The Montreal Augmentation Mammoplasty Operation (MAMO) simulator: A Novel Method of Training and Assessing Competence in Plastic Surgery

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“Success is not final; failure is not fatal: it is the courage to continue that counts”

-Winston Churchill

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MAMO: Montreal Augmentation Mammoplasty Operation
GRS: Global Rating Scale
MOAT: Mammoplasty Objective Assessment Tool
SD: Standard Deviation
ICC: Interclass Correlation Coefficient
BC: Before Christ
CBME: Competency-Based Medical Education
USA: United States of America
UK: United Kingdom
NAC: Nipple Areolar Complex
MPT: Mammoplasty Part-task Trainer
ASERF: Aesthetic Surgery Education and Research Foundation
R^2: Coefficient of determination
r_s: Spearman Correclation Coefficient
OR: Operating Room
3D: Three Dimensions
PS3: PlayStation 3
IMF: Infra Mammary Fold
BPR: Basic Performance Resources
ACGME: Accreditation Council of Graduate Medical Education
AB: Antibiotics
MISTELS: McGill Inanimate System for Training and Evaluation of Laparoscopic Skills
VR: Virtual Reality
ASPEN: Anatomical Simulator for Pediatric Neurosurgery
RCPSC: Royal College of Physician and Surgeons of Canada
OSATS: Objective Structured Assessment of Technical Skills

Abstract

Augmentation mammoplasty procedure remains the most commonly performed aesthetic procedure in plastic surgery. Residents' training and technical skills assessment in this domain can prove to be challenging due to the limited access to private clinics where such procedures take place. An advanced simulation training environment can provide an alternative tool to train and assess residents' performance, especially in the era of Competency-Based Education. The purpose of this project was to develop a simulator capable of replicating the essential steps of an augmentation mammoplasty procedure and achieve its face, content and construct validations.

After identifying the essential surgical steps of the procedure using the modified Delphi methodology, a pilot project was undertaken to develop an early prototype part-task trainer in the aim of evaluating the silicone materials used. Following satisfactory realism scores achieved by the part-task trainer, the Montreal Augmentation Mammoplasty Operation (MAMO) simulator was developed using molding and casting techniques. All anatomical structures were replicated using adequate silicone material and alterations to the benchtop simulator were made to attain maximum reusability. This study design was a prospective blinded observational study. Plastic surgeons, both staff and residents, were recruited to perform a mammoplasty procedure on the simulator. Following an instructional video, participants completed the essential steps of the procedure and their performance was filmed. The expert surgeon participants evaluated the simulator's various parameters and their overall experience. Video recordings of all participants' performances were blindly reviewed and assessed using the Objective Structured Assessment of

Technical Skills (OSATS) system: Global Rating Scale (GRS) score, Mammoplasty Objective Assessment Tool (MOAT) score and a Checklist score. Data was recorded as mean (SD).

Twenty-one participants were enrolled in this study (14 residents and 7 experts). Mean values of residents and experts were 23.4 (2.5) vs 36.9 (3.1) ($p<0.0001$) for GRS score, 30.4 (2.2) vs 40 (3.2) ($p<0.0001$) for MOAT scores and 9.7 (1.5) vs 12 (1) ($p<0.001$) for Checklist scores respectively. Construct validation was achieved by the demonstrating significantly higher performance by experts with all the objective metric tools used. Face and content validations results showed excellent results among parameters evaluated, with an overall mean score of 4.8 (0.3) on 5. Cronbach's alpha was 0.96 and 0.83 for GRS and MOAT scores respectively. Intraclass Correlation Coefficients for interrater reliability were excellent at 0.93, 0.92 and 0.89 for the total GRS, MOAT and Checklist scores respectively.

This project demonstrated the validation of face, content and construct of the MAMO simulator. It also established the MAMO simulator system as the first Plastic Surgery-specific tool capable of consistently measuring residents' performance and attributing competence in subpectoral mammoplasty procedures.

Abrégé

La chirurgie des augmentations mammaires demeure la procédure esthétique la plus effectuée en chirurgie plastique. La formation des résidents et l'évaluation des compétences techniques dans ce domaine peuvent s'avérer difficiles en raison de l'accès limité aux cliniques privées où de telles procédures ont lieu. Un environnement de formation par simulation avancé peut constituer un outil alternatif pour former et évaluer les performances des résidents, en particulier à l'époque de formation par compétence. Le but de ce projet était de développer un simulateur capable de reproduire les étapes essentielles d'une procédure d'augmentation mammaire et d'atteindre les validations de l'apparence, de contenu et de construction.

Après avoir identifié les étapes chirurgicales essentielles de la procédure à l'aide de la méthodologie Delphi modifiée, un projet pilote a été entrepris pour mettre au point un prototype de simulateur de tâche partielle dans le but d'évaluer les matériaux utilisés qui sont à base de silicone. À la suite de résultats satisfaisants obtenus par le simulateur à tâche partielle, le simulateur de MAMO (Montreal Augmentation Mammoplasty Operation) a été mis au point en utilisant la technique de moulage. Toutes les structures anatomiques ont été représentées en utilisant le matériel en silicone adéquat et des modifications ont été apportées au simulateur pour obtenir une réutilisabilité maximale. L'étude qui a été exécuté était du type prospective observationnelle aveugle. Les chirurgiens plasticiens, experts et résidents, ont été recrutés pour effectuer une mammoplastie sur simulateur. Après la vidéo d'instruction, les participants ont complété les étapes essentielles de la procédure et leur performance a été filmée. Les chirurgiens experts participants ont évalué les différents paramètres du simulateur et leur expérience globale. Les enregistrements vidéo des performances de tous les participants ont été examinés et évalués d'un façon anonyme à

l'aide du système OSATS (Objective Structured Assessment of Technical Skills): score GRS (Global Rating Scale), score MOAT (Mammoplasty Objective Assessment Tool) et score de la liste de contrôle.

Vingt et un participants ont participé à cette étude (14 résidents et 7 experts). Les valeurs moyennes des résidents et des experts étaient de 23,4 (2,5) vs 36,9 (3,1) ($p < 0{,}0001$) pour le score GRS, 30,4 (2,2) vs 40 (3,2) ($p < 0{,}0001$) pour le score MOAT et 9,7 (1,5) vs 12 (1) ($p < 0{,}001$) pour le score de la liste de contrôle, respectivement. La validation de la construction a été réalisée grâce à la démonstration de performances nettement supérieures par les experts avec tous les outils de mesure objectifs utilisés. Les résultats des validations de l'apparence et du contenu ont montré d'excellents résultats parmi les paramètres évalués, avec un score moyen global de 4,8 (0,3) sur 5. L'alpha de Cronbach était respectivement de 0,96 et 0,83 pour les scores GRS et MOAT. Les coefficients de corrélation intraclass (ICC) étaient excellents à 0,93, 0,92 et 0,89 pour les scores totaux de GRS, MOAT et Checklist respectivement.

Ce projet a démontré la validation de l'apparence, du contenu et de la construction du simulateur MAMO. Il a également établi le système de simulation MAMO comme le premier outil spécifique à la chirurgie plastique capable de mesurer de manière cohérente les performances des résidents et d'attribuer des compétences dans les procédures de mammoplastie sous-pectorale.

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CHAPTER 1 – INTRODUCTION

I. Simulation renaissance and its driving forces

The term simulation is defined as the act of replicating real life situations, typically those endangering human lives, in the aim of improving trainees' performance. More specifically for healthcare, it represents the act of recreating medical and surgical situations for apprentices to practice and develop critical psychomotor, technical and judgmental skills.

The recent enthusiasm over simulation-based training came from the need to bridge the gap between didactic and clinical practice. Traditionally, the transition between these two pillars of education resulted in patient endangerment and suboptimal patient care due to the abrupt shift from theory to practice. Simulation training provides a safe, stress-free environment that forgives failure without endangering patients' wellbeing. It also allows trainees to acquire the early phases of the learning curve in the skill in question. Most importantly, the retention of skills developed on a simulator and its transferability to clinical application has been well established in the literature[1,2].

Simulation training in healthcare is by no means a novel concept. Evidence of simulation in surgery dates back to ancient times (600 BC)[3,4]. It consisted of using simple elements such as clay and leaf to simulate the essential steps of a procedure and demonstrate the process to trainees. Unfortunately, the lack of anesthetic usage and the inability to manage infections during that era lead to the vanishing of interest in surgery. This resulted in the loss of knowledge and experience in surgical simulation use and development.

The renaissance of simulation in healthcare was attributed to the success it achieved in the aviation system. Developers in that sector built on the initial work of Edwin A. Link, the creator of the first described flight simulator[5]. Modern flight simulators apart from the faithful reproduction of the internal flight deck and external visual environment, can also be coupled with scenarios where weather conditions can be modified, radio communications can be disrupted, and technical issues can be generated. Operators faced with these scenarios learn to troubleshoot out of these technical problems in a safe environment and develop skills that can be transmitted into real-life situations. Simulation training today constitute an essential and mandatory tool to achieve pilots training.

Similar to the aviation sector, surgery can endanger human lives and necessitates adequate judgment and rapid execution in states of inadvertent events. Surgical training was taught for years using the «see one, do one, teach one» model and worked well for decades, until surgical techniques became less invasive and more refined. Technologies such as laparoscopic surgery and robotics adoption by surgical specialties steepened the learning curve to achieve competence. This transition from a three-dimensional surgical field to an on-screen two-dimensional image with limited tactile feedback represented a challenge to already-in-practice surgeons, given the entirely different skillset that is required[6,7]. Given the unstructured short training courses provided at the time to teach this new approach, a new standardized teaching platform became necessary and resulted in the development of the first surgical simulator for a laparoscopic cholecystectomy[8].

In addition, the shift in the educational paradigm towards Competency-Based Medical Education (CBME) has redefined residents' training and assessment. The guiding principle of

CBME is that trainees will have to prove proficiency in a specific skill before being allowed to proceed to another. As a result, residents will have to be observed and evaluated on each of the specialty-specific competencies periodically by an expert. This will raise the need for simulators to be used as training and assessment tools to gauge residents' performances and assess acquisition of competence. Unfortunately, the availability of such simulators for plastic surgery remains scarce.

II. Aim of the project

The nature of procedures performed in plastic surgery, being based on surgical principles rather than pre-defined surgical steps, renders the task of simulators development even more challenging. The goal of reconstructive plastic surgery revolves around improving body function by establishing normal appearance and functionality. The approach to surgical planning varies based on the location, the size of defect, the structures exposed and the post-operative management required (i.e. radiation) for any surgical defect presented with. This along other challenges, such as limited research funding to plastic surgery in general and aesthetic procedures in particular, has further contributed to the underdevelopment of the simulation sector of the specialty.

The aim of this project was to develop a benchtop breast augmentation simulator where plastic surgery resident can train and be objectively assessed on their surgical skills in inframammary subpectoral implant-based breast augmentation. The proposed model would be the first of its kind in the field and would allow for unprecedented training resource for plastic surgery residents. In addition, objective assessment scales would be developed and validated to be used along the benchtop simulator. The development of a breast augmentation simulation tool has the potential to significantly improve the way in which plastic surgery residents learn breast augmentation, and ultimately, improve patient outcomes.

Chapter 2 Methodology and overview of the projects' essentials

I. Needs assessment

According to the annual plastic surgery procedural statistics, aesthetic procedures demand is on a steady rise, reaching 17.5 million surgical and minimally invasive cosmetic procedures performed in the United States in 2017, a 2 percent increase from the previous year[9]. In addition, breast augmentations procedures remain the most commonly performed cosmetic surgical procedure. Inframammary incision approach and subpectoral implant placement are the main approaches used to achieve a more desirable aesthetic result with least post-operative complications.

Current training paradigm consists of residents' hands-on exposure on real patients in the private-clinic setting as part of devoted aesthetic rotations. Unfortunately, this exposure to aesthetic procedures has been considered deficient in recent surveys[10,11], which also recommended that structural improvements in residency training are warranted. The cause could be linked to the fact that these patients are paying out-of-pocket money to get these procedures done and are hesitant about residents' major involvement in their care. Similarly, plastic surgeons operating on private patients have their reputation on the line and might as well be less enthusiastic to offer residents' the role of primary surgeon.

Following a literature review and needs assessment, the Delphi methodology was recently utilized by our team to establish the essential steps of a breast augmentation procedure after being identified as lacking robust assessment metrics[12]. Based on these identified essential steps, we planned the development of a complete chest and breast simulator, which enables the reproduction of the majority of the essential steps, while achieving maximum reusability. Before embarking in the construction of the main simulator, initial work focused on the development of a unilateral breast augmentation prototype. The goal was to identify the adequate materials that best mimic texture and behaviour of the anatomical structures that each represents. In some instances, the reaction of certain material to heat was also taken into consideration, like the reaction of the simulated subcutaneous tissue to the heat cautery device. Materials were all tested by an expert plastic surgeon before adopting the choice of material.

II. Simulator fabrication process of the final product

An off-the-shelf anatomical skeletal thorax (Skeletons and More, Marcellus, USA) was purchased and used as the base on which the other structures were all assembled. Medipore© dressing (3M©, St. Paul, USA) was applied on the ribs to simulate periosteum and secured using silicone glue. Periosteum is used during the inframammary fold redefinition step, where sutures are placed through the periosteum into the local subcutaneous tissue. This material was chosen based on its characteristics to withstand multiples uses of suturing.

The intercostal muscles were replicated using a mixture of Dragon Skin 10 Medium® (Smooth-On©, Macungie, PA) and Slaker® (Smooth-On©, Macungie, PA) and given a red color using Silc Pig™ blood pigments. The mix was then layered between two sheets of serene wrap to flatten out the mix and was given time to cure. The muscles were individually trimmed according to the trajectory and distance between each pair of ribs then secured using silicone glue (Figure 1).

Figure 1 Intercostal muscles fitting in between the rib spaces of the thorax

The pectoralis major and minor muscles were replicated using molding and casting techniques. The shape and dimension of each of the muscles were manually designed using clay material, taking into account anatomically defined measurements published in the literature[13]. Once a satisfactory design was achieved, Mold Star 30™ silicone was used to immerse the designed clay models to form a negative impression mold. A series of different ratio mixes of Dragon Skin 10 Medium® and Slaker® was prepared to obtain samples with different softness textures. Following evaluations by experts, a consensus was obtained over the 1:0.75 ratio of Dragon skin® to Slaker® mix. Using these parameters, the mixture of silicone material and red pigments were poured into the respective molds and given time to cure (Figure 2).

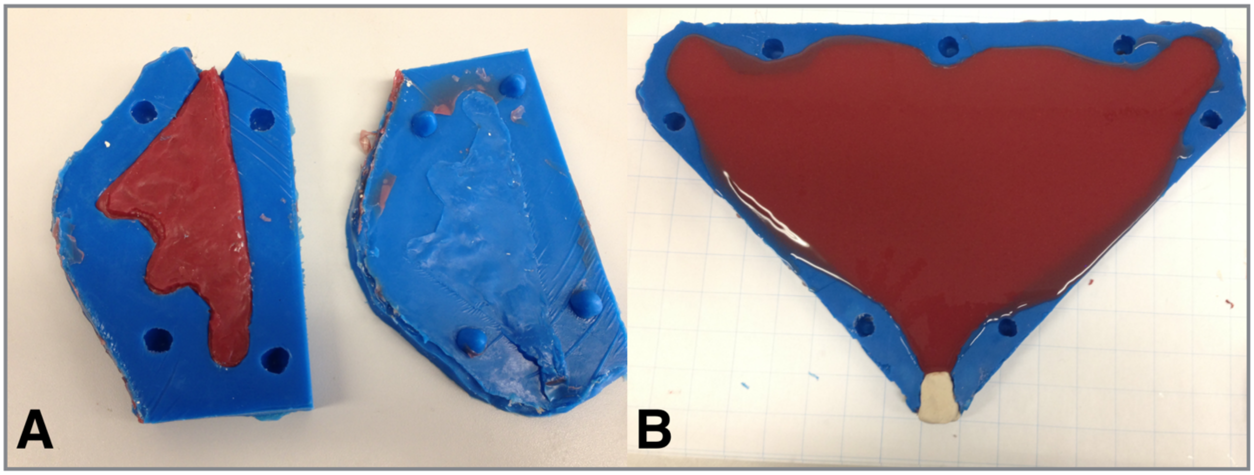

Figure 2 Pectoralis minor (A) and major (B) muscles in their respective molds

Velcro (Velcro®, London, UK) material (loops-side) was sutured to the inferior border of the under surface of the pectoralis major muscle. Velcro material (hooks-side) were also applied to the chest wall to allow the simulation of the pectoralis major muscle separation process from the thorax using a cautery device. Next, the muscles were attached to the rib cage using silicone glue and plates and screws (Figure 3).

Figure 3 Displaying the fixation methods of the different muscles onto the simulator using plates and screws and silicone glue

The external morphology of the breast was replicated from a commercial clothing thorax mannequin using molding and casting technique. The absence of the nipple-areolar complex (NAC) was replicated by manually crafting the complex on the mannequin using clay material (Figure 4A). Mold Star 30™ (Smooth-On©, Macungie, PA) silicone was brushed onto the mannequin in a series of incremental thicknesses, achieved by adding different concentrations of Thi-Vex® (Smooth-On©, Macungie, PA) to the mix. Multiple layers of plaster sheets were then applied on top of the silicone mold to provide an extra solid layer (Figure 4B).

Casting was done using Dragon Skin 10® (Smooth-On®, Macungie, USA) silicone material mixed with flesh color and red pigments to replicate the NAC and flesh color pigments for the rest of the mold. Subcutaneous and breast tissues were simulated using a mix of Soma Foama 15® (Smooth-On®, Macungie, USA) and Slacker® (Smooth-On®, Macungie, USA) in a 2:1 ratio. It was poured into and spread on the previously created skin envelope, except for a rectangular area around the inframammary fold of each breast (Figure 4C). These two areas were filled with FlexFoam-iT™(Smooth-On®, Macungie, USA), a urethane-based silicone foam that can react adequately to a cautery device.

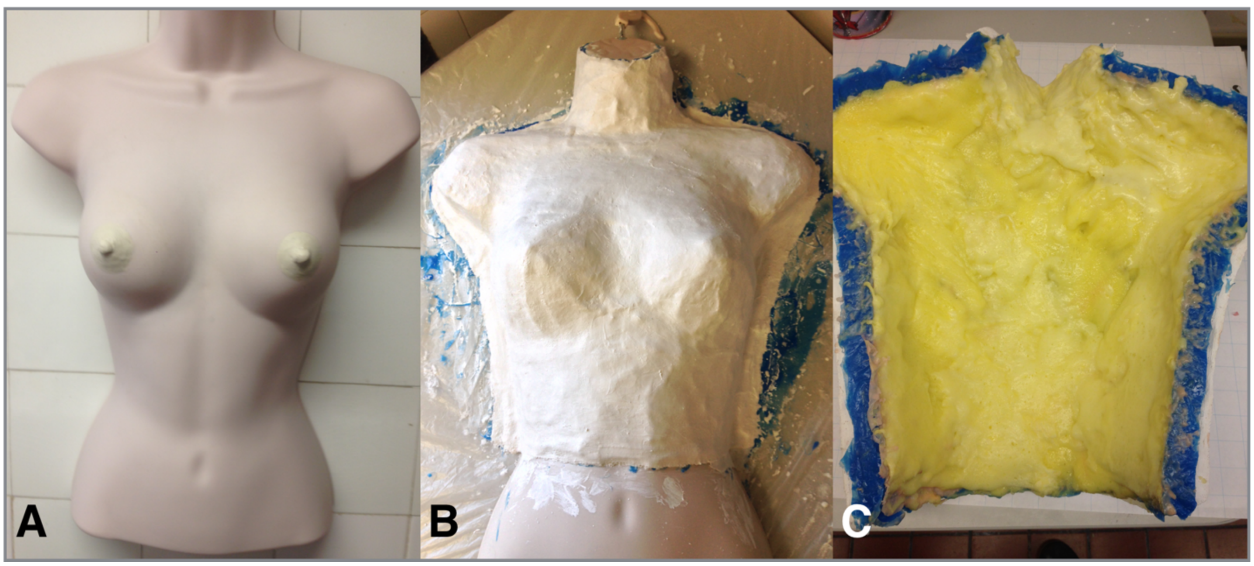

Figure 4 Displaying (A) the female chest mannequin with the replicated NAC, (B)the mold made of silicone and plaster and (C) the mold used to cast the skin and the subcutaneous tissue

Following mannequin assembly (Figure 5), a standard air balloon was inflated in the rib cage before usage as a pneumothorax indicator, which ruptures if any breach of the pleural space takes place.

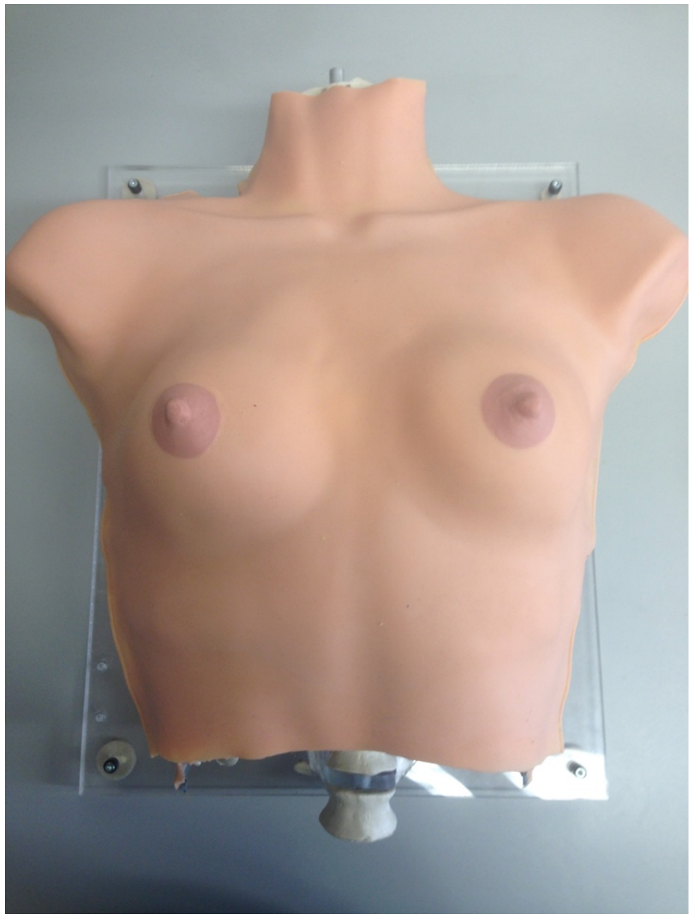

Figure 5 The breast augmentation simulator after assembly of all its components

III. Types of validation studies

Validation of a simulator is required to guarantee proper assessment of surgical skills in the procedure of interest. This process aims to determine whether the conceptual model developed is an accurate representation of the actual system being analyzed and to which extent the scores from a measure represents the variable it is intended to. For simulators that require physical input such as surgical simulators, face, content and construct validation studies have been widely used in the literature[14].

