Research Article

Transcatheter aortic valve implantation. Role of imaging

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ABSTRACT

Transcatheter aortic valve implantation (T-AVI) has shown good results in high-risk patients with severe aortic stenosis. Throughout the whole process of T-AVI, different imaging modalities are indispensable. Preoperatively, multislice computed tomography, angiography and transesophageal echo (TEE) are utilized for patient selection, valve selection, approach selection and the planning of implant placement. Intraoperatively, angiography and TEE are used for controlling placement of the guidewire and valve positioning. Quality control and follow-up require TEE imaging and can require additional CT or angiography studies. In the first half of this paper, we discuss the applicability of different imaging modalities for T-AVI in the light of the current best practice.

In the second half of this paper, we present an overview on research projects in medical engineering which aim at development of image-based methods for increasing patient safety during T-AVI. Template-based implantation planning, as it is applied in dental, orthopedic and other surgical disciplines, is proposed as an aid during implant selection in order to help reduce the incidence of complications such as atrioventricular node block and paravalvular leaks. Current research tries to apply state-of-the-art engineering techniques, such as computational fluid dynamics to optimize valve selection and positioning. For intraoperative assistance during valve positioning, real-time image processing methods are proposed to track target landmarks and the stented valve.

Keywords: Transcatheter aortic valve implantation, T-AVI, imaging

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BACKGROUND

Transcatheter aortic valve implantation (T-AVI) was first described by Cribier in 2002 [1] and since then has evolved as a routine procedure for high risk patients with aortic stenosis [2,3]. As of June 2010, 10,000 transfemoral (TF) implants of the CoreValve^{TM} prosthesis (Medtronic Inc., Minneapolis, MN, USA) and approximately a similar number of TF and transapical (TA) implants of the Edwards Sapien^{TM} prosthesis (Edwards Lifesciences Inc., Irvine, CA, USA) (Fig. 1, left) have been reported. Several additional systems are currently being developed or tested [4,5].

Several studies have proven the efficacy and efficiency of the method [3,6,7]. With respect to mortality, T-AVI clearly outperforms medical therapy in patients who are not surgical candidates [8]. Whether or under which circumstances T-AVI has better results than surgical valve replacement has not yet been established. Recent studies were able to show that the short-term and mid-term mortality of T-AVI patients are clearly below the logistic EuroScore for patients with high operative risks. Randomized data comparing T-AVI with surgical valve replacement are still pending.

COMPLICATIONS

The most common complication after T-AVI is third-degree atrioventricular block (AVB) with an incidence reported up to 36% [3,6,7]. Stimulus conduction through the AV node can be permanently interrupted through pressure induced on the tissue by the expanded stent in the left ventricular outflow tract (LVOT). Several studies indicate that inordinate valve oversizing, low valve implantation, device type, pre-existing right bundle branch block and severe calcifications in the area of the coronary sinus promote AVB after T-AVI [9–11]. If persistent, bradycardia resulting from AVB requires permanent pacemaker implantation.

Paravalvular leaks are the most common reason for postoperative aortic insufficiency (AI) after T-AVI (4%–35% [7]. Valve misplacement, eccentric local plaque and insufficient oversizing are the principal reasons for this complication [9].

Aortic dissection or perforation is reported between 0% and 4% [7]. Partial or complete coronary occlusion was reported in 0.6% of T-AVI cases in the SOURCE registry [3] (Fig. 2).

In most cases, the occlusion is caused by the displaced native leaflet rather than by the implant itself. Risk factors are excessive calcifications, a low coronary ostium (<10–12 mm from the basal leaflet insertion to coronary ostium), a narrow aortic root with shallow sinuses or combinations of these factors [12]. In such cases careful planning of the implant target position might prevent coronary occlusion.

Valve embolization due to implant undersizing or misplacement is reported in rare cases, e.g. 0.3 % in the SOURCE registry. Rare cases of aortic root rupture (e.g. [13] are reported. Causes for these events are unclear; valve oversizing or local calcifications might promote them.

