University of Cape Town

Faculty of Health Sciences

Innovation in low-cost video laryngoscopy:

Intubator V1-Indirect compared with Storz C-MAC in a simulated difficult airway

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Minor dissertation submitted in partial fulfilment of the requirements for the degree of Master of Medicine (MMed) in the

Department of Anaesthesia & Perioperative Medicine

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Declaration page

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Format

The contents of this minor dissertation are presented in the "*accepted for publication"* format.

This manuscript has been accepted for publication in *Trends in Anaesthesia and Critical Care.*

This work was previously presented at the World Airway Management Meeting (WAMM) in Amsterdam, the Netherlands, for which the abstract of this work was published in *Trends in Anaesthesia and Critical Care.*

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The authors would like to thank their colleagues in the Department of Anaesthesia and Perioperative Medicine of the University of Cape Town for participating in this study. The authors would also like to thank Karl Storz for providing a C-MAC device to conduct this study.

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Abstract

Background: Video laryngoscopy has directly impacted airway management, with numerous studies demonstrating its utility in clinical management of anatomically difficult airways. However, availability of video laryngoscopes in all clinical areas has been limited by cost. We used smartphone technology, miniature cameras and three-dimensional printing to design and create an innovative low-cost hyperangulated video laryngoscope. This has the potential to make the technique more widely available.

Objectives: The aim of this study was to determine if time to intubation with the novel device was clinically equivalent to an existing gold-standard video laryngoscope (Storz CMAC with Dörges blade).

Methods: We conducted a randomised, controlled, cross-over equivalence study with 100 skilled practitioners who had previous video laryngoscopy experience. Participants received instruction on the new device, and adequate opportunity to practice. Intubations were then performed in a randomised order on a mannikin simulating a difficult airway. Video recordings of each intubation were analysed by two independent investigators to determine time to intubation. A mean difference in intubation time of less than 10 seconds was determined a priori to denote clinical equivalence.

Results: Mean difference in intubation time between the devices was 4.92 seconds, (two one-sided test 95%CI: 2.34 – 7.49 seconds). The innovative low-cost VL was thus clinically equivalent to the industry standard in a simulated difficult airway. Further testing in vivo in a clinical environment is needed.

Conclusion: The results of this study show that a low-cost disposable hyperangulated video laryngoscope is clinically equivalent to the industry standard in a simulated difficult airway. In the context of the current global pandemic, video laryngoscopy has been advised in nearly all airway guidelines. Access to a low-cost VL which does not require reprocessing may be of great value.

Chapter 1: Introduction

Video laryngoscopy has directly impacted airway management, with numerous studies demonstrating its utility in clinical management of anatomically difficult airways. However, availability of video laryngoscopes in all clinical areas has been limited by the relatively high cost. We used smartphone technology, miniature cameras and three-dimensional printing to design and create an innovative low-cost hyperangulated video laryngoscope with the potential to make the technique more widely available.

The aim of this study was to determine if time to intubation with the novel device was clinically equivalent to an existing gold-standard video laryngoscope (Storz CMAC with Dörges blade). We conducted a randomised, controlled, cross-over equivalence study, during April and August 2019 with 100 skilled practitioners who had previous video laryngoscopy experience to determine mean difference in intubation time between the devices.

Chapter 2: Manuscript - Accepted for Publication

The manuscript has been accepted for publication in *Trends in Anaesthesia and Critical Care.*

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Innovation in low-cost video-laryngoscopy: Intubator V1-Indirect compared with Storz C-MAC in a simulated difficult airway

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Keywords: videolaryngoscopy, video laryngoscope, difficult airway, low-cost

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This study was undertaken in partial completion of the MMed degree for the first author. Findings of this study have been presented in oral and poster format at the World Airway Management Meeting in Amsterdam, November 2019, and at the South African Society of Anaesthesiologists' annual congress in Pretoria, March 2020. The abstract for WAMM was published in *Trends in Anaesthesia and Critical Care* 2020(30):e127.

Innovation in low-cost video laryngoscopy: Intubator V1-Indirect compared with Storz C-MAC in a simulated difficult airway

Abstract

Background
Video laryngoscopy has directly impacted airway management, with numerous studies demonstrating its utility in clinical management of anatomically difficult airways. However, availability of video laryngoscopes in all clinical areas has been limited by the relatively high cost. We used smartphone technology, miniature cameras and three-dimensional printing to design and create an innovative low-cost hyperangulated video laryngoscope. This has the potential to make the technique more widely available. The aim of this study was to determine if time to intubation with the novel device was clinically equivalent to an existing gold-standard video laryngoscope (Storz CMAC with Dörges blade).

Methods:
We conducted a randomised, controlled, cross-over equivalence study with 100 skilled practitioners who had previous video laryngoscopy experience. Participants received instruction on the new device, and adequate opportunity to practice. Intubations were then performed in a randomised order on a mannikin simulating a difficult airway. Video recordings of each intubation were analysed by two independent investigators to determine time to intubation. A mean difference in intubation time of less than 10 seconds was determined *a priori* to denote clinical equivalence.

Results:
Mean difference in intubation time between the devices was 4.92 seconds, (two one-sided test 95%CI: 2.34 – 7.49 seconds). The innovative low-cost VL was thus clinically equivalent to the industry standard in a simulated difficult airway. Further testing *in vivo* in a clinical environment is needed.

Conclusion:
The results of this study show that a low-cost disposable hyperangulated video laryngoscope is clinically equivalent to the industry standard in a simulated difficult airway. In the context of the current global pandemic, video laryngoscopy has been advised in nearly all airway guidelines. Access to a low-cost VL which does not require reprocessing may be of great value.

Introduction

Traditionally, the most commonly used tool for manipulation of the airway and tracheal intubation under direct vision is a Macintosh blade laryngoscope.[1] The ability to safely perform this procedure requires practice and experience, and can prove challenging where there are anatomical or situational factors associated with a difficult airway.[2-5]

In human trials, VLs have been shown to improve the view of the larynx and glottis compared to direct laryngoscopy (DL).[6 7] VLs have improved intubation first-pass success rates, decreased rates of oesophageal intubation, and increased overall intubation success for both expert and inexperienced providers, within as well as outside the operating theatre context.[6-9] Whilst DL intubation has been shown in some studies to be faster than VL, especially in experienced hands, VL may also be an important rescue technique for failed DL intubation. This is reflected in a study which showed the efficacy of the Storz CMAC video laryngoscope as a rescue device in the unanticipated difficult airway, where 86% first-pass success (FPS) was achieved after failed direct laryngoscopy.[10] The Difficult Airway Society (DAS) now recommends that video laryngoscopy should be immediately available whenever intubation is performed.[11] A United Kingdom national survey highlighted the fact that VLs are available in 93% of operating theatres, but only 54% of ICUs and 35% of emergency departments.[11] However, ICUs and emergency departments are clinical areas where unanticipated difficult airways arise commonly. These data highlight the lack of availability of VL devices in these critical medical areas, which may be due to the relatively high cost of VL devices.[11]

An effective low-cost VL device may help to increase availability of these devices in all areas where difficult airway management occurs, especially in lower income, resource-constrained countries where rescue airway devices are not readily available. Furthermore, reduction in cost may facilitate greater usage of VL, which could in turn improve patient safety and outcomes. In the context of the current global pandemic, video laryngoscopy has been advised in many airway guidelines.[12 13] Access to a low-cost VL which does not require reprocessing may be of great value.

The Intubator V1-Indirect is a is a low-cost, disposable, hyperangulated VL developed in South Africa, which is not yet available on the market. The device consists of a single-piece, injection-moulded, polycarbonate blade-handle combination which houses a CMOS camera and reusable battery-powered electronics module. Insertion of the electronics module makes a video stream available via a 2.4 Ghz wireless access point. The user views the video stream using a purpose-built mobile phone application which presents the stream on the device display. The user is thus able to perform VL using a combination of the Intubator V1-Indirect and their smartphone. The device takes advantage of the processing and display capability of modern smartphones, including recording capability. The blade-handle-camera combination is disposable, eliminating the need for sterilisation and risks of spread of pathogens. The device is lightweight, robust, portable and compact. The quality of the video image produced with the endoscopic camera and mobile application is 720P, which exceeds the resolution of the comparator (CMAC).

(Figure 1 – Intubator V1 Indirect)

The aim of this study was to determine clinical equivalence of a low-cost video laryngoscope with a current standard device, using a simulated difficult airway model. Due to the hyperangulated shaped blade of the novel device, the Storz CMAC Pocket Monitor with Dörges blade (Karl Storz GmBH, Tuttlingen, Germany) was selected as an appropriate comparator. The Dörges blade is hyperangulated and designed for a difficult airway and anterior larynx.

