Université de Montréal

Thiel Embalmed Cadaveric Tissue

A Model for Surgical Simulation and Research

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Résumé

Le Collège royal des médecins et chirurgiens du Canada met actuellement en place des curriculums basés sur les compétences, plutôt que sur le temps, dans toutes les spécialités médicales et chirurgicales. La transition devrait être complétée en 2022. Les programmes de formation en chirurgie plastique au Canada devront repenser leurs curriculums pour se plier aux directives nationales. La simulation est la pierre angulaire du modèle de formation des résidents basé sur les compétences puisqu'elle permet aux résidents d'apprendre et d'améliorer leurs compétences dans un contexte éthique, sécuritaire, et mesurable objectivement.

Un consensus récent des directeurs de programme canadiens en chirurgie plastique a nommé 154 procédures essentielles de bases que les résidents doivent maîtriser avant la fin de leur formation. Nous proposons l'utilisation du modèle cadavérique Thiel pour la simulation haute fidélité des procédures en plastie. Les spécimens Thiel ont déjà été introduits dans une multitude de spécialités, incluant la plastie pour la dissection de lambeaux et la réparation de tendons. Nous nous sommes concentrés sur l'évaluation des spécimens Thiel pour la maîtrise des anastomoses vasculaires, la réparation des nerfs périphériques, et la réparation des tendons fléchisseurs. Par ailleurs, nous avons développé des instruments d'évaluation pour chacun de ces domaines de simulation. Des trois instruments, nous avons validé les échelles d'évaluation des anastomoses vasculaires et nerveuses. Ces deux échelles ont démontré d'excellents degrés de fiabilité et de reproductibilité et sont bien corrélés avec le niveau de formation et d'expérience des sujets. Le modèle de réparation des tendons fléchisseurs a démontré un degré plus élevé de variaiblité inter-évaluateur, et, quoique prometteur, il n'a pas pu être complètement validé basé sur les données actuelles. De plus, nous avons utilisé les vaisseaux Thiel comme un modèle de recherche pour l'investigation de nouvelles techniques microvasculaires.

Notre expérience montre que les spécimens cadavériques Thiel sont un excellent modèle de simulation pour la chirurgie microvasculaire et la réparation des nerfs périphériques et des tendons fléchisseurs. Nous proposons des instruments d'évaluation pour assister à l'implémentation de ces modèles de simulation dans les curriculums basés sur les compétences en chirurgie plastique.

Mots-clés : Thiel, simulation, chirurgie, chirurgie plastique, microchirurgie, microvasculair, micro-neurorrhaphie, tenorrhaphie, reparation tendon, cadaver, technique de conservation, technique d'embaumement.

Abstract

The Royal College of Physicians and Surgeons is currently implementing a major shift from a time based to a competence based curriculum in all medical and surgical specialties. By 2022 the transition is to be complete. The plastic surgery training programs in Canada will have to rethink their curriculum in order to comply with the national directives. Simulation is a cornerstone of the competence based model of resident training as it not only allows residents to safely learn and hone their skill in a setting that is ethical and promotes patient safety, but it allows for objective evaluation of their performance.

A recent consensus statement from the Canadian plastic surgery program directors identified 154 essential core procedures for residents to master by the end of their training. We propose the use of the Thiel cadaveric model for high fidelity simulation of plastic surgery procedures. While Thiel cadaveric specimens have been proposed for use in a multitude of specialties, including in plastic surgery for flap dissection and tendon repair, we focused on evaluating the use of the Thiel embalmed specimens on three core procedures: microvascular anastomoses, peripheral nerve repair, and flexor tendon repair. In addition, we designed evaluation instruments for each of these three simulation areas to help grade performance and aid in the feedback/debriefing process. Of the three evaluation instruments, we successfully validated the microvascular evaluation and micro-neurorrhaphy evaluation scales. Both of these scales showed excellent degrees of reliability and reproducibility and correlated well with the level of training and self-declared experience of the subjects. The flexor tendon evaluation scale showed a higher degree of inter-rater variability and, while it shows promise with a larger cohort of participants and additional calibration, it could not be validated fully based on the available data. Additionally, we used the Thiel embalmed cadaveric vessels as a research model for the investigation of new microvascular techniques.

Our experience shows the Thiel cadaveric specimens to provide an excellent model for simulating microvascular, peripheral nerve and flexor tendon repairs. We propose evaluation instruments to assist in the implementation of these simulation models in a comprehensive, competence based curriculum in plastic surgery.

Keywords: Thiel, simulation, surgery, plastic surgery, microsurgery, microvascular, micro-neurorrhaphy, tenorrhaphy, tendon repair, cadaver, preservation technique, embalming technique.

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Liste des sigles

ABS: American Board of Surgery

ACS: American College of Surgeons

ALT: Anterolateral thigh flap

AO: Arbeitsgemeinschaft für Osteosynthesefragen (German for "Association for the Study of Internal Fixation")

CanMEDS: Physician competency framework implemented by the Royal College of Physicians and Surgeons of Canada

CBD: Competence by design

CI: Confidence interval

DIEP: Deep inferior epigastric perforator flap

ENT: Ear nose and throat

EPA: Entrustable professional activity

FDS: Flexor digitorum superficialis

FDP: Flexor digitorum profundus

FTES: Flexor tendon evaluation scale

GRS: Global rating scale

H&E: Hematoxylin and Eosin

HIV: Human immunodeficiency virus

HM: Horizontal mattress

ICC: Intra-class correlation coefficient

MNES: Micro-neurorrhaphy evaluation scale

OSATS: Objective structured assessment of technical skills

OSCE: Objective structured clinical exam

PACS: Picture archiving and communication system

PGY: Postgraduate year

SAMS: Structured assessment of microsurgery skills

SEM: Scanning electron microscope

SI: Simple interrupted

Three R: Replacement, reduction, and refinement

TRAM: Transverse rectus abdominis musculocutaneous flap

UWOMSA: University of Western Ontario microsurgical skills acquisition/assessment

Liste des abréviations

Dr. : Doctor

Prof.: Professor

In memory of Virgil Odobescu MD Ph.D.,
a great father and surgeon.

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Introduction

0.1. The evolution of medical simulation

It is human nature to seek medicine when treating ailments of the body, much in the same way as it is human nature to turn to religion to seek comfort for the soul. We lay our faith and future in the hands of a physician with the expectation that, through their knowledge and skill, they will help us pass through our difficulties and make us well again. This, in essence, constitutes an extraordinary leap of faith, unparalleled in any other area of social interaction. This faith is balanced by society's expectation from physicians to live by a moral code established by Hippocrates, by many considered the father of western medicine, more than two millennia ago and commonly referred to as the Hippocratic oath. As doctors, we carry the responsibility to honor and protect the confidence and faith our patients have, and always strive to do better for our patients. Yet if we look at what constituted the field of medicine at the time of Hippocrates, and compare it to what it is today, the change is nothing short of a miracle, giving us hope that we can accomplish far more in the future.

From times immemorial, medical teaching, like any other art or craft, has been passed on from one generation to another in the form of apprenticeship. Each member practicing the art would receive a certain wealth of knowledge from the teacher, crystalize and hopefully improve it and eventually pass it on to the next generation of learners. In the absence of any central regulatory body, either governmental or professional, this apprentice model must have led to a significant degree of variability in physician's skill and knowledge. While the Hippocratic Oath served as a moral beacon for medical practitioners, it took many centuries for society to evaluate the role of medicine and set standards and rules to provide order to chaos. In North America, Abraham Flexner is credited for having catalyzed the reform of medical education through his 1910 report on medical education, commonly referred to as the Flexner Report (1-3). In short, Flexner describes the state of medical education in the United States and Canada, where at his time there were 155 medical schools in existence with no set standard. He suggested the training of medical doctors should reflect society's need for such a service, and that the quality of the doctors should be high and more or less evenly distributed, such as to provide good care anywhere. As a solution to this problem, Flexner suggested a reform of the medical education system with strict admission standards, incorporate medical schools into larger universities placed in urban areas that could support the infrastructure and required patient basis. Since he considered inflation of medical doctors a sign of poor quality service, he suggested reducing the number of medical schools from 155 to 31, with the total number of graduates to echo the need of the population.

Medical simulation is somewhat of a new concept, and it was born out of the same need Flexner identified as crucial in the standardization of medical care: to offer high quality and safe medical care. Like any skill we learn in life, the surgical technique has a learning curve, sometimes steeper, sometimes less steep. In the same way, a child falls over and over again when learning how to walk, so medical students and residents “fall” when they first learn how to asses a patient, when they incise and dissect, when they handle tissue with instruments or start to suture. It is only natural and nobody is born an expert. Yet the difference between surgery and most other learning processes we encounter in life is that the patient is paying the bill for our mistakes. This is in a sense the collateral damage of medical education and patients are willing to accept it when seeking healthcare in a teaching hospital, provided they receive care from an experienced medical provider supervising the learner. For this reason, Arbogast and Rosen suggest that a revolution comparable in magnitude to Flexner’s report is now necessary; according to the authors, this is found in the form of simulation (2).

We often hear the dictum « see one, do one, teach one ». We probably all heard it many times during medical school, and we use it often ourselves, even though it implies a crude approach to skill learning and teaching. To take the example of arterial line placement: how do medical students learn to do an arterial line? They first see it done by a trainee senior to them, and then they pull themselves together and try to reproduce what they learned. One attempt, two, three, or more, eventually either the procedure succeeds or the trainee stops and hopes for a better day next time. How many tries is considered safe is subject to interpretation, and the trainee and teacher need to determine where the « do no harm » stops and the harm begins. Are there possible permanent negative consequences the patient can sustain? Certainly! The radial artery can thrombose, which can sometimes lead to hand ischemia and even necrosis. The next question becomes: what ethical alternatives do we have to learn medical and surgical skills? The answer, in short, is simulation. In the case of learning the skill of placing arterial lines, mannequins have been developed offering trainees the possibility to climb their learning curve outside the clinical setting.

While these mannequin simulators have been implemented by most medical schools in the western hemisphere in the undergraduate medical curriculum, we still teach many of the more complex surgical skills directly on patients. As medical educators, we have the responsibility to develop adequate simulation models for our trainees such that they climb most of their learning curve in a patient free setting and only then apply what they have learned to the operating room. This is a moral responsibility, much like the implementation of ethics in medical research. The interest in medical simulation research over the last two decades is proof that we are witnesses to a shift in medical education towards simulation-based learning.

0.2. From time-based to competency-based surgical training

As mentioned above, there is an ethical reason to implement simulation in the medical curriculum. We have the moral obligation to do all in our power to provide the best medical care and do no harm, and by moving along the learning curve in a simulated setting we decrease the harm inflicted on the patient. It is in this context that we have to consider two competing models of education: the time-based and the competency-based models. While the current trend in North American postgraduate medical education is to shift towards the competency-based model, most curricular are still time-based. That means that trainees are expected to spend a set time in training, hoping that the required competence is directly related to the training period. Most surgical residencies vary from 5-7 years in length. A competency-based curriculum, on the other hand, has certain objectives that trainees need to meet in order to promote to the next level.

To understand the advantages of the competence-based over the time-based curriculum, we need to consider a simple scenario: Resident A and B are at the same postgraduate level and start on rotation in a microsurgical center. Resident A has practiced microsurgery in the lab, has acquired the necessary skill to perform safely and efficiently the microvascular anastomosis. Resident B has not had the same opportunity, and the mere thought of doing microsurgery causes, as expected from the unknown, a measure of distress. Resident A will assist his attending in microsurgery and at one point the latter will offer the instruments to his resident to perform the anastomosis, of course after asking if he had done so before. Since he had practiced, the answer is affirmative, with the caveat that it had been done in a simulated setting. Resident A takes the instruments and likely performs the procedure in a safe manner. Resident B is asked the same question, and after apprehension fueled by the negative answer, the attending gives over the instruments. Since microsurgical skill differs from general surgical skill, resident B is poorly positioned, executes the suture with difficulty and possibly injures the vessel, at which point their supervisor, in the interest of patient safety, takes over. At the end of the day, resident A will be allowed to do more microsurgery, while with the normal human apprehension of the attending, resident B will be a while before doing microsurgery. The skill gap between residents A and B quickly increases, with the former soon dissecting the entire flap and the latter following a more frustrating path. This scenario, while hypothetical, is certainly not far removed from the reality of today's surgical training models. Research has shown that now all trainees acquire the necessary skill by the end of their training (4). While the resident A will likely turn out to be very well trained, his or her proficiency does not excuse the lower level of skill and knowledge of resident B. This leads us back to Flexner's principle that a good medical education has to provide a homogenous population of surgeons who will serve their patients well.

The Royal College of Physician and Surgeons of Canada has decided to move to a competency-based curriculum and all medical and surgical specialties. This program, named "Competence by Design" (CBD), is in full transition mode and is projected to be completed by 2022 (5). While the full meaning of CBD curriculum is still a matter of debate, simulation will undoubtedly play a crucial role in the development and implementation of these types of curricula.

0.3. Simulation models in surgery

The focus of this thesis is on simulation as it pertains learning and improving surgical skills and reasoning. We look at simulation as an instrument for acquiring the necessary knowledge and skill to become or improve one's level of proficiency in surgery. As such, this thesis is focused on postgraduate medical education, at the residency and fellowship levels. The other meaning of the term simulation in the field of surgery, pertaining to pre- or intra-operative modeling, while it aims to improve the outcome of a procedure, does not directly aim to improve the skill of the surgeon and as such it is left out of the spectrum of this work and analysis.

In order to define how simulation applies to surgery, a number of definitions have to be discussed. Rosen and colleagues, in their 2009 article on simulation in plastic surgery training and education, provide an excellent section on definitions and principles pertaining to simulation (6). A *model* is defined a « physical, mathematical, or logical representation of a system, entity, phenomenon, or process » (6). The Oxford dictionary provides five definitions of the noun model, of which only two could pertain to what a model is considered in surgery. A model is « a simplified description, especially a mathematical one, of a system or process, to assist calculations and predictions » or alternatively, « a three-dimensional representation of a person or thing or of a proposed structure, typically on a smaller scale than the original » (7). For the purpose of simulation in medical education, one could consider the following characteristics as necessary to represent a model: 1. simplified yet effective representation of a real life, 2. the state of which could be physical or virtual, and 3. can be used as a replacement for the reality it imitates.

Simulation refers to a « model implemented over time, from nanoseconds to centuries, displayed either in "real time" or faster or slower than real-time » (6). The Oxford Dictionaries define the verb to simulate as « imitate the appearance or character of » something else (8), which seems to be a less opportune definition than that set forth by Rosen (6). For the purpose of medical education, we can consider the following characteristics for simulation: It represents a scenario that implements the model, for the purpose of improving skill, allowing a dissection of the performance into its basic steps and analysis for the purpose of feedback. Finally, a *simulator* is « a device that uses simulation to replace a real-world system or apparatus, allowing users to gain experience and to observe and interact with the simulation via realistic visual, auditory, or tactile cues » (6). According to the Oxford Dictionaries, a simulator is « a machine designed to provide a realistic imitation of the controls and operation of a vehicle, aircraft, or other complex system, used for training purposes » (9). For the purpose of medical education, one can look at a simulator as an instrument to confer a virtual reality model, realistic properties such as visual, acoustic or tactile cues. Since the subject of this thesis pertains to a physical model, a simulator is unnecessary.

There are a number of elements that need to align in order to allow effective simulation. The first is an adequate model. In surgery, this entails a substitute for the organ or body part that is as close to reality as possible. Once this prerogative is met, the trainee needs to perform a scenario that will allow them to practice the surgical technique in question in a manner most closely resembling a real operating room setting. The better the model and scenario, the higher the fidelity of the simulation. The last element in the loop is the evaluation of the performance followed by a debriefing, which has the objective of providing insight to the trainee on the adequacy of his gestures and the areas of improvement. This allows for correction of improperly performed gestures in subsequent simulation sessions with an eventual improvement in skill.

Dr. Satava, in a 2010 article on the emerging trends in surgical simulation, provides a thorough history of simulation in surgery and the state of the art at the time of publication (3). He speculates that the implementation of simulation in the surgical curriculum is driven by two major forces: the emergence of new technology and the social and political pressure for safer patient care. The new technologies in this context could be interpreted as new models, not necessarily virtual reality models. The curricula and assessment tools are another essential element. The objective structured clinical exam, also known as OSCE, is one such instrument designed to assess the history and physical examination and has since been widely implemented in the medical curricula. On the psychomotor skills side, an instrument was developed by Resnick and colleagues entitled « objective structured assessment of technical skills », also known as OSATS, which has since been adapted to a number of specific areas, such as laparoscopy or microsurgery. Satava stresses the importance of benchmark assessment of skill, such as to allow a shift from time-based to competency-based learning (3). The principle of this is that in order to be considered proficient in performing a technique, one has to practice it, be evaluated and pass the benchmark test in order to be allowed to move on. Just having spent time seeing or doing the technique with no measure of success is not adequate in this day and age. This concept is starting to be introduced in the surgical education world, with the American Board of Surgery (ABS) requiring trainees to show proof, for example, of successful completion of the fundamentals of laparoscopic surgery simulation course before sitting for their surgery qualifying exam (2).

The American College of Surgeons (ACS) defined three phases that would span the entire spectrum of simulation as it pertains to surgery. The most basic is skills training, followed by procedure training and finally team training (3, 6). The ACS has defined twenty-one basic surgical skills that junior residents need to master. These are enumerated by Rosen et al and reproduced, with permission, in figure 1 (6). These skills are purely technical and require the trainee to familiarize and polish a set of fine motor skills that they will be able to integrate and refine (6). All these skills are undoubtedly necessary for the technical progress of any resident in surgery, regardless of subspecialty, however one has to realize that some essential skills necessary to the modern plastic surgeon are omitted on the list, and certainly far enough from these 21 skills that they cannot just be mastered by extrapolation of any of these. This topic will be further discussed in the following subchapter.

Skill	General Surgery	Plastic Surgery	Both
Advanced laparoscopy skills	+		
Advanced tissue handling: flaps, skin grafts		+	
Airway management	+		
Anastomosis: hand-sewn gastrointestinal	+		
Anastomosis: stapled gastrointestinal	+		
Anastomosis: vascular		+	
Asepsis and instrument identification	+	+	
Basic laparoscopy skills	+		
Catheterization, uretheral and suprapubic	+		
Central line and arterial line insertion	+		
Chest tube and thoracentesis	+		
Colonoscopy	+		
Introduction to inguinal anatomy	+		
Knot tying	+	+	
Laparotomy opening and closure	+		
Principles of bone fixation and casting		+	
Surgical biopsy	+	+	
Suturing	+	+	
Tissue handling, dissection, wound closure and management	+	+	
Upper endoscopy	+		
Wound management	+	+	

*American College of Surgeons/Association of Program Directors in Surgery National Skills Curriculum specifies 21 basic surgical skills for postgraduate year 1 and postgraduate year 2 surgical trainees to master.

Figure 1. ACS basic skills for PGY 1 and 2 in general surgery and plastic surgery. Reproduced with permission from Rosen et al Plast Reconstr Surg 123(2009):729-38

The procedure training builds on the base established by the skills training but adds to the complexity by combining cognitive learning in addition to the mechanical learning (6). One such example of procedure training is laparoscopic appendicectomy. The trainee needs to integrate the basic laparoscopic skills learned with knowledge of the normal and pathologic anatomy, the surgical sequence, possible pitfalls etc. In the field of plastic surgery, carpal tunnel release can be thought of as a prototypal procedure. As more than just fine motor skills need to be mastered, a model for procedure training exponentially increases in complexity, and consequently cost. Team training deals with communication and interprofessional skills that are necessary for the good undertaking of any surgery, and as such is quite similar between surgical specialties (6).

In his article on the emerging trends in medical simulation, Dr. Satava looks at simulation models as either of the traditional or emerging kind (3). Traditional models are physical models or animal parts, whereas the emerging models are mannequins, computer-based interactive programs or virtual reality models. The different simulation modalities are summarized in figure 2 as proposed by Dr. Chiniara (10).

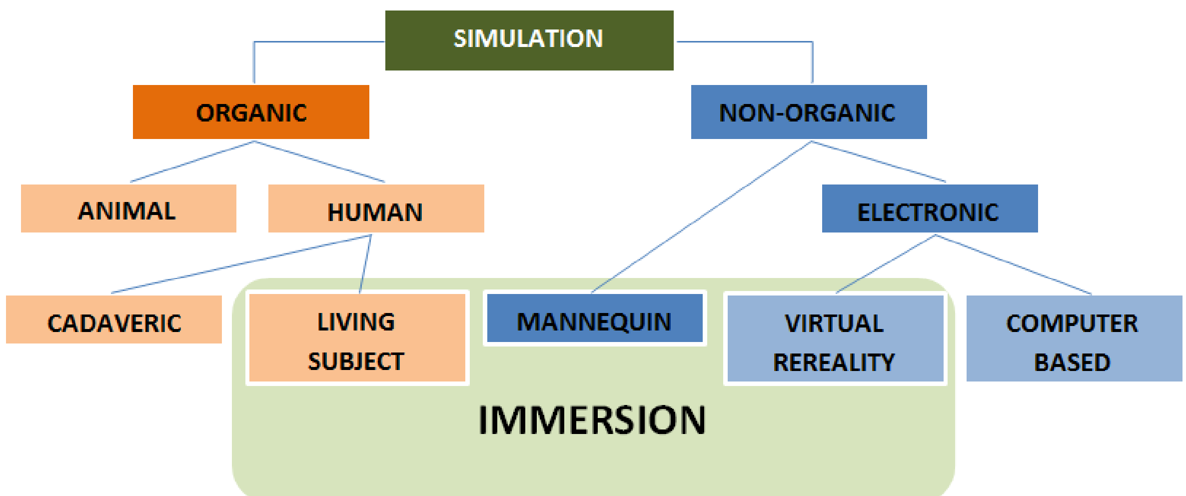

Figure 2: Classification of simulation models. Adapted with modifications from Dr. Chiniara.

Reznick and MacRae, in their New England Journal of Medicine review article on teaching surgical skills, classify surgical simulators as bench models, live animals, cadavers, human performance simulators and virtual reality simulators, and give a list of advantages, disadvantages and best use for each (figure 3) (11). These five classes described by Reznick and MacRae cover the entire spectrum of current simulation, and we think can be further classified as either physical or virtual models. Bench, live animal, cadaveric and human performance simulators are physical simulators while virtual simulators are those that involve a computer-generated virtual reality. Reznick and MacRae consider the cadaveric model as « the only true anatomy simulator » available, statement that is a testament to the irreplaceable contribution of cadaveric models in medical education. While much effort and expense have been geared towards virtual reality in an attempt to replace the cadavers with a safer, more available model that avoids the disadvantages of cadavers, there is no virtual reality simulator that is able to match the high fidelity of the cadaveric model.

Types of Simulations Available.

Simulation	Advantages	Disadvantages	Best Use
Bench models	Cheap, portable, reusable, minimal risks	Acceptance by trainees; low fidelity; basic tasks, not operations	Basic skills for novice learners, discrete skills
Live animals	High fidelity, availability, can practice hemostasis and entire operations	Cost, special facilities and personnel required, ethical concerns, single use, anatomical differences	Advanced procedural knowledge, procedures in which blood flow is important, dissection skills
Cadavers	High fidelity, only "true" anatomy simulator currently, can practice entire operations	Cost, availability, single use, compliance of tissue, infection risk	Advanced procedural knowledge, dissection, continuing medical education
Human performance simulators	Reusable, high fidelity, data capture, interactivity	Cost, maintenance, and downtime; limited "technical" applications	Team training, crisis management
Virtual reality surgical simulators	Reusable, data capture, minimal setup time	Cost, maintenance, and downtime; acceptance by trainees; three dimensions not well simulated	Basic laparoscopic skills, endoscopic and transcutaneous procedural skills

Figure 3. Types of simulation available. Reproduced with permission from Reznick and MacRae / NEJM 355 (2006) 2667, Copyright Massachusetts Medical Society.

0.4. High and low fidelity simulation

As Miller eloquently put it « simulation is not all or none, it is a matter of degree » (12). Simulation models and simulators can range from very basic, like a piece of latex glove for the teaching of microsurgical sutures, to very complex models, such as lifelike mannequins giving feedback in real time to the trainee or virtual reality models. This degree of complexity also corresponds with the associated cost, despite the fact that technology is becoming more affordable. For example, mannequins such as the SimMan® cost around 70,000$, to which one has to add the consumables and service fees. Yet does the level of complexity of a model, alone, give any indication of how good the model is? And what are the properties that make a simulator good? How closely a model emulates reality is measured by a concept called « fidelity ».

Fidelity is synonymous with faithfulness and is defined as « the degree of exactness with which something is copied or reproduced » (13). There is generally a lack of information in the medical simulation literature regarding the meaning of fidelity. While most authors use the term « high fidelity » as a branding for their simulator, the careful definition of what constitutes fidelity is less well established in medicine. As defined by Maran and Galvin, « fidelity is the extent to which the appearance and behavior of the simulator / simulation match the appearance and behavior of the simulated system » (14). We assume that the more complex a model and simulator, the more life-like it will be, however, this does not necessarily hold true. A mannequin can serve as a model for suturing, give real-time feedback regarding discomfort and pain, yet by the limitation of the artificial materials it cannot, to date, reproduce the texture, elastic modulus or feedback that a cheaper model, such as animal parts can offer. We can consider that animal skin and subcutaneous tissue, by virtue of its architecture and tissue composition, are closer to human skin and therefore confer a higher degree of fidelity. Yet fidelity is a much more complex concept than that.

An excellent description of fidelity and how it can be further subdivided is found in the article of Maran and Galvin (14). According to the authors, the distinction between engineering and psychological fidelity has been initially described by Miller (12). While he does not use the word « fidelity » in his description, Miller talks about two components to simulation: an engineering component, which relates to the degree to which a physical model and its properties are copied, and the psychological part, which relates to how well the responses learned during simulation translate into appropriate actions in real life operations. It is the engineering part of his description which matches the dictionary description of the word fidelity and also the meaning of Maran and Galvin's definition stated above; the psychological part, while considered the major aim of any simulator by Miller, is less well understood.

Perhaps the terms used by Miller, engineering, and psychologic simulation are remote of the medical reality, and contribute to the difficulty of integrating these two concepts in the medical education world. One has to consider that the work of Miller predates by decades the development of medical simulation, and comes from the field of military aviation. We need to consider this when regarding the use of terms such as engineering and psychology in his description since simulation in aviation and/or military has other technical requirements and objectives. Since models in medicine do not have to be necessarily engineered, contrary to say aviation, we can refer to this property of the model and simulator as physical fidelity. Conversely, as it applies to surgery, it seems more opportune to functional fidelity rather than psychological fidelity.

