

A Comparison of the Classic and a Modified Laryngeal Mask Airway (OPLAC™) in Adult Patients

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BACKGROUND: A modified disposable laryngeal mask airway (LMA) (Oro-Pharyngo-Laryngeal Airway Cap, OPLAC™) was developed in our department. In this study, we compared the performance of the LMA Classic™ with that of the OPLAC.

METHODS: This was a randomized, single-blinded, crossover study involving 60 paralyzed, anesthetized adult patients. Both devices were inserted into each patient in different sequences after anesthesia had been induced. In 30 patients, the LMA was inserted first and in 30 patients, the OPLAC was inserted first. The success rate, insertion time, fiberoptic view, peak airway pressure, sealing pressure, incidence of gastric insufflations, trace of blood on the device, and incidence of postoperative sore throat were evaluated.

RESULTS: The success rate of placement on the first attempt was high for both devices. The insertion time was significantly shorter and better engagement was noted on fiberoptic view with the OPLAC than with the LMA. The sealing pressure was significantly higher and the incidence of gastric insufflations was significantly lower with the OPLAC. The overall incidence of sore throat was 13.33%.

CONCLUSIONS: Both devices have comparable airflow resistance and are easy to insert. The OPLAC requires less insertion time, has less variation on insertion time, fits better into the laryngopharynx, is less likely to cause gastric insufflations, and has a higher sealing pressure. (Anesth Analg 2010;X:●●●–●●●)

The laryngeal mask is a form of supraglottic airway device. After insertion into the oropharynx, it should be seated over the laryngeal inlet. The key characteristics of supraglottic airway devices comprise the 2 following features: (1) an airway tube with a mask or a cap at its end to fit the laryngeal inlet with an effective seal that should ideally prevent air leakage as well as prevent gastric insufflations, and (2) a mechanism to keep the epiglottis from interfering with airflow, thus reducing airway resistance and airway pressure during ventilation.

There are 2 types of supraglottic airway devices according to the nature of sealing. The classic laryngeal mask airway (LMA) has a cuff and relies on the inflation of the cuff with air for sealing. In contrast, for the noncuffed supraglottic airway device, the mask is made of soft, pliable material shaped according to the anatomy of the laryngopharynx.^{1,2} Because of its pliable nature, it can be accommodated at the laryngeal inlet and molds to the soft tissue of the laryngopharynx to achieve a proper seal. The Oro-Pharyngo-Laryngeal Airway Cap (OPLAC™) was recently developed by our department as a noncuffed supraglottic

airway device. It has a mask made of 3 components: a silicone membrane, capped over a pliable ring made of thermoplastic rubber, reinforced by a fabricated cork plate anchoring around the airway tube. The pliable ring splinted by the fabricated cork plate together with its membranous cap is shaped to negotiate with the surrounding soft tissue of the laryngeal vestibule for sealing. In addition to the features mentioned above, the membranous cap, which is a novel patented^a structure, also acts as a check valve to prevent air leakage whenever there is any void between the mask and the laryngeal vestibule. While the laryngeal aperture of the membranous cap is directed to the glottis, the upper and lower pouches of the cap serve as check valves preventing air leakage and gastric insufflations, respectively. Because of the pliability and the check valve mechanism of the cap, the positive airway pressure during mechanical ventilation enhances airway sealing in the OPLAC in contrast to other supraglottic airway devices in which the high airway pressure unseats the airway sealing.

The epiglottis tends to cover the laryngeal inlet during supraglottic airway insertion as occurs during swallowing. Most devices on the market have a tube aperture at a level higher than the epiglottis. Thus, there is a chance that a redundant epiglottis can interfere with airflow and increase the airway resistance. To prevent the interference of airflow by the epiglottis, the OPLAC has a built-in epiglottis blocker system, also a patented design, navigating the epiglottis to slide over the tube aperture and to be fixed under the epiglottic compressor. Additionally, the tube of the OPLAC was designed to protrude from the bowl of the cap to approach the glottis more closely. As a result, the airflow through the OPLAC is directed to a level below

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BCL and RSCW contributed equally to this study.

