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### **ORIGINAL ARTICLE**

# Caval collapse during cardiopulmonary bypass: a reproducible bench model

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# Abstract

**OBJECTIVES**: During open heart surgery, so-called atrial chatter, a phenomenon due to right atria and/or caval collapse, is frequently observed. Collapse of the cava axis during cardiopulmonary bypass (CPB) limits venous drainage and may result downstream in reduced pump flow on (lack of volume) and upstream in increased after-load (stagnation), which in turn may both result in reduced or even inadequate end-organ perfusion. The goal of this study was to reproduce venous collapse in the flow bench.

**METHODS**: In accordance with literature for venous anatomy, a caval tree system is designed (polyethylene, thickness 0.061 mm), which receives venous inflow from nine afferent veins. With water as medium and a preload of 4.4 mmHg, the system has an outflow of 4500 ml/ min (Scenario A). After the insertion of a percutaneous venous cannula (23-Fr), the venous model is continuously served by the afferent branches in a venous test bench and venous drainage is augmented with a centrifugal pump (Scenario B).

**RESULTS**: With gravity drainage (siphon: A), spontaneously reversible atrial chatter can be generated in reproducible fashion. Slight reduction in the outflow diameter allows for generation of continuous flow. With augmentation (B), irreversible collapse of the artificial vena cava occurs in reproducible fashion at a given pump speed of  $2300 \pm 50$  RPM and a pump inlet pressure of -112 mmHg. Furthermore, bubbles form at the cannula tip despite the fact that the entire system is immersed in water and air from the environment cannot enter the system. This phenomenon is also known as cavitation and should be avoided because of local damage of both formed blood elements and endothelium, as well embolization.

**CONCLUSIONS**: This caval model provides a realistic picture for the limitations of flow due to spontaneously reversible atrial chatter vs irreversible venous collapse for a given negative pressure during CPB. Temporary interruption of negative pressure in the venous line can allow for recovery of venous drainage. This know-how can be used not only for testing different cannula designs, but also for further optimizing perfusion strategies.

Keywords: Cardiopulmonary bypass • Augmented venous drainage • Kinetic venous drainage • Cava collapse • Atrial chatter • Hypo perfusion • Cannula

# INTRODUCTION

Cardiopulmonary bypass (CPB) is used on a routine basis in cardiothoracic surgery to maintain full or partial perfusion of the body while the heart is unloaded or arrested. During open heart surgery, so-called atrial chatter, a phenomenon due to right atria and/or caval collapse, is frequently observed. Collapse of the cava axis during CPB limits venous drainage and may result downstream in reduced pump flow on (lack of volume) and upstream in increased after-load (stagnation), which in turn may both result in reduced or even inadequate end-organ perfusion.

Although the phenomenon described is ubiquitous and has been observed since the very beginning of CPB, little effort has been made for better understanding and the development of improved perfusion strategies. As a matter of fact, a PubMed search on 30 August 2013, with the search term 'caval collapse during cardiopulmonary bypass' provides only five hits, two of which [1, 2] deal with the issue raised here, whereas the others are related to hypovolemia and trauma. With the somewhat broader search term 'venous collapse during cardiopulmonary bypass', there are 154 hits, the main issue being again haemodynamic collapse (shock) due to hypovolemia, trauma, etc. but very few deal with CPB-induced collapse of the major veins. As a reminder, CPB for open heart surgery [3] consists of a loop between an arterial and a venous cannula, one or several pumps, an oxygenator/ heat-exchanger structure, reservoirs, filters and tubing [4]. For single venous cannulation, the deoxygenated blood is typically drained from the inferior of vena cava and the right atrium and flows through the venous line into the venous reservoir. With the systemic pump, the collected blood is pushed through the heat-exchanger/membrane oxygenator structure. After this artificial lung, the oxygenated (arterialized) blood is returned through the arterial line. It is the arterial cannula, usually inserted into the aorta or one of its branches, that leads the blood with the help of

