

## NEW ORAL AIRWAY:

**THAT THRUSTS AND HOLDS THE LOWER JAW FORWARDS, PREVENTS THE MOVEMENT OF THE ROOT OF THE TONGUE AND EPIGLOTTIS ON TO THE POSTERIOR PHARYNGEAL WALL; OPENS ORO-LARYNGO-NASO PHARYNX AIR PASSAGES FOR VENTILATION DURING UNCONSCIOUS, SEMICONSCIOUS STATES AND CPR; ALLOWS FOR HANDS-FREE USE**

By Dr. T.R. Shantha MD, PhD, DABA, FACA, Prof. Emeritus, BMC Medical College & Bob Wieden, President & CEO, Wedge Therapeutics, LLC

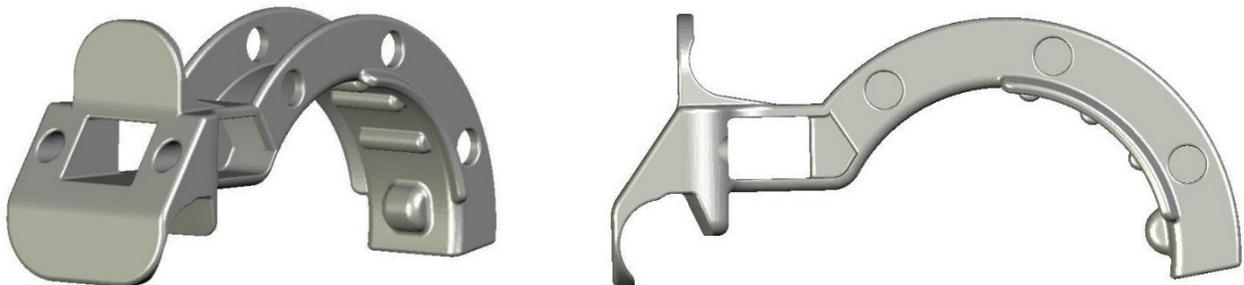
### INTRODUCTION

The first oral (oropharyngeal) airway was introduced in the year 1933 by Guedel (Guedel A. E. J. Am. Med. Assoc. 1933, 100, 1862 (reprinted in “Classical File”, Survey of Anesthesiology 1966,10, 515) and later in 1966 by Berman (U.S. Pat. Nos. 4,067,331, 4,054,135, and 3,930,507) and many others since then. The basic designs are still in use today and all conventional oral airways were modified from them. At present, there are an estimated 312.9 million major surgical procedures undertaken worldwide (Weiser et.al., 2012, Weiser et.al., 2016), in addition to millions more in CPR and other minor surgical procedures, with over 300 million oral airways used every year. To most anesthesiologists and anesthetists, oral airways are usually a mere after-thought but, unfortunately, with what we know today regarding anatomical physiology of the oropharyngeal airway, they are an old “hold over” from the past and continue to be an important overlooked device that does not adequately fulfill all the requirements to carry out the task to maintain the airway in unconscious / semiconscious patients.

This was evidenced by the studies by Kuna et.al., (2008) Isono S, (2007, 2008) showed that just using these common airways are not adequate to maintain the oropharynx airway, and it is important to protract the mandible forwards in adults to maintain the patent airway. Hence, we believe that proper oral airway use, with a protracted mandible (lower jaw thrust forwards), is important to maintain spontaneous ventilation and to save lives before, during, and after surgery; procedures under anesthesia; sedation in critical care and CPR.

Further, our studies showed that in current Guedel and Berman oral airways there are no proportional dimensional standards being employed to the length change in the bite block and the radius of the C curve back body in relation to how it would impact the oropharyngeal area. For this reason, we set out to invent an oral airway that overcomes the shortcomings of the historically-designed, disproportionately-sized oral airways and that incorporates new design elements that would advance how airway management is currently being conducted across the globe. Today, we introduce two versions of our Lower Jaw-Thrusting (LJT) & Tongue Restraining Oral Airway that increases the oropharynx airway with uniform dimensional standards.

**Figure 1. LJT Vertical Channel Airway (LJT-VC)**



**Figure 2. LJT-Horizontal Channel Airway (LJT-HC)**



## **PROBLEM/SETBACKS**

The simple fact remains that the biggest impediment, after placement of traditional oral airways is the relaxation of the soft tissue structures in the hypo-pharynx, tongue, fauces, and palate muscles. These structures are inclined to collapse, and move back towards the oropharynx, thus obstructing airflow, while occurring from both front-to-back and side-to-side, thus greatly decreasing the size of the oropharynx airway opening even with the use of traditional Guedel and Berman oral airways. Consequently, another issue with current airway placement requires the constant attention of the caregiver because the mobile jaw, with the large, muscular tongue can easily retract backwards and cause blockage of the oropharyngeal air passage.

This is why literally every patient before and after anesthesia, CPR, or sedation, is provided with a jaw thrust to prevent the tongue from falling back and obstructing the airway. Furthermore, almost every patient intubated is provided with an airway to prevent biting of the soft endotracheal tube and the tongue as they wake up. Both of these procedures involve protracting the lower jaw by pulling it forward relative to the upper jaw. When a person becomes unconscious, the muscles in their lower jaw and tongue muscles relax and allow the tongue to move inferiorly and backwards, thus obstructing the air passages. One of the most important maneuvers for opening and maintaining the oral airway for exchange of respiratory gases is the practice of mandibular protracting jaw-thrusting to establish the oral airway, and then introducing the oral airway device to maintain the oropharyngeal air passage using sizing in relation to the buccal bite block and the C curve.

