Design and Validation of a Practical Simulator for the Development of Basic Nasal Endoscopy Skills in Otolaryngology – Head and Neck Surgery

by

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Abstract

Diagnostic nasal endoscopy is the standard procedure used by Otolaryngology – Head and Neck (OHNS) surgeons in detecting and treating conditions of the nose and sinuses. Due to a reduction in time resources towards surgical residency programs, OHNS residents have less access to hands-on patient based training in the clinic and operating room (OR) to develop the basic skills required to perform this procedure. Simulation training has been established as an accessible, safe and more ethical alternative to practicing on patients. There are currently no available simulators for practicing basic diagnostic nasal endoscopy skills. The goal of the present research project was to develop a practical simulator for training basic nasal endoscopy skills in OHNS residency programs. A needs analysis was conducted by interviewing experts in OHNS to help inform the design of the simulator and detect potential barriers to adoption. The simulator was developed using additive manufacturing (AM) technology at the Institute for Reconstructive Sciences in Medicine (iRSM), Edmonton, Alberta. The simulator model was made based on computerized tomography (CT) data to closely resemble human anatomy and incorporated force sensors to function as an objective measure of performance. The model was validated through an experimental study involving novice medical students, residents, and staff from the Department of Otolaryngology – Head and Neck Surgery at the University of Alberta, Edmonton, Alberta. The model showed good face validity by the participants rating its overall utility and effectiveness as high. The model showed good construct validity with a strong correlation between the participants' performance rated on the Objective Structured Assessment of Technical Skills (OSATS) rating scale and surgical experience when performing a set of basic nasal endoscopic tasks on the model. The model failed to show construct validity as an objective measure of performance with no correlation between force measured by the force sensors in the

model and surgical experience. The simulator model developed is a practical and readily available alternative for OHNS residents to practice their diagnostic nasal endoscopy skills before they go on to practice on patients. The simulator model can help accelerate learning and improve patient safety and the overall quality of patient care.

Preface

This thesis is an original work by Laila Hanto Steen. The research project involved two studies that received ethics approval from the University of Alberta Health Research Ethics Board:

"Perceptions of Surgical Simulation in Otolaryngology Residency Training – A Qualitative Study Using the Convergent Interview Technique", Pro00046487, May 28, 2014.

"Validity of a Practical Simulator for the Development of Basic Nasal Endoscopy Skills in Otolaryngology Residency", Pro00044996, December 1, 2014.

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1. Introduction

Diagnostic nasal endoscopy has become the standard clinical procedure in Otolaryngology – Head and Neck Surgery (OHNS) to detect and treat many nose and sinus related pathologies.[1] Nasal endoscopy is considered a complicated procedure due to the challenge of navigating the scope through the narrow nasal cavities with its proximity to many vital structures.[1,2] Patients can feel pain and discomfort during the procedure if the scope makes unnecessary contact with sensitive structures such as the septum and the turbinates. Diagnostic nasal endoscopy therefore requires highly developed technical skills as well as a good familiarity with the complex anatomy of the nose and nasal cavity.[3,4]

Historically and presently, nasal endoscopy skills have been acquired in the clinical setting through the apprenticeship model, where the trainee observes the expert and then, under supervision, performs the procedure on a patient.[3,5] This model of training has recently come under scrutiny for its lack of efficacy and efficiency.[4,5] The scrutiny has largely been brought about by the significant reduction in time and resources towards surgical residency programs and the ethical implications of allowing residents to practice on live patients.[1,3] The traditional model for surgical residency training has also been criticized for not keeping up to date with current medical and surgical practice, and for lacking a shared, objectives based framework for the development and assessment of surgical competency.[4,6] Some argue that the current state of surgical residency programs fails to provide the proper structure and experience residents need, thus producing less qualified surgeons at the end of the five year residency program. This raises concern for patient safety and the overall quality of care.[7] As a result, there has been an increased effort to develop a valid alternative to the traditional education model and its exclusive reliance

on patient based training. One alternative that is becoming widely accepted is simulation training.

Over the past 40 years, surgical simulation has been increasingly accepted as way of providing safe and educationally sound experience to undergraduate students, postgraduate trainees and established practitioners.[8] Surgical simulation can refer to a wide range of training mediums such as: animals, cadavers, bench models and box trainers, anatomical models (mannequins), Virtual Reality (VR) programs, and robotics. There has been a rapid growth in both the development and implementation of simulation technology in surgical training programs, and there is accumulating evidence to show that simulation training has the ability to accelerate learning and improve patient safety.[9]

Although OHNS surgeons spend the majority of their time in the clinic,[10] much of the training and research literature is focused on surgical skills acquisition in the operating room (OR). As a result, all of the simulators that have been developed for nasal endoscopic procedures are indeed endoscopic sinus surgery (ESS) simulators intended for training more complex surgical tasks. These simulators are costly due their level of fidelity and complexity, and therefore not a practical or cost effective alternative for training the basic skills required for diagnostic nasal endoscopy.[3,4,11] Thus, there is a need for a more practical alternative that will allow residents to develop their skills before they go on to practice diagnostic nasal endoscopy on patients in the clinic. This will help accelerate the learning process for residents, improve patient safety and comfort, as well as improve the quality of patient care.

Despite the acceptance of simulation technology, there has not been a widespread implementation of the technology in Canada. At the University of Alberta, Edmonton, Alberta,

residents train the nasal endoscopy procedure on patients under the apprenticeship model. For the same reasons expressed in the literature, there is a stated need for a better alternative. The goal of the present research project was to answer that need.

1.2 Aims

The aim of the present research project was to address the need for a practical simulator for the development of basic nasal endoscopy skills in Otolaryngology-Head and Neck Surgery (OHNS) residency in three stages (Figure 1):

1. Perform a needs analysis by interviewing experts in OHNS to investigate the training needs for, and perceptions of, simulation training. This information was collected to inform the design of the simulator to ensure it usefulness, and to detect potential barriers to implementation among important stakeholders in OHNS residency programs.
2. Design and fabricate a practical simulator for the development of basic skills in diagnostic nasal endoscopy.
3. Validate the overall utility and effectiveness of the simulator through an experimental study involving both educators and trainees.

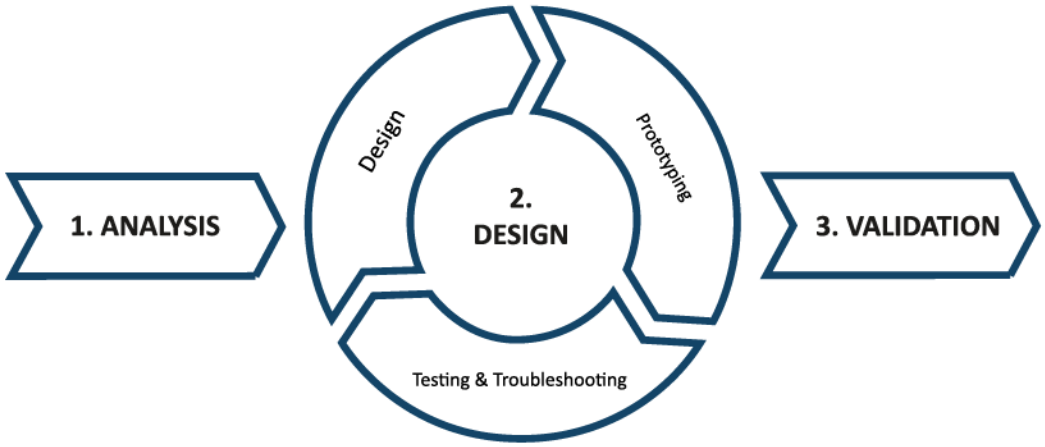

Figure 1: Project process map

The expected outcome of this project was to successfully develop a simulator that would address the needs expressed both in the literature and by central stakeholders in OHNS residency training and present a valid, useful, effective, and more accessible alternative to current training practices.

2. Background

2.1 Diagnostic nasal endoscopy

Nasal endoscopy has become routine practice in the examination and assessment of nasal function and the treatment of nasal and sinus related pathologies.[1,12] In the chapter "Office Rhinology and Surgical Biomaterials" in the text Rhinology – Diseases of the Nose, Sinuses, and Skull Base,[10] Richard R. Orlandi and Peter H. Hwang describe nasal endoscopy as a central component of several routine diagnostic rhinology examinations performed in the clinic. The following description of the procedure is based on Richard R. Orlandi and Peter H Hwang's description, as well as current practices at the University of Alberta Hospital in Edmonton, Canada.[13]

The goal of diagnostic nasal endoscopy is to provide a thorough examination of the nasal cavities to identify and assess the inflammatory state of the mucosa, potential secretions, and abnormalities such as polyps or other lesions. The standard equipment used is rigid 3-4mm diameter scopes with 0 or 30 degree lenses. The angle of the scope determines structures and areas that can be visualized. Rigid scopes are preferred over flexible scopes as they provide better image quality and can be maneuvered with only one hand, freeing up the other to handle surgical instruments such as suction cannulas, forceps, or swabs. Diagnostic nasal endoscopy is typically performed in three passes, using a technique often referred to as the 'three-pass' technique. During the first pass, the scope is passed from anterior to posterior along the floor of the nasal cavity to the nasopharynx. This pass examines the state of the mucosa, inferior turbinate, inferior meatus and Hasner's valve, inferior portion the nasal septum, nasopharynx, Eustachian tube orifice, and the vomeronasal organ. During the second pass, the scope is passed anterior to posterior between the inferior and the middle turbinate. This pass examines the

middle turbinate, inferior portion of the middle meatus, Fonatelles, sphenopalatine area, sphenoethmoidal recess, superior turbinate, superior meatus, and the sphenoid ostium. The third pass is performed as the scope is withdrawn following the second pass by rolling the scope under the middle turbinate into the middle meatus. This pass examines the middle meatus, Bulla Ethmoidalis, Hiatus Semilunaris, unicinate process, and the frontal recess area.

Before trainees can begin to identify and assess pathology, they need to learn how to maneuver the scope and handle surgical instruments. The goal of training is to develop an organized and reproducible technique that ensures a thorough examination while maintaining patient safety and comfort.[13] Good technical skills in nasal endoscopy are also foundational for the ability to perform more complex procedures in sinus surgery and skull base surgeries.[3] Thus, both routine clinical rhinology examinations and more complex surgical procedures require highly developed technical skills in diagnostic nasal endoscopy and a good familiarity with the anatomy of the nose and nasal cavities. These skills can only be developed through hours of repeated practice and clinical experience.[4]

2.2 Surgical training in Otolaryngology - Head and Neck Surgery

Diagnostic nasal endoscopy relies on good coordination and integration of cognitive, clinical, and technical skills. The definitions of these skills vary, but for the focus of this paper, cognitive, clinical and technical skills in nasal endoscopy have been defined as follows:

Cognitive and clinical skills in surgery include the ability to identify and assess anatomy and pathology, and the ability to make procedural and treatment decisions based on those assessments.[3] OHNS surgeons begin to develop their cognitive and clinical skills in medical school through instruction, observation and self-study. These skills are further fostered during

residency through bedside teaching and clinic as well as operating room cases. These acquired skills continue to develop and improve with practice and experience throughout a surgeon's career. Technical skills in surgery includes visual, perceptual, and psychomotor (motor) skills.[14] In diagnostic nasal endoscopy, these skills involve manipulating the scope efficiently while maintaining a good view of the field of interest, handling instruments, and having a good ergonomic set-up while maintaining patient comfort.[3] Technical skills in surgery are often assessed by parameters such as respect for tissue, economy of time and motion, dexterity of instrument handling, knowledge of instruments, and flow of operation.[15] The technical skills required to perform diagnostic nasal endoscopy are typically developed during residency,[3] although some initial learning may take place in medical school during elective clinical placements.

Although studies have shown that some trainees might have a certain level of innate technical ability,[16] technical skills are considered learned skills and can only be developed and improved with repeated practice. According to Fitts and Posner's three-stage theory of motor skill acquisition, which is a model that is widely recognized in surgical skills literature, the development of motor skills passes through three stages: cognition stage, integration stage, and automation stage.[17] In the cognition stage, the trainee must cognitively process and understand the mechanics of the skill. In diagnostic nasal endoscopy, this means that the trainee has to think about how to orient the scope according to the camera angle to reveal certain structures, or to avoid causing pain to the patient. At this stage, the procedure will often be performed in erratic, distinct steps. With gradual, repeated practice, the trainee reaches the integration stage. At this stage, the trainee understands the skill and can perform the procedure in a more fluid manner with fewer interruptions. In the final automation stage, the trainee no longer has to think about

how to perform the procedure or any single step, and their performance is continuous, fluid and adaptive. At this stage, the trainee can start thinking about other aspects of the procedure, such as assessing conditions or pathologies, which is the goal of the procedure.

The demand for technical proficiency during diagnostic nasal endoscopy is particularly high.[3] Navigating the endoscope and different instruments through the narrow nasal cavity, with proximity to many sensitive and vital structures, is a technically challenging task. While navigating the scope with one hand, the OHNS surgeon has to manipulate surgical instruments with the other. This requires that they develop a level of ambidexterity as both tasks demand equal control and precision. Scope navigation is further complicated by variations in scope sizes and camera angles (Erin Wright, oral communication, 2014). It has therefore been recommended that OHNS surgeons undergo rigorous training to develop the necessary skills to perform diagnostic nasal endoscopy and more complex endoscopic sinus surgery procedures.[18] In Canada, it is typically expected that OHNS residents can perform diagnostic nasal endoscopy examinations and accurately interpret findings using both rigid and flexible scopes by year 3 (PGY 3) of their 5 year residency program.[19]

OHNS residents traditionally develop their surgical skills through active participation in the clinic and the OR.[20] This model of training is referred to as the apprenticeship model, where the resident first observes the attending surgeon and then performs the procedure on the patient, under careful supervision. As they progress, the residents develop the ability and autonomy to take on more complex tasks with less supervision. The apprenticeship model has dominated surgical training since Dr. William Halsted and Dr. William Osler first helped formalize and structure surgical training at the turn of the 20th century.[20] Most current practitioners have trained under the apprenticeship model, and it is still considered a very effective way for residents to

develop technical, cognitive, and clinical skills in surgery by exposing them first hand to a large number of patients presenting with a wide variety of pathologies and patient factors.[20]

In addition to clinic and OR training, residents will usually take part in organized cadaver courses during their residency. The number of cadaver courses the residents are offered varies between institutions, and depends on factors such as cost, access, and availability. In OHNS residency programs in Canada, residents will typically participate in 1 or 2 cadaver courses during their 5-year residency (Erin Wright, oral communication, 2014). These cadaver courses are considered a valuable opportunity for residents to practice their surgical skills in a risk-free environment, without concern for patient safety.[21]

2.3. Challenges to surgical training in Otolaryngology - Head and Neck Surgery

2.3.1 Residency work week restrictions

In recent years, there has been an increased concern that changes in surgical residency programs have decreased residents' access to hands on learning.[3,4] This concern can largely be attributed to the reduction in residency duty hours over the past two decades. In 2003, the U.S restricted resident duty hours to 80hrs per week, while in France, the duty hours have been reduced to 52.5 hours per week.[4,7,22] Canada has instituted similar restrictions to the U.S, although these restrictions are regulated by union based contracts and vary between provinces.[22] Before the workweek restriction was instituted, many residents worked over 100 hours per week. This was felt to provide residents with the broad and comprehensive experience needed to develop a high level of surgical proficiency.[7] According to Matthew P. Thomas,[21] it has been estimated that surgeons require 30,000 hours of training under the traditional apprenticeship model to reach a high level of surgical proficiency, but that in some places, current residents only receive a total

of 6000 hours of training after the implementation of the duty hour restrictions. The restricted workweek was implemented in part to prevent fatigue and sleep deprivation in resident surgeons that was believed to increase the risk of medical errors.[3,22] However, a retrospective study evaluating the impact of the workweek restrictions in an OHNS residency program found that the new hour regulations did not improve patient care.[23] It has also been suggested that the efforts to increase efficiency in healthcare has limited the time faculty members and clinical preceptors can dedicate to teaching.[4] The reduction in time resources for both the residents and the faculty impedes the traditional apprenticeship model, that inherently relies on exposure to large patient volumes through a significant amount of time spent under close supervision and mentorship in the clinic and the OR.[3,4]

2.3.2 Patient safety

The exclusive reliance on intraoperative training has also raised concerns for patient safety.[24] Several studies have shown that complication rates are higher among trainees during endoscopic sinus surgeries.[25] In surgery in general, complication rates have even been shown to increase from first year (PGY 1) to second year (PGY 2) residency. This further suggests that strictly relying on intraoperative and clinical practice is not enough.[26] Although OHNS surgeons spend the majority of their time in the clinic, there are no studies that have looked at patient safety during diagnostic nasal endoscopy when performed by inexperienced residents. During these examinations, the challenge lies in navigating the scope and instruments through the nose to achieve a thorough examination, without causing too much discomfort to the patient. Although patients will typically receive topical anesthetics and decongestant to increase comfort, they will still feel pain if the scope or other instruments are rubbed against sensitive areas, particularly in

the nasal septum and the turbinates. Thus, it requires good technical proficiency on behalf of the resident to ensure the safety and comfort of the patient even during routine examinations.

2.3.4 Objective assessment of surgical competency

Recently, residency training has been criticized for its lack of structured objective assessment of surgical competency.[27] The nature of the apprentice-supervisor relationship leaves most of the evaluation up to the subjective assessment of the individual supervisor.[15,28] Until more recently, the lack of structured objective assessment was also a result of the paucity of a shared, standardized educational framework in residency programs with clearly defined competency objectives that skills could be assessed against. In the paper "Canadian Otolaryngology - Head and Neck Surgery Clerkship Curricula: Evolving Toward Tomorrow's Learners,"[6] Kate Kelly et al. point out that despite significant advancements in medicine and our understanding of education, the framework for medical education has remained much the same over the past century. This has become increasingly apparent with the scientific and technological strides that have affected how medicine is practiced, and has subsequently led to a call for educational reform. Kelly et al. cite a report published by the Carnegie Foundation in 2004, where the first of four recommendations to reform medical education was to "[s]tandardize learning outcomes and individualize learning processes to allow for the integration of new technologies, such as simulation, on-line learning, and mobile learning resources." In a similar effort to update and reform medical education, The Royal College of Physicians and Surgeons of Canada introduced, in the 1990s, the CanMEDS Physician Competency Framework. This is a standardized, outcomes oriented framework that focuses on the abilities required in doctors to ensure better patient outcomes. This framework has also become the leading framework for medical education reform in many other countries.[26] The CanMEDS framework organizes the expected

competencies according to a doctor's defined roles as a Medical Expert, Collaborator, Communicator, Manager/Leader, Health advocate, Scholar, and Professional. In 2015, the RCPSC introduced the Competence by Design (CBD) training framework as a part of the CanMEDS initiative.[26,29] The CBD framework consists of a series of specific milestones related to the roles defined in the CanMEDS framework. For example, some of the expected competency milestones for residents under the Medical Expert role include the ability to perform a procedure under direct supervision as well as appropriately set-up and position patients in preparation for the procedure. The CBD is part of the effort to move away from training and assessing surgeons strictly on the basis of rotations and time, towards a model where the trainees are assessed on the basis of achievement of shared and defined milestones of competence. The introduction of a more standardized competency-based framework for medical training has also resulted in a need for more standardized assessment instruments. Currently, the most widely recognized and validated instrument is the Objective Structured Assessment of Technical Skills (OSATS), a global rating scale instrument used to objectively assess technical proficiency in surgery, developed by the University of Toronto in Ontario, Canda.[15]

2.4 Surgical simulation in Otolaryngology - Head and Neck Surgery training

As a result of the challenges to surgical residency programs, current literature is calling for alternatives or supplements to the apprenticeship model of training and the exclusive reliance on live patient training.[6,8,20,22,24,26,29-32] Surgical simulation has been gaining acceptance as an educationally sound alternative, and is increasingly implemented into surgical training programs. In its broadest definition, simulation refers to "any activity which aims to imitate a system or environment with the aim of assessing, informing and modifying skills and behaviours."[33]

Simulation based training is not a new or novel concept, as demonstrated by its long established role in aviation, military, and space flight training.[8] Various forms of simulation based training has also been a part of medical training since the introduction of the first mannequins in the 1960s, used for mouth-to-mouth ventilation training.[34] It is not until more recently that simulation training has been proposed as a way to address some of the challenges to current training practices in surgery. This, together with advances in computing and manufacturing technologies, has helped accelerate the research and development in this area.

Simulators are valued for their ability to allow trainees to develop their surgical skills in a safe environment without concern for patient safety.[4,8,11,21,31,33,35–38] The goal of simulation training is to provide trainees with more hands-on training that allows them to develop their skills to a level of automaticity before they go on to practice on patients. This in turn can help accelerate learning and improve patient safety in the clinic and the OR. Simulation training can also be used to train residents to manage highly complex and rare surgical cases that trainees are unlikely to come across or have access to during their residency rotations.[21] Additionally, it is argued that if trainees develop some basic skills on a simulator, the valuable time spent with real patients in the clinic and the OR can be used more effectively and efficiently to focus on more complex learning.[17]

Simulation training has also been proposed as a reliable system for more objective assessment of surgical competency.[26,27] Simulation technology can function as an assessment tool in itself by collecting performance data and provide feedback.[8] While this is an obvious advantage of computer-based simulators, other types of simulation technologies have the potential to provide performance feedback as well. For example, a few studies have proposed the incorporation of force feedback in future iterations of endoscopic sinus surgery simulators to teach residents

respect for tissue and prevent unnecessary harm or discomfort to the patient.[39–41] Force feedback may be defined as the ability of a simulator to register how much force is applied during a procedure. Yamuchi et al.[39] developed a training system for endoscopic sinus surgery with an anatomical model that employed pressure sensors and force analysis (performance rating based on force feedback). The study argued that the standard metrics used to rate performance such as completion time and error ratio are not adequate in evaluating the quality of performance as a rapidly executed procedure is not necessarily a well performed one. The study concluded that force feedback is applicable to training nasal, bronchoscopic, angioscopic, and gastrointestinal surgeries.

2.4.1 Types of simulators in Otolaryngology - Head and Neck Surgery training

While the term simulation refers to a technique or a concept, the term simulator refers to the technology with which the simulated experience is delivered.[36] In surgical training, surgical simulators can refer to anything from low fidelity bench models to cadaveric models, through to fully immersive, high fidelity Virtual Reality (VR) systems.[21,38] Fidelity in this context refers to the realness of the simulation; in other words, to what level the simulator is able to duplicate the real patient scenario. Many simulators have been developed for endoscopic procedures, as this is considered a complicated surgical procedure that requires a high level of surgical proficiency.

Traditionally, human cadavers have been considered the "gold standard" alternative to live patient cases for developing surgical skills.[4] Cadavers provide a highly realistic simulation with almost identical anatomical relationships and tissue handling to that of live patients.[21] Cadaveric models have limited availability due to practical and ethical considerations of acquisition and disposal. There are also some concerns related to the exposure to infectious agents and formaldehyde present in cadavers that can pose a potential health hazard to the trainees.[4]

Animal models are used as an inexpensive and easily available alternative to cadaveric models. Lamb's heads have been found particularly useful in training basic nasal endoscopy skills as the nasal cavity is quite similar to that of humans.[42,43] The use of live animals also carries ethical issues and is prohibited in some countries such as the UK. There is also a lack of evidence to show that skills developed from training on animal models are transferrable to the clinic or OR.[21]

Bench models and box trainers have demonstrated both improvement of technical skills and transferability of skills to the real clinical scenario.[21,27,44] Bench models and box trainers typically refers to low-fidelity models made from readily available materials, with little to no anatomical accuracy.[21,27] They provide an affordable means for training psychomotor skills and instrument handling through the simulation of various tasks such as suturing and targeted injections.

Computer-based Virtual Reality (VR) simulation is currently the most widely cited simulation technology in surgical simulation literature.[11,44–46] Due to their programmability, VR simulators have infinite potential in simulating a wide range of pathologies and surgical procedures, and new developments of endoscopic sinus surgery simulators are frequently reported.[2,11] Virtual Reality refers to the recreation of an environment or an object as a computer generated image.[8] More advanced VR simulators can recreate high fidelity three-dimensional environments based on computerized tomography (CT) scans.[4] These simulators have the ability to simulate various procedures, pathologies, and complications. They can also function as an objective and reliable method for assessing skills by recording various performance data.[30] While the common criticism of VR simulators is the lack of tactile feedback, more recent developments have focused on the inclusion of haptic devices in the VR system.[3] Despite a significant reduction over the past decades, the cost of VR simulators remains high.[4] The most recognized and

validated VR system for nasal endoscopy and ESS training is the ES3 training system. The ES3 system is estimated to cost over 200,000 USD while the cheaper systems remain in the tens of thousands of dollars.[3,4] An additional limitation to VR simulators is that they are usually not portable and do not allow for the use of standard surgical instruments.

Anatomical models have been proposed as a more available alternative to cadaveric models and VR simulators.[1,5,39,47-48] Anatomical models have a long history in medical training and have been developed for many different applications, starting with the Resuci-Anne mannequin that was developed in the early 1960s for training mouth-to-mouth ventilation.[34] Anatomical models have the benefit of being portable and can be set up within a clinic or OR setting, allowing for the use of standard surgical equipment and instrumentation. In addition to providing a more realistic training scenario and better ability to provide tactile feedback, anatomical models can also have the added benefit of being reusable and non-deteriorating. A small number of high fidelity models for training endoscopic sinus surgery have been developed that show moderate to good anatomical accuracy and satisfactory tactile texture and quality. Notably, the models identified in the literature were endoscopic sinus surgery (ESS) simulators, intended to train more complex surgical procedures.[1,5,39,47-49]

2.5 Effectiveness and implementation of surgical simulation

There is now substantial evidence in the literature to demonstrate the effectiveness of simulation training in surgical skills development when added to the conventional curriculum.[9,20,22,42,43] While studies have been limited by the ability to effectively control for the intervention, surgical simulation training has been shown to accelerate learning, improve operative performance, reduce operative times, reduce operative errors, as well as increase patient comfort and staff productivity.[9] In 2012, David A. Cook[50] and colleagues published a meta-analysis on the

comparative effectiveness of technology-enhanced simulation versus other instructional methods. The authors compared results across several outcome and performance measures such as trainee satisfaction, knowledge, time, process, quality of the final product, behaviour, and effects on patient care. Effect sizes were small to moderate, although with high variability, across almost all measures. Statistically significant results were reported for satisfaction, knowledge, process skills, and product skills. Their results suggested that the effect of simulation training is higher for skills and behavioural outcomes, rather than knowledge outcomes. This supports the perception that the benefit of simulation training lies in providing hands-on practice.

Whereas previous literature was focused on the development and validation of different simulation technologies, more and more studies are now evaluating the effect of the implementation of comprehensive simulation curricula in both graduate and post-graduate training programs.[52,53] Similarly, there is an increased focus on establishing frameworks and strategies for successful implementation of simulation into training programs.[54–57] In the U.S, the Accreditation Council for Graduate Medical Education (ACGME) have mandated in the Program Requirements for Graduate Medical Education in General Surgery that "resources must include simulation and skills laboratories. These facilities must address acquisition and maintenance of skills with a competency-based method of evaluation."[58] In Canada, The Royal College of Physicians and Surgeons in Canada has not introduced such a mandate, although several Canadian institutions have established surgical simulation centres that have received Royal College accreditation.[59] Yet, despite significant progress, simulation training is still not widely implemented as a standard in surgical training. In the paper "Surgical Simulation in 2013: Why Is It Still Not the Standard in Surgical Training?"[9] Boris Zevin, Rajesh Aggarwal, and Teodor P. Grantcharov argue that better evidence of improved clinical outcomes and the cost-

effectiveness of surgical simulation is required to make simulation a mandatory part of surgical training.

2.6 Nasal endoscopy training at the University of Alberta, Edmonton, Canada

There is currently no set protocol for assessing nasal endoscopy skills in the OHNS residency program at the University of Alberta in Edmonton, Canada. Although the current curriculum is structured according to the CanMEDS framework outlined by the Royal College of Royal College of Physicians and Surgeons of Canada,[19] no specific protocol for assessing nasal endoscopy skills has been implemented. Diagnostic nasal endoscopy procedures, such as the "three-pass" technique, are typically taught under the apprenticeship model in the clinical or operative setting. Due to the same practical and ethical concerns that are expressed in the literature, there is a stated need for an alternative to this model that will allow residents to practice and assess their competency before they go on to improve skills on live patients.

2.7 Summary

The current model of surgical training is not considered as being adept in providing residents with the necessary training and feedback required to safely and properly foster the development of surgical skills required within an increasingly complex and more resource constrained environment. This has resulted in a call for education reform and the implementation of a more structured competency-based framework as well as alternatives to patient training for the acquisition of surgical skills. Surgical simulation has been proposed as a way for residents to gain more access to repeated practice, as well as a method for providing standardized, objective performance feedback. The efficacy of simulation training, especially with regards to skills training in surgery, is now well documented as a way of providing residents more access to safe,

repeated practice before they go on to practice on patients. In OHNS, diagnostic nasal endoscopy is a central skill required in everyday clinical practice. This procedure is a complex and technically demanding procedure and requires extensive, repeated practice. Despite a significant focus on the implementation of simulation technology in endoscopic sinus surgery, presently there are no practical alternatives available for the development of diagnostic nasal endoscopy skills other than live patient training. Thus, there is a need for a practical simulator that will allow residents to foster this skill in a safe and effective manner.

3. Perceptions of Surgical Simulation in Otolaryngology – Head and Neck Surgery Residency Training

3.1 Introduction

As presented in the previous chapter, surgical simulators are widely advocated as an educationally sound and ethical alternative to practicing surgical skills on live patients.[24] Notwithstanding, there has yet to be a widespread implementation of the technology in surgical residency programs. This is most likely due to limited availability and a lack of robust evidence to support its implementation into practice.[8] The goal of the present thesis project was to develop and validate a readily available simulator for training basic nasal endoscopy skills among junior residents in OHNS residency programs. To ensure its usefulness and implementation into practice it was necessary to understand the training needs and the perceptions of surgical simulation among experts and stakeholders in OHNS education. Organizing the theoretical and practical knowledge of experts in this way helped inform the design and development of the simulator and detect potential barriers to successful implementation. In addition, the present study makes a valuable qualitative contribution to the growing body of research in surgical simulation that can help further the advancements already taking place in this field.

3.2 Research objective

This study was conducted as the first of the three stages in the present research project that aims to address the need for a practical simulator for the development of basic nasal endoscopy skills in OHNS. The main objective of the study was to perform a training needs analysis (TNA) and to discover common perceptions of the use of surgical simulation in OHNS residency training by interviewing expert representatives from the field of OHNS using the Convergent Interview (CI)

technique. The information gathered from the study was used to inform the development of a new simulator for training basic nasal endoscopy skills in OHNS residency programs.

3.3 Background

Despite the wide acceptance of simulation training, there has yet to be a wide spread adoption of the technology in surgical residency programs.[60] As discussed in the previous chapter, this may be due to the lack of both validated and readily available simulators that combine the appropriate tasks and assessment tools for training desired skills, as well as a lack of studies measuring the clinical outcomes and cost-effectiveness of simulation training.[9] In addition, some authors suggest that the slow implementation can be attributed to a lack of consensus on methods regarding the development and validation of surgical simulators, grounded in a shared theoretical and methodological framework.[8,60]

In the article "Historical Review of Surgical Simulation—A Personal Perspective,"[61] Richard M. Satava presents the idea that it is about "a curriculum that incorporates the simulator." Satava argues that while much of the focus has been on the new opportunities that arise from the development of new and innovative simulation systems, the key factor for successful implementation is the simulator's ability to align with the curriculum. In other words, it is important to identify the learning goals that are outlined in the curriculum, with its related tasks and required skills, to create a simulator that is tailored to the curriculum. Thus, it is necessary to discuss with educators what the training needs are before a simulator is developed. This is supported by Schout et al. in the article "Validation and Implementation of Surgical Simulators: a Critical Review of Present, Past, and Future."[60] The article discusses some of the shortcomings of the current literature and future challenges to successful implementation of surgical simulators

into practice. To ensure a more successful bridging between research and practice, the authors recommend involving important stakeholders early in the process by performing training needs analysis (TNA) before the development of a simulator to ensure a more successful integration into the training program. The author describes the TNA phase as "concerned with organizing the existing theoretical and practical knowledge about the use of simulators with a focus on outlining training program requirements." It is further recommended that teachers, learners, educationalists and industrial designers be involved in the development and validation of the simulator. This study was considered a part of the TNA phase and involved educators and educationalists in forming a theoretical foundation for the development of the simulator, based on their knowledge, experience and position as gatekeepers and decision makers in OHNS residency programs. Industrial designers and trainees have been involved in the subsequent development and validation of the simulator.

3.4 Method

Experts in the field of OHNS were interviewed using the convergent interview (CI) technique. The execution and following description of the CI technique is primarily based on guidelines provided by Bob Dick[62] and Andreas M. Riege & Godwin Nair.[63] Additional resources have been cited accordingly. CI is an in-depth interview technique that allows researchers to quickly focus in on important issues in emerging research areas through a series of interviews. The CI technique is said to be helpful in new research areas where there is a lack of established methodologies or theories, or in research areas that show gaps in the literature.[7] The technique is most commonly used in areas such as organizational change and marketing,[65] but has more recently been utilized in qualitative health research[66,67] and in one example of Surgical Design and Simulation (SDS) research.[68] In the latter study, CI was found to be an effective tool in

understanding perceptions of SDS among surgeons as this was considered an important influence on the implementation of SDS into practice. The CI technique was chosen as an appropriate tool for the present study due to these findings as well as the similarity of the goals and scope with the SDS study. Both the present study and the SDS study involved an investigation of perceptions among experts in surgery regarding the implementation of new technology to improve practice. The SDS study suggested three areas of improvement based on their findings and assessment of the technique. The first was to formulate a question that would encourage the participants to refer more to their own experience with the technology. This suggestion was used to frame the opening question for the present study. The second suggestion was to broaden the selection of participants. This suggestion was not actively implemented in the present study due to the limited scope and availability of participants. Although the majority of the participants were recruited from within Edmonton, Alberta, Canada, they do represent a broader range of experience and training background. The third suggestion was to use a pair of interviewers instead of one to decrease interviewer bias and strengthen the analysis. This suggestion was not implemented in the present study due to the time and training required to ensure consistency and inter-rater reliability between two interviewers.

