Development and initial validation of the McGill Simulator for Endoscopic Sinus Surgery (MSESS)

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Rickul Varshney, MD, FRCSC

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PREFACE AND AUTHOR CONTRIBUTION

This thesis is in the publication-based-thesis format as specified by McGill University. The thesis contains two publications, of which I am the first author.

Manuscript 1[1]: "Development of the McGill simulator for endoscopic sinus surgery: a new high-fidelity virtual reality simulator for endoscopic sinus surgery" by Varshney R, Frenkiel S, Nguyen LH, Young M, Del Maestro R, Zeitouni A, Tewfik MA; National Research Council Canada published in Am J Rhinol Allergy. 2014 Jul-Aug;28(4):330-4 (doi: 10.2500/ajra.2014.28.4046). It is reproduced (reformatted) in Chapter 3. The contributions of each author are as follows: RV: creation and development of the MSESS (including participation in simulator creation such as labeling of nasal structures on a software, trial and error for simulator refinement), manuscript preparation. SF: creation and development of the MSESS, manuscript preparation. LHPN: creation of educational parameters of simulator, manuscript preparation. RDM: creation and development of the performance metrics, study coordination. AZ: Creation and development of the MSESS, manuscript preparation. ES: creation of software to analyze the raw data into meaningful data, analysis of performance metrics. WRJF: creation of software to analyze the raw data into meaningful data, analysis of performance metrics. NRC: Creation and development of the MSESS, creation of performance metrics. MAT: creation and development of the MSESS, manuscript preparation. All authors read and approved the final manuscript.

Manuscript 2[2]: "The McGill simulator for endoscopic sinus surgery (MSESS): a validation study" by Varshney R, Frenkiel S, Nguyen LH, Young M, Del Maestro R, Zeitouni A, Saad E, Funnell WR; National Research Council Canada, Tewfik MA. J Otolaryngol Head Neck Surg. 2014 Oct 24;43:40 (doi: 10.1186/s40463-014-0040-8). The original article is an open access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. It is reproduced (reformatted) in Chapter 4. The contributions of each author are as follows: RV: Study design, creation and development of the MSESS (including participation in simulator creation such as labeling of nasal structures on a software, trial and error for simulator refinement), data collection, data analysis, manuscript preparation. SF: Study design, creation and development of the MSESS, manuscript preparation. LHPN: Study design, data analysis and interpretation, manuscript preparation. RDM: Study design, creation and development of the performance metrics, study coordination. AZ: Creation and development of the MSESS, data analysis, manuscript preparation. ES: Data analysis, creation of software to analyze the raw data into meaningful data, analysis of performance metrics. WRJF: Data analysis, creation of software to analyze the raw data into meaningful data, analysis of performance metrics. NRC: Creation and development of the MSESS, creation of performance metrics. MAT: Study design, creation and development of the MSESS, data collection, data analysis and interpretation, manuscript preparation. All authors read and approved the final manuscript.

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ABSTRACT

Background:

The technical challenges of endoscopic sinus surgery (ESS) and the high risk of complications support the development of alternative modalities to train residents in these procedures. Virtual reality (VR) simulation has demonstrated benefit in many disciplines as an important educational tool for surgical training. Within the field of rhinology, there is a lack of ESS simulators with appropriate validity evidence supporting their integration into residency education.

Objectives:

The objectives of this study are: 1) to develop a new rhinology simulator, the McGill Simulator for ESS (MSESS); 2) to evaluate the acceptability, perceived realism and benefit of the MSESS among medical students, otolaryngology residents and faculty; and 3) to present evidence supporting its ability to differentiate users based on their level of training through performance metrics.

Methods:

The McGill Simulator for endoscopic sinus surgery (MSESS), a new sinus surgery VR simulator with haptic feedback, was developed with the National Research Council of Canada. 10 medical students, 10 junior residents, 10 senior residents and 3 expert sinus surgeons performed anterior ethmoidectomies, posterior ethmoidectomies and wide sphenoidotomies on the MSESS. Performance metrics related to quality (e.g. percentage of tissue removed), efficiency (e.g. time, path length, bimanual dexterity, etc.) and safety (e.g. contact with no-go zones, maximum applied force, etc.) were calculated. All users completed a post-simulation questionnaire related to the realism, usefulness and perceived benefits of training on the MSESS.

Results:

The MSESS allows the user to perform basic sinus surgery skills, such as an ethmoidectomy and sphenoidotomy, through the use of endoscopic tools in a virtual nasal model. The MSESS was found to be realistic and useful for training surgical skills with scores of 7.97 ± 0.29 and 8.57 ± 0.69, respectively on a 10-point Likert scale. Most students and residents (29/30) believed that it should be incorporated into their curriculum. There were significant differences between novice surgeons (medical students and junior residents) and senior surgeons (senior

residents and sinus surgeons) in performance metrics related to quality ($p<0.05$), efficiency ($p<0.01$) and safety ($p<0.05$).

Conclusion:

The MSESS demonstrated initial evidence supporting its use for residency education. This simulator may be a potential resource to help fill the void in ESS training.

RÉSUMÉ

Introduction:

La chirurgie endoscopique des sinus est une chirurgie complexe avec un risque significatif de complications. Ceci motive le développement de méthodes alternatives pour enseigner ce type de chirurgie. La simulation réalité virtuelle a démontré de bons résultats dans multiples disciplines comme outil d'enseignement. Dans le domaine de rhinologie, il y a un manque de simulateurs pour la chirurgie endoscopique des sinus démontrant un niveau de validité approprié pour l'intégrer dans le curriculum de résidence chirurgicale.

Objectifs:

Les objectives de cette étude sont: 1) de développer le simulateur de la chirurgie endoscopique des sinus de McGill; 2) d'évaluer le réalisme et les bénéfices subjectifs du simulateur; 3) d'évaluer si le simulateur peut différencier le niveau d'expertise d'un usager avec les paramètres de performance mesurés.

Méthodes:

Le simulateur de la chirurgie endoscopique des sinus de McGill a été dévelopé avec le Conseil National de Recherches Canada. 10 étudiants de médecine, 10 résidents juniors, 10 résidents séniors et 3 chirurgiens des sinus ont fait des éthmoïdectomies antérieures, des éthmoïdectomies postérieures et des grandes sphénoïdotomies sur le simulateur. Des paramètres de performance reliés à la qualité (pourcentage de tissue enlevé), efficacité (temps, distance parcourue, fréquence d'activation des pédales, etc.) et la sécurité (montant de tissu normal enlevé, force maximale, etc.). Tous les usagers ont rempli un questionnaire sur leurs perceptions du réalisme et des bénéfices subjectifs du simulateur.

Résultats:

Le simulateur permet aux usagers de compléter des tâches de base telles qu'une éthmoïdectomie et une sphénoïdotomie. Le simulateur s'est avéré réaliste et utile pour l'enseignement des habiletés chirurgicales avec des notes de 7.97 ± 0.29 et 8.57 ± 0.69, respectivement sur une échelle Likert 10-points. La majorité des étudiants et résidents (29/30) croient que le simulateur devrait etre incorporer dans leur curriculum. Il y avait une différence significative entre les chirurgiens novices (étudiants et résidents juniors) et séniors (résidents séniors et chirurgiens experts) dans les paramètres de performance mesurés ($p<0.05$)

Conclusion:

Le simulateur démontre de la validité initiale comme outil d'apprentissage. Ce simulateur pourrait éventuellement combler un besoin dans l'enseignement de la chirurgie endoscopique des sinus.

LIST OF ABBREVIATIONS

CRS	(Chronic rhinosinusitis)
ESS	(Endoscopic sinus surgery)
MSESS	(McGill Simulator for Endoscopic Sinus Surgery)
Virtual reality	(Virtual Reality)

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CHAPTER 1. INTRODUCTION

1.1 Background & thesis rationale

Chronic Rhinosinusitis (CRS) affects millions of patients in North America [3]. Its impact on healthcare utilization and patients' quality of life compares to many other chronic illnesses such as cardiovascular disease, diabetes and back pain. Although some patients can be managed with medical therapy, a significant number of patients require endoscopic sinus surgery (ESS) to manage their symptoms. Thus, over 400,000 cases of ESS are done every year in the United States, being one of the most common procedures performed by otolaryngologists[4].

Historically, students have learnt surgical skills through the apprenticeship model. In the latter, trainees observe and participate in the surgical procedure, under the supervision of the teacher. However, this model has inherent deficiencies such as lack of standardization of training between institutions and unpredictability of a trainee's surgical exposure based on patient population. Moreover, there is an obvious degree of subjectivity in this method with regards to student evaluation, as the teacher must rely on experience and his own perceptions to assess the surgical skills of the student. Finally, the ethical dilemma of patient safety versus the need to train future surgeons is at the forefront of many debates on surgical education. The latter is even more important for ESS due to delicate structures that surround the paranasal sinuses such as the eyes, the optic nerve, the brain and the carotid arteries and thus, there is potential for disastrous complications.

The deficiencies of the apprenticeship model have motivated educators to find alternative modalities to train students. Theses have included didactic teaching, 3D models and cadaveric dissection, each with their own set of inherent challenges. Another more recent innovation is virtual reality (VR) simulation training. The latter has shown promise in other surgical disciplines[5-8]. For ESS, the ES3 was the first sinus surgery simulator developed in 1998 by Lockheed Martin[9]. Multiple validation studies were completed on the simulator, demonstrating its benefits' for resident training. However, it is no longer commercially available. Other VR simulator models for ESS have been created to fill the void, but none have shown validity for resident training[10]. The problem with some of these models is that they place importance on clinical applicability such as pre-operative planning, rather than resident education[10].

The need to help fill the void in ESS education, formed the rationale of this thesis.

1.2 Thesis objectives

This thesis aimed to start the process of developing a more accurate and life-like ESS simulator. The objectives of this thesis were:

(1) to develop a new ESS simulator for residency training, the McGill Simulator for ESS (MSESS);

(2) to evaluate the acceptability, perceived realism and benefit of the MSESS among medical students, otolaryngology residents and faculty; and

(3) to present evidence supporting the simulator's ability to differentiate users based on their level of training through performance metrics.

1.3 Thesis organization

Chapter 2 presents the background & literature review to describe the necessity of developing and validating further training modalities for the education of ESS.

Chapter 3 contains the first manuscript, "Development of the McGill simulator for endoscopic sinus surgery: a new high-fidelity virtual reality simulator for endoscopic sinus surgery." by Varshney R, Frenkiel S, Nguyen LH, Young M, Del Maestro R, Zeitouni A, the National Research Council Canada, Tewfik MA (Am J Rhinol Allergy. 2014 Jul-Aug;28(4):330-4. doi: 10.2500/ajra.2014.28.4046), which describes how the simulator hardware, software and performance metrics were developed.

Chapter 4 contains the second manuscript, "The McGill simulator for endoscopic sinus surgery (MSESS): a validation study" by Varshney R, Frenkiel S, Nguyen LH, Young M, Del Maestro R, Zeitouni A, Saad E, Funnell WR; Tewfik MA (J Otolaryngol Head Neck Surg. 2014 Oct 24;43:40. doi: 10.1186/s40463-014-0040-8). This manuscript reports the initial validation process using subjective and objective measures in a cohort of students, residents and experts.

Chapter 5 provides an overall discussion of this thesis, including the limitations of the studies described. Chapter 6 provides an overall conclusion. Chapter 7 contains references and chapter 8 contains several appendices.

CHAPTER 2: BACKGROUND & LITERATURE REVIEW

2.1 Endoscopic sinus surgery (ESS)

In 2007, close to 11 million people were diagnosed with chronic rhinosinusitis (CRS) in the United States, affecting nearly 5% of the population[3]. CRS patients are initially managed medically, but a large portion often requires ESS to alleviate their symptoms[11]. Studies have demonstrated the numerous benefits of ESS in terms of quality of life improvement and cost savings in patients with CRS[12-14]. Given the large magnitude of patients with CRS, it is not surprising that over 400,000 ESS cases are performed yearly, making it one of the most common procedures performed by otolaryngologists in the United States[4]. Moreover, ESS is not only indicated for CRS, but also many different pathologies, such as patients with patients with recurrent acute sinusitis, certain sinonasal tumors, midline brain tumors, dysfunctional eustachian tubes and lacrimal system disorders, thus increasing the number of ESS procedures yearly.

