

A Comparative Anatomical Study of Laryngeal Masks

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Introduction and methodology

The clinical and commercial success of the LMA™ laryngeal mask airway has inspired a proliferation of rival devices. The 1996 FDA reclassification of laryngeal masks as Class I devices means that manufacturers no longer have to submit clinical safety and efficacy data to the FDA when registering new masks.

There is, therefore no longer a need to obtain clearance from the FDA to market a laryngeal mask device.

A research team from the University of Texas spent two years studying the behavior of laryngeal mask airways – during insertion, inflation and clinical use. Working on fresh cadavers where the soft tissues are comparable to those of live patients, the team used fluoroscopy to watch the masks being inserted and computerized tomography and fiberoptics to examine their positioning and performance.

Here are the findings.

Methodology

After being granted permission from the institutional review board, fresh human cadavers were used to study the effects of insertion of the supraglottic airways on airway structures. All insertions were performed by an anesthesiologist, who followed the manufacturer's guidelines for size selection and insertion technique for each device. Continuous lateral neck fluoroscopy was performed during each insertion. Fluoroscopic images were reviewed by a board certified radiologist.

Helical computed topography (CT) scans of the cadavers were performed with each supraglottic airway *in situ*. Three-dimensional (3-D) reconstructions of these CT scans were obtained to evaluate the positions of the devices in relation to the airway structures.

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This research was presented as a poster at the American Society of Anesthesiologists Annual Meeting in 2004, and together with additional research form an analysis of 7 Supralaryngeal Airways. This independent research was conducted with sole funding from M.D. Anderson Cancer Center.

This has been edited to form a summary of the original LMA Classic™ and the two devices closest in concept; the Portex Soft Seal™ and Ambu™ Laryngeal Mask.

Dr David Ferson, who led the research, is a participant of the American Society of Testing and Materials Committee F29 on supralaryngeal airways.

Portex Soft Seal™ is a trademark of Smiths Medical International Ltd.

Ambu™ is a trademark of Ambu International A/S.

All trademarks are acknowledged throughout.

Comparing the masks

When, in the early 1980s Dr Archie Brain began work on the first LMA™ airway design he was guided by the principle of anatomical accuracy. He took multiple plaster casts of the human pharynx, created latex models from these casts and, with Ethical Committee approval, experimented both with self-insertion and on more than 7,000 patients in the prototype phase. The result was a mask that accurately mapped the anatomy of the pharynx.

Portex Soft Seal™ and Ambu™ Laryngeal Mask airways lack the same level of anatomical accuracy. Side-by-side, the differences are obvious even to the untrained eye.



LMA™ airway

The distinctive shape of the cuff tapers at the tip, following the anatomical shape of the hypopharynx.

The back plate, deep at the rear, becomes shallower at the front. There are aperture bars.

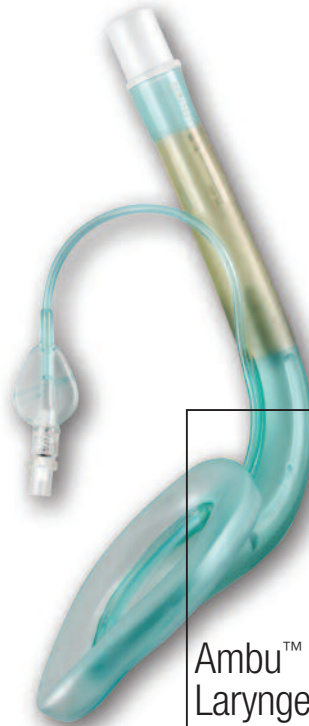
Inserting the masks

Ferson *et al* used fluoroscopy to study the behavior of the masks during insertion. The Portex Soft Seal™, which lacks the tapered leading edge of the LMA™ airway, and the back plate, was the most problematic to insert. The Ambu™ Laryngeal Mask's rigid, pre-curved airway, makes insertion easy.



Portex Soft Seal™

The cuff does not taper at the tip: it is a perfect oval. A larger diameter airway tube. No back plate. No aperture bars. Inflation line attached to airway tube.

