

ORIGINAL RESEARCH

Airway

An oropharyngeal device for airway management of conscious and semiconscious patients: A randomized clinical trial

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Abstract

Objective: No oropharyngeal devices exist for use in conscious and semiconscious trauma patients during emergency evacuation, transport, or resuscitation. We aimed to test the hypotheses that the ManMaxAirway (MMA) is better tolerated than the standard Guedel-style device in awake volunteers and that it produces a jaw thrust and improves air flow.

Methods: This was a randomized cross-over study of healthy volunteers with either the MMA or standard device. The primary outcome of tolerability was defined as maintaining the device in place for 60 seconds. Secondary outcomes included respiratory system function and jaw thrust. Resistance to airflow through the device lumen was measured in situ and when placed in subjects in the pulmonary laboratory alone. Jaw thrust was quantified as displacement between the mandibular condyle and condylar fossa apex relative to baseline visualized with magnetic resonance imaging (MRI).

Results: We enrolled 19 subjects. Of these, a convenience sample of 5 individuals was selected for MRI; the remaining individuals ($n = 14$) were randomized for the cross-over study. All 14 subjects were able to maintain the MMA for 60 seconds compared with 2/14 (14%) with the standard device (odds ratio, 145; 95% confidence interval, 6.3-3314). Subjects reported that the experimental device was more comfortable and its placement did not trigger the gag reflex. Airway resistance produced by the MMA in an oscillatory flow model was nearly an order of magnitude lower than that of the standard device (experimental vs standard, 8 Hz–0.092 vs 0.786 cmH₂O-s/L; 15 Hz–0.193 vs 1.321 cmH₂O-s/L). Rapid induction of the gag reflex precluded further measurements with the standard device. Forced oscillation pulmonary testing in conscious volunteers with and without the MMA demonstrated that the device decreased respiratory system resistance to airflow and reduced respiratory elastance ($31\% \pm 8\%$ and $44\% \pm 13.4\%$, respectively; $P < 0.05$). MRIs of the subjects ($n = 5$) with the MMA in place showed a significant jaw thrust compared with baseline (7 ± 1 mm).

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Conclusions: The MMA proved well tolerated in conscious subjects, resulting in an opening of the anatomic airway and a decreased resistance to airflow.

KEYWORDS

airway, airway management, airway obstruction, emergency, intubation, oropharyngeal airway, prehospital, trauma

1 | INTRODUCTION

1.1 | Background

The non-traumatic pharyngeal airway, first described by Arthur Guedel in 1933, provides a simple solution to a common problem during induction of anesthesia—the flaccid tongue has a tendency to obstruct the airway.¹ To improve air passage, the solution uses a hollow tube with a hockey-stick shape that facilitates its placement around the tongue. Guedel-style devices are used today in operating rooms worldwide, typically as a temporizing measure during the induction of anesthesia and before securing the airway with an endotracheal tube, but also for emergency applications for which they were not designed. Specifically, no oropharyngeal devices exist for use in patients with waxing and waning mental status; placement of the Guedel-style airway can produce pressure on the tongue, inducing a gag reflex that can be tolerated only with adequate sedation.

1.2 | Importance

An oropharyngeal device that could improve airflow in conscious or semiconscious individuals without sedation or anesthesia would serve an important role as an airway adjunct in the emergency department (ED), prehospital setting, and for delayed evacuation scenarios in austere environments.

1.3 | Goals of this investigation

To address this critical problem, we invented a new non-traumatic oropharyngeal device and designed a study to test its performance. The ManMaxAirway (MMA; manufactured by ManMax Medical, LLC) is made of non-compressible medical grade plastic and is similar in size and form to an athletic mouth guard. This design allows air to flow around the tongue, rather than over it, without directly contacting sensitive tissues in the posterior oropharynx (Figure 1). The MMA fits between the teeth with an external front flange that remains anterior to the lips. Air flows through the central lumen of the flange into 2 lateral passages within its U shape and then into the open sulcus behind the molars posterolateral to the tongue. Because most individuals have at least a slight overbite, the action of placing any oral device that opens the mouth and brings the lower and upper teeth into alignment should pull the mandible forward. We hypothesized that this mechanism of

action would move the mandible slightly anterior to the maxilla to an extent easily resolvable with magnetic resonance imaging (MRI). We further hypothesized that this degree of jaw thrust would open the airway without requiring direct depression of the tongue, thus decreasing airway resistance. The overall goal of this study was to demonstrate the advantages of the MMA over the standard device currently in clinical use. To this end, we performed a cross-over study of the MMA in healthy volunteers to (1) compare its tolerability to that of the standard device, (2) assess its effect on oral airway anatomy, (3) investigate its pressure-flow characteristics, and (4) determine its effects on pulmonary airway resistance.

