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Sealing Mechanics Study of Laryngeal Mask Airways via 3D Modeling and Finite Element Analysis

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ABSTRACT

Background: Proper sealing of laryngeal mask airways (LMAs) is critical for airway management in clinical use. A good understanding of the LMA sealing mechanism provides a scientific foundation to improve the sealing of LMAs to reduce the incidence of adverse events. However, no existing methods provide a systematic study on the LMA sealing mechanics.

Methods: Computer-aided 3D models are established to visualize LMA – pharynx interactions directly. The finite element analysis (FEA) is adopted to study the LMA sealing mechanics.

Results: Two case studies are provided in the paper. The LMA is loaded with a low cuff pressure (CP) (9 mmHg) to investigate the cause of leaking in Case I, and with a high CP (45 mmHg) to detect the critical points of high mucosal pressure in Case II. The established 3D models provide initiative visualization of the sealing situations. The visualization results are verified by pressure distribution along the contacting surface generated from FEA as the quantitative study.

Conclusions: Compared with the existing methods, the proposed method does not introduce additional cost, and can provide globe monitoring on the LMA and a comprehensive understanding of sealing mechanics in all areas. The findings on the sealing mechanism and corresponding suggestions for clinic use of LMAs and LMA design have also been presented in the paper.

Abbreviation

3D	Three Dimensional
FEA	Finite Element Analysis
LMA	Leayngeal Mask Airway
CP	Cuff Pressure
MP	Mucosal Pressure
PB	Pharynx and Bones
CT	Computerized Tomography
GUI	Graphical User Interface
ASA	American Society of Anesthesiologists

1 Introduction

Laryngeal mask airways (LMAs) are widely adopted supraglottic airway devices in airway management of operations and first aid treatments. Compared with other airway management methods, e.g., endotracheal tube ventilation, the LMA has various advantages, e.g., simple-to-use, stable circulation, fast recovery, and fewer complications¹⁻³. Therefore, LMAs have gradually become one of the most popular artificial airways.

To be self-contained, here we briefly describe the working principle of LMAs. When an LMA is inserted into the laryngopharynx for ventilation, oxygen successively passes through the ventilator, the tube of LMA, the cuff of LMA, the glottis and the bronchus, respectively, and finally enters the lung, as shown in Fig. 1. The cuff plugs the oropharynx and hypopharynx, which forms a sealing ring around the glottis to cover it similarly as a face mask covers the nose and mouth.

A good sealing LMA to the pharynx, particularly to the hypopharynx and oropharynx, is critical for ensuring successful ventilation. This can be achieved by adjusting intra-cuff pressure, i.e., adjusting its volume. On the one hand, an under-inflated LMA may not entirely block the oropharynx and hypopharynx, leading to air leakage. On the other hand, although sealing can be improved by increasing the cuff pressure (CP) of an LMA to fit the pharynx, unintended cuff hyperinflation can lead to

Figure 1. Pharynx with an inserted LMA (hypopharynx (I); laryngopharynx (II); Oropharynx (III)). .

severe complications in the upper airway by exerting high forces on pharynx structures, thus impairing mucosal perfusion⁴⁻⁷. Moreover, when an LMA is of the wrong size⁸, or not placed at the right sealing position^{9,10}, it can be challenging to find an appropriate CP avoiding air leakage and high mucosal pressure (MP) at the same time. Recent studies indicate that various factors, including volume of LMAs¹¹, pressure on the pharyngeal mucosa¹² and ventilation modes¹³, can significantly influence the sealing performance. Some studies suggested that cricoid cartilage also had a particular effect on the ventilation with LMAs¹⁴, but few studies on the impact of the other bones around the laryngopharynx on the sealing. Overall, there is a lack of consensus on the main factors leading to air leakage and high MP due to a lack of knowledge of leaking mechanism. In fact, a deep understanding on leaking mechanism of LMA will be of significance for clinic use of LMA and for LMA manufacturers to improve the design.

Early studies on LMA sealing mechanisms¹⁵ adopted direct measurement methods by installing additional measurement instruments, including stethoscopes, end-tidal CO₂, and aneroid manometers. Despite their abilities to directly obtain the oropharyngeal leakage pressure at certain locations, these methods cannot measure MP or detect the specific leakage sites of LMA, which are the main factors causing complications. To overcome the limitation of those methods, Brimacombe et al.¹⁶ implanted a pressure sensor to an LMA to measure MP and CP. In the meantime, the color of the pharyngeal mucosa was observed as an indicator of the perfusion pressure. In this manner, the stress-strain correlation can be established between the pressure inside the laryngeal mask and the mucosal perfusion pressure. However, this type of method has the following significant limitations:

- The efficacy of the proposed methods relies on the measurement hardware, which is expensive to reproduce in different patients with different LMA devices.
- Only a limited number of measurement points are picked to reduce the cost, located at the piriform fossa, lateral pharyngeal wall. Thus, this method does not cover the bone tissue locations, e.g., cricoid cartilage, superior cornu of the thyroid cartilage, and hyoid bone, where high MP occurs typically.
- The measurement electronics will inevitably affect the sealing performance of the laryngeal mask¹⁶.

