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The Glottic Aperture Seal Airway

A New Ventilatory Device

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Background: None of the presently used airway devices are ideal regarding ease of insertion, alignment with the laryngeal inlet, and provision of a high-pressure seal from the environment. The purpose of this study was to determine, in awake volunteers, the performance of a new ventilatory device, the glottic aperture seal airway, regarding ease of insertion, alignment with the laryngeal inlet, and forced exhalation seal pressure (PFES).

Methods: The glottic aperture seal airway consists of a curved tubular component that ends in the middle of an elliptical foam cushion glottic component. The posterior surface of the foam has a curved flexible plastic backing, which imparts a 60° angle between the proximal half and the distal half of the foam cushion. When the glottic aperture seal airway is properly *in situ* in a supine patient, the proximal half of the foam cushion is opposite the laryngeal inlet. The posterior surface of the plastic backing has a balloon attached to it. Inflation of the balloon presses the ventilation hole and foam cushion up against the laryngeal inlet, thereby creating a seal from the environment. Using the laryngeal mask airway as a control device, the glottic aperture seal airway was tested for time and ease of insertion, fiberoptic alignment with the laryngeal inlet, and PFES in 18 lightly sedated and locally anesthetized volunteers.

Results: The glottic aperture seal and laryngeal mask airways were inserted with equal ease and speed. The fiberoptic alignment with the larynx was excellent for both the glottic aperture seal and laryngeal mask airways. In all volunteers, the mean \pm SD PFES values at 0-, 10-, 20-, 30-, and 40-ml balloon inflation volumes of the glottic aperture seal airway were 23.4 ± 11.8 , 29.6 ± 12.4 , 42.7 ± 12.5 , 56.9 ± 5.6 , and 60 ± 0 cm H₂O, respectively; the PFES at ≥ 20 ml balloon inflation volume of the glottic aperture seal airway was significantly greater

than with the laryngeal mask airway (19.4 ± 6.7 cm H₂O, $P < 0.01$). A PFES of ≥ 60 cm H₂O was achieved with the glottic aperture seal airway in all volunteers ($n = 2$ at 10 ml, $n = 3$ at 20 ml, $n = 9$ at 30 ml, and $n = 4$ at 40 ml). The glottic aperture seal airway did not cause any trauma.

Conclusion: In awake volunteers, the glottic aperture seal and laryngeal mask airways were equally easy to insert and position. The glottic aperture seal airway was capable of achieving a higher PFES than the laryngeal mask airway. (Key words: Fiberoptic laryngoscopy; forced exhalation; larynx; laryngeal mask airway; laryngeal and pharyngeal anesthesia; vocal cords.)

At present, there are three routinely used airway devices: the face mask with or without oro- or nasopharyngeal airway, the laryngeal mask airway (LMA), and the oro- or nasotracheal tube. None of these three devices are ideal in all three categories of (1) ease of insertion (reliably atraumatic, rapid, no requirement to visualize laryngeal structures or requirement for a high level of skill); (2) good alignment with the laryngeal inlet, resulting in unobstructed spontaneous and positive pressure ventilation; and (3) reliability in providing a seal from the environment in excess of 40 cm H₂O.

The glottic aperture seal (GAS) airway (Augustine Medical Inc., Eden Prairie, MN) was developed by the Augustine Medical Inc. airway team and the author to create an easy-to-insert, well-aligned, highly sealed airway. The final design was preceded by 15 distinct developmental prototypes. This article describes the final design and performance of the GAS airway in 18 locally anesthetized adult volunteers.