Conflict of Interest: See Disclosures at the end of the article.

Reprints will not be available from the authors.

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^aUS Patent 6546931. Supraglottic airway structure specifically used for anesthesia, 2003. US Patent 7546838. Laryngeal-mask construction, 2009.

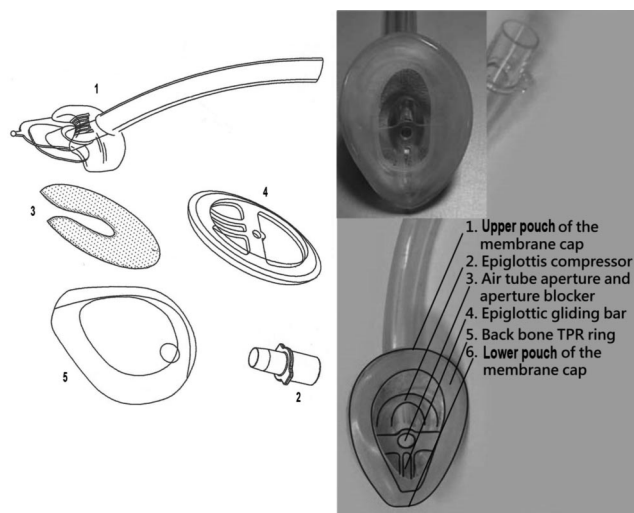


Figure 1. The Oro-Pharyngo-Laryngeal Airway Cap (OPLAC™) design. On the left is the expanded view showing the tube (1) designed to protrude into the bowl of the cap to approach the glottis more closely, the connector, (2) the fabricated cork plate (3) to support the contour, the pliable thermoplastic rubber (TPR) ring (4) with epiglottis blocker system, and the expandable silicone membranous cap (5) for sealing. On the right is the assembly of the OPLAC.

the epiglottis thus bypassing the possible obstacle of the epiglottis (Figs. 1 and 2).

In this study, we evaluated and compared the success rate of insertion, insertion time, fiberoptic view, peak airway pressure, sealing pressure, the incidence of gastric

insufflations, traces of blood noticed on the device after removal, and the incidence of postoperative sore throat after different insertion sequences of both devices.

METHODS

The study was approved by our IRB and written informed consent was obtained from the patients. The study included 60 surgical patients of ASA physical status I or II during August 2001 to May 2002. Pregnant patients, those with full stomachs, gastroesophageal reflux disease, a known airway anomaly, or a prior operation involving the upper airway were excluded. All patients received both classic LMA (LMA Classic™; LMA North America, Inc., San Diego, CA) and OPLAC insertion by a single experienced anesthesiologist, but in different sequences. With a table of random numbers, a group sequence was generated by a research assistant. The assistant enrolled patients according to inclusion and exclusion criteria. Patients were assigned to groups according to the order of inclusion. In group L (*n* = 30), the LMA was inserted first and in group O, the OPLAC was inserted first.

The head and neck were placed in the sniffing position with the occiput rested on a firm pillow 7 cm in height. After oxygen administration, anesthesia was induced with fentanyl 1 µg/kg followed 2 minutes later by propofol 2 mg/kg and atracurium 0.5 mg/kg. Patients' lungs were ventilated with a facemask for 3 minutes after loss of eyelash reflex. Anesthesia was maintained with O₂/air (fraction of inspired oxygen = 50%) and sevoflurane adjusted to 2% to 3% end-tidal concentration. The posterior

