Development and Validation of a 3D-Printed Model of the Ostiomeatal Complex and Frontal Sinus for Endoscopic Sinus Surgery Training

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Preface

Contributions of Authors

This thesis is in the publication-based format as specified by McGill University. The thesis contains two publications, of which I am the first author. Regarding the first manuscript, I was responsible for the literature review, the development of the model, the validation survey and the preparation of the manuscript. Dr. Tewfik and Dr. Nguyen contributed to the development of the model, the validation survey and the manuscript preparation. Dr. Funnell contributed to the development of the model and the manuscript preparation. Dr. Mongeau contributed to the model development. Regarding the second manuscript, I was responsible for the literature review and the design and preparation of the manuscript. Dr. Tewfik and Dr. Philip Chen contributed to the creation and preparation of the manuscript.

Claim of Originality

This thesis presents the first development and validation of a high fidelity 3D-printed model of the frontal sinus and the ostiomeatal complex.

Abstract

Background: Endoscopic sinus surgery poses unique training challenges due to complex and variable anatomy, and the risk of major complications. Training for endoscopic sinus surgery may be facilitated by the use of 3D-printed simulators.

Methods: Sinonasal CT images of a patient were imported into 3D visualization software. Segmentation of bony and soft tissue structures was then performed. The model was printed using simulated bone and soft tissue materials. Rhinologists and otolaryngology residents completed six pre-specified tasks, including maxillary antrostomy and frontal recess dissection, on the simulator. Participants evaluated the model using survey ratings based on a 5-point Likert scale. The average time to complete each task was calculated. Descriptive analysis was used to evaluate ratings, and thematic analysis was done for qualitative questions.

Results: A total of 20 participants (10 rhinologists and 10 otolaryngology residents) tested the model and answered the survey. Overall, the participants felt that the simulator would be useful as a training/educational tool (4.6/5), and that it should be integrated as part of the rhinology training curriculum (4.5/5). The following responses were obtained: Visual Appearance 4.25/5, Realism of Materials 3.8/5, and Surgical Experience 3.9/5. The average time to complete each task was lower for the rhinologist group than for the residents.

Conclusion: This thesis describes the development and validation of a novel, high fidelity 3D-printed model for the training of endoscopic sinus surgery skills. This model was highly rated by participants. There was a strong interest among participants to use this model as part of resident training.

Résumé

Contexte: La chirurgie endoscopique des sinus pose des problèmes de formation uniques en raison de l'anatomie complexe et variable ainsi qu'en raison du risque de complications majeures. Nous avons créé et validé un nouveau simulateur imprimé en 3D du nez et des sinus paranasaux.

Méthodes: Les images sériques de la tomodensitométrie d'un patient ont été importées dans un logiciel de visualisation 3D. La segmentation des tissus osseux et moelleux a ensuite été effectuée. Le modèle a été imprimé à l'aide de matériaux simulés d'os et de tissus moelleux. Les rhinologistes et les résidents d'ORL ont effectué six tâches pré-spécifiées, y compris l'antrostomie maxillaire et la dissection de la cavité frontale sur le simulateur. Les participants ont évalué le modèle en utilisant des estimations basées sur une échelle de Likert à 5 points. Le temps moyen pour effectuer chaque tâche a été calculé. Une analyse descriptive a aussi été utilisée afin d'analyser les évaluations, et une analyse thématique a été faite pour des questions qualitatives.

Résultats: Au total, 20 participants (10 rhinologistes et 10 résidents d'ORL) ont testé le modèle et ont répondu au sondage. Dans l'ensemble, les participants ont estimé que le simulateur serait utile comme outil de formation / éducation (4.6 / 5) et qu'il devrait être intégré dans le cadre du programme de formation en rhinologie (4.5 / 5). Les réponses suivantes ont été obtenues: Apparence visuelle 4.25 / 5, Réalisme des matériaux 3.8 / 5 et Expérience chirurgicale 3.9 / 5. Le temps moyen pour compléter chaque tâche était plus bas pour le groupe de rhinologistes que pour les résidents.

Conclusion: Nous décrivons le développement et la validation d'un modèle imprimé 3D de haute fidélité pour la formation des techniques de chirurgie endoscopique des sinus. L'analyse de ce modèle a révélé une appréciation des participants. Nous concluons que les participants sont fortement intéressé par l'utilisation de notre modèle dans le cadre de la formation des résidents.

Chapter 1: Introduction

1.1 Rationale

Endoscopic sinus surgery (ESS) and frontal sinus surgery pose unique training challenges owing to the complex and variable anatomy and the risk of major complications. Moreover, ESS requires technical abilities that differ from those required in most surgical procedures. Despite these challenges, the field of rhinology is still lacking a validated frontal sinus surgery simulator. Therefore, there is a need for an ESS and frontal sinus surgery simulator to help the trainee overcome these challenges. In recent years, three-dimensional (3D) printing, also known as rapid prototyping, has been utilized to create surgical simulators (1). As a result, this thesis sought to create and validate a high fidelity 3D-printed model of the sinuses to provide a realistic training environment.

1.2 Objectives

This thesis aimed to develop a more accurate and life-like 3D-printed ESS simulator. The objectives were as follows:

(1) to develop a 3D printed model of the ostiomeatal complex (OMC) and the frontal sinus that simulate the look and feel of real human tissues and anatomy;

(2) to evaluate the acceptability, perceived realism and benefit of the 3D-printed model among Otolaryngology–Head and Neck Surgery (OTL–HNS) residents and faculty;

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

(4) to summarize the recent advances and challenges in surgical simulation in relation to frontal sinus surgery.

1.3 Thesis outline

Chapter 2 of this thesis is a review of the challenges and current practice of surgical simulation, and the role of 3D printing in relation to ESS training. Chapter 3 consist of a published manuscript describing the development and validation of a 3D-printed ESS simulator. Chapter 4 presents a second manuscript summarizing available simulation models and challenges of surgical simulation in relation to frontal sinus surgery. An overall discussion of the thesis and conclusions are presented in chapter 5.

Chapter 2: Literature review

Chapter outline

The challenges of resident training are discussed in Section 2.1 of this chapter. An overview of ESS and frontal sinus surgery is discussed in Section 2.2. Surgical simulation in ESS is discussed in Section 2.3, and rapid prototyping is discussed in Section 2.4. Finally, a link to the first manuscript is presented in Section 2.5.

2.1 The challenges of resident training

Graduate medical education has undergone dramatic changes in the last decade. With the recent introduction of competency-based medical education by the Royal College of Physicians and Surgeons of Canada, learners assume greater responsibility for their own learning and the acquisition of certain skills (2). However, several factors suggest that the operating theater may no longer provide the ideal environment to develop the skills of a novice surgeon. Such factors include: increased operative time and cost associated with surgical training (3); work-hour restrictions; and the increasing complexity of cases at academic teaching hospitals. Unfortunately, these factors limit the ability of the learner to achieve certain competencies.

Historically, surgical training is strongly dependent on the apprenticeship model where trainees learn on actual patients in the operating theater. This training model is inadequate, especially for an anatomical region as complex as the paranasal sinuses. Therefore, applying it to ESS training has many limitations . One of the most serious is that untrained residents exhibit higher complication rates (4). This can lead to physicians becoming reluctant to give the entire surgical procedure to the trainee to avoid these risks.

In the current educational environment, the quality of ESS training can be limited by the insufficient number of procedures and high-complexity cases in academic centres (32). Moreover, in this traditional intraoperative setting, opportunities to perform specific procedures such as frontal sinus surgery are sporadic, and frequently there may be a mismatch between resident ability and procedure complexity. This mismatch can frustrate the learner and impede progress and learning (32,33). Finally, the assessment of surgical performance of residents can lack structure and objectivity and depend mostly on physician opinion and memory (5).

2.2 Endoscopic sinus surgery and frontal sinus surgery

Endoscopic sinus surgery (ESS) is one of the most common procedures done by otolaryngologists, so achieving the required competency level in performing this procedure is crucial during the residency program. Moreover, ESS requires specific surgical skills to maneuver an endoscope with one hand while dissecting with fine instruments in the other hand. Therefore, the surgeon must use both dominant and non-dominant hands, while maneuvering the endoscope and the instruments within the restricted 3-dimensional space of the nasal cavity and utilizing a 2-dimensional monitor to visualize the surgical field and the instruments (6).

The difficulty of ESS is increased due to the complex anatomy of the sinonasal tract and the associated potential damage of nearby critical structures (brain, orbit, carotid arteries) [Figure A] (6). The rate of major and minor complications has been reported to be approximately 0.5%

and 6.6%, respectively (7). Some examples of minor complications from ESS include bleeding, injury to normal sinonasal mucosa, perforation of the nasal septum and synechiae (scarring). Although rare, major complications can be devastating, namely injury to the brain or injury to the eye causing double vision and sometimes even blindness.

