Transactions on Additive Manufacturing Meets Medicine
Trans. AMMM, 2023, Vol. 5, No 1, Article ID 824, 9 Pages

Infinite Science Publishing

Original Research Article

Design, 3D printing, and validation of a breakaway chest drain valve

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Abstract: A chest drain is a medical tube that is inserted between the ribs in the space between the lung and internal chest wall. Air or fluid can leak into the space around the lung after infection or injury which is drained by the tube, allowing the lung to re-expand. Inserting a chest drain can be lifesaving, and it is estimated that, world-wide, millions of chest drains are inserted annually. This paper presents the design and 3D printing of the initial product development of an advanced functional prototype of a breakaway chest drain valve. This breakaway chest drain valve seeks to address the accidental removal from the patient, and to allow intentional removal and reconnection stopping air and fluid re-entering the chest. As such, this research investigates how the novel design for a breakaway valve as part of a chest drain kit could reduce the chances of drains becoming dislodged from a patient, and allow for intentional disconnection when repositioning a patient, potentially reducing patient trauma, and saving time and costs to healthcare providers.

I. Introduction

A chest drain is a medical tube that is inserted between the ribs into the pleural cavity, the space between the lungs and internal chest wall (Fig. 1) [1]. Approximately 30,000 chest drains (CDs) are inserted annually in the UK [2, 3] and in the US more than 2 million adults require CDs insert each year globally [4].

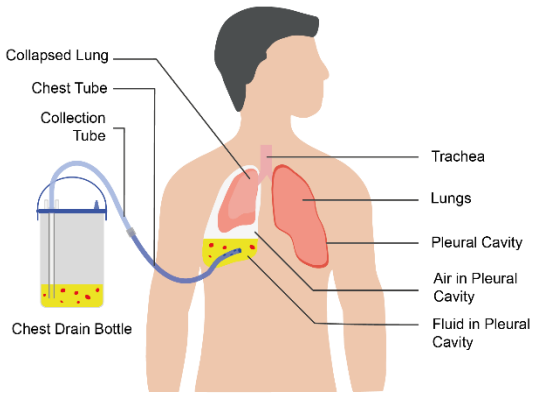

Figure 1: Details of a standard chest drain inserted into a patient.

CDs are used to treat life threatening conditions including pneumothorax, effusion, empyema, and haemothorax [5], conditions where air, serous fluid, blood, or pus leak from the lungs due to infection or injury. Pneumothoraxes, or collections of fluid, can compress the remaining lung, resulting in difficulty breathing. In severe cases, too much air becomes trapped creating a "tension pneumothorax" which puts pressure on the hearts great vessels, resulting in death if left untreated. [6, 7].

CDs are often lifesaving and are fixed in place, often by sutures [8]. Patients with CDs are often critically ill and may require regular repositioning, for example to facilitate X-rays, scans, or to prevent pressure sore injuries. When repositioning, CD tubing can get caught on bedframes or other equipment and can be accidentally pulled out by healthcare professionals, as such this results in a chest drain becoming dislodged from the pleural cavity (Fig. 2-5) [9].

During repositioning, or other manoeuvres, CDs can become dislodged. This is thought to occur in up to 7% of cases, although this may be underestimated [2]. Dislodgement also occurs where patients start to become more involved in their own care and become more mobile in and out of bed; this is a common event [10-14].

There are significant risks to the patient associated with CD dislodgement, as well as significant pain and discomfort of subsequent reinsertion [5]. As such we have been developing a breakaway chest drain valve (BCDV) which is compatible with existing chest drains used by the NHS to reduce the frequency of accidental dislodgement and to also allow for temporary disconnection at the mid-point of the tube thus providing an opportunity to safely reposition or move patients.

Critically, for the pleural cavity to be drained, dislodged chest drains must often be reinserted into the patient [15] and subsequently after reinsertion the patient will require a repeat X-ray [5] for placement confirmation. Drain reinsertion can be painful and is costly to healthcare providers (i.e., time and money to refit the drain) [5,6] and as such the ability to connect and disconnect the chest drain with a breakaway valve provides an opportunity to increase patient care and reduced costly additional procedures.

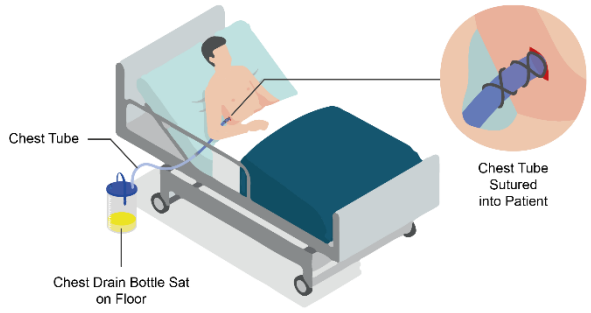

Figure 2: A chest drain inserted and sutured into a patient.

