Transcatheter Valve Repair and Replacement

36

Lars M. Mattison, Timothy G. Laske, and Paul A. Iaizzo

Abstract

Cardiac device technologies continue to advance at a rapid pace, with heart valve design and placement procedures continuing to be one of the major focus areas. Minimally or less invasive procedures to replace cardiac valves will enable an increasing number of individuals to receive this therapy, including the older and more frail individual, the adult patient with prior surgeries for repair of congenital defects, and/or an individual with previous valve replacement (valve-in-valve procedures). Transcatheter-delivered replacement valves for the four heart valves are either available on the market today or are in development. This chapter provides a brief introduction to this rapidly emerging device area, as well as general considerations related to delivering a device via catheter into the heart (e.g., percutaneous beating heart interventional procedures performed under fluoroscopic and/or echocardiographic guidance).

Keywords

Transcatheter valve repair • Transcatheter valve replacement • Transcatheter-delivered valve system • Pulmonic valve • Aortic valve • Mitral valve • Tricuspid valve

36.1 Introduction

Transcatheter valve repairs and replacements have the potential to reduce operative morbidity, expand the indications for valve replacements for nonsurgical candidates, and treat patients who have been declined for (or choose to decline) surgery. Worldwide, catheter-based valve therapies are rapidly expanding entry into the medical practitioner's arsenal.

L.M. Mattison, BS (✉) • P.A. Iaizzo, PhD
Department of Surgery, University of Minnesota,
420 Delaware Street SE, B172 Mayo, MMC 195, Minneapolis, MN 55455, USA
e-mail: matti137@umn.edu

T.G. Laske, PhD
Department of Surgery, University of Minnesota,
420 Delaware Street SE, B172 Mayo, MMC 195, Minneapolis, MN 55455, USA

Cardiovascular Division, Medtronic, Inc., Minneapolis, MN, USA

Balloon valvuloplasties for aortic and mitral stenoses were perhaps the earliest incarnations of this current, rapidly changing environment. In 1990, Cribier demonstrated the technique of balloon aortic valvuloplasty for patients with calcific degenerative aortic stenosis. Although temporarily very successful, these patients often experienced restenosis of the aortic valve and then even worsening of their symptoms. Balloon valvuloplasty was also a popular technique to treat post-rheumatic mitral stenosis but, with rheumatic fever essentially eliminated in most developed nations, this technique is currently not in widespread practice. Similarly, pulmonic stenting with bare metal stents has been utilized as a treatment for patients with recurrent pulmonary stenosis due to repaired congenital heart malformations over the past two decades or so. Both types of treatment were radically changed when Andersen demonstrated the feasibility of the first transcatheter valve replacement in 1992 in animals [1]. While this device was not suitable for use in humans at that time (device required a 41 Fr delivery system), it sparked the

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minds of other inventors who soon expanded on the idea of a transcatheter-delivered valved stent.

The first report of a transcatheter valve replacement was in 2000 by Professor Philipp Bonhoeffer and colleagues in France who successfully delivered and implanted a valved stent in a right ventricle to pulmonary artery conduit of a patient with a congenital heart malformation [2, 3]. Shortly thereafter, Cribier et al. reported on a transcatheter-delivered valve stent into the aortic position of a patient with degenerative calcific aortic stenosis [4]. Since that time, large and small medical device corporations, as well as individual inventors, have been developing techniques to treat valvular heart disease which can be delivered (or affected) via catheter. The focus of these developments has been to treat the pulmonic and aortic valves with valve replacement, with a recent shift to mitral valves as well. Currently, there are approved devices in the United States, Europe, and Canada for pulmonic and aortic valve replacement for select groups of patients. Additionally, there is a big push to develop transcatheter mitral valves; we noted 18 potential valves in development, from filing for intellectual property to *first in man* studies. In addition to market-released devices and formalized clinical trials, there are many devices which are currently being tested in preclinical animal and human cadaver feasibility trials around the world. These devices and trials will be discussed in greater detail in the following sections.

The development of transcatheter-delivered valve systems requires a combination of numerous technologies including access systems, delivery systems, a stent or support structure with a valve or repair system (i.e., a clip to capture native leaflets), closure systems, and imaging and/or navigation systems. Currently, transcatheter valve replacement stents can generally be classified as balloon-expandable or self-expanding. Balloon-expandable devices are typically made from materials such as cobalt chromium, stainless steel, or platinum iridium alloys, while self-expanding devices are usually made from nitinol (a temperature-dependent, shape memory material). Typically, the valves themselves employ either bovine jugular vein valves or bovine/porcine pericardial constructs. It should be noted that valvuloplasty is often recommended or employed prior to the placement of a transcatheter-delivered valve, but it is not necessarily required in many transcatheter repair procedures [5]. Additionally, if a minimally invasive surgical approach or procedure is employed, then additional specific technologies and/or devices are needed as well. Furthermore, depending on the valve design, a company may also be required to develop systems to load the valves within the delivery systems (e.g., crimping systems). Finally, many device developers are simultaneously creating training simulation systems for the delivery of each product type or procedural approach.

36.2 Pulmonic Valve

A transvenously delivered transcatheter pulmonic valve can be employed as a novel nonsurgical means to treat complications associated with congenital heart disease, such as pulmonary valve insufficiency [3]. A minimally invasive surgical approach is also an option if warranted, depending on individual patient history and/or other interventions that need to be performed. For example, Fig. 36.1 demonstrates that a transcatheter pulmonic valve could be delivered into position either transvenously (via the superior or inferior vena cava) through the tricuspid valve or via a transventricular puncture through the right ventricular wall.

The needs of congenital heart patients inspired the original creation of the transcatheter-delivered stented valve. As noted above, Philipp Bonhoeffer is the pioneer of this technology. One example of such a replacement system is the Melody® Transcatheter Pulmonary Valve (Medtronic, Inc., Minneapolis, MN, USA) [3]. The stent supporting the valve is composed of a platinum iridium alloy, which is expanded during delivery by balloons located within the delivery system. The valve is that of a native bovine jugular valve isolated from the vein, which is sewn to the stent. The Melody valve is delivered using the Ensemble® Transcatheter Delivery System (Medtronic, Inc.) through the cardiovascular system, eliminating the need to open the patient's chest

