ORIGINAL ARTICLE

Design of a Novel, Modular, Mouth Retractor: A Concept Testing Study

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ABSTRACT

Background and Objectives. Mouth retractors are essential in ensuring efficient yet safe exposure of the oral cavity and oropharynx. However, when applied improperly or haphazardly, retractors can cause tissue injuries and compromise patient safety. In addition, there are gaps in the usability of existing designs. This study aimed to identify the issues encountered by otorhinolaryngology surgeons in the use of commercially available mouth retractors, design and fabricate an improved retractor, and explore the use of additive manufacturing (popularly known as 3D printing) for retractor prototyping.

Methods. The study used the United States Food and Drug Administration (US FDA) Design Control as its framework. End-user requirements from otorhinolaryngologists were collected through key informant interviews. Results were organized into a Design Input template which was used to guide the design and development process. Prototype designs were iteratively created using computer-aided design software and 3D printing. Once design specifications were satisfied, a beta prototype was fabricated and given to another cohort of otorhinolaryngologists. The participants assessed the usability of the beta prototype. System Usability Scale (SUS) was used to quantify participant's feedback.

Results. Five designs were created in the course of the study. The final prototype was fabricated using a Stereolithography (SLA) 3D printer. Several features were developed to address user requirements. The primary modification was to make the retractor modular to facilitate easier and shorter mounting and assembly. Gingival injury was addressed with the replacement of the maxillary alveolus hook with support bars. Five participants evaluated the beta prototype which received a mean SUS score of 75, well above the 50th percentile threshold.

Conclusion. This study demonstrates the applicability of the US FDA Design Control Process in the local setting to improve the mouth retractor design. Clinical and ergonomic issues were identified and design solutions were proposed and some have been implemented in a low-fidelity prototype. Results of the small-scale usability test suggest that the present form factor can be the basis for further iterations. Future studies can implement the proposed features to address other clinical and ergonomic needs.

Keywords: mouth retractor, mouth gag, Dingman retractor, 3D printing, medical device

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INTRODUCTION

Otorhinolaryngologists, head and neck, and oral maxillofacial surgeons have been using mouth gags and retractors for decades. These retractors are essential in ensuring efficient yet safe exposure of the oral cavity. Several designs have been developed, patented, and marketed to achieve the perfect exposure of the oral cavity and the oropharynx.[1–3] Figure 1 shows the parts of a typical mouth retractor.

However, when the application is done improperly or the device is misaligned during the procedure, these instruments can still cause soft tissue injuries and compromise patient

