In March 2010, Edwards received the CE Mark for its Edwards SAPIEN XT THV, as well as its NovaFlex transfemoral (TF) and Ascendra2 transapical (TA) delivery systems. These products resulted from extensive engineering and testing, ensuring enhancements to both valve design and ease of use, without compromising any of the hallmark features of the Cribier-Edwards and Edwards SAPIEN THVs.

The leaflet design of this new valve is modelled after Edwards’ clinically proven surgical aortic tissue valves using bovine pericardial tissue. Its cobalt-chromium frame provides improved radial strength, an important factor in long-term valve durability. The new delivery systems are more patient-friendly and easy-to-use, facilitating valve positioning and deployment, as well as reducing procedure time and patient recovery.

As TAVI evolves...

Transcatheter aortic valve implantation integrated into daily practice

TAVI, today for tomorrow

As we look forward to a decade of further innovation in structural heart disease treatment, we can also reflect on the introduction of what are acknowledged as breakthrough technologies since the year 2000. Most notable of these was the success of TAVI, which culminated in the successful introduction of the Edwards SAPIEN transcatheter heart valve in 2007. Investment in clinical research and highly professional education has been a key driver behind our commitment to providing the Heart Team with clinical evidence to support their choice of technologies. This specialist team is one of the key reasons behind the development of the TAVI practice and the subsequent benefits to patients since the first human implantation in 2002.

Looking into this next decade, (continued on page 2)

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As TAVI evolves...

For the management of patients’ sternal functions during the procedure, which is especially important during the learning phase. Now that the Edwards SAPIEN XT THV with the NovaFlex TF delivery system is available and new, less-invasive echo techniques are also being tested, more and more cases will be able to be performed under local anesthesia/conscious sedation.

Ideally, the setting where the TAVI procedure is performed should be spacious enough to allow the participating medical specialists unrestricted access. It goes without saying that the ideal room should fulfill all requirements for sterility and high-resolution imaging in order to allow precise placement of the valve. Increasingly, now and in the future, we envision dedicated hybrid rooms—similar to the ones we have put together here in Essen—that feature laminar airfields, as well as high-end fluoroscopy machines. As the number of catheter-based treatment options for structural heart disease increases and evolves, several of these aspects will become the basis for our future treatment of cardiovascular disease. Adjunctive imaging techniques such as 3-D echocardiography will play an important role in evolving and integrating these techniques into our everyday practice.

A TRULY PERCUTANEOUS PROCEDURE

At Essen University Hospital, transfemoral TAVI is performed as a truly percutaneous procedure with the following advantages over aortic-based closure devices: for management of the puncture site. Of course, some centres employ different techniques. Based on our own experience, our centre has been using the Prostar™ in a precise technique. More recently we gained experience with the use of a single 6 Fr Proglide™ device, which can achieve reliable haemostasis in a majority of patients, even when implanting the 26 mm Edwards SAPIEN THV. A stock of peripheral balloon catheters and covered stents of adequate diameters and lengths should also be available on the shelf when starting a TAVI programme, not to mention the concomitant intervention skills, including cross-over iliac angioplasties. The latest generation low-profile NovaFlex TF delivery system received CE Mark in March. This new system has a reduction of access size which is an important step towards integrating TAVI into routine daily practice. This evolution can decrease the length of the average individual TAVI procedure, further increase patient safety and comfort, as well as facilitate daily procedure planning.

A SURGEON’S VIEW A-2 with the trans-femoral approach, transfemoral TAVI has become a therapeutic option for high-risk patients with severe AS. Performed containing and highly competitive results comparable to conventional AVR, it has now been incorporated into many routine AVR programmes. TAVI is not the only imaging randomised PARTNER IDE clinical trial (Cohort B) will be available later this year and provide us with additional information.

TAVI should not be seen as a competitive procedure to conventional AVR. As surgeons, we have learned from numerous epidemiological trials that up to 60% of the elderly patients with AS remain untreated or were even denied surgery in Europe and throughout the western world. Here, in particular, German and European cardiologists have seen more and more patients who are now referred to us, as TAVI has become more common and is known to be a reliable procedure. To date, our TAVI programme has also led to a 22% increase in our conventional AVR procedures in Essen. The improved profile of the Edwards SAPIEN XT THV and NovaFlex TF delivery catheter enables atraumatic peripheral procedures. A good common femoral artery puncture is crucial before insertion of a Prostar™ preclosure device. More challenging cases can be performed, but careful patient selection is mandatory in a multidisciplinary heart team setting.

The NovaFlex TF delivery system provides improved trackability through the vasculature and facilitates crossing of the native aortic annulus, as a result of the felicitous configurations and new tapered-tip design. The valve landing zone is highly predictable with this new system. Minimal movement is observed between the aortic root and the valve, in contrast to the current generation prosthesis. A multidisciplinary heart team setting is mandatory.

