**Proposed Research Protocol Form**
**Northwestern University Medical School**
**Department of Anesthesiology Research Committee**

Title: Does Spatial Orientation Affect the Rate of Learning Fiberoptic Intubation Skills in the Novice: A Randomized Controlled Trial

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**Research Aims:**

1. **Research Questions(s)** (1) Does spatial orientation of a novice in relation to a mannequin (supine vs upright) impact on the development of fiberoptic intubation skills (2) Is it necessary to teach both orientations or is the supine view transferable to the upright position. (3) Which method demonstrates longer skill retention.

2. **Hypotheses** (1) Both orientations must be practiced. (2) The upright skill is harder to learn but is retained for longer.

**Research significance:**

**Background:** With the introduction of the Glidescope in the 2000's, fiberoptic skills are not practiced as frequently as in the past. We are frequently challenged with difficult airways in both the operating room and ICU. Patients with adult epiglottitis, upper airway tumors, severe OSA, CHF present sitting up frequently drooling because the added weight of the lung helps "tent open" the airway. These patients are not Glidescope candidates. Currently, a mannequin consisting of a rubber model mold of the airway is the only cost effective training tool that can be used by the novice to develop the necessary hand-eye co-ordination skills needed for successful fiberoptic intubation. Virtual reality systems that incorporate a real bronchoscope handle interfaced with a computer and monitor could represent an ideal teaching tool, but are expensive. The Orsim trainer can provide fibroptic training in both the supine and upright positions, but costs $18,000. We developed a simple, inexpensive application, *iLarynx*, for the iPhone or iPad that gives the novice the ability to practice fiberoptic intubation without going to a designated skills lab. A recent MEDLINE review of the literature concludes that training on nonspecific video

games improves endoscopic performance of novices when tested on simulators. The iLarynx is available for free at the iphone app store . At present, over 75,000 copies were distributed worldwide. Our study, that the iLarynx helps improve acquisition of the skills needed for fiberoptic intubation, was accepted for publication in the journal Anaesthesia.

**Significance:**

Novices better prepared in the skills of manipulating a fiberoptic will take less time and have a higher success rate of fiberoptic intubation. These skills must be taught for both spatial orientations and practiced to be retained

**Investigational Plan:**

Following IRB approval, written consent to participate in the study will be obtained from medical students

**Phase one :**

Sixty medical students, novices in fiberoptic intubation use will be recruited and randomly assigned into one of two groups:

**Group A** (supine-supine) will first practice fiberoptic intubation with the iLarynx oriented in the supine position. Learning curves, global rating scale and checklist will then be obtained by a blinded examiner with the medical student using a real fiberoptic on a mannequin oriented in the supine, then upright position. At the end of one week,the same medical student will then perform the intubation with the mannequin in both positions.

**Group B** (upright-upright) will first practice fiberoptic intubation with the iLarynx oriented in the upright position. Learning curves, global assessment score and checklist will then be obtained by a blinded examiner with the medical student using a real fiberoptic on a mannequin oriented in the upright then supine position. At the end of one week, the same medical student will then perform the intubation with the mannequin in both positions.

**Group C** (supine –upright) will first practice fiberoptic intubation with the iLarynx oriented in the supine position. Learning curves, global assessment score and checklist will then be obtained by a blinded examiner with the medical student using a real fiberoptic on a mannequin oriented in the upright then supine position. At the end of one week, The same medical student will then perform the intubation with the mannequin in both positions.

**Group D** ( upright – supine) will first practice fiberoptic intubation with the iLarynx oriented in the upright position. Learning curves, global assessment score and checklist will then be obtained by a blinded examiner with the medical student using a real fiberoptic on a mannequin oriented in the supine, then upright position. At the

end of one week, the same medical student will then perform the intubation with the mannequin in both positions.

| | teaching | | | testing | testing | | week | testing | testing |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |
| A | supine | | | supine | upright | | i/droid | upright | supine |
| | | | | | | | | | |
| B | upright | | | upright | supine | | i/droid | supine | upright |
| | | | | | | | | | |
| C | supine | | | upright | supine | | i/droid | upright | supine |
| | | | | | | | | | |
| D | upright | | | supine | upright | | i/droid | upright | supine |

**Phase two:**

Sudy candidates will randomly be assigned (20 per group) to practice for 15minutes/day their intubations skills with the iLarynx application downloaded to their smart phones or Ipads. The other group (20candidates) will be asked not to practice their intubation skills. At the end of one week both groups will be retested on a mannequin by the same blinded examiner to obtain a new learning curve, global assessment score and checklist. Both orientations of the mannequin will be tested and the order randomly assigned.

