Latest Advances in Annuloplasty Protheses for Valvular Reconstructive Surgery

LUCA WELTERT, MD
HEART SURGEON
EUROPEAN HOSPITAL HEART SURGERY DEPARTMENT
PROFESSOR OF BIOSTATISTICS
SAINT CAMILLUS INTERNATIONAL UNIVERSITY OF HEALTH AND MEDICAL SCIENCES (UNICAMILLUS)
ROME, ITALY

ABSTRACT

This is the third and final part of our update on the latest advances in cardiac valvular replacement. Part 1 was dedicated to cardiac valvular replacement, and Part 2 focused on transcatheter cardiac valvular treatment. This part concerns annuloplasty prostheses for valvular reconstructive surgery.

The number of patients undergoing surgical heart valve repair has been increasing, particularly in high-volume centers. Annuloplasty is now considered the gold standard in mitral valve regurgitation repair secondary to degenerative, ischemic and idiopathic dilated cardiomyopathy disease. The techniques of mitral valve reconstruction have been well established, but controversies remain regarding the type of annuloplasty ring to be used. The available annuloplasty rings include rigid, flexible, complete, partial, and semi-rigid/flexible. The choice of annuloplasty ring has been the focus of extensive investigation and debate, but to date it still largely remains a matter of “surgeon’s preference” rather than an evidence-based selection.

Functional tricuspid regurgitation was traditionally treated by the classic De Vega annuloplasty, but has since evolved after the development of prosthetic tricuspid annuloplasty. Head-to-head comparisons have demonstrated superior long-term outcomes with device-based annuloplasty compared to suture-based surgery, but the type of ring to be used (flexible versus rigid) has recently been questioned, without reaching...
definitive conclusions. In contrast to mitral and tricuspid valve repair, aortic repair is more difficult with respect to specific valve features. Annuloplasty is considered to play a key role in controlling aortic regurgitation and preventing recurrence after valve repair. Various modifications of annuloplasty have been advocated (internal/external, with/without ring (suture), rigid/flexible ring), but none of them has become a de facto standard. This paper describes the various rings that are available to help orient surgeons and to serve as a reference for students.

**INTRODUCTION**

The number of patients undergoing surgical heart valve repair has been increasing, particularly in high-volume centers.

Mitrval valve repair has been widely regarded as the optimal surgical procedure to treat mitral valve dysfunction of all etiologies and is currently the most commonly performed surgical procedure for degenerative and ischemic mitral valve regurgitation. The well-accepted advantages of mitral valve repair include improved preservation of left ventricular function, superior survival and greater freedom from prosthetic valve-related complications such as thromboembolism, anticoagulant-related hemorrhage and endocarditis. 1-4

Degenerative mitral valve disease, a spectrum of conditions ranging from a single prolapsing valve segment to diffuse myxomatous degeneration with bileaflet prolapse and annular dilatation is the most repairable form of surgical mitral valve disease; repair is the most commonly recommended surgical approach, even in cases of complex valvular pathology including calcification and anterior or bileaflet prolapse. 5

Ischemic mitral valve disease (IMR) is mitral regurgitation that is a consequence of coronary artery disease. Although IMR may be short-lived and associated with acute ischemia, much more often it is caused by complete myocardial infarction (or infarctions) in the circumflex or right coronary artery distributions. Such infarctions result in complex changes in the geometry and function of the left ventricle (LV) and mitral annulus, leading to systolic leaflet restriction and annular dilatation. Generally, the leaflets and chordae are morphologically normal, and regurgitation occurs through a variable combination of Carpentier types IIIb (restriction) and I (annular dilatation) dysfunction. Choices for the surgical treatment of IMR include revascularization alone or revascularization in concert with mitral repair (annuloplasty) or replacement. Several echocardiographic parameters are associated with an increased risk of mitral valve repair failure. In functional MR, valve competence is commonly restored by an undersized annuloplasty ring that reduces the valve native anteroposterior dimensions. 6

The techniques of mitral valve reconstruction have been well established. Annuloplasty is a fundamental component in mitral valve repair. An annuloplasty ring is essential for restoring the size and shape of the native annulus, preventing future annulus dilatation, and providing functional annular dilatation. Currently available annuloplasty rings include rigid, flexible, complete, partial, and semi-rigid/flexible options. While the choice of annuloplasty ring has been the focus of extensive investigation and debate, it is still largely a matter of “surgeon’s preference” rather than an evidence-based selection. 7-11

On the other hand, tricuspid regurgitation (TR) was traditionally treated with the classic De Vega annuloplasty, but this was changed with the development of prosthetic tricuspid annuloplasty. Head-to-head comparisons have demonstrated that device-based annuloplasty provides superior long-term outcomes than suture-based surgery. However, the type of ring that has to be used (flexible versus rigid) has recently been questioned, without reaching any definitive conclusions. Tricuspid regurgitation is a common finding in patients undergoing surgery for left-sided heart valve disease, and there is a growing interest in determining how to identify and surgically correct TR. Although it was considered a “forgotten disease” for decades, recent studies showed that significant TR often does not regress after successful surgical correction of left-sided valvular lesions, and can even progress. Uncorrected TR has been associated with poor survival and functional status. Current evidence supports a more extensive evaluation of tricuspid repair at the time of correction of left-sided valve lesion, although the criteria that should be used to decide in favor of repair are still under investigation. 12-21

In contrast to mitral and tricuspid valve repair, aortic repair is intrinsically more difficult and globally at an earlier development stage. Aortic valve repair has become an attractive alternative to replacement because of some major advantages, including a low rate of thromboembolic events, the absence of bleeding events associated with the use of anticoagulants, resistance to endocarditis and lack of structural valve deterioration.