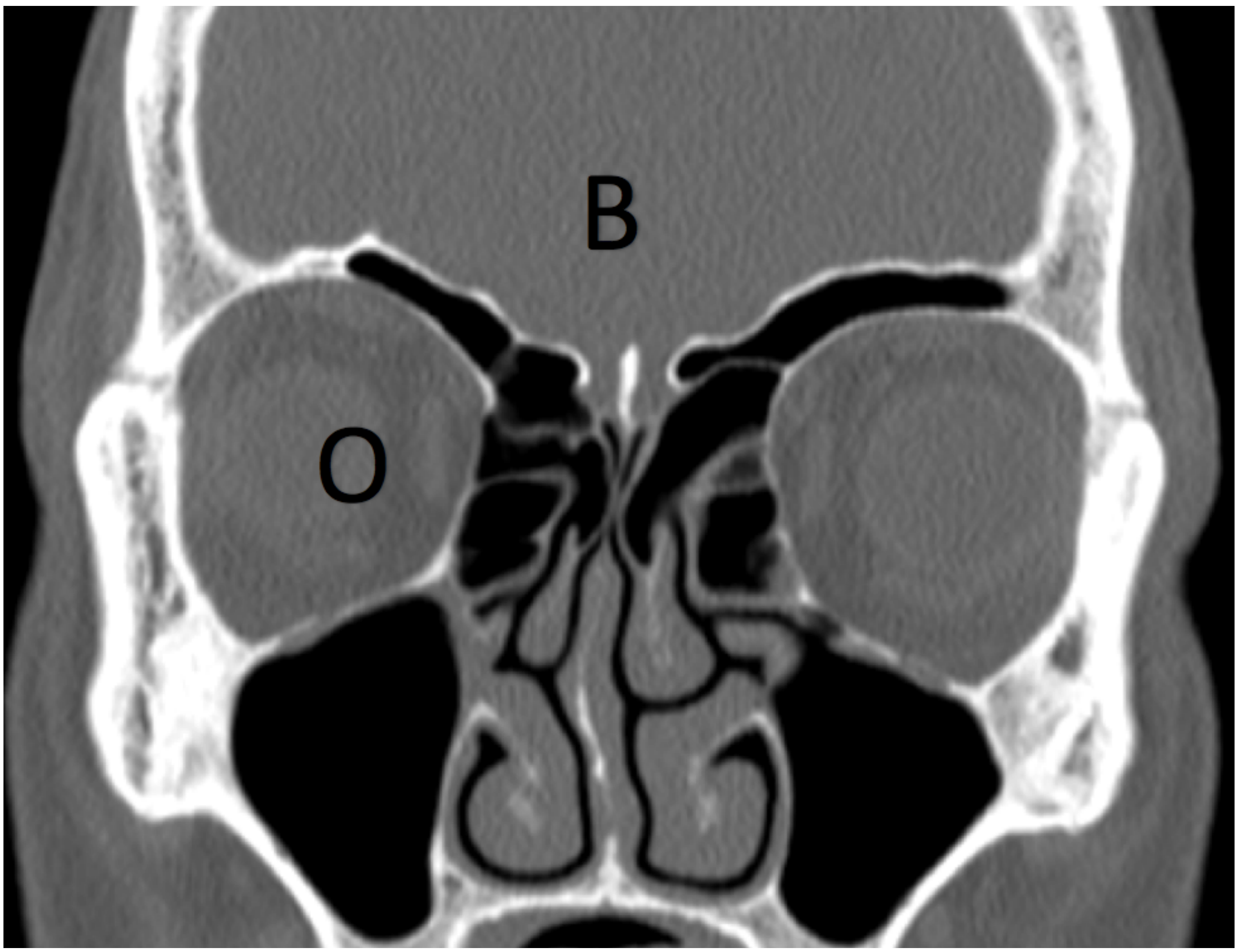

Figure A. Computer tomography scan of the sinuses. The relationship of the sinuses with the surrounding vital structures (O = orbits, B = brain).

While ESS is a complex procedure, surgery of the frontal sinus and the frontal recess remains the most challenging region of sinus surgery due to the variability and very complex nature of the cellular structures in this region (8). Therefore, the surgeon's uncertainty can result in inadequate surgery, scarring of the frontal recess or failure to achieve symptomatic relief (30,31). Thus, knowledge of the anatomy, precise preoperative planning, and meticulous surgical execution are paramount for a successful surgical outcome.

2.3 Simulation training in endoscopic sinus surgery

Surgical simulation seeks to provide a realistic operative experience in which the trainee can safely make mistakes and receive feedback that will ultimately improve technical and cognitive skills (9). Effective simulation models differ according to the baseline skill level of the trainee. Low fidelity simulators focus on specific tasks, such as precision cutting and knot tying. Low fidelity models are well suited for novice learners (10,11). However, more advanced learners typically require high fidelity simulators, in order to recreate an entire procedure, rather than just a single skill required during the procedure (10).

In the field of rhinology, surgical simulation remains in its early stages with the majority of available simulators lacking validity evidence (12). Therefore, development and validation of an ESS simulator are essential. The potential benefits of ESS simulation training include objective measurements of surgical skills, reduction of patient risk, and the standardization of residency surgical training (13). The procedure can also be practiced multiple times until proficiency is acquired, reducing the amount of time needed for a trainee to achieve competency in comparison to classical teaching environments which require multiple operating room visits (14).

Currently available ESS trainers include cadavers, high fidelity VR simulators and low to medium fidelity physical models. A promising VR ESS simulator was recently developed and has proved to be valuable for training purposes (15). This type of simulation provides real-time objective feedback to help the trainee recognize areas of weakness and strengths by detecting errors, as well as providing the tutor with objective teaching points (31). However, VR simulators remain expensive and their ability to properly simulate haptic feedback is limited.

On the other hand, physical models generally are less expensive and more readily available. The fidelity of physical models vary. Low fidelity models provide the learner with the basic ESS skills. A group from Toronto developed a low fidelity, low cost model that was shown to have a positive impact on ESS skills (20-21). Although this is important, the trainee will not be able to learn the crucial surgical steps of a given procedure. Another group, from Oklahoma City, developed a medium fidelity model that was shown to improve ESS skills among residents, but their model was difficult to build, as it was entirely molded by hand (22). More recently, a group from San Antonio developed a medium fidelity 3D printed model that was shown to be useful for basic endoscopic skills acquisition (23). To our knowledge, there is no available high fidelity physical model for ESS and frontal sinus surgery training. Accordingly, pushing the wheel of innovation to develop better simulators remains a need in this field.

2.4 Rapid prototyping and surgical simulators

In recent years, three-dimensional (3D) printing, also known as rapid prototyping, has been used to create surgical simulators. 3D printing is a methodology using a 3D digital model in order to create a physical object, typically by laying down many thin layers of a material in succession. The advancing technology of 3D printing has enabled simulation models to be created for complex anatomical structures. Recently, this technology has been used in different surgical specialties in order to create high-fidelity models for surgical training. An example in the field of OTL-HNS is a 3D printed temporal-bone model developed from computed tomography data. This was shown to be highly realistic and provided an excellent replica for temporal bone surgical training (1).

Three-dimensional objects can enhance 3D spatial learning, especially in challenging anatomical conditions (16). Moreover, the possibility of training for surgical procedures in general, as well as in patient-specific procedures of complex cases can improve the surgeon's abilities and outcomes (16). Furthermore, the pre-operative simulation of a specific complex surgery provides a unique opportunity to evaluate various possible surgical steps in order to determine the best operating strategy (17).

Finally, with further advances in 3D printing technologies and the growing range of materials to print from, this technology now has the potential to rapidly change the landscape of surgical simulation.

2.5 Link to first manuscript

Given a lack of validated simulators in the field of rhinology, there is a need for an ESS simulator with evidence of acceptability and validity to fill this void. To my knowledge, there is no high fidelity frontal sinus surgery trainer. Therefore, a study was done to create, and validate, a model for the training of both ESS and frontal sinus surgery skills.

Chapter 3: Manuscript 1 - Development and Validation of a 3D-Printed Model of the Ostiomeatal Complex and Frontal Sinus for Endoscopic Sinus Surgery Training

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3.1 Abstract

Background: Endoscopic sinus surgery poses unique training challenges due to complex and variable anatomy, and the risk of major complications. We sought to create and provide validity evidence for a novel 3D-printed simulator of the nose and paranasal sinuses.

Methods: Sinonasal CT images of a patient were imported into 3D visualization software. Segmentation of bony and soft tissue structures was then performed. The model was printed using simulated bone and soft tissue materials. Rhinologists and otolaryngology residents completed six pre-specified tasks including maxillary antrostomy and frontal recess dissection on the simulator. Participants evaluated the model using survey ratings based on a 5-point Likert scale. The average time to complete each task was calculated. Descriptive analysis was used to evaluate ratings, and thematic analysis was done for qualitative questions.

Results: Twenty participants (10 rhinologists and 10 otolaryngology residents) tested the model and answered the survey. Overall the participants felt that the simulator would be useful as a training/educational tool (4.6/5), and that it should be integrated as part of the rhinology training curriculum (4.5/5). The following responses were obtained: Visual Appearance 4.25/5, Realism of Materials 3.8/5, and Surgical Experience 3.9/5. The average time to complete each task was lower for the rhinologist group than for the residents.

Conclusion: The development and validation is described of a noel 3D-printed model for the training of endoscopic sinus surgery skills. While participants found the simulator to be a useful training and educational tool, further model development could improve outcomes.

3.2 Background:

Graduate medical education has undergone dramatic changes in the last decade. With the recent introduction of competency-based medical education by the Royal College of Physicians and Surgeons of Canada, learners assume greater responsibility for their own learning and the acquisition of certain skills (2). However, several factors suggest that the operating theater may no longer provide the ideal environment to foster the skills of a novice surgeon. These factors include, increased operative time and cost associated with surgical training (3), work hour restrictions, and increasing complexity of cases at academic teaching hospitals. Unfortunately, these factors will limit the learner in achieving certain competencies.

Endoscopic sinus surgery (ESS) is one of the most common procedures done by otolaryngologists, so achieving a certain competency level in performing this procedure is crucial during the residency program. Moreover, ESS is considered a challenging procedure, especially surgery in the frontal sinus and the frontal recess, which remains the most challenging region of sinus surgery due to the variability and very complex nature of the cellular patterns (8). To overcome these challenges, simulation technology has emerged as a reasonable approach.

In recent years, 3-dimensional (3D) printing, also known as rapid prototyping, has been utilized to create surgical simulators. 3D printing is a methodology using 3D computer-based data for producing 3D physical models. Recently, this technology has been used in different surgical specialties to create high fidelity models for surgical training. An example in the field of otolaryngology is the development of a 3D-printed temporal bone model from computed-tomography data; the model was shown to be highly realistic and provided an excellent replica for temporal bone surgical training (1).

