Leading the way

Transcatheter aortic valve implantation using HeartNavigator

Who/where
Dr. H. Schröfel
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Challenge
Providing optimum guidance for transcatheter aortic valve implantation.

Solution
Philips HearNavigator: a new software tool currently under development

Dr. Schröfel, senior cardiac surgeon

Dr. Schröfel working with HeartNavigator

The Klinik für Herzchirurgie Karlsruhe

Opened in 1995, the Klinik für Herzchirurgie Karlsruhe (Karlsruhe Heart Surgery Clinic) is a specialist hospital for the treatment of heart disease in adults, carrying out some 2,500 procedures per year. With the introduction of minimally invasive techniques, including aortic and mitral valve replacement, the hospital is regarded as being a center of excellence for the treatment of heart patients. The hospital serves the City of Karlsruhe and the surrounding area, comprising some 400,000 inhabitants, but candidates for transcatheter aortic heart valve implantation (TAVI) are also being referred from outside the area.

Transcatheter aortic valve implantation (TAVI)

Both transapical and transfemoral approaches are used for transcatheter aortic valve implantation (TAVI) procedures, depending on the clinical indications and the patient's anatomy. The transfemoral approach has the advantage of being a little less invasive but is not feasible in all patients. At present, procedures in the clinic are approximately 55% transfemoral and 45% transapical.

Both access approaches are performed on a beating heart without the need for a heart-lung machine. The number of TAVI

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sense and simplicity

procedures has increased rapidly, with an estimate of some 8000 procedures performed worldwide in 2009, which was the first full year of commercial availability of the transcatheter valve devices in most of Europe. To date around 550 TAVI procedures have been performed in the clinic, of which 75% with the Edwards Sapien valve and 25% with the Medtronic CoreValve.

TAVI makes stringent demands on the working area. Dr Schröfel explains: "TAVI demands a sterile environment, combined with the highest possible image quality and accurate navigation. In our clinic, the TAVI procedures are carried out in a hybrid operating room equipped with a Philips Allura Xper FD20 imaging system and an integrated Maquet surgical table.
The HeartNavigator software, currently under development in collaboration with Philips for planning the TAVI procedures and for live guidance".

"TAVI demands a sterile environment, the highest possible image quality, and accurate navigation".

"The Allura Xper FD20 is very user-friendly. It is easy to learn and easy to work with. However, for a surgeon, performing interventions under X-ray control represents a major change in working methods. Instead of working directly with one's hands one has to learn to work by remote control. There are no short cuts: you simply have to learn it if you are going to work in a team with a cardiologist".
The HeartNavigator system, a new tool currently under development in collaboration with Philips Healthcare, helps to overcome these issues.

HeartNavigator

Dr. Schröfel: "Planning a TAVI procedure with the HeartNavigator is almost entirely objective, rather than the conventional subjective judgment we used in the past, so that even less experienced staff can perform safe and accurate planning".

Accurate positioning of the device demands correct alignment of the X-ray system with the valve plane, and perpendicular to the device. The origins of the left and right coronary arteries should also be properly visualized. Due to variations in the individual aortic root anatomy it is sometimes difficult to find the correct view, so that the search process might involve as many as 20 X-ray acquisitions in different views to arrive at the proper angulation and rotation. This not only costs time but also means additional radiation exposure for the patient, physician and other staff.

"It is very easy to find the correct plane".

"With HeartNavigator it is very easy to find the correct plane showing all three cusps of the aortic valve, and to align the imaging system accordingly. Consequently, the working procedure is much faster and the fluoroscopy times are correspondingly shorter, resulting in less radiation exposure and the use of less contrast agent".

"Less radiation exposure and less contrast agent".

The following case is representative of the type of patient who could not have been treated in a conventional procedure, but was successfully treated by TAVI with the help of HeartNavigator.

Case study

A 76-year old female patient presented with severe calcified aortic stenosis grade III, leading to valve insufficiency (indicated by echocardiography). Following a previous infarction she had been treated for triple vessel disease by multiple bypass surgery, and had received a biventricular pacemaker implantation for AV-block type II.

