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3D Printing of Surgical Instruments for Children: Testing the Novel Concept

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BACKGROUND
Three-dimensional (3D) printing is currently being explored in various medical fields with promising results, and customized surgical instrument prototyping and production seems to be one of the promising approaches, particularly in pediatric surgery. This study aimed to test the possibility of desktop 3D printing of surgical instruments for use in pediatric surgery.

MATERIAL and METHODS
Roux retractor and infant laparoscopic trocar were designed using Solidworks 3D CAD software (Dassault Systemes, FR). Mechanical durability simulation tests were performed using Solidworks Simulation software. The instruments were printed in Ultimaker 2+ Extended 3D printer (Ultimaker, NL) using 2.85-mm polylactic acid filaments.

RESULTS
Roux retractor was designed in 15 min and printed in 90 min. Laparoscopic trocar was designed in 2 h and printed in 2 h. Application of 5-kilogram force (kgf) resulted only in 0.84-mm displacement in infant laparoscopic trocar. The 5 kgf applied to the Roux retractor's curved face caused 9.22-mm displacement. The laparoscopic trocars weighed 7.40±0.07 g, and Roux retractors weighed 12.50±0.04 g. The interior chamber of the 3D-printed laparoscopic trocars withstood a mean of 10±1.5 mmHg pressure without any obvious air leakage. Post-sterilization culture results of all prototypes were proven to be sterile.

CONCLUSION
3D printing of surgical instruments is a promising field in pediatric surgery as it offers a great versatility regarding both design and production.

Keywords: Three-dimensional printing, surgical instruments, children, pediatric surgery

INTRODUCTION

Three-dimensional (3D) printing gained widespread acceptance in many fields of industry and science. Rapid prototyping (RP) technology brought our design to real objects instantly, which allowed us to handle and modify the functional prototypes before production. Conventional manufacturing processes require complex and time-consuming molding techniques. However, RP and desktop 3D printing allow scientists to see and hold their functional prototypes in a relatively short time.

Three-dimensional printing made a quick entrance in medicine, and surgical sciences adapted this technology at the same time with the automotive engineering and aviation fields. The main applications of 3D printing in the field of surgery include manufacturing of anatomic models based on patient imaging studies, instrument, device, implant production and regenerative medicine (1-7).

Many studies have been conducted regarding organ models, prosthetics, and surgical implant manufacturing; however, few reports are available related to 3D printing of surgical instruments (8-11). To our knowledge, there is no published work

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exploring this issue in the field of pediatric surgery. In this study, we aimed to test the possibility of manufacturing 3D printed surgical instruments for use in children.

MATERIALS and METHODS

All design and manufacturing operations were performed in university-based 3D printing facilities. Ethical approval and informed consent were not required as there were no human or animal experiments. Two types of instruments were selected; Roux retractor was chosen as the low-detail level and infant laparoscopic trocar was selected as a high-detail level instrument. The instruments were designed using Solidworks 3D CAD software (Dassault Systemes, FR). Mechanical durability simulation tests were performed using Solidworks Simulation software (Dassault Systemes, FR) prior to the printing process. During design, fine meshes were created with approximately 80,000 nodes on each instrument to obtain more realistic results from the Solidworks Simulation software. The holding nodes and force-applied nodes were chosen as per the directions of surgical use of these instruments. For a better comparison, all designed instruments were tested under same conditions with 5 kgf, which is equal to 49 Newton (N). Regarding the design of the instruments, one to three faces were chosen for applying the force (Figure 1). The applied forces were expected to create mechanical stress all over the instrument since we were looking for the most vulnerable part of our designs. Mechanical stress is a physical quantity that expresses the internal forces that neighboring particles of a continuous material exert on each other. Maximum displacement is representing areas which had the most displacement under the specified forces. Irreversible plastic deformation point is defined as the point at which material goes into a stage of inability to turn back to its original state, and this condition is followed by fracture. The glass transition of polylactic acid (PLA) occurs at 60°C, and the cooling process creates few micro-fractures, but these fractures are considered negligible. For better surface finishing, the printed instruments had five outer shells, which resulted in smoother outer surface.