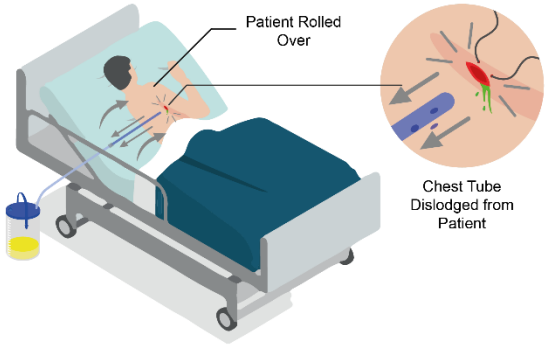

Figure 3: A chest drain dislodged inadvertently from a patient as they roll over or are rolled over.

The most common valve system used is a bottle with a water trap (Fig. 4 & Fig. 5), allowing fluid/air to drain whilst preventing air from re-entering the chest. The bottle must be lower than the patient's chest allowing gravity to drain the pleural cavity. This requires long tubing, connecting the drain to a bottle, that can easily become caught and dislodged when moving, resulting in the chest drain coming under tension; the premise is to attach a CD valve between the chest tube and the tube to the bottle.

Alternative drainage systems are available involving, for example, shorter tubing, flutter valves, or portable powered suction devices. Unfortunately, these systems are not always capable of safely draining large volumes of blood, pus or fluid. Powered systems are very effective, but are also relatively large and add additional cost. For these reasons bottle and water trap systems remain the most commonly used set-up.

To mitigate many of the issues identified, this paper focuses on the development of a BCDV that creates a weak point along a chest tube so that if tubing gets caught whilst a patient is being moved, or accidental dislodgement occurs, a controlled break occurs, thus preventing the chest drain being pulled out from the plural cavity but instead being disconnected between the chest tube and the chest drain bottle. This controlled breakpoint helps improve patient safety, but also offers an opportunity to disconnect and reconnect the CD in a controlled manner as many times as required.

Furthermore, when a healthcare worker is required to reposition a patient, they can simply temporarily activate the breakaway connection which will continue to safely drain the patient's pleural cavity during repositioning, thus making this a process more manageable.

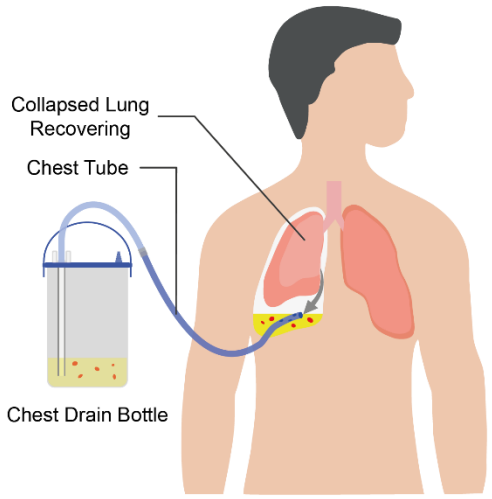

Figure 4: Standard chest drain sutured in place draining the pleural cavity allowing the lung to inflate/reinflate.

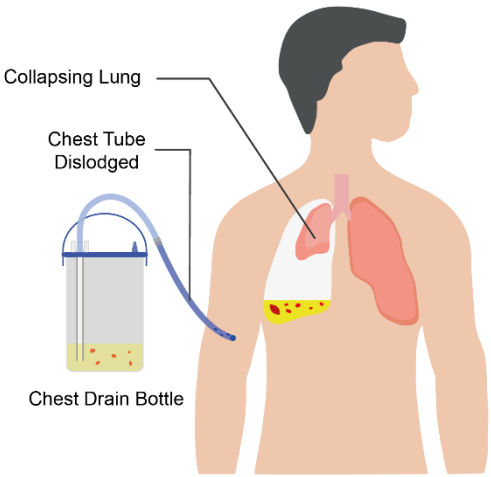

Figure 5: Standard chest drain unexpectedly dislodged resulting in the pleural cavity filling up with air and fluid resulting in a collapsed lung.

II. Material and methods

II.I. Chest drain prototype development

This section will describe the product development and prototyping of the initial BCDV including detailing the key design requirements and the design process used during the initial prototype development and 3D Printing.

II.I.I Key design requirements

The primary design requirement for the BCDV is that this must breakaway under a force significantly less than the force required to remove a drain from a patient's chest/suture. The BCDV should ensure little to no discomfort for the patient during accidental disconnection, whilst also being secure enough avoiding disconnection in everyday use. When the valve is disconnected it should create a one-way valve allowing air and fluid to leave the patient chest.

