3D PRINTED SURGICAL INSTRUMENTS

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Abstract - *Our project approach is to have a replacement for our regular metal or steel instruments used in present days where sterilization of those instruments takes a huge amount of our time than the surgical procedure. A surgical set consisting of hemostats, needle driver, scalpel handle, retractors, and forceps was designed using SolidWorks (Dassault Systems SolidWorks Corp., Waltham MA). These designs were then printed using a* ***JSC-Delta-230*300*** *Fused Deposition Modeling (FDM) printer (RPT Hubs, Coimbatore). Practicing general surgeons tested the final printed goods for ergonomic usefulness and performance, which included simulated surgery and human inguinal hernia repairs. By altering design and build metrics, improvements were identified and addressed. It took an average of three days to complete an iterative cycle that included design, production, and testing. The FDM was used to construct each surgical set, which took an average of 6 hours to complete. It is possible to create functional surgical instruments using 3D printing. When compared to traditional production methods, there are several advantages. Functional 3D printed surgical instruments are feasible. Advantages compared to traditional manufacturing methods include no increase in cost for increased complexity, accelerated design to production times and surgeon specific modifications.*

Key Words: **SolidWorks, 3D Printing, Fused Deposition Modeling, Surgical instruments**

1. INTRODUCTION

3D printing or additive manufacturing is a process of making three dimensional solid objects from a digital file. The creation of a 3D printed object is achieved using additive processes. In an additive process an object is created by laying down successive layers of material until the object is created. Each of these layers can be seen as a thinly sliced cross-section of the object.3D printing is the opposite of subtractive manufacturing which is cutting out / hollowing out a piece of metal or plastic with for instance a milling machine.3D printing enables you to produce complex shapes using less material than traditional manufacturing methods.

1.1 3D Printed Surgical Instruments

3D printing provides a cost-effective and timely way to manufacture personalized surgical instruments tailored to the needs of each surgeon and procedure. Also, these tools can be manufactured in such a short amount of time that hospitals do not have to maintain large inventory of equipment and can instead order manufacturing on demand.

Surgical instruments customized to the size and shape of each surgeon's hand, and additional adjustments for each application can significantly improve results and efficiency. In addition, a specially designed surgical guide for each patient can improve accuracy while reducing time in the operating room by eliminating the need to consult a medical record or assistant.

Forceps, retractors, needle drivers, hemostats and scalpel handles are among the wide range of surgical tools that have been produced using 3D printing technology. These instruments are also the basic surgical set used to treat and operate inguinal hernia

2. EXISTING SYSTEM

3D printing enables us to design and fabricate surgical instruments. Authors have investigated the performance of 3D printed surgical instruments in surgical procedure such as an indirect inguinal hernia. Thus, the general surgical set for inguinal hernia repair has been build using additive manufacturing. This includes hemostat, needle driver, scalpel handle, forceps, self-retaining retractor and army-navy retractor. Despite the fact that the instruments performed sufficiently well, certain feedbacks have been observed by the surgeons such as slippage of needle holder when driving through fibrous tissue and crossing of forceps tips when grasping tissue at oblique angles.

3. PROPOSED SYSTEM

The system to be developed is proposed in a way that aims at overcoming all the difficulties faced by the existing system. Metallic inserts are added into the face of the grasping surfaces of the needle driver, thus removing the slippage of needle holder that was faced during the surgical operation. Also, the profile of forceps is altered to increase off-axis instrument stiffness. This can be achieved by the use of incorporating two thermoplastic polymers that provides different properties such as stiffness, flexibility, durability, high temperature resistance, high impact strength and medical grade. Thus, Acrylonitrile Butadiene Styrene (ABS) and DuraForm ProX EX are incorporated, where ABS is an opaque thermoplastic that is relatively stiff and strong making it easy to print on and the latter is a strong, tough nylon-11 based plastic material.

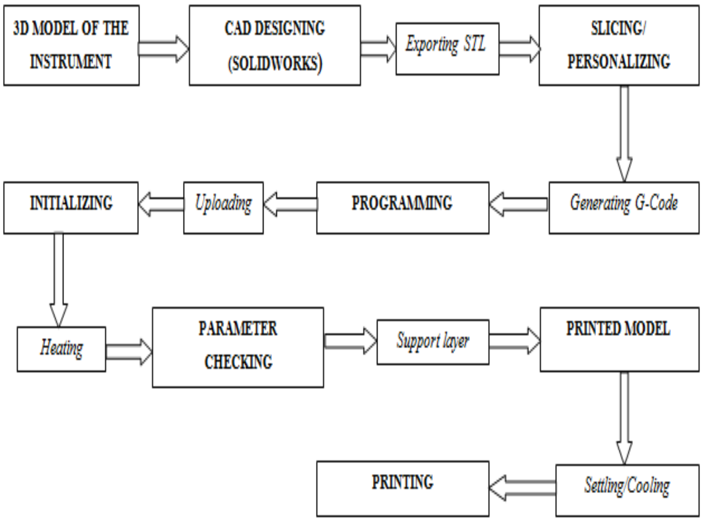

Fig -1: Block Diagram

3.1 The 3D Printing Process

[1] Making the 3D Model

The first step in using a 3D printer will be to create a 3D computer model. This can be done by scanning an existing object, downloading a model from the web, or creating a model ourselves. In this proposed system, we've created a 3D model using software. Fortunately, many software packages are available that make developing particular types of models as simple as possible.