In spite of the global use of current oral airways, and their simplistic and sometimes nonsensical design attributes which are explained herein, our LJT oral airways incorporate many dimensional embodiments and design enhancements that will prevent these obstructive jaw and tongue movements by providing a better method to control and manage the many structures that collapse around the oropharynx.

## **OUTLINE OF STUDY FINDINGS**

Safar (Safer P, et.al., 1958, 1959) showed that lay personnel could open the airway by thrusting the jaw forwards and tilting the head backwards. Practitioners slowly adopted this new technique. The study by Kuna et.al., 2008, performed measurements on how far the mandible can be advanced to maximize the depth and the breadth of the oropharynx air passage. Their measurements showed that the adult mandible can be advanced 16.8mm during propofol anesthesia compared to wakefulness. It was also found that regular airway insertion, which is used millions of times a day, did not consistently establish the patient's upper airway. In relation, it was determined that the retroglossal airway never failed to respond to mandibular advancement in obese subjects, indicating an advantage of positive-pressure ventilation through an oral airway during anesthesia induction as evidenced earlier by Safar et al. In addition, Isono et. al., 2007, 2008, pointed out that in addition to proper head and body positioning, the key mechanical intervention is maximum mandibular advancement with mouth opening for effective mask-to-mouth ventilation, and the application of positive end-expiratory pressure.

Further the study by Kuna et al., using magnetic resonance imaging (MRI) was performed in 9 normal adults during wakefulness and under propofol anesthesia. A commercially available intra-oral appliance was used to manually advance the mandible. Images were obtained during wakefulness without the appliance and during anesthesia with the participants wearing the appliance under three conditions: without mandibular advancement, advancement to 50% maximum voluntary advancement, and maximum advancement (see Table 1 below). Using computer software, the airway area and maximum anteroposterior and lateral airway diameters were measured on the axial images at the level of the soft palate, uvula, tip of the epiglottis and base of the epiglottis. The airway area across all four airway levels decreased during anesthesia without mandibular advancement compared to airway area during wakefulness ( $p < 0.007$ ). Across all levels, airway area at 50% advancement during anesthesia was less than that at centric occlusion during wakefulness ( $p = 0.06$ ), but airway area with maximum advancement during anesthesia was similar to that in wakefulness ( $p = 0.64$ ). In general, anteroposterior and lateral airway diameters during anesthesia without mandibular advancement were decreased compared to wakefulness and restored to their wakefulness values with 50% maximal advancement. It was concluded that maximum mandibular advancement during propofol anesthesia is required to restore the pharyngeal airway to its size during wakefulness in normal adults.

**Table 1**

Mean  $\pm$  SD of Pharyngeal Airway Measurements during Wakefulness and Propofol Anesthesia with and without Mandibular Advancement

|                                      | Awake             | Anesthesia No Advancement* | Anesthesia 50% advancement | Anesthesia Max advancement |
|--------------------------------------|-------------------|----------------------------|----------------------------|----------------------------|
| <b>Airway Area (mm<sup>2</sup>)</b>  |                   |                            |                            |                            |
| Soft Palate                          | 193.1 $\pm$ 76.4  | 141.9 $\pm$ 71.9           | 164.1 $\pm$ 84.9           | 223.9 $\pm$ 103.2          |
| Uvula                                | 185.3 $\pm$ 60.1  | 64.0 $\pm$ 44.5            | 106.3 $\pm$ 74.5           | 193.9 $\pm$ 98.6           |
| Tip of Epiglottis                    | 203.8 $\pm$ 88.6  | 76.0 $\pm$ 40.6            | 119.9 $\pm$ 63.0           | 212.9 $\pm$ 107.9          |
| Base of Epiglottis                   | 292.4 $\pm$ 103.4 | 219.6 $\pm$ 47.1           | 251.1 $\pm$ 85.4           | 299.8 $\pm$ 104.0          |
| <b>Lateral Diameter (mm)</b>         |                   |                            |                            |                            |
| Soft Palate                          | 21.0 $\pm$ 3.1    | 20.4 $\pm$ 3.2             | 21.1 $\pm$ 5.7             | 25.3 $\pm$ 5.4             |
| Uvula                                | 20.1 $\pm$ 3.6    | 13.9 $\pm$ 7.0             | 15.2 $\pm$ 4.5             | 21.6 $\pm$ 5.6             |
| Tip of Epiglottis                    | 25.2 $\pm$ 4.7    | 18.0 $\pm$ 8.7             | 19.1 $\pm$ 5.3             | 25.4 $\pm$ 4.2             |
| Base of Epiglottis                   | 32.6 $\pm$ 3.7    | 32.3 $\pm$ 3.7             | 33.6 $\pm$ 3.4             | 32.8 $\pm$ 5.8             |
| <b>Anteroposterior Diameter (mm)</b> |                   |                            |                            |                            |
| Soft Palate                          | 10.0 $\pm$ 2.9    | 7.9 $\pm$ 3.1              | 8.4 $\pm$ 2.6              | 9.6 $\pm$ 3.0              |
| Uvula                                | 11.8 $\pm$ 4.7    | 5.1 $\pm$ 2.3              | 7.9 $\pm$ 2.3              | 11.0 $\pm$ 3.7             |
| Tip of Epiglottis                    | 11.6 $\pm$ 4.4    | 5.4 $\pm$ 2.8              | 7.3 $\pm$ 2.3              | 9.3 $\pm$ 2.8              |
| Base of Epiglottis                   | 11.9 $\pm$ 3.1    | 9.6 $\pm$ 1.9              | 9.9 $\pm$ 2.2              | 10.9 $\pm$ 2.2             |

