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# Superior Chest Drainage With an Active Tube Clearance System: Evaluation of a Downsized Chest Tube

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**Purpose.** We developed a small-diameter (20-French [Fr]) chest drainage system that incorporates an active tube clearance (ATC) system, and we evaluated its efficacy in an acute hemothorax model.

**Description.** The ATC system includes an internal guidewire that can be advanced into the lumen of the chest tube to keep the tube from clogging. In six pigs, a 20-Fr ATC tube was placed on one side and a 32-Fr standard tube on the other, and 120 mL of fresh blood was infused into each pleural space every 15 minutes for a total of 840 mL.

**Evaluation.** The amount of drainage for 2 hours with a 20-Fr ATC tube was significantly greater than that with the 32-Fr standard tube ( $525 \pm 179$  mL vs  $183 \pm 85$  mL;  $p = 0.0032$ ).

**Conclusions.** This is the first time a smaller diameter tube has been shown to have better drainage in the setting of acute bleeding compared with larger diameter tubes.

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Chest tubes are placed after heart, lung, and trauma surgery to drain collections of fluid and air. When bleeding and clotting are expected, larger chest tubes are currently preferred. There has been considerable interest in the clinical use of smaller-diameter chest drains because of the potential advantages, such as reduced pain, safer insertion, and lower rate of infection [1]. However, concerns have been raised as to the propensity to clog, which limits their usefulness in postoperative management [2].

To address concerns with clogging of smaller diameter chest drains, we developed an active tube clearance (ATC) system (PleuraFlow Catheter System [Clear Catheter Systems, Bend, OR]) that incorporates an integrated internal tube clearance apparatus. In a recent study, we demonstrated that a 32-French [Fr] ATC tube was superior to passive chest tube clearance using the same-sized standard chest tube in a hemothorax model [3]. The purpose of this study was to evaluate the hypothesis that ATC will enable superior drainage with a smaller diameter chest tube (20-Fr) compared with passive chest drainage with a 32-Fr chest tube.

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## Technology

The PleuraFlow device is a very simple chest tube clearance apparatus that uses an integrated ATC to keep the inner diameter of a chest tube clear of clogging material [4]. The active drainage component is connected between the chest tube and the tubing leading to the canister, placing the device inline with the drainage pathway (Fig 1). The PleuraFlow device has an internal guidewire inside that has a small loop set at a 90° angle at its distal end (Fig 2). This internal clearance wire is moved in and out of the chest tube by sliding the outer housing along the guide tube, allowing the distal loop to break up and morcellate any clot, which is then pulled out toward the chest tube canister in a controlled fashion (Fig 3). Due to the novel magnetic coupling system (Fig 4), the pathway between the chest tube and the canister can be preserved in a sterile condition.

## Technique

An acute hemothorax model was used in six healthy pigs (Yorkshire mix; weight,  $52.9 \pm 2.5$  kg [Fanning Farms,

Drs Boyle and Gillinov disclose that they have financial relationships with Clear Catheter Systems.

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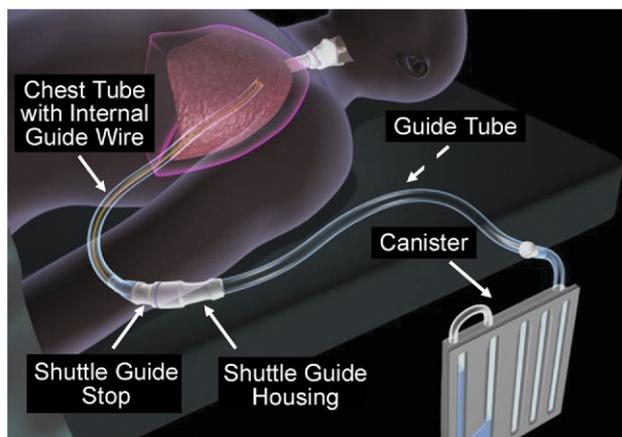


Fig 1. PleuraFlow active chest tube drainage system (Clear Catheter Systems, Bend, OR): PleuraFlow connected between the standard chest tube and the extension tube to the canister.

Howe, IN] [5]. This study was approved by Cleveland Clinic's Institutional Animal Care and Use Committee, and all animals received humane care in compliance with the Guide for the Care and Use of Laboratory Animals (Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council, National Academy Press, Washington, DC, 1996).

Anesthesia was induced with an intramuscular injection of ketamine and inhaled isoflurane, and after endotracheal intubation the animal was placed on the surgical table in a supine position under general anesthesia with isoflurane (0.5% to 2.0%). An arterial line was placed into both carotid arteries to draw blood for subsequent blood infusions into the chest cavities.

