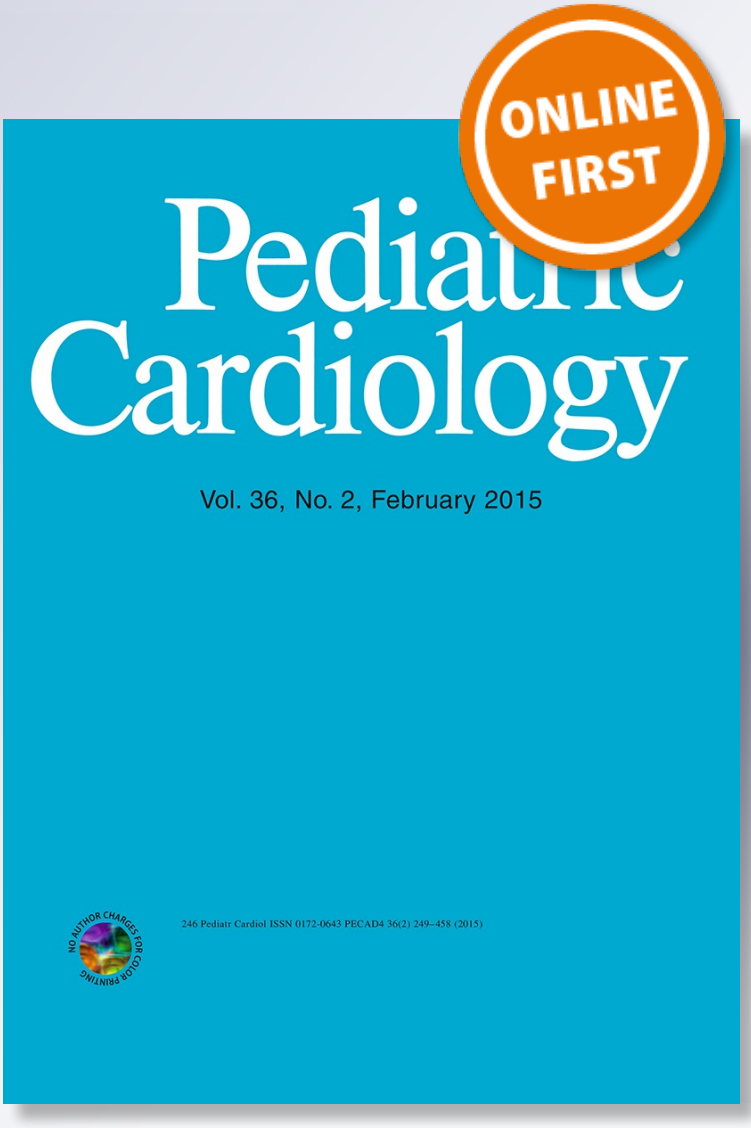
Comparison of the Occlutech® Figulla® Septal Occluder and Amplatzer® Septal Occluder for Atrial Septal Defect Device Closure

Supaporn Roymanee, Worakan Promphan, Nakharin Tonklang & Kanjarut Wongwaitaweewong

Pediatric Cardiology

ISSN 0172-0643

Pediatr Cardiol
DOI 10.1007/s00246-015-1103-y



Springer

Pediatr Cardiol
DOI 10.1007/s00246-015-1103-y

ORIGINAL ARTICLE

Comparison of the Occlutech® Figulla® Septal Occluder and Amplatzer® Septal Occluder for Atrial Septal Defect Device Closure

Supaporn Roymanee · Worakan Promphan · Nakharin Tonklang · Kanjarut Wongwaitaweewong

Received: 23 August 2014 / Accepted: 9 January 2015

Abstract The Occlutech® Figulla® septal occluder (OFSO) is a later-generation double-disk device with few reports of its success rates and complications compared with the Amplatzer® septal occluder (ASO), which is the worldwide standard device in percutaneous atrial septal defect (ASD) closure. We recruited and compared the results in 149 patients (76.5 % female) who underwent ASD device closure in our center between January 2003 and June 2012. The patients ranged in age from 2.3 to 77.2 years. There were no statistically significant differences between the two groups regarding patient baseline characteristics and procedure variables. The success rate using either device was excellent (ASO 94.4 % and OFSO 97.4 %; $p = 0.43$). Although the diameter of the ASD and the pulmonary arterial pressure in the OFSO group were slightly higher than in the ASO group, the median fluoroscopic time in the OFSO group was significantly shorter (ASO 13.7 min; OFSO 9.0 min; $p < 0.001$). The overall median follow-up time was 3.6 years (interquartile range 2.1–9.0 years). There were no significant differences between the major and minor complications when comparing the two devices. Both devices were safe and effective for percutaneous ASD closures. The OFSO had the benefit of a shorter fluoroscopic time.