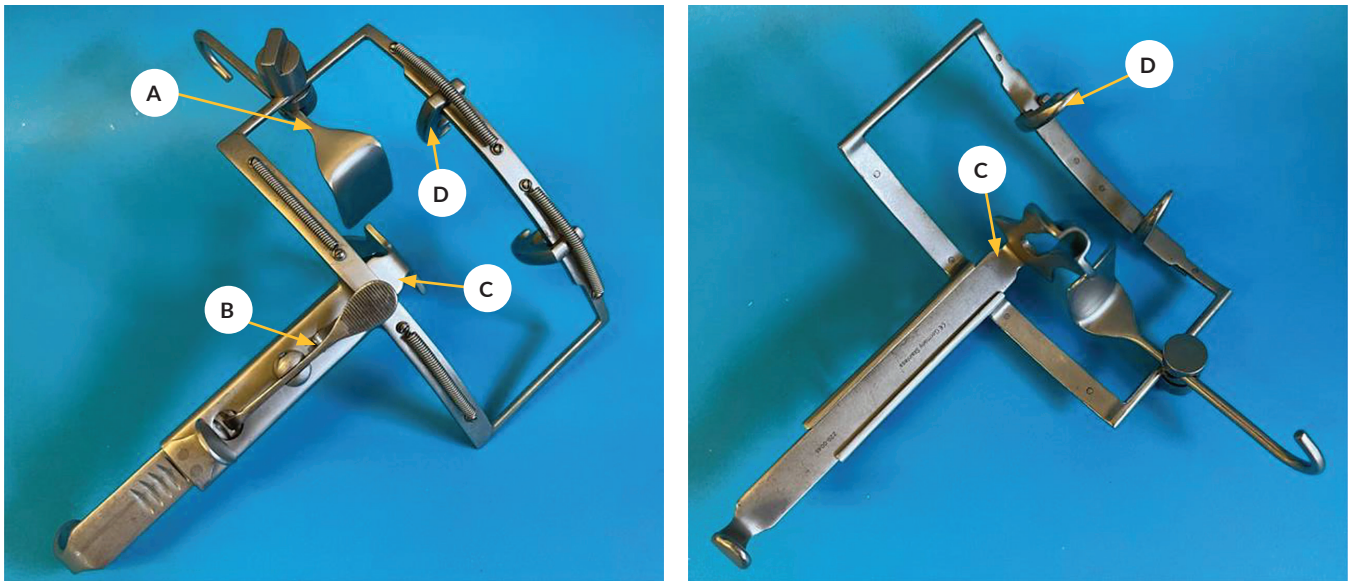

Figure 1. ***A typical Dingman mouth retractor (Model number OM105R, Aesculap AG, Germany).*** Basic parts are: **(A)** Buccal blade and holder which retracts the patient's cheeks to widen the mouth opening, **(B)** Ratchet lock to keep the tongue blade in position, **(C)** Tongue blade which pushes the tongue down, together with the lower jaw, to spread the mouth open, and expose the oral cavity and oropharynx, and **(D)** Maxillary/gingival hooks which contact the upper gingiva.

safety. A growing number of research and case studies have revealed the more urgent problems of these consequences, such as nerve and tissue injury, which can occur due to traumatic contact between the soft tissues of the oral cavity and hard metallic parts of the mouth gag.[4,5]

In certain jurisdictions, medical devices design and development must adhere to quality management system (QMS) standards. In the United States, this is articulated in the United States Food and Drug Administration (US FDA) Design Control Process for Medical Devices. Design Control is composed of four phases: Design Input, Design Output, Verification, and Validation.[6] Design Input refers to determining user need requirements. Design Output refers to features development. Verification includes documenting how each design element was evaluated and ensuring whether each element passes a predefined standard. However, it does not attempt to answer if the device will be clinically effective. That is determined in Validation, the last step in the process, where the device is tested in simulated or actual use conditions.[7]

Additive Manufacturing, more popularly known as 3D printing, is a relatively new fabrication technology that transforms digital designs into physical objects via the controlled addition of raw materials, usually through layer by layer deposition of polymers. This is in contrast to subtractive manufacturing which includes traditional machining, that removes material from a raw stock to create an engineered part. 3D printing brings benefits to the design process as it allows multiple physical prototypes to be created affordably and quickly therefore speeding up iterations.[8]

The few literatures published on innovations on the mouth retractor and similar devices focus more on the prototype and its features rather on the design process that led to the final prototype. This study aims to apply the principles of user-centered design approach and design control to generate a novel redesign of mouth retractor. In addition, the study attempts to adhere to design control principles by documenting all design decisions early on, ensuring prototypes developed in this study can be further improved in such a way that it addresses most if not all clinical requirements.

MATERIALS AND METHODS

Study Design

The study followed an iterative design and development process following the framework of the US FDA Design Control as applied to a waterfall project management methodology (Figure 2). The study primarily focused on Phase 1 of the framework, which consists of determining end user requirements, designing and fabricating a low fidelity prototype, and subjecting the low fidelity prototype to a usability test.

To document the design process in a systematic manner, the study utilized a Design Process template (Appendix A) developed by the Technology Transfer and Business Development Office (TTBDO) of the University of the Philippines Manila. The template was developed based on the principles and guidelines of the US FDA Design Control Process.[6] Approval from the University of the Philippines Manila Research Ethics Board was obtained prior to the conduct of the study.

