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## 1. INTRODUCTION

Bleeding following cardiac surgery is a major complication that results in chest reopening of around 5% of patients in the United Kingdom. Drainage of the chest following surgery aims to identify bleeding and therefore allow early appropriate intervention and to prevent the potentially catastrophic complication of cardiac tamponade. The routinely used drains have the problem of clots forming in the drain in the perioperative period and therefore concealing bleeding and giving rise to tamponade. Many units perform milking of the drains, which is dependent on personnel availability and experience.

ClotStop drains aim to reduce the clots blocking the drain, thus preventing accumulation of blood inside chest cavities and reducing the risk of tamponade with the possible serious complications. Therefore tube patency is critical in the early hours after heart surgery. This report describes early clinical experience with the use of ClotStop drains in cardiac surgery.

## 2. PATIENT INFORMATION

During the trial period from July to October 2021, a total of 19 patients received the ClotStop drain. The main demographic data is shown in Table 1. All the patients presenting for first time cardiac surgery with their disease listed in Table 2.

TABLE 1: DEMOGRAPHIC DATA OF PATIENTS

Total	19
Male / Female	12 / 7
Mean age	67.2 ± 7.2 years
Hypertension	9
Hypercholesterolemia	10
Diabetes Mellitus	3
Chronic Obstructive Pulmonary Disease	5
EuroScore II	2.12 ± 2.0

TABLE 2: CARDIAC PATHOLOGY

Primary Cardiac Condition	
Isolated Coronary Artery Disease	11
Isolated Aortic Valve Disease	3
Coronary and Aortic Valve Disease	3
Mitral Valve Disease and Atrial Fibrillation	2

## 3. TREATMENT

All 19 patients underwent their planned operations which are shown in Table 3.

TABLE 3: OPERATIONS COMPLETED

Procedure	Quantity
CABG X 2	5
CABG X 3	3
CABG X 4	3
AVR and CABG X 1	2
AVR and CABG X 2	1
Mitral Valve Replacement, AF Ablation and LAAO Device	2

<b>Drainage System:</b>	traditional underwater seal device
<b>Catheters:</b>	28 Fr straight and curved ClotStop® coated silicone catheters
<b>Tubing manipulation:</b>	None

CABG: Coronary Artery Bypass Grafts; AVR: aortic valve replacement; AF: Atrial Fibrillation; LAAO: Left Atrial Appendage Occlusion



Cardiopulmonary bypass was achieved with venous cannula in the right atrium and arterial cannula in the aorta. Mitral valve surgery was completed by bicaval venous cannulation with normal arterial cannula in the aorta. All patients had antegrade prime displacement prior to institution of routine cardiopulmonary bypass. Surgery was completed routinely utilizing cold blood antegrade cardioplegia via a cannula in the ascending aorta following aortic cross clamp.

A straight ClotStop catheter of 28 Fr was inserted in the retro-sternal space and a second ClotStop curved catheter 28 Fr in the pericardial space or the pleural space if it was opened during left internal mammary artery harvesting.

In two cases undergoing CABG both pleural spaces were opened and therefore one straight and two curved drains were utilized. The chest tubes were connected to a traditional collecting device and the suction level was set at -20 cmH<sub>2</sub>O at the end of the surgery. The patients were transferred to the ICU in stable hemodynamic conditions and without bleeding. Chest drains remained in situ and were reviewed the following morning and removed if there was less than 20 ml of blood draining per hour for two consecutive hours and no air leak was present.

No stripping, milking, tapping or sterile suction was performed on the chest tube.

**There were no reported clots blocking any of the drains and inspection of the chest tube after tube removal, showed them to be free of clots.** After drain removal, a chest x-ray was performed, which showed one pneumothorax, however it was managed conservatively.

<b>Drainage Protocol:</b>	Set pressure: -20 cmH <sub>2</sub> O
<b>Drain removal criteria:</b>	
 <b>Fluid:</b>	< 20 ml/h during 2h
 <b>Air leakage:</b>	No air leak

#### 4. OUTCOMES

All patients had their drains removed on the first postoperative day with drainage time varying between 13 to 21 hours. No patient had tamponade or developed late pericardial or pleural effusion and mean hospital stay was 7.2 ±2.1 days. There was no mortality in the group of patients and five patients developed atrial fibrillation in the postoperative period requiring medical therapy. The ClotStop drains were easy to insert once experience was gained and had prevented clots occluding the drain in any of the patients operated on. There were no complaints of pain or discomfort from the patients and no adverse comments from the nursing staff regarding the removal of the drains.