Functional fidelity is considered more important than its physical counterpart because it is the actual aim of the training session. At the end of the training, what is important is the skill learned and how well it applies to the real world application. The degree of physical fidelity, if it does not modify the functional fidelity of the model, has in itself little-added value. Miller concludes that the training problem is to « provide stimuli so that responses learned to them will transfer from training to operations with little or no loss ». Yet if we look at where the money is spent in designing a simulator, the high cost is associated with improving the physical fidelity. Miller provides an accurate if rudimentary cost-benefit analysis of simulation. The author is of the opinion that as one increases the engineering fidelity, the training value increases proportionally at the beginning, followed by a flattening of the curve where there is little training value gained for each increment in physical or engineering fidelity. If this graph is now superposed on that of cost as a function of engineering fidelity, one can determine the point along the x-axis (engineering fidelity) optimizes the training value and cost. This point is described as the point of diminished return since any increase in fidelity from this point on would result in an exponential increase in cost with only a marginal increase in training value (12). For these reasons, the objective of creating a simulation model is maximizing the training value, and not creating the most lifelike environment.

A number of authors have suggested that for acquiring simple skills a simple model can be more than adequate, especially when the trainee has very little experience (11, 14). In complex tasks and when the trainee has a higher level of proficiency, it is beneficial that the model is of high fidelity so as to avoid negative transfer (14). This increase in fidelity would reach higher and higher levels and one has to wonder when this increase in fidelity, based on the associated higher and higher costs mentioned in Miller's cost-benefit analysis above, becomes prohibitive. One has to determine when the need for simulation becomes obsolete. Somebody who is already very proficient at laparoscopic surgery need not use a simulator for further improvement; at that point, their skill would be sufficient to justify operating on patients and with perpetual practice and performance of more and more complex cases, the skills of this already proficient surgeon would improve. There is one counterargument to this way of thinking, and that is the « deliberate practice » theory proposed by Ericsson (15) and described in detail in the debriefing section below.

Based on the definitions and theories on fidelity mentioned above, the question we need to ask is: What constitutes a high fidelity simulation model or simulator in medical education? If we consider the information provided by Reznick and MacRae in the table mentioned above (16), live animals, cadavers and human performance simulators are all labeled as « high fidelity ». If we look from the perspective set forth by Miller, the label of what is high or low fidelity is more related to the specific task, more in terms of functional than physical fidelity (12). A model or simulator could potentially be high fidelity for one task and low fidelity for another. For example, a mannequin simulator such as SimMan ® is of high fidelity for training crisis management skills, such as advanced cardiac life support, yet it fails to perform as well when it comes to performing a tracheostomy, for which the pig model is more adequate. Furthermore, the proficiency level of the trainee also factors into where along the spectrum of fidelity a simulator is placed. A well-trained microsurgeon wanting to hone their skill in order to acquire proficiency on very small vessels, such as lymphatics, will exert much more scrutiny than a resident who is learning the basics of microsurgery, for whom silastic tubing can be considered of high fidelity.

0.5. Simulation models in plastic surgery

Dumestre and colleagues looked at the simulation models published in microsurgery, and out of 238 articles the authors reviewed, only 9 provided adequate validation of their described model for microsurgical skill training (17). This systematic review, while focused on the microsurgical literature, suggests that while much has been published in recent years in simulation, these studies are often of questionable quality.

As described in figure 3 above, Reznick and MacRae make the difference between bench models, cadaveric, animal, human performance simulators and virtual reality simulators (11). While Rosen and colleagues focus on the virtual reality part of the simulation (6), it would be a gross oversight to forget the lower technology simulators which have been used and continue to occupy a strong role in the simulation arsenal pertaining to plastic surgery.

Bench models are the foundation of surgical skill training. The prototypal model is learning to do a hand tie. Medical students learn their knot tying yarn to chairs or doorknobs. Ethicon Inc (Johnson&Johnson, Somerville, NJ) produces a knot tying kit that in addition allows for placement of deep knots. More specific to plastic surgery, microvascular sutures are practiced on latex gloves or increasingly more complex artificial models that are currently commercially available. These rather basic models, under magnification, allow for basic microvascular skill practice, such as suture placement, correct manipulation of the needle and suture, knot tying. Silicone tube models permit the practice of a complete anastomosis including learning how to distribute the stitches around the circumference of the vessel. Diathermy cleaning pads, polyurethane and rubber cards have been validated for basic skill training (17). Since microsurgical skill is very different from the skills one learns in other surgical specialties, the most basic of skills in microsurgery can be efficiently learned using these cheap models despite the low physical fidelity.

Higher fidelity models are needed in order to have adequate tactile feedback, lifelike tissue handling and the possibility to verify the patency of the anastomosis. Most authors would agree that the current gold standard for microvascular anastomosis practice remains the rat femoral artery (18). However, a number of problems are associated with the use of animal models:

a) Rats are expensive and cumbersome to use, as this requires a facility to breed and keep the animals, as well as the infrastructure to anesthetize and afterward euthanize the rats.

b) As training in such facilities requires assistance, this can only be done during working hours and thus conflicts arise with the clinical responsibilities of residents.

c) Rat vessels are smaller and more friable than human tissue, yielding thus a steeper learning curve than what would be necessary for the basic microsurgical training.

d) Due to the sacrifice of the animals at the end of the training session, the use of rats in microsurgery has met criticism in recent years from animal rights activists.

In keeping with the “three R” model of replacement, reduction and refinement described by Russel and Burch (19), other models for microvascular simulation have been described, including the use of animal parts, such as chicken or turkey wings, chicken thighs or rat tails, all of which can be used for dissection and anastomosis of vessels. Of these *ex vivo* animal models, chicken legs and porcine eye have been validated (17).

Regarding microneurorrhaphy bench training, the literature is quite scant. Precision, needle placement, and knot tying are similar to microvascular, and can, therefore, be practiced on latex gloves. However, there are no commercially available artificial models available. A piece of twine rolled up in saran wrap, as well as textile-covered rubber threads (20) have previously been described. Bench models for tendon repair are commercially available animal tendons that can be procured from butcher shops, or synthetic tendon substitutes, such as silicone fishing worms or other types of silicone and latex materials. Kamath and colleagues describe a model that permits the simulation of both flexor digitorum superficialis (FDS) and flexor digitorum profundus (FDP) repair, however, they fail to provide enough information as to how to construct this model (21). Higher fidelity than the silicone/rubber rods is animal tendons (22) as they provide both the feedback and tissue handling that is seen in the operating room. Rhodes and colleagues construct a « jig », as they refer to it, in order to provide placement of the pig tendon in a more anatomical position or relationship.

A silicon rod can tear, but it will not fray or pull through the way a traumatized tendon or an improperly placed suture will do in real life.

The Arbeitsgemeinschaft für Osteosynthesefragen foundation, also know as the AO foundation has courses, ranging from basic to expert level, in which they teach principles of osteosynthesis. While a good number of these courses are targeting orthopedics, the craniomaxillofacial and hand courses are equally applicable to plastic surgery. These are one to two-day courses teaching theory as well as surgical skills and procedures. Wood models for performing and understanding lag-screw fixation, as well as osteosynthesis of several facial fractures, are explained and performed in the basic course. Trainees have the opportunity to familiarize themselves with the different instrument kits, plate molding, and reduction of fractures on sawbones models. These procedures are all performed under the supervision of craniofacial or hand surgeons respectively, who provide feedback and tips. While the physical fidelity of the sawbones model is limited, the functional fidelity of the overall model using medical grade titanium plates and instruments renders the simulation exercise of good value for the purpose of learning basic craniomaxillofacial or hand techniques. Can this be replaced by a virtual reality model? It is likely that a virtual model can provide a higher physical fidelity, however, the functional fidelity learned from manipulating the actual plates would be lost. Plate molding involves trial and error with action feedback.

Cadavers have been used in surgical training from the very beginning. Whether for acquiring a better understanding of the anatomy, or to simulate procedures, surgeons have turned to both fresh frozen and embalmed cadavers. In some areas of plastic surgery formal cadaver-based training models are used, such as for example in the case of flap courses. In these courses, under the direct supervision of experienced surgeons, the trainees learn anatomy and dissection techniques necessary for raising pedicled or free flaps. The dissection exercises are usually preceded by lectures, and immediate feedback and suggestions are given by the educators during the dissection exercise itself. The cadavers have historically been formaldehyde embalmed or fresh frozen, and more recently a novel method of embalmment has been proposed and tested by Prof. Thiel of Graz, Austria (23). This method maintains the cadavers in a more lifelike state while reducing the decay and infectious risks associated with fresh frozen cadavers. In addition to flap dissection, Thiel's vessels have been used for microvascular surgery (24, 25), as well as tendon repair workshops (26). Other areas where cadaveric specimens have been used are specialized dissection courses, such as rhytidectomy course at the University of Texas, Southwestern in Dallas.

Animal models have been an invaluable tool for the practice of both flap dissection, as well as other more specific skills like microvascular anastomoses, and to lesser extent nerve repair. In microsurgery, the rat femoral artery model has been validated in two studies (17) and enjoys widespread popularity and is the closest model to a gold standard. Most major North American universities organize microsurgical training labs using rats that are euthanized at the end of the procedure. The rat sciatic nerve model is also one of the best available models for nerve repair (27). With the advent of supermicrosurgery and lymphatic surgery, the rat model has been used for the practice of lympho-venous anastomoses (28), which takes simulation to the very edge of its capabilities. Despite the high fidelity of the live rat model, a number of shortcomings exist that need to be weighed in. While these often are rats at the end of studies that would be euthanized anyway, and the euthanasia during anesthesia is an ethical way to dispose of these animals, the use of live animals in training sessions has received much criticism from animal rights activists and society at large. In addition, live animal models are expensive, require technician expertise for growing, anesthesia and euthanasia, and require specialized facilities for their use. Since the introduction of the "three R" principle (reduction, refinement, and replacement) by Russel and Burch in 1959, stricter rules regarding the use of animals in research and education have been implemented (29), and it has become the ethical responsibility of researchers and educators alike to find alternatives to animal use.

The fourth type of simulator, human performance simulators, do not seem to yet have a role in plastic surgery education, however, the virtual reality simulators have shown significant improvement in the last decade and appear to be gaining ground as an important instrument in plastic surgery training. As technology becomes more complex and more affordable, medical educators look at a virtual reality as the new revolution in medical training (3). Rosen et al, in their review of the state of simulation and plastic surgery and the path forward, put much emphasis on the development of virtual reality models, to parallel the advances in abdominal surgery simulation (6). Arbogast and Rosen give a number of virtual reality examples, such as simulators for robotic surgery, cleft lip, and palate, latissimus dorsi myocutaneous flap dissection, and Dr. McCarthy's Interactive Craniofacial Surgical Atlas (2). While these models cannot match the functional fidelity of some lower technology models, their exquisite level of physical fidelity make them an invaluable teaching tool. With further advances in technology, we can expect more from this branch of surgical simulation.

0.6. Thiel embalmed cadavers in medical simulation

Parallelling the technological boom of the 20th century, simulation has followed the same upward trend with a significant amount of research and development geared towards the development of hi-tech simulators, such as high-fidelity mannequins or virtual reality models. This high-tech high-fidelity simulation business has become very popular and the majority of authors consider this the holy grail of medical simulation. Perhaps it is, and time will tell. Yet we cannot ignore the basic principles of simulation established by Miller (12), which emphasize the functional rather than physical fidelity. And one cannot ignore the classical models for surgical simulation, of which the cadaveric model is considered by Reznick and MacRae the only true anatomic simulator in existence (11). Traditionally two cadaveric models existed: the fresh frozen cadaver which provides the highest level of fidelity to the live human tissue yet it is plagued by a quick decay and exposes the trainee to infectious risks. Formaldehyde embalmed cadavers can be preserved for an extended period of time and have a low infectious risk, however, the fixation of tissues by formaldehyde changes the color and texture of the tissues. Over the last twenty years, a new cadaveric model that combines the advantages of fresh frozen and formaldehyde cadavers has been developed and acquired fast acceptance in the anatomic community. This new model is the Thiel embalmed cadaveric model (23).

In a review article on the origins of formaldehyde tissue fixation, Fox et al give a history of formaldehyde synthesis and its introduction in the medical and biological sciences. Ferdinand

Blum is credited for the introduction of formaldehyde for the purpose of tissue fixation and anatomical labwork, including the embalming of whole cadavers (30). Because formaldehyde is very effective at preventing decomposition of the tissue and at the same time provides an antiseptic medium, it has remained the mainstay of tissue preservation to this date. The excellent tissue fixing capabilities of formaldehyde are however plagued by a number of problems. First, formaldehyde has a hardening effect on tissue, and dissection of embalmed tissue can often be cumbersome and at the very least not life-like. The colors of the tissues are also not preserved, due to the transformation of hemoglobin to methemoglobin. This change in pigmentation appears to be an effect of formic acid, the product of the oxidation reaction of formaldehyde (30). Lastly, depending on the concentration of the embalming solution, formaldehyde has a pungent, irritating smell (23), and can cause contact dermatitis (31). While it has not been conclusively shown that formaldehyde can be carcinogenic to humans, neither through animal or epidemiological studies, the health hazard posed by formaldehyde warrants, according to Pabst, the lowering of exposure to formaldehyde to minimal levels (31).

In 1992, Professor Walter Thiel from the University of Graz in Austria published a report of a new embalming solution which, contrary to formaldehyde, provided soft, life-like tissue (23). In his seminal work, he describes the evolution of embalming of whole cadavers from the introduction of formaldehyde by Blum. The few alternatives to formaldehyde which had been published in the literature had been tested by Prof. Thiel in his laboratory and found to provide soft, albeit inadequately preserved tissue. He describes in detail the development of a novel embalming technique based on Boric acid, ethylene glycol, ammonium nitrate and potassium nitrate. Over the course of two decades, from 1970 to 1991, Thiel had embalmed with this new technique 977 cadavers, perfecting the solution to the composition used in the present day (23). Professor Thiel has tested his embalming technique to prove the fixation properties as well as its antiseptic nature against some of the more concerning pathogens, such as Staphylococcus, Pseudomonas, and Mycobacterium. Its efficacy against fungi has also been proven. This was the first viable alternative to formaldehyde embalmment published in the literature.

In 2002, Prof. Thiel published a supplement to his original 1992 paper intended to give an update on the experience with the new embalmment method at his institution (32). The notable change introduced in 2002 is pertaining to the embalmment of the central nervous system. Since the Thiel method of embalming would not solidify the gray and white matter sufficiently, Prof. Thiel proposes in this supplement an initial intrathecal infusion of a formaldehyde-isopropyl alcohol followed by the « Thiel solution ». The other evolution of the method relates to the change of the mono-ethylene glycol for mono-propylene glycol in the embalming solution, the former being found to be irritating to tissues, and an increase in the concentration of formaldehyde. These changes finalized Prof. Thiel's powerful contribution to the anatomy literature and are shown in figure 4.

Basic components of Thiel solution	
Hot tap water	100
Bor acid	3
(Mono-)Ethylenglycol	30
Ammoniumnitrate	20
Potassiumnitrate	5
Chlorkresol-solution with (Mono-)Ethylenglycol	10
4-Chlor-3-Methylphenol	1

Liquids are given in millilitre, solid components are given in grammes.

Figure 4. Basic components of Thiel embalming solution. From K Wolff et al / Microsurgery 28 (2008) 273-278, reprinted with permission.

Since its publication, the Thiel technique has been met with much enthusiasm by the anatomic and scientific community, and currently, laboratories around the world utilize this technique of embalmment. The lifelike properties of the embalmed cadavers have been used in a number of fields, from ultrasound, ultrasound-guided peripheral nerve block, arthroscopy, flap dissection and other surgical simulation procedures. At the McGill University simulation center, Thiel embalmed cadavers have been used for military emergency medical simulation, including surgical airway, thoracic tubes, vascular access etc. The potential for Thiel cadaveric utilization in surgery is almost limitless; almost any surgical procedure can be simulated with success on these cadaveric specimens that maintain both the color and supple nature of living tissue.

A number of studies have looked at the adequacy of Thiel cadavers in surgical dissection. Eisma et al designed a surgical workshop for thyroidectomy where they used both Thiel and formalin embalmed cadavers (33). They enrolled 8 trainees and 4 surgeons in the workshop and had them perform a thyroidectomy on both formalin and Thiel cadavers. Each trainee performed either the first or second half of the thyroidectomy on a Thiel cadaver, after which they were asked to evaluate the two experiences. The author asked the participants to evaluate the adequacy of the skin, muscle, fat, vessels as well as nerves, as well as a number of surgical parameters, such as raising the subplatysmal flap or retraction of tissues. While the study provides no information regarding the statistical significance of the findings, the authors claim that the Thiel specimens scored higher than formaldehyde embalmed specimens in all but 10 of the 180 pairs of scores. The difference was most marked in areas where supple tissues are necessary, such as subplatysmal flap dissection or tissue retraction. The authors conclude that Thiel embalmment is superior to formaldehyde for the purpose of simulating thyroid surgery and that these findings could extend to other surgical areas as well.

Wolff and colleagues, in an article published in the Journal of Microsurgery in 2008, introduced the use of Thiel cadavers in the field of flap dissection and microvascular simulation (24). The authors report their experience with the use of Thiel cadavers in their flap dissection courses, which they consider an ideal model combining the tissue characteristics of fresh-frozen cadavers with the conservation of the formalin embalmment. They provide a vivid description of the different tissues encountered during the dissection and compare them to what would be expected during intra-operative flap dissection. The authors note that with the Thiel embalming technique, the epidermis, as well as the nails and the body hair peeled off, leaving a smooth and slightly oily surface. While they found the skin to be slightly firmer than in the living body, this was not considered an impediment. The quality of the subcutaneous fat, fascia, and muscle was reported as being of good quality, with the exception of the muscles of the back which were found soft, possibly due to the sustained pressure. The authors further continue their description of the vascular pedicles, which they consider suitable for dissection with properties similar to those found in the clinical setting. At the microscopic level, the arteries were found to be thicker, with the three layers identifiable, while the veins were found to be thinner walled and collapsible, with the valvular system preserved. During the exercise of the microvascular anastomosis, the vessels were found to offer normal tissue resistance and permit suture and knot placement. With respect to nerve tissue, this was found to be less well preserved than its vascular counterpart, with a weaker structure and less compact bundles. We note that Wolff et al describe having used the embalming solution which Professor Thiel upgraded in 2002, as described above, particularly because the preservation of the central nervous system tissues with the original solution was suboptimal (32).

While tissue handling has been reported to be lifelike (23, 24), with excellent pliability and elasticity of the tissues superior to that obtained with formaldehyde embalmment (33), one has to wonder if, at a microscopic or molecular level the properties of the tissues have been affected. Wolff et al have commented on the integrity of the vessel walls in Thiel cadavers, as well as the three layers being identifiable under magnification (24). The only report of Thiel embalmment on the histologic appearance of arteries has been published by our team (34) and is described in chapter 4 of this thesis. The suitability of Thiel embalmed nerves for simulation of peripheral nerve surgery has not previously been evaluated, neither has it been shown how Thiel preservation affects the histologic preservation of the nerves and their fascicles. The only data on Thiel embalmment of nerves comes from Prof Thiel's 2002 paper, where he made changes to the embalming solution with the purpose of improving the quality of central nervous system fixation (32), and from Wolff et al, who from a gross anatomic perspective considered the quality of the peripheral nervous tissue to be inferior to that of the vessels (24).

To date, there are two studies in the literature that looked at the effects of Thiel embalmment on tendons. Benkhadra et al looked at the effects of Thiel embalmment on the microarchitecture of muscle and tendon tissues (35). Their biopsies were obtained from the biceps muscle and the brachioradialis tendon and stained with Masson's trichrome, Sirius red and Ramon y Cajal. They compared their findings with similar samples obtained from fresh frozen cadavers and formalin preserved cadavers. When looking at the muscle biopsies, the authors found a very noticeable fragmentation of the muscle fibers with a minced appearance which did not, however, affect the alignment of the fibers. The collagen fibers within the muscle interstitium were found in continuity. This fragmentation of the muscle was not seen in either fresh frozen or formalin embalmed cadaveric tissues. The authors postulated that this muscle fragmentation with preserved alignment potentially explained the exquisite suppleness and flexibility of the Thiel embalmed cadavers. When looking at the microarchitecture of the tendons, Benkhadra concluded that histologically Thiel embalmed tendons are very similar to fresh frozen specimens.

On the other hand, Fessel et al, based on evidence from a previous biomechanical study that found a decreased elastic modulus in Thiel embalmed bone when compared to fresh-frozen controls, postulate that Thiel embalmment reduces the elastic modulus and failure stress of Thiel cadaveric tendons (36). The authors found that in cadaveric FDP tendons, the fresh frozen specimens had a significantly higher median ultimate stress than Thiel embalmed specimens (60MPa vs 38MPa, p0.048), while the failure strain and tangential elastic modulus showed a trend towards superiority of the fresh frozen specimens without reaching statistical significance. When looking at rat tendon fascicles, both stiffness and failure force of the fresh frozen specimens were superior to the Thiel exposed counterparts, with $p < 0.05$. The stress-strain and force strain relationships of the cadaveric and rat specimens respectively can be visualized in figure 5. The authors conclude that Thiel embalmed cadaveric tendons do not faithfully reflect the biomechanical properties of living tendon substance, for which the gold standard for biomechanical research remains fresh frozen tissue. However, while cautioning against the use of Thiel specimens in biomechanical studies, the authors suggest that Thiel embalmed tissue could be used in preliminary studies as long as one is aware of the biomechanical differences this model entails.

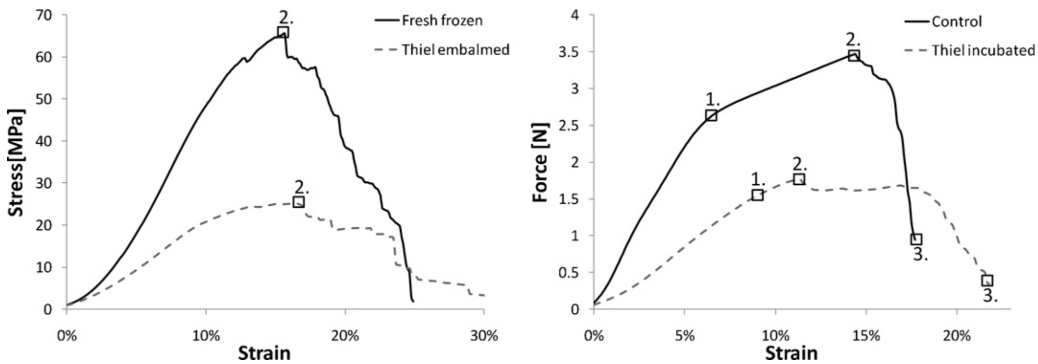

Figure 5. The stress-strain relationships in flexor tendons from fresh-frozen and Thiel embalmed cadavers. From G. Fessel et al / Annals of Anatomy 193 (2011) 237–241, reprinted with permission.

To summarize how Thiel embalmment compares to formaldehyde and fresh-frozen cadaveric specimens, one can claim that it offers the best of both worlds and maybe even more. Thiel embalmment provides tissues that are soft, pliable and which retained color and tactile feel (23, 24, 33, 35). They appear similar to the fresh frozen tissue at both macroscopic and microscopic level, perhaps with the exception of nerve tissue that has been regarded as less well preserved. On the other end of the spectrum, the Thiel solution provides effective long-term preservation of tissues with excellent antimicrobial properties, areas which have always been problematic in fresh frozen tissue. The reason why it offers more than both formaldehyde and fresh frozen cadavers is that Thiel solution is safe. It contains a much lower level of formaldehyde such that smell, irritation, the possible albeit unproven carcinogenicity are reduced (31), and it also preserves the body and reduces transmission of pathogens. Prof. Thiel proved the bactericidal and fungicidal properties of his embalming solution in his 1992 article, and speculated, based on the opinion of the microbiologist working with him, that it also has viricidal properties against the HIV (23). Furthermore, Thiel embalmed cadavers need not be kept in a refrigerated area. While there is no published cost analysis on running a Thiel lab, it has been speculated that possible disadvantages of this procedure are the relatively high cost, the length of the embalming period and the need for equipment dedicated to this technique (24). It has to be kept in mind that, like formalin embalmed cadavers, Thiel cadavers are only as good as the technique is properly applied. The lag time from death to embalmment is time during which the body decays, and therefore the longer the delay to embalming, the poorer the final result can be expected.

Therefore, it is safe to say that Thiel embalmed cadavers are the ideal model for surgical simulation, as they provide a high level of fidelity, while at the same time they offer a safe environment for the trainee and the possibility to store the specimens for an extended period of time. As for the cost-effectiveness of Thiel cadavers, a formal cost analysis needs to be undertaken.

0.7. Study objectives

The purpose of this thesis work is to establish a surgical skills simulation and research model based on the life-like tissues provided by the Thiel embalming technique described above. We define a number of objectives in order to accomplish this work:

1. Test the use of the Thiel cadaveric model for microvascular anastomoses, peripheral nerve repair, flexor tendon repair, as well as a research model for developing surgical techniques.
2. Establish procedure-specific evaluation instrument for microvascular anastomoses, peripheral nerve repair, and flexor tendon repair

0.8. Thesis overview

The thesis is organized in four chapters. Chapter 1 describes the Thiel model for microvascular simulation, proposes and validates an evaluation instrument specific to microvascular simulation. This chapter has been published in Plastic Surgery in November 2018 and is awaiting publication. Chapter 2 deals with simulation in the setting of peripheral nerve surgery. The first part of the chapter describes the Thiel cadaveric nerve model for use in microsurgical neurorrhaphy simulation and has been published in the Journal of Brachial Plexus and Peripheral Nerve Injury in April 2016. The second part of chapter 2 describes the development of an evaluation instrument for the simulation of peripheral nerve repair and provides evidence for the validation of this novel instrument.

This portion of the chapter has been accepted in Plastic Surgery in February 2019. Chapter 3 describes the use of Thiel embalmed cadaveric tendons for tenorrhaphy. Additionally, it proposed is an evaluation instrument similar to the ones described in chapters 1 and 2 for the evaluation of the gestures specific to tendon repair. The evaluation instrument was tested on a cohort of plastic surgery and orthopedic residents to test the validity of the instrument. This chapter is currently being prepared for submission. Chapter 4 describes the use of Thiel embalmed cadaveric tissue for research as exemplified in the two papers we have published on the subject. The first article was published in the Journal of plastic, reconstructive anesthetic surgery in 2014 followed by the second article published in Plastic Surgery in May 2015. The final section of this thesis provides our conclusions with regard to the use of the tibial model for microvascular, peripheral nerve and tendon simulations as well as how these models could potentially be integrated in the rapidly changing plastic surgery curriculum in Canada.

