The IntuBed: Upper Body Positioning for Surgical Intubation

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The IntuBed

Clinical Background & Need

Clinical Problem:

In the practice of anesthesiology, great care must be taken to position patients properly for endotracheal intubation. This includes extending and flexing the patient's neck and lifting the head to visualize the vocal chords by aligning the pharyngeal and laryngeal axes (Fig. 1), achieving what is known as the sniffing position. Such positioning becomes difficult when patients are overweight or have excess tissue around their necks, posing the risk of soft tissue collapse which can fully obstruct view of the vocal cords. To combat this issue ramped position is indicated to open the chest and allow excess tissue to fall back. While multiple devices exist to aid in reaching these positions, they are ignored in lieu of towels and linens (Fig. 2). Not only is this system imprecise, but it forces the care team to manually lift and position patients. This poses the risk of improperly positioning the patient for intubation which can lead to stroke risk, nerve/brain damage, or even death and puts the medical staff in risk of musculoskeletal injuries arising from excess strain.

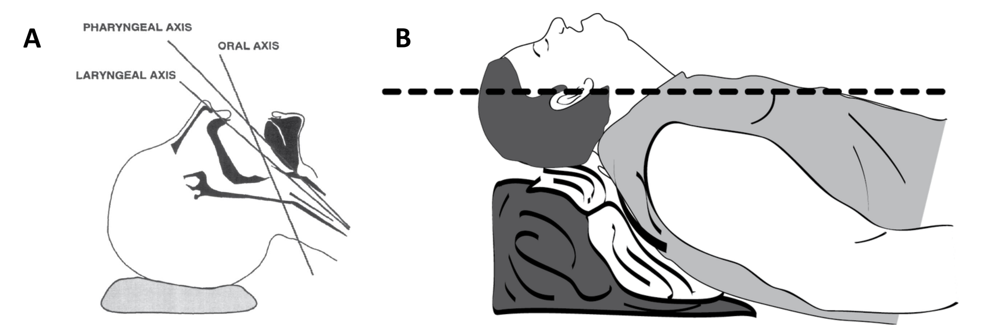


Figure 1 a-b: a. The sniffing position, demonstrating the alignment of the laryngeal and pharyngeal axes b. Schematic of a patient in a ramped position with reference to 0°.

Need Statement:

{ An adjustable mechanism is needed to safely and certainly position the upper body of patients for intubation. }

Market Gap & Goals

Market Background:

- Intended users: anesthesiologists and certified nurse anesthetists performing intubations on severely overweight to obese patients
- 42 Million+ procedures requiring intubation in the US alone
  - Comorbidities associated with common surgical causes often stem from excess weight
- Adverse outcomes can yield longer hospital stays at $2,300/night, with the potential of $100,000s more in bills depending on severity
- $1 Billion+ Forecasted market size for surgical beds in the US by 2022 with 3.9% annual growth

Current Solution Limits:

- Solutions include gel head donuts/rings, foam blocks, a ramp under the patient, and a jaw elevation device

→ Multiple options yet towels and linens are mostly used in the operating room. Why?

- Current solutions aren't adjustable, segmented, or precise, still require physical labor, and cannot be easily removed for surgery

→ These limitations form the basis of the requirements for The IntuBed

Project Goal:

- To create a stand-alone system that can adequately lift and lower a patient incrementally at the flip of a switch, thus providing a safe and effective way to achieve proper positioning during surgical intubation

Segmented — Mechanically Adjustable — No Physical Labor — Diverse — Precise

Proposed Solution

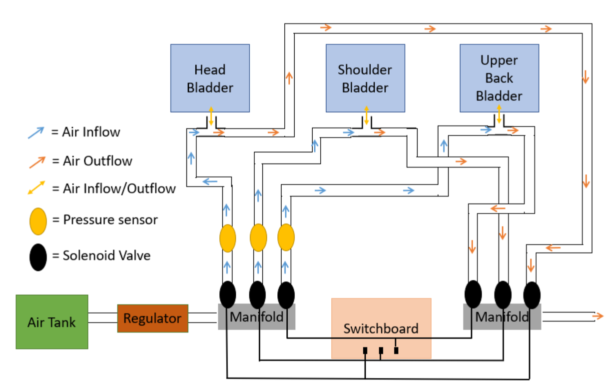


Figure 3: Schematic of device operation and airflow.

