

# Transcatheter Trans-Apical Closure of Paravalvular Mitral and Aortic Leaks Using a New Device: First in Man Experience

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This report describes the first use of a new paravalvular leak (PVL) device designed specifically to close paravalvular mitral and paravalvular aortic leaks. The first patient had severe paravalvular mitral leak that was closed using the transapical route with a rectangular designed PVL device that has an oval waist for self-centering and the second patient had moderate paravalvular aortic leak that was closed with a square designed device that has a round waist for self-centering. Both patients had complete closure.

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**Key words:** transcatheter; paravalvular leak; transapical; mitral; aortic

## INTRODUCTION

Paravalvular leaks are common complications after prosthetic/bioprosthetic valve replacement with an incidence ranging from 2–17% depending on the site of valve replacement [1–3]. Further, with the expansion of transcatheter aortic valve replacement (tAVR), paravalvular aortic leak has become increasingly important, especially, the clinical outcome may depend on the presence and severity of such leaks [4]. Effective therapy in patients in need of leak closure can be accomplished using different devices (Amplatzer PDA device, Amplatzer VSD device, Amplatzer vascular plugs, coils, etc.) and different methods of approach, including percutaneous endovascular or transapical (percutaneous vs via thoracotomy) techniques [5,6]. Over the last few years, we have been using the transapical route exclusively for patients with paravalvular mitral leaks. Initially, our approach was percutaneous transapical, however, due to development of hemothorax in two patients, we modified our technique so that each patient will undergo limited thoracotomy at the intended site for exposure of the left ventricular apex, then under fluoroscopic and transesophageal echocardiographic guidance, the puncture is made in a pursestring suture site.

Because of lack of specifically designed devices for paravalvular leaks (mitral and aortic), we report on the first use of such a device in two patients with paravalvular leaks.

## CASE 1

A 34 year-old male patient who because of rheumatic heart disease five years ago underwent both aortic and

mitral valve replacement using St. Jude mechanical valves, was admitted with shortness of breath, orthopnea, and decrease in functional capacity. He also complained of fatigue. His blood pressure was 100/60 mm Hg. There was a sinus rhythm on ECG. He had hemolytic anemia due to severe hemolysis requiring repeated blood transfusions. Two-dimensional transesophageal echocardiography detected severe mitral paravalvular leak. The site of the leak was identified by transthoracic and transesophageal echocardiography and was at the anterolateral border of the St. Jude valve, close to the left atrial appendage (Fig. 1).

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Conflict of interest: Dr. Hijazi is a consultant for Occlutech, manufacturer of the device.

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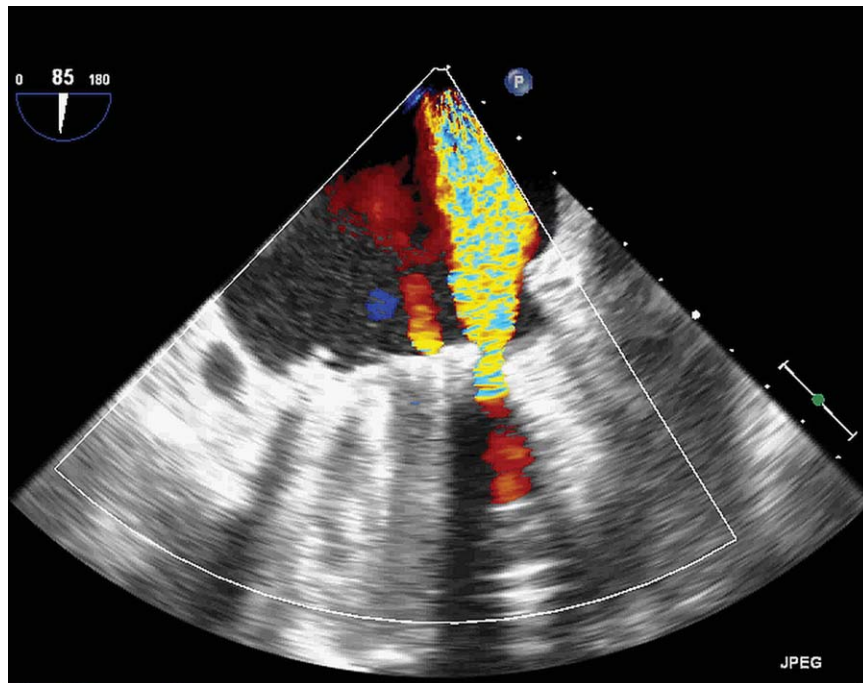


Fig. 1. Transesophageal echocardiography showed severe paravalvular leak of mitral prosthesis.

