DEVELOPMENT OF SIMULATION PLATFORM FOR
OROPHARYNGEAL AIRWAY PLACEMENT
AND DESIGN EVALUATION OF
THE BARDO AIRWAY

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ABSTRACT

DEVELOPMENT OF SIMULATION PLATFORM FOR OROPHARYNGEAL AIRWAY PLACEMENT AND DESIGN EVALUATION OF THE BARDO AIRWAY

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Off-label use of traditional Oropharyngeal Airway (OPA) as a bite-block, and the subsequent procedure of force exertion of the device by physician has caused many cases of patient's teeth damage and monetary loss, as the patient's incisors were damaged while clenching on the OPA during an adverse scenario called "Emergency Clenching". To remedy this harmful situation, Bardo OPA was developed by Dr. Theodore Burdumy. The Bardo airway has unique design to transfer the clenching force from incisor to the molar. However, the Bardo OPA is one-sized, and cannot fit most of the patients like the commonly-used OPAs, such as the Berman and Gudel OPA, which have a spectrum of sizes to ensure fit. In this project, a Computer Assisted Design (CAD) simulation platform was developed to simulate the scenario where OPA is placed in a patient's oral cavity. CAD – related technique and tools, such as 3D scanner (ScanStudio HD), RapidWorks, SolidWorks and Mimics were utilized to create the models used to construct the platform. The purpose of this platform is to generate data to support the development of additional sizes and other modification to improve the current design of the Bardo OPA. MRI sets of nine (9) patients were obtained and converted into STL mesh models. Berman and Guedel OPA were used as the standard for comparison against the Bardo OPA. It was found that the Bardo OPA was able to fit into all sample patients' models, while these models were fitted with Berman and Guedel OPA of 70-90mm (Small to medium adult) sizes. It can only be concluded that the Bardo is compatible with these OPA sizes and there was not enough evidence to show the need for additional sizes. Nevertheless, some functional features of the Bardo OPA were found potentially harmful to the patients or ineffective. Three approaches were suggested to improve the design of the Bardo to achieve better safety and efficacy.

Keywords: Oropharyngeal Airway, Oral Airway, Emergency Clenching, Bardo Airway, CAD Simulation Platform, Design Assessment/Evaluation, 3D Scanning, Materialise Mimics, SolidWorks, Design modification.

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CHAPTER ONE: INTRODUCTION

Section 1.1 – Clinical Problem

Oropharyngeal airway, commonly known as oral airway or OPA, is used to prevent airway obstruction in an unconscious patient, as the tongue relaxes, rolls back and blocks the oropharynx, which connects the lower respiratory tract. The oral airway holds the base of the tongue preventing it from obstructing the passage. The device can also be used to facilitate suctioning in an unconscious patient¹. Use of oral airway is a basic skill which EMTs, nurses and physicians in the United States are trained to use oral airway as for establishing and maintaining the breathing air flow². However, it is recommended to be used only on unconscious patients as gag-reflex would cause a conscious patient to vomit and further obstruct the airway³.

Typical OPA, like the Guedel airway shown below in figure 1, is generally made of hard plastic, and has a semicircular design that conforms to the curvature of the palate. Each oropharyngeal airway has three parts: the flange, the body, and the tip. When properly inserted, the flange rests against the lips, preventing the device from sinking into the pharynx. The body follows the contour of the roof of the mouth, and will curve over and rest on top of the tongue. The distal end, or the tip, sits at the base of the tongue. An oral airway will hold the tongue away from the posterior pharynx so air can pass through and around the device¹.

Figure 1. Illustration of the commonly-used oropharyngeal airway (top) and how oral airway is placed inside a patient's oral cavity (bottom)¹.

Oral airways are often used in an “off-label” fashion by physicians as bite-block, even though it is recommended to use an actual bite-block to keep the patient's mouth open⁴. During a procedure, patient who is under general anesthesia is kept unconscious. Endotracheal tube is inserted in the patient's respiratory tract to facilitate air flow. Oral airway is used alongside with endotracheal tube as bite-block to keep incisor from biting on the tube and damaging it. A portion of airway body at the proximal end is in contact with the incisors, keeping the mouth from closing. However, when the patient regains

conscious after the surgery, anesthesiologists would sometimes remove the airway piece while the patient is biting on it. About 0.01% of the patients who received total anesthesia experience dental injuries known as “Emergence Clenching Dental Trauma”. The problem is defined as “Placement of an airway device transfers jaw clenching forces forward to two or more incisors”⁴. This is reportedly the most common cause of malpractice claims against anesthesia providers⁵.

Although most OPA designs make use of rubber or plastic in order to reduce the risk of damaging the patient’s teeth, dental damage still occurs. It is because most designs rely on the straight section between the flange and the curved tube airway to function as bite-block which receives the patients’s jaw clenching force against the incisor. It is shown that the vertical biting force by the patient is enough to fracture incisors⁶. Since the contact surface on incisor is very small, even though human teeth are about to withstand axial pressure, it is likely that the clenching force act on the surface can fracture the incisor.

Perioperative dental damage is the most common of all medico-legal complaints related to anesthesia, according to various studies, incidence of dental injury from anesthesia cases ranges from 0.02 – 1%⁷⁻⁹, with Chen et al.¹⁰ reporting 12%. The next most common complication was cardiac arrest⁹. They found that in elective intubations, the teeth most likely to be injured were the upper incisors in patients aged 50 to 70 years^{8,9}.

Removal of airways, endotracheal tubes, and Laryngeal Mask Airways (LMA's) when the teeth are clenched during emergence can lead to partial dislocation. Several reports indicated that placement removal of oropharyngeal airway is one of the causes for dental damage¹¹⁻¹³, with Gaudio et al. reporting 0.85% of the dental injury cases are invoked specifically by using the Guedel oral airway¹⁴. The types of dental damage varies: enamel fracture and loosening/subluxation of a tooth were found to represent 55.2% of all injuries, followed by tooth avulsion (9.0%) and crown fracture (7.7%)⁹.

Dental injury comprises 33% of all medico-legal anesthetic claims^{15, 16}. In terms of monetary loss, dental injuries are also the most common insurance claims against general anesthetic. It accounts for up to 25% of available records of closed insurance claims^{17, 18}. Typical treatment of dental injuries included provisional crown on implant to osteointegrated implant, with cost ranging from 80 – 1250 Euros (105 – 1635 USD)¹⁴. Apart from monetary loss, emergency clenching on the oral airway can raise patient safety issue, as loss of access to the obstructed airway during emergence clenching can be life-threatening⁴.

Section 1.2 – Related Anatomy

Oral cavity and pharynx play important roles in both digestive and respiratory systems (Fig. 2). Oral cavity is the space bounded anteriorly by lips, laterally by cheeks, superiorly by hard palate and inferiorly by the superior surface of the tongue and muscles connected to the inner side of the mandible. The cavity houses several structures, including the upper and lower dentition, the tongue, salivary glands, and the mucosal tissue covering the hard palate. The oral cavity extends posteriorly to the pharyngeal cavity¹⁹.

The boundaries of the pharynx are the mouth and the nasal choanae anteriorly, the soft palate and portions of the skull base superiorly, the base of epiglottis inferiorly, and the pharyngeal constrictors posteriorly. Pharynx can be divided into three compartments, the nasalpharynx, the oropharynx and the laryngopharynx²⁰. Nasalpharynx extends from the base of the skull to the upper surface of the soft palate. This compartment of the pharynx joins the nasal cavity²¹. Oropharynx extends from the nasal pharynx and joins the oral cavity. The posterior of the tongue forms the anterior border of the oropharynx. The middle as well as part of the inferior pharyngeal constrictor muscles forms the lateral and posterior walls. The greater wings of the hyoid bone are included in the lateral pharyngeal wall²⁰. Because both food and air pass through the pharynx, a flap of connective tissue called the epiglottis closes over the glottis when food is swallowed to prevent aspiration²². Laryngopharynx lies inferior to the epiglottis and extends to the location where this compartment diverges into the larynx and esophagus. At that point, the laryngopharynx is continuous with the esophagus posteriorly²².

Figure 2. Sagittaral sectional view of oral cavity and pharynx.²³

The oral cavity also houses the teeth, which are greatly affected by the application of oral airway (Fig. 3). For the scope of the context of this project, only the dentition that related to the use of oral airways will be mentioned. The incisors are named from their presenting a sharp cutting edge, adapted for biting the food. They are eight in number,

and form the four front teeth in each dental arch. The crown is directed vertically, and is chisel-shaped, being beveled at the expense of its lingual surface, so as to present a sharp horizontal cutting edge. The upper (maxillary) incisors are larger and stronger than the lower, and are directed obliquely downward and forward. The central ones are larger than the lateral, and their roots are more rounded. The lower (mandibular) incisors are smaller than the upper: the central ones are smaller than the lateral, and are the smallest of all the incisors. They are placed vertically and are somewhat beveled in front, where they have been worn down by contact with the overlapping edge of the upper teeth²³.

The molars are the largest of the permanent set, and their broad crowns are adapted for grinding and pounding the food. They are twelve in number; six in each arch, three being placed posterior to each of the second premolars. The crown of each is nearly cubical in form, convex on its buccal and lingual surfaces, flattened on its surfaces of contact; it is surmounted by four or five tubercles, or cusps, separated from each other by a crucial depression; hence the molars are sometimes termed multicuspid. The upper (maxillary) molars are smaller than the lower molars. As a rule the first is the largest, and the third the smallest of the upper molars. The crown of the first has usually four tubercles; that of the second, three or four; that of the third, three. The lower (mandibular) molars are larger than the upper. On the crown of the first there are usually five tubercles; on those of the second and third, four or five²³. In most patients, healthy molars can tolerate vertical forces of 100-200 lb. On the other hand, anterior teeth tolerate vertical forces of only 25-35 lb. and horizontal forces of less than 25 lb. Diseased or restored teeth are particularly vulnerable to injury⁴.

**Figure 3. The anatomical illustrations of maxilla (left) and the mandible (right).
Notice the shape and size of the incisors and molars.²³**

Section 1.3 – History of oral airway

The first OPA (Fig. 4) was developed by Sir Frederic W. Hewitt in 1908. Hewitt's airway consisted of a 'circular metal ring, with an internal diameter of half an inch, and a deep groove in its outer circumference to allow of the ring being held firmly by the teeth. A short metal collar protrudes into the mouth and carries a rubber tube with an internal diameter of half an inch and a maximum length of three and a quarter inches. The end of the rubber was cut obliquely and, when inserted, the opening should have faced the laryngeal inlet²⁴.

Figure 4. Illustration of the Hewitt pattern oral airway²⁴

The first modern oropharyngeal airway (Fig. 5a) was developed by Dr. Arthur E. Guedel, who was a professor of anesthesia at the University of Southern California, in 1933²⁵. This airway was the first that made out of rubber with metal insert in the tube section. The design included a flange and a tube-shape structure. The flange, located at the oral end, prevented over-insertion and kept the airway from slipping further. The straight section of the tube functioned as bite-block. The metal insert provided structural strength to withstand biting, while the rubber shell allowed less dental damage. The curved

section of the tube conforms to the contours of the oropharynx, while a central channel allows exchange of respiratory and anesthetic gases²⁵.

Furthermore, since its advent in 1933, the Guedel airway has evolved into many variations to accommodate different needs. Berman airway (Fig. 5b) is another kind of oral airway popular among emergency caregivers. It was developed by Dr. Robert A. Berman in 1949. Dr. Berman found that the central channel of the Guedel airway could potentially be occluded by mucous or other substance and was not visible to physicians. To tackle this safety issue, an open-channel design was implemented on oral airway. The channels were opened so occluding matter could be cleared off easily. Moreover, the airway has a dual, open channel design which allowed simultaneous use of anesthetic gases and suction. Also the Berman airway was one of the first airways that used plastic as the main material²⁶.

Ovassapian oral airway (Fig. 5c), on the other hand, was developed as a tool to aid insertion of tubular medical device, such as fiber-optic and endotracheal tube. This airway uses a wider, flat surface instead of curved tube to compress patient's tongue. Such design opens the mid-line space of the oral cavity and allows better handling and maneuverability of inserting device like endotracheal tube or fiber optic. There are pairs of guide-wall on the straight portion functions as guide and protection for the inserted fiber-optic. The flange portion is also modified to become teeth-block while preventing over-insertion²⁷.

Figure 5. (a) The Guedel airway, (b) the Berman airway, (c) the Ovasappian airway.

Section 1.4 – OPA-Bite Block assembly

Another device evolved from the Guedel oral airway is the OPA-bite lock assembly (Fig. 6). Its inventor, Paul H. Blachly, was ambitious about the apparatus as it was designed to tackle problems of three different airway management devices. The conventional use of ventilation mask or oral airway may not fit well on patient and cause leakage.

Endotracheal tube intubation although is a more reliable way facilitating ventilation, it has the disadvantage of causing residual hoariness and irritation to patient pharynx and vocal cord. Also, patient in convulsion can bite down the tube and occlude the air passage²⁸.

The oropharyngeal airway assembly has a posterior portion having the same design as conventional oropharyngeal tubes, but a modified anterior portion to accommodate the standard connection to a ventilator bag. A U-shaped bite block is fitted about the exterior of the airway. When the assembly is placed properly in the patient's mouth, a closed airway is provided by virtue of the oral seal between lips and bite block without the need for endotracheal intubation or face masks. A tight oral seal is provided by the airway and bite block assembly of the invention, and closed pulmonary ventilation of the patient is assured without the danger of atmospheric leakage or occlusion of the airway tube. The bite block also protects the tube from occlusion. This allows the use of a softer material for the airway tube to increase patient comfort and reduce the necessity for stiffness of the airway tube to resist compression from tooth or gum pressure²⁸.