2 | METHODS

2.1 | Study design and setting

We conducted a randomized, cross-over clinical trial in healthy subjects. The study was approved by the institutional review board of the University of Vermont, registered on ClinicalTrials.gov (registration number NCT03969147), and reported according to Enhancing the Quality and Transparency Of health Research (EQUATOR) Reporting Guidelines.

2.2 | Selection of participants

Subjects were recruited using flyers distributed around the university. Informed consent was obtained from all subjects before any research activities. Subjects were screened by research personnel and included if they were healthy, older than the age of 18 years, and had no contraindications for MRI. Subjects were excluded for dental and oral anatomy abnormalities, such as missing >5 teeth or use of dentures, prognathism, or other significant malocclusion, and for gastroesophageal reflux (Figure 2)

2.3 | Interventions

The MMA and standard device (Rusch Color-Coded Guedel Airway Sizes 2–5; Teleflex) were studied sequentially in random order. Participants were enrolled by trial investigators and assigned a starting intervention following simple randomization procedures using a computer-generated random number list. Due to differences in device

shape and appearance, blinding was not feasible; however, the starting intervention was concealed from the subjects before commencing measurements. Participating subjects were instructed not to eat or drink anything for at least 3 hours before being studied.

2.4 | Outcomes

The primary outcome measure was tolerability, defined as the length of time up to 60 seconds that the device could be maintained. Secondary outcomes were the extent of upper airway opening due to jaw thrust, the pressure-flow characteristics of the MMA, and respiratory system resistance and elastance with the MMA in place.

2.4.1 | Tolerability

Subjects were instructed how to place each device by research staff, and not to maintain either device for longer than they felt comfortable. Under research staff supervision, subjects then placed either the standard device or MMA in their own oropharynx while lying in the supine position. For the standard device, subjects were allowed to select from among sizes ranging from 70 mm size 2 (small adult) to 100 mm size 5 (extra-large adult) based on what was best tolerated. Only 1 MMA size was available. Device placement was timed for 60 seconds or until the device was removed. Subjects were asked to rate the tolerability of each device on a 0–100 mm visual analog scale with 100 corresponding to completely intolerable. Subjects also responded to queries about their experience using a 5-point Likert scale, with 1 corresponding to strongly disagree and 5 corresponding to strongly agree. After a 2-minute rest period, the subjects repeated the same measurements with the alternate device.

2.4.2 | Airway anatomy

MRI of the temporomandibular joint was used to measure the jaw thrust produced by the MMA. A convenience sample of participating

The Bottom Line

Although several airway adjuncts exist for use in the obtunded or unresponsive patient, they are generally poorly tolerated in the conscious or semiconscious patient. This randomized cross-over study of healthy volunteers found that the ManMaxAirway is well tolerated in the conscious patient allowing for improved airway opening and unobstructed airflow.

subjects with no contraindications for MRI were scheduled based on MRI scanner availability. Subjects were given headphones and positioned in the MRI scanner with devices fitted to monitor pulse oximetry, 3-lead ECG, and blood pressure. After completion of the MRI scan, the procedure was repeated for each subject with the alternate treatment.

2.4.3 | Airflow resistance

The pressure-flow relationships of both the MMA and a standard device (90 mm size 4, large adult) were obtained using a calibrated computer-controlled piston pump (Flexivent) that applied sinusoidal flow oscillations of known amplitude at both 8 and 15 Hz while the driving pressure was recorded. The flow resistances of the devices were calculated from the slopes of the regression lines fit to the measured pressure versus flow.

