Percutaneous Transcatheter Mitral Valve Repair

A Classification of the Technology

Paul T. L. Chiam, MBBS,* Carlos E. Ruiz, MD, PhD†
Singapore; and New York, New York

Surgical treatment of mitral regurgitation (MR) has evolved from mitral valve replacement (MVR) to repair (MVRe), because MVRe produces superior long-term outcomes. In addition, MVRe can be achieved through minimally invasive approaches. This desire for less invasive approaches coupled with the fact that a significant proportion of patients—especially elderly persons or those with significant comorbidities or severe left ventricular (LV) dysfunction, are not referred for surgery, has driven the field of percutaneous MVRe. Various technologies have emerged and are at different stages of investigation. A classification of percutaneous MVRe technologies on the basis of functional anatomy is proposed that groups the devices into those targeting the leaflets (percutaneous leaflet plication, percutaneous leaflet coaptation, percutaneous leaflet ablation), the annulus (indirect: coronary sinus approach or an asymmetrical approach; direct: true percutaneous or a hybrid approach), the chordae (percutaneous chordal implantation), or the LV (percutaneous LV remodeling). The percutaneous edge-to-edge repair technology has been shown to be noninferior to open repair in a randomized clinical trial (EVEREST II [Endovascular Valve Edge-to-Edge REpair Study]). Several other technologies employing the concepts of direct and indirect annuloplasty and LV remodeling have achieved first-in-man results. Most likely a combination of these technologies will be required for satisfactory MVRe. However, MVRe is not possible for many patients, and MVR will be required. Surgical MVR is the standard of care in such patients, although percutaneous options are under development. (J Am Coll Cardiol Intv 2011;4:1–13)

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Mitral regurgitation (MR) is a common valvular abnormality, being present in 24% of adults with valvular heart disease and in 7% of the population ≥75 years of age (1,2). Surgical intervention is recommended for symptomatic severe MR or asymptomatic severe MR with left ventricular (LV) dysfunction or enlargement (3). Treatment of severe degenerative MR has evolved from mitral valve replacement (MVR) to mitral valve repair (MVRe) (3), because repair produces superior outcomes (4,5). For functional MR, however, the benefit of repair over MVR is less certain (6).

With increased understanding of the heterogenous pathophysiology of MR, cardiac surgeons have developed various techniques that increase the likelihood of successful repair (7). Mitral valve repair can also be achieved through minimally invasive approaches (8,9). This desire for less invasive approaches coupled with the fact that a significant proportion of patients—especially elderly persons or those with significant comorbidities or severe LV dysfunction—are not referred for surgery (10) has driven the field of percutaneous MVRe. Various technologies have emerged and are at different stages of investigation.

Percutaneous Approaches to Mitral Valve (MV) Therapies

The MV is just one of the elements of the mitral apparatus, and as such pathologies affecting the
Annulus (mitral annulus [MA]), leaflets, papillary muscle, chordae tendineae, LV, and left atrium (LA) can all produce or contribute to MR. The functional anatomy and classification of MR have been reviewed recently (7) and would not be further discussed. Surgical techniques are primarily aimed at correcting the culprit mechanism(s) (e.g., prolapsed leaflet, annular dilation) that lead to MR (7), and a combination of techniques may be used to obtain the best outcome. These surgical techniques can be broadly classified into those aimed at the leaflets, MA, commissures, chordae, papillary muscles, and LV. Current percutaneous technologies for MVR have been developed on the basis of some of these surgical principles.

These technologies have been previously grouped into those acting on the leaflets, direct annuloplasty or indirect annuloplasty (via the coronary sinus [CS]), and chamber (LV) remodeling (11–15). A modified classification of percutaneous MVR technology according to functional anatomy and device action is proposed (Table 1). This might facilitate more precise description of the current devices and accommodate emerging technologies.