(Figure 2 – Storz CMAC D-blade)

The null hypothesis is that a low cost video laryngoscope is not equivalent to the industry standard in simulated difficult airway. The primary outcome was mean difference in intubation times, with a secondary outcome of assessing laryngoscopic view obtained with each blade.

Methods

After approval by the University of Cape Town Human Research Ethics Committee (HREC REF 770/2018), a randomised, controlled, cross-over equivalence study was designed to compare the novel device to an established industry standard. Participant inclusion criteria were skilled intubators (>200 direct laryngoscopy intubations), with previous video laryngoscope experience.[14 15] One hundred participants were recruited from Groote Schuur and Red Cross War Memorial Children's Hospitals with written informed consent between April and August 2019.

Participants received one-on-one demonstration of intubation with both the CMAC and low-cost device on an airway training mannikin (Laerdal, Stavanger, Norway) in a controlled environment. The manikin was immobilized with a cervical collar to simulate a difficult airway, as described in a previous study.[16] Participants then had an opportunity to practice intubating the mannikin with a standard 7.0 mm internal diameter endotracheal tube loaded with a preformed malleable stylet with both devices. Participants could practice with the devices and were required to demonstrate at least three successful intubations with each device before they proceeded to perform their video-recorded intubations. The novel device had video streamed to a mobile phone (Samsung Galaxy S7 Android device), which participants could place at a convenient vantage point of their choice.

After practice attempts with each device, participants were randomised by blinded selection of a number from an envelope which determined the order of timed intubation attempts, with half randomised to use either the C-MAC or novel device first. Participants were asked to intubate the mannikin as swiftly as safely possible with each device and were not helped or guided during their intubation attempts. Intubation was then immediately performed with the alternate device.

Video recordings were uploaded to a notebook computer and imported to an editing suite (Sony Vegas 13C, Sony Creative Software Inc, Madison, U.S.A). Recordings were viewed frame-by-frame by two different observers. Time-point markers were placed at the start of intubation (deemed as the moment the device entered the oral cavity) and at the end of intubation (the moment the vocal cord marker on the ETT moved past the true cords). Laryngoscopic views were graded using a portion of the Fremantle score, as full , partial or no view of the glottic opening. [17]

Statistical methods:
A sample size of 97 participants was calculated using PASS software (PASS 15 Power Analysis and Sample Size Software 2017, NCSS, LLC. Kaysville, Utah, USA) for 90% power with an alpha error of 2.5%. Based on previous equivalence studies, *a priori* clinical equivalence limits were set at 10 seconds mean difference in intubation time.[18 19] Intubation times were recorded on a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, Washington, USA), from where they were exported to MedCalc for statistical analysis (MedCalc® Statistical Software, Ostend, Belgium; https://www.medcalc.org; 2020). Interrater agreement was assessed using absolute agreement of intraclass correlation coefficient. The average of the times analysed by the two observers was used

in the final analysis. The mean difference in intubation time was compared using a two one-sided test (TOST).

Results

All participants were anaesthesia trainees and consultants with video laryngoscopic intubation experience. All successfully intubated the trachea during their timed attempt, with no oesophageal intubations with either device. The mean difference for time to intubation was 4.92 seconds (95% CI 2.34 - 7.49) as seen in Figure 2. This was within the 10 second *a priori* limits for clinical significance. The fastest time and slowest times with the C-MAC D blade were 5.1 and 34.2 seconds respectively, with an average time of 13.3 seconds. By comparison, the fastest and slowest time with the novel device were 5.2 and 99.1 seconds with an average time of 18.15 seconds (Table 1). Absolute interrater agreement in intubation between the two observers was high, with an intraclass correlation coefficient of 0.9945 (95% CI 0.9927 - 0.9958).

Views when using the CMAC were graded as full and partial in 42 and 58 cases respectively, and as full and partial in 41 and 59 cases when using the Intubator. There were no cases of no glottic view. (See Table 2).

Discussion

This study demonstrates equivalence of the low-cost video laryngoscope with an industry standard device in immobilised mannikins. Participants were able to learn how to use the new device within a brief period of time, and successfully intubate a simulated difficult airway. This study was in accordance with the ADEPT guidelines, which suggest that manikin evidence should exist before a new device is to be tested for equivalence in humans.[20]

It is noteworthy that while the devices were clinically equivalent within our defined limits, the CMAC was nearly 5 seconds faster on average, with this result reaching statistical significance ($p = 0.0003$). Most of the participants in this study use the CMAC on a regular basis, as it is the video laryngoscope available in our institution. This may have led to some inherent performance bias in favour of the CMAC. However, despite a learning curve with new device, approximately one third (36/100) of participants were faster with the novel device than the CMAC.

Several other observations were made during the study in terms of the performance of the two devices. There was variability with the ease with which some participants learned how to use the novel device. Although all participants were allowed as much practice as desired and had to demonstrate at least three successful intubations prior to their recorded efforts, some participants may have rushed their training and practice attempts in order to return to their clinical duties. This may account for outliers who were significantly slower than average and may have needed more time to familiarize themselves with the new device.

The study naturally has several limitations. Participants were instructed to intubate the mannikin “as fast as possible and to the best of your ability” and the study relied heavily on the best effort during their timed intubation to give a true representation of the ability to use both devices. This may also have influenced the quality of the laryngoscopic views obtained, as participants were concentrating on swift intubation rather than obtaining the best possible view. The observers who analysed the recordings could not be blinded as to which device was in use. However, the excellent interrater agreement between observers suggests this had minimal effect. A few participants demonstrated

performance anxiety because they were being timed. We feel, however, that performing an emergency intubation also carries performance pressure, and thus this could still be an accurate reflection of their ability under stressful situations.

In accordance with previous studies in the literature, participants were experienced users. It is not known how the device might perform in the hands of inexperienced users. A subsequent study could assess how novice users might perform with two devices. The primary outcomes of this study was mean time to intubation, with laryngoscopic grading as a secondary outcome. Additional outcomes not assessed here which are often assessed in similar studies include ease of use, or airway/dental trauma.[17 21] Although these metrics could provide additional information regarding the performance of the novel device, we selected equivalence in intubation time as the specific outcome relevant to securing an airway as swiftly as possible.

The Intubator-V1 was prototyped using 3D-printing, but blade used during the study was manufactured in the same fashion as the final production version, using injection moulding of polycarbonate, which is cheap but extremely durable. The same blade was used by all participants for multiple practice attempts and intubations throughout the study, and did not accrue any damage or experience technical issues during at least 400 uses. It therefore far exceeds robustness required of a single use device. It is noted that the environmental footprint of a disposable device could add to environmental cost. However, polycarbonate is fully recyclable, and lack of requirement for processing and sterilization decreases water and hazardous chemical use, reducing the environmental effects.

Difficult airway management is a skill required by expert anaesthesiologists and junior clinicians alike. Video laryngoscopy has proven to be a powerful modality in the field, and certainly has a place as a rescue device in unanticipated failed intubation with direct laryngoscopy.[10] Furthermore, during the COVID-19 pandemic, various anaesthesia and airway societies have advocated for video laryngoscopy to help reduce healthcare worker exposure during intubation.[12 22]

Studies have highlighted that VL is more readily available in operating theatre environments than in emergency departments and intensive care units, where difficult and unanticipated emergency intubation often takes place.[11] Difficult airway society guidelines now dictate that VL be available in all clinical areas where intubation takes place.[2] The major barrier to availability of these devices is financial constraints, especially in resource-constrained low- and middle-income countries, where studies show that perioperative outcomes are worse than the developed world .[23] The goal of the inventors of this low-cost device is to make video-laryngoscopy available to all medical practitioners, with a disposable, hyperangulated blade specifically designed for the difficult airway, or as a rescue device in the unanticipated difficult airway.

There is widespread acceptance that video laryngoscopy improves management of difficult airways, but the availability thereof is limited, particularly in resource-constrained environments. This discrepancy has been further highlighted during the COVID-19 pandemic, where most guidelines recommend the use of VL. A low-cost video laryngoscope could help bridge resource gap, and allow less well-funded areas and institutions to use this life saving equipment , and ultimately improve patient outcomes. This study has shown that such a device is clinically equivalent to the industry standard in a simulated difficult airway. This opens the way to further testing of this device *in vivo* to determine clinical utility and safety, and ultimately make the device available to Africa and the world.

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The authors acknowledge the staff of Groote Schuur and Red Cross War Memorial Children's Hospitals, and the University of Cape Town Department of Anaesthesia and Perioperative Medicine for participating, and thank Karl Storz Endoscopy SA for the loan of a CMAC to perform this study. The study was supported by Departmental funds, including remuneration for a third-party statistician to confirm the results. We are grateful to Dr Dinell Behari for independent analysis of video footage to compile intubation times.

