

The Occlutech Figulla ASD Occluder: new device to close secundum atrial septal defects

Transcatheter closure using a device has become an alternative treatment strategy for a patient with an appropriate size secundum atrial septal defect (ASD). Until recently, the most widely used device was the Amplatzer Septal Occluder. Other devices used include: the Helex device (WL Gore), CardioSeal/Starflex (NMT Medical) and the Intrasept (Cardia Medical).

The Occlutech Figulla occluder is a new device recently approved and is being used with increasing frequency to close secundum ASDs.¹ We present a case of a patient with multiple defects who underwent closure with this device.

THE DEVICE

The Occlutech Figulla Occluder (Occlutech GmbH, Jena, Germany) is constructed from 0.082–0.186 mm Nitinol wires, tightly woven into two flat discs with a 4 mm connecting waist (Figure 1). The device gained CE approval in 2006. The Occluder is available in sizes ranging from 6–40 mm, generally in 3 mm increments, except for sizes 6–12 mm that are supplied in 1.5 mm increments and in 4 mm increments in the size range 36–40 mm. The left atrial disc is 12–16 mm larger and the right atrial disc is 8–10 mm larger than the connecting waist. One important feature in this device is the absence of the left atrial disc microscrew, a move that potentially decreases any chance of clot formation on the left atrial disc. The delivery sheath required varies from 9–14 Fr; however, for the smaller sizes (6–12 mm) an 8 Fr sheath can be used safely.

CASE STUDY

A female child aged four and a half years was confirmed as having secundum ASD, diagnosed after a heart murmur was detected on routine check-up. She was totally asymptomatic. At the time of the procedure, her weight was 17 kg. Her cardiac examination was remarkable for a grade II/VI systolic ejection murmur heard at the left upper sternal border. Her chest radiograph demonstrated mild cardiomegaly with mild increase in pulmonary vascular markings. Her transthoracic echocardiogram (TTE) demonstrated the presence of two ASDs and an enlarged right ventricle (end diastolic dimension = 20 mm).

The procedure was performed under general endotracheal anaesthesia with continuous transoesophageal echocardiographic (TOE) guidance. A 6 Fr sheath was inserted in the right femoral vein and haemodynamic assessment revealed normal right heart pressures. The Qp:Qs ratio was calculated at 2.4:1.

Detailed TOE was performed. This revealed the presence of two defects in the atrial septum, a 4 mm superior defect and an 8 mm inferior defect. There was a small rim of tissue measuring about 2–3 mm separating the two defects

(Figure 2). There were enough rims surrounding the defects. The superior rim measured 14 mm; the inferior rim was 7 mm, the posterior rim was 7 mm and the retro-aortic (anterior) rim was 6 mm. When colour Doppler was turned on, the width of the left-to-right colour jet was 14 mm (Figure 2). Balloon sizing to measure the stop flow diameter through the larger of the two defects revealed the diameter to be 14 mm with cessation of flow from the smaller defect. Therefore, a 15 mm Occlutech Figulla occluder was deployed using a 10 Fr Cook Mullins sheath. Assessment of device position by cine angiography prior to device release revealed a good position (Figure 3). Furthermore, TOE revealed a stable device position and no evidence of residual shunt (Figure 4). The fluoroscopy time was 8.9 minutes. Haemostasis was achieved and the patient was allowed to recover overnight. The following morning, TTE revealed good device position and no evidence of residual shunt. The patient was discharged home on 100 mg aspirin per day for six months.

DISCUSSION

Device closure of secundum ASDs has become routine practice. Only the Amplatzer device can be used to close large defects (>18 mm stretched diameter). The Occlutech Figulla Occluder is an alternative device that can be used to close small as well as large defects. The major advantages of this device are the absence of the left atrial microscrew, which minimises any chances for clot formation on the left atrial disc and the availability of this device in sizes from 6–40 mm in 3 mm increments.

This case illustrates the versatility of the Occlutech Figulla occluder in closing multiple defects using one device. The rim of tissue between the two defects was small, thus enabling us to use one device to close both defects. The device handles very well, in a similar fashion to the

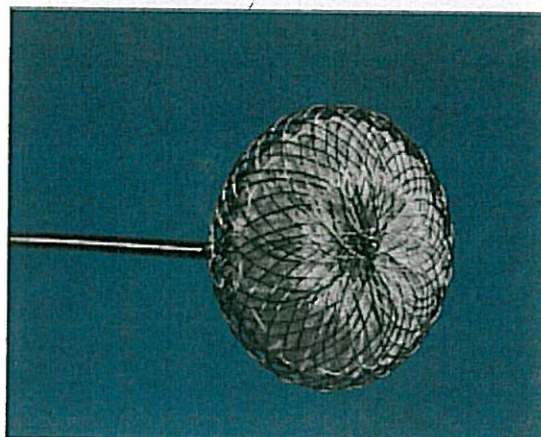


Figure 1. The Occlutech Figulla device. The device attached to the delivery cable. Note the absence of the microscrew in the left atrial disc.