3D modeling or CAD (Computer Aided Design) allows engineers and designers to build realistic computer models of parts and assemblies. A wide range of CAD software exists with different packages available for a number of different industries. The following software is used to design all of our instruments; **1.** *SOLIDWORKS – edition* 2021 **2.** *e-Drawings – edition 2021.*

[2] Slicing a 3D Model

Creating an STL file is the first part of the 3D printing process. The next step, is to divide, or slice, the file into layers that the printer can generate. The slicing program has to take into account both the physical characteristics of the printer and the geometry of the model being printed.

The **Ultimate Cura** is an open source slicing application for 3D printers, that takes an STL file and, based on settings input by the user, creates commands that can be executed by the printer. These commands are in a language called G-code. G-code is a very old command language that has been around since the 1950s to control traditional computer-driven machine tools.

[3] Driving our Printer: G-Code

The final step is to move the sliced file (G-code) onto the printer. Most open source, filament-using 3D printers are controlled with a series of commands, called G-code. G-code loads onto the printer from a host computer via USB port, although some printers have other options such as reading from an SD card. The firmware (software running on the printer itself) then interprets the G-code one command at a time and ships it off to the printer to execute. Status information (temperatures and the like) return to the user's computer through the USB. In some other cases a G-code interpreter runs on a host computer, and control signals are sent to the printer.

3.2 Results

The instruments were manufactured in RPT Hubs, Coimbatore. The contents of the general surgical set include 1 hemostat, 1 needle driver, 2 scalpel handles, 2 forceps, and 1 Army Navy retractor.

Fig -2: General surgical set including (from left to right) army-navy retractor, scalpel handles, forceps, hemostat and needle driver

An FDM printer **JSC-Delta-230*300** was used in printing all the above mentioned instruments where **ABS and DuraForm EX Prox** were incorporated. The measurements considered for designing each instrument were referred from standard dimensions used by popular manufacturers (table 4). The time it takes to print surgical instruments such as scalpel handle, forceps were up to 03 to 04 minutes while the army-navy retractor consumed time of about 10-15 minutes. On average, 3D printing the instrument takes from 08 to 10 minutes.

Overall the instruments that were fabricated using 3d printing technology helped us to prevail over the complications faced by the existing system. The scaled needle driver helped in overcoming the slippage while driving through the tissues and the forceps with lock were designed for holding properties. Also, other instruments such as hemostat, army-navy retractor and scalpel handles were scaled in order to enhance their physical properties.

The benefits of functional 3D printed surgical instruments are boundless. Time constraints on design and instrument production are minimal while surgeon customization allowed is limitless. Another advantage is that, the ABS 3D models can be recycled by a sequence of processes; a) *separation* b) *grinding* c) *melting and reforming.* 3D printed surgical instruments compared to traditional manufacturing methods include no increase in cost.

4. CONCLUSIONS

3D printing has turned into a valuable and possibly extraordinary device in various fields, including medicine. As printer execution, goal, and accessible materials have expanded, so have the applications. Researchers keep on further developing existing clinical applications that utilization 3D printing innovation and to investigate new ones. The clinical advances that have been made utilizing 3D printing are as of now huge and energizing, yet a portion of the more progressive applications, for example, organ printing, will require time to advance.

The main aim of this project was to develop 3d printed surgical instruments for inguinal hernia which has been successfully completed. The design of the instrument is made accurate using the CAD software, SOLIDWORKS.

The STL file format received from the CAD solid modeling software is then transferred into the AM machine where parameters such as position, size, layer thickness are properly set up prior to the build process. Once the AM machine has completed the build, the parts were removed. Furthermore, the parts are additionally cleaned before they are ready for use. Thus, an ABS and DuraForm incorporated surgical instruments were build successfully.

5. FUTURE SCOPE

Further scope of our outcome products are of huge impact to the upcoming generation. We can use Duraform GF and Prox PA material into the fused material of manufacturing because this particular Duraform material is of Medical grade but this material is very rare in the market. In upcoming trends if availability of Duraform GF and Prox PA shows a hike we can integrate this material for our 3D printed surgical instruments.

Surgeon's requires specific angle hemostat, retractors and forceps at certain cases of surgeries like gall bladder removal or gastrointestinal surgeries and also for ophthalmology and orthopedics to treat the defect effectively. Those kind of specific angle instruments can be designed using the same prototype of 3D printing as we have modeled for hernia repair surgery. This might result in successful and effective surgeries as per the surgeon's suggestion and requirements.

More than this the technology is not limited to planning surgeries or producing customized dental restorations such as crowns; 3D printing has enabled the production of customized prosthetic limbs, cranial implants, or orthopedic implants such as hips and knees. At the same time, it's potential to change the manufacturing of medical products—particularly high-risk devices such as implants—could affect patient safety, creating new challenges for Food and Drug Administration (FDA) oversight.

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