objects did reveal that stress applied transversely to the layer direction makes the instrument very weak. So, to ensure each instrument was as strong as it could be, the instruments were printed in specific orientations. The time each instrument took to print varied widely due to the complexity of an instrument, for example, the scalpel handle took 51 minutes to print while the sponge stick took 10 hours and 24 minutes to print.

The instrument model files were in .STL format and were printed using a Dimension Elite 3D printer with Stratasys CatalystEX 4.0.1 3D printing software. The layer resolution was at 0.178 mm (0.007"), model interior at "solid", support fill at "sparse". The orientation of each instrument was optimized for its purpose. The instrument material was ABSplus-P430 plastic, and P400 SR Soluble Support Material (Stratasys, Eden Prairie, MN)" was used as the support material. Once printed, the support structure was taken off by hand and any remaining pieces were dissolved in a bath of heated alkaline detergent solution of WaterWorks Soluble Concentrate P400SC.

In total, 13 surgeons (8 men, 5 women) were given anonymous questionnaires after completing four timed simulated tasks using the instruments. The first task was to use a sponge stick to clean and prep an area with 10% povidone-iodine solution. The second task was to clamp a cloth surgical towel with a towel clamp. The third task was to insert a #10 stainless steel surgical blade into a scalpel handle and then making a 5 cm incision. The fourth task was to use a toothed forceps to suture close a 5 cm incision. The standard deviation in the time taken to complete each task was calculated using Excel. Ratings of each printed instrument was given by the surgeons using a 5 point Likert scale and open-ended feedback was welcomed as well.

When the tools were 5.75mm or thicker, the printed tools performed less than 10% worse than conventional ABS thermoplastic. The major difference was when the stress load was applied perpendicular to the printed layers. During surgical testing of the tools, there was no major time difference in completion between the printed tools and conventional tools. When surveyed, 100% of the surgeons agreed that printed smooth forceps could replace conventional ones. In addition, 92%, 85%, 77%, 77%, and 69% of surgeons believed that tissue forceps, curved and straight hemostats, tissue and right angle clamps, respectively, would also be able to replace conventional ones. All of the surgeons were able to complete the tasks and the majority agreed that all the instruments would be viable in surgical settings

Overall, printing surgical tools from ABS thermoplastic is feasible on Earth, but a key design change is that the layers need to be along the force that is applied. While this study mainly focused on FDM printing with ABS, there are other plastics as well. The properties of different materials could affect the sterilization requirements and safety concerns. While other plastics may be stronger, they require more power, higher temperature, and longer printing times.

All the tasks were completed with the printed instruments and there was no substantial difference in completion time. Since it takes too long to print instruments, 3D printing instruments for remote settings is not viable. However, 3D printing could replace used instruments after operations or be printed before an operation. The long print times could be reduced by redesigning instruments. An upside is that 3D printing allows for optimizations and/or customizations to an instrument, and 3D printing could also reduce costs and improve the self-sufficiency of space missions. FDM printers can reduce waste for long term space missions because they can reuse waste plastic. While sterilization of the tools was not studied, other research has found that the high temperature of printing can sterilize a newly printed object and applying Decon Gel to FDM printed ABSi-AG plastic tools reduced 99.9% of living cells. Another study found that 3D printers emit billions of ultra-fine particles while printing so if printers were to operate in space, they would need to be sealed.

In September 2014, an FDM ABS printer that is gravity-independent was sent to the ISS to test functionality [6]. It was sealed to prevent gases from leaking into the ISS's system. The first item that was printed in space was a panel from the printer, showing that the printer could repair itself. The next FDM printer that is being sent to the ISS has a larger printing platform and can print using different types of material (ABS, high density polyethylene, and polyetherimide/polycarbonate). The Italian Space Agency is planning to send a FDM PLA printer to the ISS soon. This technology could allow items to be sent into space by sending a design to the ISS to 3D print it.

Currently, studies have reported that it is cost beneficial and feasible to 3D print surgical instruments, mallet splints and dental tools. The ideal 3D printed medical instruments would be able to be manufactured with onboard printer filament, be composed of local or recycled materials, relatively low power and low material cost, be printable with non-medical 3D printers, require no post-processing and minimal assembly, be reliable and customizable, and sterilized or hygienic. However, to be usable in urgent surgical emergencies, 3D printers will need to be faster at printing items. On the other hand, 3D printers could create instruments before operations, customize instruments to certain needs, resupply after operations, and make dental instruments before operations. Studies also show that FDM printers sterilize the item during printing but more research is needed into sterilization for space missions.

Space missions have many constraints which can lead to limited medical skills in-flight, resulting in health conditions and unwanted mission outcomes. Printing tools give exploration type missions the ability to provide medical care. The versatility of 3D printing can also produce instruments that can apply to different medical situations. FDM technology potentially has the ability to auto-repair, recycle, and incorporate built-in sterilization. This means that it could reduce the cost of missions and improve the health of crew members. Because of this, NASA and ESA are researching 3D printers to provide a localized resupply of items. The technique of 3D printing can address many of the challenges listed in the NASA Human Research Roadmap.

5. Conclusion

Manufacturing of surgical instruments could be greatly advanced by 3D printing. The technology can be used for low resource areas of the world, and 3D printing allows crowd-sourcing of designs. It can also be useful in many other applications such as dental instruments, instruments for patients, left handed operators, or custom splits. The discarded or waste plastic can be melted and recycled, allowing reuse of old printed instruments. Before 3D printing of instruments can be widely adopted as an approach for performing surgeries, many more instruments need to be printable and printing speed needs to be faster. Moreover, the plausibility and reproducibility of 3D printed instruments in both space and emergency settings must be evaluated. To be truly useful, 3D printed instruments must be mechanically strong, cost-effective, and usable by both skilled and unskilled operators. With further technological advances, 3D printed surgical instruments may soon achieve widespread acceptance.

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