\* n = 7; data for other 3 conditions from 9 individuals

Thus, the studies showed that mandibular advancement increases airway size when the mandible was advanced, and can easily form centric occlusion to 50% of its maximum voluntary advancement, however, airway area at this advancement was still decreased compared to that in wakefulness. Airway area during anesthesia was restored to that in wakefulness with maximum mandibular advancement. The increase in airway area was due to enlargement in the lateral and anteroposterior dimensions of the oropharyngeal air passage.

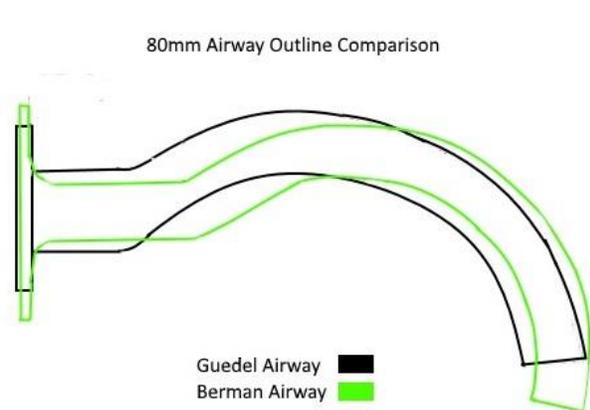
It was further concluded that mandibular advancement would thereby enlarge the oropharyngeal airway by anterior displacement of the hyoid bone and its muscular attachments and lifting the epiglottis away from the posterior pharyngeal wall, reversing the narrowing of the laryngeal inlet. The results of the current and previous studies, however, suggest that the mechanism of action is more complex than simply an action on the hyoid apparatus since this cannot easily explain the enlargement of the retropalatal pharyngeal airway with mandibular advancement or the lateral widening of the airway reported in the current and previous studies. Advancement of the mandible may impose traction on the anterior and posterior tonsillar pillars pulling the soft palate into the oral cavity and opening the retropalatal airway. Furthermore, mandibular advancement may lead to an unfolding of fauces soft tissue structures leading to the lateral widening of the airway.

This jaw-thrust maneuver is further outlined in detailed study findings by Joffe A et al., 2010, which supports the notion that the anesthesiologist is unable to advance and maintain the mandible forward an

adequate distance when using only one hand to hold the jaw at the same time. This is particularly important because changes to the retropalatal cross-sectional area differ in response to a jaw thrust between obese and non-obese patients (Kheterpal S, et.al., 2006). Therefore, in Kheterpal’s experimental model, which bypassed the retropalatal airway with the use of an oropharyngeal airway (OPA), the ability to decrease upper airway resistance would have been totally dependent on changes in the retroglottal airway, moving the epiglottis away from the posterior pharyngeal wall, and the diameter of the vocal cord inlet. Relief of obstruction at these sites has been demonstrated with use of mandibular advancement, hence our LJT airway design (Murashima K, et.al., 1998; Uzun L, et.al., 2005; Stacey MR, et.al 2005; Meier S, et.al., 2002; Whittingham H. 1960).

In relation to traditional oral airways, mandibular advancement is automatically provided by our LJT oral airways described herein and are further proof that the maintenance of upper airway patency is totally dependent on mechanical interventions. Furthermore, it is ideal for conscious sedation, monitored anesthesia care, and general anesthesia with mask ventilation, and is ideal for all clinical applications.

### PRESENT ORAL AIRWAY DESIGN CONSIDERATIONS



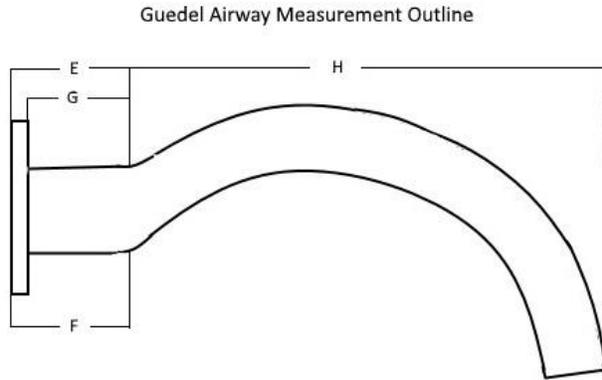
| OA Size (mm) | Size         | OA Size Change% |
|--------------|--------------|-----------------|
| 110          | XL Adult     |                 |
| 100          | Large Adult  | -9.09%          |
| 90           | Medium Adult | -10.00%         |
| 80           | Small Adult  | -11.11%         |
| 70           | Child        | -12.50%         |
| 60           | Child        | -14.29%         |
| 50           | Small Child  | -16.67%         |
| 40           | Infant       | -20.00%         |