A critical design requirement is that the BCDV should stop the patient's pleural cavity reinflating, thus reducing the risk of infection. When the valve is connected it should not obstruct or effect the rate of flow of air and fluid out of the patient.

Due to a relatively low, but by no means small disconnection rate of 7%, the valve needs to be low cost to allow for adoption to ensure a cost-effective solution can be implemented. Useability for the key stakeholders is a crucial requirement for the design solution. For the healthcare professional, the valve needs to fit seamlessly into the current chest drain kit.

Connection and disconnection should be simple and intuitive within a busy healthcare setting. For the patient, the valve should not inhibit the drainage of the pleural cavity. Finally, the overall design should have minimal crevices and make minimal use of right angles to reduce the risk of the valve catching on equipment.

II.I.II Design process

Following initial work conducted at the undergraduate level whereby initial concepts were proposed and prototyped using 3D Printing, we began an iterative design process developing the one-way valve mechanism. Springs and hinges were explored however concerns surrounding complexity of the injection molding tools and assembly ruled these initial ideas out. However, it was hypothesized that using low cost, off the shelf components could provide a potential solution.

We began looking at silicone rubber one-way valves from Minivalve International (Oldenzaal, The Netherlands). Minivalve produce a variety of valves with varying sizes and materials (Fig. 6). Through manipulating these valves, we realized that the one-way valve could not only be opened in one direction, but if you applied enough force the valve could invert. As such a concept utilizing the inverted cross slit valve was created. Having tested the basic principle inverting the valve with a pen (Fig. 7), we wanted to test this concept with a tube.

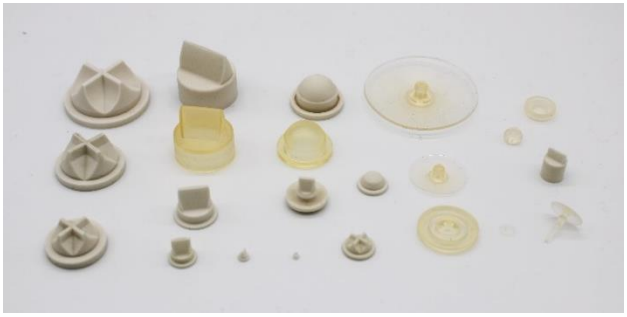

Figure 6: Selection of valves from Minivalve International ranging in size and material. Including cross slit, duckbill and umbrella valves.

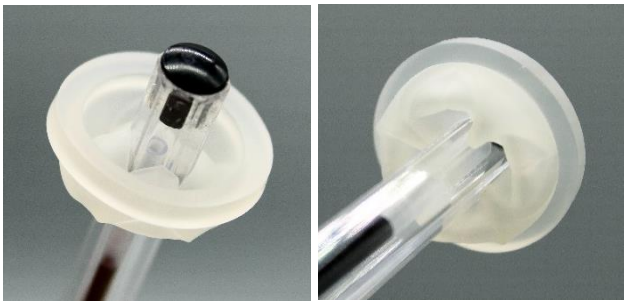

Figure 7 (Left): Pen inverting cross slit valve bottom view; (Right): Pen inverting cross slit valve top view.

Using Solidworks (Dassault Systèmes – computer aided design (CAD) modeling software), we created a 3D printed prototype to house the cross-slit valve and a protrusion/male part which is used to open the valve (Fig. 8). The initial 3D printed prototype/design demonstrated the basic proof of principle as it created a valve which creates a fully open uninterrupted flow when connected (Fig. 9). This is due to the cross-slit valve being inverted allowing fluid and air to flow from the inlet (patient) or right part of the valve to the left part of the valve at the outlet (chest drain bottle) (Fig. 8). When the valve was disconnected, it would return to its original shape as a one-way valve. Continuing the iterative design process, the concept was further developed. We optimized the length of the protrusion allowing the valve to open sufficiently, alongside making the cross-slit valve more secure and tight in its casing to allow the valve to return to its original shape.

Figure 8: Initial breakaway chest drain valve concept; Left is the male part with hollow protrusion. Right includes housing and cross slit valve.

