



Effectiveness and safety of the Levitan FPS ScopeTM for tracheal intubation under general anesthesia with a simulated difficult airway

Efficacité et innocuité du Levitan FPS ScopeTM pour l'intubation trachéale sous anesthésie générale avec des voies aériennes difficiles simulées

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Abstract

Purpose Studies show that the Levitan FPS (first pass success) ScopeTM (LFS) is analogous to a bougie in simulated difficult airways with comparable tracheal intubation success rates. In this study, the efficacy and safety of tracheal intubation with the LFS was compared with that of the Macintosh laryngoscope utilizing manual in-line stabilization (MILS) to simulate difficult airways.

Methods Ninety-four subjects successfully completed the trial. Manual in-line stabilization of the cervical spine was applied and the initial laryngoscopy was performed using either the Macintosh or the LFS in conjunction with the Macintosh. Following the initial grading, a second laryngoscopy was repeated using the second randomized technique. Cormack-Lehane grades, percentage of glottic

opening (POGO) scores, time to intubate, number of intubation attempts, and the use of alternate techniques were recorded. The anesthesiologist rated the subjective difficulty in using each technique with a numeric rating scale and a visual rating scale.

Results There was no significant difference in the primary outcome “good laryngoscopic views” (Cormack-Lehane grade 1 and 2) compared with “poor laryngoscopic views” (Cormack-Lehane grade 3 and 4) between the LFS and the Macintosh. There were higher POGO scores with the LFS compared with the Macintosh (80% vs 20%, respectively; $P < 0.0001$), but this did not translate to easier intubations, as documented by the need for an alternate intubation technique or time to intubate (< 30 and < 60 sec, respectively). The incidence of mucosal trauma, sore throat, and hemodynamic responses did not differ significantly between the two techniques.

Conclusion The LFS in conjunction with the Macintosh laryngoscope does not improve the efficacy or safety of tracheal intubation in a simulated difficult airway.

Author contributions Tracy Kok, Ronald B. George, and Dolores McKeen were involved in the conception and design of the study. Tracy Kok created the REB documents, and Aaron Pink assisted in the creation of the REB documents. Tracy Kok helped to acquire the data, and Aaron Pink assisted in data input. Ronald B. George analyzed the data and was involved in interpreting the data together with Dolores McKeen. Ronald B. George created the tables and figures. Tracy Kok was the main author in drafting and revising the manuscript for submission. Ronald B. George, Dolores McKeen, and Narendra Vakharia were involved in drafting and revising the manuscript, and Aaron Pink assisted in drafting the manuscript.

Résumé

Objectif Les études montrent que le Levitan FPS (first pass success) ScopeTM (LFS) est semblable à une bougie dans des simulations de voies aériennes difficiles, avec des taux de succès comparables pour l'intubations trachéales réussies. Dans cette étude, l'efficacité et l'innocuité de l'intubation trachéale avec le LFS a été comparée à une intubation avec un laryngoscope Macintosh dans le cas d'une stabilisation manuelle en ligne (MILS) pour simuler des voies aériennes difficiles.

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Méthodes Quatre-vingt quatorze patients ont terminé l'étude avec succès. Une stabilisation manuelle en ligne de la colonne cervicale a été appliquée et la laryngoscopie initiale a été réalisée en utilisant le Macintosh ou le LFS associé au Macintosh. Après cette première évaluation, une deuxième laryngoscopie a été effectuée en utilisant la deuxième technique randomisée. Les grades de Cormack-Lehane, le pourcentage d'ouverture de la glotte (POGO), le nombre de tentatives d'intubation et le recours à des techniques de remplacement ont été notés. L'anesthésiologiste a évalué la difficulté objective d'utilisation de chaque technique à l'aide d'une échelle d'évaluation numérique et une échelle d'évaluation visuelle.