THE ROLE OF IMAGING

Preoperative and intraoperative imaging is of utmost importance for procedural planning and execution. Preoperatively information on: (1) vascular access sites; (2) quality and tortuosity of the femoral, iliac vessels and the whole aorta; (3) relation of the apex to the chest wall; (4) angulation of
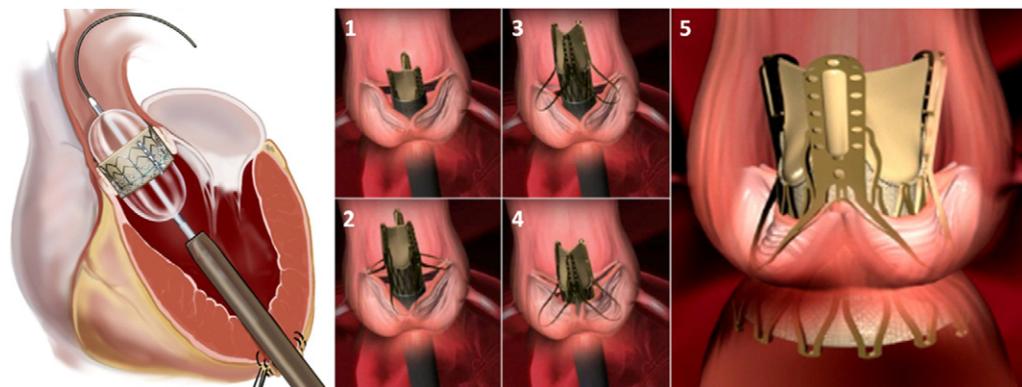

Figure. 1 Left: Transapical implantation of balloon-expanded T-AVI valve (schematic), Right: Transapical implantation of self-expanding T-AVI valve (schematic).

the left ventricle and left ventricular outflow tract in relation to the aortic root; (5) aortic valve leaflets and leaflet calcification; (6) aortic valve annular dimension, geometry and calcification; (7) distance of coronary ostia from aortic annulus; (8) the extent of concomitant coronary artery disease; (9) concomitant valvular pathology, and (10) left ventricular function need to be determined.

Intraoperatively, fluoroscopy and TEE are used to: (1) guide wire placement; (2) perform root angiography; (3) guide positioning of the balloon for balloon valvuloplasty; (4) position the implant, and (5) for quality control. There is a consensus that for intraoperative guidance both high-resolution fluoroscopy as well as TEE is required. In this paper we will describe the use of different imaging modalities in the preparation, conduction and follow-up of T-AVI.

IMPLANTATION PLANNING

The percutaneous nature of T-AVI forbids manual implant sizing during the intervention. Once implanted, percutaneous implants can only be removed surgically, requiring conversion to an open heart technique. To prevent this, T-AVI requires precise and extensive preoperative planning.

PATIENT SELECTION

Careful T-AVI planning begins with careful patient selection. There are general indications and contraindications for T-AVI. In addition, there are specific indications and contraindications for the transfemoral and transapical approach and for the available valve types that should be considered in order to select the optimal treatment.

The European Association of Cardio-Thoracic Surgery (EACTS), the European Society of Cardiology (ESC) and the European Association of Percutaneous Cardiovascular Interventions (EAPCI) released a joint statement which includes elaborate recommendations regarding patient selection for T-AVI [14]. According to these recommendations, T-AVI is indicated in symptomatic patients with confirmed severe aortic stenosis (AS) who face a high operative risk (expected mortality >20% with the logistic EuroScore and >10% with the STS score).

Severe coronary comorbidity which requires revascularization is not necessarily a contraindication for T-AVI, but for those patients who are percutaneous coronary intervention candidates, the chronology of both interventions should be discussed individually. At present, T-AVI is not recommended for patients with bicuspid valves [15].

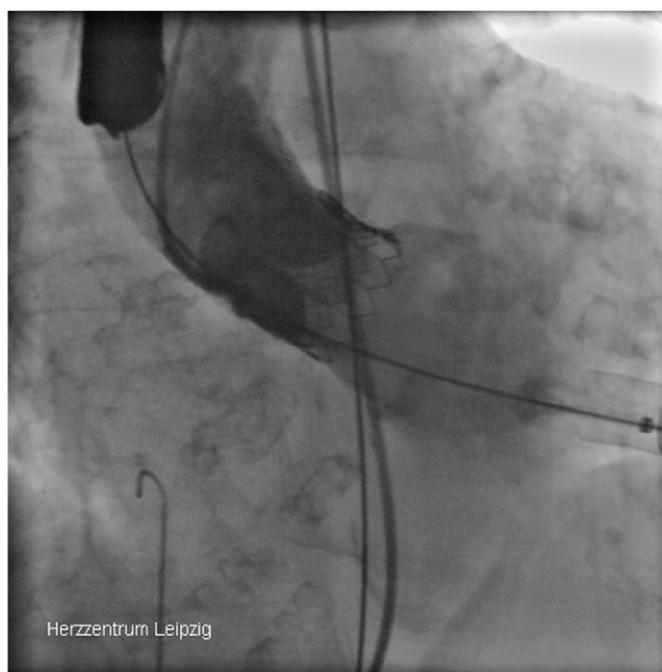The current gold standard for diagnosis of AS is transthoracic echocardiography

Figure. 2 Main stem occlusion after T-AVI.

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(TTE), transesophageal echocardiography (TEE) or invasive measurement of transvalvular pressure gradient. Non-invasive assessment of AS is also possible with MRI.