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the pressure provided by the systemic pump back to the patient's vascular arterial system. The traditional way to get the venous blood out of the patient is by adjusting the height of the operative table and/or the venous reservoir to produce negative pressure by gravity driving the blood (siphon). Another way for augmentation of venous drainage is relying on vacuum or kinetic assistance with a centrifugal pump to generate negative pressure. This latter approach can generate much higher negative pressures when compared with gravity. Unfortunately, suction on the venous line can become excessive and when the venous system collapses, the blood flow may become very limited or even completely shut off [5]. Of course, CPB is used not only in open heart surgery for coronary artery revascularization, valve repair and replacement, repair of congenital heart defects or aneurysm repair etc., but also for extracorporeal membrane oxygenation (ECMO) and extracorporeal life support (ECLS) to allow for recovery of the function of the lung and the heart, as bridge to transplantation or bridge to decision [6].

In the normal human organism, there are four main forces driving the venous blood from the periphery towards the heart: the heart cycle, the respiratory cycle, the muscle pump and the vis a tergo (Latin standing for: a force acting from behind). However, in a typical open heart surgery scenario (under general anaesthesia, open chest, arrested heart and lungs, in supine position on the operating) only one of the four natural forces, the vis a tergo, is still available, provided that there is no mechanical obstacle like cannula obstruction and thrombotic occlusion of major veins. The situation can be somewhat less dramatic in ECLS and ECMO where several natural forces may still be contributing to venous backflow up to some degree, but not necessarily. Excessive positive pressure ventilation, excessive volume controlled ventilation, excessive PEEP, air trapping and scavenging of blood in the pulmonary vascular bed [7] are just some mechanisms that interfere with good venous drainage during perfusion.

If venous drainage is not sufficiently supported by the affluent blood from the branches of the vena cava, or if the negative pressure produced by gravity, vacuum or a pump used for augmentation is too high, the venous system collapses partially or totally, temporarily or permanently, a phenomenon that reduces venous drainage further [1].

The awareness about limited venous drainage is increasing and there have been a number of improvements like increased inner lumen of cannulas, optimal cross sectional area of tubing [4], more effective grooved and swirled tip of cannulas with multiple holes and/or asymmetric design and numbers of side-holes [1] as well as more sophisticated perfusion strategies using non-occlusive centrifugal pumps for augmentation or vacuum with negative pressure limitation of -50 to -80 mmHg in order to avoid damage to the blood cells, venous wall and cavitation.

The present study was designed in order to provoke caval collapse originating from excessive venous drainage in reproducible fashion on the bench for better understanding how it is generated and hopefully prevented.

### MATERIALS AND METHODS

For previous studies for assessment of cannula performance, the test device was positioned either in a water tank (maximal flow as all cannula orifices are un-covered), in a flexible tube with external pressurization [8] or without [9] (very limited flow at high negative pressure with collapse of the tubing), and within a flexible tube with orifices [10] representing affluent veins (limited flow for some orifices covered by the collapsing wall, but not all orifices). None of these models mimics well the situation of the vena cava in nature, where all orifices providing affluent blood are not fed by a fluid in a tank but rather veins, which can again collapse if the negative pressure due to augmentation becomes excessive.

# Compilation of afferent blood flows for the vena cava model

The blood flow of the afferent vessels of vena cava is compiled from the data available in the literature and summarized in Table 1. The available data are based on the classic method

Table 1: Minimal, maximal and mean flows of the main veins as reported in the literature in studies not related to CPB (ml/min)

