Research Square

Preprints are preliminary reports that have not undergone peer review. They should not be considered conclusive, used to inform clinical practice, or referenced by the media as validated information.

A Comparison of Macintosh and Video Laryngoscopy Performed With a Prototype Rigid Anterior Commissure Laryngoscope by Experienced and Novice Users in a Manikin Model

Price Sonkarley
University of Oklahoma Health Sciences Center

Nilesh R. Vasan (Nilesh-Vasan@ouhsc.edu)
800 Stanton L Young Blvd COMB Suite 1400 Oklahoma City, Oklahoma 73104 https://orcid.org/0000-0002-9458-5286

Edward Kosik
University of Oklahoma Health Sciences Center

Michael Anderson
University of Oklahoma Health Sciences Center

Marvin Williams
University of Oklahoma Health Sciences Center

Alexis Patsias
University of Oklahoma Health Sciences Center

Michael Clampitt
University of Oklahoma College of Medicine https://orcid.org/0000-0002-6734-9050

Rachel Hardy
University of Oklahoma

Research article

Keywords: Intubation, Endotracheal, Education, Airway Management, Simulation Training

Posted Date: July 30th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-41782/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

A comparison of Macintosh and video laryngoscopy performed with a prototype rigid anterior commissure laryngoscope by experienced and novice users in a manikin model

Authors:

Price Sonkarley, MD[a]; Edward Kosik[b],DO, Alexis Patsias MD[a]; Michael Clampitt MD[a]; Michael Anderson PhD[c]; Rachel Hardy MS[d];Marvin Williams DO[e]; Nilesh R. Vasan MD[a]

a. University of Oklahoma Health Science Center, College of Medicine Department of Otolaryngology,800 Stanton L Young Blvd, Suite 1400, Oklahoma City, OK 73104
b. University of Oklahoma Health Science Center, College of Medicine, Department of Anesthesiology, 920 SL Young Blvd #1140, Oklahoma City, OK 73104
c. University of Oklahoma Health Science Center, Hudson College of Public Health, Department of Biostatistics and Epidemiology,801 N.E. 13th Street, Oklahoma City, OK 73104
d. Oklahoma State College of Osteopathic Medicine, 1111 W 17th St, Tulsa, OK 74107
e. University of Oklahoma Health Science Center, Department of Obstetrics and Gynecology, 800 Stanton L. Young Blvd, Suite 2400. Oklahoma City, OK 73104

Corresponding Author:

Nilesh R. Vasan, MD

800 Stanton L Young Blvd

COMB Suite 1400

Oklahoma City, Oklahoma 73104

405.271.5504

Nilesh-Vasan@ouhsc.edu

Abstract

Background. Intubation is a life-saving skill that can be difficult to learn and perform.

Objective. The intubation time and user preference of four intubation techniques, performed by novices or experienced individuals, were compared.

Methods. Enrolled participants were randomly assigned to one of four simulated intubation groups. Each groupfirstperformed intubation on the manikin airway without modifications ('easy' airway), followed by the same technique on a manikin with modifications to mimic a 'difficult' airway. The primary outcome measure was the time taken to inflate the manikin's lungs with the bag ventilator, with successful intubation.

Results. Ninety-eight participants were recruited and grouped according to experience: 59 novices (10 or fewer live intubations) and 39 experts (more than 10 live intubations). The total time to intubation increased significantly from the easy airway to the difficult airway for both expertise levels, and for all intubation techniques except the novel laryngoscope.

Conclusion. Repeated exposure to multiple intubation devices can result in an adequate learning curve for the novice participant. The novel laryngoscope is an uncomplicated intubation tool; in this study, itprovided novice users who intubate infrequently with a better chance of successful intubation in manikins.

Declarations:

Ethics approval and consent to participate:

Not Applicable

Consent for publication:

Not Applicable

Availability of data and materials:

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Disclosure of funding:

Vasan:None

Sonkarley: None

Kosik: None

Anderson: None

Patsias:None

Hardy: None

Clampitt: None

Williams: None

Conflict of Interest:

Vasan:Dr Vasan is the founder of Adroit Surgical LLC and provided the prototype intubating laryngoscopes for this study.

Sonkarley: None

Kosik: None

Anderson: None

Patsias:None

Hardy: None

Clampitt: None

Williams: None

Individual roles:

Vasan: Originated the concept and design of study trial. Manuscript and data preparation and review

Sonkarley: Conducted trials for data collection; Manuscript and data preparation and review

Kosik: Originated the concept, Design of study trial, Manuscript preparation and review

Anderson: Statistical analysis of data

Patsias: Conducted trials for data collection; Manuscript and data preparation and review

Hardy: Originated the concept, Design of study trial

Clampitt: Conducted trials for data collection; Manuscript and data preparation and review

Williams: Conducted trials for data collection; Manuscript and data preparation and review

Acknowledgements: Not applicable

Key words: Intubation, Endotracheal; Education; Airway Management; Simulation Training

Introduction

Intubation is a life-saving skill that can be difficult to learn[1,2] and retain.[3,4] Intubation protects the airway, prevents hypoxia and death, and is a vital procedure in the operating theatre, as well as in emergencies where a patient's airway may be compromised. Conventionalmethods of intubation include using Macintosh, Miller or video-assisted laryngoscopes, which can all be used with or without the assistance of a bougie. These tools have documented limitations;in particular, the Macintosh and Miller blades are usually substituted for video-assisted intubation systems during intubation of a difficult airway. Similarly, video-assisted intubation systems, which were developed to address the difficultairway,[5–7] can be less effective than direct laryngoscopy in uncomplicated cases.[6,8–12]

A protected,definitive airway can be required outside the controlled settingof an operating theatre. Prime examples include the hospital floor (ward),emergency department, intensive care unit,recovery room, first responder situations(emergency medical services) or ina combat theatre(combat medic). In theseenvironments, the luxury of a well-lit operating theatre, power sources or fibre-optic cables for intubating equipment are not readily available, if they exist at all. For example, the majority of emergency first responders are forced to rely on the various sizes of Macintosh and Miller blades, the insertion of supraglottic devices, or alternatively resort to a cricothyroidotomy if they are unsuccessful with intubation, which has a high rate of complications.[13]

This study utilised atechnological enhancement of the rigid anterior commissure laryngoscope.Thisnovel laryngoscope wasdevelopedto be a more favourable alternative for the 'non-ideal setting',where fibre-optic or video laryngoscopes are not available, and for patients witha difficult or traumatic airway. The standard metal anterior commissure laryngoscope used in the operating theatre requires a light box, a fibre-optic cable and a Hopkins light carrier that attaches to the laryngoscope. The novel laryngoscope design is based on the metal anterior commissure laryngoscope commonly used by ENT surgeons, but also has a translucent tube and unique light delivery system that radiates light within, through and out of the distal end of the tube, making it more resistant to visual obstruction from airway secretions and blood. The novel laryngoscope is a battery powered, self-contained, lightweight laryngoscope, with a built-inlight-emitting diode light source arranged in a ring at the

proximal end of an enclosed clear circular tube (Figure 1). The barrel is a clear enclosed tube measuring 14cm in length from the front of the handle to the tip of the tube. The barrel was made using rapid prototyping with polycarbonate plastic. The handle, which contains the light-emitting diodes and battery, was developed with three-dimensional printing technology. An on-off switch was placed within the handle.