**Table 3a. Airway Size and % Size Change**

**Figure 3. Guedel and Berman Side Outline Comparison**

After examination, the Guedel and Berman airways are dimensionally very different in relation to the proportional measurements and it is easy to see that these inconsistencies do not correspond to any design and anatomical logic (see Figure 3 and Table 3a). Even more disturbing is that the size of both oral airways in relation to the buccal bite block and C curve length are variable (see Figure 3, 4, 5 and Table 3a, 4a, 5a) in relation to the size change percentage, i.e., 110m to 100mm (-9.09%), etc. Thus, surprisingly, none of them adhere to the percentage changes of the scaling of the bite block, mouth piece and radius of the C-shaped back body and conform to this percentage change in proportion to the product size. Our premise is simple. Since these two devices are interchangeable to control and impact a subject’s airway in conscience and semi-conscience states, shouldn’t they be dimensionally similar or adhere to some core design uniformity and proportional measurement standard? The only logical answer is, “Yes”, but this is not the case.

For instance, for the Guedel airway (see Figure 4), which is made out of polyethylene (PE), it is a fact that the design and the manufacturing process dictates how the product had to be designed. The tooling to make the radius of the back-body hollow requires a constant, uniform radius to allow for the tooling to release correctly. For this reason alone, this dictates how the oral airway could be manufactured. This results in a short bite block area and a shortened circular radius back body which provides for an airway that is limited in how it can hold the tongue and oropharynx structures adequately (see Figure 3). Furthermore, the hollow body design serves no functional purpose and increases the probability to obstruct the nasopharyngeal airway. Further,

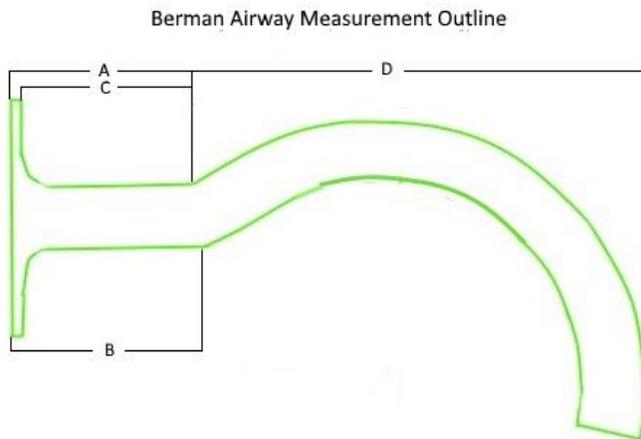


**Figure 4. Classic Guedel Airway Size and Measurement Specifications in the Market**

the smooth PE outer surface allows the tongue to easily slide/wiggle around the back body portion to cause an obstruction. It is our contention that the above design-first limitation impacts how the device can function and leads to it being an inferior design for its purpose. Also, the dimensional measurements from the front flange to the start of the main body C curve are in no proportion (see Table 4a. [G]). Even more surprising is that the change percentage G & H dimensions are not proportional in relation to the device sizing (see Table 3a). This impacts how the placement of the airway will impact the anatomical areas that it was designed to control and manage.

**Table 4a. Classic Guedel Airway Size and Dimensional Measurement Specifications in the Market**

| OA Size (mm) | Size         | Color  | E (mm) | E Size % Change | F (mm) | F Size % Change | G (mm) | G Size % Change | H (mm) | H Size % Change |
|--------------|--------------|--------|--------|-----------------|--------|-----------------|--------|-----------------|--------|-----------------|
| 110          | XL Adult     | Orange | 22     |                 | 22     |                 | 18     |                 | 88     |                 |
| 100          | Large Adult  | Red    | 21     | -4.55%          | 21     | -4.55%          | 18     | 0.00%           | 79     | -10.23%         |
| 90           | Medium Adult | Yellow | 18     | -14.29%         | 18     | -14.29%         | 15     | -16.67%         | 72     | -8.86%          |
| 80           | Small Adult  | Green  | 15     | -16.67%         | 14     | -22.22%         | 14     | -6.67%          | 66     | -8.33%          |
| 70           | Child        | White  | 14     | -6.67%          | 15     | 7.14%           | 16     | 14.29%          | 55     | -16.67%         |
| 60           | Child        | Black  | 12     | -14.29%         | 11     | -26.67%         | 12     | -25.00%         | 49     | -10.91%         |
| 50           | Small Child  | Blue   | 12     | 0.00%           | 9      | -18.18%         | 11     | -8.33%          | 41     | -16.33%         |
| 40           | Infant       | Pink   | 7      | -41.67%         | 6.5    | -27.78%         | 7      | -36.36%         | 33.5   | -18.29%         |



**Figure 5. Classic Berman Airway Size and Measurement Specifications in the Market**

On the other hand, the Berman airway, which is made out of polypropylene (PP), does not have the same design and manufacturing limitations but still the bite block length and C curve has no proportional scaling being used across the different sizes (as pointed out above this is also in the Guedel design but on a much smaller scale) (see Table 5a). As the airway sizes decrease by a known percentage, i.e., 110mm to 100mm = -9.09% decrease, then the bite block length by logic should decrease at some proportional percentage (see Table 5a [A & C]). However, this is not the case. One only has to look at the A and C Size % Change below to see the issue. When no proportional standard is employed than this impacts the radius of the back body portion and how it will control and

impact the anatomical structures of the oropharynx, i.e., epiglottis, root of the tongue, fauces, pillars of tonsils, soft palate with the uvula while simultaneously keeping the body of the tongue pressed inferiorly against the floor of the mouth. These dimensional inconsistencies, and the aforementioned cited studies, have led us to believe that they greatly impact how either airway design functions in relation to the anatomical requirements to keep an airway open.