2.4.4 | Respiratory system impedance in human subjects

Respiratory system impedance was measured using the forced oscillation technique (Flexivent) in a convenience sample of participating subjects based on pulmonary function laboratory availability. Subjects sat

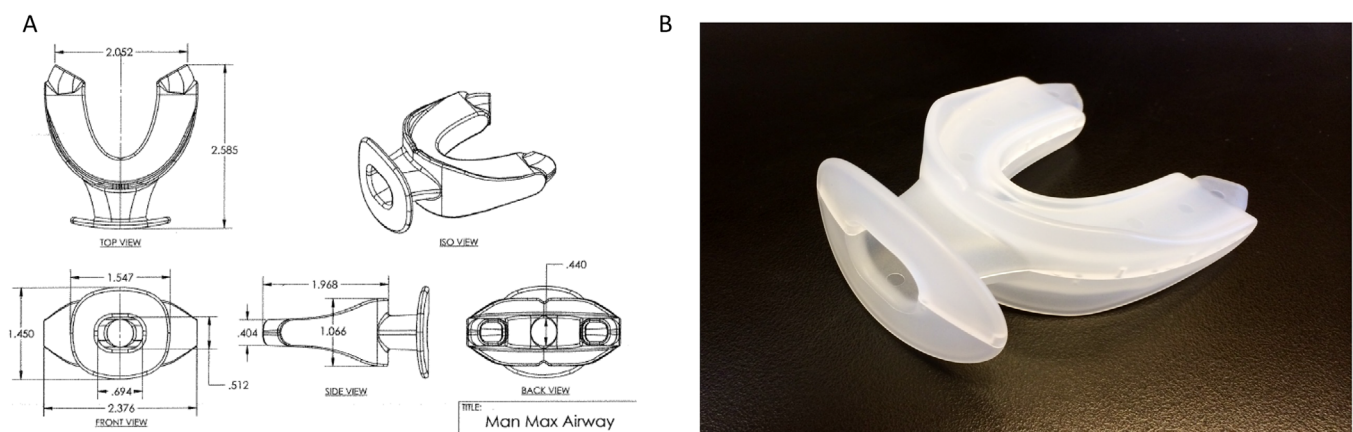


FIGURE 1 (A) Device measurements showing the triple lumen design. (B) The ManMaxAirway

CONSORT Flow Diagram

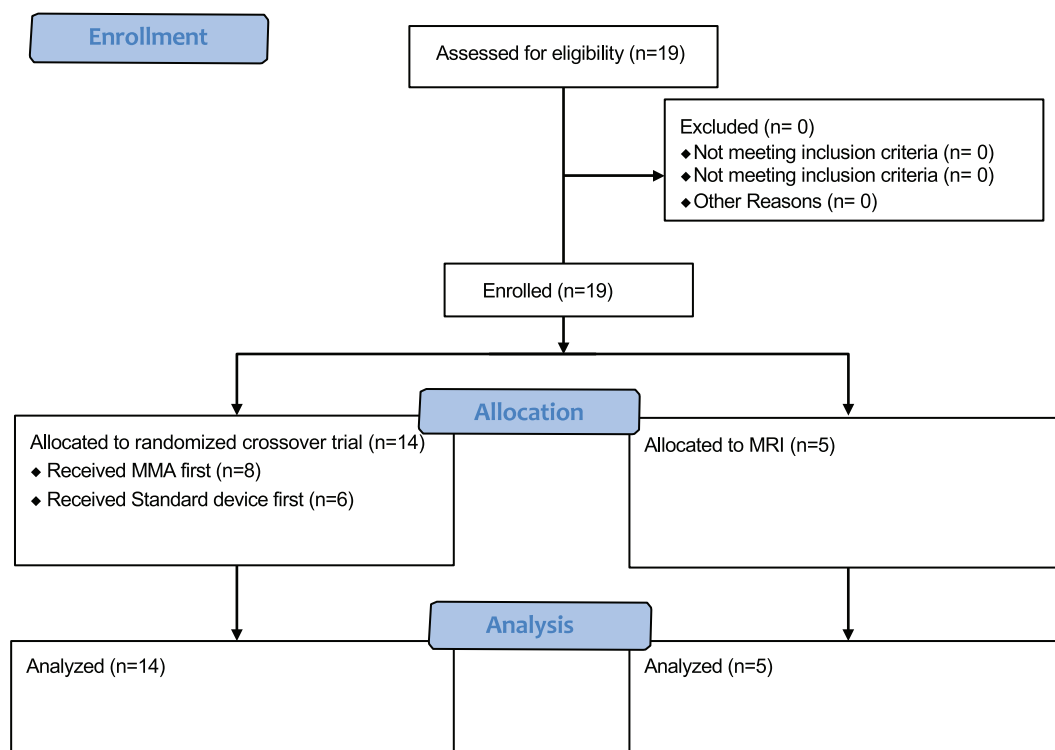


FIGURE 2 Enrollment process describing allotment to specific arms of the study and cross-over. MMA, ManMaxAirway; MRI, magnetic resonance imaging