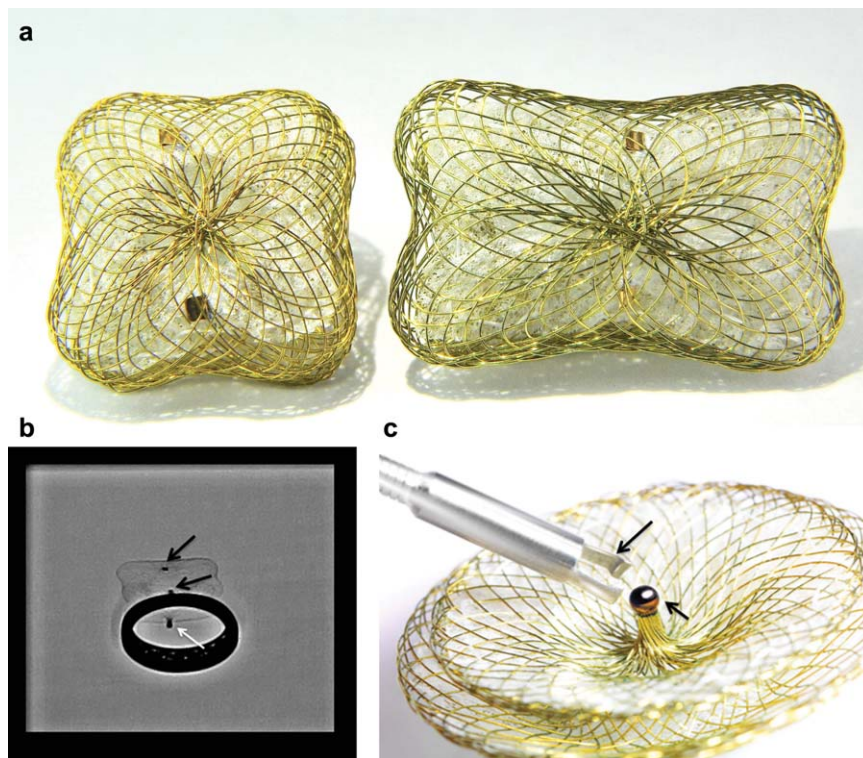
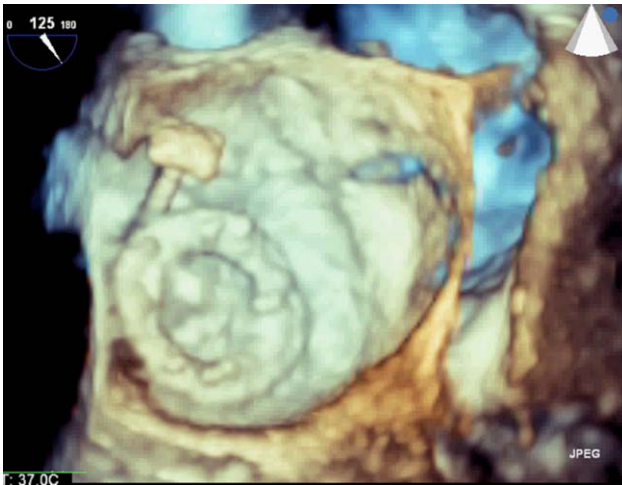


Fig. 2. (A) Photos of the two designs of the device. On the left hand side is the square shaped design and on the right the rectangular shaped design. (B) Cine fluoroscopy of the rectangular device ex-vivo showing the two markers on one disk (black arrows) and the hub where the delivery cable attaches (white arrow). (C) The Flex delivery cable attachment mechanism as shown for the Occlutech Figulla Flex device. Short black arrow (ball), attaches to the delivery cable end (longer black arrow) that is similar to a biopptome.