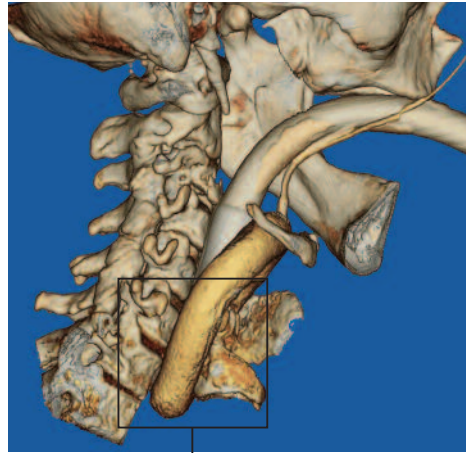


Ambu™ Laryngeal Mask

Closer in shape to the LMA™ airway, but not identical. A larger and more rigid pre-curved airway tube. No back plate. No aperture bars. Inflation line attached to airway tube.

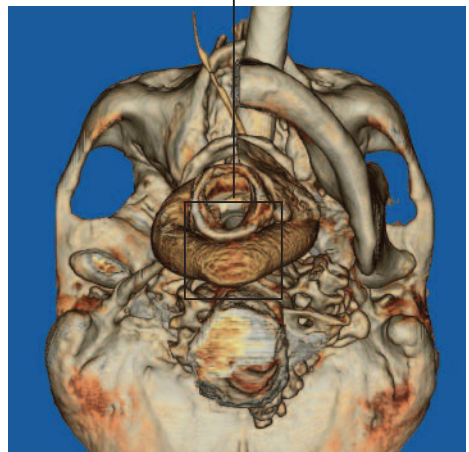
Positioning: key differences

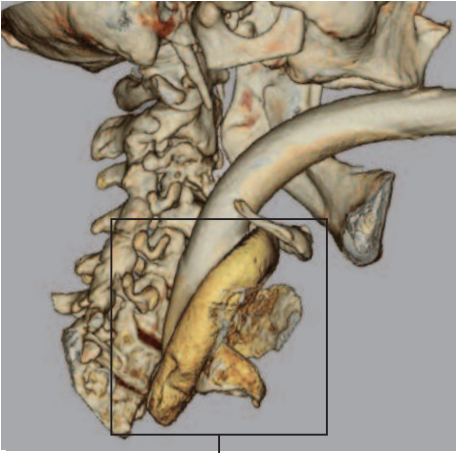
Ferson *et al* used computerized tomography and fiberoptics to examine the positioning of the three masks. These CT scan images show the masks in place within the same cadaver. Soft tissues and other inessentials have been removed from the images, giving a clear picture of how the masks behave *in situ* and how the differences in design may affect performance.



LMA™ airway

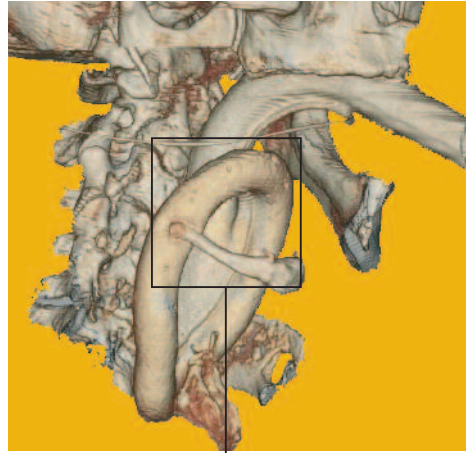
Here, the LMA™ airway sits on the upper esophageal sphincter. The cuff, shaped anatomically, retains its shape, forming a good seal.





