The Heart Surgery Forum #2005-1127
8 (4), 2005 [Epub July 2005]
doi:10.1532/HSF98.20051127

Online address: http://cardenjennings.metapress.com/link.asp?id=112496

# The Smart Canula$^{TM}$: A New Tool for Remote Access Perfusion in Limited Access Cardiac Surgery

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## ABSTRACT

Devices for venous cannulation have seen significant progress over time: the original, rigid steel cannulas have evolved toward flexible plastic cannulas with wire support that prevents kinking, very thin walled wire wound cannulas allowing for percutaneous application, and all sorts of combinations. In contrast to all these rectilinear venous cannula designs, which present the same cross-sectional area over their entire intravascular path, the smartcanula$^{TM}$ concept of "collapsed insertion and expansion in situ" is the logical next step for venous access. Automatically adjusting cross-sectional area up to a pre-determined diameter or the vessel lumen provides optimal flow and ease of use for both, insertion and removal. Smartcanula$^{TM}$ performance was assessed in a small series of patients (76 ± 17 kg) undergoing redo procedures. The calculated target pump flow (2.4 L/min/m$^2$) was 4.42 ± 61 L/min. Mean pump flow achieved during cardiopulmonary bypass was 4.84 ± 87 L/min or 110% of the target. Reduced atrial chatter, kink resistance in situ, and improved blood drainage despite smaller access orifice size, are the most striking advantages of this new device. The benefits of smart cannulation are obvious in remote cannulation for limited access cardiac surgery, but there are many other cannula applications where space is an issue, and that is where smart cannulation is most effective.

## INTRODUCTION

Connection of the pump-oxygenator to the vascular system is a crucial step in cardiac surgery. As a matter of fact, a smooth transition of the blood from the intra-corporeal vasculature to an extra-corporeal system is not only essential for reaching adequate pump flows with the corresponding gas transfers on both sides, ie, the artificial lung of the pump-oxygenator and the organs of the body, but also for proper drainage of the heart during its repair. Inadequate drainage is a major problem in open-heart surgery where not only the visibility and as a result the feasibility of the surgical procedures are at risk, but also myocardial protection and end organ perfusion may become inadequate. With regard to myocardial protection, one has to consider that significant blood quantities within the arrested heart may lead to over-distension and untimely re-warming of non- or under-irrigated myocardium. In addition, pump-flows below target due to inadequate drainage result in lower perfusion pressures on the arterial side and higher blood pressures on the venous side. The combined phenomena result in reduced trans-organ differential perfusion pressure and may seriously affect end-organ perfusion, an event prone to major collateral damage.

The relatively recent advent of limited access cardiac surgery and low prime perfusion systems, which can be used either isolated or combined, surfaced the inadequacy of traditional cannula designs. Although, the limited blood flow due to the relatively small cannula diameters, which are imposed by remote cannulation sites, can be overcome up to some degree by centrifugal pump augmentation (Figure 1) or vacuum assist [Bichell 1997, Jegger 1999, Tevaearai 1999], the target flow cannot always be readily achieved (Figure 2). In our routine practice with femoro-femoral cannulation in conjunction with kinetic augmentation of venous return, only about 90% of the calculated target pump flow was achieved [von Segesser 1999]. There are a number of approaches to handle such a low flow situation including a higher preload in the patients venous system (requires additional fluid), a higher hematocrite (requires a low prime perfusion system and/or transfusion of red cell concentrates), and insertion of additional drainage catheters (ie, a percutaneous pulmonary artery vent catheter). Alternatively, this problem can be solved by smart venous cannulation, taking advantage of the geometrical configuration of the venous system.

## TRADITIONAL VENOUS CANNULATION

The human anatomy is well adapted for handling the systemic venous return to the heart, which is mainly assumed by the upper and lower vena cava. The dimensions of the human vena cava directly reflect the blood volume to be handled with low differential pressures and therefore the cross-sectional areas are quite large. This is very much in contrast to the remote access vessels we usually rely on like the femoral, iliac,

*Presented at the 2nd Integrated Coronary Revascularization (ICR) Workshop for Interventional Cardiologists and Cardiac Surgeons, Innsbruck, Austria, February 24-25, 2005.*