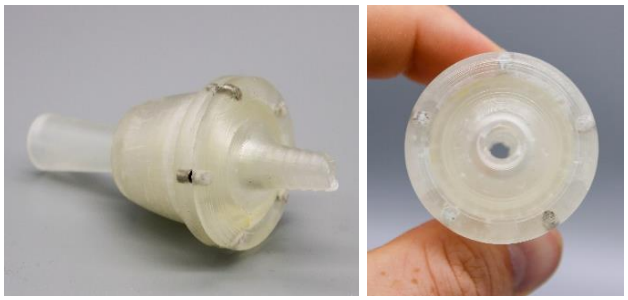

Figure 9 (Left): Initial breakaway chest drain valve concept connected; (Right): showing the one-way valve is fully open and created uninterrupted flow.

Another key aspect we focused on was how the valve would connect/disconnect; we began exploring the use of magnets as a fixing solution to align the components together providing a 'click' to confirm alignment and connection. We embedded magnets into the 3D printed parts post-production. Magnets allowed for easy adjustability of the breakaway force creating a 'click' to indicate to the healthcare professional the valve was connected and secure. To create these prototypes, recesses were created in the shroud of the valve to allow magnets to be located either side of the male and female parts; magnets were inserted/bonded using super glue.

The valve is required to fit seamlessly into the chest drain system. The current iteration used a thinner shaft which is used to open the cross-slit valve; however, the diameter was less than the thinnest point of the current chest drains system (chest drain bottle connector). Therefore, we moved to a larger 25mm cross slit valve. This meant a larger diameter of protrusion could be used minimizing any changes in pressure as fluid and air travels through the valve.

Increasing the size of the one-way valve meant the casing for the valve/male part needed to increase in size. To avoid making the valve too large, we slimmed down the casing substantially to create a leaner design (Fig. 10 & Fig. 11). Through 3D printing, alongside feedback from clinical experts, we found that having a larger valve meant it would be easier to operate (i.e., connect to the current chest drain system alongside connection and disconnection of the breakaway valve). On a busy hospital ward, it would be easier to spot if it became disconnected from a patient. Similarly, if a patient was conscious and lying on the valve the patient would more likely feel the valve and mention it to a member of staff reducing the risk of pressure sores.

However, the larger size potentially could increase the chance of the valve becoming caught on a bed frame and getting disconnected. If a comatose patient was to lie on the larger valve for long periods of time it could lead to pressure sores. Deciding between how big the valve should be is an ongoing development process using iterative design processes, expert reviews, and patient feedback to ensure all options are explored thus informing the final product development.

Figure 10: New larger break chest drain valve disconnected.

Figure 11: New larger break chest drain valve.

Another key element of the design of the valve was ensuring that when the valve was connected it would create a tight seal. Initially, we began using an 'O' ring, however, when testing the 3D printed prototypes, we found the 'O' ring would push the male and female parts apart stopping a seal and disconnecting the valve.

As such we began exploring softer materials like silicone (Platsil Gel 10 and 25) to complement the 3D printed components. Molds were 3D printed using Formlabs (Somerville, Massachusetts, USA) Clear V4 resin (Fig. 12). Following a wash and cure process, Inhibit X (Smooth-On, Inc., Macungie, USA) was applied to help the silicone cure on the 3D printed parts. A 1:1 ratio of silicone part A and B was mixed, degassed, and poured into the two-part molds before being left to cure for a few hours. 3D printing was a great way of producing fast, custom made, highly accurate molds.

The results created a thin and soft sheet of silicone around the valve to create a seal (Fig. 13). Although this seal design didn't work as planned, we plan to continue to explore these ideas alongside other configurations of O-rings and inline seals as the product development continues progresses.

Figure 12: 3D printed molds for silicone casting gasket.

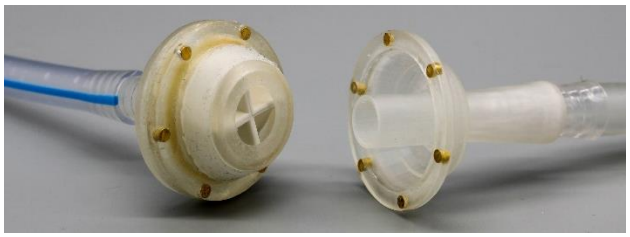

Figure 13: Silicone gasket (left) on break away chest drain valve.

To ensure the valve fits seamlessly into the chest drainage system we used the same standard connector found on the chest drain bottle (Fig. 14). These connectors were 3D printed and tested by fitting the chest drain tube (Fig. 15).

Figure 14: Christmas tree connector comparison.

Figure 15: Valve sitting in line with the chest drain system (right tube from patient, left tube to drainage bottle).

The end goal for this initial development was to be able to apply for further funding through the National Institute for Health and Care Research (NIHR) Invention for Innovation (i4i) Product Development Award (PDA) to continue the product development, support validation of the prototypes and subsequently result in the commercialization of the product. Using a realistic manikin from Simbodies Ltd (Hertfordshire, UK), we created a realistic representation of how the valve will look and work in the standard chest drain system (Fig. 16). Further visuals included illustrations explaining the breakaway valve.

