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Direct Access Valve Replacement (DAVR) — are we entering a new era in cardiac surgery?☆

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Abstract

Objective: This study validates the off-pump antegrade trans-ventricular route for ultrasound-guided direct access aortic valve replacement. Direct access aortic valve replacement using a transthoracic and valved stent-based approach offers numerous advantages over the remote access percutaneous approach and may one day provide an alternative treatment modality for aortic valve disease. **Methods:** Valved stents were implanted off-pump in 17 pigs (72.10 ± 8.4 kg) via the direct access transapical approach using a left-sided mini-thoracotomy and continuous ultrasonic and fluoroscopic guidance. Acute valved stent function was studied with intravascular and two-dimensional intracardiac ultrasound. The invasive valve gradient was assessed with pull-back pressure catheter. All valved stents were tested in vitro before insertion. Macroscopic analysis was performed at necropsy. **Results:** In 11 of the 17 pigs, valved stents were delivered to the target site over the native aortic valve leaflets without interference of coronary blood flow and with good acute valve function. Three valved stents were deployed supra-annularly, two of those occluded the right coronary orifice and one the left coronary orifice, leading to fatal outcomes. Three valved stents dislodged into the left ventricle, one because of size-mismatch and two because of failure to unfold correctly. In 11 properly sized and deployed valved stents, two showed a moderate and one a severe paravalvular leak. **Conclusions:** Seventeen pigs underwent direct access valve replacement of the aortic valve with deployment of a valved stent into the native aorta. Eleven valves observed for an average 5-h period showed satisfactory, postimplantation valve function.

Keywords: Percutaneous valve replacement; Aortic valve replacement; Valved stent; Transcatheter valve replacement; Off-pump; Minimally invasive valve surgery

1. Introduction

Increasing life expectancy and good operative results in elderly patients undergoing cardiac surgery is expected to increase the number of heart operations performed annually in the United States beyond the current rate of 300,000 [1,2]. Arguably the single most important technical innovation in the history of heart surgery, cardiopulmonary bypass is also a significant source of risk. The forefront of surgical innovation is focused on the search for less invasive technologies and techniques that might one day permit off-pump surgical therapies, thereby reducing this risk for patients. Surgical aortic valve replacement, the current standard of treatment for patients with heavily calcified, stenotic aortic valves, is a good example of a procedure that may benefit from the convergence of recent developments in interventional cardiology and minimally invasive, direct access cardiac surgery.

2. Materials and methods

2.1. Valved stent design and in vitro testing

We used a custom-designed valved stent (Fig. 1) based on a previously described prototype [3,4]. The outer scaffold is constructed of three linked nitinol Z stents that form a cylindrical structure with minimal surface coverage. The device is self-expanding, eliminating the need for balloon expansion. To complete the device, a low-profile biological valve is sutured into the stent scaffold. Before implantation in vivo, all valved stents undergo in vitro static and dynamic (30 min) performance testing inside a pulsatile hydrodynamic mock loop circuit, equipped with a high fidelity tip-mounted

Abbreviations: AcuNav, intracardiac ultrasound; AVR, aortic valve replacement; CBF, coronary blood flow; DAVR, direct access valve replacement; IVUS, intravascular ultrasound; LAD, left anterior descending; LCA, left coronary artery; LV, left ventricle; PVR, percutaneous valve repalcement; RCSSI, residual coronary sinus stent index

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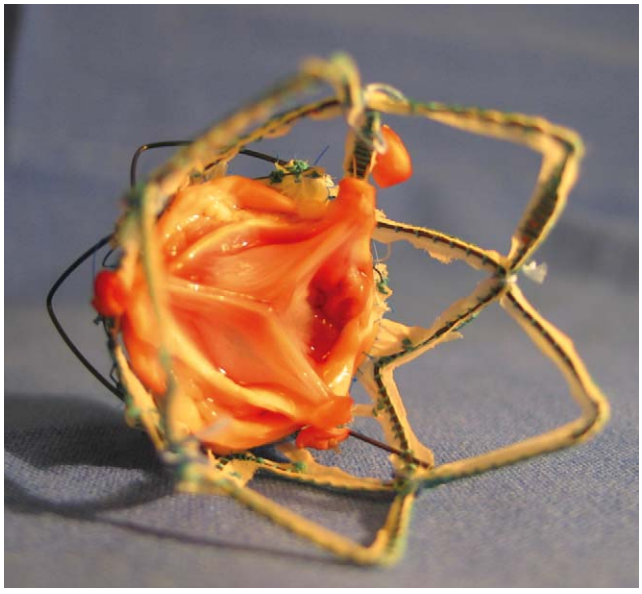

Fig. 1. The aortic valved stent used for direct access antegrade implantation is constructed of three linked nitinol Z stents housing a tissue valve.