- High pressure air tank
  - Pressure decreased by regulator
- Airflow reaches manifold
  - Air to bladders controlled via inlet solenoid valves by user
- Air moves into 1-3 bladders until reaching hydrostatic equilibrium or until valve is closed by user

→ Patient is lifted

- Air flows out once switch flipped down to open outlet solenoids
  - Bladder moves from high pressure to lower atmospheric room pressure

→ Patient is lowered

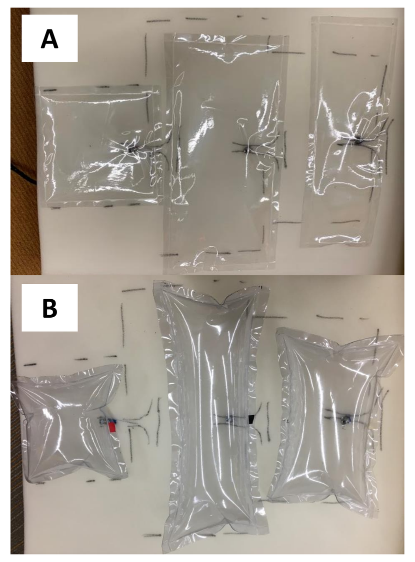


Figure 4a-b: Bladders in fully a. deflated and b. inflated states.

- Material: 8-gage Polyvinyl chloride (PVC)
  - Compliant, water-resistant, inert
- Edges heat-sealed
- ¼" quick-connect and nut fastener form dual inlet/outlet
- Able to withstand weighted cyclic strain
- Dimensioned to fit the head, shoulders, and upper back of a 1.741 m male

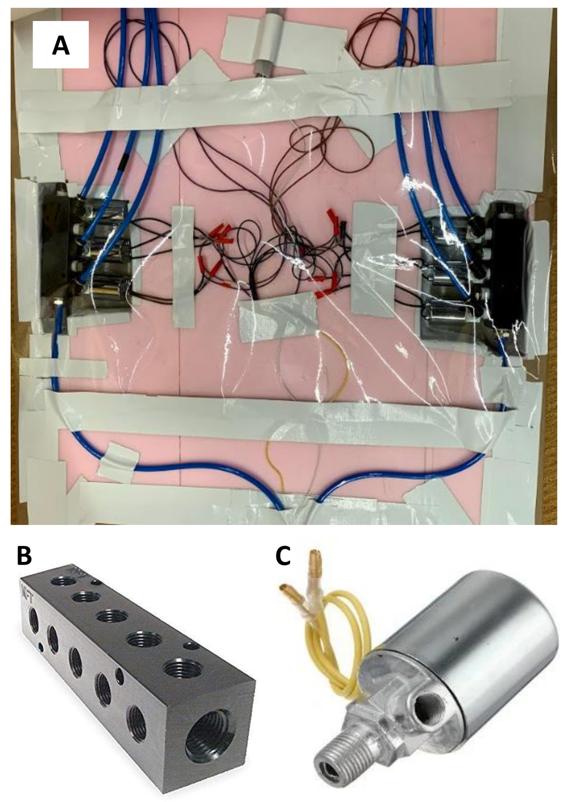


Figure 5a-c: a. Manifold and solenoids tethered into the baseboard of the device b. Detached manifold c. Detached solenoid

Manifolds

- Material: Anodized aluminum
- Dimensioned to fit three solenoids
  - Excess ports plugged with stainless steel NPT bolts and thread tape → prevent air leaks
- Functions as a diverter from one air inlet to three outlets

Solenoids

- Specs: 24V/2A, up to 120 PSI
- Electric current passes through a coil of wire, inducing a magnetic field
  - This pulls the pin of the valve open, allowing for air flow

Figure 5: Device-controlling switchboard.

- 3D printed PLA filament
- 3-way switch controls each bladder
  - Up→Inflation. inlet opens
  - Down→Deflation, outlet opens
  - Middle→Closed, inlet/outlet closed
- Switch closes circuit loop to allow solenoid to draw current from power source

Studies and Results

Finite Element Analysis Model:

To determine ideal material and thickness for bladder fabrication.