For more information, see note Page 4.
As TAVI evolves...

(for continuation from page 3)

for the management of patients’ nat... during the pro... single learning phase.

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A TRULY PERCUTANEOUS PROCEDURE

At Essen University Hospital, transfemoral TAVI is performed as a truly percutaneous procedure ensuring all the advantages of this less-invasive closure device with minimal complications.

After completion of the procedure, the valve is deployed in a semi-systolic position. The balloon is slowly deflated. The valve is deployed into and advanced within the aortic annulus. After release of the balloon, the valve is observed to be fully seated. The valve is stable and in good position.

The valve is then retrieved and the sheath removed. The femoral site and access are hemostatically managed. The patient is observed for 72 hours and then discharged the same day.

The Edwards SAPIEN XT THV is a percutaneous valve-in-valve system designed to treat patients with calcific aortic stenosis who have a failed surgical bioprosthesis.

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The Edwards SAPIEN XT THV is a percutaneous valve-in-valve system designed to treat patients with calcific aortic stenosis who have a failed surgical bioprosthesis.
Valve positioning is fundamental for procedural success and optimal outcomes during TAVI. Fortunately, this task can easily be accomplished with current transfemoral and transapical device generations, as long as some distinctive procedural features are kept in mind.

Currently, valve positioning is based mainly on fluoroscopy and angiography with echocardiography remaining a useful, but non-standardised tool. An imaging technique with unlimited scan plane orientation and real-time imaging capability (such as an MRI) may be desirable for this procedure, but is not yet available. Hence, conventional strategies have to be adapted to provide improved per-procedural guidance. The Essen approach involves anatomy-based variations of standard fluoroscopic projections commonly used for TAVI, as well as procedural refinements during valve deployment with a few distinct differences between the transapical and the transfemoral approach.*

TRANSFEMORAL APPROACH

Compared to transapical TAVI, due to the longer distance the delivery catheter must track, TF TAVI offers less direct access. However, with the RenotFx TF delivery system family--and the NovaFlex TF delivery system which is now available--the catheter is able to be easily navigated through both the centre of the aortic arch and the native aortic valve. Placement of the valve 50/50 within the calcified aortic annulus is important to obtain an optimal result. The fluoroscopic projection of paramount importance during this critical step of the procedure. Positioning the THV can be improved by the use of an “anatomical” projection displaying all three aortic sinuses aligned in a single plane perpendicular to the screen (Fig. 1a) rather than using fixed standard projections (Fig. 1a). Placement of a pigtail-catheter deep within the right coronary sinus can further facilitate positioning by providing an additional, reliable landmark for correct alignment of the THV (Fig. 1b, 1c). Once optimal positioning is achieved, right ventricular pacing is initiated to help guide the THV into the heart. The THV can be positioned in a central position within the annulus, in Essen a slow and stepwise valve deployment is used for implantation. The balloon can be inflated within the annulus, in Essen a slow and stepwise valve deployment is used for implantation. The final implantation can then be performed with full balloon inflation (Fig. 1c), and with excellent results (Fig. 1d). The transapical access route is preferred in cases of septal hypertrophy due to the fact that it is a more direct approach.

The transapical echocardiography, although routinely used at our centre, is not a requirement for the procedure. In addition to fluoroscopy, the routine use of transesophageal echocardiography for peri-procedural guidance can offer a secondary safety net. Transapical 2D and real-time 3D echocardiography not only provide valuable complementary information during valve positioning (Fig. 2a), especially in cases with no or poor valvular calcification, but also gives rapid information about valve function immediately after implantation (Fig. 2b). Furthermore, it can facilitate detection of procedure-related complications, and the use of transesophageal echocardiography varies between centres, it should, at least, be readily available during the TAVI procedure.

TRANSAPICAL APPROACH

TA TAVI offers additional procedural options for valve positioning due to the shorter catheter length and more direct transit. During TA TAVI, a central position and straight alignment of sheath, guidewire, THV and aortic root should be sought. This alignment can be obtained easily by coaxial positioning of the super stiff guidewire (Fig. 2d). Malpositioning to the right can be corrected by pushing the wire (Fig. 2a), whereas malpositioning to the left can be adjusted by pulling on the wire (Fig. 2c). By doing this, the correct and coaxial position within the centre of the aortic annulus can be obtained before definitive implantation.

