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DESIGN THINKING FOR DEVICE DEVELOPMENT FOR TRAINING IN MICROSURGERY

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ABSTRACT

Objective: Use the principles of Design Thinking (DT) to create a training model in Microsurgery. **Methods:** DT was used to develop prototypes and to validate the concepts and functionality of the device for training in microsurgical techniques. Based on the three main pillars of DT: Empathy, Collaboration and Experimentation; the creation of the training device prototype was built on 4 phases: Discover, Define, Develop and Deliver. The first phase, “Discover”,consisted of getting information from professionals, bibliography researched using Health Sciences Descriptors (DeCS) and patent banks and, finally, creating a simulation scenario. In the next phase, “Define”, the model criteria was established using the information obtained. The third phase, “Developing” was based on previous phases and included a mechanical engineer for the prototype elaboration. Finally, in the last phase, "Delivering", the microsurgical techniques training prototype was created along with its description in the spreadsheet of the patent model Canvas.**Results:** In the first phase, it was possible to identify the main difficulties in performing the microsurgical technique and the necessary skills to perform the procedures. The desk research enabled knowledge of the various training models that already exist as well as the materials and devices available. In the simulation scenario, it was possible to understand and experience the learning process involved in the technique. With the second phase, the main criteria for the device development was defined and the develop phase started, in which brainstorming sessions were held between the authors and the mechanical engineer. Finally, the prototype was designed. **Conclusion:** A synthetic training device in microsurgical techniques was developed using DT.

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INTRODUÇÃO

Microsurgery is a fundamental technique in the armamentarium of reconstructive surgery for complex treatments involving free tissue transfer. It is estimated that more than one third of the complex reconstructions performed in the world use microsurgical techniques. Its training involves years, and the financial and ethical costs should not be overlooked. It requires great decision-making ability, time management, surgical team leadership, and an advanced level of technical skills [1]. Such skills can be trained and honed in surgical training models. The training model is an important tool in learning surgical techniques, besides having an important ethical character, because the professional will perfect the techniques and improve the intervention on the model, and only then apply his skills already perfected on the human being. Despite their numerous advantages, many synthetic microsurgery training models are poorly reproducible and do not quantitatively and qualitatively compare skill development [2]. Therefore, it would be relevant to create a synthetic model that allows microsurgery skills training for surgeons in training. Design Thinking (DT) is a thinking model that has been used to develop innovative prototypes capable of bringing relevant solutions centered on the needs of humans. The origin of design thinking is credited to Herbert A. Simon in his 1969 book "The Sciences of the Artificial" [3], being considered a creative way of thinking as powerful as scientific and academic methods [4]. It is based on three main pillars: Empathy, Collaboration and Experimentation. This methodology has been widely applied in the health field and to all actions that directly or indirectly involve the prevention and/or treatment of diseases. DT aims to solve complex problems and is widely used by several disciplines. [5, 6, 7, 8, 9, 10, 11]. The purpose of this study is to describe the creation of a synthetic training model for reproducible microsurgery developed through design thinking methodology [12].

METHODS

The DT technique was employed to create the prototype of the training device and to validate its concepts and functionality. This process was defined in 4 phases: Discover, Define, Develop and Deliver [13]. The first phase "Discover" was based on the collection of information through three processes. The first was to conduct interviews with two experienced microsurgeons, aiming to identify the main difficulties in performing the microsurgical technique, understand the main skills needed to perform vascular anastomosis, and question whether a synthetic model could mimic an animal model in training. The second process was to search for existing synthetic training models in microsurgery with the Health Science Descriptors (DeCS): Microsurgery, Simulation Training, Device, Suturing Techniques and Surgical Anastomosis in the Medline database via Pubmed. The key words used, including their derivatives (singular and plural), as well as combinations of these and their respective synonyms in Portuguese and English, were: Microsurgery, Training by Simulation, Surgical Instruments and Motor Dexterity. Search included review articles, meta-analysis, clinical trials, and case series reports in the 30-year period (1990-2020). Priority search was performed to screen for registered patents and/or utility models. The websites are registered in the domains of the INPI database: http://www.inpi.gov.br/, Google patents: https://patents.google.com/, Latin American Espacenet: http://lp.espacenet.com/, Espacenet: https://worldwide.espacenet.com/, United States Patent and Trademark Office (USPTO): https://www.uspto.gov/, and World Intellectual Property Organization (WIPO): http://www.wipo.int/portal/en/index.html, State Intellectual Property Office (SIPO): http://english.sipo.gov.cn, and Japan Patent Office (JPO): http://www.jpo.go.jp.

