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Designing an Innovative Tongue Retractor Device for Oral and Maxillofacial Procedures

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***Abstract*—Developing novel medical devices is essential for enhancing precision and accessibility for several oral and maxillofacial procedures. This study focuses on designing an advanced tongue retraction device that overcomes shortfalls in the current instruments while improving ergonomic efficiency and patient comfort. A comprehensive literature review identified key challenges, including anatomical variability, limited adaptability to diverse demographics, and unsustainable design practices. Critical factors such as gender-specific mouth-opening dimensions, tongue viscoelastic properties, and ergonomic principles were integrated into the design. The proposed device incorporates sustainable materials, adjustable design elements, and improved stabilization techniques to meet clinical demands. Using CATIA for 3D modelling and finite element analysis, the designed tongue retractor was optimized to enhance surgical access, visualization, and precision while reducing operative time and surgeon fatigue. Preliminary testing in simulated surgical environments demonstrated significant ease of use, patient comfort, and retraction stability improvements. Furthermore, the design aligns with emerging trends in sustainable product development and minimizing environmental impact. This study bridges the gap in accommodating diversity, addressing ecological concerns, and offering a transformative solution that integrates functional innovation and sustainability to improve procedural outcomes and enhance patient safety, especially for kids.**

***Keywords*—Tongue retractor, 3D modelling, Biodegradable, Patents, Surgical applications.**

I. INTRODUCTION

The design and fabrication of effective instrumentation for oral and maxillofacial surgeries remain challenging because of the oral cavity's specific anatomical and functional constraints. The most critical instrument is the tongue retractor, which, quite a few times, is unstable and without control to prevent slippage or shifting during the surgical procedure. These weaknesses in design compromise surgical precision, prolong operating times, and increase the likelihood of patient complications. Additionally, most traditional retractors are large and rigid, thus incapable of fulfilling special anatomic requirements. They therefore tend to be inappropriate for many surgical conditions. A significant shortcoming with the existing designs is that they cannot meet various requirements for different groups of patient populations, particularly children.

For instance, instruments in use today are not adapted to the peculiar dimensions of the pediatric oral cavity. Anthropometric studies have exposed significant variability of mouth-opening dimensions and gender-based anatomic differences that are not equally accounted for by these current designs. This consequently results in a suboptimal surgical procedure performance, resulting in less comfort for the patient and poor results. While material science and technology continuously improve, a lack of attention is directed at incorporating innovative materials and ergonomic principles in designing a tongue retractor. These deficiencies have thus been imperative in providing solution packages with higher levels of functionality and comfort to the patient in filling these gaps.

On their part, oral and maxillofacial surgeries demand precision and rely on retractors that ensure smoothness and efficiency at work. The conventional retractors have a score of disadvantages: slipping and tilting reduce precision during surgery and give less comfort to the patient. The challenges in pediatric applications are much higher due to the essential anatomical and ergonomic considerations. Since models designed so far do not consider specific

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features regarding children, such devices do not provide stability, precision, and comfort during surgical intervention. Therefore, the limits of current retractors are strong drivers for novel solutions, including advanced technologies and materials.

Tongue retractors reflect the development stages of civilization according to the importance of oral and dental care; the technological changes caused this important dental tool to change into its modern concept and application. With tools like computer-aided design software, such as CATIA-continuous Finite Element Analysis (FEA), and 3-Dimensional (3D) printing, new frontiers have opened for optimizing medical devices, making them even more effective and patient-friendly. Most studies failed to focus on specific populations, such as Malaysian or Asian patients; thus, the most significant gap exists. Cultural and anatomic variability is seldom addressed, leading to retraction instability, time-consuming procedures, and increased patient discomfort. These shortcomings require innovative designs focusing on comfort, ergonomics, and adjustability.

The solution design will fix this problem by developing a retractor that will neither slip nor tilt to guarantee the precision and stability of the surgical procedure. The new design will achieve a higher order of magnitude improvement above the state-of-the-art devices by exploiting novel material and sophisticated manufacturing methods. Most of the literature reviewed has dwelt on the efficiencies and inadequacies of conventional retractors of the tongue. Clark and Dierks, [1], while encouraging the use of self-retaining methods for tongue retraction in dental surgeries like third molar extraction, stated that most currently available designs are unergonomic to the patient and are inefficient. McAnerney *et al.* [2] noted the ease of self-sustaining tongue retractors that minimize surgeon tiredness, but again called for continued patient comfort improvement. They both were focusing on the discomfort and inefficiency of current designs.

