University of Cape Town

Faculty of Health Sciences

Intubation during spinal motion restriction using the Lubo ™ cervical collar - a manikin simulation study

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

I, Dinell Behari, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor part of it has been, is being, or is to be submitted for another degree in University of Cape Town or any other university.

This dissertation has been submitted to the Turnitin module (or equivalent similarity and originality checking software) and I confirm that my supervisor has seen my report and any concerns revealed by such have been resolved with my supervisor.

This thesis is presented in fulfilment of the requirements for the degree of MMed (Anaesthesia).

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Sincerely,

Dinell Behari

Signed by candidate

Date : 12 June 2022

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Format

The contents of this minor dissertation are presented in the "*ready for publication"* format. It consists of two chapters:

Chapter 1: Introduction

Chapter 2: Accepted for publication manuscript

This manuscript has been submitted for publication in the *African Journal of Emergency Medicine (AFJEM)* and has been formatted according to the journal's guide for authors. This journal uses the Elsevier - Vancouver referencing format and this thesis has been prepared accordingly.

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Chapter 1: Introduction

Spinal motion restriction is an intervention considered to be at the core of the management of the patient with a suspected spinal injury. Prior generations of rigid cervical collars have been shown to decrease mouth opening, placing limitations on airway management and hinder attempts at tracheal intubation.

The current recommendation is to remove the cervical collar, or anterior part thereof, and provide motion restriction with manual in-line stabilization (MILS) during tracheal intubation.

The Lubo collar is a novel device, aimed at providing cervical motion restriction while possessing a unique external jaw thrust mechanism. Additionally, it facilitates tracheal intubation with the collar in place through the release of a specifically designed chin strap.

The aim of this study was to determine whether endotracheal intubation with the Lubo collar was equivalent to intubation with manual in-line stabilization (standard of care) in a manikin simulated environment. We conducted a randomized, cross over, equivalence study using 80 skilled anaesthesia providers during September 2020 to determine the mean difference in intubation times in both scenarios.

The results of the study showed that the time to tracheal intubation was equivalent in both scenarios.

Chapter 2: Publication-ready manuscript

Title:

Intubation during spinal motion restriction using the Lubo ™ cervical collar - a manikin simulation study

Abstract:

Introduction: The Lubo ™ collar is a cervical motion restriction device featuring a unique external jaw-thrust mechanism designed to provide non-invasive airway patency. In addition, tracheal intubation is facilitated by releasing an anterior chin strap; this allows better mouth opening than the previous generation of semi-rigid cervical collars. This study aimed to compare tracheal intubation using the Lubo ™ collar combined with manual in-line stabilization (MILS) to intubation with MILS alone. The primary outcome was the time to successful intubation. Secondary outcomes compared intubation success rate, Cormack-Lehane grade, ease of intubation and dental trauma.

Methods: A randomized, cross-over, equivalence study was performed. Eighty full-time physician anaesthesia providers were recruited. Participants performed tracheal intubation using direct laryngoscopy on a manikin under two different scenarios: with the Lubo ™ collar and MILS applied, and with MILS and no cervical collar. The time to successful intubation was measured and compared using two-one-sided and paired t-tests.

Results: Intubation times fell well within the *a priori* equivalence limits of 10 seconds, with a mean difference (95% CI) of 0.52 seconds (-1.30 to 2.56). There was no significant difference in intubation time with the Lubo ™ collar (mean [SD] 19.2 [4.5] seconds) compared to the MILS alone group (19.7 [5.2] seconds). The overall success rate was 98.7% in the Lubo group and 100% in the MILS group. Adequate laryngoscopy views (Cormack-Lehane grades I to IIb) were equivalent between groups (Lubo 92.5% versus MILS alone 93.7%).

Conclusion: In this manikin-based study, the time to intubation with the Lubo ™ collar and MILS applied was equivalent to time to intubation with MILS alone, with similar intubating conditions. Thus, the Lubo ™ collar and MILS may simplify airway management by reducing the number of steps required to perform intubation in patients requiring cervical motion restriction.

Keywords:

- Airway management
- Intubation
- Cervical collar
- Spinal motion restriction
- Lubo

African relevance:

- The Lubo ™ cervical collar is a novel cervical motion restriction device that may provide improved airway access in the prehospital setting.

- The collar functions as a non-invasive airway device with an external jaw-thrust mechanism to improve airway patency, which may serve as a stand-alone device or supplemental airway adjunct.

- This simplified airway management using the device may be beneficial in a resource-limited setting.

- This study examined the utility of the Lubo ™ collar using standard airway equipment which is widely available on the African continent.

- This device might prove to be a useful alternative to current cervical collars, which place limitations on airway management in the injured trauma patient.

Title:

Intubation during spinal motion restriction using the Lubo™ cervical collar - a manikin simulation study

Cervical motion restriction (previously referred to as 'immobilization') is an intervention considered essential in the management of patients with a suspected cervical spine injury.

The application of rigid or semi-rigid cervical collars has been shown to place limitations on airway management by prolonging attempts at intubation and worsening the Cormack-Lehane grade of view at laryngoscopy [1–3]. They are associated with reductions in mouth opening, cervical flexion and atlanto-occipital extension [3–5], making it difficult to align the airway to attain the same view that could be achieved in the optimal "sniffing" position. Due to suboptimal intubating conditions, added force is often needed to perform laryngoscopy with the rigid cervical collar in place. These additional forces have been shown to be transferred to the cervical spine, resulting in the motion of unstable cervical segments [1,4,6].

Current recommendations are to maintain cervical motion restriction with manual in-line stabilization (MILS) during tracheal intubation [7–9]. If already in place, standard practice is to remove the cervical collar (or anterior portion thereof) while an assistant provides MILS and replace the collar on completion. However, the application and removal of cervical collars has been associated with motion of cervical segments [10,11]. Due to many disadvantages with the current generation of rigid cervical collars, many practitioners now recommend against their routine use [12–16].

A novel device, the Lubo™ (Inovytec Medical Solutions LTD., Raanana 4366507, Israel), is a semi-rigid cervical collar with a few salient features. In addition to providing cervical motion restriction [17], it consists of an external jaw-thrust mechanism (Figure 1. C) aimed at improving airway patency. (This property is the subject of a separate study.) Furthermore, it allows intubation with the collar in place by release of the anterior chin strap [18] This may reduce the number of steps required to perform intubation and reduce the risk of applying additional forces to the injured cervical spine. Although it is theorized that the Lubo™ allows intubation without removal, it is unknown whether the collar provides similar intubating conditions to MILS alone.

This study compared intubation when using the Lubo™ collar with MILS to intubation with MILS alone. The primary outcome was equivalence in the time to successful tracheal intubation. As traditional cervical collars have been shown to hinder intubation attempts [1–5], our null hypothesis was that the time to intubation with the Lubo™ would be delayed when keeping the collar in place. The secondary outcomes of the study were to: (1) compare the

success of tracheal intubation, (2) assess the ease of intubation, (3) compare the Cormack-Lehane view of the larynx during laryngoscopy, and (4) assess the degree of dental trauma during laryngoscopy.

Methods:

A prospective, randomized, cross-over equivalence study was performed with ethical approval by the University of Cape Town Human Research Ethics Committee (UCT HREC 394/2020).

Physician anaesthesia providers in an academic department were considered eligible for participation if they had more than one year of full-time anaesthesia experience and had performed more than 200 tracheal intubations during their careers. After written informed consent, participants were shown a presentation highlighting the application and clinical relevance of the Lubo ^{TM} collar, and a practical demonstration was performed. Participants then each performed two manikin intubations. In one, the Lubo ^{TM} collar remained in place with MILS applied (Lubo group), and in the other, MILS was maintained with no collar in place (MILS group; standard care). To minimize sampling bias or learning effect, participants undertook each simulation in a computer-generated random order (https://justflipacoin.com). To minimize variability, MILS was provided using a standardized technique by the same trained provider for both attempts.