Physical models can enhance 3D learning, especially in challenging anatomical conditions. Furthermore, the possibility of training for surgical procedures in general as well as patient-specific procedures in complex cases can improve the surgeon's abilities and results (16). Besides, the pre-operative simulation of a specific and complex surgery provides a unique opportunity to practice surgical steps in order to determine the best operating strategy (17). Therefore, we sought to create and provide validity evidence for a novel 3D-printed simulator of the nose and paranasal sinuses.

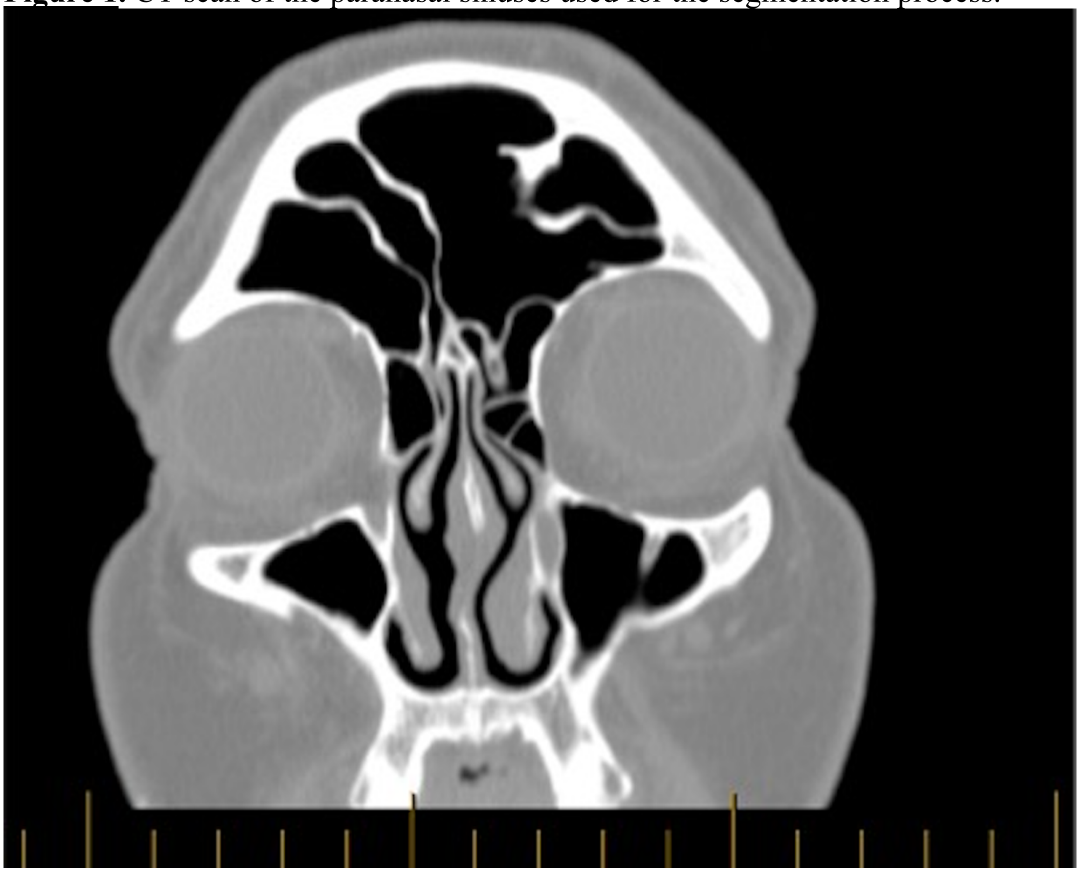
3.3 Methods

3.3.1. Model development

A) Subject selection

After receiving ethics approval, a high-resolution sinonasal CT scan of a patient was acquired. A CT image of well pneumatized sinuses with the absence of pathology and minimal mucosal inflammation were set as the criteria for the imaging (Figure 1).

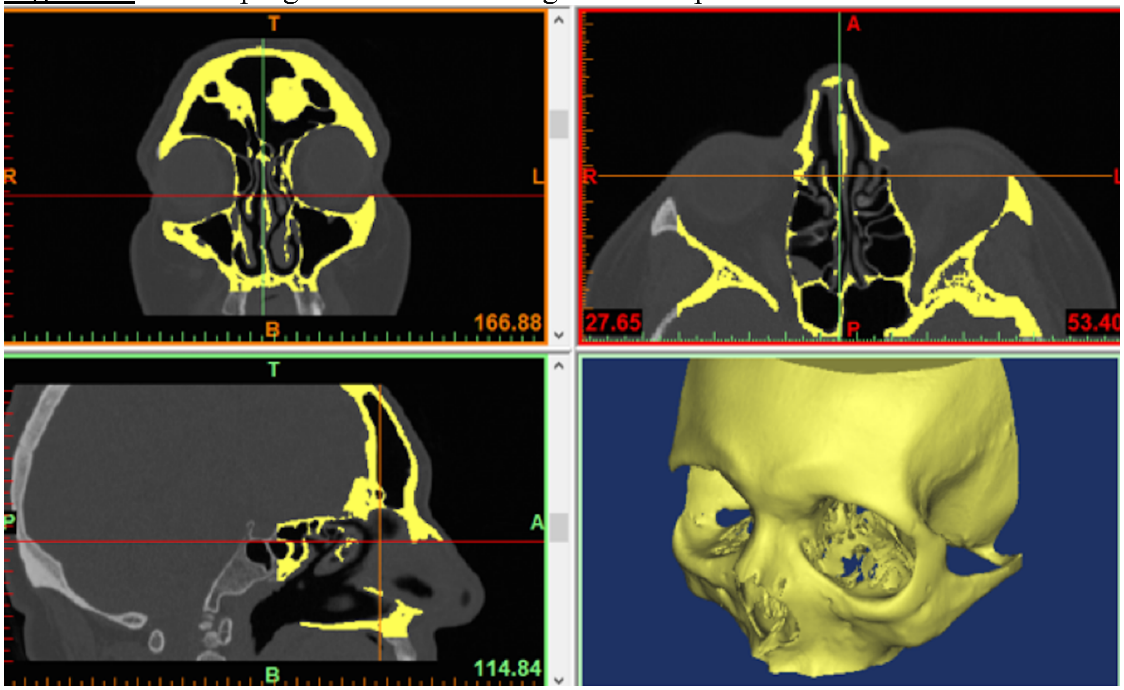
Figure 1. CT scan of the paranasal sinuses used for the segmentation process.



B) Segmentation process

The DICOM data was imported into the Mimics (Materialise NV, Leuven) medical image segmentation program. Structures of interest were segmented; the process involved the definition of two distinct types of structures -“bone” and “soft tissue” (skin and mucosa)- each with distinct material considerations (Figure 2).

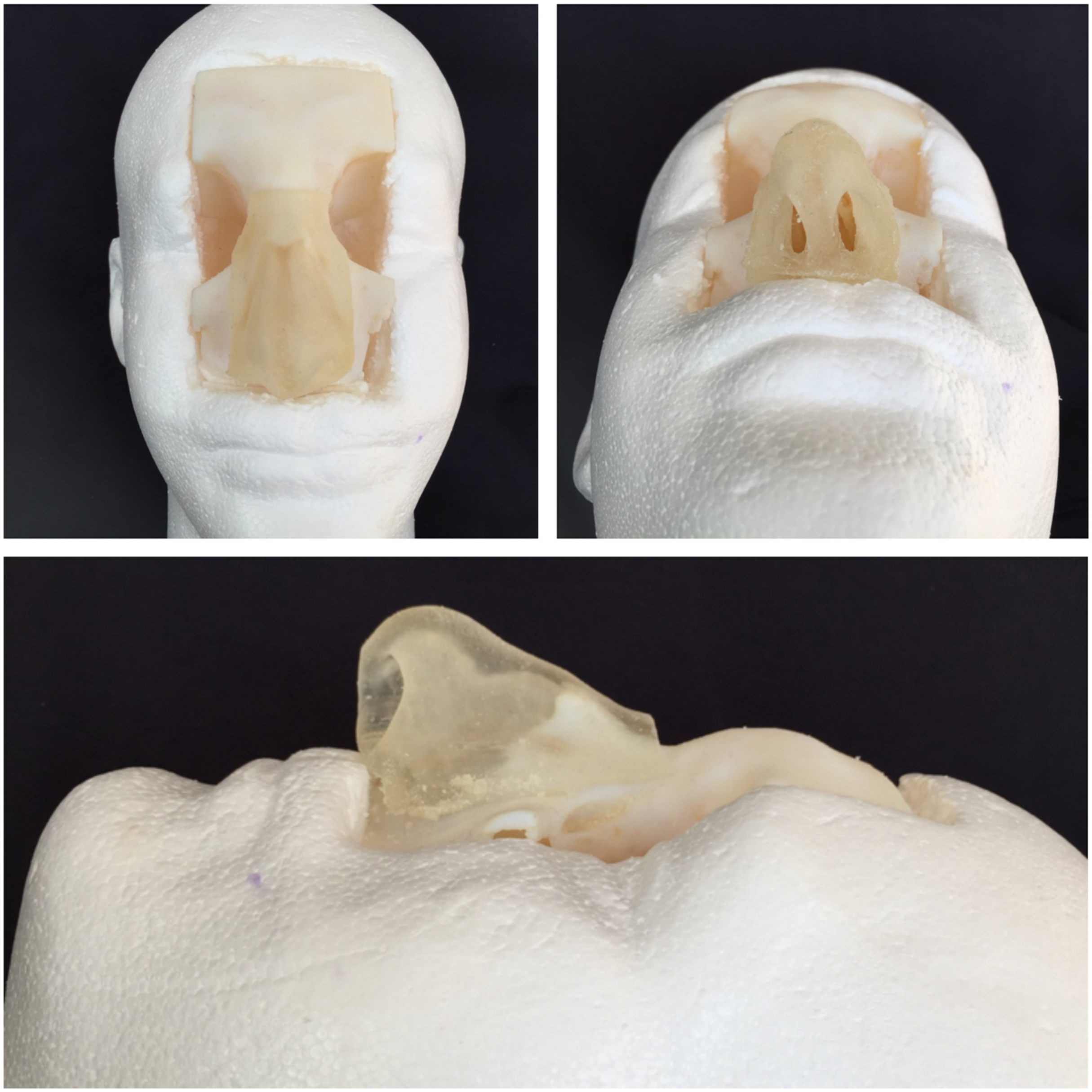
Figure 2. Mimics program used for the segmentation process.