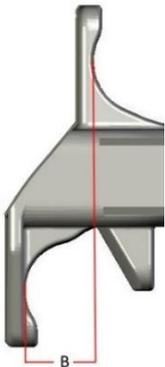
**Table 5a. Berman Airway Size and Dimensional Measurement Specifications**

| OA Size (mm) | Size         | Color  | OA Size % Change | A (mm) | A Size % Change | B (mm) | B Size % Change | C (mm) | C Size % Change | D (mm) | D Size % Change |
|--------------|--------------|--------|------------------|--------|-----------------|--------|-----------------|--------|-----------------|--------|-----------------|
| 110          | XL Adult     | Orange |                  | 36     |                 | 38     |                 | 34     |                 | 76     |                 |
| 100          | Large Adult  | Red    | -9.09%           | 31     | -13.89%         | 32     | -15.79%         | 28     | -17.65%         | 72     | -5.26%          |
| 90           | Medium Adult | Yellow | -10.00%          | 22     | -29.03%         | 25     | -21.88%         | 19     | -32.14%         | 71     | -1.39%          |
| 80           | Small Adult  | Green  | -11.11%          | 24     | 9.09%           | 26     | 4.00%           | 21     | 10.53%          | 59     | -16.90%         |
| 70           | Child        | White  | -12.50%          | 18     | -25.00%         | 19     | -26.92%         | 16     | -23.81%         | 54     | -8.47%          |
| 60           | Child        | Black  | -14.29%          | 20     | 11.11%          | 21     | 10.53%          | 18     | 12.50%          | 42     | -22.22%         |
| 50           | Small Child  | Purple | -16.67%          | 16     | -20.00%         | 17     | -19.05%         | 15     | -16.67%         | 35     | -16.67%         |
| 40           | Infant       | Pink   | -20.00%          | 13     | -18.75%         | 15     | -11.76%         | 11     | -26.67%         | 29     | -17.14%         |

**SOLUTION: LJT AIRWAYS**

LJT Oral Airways, with the jaw-thrust mechanism, was designed to adhere to standardization across all dimensional elements to bring uniformity and increased functionality for airway management. Although Kuna et. al., outlined that the maximum mandibular advancement measured 16.8mm under anesthesia for adults, we designed the jaw thrust to easily adhere to the varied anatomy of the vast patient population with anatomical differences, from adult to infant, both in semi-conscious and unconscious states. By slightly reducing the jaw thrust measurement from Kuna’s maximum advancement, we can assure that our LJT airways will conform to the broader patient population and still increase the airway across all pharyngeal airway measurements (see Figure 6 and Table 6a). By extrapolation, where Kuna saw an average of 16% increase across airway area, lateral diameter, and anteroposterior diameter at maximum mandibular advancement, we envision an average increase of 14% across these same measurements using our LJT airways.

**Figure 6. LJT Jaw Thrust**



**Table 6a. Dimensional Measurement of Airway & Jaw Thrust**

| OA Size (mm) | Airway Size  | Mandibular Jaw Thrust Length B (mm) | Jaw Thrust % Change |
|--------------|--------------|-------------------------------------|---------------------|
| 110          | XL Adult     | 14                                  |                     |
| 100          | Large Adult  | 13                                  | -7.1%               |
| 90           | Medium Adult | 12                                  | -7.7%               |
| 80           | Small Adult  | 11                                  | -8.3%               |
| 70           | Child        | 10                                  | -9.1%               |
| 60           | Child        | 9                                   | -10.0%              |
| 50           | Small Child  | 8                                   | -11.1%              |
| 40           | Infant       | 7                                   | -12.5%              |

As for functionality, we did away with the design-first limitation of the current hollow-body Guedel airway since it served no functional purpose and modified it with our own LJT design that incorporates a vertical dorsal channel to promote better airflow to the oropharynx area and to the nasopharynx, if the oropharynx is obstructed. Further, we have incorporated other design attributes (outlined in Table 8 below) into the airways to better control these anatomical structures that impacts the closure of an airway. It should also be noted that

without the jaw-thrust design element, the relaxed jaw will allow for the relaxed muscular tongue to fall back into the oropharynx because there is nothing to hold back or support it, resulting in an increased incidence of airway obstruction, causing complications for the anesthetist and the patient. As an added benefit, because the LJT design leverages the maxillary incisors as a fulcrum, with mandibular advancement, its allows for fixed positioning of the airway so it can free the hands of the practitioner, and also eliminates the need to perform a manual chin lift /jaw thrust during/after medical procedures.

