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Evaluation of the CTrach™—an intubating LMA with integrated fibreoptic system†

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Background. The laryngeal mask airway CTrach™ (CTrach) is a variant of the intubating laryngeal mask airway. It provides visualization of the larynx during intubation and is designed to increase the success rates of ventilation and tracheal intubation.

Methods. Sixty healthy anaesthetized and paralysed patients with normal airways were studied. The success rates of ventilation and intubation using CTrach™ were determined. Laryngeal view scoring ranged from grade I (full view of arytenoids and glottis), II (arytenoids and glottis partly visible), III (view of arytenoids, glottis or epiglottis blurred, or view clear with only epiglottis visible) to IV (no part of larynx identifiable). Adjusting manoeuvres were undertaken to improve the laryngeal view in grades II or worse.

Results. CTrach insertion and ventilation was possible in all patients. Initial views were scored as grade I in 22 (36.7%), grade II in 14 (23.3%), grade III in 7 (11.7%) and grade IV in 17 (28.3%) patients. Adjusting manoeuvres were undertaken in 38 patients with grade II and worse (63.3%), resulting in improved views of grade I in 33 (55.0%), grade II in 18 (30.0%), grade III in 4 (6.7%) and grade IV in 5 (8.3%) patients. Tracheal intubation was successful in 58 (96.6 %) patients at first attempt and in one at second. Tracheal intubation failed once.

Conclusions. In 60 patients with normal airways, the CTrach was used successfully for ventilation, with successful tracheal intubation in 59 patients. Tracheal intubation can be successful despite grade III or IV views.

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The Intubating Laryngeal Mask Airway™ (ILMA) was invented in 1997 as a further development of the classic laryngeal mask airway (cLMA). It was designed for use as a ventilatory device, and, in conjunction with a dedicated tracheal tube (TT), as a conduit for 'blind' tracheal intubation (TI).[1] Some authors have criticized the technique of 'blind' TI via the ILMA (i.e. without a view of laryngeal structures) because of the potential risk of arytenoid trauma or oesophageal placement.[2] Therefore, TI is often performed with the help of a flexible bronchoscope (FB), using the cLMA or the ILMA as a conduit for the passage of a TT. However, it is a cumbersome procedure and requires at least three hands to intubate the patient's trachea via the ILMA while also stabilizing the ILMA and the TT in position and operating the FB, which may lead to time delays.[2 3] The LMA CTrach™ (CTrach), in which the fibreoptic components are integrated into the device ILMA, was developed to minimize the technical effort required by the user and allow intubation with a direct view of the larynx.

The aim of this performance evaluation study was to assess the clinical efficacy of CTrach in viewing laryngeal structures and to measure the success rates for TI and ventilation.

†*Declaration of interest*: The corresponding author assures that the authors have no relationships with any firm whose product is mentioned in this article nor with any firm marketing a rival product. A total of five CTrach devices were used in this study, two of them were provided on loan by the LMA Deutschland GmbH for the duration of the study. The purchase of the CTrach included a 1-day training course given by one of the developers in Reading, UK.

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Methods

The CTrach is similar to the ILMA. However, it contains an integrated fibreoptic system. A lens lies behind the epiglottic elevator and captures an image from in front of the mask aperture which is transmitted to a detachable digital screen with a light source and a digital camera (Figs 1 and 2). The image sharpness can be adjusted with the focusing wheel located on the side of the viewer. Push buttons are used to adjust the light intensity. Image adjustments (colour intensity, image enhancement) are made using a menu-driven function key. The colour viewer is a dedicated system that can only be used with the CTrach. The CTrach is designed so that the mask aperture is located over the glottis, enabling a view of the laryngeal structures (Fig. 3). As with direct laryngoscopy (DL) with a laryngoscope blade, the real-time passage of the tube through the glottis can be observed. In contrast to the view through a laryngoscope, the viewer provides visualization from the underside of the TT. The model used in this evaluation was made commercially available in April 2005. In December 2005, the manufacturer released a newly modified version with technical alterations. The differences are detailed in the Discussion.

Before commencement of the study, one of the investigators received practical instructions in a 1-day training course, including TI with CTrach on several patients. The primary investigator performed all insertions of the CTrach.