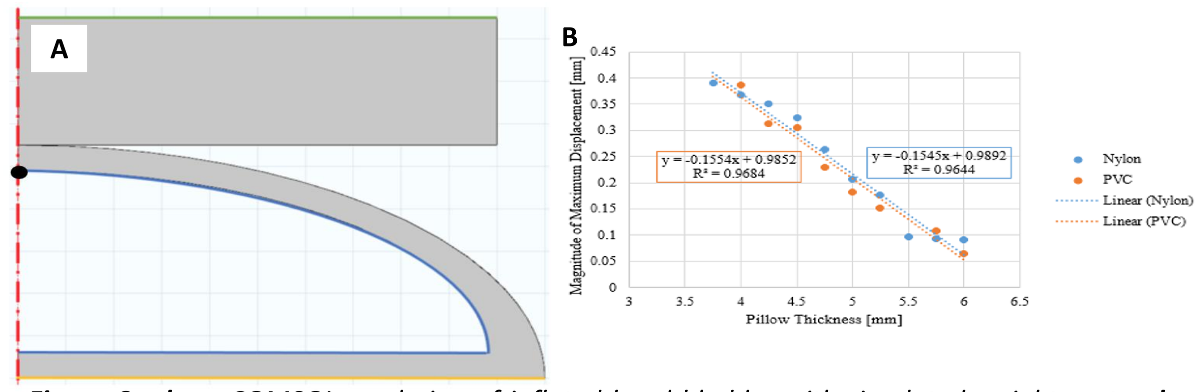


Figure 6 a-b: a. COMSOL rendering of inflated head bladder with simulated weight on top b. Maximum bladder thickness vs. displacement for 8-gage material. Linear regression shows material response is very similar, PVC can be chosen for its enhanced properties.

Cyclic Testing:

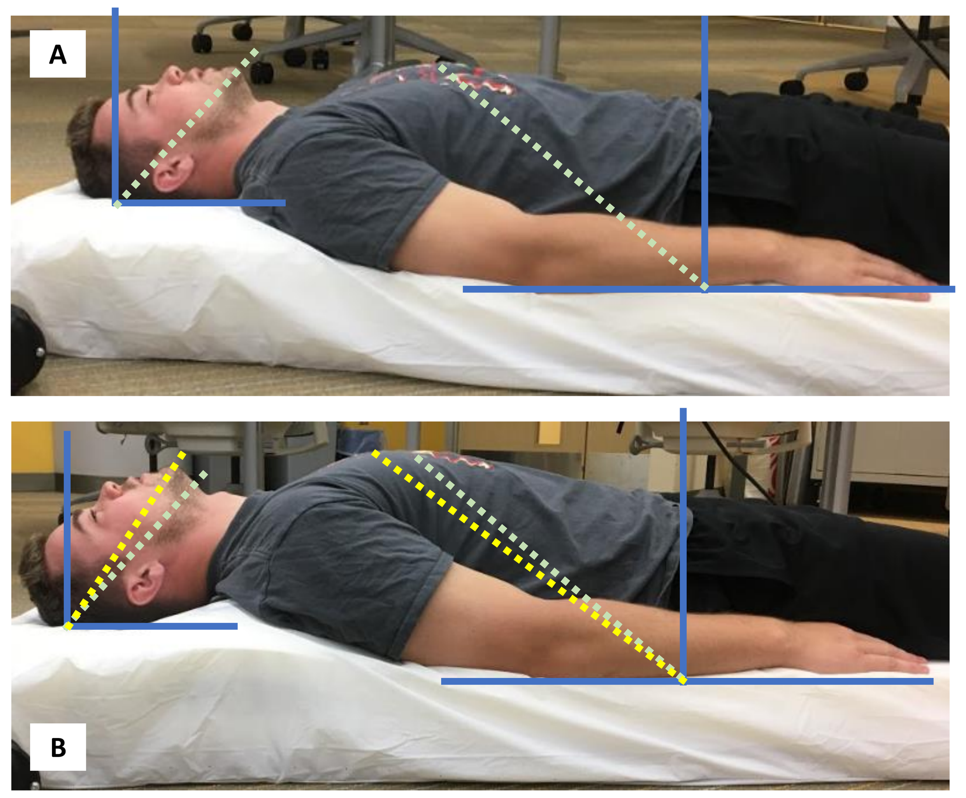
To examine limits of bladder design under repeated use.

Bladder Fate After 50 Cycles		
✓	Head	Failure Mode: N/A Bladder able to withstand cyclic strain
✓	Shoulder	Failure Mode: N/A Bladder able to withstand cyclic strain
✗	Back	Failure Mode: Tearing of material by quick connect, add nylon washer to mitigate

Table 1: Summary of cyclic testing of inflatable bladders. Head and shoulder components withstood 50 full inflation/deflation cycles, back component failed at cycle #32.

Displacement Angle Measurement:

To verify capability of system to adjust axes of patient alignment.



Measured Angles	
Neck	**Torso**
Base: 47.5°	Base: 140°
Raised: 56°	Raised: 144.5°

Figure 7: Male subject a. before and b. after elevation with the IntuBed. Dashed lines represent a. the angle from the back of the head to the end of the chin and b. the angle from the bottom of the arm to the highest point of the chest. Angles were measured using a protractor.