Instead of relying on direct measurements requiring extra hardware, this work employs computer-aided 3D modeling and finite element analysis (FEA) techniques to investigate the sealing mechanism of an LMA. Computer-aided modeling and FEA have demonstrated their efficacy in numerous engineering problems¹⁷⁻¹⁹. Recently, substantial research has been devoted to applying computer-aided modeling and FEA techniques to study biomechanics and predict biomechanical phenomena²⁰⁻²⁴. A heart and arterial finite element model was established²⁵ to simulate aortic blood flow and explore the vessel wall dynamics. Ref.²⁶ applied FEA on the mechanics of shear and tensile stresses in the articular cartilage and investigated the possibility of causing potential cartilage pathologies, such as osteoarthritis. However, to the best of the authors' knowledge, no existing research has adopted 3D modeling and FEA techniques to study airway mechanics. In this work, computer-aided 3D models are established to visualize LMA-pharynx interactions directly. The FEA technique is adopted to study the LMA sealing mechanics and quantitatively verify the visualization results. It is evident that our method of 3D modeling and FEA can provide

globe monitoring on the LMA and a detailed understanding of sealing mechanics on all areas without extra hardware cost, and therefore resolve the limitations of the existing methods.

The contributions of the paper can be summarized as follows:

- We developed a novel method to investigate the LMA sealing mechanism by using computer-aided 3D modeling and FEA techniques. This novel approach resolves the limitations of the existing methods and can provide globe monitoring on the LMA and qualitative details of sealing mechanics.
- The experimental results support three findings: a) Air leakage is most likely to occur in the oropharynx; b) High MP is most likely to happen in hypopharynx; c) High MP in laryngopharynx can increase the risk of airway obstruction.
- Based on the experimental results, we carefully make several suggestions for the clinic use of LMAs.

The rest of the paper is organized as follows. The computer aided 3D modeling process and the details of FEA settings are described in Section 2. Section 3 presents the results and the discussions. Finally, the paper is concluded in Section 4.

2 Methods

We construct a set of 3D models using Computerized Tomography (CT) to provide direct visualization of internal structure of LMA-pharynx interaction from different directions. From the 3D models, we can get an intuitive understanding of the sealing situations. Next, FEA is carried out to give a quantitative analysis of the sealing mechanics on the contacting surface. The results can help us to develop a comprehensive understanding of the essential physics of air leakage and high MP. We build a neck model by considering pharynx and bones around it as a whole to investigate the interaction between the neck and LMA. We referred the Pharynx and Bones as “PB” in the following content. The 3D models are established according to the following ideas:

- As PB provides supporting pressure that seals pharyngeal mucosa to the LMA, we simplified the neck model as a combination of pharynx and bones around it (PB model).
- To study sealing mechanics when LMA is loaded with different CPs, we created two PB-LMA models, including the PB with LMA loaded with a low CP to investigate the air leakage, referred as “LMA50”; and the PB model with LMA loaded with a high CP, referred as “LMA100”.

Two case studies are presented based an LMA inserted to a volunteer. In Case I, the LMA is deliberately loaded with a low CP (9 mmHg) to investigate the cause of leaking. In Case II, the CP is increased to 45 mmHg, a recommend value by the manufacturer to prevent air leakage, to detect the critic points of high MP.

2.1 Data source

A volunteer (male, 50 years old, 71.2kg, 171cm, ASA (American Society of Anesthesiologists) class I²⁷, no underlying conditions) were recruited for this study. A ProSealTM²⁸ LMA of size 5 was placed after induction of anesthesia and the CP inside the airbag was measured by a manometer at the same time. Written informed consent was obtained from volunteer and research was approved by the Ethics Commission of Shibe Hospital of Jingan District, Shanghai, China with an ethical report. All of the methods used in this study were carried out in accordance with the relevant guidelines and regulations²⁹.