Face validity represents the extent to which a measurement method appears "on its face" to measure the construct of interest. It is a subjective judgment call that is made by a panel of experts regarding the external characteristics of a model, which in itself represents a very weak kind of evidence of the validity of the construct. Content validity is the extent to which a measure "covers" the construct of interest. In other words, it is the process of checking the operationalization against the relevant content domain of the construct. This approach assumes that the construct has a good detailed representation of the content domain. Like face validity, content validity is not usually assessed quantitatively. Instead, it is evaluated by carefully assessing the realism and ability to replicate real-life maneuvers. Finally, construct validity refers to the degree to which inferences can legitimately be made from the operationalizations on the construct in study. It defines how well a construct measures up to its claims of assessing surgical skills and knowledge of a procedure. In the context of a surgical simulator, the study aims to prove that the construct can significantly distinguish between an expert and a novice when it comes to surgical performance.

IV. Reliability studies

In addition to the previously described validation studies, reliability measurements of attributed performance scores should also be analysed. Evaluations are carried out by experts through assigning a score to each of the items that compose an assessment tool. All the items on such measurements are supposed to reflect the same underlying construct, so expert's scores on those items should be correlated with each other. This is defined by the internal consistency of an assessment tool, which in other terms, measures the consistency of responses across the items on a multiple-item measure using Cronbach's alpha calculation.

A reliable assessment tool should also provide consistency of attributed scores between different evaluators when assessing the same performance. In practice, performance is video-recorded and blindly presented to two different evaluators to assign a score on performance. An Intraclass Correlation Coefficient (ICC) is thereafter calculated to determine whether inter-rater validity was achieved. In addition, a third reliability test is commonly performed in literature which compares consistency of scores attributed by an evaluator when assessing the same performance. In this context, evaluators are presented with video-recordings of participants performance and asked to evaluate each performance twice, then data is analyzed. The test is known as the test-retest reliability and the analysis outcome is known by test-retest reliability coefficient.

V. Overview of the project

The end goal of this project is to develop a benchtop simulator that enables residents to practice and be evaluated on their performance in breast augmentation procedures. Throughout this process, many objectives had to be achieved in order to attain the end product. The next three chapters will discuss in detail each of these objectives.

The initial goal was to identify the most appropriate material capable of simulating each of the anatomical structured encountered during a breast augmentation procedure. As a result, different materials and casting techniques were tested to achieve the most realistic looking product and haptic feedback. Chapter 3 describes the development of a prototype unilateral breast augmentation that replicates the majority of the relevant anatomical structures. The prototype was then tested and evaluated for face and content validations by four plastic surgeons, who also completed a comments section recommending areas of improvement. Construct validation was not necessary at this stage as the prototype was not meant to assess performance of operators. The main objective was to get experts' feedback on looks and function. The following chapter (four) aimed at utilizing the prototype to study the relationship between surgical skills of medical students and their performance in skill-games and videogames. The results eluded to the possibility of predicting surgical performance using test tools that requires a certain level of hand-eye coordination and hand dexterity.

Following the feedback and assessment results of the prototype breast augmentation, chapter 5 describes the process of development and validation of the final version of the mammoplasty simulator. This section of the thesis will focus on the completion of face, content and construct validations. In addition, newly developed surgery-specific assessment tool and checklist were tested for correlation and reliability of measurements compared to a gold-standard assessment tool widely used in the literature, the Objective Structured Assessment of Technical Skills (OSATS) score.

CHAPTER 3 – Article 1: A Novel Mammoplasty Part-Task Trainer for Simulation of Breast Augmentation: Description and Evaluation

A Novel Mammoplasty Part-Task Trainer for Simulation of Breast Augmentation: Description and Evaluation

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Abstract

Introduction: Since the introduction of competency-based education and the restriction of residents' working hours, simulator-aided training has obtained increasing attention for its role in teaching and assessing resident surgical skills. Within plastic surgery training, such simulators would be particularly useful for aesthetic surgery procedures such as augmentation mammoplasty where residents have fewer opportunities for hands-on experience. The aim of this study is to develop a part-task trainer that allows plastic surgery trainees to acquire skills necessary for augmentation mammoplasty and to assess its potential value as a training tool.

Methods: The mammoplasty part-task trainer (MPT) was designed to have a re-usable and rigid thorax base and "soft" disposable layers to mimic the skin and subcutaneous tissues. A mock unilateral subglandular breast augmentation was performed by four board-certified plastic surgeons using standard instruments and scored using a 0-5 Likert scale where a score of 5 was considered the most satisfactory.

Results: Four board certified plastic surgeons participated in the survey. On a scale of 0-5, the MPT's 'value' as a training tool, 'relevance to practice' and 'physical attributes' scored highest with mean values of 4.5 (0.6), 4.3 (0.5) and 4.1 (0.4), respectively. 'Realism of experience, 'ability to perform tasks' and 'the realism of material' scored 3.9 (0.5), 3.8 (0.4) and 3.7 (0.6), respectively. The observed average of the ‘global assessment’ of the MPT was 4.3 (0.5). The cost of fabrication of the MPT was estimated at around $113 CAN.

Conclusions: This study describes a preliminary novel mammoplasty task trainer that was highly valued by experts as a potential training tool.

Keywords: surgical training simulator, mammoplasty part-task trainer, competency-based education, breast augmentation, and aesthetic surgery of the breast.

Introduction

Acquisition of dexterity in specific surgical skills requires repeated practice by surgical trainees. Traditionally, this has been achieved through the gradual introduction and escalation of trainee involvement and independence in surgical procedures until graduation in a time-based training program. A number of factors, however, challenge this traditional training paradigm, such as the recent introduction of mandated objective assessment of skill competencies (i.e. competency-based education) into most North American residency programs.[1,2] An additional issue is the concomitant restriction on working hours of residents, resulting in reduced case volumes and exposure to such learning experiences.[3,4] It is not surprising, then, that surgical simulation has obtained increasing attention for its role in teaching and assessing resident surgical skills.[5-7]

Evidence that the use of simulation in healthcare is linked to improvement of trainees' performance and patients' safety[8-10], has led researchers to develop new simulators. It has been shown that training on simulators allows residents to complete the early phase of the learning curve and to acquire surgical skills related to the procedure in question.[11] Furthermore, skills acquired in simulation training have been repeatedly and consistently demonstrated to be transferable to the operating room.[12-15] These findings have led to the development of more sophisticated surgical simulators that allow the execution of the essential steps of a procedure, rather than training on simple tasks such as skin suturing and wound care. The simulation environment offers junior trainees the opportunity to develop the necessary skills at their own pace in a controlled environment and to receive objective feedback based on their performance.

Surgical simulation in general will be a necessity in the new environment of mandated assessment of surgical competence due to medico-legal and ethical concerns[16-18] involved with trainees learning and being tested solely in the live operative setting. Particular to Plastic Surgery training is the additional difficulty associated with the teaching of aesthetic surgery skills[18-20] due to the frequent marginalization of aesthetic surgeries to private clinics as a result of limited hospital (University) operative resources. Such learning is further burdened by the fact that patients pay out-of-pocket for aesthetic procedures and thus are less keen to participate in resident training.

In this study, the authors introduce the first mammoplasty part-task trainer (MPT) with the goal of providing improved technical training experiences and objective skill assessment for Plastic Surgery trainees.[20] Although early in its development, the MPT, with further refinements, could allow plastic surgery trainees to practice breast augmentation and acquire the basic skill sets before they apply the manoeuvres in the clinical setting.

Methods

Mammoplasty part-task trainer

The MPT was produced in an “anatomic” layer-by-layer manner (Figure 6). The external appearance and shape of the breast were reproduced from the right breast of a volunteer. A mold of the breast and chest wall was taken by applying silicone to the breast in multiple layers with incremental viscosity; the first layer having the lowest viscosity to pick up the finest details, then higher viscosities to harden the mould and finally a plaster layer to solidify it.

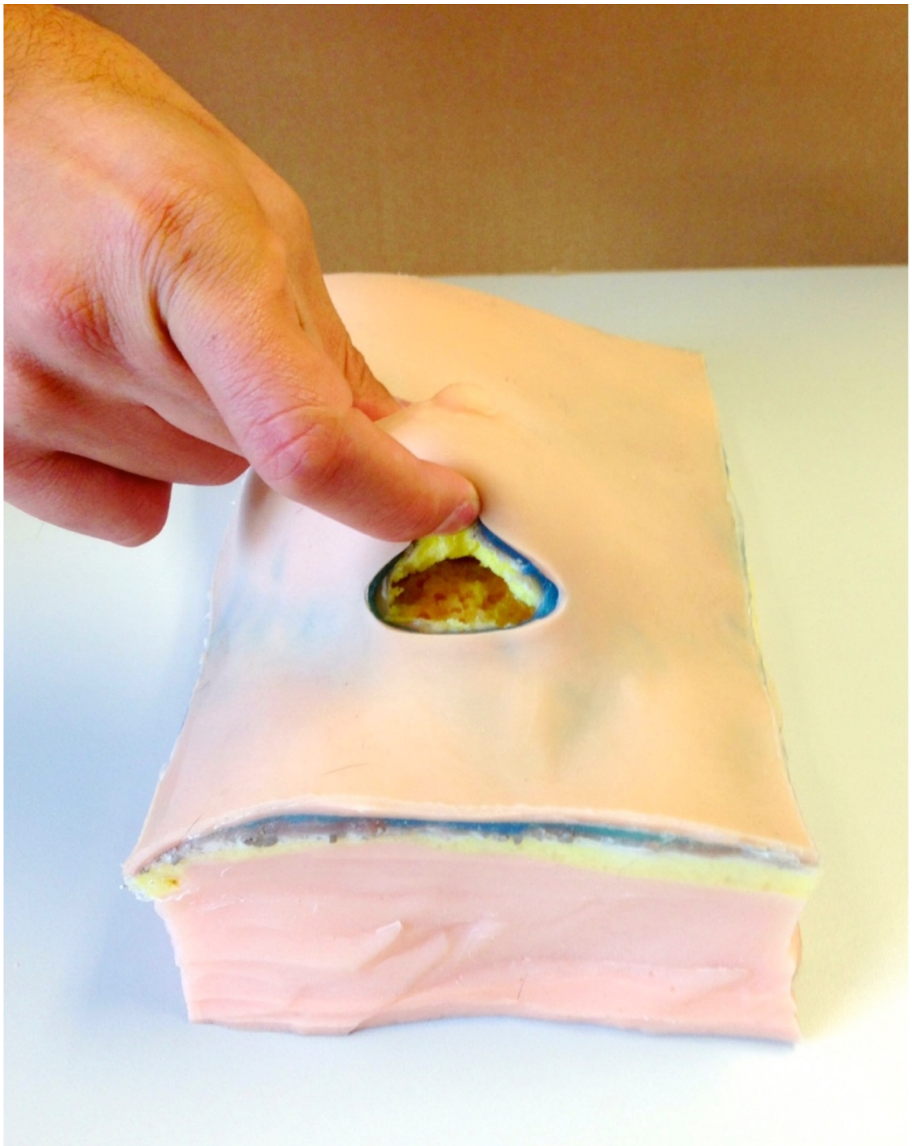

Figure 6 External appearance of the MPT, with its different layers viewed through the infra-mammary incision

Different anatomical layers were to be represented in the MPT: skin, subcutaneous fat, breast tissue and ribs (Figure 7). Each layer was composed of silicone, foam or rubber, modified in elasticity and density to provide the most realistic appearance, touch and tissue dissection resistance. Layers were dyed with the color that best mimics that of the represented tissue. The MPT includes eight different layers to represent the different tissue planes of the breast and torso.

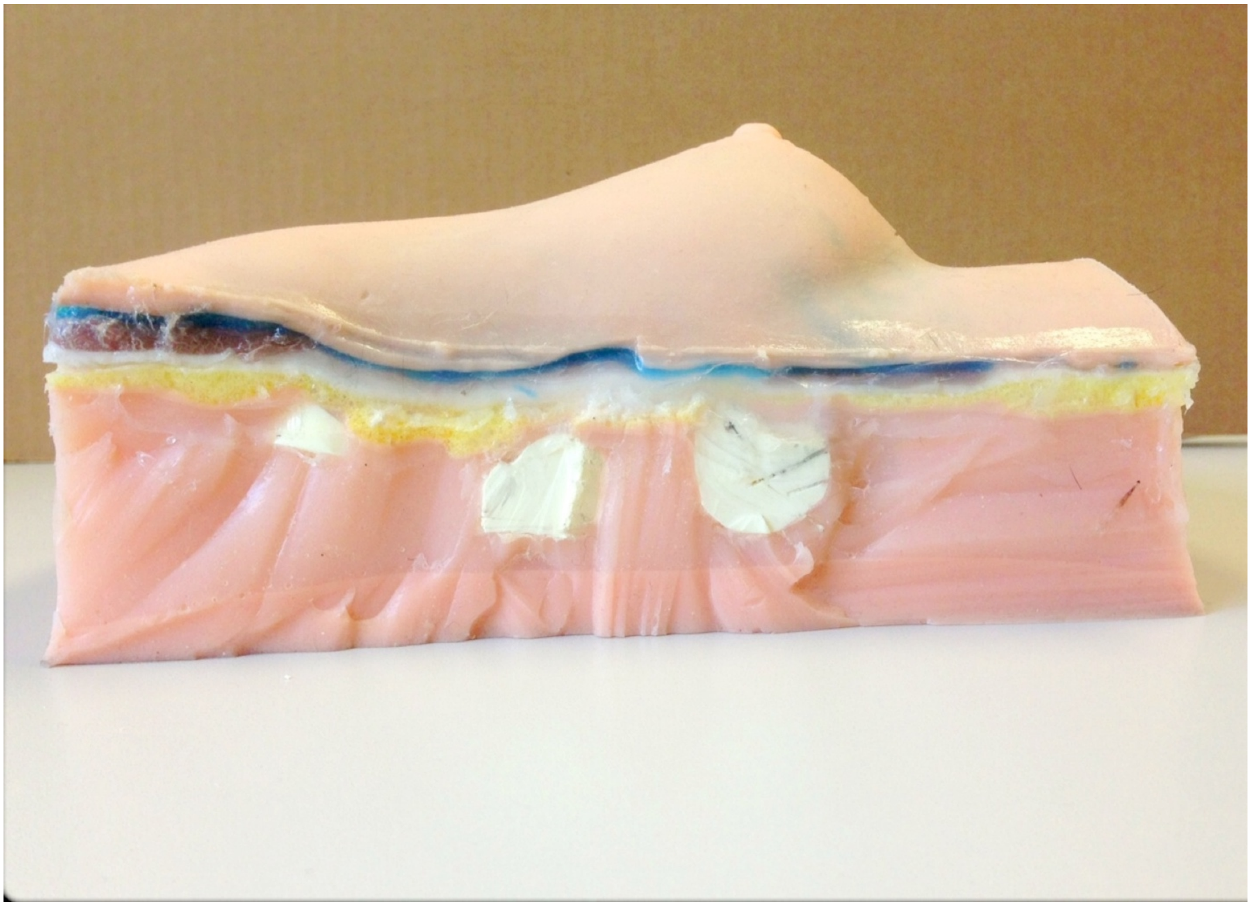

Figure 7 MPT side view: thoracic cage bones with different tissue layers

Testing the MPT

An experienced board-certified plastic surgeon and surgical educator tested the MPT's ability to simulate a breast augmentation procedure. An incision in the infra-mammary area was created with a scalpel down to simulated breast parenchyma, where dissection was continued bluntly into the subglandular plane to develop an appropriate pocket. A 90 cc textured silicone breast prosthesis (Allergan

Inc. Irvine, CA) was inserted manually with the surgeon's digits. The position of the implant was verified to ensure appropriate placement. The incision was then closed in layers, beginning with the breast parenchyma using 3-0 Vicryl® sutures (Ethicon, Inc. Cincinnati, OH)) followed by a running 4-0 monofilament subcuticular suture for the skin (Figure 8).

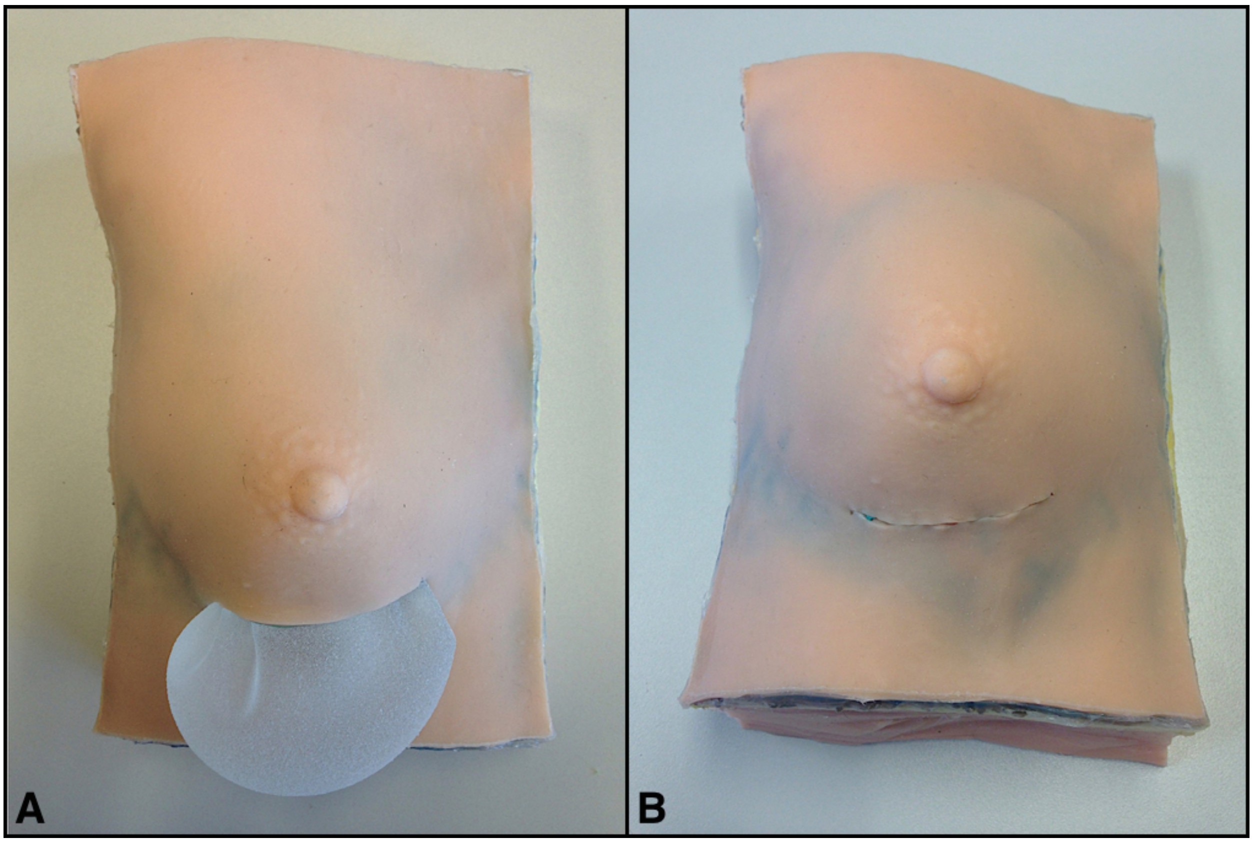

Figure 8 (A) MPT showing the silicone breast implant midway in the process of insertion; (B) final outcome after implant insertion and completion of suturing

Survey and rating procedure

A breast augmentation procedure was performed by four independent board-certified plastic surgeons not involved with this research. Each was then asked to complete an evaluation survey composed of 16 items under 7 domains, in addition to a free observation section where they could comment on attributes that the survey did not cover. The first domain described the ‘physical attributes’ of the MPT: chest circumference (unilateral), chest depth, intercostal space, landmark tactility, landmark visualisation and orientation of the breast (overall aspect). The second domain evaluated the ‘realism of material’ used to simulate the skin, subcutaneous tissue and rib cage. The third domain evaluated the ‘realism of experience’ of establishing a sub-mammary pocket for the implant and controlling proper implant positioning. Fourth domain described the ‘ability to perform tasks’ which included skin suturing and breast implant insertion. The final three domains evaluated the MPT as a training tool, its relevance to practice breast augmentation and a global assessment.

The ‘physical attributes’, ‘realism of materials’ and ‘realism of experience’ were evaluated according to the following Likert scale: 1=Not at all realistic, 2=Lacks too many features to be useful, 3=Don’t know, 4=Adequate realism, but could be improved and 5=Highly realistic, no changes needed. The ‘ability to perform tasks’ was scaled as follows: 1=Too difficult to perform, 2=Very difficult to perform, 3=Difficult to perform, 4=Somewhat easy to perform and 5=Very easy to perform. The ‘value’, ‘relevance to practice’ and ‘global assessment’ were scaled as follows: 1=No value, 2=Little value, 3=Don't know, 4=Some relevance and 5=Great deal of relevance.

Results

Observed averages

Four board-certified plastic surgeons evaluated the MPT on different aspects. The domains that scored the highest were the 'value' of the MPT as a training tool with a mean (range) value of 4.5 (4-5), the 'relevance to practice' breast augmentation with a score of 4.3 (4-5) and the 'physical attributes' with a score of 4.1 (3.8-4.5). The other domains scored 3.9 (3.5-4.3) for 'realism of experience, 3.8 (3.5-4) for 'ability to perform tasks' and 3.7 (3-4.3) for 'realism of material' (Table 1). In descending order, the items that scored above 4.0 were the 'physical attributes – chest circumference' and 'physical attributes – intercostal space' with 4.5 each, 'physical attributes – chest depth' and 'realism of – establishment of implant pouch' with a score of 4.3 each and finally, 'ability to perform tasks – skin suturing' with a score of 4.0.

Domain, item	*Rating (out of 5)*
Physical attributes (average= 4.1) (SD= 0.4)	
1. Chest circumference (unilateral)	4.5
2. Intercostal space	4.5
3. Chest depth	4.3
4. Landmark tactility (breast tactile experience)	3.8
5. Landmark visualization (visual aspect and shape)	3.8
6. Orientation of breast manikin: overall aspect	3.8
Realism of materials (average= 3.7) (SD=0.6)	
7. Rib cage	4.3
8. Skin	3.8
9. Subcutaneous tissue	3.0
Realism of experience (average= 3.9) (SD=0.5)	
10. Establishment of implant pouch	4.3
11. Control proper implant positioning	3.5
Ability to perform tasks (average= 3.8)(SD=0.4)	
12. Skin suturing	4.0
13. Insertion of breast implant	3.5
Value	
14. Value as a training tool	4.5
Relevance to practice	
15. Relevance to practice breast augmentation	4.3
Overall rating	
16. Global assessment	4.3

Table 1 Observed averages of each item and domain in the survey used to evaluate the breast MPT as a training tool

The observed average of the 'global assessment' scored 4.3 (4-5) out of a maximum of 5, which falls between the two scaling criteria of "having some relevance" (score of 4) and having "a great deal of relevance" (score of 5) as a task trainer. This indicates that the current task trainer could be considered a useful tool for teaching purposes, taking into account some improvements to be made.

Evaluators' comments

Evaluators commented on different aspects of the MPT that were not covered by the evaluation survey. Some of the skin characteristics were highly-scored such as the ability of a puncture site created by a needle to self-seal after suturing, the good shearing property allowing it to resist tearing forces and its elastic property that enables it to elongate without breaking (ex. upon retraction and/or implant insertion). Another feature that was highly-valued was the haptic feedback an operator gets upon implant insertion, which was similar to performing the surgery in the clinical setting.