ESS is performed using an endoscope (camera) in one hand and various instruments in the other hand. These tools can range from powered instruments, such as drills and microdebriders, to cold steel cutting and grasping instruments. Minimally invasive surgeries, such as ESS, require distinct technical abilities, in part because of the use of an endoscope in the restricted 3-dimensional space of the nasal cavity[15]. Moreover, the surgeon must use both dominant and non-dominant hands, while coordinating the movement of his hands with the indirect visual aid of a monitor[5], where he sees the surgical field and the instruments. All these intricacies of ESS require the surgeon to have complex ambidextrous perceptual, visuo-spatial and psychomotor performance[15].

The difficulty of ESS is accentuated by the complex anatomy of the sinonasal tract and the proximity of numerous vital structures such as the brain, orbits, and carotid arteries[15] (Figure 1). The rate of major and minor complications has been reported to be approximately 0.5% and 6.6%, respectively[16]. This may explain why ESS is the most frequent reason for otolaryngologic surgical litigation in the United States[4]. The complication rate is even higher with trainees[17]. Some examples of minor complications noted from ESS include bleeding, injury to normal sinonasal mucosa or the nasal septum and scarring. Although rare, major complications can be devastating, namely injury to the brain or the eye causing double vision and even blindness. Thus, the potential of disastrous complications and the immense number of cases performed each year make thorough and structured ESS training a must for residency programs.

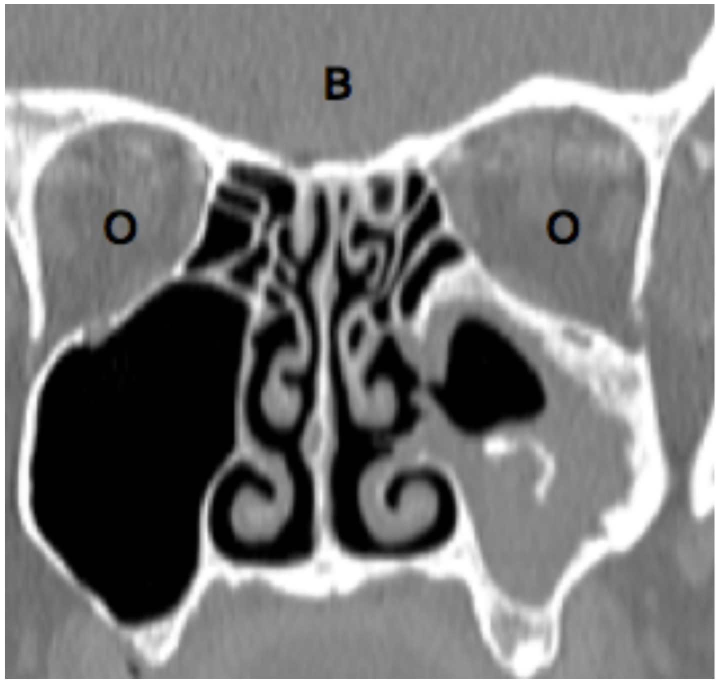

Figure 1 Compute tomography scan of the sinuses. The relationship of the sinuses with the surrounding vital structures (O = orbits, B = brain).

2.2 Surgical training in ESS

Historically, surgical training is strongly built on the apprenticeship model where trainees learn though their multitude of operative experiences[18]. Typically, a student participates in the surgery with the teacher, gradually learning different steps of the procedure. At a certain point, the student is able to perform all the steps independently and thus, the teacher subjectively deems him competent for that procedure. Despite the obvious ethical dilemmas of patient safety versus trainee education that this has created for decades, there are many other limitations to the apprenticeship model.

Currently, surgical training lasts for a distinct period of time with exposure to cases based on available patients, creating immense variability between trainees in terms of level of skill[9]. If a particular institution is situated in an area where the population is biased to not have a certain type of pathology, the trainee may not be exposed to those types of surgeries. This is further complicated by the fact that decreased resident working hours has diminished their case load to a significant degree[19]. Moreover, it has been shown that proficiency in a procedure is not a function of the number of procedures performed during training[20], rendering this apprenticeship model inadequate. There are multiple other factors than repeating a procedure over and over again that contribute to the acquisition of a surgical aptitude, such as adequate and structured feedback. Finally, attending surgeons are forced to take over the case when the trainee does not exhibit adequate technique or a complication occurs, thus, once again decreasing a trainee's surgical experience[4]. Within the apprenticeship model, the ethical dilemma of patient safety and well-being often motivates the teacher to take over when unexpected incidents occur. However, the ability to recognize and manage complications is integral to a surgeon's ability to practice independently and thus, limited with traditional teaching methods.

Furthermore, currently, there are no objective mandatory technical skill examinations for surgical residents before they start performing cases on their own as attending staff [9]. Unlike written exams for knowledge assessment, technical skills are only assessed subjectively within the apprenticeship model, despite technical expertise being an immense part of a surgeon's practice[9, 21]. Therefore, there have been worldwide efforts to develop and validate objective tools for assessment of surgical skills[22]. In an ideal setting, the evaluation methods would be free of subjectivity and standardized not only within the institution, but also at a national or international level.

The technical challenges of surgery, the high risk of complications and the limitations of the apprenticeship model have supported the development of alternative methods to assist the training of residents. These modalities have included didactic lectures, small group sessions, silicone models and cadaveric dissections[15]. However, the latter have substantial limitations with regards to the complex needs of ESS training. The use of lecture and small group sessions is limited with regards to surgical training, apart from discussion of the surgical steps and video demonstrations. The lack of tissue mobility of rigid silicone models[23] limits their ability to replicate the nasal cavity, where structures are mobile and can be retracted away for access. Cadaver dissection has been used routinely, but it is limited due to the associated costs and availability [24], along with the issue of inadequate tissue characteristics after embalmment[18]. In ESS, bleeding within the restricted space of the nasal cavity often obscures surgical landmarks and soils the endoscope. The management of the latter is often a challenge for novice surgeons, which cannot be replicated in cadavers. Fortunately, simulation training provides a potential solution to the inadequacies of the current training modalities.

2.3 Simulation training

Using simulation based and virtual reality (VR) technologies, medical students, residents, and practicing physicians can learn and refine basic and advanced procedural skills before operating on patients[20]. Seymour et al. first demonstrated the benefit of simulation training on resident OR performance and a possible reduction in complications[7]. VR training has since been used successfully in many surgical disciplines[5-8], including laparoscopic surgery, gastroenterology, plastic surgery, ophthalmology and dermatology. In Otolaryngology, there has been a great deal of work in the field of otology, with several simulation models having been created for temporal bone dissections[25-27].

The potential benefits of simulation training include objective measurements of surgical skills, reduction of patient risk, eventual simulation of complex procedures and the standardization of residency training regardless of caseload available at particular institution or access to a cadaver laboratory[21]. The procedure can also be practiced many times until proficiency is achieved, reducing the amount of time needed for a trainee to achieve comfort[20]. Furthermore, VR simulation detects errors and gives the teacher objective points to discuss with the trainee. Finally, simulators can provide objective feedback to help the trainee recognize areas of weakness and strengths even without the need of a tutor[28].

2.4 Simulation training in ESS

There has been some work in the field of rhinology with shown benefit of simulation training [4, 15, 21], but currently there are no available VR simulators with appropriate validity evidence supporting their integration into residency education. Compared to our otology colleagues, the advancements in the field of sinus surgery simulation remain underdeveloped, both in terms of the technology and the ability to render patient-specific simulator models. The inherent difficulty in ESS relates to the mobility of nasal structures in a hollow space, whereas temporal bone otology surgery is performed in an open surgical field. Also, given the osseous nature of the temporal bone, the need to simulate mobile structures is limited as opposed to the nasal cavity. Furthermore, the necessity to visualize the surgical field through an endoscope adds to the challenges of simulating ESS.

In the field of rhinology, the ES3 was the first sinus surgery simulator developed in 1998 by Lockheed Martin[9]. Their model used virtual endoscopic instrument with haptic feedback[9]. The ES3 underwent an extensive validation process. One study showed correlation between performance on the simulator and performance on other validated tests of psychomotor ability[15]. Another study was able to differentiate between students, residents and attending staff based on performance metrics[21], a concept previously known as construct validity in the education literature. Finally, one study demonstrated predictive validity in that simulator-trained residents outperformed control residents in the operating room[4]. Although the ES3 was shown to be beneficial for resident training, it is no longer in production and there are less then a handful of devices being used in North America[10]. Moreover, since it is discontinued, no new technologies or software changes have been made for the ES3 for years, making it somewhat outdated in the world of computer modeling and simulation technologies[10]. To date, rigorous published validation studies supporting routine use of ESS simulators in resident training derive uniquely from the ES3 [4, 15].

Following the discontinuation of the ES3, other VR simulator models for ESS have been created such as the Dextroscope endoscopic sinus simulator[29] and the VOXEL-MAN[30]. Furthermore, Ruthenbeck et al. recently described a VR simulator using advanced tissue rendering in order to create more a more realistic nasal cavity, with improved nasal mucosa appearance and tissue characteristics[16]. However, none have published evidence supporting their routine use in resident education[10].

2.5 NeuroTouch Simulator

The Montreal Neurological Institute Simulation Lab, which is affiliated with McGill University, has done extensive work in the field of simulation training. It has developed the NeuroTouch simulator, which is a virtual reality system for training of neurosurgical procedures[29]. Del Maestro and his team have performed validation studies with trainees of different levels of experience, including medical students and residents, in order to demonstrate face, content and construct validity[30], including validity of the simulator to assess bimanual dexterity[31]. As previously mentioned, bimanual dexterity is important in surgical disciplines, especially in ESS, where both hands are simultaneously used to navigate through the nasal cavity.

Furthermore, they defined three tiers of performance metrics with regards to the assessment of a trainee's work on a simulator[32]. The latter are measurements to evaluate the work of a participant and can be used to assess safety, quality, and efficiency of a surgeon's performance. Tier 1 measured the amount of tissue removed, including normal tissue and tissue meant to be removed. Tier 2 assessed efficiency such as time to achieve the tasks and frequency of use of pedals that activate the instruments. Finally, tier 3 measured forces, which evaluated the safety of a trainee. As will be presented further in this thesis, these three tiers of performance metrics were used as the basis for the assessment tools in the simulator we developed.

A novel approach to brain tumors is access through the nose. In fact, many midline brain tumors are now being removed using cameras through the nasal cavity with endoscopic instruments. This technique has been shown to be safe and effective, compared to traditional microscopic method[31]. Due to the expansion and increased acceptance of this approach within the neurosurgery community, residents are more routinely being trained in this approach. Thus, the NeuroTouch simulator was further expanded to include models depicting the nasal cavity as to potentially develop simulation scenarios that include endonasal approaches for brain tumors[32]. This early work on the nasal cavity model made the NeuroTouch platform ideal for the development of a sinus surgery simulator. Thus, as will be described later in this thesis, our team built upon the NeuroTouch to develop a simulator to teach Otolaryngology residents ESS.

2.6 Link to first manuscript

As stated in chapter 1, due to the lack of validated rhinology simulators, there is a need for a VR simulator with evidence of acceptability and validity to fill the void in ESS training. This teaching modality may complement the traditional apprenticeship model employed across Canadian residency programs. Furthermore, our model could be the basis for the creation of simulators in other fields of Otolaryngology, namely laryngology, microvascular free flap surgery and head and neck oncology. The next chapter presents a manuscript that describes the development of such a simulator.

CHAPTER 3: DEVELOPMENT OF THE MCGILL SIMULATOR FOR ENDOSCOPIC SINUS SURGERY (MSESS): A NEW HIGH FIDELITY VIRTUAL REALITY SIMULATOR FOR ENDOSCOPIC SINUS SURGERY (MANUSCRIPT 1)

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Keywords:
Rhinology, endoscopic sinus surgery, training, education, simulation, virtual reality, resident, minimally invasive surgery, haptic, technical abilities, performance metrics, nasal model

Manuscript 1 [1]: Reformatted version of article published in
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3.1 Abstract

Background: The technical challenges of endoscopic sinus surgery (ESS) and the high risk of complications support the development of alternative modalities to train residents in these procedures. Virtual reality simulation is becoming a useful tool for training the skills necessary for minimally invasive surgery, however there are currently no ESS virtual reality simulators available with validity evidence supporting their use in resident education.

Objective: Our aim was to develop a new rhinology simulator, as well as to define potential performance metrics for trainee assessment.

Methods: The McGill Simulator for Endoscopic Sinus Surgery (MSESS), a new sinus surgery virtual reality simulator with haptic feedback, was developed with the National Research Council of Canada. A panel of experts in education, performance assessment, rhinology and skull base surgery convened to identify core technical abilities that would need to be taught by the simulator, as well as performance metrics to be developed and captured.

