A Novel Device and Technique for Trauma-Related Tube Thoracostomy[1]

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1 Background

In the U.S., trauma is responsible for 140,000 annual deaths, making it the main cause of death in people under the age of 40 [1]. In 60% of trauma cases, patients suffer chest injuries, which account for about 25% of trauma-related deaths [2]. Patients with traumatic chest injuries require immediate medical intervention to minimize risk of morbidity and mortality. Most patients have chest tubes placed in the thoracic cavity via tube thoracostomy (TT) to drain accumulated fluid from pneumothorax, hemothorax, or hemopneumothorax. Because TT has no definite contraindications for a patient in respiratory distress [3], it is used to treat up to 85% of chest injuries [4].

Though properly placed chest tubes carry little risk to the patient, the standard of care for TT, blunt dissection (BD), is an imprecise and highly skilled procedure. Because the physician is blindly dissecting tissue with only tactile guidance, the path created is typically oversized, subjecting patients to increased pain, slower healing, and greater risk of leakage at the insertion site [5]. Furthermore, the Lim et al. [6] study found a 36.8% (28/76) rate of malpositioned tubes when TT was performed via BD in emergency conditions. Severity of complications from malpositioned chest tube (MCT) depends on type of malpositioning. For tubes placed extrathoracically, the patient's condition does not improve, and the TT procedure must be repeated. Similarly, for a tube angled incorrectly within the cavity, fluid cannot properly drain and TT must be repeated. Finally if the tube is inserted too far, it poses risk of damage to the lungs and heart.

The Seldinger technique (ST) was developed to make TT less invasive by using gradual dilators to stretch tissue only to the necessary size for tube insertion. Needle aspiration and guidewire are used to detect entrance into the thoracic cavity and minimize MCT; however, Doyle et al. [7] found that risk of lung injury increased with ST due to reduced tactile feedback when compared to BD. Another shortcoming of ST is that it is most practical for small tubes, which require fewer dilation stages. Despite increasing popularity, small-bore chest tubes have been found to have increased risk of complications compared to large bore [8].

This paper presents a novel TT device (NTTD) designed to reduce risk of MCT and improve the precision of tube placement. By guiding the chest tube along a path verified by visual feedback, the NTTD offers informed control to the clinician during the TT procedure. Balloon dilation provides benefit similar to the dilators in ST, without requiring several tools. Preliminary testing has been conducted in porcine models to validate device functionality.

2 Methods

A diagram of the NTTD is shown in Fig. 1. The hollow central shaft is slender, allowing it to be threaded through a drainage hole in the chest tube. The user squeezes the trigger to advance the shaft forward, moving the cutting tip smoothly through the patient's chest wall. As soon as the tip reaches the thoracic cavity, a blunt pin pops out to shield the cutting tip. This prompts a visual indicator (VI) in the device handle to change positions, notifying the user to stop squeezing the trigger. Next, a balloon at the distal end of the shaft is inflated to dilate the path. When the balloon is deflated, the user slides the chest tube distally along the shaft until it enters the cavity. The device is then removed, and the chest tube is pushed farther into the chest cavity as required. Secs. 2.1–2.4 provide a detailed description of each of the device features.

2.1 Controlled Insertion. A shortcoming of both BD and ST is the inability to control insertion speed when creating a path through the chest wall into the thoracic cavity. When the pleural membrane is punctured with the tip of the forceps in BD, the clinician feels a sudden drop in pressure at the instrument tip, indicating that they have reached the cavity. However, the clinician's reaction cannot be instantaneous, so it is virtually guaranteed that the forceps will be pushed farther into the cavity than intended. Though the tip is blunt, enough speed or force risks damage to the thoracic organs. In ST, the path is established using needle aspiration, in which a needle is plunged through the chest wall until fluid from the cavity is aspirated. The same issue as BD is present in this case. Relying on the user's reaction time leaves opportunity for injury to thoracic organs.

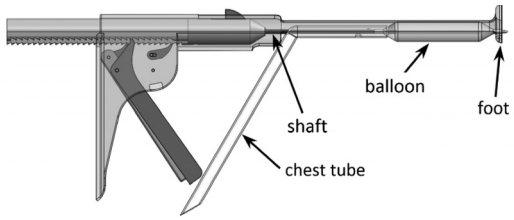

Fig. 1 Diagram of NTTD (outer shell shown transparent)

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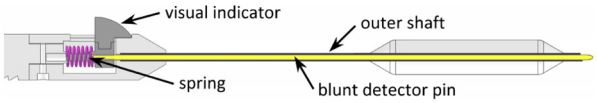


Fig. 2 Cross section of NTTD showing detection system

The NTTD utilizes a ratchet mechanism to move the shaft tip forward incrementally, rather than continuously. As a result, when the shaft tip reaches the cavity, the user must release the trigger before being able to advance farther. Additionally, although the tip experiences reduced pressure, it will not be able to plunge forward because it is constrained by the ratchet system. All motion permitted by the ratchet is relative to motion of the patient when the foot of the device is held against the patient's skin.

