

ABSTRACT

The goal of this project is to develop an endotracheal tube securing device. The device proposed would attach to the mouth and hold varying sizes of tubes. While an endotracheal tube is in the airway during surgery, internal forces from the airway and external forces from surgical environment can move the tube in and out or side to side in the mouth. This device would prevent any unexpected movement of this kind and allow for control of movement that is required for adjustment. The device would function adequately when the patient is in the prone position.

BACKGROUND

- Over 27 million surgeries are performed every year in the U.S.^[1]
- General anesthesia is used commonly among these procedures, and 80% of anesthesia cases involve endotracheal intubation.^[2]
- After insertion, the endotracheal tube is secured to the patient to prevent lateral and anterior motion of the tube in the mouth.
- Current methods:

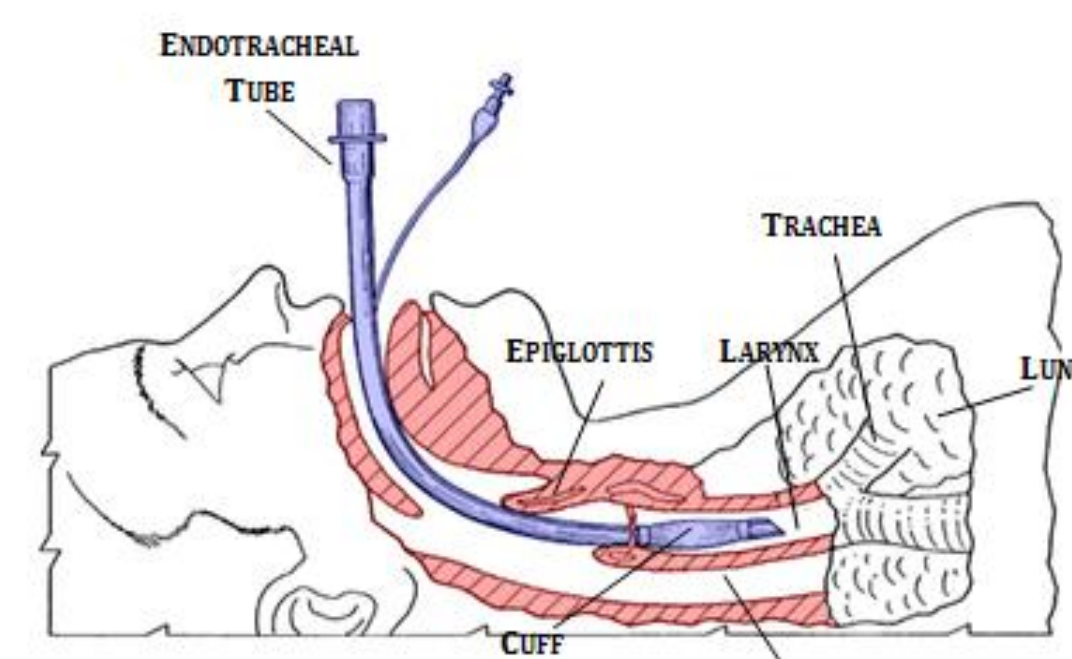


Figure 1: Diagram of endotracheal intubation^[3]



Figure 2: Standard Taping^[4]



Figure 3: Cloth Strap^[5]



Figure 4: Thomas™ Holder^[6]

MOTIVATION

PROBLEM STATEMENT: Our goal is to make a device that can hold the endotracheal tube in place during surgery, while not obstructing access to the face.

- Current methods used while patients are in the prone position do not properly hold tube in place
- Bulkiness and obstruction of access to the face can interfere with surgery

DESIGN SPECIFICATIONS

- Perform for up to 10 hours
- Adjust to different tube diameters (2mm-9mm)
- Be made of non-toxic materials
- Fit and function properly within the patient's mouth
- Patient in the prone position
- Withstand forces that would move the tube from its proper position
- Comply with Class I FDA regulations
- Designed for single use

FINAL DESIGN

- Mouth guard:** Shock Doctor Adult Max Strapped Mouth Guard
 - Heavy-duty, shock resistant outer layer
 - Fits most adult mouth sizes
 - Ethylene vinyl acetate inner lining material capable of a boil-and-bite personalized fit
 - Protrusion from front is ideal for connecting tube holder
- Tube holder:** UT Wire D-Wing
 - Small size (12.7mm x 12.7mm x 19.1mm)
 - Foam has good amount of flexibility for holding tube in place
 - Flat base for strong adhesion to mouth guard
 - Kept in place on mouth guard using cyanoacrylic glue
- In use with patient:**
 - Before surgery, the mouth guard is boiled and fit in patient's mouth
 - After inserting endotracheal tube, the mouth guard is secured in the mouth
 - Tube is inserted into foam holder and left for duration of surgery

