Mid-Term Outcomes after Percutaneous Closure of the Secundum Atrial Septal Defect with the Figulla-Occlutech Device

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Objectives: To evaluate the mid-term outcomes after percutaneous closure of the secundum atrial septal defects (ASD) using the Figulla-Occlutech device (FOD).

Background: Transcatheter closure has become the method of choice for most patients with ASD. Although the FOD may have some advantageous characteristics there is a paucity of data on later outcomes after the use of this relatively new device.

Methods: Observational, single arm study including 200 non-consecutive patients who underwent ASD closure between 04/09 and 07/15 in 2 centers. Device performance, deployment technique, and immediate and mid-term outcomes were assessed.

Results: Median age and weight were 24 years (4–72) and 58 kg (15–92), respectively. Single defects were observed in 171 patients (median size of 19 mm). The remainder had multiple or multifenestrated defects. Implantation of FOD (median size of 24 mm) was successful in all (99%), but 2 patients (1 with deficient postero–inferior rim; 1 with a large ASD for the size of the child). Embolization with device retrieval occurred in 2 (1%). Median follow-up of 36 months was obtained in 172 patients. Serial echocardiographic assessment showed complete closure in all but 2 patients, in whom an additional small non-significant posterior defect was purposely left untouched. There have been no episodes of late arrhythmias, device embolization, cardiac erosion, endocarditis, thromboembolism, wire fracture, or death.

Conclusions: Transcatheter closure of ASDs in older children, adolescents, and adults using the FOD was highly successful in a wide range of anatomical scenarios with high closure rates and no complications in mid-term follow-up. (J Interven Cardiol 2015;9999:1–8)

Introduction

The secundum atrial septal defect (ASD) is a common congenital heart defect (CHD), especially in adults.1 Most of these defects are amenable for transcatheter closure, which became the method of choice to treat most patients due to its safety and efficacy with excellent mid-to-long term outcomes.2–5 Although cardiac erosions may occur after the use of the Amplatzer Septal Occluder (ASO),6 this complication is very rare. The Figulla-Occlutech device (FOD; Occlutech, Jena, Germany) is relatively new, being a nitinol double-disk occluder with a self-centering...
mechanism provided by a central connecting waist. Although it was introduced in the mid-to-late 2000, there is a paucity of data in the literature with regards to the follow-up results after the use of such device.7–16 In this manuscript, we report the acute and mid-term outcomes in a large cohort of patients who underwent ASD closure using the FOD in 2 institutions.

Methods

Study Design. This is an observational study of a cohort of patients with secundum ASDs who underwent transcatheter closure of the ASD in a non-consecutive fashion using the Figulla-Occlutech occluder (FOD) in 2 referral centers. Data were collected retrospectively from the charts. Informed consent was obtained from patients or guardians. This study was approved by the local ethics committees.

Inclusion criteria included children, adolescents, and adults with a clinical diagnosis of single or multiple ASDs with left-to-right shunt and right ventricular volume overload on echocardiography. Exclusion criteria included other types of ASDs (sinus venosus, ostium primum); associated cardiac diseases that required surgical repair; pulmonary vascular resistance of greater than 8 Woods Units X m$^{-2}$; active infectious diseases; allergy to nickel; contraindication to anti-platelet therapy and refusal to sign the informed consent. Also excluded were secundum ASDs that were considered unsuitable for transcatheter closure including too large defects in adults (generally over 36 mm); too large an ASD in relation to the size of the patient, especially in small (10–15 kg) children in whom a large device could impair proper functioning of AV valves, pulmonary veins and coronary sinus; and ASDs with more than 1 deficient rim, especially contralateral rims. In patients >60 years, left ventricular diastolic dysfunction was assessed by echo means pre- and post-balloon occlusion of the defect, as reported previously.17,18 Diuretics and/or vasodilators were given before the procedure if judged necessary.

Transthoracic echocardiography (TTE) was employed for children and transesophageal echocardiography (TEE) for adolescents and adults to assess suitability for transcatheter closure. Patients were started on aspirin (3–5 mg/kg/day; max: 200 mg) a couple of days before the procedure.