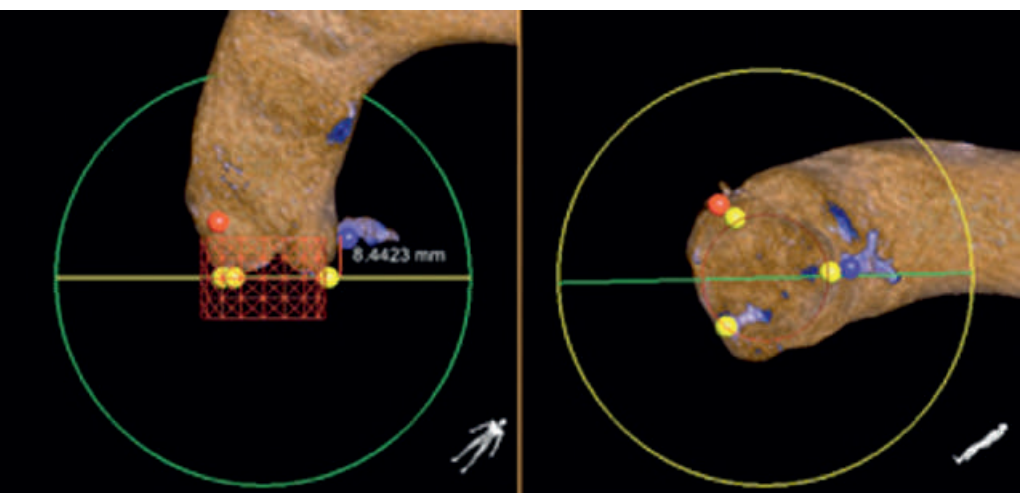

Fig. 3a

Planned optimal X-ray view showing the ostium of the left coronary artery with distance measurement between the coronary artery and the valve plane. The blue marker indicates the ostium of the LCA, the red marker indicates the ostium of the RCA, and the yellow marker indicates the bottom of the cusps. The virtual 23 mm valve, shown in red, fits within the anatomy.

Fig. 3b

View perpendicular to the planned view showing the viewplane (green line) running through the LCA.

At the time of presentation the patient was suffering from hypertension, diabetes IIb, carotid artery stenosis, and slightly limited left-ventricular function (60% ejection fraction).

Discussion by the interdisciplinary heart team concluded that the patient was not a suitable candidate for open surgery due to severe comorbidities, associated with a high surgical risk (Euroscore 34.5). The patient was referred for TAVI and, based on CT screening of the iliac vessels, a transapical approach was selected.

To prepare for the procedure, HeartNavigator viewplanning was performed, based on the pre-operative CTA.
The software automatically segmented the left ventricle, the aortic valve and the aorta, including the coronary ostia. Measurement showed a short distance between the ostium of the LCA and the valve plane of only just over 8 mm. The HeartNavigator automatically calculated views in line with the valve plane. The optimal X-ray view was determined, showing the origin of the left coronary artery: 10° LAO, 25° Cranial. This view was stored to be used during the procedure.

Virtual device implantation with the HeartNavigator (Fig. 3) confirmed the choice of the 23 mm valve size, which had previously been indicated by the ultrasound examination. After transapical access, the X-ray system was automatically positioned in the planned 10° LAO, 25° Cranial view at the touch of a button. By planning the view beforehand, based on the CTA, we avoided the need to make several aortic root angiograms to find the optimal X-ray view for this specific patient anatomy. In this way, the positioning could be performed without using any contrast agent or additional radiation exposure.

After registration, the HeartNavigator provided an overlay image showing the fluoroscopy in relation to the outline of the aortic root derived from the CTA. Balloon dilatation was performed prior to inserting the valve (Fig. 4). An Edwards Sapien XT 23 mm valve was inserted and positioned under fluoroscopy (Fig. 5).

After correct positioning had been confirmed with a final angiogram, the valve was implanted under rapid pacing at 200/min. Checkup angiography showed good positioning of the valve with respect to the left coronary ostium but also showed a severe paravalvular leak grade I-II (Fig. 6). Balloon post-dilatation resulted in a good result with no significant residual leak (grade 0-I) (Fig. 7).

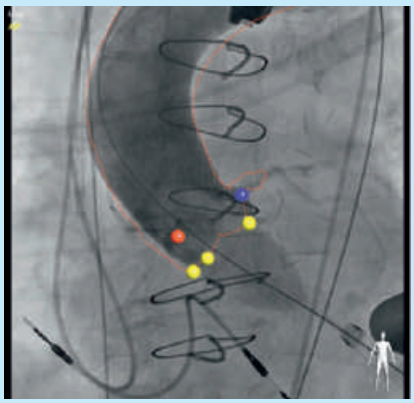

Fig. 4. HeartNavigator overlay during balloon deployment. Red outline marks the aortic root derived from the CTA.

