doi:10.1093/mmcts/mmw004 published online 30 May 2016.

MULTIMEDIA MANUAL OF CARDIO-THORACIC SURGERY

Transcatheter direct mitral valve annuloplasty with the Cardioband system for the treatment of functional mitral regurgitation

Maurizio Taramasso[a,*], Devdas T. Inderbitzin[a], Andrea Guidotti[a], Fabian Nietlispach[b], Oliver Gaemperli[b], Michel Zuber[b] and Francesco Maisano[a]

[a]Cardiovascular Surgery Department, University Hospital of Zurich, University of Zurich, Zurich, Switzerland
[b]Cardiology Department, University Hospital of Zurich, University of Zurich, Zurich, Switzerland

*Corresponding author. Klinik für Herz- und Gefässchirurgie, UniversitätsSpital Zürich, Rämistrasse 100, 8091 Zürich, Switzerland. Tel: +41-44-2551111; e-mail: maurizio.taramasso@usz.ch (M. Taramasso).

Received 8 December 2015; revised 17 January 2016; accepted 28 January 2016

Abstract

Direct mitral valve annuloplasty is a transcatheter mitral valve repair approach that mimics the conventional surgical approach to treat functional mitral regurgitation. The Cardioband system (Valtech Cardio, Inc., Or-Yehuda, Israel) is delivered by a trans-septal approach and the implant is performed on the atrial side of the mitral annulus, under live echo and fluoroscopic guidance using multiple anchor elements. The Cardioband system obtained CE mark approval in October 2015, and initial clinical experiences are promising with regard to feasibility, safety and efficacy.

Keywords: Transcatheter mitral repair • Functional mitral regurgitation • Direct mitral annuloplasty

Surgical undersized annuloplasty is effectively performed to treat patients with severe functional mitral regurgitation (FMR) as stand-alone procedure and it is associated with satisfactory results, if proper patient selection is carried out [1–5]. Undersized annuloplasty reduces the septolateral diameter of the mitral annulus, improving leaflet coaptation by balancing the coaptation defect caused by leaflet tethering [6].

Direct mitral valve annuloplasty is a promising approach for transcatheter mitral valve repair in high-risk patients since it most similarly replicates the conventional surgical approach [7].

The transcatheter Cardioband system (Valtech Cardio, Inc., Or-Yehuda, Israel) is the most similar device to a surgical ring [8]. It is delivered by a trans-septal approach and the implant is performed on the atrial side of the mitral annulus. An incomplete adjustable Dacron band is implanted from trigon to trigon, under live echo and fluoroscopic guidance using multiple anchor elements. The impact on cardiac function and haemodynamics is minimal. After the implantation, the length of the band may be shortened on the beating heart under live echo guidance to improve leaflet coaptation and reduce MR (Video 1).

The Cardioband system obtained CE mark approval in October 2015. Initial clinical experiences after implantation in high-risk patients with FMR are promising with regard to feasibility, safety and efficacy. The study included 31 consecutive high-risk patients with severe FMR (mean age 71.8 ± 6.9 years). The Cardioband device was successfully implanted in all patients (31/31). A significant reduction of the mitral septolateral dimension was observed during intraoperative adjustment of the device (from 36.8 ± 4.8 to 29 ± 5.5 mm; $P < 0.01$). Residual MR after the implant was none or trace in 6 (21%), mild in 21 (72%) and moderate in 2 (7%) patients. Thirty-day mortality was 6.5% (2/31 patients: 1 patient died from intracranial bleeding and 1 with residual moderate MR died from multiorgan failure after mitral surgery). At 30-day follow-up, 22/25 patients had MR ≤2+ [9].