The novel laryngoscope method utilises a Seldinger technique,which requires the use of a bougie. The bougie is passed through the lumen of the scope past the vocalfolds, the scope is removed with the bougie in place, and then a endotracheal tube is passed over the bougie into the trachea before the bougie is removed.[14]The unique anterior commissure design,with its angled flared open end,gives the user a view of the vocal folds with a direct

132

133 straightline of sight,which allows guidance of the bougie past the glottis and into the tracheaunder direct
134 visualisation (Figure 1). The design and technique may decrease instances of accidental intubation of the
135 oesophagus, failure to visualise the glottis, and loss of adequate lighting because of secretions and blood.
136
137 ENT surgeons have practised this method of rescue intubation for decades, but because of the capital equipment
138 required, it has not been used by other specialistsor outside of the hospital setting. This process has been
139 advocated in ENT and anaesthesia literature as a rescue technique when patients are unable to be intubated using
140 routine methods.[15–17]We hypothesised that the novel laryngoscope intubation technique would
141 bestraightforwardto learn, and would involvea more natural transitioning processwhen a clinical situation
142 changes from an easy to a difficult airwaywith no change in technique or equipment.
143
144 **Methods**
145 The University of Oklahoma Institutional Review Board approved this study with the requirement of written
146 consent for participants in the trial. Participants were recruited using flyers posted within the hospital and
147 medical school. This project included individualswith varying experience at performed intubations, ranging from
148 no experience atintubating to performing intubationsdaily. The study data were stratifiedaccording to
149 participants'expertise:those who had performed more than 10 intubations were classed as experienced, and those
150 who had performed 10 or fewer intubations were considered to have little or no experience.This prospective
151 study was conducted between August 2015 and May 2017.
152
153 ***Protocol***
154 Study participants wereprovidedwith individual, standardised instructions for each intubation device using a
155 video demonstrating the correct technique. Each study participant was then allowed time to familiarise
156 themselves with each technique utilisingan airwaymanikin.Atno point were the participants providedwith formal,
157 hands-on, instructor-guided intubation training for any of the intubation techniques outside of any previous
158 training.
159

The study used a balanced crossover design wherein data were stratified according to participant expertise (expert and novice), and was designed to ensure a balance of participants assigned to each intubation sequence. Study participantswere allowed three attempts with each of the four intubation techniques, beginning with the manikin with a normal (easy) airway and then moving on to the difficult airway. Every participant had a total of 24 intubation scenarios. The trial was randomised by giving each participant a random number that correlated with a unique order in which each technique would be tested on the studymanikins.

The trial involved the use of: a conventional laryngoscope with a Macintosh 3 blade, with or without a bougie; a GlideScope Advanced Video Laryngoscope (Verathon, Bothell, Washington, USA); and the novel laryngoscope. A size 7.0 endotracheal tubewas used for all four techniques and both easy and difficult airway scenarios. AirSim Advance manikins(TruCorp, Belfast, Ireland) were used for the simulation airway. The 'easy' airway scenario used a basic AirSim Advance manikin with the tongue deflated and neck unfixed for increased extension. The 'difficult' airway scenario had the tongue fully inflated, packing inserted underneath the floor of the mouth and the neck fixed with a hardcervical collar (Figure 2).Tape was also placed around the manikin head and jaw to allowonly 2.5cm of mouth opening. A standard bag ventilator was used to confirm tracheal intubation with inflation of the manikin's lungs.

Measurements

Demographic data were recorded, including participants' occupation, level of education, handedness, gender and estimated number of previous clinical intubations performed with each device. None of the participants had ever used the novel laryngoscope before this study.The primary outcome measure was the time taken to inflate the manikin'slungs with the bag ventilator. Timing began when the laryngoscope, endotracheal tube or any adjunct were first handled by the participant, and ended when the participant inflated the manikin's lungs with the bag ventilator. Unsuccessful intubations includedaccidental oesophageal intubations, failed intubations taking more than 90 seconds, or intubation attempts aborted by the participantfor any reason.

The ease of which a glottic view could be obtained was measured by recording the time participants required to declare they had a 'good view' of the vocal folds and were ready to place the endotracheal tube or bougie. This meant the participants could see the glottic opening; however, no assessment was made regarding the degree of glottic opening such as by using the Cormack–Lehane classification.

Participants were asked to rank each intubation method (1 to 4 for all techniques,with 1 reflecting the most preferred method)in terms of the quality of the light source, view of the glottis, perceived intubation difficulty and overall preferred method of intubation, for both the easy and difficult airway scenarios.

Statistical analysis

A randomised, balanced, crossover design was used. In order to reduce learning curve bias, participants were randomised to one of the 24 possible tool sequences. Linear mixed regression models for repeated measures were used to estimate the laryngoscope's effect on timing outcomes, while controlling for other covariates. Mean rankings of the users' preferences were computed and compared via chi-square tests for each intubation tool overall, and for each tool by gender, handedness and experience level.

A power analysis was not performed for this study given that this is the first investigation to include the novel laryngoscope. However, 98 individuals participated in the study, which allowed at least 2 replications of all 24 treatment sequences within each of the expertise groups.

Primary hypothesis

We evaluated the ease of learning the novel laryngoscope technique versus the reference intubation techniques for each airway. The three reference intubation techniques were the Macintosh laryngoscope, with and without a bougie; and the GlideScope Advanced Video Laryngoscope. Each method was evaluated on a manikin ineasy and difficult airwayscenarios. The change in the total time taken to intubate between the attempts for each technique determined the ease of learning for each laryngoscope method. The primary research hypothesis that the novel laryngoscope method is easier to learn was tested by measuring the intubation time between attempts.

In orderto support the hypothesis, the duration of each intubation attemptusing the novel laryngoscope needed to decrease at a significantly faster rate than that of the reference intubation techniques.

Subjective data on each intubation method were also obtained; this information was used to test secondary research hypotheses regarding the preferred technique and the perceived difficulty of each method.