A secondary indication for T-AVI may be major AI without relevant AS, for instance in the case of a degenerated biological implant. For diagnosis of AI, TTE, TEE, angiography or MRI can be applied. Non-invasive assessment for both AS and AI is also possible with CT [16,17].

APPROACH SELECTION

Once a patient has been identified as a T-AVI candidate, the decision for the transfemoral or transapical approach is the next step. So far, no evidence-based guidelines are available for this decision, but a number of criteria and parameters are reported in the literature which might favor one approach over the other [14]. Careful evaluation of these parameters before the decision is strongly recommended to be rendered by an interdisciplinary board including cardiology, cardiac surgery, radiology, and anaesthesiology.

Feasibility of the transfemoral approach

For the transfemoral approach, a minimum passage (6 mm for the Corevalve, 6–6.5 mm for the Sapien) through one iliac artery and the aorta is required. Calcifications, vessel tortuosity, aneurysms of the abdominal aorta, plaque and a narrow bending of the aortic arch may hinder the advancement of the guidewire and the catheter and may give favor to the transapical approach. The assessment of the diameter, calcifications and tortuosity of the iliac arteries and of the aorta is possible with multislice CT angiography (CTA) and projective angiography images. However, CT provides more comprehensive insights, especially with regards to the circularity of calcifications.

Feasibility of the transapical approach

For the transapical approach, previous surgery of the left ventricle (LV) including a patch and severe respiratory insufficiency are contraindications. Calcifications of the pericardium, the accessibility of the apex through a minithoracotomy, a narrow LV, sharp angles between the LVOT centreline, the centreline of the ascending aorta, the delivery axis through the apex and an intercostal space (Fig. 3) impede the feasibility of the transapical approach and might give favor to the transfemoral approach. The feasibility of the transapical approach is best assessed using CTA, but could in principle (and if the renal status of the patient requires this) also be investigated in 3D TTE and TEE.

ANNULUS MEASUREMENT AND VALVE SIZING

Incorrect valve sizing has been proven to be a principal cause for postoperative aortic insufficiency due to paravalvular leaks as well as for severe complications such as annular or LVOT ruptures.

Correct sizing of the valve requires a comprehensive understanding of the geometry and topology of the aortic root and LVOT [18] and accurate measurement of the diameter of the aortic annulus.

Table 1. Applicability of imaging modalities for T-AVI. (●●: recommended, ●: possible, *: applied experimentally).

Phase		Fluoro/Angio	TTE/TEE	CT	MRI	DynaCT
Preparation	Grade of Stenosis	●●	●●		●	
	Coronary Status	●●		●		
	Grade of AI	●●	●●	●	●	
	LV Function		●●		●●	
	LV & LVOT Geometry		●●	●●	●	
	Valve Calcification			●	●●	
	Root Geometry & Sizing		●	●●	●	●
	Vascular Access	●●		●●	●	
Intervention	Guide Wires	●●	●			
	Valve Positioning	●●	●		*	*
	Valve Deployment	●●	●		*	
	Impl. Valve Assessmt.	●	●●			*
	LV Function		●●		*	
	Coronary Occlusion	●●	●			
	Cardiac Tamponade	●	●●			
Follow Up	Paravalvular Leaks		●●		●	
	Valve Migration		●	●●		

Manufacturer guidelines originally restricted the usage of the SAPIEN implant to patients with an aortic annulus diameter between 18 and 25 mm; the Sapien Xt extends this range to 28 mm. The CoreValve is currently recommended for patients with an aortic annulus between 20 and 27 mm. The profile of the aortic annulus is (roughly) elliptic. In the literature, different definitions of the diameter of the aortic root are used (Fig. 4, left): The minimal diameter D_{min} , the maximal diameter D_{max} , the mean diameter $D_{mean}=(D_{max}+D_{min})/2$, and $D_{CSA}=2 \times (CSA/\pi)^{0.5}$ which is computed from the cross sectional area (CSA) of the annulus. According to Schultz et al., [19], D_{mean} and D_{CSA} produce the best approximation of a one-dimensional radius for valve selection. In the future, sizing guidelines (and stent designs) based on the two radii of a fitted ellipse (Fig. 4, right) might increase the outcome quality of T-AVI.

The highest reproducibility of annulus measurements is reached with CTA images [19,20]. Only patients whose renal status forbids CTA acquisition, 3D TEE or projected X-ray angiographies should be used for annulus measurement.

