MASTER THESIS

Virtual Laryngoscopy: Supporting Anesthesiologists in Difficult Airway Planning

J.J.M. Riksen

University of Twente
Radboudumc Nijmegen
Department of Anesthesiology
3D Lab Radboudumc

Supervisors:
Prof. G.J. Scheffer
Prof. T.J.J. Maal
Dr. Ir. F. van der Heijden
G. van de Steeg Msc
R.J. Haarman Msc

Radboudumc

UNIVERSITY OF TWENTE.

Abstract

To predict difficulties in endotracheal intubation, patients undergo preoperative evaluation in the outpatient clinic. Prediction methods that are based on the anatomical inspections of the head and neck area, perform modestly. Virtual laryngoscopy (VL) is a tool that provides intraluminal anatomical information on the airway. Previous research suggests it to be of added value in airway planning. It potentially leads to a more conservative and safer airway management in patients with head and neck pathology. The VL software used in previous studies, however, had limitations and could be improved. The VL software created in this study addresses these limitations. The software is created specifically for airway planning. It was tested in a small verification study, where the software performed well. It is user friendly according to first time users, suggesting the anesthesiologist can create a VL reconstruction without the need of outsourcing it, resulting in interactive, faster and more accessible VL software that fits the current clinical workflow of anesthesiologist. The workflow and clinical value should have been tested in a validation study with patients with a difficult airway, but due to the COVID-19 pandemic this part of the research study had to be cancelled.

Preface and Acknowledgement

In front of you lies the thesis "Virtual Laryngoscopy: Supporting Anesthesiologists in Difficult Airway Planning", of which the research is conducted at the department of Anesthesiology and the 3D Lab at the Radboudumc, Nijmegen. This thesis is the final part of the master's program Medical Imaging and Interventions in technical medicine at the University of Twente.
The focus of this research project was on virtual laryngoscopy software. The start of the project was difficult , because I had little previous experience in object oriented software programming. The final months of the project were also challenging because, due to the COVID-19 pandemic, I was unable to clinically test the software and workflow and had to develop an alternative. I had a difficult time working by myself, in particular without the stimulating environment of colleagues around to work with.

I would like to thank my supervisors for their great guidance and support during my research project. First of all I want to thank Gert van de Steeg as my daily supervisor for helping me with the development of the software and teaching me about object oriented programming. Secondly, I would like to thank my medical supervisor and head of the department of anesthesiology professor G.J. Scheffer and head of the 3D Lab professor T.J.J. Maal, for granting me the opportunity to work on this project and guiding me through the process.
Dr. Ir. van der Heijden from the University of Twente, has given me valuable advise during supervising the research project. Furthermore, I would like to thank Rian Haarman from the University of Twente for her support and guidance on my personal development. I also want to thank all the members of the 3D Lab for their help, teaching and perfect working environment. It was a valuable experience to be a part of the team. Finally I want to thank my girlfriend and my parents for supporting me. Especially their support during the COVID-19 pandemic was essential for me to finish this final thesis.

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List of Abbreviations

2D	Two-dimensional
3D	Three-dimensional
CT	Computed tomography
DICOM	Digital Imaging and Communication in Medicine
MRI	Magnetic resonance imaging
OIV	Open Inventor
PACS	Patient Archive and Communication System
ROI	Region of interest
VL	Virtual laryngoscopy

1 Introduction

General anesthesia is a reversible drug-induced coma, used to keep patients from experiencing pain during surgical procedures. Usually a combination of intravenous drugs and inhaled gasses are used to establish unconsciousness, amnesia, analgesia, akinesia and the inhibition of autonomic reflexes. [1], [2]

Arthur Ernest Guedel described four stages of anesthesia: disordered consciousness, excitement, surgical anesthesia and overdose. [3] Stage I, disordered consciousness, starts at the beginning of anesthetic inhalation and lasts until the loss of consciousness. Analgesia (state of painlessness) is progressively attained, while the patient remains conscious. Stage II, excitement, starts from the moment of loss of consciousness up to the gain of rhythmical respiration. The patient may show signs of excitement such as muscular movements, phonation and irregular respiration. This stage is not always noticeable. In stage III, surgical anesthesia, the patient emerges into a phase of narcosis. The corneal and laryngeal reflex disappear, the pupil starts dilating, and the light reflex is lost. Stage IV, overdose, results in cessation of breathing leading to failure of circulation and death.

To maintain an open airway and to ventilate the patient, tracheal intubation is performed. An endotracheal tube is inserted through the oral cavity and larynx into the trachea. In some cases, to keep the mouth accessible, nasotracheal intubation is performed via the nose. Other surgical methods are cricothyrotomy and tracheotomy. Cricothyrotomy is a potential lifesaving procedure performed in emergency circumstances to secure the airway of the patient, when unable to restore adequate oxygenation. An incision is made through the skin and cricothyroid membrane. In a tracheotomy the incision is made in the trachea. A tracheotomy is more time consuming and is a more complex surgical procedure, hence cricothyrotomy is preferred in emergency circumstances. [4], [5]

In tracheal intubation, when positioning the head and neck and using a laryngoscope to retract the tongue and floor of the mouth, a line of sight to the larynx is required. When there is no clear line of sight, a video laryngoscope may help. A video laryngoscope has a built-in camera, which makes it possible to watch the larynx on a screen during airway management. A Cochrane meta-analysis reported that using video laryngoscopy may reduce the number of failed intubations, particularly in patients with a difficult airway. However, there is no evidence that it reduces the number of intubation attempts or the incidence of hypoxia or respiratory complication. [6]

When difficult intubation is predicted, awake fiberoptic intubation should be considered. The main benefit is that patients maintain their own airway until intubation is successful, hence the procedure can be abandoned at any time. [7]

1.1 Difficult Intubation and Prediction

Difficulties in airway management has potentially serious complications. Failure in securing the airway can result in hypoxic brain injury or even death in a short amount of time. Early recognition of a difficult airway results in a more careful airway plan to minimize the potential for serious airway-related outcome. [8]

The incidence of difficult intubation depends on the definition of a difficult airway. A well-known grading system to predict difficult intubation during laryngoscopy is the Cormack-Lehane grade. [9] A grade 3 or higher represents a poor laryngoscopic view and is known to have a higher risk of several intubation attempts or failure. In apparently normal patients, an incidence of 5.8% (95% confidence interval, 5.4-7.5%) of a grade 3 or higher Cormack-Lehane grade is found. [10] The incidence of serious airway-related complications is relatively low, but the possible outcome is catastrophic. Because of the large number of tracheal intubations, it is an important field of research.

It is of great importance for the anesthesiologist to plan ahead and prevent airway related complications. To predict difficulties in endotracheal intubation before general anesthesia, patients undergo preoperative evaluation in the outpatient clinic. The prediction methods are based on the anatomical inspections of the head and neck area. Examples of prediction methods are the Mallampati-test and the thyromental distance measurement. In the Mallampati-test, the visible oropharyngeal structures in a seated patient with an opened mouth and extended tongue, are observed. [11] Based on the visible pharyngeal structures, a score between I and IV is given (Figure 1-1). The thyromental distance is the distance from the tip of the chin to the superior tip of the thyroid cartilage with the neck fully extended. Both tests perform modest - with a sensitivity of 30% to 60% - specificity of 60% to 80%, and a positive predictive value of 5% to 20%. [10], [12] Both described methods do not provide information on the airway and surrounding tissue itself, therefore predicting difficult intubation can be challenging.

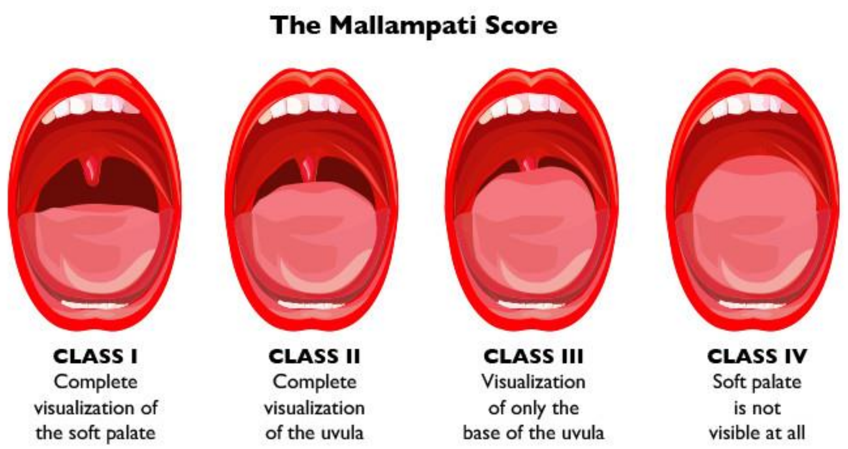

Figure 1-1: Mallampati classification, based on visible pharyngeal structures. [13]

Flexible nasopharyngoscopy is an invasive diagnostic tool to examine the nose, throat and airway. It provides an intraluminal view of the airway and is useful for airway management planning for patients with complex head and neck pathology. It does not always allow a full assessment of the subglottis and upper trachea and is poorly tolerated by a small group of patients. [14], [15]

1.2 Virtual Laryngoscopy

Patients with planned head and neck surgery, known pathology or previous surgeries are more likely to experience difficulties in the management of their airway. For these patients, in most cases, computed tomography (CT) images are already available. This CT-data can be used to create a 3D virtual laryngoscopy (VL), creating a “fly-through” segmentation. This method is an approach to use already existing CT-data in a way that is better known by anesthesiologists. Compared to the flexible nasopharyngoscopy, a virtual endoscopy is not invasive and allows full assessment of the subglottis and trachea. A VL is not hindered by the physical presence of a scope, hence it can look in any desired direction. It can provide cheap, noninvasive and quantitative data for the prediction of difficult to intubate patients and may help the anesthesiologist with planning a difficult intubation.

Ahmad et al. did a study to investigate the potential added value of VL and compared how well virtual endoscopy correlates to conventional nasopharyngoscopy. They found that the VL provides a noninvasive, safe and accurate airway assessment. [14] El-Boghdadly et al. did a prospective cohort study with 10 clinical scenarios of patients with head and neck pathology with CT-imaging, using the OsiriX (Pixmeo SARL, Bernex, Switzerland) software. The clinical scenarios were presented to 20 anesthesiologists, along with CT images, and structured questions were asked about their airway planning. After showing the VL video of the patients, the questions were repeated. This resulted in a change in the airway management plan in half of the cases. Also all 20 anesthesiologist stated that the VL videos helped with the airway assessment and stated that they would use VL when available. [16]

T. Loonen, a formal technical medicine graduate student, performed a pilot study on VL at the Radboudumc. The OsiriX viewer was used to create a semiautomatic VL, the results were discussed with anesthesiologists. From CT-data, OsiriX creates a video path through the airway after manually selecting a start and endpoint. In the evaluated cases, anesthesiologists experienced a better understanding of the seriousness of a stenosis when it was shown in a three-dimensional (3D) endoscopy compared to the two-dimensional (2D) CT-data. However, they would have preferred extra features to optimize the assessment in difficult airways. After the fly-through was rendered, there was no option to change the camera position, orientation and brightness. Also the ability to show the location of the camera position in the airway and the possibility to perform measurements during the evaluation of the endoscopy are desired. Adjustments of the created camera path were time consuming and did not provide direct feedback. [17] Ahmad et al. also wrote that despite all the benefits of VL, there are limitations. The fly-through quality is dependent on the quality of the CT-data and small lesions may not be reconstructed. Also a natural color lacks and excessive smoothing of airway walls may occur. Next to that, the technique only provides static examination. [18] A final disadvantage is the fact that the used OsiriX software only runs on MacOS (Apple Inc., California, USA), while the Radboudumc digital working environment is Windows (Microsoft, Redmond, WA, USA) based.

There are different small studies that show VL is a tool that can help with airway planning in patients with a difficult airway. The previously used OsiriX software is not specialized in VL and lacks desired features. Creating inhouse software adds the possibility to easily customize the software to optimize it for use by anesthesiologists.

1.3 Project Goals

The long term goal of this project is that the anesthesiologist can create a VL to increase the safety of the airway management. The VL helps gaining a better understanding of a difficult airway and improve the created airway plan, thus lowering the incidence of serious airway-related complications. The airway reconstruction, needed for the VL, can be created by the anesthesiologists without the help of the 3D Lab. This lowers the threshold of creating a VL and thus makes it more accessible for the anesthesiologist.

This research project takes the first steps towards achieving this goal. Interactive VL software is developed, that is more in line with the use for anesthesiologists than the previously used OsiriX software. The newly created software performance and user friendliness are tested in a verification study. The initial plan was to also validate the software to show the possible added value it has on airway planning in patients with difficult airways and to test the clinical workflow. Unfortunately, due to the recent COVID-19 pandemic, the study was cancelled.

1.4 Outline of the Report

The next chapter briefly describes the created VL software. Chapter 3 describes the design process of the VL software. First, the stakeholders, design goals and specifications are defined and substantiated. Next, the concept design and the review process is described. In the final part of this chapter, the prototype design is presented and a more in depth view on the software development is given. In Chapter 4, the performed validation- and planned verification study are described. Chapter 5, discusses the results of these studies, and offers a future perspective on the use of VL in the Radboudumc. The final chapter contains the conclusion of this research project.

2 Product overview

For the anesthesiologist a 3D representation of the airway in the form of a VL is a tool that can help with airway planning in patient with a difficult airway. This is not used in the current clinical workflow.

Software is developed that creates a VL from the, already available, CT-data. De software shows the contours of the patient and their airway anatomy. This provides a clear overview of the airway anatomy of the patient. The user can navigate a VL camera through the airway, viewing the intraluminal airway. Because the software is developed for inexperienced users, functionalities are added to help the user with navigating the VL camera. Options are provided to perform simple intraluminal measurement.

To ensure the VL software is clinically accessible, it is important that the software is user friendly and easy to use. This is the reason why, instead of a user manual, a wizard user interface is provided. It presents well-defined steps to create a step-by-step workflow. This enables the use of VL by anesthesiologists without the need of elaborate training, additional instructions, or the 3D Lab. Figure 2-1 shows an overview of the created VL software. In Figure 2-2[1], an example is given of the created VL software. The next chapter describes the software features, design, and design considerations in more detail.

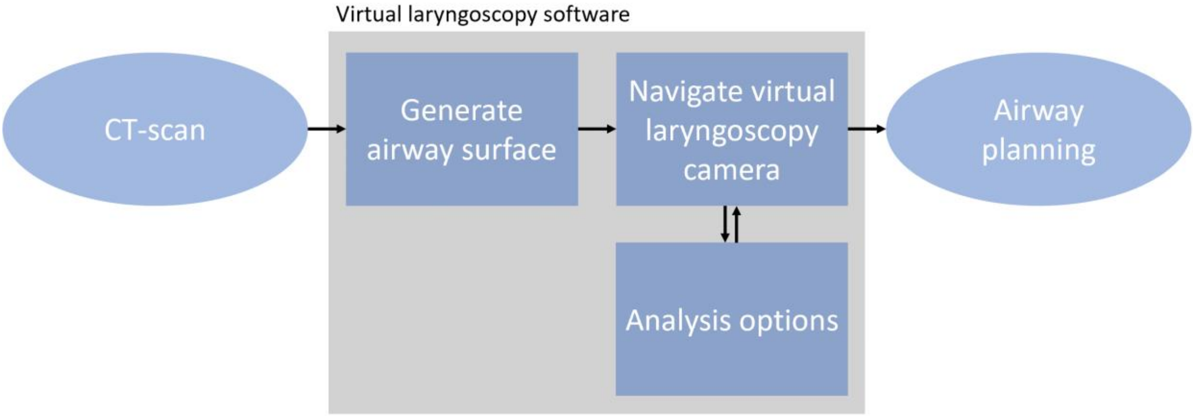

Figure 2-1: Overview of the created VL wizard. A CT-scan is loaded into the software, where the airway surface is generated. The user is able to view the intraluminal airway surface by navigating the VL camera. Simple analysis options are added to enable better airway examination. The software is designed to support the anesthesiologists in difficult airway planning.

[1] The surface is positioned to not show the face of the patient, this is done ensure the privacy of the patient.

