DESIGN OF A MEDICAL DEVICE FOR SUPERFICIAL SUTURING UPPER AND LOWER EXTREMITIES

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Received: June 15th, 2017

Accepted: September 18th, 2017

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ABSTRACT

Suturing upper and lower extremities must be done quickly, evenly and easily. Therefore, the need to design a medical device that facilitates the health professional's work arises. This work presents the design for a class 2 medical device that meets the basic requirements of the current and known suturing methods in Costa Rica. The design process was achieved in three main stages, (i)Research on similar technologies; e.g. The operation principles of a sewing machine, materials used; (ii) The study of types of skin traumas; (iii) General approach toward the suturing device, including device functionality, integration with the human body and manufacturing process. The device model was designed and fabricated using 3D printing technology, this allowed the team to analyze ergonomics, the assembly of the parts and the equipment's motion. The printed prototype made it possible for potential users to provide feedback on the design and suggestions for improvement.

RESUMEN

La suturación de tejido humano en extremidades superiores con frecuencia requiere ser realizada de forma homogénea, sencilla y rápida. La necesidad de diseñar un dispositivo médico surge con el fin de facilitar la labor a los profesionales de la salud.

Este trabajo presenta el diseño de un dispositivo médico clase 2, capaz de suplir los requerimientos básicos de los métodos de sutura en Costa Rica. El diseño fue realizado en distintas etapas, (i) La investigación de tecnologías similares existentes; e.g, los principios de funcionamiento de una máquina de coser, materiales a utilizar en hilos y agujas; (ii) Reconocimiento de tipos de traumas en la piel; (iii) Planteamiento general del dispositivo de suturación, incluyendo funcionalidad del dispositivo, su integración con el cuerpo humano y su proceso de manufactura. El dispositivo fue modelado y fabricado por impresión 3D, con la intención de analizar su ergonomía, la integración de todas sus partes y el movimiento del equipo. La impresión del prototipo permitió a los usuarios potenciales dar su opinión respecto al diseño, y realizar sugerencias de modificaciones al mismo.

Keywords:

Suture, human tissue, 3D printing, medical device, 3D design software.

Palabras clave:

Sutura, tejido humano, impresión en 3D, dispositivo médico, diseño software 3D.

Introduction

Skin plays a crucial role in protecting the human body and the health of an individual. It works as a barrier against the invasion of foreign substances and microorganisms, it helps regulate body core temperature, eliminates toxins and is the organ mainly in charge of receiving thermal and tactile stimulation [1]. However, frequently the skin suffers trauma easily resulting in open wounds.

The consequence of an open wound will usually be infection, attributable to environmental contaminants. Sutures are necessary when tissue is torn in such a way that natural healing is compromised. Left unsutured, skin takes a considerable period to join back together or will be completely unable to do so. The word "suture" describes the process of connecting blood vessels or drawing them near one and other by using a specific material [2]. When compared to other suturing techniques, suturing with thread provides the most resistant joint that will support the wound with minimal risk of dehiscence [3].

The idea for a medical device to suture arose for three main reasons. First, physicians were noticing poorly sutured wounds that would result in large scars. These in some cases required further procedures like plastic surgery. Also, time consumption, making the search for a device that would make the method faster a necessity. Finally, sutures stitched by hand are sometimes left too loose or too tight, causing bleeding from the wound. The visibility of the area is usually compromised, making the precision level of the procedure low and the variation between stiches substantial.

Suturing devices are internationally found in the market. However, they are not commonly used by hospitals in Costa Rica, mainly because they are expensive and complex. In summary, the objective of this work was to design a class 2 -FDA- electronic medical device, that minimizes tissue damage and is capable of quickly and uniformly suture a wound, leaving an aesthetically acceptable scar and allowing stitching to be simple and standardized.

Materials and Methods

The design searched for three main functions, (i) stabilize the skin, (ii) rotate the needle on its axis to join the tissue sections and (iii) initiate and finish with the least user interference possible. The result being a device that joins tissue quickly, avoiding any further hemorrhage or infection.

