

Background

Surgical mitral valve repair is the gold standard in treating severe mitral regurgitation (MR). New minimally invasive techniques have emerged, such as the transcatheter edge-to-edge repair (TEER), specifically designed to treat frail patients without the use of sternotomy or cardiopulmonary bypass.



These procedures are limited to straightforward cases, leaving a small of patients without an alternative.



The Abbott Tendyne© device recently emerged as a new alternative. We present a series of challenging cases who were not eligible for any of the standard procedures, proposing the expansion of the Tendyne© device indication spectrum.

Rationale

To date, only about 1650 Tendyne© implantations have taken place worldwide. This number is a lot smaller once the study/clinical cases are subtracted.

In the Kepler University Hospital in Linz, Austria, we have implanted 40 Tendyne© prostheses, a large number of which were off-label cases. These challenging cases did not qualify for standard fashion TMVR, and were left without a treatment option.

Patient count	Performed procedures
5	Transapical transcatheter double valve replacement (TAVR + Tendyne)
3	Tendyne implantation following previous mitral annuloplasty
1	Anterior mitral leaflet laceration using modified LAMPOON-procedure for Tendyne implantation
3	Anterior mitral leaflet laceration using endoscopic scissors for Tendyne implantation
12	Tendyne in patients with previous cardiac surgery
10	Tendyne in patients with severely reduced ejection fraction (< 35%)
1	Tendyne for Jehova's witness
2	ELASTA-Clip

Selection criteria

- 1) Symptomatic (New York Heart Association functional class > II) with severe MR;
2) Ineligibility for an on-pump surgical repair or replacement due to an increased surgical risk;
3) Ineligibility for an off-pump edge-to-edge repair due to anatomical considerations
4) Eligibility for TMVR with the Tendyne© bioprosthesis, as assessed by transesophageal echocardiography (TOE) and contrast-enhanced cardiac CT. The Abbott Tendyne© team assisted in the screening and the procedure planning process. We obtained the approval for the compassionate use of the Tendyne© device for each of these atypical cases from the institutional review board.

Case report

- 87-year-old male admitted with symptomatic severe aortic stenosis and severe recurrent MR after mitral valve annuloplasty in 2016 with a 36mm Physio II ring.