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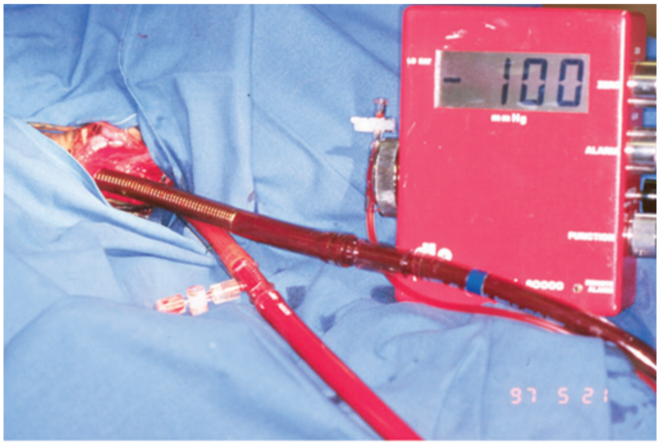


Figure 1. Remote cannulation in combination with augmentation may induce unacceptable negative pressure in the venous line and preclude full flow (experimental set-up).

subclavian, axillary, or jugular veins [Bichell 1997, Jegger 1999, Tevaearai 1999, von Segesser 1999]. There can be no doubt, cannula diameters that can usually be used for remote venous cannulation (for adults, typically 24-28 F) are far smaller than those we apply for central cannulation (for adults, typically 36-51 F). Figure 3 displays a schematic view of the inferior vena cava and its affluent veins after femoral cannulation with a typical percutaneous cannula. It is easy to recognize that the largest percutaneous cannula, which can be inserted in the groin, occupies only a small part of the inferior vena cava. If this fact is up to some degree necessary to allow the blood flow from the contralateral side to reach the right atrium prior to entering the tip of the percutaneous cannula, it is also evident that the long, narrow channel through the latter is linked to a major pressure drop, if the goal is to achieve full pump flow—a flow which is normally handled by the two vena cava with a cross-sectional area several times larger than the one of a single percutaneous cannula.

Figure 2. Unacceptable negative pressure during augmentation of venous return is often due to a collapsed venous compartment (experimental set-up).

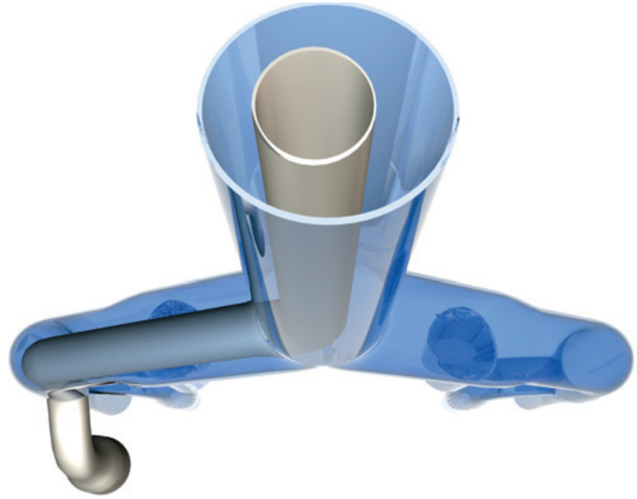

Figure 3. Schematic view of the inferior vena cava with its main peripheral affluent veins after cannulation with a percutaneous cannula: only a fraction of the cross-sectional area of the inferior vena cava is used by traditional cannula designs. During cardio-pulmonary bypass, such a cannula may have to handle more blood flow (over 100% of target flow during rewarming in a single venous cannula scenario) than the vena cava off-pump (approximately two thirds of cardiac output).

## THE SMART CANNULATION CONCEPT

The smart cannulation concept was developed in order to take advantage of the geometrical configuration of the venous vasculature in the event of remote cannulation through a smaller access vessel. Starting from the access vessel, for example, the femoral vein, the cross-sectional area of the venous vasculature is in fact constantly increasing the closer the heart is approached. Hence, the insertion of a venous cannula in collapsed state, which can be expanded within the target vessel, can almost match the diameters of the natural drainage vessels over a large proportion of its intravascular length. A schematic view of a smart canula™ (Smartcanula LLC, Lausanne, Switzerland) used for femoral cannulation of the inferior vena cava is displayed in Figure 4. It is easy to recognize that the cannula diameter can almost reach the diameter of the inferior vena cava, and this despite the fact that the access vessels diameter at the level of the femoral vein is the same as in Figure 3. Considering that a relatively short luminal restriction does barely impede flow, the advantages of the concept described does not only speak for itself, but it can also be demonstrated by computational fluid dynamics [Mueller 2002a], bench tests [Jegger 2002], and during in vivo evaluation [Mueller 2002b].