Methods and Materials

Description of the Glottic Aperture Seal Airway

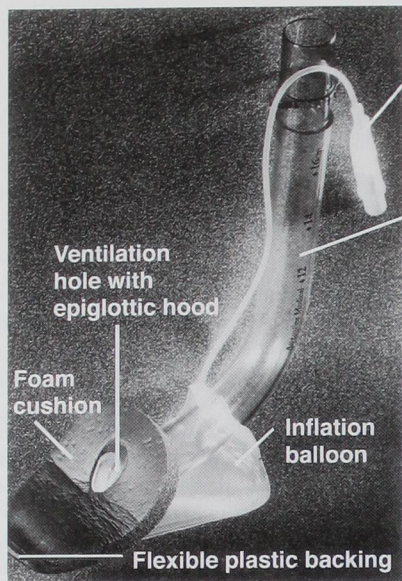
Basic Structural Features. The GAS airway has a tubular component and a glottic seal component (fig. 1). The tubular component is a flexible 18-cm polyvinylchloride curved tube with an ID of 13 mm. It terminates in an

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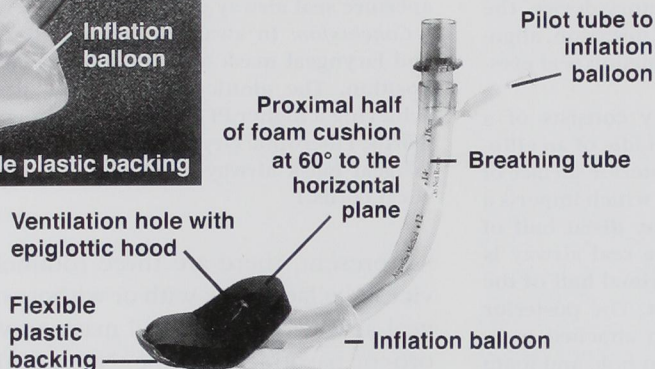
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GAS Airway - Frontal View



GAS Airway - Side View



GAS Airway - Retraction Blade

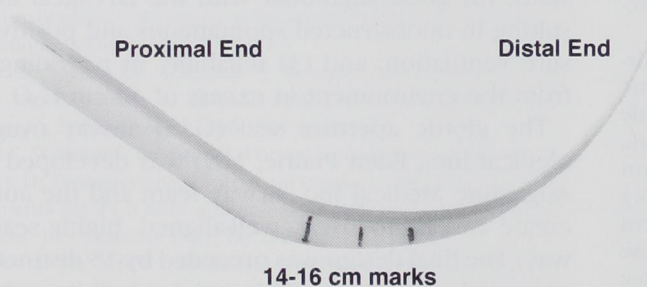


Fig. 1. Photograph of the glottic aperture seal (GAS) airway. (Top) Anterior frontal (vertical) view of the GAS airway showing the L-shaped breathing tube ending in an elliptical hole in the proximal half of the foam cushion. On the posterior surface of the foam cushion is a flexible plastic backing, which is curved through approximately 60° and which causes the proximal half of the foam cushion to be at a 50–60° angle to the distal half. The foam cushion itself is elliptical. The inflation balloon with pilot tube is attached to the posterior side of the plastic backing. (Middle) Side view showing the L-shaped breathing tube ending in the proximal half of the foam cushion. A 5-mm distal extension of the breathing tube beyond the foam cushion serves as an epiglottic hood. Otherwise, the middle figure part shows the same structural features as the top from a different angle. (Bottom) The semiflexible curved plastic retraction blade used to blindly trap the epiglottis against the base of the tongue; the centimeter markings are relative to the distal end.

elliptical orifice in the glottic seal component that is 13 mm in its vertical dimension and 8 mm wide. The anterior edge of the tubular component projects 5 mm through the anterior surface of the glottic seal component. This extension serves as a hood to keep the epiglottis out of the ventilatory channel (fig. 1, top and middle). The most posterior portion of the orifice of the tube has a 5-mm longitudinal slit that allows the elliptical distal orifice to expand easily. The glottic seal component of the airway

consists of an elliptical foam cushion supported by a molded, flexible, plastic support. The support is flexed along its midhorizontal plane to give the foam seal a 50–60° bend to the horizontal plane (fig. 1, top and middle). This degree of flexion is such that when the GAS airway is properly seated in the hypopharynx, the orientation of the upper half of the foam cushion approximates the 45° anterior-posterior slope of the plane of the laryngeal inlet (the epiglottis, aryepiglottic folds, arytenoid cartilages; fig.

