Meandros Medical And Dental Journal
doi:10.69601/meandrosmdj.1491677

HOMEMADE 3D-PRINTED AFFORDABLE AND PRACTICAL ALTERNATIVE VIDEOLARYNGOSCOPE: FIRST STEP

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ABSTRACT

Objective: Changing economic conditions make it difficult for clinics to access the medical devices they need. Videolaryngoscope is one of the devices needed in many units such as operating rooms, intensive care and emergency services. Our study aims to design a low-cost videolaryngoscope (VL) using three-dimensional printing technology and offer clinics a cost-effective alternative to traditional VLs.
Materials and Methods: Initially, three-dimensional images were obtained from the website www.thingeverse.com to form the basis of the videolaryngoscope blade. The Ultimaker Cura 4.0 program (Ultimaker B.V. Netherlands, Utrecht) was used to create three-dimensional drawings of the handle and blade prints. This drawing was produced on a 3D printer using polylactic acid as raw material. Finally, the wireless camera with 1080p HD resolution was positioned on the handle and blade. 3DPVL was tested on an intubation mannequin by a group of 30 anesthesiologists, each with at least 4 years of experience. The intubation times of the participants and their satisfaction with this process were recorded.
Results: In the study, the intubation times performed by 30 anesthesiologists on a mannequin were recorded. It was determined that the average intubation time for 3DPVL was 24.3 seconds. 90% of participants rated the experience as good or excellent. Similarly, satisfaction levels were rated as good or excellent by 60% of participants.
Conclusion: The affordable and practical of production associated with 3DPVL make it a potentially viable alternative to traditional VLs for clinicians. In the second step, a case series focusing on easy airways is planned regarding our device. In later steps, randomized controlled studies are planned between our device and traditional VL in easy and difficult airways.

Keywords: Airway management, Videolaryngoscope, 3D technology

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ÖZET

Amaç: Değişen ekonomik koşullar kliniklerin ihtiyaç duydukları tıbbı cihazlara ulaşmalarını zorlaştırmaktadır. Videolaringoskop da ameliyathane, yoğunbakım ve acil servisler gibi bir çok birimde ihtiyaç duyulan cihazlardandır. Çalışmamızda üç boyutlu baskı teknolojisini kullanarak düşük maliyetli videolaringoskop (VL) tasarlamak ve kliniklere geleneksel VL'lere uygun maliyetli bir alternatif sunmak amaçlamaktadır.
Materyal ve Metot: Başlangıçta, videolaringoskop bıçağının temelini oluşturmak üzere www.thingeverse.com web sitesinden üç boyutlu görüntüler elde edildi. Ultimaker Cura 4.0 programı (Ultimaker B.V. Hollanda, Utrecht), sap ve bıçak baskılarının üç boyutlu çizimlerini oluşturmak için kullanıldı. Bu çizim, bir 3D yazıcıda hammadde olarak polilaktik asit kullanılarak üretildi. son olarak 1080p HD çözünürlüğe sahip kablosuz kamera, sap ve bıçağın üzerine

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Recived:25.10.2023 Accepted:25.12.2023

konumlandırıldı. 3BBVL, her biri en az 4 yıllık deneyime sahip 30 anestezistten oluşan bir grup tarafından entübasyon mankeni üzerinde test edildi. Katılımcıların gerçekleştirdiği entübasyon süreleri ve bu süreçteki memnuniyetleri kaydedildi.
Bulgu: Çalışmada 30 anestezi uzmanının manken üzerinde gerçekleştirdiği entübasyon süreleri kayıt edildi. 3BBVL için ortalama entübasyon süresinin 24,3 saniye olduğunu saptandı. Katılımcıların %90'ı bu deneyimi iyi veya mükemmel olarak değerlendirdi. Benzer şekilde memnuniyet düzeyleri de katılımcıların %60'ı tarafından iyi veya mükemmel olarak değerlendirildi.
Sonuç: 3BBVL ile ilişkili düşük maliyet ve üretim kolaylığı, onu klinisyenler için geleneksel VL'lere potansiyel olarak uygun bir alternatif haline getirmektedir. Cihazımızla ilgili olarak ikinci aşamada özellikle kolay hava yollarına odaklı olgu serisi planlanmaktadır. Daha sonraki aşamalarda, kolay ve zor hava yollarında cihazımız ile geleneksel VL arasında randomize kontrollü çalışmalar planlanmaktadır.