To validate the initial design development of the breakaway CD valve, three core tests were conducted on the developed model. A computational fluid dynamics (CFD) analysis was performed on the developed CAD model and initial testing rigs/tests were performed using the developed 3D printed models to explore basic pull force testing and breakaway pull force testing. The 3D printed models were manufactured using a FormLabs Form 3B+ 3D Printer using FormLabs Clear V4 resin. The PreForm software (Version 3.27.0, Formlabs) was used to automatically generate the support structure required prior to printing; however, manual manipulation was used as required to ensure optimization of the 3D printing process.

Upon successful printing of the BCDVs, a standard Form Wash and Cure procedure was followed. For the Form Wash isopropyl alcohol (96% or higher) was used. The washed and dried models are then cured using the Form Cure using the predetermined, followed by postprocessing tasks, which include the removal of the support structure using the standard cutting tools. For the developed CD, the Form Cure was used and as such parts were cured for 15 minutes at 60°C.

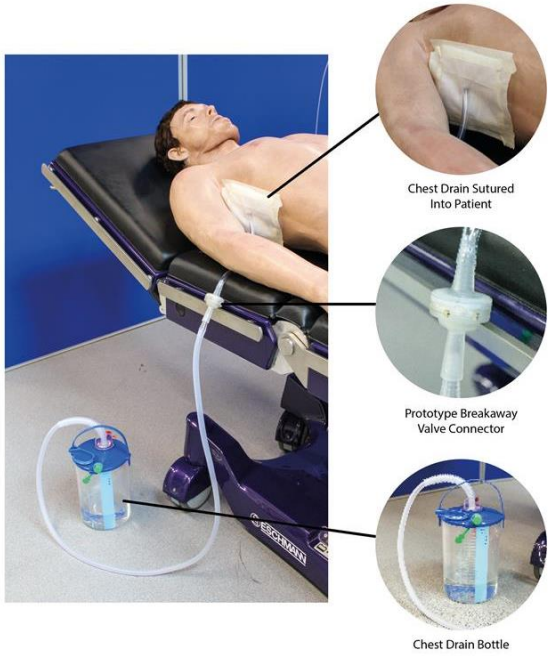

Figure 16: Visuals showing the breakaway chest drain valve in a chest drain system.

After establishing initial data and parameters defined in II.I, the developed 3D printed models are used for testing as documented in sections II.II and II.III.

II.I. CFD simulation

A CFD simulation was performed to study a variety of different fluids and viscosities travelling through the valve using ANSYS Fluent (ANSYS Inc., Canonsburg, Pennsylvania, USA, 2021 R2). These simulations provided detail in terms of flow velocity and pressure distribution for better understanding of the internal pressure change. The SST k-ε turbulent flow model was employed in Fluent. The fluid domain was defined by the internal geometry of the valve in its connected and disconnected state. The viscosity of the pleural effusions is in a range between 0.5 and 3.5 mPas, and the density is 1100 kg/m^3 [16-20]. The boundary conditions are defined as the inlet velocity at 13.4 mm/s and 107 mm/s for the air and fluid respectively, and the outlet pressure set as atmosphere, with no-slip wall boundary conditions.

The results such as pressure drop can be used to define the optimal design of the BCDVs and predict the worst case under various operating conditions. When the valve is disconnected the cross slit needs to be pushed open giving enough fluid pressure to allow discharge. When it reaches a balance point, the valve is closed and there is neither forward nor backward flow. Direction of flow was selected coming from the patient to the chest drain bottle. Air and liquid were then tested.

II.II Pull force testing

Pull-force testing was required to approximate the range of tensions that could be applied to a chest drain before chest drain dislodgement occurred.

A porcine simulacrum of the chest wall was sourced from a local abattoir, comprising parietal pleura, rubs and intercostal muscles, skin, and subcutaneous tissues. The model was clamped to a surface and a 28 French gauge chest drain was inserted through the ribs and secured using sutures. The suture fixation was completed in one of two ways, aiming to represent both good and poor fixation techniques.

Both techniques used non-absorbable suture and compliant with British Thoracic Society (BTS) guidelines. The first method used two firmly applied locking sutures; the second, a single suture less firmly applied (see Fig 17) [21]. A third method of fixation, where no sutures were used and the drain held in place only by friction, was also tested. The chest drain was connected to a further drainage tube via a "Christmas Tree" adapter (Fig. 18).

A Newton Meter spring balance was attached to the distal end of the chest drain and tension applied until either:

1. The Christmas Tree adapter became disconnected.
2. The chest drain slipped through the sutures.
3. The sutures began to pull through the porcine tissue.

