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Lateralized Laryngoscope Blade

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***Abstract*—Tracheal intubations are one of the most common surgeries that occur since they are necessary for most patients under anesthesia. Given the frequency, an error with a relatively low chance of occurring can still provide a large problem both for the patient and the hospital. We studied teeth damage that arise during tracheal intubations to determine if improvements could be made to the process to lower the chance of it occurring. Given this, we set out to improve the laryngoscope to provide a product with a novel approach that sweeps into the mouth from the left side before traveling the rest of the distance down the throat to expose the trachea and vocal cords. This design increases the view on the right side of the mouth for the physician performing the intubation, and ensures that if contact was to occur with the teeth, it would be with the pre-molars which are able to withstand a far greater amount of stress than the incisors due to the increased cross-sectional area. The course of the project followed the FDA Design Control Guidance process where five control gates were utilized to ensure customer requirements and needs were properly categorized during each phase. This also ensured the design outputs verified the design inputs and the final product validated the user needs originally established. The final project outcome delivered a successful 3D printed titanium beta prototype along with strength verification finite element models. The prototype was successfully validated by having Certified Registered Nurse Anesthetists and Anesthesiologists at Akron General successfully perform intubations on manikin heads.**

Keywords – Intubation, Laryngoscope, Trachea, Mechanical Stress, FDA Design Control Guidance, Anesthesia, Certified Registered Nurse Anesthetists (CRNAs)

I. Introduction

Each year there are approximately 50 million tracheal intubations performed global with nearly one third occurring in the United States [1]. Tracheal intubations are generally performed with a laryngoscope to lift the airway and allow insertion of the breathing tube. A laryngoscope is divided into 3 major components: a handle that attaches to the blade and functions to control the laryngoscope and house the battery, a fiber optic cable powered by the internal battery to illuminate the airway of the patient, and what this project will focus on, the blade of the laryngoscope that is used to expose the trachea and perform the intubation. There are 3 types of laryngoscope blades that are commonly used to perform tracheal intubations. A "Miller" blade that utilizes a straight, uncurved, head that is inserted through the mouth and used to lift up the epiglottis to perform the intubation. The other two types of laryngoscope blades are the "Macintosh" blade that is parabolically curved, and a "GlideScope" that is also a parabolically curved blade with a video camara attached to assist locating the airway and performing the intubation. Both of these devices function by inserting the blade through the mouth and using the tip of the blade to lift up the vallecula to locate the vocal cords and insert the breathing tube. Refer to Figure 1 for illustrated diagram of the process involving the "Macintosh" blade outlined above.

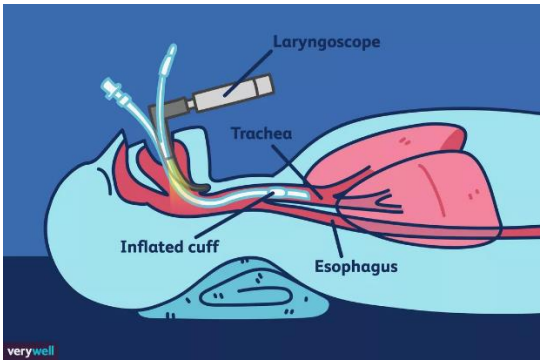

Figure 1: Diagram demonstrating how an intubation procedure would be performed while the patient is in a "sniffing" position
(Illustration by Joshua Seong. © Verywell, 2017.)

Complications during tracheal intubations such as an uncontrolled environment, poor dental hygiene, or a difficult airway can lead to improper use of the laryngoscope where

contact with the teeth can occur. This leads to damage that is costly to both the hospital and the patient. The most common teeth that are damaged during a tracheal intubation are the top four incisors, teeth 7 through 10. According to the American Dental Association (ADA) the average lifetime cost for a dental injury is between $15,000-$20,000. The rate of dental injuries due to tracheal intubations occur between .04% and 12.1% depending on risk factors, pre-existing conditions, whether the environment is controlled or not, and whether dental examinations were done prior to the intubation procedure [2,3,4,5,6,7,8]. The rate of complications in combination with the cost of repairing and restoring teeth result in a medical problem that is valued above 400 million dollars per year, not including lawsuits that might arise from the complications. The purpose of this project is to study current laryngoscopes and develop a unique blade enhancement that can perform tracheal intubations at an equal or higher rate of success with less possibility of damage being done to the top four incisors.

II. User Needs

To properly address the problems surrounding tracheal intubation, our team interviewed several Anesthesiologists and Certified Registered Nurse Anesthetists (CRNAs) about the most important factors to improve intubations. The most important customer requirements were those that every interviewee included: not obstructing the clinician's view of the mouth, throat, or vocal cords, having competitive pricing, not affecting the ease of intubation, and providing additional protection to the teeth especially for residents who lack the experience to intubate a patient consistently. Customer requirements that were not mentioned often or were not stressed as critical included: allowing for quick access in emergency situations, being disposable, and not interfering with the endotracheal tube.

III. Design Inputs

The Design Inputs gate focused on identifying and ranking requirements needed for the final product in order to satisfy all relevant standards, produce a functional model, and design a product that would be competitive to other products in the eyes of the customer. Engineering requirements were derived from current products on the market [9], standards required by the FDA for intubation equipment, and from the customer requirements. The full of list of engineering requirements can be located in Appendix A.

A QFD matrix was then created to rank and relate customer requirements and functional requirements with one another. The strength of the relationship and the importance of the category identified key features that should be focused on during the design phase to provide the most optimal product. Key takeaways from the QFD include the device being compatible with current intubation equipment, the device being able to be designed for a variety of sizes, the device being able to minimize the stress applied to the top four incisors, the cost of the product to be competitive, the device not to obstruct the view of the physician, and the device to be able to perform tracheal intubations with a high success rate. The complete figure of the QFD is included in Appendix B. The QFD also found that the current products on the market are able to satisfy functional requirements effectively but fall short in satisfying customer requirements such as ease of use, competitive price, and protection for teeth 7-10 which our blade design aims to improve.

