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Biodegradable annuloplasty rings: evolution, characteristics and surgical technique

Annulus remodeling and stabilization with a ring have been demonstrated to be a mandatory step in mitral and tricuspid valve repair to ensure effective leaflet coaptation and improve long-term results. The need for a degradable ring stems from two areas in which biodegradable ring annuloplasty can theoretically fill a void: 1 – valve repair in infected valve tissue to avoid colonization of permanent implanted ring device and infection recurrence, 2 – valve repair in children, where traditional annuloplasty rings can't be used due to the risk of acquired stenosis for lack of growth. Prophylactic anticoagulation following biodegradable ring annuloplasty is not necessary, provided that the patient has no other indication for it, as the intraannular position of the ring protects against any «blood-biodegradable ring» interaction.

Key words: annuloplasty, biodegradable ring, mitral valve, tricuspid valve.

Evolution of the mitral and tricuspid annuloplasty concept using biodegradable suture materials and rings

The idea of developing a biodegradable ring is not a recent one. In 1983, Professor A. Carpentier already predicted the potential use of biodegradable material for annuloplasty in his article entitled «Cardiac Valve Surgery – the French Correction» by stating that the «reinforcement of the dysplastic annulus using a polyethyl-collagenol resorbable ring, which dissolves spontaneously in 12 months...» is «...replaced by strong connective tissue by a process of creeping substitution» [1].

In 1986, after this insight, Duran et al. developed an absorbable flexible ring of ox bovine fibrin. They sewed it around the tricuspid annulus of dogs using a running 4–0 monofilament polypropylene suture [2]. They noticed that the ring had disappeared entirely in nine out of ten dogs between one and two months after its implantation and in all ten dogs after two months. Histological analysis showed mild to moderate ring erosion and fibrous tissue covering the ring in dogs sacrificed between two and four weeks after implantation.

In 1990, Chachques et al. described their experimental findings for a polydioxanone absorbable ring similar in shape to that of the rigid Carpentier – Edwards ring, covered with an extensible sewing sheath of high-porosity polyester, which they implanted onto the native mitral annulus as for a conventional ring [3]. At one-year, histological analyses showed only small residual particles of polydioxanone surrounded by collagen and elastic fibers, with fibroblasts in mitotic activity. No stenotic effect or other adverse affection of leaflet motion or pliability was demonstrated in growing animals, despite a fibrous reaction covering the ring within the first two weeks, increasing in thickness thereafter.

In 1992, Duran et al. reported the histological results of a De Vega annuloplasty performed using

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a 2–0 polydioxanone suture in an experimental sheep model [4]. The polydioxanone suture material remained practically intact during the first three months, and its partial resorption at five months allowed the native tricuspid annulus to restore its initial dimensions. The authors concluded that temporary reinforcement of the tricuspid annulus was possible due to the gradual resorption of polydioxanone within six months. In 1993, Duran et al. reported their clinical results for 73 patients with functional tricuspid regurgitation using a 2–0 polydioxanone suture. Based on the low rate of recurrent tricuspid insufficiency over the maximum follow-up of 2 years, they concluded that patients with functional tricuspid regurgitation and low pulmonary resistance could be adequately treated with the vanishing DeVega annuloplasty that stabilizes the tricuspid annulus for four months [5].