**Abbreviations and Acronyms**

- **CS** = coronary sinus
- **FIM** = first-in-man
- **LA** = left atrium
- **LV** = left ventricle
- **MA** = mitral annulus
- **MR** = mitral regurgitation
- **MS** = mitral stenosis
- **MV** = mitral valve
- **MVR** = mitral valve replacement
- **MVR** = mitral valve repair

### Percutaneous Leaflet Plication (Edge-to-Edge Leaflet Repair)

#### Principle.
The leaflet plication technology is based on the surgical Alfieri technique (16), which brings the anterior and posterior leaflets together with a suture, creating a “double orifice” MV. This re-establishes leaflet coaptation, thereby reducing MR. This technique is most suitable for degenerative MR, although it could be employed in functional MR.

#### Devices.
The MitraClip (Abbott Vascular, Santa Clara, California) system uses a steerable catheter to deliver a clip to the anterior leaflet and posterior leaflet via transseptal access (Fig. 1). The safety and feasibility study (EVEREST I [Endovascular Valve Edge-to-Edge REpair Study]) (17) showed that, in 107 patients, procedural success (post-procedure MR ≤2+) was achieved in 74% with <1% in-hospital mortality (17). At 1-year, freedom from death, MV surgery or MR >2+ was 66%. Freedom from death and freedom from surgery were 90.1% and 76.3% at 3 years, respectively. No clip embolized, although partial clip detachment occurred in 10 patients (9%). Subsequently, 32 patients required surgery for MR; repair—when planned—was possible in 84%, demonstrating that surgical options were preserved (17,18).

Data from the EVEREST II study, randomizing MitraClip versus surgical repair, were recently presented (American College of Cardiology 2010). Patients (n = 279) with symptomatic severe MR or asymptomatic severe MR with LV dysfunction were randomized in a 2:1 (device: surgery) fashion. Freedom from combined end point of death, MV surgery or reoperation >90 days after index procedure, and MR >2+ at 1 year was 72.4% and 87.8% in the device and surgical groups, respectively, meeting the noninferiority hypothesis. The safety end point (all predefined adverse events plus blood transfusions ≥2 U) was superior in the device group (9.6% vs. 57% for surgery). The MitraClip thus seems to be an alternative option for selected patients.

The Mobius device (Edwards Life Sciences, Irvine, California) used a suture to create a double orifice MV. Despite feasibility in the animal model, initial human experience was limited by suture dehiscence and technical difficulties (19), and the program has been abandoned.

The MitraFlex (TransCardiac Therapeutics, Atlanta, Georgia), which deploys a clip to the leaflets via the transapical route, is undergoing pre-clinical testing (this device also allows an artificial chord to be implanted during the same procedure).

#### Limitations.
The major limitation of this percutaneous technology is that the surgical Alfieri technique is typically used with an annuloplasty, because results without annuloplasty have been suboptimal with significant rates of recurrent MR and need for reoperation (20), especially in ischemic MR (21) or if annular calcification is present (20). However, in a small group of well-selected patients, 90% freedom from recurrent MR >2+ or reoperation at 5 years could be achieved (22). Another limitation is the possibility of causing iatrogenic mitral stenosis (MS) (7), although Herrmann et al. (23) reported no significant stenosis in 96 patients with successful MitraClip(s) implanted.

#### Leaflet Ablation

#### Principle.
Radiofrequency energy is delivered to the leaflet(s) to effect structural (fibrosis) or functional (reduced motion) alteration. This technology is designed to target degenerative MR.

#### Device.
The Thermocool irrigation ablation electrode ( Biosense Webster, Inc., Diamond Bar, California) is a radiofrequency ablation (RFA) catheter that is delivered via femoral artery access retrograde into the LV. The catheter is placed in contact with the anterior leaflet, and RFA is delivered, causing scarring and fibrosis and reduced leaflet motion. Proof-of-concept was demonstrated in an animal study (24).

#### Limitations.
Scarring and fibrosis from the RFA might not be precise, resulting in too-long or too-short post-ablation leaflet with residual or even worsening MR. Leaflet perforation and damage to adjacent cardiac structures might occur.
**Leaflet Space Occupier**

**Principle.** A device acting like a “buoy” is positioned across the MV orifice to provide a surface against which the leaflets can coapt, reducing MR. This could be applied to degenerative or functional MR.