The Device. The FOD is made of a Nitinol wire mesh with shape-memory properties.7–16 Two self-expandable discs are connected by a flexible connecting central waist. Two ultrathin non-woven fabrics made of PET help close the defect and provide growth of the endothelium over the occluder after placement (Fig. 1). They are individually braided using very thin (40–150 μm or 0.00157–0.00590 inches) and numerous strands of Nitinol (80 in total), which are covered by a biocompatible titanium oxide layer giving the Figulla-Occlutech occluder a golden appearance. All strands end proximally on a single weld on the right side requiring no clamp on the left disk (Fig. 1A).

![Figure 1. The Figulla-Occlutech Device.](image)
In its first generation, the FOD was connected to the delivery cable through a male–female screwing mechanism. Newer generations (Flex I available since 2010 and Flex II available since late 2014) do not have any threaded hub or clamp. Instead, they have a rounded pin (the connecting ball) at the center portion of the right atrial (RA) disc, which connects to a newer delivery system through a coupling mechanism, similar to a bioptome. This allows a tilted angle of ~30–40 degrees on the right disk before final release (Fig. 1B). Both generations of devices were used in this experience. After connection to the delivery system, the device is loaded and collapsed into a short sheath with the same profile of a compatible long delivery sheath (7–14 Fr). Once in a proper position, the occluder is released by unscrewing the delivery cable (1st generation) or by releasing the locking system (2nd generation).

The ASD device size is determined by the diameter of its waist, which is 2.5–3.5 mm long. The FODs are available in the following sizes: 4, 5, 7.5, 9, 10.5, 12, 13.5, 15, 16.5, 18, 21, 24, 27, 30, 33, 36, 39, and 40 mm. The LA disc is 7–16 mm and the RA disk is 5–11 mm larger than the waist depending on the size of the device.

In the occasional patient with a cribiform septum, the Figulla-Occlutech PFO device was used. They are available in 4 sizes: 16/18, 23/25, 27/30, and 31/35. The numbers are related to the diameters of the left and right discs, respectively.

Procedures. They were performed under general endotracheal anesthesia and 2- (2D; Fig. 2) or 3-dimensional (3D) TEE monitoring (Figs. 3 and 4). This later technology was especially useful for evaluation of complex defects (very large or multiple; Figs. 3 and 4). The right femoral vein was cannulated using a 5–7 Fr short sheath. The left femoral vein was also cannulated when 2 different devices were required (Fig. 2). Arterial access was obtained using 6 Fr sheaths solely in patients >40 years of age to perform coronary angiography. Heparin sulfate (100–150 U/kg; max: 10,000) was given to achieve an activated clotting time >200 seconds. Cephalosporins were given at the time of procedure followed by 2 subsequent doses 6–8 hours apart. Routine right heart catheterization was carried out to rule out fixed pulmonary arterial hypertension.

Balloon interrogation of the defect was performed in all cases early in our experience using the NuMED sizing balloon (PTS balloon; Numed: Cornwall, Canada). Recently, this has been applied only to defects associated with a floppy or an aneurismatic posterior septum; a large anterior defect associated with (a) smaller posteroinferior defect (s) when the use of a single device was contemplated to close all defects; 2 distant (>7–8 mm) defects requiring the use of 2 different devices; and defects that may be too large for the size of the patient, especially in young children. An occluder that was 0–2 mm larger than the stretched diameter was selected for implantation. We slightly oversized the device (2–4 mm larger than the stretched diameter) in cases with deficient rims, especially the retroaortic. Recently, in patients with a single defect surrounded by a reasonably thick
septum we have simply taken into account the largest measurement using several echo views and used a device that was 20–25% larger than the largest diameter. This same guideline was applied for very large defects (largest diameter >30 mm; Fig. 3). Device implantation was performed using several established techniques according to previously published protocols.19,20

Patients recovered overnight and were discharged home the following day. A TTE with color Doppler was performed to assess device position and the presence of residual shunt. Routine recommendations19,20 with regards to aspirin use, engagement in contact sports and endocarditis prophylaxis were given. Clinical visits were scheduled at 1, 3, 6, and 12 months and every 3 years thereafter.

Statistics. Values were expressed as absolute numbers and frequencies, means and standard deviations, or medians and range where applicable.

