# Advantages of ProSeal™ and SLIPA™ airways over tracheal tubes for gynecological laparoscopies

## *[Les avantages des canules ProSeal™ et SLIPA™ sur les tubes endotrachéaux pour les laparoscopies gynécologiques]*

Donald M. Miller FFA SA PhD, Luigi Camporota MD MRCP

**Purpose:** To compare the efficacy of the ProSeal LMA™ and SLIPA™ supralaryngeal airways (SLA) with the standard tracheal tube (TT) in 150 consecutive day-case laparoscopic gynecological surgery procedures requiring general anesthesia.

**Methods:** One hundred and fifty patients were randomized into three groups. An identical general anesthesia technique was used in all patients apart from the addition of muscle relaxants and reversal drugs in the TT group. Patients were excluded if there were risk factors for gastroesophageal reflux. Ease of use, quality of seal, ventilation, systolic pressure, response to intubation, side effects and operating room time were assessed.

**Results:** Both ProSeal LMA™ and SLIPA™ were easy to insert (100% success) and ventilate with respective mean (standard deviation) maximum sealing pressures of 31 (4.6) and 30 (5.2) $cmH_2O$ ($P = 0.4$) with no muscle relaxants. The seal quality in both ProSeal LMA™ and SLIPA™ permitted the use of low flows, 485 (291) and 539 (344) $mL \cdot min^{-1}$ ($P = 0.2$) respectively, although in the TT group significantly lower flows [377 (124) $mL \cdot min^{-1}$], ($P < 0.01$) were achieved. Systolic pressure in the SLA groups was more stable in response to insertion than in the TT. With ProSeal™ there was a lower incidence of sore throats than with TT (30% *vs* 57%), ($P < 0.05$), but there was a lesser difference as compared with SLIPA™ (30% *vs* 49%), ($P > 0.05$). With both SLAs, there was a significant reduction in operating room time (> three minutes), ($P < 0.001$).

**Conclusions:** These results suggest that the ProSeal LMA™ (reusable) and SLIPA™ (single-use) SLAs were easy to use without requiring muscle relaxants, and reduce operating room time compared to the TT technique in day case laparoscopies.

***Objectif*** *: Comparer l'efficacité des canules supralaryngées (CSL) ProSeal LMA™et SLIPA™avec celle du tube endotrachéal (TET) régulier dans 150 interventions gynécologiques laparoscopiques consécutives nécessitant une anesthésie générale.*

***Méthode*** *: Nous avons réparti 150 patientes au hasard en trois groupes. La même technique d'anesthésie générale a été appliquée chez toutes, sauf l'addition de myorelaxants et de contre-myorelaxants avec le TET. Certaines ont été exclues s'il y avait des risques de reflux gastro-œsophagien. La facilité d'utilisation, l'étanchéité, la ventilation, la tension artérielle systolique, la réaction à l'intubation, les effets secondaires et le temps en salle d'opération ont été évalués.*

***Résultats*** *: L'insertion des ProSeal LMA™ et SLIPA™ (100 % de succès) et la ventilation ont été faciles avec une moyenne respective (écart type) maximale de pression d'étanchéité de 31 (4,6) et 30 (5,2) $cmH_2O$ ($P = 0,4$) sans myorelaxants. La bonne étanchéité des ProSeal LMA™ et SLIPA™ a permis d'utiliser de faibles débits, respectivement de 485 (291) et 539 (344) $mL \cdot min^{-1}$ ($P = 0,2$), et significativement plus bas [377 (124) $mL \cdot min^{-1}$], ($P < 0,01$) avec le TET. La tension systolique chez les patients des groupes CSL, comparés au groupe TET, a été plus stable en réaction à l'insertion de la canule. Avec le ProSeal™, comparé au TET, il y a eu une incidence plus faible de mal de gorge (30 % vs 57 %), ($P < 0,05$), et une plus petite différence avec le SLIPA™ (30 % vs 49 %), ($P > 0,05$). Avec les CSL, le temps en salle d'opération a été significativement réduit (> trois minutes), ($P < 0,001$).*

***Conclusion*** *: Ces résultats montrent que, pour des laparoscopies, les CSL ProSeal LMA™ (réutilisable) et SLIPA™ (jetable) ont été faciles à utiliser sans nécessiter de myorelaxants et qu'ils réduisent le temps de salle d'opération comparativement au TET.*

From the Department of Anaesthetics, Guy's, King's and St. Thomas' School of Medicine, King's College London, London, United Kingdom.