The third process was the creation of a simulation scenario, in which we tried to understand and experience the learning process involved, from the adaptation of the instruments and microscope to the surgical skill, which also includes the time required to perform the exercises.
In the next phase, "Define", the main criteria for the development of the device were defined based on the data obtained from the interviews, desk research (literature search and search for prior art), and scenario analysis. The third phase, "Develop", was started based on the two previous phases. A mechanical engineer, with over 10 years experience in developing prototypes for patents, was contacted and, in brainstorming sessions together with the authors of this study, the characteristics of the device were defined for the development of the prototype. The brainstorming process had two phases, the creative phase, in which the participants of the session presented as many ideas and suggestions as possible without worrying about analyzing or criticizing them, and the critical phase, in which each participant justified and defended his ideas with the purpose of convincing the group. Through the latter, the ideas could be filtered and those that were better substantiated and accepted by the group remained. The last phase, "Deliver", consisted in the elaboration of the prototype for training microsurgical techniques idealized in the previous phases and its description in the spreadsheet of the patent model Canvas [14].

RESULTS

Through the interviews, it was possible to identify the major problems involved in the learning process, besides the basic skills that every apprentice needs to train. The information collected from the interviews with the two experienced microsurgeons revealed that the main technical difficulties in microsurgery were: adaptation to the instruments and optical magnification, and stereoscopy (hand-eye coordination). Regarding the most important basic skills in microsurgery training, they listed: motor dexterity, stereoscopic vision (two-dimensional hand-eye coordination), concentration and resilience. Regarding what would be necessary for a synthetic model to replace or mimic an animal model in microsurgery training, the answers from both were related to testing the patency of the microsurgical anastomosis, since in classical synthetic models, it would not be possible to test it dynamically. The desk research made it possible to learn about the various training models that already exist and the materials and devices available. In the simulation scenario, one could understand and experience the learning process involved in the technique, the main insecurities and challenges. In the patent databases, five devices with similarities to the device under study were found. None of these devices showed great similarities with the device under study, to the point of making it impossible to grant the patent. The synthetic microsurgery training model created is synthetic, does not use animals, is accessible, portable, allows the storage of instruments, facilitating transportation and reducing bureaucracy in the microsurgery training environment. The main activities performed during the "Define" phase were: creating affinity with the information gathered in the first phase, defining the essence of the problem (time, cost, etc.) and, finally, organizing and managing the information, observing the process as a whole. Thus, the main criteria for the development of the device were defined and from this, the development phase was started. The main activities during the "Develop" phase comprised brainstorms with the team. All the ideas raised were critically filtered and the best ones selected were put into practice. In the fourth and last phase, further adjustments and refinements were made, aiming to test, adjust, and validate the prototype. A device was devised that is 30x21cm divided into four microsurgery exercises. The exercises will progress with degree of technical difficulty, and training of skills needed to perform microsurgical procedures.

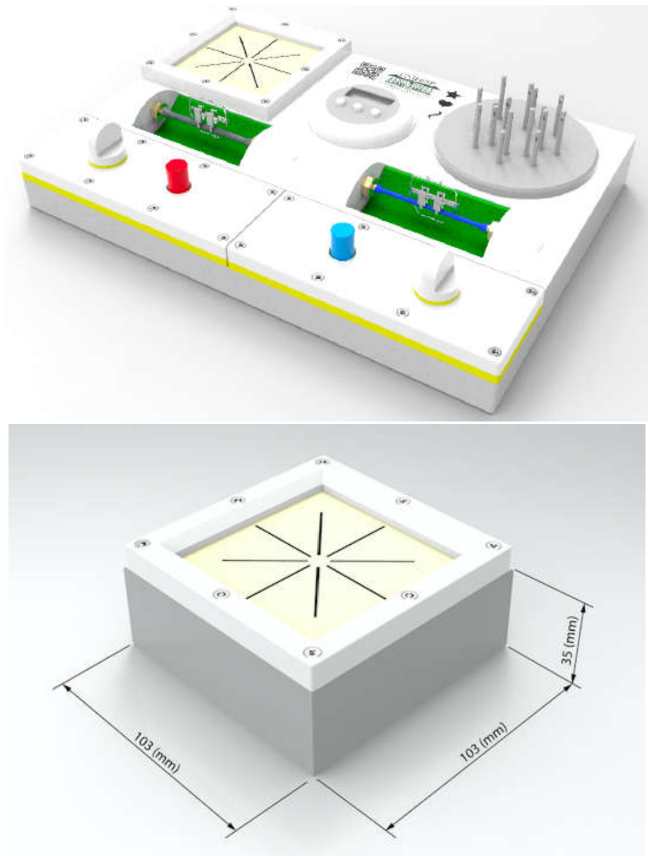

Figure 1. Device development for training in microsurgery. Right side; Prototype of the first part of the device