With the approval of Human Research Committee of the Medical School of the University of Goettingen, Germany, we studied 60 patients undergoing elective surgery requiring oral TI. Exclusion criteria included increased risk of difficult airway management and ASA IV or V. The study was conducted between April 2005 and August 2005.

Glycopyronium bromide 3 $\mu g\ kg^{-1}$ was administered to every patient 5–10 min before anaesthesia as is common practice in our department. Anaesthesia was induced with fentanyl 2 $\mu g\ kg^{-1}$, and propofol 2 mg kg^{-1}. After confirmation of face mask ventilation, rocuronium 0.6 mg kg^{-1} was given for muscle relaxation. Anaesthesia was maintained with sevoflurane 2% in oxygen during the study period.

Approximately 90 s after administration of rocuronium and before insertion of the CTrach, the Cormack–Lehane (CL) score was determined by DL. DL was always performed by the same person who subsequently placed the CTrach. The optical lens of the CTrach was prepared with one drop of an anti-fogging agent (Sigmapharm, Vienna, Austria). The CTrach, lubricated with jelly (Endosgel®, Farco-Pharma GmbH, Cologne, Germany) on the posterior surface, was inserted using the one-handed rotational technique.[4] Size 3 was used in adolescents from 30 to 50 kg body weight, size 4 in all adult females, and a size 5 in all adult males. The cuff was inflated with air to achieve a 'just airtight seal' or to a maximum pressure of 60 cm H_2O (maximum air volumes: size 3=20 ml; size 4=30 ml; size 5=40 ml) and a breathing circuit was connected to the CTrach. Ventilation via the CTrach was graded as (i) adequate—rectangular capnograph wave form with no air leak at airway pressure of 20 cm H_2O; (ii) possible—capnograph wave form with air leak at airway pressure below 20 cm H_2O, or (iii) impossible—no capnograph wave form detected. When ventilation via the CTrach proved impossible, one further attempt to insert the same sized CTrach was made.

The viewer was connected to the CTrach and the view of laryngeal structures was scored according to the criteria listed in Table 1. Whenever the laryngeal view grading was II or worse, various adjusting manoeuvres were used to improve the view (Table 2). Then, the dedicated TT (LMA Fastrach™ Endotracheal tube, LMA Company Limited, UK) was inserted through the rigid, anatomically curved airway tube of the CTrach. Correct tube placement was confirmed by direct visualization or capnography. After confirmation of correct TI, the CTrach was removed immediately. TI was considered to have failed if it could not be accomplished within 3 min or more than

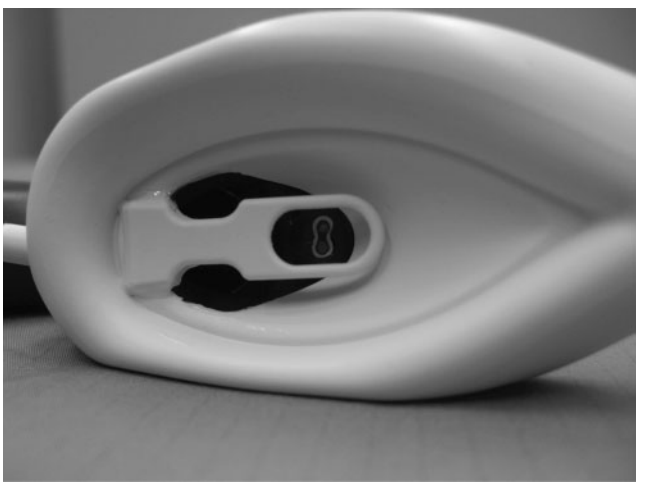


Fig 1 CTrach with a built-in fibreoptic light and image transmitters.

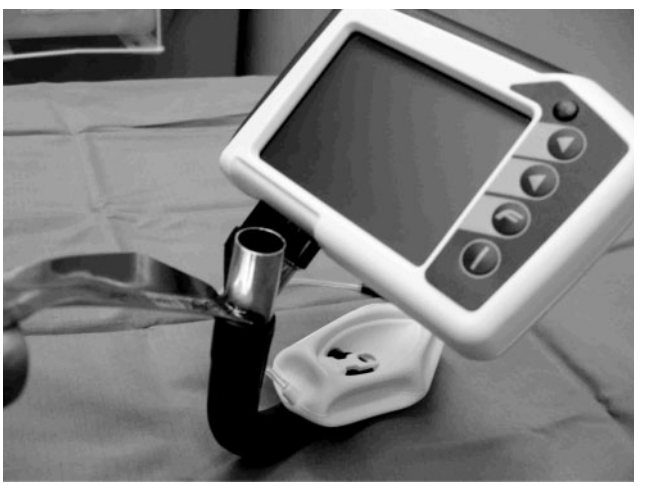


Fig 2 Lateral view with the connected monitor.

