

Cardiothoracic Anesthesia, Respiration and Airway

The ProSeal™ laryngeal mask airway: a review of the literature

[Le masque laryngé ProSeal™ : un examen des publications]

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Purpose: To analyze and summarize the published literature relating to the ProSeal LMA (PLMA): a modification of the 'classic LMA' (cLMA) with an esophageal drain tube (DT), designed to improve controlled ventilation, airway protection and diagnosis of misplacement.

Source: Articles identified through Medline and EMBASE searches using keywords 'Proseal', 'ProSeal' and 'PLMA'. Hand searches of these articles and major anesthetic journals from January 1998 to March 2005.

Principal findings: Searches identified 59 randomized controlled trials or clinical studies and 79 other publications. Compared to the cLMA, PLMA insertion takes a few seconds longer. First attempt insertion success for the PLMA is lower, but overall success is equivalent. Airway seal is improved by 50%. The DT enables early diagnosis of mask misplacement, allows gastric drainage, reduces gastric inflation and may vent regurgitated stomach contents. Evidence suggests, but does not prove, that the correctly placed PLMA reduces aspiration risk compared with the cLMA. PLMA use is associated with less coughing and less hemodynamic disturbance than use of a tracheal tube (TT). Comparative trials of the PLMA with other supraglottic airways favour the PLMA. Clinicians have extended the use of the PLMA inside and outside the operating theatre including use for difficult airway management and airway rescue.

Conclusions: The PLMA has similar insertion characteristics and complications to other laryngeal masks. The DT enables rapid diagnosis of misplacement. The PLMA offers significant benefits over both the cLMA and TT in some clinical circumstances. These and clinical experience with the PLMA are discussed.

Objectif : Analyser et résumer les publications sur le ML ProSeal (MLP) : une modification du «ML classique» (MLc), muni d'un tube de drainage œsophagien (TD), conçu pour améliorer la ventilation contrôlée, la protection des voies aériennes et le diagnostic d'une malposition.

Source : Articles trouvés dans les bases Medline et EMBASE à partir des mots clés «Proseal», «ProSeal» et «PLMA». Des recherches manuelles de ces articles et des principaux journaux d'anesthésie publiés de janvier 1998 à mars 2005.

Constatations principales : Nos recherches ont permis de découvrir 59 essais contrôlés et randomisés ou études cliniques et 79 autres publications. L'insertion du MLP, comparée à celle du MLc, prend quelques secondes de plus. Le taux d'insertion réussie au premier essai avec le MLP est plus faible, mais le taux global est équivalent. L'étanchéité de l'intubation est améliorée de 50 %. Le TD permet le diagnostic précoce d'une malposition du masque, assure le drainage gastrique, réduit le gonflement gastrique et permet de dégager les régurgitations de l'estomac. Il y a des indices, non des preuves, que le MLP bien placé, comparé au MLc, réduise le risque d'aspiration. L'usage du MLP est associé à moins de toux et de perturbations hémodynamiques que l'usage du tube endotrachéal (TE). Des essais comparatifs du MLP et d'autres canules oropharyngées favorisent le MLP. Les cliniciens ont étendu l'usage du MLP à l'intérieur et à l'extérieur de la salle d'opération, entre autres pour l'intubation difficile ou le contrôle urgent des voies respiratoires.

Conclusion : Le MLP présente des caractéristiques d'insertion et des complications semblables à celles d'autres masques laryngés. Le TD permet le diagnostic rapide d'une malposition. Le MLP offre des avantages significatifs par rapport au MLc et au TE dans certains contextes cliniques.

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Conflict of interest: Dr. Tim Cook has received honoraria for lecturing from Intavent Orthofix and the LMA company (both companies are distributors of the PLMA).

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THE ProSeal™ laryngeal mask airway (PLMA; Intavent Orthofix, Maidenhead, UK), designed by Dr. Archie Brain, is based on the classic laryngeal mask airway (cLMA). It was introduced in 2000. Modifications were designed to enable separation of the gastrointestinal and respiratory tracts, improve the airway seal, enable controlled ventilation and diagnose mask misplacement.¹ A drain tube (DT) enables diagnosis of mask misplacement and also aims to reduce risks of gastric inflation, regurgitation and aspiration of gastric contents.

Methods

Articles were found through searches using keywords 'Proseal', 'ProSeal' and 'PLMA' on Medline and EMBASE. Reference lists of these articles and the major anesthetic journals (from January 1998 to March 2005) were hand searched. Searches identified 59 randomized controlled trials (RCTs) or other clinical studies and 79 case reports, letters or abstracts.

This is a pragmatic, descriptive review. Much source material consists of reports of new applications, as small trials or correspondence. The review assumes the reader is familiar with the design and performance of the cLMA.

There are 27 PLMA RCTs and sufficient summed data to compare insertion time, insertion success, and airway seal pressure, with the cLMA. There are insufficient data on other aspects of PLMA performance [risk of aspiration and safety compared to cLMA or tracheal tube (TT)] to analyze quantitatively.

The review is presented in three sections:

I. PLMA design, technical aspects, practicalities of use and performance

Design

Size selection, adjuncts and cost

Practicalities of use

Positioning and use of the DT to diagnose malposition

Performance

Use in children

Complications: actual and potential

II. Comparisons between the PLMA and other airway devices

Comparisons with the cLMA

Comparisons with the TT

Comparisons with other supraglottic airways

III. Clinical experience with the PLMA and use of the PLMA to extend the role of the supraglottic airway

Laparoscopic cholecystectomy

Gynecological laparoscopy

Obese patients

Difficult airway management

Intensive care

Trauma and resuscitation

Other

Conclusions

I. PLMA design, technical aspects, practicalities of use and performance

Design

The PLMA, like the cLMA, consists of airway tube, bowl and cuff (Figure 1). The airway tube is reinforced with similar calibre to an equivalent reinforced/flexible LMA (fLMA). Modifications compared to the cLMA are: 1) larger and deeper bowl with no grille; 2) posterior extension of the mask cuff; 3) drainage tube running parallel to the airway tube and exiting at the mask tip; 4) integral silicone bite block; 5) anterior pocket for seating an introducer or finger during insertion. The bowl lacks the 'semi rigid shell' of the cLMA.¹

The inventor's aims of the modifications are: 1) avoidance of gastric inflation during controlled ventilation; 2) less need for tight occlusion of the upper esophageal sphincter (UES) by the mask tip in the event of regurgitation, because of the presence of the DT; 3) opportunity to pass an orogastric tube (OGT); 4) channelling of regurgitated stomach contents.¹ Changes were also designed to improve airway seal. An important design function of the DT was to allow rapid diagnosis of mask misplacement.

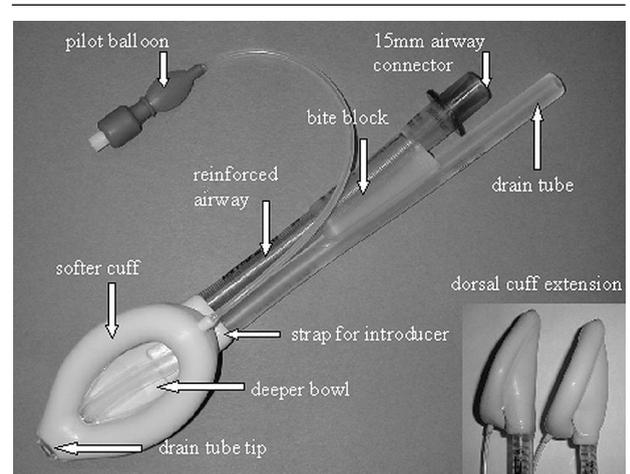


FIGURE 1 ProSeal Laryngeal Mask airway.

TABLE I PLMA dimensions and technical details

PLMA Size	Patient size	Maximum cuff inflation volume	Median volume for 60 cm H ₂ O	Max diameter orogastric tube	Distance to tip of drain tube
1½	5-10 kg	7	*	10	18.2 cm
2	10-20 kg	10	*	10	19.0 cm
2½	20-30 kg	14	*	14	23.0 cm
3	30-50 kg	20	*	16	26.5 cm
4	50-70 kg	30 mL	^26, 25^^, 28^^^ mL	16 Fr (5.5 mm)	27.5 cm
5	70-100 kg	40 mL	33^^, 37^^^ mL	18 Fr (6.0 mm)	28.5 cm

*No data available; PLMA = ProSeal laryngeal mask airway. ^ (1); ^^ (11); ^^ (12). LMA ProSeal instruction manual. Intavent Limited, 2002.

Separation of the respiratory and gastrointestinal tracts

When the PLMA is positioned correctly, the airway orifice lies over the glottis and the DT tip lies behind the cricoid cartilage at the origin of the esophagus. Airway and DT each form uninterrupted routes from these sites to outside the mouth. This functional separation of the respiratory and gastrointestinal tracts is important in understanding potential advantages of the PLMA over the cLMA and other supraglottic airway devices (SADs). In this regard one might consider the PLMA to act as an 'artificial larynx', rather than simply an airway tube.