The last outcome from the Design Inputs stage was the formulation of process failure mode effects analysis (pFMEA) to identify risk associated while performing a tracheal intubation with current equipment. The areas with the highest risk scores associated with the process include lacerations being made to soft tissue given the high rate of occurrence, and teeth chippage or being cracked. A full list of process failure modes of current products along with potential mitigations are attached in Appendix C.

IV. Design Process

The design was chosen by developing a phase 2 QFD, step 1 design evaluation matrix for different proposed designs. For brainstorming and concept generation, team members employed a modified form of the Brainwriting Method 6–3–5. Team members individually came up with three ideas and then met together and exchanged them as a group. Pros and cons were listed out for each idea, and then design improvements ideas were discussed, resulting in a total of sixteen unique design solutions.

For the design evaluation QFD, the design concepts were rated by the customer importance and were given scores using relative weights. After evaluating each score, the preferred concepts were the lateralized laryngoscope blade, and the bite block mouth guard, and we chose the lateralized blade as it had the highest score and seemed to be the most feasible to design. The lateralized blade is a modified version of the Macintosh blade, except it is angled away from the airway at the mouth. This blade approaches the larynx from an angle providing a larger and clearer view and avoids the weak maxillary incisors.

In the Phase 2 QFD, Step 2, we derived component specifications from engineering requirements for the selected design (Appendix B). The preliminary specifications for the blade were divided mainly between dimensional, functional, and material specifications. The most important dimensional specifications for the design to meet were that the lateralization had to be greater than 10 mm, the width of the tip of the blade had to be less than 20 mm, and the vertical height of the blade would be 20-42 mm. The most important functional specification (component specification) for the blade to meet was that the device would be compatible with all current intubation equipment, such as most handles. Comparing the materials to predicate devices that have similar function, the most important material specifications for the blade to meet were that the blade had to not be flexible with a Modulus of Elasticity of 2.3 GPa, the material strength could withstand 125 Newtons of force applied to the underside of the blade since this is considering a factor of safety of 2.5 [10], and the material had to be biocompatible with ISO 10993 compliancy.

V. Design Outputs

The design outputs were all derived specifically from the varying engineering requirements. The most important design outputs to mention had to do with avoiding the maxillary incisors and maintaining the functionality as a practical surgical

tool. For example, For example, the laryngoscope has a twenty-millimeter offset in the blade to avoid contact with the front teeth, and that the device would optimally be made from 316 stainless steel, to maintain the strength and material requirements for operating as a surgical instrument. Many of the engineering choices, driven by both customer and engineering requirements, in our design were satisfied simply by maintaining a laryngoscope design as well as mimicking the existing designs for other competing laryngoscopes. Some of these categories include: Biocompatibility, Sterilization, Compatibility with Other Devices, and Maintenance. A variety of other customer and engineering requirements were not relevant to the scope of the project, such as Packaging Requirements, as current solutions would be mimicked and would simply increase cost of manufacturing for prototype evaluations.

The physical changes made to the blade addressed or optimized several aspects of the laryngoscope blade. As previously mentioned, the offset of the blade is the main design component of this project. This achieves the protection of the maxillary incisors, which was the main goal when starting the design process. This design addresses this problem by moving the material of the blade laterally to provide the same function current laryngoscopes achieve while keeping any metal from contacting the front teeth at all. This fix created a strength problem, so a flat was added on the opposite side to accommodate more material to hold up under the stress of being used, which performed ideally. Another change our device exemplified was a slight lowering of the blade profile, so the cross-sectional height was decreased to allow for more visibility during laryngoscopy. Furthermore, larger radii were provided were the hand would contact the device to prevent and poking or pinching of the end user's hand, as this was seen in during preliminary research. Finally, the entire design was examined to remove any sharp edges or thin walls to prevent any avoidable soft tissue damage from occurring.

All of these design considerations were brought to life by utilizing a three-dimensional modeling software known as Solidworks. These models were pertinent for a number of reasons, including visualization of the device, revising the part as needed without producing several prototypes, ensuring assembly fit and function, finite element analysis, 3D printing, and technical drawings. The drawings were created to simulate a need for manufacturing inputs that are separate from 3D printing, as well as for quality assurance after production of the part to make sure the produced part meets the specifications of the drawing. See Appendix D to reference Solidworks Models and Drawings.

VI. Design Verification

Verification of a design ensures the design outputs meet the engineering requirements set in the design inputs stage. The log of the verification tasks outlined in this section is included in Appendix E. First, we tested the structural integrity of the lateralized blade using the Finite Element Analysis add-on in Solidworks. The results obtained in this test proved that the initial design in revisions A and C could not withstand the prescribed 125 N of force. The stress in the middle of the blade exceeded the yield stress of 316 Stainless Steel. This was corrected in revision D of the design by adding a longer flange on the blade to provide more flexural resistance. This correction was complemented by the decision to use 17-4 stainless steel which has a higher yield strength than 316 stainless steel. The Finite Element Analysis on revision D did not exceed the yield stress of 17-4 Stainless Steel. Furthermore, the highest stress regions were shifted toward the proximal end of the blade due to this design change. In the unlikely event of structural failure, the broken and likely sharp-edged end of the laryngoscope blade will not be inside the patient's mouth, preventing lacerations. Also, because the laryngoscope would still protrude from the patient's mouth, the foreign body will be easy to remove.

Another design specification tested in Solidworks was the necessity for no sharp edges to be present on the laryngoscope blade. This was tested by running the thickness analysis test, to ensure no edges were under 1 mm in thickness. One edge was found to be non-compliant in revision C. This was rectified in revision D by adding more material to remove the offending edge.

The lateralized blade design fulfills multiple engineering requirements by keeping similar material characteristics of commercially available laryngoscope blades. The FDA has approved 17-4 Stainless Steel for use in the manufacture of Class I medical devices and therefore fulfills the design requirements concerning biocompatibility, flexibility, hardness, sterilization, and functionality in temperature and humidity conditions in the mouth for this Class II medical device. The physical characteristics having to do with dimension and weight were verified by inspection of the Solidworks model and drawings (Appendix D).