S. Roymanee (✉) · N. Tonklang · K. Wongwaitaweewong
Pediatric Cardiology Unit, Department of Pediatrics, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla, Thailand
e-mail: jiewsr@yahoo.com

W. Promphan
Pediatric Cardiac Center, Queen Sirikit National Institute of Child Health, College of Medicine, Rangsit University, Bangkok, Thailand

Published online: 30 January 2015

Keywords ASD device closure · ASD percutaneous closure · Occlutech septal occluder · Amplatzer septal occluder

Introduction

Since the first non-operative atrial septal defect (ASD) closure by King and Mills in 1974 [14], transcatheter closure (TCC) has become the standard non-surgical approach for secundum ASD [7, 8, 19]. Amplatzer® septal occluder (ASO; St. Jude Medical, St. Paul, MN, USA) is the prototype of a nickel-titanium alloy (nitinol)-braided double-disk device that was approved for the US market in December 2001. ASO is currently the most widely used device worldwide because of its user-friendly properties and excellent outcomes in long-term follow-up in both pediatric and adult ASD patients [1, 6–8, 14, 16, 19, 20, 22, 23]. However, since its approval for use in the European market in 2007, the Occlutech® Figulla® septal occluder (OFSO; Occlutech GmbH, Jena, Germany) has been proven as an excellent alternative device for TCC of secundum ASD because of its unique design of an absent left atrial hub and tiltable delivery system. In our institution, both brands of double-disk nitinol devices are now available. Our aim was to compare the long-term procedural outcome, safety, and efficacy of the two devices.

Materials and Methods

Patient Selection

We retrospectively reviewed the medical records of 149 patients with at least 2 years of follow-up data who

underwent percutaneous ASD device closure in our center between January 2003 and June 2012. The inclusion criteria were (1) hemodynamically significant secundum ASD; (2) sufficient rims (defined as at least 5 mm of septum identified at the aortic, superior vena cava, inferior vena cava, posterior and atrioventricular valve areas). For those with aortic rim less than 5 mm, the defect was considered for closure if the other rims were sufficient; and (3) body weight $\geq$10 kg. The exclusion criteria were (1) non-secundum type ASD; (2) IVC rim <5 mm; (3) concomitant lesions requiring surgical correction; and (4) patients with pulmonary vascular resistance after a vasoreactivity test result >8 Wood unit/m^2, as these were deemed unsuitable for percutaneous closure. We reviewed the treatment and outcome details and divided patients into an ASO group and an OFSO group based on the device used to close their ASD.

Devices

Both devices are made of nitinol wire mesh with a polyester patch. Their self-expanding double disks have a 3- to 4-mm connecting waist with a self-centering mechanism. The OFSOs have a ceramic titanium oxide surface that creates the gold appearance of the nitinol wires. There have been three generations of OFSOs to date. The first-generation (Occlutech N) had a screw system similar to the ASO, but the difference was the absence of a left atrial hub in the OFSO and the need for a larger delivery sheath for the same device size (Fig. 1). The second-generation (Flex I) had an improved delivery system that allowed a tilt angle of 45° that eliminated tension on the implant and a new ball-shaped connector design that decreased the amount of material in the implant (Fig. 2). In the recently available third-generation (Flex II) device, the delivery system was changed to a bioptome delivery system that allows full circular movement of the device and a new design that contain less metal in the center to provide better flexibility and a smaller delivery sheath than previous generations (Fig. 3).

