Initial clinical experience with Myxo-ETlogix* mitral valve repair ring

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Objective: Complexity of mitral valve repair for myxomatous disease has led to low adoption. We report initial experience with a new ring designed specifically for myxomatous disease, the Myxo-ETlogix (Edwards Lifesciences LLC, Irvine, Calif).

Methods: From March 15, 2006, through November 19, 2007, 129 patients underwent mitral valve surgery for pure myxomatous disease, and 124 valves (96.1%) were repaired. The Myxo-ETlogix ring was used in 100 cases and the Physio ring (Edwards) in 24. The Myxo-ETlogix design includes a 3-dimensional shape to reduce systolic anterior motion and a larger orifice to accommodate elongated leaflets and decrease need for sliding plasty. Direct mitral valve measurements were made. Sizing was based on A2 height, and choice of ring type was based on unresected leaflet heights.

Results: There was no operative mortality or lasting perioperative morbidity. The Myxo-ETlogix group had taller A2, P1, P2, and P3 leaflet segments than the Physio group ($P \leq .003$). Only 1 sliding plasty was performed for asymmetry in the Myxo-ETlogix group. Predischarge and follow-up echocardiograms (n = 338 in 124 patients) disclosed transient nonobstructive chordal systolic anterior motion in 3 echocardiograms in 3 patients. No patients had 2+ or greater mitral regurgitation. At discharge, 5.7% had 1+ mitral regurgitation; this proportion was 17.3% at last follow-up (mean 6.1 ± 4.4 months).

Conclusion: In initial experience with the Myxo-ETlogix ring, nonobstructive systolic anterior motion has been rare and obstructive systolic anterior motion not observed. Ongoing prospective echocardiographic and clinical studies will elucidate the role of this etiology-specific ring.

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Mitral valve (MV) prolapse is common, occurring in 1% to 2.5% of the population.[1] Myxomatous mitral regurgitation (MR) is characterized by elongation and thickening of the valve leaflets with annular and dilatation prolapse (Carpentier type II).[2] Numerous studies have demonstrated that mitral repair generally gives a more favorable result than does MV replacement, but because of the complexity of the pathology and therefore the procedure required, it is performed in fewer than 50% of cases according to data from the United States and Europe.[3-6] Furthermore, the considerable interpatient variability has required the surgeon to approach valve repair as an art, and valve repair has been concentrated such that a minority of surgeons perform the majority of repairs. Consequently, it has been difficult for a low- or medium-volume mitral repair surgeon to develop the numerous skills necessary for successful repair, considering the wide variety of surgical techniques that may be required for complex repairs.

An additional repair problem specific to myxomatous disease is the development of systolic anterior motion (SAM), which has been reported in 2% to 16% of patients after mitral repair.[7-10] Transient SAM may be seen during first weaning from cardiopulmonary bypass and may be easily treated by volume infusion from the pump to increase the systemic blood pressure (afterload) if the patient is hypotensive and vasodilated and by stopping positive inotropes. More troublesome is persistent SAM, which may require additional medical or surgical therapy. SAM is precipitated by

Abbreviations and Acronyms
MR = mitral regurgitation
MV = mitral valve
SAM = systolic anterior motion

ACD

elongated leaflets and may cause left ventricular outflow tract obstruction and residual or recurrent MR. SAM may be caused by a short distance between the point of leaflet coaptation to the nearest point on the ventricular septum, which may be seen when the posterior leaflet is too tall or the annuloplasty ring placed is too small.[7,8] An elongated anterior leaflet may also contribute to SAM, and numerous techniques can be used to avoid or eliminate SAM, such as shortening the anterior leaflet, creating a double orifice (edge-to-edge approximation), or even myectomy.[2,11-16] Reducing the height of the posterior leaflet (sliding plasty) is the most common technique.[2,10,17] Although some would argue that SAM may be managed medically with long-term β-blocker therapy and a low late need for reoperation, persistent SAM may be associated with continuing MR, and a young patient requiring long-term β-blocker therapy has had an imperfect operation.[18,19] In an age when surgery is being performed early, in symptom-free patients, this result is less than ideal.[1] Ideally, the repair procedure would avoid SAM altogether and not require long-term medical management.