Chapter 1: Microvascular simulation

1.1. High fidelity microsurgical simulation: the Thiel model and evaluation instrument

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1.1.1. Introduction

Microsurgery is a discipline, unlike other surgical specialties. The hand-eye coordination is mediated by a microscope, which betrays even the most benign shaking and reduces the depth of field perception significantly. Harmonious surgical gestures take some additional training that macroscopic surgical procedures do not require. As such, there is a steep learning curve until trainees, who may well have mastered macroscopic surgical procedures, are able to safely perform an effective microvascular anastomosis or nerve coaptation. We emphasize “safely”, as this is in our opinion the rate-limiting step for a surgeon to allow a trainee to perform an anastomosis in a clinical setting. It is therefore important for trainees to gain experience in a simulation model before performing microvascular anastomoses in the clinical setting. Whenever possible, the learning curve should be mastered in the lab.

The fidelity of a simulation model is a measure of how realistic the model is. While fidelity is a spectrum, many authors refer to low and high fidelity models. Live animal models, such as the rat femoral vessels, are a high fidelity model for training. There are a number of drawbacks which, while not precluding the use of these models, at the very least discourage their extensive utilization. Live animals are expensive, require special facilities and staffing, have a steep learning curve. However, the foremost arguments against the use of animals in microsurgical training are of an ethical nature. Ethical concerns have prompted the “three R” principles of refinement, reduction, and replacement (19). In the case of microsurgical training, the replacement has included *ex vivo* models such as chicken wings (37, 38) or legs (39), formalin fixed cadaveric vessels (40), as well as silastic models (41). A number of these models were reviewed by Lannon et al, the authors characterizing the strengths and weaknesses of the described models (42). Douglas and Mackay compared the rat aorta, practice rat, and chicken wing vessels and found the chicken wing model to most closely resemble human vessels (43).

More recently, the Thiel cadaveric model has also been described for flap dissection as well as microvascular exercises (24). The Thiel method of embalming uses a complex solution containing Boric acid, ethylene glycol and a number of salts to denature proteins and preserve tissue. Unlike formalin embalmment, tissues maintain the texture, elasticity, volume, and color of fresh cadavers. Unlike fresh cadavers, Thiel cadavers can be used for extended periods of time. We have previously published our experience with the use of Thiel embalmed cadaveric vessels as a model for microsurgical research (34, 44). These vessels are a high fidelity model for microvascular simulation since they maintain good handling properties for extended periods of time, maintain the vascular architecture with an intima, media and adventitia, have a caliber that most surgeons may be performing microvascular repairs/anastomoses on, and at the same time they are in keeping with the “three R” ethical principles.

To our knowledge, the only two validated methods for assessing microsurgical skills was published by Temple and Ross from the University of Western Ontario in Canada (39) The “University of Western Ontario Microsurgery Skills Acquisition/Assessment” instrument (UWOMSA), inspired by the “objective structured assessment of technical skills (OSATS)” checklist (45, 46), has 2 modules: a knot tying module and an anastomosis module. Each module consists of three sub-sections, graded on a scale from 1 to 5. Although Temple and Ross contributed a valuable, validated model and evaluation instrument, it has some shortcomings. For example, one can arrive to a score of 3 on any of the subsections by a number of permutations of the gestures involved. This limits the usefulness as a feedback instrument for the trainee, as a total score of 10 could mean a whole array of different technical errors combined. Furthermore, it is not clear what score would correlate with a skill level adequate to progression of the trainee to either the animal model or the clinical setting.
The first objective of this study is to test the utility of the Thiel embalmed cadaveric vessels as a simulation model in microsurgery. The second objective was to design and validate a new evaluation instrument, geared towards microsurgery. Finally, we aim to determine what score

a trainee needs to obtain with the evaluation instrument in order to be considered “safe” to provide microsurgical assistance in the operating room.

1.1.2. Methods

1.1.2.1. Thiel vessel specimens:

Radial and ulnar arteries were harvested together with the venae comitantes from Thiel embalmed cadavers and stored in Thiel embalming solution at 4^{o} Celsius. One length of the vessel could be used for multiple microvascular anastomoses. The average diameter of the vessels was 3.5 mm. For the purpose of this module, a length of 7cm of vessel was placed in a previously modified petri dish with vascular ports on both ends as shown in figure 6. The vessel was ligated to the vascular connectors with silk suture in order to allow subsequent irrigation. For each participant, a 2 cm segment of vessel was dissected free of the venae comitantes. The vessel was then transected sharply. The trainees had to place the approximator clamps, background and perform the anastomosis. Once the anastomosis was performed, saline was instilled in the vessel to evaluate for leaks and patency. Up to 5 anastomoses could be done on the same 5 cm segment of the artery. In between uses, the vessel could be placed in Thiel solution at 4^{o} Celsius for storage.

Figure 6. The set-up used for microvascular training.

1.1.2.2. Study design:

An email inviting the residents and attending microsurgeons from two plastic surgery training programs, as well as residents from one ear, nose and throat and one neurosurgery program was sent out. Participation of residents from all levels of training was encouraged. Fifteen participants performed the simulation module, including 10 plastic surgery residents, two ENT residents, one neurosurgery resident and two attending microsurgeons. Table 1 shows participant information such as program, training level (PGY level) and self-declared microsurgical experience of the participants. Data on sex and age were also collected. The experience was grouped into three clusters: minimal (≤1 completed anastomosis), moderate (>1 but ≤10 anastomoses) and advanced (>10 anastomoses). Given the small number of participants (n=15), we could not evaluate differences between individual PGY levels since some of these groups only had one participant. Instead, the participants were clustered into three groups: junior resident (PGY 1-3), senior resident (PGY 4-5) and attending surgeons.

Table 1. Participant information

Participant	PGY	Age	Sex	Specialty	Experience (anastomoses performed)
1	5	38	M	Plastic Surgery	>1 and ≤10
2	2	25	M	ENT	≤ 1
3	3	29	M	Plastic Surgery	>1 and ≤10
4	3	26	M	Plastic Surgery	>1 and ≤10
5	2	29	F	ENT	≤ 1
6	2	39	M	Neurosurgery	≤ 1
7	2	28	F	Plastic Surgery	≤ 1
8	4	28	M	Plastic Surgery	>1 and ≤10
9	Attending	47	M	Plastic Surgery	>10
10	3	28	F	Plastic Surgery	>1 and ≤10
11	Attending	42	M	Plastic Surgery	>10
12	5	39	M	Plastic Surgery	>10
13	5	34	F	Plastic Surgery	>10
14	1	23	F	Plastic Surgery	≤ 1
15	3	25	F	Plastic Surgery	>1 and ≤10

The participants were assigned a random participation code for the purpose of blinding the evaluation process. The demographic information of the participants, identified by the participation codes were placed individually in sealed envelopes. Data collection was done one participant at a time. The subjects were shown first a teaching video of microvascular anastomosis and the different technical elements explained. This was performed regardless of the level of training of the subject, in order to ensure that they would perform anastomoses in a similar manner, facilitating consistent grading. Participants were also allowed to get accustomed to the instrument and the microscope, after which they each performed one anastomosis which was video recorded. The videos were only identified with the five number randomly generated codes. Four fellowship trained microsurgeons performed a blinded evaluation of the recordings and graded them based on the scale described in Table 2. The sealed envelopes with the identification information of the participants were only opened upon completion of the evaluation and the data was compiled.

Table 2. Microvascular Evaluation Scale (MVES)

	0	1
Adventisectomy		
Dilatation		
Perpendicular needle placement / full thickness bite		
Visualization of back wall		
Bite width and spacing between sutures		
Favorable knot placement (everted, square)		
Gentle manipulation of tissues; Instrument stabilization		
Coordination of instruments, vessel and suture		
Takes needle out on a curve		
Uses fulcrum while pulling suture		
Score:		

1.1.2.3. Microvascular evaluation scale:

The evaluation instrument was developed by a panel of four fellowship-trained microsurgeons, based on the literature and their own experience teaching microsurgery. Ten microsurgical gestures comprise the scale, with each gesture being scored either as 0 or 1, depending if it was performed inadequately or adequately. The scale is dichotomic for each evaluated gesture, with a maximum of 10 points accumulated if all gestures are performed well. This scale is shown in table 2.

1.1.2.4. Statistical analysis:

Statistical analysis was performed using IBM SPSS Statistics Version 22 and SAS 9.3 (Cary, NC, USA).

The internal validity of the instrument was assessed using the Cronbach coefficient.

To assess the external validity of the instrument, univariate and multivariate analyses were performed. We used multivariate linear mixed-effects models taking into account correlations between subjects nested in microsurgeons. This approach was favored over multivariate approaches based on ordinary least square regression since it is more flexible for a repeated measure or clustered data.

1.1.3. Results

Microvascular anastomosis videos from fifteen subjects were evaluated by four fellowship-trained microsurgeons, for a total of 60 observations. Each blinded evaluator scored all the trainees using the microvascular simulation scale.

1.1.3.1. Reliability assessment

Using the 60 observations from the four evaluators, we determined the interrater reliability, revealing an "excellent" intraclass correlation of 0.89 (0.75, 0.96).

1.1.3.2. Regression models

Using univariate analysis, the correlation coefficient between score and level of training was 0.36 ($p<0.001$) and the correlation between score and microsurgical experience was 0.79 ($p<0.001$). Multivariable linear mixed-effects models revealed statistically significant differences between the scores obtained by the attending surgeons and the junior residents ($p=0.002$), and between the senior and junior residents ($p=0.006$). The difference between senior residents and attending surgeons was not significant (p=0.28). These results are represented graphically in figure 7.

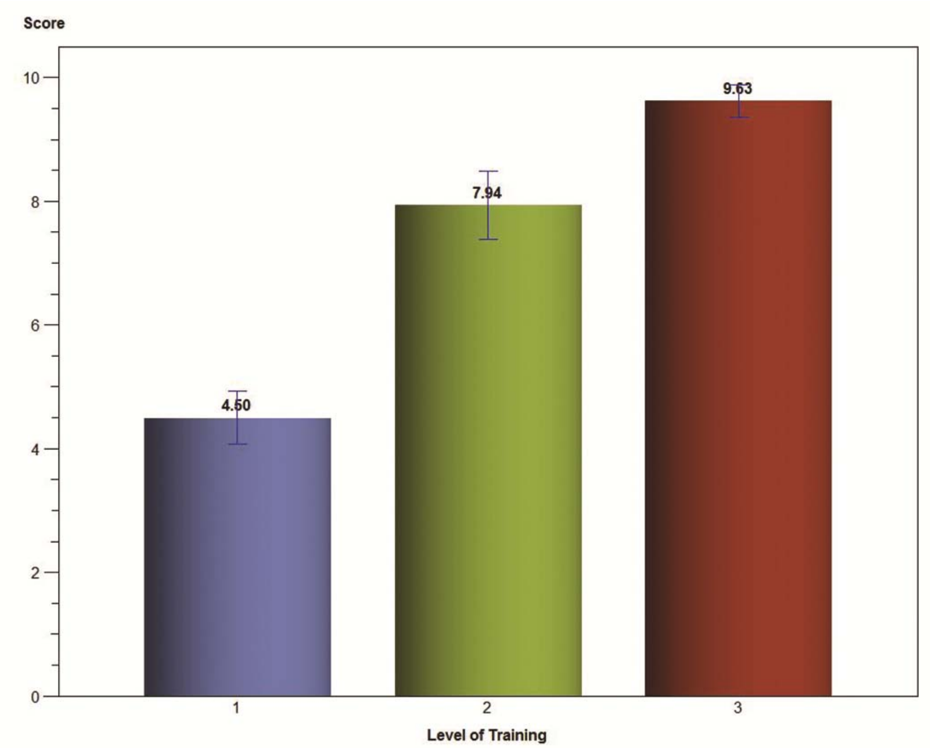

Figure 7. Level of training: Group 1 represents the junior residents (PGY 1-3), group 2 the senior residents (PGY 4-5) and group 3 are attending surgeons.

When considering the microsurgical experience, the differences were significant between the advanced and minimal experience groups (p=0.017) and between the advanced and moderate experience groups (p=0.004). The difference between minimal and moderate experience groups was not significant (p=0.35). These results can be appreciated graphically in figure 8 and are summarized in table 3.

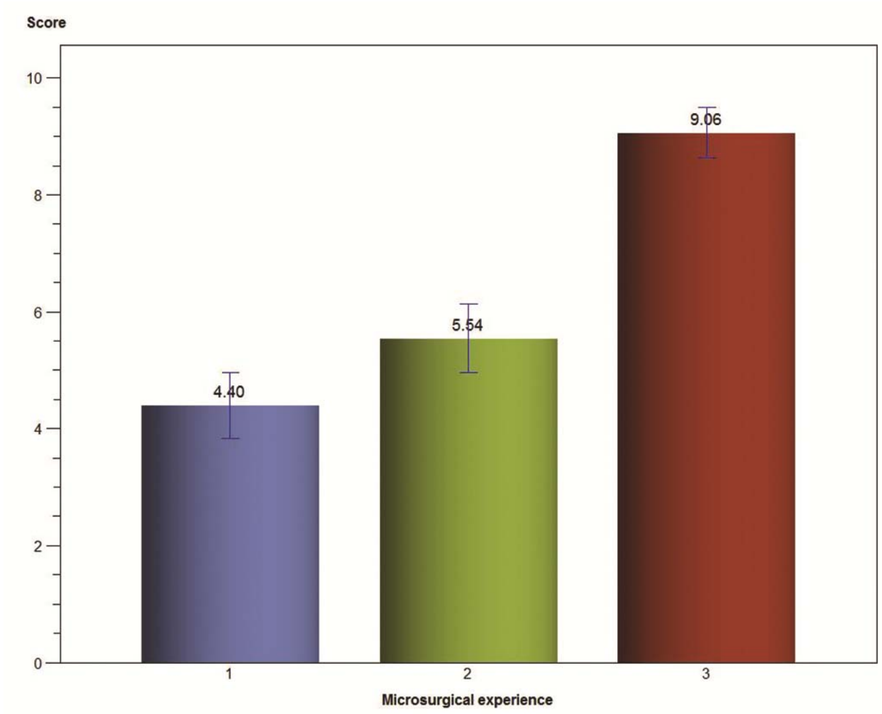

Figure 8. Microsurgical experience: Group 1 represents participants with minimal experience (≤ 1 anastomosis). Group 2 represents the moderate experience (>1 and ≤10 anastomoses) while group three is the advanced group (>10 anastomoses). Group 3 was found to perform significantly better than either group 1 and 2.

Table 3. Multivariable linear mixed models

Effect	Beta Estimate	95% Confidence Interval		p-value
Experience				
>1 and ≤10 vs >10	-3.5208	-6.2796	-0.7620	0.0166
>1 and ≤10 vs ≤ 1	1.1417	-1.4463	3.7297	0.3554
>10 vs ≤ 1	4.6625	1.7955	7.5295	0.0040
PGY				
Attending vs Junior	5.1250	2.1666	8.0834	0.0027
Attending vs Senior	1.6875	-1.5899	4.9649	0.2839
Junior vs Senior	-3.4375	-5.7117	-1.1633	0.0064

1.1.4. Discussion

Wolff et al proposed the used Thiel cadaveric model for use in microvascular simulation (48). They presented their experience with the use of this model for the dissection of flaps, as well as microvascular training and concluded that this model is versatile in the training of microsurgical and macroscopic surgical techniques. While they used this model in the setting of the entire cadaver being used, we harvested the radial and ulnar vessels from cadavers that were about to be cremated and stored them up to one year at 4^{o} Celsius with no change in vessel quality. In our opinion, the most ethical use of cadaveric specimens is not to waste any part of the donor's body, and therefore our model maximizes the ethical use of the cadavers. The shortcoming of this model is that Thiel embalmment is not yet widely used, especially in North America. It offers, however, the promise of eventually replacing formalin preservation in anatomy labs, which would make vascular specimens like those used in this study more widely available.

The quality and size of the vessels used is very similar to vessels in the clinical setting. The exception is that the muscularis layer becomes somewhat distended, and thus the overall diameter of the vessel is larger than its equivalent *in vivo* counterpart. The adventitia, muscularis, and intima can be clearly appreciated histologically in figure 9. The tissues are supple and handle well, allowing for adequate knot placement and edge eversion. The patency of the anastomosis can also be verified by instilling saline into the vessel lumen. While the future may bring virtual simulation models, such as already exist in laparoscopic simulation, the Thiel model is a high fidelity model for microsurgical simulation, offering vessels similar in size and texture to those seen in the clinical setting.

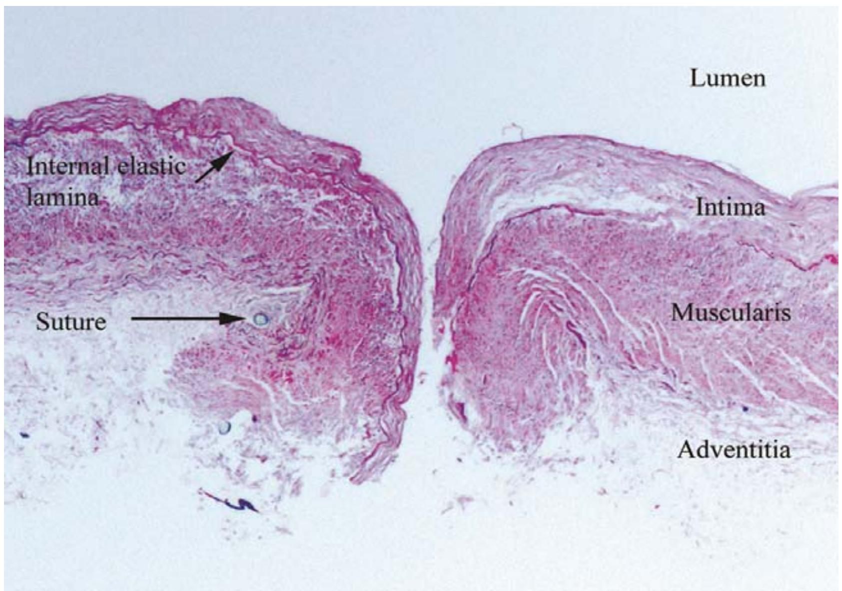

Figure 9. Histologic appearance of Thiel embalmed vessel. Histologic slide showing the interface between the two vessel ends. The three layers of the vessel wall can be appreciated, as well as the internal elastic lamina.

While a number of microsurgical models have been proposed, Temple and Ross are the only authors who have developed and validated a model and evaluation scale for microsurgical gestures. The authors used the OSATS scale (46) as a starting point for their own scale. The OSATS, developed by Reznick and colleagues found the “global score” to correlate better with the performance of the trainees they evaluated than the “checklist score”. The global rating scale they proposed is composed of seven dimensions, each encompassing some aspect of technical performance. Each of these dimensions is graded on a scale from 1 to 5. Reznick's model was developed for general surgery, the authors describe it as a universal scale that could be adapted to any procedure. Temple and Ross adapted this global scale model to microsurgery. While the global scale correlated better with performance than the checklist scale Reznick et al used, we believe a well-structured checklist can give valuable feedback to the trainee regarding the exact aspects of their technique that need improvement. Restricting the evaluation to the ten critical gestures, which we feel are essential for the safe performance of the procedure, allows for an easy transformation of the score in a percentage. Once the ten gestures were identified we opted for a binary grading for each. Performing a gesture well would be scored with a "1"; not performing it well will attribute "0". This is the Microvascular Evaluation Scale.

Furthermore, we wanted this evaluation instrument to be directly used for feedback to the trainee. Being able to visualize the success or failure on a sheet allows the trainee to identify and work on specific aspects that need improvement. This is a concept different from the OSATS used in general surgery and adapted to microsurgery by Temple and Ross at the University of Western Ontario. Those scales are constructed in three subsections, each worth 5 points for a total of 15 points. However, a number of permutations of successful and unsuccessful gestures can result in a score of three, for example. A trainee would not be able to know how that score of three was attributed and therefore it would be impossible to use that information for meaningful feedback.

The structured assessment of microsurgical skills (SAMS) contains three areas of evaluation: global rating scale (GRS), errors list and summative rating. The GRS, containing 12 items, is further subdivided in dexterity, visuospatial ability, operative flow and judgment (47). While quite complete in its assessment, the SAMS has some potential flaws as well. There are so many items to grade that it can become quite difficult for the examiner to keep track. Furthermore, some of the items are much less important than others, diluting out the key gestures. For this reason, we attempted to create a simplified, 10 point simulation scale covering the gestures our panel of microsurgeons considered most critical.

The two measures that determine the usefulness of a test or instrument are the internal and external validity. Internal validity refers to the correlation of results between two different examiners or on repeated trials. Agreement in our study was determined using the intraclass correlation coefficient, similar to UWOMSA. While the reliability of a test refers to the ability to generate the same results on repeated trials, intraclass correlation assesses of consistency of measurements made by different observers measuring the same quantity. The intraclass correlation coefficient can vary between -1 and 1. A coefficient of 0.61 to 0.8 was considered "good" agreement and a coefficient of 0.81 to 1.00 was considered "excellent". The interrater reliability of the MVES was excellent, with an intraclass correlation of 0.89 (0.75, 0.96). Comparatively, the UWOMSA scale of Temple and Ross revealed an intraclass correlation coefficient of 0.79 (0.62, 0.89). The SAMS showed an intraclass coefficient of 0.78. This indicates that our scale possesses an excellent internal validity.

Indicators of external validity were the correlations between the level of training and the scores, as well as between the microsurgical experience and the scores. Using univariate analysis we obtained an intraclass correlation coefficient for the level of training of 0.36 ($p<0.001$). Adjusted analysis using the differences of least square means showed statistically significant differences between the attending surgeons and junior residents ($p=0.002$) and between senior residents and junior residents ($p=0.006$). The difference was not statistically significant between the senior residents and attending surgeons ($p=0.28$). These results suggest that an adequate level of microsurgical proficiency could be represented by a mean score of 8. While our study may be underpowered to reveal significant differences between senior residents and attending surgeons, we think that another way of interpreting this result is that our scale does not discriminate between a good microsurgeon and an expert. It looks at essential gestures that can be well performed by an experienced technician at any level of training.

Univariate analysis of microsurgical experience and scores revealed an interclass correlation coefficient of 0.79 ($p<0.001$). Furthermore, adjusted analysis using the differences of least square means revealed results that were statistically significant between the minimal experience group and the advanced group ($p=0.017$), as well as between the moderate experience and the advanced group ($p=0.004$). The score difference was not statistically significant between the minimal and moderate experience groups ($p=0.355$). These results suggest that microsurgical performance becomes significantly better after performing more than ten anastomoses.

Surgical training is shifting from a time based on a competency-based model. Two measures followed in this study pertain to each of this model. The level of training based on PGY and/or attending status is a reflection of the time-based model of surgical training. The microsurgical experience is more in tune with the competency-based model. If we look at univariate data, we observed a better correlation coefficient between microsurgical experience and score than between level of training and score (0.79 vs. 0.36). This would suggest the microsurgical experience to be a better indicator of competency than the number of years in training.

If this simulation model and the MVES are to be implemented in a competency-based training program, it becomes important to determine a benchmark score that would be associated with the passing of the anastomosis module. If we consider the level of training model, a score of 7.9 was the average score of the senior residents, which was a statistically significant jump from the average score of 4.5 of the junior residents. The senior resident score was not statistically different than the score of 9.6 of the attending surgeons. Based on this data, a score of 8 could represent a good benchmark score if we consider the level of training. Based on the self-declared microsurgical experience, participants who performed more than ten anastomoses scored on average 9.1, which was a statistically significant change from those who performed less than ten anastomoses. This data could indicate a score of 9 as a good benchmark score. We propose a score of 8 as our benchmark, however other surgical educators may chose the stricter standard.

We believe that this study validates the evaluation instrument we constructed for the trainee population we studied. Furthermore, the Thiel cadaveric vessel model proved to be a valuable model for microsurgical training. Recently, the SAMS scale was used by Masud et al to verify the longitudinal acquisition of skills by trainees after a 3 months training program. Strengths of the Thiel microvascular model include the similar size, consistency and tissue handling capabilities of the involved tissue, while the microvascular evaluation scale described and validated above provides an easy way to score performance and provide feedback. The authors showed a significant improvement in scores for the study group vs. the control group (49). Along the same lines, future directions in our research will include a longitudinal evaluation of the progress of our resident's scores as they use the model repeatedly. This will help determine if the model is conducive to a natural progression of microsurgical skill, and if the feedback obtained from the evaluations would prove beneficial to the trainees. We plan to develop deconstructed modules that help perfect individual gestures that the trainees do not perform well, such as pulling the needle out on a curve or using a fulcrum when pulling suture. We also plan to construct similar Thiel models and evaluation instruments for other areas of plastic surgery simulation, such as flexor tendon repair or nerve repair.

Chapter 2: Peripheral nerve simulation

2.1. Thiel cadaveric nerve tissue: A model for microsurgical simulation (50)

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Peripheral nerve research, as well as nerve repair simulation, has relied heavily on the rat animal model, more specifically on the rat sciatic nerve (27). As the use of animals in experiments and training has received much criticism from animal rights activists and society at large, the field of surgical simulation is currently emerging. In microsurgery, high-fidelity Silastic models, animal parts such as chicken thighs or wings, and cadaveric specimens have been used. Based on the available experience with Thiel embalmed cadaveric tissue in simulation (24, 51, 52), we experimented with Thiel embalmed peripheral nerves for the purpose of microsurgical skill training.

We used median, ulnar, and tibial nerves from cadavers that had been used for anatomic and surgical training and had not touched the peripheral nerve tissue. The donors had previously consented to tissue utilization in postmortem research. The tissues originated from cadavers prepared with the embalming method described by Thiel (23). This technique preserves texture, volume, color, and shape of the body as perfect as possible, with the advantage of avoiding decay observed with fresh cadaveric specimens. There is no shrinking or soaking of the soft tissues. Thirteen nerve sections measuring 5 cm each were prepared on a foam board. Needles (25 G) are used to fix the nerves to the foam board. A blue background was used for the exercise, as it improves contrast. An operating microscope (Opmi Pico, Carl Zeiss, Oberkochen, Germany) at 10× magnification was used for all microneurorrhaphies.

Under magnification, the nerves were crushed in the midsection to simulate an injured nerve. The participants transected the nerve using a 15-blade scalpel and trimmed the damaged nerve tissue. The two ends were inspected for the fascicular architecture and oriented appropriately for the repair. The epineurium was then gently reflected back and the proud fascicles trimmed. Nylon 8–0 sutures were used to perform a simple epineural repair, starting with the 0- and 180-degree orientation sutures and then filling in the required sutures to obtain a well-oriented microneurorrhaphy.