**Device.** The Percu-Pro device (Cardiosolutions, Stoughton, Massachusetts) consists of a polyurethane-silicone polymer space-occupying buoy that is anchored at the apex through the MV (Fig. 2) acting as a “spacer” in the mitral orifice. A transseptal approach is required to implant the anchor in the apex. It is undergoing phase 1 trial.

**Limitations.** Possible limitations are thrombus formation on the device, residual MR, or iatrogenic MS (restricted inflow by the “spacer”).

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CS = coronary sinus; FIM = first-in-man; LV = left ventricle/ventricular; MA = mitral annulus; MR = mitral regurgitation; MS = mitral stenosis; MVR = mitral valve replacement; MVRe = mitral valve repair; NIH = National Institutes of Health.
Annuloplasty—Indirect

This approach mimics surgical annuloplasty rings, which are commonly used for repair of both degenerative and functional MR. Because surgical annuloplasty necessitates cardiac bypass, it is usually performed with another indication such as coronary artery bypass graft (25). The percutaneous devices might thus offer an alternative for those at excessive surgical-risk or who do not require another concomitant cardiac surgical procedure. Several percutaneous devices are in clinical testing, mainly for functional MR.

CS Approach (CS Reshaping)

Principle. This approach involves implantation of devices within the CS with the aim of “pushing” the posterior annulus anteriorly, thereby reducing the septal-lateral (anterior-posterior) dimension of the MA. This has been demonstrated in surgical data to improve leaflet coaptation and decrease MR (26).

Devices. The Monarc (previously Viking) system (Fig. 3)(Edwards Lifesciences) consists of an outer guide catheter, a smaller delivery catheter, and a nitinol implant. The implant has 3 sections: distal and proximal self-expanding anchors, and a spring-like “bridge” that has shortening forces. This draws the proximal CS and distal great cardiac vein closer, indirectly displacing the posterior annulus anteriorly. The Viking device produced an initial favorable effect on MR, although device fracture and recurrence of MR occurred, and the feasibility study was stopped (27). The re-engineered device (Monarc) has a reinforced bridge segment. The phase 1 trial (Evolution) of functional MR with the Monarc device demonstrated implantation success in 82% (59 of 72 patients), with 13 failures (18%) due to tortuous anatomy or inappropriate CS dimensions. Three myocardial infarctions occurred due to coronary artery compression (1 received coronary stenting, 1 treated medically, 1 fatality). Event-free survival was 81%, 72%, and 64% at 1 year and 2 and 3 years, respectively (Jan Hannek, European Society of Cardiology Congress 2010, Stockholm, Sweden). A larger Evolution II study is ongoing.

The Carillon Mitral Contour System (Cardiac Dimension, Inc., Kirkland, Washington) (Fig. 4) consists of self-expandable nitinol distal and proximal anchors connected by a nitinol bridge that are placed in the great cardiac vein and proximal CS via a catheter-based system. Tension applied on the system results in cinching of the posterior periannular tissue and deflection of the leaflets.
posterior MA anteriorly. A feasibility study showed modestly reduced septal-lateral dimension and MR when placed temporarily (28). Slippage of the anchors occurred, requiring device modification. Data from the AMADEUS trial (CARILLON Mitral Annuloplasty Device European Union Study) using the modified CARILLON XE device (Cardiac Dimension, Inc.) in functional MR due to dilated cardiomyopathy demonstrated implantation success in 62% (30 of 48 patients), with mean 1 grade reduction of MR (although it is uncertain whether this would be clinically meaningful). Implantation could not be achieved in 18 patients (38%) due to access issues (CS dissection/perforation), insufficient MR reduction, and coronary artery compression. Coronary arteries were crossed frequently (36 of 43 implant attempts), although device was recaptured in only 17% where compromise was significant (29).

The Viacor percutaneous transvenous mitral annuloplasty device (Viacor, Inc., Wilmington, Massachusetts) (Fig. 5) uses nitinol rods of varying length and stiffness, delivered via a catheter to the CS. This exerts outward force resulting in anterior displacement of the posterior annulus. Temporary human implantation was feasible. Subsequent permanent implantation was achieved although successful only in a small proportion (9 of 27 patients) (30). Problems encountered were access issues, unsuccessful MR reduction, unstable device, and technical delivery difficulties. During the study, the device remained in only 4 patients (17%) (1 device fracture, 3 underwent surgical annuloplasty, 1 died 3 months after implant) (30).