Résultats Il n'y a pas eu de différences significatives pour le critère d'évaluation principal, soit les « bonnes vues laryngoscopiques » (grades 1 et 2 de Cormack-Lehane) et les « mauvaises vues laryngoscopiques » (grades 3 et 4 de Cormack-Lehane) entre le LFS et le Macintosh. Les scores POGO ont été plus élevés avec le LFS qu'avec le Macintosh (respectivement, 80 % contre 20 %; $P < 0,0001$), mais ceci ne s'est pas traduit par des intubations plus faciles, comme le montrent le besoin de recourir à une autre technique d'intubation ou le temps nécessaire pour intuber (respectivement, < 30 et < 60 s). Il n'y a pas eu de différence significative en termes de traumatisme de la muqueuse, de maux de gorge ou de réponses hémodynamiques entre les deux techniques.

Conclusion Le LFS associé au laryngoscope Macintosh n'améliore pas l'efficacité ou l'innocuité de l'intubation trachéale dans une simulation de voies aériennes difficiles.

Manuel Patricio Rodriguez Garcia created the first laryngoscope in 1854. Since then, a variety of conventional “direct” laryngoscopes, flexible fiberoptic laryngoscopes, and video laryngoscopes have been introduced into clinical practice. Recently developed “indirect” intubating devices using fiberoptic and video technology have been purported to overcome difficulties of direct laryngoscopic visualization of the glottic opening allowing more successful tracheal intubation in routine and difficult airway situations.

The Levitan FPS (first pass success) Scope™ (LFS) is a short malleable semi-rigid fiberoptic stylet developed by Dr. R.M. Levitan (Clarus Medical, Minneapolis, MN, USA) “to fiberoptically augment direct laryngoscopy”.¹ It is intended for use in every laryngoscopy (replacing the standard stylet for shaping and handling) in a 6.0 mm internal diameter or greater endotracheal tube.¹ Its function is similar to that of the standard stylet (i.e., intubation guide), but it also consists of a fiberoptic eyepiece (i.e.,



Fig. 1 The Levitan FPS (first pass success) scope (LFS) is a short malleable semi-rigid fiberoptic stylet developed by Richard Levitan and manufactured by Clarus Medical (Minneapolis, MN, USA). Image courtesy of Dr. Orlando Hung

visualization aid) and an oxygen insufflation port (Fig. 1). The LFS is used to guide and confirm endotracheal placement of endotracheal tubes during routine laryngoscopy. In situations of poor glottic view, the tip of the LFS is placed under direct vision close to, but below and away from, the tip of the epiglottis. The fiberoptic eyepiece is then used to locate and guide the endotracheal tube into the glottic opening.¹

There is a paucity of published research on the role of the LFS as an adjunct to direct laryngoscopy, particularly in situations of difficult airways. A variety of other optical stylets on the market appear to confer a benefit for use in anticipated difficult airways. Several studies show that the LFS is analogous to a bougie in simulated difficult airways with comparable tracheal intubation success rates, yet these studies did not compare glottic views (i.e., standardized views) or were completed on mannequins.^{2,3}

We hypothesized that the LFS can be more effective and safer than the Macintosh laryngoscope alone when used for direct laryngoscopy and tracheal intubation of subjects with a simulated difficult airway using manual in-line stabilization (MILS). This study aims to extrapolate useful clinical information from the MILS simulated difficult airway scenario for use in patients with true difficult airways in the hospital setting.

Methods

The protocol was reviewed and approved by the IWK Health Centre Research Ethics Board (July 2009 – Dr. C. Fernandez, IWK Health Centre REB# 4668). Written informed consent was obtained from all participants meeting inclusion criteria. We recruited women aged 16–75 yr, American Society of Anesthesiologists’ physical

status class I-II, and undergoing elective gynecologic surgery at the IWK Health Centre under general anesthesia with planned orotracheal intubation. Exclusion criteria included patients with a history of significant gastroesophageal reflux disease and/or difficult tracheal intubation and those with clinical predictors of difficult tracheal intubation and/or a body mass index $> 45 \text{ kg}\cdot\text{m}^{-2}$.

Anesthesiologists experienced with the LFS performed the study tracheal intubations. Subject demographics, including sex, age, weight, and height were recorded. Preoperative airway assessment included measurement of mouth opening, jaw protrusion, Mallampati scores, thyromental distance, neck circumference, and assessment of range of motion of the cervical spine.