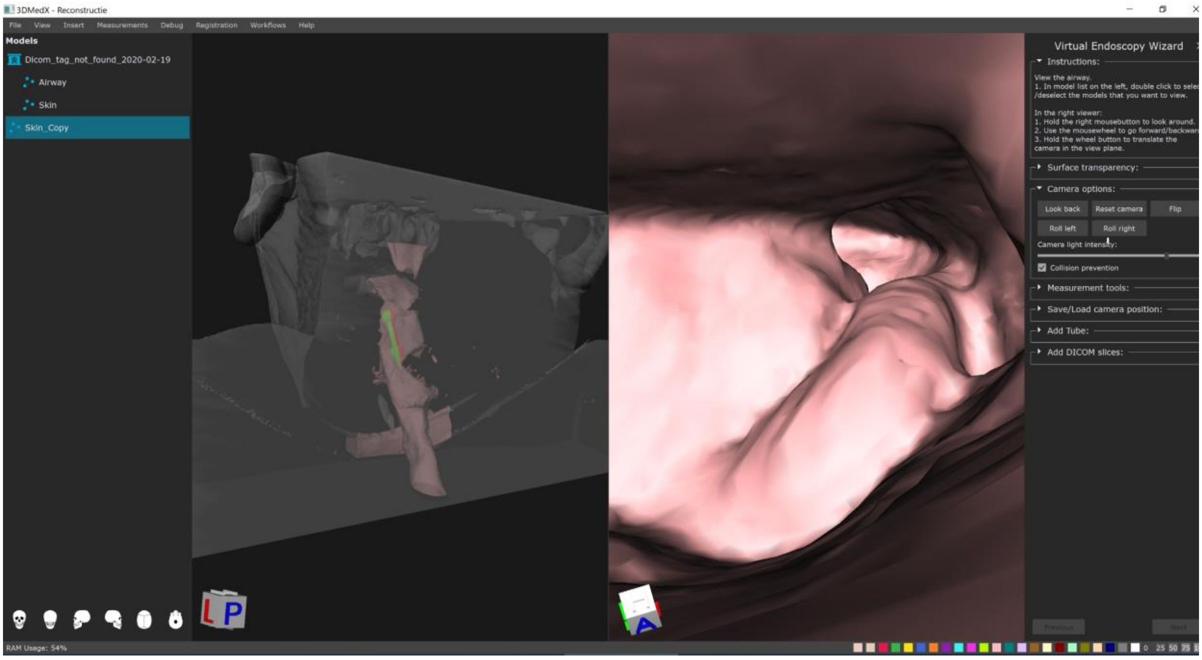

Figure 2-2: Created VL wizard. Next to the VL camera view, an overview of the anatomy is shown (left). The wizard interface, providing user instructions, is shown on the right.

3 Product design

This chapter describes the design process and functionalities of the software. First the stakeholders, design goals and requirements are defined and substantiated. Next, the created concept version is described and analyzed. The final software product created in this master thesis is described in Paragraph 3.5 Prototype Design. Finally, a more in depth view on the software design is given.

3.1 Stakeholder

The stakeholders for the designed VL software are the patients with a difficult airway, the anesthesiologists and the 3D Lab Radboudumc software engineers. The patient will be undergoing general anesthesia and wants the best possible care The anesthesiologist creates an airway plan and provides the general anesthesia with minimal risk. The anesthesiologist wants to prepare the airway in the best possible way and it is expected that using VL results in safer airway management. For the anesthesiologist to embrace this technique it should be applicable within the current clinical workflow. The VL should be intuitive and user friendly so the anesthesiologist can create and assess the VL without the direct support of the 3D Lab. The final stakeholder is the 3D Lab software engineer, who takes care of the maintenance of the designed VL software and demands low maintenance software.

3.2 Design Goals and Specifications

Based on the recommendations by T. Loonen, described in the introduction, and opinions of several anesthesiologists at Radboudumc, the following design goals and corresponding requirements are defined for the VL software. [17] In Table 3-1 an overview of the design goals (bold) and corresponding specifications (plain text) are shown, discussed in more detail below.

Table 3-1: Overview of the composed design goals (bold) and corresponding specification (plain text) for the VL software.

Basic functionalities
Create airway surface from CT-data
Add surface color and lighting to mimic airway tissue
Create camera movement through surface
Possibility of further development
Programmed within the 3DMedX software
Added features
Interactable camera
Changeable camera light intensity
Distance measurement during the VL
Show location of the camera in the airway

User friendliness
Clear interface and a wizard that guides the user through the steps of the workflow
Functionalities that assist the user in the camera controls
Only options that are required are added

Basic functionalities: the software is designed to show CT-data as a VL.
Even when available, a CT-scan of the head and neck area is often not used by anesthesiologist in case of a difficult airway. Anesthesiologists are not used to reading CT-data, because viewing three orthogonal slices is experienced as difficult. The main purpose of the software is to make the CT-data easily accessible for the anesthesiologist. The software should translate the CT-data to a VL, since anesthesiologist are familiar with the views of a flexible nasopharyngoscopy. So, the CT-scan should be used to create a surface that can be viewed in the VL.

The first step is to segment the airway from the CT-data to create the airway surface. The segmented surface should look like the airway when viewed in a nasopharyngoscopy. Therefore, color and lighting are required. After creating a realistic 3D model of the airway, the user should be able to navigate in the virtual airway with a virtual camera. The virtual camera shows the user the intraluminal airway.

Possibility of further development: the software is created in a way that the development can easily be transferred to 3D Lab programmers.
In the 3D Lab, software engineers are working on 3DMedX software. The software allows the users to create surfaces from CT-data, view and edit 3D models. It is currently used by several departments in the Radboudumc. The VL is created in 3DMedX. So, at the end of this research project, the software can be easily transferred to the current 3D Lab software team. This allows further development of the software, and collaboration with the department of anesthesiology. This ensures continuous improvement of the created VL to ultimately become part of the clinical workflow in difficult to intubate patients. The 3DMedX software already has functionalities for the segmentation of CT-data, which can be used in the VL that is created in this research project.

Added features: the software has extra features compared to the previously used OsiriX software.
At the earlier performed pilot study at the Radboudumc, the OsiriX software was used. As mentioned in the introduction, this software only has video output and is not interactable. Manual change of camera position, orientation and brightness are not available. Only distance measurements in the orthogonal slices are possible. One of the conclusions from the earlier pilot study showed that measurements in the virtual view are useful for the interpretation of the airway and should therefore be implemented. [17] Furthermore, anesthesiologists experienced difficulty in identifying at which anatomical position the virtual camera was located in the airways using the OsiriX software. The location was shown in the orthogonal CT slices, but a more clear method to show the camera position is desired.

User friendliness: The software should be user friendly; the anesthesiologist should not need previous or a user manual.
After the earlier performed pilot study at the Radboudumc, only a few virtual laryngoscopies using the OsiriX software were used. The reason of this limited use by anesthesiologists was that external engineers at the 3D Lab are required to create the VL in OsiriX. This takes extra time and effort, and is most likely the reason virtual laryngoscopies are not often requested.

To make VL more accessible, an important design requirement is to make it user friendly. Ultimately, the anesthesiologist should require no extra support and should be able to create the VL on his/her own. The interface and wizard should guide the user, possibly without previous training, through the steps of setting up the VL. The control of the virtual camera should be intuitive and the user interface should be as simple as possible. Extra options and features may overwhelm the user.

3.3 Concept Design

In this paragraph, the software functionalities and the concept version of the VL are described. The choices made during the design are substantiated.

The VL is created as a wizard within 3DMedX environment. A wizard is a user interface type that presents well-defined steps to help the user with complex tasks, it guides the user step-by-step through the workflow. The 3DMedX software uses C++ as programming language in Visual Studio 2017 (Microsoft, Redmond, WA, USA), Open Inventor 9.9.12 (ThermoFisher ScientificTM, Waltham, USA) (OIV) and Qt 4.7.2 (The Qt Company, Helsinki, Finland). OIV is a commercial 3D software development toolkit, developed for the application in medical, dental, oil, gas and engineering industries. The main benefit is the high level integration of 2D and 3D data visualizations. Qt is used to create the graphical user interfaces. A more in depth view on the software design is given in Chapter 3.6

The standard interface of 3DMedX is shown in Figure 3-1.

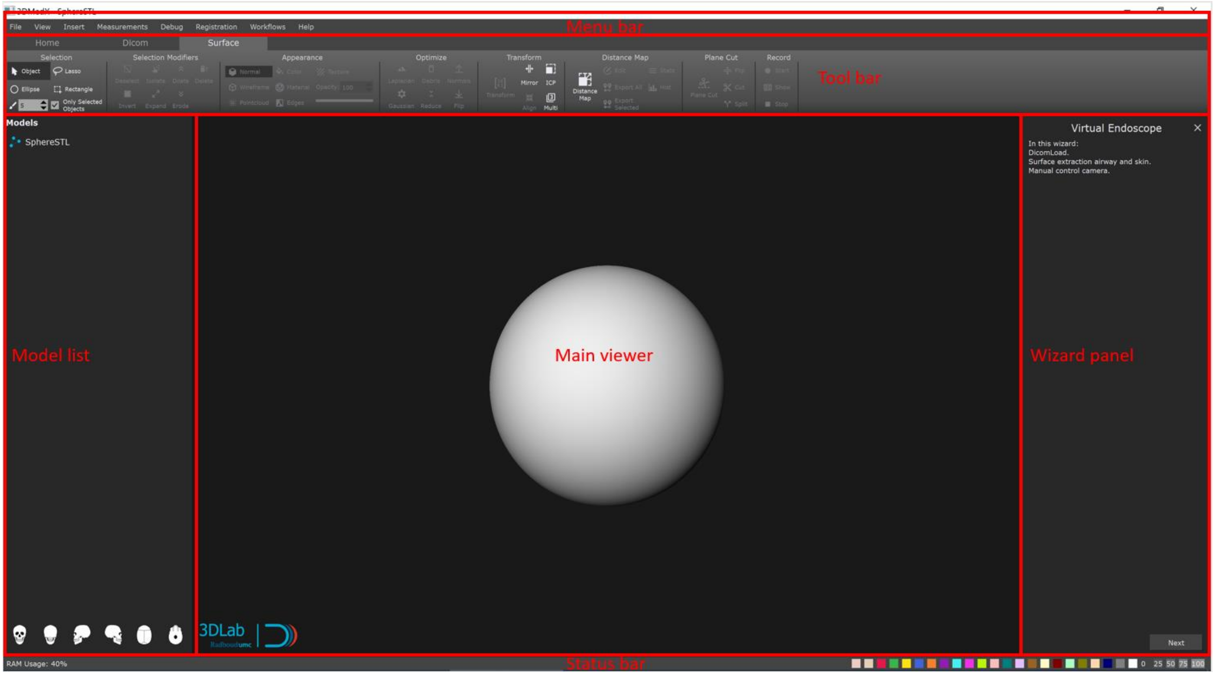

Figure 3-1: Standard lay-out of 3DMedX with the 'Menu bar', 'Tool bar', 'Model list', 'Main viewer', 'Status bar' and 'Wizard panel' highlighted.

In the 'Model list', the titles of the loaded models are shown. In the 'Main viewer' the loaded models are visualized, in the example figure a sphere. The 'Tool bar' can be used to perform different features from the 3DMedX software. The 'Wizard panel' shows the wizard, if opened by the user.

The VL wizard has different wizard pages that guide the user through the process of creating a VL. Instructions for every wizard page are provided at the top of the 'Wizard panel'. These wizard pages, along with their functionalities of the concept design, are described below and are summarized in Table 3-2.

Table 3-2: Overview of the wizard pages and their functionalities in the concept VL wizard.

Wizard pages	**Functionalities**
Introduction	Inform the user about the wizard steps
Load data	Load the desired CT-scan
Surface extraction – airway	Select starting position of the virtual camera. Select threshold area, threshold values and extract surface
Surface extraction – skin	Select threshold area, threshold values and extract surface
Virtual laryngoscopy	Dual viewer with overview and laryngoscopy view Control camera Perform added features

On the 'Introduction' page, the user is informed about the steps needed to create the VL. In the 'Load data' page, the user is asked to select the folder containing a Digital Imaging and Communication in Medicine (DICOM) files of the CT-scan. After that, a pop-up screen appears that shows the CT images along with the DICOM tags, to allow the user to check if it is the desired CT-scan. The ‘Load data’ page with the pop-up is shown in Figure 3-2. After clicking next, the CT-scan is loaded and the ‘Surface extraction – airway’ page is opened.

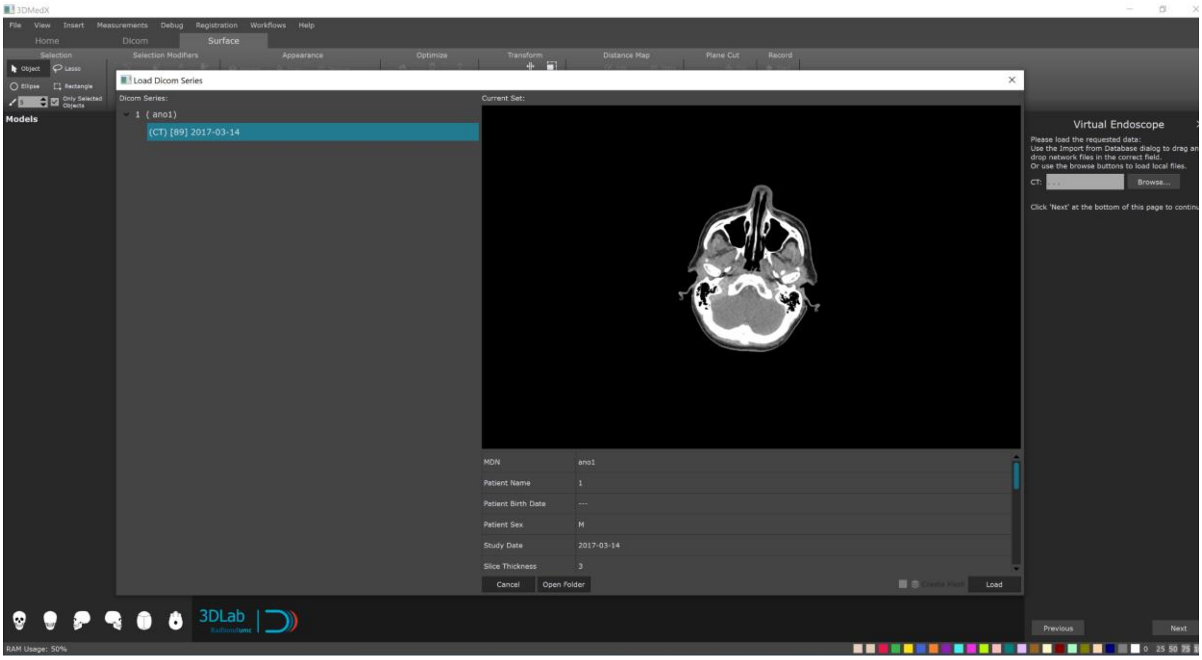

Figure 3-2: Interface of the ‘Load data’ page, after a DICOM is selected, it shows DICOM slices and tags.

The ‘Surface extraction – airway’ page opens a quad viewer as shown in Figure 3-3. On the left three viewers show the orthogonal CT-slices, the right viewer shows a volume render of the loaded CT-data. The user is asked to select an initial position and direction of the camera for the VL, that will be shown later on the ‘Virtual laryngoscopy’ page. The camera position is selected by left-clicking in one of the ‘Orthogonal viewers’: a red dot will appear that shows the selected camera position. With a next click, an arrow will appear showing the direction of the VL camera, this completes placing the initial location and orientation of the camera. It also makes a blue region of interest (ROI) appear that shows the region of the CT-scan that is extracted. Clicking a third time, resets the camera position and direction. The initial camera position and direction with the ROI are shown in Figure 3-4, this is a close up of the sagittal orthogonal viewer from the ‘Surface extraction page - airway’ in Figure 3-3.

The size and threshold of the ROI are adjustable using the spin boxes and sliders in the ‘Wizard panel’ on the right. The boxes on the boundaries of the ROI also allow the user to adjust the size of the ROI. The ‘Wizard panel’ also shows default options and actions that can be performed, they are shown by default, however they are not used in this wizard.