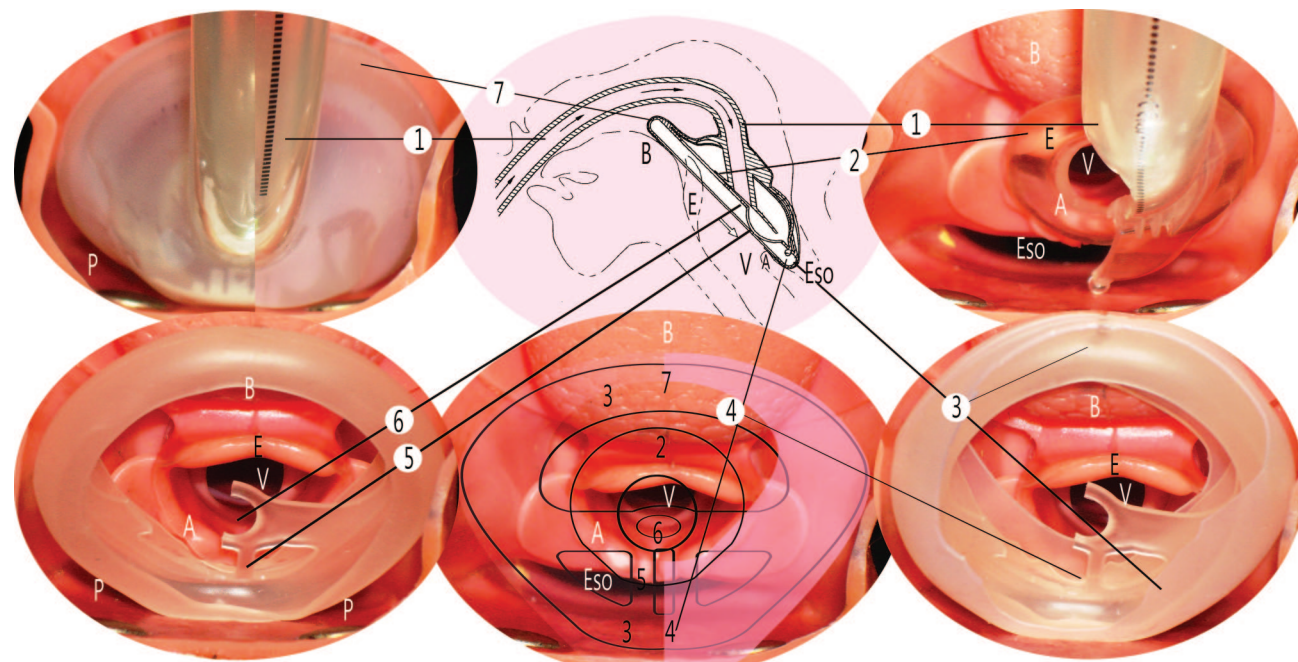


Figure 2. The relationship between the Oro-Pharyngo-Laryngeal Airway Cap (OPLAC™) and the larynx. The middle upper figure is the sagittal view of the laryngopharynx and the OPLAC. The middle lower figure is the transparent view of the OPLAC engaged with the laryngopharynx. The left upper figure shows the membrane cap of the OPLAC expanded and filling the right piriform fossa during positive pressure ventilation compared with the left side. The left lower figure shows the pliable ring engaged with the piriform fossa. The right upper figure shows the epiglottis controlled by the epiglottis compressor. The right lower figure shows epiglottis gliding bars supporting the membrane pouch. E = epiglottis; B = base of the tongue; A = arytenoids; V = vocal cord; Eso = esophagus. The epiglottis compressor (2) at the end of the tube (1); the pliable ring (3); the lower membrane pouch (4); epiglottis gliding bar (5); the aperture blocker (6); and the upper membrane pouch (7).

surface of the LMA (size 3 for women and size 4 for men)^{3,4} was lubricated and then inserted with the cuff partially inflated.⁵⁻⁸ If resistance was encountered during insertion, alternately rightward and leftward rotation was performed during advancement.⁵⁻⁷ The OPLAC (size designed for 40- to 100-kg adult male and female) was lubricated and then inserted. The insertion was completed after loss of the resistance caused by the tongue base was felt when the OPLAC engaged in the laryngopharynx. The insertion of the LMA was completed upon cuff inflation after definite resistance was felt at the base of the hypopharynx as described in the LMA manufacturer's instructions.

