

APPARATUS

Initial anatomic investigations of the I-gel airway: a novel supraglottic airway without inflatable cuff*

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Summary

The I-gel airway is a novel supraglottic airway that uses an anatomically designed mask made of a gel-like thermoplastic elastomer. We studied the positioning and mechanics of this new device in 65 non-embalmed cadavers with 73 endoscopies (eight had repeat insertion), 16 neck dissections, and six neck radiographs. A full view of the glottis (percentage of glottic opening score 100%) occurred in 44/73 insertions, whereas only 3/73 insertions had epiglottis-only views. Including the eight repeat insertions with a different size, a glottic opening score of > 50% was obtained in all 65 cadavers. The mean percentage of glottic opening score for the 73 insertions was 82% (95% confidence interval 75–89%). In each of the neck dissections and radiographs the bowl of the device covered the laryngeal inlet. We found that the I-gel effectively conformed to the perilaryngeal anatomy despite the lack of an inflatable cuff and it consistently achieved proper positioning for supraglottic ventilation.

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The laryngeal mask airway and similar supraglottic airway devices use an inflatable cuff to wedge into the upper oesophagus and provide a perilaryngeal seal [1]. The mask shape of these devices resembles a wedge-shaped doughnut in overall design. They have a tapered leading tip, a rounded proximal shape and with inflation these masks have a flat face when viewed from a lateral perspective. Inflatable masks provide an airway seal but can negatively impact on how these devices are inserted, how they are positioned and how they perform. On insertion the deflated leading edge of the mask can catch the epiglottis edge and cause it to down-fold or impede proper placement beneath the tongue. The best performance of the laryngeal mask airway occurs with semi-inflation [2–4]. Inflation using the recommended volumes increases mask rigidity, decreases conformity with perilaryngeal structures and lessens the effective seal pressure [2–4]. Mechanically, inflation can cause movement of the device because the distal wedge shape of the mask

is forced out of the upper oesophagus. Inflatable masks also have the potential to cause tissue distortion, venous compression and nerve injury [5–7]. Finally, depending upon their materials, they can absorb anaesthetic gases, leading to increased mucosal pressures [8].

The I-gel airway (Intersurgical Ltd, Wokingham, Berkshire, UK) is a novel supraglottic device made up of a thermoplastic elastomer (SEBS, styrene ethylene butadiene styrene) with a soft durometer (hardness) and gel-like feel (Fig. 1a–c). The mask of the I-gel is designed anatomically to fit the perilaryngeal and hypopharyngeal structures without the use of an inflatable cuff. A supraglottic airway without a cuff has potential advantages including easier insertion and use, minimal risk of tissue compression, stability after insertion (i.e. no position change with cuff inflation) and manufacturing advantages in terms of simplicity and decreased cost. The I-gel is designed as a single patient use, disposable device.

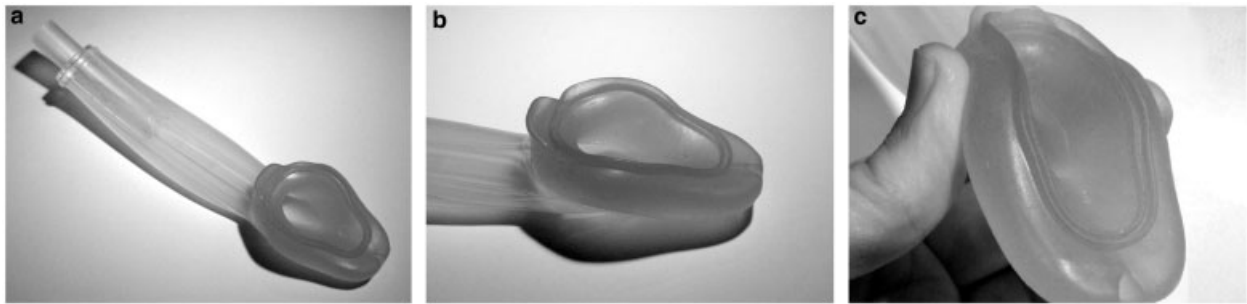


Figure 1 The I-gel airway viewed from an oblique perspective (a). Close up images of the bowl (b and c). The darker coloured bowl of the device is made of a softer durometer material than the more lightly coloured tube section. At the proximal end of the tube section there is a removable, hard plastic piece that serves as a combination bite block and 15 mm connector. With removal of the plastic connector the lumen of the device can accommodate an 8.0 mm internal diameter tracheal tube. A second lumen runs along the entire length of the device to the distal tip and accommodates a nasogastric tube. In the close up photographs note the two small, feathered edges around the top of the bowl designed to improve the mucosal seal. The small ridge projecting from the proximal section of the bowl sits against the base of the tongue and helps stabilise the device after placement. c) The sides of the bowl have been compressed slightly demonstrating the flexibility of the material, and also the inward bending movement that occurs as the lateral edges of the bowl slide under the pharyngo-epiglottic folds. The exit hole for the nasogastric lumen is seen best in this image.

