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Report:

An analysis of patents for anesthetic laryngoscopes*

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Abstract: The anesthetic laryngoscope is one of the most popular medical tools for obtaining a clear view of the larynx and facilitates tracheal intubation. The number of anesthetic laryngoscope patents, coming mainly from the anesthesiologists, has rapidly increased. Each product has a specialized use for particular patients. However, it is unclear to what extent anesthetic laryngoscopy gained acceptance in operating theaters. By retrieving patent data for more than 90 countries from the Online Retrieval of Bibliographic Information Time-share (ORBIT) system, we reviewed the anesthetic laryngoscope patent literature published before July 6, 2015, and manually analyzed patent status, general development trends, areas of competition, technology patentees, and technology classifications. The study showed that the number of anesthetic laryngoscope patent applications has stayed at a high level in the last decade. Most patent activity was carried out in the USA, with China and a number of European countries trailing behind. In addition, the patent analysis provided an opportunity to understand the trends in the development of anesthetic laryngoscope technology, to identify shortcomings in clinical use of anesthetic laryngoscopes, to assist medical manufacturing specialists in improving the design and products, and to suggest to anesthesiologists modifications of the clinical signs of difficult tracheal intubation based on the new commercial anesthetic laryngoscopes applied in the front-line.

Key words: Patent literature analysis; Anesthetic laryngoscope; Technology; Data analysis; Innovation dynamics
http://dx.doi.org/10.1631/jzus.B1600259 **CLC number:** R318.6; R562.1

1 Introduction

Laryngoscopy is commonly used to expose the epiglottis, vocal folds, and glottis in oral and tracheal medical procedures. There are two main types of laryngoscope: operative and intubating. Operative laryngoscopes are used mainly by otorhinolaryngologists to perform endolaryngeal microsurgery, such as the removal of benign vocal fold lesions (Bastian, 1996). Intubating laryngoscopes are used mainly by resident anesthetists or nurses to expose a patient's trachea opening for ease of tracheal intubation to maintain efficient ventilation. It is one of the essential tools for enabling anesthetists to secure the airway and care for anesthetized or critically ill patients.

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Intubating laryngoscopes, also called anesthetic laryngoscopes by anesthetists, were the main focus of the current study.

As early as 1878, MacEwen (1880) inserted a tube from the mouth to the trachea of a conscious patient, using his fingers as a guide, and a variety of anesthetic laryngoscope designs were then produced. In the 1940s, there were three main types of anesthetic laryngoscope (Macintosh, Soper, and Miller) designed to meet the needs of anesthetists in North America (Behringer and Kristensen, 2011). In the 21st century, the appearance of Airtraq visual laryngoscope changed the concept that a laryngoscope needed to maintain the oral, pharyngeal, and laryngeal axes in a straight line as in the past. The vocal cords could be exposed easily (Zhao *et al*., 2014) and various types of tracheal tubes could be introduced.

Tracheal intubation with an anesthetic laryngoscope to control the airway is essential to maintain the safety of surgical operations. An anesthetic laryngoscope is composed mainly of a handle, blade, mirror handle, lens connection portion, and a light source. Developments in laryngoscope technology have led to several improvements in their fundamental structure. Patent literature contains the most important technological information. Through the analysis of such literature, we can gain an understanding of the developmental trends in international patenting, distribution of key technologies, competition between sectors or countries, and directions of technological development (van Doren *et al*., 2013). In this study, we analyzed patent literature related to anesthetic laryngoscopes to help anesthesiologists and related professional and technical personnel understand the process of the development of anesthetic laryngoscope technology and provide a useful reference for future research on anesthetic laryngoscopes.

2 Methods

2.1 Determination of the object of study

The research objects identified were national and international patents related to anesthetic laryngoscopes. Patent data were sought from more than 90 countries in the Online Retrieval of Bibliographic Information Time-share (ORBIT) system.