C) Material selection and printing

After reviewing the properties of multiple materials, we found that VeroWhitePlus RGD835 (Stratasys Ltd., Eden Prairie, MN), a rigid white opaque material, would be suitable for bone. VeroWhitePlus has been used to represent bone in other 3D-printed medical applications such as the thorax and the pelvis (18,19). The material used to replicate the skin and mucosa had to be elastic and soft. TangoPlus FLX930 (Stratasys) is a rubberlike material that offers various advantageous properties, including elasticity that can simulate that of nostrils; tear resistance; and tensile strength. It has been used to represent soft tissue in a thorax model (18). To print the models, we used an Objet500 Connex multi-material photopolymer printer from Stratasys. Subsequently, the models were placed into a Styrofoam mannequin head (Figure 3).

Figure 3. External view of the 3D-printed model.



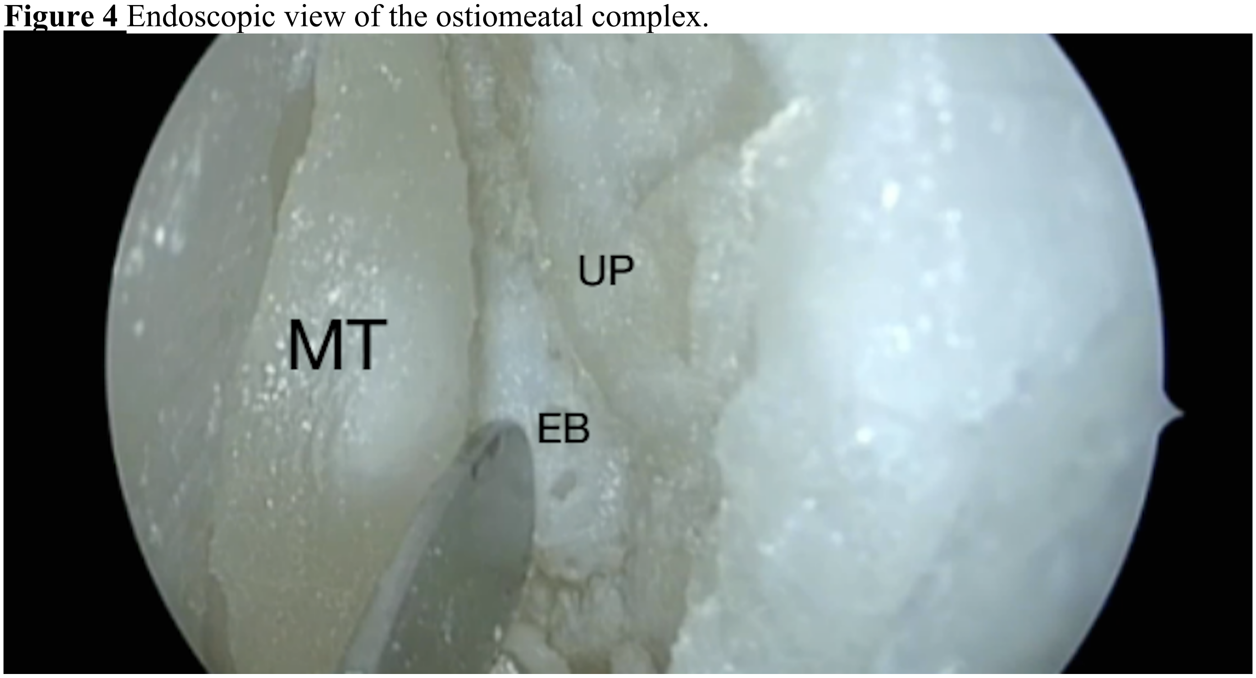
3.3.2. Study settings

After ethics approval by the McGill University IRB committee, data were collected during the Endoscopic Sinus Surgery masterclass course at McGill University in 2015. Ten international rhinologists and ten otolaryngology residents were recruited.

3.3.3. Tasks

The selection of the tasks was determined by a consensus of two expert rhinologists. The tasks were chosen to reproduce a range of skills required for ESS varying from simple to complex. They included injection of the middle turbinate; pledget insertion into the middle meatus; *middle turbinate medialization* and the identification of key landmarks (ethmoid bulla, maxillary ostia, frontal recess); uncinectomy; frontal recess dissection; and anterior ethmoidectomy (Figure 4). Each task was video-taped and the time to complete each task was recorded.

Figure 4 Endoscopic view of the ostiomeatal complex.



MT: Middle turbinate, EB: Ethmoid bulla, UP:Uncinate process

3.3.4. Survey and rating procedures

Participants evaluated the model using survey ratings based on a 5-point Likert scale. The 19-item survey included visual appearance, realism of materials, the surgical experience, the usefulness of the simulator, and one 4-point global rating scale.

3.3.5. Statistical analysis

The observed averages of the survey ratings were calculated. The average times and confidence intervals comparing rhinologists, senior residents and junior residents were analyzed using R (version 3.0.1).

3.4 Results

Twenty participants were recruited: 10 expert rhinologists from 3 countries and 10 residents (PGY1-PGY5). The residents were further divided into 5 junior residents (PGY1-PGY3) and 5 senior residents (PGY4-PGY5). Assessing the value of the simulator, the participants felt that the simulator would be useful as a training/educational tool (4.6/5), and that it should be integrated as part of the rhinology-training curriculum (4.5/5). In the visual-appearance domain, the external nose average score was 4.3, anatomy of the nasal cavity 4.1, and landmark visualization 4.2. As for the realism of the materials, realism of bone was rated at 4.0, the mucosa at 3.15 and the overall impression 3.8.

In the surgical experience domain, the average scores were 4.85 for middle turbinate *medialization, 3.8 for the realism of the ostiomeatal complex*, 3.4 for uncinectomy, 4.05 for anterior ethmoidectomy, 3.8 for frontal recess dissection, 3.45 for recognizing “danger zones”, 4.24 for haptic (touch) feedback, 4.8 for improving bimanual dexterity, 4.75 for learning hand-eye coordination and 4.3 for learning 3D anatomy. The average global rating score was 3 out of 4: the participants felt that the simulator can be considered for use in ESS training but could be improved slightly.

The average time to complete each task was lower in the rhinologist group compared to the resident groups. Completion time differences were statistically significant for the following tasks: injecting the middle turbinate, pledget insertion, identification of landmarks and frontal sinus dissection (Table1).

Table 1. Mean time to finish each task in seconds (s). Confidence intervals provided. MT: Middle Turbinate.

Procedure	Experts (s) $\bar{x}$	Junior residents (s) $\bar{x}$	Senior residents (s) $\bar{x}$	95% CI (Experts -Junior residents)	95% CI (Experts-Senior residents)
MT Injection	3.9	15	8	-15.5 , -6.7	-6.1 , -2.09
Pledget insertion	12.8	64.3	33	-88.8 , -14.2	-29 , -11.3
Ethmoid bulla Identification	5.2	25.1	9	-32.8 , -7.1	-6.9 , -0.62
Frontal recess Identification	7.9	21.5	11.25	-18.1 , -9	-5.3 , -1.3
Uncinectomy	97.4	349	139.5	-447 , -56.2	-129.8 , 45.6
Frontal sinus dissection	212.7	525.16	415	-485.4 , -139.4	-293.6 , -111
Anterior Ethmoidectomy	30.9	42	33.5	-40.2 , 18	-31, 25.9

3.5 Discussion

By using 3D printing technologies, we were able to create an endoscopic sinus surgery simulator to enhance surgical skills acquisition. The data presented here provide evidence for the content and construct validity of this training model, and suggest that this simulator is relevant to clinical settings and would be valuable as an educational tool.

Surgical simulation seeks to provide a realistic relevant operative experience in which the trainee can safely make mistakes and receive feedback, to ultimately improve technical and cognitive skills (9). Virtual reality (VR) simulators have been utilized in surgical training. For example, a promising VR simulator for ESS was developed recently and was shown to be valuable for training purposes (15). However, such simulators are limited in their ability to mimic tool-tissue interactions because it is difficult to simulate satisfactory haptic feedback, especially with currently available and affordable haptic devices.

Moreover, VR simulator use could be limited by its cost and availability. Therefore, a number of physical models have been developed. Low fidelity models provide the learner with the basic endoscopic skills (20-21), but they lack the appropriate progression in advancing these skills. A medium fidelity model has been developed that was shown to improve ESS skills among residents, but this model was difficult to build, as it was entirely molded by hand (22). More recently, one group developed another medium fidelity 3D printed model that was shown to be useful for basic endoscopic skills acquisition (23). Some factors may limit the use of these models, including need to assemble the model, inability to alter the anatomy, and the inability to perform a comprehensive ESS procedure.

The 3D-printed simulator used in the current study proved to have realistic haptic feedback, especially for the bony dissection. As for its physical appearance, the realism of the anatomy scored high and this was correlated with the ability of the model to enhance 3D learning as was reported by the participants. The weakest feature of this model was the simulation of mucosa, probably due to the elastic consistency of the TangoPlus material, combined with the inability to obtain a realistically colored material. Future technological developments should provide solutions to these deficits.