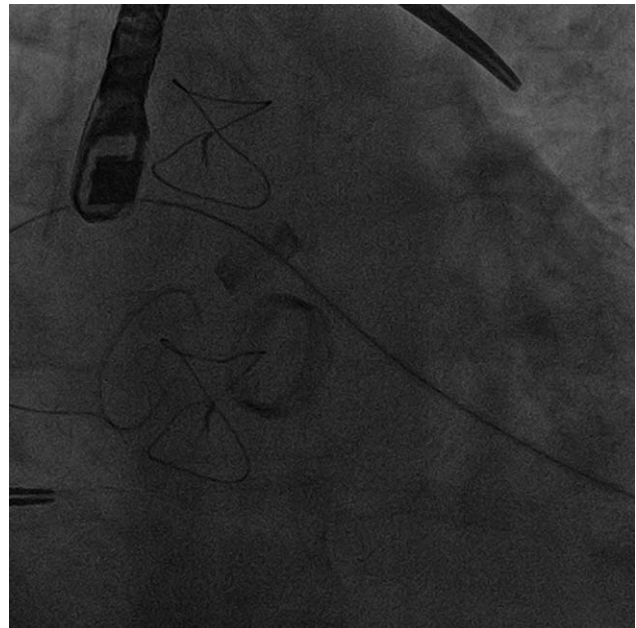


**Fig. 3.** 3D Transesophageal echocardiography showed the PVL closure device in the left atrium at the 10 O'Clock position. [Color figure can be viewed in the online issue, which is available at [wileyonlinelibrary.com](http://wileyonlinelibrary.com).]

Further, he developed hemorrhagic stroke that he sustained a year prior to the procedure. Because of his higher surgical risk, a transcatheter approach was offered to the patient. Because of the lack of a specifically designed device for leaks, the patient was offered to have his leak closed using a novel device designed specifically for paravalvular leaks. The patient was consented after the local ethics committee and the local regulatory agency have approval the use of this device.

### Device

The Occlutech PVL device (Occlutech GmbH, Istanbul, Turkey) is made of nitinol braided mesh with a wire range between 67 and 107  $\mu\text{m}$  according to the device size with either rectangular frame two discs with ellipsoid waist or square frame with circular waist. The two discs are attached with a twist bundle of wires to suit the defect anatomy and to eliminate the risk of defect enlargement. Both the rectangular and square designs (Fig. 2A) have 35% decreased surface areas (compared to a circular design) on discs sides to reduce the possibility of overlapping with valve area and to enhance endothelialization. To eliminate the possible residual shunt, the waist is chosen exactly the same size as the defect size. There are two gold radio-opaque markers to indicate the disc frame position and the largest part of the elliptical waist (Fig. 2B). This provides the implanting physician accuracy in positioning the device correctly in the paravalvular defect as seen by fluoroscopy. Further, 3D TEE images provide excellent tool to localize and guide the position of the device (Fig. 3). The device is available in different sizes ranging from 3 to 7 mm with circular waist for the square device that requires 5–7 Fr sheath and from  $4 \times 2$  to  $12 \times 5$  mm



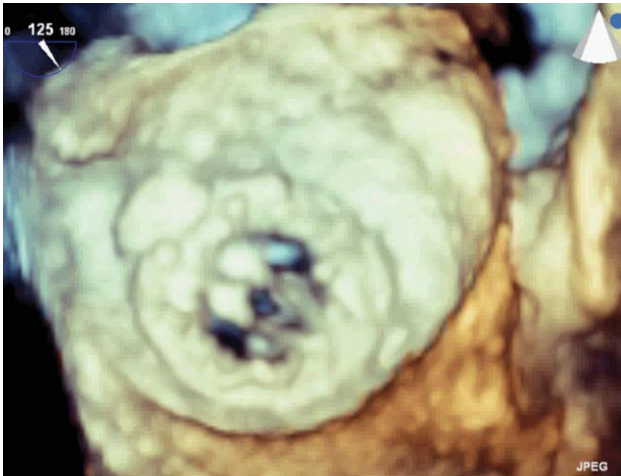
**Fig. 4.** Fluoroscopy showed that Terumo guide wire was manipulated across the leak and the catheter was advanced over the wire to the left atrium.

for the rectangular device that requires 5–8 Fr sheaths for delivery. Both designs are available for transapical or endovascular delivery and both use the Flex delivery cable for deployment. The Flex delivery cable does not involve a screwing mechanism, rather the device end has a ball that fits in a socket sleeve, somewhat similar to a biopptome (Fig. 2C). Once the device end is attached to the cable end, to prevent premature release of the device, the handle of the cable is tightened. Once the device is in good position, this security mechanism is activated to release the device.