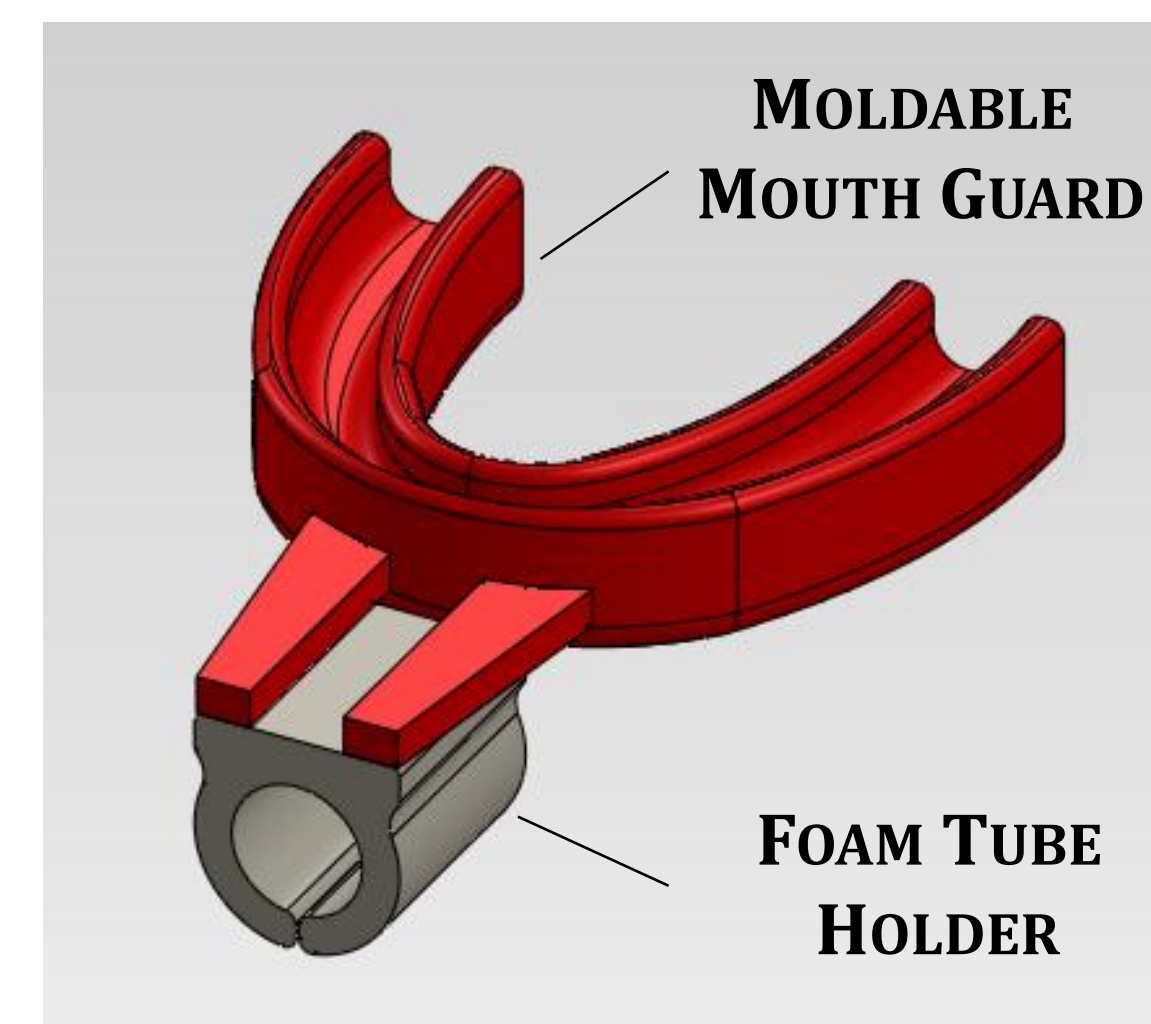


Figure 5: SolidWorks model of final design

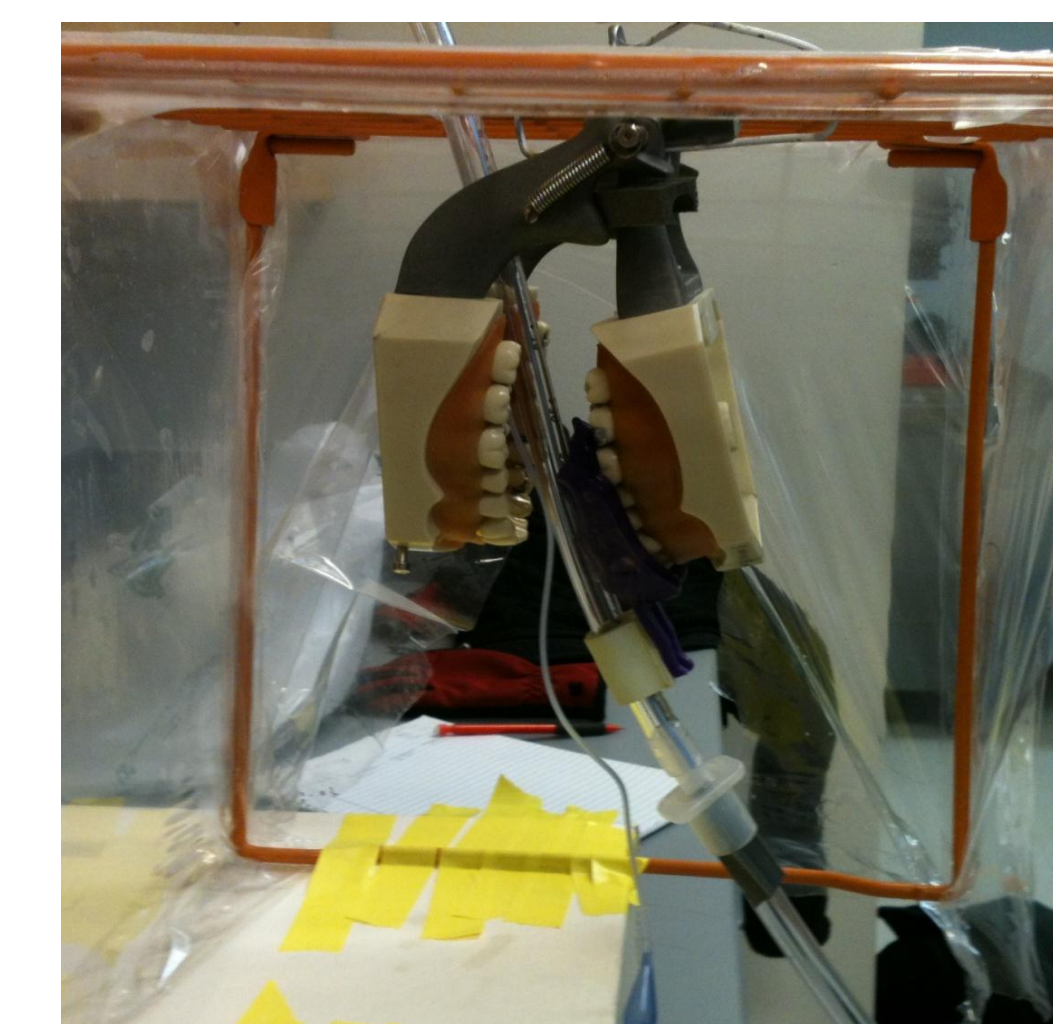


Figure 6: Fully attached device in prosthetic mouth

TESTING PROCEDURE

- Unable to test on patients; replicated human mouth environment
- Acquired prosthetic dental models (one normal set, one set missing teeth)
- Boiled and fit separate mouth guards to the model teeth
- Placed mouth guard on dampened teeth and inserted endotracheal tube
- Connected other end of tube to metal stand at same height as a ventilator and the mouth
- Two different types of tests
 - Long-term loading: 300g added weight on tube overnight to simulate average breathing circuit weight over long surgeries
 - Maximum allowable loading: weights of varying mass added on tube to simulate different breathing circuit weights (100g-900g). Additional variables below were investigated in these trials.
- Humidity was varied with presence or absence of a water boiler in plastic wrap chamber
- Angle was varied by moving the "ventilator" to different distances
- Tape was applied around the tube to test the allowable load purely of the mouth guard
- In all maximum loading tests, masses were added until the tube holder or mouth guard failed, or reached it weight greater than any standard breathing circuits