Under magnification of the operative microscope, we found the Thiel nerve tissue to show a slight gray-brown discoloration with an epineural layer that was hydrophilic, giving the impression of edematous tissue. This thicker-than-normal epineural layer, however, offers adequate support for manipulation. Unfortunately, the cadaveric nature of the model precludes the use of the vasa nervorum, which are not visible, for adequate orientation of the nerve. Upon cutting the nerve, it can be observed that the fascicles are well preserved and bound by firm endoneurium and perineurium which have not undergone the same edema as the epineurium (figure 10). Despite there being no immediate herniation of nerve fascicles upon transection, the fascicles have a tendency to be more hygroscopic, and by the end of the neurorrhaphy, one can observe some protrusion of fascicles in between suture. The fascicular pattern is easily identifiable and permits good alignment of the nerve before suturing.

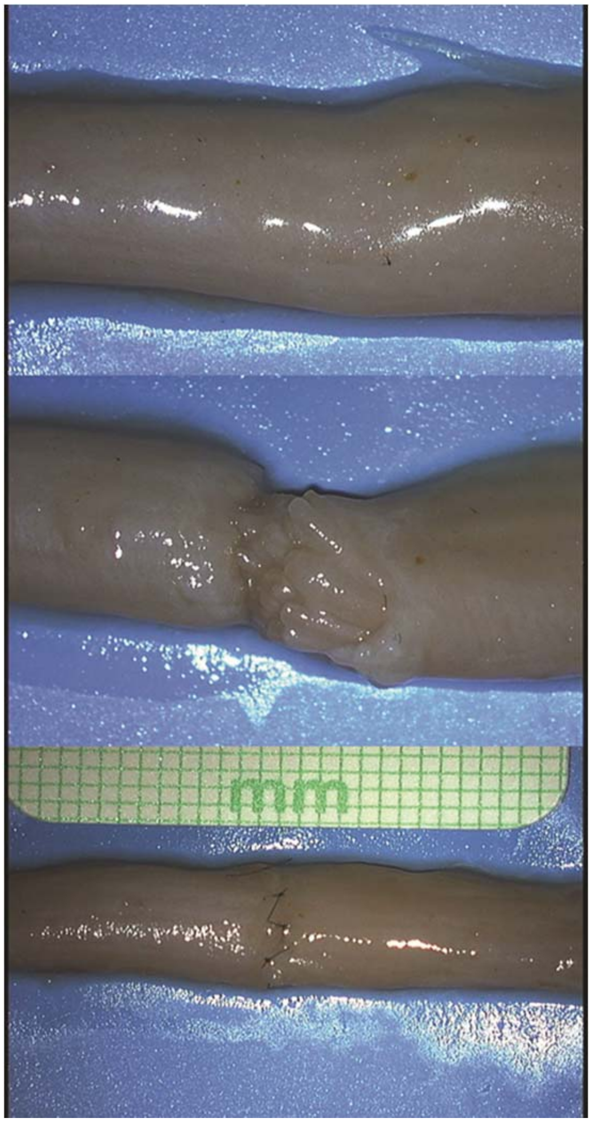

Figure 10. Thiel embalmed nerve for nerve repair simulation. (above) Intact nerve before transection showing a hygroscopic epineurium. (middle) Transected nerve showing the architecture of the fascicles. (below) completed nerve repair.

Thirteen volunteer plastic surgery, otolaryngology, and orthopedics residents utilized the model once each and filled out a post-simulation survey. The results were graded on a five-point Likert scale (strongly agree, disagree, neither agree nor disagree, agree, strongly agree).

A question regarding the frequency participants would use the laboratory with answers graded in five categories was also asked. The contents of the post-simulation survey are presented in table 4. Descriptive statistics are presented for the results of the survey questions. All participants (100.0%) agreed that they would use the module at least twice a year, with 53.9% (seven residents) stating they would use it more than once a month, 38.5% (five residents) once a month, and 7.7% (one resident) twice a year.

Table 4. Post-simulation survey

Question	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Do you find the model accurate (tissues and handling similar to clinical scenario)?	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (38.5%)	8 (61.5%)
Does the nerve module correlate with real life?	0 (0.0%)	0 (0.0%)	1 (7.7%)	4 (30.8%)	8 (53.9%)
Would you think it would be useful to have a lab where residents can have access 24/7 and practice nerve repair?	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	12 (92.3%)
Would you like to integrate modules on nerve repair simulation in your surgical curriculum?	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (15.4%)	9 (69.2%)
Regarding the impact of simulation on your training					
Do you think it would help attain a satisfactory proficiency with micro nerve repair?	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	12 (92.3%)
Do you think it would help your confidence in the O.R.?	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	12 (92.3%)
Do you think it would allow you to perform nerve repair earlier and more often during your training?	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	13 (100.0%)

The rapid development of microsurgery over the last three decades has been echoed by the development of several simulation models for the teaching and honing of microsurgical skills. Free flaps are routine procedures in most plastic surgery centers, and residents have ample opportunity to participate and perform in these procedures. As a consequence, microsurgical laboratories have been established, both on artificial, *ex vivo* animal and live animal models. Few of these models have been validated. According to a systematic review by Dumestre and colleagues, out of the 238 articles published in the literature pertaining to microsurgical training models, 9 have been adequately validated. These include several artificial pads or cards, chicken or turkey legs or wings, and the current gold standard for microvascular simulation, the rat femoral artery (17). Peripheral nerve surgery simulation is lagging behind. One of the only reports of nonanimal models for nerve microsurgical simulation comes from Senturk and colleagues, who published a model consisting of rubber threads (53). The argument for such a model is the low cost and relative similarity of the architecture, with a bundle of elastic fibers wrapped up by a mesh. Yet the physical fidelity of such a model is low. The technical difficulty of nerve repairs is often underestimated, since there is no immediate failure as seen in microvascular surgery; a poor result is often seen months later and there are often multiple causes for the outcome, including the initial trauma and scarring, yet the effect of poor technique and iatrogenic trauma during repair should not be underestimated. It is for these reasons that simulation in peripheral nerve surgery is valuable.

We believe the Thiel peripheral nerve model to be a high physical and functional fidelity model that permits trainees to become accustomed to the basic principles of microsurgical nerve repair. In addition, it allows the trainee to perform multiple repairs of one median nerve, maximizing the educational benefit per cadaveric specimen. Thiel embalmed nerves can be harvested from cadavers that have already been used for other educational exercises, to ethically maximize their use, and the specimens can be stored for extended periods of time in the appropriate Thiel solution (in our experience up to 2 years). The Thiel nerve model will need to be formally validated in future studies in terms of surgical skill improvement.

2.2. High fidelity microsurgical simulation: the Thiel cadaveric nerve model and evaluation instrument

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2.2.1. Introduction

Surgical training curriculum in North America is currently in the middle of shifting from the time-based to a competency-based model. The Royal College of physicians and surgeons of Canada has already started this transition in 2017 by implementing a "Competence by Design" method of teaching and mandating that by 2022 all medical and surgical specialties will have adopted a competency-based curriculum. While it is still unclear what all the elements of the competency-based curriculum are, the field of simulation will undoubtedly be one of the core components. Recent consensus statement published by the Canadian plastic surgery residency training programs has classified 177 procedures as core competencies in plastic surgery, of which 154 were deemed essential competencies (54). Producing a curriculum that will include these 154 essential skills and develop evaluation instruments by 2022 seems to be a Herculean task. The relative lack of a plastic surgery related simulation literature makes this task even more daunting.

With free flap reconstruction becoming mainstream, teaching residents proper microvascular technique has been a priority. The literature reflects this interest, with a number of models described for microvascular simulation, such as live animal models, chicken thighs or wings, Silastic models and more recently virtual models (37, 40-43). The same trend can be observed in the development of validated evaluation instruments for these simulation models (39, 47). This interest in microvascular simulation overshadowed other procedures involving equally complex skill development. Peripheral nerve repair, here also referred to as neurorrhaphy and nerve coaptation has received less attention despite being an essential microsurgical skill our residents need to learn before graduating. Looking at the peripheral nerve surgery literature, only a handful of models have been described, such as the live rat sciatic nerve model (27) or the use of rubber bands or a piece of twine wrapped in saran wrap (53, 55). We have previously published the use of Thiel involved cadaveric nerves as a simulation model for nerve repair (50). To our knowledge, no validated instrument has been reported for evaluating peripheral nerve simulation.

Since introduction in clinical anatomy, the Thiel method of embalming cadavers has proven to be a useful and producing life-like, supple tissues that could be used for anatomical studies as well as research endeavors. In the field of plastic surgery, there have been studies on microvascular simulation as well as reports on tendon repair (24-26). Our experience with peripheral nerve specimens has shown that Thiel involved nerves remain soft and supple, maintain a good epineural cover (albeit somewhat edematous) and preserve the internal anatomy of the nerve and its fascicles. The quality of these Thiel specimens makes these nerves a good candidate for a high fidelity simulation model (50).

This study had two main objectives: The utilization of Thiel cadaveric nerves as a model for simulating nerve surgery and the development and validation of a novel evaluation instrument, the Micro-Neurorrhaphy Evaluation Scale (MNES), to assess the surgical performance of trainees during nerve repair on Thiel cadaveric nerves. Additionally, we aim to determine benchmarks score that residents need to obtain before proceeding to safely assist with peripheral nerve repairs in the operating room.

2.2.2. Methods

2.2.2.1. Thiel nerve specimens:

Median and ulnar nerves were harvested from Thiel embalmed cadavers (23, 32) and stored in the solution described by Thiel at 4°C. A length of the nerve could, therefore, be used for multiple nerve repairs, removing the previous coaptation site and advancing the nerve ends together. We used a foam board with a blue background to provide good contrast for the coaptation procedure. The nerves were held in place using 25-gauge needles. In between uses, the specimens were stored at 4°C in Thiel embalming solution.

2.2.2.2. Study design:

An email invitation was sent to potential participants from a plastic surgery, ENT, neurosurgery, and orthopedics from one Canadian University. Sixteen residents participated in the study, 11 of which were plastic surgery, two ENT, two orthopedics and one neurosurgery residents. The level of training, as well as other participant data, are summarized in table 5. The subjects were also required to declare their experience with nerve repairs at the time of participation. These were grouped into 3 categories: Least experience (one or no nerve coaptations performed), intermediate experience (between 1 and 10 nerve coaptations performed) and highest experience (more than 10 nerve coaptations performed). Since we did not have any fellowship trained microsurgeons, hand surgeons or nerve surgeons participating, we did not have any higher degree of experience documented. The highest experience designation is only in comparison to the other two groups and does not imply expert status.

Table 5. Participant information: PGY 1-3 were further grouped as junior residents, PGY 4-6 senior residents.

Participant	Age	Sex	Specialty	PGY level	Experience (Coaptations performed)
1	27	M	Plastics	Senior	> 10
2	28	M	Plastics	Junior	>1 and ≤ 10
3	26	F	Plastics	Junior	>1 and ≤ 10
4	27	M	Ortho	Junior	≤1
5	35	M	Plastics	Senior	> 10
6	32	M	Plastics	Senior	> 10
7	26	F	Plastics	Junior	>1 and ≤ 10
8	27	M	Plastics	Junior	≤1
9	29	M	Plastics	Senior	> 10
10	26	M	ENT	Junior	≤1
11	24	M	Plastics	Junior	≤1
12	38	M	Plastics	Junior	≤1
13	28	M	ENT	Senior	≤1
14	26	M	Neurosurgery	Junior	≤1
15	24	F	Ortho	Junior	≤1
16	28	F	Plastics	Senior	> 10

Overall, we had participants ranging in PGY level 1 to 6. Due to the overall low number of participants, we, therefore, clustered the participants into junior residents or senior residents. PGY level 1 to 3 were grouped as junior residents, while the PGY 4 to 6 were grouped into a senior resident group. Upon enrollment in the study, each participant was assigned a five-digit participation code that was randomly generated. Basic data, including age, sex, specialty, PGY level and self-declared experience were recorded and labeled with her participation code. This information was then sealed in an envelope which was opened after completion of the data analysis by the evaluators. The videos were only labeled with the five-digit participation code to ensure blinded evaluation.

The exercise started with the participants watching a video to exemplify an end to end nerve coaptation using our simulation model. The participants were then allowed to get accustomed to the instruments as well as the microscope. These introductory steps were performed regardless of the experience of the participants. The participants were then allowed to perform an end to end nerve coaptation, an exercise that was video recorded and labeled with their individual participation code. The videos were then separately evaluated by 5 fellowship trained microsurgeons, 4 of which had additional training in hand surgery.

2.2.2.3. Microneurorrhaphy evaluation scale:

The evaluation instrument was designed as a checklist type instrument by the first author as well as 3 other fellowship trained microsurgeons. Similar to our previously described microvascular evaluation scale, we determined 10 gestures considered essential to the successful completion of a nerve coaptation. These gestures were graded with either a 0 if poorly performed, or 1 if well executed. Some of the gestures were performed multiple times during the procedure, such as for example taking out the needle on the curve or using a fulcrum while pulling the suture through the tissues. A 1 was assigned if the evaluator felt that the participant was performing this task well most of the time, while any egregious error, such as tearing the tissue through the tissue would be graded as a 0. The evaluation instrument is shown in table 6.

Table 6. Microneurorrhaphy evaluation scale (MNES)

	0	1
Freshening nerve ends		
Axonal trimming		
Suture only purchases epineurium		
Favorable knot placement (not too tight)		
Adequate spacing of sutures		
No axonal bunching		
Gentle manipulation of tissues; Instrument stabilization		
Coordination of instruments, nerve and suture		
Takes needle out on a curve		
Uses fulcrum while pulling suture		
Score:		

2.2.2.4. Statistical analysis:

Inter-rater agreement with respect to the microneurorrhaphy evaluation scale was assessed with the intraclass correlation using the method of Shrout and Fleiss (56). Cronbach's alpha was used as a measure of internal consistency of the test items (overall reliability of the scale). Bivariate assessments based on the average score given by the raters were used to explore covariate effects via nonparametric tests (Wilcoxon Rank Sum, Kruskal-Wallis, Spearman rank correlation), using exact tests as needed. Formal evaluation of covariates effects was carried out utilizing a linear mixed modeling approach, specifying rater as a random effect and all other variables as fixed effects, in order to take into account the correlated nature of evaluations by multiple raters. Adjustment for multiple comparisons was made using the standard Bonferroni method in conjunction with an overall 0.05 level of significance. Statistical analyses were performed using SAS® software, Version 9.4. (SAS Institute Inc., Cary, NC). Intraclass correlations were obtained using the ICC package in R 3.1.0 (R Foundation, Vienna, Austria; Adler 2005).

2.2.3. Results

The video recordings of the performed nerve repairs were evaluated by 5 surgeons, generating a total of 80 individual evaluations. Each blinded evaluator scored the trainees based on a previously agreed upon neurorrhaphy simulation scale.

2.2.3.1. Assessment of inter-rater reliability

The intraclass correlation reflecting reliability among the five evaluators was 0.75 (95% CI: 0.57 – 0.89). The results were highly significant ($p=<0.0001$). Assessments of reliability for all possible pairings of these five evaluators are given in table 7. All results were highly significant ($p<0.005$ in all instances). ICCs for individual pairings of raters ranged from 0.61 to 0.90.

Table 7. Intraclass correlations assessing inter-rater reliability of the micro-neurorrhaphy evaluation scale for all possible pairs among five evaluators.

EVALUATOR	INTRACLASS CORRELATION (95% CI)			
	2	3	4	5
1	**0.81** (0.54 – 0.93)	**0.84** (0.598 – 0.940)	**0.83** (0.587 – 0.938)	**0.68** (0.30 - 0.88)
2		**0.69** (0.31 – 0.88)	**0.69** (0.31 – 0.88)	**0.90** (0.75 – 0.97)
3			**0.79** (0.49 – 0.92)	**0.63** (0.21 – 0.85)
4				**0.61** (0.19 – 0.85)

2.2.3.2. Cronbach's alpha

Based upon all resident scorings by all five evaluators, a Cronbach's alpha coefficient of 0.77 was obtained. A Cronbach's alpha coefficient of 0.91 was obtained when the items scores used were the mean scores averaged over the five raters.

The values of Cronbach's alpha obtained when item scores were considered for each rater separately were: reviewer 1: 0.76; reviewer 2: 0.84; reviewer 3: 0.73; reviewer 4: 0.63; reviewer 5: 0.84.

2.2.3.3. The relationship between performance as measured by average micro-neurorrhaphy evaluation scale and resident characteristics – bivariate analyses

Prior to modeling, bivariate relationships between the average MNES (mean of the scores from the 5 raters) were explored. There was no suggestion of a difference in average MNES score with sex (exact p=1.0, Wilcoxon Rank Sum test) or specialty (exact p=0.61, Kruskal-Wallis test). However, associations were found with PGY level and self-reported level of experience. The average MNES was significantly higher in senior residents than in junior residents (exact p =0.0034, Wilcoxon test). This relationship is illustrated in figure 11.

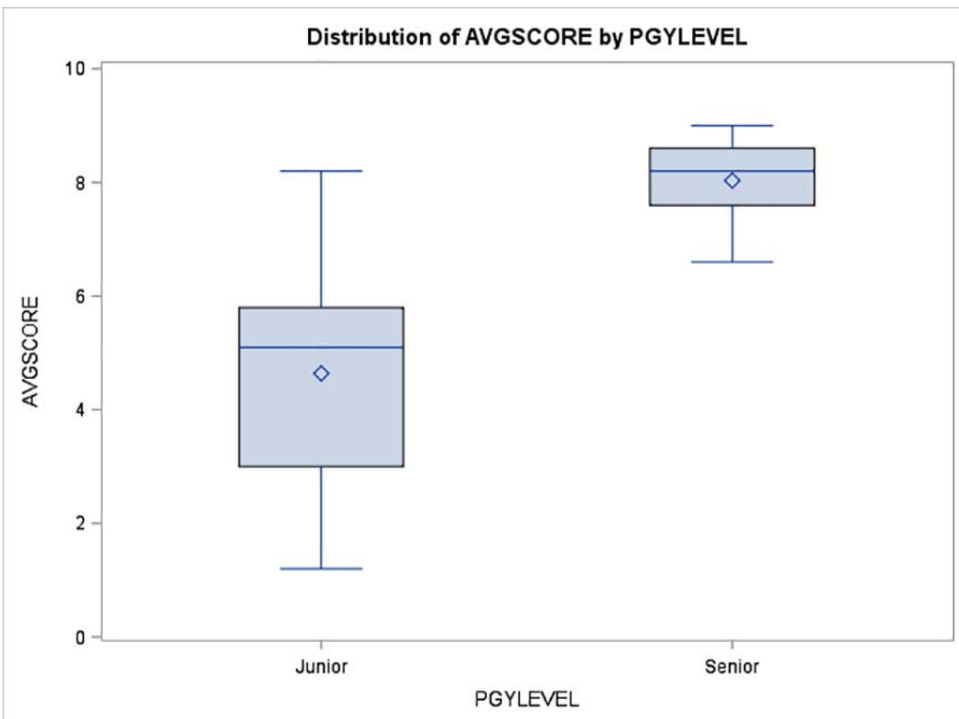

Figure 11. Average MNES score (mean score of 5 raters) for junior and senior residents

Average MNES was also significantly associated with the level of experience of the resident (exact p =0.0034, Kruskal-Wallis test). An alternative way of assessing this relationship was to look for a trend with increasing level of experience. There was strong evidence (r=.72, p=0.0018, Spearman rank correlation) that the average MNES was positively associated with the level of experience of the resident being rated. This relationship is illustrated in figure 12.

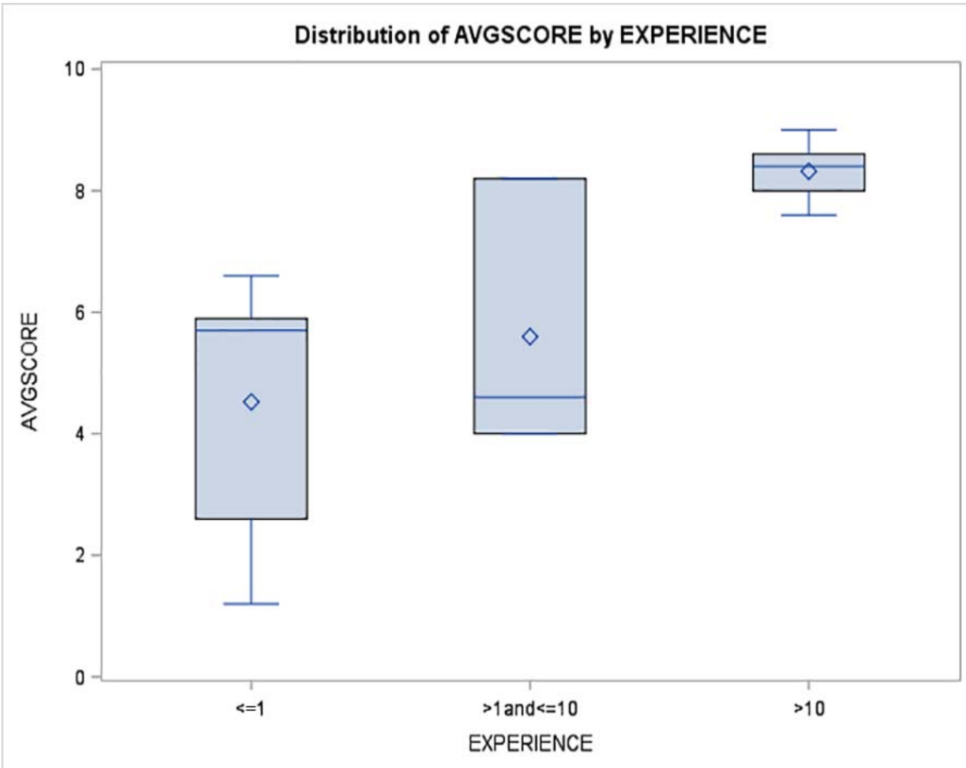

Figure 12. Average MNES score (mean score of 5 raters) for three levels of resident experience.

The data provided no evidence that the average MNES had an increasing or decreasing relationship with age (r=0.37, p=0.16, Spearman rank correlation).

2.2.3.4. The relationship between performance as measured by average micro-neurorrhaphy evaluation scale and resident characteristics – results from mixed modeling

The linear mixed modeling approach is taken specified rater as a random effect and all other variables as fixed effects. These included resident sex, age, level of seniority (PGY level:

junior or senior), specialty and level of experience, measured as one neurorrhaphy performed or less, between 1 and 10 neurorrhaphies, and over 10 neurorrhaphies. The data provided evidence that senior residents had significantly higher scores than junior residents (p=0.022). On average, junior resident scores were about 2.37 points lower than those of senior residents. The level of experience was also significantly associated with the MNES (p=0.033).

Given the strong correlation between PGY level and the self-declared level of experience, with all but one senior resident declaring an experience of >10 nerve coaptations performed and none of the junior residents declaring this level of experience (table 8), multicollinearity was suspected. Chi-square analysis revealed a p=0.0022. Therefore, we decided to model only the level of experience in four alternative ways: (1) the effect of the level experience is modeled using the three-level characterization, (2) a linear trend is fit with the three increasing levels, (3) experience is characterized as <=1 vs >1 experience, and (4) experience is characterized as <=10 vs. > 10 experiences.

Table 8. Correlation between PGY level and Experience: Chi-square analysis of PGY level and experience show a high degree of correlation (p=0.0022) with all but one senior resident having the highest level of experience. All 5 of the residents with the highest level of experience were senior plastic surgery residents.

Table of EXPERIENCE by PGYLEVEL			
EXPERIENCE	PGYLEVEL		
Frequency Percent Row Pct Col Pct	Junior	Senior	Total
<=1	7 43.75 87.50 70.00	1 6.25 12.50 16.67	8 50.00
>1 and <=10	3 18.75 100.00 30.00	0 0.00 0.00 0.00	3 18.75
>10	0 0.00 0.00 0.00	5 31.25 100.00 83.33	5 31.25
Total	10 62.50	6 37.50	16 100.00

However characterized, the level of experience was found to have a highly significant (p<0.0001) association with MNES in each of the four models considered. Of the four models, model (1), using the three-level characterization of experience, had the best fit based upon Akaike's Information Criterion. The overall test for the effect of experience was highly significant (p<0.0001), and there was strong evidence of variability associated with rater (p<0.0001). The mean MNES score for those with the most experience (>10) was 8.32. Residents with <=1 experience scored 3.80 points lower on the MNES, on average than those with the most experience (p<0.0001). Those with intermediate experience had a mean MNES score 2.72 lower than those with the most experience (p=0.0003). There was also a significant difference, between the groups with the least and with intermediate experience (p=0.0069), with mean MNES scores that were 1.08 points lower in the group with the least experience. All of the pairwise comparisons remained significant after Bonferroni adjustment for all pairwise multiple comparisons, specifying an overall 0.05 level of significance.

There was no evidence that resident sex, age or specialty were related to the MNES score after adjustment for the other variables in the model (p>0.05). There was evidence of variability among raters (p<0.001). Residual diagnostics were evaluated and were found to be satisfactory.

2.2.3.5. Subgroup analysis: plastic surgery residents

The largest subgroup among the 16 residents studied consisted of the 11 plastic surgery residents. Given the reasonably substantial size of this subgroup, and the homogeneity of their training experiences, there was interest in examining the MNES experience of this group. It should be noted that there is complete identification between having >10 experiences and being a senior resident: All senior residents had more than ten such experiences and none of the junior residents had that high a level of experience. This implies collinearity between these two measures: it is impossible to tease the effects of the two factors apart, and only one of the two can be considered in a given model at a time.

Therefore, four competing models were entertained to explore the relationship between the level of experience and MNES in the subgroup plastic surgery residents. They were: (1) the effect of the level experience is modeled using the three-level characterization, (2) a linear trend is fit with the three increasing levels, (3) experience is characterized as <_1 vs >1 experience, and (4) experience is characterized as <=10 vs. > 10 experiences. Note that (4) is the equivalent of comparing junior vs. senior residents.

However characterized, the level of experience was found to have a highly significant (p<0.0001) association with MNES in each of the four models considered. Of the four models, model (1), using the three-level characterization of experience, had the best fit based upon Akaike's Information Criterion. The overall test for the effect of experience was highly significant ($p<0.0001$), and there was strong evidence of variability associated with rater ($p<0.0001$). The mean MNES score for those with the most experience (>10) was 8.32. Plastic surgery residents with <=1 experience scored 4.65 points lower on the MNES, on average than those with the most experience ($p<0.0001$). Those with intermediate experience had a mean MNES score 2.72 lower than those with the most experience ($p<0.0001$). There was also a significant difference of -1.93 points, on average, between the groups with the least and with intermediate experience ($p=0.0069$). All of the pairwise comparisons remained significant after Bonferroni adjustment for all pairwise multiple comparisons, specifying an overall 0.05 level of significance. The positive correlation between MNES and level of experience is illustrated in figure 13.

