

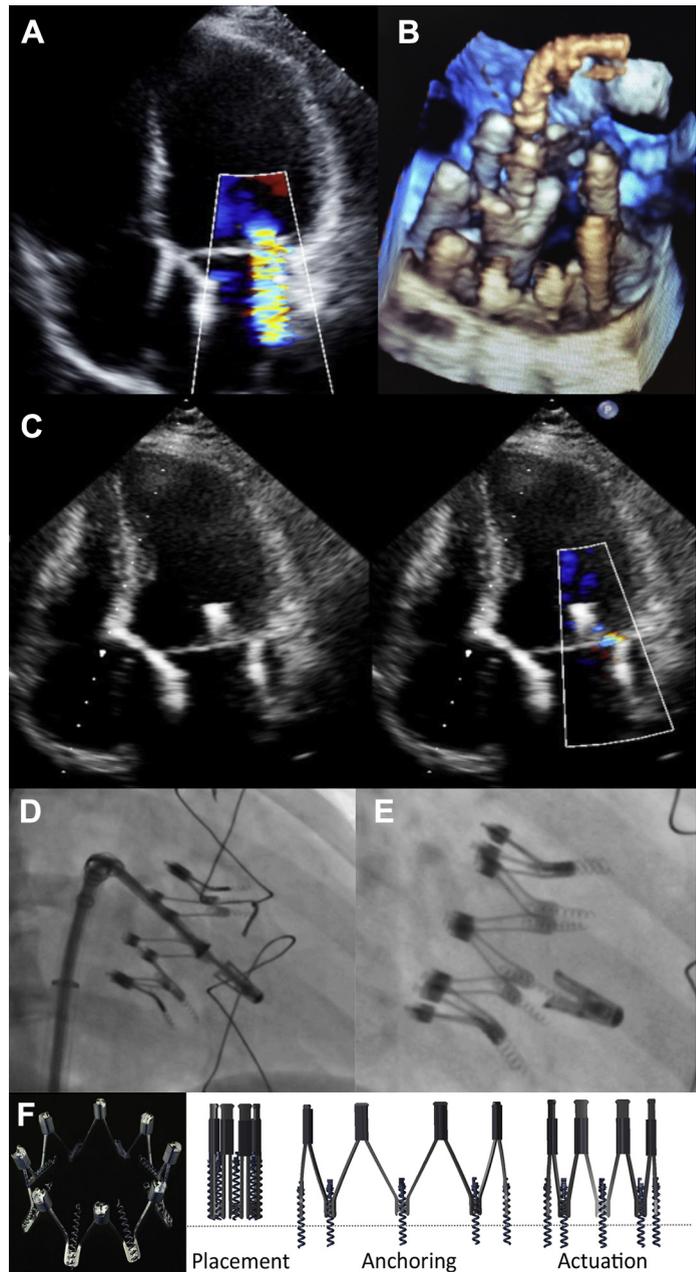
RESEARCH CORRESPONDENCE
**Combined MitraClip
 Edge-to-Edge Repair
 With Millipede IRIS
 Mitral Annuloplasty**



Because multiple mechanistic etiologies of mitral regurgitation (MR) frequently coexist, there has been interest in combining or sequentially staging transcatheter approaches to eliminate MR. Combined therapies can be performed together at the time of initial treatment, or they can be staged for the treatment of persistent or recurrent MR. For example, Latib et al. (1) reported initially using 2 MitraClips (Abbott Vascular, Santa Clara, California) in a patient with functional MR, followed by staged CardioBand (Edwards Lifesciences, Irvine, California) transcatheter mitral annuloplasty 1 year later for persistent MR. The Millipede IRIS (Millipede, Santa Rosa, California) is a transcatheter complete, semirigid annuloplasty ring that has a “zig-zag” design, with 8 helical stainless steel anchors that anchor directly into the mitral annulus. There are 8 tensioning sliders that can be used to actuate the device and reduce the annulus to the desired final septal-lateral diameter (Figure 1). We recently reported our initial clinical experience with the Millipede IRIS system for mitral annuloplasty (2). In this report, 4 patients had the IRIS ring placed surgically, and 3 patients that had the IRIS ring delivered by a transcatheter, transfemoral transeptal route. The device had robust efficacy in reducing the overall septal-lateral diameter of the mitral annulus from a baseline of 38.0 ± 4.1 mm to 25.9 ± 4.9 mm at 30 days (31.8% septal-lateral reduction, $n = 7$).