Jeng *et al.* [3] and Papadogeorgakis *et al.* [4] acknowledged the challenges in tissue stabilization and prevention of trauma on the tongue during retraction. These studies have placed a significant impetus on the design of devices to ensure minimal trauma to tissues while guaranteeing effective stabilization. Besides this, ergonomic considerations are increasingly determined to play a critical role. Gupta *et al.* [5] and Koirala and Nepal [6] revealed that considering ergonomic design reduces strain on practitioners, thereby improving their performance and resulting in procedural outcomes.

Despite these developments, tongue retractors remain designed and utilized, but they have many attendant disadvantages. According to Mills *et al.* [7], current devices have not been innovated to adapt to many different anatomical variations. Sustainable material usage in designing medical equipment also remains highly researched. Some of the tools used during the medical procedure, such as a mouth prop, a wider retractor, and a towel clip, caused uneasiness. According to Romli *et al.* [8], such remains a very proper and appropriate view by Watkins *et al.* [9]. Preventive dentistry is considered the cornerstone of dental health management. This approach limits the chances of an invasive dental intervention. Wysen *et al.* [10] listed prevention calls for special equipment to enhance visibility and access during routine checks. Campbell and Tickle [11] maintained that good quality dental care must be patient-centered and outcome-driven, which calls for creating safe, effective, and comfortable tools. Considering such principles in a new type of tongue retractor may significantly enhance the outcomes both for preventive and surgical procedures.

Soft tissue trauma and neuropathy injuries following the use of tongue retractors outline the importance of ergonomic and atraumatic designs. The two most common causes related to sharp injuries among dental professionals were identified as improper handling and design defects by Marji and Syed in 2022, while external factors, capable of increasing the likelihood of occurrence of dental traumas, were highlighted by Tindberg *et al.* [12]. These studies delineate two reasons for stressing the need for retractors to be designed with safety factors that concern pediatric patients and practitioners regarding sustainable design aspects.

Advanced technologies like CATIA and FEA are crucial in developing new tongue retractors. These design principles correspond to the rising emphasis on eco-friendly practices in healthcare. Including ergonomic designs and sustainable materials in the design of a tongue retractor better enhances practitioner efficiency and patient comfort, given the failings of the existing devices. CATIA will help make highly accurate three-dimensional modeling and design optimizations in developing devices compliant with anatomy. By finite element analysis, a simulated real-world conditions test for structural integrity and reliability. Jeong *et al.* [13] illustrated the application of 3D printing in making customized surgical instruments that are more functional and better adapted for patients, reduce surgery time, and improve patient safety.

Material selection has been described as one of the most significant factors in achieving safety, durability, and sustainability regarding medical devices. Other authors have discussed the works of Shanthi et al. on shape-memory alloys in 2014 and the works of Srivastava and Verma on their biocompatibility in 2023 [14] since both these materials are used for increasing patient safety and performance of the device. Sulaiman [15] points out that there was development of materials that could face sterilization and extended use without impairment of their properties.

Another factor to be considered critical is sustainability. According to Romli *et al.* [8] and Watkins *et al.* [9], medical device manufacturing should incorporate eco-friendly materials and processes. According to Richter *et al.* [17], if the production materials used are recyclable and biodegradable, then the environmental impact of the production will be minimized. These ergonomic designs further enhance practitioner efficiency and comfort for the patient. Various studies conducted by Gupta *et al.* [5] and Koirala and Nepal [6] have indicated that a well-designed instrument decreases physical strain and further improves procedural outcomes. 2 Accommodating design variability of anatomic retractors has been studied by Cheng *et al.* [16] and Mills *et al.* [7] concerning viscoelastic properties of tongue tissue and the anatomy of the lingual frenulum.

It designs medical devices with durable, modular components that are easy to repair and recycle. There is a need, according to Hansen [18], for "designing for failure" to extend the product life of these products to reduce overall waste. Discussion by Watkins *et al.* [9] and Ward [19] created awareness of greater collaboration across the industry in support of sustainable medical device development.

