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The use of simulation with non-living model to enhance medical students' learning in a surgical training course

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Abstract:
Introduction: *Considering the new medical curriculum program, we planned a non-Vivo model training program to teach the cutaneous flap's basic concepts. The purpose of this protocol is to create a basic flap training program for junior surgeons.*
Methods: *Seven days before the presential meeting, the didactic material and a questionnaire (pre-test) to measure the theoretical knowledge will be sent to students. At the meeting day, we will discuss the basic concepts of the cutaneous flap (15 minutes). Then the participants will design and explain several cutaneous flaps design in an ethyl-vinyl-acetate foil (30min). After this training, they will go to the wet lab, and they will perform all the cutaneous flap in a porcine belly non-living model (30min). We will assess participant performance by applying a Global rate scale, confidence level scale (Likert scale) in three different periods (pre-test, immediately post-training, and three months after surgical training). We will analyze all data using non-parametric tests to learn about the efficacy of this method.*
Discussion: *This program aims to increase the student's confidence level as this may reflect somehow his future competence. This study aims to present a step-wise learning method to teach the basic concepts of cutaneous flaps; this method will also help with the consolidation of the learning skills.*

Keywords: *flaps; education, medical; non-living model; surgery*

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INTRODUCTION

The medical curriculum requires integration between theory and practice and adapts to new education and health care policies.

In the face of these new demands, medical education must include specific characteristics: the topic addressed must be relevant, based on previous experiences, the student must have direct responsibility for their education and assume a proactive attitude, immediate practical application, based on cycles, reflections and feedback actions, mutual respect. (Agha et al., 2005)

Conscious teaching aims to mimic real-life surgical situations associated with repetitions of the procedures to build the learning curve, inserting immediate and medium-term returns to achieve the competence of these skills. (Agha et al., 2005; Stefanidis 2010)

According to Stefanidis 2010, the optimization of teaching by simulation and the acquisition of competence in complex tasks can be constructed on three sequential stages of learning: cognitive, associative, and autonomous. Each stage depends directly on the previous one. (Stefanidis, 2010)

The cognitive stage demands students to read about the basic concepts related to the activity (objective, description of necessary material, and the steps to carry it out). The associative stage deliveries theoretical knowledge into practice, connecting cognitive function to the student's skeletal and sensory muscle system. The repetition will lead to the automation stage, in which the student will automatically carry out the procedure without the need to plan and think each step of the procedure, feeling comfortable. (Gilligan et al., 1999; Milburn et al., 2012; Stefanidis, 2010)

Because of the learning curve, new animal use politics and students' attitudes are the main force to replace living models with non-living models for training purposes. (Balls, 2005; Balls & Morton, 2010; Turhan-Haktanir & Sancaktar, 2007) Also, medical education induces the student to evaluate patients with greater accuracy and make quick and effective decisions. (Gilligan et al., 1999) For these facts, our group created a surgical learning protocol to teach basic concepts of the cutaneous flap for undergraduate medical students.

At the end of this learning process, the student will be able to:

- Choose the best cutaneous flap for each lesion and region of the body.
- Plan and design a cutaneous flap

METHODS

This is a prospective study. This protocol was approved by the Ethical committee – FMUSP (1403/2019). All the participants will sign the informed consent form.

All plastic surgery residents from the Plastic Surgery Division of Hospital da Clínicas – Universidade de São Paulo undergo theoretical and practical training at the Medical Research Laboratory (LIM) of Plastic Surgery as part of the plastic surgery residency program. In this way, we will recruit our study participants during the usual training of residents of the plastic surgery residence program, inviting them to participate in our research. The inclusion criteria will consist of first and second-year plastic surgery residents of both genders and no age limit. Exclusion criteria will be senior plastic surgeons, residents who have already submitted to a flap training program, and residents who will not sign the informed consent form. The training program will take place at the microsurgery and plastic surgery Laboratory (LIM-4).

We will evaluate the student's pre-training, immediately after the training, and after 3 months. The 3-month follow up will take place through another meeting in the laboratory (LIM-04). The students will perform the same flaps in the previous meetings. All follow-up assessment will use the same scores and scales

Learning methodology

We structured the learning process into three stages. (**Table 1**, **Figure 1**)

Activities	Action	Time
Didactic material	Read the articles and watch the videos	1-2h
Live lecture	Explanation of basic concepts	15minutes
Practice 1	Flaps design in ethyl-vinyl-acetate foil	30min
Practice 2	Flaps design and suture in a non-living model	30-40 min
Case discussion	Interaction between the students and the teacher	30 min