*Address correspondence to*: Dr. Donald M. Miller, GKT Department of Anaesthetics, 2nd Floor, NGH, Guy's Hospital, London SE1 9RT, United Kingdom. Phone: +44 20 71880637; Fax: +44 20 71880642; E-mail: donald.miller@kcl.ac.uk

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THE recent advent of newer designs in supralaryngeal airways (SLAs) provides a possible alternative technique to the traditional use of tracheal tubes during laparoscopies. The advantages of SLAs are related to the fact that they may be inserted easily using a blind technique, and they allow for effective positive pressure ventilation.

The Streamlined LIner of the Pharynx Airway (SLIPA™; SLIPAmed SA Pty Ltd, Cape Town, South Africa) is a new type of SLA, fabricated from soft plastic with an anatomically preformed shape that lines the pharynx. This means positive pressure ventilation may be achieved without a cuff inflating mechanism that is required in other airway types such as the laryngeal mask (LM). A full description of this device and its limitations is accessible on the SLIPA website (www.slipa.com). Briefly, it comprises a hollow, blow-moulded chamber shaped like a boot with toe (T), bridge (B) that seals at the base of the tongue and a heel (H), which anchors the device in a stable position between the esophagus and nasopharynx. It is not necessary for the SLIPA™ to be tied or strapped into position (Figure 1). The chamber provides a large capacity (50 mL compared to 3.5 mL in the LM) for providing maximum but limited storage of regurgitated liquids should they arise from the stomach, thus preventing their inadvertent overflow into the trachea.[1] The safety advantages of simplicity and minimization of aspiration risk of a device without a cuff inflating mechanism necessitates double the number of sizes in order to obtain a good quality seal for positive pressure ventilation. The aspiration protection characteristics of both the SLIPA™ and ProSeal™ LM have been compared favourably with those of the LM in a laboratory study.[1]

In contrast with the use of tracheal tubes (TTs), the use of muscle relaxants may not be required when inserting or using SLAs for laparoscopies. The use of a muscle relaxant appears to prolong the duration of the whole procedure.[2] Conflicting evidence regarding time saving relates to different techniques used and the actual times that were measured.[3] We hypothesized that SLAs should provide satisfactory conditions for positive pressure ventilation without the use of muscle relaxants, with a reduction in side-effects and operating room time, when compared with a standard TT technique tube for day-case laparoscopic surgery. To test our hypothesis, two SLAs designed to minimize aspiration risk in the presence of regurgitation were chosen. These were the reusable ProSeal LMA™ (PLMA; The Laryngeal Mask Company Ltd, Maidenhead, UK) and the single-use SLIPA™.

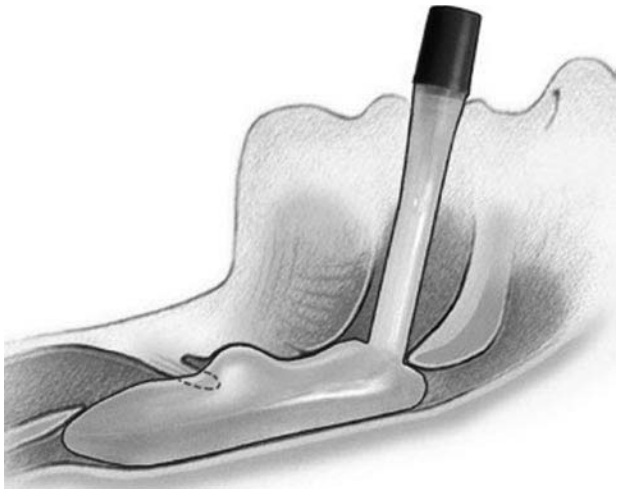

FIGURE 1 SLIPA™ shown in position with the toe (T) at the entrance to the esophagus, the bridge (B) where sealing takes place at the base of the tongue and the heel (H) in the nasopharynx.

