Comparison of Insertion of the Modified i-gel Airway for Oral Surgery With the LMA Flexible: A Manikin Study

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We previously modified the i-gel airway to enable its use in the field of oral and maxillofacial surgery and reported its fabrication methods. In general, the standard i-gel airway is quick to insert and has a high success rate, but the modified i-gel airway has yet to be assessed for these attributes. We, therefore, set out to compare the ease of insertion of the modified i-gel airway with the LMA Flexible to investigate the usefulness of the modified i-gel airway. The study participants, who included 20 new interns with no experience using either the LMA Flexible or the modified i-gel airway, inserted each device 3 times into an intubation practice manikin. The variables measured in this study were insertion time and rate of successful insertions. Mean insertion time over 3 attempts was significantly shorter for the modified i-gel™ airway (18.9 ± 4.7 seconds) than the LMA Flexible (24.9 ± 5.1 seconds, $P < .001$). The rate of successful insertions as a total of all 3 attempts was significantly higher for the modified i-gel airway (56/60 times, 93.3%) than the LMA Flexible (45/60 times, 75%; $P = .012$). When used by an inexperienced operator, the modified i-gel™ airway is faster and has a higher success rate than the LMA Flexible, suggesting that it can be easily manipulated during insertion.

Key Words: Oral and maxillofacial surgery; Supraglottic airway device; Modified i-gel™ airway.

The first laryngeal mask (LMA) was the LMA Classic, developed by Dr Brain. It was later followed by a number of groundbreaking new products, such as the LMA ProSeal, which features a high-pressure seal and a gastric tube orifice, and the LMA Fastrack that can be used to pass an endotracheal tube into the trachea. Today, these and other products comprise the LMA family. One of them, the LMA Flexible (Laryngeal Mask Company, Jersey, UK; Figure 1: top) was developed for oral and maxillofacial surgery and other types of head and neck surgery. The flexible wire-reinforced airway tube of this device has the advantages of avoidance of interference with the operative field, even in oral surgery, and being able to withstand pressure from surgical manipulation.[1,2] Thus, the LMA Flexible is currently the gold standard supraglottic device in the field of oral and maxillofacial surgery. The flexibility of the shaft of the reinforced airway tube, however, makes it difficult to exert any force on the shaft,[1,2] making insertion more difficult than with the LMA Classic.[3]

Received January 10, 2014; accepted for publication August 24, 2014.

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Anesth Prog 61:145–149 2014

ISSN 0003-3006/14
SSDI 0003-3006(14)

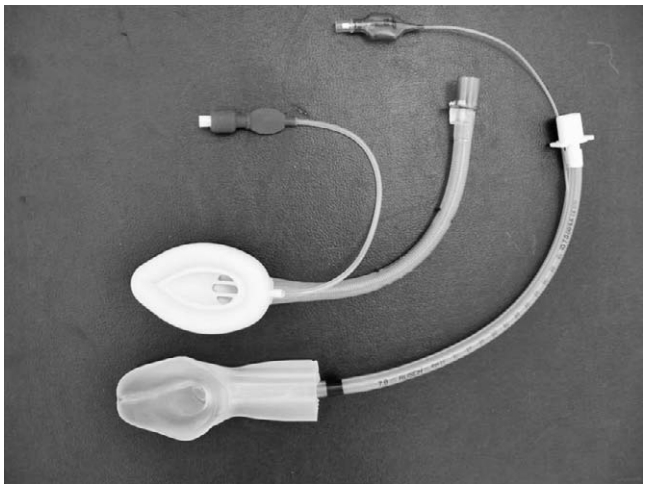

Figure 1. LMA Flexible (top) and modified i-gel airway (bottom).

The i-gel airway (Intersurgical Ltd, Wokingham, UK) is a disposable supraglottic device that was developed by Dr Nasir. It consists of an airway tube with a non-inflatable gel-like cuff designed to fit perfectly over the larynx and also has a gastric tube orifice. The i-gel airway features a high-pressure seal (pharyngeal leak pressure),[4] potentially preventing leakage of blood and water into the airway, which is a frequent problem during dental treatment and in oral and maxillofacial surgery. Hence, although this device may be very useful in oral and maxillofacial surgery, its use is limited by the thickness of the shaft of the airway.

