In cadavers, directly measured mucosal pressures are similar for the Unique™ and the Soft Seal™ laryngeal mask airway devices

[Les pressions exercées sur les muqueuses par les masques laryngés Unique™ et Soft Seal™, mesurées directement sur des cadavres, sont similaires]

Christian Keller MD,* Joseph Brimacombe MB CHB FRCA MD,† Bernhard Moriggl MD,‡ Philipp Lirk MD,* Achim von Goedecke MD*

Purpose: We compare the Soft Seal™ and Unique™ single-use, plastic laryngeal mask airway devices with respect to intracuff pressure, directly measured mucosal pressure and *in vitro* elastance.

Methods: Ten fresh male cadavers were studied. Microchip pressure sensors were attached to the following locations: A) the anterior middle part of the cuff side; B) the posterior tip of the cuff; C) the anterior base of the cuff; D) the posterior middle part of the cuff side; E) the backplate; and F) the posterior tube. The size 5 Unique™ and size 5 Soft Seal™ were inserted in random order using laryngoscope-guidance. Intracuff pressure and mucosal pressure were documented at 0 to 40 mL cuff volume in 10 mL increments. *In vitro* elastance was determined between 20 to 40 mL cuff volume.

Results: For both devices, mucosal pressure increased with cuff volume at most locations. Intracuff pressures and *in vitro* elastance (5.2 ± 0.7 cm H_2O/mL *vs* 3.8 ± 0.4 cm H_2O/mL, $P < 0.0001$) were higher for the Unique™ than the Soft Seal™ ($P < 0.0001$), but there were no differences in mucosal pressures at any location or cuff volume.

Conclusion: Intracuff pressures and *in vitro* elastance are higher for the Unique™ than the Soft Seal™, but mucosal pressures are similar suggesting that the airway morbidity will be similar.

Objectif : *Nous comparons deux masques laryngés jetables en plastique, Soft Seal™ et Unique™, quant à la pression intraballonnet, la pression sur la muqueuse mesurée directement et l'élastance in vitro .*

Méthode : *Notre expérience a porté sur dix cadavres mâles. Des microdétecteurs de pression ont été fixés sur A) la partie latérale médiane antérieure du ballonnet ; B) la pointe postérieure du ballonnet ; C) la base antérieure ; D) la partie médiane postérieure ; E) la lame dorsale et F) le tube postérieur. Les masques de grandeur 5 Unique™ et Soft Seal™ ont été insérés selon un ordre aléatoire à l'aide d'un laryngoscope. La pression intraballonnet et la pression sur la muqueuse ont été vérifiées pour des volumes de ballonnet de 0 à 40 mL en paliers de 10 mL. L'élastance in vitro a été déterminée pour un volume de 20 à 40 mL.*

Résultats : *La pression sur la muqueuse augmentait avec le volume du ballonnet pour la majorité des points de mesure et chacun des appareils. Les pressions intraballonnet et l'élastance in vitro (5,2 ± 0,7 cm H_2O/mL vs 3,8 ± 0,4 cm H_2O/mL, $P < 0,0001$) étaient plus élevées avec le masque Unique™ qu'avec le Soft Seal™ ($P < 0,0001$), mais les pressions sur la muqueuse ne présentaient aucune différence pour tous les points de mesure et tous les volumes du ballonnet.*

Conclusion : *Les pressions intraballonnet et l'élastance in vitro sont plus élevées avec le masque Unique™ qu'avec le Soft Seal™, mais les pressions sur la muqueuse sont similaires, ce qui laisse croire que la morbidité d'une telle canulation sera similaire.*

From the Department of Anaesthesia and Intensive Care Medicine,* and the Institute of Anatomy, Histology and Embryology,‡ Leopold-Franzens University, Innsbruck, Austria; and the Department of Anaesthesia and Intensive Care,† Cairns Base Hospital, Cairns, Australia.