Limitations. There are major limitations to the use of CS reshaping. The technique exploits the proximity of the CS to the MA. However, surgical anatomy suggests that the CS is located behind the LA wall at a significant distance from the MA (31,32). The projection of CS annuloplasty covered just over one-half of the total MA perimeter (32). Similarly with computed tomography angiography, there was significant variability in the relation of the CS to MA, and this distance was increased in severe MR with annular dilation (33,34). These CS devices likely shrink the MA only indirectly by traction on the LA wall. The annulus might in fact continue to dilate, reducing device effectiveness.

Furthermore, there is a risk that these devices might compress a coronary artery. It has been demonstrated that a diagonal or ramus branch crossed between the CS and MA in 16% of patients, whereas it was between 64% and 80% for the left circumflex artery (31–34). Therefore, anatomic assessment of the CS, coronary artery, and MA relationship is mandatory before considering these devices.

Other limitations include significant MA calcification, presence of CS pacing leads, coronary venous branch point variability, coronary venous system size constraints (risk of CS perforation), and structural leaflet abnormalities. This approach might theoretically jeopardize future attempts at implanting cardiac resynchron-
Asymmetrical Approach

**Principle.** This group of devices uses the proximity of the CS to the annulus to try to reshape the MA but in addition exert traction force on another portion of the LA or right atrium, resulting in asymmetrical forces. The aim is to reduce septal-lateral dimension and decrease MR.

**Devices.** The percutaneous septal sinus shortening (PS3) system (Ample Medical, Foster City, California) employed a CS anchor positioned behind posterior leaflet, a bridge (cinching wire) connecting the CS anchor to an atrial septal anchor (Amplatzer PFO occluder [AGA Medical, Plymouth, Minnesota]). Tension on the bridge reduced septal-lateral dimension and reduced MR (36).

Further device development, however, has been abandoned.

Another device by St. Jude Medical (Minneapolis, Minnesota) (Fig. 6) implanted in animal models consists of 4 helical anchors, 2 loading spacers, a tether rope, and a locking mechanism. The distal pair of anchors is delivered via the CS into the LV myocardium near the posterior leaflet scallop. The proximal pair is implanted via the right atrium into the postero-medial trigone. The 2 pairs of anchors are connected by a cable to effect cinching of the postero-medial MA. Dynamic shortening can be performed manually and reversibly, and the locking mechanism is a self-retracting, nitinol structure that maintains cinched load (37).

The National Institutes of Health cerclage technology directs a guidewire via the CS into the first septal perforator of the great cardiac vein and, under imaging, across the myocardium to re-enter a right heart chamber. It is ensnared and exchanged for a suture and tension-fixation device. Initial animal models have proved promising with success in reducing MR (38).

**Limitations.** The major drawbacks of this technology are: 1) the CS might not be in the same plane as the MA (true annuloplasty might not take place); and 2) unequal tension exerted on the CS or LA, with unknown long-term consequences. There is a theoretical risk of device erosion or fracture and possible thrombus formation on the connecting cable.

Annuloplasty—Direct: Percutaneous Mechanical Cinching Approach

**Principle.** This technology reshapes the MA directly without using the CS, approaching the MA from the LV or the LA side. Sutures or some other device are implanted onto the MA itself and used to directly “cinch” the MA. These technologies might be able to address the potential limitations of the indirect annuloplasty method and would be most useful for functional MR (although it could be employed in degenerative MR).

**Devices.** The Mitralign device (Mitralign, Tewksbury, Massachusetts) (Fig. 7) gains access to the annulus from the transventricular approach. Anchors are placed directly on the posterior MA and connected with a suture, creating a “purse-string” to
Cinch the MA. Retrograde LV access to the periannular space has been achieved reliably with successful first-in-man (FIM) results (unpublished data).

The Accucinch Annuloplasty System (Guided Delivery Systems, Santa Clara, California) uses a transventricular approach and has FIM results (unpublished data). The posterior annulus is cinched circumferentially from trigone to trigone (Fig. 8), with improvement in MR.