2.2 Formulation of search strategies

Preliminary searches were conducted in commonly used international patent databases with "laryngo-scope" as the keyword. Then the following international patent classification (IPC) codes were used as retrieval formulas to search patent titles and abstracts: A61 or A61B-001/00 or A61B-001/04 or A61B-001/06 or A61B-001/26 or A61B-001/267 or A61B-017/00 or A61B-017/24 or A61B-019/02 or A61D-007/04 or A61M-016/00 or A61M-016/01 or A61M-016/04 or G09B-023/28 or H04N-005/225. The search results were analyzed item by item to screen the retrieved data and refine the scope of the research. The characteristics of eligible literature were that it should be a published patent document related to anesthetic laryngoscopes and be focused on a specific technology or equipment judged significant by a panel of clinical professionals. The characteristics of excluded literature were that it should contain material duplicated by other patents, describe technology or equipment lacking the potential for further development, or have content that did not meet the standards of clinical professionals.

3 Results

3.1 Patent analysis process

The anesthetic laryngoscope patent research project was performed as shown in Fig. 1. One thousand and eighty-six patents were identified using the retrieval formula, from which 282 Chinese patents and 263 international patents in English were selected for the final analysis based on document recognition by our clinical professionals. The remaining 541 patents, relating mainly to endoscopes, light-guiding lenses, animal laryngoscopes, illumination devices, adapters, and other laryngoscope components, were excluded from this analysis.

3.2 Status of anesthetic laryngoscope patents

As of July 6th, 2015, 172 (31.6%) patents had been authorized, 69 (12.7%) were at the application stage, 146 (26.8%) had expired, and 9 (1.7%) had been withdrawn (Fig. 2). Less than half of the patents were between the application and authorization stages, whereas the remainder had been abandoned, expired, or revoked. Therefore, more than half of the anesthetic

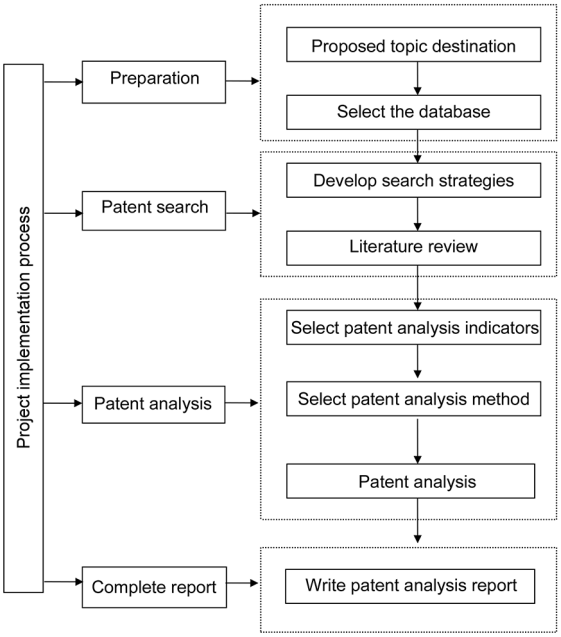

Fig. 1 Patent analysis procedure

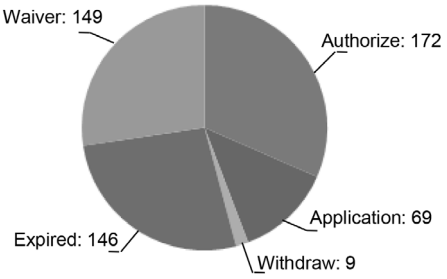

Fig. 2 Distribution of laryngoscope anesthesia patents based on legal status

laryngoscope technology products were not limited by patent protection and were available for public use.

3.3 Trends in anesthetic laryngoscope technology development

Anesthetic laryngoscope patents first appeared in the early 1900s, but a period of slow development was observed for about 60 years (Fig. 3). In the 1970s, the rate of development was steady. Rapid development in anesthetic laryngoscope technology appeared in the mid-1990s, and the number of patent applications grew rapidly. Image acquisition units appeared in laryngoscope patents in the late 1990s (Berall, 1998). The number of anesthetic laryngoscope patent disclosures has remained at a relatively high level over the last decade. The rapid development of this technology has been inextricably linked to its widespread use, especially the use of video technology as a rescue technique in difficult direct laryngoscopy (Scott-Brown and Russell, 2015).