Five of each instrument prototypes were printed in Ultimaker 2+ Extended fused deposition modeling (FDM) 3D printer (Ultimaker, NL) using 2.85-mm PLA filaments (Figure 2). All printed products were found to be contaminated with *Pseudomonas aeruginosa* (ATCC 27853) and placed in 5% sheep blood and Eosin Methlene-blue Lactose Sucrose Agars (EMB). After incubation at 37°C for 24 h, the contamination was proved (Figure 3) in both agars, and the products were sent to be sterilized using vaporized hydrogen peroxide. Sterilized products were placed again in agar for incubation. Each product was weighed and examined for the need of post-processing (sanding and polishing). Additionally, laparoscopic trocars were tested for air tightness using fluid immersion technique under constant pressure. The pressure was maintained and measured using manual manometer, and this test was repeated for comparison with the standard Karl Storz infant laparoscopic trocar (Karl Storz GmbH, Tuttingen, GE). Mean values and standard deviations were calculated using IBM SPSS v21 for Macintosh (IBM, VA, USA).

RESULTS

Design time varied for each instrument; Roux retractor was designed in 15 min, and laparoscopic trocar was designed in 2 h. During mechanical stress simulation test, the force per mm^2 in laparoscopic trocar resulted in 9.7kgf, and this force which is nearly double the originally applied force caused only 0.84-mm displacement in the instrument. The same force when applied to the Roux retractor's curved face resulted in 1.1 kgf/mm^2 and caused 9.22-mm displacement (Table 1). None of the instruments

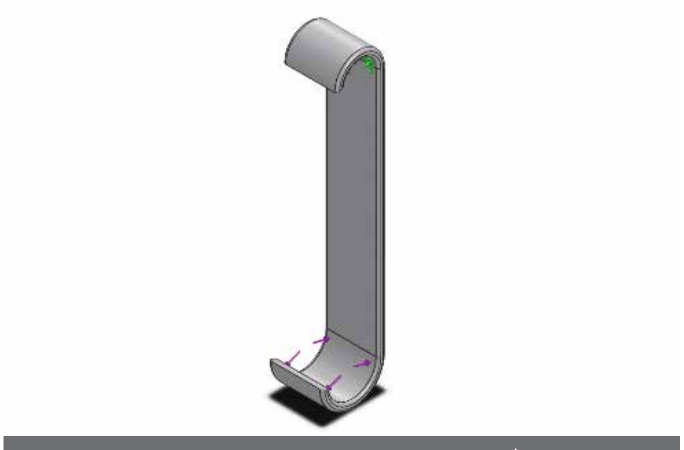

FIGURE 1. Stress simulation points in Roux retractor (Solidworks Simulation)

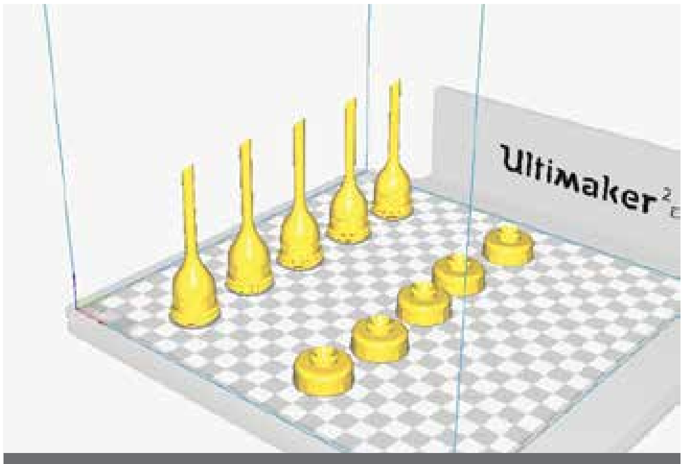

FIGURE 2. The view of five trocars on the build plate in the 3D printer slicing software

FIGURE 3. Contaminated laparoscopic trocar prototype in 5% sheep blood agar (note the intraluminal contamination)

reached the irreversible plastic deformation point during the simulation. The variability of the resulting forces per mm^2 was caused by the selection of the force application points to mimic the natural use direction of the instruments during the surgery and the design of the instrument itself.

Each Roux retractor was printed in 90 min, and each laparoscopic trocar was printed in 120 min. None of the final products required post-processing (Figure 4, 5). The mean weight of the printed laparoscopic trocars was 7.40±0.07 g and of Roux retractors was 12.50±0.04 g. The material cost was 43 and 51 Euro cents per piece respectively. All ten final products were found to be sterile in post-sterilization cultures. During the air leak tests, the interior chamber of the 3D printed laparoscopic trocars withstood a mean of 10±1.5 mmHg pressure without any air leakage, and this result was comparable with the original Karl Storz infant trocar which withstood 11 mmHg pressure.