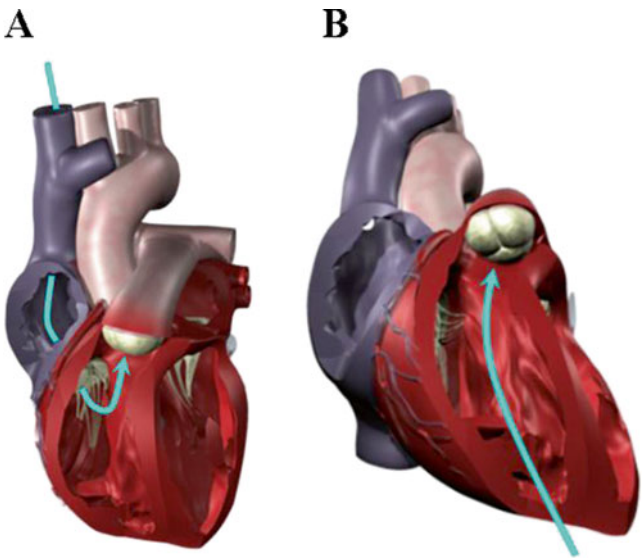

Fig. 36.1 Two potential approaches for the delivery of a transcatheter pulmonic valve: (**A**) transvenously into the right atrium, then through the tricuspid valve, or (**B**) transapically through the right ventricular wall. The later approach would require a minimally invasive surgery

Fig. 36.2 The Melody® Transcatheter Pulmonary Valve and Ensemble® Transcatheter Delivery System (Medtronic, Inc.) has received CE mark approval and is available for distribution in Europe. Additionally, a Medical Device License has been granted and the system is available for distribution in Canada. Products are available for sale in the United States for patients that have congenital heart disease. The system consists of a bovine jugular valve vein sewn inside a platinum iridium stent (**A**) and delivered via a sheathed balloon-in-balloon delivery catheter (**B**)

(Fig. 36.2). The overall procedure minimizes trauma and offers a quicker recovery than traditional surgical procedures. Furthermore, it is considered that such procedures: (1) could reduce the total number of surgeries required by these patients during their lifetimes (e.g., by postponing time to surgery while restoring pulmonic function), (2) would allow for earlier intervention and potentially better outcomes for patients while avoiding surgical complications, (3) avoid the risks of bleeding and infection associated with reoperation, and/or (4) reduce costs by avoiding postoperative intensive care [3, 6, 7].

Currently, there are two commercially available valves that have been used for transcatheter pulmonary valve replacements: the Melody (Medtronic, Inc.) and SAPIEN XT (Edwards Lifesciences, Irvine, CA, USA). To date, the Melody valve is FDA approved for patients with congential heart disease in the United States and CE marked in Europe, whereas the SAPIEN XT valve is CE marked in Europe. The largest difference between these two balloon-expandable valves is their sizing, with the Melody® valve being 18–22 mm in diameter and the Sapien XT being 23 or 26 mm. In a recent clinical assessment, both valves performed very comparably [8].

It is common that developers of these technologies partner with leading congenital interventional cardiologists and cardiac surgeons. Furthermore, managing these complex congenital heart disease patients requires a cohesive team approach. It is likely that such patients will be treated in the hybrid catheter lab/operating room by a "heart team," including an interventional cardiologist and cardiac surgeon.

36.3 Aortic Valve

Currently, transcatheter aortic valve replacement is considered for high- or extreme-risk patients with severe calcific aortic stenosis; these patients are not considered as appropriate candidates for conventional surgical valve replacements. In general, these procedures have similar benefits as those mentioned above, such as eliminating the need for cardiopulmonary bypass and allowing for shorter patient recovery times. It is conceivable that a transcatheter aortic valve could be delivered by one of four different approaches: (1) transarterially (e.g., via the femoral artery, subclavian artery, or the ascending aorta), (2) transseptally via the right heart, (3) transatrially through the left atrial wall or a port in the atrial appendage, or (4) transapically through the left ventricular wall (Fig. 36.3).

Currently, the *transfemoral* approach for the delivery of transcatheter aortic valves is the most common access route; this approach is used 69–91 % of the time [9, 10] and is the preferred access route. Primary alternate access routes are *transapical* (through the apex of the heart in the myocardium), *transaortic* (through the aorta), and *subclavian* (subclavian

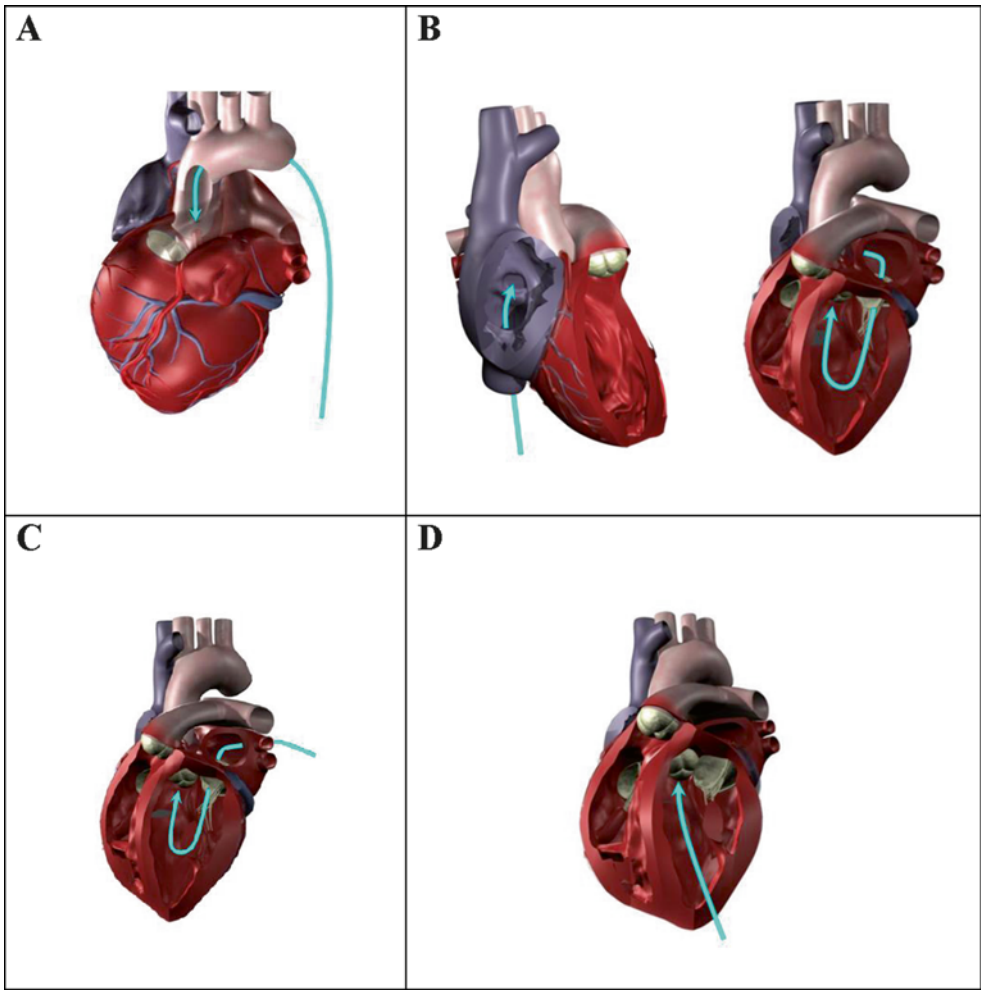

Fig. 36.3 Four potential approaches for the delivery of a transcatheter aortic valve or repair tool: (**A**) transarterially (e.g., via femoral artery access); (**B**) transseptally from the right heart (transvenous access) into the left atrium, then through the mitral valve; (**C**) transatrially through the left atrial wall or through a port in the left atrial appendage, then through the mitral valve; or (**D**) transapically through the left ventricular wall. The latter two approaches would currently require a minimally invasive surgical procedure