3.4.1 Sampling

With the CI technique, the sampling technique is purposive rather than random, and the sample size is driven by the data and the number of participants required to reach stability. Stability is reached when a stable pattern of themes emerges, and no new themes are raised in the interviews. Some studies have reported reaching stability after 5-6 interviews.[65] The participants were recruited through convenience sampling using the snowball technique where the first interviewee, who is considered the foremost representative of the field, was asked to suggest the

remaining participants for the study. The snowballing technique is considered appropriate when the focus is on a small, specialized population who are knowledgeable about the topic.[8] Initial contact was made via email with the help of the first interviewee. This person had better knowledge of potential participants and could more easily make contact through preexisting relationships. The participants were asked to contact the researcher voluntarily if they were available and interested in participating. All participants were free to withdraw from the study at any time up until the end of their interview by canceling their interview appointment or requesting that the recorded data was deleted. Data withdrawal could only be done up until the end of the interview as the data was analyzed immediately following each interview. Once data had been analyzed the participants could no longer withdraw. Data withdrawal at this point would impede the overall process of CI, where the structure of one interview is determined by the outcomes of the preceding interviews.

3.4.2 Procedure

The CI process is an inductive process where the first interview starts off completely unstructured, allowing the interviewee to share his or her thoughts, experiences, and opinions freely without being curbed by a set of interviewer questions. This way, important and sometimes unexpected themes can emerge from the interview organically and with minimal interviewer bias. After the first interview, the researcher develops a tentative interpretation of the data and lists central themes that emerged. The following interviews start off in the same unstructured manner, but as the interview progresses the interviewer use probing questions to see if there is convergence or divergence on themes that emerged in the preceding interviews. The interview process ends when stability is reached; when there is almost complete agreement on the different themes and potential disagreements can be explained, and no new themes are

emerging from the interviews.

With the CI technique the goal is to get the interviewee to talk freely and for as long as possible, about 1 hour. Hence, a great deal of consideration is put into the opening question asked by the interviewer that will encourage the interviewee to talk for an extended period of time. The opening question for the present study was "Can you tell me about your experience with surgical simulation in surgical training?" This question was chosen to encourage the interviewee to refer to his or her own experience, and not only to their professional opinion or academic knowledge.[68] The questions for the successive interviews are constructed based on the themes that emerge in the preceding interviews. The interviewer keeps the interviewee talking by using probe questions such as "Why, or why not?" or "Can you give me an example?" or by repeating back a key word or phrase. Only at the end of the interview, the interviewer can ask specific questions to help clarify concepts or bring up relevant themes from previous interviews. To conclude the interview, the interviewer asks the interviewee to summarize some of the most important themes that emerged during the interview. This is done to help confirm or clarify the interpretations made by the interviewer and ensure the accuracy of the analysis.

3.4.3 Analysis

After each interview, the interviewer performs a preliminary interpretation of the data in note form, highlighting the most important themes from the interview. This interpretation is based on the interview just completed as well as preceding interviews. The interpretation gets more involved as the interviews compile. The interviewer looks for the reoccurrence of themes, and agreements or disagreements on those themes throughout the interviews. The interviewer also looks for possible explanations in the event of disagreements. The interviewer repeats the interview and analysis process until stability is reached. For the present study, stability was

considered reached when two succeeding interviews added no significant information to the data. After the final interview is completed, the interviewer lists the most important themes and indicates if each participant is in agreement, disagreement, or if the interviewee had no opinion on the topic or it was never raised during the interview. The findings are then organized in a table with corresponding numbers of agreements, disagreements, and neither. These numbers can also be reported as a percentage sum.[61]

The themes that demonstrate high agreement are given most weight in forming conclusions from the data. Disagreements are also considered important as they add some dimension to the data and discussion and encourage a deeper exploration of some topics. Reporting disagreements is also an important aspect of preventing bias in the analysis and report. Direct quotes from the interviews are used in the report to illustrate and explain certain themes and to give credibility to the analysis.

3.4.4 Ethical considerations

There were both colleague and professor-student relationships between the researchers and the participants due to the small size of the population. To avoid undue pressure, it was made clear through informed consent (Appendix 3.1) that the study was completely voluntary. The participants were free to withdraw from the study up until the end of the interview (see Sampling). The participant's name, surname and email address were collected, as it was necessary for scheduling purposes and to build rapport with the participant during the interview. Their occupation, position, and years of experience were also collected as the main inclusion criteria for this study. Directly identifying information (name, surname and email) was removed upon completion of the data collection to preserve the participants anonymity. This was done through coding where the participant's identity was replaced with a letter (e.g. participant A,

participant B). Information about occupation, position and years of experience was retained to demonstrate the representativeness of the sample in the report of the study findings. There is a chance that this information can indirectly identify the participants in the study and the participants were made aware of this before consenting to participate in the study. Only members of the research team have knowledge of the participants' identity and at no point during or after the study have direct identifiers of the participants and the outcomes of their interviews been reported together.

Overall, the study was considered to be of minimal risk to the participants and did not subject them to any harm beyond what they are subjected to in their everyday professional occupation. Ethics approval was obtained from the University of Alberta Human Research Ethics Board, Pro00046487, May 28, 2014.

3.5 Results

Six experts in OHNS were recruited and interviewed. The interviewees' surgical experience ranged from 6 to 17 years. The data collection was concluded after the sixth interview when stability was reached. The time and location of the interviews was scheduled at the interviewees' convenience. A tape recorder was used to record the interviews to allow the interviewer to be more engaged with the interviewee. Recording the interviews also helped increase the accuracy of the data collection, allowed the researcher to use triangulation in the analysis by replaying the data, and maintained direct quotes from the interviews.[63] Before the interview started, the interviewer gave a brief introduction of the topic and the objectives of the study. The interviewee was also asked to read and sign an informed consent form (Appendix 3.1).

The interviews lasted between 25 to 70 minutes in length, depending on the interviewee's time availability. The opening question for the interviews was: "Can you tell me about your experience with surgical simulation in surgical training?" Only a few of the participants had any direct experience with simulation training other than cadaver or animal courses. Those who had experience with artificial or technology enhanced surgical simulators had mainly used them in a research context. The audio-recorded interviews were reviewed and transcribed in note format, and the thematic analysis was performed. Throughout the interviews, there were nine central themes that emerged that the majority of the interviewees agreed upon. A theme was considered important when it was raised by the majority of the participants (4/6). When there were disagreements, the interviewer was able to find explanations for those. Table 1 lists the nine themes and the corresponding level of agreements and disagreements, as well as the number of interviews where the theme was not raised, or the interviewee did not have an opinion on the matter (n/a). Agreement and disagreement on the various themes according to each participant is presented in Table 2. There was full agreement on theme 2 and 8. Disagreements were found on theme 1, 4, and 7.

Table 1: Central themes extracted from the interviews regarding the needs and perceptions of surgical simulation in OHNS residency

Theme	Agree	Disagree	N/A
1. Simulation training can accelerate learning in nasal endoscopy.	5/6	1/6	
2. Simulation can be a good supplement to current training practices.	6/6		
3. The value of simulation training depends on type and application.	4/6		2/6
4. Simulation training can have the most impact in early stages of learning during the development of technical skills.	5/6	1/6	
5. Introduction of simulation needs clearly defined objectives and outcome expectations to be worthwhile.	5/6		1/6
6. Challenges to the traditional model of surgical training is increasing the need for simulation training.	4/6		2/6
7. Patient factors and feedback is important for the transferability of skills to the real, clinical scenario.	4/6	1/6	1/6
8. Cadaver training is the current gold standard alternative to patient training, but is limited by cost, availability, and access.	6/6		
9. Computer based simulation has great potential, but is limited by cost and the lack of haptic feedback, tool handling and patient factors.	4/6		2/6

Table 2: Agreement and disagreement on central themes according to participant

A=agree, D=disagree N/A=no opinion on the topic or topic was not raised

	Participant					
Theme	**A**	**B**	**C**	**D**	**E**	**F**
1	A	D	A	A	A	A
2	A	A	A	A	A	A
3	N/A	A	A	A	N/A	A
4	A	D	A	A	A	A
5	A	N/A	A	A	A	A
6	A	N/A	N/A	A	A	A
7	A	A	A	A	N/A	D
8	A	A	A	A	A	A
9	A	A	N/A	A	N/A	A

3.5.1 Results explained

1. Simulation training can accelerate learning in nasal endoscopy.

The majority of the interviewees (5/6) believed that simulation training can help accelerate learning. Herein, they referred to the ability for residents to have more access to repeated practice so that they can develop some of their skills faster than what is currently possible within the time spent in the clinic or the operating room (OR). Simulation training was described as a way for residents to overcome challenges earlier on and develop a level of comfort so that they can get more out of patient training. One interviewee described it as allowing residents to develop skills to a minimum benchmark of competence before they train on patients, and that "If we can get them there faster, we can take them further." One subject disagreed on this topic. This disagreement can be explained by divergent views on how long it takes to become technically proficient in nasal endoscopy. The other interviewees estimated that it takes a resident 15-25

procedures to reach a level of technical competency that will allow them to perform nasal endoscopy with minimal supervision, and up to 100 procedures to become fully proficient. This interviewee suggested that only 2 procedures is necessary to develop the ability to navigate the scope without receiving directions. As such, the interviewee did not feel that simulation training is necessary or justified for training this procedure.

2. Simulation can be a good supplement to current training practices.

All of the participants (6/6) agreed that simulation training can be a supplement to, and not a replacement of, current training practices. This was mainly explained by the sentiment that simulators are limited when it comes to simulating the endless variations in pathology, anatomy, and other patient factors. The opinion was that the majority of learning is best done in the real scenario, as there is currently no alternative that is good enough to fully replace the real thing, while still being affordable and practical.

3. The value of simulation training depends on type and application.

Most of the interviewees (4/6) described the value of simulation training as being dependent on the type of simulator and its application. The interviewees suggested that some procedures are not worthwhile creating a simulator for if they are rare, easy and safe to perform on patients, or they are better learned in vivo due to the high variability between cases. The interviewees also agreed that there is not one technology or system that will be a best fit for all, and that there is a place for many different systems ranging in fidelity and cost, depending on their application.

4. Simulation training can have the most impact in early stages of learning and in the development of technical skills.

When describing where in the learning curve simulation training can have the most impact, the majority of the interviewees (5/6) agreed that simulation has the most potential in the early stages of learning. Specifically, the interviewees believed that simulation is most applicable to

early technical skills training. The explanation for this was that cognitive and procedural skill development is more complex and includes becoming familiar with the great variety of pathologies and patient factors that a simulator does not have ability to simulate. Furthermore, the interviewees believed that cognitive and procedural skill development can only be fostered after the trainee has learned how to manipulate the scope and other instruments. As one interviewee explained, simulation training is most useful in early training unless you have a simulator that can evolve, as cognitive and procedural skills are developed throughout thousands of cases. Simulation was described as a way for residents to practice repeatedly until their technical skills, such as scope navigation and tool handling, becomes automatic and effortless. This way, the resident will develop the ability and confidence to perform the procedure in a more safe and gentle manner when they perform the procedure on the patient. One interviewee stated that: "Simulation can play a role on all levels, but in its simplest generation, it can have the highest benefit, or bang-for-your-buck, early on." One interviewee disagreed with this notion, and explained that simulation training could play a more important role in training highly complex surgical procedures where there is no room for error. The interviewee believed that for these types of cases, simulation training could have the advantage of providing safer training and precise real-time feedback, and suggested that this is where the research focus in surgical simulation should be.

5. Introduction of simulation needs clearly defined objectives and outcome expectations to be worthwhile.

Almost all of the interviewees (5/6) mentioned the importance of having clearly defined objectives and expectations before introducing simulation into the curriculum. The interviewees mentioned the importance of identifying the needs and the potential benefits to justify the upfront cost associated with simulation technology. Furthermore, it is important to not only address the

reasons why simulation technology should be implemented, but also determine how to evaluate the success of the implementation. One interviewee felt that these issues have not been sufficiently addressed in the current literature, and without doing so; simulation training stands the risk of being an unfounded attempt to reinvent an already working system.

6. Challenges to the traditional model of surgical training are increasing the need for simulation training.

Many of the interviewees (4/6) viewed simulation training as an imperative to solve some of the challenges to the traditional apprenticeship model of surgical training. They pointed to diminishing case volumes due to a reduction in the demand for surgery and duty hour restrictions that has lead to a reduction in the residents' access to hands on training. One interviewee also viewed simulation training as an inevitable requirement under the current shift towards a competency-based framework for surgical training. The interviewee believed that it is therefore important to invest time and resources towards it: "because of [this shift] there will be a demand for [simulation training], so we will have to make it accessible." Although they did not explicitly express disagreement with this theme, two of the participants did not feel that the current model of surgical training in nasal endoscopy and endoscopic sinus surgery needs reform. One of the interviewees explained that they saw few circumstances where the technology is needed in OHNS, but that "I may be biased because I trained without simulators."

7. Patient factors and feedback is important for the transferability of skills to the real, clinical scenario.

Most of the interviewees (4/6) agreed that patient factors, such as anatomical fidelity, and some form of performance feedback is necessary for the transferability of skills from the simulated scenario to the real patient scenario. Herein was mentioned the importance of a simulator having some resemblance to the actual anatomy of the nasal cavity, as well as allowing for an ergonomic set-up that is similar to the clinical or OR setting. One interviewee mentioned how the

positioning of the patients' head and the orientation of the patient relative to the resident are important factors that need to be considered when trainees develop their scoping technique. Additionally, some of the interviewees suggested that it would be valuable if a simulator provided real-time feedback if errors were made, similar to how an awake patient would express pain or discomfort. This was suggested as a way to enhance the realness of the simulation. One interviewee disagreed that fidelity is central for the transferability of skills, and believed that the importance of fidelity is relative to what you are trying to teach. The interviewee suggested that even something crude could be efficient to allow new trainees to learn how to handle the scope and instruments without looking at their hands.

8. Cadaver training is the current gold standard alternative to patient training, but is limited by cost, availability, and access.

All of the interviewees referred to cadaver training as the current gold-standard alternative to live patient training. Cadaver training is recognized for its high level of fidelity and realness, and one interviewee felt that there are currently no simulator models that can replace cadaver models. All of the interviewees agreed that cadavers are limited based on factors such as limited access and availability, high cost, ethical and practical restrictions, deterioration, as well as a lack of haemorrhage and feedback. A few of the interviewees mentioned that while more access to cadaver training would be ideal, an artificial simulator could be a good alternative if it was cheaper and more available.

9. Computer based simulation has great potential, but is limited by cost and the lack of haptic feedback, tool handling and patient factors.

Most of the interviewees mentioned computer based simulation, such as Virtual Reality simulators, as having the greatest potential in simulating both high fidelity anatomy as well as the wide variety of pathologies and patient factors. These simulators were viewed as being advantageous to other types of simulators due to their programmability and modification

possibilities. The interviewees saw computer based simulation as being limited mainly by cost, lack of haptic feedback, and the inability to simulate some key technical requirements such as ergonomics of the set-up, positioning of the patient head and body, positioning of the scope, and instrument handling. One participant cited having some research experience related to virtual reality simulation. The interviewee observed that that the simulator did not allow for positioning of the patients head or positioning of tools and felt that "after having gone through that, in some cases the best simulator is a low fidelity that allows you to do all of that."

3.7 Discussion

The findings from these interviews reflect to a great extent the current literature on surgical simulation training. As presented in the previous chapter, simulation training is an effective way to accelerate learning and improve performance, especially during hands-on technical training.[9,50,20,22,42,43] Yet, two of the interviewees expressed doubt about the effectiveness and usefulness of simulation training. Both interviewees shared the opinion that the current model of surgical training works, and that there is not sufficient evidence to show that an intervention such as simulation technology is necessary and effective. They were questioning why simulation training was needed for training nasal endoscopy and sinus surgery, and one suggested that the current focus on simulation training lacks merit. As presented in the previous chapter, the current literature on the topic presents a number of issues with the traditional model of surgical training. Error rates are higher among trainees during endoscopic sinus surgery.[25] Additionally, the access to hands-on training is diminishing. This has raised concerns for the quality of learning and patient safety.[3,4] Indeed, the literature argues that simulation training is both needed and effective. A possible explanation for the incongruence between the interviewees' perceptions and the evidence in the literature is the concept of self-justification as described by behavioural

psychologists Elliot Aronson and Carol Tavris in the text "Mistakes were made, but not by me."[69] The authors describe a phenomenon that often occurs when physicians have to face new knowledge that forces them to accept that their former way of doing things were wrong. To illustrate the concept they use the Semmelwiess dilemma; when the 19th century physician Ignac Semmelweiss' discovered that making his students wash their hands before delivering babies rapidly reduced the rates of childbed fever, his colleagues refused to accept the discovery despite the concrete evidence of fewer deaths. Due to the human need for self-justification, they did not want to admit to being the cause of death to many women under their care, and chose to refuse Semmellweiss and his discovery. According to the authors, although the practice of medicine has evolved since then, the need for self-justification has prevailed. To admit that the current model of surgical training is not effective or safe would coincidently force the interviewees, as educators, to admit that mistakes can happen or that patients are unsafe on their watch. Some physicians may not be willing to admit this, which will affect their willingness to accept change and conform to new practices.

Another possible explanation for the incongruence between the literature and the interviewees' personal opinion is that the interviewees did not have knowledge of the latest evidence. Or, a more likely explanation was presented by one of the interviewees who explained that without having observed simulation in a successful application first hand, it was hard to fully embrace it. In fact, the study revealed that all the participants had very limited experience with simulation training in everyday teaching practice. It can therefore be assumed that the interviewees' opinions were primarily based on evidence presented in the literature and academic knowledge, and not personal experience. This illustrates that there is a significant gap between research and practice. As presented previously, this gap can be attributed to factors such as a lack of available

alternatives, a lack of literature looking at clinical outcomes and cost-effectiveness, as well as a lack of shared frameworks for the validation and implementation of simulation technology.

Although not a central theme, the issue of cost was raised by several of the participants as an important factor when assessing the value and availability of alternatives to patient training. It was presented as a significant limitation to cadaver training and currently available virtual reality systems. One interviewee explained that residency programs measure their budgets in the thousands to tens of thousands, not hundreds of thousands. This is important to keep in mind when defining what is accessible. Many of the currently available and most recognized endoscopic sinus surgery systems are estimated to cost tens to hundreds of thousands of dollars and might not be considered accessible. This can create a paradoxical situation where residency programs are prevented from investing in the technology, which in turn prevents better investigation into clinical outcomes and cost-effectiveness to further support the implementation of the technology into practice.

3.6 Conclusion

The main objective of the present study was to perform a training needs analysis and to discover common perceptions among important stakeholders of the use of surgical simulation in OHNS residency training. This is considered and important step in the development of simulation technology to ensure its usefulness and implementation into practice. Table 3 lists some of the key design considerations for a simulator that can be derived from the needs and perceptions expressed by the interviewees. Each design consideration is further discussed in the next chapter. Overall, the study revealed some important factors that helped inform and justify the development of the simulator. The study revealed that the general perception of surgical simulation is positive, and that there is a general agreement that simulation training can be a

useful and effective supplement to current training practice. Specifically, the majority of the interviewees believed the greatest training need and potential for simulation training is in the early stages of technical skills development. The interviewees saw simulation training as a way for residents to acquire technical skills such as scope navigation and tool handling before they go on to perform nasal endoscopy on patients. The interviewees also expressed that the fidelity of the simulation is important, and that a simulator needs to be able to simulate patient factors and ergonomic factors for skills to be transferrable to the clinic. Simulation training was also considered to contribute to better use of the time in the clinic and OR with more time dedicated to higher-level learning. These views were based on the perception that simulation training can help accelerate learning by providing residents with more access to hands-on training that is diminishing under the current training model due to time and resource restrictions. The study also revealed that there is some resistance to the introduction of simulation training. This resistance can largely be explained by diverging views on the length of learning curves, the belief that the utility and effectiveness of simulation training lacks supporting evidence, and biases from personal training experience and teaching practice.

Another significant finding from this study was that the interviewees had very limited experience with simulation training. This suggests that their opinions were primarily based on academic knowledge and not personal experience. This shows that there is a gap between research and practice and that more work needs to be done to develop available alternatives and establish and disseminate supporting evidence to help increase the implementation of surgical simulation into practice.

Table 3: Key design considerations derived from the central themes

Design consideration	Central theme	Comment
Cost	5, 8 & 9	The model needs to be cost-effective and present a more available alternative to existing simulation modalities.
Fidelity	7	The model needs to have good fidelity to ensure transferability.
Feedback	7	The model needs to be able to provide feedback to enhance the fidelity of the training experience.
Adaptability	3 & 7	A model should be adaptable to simulate different patient factors and pathologies enhance the fidelity of the training experience.
Generalizability	4	The simulator needs to be simple enough to be generalizable to the needs of early technical skills training and to allow for standard equipment and instrumentation.

3.7 Limitations

There are some limitations to this study that should be disclosed. One of the interviews lasted only 25 minutes due to the limited time the interviewee had available, while the rest of the interviews ranged from 45-70 minutes in length. Although it is not apparent that there were any losses in the data collection due to the shortness of this interview and most themes were covered in this time, Dick[62] and Riege & Nair[63] recommend that the interviews last 1 hour or more to ensure a comprehensive and rich data collection. A second limitation is that one of the interviews was conducted via phone. In a study comparing qualitative interviews conducted via phone versus face-to-face, it was found that phone interviews were generally shorter and more dominated by the interviewer due to the interviewee's tendency to provide less detail and elaboration.[70] Although it is not possible for the researcher to know whether the data from the phone interview would have been richer had it been conducted face-to-face, it should be considered a limiting factor in view of these findings. A final limitation to this study is the limited experience of the researcher in conducting qualitative interviews. Although the

researcher spent time practicing the methodology and rigorously followed the guidelines provided by Dick[62] and Riege & Nair,[63] the researcher recognizes that more experience and training in conducting interviews using the CI technique would have given more reliability to the data collection and analysis.

4. Design and fabrication

4.1 Introduction

The aim of the present research project was to address the need for a practical simulator for the development of basic nasal endoscopy skills in OHNS residency programs. This chapter will discuss the second stage of the project which involved the design and development of a simulator model based on the needs stated in the literature and by experts and stakeholders in OHNS as presented in the previous two chapters. Some of the key considerations in the development of the simulator were: cost, fidelity, objective assessment, adaptability, and generalizability. The simulator went through several rounds of prototyping and troubleshooting before arriving at a final design. The key considerations, the design process, as well as the technical and material considerations are presented in this chapter. The simulator was developed with materials, equipment, and personnel from the Institute for Reconstructive Sciences in Medicine (iRSM) at Misericordia Community Hospital, with additional support from the Alberta Sinus Centre at the University of Alberta Hospital, and the Surgical Simulation Research Laboratory (SSRL) at the University of Alberta in Edmonton, Alberta, Canada.

4.2 Background

4.2.1 Current alternatives for simulated nasal endoscopy training

In the literature review "The Role of Simulation in the Development of Technical Competence During Surgical Training" the author, Matthew P. Thomas, recommends that box trainers and virtual reality (VR) simulators should be used as an educationally superior and more ethical alternative to animal and cadaveric models in surgical simulation training.[71] Box trainers and VR simulators can be considered educationally superior by being a more available alternative that

can provide trainees with more access to repeated practice. The needs assessment presented in the previous chapter revealed that the common perception among experts in OHNS is that computer based simulators, such as VR simulators, are associated with significantly higher costs, lack the ability to mimic certain patient and ergonomic factors, and do not allow for the use of standard instrumentation. Some of these limitations are also supported in Thomas' review. Thomas therefore recommends that box trainers should be implemented into the surgical skills training curriculum, and that VR simulators should be used when resources allow. As presented in Chapter 1, although some VR simulators incorporate haptic feedback technology, physical models such as box trainers and anatomical models (mannequins) have better ability to provide tactile feedback and can thus enhance sensorimotor and psychomotor skills better than VR simulators, at a significantly lower cost.[72] These types of physical models also have the benefit of being portable and allow for the use of standard instrumentation. Several box trainers and anatomical models have been developed and found useful for training endoscopic sinus surgery procedures, from low fidelity box trainers made from found materials to high fidelity anatomical models.[1,5,27,47–49] Box trainers, while cost effective and useful for training specific tasks, are limited by their lack of anatomical accuracy.[27] Medium to high fidelity anatomical models allow for a more realistic training experience.[1,5,48,49] As presented in the previous chapter, experts in OHNS perceive fidelity as an important factor for the transferability of skills from the simulated to the real patient scenario. For these reasons, the goal for the present project was to develop an anatomical simulator model for training basic nasal endoscopy skills. This model will be an educationally superior alternative to low fidelity box trainers, and a more available and practical alternative to VR simulators.

4.3 Comparable simulator models

A few medium to high fidelity anatomical models for training endoscopic sinus surgery (ESS) procedures have been reported in the literature. The models that were considered most comparable to the present study and some of their key features are presented here.

Briner et al. developed an anatomical model for practicing ESS based on a human cadaver specimen.[47] The model was created by taking negative impressions of the cadaver to create molds that were then cast with two-component polyurethane. Three experienced surgeons evaluated the model and found that it had a reasonable resemblance to human anatomy and allowed for the most common ESS procedures to be performed.

Burge et al. developed a low-cost anatomical model for training functional endoscopic sinus surgery (FESS).[1] The model was developed using measurements derived from a CT scan and consisted of a plaster structure overlaid with silicone to mimic bone and mucosa respectively. The model showed improved skills in the development of FESS in both medical students and residents.

Chen Ge and Li Feng developed an anatomical model for training endonasal transsphenoidal pituitary surgery that can be used for different ESS procedures such as ethmoidectomy, sphenoidectomy and opening the natural ostium of the maxillary sinus.[49] The areas of incision were made to be replaceable to keep costs low.

Nogueira et al. developed an anatomical model for training endoscopic sinus surgery and skull base surgery.[48] The model consists of two parts, an external component that is reusable, and an internal component that needs to be replaced after each training procedure.

Ossowski et al. developed an anatomically correct model to train endoscopic nasal skills in

novice medical students as a more affordable and safe alternative to cadaver training.[5] Their study showed that students generally performed better using both rigid and flexible scopes after training on the model, although not all measures reached statistical significance or correlated with improved performance on a standardized patient.

Yamauchi et al. developed an endoscopic sinus surgery system that incorporated force sensors as a quantitative measure of surgical skills.[39] The model consisted of a dummy head with accurate silicone reproductions of the nasal cavities. The dummy was mounted on a platform with force sensors that measured force applied in perpendicular direction to the platform.

While these models show promise as useful training tools, many have not been sufficiently validated.[5,48,49] It is also unclear whether any of the models are commercially available. Notably, all of the models were developed for training more complex ESS procedures and are not intended for training just basic diagnostic nasal endoscopy skills. This means that they incorporate a larger anatomical area to include the sinuses. The models were designed to allow for dissection and need to be fully or partially replaced after each training procedure. A model for training basic nasal endoscopy skills, such as learning how to maneuver the scope to perform a thorough examination of the nasal cavity and carry out other simple diagnostic tasks, does not require the incorporation of the sinuses, or for parts of the model to be permanently dissected. Due to the added complexity and cost, anatomical ESS simulator models are therefore not considered a practical alternative for training the basic skills required for routine diagnostic nasal endoscopy. Thus, there is currently no practical, validated, and readily available anatomical simulator model to allow OHNS residents to train routine nasal endoscopy before they go on to perform the procedure on patients in the clinic. As discussed in previous chapters, this observed lack of training alternatives provided the basis for the present study.

4.4 Key considerations

Based on the existing literature and the needs and perceptions expressed by experts in OHNS in the previous chapter, the key considerations in the development of the simulator were: cost, fidelity, objective assessment, adaptability, and generalizability. Some of these considerations have been discussed previously, but will be addressed in more detail here.

4.4.1 Cost

Cost has been reported as one of the major barriers to the successful implementation of simulation training in surgical residency training programs.[73,74] For a simulator to be considered a worthwhile investment in a residency program, it must be cost-effective. In other words, the upfront cost must be offset by a measurable effect on learning outcomes and/or resource savings.

Involving residents in the OR is associated with a significant increase in OR time and cost.[75] Surgical simulation has been proposed as a way to prepare residents better before they enter the OR to help reduce these associated costs. A few studies have attempted to estimate the cost-effectiveness of the implementation of surgical simulators into the curriculum. One article reported the return on investment (ROI) from the Immersion Medical Endoscopy AccuTouch System, a VR simulation system that trains flexible bronchoscopy and upper and lower gastrointestinal flexible endoscopy.[76] The report showed that the simulator provided a financial benefit of $352,532, and that the upfront investment was returned within 131 days. The financial benefit was gained by reduction in instructor time, reduction in errors, faster time to complete, a reduction in equipment breakage cost, as well as alternative use of the simulator. It should be mentioned that the author of the report disclosed potential study interpretation and financial conflicts of interest.

As presented in the preceding chapter, the perception among experts in OHNS is that the costs associated with more advanced computer based simulation systems are difficult to overcome as residency programs measure their budgets in five figure numbers, while some of the best systems approach six figures.[3] In the article "Barriers to Adoption of the Surgical Resident Skills Curriculum of the American College of Surgeons/Association of Program Directors in Surgery," Patricia A. Pentiak and colleagues identified cost as one of the major barriers to the implementation of the simulation based curriculum.[74] The curriculum is constructed as a series of simulation based modules intended to standardize the skills curriculum for surgical residents. Although widely supported, the curriculum required significant capital, instrument, and personnel investments that prevented many residency programs from adopting it fully. The authors recommended that more affordable and lower-cost simulators and synthetic models should be developed to help reduce these financial barriers, and suggested that: "Cardboard, plastic sheets, and rubber bands can sometimes perform as well as cadavers, live pigs, or virtual-reality simulators, and at a fraction of the cost." By the same token, while most of the focus has been on the cost-effectiveness of computer based simulation, it has also been suggested that more evidence is necessary to investigate the cost-effectiveness of different types of simulation technology.[9]

For the present study, the assumption was that for a simulator to be a more practical and available alternative to more advanced simulation technologies, is should have a lower upfront cost. As such, the goal was to create a simulator that would present a low-cost and more available alternative to computer based simulators and cadaver or animal models. A simulator of a lower cost will be more accessible to a wider number of institutions with different sized budgets, which in turn can lead to more widespread adoption.

4.4.2 Fidelity

Fidelity refers to the simulator's ability to mimic the real scenario. In otolaryngology simulation literature, the term is often associated with computer based VR simulation due to its programmability and ability to simulate highly realistic and accurate anatomy and pathology. However, as described in the previous chapters, VR simulators are often considered limited by a lack of haptic feedback, the lack of physical interaction, and for not allowing the use of standard instrumentation. As presented in the previous chapter, most of the OHNS surgeons perceived fidelity as an important factor for the transferability of skills from the simulated to the real patient scenario. Herein was mentioned the simulators ability to mimic real patient anatomy, as well as ergonomic and environmental factors such as the orientation of the patient/simulator, set-up, instruments, setting, and patient feedback. The International Nursing Association for Clinical Simulation and Learning defines a simulator's level of fidelity as consisting of a variety of factors and dimensions:

> The level of fidelity is determined by the environment, the tools and resources used, and many factors associated with the participants. Fidelity can involve a variety of dimensions, including (a) physical factors such as environment, equipment, and related tools; (b) psychological factors such as emotions, beliefs, and self-awareness of participants; (c) social factors such as participant and instructor motivation and goals; (d) culture of the group; and (e) degree of openness and trust, as well as participants' modes of thinking.[77]

These are all important factors that should be considered when defining simulation fidelity. In a study comparing the effect of training on high-fidelity simulators to training on low-fidelity simulators, the advantage of high-fidelity simulators was found to be only minimal.[78] In the discussion, the authors describe the difference between 'engineering fidelity', whether the simulation looks realistic, and 'psychological fidelity'. 'Psychological fidelity' refers to whether

the simulation is able to simulate certain elements that inform specific behaviours to solve various tasks. The authors suggest that psychological and engineering fidelity are equivalent in their importance, which is why simulators with a low engineering fidelity can perform just as well as simulators with high engineering fidelity, as long as they have good psychological fidelity. As stated by the authors of the study, the discussion of whether to choose high-fidelity or low-fidelity simulators becomes a matter of cost. Generally, high-fidelity simulators are associated with significantly higher costs that limit their accessibility and availability. The authors therefore suggest that it may be more effective to provide trainees with unlimited access to low-fidelity simulators than limited access to high-fidelity ones.

For the present study, the goal was to balance the importance of fidelity with cost. This was done by focusing on how to maximize fidelity while still maintaining the goal of producing a low-cost model. With access to additive manufacturing (AM) technologies, it has become easier to reproduce the exact anatomy of the nasal cavity based on computerized tomography (CT) data at a relatively low-cost. Previously, exact reproduction of human anatomy would typically require to manually create casts based on negative impressions of a human cadaver, which is a much more labour intensive process.[47] To enhance the psychological aspects of the model's fidelity, other factors were also considered, such as allowing for 'patient interaction' through portability and repositioning of the model, as well as allowing for the use of standard instrumentation and equipment in a standard clinical setting. The potential incorporation of audible force-feedback would further enhance the overall fidelity of the model.

