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Review Article

# Percutaneous mitral valve repair: A new treatment for mitral regurgitation

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ABSTRACT

Mitral valve disease affects more than 4 million people in the United States. The gold standard of treatment in these patients is surgical repair or replacement of the valve with a prosthesis. The MitraClip (Abbott Vascular, Menlo Park, CA) is a new technology, which offers an alternative to open surgical repair or replacement via a minimally invasive route. We present an evidence-based clinical update that provides an overview of this technology as it relates to managing patients with significant mitral regurgitation. This review article is particularly useful to noninterventional cardiologists and interventional cardiologists who will be managing patients with this novel technology in increased volumes over the next decade but who do not perform this procedure.



## 1. Introduction

Mitral valve disease is the second most common acquired valvular heart disease in adults. Severe mitral regurgitation (MR) is the most common manifestation of mitral valve disease in the developed world. MR affects more than 4 million Americans, or almost 10% of patients over the age of 75.[1] This epidemic is increasing in frequency as the population ages.[2]

MR is classified as either primary (degenerative) or secondary (functional). Primary MR from degenerative valve disease is due to a primary disruption of the mitral valve apparatus from either prolapsed or flail leaflets. Secondary MR on the other hand is due to remodeling of the left ventricle resulting in malcoaptation of the mitral leaflets.

Severe MR when untreated can lead to progressive dyspnea, left atrial dilation, permanent atrial fibrillation, left ventricular (LV) enlargement, and dysfunction leading to systolic and diastolic congestive heart failure.[3] Severe MR has an annual mortality rate of up to 5% if untreated.[4] Medical management alone may reduce symptoms but does not alter the natural history of the disease.[3] The gold standard of treatment is surgical repair or replacement.[2] There are a substantial number of patients who are ineligible for mitral valve surgery because of prohibitive surgical risk, and for those patients, MitraClip (Abbott Vascular, Menlo Park, CA) is a new technology, which may offer an alternative treatment option.

## 2. Traditional treatment options

Mitral valve surgery is used to treat both primary and secondary MR. Surgery with mitral valve repair or replacement has been the standard of care in treating patients with primary

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MR. Patients with secondary MR are often treated medically, but surgical consideration is given if the patient requires another open heart procedure, such as coronary artery bypass grafting, or in some patients with progressive New York Heart Association (NYHA) class III and IV heart failure on optimal medical therapy. The decision to repair or replace is dependent on valve pathology and local surgical expertise. However, repair is favored over mitral valve replacement in order to preserve the native valve and sub-valvular apparatus.

Flail or billowing leaflets from prolapse are the most common pathologies amenable to resection or repair. With adequate operator experience, these techniques can result in reduced mortality, reduced risk of endocarditis, and can preclude the need for lifelong anticoagulation.[5–9] Examples of such techniques include quadrangular and triangular resection, replacement of ruptured chordae with neo-chordae, placement of an edge-to-edge stitch to anchor the prolapsing leaflet cusp to the opposing stable cusp, and implantation of an annuloplasty ring. These techniques for primary mitral valve pathology have been successful. In those in whom repair is not feasible, mitral valve replacement can be performed with either a mechanical or bioprosthetic valve. A mechanical valve lasts longer than a tissue valve but has the disadvantage of lifelong anticoagulation.

Unlike primary MR, secondary MR remains a surgical challenge. The first approach to this problem has focused on annuloplasty – either done surgically or percutaneously. Significant efforts have focused on improving results for surgical mitral annuloplasty because undersized annuloplasty rings and lack of durability of surgical annular repair have remained the Achilles heel of this procedure. Newer adjustable annuloplasty rings, whose shape and size can be adjusted postimplantation, have been developed by MitraSolutions® (MN, USA), DynaTek (MO, USA), and ValTech (Yehuda, Israel). This technological advance in mitral valve repair has spurred innovation toward the development of percutaneous annuloplasty therapies.

