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RESEARCHING THE PRODUCTION FEATURES OF SURGICAL INSTRUMENT MANUFACTURING WITH 3D PRINTING

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Abstract

Original scientific paper

The process of 3D printing begins with creating a digital 3D model of the object to be printed using CAD software. This model is then sliced into thin cross-sectional layers, which are used as a guide for the 3D printer to deposit material layer by layer. The printer follows the instructions from the digital model and adds material, typically plastic, metal, or composite, to build up the final 3D object. One of the key advantages of 3D printing is its ability to produce complex geometries that are difficult or impossible to achieve with traditional manufacturing methods. This allows for the creation of lightweight and optimized designs, reducing material waste and improving the overall performance of the finished product.

This study investigates the feasibility of SLA technology (Stereolithography) as a production method as a practical alternative for surgical instrument manufacturing. Although there are many studies on obtaining accurate prints with SLA 3D device, research on the production of surgical instruments is insufficient. For this purpose, an experimental study was conducted using an SLA type 3D printer, examining the hardware and software components in terms of print quality. First , the same size prints were taken of the tools whose geometries were scanned with a 3D scanner.

The purpose of this article is to conduct detailed research on the feasibility of lower-cost, 3D printing technology in surgical instrument manufacturing. An application was made and shared regarding the use of printed tools in artificial leather working sets.

Keywords: *3D Printers, surgical instrument, stereolithographic printing (SLA), 3D scanner, additive manufacturing.*

CERRAHİ ALET İMALATININ 3 BOYUTLU YAZICI İLE ÜRETİM ÖZELLİKLERİNİN ARAŞTIRILMASI

Özet

Orijinal bilimsel makale

Eklemeli imalat olarak da bilinen üç boyutlu (3D) baskı, malzemelerin katman katman üst üste bindirildiği katmanlı üretim prensibine dayanmaktadır. Bu teknoloji, bilgisayar destekli tasarım (CAD) modeline göre katı modelleme kullanarak malzemeyi doğru bir şekilde biriktirerek herhangi bir karmaşık şekle sahip bileşenleri hızlı bir şekilde üretmek için kullanılabilir.

Bu çalışmada cerrahi alet imalatı için , pratik bir alternatif 3 boyutlu olarak SLA (Sterolitografi) ile teknolojisinin uygulanabilirliğini üretim yöntemi olarak araştırmaktadır. SLA 3D cihazlarıyla doğru baskıların elde edilmesi üzerine birçok çalışma olmasına rağmen, cerrahi aletlerin üretimi hakkında yapılan araştırmalar yetersizdir. Bu amaçla SLA tipi 3D yazıcı kullanarak baskı kalitesi açısından donanım ve yazılım bileşenleri incelenen deneysel bir çalışma yapılmıştır. Öncelikle 3 boyutlu tarayıcı ile geometrileri taranan aletlerin aynı boyutta baskıları alınmıştır.

Bu makalenin amacı, daha düşük maliyetli, 3 boyutlu baskı teknolojisinin cerrahi alet imalatında kullanılabilirliği hakkında ayrıntılı araştırma yapmaktır. Yapay deri çalışma setlerinde baskısı alınan aletlerin kullanımına ilişkin uygulama yapılarak paylaşılmıştır.

Anahtar Kelimeler: *3 Boyutlu yazılar, cerrahi alet, sterolitografi (SLA), 3 boyutlu tarayıcı, eklemeli imalat.*

1 Introduction

In the developing world, the supply of special-purpose treatment or medical supplies to hospitals and clinics is in some cases very affected by global supply chain fluctuations. While the COVID-19 pandemic has exposed weaknesses in medical supply chains around the world, underdeveloped regions have been disproportionately affected for a variety of reasons [1–3]. The possibility of producing medical equipment locally and reliably sterilizing it can reduce this risk. 3D printing of surgical instruments and medical devices is a possible solution to this problem [4]. In their research, Francis et al printed surgical instruments from various materials. As a

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result of their study they remarked 3D printed surgical tools to develop a reliable and rapid high-level disinfection process using inexpensive and widely available methods appropriate for the austere environment [4].