The basic functionalities required for T-AVI planning (determination of diameters, cross-sectional areas and angles) are available in most modern medical image analysis software. Nevertheless, the
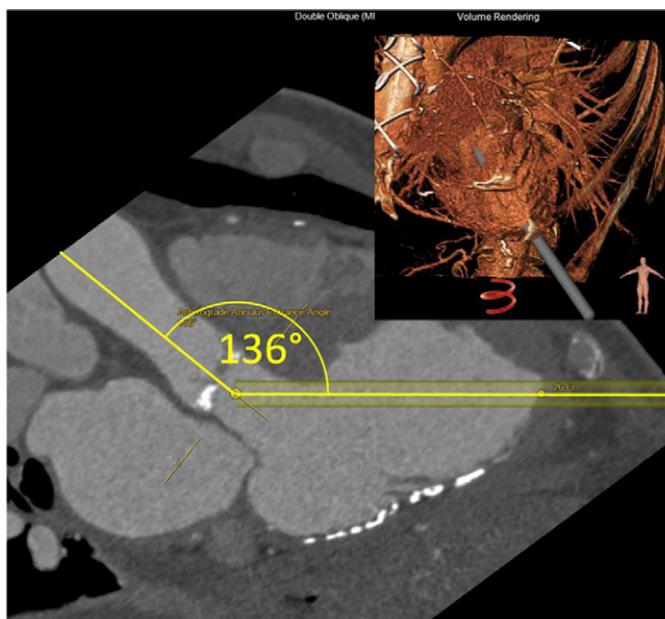

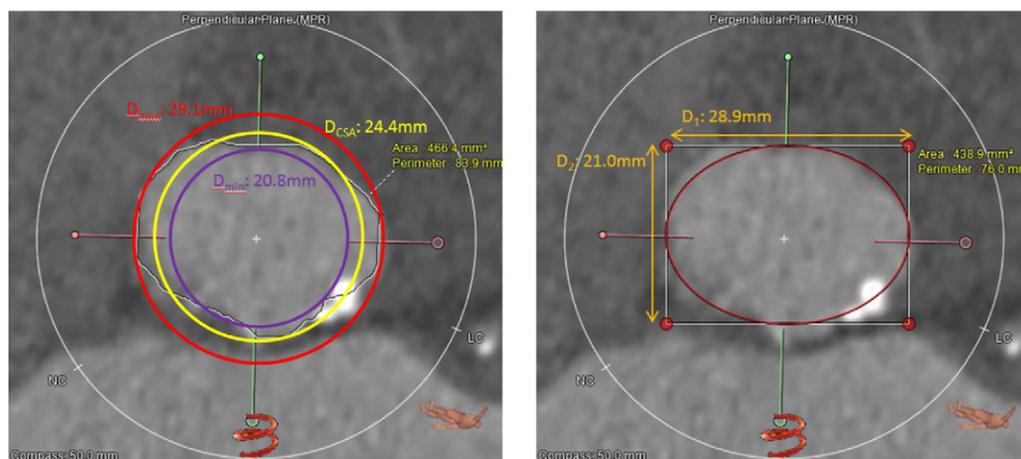**Figure. 3 Angle between LVOT and transapical entry vector through intercostal space.**

Figure. 4 Left: D_{min}, D_{max}, D_{CSA} , Right: Elliptic description of the annulus.

determination of all relevant parameters (especially the assessment of the femoral approach) can be an extremely time-consuming process with most off-the-shelf cardiology or radiology systems.

For clinical practice, the 3Mensio Valves software package (3mensio Medical Imaging BV, Bilthofen, The Netherlands, Fig. 5) implements a dedicated planning workflow for T-AVI which offers specific tools for most questions that arise during T-AVI planning.

INTRAOPERATIVE IMAGING

X-ray angiography is used to monitor guidewire placement for transfemoral aortic valve implantation (TF-AVI) as well as for transapical aortic valve implantation (TA-AVI). To confirm correct wire placement within the LV (especially to rule out interference with the subvalvular apparatus of the mitral valve), TEE can be supportive.

Accurate valve positioning is the crucial step of T-AVI. The operator has to assure a good entrenchment of the stent in the aortic annulus in order to achieve an optimal sealing of the annulus with the stented valve. Occlusion of the coronary ostia has to be avoided as well as impairment of the mitral valve. To ensure this, online imaging is required which allows identification of the coronary ostia and the annulus. A new class of anatomically shaped valve stents (Fig. 1, right) raises an additional issue regarding the orientation of the device. Whereas for implants such as the CoreValve and the Sapien, the orientation around the length axis (roll angle) is considered to have no influence on the outcome, these new devices require rotational alignment of the support frame with the cusps of the sinuses.

The clinical gold standard for imaging during valve placement is X-ray angiography. C-arm angulation is an important factor for obtaining reliable and conclusive images. The optimal projection is perpendicular to the annulus plane and orthogonal to the line through both commissures (Fig. 6, right). TEE is often used as an additional source of information during valve positioning.

Valve deployment is usually performed under angiography monitoring with the TEE probe retracted.

For patients with severe renal disorder, valve positioning and deployment under TEE guidance was proposed [21].