Following placement of standard monitors (Canadian Anesthesiologists' Society guidelines) and intravenous catheter insertion, the subjects were pre-oxygenated with 100% O_2 for three minutes.⁴ General anesthesia was induced with propofol ($1\text{--}3 \text{ mg}\cdot\text{kg}^{-1} \text{ iv}$), either fentanyl ($1\text{--}3 \text{ }\mu\text{g}\cdot\text{kg}^{-1} \text{ iv}$) or sufentanil ($0.1\text{--}0.3 \text{ }\mu\text{g}\cdot\text{kg}^{-1} \text{ iv}$), and either rocuronium ($0.4\text{--}0.8 \text{ mg}\cdot\text{kg}^{-1} \text{ iv}$) or succinylcholine ($1.0\text{--}1.5 \text{ mg}\cdot\text{kg}^{-1} \text{ iv}$). Muscle relaxation was confirmed using peripheral nerve stimulation by train-of-four before the airway intervention was initiated. Vital signs were recorded pre-induction, post-induction, and one minute post tracheal intubation. The maximal changes in mean arterial blood pressure (MAP) and heart rate (HR) were calculated as the difference between the peak MAP and HR post tracheal intubation and pre-induction measurements.

In this crossover study, the randomized laryngoscopy sequence (i.e., Macintosh/LFS or LFS/Macintosh) was determined by a computer-generated list without blocking. The results were placed in sealed opaque envelopes and opened after induction of anesthesia by the research coordinator. After induction, MILS of the cervical spine was applied and initial laryngoscopy (Macintosh or LFS) and grading were performed. Manual in-line stabilization was applied by one of the three anesthesia assistants at our institution. Bag-mask ventilation and oxygenation were interposed with a second laryngoscopy repeated using the second assigned technique. The anesthesiologist graded the laryngeal view each time using the Cormack-Lehane scale⁵ and assigned a percentage of glottic opening (POGO) score.^{6,7} When using the LFS, the view of the glottic opening was graded by inspection through the eyepiece of the optical stylet. Tracheal intubation was performed during the second laryngoscopy after grading the laryngeal view. A size 7.0-mm endotracheal tube with a malleable stylet was used to facilitate Macintosh intubation (standard practice).

For purposes of this study, no laryngeal manipulation was used during either technique, and an intubation attempt was defined as a "failure" in the following circumstances:

if the anesthesiologist was unable to visualize the glottic opening adequately despite sufficient pharyngeal visualization, if time to intubate (TTI) exceeded 60 sec, if desaturation occurred ($\text{SpO}_2 < 90\%$), or if, in the opinion of the anesthesiologist, further attempts would be unsafe and/or futile. In the event of intubation failure, MILS was discontinued and tracheal intubation was achieved using the anesthesiologist's method of choice. The TTI was documented during the second laryngoscopy and was defined as the time from the insertion of the Macintosh laryngoscope into the oral cavity to its removal (i.e., either Macintosh or LFS). At the request of the research coordinator, the attending anesthesiologist visually examined the patients for evidence of oropharynx trauma following tracheal intubation. Evidence of trauma was determined by the presence or absence of mucosal bleeding and/or blood noted on the laryngoscope blade.

The attending anesthesiologist rated the difficulty in using each technique to intubate the larynx using an 11-point numeric rating scale (NRS, 0 = intubated with ease and 10 = most difficult intubation) and a four-point visual rating scale (VRS, easy, mildly difficult, moderately difficult, difficult). Nurses in the postanesthesia care unit who were blinded to the intubation technique asked patients to report the presence or absence of a sore throat prior to discharge.

The primary outcome was the incidence of "poor laryngoscopic view" with MILS applied to the cervical spine. The secondary outcomes were the time to intubate, the number of intubation attempts, the inability to visualize the glottic opening, laryngeal trauma secondary to intubation, subjective difficulty of intubation, and the presence or absence of sore throat.