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Figure 2. Transoesophageal echocardiographic images during assessment of the ASD. A, B, short axis view without (A) and with (B) colour Doppler demonstrating the ASDs. The large defect (long arrow) and the small defect (arrowhead). C, long axis view showing the defect with colour Doppler. LA: left atrium; RA: right atrium.

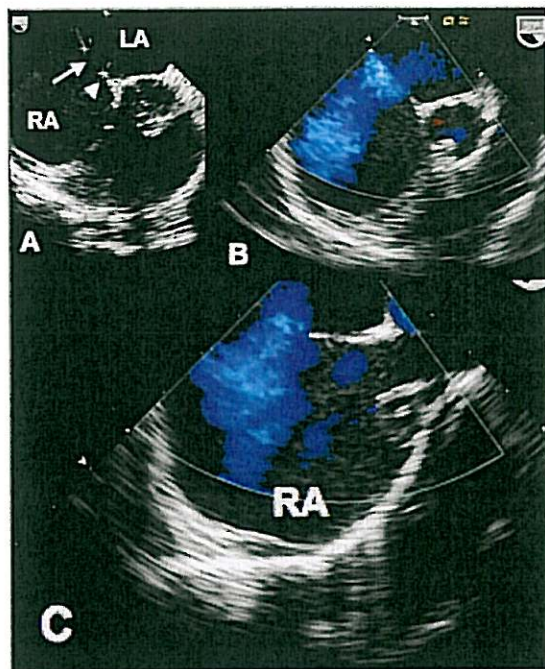


Figure 3. Transoesophageal echocardiographic images after the defect was closed with a 15-mm Occlutech Figulla device. A, short axis view demonstrating good device position. A and C, long axis view without (A) and with colour Doppler (C) showing good device position and no residual shunt. LA: left atrium; RA: right atrium.

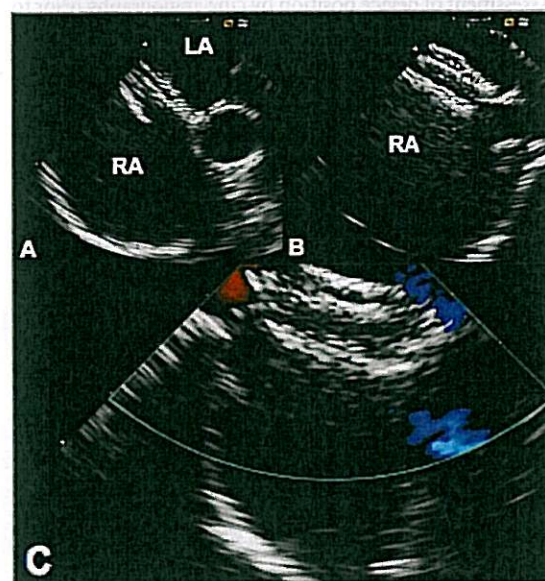
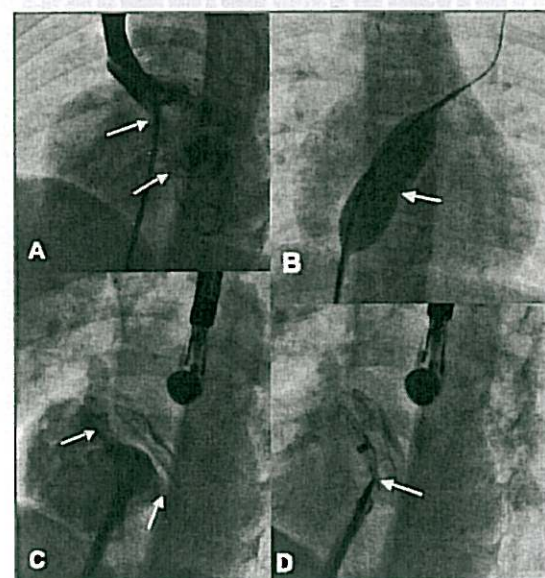


Figure 4. Cine fluoroscopic views during closure of the defect. All views except B, are in the hepatoclavicular projection (35° LAO/35° cranial), B is in straight frontal projection. A, angiogram in the right upper pulmonary vein demonstrating the presence of left-to-right shunt (arrows) via separate defects. B, cine fluoroscopy during balloon sizing. The arrow indicates the indentation in the balloon. C, angiography in the right atrium via the side arm of the delivery system showing that the right atrial disc (arrows) opacifies during the injection and the left atrial disc does not. This indicates good device position. D, cine fluoroscopy immediately after releasing the device from the delivery cable (arrow).



Amplatzer device, and can be recaptured after deployment of both disks and thus can be repositioned quite easily.

The only minor limiting factor is the size of the sheath required. It usually requires 2 Fr sizes bigger than the Amplatzer, but in our opinion this is of low concern since access is from the venous side.

For patent foramen ovale (PFO), the manufacturer has two types of PFO devices: the double layer Occlutech Figulla PFO occluder and the single layer Occlutech Figulla device (no Nitinol wire in the left atrial disc, just a polyester patch with a nitinol frame). The former device can be used similarly to the Amplatzer PFO device and is available in the following sizes: 16/18; 23/25; 27/30 and 32/35. The first number indicates the left atrial disc size and the second is the right atrial disc size.

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