Results: The MSESS allows the user to perform basic sinus surgery skills, such as an ethmoidectomy and sphenoidotomy, through the use of endoscopic tools in a virtual nasal model. The performance metrics were developed by an expert panel and include measurements of safety, quality and efficiency of the procedure.

Conclusion: The MSESS incorporates novel technological advancements in order to create a realistic platform for trainees. To our knowledge, this is the first simulator to combine novel tools such as the endonasal wash and elaborate anatomical deformity with advanced performance metrics for ESS.

3.2 Introduction

With over 400,000 cases per year, endoscopic sinus surgery (ESS) is one of the most common procedures performed by otolaryngologists in the United States[4]. Minimally invasive surgeries, such as ESS, require distinct technical abilities, in part because of the use of an endoscope in a restricted 3-dimensional space[15]. Moreover, the surgeon must coordinate hand movements with the indirect visual aid of a monitor[5]. The difficulty of learning ESS is accentuated by the complex anatomy of the sinonasal tract and the proximity of numerous vital structures such as the brain, orbits, and carotid arteries[15]. In fact, a recent report demonstrated the rate of major and minor complications to be approximately 0.5% and 6.6%, respectively[16]. This may explain why ESS is the most frequent reason for otolaryngologic surgical litigation in the United States[4]. With trainees, the complication rate is even higher[17].

The technical challenges of surgery and the high risk of complications have supported the development of alternative methods to assist the training of residents. Traditional modalities have included didactic lectures, small group sessions and cadaveric dissections[15]. Virtual reality simulators are becoming useful for training in the skills necessary for minimally invasive surgeries such as ESS[15].

In the field of rhinology, the ES3 was the first sinus surgery simulator developed in 1998 by Lockheed Martin[9]. Although the ES3 was shown to be beneficial for resident training, it is no longer in production and there are less then a handful of devices being used in North America[10]. Following the discontinuation of the ES3, other virtual reality simulator models for ESS have been created. For example, Ruthenbeck et al. recently described a virtual reality simulator using advanced tissue rendering in order to create more a more realistic nasal cavity, with improved nasal mucosa appearance and tissue characteristics[16]. However, none have published evidence supporting their routine use in resident education[10].

3.3 Objective

The objective of this article is to describe the development of the McGill Simulator for Endoscopic Sinus Surgery (MSESS), a new virtual reality simulator for ESS in a collaboration between the McGill University Department of Otolaryngology – Head and Neck Surgery, the Montreal Neurological Institute Simulation Lab and the National Research Council of Canada. We describe the physical components of the simulator, the tasks performed and the metrics measured on the simulator. The potential applications of simulation in the field of rhinology will also be discussed.

3.4 Description of the MSESS

3.4.1 Identification of core technical skills

Experts in the field of rhinology, performance assessment, skull base surgery and education evaluation identified the most important core technical skills needed to perform ESS. Their findings were cross-referenced with the work of Bakker[24], who reported survey results from a panel of otolaryngologists on the skill requirements of ESS. This lead to the identification of three core skills, namely recognition of the complex anatomy through an endoscopic view; learning to handle an endoscope and a tool with bimanual dexterity; and learning to perform discrete surgical steps in a safe and effective manner.

3.4.2 Simulator Hardware

The simulator's physical set-up consists of a monitor to visualize the surgical field, two haptic tools (endoscope and microdebrider) and two pedals (microdebrider and endonasal wash) (Figure 2); a more detailed explanation of each part of the simulator follows. There is also a touch-screen, which allows navigation of the user-interface and selection of various simulation tasks.

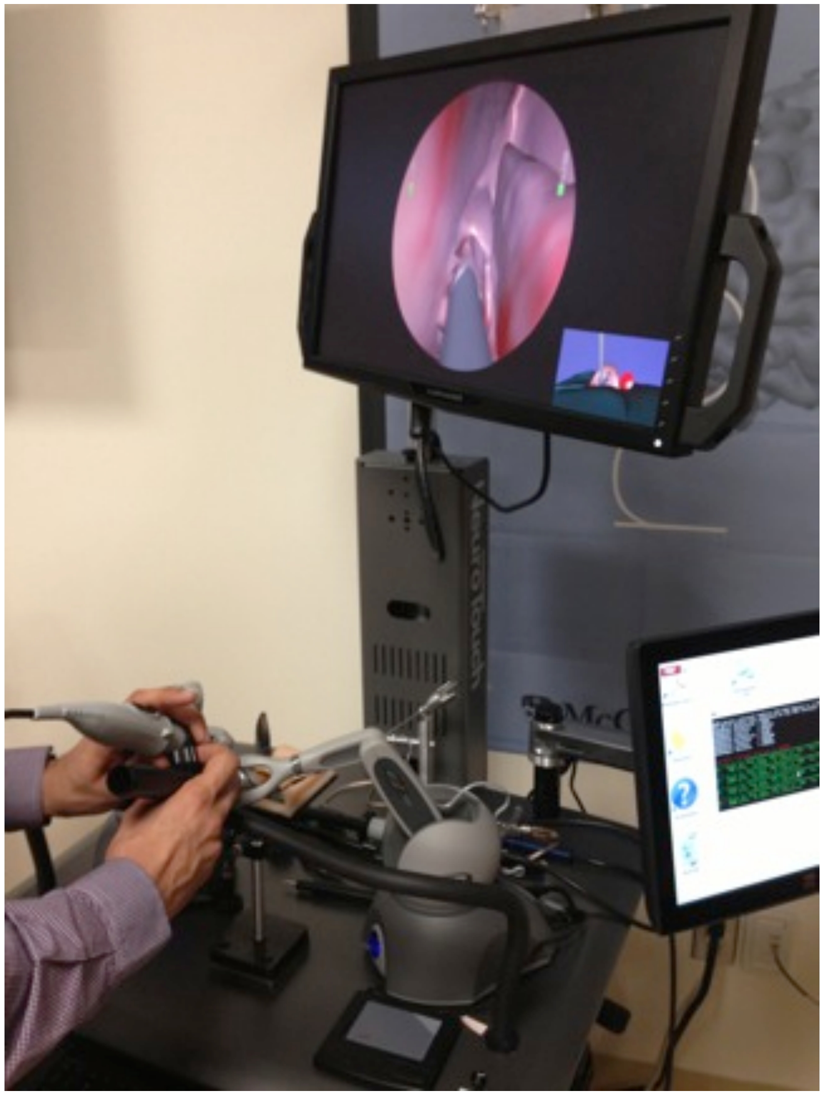

Figure 2 The McGill Simulator for Endoscopic Sinus Surgery (MSESS)

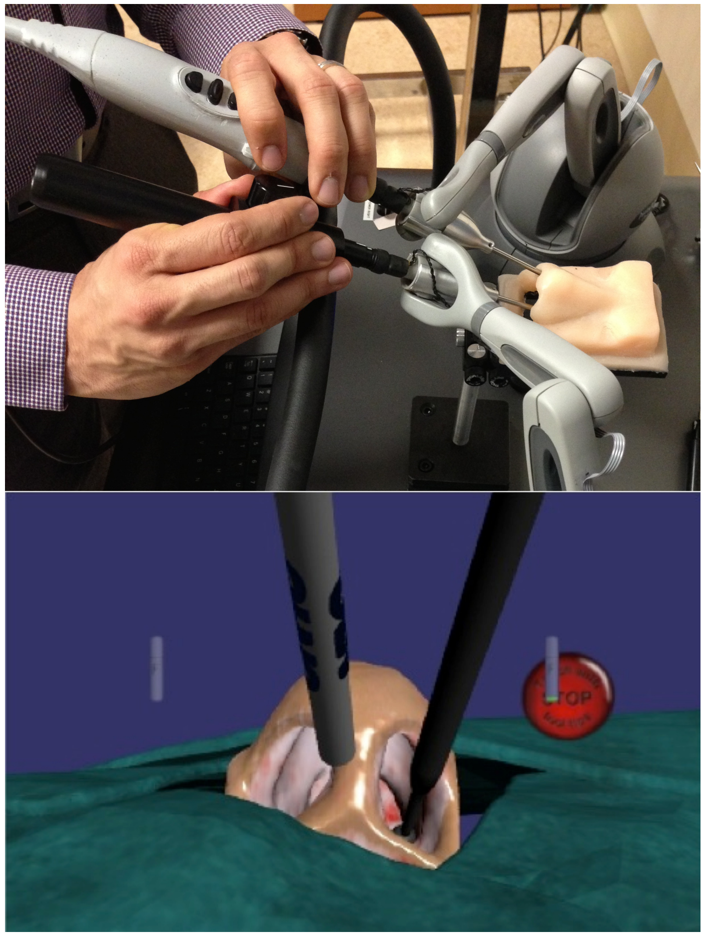

Figure 3 Hardware of the MSESS. View of the endoscope and the microdebrider handles (above) with VR view seen on the display monitor (below).

3.4.3 Nasal and Paranasal Sinus Software Model

The MSESS was developed on the NeuroTouch platform, a neurosurgical simulator previously developed by the National Research Council of Canada (NRC)[32, 33]. NeuroTouch is based on the NRC's software simulation engine, Blade, which consists of three asynchronous processes for the computation of tissue mechanics, graphics and haptic feedback. The finite-element method with explicit time integration computes tissue deformation and topology change in response to tissue rupture, cutting or erosion. The tissues are modeled as viscoelastic solids using a quasilinear viscoelastic constitutive model for the viscous part[34], and a compressible form of the generalized Rivlin constitutive model[34, 35] for the elastic part.

Modeling endoscopic procedures is particularly difficult with constitutive model-based finite-element methods due to the relatively large volume over which the surgeries occur. Furthermore, partial volume effects in medical images and the small size of nasal passages make it difficult to construct highly accurate models from imaging using purely automated methods. Therefore, a multistage method was used. A set of clinical CT images were first manually segmented using 3D Slicer (http://www.slicer.org)[36] to define both the extent of the simulated volume and the different tissues which would be tracked by the performance metrics. Then, a 3D model of the nasal cavity walls was constructed from the segmentation. Thereafter, the graphics software Blender (Blender Foundation, Netherlands) was used to correct any artifacts. Finally, with the visible anatomy defined, a finite-element mesh capable of reproducing the visible anatomy was constructed by placing a thin layer of finite-elements surrounding the visible surfaces. Realistic-feeling tissue properties were assigned to the elements, which were held in place by Dirichlet boundary conditions placed on the outer boundary of the finite-element mesh.

Extensive work was done to match tissue characteristics, including color and mobility, to enhance realism. This is of particular importance given that anatomical recognition through an endoscopic view is one of the most challenging tasks of ESS.[24] Recent advancements in software design have allowed previous models to include tissue deformability and mobility of the turbinates, which are also included in our model. This surmounts a major drawback of currently available silicone or plaster models: the inability to easily move tissues [23].

Each anatomical nasal structure was coded with a specific label as to allow measurements of performance metrics. For example, the simulator can calculate the percentage of each anatomical structure removed by the microdebrider. In addition, this individualized labeling allows specific tissue characteristics for each structure. A list of all the labeled structures is found in table 1.

Table 1 Different anatomical structures coded separately. Note items 14-18 relate to extended endoscopic approaches to the skull base

Coded anatomical structures	
1)	Nasal septum
2)	Inferior turbinate
3)	Middle turbinate
4)	Superior turbinate
5)	Lamina papyracea
6)	Orbital fat
7)	Anterior ethmoids
8)	Posterior ethmoids
9)	Skull base
10)	Basal lamella
11)	Fontanelle
12)	Optic nerve
13)	Carotid artery
14)	Sphenoid sinus anterior face
15)	Sphenoid sinus posterior wall
16)	Sphenoid intersinus septum
17)	Planum sphenoidale
18)	Clivus

3.4.4 Haptic tools

The user visualizes the surgical field on a high-definition monitor as would be seen through a routine 0 degree, rigid Hopkins rod-lens endoscope. In order to create a life-like feel to the surgery, the handle of the endoscope is akin to a real rod endoscope camera head (Figure 4). Furthermore, a novel aspect of the MSESS is the ability for the endoscope to become soiled and thus blurry when the tip virtually contacts nasal mucosa, as would be expected during real-life surgery. The endonasal wash function, which is activated using a foot pedal, is used to clean the endoscope. Although the simulated nasal mucosa does not bleed, the latter feature of the simulator encourages the user to carefully position the endoscope tip during the virtual procedure.