A 3D printed alpha prototype was also used to verify design outputs. The blade made of PLA was inserted into an existing Welch Allyn laryngoscope handle to ensure the design is compatible with intubation equipment currently in use. Members of the team also took the printed blade to Akron General to verify the lateralization of the blade is sufficient to avoid hitting the front 4 incisors. Each of these verification measures were successful and no revisions were deemed necessary after these actions.

VII. Medical Device

Our final iteration (Revision D) and beta prototype of our lateralized blade was composed of 3D printed titanium which was polished and smoothed out in order to be used in validation testing and demonstration. We leveraged the handle and the fiberoptic light source from a laryngoscope we were given from Akron General and were successfully able to attach our titanium blade to the handle and thread the fiberoptic light source through the mating portion of the blade and onto the distal blade. Our beta protype also had the same blade geometry as our revision C alpha prototype but a stronger structural integrity so our design outputs were met through this design as well. Our final prototype with the blade and handle assembly along with the device being used on a manikin head can be seen in Appendix F.

VIII. Validation Testing

The validation process ensured that the new medical device satisfied the customer requirements established in the User Needs stage of the project. On March 12, 2021, our team utilized the network of anesthesiologists and CRNAs along with the titanium beta prototype for testing on manikin heads at the simulation lab at Akron General. Seven medical professionals certified to perform intubations with varying degrees of experience used our prototype and filled out an evaluation form, comparing the lateralized blade to other common laryngoscope blades (Appendix G).

It is important to note that not a single user rated the lateralized blade as failing to meet any of the customer requirements, meaning that our device is an overall success. The scores were averaged and weighted with regards to how important the requirement is to the customer. Some of the survey results are biased due to personal preferences. Despite this, the lateralized blade received the highest overall score, with a notably higher score in not obstructing view of the mouth or larynx, the most important customer requirement (Appendix H). None of the average scores for the lateralized blade rank last among the blades rated in our survey.

Because the lateralized blade is a more geometrically complex design than laryngoscope blades already used in hospitals, our group reasons that the lateralized blade may have a higher cost due to the difficulty in manufacturing this blade. In considering this, our group recommends injection molding which would lower the overall cost and make the pricing of the blade more competitive. Also, since 17-4 Stainless Steel can undergo many sterilization cycles, a single lateralized blade would be used many times before the material will degrade and no longer be able to be used. These cost reductions, in tandem with the reduced cost of compensation by hospitals for chipped teeth, make the lateralized blade a competitively priced option.

IX. Risk Mitigation Process

As with any medical device product, we identified a few risks with our design that could pose as a hazard during the intubation process. We mitigated these risks to the best of our ability by identifying, understanding, controlling, and preventing any failures that could potentially occur using a design Failure Modes Effects Analysis (FMEA). We developed two FMEA's; one being an analysis associated with performing intubations using traditional laryngoscopes and another one associated with performing intubations using our lateralized design. The FMEA process we followed involved reviewing the intubation process and design of our device, brainstorming potential risks and failure modes, listing potential effects of each failure, assigning severity, occurrence, and detection rankings, and finally calculating risk priority numbers (RPN) and developing action plans for each identified risk. The first key risk we identified was the blade snapping at a high stress point while being used on a patient. We mitigated this risk by designing our blade with a factor of safety 2.5 times more than the force required during a standard laryngoscope procedure. We also changed the material to 17-4 Stainless Steel due to its strong material properties and high fracture toughness. Our RPN associated with this risk was lowered from a 4 to a 2 by making these changes. Another key risk we identified is obstructing the clinicians view of the air way with our design. We mitigated this risk by designing the blade with similar dimensions to on the market laryngoscopes and offsetting the proximal end by 20 mm. The RPN associated with this was lowered from a 6 to a 2. We were successfully able to lower our medium-level risks to low and maintain our low-level risk levels. Both our process FMEA and our design FMEA along with other risk and mitigation activities we performed can be seen in Appendix C.

X. Market and Manufacturing Considerations

The market for the lateralized laryngoscope blade exists but could pose a few challenges. Clinicians will need to be marketed on increased visibility rather than teeth protection as a perfectly performed laryngoscopy will damage no teeth. However, a hospital will need to be marketed on the savings and legal protections this can offer by lowering the incidence rate as well as cost per incidence of dental damage. Given this challenge, there is a market for this device in hospitals today. Another positive is that the Macintosh style blade is already preferred and rising in popularity, meaning the lateralized blade will attract the same attention as the curved design mimics the Macintosh blade.

Manufacturing of this device is twofold. One area to consider is the reusable laryngoscope market. The manufacturing for this market would include a metal blade with all parts being able to withstand repeated use and sterilization, making the product much more expensive to make per unit. However, this device is a great candidate for injection molding as a manufacturing technique, drastically lowering the price once molds are made for the blade. Given the trend toward one use laryngoscope blade and the drastic savings that injection molding could provide for this product, a reusable laryngoscope blade would most likely be the optimal choice for marketing this blade to hospitals.

XI. Summary Feasibility Discussion

This finalized design did satisfy the need identified at the beginning of the project. The validation testing results show that the clinicians feel that the product does accomplish the goal of getting out of the way of the front maxillary teeth, as well as having the addition of it providing a wider view of the airway.

The team categorizes the beta prototype as a final product because it is further developed than the alpha prototype and advanced enough to be a true medical device. The initial alpha prototype was the group of revisions that were 3D printed models, including revisions A-D composed of PLA. The beta prototype is composed of 3D printed titanium and polished to be made smooth enough for testing and demonstration. It is also strong enough to be used exactly how a clinician would utilize a laryngoscope blade during intubation. The only difference between the final beta prototype and functional surgical instrument is being cleaned, sterilized and packaged and labeled correctly.

