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Early operative and functional results with a new Contour 3D® annuloplasty ring for the treatment of functional tricuspid regurgitation

Tricuspid dilation is a progressive disease that eventually leads to tricuspid regurgitation, the failure of the heart's tricuspid valve to close properly during systole. It is commonly associated with enlargement of the right ventricle secondary to left heart disease. Annuloplasty, a surgical therapy that involves implanting a ring or band to restore the normal annular dimensions and normal leaflet closure, aims to provide the necessary long-term support of the native annulus. *Confluence* spoke with Dr Ralf Günzinger, Cardiac Surgeon and Professor Rüdiger Lange, Director of Department and Deputy Director at the Deutsches Herzzentrum, Munich, Germany, to find out more about the new Contour 3D® Annuloplasty Ring, which is the only remodelling ring that matches the shape of the healthy tricuspid valve, as determined through computed tomography (CT) images from normal tricuspid valves.

Could you give a brief overview of tricuspid regurgitation and its clinical consequences?

In the case of tricuspid regurgitation (TR), deoxygenated blood flows backwards from the right ventricle to the right atrium as a result of the tricuspid valve failing to close properly. TR in adults is most commonly functional with normal leaflets and chords, but with enlargement of the right ventricle and subsequent dilatation of the annulus. With mild or moderate TR, patients are frequently asymptomatic and TR is often diagnosed solely by echocardiography. Severe TR can result in right ventricular dysfunction and elevated central venous pressure. As a consequence, the patients present with low forward cardiac output and impaired renal and liver function.

At the German Heart Centre we see about 100–120 patients with TR per year, but it is rare to see TR as a primary pathology. Most of the patients with functional TR are referred for correction of left-sided heart disease (LHD), such as mitral valve or aortic valve pathologies. These patients often present with secondary, or functional, tricuspid regurgitation, which is diagnosed on preoperative transthoracic or transesophageal echocardiography. Leaflets and chords are morphologically normal, but there is

enlargement of the right ventricle and the tricuspid annulus. In case of tricuspid annular dilatation, the annulus is flattened, which affects coaptation of the leaflets, allowing the backwards flow of blood. In later phases of the disease, the leaflets may also become tethered. Tricuspid valve repair is usually performed as a concomitant procedure to mitral or aortic valve surgery¹ and 75% of our patients who undergo tricuspid valve repair have concomitant mitral valve surgery. It is well known that uncorrected TR may persist or even aggravate after mitral valve surgery.² Moreover, reoperations on the tricuspid valve are known to be high-risk procedures.³ TR is associated with increased mortality, but results differ with regard to the influence of other factors. Santas and colleagues found a significant and positive association between TR severity and mortality at 1 year, only in patients with a left ventricular ejection fraction (LVEF) over 50%.⁴ However, Nath and colleagues showed that increasing TR severity was associated with worse survival in men, regardless of LVEF or pulmonary artery pressure. Severe TR was associated with a poor prognosis, independent of age, biventricular systolic function, RV size, and dilation of the inferior vena cava.⁵

How is tricuspid regurgitation treated?

Tricuspid valve repair with an annuloplasty ring is the preferred treatment for functional TR and improves leaflet coaptation by restoring the normal annular shape. Dreyfus and colleagues showed that even patients with relatively mild TR can have tricuspid dilatation and, if left untreated, this can result in severe TR, which is more difficult to treat.⁶ They used a threshold tricuspid annular diameter of 70 mm from the anterior septal commissure to the anterior posterior commissure, measured intraoperatively. This corresponded to a diameter of 40 mm, as measured by echocardiography from an apical 4-chamber view. The threshold value of 40 mm is the size mentioned in the most recent ACC/AHA guidelines, and in the European Society of Cardiology Guidelines as a Level IIa indication for tricuspid annuloplasty when associated with mild or moderate TR.^{7,8} Based on these findings, we changed our policy in recent years. We treat tricuspid annular dilatation of more than 40 mm, measured by echocardiography, irrespective of regurgitation grade, with a ring annuloplasty, especially in the presence of concomitant LHD. In most cases, TR is functional, and there is no pathology of the leaflets. In 2013 we published data from 717 consecutive patients requiring tricuspid valve repair.⁹ One group was treated with the De Vega suture annuloplasty (n=255), and the other group treated with a ring annuloplasty (n=433). Twenty-nine patients underwent other types of tricuspid valve repair; 91% of patients underwent concomitant coronary artery bypass grafting and/or mitral/aortic valve surgery. We showed that the tricuspid valve repair with a ring annuloplasty was associated with improved survival and lower reoperation rate than with a suture annuloplasty alone. Therefore, we now treat all patients with a ring annuloplasty.

Are there different types of rings available, and what ring characteristics affect their suitability for tricuspid repair?