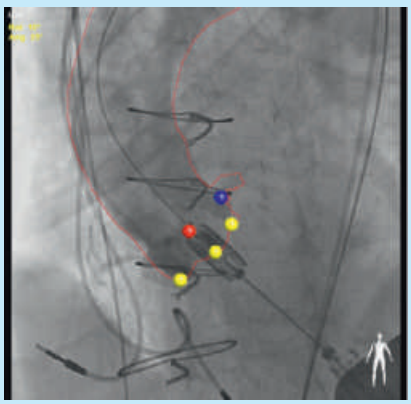

Fig. 5. HeartNavigator overlay during final positioning of the valve.

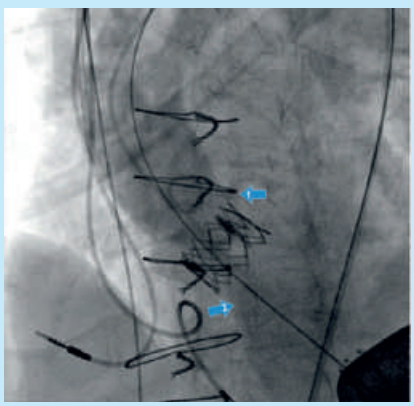

Fig. 6. Angiography after initial valve deployment. Arrow 1 indicates sufficient distance between offspring of the LCA and the valve device. Arrow 2 paravalvular leak.

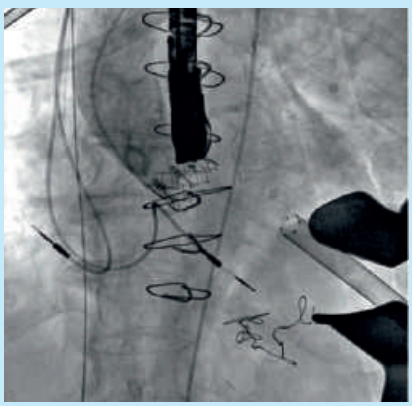

Fig. 7. Angiography after balloon post-dilatation, showing no residual paravalvular leak.

Treatment resulted in marked reduction of valve insufficiency and the patient was without adverse events at two months postoperatively.

Dr. Schröfel explains: "Accurate measurement of the distance between the valve plane and the coronary ostia is absolutely crucial, as we have to be sure that the replacement valve does not occlude the opening of one or the other coronary artery.

"Accurate measurement of the distance between the valve plane and the coronary ostia is absolutely crucial".

As a rule of thumb, patients in whom the opening of one of the coronary arteries is less than 10 mm from the annulus of the valve are regarded as unsuitable for the TAVI procedure. However, because the measurements via the HeartNavigator are more accurate than those on the CT images, it has been possible to treat patients who would have been excluded on the basis of the CT images alone".

"HeartNavigator helps integrate TAVI in the clinical routine".

"Three years ago, TAVI was still in the realms of investigation and research, but has now become a widely accepted procedure in Europe. HeartNavigator helps to integrate TAVI in the clinical routine. The initial planning takes a little time, but this is more than compensated for by the faster procedure and greater accuracy".

Conclusion

Interventional techniques for aortic valve implantation offer important advantages over open heart surgery, particularly in older and critically ill patients who are unsuitable candidates for open surgery. Both transapical and transfemoral approaches may be used, depending on the clinical indications and the patient's anatomy.

Transcatheter Aortic Valve Implantation (TAVI) has the advantage of being minimally invasive, but demands the highest possible image quality and accurate navigation.

The HeartNavigator, currently under development in collaboration with Philips Healthcare, Best, the Netherlands, allows planning of optimal X-ray views and device size before the start of the procedure, and provides live guidance during the procedure.

To conclude, Dr Schröfel says: "We are working closely with Philips on the further development of the HeartNavigator, and it also helps us to provide valuable feedback for the valve manufacturers. We keep on trying to improve our procedures, keeping an open mind for new possibilities".

"We are also sharing our experience with other hospitals, and several cardiac surgeons and cardiologists have become very enthusiastic about the possibilities of the HeartNavigator".

"Philips is a great partner to work with".

"In my view, Philips clearly provides the solutions needed for a Hybrid OR and is a great partner to work with. We are very positive about our close cooperation with Philips, which is fruitful for both sides".

After development, HeartNavigator will not yet be available in US and Canada.

Please visit www.philips.com/HeartNavigator

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