artery) routes. These alternate routes are typically used when the *transfemoral* approach is deemed not possible due to: (1) the size of the patient's arteries; (2) the tortuosity of the arteries and/or aorta; and/or (3) the degree of calcification within the aorta, some which could potentially be knocked free by the delivery system. Note that the transfemoral, transaortic, and subclavian routes all require retrograde delivery, while transapical requires an antegrade approach.

In current practice, both the *transapical* and *transaortic* approaches require a minimally invasive surgery (see Chap. 35), yet they provide the most direct anatomical approach. The *transapical* approach must go through the left ventricular wall (myocardium) which can be difficult to close if a large delivery system is used and/or if the myocardial tissue is abnormally frail. The *transaortic* approach also requires closure of a hole that is placed into the ascending aorta. This can be especially difficult if the aorta is extremely calcified, a condition known as a *porcelain aorta*. As technology advances, the need for minimally invasive surgery with these approaches may be eliminated. The *transseptal* approach, which has the advantage of employing transvenous access for the delivery system, has the potential drawback that if the system passing through the interatrial wall is large, the physician may create a septal defect which will require a subsequent repair (see Chap. 37). Additionally, the system must make a turn of approximately 180 degrees in the left ventricle, after passing through the complex structures of the mitral valve, to be positioned in the aortic valve, a maneuver that can be technically challenging. Anatomically, inferior access via a femoral vein is considered advantageous due to the proximity of the inferior vena caval ostium and the fossa ovalis, which is the preferred transseptal puncture location.

It has been reported that rapid ventricular burst pacing can be employed to facilitate transcatheter heart valve implantation. Pacing rates between 150 and 220 bpm with durations of 12 ± 3 s were relatively well tolerated ($n = 40$) when cautiously used. Rapid pacing was associated with a rapid and effective reduction in systemic blood pressure, pulse pressure, transvascular flow, as well as cardiac and catheter motion [11].

As can be observed in Fig. 36.3, the potential pathways/approaches to place a transcatheter-delivered valve in the aortic position are quite varied and have dramatic differences

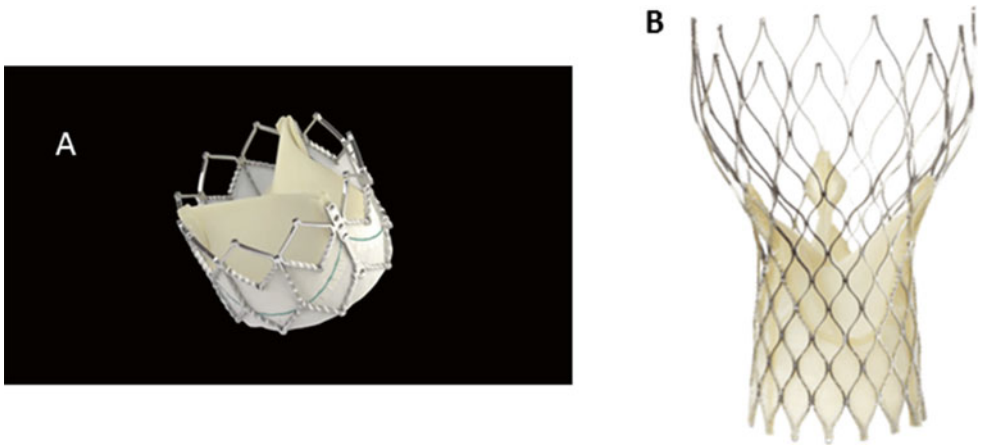

Fig. 36.4 (**A**) The Edwards Lifesciences SAPIEN XT transcatheter heart valve consists of a cobalt chromium balloon-expandable stent with an attached pericardial valve. It has been designed for transfemoral placement with the NovaFlex+ delivery system or for transapical placement with the Ascendra delivery system. It has been approved for high- and extreme-risk surgical patients in the United States and Europe. (**B**) The ReValving System by CoreValve, Inc. (Medtronic, Inc.), consists of a self-expandable nitinol stent with an attached pericardial valve. It is designed for transarterial delivery and is currently approved for high- and extreme-risk cases in the United States and Europe

in the angles and anatomical features that would be required to be navigated within or through, e.g., vessels, chamber walls, valves, or chordae tendineae. Due to this complexity, the flexibility of the delivery system (with the valve loaded inside) will be a major factor to consider when selecting a delivery approach; furthermore, the patient's cardiac anatomy is a major consideration. This is true for the delivery of the system and also for the positioning of the valve stent into the aortic position, as one must prevent obstruction to the ostia of the coronary arteries.

Currently, there are several transcatheter aortic valves available for clinical use, in clinical trials, or in animal testing. The CoreValve (Medtronic, Inc.) and the SAPIEN XT (Edwards Lifesciences) are FDA approved for high- and extreme-risk patients, and to date, several hundred thousand devices have been implanted in patients worldwide (Fig. 36.4). More specifically, for the transarterial placement of the SAPIEN XT transcatheter heart valve, the surgeon uses the NovaFlex+ delivery system (Edwards Lifesciences), whereas he/she uses the Ascendra+ delivery system (Edwards Lifesciences) for a transapical placement. The CoreValve system is also delivered via a transarterial approach in a specialized delivery catheter. In addition, several other companies that have developed (and continue to develop) competing technologies, including Boston Scientific (Marlborough, MA, USA) and St. Jude Medical (St. Paul, MN, USA) as well as smaller companies such as Direct Flow Medical, Inc. (Santa Rosa, CA, USA) and Heart Leaflet Technologies Inc. (Maple Grove, MN, USA). Nevertheless, nearly all the major players in cardiac valve replacement have a keen interest in these technologies and clinical approaches (Fig. 36.5) [12].