2.2 3D modeling of LMA-pharynx interactions

A 64-slice spiral CT (Philips, Ingenuity CT, Israel) is used to obtain the image data of the PB-LMA model. The scanning process is detailed as follows. Firstly, topical anesthesia is carried out adequately on the throat of the patient. Next, intravenous anesthesia is carried out for the patient with the monitor of vital signs. CT scans are carried out to obtain data of PB with the inserted LMA loaded with different CP values, measured by a manometer at the LMA inflation valve.

The scanning parameters are detailed as follows: 120 kV, 30 mAs, 1 mm scanning thickness, 0.75 mm × 0.75 mm in-plane resolution and 512 × 512 matrix. Firstly, CT images in DICOM format obtained for each scan, as displayed in Fig. 2, are used as references to establish 3D models of PB-LMA interactions. After threshold segmentation, dynamic region growth, 3D calculation and smoothing, the 3D models of pharynx are constructed, as shown in Fig. 3.

Figure 2. CT image displayed in the GUI of 3D modeling software from different views.

Figure 3. 3D reconstruction model of PB and LMA (A: 3D image of PBs, including cricoid cartilage (I), thyroid cartilage (II), hyoid bone (III), mandible (IV), spine (V), B: LMA50; C: 3D image of PB-LMA50; D: LMA100; E: 3D image of PB-LMA100. The position indicated by the elliptical dotted line is the closed hypopharynx).

2.3 FEA Settings

In biomechanics, human tissues are usually in complex irregular geometry. To perform the FEA calculation, we divide the 3D PB-LMA models into high-quality tetrahedral mesh instead of hexahedral mesh commonly used in the calculation of the regular geometric model. The meshing principle is to increase the meshing density at the place of mutual contact or stress concentration.

The meshing results are shown in Fig. 4. We can see the meshing density of the airbag is significantly higher than other parts.

Figure 4. The inserted LMA is divided into shell elements, and PBs are divided into tetrahedron elements.

Materials of PB-LMA models include silica gel, silicone, laryngeal soft tissue, muscle, hyoid bone etc. In this study, we define the properties based on studies^{30–32} and data provided by the manufacturer. The related parameters are summarized in Table 1.

Table 1. Element type and material parameters

Structure	Materials	Elastic Modulus (MPa)	Poisson Ratio (μ)
Cuff	Silicone	6	0.47
Tube	Rubber	10	0.43
Pharyngeal cavity	Soft tissue	13	0.4
Muscle around pharynx (tongue)	Soft tissue	13	0.4
Hyoid bone	Cortical bone	12000	0.3
Thyoid cartilage	Cartilage	60	0.4

The boundary conditions are detailed as follows. The bronchus, hyoid bone, and thyroid cartilage are attached to the airbag of LMA, which simulates PB-LMA interactions. Frictionless nonlinear contacts are assumed to those contacting surfaces to prevent displacements during loading.

The loads are summarized in Table 2. After finishing the settings, we complete the FEA calculations on a standard workstation with the following configurations: Dual CPU, each CPU has a dominant frequency of 3.33 GHz, a total of 24 cores and 48 threads; memory: 48 GB; graphics card: 5 generations of core display; bit width: 256 Bit, video memory: 2 GB. The computational time is 40 minutes, which indicates that the proposed method is computationally efficient.

Table 2. FEA loading parameters

Size of the LMA	Thickness of cuff membrane	CP (LMA100)	CP (LMA50)
5#	0.7 mm	45 mmHg	9 mmHg

3 Results and Discussion

The results presented in this section can be divided into two categories. Firstly, 3D models are presented to provide direct visualization of PB-LMA interactions, providing intuitions of critical points of air leakage and high MP. Secondly, to obtain a comprehensive understanding of the seal mechanics, FEA results are presented with a specific focus on PB-LMA interactions at those critical points.

3.1 3D visualization

Figure 5. The 3D image of PB-LMA100 (left) and PB-LMA50 (right)(cricoid cartilage (I), thyroid cartilage (II), hyoid bone (III), mandible (IV), spine (V), and the mucosa inserted with an LMA).

The 3D geometrical models of the PB-LMA100 and PB-LMA50 are shown in Fig. 5, including cricoid cartilage (I), thyroid cartilage (II), hyoid bone (III), mandible (IV), and spine (V), respectively. When LMA is inflated, bones I-V push mucosa to the inserted LMA, ensuring a proper sealing performance.

