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ORIGINAL RESEARCH

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Three-Dimensional printed instruments used in a Septoplasty: A new paradigm in Surgery

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Abstract

Objective: Three-dimensional (3D) printing has been rapidly adopted by different surgical disciplines. It has shown itself to have improved outcomes in education, pre-operative planning, and reconstruction. However, using 3D printing to create surgical instruments is a niche within the literature that has not yet been fully explored. The authors present a study in which it is hypothesized that 3D printing surgical instruments can be utilized successfully within ENT surgery.

Methods: As one of the most common ENT operations worldwide, a septoplasty was chosen as the procedure to provide proof of concept. For the septoplasty, five instruments were printed: a scalpel handle, needle holders, toothed forceps, a Cottle/Freer elevator, and a Killian's speculum. The entire set took 224 minutes on average to print, weighed 36 g, and only used approximately 86 pence ($1.20 USD) worth of polylactic acid plastic to create.

Results: All steps in performing a septoplasty on a human cadaver with the 3D printed tools were possible and were undertaken successfully. This yielded a similar outcome to using stainless steel with the added benefit of there being a large reduction in cost and the ability for rapid customization according to the surgeon's preferences.

Conclusion: As technology and mainstream interest in 3D printing develops, the availability of more precise Computer-Aided Design software will allow for more complex designs of tools to be created. Currently, 3D printing has been shown to be a promising method from which future surgical tools can be fashioned to meet the complex, dynamic demands of surgery.

Level of Evidence: N/A.

KEYWORDS
global health, otolaryngology, surgical instruments, three-dimensional printing

1 | INTRODUCTION

Three-dimensional (3D) printing originated in the 1980s, with the first successful 3D print by Hideo Kodama in 1981.[1] Over the next decade, different methods were experimented upon, until the most popular version, fused deposition modeling (FDM), became commercially available through American inventor S. Scott Crump and his company Stratasys in 1992.[2] FDM is still the most common method used in 3D printers today.

At its core, FDM relies on a single continuous filament of thermoplastic being fed through a heated extruder onto a stable surface where each layer of plastic is used to build a desired object. The extruder is guided by computer software in which 3D plane of direction to move in and on where to deposit the plastic. This leads to the possibility to create a multitude of different structures ranging in their lengths, breadths, and heights.

A variety of different materials have been trialed with FDM since its conception including acrylonitrile butadiene styrene (ABS), Nylon, and most importantly for the surgical field, polylactic acid (PLA). PLA has been thoroughly scrutinized in the literature and has been proven to be both reliable and safe[3] thus its heavy utilization in surgical devices such as suture material and implants.

The 21st century has seen the rapid adoption of 3D printing by different surgical specialties, most notably in education,[4] preoperative planning,[5] and reconstruction.[6] However, using 3D printing to create surgical instruments is a niche that has begun to emerge in the literature. Kondor and his team[7] were the first to describe the use of 3D printing to develop general surgical instruments and commented on its advantages in allowing for rapid customization and ease of modification according to the surgeons' preference. Since then, other papers have explored the use of 3D printing in surgical instrumentation.[8,9] Research in the nascent discipline of global surgery has also highlighted its potential in providing surgical care within resource scarce areas of the world.[10]

Ear, Nose, and Throat (ENT) are a poorly represented specialty in global surgery. The lack of attention given to ENT pathologies is thought to be because many of the disorders themselves are not necessarily seen as life threatening, and so patients do not always seek help.[11] Much of this is rooted in perception. Despite severely affecting quality of life, many otolaryngological diseases can be easily treated. One of the often-cited barriers to treatment is the prohibitive cost relative to how benign the condition seems.[12] This is particularly exacerbated when equipment, theatre time and staffing are just a few of the expenditures factored in.

Therefore, finding a way to lower the cost of ENT health care globally to make it more accessible will help change this perception. 3D printing surgical tools given the financial advantage it has, the ability for rapid production and the ease of sterility,[3] may be a potential part of the solution in overcoming this global problem. As surgical tools contribute to one part of the high overall financial cost of performing ENT surgery globally, we hypothesize that 3D printing will potentially allow for a less expensive way to conduct ENT surgery. By decreasing the cost in one component, namely, instruments, this should lessen the overall price. For this study, we chose to show proof of concept through printing tools for a septoplasty, as it is one of the most common ENT operations worldwide.[13]

2 | MATERIALS AND METHODS

To assess if it was possible to perform a septoplasty on human cadaveric heads using a 3D printed septoplasty toolset, the identified instruments were a Killian's speculum, Cottle/Freer elevator, toothed forceps, needle holders, and a scalpel holder (Figure 1). As this study used human cadaveric heads, in line with the recommendations of the Declaration of Helsinki, ethical approval was not sought.