Figure 7: Humidified testing environment

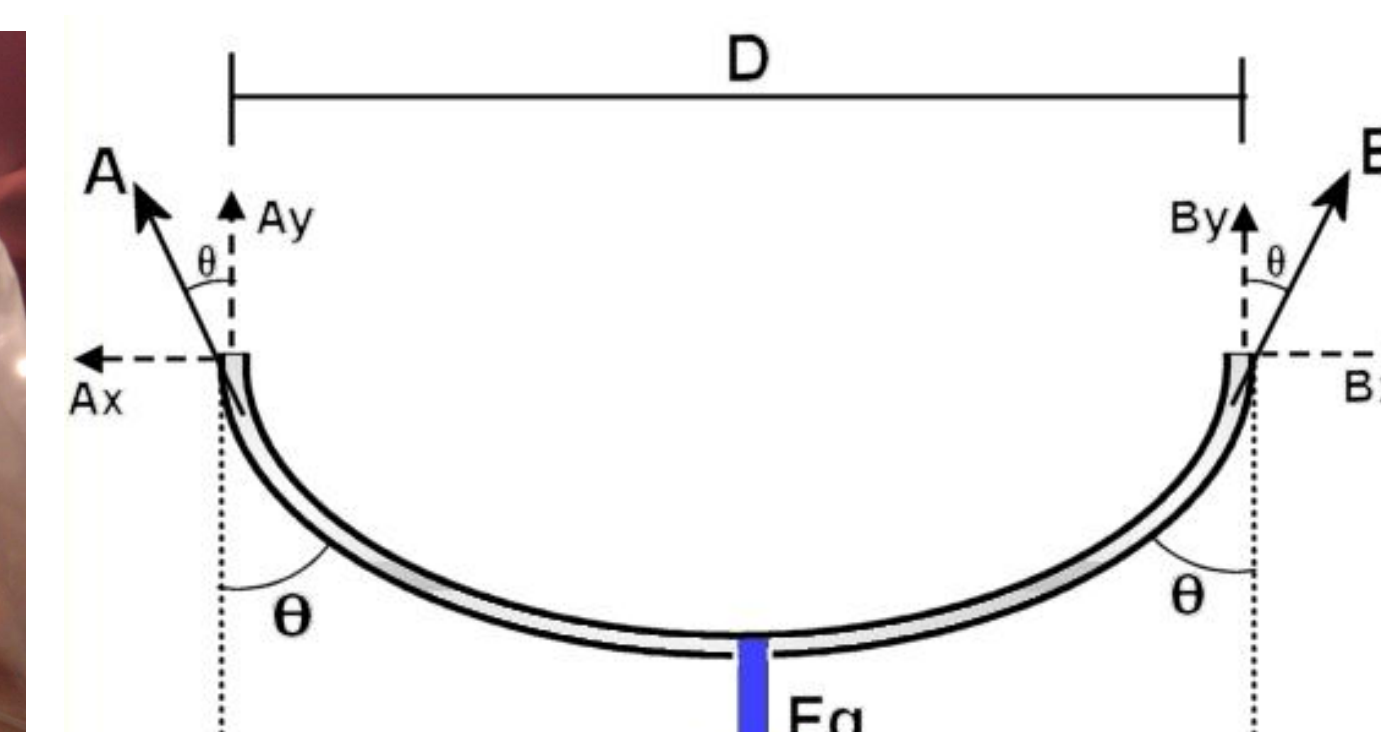


Figure 8: Free body diagram of breathing circuit tubing. The tubing is approximated as pinned at A (the patient's mouth) and B (the anesthesia ventilator). The weight of the breathing circuit is F_g and the angle of insertion is θ .