### Procedure

The procedure was performed under general endotracheal anesthesia. The apex of the heart was exposed via limited thoracotomy. A purse string suture was placed near the apex of the heart (site was chosen to be perpendicular to the site of leak as chosen by TEE). A 7 Fr short sheath was inserted in the purse string suture. A 5 Fr Judkins right catheter was introduced into the LV cavity. Under fluoroscopic and TEE guidance, a 0.035" Terumo guide wire was manipulated across the leak and the catheter was advanced over the wire to the left atrium (Fig. 4). Then the catheter and short sheath were replaced with a 7 Fr Ansell delivery sheath (Cook Medical, Denmark). A rectangular PVL device with a ellipsoid waist of  $8 \times 4$  mm from Occlutech was delivered under fluoroscopic and TEE guidance. To completely align the disc of the device with the longitudinal surface of the leak, both discs were

initially deployed in the left atrium, this allowed the two discs to rotate free and to align them parallel to the leak, then the left ventricular disc was recaptured and then redeployed in the left ventricle side of the leak. This ensured that the entire leak was covered by the two disks (Fig. 5). Repeat TEE revealed the device to be in good position and minimal flow was present. Therefore, the device was released and few minutes later, repeat TEE revealed good position and no residual shunt (Fig. 6). Sheath was removed and purse string suture tightened and the chest was closed in the usual fashion. The patient was discharged home in few



**Fig. 5.** PVL device covered the paravalvular leak as shown by 3D Transesophageal echocardiography, same position as Fig. 3.

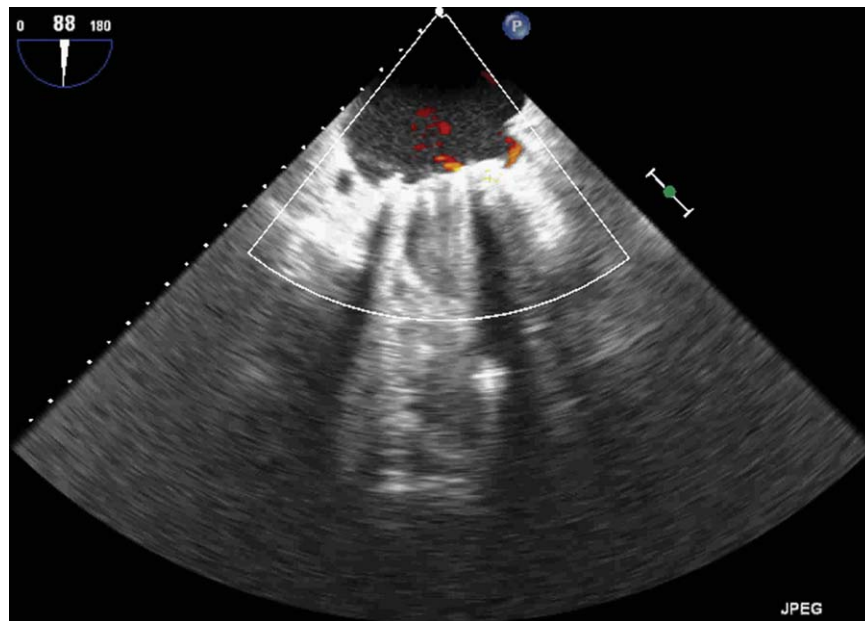
days on antiplatelet therapy (Aspirin) in addition to his Coumadin. On follow-up, at 4 months he has been doing well with no signs of hemolysis. Transesophageal echocardiography demonstrated the device to be in good position and no paravalvular leak (Fig. 7).