The higher resolution of SLA-style 3D printing allows users to do more with 3D printing. A common application of SLA printing is prototyping medical devices that require small line pieces. Fused Deposition Modelling (FDM) type 3D printers do not have high enough resolution to print such objects at the appropriate scale. There are many other applications that will be useful from small, accurate prototypes; but until a cheap and reliable SLA printer becomes available.

This technology developed will probably only be used by well-funded projects [5].

Cingoz et al made surgical dissector modelling with the measurements taken from the patient. Polylactic acid (PLA) filament was used in the devices during the printing process. They also used it in the operation of patients diagnosed with lumbar stenosis, where surgical dissectors were sterilized and measurements were checked before surgery. They stated that there were no intraoperative complications observed during the use of 3D printed surgical dissector. [6].

Keßler et al have researched .surgical implant guides .Their purpose of this in vitro study was to delineate the quality of the implant position transfer with 5-axis milled and DLP and SLA 3D-printed surgical guides. They stated that this in vitro study three-dimensional printing of resin material is appropriate for the manufacturing of surgical implant guides [7].

The study by Uddin et al. demonstrates the potential of 3D printed microneedles for enhanced delivery of anticancer drugs to skin tumors. The use of stereolithography (SLA) for fabrication and ink jetting for coating the microneedles with cisplatin formulations shows promise for in vivo transdermal delivery. The optimized printability and excellent penetration capacity of the 3D printed microneedles suggest that this approach could be a valuable tool for improving cancer treatment. Further research and development in this area could lead to more effective and targeted delivery of anticancer drugs for skin tumors [8].

The study conducted by Xu et al demonstrates the potential of SLA 3D printing technology in the development of implantable bladder drug delivery systems. By using this technology, the researchers were able to design and manufacture devices that could provide sustained release of lidocaine directly at the site of the bladder, avoiding the systemic side effects associated with traditional drug delivery methods.

The use of SLA 3D printing allowed for the precise control of drug release rates, ensuring that the lidocaine was released at a predetermined rate over a specific period of time. This could significantly improve patient compliance and treatment outcomes for bladder disorders such as overactive bladder disorder and bladder cancers.

The researchers also noted that the devices could be easily adapted for the treatment of other bladder disorders by changing the selected drug. This highlights the potential of SLA 3D printing technology in the development of personalized medical devices and treatments, tailored to the specific needs of individual patients.

Overall, the study by Xu et al demonstrates the significant potential of SLA 3D printing in the field of medicine, particularly in the development of implantable drug delivery systems. The technology has the potential to revolutionize treatment outcomes for a range of medical conditions, providing patients with more effective and personalized treatment options [9].

In this study, 3D solid models of some currently used surgical instruments, whose geometries are known, were scanned and printed with the SLA (Stereolithography) method, one of the three-dimensional production methods. The SLA method is a preferred method in the manufacturing of detailed parts.

SLA (Stereolithography) printing is an additive manufacturing process that belongs to the category of resin-based 3D printing technologies. It was one of the first 3D printing technologies developed and is still widely used for creating highly detailed and accurate 3D objects.Figure 1 shows the 3D printing technologies .

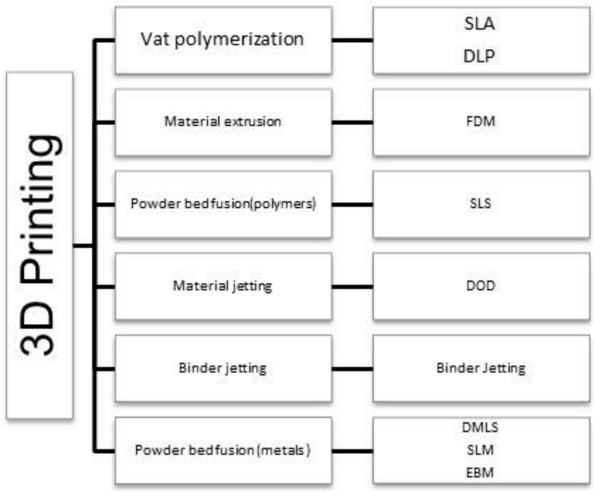

Figure 1. 3D printing Technologies [10].