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2D). A balloon, inflatable to 30–50 ml, is mounted on the posterior surface of the plastic support with attachments approximately at the 50–60° line of flexion of the rigid support and to the inferior portion of the tubular component. When the balloon is inflated, the plane of the proximal half of the foam cushion, which contains the distal end of the ventilation tube, is pressed up against the plane of the laryngeal inlet, creating a tight seal (fig. 2D).

Method of Insertion and Mechanism of Alignment and Seal. A broad (25 mm) semiflexible retraction blade is inserted blindly along the posterior curvature of the oropharynx to the hypopharyngeal level (at 14–16 cm, a moderate resistance to further passage is felt) and then is lifted anteriorly to trap the epiglottis between the retraction blade and the base of the tongue and the arytenoid cartilages anterior to the retraction blade (fig. 1, bottom, and fig. 2A). The GAS airway is then passed behind the retraction blade and advanced in a posterior and then caudad direction until firm resistance is encountered (figs. 2B and 2C). When firm resistance is encountered, the distal end of the GAS airway has engaged the hypopharynx, and the anterior surface of the sloping plane of the proximal half of the GAS airway has been pushed up against the posterior surface of the retraction blade (fig. 2C). The epiglottic retraction blade is then removed, and the outward movement of the epiglottic retraction blade maintains the normal caudad-to-cephalad orientation of the epiglottis between the foam cushion and the base of the tongue (fig. 2D). Removal of the retraction blade causes the anterior surface of the 50–60° sloping plane of the proximal half of the foam cushion to be opposite and parallel to the 45° sloping plane of the laryngeal inlet (fig. 2D). The 5-mm anterior plastic extension of the ventilating tube through the anterior proximal end of the ventilation hole in the foam cushion acts as an epiglottic hood, preventing the posterior surface of the epiglottis from sagging into the ventilation hole (fig. 2D). The proximal end of the epiglottis is proximal to the proximal end of the foam cushion (fig. 2D). Medium-sized (foam cushion 62 × 44 mm, 30-ml balloon) and large-sized (foam cushion 68 × 46 mm, 50-ml balloon) adult GAS airways was used for patients <180 or ≥180 cm tall, respectively. The GAS airway is stabilized and secured with a plastic strap that creates a moderate inward tension on the GAS airway by circumscribing the adapter of the GAS airway and the entire head at the occipital prominence level. There was no further manipulation of the GAS airway after initial insertion.

Preparation of Volunteers for Awake Insertion of the Glottic Aperture Seal and the Laryngeal Mask Airways

The sample used in this study, approved by the institutional review board (Augustine Medical Inc.), consisted of 6 female and 12 male healthy volunteers (all gave written informed consent) aged 18–36 yr, with weights 55–110 kg and heights 153–198 cm. The patients were sedated with 1.0–2.0 mg midazolam given intravenously and 100–150 µg fentanyl given intravenously. The mouth and oropharynx were topicalized with 15 ± 5 ml (mean ± standard deviation) of 4% lidocaine over 10 min; the lingual branch of the glossopharyngeal nerve was bilaterally blocked with 2.0 ml of 1.0% lidocaine at the inferior curvature of the palatoglossal arch; and the superior laryngeal nerve was bilaterally blocked with 2.0 ml of 1.0% lidocaine between the horn of the hyoid bone and cornu of the thyroid cartilage.

Measurements

The GAS airway and LMA were inserted by the author in all volunteers. The time and ease of insertion, fiberoptic alignment with the larynx, and forced exhalation pressure seal were measured and airway device-induced trauma assessed. Size of LMA, method of insertion of LMA (including instruction to swallow as the tip of the LMA reached the pharynx), and degree of LMA cuff inflation were determined according to the instructions given by Brimacombe *et al.*¹ The order between insertion of the GAS airway and the LMA and between determining fiberoptic alignment and forced exhalation seal pressure for both airways was alternated. All measurements were made when the volunteers were stable in all respects and were recorded on-line by a research assistant.