In 1994, Miyamura et al. published their short and midterm follow-up results for a clinical study carried out in children who underwent correction of their atrioventricular septal defect using a circular mitral annuloplasty with 4–0 polydioxanone or 4–0 polyglactin suture materials [6]. Seventy-seven percent of these children maintained satisfactory valve function with gradual growth of the native mitral annulus over the follow-up period. Indeed, the significant polydioxanone and polyglactin sutures disadvantages are the re-dilatation of the native annulus with the degradation process of the biodegradable material and the difficulties associated with precisely plicating the dilated posterior and the two commissural annulus segments according to the surface of the anterior mitral leaflet. For this reason, usage of absorbable suture materials can sometimes result in residual valvular stenosis or insufficiency due to over- or undercorrection of annular dilatation. Another potential disadvantage of such absorbable suture materials is their insufficient thickness for pediatric needle sizes. A minimal thickness of suture material is required to generate an optimal intra-annular fibrous reaction. Moreover, the lack of pre-designed absorbable ring shapes in conformity with the shape of the entire or posterior part of the mitral orifice for mitral annuloplasty – and with that of the anteroposterior part of the tricuspid annulus for tricuspid annuloplasty – may hinder homogeneous fibrous remodeling of the mitral annulus, and hence no longer respect the 3:4 relationship between the anteroposterior and lateral diameters of the mitral orifice, and thereby predispose the tri-dimensional contractile geometry of the mitral annulus to subsequent deformity. Despite all the above-mentioned disadvantages of such absorbable suture materials, we were encouraged by these annuloplasty techniques and especially the use of polydioxanone polymers in pediatric operations and started developing a new biodegradable annuloplasty ring in 1994, which finally received CE (Conformity Marking Europe) approval in May 2005.

Characteristics of the biodegradable ring

The Kalangos® biodegradable ring has a curved «C» segment comprised of a poly-1,4-dioxanone polymer located at the middle of a non-degradable suture material (2/0 polyvinyl monofilament for adult sizes and 3/0 for pediatric sizes) equipped with a stainless-steel needle at each extremity *(Figure 1A, 1B)*. The suture material is in continuity over the entire central portion of the biodegradable ring to increase the resistance to the tensile re-dilatory stretch of the dilated mitral and tricuspid annulus. The specific molecular weight of polydioxanone polymers, contrary to that of the biodegradable sutures, ensures

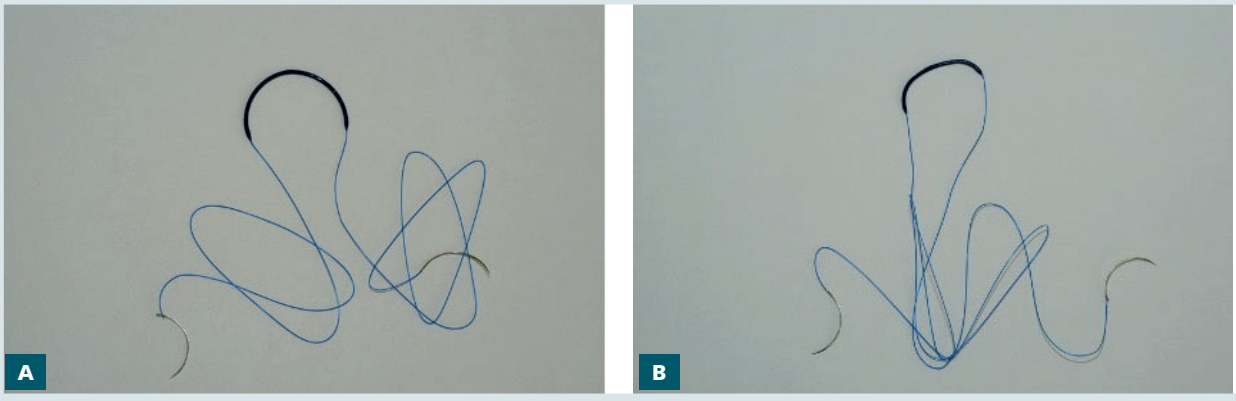

Figure 1. **A – Mitral biodegradable ring; B – tricuspid biodegradable ring**

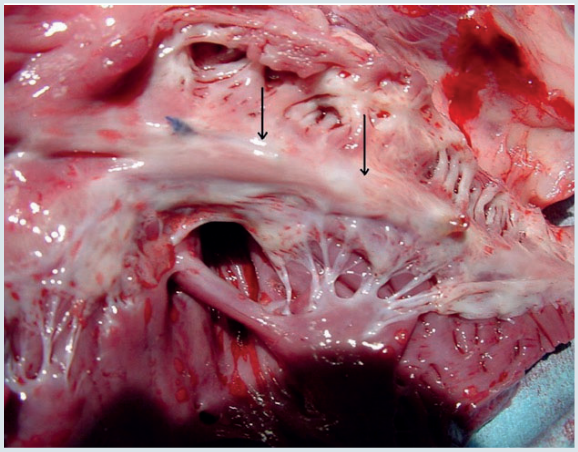

Figure 2. **Macroscopic view of gradual degradation and fibrous tissue formation of the ring within six months after implantation**