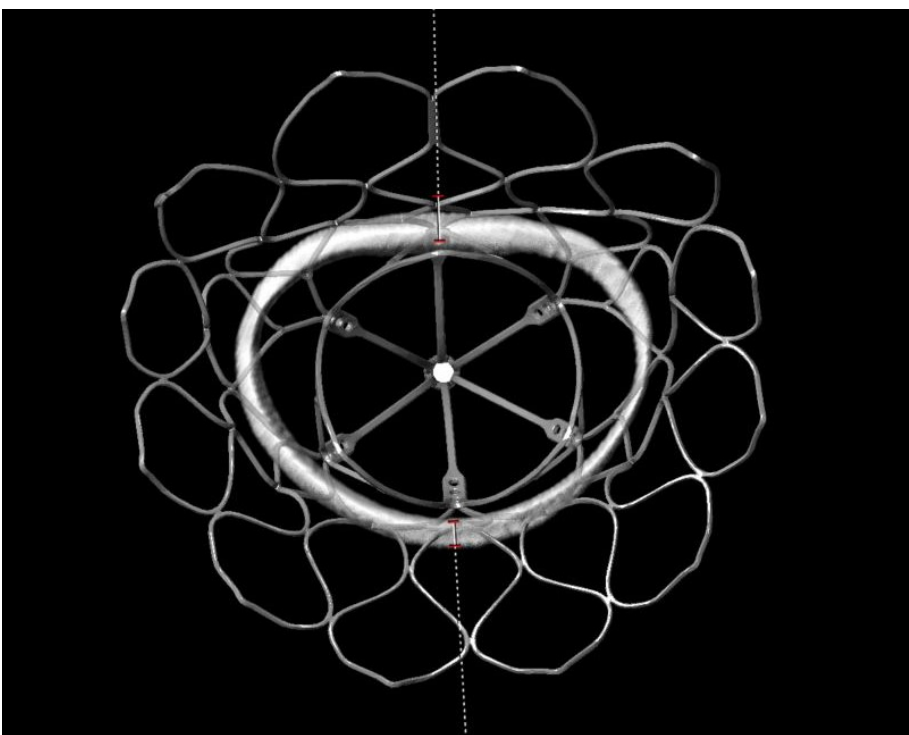
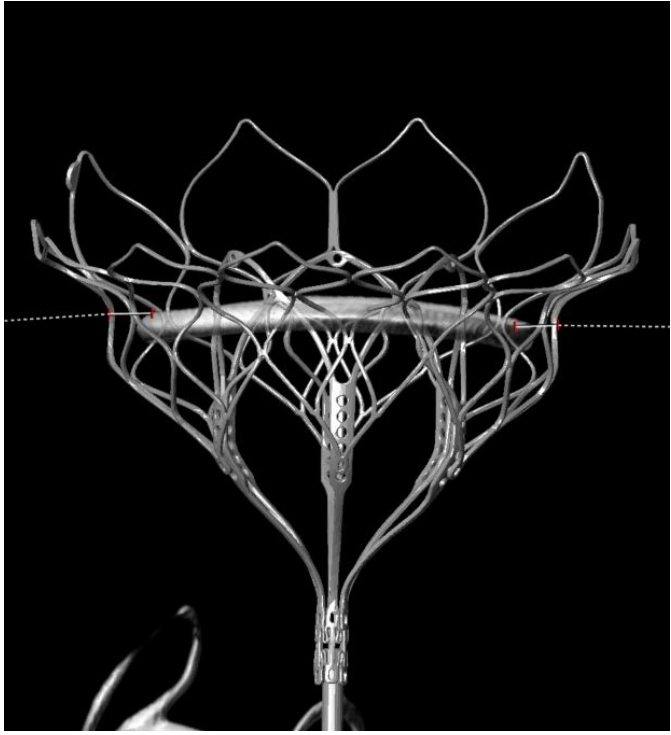
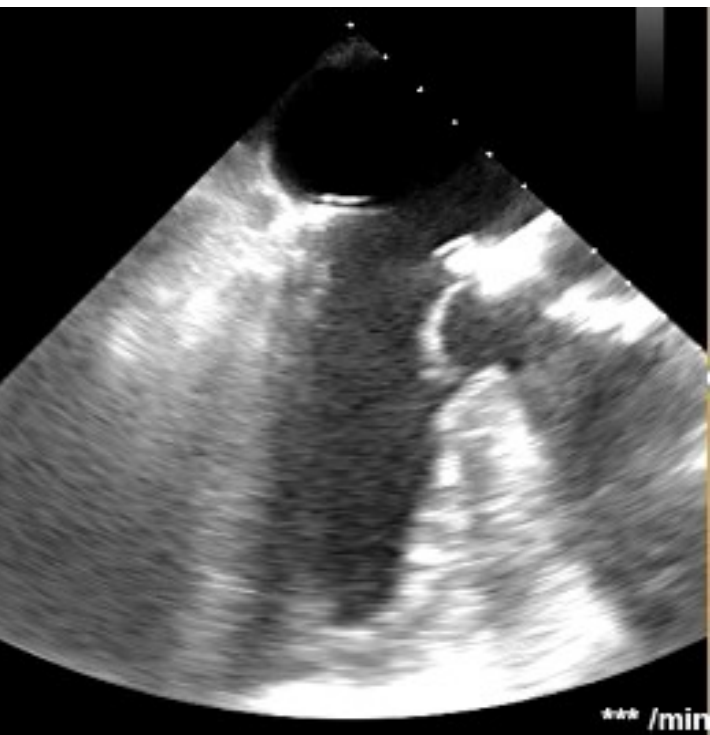


The patient was not eligible for a conventional surgical double valve replacement due to frailty.
The patient was not eligible for transcatheter mitral valve TEER due PML leaflet anatomy.



