

Problem description

A chest tube thoracostomy is a procedure in which a tube is inserted into the pleural space of a patient and suction is applied to relieve pressure on the lungs. The pleural space maintains negative pressure to allow the lungs to expand, so any pressure in this space means the lung collapses and the patient cannot breathe properly.¹ Pressure on the lungs can be caused by air (pneumothorax) or fluid in the pleural space (pleural effusion) such as blood, lymph, pus or urine. Approximately 1 million chest tubes are placed per year in the United States and the market value of thoracic drainage devices was estimated at \$615 million in 2018.^{2,3} The procedure to relieve this unwanted pressure has been used for thousands of years and is seen as a relatively low difficulty procedure for an experienced surgeon. Problems occur more often when an inexperienced surgeon or first responder is tasked with placing a chest tube.

Lack of experience with the procedure can cause it to take an excessive amount of time, cause unnecessary damage to the patient's tissue around the insertion point, or exacerbate the injury by damaging the lung, diaphragm, or intercostal vasculature. Even an experienced surgeon can take longer to perform the procedure than necessary. Other issues arise when a first responder, such as a paramedic, believes that a chest tube thoracostomy will take too long and opts instead for needle decompression. When used by a first responder needle decompression has a failure rate of 65%.⁴ This procedure can be improved upon to the point that first responders and inexperienced surgeons can insert a chest tube in a fast, effective manner while reducing the risk of excessive tissue damage and minimizing pain to the patient. Even experienced surgeons would benefit from the ability to more rapidly place a chest tube so they can move on to the root injuries causing the collapsed lung. It would also be of extraordinary benefit if first responders could easily place chest tubes so that trauma patients could arrive at the hospital with pleural effusions already draining.

Solution concept

The team developed a pair of devices called the Chest Guide and Chest Wedge that facilitate rapid placement of chest tube in a suffering patient. The Guide can be placed directly on the patient's injured side and help the user quickly locate and mark an appropriate intercostal space. The Wedge is designed to allow it to be easily pushed through the intercostal muscle to reach the pleural space. It then has a safety mechanism that activates once the pleural space has been penetrated to prevent pushing the device any farther and damaging the lung. The device is designed to allow a chest tube to be inserted after which the device can be removed from the patient, leaving only the tube in place. These features taken together will greatly reduce the time required for a thoracostomy. With minimal training it will be usable not only by surgeons but eventually by paramedics, flight for life responders, and field medics. This will significantly improve outcomes as trauma patients will have their respiratory distress relieved much sooner than with current standards.

Reduction to practice

Verification of the device came in steps that partially built on each other. Each version of the prototype would have its new features tested along with confirming previously conducted tests. Four prototypes were constructed but the first one was never mechanically operational, so it was never tested for insertion. It was tested only for the ability to insert a chest tube through it. It passed this test but the mechanism to keep the door closed evolved over time, so this test was continually repeated with each new prototype.

Every prototype after the first was tested for ability to penetrate pork ribs, which was another of the verification tests. This test was passed by our second prototype as well as the third and fourth prototypes. The amount of force required to push through ribs was quantified using the third prototype and two different tip shapes. Results of this test are shown in Figure 1 below. The pointed shape was able to get through the ribs with less force, so the final device is more reflective of this design. The final prototype will not be included in this document for IP purposes, but a drawing of the intended use of the device is included below in Figure 2 for illustrative purposes only. It is based on a very early concept and does not represent the prototype designs.

