The Development and Validation of a Synthetic Septoplasty Surgical Training Model

By

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Dedication

To my amazing mother and father, you are the greatest support a person can have. And to my loving wife, this would have been impossible without you. Tala, my daughter, you are my motivation to make you proud.

I also dedicate this work to my brothers Marwan and Mohammed, and my sister Maha, who provided me with love and support all the time.

Acknowledgments

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Abstract

Background: Septoplasty surgery is a core competency for an otolaryngologist. It is performed through the relatively small nostrils and involves multiple steps, which make the procedure difficult to observe and learn.

Objective: To develop and validate a high fidelity septoplasty training tool built using three-dimensional printing technology.

Methods: One deviated nasal septum case was chosen from among multiple computed tomography (CT) scans. The radiographic data were exported and underwent segmentation to obtain a complete computer model and used to create a synthetic replica of a deviated nasal septum using additive manufacturing. Each printed prototype was examined by two experienced otolaryngologists and changes were made as needed. The final physical replica was then evaluated for septoplasty simulation by 20 otolaryngologists with different levels of training. A survey was completed by each participant after the simulation, and observations associated with each simulation were obtained, including the time needed to complete the simulation and the rate of complications , such as the number of flap perforations that occurred.

Results: The fabricated physical replica of the nasal septum incorporated two different materials mixed to obtain different stiffnesses that approximated the properties of the nasal septum, and allowed the users to perform the basic steps of septoplasty, such as flap elevation and deviation resection. The replica was anatomically correct. The steps required to complete the simulation were found to be realistic, with scores of 4.05 (0.82) and 4.2 (1), respectively, on a 5-point Likert scale. Ninety-two percent of the residents

desired the replica to be implemented into their teaching curriculum. There was a significant difference ($p < 0.05$) between the expert, intermediate, and novice groups in the (i) time taken, (ii) nares cut, and (ii) task-specific checklist answers. However, for other performance metrics, no significant differences were found. The septoplasty task-specific checklist and global assessment tool also yielded significant differences between results from trainees with different levels of experience.

Conclusion: The replica presents a new and innovative option for the training of junior trainees in a safe environment. This is the first physical replica of the nasal septum introduced for this purpose. The findings of the study support the validity of the replica for surgical training purposes.

Résumé

Présentation: La septoplastie est une des principales chirurgies réalisées par un otorhinolaryngologiste. L'intervention se fait par les voies nasales relativement étroites et comporte plusieurs étapes, qui rendent la procédure difficile à observer et à apprendre.

Objectif: Développer et valider un outil de formation à la septoplasite à haute fidélité à l'aide de la technologie d'impression en trois dimensions.

Méthodes: Un septum dévié a été sélectionné parmi un éventail de tomographies. Les données radiographiques ont été exportées et segmentées afin d'obtenir une reproduction informatique complète. Elles ont ensuite été utilisées afin de créer une réplique synthétique d'une cloison nasale déviée à l'aide d'une méthode de fabrication additive. Chaque prototype imprimé a été examiné par deux otorhinolaryngologistes expérimentés, qui y ont apporté les changements nécessaires. La réplique physique finale a ensuite été évaluée dans le cadre d'une simulation de septoplastie par 20 otorhinolaryngologistes possédant différents niveaux de formation. Une étude a été conduite auprès de chacun des participants après la simulation, et les observations associées à chaque simulation ont été recueillies, y compris le temps nécessaire à la réalisation de la simulation et le taux de complications, tel que le nombre de perforations de lambeau.

Résultats: La réplique physique de cloison nasale est composée de deux matériaux différents combinés afin de reproduire les différentes rigidités que l'on observe dans les septums, et a permis aux utilisateurs de réaliser les principales étapes d'une

septoplastie, telles que l'élévation de lambeaux et la résection de la déviation. La réplique était anatomiquement correcte. Les étapes nécessaires à la réalisation de la simulation étaient considérées comme réalistes, avec des notes respectives de 4,05 (0,82) et 4,2 (1) sur l'échelle de Likert de 5 points. Quatre-vingt-douze pourcent des résidents souhaitent que la réplique soit utilisée dans leur programme d'enseignement. Une différence importante a été notée ($p < 0,05$) entre le groupe d'experts, le groupe intermédiaire et le groupe de novices en ce qui concerne (i) le temps nécessaire, (ii) les incisions des narines, et (iii) les réponses à la liste de contrôle des tâches. Cependant, aucune différence majeure n'a été observée pour les autres mesures de performance. La liste de contrôle des tâches de la septoplastie et l'outil global d'évaluation ont également indiqué d'importantes différences entre les apprentis de différents niveaux.

Conclusion: La réplique représente une solution innovante pour la formation des jeunes apprentis dans un environnement sûr. Il s'agit de la première réplique de cloison nasale créée à cette fin. Les conclusions de l'étude confirment l'utilité de la réplique à des fins de formation chirurgicale.

Preface

Contribution of Authors

Dr. Mahmoud AlReefi was responsible for the literature review in its entirety, the design of the replica, recruitment, data collection, entry, and analysis. Dr. Marc Tewfik provided supervision and guidance in the clinical relevance, concept, design, participants' simulations evaluation, and review of this thesis. Dr. Lily HP Nguyen provided supervision and guidance on the clinical relevance, concept, design and educational aspect of the thesis, alongside participants' simulations evaluation and review of this thesis.

Professor Luc Mongeau provided supervision and guidance on the basic science aspect along with a review of this thesis.

Claim of originality

This is the first report of a nasal septum physical replica dedicated to septoplasty surgery training. The face and construct validation process showed evidence supporting the validity of the replica as a simulation training tool.

Table Of Contents

List of tables

List of figures

Chapter One: Introduction

1.1 Rationale

The nasal septum is the midline structure that divides the nasal passage into a right and left nasal cavity. Deviation of the septum into one of the cavities may occur due to trauma or developmental causes, and may result in an ipsilateral obstruction of the airflow [1]. Septoplasty, the surgical correction of the deviated nasal septum, is the definitive treatment for this condition. Septoplasty is the most common ear, nose, and throat surgery in adults [2].

Thus, septoplasty surgery is considered a core procedure, and Otolaryngology—Head and Neck Surgery (OTL-HNS) residents are expected to learn this surgery early in their training. Septoplasty is usually performed through the relatively small nostrils, with the primary surgeon looking down into the nasal cavity from above. This provides little or no visual access for a learning assistant surgeon to observe the procedure closely, which makes learning the necessary steps to perform the surgery challenging. It has been reported that only 73% of OTL-HNS trainees in their last year feel appropriately trained to perform septoplasty without supervision [3].

Present training methods include being trained in a series of steps with immediate feedback on each step, dissection of cadaver (which usually lacks the pathology), or observation of the procedure performed endoscopically. It has been reported that trainees who were exposed to these training tools felt more adequately prepared to perform septoplasty on their own [3].

A new septoplasty simulation training tool may significantly improve trainees' abilities to perform the procedure, particularly because bench training has been proven to have a benefit improving trainees' surgical skills, provided that the model is anatomically accurate [4]. This need motivated the work presented in this thesis, The thesis objectives that are described in the next section.

1.2 Objectives

The first objective of this thesis was to develop a nasal septum physical replica (NSPR) that can be used to simulate septoplasty. The replica should be relatively inexpensive, anatomically correct, and easily fabricated using now commonly available three-dimensional printing technology. The second objective was to evaluate the replica's performance as a new training tool that could potentially be incorporated into the curriculum of OTL-HNS trainees, by testing its acceptability, face validity, and construct validity.

1.3 Hypothesis

The hypothesis of this study was that a high fidelity, relatively low-cost NSPR for surgical training can be produced using available three-dimensional (3D) printing technology and that it would enhance training for septoplasty surgery. This replica would be a useful addition to available training methods and would help trainees to achieve the required surgical skills in a safe environment.

Chapter Two: Literature Review

2.1 Deviated Nasal Septum and Septoplasty Surgery

The nasal septum is the midline structure that divides the nasal cavity into a right and left cavities. It provides support to the external nasal cartilage and skin ,and facilitates laminar airflow through the nasal cavity. It is composed of a flat quadrangular cartilaginous part located anteriorly, and a bony part located posteriorly. The latter consists of the vomer bone, and the perpendicular plate of the ethmoid bone. The lateral aspects of the septal bones and cartilage are covered in mucoperiosteum and mucoperichondrium, respectively. These are covered by a mucosal membrane layer [5] (Figure 1).

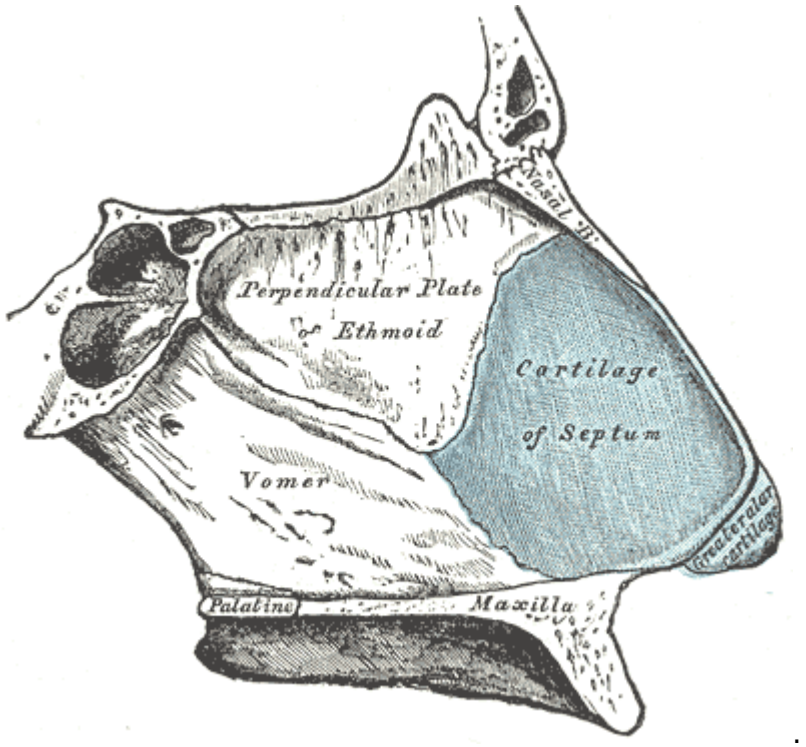

Figure 1: Bones and cartilage of the nasal septum (right side) [6]

A deviated nasal septum is a condition in which the nasal septum deviates from the midline into one of the two nasal cavities, where it obstructs normal airflow [1]. This condition usually caused by trauma or a congenital deficit. It is the most common etiology of nasal obstruction in adults [7]. In a study by Vainio-Mattila, 26% of 200 randomly examined adults had a septal deviation that was considered clinically significant [8]. The definitive treatment for this condition is septoplasty, which is the most commonly performed otolaryngology surgery in adults [2].