The insertion sequence was recorded using a video camera and was subsequently analyzed by an anesthesiologist not involved in clinical care in the study to determine the success rate, the insertion time, and the ease of insertion. Removal of either device from the mouth because of inadequate ventilation was regarded as a failed attempt. The insertion time was measured from the time any part of either device was placed into the mouth to the time of ready-to-ventilate, which is cuff inflation in the LMA and engagement of the OPLAC in the laryngopharynx. The ease of insertion was graded as (1) very easy on the first attempt, (2) insertion on the first attempt after manipulation, (3) successful on the second attempt, or (4) not successful after 2 attempts.

After a successful insertion, the patients' nostrils were obstructed and a sampling catheter connected to a gas analyzer was placed between the lips adjacent to the tube of the LMA or OPLAC. Airway sealing pressure was determined by increasing the ventilation pressure from 12 up to 30 cm H₂O at increments of 2 cm H₂O every 1 to 2 breaths under pressure-controlled ventilation with a fresh gas flow of 6 L/min. The pressure at which the gas analyzer detected CO₂ or anesthetic gases was defined as the airway sealing pressure. If no gas leakage was detected up to 30 cm H₂O, the measurement was stopped. Meanwhile, an anesthesia resident detected gastric insufflations with a stethoscope placed at the epigastrium. Anesthesia was continued with volume mode positive pressure ventilation with a tidal volume of 10 mL/kg and 12 breaths/min. The relative position of the larynx and the device was photographed using a fiberoptic scope with the tip placed at the level of the aperture bars for the LMA and at the level of the aperture blocker for the OPLAC. An independent anesthesiologist scored the engagement of the devices based on the fiberoptic photographs (Fig. 3).⁹ After approximately 10 minutes to complete the initial evaluation, the first device was removed and inspected for any trace of blood. The second device was then inserted and all of the measurements were repeated, which took another 10 minutes. The surgery started after the evaluation for both devices was completed.

Sample size was selected to detect a projected difference of 20% between the groups with respect to airway sealing pressure for a type I error of 0.01 and a power of 0.9. The power analysis was based on data from a pilot study of 10 patients in which airway sealing pressure and first attempt success rates of the OPLAC were measured and compared with those of the classic LMA.¹⁰ All data are presented as mean ± SD. Parametric variables were compared between

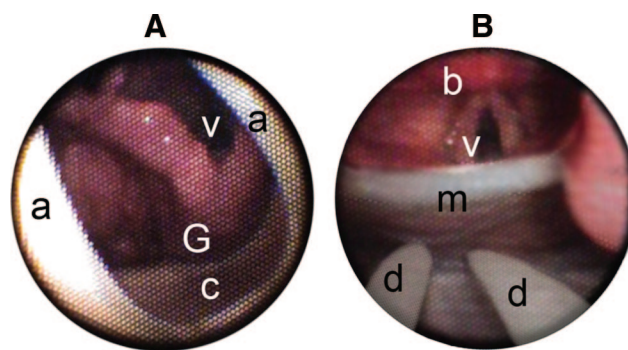


Figure 3. Fiberoptic view through the laryngeal mask airway (LMA) (A) and Oro-Pharyngo-Laryngeal Airway Cap (OPLAC™) (B). A, View with an LMA; the cushion of the LMA (c) occupying the gutter (G) of the upper esophageal aperture. B, View with an OPLAC; the gutter is covered by the recess formed by the membrane of the silicone cap (m). a = aperture bars of LMA; b = base of epiglottis; V = vocal aperture; d = epiglottis gliding bars.

Table 1. Demographic Data	
Male/female	30/30
Age (y)	39.70 ± 8.23
Weight (kg)	63.10 ± 9.20
Height (cm)	163.40 ± 8.72
Duration of anesthesia (min)	61.5 ± 32

groups with a simple *t* test. Nonparametric variables were examined using the Fisher exact test or Fisher cross table test. A *P* value <0.05 was considered statistically significant.