It is important to note that, currently, a percentage of patients that have received transcatheter-delivered aortic valves have elicited conduction abnormalities which may include heart block. Most of the self-expanding or balloon-expanded valve prostheses exert radial forces on the interventricular septal wall and surrounding structures which is required to maintain proper position and to minimize paravalvular leaks. This force, coupled with the close anatomic proximity of the atrioventricular node, the bundle of His, and/or the left bundle branch with the basal annulus of the aortic valve, is the likely explanation for this phenomenon (Fig. 36.6) (see Chap. 13).

36.4 Mitral Valve

Mitral valve dysfunction can be related to several factors including diseased leaflets [13], annular changes [14], abnormal or damaged chordae [15], and ventricular dilatation [16] causing displacement of the papillary muscles. Due to this large variability in disease process, a wide variety of transcatheter devices are being investigated for the mitral valve. These transcatheter devices can be subdivided into five general types: (1) devices for Alfieri-type edge-to-edge repair, (2) indirect annuloplasty devices deployed into the coronary sinus, (3) direct annuloplasty devices placed on or near the mitral annulus, (4) devices for dimensional control of the left ventricle or left atrium, and (5) devices for mitral valve replacement [17, 18].

The edge-to-edge technique involves placing a stitch to join the anterior and posterior leaflets at the location of regurgitation [19–21]. This technique is most commonly

	Edwards SAPIEN XT	Medtronic CoreValve	Direct Flow Medical	Boston Scientific Sadra Medical	St. Jude Medical Portico
Manufacturer					
Access	TF, TA, TAo	TF, SC, TAo	TF	TF	TF
Deployment	Balloon-expandable	Self-expandable	Inflatable	Self-expandable	Self-expandable
Support structure	Cobalt chromium	Nitinol	Inflatable	Nitinol	Nitinol
Leaflets	Bovine pericardium	Porcine pericardium	Bovine pericardium	Bovine pericardium	Bovine pericardium
Skirt	Polyethylene terephalate	Porcine pericardium	Polyester	Polyurethane	Porcine pericardium
Delivery catheter	18 Fr/19 Fr	18 Fr	18 Fr	18 Fr/20 Fr	18 Fr
R[3]	No	Partially	Yes	Yes	Yes

Fig. 36.5 This figure shows a variety of transcatheter aortic valves that are currently working through the regulatory process. It provides an insight into the design and delivery of the valve as well [12]. *SC* subclavian, *TA* transapical, *TAo* transaortic, *TF* transfemoral. ©2013 Heart Valves: From Design to Clinical Implantation, Transcatheter aortic valve implantation, Piazza N, Mylotte D, Martucci G. With kind permission of Springer Science+Business Media, New York

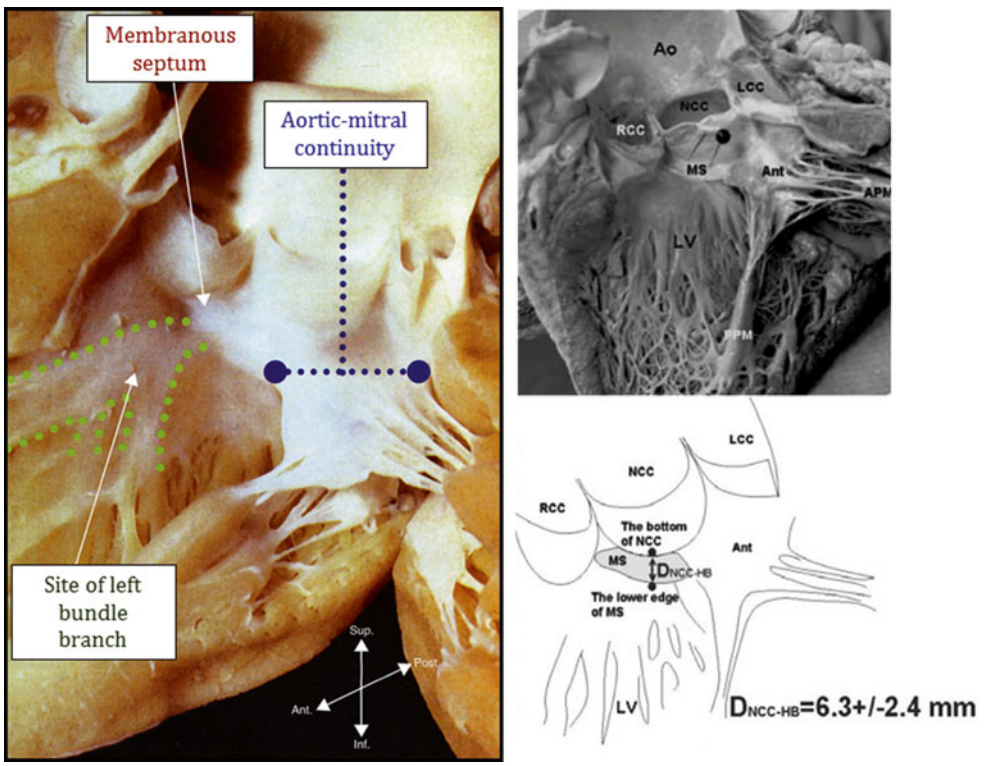

Fig. 36.6 A dissected human heart that shows the proximity of the aortic valve to the left bundle branch. The noncoronary cusp is 6.3 ± 2.4 mm from left bundle branch as depicted in the right picture. It is more common in self-expanding valves to experience issues with the conduction system in the heart [12], ©2013 Heart Valves: From Design to Clinical Implantation, Transcatheter aortic valve implantation, Piazza N, Mylotte D, Martucci G. With kind permission of Springer Science+Business Media, New York

used in patients with A2 or P2 prolapse, and the simplicity of the edge-to-edge technique has led to opportunities for percutaneous valve repair [22–24]. More recently, the MitraClip repair system was designed to use transcatheter clips to grasp the ventricular sides of the anterior and posterior mitral leaflets, leaving the clip in place upon deployment (Abbott Vascular, Bloomington, IN, USA). This technology was FDA approved in 2013.