Anahtar Kelimeler: Havayolu yönetimi, Videolaringoskop, Üç boyutlu yazıcı teknolojisi

INTRODUCTION

Video laryngoscopes (VLs) have been developed since the year 2000 (1). Emergencies, ambulances, intensive care units and operating rooms are the departments where video laryngoscopes are most needed. However, as a consequence of economic burden, it is not possible for many clinics to supply very high cost videoryngoscopes (2). In addition VLs are medical devices that contribute in education and protect the clinicians from infectious diseases (3). On the other side, 3d printing technology is promising in the field of bioengineering, both in static structures such as implants and prostheses, and manufacturing cellular and tissue constructs such as skin, cartilage, bone, nerve and blood vessels (4). For all this reason, we produced a homemade VL on a very low cost three dimensional printer that can transfer images to android phones which can be easily accessed by clinics. As the first step of the research for this three dimensional printed videolaryngoscope (3DPVL), we conducted a normal airway manikin study.

MATERIALS AND METHODS

Device design priorities
The most important design features were identified as safety, effectiveness, low cost, reusability, and disposability.
Device development
First, ready-made 3D drawings of the C-blade for intubation from www.thingeverse.com were used for the handle-blade part. Prints of the handle blade's ready-made 3D drawings were used in the Ultimaker Cura 4.0 (Ultimaker B.V., 3511 ED Utrecht, Netherland) as 3D program. Secondly, the C-blade type of handle-blade drawing was printed from polylactic acid (PLA) raw material on a 3D printer. In the third stage, the camera (wireless) with 1080p HD resolution was placed on the handle and blade. Finally, the 3DPVL was tested on the intubation manikin by thirty physicians with at least four years of experience in intubation. The images and duration of procedures were recorded. Physicians were asked about their satisfaction levels regarding the image quality and ease of intubation related to the test of the device on the model. A semi-quantitative scale was used to determine the opinion of the volunteers on image quality and satisfaction of intubation. In addition, quantitatively the percentage of glottic opening (POGO) and Cormack-Lehane (CL) were scored by volunteers. The study was carried out in the anesthesiology department in accordance with the following method: 1. A 3DPVL C blade (Fig. 1), produced as described above and a 7.5-cuffed tube with an inside stylet were prepared for intubation in a manikin. 2. The volunteer pyhsicians were allowed to reshape the stylets. 3. The fact that the 3DPVL device was lighter than other VLs could have changed clinicians' control of the device. For this reason, they were given the right to try twice before the registration attempt to adapt. The third attempt was recorded. 4. Image transfer to an android phone and the camera view angle were checked before every intubation by all physicians. 5. The point of time in which the volunteers started intubation procedure was noted. 6. Vocal cord visualization time with 3DPVL was measured. 7. The time for the passage of the intubation tube through the vocal cords with 3DPVL were also measured. 8. Volunteers were asked about image quality and intubation satisfaction level. 9. Volunteers noted the post-procedure glottic appearance by evaluating POGO and CL scores.

Statistical Analysis
Research data were evaluated using the SPSS 21.0 statistical program. The suitability of continuous variables to normal distribution was investigated using visual (histogram and probability graphs) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk tests). Descriptive statistics of the study are shown using median, interquartile range (IQR), number (n) and percentage (%).

RESULTS

Table 1: Demographic datas

3DPVL C, n=30	Median	IQR
Volunteer Age (year)	29	27-33
Volunteer Years experience (year)	5	3-6
Vocal cords are first visualized (second)	4.9	4.4-5.9
The intubation tube passes through the vocal cords (second)	20.3	17.8-25.1

All volunteers successfully intubated on their first attempt. The median values of total intubation time of voluneters were found 20.3 seconds for the 3DPVL C blade (Table 1).