The microdebrider is the tool used to complete the tasks on the simulator and is also activated using a pedal. The handle is similar to a commonly used pen-grip tool and harbors a wheel on the handle to rotate the cutting edge of the microdebrider (Figure 4). It has a 4.0mm outer diameter and a double serrating rotating tip. The tip moves at 5000rpm and has the ability to suction and remove tissue. The decision the create a simulated microdebrider was based on the fact that it is a particularly dangerous tool in ESS with potential complications of diplopia, blindness, carotid artery injury, CSF leak, brain injury and encephalocele [37].

Figure 4 MSESS tools. A = handle of the endoscope, B = handle of the microdebrider, C = virtual view of the microdebrider with the serrating rotating tip.

3.4.5 Simulated Tasks

The 5 Tasks that a user will perform on the simulator are as follows:

Task 1) Pass the endoscope from the nasal vestibule to the nasopharynx with minimal trauma to the nasal mucosa.

Task 2) Pass the endoscope and use the microdebrider to contact the maxillary ostium, sphenoid ostium and nasopharynx.

Task 3) Complete anterior ethmoidectomy (Figure 5).

Task 4) Complete posterior ethmoidectomy.

Task 5) Wide sphenoidotomy (Figure 6).

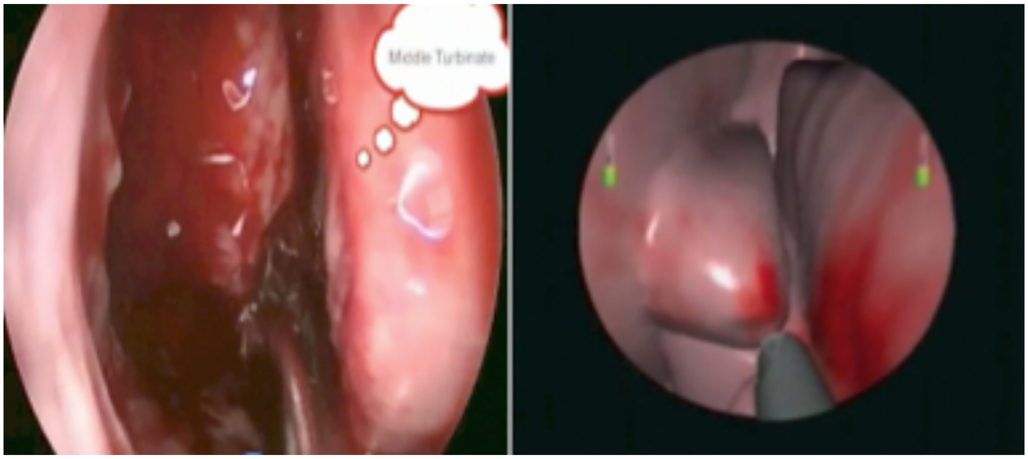

Figure 5 Anterior ethmoidectomy Left = Real-life endoscopic view. Right = simulated view on MSESS.

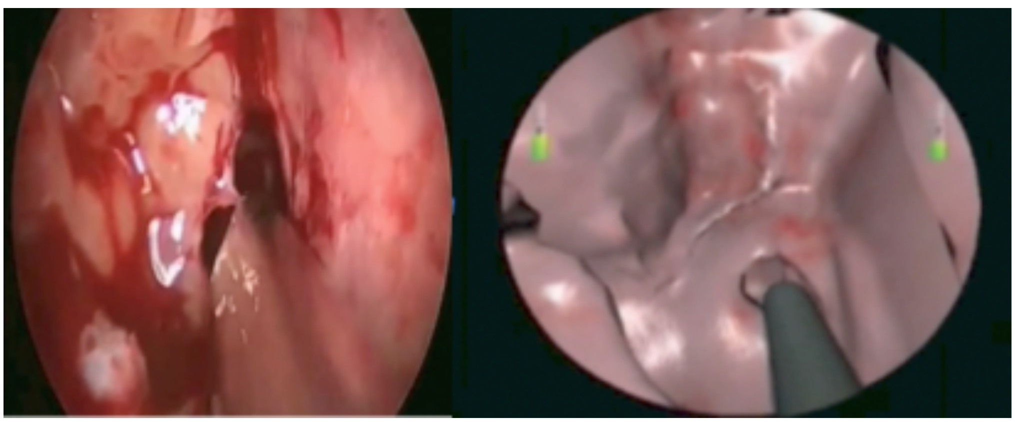

Figure 6 Sphenoidotomy. Left = Real-life endoscopic view. Right = simulated view on MSESS.

Sinus surgery is a step-based intervention, beginning with the maxillary antrostomy, then addressing the ethmoids, and finally the sphenoid sinus. The maxillary antrostomy is planned for future versions of the MSESS after the development of tools such as the sickle knife and the back-biter. Additionally, various angled scopes could be simulated. The five tasks were selected based on this step-wise approach. The tasks also increase in difficulty: tasks 1 and 2 are considered basic tasks; tasks 3 and 4 are more difficult; and task 5 is the most complex. As there is a risk of severe complications with task 5 due to proximity of the carotid artery and optic nerve, simulation training is critically important for trainees before performing such a procedure in a live patient.

3.4.6 Performance Metrics

The performance metrics collected by the MSESS can be thought of in three categories: safety, efficiency, and quality of final product. The metrics measured are quantitative data points created and exported by the simulator (transferred to a spreadsheet). Each structure within the nasal cavity has been labelled separately, which allows the measurement of metrics for each one. The metrics and their units are presented in table 2. At the end of the simulation session, the trainee is provided with a series of scores for each performance metric.

Table 2 Description of performance metrics.

Metric sphere	Definition	Metric	Units
Quality	Completeness of targeted tissue removal	Amount of residual anterior ethmoids	Percentage (amount removed/total amount of relevant tissue)
		Amount of residual posterior ethmoids	Percentage
		Amount of residual sphenoid face	Percentage
Efficiency	Task performance with the least amount of unnecessary maneuvers	Time to complete tasks	Seconds
		Path length (endoscope)	Millimeters
		Path length (microdebrider)	Millimeters
		Fluctuation in distance between tips of endoscope & microdebrider (calculated by interquartile range)	Millimeters
		Frequency of microdebrider pedal activation	Number
		Amount of endonasal washes	Number
Safety	Amount of collateral damage	Amount of normal tissue removed, namely tissue over three critical “no-go” zones (lamina papyracea, skull base and optico-carotid recess)	Percentage
		Maximal force applied on skull base and lamina papyracea	Newtons

3.5 Discussion

3.5.1 Surgical Training in ESS

Surgical trainees commonly learn ESS on live patients, with significant patient safety concerns. Training on cadavers is limited due to the associated costs and availability [24], along with the issue of inadequate tissue characteristics after embalmment[18]. Fortunately, simulation training provides a potential solution to the inadequacies of cadaver-based training, and of patient safety concerns.

Using simulation based and virtual reality technologies, medical students, residents, and practicing physicians can learn and refine basic and advanced procedural skills before operating on patients[20]. Seymour et al. first demonstrated the benefit of simulation training on resident OR performance and a possible reduction in complications[7]. Virtual reality training has since been used in many fields of medicine including laparoscopic surgery, gastroenterology, plastic surgery, ophthalmology and dermatology[5]. In Otolaryngology, there has been a great deal of work in the field of otology, with several simulation models having been created for temporal bone dissections[25]. There has also been some work in the field of rhinology with shown benefit of simulation training [4, 15, 21], but currently there are no available virtual reality simulators with appropriate validity evidence supporting their integration into residency education. Compared to our otology colleagues, the advancements in the field of sinus surgery simulation remain underdeveloped, both in terms of the technology and the ability to render patient-specific simulator models. The inherent difficulty in endoscopic sinus surgery relates to the mobility of nasal structures in a hollow space and the visualization of the surgical field through an endoscope.

The potential benefits of simulation training include objective measurements of surgical skill, reduction of patient risk, eventual simulation of complex procedures and the standardization of residency training regardless of case load available at particular institution[21]. Furthermore, the procedure can be practiced many times until proficiency is achieved, reducing the amount of time needed for a trainee to achieve comfort[20].

3.5.2 Educational Implications of MSESS

Traditionally, innovations in technology have driven the practice of teaching, whereas good teaching practices should drive technology[38]. There is in fact little standardization of metrics for the evaluation of a user's performance and minimal data on the integration of simulators into surgical educational curriculums[38]. The MSESS builds on previous simulator models to increase the educational value by providing users with advanced performance metrics in order for the trainee to identify specific areas requiring improvement. It also allows for objective comparison of their performance to those of experts, as well as to track their progression over time.

One of the innovative features of the MSESS is the large variety of performance metrics. A number of these metrics have already been validated for use in a neurosurgical model such as force, tool-path length and volume of tissue removed[39]; current work by our group aims to validate them in the sinus surgery model. As reported by Wiet and colleagues, a simulator can assess competency by objective measures, such as time of performance, rates of error and economy of movement[10], which have all been incorporated in the list of metrics currently being collected by the MSESS (table 2). Although some metrics have been validated in neurosurgical simulators, all the performance metrics are currently undergoing an extensive validation process with the MSESS. Here, we simply mention the measurement tools available to the user through the simulator.

Amongst the more novel component of the performance metrics is the measurement of force on various structures. Endoscopic surgeons are aware that certain areas of the nasal cavity such as the lamina papyracea are more sensitive to force, thus it is important to be able to measure metrics with regards to these specific structures. The importance of force also highlights a downfall of cadaveric tissues, which may not allow for adequate estimation of the force necessary to perform endoscopic sinus procedures[40]. Furthermore, as described by Bakker et al.,[24] judging the location of the endoscope and the tool was one of the most challenging tasks of ESS. Thus, the MSESS allows measurement of bimanual dexterity, particularly the position of the endoscope relative to the microdebrider.

Currently, our technology only allows the use of the model based on one CT scan, as each structure within the nasal cavity is labeled individually, which is an elaborate process to perform. Work is being done to shorten this process in order to eventually allow patient-specific models. The use of 3D printing is a potential resource to help with patient-specific models for preoperative planning and education, as demonstrated by Waran et al.[41]. In contrast, virtual reality training has the additional benefits of providing a more realistic visual environment, and providing feedback to the trainee through objective performance metrics. Future versions of the MSESS may be able to eventually address the issues of patient-specificity.

3.6 Conclusion

The MSESS incorporates novel technological advancements in order to create a realistic platform for trainees. To our knowledge, this is the first simulator to combine tools such as the endonasal wash and elaborate anatomical deformability with advanced performance metrics into a model that emulates real ESS. Research is continuing in order to collect evidence supporting the validity of the simulator, the performance metrics, and the validity of using this kind of educational technology within the current training curriculum.

3.7 Acknowledgements

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3.8 Linking statement to second manuscript

After the development of the MSESS, the next step was to perform an initial validation process to demonstrate utility for resident education. This lead to the study described in the next chapter.

CHAPTER 4: THE MCGILL SIMULATOR FOR ENDOSCOPIC SINUS SURGERY (MSESS): A VALIDATION STUDY (MANUSCRIPT 2)

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4.1 Abstract

Background: Endoscopic sinus surgery (ESS) is a technically challenging procedure, associated with significant risk of complications. Virtual reality simulation has demonstrated benefit in many disciplines as an important educational tool for surgical training. Within the field of rhinology, there is a lack of ESS simulators with appropriate validity evidence supporting their integration into residency education. The objectives of this study are to evaluate the acceptability, perceived realism and benefit of the McGill Simulator for Endoscopic Sinus Surgery (MSESS) among medical students, otolaryngology residents and faculty, and to present evidence supporting its ability to differentiate users based on their level of training through performance metrics.

Methods: 10 medical students, 10 junior residents, 10 senior residents and 3 expert sinus surgeons performed anterior ethmoidectomies, posterior ethmoidectomies and wide sphenoidotomies on the MSESS. Performance metrics related to quality (e.g. percentage of tissue removed), efficiency (e.g. time, path length, bimanual dexterity, etc.) and safety (e.g. contact with no-go zones, maximum applied force, etc.) were calculated. All users completed a post-simulation questionnaire related to the realism, usefulness and perceived benefits of training on the MSESS.

Results: The MSESS was found to be realistic and useful for training surgical skills with scores of 7.97 ± 0.29 and 8.57 ± 0.69, respectively on a 10-point Likert scale. Most students and residents (29/30) believed that it should be incorporated into their curriculum. There were significant differences between novice surgeons (10 medical students and 10 junior residents) and senior surgeons (10 senior residents and 3 sinus surgeons) in performance metrics related to quality ($p<0.05$), efficiency ($p<0.01$) and safety ($p<0.05$).