Results

Ninety-eight participants were recruited and grouped according to their intubation experience: 59 (60.2%) were novices(10 or fewer live intubations) and 39 (39.78%) were experienced (more than 10 live intubations). Table 1 demonstrates the demographic data of the participants. The vast majority were right-handed (50% medical students and 34.7% residents in training). The 'other' category included a physician assistant and non-medical staff such as administrative personnel. Four participants were excluded, as their data were either not recorded or were recorded incorrectly.

An analysis between user experience level and manikin airway difficulty was performed to determine if the intubation technique had any bearing on the ability to first visualise the vocalfolds,foreither the easy or difficult scenarios. The time taken to visualise the vocalfolds for each technique was obtained from the repeated measures regression model, averagedover the three attempts and the two experience levels. Similarly, theintubation time for each experience level was obtained by averaging over the three attempts and the four techniques.These model adjusted means areshownin Table 2. This table demonstrates that the time needed for vocalfold visualisation increased significantly from the easy airway to the difficult airway scenario for all levels and techniques ($p<0.0001$). Interestingly, experience level did not have a significant impact on the time taken to see the vocalfolds for either airwaydifficulty scenario,implying that any user could identify the vocalfolds in either scenario.

The time needed for vocalfold visualisation in the easy airwayscenario was different for all intubation techniques. However,inthe difficult airwayscenario, only the GlideScope was significantly faster than all the

other techniques.The GlideScope was significantly faster for all three attempts;in contrast, there was no difference in time between the other methods on the third attempt.

An analysis between user experience and manikin airway difficulty was performed to determine if the intubation technique had any bearing on the ability to complete intubation in the easy or difficult scenarios. The model adjusted averages, as defined above, are recorded in Table 2. This table demonstrates that total time to intubation increased significantly from the easy airway to the difficult airway scenario, for all expert levels and techniques except the novel laryngoscope (novice –easy *vs*difficult $p<0.0001$;expert –easy *vs*difficult $p=0.0017$;Macintosh –easy *vs*difficult $p<0.0001$;Macintosh with bougie –easy *vs*difficult $p<0.0001$; GlideScope –easy *vs*difficult $p=0.0292$;novel laryngoscope –easy *vs*difficult $p=0.0704$).

Experience did not significantlyaffect the total time to intubation in the easy airway scenario, but did have a significant impact inthe difficult airway scenario (easy –novice *vs*expert $p=0.5511$;difficult –novice *vs*expert $p<0.0001$).

Table 2also reveals that all intubation techniqueswere associated withsignificantly different total times to intubation in the easy airway scenario (novel laryngoscope *vs* Macintosh with bougie $p = 0.0326$; Macintosh with bougie *vs* GlideScope $p = 0.0130$; GlideScope *vs* Macintosh $p = 0.0232$). However, in the difficult airway scenario, the Macintosh and GlideScope methods had similar times, and the Macintosh with bougie and novel laryngoscope methods had similar times (Macintosh *vs* GlideScope $p = 0.5659$; Macintosh with bougie*vs*novel laryngoscope $p = 0.0617$;novel laryngoscope*vs* Macintosh$p = 0.0003$).

Figure 3ashows the total modeladjusted average timesfor intubation using the fourdifferent methods over three attempts.Figure 3b showsthe total time needed for intubating the manikin in both the ‘easy’ and ‘difficult’ airway scenarios. The total time neededfor intubation in those techniques that required the use of a bougie (novel laryngoscope and Macintosh with bougie), which added extra time, varied with the difficulty of the manikin and the attempt number. The increase in intubation time from the easy to the difficult setting for the Macintosh with

bougiewas significantly greater ($p = 0.0035$) than that for the novel laryngoscope,controlling for experience and gender. Specifically, the Macintosh with bougie had a shorter mean intubation time in the easyscenario (28.4 seconds) versus that for the novel laryngoscope (32.1seconds). However, the novel laryngoscope had a fastermean intubation time in the difficult scenario (35.3seconds) compared to that for the Macintosh with bougie (38.5seconds). While not statistically significant ($p>0.05$), it was observed that inexperienced participants had faster mean times with the novel laryngoscope on their second and third attempts (32.7seconds and29.6seconds, respectively), compared to the Macintosh with bougie(35.8seconds and 32.4seconds, respectively).

Study participants who accidentallyintubated the oesophagus, aborted attempts or took longer than 90 seconds to intubate were recorded as a 'fail'. Table 3 demonstrates the instances of accidental oesophageal intubations and failed attempts for both the easy and difficult manikin scenarios,according to level of expertise. There were numerous oesophageal intubations when using the novel laryngoscope.Unfortunately, we did not record on which attempt these accidental intubations occurred with any of the laryngoscopes used. We did note that when participants were using the novel laryngoscope,oesophageal intubations mainly occurred on the initial attempt; nevertheless, all failures and oesophageal intubations were recorded together for all attempts,so we are unable to show any improvement with each use.The numbers in the table represent participants who had at least one oesophageal intubation and/or failed attempt for each of the methods used throughout the study, as participants had three opportunities to performeach technique.

Participants'preferences

Participants were asked to assess their preferences regarding the four different techniques. Each laryngoscope and its features were ranked 1 through 4 in various categories, with '1' being the most preferred and '4'being the least preferred. Preferences were recorded for the entire group for both easy and difficult scenarios, as well as by level of experience in both easy and difficult scenarios.

Table 4 shows the participants' preferences for the techniques, in both airwayscenarios. For both the easy and difficult scenarios, not all techniques were equally preferred ($p<0.0001$ and $p<0.0001$, respectively). Specifically, for the easy scenario, the mean rankings were the lowest (most preferable) for the Macintosh laryngoscope, followed by the GlideScope, novel laryngoscope, and then the Macintosh withbougie (rankings of 2.11, 2.31, 2.57 and 3.02, respectively). The novel laryngoscope was favoured by female participants (ranking of 2.65 for males and 2.42 for females; $p = 0.0386$) and by novice participants (ranking of 3.17 for experts and2.18 for novices; $p = 0.0069$). For the difficult scenario, the mean rankings were the lowest (most preferable) for the GlideScope, followed by the novel laryngoscope, Macintosh with bougie, and Macintoshlaryngoscope (rankings of 1.71, 2.14, 2.89 and 3.27, respectively). The novel laryngoscope was the most preferred method for novice users in both the easy and difficult airway scenarios (Tables5and6). Novice users reported a significantly lower mean ranking (most preferable) for the novel laryngoscope (ranking of 1.92) in thedifficult airway scenario than the expert users (ranking of 2.48; $p = 0.0165$)(Table 6). In the difficult scenario,the novel laryngoscope had a trend towardsa more preferable mean ranking than that of the Macintosh or Macintosh with bougie,across gender, handedness and experience level.The novel laryngoscope was also ranked second out of the four methods for novice users in terms of light source, ease of use andview of the glottis, and was the overall preferred method (Table 6). In the difficult airway scenario, experienced users preferred the GlideScope overall, followed by the novel laryngoscope. For experienced participantsin the easy scenario, the most preferred method was the Macintosh blade (ranking of 1.57); the novel scope was the least preferred (ranking of 3.17) (Table 5).