The 90% of the volunteers opinion of on the image quality was noted as good and excellent. The intubation satisfaction was found to be good and excellent by the 60% of the volunteers. (Table 2). Twenty-eight volunteers rated the glottic view as 100% according to the POGO score, while two volunteers rated it at 90% and according to the CL classification, 28 volunteers were evaluated as grade 1, and 2 volunteers were evaluated as grade 2 (Table 3).

Table 2: Volunteers satisfaction

	Good and excellent	Medium
Image quality	30 (%100)	0
Intubation satisfaction	18 (%60)	12 (%40)

DISCUSSION

Twenty-eight volunteers were able to obtain a full view of the glottis by using the 3DPVL according the POGO score. On the other hand, several participants stated that they applied excessive force to the manikin for intubation. Recently, 3D technology has become common in medicine as well as in other fields. The 3DPVL can be considered as a low-cost alternative for many clinics that cannot reach traditional VLs due to economic conditions.

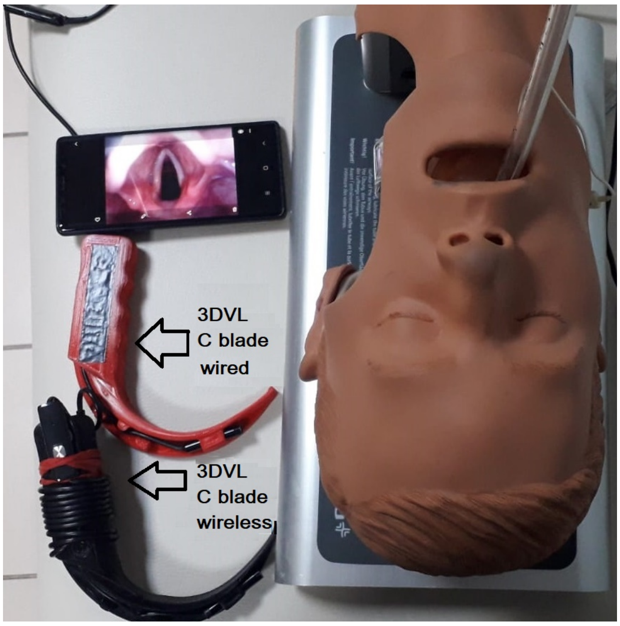

Figure 1: 3DPVL-C blade (wired and wireless)

Transferring images to your own smart android phone both reduces the cost and provides ease of use. The device is extremely simple, maintenance-free, and has only two parts, both of which can be easily replaced. The device is designed to be reusable so that clinicians can rely on it without incurring the excessive costs associated with disposable accessories. Parts of the 3DPL that touch the patient (including camera and blade) should be easy to clean by means of the standard methods used in hospitals, namely washing with soap and water and then high-level chemical disinfection with a 1% solution. This complies with the guidance issued by the US Food and Drug Administration for reprocessing of plastic devices that come into contact with mucous membranes (5). In addition, the 3DPVL has passed biocompatibility (sensitization, irritation, and cytotoxicity) tests. The camera setting problem experienced in Ataman and Altıntas's study was not observed in this study (6). Because in the part where the camera will be fixed, the image setting was checked before intubation and the camera angle was fixed. In addition, we think that transmitting the images wirelessly has prevented the problems related with cable pulling and changing the camera angle. We attribute the successful intubation of the participants in the first recorded attempt to the satisfactory image quality and comfort of the intervention and to the fact that they were given two attempts before the recording. In addition, the 70-degree angle of our C blade contributed to the success of the first attempt and the advantage in intubation time. Using an HD 1080 wireless camera has ensured that our image quality is high. One of the most important issues to be discussed about 3DPVL is the durability of the printed part. In intubation, we adjusted the PLA density above 50% to meet the 1–8 kg tensile and hanging forces to be applied in the mouth. Regarding this, there was no problem with the applications on the manikin.