We opted for a simultaneous TAVR and off-label valve-in-ring TMVR using a transapical approach.

TMVR CT screening revealed a high-risk situation for dynamic LVOT obstruction with a neo-LVOT area of 700 mm2, a distance from the AML tip to the septum of 3 mm and an anterior mitral leaflet length of 31 mm.



To avoid a TMVR screening fail, we decided to additionally lacerate the AML using endoscopic scissors prior the implantation of the Tendyne© bioprosthesis.

Procedural details - TAVR

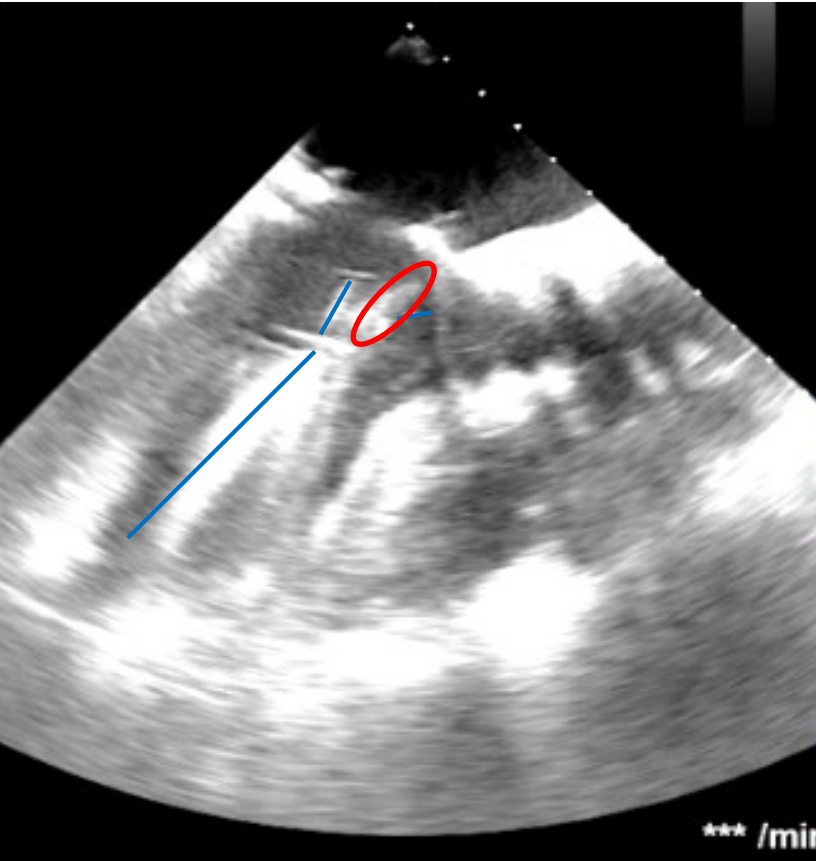
Since the apex access point differed between the TAVR and the TMVR, we chose the access best suited for the TMVR.

The procedure started with the TAVR, implanting an Edwards 29 mm Sapiens 3 valve using rapid right ventricular pacing