4.4.3 Objective assessment: Force feedback

Good sensorimotor skills are essential to avoid applying unnecessary and potentially injurious force to tissue. To develop this, surgeons must learn to control how much force they are applying

on surrounding structures as they handle surgical tools.[39] To facilitate the development of sensorimotor skills, the model has force sensors incorporated in the nasal septum and turbinates. Excessive contact with these areas during nasal endoscopy can cause great discomfort and pain to the patient.

The force sensors were incorporated in the model with the intent of serving two functions. They can provide the trainee with immediate performance feedback, and they can function as an objective measure of performance. The sensors can provide direct feedback through visual or audible signals. Auditory force feedback has been shown to help improve surgical skills during simulated ophthalmic surgery.[41] The assumption is that audible force feedback is more appropriate than visual feedback, as it does not distract the trainee's visual focus away from the endoscopic procedure. An audible signal is also similar to how real patients would provide feedback during a procedure by expressing pain or discomfort verbally. As such, audible feedback can further enhance the fidelity of the training experience. For the present study, the audible feedback signal was not incorporated in the design, as it was first necessary to validate and establish force as a relevant measure of performance during nasal endoscopy (see next chapter).

The force sensors can also function as an objective measure of performance. A resident's performance can be assessed objectively by comparing their force profile to a predetermined benchmark based on expert performance. Residents can also use their force profile to assess their own improvement over time. By providing a consistent and reliable objective measure of performance, the simulator can play a role in the move towards a more standardized and objectives based framework for surgical training.[6]

For the present study, the Finger Tactile Pressure Sensing System (FingerTPS™, Pressure Profile Systems, Los Angeles, CA, USA) was utilized. The FingerTPS™ system comes with a set of small force sensors that are designed to cover surface areas of the fingertips and the palm of the hands. The system is intended to measure the force applied to objects by the hand during gripping. The sensors were considered to have the appropriate size for the relevant surface areas of the model and were sensitive enough to provide sufficient feedback when force was applied to these areas. The FingerTPS™ system comes with the Chameleon Visualization and Data Acquisition software that records the force data. The sensors measure the force in absolute values but can also be calibrated to measure the force in Newton or pounds. The system and how the sensors were incorporated into the design of the final model is further illustrated in Appendix 4.3.

The FingerTPS™ system was utilized for the present study for convenience purposes. The system was already available to the research team through the Surgical Simulation Research Laboratory (SSRL) at the University of Alberta, and did not require any additional acquisition and development cost. However, to acquire the FingerTPS™ system is costly, and would not be a practical alternative for future iterations of the model. For future iterations, a system that is specifically designed for the simulator should be developed as a cheaper and more appropriate

alternative. For example, basic force sensors can be made from readily available materials such as conductive fabrics and connected to simple analogue or digital microcontroller hardware to produce an audible feedback signal.

4.4.4 Adaptability

The model was designed so that it can be adapted to simulate various diagnostic nasal endoscopy challenges. The modular design allows each of the internal components to be replaced to simulate various pathologies or anatomical abnormalities. For example, the septum could be replaced with a deviated septum, or the lateral walls of the nasal cavity could be replaced to simulate different pathological indicators. This allows the model to adapt as the resident progresses by simulating different and increasingly challenging tasks. The final prototype for the present study was designed to simulate some basic tasks such as collection of culture and biopsy of a lesion, but future iterations could include additional components to simulate more complex tasks. The already modular design makes this an easy task in terms of development and design. The modular design also allows the internal components to be taken apart easily. This can allow the user to creatively simulate different tasks by placing objects or artificial puss in the cavities that residents have to identify or collect. As illustrated by the present study, these can be made from readily available materials. This gives the user the opportunity and freedom to adapt the model according to their training needs by simple means. The modular design also allows each component to be inspected closely, making it a useful tool for instruction and demonstration. This can aid residents or medical students in gaining a better understanding and appreciation of the anatomy of the nasal cavity. Lastly, the modular design allows each component to be replaced individually in case of damage or deterioration.

4.4.5 Generalizability

The model was designed with a focus on simple but accurate reproduction of actual nasal anatomy, rather than a specific set of tasks. This simple concept makes is generalizable to a wider group of users. The adaptability of the design can allow it to be used and adapted by different institutions with different training needs and practices. The model can be used to practice the use of both rigid and flexible scopes with different scope sizes and camera angles. It can also be used to train manipulation and handling of many different tools and instruments. The simple anatomical model can also be a relevant training tool for other disciplines that practice nasal endoscopy. For example, by adapting the model to incorporate more of the oral pharynx and oral cavity, the model can be used to practice basic scope navigation in speech-language pathology.

4.5 Design process, materials and method

The simulator was developed using additive manufacturing (AM) technology and computer aided design (CAD) software at the Institute for Reconstructive Sciences in Medicine (iRSM) at the Misericordia Community Hospital in Edmonton, Alberta. The model was generated from a CT scan obtained with permission from the Medical Modeling Research Lab (MMRL) at iRSM. The CT data was segmented and a three-dimensional model of the area of interest was generated in Mimics® software (Appendix 4.1).

The model consists of five key components: an external cephalic housing unit, and four internal components consisting of the nose, the septum, and left and right lateral wall of the nasal cavity. The internal components of the model encompasses the anatomical area of the nasal cavity from tip of the nose anteriorly to the nasopharynx posteriorly, the hard palate inferiorly to the cribiform plate of the ethmoid bone superiorly, and from the lateral walls of the nasal cavity

horizontally (Figure 2). The cephalic housing unit encompasses some of the surrounding surface anatomy of the face.

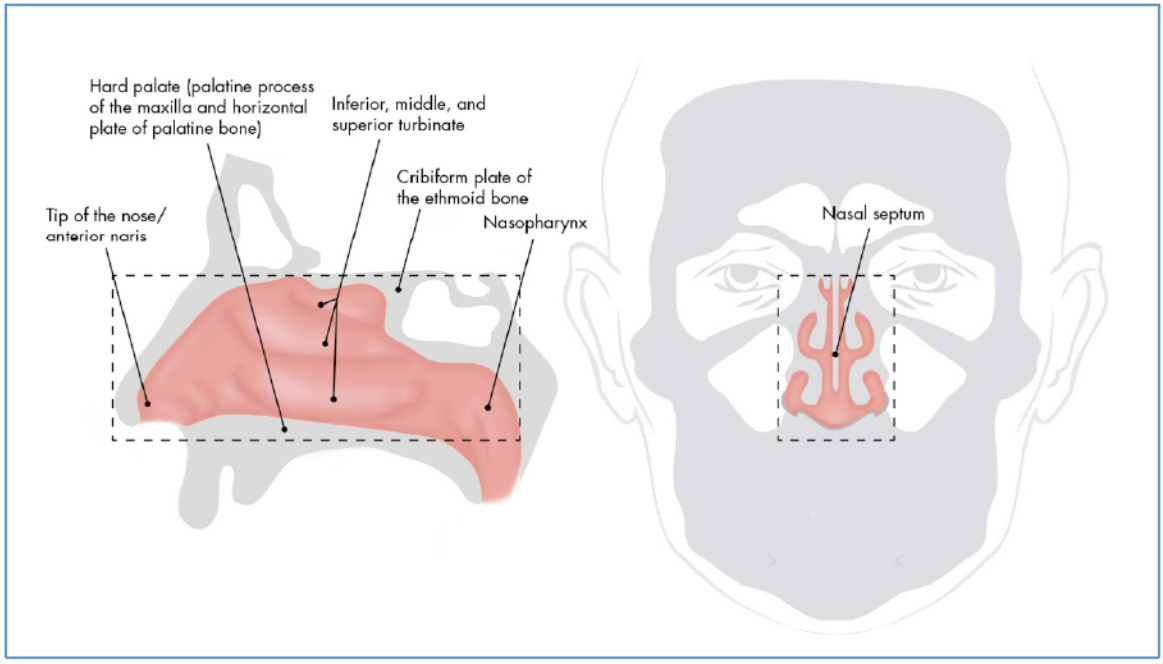

Figure 2: : Illustration showing the anatomical area included in the internal component of the simulator model.

Although the Mimics® software (Mimics®, Materialise, Leuven, Belgium) was able to maintain most of the structures of the nasal cavity, certain landmarks and minute structures were modified to become more prominent and missing anatomy was added where needed. These were the turbinates, the septum, the nasopharynx, and the eusthachian tube orifice. Corrections were made to the anatomy using Freeform® modeling software (Geomagic® Freeform®, 3D Systems, Cary, NC, USA) to create a model that had a uniform and normal anatomy (Appendix 4.2). One side of the nasal cavity was prepared and then mirrored to create the reverse side using Magics® modeling software (Magics®, Materialise, Leuven, Belgium). This was done to achieve a symmetrical and uniform anatomy in both cavities. The cephalic housing unit was designed to function as housing for the nasal cavity and to provide the proper anatomical context. The

housing unit was designed using a combination of Magics®, Freeform®, and Rhinoceros® (Rhinoceros®, McNeel, Seattle, WA, USA) modeling software.

4.5.1 Prototype 1

The first prototype was printed at 1:1 scale on the Objet Connex500™ 3D printer (Stratasys 3D Printing, Eden Prairie, MN, USA) (Figure 3 & 4). The Objet Connex500™ 3D printer is a poly-jet printer that gives high surface resolution and was therefore used to print parts that required smooth surfaces. The other printers used in this study, Dimension SST 1200es and Fortus 400mc (Stratasys 3D Printing, Eden Prairie, MN, USA), are fused deposition modeling (FDM) printers and were used for parts where the surface resolution was less important. The nasal septum was printed in a solid material (Vero White) to achieve a rigid bone-like density. The lateral walls of the nasal cavity and the nose were printed in a flexible material (Tango) to mimic soft tissue. The cephalic housing unit was printed on a Dimension SST 1200es 3D printer in ABS*plus* plastic. Upon initial testing by the research team, the flexible Tango material from the Objet Connex500™ 3D printer was too rigid to properly mimic the flexibility of the turbinates and the nares. The Tango material also had a translucent quality and lacked color. The nasal cavities were narrow and the material gave too much resistance for the scope to pass through easily. In a normal patient, the presence of mucosa provides natural lubrication for the scope, and decongestant helps shrink the turbninates to provide more room for the scope. These capabilities are missing in the model and therefore needed to be compensated for by design.

Figure 3: Prototype 1 assembled model

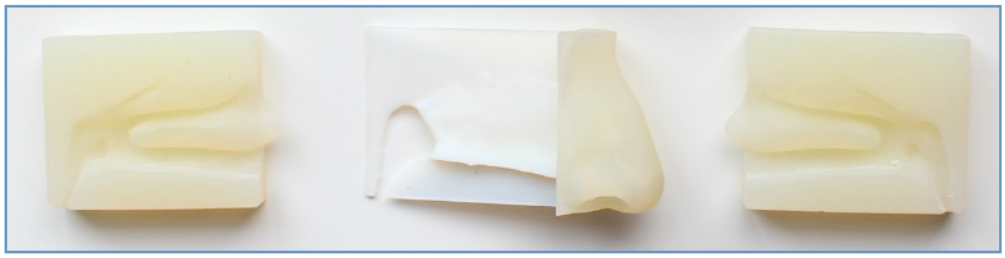

Figure 4: Prototype 1 internal components including septum, nose, left and right lateral wall of nasal cavity

4.5.2 Prototype 2

The second prototype was partly printed on the Objet Connex500™ 3D printer and partly cast in silicone in 3D printed molds (Figure 5-7). The model was scaled to 1.2:1 to provide more room for the scope and compensate for the lack of mucosa and decongestant. The septum was printed in Vero White material on the Objet Connex500™ 3D printer. Molds for the lateral walls of the nasal cavities were also printed in Vero White on the Objet Connex500™ 3D printer to achieve optimal surface quality. The molds were later printed on a Fortus 400mc in PC-ISO thermo-plastic material and allowed for satisfactory surface quality as well, at a lower cost. The mold for the nares was printed on the Dimension SST 1200es 3D printer in ABSp*lus* material. The molds were created in Magics® software by subtracting the anatomy from an appropriate size mold casing which left a negative impression. The molds were designed to be easily disassembled while minimizing the appearance of parting lines on the final cast. After printing, the molds were sprayed with MediMould* Wax Mould Sealant and Release Agent (Polymed Limited, Cardiff, Wales) and left to dry. The molds were cast using Factor II LSR-05 Silicone Elastomer (Factor II, Incorporated, Lakeside, AZ, USA) This is a two-part medical grade silicone used in the creation of facial prostheses. The silicone was coloured using Factor II Functional Intrinsic II Silicone Coloring (Factor II, Incorporated, Lakeside, AZ, USA) to create a color that resembled mucosa. The color was mixed in approximately 100 grams of the Part A silicone. This was a sufficient amount Part A silicone to cast all the molds and allowed for color consistency between all the parts. The silicone was then combined with an equal amount of the Part B silicone and mixed in a power mixer. The molds were poured and effort was made to prevent air bubbles from forming in the silicone by allowing the bubbles to rise to the surface before the molds were clamped and left to bench-cure over night. A few test-casts had to be made before a desirable

surface quality (lack of air bubbles) was achieved. Prototype 2 was considered by the research team to have good and appropriate material density, size, and color (Figure 8).

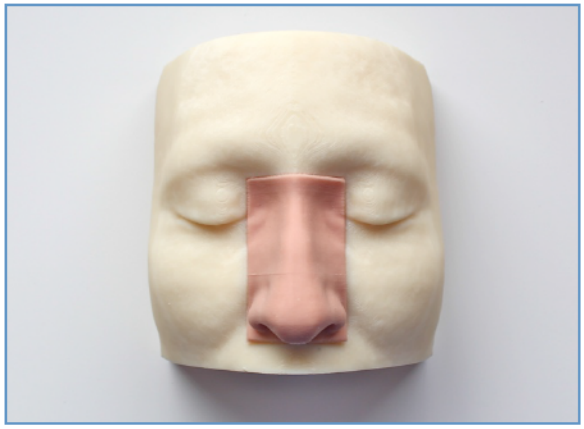

Figure 5: Prototype 2 assembled model

Figure 6: Prototype 2 disassembled with internal components incl. septum, nose, left and right lateral wall of nasal cavity

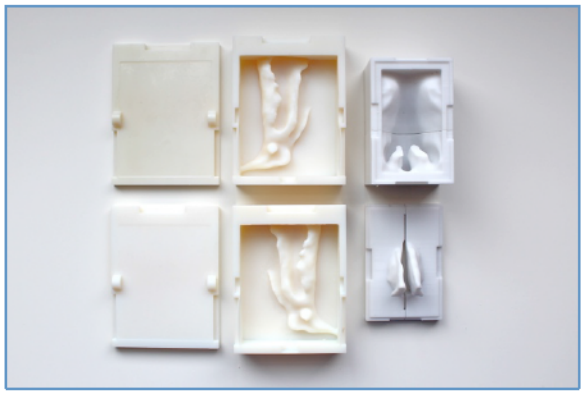

Figure 7: Prototype 2 3D printed molds for silicone casts of nose and left and right lateral wall of nasal cavity.

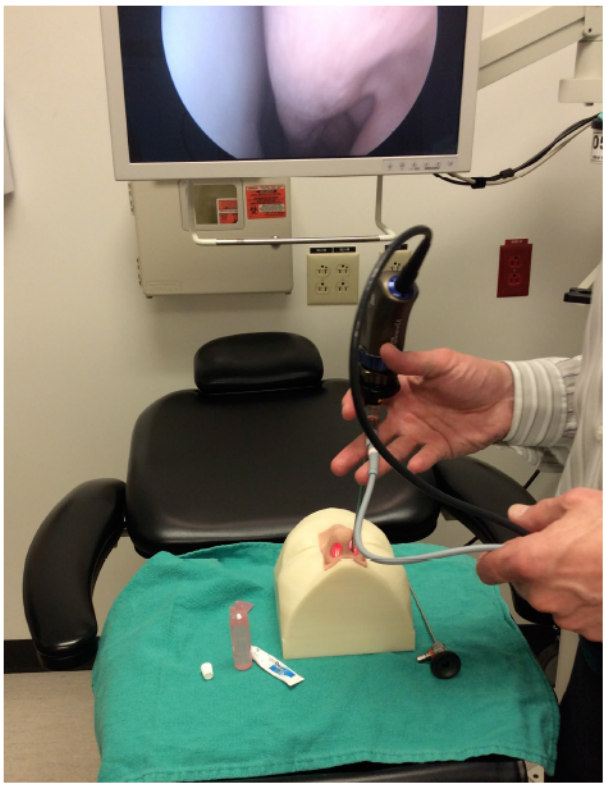

Figure 8: Initial testing of prototype 2 using standard instrumentation.

4.5.3 Final prototype

The final prototype involved the design of additional components to enhance the usability and ergonomics of the model (Figure 9-12). A hard plastic casing for the lateral walls of the nasal cavity was designed and printed on the Dimension SST 1200es in ABS*plus* plastic. The casing was designed to allow for the incorporation of sensors, and to hold the lateral walls of the nasal cavity, the septum, and the nares together. The casing made the internal components easier to remove from the cephalic housing unit so that the individual parts can be inspected, modified, or replaced. The cephalic housing unit was designed in two parts. The face was modified to include a larger anatomical area to provide better face validity. This was also done to provide a larger surface for interaction, such as resting a finger on the forehead for stability during procedures, or adjusting the orientation of the model. The face was printed in Vero White on the Objet

Connex500™ 3D printer to provide a good and resistant surface quality. The housing unit was designed separately to fit on a ball-head tripod base and printed on the Dimension SST 1200es in ABS*plus* plastic. The tripod base provides support for the model and allows the user to tilt the model in the desirable position to mimic patients seated in an upright position as in the clinical scenario, or supine as in the OR. The face and the housing unit were assembled together using standard ¼ inch bolts. The nose was designed to be detachable so that it can be replaced. This also allows for a better frontal view of the nasal cavity during instruction.

Figure 9: Final prototype assembled model.

Figure 10: Final prototype disassembled with internal components incl. septum, nose, left and right lateral wall of the nasal cavity with casing.

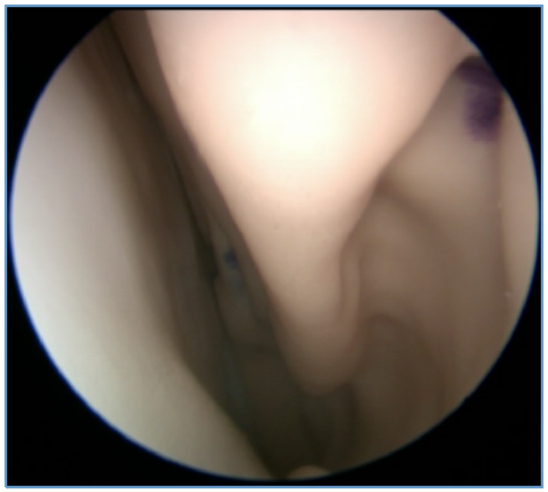

Figure 11: View of the left nasal cavity showing inferior meatus and inferior turbinate.

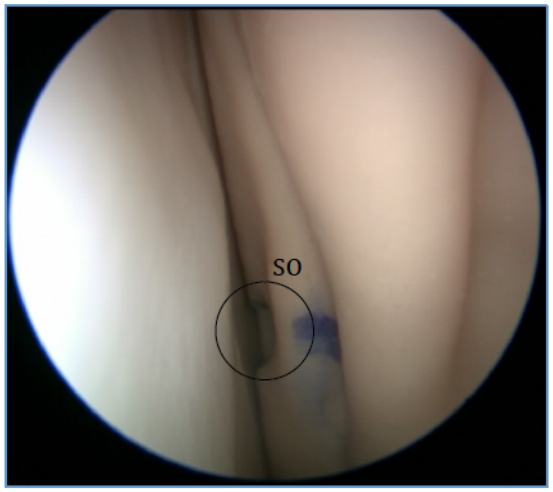

Figure 12: View of the left nasal cavity with superior turbinate, middle turbinate and sphenoid ostium.

The final prototype included some modifications to the internal anatomy of the lateral walls of the nasal cavity (Figure 13 & 14). A recess was created at the posterior end of the superior turbinate to mimic the sphenoid ostium in both the left and right cavity. The right cavity also included a recess to mimic the maxillary ostium. These openings were used to mimic pathologies during the validation study (next chapter) by holding artificial puss or lesions. Artificial puss was made from equal parts Vaseline® (Unilever, Englewood Cliffs, NJ, USA) and mineral oil to achieve the appropriate viscosity. Mixing yellow and green Factor II Functional Intrinsic II Silicone Coloring created the color. The lesion was made from Van Aken Plastalina (Van Aken,

North Charleston, SC, USA) pigmented, oil based modeling compound. A full list of all materials and equipment used to develop the final prototype is provided in Appendix 4.4. Additional images of the model is provided in Appendix 4.5.

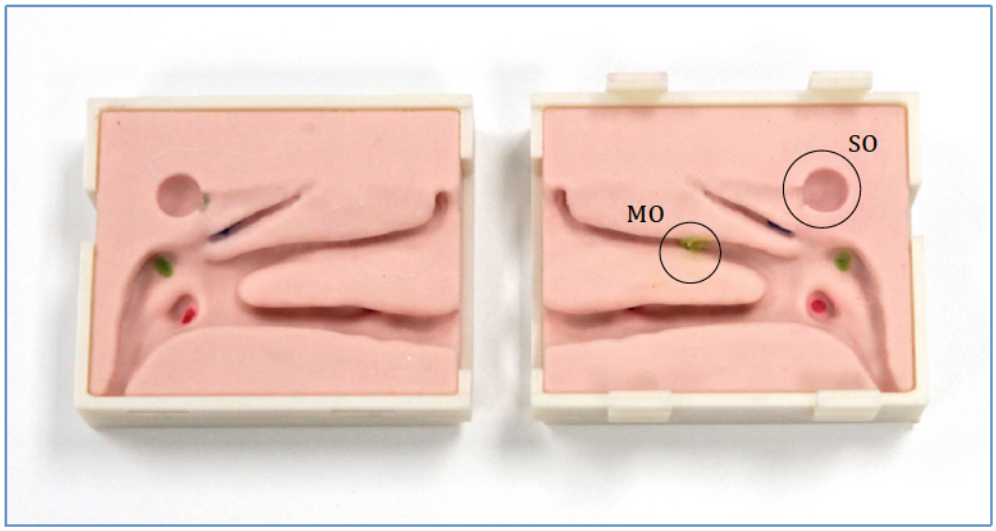

Figure 13: Lateral walls of the left and right nasal cavity with recesses to mimic the sphenoid ostium (SO) and a recess to mimic the maxillary ostium (MO) in the middle meatus of the right cavity. The coloured dots indicate important anatomical landmarks and were used as target markers during the validation study.

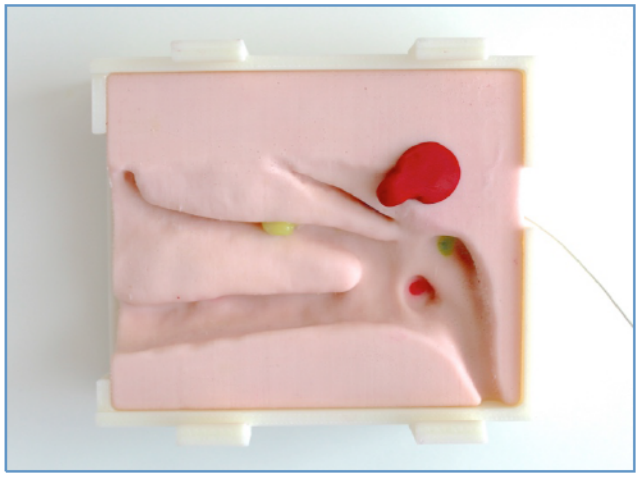

Figure 14: Lateral wall of the right nasal cavity with artificial puss in the maxillary ostium and artificial lesion in the sphenoid ostium.

4.6 Summary

This second stage of the present research project involved the design and development of the nasal endoscopy simulator model. Based on the literature and the needs expressed by the experts and stakeholders in OHNS presented in the previous chapter, the decision was to make an anatomical model that incorporated force sensors as a feedback mechanism. The key considerations in the design process were: cost, fidelity, objective assessment, adaptability, and generalizability. The simulator model was developed using additive manufacturing (AM) technology. Computer aided design (CAD) software was used to design a model, based on a CT scan, that was printed on a 3D printer. The soft-tissue components of the final simulator model were cast in silicone using 3D printed molds to allow for better tissue quality. The design process went through two stages of prototyping before arriving at a final design. The ability to develop initial prototypes for testing was very helpful in the design process, and is a great advantage of additive manufacturing technology. This way, the team was able to troubleshoot and test different solutions before the final design was determined and ready to be validated.

5. Face and Construct Validity

5.1 Introduction

The final stage of the present research project was to validate the overall utility and effectiveness of the simulator through an experimental study involving both educators and trainees. The model was validated using both subjective and objective methods of validation.[60] Face validity is a subjective method of validation that is based on the participants subjective rating of the model. This was considered relevant to gain an understanding of the opinions and perceptions among the stakeholders and gatekeepers in the program for which the simulator was developed. Construct validity is an objective method of validity where the models validity is determined through statistical analysis of various performance measures. Establishing objective validity is important for the transferability and generalizability of the model. The models face and construct validity was assessed by inviting both novice medical students as well as OHNS residents and staff to perform a set of basic diagnostic nasal endoscopy tasks on the model. The experiments were carried out at the Alberta Sinus Centre at the University of Alberta Hospital, Edmonton, Alberta.

5.2 Objectives and hypothesis

The objectives for the present validation study were:

1. Assess the face validity of the model based on the participants subjective feedback in the form of a post-test questionnaire.
2. Assess the construct validity of the model by objectively assessing the participants' performance while performing a set of basic diagnostic nasal endoscopy procedures on

the model. Construct validity will be determined by the strength of the correlation between performance as rated by the Objective Structured Assessment of Technical Skill (OSATS) and force detected by the force sensors in the model, and surgical experience as defined by years of surgical experience and number of previous nasal endoscopic procedures performed.

It was hypothesized that the model would show good face validity by the participants rating its overall utility and effectiveness as high (4 to 5 out of 5 where 5 is high), and construct validity by showing a strong positive correlation between surgical experience and performance ($r > .7$), as well as a strong negative correlation between surgical experience and the force exerted during the procedure as measured by force sensors in the model ($r > .7$).

5.3 Method

5.3.1 Sampling

A convenience sample of 13 participants was recruited through the Alberta Sinus Centre at the University of Alberta Hospital and the Department of Otolaryngology – Head and Neck Surgery University of Alberta Edmonton, Canada. The participants were recruited purposively to represent a range of experience in OHNS from novice medical students to residents, through to attending surgeons. The participants were stratified according to surgical proficiency based on their years of surgical experience and according to the number of nasal endoscopy procedures they had performed previously: 0, 1-10, 10-50, 50-100, or over 100 procedures. The participants were approached by a member of the research team in person in the clinic or contacted via email

by the research investigator. The participants were asked to contact the research investigator directly on a voluntary basis if they would like to participate in the study (Appendix 5.1).

The only exclusion criterion for this study was if a participant had performed a significantly higher or lower number of nasal endoscopy procedures than what was normal for their strata. No further exclusion criteria were established, as the sampling method was purposive and the inclusion criteria (level of experience) were considered sufficient in describing eligible participants.

5.3.2 Sample size

The goal was to recruit minimum 12 participants. Expected correlation coefficient was $r = .7$ or higher, as this indicates a strong correlation between the variables.[79] With an α-value of .05 (two-tailed) a minimum sample of n =12 was required to achieve a power of .78, derived from table C.6 in Foundations of Clinical Research by Portney and Watkins[80] (Appendix 5.2). Recruitment ended once the desired number of participants was reached, with one additional participant recruited due to loss of data, making the total sample size n = 13.

5.3.3 Study design

This construct validity test was based on the "known-groups" method.[81] The goal of this method is to test the simulator model's ability to discriminate between the different known groups (strata based on surgical experience) by rating their performance when performing a set of given tasks on the model.[82] A strong correlation between surgical experience and performance on the simulator indicates good construct validity of the model. More specifically, the skills acquired by practicing on live patients are applicable to the simulator due to its high fidelity and similarity with the construct that is being simulated: the live patient scenario. As stated in the hypothesis, it was expected that there would be a strong correlation between overall test performance and

surgical experience.

5.3.4 Ethical considerations

All the participants in this study were recruited through the same institution. Thus, there were both colleague and professor-student relationships between the researchers and the participants. To avoid any undue pressure, it was made clear through informed consent that the study was completely voluntary (Appendix 5.3). The participants were also free to withdraw from the study at any time up until the end of the data collection. The participants' name and email address were collected for scheduling purposes. Their level of surgical experience in years and number of previous nasal endoscopy procedures performed was also collected as the main inclusion criteria for this study. To preserve the participants anonymity, all the material from the data collection was anonymous, including the pre-test and post-test questionnaires, force scores, and the video recorded test-procedures. This was done through coding where the participant's identity was replaced with a letter (e.g. participant A, participant B). The participants years of surgical experience and the number of previous procedures performed was retained and used in the analysis. Only members of the research team have knowledge of the participants' identity and at no point during or after the study have direct identifiers of the participants and the results of their participation been reported together. The assessors in the study were blinded to the participants' identity and surgical experience during the assessment. Overall, this study was considered to be of minimal risk to the participants. Ethics approval was obtained from the University of Alberta Human Research Ethics Board, Pro00044996, December 1, 2014.

5.3.5 Procedure

The test was a one-time test and was performed with only one participant at a time at the Alberta Sinus Centre at the University of Alberta Hospital. The scheduling of each test was based on the availability of the participant and access to the testing facility and typically took place before or after clinic hours (before 8am or after 4pm). The participant was given additional information about the test and the issue of confidentiality was explained to them before they filled out a consent form (Appendix 5.3). Upon consent, the participants filled out a pre-test questionnaire to determine their handedness, years of surgical experience, and the number of nasal endoscopic procedures previously performed using a rigid scope. (Appendix 5.4).

The test involved performing three tasks:

1. A thorough examination of both nasal cavities and key anatomical areas using the "three-pass" technique (described in Chapter 1).
2. Collection of culture using an endoscopically guided swab.
3. Biopsy of a lesion with endoscopically guided forceps.

These tasks are commonly performed during routine, diagnostic nasal endoscopy, and were therefore considered appropriate tasks for testing basic nasal endoscopy skills. The 1st task demonstrates the participant's familiarity with nasal anatomy and their ability to perform a thorough examination of the nasal cavity through proper scope navigation and camera handling. The 2nd and 3rd task demonstrates the participant's ability to navigate the scope and surgical tools simultaneously to properly execute the tasks with maximum efficiency. All the participants were shown the same video demonstration of the three tasks prior to the test, irrespective of experience level (Appendix 5.5). The procedure was executed and recorded in two stages: first,

the three-pass examination of the nasal cavities, and second, the collection of culture and biopsy. This was to ensure that the equipment that recorded the procedure and the force data did not run for too long which could lead to corrupt or lost data. The biopsy sample and the culture swab was retained for closer inspection and to verify that the task was completed. After the test, the subjects were asked to fill out a post-test questionnaire where they rated the overall utility and effectiveness of the simulator (Appendix 5.6).

5.3.6 Set up

The model was set up in one of the examination rooms at the Alberta Sinus Centre to mimic a real patient scenario, and the participants were given standard equipment to execute the procedure. The procedure was performed with a 3mm 30° rigid scope and recorded via the Karl Storz-Endoskope Image 1 HUB™ HD system (Karl Storz, Tuttlingen, Germany). The participants were also provided a BBL™ CultureSwab™ (Becton, Dickinson and Company, Franklin Lakes, NJ, USA) to collect culture, adult nasal forceps for the biopsy, and an alcoholic prep pad to clean the lens. The model was placed on the patient chair and the chair was raised to the appropriate height. The model with the force sensors was connected to a portable computer with the Chameleon Visualization and Data Acquisition software that recorded the force exerted on the model during the procedure. The computer showing the real-time force recording was oriented away from the participant to prevent distraction from the procedure. Vaseline was applied around the anterior opening of the nares to provide some lubrication for the scope upon initial insertion. For each participant, artificial puss was injected in the maxillary ostium to mimic culture, and oil based modeling compound was placed in the sphenoid ostium to mimic the lesion in the right cavity. The set up and equipment is further illustrated in Appendix 5.7.

5.4 Data handling

5.4.1 OSATS scores

Each participant's test was recorded via the endoscopic camera and exported to an external drive after each test session. The research investigator reviewed the recordings and removed footage that was not pertinent to the assessment, for example when the scope was placed on the worktable between tasks. Any footage that could potentially identify the participants (when the scope was maneuvered around between tasks) was also removed. The videos were edited using Adobe Premier Pro CC video-editing software. The final videos were stored and labeled with the respective participant number on an external drive that was then given to the assessors. Two OHNS surgeons from the Department of Otolaryngology – Head and Neck Surgery at the University of Alberta reviewed the videos and rated the performance of each participant. The videos were reviewed in random order to avoid negative effects of comparability and ensure intra-rater reliability. The assessors were blinded to the participants' identity and level of experience to avoid detection bias in the assessment.[83]

The assessors rated the participants performance using an adapted version of the Objective Assessment of Technical Skills (OSATS) global rating scale (Appendix 5.8). The OSATS is considered the gold standard for proficiency assessment in bench model simulation scenarios[27] and consists of a procedure specific checklist and a series of global rating scales.[84] Because the design of this test mimicked that of typical bench model simulation scenarios, the OSATS was considered an appropriate rating tool. The OSATS has been validated by accurately rating performance proportionately to level of surgical skills and has been widely used since it was first developed at the University of Toronto, Canada, in the 1990's.[84] The OSATS rating sheet for the present study consisted of seven assessment items. Each item was rated on a global rating scale

from 1 to 5, where 1 indicated very poor execution, and 5 indicated excellent execution. The lowest possible total score was therefore 7 and the highest possible total score was 35.