Figure 6. The illustration of the OPA-bite block assembly²⁸

Section 1.5 – The Bardo Airway

Although the OPA-bite block assembly has the potential to reduce the incidence of dental injury during the use of oral airway, Blanchy did not pay attention to this problem, as the device was designed only to provide better air seal and reduce irritation caused by the airway. Also this device completely eliminates the option of using other airway management devices. It is until recently a novel hybrid oral airway is developed to specifically address the pitfall of dental injury during anesthesia. Dr. Theodore Burdumy, an anesthesiologist located in Santa Maria, California, invented the Bardo Airway, shown in Fig. 7 with its major features, as a potential solution for which addresses the problem previously mentioned. Like the OPA assembly, Bardo airway is a hybrid which combines an oral airway portion and a bite-block. The tongue elevator prevents the patient's tongue from blocking the upper airway. The elevator adapts the design of the Ovassapian airway. This way the Bardo airway preserves more available space inside the oral cavity. That translates into more options for using another device and better maneuverability while inserting. The side block portion is designed so the clenching force is now transferred to the molars instead of the incisor. Such design allows the force to be applied on a much larger contact area and thus reduce the axial pressure acting on the teeth. A handle knob extends from the bite block to enable better control during insertion and prevent injury due to a semi-conscious patient's biting^{4, 5, 29}. The airway is currently available in one size, with the tongue elevator measured 70mm long. It is comparable to a size 4 Guedel or Berman airway. However, since the Bardo airway does not have a flange structure like the other airway, it can be placed inward or outward to the pharynx to cover more

patients' anatomical differences, or in other words, it replaces more conventional oral airway sizes²⁹.

Apart from having a different design than the traditional oral airway, Bardo airway also makes use of a new kind of build material: DuPont special control grade Hytrel polymer. Hytrel has a few advantageous properties. First, Hytrel is softer, with hardness (Shore D test) of 44 units^{30, 31}, while High Density Polyethylene (HDPE), the material typical used for manufacturing oral airways, has hardness of about 68 units³². Softer material means the more clenching force is absorbed by the material and thus less pressure applied directly on the teeth. Also the Hytrel is non-halogenated, which is safer to patients⁴. Halogen, such as chlorine, can be toxic to human body once the material is degraded^{33,34}. In terms of regulatory aspect of the device, Hytrel is FDA-compliance³¹ and the Bardo airway received 510(k) clearance in 2011. It is classified as Class I device, belonging to Oropharyngeal Airway section³⁵.

Figure 7. The Bardo airway and its major features⁴

Section 1.6 – Device Limitation

The Bardo airway was recently developed and currently lacks academic support. There are no studies reviewing the airway design or suggesting modification. This thesis project aims to develop an evaluation platform for the Bardo airway. As mentioned above, currently Bardo airway is available in only a 70mm size. Comparatively, conventional oral airways, such as the Guedel or Berman pattern adapt a size system to accommodate different oral cavity anatomical dimension in patients. For instance, several different sizes are available for the Guedel airway to accommodate three levels of adult patient sizes: size 3-4 (60-70mm) for small adult; size 4-5 (70-90mm) for medium; and size 5-7 (90-110mm) for large adult¹.

Although this size is able to be used for larger patients' variability, it cannot be fitted properly in all patients. Therefore, it is important to implement a size system for Bardo airway to ensure better fit on a wide range of patient population. As the airway is completely different than the traditional oral airway, it is not appropriate to follow the sizing scale of the traditional airways mentioned above. Instead, a new sizing scale is needed for the Bardo airway and that requires a different approach, rather than extending the tongue elevator, to achieve the goal.

Section 1.7 -- Project Rationale

CAD modeling is an ideal technique to facilitate the evaluation because it provides higher degrees of freedom. Evaluation of a device requires extensive work of trial-and-error. By using computerized model, the Bardo airway can be modified freely using software such as SolidWorks during the trial, without the hassle of modifying numbers of physical model and avoid the waste of material. Materialize Mimics and SolidWorks are used for creating human anatomical models and oral airway solid models. In the evaluation process, the airway models are compared in terms of device-anatomical parameter (e.g. the fitness of the tongue elevator to the contour of the tongue). Using the result, one can assess how well the 70mm Bardo airway can cover for the conventional airway and using that as a reference, a sizing scale can be determined.

Finally, any improvements that are deemed necessary should be made to the Bardo airway. Many oral airway variations and patterns are based on the Guedel airway²⁶⁻²⁸. Some, like the Ovassapian airway, were designed to give better use in combination with other devices such as fiber optic. The others, like the Berman airway, were developed to enhance patient safety. Therefore, the improvement proposed here will follow the rationale of these examples with one important and ultimate purpose: To ensure better safety and efficacy.

Section 1.8 – Project Objectives and Deliverables

Oral airways are often overlooked yet it is a reliable and essential tool to emergency medical personnel. As the first academic work that provides evaluation of the design for oral airway, it is desired that this project will establish a computerized platform that allows accurate evaluation of oral airways. Using Bardo airway as an example, this project demonstrates what information this evaluation system is able to provide to researchers, and encourage investigation and studies on this valuable device. The deliverables of this project are:

1. Establish an evaluation platform for Bardo airway using CAD techniques, which consist of:
 - a. Models of OPAs and anatomical head that were used as the hardware of the platform, and
 - b. Protocols, or the software, which utilize the models to evaluate the target OPA effectively
2. Assess the performance of Bardo Airway in terms of fit and functionality
3. Propose modification that improve safety and efficacy of Bardo Airway

CHAPTER TWO: OROPHARYNGEAL AIRWAY MODELING

Computer Assisted Design (CAD) modeling plays an important role in this project.

Traditional design evaluation involves “Trial-and-Error” methods to attain desirable result. “Trial-and-Error” is an experimental method with where a correct solution or result can be found by recognizing errors from multiple trials and eliminating such errors from each trial. In device evaluation, such process could mean fabrication of multiple test models and prototypes, which could lead to excessive waste of time and material. CAD, on the other hand, eliminates the hassle of creating multiple physical models and reduces the time and material used for the evaluation process, as it provides a virtual environment that one can freely modify or combine the models, as well as the evaluation parameters. Another reason for CAD being more advantageous is that as OPA is used only on unconscious patients, it would be not feasible if the evaluation takes place in real human subjects. As the OPAs are placed in oral cavity, taking measurement would be difficult in real-life because it might hurt the subjects and be difficult as measuring tools cannot be put inside the cavity. Therefore, CAD platform is necessary to facilitate an accurate evaluation.

For this project, the CAD platform consists of two parts: the solid-models for OPAs and the anatomical models for oral cavity and throat of the subjects. In this chapter, modeling of OPA is discussed. It involves converting the physical object into CAD model. The entire process includes three major operations: Scanning, Repairing and Modifying Mesh,

as well as Rebuilding CAD models. ScanStudio HD (ScanStudio), RapidWorks (RW) and SolidWorks (SW) were used for these operations. Each operation consists of several key steps which will be discussed in following sections. (Name of functions and operations are indicated as bold and capitalized word, e.g. **Align**)

Section 2.1 – Three-Dimensional (3D) Scanning

2.1.1 – Preparation

Preparation for the objects being scanned is needed if it is reflective, or glossy. Since the 3D scanner makes use of laser to map the object surface, reflective surfaces might cause distortion of the reflected laser and reduce the accuracy of the scan. White matte paint or powder can be used to coat the objects to create dull surface. Moreover, there should be sufficient amount of bright-colored, non-glossy spots or shapes painted on the object.

Those markers are essential for aligning meshes because they are used as reference points. They should be drawn on the object surface and around the edges to ensure there are at least three such features visible when the object is viewed at any angles. It is ideal to have shapes which have well-defined features such as apexes or line intersections to allow best accuracy for alignment.

2.1.2 – Scanning

NextEngine's ScanStudio HD suite was used to scan the OPAs. The scanner consists of laser emitters and optical cameras, indicated by red arrows in Fig. 8. They were mounted

on a swivel base. The object, mounted by the clamp on a rotating base, as indicated by the blue arrow in Fig. 8, was scanned in multiple iterations for scan-parts. Each scan-part was captured by rotating the object to a certain angle, with the swivel housing rotating to allow laser emitter to shoot laser on the a section of the object surface and reflecting back to the laser camera, indicated by the green arrows, as well as to allow optical camera capturing optical images. The A scan-part was formed by processing the scanned data into a STL (STereo Lithography) format polygon mesh and attaching the object's texture information, created using the optical image. Several scanning parameters are needed to be adjusted to ensure proper scanning of the OPAs.

Figure 8. The NextEngine's 3D Scanner. (left) The 3D scanner housing laser and optical camera. (right) The rotating base and object holder³⁶.

2.1.3 – Scanner Settings

Positioning controls the rotation of the object when being scanned. Typically an object is rotated once during the scanning process and multiple scan-parts were captured.

However, if only one scan-part appeared to be defective, the object can be re-scanned partially to obtain a better scan-part for replacement.

Divisions defines the number of images the scanner captures during the scan. As mentioned an object is rotated when it is scanned and multiple scan-parts are captured. Division setting controls how the rotation is being divided, that is, how many scans are needed to be captured to complete a 360° or a partial scanning cycle.

Points/Inch² defines the density of the laser beam points placed on the object during the scan, thus this parameter controls the quality of the scan. A higher value means more points are placed on an area and the scan resolution is better. Higher setting also used more computer memory. Standard (SD) quality is used so the memory allocated can be kept the lowest while reserving a normal scan quality.

Target defines how the scanner adapted to the surface color of an object, as different colors have different absorption levels to the laser.

Range defines the field of view of the laser and optical cameras. Depending of the size of the scanned object, it will be placed at different distance from the camera. The camera can, however, only focus on the scanned object at a certain range. For example, a huge object would be placed at a larger distance from the scanner in order to have it entirely

scanned. A normal field of view will not be ideal as it result in blurred image. A far range setting is needed.

2.1.4 -- Alignment

After the scanning operation, the scan-parts need to be aligned in the correct order to forming the shape of the original object. **Align** is used to combine the scan-parts to form a rough mesh of the scanned object. As shown in Fig. 9, this operation involves two scan-parts in the scan-set. Those two scan-parts were aligned by matching the same points on the scan-parts, indicated by the green and blue arrows in Fig. 9, which can be identified from the markers painted during the preparation. The rest of the scan-parts are then aligned by the software automatically.

Figure 9. Align Operation. This image shows two scan meshes were selected for alignment. Arrows show where the pins were placed, with different colors indicating same points on different meshes. Note that the pins were all placed at well-defined points such as the middle-bottom corner of the “5”

2.1.5 – Fuse

The **Fuse** function merged the aligned scan-parts into a single 3D surface mesh. Figure 10 shows a mesh generated by the function. The operation eliminated overlapping portion of the scan-parts. It also automatically filled out some minor holes on the mesh surface. This function is essential for later use of RapidWorks because even the scan-parts are aligned and touching each other, the software recognized the overlapping portion as imperfection, which could cause complication in exporting the mesh in other formats.

Figure 10. OPA scan mesh after using the Fuse function. There were defects on the mesh such as the holes on the flange. RapidWorks was needed to repair those imperfections.

2.1.6 – Export

At this point, the 3D surface mesh can be exported as commonly-used CAD formats such as STEP or IGES, or exported as a 3D scan file, recognizable by RapidWorks.

Section 2.2 – Repairing and Modifying the Mesh

Most of the time the 3D mesh generated by ScanStudio has imperfections on the surface, such as extra bumps or holes. The imperfections raised difficulties and inaccuracy in further modeling if not removed. Moreover, the mesh created in ScanStudio usually contains around 200,000 polygons, which consumed significant amount of RAM (Random-Access Memory, which stores temporary computer data to be utilized in a short period of time). In fact, SolidWorks only allow a STL mesh of 20,000 or less polygons to be imported directly as 3D solid model. Otherwise, it can be imported as surface mesh (>30,000 polygons) or graphical object. Therefore, repairing and re-formatting for the mesh were needed. These tasks were achieved by using RapidWorks, which had useful functions to repair the mesh with great degrees-of-freedom and to alter the properties of the mesh for simpler modeling in SolidWorks.

2.2.1 – Repair

Repairing a mesh involved filling holes and eliminating extra surface features on it. After the mesh was imported, the first step performed in RW was **Healing Wizard**, with which the software automatically cleared the mesh with the minor yet abundant imperfections, such as overlapping and crossing polygons. Those small defects, shown in Fig. 11 as tiny highlighted spots on the OPA mesh, could cause unnecessary errors since usually they were hard detect, while they would bring error when the mesh is further modified.

Figure 11. Healing Wizard. Notice that there are many dots of different colors showing the tiny defects.

Next, the larger holes on the mesh were repaired using the **Fill Holes** function. This operation generated a network of polygonal bridges across a large gap, and separating the gap into smaller holes. This way the hole can be repaired with better accuracy. The entire process is shown in Fig. 12. 12a show a typical kind of hole cannot be repair simply by filing the hole. 12b shows the bridge network attached on the hole. 12c shows the result of this method of hole filling. If a hole is repaired without bridging, RW could create extra features on the surface, such as a bulged-up surface shown in Figure 13. Also, the

bridge could be used to guide the hole filling on a three-dimensional hole, for example, the open channel at Berman airway, as the inner channel surface cannot be captured with the 3D scanner.

Figure 12. Fill Holes function.
(a) shows a huge hole on an OPA scan mesh before repair.
(b) shows how the bridge network was placed on the hole.
(c) show the result of the repair operation.

Figure 13. Hole repaired without patching with bridge network.

2.2.2 – Smooth

After **Fill Holes**, **Smooth** was used to reduce the roughness on the mesh surface. This function not only was used for improving aesthetic appearance of the mesh, but also it played an important role in exporting the mesh to SolidWorks. It is because excessive feature would be recognized by the software and would cause significant complication when replacing the polygon with STEP surfaces, which is discussed in **Solidify** section. Then, **Global Remesh** should be performed to regularize the polygons in the mesh, as well as fixing imperfection not visible nor repaired in the previous steps. Regularizing the polygons meant re-sizing the polygons on the mesh to become same size. The benefit of this was that at later operations, **Segment** and **Solidify**, the result was dependent on the distribution of the polygons and a mesh with regular-sized polygonal elements could reduce the chance of having undesirable result.