For patients with annular dilatation, many devices are currently being developed to simulate a traditional annuloplasty procedure. These products are classified as either indirect, which typically involves a transvenous coronary sinus approach, or direct, which involves placing the device in direct contact with the mitral annulus. Percutaneous, transvenous mitral annuloplasty is a technology that implants a metal bar with flexible ends and a stiff midsection to reshape the posterior leaflet; it is a reversible procedure (Viacor, Inc., Wilmington, MA, USA). The Monarc system features two self-expanding stents tethered together which reshape the posterior region of the annulus in 2–3 weeks (Edwards Lifesciences). Similar to the Monarc, Carillon XE (Cardiac Dimensions, Inc., Kirkland, WA, USA) utilizes tethered stents in the coronary sinus to reshape the posterior annulus. These technologies rely on the proximity of the coronary sinus to the posterior aspect of the mitral annulus. Additionally, direct mitral annuloplasty is also being investigated; these devices are in direct contact with the mitral annulus either temporarily or permanently. MiCardia Corporation (Irvine, CA, USA) is developing adjustable annuloplasty devices which are currently implanted surgically but can be adjusted on the beating heart. The Mitralign device (Mitralign, Inc., Tewksbury, MA, USA) places implants around the annulus and then cinches them closer together, thereby reducing the orifice area of the valve. Nevertheless, the goal of these devices is to restore valve coaptation and thus eliminate mitral regurgitation.

Indirect approaches to mitral valve repair that influence left ventricular or left atrial dimensions are also under investigation. By changing left ventricular dimensions, products such as Coapsys and iCoapsys (Myocor® Inc., Maple Grove, MN, USA) are designed to improve mitral valve and left ventricular performance. The PS^3 system (Ample Medical, Inc., Foster City, CA, USA) shortens the left atrial dimension between the fossa ovalis and the great cardiac vein and consequently the septal-lateral dimension of the mitral annulus [25].

As described for the aortic valve, it is possible to deploy a transcatheter mitral valve or affect a transcatheter repair using four different approaches: (1) transarterial (e.g., via the femoral artery), (2) transseptal via the right heart, (3) transatrial through the left atrial wall or a port in the atrial appendage, or (4) transapical through the left ventricular wall (Fig. 36.7). The human mitral valve is a very complex, dynamic, and highly variable structure. Therefore, complications in the deployment of a replacement valve or repair device into this position will potentially interact with the (1) valve leaflets themselves, (2) the chordae tendineae, and/or (3) the papillary muscles. As mentioned earlier, the valvular and subvalvular anatomy can be quite variable, with some individuals eliciting bifurcated or trifurcated papillary muscles, distinct chordae tendineae patterns, and numerous scallops of each mitral valve leaflet. Due to the complexity of the mitral valve apparatus and underlying disease processes, it is likely that a combination of the aforementioned devices will be required to provide percutaneous solutions for mitral valve repair.

There is currently intense competition to develop the first reliable transcatheter-delivered mitral valve replacement. For example, we identified more than 18 transcatheter valves that are in production phases, ranging from filing intellectual property to first in man clinical studies (see Table 36.1) [26]. At present, most of these devices are further along the clinical trial process in Europe than the United States, due to different regulations (see Chap. 43). To date, the valves that are in first in man studies are the Fortis (Edwards Lifesciences), CardiAQ (Irvine, CA, USA), Tiara (Neovasc, Richmond, BC, Canada), and Tendyne/Lutter TMVR (Tendyne, Roseville, MN, USA). At least 18 additional devices have been developed to help treat mitral regurgitation. It will be exciting and interesting to see how these transcatheter mitral valve products continue to develop in the upcoming years.

36.5 Tricuspid Valve

As described for the mitral valve, the human tricuspid valve is a very complex, dynamic, and highly variable structure. The transcatheter approach to this valve structure is similar to those described for the pulmonic valve (Fig. 36.1). It is envisioned that a transcatheter mitral valve or repair tool could be delivered into position either transvenously (via the superior or inferior vena cava) or via a transapical puncture through the right ventricular wall. Furthermore, as described above for the repair and/or replacement of the mitral valve, nearly all options would hold true for the tricuspid valve, which many surgeons feel is often overlooked when treating heart failure patients (for a more detailed discussion, see Chap. 34). On the other hand, the potential complications of damaging or altering the conduction system would also be evident for procedures that involve the tricuspid septal annular structures, i.e., atrioventricular node, the bundle of His, and/or the right bundle branch of the conduction system (see Chap. 13).

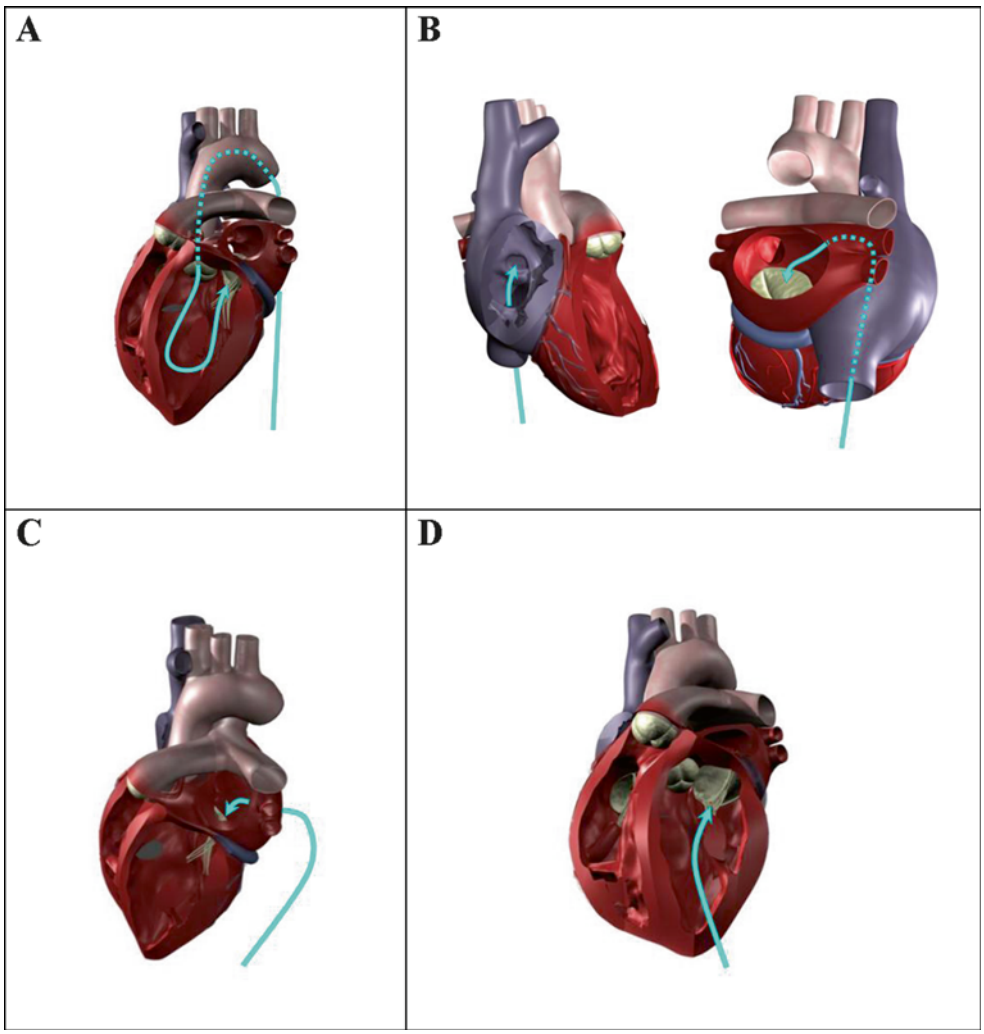

Fig. 36.7 Four potential approaches for the delivery of a transcatheter mitral valve or repair tool: (**A**) transarterially (e.g., via femoral artery access) retrograde through the aortic valve and up to the mitral valve via the left ventricular chamber; (**B**) transseptally from the right heart (transvenous access) into the left atrium, then to the mitral valve; (**C**) transatrially through the left atrial wall or through a port in the left atrial appendage, then to the mitral valve; or (**D**) transapically through the left ventricular wall. The latter two approaches currently require a minimally invasive surgical procedure