XII. Discussion, Lessons Learned, And Conclusion

This design project served as an immersing and culminating experience for us as undergraduates by integrating knowledge from previous classes and co-op experiences during our time at the University of Akron. We learned how to take a clinical need

along with a brainstormed idea, and progress it through the FDA design process and into a fully functional prototype. We gained first-hand experience developing relevant documents during each project phase such as Quality Functional Deployment matrixes, engineering requirement documents, Failure Modes Effects Analysis tables, Bill of Materials, and verification and validation plans. As a team, we gained knowledge of current practices of intubation procedure, the complications that can occur during these procedures, and the consequences hospitals can face due to these complications. As a result of our collaborative efforts along with the assistance and guidance of those in our acknowledgments, we were able to successfully build and assemble a functioning lateralized laryngoscope blade that offsets the contact from the front incisors to the back pre-molars which can withstand much more force. Developing a device that helps to reduce the number of complications that occur during intubations such as ours would result in a positive impact on the future of surgical care during tracheal intubations for patients, clinicians, and hospitals. We believe our device will go a long way in helping hospitals achieve their goal of providing the best care possible, preventing injuries during the intubation process, and reducing the cost associated with lawsuits due to dental trauma.

XIII. Future Work

The lateralized laryngoscope design developed over the course of this project was successful at reaching all of the major engineering and customer requirements except for one which was cost. Due to the limited budget and time, we had to explore 3D printing to fabricate our design which is not cost effective. Future work for this project would be to investigate the cost and functionality required to injection mold the model since that can greatly reduce the cost. Additional work would also include designing other size variations since most laryngoscopes have 3-6 different sizes depending on the patient. Our focus was to create one fully functional design but given the time and opportunity, it would be beneficial to develop alternate versions.

XIV. Individual Roles and Responsibilities

Due to the vast undertaking of creating a medical device through the FDA Control Guidance process in under a year, each team member was assigned a minimum of at least one lead role and one secondary role. Team members also contributed outside their roles when a task required more effort to be completed by the given deadline. Each team member fulfilled the duties of their given roles which led to the successful design and production of the Lateralized Laryngoscope blade. Appendix I includes a Gantt chart of the overall project over the course of the last 8 months with major tasks and the group member assigned to each task. The following list contains the specific roles and responsibilities of each team member.

- Steven Innocenzi – Primary roles and responsibilities include Project Leader, design of QFD, and research of competitor products. Secondary roles and responsibilities include Designer, verification and validation testing, and recording of meeting minutes.
- Kenneth Gregg – Primary roles and responsibilities include team workflow planning via Gantt charts, prescribing meeting agenda, recording meeting minutes, fabrication of alpha prototype, and organizing verification and validation test results. Secondary roles and responsibilities include design of QFD, verification and validation testing, and making engineering requirements.
- Regina Neugebauer – Primary roles and responsibilities include main communicator with stakeholders and clinicians, preparation of parts for testing, FEA testing on alpha prototypes, verification testing. Secondary roles and responsibilities include creator of engineering requirements, developing FMEA, validation testing
- Clarence Noronha – Primary roles and responsibilities include initial patent and market research, developing FMEA, risk mitigation activities, Parts Decision Matrix, Bill of Materials, and filling our purchase requisitions. Secondary roles and responsibilities include assisting with other quality and validation tasks.
- Jacob Myers – Primary roles and responsibilities include R&D considerations, transitioning design inputs to outputs, 3D modeling, design of device, managing manufacturing of beta prototype, and Design History File Organization. Secondary roles and responsibilities include creating customer and engineering requirement, supporting verification and validation testing, and general device consideration throughout project.

XV. Professional and Ethical Responsibilities

The design has considered the potential impact of the engineering solution in terms of global, economic, environmental, and societal contexts. Economically, this product would help reduce hospital costs overall, because teeth damage is very expensive to fix. The environmental impact would be that it would contribute to waste products because the product is disposable; it would not produce more waste in that area than before, just replace the current product, therefore not making the environmental impact any worse. For global and societal contexts, the impact would be negligible or minimal at most. Laryngoscopes are used on a global scale, but this device would be used increasingly as popularity grew but would simply replace what is currently being used and would not create a new global phenomenon. Societally, it would seem as though clinicians are using laryngoscopes at the same rate, so there should be very little impact outside of decreased dental damages.

XVI. Acknowledgements

We would like to thank Frank Fire, Simulation Specialist at Akron General, who provided a large amount of support, design feedback, and access to equipment. We would also like to thank SLICE Mfg. Studios and NextStep Arthropedix for 3D printing our prototype, J.R's Tool Crib for post processing the 3D print, and Dr. Daniel Vazquez as well as all the anesthesiologists and CRNAs that were interviewed and consulted with through the course of the project. Lastly, we would like to thank Dr. James Keszenheimer for his oversight and guidance.

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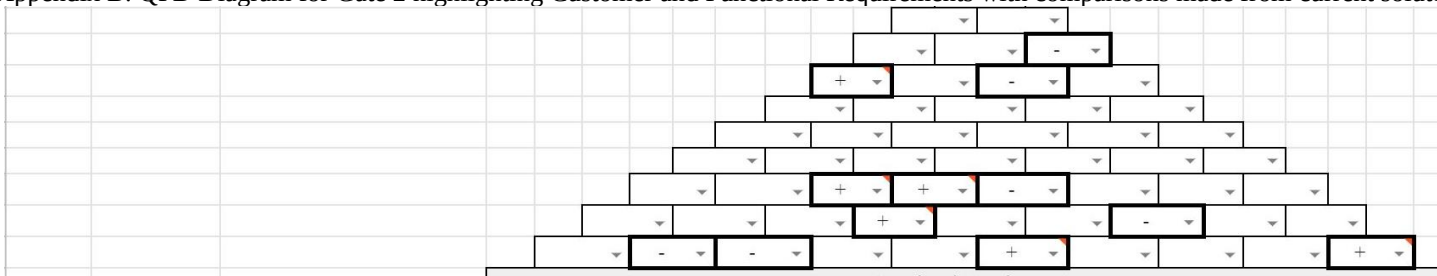
XVIII Appendix

Appendix A: List of Engineering requirements produced in the Design Inputs stage.