Yes, there are flexible bands, e.g. Cosgrove-Edwards (Edwards Lifesciences, Irvine, CA, USA) or Duran-AnCore (Medtronic Inc.), flat rigid rings, e.g. Carpentier-Edwards (Edwards Lifesciences), and rigid three-dimensional rings, e.g. Edwards MC3 (Edwards Lifesciences) or Medtronic Contour 3D® (Medtronic Inc.). The shape and flexibility of prosthetic rings for tricuspid valve repair is a topic of ongoing discussion, as residual or recurrent TR may occur. Flexible bands can reduce the annular size with a low residual TR rate early after surgery. However, there are some data to show that the TR rate may increase over time after the procedure with flexible bands.¹ Izutani and colleagues have also shown a more durable tricuspid valve repair with a rigid annuloplasty ring than with a flexible band.¹⁰ Another concept is offered by the Tri-Ad ring (Medtronic Inc.), where a semi-rigid segment is supported by soft, flexible segments.

With the development of functional TR, dilatation and progressive flattening of the tricuspid valve annulus is observed. A two-dimensional, non-profiled rigid annuloplasty ring, e.g. Carpentier-Edwards ring (Edwards Lifesciences), conserves the annulus in a horizontally flat shape after valve repair. This can impose additional stress on the suture lines, which may lead to ring dehiscence and regurgitation as shown by Pfanmüller and colleagues.¹¹

Fukuda and colleagues showed, in 2006, that the healthy tricuspid annulus has a three-dimensional shape and, based on these findings, new three-dimensional annuloplasty rings were designed (figure 1), including the MC3 (Edwards Lifesciences) and the Contour 3D® ring (Medtronic Inc.).¹²

fig. 1

Graphic illustration of the three-dimensional structure of the tricuspid valve and design of a three-dimensional valve

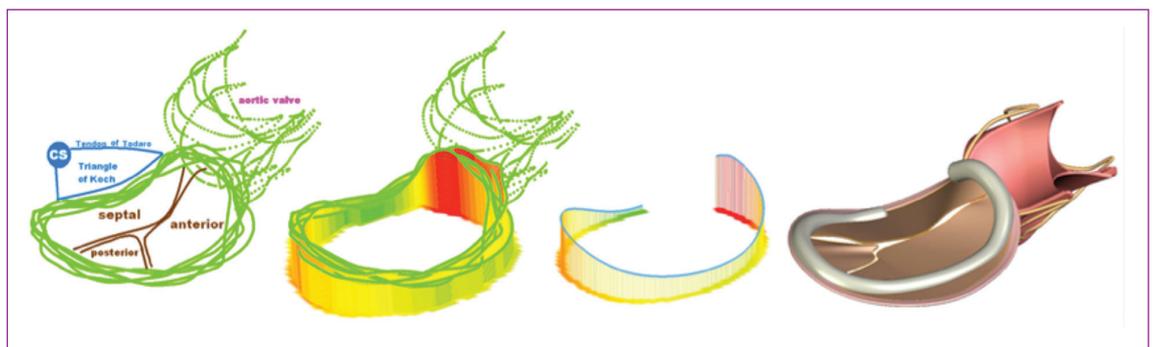


fig. 2

Intraoperative view of a fully competent tricuspid valve after implantation of a Contour 3D annuloplasty ring



Since 2010 we have been using the Contour 3D[®] ring in our department. As we know from the mitral valve, it is very important to place the stitches precisely into the annulus if you use a three-dimensional ring, because there is more force on these rings. What is unique about the Contour 3D[®] ring is that it assumes exactly the same shape as the tricuspid valve of healthy persons. Another important feature is that the open ring and low profile allow the leaflets to open and close effectively without interference with the conduction system in the heart. This allows restoration of the physiological leaflet coaptation, provides a larger area of leaflet coaptation and, therefore, prevents recurrent regurgitation.

Could you tell us about the study population and study design?

We retrospectively reviewed 200 consecutive patients (mean age 70 years) undergoing tricuspid valve repair with the Contour 3D[®] annuloplasty ring for functional TR in our department, from December 2010 to February 2013. In most patients, TR was moderate to severe, and the tricuspid repair was performed concomitantly with another procedure (87% left-sided valve surgery, 76% mitral valve surgery) and most patients had pulmonary arterial hypertension (73%). The ring-sizer provided

by the manufacturer was used to determine the appropriate ring size based on the distance between the commissures of the septal leaflet and the area of the anterior leaflet. Rings were held in place using interrupted annular sutures (figure 2). All patients were treated with cardiopulmonary bypass and under hypothermia during the surgical procedure.⁵

In the study that your group conducted, a considerably lower proportion of patients (4.3%) showed residual moderate or severe TR at discharge, compared to reports elsewhere in the literature of around 15%.^{6,7} How much of that difference do you think can be accounted for by the Contour 3D ring and why?