When aortic repair is indicated, it is paramount to know the etiology of the aortic regurgitation (AR), which is determined based on the results of transesophageal echocardiography (TEE). For this purpose, it is recommended to use an AR functional classification, based on an evaluation of aortic valve leaflet mobility according to El Khoury et al. 22

This classification is used to classify AR into three groups, and is similar to the functional classification for mitral regurgitation. The first two groups, with normal (functional AR) and excess leaflet mobility (AR caused by the prolapse of leaflets), respectively, are suitable indications for aortic valve repair. On the contrary, the third group, in which problems are caused by a restriction, is not eligible for repair. The durability of the repair depends on the quality of the valvular tissues and on the technique used to repair the valve.

Moreover, aortic repair might be associated with aortic root replacement with conservation of the aortic valve; the two most common aortic valve-sparing procedures are remodeling and reimplantation. The remodeling technique is likely physiologically superior to the reimplantation technique, since it guar-
anteces a more anatomic reconstruction of the aortic root with its sinuses. However, because the problem of annular dilatation is not addressed, the risk of late recurrence of aortic insufficiency (AI) is increased and this is particularly evident in, but not limited to, patients with inherited tissue disorders; a dilated annulus increases the probability of facing, at time of surgery, an intrinsically damaged cusp. Various annuloplasty techniques have recently been added to standard remodeling to prevent this potential long-term drawback of this technique. Moreover, various modifications of annuloplasty (internal/external, with/without ring (suture), rigid/flexible ring) have been advocated, but none has become a de facto standard.23

**Rings Evolution**

**Mitral Valve**

Mitral valve regurgitation was the first valvular disease to be approached through the application of annuloplasty, which became a fundamental pillar of valve repair through the decades. In degenerative mitral valve regurgitation, the support conferred by a prosthetic ring was shown to play a fundamental role in repair durability; the introduction of new techniques, such as edge-to-edge, or technologies, such as the MitraClip® (Abbott Laboratories, Lake Bluff, IL), give suboptimal results without annular stabilization.24 First-generation rings were developed according to the anatomical shape of the mitral annulus (D shaped), with a planar, closed design. The aim was to reproduce and freeze the "physiological" structure of the native valve. Further studies led to the concept of the open ring, or band. Studies found that only the posterior aspect of the mitral annulus was responsible for dilatation, while the anterior aspect is somehow fixed between the two trigones of the heart fibrous core. Furthermore, the systo-diastolic excursion of mitroaortic the heart fibrous core. Furthermore, the continuity is preserved with the implantation of a band, which allows enlargement of the outflow tract during systole. This characteristic may partially sacrifice the proven reliability of closed rings, so the choice is often based on the surgeon’s preference.

A different approach was taken for ischemic or functional mitral valve regurgitation. Once it was understood that the pathology lies in dysfunction of the left ventricle rather than the annulus, the aim of prosthetic rings in this field changed, and so did their shapes and structures. These rings are called “geometric”, and they seek to achieve more than “freezing” of a successful repair or the enhancement of coaptation; they aim to restore the normal shape of a dilated and dysfunctional left ventricle and the mitral valve. Thus, they are multilayer, rigid and closed. Some of them have different shapes and features, as described in detail below.

**Tricuspid Valve**

Tricuspid valve regurgitation was first addressed by the Kay procedure and De Vega annuloplasty. Further studies reported a lack of long-term durability with these approaches, and this led to a need for solid annuloplasty rings.25 Initially, the same devices that were used for the mitral valve were employed, but the characteristic anatomic and physiological features of the right-side valve led to a specific ring design: the presence of the atrioventricular node and conduction bundle imposed an open shape, which makes it possible to avoid the conduction “zone”. At the same time, an ultra-stable closed ring was not necessary, due to the lower working pressures of the right ventricle and the lower traction forces.

**Aortic Valve**

The interest in aortic valve repair by annuloplasty arose after the establishment of valve-sparing techniques as the gold standard in the treatment of aortic root aneurysms, in which aortic regurgitation is often determined by an annular ectasia. Therefore, over the past decade there has been renewed interest in aortic annuloplasty, which has led to the development of different anatomical- and physiological-based rings and three-dimensional supports, which aim to restore the original size and shape of the annulus and prevent further enlargement. The results of these implantations are still under follow-up evaluation and are far from being standardized.

<table>
<thead>
<tr>
<th>Table I</th>
<th>Mitral Annuloplasty Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model</strong></td>
<td><strong>Features</strong></td>
</tr>
<tr>
<td>Carpentier-Edwards Classic™</td>
<td>Closed</td>
</tr>
<tr>
<td>Carpentier-Edwards Physio™</td>
<td>Closed</td>
</tr>
<tr>
<td>Carpentier-Edwards Physio II™</td>
<td>Closed</td>
</tr>
<tr>
<td>Carpentier-McCarthy-Adams IMR ETlogix®</td>
<td>Closed</td>
</tr>
<tr>
<td>Cosgrove-Edwards Band</td>
<td>Open</td>
</tr>
<tr>
<td>Edwards GeoForm®</td>
<td>Closed</td>
</tr>
<tr>
<td>Medtronic-Duran AnCore® Ring</td>
<td>Open</td>
</tr>
<tr>
<td>Medtronic-Duran AnCore® Band</td>
<td>Closed</td>
</tr>
<tr>
<td>Medtronic Colvin-Galloway Future® Ring</td>
<td>Open</td>
</tr>
<tr>
<td>Medtronic Colvin-Galloway Future® Band</td>
<td>Closed</td>
</tr>
<tr>
<td>Medtronic Simulus® Ring</td>
<td>Open</td>
</tr>
<tr>
<td>Medtronic Simulus® Band</td>
<td>Closed</td>
</tr>
<tr>
<td>Medtronic Simulus® Flexible Ring</td>
<td>Open</td>
</tr>
<tr>
<td>Medtronic Simulus® Flexible Band</td>
<td>Closed</td>
</tr>
<tr>
<td>Medtronic Profile 3D®</td>
<td>Open</td>
</tr>
<tr>
<td>Medtronic Simplici-T™</td>
<td>Closed</td>
</tr>
<tr>
<td>St. Jude Medical Seguin™</td>
<td>Open</td>
</tr>
<tr>
<td>St. Jude Medical Tailor™</td>
<td>Closed</td>
</tr>
<tr>
<td>St. Jude Medical Rigid Saddle</td>
<td>Closed</td>
</tr>
<tr>
<td>St. Jude Medical Attune™</td>
<td>Closed</td>
</tr>
<tr>
<td>Carbomedics Annuloflo®</td>
<td>Closed</td>
</tr>
<tr>
<td>Carbomedics Annuloflex®</td>
<td>Closed</td>
</tr>
<tr>
<td>Sorin Sooering™ Ring</td>
<td>Closed</td>
</tr>
<tr>
<td>Sorin Sooering™ Band</td>
<td>Closed</td>
</tr>
<tr>
<td>Sorin Memo 3D®</td>
<td>Closed</td>
</tr>
<tr>
<td>Sorin Memo 4D®</td>
<td>Closed</td>
</tr>
<tr>
<td>MiCardia D’YANA</td>
<td>Closed</td>
</tr>
<tr>
<td>Bloring Kalangos®</td>
<td>Closed</td>
</tr>
</tbody>
</table>