RESULTS

Patient characteristics are shown in Table 1. The airway devices were successfully inserted within 2 attempts in all patients. The LMA was successfully inserted on the first attempt in 58 of the 60 patients and the OPLAC was successfully inserted on the first attempt in 59 of the 60 patients. The insertion time was significantly shorter and more consistent for the OPLAC than for the LMA (Table 2). There was no significant difference in peak airway pressure between the 2 devices. The airway sealing pressure was significantly higher and the fiberoptic position was better for the OPLAC than for the LMA. The OPLAC had a significantly lower incidence of gastric insufflations. The incidence of blood staining on the device was similar in both groups (group L, 5 of 30; group O, 2 of 30) (*P* = 0.21). The overall incidence of sore throat 2 hours after the operation was 13.33%. There was no significant difference in incidence of sore throat between the 2 groups (Table 3). Airway sealing pressure, fiberoptic grading, and insertion time were unaffected with different sequences of insertion.

DISCUSSION

The contour of the OPLAC is supported by the pliable ring and is reinforced by a fabricated cork plate. The pliable ring, the backbone structure of the OPLAC, is composed of thermoplastic rubber. The cap portion that actually contacts with the pharyngeal soft tissue is made of expandable silicone membrane. The smaller backbone structure that compares to LMA Classic size #3, with the expandable

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Table 2. Performance of the LMA and OPLAC

	LMA (n = 60)	OPLAC (n = 60)	P value
Ease of insertion, n (%)			0.02 ^a
Very easy insertion at the first attempt	42 (70)	54 (90)	
Insertion at the first attempt after manipulation	16 (26.7)	5 (8.3)	
Successful at the second attempt	2 (3.3)	1 (1.7)	
Insertion time, s	15.90 ± 8.04	12.62 ± 3.88	0.003 ^b
Peak airway pressure, cm H ₂ O	15.90 ± 2.52	16.08 ± 2.33	0.68 ^c
Airway sealing pressure, cm H ₂ O	23.03 ± 4.43	27.53 ± 2.78	<0.001 ^b
Gastric insufflations with ASP >18 cm H ₂ O, n (%)	10/55 (18.2)	0/59 (0)	<0.000 ^d
Blood on the first device upon removal, n (%)	5/30 (16.7)	2/30 (6.7)	0.21 ^c
Fiberoptic view, n (%)			0.001 ^{d,e}
Grade 1	25 (41.7)	25 (41.7)	
Grade 2	8 (13.3)	34 (56.7)	
Grade 3	25 (41.7)	1 (1.7)	
Grade 4	2 (3.3)	0 (0)	
Grade 1 + 2 (optimal)	33 (55.0)	59 (98.3)	
Grade 3 + 4 (suboptimal)	27 (45.0)	1 (1.7)	

LMA = laryngeal mask airway; OPLAC = Oro-Pharyngo-Laryngeal Airway Cap; ASP = airway sealing pressure.

^a Fisher 2 × 3 test; ^b Student t test; ^c not significant; ^d Fisher exact test; ^e significance determined between "optimal" and "suboptimal."

Table 3. Incidence of Postoperative Sore Throat

	Group L (LMA-OPLAC)		Group O (OPLAC-LMA)	
	2 h	24 h	2 h	24 h
Mild, n (%)	6 (10.0)	4 (6.7)	4 (6.7)	2 (3.3)
Moderate, n (%)	3 (5.0)	2 (3.3)	2 (3.3)	0 (0)
Severe, n (%)	1 (1.7)	0 (0)	0 (0)	0 (0)

LMA = laryngeal mask airway; OPLAC = Oro-Pharyngo-Laryngeal Airway Cap.

membranous cap, makes it possible to fit patients in a wide range of body size (Figs. 1 and 2).