structural memory against subsequent deformity, a critical factor in initiating the generation of fibrous tissue leading to secondary annular remodeling; it also provides tri-dimensional flexibility to the ring. The ring is available in sizes 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, and 36 for both mitral and tricuspid annuloplasty, representing the inter-trigonal distances for mitral annuloplasty. The ring has been designed for remodeling the posterior and both commissural annulus segments in the mitral position and the anteroposterior part of the annulus in the tricuspid position by inducing progressive fibrous tissue formation during its degradation by hydrolysis within six months after implantation. *Figure 2* shows the gradual degradation of the ring within six months after implantation into the native annulus and macroscopically the gradual increase in thickness of the fibrous tissue, which fills the space left by the degraded implant material and reaches the diameter of the implant at 12 months after implantation [7]. The degrading polymer stimulates inflammation, activating macrophages to secrete growth factors for fibroblastic cell proliferation. *Figures 3A* and *3B* show the histological analysis of converting the degradable ring into fibrous tissue at one month and six months after implantation into the tricuspid annulus [7].

Surgical technique

The biodegradable ring, contrary to that of traditional rings implanted onto the native mitral or tricuspid annulus, is inserted into the native annulus to promote the inflammation process which will be converted into fibrous tissue, which incidentally prevents the release of degraded particles into the left atrial cavity. For mitral annuloplasty using the biodegradable ring, insertion starts at the level of the posterior commissure (2–3 mm distant to the insertion of the posterior leaflet on the annulus and 2–3 mm in depth) using the needle attached to one of the extremities of the prosthetic mitral ring. Insertion of the ring is begun by moving the inserted needle forward into the native annu-