Throughout the implantation process TEE is used to monitor LV function, which may deteriorate after valvuloplasty due to acute onset of AV regurgitation and to detect cardiac tamponade.
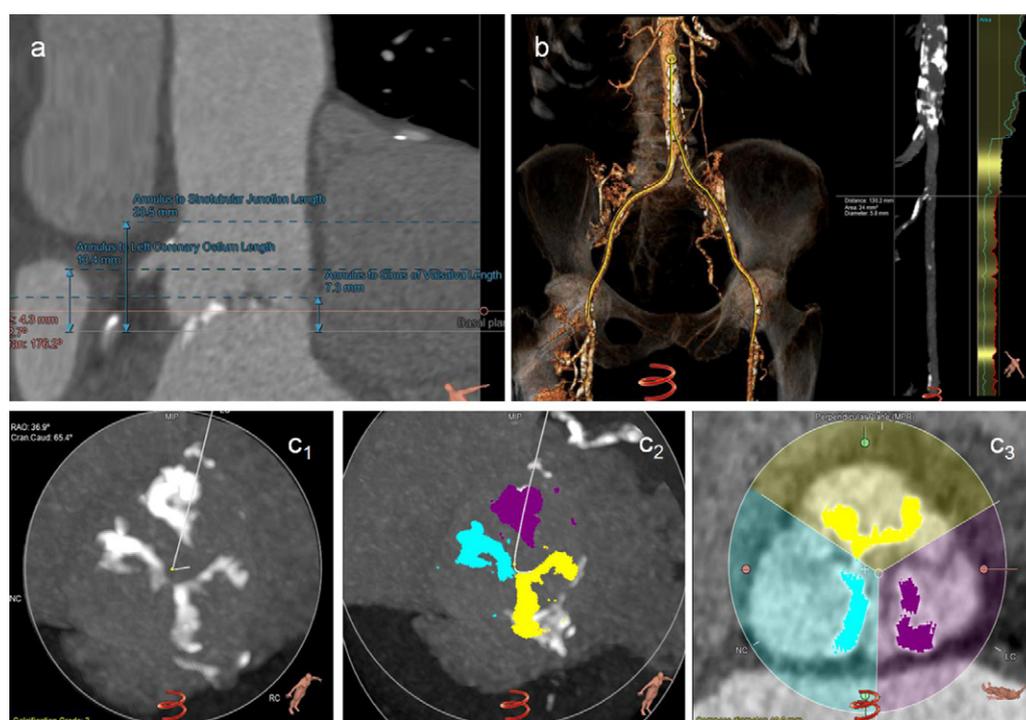
Figure. 5 T-AVI planning with 3Mensio software. (a) distance between coronary ostia, basal plane, sinuses of Valsalva. (b) clear width of iliac artery is visualized for transfemoral access. (c) Rosenhek classification of valvular calcifications.

Post-implant, the valve position is confirmed with TEE and/or angiography. Valve competence can be tested with Doppler TEE and angiography, whereby TEE provides better localization and assessment of paravalvular regurgitation.

Obstruction or occlusion of the coronary arteries is best seen in angiography.

Diagnosis of AVB requires no imaging but is best seen on the ECG. Nevertheless, the impact of both AVB and left main occlusion on the LV function may be seen in TEE.

FOLLOW-UP

The development of paravalvular leaks, as well as possible valve migration, should be checked in regular intervals during follow up. TEE should be used for regular screenings; cardiac CT is recommended in cases where TEE findings are not conclusive or indicate major complications.

FUTURE PROSPECTS

3D ANGIOGRAPHY

With the Syngo DynaCT system (Siemens AG Medical Sector, Erlangen, Germany) volumetric reconstructions similar to multislice CT images can be acquired intraoperatively with the angiography C-arm. With respect to resolution, signal to noise ratio, fidelity and motion artefacts, the resulting images are not comparable with modern cardiac CT images. It has been shown that when acquired under rapid pacing, they are sufficient for preoperative implant selection [9] and automatic generation of a 3D model which contains all relevant anatomical landmarks [22].

As long as the patient is not moved on the operating table after DynaCT acquisition, the DynaCT remains spatially registered with any angiography images acquired with the same C-arm. The optimal perpendicular view onto the aortic root can be identified by rotating the virtual model of the aortic root on screen and the system can then rotate the C-arm accordingly. During valve positioning, a 3D model extracted from the DynaCT can be superimposed on the angiography images used to guide catheter placement (Fig. 6) [23].

TEMPLATE-BASED PLANNING

The current practice of valve selection is usually based on the annulus radius alone, neglects the fact that the aortic root is a complex 3D structure that varies among patients with respect to several parameters [18]. For optimal valve selection the geometry of the aortic root as a whole needs to be considered. In 2009, the usage of geometric 3D models of the implants ('implant templates') was proposed as a means to give visual feedback on the fit between implant and anatomy during T-AVI planning [24]. The system guides the user through a landmark detection process that aims to establish a simplified model of the aortic root anatomy [18]. 3D implant templates of different valve models are registered according to the manufacturers implant placement guidelines (Fig. 7).