The test was repeated three times in each scenario and the mean value recorded.

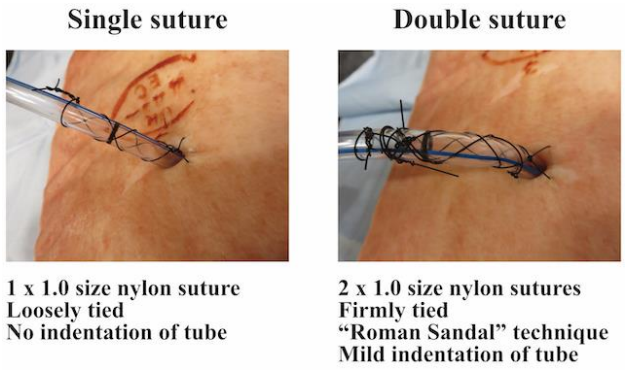

Figure 17: Two methods of chest drain fixation.

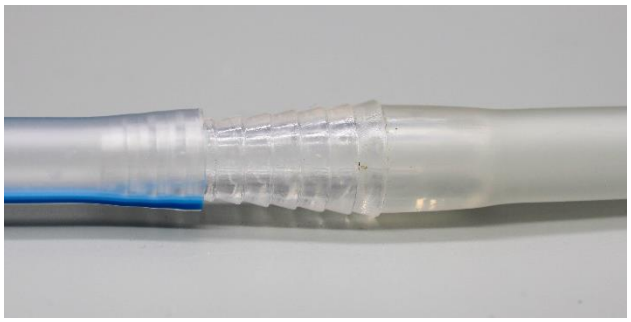

Figure 18: Christmas tree adapter.

II.III Breakaway force testing

Following the completed pull force testing an approximate figure of 10N's was identified as being sufficiently under the minimum amount of force to pull/slip a chest drain. Whilst also having enough force to not fall out under normal draining circumstances. On each female and male parts of the valve 6 x N42 Neodymium Magnets - Gold Plated (3mm diameter x 2mm thick) were used.

A Newton meter was attached to a force test rig, holes were created in both the Christmas tree connector and the inverted Christmas tree connector. The newton meter was hooked into the Christmas tree connector, and string was tied into the inverted Christmas tree connector. The weight hanger was attached to the string. Gradually and incrementally 0.5 Newtons was added to the hangers.

As the force increased and failure was becoming apparent, the force was increase by 0.1 of a Newton to establish a more accurate reading. Readings on the newton meter was recorded until the valve broke away thus establishing the breakaway force for the valve. Fig 19 presents the test rig and the gradual increase in mass.

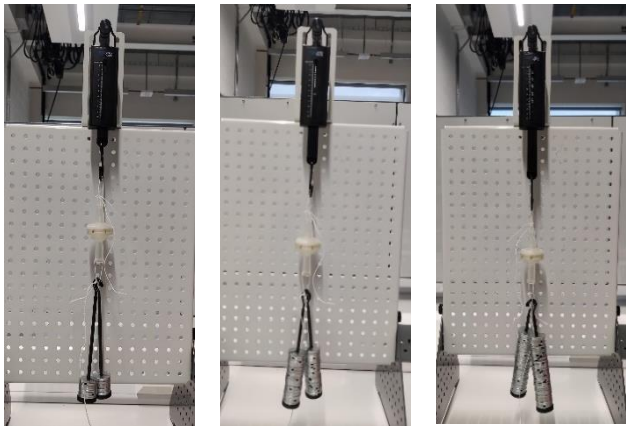

Figure 19 (left): 1.6N of Force; (middle): 5.6N of Force; (right): 9N of Force.

III. Results and discussion

The following sections present this initial testing data established from the CFD testing, pull force testing and breakaway testing experimentation. Data established through preliminary testing and literature reviewed helped inform the development of the BCDV CAD model and CD 3D printed model.

III.I. CFD simulation results

Fluid flow velocity and pressure distributions in the connected/disconnected device are shown in Fig 20-23. The one way valve has no degradation in inflow/outflow. Outlet pressure is positive to push through the rubber cross slit valve to allow valve drainage and air escape.