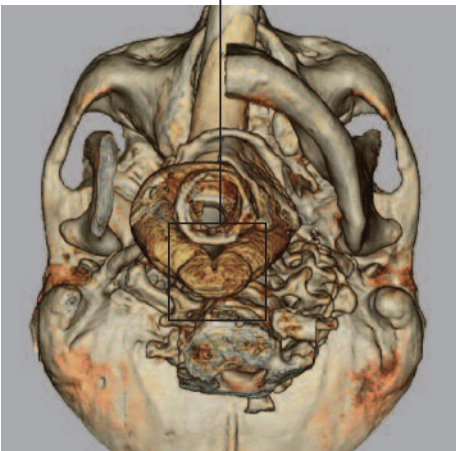
Portex Soft Seal™

The tube of the Portex Soft Seal™ extends all the way to the tip of the cuff, resulting in placement below the hyoid bone, making the mask more invasive. Using fluoroscopy, the soft tip was noted to bend backwards on insertion. Without precise anatomical shape, the cuff of the Portex Soft Seal™ is itself shaped by the pressure of surrounding tissue. At the tip the cricopharyngeal muscle causes herniation of the cuff, creating a small gap.



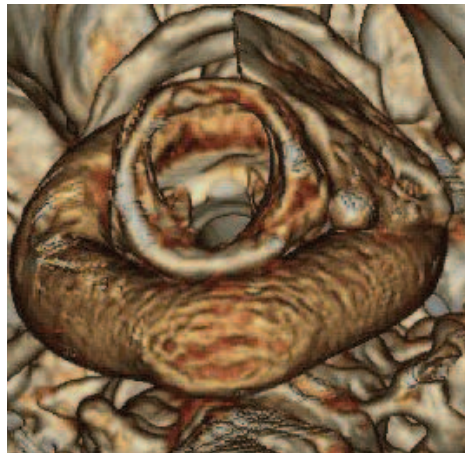
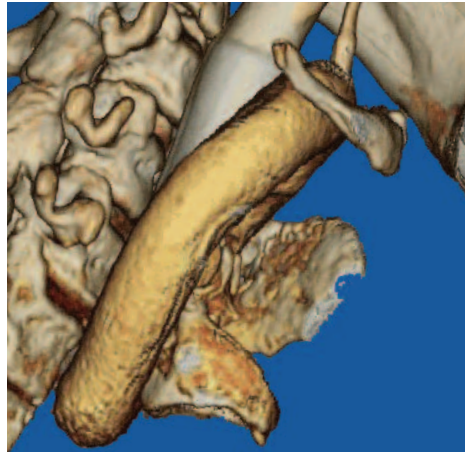
Ambu™ Laryngeal Mask

While the size and pre-curved shape of Ambu™ Laryngeal Mask's airway tube makes it easy to insert, it also causes the mask to sit much higher than the other two masks, here pressing on the hyoid bone. Because it sits higher, the Ambu™ Laryngeal Mask's tip is not in contact with the upper esophageal sphincter.



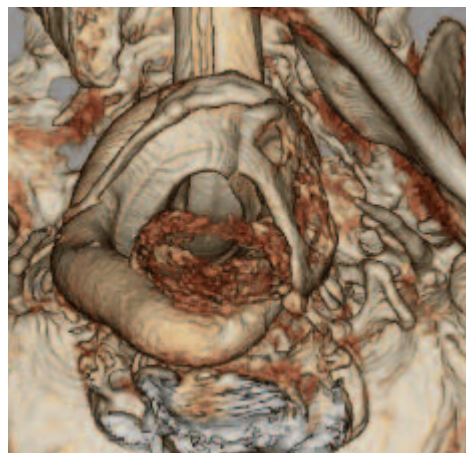
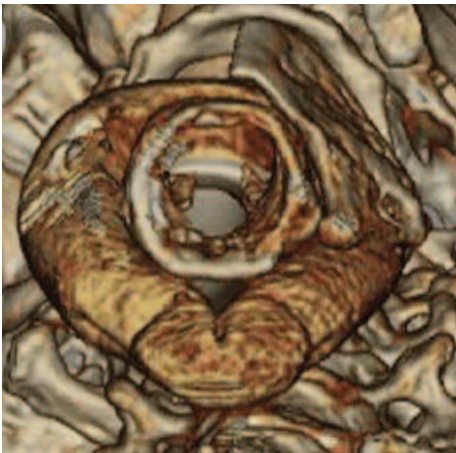
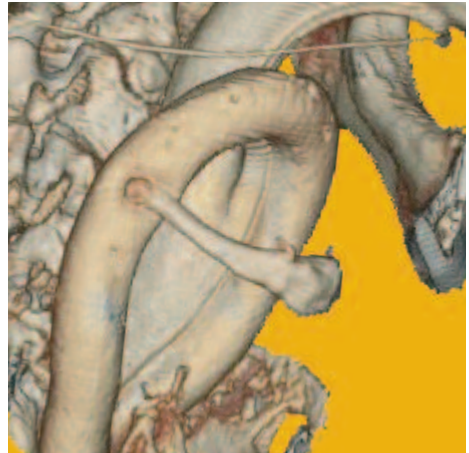
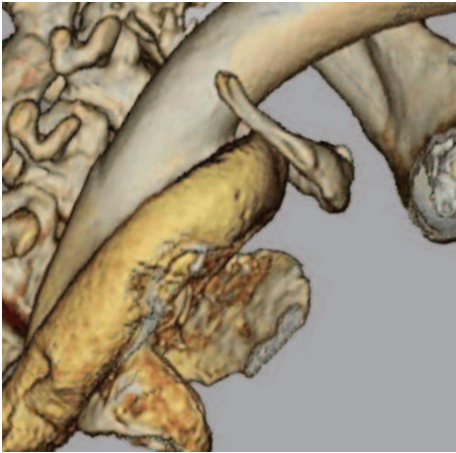
Clinical implications and risks