5.4.2 Force data

The force data was recorded for each participant with the Chameleon Visualization and Data Acquisition software. The Research Investigator reviewed the force data and exported the data to text files (.txt) that could be used in the analysis. The data output from the force sensors was cleansed to include only relevant data, and noise or negative values was removed from the data set. Noise was determined to be values less than 10. This was established after reviewing the force data and finding the maximum scores when there was no activity on the model. The data set also contained some negative values. Negative values indicated that the sensors were under tension, and often occurred immediately after high force had been exerted on the sensors. As such, negative values were considered irrelevant values and were therefore removed.

5.5 Statistical analysis

5.5.1 Variables

The variables for the statistical analysis were the following:

Independent variables:

A. Years of surgical experience.
B. Number of nasal endoscopic procedures performed using a rigid scope

In the pre-test questionnaire, the participants were asked to rank the total number of nasal endoscopy procedures using a rigid scope they had performed. The ranks were: 0, 1-10, 10-50,

50-100, or more than 100. The research team determined these ranks as levels of experience that one would expect to see reflected in the performance of the participants.

Dependent variables:

A. OSATS performance scores:

1. Respect for tissue
2. Camera/scope handling time and motion
3. Instrument handling
4. Flow of operation
5. Completion of task 1: 3-pass examination of nasal cavity
6. Completion of task 2: Collection culture
7. Completion of task 3: Biopsy of lesion/polyp
8. Total OSATS performance score

B. Force scores:

1. Force on turbinates during 3-pass examination of left nasal cavity
2. Force on septum during 3-pass examination of left nasal cavity
3. Force on turbinates during 3-pass examination of right nasal cavity
4. Force on septum during 3-pass examination of right nasal cavity
5. Force on turbinates during collection of culture from maxillary ostium in right nasal cavity
6. Force on septum during collection of culture from maxillary ostium in right nasal cavity
7. Force on turbinates during biopsy of lesion in sphenoid ostium in right nasal

cavity

8. Force on septum during biopsy of lesion in sphenoid ostium in right nasal cavity

Each participant received a set of 7 unique OSATS scores from each of the two assessors, reflecting the 7 OSATS list items. The total OSATS score for each participant was also calculated and added to the analysis. This gave each participant 16 OSATS scores in total ((7+1) scores x 2 assessors).

Two sensors recorded the force during each procedure, with the "three-pass" procedure executed on both the left and right cavity, making a total of 4 procedures. One sensor recorded the force exerted on the septum and one recorded the force exerted on the turbinates. This gave each participant a total of 8 unique force scores as listed above (2 sensors x 4 procedures). Each score reflects the mean force applied during each procedure. The maximum score for each procedure was also calculated and used in the analysis, adding an additional 8 force scores, giving each participant a total of 16 unique force scores.

With the OSATS scores and the force scores, the total number of dependent variables for each participant was 32. Correlation analysis was performed between the two independent variables and each of the 32 dependent variables, making a total of 64 correlation calculations. The statistical analysis was executed using IBM SPSS Statistics 21 for Windows (IBM Corporation, Armonk, NY, USA) and Microsoft® Excel® for Mac 2011 (Microsoft, Redmond, WA, USA). As both of the independent variables as well as the OSATS scores were non-parametric variables Spearman's rho correlation coefficient was used for all the calculations. The α-level was set to

.05, two-tailed for all the calculations. Descriptive statistics were used to further explore the data and compare means.

5.6 Results

13 participants completed the study. The recruited participants consisted of four medical students, seven residents ranging from junior (PGY 1) to chief (PGY 5) residents, and two staff members. Surgical experience ranged from 0 to 17 years, and from 0 to more than 100 nasal endoscopy procedures with a rigid scope performed (Table 4).

Table 4: Recruited participants

ID	Handedness (Left/Right)	Years of surgical experience (incl. residency)	Number of nasal endoscopic procedures performed using a rigid scope	Strata
C	R	0	0	Novice (medical student)
H	R	0	0	Novice (medical student)
K	R	0	0	Novice (medical student)
Y	R	0	0	Novice (medical student)
O	R	1	1-10	Junior resident (PGY 1)
U	R	2	1-10	Intermediate resident (PGY 2)
Z	R	2	10-50	Intermediate resident (PGY 2)
W	R	3	10-50	Intermediate resident (PGY 3)
D	R	3	50-100	Intermediate resident (PGY 3)
M	R	5	>100	Senior/chief resident (PGY 5)
R	R	5	>100	Senior/chief resident (PGY 5)
N	R	10	>100	Staff
F	R	17	>100	Staff

5.6.1 Data loss

Some data for two participants was lost due to corrupt files or computer error. The force scores for the "three-pass" examination was lost for one participant due to a computer error during the procedure. The video recording of the collection of culture and the biopsy of lesion tasks was lost for another participant due to corrupt video file. As a result, one additional participant was recruited to make up for the lost data. With only partial and different parts of the data set missing for two of the participants, it was still possible to run all the statistical analyses with a minimum of n = 12. The statistical analysis was carried out using all available data.

5.6.2 Face validity

Post-test questionnaire

Overall, the participants rated the model as an effective or highly effective and useful tool for training nasal endoscopy on the post-test questionnaire (Table 5, Statement 5 & 6). The median score for all the statements was between 4 and 5 out of 5 where 5 indicated strong agreement or highly effective/useful. The participants agreed or strongly agreed that the model helps develop fundamental camera and scope navigation skills and hand-eye coordination needed for nasal endoscopy (Statement 1 & 2), as well as dexterity, accuracy, and precision with nasal endoscopy instruments (Statement 3). The only exception was the staff that rated the models fidelity (Statement 4) as 3 out of 5, while the residents and medical students rated it as 4 and 4.5 respectively (Table 6). All of the participants agreed or strongly agreed that they would be interested in using the model for training nasal endoscopy (Statement 7, 9 & 12), and that it could help increase trainees' competency before practicing nasal endoscopy on patients (Statement 8, 10 & 13). Both residents and medical students agreed or strongly agreed that

practicing on the model would make trainees more confident when practicing their first procedure on a patient (Statement 11 & 14). There was a general tendency for the medical students to rate the model higher on all statements than the residents and the staff.

Table 5: Post-test questionnaire: Individual participant rating of the simulator model

STATEMENT	PARTICIPANT												
	C	H	K	Y	O	U	Z	W	D	M	R	N	F
Statements rated from 1=strongly disagree to 5=strongly agree													
1. This model helps develop fundamental camera skills/scope navigation needed for nasal endoscopy	5	5	4	5	4	5	4	4	4	5	5	4	4
2. This model helps develop hand eye coordination needed for nasal endoscopy	5	5	5	5	4	5	4	5	5	5	5	4	5
3. This model helps develop dexterity, accuracy and precision with nasal endoscopy instruments.	5	5	5	4	4	5	5	4	4	5	5	4	4
4. This model is able to mimic actual nasal anatomy (high fidelity model).	5	5	4	4	4	5	3	4	3	4	4	3	3
Statements rated from 1=not effective/useful to 5=highly effective/useful													
5. Please rate the overall effectiveness of the model: did the model succeed in simulating the procedures	4	5	4	5	5	4	4	4	4	5	4	4	4
6. Please rate the overall usefulness of the model: how useful is the model as a training tool?	5	5	5	5	4	4	4	5	4	5	5	4	4
Statements rated from 1=strongly disagree to 5=strongly agree													
7. STAFF ONLY: I would be interested in using this model to teach residents.												5	4
8. STAFF ONLY: This model can increase residents competency when used prior to their first nasal endoscopy procedure												4	5
9. RESIDENTS ONLY: I would be interested in using this model to practice my skills.					4	5	4	4	4	5	4		
10. RESIDENTS ONLY: This model would have increased my competency if used prior to my first nasal endoscopy procedure.					4	5	3	4	5	5	5		
11. RESIDENTS ONLY: I would have felt more confident practicing my first nasal endoscopy procedure on patients after practicing on this model.					3	5	5	5	4	5	5		
12. MEDICAL STUDENTS ONLY: I would be interested in using this model to practice my skills.	5	5	5	5									

13. MEDICAL STUDENTS ONLY: This model will increase my competency when used prior to my first nasal endoscopy procedure.	5	5	5	5
14. MEDICAL STUDENTS ONLY: I will feel more confident practicing nasal endoscopy on patients after practicing on this model.	5	5	5	5

Table 6: Post-test questionnaire: Group median rating of the simulator model

STATEMENT	MEDIAN SCORE			
	Combined	Medical students	Residents	Staff
Statements rated from 1=strongly disagree to 5=strongly agree				
1. This model helps develop fundamental camera skills/scope navigation needed for nasal endoscopy.	5	4	4	4
2. This model helps develop hand eye coordination needed for nasal endoscopy.	5	5	4.5	5
3. This model helps develop dexterity, accuracy and precision with nasal endoscopy instruments.	5	5	5	4
4. This model is able to mimic actual nasal anatomy (high fidelity model).	4	4.5	4	3
Statements rated from 1=not effective/useful to 5=highly effective/useful				
5. Please rate the overall effectiveness of the model: did the model succeed in simulating the procedures	4	4.5	4	4
6. Please rate the overall usefulness of the model: how useful is the model as a training tool?	5	5	4	4
Statements rated from 1=strongly disagree to 5=strongly agree				
7. STAFF ONLY: I would be interested in using this model to teach residents.				4.5
8. STAFF ONLY: This model can increase residents competency when used prior to their first nasal endoscopy procedure				4.5
9. RESIDENTS ONLY: I would be interested in using this model to practice my skills.			4	
10. RESIDENTS ONLY: This model would have increased my competency if used prior to my first nasal endoscopy procedure.			5	
11. RESIDENTS ONLY: I would have felt more confident practicing my first nasal endoscopy procedure on patients after practicing on this model.			5	
12. MEDICAL STUDENTS ONLY: I would be interested in using this model to practice my skills.		5		
13. MEDICAL STUDENTS ONLY: This model will increase my competency when used prior to my first nasal endoscopy procedure.		5		
14. MEDICAL STUDENTS ONLY: I will feel more confident practicing nasal endoscopy on patients after practicing on this model.		5		

Comments and suggestions

In the post-test questionnaire, the participants were also given the opportunity to provide additional feedback in the form of comments and suggestions. Four of the participants commented that it would have been useful to have some form of immediate feedback to simulate patient pain and discomfort when touching sensitive structures:

Medical student: "The only drawback to this model is not having immediate feedback with respect to pain. Otherwise very realistic and helpful."

Junior resident (PGY 1): "Good starting model but would be helpful to have real time feedback as well i.e. how much pain am I inflicting with my repeated hammering of the septum? Or at least a measure of force being applied."

Chief resident (PGY 5): "Regarding fidelity, unable to simulate patient pain/discomfort with touching sensitive structures."

Staff: "For teaching model, would need feedback of septal/nasal force to enhance tool."

Two of the participants suggested that it would be useful if the model could simulate different, more advanced procedures with varying difficulty:

Junior resident (PGY 1): "If possible, can you vary the difficulty ie. deviated septum; hypertrophy of turbinates, polyps."

Chief resident (PGY 5): "Practicing even more advanced procedures (uncinectomy, widening sphenoid ostium w/ mushroom punch etc.) would be very useful for intermediate residents."

A few participants mentioned some limitations of the models fidelity:

Intermediate resident (PGY 2): "Not completely same feel as human nose."

Staff: "Lubrication is lacking - nose naturally lubricated with secretion, in this model some stiffness due to rubber/metal friction."

Finally, some of the participants commented that the model was a good training tool for gaining experience:

Medical student: "I was a great idea to try this. I honestly never expected it to be as hard as it actually was. This seems like a great way to practice and getting used to the camera angles and using other instruments."

Chief resident (PGY 5): "High fidelity model."

Intermediate resident (PGY 2): "Very good for experience"

Additional comments:

Medical student: "Thank you!"

Staff: "Flexible swab was humbling."

5.6.3 Construct validity

5.6.3.1 Objective Assessment of Technical Skills (OSATS)

Inter-rater Reliability (IRR)

Two assessors reviewed the participants' recorded procedure and rated their performance using the Objective Assessment of Technical Skills (OSATS). Inter-rater reliability (IRR) between the two assessors (Rater A and Rater B) was high when comparing the total OSATS scores for the participants, with a significant Spearman's rho correlation coefficient of $r = 0.837$ (n=13, $p < 0.01$, two-tailed). When comparing IRR across each of the OSATS list items, IRR was moderate to high and statistically significant for all items except item 1, Respect for Tissue, where IRR was only moderate and not statistically significant ($r= 0.408$, n=13, $p > 0.05$, two-tailed) (Table 7).

Table 7: Inter-rater Reliability (IRR) for the Objective Assessment of Technical Skills (OSATS)

OSATS item	n	IRR between Rater A and Rater B Spearman's rho correlation coefficient
Respect for tissue	13	0.408
Camera/scope handling time & motion	13	.857**
Instrument handling	13	.905**
Flow of operation	13	.764**
Completion of task 1: 3-pass examination of nasal cavity	12	.862**
Completion of task 2: Collecting culture	12	.654*
Completion of task 3: Biopsy of lesion	12	.830**
Total OSATS score	13	.837**

n=12: Missing scores for one participant due to corrupt video.
**. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).

OSATS performance scores

The participants' median OSATS scores according to experience are listed in Table 8 and 9. There was a general tendency for Rater B to rate the participants lower across all OSATS items, except for the medical students, where Rater B rated the performances higher. When comparing the median scores, there is an observable relationship between the participants' level of experience and OSATS scores, where those participants with more surgical experience, both in years and number of previous procedures performed, received higher scores than those with less experienced. There are a few exceptions, where someone with more experience was given a lower OSATS score than someone with less experience. Rater B gave one participant with 10 years of experience a total OSATS score of 23 while participants with only 5 years of experience received an average score of 32. Among the residents (PGY 1-PGY 5), some participants with more experience scored lower than their juniors. One resident with three years of experience (PGY 3) scored lower than the residents with two years experience (PGY 2). This can also be observed when looking at the number of previous procedures performed, where a participant with 50-100 procedures received a lower score than those with 1-10 or 10-50 procedures, according to both assessors. According to Rater B, this participant also performed worse than those with no previous experience with the procedure. According to Rater B, those with no experience also received the same median score as those with 1-10 previous procedures performed (Table 8 & 9).

Table 8: Median OSATS scores according to number of previous nasal endoscopy procedures performed using a rigid scope

OSATS item	N	Rater A					Rater B				
		0	1-10	10-50	50-100	>100	0	1-10	10-50	50-100	>100
		n=4	n=2	n=2	n=1	n=3/4	n=4	n=2	n=2	n=1	n=3/4
1. **Respect for tissue**	13	2.5	3.5	3.5	4	5	2.5	2.5	2.5	2	4.5
2. **Camera/scope handling time & motion**	13	1.5	3.5	4	3	5	2.5	2.5	3	3	4.5
3. **Instrument handling**	13	2	3	3.5	2	4.5	2	2	3	2	4.5
4. **Flow of operation**	13	2	3	3.5	2	5	2.5	3	3	2	4.5
5. **Completion of task 1: 3-pass exam. of nasal cavity**	13	1.5	4	4	4	5	2.5	2.5	3	2	4.5
6. **Completion of task 2: Collecting culture**	12	2	2.5	3.5	2	4	2.5	2.5	2.5	1	4
7. **Completion of task 3: Biopsy of lesion**	12	3	3	4	3	5	3	2.5	3	3	5
Total OSATS score	12	13.5	22.5	26	20	33	17.5	17.5	20	15	31

n=12: Missing scores for one participant due to corrupt video.

Table 9: Median OSATS scores according to years of surgical experience

OSATS item	n	Rater A							Rater B						
		0	1	2	3	5	10	17	0	1	2	3	5	10	17
		n=4	n=1	n=2	n=2	n=2	n=1	n=1	n=4	n=1	n=2	n=1	n=2	n=1	n=1
1. Respect for tissue	13	2.5	4	3.5	3.5	4.5	5	5	2.4	2	3	2	5	3	4
2. Camera/scope handling time & motion	13	1.5	4	3.5	3.5	5	4	5	2.5	3	2.5	3	4.5	3	5
3. Instrument handling	13	2	3	3.5	2.5	5	4	4	2	2	3	2	4	3	4
4. Flow of operation	13	2	3	3.5	2.5	5	5	5	2.5	3	3.5	2	4.5	3	5
5. Completion of task 1: 3-pass exam. of nasal cavity	13	1.5	4	4	4	4.5	5	5	2.5	3	2.5	2.5	4	4	5
6. Completion of task 2: Collecting culture	12	1.5	2	3.5	2.5	5	4	4	2.5	3	2.5	1.5	5	3	4
7. Completion of task 3: Biopsy of lesion	12	3	3	4	3	5	5	5	3	2	3.5	2.5	5	4	5
Total OSATS score	12	13.5	17	25.5	21.5	33	32	33	17	18	20.5	15.5	32	23	32

n=12: Missing scores for one participant due to corrupt video.

Scattergrams were used to visually analyze the OSATS scores against surgical experience (Figure 15-18). The scattergrams revealed that the relationship between OSATS scores and years of surgical experience is non-linear. The curve shows a rapid rise at the beginning that tapers of as the experience increases and becomes convex to the vertical axis. In the scattergrams showing the OSATS scores against surgical experience in previous endoscopic procedures performed the relationship appears more linear, although the scores for those with intermediate experience (1-100 procedures performed) appear highly variable (Figure 17 & 18). These patterns are also observable throughout each OSATS item (Appendix 5.9).

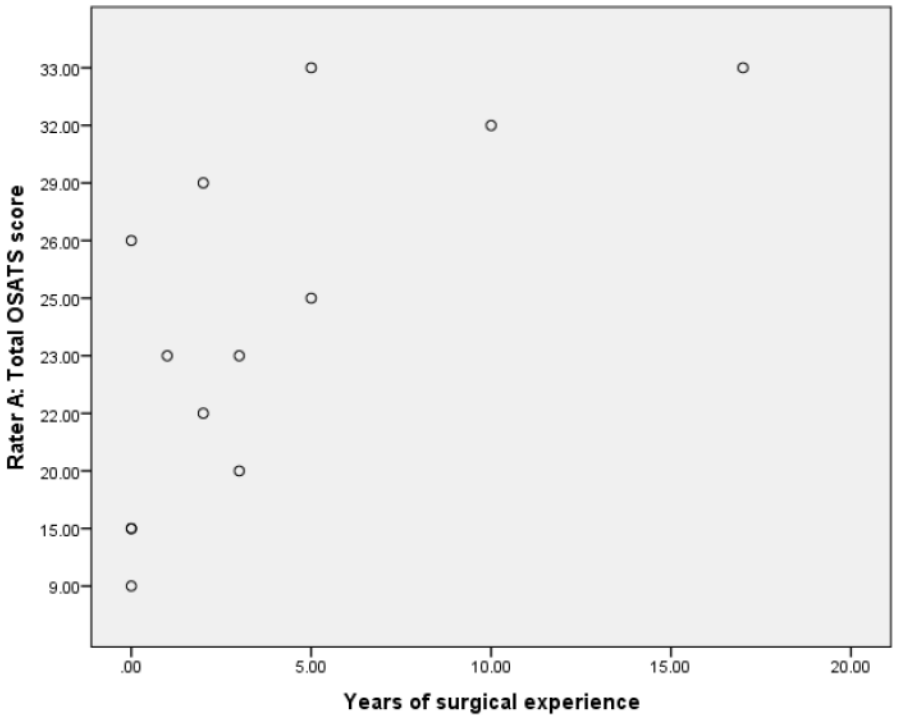

Figure 15: Rater A total OSATS scores against surgical experience (in years).

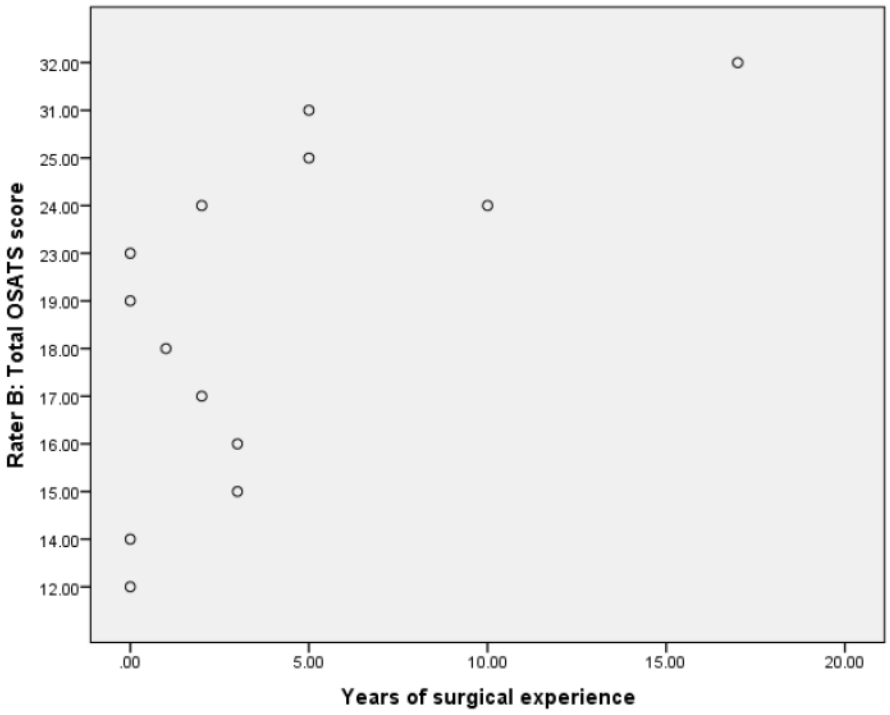

Figure 16: Rater B total OSATS scores against surgical experience (in years).

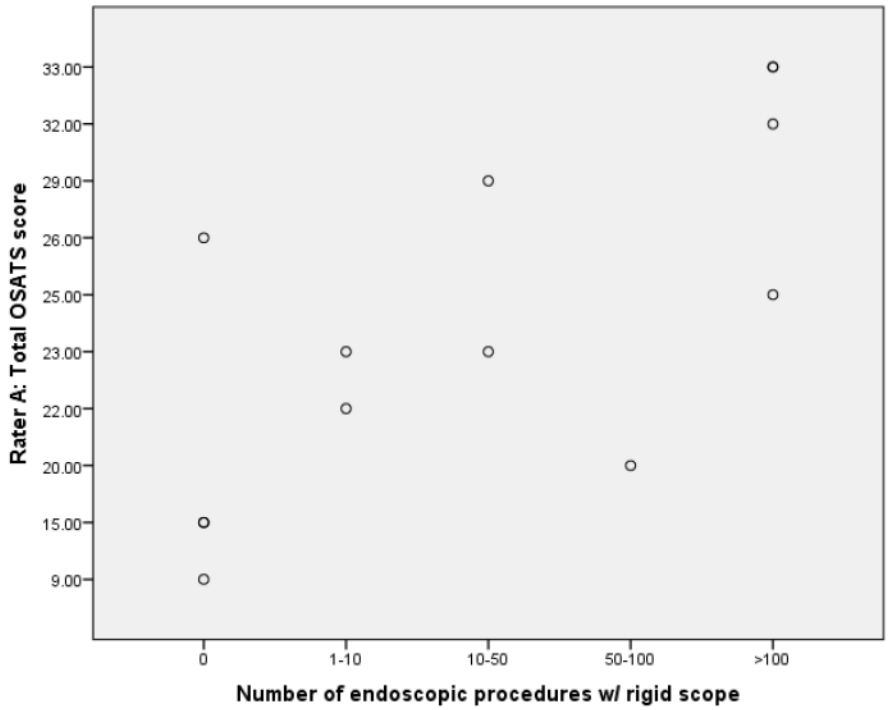

Figure 17: Rater A total OSATS scores against surgical experience (in number of previous nasal endoscopy procedures performed with a rigid scope)

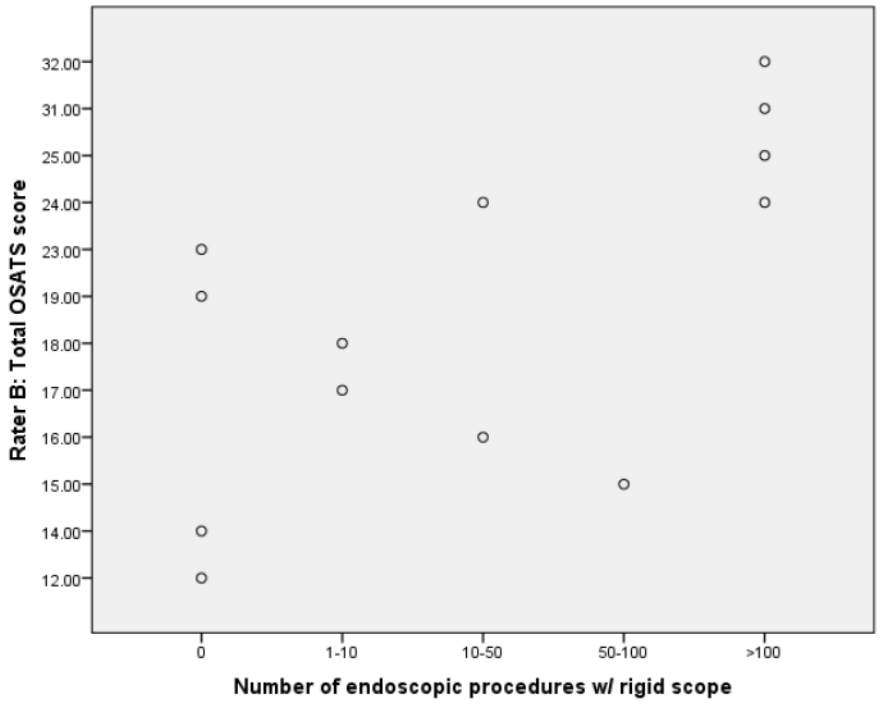

Figure 18: Rater B total OSATS scores against surgical experience (in number of previous nasal endoscopy procedures performed with a rigid scope).

Correlation between OSATS performance scores and surgical experience

The correlation between the participants' previous experience and performance on the model was used to determine the model's construct validity. A correlation value (r) between .3 and .6 is considered moderate and .7 to 1 is considered strong.[79] Expected correlation value was $r = .7$ or higher. As the sample size for this study was small (n=13), the significance of each correlation is also reported (Table 10 & 11).

Table 10: Correlation between OSATS scores and number of previous nasal endoscopy procedures performed using a rigid scope

OSATS item	n	Rater A Spearman's rho correlation coefficient	Rater B Spearman's rho correlation coefficient
1. Respect for tissue	13	.898**	.475
2. Camera/scope handling time & motion	13	.758**	.619*
3. Instrument handling	13	.751**	.810**
4. Flow of operation	13	.771**	.600*
5. Completion of task 1: 3-pass examination of nasal cavity	12	.641*	.526
6. Completion of task 2: Collecting culture	12	.766**	.431
7. Completion of task 3: Biopsy of lesion	12	.682*	.590*
Total OSATS score	12	.737**	.681*

n=12: Missing scores for one participant due to corrupt video.
**. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).

Table 11: Correlation between OSATS scores and years of surgical experience

OSATS item	n	Rater A Spearman's rho correlation coefficient	Rater B Spearman's rho correlation coefficient
1. Respect for tissue	13	.866**	.440
2. Camera/scope handling time & motion	13	.725**	.585*
3. Instrument handling	13	.700**	.737**
4. Flow of operation	13	.756**	.556**
5. Completion of task 1: 3-pass examination of nasal cavity	13	.663*	.539*
6. Completion of task 2: Collecting culture	12	.746**	.385*
7. Completion of task 3: Biopsy of lesion	12	.630*	.551*
Total OSATS score	12	.728**	.651*

n=12: Missing scores for one participant due to corrupt video.
**. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).

Correlation between OSATS performance and previous procedures performed

The correlation between the participants' total OSATS scores according to Rater A and the participants' experience based on previous nasal endoscopy procedures performed using a rigid scope was strong and significant ($r = .737$, $n = 12$, $p < 0.01$, two-tailed). The correlation between the participants' total OSATS scores according Rater B and the participants' experience based on previous nasal endoscopy procedures performed using a rigid scope was moderate to strong and significant ($r = .681$, $n = 12$, $p < 0.05$, two-tailed). The *r*-values for Rater A's OSATS scores across each OSATS item were all moderate to strong and significant. For Rater B, three of the OSATS items (item 1,5 & 6) only had moderate *r*-values and were not statistically significant.

Correlation between OSATS performance and years of surgical experience

The correlation between the participants' total OSATS scores according to Rater A and the participants' years of surgical experience was strong and significant ($r = .728$, $n = 12$, $p < 0.01$, two-tailed). The correlation between the participants' total OSATS scores according to Rater B and the participants' years of surgical experience was moderate to strong and significant ($r = .651$, $n = 12$, $p < 0.05$, two-tailed). The *r*-values for Rater A across each OSATS item were all moderate to strong and significant. For Rater B, the *r*-values were moderate to strong and significant on all items except item 1, Respect for Tissue.

Force scores

The force scores were recorded for each of the participants via three sensors: one in the lateral wall of the left nasal cavity, one in the septum, and one in the lateral wall of the right nasal cavity. The sensors in the lateral walls of the nasal cavities recorded the force exerted on the turbinates during the procedures. Each procedure gave two force scores, one for the turbinates (left or right nasal cavity) and one for the septum. The force was measured in absolute values, and the scores ranged from 11 to 796. The group-means of the average and maximum force scores for the participants according to experience level are listed in Table 12 – 15.

Table 12: Average force scores (group-mean) according to number of previous nasal endoscopy procedures performed using a rigid scope

Procedure	n Total	Number of previous nasal endoscopy procedures performed using a rigid scope				
		0 n=4	1-10 n=2	10-50 n=2	50-100 n=1	>100 n=3/4
Average force on turbinates during 3-pass examination of left nasal cavity	12	115.88	157.08	191.58	144.25	123.55
Average force on septum during 3-pass examination of left nasal cavity	12	57.93	83.02	70.26	100.19	59.00
Average force on turbinates during 3-pass examination of right nasal cavity	12	83.82	106.92	68.66	74.06	116.79
Average force on septum during 3-pass examination of right nasal cavity	12	34.08	34.23	52.01	59.56	43.00
Average force on turbinates during collection of culture in right nasal cavity	13	64.87	152.82	58.34	46.40	73.60
Average force on septum during collection of culture	13	29.00	33.06	25.37	34.97	32.69
Average force on turbinates during biopsy of lesion	13	83.76	201.52	128.95	64.09	134.73
Average force on septum during biopsy of lesion	13	35.31	40.48	49.83	25.66	34.75
Total average		63.08	101.14	80.63	68.65	77.26
Standard deviation		30.35	64.40	53.74	38.40	41.96

n=12: Missing scores for one participant due to computer error.

Table 13: Maximum force scores (group-mean) according to number of previous nasal endoscopy procedures performed using a rigid scope

Procedure	n Total	Number of previous nasal endoscopy procedures performed using a rigid scope				
		0 n=4	1-10 n=2	10-50 n=2	50-100 n=1	>100 n=3/4
Maximum force on turbinates during 3-pass examination of left nasal cavity	12	368.75	375.50	614.50	439.00	301.67
Maximum force on septum during 3-pass examination of left nasal cavity	12	201.25	257.00	288.50	396.00	219.33
Maximum force on turbinates during 3-pass examination of right nasal cavity	12	395.25	187.00	277.50	197.00	216.33
Maximum force on septum during 3-pass examination of right nasal cavity	12	125.75	71.00	136.00	163.00	89.00
Maximum force on turbinates during collection of culture	13	309.75	348.00	163.50	101.00	178.50
Maximum force on septum during collection of culture	13	91.00	73.50	104.00	123.00	62.00
Maximum force on turbinates during biopsy of lesion	13	531.25	520.00	357.00	171.00	305.75
Maximum force on septum during biopsy of lesion	13	142.25	127.50	167.50	107.00	70.75
Total average		270.66	244.94	263.56	212.125	180.41
Standard Deviation		155.45	160.48	166.34	131.45	98.30

n=12: Missing scores for one participant due to computer error.

Table 14: Average force scores (group-mean) according to years of surgical experience

Procedure	n Total	Years of Surgical Experience						
		0 n=4	1 n=1	2 n=2	3 n=2	5 n=2	10 n=1	17 n=1
Average force on turbinates during 3-pass examination of left nasal cavity	12	115.88	25.85	296.23	111.64	118.34	133.97	-
Average force on septum during 3-pass examination of left nasal cavity	12	57.93	82.20	89.84	72.44	68.26	40.47	-
Average force on turbinates during 3-pass examination of right nasal cavity	12	83.82	58.75	111.43	71.81	88.68	173.03	-
Average force on septum during 3-pass examination of right nasal cavity	12	34.08	11.25	66.07	44.32	50.53	27.94	-
Average force on turbinates during collection of culture in right nasal cavity	13	64.87	238.22	71.22	43.48	84.17	67.87	58.21
Average force on septum during collection of culture	13	29.00	11.00	27.56	42.90	20.24	44.35	45.95
Average force on turbinates during biopsy of lesion	13	83.77	175.66	181.71	92.98	115.98	105.82	201.13
Average force on septum during biopsy of lesion	13	35.31	13.24	61.28	35.24	40.29	34.15	24.26
Mean of average force for all procedures		63.08	77.02	113.17	64.35	73.31	78.45	82.39
Standard Deviation		30.35	85.73	86.81	27.57	35.16	53.46	80.40

n=12: Missing scores for one participant due to computer error.