## CASE 2

A 67-year-old man was admitted to hospital with shortness of breath, paroxysmal nocturnal dyspnea. He also complained of generalized fatigue. Five years prior to this admission, he underwent aortic valve replacement using St. Jude mechanical valve because of severe aortic stenosis. His blood pressure was 110/45 mm Hg. He was in sinus rhythm. He had evidence of hemolytic anemia requiring repeated blood transfusions. Two-dimensional transesophageal echocardiography detected severe aortic paravalvular leak. 3D TEE images, demonstrated a posteriorly located paravalvular defect. Further, he also developed hemorrhagic stroke a year prior to the procedure. Because of his higher surgical risk, this novel device designed specifically for paravalvular leaks via transcatheter approach was offered to the patient. The patient was consented after the local ethics committee and the local regulatory agency have approval the use of this device.

## Procedure

The procedure was done under general endotracheal anesthesia and TEE guidance, the right femoral artery



**Fig. 6.** 2D Transesophageal echocardiography image immediately after the device has been released showing no residual shunt.

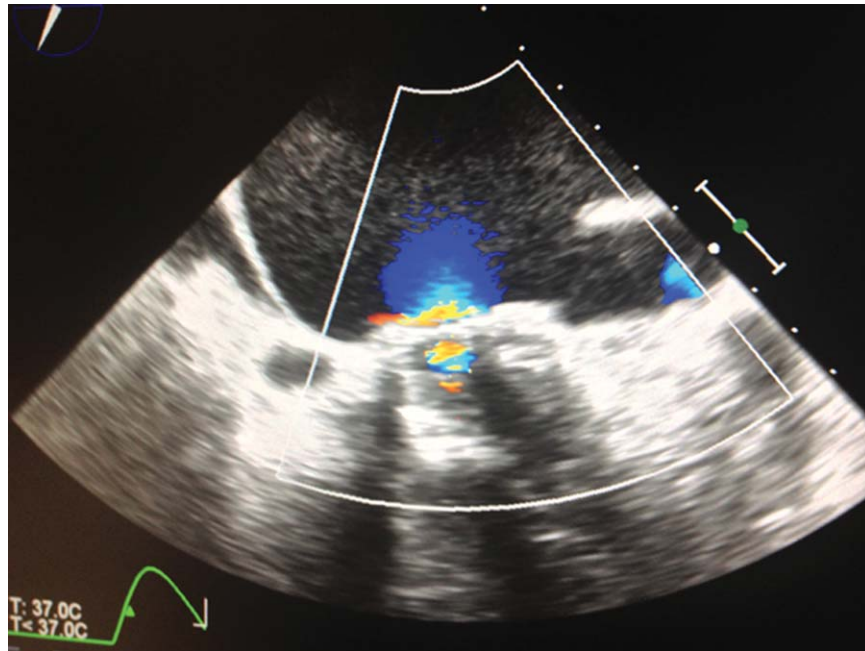


Fig. 7. Four months follow-up 2D transesophageal echocardiography image showing trivial paravalvular leak.