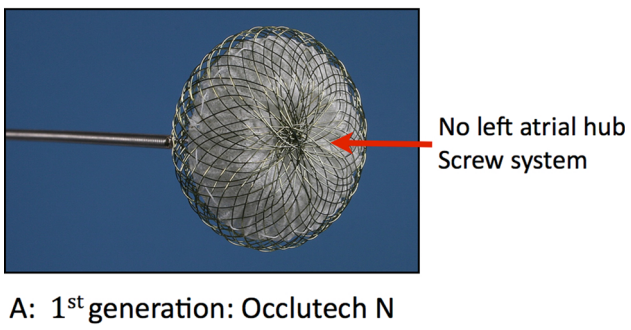


Fig. 1 The first-generation (Occlutech N) had a screw system similar to the ASO, but the difference was the absence of a left atrial hub

In 2003, the ASO was the only device available in our center. During that time, percutaneous ASD closure was a high-cost procedure at approximately $10,000 USD, and the procedure was not covered by the National Health System Governance of Thailand. As a result, few patients could afford the procedure in our country. However, since 2007, the costs of the device and procedure are partially reimbursed by the National Health Security Office, allowing more patients to undergo device closure. Since 2010, with a more affordable cost of $8,300 USD and a lower profile appearance after implantation, the ASO has been replaced by the OFSO in our center (Fig. 4).

In this study, we used the ASO in 72 patients from 2003 to 2010 and the OFSO in 77 patients from 2010 to June 2012. In the OFSO group, we used a first-generation OFSO for 66 patients and a second-generation OFSO for 11 patients. Once the second generation was commercially available, the manufacturer stopped producing the first generation, which is no longer available.

Procedure

After the first five cases, all of the study cases underwent TCC of the ASD by a same operator. We performed TCC for ASD in adults and children under general anesthesia with transesophageal echocardiography (TEE) and fluoroscopic guidance. In this study, three children had to perform device closure under transthoracic echocardiography (TTE) because of pediatric TEE probe was not functioning properly; however, their echocardiography window was sufficient to identify all rims during deployment. We routinely repeated the TEE by the operator to evaluate feasibility of device closure before the procedure. We selected the device depending on the shape and the two-dimensional size of the ASD using color Doppler. ASD was measured in three different views: four chamber, short axis, and bicaval. If the ASD was oval shaped (defined as the shortest diameter <75 % of the largest diameter), we selected a device 0–2 mm (child) and 2–4 mm (adult) larger than the maximum diameter. If the ASD shape was circular, we selected a device 2–4 mm (child) and 4–6 mm (adult) larger than the maximal diameter as measured by color Doppler. To prevent the risk of erosion, the diameter of the chosen device was never larger than 1.5 times the ASD diameter.

We stopped performing balloon sizing after the first ten cases because this step requires an experienced echocardiographer, prolongs the procedure time, and increases the procedure cost. Moreover, in our experience, balloon sizing created more complications and tended to lead to selecting an oversized device. After selecting the device size, we performed right and left heart catheterizations in all patients to evaluate the degree of shunting, pulmonary

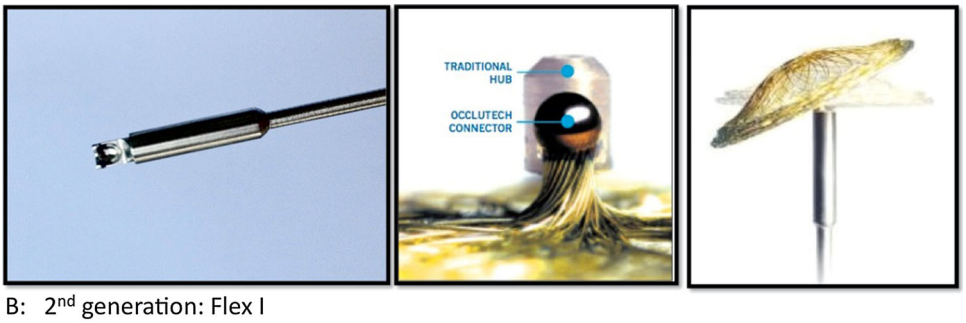


Fig. 2 The second-generation (Flex I) had a tiltable delivery system and a new ball-shaped connector design

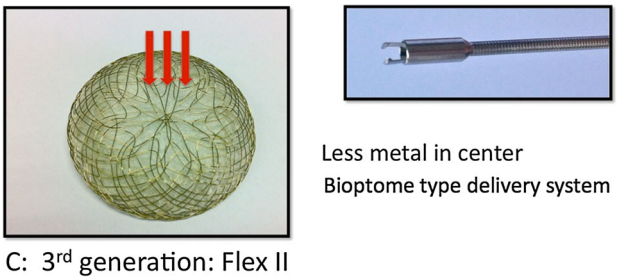


Fig. 3 The third-generation (Flex II) had a bioptome delivery system that allows full circular movement of the device and a new design that contain less metal in the center (*red arrows*)