This study aims to address the design and performance limitations of existing tongue retractors by developing a novel, ergonomically optimized device using 3D printing tailored to the anatomical needs of Malaysian children. The objectives of this research are as follows:

i. To identify the limitations of existing tongue retractor devices, focusing on ergonomics and comfort for pediatric applications.

ii. To develop a new tongue retractor that ensures controlled tongue fixation during surgery, minimizing slippage and tilting.

iii. To evaluate the effectiveness of the developed device through modeling, analysis, and simulated testing, focusing on stability, usability, and reduction in surgeon fatigue.

II. METHODS AND MATERIAL

The retractor of the tongue that follows systematic product development, optimization, and testing has been designed. The steps followed in constructing this retractor guaranteed reliability, functionality, and practical employability in clinical practice. Therefore, the information concerning variations in, for example, mouth opening, thickness of the tongue, and length of lingual frenulum in pediatric patients has been considered. The support of other Computer Aided Design (CAD) applications, such as CATIA, helped create an anterior, patient-specific, ceramic-encompassed device with an ergonomic and adjustable structure for the patient. The FEAs were then reiterated for convergence to something close to reality. Together with pursuing the choice of the most bio-compliant materials, the best high-strength polymers and shape memory alloys were sought. Other testing scenarios were bench models and cadaveric evaluation of stability, usability, and ergonomics for pediatric requirements with minimal tissue displacement and surgeon comfort. This retractor demonstrated superior performance to the original designs, enabling mechanical engineering and dentistry to acquire improvements from retractors, offered as sustainable, apposite, and modular parts congruent with the green movements in healthcare. Conceptualization and development of the prototype of the tongue retractor were done in this step. It had to be an instrument that would provide controlled fixation of the tongue without slipping out of place and, at the same time, ensure comfort to the patient, with precision to the surgeon—identifying the major functional requirements for device-stability, adjustability, and ease of operation, initiated conceptual designing as illustrated in Fig. 1.

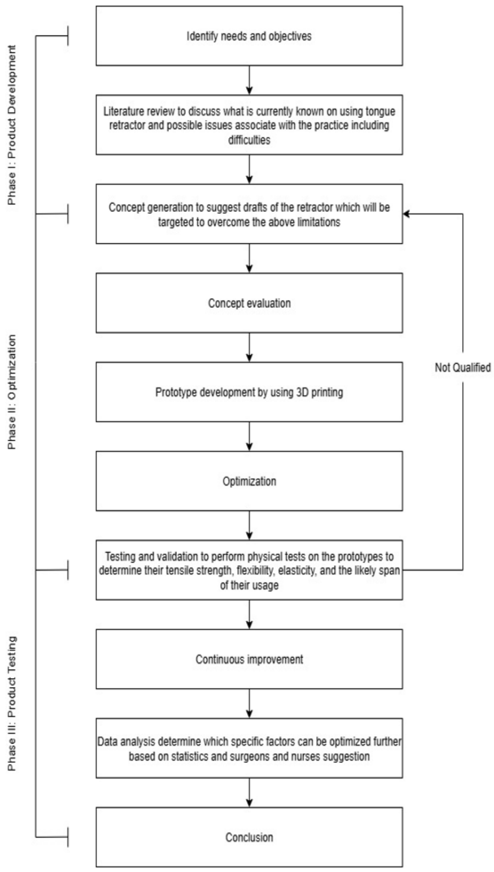


Fig. 1. Overall Flowchart procedure.

A. Phase I: Product Development

Extensive 3D modelling was performed using CATIA and CAD software to create the retractor. The methods to gain the Anthropometric Data were done by research, which stated that the dimensions of the average child's tongue, in terms of length, width, and thickness, are approximately 4 cm, 2.6 cm, and 1.2 cm, respectively, following the growth pattern throughout the pediatric population. This source was most productive in information acquisition on the mouth's width and depth, plus the average tongue size, among other issues, showing variance within a child's oral cavity. The doctor has also suggested an ergonomic design that can fulfil the objective by designing specific features for easy access. This became useful in developing key features, such as adjustable arms and nonslip surfaces, which allowed this retractor to accommodate children of different ages, from infants to teenagers, and securely fit for comfort. This allowed for the design of key elements such as nonslip surfaces to prevent tongue movement, adjustable arms for various oral cavity sizes, and smooth, rounded edges to reduce tissue trauma. The anthropometry of the user should also be considered to ensure the user can use the forceps easily. The design emphasizes lightweight construction to minimize surgeon fatigue during lengthy procedures. Material selection was crucial, with medical-grade stainless steel grade 304 that had corrosion resistance, durability, and most importantly, it meets sanitary regulations that allow the material to be sterilized, and polymeric composites chosen for their biocompatibility, strength, and sterilization resistance. These materials ensure the device's stability and durability over repeated use.