On the other hand, evaluators believed that other features could be improved. One of which is the material used to simulate the subcutaneous tissue, where evaluators recommended replacing it with a material that better mimicked the breast parenchyma texture and that could resist tearing upon suturing. Another modification recommended by the evaluators was to represent bilateral breasts on the MPT to allow comparison of symmetry and size after performing the procedure bilaterally.

Material costs

The cost to assemble one MPT was approximated to $113 CAN dollars. Broken down by individual parts, the skin was $15, the subcutaneous and breast tissue were $20, the pectoralis major muscle was $8, the ribcage was $5 and the silicone base was around 65$.

Discussion

To the best of our knowledge, the model presented here is the first part-task trainer that is designed to simulate breast augmentation for the learner. Although in its preliminary stages, our study demonstrated that it would allow the trainee to simulate tissue dissection and pocket formation in the subglandular area, followed by implant insertion and tissue closure.

This early prototype part-task trainer achieved good overall evaluations by experts; in that respect, it is similar to other novel simulators, such as a recently presented simulator for thoracoscopic diaphragmatic hernia repair.[21] Evaluators favoured the utility of the MPT as a training tool for novices based on its ability to practice the essential steps of an augmentation mammoplasty. The physical attributes that received the highest scores were chest circumference and intercostal space, given that the thorax was created according to specific measurements of an average height and weight female. The evaluators also felt that the current MPT performed well in replicating the technique needed for implant insertion and that it generated a similar experience in terms of difficulty level and haptic feedback.

On the other hand, the weakest aspect of the MPT was the realism of materials used to represent the different structures included, especially the skin and the subcutaneous tissue. This could mainly be explained by the fact that our main focus was on the ability to perform the initial steps of a mammoplasty procedure and to regenerate the overall haptic feedback from implant insertion and pocket creation rather than the realism of the individual structures that constitute the MPT.

Improvements and limitations

At this level, the authors believe that the MPT represents a valuable early tool to practice a mammoplasty procedure, although many modifications should be made to deliver a higher level of realism. As a first improvement, it would be essential to represent bilateral breasts on the MPT allowing to practice bilaterally and enabling the assessment of symmetry at the end of the procedure. Another essential modification will be the incorporation of a pectoralis major muscle that can be elevated to simulate a subpectoral pocket. Other modifications, such as the addition of a complete rib cage with intercostal muscles, will allow for better training in areas of potential surgical dissection errors such as improper identification of the subpectoral plane and inadvertant pneumothorax. Perforating vessels are essential structures to be represented during a mammoplasty procedure but are difficult to simulate in a part-task trainer and will eliminate the option of reusability. The final simulator system will function as a hybrid virtual-reality environment consisting of a physical simulator, which serve as haptic feedback to the operator and a virtual-reality environment. It will simulate the occurrence of potential pitfalls such as the aforementioned perforating blood vessels and/or significant bleeding, anatomical variants or muscle plane issues.

Despite the need for improvement, the authors foresee that junior-level residents could use such a simulator until basic technical competence is demonstrated (based on predetermined skills or steps that have been identified to require assessment) allowing subsequent participation in the clinical setting. In addition to its use for residents in training, such MPT could also be used by experienced surgeons to explore new technologies or instruments such as a Keller Funnel™ (Keller Medical, Inc, Stuart, FL) prior to employing them on their own patients in the clinical setting.

While this MPT represents an important initial step in the development of essential surgical simulators for Plastic Surgery trainees, a number of aspects still require further investigation. With this pilot study, the investigators only evaluated the value of the MPT as a training tool and the realism of the materials and experience. Further studies are needed to explore evidence relevant to its effect on novices training through clinical testing, where a comparison of performance could be done between MPT trained and non-MPT trained residents while performing in the operating room on real patients.

In summary, the authors present a novel prototype surgical simulator for augmentation mammoplasty – the first of its type. Preliminary testing by expert plastic surgeons demonstrated excellent potential for its use as a training tool for residents. The current MPT will continue to be developed into a more sophisticated hybrid platform combining virtual imaging and realistic haptic feedback to meet the needs of an evolving competency-based curriculum for plastic surgery training.

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CHAPTER 4 – Article 2: Identification of New Tools to Predict Surgical Performance of Novices Using a Plastic Surgery Simulator

Identification of New Tools to Predict Surgical Performance of Novices using a Plastic Surgery Simulator

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Abstract

Objective: To identify new tools capable of predicting surgical performance of novices on an augmentation mammoplasty simulator. The pace of technical skills acquisition varies between residents and may necessitate more time than that allotted by residency training before reaching competence. Identifying applicants with superior innate technical abilities might shorten learning curves and the time to reach competence. The objective of this study is to identify new tools that could predict surgical performance of novices on a mammoplasty simulator.

Method: We recruited 14 medical students and recorded their performance in 2 skill-games: *Mikado* and *Perplexus Epic*, and in 2 video games: *Star War Racer* (Sony Playstation 3) and *Super Monkey Ball 2* (Nintendo Wii). Then, each participant performed an augmentation mammoplasty procedure on a Mammoplasty Part-task Trainer, which allows the simulation of the essential steps of the procedure.

Results: The average age of participants was 25.4 years. Correlation studies showed significant association between *Perplexus Epic*, *Star Wars Racer*, *Super Monkey Ball* scores and the modified OSATS score with $r_s=0.85$ ($p<.001$), $r_s=-0.6941$ ($P=.005$) and $r_s=0.7309$ ($P<.003$), but not with the *Mikado* score $r_s=-0.0255$ ($P=.9$). Linear regressions were strongest for Perplexus Epic and Super Monkey Ball scores with coefficients of determination of 0.59 and 0.55, respectively. A combined score (Perplexus/Super-Monkey-Ball) was computed and showed a significant correlation with the modified OSATS score having an $r_s=0.8107$ ($P<.001$) and $R^2=0.75$, respectively.

Conclusions: This study identified a combination of skills games that correlated to better performance of novices on a surgical simulator. With refinement, such tools could serve to help screen plastic surgery applicants and identify those with higher surgical performance predictors.

Keywords

Surgical Skills, Simulation, Residents selection, Skill-games, Video Games, Plastic Surgery

Introduction

As surgical educators, we are faced with the daily challenges of imparting not only surgical judgment but also technical knowledge and skills. The acquisition of technical skills is a crucial step in the progression of surgical trainees through residency. It is well accepted that individual trainees acquire surgical skills at varying paces, which in some cases might require more time than that allotted by the current training period. In fact, it has been shown that 5% to 10% of trainees fail to reach competence by the time of graduation[15]. This difference in rate of skills acquisition has long been thought to have an innate genetic origin although no specific genes have been associated to this progression. Efforts have been invested in identifying predictor tests that could eventually forecast the rate of skills acquisition of novices[16,17]. Thus, it comes as no surprise that surgical program directors, charged with selecting the best candidates from the applicant pool, are interested in identifying applicants with genetic and innate predisposition for better hand dexterity and psychomotor skills. Unfortunately, the latter is a complex interplay of a variety of innate abilities such as hand-eye coordination, precision of movements, decision-making and rapid processing of visual information.

Identifying learners with a predisposition for faster learning curves for technical skills can benefit many parties: the trainee, patients, and educational and health care systems. It is well established that resident training in the operating room (OR) can be expensive as it prolongs length of surgery[18,19]. Though various costs exist, an average operating room charge has been estimated at $61/min[20]. Being able to identify trainees with excellent technical aptitude may lead to improved use of resources by reaching competence faster. In addition to the potential to decrease the costs of resident training in the OR, the ability to identify "fast technical learners" would liberate more time for trainees to focus on other skill sets such as patient management, knowledge enhancement and the development of surgical judgment.

Current selection criteria for residency training in North America are mainly based on academic performance, medical licensing exam scores, letters of recommendation, curriculum vitae and applicant interviews. Unlike the Canadian Dental Association that uses the Manual Dexterity Test to evaluate applicants' technical aptitude[21], surgical specialties have not yet implemented such assessment tools. On the other hand, the Royal College of Surgeons in Ireland has adopted a pre-selection testing of candidates' technical skills and fundamental abilities (psychomotor skills, visuospatial ability and depth perception), for which results are then supplied to residency interview committees to be used in the selection process[22]. Many studies have looked into the relationship between fine motor dexterity skills and surgical performance on simulators in the goal of finding tools that could predict psychomotor skills. Van Herzeel et al.[23] found an association between innate dexterity skills (measured using a fine motor dexterity test called the Perdue Pegboard) and performance on an endovascular Virtual-Reality simulator. Other studies[24,25] have looked into the effect of video game training on the improvement of residents' laparoscopic skills. To our knowledge, no study has assessed the relationship between innate hand dexterity and surgical skills in the Plastic Surgery setting. The purpose of this study was to test this association, and furthermore to gauge the ability of skill- and video games to predict novices' surgical performance on a Plastic Surgery-specific breast augmentation simulator (the Mammoplasty Part-task Trainer).

Methods

This study was conducted at the Steinberg Centre for Simulation and Interactive Learning at the McGill University Health Center. Fourteen medical students enrolled at McGill University participated in this study. After describing the purpose and the steps of the study, informed consents were signed. Demographic data, surgical experience and previous video and skill-games experience were collected. The study consisted of three parts: skill-games, video games and a breast augmentation simulator (mammoplasty part-task trainer (MPT)). The order in which these parts were completed was uniform across all participants.

Skill-games

Two skill-games were chosen for this part of the study: *Mikado*, a pick-up sticks game and *Perplexus Epic*, a 3 dimensional (3D) labyrinth game. The rationale behind choosing each of the skill-games was based on the level of technical skills each demands to achieve a good performance: hand dexterity, fine movement and hand eye-coordination. For Mikado, a pile of 41 sticks was bundled and held on a flat table surface, then released, creating a circular jumble of sticks. The participant was asked to pick up one stick after another without moving any of the remaining. This action could be done using both hands, through pressing on a stick's tip or simply picking it up with fingers, or using a previously picked stick to lift up another. The trial was complete when one of the sticks was unintentionally moved. Each participant had 10 trials in which time and score were recorded for each. The final score was based on the number of sticks picked in each trial rather than the color pattern of each stick, which normally represent a different scoring system.

Perplexus Epic was the second skill-game used. It is a 3D labyrinth game enclosed in a transparent plastic sphere, in which participants maneuver a steel ball through a 125 checkpoints track. This was done through gently tilting the sphere left, right, back and forth and occasionally giving light taps on the sphere to slowly move the ball past obstacles. A trial was complete whenever the steel ball fell off the track. Each participant had 10 trials where time and highest checkpoint number reached were recorded.

Video games

Star Wars Racer (Sony Playstation 3) and *Super Monkey Ball 2: Banana Blitz* (Nintendo Wii) were chosen for this part of the study. Both video games have previously been validated by other studies to be effective tools to enhance technical and laparoscopic skills of participants[26-30]. Both games were connected to a projector and were projected on a white screen. *Star Wars Racer* is a racing game operated on a PlayStation 3 (PS3) console using a traditional PS3 joystick. It was played in training mode where no competing vehicles were present on track and using the same racing spaceship and circuit for all participants. Controllers of the spaceship were an analog stick for right and left steering and two buttons for acceleration and braking. Each participant completed 5 laps where time for each was recorded.

Under “Party Games” mode, “Racing Birds” was chosen from the *Super Monkey Ball 2: Banana Blitz* video game. This game was played on a Nintendo Wii console using a Wii remote controller connected to a Nunchuck. The purpose of this game was to fly a bird through a 3D track while collecting floating rings. As the bird advances through the track, the size of the rings becomes smaller and the score attributed to each becomes higher. The track ends when the bird reaches the finish line or when a 3 minutes countdown is completed. The operator controls the bird by holding the Wii remote controller in one hand and the Nunchuk in the other and by tilting the controller up and down, left and right to direct the bird through space and rapidly shake the controllers simultaneously up and down to advance forward faster. Each participant completed 5 trials and a total score (a function of the number of circles collected and the time to complete each trial) was registered at the end of each.

Mammoplasty Part-task Trainer (MPT)

Participants were required to perform a breast augmentation procedure on a part-task trainer developed and validated by our laboratory as a junior-level training and assessment tool in a previous study[31]. The MPT represents a unilateral breast made out of silicone, foam and rubber materials using molding and casting techniques. Relevant anatomical structures were represented such as skin, subcutaneous tissue, nipple-areolar complex, mammary tissue and ribs (Figure 9). This allows the simulation of the essential steps of a mammoplasty procedure. These steps comprise: skin incision, subcutaneous dissection, formation of a submammary pocket using blunt dissection, insertion of a silicone gel breast implant using a digital insertion technique and incision closure. Before performing the procedure, all participants were shown a 2-minute instructional video. The latter describes in a step-by-step manner the surgical steps to be simulated on the MPT. While performing the procedure, a video recording of the surgical field was taken to allow for future evaluation of performance by an expert.

Figure 9 The mammoplasty part-task trainer showing an inframammary incision and a textured implant in the process of insertion to the pocket

After study completion, expert evaluation was completed to assess the performance of participants using a surgery-specific questionnaire and the modified Objective Structured Assessment of Technical Skills (OSATS).

Assessment scales

The modified OSATS was based on the validated OSATS score described by Reznick et al.[32]. This assessment tool evaluates surgical performance by grading overall technical proficiency for open surgery, using established anchors for each of the following assessment domains: respect of tissue, time and motion, instrument handling, flow of operation and knowledge of specific procedure (Table 2). Each domain is scored from 1 to 5, which leads to a score range of 5 – 25. The surgery-specific questionnaire was developed by our team evaluating the essential steps of an augmentation mammoplasty procedure that could be reproduced on the MPT using a Likert scale (1-Poor, 2-Fair, 3-Average, 4-Good, 5-Excellent). This scale included the following domains: timeliness, incision/dissection technique, implant insertion technique, suturing technique, participant confidence, evaluation of surgical outcome, and a global assessment. The score range of this scale is 5 – 35.

Respect for tissue:				
1	2	3	4	5
Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments		Careful handling of tissue but occasionally caused inadvertent damage		Consistently handled tissue appropriately with minimal damage
Time and Motion:				
1	2	3	4	5
Many unnecessary moves		Efficient time/motion but some unnecessary moves		Clear economy of movements and no awkwardness
Instrument handling:				
1	2	3	4	5
Repeatedly makes tentative or awkward moves with instruments		Competent use of instruments but occasionally appeared stiff ow awkward		Fluid moves with instruments and no awkwardness
Flow of Operation:				
1	2	3	4	5
Frequently stopped operating and seemed unsure of next move		Demonstrated some forward planning with reasonable progression of procedure		Obviously planned course of operation with effortless flow from one move to the next
Knowledge of specific procedure:				
1	2	3	4	5
Deficient knowledge. Needed specific instruction at most steps		Knew all important steps of operation		Demonstrated familiarity with all aspects of operation

Table 2 The modified OSATS score.

Statistical Analysis and definitions

Statistical analysis was performed using JMP 11.0.0 (SAS Institute Inc.). Correlation tests between games scores and surgical skills scores (modified OSATS scores and surgery-specific scores) were performed using Spearman's correlation test. Spearman's correlation coefficient, indicating the strength of the monotonic relationship of tested variables, was presented as r_s. Linear regression was used to find the best fit for the studied variables. The coefficient of determination is denoted as R^2. Data is presented as Mean (Standard deviation). A value of $p<0.05$ was considered significant.

The 'Mikado score' was defined as the total number of sticks picked by each participant in the 10 trials; the 'Perplexus score' as the total number of checkpoints reached in each of the 10 trials. The 'Star Wars Racer score' was defined as the total time needed to complete the 5 laps (in seconds); the 'Super Monkey Ball score' as the sum of the total score reached in each of the 5 trials.

Results

Participants

All participants completed all steps of the study; 3 missing data points resulted from the one-week post-participation self-evaluation. The average age of the fourteen participants was 25.4 (20-31) years and the male to female ratio was 9:5. Participants were all medical students enrolled at McGill University, of which 6 (43%) were in 1st year, 3 (21%) in 2nd year, 4 (29%) in 3rd year and 1 (7%) in 4th year. Participants were selected randomly following an email invitation sent to all medical students without taking into account their future residency training interest. None of the participants had played any of the skill-games or videogames in the last 5 years. The mean scores obtained by all participants for the modified OSATS score was 2.7 (0.6) and the surgery-specific score was 2.6 (0.9).

Skill-games and surgical skills

The mean ‘Mikado score’ was 65.9 (17.4) sticks (Table 3). Spearman’s correlation test showed no significant correlation between ‘Mikado score’ and either the modified OSATS score (r_s= -0.03, p= .9) or the surgery-specific score (r_s=-0.07, p= .8). The linear regression in relation to the modified OSATS score had a coefficient of determination of R^2= 0.0112 and to the surgery-specific score a R^2= 0.0146.

		Modified OSATS score		Surgery-specific score	
	Mean (SD)	**r_s**	**p-value**	**r_s**	**p-value**
Mikado score	65.9 (17.4)	-0.02	0.931	-0.06	0.8234
Perplexus Epic score	57.7 (25)	0.85	0.0001*	0.52	0.1369
Star Wars Racer score	311.5 (60.5)	-0.69	0.0059 *	-0.35	0.2251
Super Monkey Ball score	42351.5 (15642.7)	0.73	0.003 *	0.32	0.2571
Combined score	111.9 (38.6)	0.81	0.0004*	0.41	0.1413

Table 3 Mean scores of each game used in this study and the Spearman correlation analysis between each of the games and the modified OSATS and surgery-specific scores.

The mean ‘Perplexus score’ was 57.7 (25) checkpoints. A significant correlation was found with the modified OSATS score (r_s=0.85, p< .001) but not the surgery-specific score (r_s=0.42, p= .1). The linear regression in relation to the modified OSATS score is illustrated in Figure 10, showing a coefficient of determination of R^2=0.58. The coefficient of determination to the surgery-specific score was R^2=0.37.

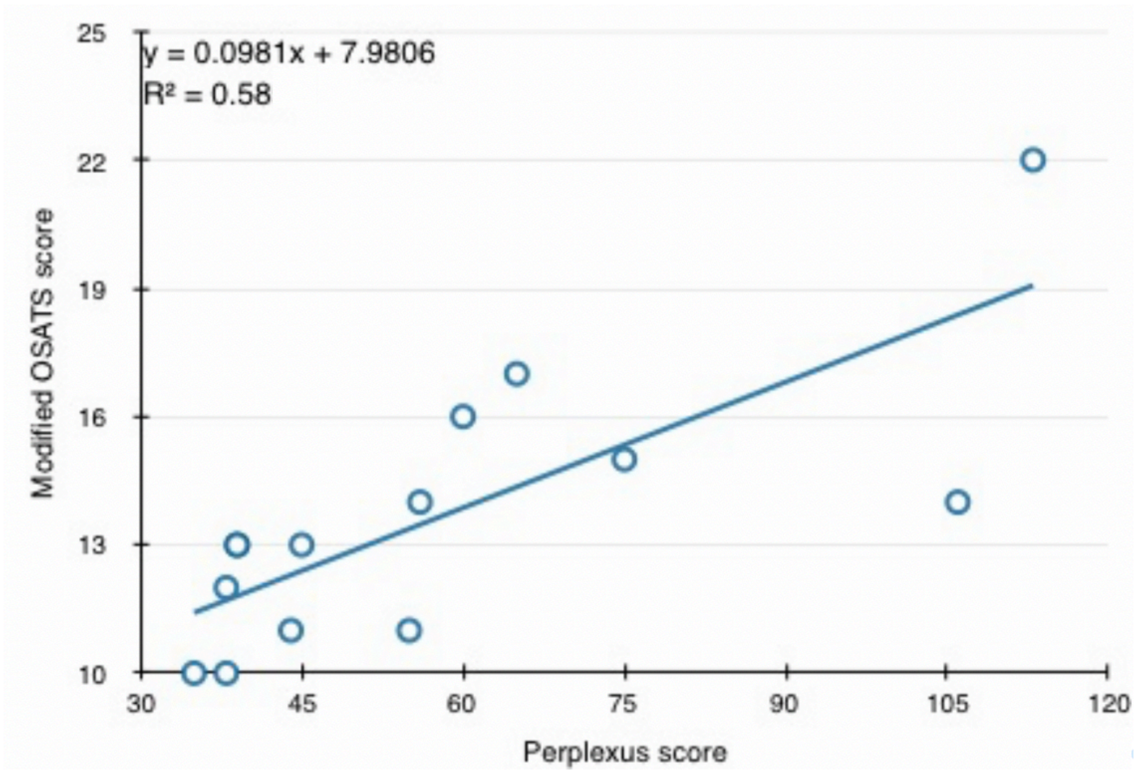

Figure 10 Graph showing the relationship between Perplexus score and the modified OSATS score with the best-fit linear regression and the coefficient of determination (R2).

Video games and surgical skills

The mean 'Star Wars Racer score' was 311.5 (60.5) sec. This score had a significant correlation with the modified OSATS score (r_s=-0.69, p=.005) but not with the surgery-specific score (r_s=-0.35, p= .2). The linear regression of the 'Star Wars Racer score' in relation to the modified OSATS score had a coefficient of determination of R^2=0.14 and R^2=0.11 to the surgery-specific score.

The mean 'Super Monkey Ball score' was 42351.5 (15642.7). A significant correlation was found with the modified OSATS score (r_s=0.73, p<.003) but not the surgery-specific score (r_s=0.32, p= .2). The coefficient of determination in relation to the modified OSATS score was R^2= 0.5497 (Figure 11) and R^2=0.24 to the surgery-specific score.

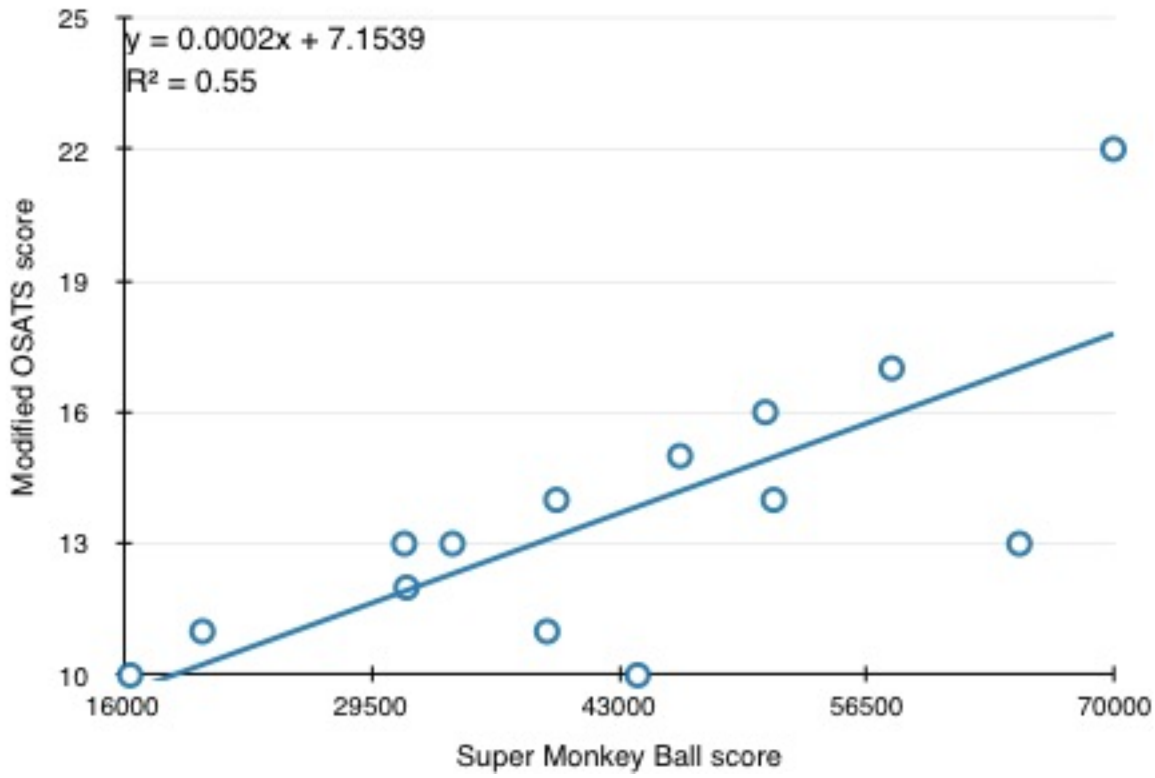

Figure 11 Graph showing the relationship between Super Monkey Ball score and the modified OSATS score with the best-fit linear regression its coefficient of determination (R2).