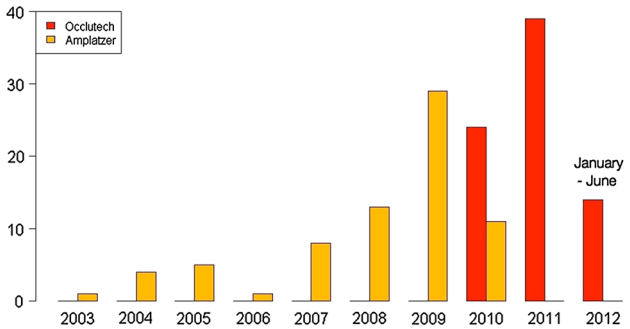


Fig. 4 Number of devices usage to close ASD in each year from January 2003 to June 2012 where *yellow color* represents Amplatzer septal occluder (ASO) and *red color* represents Occlutech Figulla septal occluder (OFSO)

artery pressure, and pulmonary vascular resistance. Coronary angiography was added in female patients >60 years of age and male patients >55 years of age or in patients with major risks of coronary artery disease. The approach was always from the femoral vein and femoral artery. We administered heparin at a dose of 50 units/kg and cefazolin at 50 mg/kg or 1 g in adults intravenously before the procedure. Once the device size was selected, we used a delivery system of the recommended size or larger and procedure was done using standard techniques as recommended [10, 12].

Follow-up

Clinical evaluation (symptoms of dyspnea, palpitation, chest pain, and migraine), chest X-ray, 12-lead ECG, and transthoracic echocardiography were routinely performed on the day after the procedure to evaluate the position of the device, degree of residual shunt, pericardial effusion, and adjacent organ obstruction. During the first 6 months after device implantation, we prescribed oral aspirin at 3–5 mg/kg/day for children or 81 mg × 2 tablets per day in adults and also recommended that the patients should receive antimicrobial prophylaxis for prevent of infective endocarditis before dental procedure that involve gingival tissue or perforation of oral mucosa (amoxicillin 50 mg/kg for children or 2 g in adults 30–60 min before procedure). All complications related to the closure procedure were monitored immediately and the day after procedure and also at 1, 3, and 6 months, then at 1, 2 years, and finally, every 2–3 years after device closure.

Success and Complications

Major and minor complications were defined according to the 2012 FDA executive summary memorandum [9]. Briefly, we defined success as no residual shunt and no need for surgical ASD closure later. Major complications were defined as life-threatening events requiring prolonged hospitalization or having long-term consequences such as death, device embolization, cardiac perforation/erosion/rupture, cardiac tamponade, endocarditis, and thromboembolic events including all strokes and device-related thrombi, and cardiac arrhythmias requiring permanent pacemaker placement or the need for long-term anti-arrhythmic medication. Minor complications included non life-threatening events not requiring surgical correction, and no long-term consequences such as fever, headache, migraine, arterial spasm, hematoma, and cardiac arrhythmias not requiring permanent pacemaker placement or long-term anti-arrhythmic medication.

Statistical Analysis

Descriptive statistics were used to describe the patient characteristics. Continuous variables with normal distribution are presented as mean ± standard deviation and as median with interquartile range (IQR) for abnormal distribution. Differences between outcomes with different devices were analyzed using the unpaired Student's *t* test or the Wilcoxon rank-sum test. Differences in the incidences of device-related adverse events were tested for significance with the Chi-squared and Fisher's exact test. A p value <0.05 was considered statistically significant, and all analyses were performed using the R project for statistical computing (www.R-project.org).

Results

We excluded 27 patients from TCC of ASD compose of two patients with sinus venosus ASD, 21 patients because of margin deficits, two patients with concomitant coronary stenosis that required surgery, and two patients because of severe pulmonary hypertension. There were 114 female patients (76.5 %) and 35 male patients (23.5 %). At the time of the procedure, the median age was 30.0 years (IQR 2.3–77.2 years) and the median body weight was 49 kg (IQR 11.0–83.0 kg). Most patients were classed as New York Heart Association Functional Class (NYHA-FC) I 91/149 patients (61.1 %) or NYHA-FC II 48/149 patients (32.2 %). There were no class IV patients. The median pulmonary-to-systemic flow ratio was 2.4 (IQR 1.8–3.5), and the median pulmonary vascular resistance was 1.5 Wood unit/m^2 (IQR 0.9–2.3 Wood unit/m^2). The median defect diameter was 20 mm (IQR 8–35 mm), and the median defect/device size ratio was 1.25 (IQR 1.21–1.45). The median length of hospital stay was 47.6 h (IQR 43.0–52.5 h). The overall closure success rate was 143/149 patients (96 %), and the major complication rate was 4/149 patients (2.7 %).