The insertion time was defined as the time needed from insertion to the time of ready-to-ventilate. Because the OPLAC is designed to seal without a cuff, the engagement of the OPLAC was signaled by loss of resistance against the tongue base. More time was spent for LMA insertion because of the need for cuff inflation and the more frequent manipulation requirement (Table 2). Besides the 3.28-second difference of the mean insertion time, the LMA had a wider variation of the insertion time, which might be significant during an emergent situation when every second counts.

Positive pressure ventilation with an airway pressure >18 cm H₂O increases the incidence of gastric insufflations, especially when the LMA position is suboptimal.¹¹⁻¹⁵ In this study, OPLAC was more likely than the LMA to have

an optimal position (grade 1-2). In addition, during positive pressure ventilation, the expandable silicone membrane is attached and pushed against the airway mucosa, thus enhancing sealing. Any increase of positive pressure needed for ventilation contributes to sealing in the OPLAC. The membranous pouch covering the hypopharynx not only diverted the airflow from the esophagus into the glottis but also acted as a check valve so that gastric insufflations were prevented (Fig. 4). This patented design makes the OPLAC a supraglottic airway device with a high sealing pressure.

The OPLAC may be suitable for operations in which a higher pressure seal is required and in which gastric insufflations should be minimized such as laparoscopic cholecystectomy. However, further comparative study on high pressure sealing among the OPLAC, cuffed supraglottic airway devices (e.g., LMA Proseal™ or LMA Supreme™, LMA North America, Inc.), and anatomically fit supraglottic airway devices (e.g., SLIPA™ [SLIPA Medical, Ltd., Isle of Man, UK] or i-gel™ [Intersurgical, Ltd., Berkshire, UK]) is needed to further validate the device.

The supraglottic airway devices cause sore throat by 2 mechanisms. One is by applying constant high pressure over the pharyngeal mucosa and the other is traumatic insertion. In the study by Miller and Camporota,¹⁶ the LMA Proseal and SLIPA both showed an airway sealing pressure above 30 cm H₂O, which was considered lower than, but approaching that, of an endotracheal tube. However, the incidences of postoperative sore throat caused by the LMA Proseal and SLIPA were 30% and 40%, respectively. OPLAC was designed to decrease the incidence of sore throat while achieving a high airway sealing pressure, which was 23.03 ± 4.43 cm H₂O in this study.

The noncuffed design of the membranous cap is implemented to reduce mucosa compression and the incidence of postoperative sore throat. In this study, LMA insertion was performed with the cuff partially inflated. This technique was preferred because an equal or higher success rate with the cuff partially inflated than deflated has been reported and is one of the most popular techniques.⁵⁻⁷ This technique was also associated with less pharyngeal mucosal trauma and a lower incidence of postoperative sore throat.⁸ In our study, every patient received insertion of both devices but in different sequences. The overall incidence of sore throat after 120 insertion attempts was 13.3%. However, there was a limitation of the crossover design to evaluate the incidence and the severity of postoperative sore throat because the same subject had both devices inserted. Head-to-head studies comparing the incidence of sore throat with the OPLAC and other supraglottic airway devices with high airway sealing pressure would be warranted.

The fabricated cork plate incorporated into the OPLAC not only acts as a splint to stabilize the structure of the OPLAC but also acts as a secretion absorber. As the fabricated cork plate absorbs the secretion in the laryngeal side, it expands and becomes softer. As the membrane cap gets more accommodated to the pharyngeal wall with time, the softened, expanded cork plate exerts less pressure