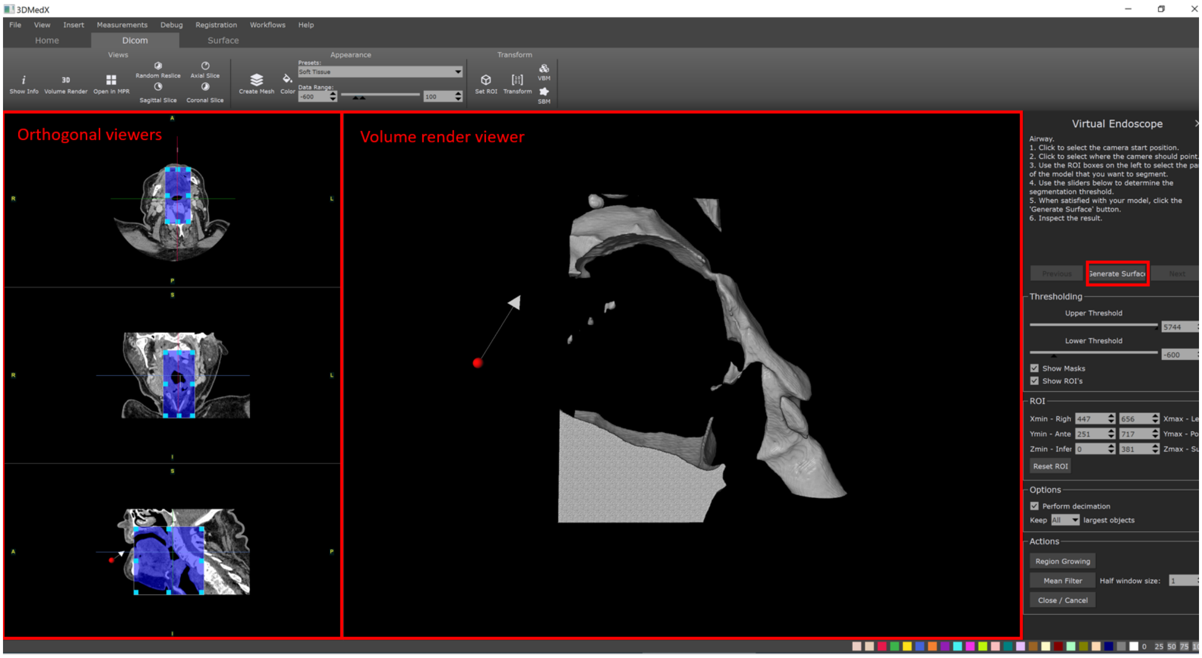

Figure 3-3: Interface of the 'Surface extraction – airway' page. Left orthogonal viewers, right the volume render viewer. In the 'Wizard panel' the 'Generate Surface' button is highlighted.

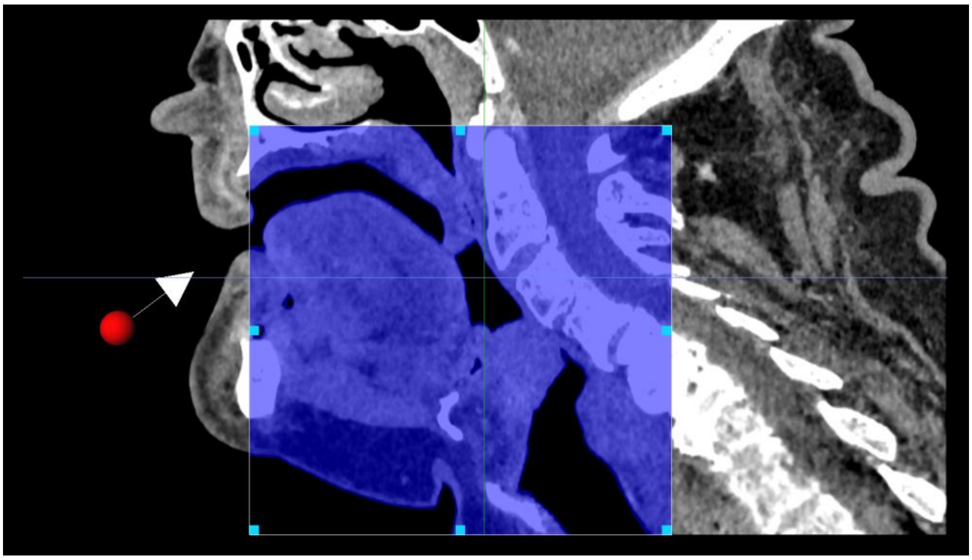

Figure 3-4: Close up of the sagittal slice of the 'Surface extraction – airway' page, the red coordinate represents the initial position of the VL camera and the arrow the direction. The blue box is the ROI and shows what is segmented.

After the desired ROI and thresholds are selected, the 'Generate surface' button will extract the airway surface and open the 'Surface extraction – skin' page. The created airway extraction will be used to create the surface of the airway that is showed in the 'Virtual laryngoscopy' page.

After the airway extraction, a skin extraction is made as shown in Figure 3-5. Only the ROI and threshold should be adjusted to create the desired extraction. The skin extraction is made to help visualize the location of the VL camera within the airway on the ‘Virtual laryngoscopy’ page.

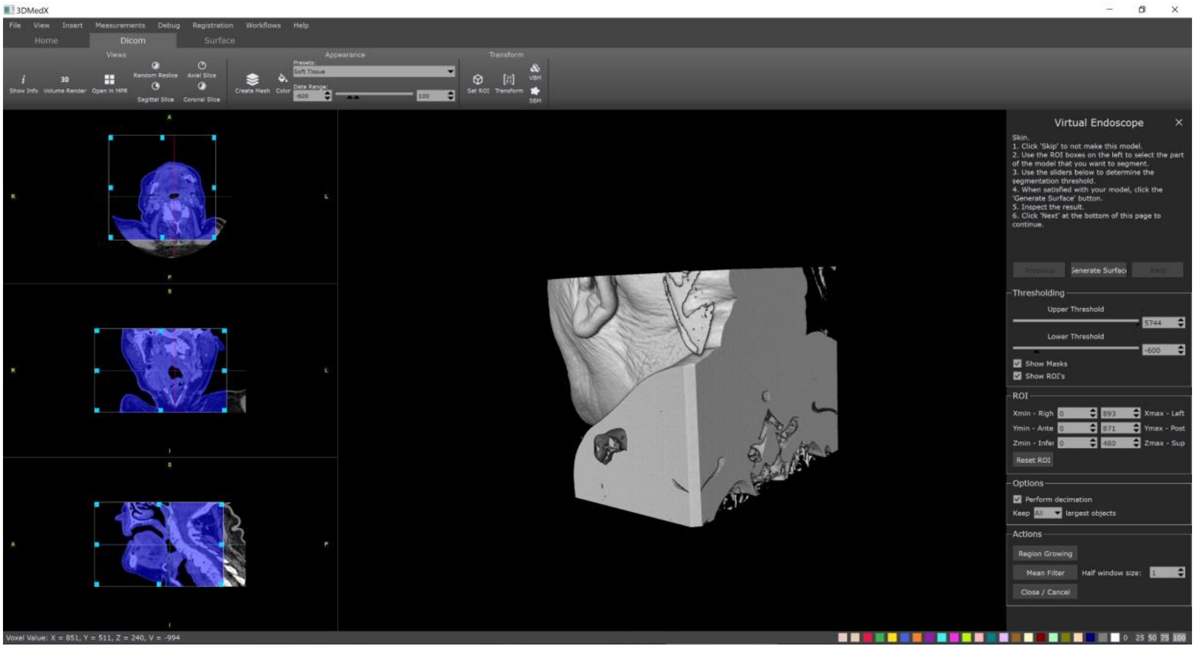

Figure 3-5: Interface of the ‘Surface extraction – skin’ page. The interface is similar to the airway page, without choosing the initial camera position and direction.

Both the function to load in the CT-data and to create extractions, already exist in the default 3DMedX software, however for the VL they are placed on the wizard pages. This way, only the VL wizard is used to guide the user through the required steps, this makes it more user friendly for users with no experience with the 3DMedX software.

After both the airway and skin extractions are made, the ‘Virtual laryngoscopy’ page is opened as shown in Figure 3-6. In the left viewer an overview of the skin and airway surface is shown. The red dot and cone represent the virtual laryngoscope camera position and direction. It is connected to the virtual camera on the ‘Virtual laryngoscopy viewer’. The right viewer shows the VL, the camera is positioned at the initial position selected in the airway extraction page. In this viewer, the user can rotate the camera by pressing the right mouse button while moving the mouse. The mouse wheel button and mouse movement can be used to translate the VL camera up, down, right and left. The mouse wheel can be used to translate the camera forwards or backwards.

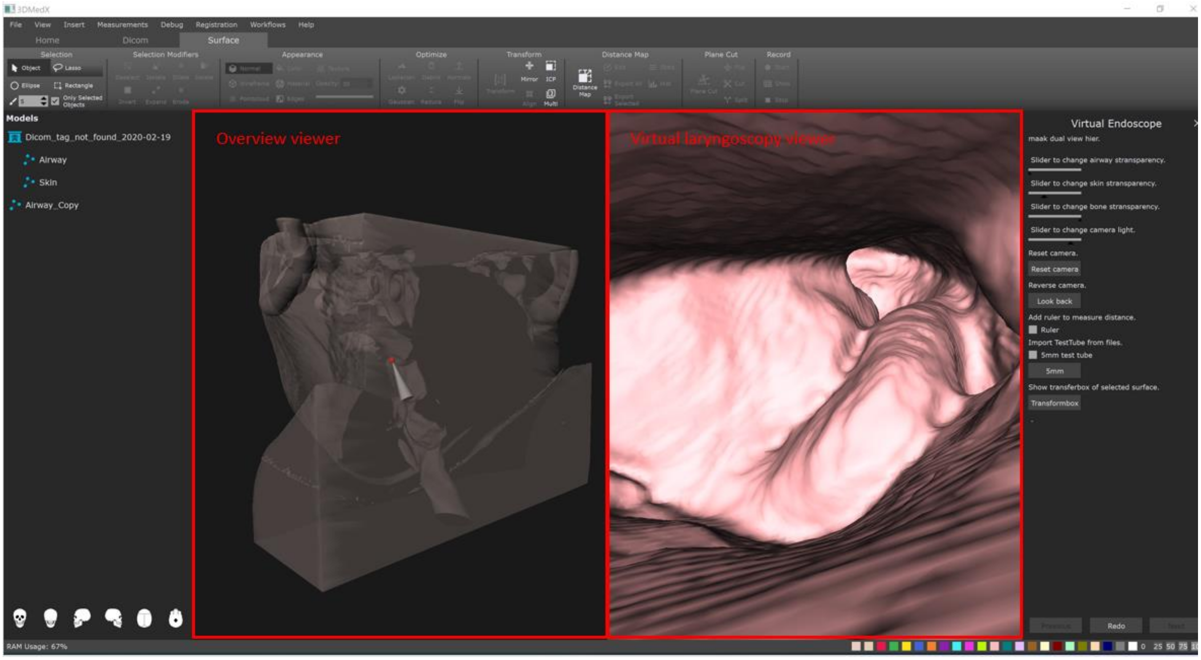

Figure 3-6: Interface of the 'Virtual laryngoscopy' page. The left 'Overview viewer' shows an overview of the skin and airway, the right 'Virtual laryngoscopy viewer' shows the VL view.

In the 'Wizard panel', sliders are added to change the transparencies of the surfaces in the 'Overview viewer' and the brightness of the VL camera. These options enable the user to adjust the view to the desired result.

Push buttons are added to help control the camera of the 'Virtual laryngoscopy viewer'. With the 'Reset camera' button, the camera can be returned to the starting position and direction. The 'Look back' button rotates the camera to point in the opposite direction.

A measurement tool can be added by selecting the 'Ruler' checkbox. While checked, left-clicking on the surface in the 'Virtual laryngoscopy viewer', adds a coordinate to the clicked location. On the second click another coordinate is added, the coordinates are connected and the distance between the coordinates is shown. On a third click the points are deleted and the user can start over again. In Figure 3-7, an example is given of this measurement. The patient shown has a stenosis of the airway, the diameter of the remaining airway passage is shown.

By checking the 'Test tube' checkbox, a tube with a 5 mm diameter is placed between 2 clicked points (Figure 3-8). This is added to give the user more sense of the distances within the VL. The test tube can be translated and rotated using a transform box.

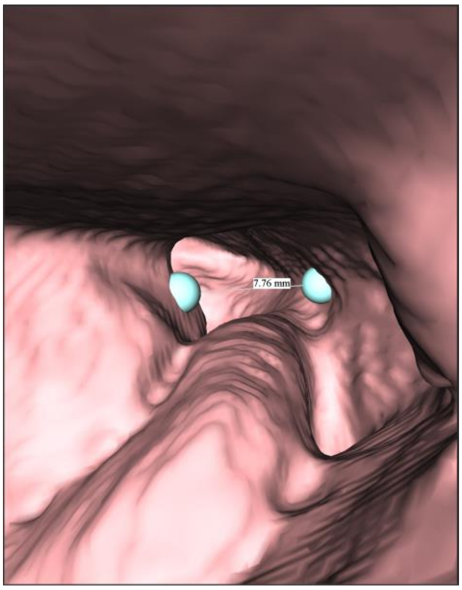

Figure 3-7: Measurement tool visualized in the 'Virtual laryngoscopy viewer'.

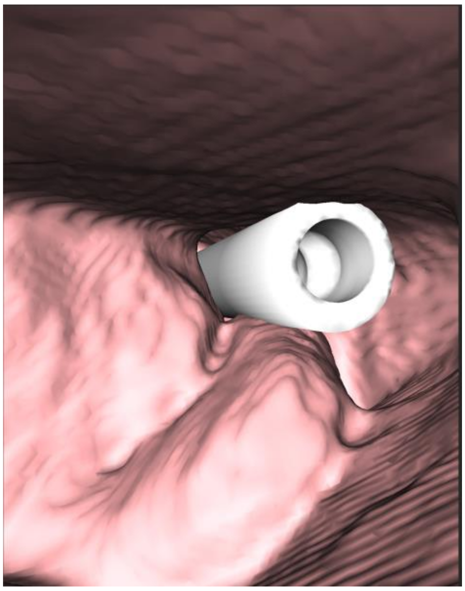

Figure 3-8: Tube visualized in the 'Virtual laryngoscopy viewer'.

The concept design is summarized in the flow chart in Figure 3-9. Each wizard page is represented as a box with the optional user actions in the body of each box.

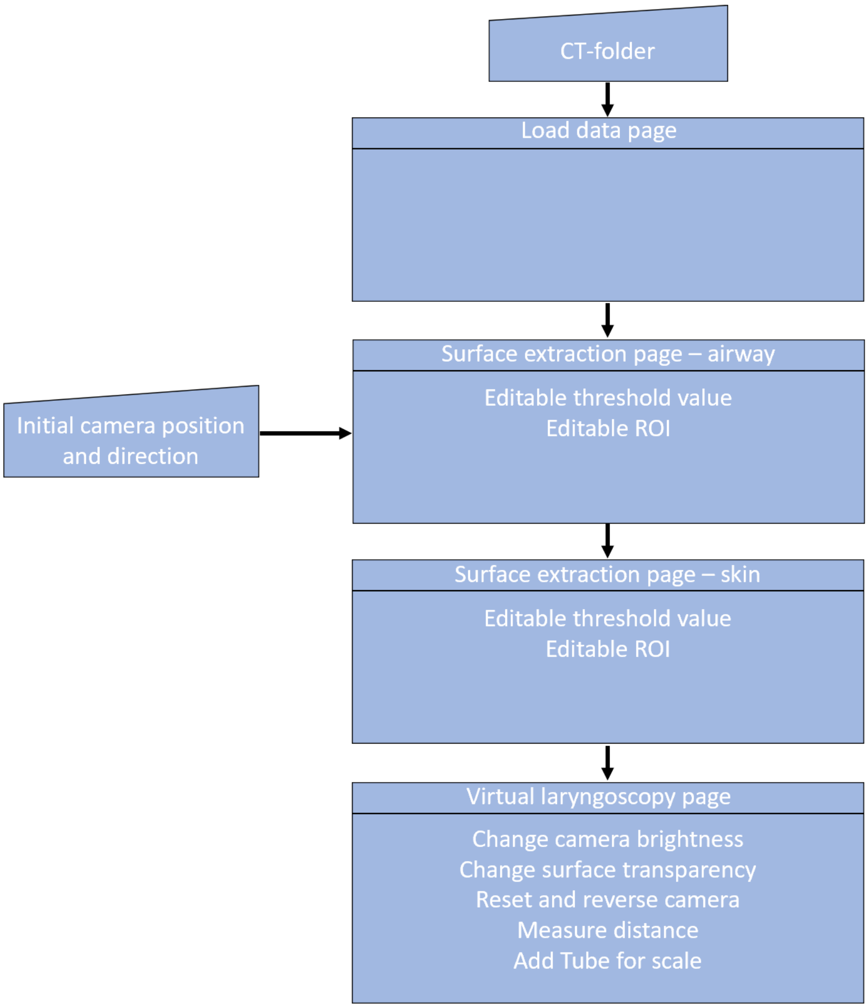

Figure 3-9: Flowchart of the software concept design. Manual inputs are the CT-folder and the initial camera position and direction. Each wizard page is represented as a box with possible actions for the user in the body of each box.

3.4 Concept Review

The previously described concept laryngoscopy wizard design was discussed with anesthesiologists and engineers. Per previously defined design goals, the concept design was reviewed. An overview of the desired improvements is shown in Table 3-3.

Table 3-3: Overview of the desired improvements after reviewing the concept VL wizard with anesthesiologists and engineers.