The open-access, browser-based, online Computer-Aided Design (CAD) software TinkerCad was used to create digital models of the surgical instruments (Figure 2). TinkerCad was chosen due to its ease of use, ready accessibility, and ability to create a multitude of designs. The designs for the needle holder, forceps, and scalpel handle were imported from the open-source website "Thingiverse" before being modified in Tinkercad, whereas the Cottle/Freer elevator and Killian's speculum were designed based on existing instruments.

Every design from TinkerCad was exported as an .stl file, before being uploaded into FlashPrint, a slicing software developed by FlashForge, where it was converted into a .fpp file which could then be read by the 3D printer (Figure 3).

The 3D printer used was the FlashForge Finder, which has a build space of 140 mm × 140 mm × 140 mm, utilizes FDM as the method of printing, and extrudes the plastic at 220°C onto a non-heated build plate (Figure 4). This printer was bought for £280.00 GBP.

PLA plastic was used to print the instruments. The overall print time of each septoplasty set, consisting of five instruments, was on average 224 minutes, with approximately 2 minutes spent to detach the instruments from the build plate, assemble the tools, or file off stray plastic residue. After each set was printed, the tools were reviewed by the senior author, an ENT consultant surgeon (SKA), for

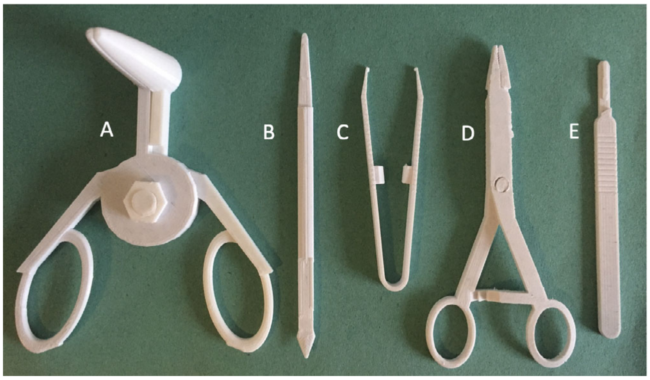

FIGURE 1 The septoplasty toolset consisted of five 3D printed instruments. They are pictured according to their labels from left to right. These are the, A, Killian's speculum, a, B, Cottle/Freer elevator, C, toothed forceps, D, needle holders, and a, E, scalpel handle

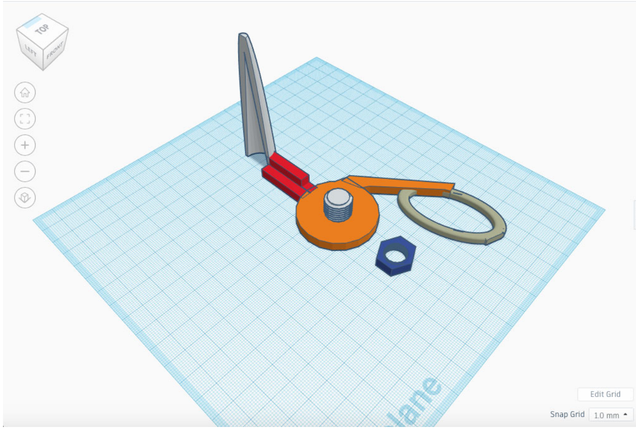

FIGURE 2 One half of the Killian's speculum designed in TinkerCad, the custom designed bolt is also included

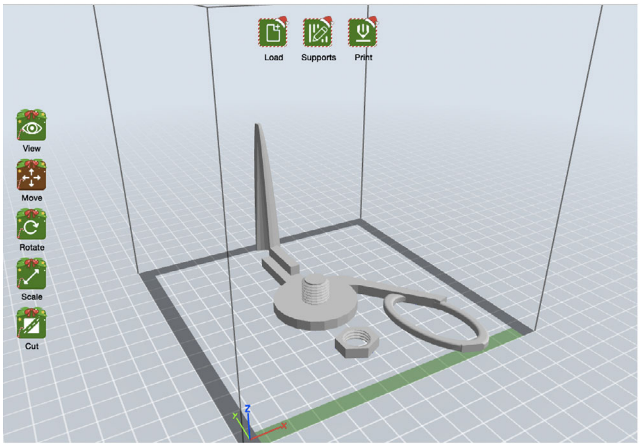

FIGURE 3 The design of the Killian's speculum exported into Flashprint, ready to be sliced by the software before being eventually printed