There are many septoplasty surgery techniques. The standard technique is to create a hemitransfixion incision in the mucous membrane in one of the nasal cavities. Thereafter, an elevator is used to lift the mucoperichondrial flap. Another mucoperichondrial flap is created on the other side through a cartilage incision or through the space created after dislocating the bony cartilaginous junction. Then, the deviated bone and cartilage is resected using a non-sharp tool. All the elevated flaps are subsequently put back in their normal anatomical position, and closed [9] (Figure 2).

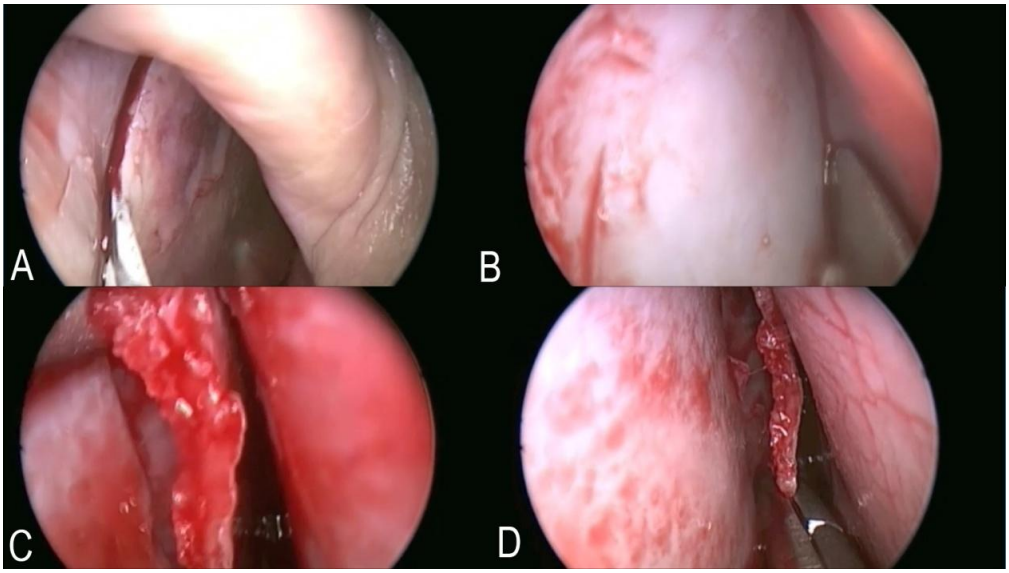

Figure 2: Intra-operative endoscopic view of the nasal cavity showing the main steps of septoplasty. A) Hemitransfixion incision. B) Elevation of the mucoperichondrial flap. C) Dislocation of the bony cartilaginous junction. D) Resecting the deviated bone.

There are several complications of septoplasty, such as post-operative bleeding, septal hematoma (collection of blood inside the nasal septum), septal perforation, residual septal deviation, and adhesions [10]. Poor surgical technique can cause complications. Forty-five percent of cases of nasal obstruction after septoplasty surgery were reported to be caused by inadequate resection of the deviated septum [6].

Annual septoplasty rates differ between countries. In 2006, in the United States, 260,000 septoplasties were performed, which represent 43% of all the ambulatory sinonasal surgeries performed during that year [11]. More than 20,000 septoplasties (3.8 septoplasties per 10,000 individuals) were performed in England between 2012 and

2013 [12]. In the Netherlands, 10,000 septoplasties (6.0 septoplasties per 10,000 individuals) were performed in 2010 [2].

2.2 Septoplasty Surgery Training

Septoplasty surgery can be difficult to teach and learn due to the diversity of nasal septal deviations, limited visual access, and the rarity of hands-on training courses [13]. In fact, a study conducted in the United Kingdom showed that 40% of junior residents and 35% senior residents felt inadequately trained to perform septoplasty without supervision [3]. Training interventions that are currently available, such as being trained in a series of steps, being trained by a professional rhinologist instead of an otolaryngologist of different specialty , or dissecting a cadaver, have proven to improve trainees' abilities and confidence for performing this surgery [3]. Unfortunately, opportunities for Otolaryngology trainees to train and gain operative experience in the operating room is declining with time. Pothier *et al.* showed that there was 20% decrease in the number of operations otolaryngology trainees are expected to perform in the period from 1999 to 2006 [14]. Another study by Varely et al. reported that the otolaryngology elective operations availablr per trainee dropped by 56% between 1997 and 2005 [15].

In a review of the available literature, no prior studies on septoplasty simulation were found.

2.3 Medical Application of Additive Manufacturing

Three-dimensional (3D) printing (also known as additive manufacturing) is a method to manufacture 3D physical objects through the addition of successive layers of materials based on a 3D computer model [16]. There are many applications of additive manufacturing in medicine [17]. For example, rapid prototyping and additive manufacturing have been used for better understanding of complex anatomical structures and for pre-surgical planning [18]. It has also been used for designing prostheses and implants, to reconstruct various anatomical structures, such as facial bones and mandibles [19]. There are also many applications of this technology in medical education, as discussed in the next section.

2.3.1 Additive Manufacturing in Medical Education

Additive manufacturing has been used to teach anatomy and to explain pathologies to medical students and patients. One study showed that medical students were highly satisfied with the incorporation of 3D printed models into their anatomy curriculum [20]. Another study showed that the students who were assigned to learn cardiac anatomy using synthetic printed models scored higher on an evaluation questionnaire than those who used cadaveric materials [21].

Physical replicas can be useful tool for explaining complex pathologies to patients. For example, after showing patients a 3D printed model of an anonymous epilepsy patient's brain hemisphere, 8 of 15 patients believed that a 3D-printed personalized brain would be helpful for them to gain a better understanding of the pathology of epilepsy [22].

2.3.2 Additive Manufacturing in Surgical Training

Usage of 2D and 3D visualization on a computer screen has been shown to be insufficient for developing a complete understanding of certain complex anatomical and pathological details [23]. For that reason, additive manufacturing is increasingly being used for educational purposes, to gain a better understanding of the anatomy and for surgical training. Anastakis et al. showed that technical skills learned on models transferred well to human cadaver models, suggesting the potential for knowledge transfer to the operating room [4].

Some models have been used for surgical training in the OTL-HNS field. For example, a 3D printed endoscopic skull-base training model, with pre-existing pathology, was created by Narayanan et al. [24]; the model they presented incorporated the anatomical pathology, which made it a realistic training tool. Cadaver models, which are the current standard method of training, usually lack the pathology of interest. The model created by Narayanan et al. allowed detailed simulation of an endoscopic skull surgery, starting with the registration of the image guidance system, up to the end of the complete surgical procedure. Fifteen participants performed seven key steps in simulation and rated the model for image guidance, surgical procedure, anatomical accuracy, and tactile feedback. The results showed that the model was suitable for learning purposes.

The temporal bone is a complex structure that has been the target of many additive manufacturing projects. A 3D printed temporal bone model with realistic microstructure was created by Hochman et al. [25]. The authors imported image data files of a temporal bone into segmentation software (Mimics, Materialize, Belgium), and printed

the resulting model, which is drillable with an otic drill. Four models were printed using different chemical infiltrates and were compared with a sheep femur for material validation. Cyanoacrylate with hydroquinone (CAH)-infused models best resembled the sheep’s femur in terms of several osseous parameters, including hardness, tactile vibration feedback during drilling, and acoustic, visual, and overall impression. The model also yielded an 88% match of the air cell system volume to that of the original cadaveric bone.

"ElePhant", an anatomical electronic phantom, is a simulation system for otorhinolaryngoscopic surgery that was developed for mastoidectomy surgery in 2006 [26]. Similar to the previously mentioned project, a computed tomography (CT) scan of the temporal bone was acquired and segmented using the Mimics software, and a 3D model was then printed using plaster as a base material and infiltrated using polyurethane and acetone. Additionally, the structures at risk (sigmoid sinus, semicircular canal, and facial nerve) were represented with electrically conductible material and fiber optics that could be detected during the simulation surgery. It was demonstrated to be a realistic simulation option and had realistic milling properties.

Cruz and Francis also validated a novel 3D printed temporal bone for surgical skill development [27]. The model showed a high degree of face and content validity, which suggests that the model can be a useful substitute for traditional training methods. The model was found to be a useful tool for teaching anatomy and a good tool for surgical planning.

