



Bernhard Voss

## The Profile 3D® ring: is a profiled annuloplasty ring suitable for repair of degenerative mitral regurgitation?

Degenerative mitral valve disease typically leads to annular dilatation and flattening of the three-dimensional (3D) mitral annulus, affecting proper closing of the mitral valve during systolic closing. However, the majority of currently available annuloplasty rings are flat and unable to restore the 3D shape of the mitral annulus in patients suffering from degenerative mitral valve disease. The Profile 3D® ring (Medtronic Inc., Minneapolis, MN, USA) was originally developed to repair functional mitral valve disease. Encouraged by the 3D design, and therefore the possibility of reshaping the mitral valve annulus to its native shape, the Profile 3D® ring started to be used in patients with degenerative mitral valve disease, and is now widely used in this indication.

*Confluence* spoke with Dr Bernhard Voss, Senior Cardiac Surgeon at the German Heart Centre, Munich, who was one of the investigators in the Profile 3D® ring trial, to discuss the results.

fig. 1

Profile 3D® ring

What are the treatment options available for patients with degenerative mitral regurgitation?

**Bernhard Voss (BV):** The goal of mitral valve repair for degenerative mitral regurgitation is to correct the annular dilatation and repair any leaflet pathologies that are present. In almost every patient, the recommended treatment would be ring dilatation by annuloplasty. The repair of mitral valve pathologies could be achieved through a wide variety of different repair techniques, such as leaflet resection or chordae repair. The repair technique has to be carefully chosen, and is an individual decision for each patient. In our hospital, the policy is to respect, rather than resect, mitral valve tissue by using artificial chordae.

When you perform a ring annuloplasty, what role does the ring play and what is the importance of the shape of the ring?

**BV:** The normal mitral valve annulus is physiologically saddle-shaped, with its highest points located anteriorly and posteriorly in the middle of the respective annulus, and its lowest points located below both commissures.



In degenerative mitral valve disease, the mitral annulus is dilated: it becomes more circular and also flattened. By using 3D rings, we reshape the flattened mitral annulus back to a nearly physiological shape. In this way, we reduce the stress on the leaflets and increase the coaptation area.

Are there any comorbidities or anatomical features that would influence your decision regarding the choice of ring?

**BV:** In comparison with other rings, the rigid Profile 3D® ring has a relative small anterior–posterior diameter (figure 1). This could be critical in cases where the anatomical configuration confers a high risk for postoperative systolic anterior motion (SAM). In these patients, the implantation of a

more flexible ring with a larger anterior–posterior diameter could be an advantage.

### What are the advantages and the disadvantages of the different type of rings available, for example, 3D, rigid, flexible or semi-rigid rings?

**BV:** The normal mitral valve annulus is physiologically flexible to allow increased inflow during diastole. When using flexible or semi-rigid rings, there is less interference with the normal movements of the mitral annulus and, theoretically, less impairment of ventricular filling, compared to rigid rings. However, in my opinion, this feature of annuloplasty rings is not as important when repairing degenerative mitral valves. This is because, in most cases, we see greatly dilated rings and there is enough valve tissue to allow the implantation of large annuloplasty rings without affecting ventricular inflow. However, after a couple of months, flexible rings tend to lose their flexibility due to ingrowing connective tissue, which surrounds the flexible ring. Therefore, I think that ring flexibility is less important in these cases of mitral valve repair. Rigid 3D rings are the only option to restore the native 3D shape of the mitral annulus, which leads to improved coaptation and less chord tension.

### In which circumstances would you recommend the use of these rigid 3D rings over semi-rigid or flexible rings?

**BV:** Rigid 3D annuloplasty rings could be recommended for almost every patient suffering from degenerative mitral valve disease without a predicted risk for the development of SAM.

### Are there any features, such as calcification, that affect this?

**BV:** If annuloplasty ring implantation is feasible and leaflet motion is not impaired by severe calcification, a mitral valve repair using a 3D ring could be performed with excellent results. However, if there are isolated calcifications in the anterior part of the native mitral annulus, the implantation of an open annuloplasty ring could be advantageous to avoid the need for stitching through calcified areas.