Valve selection and placement can be manually adjusted by the physician. In 2010, a preliminary study was presented showing that this approach can help to increase the accuracy of implant selection with respect to the incidence of postoperative AVB and AI [9].

In Fig. 8, the concept of knowledge-based implantation planning is depicted. A database of models describing the pre- and postoperative status of a cohort of T-AVI patients is created. By relating actual cases to this knowledge base of past cases, a planning system can automatically derive treatment
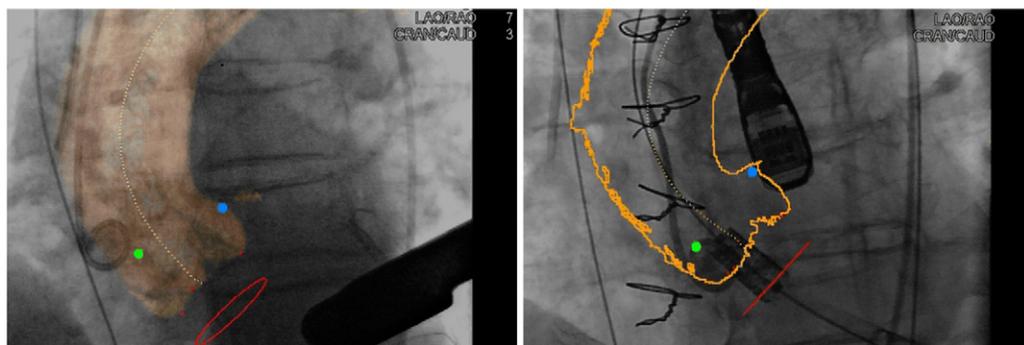

Figure. 6 Interoperative fusion of 3D information from DynaCT with 2D angiography.

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plans which reduce the risk for AI, AVB, or other complications. By integrating other future technologies (such as simulation and catheter guidance as described below), a closed loop of planning information, treatment assistance and follow-up assessment is created which allows the system to permanently extend its database.
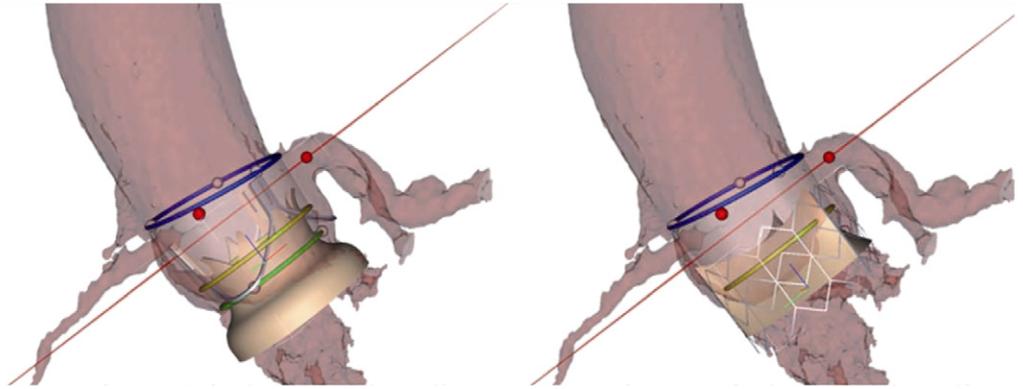