In the following section, general information will be given about the manufacturing and scanning technologies used in the study process.

1.1 What is Stereolithography (SLA)?

SLA is considered one of the additive manufacturing methods. This method is a technology that uses computer-aided design (CAD) data to produce objects layer by layer using liquid polymer.

The first additive manufacturing technology developed is the SL (Stereolithography) technique, which is based on the solidification of the light-sensitive liquid resin layer with UV (Ultraviolet)-laser. In the following years, many new technologies such as FDM, SLS (Selective Laser Sintering), LOM (Laminated Object Manufacturing), Inkjet Printing (3DP) and LAM (Laser Additive Manufacturing) have emerged [11-12]. After SL technology became widespread, studies on DLP (Digital Light Processing), DPP (Daylight Polymer Printing) and Continuous Light Interphase Printing (CLIP) technologies have been concentrated based on the same production technique [13].

Pool photo polymerization (HFP), which is the general name of SL, DLP and CLIP technologies, has started to be used in the manufacturing of small quantities of plastic parts in recent years, apart from rapid prototyping and product development areas. It is preferred in prototype product manufacturing in order to shorten product development times and receive user feedback, especially in applications such as automotive, aviation, industrial design [14].

How the 3D SLA printing process works is listed as ;

1.Design: First, a 3D model of the object to be printed is created using computer-aided design (CAD) software.
2. Slicing: The 3D model is then sliced into thin horizontal layers using slicing software, which generates a set of 2D cross-sectional images.
3. Printing: A vat of liquid photopolymer resin is used as the printing material. A build platform is lowered into the vat just below the surface of the resin. A UV laser is then used to selectively solidify the resin by tracing each layer's cross-section based on the sliced image data. The laser moves according to the design specifications, solidifying one layer at a time. Once a layer is complete, the build platform is lowered slightly, and the process continues for the next layer. This continues until the entire object is printed, layer by layer.
4. Curing: After the object is fully printed, it is typically removed from the printer. However, the object is not yet fully cured; it remains somewhat tacky. To complete the curing process and harden the object, it is often placed under a UV light source or in a UV curing chamber.

The photopolymerization process is irreversible and there is no way to convert SLA component back to liquid form. Heating these SLA pieces will cause them to burn rather than melt. This is because materials produced by SLA are made of thermosetting polymers, unlike the thermoplastics used by fused deposition modeling (FDM) [15-17].

1.2 Advantages of 3D SLA Printing

High Precision: SLA printing can produce highly detailed and intricate objects with smooth surfaces.
Accuracy: It's known for its accuracy in replicating the design from the 3D model.
Wide Material Selection: There is a variety of resin materials available, including standard, flexible, and specialty resins for different applications.
Minimal Support Structures: SLA printers often require fewer or more easily removable support structures compared to other 3D printing methods [15-17].

1.3 Disadvantages of 3D SLA Printing

Limited Build Size: SLA printers typically have smaller build volumes compared to Fused Deposition Modeling (FDM) or other technologies.
Resin Handling: Resin-based printing can be messy, and the resin itself can be toxic, so it requires careful handling and proper ventilation.
Post-Processing: Some SLA prints may require additional curing and post-processing steps to achieve the desired final result.
Cost: SLA printers and the resins can be more expensive than some other 3D printing technologies [15-17].