Competing interests

CdV and DE designed and produced the novel study device. RH is the director of the African Fellowship in Airway and Thoracic Anaesthesia, which is supported in part by an unrestricted educational grant by Karl Storz GbBH. CA has no competing interests to declare. All data and video files available at request of author.

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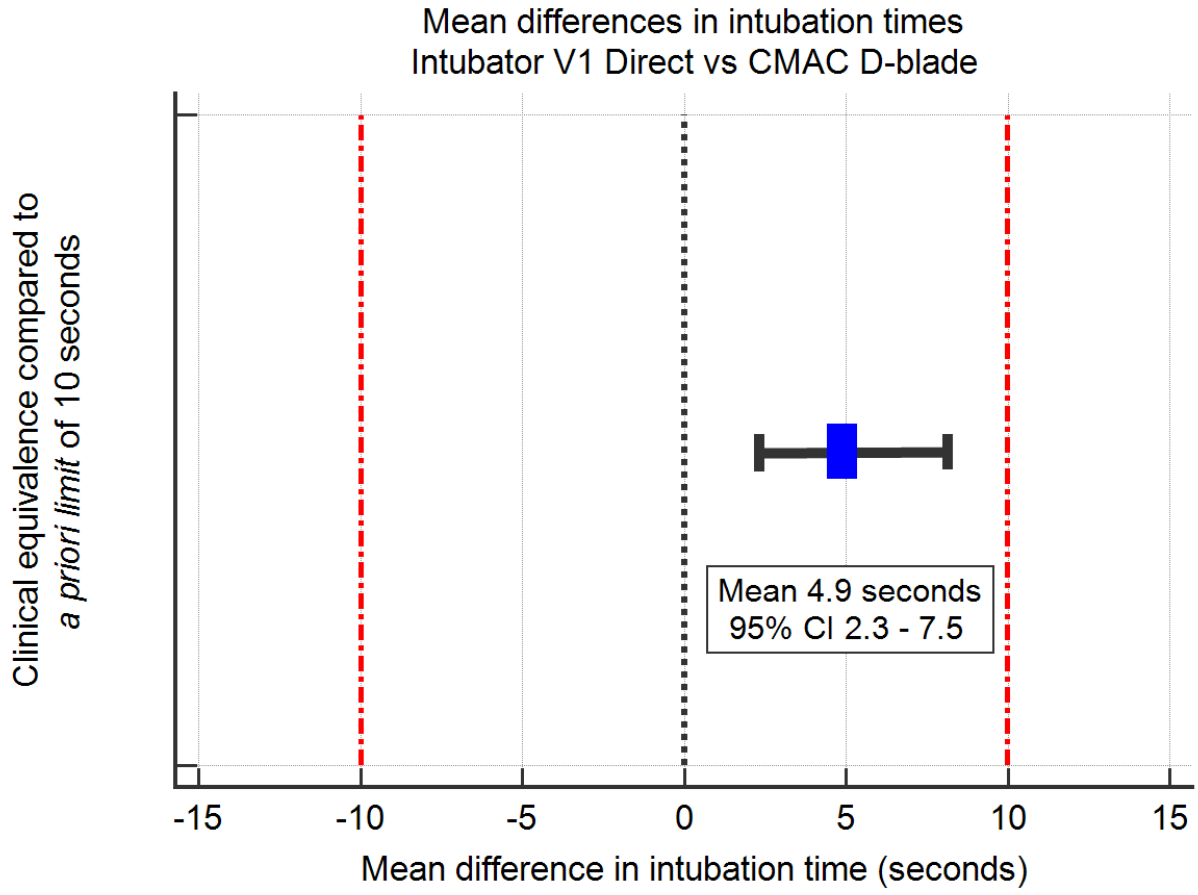
Figure 1. V1 Intubator Indirect - Novel low-cost hyperangulated disposable videolaryngoscope

Figure 2. Storz CMAC with Dörges blade (Karl Storz GmBH, Tuttlingen, Germany)

Figure 3. Equivalence plot showing mean difference in intubation time. Red dotted lines show *a priori* clinical equivalence limit of 10 seconds.



CI = Confidence interval

Table 1. Intubation time between CMAC and Intubator V1 indirect video laryngsocope

	CMAC	Intubator V1	Difference
N	100	100	-
Minimum intubation time (seconds)	5,08	5,20	-
Maximum intubation time (seconds)	34,22	98,53	-
Mean intubation time (seconds)	13,31	18,23	4,92*
95% CI of intubation time	12,18 to 14,44	15,62 to 20, 84	**2,34 to 7,49**
Standard deviation of intubation time	5,70	13,14	12,97
Interquartile range of intubation time	9,25 to 16,61	10,65 to 20,37	-1,85 to 7,73

N: number, CI: confidence interval, SD: standard deviation, RSD: relative standard deviation, Normal Distr: Normal distribution). *Mean difference in intubation time p = 0,0003.

Table 2. Fremantle[17] videolaryngoscopic score for view obtained with CMAC and Intubator.

Fremantle view grading	CMAC-D, n (%)	Intubator V-1, n (%)
Full	42 (42 %)	41 (41 %)
Partial	58 (58 %)	59 (59 %)
None	0 (0 %)	0 (0 %)
Total	100 (100 %)	100 (100 %)

Number of participants whom obtained a “Full”, “Partial” or “None” view as per Fremantle videolaryngoscopic grading.

Chapter 3 – Published Peer-Reviewed Article

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Innovation in low-cost video-laryngoscopy: Intubator V1-Indirect compared with Storz *C*-MAC in a simulated difficult airway☆

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Low-cost

ABSTRACT

Background: Video laryngoscopy has directly impacted airway management, with numerous studies demonstrating its utility in clinical management of anatomically difficult airways. However, availability of video laryngoscopes in all clinical areas has been limited by the relatively high cost. We used smartphone technology, miniature cameras and three-dimensional printing to design and create an innovative low-cost hyperangulated video laryngoscope. This has the potential to make the technique more widely available. The aim of this study was to determine if time to intubation with the novel device was clinically equivalent to an existing gold-standard video laryngoscope (Storz CMAC with Dörges blade).

Methods: We conducted a randomised, controlled, cross-over equivalence study with 100 skilled practitioners who had previous video laryngoscopy experience. Participants received instruction on the new device, and adequate opportunity to practice. Intubations were then performed in a randomised order on a mannikin simulating a difficult airway. Video recordings of each intubation were analysed by two independent investigators to determine time to intubation. A mean difference in intubation time of less than 10 s was determined *a priori* to denote clinical equivalence.

Results: Mean difference in intubation time between the devices was 4.9 s, (two one-sided test 95%CI: 2.3−7.5 s). The innovative low-cost VL was thus clinically equivalent to the industry standard in a simulated difficult airway. Further testing *in vivo* in a clinical environment is needed.

Conclusion: The results of this study show that a low-cost disposable hyperangulated video laryngoscope is clinically equivalent to the industry standard in a simulated difficult airway. In the context of the current global pandemic, video laryngoscopy has been advised in nearly all airway guidelines. Access to a low-cost VL which does not require reprocessing may be of great value.

1. Introduction

Traditionally, the most commonly used tool for manipulation of the airway and tracheal intubation under direct vision is a Macintosh blade laryngoscope [1]. The ability to safely perform this procedure requires practice and experience, and can prove challenging where there are anatomical or situational factors associated with a difficult airway [2–5].

In human trials, VLs have been shown to improve the view of the larynx and glottis compared to direct laryngoscopy (DL).[6 7] VLs have improved intubation first-pass success rates, decreased rates of oesophageal intubation, and increased overall intubation success for both expert and inexperienced providers, within as well as outside the operating theatre context [6–9]. Whilst DL intubation has been shown in some studies to be faster than VL, especially in experienced hands, VL may also be an important rescue technique for failed DL intubation. This is reflected in a study which showed the efficacy of the Storz CMAC video laryngoscope as a rescue device in the unanticipated difficult airway, where 86% first-pass success (FPS) was achieved after failed direct laryngoscopy [10]. The Difficult Airway Society (DAS) now recommends that video laryngoscopy should be immediately available whenever intubation is performed [11]. A United Kingdom national survey highlighted the fact that VLs are available in 93% of operating theatres, but only 54% of ICUs and 35% of emergency departments [11]. However, ICUs and emergency departments are clinical areas

☆ This study was undertaken in partial completion of the MMed degree for the first author. Findings of this study have been presented in oral and poster format at the World Airway Management Meeting in Amsterdam, November 2019, and at the South African Society of Anaesthesiologists' annual congress in Pretoria, March 2020. The abstract for WAMM was published in *Trends in Anaesthesia and Critical Care* 2020(30):e127.