Size selection, practical aspects, adjuncts and cost

Sizes 3 to 5 were introduced in 2000 and sizes 1½ - 2½ in 2004. Sizes 1½ - 2½ have no dorsal cuff.

Device properties and recommendations for use are summarized in Table I. The manufacturer's recommendations for size selection are identical to the cLMA.² Two studies in Japanese patients reported identical performance and higher airway seal in males with size 5 (compared to size 4). In females, size 4 produced the best compromise between insertion ease and airway seal.^{3,4} No data on other size selection in other ethnic groups exist.

The PLMA is reusable and recommended product life is 40 sterilizations.² Not all protein material can be removed by routine cleaning of laryngeal masks and this raises theoretical concerns over cross-infection risk. Interestingly there are no cases of bacterial, viral or prior disease transferred between patients by reuse of a sterilized LMA. Recently, cleaning cLMAs with a technique including potassium permanganate was reported to eliminate residual protein on 80% of LMAs and reduce protein load on the remaining 20%.⁵ Residual protein on the devices was reduced by an estimated 91%. Similar reductions in protein load would be anticipated with the PLMA.

The PLMA is accompanied by a cuff-deflator and insertion tool (Figures 2 and 3). The cuff deflator assists complete deflation and flattening the device tip before insertion to improve insertion success.

The cost of a PLMA is between 110% and 130% of the cost of a cLMA.

Insertion

DEPTH OF ANESTHESIA

A 40% increase in plasma concentration of propofol (4.3 *vs* 3.1 µg·mL⁻¹) and a 20% increase in end-tidal sevoflurane (2.8% *vs* 2.4%) was required for insertion of the PLMA compared to cLMA.⁶

INSERTION TECHNIQUE

Insertion is recommended with head extended and lower neck flexed, and may be performed with or without an introducer.

Insertion without an introducer is similar to cLMA insertion² (Figure 4). The index finger is placed in the retaining strap (Figure 1): this is made easier by lateral compression of the body of the mask to bow the strap outward. The PLMA is pressed against the hard palate and advanced into the hypopharynx until resistance is felt. The finger in the retaining strap is pushed towards the occiput, while the other hand exerts counter-pressure to maintain the 'sniffing' position.

A silicone-coated, malleable metal introducer is provided with each PLMA (Figure 2). The distal end locates in the retaining strap and the proximal end in the notch between airway tube and DT. The PLMA then resembles the intubating laryngeal mask airway (ILMA) and insertion technique is very similar,² except ideal head and neck position is 'sniffing' for the PLMA insertion, and 'neutral' for the ILMA. The bowl is placed into the mouth, guided against the hard palate and advanced in a smooth arc with the handle, until

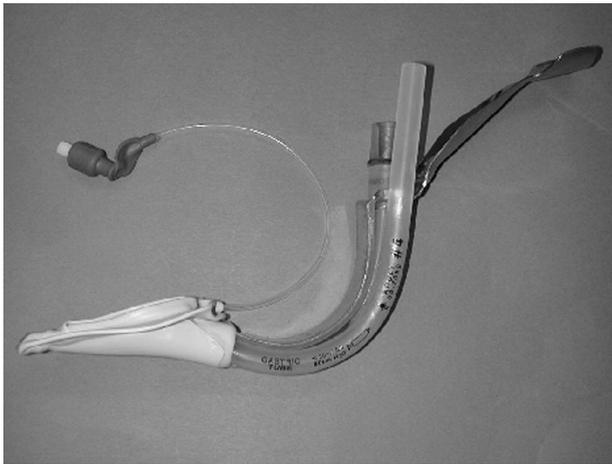


FIGURE 2 Introducer.

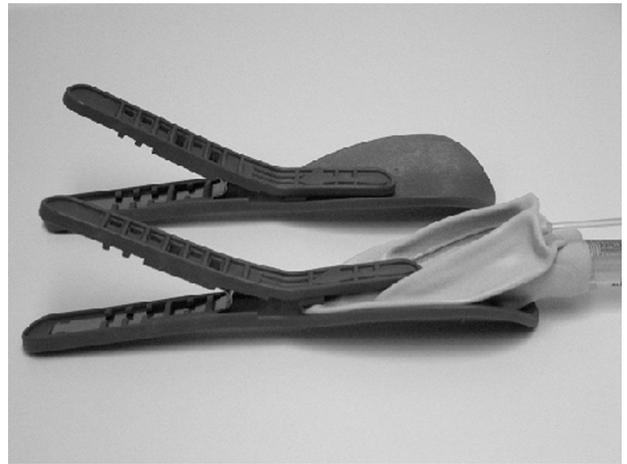


FIGURE 3 Tip flattener.

resistance is encountered (Figure 5). The introducer is then removed, taking care to avoid dental damage.

After insertion the cuff is inflated. A defined volume of air can be used, but inflation to an intracuff pressure of 60 cm H₂O is preferred¹ as this minimizes pharyngeal mucosa pressure.⁷ Correct placement produces a leak-free seal with the mask tip wedged against the UES. If positioned correctly at least 50% of the bite block usually disappears beyond the upper incisors. Where the entire bite block is visible the device is almost certainly misplaced.⁸ Inward force while the PLMA is secured reduces extrusion and misplacement.⁹

INSERTION WITH, OR WITHOUT, THE INTRODUCER AND ALTERNATIVE INSERTION TECHNIQUES

No studies have reported significant differences in insertion success between digital and introducer techniques.¹⁰⁻¹²

An alternative technique involves placing a gum elastic bougie (GEB) into the esophagus using a laryngoscope and railroading the PLMA DT over this. This technique prevents folding of the mask tip and increases correct placement of the PLMA¹³ (Figure 6). In 100 paralyzed patients first time insertion success, correct positioning (assessed clinically) and OGT passage were all 100% without evidence of increased complications or airway trauma.¹⁴

In 240 patients with three insertion techniques (a: digital, b: introducer and c: GEB-guided railroading) the railroading technique was most successful.¹⁵ First time insertion success was 84%, 88% and 100% respec-

tively ($P < 0.05$ between railroading and the conventional techniques). With three attempts there were no significant differences. The authors report > 3,000 GEB-guided insertions without mask folding.¹⁶ GEB-guided insertion requires laryngoscopy and intentional GEB insertion into the esophagus. It is therefore unlikely to be the routine first choice technique, but is useful if difficulties are encountered with conventional methods.

AIRWAY MECHANICS

The airway tube of the PLMA is shorter than the cLMA, is wire-reinforced and of similar calibre to the fLMA. The bowl has no grills. Airway resistance is 20% greater than the cLMA and more like the fLMA.¹⁷

PASSAGE OF AN OGT

A (lubricated, not refrigerated) OGT can be passed through the DT when indicated (Table I). Slight resistance may be noted as the OGT negotiates the distal end of the DT and passes the UES. Inability to pass an OGT indicates mask misplacement.¹⁸

USE OF THE DT TO CONFIRM CORRECT POSITIONING

Gel placed over the exit of the DT enables detection of mask malposition. If the gel is ejected with airway pressure < 20 cm H₂O the PLMA is probably misplaced.¹ False negatives are minimized by using no more than 5 mm depth of gel or a meniscus of non-toxic liquid soap.



FIGURE 4 Digital insertion.



FIGURE 5 Introducer insertion.

Positioning and use of the DT to diagnose misplacement

PLACEMENT AND MISPLACEMENT OF THE PLMA

When positioned correctly, the PLMA tip lies behind the cricoid cartilage (Figure 7a). There are three important misplacements:

- 1) The mask tip folds over with imperfect mask position and DT malfunction (Figure 7b).
- 2) The mask is incompletely inserted: the DT tip lies in the hypopharynx, proximal to the cricoid cartilage (Figure 7c). Ventilation is ineffective, as ventilating gases pass directly out of the DT.
- 3) The mask tip is inserted into the glottis (Figure 7d). Ventilation is obstructed, and DT function is compromised.

Identification of correct placement and diagnosis of misplacement is helped by organized placement checks (Table II and III).