2.2.3 – Segment

With **Segment** operation, RW recognized and assigned features (planes, revolution, freeform) onto the mesh surface and those features are called segments. The purpose of generating segments was to facilitate automatic solid-model building, as well as provide reference geometry for the following step, **Datum**. For this project, after the segments were recognized, the segments on the flat surface of the OPA flange and the straight “bite-block” section should be joined (**Append**) together for further used in **Datum**. Result of the **Append** function is showed in Figure 14a and 14b, with the back arrows pointing to the segments being joined.

Figure 14. Segments on an OPA mesh.

(a) and (b) show the mesh sections before and after two sections were merged as one.

The black arrow shows the position of the sections.

(c) shows the front view of an OPA mesh. The red arrow indicates a flat section created on the bite-block portion, which would be later used to extract an orientation plane.

2.2.4 – Datum

Datum created new geometric features which were utilized to establish a new coordinate system for the mesh. A datum was a feature on an object used to create a reference system for measurement³⁷. Those new features were points, lines or planes and were created from using the segments generated from the previous step. A system of three planes representing the true, or new, XYZ planes of the object was needed. Fig. 14c and 15 shows the planes extracted from several segments and were used for creating a new coordination system.

Another function, **Interactive Alignment Wizard**, then assigned those reference planes for the new coordinate system. Fig. 16 shows the user interface of the **Interactive Alignment Wizard**, where the planes shown in Fig. 14c and 15 were assigned as XYZ planes. Fig. 17 shows the difference between an old coordination system (17a), inherited from ScanStudio and a new coordination system (17b)

Figure 15. Plane extracted for altering orientation system in Datum phase.
(a) shows the hand-drawn plane (black arrow) that approximated the symmetric plane of the mesh.
(b) shows the computer-generated symmetry plane (red arrow) created by referencing the plane in (a). There was slight difference in the plane angle.
(c) shows a base plane (green arrow) was extracted from the base of the OPA flange.

Figure 16. The Interactive Alignment Wizard user interface. The plane shown previously were used to create a new coordinate system

Figure 17. Coordination system before and after the re-alignment.
(a) shows the coordinate planes before re-aligning using Datum.
(b) shows the coordinate plane after re-aligning using Datum. The new system provided convenience for further use of the mesh.

2.2.7 – Solidify

The next step, **Solidify** replaced the STL mesh with the STEP (Standard for the Exchange of Product model data) -format mesh. Figure 18 shows the transformed of a STL mesh to a STEP mesh. STEP is an ISO standard for data-exchange of manufacturing information of 3D models. It had a relatively smaller number of “surfaces” elements to replace the STL polygons, which was in thousands of number. Smaller number of mesh elements resulted in reduced amount of computer memory allocated, hence reducing the processing time. In RapidWorks, STL meshes were processed in short time, yet in SolidWorks, which was not primarily built for handling STL meshes, used much more time to process simple command such as rotating the models. In this project, approximately 350 patches were inserted to maximize model detail while utilizing minimal memory. This value is determined by trial-and-error and it was found that having more than three-hundred and fifty patches could cause SolidWorks to slow down during object rendering.

Figure 18. Meshes throughout different stage of operations in RapidWorks.

(a) shows the original STL mesh of an OPA.

(b) shows the STL mesh assigned with segments.

(c) shows STEP mesh generated by replacing “surfaces” on the STL polygons.

Section 2.3 – Solid Modeling in SolidWorks

SolidWorks provided accuracy and flexibility in solid-modeling. It allowed detailed dimension adjustment of the model, while permitting the use of different model formats on the SW interface. The STEP models imported from RW were not ideal to be used directly for the CAD evaluation platform because the meshes did not give accurate dimensions of the OPAs. Also, some of the features, such as the lumen of Guedel OPA or the opened channel of Berman OPA, cannot be scanned and repaired with RW. Therefore the model obtained from RW can only be used as a guide on which SW is used to rebuild an accurate model. The basics of solid-modeling include **Sketch**, **Extrude** (Base Extrude and Extrude Cut) and detail polish (e.g. **Fillet**). A “bottom-up approach” was used for modeling OPAs. That means the models were generated by creating parts of the airway body (flange and tube) and merging them together.

2.3.1 – Sketch

Sketch was a function in which 2D sketches of an object were drawn using different geometry drawing tools. The imported STEP mesh was used to guide the sketching. The sketches were drawn to outline the mesh. Fig. 19 shows the process of 2D sketches being drawn on an imported STEP mesh. Although the mesh provided guidance for sketching, there were defects on it. When this situation was encountered, sketch symmetry was looked at to overcome the difficulty. For instance, the more accurate half of an OPA flange would be replicated to the other side. Also, manual measurement of dimension of

some features on the OPA, such as the lumen width could be done in case the features of the mesh seemed way off.

Figure 19. Creation of SolidWorks sketch on an imported STEP mesh.

(a) shows the STEP mesh imported from RapidWorks.

(b) shows sketches drawn to outline key feature of the mesh.

(c) shows the final make-up of the sketches.

2.3.2 – Extrude

The sketch could be then extruded (in other words, pulled) from the drawing and become a 3D object, using **Extrude**. Depending the shape of the target solid-model, different type of **Extrude** operation could be performed, such as **Base Extrude** or **Sweep Extrude**.

Then **Extrude Cut** could also be used to trim off unnecessary part to create features, such as lumen or opening.

Figure 20. OPA model as a set of Extrude created from sketches.
(a) shows sketches created from outlying a mesh.
(b) shows the extrusion created from the sketches and the filleted corner features (black arrow)

2.3.3 – Fillet

Finally when the model was completed, its edges were polished by using **Fillet**. This function was used to create fillet at the corners or edges on the flange and the distal end tip, as indicated by black arrows in Fig. 20b. In term of SW, a fillet is defined as a round exterior or interior corner of a part design. In some mechanical design literature^{38,39}, however, this kind of corner is called “round” or “radius”, while a fillet means a concave interior corner of a part. Fillet is an especially important feature for medical product because sharp edge on a device could cause serious injury to the patient, so designs with round corners could reduce the risk of damaging the patients.

Section 2.4 – OPA Model Rebuilding Error Analysis

There were possibilities for errors which an OPA solid-model did not fully reproduce the dimensions of the OPA it represented. Such errors were caused by the imperfections on the STL and STEP meshes during the scanning and repairing process, and that the solid-models were built using those meshes as reference.

In order to investigate the effectiveness of the 3D scanning and solid modeling method for translating a physical object into CAD model, a study was performed to determine the difference in dimension between the real object and the CAD models of the OPAs. Three dimensions, a) width of tongue elevator; b) thickness of tongue elevator and c) the length of the OPA, as the minimum distance between the flange and the tip of the OPA, were measured for each of the OPA models as well as their corresponding physical objects. The dimensions of the physical objects were measured using a dial caliper, shown in Fig. 21. The dimensions of the solid-models were measured using the **Measure** function of SolidWorks.

Figure 21. Dial caliper used for measuring the OPAs dimensions.

Fig. 22 and 23 show the definitions of the dimensions of Berman and Guedel, respectively, in SW interface. The width (indicated by black arrows in Fig. 22 and 23) was measured as the distance between the two sides of the tongue elevator. The thickness (indicated by red arrows in Fig. 22 and 23) was measured as the distance between the outer and inner surface of the elevator. The length (indicated by green arrows in Fig. 22 and 23) was measured as the shortest distance between the two outermost points of an OPA.

Figure 22. Measurement for model error analysis.

- (a) Shows the measurement for the OPA width (black arrow indicates the dimension).**
- (b) Shows the measurement for the OPA thickness (red arrow indicates the dimension).**
- (c) Shows the measurement for the OPA length. (green arrow indicates the dimension).**

Figure 23. Measurement for model error analysis of Guedel OPA CAD model.

- (a) shows the measurement for the OPA width
(Black arrow indicates the dimension).**
- (b) shows the measurement for the OPA thickness
(Red arrow indicates the dimension).**
- (c) shows the measurement for the OPA length
(Green arrow indicates the dimension).**

Three categories of comparison were performed for the error analysis. The “Physical – Theoretical Error” analysis indicated the deviation between the actual length of an OPA measured from the physical object and its designed, theoretical length. “Model – Theoretical Error” analysis state the difference between the dimension of an OPA CAD and the designed length of the device. The “Model – Physical Error” analysis stated the deviation between the dimensions of an OPA CAD model and the dimensions of its corresponding physical device.

The error values were shown as percent difference and were calculated with the following equations:

Physical – Theoretical Error:

$$\frac{(\text{Physical Dimension} - \text{Theoretical Dimension})}{\text{Theoretical Dimension}} \times 100\%$$

Model – Theoretical Error:

$$\frac{(\text{Model Dimension} - \text{Theoretical Dimension})}{\text{Theoretical Dimension}} \times 100\%$$

Model – Physical Error:

$$\frac{(\text{Model Dimension} - \text{Physical Dimension})}{\text{Physical Dimension}} \times 100\%$$

Section 2.5 – Result

2.5.1 – Oral Airway Modeling

Two sets of oral airway were scanned and re-built using the methods discussed above. The Berman OPA set consisted of six sizes: 40, 60, 80, 90, 100, and 110mm. The Guedel OPA set consisted of six sizes: 50, 60, 70, 80, 90, and 100mm. These CAD models set are shown in Figure 24 and 25 for Berman and Guedel OPA, respectively. Note that even the Guedel OPAs were manufactured by the same company (Smith Portex Oral Airways), the shape of those OPAs varied. The CAD model of the Bardo airway was provided by Dr. Burdumy. The model was modified to replicate the latest, or machined, version of the Bardo airway, with a shorter anterior portion of tongue elevator and connection between

the elevator and the bite block. Fig. 26 shows the modified version of the Bardo airway.

Fig. 27 shows the difference between the original and the machined Bardo airway.

Figure 24. Berman OPA CAD model set. The OPA sizes are (left to right) 40, 60, 80, 90, 100, and 110mm

Figure 25. Guedel OPA CAD model set. OPA sizes are (left to right) 50, 60, 70, 80, 90, and 100mm

Figure 26. Machined version of Bardo Airway.

Figure 27. Original and Machined version of Bardo OPA.

(a) shows the CAD model of the original Bardo airway.

(b) shows the CAD model of the machined version of the Bardo airway. The blue arrow indicates the change in newer version, as the distal end of tongue elevator is shorter.

2.5.2 – Error analysis

In “Physical – Theoretical Error”, the physical object of the oral airway was compared with their designed dimensions. Since no dimensions other than the designed length of the OPAs can be determined, the comparison only evaluated the length of the OPAs. This type of comparison was shown as bar chart in Fig. 28 and 29 for Berman and Guedel OPA, respectively. The length of the physical Berman OPAs deviated from the designed value varied from 1.41% to -3.45%, with average value of -0.91%. The 90mm size had the largest error (-3.45%) and 80mm had the smallest (-0.24%). In the Guedel OPA set, lengths of all the physical objects were shorter than the proposed value. The error ranged from -2.21% to -5.05%, with average of -3.44%. The 60mm size had the largest error (-5.05%) and 70mm size had the smallest (-2.21%). Fig. 28 and 29 show the bar charts for “Physical – Theoretical Error” for the Berman and Guedel airways, respectively.

Figure 28. Physical-to-Theoretical Error of the Berman OPA. It is the analysis created by comparing the length of the physical object and the designed length of the Berman OPAs.

Figure 29. Physical-to-Theoretical Error of the Guedel OPA. It is the analysis created by comparing the length of the physical object and the designed length of the Guedel OPAs.

For comparing the model and the theoretical size of OPA, all of the Berman CAD model lengths were smaller than its designed length. The range varies from -0.825% to -3.133%, with an average of -2.15%. The 90mm size has the largest error in the Berman OPA set (-3.133%) and 40mm size had the smallest error (-0.825%) in comparison to the designed length. Length of the Guedel OPA models, on the other hand, had less deviation from the theoretical length. The error of the set ranged from 0.08% to -2.97%, with an average of -0.60%. The largest error (-2.97%) belonged to the 50mm size and the 90mm size has the smallest error (0.08%). Fig. 30 and 31 show the bar charts for “Model – Theoretical Error” for the Berman and Guedel airways, respectively.

Figure 30. Model-to-Theoretical Error of the Berman OPA. It is the analysis created by comparing the length of the CAD model and the designed length of the Berman OPAs.

Figure 31. Model-to-Theoretical Error of the Guedel OPA. It is the analysis created by comparing the length of the CAD model and the designed length of the Guedel OPAs.

Errors between the CAD model and the physical model, which suggested how well the model rebuilding process could reproduce a physical OPA as a virtual model, were determined by comparing the width, thickness and the length of the OPAs. In the Berman set, error in width ranged from -0.71% to -6.98%. 80mm had the largest error (-6.98%) and 110mm had the smallest (-0.71%). Error in thickness ranged from -0.81% to 3.68%. 110mm had the largest error (3.68%) and 90mm had the smallest (0.53%). Error in OPA length ranged from 0.05% to -3.48%. 60mm had the largest error (-3.48%) and 110mm had the smallest (0.05%).

In Guedel OPA set, error in width ranged from -1.43% to 30.77%. 60mm had the largest error (30.77%) and 80mm had the smallest (-1.43%). Error in thickness ranged from 4.37% to 29.31%. 70mm had the largest error (29.31%) and 60mm had the smallest (4.37%). Error in OPA length ranged from 0.05% to 5.63%. 60mm had the largest error (5.63%) and 50mm had the smallest (0.05%). Fig. 32 and 33 show the bar charts for “Model – Physical Error” for the Berman and Guedel airways, respectively. Note that the green bars indicate the percentage error of the length. Lengths are shown as blue bars in previous figures.

Figure 32. Model-to-Physical Error of the Berman OPA. It is the analysis created by comparing the three aforementioned dimension of the CAD model and the physical objects of the Berman OPAs.

Figure 33. Model-to-Physical Error of the Guedel OPA. It is the analysis created by comparing the three aforementioned dimension of the CAD model and the physical objects of the Guedel OPAs.