Bilateral mini-thoracotomies were performed through the sixth intercostal space. A 0-Prolene suture (Ethicon,

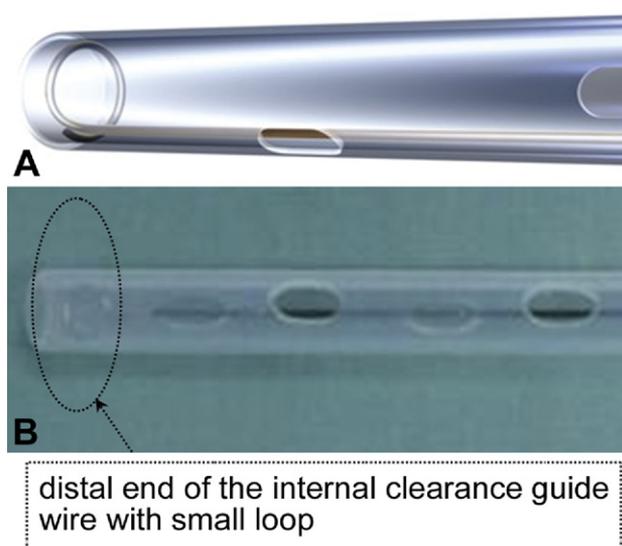


Fig 2. (A) Illustration of the distal loop of the internal guidewire used to clear the catheter. (B) Picture of the distal loop of the internal guidewire located at the distal end of the chest tube.

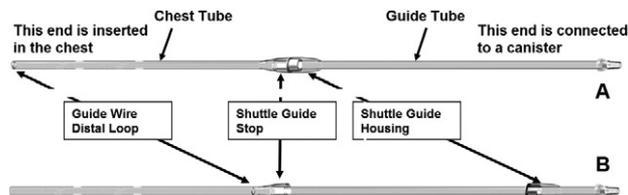


Fig 3. (A) Default position. (B) Clearance position.

Somerville, NJ) was placed 2 cm from each lung edge to enable later lung injury. A 20-Fr silicone tube for the ATC system was inserted into one side of chest cavities and a 32-Fr silicone standard chest tube (Atrium, Hudson, NH) on the other side through the chest wall at the seventh intercostal space. Both the 20-Fr ATC tube and the 32-Fr standard tube had six side holes and an end hole with the total cross-sectional area of fluid entry of 0.95 cm<sup>2</sup> and 2.80 cm<sup>2</sup>, respectively. The 20-Fr chest tube was connected to the ATC system, which is inserted between the chest tube and the tubing to the drainage canister. The extension tube was adjusted to make the same distance from the blood chamber to the skin on both sides, and then the drainage canister and suction (-20 cm H<sub>2</sub>O) were connected to each chest tube. The height of the table was approximately 90 cm, and the chest tubes and extension tubes were maintained without a dependent portion to prevent fluid from pooling in the tubing. The thoracotomies were closed. At time zero, the Prolene sutures were pulled to induce lung injury and activate the clotting cascade, and 120 mL of fresh blood drawn through the arterial line was injected into each pleural space through the soft catheter inserted through the

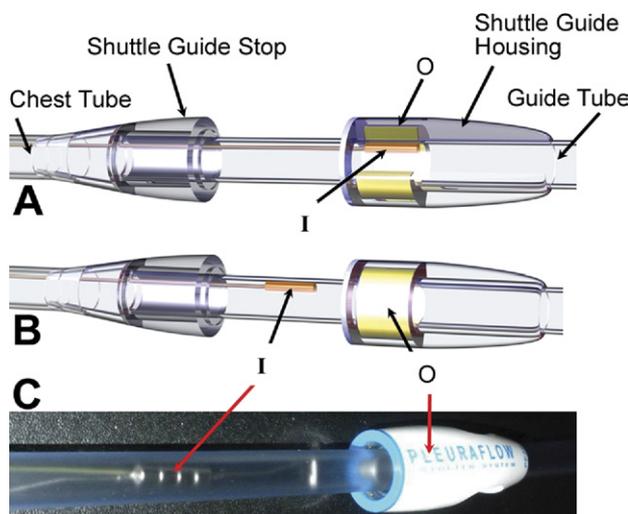


Fig 4. (A) Internal guidewire for clearance apparatus moved with magnetic coupling between the magnet (O) in the outer housing and the magnet (I) of the proximal end of the internal wire of the proximal end of the wire. Pulling the shuttle guide housing backward withdraws the internal guidewire from the chest tube. The shuttle guide stop prevents the guidewire from being pushed out of the chest tube. (B, C) The internal magnet is intentionally decoupled with the magnet of the outer sleeve so that it can be clearly seen.

thoracotomy incision into the pleural cavity. Intravenous fluid resuscitation was used to keep the mean arterial pressure above 60 mm Hg. Every 15 minutes, another 120 mL of blood was withdrawn from the arterial line and infused into each pleural cavity until a total of 840 mL of blood had been introduced into each pleural cavity. The volume of blood drained from each thoracic cavity was recorded every 15 minutes for 2 hours. Active drainage of the 20-Fr tube was accomplished by advancing and retracting the wire every 15 minutes. Neither chest tube was milked, tapped, or stripped. Chest tubes were attached to suction apparatus at a vacuum of  $-20$  cm  $H_2O$ , and this suction, in combination with gravity, facilitated drainage.