Comparisons between the ASO and OFSO devices for demographic data and procedure variables are shown in Table 1. There were no statistically significant differences between the two groups regarding sex, age, weight, height, body surface area, NYHA-FC, and pulmonary-to-systemic flow ratio. The rates of successful closure and complications were also similar among the groups. However, in the OFSO group, the diameter of the ASD and the systolic and mean pulmonary arterial pressure were significantly larger and higher than in the ASO group, while the median fluoroscopic time in the OFSO group 9.0 min (IQR 5.4–14.3 min) was significantly shorter than in the ASO group 13.7 min (IQR 10.0–25.9 min). Since both devices were used in different time periods, the operator may have benefited from previous experience with the ASO. Therefore, patients in each device were divided into subgroup of early and late experience and reanalyzed of fluoroscopic time. It was found that the average fluoroscopic times in early and late experience with the ASO were the same 16.9 min, but the average fluoroscopic times in the Occlutech subgroups were significantly different; the early experience was 14.5 min, and the late experience was 9 min ($p < 0.001$).

The overall median follow-up time was 3.6 years (IQR 2.1–9.0 years). There were no differences between the major or minor complication rates in the two groups. Details of the complications that occurred are shown in Table 2. One patient expired, a 64-year-old female patient with NYHA-FC III and an ASD diameter measured on TEE of 25 × 21 × 28 mm and from balloon sizing, 32 mm. A 34-mm ASO was used to close the defect, and during implantation, she developed bradycardia and hypotension with moderate pericardial effusion. After emergency pericardiocentesis, she was immediately transferred to an operating room, where a 0.5-cm perforation was found at the roof of the left atrium. After open-heart surgery for defect closure and to repair the left atrial roof, she lost consciousness and was complicated by atrial tachyarrhythmia and ventilator-associated pneumonia and died after 2 months of hospitalization. We retrospectively reviewed the angiograms in her case and identified that the perforation occurred during balloon sizing. The other major complication in the ASO group was a femoral arteriovenous fistula, which was surgically repaired the day following the ASD procedure with good results.

In the OFSO group, there were two cases of device embolization. The first case was a 20-year-old woman with a defect size of 18 × 15 × 12 mm (oval shape). Initially, we attempted to close the defect with a 21-mm Occlutech N, but it failed to anchor between the floppy inferior vena cava rim. After several attempts, we achieved successful implantation with a 27-mm Occlutech N using a balloon-assisted technique, but the device embolized into the right ventricle 2 h later. Because of concerns over the floppiness of the IVC rim and avoiding tricuspid valve injury from device retrieval in the right ventricle, this patient elected to undergo surgery. The second case was a 28-year-old woman with a defect size of 17 × 26 × 30 mm (oval shape) who had originally undergone device closure with a 33-mm Flex I. The procedure had gone well without immediate problems; however, the day after the procedure, although the patient was asymptomatic, transthoracic echocardiography showed that the device had embolized into the left pulmonary artery. After an unsuccessful retrieval attempt, the patient was transferred for surgical closure. The surgical reports on both of these patients indicated floppy and deficient IVC rims.

Table 1 Comparison of patient characteristics, procedure variables, and success and complication rates between the ASO and OFSO groups