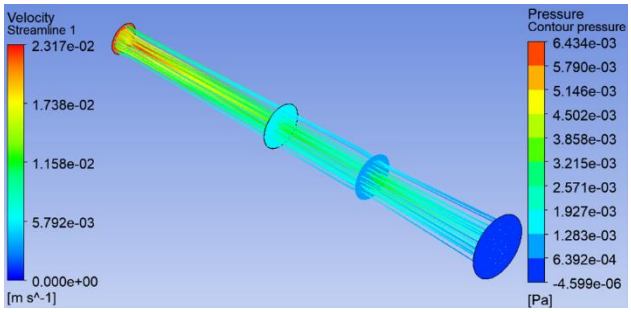

Figure 20: Results of the CFD Simulations for the air flow (Connected). Top left shows air traveling through the female part of the valve traveling from the patient (inlet) to the bottom right showing it traveling into the chest drain bottle tube (outlet).

The inlet boundary condition is 13.4mm/s inlet velocity. As velocity is shown as stripes (streamlines), the velocity value at the inlet boundary is noted in yellow-green according to the velocity colour bar on the left. The highest velocity appeared on the axial line of the pipe close to the inlet boundary (the top-left side) with a value of approximately 23 mm/s (in red), and the outlet velocity is approximately 5.79 mm/s (in cyan).

The outlet pressure is set to zero (gauge) and inlet pressure is automatically calculated by the model about 6.43e-3 Pa. The results show how the pressure and velocity is distributed when the valve is connected.

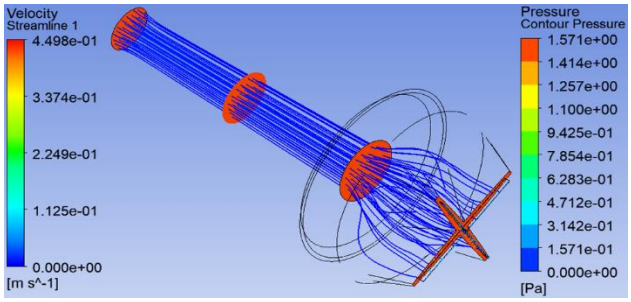

Figure 21: Results of the CFD Simulations for the air flow (Disconnected). Top left shows air traveling through the female part of the valve traveling from the patient (inlet) to the bottom right showing it traveling out of the cross-slit valve (outlet).

The pressure is shown in the four cross-sections. The colour from light blue to solid blue indicates the pressure value from approximately 1.82 Pa to zero-gauge pressure at the outlet boundary. For the velocity, it ranges from 107 mm/s at the inlet (set as boundary condition for fluid charge) to approximately 35.5 mm/s at the outlet, as shown in the streamlines.

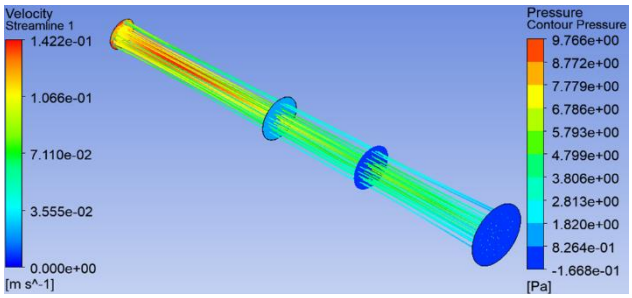

Figure 22: Results of the CFD Simulations for the fluid (Connected). Top left shows fluid traveling through the female part of the valve traveling from the patient (inlet) to the bottom right showing it traveling into the chest drain bottle tube (outlet).

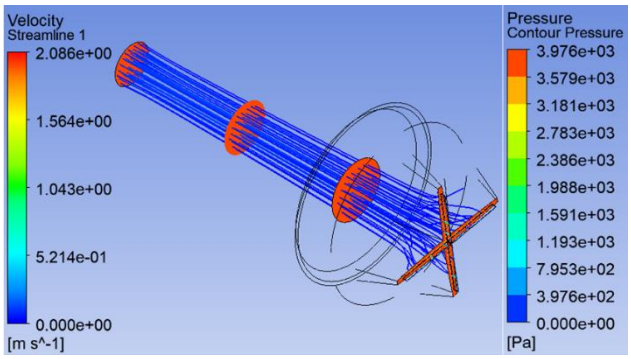

Figure 23: Results of the CFD Simulations for the fluid (Disconnected). Top left shows fluid traveling through the female part of the valve traveling from the patient (inlet) to the bottom right showing it traveling out of the cross-slit valve (outlet).

III.II Pull force testing results

Upon completion of the pull force testing, which was conducted by disconnecting/dislodging a chest drain using a porcine tissue model, Table 1 presents the average disconnection or dislodgement force (range) exhibited. These figures have been used to help determine a suitable breakaway force that has been established which is approximately 10N at which point the BCDV should disconnect without causing trauma to a patient. To determine the 10N value, this has been derived by taking the smallest average disconnection and dislodgement force for a connector, in this case the Christmas Tree Connector (53.8N) and dividing this by five to get establish a margin of safety ratio of 1:5 (i.e., 10.7N). As such with such a large margin of safety, the designed BCDV should not be capable of causing injury because of a forced or accidental disconnection.