36.6 Imaging

The development and use of transcatheter-delivered cardiac valves has transformed (and will continue to transform) heart valve procedures for those requiring open-heart surgery and/or cardiopulmonary bypass (see Chap. 33) to a "percutaneous beating heart interventional procedure performed under image guidance" (fluoroscopy or echocardiography). Yet, these imaging modalities are considered to have advantages and disadvantages. For example, cardiac computed tomography (CT) imaging is considered extremely useful for identifying the relative degree of calcification that exists on a heart valve leaflet as well as the delivery anatomy, but is not useful as an intraoperative technique, and it exposes the patient to considerable radiation doses.

Importantly, advanced imaging modalities will be required for preplanning and intraoperative guidance of these interventions. More specifically, to date, there is no single imaging modality for intracardiac interventions without clinical limitations, which include low temporal or spatial resolution, excessive exposure to ionizing radiation, and interference with the clinical operator's freedom of movement. We believe that, in the near future, a combination of imaging modes will provide the information required to guide these complex interventions. Recently, our group set out to provide "a glimpse into the future" by demonstrating the unique direct visualization of transcatheter pulmonary valve implantation utilizing the Visible Heart® techniques (Figs. 36.7, 36.8 and 36.9) [27, 28]. See also Chap. 41.

Current pre-procedural imaging consists of a combination of CT scans and echocardiography. This is important for determining the sizes of the various valve annuli and the relative amounts of calcification that may exist along the given delivery route, as well as the position of the coronary artery ostia for aortic valve replacement. Utilization of these 3D renderings can be invaluable to aid the interventional cardiologist and/or cardiac surgeon to make informed decisions about the proper treatment for each given patient (Fig. 36.10).

Table 36.1 Current products that are being developed for transcatheter mitral valve repair

Company	Valve name	Status	
		International	United States
Edwards	Fortis	First in man	In development
Caisson	Caisson TMVR		Preclinicals
CardiAQ*	TMVI-TA		Preclinicals
CardiAQ*	TMVI-TF	First in man	Preclinicals
Emory University	MitraCath		In development
HighLife	HighLife mitral valve replacement	Preclinicals	
INVALVE	INVALVE device	IP	
Medtronic	Medtronic TMVR	Preclinicals	Preclinicals
Micro Interventional Devices	Endovalve-transapical		In development
MitrAssist	MitrAssist valve	Preclinicals	
Mitralix	MAESTRO	In development	
MITRICARES	MITRICARES device	IP	
NCSI	Navigate TMVR	Clinical implants	Preclinicals
Neovasc	Tiara	First in man	First in man
Tendyne	Tendyne/Lutter TMVR	First in man	Preclinicals
Twelve	TMVR		IP
Valtech	Cardiovalve	Preclinicals	

Note that there are several first in man studies in Europe, while most valves in the United States are only in the preclinical level. A few valves are only conceptual at the moment, as intellectual property has just been filed * CardiAQ was recently acquired by Edwards

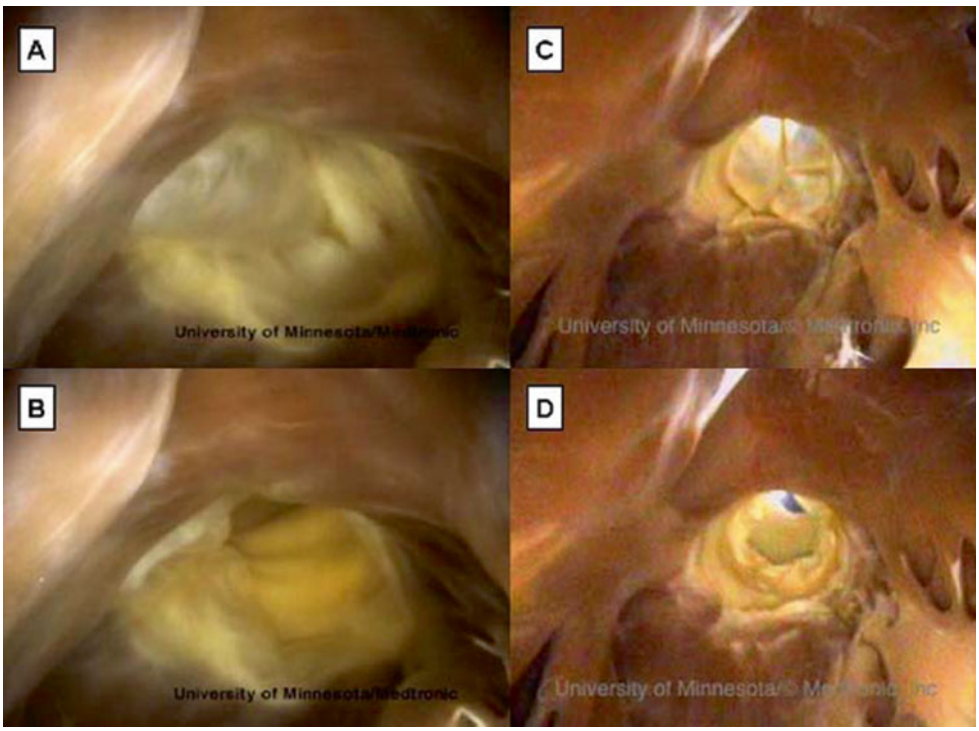

Fig. 36.8 Comparison of a human pulmonic valve (**A**) during diastole and (**B**) during systole to a transcatheter pulmonic valve placed in a human heart (**C**) during diastole and (**D**) during systole [28]. ©2008 Expert Review in Medical Devices, vol. 5, Cardiac device testing enhanced by simultaneous imaging modalities: the Visible Heart®, fluoroscopy, and echocardiography. Permission granted by Informa (http://informahealthcare.com/)

We also suggest that, as cardiac repair and device implantation procedures become less invasive, we will need to study the deployment of these systems or techniques within beating heart models. Utilization of Visible Heart® methodologies provides unique visualization of cardiac device technologies. The preparation and images obtained can be used by design engineers and physicians to develop implant methodologies as well as support clinical education and training. As more of these devices are implanted within the beating heart, unique means will be required to train individuals in the techniques to navigate and deploy them. For example, Fig. 36.9 shows simultaneously obtained images of a stent being placed in the aortic position, including endoscopic views and time-synchronized images from fluoroscopy and ultrasound (Fig. 36.11).