Statistical analysis

All discrete non-matched data were analyzed using Fisher's exact test. Discrete paired data were assessed with McNemar's test. Continuous data were analyzed using either the unpaired or paired Student's *t* test or a one-way analysis of variance. A Cormack-Lehane grade 3 or 4 view was used as the definition of a "poor laryngoscopic view". Using this definition, we estimated that 65% of subjects with immobilization of the cervical spine would have a "poor laryngoscopic view" based on a previous study with cervical immobilization.⁸ We hypothesized a 50% improvement in laryngoscopic view, as this was considered a clinically significant difference that would show a clear benefit of the LFS over the Macintosh. Using power analysis and with a 50% improvement in laryngoscopic view using the LFS (from 65% to 32.5% of subjects with a Cormack-Lehane grade 3 or 4 view), a sample size of 42 subjects in each group was needed to have a desired power

of 0.8 and alpha of 0.05 (two-sided) (G*Power version 3.0 2006). Our power calculation assumed independent observations, while our primary outcome was non-independent data. Nevertheless, paired data typically require a smaller sample size; therefore, this project had adequate power. Accounting for subject withdrawal and protocol violations, 94 subjects were recruited at the IWK Health Centre.

Results

From July 29, 2009 to March 12, 2010, 120 subjects were screened and invited for participation. One hundred five subjects were enrolled with 94 subjects completing the study (Fig. 2). Three of the subjects (one in the Macintosh group and two in LFS group) had incomplete data sets for the primary outcome due to LFS technical failure. The demographics and preoperative airway assessment characteristics are listed in Table 1.

Fig. 2 Trial profile.

MAC = Macintosh laryngoscope; LFS = Levitan FPS (first pass success) scope; BMV = bag-mask ventilation; CL = Cormack-Lehane; POGO = percent of glottic opening