MISPLACEMENT 1

The PLMA mask is bulkier and less rigid than the cLMA. The tip, formed by the distal DT, does not collapse naturally, so digital pressure or use of the cuff deflator is advisable during deflation. In a series of 2,806 conventional insertions the PLMA folded backwards in 3.5% of cases:¹⁹ of these cases, the bite block was protruding in 83% and at least slight difficulty with insertion was noted in 92%.¹⁹ Higher than average airway pressures and during controlled ventilation inability to pass an OGT may also indicate similar incorrect mask position.¹⁸ A negative suprasternal notch test may assist diagnosis (see below). If left folded over, the PLMA is suboptimally positioned for ven-

tilation and the DT will not function: risk of gastric inflation and regurgitation is increased and the device should be reinserted.^{18,20}

MISPLACEMENTS 2 AND 3

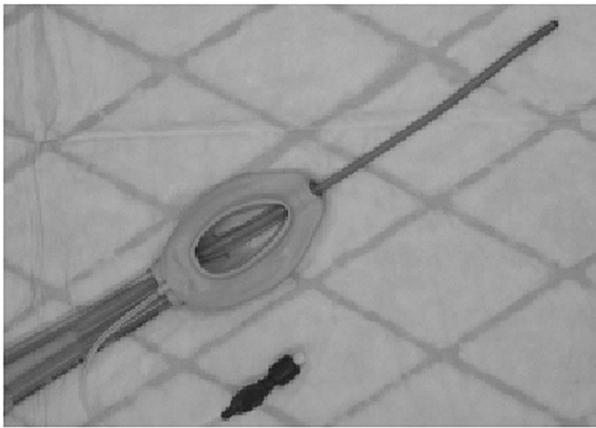
These are reduced by good insertion technique; ensuring full deflation and tip flattening before insertion, inserting fully⁸ and securing to avoid extrusion.^{9,21,22}

Misplacement of the cLMA also occurs, though the frequency of misplacements of the cLMA is unclear.²³ Misplacement impairs function of both cLMA and PLMA. The PLMA DT enables early diagnosis of misplacement: an advantage of the PLMA over the cLMA.

GEL AND 'SOAP TESTS' FOR MALPOSITION

One of the main reasons for addition of the DT in Brain's design of the PLMA was to allow diagnosis of misplacement.¹

The PLMA manufacturer advocates gel placed over the DT to diagnose misplacement, but this is unevaluated. Observation of a soapy film may be more sensitive in diagnosing misplacement: large changes in pressure within the DT lead to ballooning or rupture,²⁴ small pressure changes cause bulging or indrawing of the film. If the PLMA tip is in the glottis or is too shallow (misplacements 2 and 3), positive pressure ventilation causes bubble formation. If the PLMA tip is in the glottis, minor movements of airway gases with the cardiac cycle may make the soap-film oscillate.²⁵ Pressure on the chest causes bubble formation due to forced expiration.²⁶



1



2



3



4



5



6

FIGURE 6 Gum-elastic-bougie guided insertion.

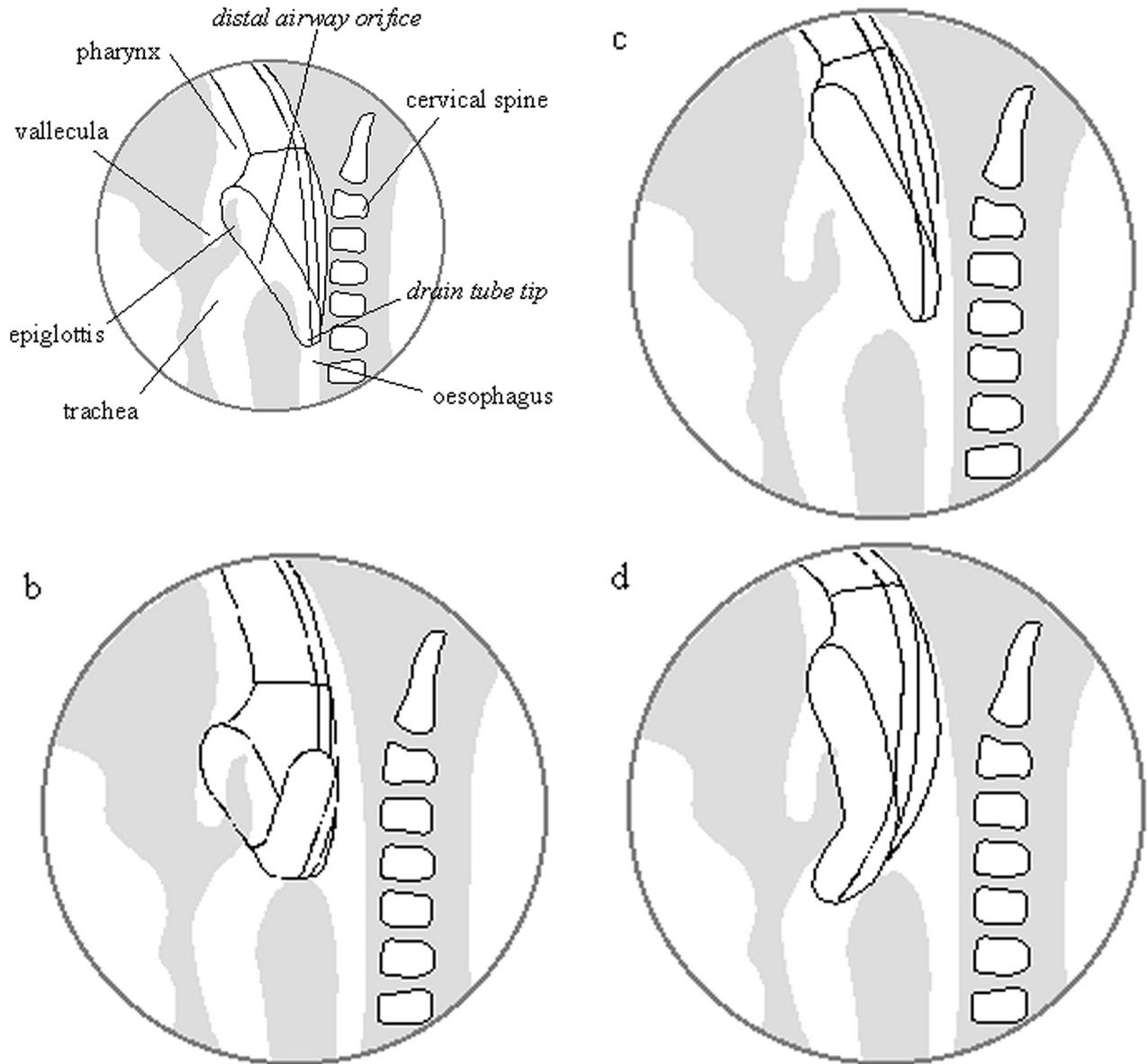


FIGURE 7 A) Correct position; B) malposition 1 (mask fold-over); C) malposition 2 (incomplete insertion); D) malposition 3 (glottic insertion).

When the PLMA is folded (misplacement 1), the DT is obstructed so pressure changes at the distal end of the DT are not transmitted proximally. This is the basis of the suprasternal notch test.²⁷ Firm tapping on the suprasternal notch is transmitted via the upper esophagus to the DT tip and causes a soapy film to bulge. If the tip has folded over, no bulging is seen. No formal evaluation of these tests is published: their reliability is unknown.¹⁸

The tests to identify correct positioning of the PLMA have been organized into an algorithm.^{18,27} We have modified this in Table II. Of note, adequate depth of anesthesia is essential before attempting insertion in non-paralyzed patients: the jaw must be fully relaxed, as indicated by no response to elevation of the angles of the jaw.²⁸ Malposition may be diagnosed by further checks (Table III).

TABLE II Tests of positioning

Algorithm:

- 1) Ensure adequate depth of anesthesia before attempting insertion
- 2) Note any resistance or hold up during insertion. This suggests folding over of the mask tip. Unexpectedly high inflation pressures may also indicate folding over of the mask tip.
- 3) Inflate cuff to 60 cmH₂O
- 4) Assess depth of insertion. >50% bite block should usually be beyond the incisors.
- 5) Assess for unobstructed inspiratory and expiratory flow, observing capnometry and spirometry. Poor compliance or reduced expiratory flow may indicate mechanical obstruction of the vocal cords.
- 6) Place a film of soapy liquid over the drain tube. A) If this blows or inflates immediately with ventilation (or oscillations of the film are seen in time with the pulse) the PLMA may be sited in the glottic opening. Pressure on the chest leading to bubble formation confirms this. B) Inflation of the film with applied pressure of less than 20 cmH₂O suggests the PLMA needs advancing further. The airway may be advanced to resolve a leak, other wise it should be removed and re-inserted.

If hold up was noted during insertion further tests to exclude tip folding should be used even if ventilation is successful. Tap on the suprasternal notch. If this pressure rise is not transmitted to the drain tube as a bubble, the tip of the mask may be folded over. Inability to pass an OGT freely to the tip of the drain tube may be used to confirm this (size 3 26.5 cm, size 4 27.5 cm, size 5 28.5 cm). If the tip is folded over the PLMA should be re-inserted.

PLMA = ProSeal laryngeal mask airway; OGT = orogastric tube.

FURTHER USE OF THE DT OF THE PLMA

The DT has been used for a variety of esophageal tubes and catheters during anesthesia (Doppler probe, esophageal stethoscope, temperature probe). Partial occlusion of the DT with another tube may prevent it from functioning as designed.

