Background: A Surgical Foundation for the MitraClip™ Device

The adaptation of a surgical technique to safely provide benefits to more patients.

Dr. Ottavio Alfieri performed the first surgical edge-to-edge mitral valve (MV) repair procedure in Milan in 1991.[1,2] This surgical technique has since been used in thousands of patients to correct mitral regurgitation (MR).[3] Dr. Alfieri's edge-to-edge repair technique is broadly usable to treat a wide range of valve disease states, including both primary (also termed organic or degenerative) and secondary (also called functional) MR etiologies.[4] The attractiveness of Dr. Alfieri's edge-to-edge valve repair technique is its simplicity, as it involves only a single modification to the native valve anatomy. Specifically, a row of sutures is placed by the surgeon to attach the free edge of a diseased leaflet to the corresponding edge of the opposing leaflet of the MV.[5] The sutures are installed directly in the lesion location on the valve leaflets—where the regurgitant jet is observed—to reestablish effective leaflet coaptation. In Figure 1, a MV is converted from a regurgitant state to a repaired double orifice valve with fully eliminated or a significantly reduced residual MR. The hemodynamic consequences of the double orifice configuration have been studied extensively and found to introduce minimal risk of stenosis. The hemodynamics of a repaired double orifice valve and a native single orifice valve have been found to be similar when the total orifice area(s) are equivalent.[6] In either valve configuration, a global mitral valve area greater than 2.5 cm^2 is associated with minimal gradients with a threshold of 1.5 cm^2 being used as a guideline to avoid symptoms.[7] When compared to other repair techniques, the Alfieri edge-to-edge repair is simpler, more reproducible, and achieves more predictable results and has been found to be more durable than other repair techniques by a large meta-analysis.[8]

Surgical edge-to-edge valve repair (Figure 1D) is simple and versatile and has been applied successfully to treat diverse pathologies, being agnostic to the underlying mechanism of regurgitation. Although surgery is appropriate for low-risk patients, many older patients with comorbidities cannot tolerate surgery and require less invasive options.[9,10] To treat these patients, the MitraClip™ device (Abbott) was designed to adapt the elegant versatility of surgical edge-to-edge repair into a minimally invasive procedure. Transcatheter edge-to-edge repair (TEER) with the MitraClip device provides effective MR reduction and has multiple advantages including:

Being safer than surgery. The minimally invasive transcatheter MitraClip procedure involves only a small incision in the groin to obtain transfemoral venous catheter access to the MV and avoids the need for cardiopulmonary bypass, thus making the procedure

"I was inspired by a rare congenital defect I observed, a double orifice mitral valve that still functioned sufficiently. This gave me confidence that an edge-to-edge repair could be a solution for diseased valves. What I found was that the technique was surprisingly simple and extremely effective."

– Ottavio Alfieri, MD

"The techniques we developed for the Alfieri stitch all apply to the MitraClip device today—the importance of the leaflet length, the symmetry of the valve, the use of deep leaflet suturing in DMR and short leaflet suturing in FMR—so while we say 20 years today, it's really more like 30 years that we have been building upon these principles for repairing the mitral valve."

– Francesco Maisano, MD

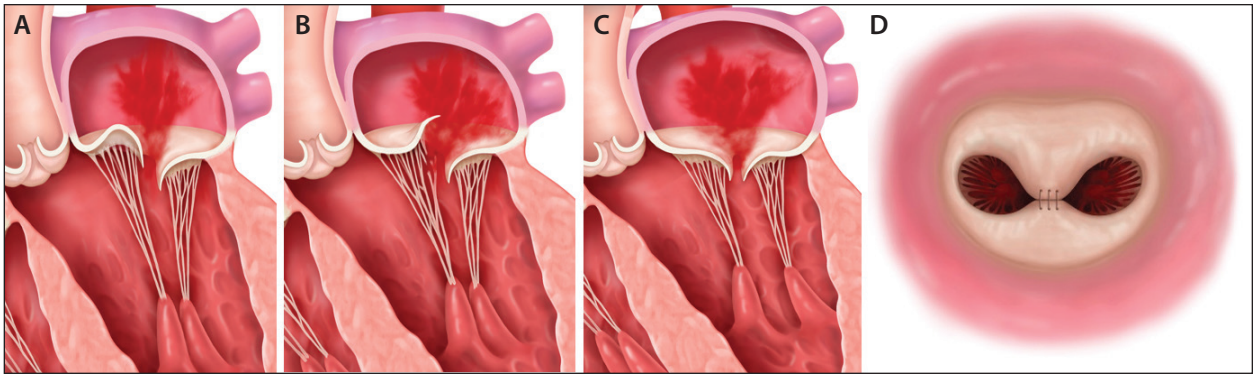

Figure 1. MR etiologies and surgical repair. Primary MR due to prolapse (A), primary MR due to flail (B), secondary MR (C), and MV with a surgically repaired double orifice (D).

much safer for select patients who are unable to tolerate invasive cardiac surgery procedures.[9,10] Additionally, transcatheter procedures allow patients to have a shorter length of hospital stay with better discharge characteristics as compared to surgery.[11]

Enabling immediate feedback on hemodynamic performance. Clearly visualizable under echocardiography and designed with the ability to grasp and re-grasp as needed, the MitraClip therapy allows for real-time assessment of the device, the MV, and the impact of the therapy on hemodynamics of the heart.

Providing real-time optimization. In addition to the immediate effect observed on MV function, the repositionable and retrievable catheter-based design of the MitraClip device ensures a safe and controlled repair. Using imaging feedback, the implanter can safely release, reposition, and re-grasp leaflets to achieve an optimal result. If needed, the implanter may also remove the Clip entirely to abort the procedure.

Stabilizing the valve leaflets and annulus. Optimal edge-to-edge MV surgical repair includes both improving leaflet coaptation and supporting the valve annulus.[12] The MitraClip device is designed to accomplish both of these important functions with controllable and lockable rigid metal arms that (1) stabilize the leaflet-to-leaflet coaptation zone to ensure sustained MR reduction and (2) interrupt or reverse annular dilatation, which is a characteristic of MV disease progression.[2] This second function of the MitraClip device provides a distinct benefit over suture-based surgical repairs and conveys how MitraClip device implantation provides a sustained reduction in MR years after implantation while ensuring a stable device-tissue interface with an optimal healing response.[13]

With these advantages, the MitraClip device was adopted as the first transcatheter valve repair option and established the field of transcatheter valve repair. With over 2 decades of learning, collaboration with physicians, and innovative device development, MitraClip therapy has continued to build upon the above advantages realized in the original design solution. As will be described throughout this supplement, each product generation is a balance of *maintaining what worked well and striving for what could be*. Each generation is the result of careful and intentional design and thoughtful analysis of the vast clinical experience built with the MitraClip therapy. ■

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