Below outlines the mathematical basis of how we arrived at our bite block and main body C curve measurements for the LJT airways. They are based on using the percentage change size reduction of the device length and applying the dimensional change to the bite block length and C curve radius (Table 7a). This allows the device to have a uniformity across both LJT designs, which allows the device to have the same control and

impact to the anatomical structures of the oropharynx i.e., epiglottis, root of tongue, palate, fauces etc. Additionally, our LJT airways incorporate a ventral protrusion to protract the tip of the epiglottis, and push the root of the tongue forwards to prevent them from causing a pharyngeal airway obstruction, thus increasing the size of the oropharynx airway. Mandibular advancement, while pulling the tongue forwards would thereby enlarge the oro-pharyngeal airway by the anterior displacement of the hyoid bone and its muscular attachments and lifting the epiglottis away from the posterior pharyngeal wall, reversing the narrowing of the laryngeal inlet in combination with the oropharynx.

**Figure 7. LJT-E and LJT-O Oral Airways: Dimensional Specifications**



**Table 7a. LJT Oral Airway Dimensional Uniformity**

| Oral Airway Size (mm) | LJT Bite Block Length I (mm) | Bite Block Size % Change | Dimensional Change (mm) | JLT Airway H (mm) |
|-----------------------|------------------------------|--------------------------|-------------------------|-------------------|
| 110                   | 27                           |                          |                         | 83                |
| 100                   | 24                           | -11.11%                  | -3.00                   | 76                |
| 90                    | 21                           | -12.50%                  | -3.00                   | 69                |
| 80                    | 18                           | -14.29%                  | -3.00                   | 62                |
| 70                    | 15                           | -16.67%                  | -3.00                   | 55                |
| 60                    | 13                           | -13.33%                  | -2.00                   | 47                |
| 50                    | 11                           | -15.38%                  | -2.00                   | 39                |
| 40                    | 9                            | -18.18%                  | -2.00                   | 31                |

Additionally, unlike the LJT airways, in all current airways there are no provisions made to connect the oral airway to a mechanical ventilator to further free the hands of the caregiver. More importantly, the lower jaw-thrust mechanism can be incorporated in other airways, such as Ovassapian, Williams, etc., for better management of an airway.

**Table 8. How the new embodiments of the LJT Oral Airway works to eliminate the problems faced by the traditional Guedel, Berman, Ovassapian, Williams airways and such.**

| <b>Problems / Setbacks:<br/>Using the current Guedel and Berman Oral Airways</b>  | <b>LJT Solution:<br/>How the New Lower Jaw Thrusting (LJT) Oral Airway Solves the Impediments</b>   |
|---|---|
| If placed improperly the lower jaw moves back with the tongue due to flaccid genioglossus and tongue muscles, it can further depress the tongue into the back of the throat, further blocking the airway. Further, sometime the oral airway can block the oropharyngeal air passage and block the nasopharynx airway resulting in lack of oxygen delivery to the posterior part of the naso-oropharynx-laryngeal pharynx. | <b>Mandibular Jaw-Thrust Flange:</b> thrusts the lower jaw to pull the flaccid tongue with the genioglossus muscle away from the oropharynx, and fauces forward by leveraging the maxillary incisor teeth which, in turn, act as a “fulcrum” without manual manipulation, thus controlling and increasing the opening of the oropharyngeal airway by preventing the tongue from covering the epiglottis, due to forward thrusting of the jaw and root of the tongue |