Afferent veins	Minimal flow	Maximal flow	Mean flow	Literature
External iliac	189 × 2	313 × 2	251 × 2 = 502	[11]
Internal iliac			251 × 2 = 502	Same as external (arbitrary value)
Renal	46 × 2	1220 × 2	633 × 2 = 1266	[12]
	45 × 2	1030 × 2	528 × 2 = 1056	[12]
	791	1750	1260	[13]
Hepatic	1016	1462	1239	[14]
	1074	2116	1595	[14]
			1020	[15]
			1260	[16]
			1530	[17]
Coronary sinus	97	147	122	[18]
	77	109	93	[19]
	83	159	122	[20]
	127	161	144	[21]
Subclavian			400 × 2 = 800	[22]
	260	450	355 × 2 = 710	[23]
Jugular			250 × 2 = 500	[24]
	320	692	506 × 2 = 1012	[25]

measuring the blood flow by means of either an electromagnetic flow meter or a Doppler flow meter. In the former variation a magnet is placed to the vascular vessel, as a fluid conductor, the detected magnitude of the voltage in produced magnetic field is proportionate to blood flow. Alternatively, the later flow meters rely on piezoelectric crystals contained within transducer heads. The transmitted sound wave between crystals is influenced by the fluid flow velocity, and the blood flow can be calculated provided the ultrasonic sampling is representative of the velocity profile.

#### Geometry of the venous tree for the caval model

In order to simulate venous drainage, the geometry of the vena cava is studied. Rough analogies show that the vena cava is composed of the inferior and the superior vena cava (SVC) and the main afferent veins to be considered in the model can be grouped in nine channels: two common iliac veins (draining the external and the internal iliac veins on each side), two renal veins, two hepatic collector veins, the coronary sinus together with the azygos vein, the anonymous vein draining the left subclavian and the left jugular vein and the equivalent on the right side.

#### Material selection

Four kinds of commercial plastic materials are assessed for this study:

- (i) Traditional surgical Penrose drain made from thin-walled latex [9]. In its original application, capillary drainage and kink resistance are achieved by a strip of gauze in the centre of the drain. In this setting, the gauze is removed, and no capillary effect is expected.
- (ii) Grooved reversed capillary drain made from silastic [10]. In its original application, the height of the grooves defines the dimension of the capillaries and also provides kink resistance. There is no capillarity for the reversed configuration, with the groves on the outer circumference. However, these ribs contribute to the wall stiffness.
- (iii) High-density polyethylene (HDPE), thickness 0.035 mm (commercial household bag designed for thermal sealing: Rotel, Schönenwerd, Switzerland).
- (iv) Low-density polyethylene (LDPE), thickness 0.061 mm (commercial household bag designed for thermal sealing: Coop, Basel, Switzerland).

### Manufacturing of the caval tree

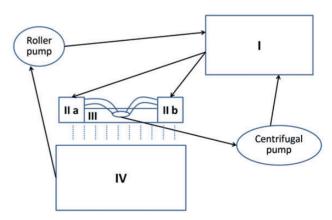
A simplified caval tree representing nine major afferent veins as outlined above and one large efferent channel is cut by a computercontrolled laser system (Versalaser, Universal Laser Systems, Scottsdale, AZ, USA) simultaneously from two stacked polyethylene layers. The goal of this approach is to achieve a watertight seal between the two layers of the plastic material by automatic welding during the cutting process, and a seamless connection of the channels to the caval axis.

# Determination of required preload for equivalence with typical human cardiac output

Before the installation of this caval tree within the flow bench, the required preload is determined. For this purpose, each affluent branch of the caval tree is mounted with ¼" CPB tubing to a right and left reservoir, respectively. Test medium is water and the flow of the branches is quantified individually and in total with a volumetric tank and timer. The set-up is tested in overflow mode for the reservoirs with three different heights (2, 4 and 6 cm) as preload with reference to the caval axis. In this way, the required preload is established in order to have continuous inflow in the caval tree model as calculated from the literature.