Time and Ease of Insertion. The time of insertion of the GAS airway and LMA were taken to be from the opening of the mouth to complete withdrawal of the epiglottic retraction blade (GAS airway) and to beginning cuff inflation (LMA), respectively. The ease of insertion for both the GAS airway and the LMA was graded subjectively on a scale of 1–5, where 1 was easiest insertion possible (minimal force used) and 5 was most difficult insertion possible (very large force required) in the experience of this investigator.

Alignment. For the GAS airway, alignment of the elliptical ventilation hole with the laryngeal aperture was graded fiberoptically. A 100% alignment meant

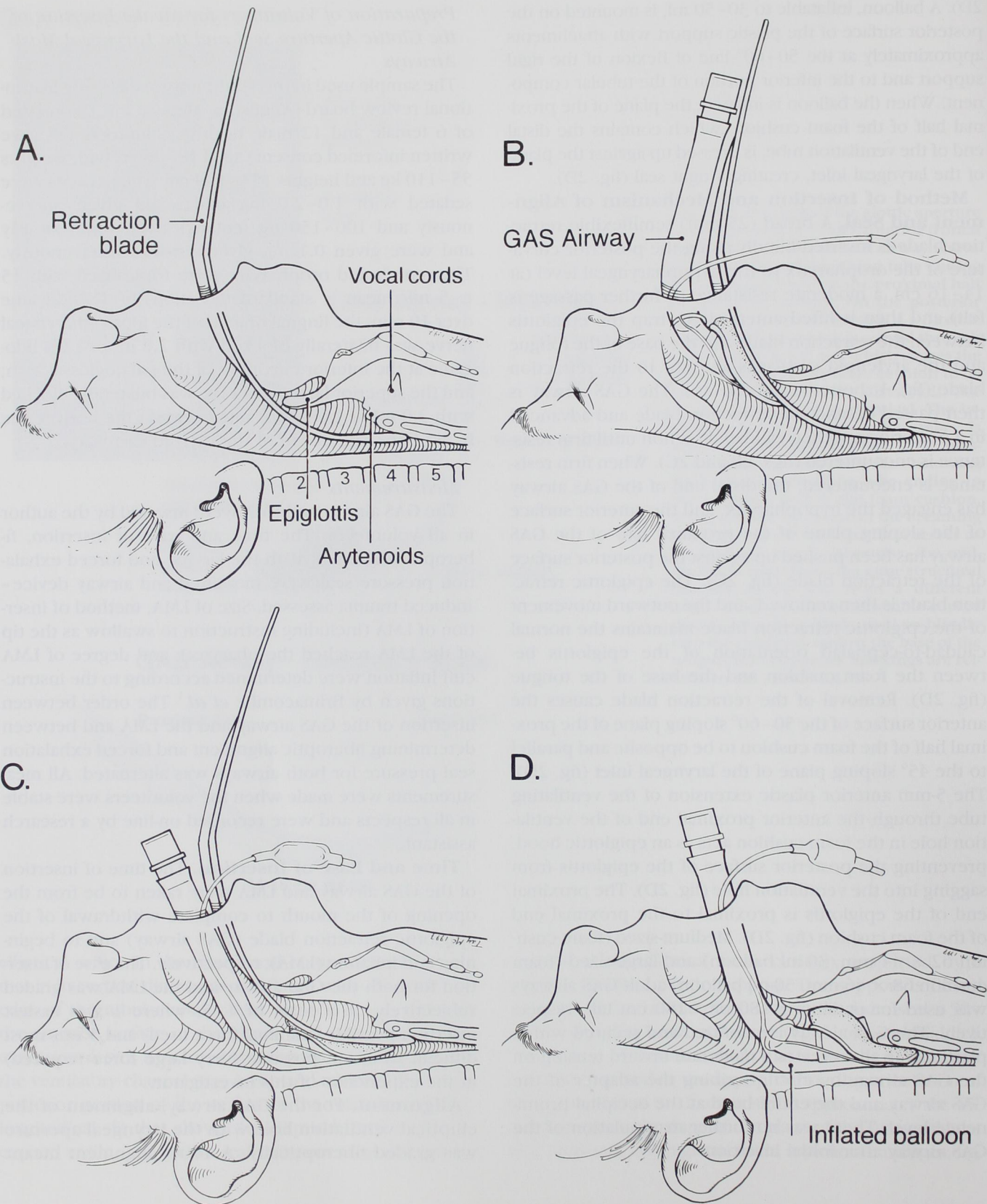


Fig. 2. Schematic of the sequence of events during insertion of the glottic aperture seal (GAS) airway. (A) The curved retraction blade traps the epiglottis against the base of the tongue. The bodies of the cervical vertebrae are numbered. (B) The GAS airway is inserted so that the anterior surface of the foam cushion slides along the posterior surface of the curved retraction blade. (C) The GAS airway is advanced until firm resistance is encountered, at which point the distal end of the GAS airway has engaged the hypopharynx and the anterior surface of the proximal half of the foam cushion has been firmly pushed against the posterior surface of the curved retraction blade. (D) The curved retraction blade has been withdrawn, and the proximal half of the foam cushion, with the ventilation hole, is against and within the laryngeal inlet. The balloon has been partially inflated, pressing the GAS airway against the laryngeal inlet. Note that the proximal edge (tip) of the epiglottis is outside of (proximal to) the proximal end of the foam cushion.

that the arytenoid cartilages and aryepiglottic folds were outside (peripheral to) the inner lining of the ventilation hole, and only the distal attachment of the epiglottis to the anterior commissure (the tubercle of the epiglottis) and the vocal cords could be seen (fig. 3). Visualization of the vocal cords was not used as criteria of alignment, because this could always be accomplished easily and fully by advancing the fiberscope just distal to the ventilation channel and by slightly flexing the fiberscope in a posterior and caudad direction. Consequently, 100% alignment of the GAS airway meant that the perimeter of the ventilation hole was entirely within the perimeter of the laryngeal inlet, *i.e.