An ideal high fidelity simulation should reproduce the entire operative procedure, rather than a single task within the procedure. ESS is a complex procedure. It requires several skills and also knowledge of the anatomy. Each step of the procedure is important for the safe performance of the full operative procedure. In our study, the participants were able to complete a range of tasks required in performing ESS - from simple to complex. Ultimately, we hope to transfer the acquired skills into the operating room. This has been done in other surgical specialties, such as general surgery, where it has been shown that surgical simulation can result in transfer of skills to the operating theater (24-26).

Current 3D printing technologies do have limitations. For one thing, high-resolution multimaterial printers are very expensive, and the materials are also expensive. It cost $230 to print each model. Furthermore, for this model in particular, because of the complex internal cavities, considerable additional labour was required for cleaning off the excess wax support material before use. However, advances in technology, including progress toward less expensive models, and soluble support material, will enable development of better high fidelity simulators of reasonable cost.

In order to advance the field of endoscopic sinus surgery simulation, more simulators need to be validated for training purposes. The addition of validated measures of performance on the simulator provides critical bench-marking data. These data are relevant to future studies on the use of these simulators in defined curricula for endoscopic sinus surgery training.

3.6 Conclusion

We describe the development and validation of a novel 3D-printed model for the training of endoscopic sinus surgery skills. While participants found the simulator to be a useful training and educational tool, further model development would improve outcomes.

3.7 Acknowledgements

This work was supported in part by the McGill Otolaryngology - Head & Neck Surgery Fund. We thank Dr. Aaron Sprecher and the Laboratory for Integrated Prototyping and Hybrid Environments (LIPHE) in the McGill School of Architecture for the use of their 3D printer and their assistance with using it, and Materialise NV for a trial version of their Mimics software.

3.8 Link to second manuscript

After developing this simulator, and other surgical simulators by our group at McGill, the next chapter will summarize our experience within the context of current simulation practice, simulation challenges, and future directions of surgical simulators in the field of rhinology.

Chapter 4: Manuscript 2 - Controversial Topics in Current Practice - Training models and techniques in frontal sinus surgery

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4.1 Introduction

Surgical management of inflammatory disease in the frontal sinus is considered by many to be among the most challenging in the realm of endoscopic sinus surgery. Surgery of the frontal sinus poses unique challenges due to anatomical complexity, risk of complications, and high failure rate (27). With regard to anatomy, the cellular patterns in the frontal recess and the anatomy of the outflow tract are highly variable (8,28). Adding to the complexity, the space is surrounded by critical structures including the eyes and the brain. As a result, the risk of major complication is a constant concern to the operating surgeon (29), causing many to be very cautious when operating in this area. Unfortunately, the surgeon's uncertainty can result in inadequate surgery with failure to improve or even worsening of symptomatology due to frontal recess stenosis (30,31). Thus, knowledge of the anatomy, precise preoperative planning, and meticulous surgical execution are paramount for a successful surgical outcome in frontal sinus surgery.

Not only can surgical intervention of the frontal sinus be difficult to execute well, but teaching the topic also has challenges. The age-old surgical training model of "see one, do one, teach one" is a vast over-simplification, especially in an anatomical region as complex as the frontal sinus. In this traditional intraoperative setting, opportunities to perform specific procedures such as frontal sinus surgery are sporadic, and are regularly combined with a mismatch between resident ability and procedure complexity. This mismatch can frustrate the learner and impede progress and learning (32,33).

In an ideal situation, the complex training of a competent surgeon addresses three main learning objectives relevant to each individual trainee: cognitive, affective, and psychomotor domains (34). In order to improve the cognitive domain, it is important for the trainee to learn to analyze and formulate a surgical plan, then to practice the surgical steps in order to improve the psychomotor domain.

The use of simulation models permits learning and practice of surgical skills in a safe environment. One anticipates that skills learned in a simulation setting will translate into confidence and improved performance in actual surgery (35). While simulation of endoscopic sinus surgery remains in early stages, a major limitation of current simulators is an inability to reproduce accurately the complexity and heterogeneous anatomy of the frontal sinuses. Recent advances in technology have resulted in models having more realistic anatomy and tissue properties (KEZLEX®, Ono & Co., Ltd., Tokyo, Japan). However, to the best of the authors' knowledge, there is no validated frontal sinus trainer. Also, no current models are available that simulate frontal sinus surgery.

Given the obstacles involved in developing a realistic validated frontal sinus simulator, an intermediate form of teaching frontal sinus anatomy and surgery is necessary. In order to enhance surgeons' understanding of the anatomy and surgical planning, this chapter describes an advanced surgical education methodology that uses a 3D conceptualization module to teach frontal sinus anatomy and surgery, followed by simulation models to practice sequences of surgical procedures.

4.2 A 3D conceptualization module to teach frontal sinus anatomy

In order to improve understanding of frontal sinus anatomy, Wormald has described a 3-D conceptualization to establish the pattern of the frontal sinus anatomy and drainage pathway following review of a CT scan in triplanar view (36). Based on a modified Kuhn classification (36, 37), building blocks are generated to represent each cell identified in the frontal recess and frontal sinus. In this methodology, the agger nasi is the key to understanding the anatomy and surgical planning. Subsequently, using coronal and parasagittal scans in tandem, each cell can identified and placed in relation to the other cells. Finally, the frontal sinus drainage pathway is identified primarily using the axial CT images, followed superiorly to inferiorly and plotted around the cells in the frontal recess.

Using this building block method to understand the anatomy, the Scopis® Building Blocks computer software has recently been developed. This software allows the user to identify building blocks on the CT scan itself, resizing and placing them over the three-dimensional cells within the viewer (Fig.1). Importantly, the frontal sinus drainage pathway can also be drawn directly on the CT scan, creating an accurate three-dimensional anatomical image. This system allows the surgeon to visualize the 3D anatomy of the frontal recess and the surrounding cells in order to formulate a surgical plan. Furthermore, this system can be used as a teaching module by allowing the trainee to review a CT scan, and then use the program to identify components of the frontal sinus anatomy, to create a 3D building-block conceptualization, and to identify the drainage pathway.

Together with Professor Wormald, an educational course has been created using anonymized CT scans from real patients. Participants in the course are taught how to use a DICOM viewer such as Scopis® software to review images in tri-planar view and then reconstruct the cellular anatomy and identify the location of the frontal sinus drainage pathway. Course instructors, who are well versed in the building block concept, assist participants as needed. Subsequently, participants watch a short video of an actual surgical dissection. Next, participants learn how to identify cellular anatomy in various patients. The first few CT scans are straightforward , but identifying the cellular anatomy becomes more difficult as the session progresses. The course employs about 10 sides and lasts 3 hours. It has been held in numerous countries, and current efforts are being made to collect data on its efficacy.

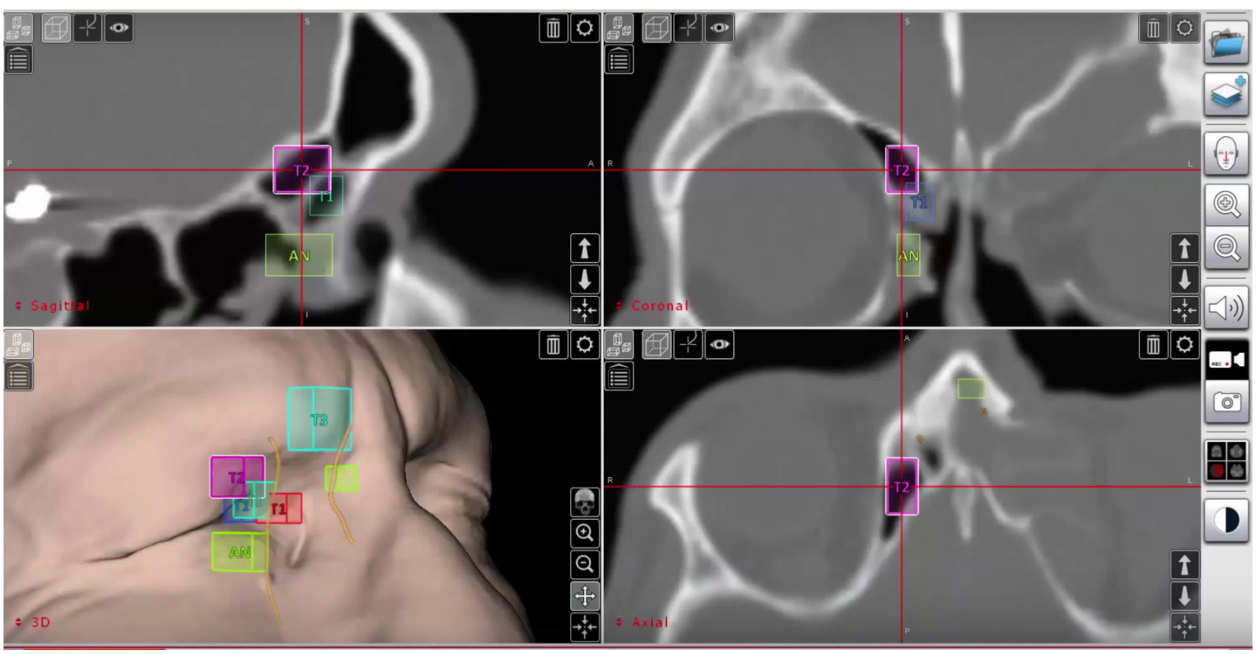

Figure 1. Pre operative surgical planning on the Scopis program.