Combined score and surgical skills

A 'combined score' was calculated taking into account the Perplexus and the Super Monkey Ball scores for each participant. The score of both games was standardized on a total score of 100, then added together for a total score of 200. The mean value of the 'combined score' was 111.9 (38.6). A strong correlation was found between the 'combined score' and the modified OSATS score (r_s=0.81, p<.001) but not with the surgery-specific score (r_s=0.41, p=0.1). The coefficient of determination of the 'Combined score' in relation to the modified OSATS score was R^2= 0.75 (Figure 12), and R^2=0.4 to the surgery-specific score.

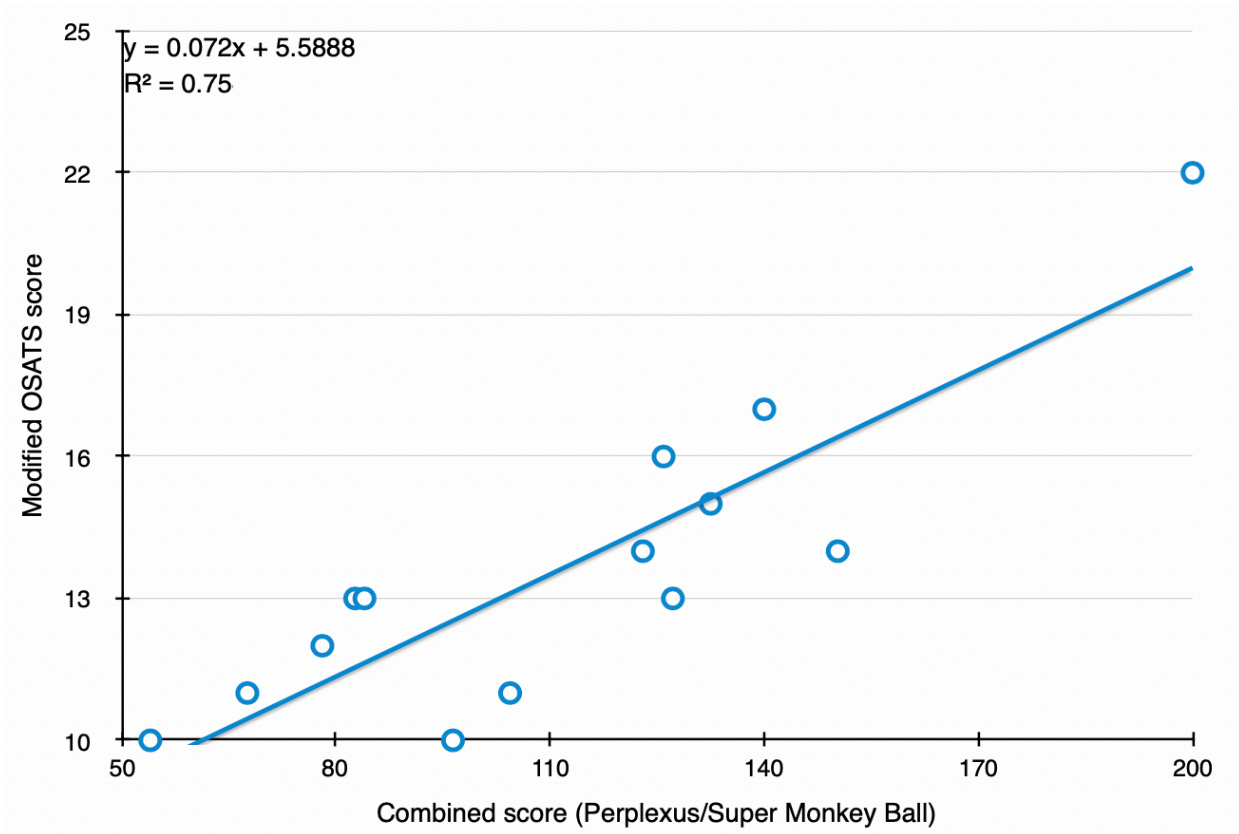

Figure 12 Graph showing the relationship between the combined score (Perplexus/Super Monkey Ball) and the modified OSATS score with the best-fit linear regression its coefficient of determination (R2).

When the relationship between the modified OSATS and the surgery-specific scores were analyzed, a significant correlation was found between both scores, with an r_s=0.59 and a p-value = 0.02. The coefficient of determination of the linear regression analysis was R^2= 0.64.

Discussion

The results of this study show that a relationship exists between novices' performance in games requiring hand dexterity and hand-eye coordination skills and surgical performance on a plastic surgery breast augmentation simulator. Correlation tests were shown to be significant between eash of Perplexus Epic, Star Wars Racer and Super Monkey Ball scores with the modified

OSATS score with p-values below 0.05. Predictive values of the aforementioned games have shown to be quite strong for Perplexus Epic and Super Monkey Ball scores with coefficients of determination of 0.59 and 0.55, respectively, and low for Star Wars Racer score with a coefficient of determination of 0.14.

The correlational relationship was not established between Mikado skill-game and the modified OSATS score. The reason behind these results may lie in the fact that Mikado lacks standardization in difficulty level between trials, as sticks pile up randomly when released on the surface, despite requiring hand steadiness and fine motor skills. The Star Wars Racer game used simple controllers to complete the task, which was enough to detect a correlation with the modified OSATS score but not to predict surgical performance of participants (low coefficient of determination). On the other hand, Perplexus Epic and Super Monkey Ball 2 games were characterized by their standardization in difficulty levels between trials and the complexity of hand-eye coordination level needed to accomplish the required tasks. Performance of participants in the aforementioned games was shown to have a 'strong' correlation (Spearman's correlation coefficient between 0.84 and 0.73) with their performance score on the mammoplasty simulator, when assessed using a well-validated objective assessment tool, the OSATS score. In addition, the linear regression coefficient of determination of these games and the modified OSATS score showed a relatively satisfying linear relation between both variables of around 0.6.

Interestingly, the 'combined score', which was calculated based on Perplexus Epic and Super Monkey Ball scores, yielded an even stronger correlation and a better linear fit with the modified OSATS score, having a r_s=0.81 and R^2=0.75. The interpretation of the linear regression infers that 75% of the variation in the modified OSATS score is determined by the linear relationship between the modified OSATS score and the 'combined score'. On the other hand, surgery-specific score did not correlate or found to have a strong linear fit with any of the game scores, possibly indicating that the latter could not be a good predictor of participants' performance when evaluating surgical steps as subunits. It seems counter-intuitive that a surgery-specific questionnaire tailored for a simulator-specific procedure would not correlate with participants' performance on video and skill games. In fact, when the process of scores attribution is closely examined, the lack of anchoring criteria used to attribute scores for each task seemed to allow for more subjectivity in assigning a score for each subunit of the surgery-specific questionnaire, thus lowering its consistency in the assessment process. In addition, OSATS score is an evaluator of global performance that could be applied to assess any open surgical procedure. Hence, evaluating the overall performance rather than surgery-specific steps is more valuable to predict surgical performance of a candidate as surgical steps vary widely from a type of surgery to another, consequently the skills required to complete each.

To our knowledge, the use of skill games in predicting novices' performance have not been previously studied in literature, unlike the use of video games, which has been considered to be associated with innate technical skill. In a study looking at the relationship between performance on video games and laparoscopic skills, Resenberg et al.[33] found that video game aptitude can predict the level of laparoscopic skills of medical students. As well, Badurdeen et al.[34] demonstrated a strong correlation ($R^2=0.72$, $p<0.001$) between performance on Nintendo Wii and a box-design laparoscopic trainer, which lead to the conclusion that surgical candidates with better performance on Wii possess higher baseline ability for laparoscopic skills. The interest of studying the relationship between video games and laparoscopic performance resulted from the principle resemblance of using controllers in three-dimensions to affect changes on a two-dimensional image. Though this principle may not apply for open surgeries, nonetheless it has the potential of depicting differences in visuo-spatial perception, hand-eye coordination and hand dexterity of novices, which is also essential for most surgical procedures.

In a recent systemic review, Louridas et al.[35] studied tools found in literature that were used as potential predictors for technical skills of surgical trainees. They came to the conclusion that none of the reported tools was shown to be a reliable predictor. In fact, most of the studied tools rely on the repetition of the same act done by the operator, measuring the time to complete the task as the performance outcome. Purdue Pegboard[36-40], Grooved Pegboard[40-43] and Crawfard Small Parts Dexterity Test[36,44-46] are the most widely tested tools in literature, all requiring the operator to transfer shaped pegs, pins or screws into the designated holes on a board as fast as possible. The speed of task repetition reflects only one component that defines technical performance, which is likely a result of complex intertwined innate abilities such as the hand-eye coordination, precision of movements, decision-making and visual information processing speed. In other words, tools should necessitate the interplay of multiple innate abilities to perform the required task in order to accurately reflect participant's technical performance.

The tools identified by our study as potential predictors of surgical performance require an interplay between different innate abilities to complete the task. As such, Perplexus Epic necessitates hand-eye coordination, precision of movements and decision making to achieve each checkpoint; the Super Monkey Ball 2 game requires hand-eye coordination, decision making and rapid visual information processing to fly the bird to the end line while collecting the most circles. Furthermore, the utilization of a battery of individual surrogate tools yields an even more sophisticated approach to predict performance, as it narrows down the effect of previously acquired skills as confounders of innate abilities. This technique was used in many studies and was shown to accurately predict performance when combining several test scores. For instance, the Basic Performance Resources (BPR), initially described by Kondraske[47], was used to assess performance on a virtual ureteroscopy simulator[48,49] and on a laparoscopic simulator[50]. It consisted of 8 measurements evaluating mainly the short-term memory, visual information processing speed and different aspects of hand strength and dexterity.

We believe that residents' selection committees should implement technical skills and fundamental abilities testing as part of their decision making. Such tools we presented in this paper could potentially be useful for this matter as they are simple, challenging and non-time consuming. The value of using such tools is the selection process instead of the simulator itself is that they're easy to obtain and can be reused indefinitely and rapidly between participants. In addition, scores can be attributed instantaneously to applicants when using skill and video games rather than needing an expert to evaluate the performance. Also, the simulator is plastic surgery-specific and would not be relevant to be used for other surgical specialties selection process. Some limitations to this study certainly exist. The breast augmentation simulator has not been tested for predicting real-world performance, but the fact that the procedure implies performing basic common tasks, such as skin incision and suturing, could be related to other validated skin incision and suturing simulators. In addition, the fact that student's performance on the simulator is not basic, meaning that it requires some basic knowledge of the procedure could constitute another limitation to this study. The latter is theoretically addressed by the instructional video shown before participants perform the procedure.

Conclusion

In conclusion, we identified skill- and video games that were predictive of medical students' (novices) performance on a plastic surgery breast augmentation simulator. As well, a combination of these scores was shown to more accurately predict surgical skills of medical students. More studies should be undertaken to establish stronger evidence, using a larger sample size and allowing more trials to establish learning curves. Such tools will likely be a valuable tool to add to the traditional methods of plastic surgery applicant selection, and will become increasingly important as our curriculum moves towards a competency-based paradigm.

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CHAPTER 5 – Article 3: The Montreal Augmentation Mammoplasty Operation (MAMO) Simulator: An Alternative Method to Train and Assess Competence in Breast Augmentation Procedures

The Montreal Augmentation Mammoplasty Operation (MAMO) Simulator: An Alternative Method to Train And Assess Competence In Breast Augmentation Procedures

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Abstract

Background: The exposure of surgical residents to augmentation mammoplasty procedures remains limited in the academic centre, since many of these procedures are performed in private practice for aesthetic purposes. The development of the Montreal Augmentation Mammoplasty Operation (MAMO) simulator aims to provide an alternative training method and assessment tool, which would serve very useful in a competency-based education program. The purpose of this study is to perform face, content and construct validations of the MAMO simulator for subpectoral breast augmentation procedures and assess the reliability of the assessment scales used.

Methods: This study design was a prospective blinded observational study. The MAMO simulator represents the external features of a female chest and incorporates the essential anatomical structures relevant to augmentation mammoplasty. Plastic surgeons, both staff and residents, were recruited to perform a mammoplasty procedure on the simulator. Following an instructional video, participants completed the essential steps of the procedure and their performance was filmed. The expert surgeon participants evaluated the simulator's various parameters and their overall experience. Video recordings of all participants' performances were blindly reviewed and assessed using the Objective Structured Assessment of Technical Skills (OSATS) system: Global Rating Scale (GRS) score, Mammoplasty Objective Assessment Tool (MOAT) score and a Checklist score. Data was recorded as mean (SD).

Results: Twenty-one participants were enrolled in this study: 14 plastic surgery residents and 7 expert plastic surgeons. Expert plastic surgeons' performances were significantly higher than residents' according to each of GRS, MOAT and Checklist scores. Mean values of residents and experts were 23.4 (2.5) vs 36.9 (3.1) ($p<0.0001$) for GRS score, 30.4 (2.2) vs 40 (3.2) ($p<0.0001$) for MOAT scores and 9.7 (1.5) vs 12 (1) ($p<0.001$) for Checklist scores respectively. Face and

content validations results showed excellent results among parameters evaluated, with an overall mean score of 4.8 (0.3) on 5. Cronbach's alpha was 0.96 and 0.83 for GRS and MOAT scores respectively. Intraclass Correlation Coefficients for interrater reliability were excellent at 0.93, 0.92 and 0.89 for the total GRS, MOAT and Checklist scores respectively.

Conclusion: This study proves the construct simulator to be valid and the assessment scales to be reliable. It establishes the MAMO simulator system as the first Plastic Surgery-specific tool capable of consistently measuring residents' performance and attributing competence in subpectoral mammoplasty procedures.

Introduction

While simulation training has become a fundamental tool for novices' formation, plastic surgery is still lacking compared to other specialties in terms of efficacy and quality of specialty-specific simulators1. Moreover, in the movement towards competency-based medical education, demand for simulators to serve as objective assessment tools has grown substantially, as validated metric tools are needed to gauge residents' aptitude in the new accreditation system.

Following a literature and resident case log database review2-5, breast augmentation was shown to be a procedure where residents notably lack exposure during training, despite being the most commonly performed aesthetic surgery6. This surgery is almost exclusively performed in the private practice setting, relying on direct payment from the patient. These factors, along with the fact that aesthetic outcome is the primary goal, tend to make most patients reluctant to have residents involved in the surgery7. Therefore, a non-human model capable of replicating the essential steps of such a procedure is in great need, fulfilling a dual goal of alternative training and assessment tool.

To date, no such model is available for breast augmentation procedures. Preliminary work done by our team led to the development of an early prototype, replicating a unilateral breast lacking muscles representation. The current study describes the development, validation and applications of the Montreal Augmentation Mammoplasty Operation (MAMO) simulator. The validation process aims to demonstrate that the assessment tool truly measures what it intends to. Three main types of validation apply to simulators: face, content and construct. In the context of technical skills assessment, face and content validations represent a measurement of how close the construct characteristics and the task practicality resemble “real-life” experience. Construct validation aims to determine whether a simulator significantly discriminates between different skill levels of users and is therefore the most important type of validity. The latter requires statistical analysis to be achieved, whereas face and content validations are solely achieved by experts’ consensus.

The purpose of this study was to conduct a face, content and construct validation of the MAMO simulator and to establish an alternative validated tool to evaluate residents’ performance. In addition, internal consistency and interrater reliability of scales will also be tested to assess reliability.

Methods

Development of the MAMO simulator

Following the development of a preliminary part-task trainer prototype8, a subpectoral breast augmentation benchtop simulator was constructed in our laboratory. Essential anatomical structures were represented and aggregated together into a compact portable simulator capable of replicating the essential steps of the procedure. The simulator encompasses the following structures: skin, nipple/areolar complex, mammary tissue, subcutaneous tissue, pectoralis major muscles, pectoralis minor muscles, intercostal muscles, periosteum and a complete rib cage (Figure 13). As well, a pneumothorax indicator was incorporated. This was achieved via molding and casting techniques and the use of a panoply of urethane- and platinum-based silicone, meticulously chosen to best mimic texture and color of each anatomical structure.

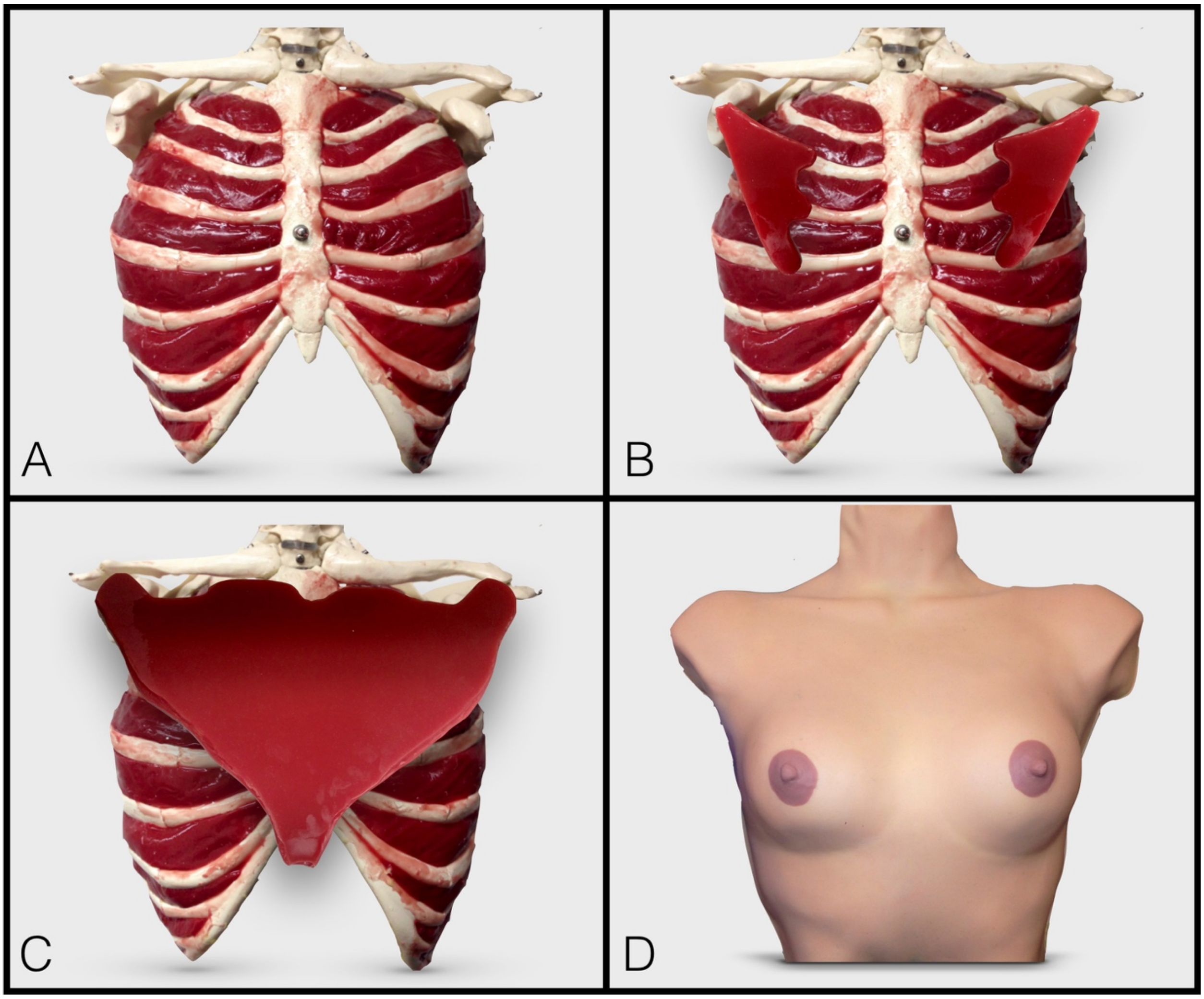

Figure 13 MAMO simulator components: (A) complete rib cage, intercostal muscles and periosteum (B) pectoralis minor muscles (C) pectoralis major muscle (D) skin, subcutaneous and mammary tissue, nipple-areolar complexes.

Reusability

For a simulator to be cost effective, maximum reusability should be achieved (Figure 14). Reusability of the skin incision step was attained by concealing an existent incision with a strip of skin. This allows completion of the markings and determination of incision location, as well as performing an incision on the skin strip. Subcutaneous dissection is the one step that contains a part that is not reusable. A rectangular foam piece, mimicking the subcutaneous layer is placed at the level of the existing incision location. This is discarded after each use. Lastly, subpectoral dissection reusability was achieved by introducing Velcro material between the pectoralis major muscle and the rib cage. Using a long tip electrocautery device, Velcro loops are released mechanically.

Figure 14 The three steps of the surgery that necessitated overcoming issues of reusability (A) the use of a skin strip to cover an existing IMF incision (B) interchangeable subcutaneous rectangles representing subcutaneous tissue (C) the use of Velcro material b

Procedure description

As mammoplasty practice varies widely between experts, a panel of plastic surgeons reached a consensus on the necessary surgical steps that should be performed on the simulator, based on a previously established list of the procedure's essential steps4 (Table 4). Thereby, participants will start with fundamental markings on the mannequin, identifying the chest midline, the 'no go' zone (1.5cm from each side), the existing Infra Mammary Fold (IMF) and the new IMF based on a 300cc round implant. Pocket dimensions should also be marked on the skin, as well as identifying incision location and length. This is followed by breast tissue infiltration with local anesthetic and placement of the nipple shield. Participants then proceed to skin incision and subcutaneous dissection. After correct plane identification, participants should start pocket dissection using a long tip cautery device following pre-operative markings. New IMF fixation should be performed by suturing rib's periosteum to adjacent subcutaneous tissue at the optimum level, followed by subcutaneous and skin closure and finally, application of appropriate dressing (Figure 15).