### Could you tell us more about the Profile 3D® ring for functional mitral valve disease?

**BV:** Originally, the Profile 3D® ring was developed by Medtronic for functional mitral valve disease.

Functional mitral regurgitation is a disorder of regional or global left ventricular remodelling in which anatomically normal leaflets fail to coapt adequately due to increased tethering forces. The key goal in surgical repair of such valves is to reduce the anterior–posterior diameter of the mitral annulus in order to restore leaflet coaptation. Conventional ‘undersized’ annuloplasty rings, however, decrease both the anterior–posterior and the commissure–commissure annular dimensions, which may excessively decrease the mitral orifice area. This can be associated with high rates of recurrent mitral regurgitation. In contrast, the Medtronic Profile 3D® ring is designed with a disproportionally reduced anterior–posterior dimension, to avoid the need for aggressive ring downsizing. For example, the anterior–posterior diameter of the 36 mm Profile 3D® ring is about 20% smaller than that of the classical 36 mm Physio II ring (Edwards Lifesciences, Irvine, CA, USA), despite both having the same numerical size.

### Would you say that patients with degenerative disease are more challenging to treat?

**BV:** Yes and no. In general, treatment of degenerative mitral valve disease is more complex and the decision regarding which reconstructive technique to use for restoration of the presented mitral valve leaflet pathologies requires a lot of experience. Additional annuloplasty is generally recommended. For the treatment of classical functional mitral valve disease, it is usually sufficient to perform a simple annuloplasty to achieve sufficient downsizing. However, some cases are more complex, for example, those requiring augmentation patch techniques.

### You were recently involved in a study investigating the use of the Profile 3D® ring for degenerative mitral valve disease. Can you tell about this study?

**BV:** The trial enrolled 200 patients with severe degenerative mitral regurgitation, who underwent mitral valve repair using the Profile 3D® annuloplasty ring. For mitral valve repair, large ring sizes (over 34 mm) were implanted in two-thirds of patients. Additional chord implantation was performed in 85% of the treated patients, while leaflet resection was only necessary in 5%. At 3 years’ follow up, we found excellent results with freedom from reoperation of up to 97%.

Thinking about the patients with degenerative mitral valve disease that you were treating, were they patients with quite severe disease, or was it a typical patient population?

**BV:** The composition of the study population ranges from simple P2 prolapse with ring dilatation to complex Barlow valves with excessive leaflet tissue and combined pathologies. Therefore, the study population reflects a typical spectrum of degenerative mitral valve disease.

What were the key findings from the study using the Profile 3D® ring in this new population?

**BV:** The main conclusion of our study is that the Profile 3D® ring could be used as a perfect alternative for the treatment of degenerative mitral valve disease, which is underlined by the excellent mid-term results for freedom of reoperation.

Do you expect the long-term data for the Profile 3D® ring to remain as good?

**BV:** We expected the long-term data to be as good as the short- and mid-term data. This assumption is based on the 3D restoration of the native valve annulus, which leads to a sufficient reduction of chord tension. Additionally, since we started using the ring in 2009, we have seen very few patients readmitted to our hospital with the need for mitral valve reoperation. A more definitive answer could be given in a couple of years when we have more data available.

What features of the ring do you think account for the low reoperation rates found?

**BV:** I would point out that the ring design is based on 3D echocardiogram and CT scans of the normal mitral valve and I think reshaping the ring to a nearly physiological situation offers the best chance of achieving the good long-term results.

What proportion of patients with functional disease and degenerative disease is the Profile 3D® ring suitable for?

**BV:** From my point of view, around 90% or even more degenerative mitral valve disease patients could be treated by implantation of the Profile 3D® ring. The main exception would be those with high risk for SAM. The estimation of patients with functional mitral valve disease that are sufficiently treated by 3D rigid annuloplasty rings is much more difficult.

Are there similarities between the Profile 3D® ring and the Contour 3D™ (Medtronic Inc.) ring for tricuspid valve repair, in terms of their design and functionality, that you think allow for these results?

**BV:** Both the Profile 3D® ring and the Contour 3D™ ring were designed based on 3D echocardiogram and CT scans of the natural valve shape. Like the mitral valve, the tricuspid valve also loses its 3D shape by progressive ring dilatation. Therefore, the implantation of 3D annuloplasty rings for tricuspid valve repair could confer a huge advantage with respect to valve durability and functionality.

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DISCLOSURES: Consultant for Medtronic.

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