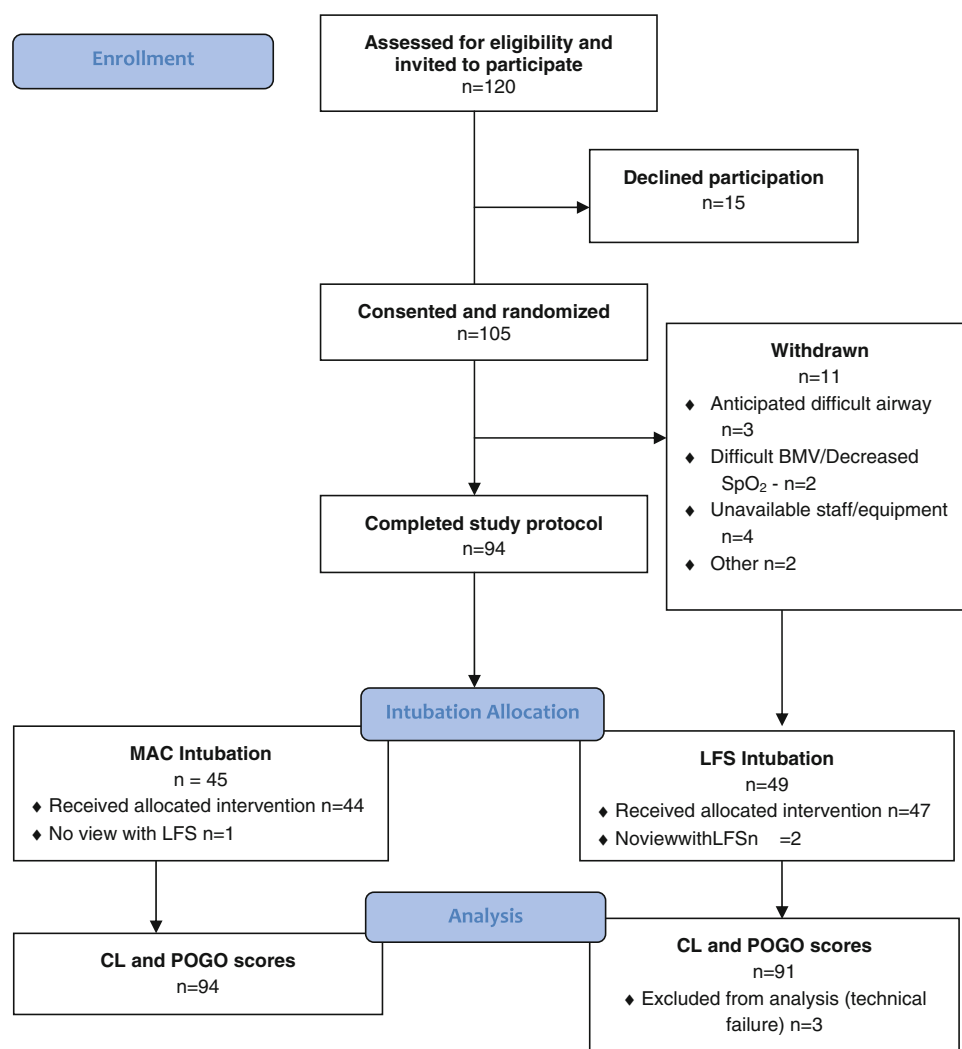


Table 1 Morphometric characteristics and airway assessment data for $n = 94$ subjects

Variable	Measure
Age (yr)	45 (13)
Weight (kg)	72.6 (13.8)
Height (m)	1.6 (0.1)
BMI ($\text{kg}\cdot\text{m}^{-2}$)	27.0 (5.2)
Mouth opening (cm)	5 [4-5]
Neck Circumference (cm)	34.4 (2.5)
Mallampati Score, $n = 94$ (1 / 2 / 3 / 4)	41 / 44 / 8 / 1
Mentohyoid Distance (cm)	8.5 [7-13]
Subluxation (cm)	1 [0.5-2]
Neck Flexion (cm)	2 [1-3]
Neck Extension (cm)	17 [15-19]

BMI = body mass index. Mean (standard deviation), median [interquartile range], $n =$ number of subjects

Using the LFS, there were 37(39%) Cormack-Lehane grade 1 views and 21(22%) grade 2 views compared with 11(12%) grade 1 views and 42 (45%) grade 2 views using the

Macintosh. When we combined the Cormack-Lehane grade 1 and 2 views to give the composite grades for “good laryngoscopic view” (Macintosh 53 [56.4%], LFS 58 [63.7%]) and compared them with the combined Cormack-Lehane grade 3 and 4 views to give the composite grades for “poor laryngoscopic view” (Macintosh 41 [43.6%], LFS 33 [36.3%]), there was no significant difference between the two techniques (odds ratio 1.64; 95% confidence interval [CI] 0.73 to 3.83; $P = 0.27$) (McNemar test) (Table 2). Using the POGO score to rate the laryngoscopic view, the median Macintosh POGO score was 20%, interquartile range [IQR; 0-50], and the median LFS POGO score was 80%, IQR [0-100]. The difference (mean difference 33.1%; 95% CI 24.1 to 42.1; $P < 0.0001$) was statistically significant with a paired Student’s t test (Fig. 3).

The number of subjects requiring more than one attempt at tracheal intubation using the Macintosh and the LFS was $n = 12$ and $n = 8$, respectively ($P = 0.6$). There were nine subjects who required an alternate technique for tracheal intubation (i.e., release of MILS or bougie) with the Macintosh and ten subjects with the LFS ($P = 0.8$). More subjects using the LFS required > 30 sec for tracheal intubation compared with those using the Macintosh, and significantly more subjects using the LFS required > 60 sec for tracheal intubation than those using the Macintosh (Table 3).

There were statistically significant differences in the changes in systolic arterial blood pressure (SBP) and heart rate (HR) between pre-induction, post-induction, and post tracheal intubation measurements (Table 4). Both the NRS and VRS results indicated that the anesthesiologists subjectively found that both techniques were easy to use ($P = 0.53$ and $P = 0.18$, respectively) (Fig. 4). The overall incidence of subjects who reported a “sore throat” on the discharge questionnaire was 28% with no difference between groups ($n = 12$ Macintosh; $n = 4$ LFS; $P = 0.5$). Fewer subjects had evidence of trauma in the LFS group ($n = 1$) than in the Macintosh group ($n = 7$), yet this difference was not significant ($P = 0.06$).