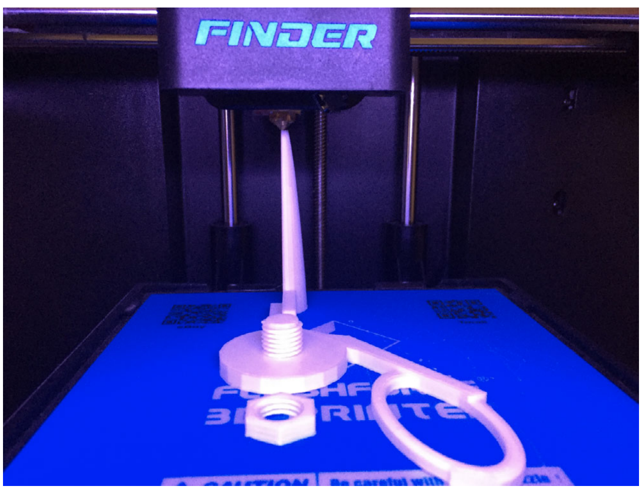

FIGURE 4 The printer, having downloaded the sliced print, is printing the same design in PLA plastic at 220°C

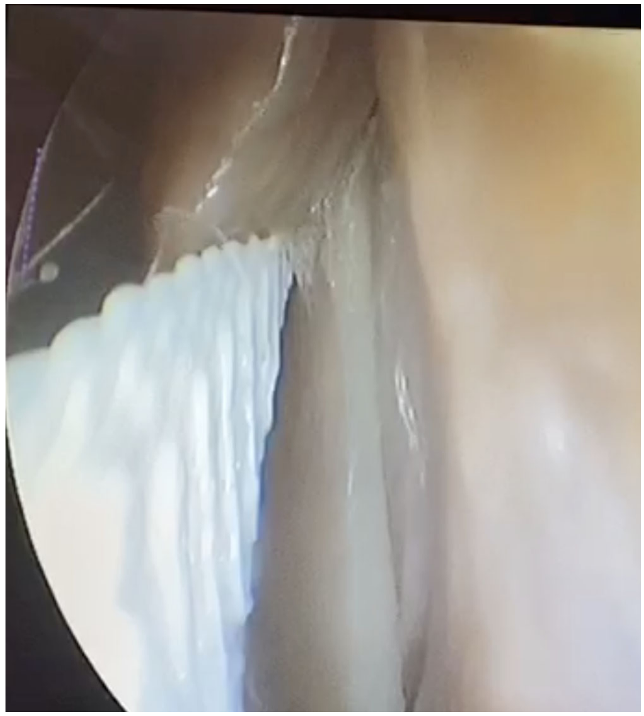

FIGURE 5 The mucoperichondrial flap being raised by the 3D printed Cottle elevator

potential design improvements until the prototypes of each instrument were deemed to be acceptable. The instruments did not require sterilization as they were tested on human cadavers.

A fresh-frozen cadaveric head was used to test the prototype septoplasty set. A standard right sided hemi-transfixion incision was made with a size 15 blade mounted on a 3D printed scalpel holder and a mucoperichondrial flap was carefully raised using a 3D printed Cottle elevator (Figure 5), and Killian's speculum (Figure 6). A bony spur and deviated piece of quadrangular cartilage was excised (Figure 7), and the septal mucosa was then placed back on the septum and fixed with a quilted vicryl suture.

3 | RESULTS

All steps in performing a septoplasty on a human cadaver were possible and were undertaken successfully.

3.1 | Killian's speculum

The Killian's speculum (Figure 1A) required the greatest number of modifications as its role in a septoplasty is to allow for the retraction and separation of the mucoperichondrial flap from the septum as well as to identify the correct surgical plane. Continuous surgeon feedback led to numerous prototypes with modifications mostly concerning its thickness, complexity of its hinge and overall ergonomics.