Category	Engineering Requirement	Derived from
Device Functions	Design shall allow for the end user to move soft tissue, including the epiglottis, to achieve a direct view of the larynx.	Customer Requirement/ Interview
	Design shall allow for an endotracheal tube to be inserted into the trachea during use.	
	Design shall allow for removal with an endotracheal tube in place.	
	Design shall avoid damage to teeth caused by laryngoscopy.	Research on damages incurred during intubation [2,3,4,5,6,7,8]
Physical Characteristics	The strength and hardness of the material shall be compliant with ISO 7376:2020 standards.	FDA Standard
	The length of a standard laryngoscope shall be greater than 60 mm, and shall not exceed 210 mm.	Current laryngoscope blades on the market [9]
	The width of a standard laryngoscope blade tip shall be less than 20 mm.	
	The height of a standard laryngoscope blade shall be no more than 42 mm.	
	The mass of the overall device shall not exceed 5 kg, including any attachments.	
Human Factors	The device should be able to be used with one hand.	Customer Requirement/ Interview
	The design should be familiar and intuitive to use.	
	The device should pass a usability inspection completed by at least two anesthesiologists.	
Safety	The device shall not have any sharp edges that could lacerate tissue.	FDA Standard
	The device shall be rigid and smooth to prevent unintended catching between the device and the patient’s tissue.	
	If the device breaks during use, the device shall fail without serious or permanent harm to the patient or end user.	Customer Requirement/ Interview
Performance	Design shall not obstruct vision on the right side of a patient's throat.	Customer Requirement/ Interview
Reliability	Device should be designed for quick ease of use in emergency situations.	Customer Requirement/ Interview
	Device shall not break during regular use according to the surgical instructions.	FDA Standard
Biocompatibility	Device shall comply with Class II Medical Device material requirements for biocompatibility.	FDA Standard
Compatibility with other devices	Device design shall be compatible with an existing laryngoscope handle.	Customer Requirement/ Interview
	Device design should allow for the insertion of endotracheal tubes.	

Appendix B: QFD Diagram for Gate 2 highlighting Customer and Functional Requirements with comparisons made from current solutions used on the market.



		Functional Requirements											Customer Competitive Assessment			
		Direction of Improvement	□	▲	▼	▼	▲	▼	▼	□	▲	▲	▲				
Relative Weight	Customer Importance	Requirements	Biocompatable to Class 2 Device standards	Laryngoscope Material Strength	Laryngoscope Flexibility	Material Hardness	No. of variable sizes	Maximum amount of stress applied to front 4 incisors	Sharpness of design	Sterilization	Compatable with intubation equipment currently in use	Functional in average mouth temperatures	Functional in average mouth relative humidity	Our Product	DentaSafe	Intugaurd	GlideScope Spectrum
16,67%	9	Protect Teeth from damage inccured by laryngoscope				●		●	○						5	5	4
18,52%	10	Does not obstruct view of the patient's mouth nor larynx					●				●				4	4	5
7,41%	4	Allow quick use in emergency situation					○	○	▽	▽	▽				3	0	4
5,56%	3	Disposable	○							○		▽	▽		5	5	5
16,67%	9	Competitive Price	○				▽			▽					4	2	1
9,26%	5	Prevent infection and unwanted reaction in the mouth of the patient	●						▽	●		▽	▽		5	5	5
7,41%	4	Allows patient to be pre-oxygenated prior to procedure									●				5	3	5
3,70%	2	Does not interfer with the endotracheal tube							○		○				5	5	5
12,96%	7	Able to perform intubation with high success rate	▽	●	○		▽				●				3	3	5
1,85%	1	Protects soft tissue from damage occured by laryngoscope				○			●						2	2	5
		Importance Rating Sum (Importance x Relationship)	163	117	39	156	219	172	94	124	369	15	15				
		Relative Weight	11%	8%	3%	11%	15%	12%	6%	8%	25%	1%	1%				
		Target Value	ISO 10993	Withstand 125 Newtons	2.3 GPa	114-126 Rockwell R Test	12	250MPa	UL Standard 1493	ICS 11.080.01		26-29 Celsuis	78-94% Relative Humidity				
		Our Product															
		DentaSafe	5			5	4	4	5	5	3	4	4				
		Intugaurd	5			5	5	5	5	5	4	5	5				
		GlideScope Spectrum	5	5	4	4	3	4	5	5	5	5	5				
		Technical Competitive Assessment															

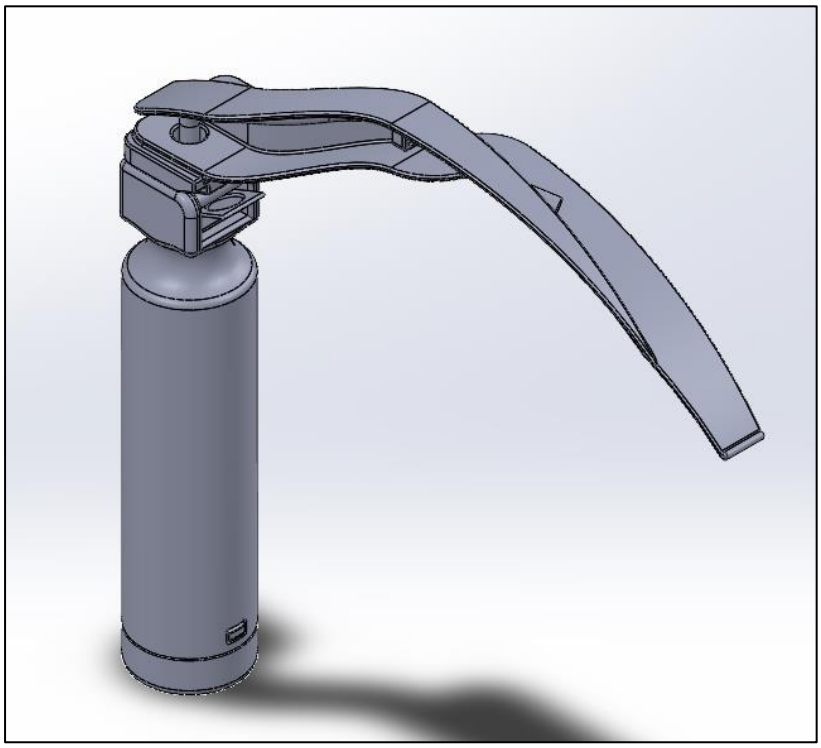
Appendix C: Process and Design Failure Mode Effects Analysis associated while performing a tracheal intubation.