## Materials and methods

### *Subjects*

Over a six-month period, 158 fasted healthy adult females (American Society of Anesthesiologists I–II) scheduled to undergo laparoscopic gynecological procedures under general anesthesia were asked to participate in the study, for which local Research Ethics Committee approval and written informed consent were obtained. Three patients refused to be part of the trial. The sample size was determined from the results of similar studies.[1-3] Patients (five) were excluded if they suffered from diabetes mellitus, morbid obesity or gastroesophageal reflux, were pregnant, or at high risk from pulmonary aspiration. Patients were randomized into one of three groups using Excel random number generation. The anesthesiologist was unaware of which airway (PLMA, the SLIPA™ or the standard TT) was to be used until five to ten minutes before administering anesthesia. The size of the PLMA was chosen, based upon body weight, according to the manufacturer's recommendations (size 3 if < 50 kg or size 4 if > 50 kg). The SLIPA™ size was chosen by matching the width across the thyroid cartilage with that of the bridge of the SLIPA™ (Figures 2A, 2B). There are three sizes primarily for women, 47, 49 and 51 mm across the bridge of the SLIPA™. The equivalent respective PLMA: SLIPA™ sizes used in these women were 3: 47 and 4: 49 or 51.


FIGURE 2 A) Sizing dimension between left and right cornu of thyroid cartilage by palpation and B) matching the dimension at level of SLIPA™ bridge.

For the PLMA and SLIPA™ groups, general anesthesia was induced with midazolam 1 mg *iv* and fentanyl 1 $\mu g \cdot kg^{-1}$ *iv*, followed within two minutes by propofol 2 to 3 $mg \cdot kg^{-1}$ *iv*. One minute later a single operator (D.M.) inserted the airway device as outlined in the manufacturer's instructions. If the initial attempt at insertion of either airway was unsuccessful, the patient received a supplementary dose of propofol up to 1 $mg \cdot kg^{-1}$ *iv* and the head was repositioned to permit one further attempt. If the second attempt was unsuccessful, it was to be recorded as a failure. For the TT group, the same induction drugs and doses were used but with the addition of atracurium 25 mg *iv* two minutes prior to intubation. Anesthesia was maintained with sevoflurane (3.5–4%) in oxygen and air, with supplementary fentanyl (50–100 µg *iv*) or morphine (5–10 mg *iv*) given as required with *iv* fluids.

For all patients in whom successful airway placement was achieved, the lungs were ventilated mechanically through a circle system using a single Frontline 560 anesthetic machine (Blease Medical Equipment Ltd, Buckinghamshire, UK). The ventilator on this machine is time-cycled and volume-controlled with a rising bellows. The inspiration: expiration ratio was varied between 1:1 to 1:2 with a respiratory rate of 18 $min^{-1}$ in order to use the lowest inflation pressure to achieve adequate ventilation. The tidal volume was adjusted to achieve an end tidal $CO_2$ value of 30 to 40 mmHg. Mild hyperventilation combined with the use of opioids meant that patients were not breathing spontaneously throughout the abdominal insufflation phase of the procedure. Systolic pressure was measured non-invasively before anesthesia, immediately following induction but before airway placement, and within two minutes of placing the airway. After surgery, women in the TT group received neostigmine and glycopyrrolate to reverse neuromuscular block. The time from start of deflation of the abdomen to the time the patient was ready to move to the recovery ward was recorded (recovery time). After surgery, all airways were removed in the operating room before transfer of the patient to the recovery room. The recovery room staff recorded the incidence of early sore throats. The number of late sore throats was recorded after a telephone survey on the first postoperative day. Even mild sensations in the throat with minimal pain were recorded as sore throats.