Absorbable |
Carpentier-Edwards Classic™ Annuloplasty Ring-Mitral

The Carpentier-Edwards Classic™ annuloplasty ring (Edwards Lifesciences, Irvine, CA) was introduced in 1971 (Fig. 1). It pioneered the concept of prosthetic devices specifically geared to mitral and tricuspid annular reconstructive surgery. In this well-established concept, a kidney-shaped mitral ring remodels the annulus by altering the anteroposterior and transverse diameters of a normal mitral valve for optimal hemodynamic performance. The ring has a titanium alloy skeleton, and the sewing ring margin is composed of a layer of silicone rubber covered by a polyester knit fabric. Although the Carpentier Classic™ ring was primarily designed for rheumatic valvular diseases, it has played an extremely important role in shaping present annuloplasty devices for all purposes.26

Carpentier-Edwards Physio™ Annuloplasty Ring

The mere addition of the word “Physio” (Edwards Lifesciences) to the name of the device was an understated declaration that a radical change was happening: the rigid ring was replaced by a semi-flexible annuloplasty ring, made of layers of Elgiloy and plastic strips, with a sewing ring margin consisting of a layer of silicone rubber covered by a polyester knit fabric (Fig. 2).27 Remodeling preserves a natural 3:4 ratio between the anteroposterior diameter and transverse diameter during systole. The Physio™ ring was the first move toward flexibility and combined two different sections: the anterior section is rigid and has a saddle-shaped curve, while the posterior section is flexible to allow for changes in the size and shape of the annulus during ventricular contraction. The anterior saddle shape adapts to the aortic root and conforms to the annulus anterior-fibrous segment. This ring was immensely popular in both open surgery and mini-invasive surgery.

Carpentier-Edwards Physio II™ Annuloplasty Ring

In 1995, degenerative valvular diseases had become predominant and an evolution of this ring was introduced: the Carpentier-Edwards Physio II™ Annuloplasty Ring (Edwards Lifesciences) (Fig. 3). The name suggested a second-generation advancement, rather than a true revolution. In fact, this is still a semi-flexible annuloplasty ring. The ring is built to restore the anatomical size and shape to provide an optimal orifice area. The progressive posterior flexibility allows for physiologic contractility of the mitral valve annulus during systole. Similar to the original version, this ring is fabricated with cobalt-chromium bands separated by polyester film strips and has a sewing cuff that consists of a layer of silicone rubber covered with a woven polyester cloth. Transverse colored threads indicate the anterior and posterior commissures.

MITRAL VALVE TABLE I
and the center of the posterior portion of the ring. The underlying concept remained the same (selective rigidity at the anterior section and selective flexibility at the posterior section, which was expected to significantly reduce stress on sutures while maintaining an annulus remodeling effect), but some major changes were made: 1) An angled holder that improves visualization and line-of-sight to the mitral valve, was introduced to facilitate repair and assessment of the valve. The Physio II has been specifically designed to integrate fifteen years of new learning on the mitral pathology and improved optimisation. 2) The Physio II addresses the full etiology spectrum of mitral valve degenerative diseases from fibroelastic deficiency to Barlow’s Disease. The small size ring has a D-shape to accommodate to FED, in the bigger size is more circular in order to accommodate to Barlow’s disease. 3) The Double Saddle shaped ring has a new anterior and posterior saddle shape to integrate the new learnings on the mitral anatomy.

**Carpentier-McCarthy-Adams IMR ETlogix® Annuloplasty Ring**

A characteristic of rings produced by Edwards Lifesciences was their symmetric shape. This changed in 2004, after Patrick McCarthy joined the team of surgeon designers, with the introduction of the Carpentier-McCarthy-Adams IMR ETlogix® annuloplasty ring (Edwards Lifesciences)(Fig. 4). At the time of its introduction, it was advertised as “the first asymmetric rigid ring designed to treat asymmetric dilatation”. This asymmetric 3D annuloplasty ring offered a solution in cases of asymmetric ischemic type IIIb dysfunction with restricted leaflet motion. The device decreases the AP distance and increases leaflet coaptation. It reduces the P2-P3 curvature and compensates for the tethered P3 segment. The increased sewing margin in the P2-P3 region, marked with a dotted line on the sewing ring to facilitate immediate recognition, is designed to accommodate a double-suture row. A recent clinical study of 140 patients with ischemic MR who were treated with the IMR ETlogix® ring and complete revascularization showed a good immediate result coupled with an impressive actuarial 4-year survival of 82%. 28,29

**Cosgrove-Edwards® Annuloplasty System**

In the portfolio of atiuroventricular valve devices at Edwards Lifesciences, the philosophy of a full ring remained predominant over the years. However, some surgeons do not like the idea of constraining the mitroaortic junction, which physiologically moves backward during systole, thus increasing the diameter of the left ventricular outflow tract, and vice versa during diastole. The Cosgrove-Edwards® Annuloplasty System (Baxter Healthcare Corporation, Edwards CVS Division, Irvine, CA) (Fig 5) is composed of a silicone rubber band impregnated with barium sulfate to enable radiographic visualization, which is wrapped with polyester velour cloth, sewn together with a single seam. Provided in multiple lengths to accommodate different posterior leaflet dimensions, it is C-shaped, with no anterior portion, and thus does not restrain movement of the anterior portion. It is marketed for use in either mitral or tricuspid repair. 32,33