'Learning curve'comparison

A repeated measures analysis of the change in intubationtime over the participants' three attempts was conducted. It was anticipated that, generally, participants' time would improve (decrease) with each attempt.The two-way interaction of technique and attempt provided an overall test to see if participants improved at the same rate with each method. In the model, the two-way interaction in terms of technique and attempt was significant ($p = 0.0044$).Figure 3a shows the mean time to intubation for each technique. This plot shows improvement in intubation times for each method from the first to third attempts, with the most significant change occurringfor the novel laryngoscope (novel laryngoscope = 12.03 seconds *vs*GlideScope = 8.27 seconds; $p = 0.0273$). The

other techniques did not change significantly in terms of total time to intubation (GlideScope = 8.27 seconds, Macintosh with bougie = 7.73 seconds, and Macintosh = 5.37 seconds).

This analysis also demonstrated a significant two-way interaction between the attempt number and the scenario difficulty (easy or difficult; $p = 0.0395$). There was a significantdifference between the first and second intubation timesregarding difficulty of airway scenario,with no significant difference between the second and third intubation times. Specifically, the manikin with the difficult airway was associated with a substantiallyhigher change from attempt one to attempt twothan the easy airway manikin ($p = 0.0161$), indicating that participantsdisplayed a more significant'learning' effect on the first two attempts of the difficult airway manikin.

In contrast, the repeated measures analysis comparing the different intubation techniques and the scenario difficulty showed a significant two-way interaction ($p = 0.0031$). This indicatedthat the time taken to intubate the manikin with each techniquedid not increase at the same rate when going from the easy to the difficultscenario. The model adjusted mean increase in intubation time when switching from the easy to difficult airway was 10.5 seconds for the Macintosh withbougie, 8.88 seconds with the Macintosh laryngoscope, 5.64 seconds with the GlideScope and 2.55 seconds with the novel laryngoscope.The increase in intubation time for the novel laryngoscope was significantly smaller than that for the Macintosh blade alone ($p = 0.0065$) and the Macintosh with bougie ($p = 0.0006$). The novel laryngoscope showeda modest increase in intubation time compared with the GlideScope, but this was not statistically significant.

Discussion

Intubation is a challenging skill to learn.[1,2]This study suggests that the novel laryngoscope is easier for those individuals with limited intubation experience to use competently and effectively within a manikin simulation, compared with other tools. However, the novel laryngoscope was not the quickest intubating device, in either the easy or difficult airway scenario.This is because the novel laryngoscope technique first requires the insertion of a bougie into the airway,prior to insertion of the endotracheal tube(i.e. Seldinger technique). The use of a bougie

347 adds to the total time required for intubation,and this additional ‘bougie use’ time was not measured during this
348 study. Previous studies comparing intubation with or without the use of a bougie suggest that its use adds a
349 median time of 10–14 seconds onto the intubation time.[18,19] In bothof those studies, however, the use of a bougie
350 contributed to improved ‘first pass success.’In a recent randomised clinical trial, performed on patients with
351 difficult airways in the emergency department, the use of a bougie was associated with a significantly higher
352 ‘first-attempt’ success rate than the use of an endotracheal tube and stylet (96% *vs* 82%).[20]
353
354 Along with having the most significant reduction in time to intubation between the first and secondattempts, the
355 novel laryngoscope users also demonstrated a reduction in the time to intubation between the easy and difficult
356 airway scenarios compared to the other groups(Figure 4). This result reached statistical significance. These
357 findings suggest that with the novel laryngoscope, learners find it is easier to utilise skills acquired on amanikin
358 in an easy scenario andcan perform intubation more easily inchallenging airways when compared to other
359 laryngoscopes.
360
361 This study has shown that in relatively routine cases, the Macintosh blade will suffice. The overall preferred
362 device used on the manikin in the difficult airwayscenario was the GlideScope,followed by the novel
363 laryngoscope. The GlideScope also demonstrated the quickest times for intubation in the difficult airway
364 scenario. Those experienced in intubating patients are familiar with the GlideScope, andthis device has been
365 introduced into the hospital operating theatre setting for cases with difficult airways.
366
367 The current study is the first to give users an opportunity to use the novel laryngoscope. We do not find it
368 surprising that inexperienced users preferred the novel laryngoscope, as the method is simple, and the user has a
369 straight line of sight to the glottis to pass the bougie through. Novice users also have no dogma regarding
370 intubation with traditional laryngoscopes with their use in an anterior-superior direction. The novel laryngoscope
371 involves gentle pressure against the upper teeth and gums, which allows the scope to obtain a laryngeal axis
372 more easily. In contrast, other methods utilise anupwards and forwards movement to displace the tongue, in
373 order to obtain a view of the glottis and to avoid damaging teeth. The tongue does not need to be swept aside to

intubate a patient when using the novel laryngoscope, and access can be attained on either the left or right side of the mouth.Individuals learning how to intubate patients are currently taught to stay off the teeth, but can easily damage the teeth because of the standard blade's high profile and metal construction.[21]It should be stated that ENT surgeons routinely place rigid metal laryngoscopes against the teeth and gums using a tooth guard,exerting significant pressure against them,and rarely encounter tooth damage. The amount of pressure applied to the teeth and gums with the anterior commissure scope for intubation,by contrast,is minimal.

The participants were not instructed in the use of any intubation device at any point during the study. This was especially challenging for novice participants, as their only method of education was an instructional video viewed at the beginning of the study. We recorded accidental oesophageal intubations and failed attempts, but this means of education is not reflective of what occurs in actual practice. Typically,those learning howto intubate patients are actively instructed on each of the devices used, and have the opportunity to receive teaching by simulation on training manikins or under direct supervision on actual patients. Despite this lack of human instruction, novice users were able to quickly develop the skills needed for intubation in most cases. Maintaining direct visualisation of the target tissue through the scope, and seeing the bougie pass the vocalfolds, was fundamental to the novel laryngoscope's success.

Our study also showed no difference between novice and experienced participantsin terms of vocalfold visualisation (Table 2), but there was an obvious statistical difference when trying to intubate the manikin in the difficult scenario,showing that experience matters when intubating complicated airways inmanikins.