Section 2.6 – Discussion and Conclusion

All of the CAD models are drafted with similar technique, by extruding a curved tube with constant diameter along the tube. This approach manifested a good rebuilding quality for Berman OPA because they have a similar simple design. However, in Guedel OPA, due to the plastic insert at the flange-end, the straight section is slightly wider than the rest of the tube. Also the shape of the end tip varies from one type of the others. The same approach may not be able to perfectly reproduce the feature. Note that while the physical Berman airways are of the same design, the Guedel OPAs have three different designs. Some OPA features are different from one type to another, as seen in Fig. 22. For example, when comparing to size 50mm and 70mm, the arc length of the tube of size 50mm was shorter, as well as the angle of the tip being different. Another example is that in Size 50 and 60, the tube is slightly thicker than the rest of the set.

The CAD model for the Bardo airway was the original CAD model for production and the dimensions were the same as the design specification. The model was modified to remove excessive portion on the tongue elevator so it opened more space for maneuvering the OPA. Such modification applied to the current version of Bardo airway on the market.

The three different error analysis methods showed the differences and relationship among the proposed design, the physical objects and the CAD models of the OPAs. “Physical – Theoretical Error (PT)” indicated how much the physical OPAs were different from the

design specification. The “Model – Theoretical Error (MT)” showed how much error presented in the CAD models comparing to the device design specification. The “Model – Physical Error (MP)” suggested the difference in the dimensions between the CAD models and the physical devices. The value of MP error should approximately equal to the value of MT subtracted by the value of PT, that is, $MP = MT - PT$. The MP error analysis was especially important because it provided information on the effectiveness of the scanning-modeling method described above.

For this study, each dimension was critical to the fitting of the OPAs. The length of OPA would affect the size of OPA inserted and how well it can fit into the patient. The thickness affects how much tongue is being compressed. The width affects the distance between the OPA and surrounding tissue, such as lips and cheek. The length however, played a more significant role because it determined which size of OPA was to be fit into a patient model. As one of the goals in this project was to show how many OPA sizes a Bardo airway was comparable to, the length should be given the most attention.

Fortunately, in most of the OPA models, length was the least deviated from that of the physical device. In Berman OPA model, error in length ranged from -3.48% to 0.33%, while the width and thickness had larger differences, with a range of -0.71% to -6.98% and -0.81% to 3.68%. On the other hand, In Guedel OPA model, error in length ranged from 0.05% to 5.63%. The Berman models had an average of -1.142% of error and for the Guedel, the average percentage error was 2.950%. A 3% error meant a difference in

scale of a few millimeters, which could slightly affect the result as the differences of the OPA sizes were 10 or 20 mm.

The CAD models for Guedel had larger deviations from the physical objects than the Berman OPA. An obvious difference between Guedel and Berman was that there were three different types of Guedel designs while Berman had only one. Nevertheless, there was no significant difference between the types in terms of the error, i.e. no particular type has more difference from the design length than the others. Therefore, errors might be due to other factors such as physical tolerance in manufacturing, bending when handling the OPA or influence from surrounding environment, such as humidity or temperature.

All in all, this modeling method leads to a minor inaccuracy, in Berman OPA, which has a simple design. On the other hand, the Guedel airway, having a slightly more complicated design and a simplified CAD modeling approach could lead to less accurate result.

CHAPTER THREE: ANATOMICAL MODELS

One of the goals of this project was to develop an evaluation platform for oral airway.

This platform consisted of anatomical model of human head which the model of the OPA in question was placed to and evaluated. To achieve better accuracy for such evaluation, the anatomical model was made with information of a real patient and Materialise Mimics, or simply Mimics, provided a tool to achieve this goal. Mimics allow user to import set of images containing information of the anatomical structure and to create models using these images. Diagnostic imaging data such as MRI and CT reveal human anatomy and internal structure in great details can be used in Mimics. The entire operation includes importing the image, thresholding, creating mask, generating the model and mesh processing.

Section 3.1 – Identifying the Body-Parts

The very first step for the modeling method was to identify body parts that would be included for the anatomical models. In this chapter, italic words, e.g. *Tongue*, represents the mask or the model-part of a body-part. The *Tongue*, *Air* and *Throat* parts were identified and created in the C-Spine (Cervical Spine) MRI scans of the patients. The *Face*, *Cheek*, *Maxilla*, *Upper Teeth*, *Lower Teeth*, *Mandible* and *Tongue* parts were identified and created in MRI scans of the patients' head.

Tongue, shown in the Fig. 34 below, highlighted in blue, was identified as the muscular tissue below the palate, above the jaw skin, anterior of the pharynx and posterior of the incisors. Note that since the patients close their mouth during the scanning, the tongue was pushed against the palate and has the same contour as the palate. The blue arrow in Fig. 34 showed the boundary between the tongue and palate.

Figure 34. The *Tongue* mask in Mimics interface. The portion of the MRI scans becoming the *Tongue* model was highlighted in blue

Throat was identified as the thin muscular tissue layer surrounding the air in throat. The muscular layer was so thin that it was difficult to capture it with **Threshold** with acceptable accuracy. Instead, the *Throat* mask was created by highlighting pixels surrounding the *Air*, shown as the yellow” lining in Fig. 35b. *Air* was identified as the large cavity portion posterior to the pharynx, as highlighted in green in Fig. 35c. Since air has no magnetic moment it did not generate any signals in MRI and thus it appeared as

zero grayscale, i.e. black color. The *Air* model was needed to better visualize the boundary of the throat in cross-sectional view.

Figure 35a-c. The *Throat* (b) and *Air* (c) mask. Original image (a) was included as reference

Cheek commonly was defined as the inner flesh lining both side of the oral cavity.

However, in MRI it was difficult to just model the lining and so the cheek was identified as the buccinator muscle, which located at the both sides of the oral cavity, as highlighted in yellow and brown in Fig. 36b. It was covered interiorly by the flesh lining which cannot be modeled, and therefore buccinator muscle sufficient to represent the cheek.

Figure 36. The *Cheek* mask and the buccinators. The buccinators muscles are highlighted in yellow and brown

The *Teeth*, including upper and lower portion, *Maxilla* and *Mandible* were all connected to each other due to low grayscale level of bony structure as shown in Fig. 37. They were then separated using model-editing technique described later. The boundary between the *Teeth* and the *Maxilla* and *Mandible* was where the exposed teeth roots reside. The boundary between *Upper* and *Lower Teeth* was defined as the groove in the middle of the teeth. *Maxilla* was defined as any bone structure above the upper teeth and ends at the bottom of the nasal cavity, (identified as sudden drop in contrast grayscale). Finally, *Mandible* was defined as the L-shaped bone structure at the sides as well as the base of the lower teeth, i.e. lower half of the bone/teeth complex without the lower teeth.

Figure 37. The *Teeth*, *Maxilla* and *Mandible*. These body-parts are being highlighted in a cross-sectional view MRI scan slice. Green area indicates the *Maxilla*, pick and cyan area indicate the *Upper* and *Lower Teeth*, respectively. The dark blue area is the *Mandible*

Face was identified as the skin layer from the back of *Mandible*, top of *Cheek* and bottom of the scan set. It was created by roughly highlighting the outer muscular layer of the patients, which can be seen in Fig 38 where such layers were highlighted in brown and pink. In Fig 39, the lips and chin were separated from the rest of the face and identified as *Face (Bottom)*, in brown. The rest was hence assigned as *Face (Top)*, in yellow color.

Figure 38. The *Face*. The mask representing the face is highlighted in brown and pink.

Figure 39. The *Upper* (yellow) and *Lower* (brown) *Face*

Section 3.2 – Materialise Mimics⁴⁰

With the body-parts identified, they would be modeled in Mimics. Although a great tool in creating models, it does not generate model automatically from scans and several key concepts and operations were needed to be recognized before the full power can be utilized. Starting this section, functions in Mimics will be written in Bold, for example, **Threshold**.

The very first important concept and operation was **Threshold**. **Threshold** captured a certain range of image contrast that represents a particular body part. This was made possible due to the fact that different body tissue absorb radiation differently (in X-ray/CT), or different tissue have different magnetic moment (in MRI). For example, in CT scans, bone tissue absorb majority of the radiation so the contrast appears to be white while muscle does not absorb much radiation so the receptor detects radiation and the muscle contrast appears to be black. In Mimics, image contrast was measured by the grayscale value, with black was lowest and white was highest in grayscale value. To determine the grayscale value of a particular body tissue/part, the first step was to draw a profile line on the target tissue. Generally, the lower limit of the threshold dictates the outline of the object and the upper limit dictate the filling of the object. In Fig. 38, both the lower and upper limit were set to black contrast regime and thus only the black contrast in the scan was outlined and filled, in red.

Figure 40. A MRI scan having the low grayscale (black) area highlighted using Threshold function

Threshold, however, does not allow user to target a certain area where the target part locates, as the operation capture the grayscale value for the entire image set. For body parts that only take up a part of the image volume, say the lower quadrant of the patient head, area select was ideal to reduce later efforts in editing the mask. The basic concept for area selected was to set up boundary for the desired volume. This can be done by deleting slices, with edit mask function, discussed in later sections, in the three view direction (Sagittal, Axial and Coronal). Once the six boundary-slices were deleted forming a “cube” encompassing the desired area, **Region Grow** can be used to create mask for that smaller, desired volume of target body part.

As mentioned above, after created the empty-slice boundary which is shown in Fig. 41 where straight black “cut lines” appeared on the mask. **Region Grow** was needed to isolate the target volume for creating a mask. The **Region Grow** operation duplicate a mask from the clicked point until it reaches disconnected pixels. An isolated volume of pixels, or voxels, like the one shown in Fig. 41 in blue, could be created.

Figure 41. A portion of a MRI scan being surrounding by empty slices and highlighted using the Region Grow function.

While the **Region Grow** could only select a volume in cube-like shape, most body parts were not cube-like. The **Edit Masks** operation was needed to add in or trim off pixels in order to produce a mask that represents the target body parts. Fig. 42 illustrates how **Edit Masks** functioned as an edit tool. The green arrow indicates an area of pixel erased from the original mask at the left, and the blue arrow indicates an arbitrary shape drawn on the empty space.

Figure 42. Demonstration of the Edit Masks function

Morphology Operation was used to alter the shape of a mask. Using the source mask as a reference, this function can perform several operations and generate a similar yet modified mask. There were two basic and two complex options for altering the mask. The basic functions were **Dilate** and **Erode**, which add or reduce layers of pixel to the original mask. **Open** and **Close** was combination of the above operations. **Dilate** was used, coupled with **Boolean Operation** (*see next section*), to create throat models. Another important concept in Mimics operation is **Pixel Connectivity**, which was an option when performing the **Morphology Operation**. **Pixel Connectivity** controlled the thickness of the pixel layers being added or removed in an operation. The 8-bit and 26-bit connectivity determined how pixels were created around each outermost pixel of a mask.

Fig. 43 and 44 shows how the pixels are added around a pixel in theory and in real-life operation, respectively.

Figure 43. Difference in pixel addition in 8-bit and 26-bit connectivity modes.

Figure 44. demonstration of pixel grow on a mask using 8-bit (blue) and 26-bit (green) connectivity.

Other than editing the mask one slice at a time, it could also be edited in the form of 3D model. The **Edit Mask in 3D** was one of the most used functions in this project. This function allowed alteration of voxels in the model-parts, as if the pixels were altered in slices using the Edit Masks function. Editing in 3D was a faster but also a coarser way to make changes. An example is shown at Fig. 45, where a portion of the Maxilla model-part was selected and deleted, shown in Fig. 45b and c, respectively. While this operation took approximately one minute to complete, it would take more than five minutes if done in Edit Masks, which deleted the pixels slice by slice. Moreover, the bone structure in the platform were create with extensive use of this function because all structures appears to be having the same grayscale value so edit in slices was impossible.

Figure 45. Demonstration of Edit Masks in 3D function.

After editing the masks, **Create 3D** was the final step in anatomical modeling. After the masks were prepared with desired features, the function can be used to create 3D models. Models can be created in different qualities. Quality indicates level of surface detail.

Higher the quality resulted in more detail on the model surface. Muscular tissue model-parts such as *Tongue*, *Cheek* and *Face*, were created in “Medium” quality. Models for the rest of the body tissues/parts were created in “Optimal” quality to achieve better surface details.

At the end, the model-parts created from the head MRI scans would be imported into the C-spine MRI set. Even though Mimics automatically re-assembled the imported model-parts, the alignment of those parts needed to be done manually. The parts were aligned by matching the contour of the *Tongue* to its surrounding boundary, such as the *Mandible*, *Lower and Upper Teeth*, as well as using the gap created from part splitting to make sure the imported parts were located at the right place.

Section 3.3 – The SLD and Scaled Set

There were two sets of model created, the San Luis Diagnostic (SLD) Set and the Scaled Set. The SLD Set was created directly using the methods discussed above. The MRI scans were provided by Dr. Fred Vernancchia of the San Luis Diagnostic Center. Ten sets of anonymous patients’ Head and C-Spine MRI scan were obtained. Only age and gender remained with the scan data. A summary of remaining patient’s information was included in Table A.

SLD Set Patient Data		
Patient #	Age	Gender
1	F	81
2	M	74
3	M	81
4	F	55
5	F	51
6	F	71
7	F	40
8	M	18
9	M	51
10	M	67
Average	-	58.9

Table A. Patient data of SLD Set. Only age and gender information were available.

Nine out of ten patients has voids at their molar, which from the shape of the voids the cause would be tooth prosthetic. Patient #8 has small-sized shadows covering the incisors. Scaled model set was created to investigate the OPA placement on patient models with large variation in physiological dimension. The SLD anatomical model set was created with the method discussed above. Analysis of patient head size was performed and it was determined that most of these patients have rather large head, when compared against the ANSUR II anthropometric database, the standard model used for this project. Therefore, a Scaled model set was created to investigate the result of the evaluation using a set of five models of different sizes. To eliminate other factors that might affect the result, the model set was derived from one sample model from the SLD Set. ANSUR II was also utilized as a reference for scaling the sample model. It was an anthropometric database established by the U.S. Army which contained statistical information on body dimension

of a group of male and female US Army pilots⁴¹. The purpose of the database was to establish anthropometric data of the soldier to guide design and sizing of protective gear, work-stations and computer-generated models. There were several similar databases like ANSUR II, such as NHANES, CAESARS and ISO Standard (ISO/TR 7250). ANSUR II was chosen because it was the only database which consists of detailed measurement of human head, which would be very useful for establish OPA evaluation platform.