Performance details

INSERTION SUCCESS

Overall insertion success, reported in 33 studies and 2,581 PLMA insertions ranged from 90 to 100%: mean 98.4% (Table IV).^{1,3,4,7,10-12,14,15,17,20,29-50}

First time insertion success, reported in 28 studies and 2,388 PLMA insertions ranges from 76% to 100%: mean 87.3% (Table IV).^{1,3,4,7,10-12,14,15,20,29-33,35-41,43-47,50}

AIRWAY SEAL PRESSURE

Average airway seal pressure reported in 24 studies and 2,017 PLMA uses ranges from 23 cm H₂O to 32 cm H₂O, in 23 studies and is 47 cm H₂O in one (Table IV).^{1,3,4,7,10-12,14,15,29-33,35,37,40,42,44-46,48-50}

Several design factors contribute to the improved airway seal of the PLMA compared to the cLMA. The larger, softer wedge-shaped PLMA cuff enables the anterior cuff to adapt to the shape of the pharynx better. Secondly, the deeper PLMA bowl helps push the PLMA forward onto the periglottic tissues. The Hidrain is a prototype of the PLMA, which lacks the posterior cuff. Hidrain seal pressure is 28 cm H₂O: between the cLMA and PLMA confirming this effect (unpublished data, T.M. Cook). Using strain gauge microchip sensors over multiple mask sites with PLMA and cLMA confirms that

TABLE III Differential diagnosis of PLMA misplacement

<i>Indicators of PLMA misplacement</i>	<i>Probable position</i>	<i>Action</i>
Hold up during insertion High airway pressures Failed ventilation Inability to pass an OGT via the drain tube	Folding of tip	Remove PLMA and reinsert.
More than 50% of bite block protruding beyond the incisors	Proximal supra glottal placement	Attempt advancing to deeper position or reinsert
Blow off of gel (or soap) from the drain tube with an airway pressure of < 20 cm H ₂ O Oscillations or bubbles blown from the drain tube Chest pressure leads to bubble formation with soap	Supra glottal placement or sited in glottal opening	Remove PLMA and reinsert
Indrawing of drain port soap/gel with inspiration (spontaneous ventilation)	Dysfunctional upper esophageal seal-possible esophageal inflation	Leave OGT indwelling Controlled ventilation should eliminate risk

PLMA = ProSeal laryngeal mask airway; OGT = orogastric tube.

TABLE IV Insertion success, OGT insertion success and airway seal pressure in published trials

<i>First author [ref]</i>	<i>Patients studied (PLMA insertions)</i>	<i>NM RA</i>	<i>First attempt insertion success (%)</i>	<i>Overall insertion success (%)</i>	<i>First attempt OGT insertion success</i>	<i>Airway seal pressure (sd) [range]</i>
Brain [1]	30 (30) i	Y	30 (100)	30 (100)	30/30 (100)	30 [15-40]
Kihara [3]	90 (90) d	Y	83 (92)	90 (100)		25
Kihara [4]	237 (237) d	Y	219 (92)	237 (100)	16	26 (8)
Keller [7]	32 (16) d	Y	14 (88)	(100)		26 [(21-31)] [^]
Brimacombe [10]	60 (60) d	Y	52 (87)	60 (100)	58/58 (100)	27
Cook [11]	180 (180) i/d	N	145 (81)	178 (99)	135/147 (92)	29 [23-38]**]
Evans [12]	300 (300) i/d	N/Y	243 (81)	294 (98)	290/300 (97)	29 (6)
Howarth [14]	100 (100) g	Y	100 (100)*	10 (100)	100/100 (100)	33 [17-40]
Brimacombe [15]	240 (240) idg	Y	217 (90)*	237 (99)		31 (8)
Natalini [17]	26 (26) n/s	Y				
Agro [20]	150 (150) d	Y	135 (87)	140 (93)	139/140 (99)	
Brimacombe [29]	30 (30) i	Y	30 (100)	30 (100)		32 (6)
Brimacombe [30]	30 (30) i	N	30 (100)	30 (100)		36 (6) ^{^^}
Brimacombe [31]	384 (192) d	N	159 (83)	189 (98)	74/95 ((78)	27 (7)[10-40]
Lu [32]	80 (40) d	Y	33(83)	40 (100)	40/40 (100)	29 (6)
Braun [33]	280 (145) n/s	N	123 (85)	145 (100)	118/135 (87)	29 (0.2)
Natalini [34]	60 (30) d	Y		30 (100)	27/30 (90)	
Keller [35]	60 (60) i	Y	54 (90)	60 (100)	60/60 (100)	32 (8)[12-40]
Figuerado [36]	70 (35) n/s	N	27 (77)	35 (100)		
Brimacombe [37]	120 (60) n/s	Y	51 (85)	60 (100)		33 (7) ^{^^}
Ovassapian [38]	20 (20) id	Y	18 (90)	19 (95)	18/19 (95)	
Kong [39]	52 (52) i	Y	41 (79)	52 (100)	52/52 (100)	
Gaitini [40]	150 (75) n/s	Y	57 (76)	72 (96)	70/72 (97)	28 (7)
Agro [41]	50 (50) d	n/s		46 (92)		
Murashima [42]	40 (40) id	Y	37 (93)	40 (100)	39/40 (98)	23 (8) ^{^^^}
Coulson [43]	60 (60) d	Y	51 (85)	54 (90)		
Cook [44]	32 (32) i	Y	32 (100)	32 (100)		27 [10-40]
Genzweucker [45]	32 (15) n/s	Y	14 (93)	15 (100)		47 [32-60]
Cartensen [46]	52 (26) n/s	N	26 (100)	26 (100)		30 16-40]
El Ganzouri [47]	82 (41) n/s	Y	33 (81)	41 (100)		
Maltby [48]	209 (37) n/s	Y				30 [14-50]
Maltby [49]	105 (50) n/s	Y			53/53 (100)	34 [18-45]
Cook [50]	32 (32) i	Y	28 (89)	32 (100)	13/13 (100)	26 [18-40]
Total	3475 (2581)	n/a	2087 (87.3)	2483 (98.4)	1316/1384 (95)	n/a

PLMA = ProSeal laryngeal mask airway; OGT = orogastric tube; Mode of insertion: i = introducer; d = digital; g = bougie assisted; n/s = not stated. *Insertion with gum elastic bougie 180/180 = 100% success. **Interquartile range. ^Cuff volume 0, 10, 20, 30, 40 mL: airway seal 18, 24, 25, 26, 27 cm H₂O. ^^Cuff volume 15 mL ("half full"): airway seal 29 cm H₂O. ^^Cuff volume 0 mL: airway seal 15 cm H₂O.

the principal cause of the improved airway seal is the device's wedge shape with lesser contribution from the posterior cuff.⁷ The dorsal cuff makes the mask shape almost conical, pushing it towards the periglottic tissues and enabling adaptation to the contours of the hypopharynx. At low inflation pressures the PLMA traps gas pockets between cuff and pharyngeal mucosa, enabling matching of anatomical contours. With increased cuff inflation, gas pockets are displaced and the mask shape is dictated more by the mask structure, and less by the pharyngeal anatomy. Over-inflation may therefore reduce seal pressure: most increase in PLMA seal pressure occurs with the first 10 to 20 mL of cuff inflation.⁷ Further inflation increases pressure exerted on the mucosa without increasing seal pressure markedly.⁷

Average seal pressure without air in the cuff was 15, 15 and 18 cm H₂O in three studies.^{7,10,42} General performance and safety of the PLMA without inflation of the cuff has not been evaluated.

USE OF THE DT TO CONFIRM CORRECT POSITION
In 150 patients with conventional PLMA insertion, ease of OGT insertion through the DT correlated with positioning of the airway over the larynx, assessed fibreoptically.²⁰ It was concluded that easy OGT passage indicates correct positioning; difficulty passing an OGT suggests the mask should be repositioned even if ventilation is satisfactory.²⁰

The GEB-guided technique ensures that the PLMA tip is optimally positioned and may be

TABLE V View of the larynx from the bowl of the PLMA

First author [ref]	Number of patients	Cords seen	Percentage	Open upper esophageal sphincter* (%)
Kihara [3]	90	86	96	1-2/30 (3-7)**
Kihara [4]	237	133	56	
Keller [7]	17	15	88	
Brimacombe [10]	60	56	93	0-7/60 (10)***
Cook [11]	178	155	87	
Evans [12]	102	94	92	
Natalini [17]	26	22	84	
Agro [20]	140	133	95	
Brimacombe [29]	30	27	90	1-2/30 (3-7)**
Brimacombe [31]	189	169	89	17/189 (9)
Braun [33]	145	131	90	
Keller [35]	60	45	74	4/60 (7)
Ovassapian [38]	19	18	95	
Agro [41]	50	47	94	
Cook [44]	32	29	91	
Cook [50]	32	32	100	
TOTAL	1407	1192	85	23-32/369 (6-9)

PLMA = ProSeal laryngeal mask airway. *Viewed via the drain tube; **Rose as intracuff pressure raised. ***1/60 with 0 mL in cuff, 2/60 with 20 mL in cuff, 7/60 with 40 mL in cuff.

favoured when correct positioning is essential or other insertion techniques fail.^{14,15}

VIEW OF THE GLOTTIS

Sixteen studies report the fiberoptic view of the larynx via the PLMA in 1,407 patients.^{3,4,10-12,17,20,29,31-34,41,44,50} Different scoring systems used make direct comparisons difficult, but the vocal cords were seen in > 80% of cases in 14 studies, mean 84.7%, (Table V). In contrast to the cLMA and ILMA, no bars or epiglottic elevator impedes the view or instrumentation of the glottis.