Recently in 2017, Alrasheed et al. developed a physical replica of the ostiomeatal complex and frontal sinus for endoscopic sinus surgery training using the same materials we used to represent different tissues (TangoPlus for soft tissues and VeroWhite for bone) but it did not have a cartilagenous part. An acceptability study was performed and the replica was evaluated as a training tool using face and construct validity. They concluded that the replica had realistic feedback especially for the bony components and that the participants felt it was a useful tool for educational purposes. However, they did not look at other otolaryngology surgical procedures for the deviated nasal septum, which is the scope of this thesis.[28]

Additive manufacturing has also been used for surgical training purposes in other medical fields. For example, multiple validated 3D printed training models have been used for laparoscopic pyeloplasty and percutaneous nephrolithotomy [29] for training in urological procedures. In neurosurgery, Waran et al. developed thalamic lesion models for training junior residents [30]. Other examples include models of a severely atherosclerotic aortic aneurysm [31] and a clubfoot [32].

2.4 Mechanical Properties of Human Tissue

Selecting the appropriate material to represent each of the components of the model requires reproduction of the mechanical properties of human tissue. In general, mechanical properties of bone vary from one bone to another, as well as within different regions of the same bone [33]. The average normal human bone density is 1.85 g/cm^3 [34], with an elastic module that is roughly one-third of that of aluminum [35]. The average nasal septal cartilage density is 1.1 g/cm^3 [36]. It is an incompressible elastic

structure [37]. The mucosa, on the other hand, is much softer and can be compressed to 45% of its original thickness [38].

2.5 Printer and Materials

2.5.1 Connex Object 500 Series Printer

The Connex Object 500 Series printer (Stratasys Ltd, Minnesota USA) has been successfully used to print medical education tools. Lambrecht et al. used it to fabricate a haptic model for undergraduate and postgraduate teaching of mandible and wisdom tooth [39].

2.5.2 VeroWhitePlus RGD835

The VeroWhitePlus RGD835 has a density of 1.17-1.18 g/cm^3 [40], and it has been used to represent bone in many additive manufacturing projects. For example, a project for predicting prostate deformation in real time used VeroWhitePlus to print replicas of the spine and pubic bones [41]. Another example is the use of VeroWhitePlus in creating the bones of a 3D printed prosthetic finger [42].

2.5.3 TangoPlus FLX930

The TangoPlus FLX930 has a density of 1.12 g/cm^3, and can elongate up to 220% of its original length [40]. It has been used to represent soft tissue in multiple medical applications. It has been used as a base material for printing a model of the descending aorta as a phantom for device testing [43]. Another example is the thorax phantom model with a moving surrogate tumor, in which TangoPlus was used to print the soft tissues [44].

In the next section, several concepts used in education theory are explained.

2.6 Face Validity and Acceptability

Face validity tests the training tool's resemblance to the clinical target. It addresses the ability of the tool to simulate the clinical material, and the extent to which it does so [45]. Acceptability, as explained by Green et al, refers to "determining how well an intervention will be received by the target population and the extent to which the new intervention or its components might meet the needs of the target population and organizational setting" [46]. This is usually measured by asking the participants to fill in a post-simulation survey. Cheung et al. asked the participants to complete a post-simulation survey to assess the face validity of their pyeloplasty model [47]. Narayanan et al. also examined the face validity of their 3D printed skull-base model by asking the participants to complete a survey expressing their views on different aspects of the model [24].

2.7 Construct Validity

Construct validity is "the degree to which a test measures what it claims, or purports, to be measuring" [48]. Waran et al. illustrated evidence for the construct validity of their 3D printed thalamic lesion model by assessing the trainees' performance during the simulation and comparing the outcome of different experienced trainees [30]. In the present study, it is demonstrated by establishing differences in outcomes among participants of different skill levels.

2.8 Summary

In view of the above, deviated nasal septum surgery is one of the most common tasks that otolaryngology surgeons will be performing during their training . As stated in section 1.1, there is a need for alternative training tools because trainees are getting less exposure to operating room training and shortage of cadavers training courses. The following section will describe the methods that were followed develop a physical replica of a deviated nasal septum, perform an acceptability study and the validation protocol based on face and construct validity.

Chapter Three: Methods

3.1 Development of the NSPR

The process of creating a 3D model can be divided into three steps:1)Image acquisition; 2)segmentation; and 3)additive manufacturing. Ethical approval for this study was obtained from the Faculty of Medicine Institutional Review Board, McGill University.

3.1.1 Image Acquisition

The NSPR was based on a CT scan of a patient with a deviated nasal septum. It is more challenging to operate on severe and posterior deviation, especially if there is a spur [49]. Thus, multiple CT scans were reviewed with the assistance of an experienced rhinologist and an otolaryngologist. The selection criteria were:

1- Moderately deviated septum. The deflection from midline toward lateral wall more than 33% and less than 66% [50]. Performing septoplasty on a severely deviated septum would be difficult while mildly deviated septum would not provide the simulation experience this project intended to do.

2-Involves both bony and cartilaginous parts of the septum.

3- Does not have other pathologies that might interfere with the simulation, such as polyps.

One case that was moderately challenging (deviation from midline = 50%) and met the other criteria was selected (Figure 3).

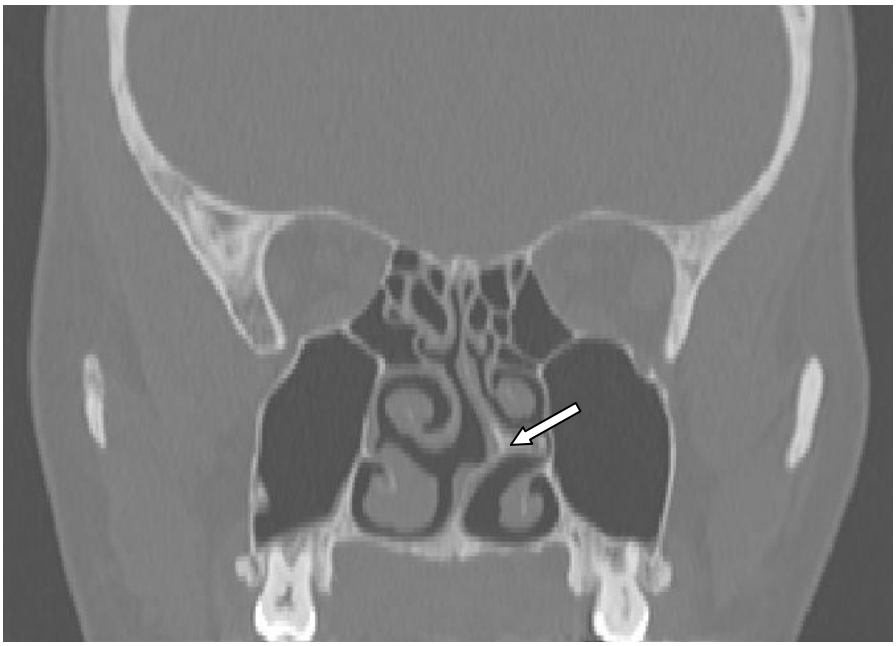

Figure 3: Coronal view from a computed tomography scan of a patient with a deviated nasal septum. The septal deviation causes the septum to be in contact with the lateral nasal wall

The CT scan was imported in axial, coronal, and sagittal views as a Digital Imaging and Communications in Medicine (DICOM) Image stack of 1,182 of 0.5mm thickness slices for segmentation.

3.1.2 Segmentation

Segmentation is the process of subdividing the CT scan data into the required material regions, such as skin, bone, and cartilage [51]. To this end, ITK-Snap, an open source software, was used (www.itksnap.org) [52].

In ITK-Snap, boundaries of the structures of interest were first determined, and then an automated segmentation procedure was performed, with different labels (bone, cartilage, and soft tissues) based on the gray level intensity of the CT scan data. Manual post-processing was needed after obtaining the segmentation results as some pixels of the scan was registered as the wrong tissue type with automatic segmentation, this occurs with tissues of similar density (for example ; part of the cartilage was registered as soft tissue, this had to be fixed manually). This required a few hours to complete, but it provided much better anatomical accuracy than automatic segmentation alone (Figure 4).

Figure 4: Screen shot of segmentation using ITK-SNAP software. Soft tissue is represented by pink, bone by white, and cartilage by green labels in each view.

The final segmentation result was saved in Standard Tessellation Language (STL) file format, which was exported to the 3D printer for printing.

3.1.3 Manufacturing

3.1.3.1 Printer

A Connex Object 500 Series printer (Stratasys Ltd, Eden Prairie, MN, USA) was used to print the NSPR. The printer has a very high accuracy and can prints layers down to 16 microns (0.015 millimeters). It can print multiple materials in a single operation, with a speed of 12 mm per h/strep. There are three modes of printing: high speed, high quality, and digital material modes. In this study, the high quality setting was used.

3.1.3.2 VeroWhitePlus RGD835

VeroWhitePlus RGD835 is a rigid, opaque white material that is compatible with Connex Objet printers. Its composition is shown in Table 1[53].

Table 1: Composition of VeroWhitePlus RGD835

Component	Percent
Acrylic monomer	< 30
Isobornyl acrylate	< 25
Phenol, 4,4'-(1-methylethylidene)bis-, polymer with (chloromethyl)oxirane, 2-propenoate	< 15
Diphenyl-2,4,6-trimethylbenzoyl phosphine oxide	< 2
Titanium dioxide	< 0.8
Acrylic acid ester	< 0.3
Propylene glycol monomethyl ether acetate	0.1–0.125
Phosphoric acid	0.002–0.015

3.1.3.3 TangoPlus FLX930

TangoPlus FLX930 is a semitransparent elastic material that is compatible with Connex Objet printers. Its composition is shown in Table 2[54].