Table 3: POGO and Cormack-Lehane (CL) clasification with 3DPVL

POGO n=30	CL
%100 (n=28)	Grade 1 (n=28)
%90 (n=2)	Grade 2 (n=2)

One of the most important advantages of 3D printing is that replaceable products can be obtained. After the prototype is created, the fact that it is edible according to the experience of the users enables it to respond to the changing and transforming needs. in addition, It is advantageous in terms of time that these changes can be made by the users themselves. on the another study, Terani ve ark. stated that produced percutaneous Tracheostomy Needle by using 3D printed tecnology and PLA as raw material, which to produce fast and need-oriented products, ,with the similar aim like us (7). When we compare the cost of 3DPVL with conventional videoryngoscopes, the prices of conventional VLs range from $3500-10000, homemade 3DPVL printing costs between 0.25-1 dollars/ per piece for the handle-blade part produced from PLA and 10-50 dollars/per piece for the camera part. The total cost of 3DPVL is around$11-51 (8). Nyrhinen et al. cost about $20 for the device they produced with 3d printing, close to our cost calculation, Lambert et al. Similarly, they reported a cost of $27 (9,10). Considering that conventional devices are not available in every clinic during economic crises and this device may be beneficial in difficult intubation conditions in emergency situations. Furthermore we believe that it can be a good alternative to conventional VLs in terms of cost and being disposable. The study has important limitations. Firstly, it is a manikin trial. Intubation of the patient brings its own difficulties, especially the deterioration of the camera due to fogging and secretions. Secondly, because it was used on a normal airway manikin, difficult airway manikin trials were not performed. Thirdly, we could not evaluate the performance of the other blades models on the model, since we designed the first prototype only as a C blade.

CONCLUSION

3DPVL may be a suitable alternative to conventional VLs for clinicians and users due to its low cost and ease of fabrication. Concerning our device, human studies in the easy airway in the second step and human studies in the easy airway compared with conventional VL in the third step are planned.

Ethics

This article does not contain any studies with human participants or animals performed by any of the authors.

Authorship Contributions

All authors contributed equally to the writing of this paper.

Declaration of competing interest

All authors declare no potential conflicts of interest in this study.

Acknowledgments

We thank to Dr.Ilyas Erdem Tonguc due to his contributes in English editing.

References

1. Pieters BM, Eindhoven GB, Acott C, van Zundert AAJ. Pioneers of laryngoscopy: indirect, direct and video laryngoscopy. Anaesthesia and Intensive Care. 2015;43($1_{s}uppl$) : 4–11.

2. Zaouter C, Calderon J, Hemmerling TM. Videolaryngoscopy as a new standard of care. Br J Anaesth. 2015;114(2):181–183.

3. Hamal PK, Chaurasia RB, Pokhrel N, et al. An affordable videolaryngoscope for use during the COVID-19 pandemic. Lancet Glob Health. 2020;8(7):e893-e894.

4. Di Prima M, Coburn J, Hwang D, et al. Additively manufactured medical products – the FDA perspective. 3D Print Med 2;2016. p 1.

5. U.S. Department of Health and Human Services: 'Reprocessing medical devices in healthcare settings: validation methods and labeling.' https://www.fda.gov/media/80265/download. [Accessed 1 september 2023].

6. Ataman AK, Altıntas E. Comparison of a commercial 3D fabricated laryngoscope (Airangel®) with a widely-used video laryngoscope (Glidescope®): randomized controlled cross-over study. Trends in Anaesthesia and Critical Care. 2021;40:e35- e40.

7. Terrani A, Bassi E, Ornaghi A, et al. The key role of 3D printing and the new medical sterilizable threads in the development of the translaryngeal Tracheostomy Needle Introducer. 3D Print Med 7;2021. p 14.

8. https://www.weerg.com/guides/how-much-does-3d-printing-cost [Accessed 1 September 2023].

9. Nyrhinen E, Lipnick M, Nyrhinen A. 3D-printed, low-cost videolaryngoscope designed for resource-constrained settings (Poster).

10. Lambert CT, John SC, John AV. Development and performance testing of the low-cost, 3D-printed, smartphone-compatible 'Tansen Videolaryngoscope'vs. Pentax-AWS videolaryngoscope vs. direct Macintosh laryngoscope: a manikin study. European Journal of Anaesthesiology— EJA. 2020;37(11), 992-998.