FIGURE 6 The Killian's speculum being used to separate the tissue within the septum, the surgeon is also continuing the dissection with the Cottle elevator

FIGURE 7 Identification of a bony spur and deviated piece of quadrangular cartilage prior to excision

Originally, it was trialed to have both parts of the speculum to be 20 mm thick, however, this proved to be too cumbersome. Further prototypes of 10 mm and 8 mm were printed, until 5 mm was found to be the optimal thickness. The instrument was printed 132 mm in length and 75 mm in width. The nasal portion of the speculum had a

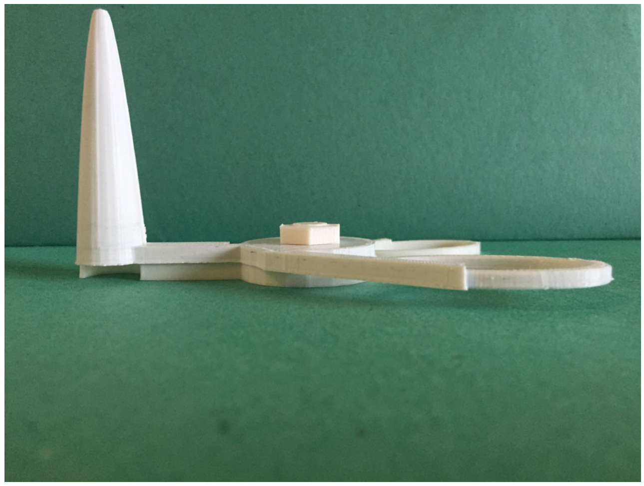

FIGURE 8 A lateral view of the Killian's speculum, showing how it is stacked as well as being kept together by a custom printed bolt

height of 75 mm. Collectively, the instrument required 730 cm of plastic filament to create.

The authors appreciated that traditionally in a septoplasty set the nasal portion of the speculums have a variety of heights; however, for this study, the authors chose an optimum height of 75 mm.

As the speculum could not be printed in one piece, it was printed in two stages to allow a functional hinge. This involved stacking two parts over one another and securing them together with a custom printed bolt (Figure 8).

A feature that was seen as an ergonomic requirement during the design conception was that a right or left-handed surgeon should be able to hold it with ease. Open handles were first used, however, there was no stability when the instrument was held. Individualized finger slots were attempted but this did not allow for ambidextrous use of the speculum. Finally, large finger holes that could fit four fingers were placed on both handles and this was found to allow for the greatest flexibility and comfort of use. The print time was on average was 133 minutes and required six iterations before an acceptable prototype was created.

3.2 | Cottle/Freer elevator

The design approach to the Cottle/Freer elevator was to have one end having the features of a Cottle elevator and the other end having the features of a Freer elevator (Figure 1B). The instrument was printed to be 145 mm in length, 8.5 mm in width, 4.8 mm thick, and used 77 cm of plastic filament to create. The greater length was achieved by printing with the instrument obliquely on the printing board.

The Cottle elevator was designed to be able to cut mucosa and lift large planes of tissue. In the CAD, a kite shape template was rotated 20° upwards and superimposed onto the tapered ending of the shaft to allow for the described functionality.

The Freer elevator had the purpose of lifting soft, fragile tissue such as mucosa and, therefore, it was decided it would be designed to contrast the sharpness of the Cottle and be rounder therefore blunter. The authors noticed that as the Freer end was only 2.75 mm in thickness, and when printing the instrument in an environment of high humidity, the tip would curve upwards by approximately 15°, but remain static in colder environments. The print time was on average was 13 minutes and required 11 iterations before an acceptable prototype was created.

3.3 | Toothed forceps

Originally the file for the design of the toothed forceps came from "Thingiverse" before it was subjected to modifications according to our requirements (Figure 1C). The file itself presented a model that was not toothed and much larger. The authors scaled down the size in order for it to be usable within the nose and added teeth for better grip. The instrument was printed to be 95 mm in length, 10 mm in width (at the finger grip end) and used 81 cm of plastic filament to create. The print time was on average was 18 minutes and required four iterations before an acceptable prototype was created.

3.4 | Needle holders

The file for the design of the needle holders came from "Thingiverse" before it was subjected to modifications according to our requirements (Figure 1D). The authors found the needle holders to be too short and therefore the only modification we made was to lengthen the instrument. The instrument was printed in two parts to accommodate for a hinge. It was 160 mm in length, 37 mm in width and used 250 cm of plastic filament to create. The print time for both parts was on average was 47 minutes and required six iterations before an acceptable prototype was created.

3.5 | Scalpel handle

The file for the design of the scalpel handle came from "Thingiverse" and was found to be acceptable on the first print (Figure 1E). When tested it was able to securely hold a number 15 blade on the first attempt. The instrument was printed to be 120 mm in length, 10 mm in width and used 83 cm of plastic filament to create. The print time on average was 13 minutes.

4 | DISCUSSION

The aim of this article was to show proof of concept detailing the process of designing, printing and evaluating 3D printed surgical instruments for use in ENT operations. The authors faced numerous obstacles to refine this process to produce a usable instrument set.