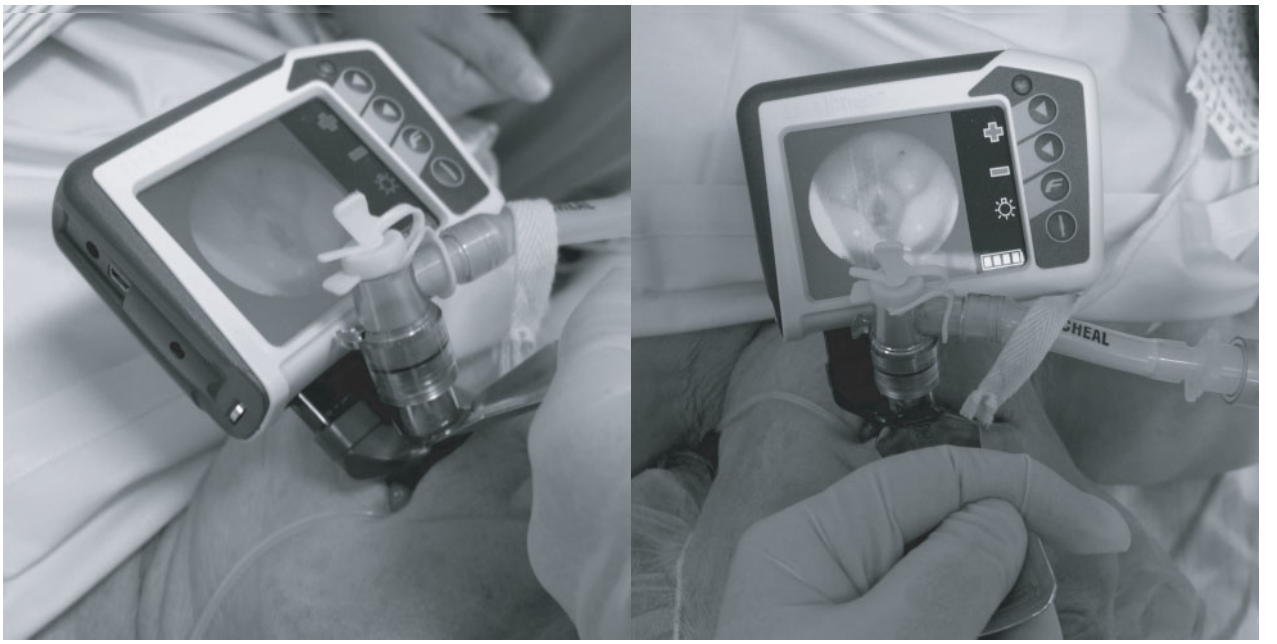


Fig 3 CTrach on a patient: view after connection to viewer (grade I).

three intubation attempts were necessary. Patients who were not successfully intubated were intubated using a Macintosh laryngoscope.

The CTrach used in this study had been cleansed and sterilized in conformity with the requirements of a reusable LMA, that is by steam autoclaving, provided the maximum temperature does not significantly exceed 135°C (275°F). There is no information as to whether autoclaving affects the quality of image or light transmission. The manufacturer guaranteed safe usage for up to 40 applications in the version used in this study.

Standard morphometric data and patient characteristics were recorded. Our primary endpoints were the overall intubation success rate, number of intubation attempts, number of CTrach insertion attempts, laryngeal view obtained immediately after insertion of the CTrach and after any measures taken as described in Table 2. We also recorded the number of adjusting manoeuvres, and reasons for a limited laryngeal view.

Statistical analysis

The effect of adjusting manoeuvres to the laryngeal view was tested by the ranked *T*-test for paired samples. Statistical analysis was performed using STASTISTICA version 6.1 (StatSoft, Tulsa, OK, USA). $P<0.05$ was considered statistically significant. This analysis aimed to illustrate the user's 'learning curve' and show any benefit from adjusting manoeuvres or improvement in viewing grade.