**Edwards GeoForm® Annuloplasty Ring**

The Edwards GeoForm® annuloplasty ring (Edwards Lifesciences) is a rigid ring that was geometrically designed to restore leaflet coaptation and reduce mitral regurgitation caused by enlargement of the left ventricle (Fig. 6). Remodeling of the mitral annulus was pioneered by the GeoForm® ideal should restore the shape and function of the left ventricle, which aims to halt the cycle of ventricular enlargement and mitral regurgitation. The GeoForm® significantly reduces the AP diameter by bringing the posterior annulus inward to counteract the outward pull of the enlarged left ventricle. As a consequence, it raises the mitral valve apparatus to counteract the downward pull of the enlarged left ventricle. Such aggressive traction on the ventricle raised some concerns when the ring was first introduced, but early studies and clinical experience proved that this ring was effective for its intended purpose. 28,29

**Medtronic-Duran AnCore® Flexible Annuloplasty Ring and Band**

Medtronic (Minneapolis, MN) is a leading manufacturer of medical devices, and it did not take long for them to market their answer to the rings from Edwards. The Medtronic-Duran AnCore® flexible annuloplasty ring and band were introduced four years after the Carpenter-Edwards Classic® Ring, and since then they have been available for 30 years (Fig. 7). Both the ring and band incorporate radiopaque markers. These devices include markings for commissural placement and the P2 central stitch, but their most...
recognizable characteristic is their flexibility. The Duran AnCore® flexible ring provides the opportunity for the annulus to decrease during systole, which makes it an option for surgeons who wish to avoid a rigid ring in reconstruction for degenerative disease. The Duran AnCore® annuloplasty band lacks an anterior intertrigonal portion, and thus is a partially flexible device that supports reconstruction when the primary pathologic findings include dilatation of the posterior annulus. The band extends beyond the trigones to provide secure suturing to the trigones. The band can also be used for tricuspid annuloplasty with protection of the conduction system. One historical pitfall of this device is the relatively frequent observation of pannus formation around the ring; considered to be a foreign-body reaction to the synthetic annuloplasty ring, it has been shown to cause functional mitral stenosis.\textsuperscript{36,37}

**Medtronic Colvin-Galloway Future® Band and Ring**

At the dawn of the new millennium, another device joined the Medtronic portfolio: the Colvin-Galloway Future\textsuperscript{®} Band (C-G Future\textsuperscript{®} Band)(Medtronic), a semi-rigid annuloplasty band that was designed with the aim to restore the natural proportions of the mitral annulus (Fig. 8). Its design combines both remodeling and flexibility. Its low-profile band design makes it easy to implant and allows predictable remodeling of the annulus to maintain apposition of the anterior and posterior leaflets.

The device is composed of an inner core of a proprietary metal alloy that combines high strength and durability. The band offers stiffness to provide remodeling, yet also flexibility to allow movement of the mitral annulus during the cardiac cycle, due to the metal alloy core. The band also has anchoring eyelets that align with the annular trigones for ease of attachment. The C-G Future® annuloplasty system was created to force the annulus to maintain apposition of the anterior and posterior leaflets. Therefore, when it is compared to other shapes, the commissure-commissural diameter appears larger than the anteroposterior diameter. While excellent results have been obtained with the original band,\textsuperscript{18}
some surgeons were concerned by the lack of anterior stabilization, but still wanted the unique diameter ratio. Medtronic responded by adding a tissue band connecting the two eyelets, with no metal core inside, and named it the Future® ring. 34-40

**Medtronic Semi-rigid Simulus® Ring, Band and Adjustable Ring**

Since flexible, rigid and semi-rigid rings all had a solid market position and scientific credibility, it seemed that all possibilities had been explored. However, the innovative Simulus® Semi-Rigid Annuloplasty Ring (Medtronic)(Fig. 9) for mitral valve repair was a hybrid between a saddle shape and a flat ring. Engineered with the aim to conform to the physiologic movement of the human mitral annulus, the Simulus® Semi-Rigid Ring rises as a saddle in systole and flattens to a planar shape in diastole. Studies of rings that respect the dynamic curvature of the annulus indicate that they reduce valvular stress, potentially increasing repair durability. 41,42 These observations led to the idea that saddle-shaped annuloplasty rings could provide superior uniform annular force distribution compared to flat rings while minimizing out-of-plane forces that could potentially be transmitted to leaflets and chords.

It is widely recognized that the Simulus® Semi-Rigid Annuloplasty Band provides support for posterior annuloplasty while preserving some of the physiologic motion of the aorto-mitral curtain. Constructed with an MP35N wire stiffener, the semi-rigid band has flexible tips that allow secure attachment at the trigones.

Another peculiar aspect of the ring is its generous suture target area with a green suture line, which provides demarcation between structural components and the suture target area. A not-unique but always appreciated side-benefit is the presence of a clear holder for use in implantation that enhances visibility and has proprietary one-cut release.

**Medtronic Simulus Flexible® Ring and Band**

The success of the Simulus® Semi-Rigid Ring led Medtronic to propose a model for surgeons who preferred non-rigid supports. The Simulus Flexible® Annuloplasty Ring and Band (Medtronic) are made of flexible, braided polyester, which maximizes natural valve dynamics (Fig. 10). The ring and band maintain their shape when used on or off the holder, enabling manipulation in varied approaches and exposures.

The designers sought to provide flexibility without elasticity, to reduce stretching, crimping, and bunching. The lack of a hard structure inside these devices offers low resistance, which enables easy needle-passage along the entire width of the ring.

