

Real-world case study

PASCAL Precision System for treating MR: Deploy the implant with procedural confidence*

With an implant designed to adapt to native anatomies and a catheter with balanced flexibility, what you see before release is what you can achieve with the PASCAL Precision system.† Here, Dr med. Kristin Marx and Dr med. Ekaterina Stellbrink from Bielefeld Clinic in Germany describe an elderly patient with mixed mitral regurgitation (MR) who experienced predictable MR reduction following mitral transcatheter edge-to-edge repair (M-TEER) with the PASCAL Precision system.



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*Performance and design data on file.

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The patient

An 80-year-old woman presented to our hospital in early 2024 with cardiac decompensation, accompanied by dyspnoea, lower limb oedema and persistent atrial fibrillation. She was diagnosed with dilated cardiomyopathy characterised by severe left ventricular (LV) dysfunction, without coronary sclerosis, and severe secondary MR. After restoring sinus rhythm, we initiated heart failure therapy in accordance with the current guidelines. Two months later, the patient continued to exhibit symptoms of heart failure and persistent severe MR (Figure 1A), with no improvement in LV function. Right heart catheterisation revealed postcapillary pulmonary hypertension with a prominent v-wave. Following a multidisciplinary discussion within the Heart Team, we decided to proceed with M-TEER.

The challenge

The patient exhibited LV dysfunction, severe atrial and ventricular dilatation and subsequent mitral ring dilatation. Additionally, the thickened, sclerotic leaflets resulted in severely reduced coaptation

length and an overriding anterior mitral leaflet (AML) with central coaptation loss. The regurgitation orifice was crescent-shaped, with confluent central medial and central lateral parts. Those anatomical features contributed to a mixed aetiology of MR and, together with curling of the posterior mitral leaflet (PML) during the procedure (Figure 1B), presented procedural challenges.

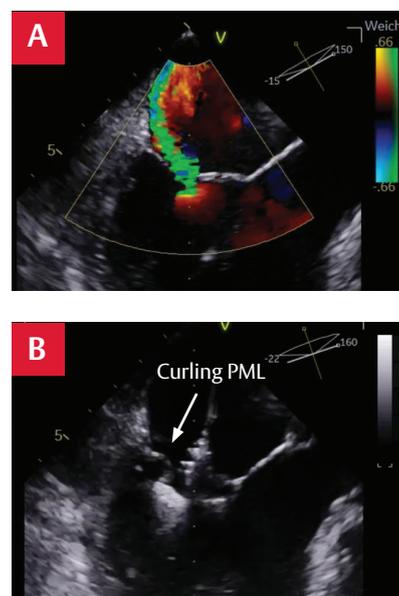


Figure 1. 2D echocardiography of the mitral valve at baseline.



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The strategy

Our strategy was to address both the approximation of the leaflets and the annular dilatation. We recognised that we would need two implants for this patient because of the large mitral annulus. We opted for the PASCAL Precision system because it allows multiple repositionings of the implants without damage to the sclerotic leaflets; it is very well suited for delicate and precise grasping. We chose the PASCAL Ace implant for its narrow profile, which facilitates the placement of two devices close to each other.

The procedure

The initial grasping attempt was suboptimal because of the curling of the PML, which resulted in the PML folding. Consequently, we decided to optimise the grasping technique, to capture the leaflet in full length and prevent folding. To achieve this, the PML was initially grasped at a deeper level, and the PASCAL Ace implant was positioned in a slight V-configuration (Figure 2A). We placed the first implant in the central medial position, using the independent clasp feature to first clasp the PML and then the AML. After the initial closure, we achieved a significant reduction

in the MR; however, a substantial lateral jet persisted (Figure 2B). Our intention was to place the second implant adjacent to the first, but the outcome of our initial grasping attempt was unsatisfactory: the clips were in a V-shaped configuration, resulting in residual MR. We subsequently adjusted the angulation of the sheath using 3D visualisation and the FlexiSlice tool and simultaneously grasped both leaflets. This manoeuvre nearly eliminated the MR, leaving only a trace jet (Figures 2C and 2D). This result was confirmed to be sustained the following day during transthoracic echocardiography (Figure 2E).

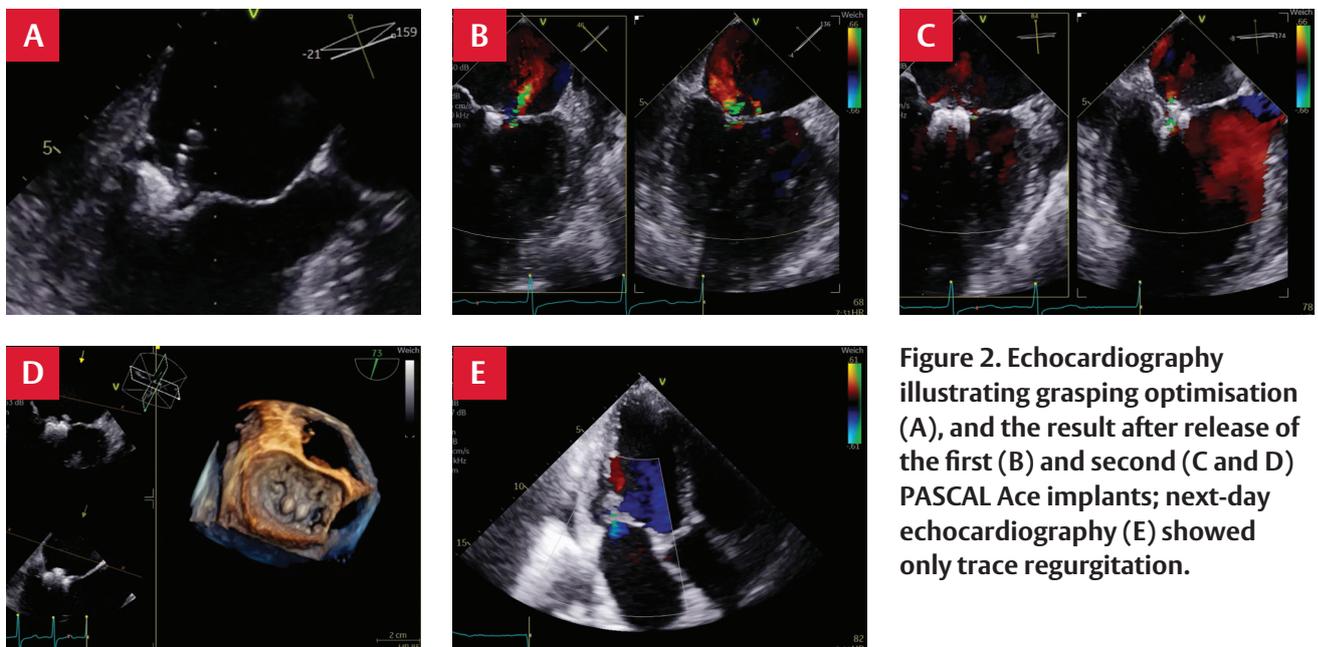


Figure 2. Echocardiography illustrating grasping optimisation (A), and the result after release of the first (B) and second (C and D) PASCAL Ace implants; next-day echocardiography (E) showed only trace regurgitation.

Key tips

Predictability is one of the advantages of the PASCAL Precision system. What you see after closure of the device is what you get after releasing the implant. In our opinion, the flexibility of the delivery system may contribute to the predictability. For new users, however, understanding how to steer the system can be challenging in the beginning. Take advantage of training that is offered to you and take your time switching between 3D and X-plane views to ensure optimal angulation, rotation and clocking, as well as full insertion of the leaflets, which should enable you to achieve excellent results.

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