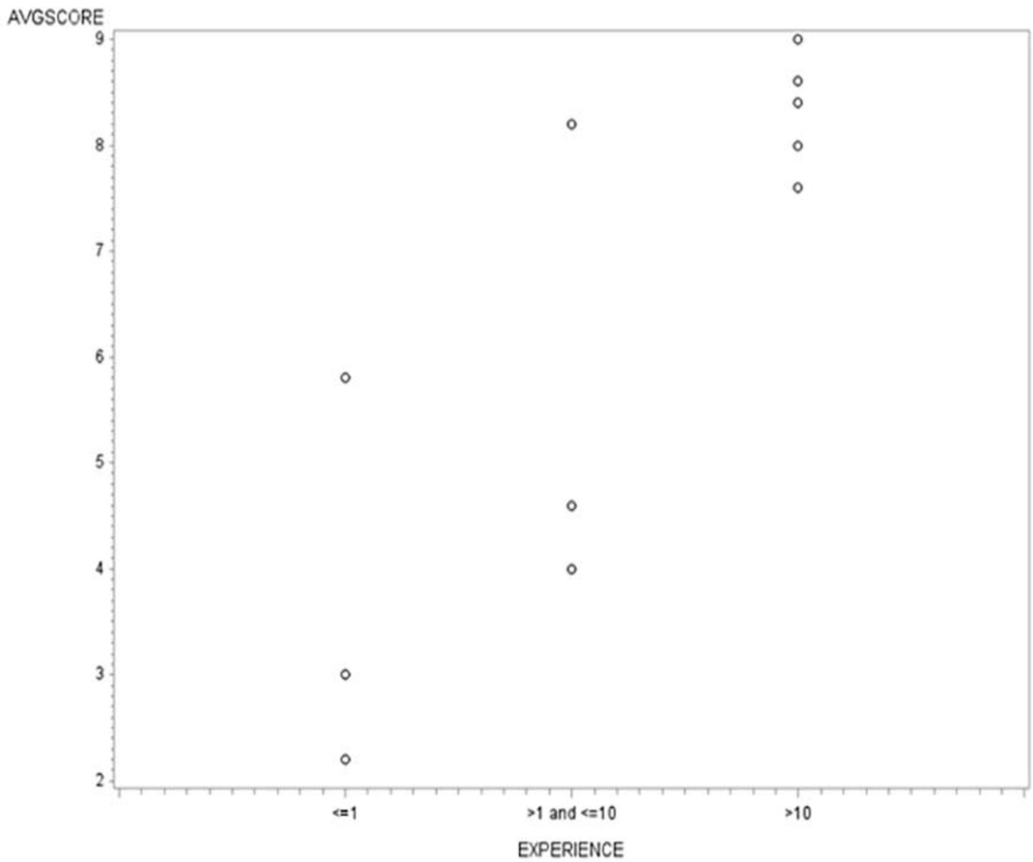

Figure 13. Average MNES score (mean score of 5 raters) vs. level of resident experience – plastic surgery residents only.

2.2.4. Discussion

The greater context of the study involves the versatile Thiel embalmed cadaveric tissues applied as models for microvascular, nerve and tendon repair simulations. This particular study focuses on the nerve tissue model has two distinct objectives. The first one is the novel use of Thiel embalmed cadaveric nerve specimens as a model for simulating nerve surgery. The second objective is to develop and validate a novel instrument for evaluating nerve coaptation. While a number of models have been described in the literature pertaining to microvascular simulation, the nerve surgery literature has few reported models for training and no instruments for evaluating nerve stimulation (27, 53, 55).

We have previously reported the use of Thiel embalmed cadaveric nerves as a model for microsurgical simulation. Using actual human median and ulnar nerves provides an excellent opportunity to practice repairing lacerated nerves and observe their internal architecture. The fascicles, as well as the perineural and epineural sheaths, were preserved, albeit the epineurium was thickened from wicking additional fluid. Individual nerve fascicles behaved very similar to *in vivo* nerves and can be adequately trimmed. The perineurium and epineurium provide good purchase for the sutures. The specimens can be procured from Thiel embalmed cadavers and preserved for long periods of time at 4°C. The only shortcomings we found compared to *in vivo* nerves as the absence of the vasa nervorum and the thickened, fluid-filled epineurium. The vasa nervorum are a useful guide when reapproximating nerve ends, while the thickened epineurium actually made it easier to place sutures. Because of the overall preserved quality of the nerve tissue and its architecture, we consider Thiel embalmed nerve tissue to be an excellent model for micro-surgical simulation that can be preserved for long periods of time.

The Micro-Neurorrhaphy Evaluation Scale (MNES) was developed to assess resident performance in medical simulations used in surgical training. While most of the microsurgical evaluation scales have been variations of the OSATS model, we previously described a checklist based evaluation instrument that showed a better correlation with self-reported surgical experience as well as the level of training. The MNES consists of 10 items or gestures that are summed to produce a total score ranging from 0 to 10. In this study, the performance of each of 16 residents was blindly evaluated by 5 surgeons. The goals of the study were to evaluate inter-rater reliability of the instrument, to assess Cronbach's alpha, and to evaluate possible relationships between performance (as measured by the micro-neurorrhaphy evaluation scale) and resident characteristics. These characteristics included age, sex, specialty, PGY level and level of experience.

The intraclass correlation and associated 95% confidence interval (CI) reflecting the reproducibility of the ratings using the micro-neurorrhaphy evaluation scale among the five evaluators were obtained using the method of Shrout and Fleiss (56). Reliability for each possible pairing of these five evaluators was assessed using the same approach. Cicchetti indicates that ICCs between .6 and .74 are considered good and those between .75 and 1.0 are regarded representing excellent agreement (57). The intraclass correlation among the five evaluators in our study was 0.75 (95% CI: 0.57 – 0.89) with p=<0.0001). This provides strong evidence of an inter-rater agreement, which was at the lower end of the range considered excellent. While there is no nerve literature to compare our data to, our similarly constructed instrument for microvascular simulation revealed an ICC of 0.89. Other microvascular simulation scales have reported ICCs of 0.79 and 0.78 (39, 47). When assessing the reliability for all possible pairings of evaluators, as shown in table 7, the results are also highly significant with p<0.005 in all instances. ICCs for individual pairings of raters ranged from 0.61 to 0.90, spanning the range of good to excellent agreement. It may be noted that the confidence intervals are fairly wide, reflecting the modest number of residents evaluated.

Cronbach's alpha was used as a measure of internal consistency of the test items (sometimes characterized as overall reliability of the scale); this was obtained using the mean item score (averaged over all five raters), and for each rater separately. A higher value of the Cronbach alpha coefficient reflects greater shared covariance among the scale items, which are therefore considered more likely to measure the same underlying concept. Although the criterion varies by discipline, a value of at least 0.70 was suggested to be desirable by Nunnally and Bernstein (58), and this guideline is widely observed. Based upon all resident scorings by the five evaluators we obtained a Cronbach's alpha coefficient of 0.77. When averaging the mean scores over the five evaluators, the Cronbach alpha coefficient was found to be 0.91. Both of these values exceed the 0.70 value referenced above. Even when considering each rater separately, all but one Cronbach's alpha obtained exceeded the 0.70 benchmark.

While the ICC and the Cronbach's alpha obtained in this study are good indicators of internal validity, a study with a relatively small number of participants is often underpowered when trying to demonstrate the external validity of an instrument. We looked at the correlation between the scores obtained by the participants and their PGY level as well as the self-reported experience with microneurorrhaphy. Bivariate analysis and mixed modeling were used to this end. Bivariate analysis revealed significantly higher scores in the senior resident group when compared to the junior resident group (p=0.0034). Using mixed modeling, the data provided evidence that senior residents had significantly higher scores than junior residents (p=0.022). On average, junior resident scores were about 2.37 points lower than those of senior residents.

When looking at the correlation between the self-reported level of experience, the average MNES was also significantly associated with the level of experience of the resident (exact p =0.0034, Kruskal-Wallis test). An alternative to assessing this relationship was to look for a trend with increasing level of experience. There was strong evidence (r=.72, p=0.0018, Spearman rank correlation) that the average MNES was positively associated with the level of experience of the resident being rated. When comparing the 3 different groups of the level of experience, while the trend could be observed, our initial modeling did not reveal the results to be statistically significant. One reason for this was the collinearity observed between the groups of residence separated by PGY level and by self-declared experience. As shown in table 8, all but 1 senior residents also performed more than 10 anastomoses and none of the junior residents were in the more than 10 anastomosis group. A side effect of the multicollinearity is that it inflates the standard error, resulting in a loss of power. We, therefore, decided to model our results with respect to experience alone. As described in the results section, this was done four alternative ways. This analysis revealed a significant correlation between the level of experience and the MNES scores. When looking at the plastic surgery resident subgroup, representing 11 of the 16 participants, the correlation between the level of experience and NMES cores was even clearer.

An interesting trend can be observed in figure 13. There seems to be a higher variability and scores obtained by the less experienced residents rather than the more experienced residents. There seems to be an outlier in both the least experienced as well as the intermediate experienced groups who scored higher than the record. This may not surprise us given that residents do not have a uniform skill level and some are more "gifted" than others. What is interesting is that the senior residents, which in the case of the plastic surgery residents coincided with the self-declared experience of more than ten nerve coaptations, had a much tighter grouping of scores with a much decreased standard deviation. While this may only be a trend, we hope that future research with a larger cohort of residence will be able to confirm this pattern. Our objective as surgical educators is to form specialists of consistently high quality. While we all may like the occasional superstar resident, a society of large is better served if specialists are uniformly good rather than spread along the spectrum from mediocrity to excellence.

The limitations of the study are twofold: (1) The number of participating residents was small and (2) We did not follow the residents longitudinally to test the effects of simulation on an individual's performance. The small number of participants makes it difficult to have a well-powered study. However, in a small specialty like plastic surgery, it is very difficult to recruit a large cohort of residents. In our case, we had 11 participants from the 15 residents in the plastic surgery program. Most residency programs in North America are much smaller and each geographic area typically has one program. The only options for recruiting more participants would be to have the simulation set at the national conference or design a multicenter study. We hope that the competence by design program by the Royal College of Physicians and Surgeons of Canada will serve as a catalyst for a large, multicenter study in Canada. The second limitation we find is the lack of longitudinal observations as residents improve their surgical skill. While we believe facilitating improvement in skill to be the ultimate objective of any surgical simulation model, the objective of the current study was to proposed and validate a novel evaluation instrument for peripheral nerve surgery.

While the objective of any simulation model is to aid in the development and consolidation of skills by the trainee, as we decided to implement simulation in the competency-based training we have to determine the benchmarks residents need to meet in order to progress to the next level of training. Our data suggest that the senior residents performed significantly better than the junior residents, while the group of residents with the highest self-reported experience also significantly outperformed those with the lowest level of experience. As described above, the bivariate analysis reached significance when it came to the level of experience, and supported an increasing trend in average score with increasing experience. Mixed modeling similarly provided evidence for statistically significant differences among the three levels of experience examined and parameter estimates provided strong evidence of an increase in score with greater experience. The group of senior plastic surgery residents coincides with those who reported more than ten nerve coaptations performed, and this group averaged a score of 8.3. We, therefore, proposed benchmarks score of 8 for surgical trainees to obtain before performing nerve crepitations in the operating room on patients.

Our experience with Thiel cadaveric nerves has been positive and we propose it as a high fidelity simulation model for training surgical trainees the basics of nerve repair. To our knowledge, this is also the first report of an evaluation instrument specifically designed and validated for nerve surgery stimulation. Future directions of study will include the longitudinal evaluation of residents over their training as well as the implementation of the Thiel nerve model and a “microsurgical boot camp week” for junior residents in plastic surgery.

Chapter 3: Tendon Repair Simulation

3.1. The Thiel cadaveric tendon simulation model and evaluation instrument

Not submitted for publication

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3.1.1. Introduction

The proper repair of flexor tendons is an essential skill plastic surgery and orthopedic surgery residents need to master. While at first glance this seems to be a simple task, flexor tendon repair, if done properly, requires as much finesse as performing a microvascular anastomosis or a nerve repair. As we are shifting from a time base to a competency-based model of surgical teaching, it is incumbent on us to develop simulation models for our residents to practice on and hone their skill before live surgery. While most plastic surgery residency programs have workshops for microvascular teaching, albeit somewhat informal and without objective instruments for evaluation, to our knowledge there are no cadaver labs for tendon surgery. A few models for tendon repair simulation have been proposed including porcine (59) (60) and sheep (61) forelimb models. Hassan and colleagues compared the Thiel flexor tendon simulation model to the porcine forelimb and found the former to perform better (26). This favorable performance of the Thiel model was mostly based on a postprocedure questionnaire answered by the participants themselves.

While describing a model is the first step in developing a simulation system, the essential next step in the process is the development and validation an evaluation instrument. In other surgical fields, there have been a number of such instruments described and implemented, such as the Objective Structured Assessment of Technical Skills (OSATS) described by Reznick et al (45), the Structured Assessment of Microsurgery Skills (SAMS) described by Chan et al (47) and the University of Western Ontario Microsurgical Skills Acquisition/Assessment instrument described by Temple and Ross (39). We could not identify any evaluation instrument designed and validated for flexor tendon repair.

The objective of this study was twofold: 1. The description of the Thiel cadaveric model for tendon repair and 2. The development and validation of an evaluation instrument for flexor tendon repair simulation.

3.1.2. Methods

3.1.2.1. Thiel tendon specimens:

Flexor digitorum superficialis and profundus tendons from Thiel embalmed cadavers (23) were harvested and stored in the embalming solution at 4°C. To simulate the tendon sheath, we used a pediatric endotracheal tube in which we cut an opening of about 1.5 cm in length to mimic the space between 2 annular pulleys. The tendon was threaded through this endotracheal tube and attached proximally and distally to rubber bands in order to replicate the tendency of flexor tendons to retract. A length of flexor tendon could be used for multiple tenorrhaphies, cutting out the segment of tendon containing the sutures and advancing the tendon in the simulated sheath from either end.

3.1.2.2. Study design:

An email invitation was sent to plastic surgery residents from one Canadian University. A total of 11 participants, ranging from PGY level 1 to 5, were recruited for the study. Basic information regarding the participants including training level as well as self-declared experience with flexor tendon repairs was collected (table 9). Due to the low number of participants, we decided to subdivide experiencing to 3 levels: Least experience (one or no tendon repairs performed), intermediate experience (between 1 and 10 tendon repairs performed) and highest experience (more than 10 tendon repair is performed). We note that the designation highest experience does not imply expert level, and only refers to the relative comparison between these three groups. Additionally, level of training was grouped into junior residents, including PGY 1 to 3 and senior residents, including PGY 5 and 6. Each participant was assigned a random 5 digit participation code. The participant information was labeled with this code and sealed in an envelope until after evaluation of the performance. Participants were then shown a video demonstrating step-by-step a four strand flexor tenorrhaphy with a modified Kessler suture followed by a horizontal mattress core suture. The tendon repair was then finished with an epitendinous repair. The core suture was 3-0 polyester while the epitendinous repair was performed with 5-0 polypropylene. Upon completion of the tenorrhaphy, the tendon was removed in order to measure the breaking strength. This was achieved by attaching one of the tendons ends to a vise while pulling on the opposite end in a horizontal direction with a Newton-meter. The breaking strength was recorded in Newtons.

Table 9. Participant information. PGY 1-3 were further grouped as junior residents, PGY 4-5 senior residents.

Participant	Age	Sex	Specialty	PGY level	Experience (Tenorrhaphies performed)
1	26	F	Plastics	Junior	>1 and ≤ 10
2	27	M	Plastics	Junior	≤1
3	35	M	Plastics	Senior	>1 and ≤ 10
4	26	F	Plastics	Junior	≤1
5	38	M	Plastics	Junior	≤1
6	24	M	Plastics	Junior	≤1
7	28	F	Plastics	Senior	> 10
8	27	M	Plastics	Senior	> 10
9	32	M	Plastics	Senior	> 10
10	29	M	Plastics	Senior	> 10
11	28	M	Plastics	Junior	≤1

3.1.2.3. Flexor tendon evaluation scale:

Similar to our previously described evaluation instruments for microvascular and peripheral nerve stimulation, we chose to construct a checklist type instrument for the tendon repair evaluation scale. Five plastic surgeons, four of which with hand fellowship training, participated to produce this evaluation instrument. We reconstructed tendon repair into ten distinct gestures, each graded with either a 0, if poorly performed, or a 1 if well performed.

This evaluation instrument named Flexor Tendon Evaluation Scale (FTES) is shown in table 10.

Table 10. Flexor tendon evaluation acale (FTES)

	0	1
Atraumatic retrieval of tendon ends		
Adequate apposition for repair (fixated with needles)		
Refreshes tendon ends adequately		
Wide core suture purchase (8-10mm)		
Appropriate placement of grasping stitch		
Central placement of core suture in tendon substance		
Appropriate epitendinous suture placement (catches peritenon)		
No fraying of tendon by suture		
Gentle manipulation of tissues; No damage to tendon end by forceps		
Favorable knot tightness (no gap or excessive bunching)		
Score:		

3.1.2.4. Statistical analysis:

Inter-rater agreement with respect to the tendon repair evaluation scale was assessed with the intraclass correlation using the method of Shrout and Fleiss (56). Cronbach's alpha was used as a measure of internal consistency of the test items (overall reliability of the scale). Bivariate assessments based on the average score given by the raters were used to explore covariate effects. Formal evaluation of covariates effects was carried out utilizing a linear mixed modeling approach, specifying rater as a random effect and all other variables as fixed effects. Adjustment for multiple comparisons was made using the standard Bonferroni method in conjunction with an overall 0.05 level of significance. Statistical analyses were performed using SAS® software, Version 9.4. (SAS Institute Inc., Cary, NC). Intraclass correlations were obtained using the ICC package in R 3.1.0 (R Foundation, Vienna, Austria; Adler 2005).

3.1.3. Results

3.1.3.1. Assessment of inter-rater reliability

The intraclass correlation reflecting reliability among the four evaluators was 0.50 (95% CI: 0.20 – 0.79). The results were highly significant (p=0.0003), providing strong evidence of inter-rater agreement; however, the level of agreement was in the range generally considered to represent only fair agreement.

Assessments of reliability for all possible pairings of these four evaluators are given in table 11. As indicated, not all results were significant. ICCs for individual pairings of raters ranged from 0.20 to 0.81. It may be noted that the confidence intervals are fairly wide, reflecting the modest number of residents evaluated.

Table 11. Intraclass correlations assessing inter-rater reliability of the tendon evaluation scale for all possible pairs among four evaluators. The overall intraclass correlation based upon ratings by all four evaluators was 0.50 (95% Confidence Interval 0. 0.20 – 0.79), with strong evidence of significant (p=0.0003) but moderate agreement.

* Intraclass correlations and associated 95% confidence intervals; the significance probability (p-value) is that associated with the null hypothesis that the intraclass correlation is zero (no agreement).

EVALUATOR	**INTRACLASS CORRELATION (95% CI)* P-Value**		
	2	**3**	**4**
1	**0.53** (-0.06 – 0.85) p=0.037	**0.46** (-0.16 – 0.82) P=0.067	**0.81** (0.44 - 0.95) P=0.0007
3		**0.37** (-0.26 – 0.78) P=0.12	**0.56** (-0.02 – 0.86) P=0.028
4			**0.20** (-0.43 – 0.70) p=0.27

3.1.3.2. Cronbach's alpha

Based upon all resident scorings by all four evaluators, a Cronbach's alpha coefficient of 0.78 was obtained. A Cronbach's alpha coefficient of 0.89 was obtained when the items scores used were the mean scores averaged over the four raters. The values obtained when item scores were considered for each rater separately were: reviewer 1: 0.77; reviewer 2: 0.75; reviewer 3: 0.78; reviewer 4: 0.82.

3.1.3.3. The relationship between performance as measured by the tendon evaluation scale and resident characteristics – bivariate analyses

Prior to modeling, bivariate relationships between the average tendon scores (mean of the scores from the 4 raters) were explored. There was no suggestion of a difference in average score with sex (exact p=0.99), or program level (PGYLEVEL junior/senior) (exact p=0.36), or the three-level classification of experience (p=0.85) based upon the exact Wilcoxon Rank Sum test.

There was a strong relationship between experience (measured as the self-reported number of procedures) and level of training (p= 0.0043, exact Wilcoxon test), as illustrated in figure 14. These results suggest strong multicollinearity between the level of training and level of experience as measured by these variables.

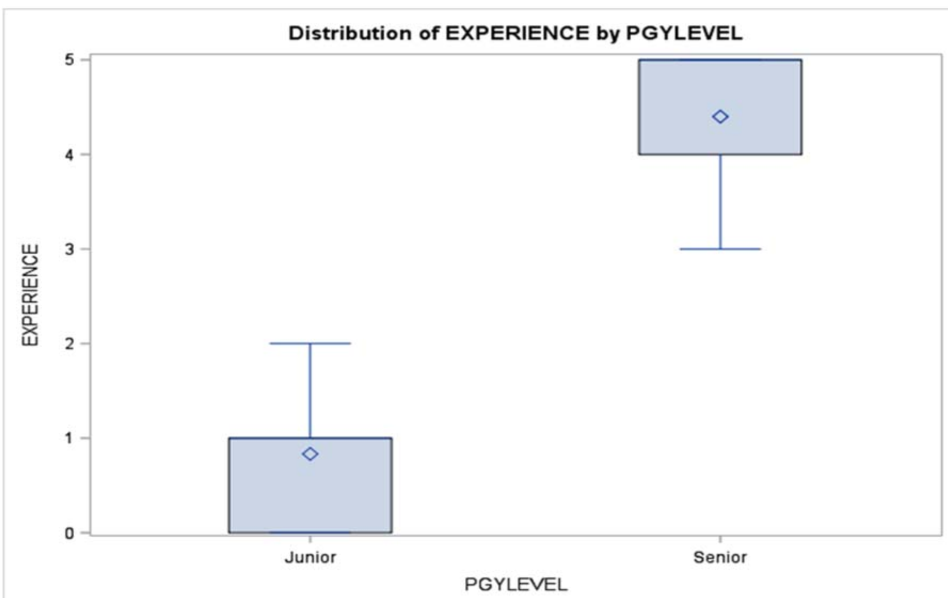

Figure 14. Differences in the distribution of the experience measured by the self-reported number of procedures performed based upon all four raters between junior and senior plastic surgery residents (p = 0.0043, exact Wilcoxon test).

3.1.3.4. The relationship between performance as measured by tendon surgery evaluation scale and resident characteristics – results from mixed modeling

The linear mixed modeling approach is taken specified rater as a random effect and all other variables as fixed effects. These included resident sex, age, level of training (PGY level: junior or senior), and level of experience, measured as a number of self-reported procedures and also classified as less or equal to 1, between 1 and 10, or more than 10. Strong evidence of multicollinearity was found between level of experience and program level (junior vs. senior), implying that both variables could not be entertained in a model at the same time.

When models specifying only a single fixed effect, taking into account the repeated nature of the data and specifying rater as a random effect, the data provided evidence that there was a positive association between breaking strength and tendon evaluation score ($p=0.038$). This relationship is illustrated in figure 15. There was strong evidence of variability among the raters ($p<0.0001$).

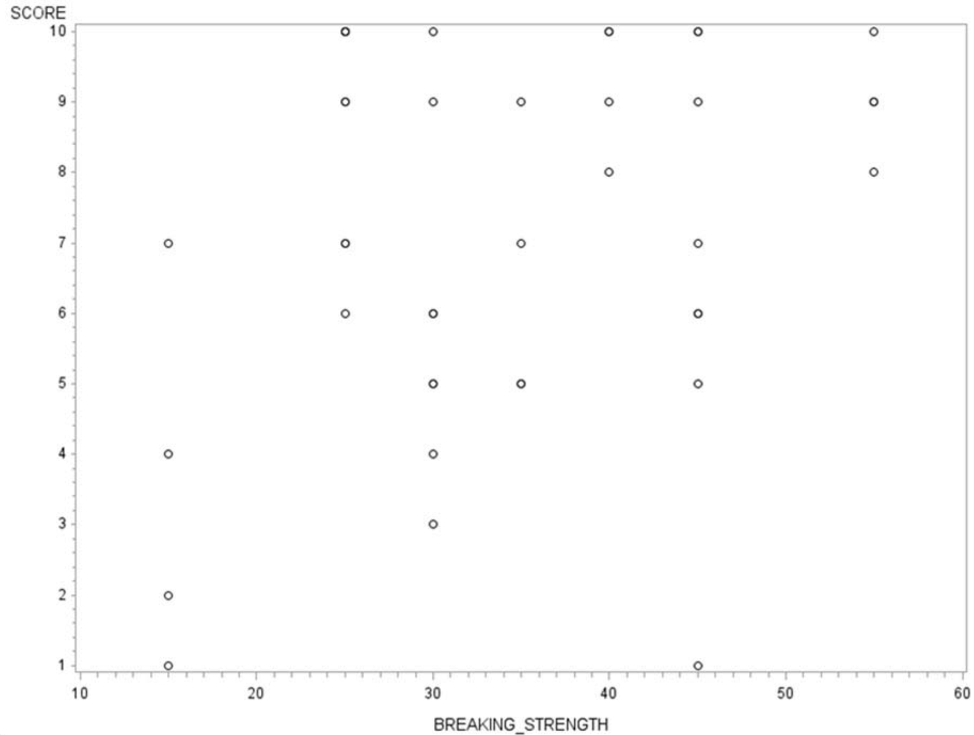

Figure 15. Plot of tendon evaluation score vs. breaking strength (in Newtons)

No other single variable achieved statistical significance (p<0.05) when considered in this manner, however, results for the level of experience (p=0.057) were suggestive, although the associations appeared to be quite modest (figure 16). In all instances, there was strong evidence of variability among the raters (p<0.0001).

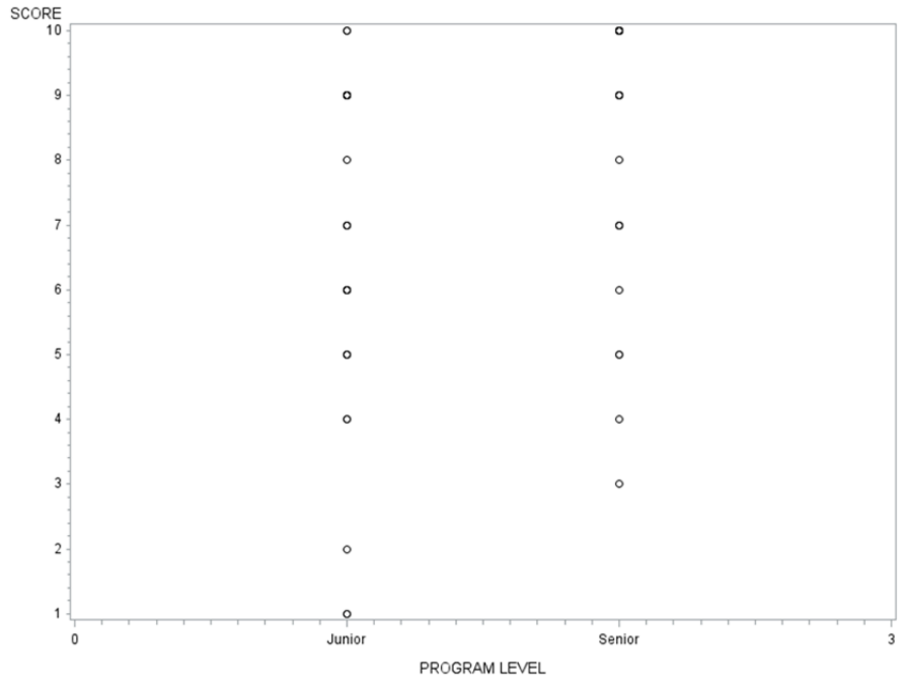

Figure 16. Plot of tendon evaluation score vs. program level

When each of the additional variables was added to the model containing breaking strength, the only variable that contributed significantly after adjustment for breaking strength was the level of experience ($p=0.036$). The bivariate relationship of score and experience level is depicted in figure 17. After adjustment for experience level, there remained an association with breaking strength ($p=0.050$). The model including both breaking strength and level of experience as fixed effects fits better than the single variable model having only breaking strength as a covariate based upon Akaike's Information Criterion. There was strong evidence of variability among the raters ($p<0.0001$). Residual diagnostics were evaluated and were found to be satisfactory.