3.4 Global anesthetic laryngoscope technology activity

Fig. 4 shows that most anesthetic laryngoscope patents published were from China, the USA, Europe, Japan, and the World Intellectual Property Organization (WIPO). The results show that technological breakthroughs were made by these countries or regions over the last two decades. In particular, China and the USA showed significant patent filing activity. South Korea and Taiwan Region of China have also shown a relatively rapid increase in patent applications in recent years. France and the United Kingdom led the technology in the past.

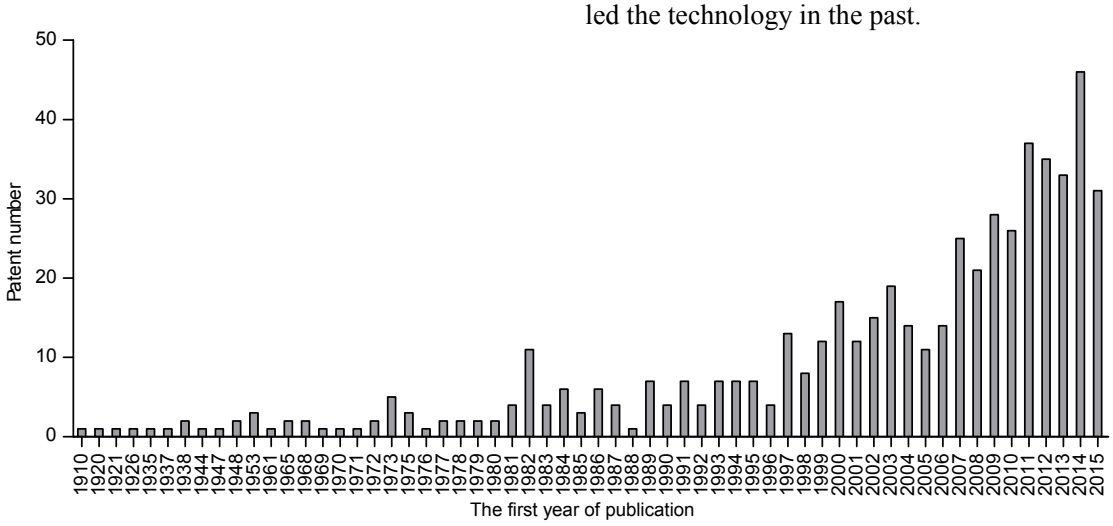

Fig. 3 Number of laryngoscope patents published per year

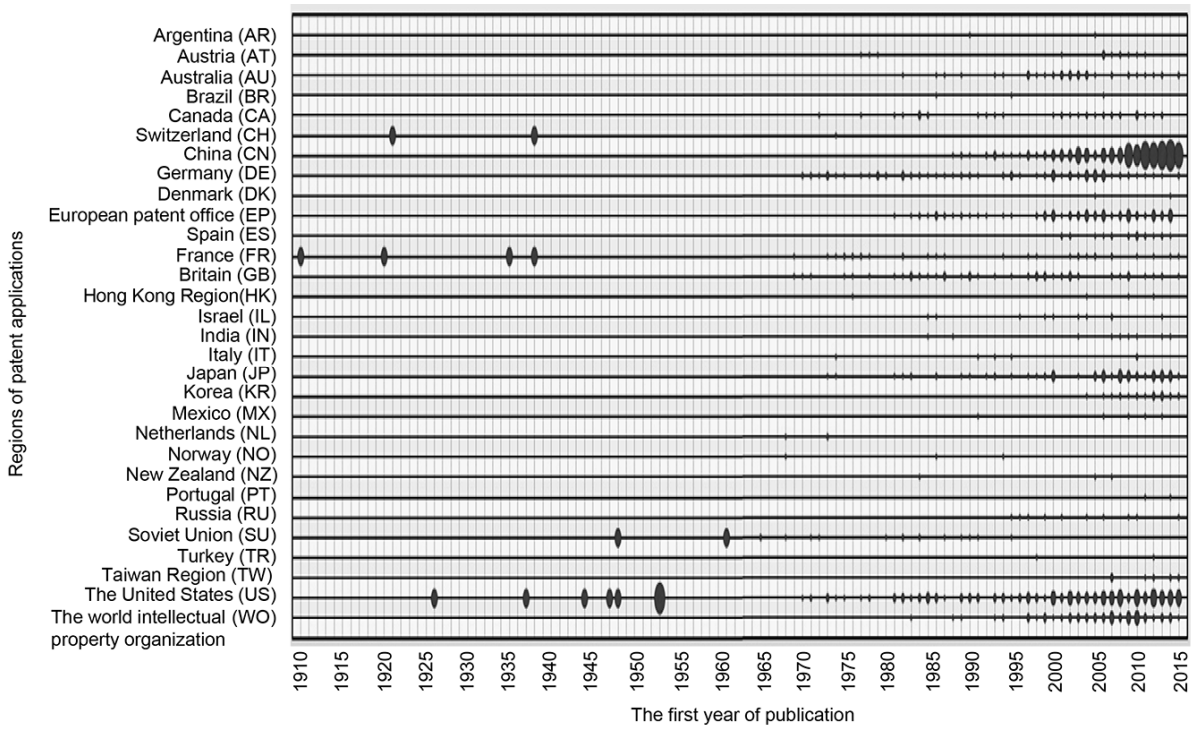

Fig. 4 Trend of laryngoscope patent publications in the period 1910–2015

3.5 Anesthetic laryngoscope patentees

Among a large number of corporations holding anesthetic laryngoscope patents, the top ten patentees were: Mercury Enterprises (USA), Karl Storz (Germany), Hangzhou Tonglu Jiangnan Medical Opics Factory (China), Richard Wolf (Germany), OptoTech (Australia), Heine Optotechnik (Germany), Welch Allyn (USA), Zhejiang Tiansong Medical Instrument (China), IntuBrite (USA), Aircraft Medical (Britain) (Fig. 5). These patentees are the main owners of the anesthetic laryngoscope technology or equipment internationally, and also the technology leaders.