This lack of experience is often evident in cases where the glottic larynx is visualised but the user cannot pass the endotracheal tube through the vocalfolds. This may account for the novel laryngoscope being the most preferred tool for intubation in the novice group for both the easy and difficult manikin scenarios (Tables 5 and6), whereas experienced users preferred the Macintosh blade forthe easy scenario and the GlideScope for the difficult airway. It should be noted that the novel laryngoscope was thesecond preferred choice (after the GlideScope) for experienced users in the difficult airway manikin, which is important if a GlideScope or another

video laryngoscope is not available or fails to function. Ultimately, the novel laryngoscope will be at a disadvantage in any study of intubation timing because of the need for a bougie, to gain access through the vocalfolds. Nevertheless, in this study, we have shown that the novel laryngoscope method was the quickest to learn (Figures 3and 4),and that there was no statistical difference in the time taken to intubate the manikin from the easy to difficult scenario(Table 2).

Table 2also showed that the different techniqueswere associated with variable intubation times in the easy airway scenario, whereas in the difficult airway scenario the Macintosh with bougie and the novel laryngoscope had similar times. This is not surprising,as both of these methods require the use of a bougie, and there is an obvious time increase associated with its use.

Experienced participants had no significantdifficulties in the easy airway scenario, but we found it interesting that a number of them did have problemsinthe difficult airwayscenario. In addition, some novice participants experiencedissues in the difficult scenario for the process of intubation itself (i.e. passing the endotracheal tube).

Intubation failures for the GlideScope concerned not being able to pass the endotracheal tube through the vocalfolds even though they were visualised.Regarding the Macintosh with bougie and the novel laryngoscope, whichboth required use of a bougie, investigators noted that when the participant picked up the bougie, they did not keep the scope in position or reposition the scope to view the vocalfolds, even though they had visualised them before obtaining the bougie. In this study, there was no assistant to pass a bougie to the participantand they sometimes had to look away from the scope to obtain it from the table. These participants were then noted to pass the bougie in some cases without looking down the scope again, so the bougie was not seen to pass the vocalfolds initially. This may explain the high total number of accidental oesophageal intubations in this group. Unfortunately, we cannot discern from the data on which attempt these oesophageal intubations occurred. Participants were quick to learn that the use of a bougie requires direct visualisation of the glottic larynx, and, just as importantly, direct visualisation of the passage of the bougie past the vocalfolds, in order for the

Macintosh with bougie and novel laryngoscope techniques to be successful. Subsequentattempts by these individuals were successful.

We did not find it surprising that novice users found the Macintosh laryngoscope and Macintosh with bougie techniques challenging in the difficult airway scenario. Ten participants had repeated difficulty with intubation for both the Macintosh laryngoscope and Macintosh with bougie, highlighting how this design of laryngoscope can be cumbersome to use in difficult situations.

The use of a bougie placed in the line of sight by the user through the novel laryngoscope, to then allow an endotracheal tube to be passed over it into the correct position, is called the Seldinger technique. This method of access is commonly used in the placement of central lines, arterial lines, percutaneous tracheostomies, and many other high-risk and invasive procedures. The rationale for this method is that it allows the procedure to be performed more safely and efficiently, while minimising complications.

Limitations

We recognise that this study has some potential biases. For example, most users, who were from the anaesthesia department, are familiar with the devices used, except for the novel laryngoscope. To avoid a potential learning curve bias, a randomised, balanced, crossover design was used. This design required careful consideration regarding: the potential order of the techniques used, and correlations among the repeated attempts for each setting and learning curve effects that could potentially confound the relationships of interest.Furthermore, a repeated measures analysis of the crossover design data was used, which allowed for the identification of optimal correlation structures for the models and the inclusion of a covariate for the attempt effects. These models were used to identify the independent effect of the intubation method, controlling for experience and attempt number, on the dependent variables of time taken to visualise the vocalfolds, and time taken to deliver the tube (total intubation time), for both easy and difficult airway scenarios.

453 The other issue is potential selection bias, as the participants were aware that the novel laryngoscope was a new
454 intubating device being used for the first time. None of the participants were personally trained in the use of any
455 intubation device and their only 'education' for each laryngoscope was via an instructional video viewed at the
456 beginning of the study. This is particularly impressive for our novice users, who had little or no experience with
457 any laryngoscope let alone the novel laryngoscope. Our statistical analysis, however, was undertaken to
458 minimise this effect when comparing groups. Several investigators conducted the study, and any errors in data
459 recording or missing data were corrected by excluding the relevant participants.
460
461 Another potential deficiency of the study is not using a Miller blade or Miller blade with a bougie as a
462 comparison laryngoscope. We accept that the Miller blade may have been a better comparison than the
463 Macintosh blade, as the tip of the blade is placed under the epiglottis in the same manner as the novel
464 laryngoscope. Given the large number of laryngoscope devices assessed in this study, it was decided not to use
465 the Miller laryngoscope blade, and to use the Macintosh blade as it is more commonly used in the clinical
466 setting. Future studies should be performed comparing the Miller laryngoscope to the novel laryngoscope.
467
468 Another limitation of the assessment of novel intubation products, in our opinion, is the fixation upon time as
469 opposed to 'first pass success'. It is challenging to conduct manikin studies where the main outcome measure is
470 first pass success. This is because most airway scenarios in manikins are not sufficiently challenging to simulate
471 difficult real-life intubations. Our difficult airway manikinwas heavily modified to make intubation as
472 challenging as possible. This difficulty was confirmed statistically when participants'experience levels and the
473 methods used to intubate the manikin were compared (Table 2). This study highlighted that our difficult scenario
474 posed a challenge for all levels of expertise and for all tools except the novel laryngoscope. This is in keeping
475 with our experience, whereby the metal anterior commissure laryngoscope scope can be used relatively easily on
476 a difficult airway patient following the failure of other intubation devices.[22]
477
478 **Conclusion**

479 The need for a reliable, safe, easy to use and transportable laryngoscope is apparent in the medical and
480 emergency medical services community, as there is still a high incidence of failed intubations.[23] Difficult
481 airways are common in the emergency situation,accounting for 20% or more cases. Although studies have
482 assessed the extent of training needed to perform endotracheal intubation,[1,2] there is no clear consensus regarding
483 the amount and type of training required to prepare someone in an emergency. This study has shown that the
484 novel laryngoscope is an easy-to-handle intubation tool, with a simple and easy-to-learn technique.The novel
485 laryngoscope lends itself to novice users who intubate infrequently. Its usemay increase the chance of successful
486 intubation outside of the operating theatre and in difficult airway situations. We believe future study designs
487 should endeavour to assess the novel laryngoscope against other laryngoscopes in an appropriate,institutional
488 review board approved, patient study.
489
490
491 **Figure 1.** The novel laryngoscope with a clear enclosed circular tube and proximal light-emitting diode light
492 source.
493
494
495 **Figure 2.** 'Difficult' airway scenario in a manikin, modified with packing within the floor of mouth, a neck
496 collar, and taping of the mouth to replicate trismus.
497
498 **Figure 3.**(a) Total time taken to intubate with four different intubating methods over three attempts, and (b) total
499 time taken to intubate using four intubating methods on the manikin in either the 'easy' or 'difficult' airway
500 scenario. MAC = Macintosh laryngoscope; Mac (w/Bougie) = Macintosh with bougie; Glide = GlideScope;
501 Novel = novel laryngoscope
502
503 (a)
504
505

506 (b)

507

508

509

510 **Figure 4.**The 'learning curve' over three attempts with the different intubating techniques: (a) Macintosh

511 laryngoscope; (b) Macintosh with bougie; (c) GlideScope; and (d) novel laryngoscope.