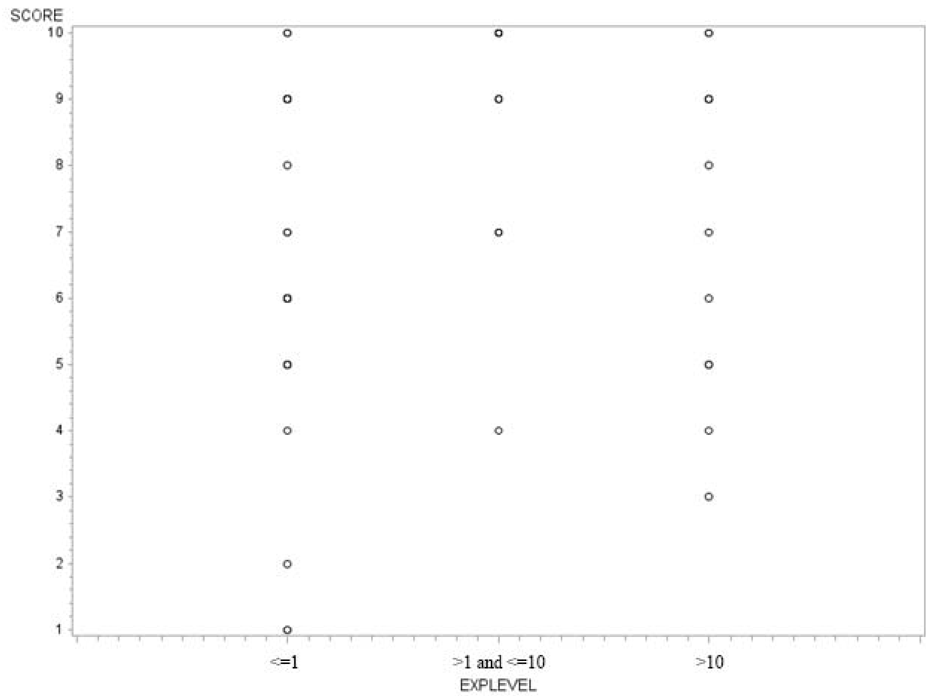

Figure 17. Plot of tendon evaluation score vs. level of experience.

3.1.4. Discussion

The intraclass correlation and associated 95% confidence interval reflecting the reproducibility of the ratings using this scale among the four evaluators were obtained using the method of Shrout and Fleiss (56). Reliability for each possible pairing of these four evaluators was assessed using the same approach. Cicchetti (1994) indicates that ICCs between .6 and .74 are considered good and those between .75 and 1.0 are regarded representing excellent agreement. We obtained an ICC of 0.50 (95% CI: 0.20 – 0.79) which places our result in the range considered to represent "fair" agreement. There was however strong evidence of inter-rater agreement with a p=0.0003. The ICCs for individual pairings ranged from 0.20 to 0.81, spanning the range from poor to excellent agreement. These results are in stark contrast with the ICCs obtained in our Microvascular Evaluation Scale (MVES) (0.89) and the Micro-Neurorrhaphy Evaluation Scale (MNES) (0.75). While the model for constructing the evaluation instruments was the same for the three models (vessel, nerve, and tendon), this significantly lower ICC may be related to intrinsic differences between the procedures or the way they are perceived on video. For example, it may be easier to perceive whether the resident pulls out the needle on a curve during a microanastomosis or adequately spaces the micro-sutures than assessing the adequate purchase of a core suture in a tendon repair. While this is just conjecture, what permeates is the only “fair” degree of reproducibility in the ratings obtained with the FTES.

Cronbach’s alpha was used as a measure of internal consistency of the test items (sometimes characterized as overall reliability of the scale); this was obtained using the mean item score (averaged over all four raters), and for each rater separately. A higher value of the Cronbach alpha coefficient reflects greater shared covariance among the scale items, which are therefore considered more likely to measure the same underlying concept. Although the criterion varies by discipline, a value of at least 0.70 was suggested to be desirable by Nunnally and Bernstein (58), and this guideline is widely observed. We obtained an overall Cronbach’s alpha of 0.78, and when calculating the coefficient using the mean scores averaged over the four raters we obtained 0.89. Both of these values exceed the suggested benchmark of 0.70.

Initial explorations of relationships with covariates were carried out utilizing the average scores (mean of the scores of the four raters): potential associations with quantitative covariates were assessed using the Spearman rank correlation, and potential relationships with categorical covariates were assessed using exact nonparametric tests, including the exact Wilcoxon Rank Sum and Kruskal-Wallis tests. There was a strong positive correlation between PGY level and the self-declared experience as seen in figure 14, suggesting a strong multicollinearity between the level of training and the self-declared experience. No statistically significant correlation was found between the PGY level and the average score ($p=0.36$). While the low ICC may explain the lack of correlation between performance and the PGY level or self-declared experience, the low number of participants is also a factor influencing the power.

A definitive evaluation of covariates effects was carried out utilizing a linear mixed modeling approach, specifying rater as a random effect and all other variables as fixed effects. Adjustment for multiple comparisons was made using the standard Bonferroni method in conjunction with an overall 0.05 level of significance. When modeling for one single fixed effect, the data showed a positive correlation between breaking strength and the scores obtained by the residents ($p=0.038$). None of the other variables achieved statistical significance although the correlation between the PGY level (senior vs. junior level) and the scores had a $p=0.057$, suggestive of a possible association. When adding all additional variables to the model, we found a significant contribution to the level of experience after adjusting for breaking strength ($p=0.036$). Throughout the modeling, there was strong evidence of variability between the raters.

When comparing the results obtained for the FTES to those obtained in the MVES and MNES, the results from the FTES are far inferior. The scales were constructed in a very similar manner, as checklist style instruments. While the Chronbach's alpha was suggestive of good internal consistency of the instrument, the fair ICC showed a high degree of inter-rater variability and a low degree of reproducibility. The statistically significant correlations obtained with mixed modeling showed significant correlations between breaking strength and level of training, comparisons that are independent of the raters. While perhaps statistical significance could have been obtained using a larger cohort, the low ICC significantly erodes the usefulness of the FTES. In the context of the validated similar instruments for microvascular and peripheral nerve simulation, we do believe the FTES holds promise despite the less than satisfactory results at this moment. Future directions include refining the instrument with respect to the gestures selected and calibrating the instrument.

Chapter 4: Thiel Research Model

4.1. A new microsurgical research model using Thiel embalmed arteries and comparison of two suture techniques (34)

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4.1.1. Introduction

Current laboratory models for non-animal research and training in microvascular surgery include computer simulation, synthetic materials, explanted animal vessels, and cadaveric human vessels (42). Human vessel models are preferred over the other models due to their similarity to the *in vivo* human model. However, fresh cadaveric vessels can only be temporarily preserved, and current fixation methods result in a loss of the normal tissue texture that results in confounding for microsurgical research and an easier anastomosis for the trainee (40).

A novel method of tissue preservation was introduced by Thiel in 1992 (23). This technique preserves texture, volume, color, and shape of the body while avoiding the decay observed with fresh cadaveric specimens. There is no shrinking or soaking of the soft tissues. It has been used in the microsurgical laboratory as a method for teaching flap harvesting. However, its utility in microsurgical anastomosis teaching and research has not been fully elucidated.

We hypothesize that a Thiel model can be successfully used for microvascular anastomosis research and teaching, and can be used to compare microsurgical techniques. We aim to evaluate the use of this model for microanastomosis of human arteries. Using a comparison of two microvascular techniques (simple interrupted (SI) and horizontal mattress (HM) sutures), we assessed the following outcomes: technique speed, vessel leakage, patency, stricture rate, microarchitecture, eversion, and intraluminal sutures.

4.1.2. Materials and methods

To test this research model, we conducted an anatomical study on radial and ulnar arteries obtained from cadavers; the donors had previously consented to tissue utilization in post-mortem research. The arteries were donated by the McGill University Anatomy Laboratory and originated from cadavers prepared with the embalming method described by Thiel (23, 32).

4.1.2.1. Model set-up

Our model consisted of the following components: two vessel ends, a table with a petri dish and microsurgical background, an approximator, microsurgical needle driver and sutures, and an operating microscope (Opmi Pico, Carl Zeiss). The microscope is attached to a camera recording system for subsequent study purposes, and the model is intended for use by one operator at a time. In order to perform anastomoses, the operator must initially dissect the adventitia and surrounding connective tissue from the vessel.

4.1.2.2. Specimen preparation

Twenty arterial sections measuring 3 cm each were prepared using the radial arteries in order to achieve a total of twenty microvascular anastomoses. The arteries had a diameter ranging between 3mm and 3.5mm. The vessels were irrigated with a physiologic saline solution. The operating microscope at 10X magnification was used for all anastomoses.

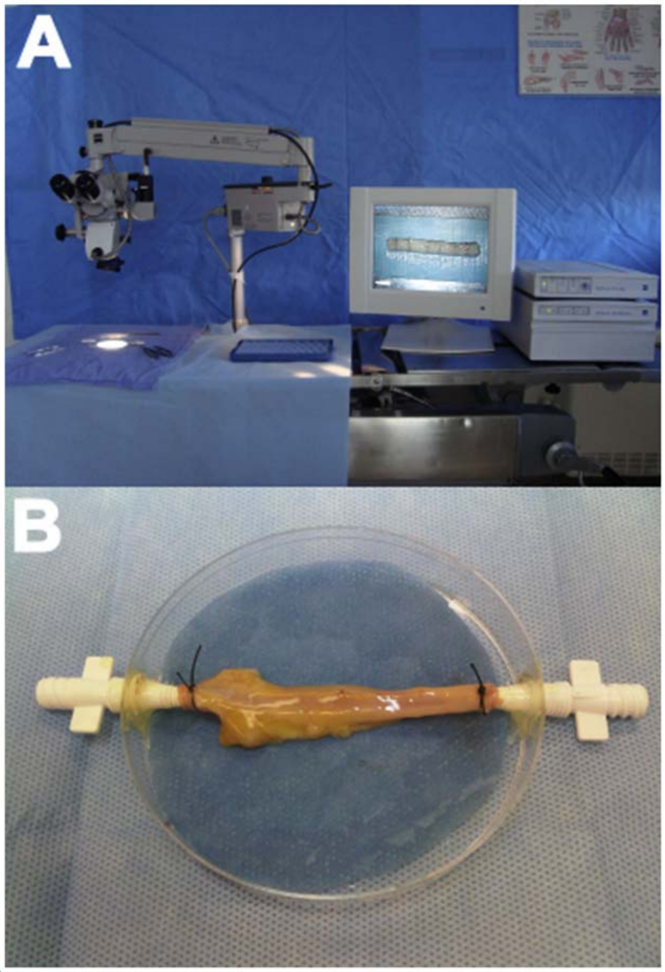

Figure 18. Research model setup (A) with the visible operative field (B).

4.1.2.3. Surgical technique

All anastomoses were performed by a single surgeon. Under 10X magnification, we initially proceed with minimal adventitia excision, removing the adventitial excess that could be pulled further than the edge of the muscularis. The two ends were then inspected for intimal integrity, dilated gently using the forceps and approximated. Ten SI anastomoses were performed using approximator clamps to serve as a control group. The orientation sutures were placed at 0° and

180°. One side of the anastomosis was completed, the clamps turned and after inspection of the back wall, the second side was sutured.

For the HM technique, approximator clamps were not necessary. Using a 9-0 nylon suture, we started with a backhand pass of the HM suture and returned with the forehand pass approximately 1 mm apart, such that the center of the suture would coincide with the zenith of the vessel. Care was taken to always visualize the intraluminal side of the vessel, ensuring that full-thickness bites were taken. The tension of the knot was adjusted to provide the optimal amount of eversion at the anastomotic site. The vessel was then flipped and two other HM sutures were placed at 120° from the first suture. The technique is schematically represented in Figure 19. Ten specimens using the HM technique were performed.

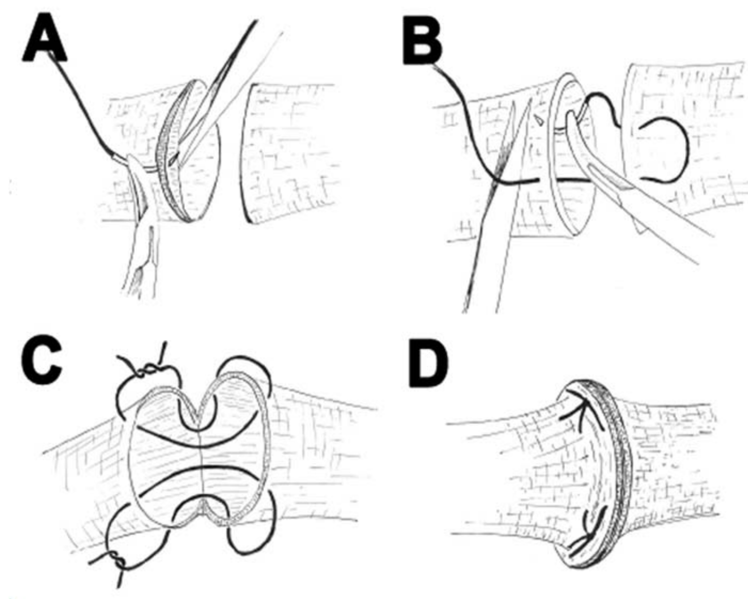

Figure 19. Schematic representation of the horizontal mattress suture technique. The first suture pass is placed backhand, making sure that the entire vessel wall is caught (A). The width of the horizontal mattress bite equals approximately 1/3 of the flap vessel diameter (B). Two additional sutures are placed evenly around the vessel circumference such that the

midpoint of each horizontal mattress is at 120 from the next (C). Final appearance of the anastomosis with the everted edges (D).

4.1.2.4. Measurement of outcomes

The anastomoses were video recorded and the time required for completion of each anastomosis was calculated. Leakage was assessed using direct microscopic evaluation by injecting physiologic saline into the anastomotic set-up. The leaks were graded as 0 in the case of no leak, 1 for minor leak/oozing and 2 representing severe leaks.

Angiography was performed to assess for stenosis at the anastomotic site. Iodine-based nonionic dye (Omnipaque 350, Sterling-Winthrop) was injected into the vessels and images captured using a standard fluoroscopy setup. The picture archiving and communication system (PACS) software was used to measure the size of the lumina, at the anastomosis as well as at the unconstructed adjacent sites.

Lastly, the specimens were examined for eversion at the anastomotic site using light and scanning electron microscopy. Twenty specimens, ten obtained using the HM and ten with the SI techniques, were opened in between two sutures and rolled out to expose the intraluminal side. Half of these specimens were prepared for scanning electron microscopy, while the other half was prepared for light microscopy.

The specimens were fixed in 2% glutaraldehyde and in a 0.1M sodium cacodylate solution at a pH of 7.3. These specimens were then kept at 4°C. Subsequently, a 20 minute dehydration period at room air was allowed prior to gold coating using a pulverizer (Agar Manual Sputter Coater). A scanning electron microscope (ESEM Quanta 200 FEG, FEI Company, Hillsboro, OR) equipped with an EDAX detector (EDX) for microanalysis was used. The observations were done at 20kV and a working distance of about 5mm. XTDocu imaging software was used to analyze the images.

For light microscopy, the specimens were fixed in formaldehyde solution, embedded in paraffin and stained for microscopy with hematoxylin and eosin (H&E) in a clinical pathology laboratory following standard protocol.

Statistical analysis was performed using IBM SPSS Statistics 19. For length, time to completion, and surface reduction between samples, the Wilcoxon rank-sum test for independent samples was used. For lumen reduction within samples, the Wilcoxon rank-sum test for related samples was used. For categorical variables, Fisher's exact t-test was used. A p-value less than 0.05 was considered statistically significant.

*4.1.*3. Results

4.1.3.1. Research model evaluation

The microsurgical system was easily mounted, specimens were prepared using standard protocol without complication and easily preserved over the study period (four weeks). All microvascular anastomoses were completed without technical difficulties and were video recorded. Leaks were examined under direct vision and standard angiography. The degree of stricture was identified using angiography as well. We successfully evaluated intimal appearance with light microscopy and SEM. Speed was easily assessed using the video recordings. The details of each evaluation for our tested suture types are presented below.

4.1.3.2. Anastomotic leaks

Anastomotic leakage was assessed under direct microscopic vision (figure 20). In the SI group, only one out of ten anastomoses had a minor leak (grade 1), while three out of ten HM anastomoses had leaks, two grade 1 and one grade 2. Although clinically important, this difference was not statistically significant (p=0.087). All of these leaks were obliterated by placement of an additional SI suture.

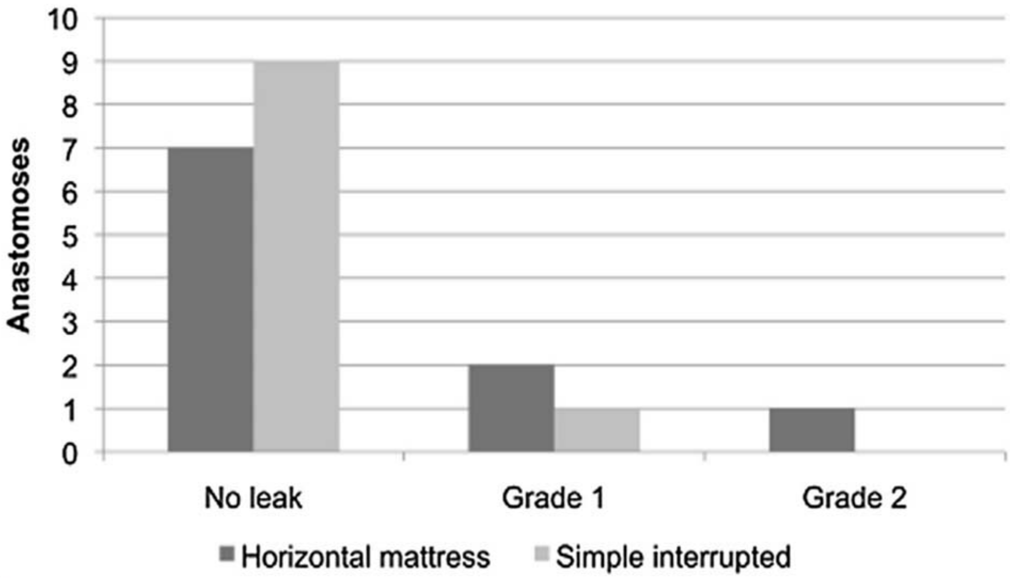

Figure 20. Leakage for simple interrupted and horizontal mattress anastomoses.

4.1.3.3. Anastomotic stricture

The amount of stricture at the anastomotic site becomes evident on the angiographic imaging (figure 21). The decrease in lumen surface was 2.25 mm^2 (95%CI, 1.79-2.70 mm^2, p=0.005) and 5.66 mm^2 (95%CI 4.69-6.64 mm2, p=0.008) for SI and HM sutures, respectively. The SI technique resulted in a mean reduction in lumen surface of 35.0% (95%CI 28.0-42.1%), whereas the HM resulted in a 60.6% reduction (95%CI 50.1-70.1%). This difference was significant (p<0.001).

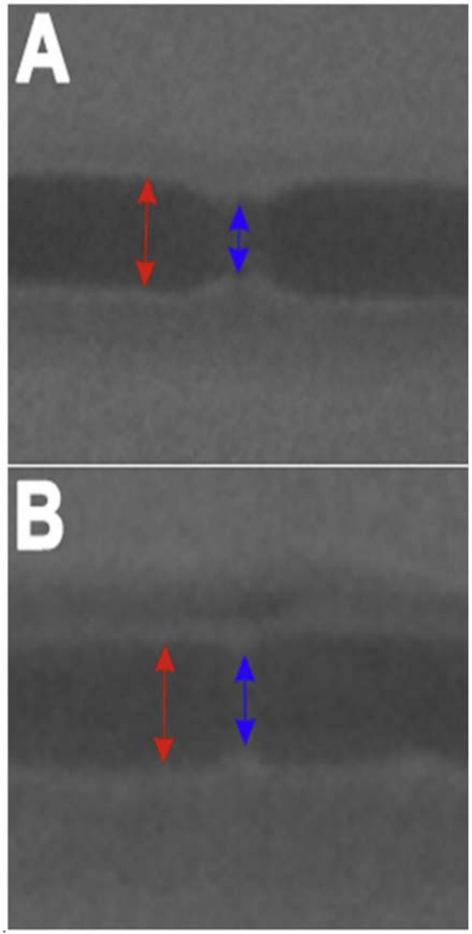

Figure 21. Angiographic evaluation of the luminal stricture. The horizontal mattress technique produced an average surface area reduction of the vessel at the anastomotic site by 60.6% (A) while the simple interrupted technique reduced the surface area by 35% on average (B).

All specimens from the HM group showed tight apposition of the intimal surfaces with no intimal flaps (figure 22 A and C). The SI group was inspected in a similar fashion; in this latter group, free intimal edges were visualized in all specimens, even though this was not a circumferential phenomenon (figure 22 B and D). H&E staining of the specimens revealed eversion of the entire wall thickness in all HM specimens, but most importantly the intima, with its darker stained internal elastic lamina, is well visualized and no intimal flap or exposed muscularis could be identified.

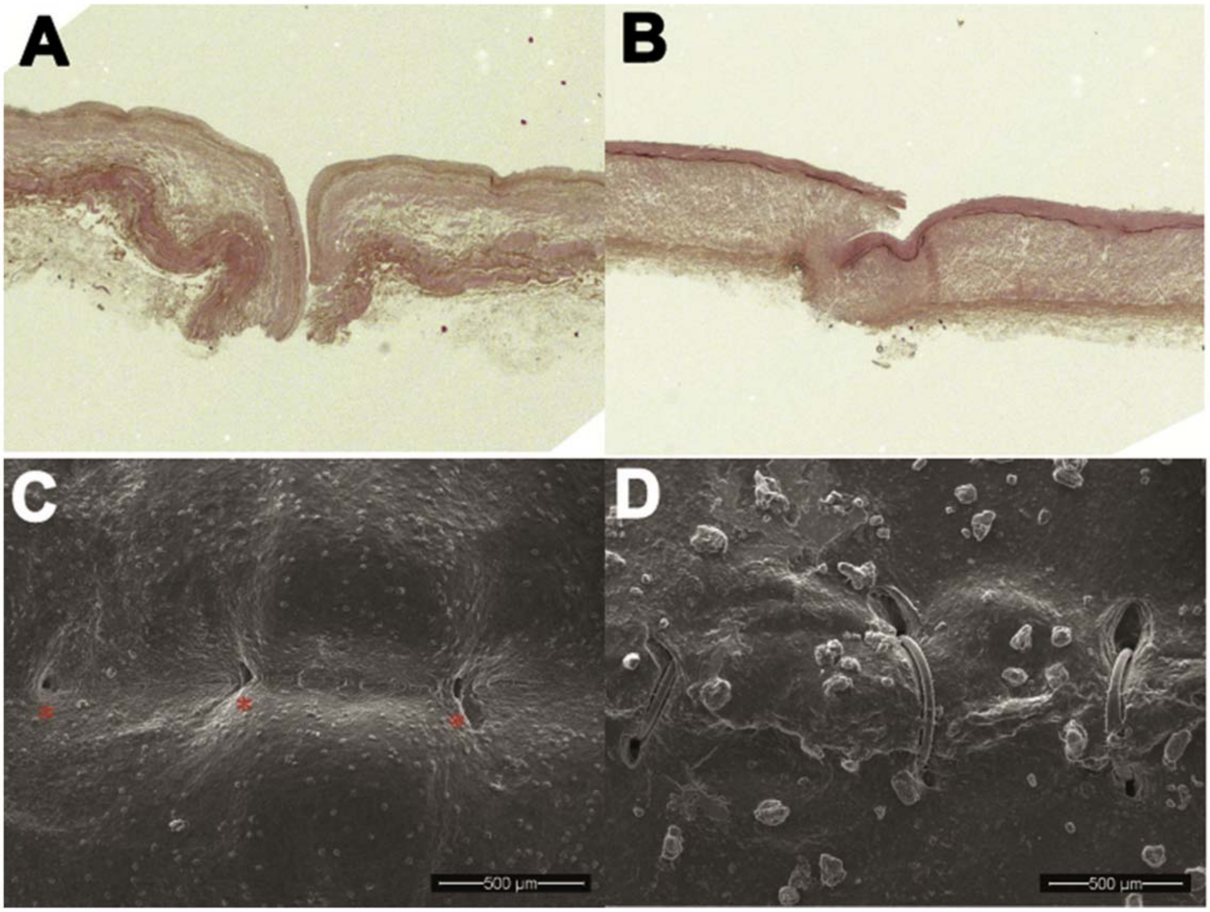

Figure 22. Light and scanning electron microscopy of the anastomotic sites. Horizontal mattress anastomosis showing eversion of the three layers of the arterial wall. Note the tight apposition of the intimal endothelium (A). The simple interrupted technique can cause intimal overlap and bunching, resulting in exposed subendothelium at the anastomotic site (B). SEM showing tight apposition and smooth transition of the intimal surfaces at the anastomosis. The red asterisks mark the location of the sutures, which are only minimally exposed in the horizontal mattress technique (C). The simple interrupted technique results in bunching of the intima and exposed intimal edge, as well as exposed intraluminal sutures (D).

4.1.3.4. Time to completion of the anastomosis

Completion of an anastomosis using the SI technique took a mean time of 12:42 minutes (95% CI 11:35-13:48 minutes) while an HM anastomosis was performed in a mean time of 7:59 minutes (95% CI 7:09-8:49 minutes). This difference was found to be statistically significant ($p<0.001$). The mean number of passes required was 10 and 6 for SI and HM sutures, respectively ($p<0.001$). The mean number of knots required was 10 and 3, respectively ($p<0.001$).