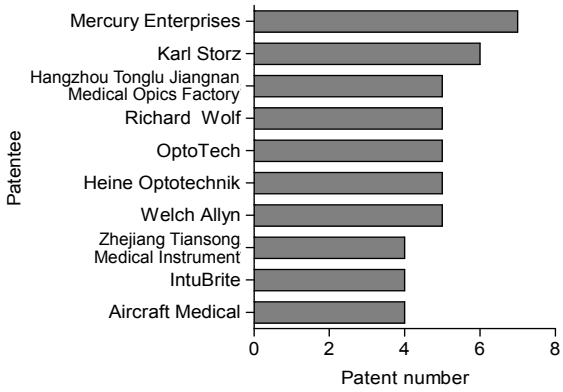

Fig. 5 Top ten patentees in the laryngoscope area

3.6 Analysis of the technical focus of anesthetic laryngoscope patents

3.6.1 Technical focus

Laryngoscopes are used mainly for intubation to maintain an open airway and assist breathing, so the main areas of research include the structure, handle, and blades of the instruments.

3.6.1.1 Anesthetic laryngoscope structure

A laryngoscope is composed mainly of a handle, blade, and lighting device. However, technological innovations have enabled a variety of improvements, such as surface anesthesia devices, endoscopic systems (Lee *et al*., 2012), attractive devices (Boedeker and Omaha, 2015), high-frequency jet ventilation devices (Wu, 2013), anti-fogging heating systems (Acha Gandarias, 2014), camera systems (McGrath, 2006), and video systems (Donaldson, 2015). Moreover, the English and Chinese patents related to laryngoscope structure have increased to 83% during the last 15 years. The advantages of improvements in structure have made the devices more convenient for use in medical procedures and clinical teaching.