One of the issues faced was optimizing the design of the hinged instruments used, in particular the Killian's speculum. When using CAD to create hinged models, both the ease of assembly and the potential compromise of structural integrity needed to be considered. The technique applied to securing the instrument is described in the methods. A pair of pliers was required to tighten the bolt into the nut. This method of assembly was easy to follow and could be undertaken in sterile conditions.

Given that the Killian's speculum main role was to retract and separate tissues, its structural strength also needed to be considered. The handles which would transmit the force of the user into the instrument needed to be of an adequate size so as to prevent the instrument bending when enough pressure was applied but also being of enough distance so that the hinge would not obstruct the operative view. The authors found that widening the angle of the handles allowed for these criteria to be met. By keeping the handles short and flat, this mitigated any issue of potential interference with the operation.

Using PLA to construct instruments as opposed to conventional stainless steel was also seen as having the obvious disadvantage that the tensile strength of PLA plastic instruments is inferior. The authors found on multiple occasions that it was difficult to print instruments of the right thickness that could withstand the required force placed upon it. This led to the conclusion that using 3D printed instruments on soft tissue may be able to produce similar results as stainless steel; however, harder tissue such as bone may require adaption and further research into finding an optimal material. Furthermore, plastic instrumentation with its lightweight nature has its own learning curve in regard to instrument balance and "feel" when it is held in the surgeon's hand.

Although the difference in tensile strength was noted, there was a significant advantage when weight and cost were considered. The septoplasty set only weighed 36 g with all the parts assembled and using a plastic spool that was purchased for £12.00 GBP per 500 g, this meant the entire set cost 86.4 pence (approximately $1.20 USD) to print. Comparing this to a stainless-steel toolset that would cost over 1000 times more and be far heavier. If similar surgical outcomes can be attained this could provide an acceptable substitute in resource scarce environments where there may also be logistical issues in transporting any instruments. The lightweight nature of the instruments could especially be seen as an advantage with shipping costs to third-world countries.

Previous literature has also questioned the sterility of instruments as they are printed. As the plastic is extruded out of the printer under high pressure and at 220°C, if the plastic was deposited on a sterile surface, and handled with sterile gloves, sterility could be maintained. Research has also shown that even using a sterilizing agent, such as glutaraldehyde, which requires instruments to be submerged in a 35°C solution for 5 minutes[3] does not weaken PLA and may further ensure the sterility of printed instruments.

Global initiatives are moving toward creating a sustainable future in which countries are becoming more aware of how efficiently they allocate their resources. Materials such as PLA present an opportunity in global surgery to make the discipline more environmentally friendly.

PLA has been seen as having the potential to be the future replacement of current plastics, due to it being derived from sustainable resources rather than hydrocarbons.[14] PLA has also been proven to be readily recyclable. There is still much debate in the literature as to how effective PLA will be, however, as research continues and technology improves, it may be possible to see a future in which 3D printed surgical instruments using PLA may lead to a model of recycling the plastic after use and converting it into spools of continuous filament that can then be used to print further instruments.

5 | CONCLUSION

3D printing surgical instruments for use in a septoplasty in a human cadaveric model has been shown to produce a similar outcome as using stainless steel with the added benefit of a large reduction in cost and the ability for rapid customization according to the surgeon's preferences. This study has shown that this proof of concept was achievable and may now be translated into many other surgical disciplines.

Global surgery is rapidly growing as a discipline and it is becoming increasingly evident that ENT does have a place in the evolution of optimizing surgical health care worldwide. However, this will require more research into improving logistics, the level of financial burden and public perception before it is widely accepted.

As technology and mainstream interest in 3D printing develops, the availability of more precise CAD software will allow for more complex designs of tools to be created. Currently, 3D printing has been shown to be a promising method from which future surgical tools can be fashioned to meet the complex, dynamic demands of an interconnected global health care system.

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The authors acknowledge the work concerning the needle holder by Josh (00sufs), as downloaded from https://www.thingiverse.com/thing:200630#Summary. The license can be found at https://creativecommons.org/licenses/by-nc/4.0/legalcode. The changes to the design have been detailed in the article and we declare its use for research only.

The authors acknowledge the work concerning the scalpel handle by Joshua Olsen (rubisco2000), as downloaded from https://www.thingiverse.com/thing:655671. The license can be found at https://creativecommons.org/licenses/by-nc/4.0/legalcode. No changes were made to the design and we declare its use for research only.

CONFLICT OF INTEREST

All of the authors declare there to be no conflict of interest.

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