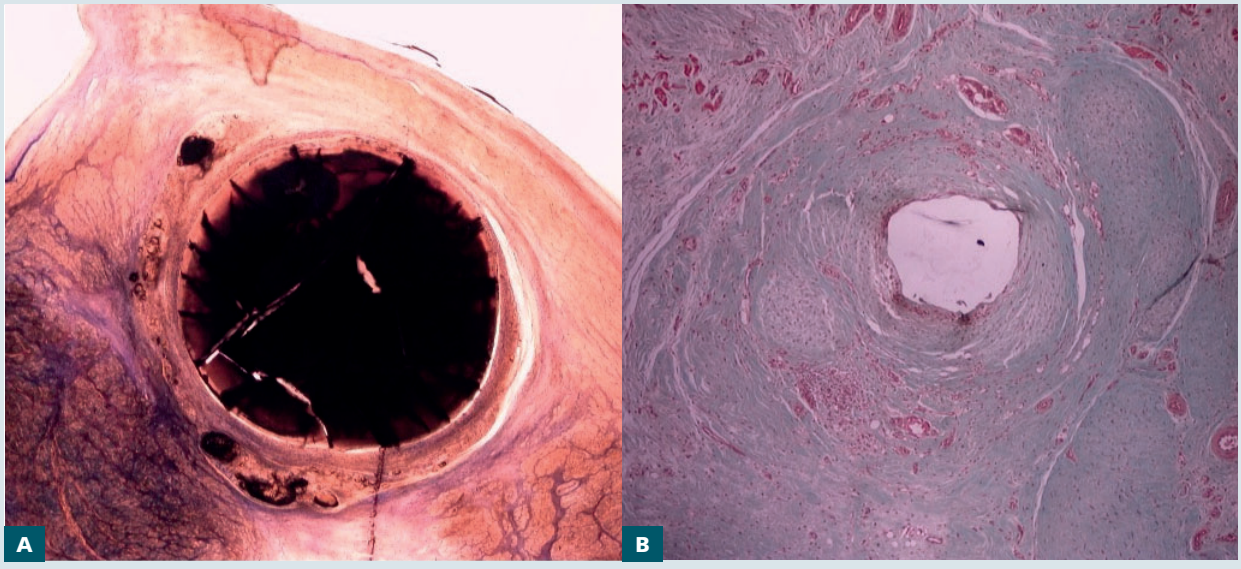

Figure 3. **A: Histological analysis of the ring at one month after implantat; B: Histological view of the ring at 6 months after implantation. The ring is completely degraded and fibrous tissue replaced the space left by the degraded ring**