Table 15: Maximum force scores (group-mean) according to years of surgical experience

Procedure	n Total	Years of Surgical Experience 0 n=4	1 n=1	2 n=2	3 n=2	5 n=2	10 n=1	17 n=1
Maximum force on turbinates during 3-pass examination of left nasal cavity	12	368.75	107.00	796.00	360.00	282.50	340.00	-
Maximum force on septum during 3-pass examination of left nasal cavity	12	201.25	224.00	335.00	296.50	275.50	107.00	-
Maximum force on turbinates during 3-pass examination of right nasal cavity	12	395.25	132.00	302.50	194.50	156.50	336.00	-
Maximum force on septum during 3-pass examination of right nasal cavity	12	125.75	12	117.00	165.50	109.00	49.00	-
Maximum force on turbinates during collection of culture	13	309.75	442.00	216.50	124.50	191.50	174.00	157.00
Maximum force on septum during collection of culture	13	91.00	11.00	68.00	165.50	36.50	104.00	71.00
rubMaximum force on turbinates during biopsy of lesion	13	531.25	412.00	455.00	301.50	284.00	271.00	384.00
Maximum force on septum during biopsy of lesion	13	142.25	18.00	166.50	173.00	80.50	84.00	38.00
Mean of maximum force for all procedures		270.66	169.75	307.06	222.63	177.00	183.12	162.50
Standard Deviation		155.45	174.94	233.90	84.48	97.53	116.90	155.95

n=12: Missing scores for one participant due to computer error.

Correlation between force and surgical experience

Overall, there was no correlation between the average and maximum force exerted on the turbinates and the septum during the procedures and the participants' surgical experience. Only one score showed a moderate and significant negative correlation between the maximum force exerted on the turbinates during the biopsy of a lesion task and the number of previous endoscopic procedures performed (r = -.585, n = 13, $p < 0.05$, two-tailed). Correlation

coefficients between surgical experience and overall force for all the procedures are listed in Table 16 and 17.

Table 16: Correlation between force scores and number of previous nasal endoscopy procedures performed using a rigid scope

Procedure	N	Spearman's rho correlation coefficient
Average force on turbinates during 3-pass examination of left nasal cavity	12	.295
Maximum force on turbinates during 3-pass examination of left nasal cavity	12	.187
Average force on septum during 3-pass examination of left nasal cavity	12	.151
Maximum force on septum during 3-pass examination of left nasal cavity	12	.252
Average force on turbinates during 3-pass examination of right nasal cavity	12	.094
Maximum force on turbinates during 3-pass examination of right nasal cavity	12	-.335
Average force on septum during 3-pass examination of right nasal cavity	12	.288
Maximum force on septum during 3-pass examination of right nasal cavity	12	-.014
Average force on turbinates during collection of culture in right nasal cavity	13	.198
Maximum force on turbinates during collection of culture	13	-.470
Average force on septum during collection of culture	13	.048
Maximum force on septum during collection of culture	13	.-111
Average force on turbinates during biopsy of lesion	13	.224
Maximum force on turbinates during biopsy of lesion	13	-.585*
Average force on septum during biopsy of lesion	13	.883
Maximum force on septum during biopsy of lesion	13	-.147

n=12: Missing scores for one participant due to computer error.
*. Correlation is significant at the 0.05 level (2-tailed).

Table 17: Correlation between force scores and years of surgical experience

Procedure	N	Spearman's rho correlation coefficient
Average force on turbinates during 3-pass examination of left nasal cavity	12	.290
Maximum force on turbinates during 3-pass examination of left nasal cavity	12	.179
Average force on septum during 3-pass examination of left nasal cavity	12	.097
Maximum force on septum during 3-pass examination of left nasal cavity	12	.168
Average force on turbinates during 3-pass examination of right nasal cavity	12	.193
Maximum force on turbinates during 3-pass examination of right nasal cavity	12	-.311
Average force on septum during 3-pass examination of right nasal cavity	12	.247
Maximum force on septum during 3-pass examination of right nasal cavity	12	.007
Average force on turbinates during collection of culture	13	.101
Maximum force on turbinates during collection of culture	13	-.495
Average force on septum during collection of culture	13	.201
Maximum force on septum during collection of culture	13	0.17
Average force on turbinates during biopsy of lesion	13	.297
Maximum force on turbinates during biopsy of lesion	13	-.496
Average force on septum during biopsy of lesion	13	.053
Maximum force on septum during biopsy of lesion	13	-.115

n=12: Missing scores for one participant due to computer error.

5.7 Conclusion

The models face validity was high, with average ratings between 4 and 5 out 5 for all statements. This confirms the hypothesis that the model would show good face validity by the participants rating its overall utility and effectiveness high.

The model showed construct validity based on the correlation between OSATS performance and surgical experience, with moderate to high and statistically significant correlations across all measures, with only a few values not showing statistical significance. This confirms the hypothesis that the model would show good construct validity with a high positive correlation between OSATS performance and surgical experience.

The model failed to show construct validity based on the correlation between force exerted on sensitive structures during the procedures and surgical experience, with low and non-significant correlations across all measures, with only one value showing a moderate and significant correlation. This rejects our hypothesis that the model would show construct validity with a high negative correlation between force exerted during the procedures and surgical experience.

5.8 Discussion

5.8.1 Face validity

While the fidelity of the model was rated high overall, a few of the residents and staff rated the fidelity as medium (3 out of 5). In the comments, one participant attributed this to the lack of lubrication and the resulting friction between the silicone material and the scope. Providing more lubrication to the walls of the nasal cavity or to the scope itself could solve this. For future iterations of the model, it may also be worthwhile to explore other rubberlike materials that have a lesser coefficient of friction than silicone.

One key item of feedback from the post-test questionnaire was that all the participants agreed or strongly agreed that they would be interested in using the model for training. The majority of the residents and medical students believed that a model would help, or have helped, increase their competency and confidence prior to practicing on patients. Although these statements are not sufficient to verify that there is a need for a simulator, it does suggest that such a model is a desirable solution to help trainees gain some initial experience with performing basic nasal endoscopy in a safe and less precarious environment. Some initial experience on the simulator model can help prepare them better for what to expect when entering the real patient scenario. This is well illustrated in a statement by one of the medical students: “It was a great idea to try this. I honestly never expected it to be as hard as it actually was.” The simulator model developed for the present research project would provide trainees the necessary hands-on experience to discover “how hard” endoscopy actually is in advance, and adjust and improve their technique accordingly so as to be better equipped to carry out the procedure on the patient.

5.8.2 Force feedback

A key finding from this study was that there was no significant correlation between the force exerted on the model during the procedure and the participants' surgical experience. There are many possible explanations for this. First, it can be observed that the force scores for the novice medical students were often lower than the resident and staff scores. From this, it can be inferred that the medical students' lack of experience caused them to be more careful than the more experienced participants. The medical students also generally scored low on the OSATS, failed to execute certain tasks properly, and struggled to reach and visualize certain structures with the camera. In some instances, it is necessary to exert force on structures such as the turbinates to get the camera or tool in the appropriate position. This can explain why the more experienced participants often had higher force scores during certain procedures.

The maximum force exerted on the turbinates during the biopsy of a lesion indicated a moderate but significant negative correlation between force and surgical experience in number of previous procedures performed ($r = -.585$, $n = 13$, $p < 0.05$, two-tailed). The correlation between force and years of surgical experience was moderate ($r = -.496$) but non-significant. The task involved navigating the scope and the forceps simultaneously in the very narrow space of the nasal cavity. The correlation between force and experience suggests that this is a more challenging task, where lack of experience in how to handle and navigate the instruments results in increased force on the turbinates. Although there were no other instances of correlation between force and experience, this finding suggests that there may still be a relationship. However, the initial assumption was that this relationship is exponential and would yield a high r-value, was false. As such, the concept will need to be approached differently.

It can be assumed that more experienced OHNS surgeons develop an understanding of the maximum force they can apply on surrounding tissue, to maintain patient comfort, while executing the procedure in the most thorough and efficient manner. This can be observed by comparing the maximum force for each procedure, where the more experienced participants generally have the lowest overall scores (Table 13 &15 and Appendix 5.10). The more experienced participants, with over 5 years of experience and more than 100 procedures performed (n=4), never exerted average maximum force higher than 384, while the participants with less than 5 years of experience and less than 100 procedures performed (n=9) occasionally exerted force over 400 and as high as 796. This suggests that those with more experience have developed the ability to execute all the tasks while exerting a lower maximum level of force on the surrounding structures. This level can be used a threshold that, when exceeded, can provide the trainee with immediate feedback in the form of an audible signal. It can also be used an objective measure of performance by functioning as a benchmark that trainees' performance can be assessed against. Four of the participants, from medical student to staff, also commented that it would be helpful to have some form of immediate feedback based on force to mimic patient pain in the model. This suggestion supports our thesis that a force feedback system could be relevant and beneficial to enhance the fidelity of the simulation scenario. So although the present study failed to show a strong correlation between force and surgical experience, force can still be a relevant measure of surgical proficiency during nasal endoscopy and can thus be applicable to simulation training. This should be explored through further study with larger sample sizes to better establish force benchmarks, and to see if force feedback contributes to enhanced performance over time.

5.8.3 Relationship between performance and surgical experience

Spearman's rho correlation coefficient assumes a linear relationship between non-parametric variables by organizing the data into ranks. This is beneficial when working with a small sample as it reduces the effect of outliers and extreme values. As the scattergrams in Figure 15-18 revealed, the relationship between OSATS performance scores and years of surgical experience is non-linear and appears convex to the vertical axis with an initial steep incline that plateaus at a certain level of experience. This curve is reflective of a typical 'learning curve'. The learning curve is a well-established concept in learning psychology, and is often applied to the acquisition of surgical skills. In the paper "Measuring the Surgical 'learning curve': Methods, Variables and Competency," Nuzhath Khan et al. describes the concept of the learning curve as "[...] learning a practical skill becomes easier with time, with an initial period of difficulty followed by a rate of improvement and stabilization in performance."[85] The observation that the participants' performance on the model reflects a conventional performance pattern or 'learning curve' further strengthens the simulator models construct validity and suggests that the simulation is comparable to the real scenario.

When comparing the OSATS performance scores against surgical experience based on number previous nasal endoscopy procedures performed, the relationship appears more linear. This is a result of the ranking of the participants experience into ranges of 0, 1-10, 10-50, 50-10 and over 100 procedures performed. The collapsing of the participants experience into ordinal ranks eliminates possible variations within the groups and does not factor in the differences in the size of experience between each range and each participant. It therefore eliminates the subtle differences that one would have potentially observed as the performance score stabilizes among

the more experienced participants.

5.8.4 Inter-rater reliability

Although overall inter-rater reliability was high ($r = 0.837$ n=13, $p < 0.01$, two-tailed), there was some variation between the two assessors' OSATS ratings. As mentioned, Rater B had a tendency to rate the participants' performances lower than Rater A. The correlation between the participants' surgical experience and performance assessed by Rater B was also lower overall. One possible explanation for this is that Rater B had less surgical experience and thus less experience in training and evaluating residents performance than Rater A. It may be that the lack of experience influenced the reliability of Rater B's assessment, while the convention is to use more expert raters, or conduct rater training prior to the study.[84]

5.8.5 Multiple comparison correction

It was concluded that the model showed construct validity based on the correlation between OSATS scores and surgical experience. One challenge with this conclusion might be that there was no correction made to protect against a type 1 error when running multiple correlations.[86] A Bonferroni correction would divide the alpha level of 0.05 by the number of correlations that was performed (0.05/32 = 0.0016). This type of correction protects against a researcher falsely making a conclusion that there is a correlation of significance by chance alone. However, one consequence of making too much adjustment to the alpha is that there may be an increased likelihood of making a type 2 error (concluding that there is no correlation of importance, when in fact there is). In this study the majority of the calculations yielded a strong and significant correlation. Of the 32 calculated r-values, including both Rater A and Rater B scores against both measures of experience, 28 were statistically significant of which 15 were significant at the .01 level (two-tailed) and the rest at the .05 level (two-tailed). These findings indicate a correlation

that likely supports the hypothesis for this study. However, this was a pilot investigation in a novel area. It is possible that some of these correlations are significant by chance alone, but there was also the worry that, had all of the correlations been corrected for, important correlations that are likely to be real could have been missed.[86] The significant correlations with the small number of data points seem to be pointing to very real effects. Future, non-pilot, investigations need to correct for the multiple correlations.

5.8.6 Additional observations

Some additional observations were made during the study that merits the need for incorporation of simulation in basic nasal endoscopy skills training. Many of the less experienced participants would not be aware of how they oriented themselves and the scope relative to the model. For example, many of the medical students would position themselves in front of the model. During a real patient setting, this would not only be impossible because of the physical presence of the patient, but it would also most likely affect the patients level of comfort. The proper orientation is to one side of the patient, depending on the handedness of the person executing the procedure. These factors are key to develop a good and thorough scoping technique. Although this can be developed with instruction on real patients during clinic rotations, it would be beneficial to have a simulated set-up where more time could be dedicated to this, and not take unnecessary time away from the actual clinical examination of the patient. Another observation was that even more experienced participants (PGY 1 – PGY 3) performed poorly or made unnecessary mistakes during the execution of some of the basic tasks. In some instances, experienced residents would hold the forceps above the endoscopic camera and thus obstruct their view during the biopsy task. One resident who, despite three years of experience (PGY 3) and between 50-100 procedures performed, scored lower than those with less experience. This should be of

concern as residents are expected to be fully proficient in performing the procedure by the third year of their residency.[19] The poor performance on behalf of the more experienced residents may be a result of the residents not having had the opportunity, due to limited time or access, to exclusively focus on these technical considerations to develop their technique. Simulation would be a good way to facilitate this, without concern for time or patient safety and comfort.

5.9 Limitations

One of the limitations to this study was the small sample size. Although the sample size calculation suggested that a sample of n=12 would be sufficient to achieve power, it is recommended that correlation studies involve at least 100 participants to be acceptable. Otherwise, extreme scores can skew the data and result in false correlations, or no correlation where one might actually exist.[79] To avoid this, the significance of each correlation is reported to show that the correlations did not occur by chance. The scattergrams for each correlation between OSATS scores and surgical experience (number of procedures performed) is also provided in Fig. 15-18 and Appendix 5.9 to illustrate the nature of the relationship between the variables.

Another limitation of this study was that the participants were all recruited from the same institution. There were both student-professor and collegial relationships between the participants that may have lead to pressure to participate, or bias in the feedback in the post-test questionnaire. Every effort was made to minimize this by informing the participants that the participation was completely voluntary, and by preserving their anonymity by coding all the data from the study and blinding the assessors to the identity of each participant.

A final limitation pertains to the structure of the post-test questionnaire (Appendix 5.6). All the participants were given the same questionnaire. On the second page of the questionnaire the participants were asked to only fill out the questions that pertained to them as a medical student, resident, or staff. Allowing the participants to see that potentially their students or their instructors would also be rating the model may have influenced their ability to give their unbiased opinion. For future studies, it would be advisable to give the participants different questionnaires related to their level of training.

6. Conclusion

The aim of the present research project was to address the stated need for a practical simulator for the development of basic nasal endoscopy skills in OHNS residency programs. As residency programs are adapting to an increasingly complex and resource constrained environment, alternatives to the traditional model of surgical training that has remained largely unchanged over the past century, is needed. Together with the shift towards a more competency-based framework for surgical training, this warrants the need for more available, reliable, and accurate alternatives to the exclusive reliance on patient based training. The simulator model developed for training basic nasal endoscopy skills presents a valid, useful, effective, and more accessible alternative to current training practices. Specifically, it can facilitate a standardized platform for both the development and assessment of some of the Medical Expert competency milestones outlined in the Competency by Design framework.[29]

As demonstrated in the validation study, the need for a safe and accessible environment for the development of technical skills in nasal endoscopy is warranted for both novice and more experienced trainees. Allowing residents' to practice their skills and develop a good and reproducible technique on the model will prepare them better for the real patient scenario. This will help improve their confidence, allow for more efficient use of clinic and OR time, and improve the comfort and safety of patients.

Although the present study failed to establish force feedback as a relevant objective measure of performance during nasal endoscopy, the concept is considered valuable for further inquiry. It should be investigated whether force can be used as a way of establishing benchmarks based on expert performance that trainees' performance can be assessed against. There should also be an

investigation into whether audible force feedback can help enhance the fidelity and effect of training on the simulator, compared to no feedback.

The success of this project can largely be attributed to the process of development. By first examining the training needs and perceptions of simulation technology among important stakeholders and gatekeepers in OHNS programs, facilitated development of a simulator that was tailored and relevant to the curriculum and the needs of both OHNS residents and faculty. Furthermore, having a multidisciplinary research team consisting of both experts in OHNS, surgical training, surgical simulation, and design contributed to the quality of the final product.

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Appendix 3.1: Information letter and consent form

INFORMATION LETTER

Perceptions of Surgical Simulation in Otolaryngology Residency Training: A Qualitative Pilot Study Using the Convergent Interview Technique

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Background

- A group of researchers from the Institute for Reconstructive Sciences in Medicine (IRSM), the Faculty of Rehabilitation Science and the Department of Surgery at the University of Alberta has come together to develop a surgical simulator for training nasal endoscopy in surgical residency programs.
- You have been asked to participate in this pilot study based on your academic background and/or professional experience.
- You received an email from the Research Investigator and/or the Supervisor asking you to participate in this study and you contacted the Research Investigator on a voluntary basis to express your interest in participating.
- The results of this pilot study will be used in support of the Research Investigator's Master of Science in Rehabilitation Science thesis project.
- The research findings of this study may be published and have the potential for commercialization.

Purpose

- This pilot study aims to detect the needs and perceptions of surgical simulation among experts in the field of otolaryngology through a series of interviews. The findings of the study will help inform a succeeding study that involves the development of a surgical simulator for training nasal endoscopy in surgical residency programs.

Study Procedures

- You are asked to take part an in-depth interview. The interview is expected to take 1 to 1.5 hrs.
- Type(s) of personal data to be collected:
  - Name and surname
  - Email address
  - Professional title and years of experience

Benefits

The findings from this study will help form a theoretical background for the development of a surgical simulator for training nasal endoscopy in surgical residency programs. This simulator has the potential to accelerate residents learning curve, improve patient safety and comfort, and reduce both time and material cost related to the training of surgical residents. On its own, this study will also make a valuable, qualitative contribution to the growing body of knowledge in the field of surgical simulation. The benefit

to you as a participant is the future potential to utilize simulators in your professional practice, as well as the opportunity to contribute your valuable knowledge and experience to a new and expanding research area.

Risk

- There are no risks associated with this study.

Voluntary Participation

- You are under no obligation to participate in this study or to answer any specific questions even if participating in the study. The participation is completely voluntary.
- Even if you agree to be in the study you can change your mind and withdraw at any time up until the completion of the interview. If you withdraw, we will recruit a new participant in your place if needed.

Confidentiality & Anonymity

- This research is part of a MSc thesis project and its findings may also be part of research articles, presentations, teaching, or web postings. In none of these instances will your name be included or in any possible way revealed.
- Your name and contact information will only be known to the research team for scheduling purposes, and will not be included in the research findings. The research data will be made publicly available, but without any direct identifiers that can be related back to you as a participant. However, your professional title and years of experience will be reported as these are necessary to demonstrate the expertise and representativeness of the selected participants.
- Anonymity will be maintained by replacing your name with a number or letter that will be associated with the research data. The list of identifiers (names and corresponding numbers) will only be known to the research team.
- Your personal data (name and contact information) will be kept on a password protected computer only accessible by the Research Investigator during the research project. This data will be destroyed immediately upon completion of the study in April 2015. The research data will be kept in a secure place for a minimum of 5 years following completion of the research project.
- We will use the data we get from this study in future research, but if we do this it will have to be approved by a Research Ethics Board.

Further Information

- If you wish to receive a copy of the final thesis report for this project, you can indicate so at the bottom of this page and a copy will be emailed to you once the project has been completed.
- If you have any further questions regarding this study, please do not hesitate to contact the Research Investigator Laila Steen by phone: 780.999.1560 or email: lsteen@ualberta.ca or the Supervisor: Dr. Erin Wright by phone: 780.XXX.XXX or email: xxxx@xxx.xx
- The plan for this study has been reviewed for its adherence to ethical guidelines by a Research Ethics Board at the University of Alberta. For questions regarding participant rights and ethical conduct of research, contact the Research Ethics Office at (780) 492-2615.

CONSENT FORM

Perceptions of Surgical Simulation in Otolaryngology Residency Training: A Qualitative Pilot Study Using the Convergent Interview Technique

Research Investigator: Laila Steen
Phone Number(s): 780.999.1560
Supervisor: Dr. Erin D. Wright, MDCM, MEd, FRCSC
Phone Number(s): 780.XXX.XXX

	YES	NO
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Letter?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to leave the study at any time, without having to give a reason and without any consequences to you?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐

Who explained this study to you?_____

I agree to take part in this study:

Signature of Research Participant:_____

Printed Name:_____

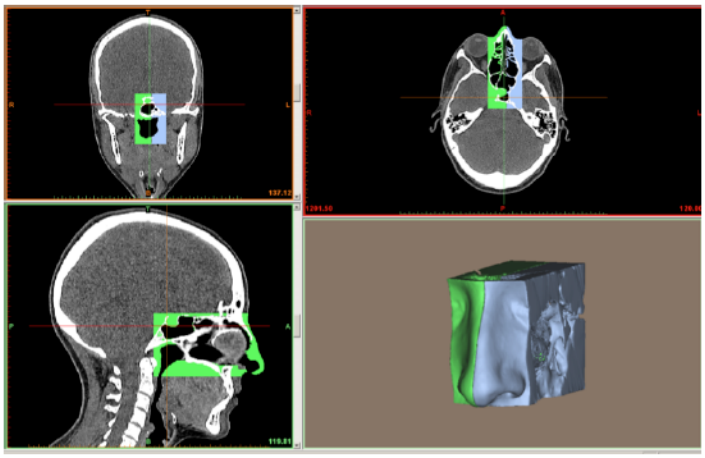
Date:_____ Place:_____

Contact information:

Email:_____ Phone (optional):_____

☐ I wish to receive a copy of the research report

Appendix 4.1: Segmentation of CT data to generate 3D models in Mimics®



Segmentation and generation of a 3D model of the left and right nasal cavity including the nose in Mimics® software based on CT data.

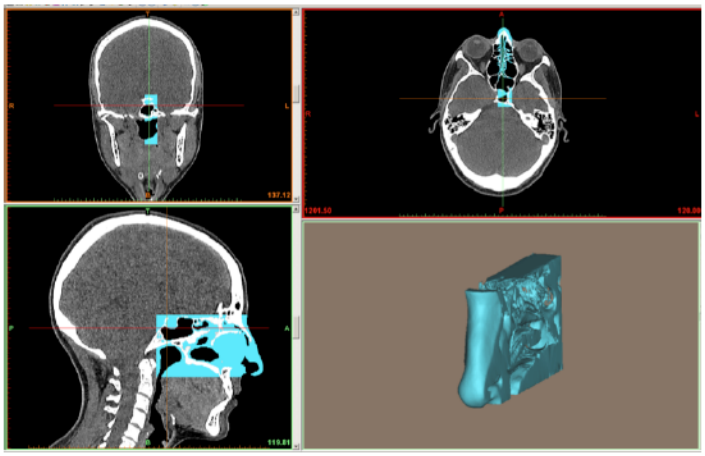
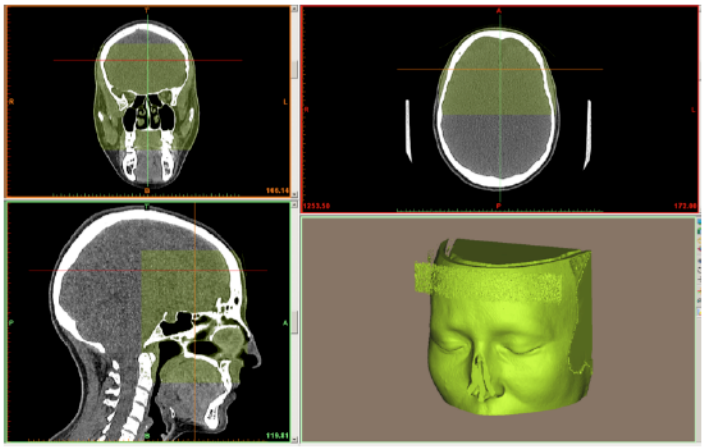
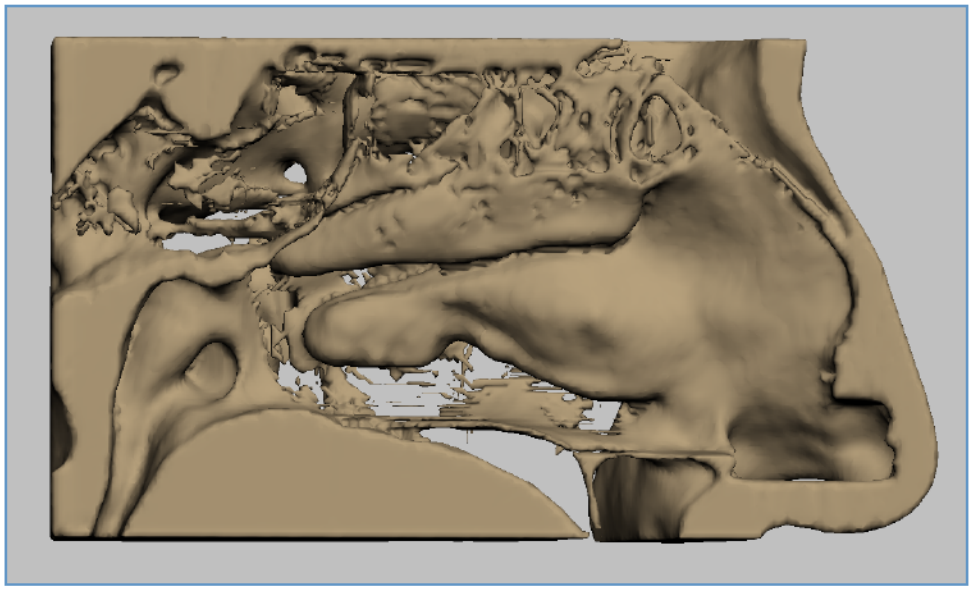


Image 2: Nasal septum.

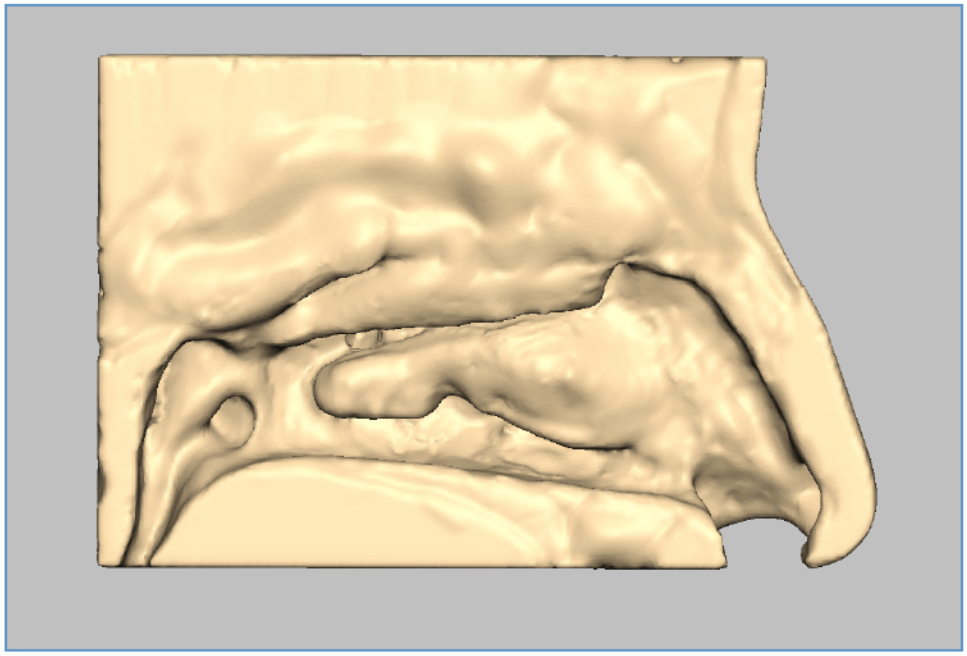


Facial anatomy for the cephalic housing unit.

Appendix 4.2: Corrections for missing anatomy in the computer generated model



The initial computer-generated model of the lateral wall of left nasal cavity based on the CT scan. Some of the thin bony anatomy between the nasal cavity and the sinuses is missing and had to be added using Freeform® software.

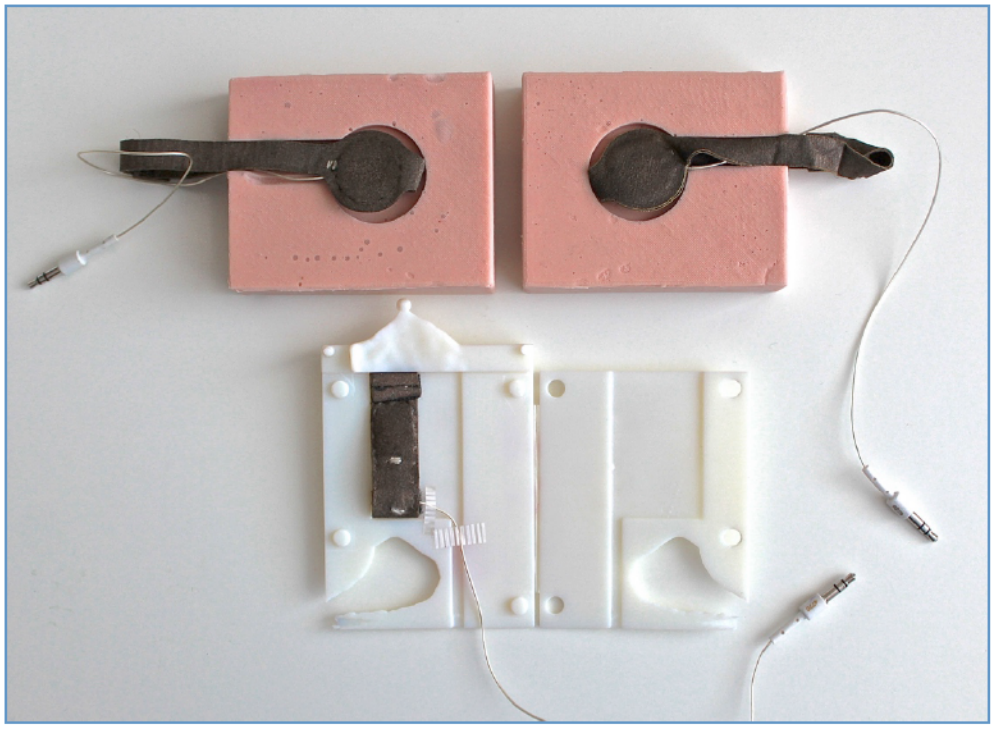


The lateral wall of the left nasal cavity after initial adjustments to correct for the missing anatomy. Once finalized, the lateral wall of the left nasal cavity was mirrored to produce the lateral wall of the right cavity.

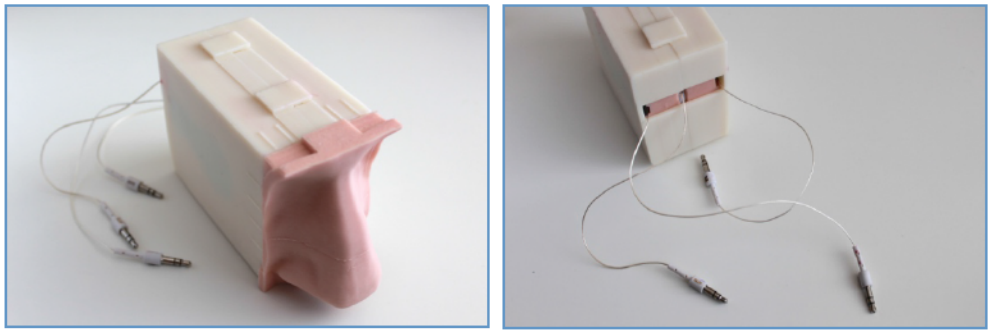
Appendix 4.3: Force sensors

The PPS FingerTPS™ system.
Note: from Pressure Profile Systems. *FingerTPS Pressure Sensor System.* 2015. Available at: http://www.pressureprofile.com/fingertps. Accessed May 11 2015.

The PPS FingerTPS™ system connected to the simulator model. The output from the Chameleon Visualization and Data Acquisition software is showing on the left.

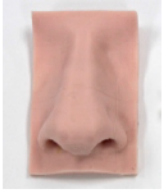


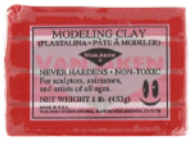
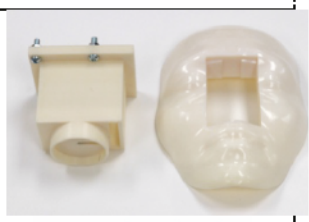
Placement of the force sensors in the model. The design of the internal components was adapted to fit the different sensors. Palm sensor pads were used in the lateral walls of the nasal cavity and a finger sensor pad was used in the septum.