Table 2: Composition of TangoPlus FLX930

Component	Percent
2-Propenoic acid, 2-[[(butylamino)carbonyl]oxy]ethyl ester	< 70
Isobornyl acrylate	< 25
Phosphine oxide, phenylbis(2,4,6-trimethylbenzoyl)-	< 2
Benzyl alcohol	< 0.5
Acrylic acid ester	< 0.3
Dipentene	< 0.1
Isoamyl acetate	< 0.1
Citral	< 0.1
Geraniol	< 0.01
2,6-Di-tert-butyl-p-cresol	< 0.01

3.1.3.4 Model Fabrication

The NSPR consists of three layers: bone, which was printed using the rigid material VeroWhitePlus RGD835, soft tissues (the external nose and mucosa), which was printed using the rubbery material TangoPlus FLX930, and cartilage, which was printed using a combination of both materials. The two materials could be combined at different

ratios. The hardness, or stiffness of each material is defined by their “shore” values: the higher the shore value, the harder the resulting material is, and vice versa. To ensure the best quality and resemblance to human cartilage, three models of the cartilage layer with different shore values (70, 85, and 90) were printed.

After the STL files of the segmented CT scan were imported into the printer's software, printing took about 6 hours (unsupervised) to complete printing of each NSPR. During printing, the printer deposited waxy support material (SUP507) within the empty spaces to maintain the objects’ shape and print quality. The support material had to be removed using a high-pressure water jet (Figure 5).

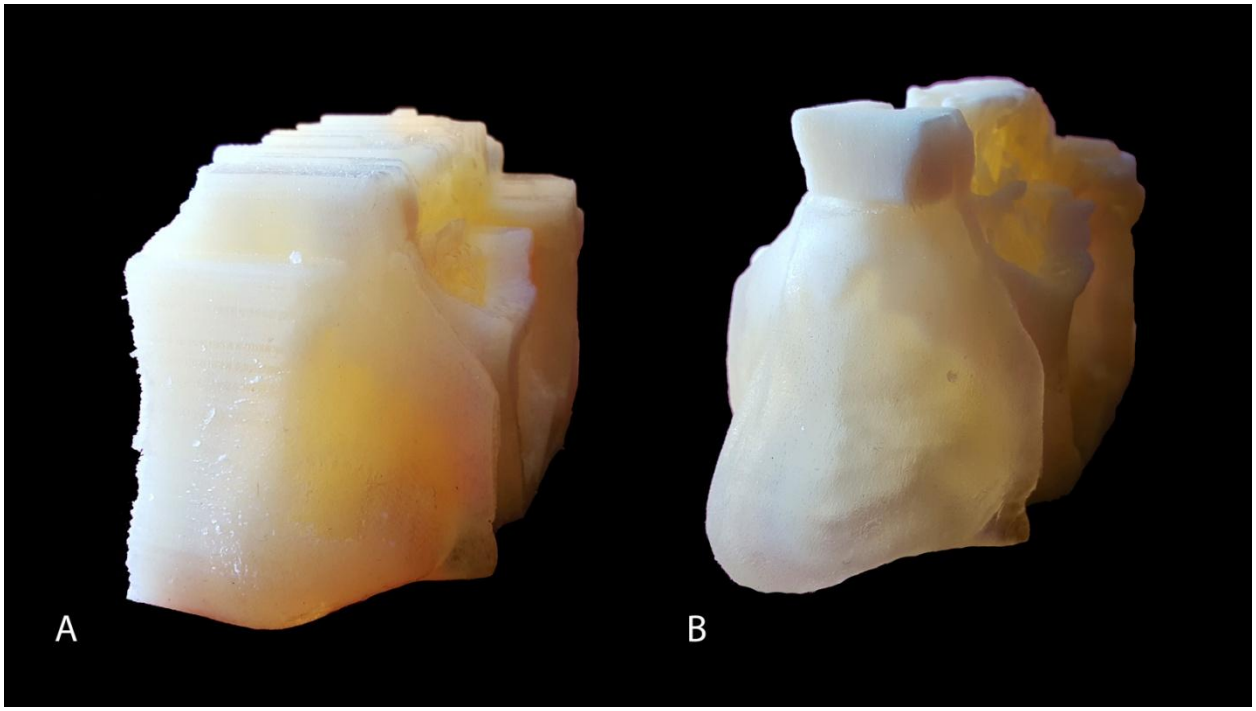

Figure 5: A) The nasal septum physical replica (NSPR) before cleaning the support material. B) The same NSPR after cleaning.

After printing, the NSPR was removed from the printer, and the waxy support material was removed. The external wax was removed using simple sculpture tools, and the internal wax was removed using a high-pressure water jet. The post processing took 10–15 minutes for each replica.

The cost of each replica was based on how many grams of each material were used. TangoPlus cost 0.65 CAD/g, VeroWhitePlus cost 0.50 CAD/g, and the support material cost 0.30 CAD/g. Additionally, there were operating and printer cleaning fees (100 CAD each) . The total cost of the first prototype was 360 Canadian Dollars (CAD) per model compared with the final model, which was 186 CAD per model.

3.1.4 Head Mounts

A free-standing plastic tabletop male mannequin head (bought online on eBay) was filled with expanding urethane foam. It provided a solid core that could be sculpted to the needs of the replica. A cavity was then cut to host the NSPR.

3.2 Product Evaluation

After printing, the replicas were examined by two experienced otolaryngologists for any potential errors and possible improvements. T he segmentation files were edited accordingly. The workflow of the validation process is shown in Figure 6.

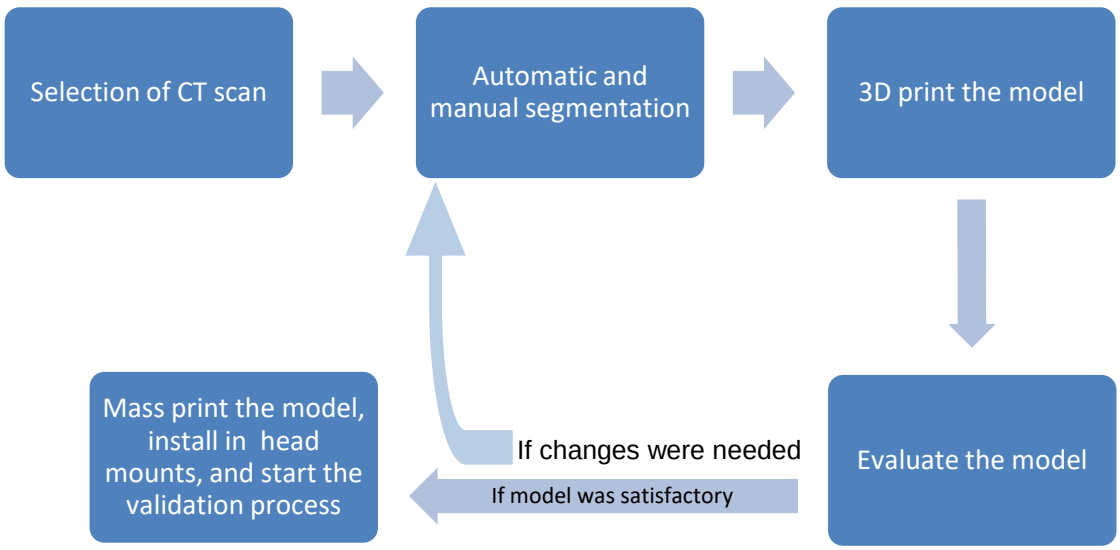

Figure 6: Flowchart of the development of the model.

The NSPR was evaluated for anatomical accuracy, material tactile feedback, and the overall realism of the simulation. Successive changes, explained in the next section, were made to improve the quality of the NSPR.

3.2.1 Prototype Evolution

Design iterations were made to obtain an appropriate and satisfactory replica for training purposes. Four prototypes were produced. The fifth was selected as the final replica. Table 3 states each replica's strengths, weaknesses, improvements, and price.

Table 3: Strengths, weaknesses, price, and improvements of each prototype

Prototype	First	Second	Third	Fourth
Strengths/ improvement	- External anatomy was precise	- Smaller overall size - Better nostril elasticity - Smaller turbinates - Thinner septum - Fixed perforation	- Mucous membrane was more realistic to elevate using air bubble layer* - Bone thickness was more realistic - Turbinate size was appropriate	- Cartilage felt more realistic. The cartilage shape and bony cartilaginous junction was fixed - Nostrils were bigger allowing a better view - Thicker mucous membrane
Weaknesses	- Unnecessary external components were included, causing the replica to be large and expensive - Nostrils were too rigid - Bony septum was perforated - Nasal cavity was narrow; the septum was unrealistically thick.- Big, firm turbinates.	- Mucous membrane was sturdily attached to cartilage and bone, making it difficult to elevate - Vomer and perpendicular plate of the ethmoid were thicker and harder than real bone, making it difficult to fracture - Inferior turbinates were large and stiff - Rubbery cartilage	- Cartilage was still rubbery and difficult to cut - Mucous membrane was very thin at some points, causing a few perforations even when little force was applied - The bony cartilaginous junction was posterior to where it should be. - Nostrils were small and restricted the view	- The deviation proved to be very sharp and difficult to correct (especially for junior trainees)

Prototype	First	Second	Third	Fourth
Suggested improvements	- Remove unnecessary components. - Change the external nose material to improve its manipulability. - Fix perforations - Produce thinner septal bones and cartilage. - Reduce the size of the turbinates	- Add disseminated micro-bubbles of air between the mucous membrane and the cartilage and bone to lessen the adhesion. - Thin the bone. - Reduce the size of the large turbinates - Use higher shore value for the cartilage	- Use a higher shore value for the cartilage - Produce a thicker mucous membrane. - Fix the cartilage shape and bony cartilaginous junction. Broaden the nostrils	- Reduce the deviation

3.2.2 Changes in the Development of the NSPR and Their Solutions

The first problem encountered during the development of the NSPR was that the nasal cavity was too narrow, which made simulations impossible. This was corrected by reducing the size of the turbinates as well as the thickness of the nasal septum. The second problem was that the nostrils were too stiff, which made the simulations unrealistic. This problem was solved by changing the material used for the external nose (TangoPlus) and by enlarging the diameter of the nostrils.