comfortably and breathed normally while low-amplitude oscillations in airflow were applied to the lungs for 8 seconds during which a nose clip was in place and the cheeks were supported by the subject's hands. The flow oscillations contained 6 frequencies spaced roughly equally over the range 5–19 Hz. Fourier analysis of the pressure and flow measured at the mouth provided the input impedance of the respiratory system to which a single-compartment linear model was fit, yielding values for respiratory system resistance (R_{rs}) and elastance (E_{rs}). Measurements were made in triplicate both with and without the MMA in place.²

2.5 | Analysis

Based on anecdotal experience, we powered our study to have a 95% probability of detecting a difference of 0.70–0.80 for the primary outcome of tolerability as defined by the proportion of subjects who tolerate the standard device for 60 seconds (reference population) relative to the MMA. This requires 6–10 subjects for each group (standard device and MMA) at a 2-sided P value of 0.05. Results are reported with graphics including bar charts to allow ready comparison between interventions. Device tolerance time is expressed using a Kaplan-Meier survival curve. R_{rs} and E_{rs} measurements were normal-

ized to those obtained without the MMA in place to compare changes due to the MMA. Statistical analyses were performed using Prism (version 8.0, GraphPad).

3 | RESULTS

3.1 | Characterization of study subjects

We enrolled a total of 19 healthy subjects from May 2016 to February 2019. Demographic information for these subjects include height (154.9–190.5 cm), weight (45.36–113.4 kg), and age (19–60 years). A total of 14 subjects, 4 of whom were women, performed the tolerability test. A total of 5 subjects, 3 of whom were women, received MRI imaging. A total of 3 men and 2 women who performed the tolerability test also underwent the measurement of R_{rs} and E_{rs} .

3.2 | Main results

Tolerability measurements of each device quantified by subject self-reporting and length of time of placement demonstrated that the MMA was significantly more tolerable than the standard device (Figure 3A).