Figure 5 displays a sample smart canula™ (Smartcanula LLC, Lausanne, Switzerland: www.smartcanula.com) in collapsed configuration (upper smartcanula™) and one in expanded configuration (lower smartcanula™). The smartcanula™ shown, is made from shape memory alloy, can be stretched with a hollow mandrel in order to reduce its profile and fed over a guide wire (entering a small hole at its tip) into the access vessel. Once its tip is in the right position within the target vessel, the guide wire and the mandrel are removed and the smartcanula™ expands either to its predetermined

Figure 4. Schematic view of the inferior vena cava with its main peripheral affluent veins after cannulation with a smart canula which expands within the target vessel, thus allowing for much larger cross-sectional area over the major proportion of its length. As a result, there is only a relatively short narrow cannula segment at the level of the access vessel (eg, femoral vein).

diameter or to the lumen of the host vessel. A traditional cannula and a smartcanula$^{TM}$ are shown within the corresponding orifices of a template in Figure 6 and it is easy to recognize that the larger smartcanula$^{TM}$ accommodates to a smaller orifice as compared to the traditional wire wound cannula, which needs an orifice one size above its nominal diameter. With regard to the optimal cannula diameter, it should be mentioned here that a cross-sectional area of 1 $cm^2$ (equivalent to 34 F) is sufficient for achieving full flow, as this same cross-sectional area appears to be adequate for the venous line in adults [Ni 2001].

## IN VIVO EVALUATION OF THE SMARTCANULA$^{TM}$

It is no surprise that the luminal width of a traditional cannula placed within the inferior vena cava as assessed by

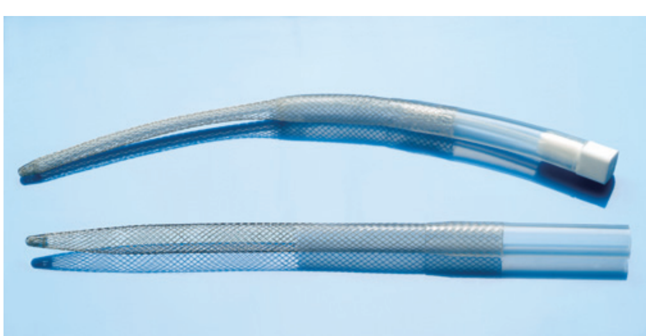

Figure 5. The smartcanula$^{TM}$ by Smartcanula LLC, Lausanne, Switzerland in collapsed configuration (upper smartcanula$^{TM}$) and in expanded configuration (lower smartcanula$^{TM}$). For more go to www.smartcanula.com.

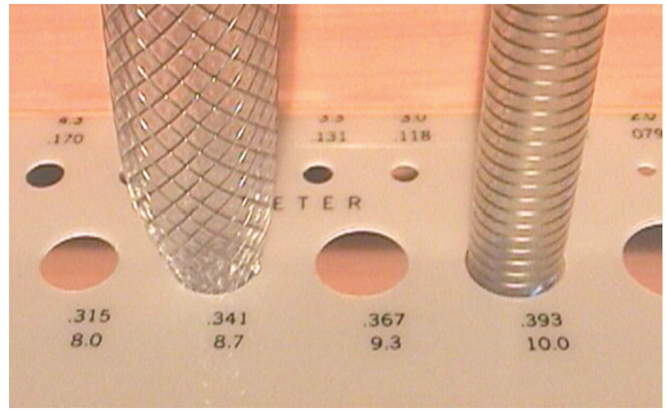


Figure 6. Despite its much larger diameter, the expanded smartcanula$^{TM}$ on the left passes well through a 26 F orifice (8.7 mm) whereas a typical traditional 28 F cannula does not fit into the 28 F orifice (9.3 mm), and requires the 30 F orifice (right).

intravascular ultrasound (IVUS, Boston Scientific, Bulach, Switzerland) is much smaller (Figure 7) than the one achieved by the smartcanula$^{TM}$ (Figure 8). As a result, the cross-sectional area of a smartcanula$^{TM}$ is practically the double of the one achievable with a traditional cannula for the same veinous vascular bed. In the experimental setup, the smartcanula$^{TM}$ allowed for an increase of the venous return by more than 70% as compared to a traditional lighthouse tip cannula with a 24 F diameter and access [Mueller 2002a], whereas the advantage still reached over 40% for comparison with a 25 F thin wall percutaneous cannula [Mueller 2002b]. It was demonstrated in addition that the advantage of the smartcanula$^{TM}$ increased with decreasing size of the access orifice. Interestingly enough, no additional blood trauma was demonstrated for the higher blood flows achieved with the smartcanula$^{TM}$ [Mueller 2002c],