**Airway insertion times**

The insertion of the airway was considered easy and uncomplicated if achieved within 15 sec. A second insertion, because of the wrong size having been chosen or because placement was not straightforward,

TABLE I Demographics and surgical times

| | *TT (n = 50)* | *SLIPA™ (n = 50)* | *PLMA (n = 50)* |
|---|---|---|---|
| Age (yr) | 35.2 (8) | 35.2 (8.3) | 33 (7) |
| Weight (kg) | 65 (11) | 66 (10) | 66 (11) |
| Duration of surgery (min) | 44 (19) | 38 (16) | 40 (20) |
| Mallampatti score > 1 | 13.5% (5/37) | 25% (11/44) | 19% (8/42) |

TT = tracheal tube; SLIPA = SLIPA™; PLMA = ProSeal LMA™. The demographic characteristics of the three study groups: TT, SLIPA and PLMA. The results are either mean and (standard deviation) or incidence/possible total.

would automatically fall outside the 15-sec period. The time for the insertion process was taken from the moment placement of the airway commenced to the generation of the first satisfactory breath of at least 7 $mL \cdot kg^{-1}$.

*Quality of airway seal*

In addition to recording peak airway inflation pressures, the quality of the airway seal was measured in two ways:

1. Airway sealing pressure was measured using a manometric stability technique.[4] The maximum inflation pressure generated when using a gradual, slow manual inspiration over 1.5–2 sec with the expiratory valve closed and with the fresh gas flow into the circle absorber system limited to 2 $L \cdot min^{-1}$ was the value taken.
2. The minimum flow rate required to keep the ascending bellows of the ventilator fully inflated was recorded.

*Recovery time*

In order to exclude variations in the surgical times, the recovery time was measured from the beginning of abdominal deflation until the patient was deemed by the anesthesiologist to be ready for transfer to the recovery room with the airway removed.

*Statistics*

Distribution of baseline variables was assessed by the Kolmogorov-Smirnov and Shapiro-Wilk W tests. For each study, parameter summary statistics were tabulated. Differences in baseline variables between study groups were compared using two-tailed t tests or the Mann-Whitney U test for continuous data, and Chi-square with Yates' continuity correction for discrete data. Comparison among study group was performed by analysis of variance (ANOVA). If ANOVA was significant, the differences among the three groups were assessed by the Student-Newman-Keuls test to allow for multiple comparisons. For non-normally-distributed continuous data, the Kruskal-Wallis test (non-parametric ANOVA) and Dunn's test for multiple comparisons were employed. A $P$ value $< 0.05$ was considered statistically significant.

## Results

There were no differences between groups with respect to age, weight, procedure time or Mallampatti score (Table I).

The results are presented in Table II. There was a high success rate for first time insertion with the PLMA (48/50) and the SLIPA™ (49/50). From 150 24-hr follow-up telephone calls made to ascertain information regarding sore throats, 27 did not yield satisfactory information. Of the 27, 19 were not contactable the next day and the information from the other eight related to linguistic difficulties without suitable translators available. There was only one moderately severe sore throat reported in the TT group; otherwise all other sore throats were either mild or minimal in severity.

## Discussion

This study demonstrates that both the PLMA and SLIPA™ were used with complete success and were easy to insert; with respective first insertion success rates of 96% and 98%. The anesthesiologist inserting the airways was an experienced operator, having used each type of device over 100 times before the trial began. Nevertheless, an independent study has shown good success and ease of use of the SLIPA™ even in inexperienced hands.[5]

We found that the TT sealed significantly better than both SLAs as demonstrated by the lower minimum flow rate into the absorber system. However, airway sealing pressures demonstrated SLA sealing qualities almost as good as those of a TT. The minimum flow rate required was well below 1 $L \cdot min^{-1}$ thus allowing low flow anesthesia. The difference between the two SLAs was not significant. After abdominal insufflation of the abdomen with $CO_2$, the lower inflation pressures noted when using the TT may well be due to the use of the muscle relaxant. When comparing the TT with the SLAs, the differences in the rise in systolic pressures in response to airway placement was of a clinically important magnitude (> 15%). However, the SLIPA™ and PLMA are associated with similar hemodynamic responses.