OGT INSERTION

Seventeen studies with 1,384 attempts report 95% first time OGT passage (Table IV).^{1,10-12,14,20,31-35,38-40,42,49,50}

Higher success rates for OGT passage (up to 100%) are reported when efforts are made to eliminate folding of the mask tip.¹⁴⁻¹⁶

Whether the OGT tube should be left in place (to enable further gastric drainage) or removed (to enable the DT to act as a vent and drain) has not been examined, and probably depends on the clinical situation.

STABILITY OF THE PLMA WITH MOVEMENT OF THE HEAD AND NECK

The effect of altering head and neck position on airway seal and position of the PLMA is similar to reports with the cLMA and fLMA.²⁹ Airway seal pressure

increased approximately 25% with neck flexion and rotation, and decreased 25% with neck extension. The authors attributed this to differences in pharyngeal volume in these positions. Fiberoptic examination confirmed the airway and DT position did not alter with movement of head and neck. Seal pressure was higher with PLMA than cLMA in all positions.

HEMODYNAMIC RESPONSES TO INSERTION

Previous laryngeal mask studies indicate only minor hemodynamic responses to cLMA insertion with a 0 to 20% increase in heart rate and mean arterial blood pressure.²³ Hemodynamic responses to PLMA insertion were similar to those of the cLMA in a randomized comparative trial of 280 patients anesthetized with a standard technique.³³ Two non-randomized studies of 335 patients with varying anesthetic techniques reported hemodynamic variables change less than 10%.^{12,36} An abstract reports hemodynamic response to insertion/removal of the PLMA as significantly less than for tracheal intubation/extubation.⁴⁷

PLMA use in children

There are limited clinical data on PLMA use in children. PLMA sizes 1½- 2½ do not have posterior cuffs and performance may differ from larger PLMAs. A lower seal pressure is unlikely to have major clinical implications due to the high compliance of most children's lungs.

TABLE VI Sore throat and mucosal injury.

First author [ref]	Sore throat	Mucosal injury
Brain [1]		2/30 (7)
Kihara [3]	18/90 (20)	
Kihara [4]	43/237 (18)	13/237 (5)
Evans [12]	60/265 (23)	
Howarth [14]	21/40 (53)	3/40 (7)
Brimacombe [15]		9/240 (4)
Brimacombe [31]	46/192 (24)	34/192 (18)
Lu [32]		6/40 (15)
Natalini [34]	6/30 (20)	
Figuerado [36]	9/35 (26)	4/35 (11)
Brimacombe [37]	7/60 (12)	4/60 (7)
Ovassapian [38]	1/19 (5)	2/19 (11)
Kong [39]	5/52 (10)	4/52 (8)
Gaitini [40]	9/75 (12)	12/75 (16)
Agro [41]	1/50 (2)	
Genzweurker [45]	2/15 (13)	
El Ganzouri [47]	20/41 (49)	
Total	256/1305 (21)	3126/1157 (10.9)

* Occult blood detected on 58/240 (24%) ProSeal laryngeal mask airways.

Two studies compared the size 2 PLMA with the cLMA. In 30 children weighing 10 to 21 kg first time insertion was always successful. The PLMA was associated with a higher seal pressure and maximum tidal volume, less gastric inflation and improved laryngeal view compared to the cLMA.⁵¹ In another study of 60 children: insertion, airway seal and fiberoptic view were all equivalent.⁵² OGT passage was successful in all patients in both studies. Type II errors are possible in these small studies.

Complications: actual and potential

1. MUCOSAL INJURY AND SORE THROAT

Mucosal injury, recognized by blood on the PLMA after removal, in 1,235 patients ranged from 3 to 28%: mean 10.2%.^{1,3,4,14,15,31-33,36-40} (Table VI). The incidence of sore throat after 1,586 PLMA uses ranged from 2 to 49%, mean 18%.^{3,4,12,14,15,31,33,34,36-41,45,47} (Table VI).

One potential cause of sore throat is pressure exerted on the pharyngeal mucosa by the PLMA.⁷ The relationship between cuff volume, mucosal and airway seal pressures was studied in 32 patients with PLMA and cLMA. Intra-cuff pressures were lower and airway seal pressure higher with the PLMA for any given intracuff volume.⁷ The pressure exerted on the mucosa was below that considered critical for mucosal perfusion.⁷ Therefore, the PLMA forms a more effective seal without an increase in mucosal pressure. The ILMA exerts higher mucosal pressures than the cLMA or PLMA:^{7,23} thus, when using recommended intracuff

volumes/pressures, the PLMA is the least likely of the LMA devices to impair mucosal perfusion.⁷

2. AIRWAY PROTECTION, GASTRIC INFLATION, REGURGITATION AND ASPIRATION

Design and performance features of the PLMA are expected to reduce gastric inflation, regurgitation and pulmonary aspiration compared to the cLMA.

In a bench study fluid was injected into a model esophagus: at 15 mL·sec⁻¹ the PLMA prevented aspiration; at 30 mL·sec⁻¹, or with the DT occluded, protection was reduced but better than the cLMA.⁵¹

In ten fresh cadavers with a PLMA in place and the DT open, incremental filling of the esophagus did not cause tracheal soiling.⁵³ The PLMA provided better airway protection during 'regurgitation' than the cLMA. With the DT occluded the PLMA protected the airway from soiling at pressures up to 68 cm H₂O. With the DT open no soiling occurred even with higher pressures. Passive regurgitation generates esophageal pressures < 12 cm H₂O, and intragastric pressure is rarely above 34 cm H₂O.⁵³

In 103 paralyzed and non-paralyzed anesthetized adults the PLMA DT was filled with methylene blue (representing a pressure of 12 cm H₂O) and kept filled throughout anesthesia.⁵⁴ In 101 patients no soiling of the PLMA bowl was seen. In two patients soiling was attributed to intraoperative movement. It was concluded that a properly positioned PLMA isolates the airway from fluid within the hypopharynx.

If high ventilation pressures are used during PLMA use, gas leakage occurs, but less so than with the cLMA. Gas leaks into the oropharynx in 95% of cases^{7,12,32,35} similar to the cLMA.^{7,32} The DT of the PLMA (unlike the cLMA) enables venting of gas leaking to the esophagus, making gastric inflation less likely.

There are 15 reported cases of regurgitation without aspiration with the PLMA^{36,55-63} In all cases the DT vented liquid or solid gastric contents without airway soiling.

The PLMA should not be regarded as absolutely safe where there is an increased risk of regurgitation or aspiration. Importantly, the drainage tube tip must be positioned correctly for it to work correctly. There are three cases reported of definite aspiration^{41,64,65} and two of possible aspiration.^{49,66} Malposition was a recognized cause in one case of aspiration.⁶⁴

UES PRESSURE AND FUNCTION

It has been suggested that the larger PLMA tip may mechanically open the UES¹ contributing to regurgitation.²² The PLMA DT allows fiberoptic inspection of the UES during use. The UES was open in two

cases of regurgitation^{57,59} and during routine use in 3 to 9% of cases (Table V).^{3,10,29,31,35} The UES should not be visible via a correctly positioned cLMA, but is seen in the mask bowl in 15% of routine cases.⁶⁷

The effect of PLMA and cLMA on upper and lower esophageal sphincter (LES) performance was studied in awake patients, using topical oropharyngeal local anesthesia.⁶⁸ Neither device altered sphincter pressures, while both increased deglutination rate. The authors concluded that any PLMA effect on the UES is similar to the cLMA. Whether the results are generalizable to performance during general anesthesia is unclear.

ASPIRATION RISK WITH cLMA AND PLMA COMPARED

Reported evidence suggests the PLMA reduces aspiration risk compared to the cLMA: proof is difficult. Meta-analysis of cLMA use estimates the incidence of clinically detectable regurgitation as 18 in 10,024 and aspiration one in four to 11,000.⁶⁹ No large series of PLMA use exists to provide comparative data with the cLMA. In an estimated 1,000,000 uses of the PLMA (data on file LMA company) there are three cases of confirmed, and two of possible pulmonary aspiration (incidence one in 200,000–300,000).^{40,49,64–66} To have an 80% likelihood of detecting a genuine 50% reduction in aspiration with the PLMA would require a trial of 2,600,000 patients.

There is design, laboratory, cadaver and clinical evidence to support the view that the correctly placed PLMA is less likely to cause gastric inflation or allow aspiration than the cLMA. Both devices affect LES and UES similarly: however reduced aspiration risk with the PLMA has not, and probably cannot be, proven.