The first part of the exercise measures 10,3x10,3 cm and consists of planar suturing in several directions (to adapt to the instruments and microscope). The learner will have to execute plane sutures in directions that alternate every 450. The material used in this exercise is latex. Two latex films have been placed, with the superficial film showing the cracks that will need to be sutured, and the deeper film being intact. The learner's ability to perform a flat suture on the superficial film, without damaging the deeper film during suturing, will be evaluated. This first device is removable, allowing the learner to evaluate if the suture was restricted to the superficial film only. In this exercise we are training the adaptation to the instruments and optical magnification, dexterity and motor refinement.

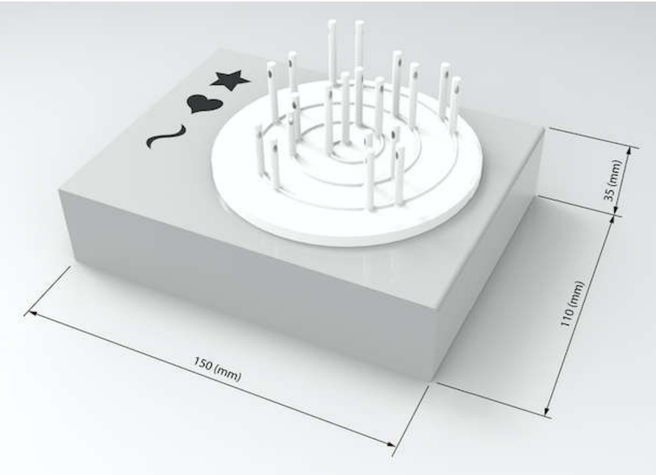

Figure 2. Prototype of the second part of the device

In the second part, the apprentice will have to pass the surgical thread and perform the suture, through the holes of vertical structures arranged in pairs in a helical direction. Each pair of these vertical structures has an opening at its end that will allow the passage of the needled thread, and will be at different heights. This will train the student's stereoscopy. For it will be necessary to visually adapt to these height discrepancies in the same focal field of magnification.

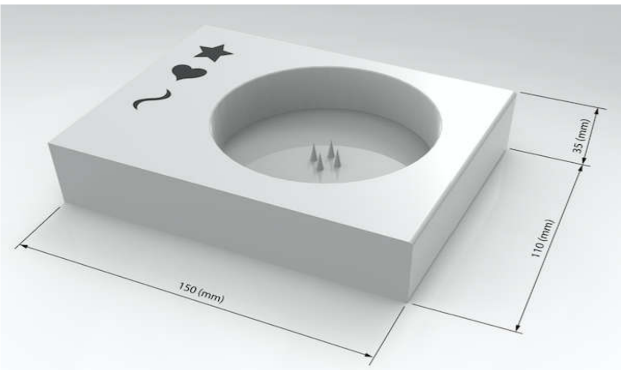

Figure 3. Prototype of the third part of the device

The third exercise will be grape training. The dissection of a grape skin will be performed, which will be centered and fixed on a base with a central fixator. This dissection cannot damage the pulp of the fruit, and three figures will be made on the skin of the grape, which will be arranged on the side of the exercise (star, heart, and crescent moon).This exercise will reinforce motor dexterity and concentration.

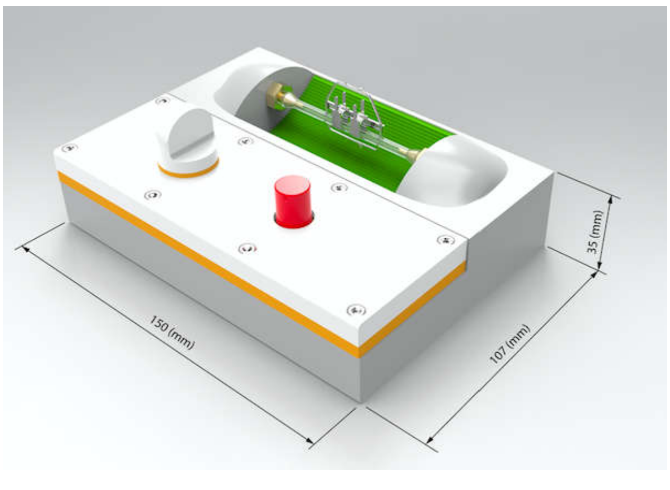

Figure 4. Prototype of the fourth part of the device (arterial model)

