Case Reports

A New Device to Close Secundum Atrial Septal Defects: 
First Clinical Use to Close Multiple Defects in a Child

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Transcatheter device closure of secundum atrial septal defects (ASD) has become an
accepted treatment modality. Currently, the only device that can be used for large
defects is the Amplatzer Septal Occluder. We report on a new device (Occlutech
Figulla), to close multiple ASDs in a child with two large defects using 12 and 15 mm
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Key words: device; interventional; ASD

INTRODUCTION

Percutaneous closure of atrial septal defects (ASD) is a safe procedure and has been routinely performed in children and adults using many devices including the Amplatzer Septal Occluder (ASO), The Helex device, The CardioSeal/Starflex devices, and the Cardia Intraspect device. Certain characteristic features should be present in any device that is expected to be widely used for catheter closure of ASD, including the ability to recapture and redeploy the device before its release from the delivery system if the device position is not optimum; the device should possess the self-centering ability that leads to high closure rates and among others the ability to close wide range of defects, from small to large (few millimeters-36 mm) sizes. Currently, the ASO is the most widely used device because of the above features that it meets. A new device (Occlutech Figulla) was recently introduced for closure of secundum ASD. In this article, we describe the features of this device and compare it with the ASO and report the use of two devices to close multiple defects in a child.

The Device

The Occlutech Figulla device (Occlutech GmbH, Jena, Germany) is constructed from 0.082 to 0.186 mm Nitinol wires, tightly woven into two flat disks with a 4 mm connecting waist (Fig. 1). The device diameter is dictated by the diameter of the waist and is available in sizes ranging from 6 to 40 mm with a 3 mm increment, except from size 6 to 12 in 1.5 mm increments and in 4 mm increment from 36 to 40 mm. For device sizes 6–9 mm (waist), the left atrial disc is 12 mm and the right atrial disc is 8 mm larger than the waist; and for device sizes 12–21 mm (waist), the left atrial disc is 14 mm and the right atrial disc is 10 mm larger than the waist and for devices 24–33 mm (waist), the left disk is 15 mm and the right disc is 11 mm larger than the waist and for device size 36 mm (waist), the left disc is 16 mm and the right disc is 10 mm larger than the waist and for device size 40 mm (waist), the left disc is 15 mm larger and the right disc is 10 mm larger than the waist. The prosthesis is filled (left and right disc and the connecting waist) with a polyester patch (thickness of 30–45 μm) to enhance thrombogenicity. There is only one stainless steel hub (microscrew) at the right atrial disc for cable connection (Fig. 1). The delivery sheath required ranges in size from 9 to 14 Fr (devices size 6–9 mm require 9 Fr; devices size 12 & 15 mm require 10 Fr; devices size 18–27 mm require 12 Fr; and devices size 30–40 mm require 14 Fr). The most unique features of this device are the absence of the left atrial stainless

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steel hub and the ability to reposition the device after deployment of the left and right atrial discs, before device release.