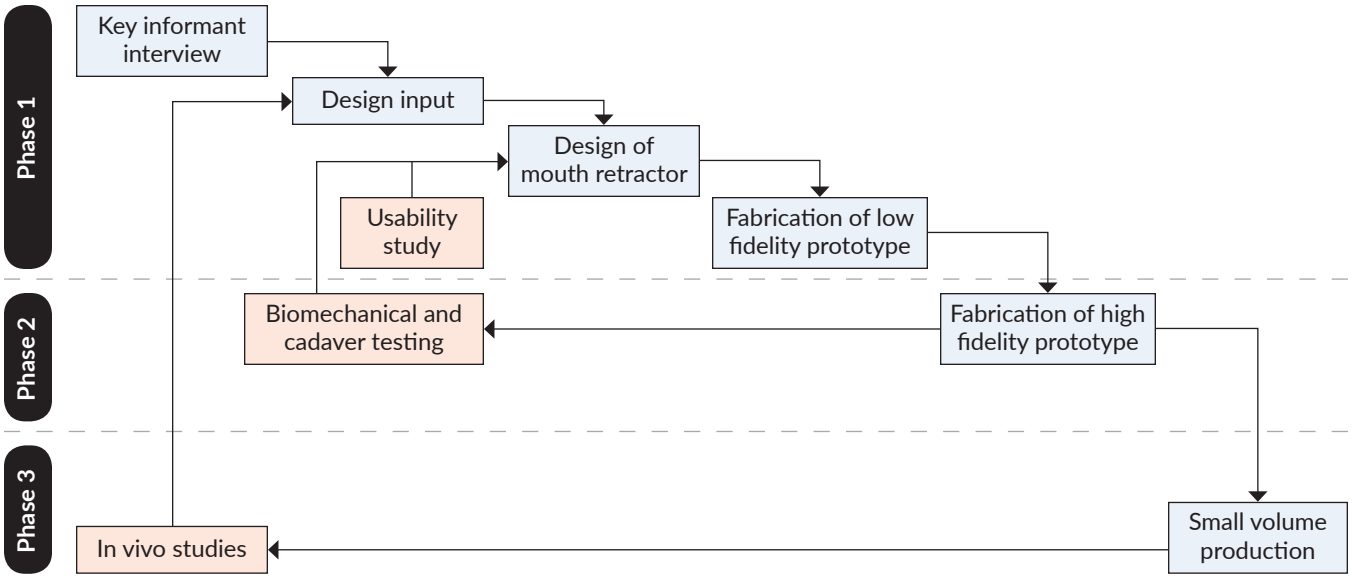

Figure 2. ***Study methodology for designing and developing the prototype mouth retractor.*** This paper reports the results of Phase 1. The succeeding phases will be pursued in a future study.

Study Participants

Study participants were recruited from the Department of Otolaryngology-Head and Neck Surgery of the Philippine General Hospital. Informed consent was secured before data collection. Recruitment was done via purposive sampling. The study has two separate cohorts. One group was recruited for the user needs assessment and another group was recruited for the usability test. Inclusion criteria for the user needs assessment group are: they are faculty members of the department, and they are willing to partake in an interview. For the usability test group, the inclusion criteria are: they are resident trainees of the department and are willing to participate in an in-person usability test. Each cohort has a sample size of five participants which is based on the minimum standard for usability engineering of medical devices.[9]

Design Input

Recruited faculty members underwent key informant interviews (KII) regarding their experiences in using mouth retractors. Participants were asked open-ended questions regarding usability, performance, reliability, and safety of the commercially available mouth retractor design as well as improvements they would like to see in a redesigned mouth retractor. Questions were based on the Biodesign Handbook (Appendix B).[10] All interviews were done by the primary author. Results of the interviews were then summarized into the design input table of the design process template.

All results from the KII were condensed by the primary investigator into several user need statements. The other two investigators then reviewed the initial user statements and changes were made by consensus. The user-need statements followed the pattern of *As a [role], I can [feature] so that [reason]*. This template statement is commonly utilized in the Agile software development framework to ensure a user-centric approach to writing technical requirements.[11] The study investigators then gave each user-need a priority rating, a quantitative parameter, and one or several design input specifications.

Design Output

Based on the design input generated in the previous phase, a 3D model of a mouth retractor was created using the computer-aided design software package Solidworks (Dassault Systèmes, France). The first design addressed only some of the Design Inputs. A physical prototype was fabricated using additive manufacturing or 3D printing for internal evaluation. Revisions were then made to the 3D model so that it satisfies more requirements stated in the Design Input and a new physical prototype was fabricated. Evey implemented feature or component was documented in a Design Output document. In the Design Output, objective and/or subjective tests for each feature were proposed and recorded. Device inspection and dimension check tests were done while more complex tests were planned for a future study. This process was repeated iteratively until the prototype passed all device inspection and dimension check tests.

Usability Testing

The low-fidelity prototype was fabricated using a Form 3L SLA 3D printer (Formlabs, USA). The resident participants were presented with a low fidelity prototype to view and assess in an office setting. Investigators were onsite to discuss and demonstrate the capabilities of the new design. No patients were involved in this part of the study.

Afterwards, the participants were given a System Usability Scale (SUS) questionnaire to answer. The SUS is a ten-item

Likert scale on the user perspective of a device's usability.[12] Items in the questionnaire alternate between positive (e.g., "I would like to use this product frequently.") and negative statements (e.g., "I found the system unnecessarily complex."). It provides a reliable way to quickly differentiate usable from unusable prototypes. It is a widely used usability study tool due to its simplicity, nonproprietary nature, and technology agnosticism.

To evaluate the final prototype, the SUS scores from each participant were converted to a percentile rank via normalization.[13–15] Normalization and computing the standard SUS score is done using the formula:

$$\text{SUS} = 2.5 \times [20 + (\text{Sum of odd numbered items}) - (\text{Sum of even numbered items})]$$

A score of 68 in the SUS corresponded to a percentile rank of 50%.[15] Hence, if the prototype were to receive a score of less than 68 then the device would be deemed unusable and major design revisions would be required.

RESULTS

As mentioned in the previous section, pertinent findings from the KII were organized and summarized following the Design Document template into a Design Input matrix (Table 1). Due to the exploratory and iterative nature of product development, some design input specifications (e.g., target setup time) were left blank with a value of *to be determined* or [TBD].[7] The rationale for each Design Input is stated under the Reasons column and where appropriate external references or standards are used.[16–18] Based on the Design Input, we created a Design Output table listing the technical features needed as well as the appropriate verification or test for each Design Output (Table 1).