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2210-8440/

where unanticipated difficult airways arise commonly. These data highlight the lack of availability of VL devices in these critical medical areas, which may be due to the relatively high cost of VL devices [11].

An effective low-cost VL device may help to increase availability of these devices in all areas where difficult airway management occurs, especially in lower income, resource-constrained countries where rescue airway devices are not readily available. Furthermore, reduction in cost may facilitate greater usage of VL, which could in turn improve patient safety and outcomes. In the context of the current global pandemic, video laryngoscopy has been advised in many airway guidelines.[12 13] Access to a low-cost VL which does not require reprocessing may be of great value.

The Intubator V1-Indirect is a is a low-cost, disposable, hyperangulated VL developed in South Africa, which is not yet available on the market. The device consists of a single-piece, injection-moulded, polycarbonate blade-handle combination which houses a CMOS camera and reusable battery-powered electronics module (see Fig. 1). Insertion of the electronics module makes a video stream available via a 2.4 Ghz wireless access point. The user views the video stream using a purpose-built mobile phone application which presents the stream on the device display. The user is thus able to perform VL using a combination of the Intubator V1-Indirect and their smartphone. The device takes advantage of the processing and display capability of modern smartphones, including recording capability. The blade-handle-camera combination is disposable, eliminating the need for sterilization and risks of spread of pathogens. The device is lightweight, robust, portable and compact. The quality of the video image produced with the endoscopic camera and mobile application is 720 P, which exceeds the resolution of the comparator (CMAC).

The aim of this study was to determine clinical equivalence of a low-cost video laryngoscope with a current standard device, using a simulated difficult airway model. Due to the hyperangulated shaped blade of the novel device, the Storz CMAC Pocket Monitor with Dörges blade (Karl Storz GmBH, Tuttlingen, Germany) was selected as an appropriate comparator. The Dörges blade is hyperangulated and designed for a difficult airway and anterior larynx (see Fig. 2).

The null hypothesis is that a low cost video laryngoscope is not equivalent to the industry standard in simulated difficult airway. The primary outcome was mean difference in intubation times, with a secondary outcome of assessing laryngoscopic view obtained with each blade.

2. Methods

After approval by the University of Cape Town Human Research Ethics Committee (HREC REF 770/2018), a randomised, controlled, cross-over equivalence study was designed to compare the novel device to an established industry standard. Participant inclusion criteria were skilled intubators (>200 direct laryngoscopy intubations), with previous video laryngoscope experience.[14 15] One hundred participants were recruited from Groote Schuur and Red Cross War Memorial Children's Hospitals with written informed consent between April and August 2019.

Participants received one-on-one demonstration of intubation with both the CMAC and low-cost device on an airway training mannikin (Laerdal, Stavanger, Norway) in a controlled environment. The manikin was immobilized with a cervical collar to simulate a difficult airway, as described in a previous study [16]. Participants then had an opportunity to practice intubating the mannikin with a standard 7.0 mm internal diameter endotracheal tube loaded with a preformed malleable stylet with both devices. Participants could practice with the devices and were required to demonstrate at least three successful intubations with each device before they proceeded to perform their video-recorded intubations. The novel device had video streamed to a mobile phone (Samsung Galaxy S7 Android device), which participants could place at a convenient vantage point of their choice.

After practice attempts with each device, participants were randomised by blinded selection of a number from an envelope

Fig. 1. V1 Intubator Indirect - Novel low-cost hyperangulated disposable videolaryngoscope.

Fig. 2. Storz CMAC with Dörges blade (Karl Storz GmBH, Tuttlingen, Germany).

which determined the order of timed intubation attempts, with half randomised to use either the *C*-MAC or novel device first. Participants were asked to intubate the mannikin as swiftly as safely possible with each device and were not helped or guided during their intubation attempts. Intubation was then immediately performed with the alternate device.

Video recordings were uploaded to a notebook computer and imported to an editing suite (Sony Vegas 13C, Sony Creative Software Inc, Madison, U.S.A). Recordings were viewed frame-by-frame by two different observers. Time-point markers were placed at the start of intubation (deemed as the moment the device entered the oral cavity) and at the end of intubation (the moment the vocal cord marker on the ETT moved passed the true cords). Laryngoscopic views were graded using a portion of the Fremantle score, as full, partial or no view of the glottic opening [17].

2.1. Statistical methods

A sample size of 97 participants was calculated using PASS software (PASS 15 Power Analysis and Sample Size Software 2017, NCSS, LLC. Kaysville, Utah, USA) for 90% power with an alpha error of 2.5%. Based on previous equivalence studies, *a priori* clinical equivalence limits were set at 10 s mean difference in intubation time.[18 19] Intubation times were recorded on a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, Washington, USA), from where they were exported to MedCalc for statistical analysis (MedCalc® Statistical Software, Ostend, Belgium; https://www.medcalc.org; 2020). Interrater agreement was assessed using absolute agreement of intraclass correlation coefficient. The average of the times analysed by the two observers was used in the final analysis. The mean difference in intubation time was compared using a two one-sided test (TOST).

3. Results

All participants were anaesthesia trainees and consultants with video laryngoscopic intubation experience. All successfully intubated the trachea during their timed attempt, with no oesophageal intubations with either device. The mean difference for time to intubation was 4.9 s (95% CI 2.3−7.5) as seen in Fig. 3. This was within the 10 s *a priori* limits for clinical significance. The fastest time and slowest times with the *C*-MAC D blade were 5.1 and 34.2 s respectively, with an average time of 13.3 s. By comparison, the fastest and slowest time with the novel device were 5.2 and 99.1 s with an average time of 18.2 s (Table 1). Absolute interrater agreement in intubation between the two observers was high, with an intraclass correlation coefficient of 0.995 (95% CI 0.993−0.996).

Views when using the CMAC were graded as full and partial in 42 and 58 cases respectively, and as full and partial in 41 and 59 cases when using the Intubator. There were no cases of no glottic view. (See Table 2).

4. Discussion

This study demonstrates equivalence of the low-cost video laryngoscope with an industry standard device in immobilized mannikins. Participants were able to learn how to use the new device within a brief period of time, and successfully intubate a simulated difficult airway. This study was in accordance with the ADEPT guidelines, which suggest that manikin evidence should exist before a new device is to be tested for equivalence in humans [20].

It is noteworthy that while the devices were clinically equivalent within our defined limits, the CMAC was nearly 5 s faster on average, with this result reaching statistical significance ($p = 0.0003$). Most of the participants in this study use the CMAC on a regular basis, as it is the video laryngoscope available in our institution. This may have led to some inherent performance bias in favour of the CMAC. However, despite a learning curve with new device, approximately one third (36/100) of participants were faster with the novel device than the CMAC.

Several other observations were made during the study in terms of the performance of the two devices. There was variability with the ease with which some participants learned how to use the novel device. Although all participants were allowed as much practice as desired and had to demonstrate at least three successful intubations prior to their recorded efforts, some participants may have rushed their training and practice attempts in order to return to their clinical duties. This may account for outliers who were significantly slower than average and may have needed more time to familiarize themselves with the new device.

The study naturally has several limitations. Participants were instructed to intubate the mannikin “as fast as possible and to the best of your ability” and the study relied heavily on the best effort during their timed intubation to give a true representation of the ability to use both devices. This may also have influenced the quality of the laryngoscopic views obtained, as participants were concentrating on swift intubation rather than obtaining the best possible view. The observers who analysed the recordings could not be blinded as to which device was in use. However, the excellent interrater agreement between observers suggests this had minimal effect. A few participants demonstrated performance anxiety because they were being timed. We feel, however, that performing an emergency intubation also carries performance pressure, and thus this could still be an accurate reflection of their ability under stressful situations.

In accordance with previous studies in the literature, participants were experienced users. It is not known how the device might perform in the hands of inexperienced users. A subsequent study could assess how novice users might perform with two devices. The primary outcomes of this study was mean time to intubation, with laryngoscopic grading as a secondary outcome. Additional outcomes not assessed here which are often assessed in similar studies include ease of use, or airway/dental trauma.[17 21] Although these metrics could provide additional information regarding the performance of the novel device, we selected equivalence in intubation time as the specific outcome relevant to securing an airway as swiftly as possible.

The Intubator-V1 was prototyped using 3D-printing, but blade used during the study was manufactured in the same fashion as the final production version, using injection molding of polycarbonate, which is cheap but extremely durable. The same blade was used by all participants for multiple practice attempts and intubations throughout the study, and did not accrue any damage or experience technical issues during at least 400 uses. It therefore far exceeds robustness required of a single use device. It is noted that the environmental footprint of a disposable device could add to environmental cost. However, polycarbonate is fully recyclable, and lack of requirement for processing and sterilization decreases water and hazardous chemical use, reducing the environmental effects.