The Millipede system (Millipede, LLC, Ann Arbor, Michigan) involves placement of a novel repositionable and retrievable annular ring with a unique attachment system via percutaneous (transseptal) or minimally invasive methods.

Annuloplasty—Direct: Percutaneous Energy-Mediated Cinching Approach

Principle. Heat energy is applied to the MA, causing scarring and shrinkage of the MA.

Devices. By the transatrial (transseptal) route, the QuantumCor (QuantumCor, Lake Forest, California) uses a transventricular approach and has FIM results (unpublished data). The posterior annulus is cinched circumferentially from trigone to trigone (Fig. 8), with improvement in MR.

The Millipede system (Millipede, LLC, Ann Arbor, Michigan) involves placement of a novel repositionable and retrievable annular ring with a unique attachment system via percutaneous (transseptal) or minimally invasive methods.

Annuloplasty—Direct: Hybrid Approach

Principle. An annuloplasty ring is implanted surgically and can be subsequently adjusted via transseptal access if MR recurs or worsens.

Devices. The Adjustable Annuloplasty Ring (MitraSolutions, Fort Lauderdale, Florida) (Fig. 10) is implanted surgically and can be adjusted with a mechanical rotating cable, whereas the Dynamic Annuloplasty Ring System (MiCardia, Inc., Irving, California), which recently had FIM results, is adjusted with radiofrequency energy.

Limitations. Although this approach seems an effective way of customizing device size-shape to each patient under real-life loading conditions, initial surgical implantation is required. Therefore, these technologies are more of a hybrid technique. It is conceivable that they might evolve into true percutaneous technologies. Both are in pre-clinical development.

Chordal Implantation

Principle. Synthetic chords or sutures are implanted either from a transapical or transseptal approach and anchored onto the LV myocardium at one end, with the leaflet at the other. The length of the chord is then adjusted to achieve optimal leaflet coaptation and reduce MR. This approach would be mainly for degenerative MR.

Devices. There are 3 devices currently in development: the transapically delivered MitraFlex (TransCardiac Therapeutics) and NeoChord (NeoChord, Inc., Minnetonka, Minnesota) devices, and the transapical-transseptal route of the Babic device (Fig. 11). The MitraFlex and NeoChord devices place an anchor in the inner LV myocardium and another on the leaflet via a transapical approach and connect the 2 with a synthetic “chord.” In the Babic device, 2 continuous suture tracks are created from the LV puncture.
Figure 7. Mitralign Device

Figures showing the Mitralign device (Mitralign, Tewksbury, Massachusetts) gaining access via the left ventricle (top left), placement of anchors on the posterior mitral annulus (top right, bottom left), and after cinching (bottom right).

Figure 8. Accucinch Annuloplasty System

Figure (left) showing action of the Accucinch device (Guided Delivery Systems, Santa Clara, California) and animal model (right) of the deployed Accucinch system (arrows denote suture along the posterior annulus).
site through the puncture of the target leaflet and are exteriorized via the transseptal route. A pledget is apposed onto the exteriorized venous sutures and anchored onto the atrial side of the leaflet by retracting the guiding sutures from the epicardial end. A polymer tube is then interposed between the leaflet and free myocardial wall and secured at the epicardial surface by an adjustable knob.

**Limitations.** Possible problems that might be encountered with this technology are residual leaflet prolapse (artificial chords too long) or leaflet restriction (chords too short) and residual MR (7) and device thrombus formation.

**LV Remodeling**

**Principle.** A device is used to reduce the anterior–posterior dimension of the LV. This indirectly decreases the septal-lateral annular distance and also brings the LV papillary...
muscles closer to the leaflets. This approach seems suitable mainly for functional MR due to ischemic or cardiomyopathic etiologies.

The percutaneous iCoapsys technology was based on the Coapsys surgical system (Myocor, Maple Grove, Minnesota), which places pads on either side of the LV with a cord passing through the LV cavity to apply tension to the MA and basal LV wall, moving the posterior leaflet to better coapt with the anterior leaflet. Surgical data demonstrated implantation safety, reduction in MR, and positive LV remodeling (40). Although transpericardial percutaneous device implantation via a sub-xiphoid approach was feasible in animal models (41), device development has been discontinued.