4.1.4. Discussion

The three guiding principles for animal use in research are replacement, reduction, and refinement (19). We propose a suitable model for microvascular research that can help achieve the goals behind this principle by accomplishing many of the endpoints desirable in microsurgical research such as evaluation of patency, leak, stricture, vessel wall architecture, and speed. Our model can mostly contribute to reduction and replacement of the animal model for a number of studies and for training purposes.

The objective of this study was to investigate the suitability of the Thiel artery model for evaluation of microvascular anastomoses in human arteries for research and training purposes. To that effect, we performed anastomoses on Thiel cadaveric arteries to evaluate vessel leakage, patency, stricture rate, microarchitecture, eversion, and intraluminal sutures. This cadaveric study provides evidence towards the advantages and disadvantages of the HM technique with respect to the gold standard SI technique.

Leakage was evaluated using direct inspection under the microscope while injecting saline into one end of the vessel. This technique is similar to what is used *in vivo* when operating under the microscope and permitted us to correct leaks when they were identified. However, the disadvantage is that the system used is not pulsatile at pressures similar to human hemodynamics, which evokes the possibility of nonidentified leaks. This drawback is common to most microsurgical laboratory techniques. Pulsatile systems have been developed using animal limbs (37, 62, 63) and mannequin heads (64), however, it is evident that no artificial pulsatile system can perfectly mimic the hemodynamic changes encountered in a human body. Leakage remains, therefore, a parameter best investigated *in vivo*.

Vessel patency and stricture rate were evaluated using angiography. All anastomoses were patent both radiologically and clinically by observing a steady stream of saline through the vessels. The set-up was simple and straightforward and required minimal resources in the angiography laboratory. This permitted us to compare both techniques. Stricture rates were significantly higher in the HM technique (60.6% vs. 35.0% surface reduction, $p<0.001$). The higher stricture rate is not surprising since geometrically any flaring of the wall of a cylinder will result in the corresponding stricture. More impressive is the severity of the stricture. According to Poiseuille's equation (63), the most important contributor to flow is the radius, as the flow is directly proportional to the radius to the fourth power. When length, pressure, and viscosity are held constant, a reduction in the radius of a smaller vessel using the HM technique might result in a larger decrease in vessel flow than in a larger vessel. This must be taken into consideration in further studies and clinical application of the HM technique. Most workhorse free flaps, including the radial forearm flap, ALT, DIEP or free TRAM are based on large vessels that could be amenable to the HM technique.

Interestingly, *in vivo* studies have shown that a flap can nearly completely compensate for repeated flow reductions of up to 70-80% due to flap autoregulation mechanisms (65). A decrease in vessel size, however, may not necessarily contribute to thrombosis as a decrease in size increases shear stress and shear rate, which decrease the risk of platelet adherence and degranulation (65). Furthermore, there is some clinical evidence showing favorable results in arterial anastomoses performed with couplers (66), the authors reporting no flap loss. This coupled anastomosis would be expected to create a similar constriction as the HM anastomosis. Whether or not the increased stricture with the HM has a negative influence is subject to conjecture; an *in vivo* study will need to address that issue.

Moreover, the HM technique produces an anastomosis that is radiologically very similar to that produced by coupling devices. It produces circumferential eversion of the vessel edges such that intima is in direct apposition to intima, with no exposed subendothelial structures and minimal suture material intraluminally. In venous anastomosis, the coupling device adds a certain rigidity, or splinting effect, that sutures cannot reproduce; however, in dealing with arterial anastomosis, the pressure inside the lumen should provide this stenting effect. While the use of couplers in arterial anastomosis has been described in the literature, it remains of marginal use because of the technical difficulty induced by the thick vessel walls that need to be manipulated over the pins. The HM provides the same architecture but avoids these technical difficulties.

To assess histological anastomosis architecture and intraluminal sutures, scanning electron microscopy and histologic staining was employed. While both of these microscopic techniques are known to work on freshly fixed tissue, the cadaveric tissue is stored for many months in embalming solution undergoes decomposition. As observed from the histologic sections (figure 22), the morphology of the vessel wall is overall preserved using the Thiel embalming method such that the intima, media, and adventitia can be readily identified. However, cellular morphology is lost with decayed nuclei. For the purpose of microvascular technique investigations, the preserved gross morphology is satisfactory. Intimal appearance on histology and SEM was devoid of any intimal flaps for HM sutures when compared with SI sutures.

It is widely known that exposed subendothelial tissue is very thrombogenic (67). As can be observed in the histological and SEM sections, the HM anastomoses are well everted with no subendothelial tissue exposure, compared to the SI anastomoses, suggesting improved architecture with the HM technique. The microarchitecture of the two anastomotic techniques provides in our opinion the essential details to understanding the hemodynamic implications. On the one hand, there is the HM technique that provides excellent eversion of the intima all-around at the cost of increased stenosis. The SI technique does the opposite: minimal stenosis but higher exposure of intimal flaps and thus exposed muscularis. Given the cadaveric nature of the present study, it is difficult to conclude which of the two options is more advantageous.

In our study, the HM technique was faster than the SI technique, and this was statistically significant. The SI technique took on average almost 5 minutes more to perform since it required on average three or four extra passes and six to seven extra knots. The limiting factor for the completion of the HM anastomosis is the backhand pass that commences each of the HM sutures. With practice, however, the precision and speed of the backhand pass can be improved rendering an even faster anastomosis. However, this 5 minute gain might not be clinically significant in a major surgical reconstruction case that requires several hours to complete, and the time required to place the additional SI suture in an HM anastomosis might decrease the time gain.

In dealing with an *ex vivo* tissue, several limitations of the model can be identified. Most importantly, the thrombogenic potential cannot be identified. While using microscopy and angiography the better eversion at the expense of decreased lumen diameter in the HM over the SI technique can be determined, only an *in vivo* model can prove an advantage in decreasing the rate of thrombosis. Second, while leaks can be assessed by injecting saline into the lumen, it is impossible to recreate the *in vivo* aspects of anastomotic leakage since it is dependent on the intraluminal, pulsating pressure, rheology and coagulation. Anastomotic leakage also needs to be addressed in an animal study. Overall, we found the Thiel model useful investigate the potential of the HM technique in microvascular surgery. The information obtained herein will guide our next research protocol in an *in vivo* animal model to address the leakage, decrease in flow across the anastomosis and the short and medium term patency rate.

The HM suture technique has been attempted in an *in vivo* rat model in two studies in the literature (40, 68). Orak et al studied outcomes of microvascular anastomosis on rat femoral arteries using an HM technique on three vessel flaps created using three longitudinal incisions

120 degrees apart. Their study showed significantly faster anastomosis time when compared with the SI technique, and similar patency rates at three weeks. These results correspond to what has been found in our study. However, their study also showed increased intimal and medial damage on histopathological study (68). Turan et al also conducted a similar study on rat femoral arteries, although they did not use a fishmouth incision, similarly to our study. In this study, interrupted HM sutures were not performed faster than SI sutures. Furthermore, all anastomoses in the interrupted HM group had leakage, whether grade 2 (25%) or 3 (75%) (69). However, all of the SI sutures also leaked, which does not correlate with our results. They also reported less intimal hyperplasia and less suture reaction than with SI sutures.

There are several advantages of using our model in a research setting. The specific novelty of this system is the possibility to preserve for a prolonged duration using the Thiel method. In addition to evaluating leakage under direct vision, vessels can be subjected to angiography for patency and stricture evaluation, and histological evaluation, as well as SEM, can be used to evaluate microarchitecture, eversion, and intraluminal sutures. The disadvantages of not being able to evaluate thrombosis rates and flap survival are inherent in a cadaveric model. However, we believe that the specific advantages of this *ex vivo* model can be used in a variety of settings, such as the evaluation of the effect of a new suture (the HM suture in our case) on the vessel wall.

This system can also be beneficial for training purposes. A Thiel model that preserves intact tissue texture to better simulate the intraoperative environment. The benefit of such a system over traditional microvascular animal laboratories is that much fewer resources are required: there are no animals required, no technicians for animal maintenance and anesthesia, and a simpler setup. The trainee can focus purely on the anastomotic technique on a human vessel. The specific disadvantage of a non-pulsatile system is evident, and future directions include developing a pulsatile system using Thiel embalmed arteries, which has not been developed to date to our knowledge.

The Thiel arterial tissue provides a useful model for in vitro microsurgical studies. It permits the evaluation of patency and stricture using angiography, as well as anastomotic architecture using histology and SEM. This model is limited when it comes to evaluating leaks due to it being non-pulsatile. Due to its *ex vivo* nature, the Thiel model cannot provide evidence for the patency and thrombotic potential of an anastomosis, which is the ultimate objective of microvascular surgery. *In vivo* studies with longer follow-up and assessment of flow dynamics across vessels are warranted, however useful initial evidence can be obtained with regard to architecture and stricture before one commits to an animal study.

4.2. Horizontal mattress technique for the anastomosis of size mismatched vessels (44)

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4.2.1. Introduction

The patency of the microvascular anastomosis is paramount for flap survival in microsurgery (70). Along with endothelial dysfunction and hypercoagulability, flow turbulence is an essential part of Virchow's triad and must be minimized in order to prevent anastomotic thrombosis (71). Unfortunately, the microsurgeon sometimes runs into a case where mismatched vessels must be anastomosed, which is a situation at high-risk for flow turbulence and thrombosis (70).

Mismatch, defined as a vessel diameter ratio of 1.5:1 or greater, is typically encountered in 33% of arterial and 50% of venous anastomoses (72). Multiple technically-demanding techniques to overcome this problem have been described which include coupling devices, forced dilatation of the smaller vessel, oblique cuts, fish mouth incisions, end-to-side anastomoses, and interposition grafts (70).

We describe a simple technique using horizontal mattress sutures, based on our previously published work in size-appropriate arteries (34). We believe this can overcome the problem of size-mismatched arteries without excessive manipulation of the vessels in an end-to-end fashion.

4.2.2. Materials and Methods

We have conducted an experimental study on 1.5:1 size mismatched cadaveric arteries. Thiel embalmed cadaveric arteries were used (23). The operating model has been described in our previous work (34).

4.2.2.1. Specimen preparation

Eight arterial sections measuring 3 cm each were prepared using radial and ulnar arteries in order to achieve a total of four microvascular anastomoses. The radial arteries had a diameter of 3 mm, and the ulnar arteries had a diameter of 2 mm. The vessels were irrigated with a physiologic saline solution. The operating microscope at 10X magnification was used for all anastomoses. In order to perform anastomoses, the operator must initially dissect the surrounding connective tissue from the vessel.

4.2.2.2 Surgical technique

The HM technique for end-to-end anastomosis was previously described by the authors. In the case of size mismatched anastomosis, the technique is similar with the exception of the variable pitch from one side of the vessel to the other. Any overhanging adventitia was carefully cleaned, however, a complete adventisectomy was not performed. Approximator clamps were not necessary. Using a 9-0 nylon suture, we started with a backhand pass of the HM suture on the larger vessel and returned with the forehand pass. The difference from the technique on similar sized vessels is the calculation of the pitch which has to be proportional to the size of the vessel. Care was taken to always visualize the intraluminal side of the vessel, ensuring that full-thickness bites were taken. The tension of the knot was adjusted to provide the optimal amount of eversion at the anastomotic site. The vessel was then flipped and two other HM sutures were placed at 120° from the first suture, while once again adjusting the width of the bite to the size of the vessel. The technique is schematically represented in figure 23.

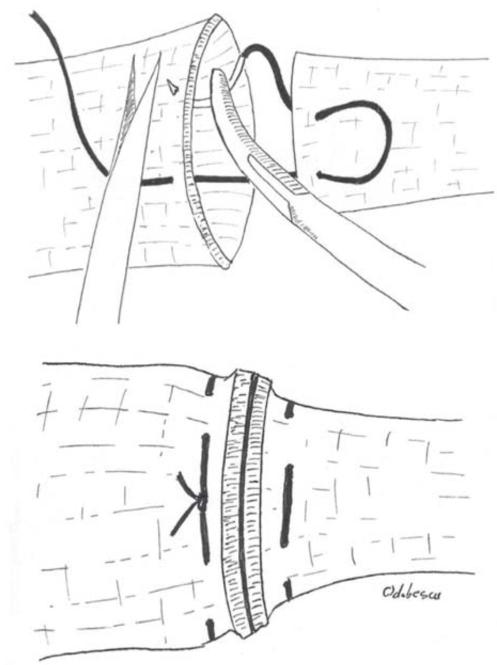

Figure 23. Illustration of the technique used for size-mismatched vessel anastomosis

In the smaller caliber vessel, the bite on the smaller side was proportionally narrower than on the larger side. The appearance of the anastomosis can be appreciated in figure 24.

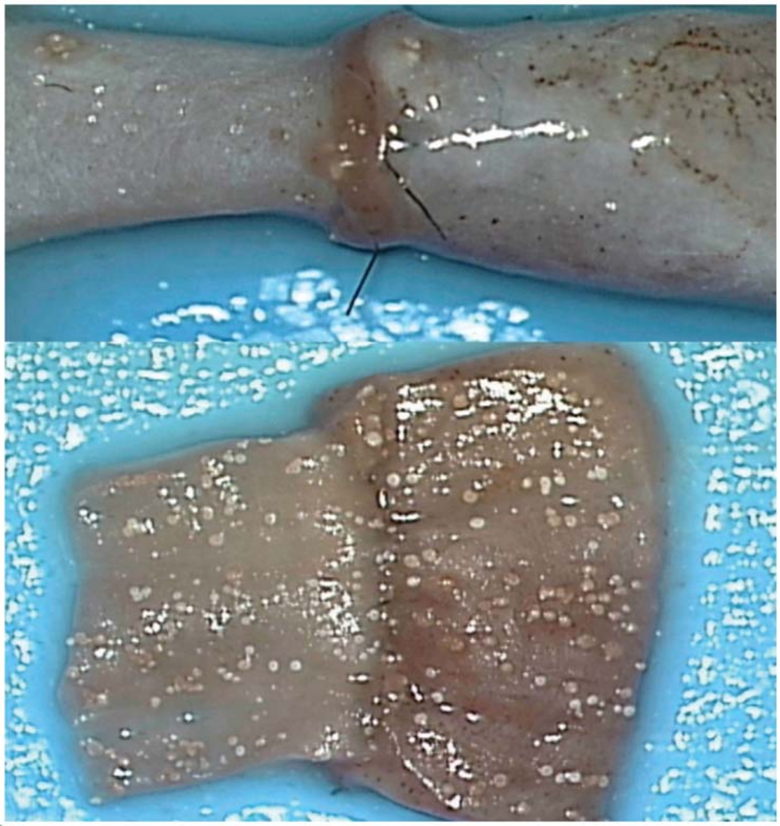

Figure 24. The appearance of anastomosis. Funneled out smaller vessel that meets a cinched-down larger vessel (top panel). Intraluminal appearance after the opening of the vessel showing good intimal apposition and no foreign material in the lumen (bottom panel).

4.2.2.3. Measurement of outcomes

The anastomoses were video recorded. Leakage was assessed using direct microscopic evaluation by injecting physiologic saline into the anastomotic set-up. The leaks were graded as 0 in the case of no leak, 1 for minor leak/oozing and 2 representing severe leaks.

Lastly, the specimens were examined for eversion at the anastomotic site using light and scanning electron microscopy. The specimens were opened in between two sutures and rolled out to expose the intraluminal side. Two specimens were prepared for scanning electron microscopy, and two were prepared for light microscopy.

The specimens were fixed in 2% glutaraldehyde and in a 0.1M sodium cacodylate solution at a pH of 7.3. These specimens were then kept at 4°C. Subsequently, a 20 minute dehydration period at room air was allowed prior to gold coating using a pulverizer (Agar Manual Sputter Coater). A scanning electron microscope (ESEM Quanta 200 FEG, FEI Company, Hillsboro, OR) equipped with an EDAX detector (EDX) for microanalysis was used. The observations were done at 20kV and a working distance of about 5mm. XTDocu imaging software was used to analyze the images.

For light microscopy, the specimens were fixed in formaldehyde solution, embedded in paraffin and stained for microscopy with hematoxylin and eosin (H&E) in a clinical pathology laboratory following standard protocol.

4.2.3. Results

Following the completion of the anastomosis, the vessels were tested by infusion of saline and were found to be patent in all cases, with grade 0 leaks.

The external and intraluminal appearance of the anastomoses were evaluated (figure 24). Intima on intima apposition with no intraluminal exposure of neither muscularis nor adventitia were observed. Microscopic evaluation was performed using light and electron microscopy, as exemplified in figure 25, and reveals perfect eversion and intimal apposition.

Figure 25. Scanning electron micrograph (top panel) and hematoxylin and eosin staining (bottom panel) of two size-mismatched vessels. Note the tight intimal apposition, good eversion, and distribution of excess tissue on the larger vessel.

4.2.4. Discussion

We have shown the technical feasibility of anastomosing size-mismatched arteries in an end-to-end fashion using our simple HM technique. We have shown the absence of leaks, and perfect eversion and intimal apposition using this technique.

Microvascular anastomoses of size mismatched vessels pose a challenge in itself. While most microsurgeons try to avoid working with size mismatched vessels, by their choice of recipient vessel and the vascular flap pedicle that corresponds in size, this luxury is not always possible. In these instances, one needs to adapt and make use of the vessels available. Various techniques have been described to address mismatch. However, force dilatation of a vessel to more than 1.5 times its size can cause endothelial damage, with an associated failure rate as high as 80% reported for vessels with a 1:2 size discrepancy (73). End-to-side anastomosis can overcome this problem, although it creates turbulence and increases flap failure rates (72, 74). Interpositional vein grafting is another option, although it involves two anastomoses, which increases the risk of thrombosis (75). Other techniques have been described (76), such as a fish-mouth incision, oblique section, differential suture bites, wedge excision of the larger vessel, vessel invagination, although these are more technically demanding, and not a single one has emerged as the gold standard.

The horizontal mattress suture for microanastomosis has been previously described in two *in vivo* studies (68, 69). For size mismatched vessels, it has been previously described by De Lorenzi et al in a series of 190 microvascular reconstructions using HM stitches, with a five percent failure rate (77). However, H&E images were not presented. The authors suggest that an alternative technique is used for size discrepancy larger than 3:1, such as end-to-side or Y-shaped anastomoses. Despite this large series with a low failure rate, this technique has not been further investigated in other papers. Our results confirm the technical feasibility of this anastomotic technique.

The disadvantages of not being able to evaluate thrombosis rates and flap survival are inherent in a cadaveric model. However, we believe that the specific advantages of this *ex vivo* model can be used in a variety of settings, such as the evaluation of the effect of a new suture (the HM suture in our case) on the vessel wall. A possible clinical limitation of the horizontal mattress technique is related to the reduced lumen at the anastomotic site. We have previously reported this finding in anastomoses of vessels of equal size (34). While a reduction in lumen size may seem problematic, the horizontal mattress technique provides a superior architecture at the anastomotic site with circumferential eversion of the vessel wall and intima on intima apposition.

This study provides an alternative method to addressing size mismatch between donor and recipient vessels by means of the horizontal mattress technique in a cadaveric model. This technique gives an even distribution of the excess tissue around the entire circumference of the anastomosis, funneling out the smaller vessel and cinching down the larger vessel to create a smooth transition (figure 25). The challenge in performing a size mismatched anastomosis is the even distribution of the excess around the entire circumference. Taking the example of anastomosis of a 3mm vessel with a 2mm vessel, and considering that 8 simple interrupted sutures will be used, even distribution of the sutures around both vessels would imply a pitch of 1.2mm in between sutures on the 3mm vessel and 0.8mm on the 2mm vessel. If the proportions are not perfectly respected, the anastomosis will not be even.

While the horizontal mattress technique as described in this article is intended to be performed with only horizontal mattress sutures and was performed in this case with three such sutures, larger vessels can be sutured four such sutures oriented at 90 degrees from each other. Additionally, single horizontal mattress sutures can be used in conventional anastomoses to take care of excess tissue that occasionally ends up collected on the larger vessel. The use of such individual sutures has been utilized by the senior author with success for many years.

Chapter 5: Discussion and conclusions

5.1. From time base to competency-based resident training

The traditional model for postgraduate medical education has been time-based. This assumes that a trainee, by spending enough time in training, would acquire the competencies that are necessary for the unsupervised practice of medical acts. Given a homogeneous cohort of trainees, this model may produce consistent results. Unfortunately, as early as the 1960s, it has been noted that students with different aptitudes developed differently with some acquiring competency faster than others. In some unfortunate cases, students fail to obtain the required competencies by the end of training (4). The competency-based model differs from this traditional model in that it focuses on specific domains of competence while at the same time being less dependent on the amount of time spent in training. A trainee only promotes to the upper levels of training if they successfully complete the lower competencies.

From its very beginning, Canada has been at the forefront of medical science and education. From Sir William Osler, arguably the most famous medical educator in the English speaking world, to the introduction of the canMEDS system in the 1990s and to the present day, Canada has created some of the most innovative medical programs in the world. Today, the Royal College of Physicians and Surgeons of Canada is in the middle of a reformation. Starting July 1, 2017, the medical and surgical residency programs in Canada are moving over to a competency-based method of teaching called “Competence by Design" (CBD). By 2022 it is projected at all medical and surgical residency programs in Canada will have a transition to this model of training. Plastic surgery has been assigned to cohort #4 in the transition process, with a specialty committee working on the CBD starting in 2017 and the projected implementation of the CBD based program starting as early as 2019 (5).

The Royal College of Physicians and Surgeons of Canada states that this new CBD model is not a one size fits all approach. It will be tailored to the individual specialties and their needs.

As the philosophy of medical education is changing rapidly before our eyes, we have to ask ourselves two questions: (1) Is this change needed and (2) do we have the necessary technology and support to be effective in implementing a new system?

To answer the first question, it is important to determine if the current system is effective. As mentioned above, the current model of medical and surgical education is at “time-based model”. This means that as a surgical trainee it is expected to spend a certain period of time in training, hoping that that exposure will somehow translate into competency. While this may be a system that works well in the pre-University setting, where spending a certain time in the classroom may be sufficient to prepare a student for a job or higher education, in medicine things are quite different. We expect our medical graduates to be competent. As a society, we want physicians and surgeons who can offer a consistent level of medical care irrespective of were they practice. While we cherish exceptional physicians, we cannot tolerate mediocracy. It is for this reason that our focus as medical educators should be the consistent quality of medical graduates and that degree of consistency cannot be guaranteed in a system where the time spent in education is to be the primary measure of competence. We believe that change has been a long time coming and competency-based training is the natural alternative to the current system. The Royal College of Physicians and Surgeons of Canada has shown once again that the Canadian medical education will be spearheading this revolution of medical education in the decades to come.

When it comes to answering the second question, things are less clear. Choosing a new philosophy of CBD is one thing, but having the required technology and support to implement such a change is another. The specialty committee for plastic surgery will most likely find that there are insufficient instruments in the literature for evaluating surgical performance in the different disciplines of plastic surgery. The fact that the specialty is so broad makes their task even more daunting. While the national transition to competency-based training opens the possibility of incredible research into the effectiveness of medical simulation and surgery, we cannot afford to gamble with the future of this transitional generation of plastic surgeons.

Before jumping headfirst into a competency-based curriculum, we need to develop and validate a set of instruments that will make "competence by design" successful. Per the Royal College of Physicians and Surgeons of Canada, the competence by design model breaks down training into discrete stages, such as the transition to the discipline, foundations of the discipline, the core portion of the discipline and finally the transition to practice. Each stage has its own entrustable professional activities (EPA) and milestones. As defined by the Royal College, "a milestone is an observable marker of an individual's ability along a developmental continuum" while an EPA is "a task of the discipline [that can] be delegated to a resident and observed by a supervisor" (78).

At the time when our research started, there were indications of a transition to competency-based training. At this moment our specialty is in full transition mode. The objective of this research project was to develop a high fidelity simulation system that would be used to practice and evaluate a set of competencies that are the cornerstone of plastic surgery. The three EPAs we chose were microvascular anastomosis, peripheral nerve repair, and flexor tendon repair. At the same time, we aim to develop and validate a set of instruments to accurately evaluate the performance of residence during the simulation sessions. By constructing a checklist type instrument, each item on the checklist is a milestone that the trainee has to master, making feedback an easy process. This concept circles back to Miller's concepts of action and learning feedback (12). Using a checklist type evaluation system, a trainee can look back at the result and understand where they are making mistakes. By identifying the source of error, the trainee can use their experience to obtain improved performance in subsequent trials. Ericcson's "deliberate practice" starts by identifying an aspect that needs improvement, applies the immediate feedback and repeats the task to consolidate the improvements (15).

5.2. The versatility of the Thiel model: microvascular, nerve and tendon

Compared to the other models we currently have, the Thiel cadaveric model offers both advantages and disadvantages. These have to be weighed in order to see if Thiel cadavers are a long-term solution to the simulation-based training residencies will implement. Live animal models, while offering the highest level of fidelity, are very expensive and ethically questionable in today's society. While there is certainly place for training on live animal models in the foreseeable future, the idea of switching resident training to a simulation-based model of teaching will require much higher resources than previous. A cheap model that is easily stored for long periods of time and at the same time offering lifelike tissue properties would be the ideal simulation system. We believe that the Thiel cadaveric model is an excellent, albeit imperfect model for simulation and research. Its use is not widespread at the moment, which limits availability, however, specimens can be stored for long periods of time and while at the same time offering tissue properties very similar to fresh frozen cadaveric tissue.

Increasing the availability of Thiel cadavers in medical training programs would render this particular model extremely versatile. While we are not there at this moment, some changes in the embalming technique developed at McGill University in Montréal may help overcome some limitations. As described by Professor Thiel, the embalming method was very time consuming, extending over a period of months during which the cadaver would have to be submerged in the embalming solution. The Department of Anatomy at McGill University has worked on perfusing the involving solution through the vascular system of the cadaver to reduce the overall embalming process to 6-8 hours, after which the cadaver is kept submerged in embalming solution until use. We will look forward to the publication of these innovative techniques and are hopeful that they will spark the interest of other Canadian training programs to adopt this versatile model.

5.3. Validation of the evaluation instruments: microvascular, nerve and tendon

This thesis presents three simulation models based on Thiel cadaveric tissues and proposes corresponding instruments to aid in the evaluation of the trainees. Any instrument is only useful if it is validated, and therefore a number of tests were used in order to validate our instruments. The intra-class correlation coefficient (ICC) is a measure of reproducibility, sometimes referred to as reliability. We used the ICC to determine de assess the reproducibility of the quantitative measurements made by the different reviewers evaluating the same set of subjects. The microvascular simulation instrument (MVES) and the micro-neurorrhaphy instrument (MNES) had ICCs of 0.89 and 0.75 respectively. These results show an excellent correlation in the case of the microvascular instrument and good correlation for the nerve instrument. In the case of the flexor tendon evaluation instrument (FTES), the ICC was 0.5, which only met the "fair agreement" benchmark suggesting a low reproducibility of the results.