	ASO ($N = 72$)	OFSO ($N = 77$)	P (* = <0.05)
Patient characteristics			
Median age (year)	22 (11, 43)	32 (18, 47)	0.11
Median weight (kg)	47 (30, 58)	50 (40, 58)	0.31
Median height (cm)	154 (131, 161)	156 (150, 162)	0.16
Female number (%)	58 (81 %)	56 (73 %)	0.35
NYHA-FC number (%)			
I	44 (61 %)	47 (61 %)	0.99
II	23 (32 %)	25 (33 %)	
III	5 (7 %)	5 (7 %)	
Procedure variables			
Mean ASD size from TTE (mm)	18.6 ± 5.0	20.5 ± 5.6	0.03*
Mean ASD size from TEE (mm)			
Four-chamber view	18.7 ± 5.6	19.9 ± 5.6	0.20
Short-axis view	16.3 ± 4.9	18.7 ± 5.5	<0.01*
Bicaval view	16.7 ± 4.8	19.3 ± 5.1	<0.05*
Device size (mm)	23.5 ± 6.3	26.2 ± 6.5	0.01*
Qp/Qs	2.4 (1.9, 3.8)	2.4 (1.7, 3.4)	0.39
Rp/Rs	0.1 (0.1, 0.1)	0.2 (0.1, 0.2)	<0.05*
PVR (Wood.unit/m^2)	1.1 (0.6, 1.6)	1.9 (1.3, 2.9)	<0.001*
Systolic PA pressure (mmHg)	30 (24, 37)	35 (27, 44)	0.02*
Mean PA pressure (mmHg)	19 (15, 23)	23 (18, 28)	<0.001
Outcomes and complications			
Fluoroscopic time (min)	13.7 (10.0, 25.9)	9.0 (5.4, 14.3)	<0.001*
Hospital stay (h)	47.8 (42.9, 54.0)	47.5 (43.0, 50.0)	0.31
Closure success (number, %)	68 (94.4 %)	75 (97.4 %)	0.43
Complications			
Major (number, %)	2 (2.8 %)	2 (2.6 %)	1
Minor (number, %)	13 (18.1 %)	10 (13.0 %)	0.53

Table 2 Major and minor complications in each group

	ASO ($N = 72$) number (%)	OFSO ($N = 77$) number (%)
Major complications		
Death	1 (1.4 %)	–
Cardiac perforation/erosion	1 (1.4 %)	–
Vascular complication requiring surgery	1 (1.4 %)	–
Device embolization/migration	–	2 (2.6 %)
Minor complications		
Fever or infection related to procedure	4 (5.6 %)	2 (2.6 %)
Migraine	3 (4.2 %)	3 (3.9 %)
Allergic reaction	2 (2.8 %)	1 (1.3 %)
Ventricular tachycardia	1 (1.4 %)	–
Vascular complication not requiring surgery	–	2 (2.6 %)

Most patients had normal sinus rhythm on their baseline electrocardiograms. Four patients had preexisting atrial fibrillation (4/149, 2.7 %), and one patient had junctional rhythm (1/149, 0.7 %). One patient in the ASO group, who had preexisting myocardial dysfunction from coronary artery disease, developed a brief period of ventricular tachycardia during the procedure, which resolved after administering 300 mg amiodarone with no need for a long-term antiarrhythmic drug. The remaining patients had no new-onset arrhythmia after ASD device closure. Two

patients, one each from the ASO and OFSO groups, had atrial fibrillation, which resolved after defect closure.

Discussion

Since the first report using OFSO to close ASDs by Halabi and Hijazi in 2008 [11], the device has shown favorable outcomes for clinical use [1, 3–5, 13, 15, 17, 21]. However, clinical studies comparing ASO and OFSO results are lacking.

Our results showed a slightly higher success rate in the OFSO group, but the difference was not statistically significant; however, fluoroscopic time deploying the OFSO was statistically significantly shorter using the OFSO even in patients with larger defects and higher pulmonary arterial hypertension. We acknowledge that operators using the OFSO after using the ASO may benefit from previous experience with the ASO, which could explain the reduced fluoroscopy time in the OFSO group. However, based on our experience with the OFSO, the advantages of the tilt table delivery system create less tension and the single hub design provide better conformity of the device to the ASD, making deployment and repositioning easier even in more challenging cases.

We found no statistically significant differences in major and minor complication rates between the two groups. One case died in the ASO group, which was not directly related to the device but was related to a known risk factor of this intervention. The overall mortality for ASD device closure was 0.09 % in a previous study, with no statistically significant difference compared with the mortality rate for surgical ASD closure of 0.13 % ($p = 0.65$) [6]. The major complication rate in our OFSO group was 2.6 %, and all were device embolization. We found no embolized devices in the ASO group. Previous studies have reported OFSO device embolization rates of 0–3.0 % [4, 5, 17] and a US Food and Drug Administration executive summary memorandum reviewed seven cohort studies and reported rates of device embolization when using the ASO device of 0.3–3.5 %. Considering these rates, we speculate that embolization is unrelated to the different properties of these two devices, and more likely related to other factors such as a deficient and floppy IVC rim as the most important issue. To avoid device embolization, we agree with other researchers that in situations where a floppy rim is a factor, we recommend a device one size larger than would ordinarily be used [24].