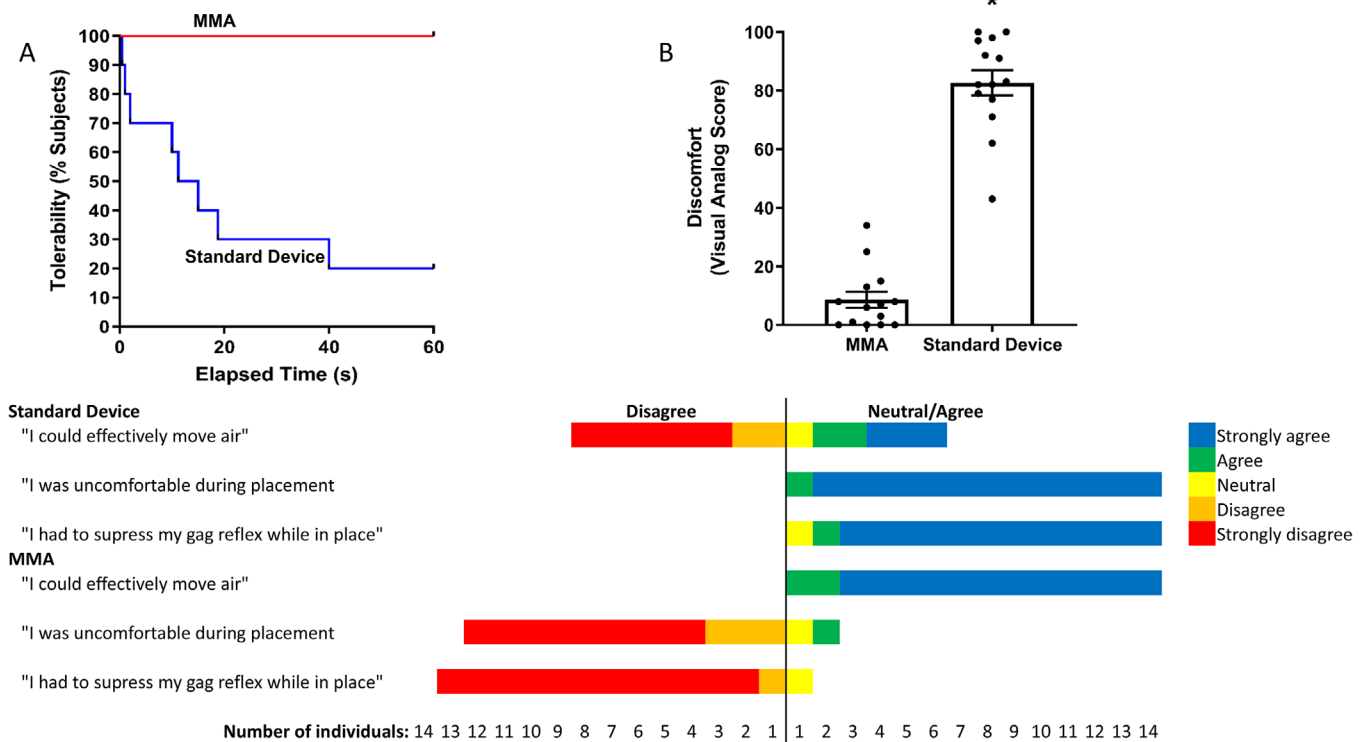


FIGURE 3 (A) The ability to tolerate each device was represented using a survival curve. Removal of the device was treated as a "death" ($n = 14$; $P < 0.05$, Mantel-Cox test). (B) Response frequency to a 100 mm visual analog scale showed the most amount of reported discomfort with the MMA was less than the least reported amount of discomfort in the standard ($n = 14$; $P < 0.05$, Wilcoxon signed-rank test). (C) Responses to the Likert scale using a diverging bar chart showing the number of individual responses to each question. Negative answers were reported diverging separately from uncertain or positive answers. MMA, ManMaxAirway

Only 2 of the 14 subjects (14%) could tolerate the standard device for a full 60 seconds, whereas 100% of the subjects tolerated the MMA for 60 seconds (Figure 3B). These proportions were significantly different (odds ratio, 145; 95% CI, 6.3–3314). The 2 subjects who tolerated the standard device for 60 seconds were the only subjects who did not experience gagging, whereas no subject experienced gagging with the MMA. The MMA fit all subjects well despite being the same size for all subjects. There were no significant correlations between ability to tolerate the MMA and height, weight, age, or sex.

In a post-procedural questionnaire, all subjects reported discomfort with the standard device relative to the MMA (Figure 3C). Although there was some disagreement on the ability to move air through the standard device, all subjects reported needing to suppress the gag reflex to maintain it in place. Conversely, all subjects reported that air could be moved through the MMA effectively and it was unnecessary to suppress the gag reflex, although some subjects reported increased salivation with the MMA in place.

The resistances to 8 Hz flow oscillations for the MMA and standard device were 0.092 cmH₂O·s/L and 0.786 cmH₂O·s/L, respectively. At 15 Hz, the resistances were 0.193 cmH₂O·s/L and 1.321 cmH₂O·s/L, respectively. The mean slopes of the pressure-flow relationships were 0.98 cmH₂O·s/L for the MMA and 1.59 cmH₂O·s/L for the standard device (Figure 4A). The MMA thus exhibited a substantially lower resistance to airflow compared with the standard device.

R_{rs} and E_{rs} were significantly decreased by $31\% \pm 8\%$ and $44\% \pm 13.4\%$ (mean \pm SD; paired t test, $P \leq 0.05$) with the MMA versus the standard mouthpiece in place (Figures 4B and 4C).

MRI images of the temporo-mandibular joint were successfully obtained in 5 subjects both with and without the MMA in place. The extent of jaw thrust was measured as the difference in displacement between the mandibular condyle and the condylar fossa apex in the sagittal plane with the MMA compared with no device in place (Figure 5). The average displacement produced by the MMA was 7 ± 1 mm (mean \pm SD).