Fig. 6 shows the relative displacements of bones I-V after inflating the LMA cuff, respectively, with respect to the spine (V). This can be viewed as an indicator of the force acting by bones I-V on the mucosa. We can see from Fig. 6 there is almost no displacement of mandible, even when the LMA is loaded with a high CP. This implies very little support is acted on mucosa from the mandible, indicating a possible critical point of air leakage. There are significant displacements on the cricoid cartilage (I), the thyroid cartilage (II), and the hyoid bone (III), especially when a high LMA CP is applied. This implies Bones I-III could be potential critical points of high MP. in Fig. 5 also verifies these findings. These findings can also be verified by direct observation of 3D models in Fig. 5, where few folds appear around the mandible (IV) while several notches around Bones I-III.

This subsection gives qualitative results of the sealing situations on the several positions. In the following subsection, FEA results will be presented to provide a more comprehensive quantitative study of PB-LMA interactions, especially on those critical points.

3.2 FEA MP distribution results

This subsection provides a detailed quantitative analysis to provide a more comprehensive analysis of sealing mechanics. To better demonstrate the LMA-pharynx interactions, we present MP distribution diagrams after completing the FEA calculation. Based on the separation of the pharynx as defined in Fig. 1, the MP distribution diagrams are reorganized into three groups

- MP distributions in the hypopharynx, where the primary interactions are between Bones I-II and mucosa;
- MP distributions in the laryngopharynx, where the primary interactions are between Bones II-III and mucosa;

Figure 6. Displacement of pharyngeal Bones I-IV caused by LMA inflation, with respective to the spine (V).

- MP distributions in the oropharynx, where the primary interactions are between Bone IV and mucosa.

Hypopharynx

Fig. 7 shows the pressure distribution of hypopharyngeal mucosa when the CP values of LMA are 9 mmHg (PB-LMA50, left) and 45 mmHg (PB-LMA100, right), respectively. We can see that in both cases, the high MP points appeared in Area I, where the cricoid cartilage (Bone I) presses the mucosa from the top, and Area II, where the thyroid cartilage (Bone II) squeezes the mucosa from sides.

As the LMA CP increased from 9 mmHg to 45 mmHg, the peak MP magnitudes in Areas I-II increase significantly, e.g., from 7.5 kPa to 49.9 kPa in Area I, and from 26.1 kPa to 114.7 kPa in Area II. This is because Bones I-II limits volume of hypopharynx, as directly observed from the 3D models presented on the left top corners 7. When LMA is inflated, Bones I-II introduce heavy reactive effects, leading to high MP in those Areas.

Laryngopharynx

Fig. 8 shows the CP distribution on the laryngopharyngeal mucosa when the LMA CP values are 9 mmHg (PB-LMA50, left) and 45 mmHg (PB-LMA100, right), respectively. Comparing Fig. 8 with Fig. 7 shows that the MP in the laryngopharynx is much smaller than in the hypopharynx. When the LMA is loaded with a 45 mmHg CP value, two high MP Areas III-IV appear on both sides of the LMA, located at the areas of the hyoid bone and the super corner of the thyroid cartilage. The peak MP magnitudes are roughly 1/5 to 1/8 of the peak MP in Area I. This is because in laryngopharynx, the volume is not as tightly restricted as in hypopharynx.

It is also worth noticing that the super horns of the thyroid cartilage (Bone II) and the hyoid bone (Bone III) form a U-shape squeezing both sides of the LMA, which limits the width of the LMA.

Oropharynx

Fig. 9 shows the pressure distribution of oropharyngeal mucosa when the inserted LMA is loaded with a 9 mmHg CP (PB-LMA50, left), and a 45 mmHg CP (PB-LMA100, right), respectively. We can see that when the CP is 9 mmHg, in most part of the oropharynx, the MP is close to 0, which implies very little pressure support from PB in oropharyngeal area to seal the mucosa to LMA, leading to high risk of air leakage in LMA ventilation.

When the CP is increased to 45 mmHg, the air leakage problem is significantly reduced. This is because a line of pressure support is provided by the PB (the white dash line in the right subfigure of Fig. 8) along the contacting surface between the oropharyngeal mucosa and the inserted LMA, to prevent the air leakage into the oral.

We also notice that the peak MP is 10 kPa, indicating high MP to be a less prominent problem in oropharynx than in other parts of the pharynx.

3.3 Discussion

It can be seen that the FEA results are highly in keeping with visualization results and provide qualitative details on the sealing mechanics. The results obtained from the previous two subsections support the followings:

Figure 7. The pressure on hypopharyngeal mucosa of PB-LMA50 (left) and PB-LMA100 (right). Area I shows the impact of the cricoid cartilage (Bone I) pressing the mucosa from the top; Area II shows the impact of the thyroid cartilage (Bone II) squeezing the mucosa from the sides. The peak MP magnitudes are 7.5 kPa (Area I, 9 mmHg), 49.9 kPa (Area I, 45 mmHg), 26.1 kPa (Area II, 9mmHg) and 114.7 kPa (Area II, 45 mmHg), respectively.

