

Percutaneous MitraClip Repair for Degenerative and Functional Mitral Regurgitation

► Interventional cardiologists at Penn Medicine are using the MitraClip® System (Abbott Vascular, Santa Clara, CA) to restore mitral valve competency in patients with severe degenerative mitral regurgitation (DMR) and, more recently, patients with secondary or functional mitral regurgitation (FMR).

First used at Penn Medicine in 2003 by Howard Herrmann, MD, and colleagues, the MitraClip System received FDA approval in 2013 for DMR, in part as a result of studies performed at Penn in patients who had been judged to be too high-risk for surgery.

A novel percutaneous device, the MitraClip is introduced percutaneously via the femoral vein and fastened edge-to-edge to the middle scallops of the posterior and anterior leaflets of the mitral valve to create a double orifice-improving coaptation (or joining) that replicates the Alfieri surgical repair. ACC/AHA guidelines now recommend consideration of transcatheter repair for severely symptomatic patients with chronic severe primary DMR, reasonable life expectancy and high or prohibitive surgical risk attributable to severe comorbidities.

MitraClip 2019 Update

In March 2019, the FDA also approved MitraClip for the treatment of secondary mitral regurgitation (MR) in patients with heart failure. Secondary MR, also called functional MR, is more common than DMR, has a very poor prognosis, and is the leading indication for MitraClip outside of the United States. The FDA approval was based largely on findings from a study which included Penn patients, the Cardiovascular Outcomes Assessment of MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation [COAPT] trial.

COAPT, a multi-center, controlled trial, involved more than 600 patients with heart failure and moderate-to-severe or severe secondary MR with symptomatic disease despite the use of maximal doses of guideline-directed medical therapy. Patients were randomly assigned to transcatheter mitral-valve repair plus medical therapy (device group) or medical therapy alone (control group). The primary effectiveness endpoint was all hospitalizations for heart failure within 24 months of follow-up. The primary safety endpoint was freedom from device-related complications at 12 months.

The annualized rate of all hospitalizations for heart failure within 24 months was 35.8% per patient-year in the device group as compared with 67.9% per patient-year in the control group. The rate of freedom from device-related complications at 12 months in the device group was 96.6%. Death from any cause within 24 months occurred in 29.1% of the patients in the device group vs. 46.1% in the control group. All of these findings were clinically significant. The COAPT findings were reported in the [New England Journal of Medicine in December 2018](#).



► **Figure 1:** The MitraClip (shown) is fastened to the edges of the middle scallop of the posterior and anterior leaflets of the mitral valve to create a double orifice.

CASE STUDY

Mr. M, an 82-year-old man with a 10-year history of grade III/IV mitral regurgitation and atrial fibrillation, was referred to Penn Interventional Cardiology for assessment when surgeons at an outside hospital deemed his potential comorbidities an untenable risk for open surgery. Mr. M's medications included Coumadin (2-4 mg day), lisinopril 30 mg and hydrochlorothiazide, 25 mg. On examination, his BMI was 32; his BP was 143/93. His symptoms included dyspnea at rest and fatigue.

A transesophageal echocardiography (TEE) was performed. Mr. M's LV ejection fraction was estimated to be 42-45%; his LV end-diastolic volume was 193 mL; thickening and prolapse of the posterior mitral leaflet was evident, with flail at the middle scallop and enlargement of the left atrium. Given his age and other risk factors, the cardiac surgery team and anesthesiologists of Penn Heart & Vascular confirmed that Mr. M was too high risk for open surgery. After a consultation with his personal physician, he chose to proceed with a MitraClip percutaneous repair.

At surgery, Mr. M was placed under general anesthesia. A steerable guide catheter was inserted into his femoral vein and guided under fluoroscopy into the right side of the heart, where the interatrial septum was punctured and heparin administered. The Clip Delivery System was then introduced and advanced into the left atrium. Under fluoroscopic and echocardiographic guidance, the clip was then centered over the mitral leaflets, advanced into the left ventricle and retracted until both leaflets were grasped and coapted. Leaflet insertion and MR reduction were then evaluated by echocardiography.

Mr. M remained in the hospital overnight for observation and went home the next day. At his six-month evaluation, he reported a substantial improvement in energy and activity level. A TEE at this time confirmed the success of the procedure and a significant reduction in MR volume.

FACULTY TEAM

Penn Interventional Cardiology is comprised of a team of nationally recognized interventional cardiologists working in close collaboration with cardiac surgeons and cardiologists to perform catheter-based procedures for a variety of cardiovascular disorders.

Performing MitraClip Surgery at Penn Medicine

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Clinical Research in Transcatheter (Percutaneous) Therapy for Mitral Regurgitation at Penn Medicine

Clinician researchers at Penn Interventional Cardiology are currently conducting trials of a number of novel investigational therapies for patients with MR. These include:

- The Pascal Edge-to-Edge Repair Device ([CLASP IID/IIF trials](#)). This device mimics the edge-to-edge repair of MitraClip but may have some potential benefits, including independent grasping arms and a central spacer. Penn Interventional Cardiology recently treated its first patient with this device.
- [Transcatheter Mitral Valve Replacement \(TMVR\) with the EVOQUE prosthesis in a non-randomized registry](#). The hypothesis of this US early feasibility trial is that more complete elimination of MR using a full valve prosthesis instead of a repair technique will improve outcomes.
- [The CARILLON Trial - Assessment of the Carillon Mitral Contour System in Treating Functional Mitral Regurgitation Associated With Heart Failure](#). The objective of this multi-center, randomized, double-blind trial is to assess the safety and efficacy of the CARILLON Mitral Contour System in treating subjects with functional regurgitation (FMR) associated with heart failure, compared to a randomized Control group medically managed according to heart failure guidelines.

For more information about these studies, please contact Howard Herrmann, MD, at 215.662.2180.

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