4 | LIMITATIONS

A limitation of our study is that the MMA was not compared to nasopharyngeal airways (NPAs). Although NPAs are widely available and can be placed in awake patients by experienced practitioners, it was reasoned that it would be much more difficult to recruit awake individuals to placing an NPA in their own nasopharynx compared with placing a Guedel in their own oropharynx, but it is not known if this is actually true. In addition, the generalizability of our study to trauma or other emergency patients may be limited because only healthy conscious individuals were studied. Both men and women were included in the trial, and although more men were enrolled, there is no reason

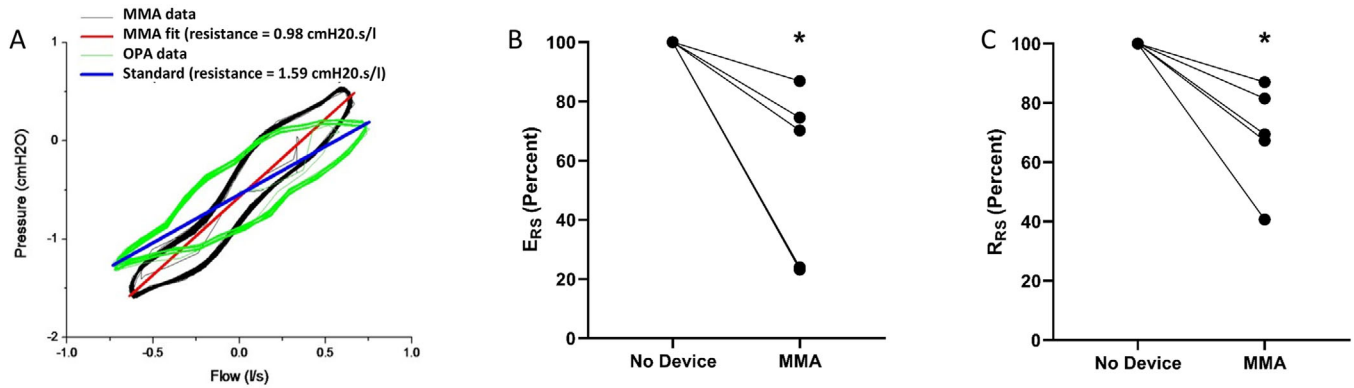


FIGURE 4 (A) Pressure/flow relationships for the MMA and standard device, showing pressure as a function of airflow. The higher slope for the MMA relative to the standard device indicates that both negative and positive pressure increases produce a larger change in airflow. Thus, the MMA resists pressure changes less than standard device. (B) R_{RS} values of the system and (C) E_{RS} were normalized and compared with baseline for each participant. Both R_{RS} and E_{RS} decreased in the MMA relative to baseline. E_{RS} , elastance; MMA, ManMaxAirway; OPA, oropharyngeal airway; R_{RS} , resistance