We previously modified the i-gel airway (modified i-gel airway; Figure 1: bottom) to enable its use in the field of oral and maxillofacial surgery and reported its fabrication methods.[5] In general, the standard i-gel airway is quick to insert and has a high success rate, but the modified i-gel airway has yet to be assessed for these attributes. We, therefore, set out to compare the ease of insertion of the modified i-gel airway and the LMA Flexible to investigate the usefulness of the modified i-gel airway.

METHODS

The study was approved by the ethics committee of Hyogo College of Medicine (approval 883). Study participants included 20 new interns (doctors) with no experience using either the LMA Flexible or the modified i-gel airway (5.7 ± 4.2 months of clinical experience, 10 women and 10 men). Before starting, participants were given an overview of the study and gave consent to participate.

The modified i-gel airway was made according to previously reported methods.[5] A size 4 i-gel airway was cut to an airway tube shaft length of 5.5 cm. A reinforced endotracheal tube (inner diameter 7.5 mm, outer diameter 10.2 mm, Rüsch, Kernen, Germany) was passed into the i-gel airway tube.[5] The distal end of the reinforced airway tube just fits into the i-gel airway, so that the tip does not protrude through its ventilation hole.[5] To fix the i-gel airway and reinforced airway tube tightly together, the cuff of the reinforced airway tube was inflated (approximately 2.5 mL of air).[5]

Before starting measurements, the participants were given a demonstration on insertion of each device. To insert the original i-gel airway, the proximal end of the airway tube is usually gripped with the thumb and index finger. The airway tube of the modified i-gel airway, however, is difficult to grip in this manner because the proximal end is modified into a reinforced airway tube. To insert the modified i-gel airway, participants were instructed to grip the thick airway tube shaft with the thumb, index, and middle fingers, and to push the base of the airway tube with the index and middle fingers to guide it into the pharynx. To insert the LMA Flexible, participants were instructed to use the insertion method prescribed by Dr Brain.[6] After watching the demonstration, participants were allowed to practice inserting each device once into an intubation practice manikin (Airway Management Trainer, Laerdal, Stavanger, Norway) to learn the insertion methods. Afterwards, participants inserted each device into the intubation practice manikin 3 times. The order for inserting the modified i-gel airway and the LMA Flexible was randomized with a random number table and subjected to a crossover trial. For this study, a size 4 tube was used for both the LMA Flexible and the modified i-gel airway.

The variables measured in this study were insertion time, rate of successful insertions, and device insertion ease. The insertion time was the time from picking up the supraglottic device until performing ventilation with a bag and mask. The LMA Flexible cuff was quickly

Rate of Successful Insertion With the Two Airways

	LMA Flexible	*Modified i-gel airway*	P *Value*
Overall success rate, n (%)	45/60 (75)	56/60 (93)	.012
First attempt, n (%)	14/20 (70)	18/20 (90)	.235
Second attempt, n (%)	15/20 (75)	19/20 (95)	.181
Third attempt, n (%)	16/20 (80)	19/20 (95)	.341

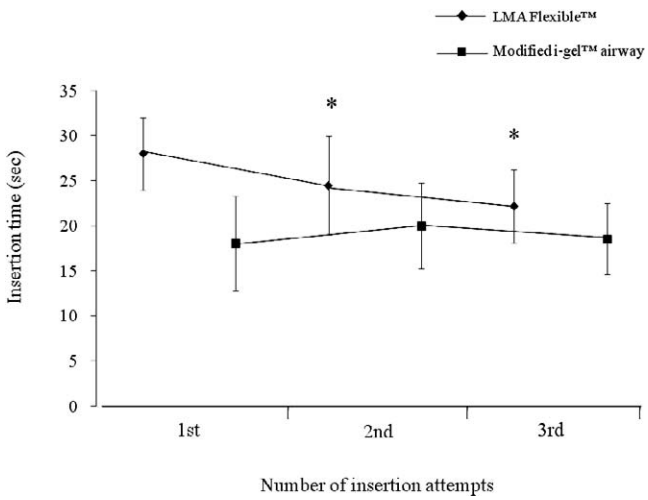

Figure 2. Time to successful intubation with the LMA Flexible and modified i-gel airway. The x-axis represents the number of intubation attempts, and the y-axis represents the intubation time (seconds). Data represent mean (SD). * $P < .05$ versus the first attempt.