Besides MR reduction, the most significant result in terms of efficacy is the reduction of the septolateral mitral annular dimension observed after the adjustment. The majority of surgeons prefer to perform undersized annuloplasty with a complete rigid ring to address FMR. However, surgical experience suggested that the main determinant for repair durability after undersized annuloplasty in FMR is the achievement of good leaflet coaptation rather than the type of ring (a coaptation length of at least 8 mm should be obtained to ensure a durable repair), and coaptation length is strictly related to the reduction in the septolateral dimension [10, 11]. After the final adjustment, a more than 21% reduction in the septolateral dimension was observed with Caridoband, which is comparable with that obtained after surgical undersized annuloplasty with a complete ring (22% with Edwards Physio II ring and 25% with the IMR ETlogix ring) [12]. Moreover, compared with conventional surgical rings, the possibility of beating-heart adjustment of the Cardioband may allow optimizing the reduction in septolateral diameter and the final coaptation length.

The Cardioband adjustable annuloplasty system includes the implant and three main accessories:

(i) The implant is a polyester sleeve with radiopaque markers spaced 8 mm apart from one another (Fig. 1A and B). The sleeve is mounted on the delivery system and the anchor deployed from the internal part. A contraction wire in the Cardioband is connected to an adjusting spool. Activating the spool enables to shorten the implant. Hence, the implant size is reversibly adjusted to the patient's needs under TEE guidance.

© The Author 2016. Published by Oxford University Press on behalf of the European Association for Cardio-Thoracic Surgery. All rights reserved.

(ii) *Delivery system*: the Cardioband delivery system (CDS) consists of the implant delivery system (IDS) and the 25F transseptal steerable sheath (TSS). The IDS comprises a steerable guide catheter and an implant catheter with the Cardioband implant mounted on its distal end (Fig. 1C).

(iii) *Implantable metal anchors and anchor delivery shafts*: Implantable 6-mm long anchors of stainless steel are used to securely fix the Cardioband implant to the annulus. Between 12 and 17 anchors are implanted using a delivery shaft. The anchors are fully repositionable and retrievable until final deployment of the device.

(iv) *Size adjustment tool (SAT)*: The SAT distal tip is connected over the implant wire and is used to control the implant adjustment spool and the implant size.



Video 1: Transcatheter mitral valve repair with the Cardioband annuloplasty device.

We here describe the case of a 69-year-old symptomatic patient (New York Heart Association III–IV) with severe idiopathic FMR and impaired ventricular function (left ventricle ejection fraction: 29%). The reduced ventricular function and multiple concomitant pathologies (severe chronic obstructive pulmonary disease, chronic renal failure and severe pulmonary hypertension) increased the perioperative risk for conventional surgical mitral valve repair. Therefore, a transcatheter approach was suggested after interdisciplinary discussion in the Heart Team. Since the main mechanism of MR was