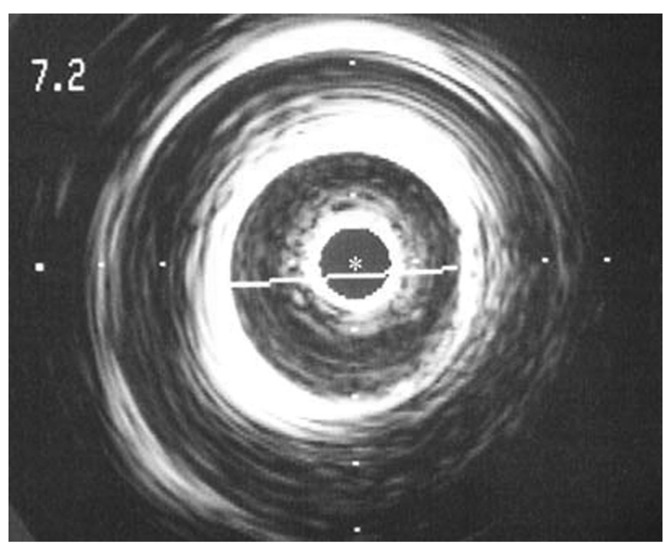


Figure 7. Intravascular ultrasound (IVUS) assessment of a traditional 28 F cannula (same as Figure 6) shows a luminal width of 7.2 mm, which accounts for a cross-sectional area of 40.7 $mm^2$—a fraction of the available diameter of the inferior vena cava (porcine experiment).

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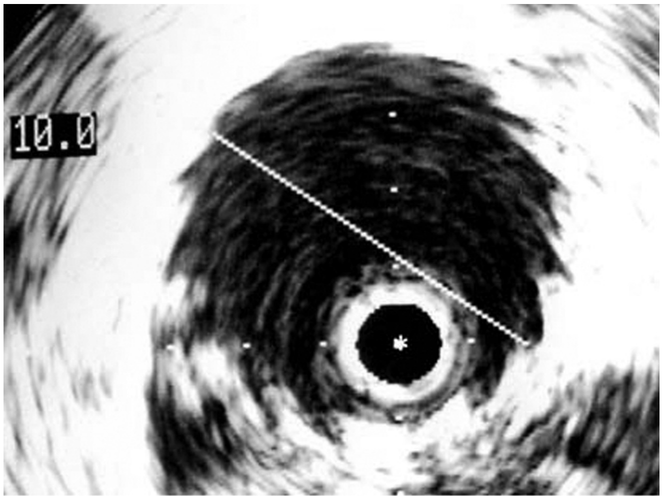


Figure 8. Intravascular ultrasound (IVUS) assessment of a self-expanding smartcanula$^{TM}$ (same as Figure 6) shows a luminal width of 10.0 mm, which accounts for a cross-sectional area of 78.5 mm$^2$—almost the double of the traditional cannula shown in Figure 7 in the same inferior vena cava (same porcine experiment).

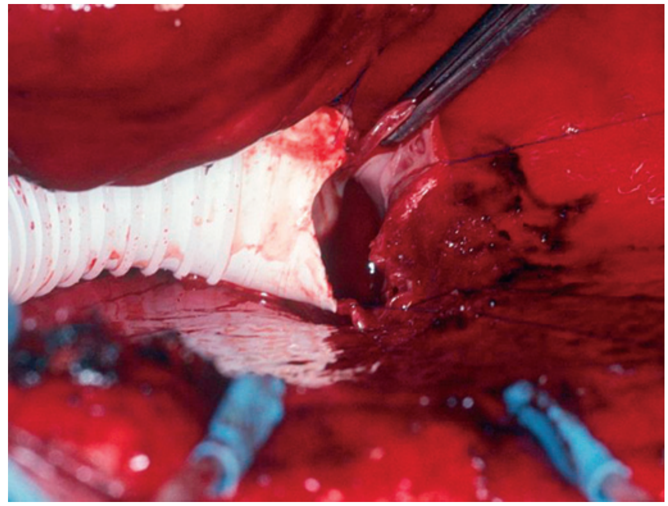

Figure 9. Smart cannulation of the femoral vein allows for open technique without snares around the inferior vena cava during implantation of an extra-cardiac conduit for Fontan-completion. Working within the open inferior vena cava is possible because the smartcanula$^{TM}$ drainage orifice is at a remote location (groin) with regard to the surgical procedure.

and also smartcanula$^{TM}$ removal proved to be surprisingly easy due to its collapsing properties under traction.