The investigators iterated with over 11 designs during the prototype development phase (Figure 3). Early designs were printed using Fused Deposition Modeling 3D printers due to the low cost of operation and material input. Later designs were printed in resin material using Stereolithography (SLA) 3D printers for a smoother surface finish, higher detail fidelity, and increased mechanical stiffness (Figure 3F).

Modularity via an angular mechanism (Figure 4A) was identified as a possible design solution for easier and shorter mounting and assembly of the retractor and to allow

Table 1. For each User Need Derived from the Key Informant Interview, One or Several Design Inputs (feature and capability) are Specified to Address Said User Need. The specific implementation is shown under Design Output.

User Need *"As a [role], I can [feature] so that [reason]"*	Priority rating	Parameter	Design Input *With key for reference (1A, 1B, 2A, etc.)*		Reason (for design input)	Design Output	Verification Method	Test Result
As a health professional, I have adequate exposure to the oral cavity so that I can see all structures and utilize my surgical tools with ease	High	Retraction distance (mm)	1A	The retractor should be able to achieve at least 37 mm mouth opening	Range of mouth opening of the Filipino population[16]	Frame has dimension of 137 mm by 65 mm with maximum retraction of 54 mm	Device inspection	Passed
		Number of oral cavity structures visible (n)	1B	The following 11 structures must be visible: buccal mucosa, tongue and palatal gingiva, hard palate, floor of mouth, tongue, soft palate, palatine and pharyngeal arches, tonsils, and posterior pharyngeal wall	End-user input		In vivo test	TBD
		Holding force (N)	1C	Maintain retraction by resisting closing forces of [TBD] N	Patient safety	Tongue blade rachet lock	Biomechanical test	TBD
		Angulation range (degrees)	1D	Tongue blade can be angulated up to 90 degrees with respect to the coronal plane	End-user input	Angular lock	Device inspection	End-user input
As a health professional, I have adequate illumination of the oral cavity during oral surgery so that I can see all structures I am operating on	High	Illumination (lux)	2A	The retractor should provide mounting for light source capable of producing at least 15,000 lux	ISO 9680: standards for illumination of the oral cavity of patients[17]	The tongue blade stem has an internal channel for mounting a 4-5 mm diameter light source	Device inspection	TBD

Table 1. For each User Need Derived from the Key Informant Interview, One or Several Design Inputs (feature and capability) are Specified to Address Said User Need. The specific implementation is shown under Design Output. *(continued)*

User Need *"As a [role], I can [feature] so that [reason]"*	Priority rating	Parameter	Design Input *With key for reference (1A, 1B, 2A, etc.)*		Reason (for design input)	Design Output	Verification Method	Test Result
As a health professional, the retractor is easy to clean and sterilize	High	Cleaning time (mins or sec), microbial load	3A	Exposed parts/minimal internal cavities	Ease of use / Patient safety[18]	Smallest features (angular lock teeth) are 1.3 mm thick	Time motion study	TBD
		Material is rated for standard autoclave temperature (132°C) and pressure (215 kPa)	3B	Use metal and/or high temperature plastics		Device dimension and features designed for both CNC machining (surgical stainless steel) and SLA	Temperature and humidity stress test, microbial challenge	
As a health professional, I do not need to frequently release the tongue blade to avoid lingual edema so that there are less interruptions in the surgery	High	Pressure/force exerted on the tongue (kPa, N)	4A	Larger tongue blade size, tongue blade with some degree of freedom	Reduce lingual pressure	Feature not implemented		
As a health professional, I can mount the retractor on the patient's oral cavity without causing injury to the patient's gingiva	High		5A	Maxillary retractor with larger contact area	Minimize soft tissue damage	Maxillary support bars instead of maxillary hooks	Biomechanical test	TBD
			5B	Use of softer materials, curved geometry				
As a health professional, I can easily retract/depress tongues of any size so that I have adequate exposure of the oral cavity	Medium	Dimensions and area range of patient tongues (cm, cm^2)	6A	Larger tongue blade size	Ease of use	The prototype tongue blade has an approximate area of 15.6 cm^2	Device inspection	Passed
As a health professional, I quickly and easily assemble the full mouth retractor without any assistance so I can avoid delays in the operation	Medium	Assembly time (min or sec) Number of components	7A	First-time users reading device instructions should be able to set the device within [TBD] seconds	Ease of use	Modular and snap-on components	Time motion study	TBD
							User usability questionnaire	Mean SUS score of 75
As a health professional, I do not need to disassemble the tongue depressor for adjustments so that there are less interruptions in surgery	Medium	Number of times tongue blade was released/adjusted during OR (n)	8A	Snap-on tongue blade/ tongue blade that latches on top of the retractor rather than underneath	Ease of use	Feature not implemented		
As a health professional, I have somewhere to securely hang sutures during surgery so that I can work efficiently	Low	Pull force on the sutures (N)	9A	Holes in the frame	Ease of use	Feature not implemented		