Surgical steps	**Detailed description**
1. Preoperative markings	Start by identifying the supratrochlear notch and draw the midline line, then delineate the "no go" zone of 1.5 cm around it. Mark the existing and the new IMF, 7.5 cm from the nipple, then the superior and lateral dissection borders based on implant base dimensions. A 5-cm incision should be located on the new IMF starting at the level of areolar medial border.
2. Application of nipple shield	Nipple shield should be placed at the beginning of the surgery to prevent implant contamination with nipple bacterial flora.
3. Infiltration of mammary tissue with local anesthetics	Mammary tissue should be infiltrated to minimize bleeding during surgery. A pneumothorax indicator is in place to detect any breach of plane.
4. Inframammary incision	Incision should be performed on the skin strip then proceed through the existing incision underneath.
5. Subcutaneous dissection	Using a cautery pen, subcutaneous dissection should be performed until reaching the pectoralis major muscle plane.
6. Subpectoral pocket dissection	The subpectoral plane should be identified and dissected by elevating the pectoralis major muscle from the rib cage. This step necessitates the use of a long tip cautery device as well as a light-mounted retractor. Dissection should be limited to the preoperative markings.
7. Implant insertion into the pocket	Before handling the implant, the participant should ask the assistant for a new pair of gloves and to soak the implant and irrigate the pocket with a triple antibiotic solution. Then using the no-touch technique, participant should proceed with implant insertion, minimizing its contact with the skin.
8. New inframammary fold fixation	When the implant is in place and secured, participant should proceed to the fixation of the new IMF by suturing ribs' periosteum to the adjacent subcutaneous tissue.
9. Subcutaneous suturing	Simple interrupted sutures should be placed to close the subcutaneous tissue.
10. Skin suturing	Running subcuticular suturing should be used to close the dermis, then apply the adequate dressing.

Table 4 Detailed description of the essential steps of a subpectoral augmentation mammoplasty procedure to be performed on the MAMO simulator.

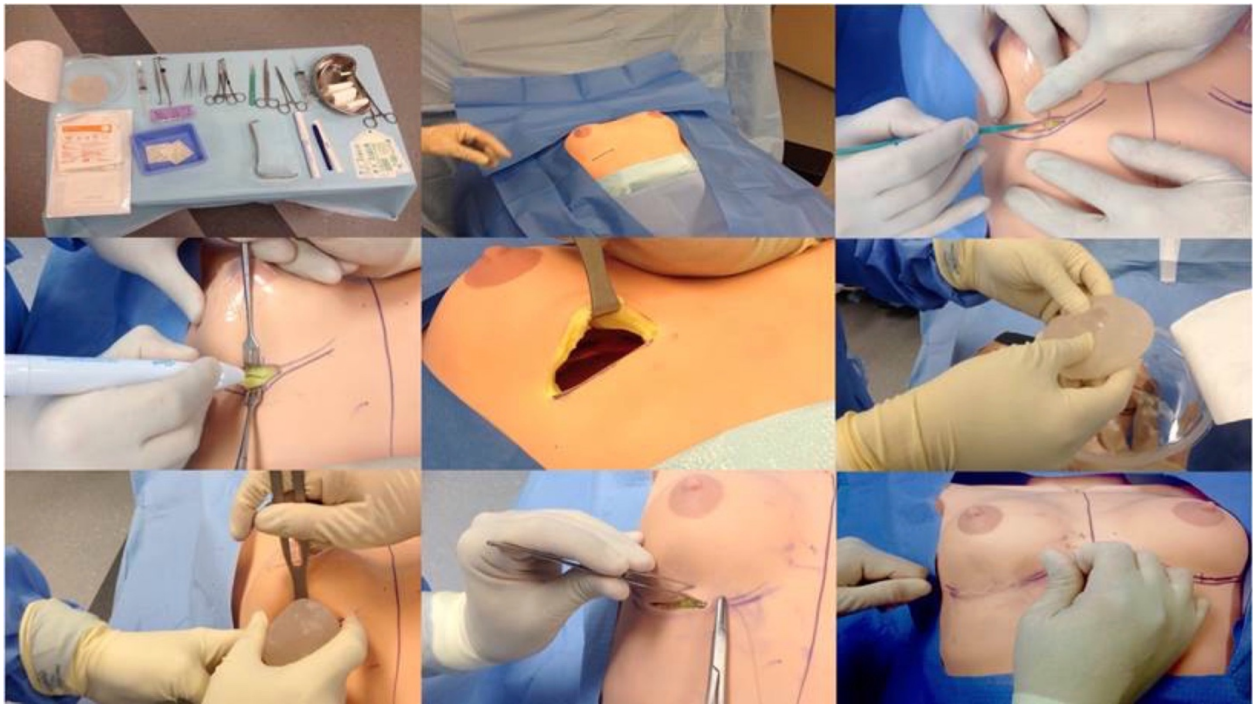

Figure 15 Sequence of images showing the progression of an augmentation mammoplasty done using the MAMO simulator.

Validation study

After Institutional Review Board approval, a total of 21 participants were recruited from the Montreal area to participate in the study. For standardization purposes, a five-minutes informative video depicting the essential surgical steps was shown to all participants. Using standard surgical instruments, plastic surgery residents and expert plastic surgeons performed a subpectoral mammoplasty procedure on the MAMO simulator. Participants' performance was video recorded for future evaluations, with a focus on the surgical site, and withholding participants' identity. Participants wore gowns and gloves to further hide any identifiable personal characteristics (Figure 16). After completing the procedure, expert plastic surgeons completed a survey assessing different components of the simulator. Evaluation consisted of four domains: physical attributes, realism of experience, realism of material and an overall assessment.

Figure 16 Participant performing an augmentation mammoplasty on the MAMO simulator, demonstrating the setup and the view captured by the video recording used for evaluation.

Method of evaluation

For confidentiality purposes, each participant was assigned an identification code. Evaluations were performed separately with each grader (R.K. and A.V.M.) blinded to the others results and blinded as to the identity of the participant. This was achieved using the Objective Structured Assessment of Technical Skills (OSATS) scoring system9-11, which encompasses (a) a Global Rating Scale (GRS) score (b) a surgery-specific Mammoplasty Objective Assessment Tool (MOAT) score and (c) a surgery-specific Checklist score.

The GRS score is a validated global rating tool used to objectively mark candidates' technical performance11-13. It is comprised of eight categories scored on a Likert scale (1 to 5), each tied with descriptive anchors, giving a maximum total score of 40 (Table 5). The surgery-specific MOAT score is tailored to a subpectoral augmentation mammoplasty procedure and was developed by our team. It is comprised of nine categories evaluating the essential surgical steps. Each category is evaluated on a Likert scale, giving a maximum score of 45 (Table 6). As well, a surgery-specific Checklist of the essential steps of the procedure was developed by our team, which comprised of 14 categories, giving a maximum score of 14 (Table 7).

	1	2	3	4	5
Respect of tissue	1 Frequently used unnecessary force on the issue of tissue or caused damage by inappropriate use of instruments	2	3 Careful handling of tissue but occasionally caused inadvertent damage	4	5 Consistently handled tissues appropriately with minimal damage
Time and motion	1 Make unnecessary moves	2	3 Efficient time/ Motion but some unnecessary moves	4	5 Clear economy of movement and maximum efficiency
Instrument handling	1 Frequently asked for the wrong instrument or used an inappropriate instrument	2	3 Competent use of instruments although occasionally appeared stiff or awkward	4	5 Fluid moves with instruments and no awkwardness
Suture handling	1 Awkward and unsure with the repeated entanglement, poor knot tying and inability to maintain tension	2	3 Careful and slow with the majority of knots placed correctly with appropriate tension	4	5 Excellent suture control with placement of knots and correct tension
Flow of operation	1 Frequently stopped operating or needed to discuss the next	2	3 Demonstrated some forward planning and reasonable progression of procedure	4	5 Obviously planned course of operation with efficiency from one to another
Knowledge of procedure	1 Insufficient knowledge. Look unsure and hesitant	2	3 Knew all important steps of the operation	4	5 Demonstrated familiarity with all steps of the operation
Overall performance	1 Very poor	2	3 Competent	4	5 Clearly superior
Quality of final product	1 Very poor	2	3 Competent	4	5 Clearly superior
Total score:					

Table 5 Global Rating Score used in the OSATS.

	1	2	3	4	5
Preoperative markings and incision placement	1 - Inadequate markings - Inadequate incision location and length	2	3 - Adequate markings - Correct incision placement	4	5 - More complete markings, including pocket dimensions - Correct incision placement and length
Subcutaneous tissue dissection	1 - Inadequate tissue dissection - Takes too much time to complete task	2	3 - Adequate tissue dissection using cautery - Takes adequate time to complete task	4	5 - Excellent tissue dissection using cautery - Clear economy of time without tissue damage
Separation of pectoralis major muscle and pocket formation	1 - Repeatedly makes tentative with awkward movements of instruments - Took too much time to complete task	2	3 - Adequate performance of task - Took adequate time to complete task	4	5 - Smooth performance of task - Clear economy of task - Used preoperative markings
Application of evidence-based techniques	1 Have not performed any of the steps	2	3 Performed 2 steps correctly	4	5 - Nipple shield placed at the adequate moment - Clean gloves when handling implant - Asked to soak implant in AB solution - Asked for pocket irrigation
Implant insertion technique	1 - Exaggerated number of movements to insert implant - Took unacceptable time to insert the implant - Skin contamination	2	3 - Acceptable number of motions - Efficient time to complete task - Limited skin contamination	4	5 - Smooth implant insertion - Clear economy of movements and time - Minimal skin contamination
Inframammary fold fixation	1 - Skipped this part of the procedure or difficulty to complete it - Awkward and unsure with poor knot tying - Did not protect prosthesis from perforation	2	3 - Adequate IM fixation - Competent suturing with good knot placement - Protected prosthesis from perforation	4	5 - Smooth IM fixation - Excellent suture control with correct placement and tension - Protected prosthesis from perforation

Subcutaneous suturing	1 - Unacceptable time to complete task - Awkward and unsure with poor knot tying and inability to maintain tension	2	3 - Acceptable time to complete task - Competent suturing with knot good knot placement and inappropriate tension	4	5 - Efficient time to complete task - Excellent suture control with correct suture placement and tension
Skin suturing technique	1 - Unacceptable time to complete task - Awkward and unsure with poor knot tying, and inability to maintain tension	2	3 - Acceptable time to complete task - Competent suturing with good knot placement and appropriate tension	4	5 - Efficient time to complete task - Excellent suture control with suture placement and tension
Skin suturing aesthetic result	1 Bad approximation of incision	2	3 Good approximation of incision	4	5 Excellent approximation of incision

Table 6 Mammoplasty Objective Assessment Tool scale.

List of tasks of a subpectoral augmentation mammoplasty procedure	Done (1 Point)	Not Done (0 point)
1. Identified existing and new IMF correctly		
2. Marked medial/lateral/superior pocket dissection borders		
3. Correct identification of IMF incision location		
4. Infiltration of breast tissue and incision line		
5. Placement of a nipple shield before incision		
6. Adequate skin incision and subcutaneous dissection		
7. Used pre-op marking to limit pocket dissection borders		
8. Used sterile gloves before handling implant w/o contamination		
9. Asked to soak implant and tip of retractor in triple AB solution		
10. Pocket irrigation with triple AB solution		
11. Implant insertion technique: minimal implant contact with skin		
12. Proper implant positioning in subpectoral pocket		
13. Adequate inframammary fold fixation technique		
14. Adequate subcutaneous and skin suturing		

Table 7 Checklist score.

Statistics

Statistical analyses were performed using JMP 11 (SAS Institute Inc.) and SPSS Inc. (IBM Corporation 1989-2016). Data is presented as Mean (Standard Deviation). Student t-test was used to compare mean values of GRS, MOAT and Checklist scores between residents and experts. Pearson correlation test was used to examine the correlation between GRS and MOAT scores. Internal consistency of GRS and MOAT scores were estimated using Cronbach's alpha14. Interrater reliability was calculated using the Intraclass Correlation Coefficient (ICC) for the total scores and for each item that constituted these scores. A p-value<0.05 was considered significant.

Results

Twenty-one participants were enrolled in this study: 14 plastic surgery residents and 7 expert plastic surgeons. Demographic data are presented in Table 8.

	Residents (n=14)	Expert plastic surgeons (n=7)
Age mean (range)	28 (25-32)	49 (33-61)
M:F ratio	8:6	6:1
PGY level (I:II:III:IV:V), Years of experience	3:4:3:1:3	17 (11)
Time to complete procedure in minutes mean (SD)	19 (4)	17 (3)
No. of aesthetic mamoplasties performed:		
>100	0	6
51-100	0	1
31-50	3	0
21-30	1	0
11-20	1	0
0-10	9	0

Table 8 Demographic data of participants. Data are presented as Mean (SD).

Face and content validation

Seven board-certified plastic surgeons evaluated different aspects of the MAMO simulator upon procedure completion. Face and content validations results showed excellent results among parameters evaluated, with an overall mean score of 4.3 (0.3) on 5. Out of four domains, “physical attributes” scored the highest with a mean of 4.5 (0.3) out of 5, followed by the “overall evaluation” domain with a 4.4 (0), then “realism of experience” with 4.1 (0.2) and lastly “realism of material” with 4.1 (0.4) (Table 9). The observed average of the “global assessment”, “value as a training tool” and “relevance to practice” items each scored 4.4 (0.8), which falls between the 2 scaling criteria of “Good” (score, 4) and “Great” (score, 5). This indicates that the MAMO simulator is relevant for the use as a training and assessment tool for mammoplasty procedures as it achieves face and content validations.

	Likert scale					
Questionnaire item	**1**	**2**	**3**	**4**	**5**	**Average (SD)**
Physical attributes	**Not realistic at all**	**Inadequate, but has some realism**	**Neutral**	**Adequate realism, could be improved**	**Highly realistic, no need for improvements**	**4.5 (0.3)**
1. Chest circumference	0)	0	0	2	5	4.7 (0.5)
2. Skin and subcutaneous thickness	0	0	2	3	2	4 (0.8)
3. Pectoralis major thickness	0	0	1	1	5	4.6 (0.8)
4. Rib cage realism	0	0	0	2	5	4.7 (0.5)
5. Intercostal muscles realism	0	0	0	3	4	4.6 (0.6)
Realism of experience	**Not realistic at all**	**Inadequate, but has some realism**	**Neutral**	**Adequate realism, could be improved**	**Highly realistic, no need for improvements**	**4.1 (0.2)**
6. Pre-operative markings and measurements	0	0	0	3	4	4.6 (0.5)
7. Skin incision	0	0	1	4	2	4.1 (0.7)
8. Tissue dissection	0	0	1	4	2	4.1 (0.7)
9. Pectoralis major muscle separation from rib cage	0	0	2	3	2	4 (0.8)
10. Implant insertion	0	1	0	3	3	4.1 (1.1)
11. Inframammary fold fixation	0	0	3	1	3	4 (1)
12. Subcutaneous suturing	0	1	1	3	2	3.9 (1.1)
13. Skin suturing	0	1	0	3	3	4.1 (1.1)
Realism of materials	**Not realistic at all**	**Inadequate, but has some realism**	**Neutral**	**Adequate realism, could be improved**	**Highly realistic, no need for improvements**	**4.1 (0.4)**
14. Skin	0	1	0	4	2	4 (1)
15. Subcutaneous tissue	0	1	1	4	1	3.7 (1)
16. Muscles	0	0	2	3	2	4 (0.8)
17. Ribs	0	0	0	2	5	4.7 (0.5)
Overall evaluation	**Bad**	**Below average**	**Neutral**	**Good**	**Great**	**4.4 (0)**
18. Value as a training tool	0	0	1	2	4	4.4 (0.8)
19. Relevance to practice mammoplasty procedure	0	0	1	2	4	4.4 (0.8)
20. Global assessment	0	0	1	2	4	4.4 (0.8)

Table 9 Observed averages of each item on the evaluation form as completed by expert plastic surgeons, evaluating anatomical accuracy, realism of material and experience as well as an overall value of the simulator as a training and assessment tool for augmentation mammoplasty procedures.

Construct validation

After a blind evaluation of participants' performance, expert plastic surgeons' performance was significantly higher than residents' according to GRS, MOAT and Checklist scores (Table 10). Based on evaluator 1, mean values of residents and experts were 23.4 (2.5) vs 36.9 (3.1) ($p<0.0001$) for GRS score, 30.4 (2.2) vs 40 (3.2) ($p<0.0001$) for MOAT scores and 9.7 (1.5) vs 12 (1) ($p<0.001$) for Checklist scores respectively (Figure 17, 18, 19). Based on evaluator 2, mean values of residents and experts were 25(3.2) vs 36.9(1.3) ($p<0.0001$) for GRS scores, 31(2) vs 38.4(3.8) ($p<0.001$) for MOAT scores and 10.3(1.4) vs 12.1(0.9) ($p<0.001$) for Checklist scores. Checklist items that residents omitted or incompletely performed the most frequently were "skin markings of medial/lateral/superior borders of the pocket" in 13 out of 14 cases (93%) (10 out of 14 (71%) based on evaluator 2), followed by achieving a "proper implant placement inside the subpectoral pocket" omitted by 8 out of 14 residents (57%) (7 out of 14 (50%) based on evaluator 2). The steps experts omitted were the "mammary tissue infiltration" step in 4 out of 7 cases (57%), followed by "correctly marking old and new IMF" in 3 out of 7 cases (43%), as assessed by both evaluators.

Pearson correlation studies between GRS and MOAT scores showed a strong correlation with 0.95 ($p<0.0001$) and 0.94 ($p<0.0001$) according to evaluator 1 and 2 respectively. Predictive linear regressions were strong between the two score with a coefficient of determination (R^2) of 0.9 based on evaluator 1 (Figure 20) and R^2= 0.89 based on evaluator 2 (Figure 21).

	Scores	Residents	Experts	p-value
Evaluator 1	**GRS**	23.4 (2.5)	36.9 (3.1)	< .0001
	MOAT	30.4 (2.2)	40 (3.2)	<.0001
	Checklist	9.7 (1.5)	12 (1)	<.001
Evaluator 2	**GRS**	25 (3.2)	36.9 (1.3)	< .0001
	MOAT	31 (2)	38.4 (3.8)	<.001
	Checklist	10.3 (1.4)	12.1 (0.9)	<.001

Table 10 Scores Averages (SD) comparison between experts and residents according to each evaluator.

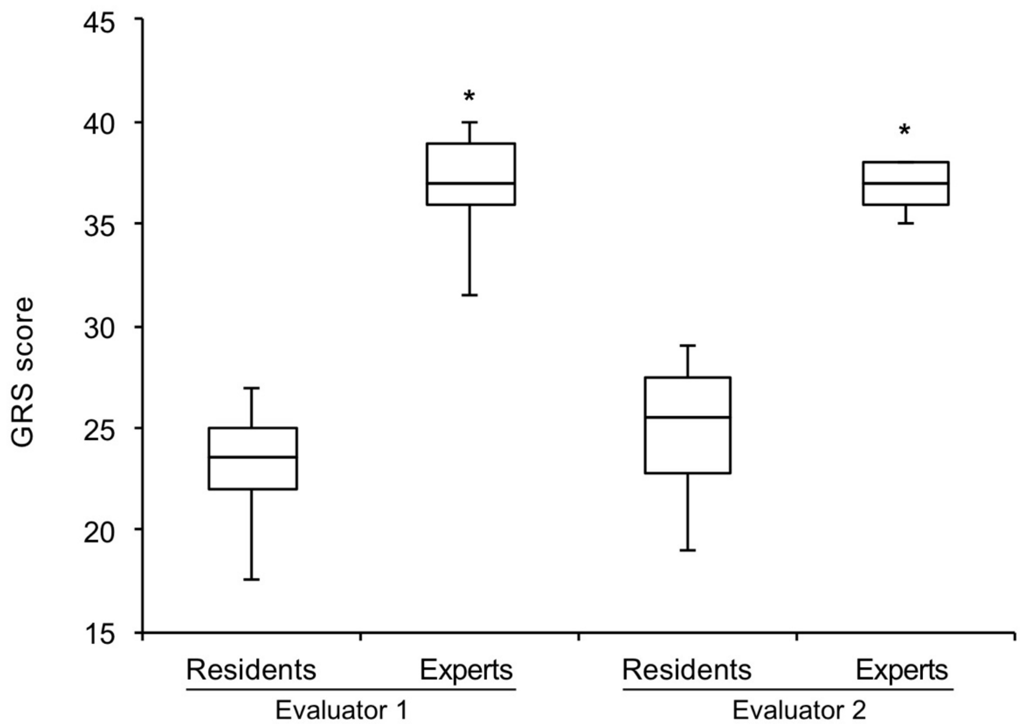

*Figure 17 Figure 5. Box plot representation of the GRS score of each group for both evaluators. * for p<0.05*

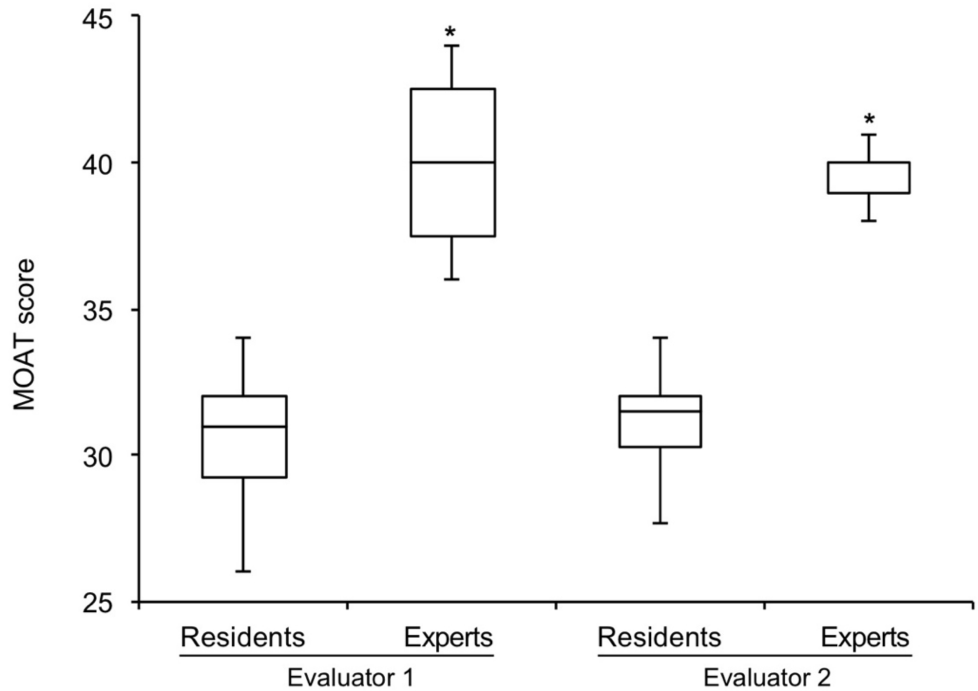

*Figure 18 Box plot representation of the MOAT score of each group for both evaluators. * for p<0.05*