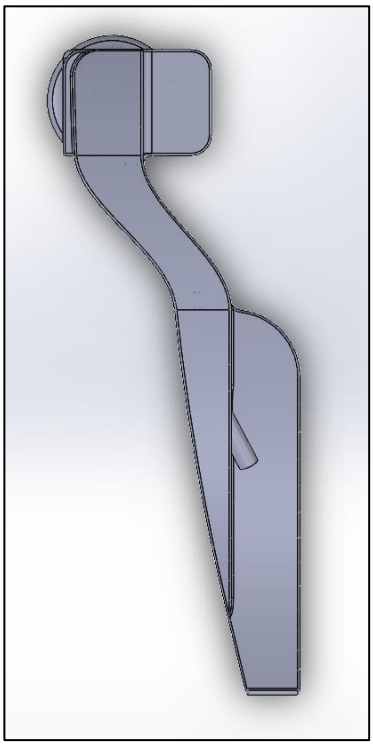
No	Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) Mechanism(s) of Failure	Severity	Occurence	Detection	RPN	Level	Suggested Mitigation	Verification	Recommended Actions
1	Move soft oral tissue to acheive a view of the larynx	Blade could make too forceful of contact with soft tissue	Lip lacerations	•Blade is sized incorrectly •Edges of blade are not smoothed out properly •Improper user training	1	3	2	6	MEDIUM	Follow design specifications for current marketed laryngoscopes	Measure blade length, hardness, and sharpness using appropriate testing	•Size blades appropiately to ISO standards •Provide proper instruction and training to user prior to use
			Tongue lacerations		1	2	2	4	MEDIUM			
2	Provide protection against damage to teeth	Blade could make unwanted contact with teeth	Teeth chipage	•Blade is sized incorrectly •Blade is not properly curved or angled •Positioning of handle is not intuitive and does not allow for proper scope manipulation • Improper user training	2	2	1	4	MEDIUM	•Design blade with material hardness properties less than that of teeth •Design a protective insert that can attach onto laryngscope	•Measure blade length, hardness, and sharpness using appropriate testing •Test laryngoscope on mannequin to ensure teeth are not impacted	•Size blades appropiately to ISO standards •Provide proper instruction and training to user prior to use
			Teeth crackage		2	2	1	4	MEDIUM			
			Teeth breakage		3	1	1	3	LOW			
3	Allow for endotracheal tube to be inserted into trachea during use	Tube could potentially enter the esophagus	Severe brain damage	•Scope obstructs the users view due to incorrect blade sizing •Improper user training	3	1	1	3	LOW	Design laryngscope so it does not obstruct view of the user	Perform trials on mannequin that ensure user has a clear view of the airway	Utilize CO2 sensor
			Death		3	1	1	3	LOW			
4	Hold down tongue during laryngscope manipulation	Handle could separate from blade	Tissue damage	Improper welding between handle and blade	3	1	1	3	LOW	Keep fabrication process similar to currently marketed laryngscopes	Run appropriate fracture toughness/fatigue tests	Ensure all parts are properly welded
			Teeth damage		2	1	1	2	LOW			
			Choking hazard		3	1	1	3	LOW			
5	Illuminate the airway	Light source could detach from scope	Electrical hazard	Improper attachement or welding between light source and scope	2	1	1	2	LOW	Keep fabrication process similar to currently marketed laryngscopes	Run appropriate mechanical testing	Ensure all parts are properly welded
			Chocking hazard		3	1	1	3	LOW			

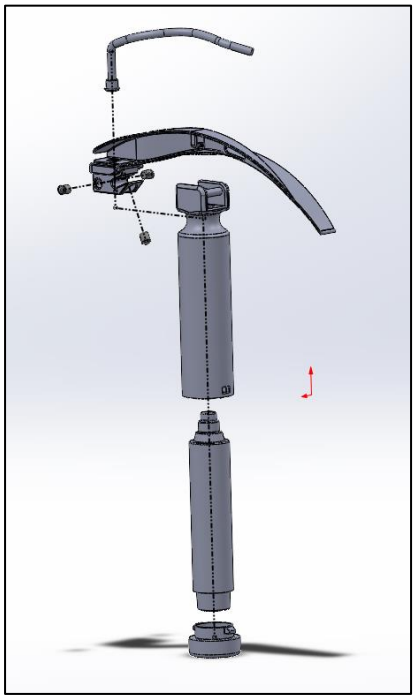
Appendix C: Continued.