A tungsten and barium sulfate core is used to provide radiographic visualization, and trigone markers are present to assist in suture placement and ring/band positioning.

**Medtronic Asymmetrical Profile 3D® Ring**

In an effort to counterbalance the wide spectrum of devices available from competing brands, Medtronic also produces an asymmetrical ring, with the same purpose and philosophy as for the Edwards GeoForm® Ring. The Medtronic Profile 3D® Annuloplasty Ring (Fig. 11) is a fully-rigid remodeling ring with a so-called physiologic mitral valve shape (very prominent commissure-commissural diameter). It is indicated to treat functional mitral valve diseases, such as ischemic mitral regurgitation and dilated cardiomyopathy. 45

**Medtronic Simplici-T™ Annuloplasty System**

While the landscape of annular supports is populated by all sorts of subtle variants, the core idea is always the same: to provide some form of sewable continuous support to “stabilize” the annular shape and size over time. The Simplici-T™ system (Medtronic) is one of the few exceptions to this general rule. It seeks to provide a flexible band that eliminates the need for traditional sizing, providing a custom fit for every patient and requiring less inventory space (Fig. 12).

Annuloplasty is believed to be crucial to the long-term results of mitral repair, but correct annuloplasty support sizing is essential, as a support that is too big might lead to a lack of coaptation, and one that’s too small might enhance the problem of systolic anterior motion.

The ideal sizing of a flexible support should theoretically lead to better early postoperative LV systolic function compared to that in patients with a rigid ring, allowing the annulus size and configuration to adapt to changes throughout the cardiac cycle, and should grant better diastolic blood flow across the mitral valve, particularly during exercise.

All of these effects should ideally not require placing more stress on the sutures during systole, thus minimizing the likelihood of dehiscence. The Simplici-T™ was marketed as having all of these characteristics in a compact and practical approach to ‘annular support’. 46,47

---

*Figure 11. Medtronic Asymmetrical Profile 3D® Ring*

*Figure 12. Medtronic Simplici-T™ Annuloplasty System*
device. While the idea is promising, clinical experience remains limited.\textsuperscript{44,45}

**St. Jude Medical Seguin™ Semi-Rigid Annuloplasty Ring**

Former St Jude Medical (now Abbott) could not miss the occasion to propose its own set of annuloplasty devices. The St. Jude Medical Seguin\textsuperscript{™} annuloplasty ring (St. Jude Medical, Inc., St. Paul, MN; Fig. 13) is made of a solid, one-piece core that consists of ultra-high molecular weight polyethylene that is thicker in the anterior portion and thinner in the posterior portion to enhance flexibility. The usual markings on the sewing cuff make implant intuitive. This device has provided favorable results since it was introduced in 1996.\textsuperscript{46}

**St. Jude Medical Tailor™ Annuloplasty Ring**

The St. Jude Medical Tailor\textsuperscript{™} plasty ring (Fig. 14) is unique in that it supports multiple repair options. The ring is fully flexible to accommodate natural movement of the annulus and can be cut anywhere within the inter-trigonal area to create a customized C-ring. The ring can be used for either complete or partial annuloplasty and either mitral or tricuspid repair, and is as close as it gets to a single solution that can be adapted to many repair styles.\textsuperscript{47}

**St. Jude Medical Rigid Saddle Annuloplasty Ring**

Saddle-shaped rings have gained momentum. The Rigid Saddle annuloplasty ring from St. Jude Medical (Fig. 15) was designed to restore and maintain the natural saddle shape of the mitral valve annulus and the natural 3D shape of the valve leaflets. A titanium core maintains the anatomical shape and provides annular remodeling. Once again, the idea behind a saddle shape is that it should contribute to the efficient distribution of leaflet stress and chordal tension, which may in turn increase repair durability.

**St. Jude Medical Attune™ Flexible Adjustable Annuloplasty Ring**

The St. Jude Medical Attune\textsuperscript{™} annuloplasty ring (Fig. 16) was designed with strings for tightening of the prosthesis to reduce the dimension of the posterior mitral annulus. To achieve this degree of post-implant fine-tuning, the ring must be fully flexible. Once in place, the ring should provide symmetrical and asymmetrical adjustability to achieve ideal leaflet coaptation and match each patient’s unique annulus. Adjustability after placement is a novel feature on the market and an intriguing concept, but actual experience is still limited. One potential advantage of this support is that it is suitable for implant using open sternotomy, minimally invasive and robotic approaches.

**Carbomedics Annuloflo®**

Carbomedics is another important manufacturer of surgical devices. Their
rigid ring is the Annuloflo® annuloplasty ring (Carbomedics, LivaNova PLC, London, UK)(Fig. 17). This ring has a titanium rigid core that should provide annulus remodeling, restore the natural D-shape anatomy of the mitral annulus and prevent further posterior segment dilatation. Its rigidity and strength make the Annuloflo® a viable choice for ischemic cardiomyopathy. The patented Carbo-Seal™ coating enhances bio- and hemocompatibility.

**Carbomedics Annuloflex®**

The Annuloflex® is Carbomedics’s entry for flexible annuloplasty (Fig. 18). For added convenience it can easily be converted from a complete to a partial ring simply by removing the anterior/septal portion via two suture cut-points. In the open configuration, the ring is potentially suitable for tricuspid repair. Its full flexibility means three-dimensional compliance: it should mirror natural valve dynamics. The physiologic response of the Annuloflex® during the cardiac cycle minimizes the risk of suture dehiscence. This ring contains barium-impregnated silicone for radiographic visualization and its reduced implant cross-sectional diameter minimizes the risk of hemolysis. 48

**Sorin Sovering™ Annuloplasty Rings**

The LivaNova group (formerly Sorin) developed Sovering™ annuloplasty rings (Sorin, LivaNova Group, Saluggia, Italy)(Fig. 19), which are flexible annuloplasty rings designed to avoid constraining the natural 3D motion of the mitral annulus. To address every possible need, they produce a closed ring, an open band and another open band with a unique shape dedicated to tricuspid annuli. The radio-opaque silicone core is barium-impregnated and covered by knitted PET fabric coated with Carbofilm™. The Sovering™ Miniband has the same design characteristics, but a shorter length (in fact, the Sovering™ mitral Miniband is the shortest band available) because it was designed for aggressive over-reduction of the posterior mitral valve segment. 49

