Intubation Soft Robot

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Problem:

- Endotracheal intubation is a life-saving procedure for patients with acute respiratory failure
  - It allows for mechanical ventilation in patients who can't breath on their own
  - Helps maintain blood oxygen levels
- 25% of endotracheal tubes in the US are misplaced in pre-hospital settings[1]
- The gold-standard to verify endotracheal tube placement is a chest x-ray
  - Expensive
  - Does not provide real-time feedback
  - Requires trained staff, specialized equipment

Need Statement:

We aim to develop an endotracheal tube placement & imaging system that together are **time efficient, cost-effective**, **accurate**, and **easy to use** relative to current solutions for patients requiring intubation in prehospital settings.

Proposed Solution:

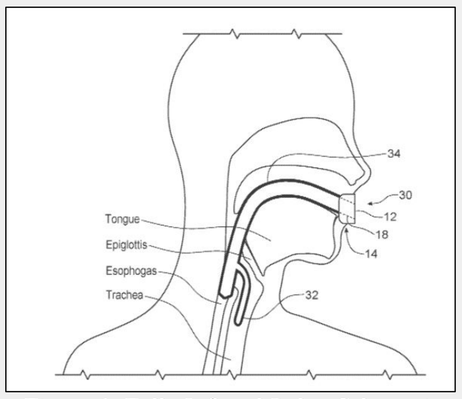

Figure 1. Fully Inflated Robot Schematic

- A two-armed, nylon soft robot acts as a guide for the placement of a standard endotracheal tube
- One arm extends from the patient's mouth into the esophagus. The end is sealed shut and blocks off the esophagus.
- An open-end side arm branches into the trachea
  - ETT can pass through fro intubation
- Robot is endoscope compatible for rapid placement verification

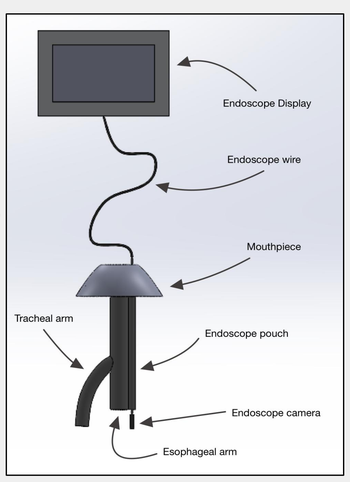

Figure 2: Intubation vine robot CAD illustration

Figure 3: Intubation Vine Robot Prototype

Success Rate and Inflation Time Testing:

Methods:

- Vine robot is repeatedly inflated at 2.8 psi in a "maze" that matches the dimensions of an adult airway
- Inflation time is measured as the time for the tracheal arm of the robot to fully extend
- Successful inflation is classified as the robot correctly pathfinding in the maze and inflating completely without getting stuck (stopped >10 sec. in 1 location)

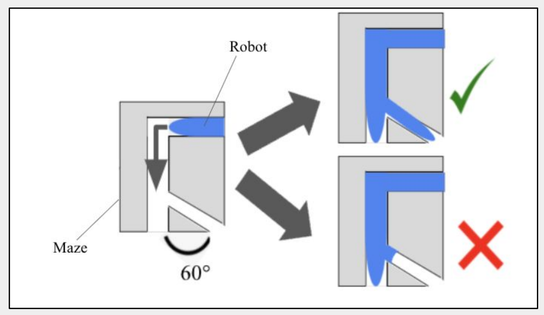

Figure 4. Success Rate & Inflation Time Testing Set-up

***Results*:**

- N = 20
- Robot did not deploy correctly from the mouthpiece on 1 trial (folding issue)

Success Rate: 95%

Average Inflation Time: 1.48 ± 0.26 seconds

Intubation & Verification Testing:

Methods:

1. Inflate the soft robot (2.8 psi) through the mouthpiece
2. Remove hose delivering air from the mouthpiece
3. Feed the ETT through main port of the mouthpiece
4. Insert endoscope through the port in the mouthpiece
5. Verify placement using the image displayed

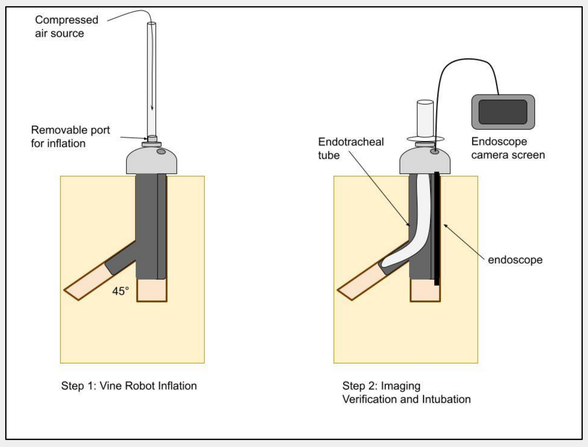

Figure 5. Intubation Time and Success Rate Testing Set-up

***Results*:**

- N = 10
- All trials successful for robot deployment and correct ETT placement
- 1 outlier: tracheal tube had trouble inflating due to improper folding → delay in inflation
- Note: users had no previous intubation experience

Correct ETT Placement Rate: 100%

Average Time to Inflate, Intubate & Verify: 30.27± 5.05 seconds

Costs, Regulations, Patents, Reimbursement:

Associated Costs:

Vine Robot	$6.27
Mouthpiece	$5.07
Assembly/Packaging	$6.00
Tuning/Debug/QC	$1.75
Total Manufacturing Cost	**$19.09**

Regulatory Information:

- No FDA-approved devices with a similar MOA
- Soft robotics has not yet been used in the body
- Expect device to need a PMA from the FDA

Patentability:

- A patent exists for a similar device
- Our design incorporates imaging capability
- We would license our product to avoid patent infringement

Reimbursement:

- Unique nature of device would likely require new reimbursement codes
- Expect it to eventually be reimbursable by Medicare/Medicaid (intubation is a life-saving, necessary procedure)

Summary & Conclusion:

- Our intubation soft robot can consistently path find its way from the mouthpiece into the trachea both quickly and successfully
- Using the robot as a guide, a standard endotracheal tube can be easily and correctly placed
- An endoscope can be used to verify placement.
- The average time to complete these steps (without any training) is significantly faster than traditional methods

Future Work:

- Pressure testing to determine a safe and effective inflation pressure
- Redesign endoscope pouch to visualize trachea
- Make robot steerable for difficult airways

Acknowledgements

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Bibliography

[1] Katz SH, Falk JL. Misplaced endotracheal tubes by paramedics in an urban emergency medical services system. Ann Emerg Med. 2001 Jan;37(1):32-7. doi: 10.1067/mem.2001.112098. PMID: 11145768.