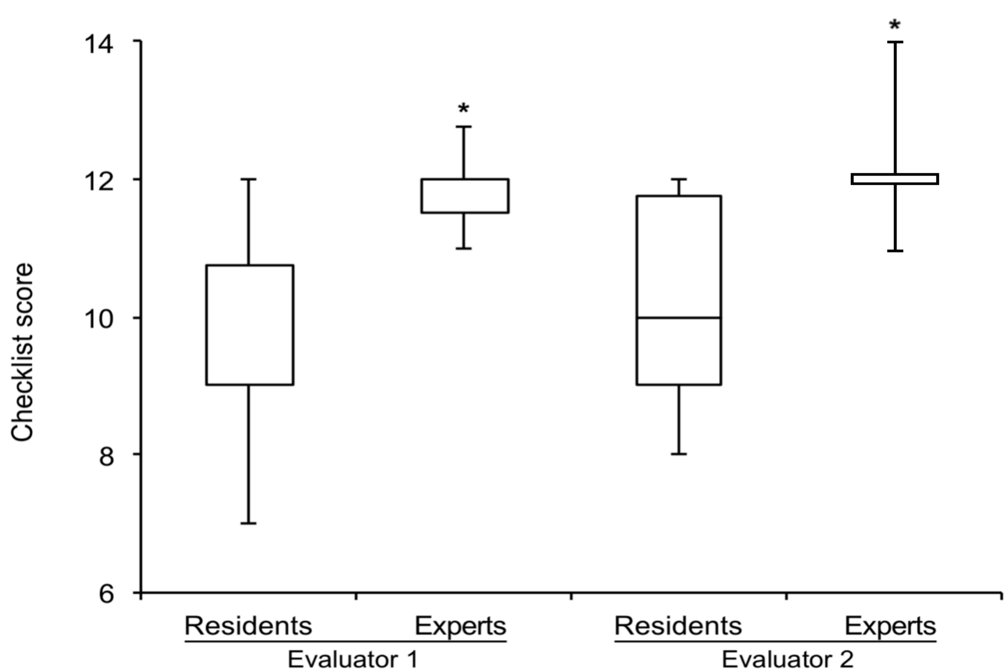

*Figure 19 Box plot representation of the Checklist score of each group for both evaluators. * for p<0.05*

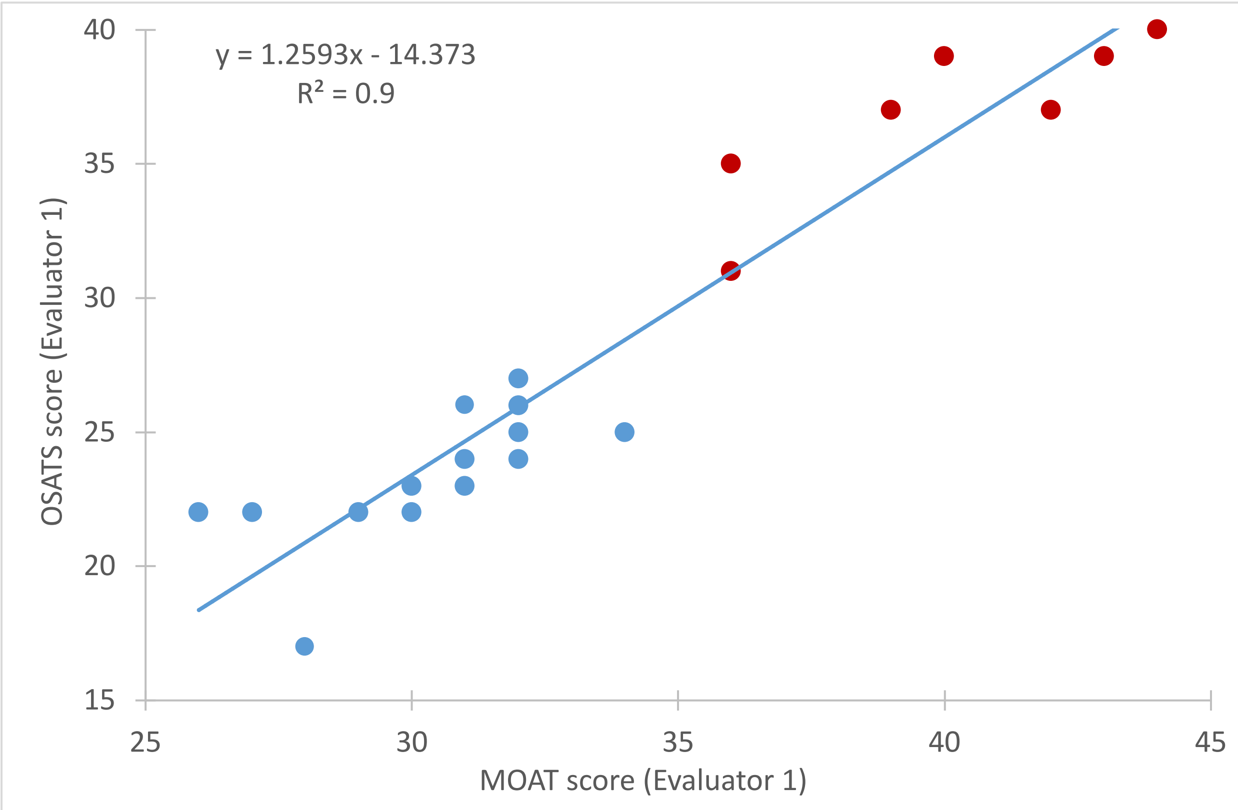

Figure 20 Linear regression of the MOAT and GRS scores based on evaluator 1. Red dots are expert scores, blue dots are residents scores.

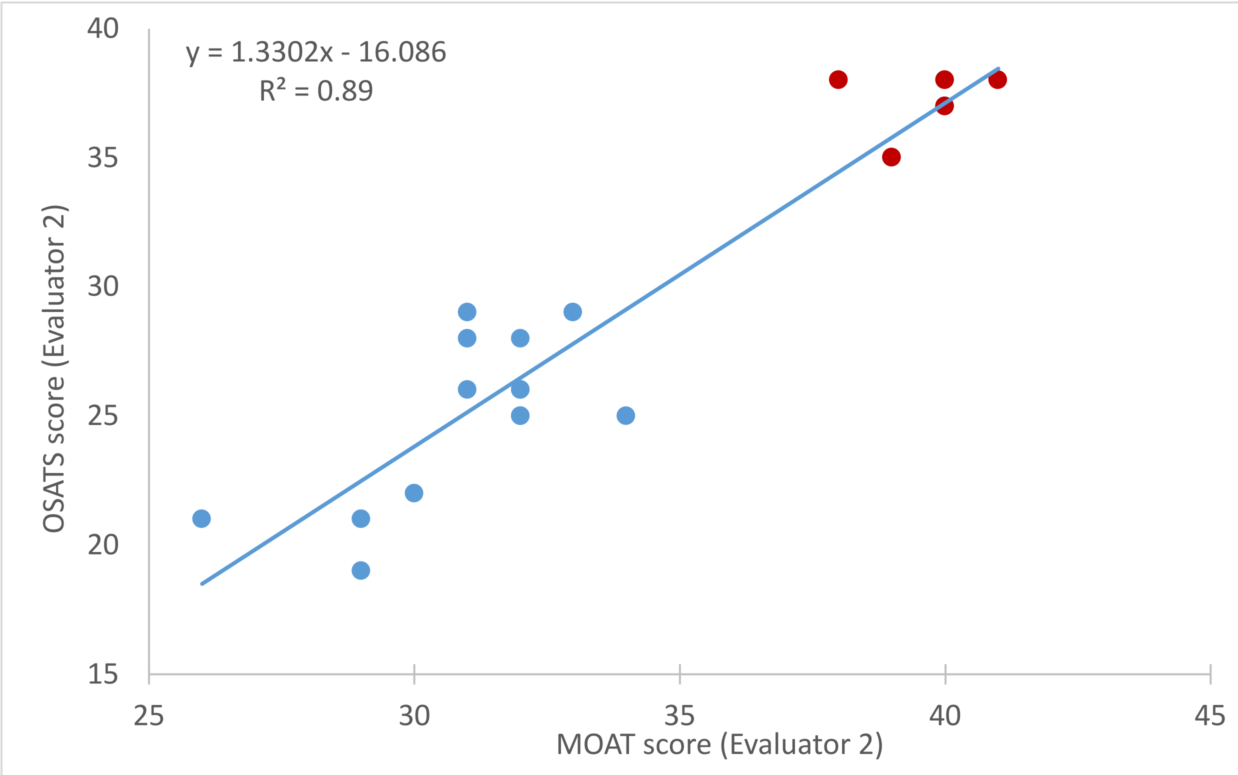

Figure 21 Box plot representation of the Checklist score of each group for both. Red dots are expert scores, blue dots are residents scores.

Internal consistency

Cronbach's alpha for the GRS score based on evaluator 1 was 0.96 and based on evaluator 2 was 0.94, which indicates that internal consistency of GRS score is "excellent" (Table 11). Internal consistency could not be improved with the elimination of any items that constitute the score. Cronbach's alpha for the MOAT score was 0.83 and 0.82 for evaluator 1 and 2 respectively (Table 12), which means that internal consistency of MOAT score is "good" and would be slightly improved to 8.4 with the elimination of the "Application of evidence-based techniques" item.

GRS items	Evaluator 1		Evaluator 2		ICC
	Mean	**SD**	**Mean**	**SD**	
1. Respect of tissue	3.8	0.8	3.8	0.6	0.61
2. Time and motion	3.4	1.0	3.5	1.2	0.91
3. Instrument handling	3.5	1.0	3.8	0.9	0.75
4. Suture handling	3.7	0.8	3.8	0.8	0.8
5. Flow of operation	3.2	1.3	3.4	1.2	0.86
6. Knowledge of procedure	3.4	1.2	3.4	0.9	0.91
7. Overall performance	3.6	1.0	3.6	1.1	0.9
8. Quality of final product	3.4	0.9	3.6	0.7	0.81
Cronbach's alpha	**0.95**		**0.94**		

Table 11 Mean averages of each GRS score item and Intraclass Correlation Coefficients of each according to the two evaluators.

MOAT items	Evaluator 1		Evaluator 2		ICC
	Mean	**SD**	**Mean**	**SD**	
1. Preoperative markings and incision placement	3.3	1.0	3.4	1.0	0.81
2. Subcutaneous tissue dissection	4.1	0.7	3.9	0.6	0.66
3. Pocket formation	3.6	1.1	3.4	0.7	0.84
4. Application of evidence-based techniques	4.3	0.6	4.2	0.6	0.97
5. Implant insertion technique	3.6	1.2	3.7	1.1	0.94
6. Inframammary fold fixation	3.1	1.1	3.4	0.9	0.63
7. Subcutaneous suturing	3.5	0.9	3.7	0.8	0.84
8. Skin suturing technique	4.0	0.7	4.1	0.5	0.81
9. Skin suturing aesthetic result	4.2	0.4	4.0	0.5	0.65
Cronbach's alpha	**0.83**		**0.82**		

Table 12 Mean averages of each MOAT score item and Intraclass Correlation Coefficients of each according to the two evaluators.

ICCs for interrater reliability were excellent at 0.93, 0.92 and 0.89 for the total GRS, MOAT and Checklist scores, respectively, which indicates that at least 93%, 92% and 89% of the variance in each of the respective scores can be attributed to a true difference between participants. Correlation studies of each score between evaluators were all higher than 0.8 between evaluators (Table 13).

When broken down into items, ICCs for GRS score items between evaluators were all above 0.8 expect “instrument handling” and “respect of tissue” items with scores of 0.7 and 0.6, respectively (Table 11). Similarly, ICCs of the MOAT score items between both evaluators were all above 0.8 except, except “subcutaneous tissue dissection”, “skin suturing aesthetic” and “inframammary fold fixation” items with a score of 0.6 for each (Table 12).

	Internal consistency			
	Correlation	**ICC**	**CI (95%)**	**p-value**
GRS score	0.88	0.93	[0.83 - 0.97]	<.0001
MOAT score	0.87	0.92	[0.81 - 0.97]	<.0001
Checklist score	0.83	0.89	[0.72 - 0.96]	<.0001

Table 13 Internal consistency and correlations of each of the scores between the two evaluators.

Discussion

The implementation of the new accreditation system by the Accreditation Council of Graduate Medical Education (ACGME) is aimed to guarantee that graduates of accredited residency programs possess the necessary knowledge, skills and attitude for safe, effective and compassionate practice15. Residents are no longer deemed competent by merely completing the duration of residency. Alternatively, competence must be established using objective assessment tools and predefined milestones. Although most experts have acknowledged the convenience of such transition, the availability of tools and scales that objectively assess competence has been problematic16. This is particularly true to Plastic Surgery, which is lacking behind other specialties in terms of availability of simulators, despite it being classified as the most desirable tool to assess surgical skills by the ACGME17.

To fulfill this need, the MAMO simulator has been meticulously developed to represent accurate anatomical structures and landmarks, as well as to provide realistic haptic feedback to the operator. It serves as both a training and assessment tool. The simulator environment is a highly realistic operating-room-like experience, ensured by including draping and personal assistance, and by using accurate surgical instruments. The main advantage of a benchtop synthetic simulator over other technologies, such as augmented reality, is the haptic feedback that operators can experience. Its limitation is its inability to integrate blood vessels and reproduce a bleeding effect, as reusability of such model would not be possible. A hybrid model appears to be the most convenient in this type of procedure, where bleeding animation can be projected to the operator using augmented reality technology and actions aimed to stop the bleeding can be achieved by tracking cautery's position in a 3D coordinate system using a magnetic tracking system.

The MAMO simulator achieved face and content validations by reaching a consensus among expert plastic surgeons on the resemblance of appearance and experience to that of 'real-life' surgeries. Each of the four domains evaluated for this purpose (physical attributes, realism of material, realism of experience and the overall evaluation) scored a mean value above 4 out of 5, representing the two evaluation criteria of 'Good' and 'Great'. Construct validation of the simulator was as well achieved by the performance analysis that showed a discriminatory power between the different levels of expertise. Statistically significant differences were observed between residents' and experts' scores using the GRS, MOAT and Checklist scales. This technique of construct validation is widely used and recognized as the gold standard18-22.

After attaining validity for the MAMO simulator, it was crucial to determine whether the scales used to achieve validity are themselves reliable. Reliability refers to the degree to which an assessment tool is consistent in its outcome. Frequently used items to evaluate reliability are internal consistency and inter-rater reliability. The latter is a measure of consistency, where it measures the degree of scores agreement between two raters testing the same subject. Internal consistency of a scale evaluates the degree to which every test item measures the same construct. Cronbach's alpha represents internal consistency coefficient of a scale ranging from 0 to 1. Generally, 0.8 is accepted as a threshold for good reliability. Results have shown an excellent internal consistency for the GRS score as per evaluator 1 and 2 with 0.96 and 0.94, respectively. Similarly, the MOAT score has a Cronbach's alpha of 0.83 and 0.82 for evaluators 1 and 2, respectively. The exclusion of the 'use of evidence-based techniques' item from the MOAT score has shown to improve Cronbach's alpha to 0.84. Although true, this slight improvement will not add more significant reliability to the score. Standardization of assistance and delivery of instructions to each participant anticipated the existence of little variation between evaluators. In fact, the ICC of the interrater reliability for the total scores of GRS, MOAT and the Checklist were all equal or higher than 0.9. In other words, at least 90% of the variation can be attributed to a true difference between participants.

The OSATS scoring system, although reliable, has its drawbacks. The process of evaluations is time consuming and, if operator's identity was revealed, can generate a human-factor bias to the scoring system. In order to incorporate the MAMO simulator as an evaluating tool for residents' performance in mammoplasty procedures, the addition of a completely objective tool in assessing critical steps of the procedure would add an even greater value. Such technologies could include hand motion patterns23, path-length24 and eye motion tracking analyses25-27. Preliminary work was achieved by our team to incorporate an objective measure of pocket dissection performance, a crucial step that directly impacts post-operative aesthetic outcome. Using magnetic tracking system technology, a sensor was incorporated into a long tip cautery device to track its position in X, Y and Z coordinates and a computer interface was generated to illustrate the path and pocket's surface area dissected. An algorithm was implemented to assess pocket dissection based on the percentage of surface dissected and over-dissected in reference to a predefined ideal pocket dimension and location. Such addition to the current simulator system would further improve the assessment method and enhance its objectivity.

Conclusions

Validity of the construct simulator and reliability of the assessment scales establishes the MAMO simulator system as the first Plastic Surgery-specific tool capable of consistently evaluating residents' performance and attributing competence in subpectoral mammoplasty procedures.

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CHAPTER 6 Discussion

Simulation in plastic surgery appears to be relatively underdeveloped when compared to its counterparts in other surgical specialties. While general surgery adopted elite technologies to develop laparoscopic virtual-reality simulators, plastic surgery could not take advantage of such advancements considering the difference in the nature of its operations, none of which requiring projection on a 2-D screen. This fact contributed significantly in delaying the advancement in simulators for plastic surgery. However, the need for multiple competencies assessment throughout the course of residency training that come along CBME, constituted the trigger to develop specialty-specific simulators to be used as assessment tools.

In the current project, the choice of simulating an aesthetic procedure besides its need as a performance assessment tool, stems from the lack of residents' exposure to such procedures. As a matter of fact, aesthetic surgeries remain the most inconsistently taught portion of plastic surgery despite constituting an important portion of board examination. The privatization of the procedures and patients' high aesthetic expectations are the main factors that lead to this situation. As a result, we opted to develop and validate the first augmentation mammoplasty simulator.

Before proceeding with the benchtop simulator development, it was primordial to determine the essential steps of the procedure required to assess competence. As a result, our team sent out an online survey to a panel of Canadian plastic surgeons and identified 17 essential surgical steps that reached consensus amongst the panel using the Delphi methodology[12]. Another challenge to this project was to identify materials that best mimic the characteristics of each anatomical structure intended to be replicated on the simulator. Consequently, initial work on the unilateral breast augmentation prototype aimed at the identification of the most appropriate material to use in the simulation of each of the anatomical structures. The material of choice has to replicate the shape, color and texture, as well as to adequately react to surgical acts like resistance to shearing and reacting to cautery devices. Following a testing session on the simulator, expert plastic surgeons completed an evaluation form composed of four different domains: physical attributes, realism of material, realism of experience and ability to perform tasks. The high scores obtained on all evaluated parameters, with a "global assessment" mean score of 4.3 over 5, completed the face and content validation of the part-task trainer. This supports the fact that the prototype accurately represent what it is intended to. More importantly, experts highly valued the physical proprieties of simulated skin such as its ability to self-seal puncture sites after suturing, as well as its good shearing resistance and elastic properties. On the other hand, evaluators suggested that the subcutaneous tissue material used could be improved upon by using material that is less sticky and that could react appropriately to cautery stimulation. Other suggested modifications focused on representing bilateral breasts to allow symmetry assessment and replicating bleeding scenarios.

Subsequently, the part-task trainer was used to study the relationship of performance in games requiring hand dexterity and hand-eye coordination skills with surgical performance of medical students. The aim was to identify tools that can predict surgical performance of novices which could be implemented by residents' selection committees in their selection process. Correlation and linear regression studies between each of the game scores and the surgical skills were analysed. Perplexus Epic and Super Monkey Ball scores showed to have strong correlations with surgical performance using the modified OSATS score and a relatively strong linear regression with a coefficient of around 0.6. Moreover, a combination of both aforementioned scores yielded a stronger correlation and better linear fit with surgical performance scores. The results indicated that 75% of modified OSATS score variations are determined by the linear relationship between the modified OSATS score and the combined score. This combined score of Perplexus Epic and Super Monkey Ball could potentially represent a useful tool for residents' selection committees to identify applications with superior innate predisposition for better hand dexterity and psychomotor skills. Although eluded to from the results of the study, this claim needs further studying using a bigger sample size. The advantage of using such a tool is that it is simple to administer, can be used indefinitely and scores can be attributed instantaneously.

On the other hand, the two other tested games, Mikado and Star War Racer, did not correlate or have a strong linear fit with performance scores. The lack of standardization and consistency of difficulty levels of each trial for Mikado and the relatively simple controller used in Star War Racer might have been the respective causes behind the absence of significant results. As well, the surgery-specific score developed based on the surgical steps that could be replicated on the part-task trainer did not seem to correlate or to have a strong linear fit with any of the games. This might be attributed to the fact that the score lacks anchoring criteria for each of the Likert score subunit to guide the evaluator and further objectify the score.

The MAMO simulator came as a result of the efforts and investigations in the Delphi methodology and the lessons learned from the unilateral breast augmentation part-task trainer. Fifteen out of the 17 surgical steps that reached consensus amongst a panel of experts can be replicated on the simulator, excluding patient positioning on the table and achieving hemostasis steps. In addition, all the relevant anatomical structures were meticulously replicated to represent accurate anatomical structures and landmarks, as well as to provide realistic haptic feedback to the operator. Following MAMO simulator testing, face and content validations were achieved by reaching a consensus among seven plastic surgeons on the resemblance of appearance and experience to that of the "real-life" procedure. Each of the four domains evaluated for this purpose (physical attributes, realism of material, realism of experience and the overall evaluation) scored a mean value above 4 out of 5, representing the two evaluation criteria of 'Good' and 'Great' from the Likert scale. The intercostal and pectoralis muscles as well as thorax characteristics were the physical attributes that scored the highest. "Preoperative measurement and marking" step was the item that scored the highest (4.7/5) from the realism of experience. The lowest scores in each category were all related to the subcutaneous tissue. For instance, the realism of material used to replicate the subcutaneous tissue scored an average of 3.7 and subcutaneous suturing in the "realism of experience" scored an average of 3.9 (over 5). Despite our efforts to optimize all simulator components, there eventually came a point where there was a trade-off between realism and functionality. The choice of material used to replicate subcutaneous tissue was made based on its proprieties to react to heat-cautery although the texture was dry and less elastic compared to real tissue.

Construct validation was achieved by showing significant differences in performance between experts and residents. This was true across all the evaluation scales utilized from the OSATS score. GRS is considered the gold-standard for surgical performance assessment on a simulator which can be applied for any surgical procedure. GRS score showed a strong correlation and a strong predictive linear regression with the MOAT score. This relationship could not be studied between GRS and the checklist score due to the nature of the binary data that the latter provides. Performance evaluations were completed by 2 independent evaluators who were blinded to the identity of the participants. In order to analyse the reliability of the assessment tools used during the evaluations, internal consistency and inter-rater reliabilities were studied. Inter-rater reliability is a measure of the degree of consensus between two raters testing the same subject using the interclass correlation coefficient. The internal consistency of a test evaluates the degree to which each test element measures the same construct measured using Cronbach's alpha. These results demonstrated high consistency and reliability of the yielded results from both the GRS, MOAT and checklist scores. The ICC for all three scores were equal or higher than 0.9, meaning that at least 90% of the variation in scores can be attributed to the true difference between participants.