inflated with 15 mL of air by an assistant, immediately after placement into the manikin's pharynx and before performing ventilation. The insertion attempt was deemed successful if the chest of the manikin visibly expanded upon ventilation with the bag and mask. Immediately after completing the 6 insertion attempts, participants reported their ease of placement with each device using a 100-mm visual analog scale (VAS; 0 mm = extremely easy, 100 mm = extremely difficult).

Prior to the present study, a pilot study was conducted with new interns (doctors) to determine the required sample size. The mean insertion time in the pilot study was 20.9 seconds with the modified i-gel airway and 27.2 seconds with the LMA Flexible. The standard deviation (SD) of the LMA Flexible of 6.4 seconds was set as the SD of both devices. Given $\beta = .2$ and $\alpha = .05$, the minimum required sample size was calculated as 17 people. Considering the possibility of participant withdrawal, we set the sample size as 20 people.

Insertion time was expressed as mean (SD), and the main insertion time over 3 attempts was compared using unpaired *t* tests. Repeated measures analysis of variance (ANOVA) was used for intragroup comparisons of insertion time for each device, and Dunnett test was used for multiple comparisons. The Yate χ^2 test was used to compare the rate of successful insertions. VAS scores were expressed as medians (10th–90th percentile range) and compared using the Mann-Whitney *U* test. The level of statistical significance was set as $P < .05$.

RESULTS

All 20 participants completed the study. Mean insertion time over 3 attempts was significantly shorter for the modified i-gel airway (18.9 ± 4.7 seconds) than the LMA Flexible (24.9 ± 5.1 seconds, $P < .001$). The insertion time for each attempt is shown in Figure 2. For the LMA Flexible, the insertion time was significantly shorter on the second (24.5 ± 4.0 seconds, $P = .009$) and third (22.4 ± 4.1 seconds, $P < .001$) attempts than the first attempt (28.0 ± 4.0 seconds). In contrast, there were no significant differences in insertion time between attempts when inserting the modified i-gel airway ($P = .187$).

The total rate of successful insertions considering all 3 attempts was significantly higher for the modified i-gel airway (56/60 times, 93.3%) than the LMA Flexible (45/60 times, 75%, $P = .012$; Table). However, no differences were seen in rate of successful insertions between attempts (Table).

The VAS score expressing ease of insertion was 35.5 (23.9–63.2) mm for the modified i-gel airway, which was significantly lower than that with the LMA Flexible of 48.0 (20.4–53.7) mm ($P = .045$).

DISCUSSION

The results of the present study demonstrated that, when used by an inexperienced operator, the modified i-gel airway is faster, has a higher success rate, and can be inserted more easily than the LMA Flexible. Moreover, while insertion time became significantly shorter with increasing number of attempts when using the LMA Flexible, demonstrating the presence of a learning curve, the modified i-gel airway could be inserted very quickly from the very first attempt.

Stroumpoulis et al[7] compared the insertion time and rate of successful insertions between the original i-gel and the LMA Classic. The results revealed the rate of successful insertions to be significantly higher for the i-gel airway, at 90.5% (105/116 participants), as compared to that with the LMA Classic, at only 63.8% (74/116 participants).[7] In addition, the insertion time of the i-gel airway (13.32 ± 4.99 seconds) was significantly shorter than that of the LMA Classic (17.99 ± 6.87 seconds).[7] These results match those of the present study comparing the modified i-gel airway and the LMA Flexible. The reasons for the success of the modified i-gel airway may be that the noninflatable cuff can be smoothly inserted into the pharynx, and that its thick airway tube shaft is easier to grip, enabling efficient transmission of force to the shaft.