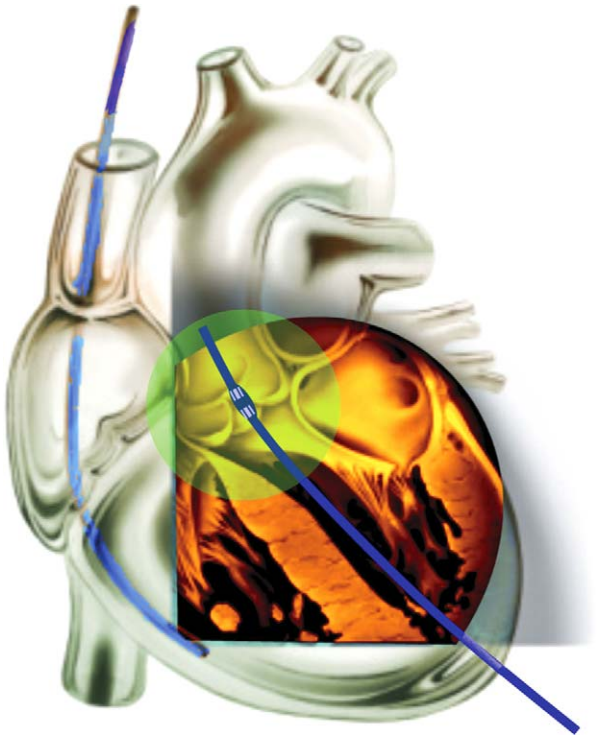

Fig. 2. Ultrasound-guided intracardiac navigation is achieved through simultaneous use intracardiac (AcuNav) and intravascular ultrasound (IVUS). The AcuNav probe is placed in the right atrium and the IVUS probe is placed through the left apex into the aortic valve annulus. AcuNav inserted through the R jugular vein.

Millar pressure transducer. Acute valve function is monitored in vivo with real-time intravascular ultrasound (IVUS) (12.5 MHz, 6F) (Clearview, Boston Scientific Corporation, Sunnyvale, CA, USA). Criteria determining suitability for implantation include transvalvular gradient <8 mmHg and regurgitation value $\leq 1^{\circ}$.

2.2. Animal studies

Direct access valved stent implantation was performed in 17 pigs (72.10 ± 8.4 kg). All animals received humane care in compliance with the 'Principles of Laboratory Animals' formulated by the National Society of Medical Research and the 'Guide for the Care and Use of Laboratory Animals' prepared by the Institute of Laboratory Animal resources; published by the National Institutes of Health (NIH publication 85-23, revised 1985). All data are expressed as mean $\pm$ standard deviation.

2.3. Surgical access

The animals are prepared for surgery by mobilizing the jugular veins and carotid arteries for complete invasive monitoring, including insertion of a Swan–Ganz catheter for continuous cardiac output measurement. An 11-F introducer (B-Braun, Medical Inc., Bethlehem, PA, USA) is inserted into the right femoral or the right jugular vein to provide access for intracardiac ultrasound (AcuNav). A 5–10 cm left mini-thoracotomy incision is made and access gained through the sixth intercostal space. A Xylocaine (1.5 mg/kg) drip is used to minimize arrhythmias. Two purse-string sutures (Prolene 4-0) are placed on the left ventricular (LV) apex using the native pericardial sac for reinforcement. After heparinization (300 IU/kg), the 10-F AcuNav probe (Sequoia, operating frequencies 4.0–10.0 MHz, 90 cm insertion length, Acuson Corporation, Mountain View, CA, USA) is inserted into the right atrium (Fig. 2), permitting visualization and predeployment measurements of the native aortic valve, root, and coronary ostia configuration. Obtaining these measurements with the AcuNav probe is superior to TEE, which picks up postdeployment interference caused by the echo dense structure of the struts.