Results

A total of 60 applications of the CTrach were assessed. No single CTrach was used more than 20 times. Sixty-seven percent of the patients in the sample were females, the mean age (range) was 53.4 (12–84) yr and the mean BMI (SD) was 25.5 (4.8) kg m^2. Sixteen patients were ASA I, 30 ASA II and 14 ASA III. During DL, 46 patients were observed to have CL grade I, 11 grade II, 2 grade III and 1 patient was grade IV. No coughing or traumatic laryngeal or supralaryngeal alterations were observed during DL.

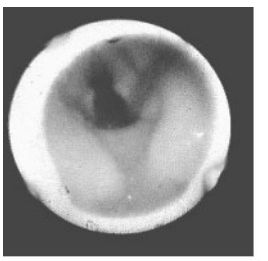
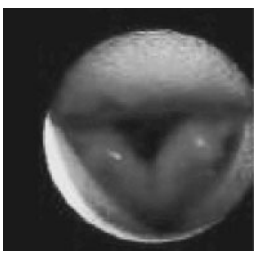
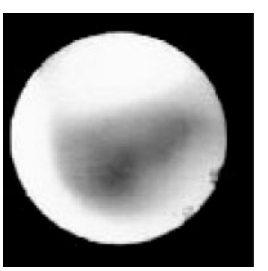
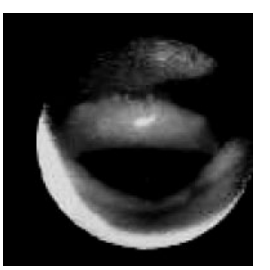
Ventilation with CTrach was possible in all patients. Ventilation quality was classified as adequate in 55 (91.7%) patients and possible in 5 (8.3%) patients. In 59 (98.3%) applications, ventilation was successful at first attempt, with only one case it required a second attempt.

The initial view was scored as grade I in 22 (36.7%), grade II in 14 (23.3%), grade III in 7 (11.7%) and grade IV in 17 (28.3%) patients. In 38 patients (63.3%), measures were undertaken to improve the view. The most frequent causes of poor image quality were secretions in front of the lens and an inadequate light intensity, each occurring 30% of the time.

Adjusting manoeuvres significantly improved the view to grade I in 33 (55.0%), grade II in 18 (30.0%), grade III in 4 (6.7%) and grade IV in 5 (8.3%) patients. Table 3 shows the impact of the adjusting manoeuvres on the distribution of the view grades. In 20 patients, the view improved, in 1 patient the view worsened. No manoeuvres were performed in the 22 patients with a grade I view. The view remained unchanged in 11 patients with grade II view, in 2 patients with grade III and in 4 patients with grade IV views. ($P<0.001$, ranked *T*-test for paired samples.)

Subsequent TI was performed independent of tracheal view scoring. TI was successful at first attempt with all grade I and II views and in 7 of 9 patients with grade III and IV views. TI was successful at the second attempt with one grade IV view. Between the first and the second TI

Table 1 Grading the laryngeal view (based on a suggestion by C. Verghese, A. Patil, D. Ferson and A. Ovassapian, personal communication)

Grade I Full view of the arytenoids and glottis	
Grade II The arytenoids and glottic opening are partly visible, the structure of cords is difficult to see. View may improve as the tracheal tube is passed	
Grade III View includes dark areas indicating an open space: (**a**) View to arytenoids, glottis or epiglottis is blurred because of excess light, poor focus, secretions or lubricant. (**b**) Insufficient depth of insertion into larynx (e.g. only the tip of the epiglottis visible)	a  b 
Grade IV No part of the larynx can be identified. (**a**) White-out or red-out indicates epiglottis or other tissues are blocking the view or obstruction by secretions or lubricant. (**b**) Black-out indicates insufficient light to view tissue, insufficient depth of insertion into the larynx, or both	a  b 

attempt, this patient was ventilated through the CTrach. The laryngeal view remained unchanged between the two TI attempts. One patient, a 64-yr-old man weighing 106 kg and measuring 1.89 cm in height, could not be intubated with CTrach. After insertion of the CTrach™, only the tip of the epiglottis could be seen (grade IIIb), and the tip of the CTrach™ could not be manoeuvred as the handle was already lying on the maxilla. The tracheal tube could not be guided into the trachea. However, DL with a size 4 Macintosh blade revealed a CL grade I view.