#### Set-up of bench tests

As outlined above, the afferent veins of the caval model are connected with Reservoirs IIa and IIb (Fig. 1) which provide in overflow mode a constant inflow at a defined preload of  $6 \text{ cmH}_2\text{O}$  as a function of their height relative to the caval axis. A percutaneous venous cannula (23-Fr Biomedicus, Medtronic) is inserted axially into the caval tree and snared at the point of insertion. The caval tree model with the cannula inside is positioned under water (2 cmH<sub>2</sub>O) in Reservoir III. Reservoir III is required to provide a water seal in order to prevent aspiration of air from the environment. The latter would interfere negatively with the performance of the centrifugal pump. The overflow from the Reservoirs II and III drops into Reservoir IV and is continuously pumped to Reservoir I in order to maintain the defined immersion of the caval tree. Reservoir I is positioned at 80 cm above the caval axis, thus providing a physiological after-load of 60 mmHg for the cannula-centrifugal pump set-up connected to Reservoir I.



**Figure 1:** Schematic view of the flow circuit: a bench is built including a lower Reservoir III holding Reservoirs IIa and IIb (preload 4.4 mmHg in overflow mode) with a caval tree built by taking into account the main affluent vessels and their flows. The water from Reservoir I flows by gravity to Reservoirs II and III and is pumped back to Reservoir I (80 cm above the water level in Reservoir III) through a 23-Fr wire wound percutaneous cannula which is connected to centrifugal pump simulating percutaneous cannulation for mini-invasive heart surgery or ECMO etc. The caval axis is positioned in Reservoir III and covered by 2 cm of water in order to avoid aspiration of air during the test runs. The overflowing water from Reservoirs II and III is collected in Reservoir IV and continuously pumped back to Reservoir I.

Table 2: Average flow for afferent vein pairs and totalcompiled from Table 1 for the development of the cavalmodel (ml/min)

Afferent veins	Average mean flow in ml/min	
Common iliac	1004 ± 0	
Renal	1171 ± 120	
Hepatic	1135 ± 234	
Coronary sinus	120 ± 21	
Subclavian	755 ± 64	
Jugular	756 ± 362	
Sum	4941 ± 138	

#### RESULTS

### **Target flow values**

The blood flows in Table 1 summarize the published data with different measuring tools. For each afferent vein of the vena cava, the average flow is calculated and summarized in Table 2. Hence, typical flow for the two common iliac veins appears to be  $\sim 1004$  ml/min for the two renal veins, whereas it is  $1171 \pm 120$  ml/min for the two renal veins, for all hepatic veins  $1135 \pm 234$  ml/min, for the coronary sinus  $120 \pm 21$  ml/min and for the two subclavian and jugular veins  $755 \pm 64$  and  $756 \pm 362$  ml/min, respectively. The total accounts for  $4941 \pm 138$  or roughly 4.9 l/min. For simplification in this setting, all nine afferent veins are considered equal and, therefore, the target inflow per afferent vein is set at 500 ml/min, the flow from the azygos veins being added to the coronary sinus.

# Geometry of caval afferent veins

The lowest major afferent veins at the inferior vena cava (IVC) are right- and left common iliac veins which are formed by the external and internal iliac veins. The two renal veins get the venous blood from kidneys. The left renal vein has four afferent veins and is because of unsymmetrical lateral IVC position longer than the right one. The right renal vein directly drains blood from kidney to IVC. There are three main veins at the liver: left- middle and right hepatic veins. The right hepatic vein runs separately to IVC. The other hepatic veins usually share a common orifice. Some small hepatic veins will be not considered in our caval tree system. The coronary sinus collects the venous blood from the heart muscle and delivers to the right atrium which is in between the IVC and SVC. The azygos vein runs into the SVC but is not represented geometrically in this model. Functionally, its flow as well as the flow of other small venules is added to the coronary sinus channel in this caval model. Otherwise, for the SVC, the venous blood is mainly originating from anonymous vein for the left side which is fed by the subclavian vein from the arms and jugular veins from the face and the brain and its equivalents on the right side. Overall, the listed affluent veins can be modelled by nine afferent channels as shown in Fig. 2. In addition, an effluent channel representing the tricuspid orifice is incorporated at the level of the right atrium in-between the SVC and IVC equivalents for measurements and natural outflow simulation.