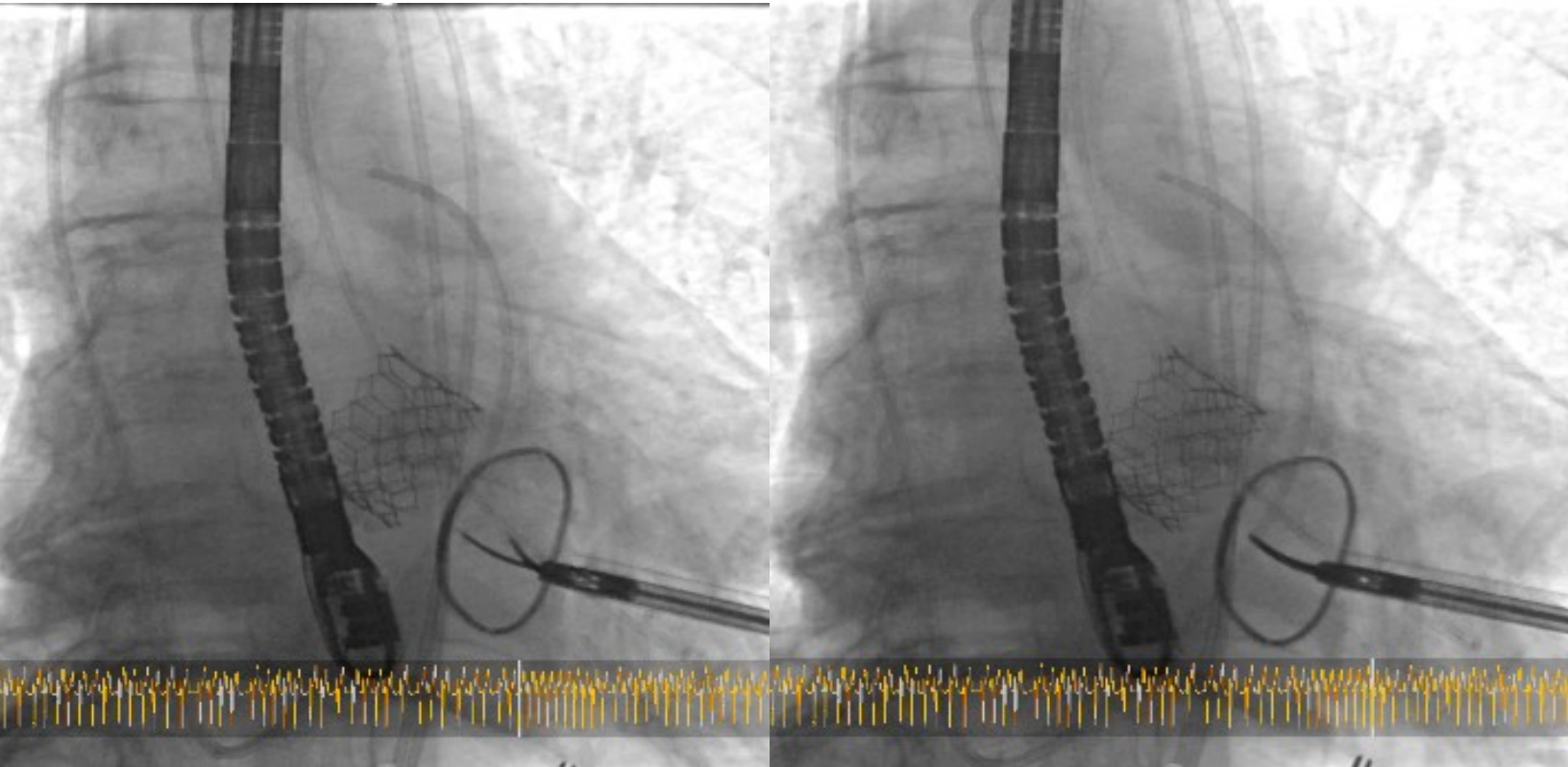
The intraoperative TEE showed normal valve function without any paravalvular leakage.

Procedural details - TMVR

Laceration of the anterior mitral leaflet using a 22 French sheath containing the endoscopic scissors.
Under x-plane TOE and fluoroscopic guidance, we opened the scissors aiming towards the middle of the A2 segment, successfully lacerating it.



Graphical representation of the endoscopic scissors with the blue lines and the AML encircled by the red line.



Fluoroscopy with the implanted TAVR, open and closed endoscopic scissors through the prior annuloplasty ring.



Successful AML laceration

Lastly, a 29 low-profile Abbott Tendyne© valve was implanted.

Case results:

- No signs of central or paravalvular mitral regurgitation
• No signs of LVOT obstruction
• Total procedure time (skin incision – completion of all procedure-related activities) 111 min
• The patient showed an uneventful postoperative course

Take-home message

These challenging cases of patients not eligible for any of the standard procedures demonstrate a possible expansion of the Tendyne© device implantation spectrum.