4.3 VR simulators

Virtual reality (VR) surgical simulators have the advantage of providing trainees with the opportunity to practice surgical skills in a low-risk environment. Furthermore, the dynamic nature of the VR software permits programming of different clinical conditions to improve training content and to allow for individualized, proficiency-based training. Many of the currently available VR surgical simulators also have the advantage of being capable of providing performance feedback, using various metrics (e.g., time to complete a task; percentage of normal tissue removed; force measurements during contact with vital structures). This built-in assessment functionality enables self-directed learning and proficiency-based training.

The ES3 was the first VR sinus surgery simulator developed in 1998 by Lockheed Martin (38). Although the ES3 demonstrated tangible benefits for resident training, it is no longer in production and there remain less than a handful of devices in North America (39). After the discontinuation of the ES3, other virtual reality simulator models for ESS have been created, However many of these devices have not been validated (12). The McGill simulator for ESS is a VR simulator with advanced 3D and tissue characteristics. The simulator is capable of measuring objective performance metrics in order to provide the trainee with constructive feedback to improve performance (15). However, VR simulators are limited in their ability to mimic tool-tissue interactions and few have been able to simulate haptic feedback successfully. (Figure 2 and 3)

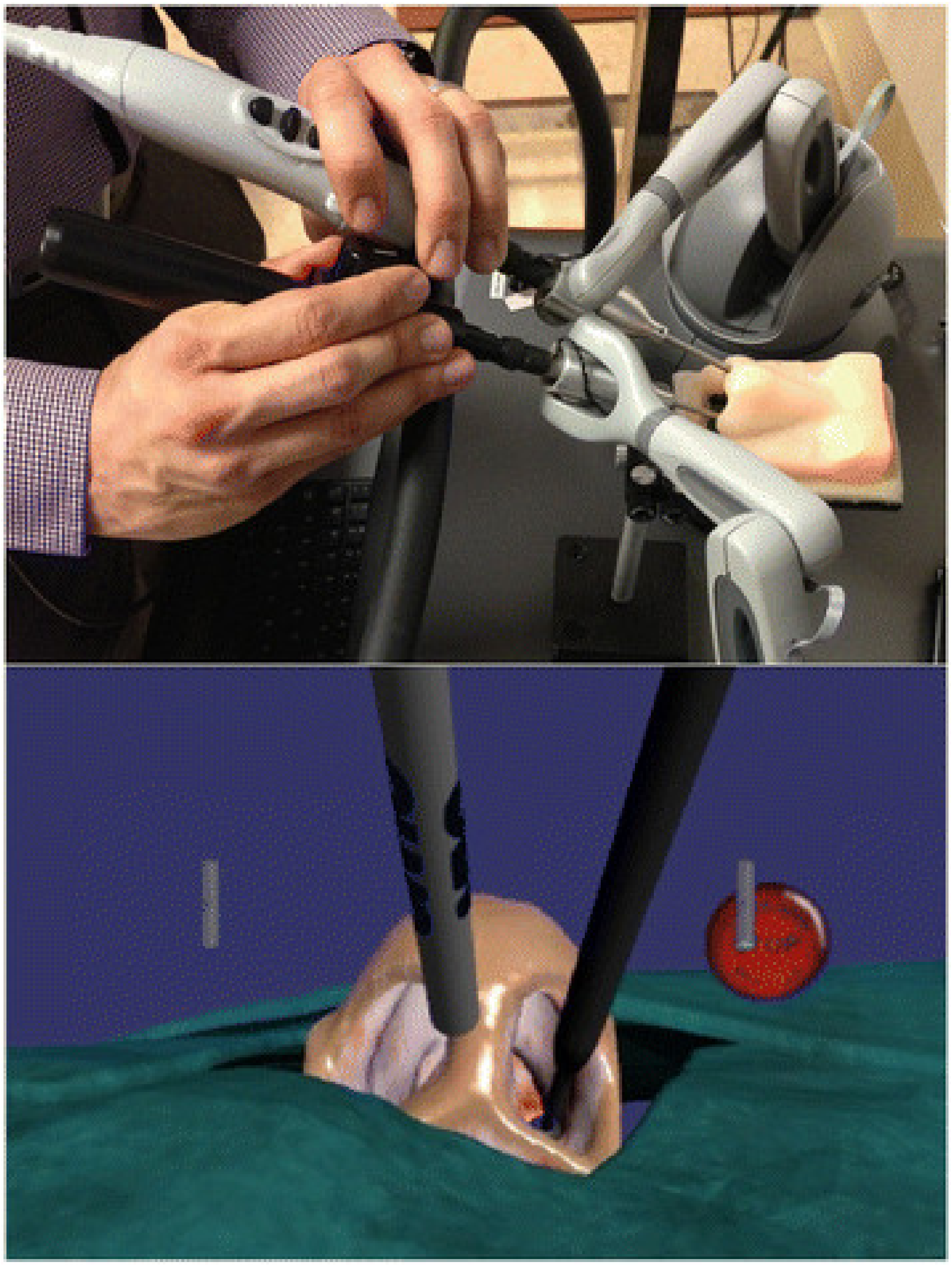

Figure 2. Virtual reality simulator with the user placing the endoscope and the microdebrider within the nasal cavity.

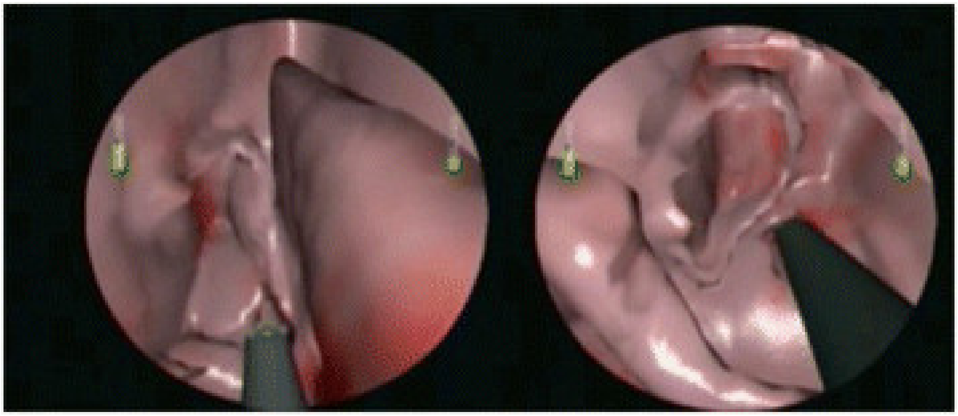

Figure 3. Virtual view of user performing sphenoidotomy.

4.4 Training Models

Surgical simulation models range from part-task simulators to procedure-specific simulators. These synthetic models give trainees the opportunity to practice specific surgical skills in a low-risk environment.

In recent years, 3-dimensional (3D) printing, also known as rapid prototyping, has been utilized to create surgical simulators. 3D printing is a methodology using three-dimensional computer-aided design data sets for producing 3D haptic physical model. Recently, this technology has been used by different surgical specialties to create high fidelity models for surgical training. An example in the field of otolaryngology is the development of a 3D printed temporal bone model using computed tomography data. The model is considered to be highly realistic and an excellent replica for temporal bone surgical training (1).

Rapid prototyping objects enhance 3D learning especially when simulating challenging anatomical conditions. Furthermore, the possibility of training surgical procedures in general, as well as in patient-specific procedures involving complex cases improves the surgeon's abilities and results (16). The pre-operative simulation of a specific and complex surgical case provides a unique opportunity to evaluate various potential surgical step sequences in order to determine an optimal operating strategy (17).

At McGill, we have developed a 3D printed simulator of the osteomeatal complex and the frontal sinus by segmenting a CT scan of the paranasal sinuses (*** reference required ***). The model reproduced both bony and soft tissue characteristics (Fig.4). After experts performed a set of tasks on the model, the model was rated highly in terms of haptic feedback and surgical experience. Furthermore, the model significantly differentiated between expert and novice surgeons, which made it useful as a resident training tool, and as a means of providing feedback on a resident's surgical performance (Fig. 5 & 6). Moreover, the model allowed the performance of surgical maneuvers required for the frontal recess dissection. The advantage of a 3D printed model is the ability to print the variable frontal recess anatomy and enable the trainee to perform the maneuvers required in a safe environment. Furthermore, it allows the trainee to practice manipulating angled endoscopes and the special instruments necessary to operate in this delicate area.

However, 3D printing technologies do have limitations. To start, the printer and materials are expensive to acquire. Second, for this model in particular, additional time and effort was required to remove excess support materials (wax) before use. However, with advancements in technology, cheaper models with little to no wax materials and a more life-like feel are expected to become available. This should enable trainees to practice in a safer and more realistic environment.