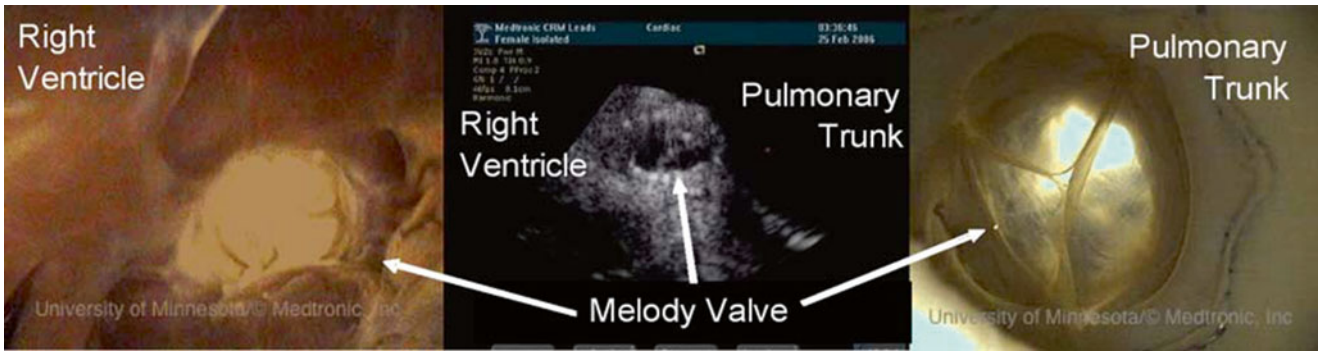

Fig. 36.9 Simultaneous endoscopic images on the left and right depict a deployed transcatheter pulmonary valve (Melody® Transcatheter Pulmonary Valve, Medtronic, Inc.) in the native right ventricular outflow tract, with the corresponding ultrasound image displayed in the center [28]. ©2008 Expert Review in Medical Devices, vol. 5, Cardiac device testing enhanced by simultaneous imaging modalities: the Visible Heart, fluoroscopy, and echocardiography. Permission granted by Informa (http://informahealthcare.com/)

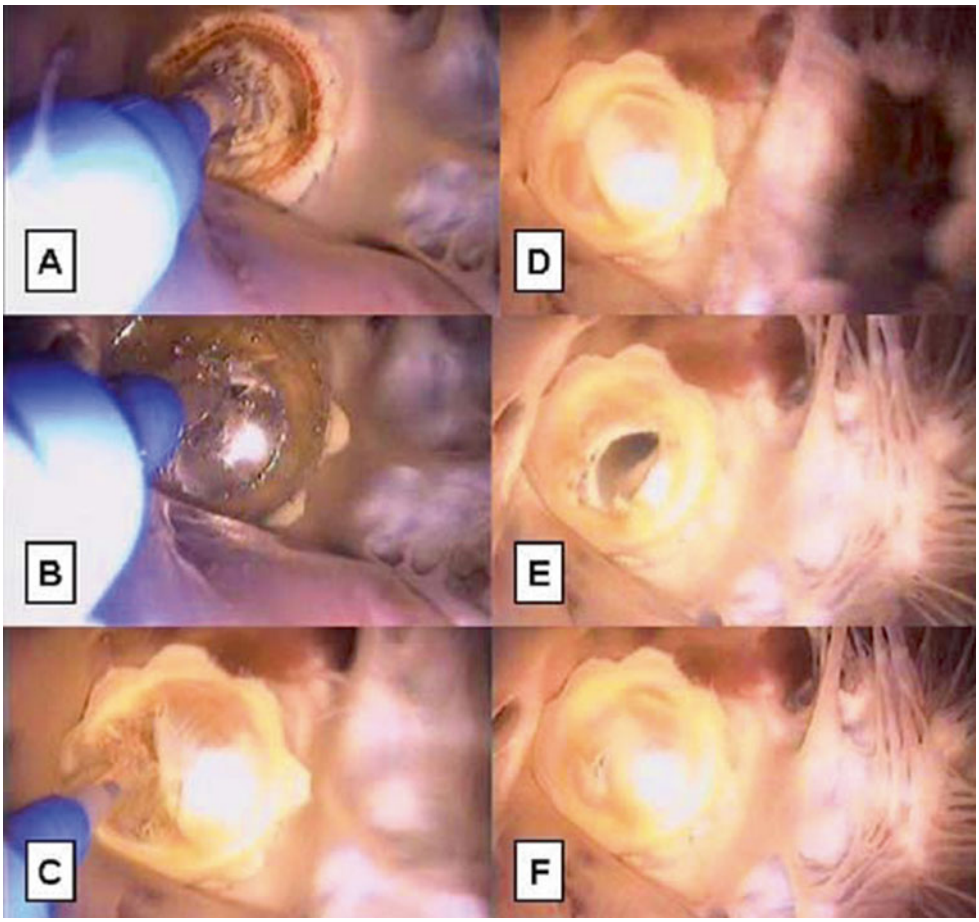

Fig. 36.10 Positioning (**A**), deployment (**B** and **C**), and function (Panels **D**–**F**) of a transcatheter aortic valve implanted into a surgically placed bioprosthetic aortic valve. It is interesting to note the lack of (or minimal) interactions between the implanted aortic valve and the native mitral valve [28]. ©2008 Expert Review in Medical Devices, vol. 5, Cardiac device testing enhanced by simultaneous imaging modalities: the Visible Heart®, fluoroscopy, and echocardiography. Permission granted by Informa (http://informahealthcare.com/)

36.7 Training Systems

The complexity of intracardiac interventions has increased with the advent of transcatheter valve replacement and is expected to further escalate as clinicians become more comfortable with complicated cardiac repairs within the beating heart and as engineers invent new product solutions. Simulators designed to demonstrate the technical aspects of transcatheter-delivered valves have already been developed. Many state-of-the-art patient simulators enable pseudo-visualization via various imaging modes. For instance, one can practice using fluoroscopy for the valve implant without any exposure to radiation. The delivery systems for these transcatheter valves are often complex and require guidewires, introducers, and/or dilators; hence, prior practice on handling such tools is essential.