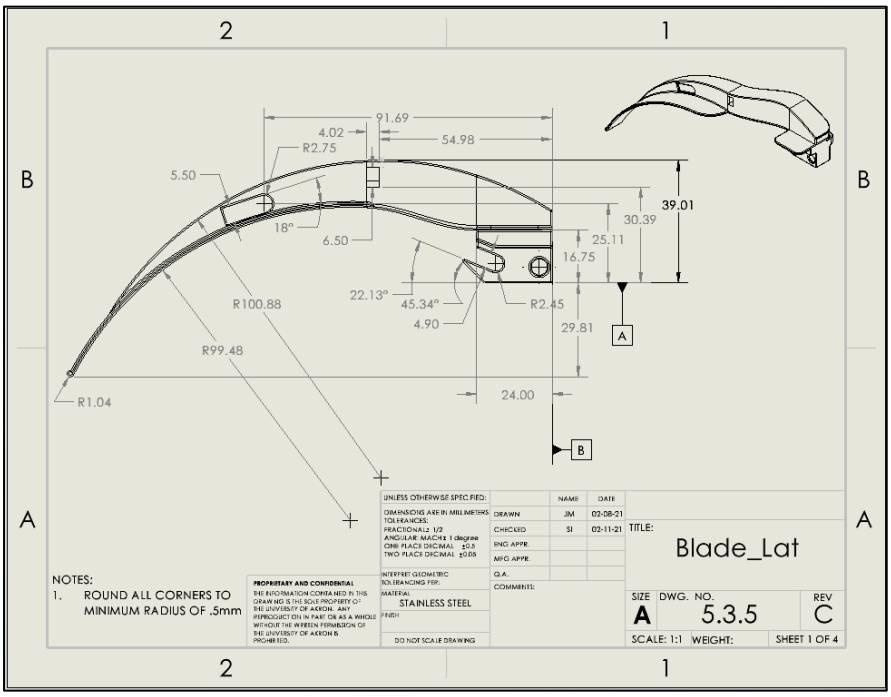
Failure Modes Effects Analysis - "Lateralized Blade"												
No	Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) Mechanism(s) of Failure	Severity	Occurence	Detection	RPN	Level	Suggested Mitigation	Verification	Recommended Actions
1	Provide protection against damage to teeth	Blade may make forceful contact with molars and/or incisors	Teeth Chippage/Crackage	•Material of blade is too hard •Blade is sized incorrectly •Blade is not properly curved or angled •Device is not handled properly by user	2	1	1	2	LOW	•Design blade with lower material hardness properties •Design blade with alternate curvature to avoid contacting teeth	•Measure blade length, hardness, and sharpness using appropriate testing •Test laryngoscope on mannequin to ensure teeth are not impacted	•Size blades appropiately to ISO standards •Provide proper instruction and training to user prior to use
			Soft Tissue Damage		1	2	1	2	LOW			
2	Provide view of airway to clinician	Blade becomes deformed	Minor visibility impairment	•Material of blade is not hard enough (especially plastics) •Blade is sized incorrectly •Blade is not properly curved or angled •Device is not handled properly by user	1	2	1	2	LOW	•Design blade with greater material hardness properties •Ensure laryngscope blade is sized correctly to patient so as to not deform	•Measure blade length, hardness, and sharpness using appropriate testing •Test laryngoscope on mannequin to ensure blade does not deform	•Size blades appropiately to ISO standards •Provide proper instruction and training to user prior to use
			Inability to intubate		3	1	1	3	LOW			
			Accidental esophageal intubation		3	1	1	3	LOW			
3	Hold down tongue during laryngscope manipulation	Blade could break/snap into two or more pieces	Metal pieces can get stuck down patient's trachea or esophagus	•Force applied could be too great for the strength of the design •Blade is sized incorrectly •Blade is not properly curved or angled •Device is not handled properly by user	3	1	1	3	LOW	•Design blade with greater material strength properties •Ensure laryngscope blade is sized correctly to patient so as not to snap/break	•Measure strength of blade using FEA or other appropriate testing •Test laryngoscope on mannequin to ensure blade does not snap/break	•Size blades appropiately to ISO standards •Provide proper instruction and training to user prior to use
			Tissue/teeth damage		2	1	1	2	LOW			
4	Hold down tongue during laryngscope manipulation	Hand Guard on handle can snap/wear out	Tissue/teeth damage	•Repeated use of laryngscope •Force applied could be too great for design •Device is not handled properly by user	2	1	1	2	LOW	•Design hand gaurd with greater material strength properties •Ensure hand guard is welded properly to laryngoscope	•Measure strength of hand guard using FEA or other appropriate testing •Test laryngoscope on mannequin repeatedly to ensure hand guard does not wear/snap over time	•Ensure proper welding •Provide proper instruction and training prior to use
			User discomfort		1	1	1	1	LOW			

Appendix D: Solidworks Model Images and Drawing Example





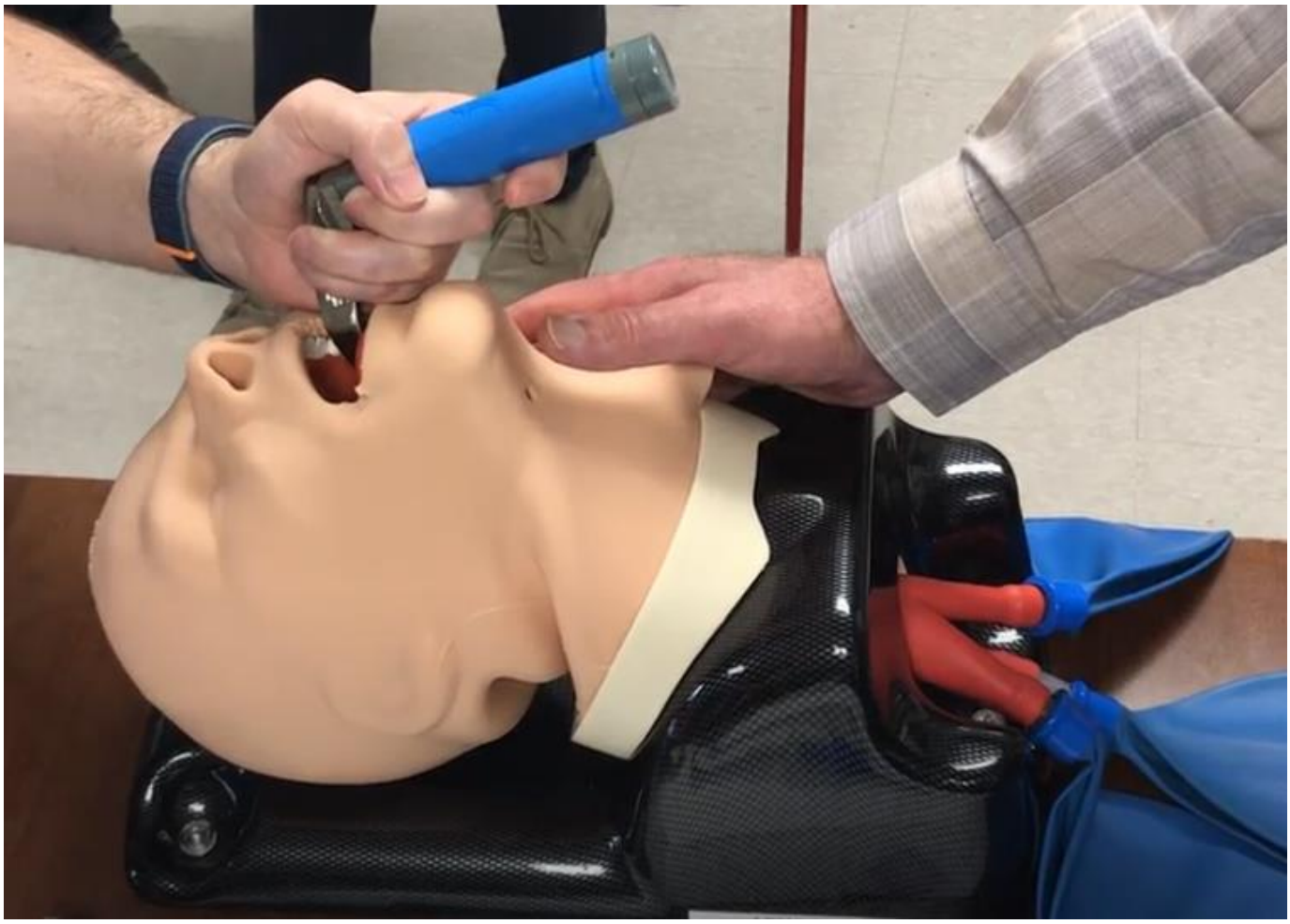




Appendix E: Verification log containing verification tasks, outcomes, and correction methods.