3.6.1.2 Anesthetic laryngoscope handle

The anesthetic laryngoscope handle has a hand-held end, gripped by the physician in performing endotracheal intubation. The laryngoscope handle comprises of a first end, second end, inner surface, and outer surface. Disposable laryngoscopes are manufactured as a single-piece handle and blade construction. Commonly used laryngoscopes comprise a detachable blade with a removable bulb that connects to the handle which contains a battery. The detachable handle is re-usable and removable. Handles of several different sizes are available, including standard, large, bantam, and slender (for pediatric), identified by different embedded colored bands. Each handle usually has a set of coordinated interchangeable blades. The outer surface of a conventional cylindrical stainless steel handle is roughened to enhance the grip of the anesthesiologist's hand. Some of the handles have a bent and angled shape (Tenger *et al*., 2012). The inner surfaces of some of the straight or bent handles have finger-shaped indentations with grip features (Bartlett, 1990; Tenger *et al*., 2012). This kind of design facilitates comfortable handling by the operator. A detachable laryngoscope is usually stored in a folded condition, with the handle generally aligned parallel to the blade. An electrical contact is integrated in the bayonet connection on the second end of the handle upper surface which can be connected to the blade. Some handles include an adjustable angle adapter on the second end (Soloway, 1986), allowing the blade to be positioned at variable angles with respect to the handle for special purposes. The application of adapter design facilitates intubation in obstetric practice.

3.6.1.3 Anesthetic laryngoscope power source

An electrical power source such as an alkaline battery or rechargeable nickel metal hydride battery can be included in the handle's cavity. It provides a light to enable anesthesiologists to view the larynx and see where the endotracheal tube is going.

3.6.1.4 Anesthetic laryngoscope blade

A laryngoscope insertion section is typically referred to as a blade. It acts as a tongue depressor and a viewing channel for placing the endotracheal intubation. The blade is an invasive semi-critical section. It can extend into a patient's oral cavity, and make contact with mucous membranes, saliva, and blood, so proper sterilization is needed (Telang *et al*., 2010). Modern blades are removable to facilitate their sterilization and to obviate repeatedly sterilizing the entire laryngoscope (McGrath and Inglis, 2013). Blades can be either durable or disposable (Williams and Doerr, 2010). The stainless steel construction of durable blades extends their life even following extensive autoclaving at 134 °C and 18 min cycles, which is considered as an efficient treatment against prions (Sleth *et al*., 2013). Disposable and replaceable blades include plastic and metallic materials. A single-use blade has been designed for single patient use, which eliminates the risk of cross contamination.

A laryngoscope blade is composed mainly of a base, light source, tongue spatula, flange, and leading tip.

The base of the blade is connected to the top of the handle via a bayonet connection. The bottom of the base has a second electrical contact, connected to an electric lamp carried by the blade. When the blade is in its operating position, the two electrical contacts engage to turn on the lamp. If an adjustable angle adapter is inserted between the handle and blade, the wire is directly connected to the batteries.

A light bulb serving as a light source is placed in the distal third of a conventional laryngoscope blade. The bulbs and batteries need to be checked on a regular basis to maintain the quality of the light produced by traditional laryngoscopes. Anesthetic laryngoscopes often use natural white light sources, such as cool white light-emitting diodes (LEDs), halogen light bulbs, or Xenon light bulbs (Milne *et al*., 2014). However, a combined ultraviolet and white light source has been found to act as a black light source that emits electromagnetic radiation at a wavelength of 300–450 nm. This wavelength illuminates natural phosphor-containing elements in the vocal cords, increasing their visibility during the intubation process (Tenger *et al*., 2012).

The tongue spatula of a laryngoscope blade is designed for placement in the valleculae and is pressed on the median glossoepiglottic ligament to displace the tongue and focus light into the patient's mouth. The shape of the tongue spatula mainly determines the shape of a laryngoscope blade. There are three main types of laryngoscope blades available commercially: a curved blade known as the Macintosh blade, a straight blade known as the Jackson or

Wisconsin blade, and a straight blade with a curved tip known as the Miller blade (Cartledge and Lane, 2003).