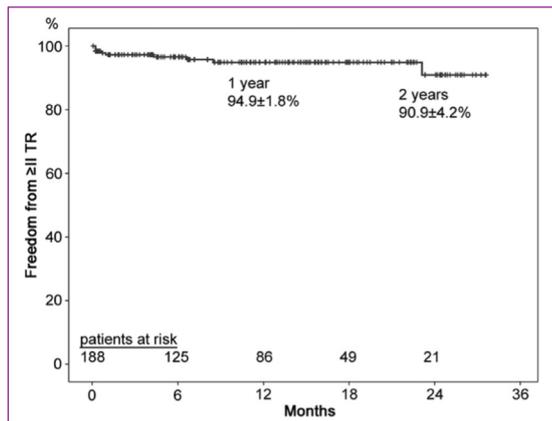
I think the reduced rate of regurgitation is mainly due to the three-dimensional shape of the Contour 3D[®] ring. There are some publications also showing good results with the Edwards MC3 Tricuspid annuloplasty ring (Edwards Lifesciences), with 85–90% freedom from moderate to severe TR at 3 years.^{10,13,14} I think what we have learned is that with three-dimensional annuloplasty rings, there is a larger area of leaflet coaptation, which may account for a higher rate of freedom from recurrent moderate or severe TR than with two-dimensional annuloplasty rings.

Long-term results from the study are good, with 90.9% of patients free from grade 2 regurgitation at 2 years (figure 3). What advice can you give to other colleagues in the area to help them to achieve such great results?

I think the first important aspect is that a ring annuloplasty provides better results than a suture annuloplasty, and the second is the fact that using a three-dimensional ring gives you the best results. Secure anchoring of a three-dimensional device is very important in order to prevent ring dehiscence. Selection of the appropriate ring size remains a controversial topic, and we base our ring sizing on the area of the anterior leaflet and the distance between the commissures of the septal leaflet (our ring sizes mainly used were 30, 32 or 34 mm) with very low rates of residual or recurrent TR. Izutani and colleagues and Ghoreishi and colleagues found a very low incidence of residual TR using three-dimensional rings in smaller sizes (26 or 28 mm).^{10,15}

fig. 3

Kaplan–Meier estimate of freedom from moderate to severe tricuspid regurgitation



What do you think it is about the Contour 3D® that allows patients to have better outcomes overall?

I know that the Contour 3D® ring is designed based on three-dimensional echocardiographic and MRI data from normal healthy subjects. I am not aware of how other three-dimensional rings were designed, but it may be this approach that provided its advantages. I think addressing the tricuspid valve has benefits for the patients and does not add risks to the patients. The risk of recurrent moderate or severe TR during follow up after ring annuloplasty

for functional TR is low. That's why I think patients with tricuspid annular dilatation, even with mild TR, will have an improved long-term survival after ring annuloplasty, especially in the presence of LHD. Our study only provides outcomes for 2 years postoperatively, and therefore I think long-term data still need to be assessed.

Do you think that there are more steps to be taken to improve annuloplasty rings or is the technology as good as it is going to get?

When we look at the data available for three-dimensional tricuspid annuloplasty devices, I think the Contour 3D annuloplasty ring is currently the best such product on the market. However, everything can be improved based on newer technology. It is conceivable that the three dimensional shape of a ring like the Contour 3D could be constructed from another material, maybe Nitinol, which is cut in a way that it supports the physiological three-dimensional shape while still allowing some flexibility to the dynamic changes of the annular geometric dimensions during systole and diastole.

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REFERENCES:

1. McCarthy PM, et al. *J Thorac Cardiovasc Surg* 2004;127(3):674-85.
2. Matsuyama K, et al. *Ann Thorac Surg* 2003;75(6):1826-8.
3. Bernal JM, et al. *J Thorac Cardiovasc Surg* 2005;130(2):498-503.
4. Santas E, et al. *Circ J* 2015;79(7):1526-33.
5. Nath J, et al. *J Am Coll Cardiol* 2004;43(3):405-9.
6. Dreyfus GD, et al. *Ann Thorac Surg* 2005;79(1):127-32.
7. Nishimura RA, et al. *J Am Coll Cardiol* 2014;63(22):e57-185.
8. Vahanian A, et al. *Eur Heart J* 2012;33(19):2451-96.
9. Guenther T, et al. *Eur J Cardiothorac Surg* 2013;43(1):58-65.
10. Izutani H, et al. *Heart Int* 2010;5(2):e13.
11. Pfannmüller B, et al. *J Thorac Cardiovasc Surg* 2012;143(5):1050-5.
12. Fukuda S, et al. *Circulation* 2006;114(1 Suppl):I492-8.
13. Yoda M, et al. *Interact Cardiovasc Thorac Surg* 2011;13(1):7-10.
14. De Bonis M, et al. *J Card Surg* 2012;27(3):288-94.
15. Ghoreishi M, et al. *Ann Thorac Surg* 2011;92(1):89-95.

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