Case

An 8-year-old female child was diagnosed to have secundum type atrial septal defect at age 5 years after a heart murmur was detected on routine check up. She was totally asymptomatic. Her cardiac examination was remarkable for normal S1 and fixed splitting of S2 with grade II/VI systolic ejection murmur heard at the left upper sternal border. Her electrocardiogram (EKG) was remarkable for right axis deviation and incomplete right bundle branch block. Transthoracic echocardiography (TTE) revealed the presence of left to right shunt at the atrial level via perhaps two atrial septal defects (ASDs). She had right atrial enlargement and right ventricle volume overload (RVEDD = 26 mm). The procedure was performed under general endotracheal anesthesia with continuous transesophageal echocardiographic (TEE) guidance. Her weight was 32 kg and the venous access was obtained from the right and left femoral veins using two 9 Fr sheaths. The right heart pressures were normal and the calculated Qp:Qs ratio was 1.8:1. TEE revealed the presence of two separate defects with a rim of tissue measuring >8 mm between the two defects. The superior anterior defect measured 8 mm and the inferior posterior one measured 11 mm (Fig. 2). Initially, both defects were crossed separately and balloon sizing using the AGA sizing balloon (AGA Medical Corp., Plymouth, MN) revealed the “Stop-flow” diameter of the balloons were 11 and 13 mm for the anterior/superior and inferior/posterior defects respectively (Fig. 3). The proper size delivery sheaths (9 Fr) were positioned across each defect and a 12 mm and a 15 mm Occlutech Figgula devices were loaded and deployed similar to the technique used for closure of multiple ASDs using multiple Amplatz devices [1,2]. Figures 2 and 3 demonstrate the steps of closure in this patient using transesophageal echocardiography and fluoroscopy, respectively. Once both devices were deployed and before release, repeat TTE and fluoroscopy demonstrated good devices position. Both devices were released sequentially starting with the smaller superior/anterior device. The fluoroscopy time was 12.7 min and the total procedure time was 90 min. The following day, repeat TTE demonstrated good devices position and no evidence of residual shunt or any complication. The patient was discharged home the following day on 100 mg aspirin per day for 6 months. At one-month follow-up, the cardiac examination was normal, the EKG was remarkable for slight intraventricular conduction delay and minimal right axis deviation. Repeat TTE demonstrated the devices
Fig. 2. Transesophageal echocardiographic images during closure of multiple atrial septal defects. A and B: View without and with color Doppler in between short and long axis demonstrating two defects (arrows) with left-to-right shunt. The superior/anterior defect measured approximately 8 mm and the inferior/posterior defect measured 11 mm. C and D: Without and with color Doppler after deployment of the first device (12 mm) in the superior/anterior defect. Note, the shunt via the inferior/posterior defect. E and F: The second device (15 mm) has been deployed but not released yet (E) and after both devices have been released (F) demonstrating good device position. LA, left atrium; RA, right atrium. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

Fig. 3. Fluoroscopic images during closure of the two defects. (A, E, F, and G) in hepatoclavicular projection and (B, C, D, and H) in straight frontal projection. A: Angiogram in the right upper pulmonary vein demonstrating two atrial level shunts (arrows). B: Cine during balloon sizing of both defects. Note the indentation in both balloons (arrows). C: Cine image during passage of two 9 Fr delivery sheaths via the defects into the left atrium (arrows). One device already has been passed inside the superior sheath. D: Cine image after the first device (12 mm) (arrow) has been deployed but not released. E: Cine image after the second device (15 mm) has been deployed (arrow). Note both devices are still attached to their delivery cables. F: Angiogram via the side arm of the delivery sheath demonstrating good device position. G: Cine image after the first device has been released from the delivery cable (arrow) while the second device was still attached. H: Cine image after both devices have been released.

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to be in good position and no evidence of residual shunt. The RVEDD was 20 mm.

DISCUSSION

Transcatheter closure of secundum ASDs with the Amplatzer Septal Occluder (ASO) implantation in pediatric and adult patients has a high success rate and excellent results that have been documented in several studies [3–10]. The ASO is the most widely used device in the world. The Helix device received US Food and Drug Administration approval to close defects up to 18 mm stretched diameter. This leaves no alternative device that can be used for both small and large defects. The Occlutech Figulla device is another device designed to close the full range of defects. Although it looks similar to the Amplatzer device, there are important differences between the two devices. The ASO is made up of a Nitinol wire tube that is clamped in two stainless steel hubs, one on each side of the disc. In contrast, the Occlutech Figulla device is individually braided, avoiding a distal clamp. This may be of potential benefit to decrease the chance of a clot formation on the left atrial disc and increases flexibility of the device. Further, the Occlutech Figulla device is available in 14 separate sizes compared with the ASO that is available in 27 different sizes. This is important when cost is an issue. We believe that the Occlutech Figulla device should perform similar to the ASO in terms of acute and long-term results and complication rate. There will be no learning curve using this device since the implantation technique is similar to the ASO.

Further, as we have seen in this patient, this device can be used to close multiple defects with good results.

The manufacturer also has developed another device that can be used to close patent foramen ovale. This device is available in two formats: double layer and single layer devices. The double layer device is similar in design (except the absence of the left atrial disc hub) to the Amplatzer PFO device and the single layer device has no Nitinol wire mesh in the left atrial disk, just the polyester patch with Nitinol frame, thus potentially less thrombogenic.

In conclusion, the Occlutech Figulla device is another alternative septal occluder that can be used to close full range of secundum type defects.

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REFERENCES