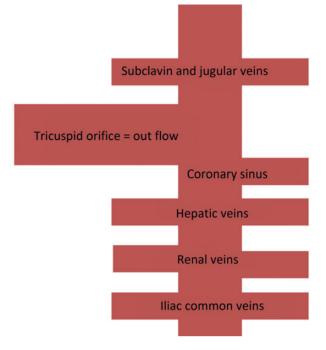


Figure 2: The caval tree model: the caval tree is made of the inferior vena cava, the superior vena cava, connected by the right atrium, and the main afferent veins. From the lower to upper body part the afferent veins include two common iliac veins, two renal veins, two hepatic veins, one coronary sinus together with the azygos vein and two subclavian veins combined with the corresponding jugular veins. All together, there are nine major afferent veins with one outflow channel termed tricuspid orifice, which is designed for measurement purposes, and simulation of atrial chatter.

# Choice of caval tree material

The material to be selected for this model must meet the following criteria:

- (i) Has to mimic the human vein and, therefore, it should collapse when empty.
- (ii) Must allow for production of a hollow branched tree.
- (iii) Connection of afferent veins should be seamless.
- (iv) Should be transparent.

The traditional surgical Penrose drain (Material A) made from thin-walled latex and used previously [9] is ruled out in this setting because of intrinsic stiffness, availability as tube only and its opaque wall. The grooved reversed capillary drain (B) made from silicones which was used for subsequent studies [10] is also ruled out because of intrinsic stiffness, availability as tube only and opaque wall. The HDPE, thickness 0.035 mm (C), is semitransparent and suitable for laser cutting with our equipment, but failed to seal properly. Furthermore, visual detection of bubble formation might be difficult. In contrast, the LDPE, thickness 0.061 mm (D), is transparent, allows for laser cutting and simultaneous welding of the borders in reliable fashion and is therefore selected for this study (Fig. 3).

### Preload determination and atrial chatter

Serial tests with various heights of the inflow reservoir in overflow mode with reference to the level of the caval axis are realized with

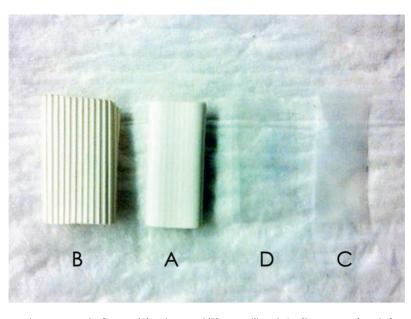


Figure 3: Displayed are four different tube segments. the first two (A) and reversed (B) are capillary drains (Penrose type) made from silicones, which were used previously [10]. It is easy to recognize that segments (A and B) are three-dimensional structures (shadow) and do not collapse even if completely empty. Segments (C and D) are commercial plastic materials that were both studied for manufacturing of the caval tree. Due to weld quality, flexibility and transparency, the soft material (D) (PE, 0.061 mm) was eventually selected.



Figure 4: Flow measurements (volumetric tank and timer at the outflow connected to the tricuspid orifice) for preload determination with the caval tree connected to the two inflow reservoirs (IIa and IIb) in overflow mode. The preload can be adjusted with metal blocks of 2 cm height (3 blocks = 6 cm). A wire wound percutaneous venous cannula is positioned within the vena cava and its tip is in the right atrium opposite to the tricuspid orifice.

metallic blocks of 2, 4 and 6 cm height positioned under the Reservoirs IIa and IIb. In order to reach an out-flow of 4.5 l/min (equal  $9 \times 500$  ml/min per afferent vein as described above) at the tricuspid equivalent of this caval tree, a preload of 6 cm is required, a quite physiological 4.4 mmHg (Fig. 4).