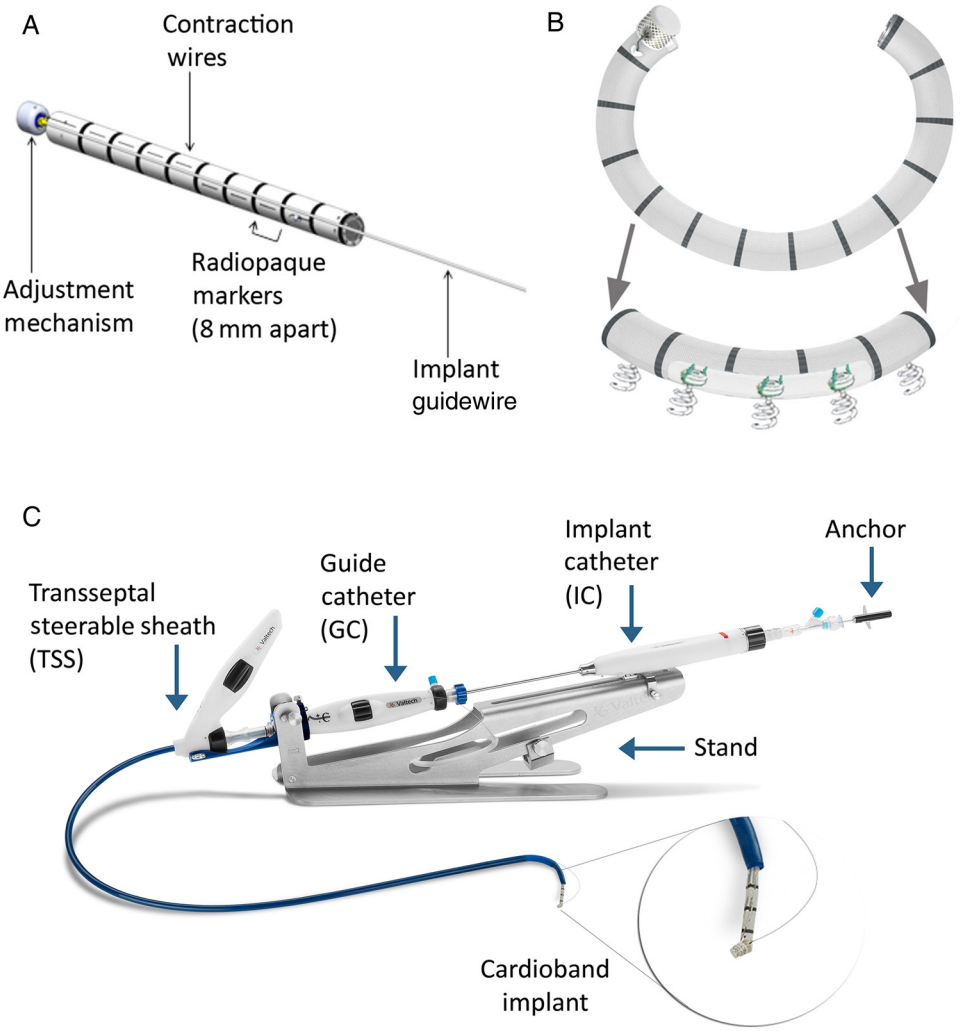


Figure 1: Cardioband implant before implantation (**A**) and after implantation (**B**). The implant is a polyester sleeve with radiopaque markers spaced 8 mm apart. (**C**) The Cardioband delivery system (CDS), assembled in the implantation mode. The CDS consists of the implant delivery system (IDS) and the 25F trans-septal steerable sheath (TSS). The IDS comprises a steerable guide catheter (GC) and an implant catheter (IC) with the Cardioband implant mounted on its distal end.

annular dilatation with limited tethering in the absence of structural leaflet pathology, the patient was considered an ideal candidate for transcatheter annuloplasty with the Cardioband system.

Preprocedural coronary angiography showed a normal coronary status with left-sided dominance.

Preprocedural angiographic CT scan is mandatory to assess the patient's eligibility and for procedural planning predicting the optimal fluoroscopic planes to implant the anchors. Moreover, it allows the operator to rule out annular calcifications (which represent the major anatomical contraindication to Cardioband implantation), to size the length of the posterior mitral annulus, to plan the optimal location for trans-septal puncture and to assess the distance between the annulus and the left circumflex coronary artery to evaluate the potential risk of coronary injury.

In this case, significant annular calcifications were ruled out by CT scan prior to the intervention. The proper implant size of the Cardioband was selected according to the measurements of the mitral annulus on CT scan. In this specific case, CT scan showed clearly that the distance between the mitral annulus and the circumflex artery was enough to allow safe anchor implantation (Video 2).

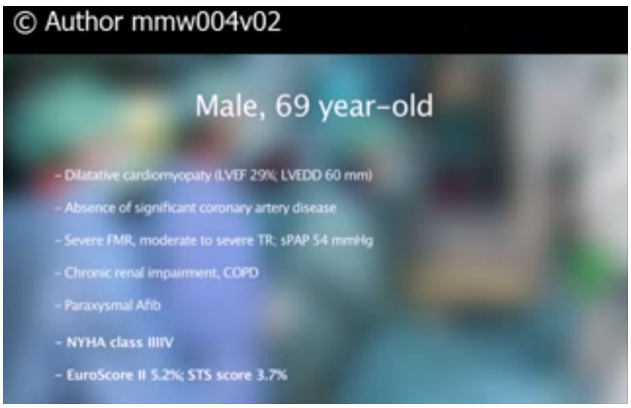
Two femoral accesses are provided (venous and arterial). The venous access is the therapeutic access and it is pre-closed with a Proglide device. Using the arterial access, the left coronary artery is engaged with a diagnostic JL 4 catheter and a Balance coronary wire is positioned in the circumflex artery as a reference.