Figure 3. Large atrial septal defect closure using 3-dimensional echocardiography monitoring. A: Left atrial view showing a large (33 × 30 mm) ASD with sufficient rims all around. B: Left atrial view after device release displaying the left atrial disc well abutted onto the interatrial septum. The left atrial disc surface has a somewhat concave shape and a smooth appearance with no central pins. SVC, superior vena cava; IVC, inferior vena cava; ASD, atrial septal defect; Ao, aorta; MV, mitral valve.

Figure 4. Multiple atrial septal defects and complex interatrial septum anatomy as assessed by 3-dimensional echocardiography. A: Right atrial view showing multiple atrial septal defects (marked by asterisks) in multiple locations of the interatrial septum near the SVC, IVC, behind the aorta and in the more posterior portion of the interatrial septum (arrow). B: Right atrial view after implantation of 2 devices. The smaller one was implanted in the superior defect and the larger one in the more inferior defect. The tiny posterior defect (arrow) was not covered by any of the devices and was left untouched. SVC, superior vena cava; IVC, inferior vena cava; Ao, aorta; SD, smaller device; LD, larger device.
Results

Patients. From April 2008 to July 2015, transcatheter ASD closure with the FOD was attempted in 200 patients. Patient demographics are displayed in Table 1. All patients had normal or slightly elevated pulmonary arterial pressures. Five elderly patients were in atrial fibrillation prior to the procedure that remained unchanged after implantation.

Procedures. Seventy-five procedures were performed using the first-generation device while the Figulla Flex I and II were used in the remainder. Defect and device characteristics are displayed in Table 2. In 52 patients, balloon interrogation of the defect was not performed. Successful implantation was achieved in all but 2 patients. One patient had 2 distant defects and a deficient (<5 mm) postero–inferior rim. Two devices were sequentially and successfully implanted. However, after releasing both devices, the inferior one (Flex I—15 mm) started to tilt and was considered to be in an unstable position, which prompted device removal. It was partially retrieved with some difficulty using a snare that brought the right disc into a 12 Fr sheath followed by complete removal using a 6 Fr bioprobe that grabbed the proximal pin inside the sheath. This patient was sent to surgery the following day with uneventful recovery. In a 10-year-old girl weighing 30 kg with a large ASD (26–27 mm), a well-positioned 30 mm device abutted the anterior leaflet of the mitral valve resulting in mitral insufficiency, prompting device removal. The procedure was abandoned and a recommendation for elective surgical repair was made. In the remaining patients with deficient rims device were implanted successfully with no complications.

There were 2 instances of device embolization to the aorta. In both cases, the devices (12 mm 1st generation with a screwing female pin and a 10.5 mm Flex II) were retrieved using a snare followed by successful closure of the defect using a larger device. In 1 patient, there was thrombus formation within the sheath that resolved with judicious aspiration and anticoagulation optimization. In 4 patients, the initial selected device was changed to a larger (in 3) or a smaller (in 1) one because it was felt to be too small or large after echocardiographic evaluation or embolization (see above). No patient experienced significant and prolonged arrhythmias. We observe a cobra-formation during deployment in 1 device, which was replaced. Occasionally, especially when using larger devices (>30 mm), the LA disk of the FOD did not reconfigure entirely, remaining with a globe appearance. This was managed by gently pushing the left disc against the roof of the LA to flatten the disc out. Also, the tip of the delivery system of the Figulla Flex I and II occasionally got entangled with the wire mesh of the device after release. Slight rotation of the cable freed the system uneventfully.

One patient with a very large defect (33 × 36 mm) in whom a 40 mm device was implanted remained with a small residual leak (2 mm) at the postero–inferior aspect (near the inferior vena cava) of the atrial septum. Out of the 6 remaining patients with multiple defects that required 2 devices, 2 remained with a 2 mm postero–inferior defect that was left uncovered after implantation of 2 devices (Fig. 4) and 1 had a residual defect.

Table 1. Patient Demographics

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<th>Variable</th>
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<tbody>
<tr>
<td>Number of patients (n)</td>
<td>200</td>
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<tr>
<td>Gender (F/M)</td>
<td>125/75</td>
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<tr>
<td>NYHA class I or II</td>
<td>200</td>
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<tr>
<td>Median age in years (range)</td>
<td>24 (4–72)</td>
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<tr>
<td>Patients &gt;18 years</td>
<td>122/200</td>
</tr>
<tr>
<td>Patients &lt;10 years</td>
<td>32/200</td>
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<tr>
<td>Median weight in kg (range)</td>
<td>58 (15–92)</td>
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F, female; M, male.

