

**'On the value of knowing physical characteristics of the
airway device before using it'**

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Editorial
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**'On the value of knowing physical
characteristics of the airway device before
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Short Running Title: The value of knowing airway devices before using it.

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For many years there was arguably little progress at the frontline of airway management as all we had was our hands, then a classic laryngoscope and later, a classic laryngeal mask to control the airway. Since then, the airway armamentarium has progressed in quantum leaps, particularly with the introduction of videolaryngoscopy and a wide range of supraglottic airway devices (SADs).¹ At present, SADs have collectively enjoyed an unparalleled safety record and are very popular devices in everyday practice² with broadening indications. Of the globally ~250 million patients undergoing major surgery under general anaesthesia on an annual basis, some 60% receive such a device to maintain a patent airway.³⁻⁵ The vast majority of anaesthetics in patients undergoing elective surgery are performed using some form of SAD. Since the initial introduction of the LMA-Classic,⁶ the evolution in supraglottic airway designs has been a continuous process.⁷ Consequently, many new characteristics have been added in an attempt to combine efficacy with safety.^{8,9} Some of these changes were subtle, e.g. from re-usable to single use disposable or progression from classic to flexible SAD. Other changes genuinely added innovations in functions through design, e.g. facilitation of tracheal intubation, or of stomach decompression via an oesophageal vent.

Anaesthetists are faced with a multitude of different SADs being introduced to their clinical practice and the problem is that many lack the evidence of efficacy and safety to inform evidence based decision making regarding which devices to adopt. In order to introduce new devices into clinical practice or develop an appropriate clinical trial, detailed knowledge of the physical characteristics and potential application is essential. Only by careful analysis of the design of new devices, with appropriate preclinical research and development followed by preclinical testing can specific

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3 hypotheses be generated that are amenable to clinical testing. We demonstrate this
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5 through the recently introduced LMA-ProtectorTM for which limited clinical evidence
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7 exists."
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10 Faced with the concern that an increasing number of airway management devices
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14 were being introduced into clinical practice with little or no prior evidence of their clinical
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16 efficacy or safety, the Airway Device Evaluation Project Team (ADEPT) was formed by
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18 the Difficult Airway Society (DAS) in the UK in 2011.¹⁰ The ADEPT strategy
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20 proposes 'procurement pathways' for evaluating airway equipment so that: 1) evidence-
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22 based principles should be applied to institutional purchasing decisions regarding airway
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24 management products; 2) products with documented evidence of efficacy and safety
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26 should be preferred to those where evidence is lacking; and 3) anaesthetists should play a
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28 more active role in local device/equipment evaluation and in selection and purchasing
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30 decisions). Regulators, manufacturers and clinical researchers need to co-operate to
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32 improve the overall successful introduction of any new SAD into clinical practice and the
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34 market place rather than rely on the CE 'mark' alone. Quite often, manufacturers make
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36 modifications without notifying the users, and newer versions of SADs automatically
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38 replace older versions stock, such that it is not necessarily the same device as described in
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40 earlier device versions and their accompanying publications. Furthermore, no patient
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42 should be confronted with new equipment used by anaesthetists who lack the knowledge
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44 of basic characteristics of the new device.
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52 Recently a new second-generation single-use CE-marked SAD, the LMA-
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54 ProtectorTM was introduced into medical practice (Fig. 1A-1H). The LMA-ProtectorTM
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56 shares common features¹¹⁻¹⁵ of previous LMA devices, such as the LMA-ProSealTM (high
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3 oropharyngeal leak pressure, gastric access and bite block), the LMA-FastrachTM (fixed-
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5 curved tube and guiding handle), the LMA-UniqueTM (single use) and the LMA-
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7 SupremeTM (a firm anatomically shaped airway tube (Fig. 1B, 1C) incorporates a drain
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9 tube within its lumen to separate the respiratory and gastrointestinal tracts; an oval-
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11 shaped tube (Fig. 1E,1F) to match better the shape of the mouth and to reduce rotation in
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13 the pharynx).