In order to maintain a stable and correct left ventricular position within the annulus, in Essen a slow and stepwise valve deployment offers the possibility for repositioning the THV towards the left ventricle or the ascending aorta by “pushing” or “pulling” the introducer sheath. Once the balloon is in place (Fig. 3a) and semi-expanded (Fig. 3b), the mid-point of the stent can be precisely aligned at the annulus level using aortic root angiography (Fig. 3a). The final implantation can then be performed with full balloon inflation (Fig. 3c), and with excellent results (Fig. 3d). The transapical access route is preferred in cases of septal hypertrophy due to the fact that it is a more direct approach.

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*NOTE: The Edwards SAPIEN TF system is designed to deploy the THV by inflating the balloon with the entire volume in the inflation device and to hold that inflation for 3 seconds. The Edwards SAPIEN Training Manual states valve positioning / deployment may range from 3 to 10s, according to physician judgement.
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*A NOTE: The Edwards SAPIEN TX catheter is designed to deploy the THV by inflating the balloon with the entire volume in the inflation device and to hold that inflation for 3 seconds. The Edwards SAPIEN TX catheter states valve positioning post-deployment may range from 0% to 60% according to physician judgement.

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**Evanston, IL, USA

**TAVITALK**
Understanding the design choices of the advanced Edwards SAPIEN XT transcatheter heart valve frame

In the last issue of TAVItalk, we reviewed bovine pericardium and tissue processing as key components for sustained valve durability. We specifically noted that treated bovine pericardial tissue has been clinically proven from many years of its successful use in surgical aortic valve replacements. We also characterised this success as being a result of having a multi-layered, high strength collagen structure and ThermaFix anti-calcification treatment, a proprietary process eliminating up to 98% of calcium binding sites on the tissue.

This edition focuses on two important components to the valve frame design: low frame height and high radial strength. These features are critical in obtaining a safe, high performance valve. Both of these characteristics have been maintained and enhanced in the transition from the Edwards SAPIEN THV to the Edwards SAPIEN XT THV and are the cornerstones to optimal performance and durability.

Why is the valve frame height important?

The valve is designed to treat severe aortic stenosis without creating any secondary patient compromises. Frame height is key as it is important that the valve stent does not interfere with the anatomical parts surrounding the native annulus. By choosing a low frame height — between 14 and 17 mm for the SAPIEN XT THV — the valve may be safely anchored in the aortic annulus, minimising both the risk of unwanted obstruction or interference with the coronary ostia, as well as access for future PCIs. In addition, a key design goal was to minimise any conduction abnormalities or interference with the mitral apparatus. By keeping a similar height to the SAPIEN THV, we anticipate comparable positive results concerning these areas, including a very low (<1%) coronary obstruction as well as low permanent pacemaker implantation (<7%) as shown in the SOURCE 30-day Registry results.

Why is the radial force of the valve frame important?

To understand why radial strength is important, we need to explore key aspects to providing durable and positive clinical results. Both surgical and transcatheter valves are designed to be round, with commissures 120 degrees apart from each other in order to best distribute the stresses caused by millions of ‘opening-closing’ cycles that leaflets have to endure. Changes in geometric distribution could potentially cause premature valve failure, due to additional stretching or uneven load on one or more of the leaflets. Over time, this could result in superficial tissue tearing, which would allow calcium to bond on it at a faster rate. Radial force is also important in minimising under-deployment, which could lead to tissue abrasion or premature valve failure.

The design has been carefully engineered to have sufficient radial strength, even in heavily calcified annuli.

How is the high radial force achieved?

Radial force comes from both the frame geometry and material used. Finite element analysis modelling, together with extensive bench-top testing are performed to test and design frames that will perform safely. Stresses on all parts of the frame are assessed, including during both crimped and expanded phases. 2D and 3D computer models are used in static and dynamic conditions. The dynamic condition is especially important as it takes into account fatigue resistance over time, under exaggerated conditions (equivalent to 15 years). In the coming issues of TAVItalk, we will further explore the rationale behind the selection of cobalt-chromium for the SAPIEN XT THV frame. This has enabled us to improve the radial strength, along with lowering its crimped profile. We will also talk about key factors in leaflet shape and optimal coaptation as additional factors in further enhancing valve performance.

Innovation and evolution

Two new delivery systems have brought significant enhancements to TAVI.

- Lower profile geometry
- Proprietary surgical leaflet shape
- Bovine pericardial tissue
- Edwards proprietary leaflet matching process
- Carpenter-Edwards ThermaFix process

TAVI, today and tomorrow

(continued from page 1)

in addition to the US randomised controlled trial of the Edwards SAPIEN device, Edwards plans to continue investment in clinical research and product development. We are especially pleased by the ongoing launch of the Edwards SAPIEN XT THV associated with the new NovaFlex transfemoral and Ascendra2 transapical delivery systems, as well as the emergence of new products in the coming years. Finally, I would like to offer a special note of thanks to two groups without whose help we could not produce this newsletter or continue to develop innovative products. First, thank you to our authors for taking the time to provide the TAVItalk team with a series of excellent articles on a range of TAVI-related topics. And finally to all our clinical investigators and their teams without whom we would never complete feasibility studies, receive CE Mark and, most importantly, provide you with technologies from which your patients will benefit.

