Flexible Ring for Dilated Mitral Valve

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Numerous studies show that mitral valve repair performed by standardized techniques is reproducible and associated with low operative morbidity and mortality. The introduction of the Sulzer Medica AnnuloFlex™ flexible annuloplasty ring system affords the cardiothoracic surgeon intraoperative flexibility.

Early on, cardiac surgeons recognized the need to repair mitral valve leaflets. They discovered mitral valve repair preserved the subvalvular structures and optimized cardiac output. In 1971, a French surgeon named Alain Carpentier introduced the first rigid prosthetic annuloplasty ring. This rigid ring allowed surgeons to re-shape a dilated mitral valve, recreating its normal shape and function (Fig. 1a). At the same time, Prof. Carpentier began to develop valvuloplasty techniques that today are considered state of the art for mitral valve repair. These techniques have made the procedure more predictable and reproducible, thus revitalizing interest in the conservative approach to managing mitral valve disease.

25 000 ANNULOPLASTY RINGS PER YEAR

Subsequent experimental and clinical echocardiographic studies showed that the mitral valve changes continuously in size and shape during the cardiac cycle. In 1975, these results prompted Carlos Gomez Duran, working at that time in Spain, to develop a completely flexible annuloplasty ring that would adapt to those continuous changes. There are approximately 25 000 annuloplasty rings implanted annually worldwide. In recent years, the market preference has been shifting from rigid to flexible due to the improved hemodynamic function reported with flexible rings. In 1998, Sulzer Medica introduced the AnnuloFlo™ rigid annuloplasty ring system (see STR 2/98, p. 10). It redefined the standards of annuloplasty ring instrumentation.

In January 2000 and in conjunction with the annual meeting of the Society of Thoracic Surgeons in Fort Lauderdale (USA), Sulzer Medica introduced the AnnuloFlex™ flexible annuloplasty ring system (Fig. 2a) after having received FDA clearance. In April, AnnuloFlex received the CE mark and was introduced in Western Europe.

TWO BASES FOR A NEW RING …

The AnnuloFlex annuloplasty ring design is based on two philosophies: one was developed by Prof. Duran, the other by Dr. Delos M. Cosgrove of the Cleveland Clinic Foundation (USA), both of whom are considered key opinion leaders with regard to mitral valve repair. Prof. Duran developed a complete
fully flexible annuloplasty ring which reinforces the entire native annulus. The ring adapts to the continuous changes in annular size and shape that occur during the cardiac cycle. Dr. Cosgrove designed a partial fully flexible annuloplasty ring which reinforces only the posterior aspect of the native annulus. That is possible because the anterior portion of the mitral annulus does not dilate with the disease process. The advantage of not placing sutures in the anterior portion of the mitral annulus is that this eliminates the possibility of deforming or injuring the aortic valve leaflets with sutures. The ring allows the mitral annulus to function physiologically and adapts to the three-dimensional contour of the annulus.

... COMBINED TOGETHER

The AnnuloFlex annuloplasty ring combines the two designs into one annuloplasty ring (Fig. 3*) and affords additional advantages. It can be implanted as a complete or as a partial ring, based on the patient’s valve pathology or surgeon preference. A hospital inventory advantage is that they have to only stock one ring from one manufacturer versus two rings from two different manufacturers. The AnnuloFlo and AnnuloFlex annuloplasty ring systems combined with the new CardioFix™ Pericardium (see STR 3/2000, p. 28) provide the cardiothoracic surgeon with a comprehensive repair product offering.

FOR MORE DETAILS
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* Drawing of an AnnuloFlex annuloplasty ring in place. Together with the AnnuloFlo™ system, Sulzer Medica is now offering both a flexible and a rigid annuloplasty ring.

* The AnnuloFlex system can be implanted as a complete (left) or as a partial ring with the anterior segment removed (right), based on the patient’s valve pathology or surgeon preference.