Added features
Camera collision prevention
Change camera model
Add bone extraction
Change measurement coordinates after placement
Angle measurement
Add tube model with easy translation and rotation
User friendliness
Remove unnecessary parts of the interface
Instructions should be added to guide the user through the wizard

Basic functionalities

In general, the reviewers were happy with the basic functionalities provided by the VL software. It could be concluded that in the concept laryngoscopy wizard, the basic features are working properly. The surface extraction works well and the surface color mimics airway surfaces good. The camera moves smoothly through the airway surface.

Possibility of further development

The VL, being created in the 3DMedX software in the form of a wizard, allows further development. Programmers at 3D lab created this environment and thus are well-known with it, which makes further development convenient.

Added features

The interactable VL camera allows the user to freely roam through the airway. Compared to OsiriX, the user is not bound to video footage of a fly-through through the airways. The created concept allows the user to get a better view on specific, self-chosen, surface areas. However, this feature may also lead to difficulties. Because the user can move the camera freely through the airway surface, it may disorient the user when the VL camera gets outside of the airway surface. Collision prevention, which helps the user to keep the VL camera within the airway surface, is a desired feature to prevent this situation. The sliders to change the camera light intensity and surface transparency work properly, it allows the user to customize the view to the desired result.

The ‘Overview viewer’, showing the skin and airway make it easy to know where the laryngoscopy camera is within the airway surface. The red dot and the cone show the VL camera position and direction within the surface of the skin. However, it is not clear to the user in what direction the camera model is pointing. Furthermore, the reviewers concluded that a bone surface is desired, because anesthesiologists often orient via anatomical landmarks on bony structures.

The reviewers concluded that the measurement tool works properly, however an extra feature is desired to adjust the measurement coordinates that make it easier to measure the desired distance. Also an angle measurement seemed useful, to create an even better view of the intraluminal airway.

The test tube placement works, however transforming it using the transform box is considered very difficult. The test tube needs to be replaced with a tube model and translating and rotating it should be easier.

User friendliness

The functionalities to control the VL camera are useful to simplify the camera movements. Because it is a concept, the interface design was not prioritized. Not required parts of the interface and wizard should be removed to make it more user friendly and simple to use. For example, the ‘Tool bar’ should be removed, because it shows many options that are not used in the VL wizard.

Instructions need to be added on every wizard page to guide the user through the process, without the use of a user manual or previous experience.

3.5 Prototype Design

The final prototype design is described below, the desired improvements described in the concept review are added to the prototype design. In Paragraph 3.3 Concept Design, the main features and application of the software have been described. This paragraph exclusively describes the changed or added feature. These are, again, described per wizard page in chronological order.

The ‘Introduction’ page, shown in Figure 3-10, introduces the user to the content of the wizard and instructs the user to follow the instructions given by the wizard. Compared to the concept version, the ‘Tool bar’ hides when the VL wizard is started. Users found it distracting and there is no need for it while using the wizard.

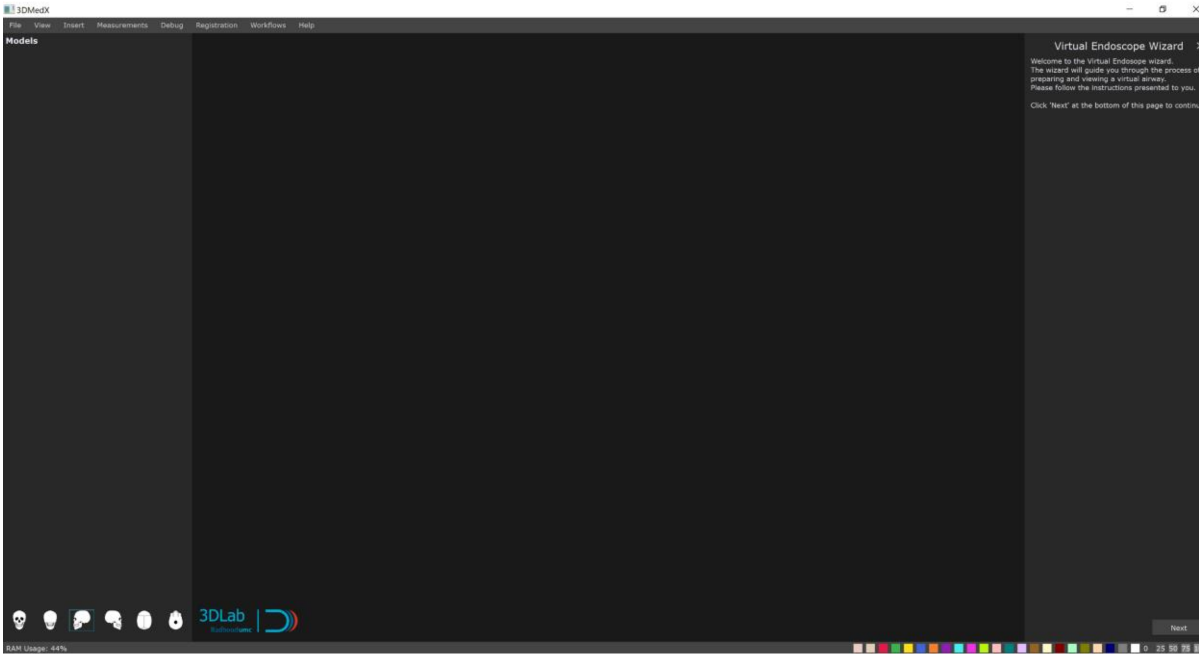

Figure 3-10: Interface of the 'Introduction' page that introduces the user to the content of the wizard. The 'Tool bar' is collapsed when the VL wizard is opened.

A new feature at the 'Load data' page is, that the user also has the option to load a previously created reconstruction. If this option is chosen, the user is asked to select the location of the previously created '.3med' file[2]. In Figure 3-11 the interface of the 'Load data' page is shown after a previously made reconstruction is loaded. In the orthogonal viewers on the left, the user can pick the initial camera position and direction in the same way as described in the concept design. When the 'Next' button is pressed, the 'Virtual laryngoscopy' page is opened. This saves time, because the steps needed to create the airway and skin extraction can be skipped.

In the prototype design, the wizard only enables buttons that can be selected by the user. This makes it easier to follow the wizard instructions. For example, in Figure 3-11, a file is already loaded, so only the 'Next' button is enabled to help guide the user.

[2] File format created by 3DMedX.

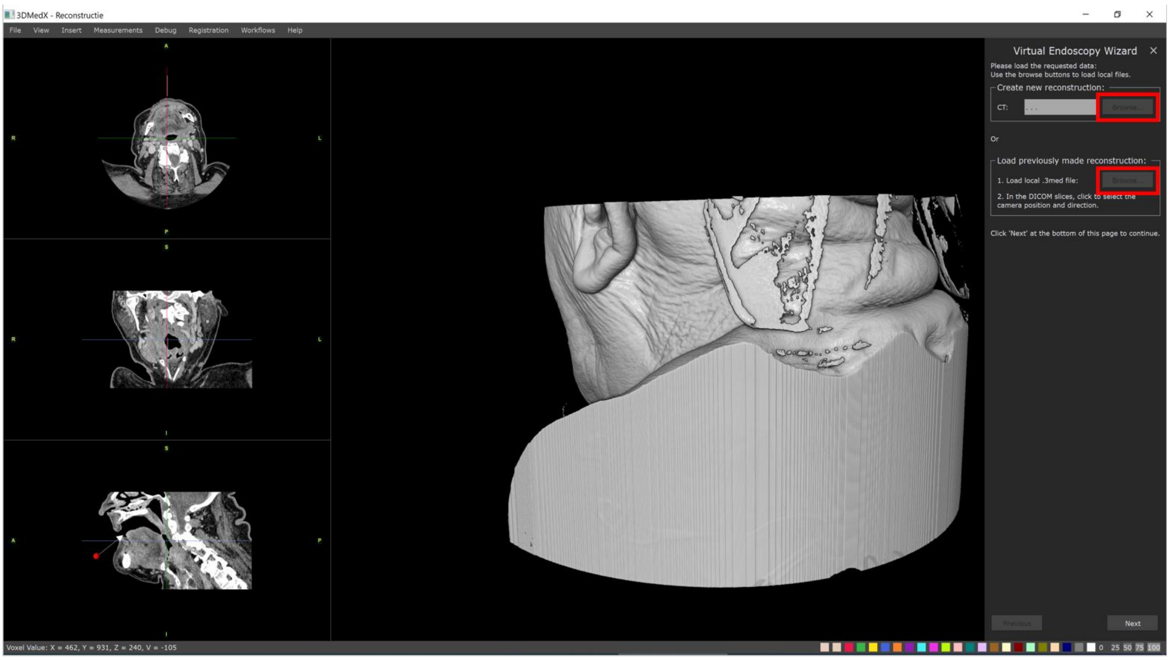

Figure 3-11: Interface of the ‘Load data’ page after a ‘.3med’ file is loaded. The camera position and direction are manually picked on the orthogonal slices. The highlighted buttons are disabled because the action is already performed.

The updated prototype ‘Surface extraction – airway’ page, is shown in Figure 3-12. Compared to the concept version, unnecessary options are hidden in the wizard panel to keep the user interface simple. Identical to the concept version, the user selects the camera position and direction, and selects the desired ROI and thresholds so the airway is visible in the volume render viewer.

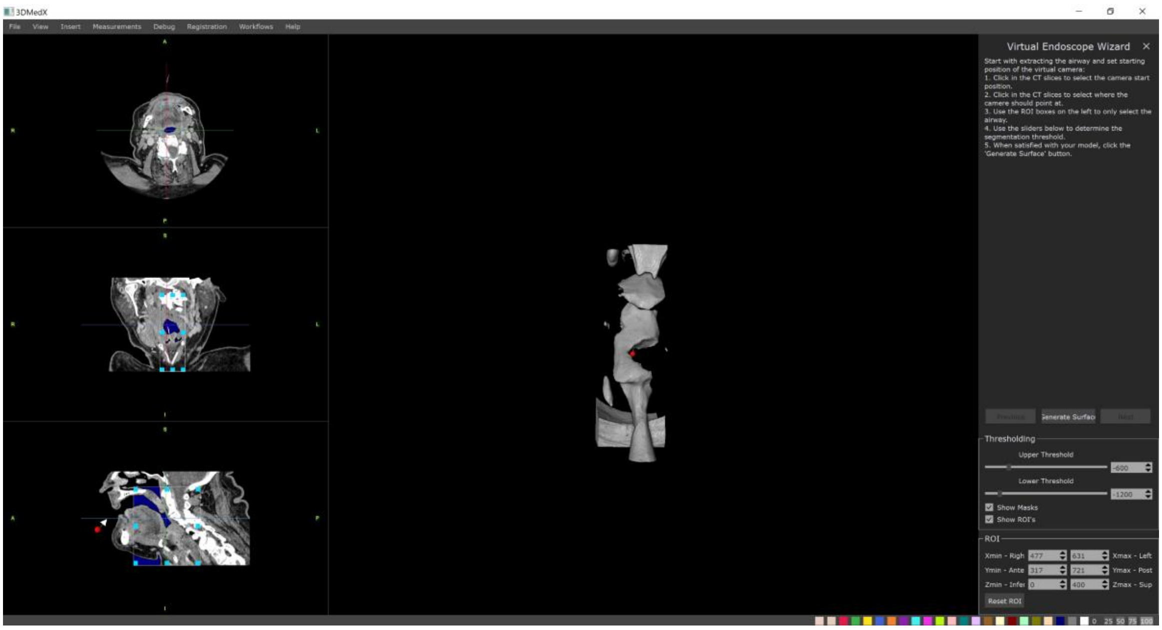

Figure 3-12: Interface of the ‘Surface extraction – airway’ page. In the ‘Wizard panel’ options are hidden.

The ‘Surface extraction – skin’ page, shown in Figure 3-13, is almost similar to the concept version. The two changes on this page are: again, unnecessary options in the wizard panel are hidden and secondly the skin extraction is skippable.

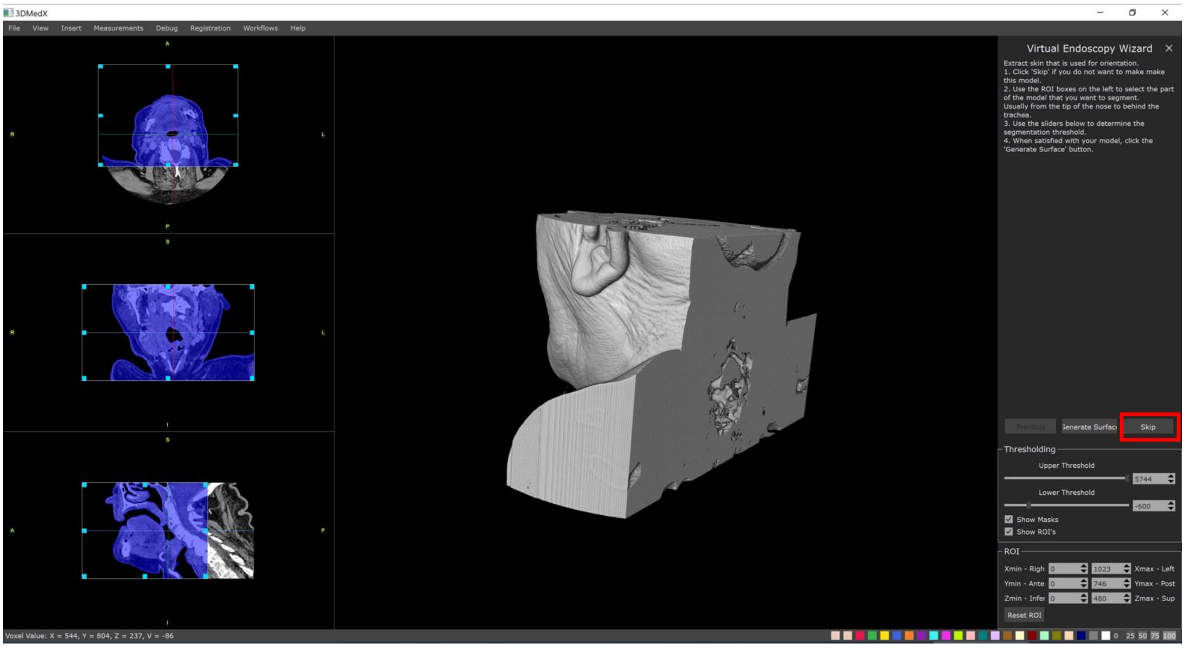

Figure 3-13: Interface of the 'Surface extraction – skin' page. The added 'Skip' button is highlighted.

After the 'Surface extraction – skin' page, a new 'Surface extraction – bone' page is opened. Both the skin and bone extraction, that help the user with orientation at the 'Virtual laryngoscopy' page, are optional. They are both skippable to save time, depending on the preference of the user. When skipped the user only has the airway surface available in the 'Virtual laryngoscopy' page. After the extractions are made or after a '.3med' file is loaded, the wizard opens the 'Virtual laryngoscopy' page as shown in Figure 3-14. Similar to the concept version, the left viewer shows an overview and the right viewer the VL.

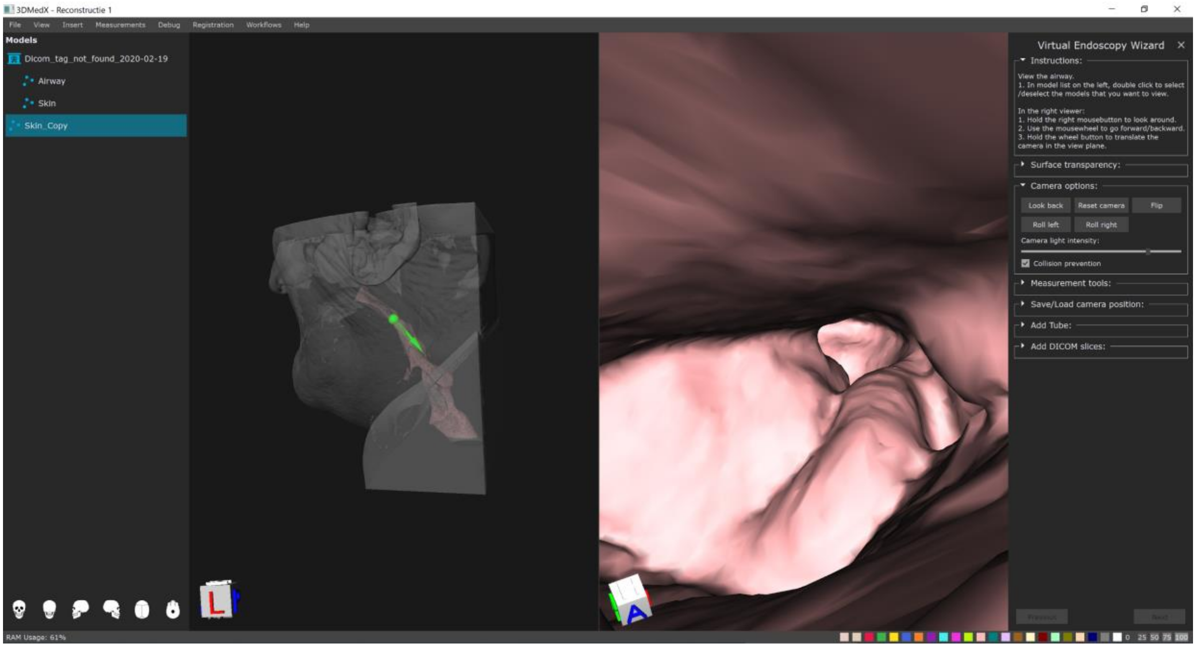

Figure 3-14: Interface of the 'Virtual Laryngoscopy' page. In the left bottom corner of the viewers a medical compass is added. In the 'Wizard panel' the functionalities are grouped in boxes.