Address correspondence to: Dr. Joseph Brimacombe, Department of Anaesthesia and Intensive Care, Cairns Base Hospital, The Esplanade, Cairns 4870, Australia. E-mail: jbrimaco@bigpond.net.au

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THE Soft Seal™ laryngeal mask airway (LMA; Soft Seal™; Portex Ltd., Hyathe, UK) is a new single-use, plastic LMA similar to the single-use, plastic Unique™ LMA (Unique™; Intavent, Henley-on-Thames, UK), but it has a deeper bowl, a blunter distal cuff, a wider airway tube fused to a larger portion of the bowl, an integral inflation line and no mask aperture bars (Figure). The Unique™ has been shown to have a similar clinical performance to the Classic™ LMA,[1,2] but there are no published data on the Soft Seal™. The differences in design suggest that the clinical performance of the Soft Seal™ will differ from the Unique™. In the following cadaver study, we compared the Soft Seal™ and Unique™ with respect to directly measured mucosal pressure, intracuff pressure and *in vitro* elastance.

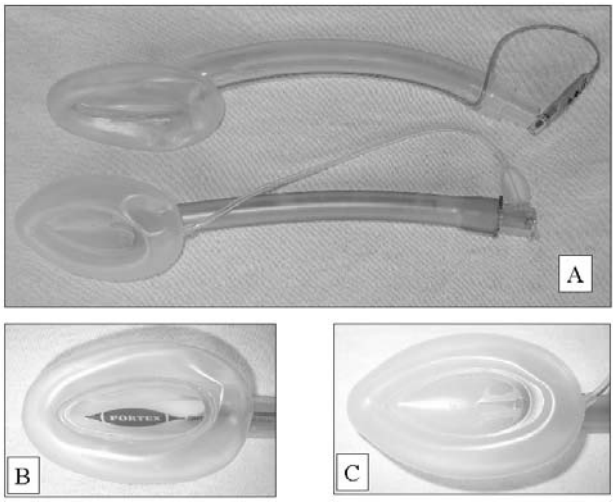

FIGURE The Soft Seal™ (top) and Unique™ (bottom) laryngeal mask airways (A). View of the bowl of the Soft Seal™ (B) and Unique™ (C) illustrating the lack of mask aperture bars for the Soft Seal™.

Methods

Research Committee approval was obtained and patients, or their next of kin, consented to post-mortem research. Ten fresh male cadavers (six to 24 hr post-mortem) were studied. Cadavers with known upper esophageal or laryngopharyngeal pathology were excluded. Directly measured mucosal pressure was determined using six 1.2-mm diameter strain gauge silicone microchip sensors (Codman® MicroSensor™, Johnson and Johnson Medical Ltd., Bracknell, UK) attached to the external surface of the size 5 Unique™ and size 5 Soft Seal™ LMA devices with clear adhesive dressing 0.45 μm thick (Tegaderm™, 3M, ON, Canada), as previously described[3,4] and validated.[5] New devices were used for each cadaver. The size 5 was used as this has been shown to be best for males.[3,6] The sensors were attached to the following locations (corresponding mucosal areas): A) the anterior middle part of the cuff side (pyriform fossa); B) the posterior tip of the cuff (hypopharynx); C) the anterior base of the cuff (base of tongue); D) the posterior middle part of the cuff side (lateral pharynx); E) the backplate (posterior pharynx); and F) the posterior tube (oropharynx). The sensing element was oriented towards the mucosal surface and was accurate to ± 2%. The position/orientation/accuracy of all the sensors were checked over the entire inflation range *in vitro* before and after use in each cadaver.[3,4] Each device was connected to a lightweight circle breathing system. The pilot balloon was attached via a three-way tap to a 10-mL syringe and a calibrated pressure transducer accurate to ± 5%. The LMA Unique™ and Soft Seal™ were inserted in random order (by opening a sealed opaque envelope) into the cadaver using laryngoscope-guidance to allow the cuff to be accurately positioned. Intracuff pressure (primary variable), mucosal pressure (primary variable), oropharyngeal leak pressure (secondary variable) and fibreoptic position (secondary variable) were documented at zero cuff volume and after each additional 10 mL up to 40 mL. The number of attempts at insertion were also noted (secondary variable). A failed attempt was defined as removal from the mouth. Oropharyngeal leak pressure was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3 $L \cdot min^{-1}$, and noting the airway pressure at which the dial on the aneroid manometer reached equilibrium.[7] Fibreoptic position was determined using an established scoring system.[8] Measurements were made with the head/neck in the neutral position with the occiput rested on a firm pillow 5 cm in height. Care was taken to ensure that no weight from the circle breathing system was transmitted to the airway device. *In vitro* elastance was determined by comparing intracuff pressure changes between 20 and 40 mL cuff volume with the LMAs suspended in the air.

