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Staged clasping with PASCAL device for mitral regurgitation with leaflet laceration

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Short title: independent clasping to capture a leaflet defect

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Classifications: Mitral regurgitation, mitral valve repair, specific closure device/technique

An 84-year-old woman, presenting with dyspnoea (New York Heart Association class III) and edema, underwent an edge-to-edge mitral valve repair with the MitraClip XTR system (Abbott, Santa Clara, USA) for the treatment of severe functional mitral regurgitation (MR) (**Online video S1**). After grasping the leaflets and closing the MitraClip, intraprocedural transesophageal echocardiography detected a new substantial regurgitation through an iatrogenic laceration in the anterior leaflet that was believed to be caused by tension stress on the XTR device (**Figure 1A-B; Online video S2-3**). Because the device's arms could not reach far enough to cover the laceration in the several attempts that were made, the MitraClip was not implanted and the system was extracted.

Owing to the patient having a high surgical risk (STS-PROM score: 6.40%, EuroSCORE II: 7.82%), frailty, and unsuitable anatomy (small left-ventricular outflow tract) for open-heart or transcatheter mitral valve replacement, the heart team decided next to attempt edge-to-edge mitral valve repair with the PASCAL system (Edwards Lifesciences, Irvine, USA). The PASCAL device was first placed in the original MR jet area, but the MR through the laceration remained (**Figure 1C-D**; **Online video S4**). Hence, to maximize leaflet insertion and cover the laceration, first, the posterior leaflet was independently attached and then the device was directed to the anterior leaflet, which was extensively captured including the leaflet defect (**Figure 1E**; **Online video S5**). This led to good coverage of the laceration and a significant reduction in MR (**Figure 1F**; **Online video S6**). At one-month follow-up, transthoracic echocardiography showed only trivial residual MR with a trans-mitral pressure gradient of 2.3 mmHg.

Edge-to-edge mitral valve repair is currently the most prevalent transcatheter technique for patients with severe MR. The PASCAL system offers an optional independent leaflet clasping, thereby allowing it to overcome challenging anatomies that might be inaccessible with the MitraClip system¹. Furthermore, the unique design of the system (i.e., wide paddles, spacer,

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nitinol frame) enables to prevent excess tension stress on leaflets. A multicenter study reported the procedural safety and efficacy of the PASCAL system, regardless of the anatomical complexity². Therefore, staged independent clasping using the PASCAL device may be an efficient therapeutic option to overcome challenging MR pathologies, such as a leaflet laceration.

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Conflict of interest: JM Sinning and G Nickenig have received speaker honoraria and research grants from Medtronic, Boston Scientific, Edwards Lifesciences, and Abbott vascular. All other authors have no conflicts.

Figure Legend

Figure A: A laceration in the medial half of the anterior mitral leaflet (arrow), caused by grasping with the MitraClip XTR device. Figure B: Two jets of mitral regurgitation: one is due to leaflet tethering; the other (arrowheads) is through the iatrogenic laceration (arrow). Figure C: Simultaneous clasping of the leaflets (arrows). Figure D: Residual regurgitation (arrowheads) through the mitral leaflet laceration. Figure E: The posterior leaflet was independently attached (arrow). Then, the PASCAL system was directed to the anterior leaflet to maximize leaflet insertion and cover the laceration (yellow arrow). Figure F: No residual regurgitation through the iatrogenic laceration on the anterior leaflet.

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Supplemental Video Legends

Online Video S1

Baseline transesophageal echocardiography shows severe functional mitral regurgitation (proximal isovelocity surface area, 0.8 cm; effective regurgitation orifice area, 0.32 cm²; regurgitant volume, 45 ml; anterior-posterior annulus diameter, 36 mm).

Online Video S2

During the initial procedure with MitraClip, intraprocedural transesophageal echocardiography detected a new substantial regurgitation through an iatrogenic laceration in the anterior leaflet, approximately 5 minutes after grasping the leaflets.

Online Video S3

Three-dimensional transesophageal echocardiography shows a laceration in the medial half of the anterior mitral leaflet.

Online Video S4

The PASCAL device was first placed in the original mitral regurgitation jet area, but the regurgitation through the laceration remained.

Online Video S5

The posterior leaflet was independently attached, then the PASCAL system was directed to the anterior leaflet to maximize leaflet insertion and cover the laceration.

Online Video S6

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No residual regurgitation through the iatrogenic laceration on the anterior leaflet.