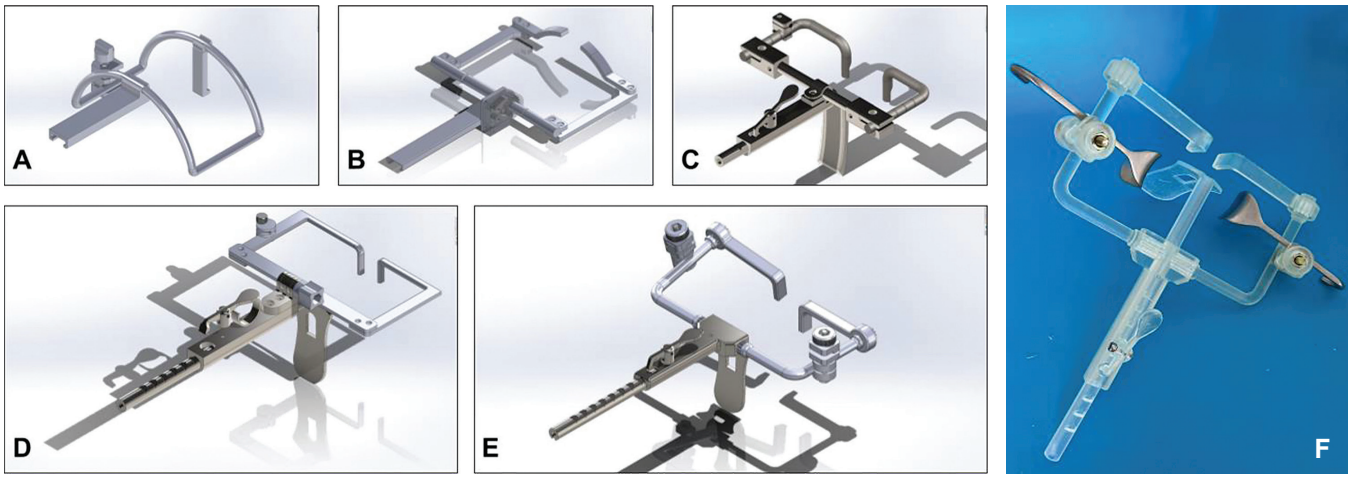

Figure 3. ***The five main model designs created in the course of the study:*** from the earliest **(A)** to the latest **(E)**. **(F)** 3D-printed low fidelity prototype of the modular mouth retractor.

mounting at an angle (Figure 4C). Modularity can allow users to assemble the retractor in different configurations depending on the needs of the patient or procedure. This contrasts with the monolithic design of the Dingman and other mouth retractors.

To minimize damage to the gingiva, the maxillary alveolus hook of the Dingman retractor was replaced by modular "maxillary support bars" with a medial gap to provide access and exposure to the surgical field in palatal and alveolar cleft surgery (Figure 4B). A clamp was developed with snap-fit functionality to allow easier and faster mounting of the buccal blade (Figure 4D and 4E). The tongue blade stem has an inner diameter of 5 mm to allow the mounting of a 4 or 5 mm diameter light source inside to facilitate better illumination of the oral cavity.

Out of the 14 design input specifications, 10 were included in the final prototype with four having passed their respective verification methods. Five tests are pending results as tests will be pursued once a high fidelity prototype is made, which may be the objective of future studies.

Usability Study

Figure 5 shows the score given by each rater. The highest score received was 90 out of 100 while the lowest score was 62.5. The mean SUS score was 75 with a standard deviation of 10.6. This mean score corresponds to a Percentile rank of 70 – 79.[13] Breakdown of user response to positive and negative SUS items are shown in Figure 6. Comments were collated from the participants and the full list is enumerated in Table 2.

The SUS contains both positive and negative statements. Among the positive statements, three out of five respondents strongly agreed with the statement "The various functions in this system are well integrated." This matches what is seen in the negative statement with the majority strongly disagreeing with the statement "I observed too much inconsistency in this product." The prototype scored the lowest in the positive statement "I felt very confident using the system," and the negative statement "I found the system very cumbersome to use."