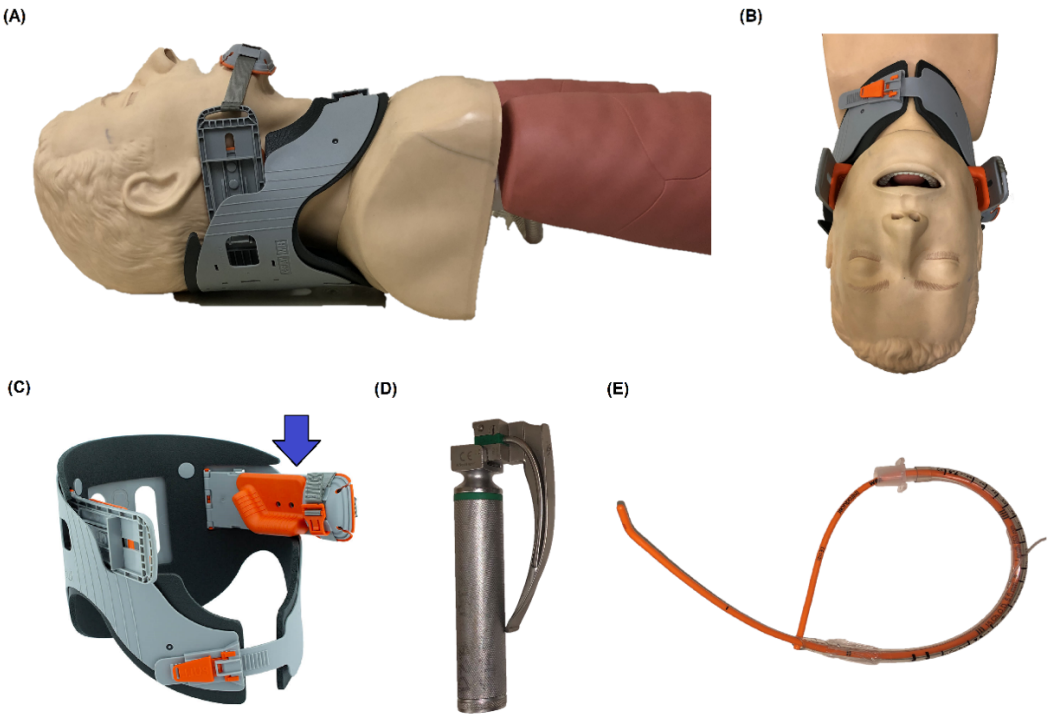

Fig. 1

Equivalence testing was used to compare the mean intubation times between the two groups. Sample size estimation was based on a review of data obtained from a previous study by *Smereka* [2], with the mean time to intubation for the two respective groups estimated at 27 (±7) and 23 (±5) seconds. An equivalence limit of 10 seconds was deemed to be clinically relevant. To achieve 90% power with an equivalence limit of 10 seconds and an alpha error of 0.025 using a two-one-sided test (TOST), we calculated that 59 subjects in a cross-over design would be required. However, a sample size of 80 participants was chosen to account for inaccuracy in sample size estimation, and loss of data pairs due to any failed intubations.

Data were collected over one month at training hospitals associated with the University of Cape Town Department of Anaesthesia and Perioperative Medicine (Groote Schuur, New Somerset, and Red Cross War Memorial Hospitals), Cape Town, South Africa. Participants were afforded two practice attempts with no cervical immobilization before randomization. Participants then performed one attempt at intubation under both scenarios. Intubation times were measured in seconds from the participants' first contact with the laryngoscope until visual confirmation of successful lung inflation, using a digital stopwatch (Volkano Track Series, Volkano, New York, NY, USA). An attempt was deemed a failure if successful lung inflation could not be demonstrated, if oesophageal intubation occurred, or if the intubation attempt exceeded 60 seconds. All intubation attempts were performed on a Laerdal® Airway Management Trainer manikin (Laerdal Medical, Stavanger, Norway). Direct laryngoscopy was performed using a standard size 4 Macintosh laryngoscope. A size 7.5 cuffed endotracheal tube (Curity®, Tyco Healthcare, Mansfield, MA, USA), pre-loaded with a coude-tip introducer utilizing the DuCanto 'D-grip' [19] was used for all attempts at intubation.

Dental trauma was assessed by the surrogate measure of evaluating the number of manikin "teeth clicks'' audible during laryngoscopy (induced by excessive force being applied to the teeth of the manikin). A modified Cormack-Lehane (Yentis and Lee) [20] grading system was used to evaluate the laryngoscopy view reported by participants in both scenarios . Subjective ease of intubation was ranked by each participant using a visual analogue scale (virtual slider), ranked from '0 to 100', with '0' being very easy and '100' being very difficult.

Study data were collected and managed using REDCap (Research Electronic Data Capture)[21,22] electronic data capture tools. Data were then exported into MedCalc, Statistical Software, version 19.6 (MedCalc Software LTD, Ostrend, Belgium; http://www.medcalc.org; 2020) for further statistical analysis. Data were summarized using

descriptive statistics, and the D'Agostino-Pearson test for normality was applied. The primary outcome was assessed using the two-one-sided and paired t-tests.

Results:

Eighty participants completed the study, 42 of whom (52.5%) were female. The mean experience as a full-time anaesthesia provider was 8.9 years (95% CI 7.5 to 10.3). Participant level of qualification is shown in Table 1; more than 75% were highly experienced intubators of a senior registrar or consultant level.

Table 1. Qualification level of participants

Qualification	Number (n=80)	(%)
Consultant	35	43.7
Senior registrar	26	32.5
Junior registrar	12	15.0
Medical officer	7	8.8

Mean difference (95% CI) in intubation time between the two groups was 0.52 seconds (-1.3 to 2.6), falling within the *a priori* equivalence limit of 10 seconds (Figure 2). Further assessment showed no significant difference in intubation time with the Lubo ™ collar (mean [SD] 19.2 [4.5] seconds) compared to the MILS alone group (19.7 [5.2] seconds). One failure (oesophageal intubation) occurred in the Lubo group. As there was no time to tracheal intubation for this participant, they were excluded from analysis of the primary outcome.