3. AIRWAY OBSTRUCTION

The PLMA may cause airway obstruction. Three mechanisms are: 1) the PLMA tip (and DT) enter the glottis leading to obstruction or failed ventilation through gas leak; 2) the sides of the PLMA bowl (larger and more pliable than the cLMA) fold inwards with partial or complete glottic occlusion by the device cuff; 3) the PLMA tip behind the larynx compresses the posterior larynx causing arytenoid malfunction or rotation and vocal cords shortening; paradoxical cord movement during spontaneous ventilation and mechanical closure during positive pressure ventilation might be observed. Notably, these problems also occur with the cLMA,²³ but the larger size and softer material of the PLMA may increase their frequency.

Several cases of obstruction are reported.^{21,25,33,70,71} The soap test may help with detection and differential diagnosis.²⁵

Two authors have quantified the frequency of PLMA-associated airway obstruction. Brimacombe reported 19 cases of partial obstruction during 6,321 PLMA uses (0.3%) in paralyzed patients.⁷²

The maximal minute ventilation (MMV) test may be used to detect obstruction:⁷³ during maximal attempted manual ventilation, supraglottic obstruction slows expiration, reduces anesthetic reservoir-bag refilling and limits MMV (independent of ventilation rate). MMV was measured in 317 patients. Fiberoptic examination confirmed supraglottic or glottic obstruction in 15 of 17 cases with MMV < 12 L·min⁻¹. All devices were considered 'correctly positioned'. The authors report partial obstruction in approximately 5% PLMA uses with removal required in 2%. There are several criticisms: the measurement of MMV appears prone to observer bias; no patients with normal MMV underwent fiberoptic examination; and observer bias might influence interpretation of fiberoptic findings. Obstruction in this study is higher than reported by other authors.

An algorithm for management of airway obstruction with the PLMA has recently been recommended.⁷⁴

4. ESOPHAGEAL AND GASTRIC INFLATION

There are several reports of esophageal or gastric inflation during PLMA use from one author group.

Intermittent esophageal inflation was reported in two cases: partial glottic obstruction caused sub-atmospheric intrathoracic pressure during inspiration; air was drawn in via the DT during inspiration and expelled during expiration.²¹ No gastric inflation or complications occurred. Gastric inflation is unlikely without supranormal inspiratory effort. Paralysis, controlled ventilation, or repositioning the PLMA should resolve the problem. Similar effects can occur with the cLMA: without the DT, marked sub-atmospheric pressure may develop leading to risk of pulmonary edema.⁷⁵ The PLMA DT likely limits negative intrathoracic pressure and therefore protects against further complication.⁷⁵

Esophageal inflation with gastric inflation occurred during spontaneous ventilation.⁷⁰ PLMA placement led to arytenoid dysfunction with glottic narrowing and paradoxical motion causing stridor. It is unclear whether LES dysfunction contributed to air advancing to the stomach. The authors suggest the 'soap test' to diagnose the problem: soap on the DT will be forcibly indrawn during inspiration. Once detected, OGT passage and controlled ventilation should resolve the problem. The PLMA is designed for use with controlled ventilation (with or without muscle relaxation), and the inventor, responding to these reports, advises use with controlled ventilation in preference to spontaneous ventilation.^{31,75}

TABLE VII Insertion and seal pressure results for comparative trials between cLMA and PLMA

<i>Study [reference]</i>	<i>Number of patients in study</i>	<i>First time insertion success (%); PLMA vs cLMA</i>	<i>Overall insertion success (%) PLMA vs cLMA</i>	<i>Seal pressure cmH₂O; PLMA vs cLMA</i>	<i>Insertion time: seconds; PLMA vs cLMA</i>
Brain [1]	30 x	100 vs 100	100 vs 100	30 vs 16*	
Keller [7]	32	88 vs 100	100 vs 100	26 vs 17*	
Brimacombe [10]	60 x	87 vs 100	100 vs 100	27 vs 16*	18 vs 9*
Cook [11]	180 x	81 vs 89	99 vs 100	27 vs 18*	15 vs 10*
Brimacombe [29]	30 x	100 vs 100	100 vs 100	30 vs 22*	
Brimacombe [30]	30 x	100 vs 100	100 vs 100	36 vs 21*	
Brimacombe [31]	384	83 vs 91	98 vs 100	27 vs 22*	41 vs 31*
Lu [32]	80	83 vs 100	100 vs 100	29 vs 19*	
Braun [33]	280	85 vs 93	100 vs 100	29 vs 20*	35 vs 34
Total	1436**	85 vs 93*	99 vs 100 n/s	-	

cLMA = classic laryngeal mask airway; PLMA = ProSeal laryngeal mask airway. X = cross-over randomized controlled trial. *Statistically significant result $P < 0.05$; **723 PLMA, 713 cLMA insertion attempts.

Finally, the same authors report esophageal inflation during controlled ventilation with a correctly placed PLMA.²² They concluded that during peak inspiratory pressure rise, the PLMA was distracted from the glottis, enabling leakage of gases via the pyriform fossa to the upper esophagus. The DT failed to vent this gas due to occlusion by the mucosa during inspiration. OGT passage vented the gas without gastric inflation. Seating and securing the PLMA correctly will minimize the likelihood of this problem; OGT passage may prevent or treat it.

The above complications may also occur with the cLMA (and other supraglottic airways). The PLMA DT enables early diagnosis of complications, and in many cases a route to resolve them. The incidence of these complications with other airways is unknown. Ability to diagnose these problems accurately with the PLMA may lead to reporting bias, without comparative data, and it would be wrong to assume these complications arise more (or less) frequently with the PLMA.

II. Comparisons between the PLMA and other airway devices

When considering studies comparing the PLMA with other devices (cLMA, TT and other supraglottic airways) it should be noted that some of these are small and measure multiple outcomes. Where 'no difference' is reported between devices this may arise because a study was too small (type II error): particularly when the study was not powered to examine that particular measure.

Comparisons between the PLMA and cLMA

Ten RCTs comparing PLMA and cLMA (1,150

patients, 753 PLMA uses) have been published.^{1,7,10,11,29-34}

INSERTION SUCCESS

In direct comparison studies of 1,436 patients first time PLMA insertion ranged from 81 to 100% with summed success of 616/723 (85%), for the cLMA 89 to 100%, summed 662/713 (93%) (meta-analysis $\chi^2 = 20.66$, $P < 0.0001$),^{1,7,10,11,29-33} (Table VII).

Success increases when three attempts are allowed. In eight comparative trials overall success is: PLMA 718/723 (99.3%), cLMA 713/713 (100%) (meta-analysis $\chi^2 = 3.16$, $P 0.076$),^{1,7,10,11,29-33} (Table VII).

PLMA insertion time is longer than the cLMA in three studies^{10,11,31} and equivalent in one.³³ The difference is a few seconds (of negligible clinical importance) in all studies reporting a difference (Table VII).

PLMA insertion difficulty may be caused by the larger, deeper, softer bowl and the non-linear leading edge formed by the DT. A learning curve has not been studied, but it has been suggested the PLMA requires 20 to 30 insertions before achieving competence.¹¹ Most comparisons of cLMA with PLMA involved operators with greater experience with cLMA than PLMA. After training by lecture and manikin, nurses naive to both devices (using digital insertion technique) achieved similar insertion time and success rates with both devices.⁴ Use of a GEB-guided technique, might increase this further.¹⁵

AIRWAY SEAL AND VENTILATION

Nine studies (1,470 adult patients) compare cLMA and PLMA seal pressures.^{1,7,10,11,29-33} Eight studies (858 comparisons) report significantly higher seal

TABLE VIII Ability to view the vocal cords from the device in comparative trials between cLMA and PLMA

Study [reference]	Number of patients in fiberopted via PLMA	Total cords seen (%)	Number of patients fiberopted via cLMA	Total cords seen (%)	Statistical significance
Brain [1]	20	>15 (>75)	20	>13 (>65)	No
Keller [7]	17	15 (88)	16	15 (94)	No
Brimacombe [10]	60	56 (93)	60	59 (98)	No
Cook [11]	178	176 (99)	176	173 (98)	No
Brimacombe [29]	30	27 (90)	30	28 (93)	No
Brimacombe [31]	189	169 (89)	190	178 (94)	Yes
Braun [33]	145	131 (90)	135	125 (93)	No
Total	639	589 (92)	591	627 (94)	No*

cLMA = classic laryngeal mask airway; PLMA = ProSeal laryngeal mask airway. *Chi-square statistic = 1.85, $P = 0.173$.

with PLMA than cLMA (Table VII). Results are similar in paralyzed^{1,7,10,29,32} and non-paralyzed patients.^{11,30,31,33} Median PLMA and cLMA seal pressures are approximately 30 cm H₂O and 20 cm H₂O respectively. In 20% of cases PLMA seal exceeds 40 cm H₂O.^{11,30}

VIEW OF THE GLOTTIS FROM THE PLMA

Fiberoptic view is equivalent in three^{1,11,17} and better with the cLMA in six^{7,10,29-31,33} studies. Differences are generally small with grading not showing statistically significant differences, but direct comparison in crossover trials favours the cLMA. No clinical importance of these differences has been established. Meta-analysis of the ability to see the vocal cords from the mask bowl shows no significant difference between devices (Table VIII).