Interestingly enough, atrial chatter can be produced for this setting at a flow of 4.5 l/min and unrestricted outflow through the channel termed tricuspid (Supplementary Video 1). With slight restriction of the tricuspid channel however, the outflow can be made continuous.

# Drainage test with the caval model in the circuit system and caval collapse

Again, water is used as test medium for simplicity. Flow is measured with a clamp-on sonometric flow meter (Transonic Systems, Inc., Ithaca, NY, USA), which is calibrated by volumetric tank and timer, and the negative pressure at the inlet of the centrifugal pump is measured by micro-tip pressure transducers (Millar Instruments, Houston, TX, USA) all connected to the computerized test bench as reported previously [2]. The determination of caval collapse is

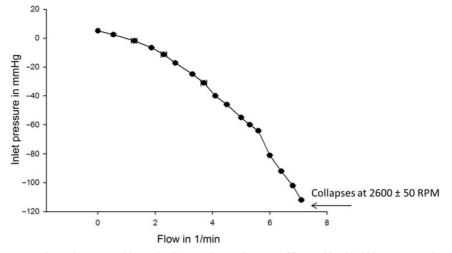


Figure 5: Flow/pump-inlet-pressure relationship: irreversible caval collapse with complete stop of flow and local bubble creation at the cannula tip (cavitation) occurs at 2600 ± 50 RPM in reproducible fashion. Drastic reduction in the pump speed is required for resuming flow. At this point, the bubbles interfere with the flow measurement which is based on ultrasound.

realized by stepwise increase in the number of pump revolutions (RPM) of the centrifugal pump (calibrated with a stroboscope) with increments of 100 RPM. RPM, pump flow and negative pump inlet pressure are recorded three times after stabilization. The starting point is determined as zero flow and the pump run ends with irreversible caval collapse at a given RPM number.

During the measurement cycle, the percutaneous cannula is well positioned with its tip at the level of the tricuspid orifice, thus mimicking the clinical situation. All nine affluent branches are continuously filled by the Reservoirs IIa and IIb with a preload of 4.4 mmHg, no air, and no interruption of water flow is observed. In this setting, caval collapse occurs in reproducible fashion when the centrifugal pump speed arrives at  $2600 \pm 50$  RPM (Fig. 5). At this point, the negative pressure at the pump inlet (suction) is  $-112.2 \pm 0.3$  mmHg for a flow of 7.1 l/min.

The modelled vena cava in this case collapses at the tip of the cannula despite its multiple holes (open tip and lateral orifices). At this point of time, the flow drops to zero, and bubbles occur, although the entire caval tree is under water. The flow does not recover if the pump speed is not reduced dramatically.

#### DISCUSSION

Atrial chatter and caval collapse during CPB can be reproduced in reliable fashion in a bench set-up using an artificial caval tree made from collapsible plastic with seamless connection of the branches. The geometry selected for the simplified caval tree allows for differentiation between atrial chatter (reversible segmental collapse of the venous system) and caval collapse (irreversible for a given pump speed inducing cavitation).

The chosen flexible plastic caval axis with a circumference of 60 mm is equal to a real adult's vena cava diameter of 19 mm. Each of the nine branches has a circumference of 32 mm, which is equivalent to 5 mm diameter. The tricuspid orifice of the system measures 22 in diameter (66-Fr) and can accept typical venous cannulas for simulation of central cannulation. The tricuspid channel also allows for control measurements of total caval inflow, which is equivalent to the tricuspid outflow in nature. The selected outflow of 4.5 l/min with a preload of 4.4 mmHg is very close to the perfusion standard with a target

pump flow of 2.4  $I/m^2/min$ . For an average body surface area of 1.79 m<sup>2</sup> this translates into a target pump flow of 4.3 I/min. Interestingly enough, the typical total caval blood flow compiled from data in the literature (not specific for CPB) adds up to 4.9 I/min, a number that is familiar to many of us because it is also the estimated blood volume in a 70 kg human (=7% of bodyweight).