Table 1. The learning process program to teach basic steps for cutaneous flap

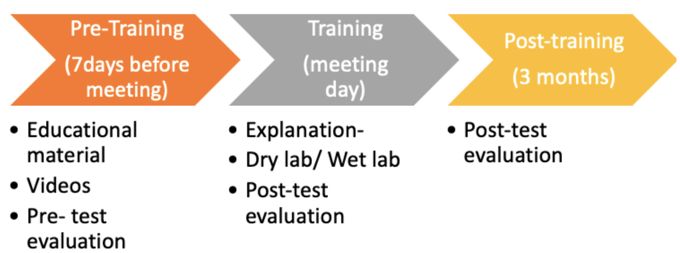

Figure 1. Training Timeline

The students will receive didactic material seven days before the presential meeting to learn about the cutaneous flap's basic concepts. (Lucas, 2017; Reckley et al., 2017; Shew et al., 2017; Starkman et al., 2017)

Additionally, we will send a questionnaire to evaluate the theoretical knowledge regarding the cutaneous flap planning and its design. (**Appendix A**)

On the meeting day, the instructor will explain the significant steps on the flap design. After this briefing, the students will receive an ethyl-vinyl-acetate foil (40 x 60 x 0.2cm), a ruler (cm), and a permanent marker pen (Sharpie, Newel, USA). At this moment, the students will design different types of flaps and discuss the pivotal point, angles, and extension for the following flaps types: rotation flaps, translocation flaps, advancement flaps, Rhombic (Limberg) flaps, and zetaplasty. They will receive synchronous feedback to correct and check the flap's designs. (Lucas, 2017; Reckley et al., 2017; Shew et al., 2017; Starkman et al., 2017).

After the design and discussion of the technical details, the student will go through the next step. The student will move into the wet laboratory to perform these flaps on a porcine belly non-living model. (Andrade et al., 2015) The student must perform the previous cutaneous flap and explain how they planned the flap design.

The primary endpoint will be the proportion of the responder rate in the Global Rate Scale (defined as an improvement of ≥ 2 points). The secondary endpoints are the improvement of theoretical knowledge related to cutaneous flap planning and design, number of repetitions, time to perform the surgical flaps, the proportion of responder rate in Confidence scale (defined as an improvement of ≥ 2 points).

Student assessment

During the activities, the instructors will supervise the student and give synchronous feedback as a formative assessment task. We will film all the students, and two independent reviewers (senior plastic surgeons) will assess each student using the Global Rate Scale (Agha et al., 2005)

We will assess pre-training and post-training (immediately and 3-months) knowledge using two validated scales (10 questions). We will adopt two scales to test competence and confidence.

The Objective Structured Assessment Technical Skills (OSATS) is a validated scale compounded by seven domains. Because of the surgical procedure's nature, we will check six of them (excluding the domain: use of assistant). The OSATS score can range from 0 - 30 points. (Winckel et al., 1994)

Moreover, we will apply a confidence scale for self-assessment. Both scales are based on the 5-point Likert scale (**Table 2**). (Niitsu et al., 2013; Van Hove et al., 2010)

	1	3	5
Respect for tissue	Frequently used unnecessary force on tissue or cause damage by inappropriate use of the instruments	Careful handling of tissue but occasionally caused inadvertent damage	Consistently handled tissue appropriately with minimal damage
Time and Motion	Many unnecessary moves	Efficient time/motion but some unnecessary moves	Clear economy of movement and maximum efficiency
Instruments handling	Repeatedly makes tentative or awkward moves with the instruments by inappropriate use of the instruments	Competent use of instruments but occasionally appeared stiff or awkward	Fluid moves with instruments and no awkwardness
Knowledge of Instruments	Frequently asked for wrong instruments or used inappropriate instruments	Knew names of most instruments and used appropriate instruments	Clearly familiar with the instruments and their names
Flow of operation	Frequently stopped operating and seemed unsure of the next move	Demonstrate some forward planning with the reasonable progression of the procedure	Clearly planned course of operation with effortless flow from one move to the next
Use of assistant	-	-	-
Knowledge of specific procedure	Deficient knowledge. Needed specific instruction at most stages	Knew all important steps of operation	Demonstrated familiarity with all aspects of the operation

Table 2. The Global rating scale for efficient performance. Adapted from van Hove et al., 2010.

Suwanrath et al. 2016, analyzed a Likert scale for student's self-assessment confidence level (1=least confidence and 5=most confidence), with 4-5 deemed competent. The confidence score can range from 0 to 5. (Suwanrath et al., 2016)

Sample size calculation

We hypothesized that the proportion of flap procedure success in pre-training, immediately post-training, and 3-months post-training will be 0.5; 0.8; 0.8, respectively. We considered an alpha level of 5% and a power of 80%.