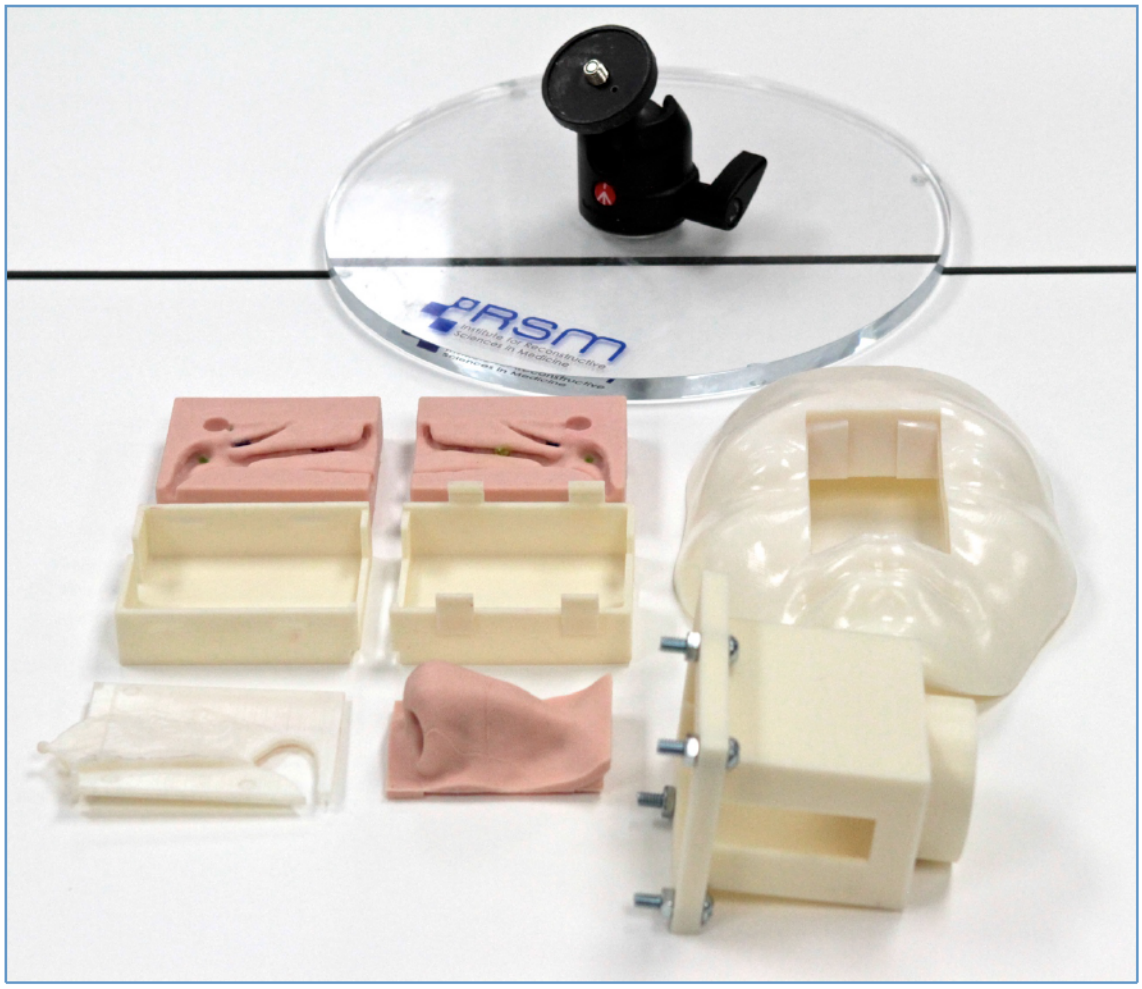
The internal components assembled with sensors in place. The connector pins connect the model to the PPS FingerTPS™ system.

Appendix 4.4: List of materials and equipment for final prototype:

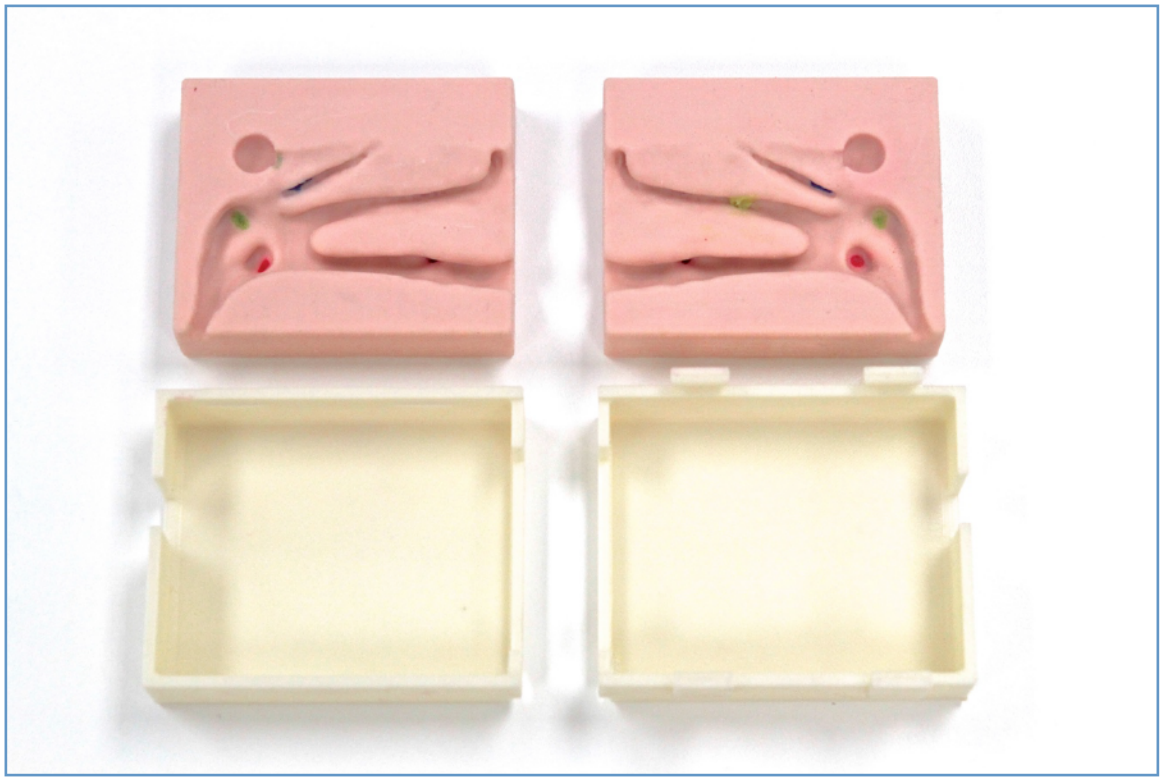
Part	Material	Machine/ equipment	Company	Thumbnail
External component face	Vero White	Objet Connex500™ 3D printer	Stratasys 3D Printing, Eden Prairie, MN, USA	
Septum	Vero White	Objet Connex500™ 3D printer	Stratasys 3D Printing, Eden Prairie, MN, USA	
External component housing unit	ABS*Plastic*	Dimension SST 1200es 3D printer	Stratasys 3D Printing, Eden Prairie, MN, USA	
Casing for lateral walls of the nasal cavity	ABS*Plastic*	Dimension SST 1200es 3D printer	Stratasys 3D Printing, Eden Prairie, MN, USA	
Molds for the lateral walls of the nasal cavity	PC-ISO thermoplastic	Fortus 400mc 3D printer	Stratasys 3D Printing, Eden Prairie, MN, USA	
Molds for the nares	PC-ISO thermoplastic	Fortus 400mc 3D printer	Stratasys 3D Printing, Eden Prairie, MN, USA	
Nares	Factor II LSR-05 Silicone Elastomer, Factor II Functional Intrinsic II Silicone Coloring		Factor II, Incorporated, Lakeside, AZ, USA	

Left and right lateral wall of the nasal cavity	Factor II LSR-05 Silicone Elastomer, Factor II Functional Intrinsic II Silicone Coloring		Factor II, Incorporated, Lakeside, AZ, USA	
Artificial puss	Vaseline®, mineral oil, Factor II Functional Intrinsic II Silicone Coloring		Unilever, Englewood Cliffs, NJ, USA Factor II, Incorporated, Lakeside, AZ, USA	
Artificial lesion	Van Aken Plastalina pigmented, oil based modeling compound.		Van Aken, North Charleston, SC, USA	 
Ball-head tripod		Manfrotto 486 Compact Ball Head tripod	Manfrotto Supports, Cassola, Italy	
Base	Clear acrylic			
Hardware for attaching the face to the housing unit	¼ x 1 inch bolt w/nut x4			 

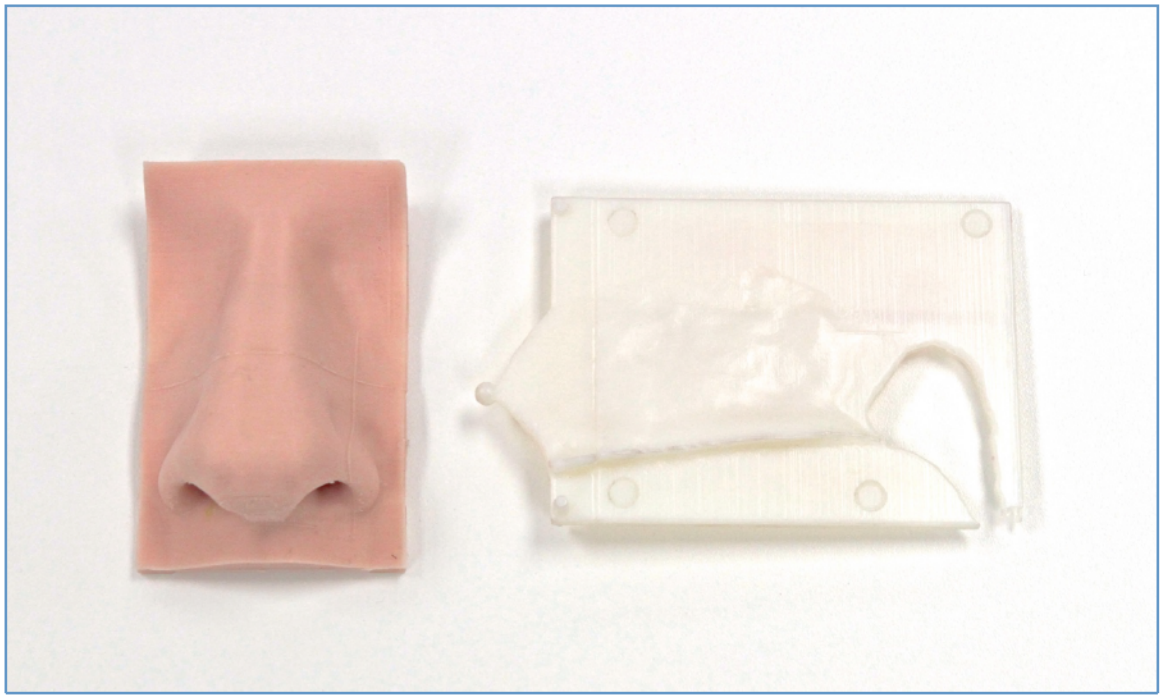
Appendix 4.5: Simulator model images



Final prototype disassembled.

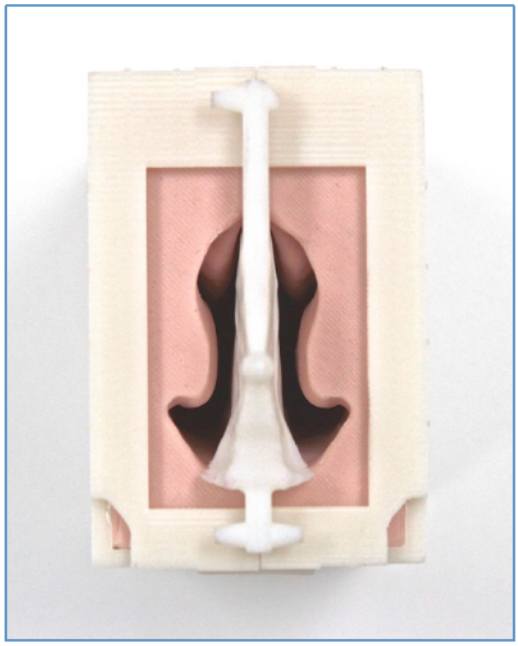


Left and right lateral wall of nasal cavity with casing.



Nose and septum.

Housing unit and face.



Anterior view of Internal component without nose.

Internal component with nose.

Appendix 5.1: Letter of initial contact

Institute for Reconstructive Sciences in Medicine

T: 780.735.2660 F: 780.735.2658
E: irsm@albertahealthservices.ca W: www.irsm-canada.com
1W-02, 16940–87 Ave. Edmonton, AB, Canada T5R 4H5

Dear Sir or Madam,

My name is Laila Steen and I am a graduate student in the Faculty of Rehabilitation Medicine with a research focus in Surgical Design and Simulation. As a part of my thesis project, I am working together with a group of researchers from the Institute for Reconstructive Sciences in Medicine (IRSM), the Faculty of Rehabilitation Science and the Department of Otolaryngology - Head and Neck Surgery at the University of Alberta to develop and validate a surgical simulator for training nasal endoscopy in otolaryngology residency programs.

I have contacted you to ask if you would like to contribute to our study by participating in an experiment to validate the simulator. The experiment involves you performing a set of basic nasal endoscopic tasks on the simulator and filling out a short questionnaire. The experiment should take no more than 1 hour of your time.

It is our belief that this simulator has the potential to accelerate residents' learning curve, improve patient safety and comfort, and reduce both time and material cost related to the training of surgical residents. The benefit to you as a participant is the future potential to utilize simulators in your professional practice.

If you would like to learn more about this study and how to participate please email me at your earliest convenience. It is important to know that this letter is not to tell you to join this study; it is your decision and your participation is voluntary.

If I do not hear from you within two weeks, you may be approach again to ask for your participation.

Thank you for your time and consideration.

Sincerely,

Laila Steen (Research Investigator)

lsteen@ualberta.ca
780.735.2660

Dr. John Wolfaardt (Supervisor)

johan.wolfaardt@albertahealthservices.ca
780.735.2660

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Appendix 5.2: Sample size calculation table

TABLE C.5.1 POWER OF THE CORRELATION COEFFICIENT, r ($\alpha_1 = .05$)

	r								
n	.10	.20	.30	.40	.50	.60	.70	.80	.90
8	08	12	18	26	37	52	68	85	97
9	08	13	20	29	42	57	74	90	99
10	08	14	22	32	46	62	79	93	99
11	09	15	23	35	50	67	83	95	
12	09	15	25	38	54	71	87	97	
13	09	16	26	40	57	74	89	98	
14	10	17	28	43	60	78	91	98	
15	10	18	30	45	63	81	93	99	
20	11	22	37	56	75	90	98		
30	13	28	50	72	90	98			
40	15	35	60	83	96				
50	17	41	69	90	98				
60	19	45	76	94	99				
80	22	45	86	98					
100	26	64	82	99					
200	41	89							
500	72								
1000	94								

TABLE C.5.2 POWER OF THE CORRELATION COEFFICIENT, r ($\alpha_2 = .05$)

	r								
n	.10	.20	.30	.40	.50	.60	.70	.80	.90
8	06	07	11	16	25	37	54	75	94
9	06	08	12	19	29	43	62	82	97
10	06	08	13	21	33	49	68	87	98
11	06	09	14	23	36	54	73	91	99
12	06	09	16	26	40	58	78	93	99
13	06	10	17	28	44	63	82	95	
14	06	10	18	30	47	66	85	96	
15	06	11	19	32	50	70	88	98	
20	07	14	25	43	34	83	96		
30	08	19	37	61	83	95			
40	09	24	48	74	92	99			
50	11	29	57	83	97				
60	12	34	65	90	99				
80	14	43	78	96					
100	17	52	86	99					
200	29	81	99						
500	61	99							
1000	89								

Adapted from Tables 3.3.2 and 3.3.5 in Cohen, J. *Statistical Power Analysis for the Behavioral Sciences*, ed 2. Hillsdale, NJ: Lawrence Erlbaum Associates, 1988. Used with permission of the publisher and author.

Note. From Foundations of clinical research: Applications to practice (2nd ed.) p. 724, by L.G. Portney & M. P. Watkins, 2000, Upper Saddle River, NJ: Prentice Hall.

Appendix 5.3: Information letter and consent form

Institute for Reconstructive Sciences in Medicine

T: 780.735.2660 F: 780.735.2658
E: irsm@albertahealthservices.ca W: www.irsm-canada.com
1W-02, 16940–87 Ave. Edmonton, AB, Canada T5R 4H5

INFORMATION LETTER & CONSENT FORM

Validity of a Practical Simulator for the Development of Basic Nasal Endoscopy Skills in Otolaryngology Residency Programs

Research Investigator:
Laila Steen (MSc student)
University of Alberta
and 85 Ave, Edmonton
AB T6G 2R3
lsteen@ualberta.ca
780.735.2660 (IRSM)

Supervisor:
Dr. Johan Wolfaardt
Institute for Reconstructive Sciences in Edmonton, 116 St
Medicine, University of Alberta
Edmonton, AB Canada T5R 4H5
1W-02, 16940–87 avenue
johan.wolfaardt@albertahealthservices.ca
780.735.2660 (IRSM)

Background

- A group of researchers from the Institute for Reconstructive Sciences in Medicine (IRSM), the Faculty of Rehabilitation Science and the Department of Otolaryngology - Head and Neck Surgery at the University of Alberta has come together to develop and validate a surgical simulator for training nasal endoscopy in otolaryngology residency programs.
- You have been asked to participate in this study based on your academic background and/or professional experience.
- You received an email by a member of the Department of Otolaryngology-Head and Neck Surgery at the University of Alberta *or* you were contacted in person by a member of the Department of Otolaryngology-Head and Neck Surgery at the ENT clinic at the University of Alberta Hsopital and then contacted the Research Investigator on a voluntary basis to express your interest in participating in this study.
- The results of this study will be used in support of my thesis.
- The research findings of this study will be published and have the potential for commercialization.

Purpose

- The purpose of this study is to test a model that has been developed for training basic nasal endoscopic skills in surgical residency programs. By improving skills we hope to better patient care and safety.

Study Procedures

- Upon filling out this consent form, you will be asked to fill out a pretest questionnaire determining certain traits and your level of surgical experience. On this questionnaire you will be assigned a participant number which will be your only identifier in this study (your name and contact information will not be disclosed and will only be kept by the Research Investigator for scheduling purposes).
- On the day of the test, you will be asked to perform a set of tasks on a plastic model of the nose that are common nasal endoscopic procedures. You will also be asked to fill out a post-test questionnaire to rate the model.
- The only expectation is that you complete the tasks assigned. The pre-test questionnaire, the test and the post-test questionnaire is expected to take no more that 1hr to complete.
- Type(s) of data to be collected:
    - Name, email (in consent form).
    - Pre-test questionnaire asking handedness (left/right), years of surgical experience, and number of nasal endoscopic procedures performed.

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INFORMATION LETTER & CONSENT FORM

- During the test, your performance will be recorded via the endoscopic camera. Your identity will not be revealed in the recording.
- Your performance will be assessed at a later point using the Objective Assessment of Technical Skills (OSATS) global rating scale sheet. The assessor will not know your identity.

Benefits

- The simulator proposed by this study will provide a readily available tool for training nasal endoscopy skills in surgical residency programs. The model will allow residents to safely practice skills to the level of automaticity before they go on to practice on real patients in the clinic. This will increase the efficiency and safety of the procedure and hopefully increase the quality of patient care. The benefit to you as a participant is the future potential to utilize simulators in your professional practice, as well as the opportunity to contribute to a new and expanding research area.

Risk

- There are no risks associated with this study.

Voluntary Participation

- You are under no obligation to participate in this study or to answer any specific questions even if participating in the study. The participation is completely voluntary.
- Even if you agree to be in the study you can change your mind and withdraw at any time. If you withdraw, we will recruit a new participant in your place.

Confidentiality & Anonymity

- This research is part of a MSc thesis, and its findings may also be part of research articles, presentations, teaching, or web postings. In none of these instances will your identity be included or in any possible way revealed.
- Your personal data will only be known the Research Investigator for scheduling purposes, and will not be included in the research findings. The research data will be made publicly available, but without any identifiers that can be related back to you as a participant.
- Anonymity will be maintained by replacing your name with a number that will be associated with the research data. The list of identifiers (names and corresponding numbers) will only be known by the Research Investigator.
- Your personal data (name and contact information) will be encrypted and kept on a password protected computer only accessible by the Research Investigator during the research project. This data will be destroyed immediately upon completion of the study in December 2015. The research data will be kept in a secure place for a minimum of 5 years following completion of research project.
- We may use the data we get from this study in future research, but if we do this it will have to be approved by a Research Ethics Board.

Further Information

- If you wish to receive a copy of the final thesis report for this project, you can indicate so in the consent form and a copy will be emailed to you once the project has been completed.
- If you have any further questions regarding this study, please do not hesitate to contact the Research Investigator, Laila Steen, by phone: 780.999.1560 or email: lsteen@ualberta.ca.
- The plan for this study has been reviewed for its adherence to ethical guidelines by a Research Ethics Board at the University of Alberta. For questions regarding participant rights and ethical conduct of research, contact the Research Ethics Office at (780) 492-2615.

INFORMATION LETTER & CONSENT FORM

Validity of a Practical Simulator for the Development of Basic Nasal Endoscopy Skills in Otolaryngology Residency Programs

Research Investigator: Laila Steen **Phone:** 780.735.2660
Supervisor: Dr. Johan Wolfaardt **Phone:** 780.735.2660

	YES	NO
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Letter?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to leave the study at any time, without having to give a reason and without any consequences to you?	☐	☐
Do you understand who will have access to the information you provide?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐

Who explained this study to you? _____

I agree to take part in this study:

Signature of Research Participant: _____

Printed Name: _____

Date: _____ Place: _____

Contact information:

Email: _____ Phone (optional): _____

☐ I wish to receive a copy of the research report

Appendix 5.4: Pre-test questionnaire

Institute for Reconstructive Sciences in Medicine

T: 780.735.2660 F: 780.735.2658
E: irsm@albertahealthservices.ca W: www.irsm-canada.com
1W-02, 16940–87 Ave. Edmonton, AB, Canada T5R 4H5

#: _____ Date: _____

Pre-test questionnaire

1. Handedness:
   - ☐ Right
   - ☐ Left

2. Years of surgical experience (incl. residency): _____

3. Number of nasal endoscopic procedures performed using a rigid scope (incl. routine clinical examinations):
   - ☐ 0
   - ☐ 1-10
   - ☐ 10-50
   - ☐ 50-100
   - ☐ >100

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Appendix 5.5: Stills from the instruction video

Simulated
Diagnostic Nasal Endoscopy

In this exercise, you will perform the following procedures:

(1) Three-pass examination of right and left nasal cavity

(2) Collection of culture using endoscopically guided swab

(3) Biopsy of a lesion using endoscopically guided forceps

(1)
Three-pass examination

Start by examining the LEFT cavity...

Equipment

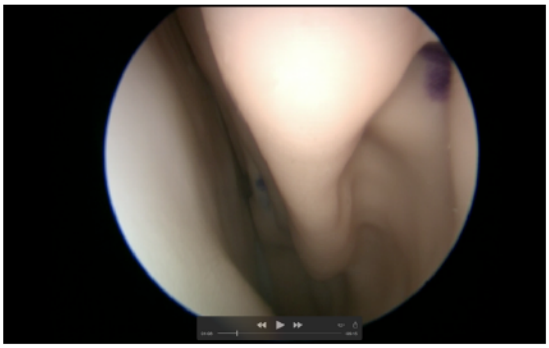
3mm/4 mm 30° rigid scope

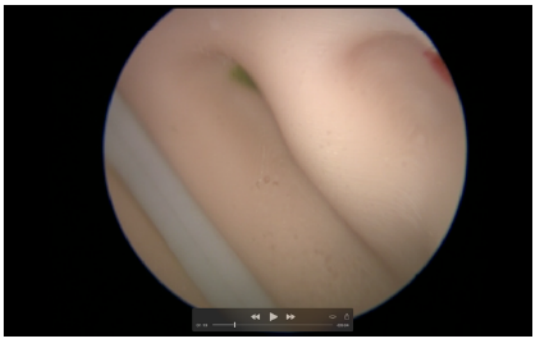
Alcohol pad to clean lens

First pass

- Pass the scope along the floor of the nose to the nasopharynx
- Examine:
  - Inferior turbinate
  - Inferior meatus
  - Septum
  - Eustachian tube orifice
  - Nasopharynx

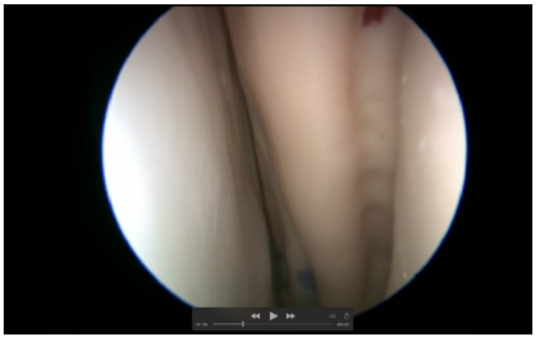
Some areas are highlighted with color

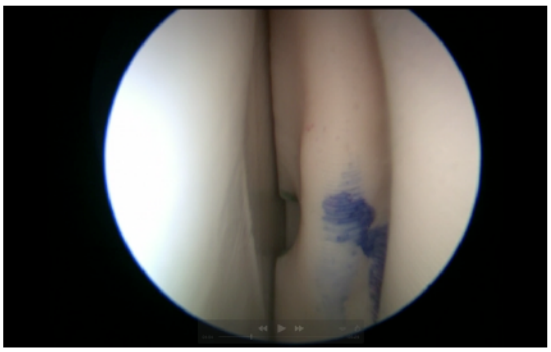




Second pass

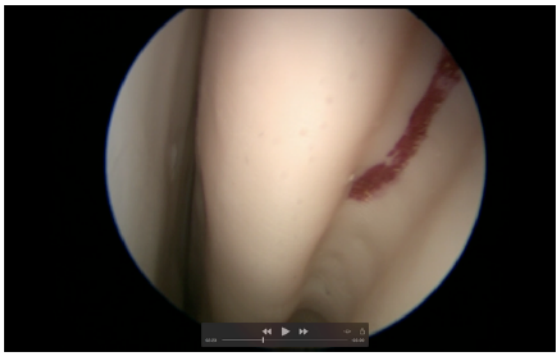
- Pass the scope between the inferior and the middle turbinate
- Examine:
  - Middle turbinate
  - Middle meatus (inferior)
  - Sphenoid ostium
  - Superior turbinate
  - Superior meatus





Third pass

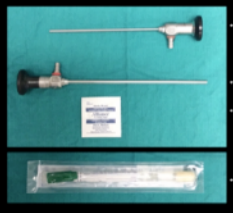
- As you withdraw the scope from the second pass, roll under the middle turbinate and into the middle meatus
- Examine:
  - Middle meatus
  - Frontal recess area



Repeat the three passes in the RIGHT cavity...

(2)
Collection of culture

Equipment



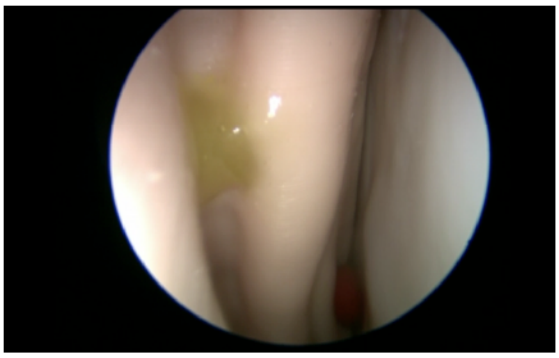
3mm/4 mm 30° rigid scope

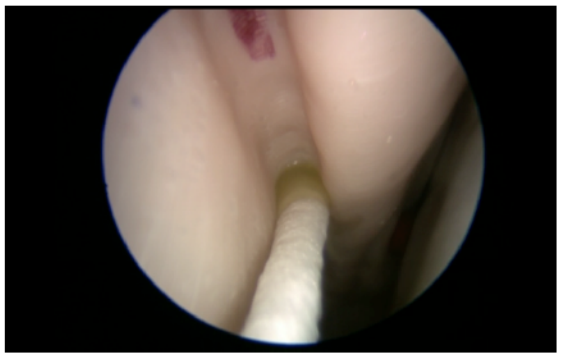
Alcohol pad to clean lens

Swab

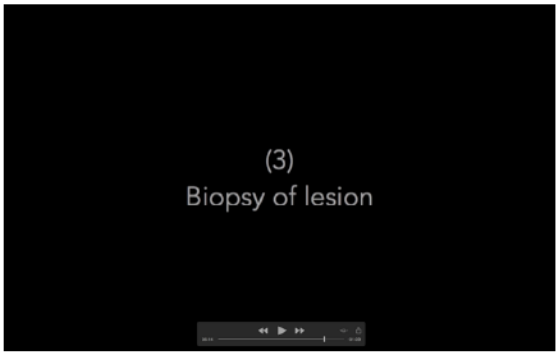
In the RIGHT cavity...

- Guide the swab to collect culture from the secretions in the maxiallry ostium
- Once you have collected your sample, insert the swab back into the tube

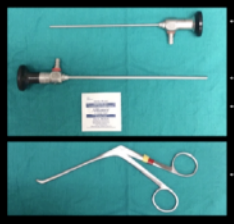




(3)
Biopsy of lesion



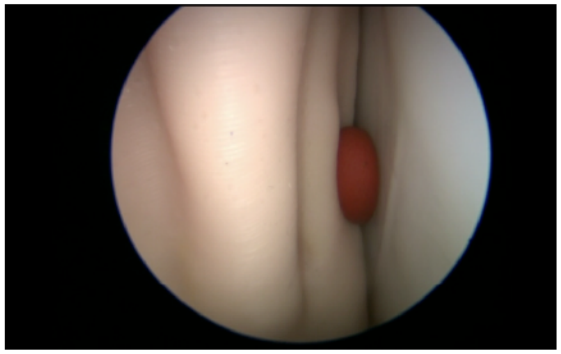
Equipment



3mm/4 mm 30° rigid scope

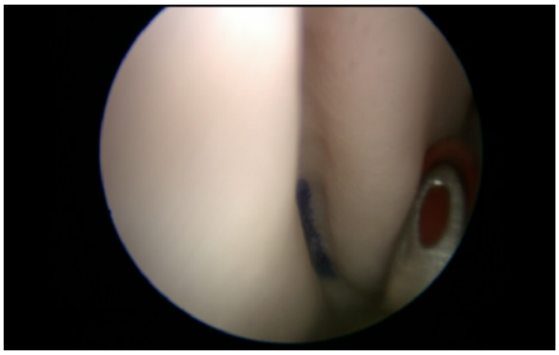
Alcohol pad to clean lens

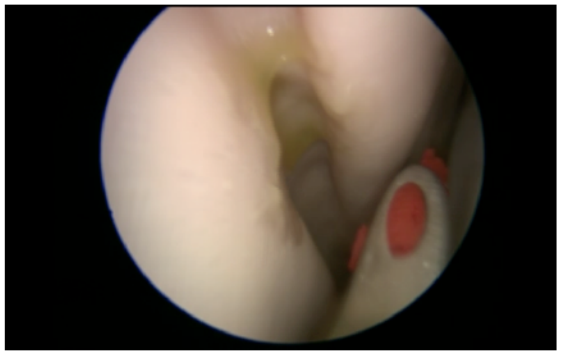
Forceps



In the RIGHT cavity...

- Guide the forceps to perform a biopsy of the lesion located in the sphenoid ostium
- Place the forceps with the biopsy sample on the gauze provided





Appendix 5.6: Post-test questionnaire

Institute for Reconstructive Sciences in Medicine

T: 780.735.2660 F: 780.735.2658
E: irsm@albertahealthservices.ca W: www.irsm-canada.com
1W-02, 16940–87 Ave. Edmonton, AB, Canada T5R 4H5

#: _____ Date: _____

Post-test questionnaire

[Please rate the statements from 1=strongly disagree to 5=strongly agree]

1. This model helps develop fundamental camera skills/scope navigation needed for nasal endoscopy.

   1 2 3 4 5

2. This model helps develop hand eye coordination needed for nasal endoscopy.

   1 2 3 4 5

3. This model helps develop dexterity, accuracy and precision with nasal endoscopy instruments.

   1 2 3 4 5

4. This model is able to mimic actual nasal anatomy (high fidelity model).

   1 2 3 4 5

[Please rate the statements from 1=not effective/useful to 5=highly effective/useful]

5. Please rate the overall effectiveness of the model: did the model succeed in simulating the procedures?

   1 2 3 4 5

6. Please rate the overall usefulness of the model: how useful is the model as a training tool?

   1 2 3 4 5

Alberta Health Services | Covenant Health | University of Alberta

#: _____ Date: _____

For staff only:
[Please rate the statements from 1=strongly disagree to 5=strongly agree]

7. I would be interested in using this model to teach residents.

1 2 3 4 5

8. This model can increase residents competency when used prior to their first nasal endoscopy procedure

1 2 3 4 5

For residents only:
[Please rate the statements from 1=strongly disagree to 5=strongly agree]

9. I would be interested in using this model to practice my skills.

1 2 3 4 5

10. This model would have increased my competency if used prior to my first nasal endoscopy procedure.

1 2 3 4 5

11. I would have felt more confident practicing my first nasal endoscopy procedure on patients after practicing on this model.