Conclusion: The MSESS demonstrated initial evidence supporting its use for residency education. This simulator may be a potential resource to help fill the void in endoscopic sinus surgery training.

4.2 Introduction

Endoscopic sinus surgery (ESS) requires specialized technical skills involving complex spatial, perceptual and psychomotor performances[15]. Expertise in this minimally invasive surgery necessitates synchronous bimanual dexterity within a small 3-dimensional space[15], avoidance of key vital structures (i.e. orbits, brain and carotid artery), thorough applied knowledge of the intricate anatomy, and proficiency in maneuvering with the indirect visual aid of a 2-dimensional monitor[5]. Given the proximity of the paranasal sinuses to critical structures such as the orbits and skull base, it can be understood why ESS is the most frequent reason for otolaryngic surgical litigation in the United States[4], and why the rate of complications during ESS is higher in trainees when compared to attending physicians[17].

Those teaching ESS have found alternative modalities to the traditional apprenticeship training model such as cadaveric dissections and 3D silicone models[15]. However, the latter have substantial limitations with regards to the complex needs of ESS training, such as the lack of tissue mobility of rigid silicone models[23] and the inadequate representation of tissue rigidity in cadavers[40]. Virtual reality (VR) simulators solve these deficiencies, as well as offer a standardized environment for a trainee to repeat a procedure multiple times until proficiency is achieved[42]. Additional benefits of VR simulation documented in other surgical domains include the ability to objectively assess surgical skills without the need of a tutor[28], reduction of patient risk, and the standardization of residency training regardless of a particular institution's practice profile or access to a cadaver laboratory[21]. VR simulation has been demonstrated to be beneficial in many surgical disciplines[5-8], including otolaryngology[26, 27].

In the field of ESS, the first VR sinus surgery simulator, the ES3, was developed in 1998[10]. To date, rigorous published validation studies supporting routine use of ESS simulators in resident training derive uniquely from the ES3 [4, 15]. However, the ES3 is no longer commercially available and currently, there are only a few devices available in the United States[10]. Other simulators, such as the Dextroscope endoscopic sinus simulator[29] and the VOXEL-MAN[30], have yet to demonstrate evidence to support their use for training. Thus, there is an obvious need for a VR simulator with evidence of acceptability and validity to fill the void in ESS training.

The McGill Simulator for Endoscopic Sinus Surgery (MSESS) is a VR simulator that aims to address this issue. The objectives of this study were to assess the feasibility, usability, perceived value, and initial evidence supporting the validity of the simulator.

4.3 Methods

4.3.1 Description of the participants

Ethical approval was obtained from the Institutional Review Board at McGill University. Between May and October 2013, the following participants were recruited into the study: senior medical students (third or fourth year) and otolaryngology residents. The residents were divided into two groups: junior residents (PGY1-3s) and senior residents (PGY4-5); the former group having limited or no operative experience in ESS. Furthermore, in order to have performance metrics from expert surgeons, 3 attending staff proficient in ESS (fellowship trained in rhinology or that perform an average of one day of ESS or skull base procedures every week) were also recruited.

Each user was given a brief tutorial concerning the functionality of the tools, as well as a video demonstrating the tasks to be performed and the danger zones within the nasal cavity. They were also given a 5-minute period to familiarize themselves with the movement and haptic feedback of the tools and the use of the pedals prior to beginning the simulated tasks.

4.3.2 Description of the MSESS

The MSESS was created by the Department of Otolaryngology – Head and Neck Surgery at McGill University and the National Research Council of Canada. It was developed upon the NeuroTouch platform, which is a neurosurgery simulator made by the National Research Council of Canada[32, 33]. Validity of the neurosurgery simulator as a training tool has previously been described[39]. The simulated 3D nasal model was rendered using a single patient's CT scan. Each anatomic structure within the simulated 3D nasal model was coded separately as to allow specific measurements of performance at each point within the nasal cavity.

By providing a 0-degree endoscope in the non-dominant hand and a microdebrider in the dominant hand, the MSESS allowed the user to perform basic ESS tasks while viewing a virtual representation of the nasal cavity and the instrument tip on a flat panel display (1). A10-member panel of sinus surgeons and education experts opted to develop a microdebrider as the first simulated tool as it is commonly used in ESS, can perform a variety of tasks, and has a potential for serious complications[37]. The user received haptic feedback from the instruments, such as resistance from the contact of nasal tissues and vibration from the microdebrider activation.

A novel feature of the MSESS was its ability to simulate visual field blurring caused by soiling of the tip of the endoscope with nasal tissue contact. In this instance, the user had to activate an endonasal wash function via a foot pedal in order to regain clear visualization.

4.3.3 Simulation Tasks

The tasks chosen to be evaluated on the MSESS included: 1) passing the endoscope from the nasal vestibule to the nasopharynx, 2) anterior ethmoidectomy, 3) posterior ethmoidectomy and 4) wide sphenoidotomy. The four tasks were chosen by the panel because they represented increasing levels of difficulty, and mimicked the step-wise approach found in sinus surgery where the surgeon typically addresses first the maxillary sinus, then the ethmoids, and finally the sphenoid sinus. The uncinectomy and maxillary antrostomy were not assessed since it cannot be safely performed with a microdebrider and other instruments have not yet been simulated.

4.3.4 Performance Metrics

Dimensions of quantitative data generated include constructs of *quality*, *efficiency*, and *safety.* A list of the metrics and their definitions can be found in table 2.

4.3.5 Post-simulation questionnaire

After their simulation session, participants answered a questionnaire (see 8.1: appendix) regarding their perceptions of simulator realism, potential educational benefits and skills practiced. Responses were collected via both a 10-point Likert scale, anchored as appropriate for the question, and open-ended questions. Prior to implementation, this questionnaire had been sent to 5 faculty members on the research team to ensure that it was appropriate, intelligible, unambiguous, unbiased, complete, appropriately coded and aligned with our constructs of interest. Thereafter, a panel of 5 otolaryngologists and education experts assessed the questionnaire independently to validate it. Finally, residents and physicians were recruited to perform the initial pilot testing including assessment of intra-rater reliability for a final review of the post-simulation questionnaire.

4.3.6 Data analysis

An average for each metric was calculated per group of participants (medical students, junior residents, senior residents, attending faculty), and used for comparison across participant groups.

Differences between groups' performance metrics were first investigated using the analysis of variance - Kruskal Wallis Test. All metrics that showed a difference between groups were then sub-analyzed using the Mann-Whitney test to demonstrate which groups showed a difference ($p<0.05$ was considered significant). Descriptive statistics were used to analyze the quantitative portion of the questionnaire, while content analysis and thematic description was applied to qualitative data.

4.4 Results

4.4.1 Participants

10 medical students, 10 junior residents, 10 senior residents and 3 attending staff agreed to participate in the study. All the participants completed the required simulation tasks, as well as the post-simulation questionnaire.

4.4.2 Post-simulation questionnaire

Data relating to the assessment of perceived realism and educational value of the MSESS are presented in Tables 3 and 4, respectively. Participants across all groups, on average, rated items related to the realism of the MSESS at least 7 on a 10 point-Likert scale, corresponding to the anchor “realistic” (Mean = 7.97±0.29). Similarly, participants across all groups rated items related to the perceived educational value of the MSESS at least 7 on a 10, corresponding to “useful” (Mean = 8.57±0.69).

Table 3 Perceived assessment of the realism of the MSESS.

		Medical Students Mean score (SD)	Junior Residents Mean score (SD)	Senior Residents Mean score (SD)	Attending faculty Mean score (SD)
Appearance VR Nasal Model	Nasal Cavity	8.0 (0.67)	7.6 (1.83)	8.11 (1.53)	7.67 (0.57)
	Sinuses	7.9 (0.73)	7.7 (1.83)	8.11 (1.45)	7.67 (0.57)
	Medicalization turbinate	8.3 (0.82)	7.3 (1.88)	8.0 (1.58)	7.33 (0.57)
Appearance and Functionality of Tools	Microdebrider	8.4 (0.84)	7.7 (1.63)	8.33 (1.11)	7.33 (0.57)
	Suction on microdebrider	7.7 (0.82)	7.6 (1.83)	8.11 (1.26)	8.33 (0.57)
	Physical Tool Handles	8.5 (1.18)	7.4 (1.83)	7.89 (1.45)	8.33 (0.57)
	Haptic Feedback	7.2 (1.22)	7.8 (1.75)	7.89 (1.16)	7.67(0.57)
	Endonasal Wash	8.6 (1.07)	7.3 (1.57)	8.11 (0.93)	8.66 (0.57)
Ability to simulate surgical steps	Anterior Ethmoidectomy	8.5 (0.53)	7.9 (1.63)	8.22 (0.83)	8.33 (0.57)
	Posterior Ethmoidectomy	8.5 (0.53)	7.7 (1.63)	8.22 (0.97)	8.0 (0)
	Sphenoidotomy	8.5 (0.71)	7.5 (1.84)	8.22 (0.97)	8.33 (0.57)

Scores were on a 10-point Likert scale. The anchors to the scale were 1=No resemblance at all, 4=Some resemblance, 7=Realistic, 10=Real-Life.

Table 4 Perceived educational value of the MSESS.

		Medical Students Mean score (SD)	Junior Residents Mean score (SD)	Senior Residents Mean score (SD)	Attending faculty Mean score (SD)
Learn theory	Anatomy	9.4 (0.84)	8.3 (2.0)	9.0 (1.0)	8.67 (0.57)
	Steps - anterior ethmoidectomy	9.7 (0.67)	8.2 (1.93)	8.78 (1.09)	7.67 (0.57)
	Steps – posterior ethmoidectomy	9.7 (0.67)	8.4 (1.89)	8.78 (1.09)	7.66 (1.15)
	Steps - sphenoidotomy	9.6 (0.69)	8.2 (1.75)	8.45 (1.23)	7.0 (1.0)
Practice Technical Skills	Hand-eye coordination	9.5 (0.84)	8.1 (2.18)	9.0 (1.32)	7.67 (1.41)
	Bimanual Dexterity	9.5 (0.84)	8.1 (2.28)	8.89 (1.36)	8.0 (0)
	Efficiency	9.6 (0.69)	7.9 (1.75)	8.44 (1.23)	7.33 (2.08)
Safety	Identify No-go zones*	9.4 (0.84)	8.7 (1.94)	8.0 (1.64)	9.0 (1.0)

Scores were on a 10-point Likert scale. The anchors to the scale were 1=Not at all useful, 3=Minimally useful, 5=Adequate, 7=Useful, 10=Extremely useful.

***No-go zones referred to the lamina papyracea, orbital fat, skull base and optico-carotid recess.**

All medical students (*n*=10/10) felt that the MSESS would be useful for their level of training, as compared to 80% of junior residents (*n*=8/10) and 80% (*n*=8/10) of senior residents. Similarly, 100% of medical students (*n*=10/10) stated that the MSESS would be a useful adjunct to their surgical curriculum, as did 80% of junior residents (*n*=8/10) and 80% of senior residents (*n*=8/10). Finally, when asked if the MSESS should be readily available for their rhinology surgical education, 29/30 students and residents responded yes.

The responses to open-ended questions for strengths of the simulator were grouped into three main themes: the realism of the VR model, the ability to practice bimanual technical skills and the necessity for such simulators to complement traditional teaching modalities. Weaknesses related to perceived imprecision of fine tool movements and the lack of bleeding in the VR model.

4.4.3 Performance Metrics

4.4.3.1 Quality

There was no statistically significant difference (Figure 7) between all 4 groups with respect to the surgical completeness of the anterior ethmoidectomy, posterior ethmoidectomy and wide sphenoidotomy (p>0.05). However, when combining the groups into novices (medical students and junior residents) and senior surgeons (senior residents and attending faculty), there was a significant trend towards making a wider sphenoidotomy with increasing level of expertise (p=0.01).