The 'Overview viewer' shows a transparent surface of the airway and, if made, skin and bone are shown. The different surfaces now have different colors, resulting in easy to distinct 3D surfaces. The camera model to show the VL camera within the airways, is changed to an arrow. This makes it easier to see the position of the VL camera and the direction the camera is pointing to. The arrow has a red and green side, representing the left and right side of the VL camera. A medical compass is added in the bottom left of the viewer, showing the orientation of the airway. These features help the user to know in what position the VL camera is inside the airway.

In the right viewer the VL is shown. The controls of the VL camera are the same as in the concept version. To make navigation through the airway more user friendly, the camera has collision prevention to prevent the camera to translate out of the airway surface.

On this page, many new options were added. To keep these organized, they are grouped according to functionality, preventing too many options being shown at the same time. This resulted in eight collapsible group boxes, enhancing the user friendliness of the VL. By default, only the 'Instructions' and 'Camera options' group boxes are unfolded. The other group boxes are collapsed, since they are not always required.

In the 'Instructions' group box, user instructions for the 'Virtual laryngoscopy' page are shown.

In the 'Camera options' group box, buttons are added to perform camera movements. The originally designed buttons and camera brightness slider are moved to this group box and are added to help the user control the camera through the virtual airway surface. The new functionalities in this group box are:

- The ‘Flip’ button performs a roll of 180 degrees to flip left and right of the VL camera.
- The ‘Roll left’ and ‘Roll right’ buttons slightly rotate the VL camera around the view direction of the camera.
- An option is added to disable the collision prevention. When the airway is fully closed, it would not be possible to proceed behind a closed airway. The camera needs to move through the surface to get to the other side of a closed airway to continue VL.

The ‘Surface transparency’ group box groups the already created transparency sliders.

The ‘Measurement tools’ group box, allows the user to perform distance and angle measurements. The ‘Ruler’, that measures distance, works similar to the concept version. However, the measurement coordinates can now be moved after positioning to make small adjustments. A newly added ‘Angle’ option works similar to the ‘Ruler’. Three coordinates are placed on the surface, the angle between the spheres is calculated and visualized in the viewers. It can be used to generate more specific information on the airway structures. An example of the ‘Ruler’ and ‘Angle’ tool are shown in Figures 3-15 and 3-16.

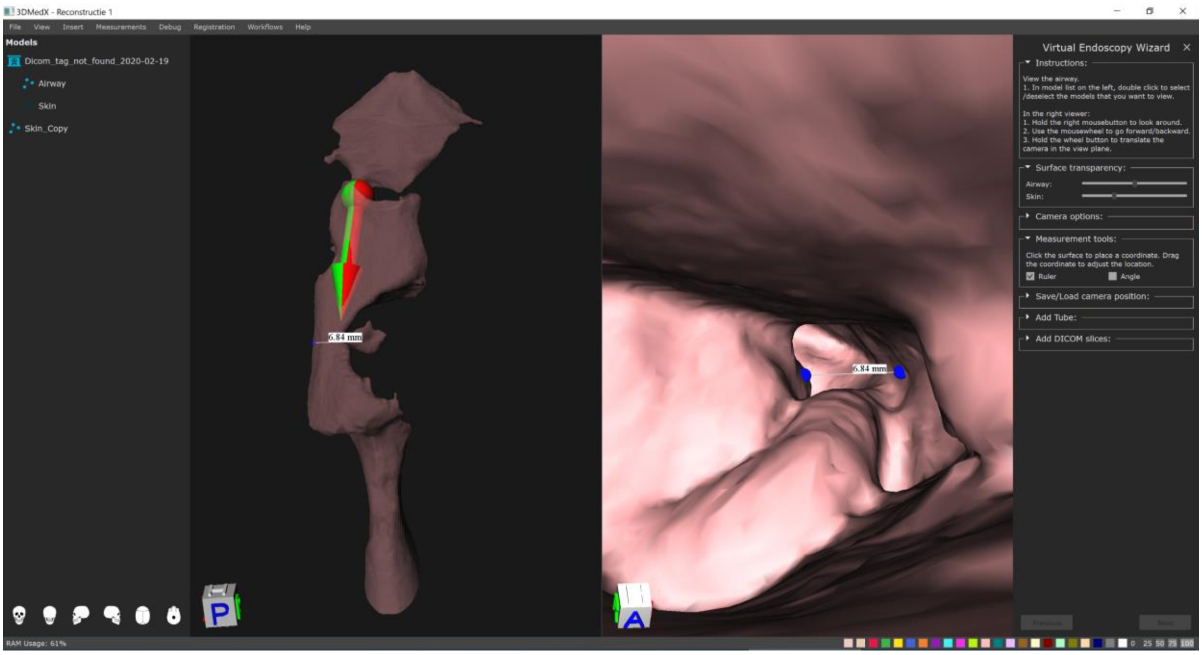

Figure 3-15: Example of a ‘Ruler’ measurement tool to measuring the diameter of the airway.

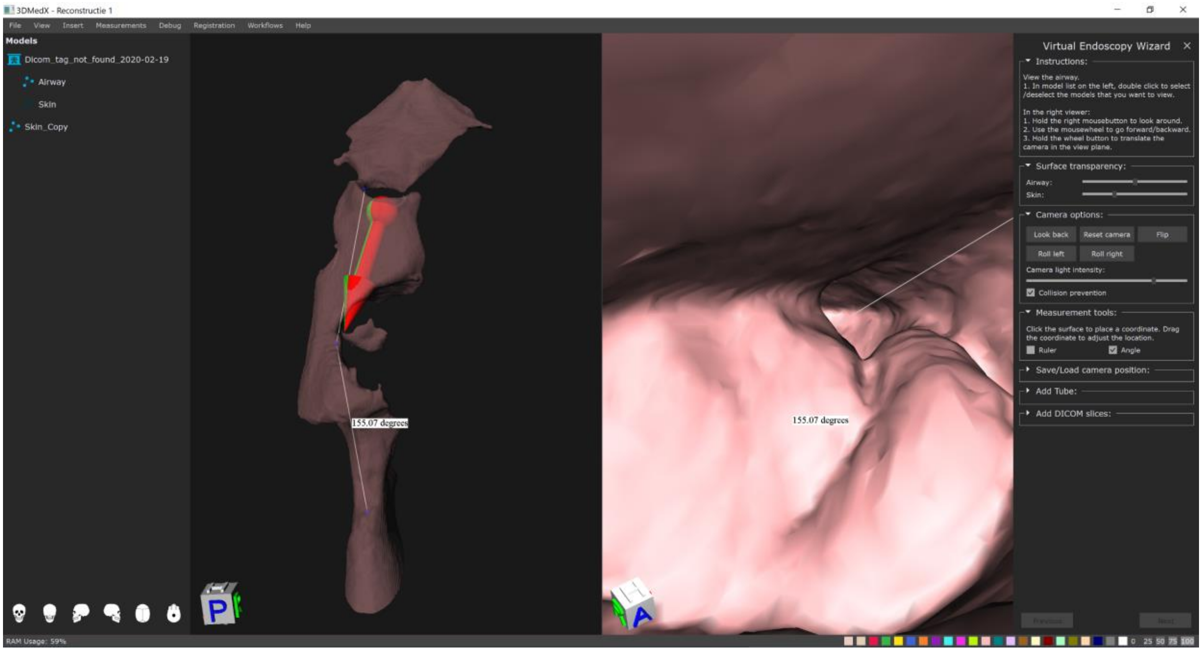

Figure 3-16: Example of the ‘Angle’ measurement tool, measuring an angle in the virtual airway.

The ‘Save/Load camera position’ group box can be used to save chosen camera positions and orientation, allowing easier and faster navigation of the camera.

The ‘Add tube’ group box can be used to add a transparent endotracheal tube model to the viewer. This may help the user to visualize the actual size of the airways. Standard endotracheal tubes with a diameter of 6, 7, 7.5 and 8 mm can be selected. When a tube is selected, the user has to choose a starting position and the tube is placed. The tube can be rotated and translated using the sliders. This is more user friendly for new users than the previously used transform box, because the user does not need experience to understand the sliders. In Figure 3-17 an example of a tube placement is visualized.

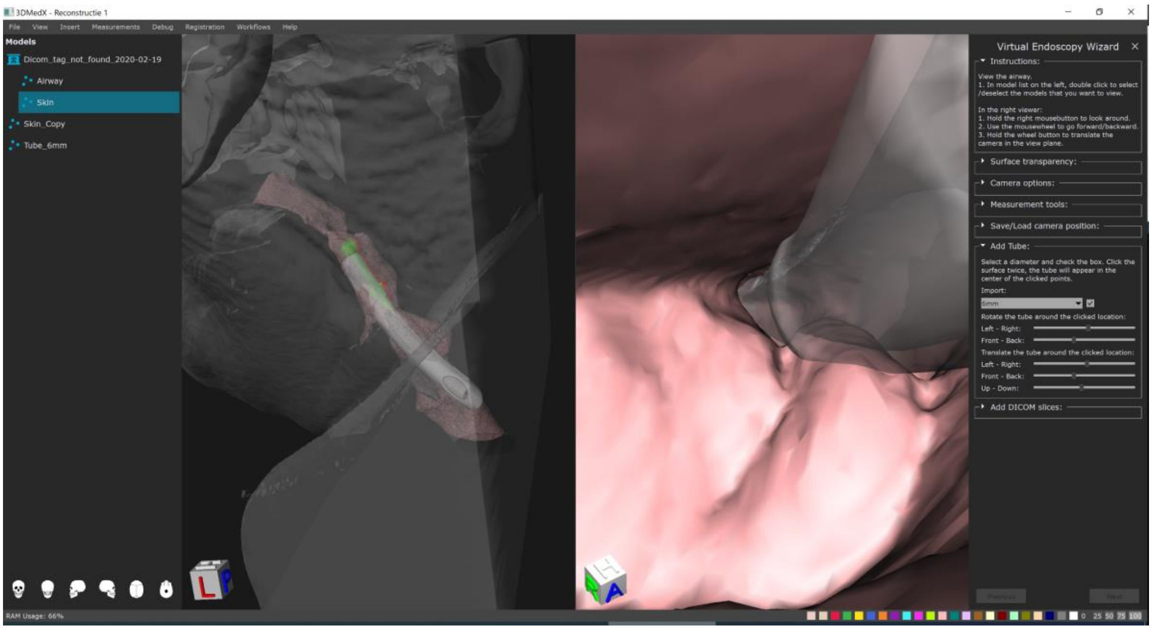

Figure 3-17: Example of virtual tube placement. The ‘Add tube’ group box can be used to translate and rotate the position of the tube

The ‘Add DICOM slices’ group box allows the user to add orthogonal DICOM slices to the ‘Overview viewer’. Using the checkboxes the axial, sagittal and coronal slices can be added to compare the CT-data with the created surfaces. The slider changes the visualized slice number, to move the plane through the visualize surfaces. This option is shown in Figure 3-18 and can be used by users that have experience with assessing CT-data.

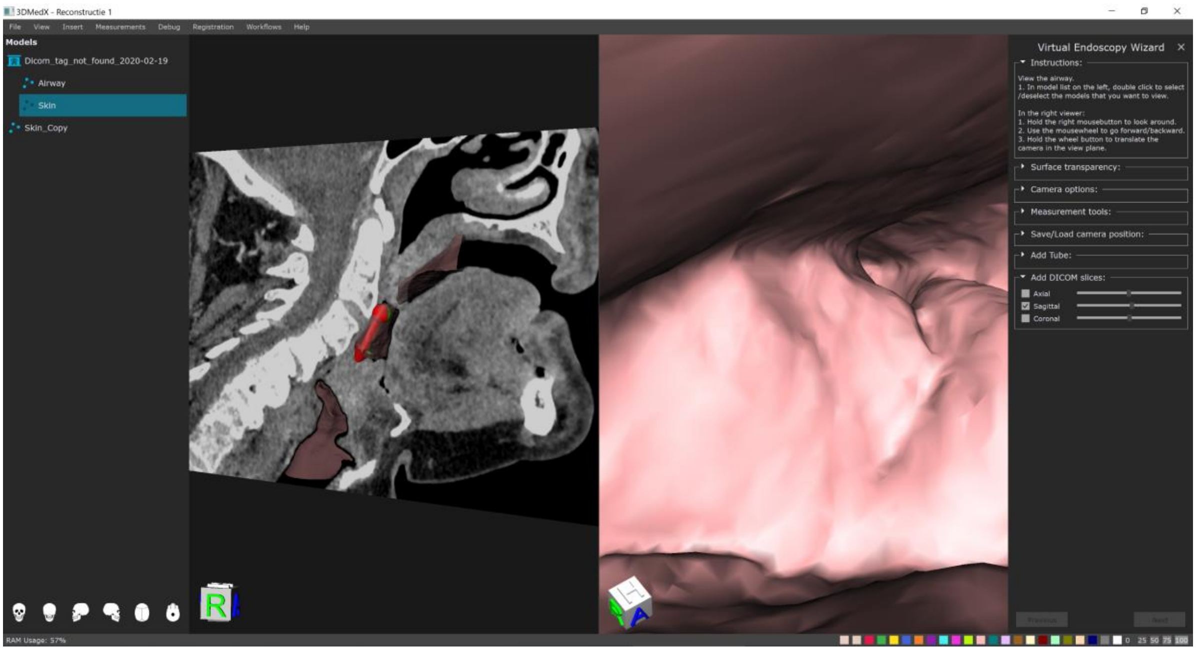

Figure 3-18: In the ‘Overview viewer’ a sagittal CT- slice is added. The sliders in the ‘Add DICOM slices’ group box can be used to change the visualized CT-slice.

After the VL is viewed by the user, the extracted surfaces can be saved. This allows the user to save time by skipping the extractions the next time when the VL wizard is opened.

The prototype design is summarized in the flow chart in Figure 3-19. Wizard pages are, again, represented as a box with the optional user actions in the body of each box.