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17 The LMA-ProtectorTM is made with medical-grade silicone (except the 15mm
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19 connector), which makes it a more flexible and potentially a less traumatic device than
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21 the LMA-SupremeTM, which is made of PVC. The LMA-ProtectorTM provides access to,
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23 and functional separation of the ventilation and digestive tracts, with the presence of two
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25 drainage channels, which emerge proximally as separate ports and enter a chamber,
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27 located behind the cuff bowl. Removal of gastric fluid through the upper oesophageal
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29 sphincter can be performed by attaching suction to the male suction port or by insertion
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31 of a gastric tube through the female drainage port to the stomach (Fig. 1A).
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37 Primary research using assessing the LMA-Protector is sparse (eg, whereas a
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39 PubMed search of LMA-Supreme yields ~101 results, searching for LMA Protector (or
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41 similar terms) yields no results. From the above mentioned properties, it becomes clear
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43 that physical properties including the flexibility (objectively measured), degree of trauma
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45 and efficacy of the gastric drainage system (which might be a combination of the ease
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47 with which a gastric tube can be passed as well as any inherent reflux of material via this
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49 channel) must be understood by the anaesthetist when using this new device.
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54 Prevention of aspiration requires a good-quality oropharyngeal airway seal (Fig.
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56 1G-1H) within the laryngopharynx (1st seal) and oesophagus (2nd seal). Airway seal
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pressures using the device therefore need to be studied. Venting of the stomach with a gastric tube channel allows stomach gas and contents to escape. The internal volume of the drainage pathway for sizes 3, 4 and 5 of the LMA-ProtectorTM (Table 1) is about 5 times more (31:41:42 ml) than those of the LMA-SupremeTM (6:6.5:7 ml). Table 1 details the physical characteristics of LMA-ProtectorTM and the LMA-SupremeTM. Notably the LMA-ProtectorTM has two gastric tubes; no mask aperture bars; is dynamically flexible; and may be used as an intubation conduit for endotracheal tubes. This is an aspect that can be readily assessed, using research methodologies that are well established.^{16,17} Both the LMA-SupremeTM and the LMA-ProtectorTM have an elliptical cuff at the distal drainage orifice and a 10° slant (Fig. 1C) which allows the cuff to follow the contours of the upper oesophageal sphincter which may improve placement and seal.¹⁴ Furthermore, the incorporation of the gastric channel into the tip of the mask also reinforces the tip and may prevent spontaneous folding on itself. Once inflated with the device in its correct position, the distal cuff may provide a tight apposition to the oesophageal opening and may prevent reflux (Fig. 1B). The length of the integral bite block may differ depending which size is used. In the LMA-SupremeTM and LMA-ProtectorTM, there is no difference between a size 4 and a size 5 (identical cuff size). However, the bite block in a size 4 is shorter than in a size 5, adding to the overall length of the device in the latter. Ideally there should be a minimum of one cm gap between the fixation tab and the patient's upper lip. If that is not the case, a larger size laryngeal mask may be needed. If the fixation tab is more than 2.5 cm from the upper lip after fixation, it may be advisable to use a smaller size laryngeal mask. The LMA-ProtectorTM will be available with the pilot balloon or with the Integrated Cuff PilotTM (Fig. 1D). In contrast

to the LMA-SupremeTM, the LMA-ProtectorTM does not provide paediatric sizes of the device as yet.

The use of the LMA-SupremeTM as an intubation conduit for an endotracheal tube is not easy to perform and needs extra adjuncts, such as a bronchoscopic/Aintree Intubation Catheter-guided technique.¹⁸ The airway lumen of the LMA-ProtectorTM (max. I.D. 13 mm) is wide enough to pass an adequately sized adult tracheal tube directly without the use of an intermediate exchange catheter, i.e. a maximal size tracheal tube of 6.5; 7.5 and 7.5 for the devices 3, 4 and 5. As such, using the LMA-ProtectorTM as a conduit for fiberoptic-assisted rescue intubation should be easier to accomplish than using a LMA-SupremeTM or LMA-ProSealTM. However, these hypotheses require investigation through appropriately statistically powered studies. Maximum diameters of orogastric tubes which can be inserted through the gastric channels of the respective sizes 3:4:5 of the LMA-SupremeTM are 14:16:16 Fr, versus 16:18:18 Fr for the LMA-ProtectorTM.

Laryngeal masks have a prominent place in the most recent ASA and Obstetric Anaesthetists' Association and Difficult Airway Society guidelines for difficult airway management.^{19,20} As for all medical devices, end-users of SADs need to know the instructions for use and the manoeuvres to correct incorrect mask positions.

The role of the LMA-ProtectorTM as a routine second generation SAD in anaesthesia has not yet been studied. We agree with Pandit et al.'s concerns that an increasing number of airway management devices are being introduced into clinical practice with little or no prior evidence of their clinical efficacy and safety.¹⁰ The purpose of this article is to show how, by careful analysis of the design and structure of the

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3 device, a range of specific hypotheses can be generated that are amenable to clinical
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5 testing. In this editorial, by providing information about the similarities and differences of
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7 the physical characteristics of a new airway device, we hope anaesthetists are better
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9 informed before they actually introduce the device into clinical practice.
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Declaration of interest

No external funding was obtained for this manuscript.

Dr. M. Skinner and Dr. S. Luney have previously undertaken postmarketing clinical use and evaluation of the LMA-ProtectorTM.