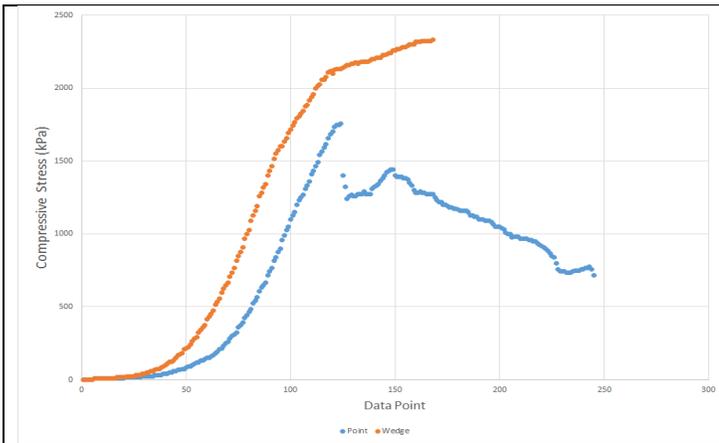


Figure 1. Compression strength test with wedge tip and pointed tip

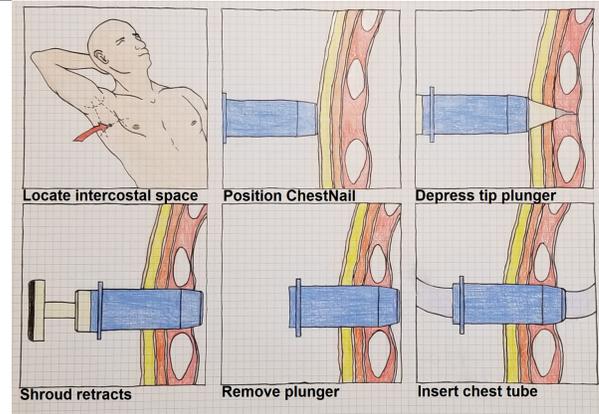


Figure 2. Illustration of proposed use of Chest Door device

The validation test for the device being able to arrest its own movement was also run on multiple prototypes. This was the most difficult test and the first round was a failure. The second round was considered a pass and proved the concept. Some adjustments to improve the safety of the arresting mechanism were made for the final prototype and the device passed again. With proof of concept for the arresting mechanism, the team considers the device proven to be functional. It passed all important functional validations tests, namely it can penetrate ribs without breaking or deforming, stop itself from moving once it enters the pleural cavity, and easily have a chest tube inserted through it.

Pathway to commercialization

A freedom-to-operate analysis was performed and concluded that no patents are interfering with the intellectual property or right to distribute this device. A preliminary patent application has been drafted and will be filed in the near future. The team made the prototypes out of 3D printed PLA which is not the expected final material of the product. A manufacturing and assembly cost analysis was performed for the device being injection molded out of high-density polyurethane. This pointed to a price point of \$40-100 depending on scale of manufacturing and cost of FDA approval. Currently the device is seen as a Class II device due to the moderate risk and will require general and special controls to address the risks. This device has no obvious predicate and will require a de novo approval pathway.

The prototypes passed all validation tests but once copies are produced using final materials, they will need to be re-tested. All verification test plans are available and validation test plans have also been drafted. Verification tests will be performed by Dr. Idrovo and during clinical trials. A preliminary User Manual has already been drafted which includes safety information and step-by-step instructions. The final prototypes and all documentation will be turned over to the project sponsor for use by a future development team.

References

1. E. N. Marieb and S. M. Miller, "Chapter 13: The Respiratory System," in *Essentials of Human Anatomy and Physiology*, 12th ed., New York, NY: Pearson Education Canada, 2017, pp. 468–474.
2. G. Utter, "The Rate of Pleural Fluid Drainage as a Criterion for the Timing of Chest Tube Removal: Theoretical and Practical Considerations", *The Annals of Thoracic Surgery*, vol. 96, no. 6, pp. 2262-2267, 2013. Available: 10.1016/j.athoracsur.2013.07.055.
3. "Thoracic Drainage Devices Market by Type, End user & Forecast to 2027 – TMR", *Transparencymarketresearch.com*, 2020. [Online]. Available: <https://www.transparencymarketresearch.com/thoracic-drainage-devices-market.html>.
4. C. G. Ball, A. D. Wyrzykowski, A. W. Kirkpatrick, C. J. Dente, J. M. Nicholas, J. P. Salomone, G. S. Rozycki, J. B. Kortbeek, and D. V. Feliciano, "Thoracic needle decompression for tension pneumothorax: clinical correlation with catheter length," *Canadian journal of surgery. Journal canadien de chirurgie*, Jun-2010. [Online]. [Accessed: 04-Sep-2019].