The OFSO has no left atrial hub (the most distinct difference from the ASO), which decreases the chance of a clot or thrombus formation. However, in our series, we found no identifiable clots or thrombi in either group, nor any difference in the rate of migraine, suggesting that the absent left atrial hub in the OFSO may not change outcomes related to thrombus formation. The size increment of the OFSO is 3 mm and may lead to selecting an overly large device for implantation. However, with the single hub design, the OFSO usually remains in a flat conformation and results in less tension even with an oversized device. None of our patients developed early or late erosion with either device. The drawback of the ball-shaped design of the OFSO in the right atrial hub is that it slips easily and is difficult to retrieve when it embolized. In our experience, it was difficult to firmly grasp the ball-shape connector at the right atrial hub.

Our findings support the idea that balloon sizing is not necessary in all cases of percutaneous ASD closure. In our study, 139 patients underwent ASD device closure without balloon sizing. We carefully selected an appropriate device with an upper limit not larger than 1.5 times the ASD diameter to prevent long-term complications potentially arising from an oversized device [2]. Other researchers also did not use balloon sizing and recommended a device size 4–5 mm and 5–7 mm larger than the maximal diameter of the defect for maximal defects <14 mm and ≥ 14 mm, respectively [24]. The authors also recommended that the device not be >10 mm larger than the maximal ASD diameter [24]. Another report recommended selecting a device that is approximately 120 % of the largest diameter of the ASD [18]. We suggest that in centers that have limited personnel and budgets, balloon sizing is no longer a crucial part of ASD device closure.

The limitation of this study was the lack of a non-randomized blinded control because these two devices are completely different in color and delivery system and our device size selection was based on device available and individually the patient's ASD maximal diameter and shape.

The strength of our study is that the majority of the 144 patients (97 %) underwent ASD device closures by a single operator in one center, which removes possible confounding factors that might arise from multiple operators and techniques. We also have no conflict of interest in either device. To the best of our knowledge, our study has the largest number of patients comparing the Occlutech® and the Amplatzer® septal occluders in ASD closures. Further prospective randomized multicenter trials remain necessary to compare the technical aspects and long-term results of both devices.

Conclusion

Our results confirmed that the OFSO is an attractive alternative device to use in pediatric and adult ASD patients. Its success rate and safety are comparable with the ASO, while it has the distinct advantage of a shorter fluoroscopic time.

Acknowledgments The Prince of Songkla University Research Fund provided a grant for this study.

Ethical standard The authors declare that they have no conflict of interest. The study was approved by the Prince of Songkla University Institutional Ethics Committee, and all procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required.