**Statistical Methods:**

60 medical students will be consented to allow for dropout. Based on a repeated – measures design with one between-factor design (supine vs upright) and one within factor (repetitions), four groups with 10 subjects each with each subject measured 10 times, achieves 87% power to measure a difference in time to visualize the carina using a Geisser -Greenhouse Corrected F-test at a 5% significance level assuming an effect size of 0.7. Groups A ,B,C,D will be compared. The two outcome measures global rating scale (GRS) and examiner check list (ECL) scores will be analyzed using a two-way, mixed design ANOVA. Categorical data such as success failure will be analyzed by Fisher exact test. Time to intubation will be analyzed using the MannWhitney U test.

**Inclusion Criteria:**

**Medical Student:**

Inclusion criteria for the medical student:

-Medical student or intern rotating through the anesthesiology department

Exclusion criteria for the medical student:

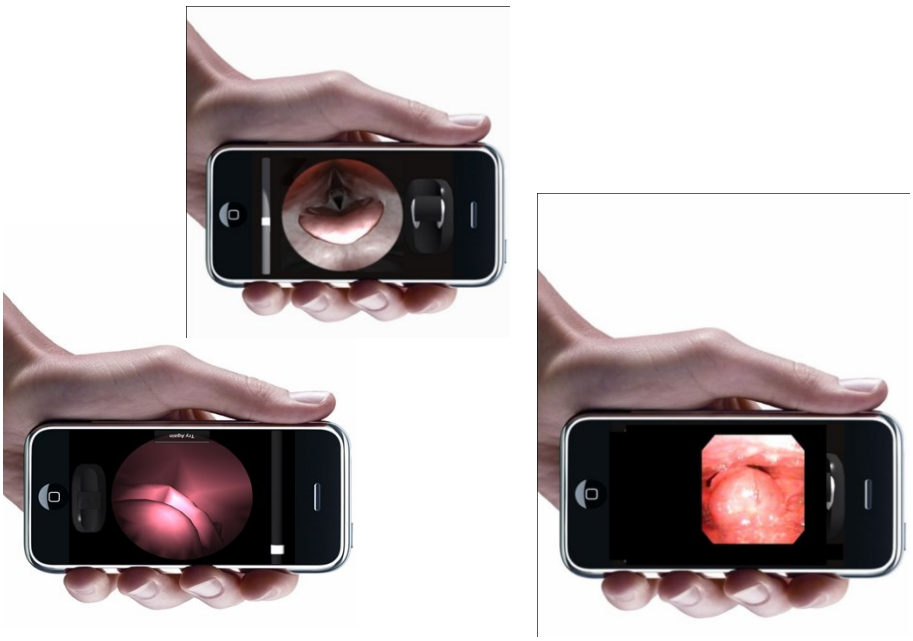
- Previous fiberoptic training
- Refuses participation

**Risks/Benefits:**

There is a risk of loss of confidentiality for the medical student. The medical student may feel anxious performing tasks while being evaluated. The benefit of this study is that the students may benefit by acquiring more quickly the skill set needed for fiberoptic intubation of a mannequin.

**Confidentiality:**

The medical students' identity will be guarded by assigning a numerical code which is only known by the principal investigator. Data is stored in a department computer which is password protected. Subject data will be stored on secure computers at Northwestern University. Data access will be password protected and only available to study investigators. The data forms are only identified using study code number. Data will be destroyed 7 years post manuscript acceptance. The departmental protocol will be followed using current vendors for paper and electronic record destruction.