Caval collapse during simulated CPB with augmented venous drainage can be reproducibly generated for flows and pressure drops derived from *in vivo* data. The phenomenon of collapse extends from the multiple holes at the tip of the cannula, where the velocity appears to be the highest. This phenomenon is followed by an increasing number of bubbles, which must be due to cavitation as the water seal prevents any entrance of air from the environment. Simultaneously, the negative pressure at the pump inlet increases to non-physiological levels. The gradual development of venous collapse can and should be reversed in this model quickly by decreasing the RPM of the centrifugal pump. The drawbacks of excessive suction including haemolysis, endothelial damage and gaseous emboli are well known.

The main issue here is that the natural vena cava collapses if there is nothing inside (cross-sectional area is zero). It is only the fluid inside that provides the lumen required for flow. With the cannula studied, it is impossible at 2300 RPM assisted centrifugal pump velocity to get sufficient drainage supported from caval branches despite the fact that adequate volume is available for full flow. It has been previously reported for paracorporeal assist devices that pump flow can be improved if the drainage from the atria is continuous (personal communication by M. Lachat, Zurich, Switzerland). As a matter of fact, a regimen of optimal continuous flow can be found by limited relatively low drainage load in contrast to maximal drainage load, which results in recurrent interruption of the blood column also known as atrial chatter. Like roller pumps which are routinely adjusted for being 'just not occlusive', venous drainage should be 'just not collapsing'. Inlet pressurecontrolled pumps with intelligent algorithms may be a technical solution for this.

The limitations of this model include the simplified geometry of the caval tree, the choice of diameters, the practically unlimited availability of pump medium at the inflow into the standardized venous channels leading to the caval axis, the lack of compliance of the selected material, the low viscosity of water when compared with blood, etc. Prima vista the mentioned limitations result in an overestimation of the pump flows reached here when compared with nature. With regard to the viscosity, which is an important contributor to the friction of the blood with the vessel walls, it must be remembered that the viscosity of water is 1 cP when compared with 3-4 cP for blood with haematocrite of 40% at 37°C. The higher perfusion temperature when compared with the temperature of the test fluid (20°C) and the haemodilution, which are routine in clinical practice, compensate for these differences partially. As a matter of fact, we have previously studied bench perfusion set-ups with blood at a haematocrit of 26 ± 4% at a perfusion temperature of 32°C [4] and found very little impact of such low haematocrits on flow in relatively large bore tubings typical of perfusion packs (1/4'' - 1/2''). In contrast, the perfusion temperature had major effects on the wall stiffness of PVC tubings (prone to kinking at higher temperatures) but not on silastic tubings as preferred for this model.

In summary, this caval model provides a realistic picture for the limitations of flow due to spontaneously reversible atrial chatter vs irreversible venous collapse for a given negative pressure during CPB. It can be used for testing not only different cannula designs, but also remote control of the pump in order to optimize flow under physiological conditions preventing the occurrence of collapse and further optimizing perfusion strategies in open chest heart surgery as well as closed chest ECLS. It is already clear at this stage that in the presence of atrial chatter and venous collapse during venoarterial perfusion, increasing suction on the venous line will not improve flow, but make things worse. Temporary interruption of negative pressure in the venous line (cross clamping for a few seconds) and gentle resuming venous drainage with initial very low negative pressure is a more promising strategy because it may allow for resolving a complete collapse of the caval axis.

#### SUPPLEMENTARY MATERIAL

Supplementary material (Video 1) is available at *EJCTS* online.

Video 1: Atrial chatter occurs in reproducible fashion with free tricuspid outflow as shown in Fig. 4 for this caval model with nine afferent veins running in overflow mode: obviously, the flow generated by gravity is superior to the inflow and therefore interrupted periodically.

**Conflict of interest**: Ludwig von Segesser is founder and shareholder of Smartcanula LLC, Lausanne, Switzerland.

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