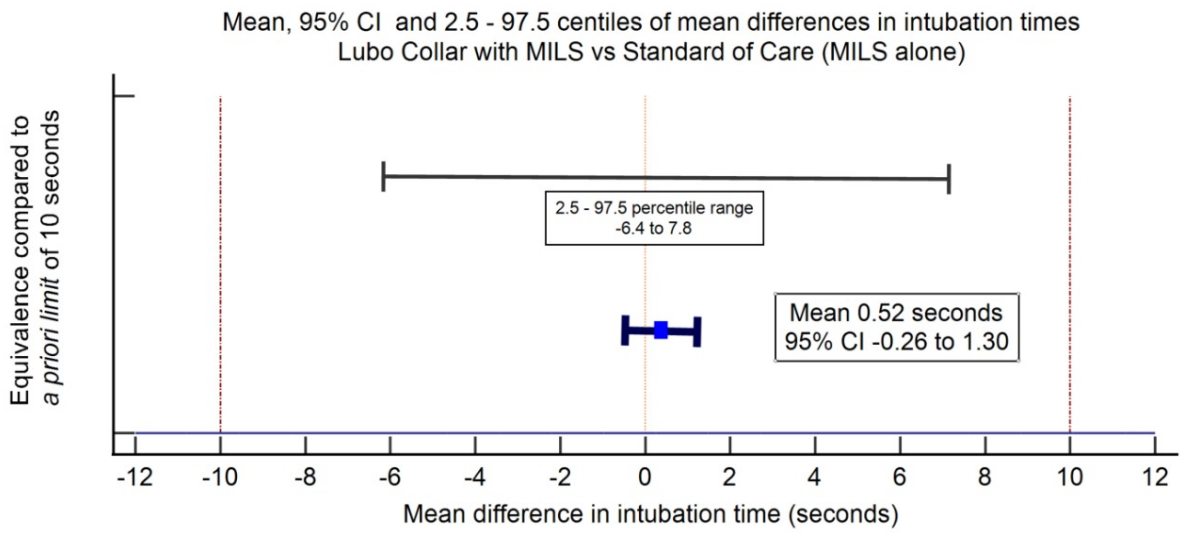

Fig. 2

Table 2. Frequency table

	MILS Alone	Lubo + MILS	Mean difference (95% CI)	p-value
Intubation success, n (%)	80 (100)	79 (98.8)	1.2 (-3.59 to 6.67)	0.33
Intubation time in seconds, mean (SD)	19.74 (5.12)	19.20 (4.51)	0.52 (-1.30 to 0.26)	0.19
Ease of intubation [0-100], median (IQR)	40.5 (20-53)	32 (18-55)	1.2 (-3.45 to 5.78) [Mean 38.1 vs 36.9]	0.62
Number of teeth clicks (%)				
0	65 (81.2)	69 (86.2)		
1	7 (8.8)	9 (11.3)		
2	8 (10)	0 (0)		
3	0 (0)	1 (1.3)		
4	0 (0)	1 (1.3)		
Cormack-Lehane Grade (%)				
1	14 (17.5)	24 (30)		
2a	40 (50)	32 (40)		
2b	21 (26.2)	18 (22.5)		
3	5 (6.2)	6 (7.5)		
4	0 (0)	0 (0)		

Secondary outcomes are depicted in Table 2. The overall success rate was 98.8% in the Lubo group and 100% in the MILS group. As noted above, the failure in the Lubo group involved an oesophageal intubation.

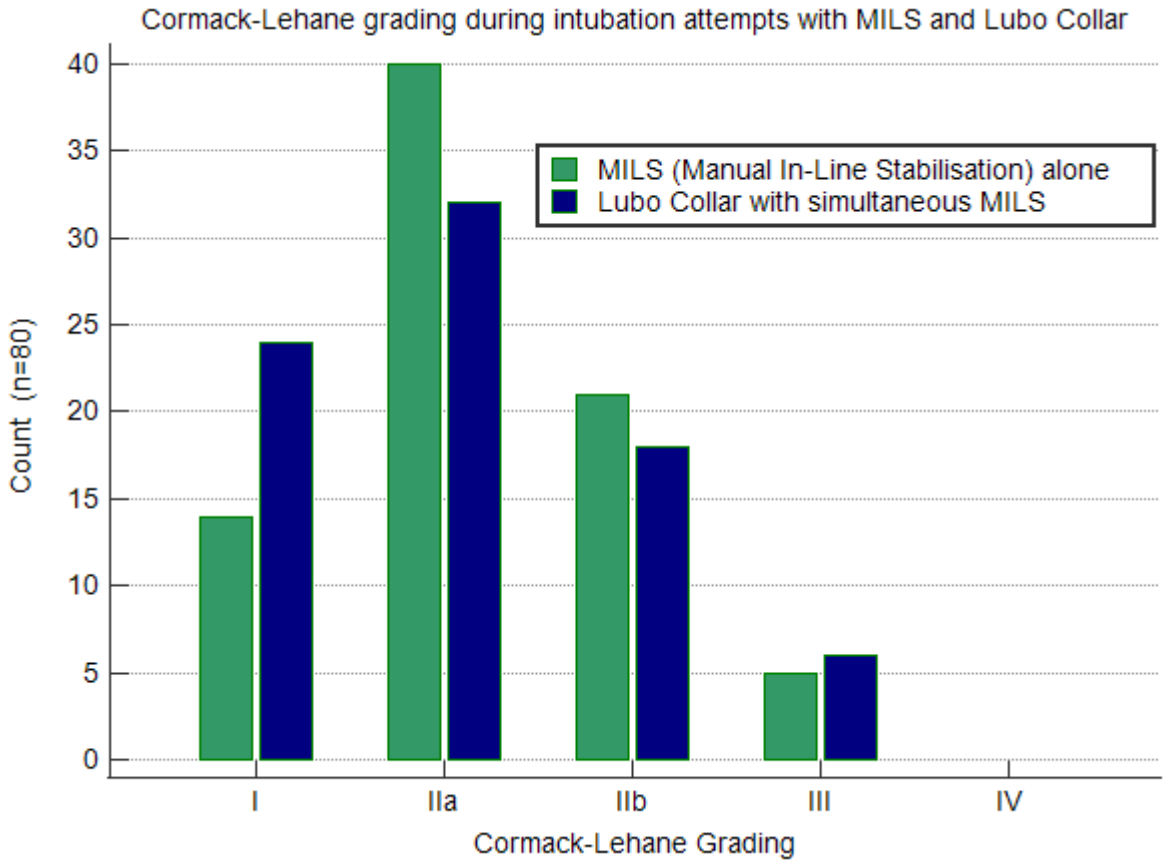

Fig. 3

Adequate laryngoscopy views (Cormack-Lehane grades I to IIb) were equivalent between groups (Lubo 92.5% versus MILS alone 93.7%). However, there were more Cormack-Lehane grade I views in the Lubo group (30% compared to 17.5%). No grade IV views were reported in either scenario. (Figure 3)

The ease of intubation is depicted in Figure 4. In the MILS alone scenario, participants reported ease of intubation with a median of 40.5/100 (IQR 20-53). In the Lubo scenario, ease of intubation with a median of 32/100 (IQR 18-55) was reported. There was no observable trend in ease of intubation with either device at any level of provider experience.