The information on lip protrusion – back of head and trignon – back of head were used for analysis and scaling. These two dimensions were used because they were related to how OPA was estimated for fit when physician placed the OPA between the lip and the trignon. Table B shows the percentile data of the two dimension for the nine patients used for the evaluation. Note that all of the patients lie within 75 to 99+ percentile when compared against the ANSUR database. This supported the need of creating the additional Scaled Set in order to investigate the size difference.

	Lip (Percentile)	Trignon (Percentile)
1	80	98
3	99+	75
4	95	85
5	90	75
6	85	95
7	95	90
8	80	90
9	99+	99+
10	99+	85

Table B. Percentile data on the critical dimensions used to determine the patients' head size

Patient #8 was chosen as the source model for this Scaled Set. According to the Table B, Patient #8 belonged to 80 and 90 percentile group in terms of the Lip protrusion and Tragon dimension, respectively. So the head model of Patient #8 was assumed to be in the 85 percentile group. The Set #8 model was then scaled to 90, 70, 50, 30, 10 percentile of the population in ANSUR II. The distance between lips to back of head was used to determine the scaling factor. Calculation, using the following equation, was made to obtain the factor needed to enlarge the model to larger or shrink to smaller size. Table C shows a summary of the scaling factors used to scale model-parts to the new size.

$$\frac{\text{Scaled Length}}{\text{Original Length}} = \text{Scaling Factor}$$

Percentile	Lip Protrusion Length	Scaling factor
85 (Original #8)	20.57	1
10	18.79	0.913466
30	19.36	0.941176
50	19.75	0.960136
70	20.16	0.980068
90	20.78	1.010209

Table C. Scaling factor for the Scaled Set to alter the size of the model-parts in SolidWorks

To scale the model-parts, each part was exported as binary STL file and imported into SolidWorks. They were then scaled using the **Scale** tool to alter the size. The part was scaled at its centroid and with the factor determined previously. The model-parts were then imported back to Mimics and assembled as complete head model.

Section 3.4 – Result

Each of patient models consists of twenty-two parts and the parts were color-coded. Fig. 46 show the full assembly of model-parts and Fig. 47 illustrated the head model in cross-sectional view, which was made by splitting the model-parts in halves. Fig. 48 - 52 showed these model-parts individually or in group. Table D lists the information of each part and their corresponding figure. The mouth motion of the model, demonstrated in Fig. 53, was generated by rotating *lower face*, *mandible*, *lower teeth* and *top tongue* together along an axis. A defined point at the top, posterior side of the mandible was picked for each model where the rotational point was placed in saggital plane, and hence the point extend and become rotational axis in 3D space. Assumptions listed below were established for the model to identify and clarify potential source of confusion.

1. It was assumed that model-parts representing muscular and skin tissue were elastic.
2. It was assumed that overlapping soft tissue model-parts, being elastic, were compressed when being overlapped or protruding from one another.
3. The cut-off representation of model-parts, such as the Tongue and Face shown in Fig. 49 and 52, were separated for ease of rotating the model. In reality those body-parts were connected.

Figure 46. The fully assembled head model used for evaluation.

Figure 47. The cross-sectional view of the head model.

	Part Name	Color-Code	Figure #
1	Throat	Green	48
2	Air	White	48
3	Tongue (Top)	Pink	49
4	Tongue (Bottom)	Red	49
5	Maxilla	Cyan	50
6	Upper Teeth	Blue	50
7	Lower Teeth	Purple	50
8	Mandible	Dark Blue	50
9	Cheek	Orange	51
10	Face (Top)	Yellow	52
11	Face (Bottom)	Brown	52

Table D. Model-parts designation and corresponding figures

Figure 48. The *Throat* and *Air* model-parts.

Figure 49. The *Tongue (Top)* and *Tongue (Bottom)* model-parts.

Figure 50. The *Maxilla*, *Upper Teeth*, *Lower Teeth* and *Mandible* model-parts.

Figure 51. The *Cheek* model parts.

Figure 52. The *Face (Top)* and *Face (Bottom)* model parts

Figure 53a-c. Rotation of the mouth in head model. The head model with closed mouth. (b) A defined point was selected to place the rotational axis. (c) The result of mouth rotation.

Section 3.5 – Discussion

The models serve as an evaluation platform and it needs to be accurate in order to show the effects of the OPA placement and the limit of the Bardo OPA. However, this platform was first of its kind using Mimics and the project was limit by its scope and time; there were some issues which could influence its accuracy in replicating the anatomy of the patients. These issues can be categorized as the Background issue, the Technical issues and the Model-part issues.

3.5.1 – Sample Population Issue

The section was focused on the sample patient population used in this project. The main concern was that the sample lacked diversity. Most of the patients were at elderly age. Most have a common problem of having what was speculated to be tooth prosthesis and can be seen in the MRI scan as the voids of different size found at the locations of molars. All but one patient, Patient #8, have such problem. Patient #8 had also small voids at the incisors. The voids inevitably affected the OPA placement simulation but the were not as influential as the voids in molar, as the purpose of incisors was only used as a pivot point during the placement, while the voids in the molar could affect measurement results and lead to greater error as it was closer to the rotation axis. Moreover, the patients were expected to be coming from surrounding area of California central coast. While it was out of the scope of this project to discuss the patient demography in detail, the population homogeneity, that the population were mostly elderly and from an area with near 70% white population, which on average had larger build could affect the diversity of the

sample population used for this research, making the SLD set somewhat useless to determine the sizing limit of the Bardo OPA to general population.

3.5.2 – Technical Issue

The technical focused on the general and technical issues found in the two model sets. Issues related to the body-part models were discussed in the next section. One of the important issues raised in both model sets was that the quality of the models was low and lacking surface details. This was actually intended to allow better performance with the software, as the low quality models use significantly less amount of time to be generated and maneuvered in the Mimics interface. In this project, model parts for muscular tissue, such as *tongue*, *cheek* and *lower/upper face* were created in medium quality while the rest were created in optimal quality. The reason for lower quality for those parts was that muscular tissue did not appear with sharp contrast in the MRI scan. Most of the time the masks for those parts were drawn and edited manually, slice by slice, with minimal usage of **Threshold**. It was very common to have rough surface with extra pixels protruding from the surface of the model. Also, since muscular tissue were elastic in reality, their surface changes frequently. So the quality of the model surface was not as important as those which have rigid tissue, such as teeth.

All the patients were not the same and the MRI scan sets were not intended to be used for creating OPA evaluation platform. Therefore, there were patients' MRI scans of undesirable quality and some to be used extensively over the others. For instance, Patient #2's set was not used because the imaging artifacts in the patient mouth were so large that

it covered large part of the tongue and teeth, which were the most important part in the evaluation process. Like mentioned previously, some small artifacts could be trimmed off using editing techniques, as long as differentiation could be found between teeth and artifacts. However, the loss of image was not tolerable in Patient #2 scans and there was no telling of the location and number of the teeth, and therefore, this model was dropped. On the other hand, Patient #8 was chosen to be used as the source model for Scaled model set because of two reasons. First, the patient of model #8 was the youngest (18 years old) of the patients in the SLD set. One major of problem in the SLD set was that most of the patients' MRI scans have artifacts that cover part or entire tongue and teeth. Those artifacts were mostly located at the molars and were believed to be caused by prosthetic teeth. The artifacts cover some of the key areas which could affect the result of the evaluation. Patient #8's scans did not show those artifacts at the molars. The only artifacts occurred at the incisors covered only small part of the tip of the tongue. Such artifacts were more tolerable because it would hardly affect the measurement results.

One later-found source of error was that Patient #8 was assumed to be in the 85 percentile group. It was determined as the tragion dimension belonged to 90 percentile and the lip belonged to 80, the two values were averaged. A more appropriate approach could be using the lip protrusion as the standard because it was more relevant to the OPA fit since the dimension included the length of oral cavity.

3.5.3 – Model-Part Issue

In this section, issues of the model-parts and some modeling methods were explained and addressed. The shape of the *Mandible* was one of the major problems found in the models and it was due to error in creating the parts. In reality, the rotation of mandible was facilitated at the Temporomandibular Joint (TMJ). It was a hinge joint attached to posterior maxilla by ligament. However, in the models the TMJ was not modeled because the joint was not quiet visible. The resulting TMJ portion would be appeared as broken pieces, as pointed out in Fig. 54 below by the yellow arrow, so it was omitted in the model. Instead of creating the TMJ on the models, the rotation axis was placed on a well-defined point on mandible closest to the TMJ. Obviously that could cause error and lead to imperfection in simulating the mouth opening motion. However, without the TMJ, this approach would be the only feasible one because an easily-identifiable point was needed to ensure every rotation on a particular model was identical. Error brought by using TMJ with shattered surface could impact even more.

Figure 54. A *Maxilla* model with Temporomandibular Joint. The arrow indicates where the joint appeared to be “shattered”.

Some sources of error inherited with the model-parts which simulated the soft-tissue structure. Among the patients’ head models, the shape of *Tongue* varied. The main reason was that the tongue was not the focus of imaging when the MRI was taken, and that the patients moved their tongue during imaging process. For example, in Patient #10, as shown in Fig. 55, the tongue was vertically longer than the rest of the patient, causing the tongue significantly shorter horizontally. Moreover, tongue shape was different when the mouth was opened and closed. This makes the tongue shape created from the MRI not ideal for simulating opened mouth used for OPA placement.

Figure 53. The cross-sectional view of Patient #10 head. The tongue was greatly deformed possibly due to movement when the MRI scans were taken.

Apart from the Tongue, the shape of cheek models varies hugely because of the quality of the MRI scans. The cheek parts of other models have different shape due to blended contrast between the muscle and the surrounding tissue, and lack of the gap between those tissues. Among the models the cheek in Set #8 was the most accurate. An ideal cheek model should appear similarly to the one displayed on the BioDigital Human⁴², an online source for human anatomical structure models. A comparison of the *Cheek* model from Biodigital Human and the Patient #8 model were shown in Fig. 56. Although no

quantitative comparison was done, the models appeared to be similar meaning the *Cheek* model in SLD Set, although in low quality, was accurate qualitatively.

Figure 56a-b. (a) The buccinator model showed in BioDigital Human. (b) The Cheek (buccinators) model-parts created for this project.

Section 3.6 – Conclusion

At this point, the models needed to establish an evaluation platform were prepared. Using the Materialise Mimcs, MRI scans of nine patients were converted into 3D head models, becoming the SLD Set, and one of those models was processed to form another set, the Scaled Set. SLD Set, as created using real patient information, would be used as the sample population to test out the platform. On the other, the Scaled Set would be needed to assess the size limit of the Bardo OPA against the traditional OPAs. In the next chapter, the “software” of the platform, which was the protocol used to measure the performance of an OPA would be introduced. Also, the result of the evaluation process will be revealed as well.

CHAPTER FOUR: PROTOCOLS AND EVALUATION

With both the OPA and head model prepared, these models could be put together to simulate OPA placement at a patient's head and to assess the performance and impact on the oral cavity of the model in question. In this chapter, the protocol of how the simulation was carried out, as well as the results will be introduced.

Section 4.1 – OPA Placement

Generally, fitting an OPA into a patient model mouth has several physical criteria. First, the flange would not be placed inside the lips. Second, the teeth should touch only the straight portion of the tube or the bite-block to prevent OPA from moving when the patient is biting. The third requirement was that tongue compression must not be too great, as compressive pressure of above 25cm H₂O, or approximately 2.4kPa, would cause tissue necrosis. The value of pressure can be calculated by the following equation:

$$\frac{\text{Force applied on the Tongue by the OPA (N)}}{\text{Surface area of OPA contacting the Tongue (m}^2\text{)}} = \text{Compressive pressure (Pa)}$$

Last but not the least, the distal end of the OPA must not block the throat opening to oral cavity. An OPA was considered fit to a particular patient model only if these four requirements were fulfilled.

Fitting the Guedel or Berman OPA into the virtual head model was similar to what physicians do in reality, yet it was instead easier because the OPA can be put into the patient's mouth without concerning the patient's safety. OPA were sized differently to provide fit to patient's oral cavity, for example, a size 70mm for a small-sized adult, could be used initially. A different size might be used if the OPA went too deep toward the bottom of the tongue. To be considered a good fit, OPA should have clearance from the bottom of the tongue. To be considered a good fit, OPA should have clearance from the throat opening to ensure airflow and the flange to be very close to the edge of the lip, without compressing the tongue too much.

Figure 57. Head model fitted with a Guedel OPA.

On the contrary, the fitting requirement for the Bardo airway is different than that of the Guedel or Berman airways due to design differences. To be considered a good fit, the

Bardo OPA would be located at the top side of the oral cavity, where the bite-block has sufficient area of contact with the molar. The OPA also needed to be able to slide in and out of the oral cavity to ensure reasonable air passage.

Figure 58. Head model fitted with a Bardo OPA

Section 4.2 – Measurement and Statistical Analysis

Measurements of the model were obtained using Mimics. Dimensional measurements obtained from the platform represent the relationship between the OPA and the surrounding soft tissue, and the performance of the OPA for creating air passage. These

dimensions were formulated to evaluate the damage of patient's soft tissue during OPA placement and assess if placing OPA would actually block air passage.

With the dimensional data of the OPA placement, the fit of the each OPA to the patient can be determined by comparing the measurement statistically. Minitab 16 was used and One-Way ANOVA was performed to compare the values between the Berman, Guedel and Bardo Airway. This analysis method was used because it provided grouping of the sample being compared and can provide a reference as if the Bardo was significantly different than the traditional airways. The grouping results were represented in boxplots.