Interestingly, satisfactory conditions for ventilation were consistently achieved without muscle relaxants

TABLE II Airway observations and recovery times

| | *TT (n = 50)* | *SLIPA (n = 50)* | *PLMA (n = 50)* | *P value TT:SLIPA* | *P value TT:PLMA* | *P value SLIPA:PLMA* |
|---|---|---|---|---|---|---|
| Airway insertion > 15 sec | n/a | 10% (5/50) | 18% (9/50) | n/a | n/a | ns |
| Airway sealing pressure (cm $H_2O$) | n/a | 30 (5.2) | 31 (4.6) | n/a | n/a | ns |
| Paw before insufflation (cm $H_2O$) | 15.7 (3.6) | 16.1 (3) | 15.6 (2.6) | ns | ns | ns |
| Paw after insufflation (cm $H_2O$) | 20.2 (2.8) | 22.6 (3.1) | 21.3 (3.7) | < 0.05 | ns | ns |
| Minimum flow rate (mL $min^{-1}$) | 377 (124) | 539 (341) | 487 (268) | < 0.01 | < 0.01 | ns |
| SBP change (post-induction) % | 21.2 (16) | 3.8 (12) | -1.2 (11) | < 0.001 | < 0.001 | ns |
| SBP change (pre-induction) % | -2.2 (15) | -17 (12) | -18.5 (14) | < 0.001 | < 0.001 | ns |
| Sore throat | 57% (24/42) | 49% (23/47) | 30% (13/43) | ns | < 0.05 | ns |
| Recovery time (min) | 8.1 (2.8) | 4.8 (1.2) | 4.7 (1.2) | < 0.001 | < 0.001 | ns |

TT = tracheal tube; SLIPA = SLIPA™; PLMA = ProSeal LMA™; Paw = peak airway pressure; SBP = systolic blood pressure; ns = non significant; n/a = not applicable. Results with TT, SLIPA and PLMA groups compared. Results are either % (incidence/ total) or mean (standard deviation). Minimum flow rate ($mL \cdot min^{-1}$) = minimum flow rate into circle system to keep the ascending ventilator bellows fully inflated. SBP change (postinduction) % = systolic pressure after airway or TT insertion minus postinduction value divided by preinduction systolic pressure × 100%. BP change (preinduction) % = systolic pressure after airway or TT insertion minus preinduction value divided by preinduction systolic pressure × 100%.

using both SLAs. Recovery time was significantly lower when using either SLAs compared with the TT. The time saved using the SLAs most probably relates to the avoidance of the need for muscle relaxants and the associated time for reversal and extubation.[1] The mean time saved in the operating room *based only on recovery time* was greater than three minutes. Given the average time taken for each procedure (Table I), cumulative time saving could mean that, on average, one extra case per day could be performed in the day-surgery unit.

The combined incidence of both early and late sore throats showed that the PLMA caused the least sore throats. All sore throats recorded in the SLAs were mild or minimal in nature and required no treatment. There was only one moderate sore throat experienced by a patient in the TT group. The 9% loss to follow up related only to the 24-hr follow-up over the phone sore throat report. Considering that the patients were discharged the same day of the procedure (day surgery), we expected that we would be unable to contact some patients for the 24-hr follow-up. This is unlikely to be of clinical importance and, therefore, unlikely to have made an important difference to the final report.

The design of the PLMA is based upon the classical LMA™ but with better maximum seal pressure, and it has a drainage tube, making it more suitable for laparoscopic work.[6] However, it is not a single-use product. The SLIPA™ is designed for single-use, and has a means of minimizing aspiration risk if regurgitation occurs.[1] This relates to the large capacity within its hollow structure for entrapment of regurgitated liquids. Storage volumes (50mL)[1] before aspiration occurred in the lung model were almost double the volume of the contents in fasted patient's stomachs (26 mL).[7,8] The effectiveness of the mechanism during a laparoscopy in the clinical part of the study was demonstrated in one patient who regurgitated 15 mL into the SLIPA™ without any aspiration.[1] As the reported incidence of aspiration with SLAs is very low, we can only know for certain that this proposed mechanism for preventing aspiration is reliable after it is widely used and perhaps after multicentre studies.

In conclusion, PLMA and SLIPA™ SLA have been shown to be equally efficacious for use in gynecological laparoscopies without requiring muscle relaxants, with time-saving advantages and fewer side effects. There is less systolic pressure response to placement and fewer sore throats are experienced compared to airway management with a TT technique.

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