Discussion

Using manual in-line stabilization to simulate a difficult tracheal intubation scenario proved to be no more effective using the LFS with the Macintosh laryngoscope than using

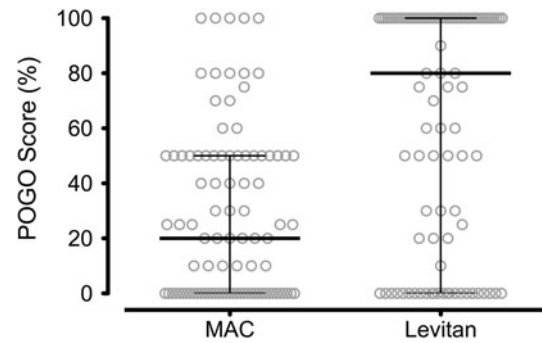


Fig. 3 Percent of glottic opening (POGO) scores for the Macintosh laryngoscope and Levitan device (median [thick line], interquartile range [IQR; thin line], and data points [grey circles])

the standard Macintosh laryngoscope alone. We have shown with our primary outcome variable that there was no statistically significant reduction in the incidence of “poor laryngoscopic view” between using the LFS and using the Macintosh laryngoscope alone, as measured by the clinically relevant composite Cormack-Lehane scale.

The LFS did provide a superior view of the larynx, as measured by the individual Cormack-Lehane grades and POGO score, yet this did not improve the time to intubate (< 30 sec and < 60 sec). Our current study confirms the results of previous studies using indirect laryngoscopy, i.e., an improved glottic view does not necessarily translate into tracheal intubation success. This may be explained by the fact that direct laryngoscopy grading requires a straight line of sight on the glottic opening, while the LFS allows a view of the glottis and grading without alignment of the oral, pharyngeal, and tracheal axes. Manual in-line stabilization limits motion of the cervical spine making it difficult to align the laryngeal, pharyngeal, and tracheal axes.

The lack of tracheal intubation success with these indirect devices may be due to the mal-alignment of the axes or the dimensions of the device, both of which may inhibit the endotracheal tube from advancing through the glottis.⁹ The LFS has an advantage over other indirect fiberoptic devices in this respect. The view produced by the LFS is at the tip of the stylet with the endotracheal tube preloaded on the stylet. It should therefore be easier to advance the tube through the glottic opening using the LFS compared with using other indirect laryngoscopy devices (e.g., Glidescope).

Table 2 Comparison of Cormack-Lehane laryngoscopy between the Macintosh and the LFS with MILS

Cormack-Lehane Laryngoscopy grade	MAC ($n = 94$)	LFS ($n = 91$)	P value	Odds Ratio (95%CI)
“Good laryngoscopic view”	53	58	0.26	1.6 (0.7 to 3.88)
“Poor laryngoscopic view”	41	33		

MAC = Macintosh; CI = confidence interval. LFS = Levitan first pass success scope; MILS = manual in-line stabilization

Table 3 Measures of airway efficacy variables comparing Macintosh and LFS devices

	MAC	LFS	<i>P</i> value*	Odds Ratio (95%CI)
> 30 sec (<i>n</i> = 94)	11 (22.4%)	31 (68.9%)	< 0.0001	7.6 (3.0 to 19.2)
> 60 sec (<i>n</i> = 94)	2 (4.1%)	9 (20.0%)	0.02	5.9 (1.2 to 28.9)
> 1 attempt (<i>n</i> = 93)	12 (24.5%)	8 (17.8%)	0.61	0.7 (0.3 to 1.9)
Alternate technique used (<i>n</i> = 94)	9 (18.4%)	10 (22.2%)	0.80	0.8 (0.3 to 2.2)

* Fisher's exact test; MAC = Macintosh; LFS = Levitan first pass success scope; CI = confidence interval

Table 4 Hemodynamic changes associated with induction and tracheal intubation

	Post-induction	Post tracheal intubation
Pre-induction		
SBP	20.5 (13.9 to 27.1)	7.0 (0.4 to 13.6)
HR	0.3 (−3.6 to 4.2)	−11.5 (−7.6 to −15.4)
Post-induction		
SBP		−13.5 (−6.9 to −20.1)
HR		−11.8 (−7.9 to −15.7)