#### 5. DISCUSSION AND CONCLUSION

The need for an improved catheter that can prevent clot blockage is high. **According to our experience, the ClotStop catheter presents a safe, efficient and reliable alternative to conventional catheters that maintains chest tube patency for efficient drainage in the early hours after cardiac surgery.** It was easy to handle and no clotting was observed in the catheter despite a significant drainage. Insertion of the ClotStop initially was slightly difficult to pass through the chest or abdominal wall as the drain end was getting stuck. After review and reflection, it was figured out that applying the Roberts instrument across the two sides of the end of the drain as shown in Figure 2 rather than Figure 1 made the passage of the drain much easier and avoided any tissues entering the drain.



Fig. 1: Incorrect way of inserting the drain through the chest/abdominal wall



Fig. 2: Correct way of holding the end of the drain to pull through the chest/abdominal wall

Furthermore the removal of the chest tube seemed to be less painful for the patient compared to conventional catheters.

**I believe these drains are an excellent addition to the tools used in cardiac surgery to minimize retained clots and tamponade.**

Disclosure: The ClotStop drains were provided by Medela AG.

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**KEYWORDS:** THORACIC SURGERY | CLOTSTOP DRAINS



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## 1 INTRODUCTION

At the Clinic for Thoracic Surgery at the Wangen Specialist Clinics, the use of 30 ClotStop catheters, provided by Medela, was tested in the period from 16.09.2021 to 13.10.2021 as part of an application observational study. The Clinic for Thoracic Surgery at the Wangen Specialist Clinics is certified as a center of competence of the German Society of Thoracic Surgery and as a lung cancer center of the German Cancer Society. The surgical spectrum covers the entire field of thoracic surgery except lung transplantation.

## 2. PROCEDURE

The ClotStop catheter, size 28 Charriere, was routinely inserted into the pleural space at the end of each operation instead of the 28 Charrière chest drains commonly used in our clinic. The catheters commonly used in our clinic are made of transparent, heat-sensitive PVC. This catheter has numerical depth markings in 2 cm increments for easy and precise positioning. The angled connector can be cut to connect to a funnel connector from a chest drainage system.

In most cases, the operations were performed using the minimally invasive procedure (VATS). A smaller proportion of the operations were performed in the open procedure via anterolateral thoracotomy. A single drain was predominantly created by an intercostal stab incision (N = 17); in five cases, two chest drains were placed. The ClotStop catheters were prepared in a sterile water bath for two minutes before insertion into the thorax in order to activate the anti-adhesive hydrogel polymer coating.

The surgical spectrum at the end of which the ClotStop catheter was inserted into the pleural space ranged from **anatomical resections in bronchial carcinoma to atypical resections, including pleural empyema operations and talc pleurodeses.** Especially in pleural empyema and talc pleurodesis, the risk of drainage clogging due to intraluminal coagulum is increased.

<b>Drainage system:</b>	Thopaz+
<b>Catheter:</b>	28 Fr ClotStop® coated catheters straight and curved
<b>Tube handling:</b>	milking and wiping off in case of blockage

## 3. RESULTS

Unlike the PVC catheters we usually use, the ClotStop catheter is made of silicone and therefore has a softer consistency. The coating makes it feel more slippery during implantation. Since the ClotStop catheter has a slanted connection connector similar to the one we usually use, the overall handling when implanting the ClotStop catheter was comparable to that of the catheters we usually use. Because the ClotStop catheter is made of softer silicone, care should be taken when securing the catheter to the suture to prevent stenosis by overtightening the fixation thread on the ClotStop catheter.

Subjectively, the ClotStop catheter seemed **less pain provoking than** the harder PVC catheter due to the softer material. Despite the flexibility of the ClotStop catheter, we have not observed any kinking during use.