A third problem was harder to solve: reproducing a realistic flap elevation procedure. The material that was being used to represent soft tissue (TangoPlus) adhered strongly to the underlying materials representing the bone and cartilage. This made the elevation of the flap (a cornerstone of the septoplasty procedure) unrealistic, as it required too much force and effort. To overcome this, a layer of small air bubbles was added

between the mucous membrane layer and the underlying structures. This reduced the attachment between the mucous membrane-simulation material and the material used for the bone and cartilage. Consequently,the flap elevation simulation became more realistic (Figure 7).

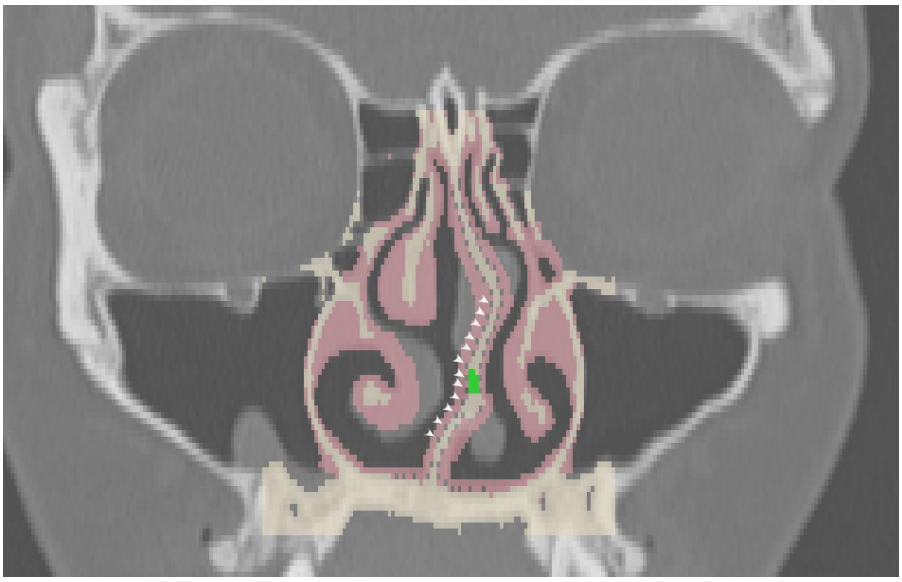

Figure 7: Coronal computed tomography view of the deviated nasal septum during the segmentation process. Arrowheads indicate the air bubbles added to the right side of the septum to reduce the adhesion between the mucosa and both bone and cartilage.

Unfortunately, several problems could not be resolved: coloring and support material debris. VeroWhitePlus is white in color, which made it a perfect fit for bone, and the combination thereof with Tangoplus also yielded a cartilage-like coloration. On the other hand, Tangoplus is whitish and semitransparent, differing from a pink mucous membrane. Unfortunately, the additive manufacturing technology employed did not offer

coloring options. Efforts to color materials manually using water-based and acrylic-based coloring did not lead to satisfactory results.

The usage of a wax support material is an integral part of additive manufacturing. However, complete wax removal could be difficult. It was relatively easy to remove wax from the external parts of the replica, either manually or by using a high-pressure water jet. On the other hand, it was not as easy to remove wax from the internal nasal cavity. This difficulty arose because of the risk that manual removal of the internal supportive wax using sculpture tools might damage the nasal cavity lining. Therefore, a water jet was used under very low pressure. This permitted successful removal of most of the internal wax. But small pieces of wax remained, which partially blocked the endoscopic view of internal structures for those performing the simulated septoplasty.

Another problem with the developed NSPR was that the replica could not reproduce bleeding, which would be an important element of a realistic simulation. It should be added that the materials are not biodegradable, and the contents/container have to be disposed of in an approved waste disposal plant.

3.3 Validation and Acceptability Study

Validity refers to how well the item measures the attribute it is intended to measure [55]. To test validity of the NSPR, 20 simulation replicas were printed. Each was placed in a head mount (Figure 8) and presented to the participants to perform a simulated endoscopic septoplasty. An endoscopic simulation approach was chosen over conventional septoplasty, because it would be easier to record and to observe the tasks

performed inside the simulated nasal cavity, which would be required to make the validation easier.

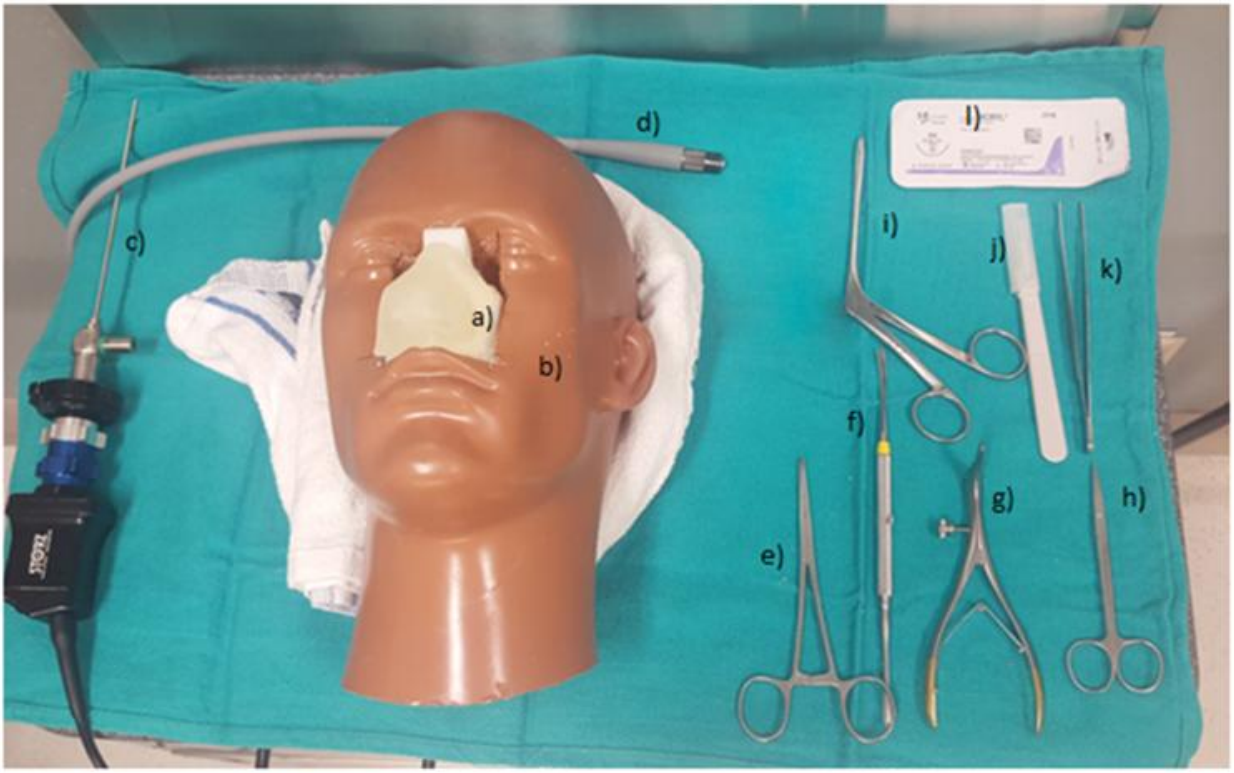

Figure 8: The secured replica in the head mount and the tools used to perform simulated septoplasty. a)NSPR; b)Head mount; c) 4mm rigid nasal endoscope; d)light source; e)needle holder; f)freer elevator; g) killian nasal speculum; h)scissor; i)ethmoid forceps ; j)disposable size 15 blade; k)forceps ; l) 3-0 vicryl suture

3.3.1 Recruitment of Participants

The study was conducted during the September 2015 North American Masterclass in Endoscopic Sinus Surgery and Residents' Sinus Course in February 2016, both of which took place at McGill University, Quebec, Canada. Twenty otolaryngologists with

different levels of surgical experience were recruited. The participants were already trained or currently training in various training centers. Each user was given a brief tutorial concerning the functionality of the NSPR and tools, as well as a video demonstrating the tasks to be performed, namely inspecting the nasal cavities, perform the correct incision, elevate the mucoperichondrial flap, dislocate the bony cartilaginous junction, resect the deviated cartilage and bone and inspect the nasal cavity again.

3.3.2 Study Design and Setting

3.3.2.1 Face Validity and Acceptability Study

Face validity is defined as the subjective assessment of the scope and completeness of a tool and is usually measured in the early stages of an instrument's development [55]. Acceptability, as explained by Green et al, refers to “determining how well an intervention will be received by the target population and the extent to which the new intervention or its components might meet the needs of the target population and organizational setting” [46].

Face validity and acceptability were assessed using a three-part questionnaire that was completed after the participants had finished the simulation. The questionnaire's first part asked about the participants’ demographics, training level, previous septoplasty experience, and current septoplasty performance level. They were also asked about the likelihood of using the NSPR as a part of the training before performing septoplasty surgery in the operating room. The second part of the questionnaire consisted of 21 Likert scale questions; value 1 was assigned to "Strongly Disagree" and value 5 to "Strongly Agree”. The first 10 questions asked about the simulation realism; the next

five questions asked about visual accuracy, followed by six questions that asked about the overall impression of the tool as a training alternative. The third part of the questionnaire contained three open-ended questions that asked the participants three perceived strong points as well as three perceived weaknesses of the NSPR. They were asked if they had any recommendations for improving the model.

3.3.2.2 Construct Validity

Construct validity is defined as the measurement of how effective the tool is when it is in practical use [55]. This can be achieved by showing the difference in the performance of the tool between users with different levels of experience [56].