We used the software power and sample size calculators (http://powerandsamplesize.com/Calculators/Compare-k-Proportions/1-Way-ANOVA-Pairwise) and calculated a sample size of 55 participants considering post-training minus pre-training differences.

Statistical analysis

We will describe all the variables using the median and interquartile range. We will compare pre-training and post-training data using the Kruskal Wallis test, if significant, we will perform a post hoc test with correction for multiple analysis using Bonferroni correction. To compare the data in three different follow-ups (pre-training, immediately and 3-months post-training), we will use McNemar's test and if significant Dunn's test as a post hoc pair-wise analysis. We will consider the alpha level of 5% and power of 80%.

All the analyses will be done using STATA v14 (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

DISCUSSION

In surgical history, Dr. Halsted implemented the principle for teaching surgery: "See One, Do One, Teach One." This idea was one of the stakeholders in surgical teaching methods for years. However, this method is no longer applicable mainly because of concerns for patient safety, new health policies, and reductions in resident work hours. (Kotsis et al., 2013)

The idea of implementing a non-living model program will answer all the previous factors to introduce a new learning method. This study aims to present a stepwise learning method to teach the basic concepts of cutaneous flaps. According to Miller's pyramid (1990), this program will implement the steps to knowledge acquisition (know, know-how, shows how does). (Miller ,1990)

The theoretical knowledge is necessary for the student to understand and reflect upon the principles of surgical technique, indications, contra-indications, and significant steps and principles of the flap design. With the theoretical background serving as a roadmap, we will work on motor acquisition (semantic memory) skills.

The next step will discuss questions related to the surgical procedure and show the most common technical errors and how to avoid them. After this summary, the student will design the required type of cutaneous flap as many times as necessary to exercise associative interconnections. This stage and the next one can vary according to the student's previous experience and handling. The final step of the evaluation is the direct observation of the student's performance. In terms of content and construct validity these steps will create a gold-standard evaluation. (Beard, 2008)

We will prepare the students to think which flap will be more effective in lesion dimensions and lesion region. Moreover, we will stimulate the student to describe all the operative procedure steps during the evaluation. (Niitsu et al., 2013; Van Hove et al., 2010)

We will evaluate the student learning process in three phases during the procedure with direct feedback. Therefore, we will correct any flap technical discrepancy. The second phase of the evaluation will compare the pre-test, and post-test questionnaire results, to test semantic and procedural knowledge acquisition. (Beard, 2008; Camina, 2017)

The number of repetitions will build neurological venues to build the necessary synapses to memory acquisition ("fire together, wire together "). Dealing with surgical learning, the instructor needs to deal with two different neurological pathways: the theoretical acknowledgment – semantic memory and procedural memory. The first one will activate prefrontal areas to interact with the cortex. The motor learning requires the cerebellum, basal ganglia via to adapt the brain to this new condition, in this case, cutaneous flap surgical procedure. (Camina,2017; Seidler 2010)

For some authors, the student's confidence level reflects somehow their competence. A group from Thailand applied a different medical skill (venous puncture, central venous catheter, episiotomy). The students had to analyze their confidence level using a Likert scale (1=least confidence and 5=most confidence), with 4-5 deemed competent. This study showed the student self-confidence status is directly related to the complexity of the procedure. To illustrate the importance of self-confidence, these authors showed the number of procedure repetitions to achieve a satisfactory level of confidence (4-5): a venous puncture demands 3-5 repetitions, while a central venous catheter procedure demanded 10-15 repetitions. (Suwanrath et al., 2016)

This protocol has some limitations: we will not plan a control-group, we will analyze the outcomes by the same student's performance. Moreover, we will assess the retrieval memory after 3-months of the training. The results of this trial will help us to plan a randomized clinical trial with placebo control (no-structured flap training). Another limitation is the Hawthorne potential effect on the participant's behavior. Several authors discussed the effect of the observer's performance (Hawthorne effect) in medical education and developed some strategies that could mitigate the Hawthorne effect. ((Paradis et al., 2017; McCambridge et al,2014a; McCambridge et al,2014b)

According to these authors, we will establish an excellent social interface with the participants to feel comfortable at a reasonable pace, explain the purpose of the study, improve the process), and collect data follow-ups to diminish training process stress. (Paradis et al., 2017; McCambridge et al,2014)

Conflict of interest

The authors declare no conflict of interest. CP is an associate editor of the Principles and Practice of Clinical Research journal. Therefore, she excused herself from the editorial process, she did not influence the editorial process and final publication decision.

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