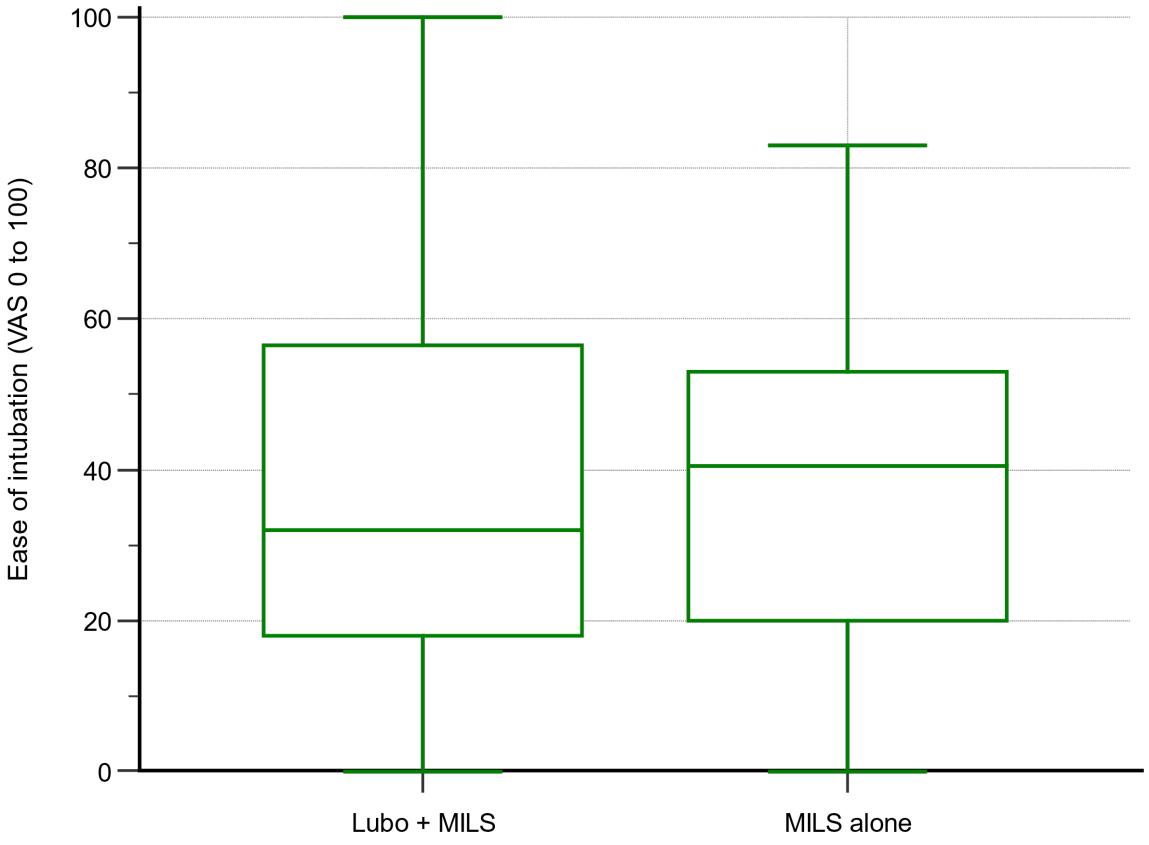

Fig. 4

Discussion:

This study suggests that the time to successful manikin intubation with the Lubo ™ cervical collar with MILS is equivalent to intubation with MILS alone. Therefore, it can be extrapolated that the Lubo ™ collar provides similar intubating conditions to manual in-line stabilization in a manikin. Further study will be required to identify whether this translates to clinical practice.

The secondary outcomes suggest further equivalence. The combined number of Cormack-Lehane grade I and IIa views are comparable in both scenarios, with no grade IV views produced in either scenario. It is interesting to note that there was a larger proportion of grade I views in the Lubo group, which may be related to the jaw-thrust mechanism or the anterior portion of the collar applying external force on the larynx of the manikin, akin to external laryngeal manipulation often used to improve view during intubation. Whether this would translate to clinical practice is purely speculative.

A limitation of this study is that tracheal intubations were not performed on live patients. The Lubo ™ collar is a novel device, and studies examining its effects in clinical practice are limited.

Therefore, its application on a patient-based sample group with limited prior evidence of its effect on the invasive procedure of endotracheal intubation was not ethically feasible. The positive attributes to performing a manikin-based study are that the conditions surrounding each intubation attempt are easily reproducible in a safe and controlled environment.

Indirect laryngoscopy may have favorable advantages over direct laryngoscopy in the context of cervical motion restriction. Video laryngoscopy has been shown to produce better views of the glottic opening and faster intubation times than direct laryngoscopy, with no significant difference in intubation success rates or incidence of aspiration, hypoxia and mortality [2,23–27] Intubation using a lighted intubating stylet, video laryngoscopy and fibre optic intubation have been shown to cause less cervical motion and create better views of the larynx [28–31]. However, these devices are often costly, require additional expertise and training and are seldom available in the often resource-limited and prehospital setting. Direct laryngoscopy is widely available and remains common practice and was thus chosen as the most appropriate modality to test the intubation with the Lubo ^{TM} collar.

The authors had concerns about the potential for cervical motion upon release of the Lubo ^{TM} chin strap, as this component contributes to the collar's ability to provide motion restriction. It is for this reason manual in-line stabilization was applied for all intubations involving the Lubo ^{TM} collar. The time taken to release the chin strap was not included in the measured time to intubation. This additional step would not have had any likely effect on the overall success of intubating but may have lengthened the time to intubation in this group.

It was difficult to draw any conclusions about the significance of any forces transferred to the cervical spine when removing a semi-rigid cervical collar due to the paucity of evidence, with only small studies in cadaveric models [10,17]. Subsequent to the performance of our study, Jung et al. compared the Lubo ^{TM} to two traditional rigid collars, measuring cervical motion restriction. In this setting, although all collars showed some movement, the Lubo ^{TM} performed the poorest in limiting flexion [17].

A further limitation is that this study did not examine the motion of cervical segments during laryngoscopy. This is beyond the scope of this study, and thus we do not make any inferences regarding the degree of cervical motion restriction provided by the Lubo ^{TM} collar during intubation.

In conclusion, in a manikin simulation model, intubation using the Lubo ^{TM} cervical collar and manual in-line stabilisation during tracheal intubation was equivalent to MILS alone. Further studies of the clinical efficacy of the device are required.

Dissemination of Results:

The results of this study were shared with staff members at the Department of Anaesthesia and Perioperative Medicine at the University of Cape Town, South Africa.

Authors Contribution:

Authors contributed as follow to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content:

DB contributed 40%, RJ contributed 10%, KB contributed 10%, RH contributed 40%,

All authors approved the version to be published and agreed to be accountable for all aspects of the work.

Declaration of competing interest:

The manuscript will be submitted for a Master of Medicine (MMed) dissertation at the University of Cape Town, South Africa. Lubo ™ collars were provided at no cost by Supra Healthcare (Pty) Ltd (Suprahealthcare, Avacare Health, Gauteng, South Africa). No external funding was received, and the authors received no remuneration for this study. The authors have no conflicts of interest.

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[31] Maruyama K, Yamada T, Kawakami R, Hara K. Randomized cross-over comparison of cervical-spine motion with the AirWay Scope or Macintosh laryngoscope with in-line stabilization: A video-fluoroscopic study. British Journal of Anaesthesia 2008;101:563–7. https://doi.org/10.1093/bja/aen207.

Captions:

Fig. 1. (A) Manikin with Lubo ™ applied, (B) Lubo ™ with chin strap released, (C) Jaw-thrust mechanism, bilateral ridges facilitate anterior displacement of the mandible, (D) Macintosh laryngoscope, (E) Endotracheal tube pre-loaded with a gum-elastic bougie utilizing the DuCanto 'D-grip' [19]

Fig. 2. Mean difference in intubation times of both scenarios

Fig. 3. Modified Cormack-Lehane grade view for Lubo with MILS scenario versus MILS alone scenarios

Fig. 4. Box and whisker plot showing ease of intubation. Subjective ease of intubation was ranked by each participant using a visual analogue scale (virtual slider), ranked from '0 to 100', with '0' being very easy and '100' being very difficult.

Appendix 1: Human Research Ethics Committee approval

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

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

08 September 2020

HREC/REF:394/2020

A/Prof A Hofmeyr
Department of Anaesthesia & Perioperative Medicine
Ward D -23 NGSH
Email: ross.hofmet@uct.ac.za
Student: dinell.behari@gmail.com

Dear A/Prof Hofmeyr

Project Title: INTUBATION WITH SPINAL MOTION RESTRICTION USING THE LUBO™ CERVICAL COLLAR-MMED CANDIDATE-DR DINELL BEHARI

Thank you for your letter to the Faculty of Health Sciences Human Research Ethics Committee dated 31 August 2020.

The HREC has approved your request to re-open the study to recruitment.
Please supply feedback every 2 weeks for 8 weeks.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR MARC BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

HREC/ref:394/2020se

Appendix 2: Electronic consent form and data capture tool

Confidential

Lubo Manikin Study

Information and Informed Consent

Thank you for considering taking part in this manikin study. The investigative team is as follows:

MMed Candidate:
Dr Dinell Behari
Principle Investigator:
Prof Ross Hofmeyr
Co-Authors and other contributors:
Dr Kobus Bergh, Dr Rudhir Jaga
Organization:
UCT Department of Anaesthesia and Perioperative Medicine

Part I: Information

Thank you for participating in this study investigating the Lubo collar. The Lubo collar is a new semi-rigid cervical collar which has been developed to prevent damage to the spinal cord in patients with neck injuries. It is a unique device able to immobilise the neck and cervical spine while also able to provide a jaw thrust, maintaining airway patency. The purpose of this study is to evaluate the ability of the device to facilitate intubation by comparing it to manual in-line stabilization. Participation in this research study is completely voluntary. Please feel free to ask questions at any time and we will take time to answer them.