In the present study, we focused on insertion action. In addition to this, we identified a number of other benefits

of the modified i-gel airway over the LMA Flexible for inexperienced operators in the field of oral and maxillofacial surgery. In dental treatment or in oral and maxillofacial surgery, there is often a need to open the mouth or reposition the head during the procedure. As these actions cause a change in internal pressure of the cuff and pharyngeal leak pressure in supraglottic devices like the LMA Flexible that have an inflatable cuff,[8–10] the cuff must be deflated after the action is complete and then readjusted. In contrast, the modified i-gel airway uses a noninflatable cuff, which may greatly simplify its usage during a procedure. Another advantage of the i-gel airway is that it allows insertion of a gastric tube, which has the benefit of potentially reducing the risk of gastric distention and reflux of gastric contents. Furthermore, the i-gel airway provides a high-pressure seal (pharyngeal leak pressure),[4] potentially preventing leakage of blood and water into the airways, which is a common problem when patients are put under general anesthesia for dental treatment or oral and maxillofacial surgery. One disadvantage of the modified i-gel airway is the risk of the reinforced airway tube disengaging from the i-gel airway in the oral cavity when removing the i-gel airway. The connection between the reinforced airway tube and the i-gel airway relies completely on the cuff of the reinforced airway tube that has been inflated with about 2.5 mL of air. Great care must be taken when removing the modified i-gel airway, for example by directly gripping the i-gel airway tube with Magill forceps.[5]

The LMA Flexible is often inserted together with a stylet, pediatric tracheal tube, or other introducer, and many different methods have been reported for combined insertion with an introducer.[2,11–15] Although evaluation methods and subjects vary somewhat, the rate of successful insertions for the LMA Flexible is generally 70 to 80%.[16,17] This success rate rises to around 90% when the device is combined with a pediatric tracheal tube, stylet, or other introducer.[13,16,17] However, Casey et al[18] reported a case in which combined insertion with a Bosworth introducer caused a severe abscess on the posterior wall of the pharynx, suggesting that combining the LMA Flexible with an introducer has the potential to cause pharyngeal trauma. The present study showed the rate of successful insertions with the modified i-gel airway to be around 90%, which is just as high as that of the original i-gel airway and the LMA Flexible combined with an introducer. The modified i-gel airway, therefore, offers equal success of use without the need for an introducer for insertion, which may be considered a benefit of this device. It should, however, be noted that various safety aspects need to be considered before actual use of the modified i-gel airway. The device should not be used as is in clinical practice, and must be further developed as an i-gel airway product for use in oral and maxillofacial surgery.

The present study has 3 main limitations. The first is that participants were inexperienced operators. We determined in this study that the learning curve affects insertion time with the LMA Flexible. This means that ability to insert the LMA Flexible varies with experience. If we had compared the modified i-gel airway and the LMA Flexible when used by operators with experience using the LMA Flexible, we may have seen different results. The other limitations are that since an intubation practice manikin was used for insertion, the study results cannot be directly extrapolated to humans. Further, the study was not blinded, since blinding was impossible due to the nature of the study design.

CONCLUSIONS

When used by an inexperienced operator, the modified i-gel airway can be inserted faster and more easily and has a higher success rate than the LMA Flexible, suggesting that it can be easily manipulated during insertion. It should be noted that our modification still has various unresolved safety issues that need to be considered before actual use of the modified i-gel airway in clinical practice. The device should not be used as is in clinical practice, but must be further developed as an i-gel airway product for use in oral and maxillofacial surgery.

ACKNOWLEDGMENTS

This study was funded in part by a 2010 Osaka Dental University Oral Implant Research Grant. We would like to take this opportunity to thank Dr Toshio Tamaki and Dr Hirokazu Hojo, visiting professor emeritus at Osaka Dental University, for granting the funds for this study.

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