**LivaNova (formerly Sorin) Memo 3D® Annuloplasty Ring**

The Sorin Memo 3D® annuloplasty ring (LivaNova)(Fig. 20) is a semi-flexi-
ble (or semi-rigid, depending on your perspective) ring that aims to combine the positive features of both flexible and rigid designs. The patented cell-structure design is intended to mimic the physiologic 3D motion of the native mitral annulus and accommodates the anatomical saddle shape while remodeling the mitral annulus and ensuring leaflet coaptation during systole. Its design is based on a shape-memory alloy core, which is aimed at restoring the natural systolic 3:4 diameter ratio. The Memo 3D® also has LivaNova’s exclusive Carbofilm™ coating for enhanced hemo- and biocompatibility.50

LivaNova (formerly Sorin) Memo 4D® Annuloplasty Rings

In June 2018, LivaNova received FDA clearance to proceed with a new generation of its 3D-shaped rings, called the Memo 4D® (Fig. 21). Although no evidence in humans is available for publication, its engineering features offer a remarkable improvement over the Memo 3D®.

One signature characteristic (already introduced as a modification in the latest version of the Memo 3D®) is the presence of premade loops on the posterior portion that make neo-chord implantation faster and act as temporary reference points. These loops are called the “ReChord chordal guidance system”. While the core is still a nitinol frame, the flexibility coefficient has changed (stiffer in the anterior portion and more flexible in the posterior portion) to give better systo-diastolic compliance. It also has a saddle shape that is progressive: the smallest ring (34 mm) is nearly flat, with the anterior part displaced by only 2 mm from the plane, while the largest (42 mm) has 5.5 mm of displacement (Fig. 22). In combination with a similarly progressive increase in the anteroposterior ratio, this is intended to accommodate excess tissue and therefore to help prevent systolic anterior motion. Finally, this ring has a unique feature in sizing design: it has a 42mm version that could potentially overcome traditional sizing problems with massive valves in Barlow’s disease.

MiCardia DYANA Annuloplasty System

Still a niche proposal from a relatively new company, the MiCardia DYANA annuloplasty system (MiCardia Corp., Irvine, CA) (Fig. 23) is a nitinol-based dynamic complete ring that allows modification of the septal-lateral diameter under TEE guidance in the loaded beating heart after mitral valve repair. Shape alteration is achieved by radiofrequency via detachable activation wires. Despite the fascinating approach, very little clinical experience is currently available and studies are ongoing.51
Bioring Kalangos®

The Kalangos® ring (Bioring, Lonay, Switzerland) was developed for pediatric annuloplasty to address a problem that is peculiar to pediatric heart surgery: preserving the growth potential of the child’s heart (Fig. 24). It is also suitable for adult annuloplasty and is now commercially available.

The device per se does not provide a mechanical support, except in the first brief period following implantation. Instead, it is made of biodegradable polydioxanone that promotes the growth of autologous fibrous tissue to reinforce the deficient annulus. Moreover, it was designed to facilitate its implantation.

The device is introduced within the native annulus and simply secured to the anterior and posterior trigones by knotting the integrated monofilament sutures equipped with crimped stainless steel atraumatic needles. This intrannular implantation prevents the device from being in contact with blood. This avoids thromboembolic complications that require systemic anticoagulation therapies until the endocardium covers the traditional rings sutured on the native annulus. As a result of its design principle, this device might be a useful choice in the presence of endocarditis. 52,53

Carpentier-Edwards Classic™

The Carpentier-Edwards Classic™ annuloplasty ring (Edwards Lifesciences) has an opening in the anteroseptal commissure that avoids sutures in the area of the Bundle of His. The rings are formulated from titanium alloy, with the sewing ring margin composed of a layer of silicone rubber covered with a polyester knit fabric. As stated above in the mitral valve section, the Carpentier Classic™ ring was primarily designed for rheumatic valvular diseases. 36

Table II

<table>
<thead>
<tr>
<th>Model</th>
<th>Features</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carpentier-Edwards Classic™</td>
<td>Open, Rigid</td>
<td></td>
</tr>
<tr>
<td>Carpentier-Edwards Physio™ Tricuspid</td>
<td>Open, Semi-rigid</td>
<td></td>
</tr>
<tr>
<td>Edwards MC3™</td>
<td>Open, Rigid</td>
<td></td>
</tr>
<tr>
<td>Cosgrove-Edwards Band</td>
<td>Open, Flexible</td>
<td></td>
</tr>
<tr>
<td>Medtronic-Duran AnCore™ Band</td>
<td>Open, Flexible</td>
<td></td>
</tr>
<tr>
<td>Medtronic CONTOUR 3D™</td>
<td>Open, Semi-rigid</td>
<td></td>
</tr>
<tr>
<td>Medtronic Tri-Ad™</td>
<td>Open, Semi-rigid</td>
<td></td>
</tr>
<tr>
<td>Medtronic Simulus™ Flexible</td>
<td>Both, Flexible</td>
<td></td>
</tr>
<tr>
<td>Medtronic SimpliCi-T™</td>
<td>Both, Flexible</td>
<td></td>
</tr>
<tr>
<td>St. Jude Medical Tailor™</td>
<td>Both, Flexible</td>
<td></td>
</tr>
<tr>
<td>Carbomedics Annuloflex®</td>
<td>Both, Flexible</td>
<td></td>
</tr>
<tr>
<td>Sorin Sovering® Band</td>
<td>Open, Flexible</td>
<td></td>
</tr>
</tbody>
</table>