512

513 (a)

514

515 (b)

516

517

518 (c)

519

520 (d)

521

522

523 **Table 1.**Study participant demographics

524 CRNA = Certified registered nurse anaesthetist

Demographic parameter	Novice (*n*)	Expert (*n*)	Total (*n*)
Study population			
– Medical student	49	0	49
– Resident	5	29	34
– Anaesthesiologist or CRNA	0	10	10
– Other	5	0	5
Gender			
– Male	43	27	70
– Female	16	12	28
Handedness			
– Left	3	5	8
– Right	56	34	90

525

526

527 **Table 2.**Time taken to visualise vocalfolds and time taken to intubate,according to participant experience, tools

528 used and airway difficulty

529 Data represent model adjusted mean (standard error), in seconds. Subscripts (superscripts) compare the means

530 within a column (row). Means with the same subscript (superscript) are not significantly different.

531

Parameter	Time taken to visualise vocal folds		Time taken to intubate	
	Easy airway scenario	Difficult airway scenario	Easy airway scenario	Difficult airway scenario
Participants' intubation experience				
– Expert	7.65 $^{b}_{A}$ (0.57)	12.19 $^{a}_{A}$ (0.57)	25.44 $^{b}_{A}$ (1.01)	29.97 $^{a}_{B}$ (1.04)
– Novice	7.67 $^{b}_{A}$ (0.45)	12.94 $^{a}_{A}$ (0.45)	26.19 $^{b}_{A}$ (0.80)	35.13 $^{a}_{A}$ (0.82)
Intubation tool				
– Macintosh laryngoscope	7.40 $^{b}_{BC}$ (0.71)	13.19 $^{a}_{A}$(0.72)	19.55 $^{b}_{D}$ (1.27)	28.61 $^{a}_{B}$(1.32)
– Macintosh with bougie	7.99 $^{b}_{AB}$ (0.71)	14.34 $^{a}_{A}$ (0.72)	28.11 $^{b}_{B}$ (1.28)	38.77 $^{a}_{A}$ (1.34)
– GlideScope	5.78$^{b}_{C}$ (0.71)	8.34 $^{a}_{B}$ (0.71)	23.63$^{b}_{C}$ (1.28)	27.56 $^{a}_{B}$ (1.28)
– Novel laryngoscope	9.49$^{b}_{A}$ (0.71)	14.41 $^{a}_{A}$ (0.71)	31.96$^{a}_{A}$ (1.28)	35.27 $^{a}_{A}$ (1.31)

532

533

534 **Table 3.**Accidental oesophageal and failed intubations

Participants' intubation experience	Airway difficulty	Macintosh laryngoscope (*n*)	Macintosh with bougie (*n*)	GlideScope (*n*)	Novel laryngoscope (*n*)
Expert	Easy				
	– Accidental oesophageal intubation	0	0	0	1
	– Failed intubation	0	0	0	1
	Difficult				
	– Accidental oesophageal intubation	2	2	0	2
	– Failed intubation	3	3	2	4
Novice	Easy				
	– Accidental oesophageal intubation	2	1	0	5
	– Failed intubation	1	5	2	4
	Difficult				
	– Accidental oesophageal intubation	10	13	0	10
	– Failed intubation	7	12	5	4

535

536

537

538 **Table 4.**Participants' ratings of technique according to airwaydifficulty

539 Data represent mean subjective use ratings, with 1 being the highest rated to 4 being the worst rated (numbers in

540 parentheses indicate the rank of the device within the row).

Attribute	Airway difficulty	Macintosh blade	Macintosh blade with bougie	GlideScope	Novel laryngoscope
Quality of light source	Easy	3.00 (3)	3.28 (4)	1.43 (1)	2.29 (2)
	Difficult	3.26 (3)	3.35 (4)	1.33 (1)	2.06 (2)
View of glottis	Easy	2.88 (3)	3.34 (4)	1.35 (1)	2.43 (2)
	Difficult	3.32 (3)	3.34 (4)	1.25 (1)	2.09 (2)
Ease of use	Easy	2.36 (2)	3.02 (4)	2.04 (1)	2.57 (3)
	Difficult	3.28 (4)	2.97 (3)	1.65 (1)	2.09 (2)
Preferred technique	Easy	2.11 (1)	3.02 (4)	2.31 (2)	2.57 (3)
	Difficult	3.27 (4)	2.89 (3)	1.71 (1)	2.14 (2)

541

542

543

544 **Table 5.**Participants' ratings of techniquein easy airway scenario according to intubation experience

545 Data represent mean subjective use ratings, with 1 being the highest rated to 4 being the worst rated (numbers in

546 parentheses indicate the rank of the device within the row).

Attribute	Experience	Macintosh blade	Macintosh blade with bougie	GlideScope	Novel laryngoscope	*p*-value
Quality of light source	Expert	2.58 (2)	3.26 (4)	1.29 (1)	2.87 (3)	0.0131
	Novice	3.20 (3)	3.38 (4)	1.46 (1)	1.96 (2)	
View of glottis	Expert	2.55 (2)	3.35 (4)	1.32 (1)	2.77 (3)	0.0113
	Novice	3.04 (3)	3.31 (4)	1.39 (1)	2.25 (2)	
Ease of use	Expert	2.10 (2)	2.94 (3)	1.87 (1)	3.10 (4)	0.1056
	Novice	2.65 (3)	3.04 (4)	2.08 (1)	2.24 (2)	
Preferred technique	Expert	1.57 (1)	2.93 (3)	2.33 (2)	3.17 (4)	0.0069
	Novice	2.55 (3)	3.04 (4)	2.24 (2)	2.18 (1)	

547

548

549 **Table 6.**Participants' ratings of techniqueratings in difficult airway scenario according to intubation experience

550 Data represent mean subjective use ratings, with 1 being the highest rated to 4 being the worst rated (numbers in

551 parentheses indicate the rank of the device within the row).