The Mardil-BACE (Mardil, Inc., Morrisville, North Carolina) (Fig. 12) device requires a mini-thoracotomy but is implanted on a beating heart. A silicone band is placed around the atrioventricular groove with built-in inflatable chambers placed on the MA. This reshapes the MA for better leaflet coaptation and can be remotely adjusted after implantation. No coronary artery compromise was shown in animal models, and proof-of-concept was demonstrated in 15 patients, although no further details were made available (unpublished data).
Limitations. There are sparse clinical data, and longer-term outcomes and adverse events are unknown.

**Target Patient Populations**

Despite the enthusiasm generated by these emerging devices, it is important to consider what patient populations are suitable for these technologies. The 2 etiologies of MR most amenable to surgical repair are degenerative and functional. Annuloplasty is the main technique used in functional MR, whereas leaflet repair is also usually performed in degenerative MR.

In the EuroHeart survey, degenerative and functional etiologies accounted for 61% and 7%, respectively (2). From a global perspective, however, rheumatic disease (which has a low probability of repair) will take on greater prominence (up to 50%) (42).

Despite numerous surgical techniques and performance under direct vision, repair was performed in just under one-half of patients with MR who required surgery in the U.S. and Europe (2,43), with unfavorable anatomy, absence of surgical expertise, and failure of conservative surgery being the major reasons (2). In addition, certain pathologies (rheumatic, endocarditic, inflammatory, and so forth) are often not repairable. Therefore, current percutaneous options might be useful only in a selected patient pool. The need for a cautious approach to percutaneous MVR is further emphasized by the excellent results of surgical repair and the low perioperative mortality (44).

**Percutaneous MVR**

A combination of percutaneous techniques will most likely be needed if results comparable to surgery are expected. Despite the armamentarium available to surgeons and the increasing preference for repair, in a significant proportion...
of patients, surgical MVR is not possible or fails, and MVR is required (45).

In the future, the novel technology of percutaneous MVR might become a possible alternative in a selected group of patients with a low probability of successful repair. However, the challenges are formidable. The MA has an asymmetrical saddle shape, and different anchoring designs might be required for different MR etiologies. Left ventricular outflow obstruction might occur due to retained native valve tissue. Paravalvular leaks might also pose a problem.

There are 3 devices in development. The Endovalve-Herrmann prosthesis (Endovalve Inc., Princeton, New Jersey) (Fig. 13) is implanted from the LA side via a right mini-thoracotomy on a beating heart. The device is a foldable nitinol structure that attaches to the native valve with specially designed grippers, is fully valve sparing, and repositionable before release. Animal models have been successful, and a true percutaneous version is planned. The Lutter prosthesis, a nitinol stent-valve, has been implanted transapically in porcine models (46). The CardiAQ (CardiAQ Valve Technologies, Inc., Winchester, Massachusetts) prosthesis (Fig. 14) is in pre-clinical development and is delivered transseptally. Given the complexities involved with this approach, further improvements to these technologies will be required before clinical testing.

Conclusions

The field of percutaneous transcatheter MVR is evolving exponentially. These emerging technologies can be classified by their site of action and device mechanism. The proposed classification is based on therapies aimed at the leaflets (leaflet plication, leaflet coaptation, leaflet ablation), annuloplasty (indirect: CS approach or asymmetrical approach; and direct: true percutaneous or hybrid), percutaneous chords, and LV remodeling. Percutaneous edge-to-edge leaflet repair has been shown to be noninferior to surgery in a randomized trial. Several other technologies—including various direct and indirect annuloplasty and LV remodeling devices—have achieved first-in-man results or are in preclinical testing. Most likely a combination of these technologies will be required for satisfactory MVR. However, for many patients repair will not be possible, and MVR will be required. Although there are significant challenges, several percutaneous MVR prototypes are already in development.

Reprint requests and correspondence: Dr. Carlos E. Ruiz, Lenox Hill Heart and Vascular Institute, 130 East 77th Street, New York, New York 10021. E-mail: cruiz@lenoxhill.net.

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