RESULTS & DISCUSSION

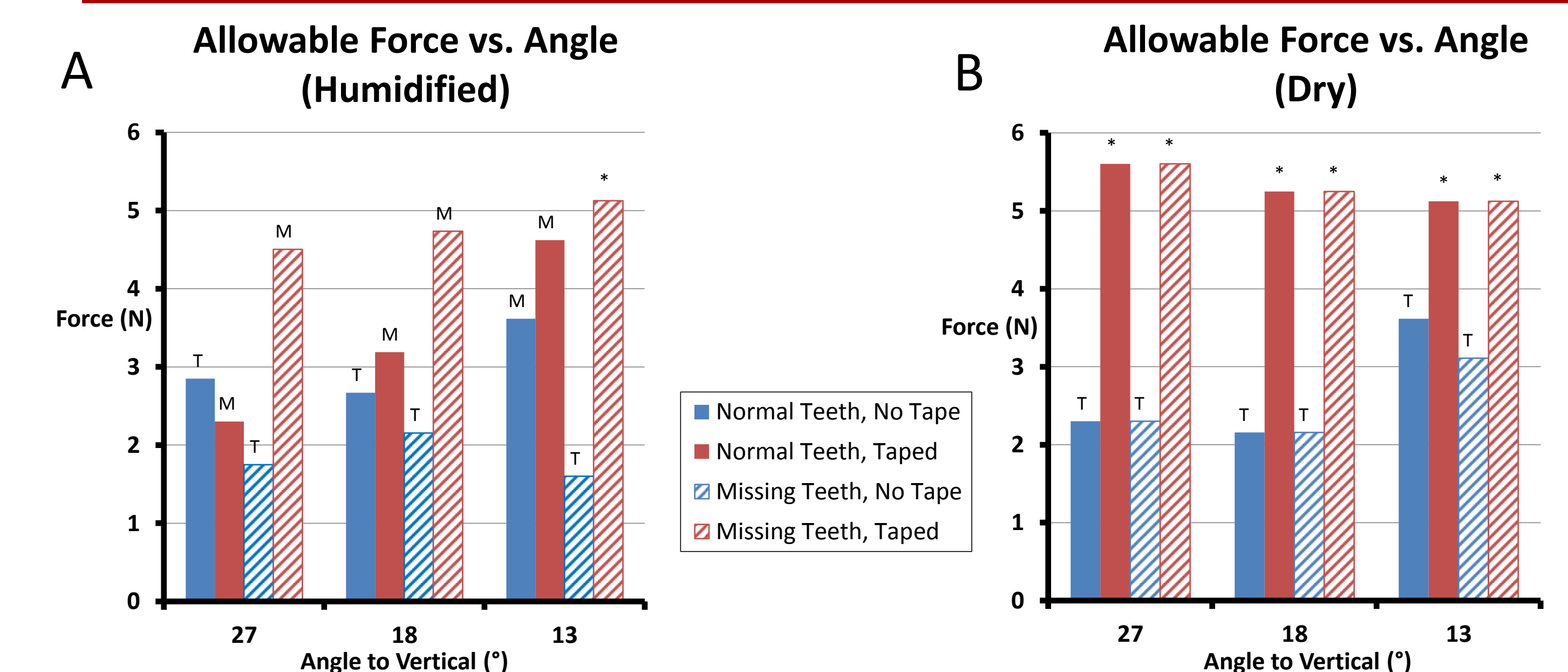


Figure 9: Maximum force allowed before failure. (A) In a humidified chamber, maximum force allowed versus angle between endotracheal tube trajectory and the vertical (see Figure 8) is shown. Force was applied as added weight to center of the simulated breathing circuit. One standard prosthetic mouth model (solid bars) and one model with missing teeth (striped bars) were tested. To determine the force required to cause the mouth guard to dislodge, separately from the force required to displace the tube from the tube holder, the tube was secured to the holder with tape in one condition (red). It remained unsecured in the other condition (blue). ^M denotes a failure in which the mouth guard was dislodged. ^T denotes a failure in which the tube was dislodged from the tube holder. * denotes a trial in which the device withstood an excessively high force and did not fail. (B) In a dry chamber, the same experimental conditions as (A) were applied.

DISCUSSION:

- The design remained intact after long-term loading at .418kg for 10 hours, longer than the average surgery^[2]
- Regardless of conditions, the device had a higher maximum allowable loading force than would be applied by widely-used breathing circuits^[1] (calculated as 1.61 N)
- Generally, allowable force increased as angle decreased
- Humidity decreased the allowable loading compared to the dry condition
- The device performed equally for the two sets of prosthetic teeth
- In the taped condition, the device withstood more force
- Many failures in all of the non-taped (normal) conditions were tube holder malfunctions, suggesting mouth guard portion of the design was successful

FUTURE WORK

- Find material for tube clamp that is more compatible with mouth guard
- Adjust design to include altered tube clamp
- Adjust mouth guard design for increased stability
- Expand testing protocol
- Formulate plan for mass production

ACKNOWLEDGEMENTS

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