Section 4.3 – Results

The models from the two modeling sets were fitted with three types of OPAs using the methods described above. Table E summarized the size of traditional OPA placed in each. In SLD Set, majority of the models were fitted with 80mm OPAs. In Scaled Set, all of the models were fitted with 80mm Berman regardless of their model size. The 90 and 70 percentile models were fitted with the 80mm Guedel OPA while the rest were fitted with 70mm airways.

OPA Size								
	<i>SLD Set</i>				<i>Scaled Set</i>			
	Berman	Guedel	Bardo			Berman	Guedel	Bardo
1	90mm	90mm	-		#8 (90 %)	80mm	80mm	-
3	80mm	80mm	-		#8 (70 %)	80mm	80mm	-
4	80mm	80mm	-		#8 (50 %)	80mm	70mm	-
5	80mm	70mm	-		#8 (30 %)	80mm	70mm	-
6	80mm	70mm	-		#8 (10 %)	80mm	70mm	-
7	90mm	90mm	-					
8	80mm	80mm	-					
9	80mm	90mm	-					
10	80mm	80mm	-					
Avg	82.22	81.11			Avg	80.00	74.00	
STD	4.41	7.82			STD	0.00	5.48	

Table E. OPA size data for the model sets. Bardo OPA was one-sized thus no information was available.

Measurements of the placement of Berman & Guedel Airway were performed in three different views of the head model. The evaluation of Bardo airway is slightly different than that of the traditional OPAs. No angled placement of the OPA was done. Instead there are some different measurements obtained which was not obtained in the evaluation of the Berman and Guedel OPAs. Each type of OPA was measured against an array of dimensions designed to evaluate their interaction with the surrounding tissue. These measurements were shown below in three categories based on the view point they were obtained.

4.3.1 – Cross-sectional View

In this chapter the name of the measured dimensions will be written in Bold, such as **Tongue Compression**. Three dimensions were obtained from the area where the tongue met the throat, which was illustrated in Fig. 59, where a Berman OPA was placed and Fig. 60, where a Bardo OPA is placed. **Tongue Compression** represents the thickness of tongue being compressed due to OPA placement. In model it is the thickness of the tongue model-part being overlapped by the throat and the OPA, measurement from the outer surface of the tongue to the bottom of the tongue elevator of an OPA. From the measurement data shown in Table F, the Guedel OPA created the largest compression at the tongue, while Berman OPA compressed the least amount of tongue tissue. From the ANOVA test results generated for both the SLD and Scaled Sets, shown in Figure 61 and 62 respectively, Bardo's performance in this category was comparable to that of Guedel OPA, as both OPA were assigned to the same group. Berman OPA had a significantly lower average in compressing the tongue.

Figure 59. Measurement taken at the posterior part of head with Berman OPA placed

Figure 60. Measurement taken at the posterior part of head with Bardo OPA placed

Tongue Compression								
SLD Set					Scaled Set			
	Berman	Guedel	Bardo			Berman	Guedel	Bardo
1	13.64	16.83	12.63		#8 (90%)	15.05	24.06	17.40
3	7.64	14.25	13.78		#8 (70%)	14.15	20.64	16.27
4	15.82	25.21	23.65		#8 (50%)	13.60	18.76	15.69
5	11.90	13.75	16.00		#8 (30%)	13.01	16.86	16.61
6	9.96	13.32	13.48		#8 (10%)	10.68	16.90	16.93
7	13.42	20.63	18.72					
8	14.69	22.48	16.97					
9	12.28	18.52	17.71					
10	12.45	18.07	17.28					
Avg	12.42	18.12	16.69		Avg	13.30	19.44	16.58
STD	2.46	4.10	3.35		STD	1.64	3.01	0.65

Table F. Measurement data for Tongue Compression.

Figure 61. ANOVA boxplot for the Tongue Compression measurement results in SLD Set

Figure 62. ANOVA boxplot for the Tongue Compression measurement results in Scaled Set

Throat Clearance is the vertical distance between the Outer surface of the tongue elevator of an OPA and the throat. The measurement was shown in Fig. 59 for traditional OPA and Fig. 60 for Bardo airway. This clearance represents air passage with an OPA placed. An OPA was not fit if **Throat Clearance** was not a positive number. From the measurement data and corresponding ANOVA boxplot indicated in Table G, Fig. 62 and 63, no significant difference were found among the three OPAs. Note that in SLD set, data from patient #10 was not available.

Throat Clearance								
SLD Set					Scaled Set			
	Berman	Guedel	Bardo			Berman	Guedel	Bardo
1	2.03	1.27	1.50		#8 (90%)	1.80	1.28	0.88
3	3.39	2.58	4.34		#8 (70%)	2.00	0.77	1.34
4	1.39	0.64	0.90		#8 (50%)	1.87	1.63	1.16
5	2.09	1.50	2.12		#8 (30%)	1.05	0.78	1.03
6	1.36	1.05	2.75		#8 (10%)	0.46	1.11	2.41
7	1.30	1.40	1.89					
8	1.66	0.48	0.88					
9	0.96	0.41	1.14					
10	N/A	N/A	N/A					
Avg	1.77	1.17	1.94		Avg	1.44	1.11	1.36
STD	0.76	0.71	1.16		STD	0.66	0.36	0.61

Table G. Measurement data for Throat Clearance.

Figure 63. ANOVA boxplot for the Throat Clearance measurement results in SLD Set

Figure 64. ANOVA boxplot for the Throat Clearance measurement results in Scaled Set

Elevator Reach is the reach of the OPA tongue elevator at the base of tongue. As shown in Fig. 59 and 60, only the portion of the elevator below the throat opening, which was indicated by a dashed-line, was counted as the portion holding the tongue. This dimension represented how much of the tongue an OPA could hold when the patient was unconscious. From the measurement data shown in Table H, negative value of elevator reach were found in Patient #10 with Berman and Bardo OPA placed. That meant the tongue elevator was actually above the dashed indicative line. The boxplot of ANOVA analysis, shown in Fig. 65 and 66, showed that there was no significant difference between the OPAs' performances.

Elevator Reach								
SLD Set					Scaled Set			
	Berman	Gudel	Bardo			Berman	Gudel	Bardo
1	17.87	15.16	14.50		#8 (90%)	6.33	12.01	3.99
3	6.77	10.24	6.21		#8 (70%)	7.59	8.99	4.02
4	4.94	6.88	5.55		#8 (50%)	5.68	5.97	1.98
5	8.35	1.25	10.06		#8 (30%)	5.66	1.67	2.10
6	13.15	8.24	14.14		#8 (10%)	1.42	2.53	3.99
7	9.67	13.42	9.58					
8	8.03	9.63	3.54					
9	0.00	5.46	N/A					
10	-10.48	10.56	-8.12					
Avg	8.60	8.98	9.08		Avg	5.34	6.23	3.22
STD	5.33	4.18	4.23		STD	2.33	4.35	1.07

Table H. Measurement data for Throat Clearance. Negative values meant the tip of the OPA did not reach below the throat opening. The measurement of Bardo OPA of Patient #9 in SLD Set was missing

Figure 65. ANOVA boxplot for the Elevator Reach measurement results in SLD Set

Figure 66. ANOVA boxplot for the Elevator Reach measurement results in SLD Set

OPA-Maxilla Vertical Distance is the vertical distance between the OPA elevator and the bottom surface of the Maxilla. As shown in Fig. 67 for Berman Airway and Fig. 60 for Bardo Airway, the location was also where the palate can be found and it was supposed to be the part that could be injured. However, palate was difficult to be identified and generated as a model precisely. The measurement data and the ANOVA boxplot, as shown in Table I, Fig. 68 and 69, indicated that Bardo OPA was significantly different to the other two types of OPA in both sets. Also, in the scaled set, significant differences was found between Berman and Guedel OPA.

Figure 67. Illustration of OPA - Maxilla Vertical Distance measurement

OPA - Maxilla Vertical Distance								
<i>SLD Set</i>					<i>Scaled Set</i>			
	Berman	Guedel	Bardo			Berman	Guedel	Bardo
1	15.69	16.82	28.88		#8 (90%)	3.32	6.59	22.06
3	3.58	7.37	25.64		#8 (70%)	3.82	4.84	21.22
4	7.42	9.57	25.84		#8 (50%)	4.20	6.52	20.20
5	7.23	5.35	23.10		#8 (30%)	5.43	4.80	21.47
6	8.42	8.58	22.87		#8 (10%)	3.45	6.00	22.99
7	1.53	0.24	20.00					
8	4.08	5.53	20.61					
9	5.82	9.75	28.72					
10	15.67	15.47	32.32					
Avg	7.72	8.74	25.33		Avg	4.04	5.75	21.59
STD	5.00	5.10	4.11		STD	0.85	0.88	1.03

Table I. Measurement data for OPA - Maxilla Vertical Distance

Figure 68. ANOVA boxplot for the OPA - Maxilla Vertical Distance measurement results in SLD Set

Figure 69. ANOVA boxplot for the OPA - Maxilla Vertical Distance measurement results in Scaled Set

Mouth opening is the shortest distance between the upper and lower incisor. Typically a mouth could be opened for forty to sixty millimeters, which is about the width of two to three fingers. The measurement of mouth opening was illustrated in Fig. 70 and 71, for Berman and Bardo OPA placement, respectively. The Bardo Airway was significantly different than the traditional designs, both in SLD and Scaled sets, as shown in the boxplot of Fig. 72 and 73. In Table J, Bardo had mouth opening distance more than twice as the Berman and Guedel Airways.

Figure 70. Measurement taken at the anterior part of the head with Berman OPA placed

Figure 71. Measurement taken at the anterior part of the head with Bardo OPA placed

Mouth Opening							
<i>SLD Set</i>				<i>Scaled Set</i>			
	Berman	Guedel	Bardo		Berman	Guedel	Bardo
1	8.41	11.92	32.69	#8 (90%)	9.95	15.87	28.86
3	13.59	18.92	28.62	#8 (70%)	10.11	14.77	37.72
4	10.03	15.69	31.25	#8 (50%)	9.91	13.51	25.53
5	15.16	14.07	28.89	#8 (30%)	10.15	12.52	28.11
6	10.62	12.92	25.82	#8 (10%)	9.78	12.50	26.06
7	14.43	16.87	34.39				
8	18.92	15.14	27.78				
9	9.07	15.94	29.85				
10	8.50	16.43	30.73				
Avg	12.08	15.32	30.00	Avg	9.98	13.83	29.26
STD	3.64	2.12	2.60	STD	0.15	1.47	4.93

Table J. Measurement data for Mouth Opening

Figure 72. ANOVA boxplot for the Mouth Opening measurement result in SLD Set

Figure 73. ANOVA boxplot for the Mouth Opening measurement result in Scaled Set

OPA-Lip Vertical Compression was the vertical thickness of the lips compressed by a placed OPA. As illustrated in Fig. 70 and 71, this dimension was slightly different in traditional airway and Bardo OPA, due to the different OPA designs. The ANOVA boxplots for SLD Set, shown as Fig. 74, suggested that all three OPA types had similar compression on patients' lips. In Scaled Set, with boxplot illustrated in Fig. 75, the Bardo and Berman were different than each other, as Berman was assigned to Group A while Bardo was assigned to B. On the other hand, the Guedel was statistically similar to both OPAs, belonging to Group A and B.

OPA - Lip Vertical Compression								
<i>SLD Set</i>					<i>Scaled Set</i>			
	Berman	Guedel	Bardo			Berman	Guedel	Bardo
1	7.44	7.96	14.13		#8 (90%)	3.60	2.13	1.26
3	0.64	0.10	4.49		#8 (70%)	2.59	2.32	0.00
4	5.80	5.40	1.29		#8 (50%)	2.74	1.97	2.10
5	0.00	2.34	0.77		#8 (30%)	1.74	2.00	0.55
6	3.31	4.35	3.04		#8 (10%)	2.28	1.15	0.73
7	1.87	2.92	0.00					
8	3.01	2.30	1.53					
9	3.99	4.00	4.28					
10	1.30	0.22	0.00					
Avg	3.04	3.29	3.28		Avg	2.59	1.91	0.93
STD	2.43	2.49	4.40		STD	0.68	0.45	0.79

Table K. Measurement data for OPA - Lip Vertical Compression

Figure 74. ANOVA boxplot for the OPA - Lip Vertical Compression measurement result in SLD Set

Figure 75. ANOVA boxplot for the OPA - Lip Vertical Compression measurement result in Scaled Set

4.3.2 – Front View

OPA-Lip Horizontal Compression was the compressed (overlapped) distance by the Bardo bite-block to the lip commissure. Due to the unique bite-block design of the Bardo airway, only models fitted with Bardo airway were evaluated for this dimension. The dimension was measured for the left side of the mouth, as shown in Fig. 76. No comparison was performed. About three millimeter of lip commissure was compressed in both sets. Table L listed the measurement data for this dimension.

Figure 76. Illustration of OPA - Lip Horizontal Compression with Bardo OPA

OPA - Lip Horizontal Compression								
<i>SLD Set</i>					<i>Scaled Set</i>			
	Berman	Guedel	Bardo			Berman	Guedel	Bardo
1	-	-	4.80		#8 (90%)	-	-	2.49
3	-	-	2.93		#8 (70%)	-	-	4.35
4	-	-	1.61		#8 (50%)	-	-	2.78
5	-	-	5.14		#8 (30%)	-	-	2.60
6	-	-	1.94		#8 (10%)	-	-	4.76
7	-	-	1.38					
8	-	-	5.09					
9	-	-	0.00					
10	-	-	3.23					
Avg			2.90		Avg			3.40
STD			1.83		STD			1.07

Table L. Measurement data for OPA - Lip Horizontal Compression

4.3.3 – Angled Placement

The OPA was placed at an angle to create the “worst-case scenario” of placement of traditional OPA. This placement could be observed when there is additional device, such as optical fiber scope, placed in the oral cavity to aid oral intubation. In such case, physicians usually placed the OPA sideways to allow more space for maneuvering the scope. In the simulation, the Berman or Guedel OPA was rotated with the rotating axis placed on the middle of the airway where it meet the throat opening, and then the model was rotated until the side of OPA was in contact with the right side corner of the mouth. The OPA-Cheek horizontal compression was measured for the Berman and Guedel OPA with this configuration.