Trans-septal puncture is performed with the standard pull-back technique under TEE guidance. The ideal puncture location is infero-anterior. A low rather than high puncture is recommended. A Super-stiff wire is then advanced in the left superior pulmonary vein (Video 3).

The TSS is then inserted over the wire across the interatrial septum into the left atrium. This manoeuvre is performed in fluoroscopic left anterior oblique projection. In right anterior oblique projection, the TSS is steered towards the left ventricle (LV) apex to address the mitral valve in its mid-portion. Intercommissural 2D and surgical 3D views help confirming the position (Video 4).

The IDS is inserted in the TSS. The IDS comprises a steerable guide catheter and an implant catheter with the Cardioband implant mounted on its distal end. A stabilization wire is advanced through the mitral valve in the LV. Under 3D echo guidance, the guide catheter is moved towards the anterolateral commissure of the mitral valve. Subsequently, the tip of the implant catheter is placed above the anterolateral commissure. Confirmation of the proper location is obtained with 3D TEE; 2D echo assures that the tip of the implant catheter is pointing to the mitral annulus rather than to the leaflets and enables to assess the optimal angle for anchor implantation, which should enter the annular tissue perpendicularly. A left coronary angiogram is performed to assess the distance from the circumflex artery before the implant of the first anchor (Video 5).

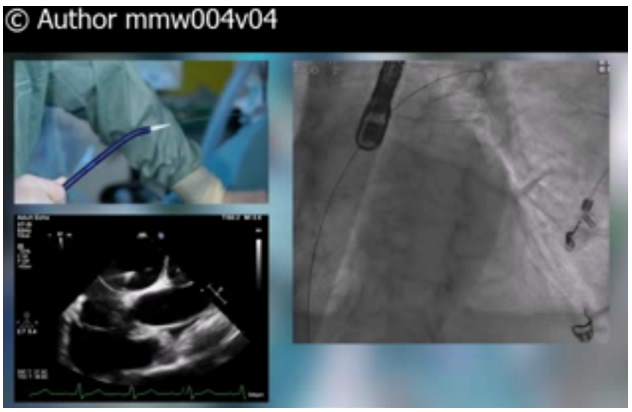
Once the desired position is achieved, the first anchor is implanted in correspondence with the anterolateral commissure.



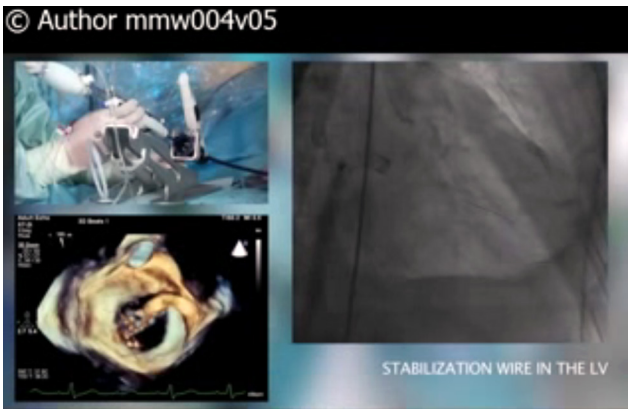
Video 2: Clinical presentation of the patient.



Video 3: Access preparation and trans-septal puncture.



Video 4: Insertion of the trans-septal steerable sheath in the left atrium and steering towards the mitral valve.