Table 2. Summary List of Qualitative Comments Given by the Participants during the Usability Test

1.	Having positional markers or labels on the angular lock-key system to allow easier symmetrical assembly of the retractor
2.	Provide ET tube mounting in the tongue blade similar to the Dingman retractor
3.	Create other modular components or accessories like bite blocks and light sources
4.	Provide a tighter fit for the splined shaft lock system
5.	Addition of a soft material like rubber to the maxillary support
6.	Add an inferior lip in the buccal blade clamp to provide more secure mounting of the blade
7.	Maxillary support bar can be made available in multiple sizes (depending on patient's age, size, etc.)
8.	Orient the caudal shaft posteriorly, following the curvature of the maxillary arch along the cross-sectional plane

DISCUSSION

In the past few years, many product development efforts focused on retractors for transoral surgery. Specifically for mouth retractors for open surgery like the Dingman, only a handful of major redesigns and innovations have been published in the past two decades. Majority of the publications

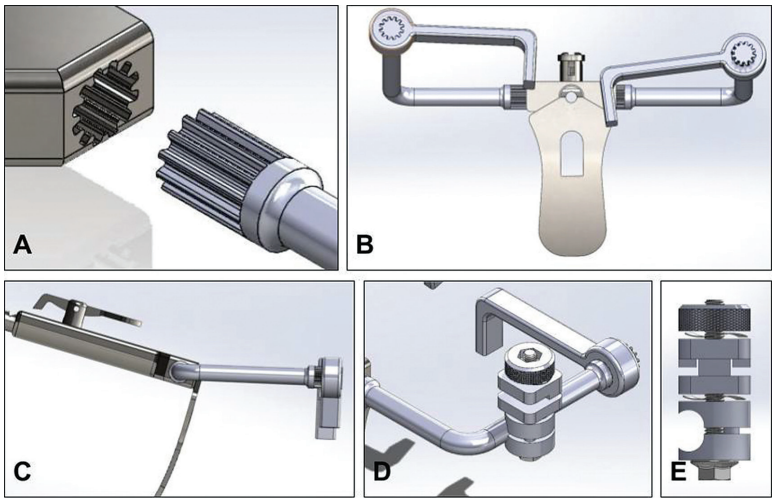

Figure 4. ***Key features of the low-fidelity prototype:*** **(A)** Angular lock; **(B)** Modularity allows mounting of the components at different angles and planes; **(C)** Angulation of the tongue blade with respect to the coronal plane; **(D)** Buccal blade clamp; **(E)** Side view of the buccal blade clamp.

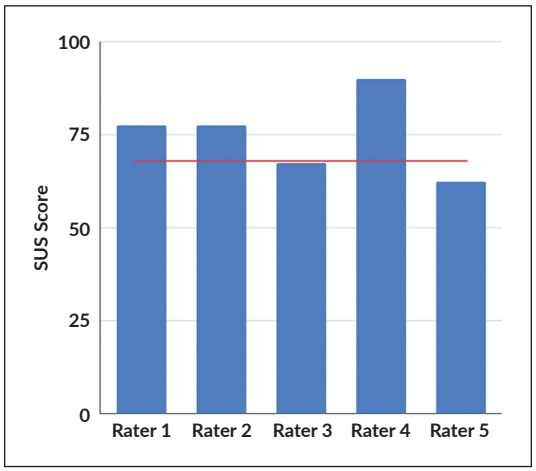

Figure 5. ***SUS scores from the five raters.*** A red line shows the threshold value of 68 which corresponds to the 50th percentile.

are patent filings and none discussed in depth the design and development process.[2,19,20]

In 2004, Rosenberg patented an improvement to the Dingman close frame design by using a substantially larger planar frame to provide a better surgical view.[19] Most retractors available locally still follow the original dimensions of their base design and the need for better exposure remains as evidenced by the first user need statement in the Design Input (Table 1). Specification 1A attempts to address this need by setting the minimum frame dimensions to match an objective anthropometric standard (Table 3).

Another innovation in mouth retractor design was presented by Hoefert et al. To prevent dislocation and provide a more stable mounting, the design of the one-sided Denhart mouth gag was modified with pivotal pads contacting the

Table 3. Test Result of Design Input Specification Implementation with Corresponding Priority Ratings

	High	Medium	Low	Total
Passed	3	2	0	5
	1A, 1C, 1D	6A, 7A	N/A	
To be determined	5	0	0	5
	1B, 2A, 3A, 3B, 5A	N/A	N/A	
Not implemented	2	0	2	4
	4A, 5B	N/A	8A, 9A	