The application of computer assisted design (CAD) software SolidWorks® enabled the team to create a preliminary model design and check the specific movement capacity of each part, as shown in Figure 1. The height of the shell had to be redesigned while checking the movement on the software. The measurement of height had to permit the rotation of the needle on its axis without compromising the tissue against the device. The final design was oriented to have the area and volume of the shell as similar as possible for the needle to rotate 360° without any problem.

The design was 3D printed commercially to obtain a semi functional prototype. The parts for assembly were printed from STL files (Standard Tessellation Language). The first printer used was a Polyjet printer. This technology uses a liquid photopolymer that solidifies when exposed to an ultraviolet (UV) laser. The precision is considered high for this specific printer [4]. The piston was printed with this technology. The second printer used fused deposition modeling (FDM) technology, here the material is deposited from a nozzle were the material is added by layers. Layers can be modified by thickness and by a specific pattern [5]. Most of the parts were printed with this technology.

The use of a prototype allowed testing of certain functionality features before investing on an official model [6]. Figure 1 presents the 3D model that was used for the files printed.

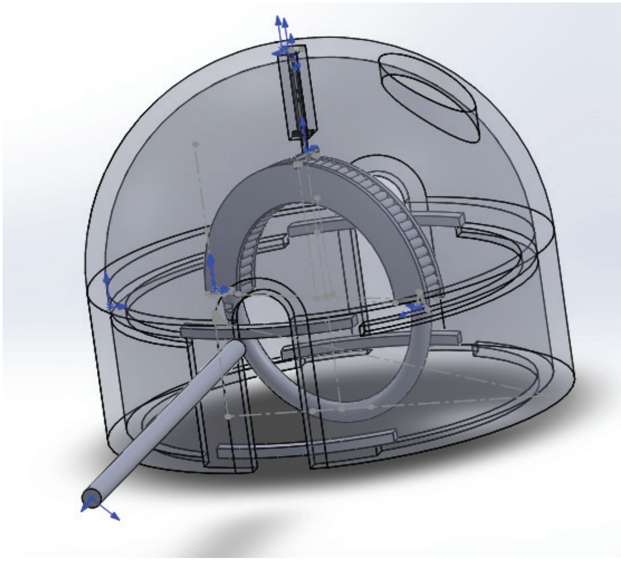

Figure 1. SolidWorks® design of the medical device to be printed.

The specifications of the model were as follows; functionality, cost, durability, modularity and reliability. The functionality looked for the suturing of upper and lower extremities with the least interference from the physician. The cost of generating the prototype was low due to the 3D printing technology used. The durability looked at lifespan. Materials have been contemplated for future production. The materials for a reusable medical device must be able to endure the sterilization process without compromising the device. The alloy AISI 316L was chosen for its resistance to fatigue and corrosion, its low friction coefficient, high strength and toughness [7]. The modularity will come in handy when re-loading the thread or switching needles. Finally, it's expected to work without problems or need of technical support covering reliability.

After the prototype was assembled and design functions checked, the final step required a survey. The prototype was presented to three Costa Rican physicians, (1) Dr. Stephanie Gómez Najéra, (2) Dr. Pamela Villareal Valverde and (3) Dr. Tatiana Piedra Chacón. The study contained questions about the medical device presented via prototype and they were asked to elaborate on their answers regarding their opinion as health professionals.

Results and Discussion

Table 1 presents the 6 main components of the suturing device. Each part is described briefly on its specific function. The type of threads this device was designed for are also shown in Table 1.

Table 1. Suturing medical device parts and functionality.

Part	Description
Shell	The device is held inside this part, its function is to work as main case for the device.
Guides	The guides allow the movement of the guide pin, it will fall in place by gravity. Each device has two guides.
Guide Pin	This pin is used to tie the knot. It is necessary that the device can perform a double knot.
Rollers	Main mechanism for the movement of the needle, the rotational movement that makes the suturing possible. It has two parts, the rollers and the restriction so the needle stays in place.
Piston	Provides the roles with the movement they require. Its parts are; Holder (holds roles), Pin (moves the holder in an axial fashion ±Y and 360°) and its Base that is fixed to the shell.
Needle	A ½ circle with tapered tip. Commonly used to suture.
Thread	For extremities gauges of 3/0 and 4/0, or thick gauges 1/0 and 2/0 are used. The material to be used is nylon, which is a polyamide obtained by chemical synthesis. Due to its elasticity, it is particularly useful for skin retention and closure [8].