Difficult airway management is a skill required by expert anaesthesiologists and junior clinicians alike. Video laryngoscopy has proven to be a powerful modality in the field, and certainly has a place as a rescue device in unanticipated failed intubation with direct laryngoscopy [10]. Furthermore, during the COVID-19 pandemic, various anaesthesia and airway societies have advocated for video laryngoscopy to help reduce healthcare worker exposure during intubation.[12 22]

Studies have highlighted that VL is more readily available in operating theatre environments than in emergency departments

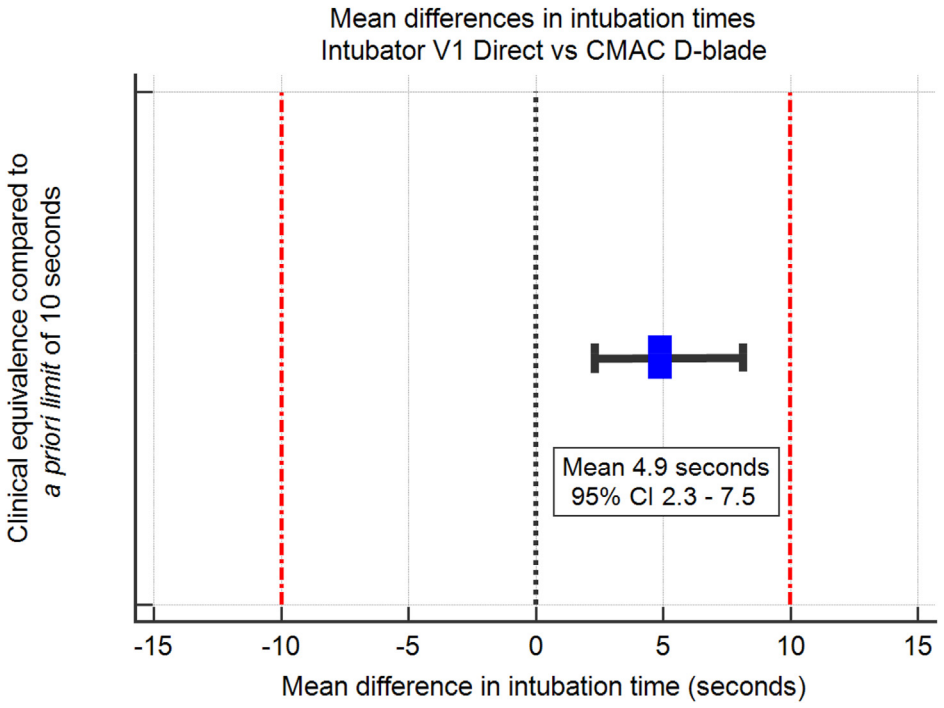

Fig. 3. Equivalence plot showing mean difference in intubation time. Red dotted lines show *a priori* clinical equivalence limit of 10 s. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Table 1
Intubation time between CMAC and Intubator V1 indirect video laryngsocope.

	CMAC	Intubator V1	Difference
N	100	100	–
Minimum – maximum intubation time (seconds)	5,1–34,2	5,2–99,1	-
intubation time (seconds) mean (SD)	13,3 (5,7)	18,2 (13,1)	4,9[a]
95% CI of intubation time	12,2 to 14,4	15,6 to 20, 8	2,3 to 7,5

N: number, CI: confidence interval, SD: standard deviation.
[a] Mean difference in intubation time p = 0,0003.

Table 2
Fremantle [17] videolaryngoscopic score for view obtained with CMAC and Intubator.

Freemantle view grading	CMAC-D, n (%)	Intubator V-1, n (%)
Full	42 (42%)	41 (41%)
Partial	58 (58%)	59 (59%)
None	0 (0%)	0 (0%)
Total	100 (100%)	100 (100%)

Number of participants whom obtained a “Full”, “Partial” or “None” view as per Fremantle videolaryngoscopic grading.

and intensive care units, where difficult and unanticipated emergency intubation often takes place [11]. Difficult airway society guidelines now dictate that VL be available in all clinical areas where intubation takes place [2]. The major barrier to availability of these devices is financial constraints, especially in resource-constrained low- and middle-income countries, where studies show that perioperative outcomes are worse than the developed world [23]. The goal of the inventors of this low-cost device is to make video-laryngoscopy available to all medical practitioners, with a disposable, hyperangulated blade specifically designed for the difficult airway, or as a rescue device in the unanticipated difficult airway.

There is widespread acceptance that video laryngoscopy improves management of difficult airways, but the availability thereof is limited, particularly in resource-constrained environments. This discrepancy has been further highlighted during the COVID-19 pandemic, where most guidelines recommend the use of VL. A low-cost video laryngoscope could help bridge resource gap, and allow less well-funded areas and institutions to use this life saving equipment, and ultimately improve patient outcomes. This study has shown that such a device is clinically equivalent to the industry standard in a simulated difficult airway. This opens the way to further testing of this device *in vivo* to determine clinical utility and safety, and ultimately make the device available to Africa and the world.

Author statement

Christiaan de Villiers:Conception or design of the work, data collection, data analysis and interpretation, drafting the article. Christella Alphonsusata analysis and interpretation, drafting the article. Dylan Eave: Conception or design of the work, drafting the article. Ross Hofmeyr:Conception or design of the work, data analysis and interpretation critical revision of the article.

Declaration of competing interest

CdV and DE designed and produced the novel study device. RH is the director of the African Fellowship in Airway and Thoracic Anaesthesia, which is supported in part by an unrestricted educational grant by Karl Storz GbBH. CA has no competing interests to declare. All data and video files available at request of author.

Acknowledgements

The authors acknowledge the staff of Groote Schuur and Red Cross War Memorial Children's Hospitals, and the University of Cape Town Department of Anaesthesia and Perioperative Medicine for participating, and thank Karl Storz Endoscopy SA for the loan of a CMAC to perform this study. The study was supported by Departmental funds, including remuneration for a third-party statistician to confirm the results. We are grateful to Dr Dinell Behari for independent analysis of video footage to compile intubation times.

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List of appendices

Appendix 1: TACC Acceptance for Publication

Gmail **Christiaan de Villiers <christiaandevilliers@gmail.com>**

Decision on submission to Trends in Anaesthesia and Critical Care
1 message

Trends in Anaesthesia and Critical Care <em@editorialmanager.com> Thu, Jul 1, 2021 at 6:06 PM
Reply-To: Trends in Anaesthesia and Critical Care <tacc@elsevier.com>
To: Christiaan de Villiers <christiaandevilliers@gmail.com>

CC: zoltanszucsmd@gmail.com

Manuscript Number: TACC-D-21-00083R1

Innovation in low-cost video laryngoscopy: Intubator V1-Indirect compared with Storz C-MAC in a simulated difficult airway

Dear Dr de Villiers,

Thank you for submitting your manuscript to Trends in Anaesthesia and Critical Care.

I am pleased to inform you that your manuscript has been accepted for publication.
Your accepted manuscript will now be transferred to our production department. We will create a proof which you will be asked to check, and you will also be asked to complete a number of online forms required for publication. If we need additional information from you during the production process, we will contact you directly.

We appreciate and value your contribution to Trends in Anaesthesia and Critical Care. We regularly invite authors of recently published manuscript to participate in the peer review process. If you were not already part of the journal's reviewer pool, you have now been added to it. We look forward to your continued participation in our journal, and we hope you will consider us again for future submissions.

Kind regards,
Robert Greif, MD, MME
Editor-in-Chief

Trends in Anaesthesia and Critical Care

Editor comments:
Dear author,
The changes requested by the reviewers have been expanded and edited in a correct manner.
Excellent, interesting and useful work. Minor discrepancies remained in the numbers between the table and the results section. After editorial correction, I think the manuscript is already suitable for publication.

Appendix 2: TACC Reviewer Comments

Gmail Christiaan de Villiers <christiaandevilliers@gmail.com

Decision on submission to Trends in Anaesthesia and Critical Care
6 messages

Trends in Anaesthesia and Critical Care <em@editorialmanager.com> Fri, Jun 11, 2021 at 1:08 PM
Reply-To: Trends in Anaesthesia and Critical Care <tacc@elsevier.com>
To: Christiaan de Villiers <christiaandevilliers@gmail.com>

Manuscript Number: TACC-D-21-00083

Innovation in low-cost video laryngoscopy: Intubator V1-Indirect compared with Storz C-MAC in a simulated difficult airway

Dear Dr de Villiers,

Thank you for submitting your manuscript to Trends in Anaesthesia and Critical Care.

I have completed my evaluation of your manuscript. The reviewers recommend reconsideration of your manuscript following minor revision and modification. I invite you to resubmit your manuscript after addressing the comments below. Please resubmit your revised manuscript by Jul 11, 2021.