Two independent, blinded raters evaluated the videos and the post-simulation NSPR of each procedure. First, each simulation was evaluated using three major categories of performance metrics: quality, efficiency, and safety. The list of metrics is presented in Table 4. Then, the raters assessed each step of the procedure using the septoplasty-specific checklist and the septoplasty assessment tool, both of which are used as an operative competence assessment tool for nasal septoplasty surgery [57]. One-way analysis of variance (ANOVA) was used to determine whether there were any statistically significant differences between the means of the groups. Spearman's correlation coefficient (one-tailed, alpha value 0.05) was used to establish inter-rater reliability. For all statistical purposes, a value of $p < 0.05$ was considered significant.

Table 4: Performance metrics

Area	Metric	Unit	Note
Quality	Final product analysis	Score/5	The post-simulation NSPR was rated for overall outcome for each participant
Efficiency	Time	Minutes	Time was calculated from the start of incision to the end of the simulation
Safety	Total length of flap	mm on each side	
	Perforations		
	Bilateral overlapping perforations	Yes or No	
	Diameter of holes in the mucosa	mm on each side	
	Total length of external nose tears	mm on each side	

Chapter Four: Results

4.1 Demographic Data

Eight professional rhinologists, six senior residents, and six junior residents participated in the evaluation of the NSPR. There were 15 male (75%) and five female rhinologists (25%). Nineteen were right-handed (95%), and one was left-handed (5%). The average age of the participants was 35.15 (13.27). The average number of septoplasties done by residents is shown in Table 5.

Table 5: Average number of septoplasties performed by residents

	Type of septoplasty and period	Senior Residents	Junior residents
As a primary Surgeon	Regular septoplasty in the past 12 months	4.16 (2.31)	0 (0)
	Regular septoplasty during all training	8.5 (3.56)	0 (0)
	Endoscopic septoplasty in the past 12 months	1.83 (1.83)	0 (0)
	Endoscopic septoplasty during all training	2.83 (2.85)	0 (0)
As an assistant surgeon	Regular septoplasty in the past 12 months	1.5 (2.07)	0 (0)
	Regular septoplasty during all training	4.83 (4.21)	0 (0)
	Endoscopic septoplasty in the past 12 months	1.33 (2.06)	0 (0)
	Endoscopic septoplasty during all training	4.5 (5.64)	0 (0)

All the junior residents and three (50%) of the senior residents strongly agreed that they would like to practice on the septoplasty simulator as a part of their OTL-HNS training, while two senior residents (33.33%) agreed, and one (16.66%) strongly disagreed.

All the professional rhinologists were completing or had completed a fellowship in rhinology. The average time passed since completing this fellowship was 14.3 years (16.58). The average time they had been practicing OTL-HNS was 18.25 years (17.53). All the professional rhinologists practiced mainly in a tertiary care center, and all of them performed septoplasty as a routine part of their practice. The mean number of septoplasties performed by these individuals in the past year was 125.83 (115.34).

4.2 Post-Simulation Questionnaire

Four (20%) of participants suggested that the NSPR should be introduced to residents in their first year of training (PGY1), 12 (60%) felt this should happen in PGY2, and four (20%) in PGY3.The open-ended questions showed that the major strengths of the NSPR were the anatomical accuracy (85%), that the surgical steps were well reproduced (40%), and that the bone material (VeroWhite) closely resembled bone texture and rigidity (40%). However, the main weaknesses of the NSPR reported by the participants were that the residual supporting wax material debris sometimes blocked the view (50%, that TangoPlus did not adequately reproduce the physical characteristics of mucous membranes (40%), that the NSPR did not reproduce bleeding (15%), and that the nostrils were unrealistically rigid (15%).

The results of the post-simulation questionnaire are summarized in Table 6.

Table 6: Summary of the post-simulation questionnaire results

Simulation Reality	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The NSPR reproduces the skills for elevating the mucoperichondrial flap	1 (5%)	1 (5%)	1 (5%)	7 (35%)	10 (50%)
The NSPR reproduces the skills for cartilage excision	1 (5%)	0	2 (10%)	9 (45%)	8 (40%)
The NSPR reproduces the skills for bone excision	0	1 (5%)	1 (5%)	8 (40%)	10 (50%)
The NSPR reproduces the skills for closure of the septal pocket and incision	2 (10%)	4 (20%)	2 (10%)	4 (20%)	7 (35%)
The feedback feeling from the tissues upon handling was realistic	1 (5%)	1 (5%)	4 (20%)	10 (50%)	4 (20%)
Steps performed on the NSPR to create the flap were realistic	1 (5%)	0	2 (10%)	8 (40%)	9 (45%)
Steps performed on the NSPR to redefine the cartilage and bone were realistic	0	2 (10%)	2 (10%)	10 (50%)	6 (30%)
Bone material behaved like human bone	0	0	2 (10%)	10 (50%)	8 (40%)
Cartilage material behaved like human cartilage:	1 (5%)	2 (10%)	4 (20%)	5 (25%)	8 (40%)
Soft tissue material behaved like human soft tissue	1 (5%)	4 (20%)	5 (25%)	6 (30%)	4 (20%)

Visuals	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The NSPR overall is visually realistic	1 (5%)	0	0	10 (50%)	4 (20%)
Bones are anatomically correct	0	0	1 (5%)	8 (40%)	10 (50%)
Cartilage is anatomically correct	0	0	1 (5%)	9 (45%)	10 (50%)
Soft tissues (skin and mucous membranes) are anatomically correct	0	2 (10%)	1 (5%)	9 (45%)	8 (40%)
Positioning and angle that the NSPR replicated were realistic	1 (5%)	1 (5%)	2 (10%)	6 (30%)	10 (50%)
Overall Impression	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
The NSPR improves the ability of the trainee to perform septoplasty	1(5%)	0	0	8(40%)	11(55%)
I feel better prepared to do septoplasty after training using this NSPR	2 (10%)	0	4 (20%)	6 (30%)	8 (40%)
The training NSPR met my expectations	1 (5%)	0	2 (10%)	8 (40%)	9 (45%)
Residents should use this training method before performing septoplasties on patients	1 (5%)	0	1 (5%)	6 (30%)	12 (60%)
This NSPR should be implemented into the residency training curriculum	1 (5%)	0	1 (5%)	7 (35%)	11 (55%)

4.3 Simulation Assessment

4.3.1 Performance Metrics

In the efficiency category, the average time needed to complete the procedure was 21.20 minutes (16.83 minutes) for the professional group, as compared to the senior resident's group who averaged 24.94 min (10.01 min) and the junior resident group who had an average time of 51.66 min (25.7 min). There was a significant difference in the time required by the different groups (p-value = 0.017; Figure 9). In the quality category, the final product analysis showed that the average rating of the expert, senior residents', and junior residents' groups were 3.81 (0.8), 3.58 (0.8), and 2.5 (1.03) respectively; there was a statistically significant difference in the ratings among the groups (p-value < 0.05). Raters' correlation was 0.68 (Figure 10). With regard to external nares tears, there was a statistically significant difference between the average tear lengths (in millimeters) between groups ($p < 0.05$). On the other hand, 37.5% of the professional group participants caused bilateral overlapping perforations, compared with 50% of the senior and 0% of the junior resident groups. There was no statistically significant difference between groups for the remaining metrics in Table 3

Table 7: Post simulation performance safety analysis

Tasks	Professional rhinologists	Senior residents	Junior residents	p-value
Right nares tears (mm)	0(0)	0.166(0.41)	1.33(2.66)	0.23
Left nares tears (mm)	1.5(2.82)	4(3.94)	7.33(4.36)	0.03*
Total length of right side perforations (mm)	7.87 (8.21)	9.5(15.12)	5.83(5.5)	0.82
Total length of left side perforations (mm)	26(10.4)	34(13.3)	37.33(11.3)	0.19
Perimeter of holes on the right side (mm)	2.62(7.42)	0(0)	1.33(3.26)	0.64
Perimeter of holes on the right side (mm)	13(24.26)	17.33(13.91)	5.33(8.64)	0.51

* Indicates a significantly statistic p-value

4.3.2 Septoplasty-Specific Checklist and Septoplasty Assessment Tool

Each reader evaluated 14 variables for each simulation. The inter-rater correlation was 0.63. The nasal cavity incision average scores of the professional group, senior residents' group, and junior residents' group were 4.06 (0.82), 2.83 (0.75), and 2.25 (0.76) (p-value = 0.02). In flap elevation, the average scores of the professional group, senior residents' group, and junior residents' group were 4.06 (0.82), 3.17 (0.68), and 2.58 (0.74) (p-value <0.01). The average global overall assessment for the entire simulation in the professional group was 3.69 (1.07), followed by the senior residents at 3.25 (0.52), and finally the junior residents at 2.42 (0.86) (p-value < 0.05). These results

are shown in Table 7.

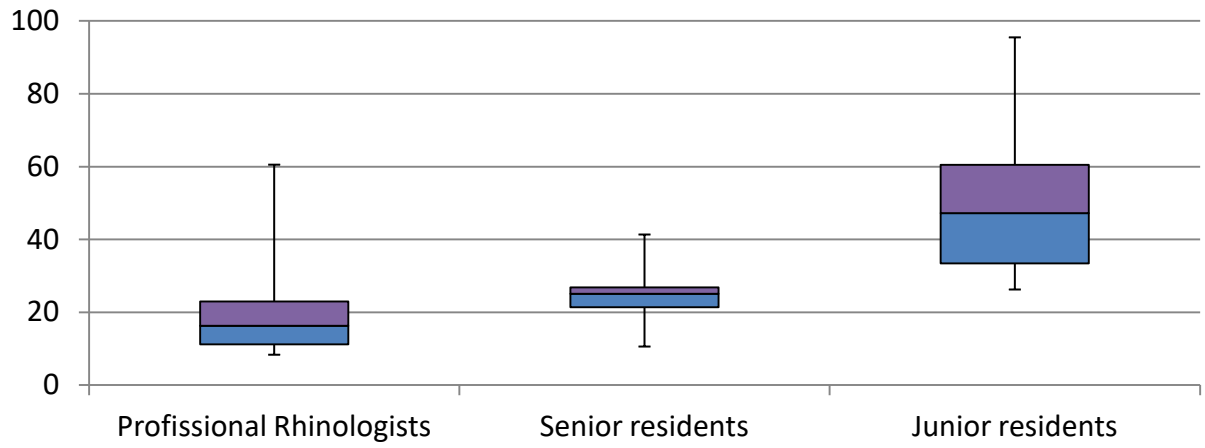

Figure 9: Box and whiskers plot comparing the average time to perform the simulation between groups.