## CLINICAL ASSESSMENT OF THE SMARTCANULA$^{TM}$ DURING REMOTE ACCESS CARDIOPULMONARY BYPASS

Smartcanula$^{TM}$ performance was assessed in a small series of patients (mean age 62 ± 7 years; males 2/5, females 3/5) undergoing redo procedures of the aortic valve (2/5), ascending aorta (2/5), or the thoraco-abdominal aorta (1/5). For a mean body weight of 76 ± 17 kg (range from 55 kg to 98 kg) and a body surface area of 1.85 ± 0.25 m$^2$ (range from 1.5 m$^2$ to 2.2 m$^2$) the calculated target pump flow (2.4 L/min/m$^2$) was 4.42 ± 0.61 L/min (range from 3.6 L/min to 5.3 L/min). Mean pump flow achieved during cardio-pulmonary bypass was 4.84 ± 0.87 L/min or almost 10% more than the target pump flow of 4.42 L/min. This result is contrasting considerably with our previous experience for traditional percutaneous cannulation with augmentation, where the flow remained about 10% below target as reported previously [von Segesser 1999]. Hence, the improvement demonstrated here accounts for practically 20% above the flows achievable with traditional percutaneous cannulae.

The advantages of "collapsed insertion and expansion in situ" as described above for the smartcanula$^{TM}$ in peripheral cannulation are also of interest for central cannulation. The most apparent benefit is of course the fact that full blood flow can be achieved through a relatively small access hole. As a matter of fact, 4 L/min can be achieved with a 20 F orifice for access, which is a fraction of the traditionally used orifice sizes for right atrial central cannulation. Cannulation of a small right atrium, a so-called "crowded" right atrium, and a previously operated right atrium are just a few examples, where access orifice size matters. The self-expansion capability is also quite an advantage during cardiac surgical procedures requiring significant mobilization of the heart, where the smartcanula$^{TM}$ has proved to be relatively kink resistant for both, the experimental and the clinical set-up. It is the same material memory effect of the smartcanula$^{TM}$, which limits the possibility of the venous wall to collapse (resulting in temporary interruption of the venous flow), and allows for a significant reduction of "atrial chatter."

## OUTLOOK

Devices for venous cannulation have seen significant progress over time. Until today, the original, rigid steel cannulas have evolved toward flexible plastic cannulas with wire support that prevent kinking, very thin walled wire wound cannulas allowing for percutaneous application, and all sorts of combinations. In contrast to all these rectilinear venous cannula designs which present the same cross-sectional area over their entire intravascular path, the smartcanula$^{TM}$ concept of "collapsed insertion and expansion in situ" is the logical next step for venous access. Automatically adjusting cross-sectional area up to a pre-determined diameter or the vessel lumen provides optimal flow and ease of use for both, insertion and removal. Reduced atrial chatter, kink resistance in situ, and improved blood drainage despite smaller access orifice size, are the most striking advantages of this new device. The fact that flexible, self-expanding venous cannulas of a given size cover various diameters of cannulas with traditional design, will certainly reduce the number of cannulas that have to be kept in stock.

A very promising advantage of smart cannulation is that this technology allows for intracardiac surgery and fully open right atrium without snaring the inferior vena cava [Corno 2004]. For femoral cannulation, this feature is due to the smartcanula$^{TM}$ providing a remote entry point for the blood to be drained toward the venous line, which is close to the groin, even if the self-expanding grid of the smartcanula$^{TM}$ reaches the level of the intrahepatic veins. Figure 9 displays an anastomosis, which is realized with open technique during implantation of an extra-cardiac conduit for Fontan completion. We have used the same technique for repair of the inferior vena cava, as well as for hepato-atrial anastomoses in patients with Budd-Chiari syndrome.

In conclusion, the smartcanula$^{TM}$ principle of collapsed cannula insertion and expansion in situ provides an efficient new solution for an old problem, which is inadequate venous drainage during perfusion. The benefits of smart cannulation are obvious in remote cannulation for limited access cardiac surgery, but there are many other cannula applications where space is an issue, and that is where smart cannulation is most effective.

## DISCLOSURE

Dr. Ludwig K. von Segesser is co-founder and shareholder of Smartcanula, LLC, Lausanne, Switzerland.

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