Figure 77. Cross-sectional and Front View of angled placement of OPA. The arrow indicated where the rotational axis was set.

OPA-Cheek Horizontal Compression was the compressed thickness of the cheek tissue when the OPA was placed sideways. This value was obtained by measuring the distance of the cheek overlapped by the OPA. It was generated differently in the traditional OPAs and the Bardo airway. In the case which Berman or Guedel OPA were placed, as illustrated in Fig. 78, the compression was created by rotating the OPA until it was in contact with the lip commissure (the tip of mouth), and the cheek would then be overlapped. In the case of Bardo Airway, which was shown in Fig. 79, the compressed was caused by the Bardo bite-block to the cheek tissue. The Bardo was placed with its regular centered-placement. Note that in the measurement data shown in Table M, in the SLD set there were negative values, which represented that the cheek was not compressed. From the following boxplots, it was found that in SLD set, shown in Fig. 80, the three types of OPA performed similarly to each other, while in Scaled set, shown in Fig. 81, the Bardo had significantly more compression on the patient's cheek.

Figure 78. Illustration of the measurement of OPA-Cheek Compression measurement, with Berman OPA placed at an angle.

Figure 79. Illustration of the measurement of OPA-Cheek Compression measurement, with Bardo OPA being placed.

OPA - Cheek Horizontal Compression (Angled)								
SLD Set					Scaled Set			
	Berman	Guedel	Bardo			Berman	Guedel	Bardo
1	-4.58	-2.65	-1.33		#8 (90 %)	3.58	2.00	8.29
3	10.23	9.82	13.60		#8 (70 %)	2.92	1.66	8.85
4	11.38	11.28	6.95		#8 (50 %)	2.97	1.52	8.15
5	14.74	8.93	9.67		#8 (30 %)	2.45	2.35	6.82
6	11.32	8.85	7.45		#8 (10 %)	1.61	0.00	7.60
7	8.92	11.39	14.10					
8	3.57	4.35	10.67					
9	9.16	8.42	5.21					
10	2.71	-1.04	5.71					
Avg	7.49	6.59	8.00		Avg	2.71	1.51	7.94
STD	5.90	5.22	4.74		STD	0.73	0.90	0.77

Table M. Measurement data for OPA - Cheek Horizontal Compression. Note that the measurement was obtained when the traditional OPA were placed at angle while the Bardo was placed in regular configuration. Negative value represents non-compressive distance.

Figure 80. ANOVA boxplot for the OPA – Cheek Horizontal Compression measurement result in SLD Set

Figure 81. ANOVA boxplot for the OPA – Cheek Horizontal Compression measurement result in Scaled Set

4.3.4 – Top View

There were several dimensions critical for the molar-related functions of the Bardo Airway, which can be only evaluated in the top-view perspective. These attributes included the distance between the OPA and molar, as well as the contacting surface area of the bite-block with the molars. The first measurement was the **OPA-Molar Horizontal Distance**. It was the lateral distance between the inner side of the molar and the tongue elevator. This distance represented the clearance for the tongue tissue to squeeze into when the elevator was compressing the tongue. In the measurement table showed in Table N, no measurement could be obtained in patient #3, 6 and 9. This was because the tongue elevator of the placed Bardo Airway was completely above the molar

so no horizontal dimension could be measured. In SLD Set, the average clearance was 6mm, while in Scaled Set, the average was about 8.5mm.

Figure 82. Illustration of the measurement of OPA – Molar Horizontal Distance measurement, with Bardo OPA being placed

OPA - Molar Horizontal Distance								
<i>SLD Set</i>					<i>Scaled Set</i>			
	Berman	Guedel	Bardo			Berman	Guedel	Bardo
1	-	-	11.48		#8 (90%)	-	-	9.70
3	-	-	N/A		#8 (70%)	-	-	6.83
4	-	-	5.35		#8 (50%)	-	-	9.00
5	-	-	3.16		#8 (30%)	-	-	9.75
6	-	-	N/A		#8 (10%)	-	-	7.80
7	-	-	2.90					
8	-	-	7.84					
9	-	-	N/A					
10	-	-	5.66					
Avg			6.07		Avg			8.62
STD			3.21		STD			1.27

Table N. Measurement data for OPA – Molar Horizontal Distance. No measurement was obtained for the Patient #3, 6 and 9.

of Teeth-Contacting Slots denoted the number of slots at the Bardo bite-block in contact with the molar. This value represented the surface area for contact in terms of the slots. Note that two values were obtained for this measurement representing the top and bottom face of the bite-block. From the evaluation, the top surface had more contacting surface than the bottom. This could be observed from the simulation shown in Figure 83a, showing the bottom surface and Figure 83b, showing the top surface. This observation was also supported further by the measurement, listed in Table O and P, as the average number of slots at the top surface was about 5 slots and that of the bottom surface was about 2 slots. In one row of the slots, the inside slot was always occupied before the outside slot, and the inner (distal) row would be occupied before the outer row.

Figure 83a-b. Illustration of the measurement of number of teeth-contacting slots on the bite-block of bardo OPA. The bottom (a) and top (b) sides of the block are illustrated.

# of Teeth-Contacting Slots (Top Side)								
<i>SLD Set</i>					<i>Scaled Set</i>			
	Berman	Guedel	Bardo			Berman	Guedel	Bardo
1	-	-	4.00		#8 (90 %)	-	-	6.00
3	-	-	6.50		#8 (70 %)	-	-	5.00
4	-	-	5.50		#8 (50 %)	-	-	5.50
5	-	-	5.50		#8 (30 %)	-	-	4.00
6	-	-	4.50		#8 (10 %)	-	-	4.50
7	-	-	7.00					
8	-	-	4.50					
9	-	-	7.50					
10	-	-	4.50					
Avg			5.50		Avg			5.00
STD			1.25		STD			0.79

Table O. Measurement data for Number of Teeth-Contacting Slots at the top side of Bardo OPA bite-block.

# of Teeth-Contacting Slots (Bottom Side)								
<i>SLD Set</i>					<i>Scaled Set</i>			
	Berman	Guedel	Bardo			Berman	Guedel	Bardo
1	-	-	2.50		#8 (90 %)	-	-	2.00
3	-	-	3.00		#8 (70 %)	-	-	1.50
4	-	-	0.50		#8 (50 %)	-	-	2.00
5	-	-	1.50		#8 (30 %)	-	-	2.50
6	-	-	1.00		#8 (10 %)	-	-	1.50
7	-	-	2.00					
8	-	-	1.50					
9	-	-	4.00					
10	-	-	1.00					
Avg			1.89		Avg			1.90
STD			1.11		STD			0.42

Table P. Measurement data for Number of Teeth-Contacting Slots at the bottom side of Bardo OPA bite-block.

Section 4.4 – Discussion

4.4.1 – Statistical Analysis

From the evaluation measurement and statistical analysis shown above, there were three aspects of the Bardo OPA which were different than the traditional OPAs. The first one was the distance between the elevator and the Maxilla. From the corresponding data Table I, the difference was approximately 20mm. The Bardo had more clearance between the elevator and the maxilla, or the palate. The most obvious reason for that was the thickness of Bardo airway was smaller than that of the Berman or Guedel. The elevator of Bardo OPA was flat, while the elevator in Berman or Guedel was in tube shape. This attribute of Bardo was ideal because larger clearance space allowed the physician to maneuver and place the OPA or additional device such as endotracheal tube. Another aspect of Bardo which was different than the traditional OPAs was the **Mouth Opening**. With its unique bite-block design, the Bardo airway required more mouth opening to fit the bite block in between the upper and lower molars. Shown in Table J, while in average the Berman or Guedel Airways required 10mm of opening, the Bardo Airway needed as much as 37mm to be fit in. Excessive opening could cause muscle fatigue and damage to the patients. However, as mentioned above, the normal maximum opening was about 40 to 60mm and hence the more opening by Bardo did not reach dangerous level. Last but not least, the **OPA-Cheek Compression** in Bardo was also one of the traits which were different than the Berman and Guedel. In Scaled Set, as shown in Table M and Fig. 81, the value of Bardo was more than double when comparing to the other two OPAs, with 8mm of compression versus 2 to 3mm of compression in Berman. This could be more dangerous as indicated because the angled placement of traditional OPA was temporarily

while the placement of Bardo OPA was permanent in the time frame of the use of OPA. Modification on the bite-block design would improve this situation and will be discussed in the next chapter.

However, there are dimensions where the Bardo showed differences with one of the traditional OPAs but are same as another one, and that makes the result inconclusive. Assuming that both Berman and Guedel were as efficient, if it showed the two OPAs were different, conclusions could not be confirmed if the Bardo was different than these two OPAs. For instance, in the comparison of Tongue compression, the Bardo is actually shown being similar to the Guedel OPA in the SLD set, as shown in Fig. 61, as well as in Fig. 62 where the comparison of Scaled Set was shown, the Bardo in fact was similar to the Berman and Guedel, while the traditional ones were different to each other. Another case of inclusive result was in the **OPA-Lips Vertical Compression**. In the Scaled set, the Bardo was similar to the Guedel OPA but not to the Berman OPA.

4.4.2 – OPA Sizing Error in Scaled Set

One strange problem observed from the Scaled Set was that although the model was scaled to the extreme end of the population found in ANSUR II, where its 10 and 90 percentile sizes should represents the smallest and largest 10% size of the population, OPA sizes fitted into those scaled models did not vary much. For example, size 100 or 110mm OPA was expected to be fitted into the 90 percentile model, while the 10 percentile model was expected to be fitted with a small sized OPA, such as a 60 or 70mm OPA. However, from what was observed in Table E, all of the models were fitted with an

80mm Berman OPA. The larger two models were fitted with 80mm Guedel and the smaller ones are fitted with 70mm. Such observation suggested three possibilities. One possibility would be error in the Patient #8 model. The Scaled Set was created from the Patient #8's model. As mentioned previously, Patient #8 was chosen because it had the least amount of flaws. This model was then scaled using the ANSUR II data as reference. When the OPAs were placed in the Scaled Set, they were all placed in similar way. Although that can produce consistent results, any error or outlining measurements inherited with this particular model was replicated for all models in the scaled set. For example, in the **OPA-Cheek Compression** measurement, Fig. 80, the boxplot of the SLD set, showed that all OPA performed similarly. Nevertheless, as showed by the boxplot of the Scaled Set in Fig. 81, the Bardo performed differently. If look closely to the corresponding datasheet, Table M, the measurement of Bardo from Patient #8 was the outlining point because it was more than double the value of the traditional OPAs. In other patients, the Bardo measurements were closer to the others. While this outlining effect was averaged out by the other sample, in Scaled Set where only Patient #8 was used, the outlier might create misleading results.

Placement of OPA in the simulation became another major source of error in this evaluation platform. The placement method described in Chapter 1 was a very common method of placing OPA. It relied on the fact that the OPA was secured by the force exerted by the elastic tongue and the clenching of jaw. Haptic feedback to the physician who inserted the device was also helpful in placing the OPA correctly. However, in the model, the OPAs were free floating and could be overlapped by each other. The only

limitation that could help lower the degrees of freedom of placing OPA was the boundary of each model and empty space to ensure tight fit and adequate air passage were simulated. Because of these, the OPA was determined to be able to fit a patient when the OPA did not interfere with the supposedly-rigid model-parts and that there was air passage. In reality, these criteria were not enough to determine if the OPA was a good fit. This error could lower the reliability of this evaluation platform.

Last but not the least, the differences between the model-parts and body-parts resulted from the non-ideal imaging conditions, as discussed briefly in section 3.5.3, could also be a major source of error in OPA sizing. Due to the fact that the patients' mouths were closed when the MRI scans were taken, the model-parts created for this platform could not be replicated exactly how the body-parts would look in reality when an OPA was placed. When the mouth was closed, the tongue was compressed and the throat opening reduced. The OPA placement method relied heavily on the relative distance between the tongue, throat and the tip of the OPA to generate a close estimation of the OPA location. Therefore, inaccuracy in these model-parts could significantly deviate the accuracy of the OPA placement.

4.4.3 – Angled Placement

Beside the error-causing issue of the OPA placement, another aspect of this platform that was worth paying attention to was the reason and method of Angled placement of placing an OPA at angle . In such scenario, like the one shown in Fig. 77, an OPA was placed in an angle position to represent an usually seen situation when physician move the OPA to

the side to allow more visual space for the physician to maneuver and insert an endotracheal tube. While it may not be the case for every patient that the physician rotated the OPA until it touched the corner of the mouth, the method of how the OPA being rotated was to give consistency for all the models. The OPA was not always rotated at the throat opening, but this method was an educated estimation that the physician would like to maintain insertion of the OPA while steering the OPA to the side and not stretching too much at the corner to cause damage. No stretching is simulated in the rotation to keep consistent and simple.

Another purpose of having angled OPA placement was to generate a worst-case scenario for the traditional OPA so a comparison could be facilitated between the interaction of traditional OPA with the patient mouth and that of the Bardo airway. If placed at mid-line position, the traditional OPA was safe to the lips because of narrow lateral profile of the OPA. However, the Bardo airway has a much wider profile and the bite-block portion would often stretch the patient mouth.

Section 4.5 – Conclusion

From the result and analysis shown above, this evaluation platform did not identify the limit of the Bardo airway against the traditional OPAs such as Berman and Guedel Airways. All of the models could be fitted with the Bardo Airway while sizes 70-90mm of the traditional OPAs were used. Although the primary goal of finding the compatibility of the Bardo airway was not achieved, the platform successfully identified at least one

attribute which the Bardo Airway could become harmful to the patients: the OPA-Cheek Compression. This case provided a good example for creating modification for this novel device. The next chapter will be focused on discussing aspects where the Bardo can be improved and how it is modified to achieve better safety and efficacy.