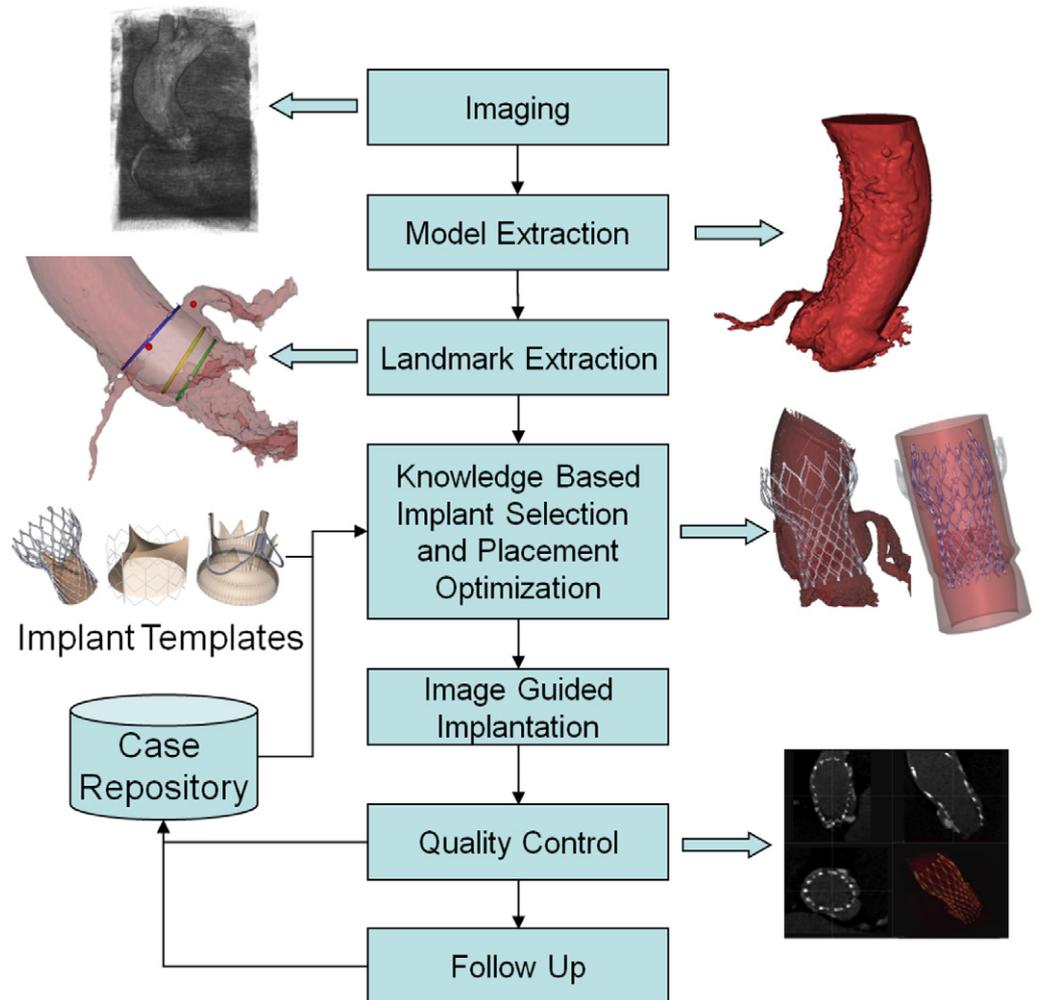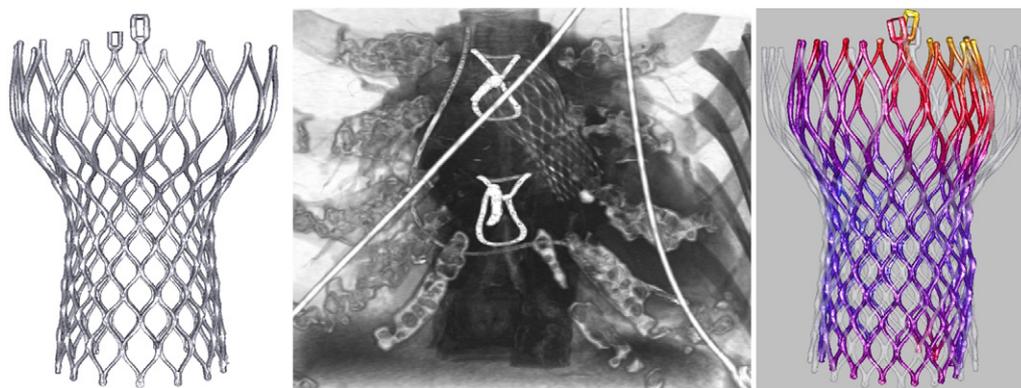Figure. 7 3D template-based preoperative T-AVI planning with Emracer and Sapien valve.

Figure. 8 Workflow and dataflow for knowledge-based implant selection and implantation support.

Figure. 9 Deformation analysis of T-AVI stent: undeformed stent model (left), postoperative CT (center), deformed stent model (right).

SIMULATION

Numerical simulation of flow conditions through aortic valve implants have been an indispensable engineering tool in the development of new devices for many years [25]. In recent research, several groups have applied the same methods for simulating the hemodynamics in the aortic root after percutaneous valve implantation in a patient specific manner [26]. Analysis of stent deformation under implantation (Fig. 9) allows patient-specific simulation of the leaflets mechanics to assess coaptation [27].

In the future, such approaches could be employed for determining the optimal treatment preoperatively or for postoperative prediction of the long-term outcome, valve degeneration [28] or valve migration [29].

CATHETER GUIDANCE

The most specific planning is only useful to the extent of accuracy which can be reached regarding valve placement intraoperatively. Advanced image processing technology and mechatronic systems could in the future help to avoid placement errors or even actively support positioning of the valve.

A system was presented in 2010 [30] for intraoperative tracking of the coronary ostia as well as the stented valve. A screenshot of the intraoperative system output is presented in Fig. 10. Preoperatively, the distance between the coronary ostia and the aortic annulus is measured, e.g. in DynaCT or multislice CT images. In a perpendicular projection, the coronary ostia (red dots) are then used to determine the target area (green box) for the distal perimeter of the stented valve (magenta box). This development aims at providing passive assistance by preventing the operator to deliver the device in a position where coronary occlusion is likely to occur. In the current stage this system cannot be used during surgery as it does not function in real-time.