During the postoperative process, the thoracic drainage system is routinely checked for functionality at appropriate intervals by both nursing staff and medical colleagues. The quality of the pleural secretions and the presence of air fistulas are documented. If coagulation of the pleural secretion occurs in the drainage system, the lumen of the tube is made continuous again by manual milking or rolling out.

**This procedure did not lead to clogging of any of the ClotStop catheters used.** The duration of use of the ClotStop catheters was between 24 hours and five days.

The ClotStop catheters were removed as usual. Some colleagues complained about the limited lubricity of the catheter compared to the catheter we usually use.

As the ClotStop catheter does not have a numerical depth marking, it was difficult to withdraw the ClotStop catheter because the distance between the skin level and the lateral eyes on the ClotStop catheter cannot be estimated. According to information from Medela, the ClotStop catheters now available on the market have depth markings in 1 cm increments.

**Criteria for catheter removal:**

 **Fluid amount:** < 300 - 500 ml per day

 **Air leak:** none

3 days minimum for talc pleurodesis and pneumothorax operations

#### 4. DISCUSSION AND CONCLUSION

Overall, however, it can be stated that the ClotStop catheter is a simple chest drain comparable to established products. **Because of the softer consistency, nerve irritation at the site appears to be less severe.** Whether the non-stick coating of the ClotStop catheter reduces the formation of thrombi in the catheter tube must be clarified in a controlled comparative study with the usual PVC catheters.



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**KEYWORDS:** THORACIC SURGERY | CLOTSTOP DRAINS



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## 1 INTRODUCTION

The Thoracic Surgery Department of the Hemer Lung Clinic received and used a total of 20 straight and 5 curved 24 Fr ClotStop catheters from Medela for observational purposes. Chest drains are a major cause of post-operative local pain and are therefore removed as early as possible. Softer drains could perhaps reduce local discomfort, according to our hypothesis and motivation for observing the application. Our clinic offers the full range of thoracic surgeries, except lung transplantation.

## 2. PROCEDURE

Over a period of 2 weeks in June and July 2021, the drains were used consecutively in VATS lobectomies, wedge resections, pneumothorax surgery and VATS empyema removals. With the exception of the empyema drain (1 straight and 1 curved drain), only singular drains were used. For many years, we have been using standard drains from another manufacturer, which are slightly more rigid in terms of consistency.

The ClotStop catheters were passed at the end of the procedure, immersed in NaCl and usually inserted transcutaneously or via a camera trocar access.

The moistened drain feels slightly softer and has less rigidity than our standard drain. It must be inserted and placed under visual control.

<b>Drainage System:</b>	Thopaz+
<b>Catheter:</b>	24 Fr, straight and curved catheter
<b>Tube handling:</b>	None

## 3. RESULTS

Due to the lower stiffness, the drain appears to "mould" itself better to the surface of the thorax. Conversely, it was observed that when pushed forward through a trocar access port, the tip of the drain easily snapped off at the level of the first drain side hole, provided the tip got caught on a resistance. This is easily corrected under visual control with the help of an instrument. The softer consistency of the drain certainly benefits patient comfort and could cause less irritation in the intercostal space. However, this hypothesis would have to be evaluated in a prospective comparative study.

Suture fixation of the drain is easy, the connection to the double lumen Thopaz tubing is stable and no problems were encountered during the application. Drain removal at end expiration was done without problems. No catheter blockage or kinking outside the thorax was observed. In one case, we performed 3 autologous blood pleurodesis through a straight drain. On the day of drain removal, a blood- fibrin clot was observed that extended from the thorax to the double lumen drainage tube, filling most of the ClotStop catheter, but not adhering to the inner side of the catheter, and this could be extracted in its entire length.

### Criteria for catheter removal:

<b>Fluid quantity:</b>	Fluid: < 300 ml /24h
<b>Air leak:</b>	< 10 ml/min

## 4. DISCUSSION AND CONCLUSION

In summary, I consider the ClotStop catheter to be a promising product that can improve patient comfort due to its softer consistency. It is easy to handle, should be checked in position before fixation and meets all the requirements for modern and safe chest drainage. Due to its consistency and coating, the risk of drainage clogging appears to be significantly lower. If the product were to be launched on the market with an attractive price-performance ratio, we would plan a routine application.

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