TRICUSPID VALVE TABLE II

Before addressing some of the rings that are available for tricuspid design we should clarify that, after clinical studies demonstrated the poorness of the Kay and De Vega approaches, almost all open mitral rings were designed to reshape the mitral annulus, with various results and degrees of surgical satisfaction. However, dedicated tricuspid rings were soon introduced. Many manufacturers entered the market with various types of rings, either designed from scratch or, more often, as an adaptation or rebrand of their consolidated mitral portfolio. 25

Carpentier-Edwards Physio™ Tricuspid Annuloplasty Rings

The Carpentier-Edwards Physio™ Tricuspid (Edwards Lifesciences) is a semi-rigid annuloplasty ring (Fig. 26) that is used in tricuspid valve repairs. The ring has a waveform contour with selective flexibility among the different segments to adapt to the complex motion of the annulus. The progressive flexibility of the ring is the result of special processing of the titanium band. The device maintains support of the tricuspid annulus to prevent excessive dilatation while theoretically adapting to the dynamic motion of the tricuspid annulus in the direction of flow during the cardiac cycle. The septal segment opening helps to avoid the conduction system. 54
Edwards MC3™ Annuloplasty System

The Edwards MC3™ annuloplasty system (Edwards Lifesciences) is a 3D ring designed for tricuspid valve repair. It was introduced on the market with the claim of being the first anatomically correct 3D ring (Fig. 27). This “anatomically correct” design conforms to the 3D tricuspid orifice and should minimize stress at the time of implantation. The ring is implanted with Edwards’s patented system, which allows visual orientation of ring placement and stabilizes the ring during suturing. The Edwards MC3™ ring is meant to be an advancement of the Carpentier-Edwards tricuspid annuloplasty ring with a 3D aspect, although both rings help to avoid suturing in the area of the Bundle of His.55

Cosgrove-Edwards Annuloplasty System

The Cosgrove-Edwards Annuloplasty System (Edwards Lifesciences) has been described above in the mitral valve section (Fig. 5). When used for tricuspid repair, it results in a measured plication of the valve that should allow physiologic motion. By plication of the annulus in the area of the anterior and posterior leaflets, valve competence is restored and the conduction system of the heart is not jeopardized, since sutures are not placed in this vicinity. From a theoretical perspective, a flexible annuloplasty preserves the physiologic shape and normal sphincter mechanism of the valve.

Medtronic-Duran AnCore® Flexible Annuloplasty Ring and Band

The Medtronic-Duran AnCore® flexible annuloplasty ring and band (Medtronic)(Fig. 7) have already been described in the mitral valve section. Their flexibility provides the opportunity for the annulus to decrease during systole.

Medtronic CONTOUR 3D® Tricuspid Annuloplasty Ring

The Contour 3D® annuloplasty ring (Medtronic)(Fig. 28) is a three-dimensional, anatomically shaped remodeling ring for treatment of functional tricuspid valve disease.

Marketed as "(t)he first annuloplasty system to offer single-use and reusable sizers," it features an open design, which helps avoid interference with the heart's conduction system, and incorporates septal lateral compression to address annular dilation. The ring profile height is 3.3 mm, 15% shorter than the Edwards Lifesciences MC3™ Ring, which is its main competitor.56
Medtronic Semi-Rigid Tri-Ad™

Tricuspid Annuloplasty Ring

The Tri-Ad™ Adams tricuspid ring (Tri-Ad™, Medtronic)(Fig. 29) is a semi-rigid support device with a large open area designed to protect the conduction system. It has flexible ends and a 3D semi-rigid mid-portion. A short septal-lateral dimension allow optimal correction of the main lesion while protecting the delicate tissue around the tricuspid valve.¹⁷

Medtronic Simulus Flexible® Ring and Band

The Simulus™ Flexible Annuloplasty Ring and Band (Medtronic)(Fig. 10) have already been described in the mitral valve section. The open version is suitable for tricuspid annuloplasty.

Medtronic Simplici-T™

Annuloplasty System

The Simplici-T™ system (Medtronic)(Fig. 12) has also already been described in the mitral valve section. As a band, it is natively compatible with a tricuspid configuration.

St. Jude Medical Tailor™

Annuloplasty Ring

As described in the mitral valve section, the St. Jude Medical Tailor™ plasty ring (St. Jude Medical)(Fig. 14) can be used for either mitral or tricuspid repair.

Carbomedics Annuloflex®

The Carbomedics Annuloflex® anuloplasty ring (Carbomedics, LivaNova)(Fig. 18) has been described in the mitral valve section. In the open configuration, the ring is potentially suitable for tricuspid repair.

Sorin Sovering™ Annuloplasty Rings

The LivaNova (formerly Sorin) Sovering™ annuloplasty rings have been described in the mitral valve section. As one open band, they allow natural 3D motion of the tricuspid annulus (Fig. 19).

Biostable HAART™ Internal Geometric Annuloplasty Ring

As described in the mitral valve section, the use of an internal geometric annuloplasty ring (HAART™; BioStable Science & Engineering, Austin, TX)(Fig. 30), proposed by Rankin in 2012,²⁹ not only restores the appropriate dimensions of the aorto-ventricular junction (AVJ), but also stabilizes it and, most importantly, should create the anatomical conditions to reconfigure the aortic ostium to its optimal, elliptical shape.²⁹ The design of the HAART™ ring was based on mathematical calculations obtained by analyzing human aortic valves (both harvested from cadavers and derived from mesh-reconstruction of volumetric acquisition by contrast-enhanced computed tomography). The HAART™ rings are available as the HAART™ 300, for tricuspid aortic valve repair, and the HAART™ 200, for bicuspid valves. Moreover, the HAART™ 200 forces the commissures of an insufficient bicuspid aortic valve to a 50/50 position (180 degrees), which significantly facilitates cusp correction and, as a result, valve repair.³⁰ The titanium stent of the ring is coated with Dacron fabric, while the number of “posts” (angled 10 degrees outwards to ease implantation) depends on the number of commissures – two for the bicuspid valve and three for the tricuspid valve.