Biocompatibility Assessment:

To ensure inertness of nylon overlay on bare skin during the surgical window.

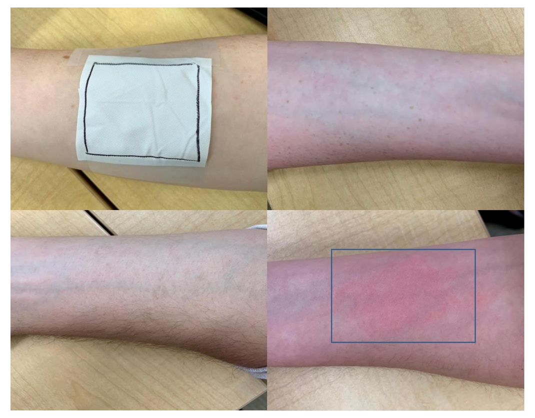


Figure 8 a-d: a. 50x50 mm nylon patch as taped onto patient's forearm for 24 hours b-c. Subjects 1 and 2 (female and male) after removal of patch – no irritation visible or reported. d. Subject 3 (female) after removal of patch – irritation visible and reported.

Validation

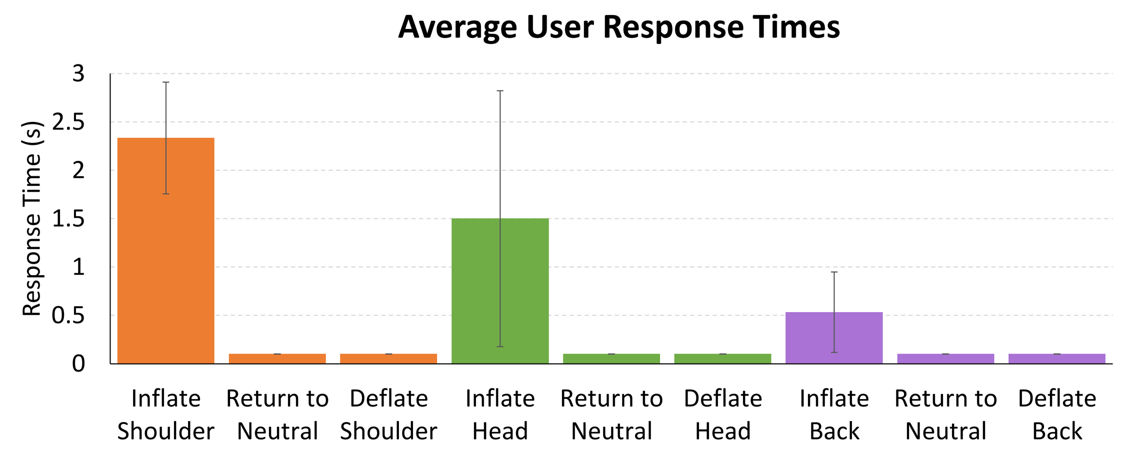


Figure 9: Validation of device usability from three test users. Users with no prior introduction to the IntuBed were given a series of commands and response time was recorded. The decreasing time trend indicates that users were able to quickly intuit the method of operation.

Clinician Feedback:

+

- Auditory input of valves opening/closing
- Addition of back bladder to lift entire torso
- Clean design

Δ

- High power drain
- Lack of pressure sensors
- Electronics close to patient

Conclusions

The IntuBed is successful in lifting patients in a manner that adjusts the reference axes of the head and neck while pushing the chest out and torso up. This allows for excess tissue to fall back towards the lower body, opening the visual field for endotracheal intubation. Not only does this system mitigate the risk of patient injury from improper intubation, but also provides clinicians an alternative to manually lifting and positioning a patient. Compared to current devices, the IntuBed provides greater control over upper body position and can be left underneath the patient during the course of the surgery while providing padding and support supplemental to the operating table, making the IntuBed an attractive alternative to what is available on the market.

Future Directions

Use In Operating Room

- Integrate soft base pad and tethering mechanism to operating table
- Test inflation with operating room air line

Upgrades

- Use smaller solenoid valves to decrease energy demands
- Explore use of pressure sensors for closed-loop feedback to prevent excess pressure in bladders
- Survey other bladder fabrication materials for increased longevity

Expand Applications

- Develop dimensions and adjust specs for a broader range of sizes, expanding market to slimmer patients and children
- Examine potential market expansion opportunities: sleep apnea, spine pain & neuropathy, third-world & emergency medicine

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