2.4. Left ventricular valved stent implantation

At this point in the operation, the animal is prepared to receive the implant. The implant is hand-crimped to the delivery device (Fig. 3). The LV apex is punctured with an over-the-needle catheter and a guide-wire is inserted under fluoroscopic guidance. An 8-F introducer (Arrows, Reading, PA, USA) is advanced over the guide-wire, which is passed through the aortic valve into the descending aorta. Catheter location is confirmed by AcuNav. The monorail wire-guided disposable IVUS 6-F catheter transducer (Sonicath Ultra 6, 12.5 MHz Imaging Catheter, Medi-tech, Watertown, MA, USA) is advanced for aortic road-mapping. The location of the IVUS probe is monitored with AcuNav and fluoroscopy for target site identification. Four radiopaque markers are placed on the skin to provide additional fluoroscopic reference points (1) at the level of the aortic annulus, (2) end of the native leaflet in systole, (3) sino-tubular junction, and (4) beginning of the brachiocephalic trunk. The fluoroscopic C-arm and operating table are locked into position to avoid parallaxes.

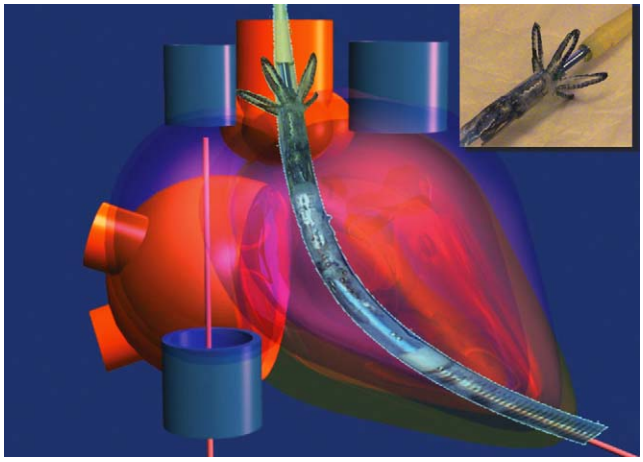

Fig. 3. Photo reconstruction of a valved stent delivery system: the valved stent is collapsed radially and then manually loaded into a standard endoprosthetic delivery device with a maximum diameter of less than 10 mm in order to deliver the valved stent into the target location. AcuNav inserted through the R femoral vein.

2.5. Deploying the valved stent

After removing the IVUS and 8-F introducer, the valved stent delivery system is advanced over the guide-wire under fluoroscopic and AcuNav guidance (Fig. 3). When fluoroscopic and sonographic target sites reach congruency, the valved stent is deployed orthotopically over the native valve leaflets in two steps. The distal end is released first. Then, if the device position remains stable, the proximal end is released. The valved stent is initially targeted to land slightly above the target site, to permit fine adjustments in positioning. The device can be pulled back slightly, but it cannot be advanced into position. In this way, after opening the first row of Z stents, the whole device can be pulled back until the target site lines up fluoroscopically and sonographically.

The self-expanding nitinol stent has a low metal-to-stent ratio with minimal contact area between the interface of the stent and aortic wall. These features increase the expansion force at the interface, creating a firm attachment to the aortic root, without injuring the aortic wall. This stent design has been successfully used for thoracic aortic endovascular and endoluminal aortic valve procedures [3,5].

2.6. The residual coronary sinus stent index (RCSSI)

We used the residual coronary sinus stent index to evaluate CBF impairment. The RCSSI is a comparison between the coronary cross-sectional surface area and the plane defined by the valved stent and the native aortic wall. This index compares the flow ratio between the native coronary flow with the blood flow that passes through the valved stent after implantation. Measurements required to calculate the index include (a) the coronary diameter, which is measured at the termination of the sinus portion, and (b) the residual stent aortic wall plane, which is measured at the level of the coronary orifice. All measurements are obtained with intracardiac ultrasound. To calculate the index value, the distance of the stent from the aortic wall (residual gap at the level of the aortic sinus portion) is divided by the coronary diameter [3]. No CBF impairment was observed in this series for index values >1.

2.7. Outcome assessment

All valved stents were monitored in vivo to assess leaflet motion, planimetric valve orifice, RCSSI, CBF, characteristics of the left coronary artery (LCA), transvalvular gradient, regurgitation, and paravalvular leak. All animals were sacrificed at the conclusion of the experiment and macroscopic analysis was performed at necropsy.

3. Results

3.1. In vitro study

Before implantation, all of the valved stents demonstrated good valvular function with a pressure gradient of 5.5 ± 2.1 mmHg at mean pulsatile flow rate of 4.5 ± 1.8 L/min. IVUS imaging exhibited full opening and closing of the pericardial leaflets in all valved stents.

3.2. In vivo study

Eleven of the 17 valved stents implanted in 17 pigs (72.10 ± 8.4 kg) were delivered accurately into the predefined target location without any evidence of CBF impairment. Three valved stents were deployed too high, into a supra-annular position and two of those obstructed the right coronary artery and the third valved stent occluded the orifice of the left main coronary artery. All animals died as direct consequence of impaired CBF.