Design Specification	Test Method	Date	Revision	Name of Tester	Target Values	Pass/Fail?	Correction
Compatible with intubation equipment currently in use	3D printed and inserted into existing Welch Allyn handle	2/2/2021	A	Ken, Gina	--	Pass	--
Laryngoscope Material Strength	Finite Element Analysis	2/4/2021	A	Gina	Withstand 125 Newtons	Fail	Add material on proximal end of blade, lateral side
Maximum amount of stress applied to front 4 incisors	3D printed and inserted into practice manikin at Akron General to see if lateralization made clearance for teeth	2/5/2021	B	Gina, Jacob, Clarence, Steven	250 MPa	Pass	--
No Sharp Edges	Thickness evaluation in Solidworks	2/8/2021	C	Ken	all edges thicker than 1mm	Fail	Remove window which contains offending edge, or apply 0.5mm fillet
Laryngoscope Material Strength	Finite Element Analysis	2/8/2021	C	Gina	Withstand 125 Newtons	Fail	Extend material on proximal end of blade, lateral side
Laryngoscope Material Strength	Finite Element Analysis	2/22/2021	D	Gina	Withstand 125 Newtons	Pass	Extended material on proximal end of blade, changed material to 17-4 Stainless Steel
No Sharp Edges	Thickness evaluation in Solidworks	3/19/2021	D	Ken	All edges thicker than 1mm	Pass	Removed window which contained offending edge

Appendix F: Pictures of beta prototype demonstration on mannikin head.



Appendix G: Validation survey to be completed by intubation-certified medical professionals.

Thank you for participating in the validation of our medical device. Please fill out the following form by assigning a rating to each laryngoscope blade. 1 is the lowest rating and 5 is the highest. Rating 1-2 is a FAIL, while 3-5 is passing.

Customer Requirement	Lateralized	Macintosh	Miller	GlideScope
Does not obstruct view of the patient's mouth nor larynx	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Protects teeth from damage incurred by laryngoscope	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Able to perform intubation with high success rate	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Allow quick use in emergency situation	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Does not interfere with the endotracheal tube	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Protects soft tissue from damage incurred by laryngoscope	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

Additional Comments: _____

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Appendix H: Validation survey results from 03/12/2021.

Relative Weight	Customer Importance	Laryngoscope Blade Design / Customer Requirements	Lateralized	Macintosh	Miller	GlideScope
30.30%	10	Does not obstruct view of the patient's mouth nor larynx	4.86	4.29	3	4.5
27.27%	9	Protect Teeth from damage inccured by laryngoscope	4.5	3.5	3.25	4.4
21.21%	7	Able to perform intubation with high success rate	4.57	4.57	3.8	5
12.12%	4	Allow quick use in emergency situation	4.83	4.71	4	4.33
6.06%	2	Does not interfere with the endotracheal tube	4.83	4.33	3.75	3.8
3.03%	1	Protects soft tissue from damage incurred by laryngoscope	4.14	4.29	3.4	4.5
		Overall Weighted Average:	4.67	4.19	3.42	4.52

Appendix I: Overview Gantt chart showing progress from 9/14/2020 to 4/23/2021

Intubation Damage Solution Project Gantt Chart

Task	Owner	Start Date	End Date	Timeline	Status
Senior Design Project Timeline	Team	9/14/2020	4/23/2021		
Gate/Phase 1: User Needs	Team	9/14/2020	9/28/2020		Complete
General Research on Problems to Solve	Team	9/14/2020	9/21/2020		Complete
Interviews, Formulation of User Need Statement and Customer Requirements	Team	9/16/2020	9/28/2020		Complete
Gate/Phase 2: Design Inputs	Team	9/28/2020	11/2/2020		Complete
Translate user needs into engineering requirements	Jacob, Ken, Gina	10/5/2020	10/14/2020		Complete
Apply a House of Quality (QFD) to engineering requirements	Steven, Clarence	10/8/2020	10/28/2020		Complete
Risk Assessment	Clarence, Steven, Gina	10/14/2020	11/1/2020		Complete
Gate/Phase 3: Design Process	Team	11/2/2020	11/30/2020		Complete
Brainstorming Designs	Team	11/2/2020	11/11/2020		Complete
QFD Downselect, Functional QFD, Part Design Matrix	Steven, Ken	11/11/2020	11/27/2020		Complete
Failure Mode Effects Analysis	Clarence, Gina	11/18/2020	11/27/2020		Complete
Gate/Phase 4: Design Output	Team	1/11/2021	2/15/2021		Complete
SOLIDWORKS Modeling and Drawings	Jacob, Steven	1/11/2021	2/14/2021		Complete
Alpha Prototyping, Purchasing	Ken, Clarence	1/28/2021	2/14/2021		Complete
Verification Testing	Team	1/28/2021	2/14/2021		Complete
Gate/Phase 5: Medical Device	Team	2/15/2021	4/23/2021		Active
Rev D SOLIDWORKS Modeling, Drawings, and Verification	Jacob, Steven, Gina, Ken	2/15/2021	2/22/2021		Complete
Beta Prototype Fabrication	Jacob, Gina, Clarence	2/22/2021	3/12/2021		Complete
Validation of Medical Device	Team	3/12/2021	3/15/2021		Complete