Study procedures/schedule

If you agree to participate in this study, you will perform two intubations on a manikin, one with manual in-line stabilization alone (MILS) and one with the Lubo cervical collar applied with MILS. You will be afforded two practice attempts. The intubation times will be measured and you will be asked a few questions regarding both scenarios. Confidentiality of all participants will be maintained throughout. This is a non-competitive exercise and is purely for research purposes.

Contact information for questions and concerns:

Dr Rudhir Jaga - Tel:+27823728251, Email: rudhir.jaga@gmail.com

Dr Dinell Behari – Tel:+27833032317, Email: dinell.behari@gmail.com

The UCT's Faculty of Health Sciences Human Research Ethics Committee can be contacted on 021 406 6338 should you have any concerns or questions about your rights or welfare as a participant on this research study.

The investigators will guide you through the process of capturing the information below.

Please indicate the name of the investigator who has explained the study and answered any questions regarding participation and consent to you:	◯ Dr Dinell Behari ◯ Dr Rudhir Jaga ◯ Dr Kobus Bergh ◯ Prof Ross Hofmeyr
COVID screening completed?	◯ Yes ◯ No
Have you performed at least 200 tracheal intubations on live patients during your career?	◯ Yes ◯ No
How many years of full-time anaesthesia training and/or experience have you completed?	_____ (This includes full-time anaesthesia experience or training as an MO or registrar.)

Do you consent to participation in this study?	◯ YES - I consent to participate ◯ NO - I *DO NOT* consent to participate
Please sign on the screen to confirm your consent to participate:	_____

Participant information

This information is for our records only, and to allow us to contact you for follow-up if needed. It will not be shared with any outside parties.

Surname	_____
First Name	_____
Age today	_____
Gender	◯ Male ◯ Female ◯ Other
Level of qualification	◯ Medical officer ◯ Junior registrar (< 2 years) ◯ Senior registrar (>2 years) ◯ Consultant
Email address	_____
Contact telephone number	_____
Would you like to receive results of this study after it has been completed?	◯ Yes ◯ No

Randomisation & Data Collection

Perform the coin-flip randomisation Use a physical coin, or go to justflipacoin.com If the coin flip is HEADS, perform the intubation with the Lubo collar and MILS first. If the coin flip is TAILS, perform the intubation with MILS alone first	◯ Heads ◯ Tails

Number of "teeth clicks" with the Lubo collar	◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
Cormack-Lehane grade achieved with the Lubo collar	◯ Cormack-Lehane 1 ◯ Cormack-Lehane 2a ◯ Cormack-Lehane 2b ◯ Cormack-Lehane 3 ◯ Cormack-Lehane 4
Lubo collar intubation successful?	◯ Success ◯ Failure (Failure is defined as oesophageal intubation (no lung inflation when ventilating with BVMR) or intubation time greater than 60 seconds)
Lubo collar intubation time	_____ (Please enter in seconds to one decimal place)
Rank the ease of intubation with the Lubo collar	100 = Extremely difficult 0 = Very easy 50 = Normal *(Place a mark on the scale above)*
Number of "teeth clicks" with the MILS alone	◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 or more
Cormack-Lehane grade achieved with the MILS alone	◯ Cormack-Lehane 1 ◯ Cormack-Lehane 2a ◯ Cormack-Lehane 2b ◯ Cormack-Lehane 3 ◯ Cormack-Lehane 4
MILS-only intubation successful?	◯ Success ◯ Failure (Failure is defined as oesophageal intubation (no lung inflation when ventilating with BVMR) or intubation time greater than 60 seconds)
MILS only intubation time	_____ (Please enter in seconds to one decimal place)
Rank the ease of intubation with the MILS alone	100 = very difficult 0 = very easy 50 = normal *(Place a mark on the scale above)*

Closing comments	
Which technique was performed FIRST?	◯ Lubo with MILS ◯ MILS alone
Do you have any specific comments?	_____

Appendix 3: AFJEM reviewers' comments

From: "Stevan Bruijns" <em@editorialmanager.com>
Subject: Decision on submission to African Journal of Emergency Medicine
Date: 11 April 2022 at 20:02:43 SAST
To: "Dinell Behari" <dinell.behari@gmail.com>
Reply-To: "Stevan Bruijns" <stevan.bruijns@afjem.com>

Ref.: Ms. No. AFJEM-D-22-00032
Intubation during spinal motion restriction using the Lubo TM cervical collar - a manikin simulation study
African Journal of Emergency Medicine

Dear Dr Behari,

Thank you for submitting your manuscript to African Journal of Emergency Medicine. I have received comments from reviewers on your manuscript. Your paper should become acceptable for publication pending suitable minor revision and modification of the article in light of the appended reviewer comments.

When resubmitting your manuscript, please carefully consider all issues mentioned in the reviewers' comments, outline every change made point by point, and provide suitable rebuttals for any comments not addressed.

Please use the manuscript template to structure your manuscript.

To submit your revised manuscript go to https://www.editorialmanager.com/afjem/ and log in as an Author where you will see a menu item called 'Submission Needing Revision'.

Please resubmit your manuscript by May 02, 2022.

I look forward to receiving your revised manuscript.

Kind Regards,

Stevan Bruijns
Editor-in-Chief
African Journal of Emergency Medicine
Comments from the Editors and Reviewers:

Editor: Please also review the references for formatting and completeness.

Reviewer #1: Many thanks for giving me the opportunity to review this manuscript. I have suggested some moderate changes below.

Minor changes:
"Click or tap here to enter text".- Line 20 page 5

- Consider restructure of the 2nd and 3rd paragraphs. As currently reads you recommend not using collars during intubation and then tell us the problems if you did. Could you reverse this logic?

Title : Please consider: Time to intubation during spinal motion restriction using the Lubo TM cervical collar - a manikin simulation study (or similar)

Background:

Paragraph 4 - do we know collar removal for intubation leads to meaningful additional movement? Develop this hypothesis and reference.

Include any references related to the qualities / properties of Lubo collar in movement restriction.

Can you explain why you performed and equivalence and not a superiority trial?

Can you provide broader context to this statement : We hypothesized that the time to intubation with the Lubo TM would be delayed due to the physical limitations of keeping the collar in place.

Results:

I found figure 2 difficult to interpret. Could you consider doing a direct comparison (and showing the 95%CI) of the two methods in this figure instead? With the x axis being intubation time?

Please could you add explanation how you dealt with the "time" associated with the intubation failure - this seems to have been excluded from your analysis completely? (perhaps consider in discussion as well)

Figure 4 - please add an explanatory note (or include in a figure label which seems to be missing) explaining the type of chart this is

Discussion:

"Therefore, it can be extrapolated that the Lubo TM collar provides similar intubating conditions to manual in-line stabilization" this statement is perhaps overly strong - how good is the literature in comparing manikin performance to real life performance?

Please could you add in an appropriate area of the manuscript the funding source - particularly if there was a supply of collars etc from the Lubo manufacturer?

Reviewer #2: My compliments to the authors for a well-designed study with a well written manuscript. The manuscript is clear on the aims of the study, the methodology is clearly described and appropriate, the primary and secondary end points as well as the description of the results is clear and concise. The statistical analysis methods used are appropriated and aligned too norms for the study design in question. The conclusions of the study follows on clearly from the results. Some improvement in the reporting of the statistical analysis may be helpful, more details below.

Below a few comments for the authors which may clarify some areas or enhance some elements of the manuscript for the reader.

1. With regards to the randomization of attempts, described on 5 line 14. It may be helpful for the reader if the authors clarified that the randomization in question relates to the randomisation of the type of intubation attempt (MILNS or Lubo + MILNS). Some readers, not familiar with the cross-over trial design may not pick up on this nuance from the current explanation in the manuscript.