Two valved stents were incorrectly sized (too small) which caused them to dislodge into the left ventricle after they were initially appropriately placed. Another valved stent failed to unfold correctly and slipped back into the left ventricle.

Measurements from intracardiac and intravascular ultrasound showed good valve function in all 11 valved stents with low transvalvular gradient of less than 6 mmHg. On invasive measurement transvalvular gradient was 5.5 ± 2.7 mmHg and 5.8 ± 3.4 mmHg in two-dimensional intracardiac measurements. The overall planimetric valve orifice area was equally good at 2.9 ± 1.3 cm^2. There was complete leaflet excursion and competent closing in all 11 correctly deployed and sized valved stents. Of these, two had a mild-to-moderate and one a moderate-to-severe paravalvular leak.

Continuous cardiac output remained stable 5.6 ± 1.0 L/min (preimplantation) versus 4.2 ± 0.7 L/min (postdeployment) for the 11 correctly delivered valved stents. Intracardiac color Doppler imaging revealed laminar blood flow.

The procedure time was typically 2 h, and device delivery and deployment time was between 4 and 6 min. No signs of coronary flow impairment were observed in 11 of the 17 valved stents.

The RCSSI was obtained to evaluate possible flow impairment in the left coronary artery. Absence of interference with coronary blood flow was confirmed by RCSSI index, which was >1 in all 11 correctly positioned and

deployed valved stents. Postmortem examination also confirmed the position and safe anchoring of the device to the aortic wall in 11 of the 17 valved stents. None of the stents showed signs of coronary obstruction. Necropsy confirmed the above-described results. Macroscopic analysis provided no evidence of damage to the aortic wall and no sign of dissection or hematoma. All valved stents were free of thrombus and structural damage.

4. Discussion

Surgical valve repair or replacement is the current treatment of choice for stenotic or insufficient valve pathologies. Yet, surgical valve repair or replacement typically requires the use of extracorporeal cardiopulmonary bypass, which is associated with known risks and limitations. The convergence of new techniques in interventional cardiology with minimally invasive cardiac surgery techniques has given rise to several potential new therapies, including percutaneous valve replacement (PVR) [6—9]. The PVR movement began with Anderson et al. [10], in 1992, who performed the first remote access transcatheter implant of an expandable aortic valve in closed chest pigs. That same year, Pavcnik et al. [11] published his experimental evaluation of an integrated valved stent implanted via remote access. Sochman et al. [12] followed suit in 2002, performing a feasibility study of percutaneous transcatheter aortic disc valve implantation via remote access. Also in 2002, Bonhoeffer et al. [13] performed the first successful human percutaneous implantation of a pulmonary valved stent in a pulmonary artery conduit via remote access. Finally, Cribier et al. [14] conducted the first clinical remote access percutaneous implantation of a valved stent into a heavily calcified aortic valve.

4.1. Limitations of remote access PVR

Obstacles remain before PVR can be safely used in humans for the treatment of aortic valve disease. Fish [15] has recently published a summary of these limitations. First and foremost, the complication profile is high for the insertion of large introducer systems such as would be needed to navigate through and work on diseased valves. These include local complications such as vessel rupture, dissection, pseudoaneurysm formation, bleeding, vessel stenosis, and thrombus. PVR also creates new complications associated with traversing implements and devices through a long vascular path to reach the desired target in the heart. These include increased risk of kinking, higher shear stress on the vessel wall, and a demanding and cumbersome delivery process that hinders the precise delivery of the implantation device. Small vessel diameter also limits the size of the delivery device, making removal of diseased valves nearly impossible. Some of the potential problems of using PVR for aortic valve disease were demonstrated by Cribier et al. [16] in 2004. Cribier et al. [16] used a transseptal approach and reported significant complications in end-stage inoperable patients with calcified aortic stenosis. One-third of patients developed severe mitral incompetence, from injury caused by passing the guide-wire through the mitral valve and in a substantial part of patient the valved stent showed severe paravalvular leakage.