So far the research has demonstrated clear differences in the design of three masks and in their positioning. But what are some of the potential clinical implications?



LMA™ airway

No clinical implications with proper sizing, insertion and inflation volumes.



Portex Soft Seal™

As well as being potentially more invasive and more difficult to insert, the cuff of the Portex Soft Seal™, as we have seen in this case, herniates. That makes it more prone to imperfect sealing. The channel that is created in this instance between the esophagus and the trachea increases the risk of gastric insufflation, regurgitation and aspiration.

Ambu™ Laryngeal Mask

The Ambu™ Laryngeal Mask's high position is dictated by the pre-curved shape and the rigidity of its tube. This design helps insertion but may cause the cuff to press against the hyoid bone in some cases. There is a danger that the hypoglossal nerve, which governs motor functions of the tongue can be caught between the mask and the hyoid bone, leading to nerve palsy and problems with speech and swallowing. The failure to cover the esophagus also increases the risk of gastric insufflation, regurgitation and aspiration.

Comparisons and conclusion

	LMA™ airway	Portex Soft Seal™	Ambu™ Laryngeal Mask
Main differences	Anatomical shape of cuff and back plate. Aperture bars.	Oval cuff. No back plate. No aperture bars.	Pre-curved, rigid airway tube. No back plate. No aperture bars.
Insertion	Easy insertion, minimal risk of trauma.	Risk of problematic insertion.	Easy insertion, minimal risk of trauma.
Positioning	Cuff retains shape. Sits on the esophagus.	More invasive. Cuff can herniate.	Sits high, potentially pressing on hyoid bone. Possible lack of contact with esophagus.
Clinical implications	None, provided proper sizing, insertion and inflation volume.	Prone to imperfect sealing. Greater risk of gastric insufflation, regurgitation and aspiration.	Hypoglossal nerve may be caught between mask and hyoid bone. Greater risk of gastric insufflation, regurgitation and aspiration.

This important study has established that these three laryngeal mask airways are not the same. Instead they are designed differently, behave differently and – most importantly – their use carries very different clinical implications.

Choosing a laryngeal mask airway is not just about cost or what you are used to. There is a clinical consideration and a risk assessment that needs to be made too.

Find out more

We hope you have found this edited summary of independent research informative.

To find out more about LMA™ airways
— International call **+44 (0) 1628 852 400** or
www.LMACO.com
— United States call **(800) 788-7999**
or **www.LMANA.com**

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The information given in this document is correct at the time of going to press. The manufacturer reserves the right to improve or modify the products without prior notification.

Consult the instructions on indications, contraindications, warnings and precautions, or information on which LMA™ airways are best suited for different clinical applications.

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