JEAN-LUC LEMERCIER

Views from the Proctors’ meeting

OLAF WENDLER, MD, PhD
Clinical Director for Cardiology and Cardiothoracic Surgery, Surgical PI for the SOURCE Registry, King’s College Hospital, London, UK

At the end of 2009, IC and CS Proctors together shared their collective experiences from several thousands of proctored cases. The group agreed on a series of patient selection criteria to help standardise technical aspects of the procedure as well as the variables for initial training and proctored cases. This has resulted in further improvements to the TAVI Heart Team training programme.

- Arterial screening, access and dilatation
Get all information in advance of case.

- Anulus measurement and valve size
Should be measured by TEE prior to procedure.

- Apex location
Use transthoracic ECHO for identification.

- Angulation
TEE guidance is useful to check for any interference with initial valve. Keep guidewire in long axis.

- Coronary obstruction
Make sure to measure and evaluate the distance between annulus and left main ostia (should be >8mm).

Key Highlights

- Arterial pressure
Ensure patient is haemodynamically stable before further intervention, do not use hypotensive drugs.

- Valve management and migration
4-5 second slow inflation, no bicupid valves.

- Sheath removal
Smoothly remove under moderate rotation. be gentle if you encounter resistance. Keep guidewire in place until final angiogram.

- Have back-up equipment in advance
For any potential unexpected situations. This can be reviewed with your Edwards Clinical Specialist or Proctor.

The NovaFlex Transfemoral Delivery System

Designed for easy, precise balloon-expandable delivery, the new delivery system offers controlled navigation, smooth crossing and reliable placement across the native valve. Crimping the valve proximal to the balloon, coupled with the reduction in wall thickness/strut design of the frame, has enabled the valve to be deployed using an 18 Fr sheath.

The Ascendra2 Transapical Delivery System

This system enhances procedural control and improved outcomes for the transapical approach by optimising apical access and closure. The sheath size has been reduced by 30% (from 26 Fr to 22 Fr).

References:
1. Clinical communiqué 2010 re valve 40023305
2. Data on file at Edwards Lifesciences
3. Data on file at Edwards Lifesciences

The Edwards Transcatheter Heart Valve Newsletter

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Europe/May 2010

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Q + A

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References:
1. Clinical communiqué 20 yr results ar002835
2. data on file at Edwards Lifesciences
3. Clinical communiqué 20 yr results (continued from page 1)
The first human transcatheter aortic valve implantation by Alain Cribier in 2002 represents a landmark in the treatment of valvular heart disease and a milestone in the history of TAVI; a pioneering step towards the current widespread clinical applications of this minimally invasive treatment option for high-risk patients with severe symptomatic aortic stenosis.

On 18 May, 2005 the first German implantation of the balloon-expandable Cribier-Edwards THV was performed by the Heart Team at the West German Heart Centre in Essen, with Professor Stefan Sack as the primary operator. The 77 year-old patient, a mentally fit man, who had undergone previous surgery for severe carotid artery stenosis and for an abdominal aortic aneurysm, presented with decompensated physically disabling aortic stenosis. He had been deemed inoperable and rejected for open heart surgery by four independent surgical centres. TAVI—at that time still an experimental treatment—could successfully be performed as a last option using the initial, now historical, antegrade transvenous, transseptal approach.

In 2009, the patient is proud of his new and fuller life after TAVI, with significantly improved physical ability. Something he had dreamed of doing, but never imagined he would be able to do again. Today, five years later, the patient presents himself in significantly improved shape, reporting lasting clinical improvement: “The new heart valve has enabled me to lead a new life. I feel ten years younger”.

This procedure resulted in a remarkable improvement in physical activity for our patient. Soon after TAVI, he was able to go on a walking tour through the Spreewald in Brandenburg. Echocardiographic follow-up showed no structural valve deterioration, with continued haemodynamic improvement. In a letter from the local cardiologist who follows him in Cologne, we have further confirmation that this patient continues to do well and the results after TAVI are optimal.

This patient clearly demonstrates why TAVI is an important new treatment option for patients with severe aortic stenosis, which not only can save lives, but significantly improves the quality of life of many patients as well.

References:
1. Data on file in Essen, Germany
2. One of Pr. Cribier’s early patients, treated in Sept. 2003 is still alive with a well-functioning THV. (Data on file in Rouen, France)