When revising your manuscript, please consider all issues mentioned in the reviewers' comments carefully: please outline every change made in response to their comments and provide suitable rebuttals for any comments not addressed. Please note that your revised submission may need to be re-reviewed.

To submit your revised manuscript, please log in as an author at https://www.editorialmanager.com/tacc/, and navigate to the "Submissions Needing Revision" folder under the Author Main Menu.

Trends in Anaesthesia and Critical Care values your contribution and I look forward to receiving your revised manuscript.

Kind regards,

Robert Greif, MD, MME

Editor-in-Chief

Trends in Anaesthesia and Critical Care

Editor and Reviewer comments:

Reviewer #1: Innovation in low-cost video laryngoscopy: Intubator V1-Indirect compared with Storz C-MAC in a simulated difficult airway

Overall a well conducted manikin study of comparing intubator 1 with C-MAC.
1. Introduction can be further improved. Second paragraph in the introduction is not necessary and can be removed.
2. The background on benefits of video laryngoscopy can be more concise. One paragraph with key references for VLs improve the success rate, shorter intubation time…etc should be fine.
3. I suggest that the paragraph describing the Intubator V1-direct from methods section to be moved to the introduction
4. I suggest to revise the introduction as below

First paragraph: the existing paragraph is fine, second paragraph: Concise benefits of VL, third paragraph:

Intubator V1, fourth Paragraph: The reason for choosing CMAC and aim of the study
Results:
1. Please provide the grade and clinical experience of the participants. Did all participants intubated the trachea in first attempt?
2. The second paragraph, the first sentence should be moved to Methods section. How you scored the laryngoscopy view should be under methods, provide reference to Fremantle score.
3. Table1. The 4th column second row, under difference 100 (should it be 0 or leave the cell blank). Also provide p value where applicable
4. Table 2. The title is incomplete Please provide more details to the title, not sure what those numbers in the table are. Also provide p value.
Discussion: Fifth paragraph, end of 4th line a typo, delete repeated word not

Reviewer #2: The current version of the manuscript is not suitable for publication and I urge the authors to basically change the entire manuscript, as there are major flaws:

Introduction:
The introduction needs to be re-written. Only some selective publications have been cited, although there are much more recent and larger trials in the field. Several strong statements, like "for both expert and inexperienced providers" are not supported by adequate references. Authors have at least mention, that there are also some controversial publications, especially dealing with experienced providers and do not indicate any superiority of videolaryngoscopy over direct laryngoscopy. Another example in the fifth paragraph "has been advised in nearly all airway guidelines". Please provide adequate references to support this statement.
References are used randomly. For example first sentence of the introduction. Although most readers might agree, the reference should not focus on pediatric intubations.
The introduction should inform readers about current knowledge, but should generally not focus on a few studies only. Instead of reporting too much details about a few studies, authors should provide a summary and indicate, why this study is needed to gain more knowledge/evidence.
Although the aim of this project is listed at the end of the introduction, neither the hypothesis nor the definitions of the outcomes are provided throughout the manuscript. This is quite unacceptable at this stage of the submission process.

Methods:
This section should be separated in at least 4 parts: Study setting/ study population, Study protocol, measurement, statistical methods. Please revise the current form.
Further comments:
Time when the study was performed is missing.
Study project was not a priori registered in clinicaltrials.gov.
I don't practice in Europe and I therefore have no idea about the Doerges blade. Please provide more information's about this blade.
Informations about the blade should be reported in the introduction, NOT in the methods.
Please provide further informations about the randomization. When? By whom?
Outcomes including exact definitions are still unclear. I assume that time to intubation was chosen as the primary outcome, which is regretful. Although time to intubation is commonly used in airway trials, the clinical relevance and importance is questionable. Most of clinicians would agree, that a difference of even 10 seconds might be highly statistical significant, but clinically absolutely unimportant. Safety, airway injuries, number of intubation attempts, intubation failure, and unrecognized esophageal intubations are much more important clinical outcomes.
Statistical analysis is basically missing at all.

Results:
It is still unclear to this reviewer, which outcomes have been defined a priori.
Authors should not provide any discussion like "it is thus…" in this section □ please move this to the discussion section.
Laryngoscopic view is definitely not fair. Anesthesia providers were asked to intubate as soon as possible, but were not asked to provide the best visualization possible. Therefore, providers might not have been focusing on obtaining better visualization, although it would have been possible by maybe even minor improvements.

Discussion:
This needs to be rewritten. Please focus on the current study and discuss the new findings in the context of currently known evidence. Authors do not have to defend this study, or why it is so important to do this study (□ this should be clear after the introduction).

Figure 1. I would suggest to add another picture of the device from the side to indicate the exact curvature of the blade. Maybe also add the comparison blade, so that reader have an idea, if these blades are comparable.
Figure 2. Although technically correct, this figure does not add anything. I would suggest to delete.
Table 1. was performed in a sloppy style. There are several empty rows at the bottom.
Table 2. Why did the authors choose to report the fremantle score? POGO or even modified C+L would be alternatives

I am just wondering, but is this device protected by any patent?

TACC-D-21-00083 – Authors' response to reviewers

Thank you for your review, and the comments below. We have responded in **red/bold** to each comment, and highlighted the changes in the accompanying revised manuscript.

Reviewer #1: Innovation in low-cost video laryngoscopy: Intubator V1-Indirect compared with Storz C-MAC in a simulated difficult airway

Overall a well conducted manikin study of comparing intubator 1 with C-MAC.

>> Thank you.

1. Introduction can be further improved. Second paragraph in the introduction is not necessary and can be removed.

>> Introduction amended as per suggestion.
>> 2nd paragraph removed.

2. The background on benefits of video laryngoscopy can be more concise. One paragraph with key references for VLs improve the success rate, shorter intubation time...etc should be fine.

>>Background section revised.

3. I suggest that the paragraph describing the Intubator V1-direct from methods section to be moved to the introduction

>>Moved to introduction section as suggested

4. I suggest to revise the introduction as below
First paragraph: the existing paragraph is fine,
second paragraph: Concise benefits of VL,
third paragraph: Intubator V1,
fourth Paragraph: The reason for choosing CMAC and aim of the study

>> 1st paragraph unchanged as suggested
>> 2nd paragraph as suggested
>> 3rd paragraph... Intubator V1 moved from Methods to introduction as suggested
>> 4th paragraph..Aim of study

Results:
1. Please provide the grade and clinical experience of the participants.

>> Participants clinical experience updated

Did all participants intubated the trachea in first attempt?

>> Yes, this has been added.

2. The second paragraph, the first sentence should be moved to Methods section. How you scored the laryngoscopy view should be under methods, provide reference to Fremantle score.

>> Thank you; this has been amended and added.

3. Table1. The 4th column second row, under difference 100 (should it be 0 or leave the cell blank). Also provide p value where applicable

>> Thank you – the table has been altered to indicate where the "difference" is not applicable, and a p-value for the mean difference in intubation time has been added to the comments.

4. Table 2. The title is incomplete
Please provide more details to the title,

>> Amended

not sure what those numbers in the table are.

>> Amended labels to improve clarity

Also provide p value.

>> We have not performed any statistical analysis on this data, as the study was not powered for this outcome, and it is obvious to the reader that the numbers are nearly identical.

Discussion: Fifth paragraph, end of 4th line a typo, delete repeated word not

>> Amended

Reviewer #2: The current version of the manuscript is not suitable for publication and I urge the authors to basically change the entire manuscript, as there are major flaws:

Introduction:
The introduction needs to be re-written.
Only some selective publications have been cited, although there are much more recent and larger trials in the field.

>> We appreciate the reviewer's candour. We have taken pains to re-write the introduction and move sections in line with the other reviewer's comments, as well as reviewing and changing the referencing to be more specific.

Several strong statements, like "for both expert and inexperienced providers" are not supported by adequate references.

>> We have provided 4 references in support of this statement.

Authors have at least mention, that there are also some controversial publications, especially dealing with experienced providers and do not indicate any superiority of videolaryngoscopy over direct laryngoscopy.

>> We have added a comment at the start of the third paragraph to indicate this.

Another example in the fifth paragraph "has been advised in nearly all airway guidelines". Please provide adequate references to support this statement.

>> X2 Reference added

References are used randomly. For example first sentence of the introduction.
Although most readers might agree, the reference should not focus on pediatric intubations.

>> Reference changed

The introduction should inform readers about current knowledge, but should generally not focus on a few studies only. Instead of reporting too much details about a few studies, authors should provide a summary and indicate, why this study is needed to gain more knowledge/evidence.

>> Introduction more concise and summarised

Although the aim of this project is listed at the end of the introduction,
neither the hypothesis

>> null hypothesis added

nor the definitions of the outcomes are provided throughout the manuscript.
This is quite unacceptable at this stage of the submission process.