2. With regards to the use of MILNS in the study. It would be useful to describe whether MILNS was performed by the same person for all intubation attempts in the study. As the provider maintaining MILNS may vary in the degree to which they restrict movement during laryngoscopy this may have an influence on the grade of view or perceived intubation difficulty outcomes. As a reader it would also be useful if the authors can give their view on how this may have influenced the observed difference in intubation difficulty reported in this study and whether the absence of a collar in the MILNS only group may have prompted a difference in how MILNS was maintained during laryngoscopy. Another element to which the authors views may be helpful is whether the jaw thrust design feature of the Lubo collar may have influenced difficulty of laryngoscopy in any way.

3. In the study only dental trauma is included as an adverse event. In the limitation section the author addresses the issue of cervical segment movement (page, 11 line 4) and forces applied to the cervical spine. Considering that this is a manikin study and the measurement of cervical segment movement and forces is not possible, and this point is taken. It would be helpful to include a discussion as to why the observation of other movements such as externally observable neck extension, flexion or rotation during the intubation attempts were not included as an adverse event? One of the reasons for intubation with MILNS or both Lubo + MILNS methods after all is to prevent this type of movement as well, and this could be observed and may have been useful in the comparison between the two methods as a proxy

measure for possible cervical spine segment movement. Reference to pervious research addressing the use of such proxies may also be helpful.

4. In the manuscript the authors report the level of perceived difficulty and the grade of view achieved by participants. As illustrated in figures 3 & 4, the two methods are shown to be equivalent, however it would be useful for the authors to comment on whether any participants (who are acting as their own controls) had significant variation in difficulty or grade of view level when going from one technique to the other, and whether there was any relationship to experience level. This may be useful in the analysis as the sample of participants was somewhat biased towards more experienced providers as shown in table 1. The reviewers concern is that the current analysis does not address whether some individual participants had difficulty with for instance the MILNS only technique and found the LUBO+MILNS easier while other participants experienced the opposite, creating the appearance of equivalence overall for the perceived difficulty or grade of view outcomes, but not reflecting the experiences of some individual participants or a particular subgroup such as experience level for instance. The reported IQR values for perceived difficulty for instance does show some variation between the two methods, but it does not clarify whether this variation occurred for individual participants or between participants. It would be helpful if the authors could address this observation and provide their views as well.

5. It would be helpful to report all values for statistical significance testing. 95% Confidence intervals for the primary outcome is reported for comparison however none are reported for secondary outcome measure comparisons. If it is the case that these are non-significant (implying equivalence) it would still be important to show the test results to substantiate the claim of equivalence. As is the reader is left to deduce this from the data without the benefit of seeing the statical results of the t-tests which where performed.

6. The authors state no conflict of interest in the manuscript but there is no declaration of the funding sources for this study in the manuscript. As the study relates to some of the marketing claims of the Lubo product made by the manufacturer it would be appropriate for the authors to declare the funding sources for the project explicitly.

Appendix 4: Authors' response to reviewers

Ref.: Ms. No. AFJEM-D-22-00032

Intubation during spinal motion restriction using the Lubo TM cervical collar - a manikin simulation study

African Journal of Emergency Medicine

Dear colleagues,

Thank you for your time and effort in reviewing the above manuscript and for insightful comments and suggestions. We have carefully assessed the reviewers' recommendations and believe that the manuscript is strengthened as a result. I include the reviewers' comments below with our responses and relevant changes in the revised manuscript.

Comments from the Editors and Reviewers:

Editor: Please also review the references for formatting and completeness.

> Thank you for picking up on the formatting errors – we have corrected in the revised submission.

Reviewer #1: Many thanks for giving me the opportunity to review this manuscript. I have suggested some moderate changes below.

> Thank you for your useful comments. We have detailed the responses/changes below.

Minor changes:
"Click or tap here to enter text".- Line 20 page 5

> Thank you – we are not sure how this slipped into the document and have removed the text.

- Consider restructure of the 2nd and 3rd paragraphs. As currently reads you recommend not using collars during intubation and then tell us the problems if you did. Could you reverse this logic?

> Your comment is very useful. We have restructured these two paragraphs to make the argument follow more logically, with minor edits to the grammar to make it read more easily as well.

Title : Please consider: Time to intubation during spinal motion restriction using the Lubo TM cervical collar - a manikin simulation study (or similar)

> Thank you for the suggestion, which we have debated extensively. We would prefer to keep the original title rather than specifically highlight only the primary outcome, as the study speaks to several aspects of intubation.

Background:

Paragraph 4 - do we know collar removal for intubation leads to meaningful additional movement? Develop this hypothesis and reference.

> There are limited formal studies which specifically address movement *during* collar application and/or removal, but this has indeed been documented. The existing reference (Prasarn *et al.*) has been supplemented with a further paper (James *et al.*) which described movements during collar application using four different collars.

Include any references related to the qualities / properties of Lubo collar in movement restriction.

> At the time of performing the study, there were no published trials specifically addressing the immobilisation properties of the Lubo. However, Jung *et al*. have subsequently published a comparative trial. We have referenced this in the 4th paragraph and included a brief synopsis in the discussion.

Can you explain why you performed and equivalence and not a superiority trial?

> We are of the opinion that the collar is unlikely to *improve* intubating conditions compared to MILS alone, but we hypothesized that keeping the collar in place during intubation would not *worsen* conditions. This is in contrast to doing so with a standard/traditional rigid collar in place. As we were trying to demonstrate equivalence to intubation with MILS alone, and equivalence rather than superiority trial design is the most appropriate. For more details and a good reference on equivalence and non-inferiority trial design and reporting, we found the 2011 paper by Walker and Nowacki very useful (https://dx.doi.org/10.1007%2Fs11606-010-1513-8)

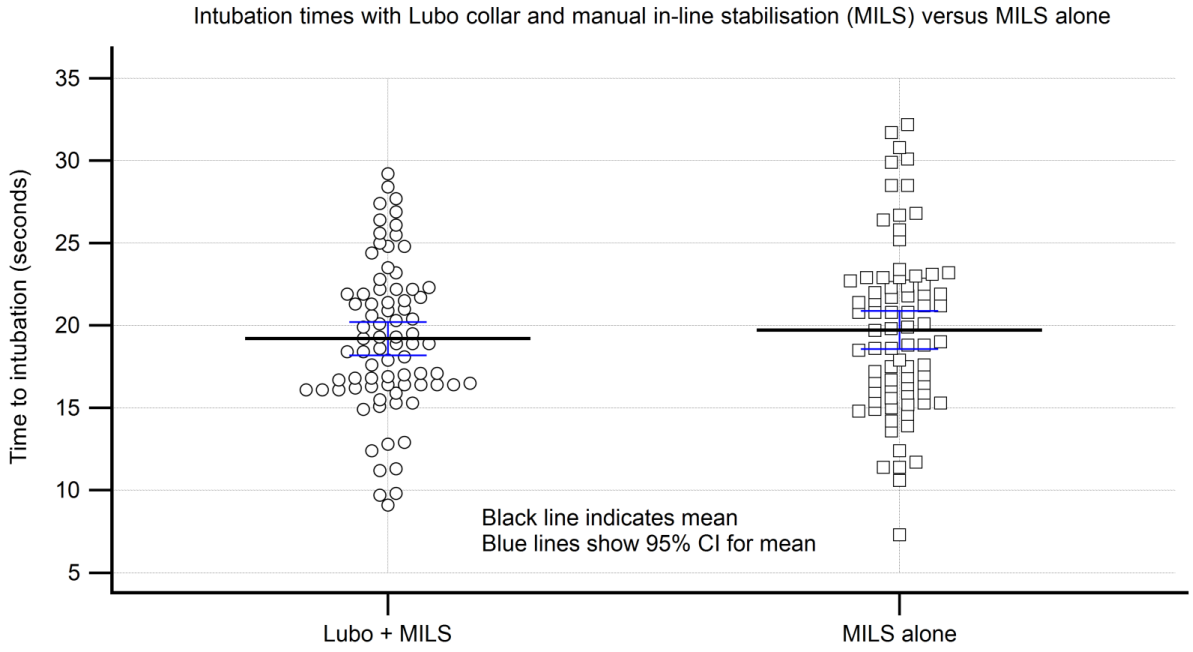
Can you provide broader context to this statement : We hypothesized that the time to intubation with the Lubo TM would be delayed due to the physical limitations of keeping the collar in place.