Table 1. Selection of the most essential parts of the product.

Description	Weight	Jaws	Locking System	Handle
Cost	1	0	0	0
Durable	3	+	0	+
Slippery	5	+	-	+
User experience	5	+	+	+
Safety	3	+	+	0
Needs/ Market	1	+	+	+
+		17	9	14
0		0	0	0
-		0	-5	0
Net Score		17	4	14

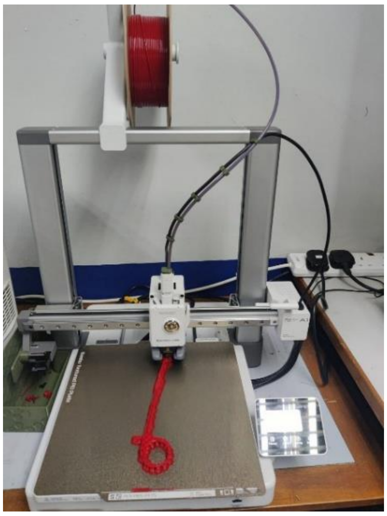


Fig. 2. Bambu Lab A1 3D printer.

The prototype was developed first by following the steps shown in Table I, which is the part that needs improvement most, and is more focused on creating a new tongue retractor. CATIA CAD software was used to develop the model by following the dimensions of the tongue to make a new model that complies with the solution needed. This software allowed intricate designing of essential characteristics, including the arm tilt, a non-slip surface, and only smooth and polished edges to enhance comfort and reduce tissue damage. After the completion of the design process, it was processed to be exported in STL format for the fabrication process through 3D printing, making it sliced into compatible layers. The prototype was developed using the Bambu Lab A1 3D printer (Fig. 2) with a Fused Deposition Modeling (FDM) process. The used material, PLA filament, was termed to be facile to use, reconciled with generating a reasonable surface finish, and compatible with the needed rapid convincing process. The printer operated at 220°C to melt the PLA filament, accurately shaping the product while adhering to the project's needs and priorities.

During the print process, measures were taken to ensure the model was built correctly without defects such as warping or poor material properties. After the completion of the 3D printing, fabrication post-processing procedures were performed to enhance the appearance of the fabricated prototype. These steps provided additional refinement in the model's appearance and utility by removing supports and refining some of the surfaces that formed the model. The nonslip features and the adjustable arms were also challenged to ascertain their ability to provide the performance of the device, especially in matters related to paediatric patients, by adjusting various parts to suit different patients.

B. Phase II: Optimization

The prototype underwent thorough testing to meet the specified design criteria, focusing on dimensions, weight, surface smoothness, and structural stability. Bench tests confirmed that the retractor could effectively secure the tongue, resist slipping, and enhance surgical accessibility. This served as a foundation for the subsequent optimization phase. The second phase involved designing an optimal tongue retractor specifically for pediatric patients in Malaysia, beginning with collecting anthropometric data regarding the tongue's width, thickness, and mobility across different age groups. This data ensured that the design accommodated localized anatomical variations often overlooked in existing retractors.

Finite Element Analysis (FEA) was conducted using CATIA to assess the mechanical performance of the device, evaluating stress distribution and potential deformation. The results from the FEA identified weak points in the design, guiding improvements to enhance structural integrity and safety. Dimensions and features of the retractor were adjusted based on the FEA findings to maximize both performance and comfort. The revised design improves adaptability to various oral cavity sizes, effectively addressing fixation challenges in pediatric surgeries compared to previous models.

C. Phase III: Product Testing

The final testing and validation phase will confirm that the optimized tongue retractor meets clinical safety, performance, and usability standards. The device underwent bench testing simulating surgical conditions, employing surgical simulators to evaluate its effectiveness in securing the tongue, preventing slippage, and enhancing surgical precision. Additionally, the assessment examined the structural integrity of the retractor under various conditions to ensure it could withstand operational stresses.