4.2. Direct access valve replacement (DAVR)

The direct access valve replacement technique [17,18] we propose has the potential of eliminating many of the disadvantages of remote access PVR. This technique represents a true convergence of the interventional and standard surgical approach and has the potential to be applied to the most severe forms of aortic valve disease. DAVR involves the percutaneous transmyocardial entry of any cardiac cavity, with preference for the (a) ventricular apex in aortic or pulmonary valve procedures and (b) atrial wall in mitral or tricuspid procedures [19]. Essential to this technique is the simultaneous use of intravascular and intracardiac ultrasound. These instruments are used to measure and identify the coronary anatomy, monitor stent delivery and deployment, and assess postimplantation coronary blood flow, unhampered by artifact from the highly echodense Z struts of the implantation device, a significant drawback of using transesophageal echocardiography (TEE). Other advantages of DAVR include the straight line access to the target site (Fig. 4), which improves handling and permits insertion of long handled decalcification tools, increased caliber delivery systems, and simultaneous use of other interventional tools, such as embolic projection devices or temporary ventricular support pumps.

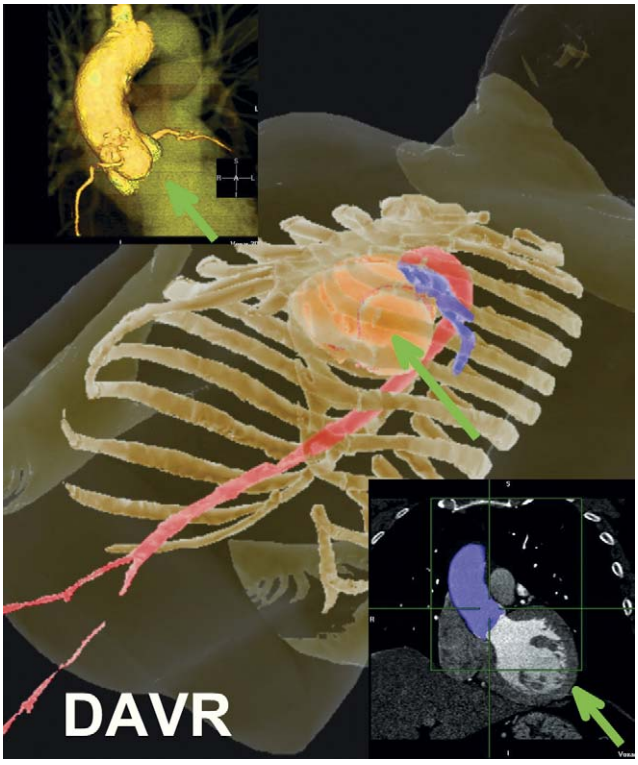

Fig. 4. Anatomical relationship illustrating the straight-line approach of the direct access implantation technique through a mini-thoracotomy and via the left ventricular apex. DAVR decreases the working distance to 'surgical dimensions,' permitting the surgeon to work in close proximity to the aortic target.

DAVR eliminates many of the traditional drawbacks of remote access PVR described above, while preserving and potentially improving upon the low patient morbidity and mortality rates associated with cardiac surgery. The capability of using embolic filters, temporary valve-tipped catheters, or short-term axial ventricular assist devices could, in future, elevate DAVR to the position of therapy of choice for patients with valvular cardiomyopathy and other selected conditions.

4.3. Intracardiac ultrasound for adequate visualization

Good outcome with DAVR depends on adequate visualization of the target area and precise monitoring of valved stent delivery. Our good results with IVUS used for endovascular aneurysm repair [20] prompted us to extend this technique into endoluminal cardiac procedures. To this, we added intracardiac ultrasound (AcuNav), which permitted enhanced visualization despite the echodense stent structures, which interfered with TEE (Fig. 2). AcuNav also permitted postimplantation flow monitoring. Finally, AcuNav supported three-dimensional assessment, helping us to monitor delivery of valved stent on target. Routine use of IVUS and AcuNav ultrasound guidance provides real-time out of the lumen dimensions and identification of the coronary configuration. Together the above elements overcome many of the shortcomings of the remote access approach.

5. Conclusion

This novel technique to implement surgical aortic valve replacement off-pump while promising, is premature; surgical aortic valve repair/replacement remains the standard of care. Maneuvering through the complex aortic root configuration generates a need for technology more sophisticated than is currently available, for example, a self-orienting valved stent that can be safely anchored to the aortic wall without injuring the aortic annulus. The necessity of removing a highly calcified, stenotic aortic valve will require specialized tools, temporary ventricular support, and embolic protection devices. However, DAVR may ultimately be the best approach to the aortic and mitral valve [21]. In comparison to remote access techniques, DAVR decreases the working distance to 'surgical dimensions,' permitting the surgeon to work in close proximity to the aortic target (Fig. 4). Direct access through the left ventricular apex also permits simultaneous insertion of valve decalcification and removal tools, embolic protection, and ventricular assist devices, as well as larger delivery systems.