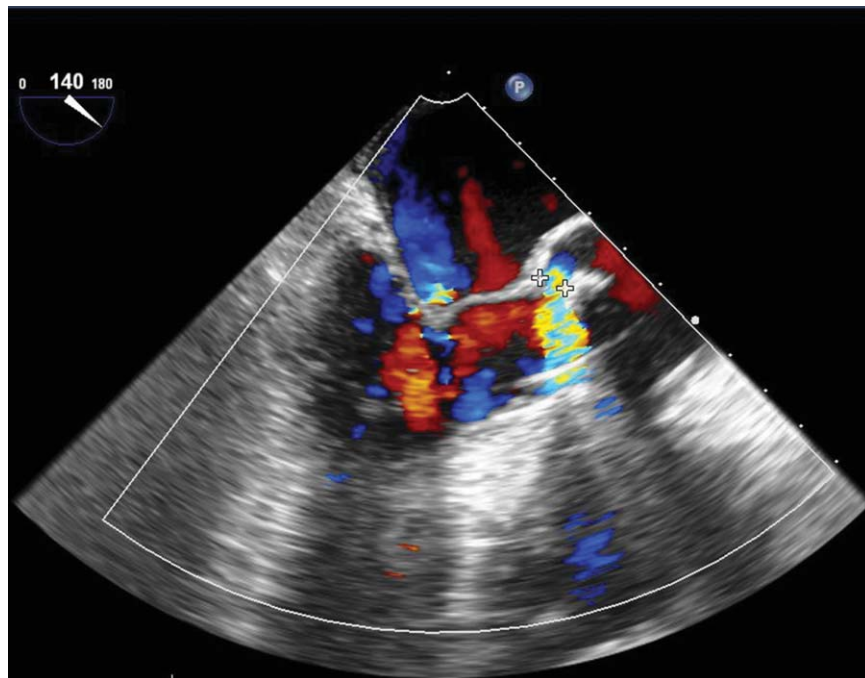
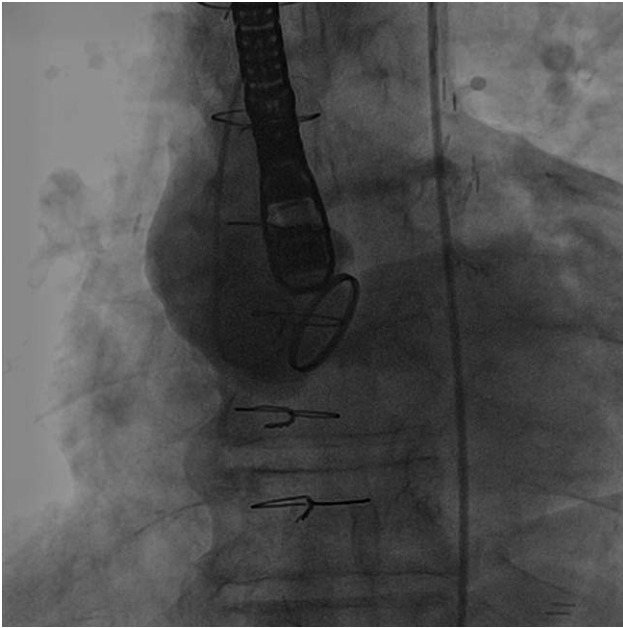


Fig. 8. Transesophageal echocardiography showed moderate to severe paravalvular leak of prosthetic aortic valve.

was accessed using a 7 Fr short sheath. TEE revealed the presence of a posterior leak (Fig. 8). An ascending aorta angiogram was done that revealed presence of severe paravalvular aortic regurgitation (Fig. 9). Using a 0.035" Terumo guide wire, the leak was crossed and

a 7 Fr JR guide catheter (inner lumen is 0.074") was advanced over an Amplatz extra stiff guide wire to the left ventricle cavity. A square designed device with a circular waist of 7 mm was used to close the leak. Repeat ascending aorta angiogram revealed good



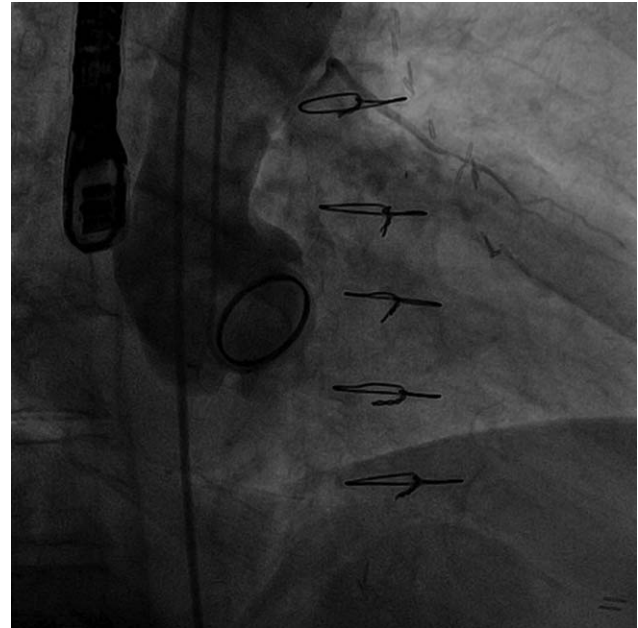
**Fig. 9.** Aortography showed moderate to severe aortic regurgitation before the procedure.

device position and minimal residual shunt (Fig. 10) that disappeared few minutes later as documented by TEE (Fig. 11). This patient is also doing well with no signs of hemolysis, at 4 months' follow-up. Echocardiography demonstrated good device position and trivial paravalvular leak.