Sample size was selected for a type I error of 0.05 and a power of 0.9 and was based on a pilot study of five cadavers and a previous study determining intracuff and mucosal pressures for the LMA Unique™.[9] Statistical comparisons were made between devices for oropharyngeal leak pressure, fibreoptic position and directly measured mucosal pressures at similar locations. The distribution of data was determined using

TABLE Oropharyngeal leak pressure (OLP), fibreoptic score (FOS) and directly measured pharyngeal mucosal pressures with increasing cuff volume for the Unique™ and the Soft Seal™ laryngeal mask airway devices

					Directly measured mucosal pressures					
	Vol mL	*OLP*	*FOS 4/3/2/1 (**n**)*	*Intracuff pressure*	*A Pyriform fossa*	*B Hypo-pharynx*	*C Base of pharynx*	*D Lateral tongue*	*E Posterior pharynx*	*F Oro-pharynx*
Unique™	0	7 ± 3	1/3/3/3	-26 ± 3	5 ± 5	4 ± 4	3 ± 3	2 ± 2	5 ± 2	7 ± 3
	10	12 ± 4	1/4/2/3	20 ± 7†	11 ± 6	10 ± 7	9 ± 6	6 ± 3	12 ± 6	14 ± 7
	20	16 ± 5	2/3/3/2	53 ± 13†	16 ± 9	13 ± 7	16 ± 13	10 ± 4	16 ± 8	20 ± 10
	30	18 ± 6	3/2/3/2	113 ± 15†	19 ± 5	18 ± 6	23 ± 14	15 ± 7	22 ± 17	30 ± 14
	40	18 ± 6	4/1/3/2	208 ± 15†	26 ± 7	23 ± 8	32 ± 17	22 ± 11	28 ± 18	42 ± 23
Soft Seal™	0	6 ± 4	1/0/5/4	-26 ± 3	5 ± 4	6 ± 3	8 ± 3	3 ± 2	6 ± 3	9 ± 4
	10	10 ± 5	1/0/6/3	1 ± 5	10 ± 5	11 ± 4	12 ± 5	8 ± 5	12 ± 6	16 ± 8
	20	14 ± 6	1/1/5/3	27 ± 9	15 ± 5	16 ± 7	18 ± 8	11 ± 4	17 ± 6	23 ± 9
	30	18 ± 5	1/1/6/2	64 ± 12	21 ± 9	20 ± 9	24 ± 11	16 ± 5	23 ± 14	32 ± 11
	40	18 ± 5	1/1/6/2	141 ± 17	26 ± 11	23 ± 9	33 ± 21	24 ± 9	30 ± 22	43 ± 25

Data are mean ± SD. Pressures are in cm H_2O. Fibreoptic score 4 = only vocal cords visible; 3 = vocal cords plus posterior epiglottis; 2 = vocal cords plus anterior epiglottis; 1 = vocal cords not seen. †$P < 0.0001$ Unique™ *vs* Soft Seal™.

