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In this issue…

PleuraFlow Clearance System wins prestigious EACTS 2009 award

Techno College winner 2009: Co-inventor Edward Boyle

***EACTS Daily News* is pleased to announce the 2009 EACTS Techno College Award was won by Dr Edward M Boyle, the founding CEO of Clear Catheter Systems and the co-inventor of the PleuraFlow Active Tube Clearance System.**

This novel device was developed by cardiothoracic surgeons to keep chest drains clear after heart and lung surgery. Chest tube clogging with blood and other fibrinous material is not uncommon and can contribute to retained haemothorax, pleural effusion, empyema, pneumothorax, and subcutaneous emphysema, all of which can result in poor patient outcomes and even death.

To minimise potential for clogging, surgeons generally choose larger diameter chest tubes, which are often more painful. Small diameter chest tubes are less painful than large diameter chest tubes; however, they are more prone to clogging with clotted blood.

To address this unmet need, Clear Catheter Systems teamed up with practicing cardiac and thoracic surgeons to develop the PleuraFlow Active Tube Clearance System, which allows care providers to actively clear the internal diameter of a chest tube in a reproducible, sterile fashion, removing any obstructing or occluding material towards the drainage canister. To deploy this device, a full length chest tube (32F or 20F) is inserted and secured in the usual fashion. A guide tube is connected between the implanted chest tube and a blood collection canister (in place of the usual tubing connector). Within the guide tube there is a guide wire with a loop set at 90 degrees that can be advanced in and out of the tube to clear the internal diameter of any occluding material such as clot. The guide wire is then manually advanced into and out of the chest tube by a proprietary external magnetic drive, maintaining a sterile environment within the tube. (Figure 1) The guide wire distal loop morcellates clot from the inside of the chest tube and moves it towards the collection canister when the shuttle guide is moved along the guide tube. This is facilitated by the suction within the drainage canister. This external and internal magnet coupling is the key innovation making this system very simple, while maintaining the sterile environment within the tubing. (video animation available at www.pleuraflow.com)

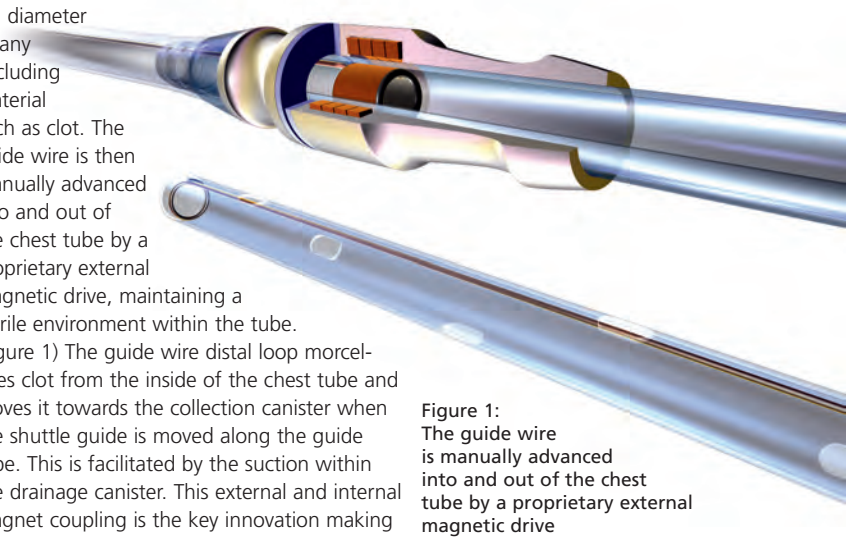

Figure 1: The guide wire is manually advanced into and out of the chest tube by a proprietary external magnetic drive

Testing this with in vitro studies (chest tubes filled with gelatin, and later bovine blood) we found that a 0.035mm guide wire is flexible yet stiff enough to advance in and out of the tube without bending the tube, kinking guide wire or decoupling the magnetic drive assembly. Utilising *in vivo* studies in a porcine haemothorax model at the Cleveland Clinic (principle investigators Marc Gillinov, MD, and Kiyotaka Fukamachi, M.D., Ph.D.) it was demonstrated that a 32Fr PleuraFlow drained significantly better (side by side drainage comparison, evaluating total drained and residual hemothorax) than that with a 32Fr standard chest tube. Next the hypothesis that the Active Tube Clearance system would allow a minimally invasive tube, size 20Fr, to function as well or better than a standard 32Fr chest tube in the setting of an ongoing haemothorax was evaluated. In fact the drainage using the Active Tube Clearance system at 20Fr was superior to a standard 32Fr chest tube, demonstrating that active clearance appears to allow the minimisation of the diameter of chest tubes while actually improving drainage capacity. A first in man feasibility testing is planned for late 2009 with an anticipated commercial launch in early, 2010.

Edward Boyle

Congratualtions to Dr Boyle and his colleagues at Clear Catheter Systems

YESTERDAY'S HIGHLIGHTS

Descending aortic aneurysm repair: Is EVAR better than conventional replacement?

Joseph E Bavaria
Hospital of the University of Pennsylvania, USA

Thoracic endovascular aortic repair (TEVAR) has evolved over the past 15 years from hand-sewn experimental devices to become the predominant technique for repair of most thoracic aortic pathology. We began the TEVAR programme at the University of Pennsylvania in 1999, initially treating patients enrolled in pivotal trials with atherosclerotic aneurysms and occasional uses of stent-grafts for other indications in dire emergencies. After the first TEVAR device approval in March 2005 (WL Gore – TAG thoracic nitinol endograft), we expanded our indications to include a variety of aortic pathologies such as type B dissections, transections, hybrid arch replacement and hybrid treatment of the proximal descending thoracic aorta in acute type A dissections.

Evolution of the multi-disciplinary TEVAR team to include cardiac and vascular surgeons, cardiovascular anaesthesia, diagnostic radiology and neurologists has enabled application of this technology to sicker patients while maintaining outcomes.

TEVAR has been demonstrated to reduce operative mortality versus open surgery in higher risk patients with aneurismal disease. Operative morbidity is decreased in virtually all thoracic aneurysm patients with TEVAR versus open surgery. TEVAR has also become the standard therapy for malperfusion syndromes in acute Type B aortic dissections with vastly improved operative survival. The role of TEVAR in acute, uncomplicated Type B dissections is less well understood. The INvestigation of STEnt Grafts in Patients With Type B Aortic Dissection (INSTEAD) trial comparing TEVAR to medical therapy in a lower risk cohort did not show any benefit for using TEVAR in these patients. However, TEVAR used in patients with an elevated predilection for rapid aneurismal degeneration of the aorta may be of benefit and an NIH-sponsored trial to study this is currently underway.

Joseph Bavaria

In a recent review of our first decade of experience with TEVAR in over 500 patients, we found that operative mortality was higher in patients undergoing TEVAR for hybrid arch replacement, traumatic transection and acute Stanford Type A dissection, findings not surprising given the higher acuity and/or anatomic complexity in these patients. Hybrid arch replacement and traumatic transection repair were also more likely to be associated with perioperative paraplegia. In the longer-term, patients with TEVAR for Type B dissection complicated by limb or visceral malperfusion, refractory hypertension or pain, or rupture or

Continued on page 2