*, within the laryngeal vestibule. Percent decreases (covering of the breathing hole) from this 100% control by any of the laryngeal inlet struc-

tures (arytenoids, aryepiglottic fold, epiglottis proximal to the tubercle) were estimated at zero balloon inflation and at the balloon inflation that resulted in a forced exhalation seal pressure ≥ 60 cm H₂O (see Forced Exhalation Seal Pressure). For the LMA, the percent coverage of the area of the aperture bars by the epiglottis and failure of the bowl of the mask to surround the laryngeal inlet in any respect were noted fiberoptically.

Forced Exhalation Seal Pressure. Determination of forced exhalation seal pressure for both the GAS airway and the LMA were done by asking the patient to inhale to total lung capacity and then, while the breathing tube of the GAS airway or LMA was occluded, to forcefully, but slowly and steadily, exhale; observation of an in-line dry gas manometer was done until either an audible leak occurred or a plateau pressure without audible leak was obtained. The forced exhalation seal was measured at GAS airway inflation balloon volumes of 0, 10, 20, 30, and 40 ml (depending on the GAS airway size used) and with the LMA. If the forced exhalation pressure seal of the GAS airway equaled or exceeded 60 cm H₂O at any balloon inflation volume, then no further air was added to the balloon, and the results were recorded as 60 cm H₂O. With all tests of the forced exhalation seal pressure, the patient was required to have the lips parted so that the separated teeth could be observed.

Trauma. Assessment of trauma after removal of the GAS airway and LMA was done by direct laryngoscopic and flexible fiberoptic examination of the pharynx and laryngeal aperture. Using a scale of mild, moderate, and severe, these areas were observed for degree of punctuate, streaking, or generalized redness or for the presence of any degree of bleeding or clot formation. In addition, the volunteers were interviewed by telephone 24 h after the study for duration and intensity of sore throat and difficulty in swallowing.