Intradevice statistics

					Directly measured mucosal pressures					
	Vol change (mL)	*OLP*	*FOS 4/3/2/1 (**n**)*	*Intracuff pressure*	*A Pyriform fossa*	*B Hypo-pharynx*	*C Base of tongue*	*D Lateral pharynx*	*E Posterior pharynx*	*F Oro-pharynx*
Unique™	0-10	< 0.0001	NS	< 0.001	0.001	0.003	0.03	0.002	0.004	0.02
	10-20	< 0.0001	NS	< 0.001	0.01	0.02	0.03	0.01	0.01	0.01
	20-30	0.04	NS	< 0.001	NS	0.02	NS	0.005	NS	0.004
	30-40	NS	NS	< 0.001	0.001	0.002	0.002	NS	0.04	NS
Soft Seal™	0-10	< 0.0001	NS	< 0.001	0.009	0.007	0.005	0.01	0.01	0.007
	10-20	< 0.0001	NS	< 0.001	0.003	0.009	0.01	NS	0.004	0.008
	20-30	0.004	NS	< 0.001	0.01	0.01	0.009	0.002	NS	0.01
	30-40	NS	NS	< 0.001	0.002	NS	NS	0.007	NS	NS

NS = not significant.

Kolmogorov-Smirnov analysis.[10] Statistical analysis was with Chi-squared test, paired t test (normally distributed data) and Friedman's two-way analysis of variance (non-normally distributed data). Unless otherwise stated data are presented as mean ± SD. Significance was taken as $P < 0.05$. Statistical analysis was performed on an IBM computer using SPSS v 11.0 (SPSS Inc., Chicago, IL, USA).

Results

The mean (range) age, height and weight was 71 (45–92) yr, 173 (161–190) cm and 76 (55–110) kg respectively. Intracuff pressures and *in vitro* elastance (5.2 ± 0.7 cm H_2O/mL *vs* 3.8 ± 0.4 cm H_2O/mL, $P < 0.0001$) were higher for the Unique™ than the Soft Seal™ ($P < 0.0001$), but there were no differences in mucosal pressures at any location or cuff volume (Table). For both devices, intracuff pressure increased with cuff volume, but there was no change in fibreoptic position. For both devices, oropharyngeal leak pressure increased until cuff volume was 30 mL and was stable thereafter. For both devices, mucosal pressure increased with cuff volume at most locations. Insertion was always successful at the first attempt. There were no differences in oropharyngeal leak pressure or fibreoptic position between devices at any cuff volume (Table).

Discussion

Mucosal pressures were similar for the Unique™ and the Soft Seal™ over the range of cuff volumes suggesting that the two cuffs interact with the pharynx in a similar fashion despite differences in design. Pharyngeal perfusion is progressively reduced when mucosal pressure is greater than 34 cm H_2O.[11] The mean value for mucosal pressure only exceeded 34 cm H_2O at maximum cuff volume suggesting that high cuff volumes should be avoided to reduce the risk of mucosal ischemic injury. Mucosal pressures were highest in the oropharynx where the tube presses against the anterior body of the cervical vertebrae, as previously demonstrated for the Unique™.[9]

Intracuff pressure was higher for the Unique™ than the Soft Seal™. This is related to the higher elastance of the Unique™ since mucosal pressures were similar. The differences in elastance may be related to the type of plastic used, its thickness or the size of the cuff. Bench testing showed that *in vitro* intracuff pressure becomes positive for the Unique™ at around 20 mL *vs* 30 mL for the Soft Seal™ suggesting that the cuff of the Unique™ is smaller. Interestingly, both the Soft Seal™ (bench test data) and Unique™ [2] cuffs are sufficiently thick to prevent increases in cuff volume during nitrous oxide anesthesia.

We studied cadavers to minimize patient trauma since there are no published data about the Soft Seal™ and extraglottic airway devices can exert high pressures against the mucosa.[12,13] Also, there is evidence that the performance of extraglottic airway devices in cadavers is similar to anesthetized patients[14] and awake volunteers,[12] suggesting that rigor mortis does not influence the results. The similarity in mucosal pressures for the Unique™ in the current cadaver study compared with anesthetized paralyzed patients using similar methodology[9] suggests that our results are applicable to anesthetized patients. A limitation of our study is that it was not sufficiently powered to compare ease of insertion, oropharyngeal leak pressure or fibreoptic position; however, these were similar between devices.