2.2 Thoracic Cavity Detection. In BD, the clinician cannot definitively know whether the forceps has reached the thoracic cavity. Often the clinician will insert a finger into the dissected tissue to confirm position using tactile recognition. Not only must this strategy be learned from experience but also there is risk of injury to the clinician if the patient has a broken rib with sharp edges [7].

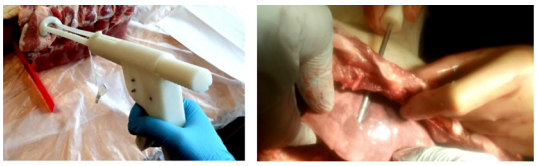
The NTTD utilizes a detection method reminiscent of the Veress needle. A blunt spring-loaded pin, running through the hollow shaft, is retracted while the cutting tip of the shaft pushes through tissue. When a cavity is reached and resisting tissue is absent, the spring pushes the blunt pin forward to shield the cutting tip (Fig. 2). The pin is coupled to a VI on the handle, which similarly pops forward when the cavity is reached, alerting the user to stop ratcheting farther.

2.3 Precise Positioning. The foot described in Sec. 2.1 also serves as a target used to decide, before inserting, where the chest tube should enter the cavity. The foot is a semicircular ring, allowing the user to place the center of the arc to aim the device. Unlike in BD, the NTTD foot remains stationary for the duration of the procedure, acting as a fixed reference at the targeted position.

2.4 Tissue Path Creation and Dilation. While ST eliminates the BD problem of creating an oversized path, it requires several incremental dilators. The NTTD instead uses balloon dilation to expand the path created by the slender shaft. Once the shaft tip reaches the thoracic cavity, a saline-filled syringe is used to inflate a balloon that expands around the distal end of the shaft. When the balloon is deflated, the surrounding tissue remains loose, easing passage of the chest tube over the balloon and into the thoracic cavity.

3 Results

A prototype of the device (Fig. 3(*a*)) and isolated modules were tested in porcine tissue on three occasions. The first testing, conducted at Massachusetts General Hospital (MGH) in Boston, MA, was on live porcine tissue. During this test, the cavity detection system was tested and refined. Safety of the spring-loaded pin was verified by inserting the shaft while holding lung tissue directly against the interior chest wall. In multiple iterations of this test, no damage to the lung was observed (Fig. 3(*b*)).



(*a*) (*b*)

Fig. 3 (*a*) NTTD prototype test on pork ribs and (*b*) isolated detection system being tested for safety in porcine tissues

The remaining testing was conducted at Massachusetts Institute of Technology (MIT) in Cambridge, MA, on sections of pork ribs. The first test focused on efficacy of balloon dilation. When situated in the chest wall, the balloon was inflated with water to test burst strength and observe the resulting tissue dilation. Due to assembly technique, the balloon seal failed in most trials, but the tissue still dilated enough to pass a 28Fr tube through the resulting opening.

For the third test, improved assembly techniques allowed the balloons to remain intact through several trials. The full TT procedure was performed, demonstrating the capability to successfully place a chest tube using the NTTD. The shaft smoothly cut through the chest wall without excessive force required by the user. The cavity detection system reliably alerted the user when to stop advancing. The balloon created an opening in the tissue that permitted a 28Fr tube to be pushed into the cavity. The main difficulties encountered were again due to flawed attachment of the balloon to the shaft, requiring that the tip be advanced an extra centimeter into the cavity before the balloon was in proper position for inflation.

4 Interpretation

The NTTD presented in this paper aims to improve upon BD and ST by providing definitive feedback about entrance to the thoracic cavity without increasing patient risk, controlling speed and direction of insertion, and creating a uniformly dilated path through which the chest tube is guided. The device has potential to reduce complications and patient pain associated with TT. Preliminary testing shows promising results that validate functionality of the features discussed in Sec. 2. Further work must be done to improve assembly techniques, particularly for the balloon. The user interface must also be refined to improve grip design and implement pivoting at the foot to permit varying angles of entry.

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