Thank you for highlighting the fact that this argument can be stated more clearly – we have added reference to the earlier statements regarding the effect of traditional cervical collars on intubation to clarify, and stated that the delay intubation time was in fact our null hypothesis.

Results:

I found figure 2 difficult to interpret. Could you consider doing a direct comparison (and showing the 95%CI) of the two methods in this figure instead? With the x axis being intubation time?

The graph supplied as Figure 2 is the appropriate type of plot for reporting results of an equivalence study. The reference provided in the earlier response about trail design (https://dx.doi.org/10.1007%2Fs11606-010-1513-8, see above) has good examples of how to interpret these plots. For the reviewer's sake, we have also created a direct comparison plot, which is shown below. While this is not the ideal way of reporting the data, if the editor feels that it is a useful indication of the data spread, this could be included as a supplementary figure:



Please could you add explanation how you dealt with the "time" associated with the intubation failure - this seems to have been excluded from your analysis completely? (perhaps consider in discussion as well)

Thank you for highlighting this; the exclusion was noted under the secondary outcomes, and thus might have been missed/unclear. We have moved this to the primary outcome paragraph and clarified for emphasis.

Figure 4 - please add an explanatory note (or include in a figure label which seems to be missing) explaining the type of chart this is

> Description of the chart type and how the ease of intubation was graded has been added.

Discussion:

"Therefore, it can be extrapolated that the Lubo TM collar provides similar intubating conditions to manual in-line stabilization" this statement is perhaps overly strong - how good is the literature in comparing manikin performance to real life performance?

> This is a very valid comment. We have added the phrase "*…in a manikin*" and stated explicitly that further work is required to see whether this translates to clinical practice.

Please could you add in an appropriate area of the manuscript the funding source - particularly if there was a supply of collars etc from the Lubo manufacturer?

> Thank you for highlighting this – we have added a statement to this effect and clarifying the provision of collars but no other funding.

Reviewer #2: My compliments to the authors for a well-designed study with a well written manuscript. The manuscript is clear on the aims of the study, the methodology is clearly described and appropriate, the primary and secondary end points as well as the description of the results is clear and concise. The statistical analysis methods used are appropriated and aligned too norms for the study design in question. The conclusions of the study follows on clearly from the results. Some improvement in the reporting of the statistical analysis may be helpful, more details below.

> Thank you very much for the kind and supportive comments.

Below a few comments for the authors which may clarify some areas or enhance some elements of the manuscript for the reader.

1. With regards to the randomization of attempts, described on 5 line 14. It may be helpful for the reader if the authors clarified that the randomization in question relates to the randomisation of the type of intubation attempt (MILNS or Lubo + MILNS). Some readers, not familiar with the cross-over trial design may not pick up on this nuance from the current explanation in the manuscript.

Thank you – we have rephrased to try and clarify this part of the design.

2. With regards to the use of MILNS in the study. It would be useful to describe whether MILNS was performed by the same person for all intubation attempts in the study. As the provider maintaining MILNS may vary in the degree to which they restrict movement during laryngoscopy this may have an influence on the grade of view or perceived intubation difficulty outcomes.

This is a useful critique. We have added a statement clarifying that the person providing MILS was the same, trained provider for both scenarios.

As a reader it would also be useful if the authors can give their view on how this may have influenced the observed difference in intubation difficulty reported in this study and whether the absence of a collar in the MILNS only group may have prompted a difference in how MILNS was maintained during laryngoscopy.

The MILS technique used was standardized to reduce variability as far as possible. We have made sure that this is stated explicitly in the text.

Another element to which the authors views may be helpful is whether the jaw thrust design feature of the Lubo collar may have influenced difficulty of laryngoscopy in any way.

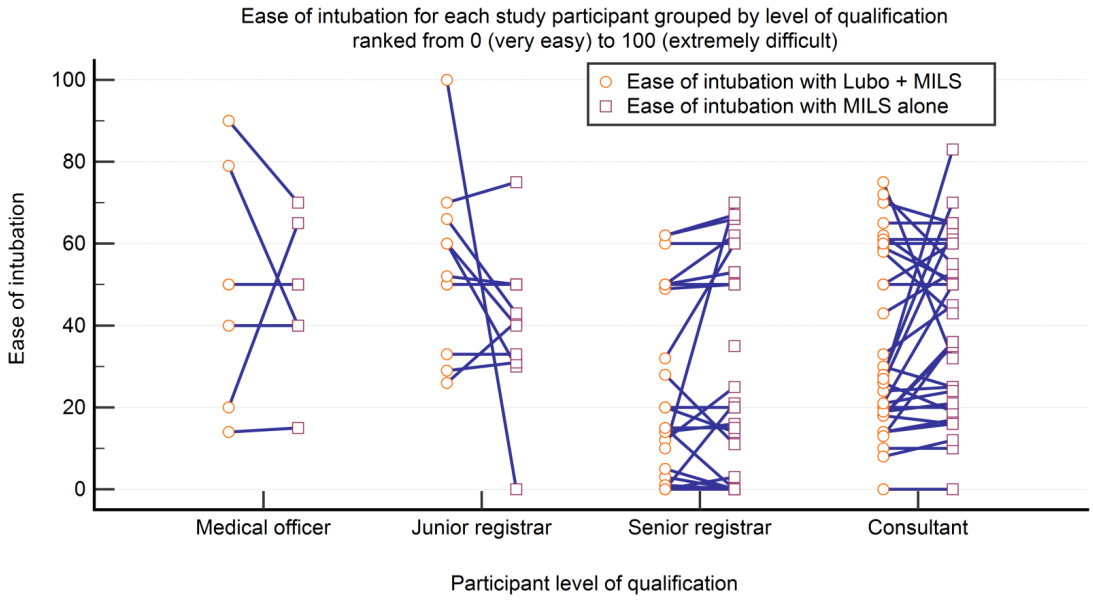
We had, in fact, made a comment about this in an earlier version of the manuscript, but removed it due to the speculative nature. However, we have now re-introduced this concept in the discussion, with a caveat that it may not translate to clinical practice: *"It is interesting to note that there was a larger proportion of grade I views in the Lubo group, which may be related to the jaw-thrust mechanism or the anterior portion of the collar applying external force on the larynx of the manikin, akin to external laryngeal manipulation often used to improve view during intubation. Whether this would translate to clinical practice is purely speculative."*

3. In the study only dental trauma is included as an adverse event. In the limitation section the author addresses the issue of cervical segment movement (page, 11 line 4) and forces applied to the cervical spine. Considering that this is a manikin study and the measurement of cervical segment movement and forces is not possible, and this point is taken. It would be helpful to include a discussion as to why the observation of other movements such as externally observable neck extension, flexion or rotation during the intubation attempts were not included as an adverse event? One of the reasons for intubation with MILNS or both Lubo + MILNS methods after all is to prevent this type of movement as well, and this could be observed and may have been useful in the comparison between the two methods as a proxy measure for possible cervical spine segment movement. Reference to pervious research addressing the use of such proxies may also be helpful.