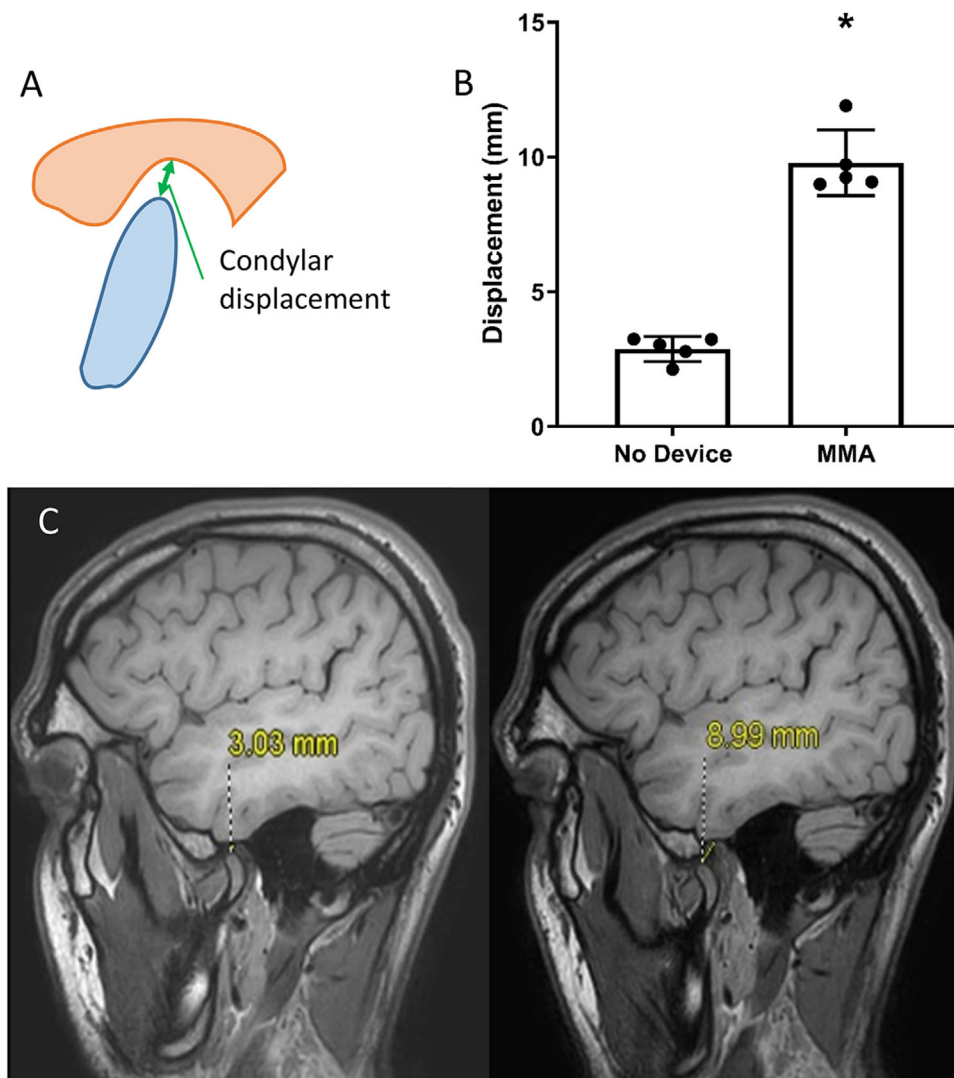


FIGURE 5 (A) The diagram shows a simplified view of the measurement the radiologist used to quantify the jaw displacement. (B) The MMA produced a significant jaw displacement compared with normal ($n = 5$; $P < 0.05$, paired t test). (C) Representative magnetic resonance images show jaw displacement and how measurements were taken

to suspect this imbalance would impact our results or their interpretation. The MMA is not suitable for individuals with dentures or other dental abnormalities.

5 | DISCUSSION

Oropharyngeal devices have been an integral part of the anesthesiologist's toolkit for more than a century. These simple devices help to maintain a patent oral airway in anesthetized or otherwise unconscious or semiconscious patients and help to facilitate bag-mask ventilation. The origins of today's current designs can be traced back to a device first described by Dr. Frederic Hewitt, a British anesthesiologist, in 1908.³ In 1933, American anesthesiologist Dr. Arthur Guedel made several modifications to the Hewitt design and widely popularized its use.^{1,3} To this day, it remains a simple curved metal or hard plastic ovoid tube that is inserted into the mouth and over the back of the tongue into the posterior pharynx with a small flange that remains anterior to the teeth to help keep it in place. If the patient's gag reflex is intact, sedation is required to place this oropharyngeal device or execute other advanced maneuvers to secure the airway.

Although the design of the Guedel-style device remains essentially unchanged from its inception, reported issues with its use in the prehospital and emergency settings indicate that there is room for improvement. It is easily mispositioned or expelled, leading to risk of aspiration,⁴ which is especially problematic in conscious or obtunded patients who may be moving and in whom the gag reflex is still easily triggered as compared with anesthetized patients. This may result in inadequate ventilation and thus lead to unnecessary placement of a laryngeal device or endotracheal tube, causing increased morbidity and mortality.⁵ There also have been case reports of serious complications and injury as a result of the poor fit and retention of the Guedel device,⁶ including occlusion of the trachea^{7,8} as well as traumatic injury to the tongue and posterior pharynx.⁹ Furthermore, the Guedel device is narrow and constructed of rigid materials, thus making it a poor bite block in patients who are seizing and clenching,¹⁰ such as those with traumatic brain injuries (TBIs). Often, a separate bite block is necessary in these patients, the placement of which requires removal of the Guedel device, potentially compromising the airway, and increases the risk of dental injury.¹¹ Ultimately, most unconscious patients who require emergency airway management are intubated, but this is not always feasible or even ideal in the prehospital setting. Indeed, endotracheal intubation in the out-of-hospital setting has been linked to adverse outcomes in patients with TBIs,¹² and endotracheal intubation has recently been questioned as the preferred first-line strategy for airway management of out-of-hospital cardiac arrest in emergency medical services (EMS) systems with limited exposure to advanced airway management.¹³⁻¹⁵ EMS technician's experience may be highly variable, and prehospital intubation success rates are relatively low in some reports.^{13,16}

In the initial resuscitation of trauma victims who cannot tolerate an oropharyngeal device, current practice is to apply a jaw thrust

and administer bag valve mask (BVM) ventilation while preparing for definitive airway management. The jaw thrust serves to open the anatomic airway by mechanically moving the mandible anterior to the maxilla. However, physically maintaining a patient airway in this fashion requires constant application and monitoring during emergency management to be effective.¹⁷ In addition, it may be difficult to physically maintain the airway during BVM, especially during transport. The MMA was designed specifically to temporarily improve airway status in patients with an intact gag reflex during initial emergency management.