We sought to develop a new MV repair ring designed to accommodate the specific pathologic conditions of myxomatous disease. This etiology-specific ring, the Myxo-ETlogix (Edwards Lifesciences LLC, Irvine, Calif) ring has a larger orifice than does a Physio (Edwards Lifesciences) ring (which is based on normal anatomy) to accommodate the elongated leaflets. It also has a 3-dimensional shape that moves the coaptation point away from the septum (increasing the distance between the point of leaflet coaptation to the nearest point on the ventricular septum), thereby reducing the risk of SAM.[8,14] Because this etiology-specific ring has a larger orifice, a secondary advantage would be that extensive leaflet reconstruction to reduce the size of the leaflets back to "normal" (sliding plasty) would not be needed, or at least would be needed much less frequently. This would reduce the complexity of myxomatous valve repair and ideally make it more generalizable. Furthermore, the larger orifice leads to a low or normal gradient. This is the first report of the concepts behind the new Myxo-ETlogix, the impact that it had on our use of other mitral repair rings and techniques, and the initial clinical results.

Materials and Methods

Patient Characteristics

Patient information and follow-up data were obtained from the prospectively maintained cardiac surgery outcomes registry of the Bluhm Cardiovascular Institute, which was approved by the Northwestern University Institutional Review Board for use in research. The study ran from the date of first use of Myxo-ETlogix (March 15, 2006) until the date of 100th Myxo-ETlogix implant (November 19, 2007). For the purposes of this study, we analyzed only those patients with MR caused by isolated myxomatous degenerative MV disease (n = 129). The diagnosis of myxomatous disease was determined by echocardiographic and surgical findings of elongated MV leaflets with prolapse (type II). Patients were excluded if they had rheumatic valve disease, ischemic valve disease, cardiomyopathy, endocarditis, or mixed pathology. Among the 129 myxomatous MR cases, MV repair was performed in 124 patients (96.1%), and MV replacement was performed in 5 patients (3.9%). These 5 patients had ages of 65, 72, 74, 78, and 84 years, and all had annular and leaflet calcification. Patients included in this analysis were operated on by two surgeons at a single institution, Northwestern Memorial Hospital.

In the repair group, 100 patients received the Myxo-ETlogix annuloplasty ring, which is a Food and Drug Administration–approved ring for patients undergoing MV repair. During the same period, the Carpentier–Edwards Physio ring was used to repair 24 valves in patients with myxomatous MV disease. Thus 80.6% of the patients with myxomatous disease underwent repair with the Myxo-ETlogix ring, and 19.4% underwent repair with a Physio ring. According to our practice, all patients in the group were prospectively followed up by a specific valve nurse who was available to answer patient questions, arrange follow-up visits, and facilitate entry into prospective 3-dimensional echocardiographic and other imaging studies. The characteristics of the patients who received the Myxo-ETlogix ring are compared with those of the patients who received a Physio ring in Table 1. Overall, the age of the patients was 57 $\pm$ 13 years, and the Myxo-ETlogix patients were younger ($P = .047$). The Myxo-ETlogix patients had more MR (97% with 4+, $P < .001$). Other significant differences between the groups included smaller body mass index and more white patients in the Myxo-ETlogix group (patient self-report), whereas patients in the Physio group were more likely to have chronic obstructive pulmonary disease. The 5 patients who underwent MV replacement were significantly older than the 124 repair patients ($P < .001$), and their operative findings precluded safe, durable MV repair. All these patients underwent valve replacement with a bioprosthetic bovine pericardial valve. In keeping with the trend toward early repair in patients with myxomatous MV disease, most of the patients in the repair group were in New York Heart Association functional class I or II (81.4%).

Characteristics of the Myxo-ETlogix Ring

The Myxo-ETlogix ring was designed as a complete annular remodeling ring with etiology-specific variations from the Physio ring (Figure 1).[20] The anteroposterior dimension of the ring was increased 29% to accommodate elongated myxomatous leaflets. Depending on the exact size of the ring, this led to an increase in anteroposterior diameter of 5 to 8 mm, designed to correspond to typical reduction in posterior leaflet height in patients who undergo sliding plasty. Rather than the surgeon performing extensive reconstruction to reduce the height of the posterior leaflet by 5 to 8 mm, instead the ring pulls the posterior leaflet down by a corresponding amount. This also creates a 16% increase in the total orifice area for the Myxo-ETlogix ring. The largest anteroposterior diameter of a size 40 Physio ring is 27.2 mm, which corresponds most closely to a size 32 Myxo-ETlogix ring (28.0 mm). A size 40 Myxo-ETlogix