Intraoperative MRI guided T-AVI was first attempted around the year 2004. It was reported that due to the radiofrequency shielding effect of ferromagnetic stents, imaging quality was impaired during and after valve deployment, but was, in principle still possible [31]. Immel et al. presented an experiment in which they equipped self-expanding stents with resonance circuits to overcome the shielding effect [32]. The feasibility of MRI guidance of T-AVI can also be increased by attaching ferromagnetic markers to the stents [33,34]. Some groups, e.g. Li et al. and Yeniaras et al., work on the development of robotic systems for transapical valve placement under MRI guidance [35,36].

DISCUSSION

During all steps of the T-AVI workflow imaging plays an important role. In order to guarantee safe and accurate conduct of T-AVI interventions, state-of-the-art imaging equipment and image analysis software are essential. Multimodality approaches including TEE, X-ray angiography and multislice CT are promoted as the best practice standard by a number of notable publications. Still, T-AVI is afflicted with a number of frequent complications. Ongoing research is revealing the reasons for these complications and leads to the development of new image-based techniques for more accurate patient selection, intervention planning and valve placement. T-AVI is an interdisciplinary technique, which requires surgeons, cardiologists, radiologists, and anesthesiologists to find an optimal
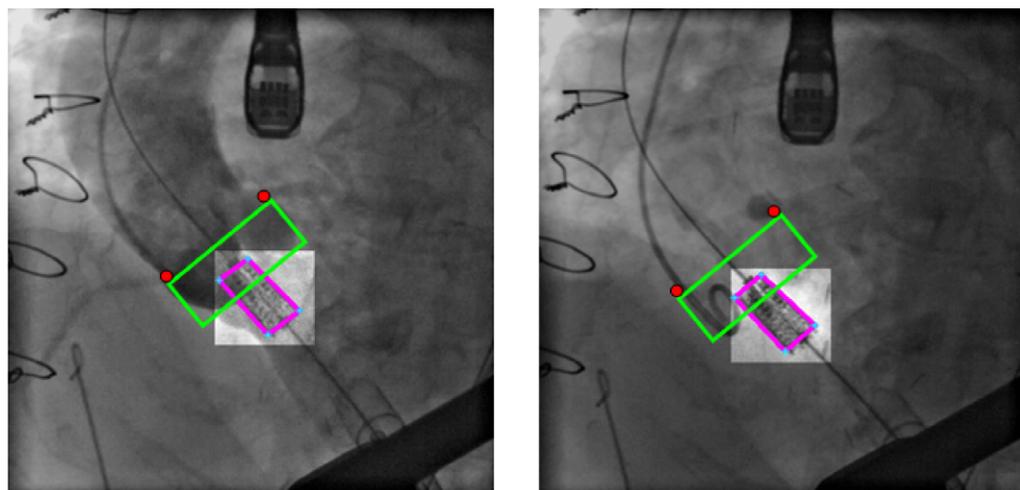
Figure. 10 Interoperative tracking of stented valve and coronary ostia (red dots with and without contrast agent [karar2010].

treatment for a patient in a cooperative manner. Appropriate image analysis and visualization tools can help in the formation of and communication within such interdisciplinary teams.

ABBREVIATIONS USED IN THE TEXT

AI	Aortic insufficiency
AS	Aortic stenosis
AVB	Atrioventrciular node block
CT	Computed X-ray tomography
CTA	CT angiography
LV	Left ventricle
LVOT	Left ventricular outflow tract
MRI	Magnetic resonance imaging
T-AVI	Transcatheter aortic valve implantation
TA	Transapical
TEE	Transesophageal echocardiography
TF	Transfemoral
TTE	Transthoracic echocardiography

AUTHOR CONTRIBUTIONS

Michael Gessat did the technical development of the workflow and planning software presented in the second part of the software. He was also leading the process of drafting the whole document. Thomas Frauenfelder, Lukas Altwegg, Jürg Grünenfelder and Volkmar Falk have provided the clinical background for the development of the workflow and planning software presented in the second part of the paper and wrote and/or revised parts of the review presented in the first part of the paper. All authors have given final approval to the manuscript version submitted for publication.

COMPETING INTERESTS

Michael Gessat has no competing interests to disclose. Thomas Frauenfelder has no competing interests to disclose. Lukas Altwegg is a Proctor for Edwards Lifesciences. Jürg Grünenfelder has no competing interests to disclose. Volkmar Falk has applied for a patent for a Method of Imaging for Heart Valve Implant Procedure (US Patent No 08,0256).

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