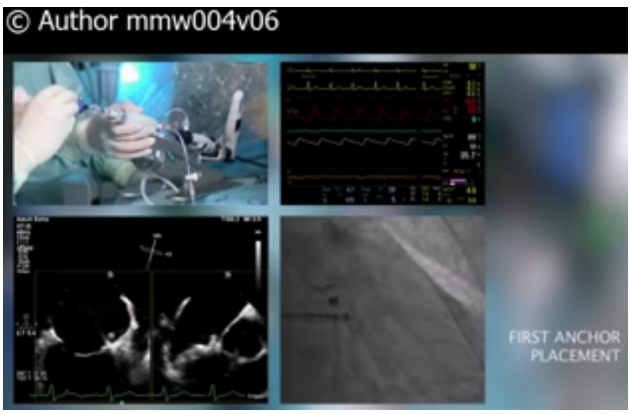
Video 5: Insertion of the implant delivery system and navigation to the lateral commissure.

Extra-systolic beats visible on the ECG suggest that the anchor is fixated to the LV muscular tissue. The application of the anchor is observed live on fluoroscopy. A push and pull test is performed to document a firm implantation of the anchor. If the position is correct, the anchor is released. The stabilizing wire then is removed. The next portion of the Cardioband is released up to the next radiopaque marker that turns visible (Video 6).

The implant catheter tip is then navigated to the next suggested anchoring point along the posterior annulus under transesophageal echocardiography (TEE) guidance by operating the TSS and guide catheter steering knobs. This process is repeated until reaching the last anchoring site on the posteromedial commissure. In this case, a total of 16 anchors were deployed to cover the entire length of the atrial side of the posterior mitral annulus. Video 7 shows the implantation of the second and third anchors. An uncut fast-forward video shows the implantation of the remaining anchors from 4th to 16th, which took 70 min.

After the implantation of the last anchor, the implant is disconnected from the IDS, which subsequently is removed. The SAT is then inserted through the TSS over the implant guide wire until its distal end reaches the adjustment spool of the implant (Video 8).

After SAT connection, the implant is contracted stepwise by clockwise rotation of the adjustment roller. Adequate reduction of MR is assessed simultaneously by TEE under beating-heart conditions. Improvement of the haemodynamic can be observed immediately [left atrium (LA) pressure decrease and V-wave changes on the monitor]. After the achievement of an appropriate implant size, the SAT is detached from the adjustment spool with the implanted Cardioband at its defined level of contraction (Video 9).



Video 6: Implant of the first anchor.



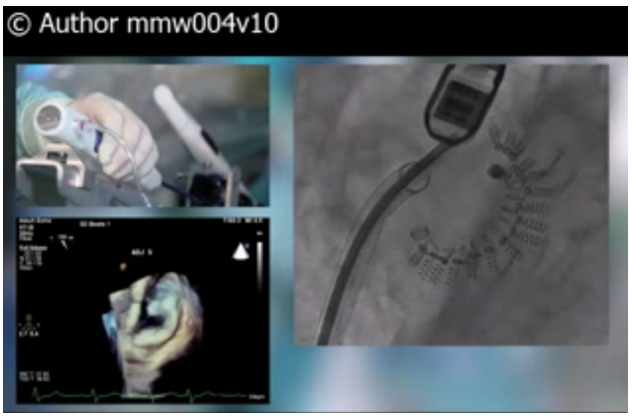
Video 7: Implant of second and third anchors. Implantation of anchors from 4th to 16th is shown as uncut fast-forward video.



Video 8: Disconnection of the implant delivery system and insertion of the size adjustment tool.



Video 9: Adjustment of the Cardioband with live reduction of mitral regurgitation. Improvement of the haemodynamic can be observed immediately (LA pressure decrease and V-wave changes on the monitor).



Video 10: Disconnection of the size adjustment tool and removal of the Cardioband delivery system. Finally, percutaneous closure of the venous access is obtained.