1.4 Stereolithography Materials

Epoxy resins are indeed commonly used in SLA and other 3D printing processes due to their ability to produce strong and durable models with high accuracy. They are particularly suitable for fit, form, and function testing purposes.

The mention of a low heat tolerance with typical heat deflection temperatures around 110-120°F suggests that these materials may not be suitable for applications that involve exposure to high temperatures [18]. Heat deflection temperature (HDT) is a measure of a material's ability to withstand deformation under load at elevated temperatures.

2 Material and Method

2.1 CMM (Coordinate Measuring Machine)

The printed surgical instruments were scanned with an optical 3D scanner (CMM) using structured light technology.

3D scanning devices create 3D models of the surfaces of objects using laser or optical systems. These scans are transferred to a computer and converted into 3D models using software. As a result, a point cloud consisting of millions of points is created for each surface of an object [19-20].

With the developing technology, 3D data in the digital environment has gained importance as all processes such as design, product development, prototyping, simulation and quality control are now computer-aided. The data obtained by 3D scanning provides important data to designers and manufacturers in different areas such as reverse engineering and quality control.

3D scanning technology allows for the creation of highly accurate digital models of physical objects, which can then be used for a variety of purposes. In reverse engineering, 3D scanning can be used to create digital models of existing parts or products, allowing for the recreation of those items or the development of new designs based on the scanned data.

Indeed, 3D scanning has revolutionized the way we capture and replicate physical objects. The use of high-tech optical and laser scanners has significantly expedited the process, providing precise and detailed results within a short timeframe. This technology has proven to be versatile, capable of capturing objects of various colors, sizes, and complexities with exceptional clarity. As a result, 3D scanning has become an invaluable tool across numerous industries, from manufacturing and design to archaeology and healthcare.

The advancements in 3D scanning technology have indeed revolutionized the speed and precision of data acquisition. High-tech optical and laser scanners have significantly reduced the time required to capture detailed 3D data, enabling quick and accurate results regardless of the object's color, size, visual details, or geometric complexity. This level of flexibility and efficiency has made 3D scanning an invaluable tool across various industries, from manufacturing and design to cultural preservation and medical applications. As technology continues to evolve, we can expect even greater advancements in 3D scanning, further enhancing its capabilities and applications.

While traditional engineering is the concrete manifestation of a product idea through the design and manufacturing process, reverse engineering works the exact opposite. In figure 2 scanning process is shown as below.

Figure 2.3D Scanning process.

2.2 Printing by Stereolithography (SLA)

Figure 3 shows the three-dimensional solid models obtained after scanning.

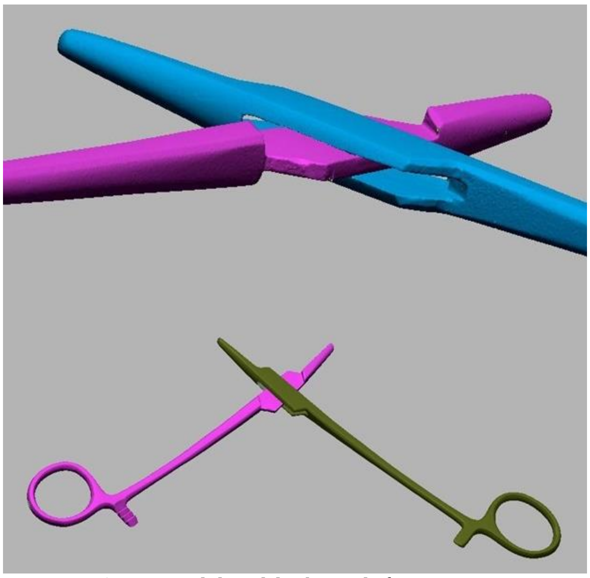

Figure 3. Solid models obtained after scanning.

CAD model created geometries were sliced with Anycubic Photon Workshop Slicer for printing.