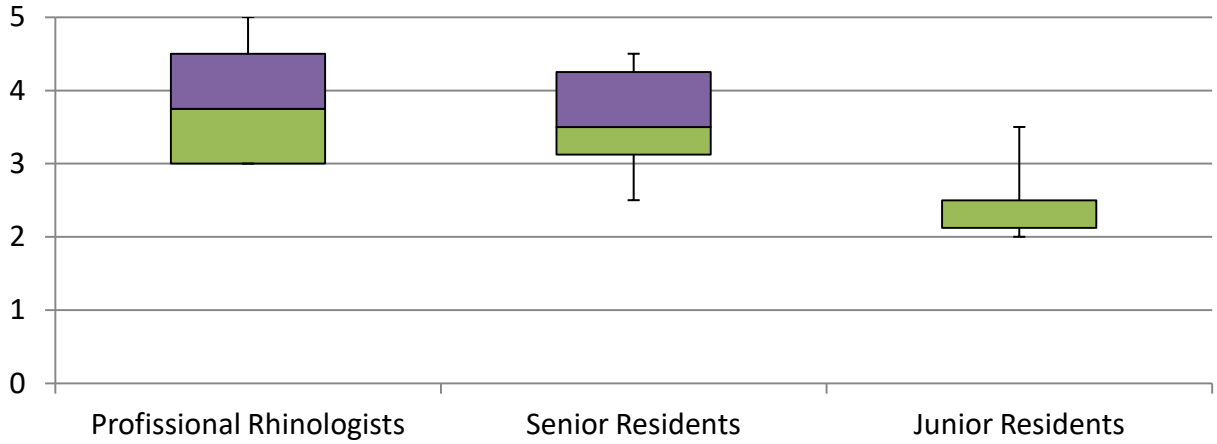

Figure 10: Box and whiskers plot comparing the average final product analysis scores between groups.

Table 8: The average scores of the tasks and global assessment tools for each group

Tasks	Professional rhinologists	Senior residents	Junior residents	p-value
Nasal cavity inspection	4.19 (1.00)	3.75 (0.69)	3.67 (0.52)	0.43
Incision	4.06 (0.82)	2.83 (0.75)	2.25 (0.76)	0.02*
Flap elevation	4.00 (0.80)	3.17 (0.68)	2.58 (0.74)	0.01*
Bony cartilaginous joint dislocation	3.81 (0.88)	3.42 (0.58)	3.00 (1.00)	0.23
Cartilage resection	3.63 (1.22)	3.08 (0.58)	2.08 (0.97)	0.03*
Bony resection	3.75 (0.80)	3.25 (0.52)	2.75 (0.69)	> 0.05
Final nasal cavity inspection	3.81 (3.42)	3.42(0.58)	3.50 (0.89)	0.68
Global assessment tool				
Respect for tissues	3.25 (1.16)	2.83(0.75)	2.83 (1.03)	0.67
Time and motion	3.81 (1.03)	3.25 (0.52)	2.17 (0.75)	0.01*
Instrument handling	4.13 (0.99)	3.25 (0.69)	2.17 (1.03)	< 0.01*
Flow of the simulation	3.88 (1.09)	3.17 (0.52)	2.42 (0.86)	0.02*

* Indicates a significantly statistic p-value

Chapter Five: Discussion

In this study, an NSPR was built and refined through multiple successive modifications to evolve into a replica that was as realistic as possible. Using available additive manufacturing technology and segmentation software. The segmentation process was reviewed meticulously for anatomical accuracy and possible improvements. After printing, the NSPRs were examined carefully by experienced otolaryngologists for feedback.

Utilization of support material is an integral part of additive manufacturing, but removing it can be challenging. It was relatively easy to remove the wax from the external parts of the NSPR, either manually or with a high-pressure water jet, but it was not as easy to remove it from the nasal cavity. Manual removal by means of sculpture tools was expected to damage the nasal cavity lining, and thus, a water jet was used under very low pressure. This was successful in removing most of the wax, although there were remnants that mildly obscured the view of the surgeons performing the simulated septoplasty. Another potential weakness of the NSPR is that the materials were not biodegradable and should be disposed in accordance with local regulations.

Given the current lack of septoplasty simulators, the data presented here are the first step toward addressing the deficiency in septoplasty training options.

Unlike in the operating room, the NSPR provided a safe environment for inexperienced surgeons to practice septoplasty without the risk of causing complications. It can be produced as needed, relatively cheaply, making it superior to the cadaver training method, which is more expensive and not easily accessible.

The acceptability study showed that the NSPR was received well by all participants as a training option and for honing their skills in the operation room. It was clear that the bone material (VeroWhite Plus) and the cartilage (combination of Verowhite and TangoPlus) were more realistic and resembled real life tissues better than did the soft tissue material (TangoPlus), which was not perceived as realistic. VeroWhite replicated the bone anatomy, texture, and rigidity very well. The bone excision part of the simulation was found to be the most realistic, followed by the flap elevation, cartilage excision, and soft tissue feedback. As the open-ended questions showed, the soft tissue material was more fragile than real mucous membrane, which caused multiple perforations even in the absence of excessive force. The model was inflexible at the nostrils, which made scope movement and instrument manipulation more difficult that it should be. The current available 3D printing technologies cannot print fluids; thus, bleeding, which is an important part of the surgery, could not be simulated. Bleeding should be included if newer printer models are able to add fluids to the printed structures. Newer models of the printer used in this study have the ability to add coloring to different parts of the printed 3D models, which could improve the realism of simulation visuals.

To demonstrate the validity of educational tools, previous studies have focused on showing the difference in performance between users with different levels of experience [56]. As shown in the results of the quality, safety, and efficiency performance metrics, the professional rhinologists group performed better septoplasties, followed by the senior resident's group, and then the junior residents. The former group also required less time to complete the simulation, followed by the senior residents and then the junior

residents. Additionally, the less experienced surgeons were more likely to damage the external nares. This showed that, with advanced levels of experience, the surgeons were able to adapt to the stiff nares and manipulate the scope and the instruments without causing much damage to the tissues. Moreover, the average length of the flap perforations was the least in the group of professional rhinologists, followed by the senior residents, and then the junior residents. Additionally, the novice surgeons used excessive force to elevate the left-side flap at first, perforating it, but subsequently they used markedly less force on the right side, elevating it inadequately. They also did not resect the posterior, more difficult to excise parts of the bony deviation. Because of these two factors, less experienced surgeons caused fewer perforations on the right side and, subsequently, had fewer overlapping perforations.

The construct validity of the developed NSPR was assessed based on its ability to discriminate between participants with different experience levels. The results of the task-specific septoplasty checklist showed that professional rhinologists obtained the highest average score, followed by the senior residents, and then the junior residents. The differences were significant for all tasks, except the nasal cavity inspection at the beginning and end of the simulation, and the obstruction of the scope's camera by the wax debris might have been the reason for this discrepancy. The global assessment tool average scores were also highest for the professional group followed by senior and then junior residents. The inter-rater reliability is an important factor in the evaluation process, and the NSPR achieved an acceptably strong reliability score.

Given the lack of septoplasty simulators, the performance of the NSPR could not be compared to that of others. However, the data presented here represent the first step toward offering more septoplasty training options.

A potential weakness of the NSPR as a training tool is the lack of diversity of the pathology. A suggestion for overcoming this would be to provide multiple NSPRs representing different septal deviation types, severity, and sides, based on a classification system [58]. The next step should be to compare this NSPR with other training modalities, including cadaver and operating room training, to further assess its validity and the effect on transferring the skills to the operating room.

Chapter Six: Summary and Conclusion

There are currently no accepted septoplasty simulation tools available for training purposes. The NSPR presented in this thesis offers an easily reproducible, relatively cheap training method that has been shown to be anatomically correct, and to provide realistic tissue simulation. The survey showed that the NSPR was well received as a training tool by professional rhinologists and by residents alike. The observed difference between experienced and novice surgeons provided an evidence of its effectivness.

Chapter Seven: List of References

1. Korkut, A.Y., et al., *Evaluation of inferior turbinate hypertrophy in patients with congenital and traumatic nasal septum deviation.* J Laryngol Otol, 2012. **126**(8): p. 784-8.
2. van Egmond, M.M., et al., *Effectiveness of septoplasty versus non-surgical management for nasal obstruction due to a deviated nasal septum in adults: study protocol for a randomized controlled trial.* Trials, 2015. **16**: p. 500.
3. Gupta, S., et al., *Septoplasty training revisited.* The Bulletin of the Royal College of Surgeons of England, 2014. **96**(2): p. e10-e13.
4. Anastakis, D.J., et al., *Assessment of technical skills transfer from the bench training model to the human model.* Am J Surg, 1999. **177**(2): p. 167-70.
5. Stevens, M.R. and H.A. Emam, *Applied surgical anatomy of the nose.* Oral Maxillofac Surg Clin North Am, 2012. **24**(1): p. 25-38.
6. Kuduban, O., et al., *The Reason of Dissatisfaction of Patient after Septoplasty.* Eurasian J Med, 2015. **47**(3): p. 190-3.
7. Reitzen, S.D., W. Chung, and A.R. Shah, *Nasal septal deviation in the pediatric and adult populations.* Ear Nose Throat J, 2011. **90**(3): p. 112-5.
8. Vainio-Mattila, J., *Correlations of nasal symptoms and signs in random sampling study.* Acta Otolaryngol Suppl, 1974. **318**: p. 1-48.
9. Most, S.P. and S.F. Rudy, *Septoplasty: Basic and Advanced Techniques.* Facial Plast Surg Clin North Am, 2017. **25**(2): p. 161-169.
10. Kim, J.S. and S.H. Kwon, *Is nonabsorbable nasal packing after septoplasty essential? A meta-analysis.* Laryngoscope, 2017. **127**(5): p. 1026-1031.