## DISCUSSION

Paravalvar mitral and aortic leaks after surgical valve replacement is not uncommon, with an incidence varying between 2% and 17% [1–3]. Patients with significant leaks may present with heart failure and or hemolysis. Repeat surgery for such leaks carry certain risk of morbidity and mortality [7], as well as recurrence of the leak. Therefore, a transcatheter approach is welcomed by both surgeons and patients.

Transcatheter approach has been reported for the first time in 1992 using umbrella type devices with good results [8]. Since then, a multitude of devices have been used to close paravalvar mitral and aortic leaks [5,6,9]. The major issue using such devices that were designed to close different defects (ASD, PDA, VSD) for the purpose of closing such leaks is the high incidence of residual shunt [5,6]. Therefore, having a device specifically designed to close such leaks should bring with it lower incidence of residual shunt. An ideal device that should be used to close paravalvular leaks (mitral and aortic) should possess the following criteria: the device should be user/patient friendly; should achieve complete closure; should be repositionable/retrievable; should not interfere



**Fig. 10.** Aortography showed mild paravalvar regurgitation after the device has been released. The device is at 7 O'Clock position.

with prosthetic valve leaflets; should not be thrombotic; should require small delivery sheath (so that in tight and tortuous leaks, one can advance a small catheter for delivery); and last but not least not interfere with flow dynamics should embolization occur.

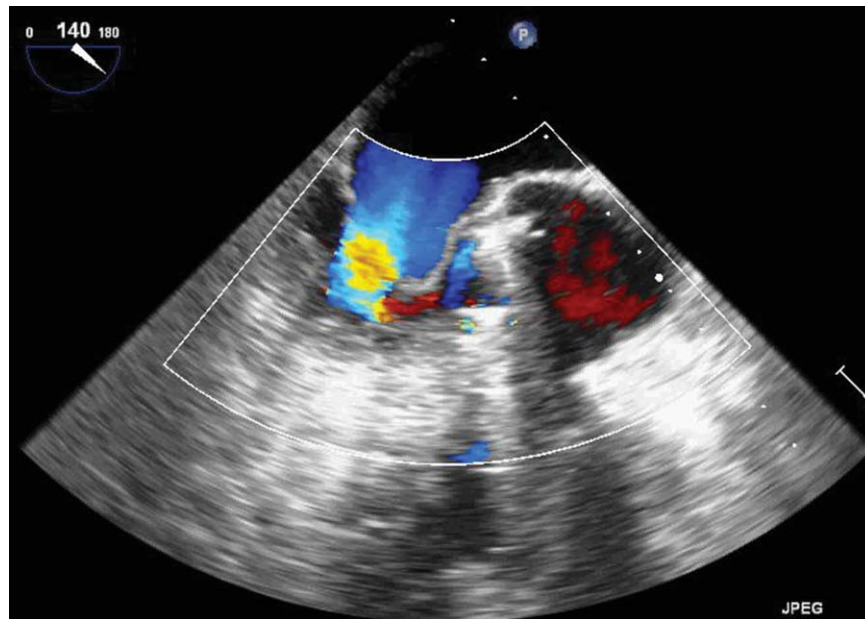
The Occlutech PVL device is designed to meet such wish list. The designs of the device allow one to align it over the leak and therefore the ability to achieve complete closure. The device can be delivered from various routes (transapical, transfemoral) using small delivery catheters. The two cases performed for the first time highlight the versatility of this device. In the mitral case, a rectangular shape device was important to cover the crescent shape defect and in the aortic case, a square shaped device with a round waist was needed and in both complete closure was achieved. The presence of gold markers in the device enhanced the visibility of the device and accurate deployment across the defect.

## CONCLUSION

The Occlutech PVL devices are designed specifically for the mitral and aortic para valvar leaks and they seem to be working very well. These devices will undergo further trials before widespread dissemination.

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**Fig. 11.** Transesophageal echocardiography image showing mild residual paravalvar regurgitation immediately after the device has been released.

his ingenuity designing such a device. Also, we want to thank the entire staff of the cath lab at Bezmialem University for their help during the procedures.

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