Fiberoptic View of Laryngeal Inlet From Distal End of GAS Airway

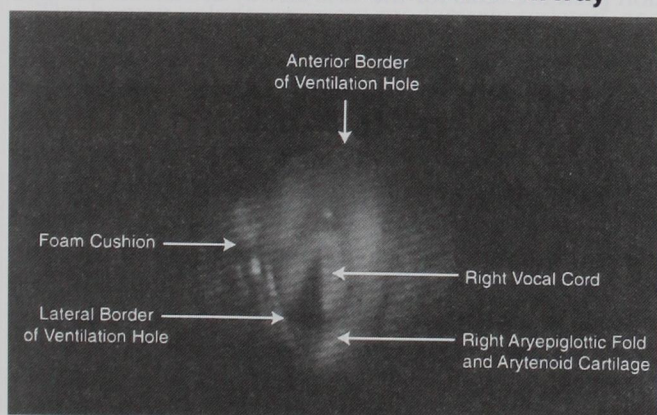


Fig. 3. Typical fiberoptic view of the laryngeal inlet from just within the distal end of the ventilation hole of the glottic aperture seal airway, showing that the end of the ventilation hole is just within the laryngeal inlet. The right aryepiglottic fold and arytenoid cartilage are observed through the very distal end of the right lateral wall of the breathing tube.

Statistical Analysis

For all objective observations, results are expressed as mean \pm SD (range). The forced exhalation seal pressure at each different GAS airway balloon inflation volume were compared with each other and with the LMA using Dunnett's *post hoc* two-tailed multiple comparison procedure for groups of unequal size, with a probability value <0.01 considered significant. Paired *t* test analysis was used for comparison of GAS airway and LMA insertion times.

Results

Objective Observations

Time and Ease of Insertion. The times of insertion for the GAS airway and LMA were 13 ± 4 (8–22) and 17 ± 6 (10–25) s, respectively (not significant), and both were inserted successfully on the first attempt in all volunteers. The depth of insertion of the GAS airway was 15 ± 1 (13–17) cm. The GAS airway and LMA were judged to be equally easy to insert in all volunteers with median (range) insertion grades of 2 (1–3).

Fiberoptic Alignment with the Laryngeal Inlet. The degree of alignment of the ventilation hole of the GAS airway with the laryngeal aperture was 96 ± 8 (70–100) %. Fourteen of the 18 volunteers had a 100% alignment (fig. 3), and two volunteers had 70% alignment, which consisted of one arytenoid cartilage and its aryepiglottic fold being inside a lateral border of the ventilation hole. The proximal esophagus was not visualized in any volunteer. Although the plane of the ventilation hole of the GAS airway typically tilted slightly upward into a slightly more anterior-facing orientation ($\approx 10 \pm 5^\circ$), the fiberoptic alignment and view of the laryngeal inlet did not change with the GAS airway balloon inflation. By looking through the anterior wall of the breathing tube, the proximal end of the epiglottis was seen fiberoptically to be proximal to the proximal end of the foam cushion in all volunteers. The area of the LMA aperture bars covered by the epiglottis was 49 ± 31 (0–90)%. In all volunteers, the LMA was bilaterally lateral to (outside of) the aryepiglottic folds; in two volunteers the esophagus was barely visible; in two volunteers only the posterior surface of epiglottis could be seen; and in two volunteers the epiglottis was not visible. The ease of spontaneous ventilation through both the GAS airway and LMA were rated equivalent to the natural airway by all volunteers.