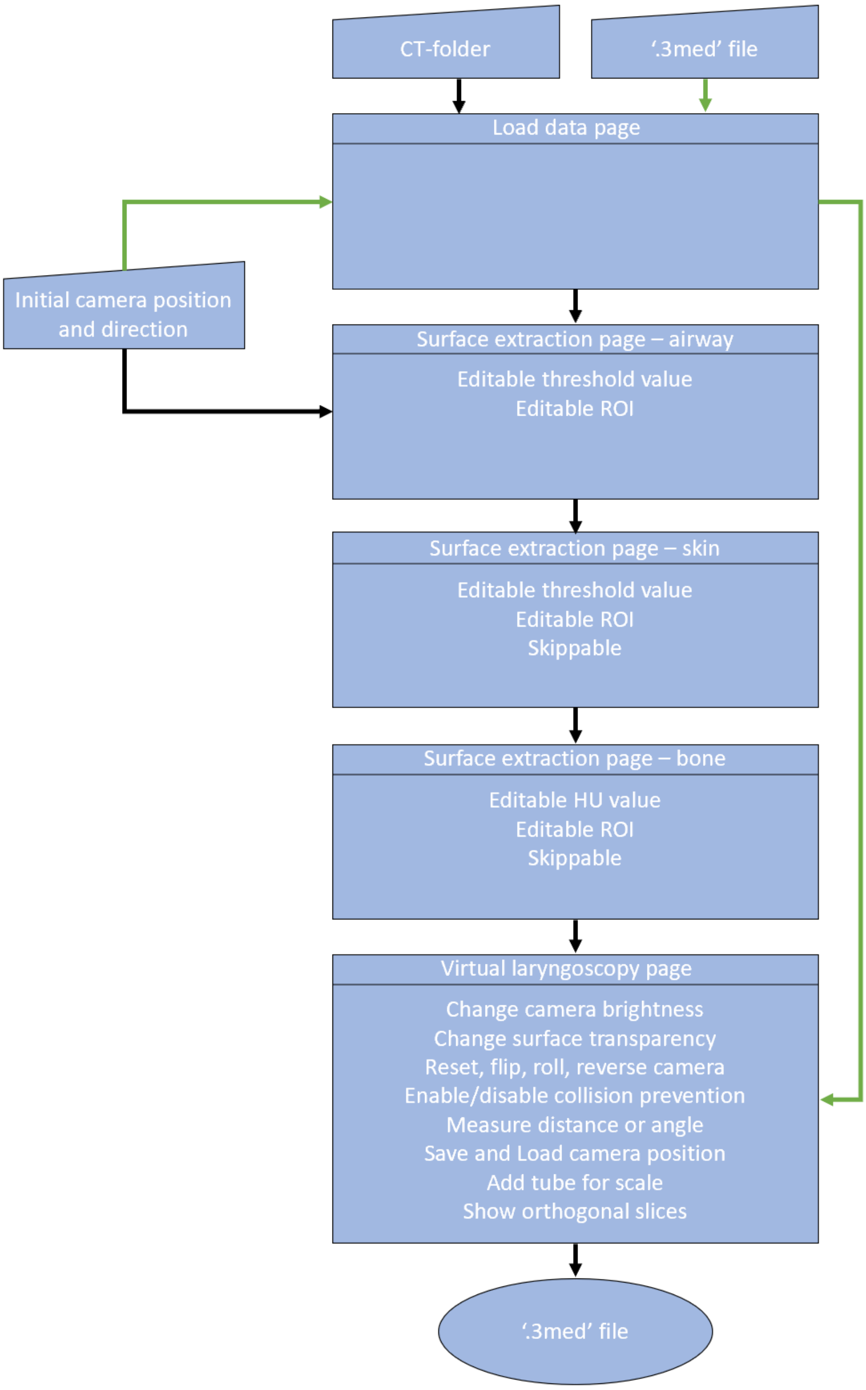

Figure 3-19: Flowchart of the software prototype design. Each wizard page is represented as a box with possible actions for the user in the body of each box. If a new reconstruction is made, the CT-folder is manually inputted and the black arrows are followed. At extraction – airway, the initial camera position and direction are manually inputted. The final result can be saved as a '.3med' file. If a previously made reconstruction is loaded, the green arrows are followed, that skip the extraction wizard pages and saves time. In this pathway, the initial camera position and direction are manually inputted on the 'Load data' page.

3.6 Software Design

The 3DMedX software is written using object-oriented programming, structuring the software program into reusable pieces of code. It combines built Med classes with OIV and Qt.

Qt is used to build the interface of the software. In the created VL wizard, the buttons, sliders, and text boxes are all made using Qt and connected with code from Med classes. For example, the ‘Ruler’ check box, described in the prototype design, is a Med class that is used when the checkbox is checked.

OIV can be described as a set of building blocks to create interactive 3D graphics applications. OIV stores information about used object in a scene database and organizes it in a scene graph. The scene graph is made up of nodes, each holding a piece of information, such as a surface material, shape description, geometric transformation, light or camera. In a scene graph, an ordered selection of connected nodes is stored. Three basic categories of nodes are:

- Shape nodes that represent 3D geometric objects
- Property nodes that represent appearance and other qualitative characteristics of a scene
- Group nodes that are containers to collect nodes into graphs, used to change a hierarchy

Each node contains at least one set of data elements, called fields. For example, a shape node for a cylinder has fields containing information about the height and radius of the cylinder. During rendering, the scene graph is traversed from left to right and from top to bottom. All states set by previous nodes, are inherited by nodes later in the scene graph. The simplified scene graphs for the created viewers in the ‘Virtual laryngoscopy’ page are described below. [19], [20]

As seen in Figure 3-14 the ‘Overview viewer’ displays the camera arrow and surfaces of airway, skin and bone. The scene graph in Figure 3-20 represents the ‘Overview viewer’. The Med Root (3) is the top separator of the scene, all nodes that are shown in the scene are added to the Med Root. The Med DICOM Object Kit (4) is a created DICOM object that holds information about the loaded DICOM. It contains Med Surface Kits (6-8) that create surfaces of airway, skin and bone. The Med DICOM Object Kit and Med Surface Kits are created or loaded in the previous wizard pages. The surfaces are visible in the left viewer because they are added to the Med Root (3). Also a Separator (5) node is added to the Med Root (3). The follow up nodes are a Transform (9) and another Separator (10) node. These create the arrow that is connected to the VL camera of the right viewer. This Separator (10) node is used to isolate the group from the scene graph, resulting in a different hierarchy. In the Separator (10), the arrow is created using different Shape nodes (13), each having its own Transform (12) to move it to the correct location to create the arrow. The Material (11) nodes are used to give the shapes the colors red or green, used to indicate the left or right side of the VL camera. The Transform (9) has fields for translation and rotation, these values are connected to the translation and rotation fields of the camera from the ‘Virtual laryngoscopy viewer’ using a sensor. Since this Transform (9) is to the left of the Separator (10), that builds the arrow, it has effect on all the created arrow parts below the Separator (10).

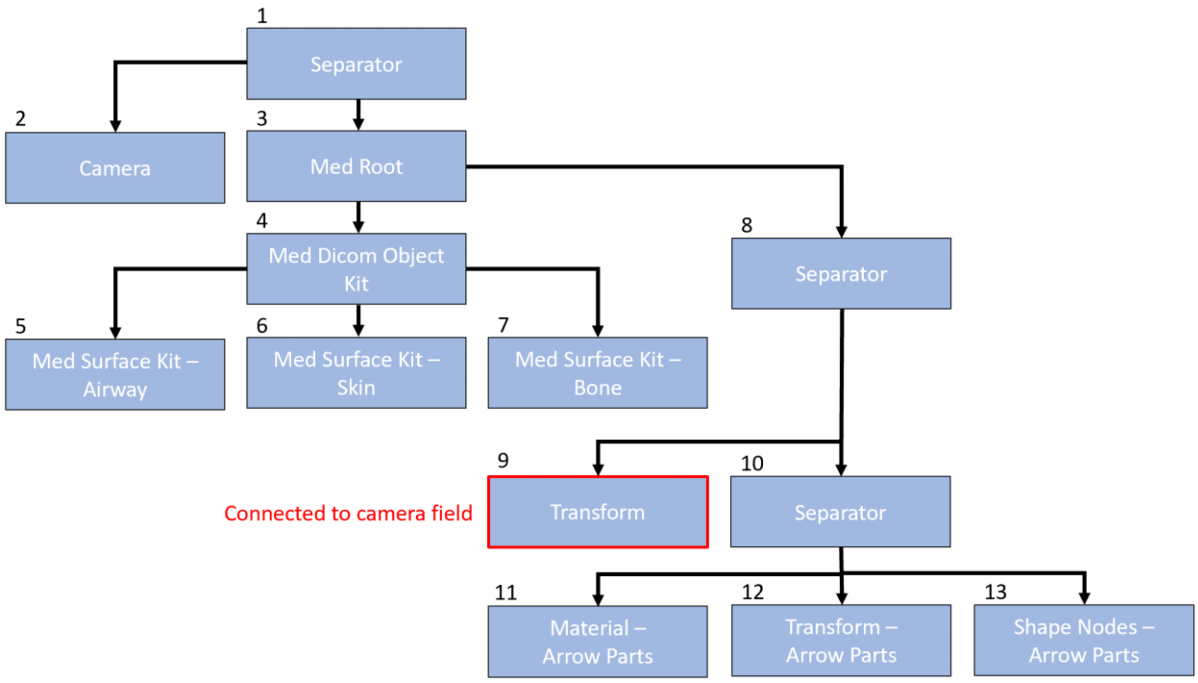

Figure 3-20: OIV scene graph of the 'Overview viewer' (left viewer) on the 'Virtual laryngoscopy' page. The Transform (9) is connected to the position of the VL camera.

The 'Virtual laryngoscopy viewer' scene graph is shown in Figure 3-21. The Med Root (3), again, holds all nodes that are added to the scene. This time Event Callbacks (4) are added. These are the callbacks that control the VL camera (2) by using the right mouse button and mouse wheel. A Point Light (camera light) is added that is connected to the location of the camera to mimic a video laryngoscopy. Dependent on the available Med Surface Kits, either the skin or airway surface is added to the Med Root (3).

The users' interaction with the wizard panel or viewers, change the scene graph. For example, the camera position field changes if the user interacts with the viewer and moves one of the cameras. If the user selects the 'Ruler' measurement option, a Med Ruler (7) is added to the scene.

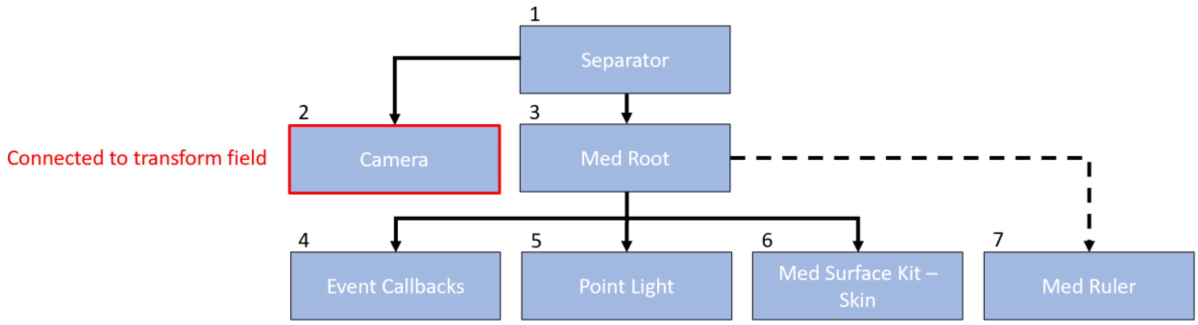

Figure 3-21: OIV scene graph of the 'Virtual laryngoscopy viewer' (right viewer) on the 'Virtual laryngoscopy' page. The Camera (2) location field is connected to the Transform (9) of the 'Overview viewer'.

4 Proof of Concept

In this chapter, the performed verification study and planned validation study are discussed.

4.1 Verification

To determine if the VL software meets the composed design goals and specifications, a verification study was performed. The basic functionalities, added features and user friendliness of the VL wizard were tested by subjects that used the created VL wizard to create a VL and perform actions using it.

4.1.1 Study Design

Initially the verification study should have been performed with anesthesiologist, because the VL wizard is specifically designed for them. Unfortunately, due to the COVID-19 pandemic, there were no available anesthesiologists for this study. Instead of anesthesiologists, three technical medicine specialists from the 3D Lab and three anesthesiology residents were recruited to perform the verification study. The 3D Lab subjects have experience with the 3DMedX software and therefore can provide useful feedback about the design and functionalities of the VL software. The anesthesiology residents have no previous 3D software experience and are well suited to assess the user friendliness of the VL software. Both subject groups had no previous experience with the VL wizard in the 3DMedX software. Also, three technical medicine students, without previous 3DMedX software experience, were asked to join the study. The reason for this decision was the uncertainty of the availability anesthesiology residents. Because of the COVID-19 pandemic it was only possible to complete the study using TeamViewer (TeamViewer GmbH, Göppingen, Germany). TeamViewer lets the subject control the laptop with the CT-data and 3DMedX software from another location.

All subjects were asked to create a VL, perform tasks in the ‘Virtual laryngoscopy’ page, and score the software afterwards. A CT-scan of a patient with a stenosis in the larynx, with a pixel spacing of 0.25mm and a slice thickness 0.5mm, was used. For the creation of the VL, the subjects followed the steps presented in the wizard. The time of the VL creation is tracked. The performed tasks covered the main functionalities of the software, to introduce the subjects to these functionalities. The tasks presented in the verification protocol were:

- Translate the VL camera in all directions
- Look around with the VL camera
- Look at the airway with the ‘Overview viewer’
- In the ‘Wizard panel’, change the transparency of the surfaces in the left viewer to the desired level
- Navigate the VL camera through the oral cavity until the stenosis is reached
- Measure the airway diameter on the level of the stenosis
- Navigate past the stenosis
- Look back at the stenosis using ‘Camera options’

- In the wizard panel, add the sagittal slices and check if the airway surface matches the CT-data
- Save the created surface
- Reopen the surface in a restarted 3DMedX
- Navigate through the airway again

After finishing the tasks, using the VL wizard, the subjects were asked to score and clarify the statements in Table 4-1. The statements covered the composed design goals; the basic functionalities, added features, and user friendliness. They also had the opportunity to add comments in a free comment field.

Table 4-1: Statements that were scored and clarified by the subjects.

Statement	**Score 1 – 10 (Strongly disagree – strongly agree)**	**Clarify the score**
Basic functionalities		
The surface extraction was easy to create		
Choosing the initial camera position was clear		
Added features		
The measurement tool worked as desired		
The location of the VL camera within the airway was clear		
User friendliness		
The interface was user friendly		
The wizard text guides the user easily through the wizard		
The camera was easy to control		
The function of buttons was clear		

4.1.2 Results

The average, minimum, and maximum scores given to the asked statements are shown in Table 4-2.

Table 4-2: Statements scored after the verification protocol was completed by three technical medicine 3D Lab employees, three anesthesiology residents and three technical medicine students.

Statement	Average score (min – max) 3D Lab employees	Average score (min – max) anesthesiology residents	Average score (min – max) students
Basic functionalities			
The surface extraction was easy to create	8.6 (8.0 – 9.0)	8.7 (8.0 – 9.0)	7.2 (6.0 – 8.0)
Choosing the initial camera position was clear	7.7 (7.0 – 8.0)	8.0 (7.0 – 9.0)	8.0 (7.0 – 9.0)
Added features			
The measurement tool worked as desired	9.0 (8.0 – 10)	9.0 (8.0 – 10)	9.2 (8.5 – 10)
The location of the VL camera within the airway was clear	9.2 (8.0 – 9.5)	9.3 (9.0 – 10)	9.0 (8.0 – 10)
User friendliness			
The interface was user friendly	8.7 (8.0 – 9.0)	8.7 (8.0 – 9.0)	7.5 (7.0 – 8.0)
The wizard text guides the user easily through the wizard	8.5 (8.0 – 9.5)	8.3 (8.0 – 9.0)	7.5 (7.0 – 8.0)
The camera was easy to control	8.3 (8.0 – 9.0)	8.0 (7.0 – 9.0)	9.3 (8.0 – 10)
The function of buttons was clear	8.5 (8.0 – 9.5)	8.7 (8.0 – 9.0)	8.7 (8.0 – 10)

Loading and preparing the VL from CT-data took the group of 3D Lab employees on average 7.3 minutes. The group of anesthesiology residents and technical medicine students, both with no previous experience, took on average 9.7 and 11.7 minutes. Loading the previously created '.3med' file took less than a minute for all subjects.

In total two minor software bugs were encountered. The first bug was a push button being disabled after the user cancelled browsing for files. The second bug occurred when the user saved the '.3med' file when a DICOM slice was visualized, it caused a crash.

The feedback given by the subjects, are listed below per design goal.

Basic functionalities

All subjects stated, that at first use, it was necessary to exactly follow the instructions of the VL

wizard to create the VL, which required careful reading. However, they expressed that afterwards, it was very easy to execute the required steps.
In the surface extraction, the ROI box used for selection of the segmentation, was found hard to adjust. Clicking the boxes on the boundaries should enable readjusting the ROI, however it was sometimes difficult to click the adjustment boxes in the corners. The subjects found the clickable boxes too small. Also, when choosing the initial camera position, it was not clear how to reset the camera position and direction.

The anesthesiology residents stated that, because they had no previous experience in viewing VL footage, the anatomy was hard to recognize.

Added features
Subject found that the measurement tool worked effortless and intuitive. Moving the measurement spheres was easy and provided direct feedback. The location of the VL camera within the airways was clear; at no time users got lost within the airway surface. The ‘Overview viewer’ gave direct feedback on the camera position and direction. However, the subjects sometimes forgot to use the ‘Overview viewer’, because this feature had not yet become sufficiently familiar. Some subjects had difficulties in positioning the camera of the ‘Overview viewer’. They would have liked camera control options in both the ‘Overview viewer’ and the ‘Virtual laryngoscopy viewer’.

User friendliness
The subjects stated that the software was intuitive and user friendly. The limited number of buttons and options ensured nothing could go wrong. The interface and wizard text gave sufficient information to complete the VL without previous experience. However, the subjects stated that first time use required careful reading and it therefore took more time to complete the VL. Some subjects suggested that the user could be helped even more by adding animations or a video guide.