Discussion

This study is the first to describe the clinical performance of the CTrach. In the sample recruited, ventilation was successful in all 60 patients. The measures we listed significantly improved the view of laryngeal structures. In 15% of patients, however, a direct view of the laryngeal structures was not obtained. Despite this, TI was successful at the first or second attempt in 98% (59 of 60) of the patients.

As this report is the first description of this new device for airways management, there are no comparative studies by which to measure ventilation or intubation outcomes. Because the shape of the CTrach is the same as the ILMA, it can be expected that the rates of successful ventilation will be comparable to those achieved with the ILMA. In a meta-analysis by Brimacombe[5] comprising a total of 4512 applications of the ILMA in normal airways, successful ventilation was achieved in 91.0% at first attempt and in 99.5% overall. The 98.3% rate of successful at first-attempt ventilations determined in the study presented here and the overall rate of 100% were comparable.

Table 2 Recommended adjusting manoeuvres to improve the view grade

Grade	Adjusting manoeuvres
I	None
II	Slightly shift the tip of the CTrach Advance the CTrach further Increase light intensity on viewer
IIIa	Perform suction through the channel for intubation using a suction catheter (without lubricant) If appropriate, re-insert the CTrach
IIIb	Try to position the tip of CTrach below the epiglottis under direct vision
IVa	Advance the suction catheter (without lubricant); if the glottic aperture or the vocal cords become visible when lifting the epiglottic elevating bar, advance the CTrach further and/or perform intubation Advance the CTrach further or retract under direct vision until laryngeal structures are identifiable If appropriate, re-insert the CTrach
IVb	Increase light intensity on viewer

If manoeuvres fail, perform intubation even with limited or no view; verify intubation by capnography

Table 3 Presentation of how manoeuvres affected view grade based on a contingency table. Data in the shaded boxes indicate no change in view after manoeuvres, values to the left and below the shading show an improved view and values to the right and above the shading indicate that the view worsened. In 20 patients, the view improved, in 1 patient the view worsened. No manoeuvres were performed in the 22 patients with a grade I view. ($P<0.001$, ranked T-test for paired samples)

		View after manoeuvres			
	Grade	I	II	III	IV
Initial view	I	22	No manoeuvres performed		
	II	3	11	0	0
	III	3	1	2	1
	IV	5	6	2	4

Table 4 Impact of experience on laryngeal view score (mean of a series of 20 applications). No., number of applications in chronological order; n.s., not significant; *P value for changes before and after adjusting manoeuvres (ranked T-test for paired samples)

No.	Initial view	View after adjusting manoeuvres	P-value*
1–20	2.25	2.10	n.s.
21–40	2.40	1.30	<0.001
41–60	2.30	1.65	<0.01

The meta-analysis also demonstrated that TI through the cLMA or ILMA was successful without auxiliary devices in a total of 59 and 90%, respectively. By using fibrescopic-guided intubation via the cLMA or ILMA, these success rates were increased to 79 and 93%. The results we obtained with CTrach were higher, namely 98%. This high success rate is surprising given the grade III and IV laryngeal view in 7 and 8%. With one exception, the view in these instances was impaired by mucous secretions, or by the epiglottis covering or being too close to the optical lens, as is the case in grade IIIa and IVa views. In these cases, it can be presumed that the CTrach was positioned correctly and intubation was thus possible without vision. There was only one instance where the CTrach could not be manoeuvred into optimal position despite good image transmission, because the handle was already lying on the maxilla of a relatively large patient and prevented it from being advanced further (grade IIIb). For these rare cases, consideration should be given to developing a larger CTrach for very large patients.

A disadvantage of the scoring system for the laryngeal view using CTrach, as used in this study, lies in the lack of determination as to whether a grade IIIa or IV view results from anatomical or technical reasons. Grade IIIa describes an 'anatomical' view I to III, but with some fluids covering the lens. These imbrications make clear identification of the laryngeal structure impossible for technical reasons, assuming that the CTrach was correctly placed. A grade IVa view can be either attributed to complete obstruction by laryngeal and pharyngeal structures (anatomical reasons) or result from saliva, blood and other fluids obscuring the surface of the lens (technical reasons). All are factors that prevent a clear view. If the epiglottis is over the lens, a view to the vocal cords, arytenoids or glottis might be made visible by passing a tube or suction catheter over the CTrach and lifting up the epiglottis with the glottic elevating bar. A grade IVb view can result from incorrect anatomic positioning of the CTrach's aperture in the pharynx, or from insufficient brightness of the light source and the transmitting fibres; circumstances which can arise despite correct anatomical positioning of the CTrach. However, TI should be attempted in these cases. We were successful in all of the four IIIa and five complete white, red or black-out views (after manoeuvres) in the first attempt, indicating technical rather than anatomical reasons for the grade IIIa and IV views.