Table 2 presents a step-by-step schematic representation on how the device works. The usage is simple, with the steps described as follows. (1) The needle is threaded while it is in its initial position, here the needle is out of the rollers and directed to the top of the shell. (2) The threaded needle is set in the rollers. (3) The piston is now in charge of lowering the shell. (4) The needle is rotated 270° pinching the tissue that will be sutured. (5) The rollers turn 45° to the right to initiate the knot while being guided by the holder. (6) The pin sets in place over the guide. (7) The needle turns 360° once more on its axis. (8) The guides now turn over the shell and release the guide pin, letting it fall due to gravity over the guides bellow, finishing what is the first knot. (9) The holder then takes the rollers to their initial position, (10) The holder turns 45° to the right again to start the second knot. (11) The needle rotates 360° on its axis. (12) The user will now tense the thread through the upper hole until the guide pin keeps it tense. (13) The lower guides will then release and the guide pin is removed. (14) The double knot is completed and the thread left should be cut with sterilized scissors.

The survey results are presented in Table 3. The numbers shown are the average between the three physicians that were part of the study. The scale used for the survey is based on the Likert scale. The scale goes for 1 to 5, specifically: strongly disagree, disagree, neutral, agree, strongly agrees, respectively.

The first question of the survey was met with both approval and disapproval. Two doctors said it would be useful time saving but only in simple suturing cases, the third doctor disagreed explaining that is a very simple procedure however, made a point that a person with very little training could suture with the device. The second question was met with similar responses, respectively to the use at their specific place of work. The comments referenced that the usefulness depends on the context of where it would be applied, for example a jail or emergency room. The following questions related to the design were well-received. One main drawback is that the device may not be suitable for all types of wounds. Other concerns raised by the physicians were related to the price and size of the device.

Table 2. Schematic representation of the function of the suturing medical device

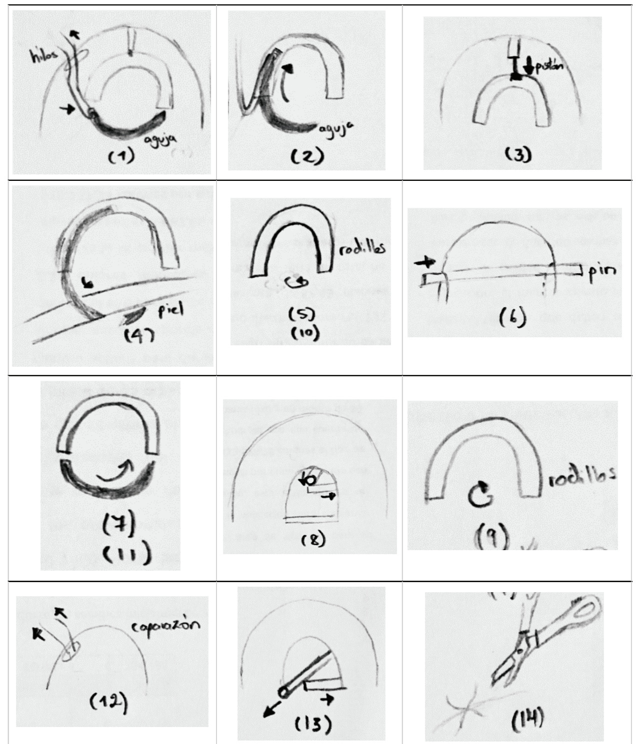

Table 3. Survey on trained medical physicians

Question	Item	Average
1	The device would be useful for myself	4
2	The device would be useful for my place of work	4
3	I would purchase a medical device like the one presented	4
4	The design is ergonomic	5
5	The device looks easy to use	5
6	The device resolved the need mentioned for suturing	5
7	The idea is original	5
8	The device can be used for different types of wounds.	3

Figure 2 shows the final design. The top figures show the 3D model and the bottom figures the final prototype, which was slightly modified to improve its ergonomic factor. The improvement was done at the top of the shell, and a holder was added to make it easier to manipulate and to add stability to the user. The change was made based on the observations obtained from the survey.