When controlling the VL camera, the users noticed a steep learning curve. First time camera use was experienced as a bit out of habit, the second time navigating through the airway was clearly experienced as much easier. The camera worked well and operated smoothly, however the look around direction while holding the right mouse button, felt contra intuitive by most subjects. The camera collision preventions feature functioned well, but it was unclear when the collision prevention was active.

Some subjects stated that the arrow that indicates the VL camera in the ‘Overview viewer’, is big and therefore sometimes limits the visibility in the ‘Overview viewer’.

4.2 Validation

A single center experimental feasibility study was planned with the primary objective to determine whether using the VL wizard on patients who are suspected of a difficult airway, results in better airway planning for the anesthesiologist, and to test the workflow. The composed research protocol is described below. Unfortunately due to the recent COVID-19 pandemic, the planned study was cancelled and the report lacks results. The required forms for the committee on medical ethics were not yet submitted. They can be found in Appendix A, B and C.

4.2.1 Study Design

The current clinical workflow for general anesthesia can roughly be described in three phases. In the outpatient clinic, the patient is seen for preoperative evaluation, general inspection and bedside tests are performed and reported in the electronic health record. In preparation of the general anesthesia, this report is read by the anesthesiologist who performs the general anesthesia. In the final phase, the anesthesiologist creates an airway plan to realize general anesthesia for the patient. The current clinical workflow is visualized in dark blue in Figure 4-1.

In this study, in addition to the regular workflow, already available CT-data is used to create the VL in the 3DMedX software. The VL is controlled by the research team to eliminate the influence of the skill factor of the anesthesiologists. After examining the VL, the airway plan is redone. The most cautious airway plan is used. So adding the VL can only result in a more cautious approach.

After the procedure, the anesthesiologists are questioned about the workflow and usefulness of the VL, covering the following topics:

- Better view on the difficult airway?
- Influence your airway plan? If yes, how?
- More cautious airway plan?
- Use VL as an additional tool if it was available?

The clinical workflow of this study is represented in Figure 4-1.

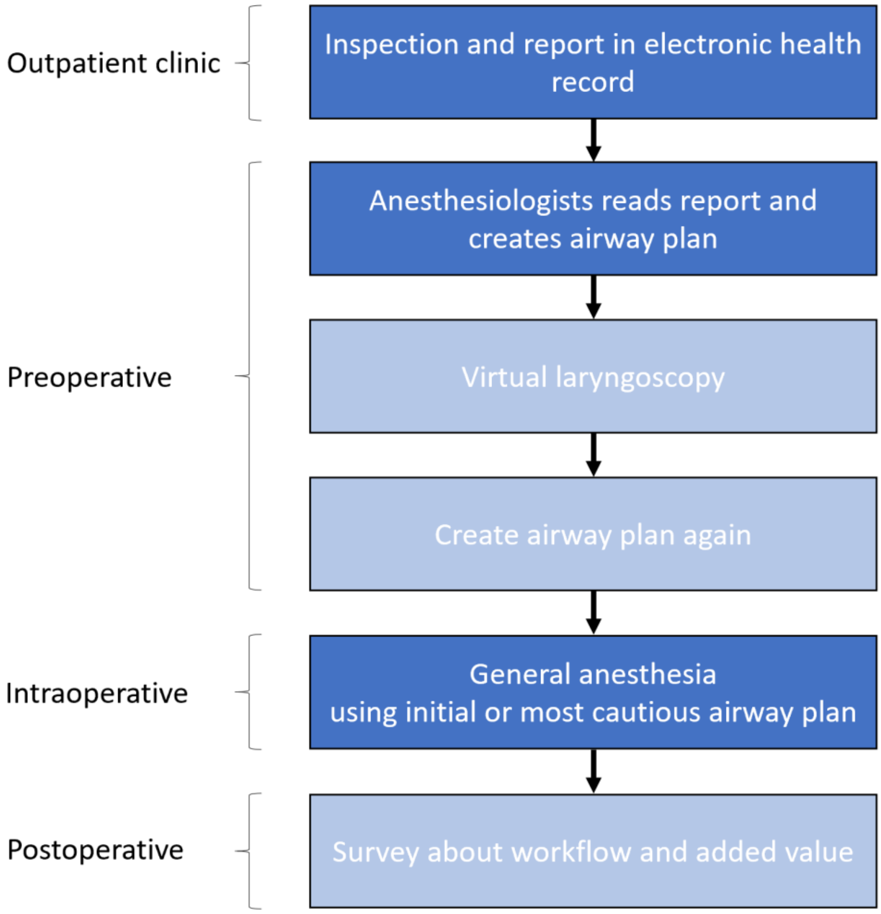

Figure 4-1: Clinical workflow of the validation study. Dark blue represents the standard clinical workflow, light blue the steps added for this study.

Because this is an experimental feasibility study, only 5 patients will be included. The airway plans and experience of the various anesthesiologists will be used to conclude if VL is of added value in patients with difficult airways. If the results are promising, eventually the VL may be added to the workflow for the anesthesiologists in patients with difficult airways.

The main parameters are the primary, secondary and tertiary airway plan from the anesthesiologists, with and without knowledge gained by the VL and the survey about the workflow and added value of the VE.

The inclusion criteria of the study are:

- Age 18 years or older
- Patients with planned surgery who undergo general anesthesia
- Patients with a difficult airway, originating in the larynx or trachea, to be judged by the anesthesiologists
- Patients with recent (<3 months) available CT-data of the airway
- Patients willing to participate (written informed consent)

In the outpatient clinic, patients who meet all the inclusion criteria are asked by the anesthesiologists whether they are interested in participating in this study. When interested, they are provided with the necessary information about this study. After consideration, these patients can give written informed consent if they are willing to participate. The patient information letter and consent form can be found in Appendix A and B.

In this study, the VL is added to the standard clinical workflow. No extra interaction with the patient or additional CT-data is needed. The anesthesiologists are questioned about their airway plan and their view on the added value of the VL. The anesthesiologists will always execute the most cautious plan. So, this protocol can only result in an even more cautious and safer approach, without the extra burden of additional patient contact.

5 Discussion

In this research study the first steps are made towards using VL to gain a better understanding of a difficult airway in order to better prepare endotracheal intubation. New VL software is created, specifically designed for the anesthesiologist, in collaboration with the anesthesiologists of the Radboudumc. In the software design the following goals were taken into account: basic functionalities, possibility of further development, added features, and user friendliness.

There is yet little reported on the clinical value of the use of VL in difficult airway planning. As stated in Paragraph 1.2, Bogdadly et al. found that with the use of OsiriX VL software, more than half of the anesthesiologists changed their airway plan. All anesthesiologists stated that the VL helped with their airway assessment in all the ten proposed scenarios. This suggests that the use of VL has a positive effect on patient outcome. [16] Compared to the OsiriX software, the created VL allows the user to interactively control the camera and perform measurements, presumably resulting in a better airway assessment.

When using VL in general, the following should be considered. Since VL is based on a CT-scan, the VL shows the airway in the position of an awake patient during the CT-scan. This differs from the position of the patient during endotracheal intubation.
Also, in reality, soft airway tissue is movable and stretchable. VL software provides no feedback on the movability and stretch ability. The use of muscle relaxant drugs increases this effect even more. The VL also shows the state of the pathology in the difficult airway at the time of the CT-scan. It requires individual assessment to determine whether the CT-scan is still comparable to the pathology during the airway assessment.

The VL wizard uses thresholding to segment the air from the surrounding tissue. In the designed VL software, on both conventional and cone beam CT-data, the segmentations functioned well. The quality of the VL surfaces depend fully on how well the airway is segmented in the CT-scan. Higher quality CT-data results in a more detailed VL, however this takes considerably longer to segment.

Small artefacts caused by oral implants will probably not affect the segmentation of air in the larynx or trachea. If a larger artefact is present in the CT-data, the thresholding method will most likely not result in a sufficient segmentation for the use of VL. A different segmentation approach can possibly correct the artefact to create a proper segmentation for the VL. The created VL wizard in this research project, currently only supports thresholding.

During the development of the VL wizard, only CT-data is used to create the VL. In Magnetic resonance imaging (MRI) data, the airway is usually harder to threshold. When a good quality T1-weighted MRI scan is used, it will probably result in acceptable segmentation and VL. However, in most MRI sequences, the airway is not easily segmented by thresholding. A different segmentation approach is needed to create a good airway segmentation for the VL.

5.1 Verification and Software Improvements

The verification study was performed to test whether the software meets the defined design goals and specifications. 3D Lab employees, anesthesiology residents, and technical medicine students tested the software and were asked to score and clarify statements afterwards.

Every subject completed the VL wizard and provided positive scores on the various statements. Subjects stated it was a bit of a search at first, but they understood it well after a short amount of time. The high scores, especially from the subject without 3DMedX software experience, make it presumable that anesthesiologists will be able to create a VL in the 3DMedX software, without the need of outsourcing it to the 3D Lab. Also, training or an extensive user manual are probably not needed for the anesthesiologists to use the VL wizard. Some subjects stated that a video guide of how to use the VL wizard can be of added value for first time users. An instruction video is well suited for the VL wizard, because the usage of the VL wizard is a linear process.

On average the groups of inexperienced users, the anesthesiology residents and the technical medicine students, took, respectively, 9.7 and 11.7 minutes to create the VL. An experienced user can complete the VL reconstruction within two minutes. This is faster than the VL creation time in the OsiriX software, reported by El Boghdadly et al. In OsiriX, anesthesiologist with no previous experience produced the videos in approximately 20 minutes, while advanced users could produce videos in five minutes. This suggests that the creation of a VL in 3DMedX is probably two times faster than using the OsiriX software. This makes it more suitable to fit into the clinical workflow of the anesthesiologist. The time to create a VL is strongly dependent of the size of the CT-data. During the verification study a high quality CT-scan was used, resulting in relatively long reconstruction times (around one minute). A cone beam CT has a processing time of approximately half a minute.
After the reconstruction was made by the subjects, it took them less than a minute to reopen the VL.

Besides two minor software bugs, the software performed as planned. The two software bugs, found by the subjects and described in Section 4.1.2, are fixed.

Although the user friendliness of the software scored very well, the feedback of the subjects can still be used to improve the workflow of the VL wizard. Several users stated that the ROI box, used in the reconstruction pages, was difficult to adjust by using the clickable boxes on the boundaries. Especially when combined with the placement of the VL camera position and direction, this resulted in difficulties. When a miss click occurred, it changed the VL camera placement. An additional button in the 'Wizard panel' should be added to reset the VL camera and position. This way, a miss click of the ROI box will not change the VL camera placement. To make the ROI box more user friendly, the clickable boxes on the boundaries should be increased.
The arrow in the 'Overview viewer' gave the subjects a clear understanding of where the VL

camera was within the airways. However, the arrow sometimes gets in the way of the desired view. An option to hide the arrow should be implemented to temporarily hide it when it obstructs the view. Also, options to help the inexperienced user with the 'Overview viewer' camera movement should be added, similar to the 'Camera options' group box that is currently only available for the 'Virtual laryngoscopy viewer'. The use of the VL camera is experienced as easy. However, the mouse movement to look around with the camera, should be inverted because users found it contra intuitive. The created collision prevention worked properly. It can be improved by giving the user feedback when a collision occurs. A red light should be added that blinks when a collision occurs.

The anesthesiology residents stated that they had a hard time recognizing the anatomy with the stenosis in the larynx, because they had no reference VL of a healthy airway. They only had experience watching the larynx during a regular laryngoscopy. They stated that they would definitely use the VL software in case of a difficult airway, but would probably need some training or experience in assessing the VL reconstruction.

The performed verification study had a couple of limitations, caused by the restrictions of the COVID-19 pandemic. The study was performed using TeamViewer, resulting in a small time delay for the users. This also caused a lower frame rate for the user, influencing the perceived performance of the software (less smooth). The subjects in this study were all digital natives[3], less computer skilled users may experience difficulty in using the software. The previously described instruction video can very likely help these users to use the VL wizard. The subjects, who participated in the verification study were not the targeted software users. It is assumed that the results of the study also apply to anesthesiologists.

Due to the limited time of this internship and the time investment in learning to program using C++, OIV, and Qt, not all software ideas could be realized. The following software ideas were planned to optimize the developed, well-functioning, VL wizard. An extra wizard page after the 'Surface extraction – airway' page could be used to optimize the extracted airway surface. In the current design, air on the exterior of the patient may be extracted when inside the selected ROI box. In the extra wizard page, the user should be able to remove this unwanted extra surface. The next 3DMedX version has a function that detects clusters. This function can be used to easily select only the desired part of the airway extraction. The final idea to implement, is to set the initial camera position for the VL camera in front of the patient by default. This would make placing the initial camera position in the 'Surface extraction – airway' page, optional. The default position can be determined by using the center of the anterior plane of the ROI box of a created extraction, with the direction facing toward the posterior plane of the ROI. This would result in the possibility to skip an extra step, which makes the VL easier for new users.

[3] A person who has grown up in the digital age.

5.2 Validation

The study performed by Ahmad et al. stated that the use of virtual endoscopy leads to more conservative and potentially safer airway management strategies. [14] This concerned a small single center study, using different VL software, which makes it of interest to compare those results to this study performed in the Radboudumc with the newly created VL software. Unfortunately, due to the COVID-19 pandemic this study was cancelled. However, during the development of the software, various involved anesthesiologist stated that they are convinced virtual endoscopy is of added value in understanding the difficult airway and may lead to safer airway management in some cases.

During this research project one airway reconstruction of a patient was made with the final prototype design described in this report. The reconstruction was made after tracheal intubation of the patient with a stenosis in the larynx. The anesthesiologist that performed the tracheal intubation, stated that the virtual endoscopy showed similar anatomy and would have helped in the preparation of the airway plan.

5.3 Future Perspective – Clinical Implementation

Currently virtual endoscopies using the created VL wizard can be created on request, by the 3D Lab only. This is due to the requirement of a Patient Archive and Communication System (PACS), K-PACS (IMAGE Information Systems, Rostock, Germany), to export the DICOM data to a local computer, where the VL can be generated using the 3DMedX software. K-PACS is only available for the 3D Lab to create reconstructions and 3D prints. Currently the software cannot be implemented in the Radboud digital working environment, because of hardware restrictions. For the department of anesthesiology, to make its own VL, a computer with K-PACS, to export DICOM data, and the 3DMedX software are required. This way, less people are required in the process of creating a VL and it becomes more accessible and faster for the anesthesiologists. Ideally the 3DMedX software can import DICOM data directly from PACS, without the use of K-PACS. The possibilities should be investigated in more detail.

There is still little reported on the clinical value of a VL. However, VL is expected to provide a better view on a difficult airway before airway management. [16], [18] VL requires no additional patient contact, because the CT-scan that is used is already available. VL seems a good way to evaluate the airway for anesthesiologist who lack experience in interpretation of orthogonal CT-data, and should be considered when a patient with CT-data available and a difficult airway, is planned.

A validation study with the created VL software, as described in this research project, should be performed to test the added clinical value and clinical workflow. Next, a larger prospective randomized study with more patients can be performed to find out more about the added value of VL using the created software. Since the VL in 3DMedX software is in-house software it can easily be improved and further adjusted to the preferences of the anesthesiologists.

The created VL software may also be used for educational purposes, as the clear 3D view of the airway within the patient does not require knowledge about the interpretation of conventional 2D medical images. It is a useful tool to give inexperienced anesthesiologists more insight on what a difficult airway looks like.

6 Conclusion

This research study presents new VL software specifically designed for the anesthesiologist to support airway planning in case of difficult airways. The software was created, using the input from several anesthesiologists and previous research. In the software design the following goals were taken into account: basic functionalities, possibility of further development, added features, and user friendliness. A verification study is performed to test whether the software can be operated by the anesthesiologist, without outsourcing it to the 3D Lab. This lowers the threshold to create a VL when needed. The verification study shows the software is user friendly and can most likely be used without the help of an additional user manual. Small additions to the created VL software are suggested that may result in an improved user friendliness. The created VL software allows first time users to create a VL reconstruction in approximately eleven minutes and experienced users in two minutes. This is twice as fast as the reconstructions made in the previously used OsiriX software. Previous research and the opinion of various anesthesiologists, indicate that the use of VL may improve the airway plan for difficult airways. A validation study is designed, to determine whether using the created VL software on patients with head and neck pathology, results in better airway planning. However this validation study is not executed because of the recent COVID-19 pandemic.

Before clinically implementing the use of VL for patients with a difficult airway, the added value and impact on the workflow needs more research. After positive results, the department of anesthesiology should invest in the required hardware to use the VL software, to be able to use the software without the support of the 3D Lab and make it more accessible.