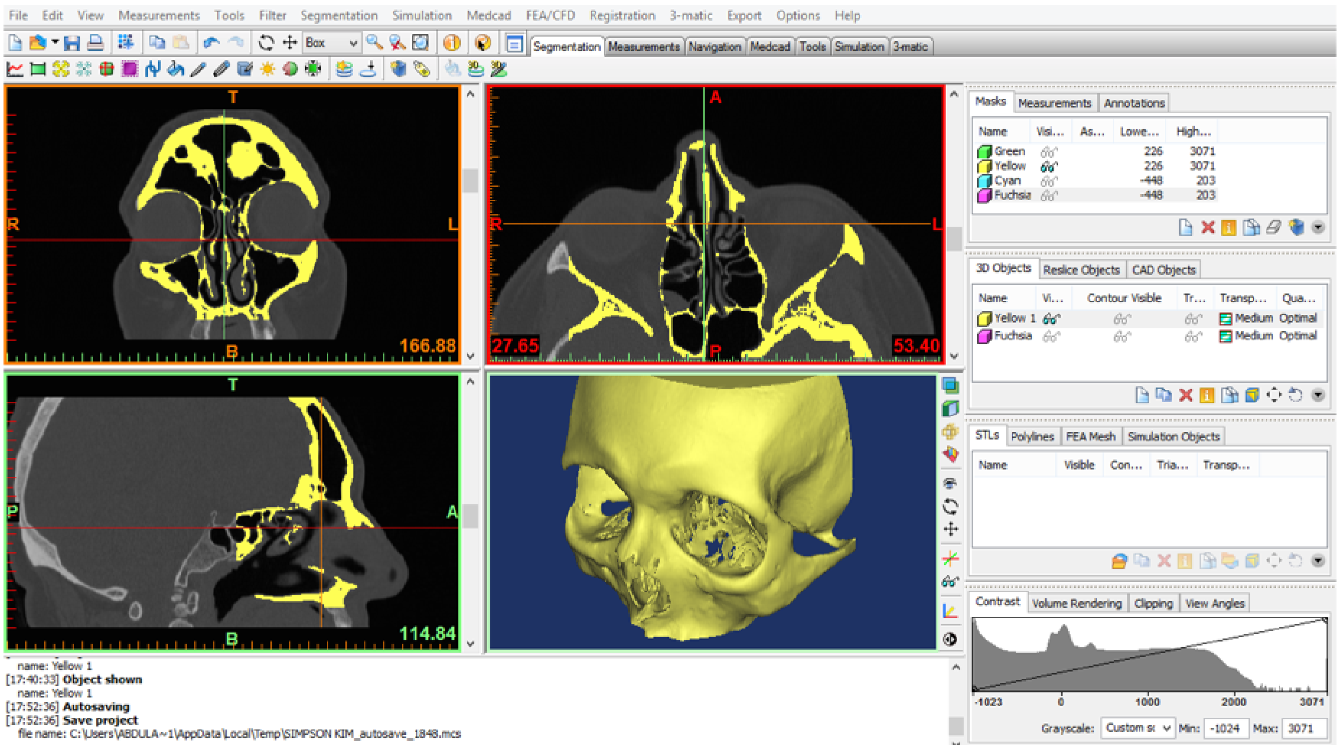

Figure 4. Mimics program used for the segmentation process.

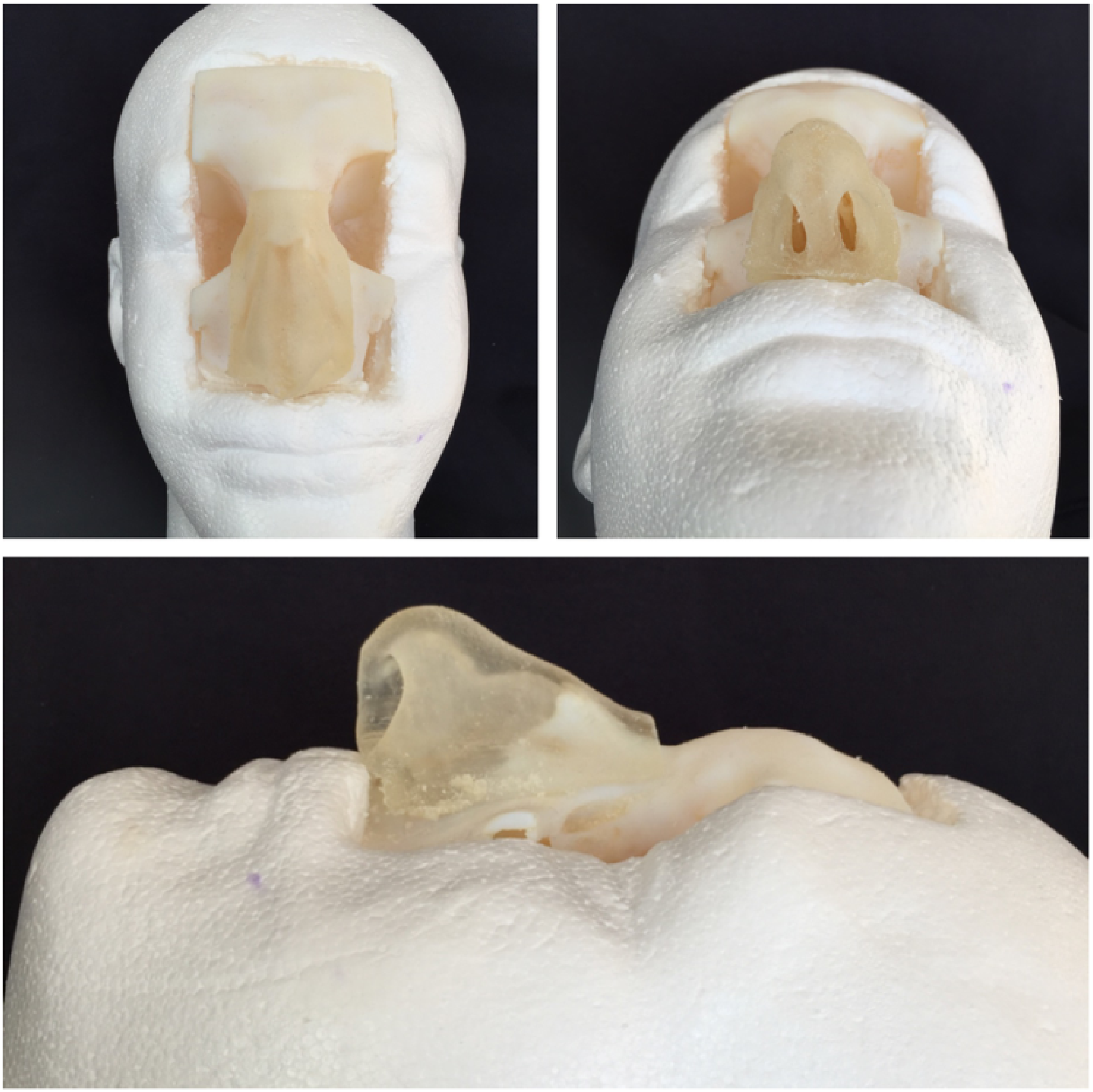

Figure 5. The printed model employing 2 different materials simulating bone and soft tissue mounted within a Styrofoam head.

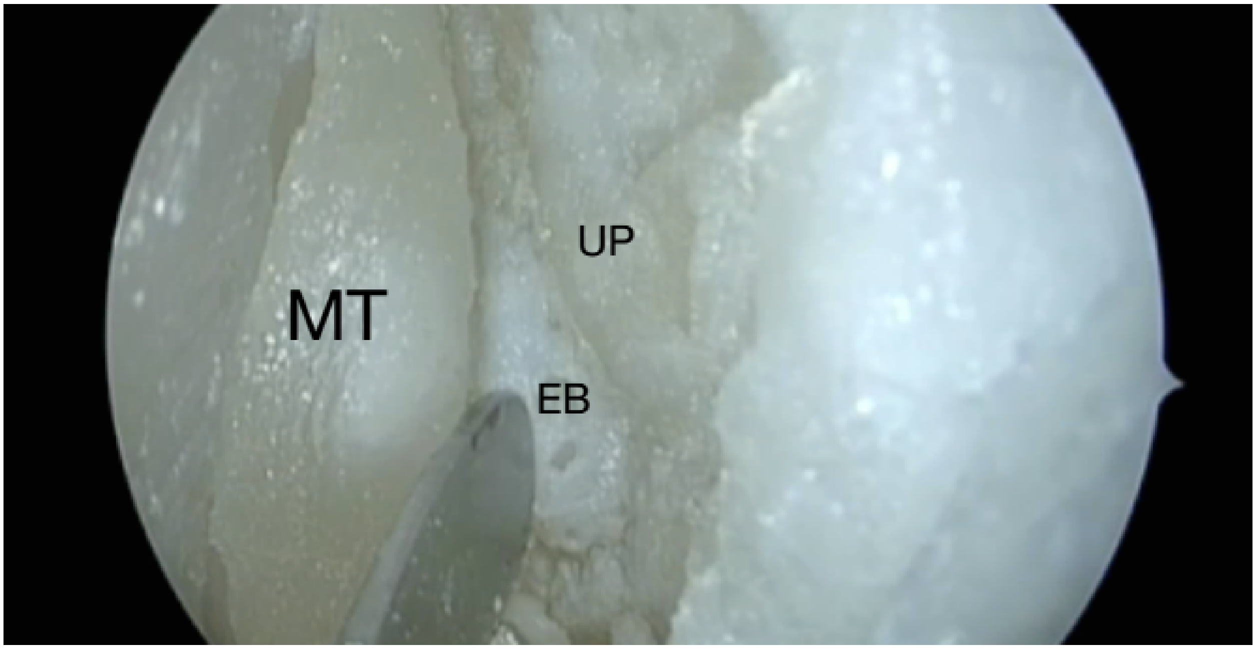

Figure 6. Endoscopic view of the middle meatus.
MT: Middle turbinate, EB: Ethmoid bulla, UP:Uncinate process

4.5 Conclusion

Frontal sinus surgery remains one of the most challenging aspects of current rhinology practice. Frontal recess anatomy is variable, often confusing, and frequently changed by underlying pathology. These difficulties must be dealt with within the narrow confines of a surgical corridor using angled instruments and endoscopes. The challenges become even greater. In order to advance the teaching of frontal sinus surgery, a broad training curriculum encompassing 3D conceptualization of preoperative imaging, and simulation of surgical maneuvers needs to be developed and validated. The possible application of validated measures of performance on the simulator should provide critical bench-marking data. These data are relevant to the future application of simulation curricula for endoscopic sinus surgery training.

Chapter 5: Overall Discussion and Limitations

Chapter outline

This chapter will present an overall discussion, an outline of the limitations of this thesis and the overall conclusion.

5.1 Discussion

The purpose of this study was to create and validate a high fidelity, anatomically correct simulator for ESS and frontal sinus surgery. In assessing the realism of the anatomy, our model scored high and this is correlated with the ability of the model to enhance 3D learning as reported by the participants. Moreover, our 3D-printed simulator proved to have realistic haptic feedback, especially for the bony dissection. These features of the model and the ability to practice essential ESS skills were appreciated by the participants, as they rated the model highly as an educational tool, especially for the level of junior residents.