Attribute	Experience	Macintosh blade	Macintosh blade with bougie	GlideScope	Novel laryngoscope	*p*-value
Quality of light source	Expert	1.57 (1)	2.93 (3)	2.33 (2)	3.17 (4)	<0.0001
	Novice	3.39 (4)	3.35 (3)	1.41 (1)	1.84 (2)	
View of glottis	Expert	3.19 (3)	3.39 (4)	1.06 (1)	2.37 (2)	0.2495
	Novice	2.37 (4)	3.29 (3)	1.37 (1)	1.96 (2)	
Ease of use	Expert	3.52 (4)	2.81 (3)	1.35 (1)	2.32 (2)	0.0807
	Novice	3.10 (3)	3.10 (3)	1.86 (1)	1.94 (2)	
Preferred technique	Expert	3.58 (4)	2.58 (3)	1.35 (1)	2.48 (2)	0.0165
	Novice	3.10 (4)	3.04 (3)	1.94 (2)	1.92 (1)	

References

1 Mulcaster JT, Mills J, Hung OR, MacQuarrie K, Law JA, Pytka S*et al*. Laryngoscopic intubation: learning and performance. *Anesthesiology* 2003;**98**:23–7

2 Konrad C, Schupfer G, Wietlisbach M, Gerber H. Learning manual skills in anesthesiology: is there a recommended number of cases for anesthetic procedures? *AnesthAnalg* 1998;**86**:635–9

3 Nelson MS. Medical student retention of intubation skills.*AnnEmerg Med* 1989;**18**:1059–61

4 Maharaj CH, Costello J, Higgins BD, Harte BH, Laffey JG. Retention of tracheal intubation skills by novice personnel: a comparison of the Airtraq and Macintosh laryngoscopes. *Anaesthesia* 2007;**62**:272–8

5 Shippey B, Ray D, McKeown D. Use of the McGrath videolaryngoscope in the management of difficult and failed tracheal intubation. *Br JAnaesth* 2008;**100**:116–19

564 6 Sun DA, Warriner CB, Parsons DG, Klein R, Umedaly HS, Moult M. The GlideScope Video Laryngoscope:
565 randomized clinical trial in 200 patients. *Br J Anaesth*2005;**94**:381–4
566 7 Enomoto Y, Asai T, Arai T, Kamishima K, Okuda Y. Pentax-AWS, a new videolaryngoscope, is more
567 effective than the Macintosh laryngoscope for tracheal intubation in patients with restricted neck movements: a
568 randomized comparative study. *Br J Anaesth*2008;**100**:544–8
569 8 Kim JT, Na HS, Bae JY, Kim DW, Kim HS, Kim CS*et al*. GlideScope video laryngoscope: a randomized
570 clinical trial in 203 paediatric patients.*Br JAnaesth* 2008;**101**:531–4
571 9 Lim TJ, Lim Y, Liu EHC.Evaluation of ease of intubation with the GlideScope® or Macintosh laryngoscope
572 by anaesthetists in simulated easy and difficult laryngoscopy.*Anaesthesia* 2005;**60**:180–3
573 10 Lim Y, Lim T-J, Liu EHC. Ease of intubation with the GlideScope or Macintosh laryngoscope by
574 inexperienced operators in simulated difficult airways. *Can JAnaesth* 2004;**51**:641–2
575 11 Leung YY, Hung CT, Tan ST. Evaluation of the new Viewmax laryngoscope in a simulated difficult
576 airway.*ActaAnaesthesiolScand* 2006;**50**:562–7
577 12 Walker L, Brampton W, Halai M, Hoy C, Lee E, Scott I*et al*. Randomized controlled trial of intubation with
578 the McGrath® Series 5 videolaryngoscope by inexperienced anaesthetists. *BrJAnaesth* 2009;**103**:440–5
579 13 Bair AE, Panacek EA, Wisner DH, Bales R, Sakles JC.Cricothyrotomy: a 5-year experience at one institution.
580 *JEmergMed* 2003;**24**:151–6
581 14 Shah KH, Kwong BM, Hazan A, Newman DH, Wiener D. Success of the gum elastic bougie as a rescue
582 airway in the emergency department. *J EmergMed* 2011;**40**:1–6
583 15 Davies R, Balachandran S. Anterior commissure laryngoscope.*Anaesthesia* 2003;**58**:721–2
584 16 Sofferman RA, Johnson DL, Spencer RF. Lost airway during anesthesia induction: alternatives for
585 management. *Laryngoscope* 1997;**107**:1476–82
586 17 Bailey BJ, Johnson JT, Newlands SD. *Head & Neck Surgery – Otolaryngology*. Philadelphia: Lippincott
587 Williams & Wilkins, 2006
588 18 Nolan JP, Wilson ME, Nolan JP, Wilson ME. An evaluation of the gum elastic bougie.*Anaesthesia*
589 1992;**47**:878–81

590 19 Driver B, Dodd K, Klein LR, Buckley R, Robinson A, McGill JW*et al*. The bougie and first-pass success in
591 the emergency department.*AnnEmerg Med* 2017;**70**:473–8
592 20 Driver BE, Prekker ME, Klein LR, Reardon RF, Miner JR, Fagerstrom ET*et al*. Effect of use of a bougie vs
593 endotracheal tube and stylet on first-attempt intubation success among patients with difficult airways undergoing
594 emergency intubation: a randomized clinical trial. *JAMA* 2018;**319**:2179–89
595 21 Mourão J, Neto J, Luís C, Moreno C, Barbosa J, Carvalho J*et al*. Dental injury after conventional direct
596 laryngoscopy: a prospective observational study. *Anaesthesia* 2013;**68**:1059–65
597 22 Vasan NR, Kosik E, Collins B, Clampitt M. Surgeon-performed intubation in awake patients utilising an
598 anterior commissure laryngoscope with bougie: a retrospective case series. *J LaryngolOtol*2019;**133**:986–91
599 23 Katz SH, Falk JL.Misplaced endotracheal tubes by paramedics in an urban emergency medical services
600 system.*Ann Emerg Med* 2001;**37**:32–7

Figures

Figure 1

The novel laryngoscope with a clear enclosed circular tube and proximal light-emitting diode light source.