We found that oropharyngeal leak pressure reaches its maximum at approximately three quarters the maximum recommended cuff volume whereas mucosal pressure continues to increase with cuff volume. This confirms the findings of a previous study for the Unique™ [9] and studies of reusable LMA devices,[13,15] and suggests that routine inflation of the cuff to the maximum recommended volume increases the risk of mucosal injury without an improvement in seal.

We conclude that intracuff pressures and *in vitro* elastance are higher for the Unique™ than the Soft Seal™, but mucosal pressures are similar, suggesting that airway morbidity will be similar.

References

1 *Verghese C, Berlet J, Kapila A, Pollard R.* Clinical assessment of the single use laryngeal mask airway–the LMA-Unique™. Br J Anaesth 1998; 80: 677–9.

2 *Brimacombe J, Keller C, Morris R, Mecklem D.* A comparison of the disposable versus the reusable laryngeal mask airway in paralyzed adult patients. Anesth Analg 1998; 87: 921–4.

3 *Brimacombe J, Keller C.* Laryngeal mask airway size selection in males and females: ease of insertion, oropharyngeal leak pressure, pharyngeal mucosal pressures and anatomical position. Br J Anaesth 1999; 82: 703–7.

4 *Brimacombe J, Keller C, Giampalmo M, Sparr HJ, Berry A.* Direct measurement of mucosal pressures exerted by cuff and non-cuff portions of tracheal tubes with different cuff volumes and head and neck positions. Br J Anaesth 1999; 82: 708–11.

5 *Brimacombe J, Keller C.* Pharyngeal mucosa pressures (Letter, reply). Anesthesiology 2000; 92: 620–1.

6 *Brimacombe J, Keller C.* Performance of the size 5 laryngeal mask airway in males and females. Anaesthesiol Intensivmed Notfalmed Schmerzther 2000; 35: 567–70.

7 *Keller C, Brimacombe JR, Keller K, Morris R.* Comparison of four methods for assessing airway sealing pressure with the laryngeal mask airway in adult patients. Br J Anaesth 1999; 82: 286–7.

8 *Keller C, Brimacombe J, Puehringer F.* A fibreoptic scoring system to assess the position of laryngeal mask airway devices. Interobserver variability and a comparison between the standard, flexible and intubating laryngeal mask airways. Anaesthesiol Intensivmed Notfalmed Schmerzther 2000; 35: 692–4.

9 *Keller C, Brimacombe J.* Mucosal pressure, mechanism of seal, airway sealing pressure, and anatomic position for the disposable versus reusable laryngeal mask airways. Anesth Analg 1999; 88: 1418–20.

10 *Gaddis GM, Gaddis ML.* Introduction to biostatistics: part 5, statistical inference techniques for hypothesis testing with nonparametric data. Ann Emerg Med 1990; 19: 1054–9.

11 *Brimacombe J, Keller C, Puehringer F.* Pharyngeal mucosal pressure and perfusion. A fiberoptic evaluation of the posterior pharynx in anesthetized adult patients with a modified cuffed oropharyngeal airway. Anesthesiology 1999; 91: 1661–5.

12 *Keller C, Brimacombe J, Boehler M, Loeckinger A, Puehringer F.* The influence of cuff volume and anatomic location on pharyngeal, esophageal, and tracheal mucosal pressures with the esophageal tracheal combitube. Anesthesiology 2002; 96: 1074–7.

13 *Keller C, Brimacombe J.* Pharyngeal mucosal pressures, airway sealing pressures, and fiberoptic position with the intubating versus the standard laryngeal mask airway. Anesthesiology 1999; 90: 1001–6.

14 *Brimacombe J, Keller C.* The laryngeal mask airway in fresh cadavers versus paralysed anaesthetized patients: ease of insertion, airway sealing pressure, intracuff pressures and anatomic position. Eur J Anaesthesiol 1999; 16: 699–701.

15 *Keller C, Brimacombe J.* Mucosal pressure and oropharyngeal leak pressure with the ProSeal versus laryngeal mask airway in anaesthetized paralysed patients. Br J Anaesth 2000; 85: 262–6.