CHAPTER FIVE – MODIFICATIONS FOR BARDO AIRWAY

One of the original goals for this project was to determine how the one-sized Bardo OPA is comparable to the full range size of the Berman or Guedel OPA. It was planned that using the Scaled Patient #8 Set, the sizes of the traditional design compatible with the one-sized Bardo could be found out. However, as indicated from the result, the Bardo airway can fit into all of the models in a similar way, while most of the models were fitted with Size 7 or 8 traditional OPAs. Therefore, the upper and lower size limit of the Bardo OPA cannot be determined with respect to traditional OPA size, and thus no modification was proposed. However, some problems were found while fitting the Bardo airway into the models. These problems gave the opportunity to challenge the Bardo Airway in term of its functionality, which in turn, can improve the safety and efficacy of the device.

Section 5.1 – Approach #1: Reducing the Width of Tongue Elevator

The first recommendation was aimed to reduce the risk of trapping or pinching tongue tissue to inner-side of molars. From the measurement data shown in Table N in Chapter 4, the average lateral distance between the tongue elevator of Bardo OPA and the molar was 6.07mm and 8.62mm, for the SLD Set and the Scaled Set respectively. In some cases the distance was as low as 2 -3mm. Although not shown in the simulations, when tongue tissue is compressed and raised, it is possible that the tissue would be caught in the gap for prolonged time. Also, the current design of Bardo OPA has rounded edges, which could concentrate the pinching force at a small area. Such small volume of tissue might not withstand the pressure and would cause tissue necrosis.

This problem does not present in any of the traditional OPA because they have a rather slender tongue elevator design. However, the Bardo OPA has a wider elevator and that became a serious issue. The traditional OPA provides a good example for improving the design of Bardo OPA for this situation. The width of the tongue elevator could be reduced to lower the risk of trapping tongue tissue between the side of the OPA and the molars.

Figure 84. Bardo OPA with narrowed tongue elevator

Figure 85. Area trimmed off from the original Bardo Airway. The model in green color is the modified Bardo OPA. The red model illustrates the removed portion.

Section 5.2 – Approach #2: Increasing the Bending Angle of the Tip of the Tongue Elevator

This second approach is to create more bending at the tip of the tongue elevator to increase the area of contact with tongue, thus more effective in holding the tongue. In the measurement of Elevator Reach shown in Table H in Chapter 4, there were two occasions (Patient #9 and #10) of negative elevator reach in the SLD sets. The reason for the negative elevator reach was that the closest point where the tongue elevator was in contact, hence holding, the tongue is above the throat opening. Thus there is a risk where the elevator is not holding deep enough of the tongue to prevent it from obstructing the airway.

To remedy this situation, one solution is to bend the tip of the tongue elevator so its inner surface has more surface contact with the tongue. Bending the tip would 1) increase the value of elevator reach, and also 2) generate more holding force to the tongue. To modify the design, first thing is to find out the length of the elevator needed to be bent and the angle it needed to be bent. From the evaluation the following data were collected.

From the two sets the larger value of the distance, average is 4.68mm in length and at an angle of 42.77°. The model can then be modified using the Flex operation in SolidWorks as described in Chapter 2.

Figure 86. The modified Bardo Airway with bent elevator tip

Figure 87. Comparison of the original design and modified design of Bent tip.

Figure 88. A close-up view of the comparison between the original design and modified tip design.

The result of this modification is visually insignificant compared to the overall length of the tongue elevator to the length of the bent portion. After all this modification was based on the parameter set for this evaluation and was generated to solve the problem observed. A modified elevator tip would help but it required more testing and calculation to create the best solution for this approach.

Section 5.3 – Approach #3: Trimming Off Unnecessary Portion of the Bite-Block

The purpose of trimming off unnecessary portion at the bite-block is to decrease the stretching pressure on the mouth commissure and cheek. Most stretching at mouth commissure and the cheek occur at the same place on the OPA. In real life situation, insertion of OPA would worsen the stretching as the tissue has to withstand not only lateral stretching force, but also the shear force in anterior-posterior direction. In the case of general anesthesia, vomit is very common during extubation, if the commissure and inner cheek were damaged by using the Bardo airway during intubation procedure, the tissue might be infected by vomit. Eliminating this bite block portion can ease up the contacting and stretching force at the parts of the oral cavity.

The measurement data in Table M in Chapter 4 shows the compression of the Bardo's bite block at the cheek. Note that cheek is behind the commissure and its location has less contact with the bite block. Since bite block is straight from the commissure to the cheek, the compression at the corner of mouth would be larger than that at the cheek tissue.

Figure 89. A Bardo Airway with trimmed bite-block

Figure 88. Comparison of the original bite-block and the modified bite-block.

Section 5.4 – Conclusion

From the evaluation discussed in the previous chapter, the Bardo Airway is somewhat compatible with all the OPA sizes used for evaluation. Therefore there is not enough evidence to show the compatibility of the one-sized Bardo to the sizes of the traditional OPA. Some of the measurements could display similarities between all three OPAs, while the others suggested significant difference. Although, it is inconclusive about the size of the OPA, there are some measurement indicated disadvantages in functionality. Therefore, modifications were proposed to remedy those pitfalls in order to improve the safety and efficacy of the device.

This part of the project made use of solid models to visualize the modification. Three modifications were proposed. The first one was to trim off the width of the tongue elevator to avoid tongue tissue from getting caught and pinched between the elevator and the molars. The second one was to bend the elevator tip to increase elevator reach and surface contact, to provide a larger force at the base of the tongue and prevent it from obstructing airway. The last one was to remove excessive portion of the bite block to reduce the compression force applied on the commissure and the cheek, which will help to prevent damage to those tissue. These new modifications, however, were not re-evaluated using the platform due to time constraints of the project. Further investigation on these approaches would result in valuable feedback to improve the design of the Bardo Airway.

CHAPTER SIX – CONCLUSION

Section 6.1 – Conclusion

Emergency clenching caused 33% of legal-medical claims related to general anesthesia. It happens to 1% of patients who received general anesthesia. The damage was usually caused when a physician was trying to pull the OPA out of the patient's mouth while patient still clenching on it, resulting in patient biting on the OPA. Moreover, physicians tend to use OPA in an "off-label" fashion where they will use them as a bite block to keep the patient's mouth open. As the contact surface is very small on incisor, the clenching force can generate high pressure ($Pressure = \frac{Force}{Area}$, the pressure is higher when area is smaller) which could fracture or even dislocate teeth.

Oropharyngeal Airway (OPA), or Oral Airway, is usually used on patients who are unconscious or under general anesthesia. The tongue of an unconscious patient will naturally fall back to the airway due to relaxed muscle. The OPA is designed to be inserted inside patient's oral cavity to keep the tongue from rolling back and obstructing the throat during surgeries. Regardless of how OPA were used, there exists a risk of damaging the patients' teeth. Such damages can cause burdens on the physicians, the patient and the insurance company in different ways. Dr. Theodore Burdumy realized this problem and designed the Bardo Airway. It has a unique design with a dedicated bite-block portion to provide area for patients to bite on while keeping the mouth opened. The contact point is at the molars, which have more surface area and will provide more

support as they are stronger than other teeth. The thin tongue elevator can eliminate the contact with the incisors, and provide physicians with a better view to the airway.

The Bardo, as a new device, is currently designed to have one size. On the other hand, traditional OPA such as Berman and Gudel airway have a spectrum of sizes to fit different patients with various physiological variations. Although the fit of Bardo is more flexible than the traditional one as its placement can be adjusted, it still cannot fit every patient.

The purpose of this project is to evaluate the design of the Bardo Airway by simulating the OPA insertion and placement in patient's airway. To achieve this goal an evaluation platform was established. There were three deliverables targeted for this project, which contains:

1. Method of Creating models serve as the hardware of the platform, and
2. Protocols, or the software, required to effectively utilize the hardware to simulate oral airway insertion
3. Modification for the Bardo OPA, in two approaches:
 - a. Create additional size for Bardo
 - b. Propose functionality improvements

The first step in creating the hardware of the platform was to build the 3D model of the oral airway to be evaluated. The OPA were scanned using ScanStudio HD. The scanner emitted lasers to the object and the reflection provides surface information of the scanned object. A rough 3D point mesh was created as raw data. The raw 3D point mesh was then imported and repaired using RapidWorks. Using this software the mesh can be repaired, resized and optimized for further use. The repaired mesh is then imported into SolidWorks for rebuilt. The mesh, even though was repaired, was not adequate for accurate simulation. The best way to create a reliable model was to create a solid model with determined dimensions. Using the mesh as a reference, precise models were built.

As the solid model was built using scan mesh, it was not perfect and analysis was hence performed to estimate the error of the scanning and re-building method. Dimensions of the OPA models were compared against the physical objects. It was found that the error of the length was ranging from -3% to 5%, which is about 1.5-3mm deviation from original, and that translated to be less than the size difference (10mm) between sequential OPA sizes.

The second part in creating the platform was to create the anatomical model of human head. This was achieved by converting the MRI scans into 3D model using Mimics. MRI scans of nine patients were provided by San Luis Diagnostics (SLD) Center. The patients had an average age of 59 years old. The SLD Model Set was made by converting head and C-Spine MRI scans of these nine patients into solid models. The conversion process was mainly done by using Materialise mimics. However, the models from SLD Set were

in the same size with similar demographic background. This prevented the Bardo airway to be tested thoroughly. So a model was scaled using information obtained from ANSUR II, an anthropometric database created by the US Army.

With both the oral airways and anatomical models built, they could be put together for evaluation. Each patient's model was fitted with the Berman, Guedel and Bardo Oral Airway. Like placing an OPA in reality, an OPA size was picked for the patient and the OPA was rotated and superimposed on the cross section of the mouth-opened patient model for a visual check for fit. Then the position of the OPA was adjusted so it could fit into the oral cavity using the incisor and the throat opening as the reference points. The mouth section of the model-part was then closed to form a closed fit. Then the OPA-fitted model would be evaluated by performing a series of measurement at different view to determine the distance of the OPA to the boundary of the oral cavity.

From the measurements, it was found that all of the models in both sets were fitted with OPAs of size 70 to 90mm, even at the "extreme-case" models which belong to highest and lowest 10 percentile of the population size. The Bardo OPA, which was fitted into the model using similar method as the traditional OPA, could fit into all models without incompatibility. It can be concluded that the Bardo airway was comparable to 70, 80 and 90mm OPA, but it was inconclusive of the limit of the Bardo airway in terms of the OPA sizes and therefore no modification for different size of Bardo can be recommended.

Although it was inconclusive for determining the size limit for the Bardo Airway, there were some observations found which show pitfalls of its unique designs, and from these observations, suggestions for modifying the functionality of the Bardo airway were made. Three aspects of the Bardo airway can be modified based on the finding of the evaluation to improve safety and efficacy.

Section 6.2 – Limitations and Future Work

There are some limitations observed from this evaluation platform. First, the model-parts were made as solid models. This representation is simple and effective for displaying rigid parts such as the bone and teeth. However, for soft tissues inside oral cavity, solid model is somewhat unrealistic for simulation. For example, when the mouth is opened and rotated, the tongue will be compressed in an unrealistic way, with part of the model protruding from its own boundary. Using dynamic modeling methods, or extensive use of Flex function in SolidWorks, would allow the simulation to become more realistic.

Secondly, OPA is considered fit into a patient's oral cavity model if it is placed longitudinally without interfering rigid tissues, which are the throat, maxilla and incisor. No limitation was set for the soft-tissue model part to determine appropriate fit. Therefore, the soft tissue can be stretched or compressed by an OPA to a point that it is unsafe in reality but still considered fit. Using Finite Element Analysis can eliminate this pitfall as the additional simulation could provide information at the body part.

Finally, patient population of this project was obtained from a single source and most of the patients were older than 40 years old. When compared against the percentile chart from ANSUR II, the head size of these patients were among the 80-95 percentile range, which means they are of larger sizes. This limits the sizes of OPA used and prevent one of the objectives, to determine the limit of the Bardo OPA size, to be concluded. In the future, larger sample size is needed and more importantly, the population needs to be more diverse. The objective of this project is to make sure the Bardo OPA is safe and effective on most patients, as a result, it is vital to have a sample patient population which can represent majority of patients.

Although this project had some pitfalls which affected the results, it nevertheless served a purpose as the foundation for further studies. Evaluation platform of oral cavity is rare, yet the oral airways are very important in the field of medicine. Klock⁴³ suggested that simulation platform like this one is demanded, and this view was supported by Schebesta et al.⁴⁴, who thinks that mannequins commonly used for training nowadays was actually far from reality and so simulation generated from real patients can serve better for education purpose. Some devices are life-depending. The fit of such devices could determine if the devices can be relied on during life-threatening situations. Although this investigation is not perfect, it demonstrated some techniques and methods which would help students and scholars to create platforms in the future. With better protocol and more realistic simulation, these platforms would help physicians and engineers to determine if their inventions can help more patients, who can be our loved ones.

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Appendix A: Pre-Evaluation Modification

Approaches for Bardo Airway

Approach I: Grooved Elevator

Purpose: The mid-line groove is created on the tongue elevator to secure the position of any additional airway management devices, such as flexible fiberoptic scope or suction tubing. This idea originated from the Ovassapian OPA (see figure at right), which has unique design for accommodating those devices.

Approach II: Modular Design

Purpose: It is created as an alternative approach to solve the problem of lacking additional sizes to cover more patient physiological variations. The two key portions of the Bardo Airway, the Bite-block and the Tongue Elevator, are designed to be detachable from the main body of the OPA. Parts of different shapes and sizes, or even customized parts, can be attached to the main body to ensure better patient fit. The connection point is designed as anchor-type structure so the parts can be secured to the main body without the risk of falling apart.

Appendix B: ScanStudio HD Scanning Parameters

Positioning: 360 (Bracket or Single used to add additional frames)

Divisions: 8

Points/In.²: 2.5k (To have standard quality (SD) while minimizing memory usage)

Target: Neutral (Dark and Light settings are used in extreme cases)

Range: Marco (Wide is used when object is laterally large, Extended is used when object is placed outside of the Max (9") range)

Note 1: Use minimal tolerance for align and fuse settings, to minimized error.

Note 2: Review and Export the fused mesh without texture can dramatically reduce memory usage.