We agree that measuring the motion restriction with the collar and with MILS alone is useful information. This, however, was beyond the scope of the present study. As per the response to Reviewer 1 above, we have included reference to a recently published paper looking at the quality of motion restriction with the Lubo versus other collars, and included a comment on this in the discussion.

4. In the manuscript the authors report the level of perceived difficulty and the grade of view achieved by participants. As illustrated in figures 3 & 4, the two methods are shown to be equivalent, however it would be useful for the authors to comment on whether any participants (who are acting as their own controls) had significant variation in difficulty or grade of view level when going from one technique to the other, and whether there was any relationship to experience level. This may be useful in the analysis as the sample of participants was somewhat biased towards more experienced providers as shown in table 1. The reviewers concern is that the current analysis does not address whether some individual participants had difficulty with for instance the MILNS only technique and found the LUBO+MILNS easier while other participants experienced the opposite, creating the appearance of equivalence overall for the perceived difficulty or grade of view outcomes, but not reflecting the experiences of some individual participants or a particular subgroup such as experience level for instance. The reported IQR values for perceived difficulty for instance does show some variation between the two methods, but it does not clarify whether this variation occurred for individual participants or between participants. It would be helpful if the authors could address this observation and provide their views as well.

We have interrogated the data to see if there is a specific pattern of ease/difficulty that emerges across different levels of experience/qualification, and reported it on a per-participant basis in the paired samples dot-and-line graph below. As the reviewer will observe, there is no clear trend in any of the groups. Thus, while individual participants may have found one or the other technique easier, overall and at an individual level this does not appear to be related in any way to their level of experience. We have added a sentence to this effect in the results. Again, at the editor's preference, we could consider adding this as a supplementary figure:



5. It would be helpful to report all values for statistical significance testing. 95% Confidence intervals for the primary outcome is reported for comparison however none are reported for secondary outcome measure comparisons. If it is the case that these are non-significant (implying equivalence) it would still be important to show the test results to substantiate the claim of equivalence. As is the reader is left to deduce this from the data without the benefit of seeing the statical results of the t-tests which where performed.

> Thank you for the suggestion. We have added the mean differences and 95% CI's in the frequency table, as well as the p-values which show no significant differences. We caution the reader to remember that the lack of a significant difference does not imply equivalence.

6. The authors state no conflict of interest in the manuscript but there is no declaration of the funding sources for this study in the manuscript. As the study relates to some of the marketing claims of the Lubo product made by the manufacturer it would be appropriate for the authors to declare the funding sources for the project explicitly.

> Thanks for raising this point – we have included an explicit statement as per our response to Reviewer 1.

#AU_AFJEM#

To ensure this email reaches the intended recipient, please do not delete the above code

Appendix 5 : AFJEM guide to authors

AFRICAN JOURNAL OF EMERGENCY MEDICINE

TABLE OF CONTENTS

AUTHOR INFORMATION PACK

ISSN: 2211-419X

The *African Journal of Emergency Medicine* (*AfJEM*) is the official journal of the African Federation for Emergency Medicine. It is an Africa-centric, peer-reviewed journal aimed in particular at supporting emergency care across, you guessed it, Africa. *AfJEM* publishes original research, reviews, brief reports of scientific investigations, case reports as well as commentary and correspondence related to topics of scientific, ethical, social and economic importance to emergency care in Africa. Articles will be of direct importance to African emergency care, but may have originated from elsewhere in the world.

AfJEM publishes manuscripts of international quality. This is ensured through a process of rigorous peer-review (see below) where manuscripts are evaluated for

accuracy, novelty and importance. It is however recognised that African researchers in emergency care are disadvantaged in the available range of journals into which they can publish their work. The editorial team is aware that this is due to many reasons, including that developing world topics are often considered too basic for western Emergency Medicine journals, or that topics are concerned with conditions which are largely irrelevant to those audiences. Furthermore, the quality of submitted manuscripts is often lower than acceptable international journal standards due to inadequate research training. *AfJEM* is dedicated to support all authors who wish to make an attempt at publication on an African Emergency care topic. In order to maintain and produce a high quality, international standard Emergency Medicine journal, *AfJEM* has devised *Author Assist*. For more detail go to http://www.afjem.com/author-assist.html.

AfJEM is uniquely tailored to the needs and requirements of emergency care workers dedicated to improving emergency medicine in Africa. *AfJEM* specifically aims to address resource limitations as it pertains to the African continent. It will be ideal reading material for physicians, nurses and pre- hospital care workers wishing to improve their knowledge on general emergency medicine, trauma care, paediatrics, injury and disease prevention, service improvement, policy and ethics, disaster preparedness and response, and all other aspects of emergency care. In keeping with the African Federation for Emergency Medicine, it is our aim to be recognised as the international voice of quality emergency medical care in Africa.

ABSTRACTING AND INDEXING

PubMed CentralScopusEBSCOhostEmbaseEmerging Sources Citation Index (ESCI)Directory of Open Access Journals (DOAJ)South African Department of Higher Education and Technology African Index Medicus

EDITORIAL BOARD

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GUIDE FOR AUTHORS

INTRODUCTION

The African Journal of Emergency Medicine (AfJEM, ISSN: 2211-419X) is the official journal of the African Federation for Emergency Medicine. It is an international, peer-reviewed journal aimed in particular at supporting emergency care across Africa. AfJEM publishes original research, reviews, brief reports of scientific investigations, case reports as well as commentary and correspondence related to topics of scientific, ethical, social and economic importance to emergency care in Africa. Articles will be of direct importance to African emergency care, but may have

originated from elsewhere in the world.

TYPES OF ARTICLES

Original Article: Original studies of basic or clinical investigations in areas relevant to emergency medicine. Reference to the relevance of the research in a resource poor setting is essential and should be alluded to in the discussion section. References and a structured abstract (see Preparation below) are required. Maximum length: 3,000 words, 5 tables and/or figures, plus the abstract (300 words) and references (max 50). The checklists found on the following websites should be used to structure your manuscript (a copy of the checklist indicating which elements of the reporting format you adhered to, a signed conflict of interest form - see below- should be submitted with your manuscript):

a. For randomised control trials: http://www.consort-statement.orgb. For cohort, case-control, and cross-sectional studies: http://www.strobe-statement.org/ c. All other studies: http://www.equator-network.org/

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[dataset] [6] Oguro M, Imahiro S, Saito S, Nakashizuka T. Mortality data for Japanese oak wilt disease and surrounding forest compositions, Mendeley Data, v1; 2015. https://doi.org/10.17632/ xwj98nb39r.1.Note shortened form for last page number. e.g., 51–9, and that for more than 6 authors the first 6 should be listed followed by 'et al.' For further details you are referred to 'Uniform Requirements for Manuscripts submitted to Biomedical Journals' (J Am Med Assoc 1997;277:927–34) (see also Samples of Formatted References).

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Appendix 6 : AFJEM acceptance for publication

Date: Jun 24, 2022
To: "Dinell Behari" dinell.behari@gmail.com
cc: r.pareenargunam@elsevier.com
From: "Stevan Bruijns" stevan.bruijns@afjem.com
Subject: Decision on submission to African Journal of Emergency Medicine

Manuscript Number: AFJEM-D-22-00032R1

Intubation during spinal motion restriction using the Lubo TM cervical collar - a manikin simulation study

Dear Dr Behari,

Thank you for submitting your manuscript to African Journal of Emergency Medicine.

I am pleased to inform you that your manuscript has been accepted for publication.

My comments, and any reviewer comments, are below.
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 you submitting your manuscript to African Journal of Emergency Medicine and hope you will consider us again for future submissions.

Kind regards,
Stevan Bruijns
Editor-in-Chief

African Journal of Emergency Medicine

Editor and Reviewer comments:

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I also believe it might be valuable to include the additional figures in a supplementary file.

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