As life expectancy increases and cardiac valve procedures improve, more and more elderly patients will require new or outlive old valve operations justifying reoperation for replacement or re-repair. Particularly in this age group, efforts to reduce the stress of surgery through the use of minimally invasive procedures and development of off-pump surgical techniques are paramount. Nevertheless, in the setting of redo-aortic valve surgery any percutaneous intervention is facing one major challenge—the risk of patient-prosthesis mismatch in particular in patients with a previous small prosthetic valve. In order to avoid a mismatch situation the prosthetic valve would need to be removed first. None of the percutaneous techniques has addressed the problem of removing a prosthetic heart valve yet, but the transapical direct access valve replacement approach is certainly the most promising in order to provide the necessary access and tools for this undertaken.

Furthermore, the design of the valved stent might need to be modified in order to allow for increased effective orifice area by using parts of the former prosthetic valve as additional structural elements. And finally, the venue of the percutaneous techniques as new therapeutic options for heart valve disease might lead to design modifications or new designs of the standard biological or even mechanical prosthetic heart valve in order to permit a later percutaneous intervention.

More research will be needed before DAVR can be safely and successfully applied in humans, but the results of our current animal studies [17,18] support the feasibility of this approach. It behooves the cardiac valve surgeon to support and explore surgical innovations based on developments in DAVR and PVR, advancing the art and science of minimally invasive cardiac techniques.

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Appendix A. Conference discussion

Dr M. Antunes (*Coimbra, Portugal*): Do you think that with this we will be in a position to compete with our fellow cardiologists, because they have gone first and appear to be a bit more advanced? But this appears to be to me far more precise than the methods that they are using. What is your current thinking about that?

Dr Huber: I think there are obvious advantages of being a cardiac surgeon: you have direct visualization, you know the anatomy much better, you understand the valve function, you know the disease. If you look at the cardiologists, obviously they have very good experience as well and they have had very good results, very early results. But if you think about the first US clinical trial the antegrade percutaneous approach, that soon after its start was discontinued by the FDA or the medical device company, it very much looks like that using not mature techniques too early might set you up for drawbacks. Maybe cardiac surgeons are a little bit more conservative and try to aim on the safe side, but they are certainly very innovative. Seeing the amount of interest in novel techniques and the strong presence at the techno college shows, I think, that we are moving in the right direction, and we certainly will not stay behind the cardiologists.

Dr T. David (*Toronto, Canada*): What measures do you take to prevent the valve from tilting when you deliver it? In other words, unless you can deploy the valve absolutely perpendicular to the level of the annulus, which in the humans it is frequently not perpendicular to the outflow tract because the noncoronary sinus and annulus tend to be lower than the other two, the deployed valve would be slightly tilted.

You didn't show us any specimen of the aortic cusps against the coronary orifices. It troubles me that if one deploys a valve in the presence of normal cusps, they may obstruct the coronary arteries, at least partially.

Dr Huber: Answering your first question, well, the delivery device is at a very early stage of development and it is pretty hard to very precisely keep the perpendicular level to the aortic outflow tract or the aortic valve, but the intravascular ultrasound gives very good visualization of the target zone and certainly helps the monitoring of the deployment.

Regarding your second question, we presented our concept at the EACTS in 2003. We were concerned about the native leaflets staying in place while the new valved stent was delivered into the aortic root about potential obstruction of the coronaries.

But looking at postmortem specimens as well as ultrasonic images, we realized that actually when the valved stent is deployed into the aortic root, the native leaflets will get spread and stretched out around the valved stent, so therefore will stay away from the native aortic wall because they are attached at two points, and stretching these two points will make the leaflets come centerwise, rapping around the stent structure. Furthermore, the presence of the natural sinuses in front of the coronaries are natural distance-keepers between the valved stent and the native aortic wall if you don't oversize the valved stent too much. Therefore, we came up with the residual coronary sinus stent index (RCSSI). We hypothesized that if the distance from the stent to the aortic wall is at least as big or bigger as the native coronary orifice, the cross-sectional area of this surface here will allow or permit enough flow through the coronaries to not impair coronary flow.

The only time we really experienced ischemia was while the valved stent was deployed too high, and the annular part that anchors the valve in the stent unfortunately positioned itself in front of the coronary orifice. Therefore, certainly all measures need to be taken to be make sure that the annular part of the valved stent is delivered precisely in the aortic annulus and anchored there very safely.