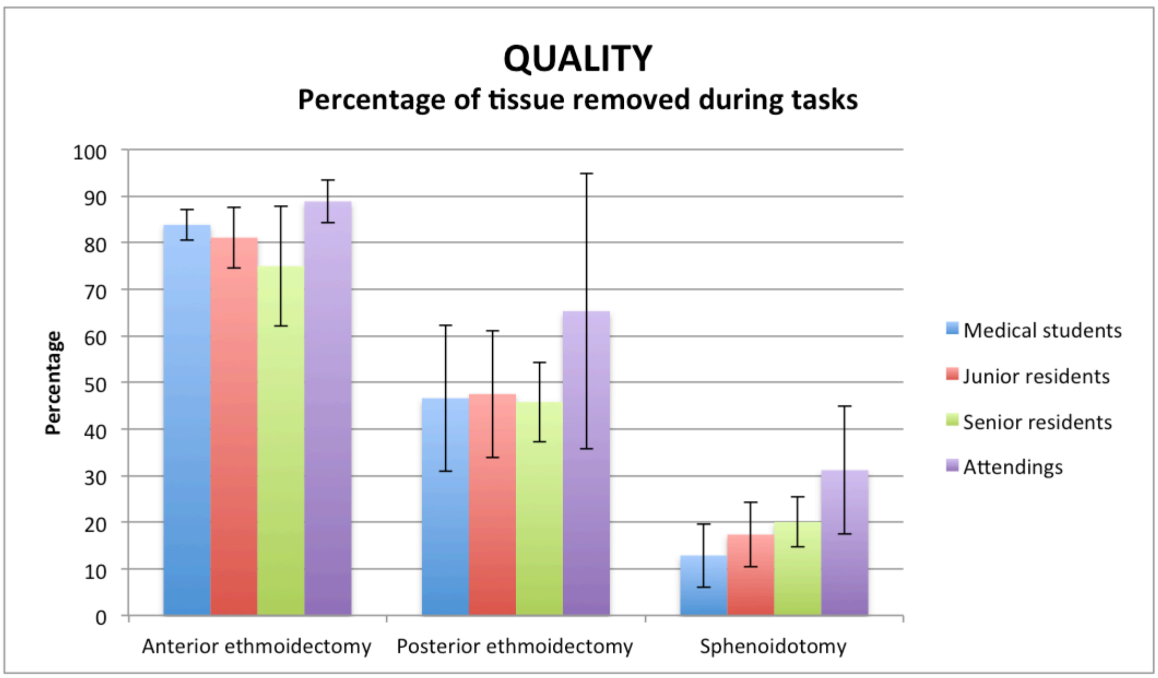

Figure 7 Percentage of tissue removed during simulation tasks. The graph represents means +/- SD. There was no statistically significant difference (*p*>0.05) between all 4 groups for all three surgical tasks. When combining the groups into novices (students and junior residents) and senior surgeons (senior residents and attending faculty), there was a statistically significant difference for the wide sphenoidotomy (*p*=0.01).

4.4.3.2 Efficiency

Time required to complete the tasks is presented in Figure 8. The only significant difference was between the junior residents group and the senior residents (p<0.005). With regards to path lengths for the endoscope and the microdebrider (Figure 9), both metrics demonstrated a statistically significant difference between junior residents and senior residents (p<0.001).

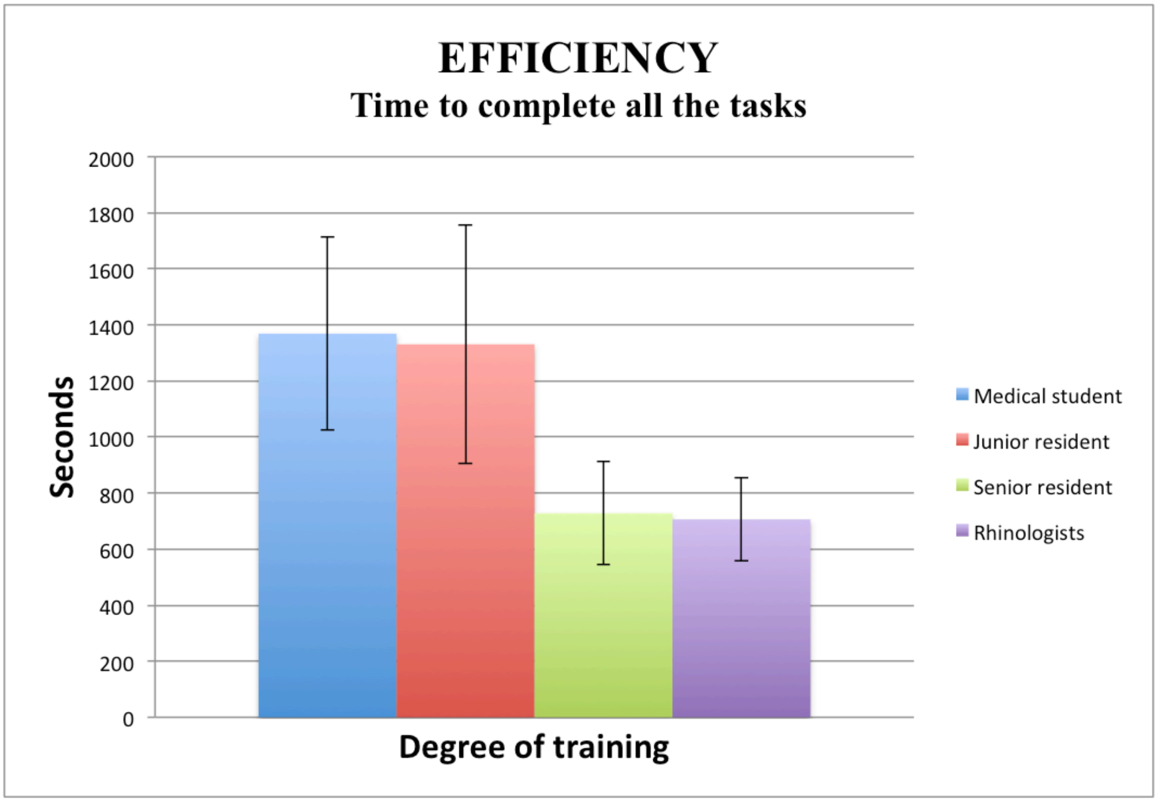

Figure 8 Time to complete the simulation tasks. The graph represents means +/- SD. Statistically significant difference (*p*<0.005) between junior residents and senior residents. No difference between medical students and junior residents, nor between senior residents and attending faculty.

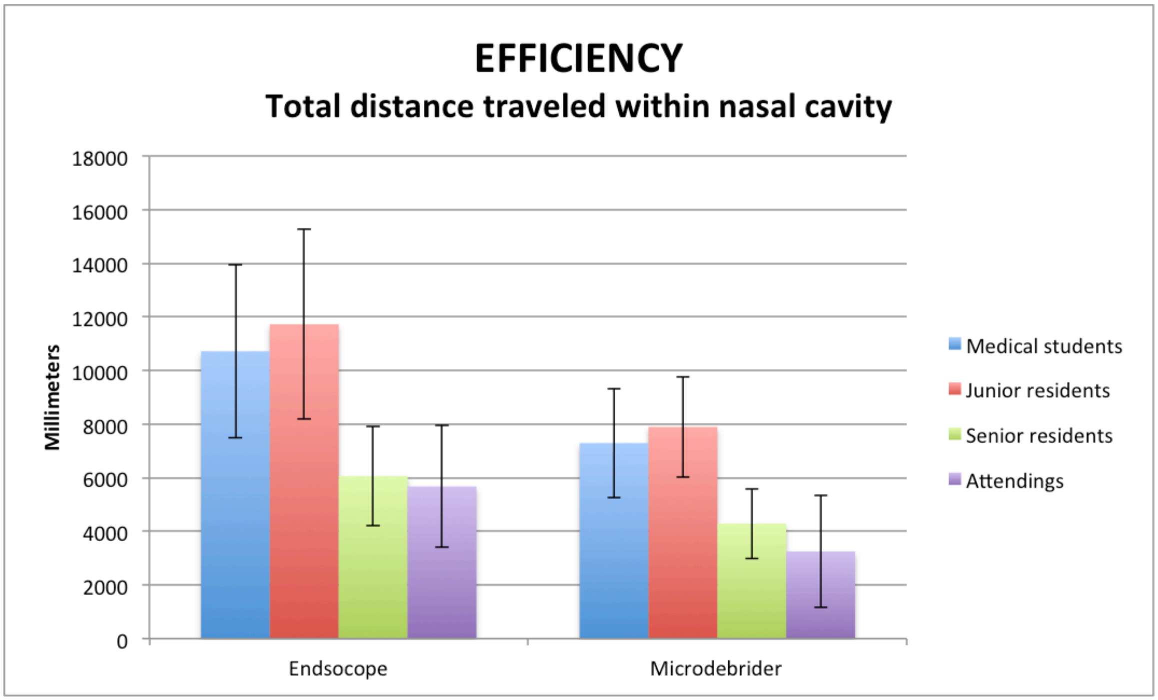

Figure 9 Path length (Distance travelled within nasal cavity). The graph represents means +/- SD. Statistically significant difference between junior residents and senior resident for both the endoscope (*p*<0.001) and the microdebrider (*p*<0.001). No difference between medical students and junior residents, nor between senior residents and attending faculty.

The average fluctuation in distance between the tips of the endoscope and the microdebrider for the medical students, junior residents, senior residents and attending faculty were 12.64±3.04mm, 12.23±3.91mm, 9.91±2.45mm and 6.98±2.39mm, respectively. There was a statistically significant difference between junior residents and senior residents (*p*<0.01). A graphical illustration of distance between tool tips for users of different levels of expertise is presented in Figure 10.

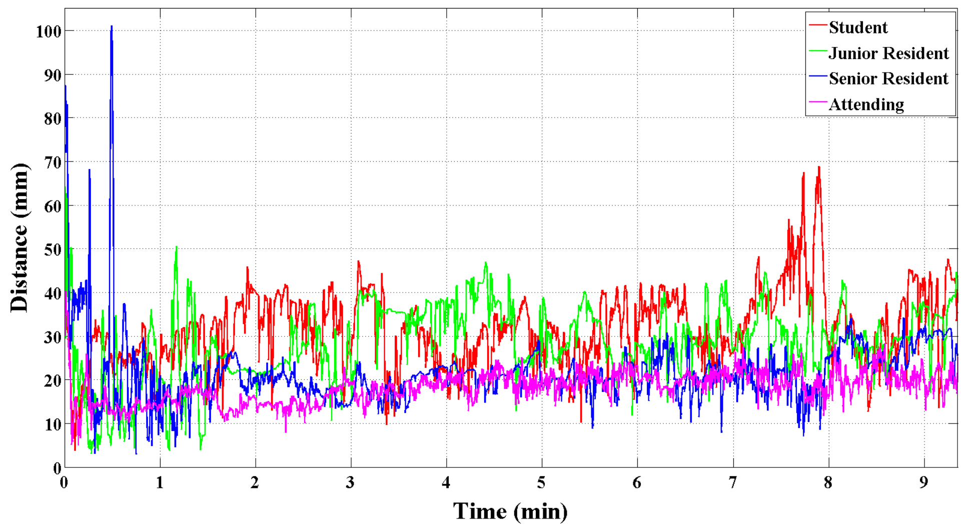

Figure 10 Distance between tool tips through the simulation tasks. The senior residents and attending faculty demonstrate far less fluctuation than medical students and junior residents.

The frequencies of activation of the microdebrider pedal for medical students, junior residents, senior residents and attending faculty were 188±65, 173±64, 87±37 and 104±17 times, respectively. There was a significant difference between junior residents and senior residents (p<0.001). With regards to the frequency of use of the endonasal wash, there was a trend towards less use with increased training: 17±12, 12±10, 7±3 and 2±2 times, respectively. Again, there was a statistically significant difference between junior residents and senior residents (p<0.01) for these metrics.

All the metrics related to efficiency showed a difference between junior residents and senior residents. However, there were no significant differences between medical students and junior residents, nor between senior residents and attending faculty.

4.4.3.3 Safety

With regards to violation of the no-go zones (Figure 11), there was a significant difference between junior residents and senior residents with regards to the percentage of lamina papyracea mucosa removed ($p<0.005$). With respect to the skull base, all four groups removed a minute amount of tissue (<0.25 %), with no significant difference ($p>0.05$). Medical students and junior residents removed 0.02% and 0.08% of the mucosa surrounding the optico-carotid recess, whereas seniors and attending faculty had no contact with that region.