Advanced learners typically require high fidelity models, aiming to recreate an entire procedure, rather than just a single skill required during the procedure. This type of model helps the learner to master the simple and advanced surgical skills required to perform endoscopic sinus surgery, more specifically frontal sinus surgery. The participants in this study were able to perform all the steps necessary in performing a frontal sinusotomy, progressing from decongesting the nasal cavity to the removal of the agger nasi cell and identifying the frontal sinus ostia. We anticipated that expert surgeons would finish each step within the procedure faster than novice surgeons, which was demonstrated in our results, especially with the advanced maneuvers (for example, frontal sinusotomy).

Current residency programs recognize the importance of developing a comprehensive training curriculum. In this study, the participants felt our training model should be integrated into a rhinology training curriculum. This is expected due to the high educational value of such a model. Furthermore, the simulator developed in this thesis will help to overcome some of the challenges related to surgical exposure in residency programs. Surgical programs are now under increasing pressure to efficiently achieve and document competency in both skills acquisition and cognitive learning. Such a model will help programs to monitor and document trainee surgical skills acquisition.

Despite the challenges associated with frontal sinus surgery, including complex anatomy, the anatomical and pathological variability and the close association with critical structures, frontal sinus simulators are still lacking. Unfortunately, cadavers remains expensive and difficult to access by many residency programs. Previously available physical models and virtual reality simulators may provide some of the basic ESS skills, but they do not provide the trainees with the opportunity to practice advanced skills required for frontal sinus surgery. Our model allows the trainees to foster such skills and to go beyond the basic skills. Moreover, since 3D printers are now widely available, this may grant residency programs easy access to similar models.

5.2 Limitations

There are several limitations to this study. One limitation is the lack of multiple objective measures of trainee performance. The present study only used two objective performance measures: (a) completion time and (b) the presence of major complications (injury to the orbit or skull base). Developing more objective measures would allow better comparison of surgical performance between trainees. The model has some limitations as well. The mucosa did not score high on realism because of the material properties and the lack of realistic colouring. This may change in the future with advances in material technologies. Other limitations include the high cost of materials, the long printing time and the need to remove the waxy support material within the model.

5.3 Future directions

Future studies should aim to establish whether practicing on such models would improve intraoperative skills and proficiency. We also hope to integrate our training model within the residency program curriculum and study the effect of such an addition. It would be desirable to develop a data bank of anatomical variations of the paranasal sinuses and different sinonasal pathologies. This could better match training to the level of the trainee and their educational goals. With further advances in 3D-printing technologies, this will be more feasible to do.

5.4 Conclusion

This thesis has described the development and validation of a high fidelity 3D-printed model for the training of endoscopic sinus surgery and frontal sinus surgery skills. The developed simulator has produced initial evidence strongly suggesting that it is realistic and useful from the perspective of trainees and experts. The model can provide feedback on surgical performance, and it can be used to develop better ESS training programs in the future.

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7. Appendix

8.1 Validation Survey

Validation survey of ESS training model

1- Age:

2- Gender (optional):

☐ Male ☐ Female

3- Dexterity:

☐ Right handed ☐ Left handed

TRAINEES:

4- Your level of training in Otolaryngology:

A. Medical student

B. PGY 1

C. PGY 2

D. PGY 3

E. PGY 4

F. PGY 5

G. Fellow (specify subspecialty: ___________________________)

5-Please approximate the number of ESS that you performed as a PRIMARY* surgeon.

Please consider each side of a nasal cavity as a separate case

*Primary surgeon = Performed key portions of the procedure or supervised another resident through key portions

	Past 12 months	During entire training
ESS (Maxillary & Ethmoid)		
Frontal ESS		

6- Please approximate the number of ESS that you performed as a SECONDARY* surgeon (i.e. assistant surgeon, not as an observer). Please consider each side of a nasal cavity as a separate case.

*Secondary surgeon = Scrubbed, participated in pre-operative planning and assisted a senior surgeon in key portions.

	Past 12 months	During entire training
ESS (Maxillary & Ethmoid)		
Frontal ESS		

7- What is your level of comfort in performing ESS independently

1	2	3	4	5
Requires complete hands on guidance	**Requires constant direction**	**Some independence, requires direction**	**Complete independence**	**Independent, supervisor in the room**

8- I would like to practice on an ESS simulator prior to performing the surgery in the OR:

1	2	3	4	5
Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**

STAFF:

1- I completed my Rhinology fellowship* ( ) years ago. ***Please use x if you did not do a fellowship.

2- I have been practicing otolaryngology for ( ) years.

3-What best describes your surgical practice (check as many as applicable).

☐ Tertiary care center ☐ Community hospital ☐Private office

4- Do you perform Frontal ESS surgery as a routine part of your practice?

☐ Yes ☐No

5-Approximate how many Frontal ESS have you performed in the past 12 months

(Please consider each side of a nasal cavity as a separate case.)**: ____**

Please take a moment to complete the rating scale below

	Not realistic (1)	Lacks too many key features to be useful (2)	Lacks some key features but can be useful (3)	Adequate realism of key features (4)	Highly realistic (5)
Visual appearance					
External nose/ nostrils					
Anatomy of the nasal cavity					
Landmarks visualization					
Realism of materials					
Mucosa/skin					
Bone					
Overall impression					
Surgical experience					
Middle turbinate medialization					
Performing uncinectomy					
Anterior ethmoidectomy					
Frontal recess dissection					
Realism of anatomy of OMC					
Recognizing "danger zones"					
Haptic feedback					
Improving bimanual dexterity					
Learning hand-eye coordination					
Learning 3D anatomy					

Please rate the value of the simulator

	Not at all (1)	**Minimally (2)**	**Adequate (3)**	**Useful (4)**	**Extremely useful (5)**
The usefulness of the simulator as a *training/educational tool*					
Usefulness as part of your Rhinology training curriculum?					

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

☐ Medical students

☐ Junior residents (PGY1-PGY3)

☐ Senior residents(PGY4-PGY5)

☐ Fellows

☐ Non-rhinology staff

☐ Rhinology staff

Global rating- Please check the one statement that you most agree with.

1-The simulator requires a number of improvements before it can be considered for use in ESS training.

2-The simulator requires a few changes before it can be considered for use in ESS training.

3-The simulator can be considered for use in ESS training, but could be improved slightly.

4-The simulator can be considered for use in ESS training, no further improvements are needed.

- **<u>Please reflect on the top three strengths of this model</u>**
- ____
- ____
- ____

- **<u>List three weaknesses of this model</u>**
- ____
- ____
- ____

- **<u>Do you have any recommendations to improve this model?</u>**

<u>Any additional points you want to share?</u>

8.2 Consent Form

SUBJECT INFORMATION AND CONSENT FORM

Validation of a 3D printed Ostiomeatal Complex and Frontal Sinus Training Model for Endoscopic Sinus Surgery

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Consent Form

McGill University requires that all subjects participating in research protocols do so voluntarily with written informed consent being the preferred method to document their willing involvement. This consent form should give you a basic understanding of the goals of this research project and what your participation, including any potential risks and benefits, will entail. We kindly ask you to read the following description and indicate whether or not you agree to participate in this study. If you require more information concerning the study, please feel free to ask at any time.

Introduction

The primary purpose of this study is to assess whither a 3D printed sinus model will accurately reproduce the look and feel of performing ESS and Draf 2A frontal recess dissection. Our main outcome is to validate this model by collecting data from your performance and receiving a subjective feedback.

Study procedure

If you agree to join the study, you will be asked to fill out a post simulation survey. You will be asked to perform a Draf 2a frontal endoscopic sinus surgery on the model. Your performance will be videotaped. The authors believe the study to be of scientific merit and hope to submit a manuscript for publication when the study is completed.

Benefits and Risks

We do not anticipate any harm or side effect of participating in the study. The information obtained will not be placed in your resident file. Subjects stand to benefit by receiving constructive feedback from the simulator on their rhinology skills, which may enhance their operating room performance.

Withdrawal from study

Your participation in this study is entirely voluntary, and you may refuse to participate or withdraw from the study at any time with no penalty or loss of benefits, and your future assessment will not be affected. You may also refuse to answer any question that you do not wish to answer any time during the study. The study investigators may decide to withdraw you from the study at any time, if they feel that it is in your best interests.

Cost / Insurance

There are no costs to the participants in the study.

Compensation

No compensation will be provided.

Subject Rights

You have the right to ask questions at any time and your participation is voluntary. There will be no penalty if you refuse to participate. You also have the right to discontinue participation at any time without penalty.

Confidentiality

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. All information obtained from the subjects will be identified only by a code number. None of the information obtained will be placed in your resident file. No records that identify you by name or initials will be allowed to leave the Investigators' offices.

Who Do I Contact if I Have Questions About the Study?

If you have any questions or desire further information with respect to this study before or during your participation, you may contact Dr. Abdulaziz Alrasheed at 514-659-4544. If you have any concerns about your rights as a research subject and/or your experiences while participating in the study, you may contact Ilde Lepore, Senior Ethics Administrator with the McGill Institutional Review Board (IRB) at 514-398-8302.

- I agree to participate in this study by filling out the surveys and completing the tasks on the simulator.
- I understand that my participation in this study is entirely voluntary and I am completely free to refuse to participate or withdraw from this study at any time without affecting my training or evaluations in the Training Program.
- I understand my identity will be protected and that all records will be coded to guarantee anonymity.
- I have read this form and I freely consent to participate in this study.
- The study has been explained to me and my questions have been answered to my satisfaction. I agree to participate in this study. I do not waive any of my rights by signing this consent.

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Printed name of subject Signature Date

(PLEASE PRINT CLEARLY)