The Macintosh blade is used to hold the epiglottis posteriorly and raise it out of the visual pathway, and is usually used for adults. Macintosh laryngoscopes with a No. 3 blade (routinely used for female and male adult patients) (Yardeni *et al*., 2002) or No. 4 blade (routinely used for tall adult individuals) (Choi *et al*., 2016) are often used as a reference for evaluating new blade designs because they achieve the best combination scores based on clinical trial and radiographs taken during laryngoscopy (Marks *et al*., 1993). Jackson or Wisconsin blades have a very modest curve at the end of their slightly wide tip to hold the epiglottis directly, and are commonly used for infants. Miller blades are used to directly lift the epiglottis anteriorly to expose the glottis and vocal folds (Kimberger *et al*., 2006), and are primarily used for infants and small children, who tend to have a rather floppy epiglottis.

Video-laryngoscopes consist of a handle and a blade, with a video camera fitted at the end. New fiber optics, light and anti-fog lenses are used to avoid atomization of the laryngoscope blade. This design enables the operator to visualize the glottis indirectly on a video screen. There are three main categories of commercial video-laryngoscopes: Macintosh optical laryngoscopes and video-laryngoscopes with an anatomically shaped blade, either with or without a tube guide (Scott-Brown and Russell, 2015). Video-laryngoscopes have rapidly gained in popularity as they allow a wide viewing angle and make alignment of the oral, pharyngeal, and tracheal axes unnecessary (Paolini *et al*., 2013). Patents for video-laryngoscopes are a current trend in anesthetic laryngoscopy.

There are many different styles of laryngoscope blade designs for patients who wear false teeth, or who have a swollen tongue or throat. The size of the tongue, anatomical features of the airway, and the anesthesiologist's personal experience and preference play a part in determining which blade is used for intubation.

The blade length of commercial anesthetic laryngoscopes is determined mainly according to the international standard ISO 7376:2009 (ISO, 2009) and the laryngoscope standard of the country of manufacture. The correct choice of blade size depends on numerous clinical parameters such as the patient's age, gender, weight, modified Mallampati score, Cormack-Lehane score, thyromental distance, sternomental distance, inter-incisor distance, neck circumference, Wilson risk score, and mean durations of the laryngoscopy and intubation (Türkay *et al*., 2016), and the conditions. Laryngoscope suppliers usually gave the main selection guidance parameters as the patient's age and weight.

A standard anesthetic laryngoscope blade has a flange for displacing the tongue to the side for visualization of the larynx. A blade without a flange has been designed (Bizzarri and Giuffrida, 1958) and also a blade in which the proximal part of the flange can be removed to decrease the risk of dental injury, even when the anesthetist must rotate the distal end of the blade to visualize the larynx (Kimberger *et al*., 2006). However, the absence of a flange cannot prevent the tongue falling into the line of vision (Gerlach *et al*., 2003).

The leading tip of the blade is used for lifting the epiglottis so that an endotracheal tube can be inserted into the trachea.

3.6.2 Clinical applications

Before use, the laryngoscope handle and blade must be connected via a bayonet connection. The traditional method of endotracheal intubation requires a patient's head to be tilted backwards as far as possible to align the axes of the mouth, pharynx, and larynx. During intubation, with the left hand holding the laryngoscope handle, the operator needs to pull the patient's lower lip with his/her right thumb, and insert the blade into the patient's mouth from the right side. Then, using the flange of the blade to keep the tongue to the left for visualization of the larynx, the epiglottis and glottis can be exposed. The endotracheal tube is inserted safely into the channel where it remains throughout the surgery, carrying air and anesthetic gases into the patient's lungs. The laryngoscope is then removed, leaving the tube in place.