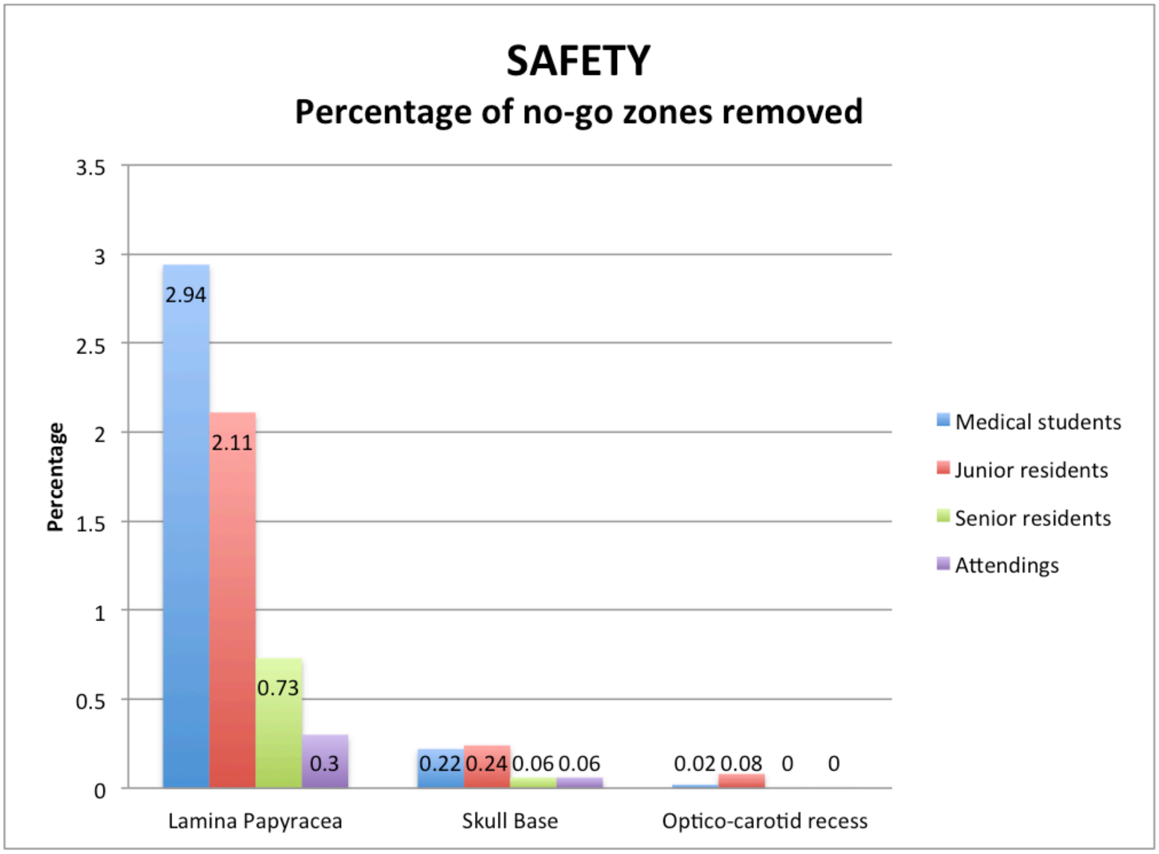

Figure 11 Percentage of no-go zones removed. The graph represents means. Statistically significant difference between junior residents and senior residents for the percentage of lamina papyracea removed ($p<0.005$). No difference between medical students and junior residents, nor between senior residents and attending faculty. No statistical difference for other no-go zones.

Medical students and junior residents applied a maximal force of 0.75±0.67 N and 0.15±0.31 N on the lamina papyracea, respectively. The senior residents and attending faculty applied a negligible force on the lamina. The maximal force applied on the skull base was 0.93±0.54 N, 0.53±0.68 N, 0.24±0.49 N and 0 N, respectively, with increasing level of training. The only significant differences were between junior residents and senior residents ($p<0.05$).

4.5 Discussion

Attributes available on the MSESS include increasing task difficulties, blurring of the camera field with tissue contact, an endonasal wash function, a microdebrider, and mobility of the nasal tissues. Compared to previous sinus simulators, we believe that a combination of these unique attributes allow the user to experience a more realistic, higher fidelity physical and visual environment. Furthermore, measurement of performance metrics from both hands independently, including measures of bimanual dexterity, as well as the ability to identify contact with danger zones allow a more elaborate performance assessment.

Given the lack of available ESS simulators with enough data supporting validity as a training tool, the current initial validation study of the MSESS is the first step towards filling this void. In fact, we demonstrated that participants from all levels of training found the simulator to be realistic in terms of visual appearance and content. They also responded that the simulator allowed them to practice the technical skills required for ESS. Furthermore, through analysis of the performance metrics, not unexpectedly, novices fared significantly worse than senior surgeons in measures of operative efficiency, which echoes previous reports in studies of surgical simulators[43, 44]. Similarly, within the field of ESS simulation, Edmond showed that novice surgeons without ESS experience performed worse on simulation training[45].

The inability of the performance metrics to differentiate medical students from junior residents is likely related to the fact that residents do not routinely perform ESS until their senior years. Moreover, the lack of difference between senior residents and attending faculty on the performance metrics may be related to the small number of attending faculty (n=3), as some metrics, namely those related to efficiency, demonstrated a trend towards improved performance by the attending faculty compared to senior residents. Nevertheless, these findings may indicate that the learning curve for performing simple ESS tasks is relatively steep and that the MSESS may be most valuable for junior residents prior to direct patient contact.

Research has demonstrated that recognition of anatomy with an endoscopic view is one of the more challenging parts of ESS[24]. In fact, authors have reported that a strong familiarity with intranasal 3D relationships and spatial boundaries are more vital for operative success than the technical skills of sinus surgery[15, 45] Thus, one of the main focuses during the development of the MSESS was to develop a simulated nasal model that was as realistic as possible, reflected by the participants' high assessment scores on the questionnaire.

Furthermore, the MSESS was tailored to help train users on complex technical skills, such as bimanual dexterity and hand-eye coordination, which are prerequisite skills for ESS[5]. The fact that there was decreasing fluctuation in the distance between the two tool tips with increasing degree of experience suggests that there is a notable learning curve for bimanual dexterity, which has previously been shown to vary with level of expertise[46]. In fact, Narazaki et al. demonstrated that experts outperformed novices in terms of bimanual dexterity skills significantly on a laparoscopic surgery simulator and advocated for its' testing as a means to objectively assess the proficiency of a surgeon[47].

In order to demonstrate validity as an educational tool, many studies on simulators have aimed to show a difference between users of different degrees of experience[48]. The latter shows that the simulator actually measures the technical skills that are intended to be measured[5]. Previous simulators have demonstrated this metric in support of "construct validity", including simulators for surgical skills in laparoscopic surgery[49], bone sawing skills[50], neurosurgery[39] and ESS[21, 51], as well as diagnostic skills such as coronary angiography[52], obstetrical ultrasonography[53] and colonoscopy[54].

The performance metrics recorded by the MSESS – divided into measures of quality, efficiency and safety – allowed us to test this form of validity. With regards to quality, users across all groups removed similar percentages of the anterior and posterior ethmoids. This is not surprising as removing tissue is not a difficult task in and of itself, but doing so efficiently and safely differentiates a novice from an experienced surgeon. Furthermore, a notable trend was observed towards increasing extent of the sphenoidotomy with advancing level of expertise, most likely explained by the fact that more experienced surgeons had a heightened awareness of what is safe to remove in the sphenoid sinus and what are danger zones for injury to critical structures such as the optic nerve and carotid artery. In contrast, junior surgeons are more apprehensive in this region and thus elect to be more conservative.

Moreover, despite this suspected apprehensiveness demonstrated by juniors, users in the medical students and junior residents groups made contact with “no-go” zones such as the lamina papyracea and optico-carotid recess more commonly. Edmond demonstrated that the most discriminating performance factor during the novice mode on a previous ESS simulator was the ability to avoid hazards[45], which is a skill that senior surgeons learn with experience and thorough anatomy knowledge. Through recognition of these errors, novice surgeons may learn to avoid trauma to collateral tissue. In fact, decreased tissue injury during technical skills assessments after training on VR simulators has previously been demonstrated[42].

Endoscopic sinus surgeons are cognizant of the fact that the lamina papyracea and skull base are sensitive areas due to their fragility as well as the structures that they protect, thus it is important to be able to measure the amount of force that is applied upon them by our tools. Our study demonstrated that there was a significant difference in the maximal force applied between novice surgeons and more senior surgeons. The importance of force measurements also highlights a pitfall of training on cadaveric tissues, which do not adequately estimate the force necessary to perform endoscopic sinus procedures[40] and thus, do not show trainees the acceptable force allowed during ESS. Although novice surgeons applied more force in our study, the next step would be to determine the critical amount of force that would be needed to cause damage and assess whether the increased force applied by junior surgeons is truly clinically dangerous.

The benefits of simulation training are highlighted by the difference in efficiency between junior and senior surgeons. Simulation training allows residents to be more efficient, thus saving time in places, especially in the operating room, where time is limited and expensive[55]. The premise of training on the MSESS is that if a junior can practice ESS on the simulator, he begins hands-on training at an earlier stage, prior to direct patient contact[45] and thus is better prepared when in the operating room. Furthermore, with decreased resident working hours[56], it is even more essential to have alternative methods for junior surgeons to practice their technical skills.

4.6 Conclusion

The MSESS demonstrated initial evidence supporting its use for residency education with regards to being a realistic and useful training tool. The performance metrics relating to quality, efficiency and safety also demonstrated a dichotomy between novice and senior surgeons. The next step in this validation process will be to assess the predictive validity of the MSESS and demonstrate translation of technical skills in the setting of live patient interactions.

4.7 Additional details

4.7.1 Competing Interests

The National Research Council of Canada has property rights to the MSESS. The senior author and the Department of Otolaryngology – Head and Neck Surgery of McGill University have no financial competing interests with this study.

4.7.2 Authors Contributions

RV: Study design, creation and development of the MSESS, data collection, data analysis, manuscript preparation. SF: Study design, creation and development of the MSESS, manuscript preparation. LHPN: Study design, data analysis and interpretation, manuscript preparation. RDM: Study design, creation and development of the performance metrics, study coordination. AZ: Creation and development of the MSESS, data analysis, manuscript preparation. ES: Data analysis, creation of software to analyze the raw data into meaningful data, analysis of performance metrics. WRJF: Data analysis, creation of software to analyze the raw data into meaningful data, analysis of performance metrics. NRC: Creation and development of the MSESS, creation of performance metrics (except force calculations). MAT: Study design, creation and development of the MSESS, data collection, data analysis and interpretation, manuscript preparation. All authors read and approved the final manuscript.

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4.7.4 Funding sources

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CHAPTER 5: OVERALL DISCUSSION & LIMITATIONS

As previously mentioned, the current sinus surgery simulator was built upon the NeuroTouch platform, which had early work done on a simulated nasal model. This was further refined to include key structures of the nasal cavity, necessary to simulate sinus surgery. There were various versions created, with continued fine-tuning, in order to create a realistic training environment. Some of the challenges included simulation of fine hand movements, creating realistic soft tissue mobility and characteristics, depiction of a large amount of details with continued high-speed performance of the software and realistic creation of the simulated instruments. This required immense collaboration between the engineering team at the National Research Council and the surgical team at McGill University. Currently, the simulator used in this study only allows simulation of the nasal cavity based from one CT scan, as each structure within the nasal cavity was labeled individually, which was an elaborate process to perform (Figure 12).