The recommended adjusting manoeuvres in our study significantly improved the viewing score. These manoeuvres were partly based on the suggestions provided by other workers (C. Verghese, personal communication) and partly on our own experience. Table 4 shows the impact of experience on the laryngeal view score. There was no statistically significant difference in the initial view over the course of time. However, the view after adjusting manoeuvres was better than the initial view, but only after the sequence of the first 20 applications. The view after adjusting manoeuvres also improved over time, with a slight increase in grade of view being observed in the last series of applications. This was because of two grade IV views despite adjusting manoeuvres. In both cases, TI was successful in the first attempt, indicating a correct anatomic position of the CTrach and obstruction of the view by secretions or lubricant. However, these data support the view that users should familiarize themselves with this new device to benefit from intubation under vision.

This performance evaluation study did not investigate the quality of image transmission. However, the principle

investigator complained about this in approximately 1/3 of the applications. In particular, the poor light intensity and impairment of the view by deposits were criticized. Moreover, it was the investigators' subjective impression that the light intensity and the sharpness of the image declined over the course of the applications. Compared with a flexible fibreoptic endoscope, the CTrach viewer offered a poorer image quality. Some of the factors contributing to this difference were the CTrach's lens system, fibre optics, and the granularity and grade of the optic fibres. Resolution (number of pixels) and interface between image-converting systems might also be to blame for this observation. According to the manufacturer's information (J. Haering, Product & Marketing Manager, Anaesthesia and Emergency Medicine, Karl Storz GmbH & Co. KG, Tutlingen, Germany, personal communication) a battery-operated 5.0 mm flexible fibreoptic endoscope supplies a light intensity of up to 50 000 lux and a resolution of ~18 500 pixels. By contrast, the light intensity of the CTrach is only around 100 lux with a resolution of ~10 000 pixels (G. White, Product Manager CTrach™, The Laryngeal Mask Company Limited, UK, personal communication). Nonetheless, it is not clear what level of image quality is required for performing fibreoptic intubation, when no diagnostic criteria have to be met.

Since its commercial release in April 2005, the design of the CTrach has been changed. These modifications are reflected in the model released in December 2005. The design improvements include a change in the epiglottis elevator bar from white to blue, application of a coating to the optic lens to improve image quality, a reduction in warranty from 40 to 20 applications, improved connection between airway and viewer and additional functions on the viewer to allow horizontal and vertical image adjustment (G. White, Product Manager CTrach™, The Laryngeal Mask Company Limited, UK, personal communication). The CTrachs used in this study were purchased in April 2005 and not used more than 20 times. The modifications were primarily designed to improve the quality of image transmission. With the experience gained in this study, we do not expect that these modifications will have an impact on the anatomical positioning of the CTrach or change any technical reasons that a clear view might be blocked.

Further studies should look at the potential for reducing laryngeal trauma, sore throat, dysphonia or oesophageal complications. The device has potential as with CTrach intubation is carried out under vision compared with 'blind' intubation with ILMA. The usefulness of the device in difficult intubation should also be examined. Repeatedly futile attempts at laryngoscopic intubations can be expected to cause trauma to the upper airways, subsequently obscuring the view by blood and secretions. However, several studies have shown that the ILMA can be used successfully, irrespective of the laryngoscopic finding.[6–8] A chance finding of this study was that the three patients with CL grade III and IV views were intubated easily with the CTrach™ whereas laryngoscopy had proved difficult.

In conclusion, CTrach provides a high success rate for both ventilation and TI in patients without anticipated difficult airways. Despite correct positioning of the CTrach, grade IIIa or IV views can occur because of secretions or epiglottic structures obscuring the optical lens. Our experience suggests that TI can often be successful even if there is a grade III or IV view. Development of a CTrach for large patients might increase the intubation success rates.

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