11. Bhattacharyya, N., *Ambulatory sinus and nasal surgery in the United States: demographics and perioperative outcomes.* Laryngoscope, 2010. **120**(3): p. 635-8.

12. Herman, M., *Hospital episode statistics: Admitted patient care-England 2012/13. NHS The Information Centre*. 2013.

13. Heo, S.J., C.M. Park, and J.S. Kim, *Learning curve of septoplasty with radiofrequency volume reduction of the inferior turbinate.* Clin Exp Otorhinolaryngol, 2013. **6**(4): p. 231-6.

14. Pothier, D.D., et al., *Trends in operative training opportunities for junior and senior trainees in otolaryngology.* Clin Otolaryngol, 2009. **34**(2): p. 179-84.

15. Varley, I., J. Keir, and P. Fagg, *Changes in caseload and the potential impact on surgical training: a retrospective review of one hospital's experience.* BMC Med Educ, 2006. **6**: p. 6.

16. Peltola, S.M., et al., *A review of rapid prototyping techniques for tissue engineering purposes.* Ann Med, 2008. **40**(4): p. 268-80.

17. Rengier, F., et al., *3D printing based on imaging data: review of medical applications.* Int J Comput Assist Radiol Surg, 2010. **5**(4): p. 335-41.

18. Wagner, J.D., et al., *Rapid 3-dimensional prototyping for surgical repair of maxillofacial fractures: a technical note.* J Oral Maxillofac Surg, 2004. **62**(7): p. 898-901.

19. D'Urso, P.S., et al., *Custom cranioplasty using stereolithography and acrylic.* Br J Plast Surg, 2000. **53**(3): p. 200-4.

20. Fasel, J.H., et al., *Adapting anatomy teaching to surgical trends: a combination of classical dissection, medical imaging, and 3D-printing technologies.* Surg Radiol Anat, 2015.
21. Lim, K.H., et al., *Use of 3D printed models in medical education: A randomized control trial comparing 3D prints versus cadaveric materials for learning external cardiac anatomy.* Anat Sci Educ, 2015.
22. Naftulin, J.S., E.Y. Kimchi, and S.S. Cash, *Streamlined, Inexpensive 3D Printing of the Brain and Skull.* PLoS One, 2015. **10**(8): p. e0136198.
23. Kim, M.S., et al., *Rapid prototyping: a new tool in understanding and treating structural heart disease.* Circulation, 2008. **117**(18): p. 2388-94.
24. Narayanan, V., et al., *Endoscopic skull base training using 3D printed models with pre-existing pathology.* Eur Arch Otorhinolaryngol, 2015. **272**(3): p. 753-7.
25. Hochman, J.B., et al., *Generation of a 3D printed temporal bone model with internal fidelity and validation of the mechanical construct.* Otolaryngol Head Neck Surg, 2014. **150**(3): p. 448-54.
26. Grunert, R., et al., *ElePhant--an anatomical electronic phantom as simulation-system for otologic surgery.* Conf Proc IEEE Eng Med Biol Soc, 2006. **1**: p. 4408-11.
27. Da Cruz, M.J. and H.W. Francis, *Face and content validation of a novel three-dimensional printed temporal bone for surgical skills development.* J Laryngol Otol, 2015. **129 Suppl 3**: p. S23-9.

28. Alrasheed, A.S., et al., *Development and validation of a 3D-printed model of the ostiomeatal complex and frontal sinus for endoscopic sinus surgery training.* Int Forum Allergy Rhinol, 2017.

29. Turney, B.W., *A new model with an anatomically accurate human renal collecting system for training in fluoroscopy-guided percutaneous nephrolithotomy access.* J Endourol, 2014. **28**(3): p. 360-3.

30. Waran, V., et al., *Injecting realism in surgical training-initial simulation experience with custom 3D models.* J Surg Educ, 2014. **71**(2): p. 193-7.

31. Schmauss, D., et al., *Three-dimensional printing for perioperative planning of complex aortic arch surgery.* Ann Thorac Surg, 2014. **97**(6): p. 2160-3.

32. Windisch, G., et al., *A model for clubfoot based on micro-CT data.* J Anat, 2007. **210**(6): p. 761-6.

33. Rho, J.Y., M.C. Hobatho, and R.B. Ashman, *Relations of mechanical properties to density and CT numbers in human bone.* Med Eng Phys, 1995. **17**(5): p. 347-55.

34. Yang, J., et al., *A new device for measuring density of jaw bones.* Dentomaxillofac Radiol, 2002. **31**(5): p. 313-6.

35. Ritchie, R.O., M.J. Buehler, and P. Hansma, *Plasticity and toughness in bone.* Phys Today, 2009. **62**(6): p. 41-47.

36. Homicz, M.R., et al., *A compositional analysis of human nasal septal cartilage.* Arch Facial Plast Surg, 2003. **5**(1): p. 53-8.

37. Mansour, J.M., *(2013). Biomechanics of cartilage. In Kinesiology: The Mechanics and Pathomechanics of Human Movement: Second Edition (pp. 69-83). Wolters Kluwer Health.*

38. Picton, D.C. and D.J. Wills, *Viscoelastic properties of the periodontal ligament and mucous membrane.* J Prosthet Dent, 1978. **40**(3): p. 263-72.

39. Lambrecht, J.T., et al., *Haptic model fabrication for undergraduate and postgraduate teaching.* Int J Oral Maxillofac Surg, 2010. **39**(12): p. 1226-9.

40. *PolyJet Materials Data Sheet.* http://usglobalimages.stratasys.com/Main/Files/Material_Spec_Sheets/MSS_PJ_PJMaterialsDataSheet.pdf?v=635785205440671440.

41. Jahya, A., M. Herink, and S. Misra, *A framework for predicting three-dimensional prostate deformation in real time.* Int J Med Robot, 2013. **9**(4): p. e52-60.

42. Cabibihan, J.J., *Patient-specific prosthetic fingers by remote collaboration--a case study.* PLoS One, 2011. **6**(5): p. e19508.

43. Biglino, G., et al., *Rapid prototyping compliant arterial phantoms for in-vitro studies and device testing.* J Cardiovasc Magn Reson, 2013. **15**: p. 2.

44. Mayer, R., et al., *3D printer generated thorax phantom with mobile tumor for radiation dosimetry.* Rev Sci Instrum, 2015. **86**(7): p. 074301.

45. Schijven, M. and J. Jakimowicz, *Face-, expert, and referent validity of the Xitact LS500 laparoscopy simulator.* Surg Endosc, 2002. **16**(12): p. 1764-70.

46. Green, L.W. and M.W. Kreuter, *Health promotion planning : an educational and environmental approach*. 2nd ed. 1991, Mountain View, CA: Mayfield Pub. Co. xxi, 506 p.

47. Cheung, C.L., et al., *Use of 3-dimensional printing technology and silicone modeling in surgical simulation: development and face validation in pediatric laparoscopic pyeloplasty.* J Surg Educ, 2014. **71**(5): p. 762-7.

48. Cronbach, L.J. and P.E. Meehl, *Construct validity in psychological tests.* Psychological bulletin, 1955. **52**(4): p. 281.

49. Getz, A.E. and P.H. Hwang, *Endoscopic septoplasty.* Curr Opin Otolaryngol Head Neck Surg, 2008. **16**(1): p. 26-31.

50. Salihoglu, M., et al., *Examination versus subjective nasal obstruction in the evaluation of the nasal septal deviation.* Rhinology, 2014. **52**(2): p. 122-6.

51. Boscolo, R., M.S. Brown, and M.F. McNitt-Gray, *Medical image segmentation with knowledge-guided robust active contours.* Radiographics, 2002. **22**(2): p. 437-48.

52. Yushkevich, P.A., et al., *User-guided 3D active contour segmentation of anatomical structures: significantly improved efficiency and reliability.* Neuroimage, 2006. **31**(3): p. 1116-28.

53. *Stratasys Inc 2011 VeroWhitePlus RGD835 material safety data sheet.* www.stratasys.com/~/media/Main/Secure/MSDS/Rigid%20Opaque%20Materials/DOC-06124--Objet-VeroWhitePlusRGD835-US.pdf.

54. *Stratasys Inc 2011 TangoPLus FX 930 material safety data sheet.* http://usglobalimages.stratasys.com/Main/Secure/MSDS/Rubber-like%20Materials/DOC-06128-Objet-TangoPlus-FLX930-US.pdf?v=635508832908228903.

55. Litwin, M.S. and J. Bergman, *Outcomes Research*, in *Campbell-Walsh urology*, A.J. Wein, L.R. Kavoussi, and M.F. Campbell, Editors. 2012, Elsevier Saunders: Philadelphia, PA.

56. Downing, S.M., *Validity: on meaningful interpretation of assessment data.* Med Educ, 2003. **37**(9): p. 830-7.

57. Obeid, A.A., et al., *Development and testing for an operative competency assessment tool for nasal septoplasty surgery.* Am J Rhinol Allergy, 2014. **28**(4): p. e163-7.

58. Teixeira, J., et al., *Nasal Septal Deviations: A Systematic Review of Classification Systems.* Plast Surg Int, 2016. **2016**: p. 7089123.