Data presented as mean difference and 95% confidence intervals (paired one-way analysis of variance). SBP = systolic blood pressure; HR = heart rate

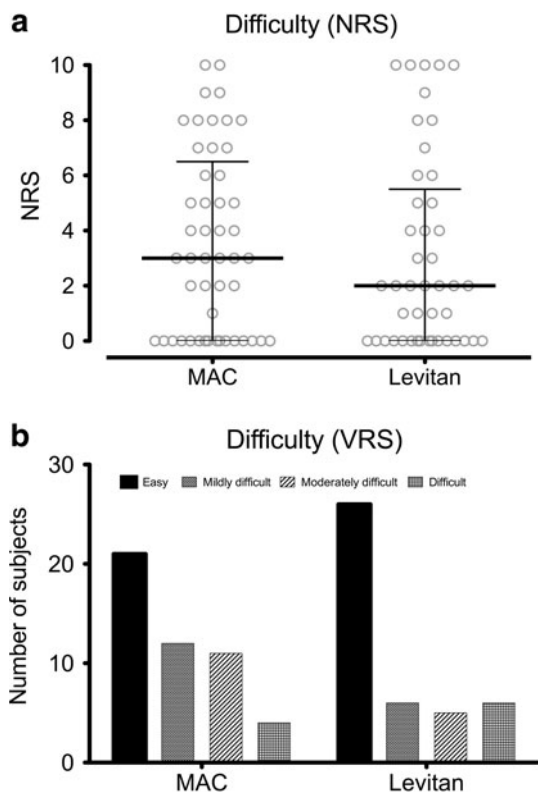


Fig. 4 (a, b) Difficulty ratings with the numeric rating score (NRS) (a) and visual rating score (VRS) (b) scores for the Macintosh laryngoscope and Levitan device (median [thick line], interquartile range [IQR; thin line], and range [circles])

These results support Greenland *et al*'s previously reported findings published in a similar bougie *vs* LFS study.² These authors reported longer LFS insertion times, yet both techniques were equal in time to intubate and success at intubating the trachea in standardized simulated grade IIIa difficult airways.

There were three subjects who did not have primary outcome data due to the technical failure of the LFS device. These failures were described and considered as secondary to secretions in the pharynx and an inability to visualize the glottic opening due to mucosal crowding of the LFS / tracheal tube tip from the narrow hypopharyngeal space. Sensitivity analysis was completed, including the three technical failures that occurred using the LFS, assuming worse case ratings of POGO 0 and a Cormack-Lehane 4 view. The addition of these technical failures still resulted in no significant difference between the two techniques in the number of subjects with "good laryngoscopic view" and those with "poor laryngoscopic view."

We chose to use both the Cormack-Lehane scale and the POGO score to document laryngoscopic views. The Cormack-Lehane scale was initially designed for rating quality of laryngeal view by direct laryngoscopy, while the POGO score is a continuous scale allowing a finer distinction between different laryngeal views. The Cormack-Lehane scale shows excellent intra-physician reliability but very poor inter-physician concordance,⁶ while the POGO score has been shown to have a high intra- and inter-physician reliability. This suggests that the POGO score has greater reliability in studies with multiple laryngoscopists.

More recently, the Cormack-Lehane scale and POGO score have been used to rate the quality of views using indirect laryngoscopy devices (i.e., Glidescope). At present, there is no other comparable grading scale for use with indirect laryngoscopy, and neither scale has been validated for use with an indirect device like the LFS. In previously published studies evaluating newer fiberoptic scopes, the laryngeal view was not graded or the mannequin or patients had a predetermined Cormack-Lehane grade.^{2,10,11}

With respect to safety, we found no difference in the frequency of trauma or complaints of sore throats between

the LFS and Macintosh as the technique used for actual tracheal intubation. The overall incidence of sore throat in our study was 28% compared with previous incidences reported as high as 40%.¹² One of the factors that may influence the development of a sore throat is the force applied to the laryngoscope blade during tracheal intubation,¹³ and it has been shown that stronger force is needed with the Macintosh laryngoscope when MILS is applied.¹⁴ Theoretically, the LFS should decrease the incidence of sore throat because less force would be needed to obtain a view of the glottis, but since each subject was exposed to both techniques, trauma associated solely with the LFS would not have been recognized in this study.