AIRWAY TRAUMA AND SORE THROAT

Airway trauma (blood on the device after removal), is higher for PLMA than cLMA in several comparative studies^{1,11,31-33} but reached statistical significance in only one study.³¹ Blood was detected in 9 to 18% of cases, which is comparable to larger reports with cLMA.²³

Incidence of sore throat in comparative studies is similar to the cLMA,^{11,31,32} or lower,³³ ranging from 5 to 23% compared to 5.8% to 34%²³ after cLMA use.

Comparisons between the PLMA and tracheal intubation

There are four reports comparing PLMA use with a TT: one during laparoscopic cholecystectomy,⁴⁹ two during gynecological laparoscopy^{48,76} and one comparing hemodynamic changes during airway insertion/removal.⁴⁷ In each study the PLMA caused less post-extubation coughing (TT 50%, 96%, 86% vs

PLMA 0%, 4%, 15% respectively).^{47-49,76} In two studies the PLMA reduced hemodynamic changes at intubation and extubation.^{47,48}

Comparisons between the PLMA and other SADs

The PLMA has been more thoroughly evaluated, by peer reviewed publication, than other new SADs introduced in the last five years. These include the Laryngeal Tube®, Laryngeal Tube Sonda®, Airway Management Device®, Pharyngeal Airway Xpress® and Cobra Perilaryngeal Airway®. Unlike these devices, many of which have been modified on several occasions since introduction, the PLMA has not. Comparative evaluations are only available with the Laryngeal Tube (LT) and Laryngeal Tube Sonda (LTS).

LT AND LTS

The LT is a reusable, SAD designed for use with controlled and spontaneous ventilation, with a higher airway seal than the cLMA.⁷⁷

There is only one study comparing the currently available LT and the PLMA during controlled ventilation:⁴⁴ airway seal and insertion were equivalent. The PLMA required fewer manipulations at insertion and during maintenance, enabled better ventilation and was sited over the glottis more frequently.

LT and PLMA were compared in 70 anesthetized patients breathing spontaneously.³⁶ Insertion success and maneuvers required to maintain a clear airway favoured the PLMA. Spontaneous ventilation was unsuccessful in 37% with LT and 9% with PLMA. Repositioning the device corrected this in all PLMA cases and 46% of LT cases. This study might be criticized as neither device performs optimally during spontaneous ventilation⁴⁴ and PLMA positioning appeared imperfect.

In a cadaver study pharyngeal mucosal pressures were higher with the LT than the PLMA, most markedly when airway seal pressures exceeded 25 cm H₂O.⁷⁸

The LTS is a modification of the LT with a DT running posterior to the airway tube. One study and three abstracts compare LTS and PLMA in 266 patients.^{40,45,46,50} Performance of the two devices was equivalent in three studies. Airway seal pressure did not vary between devices but varied between studies from 27 cm H₂O⁴⁵ to 47 cm H₂O.⁴⁵ A cross-over study of 32 patients found markedly different performance: insertion success, required manipulations, airway seal and positioning over the larynx all favouring the PLMA.⁵⁰ The LTS had to be abandoned in 22% of cases. The explanation for the difference between study results is not clear. Of note the LTS was redesigned in late 2004 and replaced by the LTS II: extrapolation of results from the above studies may not be appropriate.

III. Clinical experience with the PLMA and use of the PLMA to extend the role of the supraglottic airway

Improved ventilation and the likelihood of increased airway protection, have led clinicians to extend the use of the PLMA into areas where SADs are not used routinely. These include during lower and upper abdominal laparoscopy, and open abdominal surgery, surgery in obese patients, those with gastroesophageal reflux, those with difficult airways, and for rescue after failed tracheal intubation. In one report⁷³ the authors stated that 40% of 317 patients managed with a PLMA would previously have been intubated. Cases included hysterectomy, prostatectomy, laparotomy and major colonic resection. PLMA use outside the operating theatre is reported in the intensive care unit (ICU). Describing reports of PLMA use in the following circumstances does not imply endorsement by the authors of this review.

Laparoscopic surgery

Laparoscopic cholecystectomy

Use of a PLMA or TT was compared in 109 patients undergoing laparoscopic cholecystectomy.⁴⁹ A surgeon blinded to the airway used, observed stomach distension. In non-obese patients [body mass index (BMI) < 30 kg·m⁻²] both devices provided equivalent ventilation. The PLMA provided smoother emergence (markedly reduced coughing). Four obese patients were crossed over from PLMA to a TT and their data excluded from analysis. Reasons for cross-over were: PLMA insertion failure with desaturation, high airway pressures and rhonchi in the lung fields (possible aspi-

ration), sudden onset of gas leak, and sudden increase in airway pressure. These four cases may represent a learning curve, or may demonstrate genuine superiority of the TT for some obese patients.

Eighty paralyzed, non-obese patients were randomized to controlled ventilation via PLMA or cLMA during laparoscopic cholecystectomy.³² The PLMA required more insertion attempts but achieved higher seal pressures. OGT passage via the PLMA was 100% successful. Ventilation was successful before peritoneal inflation in both groups, but failed in 20% in the cLMA group during pneumoperitoneum. Gastric inflation occurred in three cases with the cLMA and none with the PLMA. The authors considered the PLMA (but not the cLMA) suitable for laparoscopic cholecystectomy.

At least one authority believes SADs should not be used for cholecystectomy because of bile reflux.⁷⁹ One author reported three cases of regurgitation, without aspiration, after laparoscopic cholecystectomy using a PLMA.⁶⁰ One possible case of aspiration during laparoscopic cholecystectomy is described above⁴⁹ and one confirmed case occurred with unrecognized PLMA malposition.⁶⁴ Whether laparoscopic cholecystectomy increases aspiration risk is not clear.

Although modest benefit has been demonstrated during emergence, unless further advantages are demonstrated, PLMA use during laparoscopic cholecystectomy will remain controversial.⁸⁰

Gynecological laparoscopy

PLMA and cLMA were compared with tracheal intubation for gynecological laparoscopy in 209 paralyzed patients.⁴⁸ A PLMA was used in the laryngeal mask group when BMI was > 30 kg·m⁻² (17 patients) and a cLMA when BMI < 30 kg·m⁻². Hiatus hernia and reflux were not considered contraindications. Ventilation and gastric inflation were equivalent between groups and there were no device failures. Use of a laryngeal mask reduced extubation coughing and sore throat. An accompanying editorial questioned the use of laryngeal masks for laparoscopic surgery.⁸⁰ However, like a similar UK editorial,⁸¹ this focused only on the potential problems of laryngeal mask use, without considering problems of TT use. Up to 65% of cases of aspiration occur around the time of laryngoscopy, and difficult intubation (which is causally associated with multiple complications) occurs in nearly 2% of cases.

Obese patients

Several studies demonstrate clinical utility of the PLMA in this population. Whether the PLMA is safer for obese patients than the cLMA, is unknown: the

TABLE IX Airway rescue with the PLMA

<i>Clinical situation [study reference]</i>	<i>RSP?</i>	<i>Comment</i>
Unanticipated lingual tonsil in patient requiring surgery [86]	no	FOI failed. Ventilation via ILMA failed
Thoracic surgery, unstable neck, patient refused awake intubation [87]	no	Bronchial blocker inserted via PLMA for OLV
ICU admission in extremis: known impossible intubation [88]	no	PLMA insertion followed by immediate percutaneous tracheostomy
Accidental extubation on ICU: failed reintubation and cLMA ventilation [89]	no	PLMA insertion followed by fibroscope guided intubation
Emergency appendectomy, failed intubation [90]	yes	Attempted rescue with cLMA failed. Surgery completed with PLMA.
Laparotomy and failed intubation. Profound laryngo-spasm during attempts to wake up [91]	yes	Attempted rescue and intubation via cLMA failed. Surgery completed with PLMA
Emergency LSCS and failed intubation [91]	yes	Surgery completed with PLMA
Emergency LSCS and failed intubation [92]	yes	Surgery completed with PLMA
Emergency LSCS and failed intubation with HELLP [93]	yes	Surgery completed with PLMA. Ventilated and weaned on ICU for 8 hours via PLMA
Elective LSCS and failed intubation [95]	yes	Surgery completed with PLMA.

RSI = rapid sequence induction; ICU = intensive care unit; LSCS lower segment Cesarean section; HELLP = hemolysis elevated liver enzymes and low platelets; FOI = fiberoptic intubation; OLV = one-lung ventilation; ILMA = Intubating laryngeal mask airway; PLMA = ProSeal laryngeal mask airway; cLMA = classic laryngeal mask airway.

very large studies required to test this hypothesis do not exist. Design features and performance characteristics make the PLMA intuitively a more appropriate and safer SAD for obese patients, who are at increased risk of gastric distension, regurgitation, low airway compliance and airway difficulties.