|  |  |
|--|--|
| <p>Current oral airways designs do not address the needs for overweight / obese patient populations. The obese patient population is more difficult to extend the neck, thrust the jaw forwards and hold it in position to establish an easy ventilation airway. It also increases the difficulty of mask ventilation since they tend to have larger, short, thicker necks and tongues, along with more redundant soft tissue in the oropharyngeal air passage and fauces.</p> | <p><b>Obese Support:</b> The LJT design addresses the need to establish an easy ventilation airway for overweight or obese patients as well as for fiberoptic applications to introduce endotracheal tubes and for fiberoptic examination of the laryngo tracheobronchial tree and GI tract.</p>   |
| <p>During induction of anesthesia and CPR, it is currently necessary to use both hands to maintain the mandibular protracting jaw-thrusting oral airway maneuver, while usually needing another person's assistance. Thus, preventing or, at least, making it more difficult from attending to the comatose, sedated or anesthetized patient. Once the oral airway is placed, it is still difficult to free one or both hands.</p>   | <p><b>Hand Free Use:</b> Once the airway is inserted, both hands of the caregiver / practitioner are free to attend to other needs of the patient because the device is locked in place by a "fulcrum". This airway will open the oropharynx airway and be wide open due to mandible thrusting by the pulling of the tongue by genioglossus muscle and tongue away from the palate and posterior airway of the oropharyngeal air passage.</p>  |
| <p>As the oral airway is introduced, the tongue can slip around the oral airway and obstruct the airway. There is nothing to prevent the tongue falling back and causing airway obstruction. The present commonly used oral airways lack any such embodiment to overcome this.</p>   | <p><b>Horizontal Ventral Ridges:</b> current oral airways cannot prevent the backward movement of the slippery flaccid tongue so the addition of horizontal ridges on the ventral body surface applies pressure to provide better support of the tongue and prevents the falling back to the hypo-pharynx, thus stabilizing the oropharynx airway opening.</p> <p><b>Ventral Plate Extension:</b> the plate extensions placed ventrally lower to the curved part of the airway provides better support from the tongue falling laterally, thus increasing the side-to-side dimensions of the oral airway opening, and holding it fixed to the center of the mouth.</p> |
| <p>Current airways have no mechanism to prevent the root of the tongue moving back on the epiglottis and to the pharyngeal wall. The present commonly used oral airway lack such an embodiment.</p>  | <p><b>Ventral Hump:</b> a projection which depresses the root of the tongue above the epiglottis. It prevents it from moving back on the epiglottis and oropharynx to block the oral airway in the unconscious or semiconscious. It holds the tongue away from the posterior pharyngeal wall allowing air to enter the larynx on both sides of the projections also.</p>   |
| <p>When ventilation is assisted with Ambu bag, it is necessary to use extra force to get the air into the air passage and the lungs due to the soft tissue of the flaccid tongue falling back, and the fauces collapsing along with the jaw moving back.</p>   | <p><b>Less Exertion:</b> due to mandibular protracting jaw-thrusting effect, the oropharynx airway is unobstructed, allowing for easy ventilation with Ambu bag with the least amount of exertion, and with increased airflow pressure.</p>  |
| <p>The various sizing of the buccal bite block and C curve in the present Guedel and Berman oral airway have no uniformity or standardization resulting in mixed performance and control of the oropharynx airway.</p>   | <p><b>Uniform &amp; Standardized:</b> LJT airways are all designed adhering to uniformed and standardized calculations, measurements and dimensions so as to control the tongue and oro-pharynx airway from patient to patient.</p>  |
| <p>During intubation and fiber optic scoping of airways and esophagus, present commonly used oral airways lack access points and cannot be modified to be used for these examinations and intubation.</p>  | <p><b>Bite Block Inlet Openings:</b> newly designed side ports function as intubation guides to facilitate multiple insertion routes for endoscopes, suction or oxygen delivery catheters, endotracheal tubes, and related medical devices due to its free-floating design of the mouth piece and C curve in the oral cavity.</p>  |

|   |   |
|---|---|
| <p>The present Guedel airway lacks any provision for ventilation and for suction of secretions from the rest of the oral cavity from the sides due to lack of holes</p> | <p><b>Ventilating Holes:</b> holes on the dorsolateral surface of the LJT airway allows oxygen and air to enter the nasopharynx, in case the oropharynx is obstructed due to any number of reasons. Sometime the oral airway can block the oropharyngeal air passage and block the nasopharynx airway due to lack of oxygen delivery to the posterior part of the naso-oropharynx-laryngeal pharynx. The presence of holes on both mid-lateral positions will allow the oxygen to enter this area and also helps in the suctioning of secretions and regurgitated fluids from the oral cavity, delivery of air to nasopharynx, if the oropharynx is obstructed.</p> |
| <p>Current airways do not allow for hands-free ventilation.</p>   | <p><b>Connector for Ventilator:</b> can be provided to allow connection to the LJT oral airway external opening with a mechanical ventilator or Ambu bag away from the patient's mouth for ventilation, thus freeing both hands, or away from the patient for another practitioner to ventilate, thus freeing the primary caregiver so they can attend to other patient needs.</p>  |

**TESTING**

The LJT oral airway was tested on 10 healthy adult volunteers under oral cavity local anesthesia to prevent gagging and retching. After inserting the LJT, it was obvious that the airway allowed for increased ventilation, which led us to the conclusion that the airway was successful in controlling the many structures and, thus, increasing the opening of our subject's airway, as outlined by the Kuna study. We also ventilated with Ambu bag with ease. The volunteers did not feel any discomfort. After one-hour of use, we examined the oral cavity and did not notice any mechanical trauma to the mucosa of the oral cavity using our new LJT oral airway.

Another key finding was that the LJT design addressed the need and established an easy ventilation airway for the overweight or obese volunteers we tested. Using the LJT airway allowed them to breath with ease, which indicated this airway is well suited to use in obese patients who have breathing problems, and in patients the macroglossia. This patient population increases the difficulty of mask ventilation since they tend to have larger, thicker necks and tongues, along with more redundant soft tissue in the oropharyngeal area. Therefore, it is more difficult to extend the neck and thrust the jaw forwards to establish an easy ventilation airway since surrounding structures are being forced to collapse due to an oversized tongue, narrow fauces, fatty tissue and gravity.

As we continue to educate the anesthesiology community on the LJT airway design and on its many advantages, we will continue to test this in a university and other research settings, and the subsequent study will be published in a peer reviewed journal.