The Cronbach alpha was used to assess to what extent the instrument is a consistent measure of a concept. In other words, to what extent was each item in the instrument used by the evaluators to measure the same thing. The MVES produced a Cronbach alpha of 0.88, the MNES 0.91 and the FTES instrument 0.89. All three Cronbach alpha coefficients exceeded the 0.7 benchmark accepted to represent desirable outcomes (58).

Another measure of validity sometimes referred to as external validity, is related to how the scores obtained using the instrument correlate with the real-life expertise of the individual subjects. In other words, while the ICC and Cronbach alpha provide good measures of the reliability and reproducibility of the instrument, whether the scores are a true reflection of the real-life experience of the subjects is equally important. Our modeling revealed a statistically significant correlation between the scores obtained using the MVES and MNES instruments and the level of training and the self-declared level of experience, suggesting a high degree of external validity of the instrument. In the case of the FTES, this correlation between scores and experience and level of training was not significant, likely due to the high degree of inter-rater variability. Overall, our data validates the MVES and MNES; however, it does not validate the FTES.

5.4. The implementation of simulation and the plastic surgery curriculum in Canada

The University of Toronto department of orthopedics has been a leader in the development and implementation of a competency-based curriculum for surgical residents (79). Starting as early as 2009, the department of orthopedics has been working on developing a curriculum that would replace the time-based model of surgical training and implement a series of modules that according to the authors intensified the structured learning of the residence as well as their assessment. After 4 years of refining this new curriculum, the department of orthopedics at the University of Toronto transitioned to a competency-based curriculum and the 2013-2014 academic year. They chose to construct 21 discrete nodules that were grouped and one of 3 phases depending on the complexity of the knowledge and skills involved. One of these modules, titled " introduction to basic surgical skills" (also referred to as "Orthopaedic Boot Camp") is dedicated to the development of core technical competencies. This description is somewhat vague and there is no detail of what exercises and what evaluation instruments the University of Toronto department of orthopedics is using for this introductory module to surgical technique. But they do specify that as a whole, the curriculum is structured in such a way that the trainee only advances to the next module once the objectives of the previous module are met. Another interesting concept is that each of their modules is assessed by a minimum of two "entrustable professional activities (EPAs). To give an example that would be applicable to plastic surgery as well, and the hand and upper extremity module the EPAs are carpal tunnel decompression, shoulder hemiarthroplasty, arthroscopic shoulder decompression. While the curriculum adopted by the University of Toronto department of orthopedics appears to be very thorough and well thought off, it does seem to be quite laborious on the part of the teachers. While at the University of Toronto, the largest medical institution in Canada, it may be feasible to have an attending surgeon in charge of each module, in smaller programs this becomes almost impossible to implement. It would imply having each attending surgeon in charge of multiple modules. While this may be possible in the hypothetical setting of a medical educator being only responsible for teaching, most surgeons have significant clinical and research duties to fulfill at the same time.

At the present time, there is limited data available with respect to competency-based curricular in Canada and abroad. With the implementation of the competence by design model throughout all postgraduate medical training programs in Canada, we will hopefully soon see a variety of different models and studies evaluating their efficacy. For the time being, however, we hope that our research presented in this thesis will provide some of the building blocks for the development of a plastic surgery curriculum that uses simulation modules for the teaching and evaluation of specialty-specific competencies.

5.5. Future directions

We plan to further evaluate the impact of the three simulation models and evaluation instruments described in this thesis with respect to their direct impact on patient care. The 4th level in the Kirkpatrick pyramid (80) is the last and most important impact medical education can have, without which all others are purely academic. The Kirkpatrick pyramid is shown in figure 26.

Figure 26. Kirkpatrick pyramid of learning. Adapted with permission from Kirkpatrick D. 1994. Evaluating training programs: the four levels. San Francisco, CA, USA: Berrett-Koehler.

This thesis addressed three areas of competence that plastic surgery residents need to acquire. Microvascular repair, nerve coaptation and tendon repair are cornerstone skills for plastic surgeons, however, in order to develop a full competency-based curriculum and plastic surgery, there will need to be work done in other areas of simulation. These will have to range from skills such as split-thickness skin graft harvest to more complex procedures such as flap planning and elevation. Extrapolating from our current experience, we believe that the Thiel cadaveric model can be used in a number of different areas of simulation which transcend specialties. For example, to make the most use of the cadavers, plastic surgeons could use the skin and subcutaneous tissue for flap elevation while orthopedic residents could use the legs for intramedullary nailing of the tibia and the ENT residents can make use of neck dissection. By ensuring that all parts of the cadavers are used to the fullest extent, we can ensure that the gift donors are making to medical science is fully and ethically utilized.

With regard to the format of the competency-based curriculum and plastic surgery, the decisions will be taken in the specialty committee of the Royal College of Physicians and Surgeons of Canada. This decision will have important implications for the next generation of plastic surgeons in Canada and it is therefore even more important to have an evidence-based approach to program development. We hope that the specialty committee will take a look at the current literature on the subject of medical simulation and integrate the models into the competency-based curriculum.

Bibliography

1. Flexner A. Medical education in the United States and Canada. From the Carnegie Foundation for the Advancement of Teaching, Bulletin Number Four, 1910. Bulletin of the World Health Organization. 2002;80(7):594-602.

2. Arbogast P, Rosen J. Simulation in Plastic Surgery Training: Past, Present and Future. In: Agullo FJ, editor. Current Concepts in Plastic Surgery: InTech; 2012. p. 235-56.

3. Satava RM. Emerging trends that herald the future of surgical simulation. The Surgical clinics of North America. 2010;90(3):623-33.

4. Ten Cate O. Competency-Based Postgraduate Medical Education: Past, Present and Future. GMS J Med Educ. 2017;34(5):Doc69.

5. Compentence by design implementation [Available from: http://www.royalcollege.ca/rcsite/cbd/cbd-implementation-e.

6. Rosen JM, Long SA, McGrath DM, Greer SE. Simulation in plastic surgery training and education: the path forward. Plastic and reconstructive surgery. 2009;123(2):729-38; discussion 39-40.

7. Model. [cited 2014 Aug 14]: Oxford University Press; 2014 [Available from: http://www.oxforddictionaries.com/definition/english/model.

8. Simulate. [cited 2014 Aug 14]. Available from: http://www.oxforddictionaries.com/definition/english/simulate. Oxford Dictionaries [Internet]: Oxford University Press; 2014.

9. Simulator. [cited 2014 Aug 14]. Available from: http://www.oxforddictionaries.com/definition/english/simulator. Oxford Dictionaries [Internet]: Oxford University Press; 2014.

10. G C. Simulation médicale pour acquisition des compétences en anesthésie. Congrès national d'anesthésie et de réanimation; 20072007. p. 41-049.

11. Reznick RK, MacRae H. Teaching surgical skills--changes in the wind. The New England journal of medicine. 2006;355(25):2664-9.

12. Miller RB. Psychological considerations in the design of training equipment. Ohio: Wright-Patterson Air Force Base; 1954. Contract No.: WADC TR54-563.

13. Fidelity. [cited 2014 Aug 18]. Available from: http://www.oxforddictionaries.com/definition/english/fidelity

Oxford Dictionaries [Internet]: Oxford University Press; 2014.

14. Maran NJ, Glavin RJ. Low- to high-fidelity simulation - a continuum of medical education? Medical education. 2003;37 Suppl 1:22-8.

15. Ericsson KA. Deliberate practice and the acquisition and maintenance of expert performance in medicine and related domains. Academic medicine : journal of the Association of American Medical Colleges. 2004;79(10 Suppl):S70-81.

16. Reznick RK, MacRae H. Teaching surgical skills - Changes in the wind. 2006.

17. Dumestre D, Yeung JK, Temple-Oberle C. Evidence-based microsurgical skill-acquisition series part 1: validated microsurgical models--a systematic review. J Surg Educ. 2014;71(3):329-38.

18. Schaverien MV, Butler CE, Suami H, Liu J, Selber JC. Comparison of Live Rat Femoral Artery Model with Intraoperative Microvascular Anastomosis. J Reconstr Microsurg. 2017;33(9):641-8.

19. Russell WMS, Burch RL. The principles of humane experimental technique. London,: Methuen; 1959. 238 p. p.

20. Senturk S, Tosun Z, Ozkan A. Microsurgical training model for nerve repair. Journal of Reconstructive Microsurgery. 2005;21(7):491-2.

21. Kamath J, Chandra G, Kamath R, Kumar A, Bhardwaj P. Flexor tendon repair simulator. Techniques in hand & upper extremity surgery. 2009;13(2):117-8.

22. Rhodes ND, Wilson PA, Southern SJ. The flexor-tendon repair simulator. Br J Plast Surg. 2001;54(4):373-4.

23. Thiel W. [The preservation of the whole corpse with natural color]. Annals of anatomy = Anatomischer Anzeiger : official organ of the Anatomische Gesellschaft. 1992;174(3):185-95.

24. Wolff KD, Kesting M, Mucke T, Rau A, Holzle F. Thiel embalming technique: a valuable method for microvascular exercise and teaching of flap raising. Microsurgery. 2008;28(4):273-8.

25. Hassan S, Eisma R, Harry LE. Surgical training of anastomotic technique using Thiel cadavers. Journal of plastic, reconstructive & aesthetic surgery : JPRAS. 2014.

26. Hassan S, Eisma R, Malhas A, Soames R, Harry L. Surgical simulation flexor tendon repair using Thiel cadavers: a comparison with formalin embalmed cadavers and porcine models. The Journal of hand surgery, European volume. 2014.

27. Tamai S, Usui M, Yoshizu T. Experimental and clinical reconstructive microsurgery. Tokyo: Springer; 2003.

28. Yazici I, Cavusoglu T, Karakaya EI, Comert A, Siemionow M. Microsurgical training model for lymphaticovenous anastomosis in rat. Microsurgery. 2012;32(5):420-2.

29. Balls M. Replacement of animal procedures: alternatives in research, education and testing. Laboratory animals. 1994;28(3):193-211.

30. Fox CH, Johnson FB, Whiting J, Roller PP. Formaldehyde fixation. The journal of histochemistry and cytochemistry : official journal of the Histochemistry Society. 1985;33(8):845-53.

31. Pabst R. Exposure to formaldehyde in anatomy: an occupational health hazard? The Anatomical record. 1987;219(2):109-12.

32. Thiel W. [Supplement to the conservation of an entire cadaver according to W. Thiel]. Annals of anatomy = Anatomischer Anzeiger : official organ of the Anatomische Gesellschaft. 2002;184(3):267-9.

33. Eisma R, Mahendran S, Majumdar S, Smith D, Soames RW. A comparison of Thiel and formalin embalmed cadavers for thyroid surgery training. The surgeon : journal of the Royal Colleges of Surgeons of Edinburgh and Ireland. 2011;9(3):142-6.

34. Odobescu A, Moubayed SP, Harris PG, Bou-Merhi J, Daniels E, Danino MA. A new microsurgical research model using Thiel-embalmed arteries and comparison of two suture techniques. Journal of plastic, reconstructive & aesthetic surgery : JPRAS. 2014;67(3):389-95.

35. Benkhadra M, Bouchot A, Gerard J, Genelot D, Trouilloud P, Martin L, et al. Flexibility of Thiel's embalmed cadavers: the explanation is probably in the muscles. Surgical and radiologic anatomy : SRA. 2011;33(4):365-8.

36. Fessel G, Frey K, Schweizer A, Calcagni M, Ullrich O, Snedeker JG. Suitability of Thiel embalmed tendons for biomechanical investigation. Annals of anatomy = Anatomischer Anzeiger : official organ of the Anatomische Gesellschaft. 2011;193(3):237-41.

37. Olabe J, Olabe J. Microsurgical training on an in vitro chicken wing infusion model. Surg Neurol. 2009;72(6):695-9.

38. Krishnan KG, Dramm P, Schackert G. Simple and viable in vitro perfusion model for training microvascular anastomoses. Microsurgery. 2004;24(4):335-8.

39. Temple CL, Ross DC. A new, validated instrument to evaluate competency in microsurgery: the University of Western Ontario Microsurgical Skills Acquisition/Assessment instrument [outcomes article]. Plastic and reconstructive surgery. 2011;127(1):215-22.

40. Tellioglu AT, Eker E, Cimen K, Comert A, Karaeminogullari G, Tekdemir I. Training model for microvascular anastomosis. J Craniofac Surg. 2009;20(1):238-9.

41. Tehrani H, McPhail J, Graham K. A simple training model for microvascular repair. Journal of plastic, reconstructive & aesthetic surgery : JPRAS. 2010;63(6):1063.

42. Lannon DA, Atkins JA, Butler PE. Non-vital, prosthetic, and virtual reality models of microsurgical training. Microsurgery. 2001;21(8):389-93.

43. Douglas HE, Mackay IR. Microvascular surgical training models. Journal of plastic, reconstructive & aesthetic surgery : JPRAS. 2011;64(8):e210-2.

44. Odobescu A, Moubayed SP, Daniels E, Danino MA. Horizontal mattress technique for anastomosis of size-mismatched vessels. Plast Surg (Oakv). 2015;23(2):100-2.

45. Reznick R, Regehr G, MacRae H, Martin J, McCulloch W. Testing technical skill via an innovative "bench station" examination. Am J Surg. 1997;173(3):226-30.

46. Martin JA, Regehr G, Reznick R, MacRae H, Murnaghan J, Hutchison C, et al. Objective structured assessment of technical skill (OSATS) for surgical residents. Br J Surg. 1997;84(2):273-8.

47. Chan W, Niranjan N, Ramakrishnan V. Structured assessment of microsurgery skills in the clinical setting. Journal of plastic, reconstructive & aesthetic surgery : JPRAS. 2010;63(8):1329-34.

48. Wolff KD. Components of the Thiel solution. 2008.

49. Masud D, Haram N, Moustaki M, Chow W, Saour S, Mohanna PN. Microsurgery simulation training system and set up: An essential system to complement every training programme. Journal of plastic, reconstructive & aesthetic surgery : JPRAS. 2017;70(7):893-900.

50. Odobescu A, Moubayed SP, Danino MA. Thiel Cadaveric Nerve Tissue: A Model for Microsurgical Simulation. J Brachial Plex Peripher Nerve Inj. 2016;11(1):e18-e20.

51. Hassan S, Eisma R, Malhas A, Soames R, Harry L. Surgical simulation flexor tendon repair using Thiel cadavers: a comparison with formalin embalmed cadavers and porcine models. J Hand Surg Eur Vol. 2015;40(3):246-9.

52. Hassan S, Eisma R, Harry LE. Surgical training of anastomotic technique using Thiel cadavers. J Plast Reconstr Aesthet Surg. 2014;67(10):e250-1.

53. Senturk S, Tosun Z, Ozkan A. Microsurgical training model for nerve repair. Journal of reconstructive microsurgery. 2005;21(7):491-2.

54. Knox ADC, Shih JG, Warren RJ, Gilardino MS, Anastakis DJ. Consensus of Leaders in Plastic Surgery: Identifying Procedural Competencies for Canadian Plastic Surgery Residency Training Using a Modified Delphi Technique. Plastic and reconstructive surgery. 2018;141(3):417e-29e.

55. Shah S, Wain R, Syed S. A novel training model for nerve repair. Ann R Coll Surg Engl. 2010;92(3):260.

56. Shrout PE, Fleiss JL. Intraclass correlations: uses in assessing rater reliability. Psychol Bull. 1979;86(2):420-8.

57. DV C. Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. Psychological Assessment 1994(6):284–90.

58. Nunnally JC BI. Psychometric Theory. Third Edition ed. New York: McGraw-Hill; 1994.

59. Smith AM, Forder JA, Annapureddy SR, Reddy KS, Amis AA. The porcine forelimb as a model for human flexor tendon surgery. J Hand Surg Br. 2005;30(3):307-9.

60. Rhodes ND, Wilson PA, Southern SJ. The flexor-tendon repair simulator [5]. Br J Plast Surg. 2001;54(4):373-4.

61. Tan S, Power D, Rajaratnam V. Animal models for training in tendon surgery: sheep's forelimbs. The Journal of hand surgery, European volume. 2010;35(2):152-3.

62. Colpan ME, Slavin KV, Amin-Hanjani S, Calderon-Arnuphi M, Charbel FT. Microvascular anastomosis training model based on a Turkey neck with perfused arteries. Neurosurgery. 2008;62(5 Suppl 2):ONS407-10; discussion ONS10-1.

63. Phoon AF, Gumley GJ, Rtshiladze MA. Microsurgical training using a pulsatile membrane pump and chicken thigh: a new, realistic, practical, nonliving educational model. Plast Reconstr Surg. 2010;126(5):278e-9e.

64. Takeuchi M, Hayashi N, Hamada H, Matsumura N, Nishijo H, Endo S. A new training method to improve deep microsurgical skills using a mannequin head. Microsurgery. 2008;28(3):168-70.

65. Bonde CT, Holstein-Rathlou NH, Elberg JJ. Blood flow autoregulation in pedicled flaps. J Plast Reconstr Aesthet Surg. 2009;62(12):1671-6.

66. Spector JA, Draper LB, Levine JP, Ahn CY. Routine use of microvascular coupling device for arterial anastomosis in breast reconstruction. Ann Plast Surg. 2006;56(4):365-8.

67. Esclamado RM, Carroll WR. The pathogenesis of vascular thrombosis and its impact in microvascular surgery. Head Neck. 1999;21(4):355-62.

68. Orak I, Guneren E, Yildiz L. A new technique for microvascular anastomosis: eversion with 3 horizontal mattress sutures. Ann Plast Surg. 2006;57(1):80-3.

69. Turan T, Ozcelik D, Kuran I, Sadikoglu B, Bas L, San T, et al. Eversion with four sutures: an easy, fast, and reliable technique for microvascular anastomosis. Plast Reconstr Surg. 2001;107(2):463-70.

70. Turker T, Tsai TM, Thirkannad S. Size discrepancy in vessels during microvascular anastomosis: two techniques to overcome this problem. Hand Surg. 2012;17(3):413-7.

71. Harris JR, Seikaly H, Calhoun K, Daugherty E. Effect of diameter of microvascular interposition vein grafts on vessel patency and free flap survival in the rat model. J Otolaryngol. 1999;28(3):152-7.

72. Cakir B, Akan M, Akoz T. [The management of size discrepancies in microvascular anastomoses]. Acta Orthop Traumatol Turc. 2003;37(5):379-85.

73. Monsivais JJ. Microvascular grafts: effect of diameter discrepancy on patency rates. Microsurgery. 1990;11(4):285-7.

74. Lopez-Monjardin H, de la Pena-Salcedo JA. Techniques for management of size discrepancies in microvascular anastomosis. Microsurgery. 2000;20(4):162-6.

75. Jones NF, Johnson JT, Shestak KC, Myers EN, Swartz WM. Microsurgical reconstruction of the head and neck: interdisciplinary collaboration between head and neck surgeons and plastic surgeons in 305 cases. Ann Plast Surg. 1996;36(1):37-43.

76. Rickard RF, McPhaden AR, Hudson DA. Healing of two microarterial anastomoses with diameter mismatch. J Surg Res. 2014;191(1):239-49 e3.

77. De Lorenzi F, van der Hulst R, Boeckx W. Interrupted micro-mattress sutures solve vessel-size discrepancy. Journal of reconstructive microsurgery. 2005;21(2):125-30.

78. RCPSC EPAs and milestones [Available from: http://www.royalcollege.ca/rcsite/cbd/implementation/cbd-milestones-epas-e.

79. Nousiainen MT, Mironova P, Hynes M, Glover Takahashi S, Reznick R, Kraemer W, et al. Eight-year outcomes of a competency-based residency training program in orthopedic surgery. Med Teach. 2018:1-13.

80. D K. Evaluating training programs: the four levels. San Francisco, CA, USA: Berrett-Koehler; 1994.

Annexe 1: Search Strategies

Search Strategy Medline

First Search

1 (education* or training or trainer or teach* or curriculum or learn* or preparation*).tw,kw. (1184338)

2 Education, Medical/ or Education, Special/ or Education/ or Education, Medical, Continuing/ or Education Department, Hospital/ or Education, Continuing/ or Education, Professional/ or Education, Graduate/ or Education, Medical, Graduate/ or Education, Professional, Retraining/ (127359)

3 Hospitals, Teaching/ or Teaching/ (60467)

4 Models, Educational/ or Learning/ (53874)

5 Curriculum/ (58177)

6 or/1-5 (1268284)

7 General Surgery/ (33912)

8 (surger* or surgical or operation or operating or (operative adj2 procedure*)).tw,kw. (1502263)

9 or/7-8 (1516683)

10 Computer Simulation/ or Patient Simulation/ (142559)

11 Manikins/ (3163)

12 Computer-Aided Design/ (10721)

13 (mannequin* or manikin* or simulation* or simulator* or SAGAT).tw,kw. (194963)

14 or/10-13 (288985)

15 6 and 9 and 14 (3810)

Second Search

1 Microsurgery/ (21884)

2 ((plastic or reconstructive or hand* or nerve* or cosmetic or esthetic or microvascular or tendon*) adj2 surger*).tw,kw. (27870)

3 Surgery, Plastic/ (22859)

4 Reconstructive Surgical Procedures/ (29532)

5 Microvascular Decompression Surgery/ (140)

6 or/1-5 (90700)

7 Computer Simulation/ or Patient Simulation/ (142559)

8 Manikins/ (3163)

9 Computer-Aided Design/ (10721)

10 (mannequin* or manikin* or simulation* or simulator* or SAGAT).tw,kw. (195030)

11 or/7-10 (289052)

12 6 and 11 (741)

Third Search

1 Computer Simulation/ or Patient Simulation/ (142559)

2 Manikins/ (3163)

3 Computer-Aided Design/ (10721)

4 (mannequin* or manikin* or simulation* or simulator* or SAGAT).tw,kw. (195030)

5 or/1-4 (289052)

6 (summarizing or debrief* or wrap-up or recapitulation*).tw,kw. (8172)

7 (after adj2 simulation).tw,kw. (542)

8 (skill adj2 retention*).tw,kw. (180)

9 Program Evaluation/ (46342)

10 (post adj2 simulation*).tw,kw. (131)

11 6 or 7 or 8 or 9 or 10 (55157)

12 5 and 11 (1968)

Search Strategy EMBASE

First Search

1 (education* or training or trainer or teach* or curriculum or learn* or preparation*).tw,kw. (1441836)

2 Hospitals, Teaching/ or Teaching/ (96916)

3 Models, Educational/ or Learning/ (134249)

4 education/ or residency education/ or continuing education/ or education program/ or medical education/ or clinical education/ or postgraduate education/ (505904)

5 curriculum development/ or curriculum/ (64898)

6 or/1-5 (1717562)

7 Computer-Aided Design/ (13393)

8 (mannequin* or manikin* or simulation* or simulator* or SAGAT).tw,kw. (196479)

9 simulation/ or computer simulation/ (164067)

10 7 or 8 or 9 (276033)

11 General Surgery/ (8390)

12 (surger* or surgical or operation or operating or (operative adj2 procedure*)).tw,kw. (1907727)

13 surgery/ (264533)

14 or/11-13 (1978216)

15 6 and 10 and 14 (5442)

16 limit 15 to embase (4073)

Second search

1 Microsurgery/ (22335)

2 ((plastic or reconstructive or hand* or nerve* or cosmetic or esthetic or microvascular or tendon*) adj2 surger*).tw,kw. (36779)

3 Surgery, Plastic/ (55104)

4 microvascular decompression/ (347)

5 or/1-4 (99842)

6 Computer-Aided Design/ (13397)

7 (mannequin* or manikin* or simulation* or simulator* or SAGAT).tw,kw. (196542)

8 simulation/ or computer simulation/ (164108)

9 6 or 7 or 8 (276111)

10 5 and 9 (699)

11 limit 10 to embase (398)

Third search

1 Computer Simulation/ or Patient Simulation/ (148437)

2 Manikins/ (27822)

3 Computer-Aided Design/ (13397)

4 (mannequin* or manikin* or simulation* or simulator* or SAGAT).tw,kw. (196542)

5 or/1-4 (333991)

6 (summarizing or debrief* or wrap-up or recapitulation*).tw,kw. (10556)

7 (after adj2 simulation).tw,kw. (726)

8 (skill adj2 retention*).tw,kw. (273)

9 Program Evaluation/ (1218)

10 (post adj2 simulation*).tw,kw. (188)

11 6 or 7 or 8 or 9 or 10 (12857)

12 5 and 11 (1979)

13 limit 12 to embase (1404)

Search Strategy EBM reviews

First search

1 (education* or training or trainer or teach* or curriculum or learn* or preparation*).af. (93649)

2 Hospitals, Teaching/ or Teaching/ (1706)

3 Models, Educational/ or Learning/ (1524)

4 education/ or residency education/ or continuing education/ or education program/ or medical education/ or clinical education/ or postgraduate education/ (815)

5 curriculum development/ or curriculum/ (918)

6 or/1-5 (93649)

7 Computer-Aided Design/ (91)

8 (mannequin* or manikin* or simulation* or simulator* or SAGAT).af. (6466)

9 simulation/ or computer simulation/ (1454)

10 7 or 8 or 9 (6550)

11 General Surgery/ (293)

12 (surger* or surgical or operation or operating or (operative adj2 procedure*)).af. (115546)

13 surgery/ (245)

14 or/11-13 (115546)

15 6 and 10 and 14 (534)

16 remove duplicates from 15 (529)

Second search

1 Microsurgery/ (391)

2 ((plastic or reconstructive or hand* or nerve* or cosmetic or esthetic or microvascular or tendon*) adj2 surger*).af. (2731)

3 Surgery, Plastic/ (104)

4 Reconstructive Surgical Procedures/ (534)

5 Microvascular Decompression Surgery/ (4)

6 or/1-5 (3540)

7 Computer Simulation/ or Patient Simulation/ (1715)

8 Manikins/ (412)

9 Computer-Aided Design/ (91)

10 (mannequin* or manikin* or simulation* or simulator* or SAGAT).af. (6466)

11 or/7-10 (6550)

12 6 and 11 (39)

Third Search

1 Computer Simulation/ or Patient Simulation/ (1715)

2 Manikins/ (412)

3 (mannequin* or manikin* or simulation* or simulator* or SAGAT).tw,kw. (5536)

4 or/1-3 (6227)

5 (summarizing or debrief* or wrap-up or recapitulation*).tw,kw. (736)

6 (skill adj2 retention*).tw,kw. (76)

7 (post adj2 simulation*).tw,kw. (11)

8 or/5-7 (822)

9 4 and 8 (78)