In clinical work, many patients have problems with their airway such as the inability to open the mouth, poor cervical spine mobility, micrognathia, a large tongue, prominent incisors, a short muscular neck, or morbid obesity. These anatomical characteristics result in a poor view of glottis and difficult tracheal intubation (DTI) of laryngoscopy. Several clinical signs including the Mallampati score, mouth opening (MO), thyromental distance (TMD), and body mass index (BMI) are used to predict DTI

(Langeron *et al*., 2012). This can help anesthesiologists to modify their airway management strategy and reduce the incidence of adverse events. In recent years, video-laryngoscopes have been used primarily in patients with Mallampati grade 3 or 4 and beyond the risk of pregnancy, and for emergency surgery (Aziz *et al*., 2012).

Video-laryngoscopes have a video camera embedded in the blade and connected to a liquid crystal display color monitor by a cable supplying power and transmitting video signals. The curvature of a video laryngoscope blade enables an adequate laryngoscopic view to be obtained with a much lower lifting force and without relying on a direct line of sight. Video-laryngoscopes can obtain excellent visualization of the glottis, and have been rapidly applied in operating theaters. This has led specialists in anesthesia to consider modifying the algorithms for difficult intubation.

3.6.3 Laryngoscope target populations

Most of the laryngoscope patents were related to adult populations. About 6.5% English and Chinese patents targeted pediatric populations during the last 15 years.

4 Expert commentary and five-year view

The anesthetic laryngoscope is an essential tool for the implementation of clinical anesthesia and cardiopulmonary resuscitation. Difficult airway management has been the main motivation to improve the structure of anesthetic laryngoscopes. Continual improvement of the handle, blade, and light source has enabled a much lower lifting force to be used and clearer images to be obtained, with improved glottic visualization, high successful intubation rates, short intubation time, and less serious complications of laryngoscopy. However, operators may sometimes pay more attention to the monitor when a video-laryngoscope is being used and may tend to ignore the situation in the mouth (Dupanovic, 2010). The existence of a potential blind spot in the oropharynx may cause operators to use increased force when the operation is not proceeding smoothly, resulting in soft palate injury (Alfahel *et al*., 2016). An experienced anesthesiologist recommended that operators look into the patient's mouth and view the monitor several times while the video-laryngoscope blade is being slowly introduced into the airway (Dupanovic, 2010). In the coming years, research should focus on the establishment of new operating procedures for using new anesthetic laryngoscopes. A deeper investigation of the potential value of laryngoscope innovation is needed, including commercial success, front line anesthetist acceptance, the collection of more clinical practice data, and documentation of literature by meta-analysis.

5 Key issues

The primary aim of the development of clinical anesthetic laryngoscopes is to enhance the safety and success rate of intubation for clinical anesthesia and cardiopulmonary resuscitation.

The shortcomings of laryngoscopes exposed in daily clinical practice have promoted improvements in their structural design and manufacturing materials.

The laryngoscope technology patent data exposed areas of potential competition and provided a reference for future development of the laryngoscope.

A new airway management procedure is needed to ensure patient safety and efficient use of new anesthetic laryngoscopes.

Compliance with ethics guidelines

Cheng-dong JI, Xin PAN, Yuan-chang XIONG, Xuan GUO, Shu-wen QIAN, Chang XU, Qiang-qiang FU, Zhi-ping YANG, Yu MA, and Yue-zhu WAN declare that they have no conflict of interests.

This article does not contain any studies with human or animal subjects performed by any of the authors. This research proposal was approved by the Ethics Committee of Yangpu Hospital, School of Medicine, Tongji University, Shanghai, China (No. LL-2015-KY-003).

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中文概要

题　目：基于专利文献的麻醉喉镜研发分析

概　要：本文评估专利文献在麻醉喉镜技术研发中的引领作用，探讨麻醉喉镜专利研发的技术重点。结果显示，近 10 年来麻醉喉镜专利数量较以往增长显著（图 3），呈现以美国领跑，中国和一些欧洲国家紧随其后的态势（图 4）。商品化的麻醉喉镜其专利技术经受了临床实践与市场的考验，其专利持有者掌控的关键技术更加丰富（图 5）。可视化喉镜因解决了困难气管插管问题而成为未来发展的一个重要方向，其相应的操作规程也期待进一步完善。

关键词：专利文献分析；麻醉喉镜；技术；数据分析；创新动态