Percutaneous atrial septal defect closure with the Occlutech Figulla Flex ASD Occluder.

First case with a novel delivery system.

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Case report

A 46 year old male was referred to our hospital with progressive dyspnea (NYHA III) and palpitations. There were no medical antecedents, except nicotine and alcohol abuse. He did not take any medication.

Physical examination revealed clinical signs of left and right heart failure, a normal blood pressure, and a persistent irregular pulse. Chest X-ray at admission showed an enlarged heart (figure 1A), the electrocardiogram documented atrial fibrillation (figure 2). Liver tests were only slightly disturbed, but NT-proBNP was increased to 1588 ng/l (normal < 172 ng/l). Transthoracic echocardiogram showed an impaired left ventricular function (EF 45%), a dilated right ventricle, and mild pulmonary hypertension. Both atria were enlarged.

Heart failure treatment was initiated (ACE-inhibitor, bètablocker, spironolactone, and diuretics), and in advance for a direct current cardioversion, a transoesophageal echocardiogram was performed. The left atrial appendage was free of thrombi, and by chance a secundum type atrial septal defect was detected (figure 3). The cardioversion was successful, the patient was dismissed with heart failure treatment and oral anticoagulants, and percutaneous closure of the defect was scheduled.

Six weeks later, the patient was admitted for the intervention. Now, he functioned in NYHA II and no clinical signs of left or right heart failure were present. Unfortunately, the heart was irregular and atrial fibrillation was documented by an electrocardiogram. Oral anticoagulants were temporarily switched to a therapeutic dose of subcutaneous heparin.

The patient was taken to the catheterization laboratory, endocarditis prophylaxis and general anesthesia were applied. The femoral vein was punctured, a short 9 French sheath (Cordis, Miami, FL, USA) was introduced, and 5000 u of intravenous heparin were given. The atrial septal defect could be crossed with a 6 French Lehman catheter (Medtronic, Minneapolis, MN, USA), through which an Amplatz extra stiff wire 0.035” (Cook, Bloomington, IN, USA) was positioned into the left upper pulmonary vein. The Lehman catheter was removed and a PTS 30 mm sizing balloon (NMT, Boston, MA, USA) was advanced over the Amplatz wire, just at the atrial septal defect. The defect was sized up to 20 mm under transoesophageal monitoring. It was decided to implant a 21 mm Occlutech Figulla ASD Flex Occluder (Occlutech, Helsingborg, Sweden).

In the older version, the delivery wire is clockwise screwed in into a hub on the central part of the right sided disk (figure 4). There is always the potential risk for damaging the screwing in mechanism when the delivery wire is connected to the device. Unscrew problems might occur when the screw is fixed too tight into the hub or when the angle between the right sided disk and the axis of the delivery wire is too sharp. The latter might be also responsible for tension on the atrial septum, what can increase the risk of developing per-procedural arrhythmias. The new connector system might overcome these problems. The screw in
mechanism is replaced by a small connector which needs to be grasped by Flex-Pusher delivery system (figure 4 and figure 5).

After attaching to the Flex-Pusher delivery system, the device was loaded into a short 12 French sheath. The short 9 French sheath was replaced by a long 12 French sheath, and the device was advanced through the long sheath. Conform the delivery instructions, the left sided disk of the device was deployed in the left atrium, pulled against the atrial septum, and followed by the deployment of the right sided disk (figure 6A). Finally, the device was easily detached and because the axis of the device did not change after delivery, no or only low per-procedural tension on the septum was suggested (figure 6B).

At the end of the procedure, a left heart catheterization was done, which showed normal coronary arteries, and it was decided for a new direct current cardioversion, which was successful. The fluoroscopy time for the sizing and closing the atrial septal defect was less than 5 minutes.

The day after the procedure, the patient was dismissed from the hospital in sinus rhythm, clinically re-compensated (chest X ray, figure 1B), with a correct position of the septal occluder on transthoracic echocardiography (figure 7). It was decided to add a low dose of aspirin (80 mg) to the oral anticoagulants; the heart failure treatment was unchanged; prophylaxis of subacute endocarditis was proposed for at least 6 months.

**Summary**

This case illustrates the typical history of “by chance” detection of an atrial septal defect with its potential complications. The case documents also that percutaneous closure of the secundum type atrial septal defects can be considered as the first choice of treatment. Feasibility of the new Flex-Pusher delivery system of the Occlutech Figula ASD Flex Occluder has been shown.
**Figure legends**

Figure 1 A. Chest X-ray at admission. The heart is significantly enlarged, both pulmonary vascular hili were prominent.

Figure 2 A. Chest X-ray after treatment with heart failure medication, atrial septal defect occlusion, and sinus rhythm.

Figure 2. Electrocardiogram at admission. The electrocardiogram shows atrial fibrillation.

Figure 3. Transoesophageal echocardiogram. By transoesophageal echocardiogram, the secundum type atrial septal defect was detected (circular 1.5 cm). There was a moderate left to shunt with volume overload of the right ventricle (Qp/Qs 1.5/1).

Figure 4. Representation of the traditional hub, where the delivery wire has to screwed in. Representation of the Occlutech connector, which has to be grasped by the Flex-Pusher delivery system wire.

Figure 5. Flex-Pusher delivery system wire. Left sided; wire disconnected from the device, right sided, wire connected to the device.

Figure 6 A. 21 mm Occlutech Figula Flex ASD occluder implanted in the interatrial septum (white arrow), but still attached to the delivery system. The dotted line indicates the radial axis of the device.

Figure 6 B. 21 mm Occlutech Figula Flex ASD occluder implanted in the interatrial septum (white arrow). The dotted line indicates the radial axis of the device and is not changed after delivery after delivery.

Figure 7. Transthoracic echocardiogram, the day after device implantation (white arrow). The device was well fixed in the interatrial septum, no atrio-ventricular valve interference, no pericardial effusion.
Figure 1

A

B
Figure 5