Thereafter, the SAT is disconnected from the implant and the CDS is removed. Finally, percutaneous closure of the venous access is obtained (Video 10).

Clinical postoperative course was regular and the patient was discharged 4 days after the procedure.

In conclusion, preliminary experience showed that this technology, based on a solid surgical background, is safe and effective in selected high-risk patients with severe FMR. It valuably contributes to the current mitral valve interventions and may even be expanded to a larger number of patients with an increased risk for conventional mitral surgery. Furthermore, Cardioband may improve the efficacy and durability of mitral interventions if combined with currently available techniques of leaflet repair such as MitraClip.

Conflict of interest: Andrea Guidotti and Francesco Maisano have a financial relationship with Valtech Cardio.

REFERENCES

[1] Magne J, Pibarot P, Dumesnil JG, Senechal M. Continued global left ventricular remodeling is not the sole mechanism responsible for the late recurrence of ischemic mitral regurgitation after restrictive annuloplasty. J Am Soc Echocardiogr 2009;22:1256–64.

[2] Braun J, Bax JJ, Versteegh MI, Voigt PG, Holman ER, Klautz RJ *et al.* Preoperative left ventricular dimensions predict reverse remodeling following restrictive mitral annuloplasty in ischemic mitral regurgitation. Eur J Cardiothorac Surg 2005;27:847–53.

[3] Calafiore AM, Di Mauro M, Gallina S, Di Giammarco G, Iaco AL, Teodori G *et al.* Mitral valve surgery for chronic ischemic mitral regurgitation. Ann Thorac Surg 2004;77:1989–97.

[4] Mann DL, Kubo SH, Sabbah HN, Starling RC, Jessup M, Oh JK *et al.* Beneficial effects of the CorCap cardiac support device: five-year results from the Acorn trial. J Thorac Cardiovasc Surg 2012;143:1036–42.

[5] De Bonis M, Taramasso M, Verzini A, Ferrara D, Lapenna E, Calabrese MC *et al.* Long-term results of mitral repair for functional mitral regurgitation in idiopathic dilated cardiomyopathy. Eur J Cardiothorac Surg 2012;42:640–6.

[6] Bolling SF, Pagani FD, Deeb GM, Bach DS. Intermediate-term outcome of mitral reconstruction in cardiomyopathy. J Thorac Cardiovasc Surg 1998;115:381–6; discussion 387–88.

[7] Taramasso M, Guidotti A, Cesarovic N, Denti P, Addis A, Candreva A *et al.* Transcatheter direct mitral annuloplasty with Cardioband: feasibility and efficacy trial in an acute preclinical model. EuroIntervention 2015;11. 10.4244/EIJY15M11_06.

[8] Maisano F, Taramasso M. The Cardioband transcatheter direct mitral valve annuloplasty system. EuroIntervention 2015;11(Suppl W):W58–9.

[9] Maisano F, Taramasso M, Nickenig G, Hammerstingl C, Vahanian A, Messika-Zeitoun D *et al.* Cardioband, a transcatheter surgical-like direct mitral valve annuloplasty system: early results of the feasibility trial. Eur Heart J 2016;37:817–25.

[10] Mihaljevic T, Lam BK, Rajeswaran J, Takagaki M, Lauer MS, Gillinov AM *et al.* Impact of mitral valve annuloplasty combined with revascularization in patients with functional ischemic mitral regurgitation. J Am Coll Cardiol 2007;49:2191–201.

[11] Wu AH, Aaronson KD, Bolling SF, Pagani FD, Welch K, Koelling TM. Impact of mitral valve annuloplasty on mortality risk in patients with mitral regurgitation and left ventricular systolic dysfunction. J Am Coll Cardiol 2005;45:381–7.

[12] Wong VM, Wenk JF, Zhang Z, Cheng G, Acevedo-Bolton G, Burger M *et al.* The effect of mitral annuloplasty shape in ischemic mitral regurgitation: a finite element simulation. Ann Thorac Surg 2012;93:776–82.