This type of validation has been extensively used in the literature to evaluate simulators in different surgical specialties and is widely accepted by experts in the field[51-56]. The face validity represents the subjective assessment of whether or not the test measures what it is supposed to measure. Content validity refers to the extent to which a measure represents all facets of a given construct. Construct validity, in the context of simulation, evaluates the degree to which the results of participants' performance on the simulator reflect the actual skill of a trainee who is being assessed. This method of validation is referred to as the "classical validation framework". However, a different framework regarding validation interpretations initially developed by Messick in 1989[57] has been progressively gaining acceptance amongst educational experts and relies on the basis that validity is a construct with various facets[58,59]. This framework proposes five sources of validity evidence that overlap in part with the classical framework. First source is *content* evidence, which refers essentially to the same concept of content validity from the classical validation framework. Second, the *internal structure* evidence refers to the relationship of individual assessment items of a score with each other, which was tested in our model using Cronbach's alpha for internal consistency. Third, *relationships with other variables* evidence which corresponds closely to the classical notions of criterion and construct validity. In our model, construct validation was performed by proving a significant difference in performance scores between novices and experts on the simulator. Fourth, the *response process* evidence evaluates raters' performance which might potentially interfere with the quality of responses. Poorly trained evaluators, low-quality video recordings and inability to adequately hide operator's identity are examples of factors that alter the quality of assessment. In our model, we tested for inter-rater reliability, a measure of the degree of consensus between two raters testing the same subject using the interclass correlation coefficient. Finally, *consequences* evidence looks at the impact of assessment and decisions that result. This corresponds to the establishment of pass/fail score and their suitability, as well as to whether the tested simulator has effects on examinees and evaluators such as a change in the knowledge or skills. Regardless of the terminology used to describe and interpret the results of the validation process of the simulator, the main concept remains fairly similar.

Despite the satisfactory results with regards to validation studies and reliability measurements of the assessment tools used, one of the drawbacks to this assessment methodology using the OSATS score is that it can be time consuming to evaluators. In addition, these tools where reliable when the identity of the operator was kept anonymous from the evaluator, a scenario that does not apply in real-life residency training. This might generate a human factor bias to the scoring system, thus skewing the objectivity of the assessment process. Another shortcoming of this study is the fact that the surgical planes were relatively easy to identify compared to real life, especially the identification of the subpectoral plane. Similarly, some physiological phenomenon such as bleeding where also omitted from this simulator. These steps had to be compromised where reusability was prioritized over realism in a few instances.

The development of a benchtop simulator that can reproduce all the exact steps of a procedure might not be a necessary criteria when developing future simulators. We believe that a simulator such as the MAMO simulator would rather familiarise residents to the sequence of surgical steps than acquiring new surgical skills. Anticipation of the next surgical step in a procedure is a sign of advanced knowledge but would not necessarily predict technical skills. It would be of interest to identify the most challenging steps of a procedure and develop a simulator that allows to refine technical skills that can potentially be transferred into the operating room.

Fidelity of a simulator refers to the level of realism that the model reflects compared to real-life (physical fidelity) and to the degree to which the skill in the real task is captured in the simulated task (functional fidelity)[60]. The MAMO simulator belongs to the medium-fidelity category, which is defined as having a more realistic representation of the task while lacking sufficient cues for the operator to be fully immersed. The other 2 categories are low- and high-fidelity, the first generally focuses on a single skill that allows operators to practice on their own time without much required feedback, whereas the latter provides adequate cues and performance to allow full immersion and response to surgical interventions. A good example for each would be a suturing kit simulator for low-fidelity and a virtual reality laparoscopic simulator for high-fidelity which allows objective assessment and action-reaction response to surgical input. Generally, the better the physical fidelity, the higher the cost; however, sometimes increasing the physical fidelity of a simulator does not always lead to better skill acquisition results. Many studies have looked into the effect of level of fidelity to surgical skills, knowledge, self-perceived comfort and competence[61-65]. These results suggest that high-fidelity simulators may not be uniformly advantageous and may lead to inefficient learning by increasing irrelevant cognitive load in novice learners. Other data suggest that training on a low-fidelity simulator can teach skills that could be successfully transferred to a high-fidelity simulator[66,67].

On the verge of CBME adoption by residency training programs in North America, future studies are necessary to address the eminent role of simulation in training and assessing trainees' competence on the predefined Milestones. Despite its anticipated role in improving surgical skills and evaluating residents' performance, simulation must be able to reflect the level of performance in the operating room. After all, if technical and cognitive skills developed on a simulator will not improve performance in the real setting, then the concept of simulation training and assessment is no more relevant. As a result, it is primordial to assess for transferability of skills learned on a simulator to the operating room for every simulator, which should be considered the next step for the MAMO simulator.

This aspect of simulators investigations was tackled by different specialties through comparing the performance of simulator-trained versus non simulator-trained residents on a cadaver[68], an animal model[69] or directly in the operating room[70]. Despite the differences in skills transfer assessment and metric tools used, many of these simulators showed some sort of improvement in intraoperative skills, which was significant in the majority of the studies. Nevertheless, this type of comparison remains the most challenging part in the course of simulators validations. Unlike performing on a simulator, residents do not execute all the steps of a procedure on their own for the vast majority of cases, therefore comparing performance of individuals between the two settings is not always achievable. An alternative would be to develop part-task trainers that allow residents to practice specific tasks that would be considered challenging for a given procedure, then assess performance on that specific task in the operating room.

CHAPTER 7 Conclusions

This project has achieved a list of distinct contributions to knowledge. First, it identified and listed the most adequate material used to replicate specific anatomical structures with regards to consistency and physical proprieties. Second, it generated a combined score using 2 skill-games that could potentially predict surgical performance of medical students. This score is characterized by being easy to implement during residency selection interviews and can provide scores immediately, without the need for an expert's evaluation. This last statement is yet to be further studied using a larger sample size and compared to a different set of skills simulator. Third, this project resulted in the development of a novel breast augmentation simulator, which successfully achieved face, content and construct validations. The MAMO simulator can potentially be of great value for the CBME model, with which residents can be evaluated for competence in subpectoral breast augmentation procedure. Finally, this project paves the way for further studies and simulators development, such as evaluating the transferability of skills developed on the MAMO to the operating room and development of a breast reconstruction or a breast mastopexy simulator.

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Appendix – Article 4: The Evolution of Surgical Simulation: The current State and Future Avenues for Plastic Surgery Education

The Evolution of Surgical Simulation: The Current State and Future Avenues for Plastic Surgery Education

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Abstract

Alongside the ongoing evolution of surgical training towards a competency-based paradigm has come the need to reevaluate the role of surgical simulation in residency. Simulators offer the ability for trainees to acquire specific skills and for educators to objectively assess the progressive development of these skills. In this paper, we will discuss the historical evolution of surgical simulation, with a particular focus on its past and present role in plastic surgery education. The authors will also discuss the future steps required to further advance plastic surgery simulation in an effort to continue to train highly competent plastic surgery graduates.

Introduction

Surgical training has long been based on the “see one, do one, teach one” principle central to the traditional surgical apprenticeship model. Such 100-year plus Halstedian principles, marked by graded responsibilities and incumbent upon progressive development of skills, continue to be the core tenet of current surgical education curricula. The most important change, however, involves the manner by which surgical trainees are deemed “ready for practice”. The conventional “time-based” approach, where competency is assumed to be attainable within a defined period of residency training, may be supplanted by a competency-based approach. Indeed, in 2013, in the United States the Accreditation Council for Graduate Medical Education (ACGME) recently introduced the Next Accreditation System (NAS) which has Milestones, or competency-based evaluation as one of its principle additions to residency education.[1] The latter teaching paradigm requires competence to be demonstrated prior to completion of training, regardless of whether the period of training was shorter or longer than its previously prescribed time frame.

While there exists a large amount of evidence espousing the value of a competency-based medical education (CBME) residency model, the major driving force driving the shift is a newly appreciated societal need to ensure physicians are competent in light of an ever-expanding field. Constant advancements in surgical techniques and the introduction of new technologies combined with new legislation restricting residents working hours have fueled this educational transition. Now more than ever, surgical specialties are developing and incorporating surgical simulation into their curricula, as a potential venue to develop skills and objectify skill(s) acquisition prior to entering the clinical realm. Such simulators can either be low- or high-fidelity, but are unified by the central principle of developing a core set of predetermined skills[2].

Similarly to other surgical specialties, plastic surgery defined its core competencies and their respective milestones in the plastic surgery NAS Milestones project and has officially implemented the new accreditation system since 2014. In this paper, we will discuss the role of surgical simulation in this new apprenticeship model, the current state of simulation in plastic surgery and the steps that need to be adopted to further develop this field. In addition, a historical review of the evolution of simulation will be presented.

Historical Evolution of Simulation

Evidence of simulation use goes back to the age of antiquity where clay and stone were used to simulate clinical features of diseases and as diagnostic tools in certain cultures[3]. At the beginning of the 20th century, simulation progressively gained interest as a training tool for tasks that endangered human lives, particularly in aviation. In 1930, Edwin A. Link (1904-1981) developed the first flight simulator, which later became known as the “Link Flight Simulator”[4]. The trainer was based on vacuum technology used in musical instruments by his father’s automatic piano and organ factory, where he worked as a technician. The simulator was capable of replicating basic movements of a plane and simulating severe weather circumstances that were responsible for the death of many pilots[5]. Although initially used as a coin-operated carnival ride machine, it rapidly caught the interest of the US Army Air Corps as a training tool for its pilots, prompting massive production of such simulators. Today, aviation simulators are considered essential tools for training and assessing pilots.

Simulation training gradually began infiltrating other areas such as military combat training, nuclear power plant operations and aerospace. Nonetheless, it was not until the early 1960s that simulation in health care became more popular. The first mannequin allowing the simulation of a medical act was “Resusci-Anne,” which was a full-sized mannequin designed to teach the principles of cardiopulmonary resuscitation[6]. Peter Safar, MD (1924-2003), a pioneer in cardiopulmonary resuscitation techniques, collaborated with Laerdal®, a soft-toy manufacturer from Norway, to produce a mouth-to-mouth ventilation mannequin, which was later modified to allow external chest compressions. The establishment of the principles of resuscitation with its Airway, Breathing and Circulation components, published by Safar in 1968[7], led to the rapid spread of the simulator around the world. Today, a more sophisticated version is available, “Resusci-Anne QCPR®”, which enables high quality cardiopulmonary resuscitation capable of providing measurements, assessment and quality feedback on performance. Around the same period, Michael Gordon, MD, described the Cardiology Simulator Patient[8], which was later known as “Harvey” as a tribute to his mentor Dr. Proctor Harvey. “Harvey” was a full-sized mannequin capable of simulating more than 20 cardiovascular diseases through the alteration of physical findings such as blood pressure, breathing, pulse, auscultated heart sounds and murmurs. After extensive testing for validation as an effective training tool[9-12], it was widely adopted by medical and nursing schools, residency programs and licencing bodies for family physicians seeking continuing medical education.

Simulation training continued to make its way into other fields as strong evidence of its effectiveness became indisputable. The driving force for the initiation of surgical simulation was the momentous impact of laparoscopic surgery on the surgical field ever since its introduction in

1988. With the increasing evidence of its advantages to traditional open techniques in terms of complication rate and length of hospital stay, patients began seeking physicians who could perform the new "same day" surgery, which was aggressively advertised and promoted by competing hospitals[13]. Yielding to market pressure and the risk of early obsolescence, surgeons already in practice experienced the need to rapidly learn and implement this new technique. Weekend or short-term training courses were offered to surgeons to teach the new skill sets related to laparoscopy before attempting the techniques clinically[14]. This relatively unstructured educational technique was not effective and endangered patient safety, as it consisted of didactic teachings followed by direct clinical application.[15] The result was a search for alternative training methods and the stimulus to develop simulators that could improve the acquisition of specific skills, such as those required to safely perform a laparoscopic cholecystectomy.

As such, laparoscopic cholecystectomy became the first procedure for which a simulator was constructed (see Figure 22).[16] The "Laparoscopic Cholecystectomy Simulator" allowed learners to practice the isolation and clipping of the cystic duct and dissection of the gallbladder from its bed. It consisted of a square frame and a stainless steel tray on which a gallbladder was fixed. Openings in the square frame were made for laparoscopic instruments and a video camera was attached to the telescope and projected on a monitor.

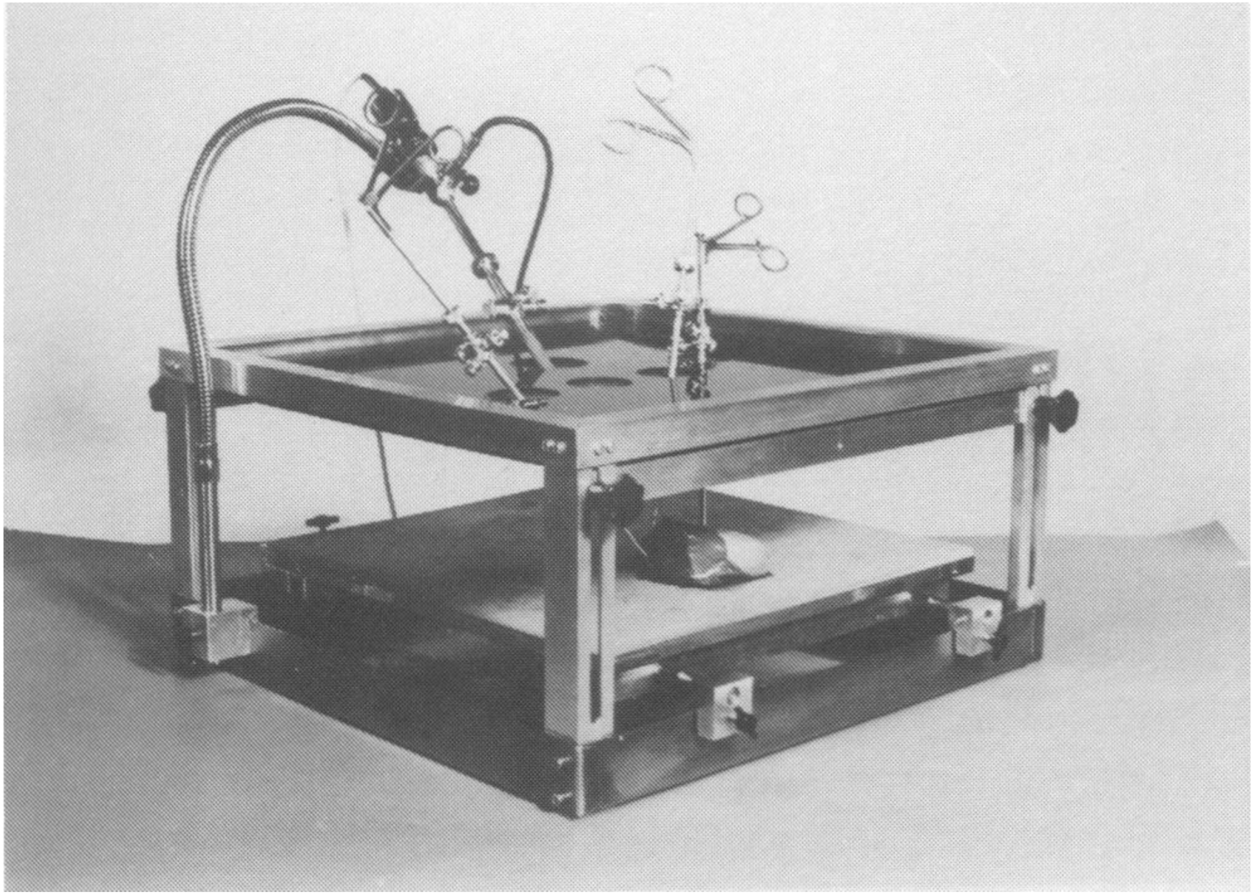

Figure 22 The Laparoscopic Cholecystectomy Simulator, the first described laparoscopic simulator in the literature (photo courtesy of Majeed et al. 1992, Copyright The Royal College of Surgeons of England. Reproduced with permission).

Although the simulator has evolved, its use now is considered mandatory as part of a structured course termed Fundamentals of Laparoscopic Surgery for General Surgery residents. Successful completion of this course is currently required to achieve board certification in General Surgery.

Coinciding with the rapidly growing demand for such physical simulators was a surge in digital technologies such as three-dimensional (3D) animation, allowing simulation to become computer-based. The processing power of computers now enabled smooth animation and real-time alteration of events based on actions undertaken by an operator. Furthermore, the quality of frame renderings allowed 3D animation to look even more photorealistic. Today, virtual reality simulation takes advantage of such technological advancements and has become more sophisticated in terms of training and assessment methods.

Current State of Surgical Simulation

Traditional low-fidelity simulation consisted of using animal models, which provided increased realism and the possibility to mimic complications, and human cadaver models offering the most realistic anatomy for trainees. Difficulty of preservation, high costs, limited reusability and rising ethical concerns were limiting factors. Gradually, synthetic bench top and computer-based models have replaced these earlier models. Synthetic bench top models have the advantage of being portable, reusable and lower cost that traditional cadaver or animal models. While computer-based simulation is also reusable and portable, it has the added advantage of being able to simulate intraoperative events (ex. unexpected bleeding, pneumothorax, etc.) and scenarios, as well as being capable of providing trainees with objective metric assessments. Recently, another form of simulation using perfused fresh human cadavers is being utilized, offering a high level of anatomic and hemodynamic realism. It consists of re-establishing blood flow circulation at the microvascular level in a fresh cadaver while maintaining adequate arterial and venous pressures.[17] While this type of simulation is considered to be the closest offering to life-like surgery conditions, the disadvantages include the need for personnel with expertise in the technique, the limited window of accessibility (fresh cadavers) and the high cost, somewhat limiting its usability for regular training sessions.

Training novices on synthetic simulators has been demonstrated to aid in the acquisition of necessary surgical skills and in the transmission of those skills into the operating rooms[18,19], allowing trainees to focus on the cognitive component of a procedure rather than its psychomotor component. Skills learned from such simulators ranged from skin suturing and intra-abdominal vessel ligation[20] to pediatric laparoscopic pyeloplasty[21] and bowel anastomosis[22]. Probably the most well-described and validated simulator is the McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS), initially introduced in 1998[23]. It consists of five tasks performed on a box trainer, which objectively assesses and trains novices on acquiring laparoscopic skills. Objective grading is given to each task based on accuracy and speed of execution of each: pegboard transfer, pattern cutting, ligation loop, intracorporeal and extracorporeal knots. Despite the basic nature of this and other similar simulators, the (low) level of fidelity of such bench top simulators has not been shown to alter the level of skills acquisition by novices as demonstrated in a study testing endourological skills[24].

Computer-based simulators, especially Virtual Reality (VR) training, has witnessed significant advancements in the past few years. The first VR simulator was described in 1993, when Richard Satava, MD, introduced the "virtual abdomen"[25]. This simulator illustrated the major organs that constitute an abdomen and some surgical tools, such as a scalpel and clamps. The operator was required to wear a head-mounted display to visualize the virtual abdomen and "DataGlove" to track hand movements, providing the operator with the possibility of visualizing organs in three dimensions and to cut through them. Today, VR simulators are increasingly sophisticated in terms of realism, level of interaction, possibility of objective assessment and haptic feedback. It has been shown that skills obtained on a VR simulator are transferable to the operating room[26,27]. For instance, LapVR is a virtual reality laparoscopic simulator consisting of two laparoscopic instrument handles, a camera, two foot pedals and a screen[28]. The operator can choose the type of desired training from four integrated modules: essential skill, procedural skill, obstetrics/gynecology module and general surgery procedures modules. After completing a procedure, the operator is provided with a printout of a comprehensive evaluation and a total score of his or her performance based on 100 integrated parameters such as time to complete a task, number of errors and path lengths of instruments.

With the previous introduction of Google Glass, the notion of "next generation" simulators or virtual surgery became one step closer. Although its discontinuation was disappointing in the realm of surgical education, other technologies such as the Microsoft Hololens have emerged and rekindled the potential role for such devices in simulation and training. With a potential introduction in 2016, Microsoft is slated to offer a "Development Edition" which will likely serve as the springboard for future applications of this technology in a variety of fields. One key difference and advantage of the Hololens over Google Glass is the 3-dimensional holographic image that the former produces, facilitating surgical simulation in real-time. The latter advance would allow the trainee to review anatomy or rehearse the steps of an operation virtually, amongst other skill acquisition tasks.

A more immersive experience into the VR world can be achieved via the Oculus Rift® (from Oculus VR, LLC), a new head-mounted device, which enables the perception of being physically present in a non-physical, computer-designed 3D environment. The interaction of the operator with the VR environment can be achieved using a hand position and motion detector such as the Leap Motion® (Leap Motion, San Francisco, US) device. The latter uses an advanced algorithm to analyze and reconstruct 3D images of the hands and instruments and project them into the VR environment. The device has a viewing range of 2.6 feet radial to itself and can filter undesired objects from the tracking process[29]. The combination of Oculus Rift® and Leap Motion® technologies would allow a trainee to perform an open surgery in a VR environment using both hands and the necessary surgical tools.

The evolution of VR simulators is not only beneficial in the realism of the training environment, but also holds the key to more detailed assessment of learner performance. Objective assessment of the trainee is a key tenet of a competency-based educational paradigm. A number of assessments have been developed, including the Objective Structured Assessment of Technical Skills (OSATS), introduced in 1997 by Reznick et al, which became the standard for surgical skills evaluation, in addition to a validation tool for new bench top model simulators[30]. Due to the digital environment of VR simulation, it can incorporate additional, more sophisticated methods of assessment, such as recording path length of hands/instruments[31,32] and eye tracking[33-35]. Studies have shown that significant differences in path length and eye tracking patterns exist between novices, intermediates and experts, providing another set of tools to objectively assess the learner's acquisition of skills.

The implementation of simulation training is not without cost. Simulators can range from about $5000 for basic laparoscopic simulators to up to $200,000 for highly sophisticated simulators[36]. Additionally, space for such simulation (simulation centers), funding for staff and or specialized training of educators/assistants and maintenance and/or disposables (for simulators that have a disposable physical component) cost, must also be considered. However, while simulation use may have some fixed costs associated with its implementation, there are potential financial advantages. Bridges and Diamond calculated that the additional time associated with resident participation in surgical cases amounts to a cost (estimated revenue loss) of $50,000 per resident over four years.[37] Should the use of surgical simulation for junior level residents provide them with a higher baseline skill level (ex. Dexterity or comfort with a surgical procedure), conceptually there may be a compensating time/income advantage to surgical educators that have residents trained ahead of time on simulators.

Plastic Surgery Simulation: Past and Present

Historically, the first surgical simulation in plastic surgery dates back to 600 BC. Sushruta Samhita, a preeminent Indian physician, used a leaf and clay model to simulate the steps of a forehead nasal flap reconstruction[38,39]. This simulation was performed to illustrate the steps of the procedure and did not aim to develop any surgical skills. The latter is an important point regarding the term "simulation". Sushruta simulated a procedure in an effort to determine the outcome of a procedure. In current terms, this could be analogous to computer-assisted design or simulation, which is increasingly used, in plastic surgery reconstructive procedures. Such software (ex. ProPlan CMF by Materialise©, Leuven, Belgium) is currently used to plan the oncologic reconstruction of mandible with a free osseous graft or the vectors and osteotomies of a pediatric mandibular distraction. This type of simulation differs from that designed to demonstrate (educate) the steps of a procedure to novices. A current example includes the cleverly animated SmileTrain Cleft lip videos, which elegantly demonstrate the numerous steps of a lip repair in three dimensions. The third definition of a surgical simulator pertains to the competency-based educational paradigm, and involves the use of the training device to develop a skill, and objectively demonstrate its competent performance.

Since the time of Sushruta, physical simulation use in plastic surgery has progressed slowly due to the ability to develop surgical skills on animals, cadavers and on patients in the operating room. To date only few physical simulators for plastic surgery trainees have been developed (Figure 23).