Table 2. Defect and Device Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>Single defect</td>
<td>171 (85.5%)</td>
</tr>
<tr>
<td>Multiple defects (1 device)</td>
<td>20 (10%)</td>
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<tr>
<td>Multiple defects (2 devices)</td>
<td>7 (3.5%)</td>
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<tr>
<td>Multifenestrated septum</td>
<td>2 (1%)</td>
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<tr>
<td>Deficient rim</td>
<td>93 (46.5%)</td>
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<tr>
<td>Antero–superior</td>
<td>88 (44%)</td>
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<tr>
<td>Postero–inferior</td>
<td>3 (1.5%)</td>
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<tr>
<td>Postero–superior</td>
<td>2 (1%)</td>
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<tr>
<td>Floppy/Aneurysmal septum</td>
<td>45 (22.5%)</td>
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<tr>
<td>Median ASD size in mm (range)</td>
<td>19 (6.5–36)</td>
</tr>
<tr>
<td>Median device size in mm (range)</td>
<td>24 (9–40)</td>
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ASD, atrial septal defect.
between both devices implanted. The remainder had complete immediate closure of the defect. All, except 3 patients were discharged home the following day.

**Follow-Up.** Follow-up time was a median of 3 years in 172 patients. All were in NYHA functional class I. Two patients (with 2 devices) remained with a small (<2 mm) residual leak through an additional defect during follow-up despite having normal right ventricular size on TTE. In only 11 patients (all >40 years of age), right ventricular size did not return to normal size despite complete closure of the defect. All patients remained in sinus rhythm except for those who had had atrial fibrillation prior to the intervention. There was no late embolization (even in patients with deficient rims), erosion, wire fracture on chest X-ray, thrombus formation on TTE, endocarditis, or AV valve dysfunction. Immediate and follow-up results are summarized in Table 3.

**Discussion**

Transcatheter closure has become the method of choice to manage most patients with secundum ASDs21–24 with the ASO (St. Jude Medical, St. Paul, MN) probably being the gold-standard device for closure. Although excellent mid-to-long term outcomes have been published with this device,2–5,25–27 the occurrence of erosion6 has been a reason for concern. A post-market study to determine the real incidence of this complication and its impact on clinical care is being conducted at the time of this writing. Also, thrombus formation on the left sided disc has been described, albeit being a rare occurrence.28,29 As such, it seems worth exploring the role and clinical safety and efficacy of other devices available for ASD closure.

This article reports the mid-term outcomes after the use of the FOD to close the secundum ASD in a large cohort of patients with a broad anatomical variety of defects.13,16 Although we have used this device mainly for adults, it was also safe and effective for older children and adolescents. Because of the higher profile of the sheaths required for implantation of the 1st and 2nd generation devices we preferentially avoided their use in smaller children. When compared to the ASOs, the FOD usually require sheaths 2–3 Fr larger for the same size of device. The 3rd generation of the device (Figulla Flex II) has a lower profile, which was useful to expand the indications for smaller children, as already reported in the literature.30 Also, the pivoting system between the RA disc ball and the delivery cable was further improved allowing for a 50–60 degrees rotation. This further decreased the tension before device release allowing a better assessment of device position, especially the RA disc.

A wide range of underlying anatomies including single small to very large defects; multiple and multifenestrated defects; ASDs associated with aneurismal, floppy or standard septae; and defects in different locations with sometimes deficient surrounding rims could all be addressed using the FOD. All these observations attest to its versatility. The 2 failed implantations observed in this experience seem to be due to inappropriate patient selection instead of limited device performance. The mid-term outcomes encountered in this experience were encouraging. There was a high rate of complete closure and no complications. This is in line with previously published reports.7–16