Figure 8. The pressure on laryngopharynx mucosa of PB-LMA50 (left) and PB-LMA100 (right). Areas III-IV show the impact of the super horns of the thyroid cartilage (Bone II), and the hyoid bone (Bone III), squeezing the mucosa from the sides. The peak MP magnitudes are 5.2 kPa (Area I, 9 mmHg), 21.7 kPa (Area I, 45 mmHg), 3.9 kPa (Area II, 9 mmHg) and 14.9 kPa (Area II, 45 mmHg), respectively.

Figure 9. The pressure on oropharyngeal mucosa of PB-LMA50 (left) and PB-LMA100 (right) (lateral view). The pressure of most oropharyngeal mucosa is almost 0 kPa in PB-LMA50; the white dash-dotted line in left image means a line sealing pressure is developed when the cuff pressure increased to recommended value.

- Air leakage is most likely to occur in the oropharynx, especially when LMA is loaded with an insufficient CP. This is because the mandible (IV), as part of the skull, has a relatively large distance to the spine, providing little supporting pressure to the soft tissues in this space to seal the mucosa to the inserted LMA. However, as we increase CP to the recommended value by the manufacturer, a line of sealing pressure is developed, as shown in Fig. 9, which remarkably improves the sealing performance in preventing air leakage into the oral.
- As the increase of CP, the MP in the hypopharynx increases sharply, especially around bones (I-II). This is because Bones I-II that protect and support the glottis and bronchus in normal conditions, are pulled by the hypopharyngeal constrictor and bronchus close to the spine before the insertion of LMA, as shown in the Element A in Fig. 5.
- The pressing and squeezing effect of Bones II-III reduce mucosal perfusion and result in a series of complications in the hypopharynx, of which the most common one is the sore throat. Moreover, due to the squeezing effect from the upper corners thyroid cartilage and hyoid bone, the airway inside of LMA will shrink, leading to a potential risk of airway obstruction, especially when the LMA is hyperinflated. In summary, mucosal perfusion is most likely to occur in laryngopharynx and a hyperinflation on LMA may lead to airway obstruction.

These findings are also reflected in our clinical practices at the department of Anesthesia, Shanghai Shabei Hospital. The air leakage phenomena are monitored by Primus™ Anesthesia Machine³³. A photo of detecting air leakage in daily practice using the anesthesia machine is shown in Fig. 10. The high MP is reflected by patients reporting sore throat complications after the operation.

In line with the findings above and our practical clinical experience, we make the following suggestions for clinic use and manufacture design:

By combining the results of this paper and our practical clinical experience, we make the following suggestions:

- the size of the LMA must be carefully determined according to the volume of the hypopharynx, and the width of the thyroid cartilage super horns and hyoid bone super horns. It would be better for supplier to provide LMAs with finer sizes.
- the CP must be gradually increased to a proper value that the air leakage is just avoided, i.e. the minimum CP avoiding air leakage. This helps to reduce the complication risk caused by high MP.
- the shape of LMA plays a key part in LMA sealing performance. When a trade-off between high MP and air leakage is inevitable, we may require LMAs with smarter designs that fulfils shape variation. Alternatively, the LMA should be made of softer and more flexible material so that it can gently wrap the sharp area such as bones (I-II) and meanwhile fill into sunken area such as oropharynx.

Figure 10. The air leakage during LMA ventilation is detected by Primus™ Anesthesia Machine. (The red box shows the leakage value)

4 Conclusion

This work has developed a novel method for investigation of LMA sealing mechanism by using computer-aided 3D modeling and FEA techniques. Compared with the existing methods, our method does not introduce any additional hardware costs and is capable of providing globe monitoring on the LMA and detailed understanding of sealing mechanics on all areas. A set of 3D models have been established based on CT data for directly visualizing LMA-pharynx interactions, identifying the critical areas where air leakage and high MP occur. Furthermore, FEA technique is adopted to provide quantitative analysis on MP distribution in those crucial areas.

It has been found that the FEA results are highly in line with visualization results and provide qualitative details of the sealing mechanics on the critical points. The experimental results support the following findings: 1) Air leakage is most likely to occur in the oropharynx; 2) High MP is most likely to occur in hypopharynx; 3) High MP in laryngopharynx can increase the risk of airway obstruction.

Based on the findings and our practical clinical experience, corresponding suggestions and guidelines are also given for clinic use of LMAs and for LMA design. Our future work will be focused on extending this study to a group of clinical cases sharing similar complications.

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