DISCUSSION

Three-dimensional printing is developing very fast in the field of surgery, and this is the right time for pediatric surgeons to adopt this new technology. Till date, the most striking application of this technology is printing organ and tumor models for preoperative planning (4-6, 12). At the same time, 3D bioprinting is on the way to start a whole new era for the surgeons (13).

TABLE 1. Results of stress simulation tests for the designed instruments

Part	Applied Force (kgf)	Number of Applied Faces	Resulting Maximum Stress (Kgf/mm^2)	Number of Nodes	Max. Displacement (mm)
Laparoscopic Trocar	5	3	9.7	88974	0.84
Roux Retractor	5	1	1.1	79511	9.22

* total sensitivity was calculated by the number of sensitive organisms/total organisms (47)

FIGURE 4. 3D printed laparoscopic trocar (with the inserted original Karl Storz 3-mm instrument)

FIGURE 5. 3D printed Roux retractor

Currently, there are about 15 different technologies in three dimensional printing additive manufacturing, and all of them use different methods and polymers. The most frequently used methods are FDM, stereolithography (SLA), and selective laser sintering. Among those three, the most user-friendly method is the FDM technology which utilizes the thermoplastic polymers running through a heated nozzle system and adds the molten plastic layer by layer on the printing bed. The main advantage of FDM printing is the ability to print PLA, which is an FDA-approved biocompatible, biodegradable, and environment friendly polymer (14-16).

Before manufacturing a surgical instrument from thermoplastic, we knew that it had to face competition with its stainless steel counterparts. This issue was taken into consideration; the designs were modified to be slightly thicker than the conventional stainless steel instruments and were repeatedly tested for mechanical strength in Solidworks Simulation software prior to manufacturing. The main advantage of the simulation program over the conventional stress tests was the ability to observe the exact weak points of the final product and modify the design accordingly prior to printing. The printing process started after the tests proved that the instruments were resistant to stress. The final products were strong enough to be used as disposable instruments. One of our observations was that printing the part with 100% infill created a more solid and durable instrument. This issue also increased the reliability of our simulation tests. Conventional stress tests were avoided as we noticed little displacement in the simulation, and intended use was in the field of pediatric surgery in which the surgeons do not apply excessive stress on the instruments.

The other important issue was sterilization of the products after printing. Our end products were contaminated with *P. aeruginosa*, and sterilization was performed using vaporized hydrogen peroxide, which is generally recommended for hospital grade plastic instrument sterilization. Post-sterilization culture results showed that all the products were completely sterile. We did not need to test another pathogen, and we did not perform polymerase chain reaction to detect bacterial DNA, as it is known that vaporized hydrogen peroxide has good material-penetrating sterilization characteristics (14). Some authors claim that 3D printed instruments can be directly printed in operation room and used without need of sterilization due to high temperatures during printing (210°C-215 °C) (8). In theory, this approach seems to be reasonable but we do not advise it until more studies are conducted.

Retractors were produced and easily tested during our study. Laparoscopic infant trocar production was more challenging due to required strength and air tightness. As we did not have possibility to print the rubber leaflet valves which prevent air leak in te trocar, we designed the trocar cap to fit the original Karl Storz (Karl Storz GmbH, Tuttingen, GE) leaflet valves and used the original valves. Interior chamber of printed trocars sustained considerable pressure with the conventional infant laparoscopic trocar. Besides that, to increase air tightness, we plan to print the leaflets with new flexible PLA or thermoplastic polyurethane filaments in near future.

Three-dimensional printing still has challenges to overcome, but the advantages it offers encourage us to carry on with research and development in this field. The most obvious disadvantage is longer production time compared to the conventional fabrication process. Another drawback is the scarcity of FDA-approved polymers for 3D printing. The concept of 3D printing is about rapid production of functional prototypes than mass production.

The major limitation of our study was the lack of animal or human experiments. We plan to overcome this issue as soon as porcine models are available in our animal test laboratory. The other limitation was that we have only designed and printed two types of instruments, so it is impossible to generalize and apply our results to the whole set of surgical instruments. However, we think that our preliminary study showed promising results, and this urges us to continue research.

Three-dimensional printing of surgical instruments has benefits for low-income countries and far rural areas. In addition, this method can be used in military and aerospace missions where instead of carrying loads of instruments, one can just place a computer loaded with designs and several 3D printers. For pediatric surgeons, the most obvious advantage is the ability to modify and scale the instruments to the patient's size and the ability to produce dedicated instruments for special surgical cases particularly for neonatal congenital conditions.

Three-dimensional printing of surgical instruments for children deserves to be studied and developed as it offers the possibility to produce customized and scalable equipment for use in pediatric surgery.

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