**Virtual vallecular cyst** **Real vallecular cyst**

# Figure 1: iLarynx

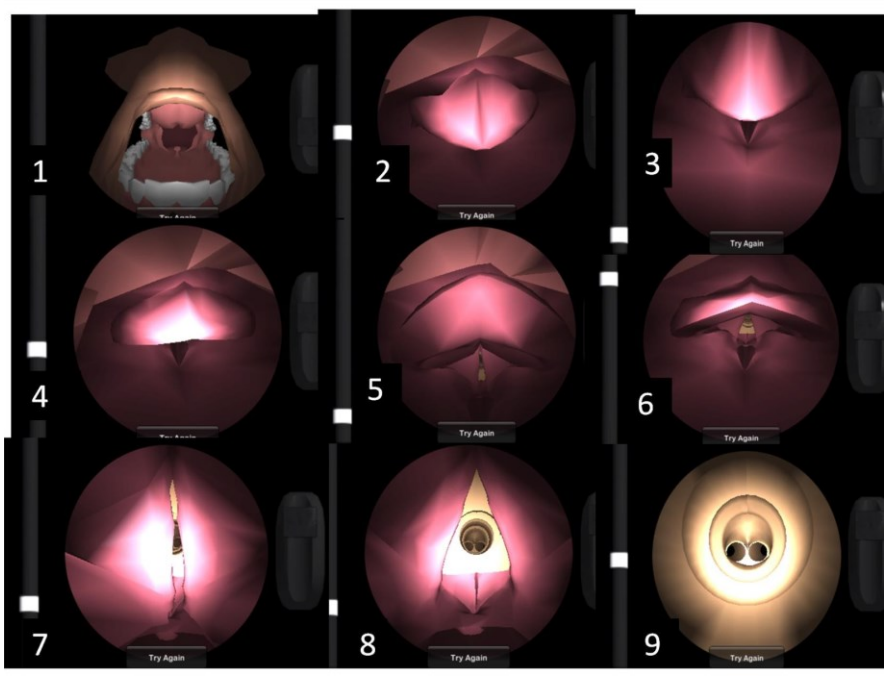
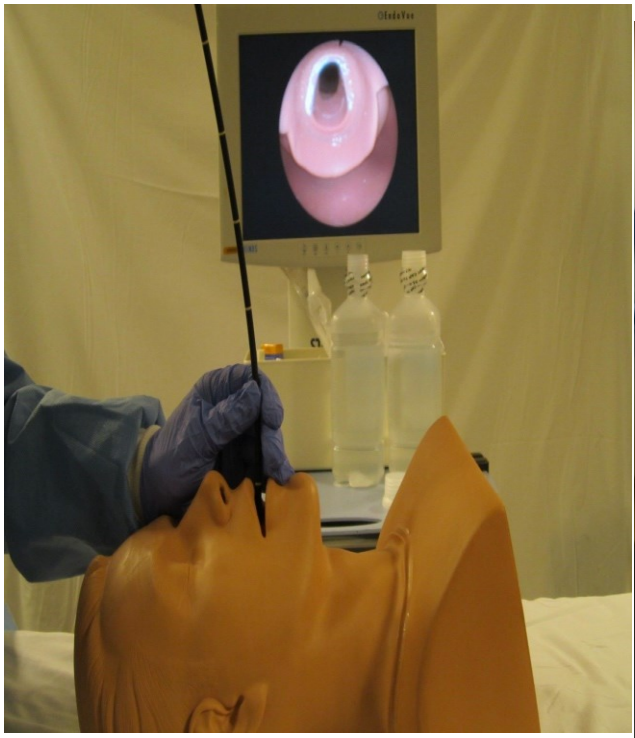



**Figure 2 iLarynx supine view**

# Figure 3 : orientation (supine vs upright)



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Five-Point Global Rating Scale of Fiberoptic Bronchoscope Manipulation Ability:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| Repeatedly makes tentative or awkward moves with bronchoscope by inappropriate use of scope | | Competent use of instruments but occasionally appears stiff or awkward | | Fluid manipulation of bronchoscope and no awkwardness |
| Very poor | | Competent | | Clearly superior |

***EXAMINER CHECKLIST***

| | | CORRECTLY | INCORRECTLY |
|---|---|---|---|
| 1 | Hold control section correctly in one hand with thumb positioned for flex/ext control, and index finger for suction | | |
| 2 | Focuses scope using appropriate external object | | |
| 3 | Controls tip of scope with other hand | | |
| 4 | Introduces bronchoscope into mouth, centered | | |
| 5 | Maneuvers bronchoscope through oropharynx and visualizes cords | | |
| 6 | Passes cords | | |
| 7 | Continues insertion of bronchoscope to level of carina | | |
| 8 | Passes endotracheal tube atraumatically | | |
| 9 | Reconfirms vision of carina after ET tube in situ | | |
| 10 | Removes bronchoscope smoothly | | |
| 11 | Checks for $etCO_2$ | | |

Time Elapsed: _____

Overall Rating: _____

**Consent:** Attached