Aynycubic Photon Workshop slicer software slices the STL mesh file of the target part. This software creates an image file (like Xray imaging) for each layer. The SLA printer cures the liquid polymer in a selective area by reflecting (illuminating) the image mask. Figure 4 shows sliced images of the forceps and needle holder.

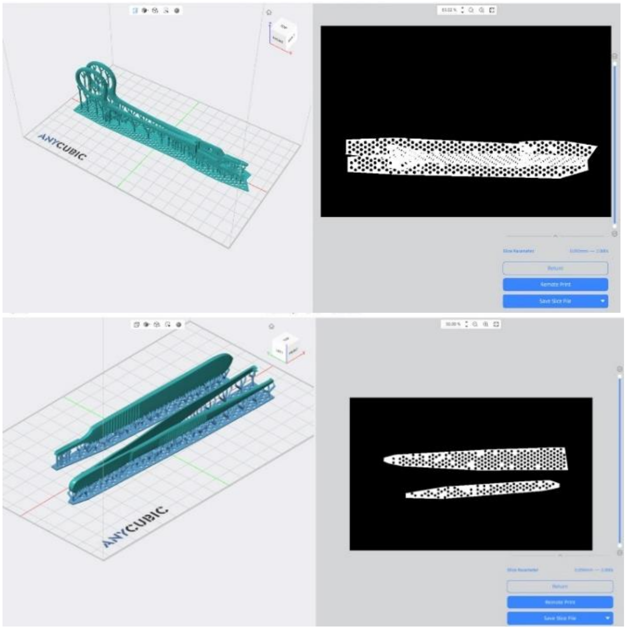

Figure 4. Sliced images of forceps and needle holder.

Figure 5 shows how solid models will be placed on the printing plate. This means the printer printed the objects in this order as shown in Figure 5.

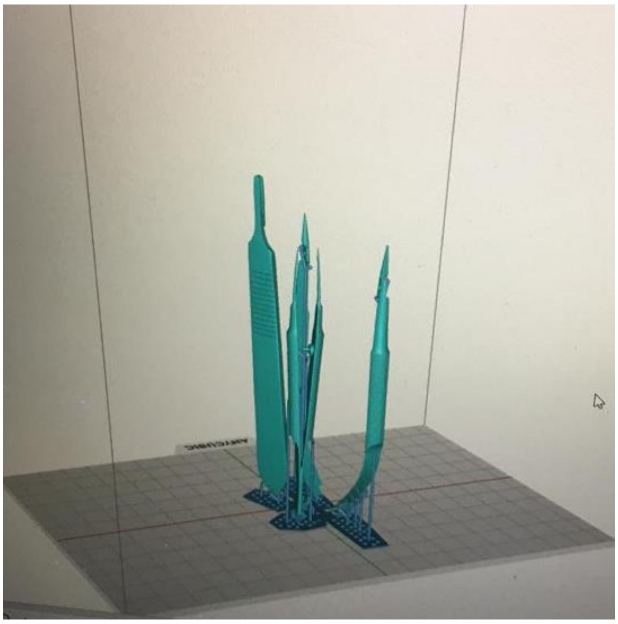

Figure 5. Planned view of solid models on the printing plate.

Printing was done with Anycubic Photon Mono X 4K Resin 3D Printer, which works with LCD-based SLA printing technology. Figure 6 shows the 3D device. Printing time was determined as 2 hours 56 minutes. Printing parameters are shown in Table 1.