From this initial clinical experience, we now report the staged use of MitraClip edge-to-edge repair 15 months after index combined surgical Alfieri repair and Millipede IRIS mitral annuloplasty. The patient was a 48-year-old woman with hypertension, preserved left ventricular ejection fraction, and severe MR from P2 flail and associated annular dilation. At the time of surgery, a Millipede IRIS mitral annuloplasty ring was placed in addition to an A2/P2 Alfieri leaflet repair performed in standard fashion with 2-0 Ethibond suture (Ethicon, Somerville, New Jersey). Intraoperative transesophageal echocardiography post-repair showed 1+ mitral insufficiency and a final septal-lateral diameter of 26 mm. The baseline mean diastolic transmitral gradient was 2 mm Hg, and the post-procedure gradient was 4 mm Hg.

FIGURE 1 Combined MitraClip and Millipede IRIS Mitral Valve Repair



(A) Transthoracic echocardiography of recurrent lateral severe mitral regurgitation (MR) jet 15 months after surgical mitral valve repair. (B) Three-dimensional transesophageal echocardiography showing the MitraClip (Abbott Vascular, Santa Clara, California) being aligned within the Millipede IRIS (Millipede, Santa Rosa, California) mitral annuloplasty ring. (C) Transthoracic echocardiography after MitraClip procedure showing trace residual MR (right panel with color Doppler). (D) Fluoroscopic image of the MitraClip being driven through the IRIS ring. (E) Final post-deployment appearance of the MitraClip and IRIS ring. (F) The Millipede IRIS annuloplasty ring (left). The ring is positioned over the mitral annulus and expanded. It is then anchored by rotating helical anchors into the mitral annulus, followed by actuation of the device (right), which results in controlled reduction of the mitral septal-lateral diameter.

Post-operatively the patient did well, but after 12 months she developed symptomatic New York Heart Association functional class III symptoms secondary to recurrent moderate-severe 3+ MR. A TEE was performed, which demonstrated newly ruptured chordae tendineae just lateral to the original Alfieri stitch. A single MitraClip was deployed using a transfemoral, transseptal approach with reduction of MR to trace. The final mean diastolic transmitral gradient was 6 mm Hg, with improvement in pulmonary vein flow from systolic blunted to systolic dominant. The MitraClip was steered without difficulty inside the IRIS ring using standard transesophageal and fluoroscopic guidance. Thirty days post-treatment the patient was improved to New York Heart Association functional class I and had only trace residual MR (Figures 1A to 1F).

In summary, we report the feasibility of combining a mature transcatheter leaflet repair technology (MitraClip) with the Millipede IRIS ring. In the patient presented in this report, recurrent MR was due to progressive degenerative disease after 12 months, and not due to early failure of the initial annuloplasty or surgical leaflet repair. The IRIS ring is highly visible on fluoroscopy, which aids in steering the MitraClip between the struts of the IRIS frame. Future catheter-based mitral repair strategies could include transcatheter IRIS annuloplasty in combination with a transcatheter edge-to-edge leaflet repair either as a simultaneous procedure or sequentially after initial transcatheter edge-to-edge

repair. By performing annuloplasty first, leaflet coaptation may be improved to allow easier subsequent leaflet grasping and edge-to-edge repair. It may also allow patients that are not anatomical candidates for edge-to-edge repair because of excessive leaflet coaptation distance to undergo a more effective mitral repair.

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Please note: Drs. Rogers and Boyd have served as consultants to Millipede. Dr. Smith has served as a consultant for Abbott Vascular and Millipede. Dr. Bolling has served as a consultant for and owns stock options in Millipede. Dr. Ebner has reported that he has no relationships relevant to the contents of this paper to disclose.

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