Usability testing involved practical trials conducted by oral and maxillofacial surgeons, yielding valuable feedback regarding handling ease, comfort of the grip, and the ability to adjust the angle. This evaluation provided crucial insights into the device's clinical feasibility and identified areas for further refinement. A comparative study was also undertaken to quantify the retractor's performance against currently available devices, focusing on key metrics such as slippage rate, positioning accuracy, and overall surgeon satisfaction. The new design primarily underscores improvements in stability and precision.

Data from these tests were analyzed to confirm that the retractor met established clinical benchmarks for safety and performance. The findings indicated that this device is suitable for pediatric oral and maxillofacial procedures, improving access and precision. The development of the retractor required the use of several advanced tools and instruments, including CATIA and FEA (CAD software) for 3D modeling and design optimization, in addition to a 3D printer for rapid prototyping. Each tool was carefully selected based on its precision and relevance to the research objectives, with careful management of their limitations to ensure reliable results, given their dependence on accurate input data and computational resources.

D. Validation and Limitations

The finite element analysis for structural stability and material performance was pursued regarding the distribution of stress and deformation of the tongue retractor under simulated loads. This was supported by Mahoney [20] and Romli *et al.* [8] to ensure that the materials used in the replica of surgical conditions to verify safety and durability are biocompatible. Following Gupta *et al.* [5], comfort was optimized by design, considering the ergonomic position of the surgeon and the patient. As in McAnerney *et al.* [2] and Papadogeorgakis *et al.* [4], under controlled lab conditions, essential features were proven to be valid, such as those related to physical stability, non-slippage, and ease of usage. Sterilization and biocompatibility tests were performed following the protocol by Jeng *et al.* [3] for the mask to be impervious to microbial contamination and thus often safe to use with any patient. Moreover, fast prototyping through Jeong *et al.* [13] and Sulaiman [15] allowed for quick iterations of the prototype for an accurate anatomical dimension using advanced additive manufacturing techniques to fit Malaysian children. It will enable modification of size and curvature to suit and result in a practical design for the purpose outlined in the scope.

Based on Shaari *et al.* [21], the focus is on Malaysian children, as anatomical data limited its generalizability to populations with different mouth structures. FEM simulations, while providing insight into the problem at hand, were run under very idealized conditions, not taking into account saliva and possible dynamic forces during actual surgeries, but this was likewise echoed by Hansen [18]. Furthermore, 3D-printed prototypes did not fully represent the mechanical properties of final production materials, the same observation recorded by Richter *et al.* [17]. It has also been limited to conducting live surgical trials with the device. The inability to conduct live surgical trials limits full validation under actual surgical conditions considered necessary by Jamieson *et al.* [22]. Laboratory testing gave some initial results, but no real-world validation was essential for a thorough performance assessment. Because of budget limitations and time constraints, not many prototypes can be fabricated and tested along with their alternative materials and designs, as agreed upon by Ward [19]. Usability feedback from surgeons was subjective toward personal preference and experience level, thus giving rise to subjectivity in the assessment. As Cheng *et al.* [16] suggested, involving a larger participant pool with varied expertise would lead to more robust data. The iterative design and validation processes, notwithstanding these limitations, addressed major functional and ergonomic issues, thus paving the way for future refinements.

Despite these limitations, several future directions can be given to improve the proposed methodology and validate the classification results. First, it is logical to perform clinical trials using live matter, and surgical testing should be the focus of further project development. In addition, involving a larger and more diverse group of surgeons and other medical personnel would lead to better-quality usability feedback. Moreover, in subsequent versions of the cutting, further changes may be made to install the retractor for a larger range of paediatric patients of different populations. It is expected that clinical trials will be supported by an elaborate plan for clinical validation and a clear strategy for commercial production. This would include putting good practices in the system, in that it seeks to preserve the sound quality and performance of the device, regardless of the setting in which it is used. However, significant assessment of the paediatric retractor has been made, including preclinical prototypes and human large animal models, live versions that assist in real surgeries, performance of the reusable material, and better user feedback, which warrants further enhancement of this paediatric retractor. Future work should address this limitation through clinical trials, other anatomical considerations, and a well-defined validation plan to prove that the device will work in a clinical setting.