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Appendix A: Patient information letter

Informatiebrief deelname aan het onderzoek: "Het gebruik van virtuele laryngoscopie voor algehele anesthesie bij moeilijke luchtwegen"

Geachte heer/mevrouw,

Omdat u binnenkort algehele anesthesie ondergaat vragen wij u vriendelijk om mee toe doen aan een medisch-wetenschappelijk onderzoek (zie titel). U beslist zelf of u wilt meedoen. Voordat u de beslissing neemt, is het belangrijk om meer te weten over het onderzoek. Lees deze informatiebrief rustig door. Hebt u na het lezen van de informatie nog vragen? Dan kunt u terecht bij de onderzoeker.

Introductie
Bij narcose wordt er gebruik gemaakt van intubatie. Hierin wordt er een buis (endotracheale tube) ingebracht tot net onder de stembanden en wordt er een ballonnetje om de buis opgeblazen. Hierdoor is de luchtweg afgesloten en vind de beademing via de buis plaats. Om het plaatsen van de buis goed te laten verlopen is het belangrijk dat de anesthesioloog goed inzicht heeft over de luchtweg.
Bij virtuele laryngoscopie wordt er gebruik gemaakt van al bestaande CT beelden om een 3D weergave te maken van de binnenkant van de luchtweg. Het doel hiervan is om de anesthesioloog een beter inzicht te geven over het verloop van de luchtweg.

Doel van het onderzoek
Het doel van het huidige onderzoek is om te kijken of het gebruik van virtuele laryngoscopie leidt tot betere luchtwegplanning bij patiënten met een moeilijke luchtweg.

Wat er nodig is voor het onderzoek
Voor het onderzoek worden CT-beelden van de patiënten gebruikt om een virtuele laryngoscopie te maken. Deze virtuele laryngoscopie wordt vervolgens voor de algehele anesthesie bekeken om een beter beeld te krijgen van de luchtweg. Achteraf wordt er met de anesthesioloog geëvalueerd over de invloed van de virtuele laryngoscopie.

Wat er van u gevraagd wordt voor het onderzoek
Als u mee wilt doen met het onderzoek, dan worden uw CT beelden gebruikt voor een virtuele laryngoscopie. Er wordt gebruik gemaakt van al bestaande CT beelden, het kost dus geen extra tijd en geeft geen extra risico voor de gezondheid.

Gebruik van uw gegevens
Met uw gegevens wordt met de grootste zorgvuldigheid omgegaan en deze zullen enkel worden gebruikt in het kader van dit onderzoek. In de toestemmingsverklaring kunt aangeven of u wel of niet toestemming verleent om uw CT beelden te gebruiken voor publicatiedoeleinden. U kunt uw toestemming voor het gebruik van uw gegevens altijd weer intrekken. Voor algemene informatie over uw rechten bij verwerking van uw gegevens kunt u de website van de Autoriteit Persoonsgegevens raadplegen. (https://autoriteitpersoonsgegevens.nl/)

Hopende u zo voldoende te hebben geïnformeerd,

J.J.M. Riksen, BSc
Master Student Technische geneeskunde
Radboudumc

Prof. Dr. G.J. Scheffer
Afdelingshoofd afdeling anesthesiologie
Radboudumc

Appendix B: Consent form

<u>TOESTEMMINGSVERKLARING</u>

voor deelname aan het wetenschappelijk onderzoek:

Het gebruik van virtuele laryngoscopie voor algehele anesthesie bij moeilijke luchtwegen

- Ik ben naar tevredenheid over het onderzoek geïnformeerd en ben in de gelegenheid gesteld om vragen over het onderzoek te stellen.

- Ik heb goed over deelname aan het onderzoek kunnen nadenken.

- Ik heb het recht mijn toestemming op ieder moment weer in te trekken zonder dat ik daarvoor een reden behoef op te geven.

- Ik heb uitleg gekregen over het eventuele gebruik van mijn CT-scan voor publicaties in wetenschappelijke vakbladen. Mijn instemming met het gebruik van de CT-scan voor deze publicatiedoeleinden staat volledig los van mijn deelname in dit onderzoek.

- Ik verleen de arts **wel / geen*** toestemming om mijn CT-scan te gebruiken voor publicatiedoeleinden. Dit staat los van mijn eventuele deelname aan het onderzoek.

**Doorhalen wat niet van toepassing is*

Ik stem toe met deelname aan het wetenschappelijk onderzoek.

Naam : ....

Geboortedatum : ....

Datum : ....

Handtekening : ....

Appendix C: Research protocol

Protocol title

The use of virtual laryngoscopy in general anesthesia with a difficult airway.

Dutch protocol title in information for patients and informed consent form

Het gebruik van virtuele laryngoscopie voor algehele anesthesie bij moeilijke luchtwegen.

Date submission CMO Radboudumc

..-..-2020

Principal investigators

Prof. G.J. Scheffer, MD, PhD

Research team

Name	Profession
J.J.M. Riksen, BSc	Technical Medicine Intern
G. van de Steeg, MSc	Researcher, programmer
Prof. G.J. Scheffer, MD, PhD	Head of the department of Anesthesiology
Prof. T.J.J. Maal, PhD	Coordinator of 3D lab Radboudumc

Rationale

To predict difficulties in endotracheal intubation before general anesthesia, patients undergo preoperative evaluation. Prediction is of great importance for the anesthesiologist to plan ahead and prevent airway related complications. The evaluation is based on anatomical evaluation of the head and neck area. Examples of laryngoscopy prediction methods are the Mallampati-test and the thyromental distance. Both tests perform modest, with a sensitivity of 30% to 60%, specificity of 60% to 80%, and positive predictive value of 5% to 20%. [1], [2]

Both described methods do not provide information about the airway and surrounding tissue itself, therefore predicting difficult intubation can be challenging. Patients with planned head and neck surgery, known pathology or previous surgeries are more often difficult to intubate and have medical imaging available. This CT data can be used to create a 3D virtual endoscopy (VE) of the larynx, creating a “fly-through” segmentation. It can provide cheap, non-invasive and quantitative data for the prediction of difficult to intubate patients.

Ahmad et al. did a study to investigate the potential added value of virtual laryngoscopy. They found that, compared to conventional fiberscope, the virtual laryngoscopy represents a noninvasive, safe and accurate airway assessment. [3] El-Boghdadly et al. did a prospective cohort study with 10 clinical scenarios of patients with head and neck pathology with CT-imaging, using the OsiriX (Pixmeo SARL, Bernex, Switzerland) software. The clinical scenarios were presented to 20 anesthesiologists and structured questions were asked about the airway planning, after showing a VE video the questions were repeated. They showed a change in the airway management plan in half of the cases after VE videos were shown. Also, all 20 anesthesiologist stated that the VE videos helped with the airway assessment and stated that they would use VE when available. [4]

From CT-data, OsiriX creates a path after manually selecting a start and endpoint. However, the software misses features to optimize the assessment in difficult airways. After the “fly-through” was rendered, there is no option to change the camera position, orientation and brightness. Also, the ability to show the camera position and perform measurements during the evaluation of the endoscopy are desired. [6] However, in-house 3DMedX software (figure 1) does provide these missing features, making it a more suitable software choice than OsiriX.

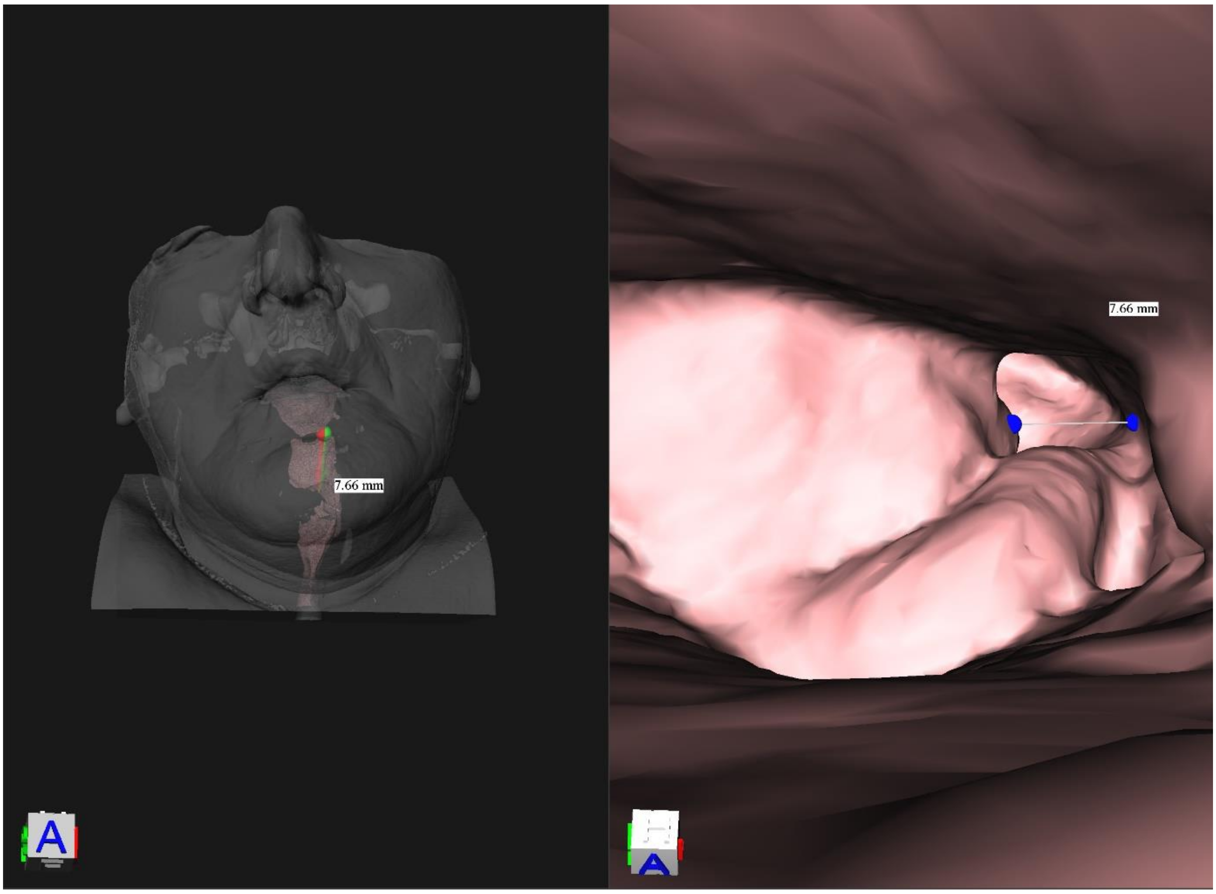

Figure 1: Virtual laryngoscopy using 3DMedX software.

Objectives

Primary Objective:

Determine whether using a virtual laryngoscopy on patients who are suspected of a difficult airway results in better airway planning for the anesthesiologist.

Main study parameters

- Primary, secondary and tertiary Airway plan from anesthesiologist. With and without knowledge of the virtual laryngoscopy

- Experience of the anesthesiologist using the VE software :
    - Better view on the difficult airway?
    - Will this influence you airway plan? If yes how?
    - More cautious/ less cautious airway plan?
    - Did the VE help in your airway assessment.
    - Would you use VE as an additional tool if it was available?

Study design

The proposed study is a single center experimental feasibility study. The primary, secondary and tertiary airway plan is made using the standard clinical method, based on the report created in the outpatient clinic. Additional to the regular workflow, already available CT data is used to create the virtual laryngoscopy in the 3DMedX software. The airway is viewed and if needed, distance measurements and tube visualizations are used. The virtual laryngoscopy is managed by the research team to eliminate the skill factor of the anesthesiologist. After viewing the virtual laryngoscopy, the report in epic and airway plan are made again. During the general anesthesia, the initial or most cautious airway plan is used. So adding the virtual laryngoscopy can only result in a more cautious approach. After the general anesthesia, the anesthesiologist is questioned about the workflow and helpfulness of the virtual laryngoscopy. The standard clinical workflow is shown in figure 2, the workflow of this study in figure 3.

Because this is an experimental feasibility study, only 5 patients will be included. The airway plans and experience of the anesthesiologist will be used to conclude if virtual laryngoscopy will be of added value in patients with difficult airways. If the results are promising, eventually the virtual laryngoscopy might be added to the workflow for the anesthesiologist in patients with difficult airways.

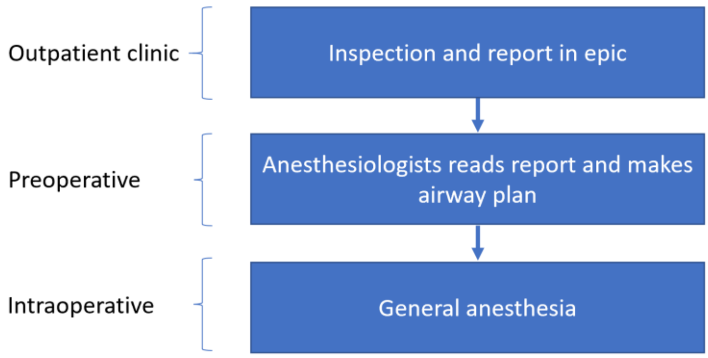

Figure 2: current clinical workflow for general anesthesia.

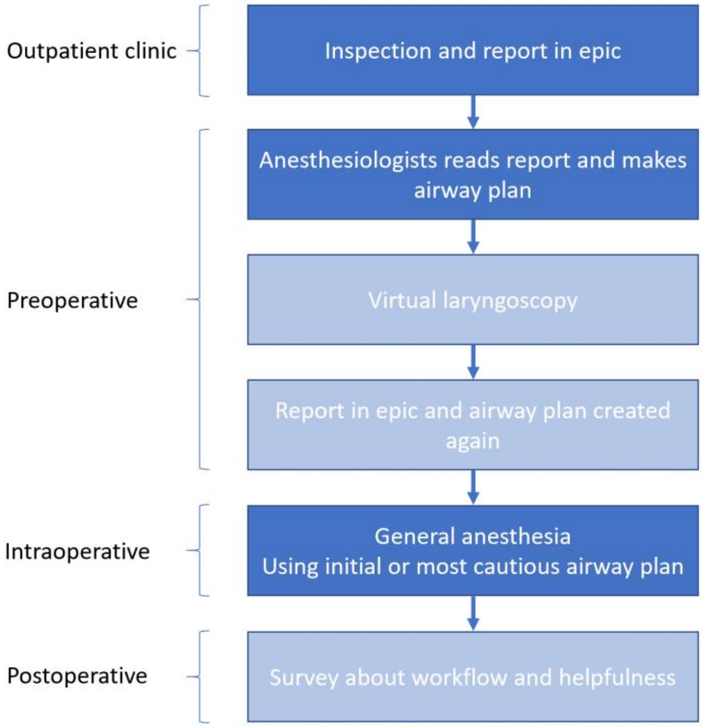

Figure 3: the clinical workflow in this study.

Inclusion criteria

- Age 18 years or older.
- Patients with planned surgery who undergo general anesthesia.
- Patients with a difficult airway originating from the larynx or trachea .
- Patients with available CT-data of the airway.
- Patients willing to participate (written informed consent).

Exclusion criteria

- No recent (<3 months old) CT scan available
- No informed consent

Sample size calculation

Not applicable. Feasibility/pilot study.

Recruitment and consent

In the outpatient clinic, patients who meet all the inclusion criteria are asked by the anesthesiologist whether they are interested in participating in this study. When interested, they are provided with the necessary information about this study. After consideration, these patients can give written informed consent if they wish to participate.

Withdrawal of individual subjects

Patients can deny consent, or leave the study at any time for any reason if they wish to do so without any consequences.

Data acquisition

Patient names, MDN, age, clinical history and diagnosis are collected from the medical records..

The Digital Imaging and Communications in Medicine (DICOM) data is obtained using the Patient Archive and Communication System (PACS).

The airway plan of the anesthesiologist and questions about the experience of the anesthesiologist using the VE software are collected.

Handling and storage of data and documents

Patient data collected from the medical records are stored in CastorEDC. The patient MDN corresponding with the record numbers from CastorEDC are stored in an encrypted file stored on the Radboudumc server, which can only be accessed by the researchers of this study. When available, the DRE will be used to store the study data.

The CT data will be stored on a Radboudumc server, the directory is only accessible by the researchers of this study.

Data analysis

The airway plans and experience of the anesthesiologist will be compared.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness

The virtual laryngoscopy is added to the standard clinical workflow. No extra interaction with the patient or additional CT data is needed. The anesthesiologist is questioned about his airway plan and his view on the helpfulness of the virtual laryngoscopy. This might affect the airway plan of the anesthesiologist. The anesthesiologist will always execute the initial or most cautious plan. So adding the virtual laryngoscopy can only result in a more cautious approach. So for the patient, this protocol can only result in a more cautious approach and takes no extra time or effort.

Ethical considerations

The principles of the Declaration of Helsinki will be taken into account.

Costs

At this stage, Radboudumc departments involved will take care of the costs, without external funding.

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