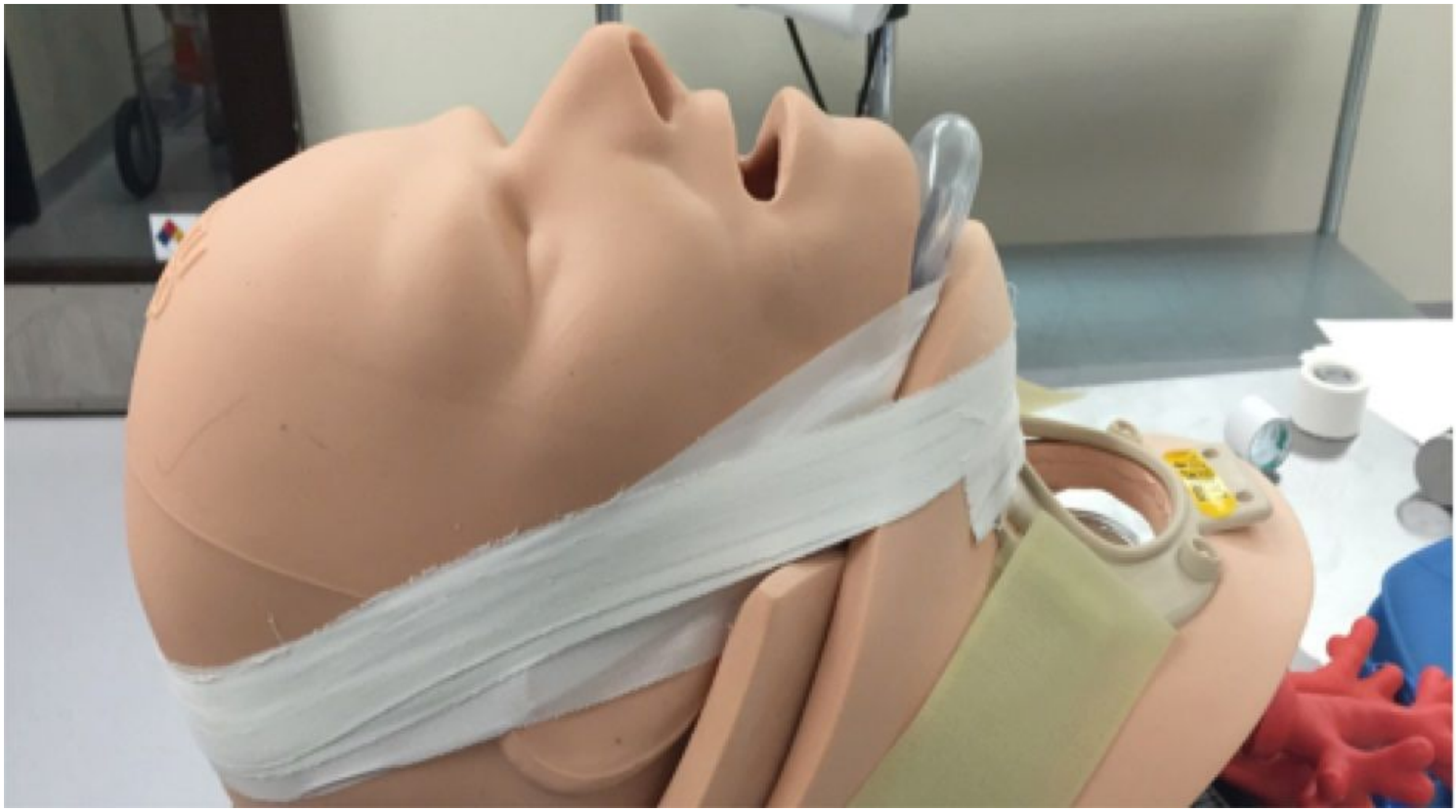

Figure 2

'Difficult' airway scenario in a manikin, modified with packing within the floor of mouth, a neck collar, and taping of the mouth to replicate trismus.

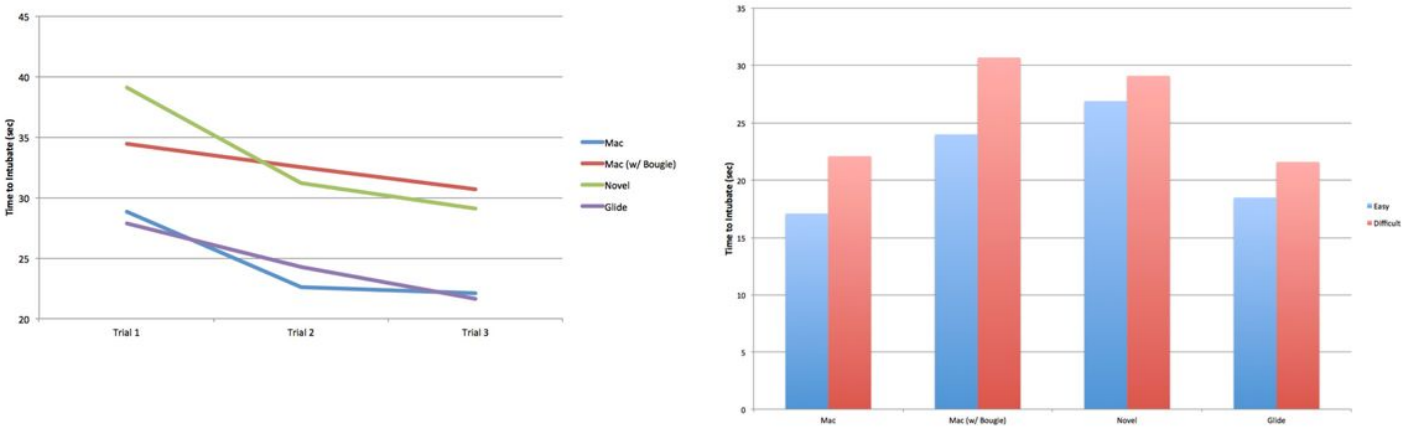

Figure 3

(a) Total time taken to intubate with four different intubating methods over three attempts, and (b) total time taken to intubate using four intubating methods on the manikin in either the 'easy' or 'difficult' airway scenario. MAC = Macintosh laryngoscope; Mac (w/Bougie) = Macintosh with bougie; Glide = GlideScope; Novel = novel laryngoscope

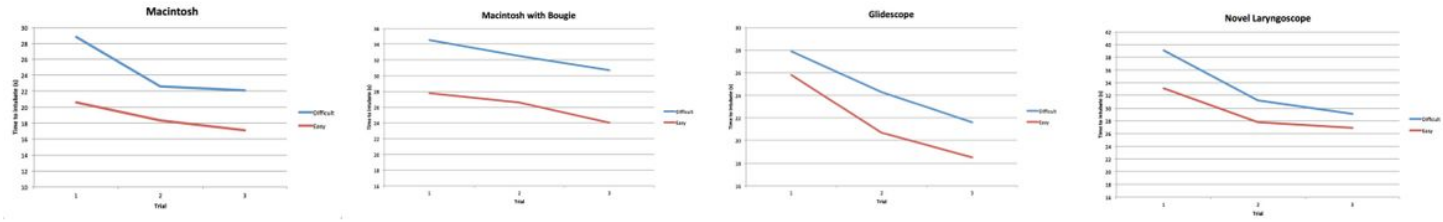

Figure 4

The ‘learning curve’ over three attempts with the different intubating techniques: (a) Macintosh laryngoscope; (b) Macintosh with bougie; (c) GlideScope; and (d) novel laryngoscope.