The prototype achieved its initial purpose. The next stage will be directed toward the mechanisms that will generate the movements of the device such as: motors, servomotor, sensors and electronic systems. The next step for the design would be the standardization of parts of the prototype allowing some specific pieces to be bought in the market instead of manufactured specifically for the device. The device is required to be transparent in some extend enabling an internal view of the affected area that is in need for suturing.

The end of this stage will allow the team to have a final model that meets the necessities described by the physicians in the survey. The manufacturing is expected to be simple allowing the device to reach the specific population it is designed for. The help of health professionals will continuously be needed during the process for guidance and recommendations.

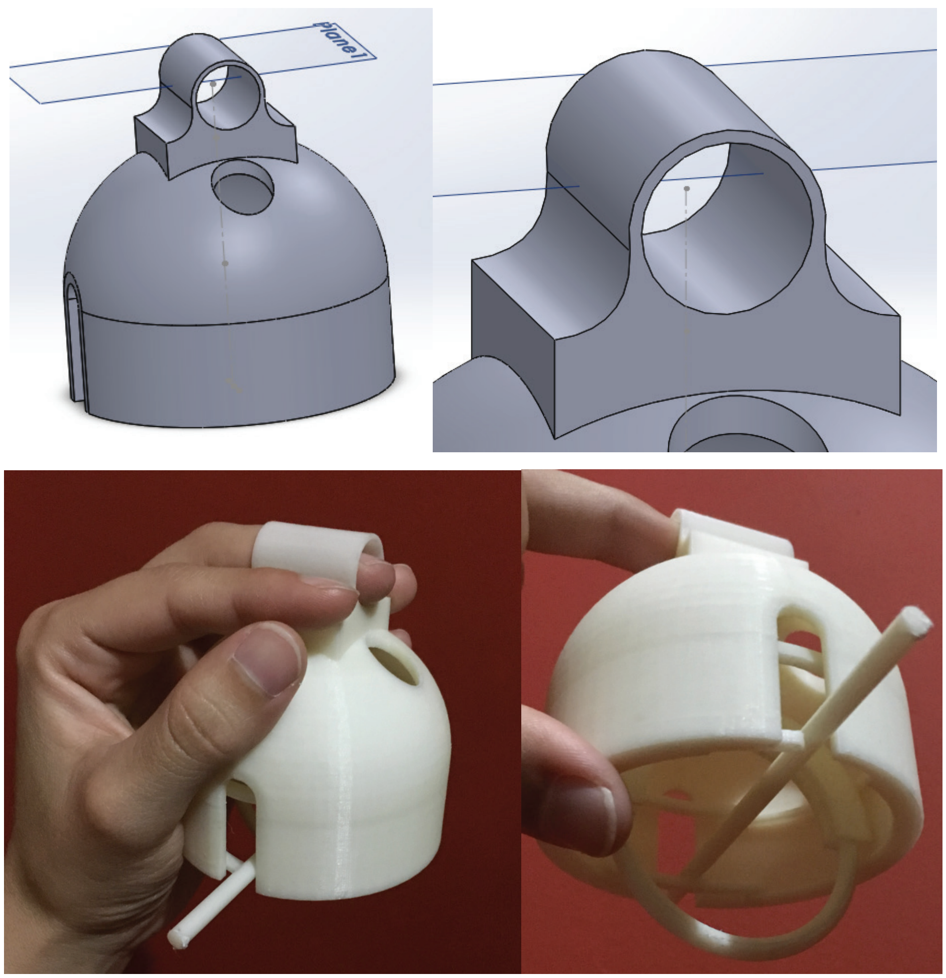

Figure 2. Final design for the suturing medical device

Conclusions

1. The suturing device was accepted by the physicians during the development, and it would be useful for a lot of medical facilities. For the physicians, it is easy to use, and it needs a very low level of expertise.
2. The device adapts to wounds that requires suturing variations.
3. The idea is original and none of the doctors surveyed had seen anything similar.

Acknowledgements

The authors are grateful to Dr. Stephanie Gómez Najéra, Dr. Pamela Villareal Valverde and Dr. Tatiana Piedra Chacón for their participation in the survey, their collaboration with ideas and support for this study.

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