Numerous percutaneous annuloplasty techniques are being tested in clinical trials. The Carillon Mitral Contour System (Cardiac Dimensions, Inc., WA, USA) is currently under investigation in Europe. Alternative direct annuloplasty approaches have since emerged. A direct suture annuloplasty system has been developed by MitrAlign® (MA, USA). This device uses a suture-pledget system to cinch the mitral annulus and reduce the mitral orifice area. Early results for this technique have been encouraging.[10] Furthermore, Accucinch® (CA, USA) has developed a similar technology but uses multiple anchors along the entire posterior annulus, which is also under early development.[11] Finally, the CardioBand® system (Valtech Cardio, Yehuda, Isreal) uses a transseptal approach to deliver a flexible ring to the annulus via an automated suture technique. Animal models have demonstrated short-term success, and human studies are underway.[12]

A second approach to this problem of secondary MR focuses on the leaflets themselves. The MitraClip (Abbott Vascular, Menlo Park, CA) is a percutaneous technology that allows for minimally invasive repair of the mitral valve (Fig. 1). This technology is the focus of this review.

In addition to surgical and percutaneous intervention, a third viable option for secondary MR patients is optimal medical management of heart failure. The MitraClip repair system is being compared to optimal medical management, in addition to biventricular pacing in a randomized control trial that is currently enrolling patients, known as the Clinical Outcomes Assessment of the MitraClip Percutaneous Therapy for Extremely High-Surgical-Risk Patients (COAPT) trial for functional MR patients with NYHA class III and IV heart failure. The results of this trial will alter the treatment paradigm for this very sick cohort of patients.[13]

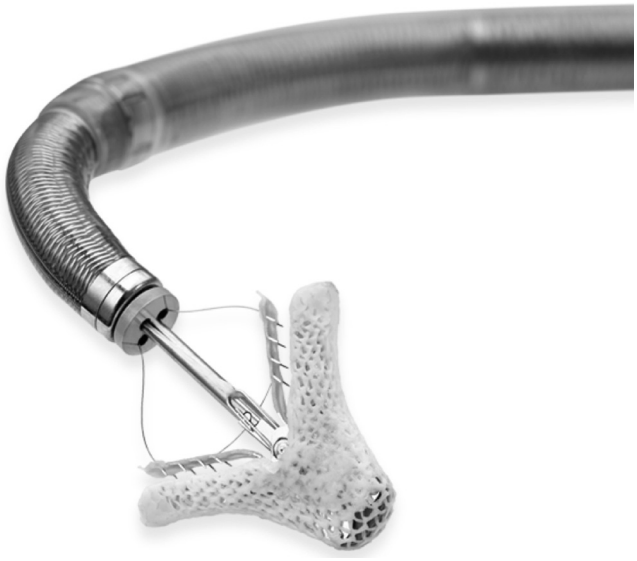

**Fig. 1 – Industrial illustration of the MitraClip (Abbott Vascular, Menlo Park, CA) device.**

## 3. Overview of technology

The MitraClip (Abbott Vascular, Menlo Park, CA) applies the concept of the Alfieri procedure, which is an ''edge-to-edge'' surgical technique that creates a double orifice mitral valve by fixing the cusps of the anterior and posterior mitral leaflets together using a double stitch at the point of maximal regurgitation.[14] The MitraClip is the first and only device currently available for percutaneous treatment of MR. The Food and Drug Administration (FDA) approved its use commercially in 2013 for cases of degenerative MR in patients with prohibitive surgical risk for open surgical repair or replacement.[15] The MitraClip is being investigated for functional MR as part of an Investigational Device Exemption (IDE) Trial, COAPT, which is actively recruiting patients at the time this review paper is being written.

The MitraClip procedure is performed by the heart-team comprising of an interventional cardiologist experienced in managing patients with mitral valve disease, a cardiac surgeon experienced in mitral valve surgery, a cardiac anesthesiologist, an echocardiographer, catheterization laboratory technicians, nurses, and industry proctors who are trained in the coordinated delivery and care of this complex therapy. A cardiac surgeon may be the implanting physician or may be present in the event a complication occurs. The procedure is performed in the cardiac catheterization laboratory or Hybrid