1 2 3 4 5

For medical students only:
[Please rate the statements from 1=strongly disagree to 5=strongly agree]

12. I would be interested in using this model to practice my skills.

1 2 3 4 5

13. This model will increase my competency when used prior to my first nasal endoscopy procedure.

1 2 3 4 5

14. I will feel more confident practicing nasal endoscopy on patients after practicing on this model.

1 2 3 4 5

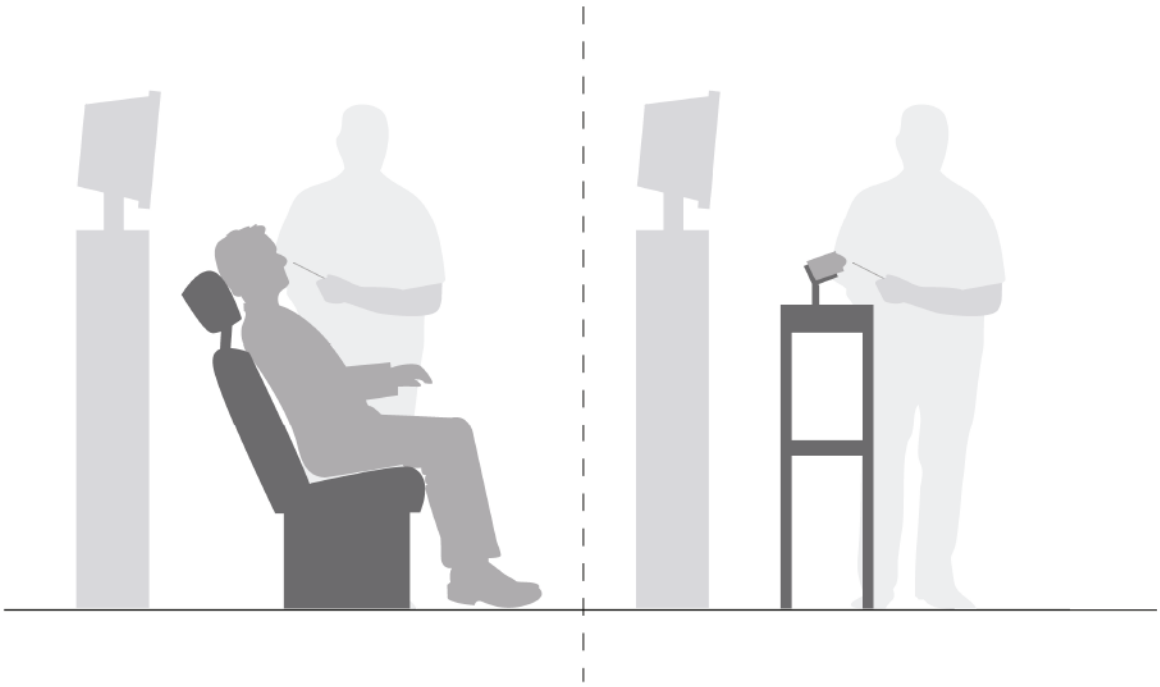
#: _____ Date: _____

Please provide other feedback and/or suggest improvements:

Appendix 5.7: Set-up & equipment

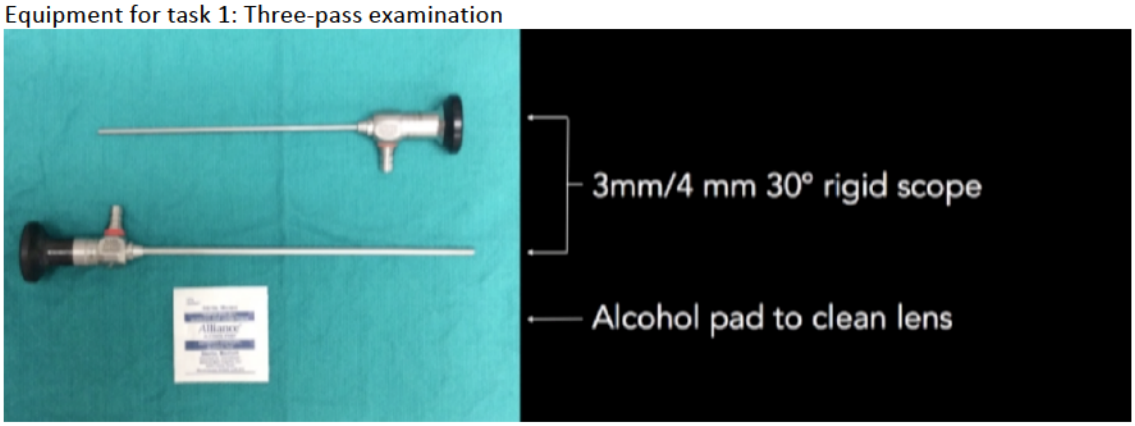
Set-up: Concept

Actual scenario *Simulated scenario*

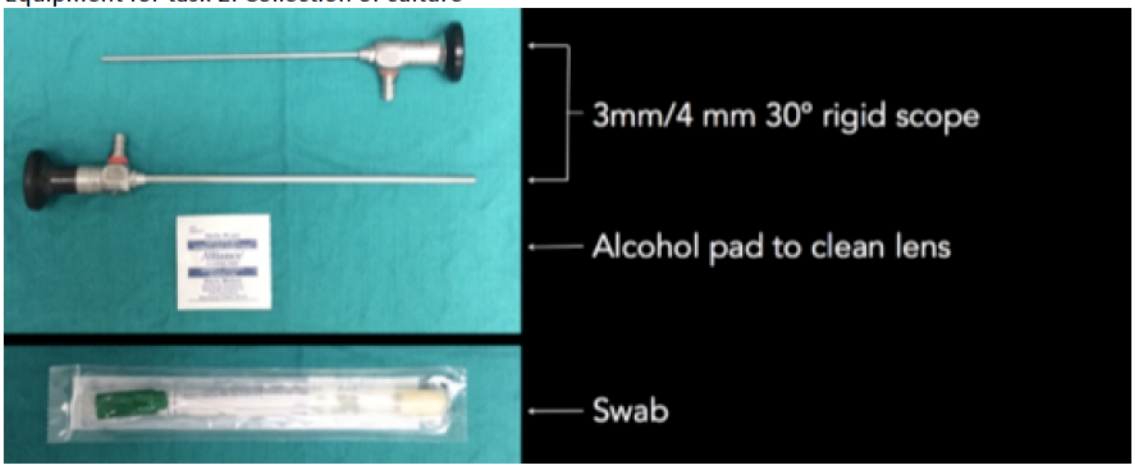


Set-up: Final

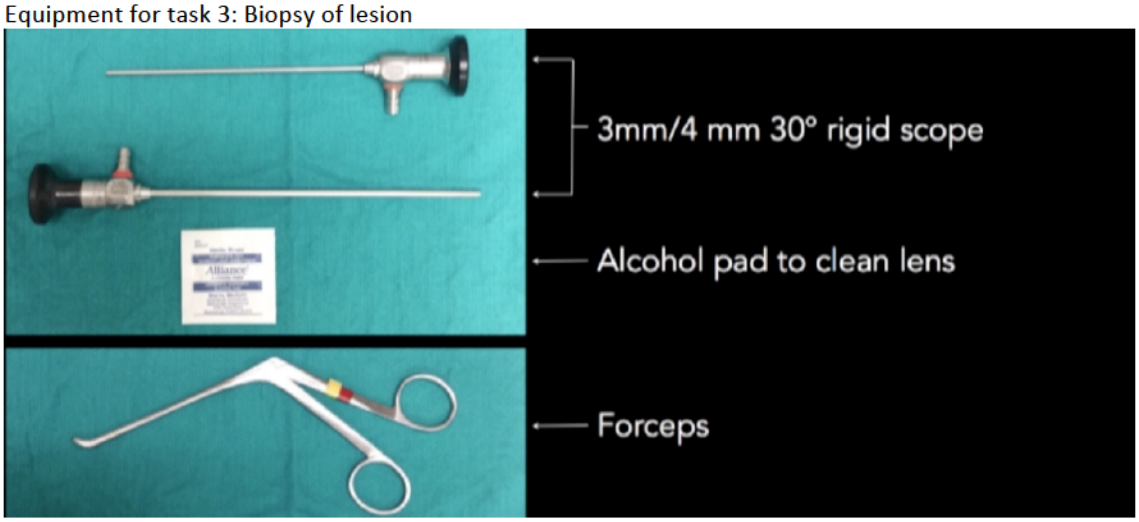
Equipment for task 1: Three-pass examination



Equipment for task 2: Collection of culture



Equipment for task 3: Biopsy of lesion



Appendix 5.8: Objective Assessment of Technical Skills (OSATS)

OBJECTIVE ASSESSMENT OF TECHNICAL SKILLS (OSATS)

#: _____ Date: _____

Respect for Tissue:

1	2	3	4	5
Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments		Careful handling of tissue but occasionally caused inadvertent damage/contact with nasal structures		Consistently handled tissue appropriately with minimal damage

Camera/scope handling time and motion:

1	2	3	4	5
Did not properly visualize and examine the structures and used many unnecessary moves		Visualized and examined the structures but with some unnecessary moves		Properly visualized and examined the structures with clear economy of movement and maximum efficiency

Instrument handling:

1	2	3	4	5
Repeatedly made tentative or awkward moves with instruments by inappropriate use of instruments		Competent and appropriate use of instruments but occasionally appeared stiff or awkward		Proper use and fluid moves with instruments and no awkwardness

Flow of operation:

1	2	3	4	5
Frequently stopped during the operation and seemed unsure of next move		Showed reasonable progression throughout the operation		Consistent and effortless flow from one step to the next

Completion of task 1: 3-pass examination of nasal cavity

1	2	3	4	5
Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all		Completed task but with reduced efficiency and quality of outcome		Completed task with maximum efficiency and good quality of outcome

Comments:

1

Completion of task 2: Collecting culture

1	2	3	4	5
Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all		Completed task but with reduced efficiency and quality of outcome		Completed task with maximum efficiency and good quality of outcome

Comments:

Completion of task 3: Biopsy of polyp

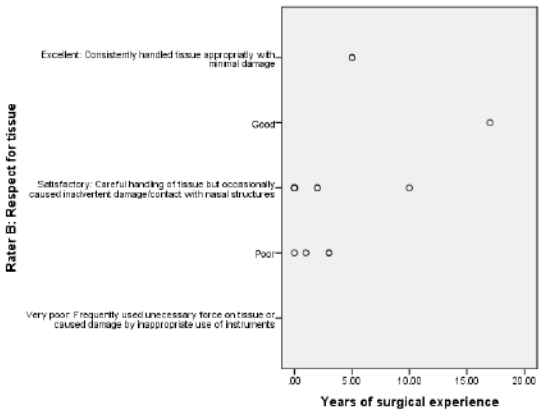
1	2	3	4	5
Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all		Completed task but with reduced efficiency and quality of outcome		Completed task with maximum efficiency and good quality of outcome

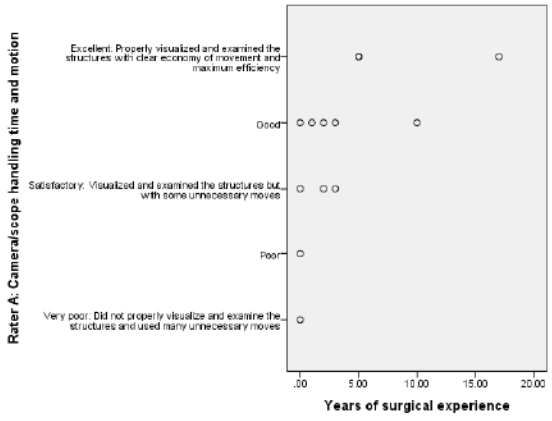
Comments:

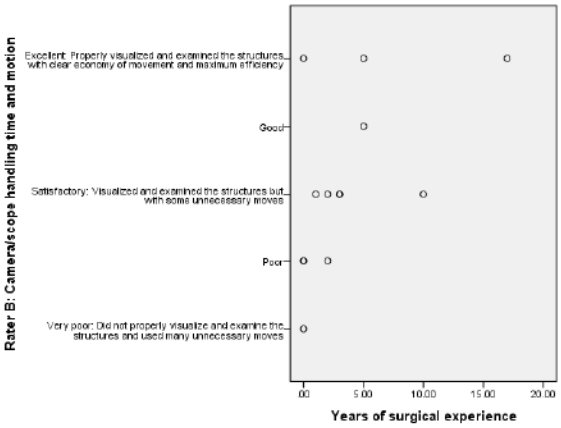
Appendix 5.9: OSATS scores for Rater A & Rater B

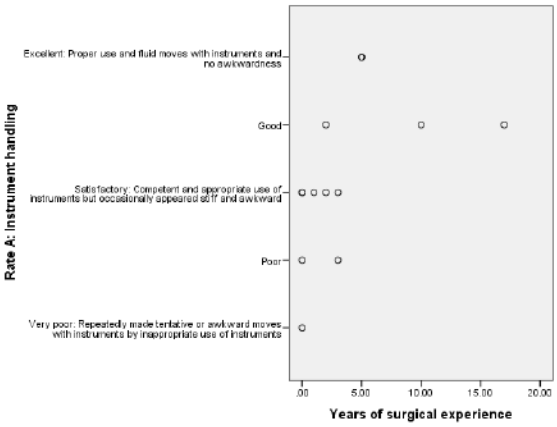
OSATS score/Years of Surgical Experience

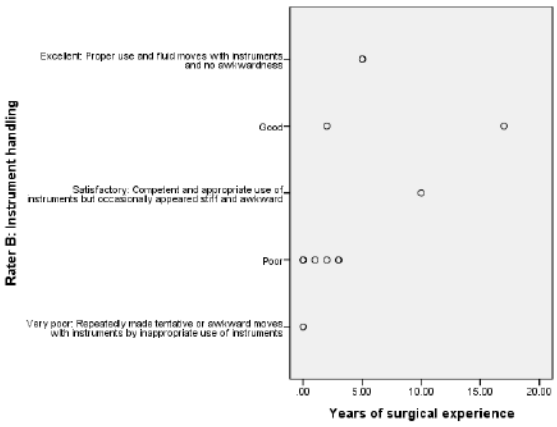
(Excellent=5, Very poor=1)

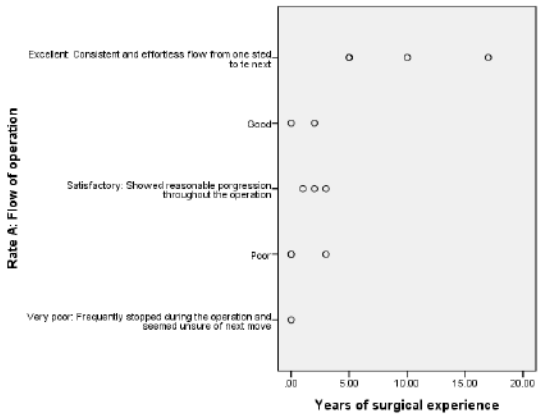


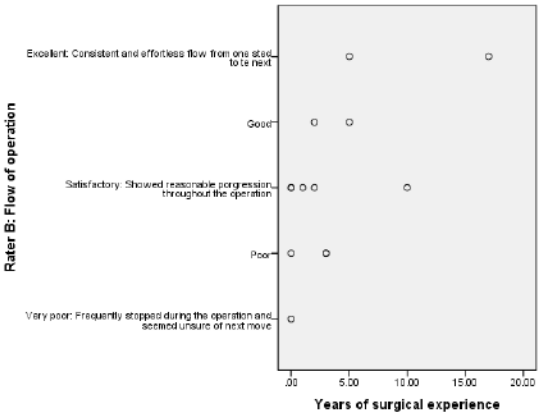


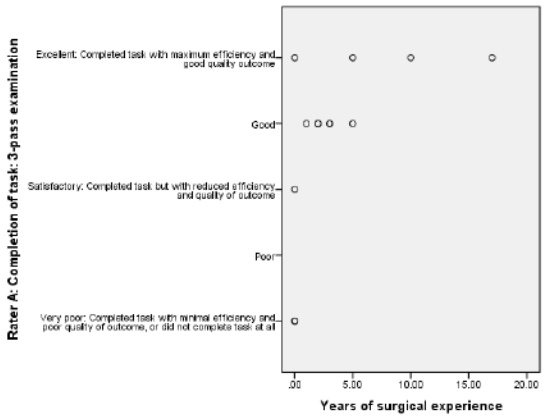




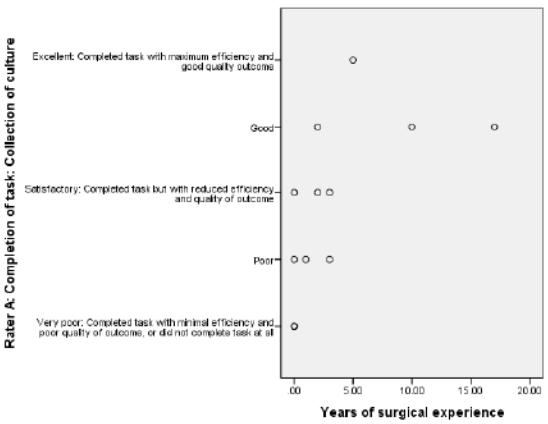


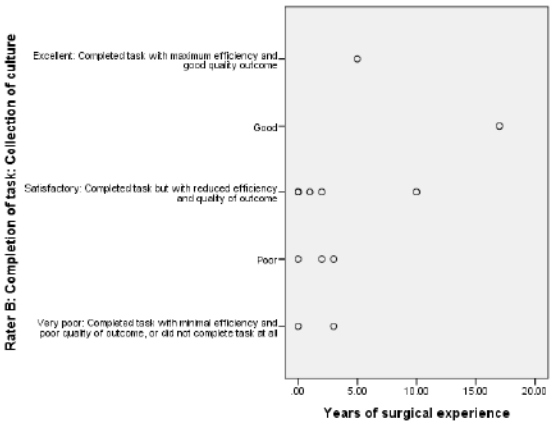

Rate A: Flow of operation
Excellent: Consistent and effortless flow from one step to te next
Good
Satisfactory: Showed reasonable porgression throughout the operation
Poor
Very poor: Frequently stopped during the operation and seemed unsure of next move
.00
5.00
10.00
15.00
20.00
Years of surgical experience

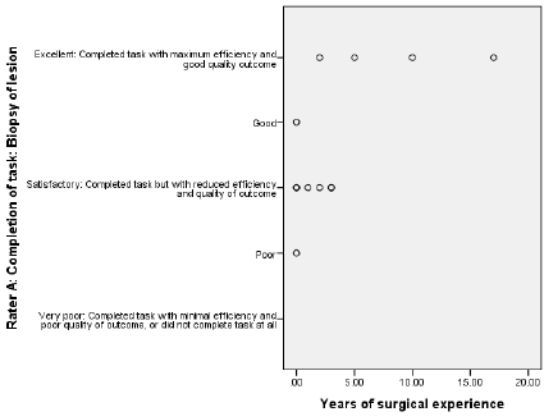

Rater B: Flow of operation
Excellent: Consistent and effortless flow from one step to te next
Good
Satisfactory: Showed reasonable porgression throughout the operation
Poor
Very poor: Frequently stopped during the operation and seemed unsure of next move
.00
5.00
10.00
15.00
20.00
Years of surgical experience

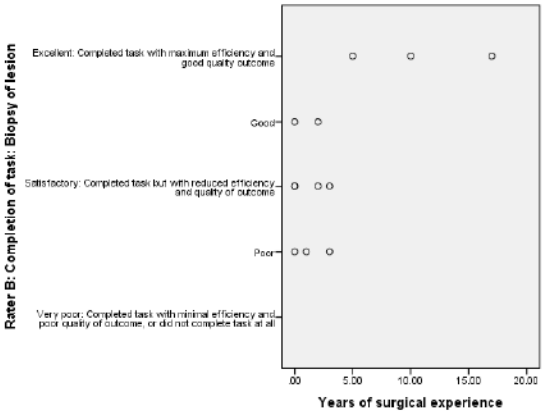

Rater A: Completion of task: 3-pass examination
Excellent: Completed task with maximum efficiency and good quality outcome
Good
Satisfactory: Completed task but with reduced efficiency and quality of outcome
Poor
Very poor: Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all
.00
5.00
10.00
15.00
20.00
Years of surgical experience


Rater B: Completion of task: 3-pass examination
Excellent: Completed task with maximum efficiency and good quality outcome
Good
Satisfactory: Completed task but with reduced efficiency and quality of outcome
Poor
Very poor: Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all
.00
5.00
10.00
15.00
20.00
Years of surgical experience


Rater A: Completion of task: Collection of culture
Excellent: Completed task with maximum efficiency and good quality outcome
Good
Satisfactory: Completed task but with reduced efficiency and quality of outcome
Poor
Very poor: Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all
.00
5.00
10.00
15.00
20.00
Years of surgical experience

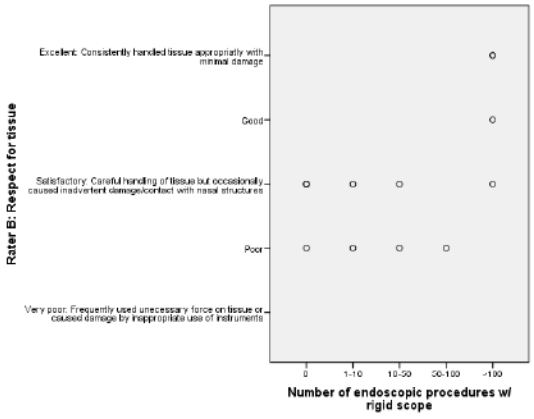

Rater B: Completion of task: Collection of culture
Excellent: Completed task with maximum efficiency and good quality outcome
Good
Satisfactory: Completed task but with reduced efficiency and quality of outcome
Poor
Very poor: Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all
.00
5.00
10.00
15.00
20.00
Years of surgical experience

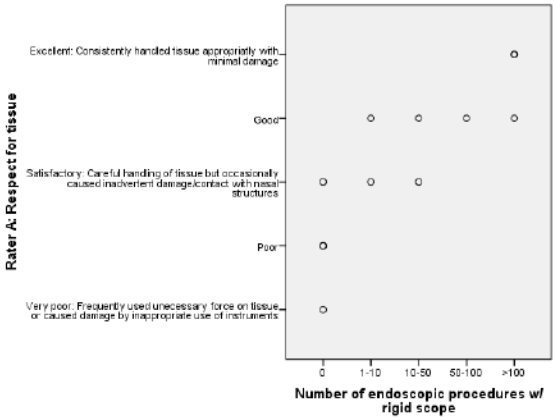


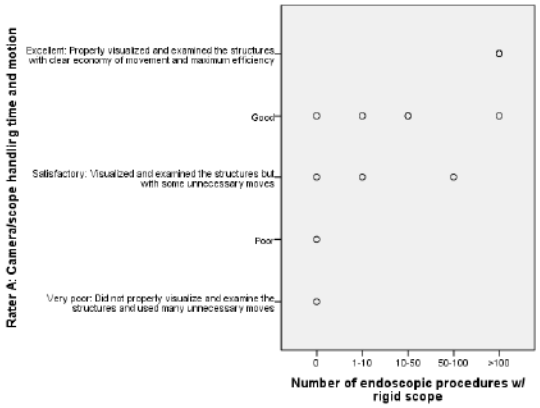


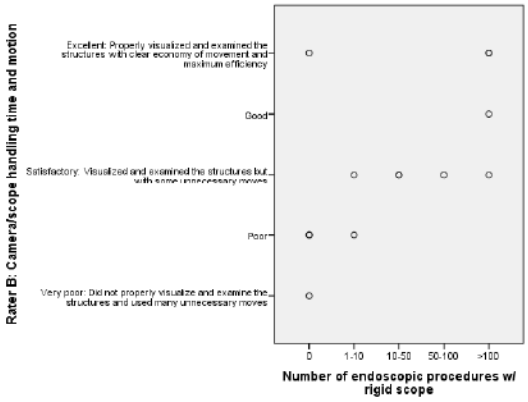
OSATS score/Number of nasal endoscopy procedures performed with a rigid scope

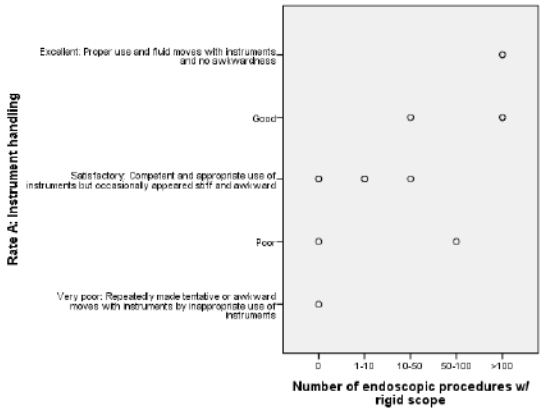
(Excellent=5, Very poor=1)

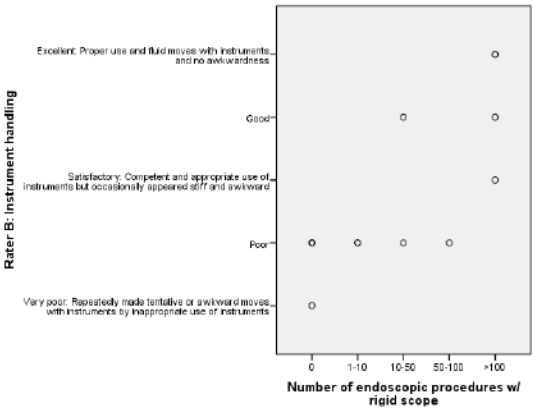


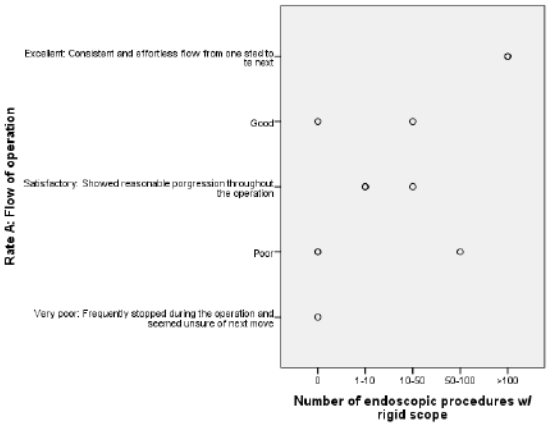


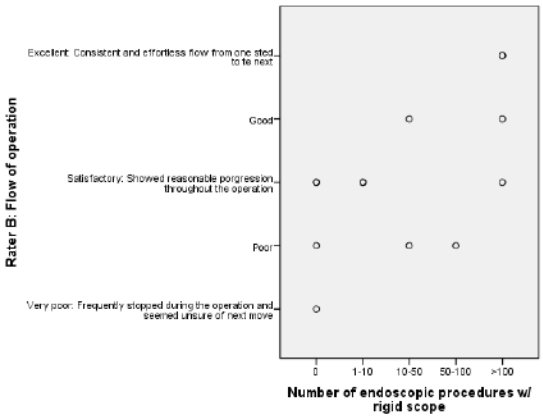


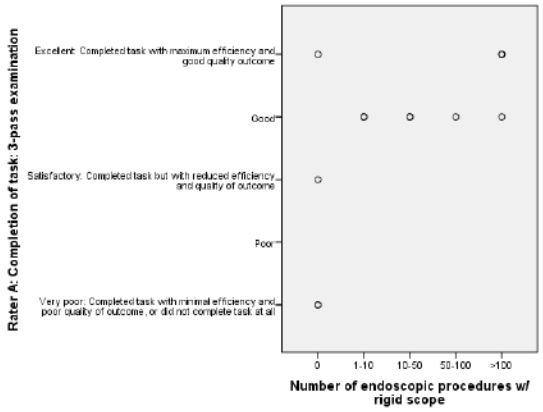


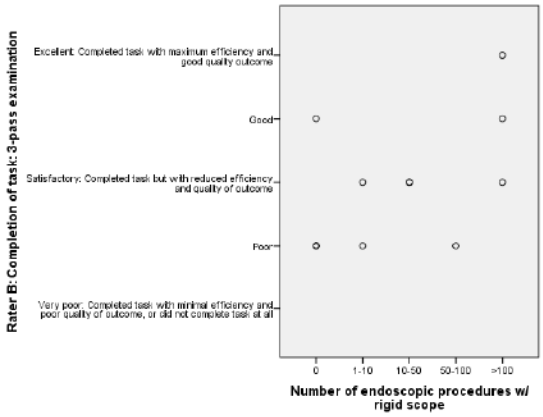

Rate A: Instrument handling
Excellent: Proper use and fluid moves with instruments and no awkwardness
Good
Satisfactory: Competent and appropriate use of instruments but occasionally appeared stiff and awkward
Poor
Very poor: Repeatedly made tentative or awkward moves with instruments by inappropriate use of instruments
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

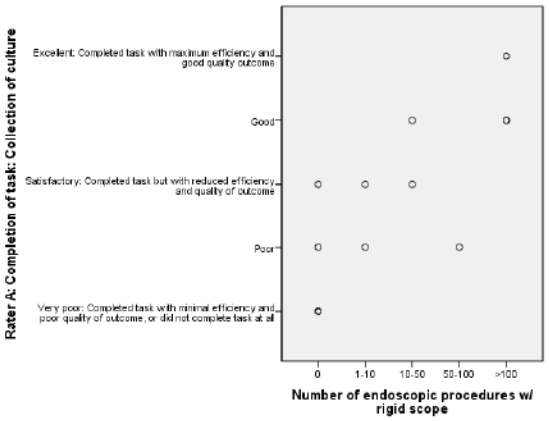

Rater B: Instrument handling
Excellent: Proper use and fluid moves with instruments and no awkwardness
Good
Satisfactory: Competent and appropriate use of instruments but occasionally appeared stiff and awkward
Poor
Very poor: Repeatedly made tentative or awkward moves with instruments by inappropriate use of instruments
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

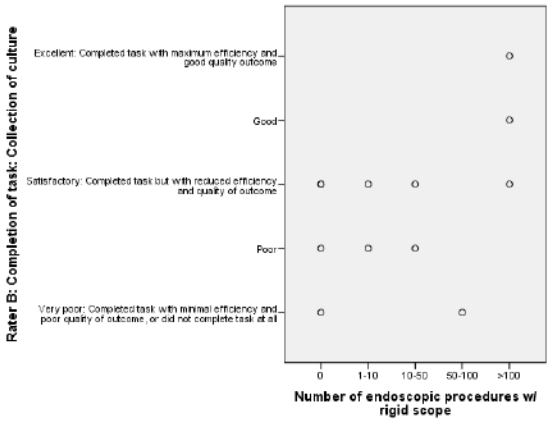

Rate A: Flow of operation
Excellent: Consistent and effortless flow from one step to the next
Good
Satisfactory: Showed reasonable progression throughout the operation
Poor
Very poor: Frequently stopped during the operation and seemed unsure of next move
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

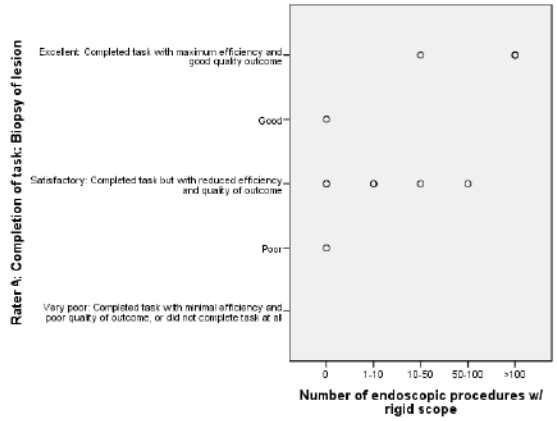

Rater B: Flow of operation
Excellent: Consistent and effortless flow from one step to the next
Good
Satisfactory: Showed reasonable progression throughout the operation
Poor
Very poor: Frequently stopped during the operation and seemed unsure of next move
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

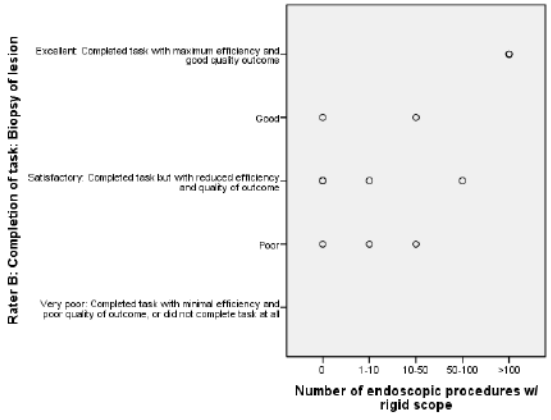

Rater A: Completion of task: 3-pass examination
Excellent: Completed task with maximum efficiency and good quality outcome
Good
Satisfactory: Completed task but with reduced efficiency and quality of outcome
Poor
Very poor: Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope


Rater B: Completion of task: 3-pass examination
Excellent: Completed task with maximum efficiency and good quality outcome
Good
Satisfactory: Completed task but with reduced efficiency and quality of outcome
Poor
Very poor: Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

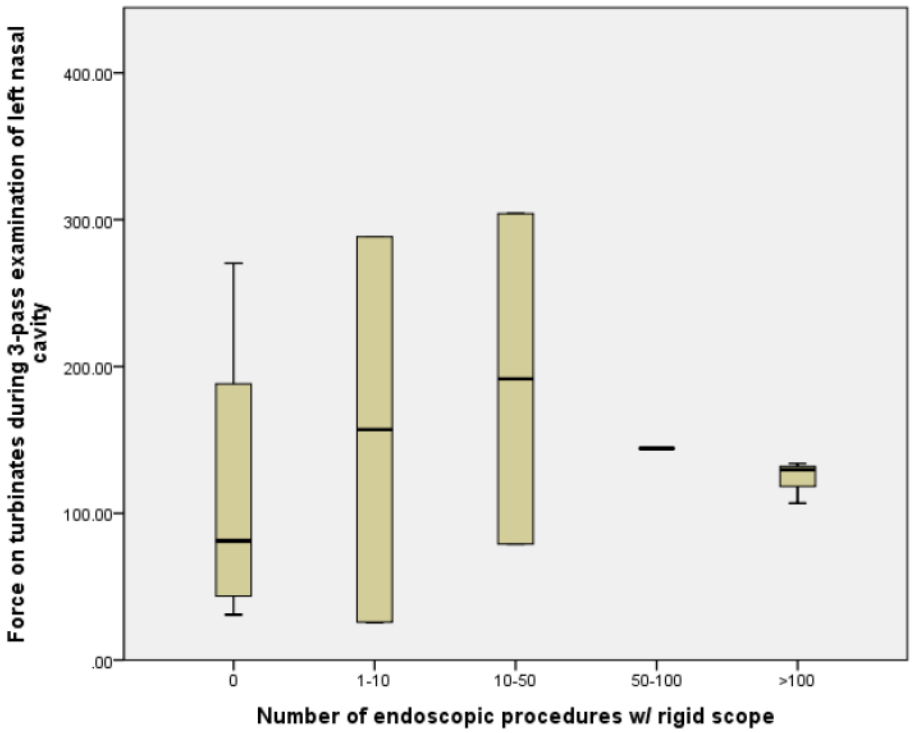

Rater A: Completion of task: Collection of culture
Excellent: Completed task with maximum efficiency and good quality outcome
Good
Satisfactory: Completed task but with reduced efficiency and quality of outcome
Poor
Very poor: Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