The objective of this study on fresh cadavers was to assess anatomically the performance of this new supra-glottic airway through endoscopic imaging, neck dissections and lateral radiographs.

Methods

The study was approved by the Institutional Review Board of the University of Pennsylvania and took place at the University of Maryland Medical Center, in a facility operated by Anatomy Board of the State of Maryland. Consent for medical education and research for all the bodies had previously been obtained through direct anatomic donation or through their families.

This study used 65 non-embalmed fresh cadavers collected over 5 months. The properly sized I-gel (No. 4 or 5) was selected at the discretion of the lead author; as with laryngeal mask airway sizing, a no. 4 I-gel is used for most women and small men and a no. 5 I-gel for larger men.

Endoscopy was performed by sliding a malleable, high resolution, optical stylet (Seeing Optical Stylet, Clarus Medical, Minneapolis, MN) down the main lumen of the I-gel after placement [9]. An endoscopic camera (MedCam Pro, MedCam Technologies, Sunrise, FL) was mounted on the eyepiece of the stylet and the image from the camera was digitally recorded (Sony GDV-900 mini-DV deck, Sony Corporation, Tokyo, Japan). All endoscopies were performed by the lead author. Frame-by-frame analysis of the video recordings assessed the visibility of the laryngeal inlet as the endoscope exited the lumen of the I-gel. Laryngeal view was evaluated (by the second author) using a percentage of glottic opening score [10]. This means of grading laryngeal view has been

previously shown to have good inter- and intra-observer reliability [11].

Block dissections of 16 cadavers were carried out through neck incisions just below the hyoid bone, at the cricothyroid membrane and at the upper trachea.

Radiographic evaluation involved soft tissue lateral neck films after placement of the I-gel in six cadavers.

Results

Seventy-three endoscopies were performed on 65 cadavers. In eight cadavers a repeat endoscopy was done using a different size I-gel. All 73 endoscopies were used for data analysis. In 70/73 endoscopies a portion of the glottic opening was visible immediately upon exiting the lumen of the device. A full view of the glottis was achieved in 44 cases, and a glottic opening score of > 50% was attained in 65/73 insertions (Fig. 2a–c). In three cases, the epiglottis obscured any view of the glottic opening, but the aperture at the base of the I-gel bowl was not occluded. Including the eight repeat insertions with different sized I-gels, a glottic opening score of > 50% was obtained in all 65 cadavers studied. The overall mean glottic opening score in 73 endoscopies was 82% (95% confidence interval 75–89%).

In all 16 dissections, the proximal bowl of the I-gel was seen adjacent to the epiglottis and the main cup of the device covered the laryngeal inlet (Fig. 3a–c). With repeat insertion and removal it was evident in each cadaver that the sides of the I-gel bowl bent slightly inward beneath the pharyngo-epiglottic folds as the device was completely inserted. This movement appeared to slightly increase the anterior–posterior dimension of

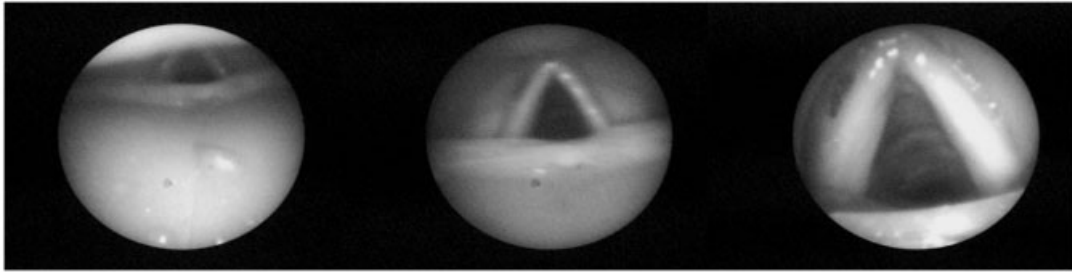


Figure 2 Endoscopic images recorded upon exiting the tube section of the I-gel. The tube portion of the device is visible at the lower portion of the images.