Table 1. Printing Parameters

Printing Parameters	
Print volume:	192x120x245 mm
Source of light :	405 nm
XY Resolution:	0,050 mm 3840 * 2400
Z Axis Resolution:	0.01mm
Layer Resolution:	0,01 - 0,15 mm
Print Speed:	MAKS. 60 mm / hour
Strength	120W
Lighting:	Matrix
Layer curing time:	1-2 second

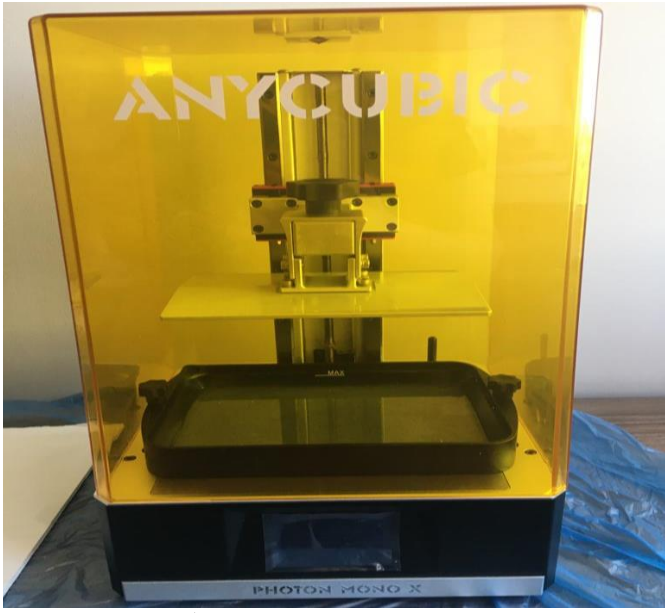

Figure. 6. 3D printing equipment.

The printed materials were washed with alcohol and cured for 15 minutes. The curing process is shown in Figure 7.

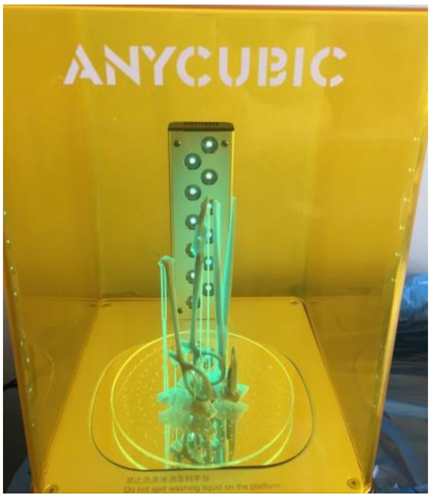

Figure 7. Curing process.

The printed surgical instruments are shown in Figure 8. These are needle holder, forceps and scalpel handle respectively.

Figure 8. Printed surgical dressing set.

At the end of printing procedure for testing printed surgical dressing set a training stitch set is used as shown in Figure 9.

Figure 9. The training suture set.

4 Results & Discussion

In this study, surgical instruments were manufactured using 3D technology, which is a method other than the traditional method. The scanning process, which is the first stage of manufacturing, was done precisely with a CMM. This is how existing geometries created the solid model. STL files were sliced with a program compatible with 3D printers and made ready for printing. Successful prints were obtained on the first try. However, the needle holder broke during the cleaning of the support parts of the printed parts. The printed parts have smooth and high-quality surfaces. Sewing application was tried on the artificial skin set with the printed tools. KVS Dr. Gülden SARI's experiences were shared. First , a suture set was used while stitching. Then, the stitching was done with a free needle. Figure 10 shows the use of a suture set and a free needle. The stitching process was performed with both types of needles.

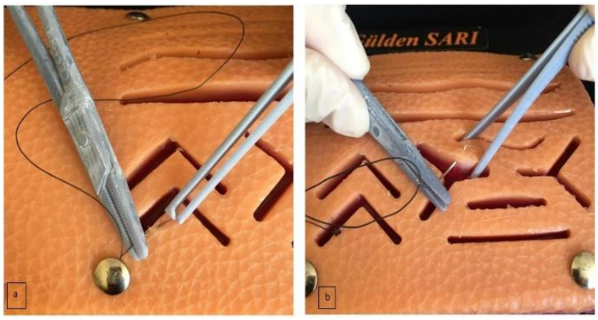

Figure 10. With the surgical dressing set printed with 3D a) Use of the suture set b) Use of the free needle.