III. RESULTS AND DISCUSSION

The product for a 3D prototype for the tongue retractors was done using CATIA, using the dimensions shown in Fig. 3 regarding the detailed dimensions of the tongue retractor. The prototype was done as shown in Fig. 4(a) and fabricated using the Bambu Lab A1 3D-Printer shown in Fig. 4(b). The tongue retractor underwent testing with a simulated force of 7.4 N, typical for clinical procedures. Finite Element Analysis (FEA) showed stress levels ranging from a minimum of 29.40 N/m² to a maximum of 1.81×10^7 N/m², with the highest stresses concentrated at the joint between the handle and the gripping surface, a key area for structural integrity. The prototype was made using polylactic acid (PLA) for its easy production with the Bambu Lab A1 3D printer, which is cost-effective for initial testing. However, PLA's mechanical properties limit its long-term durability and clinical use due to low yield strength and inadequate resistance to sterilization, as shown in Fig. 5.

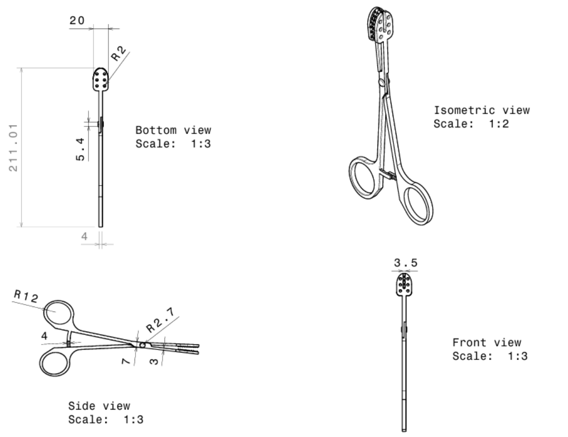
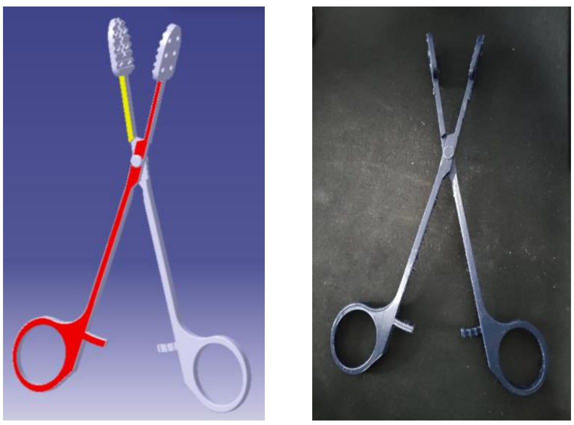


Fig. 3. Dimension of the prototype of the tongue retractor.



(a) 3D prototype (b) Final 3D printing

Fig. 4. (a) Prototype before 3D-Printing by using CATIA, (b)Actual 3D-Printing tongue retractors by using Bambu Lab A1.

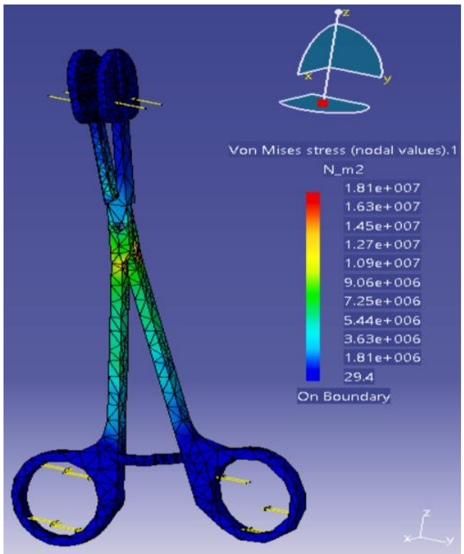
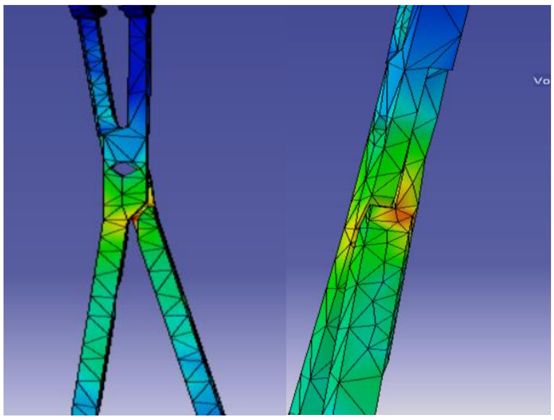


Fig. 5. Analysis of the 3D model for tongue retractors by using Catia.