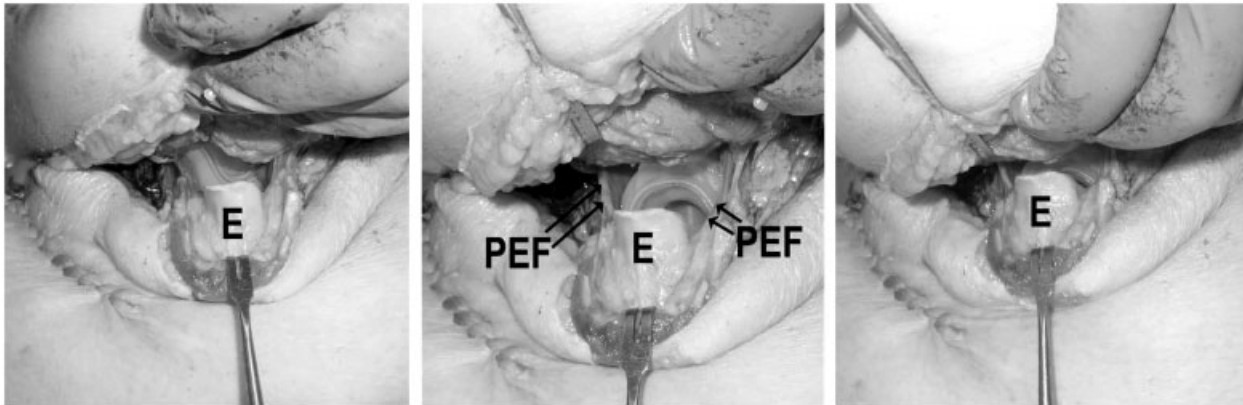


Figure 3 Sequential images from left to right of insertion of the I-gel after neck dissection at the level of the hyoid. The tip and distal section of the bowl of the I-gel is visible passing beneath the epiglottis in the image on the left; in the image on the right insertion is complete and the proximal portion of the bowl is barely visible. The sides of the bowl are seen passing beneath the pharyngo-epiglottic folds in the middle image. The epiglottis is marked E, and the pharyngo-epiglottic folds are marked PEF.

the bowl upon full insertion. The size of the device and the bending inward of the lateral edges of the bowl seemed to influence the final insertion position. The point at which further advancement became limited correlated with the tip of the device seating itself behind the cricoid cartilage in the cervical oesophagus. A small ridge on the proximal bowl of the I-gel caught against the base of the tongue and effectively prevented the device from sliding upwards after insertion (Fig. 1a–c).

The tube section of the I-gel is not a conventional rounded tube but has a widened and symmetrical, laterally flattened, cross-sectional shape (Fig. 1a). This design provided good vertical and lateral stability on insertion. The tube section is harder and more rigid than the soft bowl of the device. The firmness of the tube section and its natural straightness (because of the manner in which it is moulded) allowed the device to be inserted by grasping the proximal end of the I-gel and guiding the leading edge against the palate into the pharynx. It was not necessary to insert fingers into the mouth for full insertion of the device. The smooth contiguous undersurface of the

device from the tip of the bowl and throughout the entire tube section helps it to easily slide posteriorly along the palate, pharynx and hypopharynx. In none of the 16 dissections did the device catch or become hung up on the tongue or epiglottis edge.

In all six lateral radiographs the bowl of the device was located over the laryngeal inlet, and the distal edge of the device was positioned in the cervical oesophagus. The ridge on the proximal edge of the I-gel bowl was clearly visible at the base of the tongue in all radiographs (Fig. 4). The position of the epiglottis relative to the bowl of the I-gel was difficult to assess consistently because of overlapping structures, the opacity of the device and calcifications over the hyoid bone and thyroid cartilages.

Discussion

The bowl of the I-gel has a sophisticated three-dimensional structure intended to mirror perilaryngeal anatomy. Images of the laryngeal inlet made with the Glidescope Video Laryngoscope [12] display the anatomic complex-

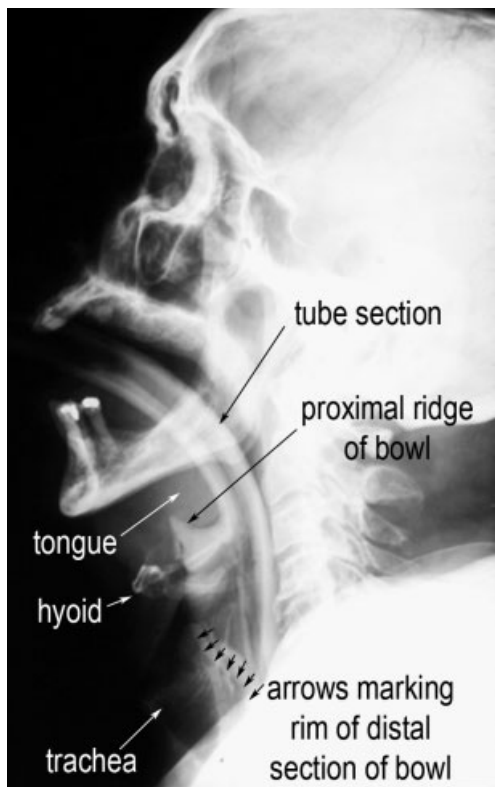


Figure 4 Lateral radiograph of the neck, showing the position of the I-gel after placement. The I-gel bowl covers the laryngeal inlet, and the distal tip is in the cervical oesophagus. The epiglottis is poorly defined.