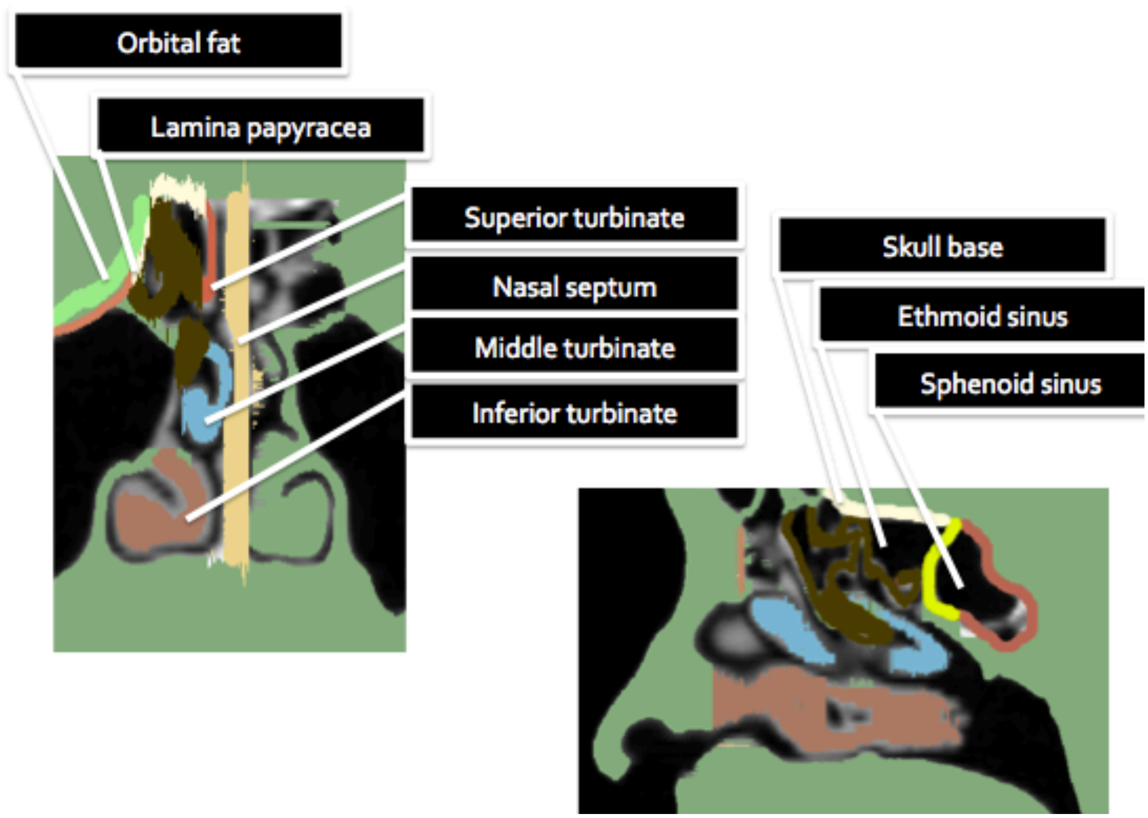

Figure 12 Intranasal structure labeling. Depiction of some of the individual structures that have to be manually labeled one at a time.

The next step would be to shorten or automate this process to allow for patient-specific simulated software. The ability to have patient specific models is available through the use of 3D printing, which allows preoperative planning and education, as demonstrated by Waran et al.[41]. However, these do not provide haptic feedback, which is an essential part of surgery. Furthermore, if we could develop patient-specific VR models, there would be the additional benefits of providing a more realistic visual environment, haptic feedback and of providing measurements of objective performance metrics. Future versions may be able to eventually address the issues of patient-specificity. Moreover, the only instruments available at the time of this study were the 0 degree endoscope and microdebrider. However, in order to perform complete and safe ESS, one requires other tools as well as angled endoscopes, to work around corners and in the sinuses. Further versions of the simulator may provide an increased armamentarium of instruments. Finally, the next version of the simulator would require refinement of the haptic tools. Currently, there is occasionally a slight discrepancy between the movements the user performs with hands and how the latter are reflected in the simulated surgical field. This is especially true as the user navigates deeper into the nasal cavity, with occasional occurrences of haptic artifact.

Another important next step would be to establish proficiency performance benchmarks. This would entail having a large number of trained rhinologists perform simulated scenarios and tabulate their scores to establish an average for each performance metric. This would allow a trainee to compare their score to the average of the experts and give them an understanding of their areas of weakness and strength. This concept of proficiency benchmarks has been demonstrated by AlZhrani et al. with the NeuroTouch neurosurgery model[57]. The current study compared the performance metrics of students, residents and experts. All the participants watched a video of the steps required to perform the tasks, as well as the areas to avoid (no-go zones). This video helped guide participants about the tasks to complete, as well as the performance metrics that would be used to assess their ability to perform these tasks. With the creation of proficiency performance benchmarks, they would be able to not only compare the final product of surgery with the expert through a video, but also compare the quality, efficiency and safety of the simulated surgery.

Furthermore, the current version of the simulator does not have bleeding from tissues as a feature. One of the inherent difficulties of ESS is that the narrow nasal cavity and its structures can become masked by blood. The ability to perform safe surgery despite this bleeding is one of the technical abilities that a surgeon must master. The novel feature of the MSESS, where the endoscope becomes soiled with tissue contact is a good surrogate to help trainees avoid dirtying their endoscope in the blood. However, further versions of simulators may be able to simulate bleeding tissues. The ability to simulate bleeding has already been demonstrated in the NeuroTouch neurosurgery model[58].

Finally, the Royal College of Surgeons has recently mandated competency-based assessment, where a trainee has to demonstrate competency in a procedure prior to graduation. Additional training modalities will be necessary to reach this competency. However, prior to incorporation in the surgical curriculum, further validation studies would need to be performed. The next step would be to demonstrate predictive validity with translation of technical skills acquired in simulation into the setting of live patient interactions. This would demonstrate that improvement of surgical technique at the simulated level would result in improved surgeon performance, which is essentially the end goal of all surgical training.

Reflecting on the research in this thesis, it is thought that this study will be useful to medical educators and clinicians. It will allow an increase of modalities available to train medical students and residents in ESS. This may result in trainees being more prepared prior to patient contact in the operating room, translating into better utilization of their limited operative experience. Furthermore, if residents are able to learn from the mistakes they make during simulation training through objective measures of performance, they should be able to work on their weaknesses prior to entering the operating room. Finally, causing and managing surgical complications on a simulator may prepare trainees to better avoid these in real-life. It is important to note that simulation training is one modality amongst many to train a surgical student. It does by no means completely replace the current training model of learning in the operating room. Rather, it is believed that simulation training will complement the apprenticeship model, and help tip the long discussed balance between trainee education versus patient safety towards the latter.

CHAPTER 6: CONCLUSION: CLAIMS OF ORIGINALITY

The McGill Simulator for Endoscopic Sinus Surgery, or MSESS, has been developed as a training tool for residency training in ESS. To my knowledge, this is the first simulator to allow a user to employ a combination of tools such as the endonasal wash and microdebrider in a model that emulates real ESS. The MSESS has produced initial evidence strongly suggesting that it is realistic and useful from the perspective of trainees and experts. The performance metrics relating to quality, efficiency and safety also demonstrated the expected dichotomy between novice and senior surgeons, a result supporting its usefulness.

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CHAPTER 8: APPENDIX

8.1 Post-simulation questionnaire

Validation of rhinology high fidelity surgical simulator

DEMOGRAPHICS

1) Age ____________

2) Gender (optional)

☐ Male ☐ Female

3) ☐ Right-handed ☐ Left-handed

MEDICAL STUDENTS (MED 3-4)

1) What surgical rotations have you completed in your 3^{rd} and 4^{th} year?

____

2) What is your top choice for residency specialty, including family medicine?

____

3) Have you observed endoscopic surgeries in the past, including laparoscopic surgeries?

YES NO

If yes, how many surgeries________________________________

4) Have you ever performed any parts of an endoscopic/laparoscopic surgery?

YES NO

If yes, what parts and how many times?

RESIDENTS

1) What year are you in?

☐ PGY-1 ☐ PGY-2 ☐ PGY-3 ☐ PGY-4 ☐ PGY-5 ☐ Fellow

2) Are you interested in a fellowship in rhinology?

☐ Yes ☐ No ☐ Currently a fellow

3) What sinus courses have you participated in? Please list them.

4) In the past 12 months, please estimate how many of each of the following types of surgeries have you performed as **secondary** surgeon (you conducted less than 50% of the entire procedure). Please consider each side of a nasal cavity as a separate case

   a. Anterior ethmoidectomy________
   b. Posterior ethmoidectomy________
   c. Sphenoidotomy (putting suction is ostium) ________
   d. Wide sphenoidectomy________

5) In the past 12 months, please estimate how many of each of the following types of surgeries have you performed as **primary** surgeon (you conducted more than 50% of the entire procedure). Please consider each side of a nasal cavity as a separate case

   a. Anterior ethmoidectomy________
   b. Posterior ethmoidectomy________
   c. Sphenoidotomy (putting suction is ostium) ________
   d. Wide sphenoidectomy________

6) What is your level of comfort of performing these procedures as primary surgeon

a. Anterior ethmoidectomy

1 2 3 4 5

Uncomfortable Can do parts Independent

b. Posterior ethmoidectomy

1 2 3 4 5

Uncomfortable Can do parts Independent

c. Sphenoidotomy (putting suction is ostium)

1 2 3 4 5

Uncomfortable Can do parts Independent

d. Wide sphenoidectomy

1 2 3 4 5

Uncomfortable Can do parts Independent

STAFF

1) I completed my fellowship _______ many years ago

2) Are you fellowship-trained in rhinology?

☐ Yes ☐ No

3) What best describes your practice (check as many as apply to you), i.e. where is most of your operative time spent?

☐ Tertiary care center ☐ Community hospital ☐Private office

4) What sinus courses have you done? Please list them

5) Do you perform skull base cases as part of your routine otolaryngology practice?_______

6) In the past 12 months, please estimate how many of each of the following types of surgeries have you performed. Please consider each side of a nasal cavity as a separate case

    e. Anterior ethmoidectomy________
    f. Posterior ethmoidectomy________
    g. Sphenoidotomy (putting suction is ostium) ________
    h. Wide sphenoidectomy________

POST-SIMULATION QUESTIONNAIRE

REALISM

1) How realistic is the visual appearance of:

	1 Not at all	2	3	4 Some rese-mblance	5	6	7 Real istic	8	9	10 Real -life
Nasal cavity										
Sinuses										
Medialisation of middle turbinate										
Microdebrider										

a. the appearance of the SUCTION of the microdebrider?

1 2 3 4 5 6 7 8 9 10

Not at all Some Resemblance Realistic Real-life

b. the feel of the haptic feedback of the microdebrider?

1 2 3 4 5 6 7 8 9 10

Not at all Some Resemblance Realistic Real-life

c. the appearance of the handles of the instruments (Scope and debrider)?

1 2 3 4 5 6 7 8 9 10

Not at all Some Resemblance Realistic Real-life

d. endoscope becoming blurry during tissue contact?

1 2 3 4 5 6 7 8 9 10

Not at all Some Resemblance Realistic Real-life

TASKS

1) **How realistic was the simulator in allowing you to perform the steps necessary to do an:**
   a. Anterior ethmoidectomy________
   b. Posterior ethmoidectomy________
   c. Sphenoidotomy (putting suction is ostium) ________
   d. Wide sphenoidectomy________

SURGICAL SKILLS

1) **In your opinion, would this simulator be a useful tool to help students learn:**
   a. anatomy of the nasal cavity and paranasal sinuses?

1 2 3 4 5 6 7 8 9 10

Not at all Minimally Adequate Useful Extremely useful

b. hand-eye coordination for ESS skills?

1 2 3 4 5 6 7 8 9 10

Not at all Minimally Adequate Useful Extremely useful

c. **bimanual dexterity required for two-handed surgical procedures (including sinus surgery)?**

1 2 3 4 5 6 7 8 9 10

Not at all Minimally Adequate Useful Extremely useful

d. **the surgical steps of an anterior ethmoidectomy?**

1 2 3 4 5 6 7 8 9 10

Not at all Minimally Adequate Useful Extremely useful

e. **the surgical steps of a posterior ethmoidectomy?**

1 2 3 4 5 6 7 8 9 10

Not at all Minimally Adequate Useful Extremely useful

f. **the surgical steps of a wide sphenoidectomy?**

1 2 3 4 5 6 7 8 9 10

Not at all Minimally Adequate Useful Extremely useful

g. **to work efficiently during ESS?**

1 2 3 4 5 6 7 8 9 10

Not at all Minimally Adequate Useful Extremely useful

h. **to recognize where the 'danger zones' are during ESS?**

1 2 3 4 5 6 7 8 9 10

Not at all Minimally Adequate Useful Extremely useful

OVERALL

1) **Overall, was practicing surgical skills on this sinus simulator useful for your level of training?**

1 2 3 4 5 6 7 8 9 10

Not at all Minimally Adequate Useful Extremely useful

2) **Would the simulator be useful as part of your technical skills curriculum?**

1 2 3 4 5 6 7 8 9 10

Not at all Minimally Adequate Useful Extremely useful

3) **Do you feel that this sinus simulator should be readily available for residency education? YES NO**

4) **If the simulator were readily available, how often would you like it to be available to you for practicing your ESS skills?**

☐ before every case ☐ before every difficult case ☐ once per month ☐ once per 6 months ☐ once per year ☐ one time only

5) **For what level of training do you think the simulator is useful? (check all that apply)**

☐ Medical students

☐ Junior residents

☐ Senior residents

☐ Fellows

☐ Non-rhinology staff

☐ Rhinology staff

6) **Overall, I felt that working on the simulator was:**

1 2 3 4 5 6 7 8 9 10

Waste Didn't Neutral Enjoyable Amazing

of time enjoy

Please list 3 strengths of the simulator?

Please list 3 weaknesses of the simulator?

Suggestions for improvement?