The final device will be constructed from Stainless Steel 304, a premier choice for medical instruments, thanks to its exceptional mechanical and chemical properties. This material boasts outstanding corrosion resistance, impressive mechanical strength, and excellent biocompatibility, making it ideal for applications demanding hygiene and durability. With its superior Young's Modulus and yield strength, Stainless Steel 304 guarantees structural integrity for repeated use and reliably withstands rigorous cleaning and sterilization processes. According to P. J. Andersen [23], Stainless Steel 304 is suitable for medical applications as it resists rust and is easy to maintain in hygienic environments.



(a) Front view (b) Side view

Fig. 6. Analysis of the 3D model for tongue retractors using Catia from (a) front view and (b) side view on the critical area.

The stress analysis results from Fig. 6 above indicate that the retractor's design can adequately support the anticipated mechanical loads. Fig. 6 (a) and (b) show the maximum calculated stress in the critical area, where the most vital area occurs. The figure above indicates that the maximum calculated stress is 1.81×10^7 N/m², significantly lower than the yield strength of stainless steel 304, which is 2.5×10^8

N/m². However, it is essential to note that PLA may deform or fail with prolonged use due to its considerably lower yield strength.

Grip efficiency is another crucial factor in this study, especially for pediatric applications, as the tongue is sensitive and necessitates gentle handling in children; as documented by Potter *et al.* [24], the strength of the tongue ranges from 44 kPa for a 6-year-old up to 62 kPa for a 12-year-old, underlining that the grip needs to be secure but not harmful. Incorporating a soft coating, such as rubberized or silicone materials, onto stainless steel further minimizes tissue trauma and enhances grip efficiency.

While the prototype was tested in a simulated clinical environment and evaluated through Finite Element Analysis (FEA), end-users or external professionals, such as oral surgeons or clinical staff, did not receive direct feedback. Future validation should involve structured usability trials and feedback sessions with practicing dental and oral-maxillofacial surgeons to assess the design's ergonomics, grip comfort, and practical applicability. Involving industrial experts could also help benchmark the retractor against commercially available models, thus substantiating its clinical viability. Additionally, patient-centred feedback (simulated or real) could help refine the comfort and safety aspects, especially for paediatric use.

This study primarily serves as a feasibility assessment regarding design and functionality; therefore, the materials evaluated are not appropriate for clinical use. Utilizing stainless steel 304 for the final device will ensure durability and reliability while meeting the hygiene standards mandated by medical requirements. Additionally, implementing a soft gripping surface and regulating the forces applied during procedures will enhance patient safety and comfort.

IV. CONCLUSION

This study highlights the device's potential to enhance surgical precision, reduce operating times, and improve patient and practitioner comfort. Using CATIA for 3D modeling, finite element analysis for structural optimization, and 3D printing for prototype development, preliminary testing has demonstrated remarkable stability, usability, and adaptability improvements, particularly for pediatric applications. Furthermore, the design adheres to sustainable principles aimed at minimizing environmental impact. These findings underscore the revolutionary potential of the proposed retractor in oral and maxillofacial surgeries. However, challenges related to real-world validation and material limitations were encountered during the prototyping phase. The absence of live surgical trials is a restraint that would not allow determining the definite efficiency of the retractor operating in real life, and a few demographic tests indicate that the device could be effective only within a limited population, oriented mainly at Malaysian children. To address these issues, the future work will call for 'live' operating surgical trials to ascertain the viability of the retractor and subject the tests to a broader range of paediatric populations in various regions and of different colours. Continued research is essential to focus on clinical trials, address broader demographic concerns, and enhance the design for more excellent utility, which will facilitate broader adoption and improve procedural outcomes.

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AUTHOR CONTRIBUTIONS

Dannial Asyraff Bin Azmi: Conceptualization, Methodology, 3D Modelling, Finite Element Analysis (FEA), Data Curation, Writing – Original Draft Preparation.
Nurnida Elmira Binti Othman: Conceptualization, Methodology, Supervision, Validation, Visualization, Writing – Review & Editing, Project Administration, Corresponding Author.
Kherman Bin Suparman: Clinical Validation, Investigation, Resources, Writing – Review & Editing.

CONFLICT OF INTERESTS

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

ETHICS STATEMENTS

Our publication ethics follow the Committee on Publication Ethics (COPE) guidelines. https://publicationethics.org/

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