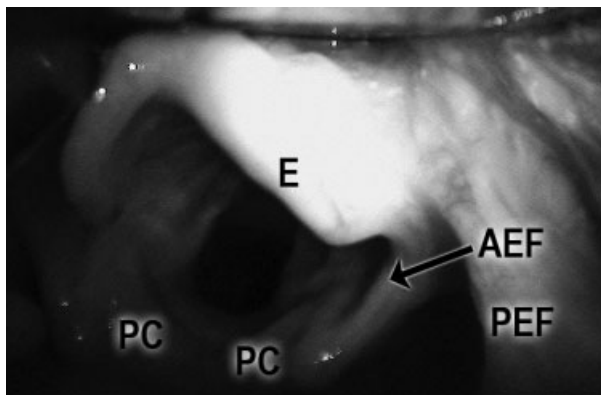


Figure 5 Glidoscope Video Laryngoscope image of the laryngeal inlet demonstrating the structures that the I-gel bowl is designed to match against. Note the projection of the epiglottis (E) and the step angle of the aryepiglottic folds (AEF) going down to the posterior cartilages (PC). The pharyngo-epiglottic fold (PEF) is visible on the extreme right side of the image.

ity of this area (Fig. 5). The epiglottis extends proximally for a considerable distance before the aryepiglottic folds on either side slant abruptly downward to the posterior

cartilages. The I-gel is intentionally designed to mirror these structures and the adaptive nature of the mask material permits further conformity to variations between patients. The small width and height of the I-gel tip is intended to fit into the postcricoid cervical oesophagus. Just proximal to the distal tip, the bowl enlarges slightly in width but more significantly in height. This section of the device contacts the posterior cartilages. The wide middle section of the bowl abuts the aryepiglottic folds and pharyngo-epiglottic folds. The most proximal portion of the bowl interacts with the tip of the epiglottis and the base of the tongue.

The I-gel is not the first supraglottic airway designed specifically to fit the perilaryngeal structures. The SLIPA, or Streamlined Liner of the Pharynx Airway, is also anatomically preshaped and does not use an inflatable cuff [13, 14]. The SLIPA, however, is made of moulded plastic (polypropylene) that does not conform to anatomic structures, requiring six different sizes for adult patients [15].

The tensile properties of the I-gel bowl, along with its shape and the ridge at its proximal end, contribute to the stability of the device upon insertion. Upon sliding beneath the pharyngo-epiglottic folds it becomes narrower and longer, creating an outward force against the tissues. The ridge at the proximal bowl catches the base of the tongue, also keeping the device from moving upwards out of position (and the tip from moving out of the upper oesophagus).

The I-gel does not use aperture bars like some supraglottic airways. In our endoscopies this was not a problem. This may be due to the greater depth of the I-gel bowl and the positioning of the aperture of the tube section at the deepest and most proximal section of the bowl.

An anatomic study of the I-gel in fresh cadavers has some limitations. The positioning and tone of the epiglottis and the pharynx in cadavers is not identical to that of anaesthetised patients. Dissections disrupt the relationship of tissues and it is difficult to peer inside the circumferentially closed space of the hypopharynx during dissection without affecting surrounding tissues. It appeared that our high incision at the hyoid allowed a good perspective, looking downward on the mechanical interaction of the device with the epiglottis and pharyngo-epiglottic folds without distorting the circular structures of this area.

The use of a relatively rigid optical stylet curved to slide through the device may have permitted inadvertent movements, which could have influenced our endoscopy results. Conversely, compared to a flexible scope that can be used to manoeuvre around visual restrictions, the optical stylet has a narrow viewing angle (70°) and no articulating tip, so very little manoeuvring was possible

upon emerging from the tube into the I-gel bowl. We suspect that a flexible endoscope would have yielded even better laryngeal views.

In summary, the I-gel was consistently positioned over the laryngeal inlet in this cadaver study, as shown by endoscopy, dissection and radiography. The unique gel-like material of the mask performed as intended, conforming to the perilaryngeal anatomy. This study provides the foundation for initiating research on live patients focusing on ventilation and seal pressures.

Acknowledgements

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