Fig. 36.11 3D model of a patient's ascending aorta, aortic arch, and descending aorta. The vessel is modeled in the gold color, while the calcium deposits are white in color. It is also possible to see the coronary arteries that come off the root. Using this model the size of the aortic annulus can be measured, as well as the height of the coronaries from the annulus [29]

Furthermore, for those physicians not familiar with performing such catheter-delivered and/or minimally invasive surgical approaches, these training sessions can be invaluable and highly educational. If such procedures are performed in a newly instrumented hybrid catheter lab/operating room, then the dynamics of team interactions could also be developed in such training sessions. More specifically, studies employing virtual reality simulation of such procedures have indicated that there is a documented learning curve, and catheter handling errors significantly decrease as assessed with measurable dynamic metrics with high test-retest reliability [30] (Fig. 36.12).

36.8 Summary

The clinical application of transcatheter delivery systems to repair or replace cardiac valves is an area of intense growth, and there is also continued research development. The potential to treat patients with valvular disease without the use of open-heart surgery will ultimately affect millions of individuals worldwide, improving quality of life for these patients. The future of this field will likely see smaller delivery systems with greater intracardiac mobility, as well as replacement valves that better mimic healthy native valve function. Affecting the ultimate clinical success of these therapies will be adequate cardiac visual and function assessments prior to, during, and after these procedures. One can also foresee that simulation training will be employed even before such techniques are performed in preclinical animal studies, as many procedures will require numerous tool components (e.g., introducers, dilators, balloon catheters, delivery catheters, etc.). For additional detailed discussions on these topics, the reader is referred to manuscripts by Schoenhagen and To [31], Quill et al. [32], Scheivano et al. [3], and Piazza et al. [5].

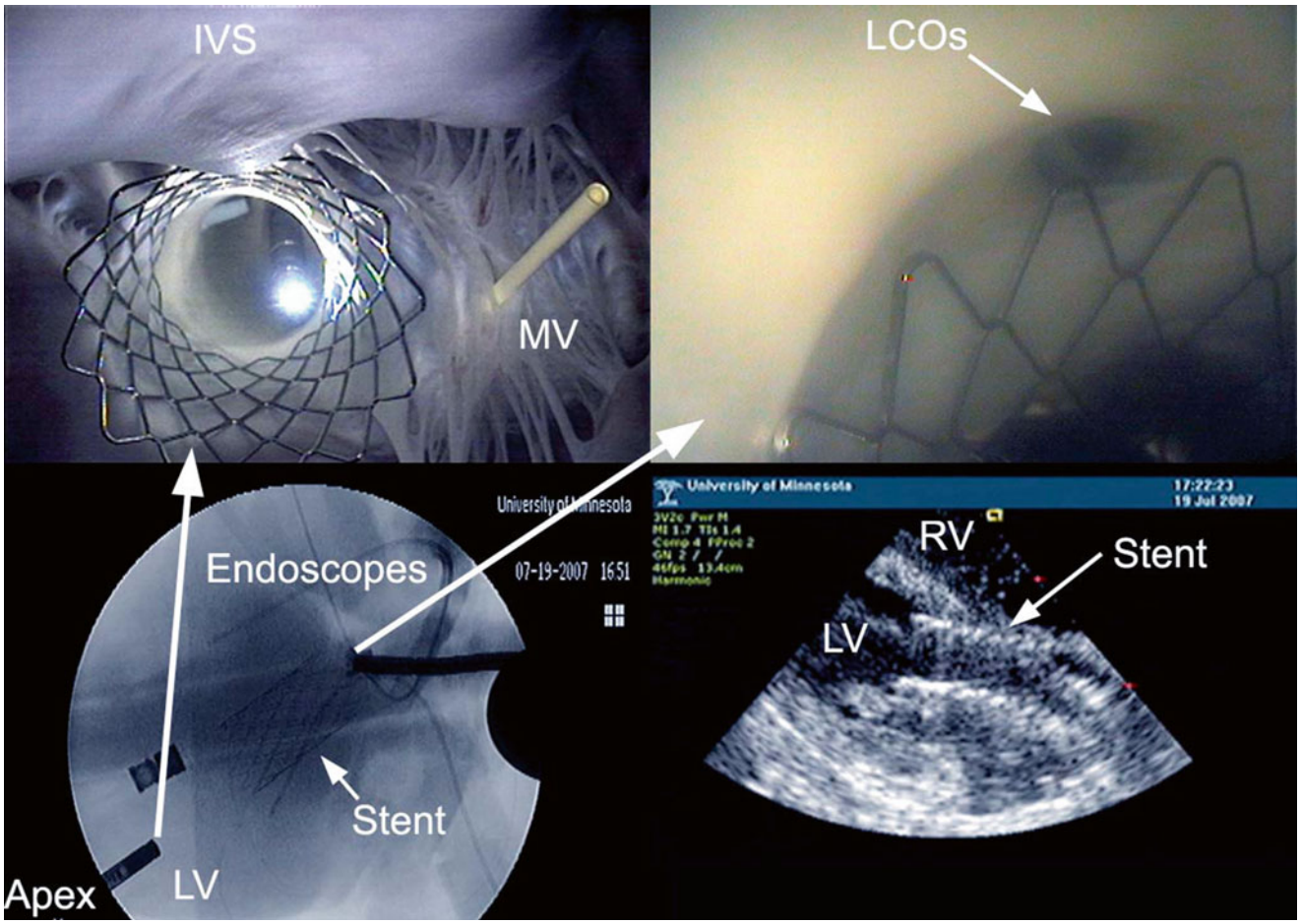

Fig. 36.12 *Top images* show endoscopic views of a prototype stent placed in the aortic position, and *bottom images* show time-synchronized images from fluoroscopy (*lower left*) and ultrasound (*lower right*). The *upper left image* shows the view from the ventricle; the interventricular septum (IVS) is at the top and the mitral valve (MV) is located on the right. The *upper right image* is a view from the aorta, specifically showing the interaction of the stent and left coronary artery ostium (LCO); in this case, there would be minimal obstruction of flow into the left coronary artery. The fluoroscopic image clearly shows the stent as well as the endoscopes in the left ventricle and aorta. The stent is also visible on the ultrasound image, projecting slightly into the left ventricle (LV). The right ventricle (RV) is located at the top of this image [23]. ©2008 Expert Review in Medical Devices, vol. 5, Cardiac device testing enhanced by simultaneous imaging modalities: the Visible Heart®, fluoroscopy, and echocardiography. Permission granted by Informa (http://informahealthcare.com/)

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