Figure 11 shows the stitches made with the suture set and free needle set.

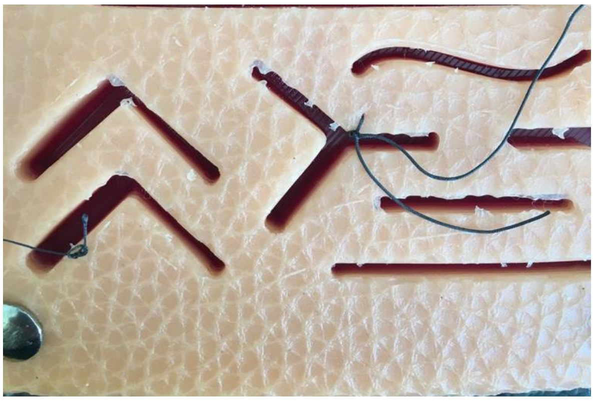

Figure 11. The stitches made with the surgical dressing set printed with 3D were made with a suture needle in the incision and a free needle in the incision.

In order to compare the stitches in terms of shape, stitches were applied with a dressing set manufactured with the traditional method. The mentioned stitches are shown in Figure 12. The stitches made with the traditionally manufactured surgical dressing set and the stitches made with the 3D printed set are shown in the figure. The stitches in the box were made with the 3D printed set.

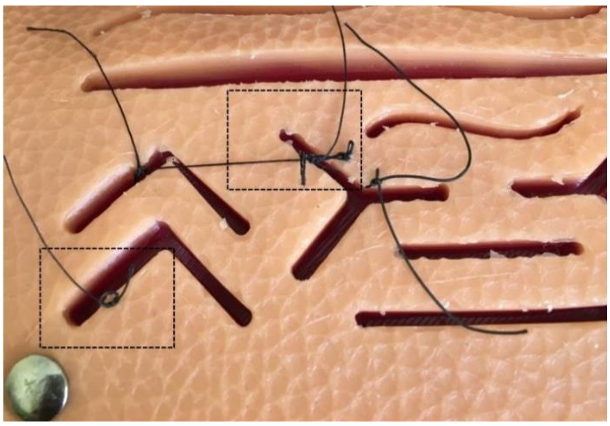

Figure 12. Stitches made with 3D and traditional set.

After the stitching process was completed, the threads were cut with a steel scalpel attached to the 3D printed scalpel handle. Figure 13 shows the thread cutting process.

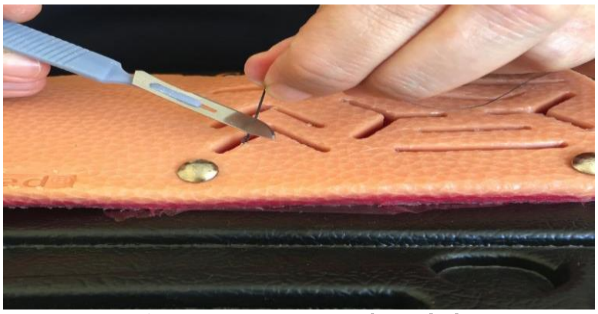

Figure 13. Cutting rope with a scalpel.

5 Conclusion

In this study, surgical instruments were manufactured using 3D technology, which is a method other than the traditional method. Stitches application was tried on the artificial leather set with the printed tools KVS Dr. Gülden SARI's experiences were shared on suturing and using instruments.

The doctor stated that 3D printed instruments are lighter than steel ones. However, she stated that it was relatively difficult to hold the thread with the needle holder. But for about forceps and scalpel handle she states that there is no difference in use depending on the steel type, but it is weaker in terms of strength.

Studies can be carried out with different methods in terms of developing three-dimensional printing technology and material diversity. There are few studies on the subject in the existing literature. Detailed studies need to be carried out to replace steel, which is the material of existing tools, and traditional manufacturing methods.

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Declaration

Ethics committee approval is not required.

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