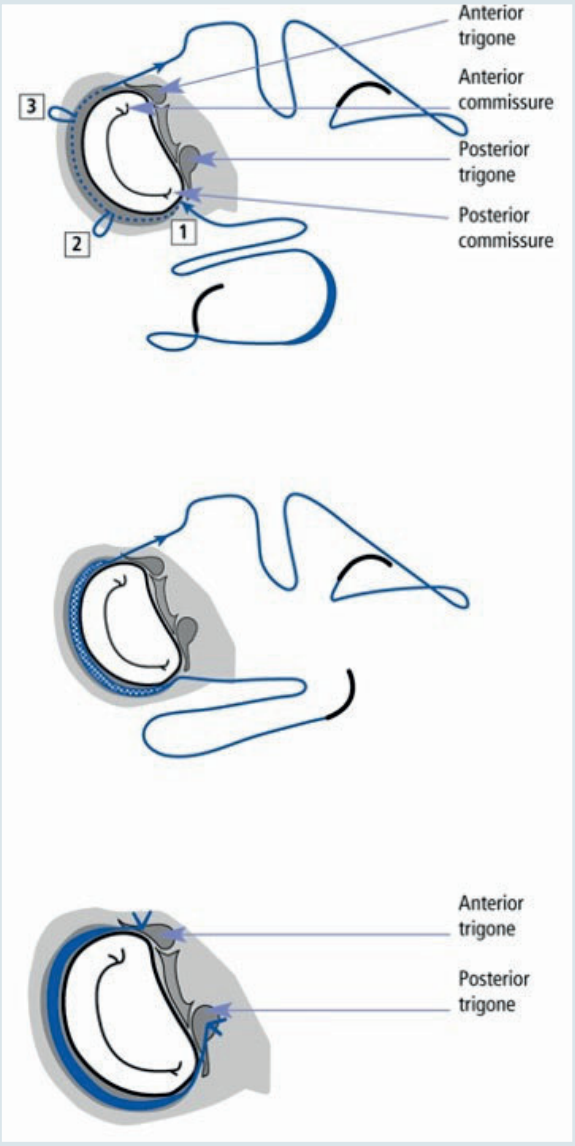

Figure 4. **Implantation technique of the mitral biodegradable ring**

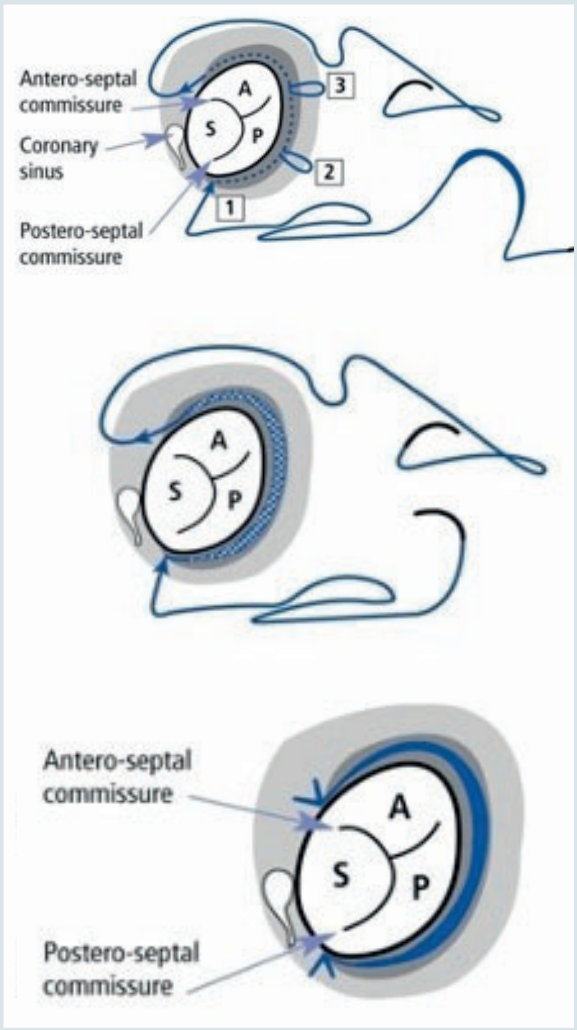

Figure 5. **Implantation technique of the tricuspid biodegradable ring**

lus as far as possible and then pulling up the attached suture *(Figure 4 (1))*. The subsequent insertion of the needle is performed through the first exit point of the first bite *(Figure 4 (2))*, allowing the ring to move forward into the annulus up to the next exit point *(Figure 4 (3))*. Repeating the same insertion steps and pulling up the suture material through the second exit point *(Figure 4 (3))* up to the third one (close to the anterior commissure), the complete insertion of the ring within the native mitral annulus is achieved.

The anterior suture material is then moved forward twice from the anterior trigone down to the anterior commissure, the first loop allowing for fixation of the anterior extremity of the ring to the anterior trigone and the second loop for tying the anterior suture material on itself. The posterior needle is then moved forward twice through the first entry point up to the posterior trigone, the first loop allowing for fixation of the posterior extremity of the ring to the posterior trigone and the second one for tying the posterior suture extension on itself *(Figure 4)*.

The biodegradable ring – a partial ring in design – can also be converted into a complete ring by moving the suture material extensions to the midpoint of the anterior mitral annulus from both commissures and tying them together after fixing both extremities of the ring to the respective trigones with the first loop. The complete insertion technique is especially recommended

for correcting ischemic mitral insufficiency and mitral regurgitation associated with idiopathic dilated cardiomyopathy, as the ring's resistance to tensile stretch is better distributed with the complete configuration, a factor crucial in preventing annular re-dilatation.

For tricuspid annuloplasty, ring implantation into the native annulus starts at the level of the postero-septal commissure, advancing up to the antero-septal one by respecting the same principles of insertion as for mitral annuloplasty: pulling up the suture material and progressively positioning the ring into the annulus, insertion is usually accomplished after only three bites *(Figure 5)*.

In conclusion, we can emphasize that this new technology of biodegradable rings undoubtedly contributes to the evolution of ring annuloplasty concept by introducing some new advantages over conventional ones.

Conflict of interest. The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Participation of authors: collection of material and design of the article – A.K.; article writing – N.S.

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Біорозкладні кільця для анулопластики: еволюція, характеристики та хірургічна техніка

Продемонстровано, що ремоделювання нативного кільця та його стабілізація за допомогою кільця є обов'язковим етапом у пластиці мітрального та тристулкового клапанів для забезпечення ефективної коаптації стулок та поліпшення довгострокових результатів. Анулопластика кільцем, яке біологічно розкладається, застосовується у випадках, коли біорозкладне кільце теоретично може заповнити порожнечу: 1) пластика клапана з інфікованою тканиною – для уникнення колонізації перманентно імплантованого кільцевого пристрою та рецидиву інфекції; 2) пластика клапана в дітей, коли традиційні кільця для анулопластики не можуть бути використані через ризик набутого стенозу, зумовленого відсутністю росту. Профілактична антикоагуляційна терапія після анулопластики біорозкладним кільцем не потрібна, якщо в пацієнта для неї немає інших медичних показань, оскільки внутрішньотканинне розташування кільця захищає від будь-якої взаємодії «кров–біорозкладне кільце».

Ключові слова: анулопластика, біорозкладне кільце, мітральний клапан, тристулковий клапан.