Forced Exhalation Seal Pressure. The forced exhalation

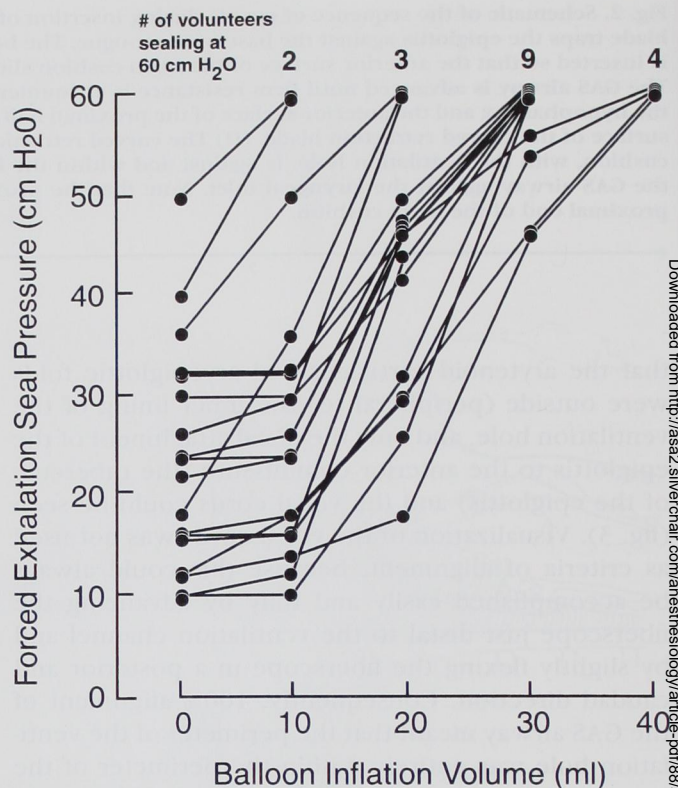


Fig. 4. Forced exhalation sealed pressure as a function of balloon inflation volume of the glottic aperture seal airway for all 18 volunteers. The top axis shows the number of volunteers sealing at ≥ 60 cm H₂O at the indicated balloon inflation volume; all volunteers sealed at ≥ 60 cm H₂O at a balloon inflation volume ≤ 40 ml.

tion pressure seals for the GAS airway at balloon inflation volumes of 0, 10, 20, 30, and 40 ml are shown for individual volunteers in figure 4 and as group data in table 1. The differences between forced exhalation seal pressure at different inflation volumes was significant ($P < 0.01$) for 10 versus 20 ml, 20 versus 30 ml, and 30 versus 40 ml. At GAS airway balloon inflation volumes of 10, 20, 30, and 40 ml, the numbers of volunteers that had forced exhalation seal pressures ≥ 60 cm H₂O were two, three, nine, and four, respectively. The forced exhalation seal pressure for the LMA was 19.4 ± 6.7 (10–36) cm H₂O. The forced exhalation seal pressure at a GAS airway balloon inflation volume of ≥ 20 ml was significantly greater than the LMA. The entire experimental time was 20–25 min.

Subjective Observations

Despite lack of complaint from the volunteers, a mild degree of laryngeal spasm was observable in approxi-

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Table 1. Forced Exhalation Seal Pressure at Various Levels of Gas Airway Balloon Inflation Volumes

Gas Airway Balloon Inflation Volume (ml)	No. of Volunteers Left at This Level	No. of Volunteers Who Had Sealed at ≥ 60 cmH ₂ O	Mean (cmH ₂ O)	SD (cmH ₂ O)	Range (cmH ₂ O)
0	18	0	23.4	11.8	10–50
10	18	2	29.6	12.4	10–60
20	16	5	42.7	12.5	18–60
30	13	14	56.9	5.6	46–60
40	4	18	60	0	60

mately one third of the volunteers in the form of transient (several seconds) partially adducted vocal cords, arytenoid cartilages, and aryepiglottic folds. The spasm was most noticeable immediately after insertion of either the LMA or GAS airway and usually dissipated over the ensuing minute. The poststudy rigid laryngoscopic and flexible fiberoptic assessment of trauma revealed no increase ($n = 15$) to a very mild increase ($n = 3$) in redness of the posterior pharyngeal wall. In all volunteers, the entire laryngeal aperture was within normal limits. Mild sore throat, lasting 1 day, occurred in one of the three volunteers who had mild redness of the posterior pharynx on poststudy laryngoscopy.