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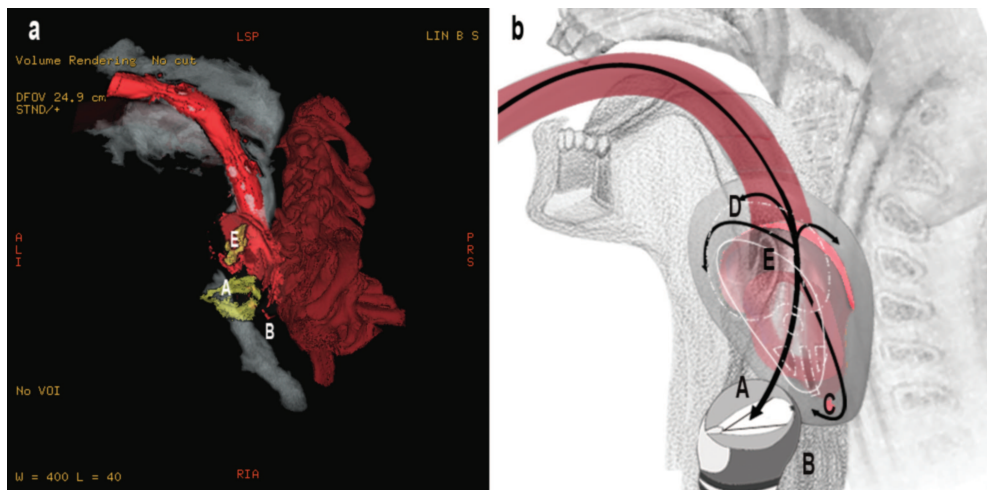


Figure 4. Schematic diagram illustrating how the Oro-Pharyngo-Laryngeal Airway Cap (OPLAC™) seals. a, Computed tomographic reconstruction of the OPLAC inserted in the throat showing the relationship among the tube aperture, the epiglottis (E), and the glottis (A). b, Illustration of the airway directed below the level of the epiglottis (E) toward the glottis (A) through the aperture of the membranous cap. The upper (D) and lower (C) pouches of the membranous cap as check valves prevent air leakage and gastric insufflations through the hypopharynx (B), respectively. The positive airway pressure during mechanical ventilation enhances airway sealing in the OPLAC.

over the mucosa while maintaining the seal. Upon extubation, the expanded OPLAC itself theoretically sweeps out the secretion. The secretion absorbed by the fabricated cork plate is also removed. This theoretical design was, however, not tested in this study. The secretion-absorbing performance would also be a future direction of studies on the OPLAC.

In this randomized, single-blinded, crossover study in paralyzed adult patients, we found that the noncuffed OPLAC was easy to insert. Compared with the cuffed LMA Classic, the OPLAC required less insertion time, and the insertion time was less variable for the OPLAC. The OPLAC fit better to the laryngopharynx and created a better airway sealing than the cuffed LMA Classic. We also found that the OPLAC had a higher sealing pressure and was associated with a lower incidence of gastric insufflations than the LMA Classic. ■■

DISCLOSURES

Name: Bih-Chern Lin, MB, BS.

Contribution: This author helped to design the study, conduct the study, analyze the data, and write the manuscript.

Attestation: This author has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.

Conflicts of Interest: Bih-Chern Lin is the inventor of the OPLAC™ laryngeal mask airway and may possibly benefit indirectly from its sale.

Name: Rick S. C. Wu, MD.

Contribution: This author helped to design the study, conduct the study, and analyze the data.

Attestation: This author approved the final manuscript.

Conflicts of Interest: This author reported no conflicts of interest.

Name: Kuen-Bao Chen, MD.

Contribution: This author helped to write the manuscript.

Attestation: This author has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Conflicts of Interest: This author reported no conflicts of interest.

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Contribution: This author helped to write the manuscript.

Attestation: This author approved the final manuscript.

Conflicts of Interest: This author reported no conflicts of interest.

Name: Yu-Chien Lo, MD.

Contribution: This author helped to conduct the study and analyze the data.

Attestation: This author approved the final manuscript.

Conflicts of Interest: This author reported no conflicts of interest.

Name: Yi-Ying Chiang, MD.

Contribution: This author helped to conduct the study and write the manuscript.

Attestation: This author approved the final manuscript.

Conflicts of Interest: This author reported no conflicts of interest.

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AUTHOR QUERIES

AUTHOR PLEASE ANSWER ALL QUERIES

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AQ1— Please check added manufacturer information in the paragraph that begins “The OPLAC
may be...”