<table>
<thead>
<tr>
<th>Model</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biostable HAART™</td>
<td>Closed</td>
</tr>
<tr>
<td>CORONEO Extra-Aortic™</td>
<td>Closed</td>
</tr>
<tr>
<td>Scharfschwerdt</td>
<td>Closed</td>
</tr>
</tbody>
</table>

AORTIC VALVE  TABLE III

RIGID RINGS

<table>
<thead>
<tr>
<th>Model</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAART™ 300</td>
<td>Rigid</td>
</tr>
<tr>
<td>HAART™ 200</td>
<td>Flexible</td>
</tr>
</tbody>
</table>

Figure 29. Medtronic Semi-Rigid Tri-Ad™ Tricuspid Annuloplasty Ring

Figure 30. Biostable HAART™ Internal Geometric Annuloplasty Ring
FLEXIBLE EXTERNAL RING

CORONEO Extra-Aortic™

Proposed by Emmanuel Lansac, the Extra-Aortic™ (CORONEO, Inc., Montreal, QC, Canada)(Fig. 31) is an expandable aortic ring intended for seating externally around the remodeled aortic root to achieve a complete and calibrated annuloplasty in diastole, while maintaining systolic expansibility of the aortic root. As such, the cusp coaptation height is increased, thus reducing stress on the cusps and protecting the repair. The prosthesis comes in the form of a band that can be slipped down the takeoff of the coronary ostia and then sutured with a couple of stitches to obtain a continuous ring, which is a practical way to obtain proper positioning with minimal effort. The Extra-Aortic™ ring was invented to address the main pitfall of the remodeling technique of replacement of the aortic root while preserving the aortic valve, which historically represented a destabilization of the aortic annulus that could enlarge over time. This approach narrowed the difference between the remodeling (aka Yacoub) technique and the reimplantation (aka David) technique.61,62

Scharfschwerdt Rings

These annuloplasty devices were first presented in 2011, with an elegant in vitro study on their hemodynamic impact on the aortic annulus and trans-aortic flow.63 The external ring consists of a custom-made open circular metal ring surrounding approximately two-thirds of the aortic circumference, with a Dacron cover for suturing and flexible connection parts at the open ends of the metal ring (Fig. 32). The flexible ends can easily be guided below the coronary arteries and bound to each other between the left and right sinus. In contrast, the intra-annular ring is constructed of a flexible, flat wire frame in a closed, circular configuration surrounded by a thin woven Dacron layer. To avoid affecting the atrioventricular conduction system, both annuloplasty rings incorporate a triangular notch between the right and non-coronary sinus. A commercial model is believed to be close to release, although no firm date has been established.

DISCUSSION

Annuloplasty rings or bands are implanted in almost all repair procedures for either mitral, tricuspid or aortic regurgitation.

Historically and epidemiologically, the mitral setting is by far the most relevant of the three. Annuloplasty is performed to restore a sufficient amount of leaflet coaptation and the size and shape of the mitral annulus, and to provide a durable repair. Despite its fundamental role in mitral repair surgery, there is still a lack of consensus on the choice and sizing of the annular prostheses.6,7

The shape and material of annuloplasty devices come in a large range of options, and the various supports now available have different fabrics. Open and closed shapes, as well as rigid, flexi-
ble or semi-rigid characteristics are the main features for differentiating between the devices. The ratio between the septo-lateral and intercommisural diameters also characterizes each device. Finally, to enrich this wide surgical armamentarium, three-dimensional rings have recently been developed in addition to traditional bidimensional devices. According to the state of the art, there is no clear consensus on which is the best annuloplasty device to use and the choice can vary widely according to the surgeon’s judgment or the manufacturer’s recommendations. Some devices are dedicated to functional mitral regurgitation for both ischemic or dilated mitral regurgitation. In the setting of degenerative mitral disease, rings dedicated to myxomatous mitral regurgitation with unique features with respect to the “classic” rings are available.

The sizing of annuloplasty rings is another crucial aspect that is definitely not standardized. Even if Carpentier’s suggestions remain a worldwide reference in this regard, the choice of the annuloplasty size depends on the surgeon’s experience. Annuloplasty ring-sizing strategies vary significantly and several aspects are more art than science. In the great majority of cases, ring-sizing is performed by the use of dedicated sizers, however several aspects of this step depend on surgeon experience. Parameters that are used for ring-size selection with specific ring-sizers are the intertrigonal distance, the intercommisural distance or the anterior leaflet length. Many surgeons use one or more of these parameters according to their own experience and, occasionally, eminent authors suggest their sizing strategies, which can contradict the manufacturer’s recommendations.64

Furthermore, rings and bands available on the market are not always adequately labeled. Despite several efforts to match the ring dimensions to the anatomic dimensions of the mitral valve, we still face a lack of standardization, in part due to difficulties in precisely measuring the intertrigonal or intercommisural diameter as well as the precise length or surface of the anterior mitral leaflet, either intraoperatively or by TEE.

It is well known how a mistake in annuloplasty implantation may result in repair failure. In the setting of mitral valve prolapse, which frequently involves a small and hyperkinetic heart, especially today with the tendency to early surgery, the choice of the annuloplasty device has to be tailored while keeping in mind the risk of post-repair systolic anterior motion (SAM) of the anterior leaflet. In fact, a small annuloplasty size, in this setting, could increase the risk of post-repair SAM. On the contrary, a large annuloplasty could reduce the coaptation length, with the risk of residual mitral regurgitation or poor follow-up results.65

In conclusion, given these inconsistencies and the complexity of mitral repair procedures (and this is even more applicable for tricuspid and aortic support), there is no standardized method for predicting which would be the best ring or band, or which size should be used in a specific case, and the choice is still completely based on the surgeon’s judgment and experience.66

Even though it appears that, for annuloplasty, “science stops and voodoo begins,” there is wide consensus that this is a pivotal and effective part of every durable repair.31

The authors declare that they have no conflicts of interest.

REFERENCES

Latest Advances in Annuloplasty Prostheses for Valvular Reconstructive Surgery

WELTERT/LICIT RA /SALICA/IR ACE/IRAC E/DE PAULIS