>> The primary outcome is stated at the end of the introduction. We have added the secondary outcome to this paragraph. The specifics of measuring these outcomes are listed in the Methods section.

Methods:
This section should be separated in at least 4 parts:

Study setting/ study population,
Study protocol,
measurement,
statistical methods.
Please revise the current form.

>> Thank you – this is not specified in the instructions to authors, but we have revised as per the reviewer's suggestion

Further comments:
Time when the study was performed is missing.

>> Thank you, this has been added

Study project was not a priori registered in clinicaltrials.gov.

>> This study was not a clinical trial; the intervention was performed solely on manikins.

I don't practice in Europe and I therefore have no idea about the Doerges blade. Please provide more information's about this blade.

>> It is unfortunate that the reviewer is unfamiliar with the CMAC system and Dörges blade, as these are used widely around the world. It is worth noting that the authors, too, do not practice in Europe. We have included further information for the reader.

Informations about the blade should be reported in the introduction, NOT in the methods.

>> This has been changed

Please provide further informations about the randomization. When? By whom?

>> This has been added

Outcomes including exact definitions are still unclear. I assume that time to intubation was chosen as the primary outcome, which is regretful. Although time to intubation is commonly used in airway trials, the clinical relevance and importance is questionable. Most of clinicians would agree, that a difference of even 10 seconds might be highly statistical significant, but clinically absolutely unimportant. Safety, airway injuries, number of intubation attempts, intubation failure, and unrecognized esophageal intubations are much more important clinical outcomes.

>> We note the reviewer's comments. In terms of outcome definitions, we refer the reviewer to the methods section where we describe the frame-by-frame review of the video recordings to obtain precise intubation times. As the reviewer indicates, time to intubation is widely used in intubation studies, as it is a continuous variable and useful for statistical analysis. As all participants successfully intubated the trachea on the first

attempt, neither intubation success rate nor number of attempts is a useful or comparable outcome. There were no oesophageal intubations with either blades. Assessing "safety" and airway injuries is beyond the scope of this study, and not readily achievable in a manikin model.

Statistical analysis is basically missing at all.

>> We are unsure what details the reviewer is missing. The sample size calculation and methods are described in the methods section, as are the statistical methods for assessing interrater agreement and mean difference in intubation time (two one-sided test).

Results:
It is still unclear to this reviewer, which outcomes have been defined a priori.
Authors should not provide any discussion like "it is thus..." in this section ◊ please move this to the discussion section.

>> As stated in the statistical methods and results, the 10 second limit was defined *a* priori. We have taken note of the discussive nature of the statement referred to, moved it to the discussion and amended the text.

Laryngoscopic view is definitely not fair. Anesthesia providers were asked to intubate as soon as possible, but were not asked to provide the best visualization possible. Therefore, providers might not have been focusing on obtaining better visualization, although it would have been possible by maybe even minor improvements.

>> This is a valid comment. Laryngoscopic view was included as an data point to but is not the primary outcome. We have thus included the result for the interest of the reader. We does not necessarily translate to outcome as you correctly point out; we have added a sentence in the discussion reflecting on thi

Discussion:
This needs to be rewritten. Please focus on the current study and discuss the new findings in the context of currently known evidence. Authors do not have to defend this study, or why it is so important to do this study (◊ this should be clear after the introduction).

>>Much of the information provided in the discussion regarding the limitations has been inserted at the request of a prior reviewer, and serves to provide context.

Figure 1. I would suggest to add another picture of the device from the side to indicate the exact curvature of the blade.

>>Side on photo added

Maybe also add the comparison blade, so that reader have an idea, if these blades are comparable.
>> photo added

Figure 2. Although technically correct, this figure does not add anything. I would suggest to delete.

>>Figure 2 (now 3) is a graphical representation of the primary outcome, and is useful for showing both the fact that the devices were equivalent within our ***a priori*** limits, but also that the CMAC was faster. We feel that it therefore has value.

Table 1. was performed in a sloppy style. There are several empty rows at the bottom.

>> amended

Table 2. Why did the authors choose to report the fremantle score? POGO or even modified C+L would be alternatives

>> Numerous studies in the field have examined the use of different scoring systems for VL view grading. There is consensus that the (modified) Cormack-Lehane grading was neither designed for, nor is fit for this purpose. It is illustrative that all views obtained in this study would be C-L Grade 1. The POGO score is used in some research, but the Freemantle grading has been shown to have a better combination of accuracy and interrater reliability than the POGO (and C-L grade) – we refer the reviewer to the work of O'Loughlin et al in ***Anaesthesia*** (https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/full/10.1111/anae.13837)

I am just wondering, but is this device protected by any patent?

>> Yes, the device is patented.

Appendix 3: Abstract Publication TACC

Article

Innovation in low-cost videolaryngoscopy: Intubator V1-Indirect compared with Storz C-MAC in a simulated difficult airway

February 2020 · Trends in Anaesthesia and Critical Care 30:e127
DOI:10.1016/j.tacc.2019.12.312
Project: Context-sensitive airway management in resource-constrained settings

Authors:

Ross Hofmeyr
University of Cape Town

Christella Alphonsus

Christiaan de Villiers
University of Cape Town

Dylan Eave
University of Cape Town

Abstract

Videolaryngoscopy (VL) has revolutionised airway management with numerous studies demonstrating its utility to improve airway management and as an emergency device in unanticipated difficult intubation. Availability of VL in all clinical areas has been curtailed by its relative high cost, especially in resource-constrained practice environments such as most of Africa, where research has shown, perioperative outcomes are significantly worse. Advancements in mobile technology, cameras and 3D printing, enabled the design of an innovative low-cost VL, with the vision of making it available to all practitioners. A novel hyper-angulated blade was designed and prototyped using 3D printing. Equipped with a disposable, low-cost, endoscopic camera, it transmits video via a reusable wireless module to a free application on the practitioner's mobile device. The device presents a significant cost reduction to produce, and affordability will enable all practitioners to own a device. In accordance with ADEPT guidelines, a randomised, controlled, crossover equivalence study compared the novel device to an established industry standard (Storz CMAC with D€orges blade). A sample size of 97 participants was calculated using PASS software, to power the study to 90% with an alpha error of 2.5% using a clinically determined equivalence limit of 10 seconds mean difference in intubation time. After approval by the UCT Human Research Ethics Committee, 100 skilled intubators, with previous VL experience, received instruction and adequate practice on the new device. They then intubated a Laerdal airway mannikin immobilised to simulate a difficult airway in a randomised order. Video recordings of each device were analysed frame-by-frame to determine time to intubation, measured as the time when the device entered the oral cavity to the time when the ETT black marker moved past the vocal cords. Using the two one-sided test (TOST) method, the mean difference was 4.91 seconds and the 95% confidence limits for the mean difference was between 2.34 e 7.49 seconds, meeting our a priori limits for equivalence, although the C-MAC was faster on average. The innovative low-cost VL was thus equivalent to the industry standard in a simulated difficult airway. Further testing in vivo in a clinical environment is warranted.

Appendix 4: Human Research Ethics Committee approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.arlefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

23 November 2018

HREC REF: 770/2018

A/Prof R Hofmeyr
Department of Anaesthesia & Perioperative Medicine
D-23
NGSH

Dear A/Prof Hofmeyr

PROJECT TITLE: LOW COST VIDEO LARYNGOSCOPE, THE INTUBATOR V-1-INDIRECT, COMPARED WITH STORZ-C-MAC WITH D-BLADE IN A SIMULATED DIFFICULT AIRWAY (Masters candidate-Dr C de Villiers)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 November 2019.

- The study will require the director of Student affairs approval.
- Please add to the I/C document how confidentiality will be protected.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Dr Christiaan de Villiers will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN

Appendix 5: Mannikin study Consent form

CONSENT FORM

TITLE OF THE RESEARCH PROJECT:
Low cost video laryngoscope, the Intubator V1-Indirect, compared with Storz C-MAC with D-Blade in a simulated difficult airway.

PRINCIPAL INVESTIGATOR: Prof R Hofmeyr

CO-INVESTIGATORS: Dr CT de Villiers, Dr C Alphonsus, Dr D Eave

CONTACT DETAILS: Dr CT de Villiers (0825564397, christiaandevilliers@gmail.com)
Dr D Eave (0837765030, doceave@gmail.com)

Dear Practitioner

We are excited to invite you to participate in a research project. Your participation in this research is voluntary and you remain free to withdraw from the research at any point even after you have agreed to take part.
Please take some time to read the information provided below which describes the nature of this research project.You are encouraged to contact the investigators should you have further questions pertaining to this research project.

Your experience, time and cooperation are greatly valued.