At 2 hours, the animals were sacrificed by intravenous administration of potassium chloride under deep anesthesia, and all residual blood and clots in each pleural space were evacuated and weighed to record the unevacuated blood.

All data are presented as group means  $\pm$  standard deviation. A paired *t* test was performed to compare the data with 20-Fr ATC and the 32-Fr standard tube.

### Clinical Experience

The ATC system was operated easily, and the total volume of drainage was  $525 \pm 179$  mL, significantly greater than that with the 32-Fr standard tube ( $183 \pm 85$  mL;  $p = 0.0032$ ). The volume of clot and blood remaining in the chest cavity with 20-Fr ATC tube ( $314 \pm 132$  mL) was significantly lower than with the 32-Fr standard tube ( $592 \pm 105$  mL;  $p = 0.0058$ ). Although all 32-Fr tubes had retained clot in the lumen, there was no clot in the 20-Fr tubes.

### Comment

Drainage and decompression of the pleural and mediastinal spaces is necessary in nearly all cardiothoracic surgery cases. Failure to adequately drain the chest after heart and lung surgery, or in the setting of chest trauma, can lead to hemothorax, pneumothorax, effusions, and infections, any of which can lead to poor outcome and even death. In a recent survey, cardiothoracic surgeons reported that the concern about clogging often leads them to select larger diameter tubes in case one tube becomes clogged [2]. Therefore, there is a clinical unmet need to develop a system that can remain patent and adequately clear blood, fluid, and air with small-diameter drains.

Maintaining chest tube patency is especially a concern in the early hours after heart surgery. Medical caregivers often tap, squeeze, milk, or strip chest tubes to break up and attempt to remove obstructing material. These techniques not only pull medical caregivers away from other important tasks, but also have never been shown to increase the drainage, and activities such as chest tube stripping are potentially dangerous, as negative pressures in the tube up to  $-400$  cm  $H_2O$  can be generated [6]. In extreme cases, surgeons are called to take apart the

chest tube at the tubing connector and advance a suction element into the chest tube to break up and remove the clot [7]. This has the disadvantage of breaking the sterile environment of the lumen of the tube and allowing air to enter the chest, which can lead to pneumothorax. In addition, once a chest tube fails, blood can collect and form a solid clot that is retained within the chest, leading to hemothorax. In the worst-case scenario, an air leak or bleeding in the setting of impaired chest tube drainage can lead to cardiopulmonary collapse, leading to death or an emergent trip back to the operating room to remove the clot and restore patency to the chest tubes.

The purpose of this study was to assess if ATC can keep chest tubes open when bleeding is brisk, simulating the early hours after heart surgery. To accomplish this, the ATC system uses a magnetically coupled internal guidewire that is manually advanced in and out of the tube to break up, morcellate, and pull solid material out of the tube. This easy-to-use system eliminates the need to break the sterile environment to advance the clearance mechanism. With complete clearance of the tubes in this study, milking, tapping, and stripping the chest tube were unnecessary. The device is simple to insert and operate, and therefore it can be routinely used to prevent clogging and obstruction.

Investigators have shown that smaller diameter Blake drains can drain equivalently to larger diameter chest tubes, but never in a superior fashion [8, 9]. Therefore, even though some surgeons would like to use smaller diameter tubes, concerns about the adequacy of drainage have persisted. This is the first time a smaller diameter chest tube has been shown, with the ATC, to drain better than a larger diameter chest tube. We chose the 2-hour time at high volumes of bleeding to simulate the early hours after heart surgery. Furthermore, we chose not to manipulate the control tubes, based on considerable evidence from the literature that these techniques are not useful and may in fact be dangerous [10]. Finally, in the event that this ATC system is found to be reliable, efforts will need to be undertaken to assure that it is cost effective for routine clinical use.

In conclusion, this is the first time a smaller diameter tube has been shown with ATC to have better drainage in the setting of acute bleeding compared with a larger diameter tube. Subsequent studies are indicated to determine if ATC may enable physicians to use smaller diameter chest tubes, safely decreasing patient pain and improving drainage.

### Disclosures and Freedom of Investigation

The PleuraFlow Catheter System is being developed by Clear Catheter Systems (Bend, OR). Dr Boyle has financial interests in the company that include ownership in shares in Clear Catheter Systems and a royalty agreement; he is also the founder and CEO of Clear Catheter Systems.

Dr Gillinov has financial interests in the company that include ownership of shares in Clear Catheter Systems and a royalty agreement. He is also a member of the

Scientific Advisory Board for Clear Catheter Systems. The authors had full control of the design of the study, methods used, outcome measurements, and production of the written report.

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## Disclaimer

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