**CONCLUSION**

After taking a hard look and thoroughly testing current airways on the market, examining the studies of Kuna et.al. and Isono et al., it is easy to understand why the newly designed LJT airway which incorporates uniformity, standardization, and the jaw-thrust mechanism that holds the lower jaw forwards, and which pulls the genioglossus muscle of the tongue and prevents it from falling back to limit the obstruction of the oropharyngeal airway is a major step forward. In combination, it also lifts the hyoglossus muscle with the root of the tongue, and the epiglottis, opening the pharyngeal airway. And by adding other important embodiments, improves the functionality to open the oropharyngeal airway, ventilation through nasopharyngeal airway, opens the fauces and increases the practitioner's ability to provide better ventilation directed to the larynx and

respiratory passages of the lungs, and at the same time provides for improved patient care. Furthermore, we also understand that change is hard but our hope is that with all of the improvements incorporated, it should change how airways are viewed and disrupt the oral airway market while providing a better solution to an age-old issue associated with the use of current dated products. In time, LJT airways should become the airway management device that is demanded by practitioner's and should become the de facto standard oral airway used all over the world. The time has finally arrived to advance this aspect of the past.

#### References cited and consulted:

- 1) Guedel A. E. J. Am. Med. Assoc. 1933, 100, 1862 -reprinted in "Classical File", Survey of Anesthesiology 1966,10, 515.
- 2) Dickinson Ed; Dan Limmer; O'Keefe, Michael F.; Grant, Harvey D.; Bob Murray (2008). Emergency Care (11th Edition). Englewood Cliffs, N.J: Prentice Hall. pp. 157–9.
- 3) Aaron M. Joffe et.al., A Two-handed Jaw-thrust Technique Is Superior to the One-handed "EC-clamp" Technique for Mask Ventilation in the Apneic Unconscious Person. Anesthesiology 2010; 113:873–9.
- 4) Berman: U.S. Pat. Nos. 4,067,331, 4,054,135, and 3,930,507.
- 5) Aaron M. Joffe, D.O.; Scott Hetzel, M.S.; Elaine C. Liew, M.D. A Two-handed Jaw-thrust Technique Is Superior to the One-handed "EC-clamp" Technique for Mask Ventilation in the Apneic Unconscious Person. Anesthesiology 10 2010, Vol.113, 873-879).
- 6) Kheterpal S, Han R, Tremper KK, Shanks A, Tait AR, O'Reilly M, Ludwig TA: Incidence and predictors of difficult and impossible mask ventilation. Anesthesiology 2006; 105:885–91
- 7) Murashima K, Fukutome T: Effect of jaw-thrust maneuver on the laryngeal inlet. Anaesthesia 1998; 53:203– 4.
- 8) Uzun L, Ugur MB, Altunkaya H, Ozer Y, Ozkocak I, Demirel CB: Effectiveness of the jaw-thrust maneuver in opening the airway: A flexible fiberoptic endoscopic study. ORL J Otorhinolaryngol Relat Spec 2005; 67:39 – 44.
- 9) Stacey MR, Rassam S, Sivasankar R, Hall JE, Latto IP: A comparison of direct laryngoscopy and jaw thrust to aid fibreoptic intubation. Anaesthesia 2005; 60:445– 8.
- 10) Meier S, Geiduschek J, Paganoni R, Fuehrmeyer F, Reber A: The effect of chin lift, jaw thrust, and continuous positive airway pressure on the size of the glottic opening and on stridor score in anesthetized, spontaneously breathing children. Anesth Analg 2002; 94:494 –9.
- 11) Shantha T.R: continuation patent application on new airway, and claims priority under 35 U.S.C. §120 to, U.S. nonprovisional patent application Ser. No. 62490658 filed on April 27<sup>th</sup> 2017, which nonprovisional patent application is incorporated by reference herein- Utility patent and worldwide patents pending.
- 12) Weiser TG et.al., Size and distribution of the global volume of surgery in 2012, *Bulletin of the World Health Organization* 2016;94:201-209F.
- 13) Weiser et.al., An estimate of global volume of surgery; Lancet 2008; 372: 139–44.
- 14) Safar P, Escarraga LA, Elam JO: A comparison of the mouth to mouth and mouth-to-airway methods of artificial respiration with the chest-pressure arm-lift methods. N Engl J Med 1958; 258:671–7.
- 15) Safar P, Lourdes A, Chang F: Upper airway obstruction in the unconscious patient. J Appl Physiol 1959; 14:760 – 4). In 1958–9,
- 16) Whittingham H, Discussion on Artificial Respiration Proc R Soc Med. 1960 May; 53(5): 311–316.
- 17) Kuna ST, Woodson LC, Solanki DR, Esch O, Frantz DE, Mathru M: Effects of progressive mandibular advancement on pharyngeal airway size in anesthetized adults. ANESTHESIOLOGY 2008; 109:605–12.
- 18) Isono S: Optimal combination of head, mandible and body positions for pharyngeal airway maintenance during perioperative period: Lesson from pharyngeal closing pressures. Semin Anesth Periop Med Pain 2007; 26:83–93
- 19) Isono S, Tanaka A, Tagaito Y, Sho Y, Nishino T: Pharyngeal patency in response to advancement of the mandible in obese anesthetized persons. ANESTHESIOLOGY 1997; 87:1055–62.
- 20) Murashima K, Fukutome T. Effect of jaw-thrust manoeuvre on the laryngeal inlet. Anaesthesia 1998;53:203–204.
- 21) Nandi PR, Charlesworth CH, Taylor SJ, Ninn JF, Dore CJ. Effect of general anesthesia on the pharynx.Br J Anaesth 1991;66:157–162.