PLMA use is reported in patients with raised BMI: up to 47 kg·m⁻²,⁴⁹ 49 kg·m⁻²,⁴⁸ and 65 kg·m⁻².⁸ Airway seal increased as BMI increased in Brain's early study.¹

In 60 morbidly obese patients (mean BMI 43 kg·m⁻², range of 35–60 kg·m⁻²) undergoing abdominal surgery, a PLMA was inserted after induction without neuromuscular blockade.³⁵ Ventilation without leak was achieved in 95%. Mean airway seal pressure was 32 cm H₂O and OGT insertion was 100% successful.

PLMA efficacy was compared to the cLMA (with an OGT placed) in mild/moderately obese patients (BMI mean 33.5 kg·m⁻², 97% < 40 kg·m⁻²).³⁴ Airway cuffs were inflated to 60 cm H₂O. Controlled ventilation with 10 cm H₂O of positive end-expiratory pressure was applied. If leak fraction was > 15%, intracuff volume was increased (45% in the cLMA group, 13% in the PLMA group). Performance was equivalent, with minimal side effects. Leak fraction, 6%, was comparable to that with a TT. Limitations of the study were that peak

airway pressure was generally < 30 cm H₂O, up to 10% of PLMAs were probably malpositioned and OGT passage before cLMA use is not routine clinical practice.

Difficult airways

The PLMA has been used as a dedicated airway/conduit to the trachea in patients known (or predicted to be) difficult to intubate, and also for airway rescue after failed intubation. Theoretical advantages over other laryngeal masks include the large bowl and absence of a grille: both might improve laryngeal access. The glottis is visible from both PLMA and cLMA (Table VIII) more frequently than from the ILMA.²³ The improved airway seal and DT offer potential benefits where ventilation proves difficult or when the stomach is full. Tracheal intubation via the PLMA requires a small long tube or a catheter exchange technique.⁸²

ELECTIVE CASES OF KNOWN DIFFICULT AIRWAY

There are four reports of use of the PLMA to overcome known airway difficulties.^{82–85} In three cases the PLMA was used instead of tracheal intubation. In one case the PLMA was placed awake, using topical anesthesia.⁸⁴

USE OF THE PLMA IN 'AIRWAY RESCUE'

There are ten reports of PLMA use for airway rescue following failed or difficult intubation (Table IX).

Five cases (two elective and one emergency surgery, two emergencies on ICU) where conventional intubation failed (with ventilation problems in two cases) were successfully managed by PLMA placement and controlled ventilation.^{86–89}

On six occasions the PLMA secured airway rescue after failed intubation at rapid sequence induction (RSI).^{90–94} Four were obstetric emergencies^{91–94} and two non-obstetric.^{90,91} Three cases were associated with difficult ventilation.^{90,91} In two cases rescue with a cLMA was attempted but failed before a PLMA was used.^{90,91} In all cases the PLMA was used uneventfully to completion of the case.

The PLMA has design features and performance evidence that support its use for airway rescue after failed intubation. Failed intubation with difficult ventilation after RSI is a particularly suitable application, as controlled ventilation and ability to drain the stomach are desirable. After successful airway rescue, the decision to continue surgery rather than awakening the patient will depend on clinical circumstance.

A novel approach to difficult RSI is described where the GEB facilitates passage of a TT if the vocal cords are partially visible and passage of a PLMA, as early ‘rescue’, when they are not.⁹⁵

OBSTETRIC PRACTICE

Increased airway protection with the PLMA has aroused interest in its use in obstetric practice. The PLMA has not been reported for use during elective Cesarean section but a study is underway.⁹⁶

THE ICU

There are four reports of PLMA use in ICU. These include use in patients with intubation difficulty: for eight hours ventilation after failed intubation,⁹³ for securing the airway prior to immediate tracheostomy,⁸⁸ and for airway rescue after accidental extubation and failed reintubation.⁸⁹ The PLMA was used during bronchoscopic guided percutaneous tracheostomy in 25 patients.⁶³ Potential advantages of the PLMA over other laryngeal masks include increased seal pressure (important in non-compliant lungs) and the absence of glottic aperture bars, enabling bronchoscopic tracheal access. A ‘leak test’ to identify supraglottic edema is recommended before PLMA insertion and tracheal extubation.⁹⁷

The ability to ventilate with higher pressures than the cLMA, and the ability to access the stomach, infers advantages over other SADs in the event of difficulty or failure with primary airway devices. It is possible that short periods of lung ventilation on ICU via the PLMA might be suitable in selected patients.

Trauma and cardiopulmonary resuscitation (CPR)

There are no clinical case reports of the use of the PLMA in the trauma setting. During manual in-line stabilization of the neck, in 20 anesthetized volunteers, PLMA and cLMA insertion were compared using a cross-over technique.⁹⁸ PLMA insertion was easier and seal pressures higher. The authors suggested the PLMA introducer improved ease of insertion. Neck movement was not measured. This study suggests a potential role for the PLMA during airway rescue in trauma.

During CPR, the PLMA has potential advantages over the cLMA of improved airway seal, ability to drain the stomach (and so reduce aspiration). A manikin study compared different laryngeal masks (cLMA, ILMA, PLMA, Unique LMA) with facemask or tracheal intubation during simulated CPR.⁹⁹ During uninterrupted chest compressions the PLMA functioned as well as the TT and better than all other masks. In a similar manikin study the PLMA performed similarly to the LTS and the Combitube.¹⁰⁰

After education and manikin practice, nurses naive to both cLMA and PLMA established an airway in anesthetized paralyzed patients equally rapidly with either device.⁴³ Digital insertion enabled first attempt success within 45 sec in 85% of cases. The authors suggested that the introducer tool might increase PLMA insertion success further. These three studies offer support for clinical trials in resuscitation: as yet, none have been undertaken.

Other potential clinical uses

The PLMA has potential advantages over the cLMA and tracheal intubation in several other clinical areas. These include cardiac anesthesia (controlled ventilation is routine, reduced hemodynamic stimulation and smooth recovery are desirable), carotid endarterectomy (hemodynamic stability during airway manipulation is desirable), and neuroanesthesia (controlled ventilation is routine but vascular and intracranial hypertension might be minimized by avoiding tracheal intubation and extubation). To date, no studies have been reported in these areas.

MARKET SHARE OF THE PLMA

The PLMA has been available since 2000. In 2002, sales of the PLMA, as a fraction of sales of all laryngeal masks, (which may indicate trends in clinical practice), varied widely from 40% in Hong Kong to less than 1% in the UK.

Conclusions

The PLMA is an improvement on the cLMA for controlled ventilation. The introducer enables insertion

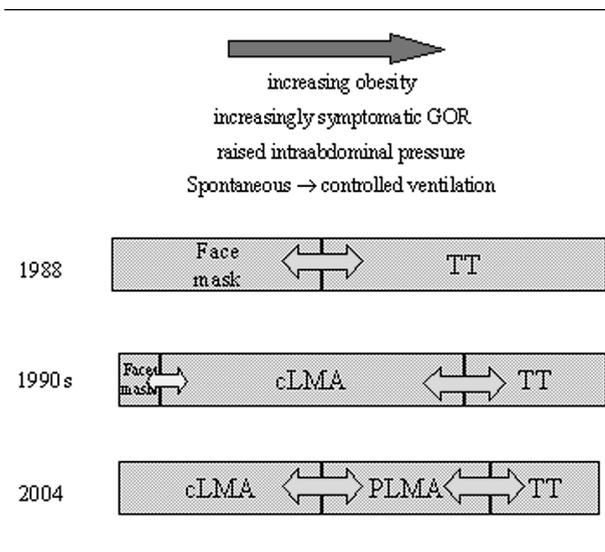


FIGURE 8 A proposal for modern airway management. Boxes represent use of the airway. \leftrightarrow represents variation in individual practice or 'margin of disagreement'.

without placing a finger in the patient's mouth and bougie-guided insertion is highly reliable. Insertion is more demanding and takes marginally longer than the cLMA. The DT enables misplacement to be detected more readily than with the cLMA. A correctly positioned PLMA separates the gastrointestinal and respiratory tracts (acting as an 'artificial larynx'), enables access to the stomach, improves airway seal 50% and reduces the risk of gastric inflation. Available evidence (design, laboratory, cadaver and clinical) all suggests the PLMA increases protection against aspiration of gastric contents. Evidence also supports the use of the PLMA with controlled rather than spontaneous ventilation. Complications are similar to the cLMA and include partial airway obstruction, and 'esophageal breathing'.

The PLMA has been used for laparoscopic and abdominal surgery, in increasingly obese patients, for management of anticipated or actual difficult airways, and after failed intubation in selected cases. Presently, the safety of these developments can neither be confirmed nor refuted: however, the PLMA is a welcome addition to the airway armory and is likely to increase the safety margin when using controlled ventilation via a laryngeal mask.

Before 1988, the airway was managed routinely during anesthesia with the facemask or TT. Use of a cLMA became increasingly widespread, but reservations remain about use during controlled ventilation

and the risk of regurgitation. The PLMA offers an airway that bridges some of the gap between the cLMA and the TT (Figure 8).

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