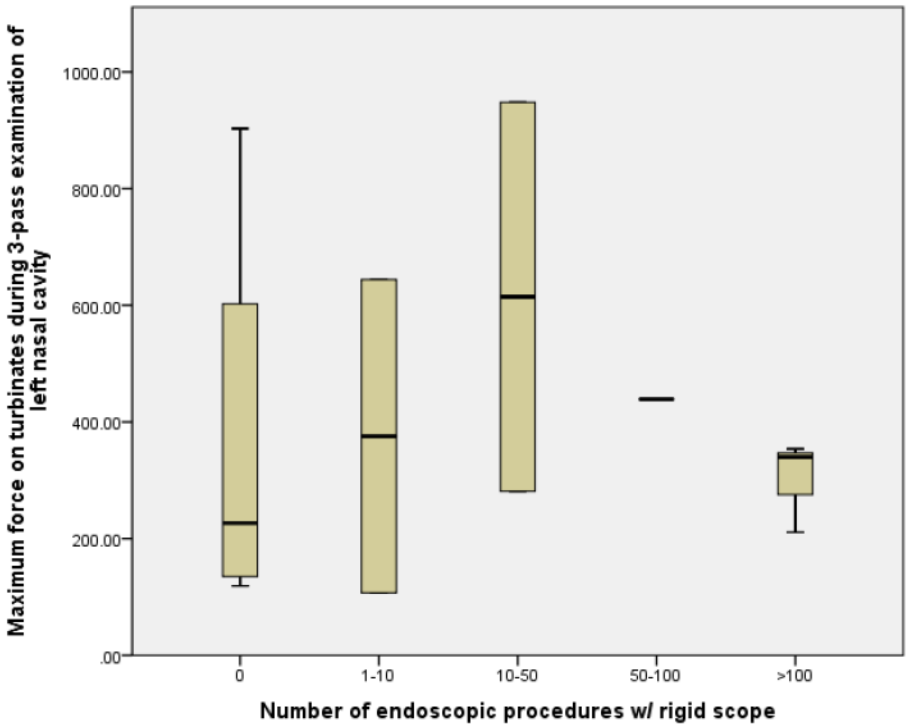

Rater B: Completion of task: Collection of culture
Excellent: Completed task with maximum efficiency and good quality outcome
Good
Satisfactory: Completed task but with reduced efficiency and quality of outcome
Poor
Very poor: Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

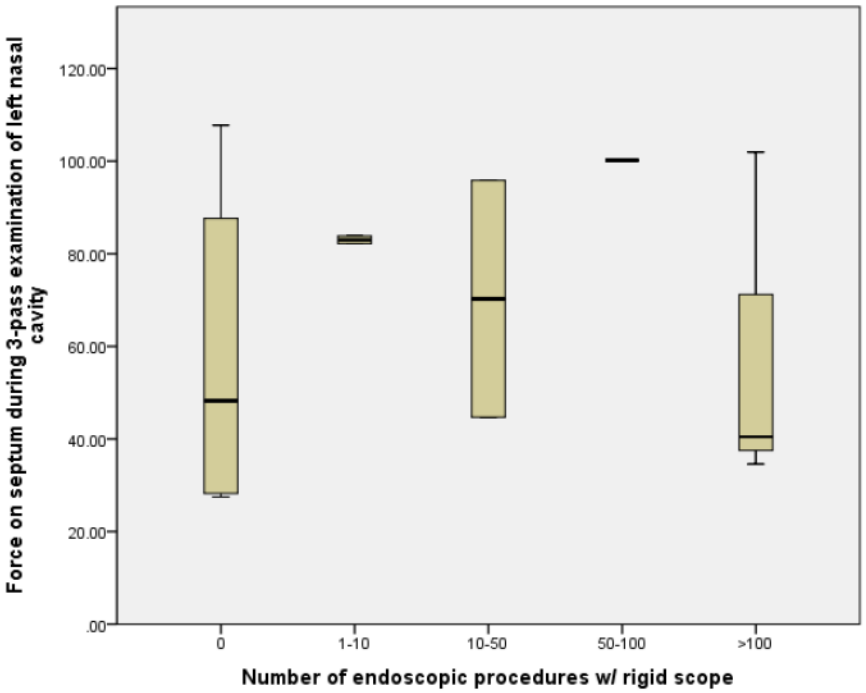

Rater A: Completion of task: Biopsy of lesion
Excellent: Completed task with maximum efficiency and good quality outcome
Good
Satisfactory: Completed task but with reduced efficiency and quality of outcome
Poor
Very poor: Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

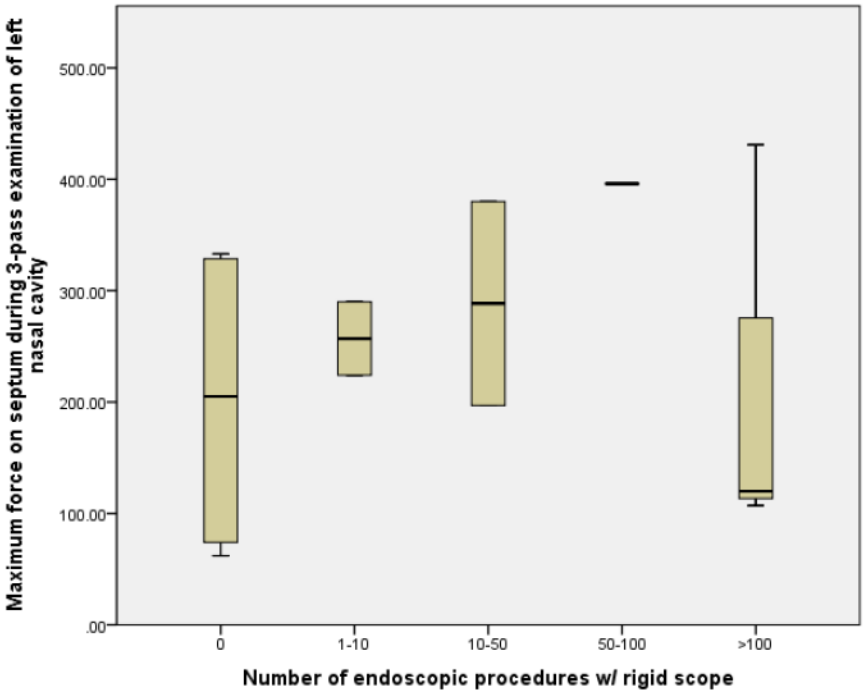

Rater B: Completion of task: Biopsy of lesion
Excellent: Completed task with maximum efficiency and good quality outcome
Good
Satisfactory: Completed task but with reduced efficiency and quality of outcome
Poor
Very poor: Completed task with minimal efficiency and poor quality of outcome, or did not complete task at all
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

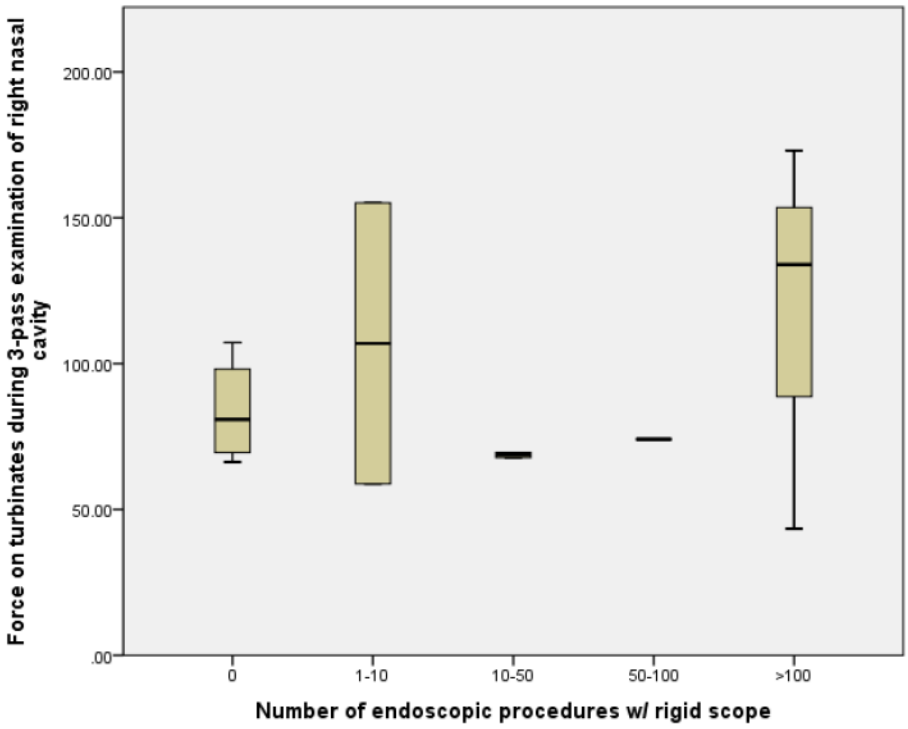
Appendix 5.10: Average and maximum force/ Number of nasal endoscopy procedures performed with a rigid scope

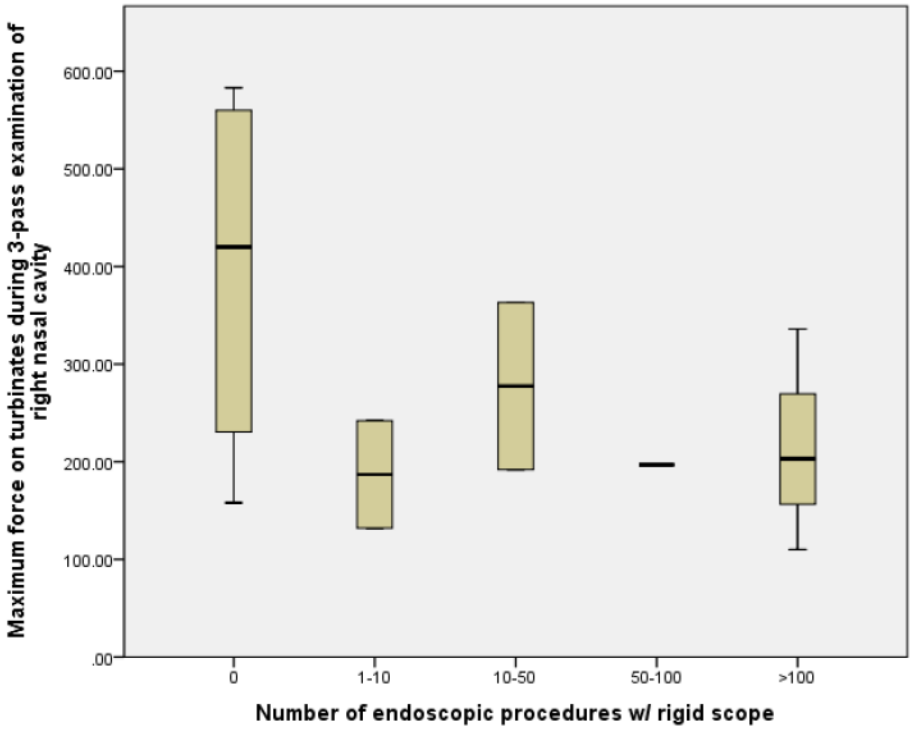


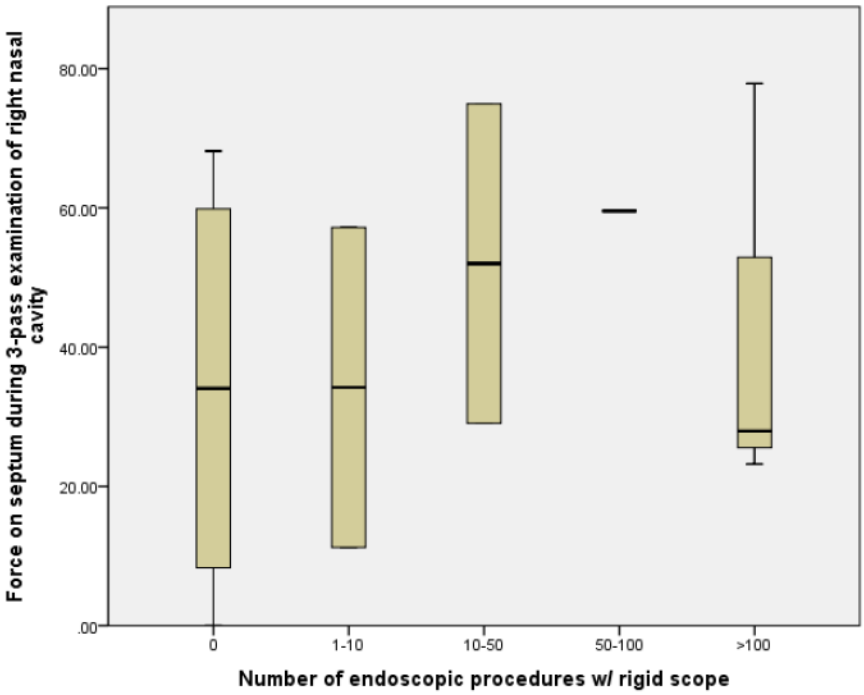

Maximum force on turbinates during 3-pass examination of left nasal cavity
1000.00
800.00
600.00
400.00
200.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

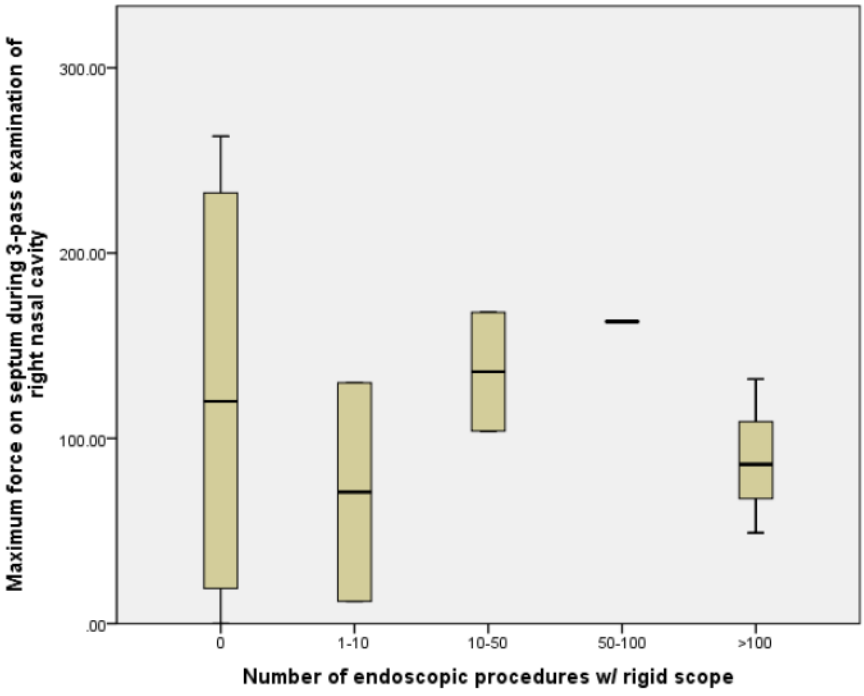

Force on septum during 3-pass examination of left nasal cavity
120.00
100.00
80.00
60.00
40.00
20.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

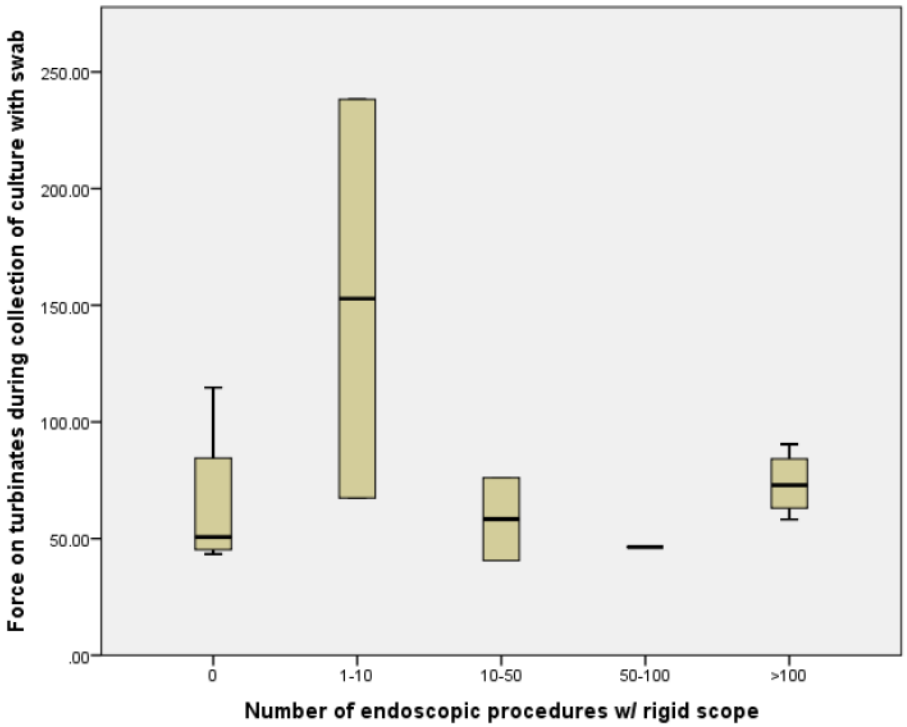

Maximum force on septum during 3-pass examination of left nasal cavity
500.00
400.00
300.00
200.00
100.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

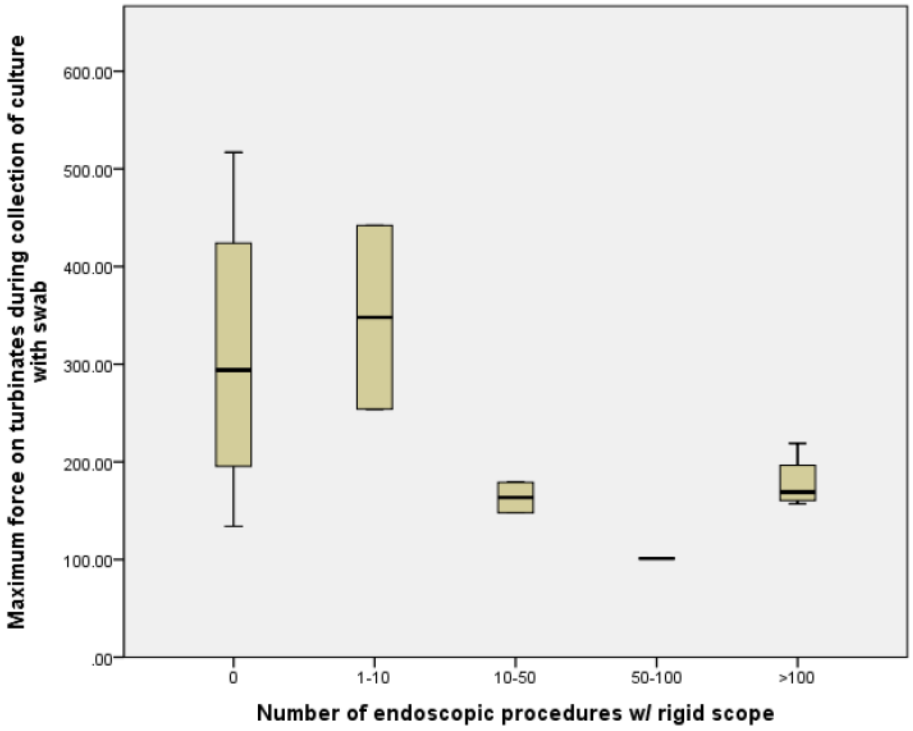

Force on turbinates during 3-pass examination of right nasal cavity
200.00
150.00
100.00
50.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

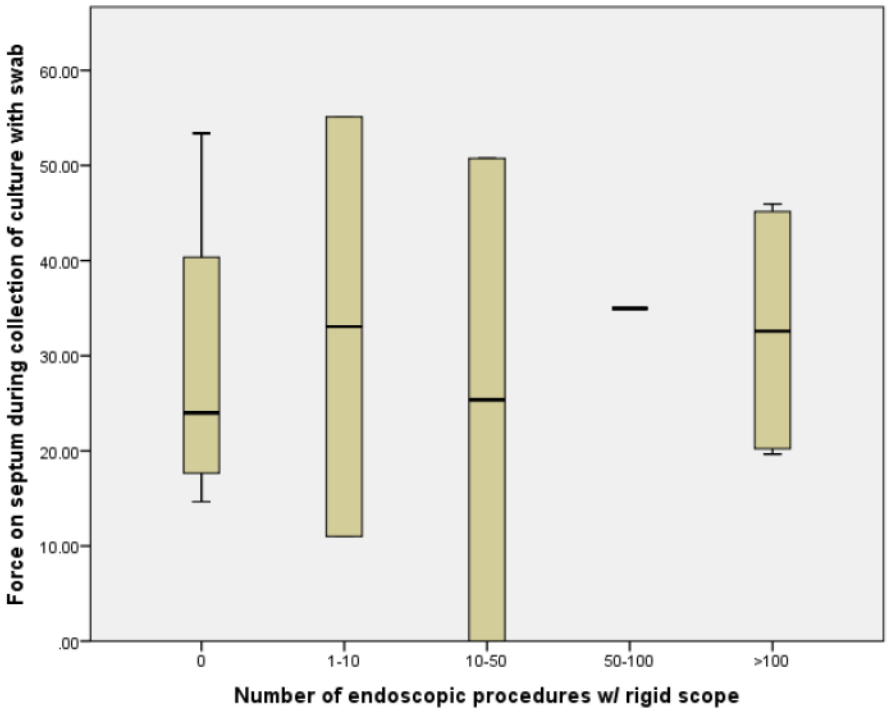

Maximum force on turbinates during 3-pass examination of right nasal cavity
600.00
500.00
400.00
300.00
200.00
100.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

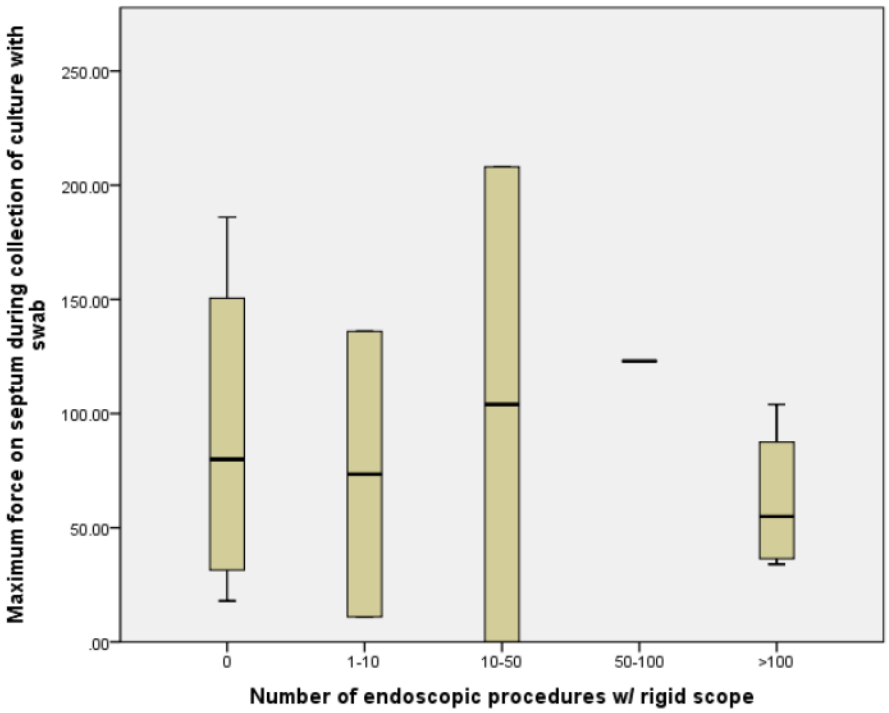

Force on septum during 3-pass examination of right nasal cavity
80.00
60.00
40.00
20.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

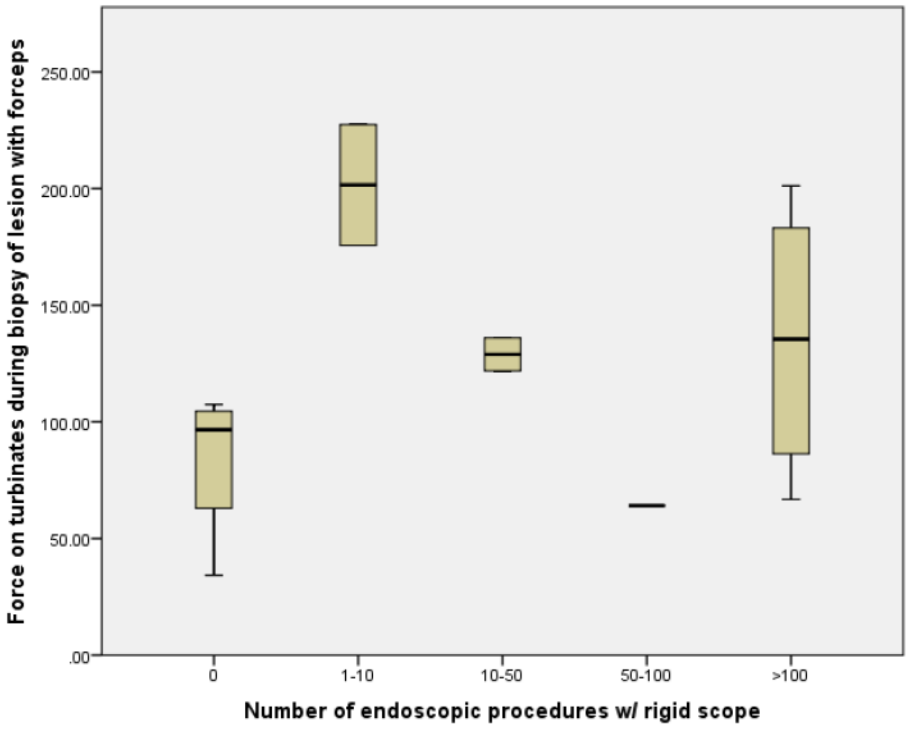

Maximum force on septum during 3-pass examination of right nasal cavity
300.00
200.00
100.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

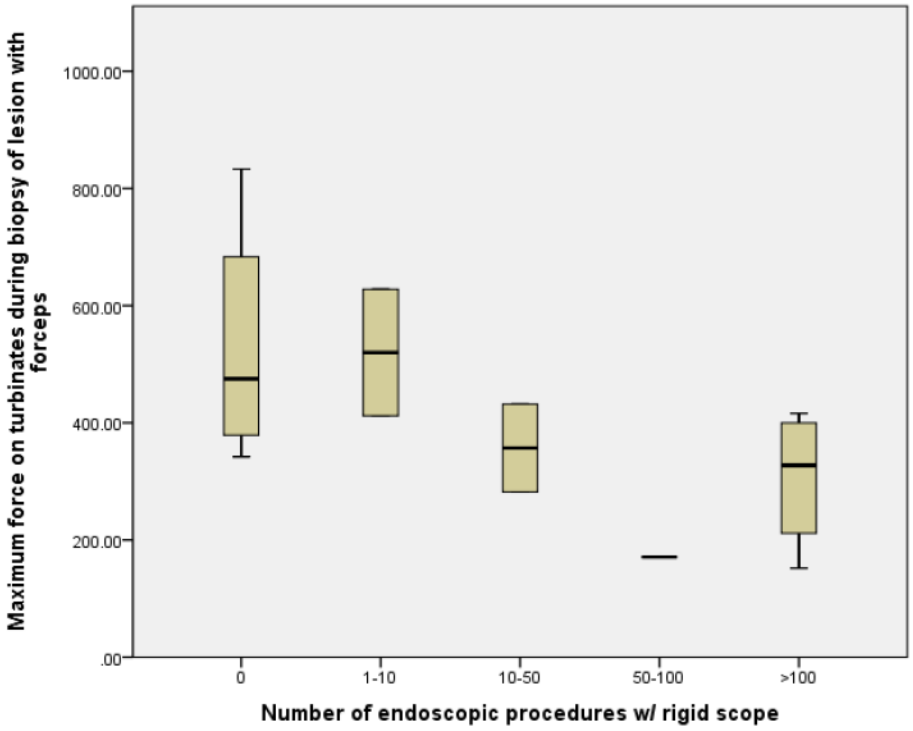

Force on turbinates during collection of culture with swab
250.00
200.00
150.00
100.00
50.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

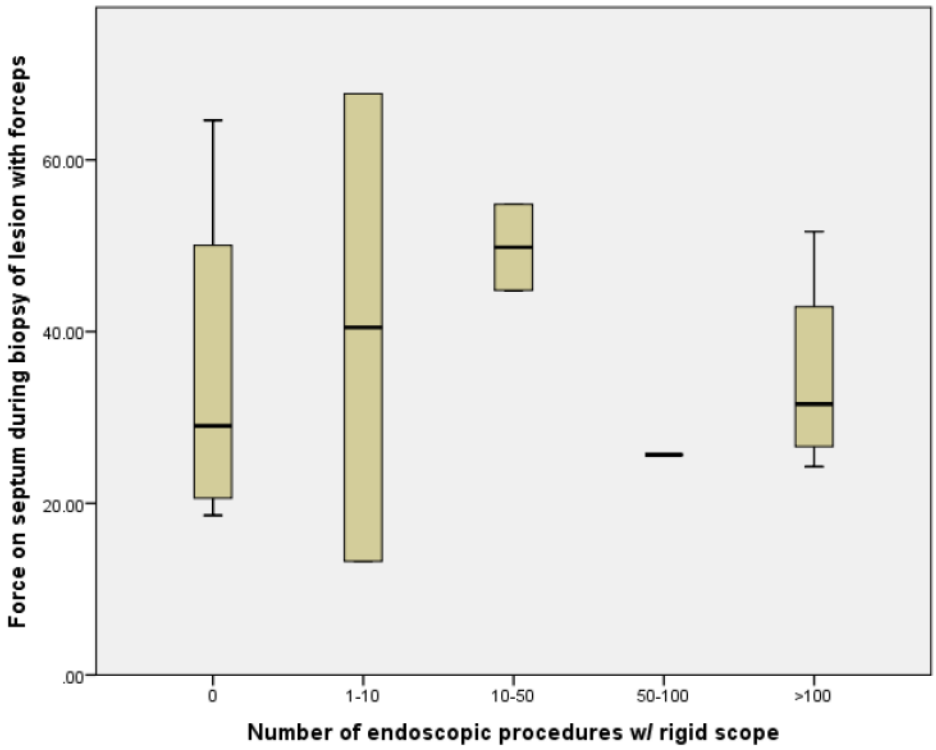

Maximum force on turbinates during collection of culture with swab
600.00
500.00
400.00
300.00
200.00
100.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope

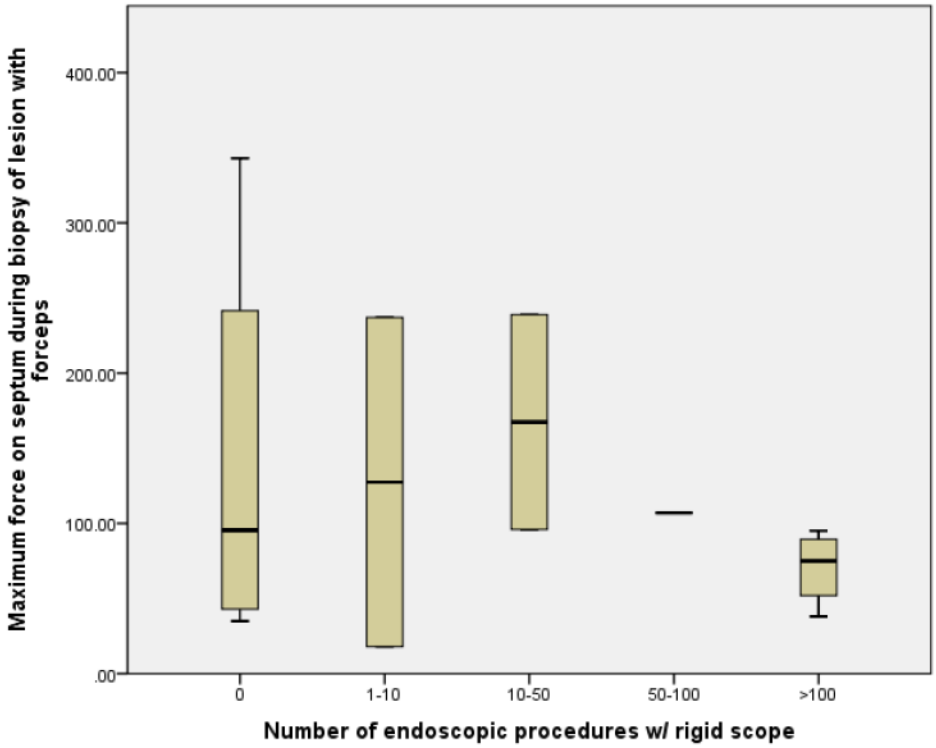

Force on septum during collection of culture with swab
60.00
50.00
40.00
30.00
20.00
10.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope


Maximum force on septum during collection of culture with swab
250.00
200.00
150.00
100.00
50.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope


Force on turbinates during biopsy of lesion with forceps
250.00
200.00
150.00
100.00
50.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope


Maximum force on turbinates during biopsy of lesion with forceps
1000.00
800.00
600.00
400.00
200.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope


Force on septum during biopsy of lesion with forceps
60.00
40.00
20.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope


Maximum force on septum during biopsy of lesion with forceps
400.00
300.00
200.00
100.00
.00
0
1-10
10-50
50-100
>100
Number of endoscopic procedures w/ rigid scope