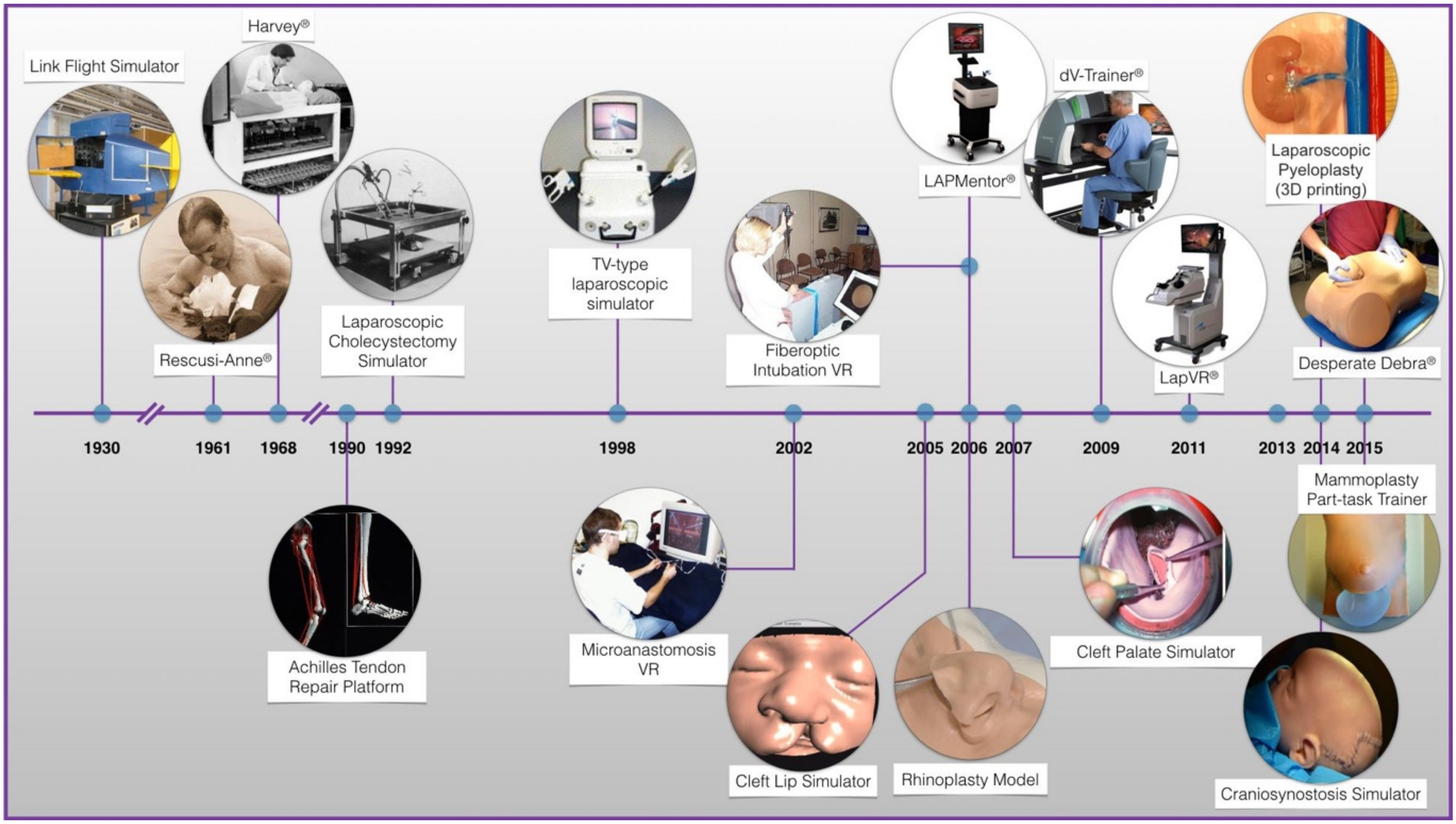

Figure 23 A timeline of simulation progression in healthcare (above) contrasted with the specific field of plastic surgery (below) showing the evolution from simple to more sophisticated simulators. Note the fewer and less-sophisticated nature of plastic surgery simulators compared to other medical fields (Credits: Rescusi-Anne® and Harvey® courtesy of Cooper JB et al. 2004, Laparoscopic cholecystectomy simulator courtesy of Majeed AW et al. 1992, Copyright The Royal College of Surgeons of England. Reproduced with permission, TV-type laparoscopic simulator courtesy of Korndorffer JR et al. 2006, Fiberoptic intubation VR courtesy of Goldmann K et al. 2006, LapMentor® courtesy of LAP Mentor, 3D Systems, dV-Trainer® courtesy of Mimics Technologies, Inc, LapVR® courtesy of © 2016 Images courtesy of CAE Healthcare, Laparoscopic pyeloplasty courtesy of Cheung CL et al. 2014, Desperate Debra® and Rhinoplasty model courtesy of Adam,Rouilly Ltd., Achilles tendon repair platform courtesy of Delp SL et al. 1990, Microanastomosis VR courtesy of Brown J 2001, Cleft lip simulator courtesy of Schendel S et al. 2005, Cleft palate simulator courtesy of Vadodaria S et al. 2007, Craniosynostosis simulator courtesy of Coelho G et al. 2014, Mammoplasty part-task trainer courtesy of Kazan R et al. 2015)

One of the earliest physical simulators for plastic surgery was a vessel anastomosis microsurgical kit[40] designed to train residents on end-to-end and end-to-side vessel anastomosis, an essential skill used in microsurgery. Anastomosis was performed under microscopy using 2-3 mm polyvinyl vessels and 9-0 nylon sutures and was shown to significantly improve trainee performance in the clinical setting. Another microsurgical simulator module[41] composed of a didactic and a technical component has been shown to enhance trainee's knowledge and technical proficiency in microsurgical anastomoses. Furthermore, a cleft palate repair simulator[42] was developed using a conical plastic jug to simulate the mouth opening of a 6 month old child, and latex and dense foam to simulate the mucosa and muscle layers (Figure 24). This simulator allows the operator to develop basic skills of cleft palate repair such as cutting and suturing in a limited space; however, it has not yet been validated. Other plastic surgery related bench top simulators have been found in the literature, such as a Z-plasty trainer[43] and a local flap transfer after basal cell carcinoma resection[44]; neither of which have been validated.

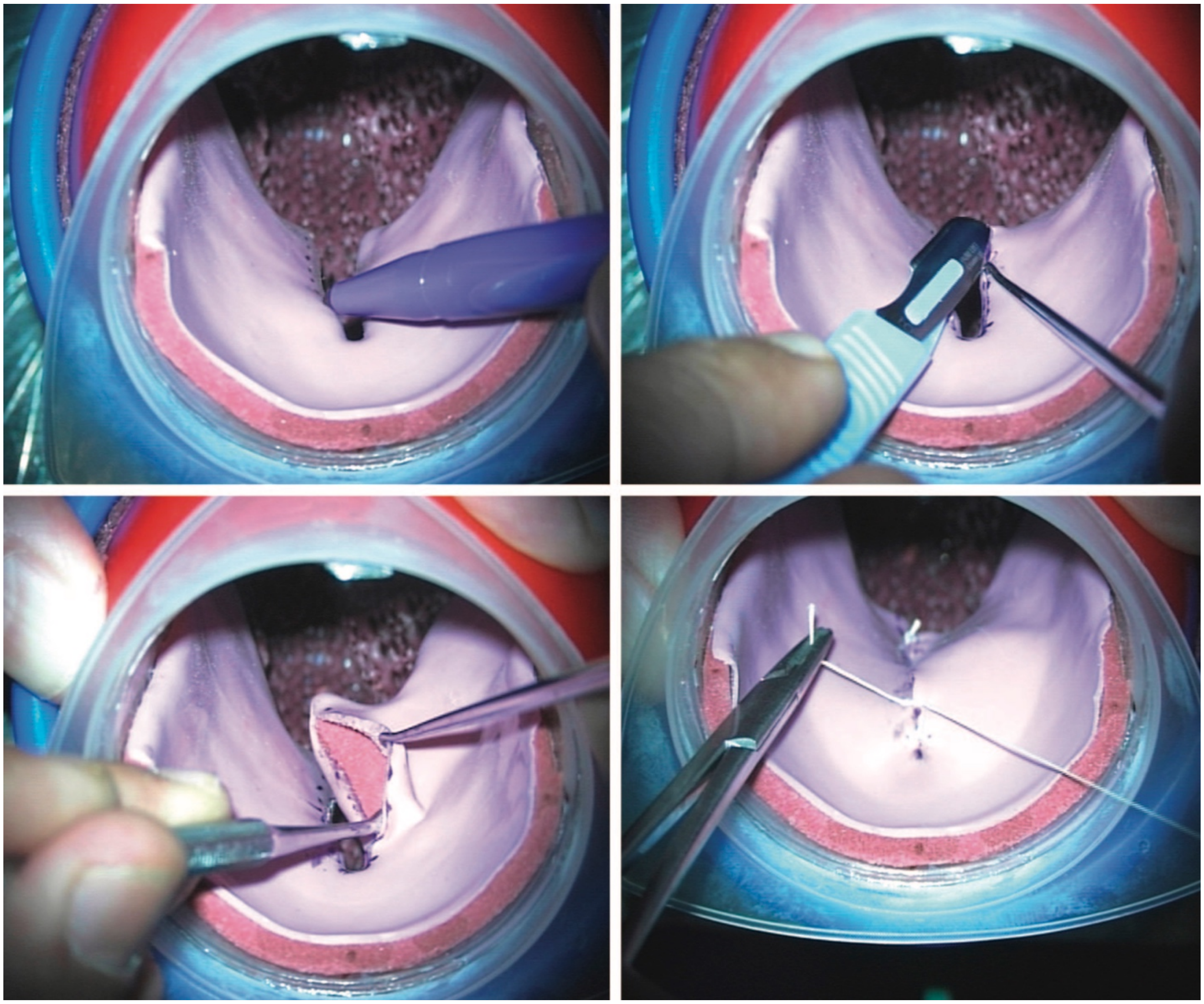

Figure 24 Cleft palate repair simulator showing the steps of the procedure (photo courtesy of Vadodaria S. et al. 2007).

Probably one of the most sophisticated bench top simulators is a craniosynostosis surgical simulator developed by a team from Sao Paulo, Brazil in collaboration with Harvard Medical School. The simulator, known as Anatomical Simulator for Pediatric Neurosurgery (ASPEN)[45], consists of a full body pediatric mannequin that allows the simulation of all surgical steps of the procedure from positioning to skin closure (Figure 25). The simulator can mimic bleeding from the superior and transverse sinuses, in addition to the ability to obtain pre- and post-operative CT scan images. The main drawbacks of the model are its time-consuming fabrication, cost and finally, that it has not yet been validated.

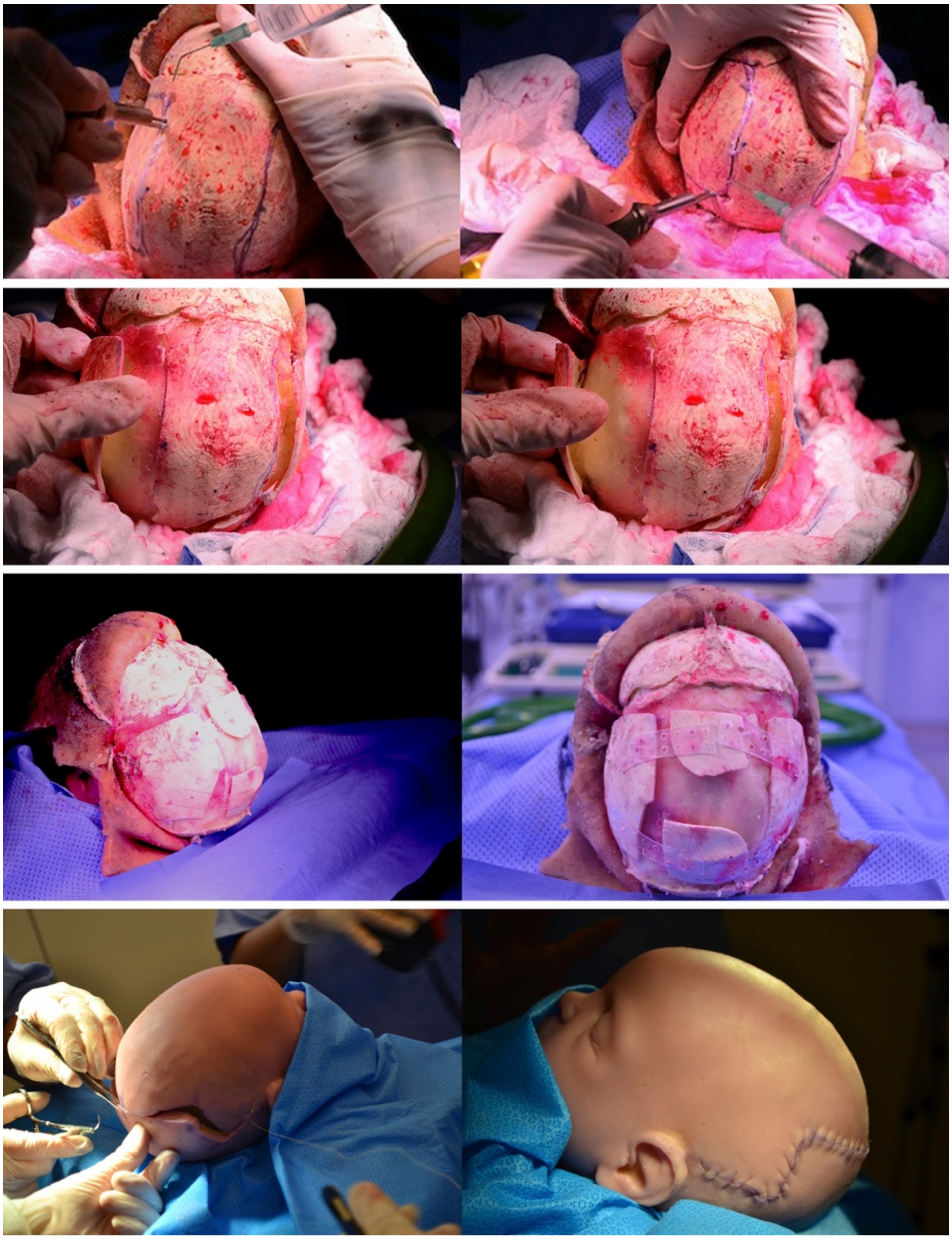

Figure 25 Craniosynostosis surgical simulator showing the steps of the procedures (photo courtesy of Coelho G et al. 2014).

Another more recent type of simulation (alluded to earlier in this report) for Plastic Surgery has been the adaptation of perfused fresh human cadavers by a team from the University of Southern California[17,46,47]. This model is capable of restoring the blood circulation in a fresh cadaver, thus enabling the simulation of a variety of plastic surgery specific procedures with a high level of realism, such as wound closures, flap dissections on pedicles and microvascular anastomoses. The team assessed residents' confidence level before and after the performance of the various procedures and have shown a significant improvement in their confidence level. As mentioned earlier, the complex nature of the set-up, the limited number of cadavers and time window, and high costs will likely limit the wide use of this type of simulation by residency programs.

Aesthetic surgery as a field has also had a surprisingly small amount of simulator development, despite the significant lack of hand-on exposure of trainees to such procedures. Due to the out-of-pocket cost nature of aesthetic surgery, there is often a reluctance for patients to accept resident participation to the same level as reconstructive surgery procedures. As aesthetic surgeries are not covered by healthcare insurance, the development of simulators in this field has had limited funding from governmental funding bodies although the number of aesthetic procedures performed yearly is still on the rise. The only synthetic bench top simulator found in literature that allows the performance of an aesthetic procedure is a mammoplasty part-task trainer developed by the current authors[48] (Figure 26). This simulator allows the performance of the essential steps of an augmentation mammoplasty procedure including skin incision, tissue dissection, pocket creation, implant insertion, skin and subcutaneous suturing. It was constructed using silicone, foam and rubber material and has undergone face and content validation.

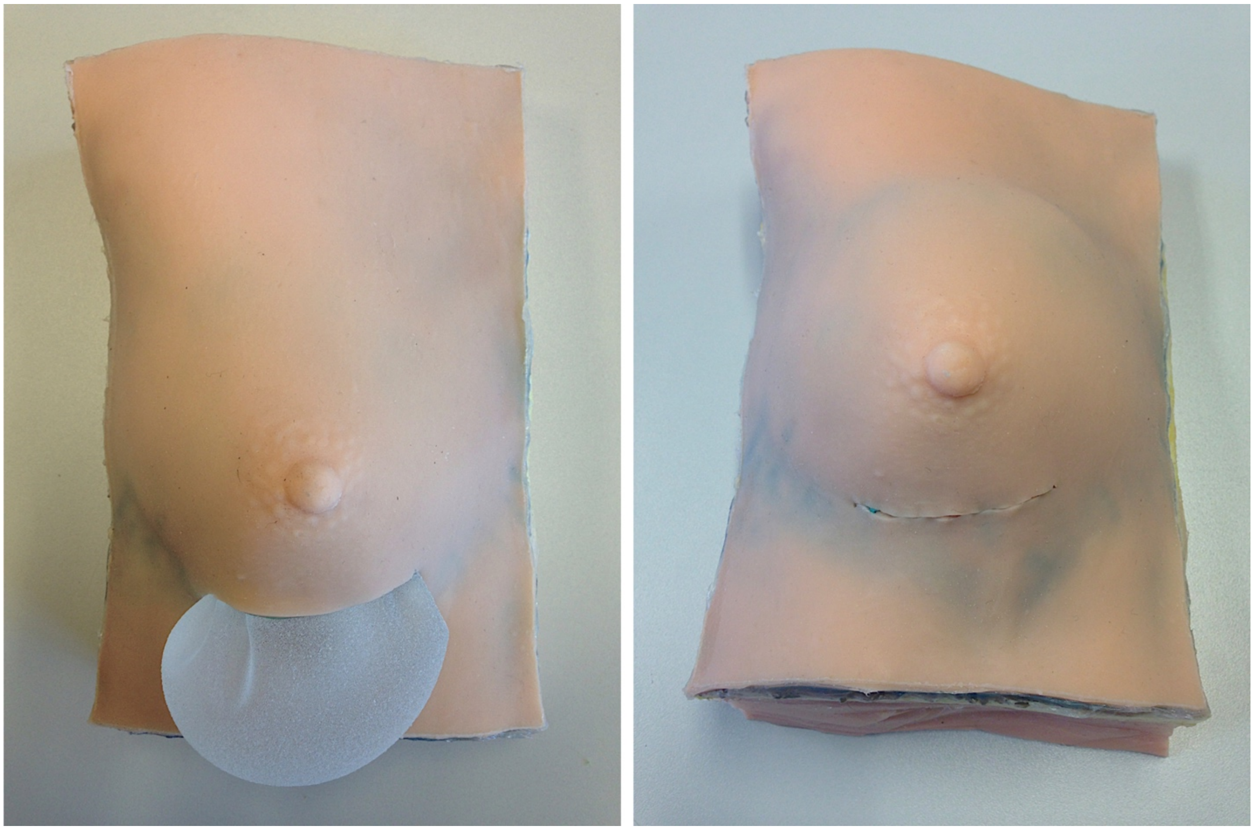

Figure 26 A mammoplasty bench top simulator that allows the performance of the main surgical steps of an augmentation mammoplasty procedure (photo courtesy of Kazan R et al. 2016).

Virtual reality simulation is the least advanced type of simulation used in plastic surgery education so far. Unlike general surgery, obstetrics-gynecology and urology, our specialty has yet to benefit from the advancements made in laparoscopic VR simulation. To date, the only plastic surgery specific, VR simulator available was developed by a team from Stanford University for microanastomosis simulation. The latter allows the performance of a vessel end-to-end anastomosis. Viscoelastic properties of blood vessels were generated in the virtual world and suturing filaments were also represented allowing the operator to perform the anastomosis in a highly realistic environment. Although potentially beneficial, this simulator has not been validated.

Educational Restructuring and the Evolving Role of Simulation in Plastic Surgery

The evolving role of CBME within plastic surgery has spawned from a growing pressure from regulatory bodies such as the Accreditation Council of Graduate Medical Education (ACGME) in the US and Royal College of Physician and Surgeons of Canada (RCPSC) in Canada, to effectively demonstrate competence and safe-practices of graduating trainees[49]. The Plastic Surgery Milestone Project (released in December 2013) has paved the initial steps towards a CBME curriculum for plastic surgery, defining specialty-specific global competencies or "milestones" to guide learners' progression. Together with the American Board of Plastic Surgery, the ACGME also produced assessment tools as part of this initiative, consisting of questionnaires and evaluation forms[50]. However, surgical simulators, despite being classified by the ACGME as the most desirable tool for evaluation of surgical skill, unfortunately continue to remain scarce for plastic surgery trainees.

To that end, substantial effort and financing need to be invested in the development and advancement of simulators for plastic surgery. Our specialty should take advantage of emerging and rapidly expanding technologies in order to construct more sophisticated simulators to meet the educational needs. Computation and information processing has become very potent allowing the construction of complex animations for virtual reality systems. The advancements in VR goggles, tracking systems and high quality graphical design software, further facilitate the construction of virtual reality environments, which could enable the operator to use physical instruments and perform surgical tasks on a virtual model projected directly through the goggles. On a similar note, the new emerging 360-degree video camera recording technology, such as the Bublcam (Bubl, Toronto, Canada) and the 360cam (Giroptic, San Francisco, US) can provide a fully immersive experience when visualized using a smartphone and head-mounted VR gear. The development of a 360-degree video library for plastic surgery procedures can represent a valuable learning tool for residents by allowing more aspects of a surgical procedure than recorded with traditional video (ex. Patient positioning, assistant's maneuvres, etc) to be appreciated by trainees. Furthermore, the rapid evolution of 3D-printing technology could be beneficial for the development and production of cost-effective, reusable bench top simulators.[51,52]

Importantly, the developers of such simulators must also be encouraged to perform validation studies to determine the utility of these tools as training devices. Face and content validation involves evaluating the level of realism of a simulator's features, the ability to perform the intended tasks and the value of the simulator as a training tool. Construct validation of a simulator, in turn, judges the simulator's ability to demonstrate a significant difference in performance between the different levels of experience (i.e. novices vs. experts). It is only with such data (face, content and construct validity) that these newly developed tools can be considered as effective and useful training or assessment tools.

From a program perspective, educational leaders should aim to implement a simulation-based assessment curriculum that matches the predefined milestones of the specialty. Residents' knowledge and technical skills should be periodically assessed in a non-clinical setting in order to standardize assessment conditions. This will lead to the identification of potential deficiencies across a range of both technical and non-technical skills, thus providing more accurate and unique data about residents' performance. In addition, simulation training could be implemented as a prerequisite for certain types of surgeries classified as "high technical skills" procedures such as microsurgery or “low exposure” procedures such as certain aesthetic surgeries performed less often by residents in an independent manner. Such a curriculum would improve baseline technical skills in novice residents, leading to a faster learning pace in the operating room.

Conclusions

Simulation in plastic surgery is still nascent, but with the introduction of competency-based education, demand may exponentially grow. Operative simulation is an area which plastic surgery should embrace, as it may be essential for the training of the future leaders in our specialty.

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