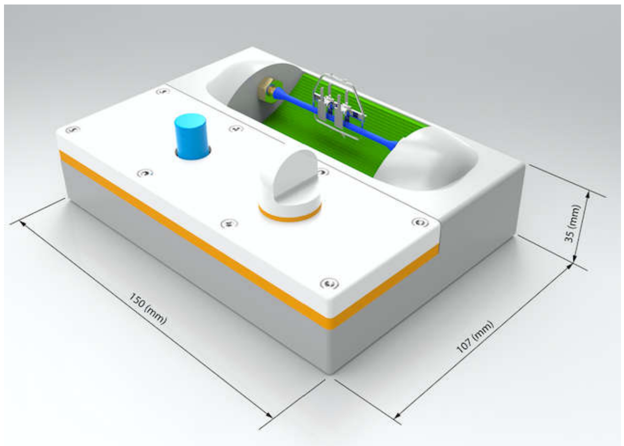

Figure 5. Prototype of the fourth part of the device (venous model)

The fourth training station will be the circumferential end-to-end and end-to-side sutures. This station will mimic an artery and a vein of 2mm and 1mm, respectively. The vein will have latex as its base material, mimicking the vein, because when it is without content inside, the walls collapse. The artery will be mimicked with silicone and polypropylene material, presenting a structure similar to the adventitial muscle layer of the artery, which does not collapse when its interior is emptied. In this exercise, the student will use a double clamp similar to the one used in microsurgery, and will perform the circumferential suture according to the microsurgical routine. He will start with the anterior wall, followed by the posterior wall. It is possible to perform both end-to-end, end-to-side, and latero-lateral suturing. A hydraulic system was designed to check the patency of the anastomosis after the anastomosis has been performed. The user of the device, at the end of the anastomosis, will push a button on the bottom of the device. This button will press the liquid from a side compartment into the artificial vessel. If the artificial vessel fails to continence, the liquid will leak between the points, indicating technical failure of the anastomosis. In this training stage, all the acquired skills will be reinforced: motor dexterity, stereoscopy, concentration, and resilience.

DISCUSSION

The development of surgical skills is a slow, continuous process, which requires immense dedication for its success. And when it comes to microsurgery, training is even more difficult because of the need to apply fine motor dexterity associated with stereostopic adaptation magnified by the magnifying glass or microscope. [2]. Reconstructive microsurgery continues to evolve, and increasingly, there is a need for a greater number of trained and skilled surgeons to perform complex procedures. Training requires a high degree of dedication, and mastery of the technique must first be obtained in the laboratory, gradually, before it is employed in clinical practice. [1]. The four phases of DT made it possible to map the divergent and convergent stages of the design process, showing the different ways of thinking. Unlike the scientific method, which defines all procedures before the project begins and progresses gradually in a unidirectional manner, DT follows a process with predictable inputs and outputs [13]. In designing this research, it was observed that the approach enabled a broad and flexible picture of the idealized training device. The desk research about information on synthetic microsurgery training devices evidenced several simplified training methods on gloves, synthetic silicone materials that are used for another medical purpose, such as jelcos, drains or expanders. However, there has been more focus on this material for initial microsurgery training. The search for scientific articles revealed the state of the art of synthetic device training in microsurgery, with emphasis on simplified, low fidelity models, and the scarce existence of high fidelity devices for training. Putting into focus the simulation of each stage of training performed by the apprentice of microsurgery, the following aspects were trained: motor dexterity, stereoscopy, concentration and resilience, from activities such as: simple sutures in several directions, use of delicate instruments, dissection of the grape skin without aggression to the pulp and performance of circumferential anastomoses. It is worth mentioning that difficulties are added to the activities, which includes the adequacy to optical magnification. The criteria for the creation of the device were based on the results of the interviews, desk research and the scenario, they are: to ensure that the apprentice correctly performs the training in microsurgery; the use of a device that is complete in training the necessary skills, improving dexterity, motor refinement, stereoscopic vision, concentration and resilience; accessibility and portability to the use of the device by not requiring the use of animals to perform the training.

CONCLUSION

Specific knowledge and training of microanastomosis techniques improves the education of the specialist, who will need this technical skill during practical activity. In order to provide surgeons with specific technical training in microsurgery, as well as to reinforce the basic concepts of technique, a portable, reusable and high-fidelity synthetic training device was developed.

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