Advantageous characteristics of this device include no clamp and less amount of uncovered metallic material on the left disk, which may facilitate endothelialization and avoid thrombus formation. Although the lack of the distal clamp may partially explain the globe appearance of the LA disk that is occasionally observed when deploying larger devices, it minimizes the risks of inadvertent trauma to the adjacent cardiac structures. More importantly, enhanced flexibility results from a

<table>
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<tr>
<th>Variable</th>
<th>Successful implantation: n (%)</th>
<th>Mean fluoroscopic time in minutes</th>
<th>Mean procedure time in minutes</th>
<th>Immediate closure rate: n (%)</th>
<th>Lost to follow-up: n (%)</th>
<th>Median follow-up in months (range)</th>
<th>Late closure rate: n (%)</th>
<th>Early or late erosions: n (%)</th>
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</thead>
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<tr>
<td>Successful implantation: n (%)</td>
<td>198/200 (99%)</td>
<td>8.5 ± 3.7</td>
<td>89 ± 21</td>
<td>196/198 (&gt;99%)</td>
<td>26/198 (&lt;13%)</td>
<td>36 (1–72)</td>
<td>170/172 (&gt;99%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Two devices: n (%)</td>
<td>7/198 (3.4%)</td>
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<tr>
<td>Embolization with retrieval and new implantation: n (%)</td>
<td>2/198 (&lt;1%)</td>
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Table 3. Immediate and Follow-Up Outcomes
OUTCOMES AFTER ASD CLOSURE WITH THE FIGULLA DEVICE

single weld on the right side and the use of thinner and more numerous strands of nitinol. Whether this characteristic may be associated with better intra-atrial conduction and P wave dispersion after device ASD closure when compared to the ASO remains to be seen with larger number of patients and longer follow-up. Additionally, the Flex I and II delivery systems have a pivoting mechanism that minimizes the amount of tension between the RA disk and the delivery cable before release.

On the other hand, the smaller and rounded pin on the right disc of the Figulla Flex I proved to be more difficult to be snared and pulled into the sheath in a patient with a mal-positioned device in this experience. After partial recapture, a bioptome had to be used to completely remove the device. This was not observed in a patient in whom de Flex II device was retrieved using a small snare. Similar techniques for retrieval have been described. Additionally, the absence of a pin on the LA disc impairs grabbing the device from both sides, which may be useful in some situations for complete stretching before removal through a small vessel or into a sheath. Conversely, due to its enhanced flexibility it may be easier to drag it in a partially collapsed form. In order to avoid entanglement of the tip of the delivery cable within the wire mesh, the coupling pin should be brought into the distal pod before bringing the delivery cable into the long sheath. If there is still some resistance, the cable should be rotated slightly to free the system.

Although the lack of reports of cardiac erosion or perforation after the use of the FOD is encouraging, this must be interpreted with caution. If the estimated incidence of erosion of 0.1% as published by Amin et al. after the use of the ASO was observed with the FOD, we would expect at least 20 cases out of 20,000 implants performed worldwide until 2013 (according to the company track record). This has not been observed and might be due to a variety of reasons. The denominator may be overestimated since the company tracks shipped devices and not necessarily implanted ones. It is possible that this complication might be under-reported in the literature. On the other hand, it may have been possible that operators implanting the Figulla device have learned with the previously accumulated experience with the ASO and have avoided the use of oversized devices in high-risk situations, eventually decreasing the rate of erosions. Finally, the FOD may as well be less traumatic to the antero–superior atrial wall and adjacent aorta due to its enhanced flexibility, although this physical property has not been proved in experimental studies. With such a low estimate of the incidence of erosions, only a very large number of patients (maybe those specifically at a higher risk) followed for a long period of time will determine the real incidence of this complication with this device.

This study is limited by its observational non-randomized design. Also, we did not employ detailed fluoroscopic assessment to look for wire fractures during follow-up. Additionally, minor residual leaks and/or small thrombus on the device might have been overlooked using TTE and not TEE for serial follow-up evaluations. Finally, some patients were lost to follow-up.

Conclusions

Transcatheter closure of ASDs using the FOD was operator friendly, safe, and effective in this large experience in older children, adolescents, and adults. The device performed as well as the ASO in a wide range of anatomical scenarios resulting in excellent mid-term outcomes. Much larger number of patients and longer follow-up are needed to determine whether this device is associated with a decreased risk of erosion.

References