This study has been approved by the Health Research Ethics Committee at University of Cape Town, HREC Ref 770/2018 and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is being researched?
We are using a high fidelity airway manikin configured with a cervical collar to simulate difficult intubation, to compare the performance of a low cost, hyperangulated, disposable videolaryngoscope device- *Indirect V1 by DisaTech* with that of the *C-MAC D blade by Storz Medical.*

Why have you been invited to participate?
You are a healthcare professional who has experience with direct laryngoscopy in difficult airways. You are also a healthcare professional who may benefit from the availability of another device in your armamentarium for the management of such airways.

How will this research project be conducted?
This research project requires you to practice using both devices, attempt intubation with each device in a predetermined order. Video recorded during the use of the video laryngoscope as well as time taken for intubation attempts with both devices will be captured against your participant number (not your name). Your participation will remain confidential and all data collected will not be traceable back to you. It is estimated that this will take 15 minutes of your time. You will not be remunerated for your involvement in this study.

What is your responsibility if you choose to participate in this research project?
For the duration of the study you will be responsible only for completing all the steps described above to the best of your ability.

Should you have an ethical concern which has not been adequately addressed by the researchers please contact UCT Health Research Ethics Committee at 0214066492. HREC REF 770/2018

Please answer the following questions:
Have you ever used a videolaryngoscope before? Yes _____ No _____

Have you performed more than 200 intubations? Yes _____ No _____

I,_____ , the undersigned, hereby consent to take part in the study as described above, and will do so to the best of my ability.

Date: _____ **Venue:** _____ **Signature:** _____

_____

PARTICIPANT DATA CAPTURE FORM

Date of Testing: _____

Participant No:	
Which device is tested first?	
Device tested now?	
First or second device:	
Successful:	
Time of Video Capture/ Testing:	

Participant No:	
Which device is tested first?	
Device tested now?	
First or second device:	
Successful:	
Time of Video Capture/ Testing:	

Appendix 7: Guide to authors TACC

TRENDS IN ANAESTHESIA AND CRITICAL CARE

AUTHOR INFORMATION PACK

TABLE OF CONTENTS

ISSN: 2210-8440

DESCRIPTION

Trends in Anaesthesia and Critical Care provides reviews and comment on highly topical subjects and the latest breakthroughs in basic, clinical and translational research.

Trends in Anaesthesia and Critical Care is an international peer reviewed journal, which provides reviews, opinion articles, lessons from clinical practice, and letters to the editor on highly topical subjects and the latest breakthroughs in basic, clinical and translational research in anaesthesiology and critical care medicine. TACC welcomes also original research articles in airway management.

The journal's objective is to provide a platform for discussion, analysis and debate of topics across a diverse, multidisciplinary audience of basic scientists and clinicians, who share the common goal of understanding clinical practice of **anaesthesiology, critical care**, aspects of related **emergency medicine and resuscitation**, as well as **airway management** with a view to new clinical practice. Communicating emerging concepts and ideas will be facilitated with opinion articles or letters to the editor and help to progress the exciting and evolving field of anaesthesia and critical care.If you are interested in suggesting an article for consideration, please consult the guide for authors of TACC. Authors should note that all articles are subject to peer review.

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GUIDE FOR AUTHORS

Submission checklist

You can use this list to carry out a final check of your submission before you send it to the journal for review. Please check the relevant section in this Guide for Authors for more details.

Ensure that the following items are present:

One author has been designated as the corresponding author with contact details:
- E-mail address
- Full postal address

All necessary files have been uploaded:
Manuscript:
- Include keywords
- All figures (include relevant captions)
- All tables (including titles, description, footnotes)
- Ensure all figure and table citations in the text match the files provided
- Indicate clearly if color should be used for any figures in print

Graphical Abstracts / Highlights files (where applicable)
Supplemental files (where applicable)

Further considerations
- Manuscript has been 'spell checked' and 'grammar checked'
- All references mentioned in the Reference List are cited in the text, and vice versa
- Permission has been obtained for use of copyrighted material from other sources (including the Internet)
- A competing interests statement is provided, even if the authors have no competing interests to declare
- Journal policies detailed in this guide have been reviewed
- Referee suggestions and contact details provided, based on journal requirements

For further information, visit our Support Center.

Article Types

Lessons from Clinical Practice. These are an opportunity to publish an interesting case or case series which you have encountered. They should not be regarded as the traditional 'case report' because they are more detailed than that. Authors are asked to submit an interesting case or clinical lesson for consideration. Each will be considered individually and only those with a real interesting clinical lesson will be regarded as possibly suitable for publication. If it is accepted then it will be sent on to an expert who will write an accompanying piece providing a critique or further information concerning the situation. It should not be used as an opportunity to try to get random case reports published, to promote original work, or to introduce new data.

Lessons should be interesting and novel. They should aim to tell the reader about an interesting case or situation from which real lessons can be learnt. Very rare cases would only be suitable for consideration if they illustrated an important lesson. The format should be to start with a brief introduction (contextual background) followed by an account of what happened or was observed. A discussion section should then be included. The lesson should be referenced accordingly.

Remember that you are writing for a wide audience - not only for readers in your own field. You can assume that your audience is competent in the basic language of the subject, but may require explanation or definition of technical terms, concepts and assumptions specific to your topic.

Length: 500-800 words, 12 references, 1 figure/box/table.
Authors names: No more than 3 authors. Full contact details for all authors (indicate corresponding author).
Abstract: Briefly explain the necessary background and encapsulate the take-home message for a non-specialist readership. 100 to 120 words.

Figures (optional): Should always have a short, explanatory title (as well as legend). Legends must fully explain the figure without reference to the text
Tables (optional): Require a single-sentence title but no legend. Abbreviations (if not defined in the main text) and full explanations should be footnoted (using letters).
Text Boxes (optional): Ideal for providing explanations of basic concepts or theories, giving detailed mechanisms or discussing case studies. Text Boxes can occasionally contain small figures and tables. 200 words max per Box (references to be listed in main reference list only).
The commentary will be written by an expert in the field and will have the same limits as those given above, i.e. maximum of 500-800 words, one figure or table and 12 references.

Letters to the Editor are reserved for genuine synthesis only.
Letters should have a journalistic flavour: aim to tell a story and communicate your enthusiasm for the subject. Start with some very brief contextual background, and be sure to alert the reader to the main message of your letter before the end of the first paragraph.
You are writing for a wide audience, not only for readers in your own field. You can assume that your audience is competent in the basic language of the subject, but may require explanation or definition of technical terms, concepts and assumptions specific to your topic. Avoid jargon, but do not oversimplify, be accurate and precise throughout. Use sections and subheadings to lead your reader through the discussion.
Length: 750-800 words, 12 references, 1 figure/box/table.
Authors names: No more than 3 authors. Include full contact details for all authors (indicate corresponding author).
Figures (optional): Should always have a short, explanatory title (as well as legend). Legends must fully explain the figure without reference to the text.
Tables (optional): Require a single-sentence title but no legend. Abbreviations (if not defined in the main text) and full explanations should be footnoted (using letters).
Text Boxes (optional): Ideal for providing explanations of basic concepts or theories, giving detailed mechanisms or discussing case studies. Text Boxes can occasionally contain small figures and tables. 200 words max per Box. References to be listed in main reference list only.

TACC Opinions should present a personal viewpoint on a research-related topic, rather than a review of this topic. The aim should be to stimulate debate or new research, cover controversial topics, or provide a new framework for, or interpretation of, an old problem or current issue, or speculate on the implications of recent research and clinical advances in health care infrastructure concerns at national or international level.
Articles that outline recent advances in a field rather than give a strong opinion on them are not suitable for this section of the journal. Our audience ranges from student to professor, and so articles must be accessible to a wide readership.
TACC Opinions must not include unpublished original data. Although subjective, an opinion article should not be used to dwell excessively on the author's own research or excessively criticise others', except where criticism is constructive.

Title: Should be short and enticing (no more than eight words).
Authors: No more than 3 authors. Full contact details for all authors (indicate corresponding author).
Abstract: Briefly explain the necessary background and encapsulate the take-home message for a non-specialist readership. Please emphasize the opinion you are putting forward. 100 to 120 words. Do not include reference citations.
Opinion structure: Please start with an accessible introduction outlining the timeliness, importance and rationale behind your article (why the subject is important, why now). Restate your opinion clearly. Use concise logical subheadings and provide clear links between sections. Finish with clearly stated conclusions, including an indication of future directions.
Length: 2500-3500 words: This limit does not include text in boxes, abstract, references, tables or figure legends. Figures: Should always have a short, explanatory title to preface the legend. Legends must fully explain the figure without reference to the text.
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Tables: Require a single-sentence title but no legend. Abbreviations (if not defined in the main text) and full explanations should be footnoted (using letters).

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