Here, we compare the performance of the MMA to the current standard of care, the Guedel-style device, in awake individuals. We show not only that the new device is more tolerable in conscious patients but also that air delivery via the MMA is more efficient when compared with the standard device under identical test conditions. As anticipated, the magnitude of the difference in tolerability between devices was so large that a relatively small sample size was sufficient to demonstrate a statically significant benefit of the MMA. Secondary outcomes, including patient self-reports of discomfort, need to suppress the gag reflex, and perception of air movement through the device, all favored the MMA. We further aimed to show that the MMA could provide a significant jaw thrust to effectively open the airway. Under MRI, subjects with the device in place showed an average displacement between the condylar fossa apex and mandibular condyle of 7 ± 1 mm, which was statistically significant compared with baseline with no device.

Both the MMA and the standard device are large caliber air delivery systems and thus it was no surprise that the airflow resistances of both devices were relatively low compared with the airway resistance of a normal lung. However, at both oscillation frequencies tested, the resistance of the MMA was found to be 7 to 8 times less than that of the standard device. It was also observed that the resistances of both devices increased as frequency increased, indicating that the resistances were flow dependent. This can be attributed to the presence of turbulence within the lumen as well as entrance/exit effects on airflow in each device. More significant from a physiological perspective, the MMA produced a significant decrease in both R_{rs} and E_{rs} compared with the standard device. The decreased R_{rs} is not surprising given that the jaw thrust produced by the MMA increases the lumen of the oropharynx, thereby allowing freer passage of air into and out of the lungs. The reasons for the associated decrease in E_{rs} are perhaps less intuitively obvious, but they may relate to decreased shunting of applied flow oscillations into the relatively stiff upper airways as a result of a decrease in the flow-resistive pathway leading into the lungs.¹⁸ Also, the rigid arms of the MMA that are clamped between the teeth present a firm barrier against which the cheeks can be compressed by the hands during impedance measurement, which could help reduce the compliance of the proximal soft-tissue structures into which flow oscillations would otherwise be shunted.

A comprehensive cost-benefit analysis of the utility of the MMA in EMS and ED airway protocols is outside the scope of our work, but it is important to note that the cost of the MMA is relatively low compared with most medical devices. The cost of a single MMA device at

the time of this article preparation was \$10–\$15. This is more than a Guedel-style oropharyngeal airway, which can be purchased online for as low as \$1, but less than the \$40–\$100 cost of a supraglottic airway device.

6 | CONCLUSIONS

We have described a new device, the MMA, that is well tolerated in conscious subjects. Imaging confirms that it produces a mandible displacement that opens the airway, and mechanical measurements show that it reduces resistance to airflow into and out of the lungs. We, therefore, conclude that the MMA is a more effective air delivery device than the standard device in healthy individuals, and its use has the potential to improve comfort and airway patency in conscious and semiconscious patients requiring emergency airway support.

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CONFLICTS OF INTEREST

Phil Buttaravoli has reported equity interest in ManMaxAirway, LLC. No other disclosures were reported.

AUTHOR CONTRIBUTIONS

The study was conceptualized and designed by Kalev Freeman, Robert Ramsey Herrington, Nathan Dreyfus, Philip Buttaravoli, and Jason Bates. Data collection was overseen by Kalev Freeman, Zachary D. Miller, Robert Ramsey Herrington, Nathan Dreyfus, Joshua P. Nickerson, Nirav Daphtary, and Jason Bates. The article was drafted by Kalev Freeman, Zachary D. Miller, Adam Burgess, and Jason Bates. Zachary D. Miller and Nathan Dreyfus oversaw patient recruitment and enrollment. Kalev Freeman and Jason Bates were responsible for analytical oversight, and data analysis was performed by Zachary D. Miller. Kalev Freeman takes responsibility for the overall conduct of the trial as well as data integrity and accuracy of the data analysis.

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