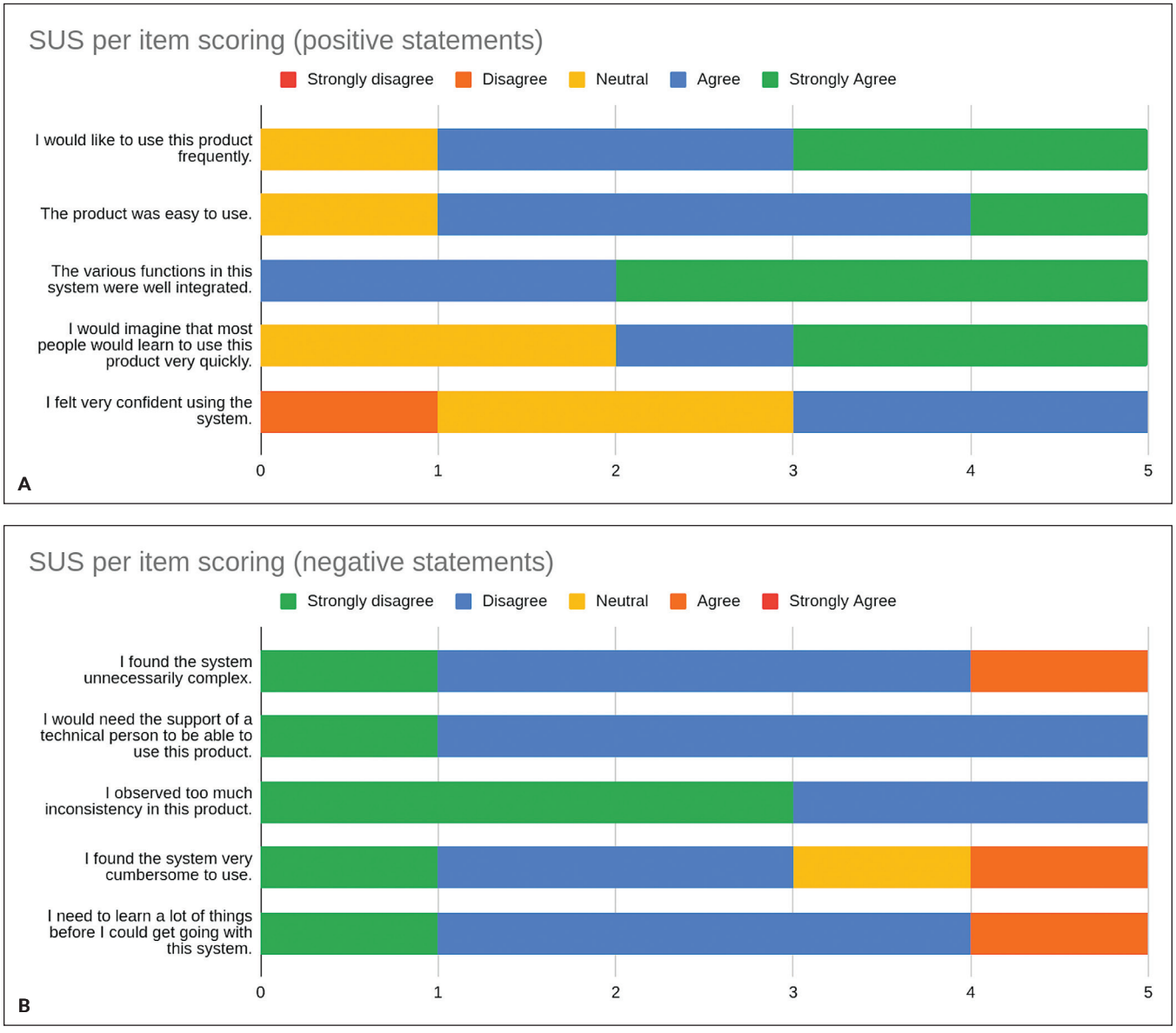

Figure 6. ***Breakdown of the SUS scores per item.*** **(A)** Positive statements. **(B)** Negative statements.

alveolus.[2] Preventing dislocation did not come up in the user needs assessment of this study. The most similar user need identified was with regard to ease of assembly.

Hoefert et al. discussed an overview of their retractor but did not elaborate on the design process. In this study, we utilize the Design Control framework to document all activities in the product development cycle including arbitrary decisions. This makes all factors in the process explicit and therefore can be reviewed and improved upon in the future.

The most pressing problem identified in the user assessment is soft tissue injury and lingual edema. This is consistent with issues on mouth retractors reported in literature.[4,5]

Mouth retractors have been known to cause hemodynamic changes similar to laryngoscopy. Specifically, it has been documented to increase intracranial pressure (ICP) with the risk of reducing cerebral perfusion. An observational study involving 37 children utilized the optic nerve sheath diameter (ONSD) as a proxy for ICP. The results of the study showed that mouth retractor placement increases ONSD significantly and hence ICP. It has been theorized that the contact with tongue blade and forces on the muscles of mastication induces an autonomic response leading to ICP.[21]

For lingual edema, its pathophysiology was explored in an investigatory case series of three patients. Lingual pressure for the three patients was measured during retraction using a Dingman retractor. There was an acute rise in lingual pressure between 3 to 10 times the baseline that only subsided when the retractor was removed. Although there is no empirical evidence yet for a specific pressure threshold, such acute pressure rise can plausibly cause venous congestion and lead to edema.[22] Moreover, these complications are not rare. A retrospective study of 247 palatoplasties found that in 5.7% of these operations, there was an occurrence of lingual edema leading to airway obstruction.[5]

Several methods have been tried to reduce the hemodynamic changes and postoperative edema. Some surgeons periodically release the retractor during the operation.[22] For lingual edema specifically, preoperative steroid injections have been proposed.[22,23] So far, no new design has been developed to specifically address this problem.