References

1. Abaci A, Unlu S, Alsancak Y, Kaya U, Sezenoz B (2013) Short and long term complications of device closure of atrial septal defect and patent foramen ovale: meta-analysis of 28,142 patients from 203 studies. Catheter Cardiovasc Interv 82:1123–1138. doi:10.1002/ccd.24875
2. Amin Z, Hijazi ZM, Bass JL, Cheatham JP, Hellenbrand WE, Kleinman CS (2004) Erosion of Amplatzer septal occluder device after closure of secundum atrial septal defects: review of registry of complications and recommendations to minimize future risk. Catheter Cardiovasc Interv 63:496–502
3. Ammar RI, Hegazy RA (2013) Transcatheter closure of secundum ASD using Occlutech Figulla-N device in symptomatic children younger than 2 years of age. J Invasive Cardiol 25:76–79
4. Aytemir K, Oto A, Ozkutlu S, Kaya EB, Canpolat U, Yorgun H, Sahiner L, Kabakçi G (2012) Early-mid term follow-up results of percutaneous closure of the interatrial septal defects with occlutech figulla devices: a single center experience. J Interv Cardiol 25:375–381
5. Cansel M, Pekdemir H, Yağmur J, Tasolar H, Ermis N, Kurtoglu E, Acıkgoz N, Atas H, Ozdemir R (2011) Early single clinical experience with the new Figulla ASD occluder for transcatheter closure of atrial septal defect in adults. Arch Cardiovasc Dis 104:155–160
6. DiBardino DJ, McElhinney DB, Kaza AK, Mayer JE Jr (2009) Analysis of the US Food and Drug Administration Manufacturer and User Facility Device Experience database for adverse events involving Amplatzer septal occluder devices and comparison with the Society of Thoracic Surgery congenital cardiac surgery database. J Thorac Cardiovasc Surg 137:1334–1341. doi:10.1016/j.jtcvs.2009.02.032
7. Du ZD, Hijazi ZM, Kleinman CS, Silverman NH, Larntz K (2002) Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults: results of a multicenter nonrandomized trial. J Am Coll Cardiol 39:1836–1844
8. Durongpisitkul K, Soongswang J, Laohaprasitiporn D, Nana A, Sriyoschati S, Ponvilawan S, Subtaweesin T, Kangkagate C (2002) Comparison of atrial septal defect closure using amplatzer septal occluder with surgery. Pediatr Cardiol 23:36–40
9. FDA executive summary memorandum (2012) Transcatheter ASD occluders: clinical update and review of events, [online]. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM304924.pdf. Accessed 17 July 2014
10. Fu YC, Cao QL, Hijazi ZM (2007) Device closure of large atrial septal defects: technical considerations. J Cardiovasc Med 8:30–33
11. Halabi A, Hijazi ZM (2008) A new device to close secundum atrial septal defects: first clinical use to close multiple defects in a child. Catheter Cardiovasc Interv 71:853–856
12. Harper RW, Mottram PM, McGaw DJ (2002) Closure of secundum atrial septal defects with the Amplatzer septal occluder device: techniques and problems. Catheter Cardiovasc Interv 57:508–524
13. Ilkay E, Kaçmaz F, Özeke Ö, Turan RS, Firat S, Pampal K, Ozer E, Bilgin S (2010) The efficiency and safety of percutaneous closure of secundum atrial septal defects with the Occlutech Figulla device: initial clinical experience. Turk Kardiyol Dern Ars 38:189–193
14. King TD, Mills NL (1974) Nonoperative closure of atrial septal defects. Surgery 75:383–388
15. Krizanic F, Sievert H, Pfeiffer D, Konorza T, Ferrari M, Hijazi Z, Jung C, Lauten A, Figulla HR (2010) The Occlutech Figulla PFO and ASD occluder: a new nitinol wire mesh device for closure of atrial septal defects. J Invasive Cardiol 22:182–187
16. Masura J, Gavora P, Podnar T (2005) Long-term outcome of transcatheter secundum-type atrial septal defect closure using Amplatzer septal occluders. J Am Coll Cardiol 45:505–507
17. Pac A, Polat TB, Cetin I, Oflaz MB, Balli S (2009) Figulla ASD occluder versus Amplatzer Septal Occluder: a comparative study on validation of a novel device for percutaneous closure of atrial septal defects. J Interv Cardiol 22:489–495
18. Quek SC, Wu WX, Chan KY, Ho TF, Yip WC (2010) Transcatheter closure of atrial septal defects: is balloon sizing still necessary? Ann Acad Med Singapore 39:390–393
19. Suchon E, Pieculewicz M, Tracz W, Przewlocki T, Sadowski J, Podolec P (2009) Transcatheter closure as an alternative and equivalent method to the surgical treatment of atrial septal defect in adults: comparison of early and late results. Med Sci Monit 15:CR612–CR617
20. Tomar M, Khatri S, Radhakrishnan S, Shrivastava S (2011) Intermediate and long-term follow up of percutaneous device closure of fossa ovalis atrial septal defect by the Amplatzer septal occluder in a cohort of 529 patients. Ann Pediatr Cardiol 4:22–27
21. Van Den Branden BJ, Post MC, Plokker HW, Ten Berg JM, Suttorp MJ (2011) Percutaneous atrial shunt closure using the novel Occlutech Figulla device: 6-month efficacy and safety. J Interv Cardiol 24:264–270
22. Vijarnsorn C, Durongpisitkul K, Chanthong P, Chungsomprasong P, Soongswang J, Loahaprasitiporn D, Nana A (2012) Transcatheter closure of atrial septal defects in children, middle-aged adults, and older adults: failure rates, early complications; and balloon sizing effects. Cardiol Res Pract 2012:584236
23. Walters DL, Boga T, Burstow D, Scalia G, Hourigan LA, Aroney CN (2012) Percutaneous ASD closure in a large Australian series: short- and long-term outcomes. Heart Lung Circ 21:572–575
24. Wang JK, Tsai SK, Lin SM, Chiu SN, Lin MT, Wu MH (2008) Transcatheter closure of atrial septal defect without balloon sizing. Catheter Cardiovasc Interv 71:214–221