Table 1: Average force required to disconnect or dislodge a chest drain using a porcine tissue model.

	Average disconnection or dislodgement force (range)
Christmas tree connector	53.8 N (39-70)
Poorly sutured	68.2 N (41-79)
Double sutured with indentation	132.0 N (117-147)
No suture fixation	2.3 N (2.2-2.4)

III.III Breakaway force testing results

To test the viability of a breakaway force of equal or less than 10N when using the BCDV, the 3D printed model which contains 12 magnets that snap fit the two components of the BCDV together has been tested. By applying weights incrementally, we were able to establish that the average breakaway force prior to disconnection for the 3D printed model which contains the 12 x (3mm dia x 2mm thick N42 Neodymium Magnets - Gold Plated), this was 9N of force. To further validate this, additional testing methods are being explored to further validate the results including determining a force by the strength and distance of the magnets and observing whether any loss of connecting force is observed anywhere (e.g., the seal pressing the parts apart).

IV. Conclusions

Throughout the product development process and initial testing, 3D printing has played a crucial role in the design and development of the BCDV. From initial concepts through to CAD modelling, design for manufacture and assembly (DFMA) principles were adhered to, thus allowing the 3D printing of suitable models/prototypes to validate. As such these models provided an opportunity for both aesthetic and functional assessment.

Product development and 3D printing conducted through iterative design processes have allowed for the development of the inverted cross slit valve concept. The development of the concept was strongly driven by the 3D printing and DFMA principles. To ensure suitable functional testing could be completed, the 3D printing process required fine tuning and dimensional control considering tight tolerances to ensure a tight casing around the cross-slit valve could be created. This was important to help make the valve return to its original shape when disconnected.

Furthermore, it was important to consider the models development and dimensioning in relation to the cross-slit valve to allow the creation of a larger protrusion where needed to provide greater flow through the valve thus making the valve fit seamlessly into the chest drainage system. The experimentation of these parameters was a key factor in determining the success or failure of a model/prototype during the iterative design process. 3D printing has not only informed several design decisions but transformed and realised an idea that could make a significant impact to a patient and healthcare provider in a healthcare setting.

The pull force testing conducted by suturing a chest tube through a porcine airway has allowed us to establish an initial pull force of 10N which is likely to be sufficiently lower than any predicted forces likely to dislodge or disconnect a CD. Angular moments and forces have been minimised/controlled through the design of the BCDV to ensure only one lateral direction of motion is exhibited in the disconnection/reconnection of the BCDV. Although further testing is required, these preliminary tests suggest a 10N breakaway force would leave a sutured CD tube in place even with a forced and unexpected disconnection.

The breakaway testing of the BCDV established that a pull force of no greater than 10N could be achieved as highlighted above. Through user testing of the prototype, we believe 10N is approximately a desirable breakaway force, however further testing will need to be conducted via a cadaveric study to validate an optimum valve breakaway force in a human model. Further development is required to optimise the design of the valve to meet the pull force required. Further testing is required to validate the breakaway force, this will also be needed to validate the design. However, at this stage of the project having a 9-10N breakaway force is sufficient to allow for further development.

The initial CFD testing has highlighted that the flow of air and fluid when traveling through the breakaway CD one way valve has no degradation in inflow/outflow. The outlet pressure is large enough to push through the rubber cross slit valve to allow valve drainage, thus demonstrating proof of principal of the CD using the developed 3D printed models.

The development of BCDV has been possible through iterative design processes using 3D printing which has high precision and tolerances. It is important when developing prototypes for medical and healthcare settings that realistic targets are set and subsequently achieved, as such the iterative design process utilised and modelling/prototyping conducted has ensured that the initial product development has been successful. Finally, should the BCDV be commercialised after further product development has occurred, the impact globally is likely to be significant, as this will not only improve the patient experience and outcomes, but could reduce the costs healthcare providers incur.

ACKNOWLEDGMENTS

This research is funded by the National Institute for Health and Care Research - i4i Product Development Awards (PDA) - Breakaway Chest Drain Valve (Reference: NIHR204562). The porcine testing conducted was prior to acquiring NIHR i4i funding and was neither funded of associated with the NIHR.

The authors would like to acknowledge Mr Joseph Meeks for his work with early prototyping, product development and parameter testing. Furthermore, the authors would like to acknowledge the technical support provided by technicians and technical specialists based in the School of Architecture Design & Built Environment and the Department of Engineering at Nottingham Trent University.

AUTHOR'S STATEMENT

Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study.

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