In this study, specifications 4A, 5A, 5B, 6A, and 8A were proposed to address the issue of soft tissue injury and lingual edema based on the framework of reducing and more effectively distributing contact pressure. Only 5A (maxillary support bars) and 6A (larger tongue blade size) were implemented in the present design. Specification 4A (flexible hinge) was not pursued due to concerns regarding fatigue failure. Meanwhile, specification 5B (using soft materials) could not be implemented in the present design due to limitations in access to materials and fabrication technologies. More importantly, consultations with anesthesiologists revealed that the tongue becomes flaccid from the anesthetic drugs used during oral surgical procedures, which necessitates a rigid tongue blade to maintain the retraction.

For the maxillary support bars, the need for a soft material cover was specifically mentioned by one of the participants during the usability test. Hence, a rubber or silicone attachment is already being designed for the next iteration.

Specification 8A (snap-on tongue blade) was conceptualized to facilitate easier periodic release of the retractor. However, it was not pursued due to difficulty in implementing a compact and cost-effective mechanism. In addition, the implemented modularity feature (Specification 7A) might be sufficient for this requirement although this will have to be confirmed by testing the device in a simulated or actual surgery.

This study used a small sample sized SUS test for initial usability verification of the low fidelity prototype. Due to the iterative nature of product development, simple tests are done at early stages of the cycle while more complex tests (or with larger sample sizes) are used for more mature prototypes. The threshold score for the SUS is 68 and corresponds to the average score (at the 50th percentile). A score lower than this signifies a need to redesign the prototype. With a mean score of 75, the low fidelity prototype can be considered to have above-average usability and the present form factor is "acceptable" from a user perspective.[16] However, it must be noted that only three out of five raters scored the beta prototype higher than 68. Based on these results, the device is not ready for actual use or even testing in an operational environment. However, from a product development perspective, future iterations and improvements can be built upon the present design. In addition, any major change to the form factor will need to be justified with another usability test.

This study only completed the initial phase of a proposed methodology for medical device development. It is recommended that higher fidelity prototypes be subjected to usability tests with larger sample sizes and cohorts recruited from multiple institutions. At present, we are beginning fabrication of a metal prototype to do Phase 2, which will focus on evaluating the biomechanics of the design.

CONCLUSION

This study demonstrates application of the US FDA Design Control Process in the local setting to improve the design of a surgical device. In this study, we were able to identify both clinical and ergonomic issues of mouth retractors. Design solutions have been proposed and some have been implemented in the low fidelity prototype. Results of the small-scale usability test suggest that the present form factor can be the basis for further iterations. Future studies can implement the proposed features to address other clinical and ergonomic needs, and conduct biomechanical tests and larger usability tests for verification. Finally, clinical validation of a high fidelity prototype is warranted.

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Statement of Authorship

All authors certified fulfilment of ICMJE authorship criteria.

Author Disclosure

All authors declared no conflict of interest.

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APPENDICES

Appendix A. Design Document Template

User Needs Assessment		
User Need	**Source**	**Context**
"As a [role], I can [feature] so that [reason]"	(document identifier)	

Design Input						
User Need	**Parameter**	**Design Input**	**Verification Method**	**Reason (for design input)**	**Approved/ Denied, Author(s)**	**Reason for Approval/ Denial**
"As a [role], I can [feature] so that [reason]"						

Design Output						
Parameter	**Design Input**	**Design Output**	**Verification Method**	**Design testing document reference, author(s)**	**Test Result (passed/failed)**	**Reason for failure**

Product Specification	
User Need	**Specifications**

Source: Technology Transfer and Business Development Office (TTBDO), University of the Philippines System

Appendix B. Interview Questionnaire

Key Informant Interview
Baseline: 1. Do you use any specific brand or category of mouth retractor? 2. In what procedure do you use these devices? 3. How long has this device been the standard? 4. What were the devices/techniques used before the mouth retractor?
End-user Experience: 5. Does the device perform as you want or need it to? 6. How do you use the device? Can you demonstrate it with the model we have here? 7. Do you feel confident or comfortable using this device? 8. Do you experience any difficulties when using the device? 9. Do you need assistance when using the device? (e.g., residents or nurses) 10. Do patients experience any kind of injury or complication as a result of using this device?
Improvements: 11. What sort of changes or improvements would you like to see in the device?
Alternatives / Thinking outside the box: 12. Going further, assuming that resources or physics or biology is not a constraint, how might we do these procedures using other devices or solutions (e.g., paralyzing the mandibular muscles)

Source: Zenios S, Makower J, Yock P. Biodesign: The Process of Innovating Medical Technologies, 2nd ed. Cambridge: Cambridge University Press, 2015.