Discussion

This study found that the GAS airway was as easy to insert and to align with the airway as the LMA, but it provided a higher forced exhalation seal pressure when the sealing balloon was inflated to ≥ 20 ml.

The human volunteers were moderately sedated, and pharyngeal/laryngeal anesthesia was achieved with a combination of nerve blocks and topical application of a local anesthetic agent. All volunteers tolerated the insertion of the GAS airway and LMA with minimal complaint, and there was no obvious bucking or gagging. Some volunteers had transient laryngeal spasm immediately after insertion of both the GAS airway and LMA, however, which usually dissipated within 1 min. Because forced exhalation pushes the GAS airway and the LMA away from and spontaneous inhalation pulls the GAS airway and LMA toward the laryngeal inlet, inhalation seal pressure is always greater than exhalation seal pressure. Consequently, forced exhalation pressure was used to determine the level of seal. The ability to determine the forced exhalation pressure at which leak was audible (or seal was just lost) was determined, in part, by the rate of increase of pressure, and this in turn,

was determined by the patient. This timing problem is estimated to have resulted in a maximum pressure measurement error of ± 4 cm H₂O. The fiberoptic assessment of percent alignment of the GAS airway with the laryngeal inlet and the percent coverage of the LMA aperture bars by the epiglottis is estimated to be accurate within $\pm 10\%$. The time of insertion measurements are estimated to be ± 2 s. The assessment of pharyngeal-laryngeal trauma was complete and was made by an experienced anesthesiologist.

The elliptical ventilation hole of the GAS airway aligns itself with the laryngeal aperture because the distal progress of the device on insertion is first terminated by the curvilinear anterior surface of the GAS airway being pushed against the posterior surface of the retracting blade and then, after removal of the retracting blade, against the laryngeal aperture. Therefore, the mechanism by which distal movement is terminated also determines the alignment of the ventilation hole with the laryngeal inlet.

The main difference between the GAS airway and the LMA in this awake volunteer study was that the forced exhalation seal pressure was significantly greater with the GAS airway than with the LMA. There are two theoretical implications of this finding. First, the GAS airway may permit positive pressure ventilation without a leak at a higher airway pressure than the LMA. The physiologic basis for this implication is the finding that the pressure gradient for forced exhalation is the same as for positive pressure ventilation. Second, positive pressure ventilation with the GAS airway may result in less gastric ventilation, and the risk of pulmonary aspiration may be less than with the LMA. The anatomic basis for this implication is the finding that the foam cushion of the GAS airway seals directly against the base of the epiglottis, aryepiglottic folds, arytenoid cartilages, posterior commissure, and the external posterior wall of the larynx, thereby creating a barrier over the entire

surface area of the laryngeal inlet. Third, the GAS airway may cause more local trauma than the LMA because it may press harder against the airway mucosa. This implication remains a possibility, but the risk may be minimized using a "just seal volume" of balloon inflation. It must be stressed that this study did not examine any of these issues, and they can only be resolved by future clinical studies.

The GAS airway findings in this awake volunteer study cannot necessarily be extrapolated to the patient undergoing general anesthesia for three important reasons. First, loss of muscle tone may bring the epiglottis in closer relation to the posterior pharyngeal wall, thereby increasing the risk of downfolding the epiglottis on insertion of the retraction blade. If the epiglottis is downfolded, the ventilation hole may be obstructed by the epiglottis. Second, although the anesthetic requirements for successful insertion of the retraction blade and the GAS airway are unknown at this time, the induction of general anesthesia may increase the distensibility of the pharyngeal and hypopharyngeal compartments,

thereby altering alignment and seal. Third, the effect of stimulation of the larynx by the retraction blade and laryngeal seal on cardiovascular and airway reflexes is unknown.

The GAS airway is easy to insert, has good alignment with the airway, and provides a well-sealed airway in awake volunteers. This study suggests that the GAS airway may have a useful clinical role. Further studies in patients undergoing general anesthesia are necessary.

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