Professor J.J. Pandit sits as elected Member of Council, Royal College of Anaesthetists, and sat on The Association of Anaesthetists of Great Britain and Ireland Working Parties on developing guidelines for managing the obese patient and minimum monitoring during anaesthesia. He is Scientific Officer of the Difficult Airway Society and an editor of Anaesthesia. The views expressed are his own and not of these organisations.

Author's contributions

All authors approved the final manuscript, attests to the integrity of the original data, and the analysis reported in this manuscript.

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Table Legends

Table 1 List of specifications for LMA-Supreme™ and LMA-Protector™

Figure Legends

Fig 1 LMA-Protector™ in situ showing 2 ports (A); CT-scan of LMA-Protector™ in situ (B); LMA-Supreme™ and LMA-Protector™, showing the 10° slant of the tip of the distal part of the cuff (C); Cuff Pilot Valve™ (D); LMA-Supreme™ and LMA-Protector™ lateral (E) and frontal view (F); and CT reconstruction of LMA-Protector™ showing tissue and gastric tube path in the lateral (G) and frontal view (H). Lateral x-ray image of LMA-Protector™ in situ (J); AP x-ray image of LMA-Protector™ in situ (K).

Table 1 List of specifications for LMA-Supreme™ and LMA-Protector™

	LMA-Supreme™	LMA-Protector™
Indication for use as airway device		
• Routine anaesthetic procedures	• Yes	• Yes
• Rescue airway device CPR [ref # 6]	• Yes	• Yes
• Rescue airway device in known or unexpected difficult airway cases [ref #9]	• Yes	• Yes
Available LMA sizes	1:1.5:2:2.5:3:4:5	3:4:5
Material, both cuff + tube	Polyvinyl Chloride	Medical-grade silicone
Number of uses	Single-use	Single-use
Functional separation ventilation – digestive tracts	Yes	Yes
Number of ventilation tubes, n	2 lateral (ventilation paths divided by drain tube)	1 central (max. I.D. 13 mm)
Number of gastric tubes, n	1	2 (male suction port + female drainage port)
Position proximal gastric drainage orifice	Behind 15-mm connector	Two separate ports on each side of airway tube
Position drain tube	Runs in middle of airway tube	On each side of airway tube
Design distal drainage orifice	Elongated cuff - 10° slant	Elongated cuff - 10° slant
Drainage chamber behind cuff bowl	N/A	Yes, two drainage channels continue distally / enter chamber
Nominal length internal ventilation pathway LMA sizes 3:4:5, cm	16:17:19	16:18:20
Nominal length internal drainage pathway LMA sizes 3:4:5, cm	22:24:26	18:21:23
Internal volume ventilatory pathway for LMA sizes 3:4:5, ml	18:23:26	18:22:23
Internal volume drainage pathway for LMA sizes 3:4:5, ml	6:6.5:7	31:41:42
Design cuff	Enlarged air-inflatable cuff, high airway seal cuff, reinforced tip	Enlarged air-inflatable cuff, high airway seal cuff, reinforced tip
Design tube	Firm anatomically shaped oval tube / Semi-rigid fixed curved tube (2 lateral grooves in airway tube)	Anatomically shaped oval tube / Flexible-curved tube

1			
2	Cross-section airway tube	Elliptical	Elliptical
3			
4	Mask aperture bars, n	2 “fins” to prevent epiglottic	None
5		downfolding	
6			
7	Guiding handle/Fixation Tab	Yes	Yes
8			
9	Colour; cuff:tube	Transparent	White:blue transparent
10			
11	Built-in bite block – long version	Yes	Yes
12			
13	Minimal interdental gap sizes 3:4:5, mm	19:20:20	28-32-32
14			
15	15-mm connector – ISO 5356-1	Fixed	Detachable
16			
17	Latex-free	Yes	Yes
18			
19	Phthalates (DHEP)-free	No	Yes
20			
21	Inflation valve - Luer cone – ISO 594-1	Yes	Yes
22			
23	Cuff pilot	Separate cuff pilot balloon	Separate cuff pilot balloon or
24			Integrated Cuff Pilot™
25			
26	Cuff pressure maximum, cm H ₂ O	60	60
27			
28	Magnetic Resonance Imaging, MRI	MR conditional (metallic spring)	MR conditional (metallic spring)
29			
30			MR compatible Integrated Cuff
31			Pilot™
32			
33	LMA as intubation conduit		
34			
35	• for LMA sizes 3:4:5	Requires special technique [ref # 8)	Yes
36	• max size TT, mm	N/A	TT: 6.5:7.5:7.5
37			
38	Maximum orogastric tube through drain tube		
39	for LMA sizes 3:4:5	14:16:16 Fr	16:18:18 Fr
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41 N/A: not applicable; TT: tracheal tube; CPR: cardiopulmonary resuscitation; LMA: Laryngeal Mask Airway

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