Although the TTI was > 60 sec in a majority of tracheal intubations with the LFS, anesthesiologists rated the technique as comparable with the Macintosh laryngoscope in terms of ease of use. Anesthesiologists may not have been acutely aware of the passage of time during intubation and therefore may not have factored it into their assessment for the ease of use of the LFS. The NRS and VRS have traditionally been used to evaluate the severity of subjective symptoms such as pain and dyspnea.^{15,16} They have not been validated to determine the difficulty in using an airway device but are being used more frequently in airway studies.¹⁷

We acknowledge several study limitations. This is a randomized crossover clinical trial where both laryngoscopic grading techniques were applied to the same patient. This possibly allowed for bias, learning, and carryover so that knowing the grade on the first laryngoscopy may have influenced the grade assigned during the second laryngoscopy. To minimize this learning effect, we sequentially randomized the laryngoscopy sequence (i.e., Macintosh/LFS or LFS/Macintosh) such that the equipment first used on each subject and the knowledge of prior grade would occur equally.

There may have been varied experience using the LFS prior to the study and the need for greater technical expertise for the use of the LFS. Our requirement was that the anesthesiologists had used the LFS technique “successfully” in more than ten intubations. We did not inquire about the number of times the technique had been used unsuccessfully, but would assume the total experience would be greater. Therefore, our results may have produced a bias against the LFS and may not be applicable to inexperienced anesthesiologists. The relative inexperience using the LFS could have affected the time to intubation since most anesthesiologists use the Macintosh laryngoscope on a daily basis and have used it many times for tracheal intubation. We do point out that there was no significant difference in the number of “attempts at intubation” between the LFS and Macintosh laryngoscope alone, and this suggests that the LFS is at least as straightforward to use as the Macintosh laryngoscope.

We simulate difficult laryngoscopy using MILS, and this allows for airway studies to be performed with a smaller number of patients, as it would be difficult to recruit the large numbers needed to capture the incidence of true difficult airways. Results obtained from simulated difficult airways may not be fully generalizable to the true difficult airway population.

The MILS was applied by a number of different anesthesia assistants, and this could have affected the Cormack-Lehane grades and POGO scores for each technique. The generalizability of our results may be limited by the fact that our subjects were all women, as our study was conducted at the IWK Health Centre, a hospital specific for women and children. Nevertheless, sex is not known to be associated with the incidence of difficult tracheal intubation.

We acknowledge the limitation that the unblinded observers had to be familiar with collecting intraoperative data and that this could be a potential source of bias. However, the attending anesthesiologists were not informed of the actual measurements (i.e., time to intubate), and there were protocol predefined end points that constituted how such measurements were to be recorded. Hemodynamic measurements were considered to be objective measures as these were timed intervals preset on the anesthesia machine. The anesthesiologist, at the request and in conjunction with the research coordinator, made the assessment for the presence or absence of trauma and/or mucosal bleeding. While both were not blinded to the intubation technique, both had to agree to the presence or absence of trauma and/or bleeding.

Our power calculation assumed independent observations, while our primary outcome is non-independent data; however, since paired data typically require a smaller sample size, we thus considered we had adequate power. We assumed from previous publications that the incidence of difficult airways with MILS using a Macintosh laryngoscope would be 65%. However, in our study, there were only 43.6% of subjects who had a “poor laryngoscopic view.” This resulted in our study being underpowered as shown by a *post-hoc* power analysis, and this may have been due to applying a definition of “poor laryngoscopic view” that was too strict.

In conclusion, our study suggests that indirect laryngoscopy with the LFS in conjunction with the Macintosh laryngoscope in simulated difficult airways does not improve the safety or efficacy of tracheal intubation as measured by the Cormack-Lehane scale.

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Conflicts of interest None of the authors has any relevant conflicts of interest to disclose.

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