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Research Article

Percutaneous Atrial Septal Defect Closure Using the Occlutech Figulla Device in Adults: More than 800 Patient-Years of Follow-Up

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Purpose. The Occlutech Figulla occluder has been proven safe and effective at midterm follow-up after percutaneous atrial septal defect (ASD) closure. We describe the safety and efficacy at long-term follow-up in adults. *Methods*. All consecutive adult patients that underwent ASD closure between 2008 and 2015 were included. All complications were registered. Residual left-to-right shunt (LRS) was diagnosed using color-Doppler transthoracic echocardiography (TTE). Right-to-left shunting was diagnosed using contrast TTE. Successful closure was defined as no LRS at follow-up. *Results*. In total, 166 patients (mean age 56.7 ± 16.1 years; 62% female) underwent percutaneous ASD closure using the Occlutech Flex I (70%) or Flex II (30%) device (diameter 24 mm; range 10–40 mm) under general anaesthesia and transoesophageal echocardiographic guidance. Long-term follow-up data were available for 144 patients (87%) with a mean follow-up of 5.9 ± 2.6 years, a total of 814 patient-years. During hospitalization, device embolization occurred in three patients (1.8%) with successful extraction in all. During the long-term follow-up, 15 patients (9.8%) suffered new-onset atrial fibrillation and stroke occurred in 2.1%. There was no residual LRS at 12-month follow-up. No device embolization occurred during the long-term follow-up. *Conclusion*. Percutaneous ASD closure using the Occlutech device appears to be safe at long-term follow-up with a high successful closure rate at one year.

1. Introduction

Atrial septal defects (ASDs) are a common cardiac congenital finding with complications due to the left-to-right shunt (LRS). Percutaneous closure of an ASD is considered to be the first choice and has been proven safe and effective using different devices [1, 2]. Worldwide, there is a lot of good experience with the Amplatzer septal occluder. The Occlutech Figulla septal ASD occluder (OFSO) was developed to improve the feasibility of implantation and lower the rate of possible complications such as device thrombosis with an absent left atrial hub. In the past decade, three generations of the OFSO device were developed. All generations have proven to be safe and effective with a low complication rate during short- and midterm follow-up [3–6]. However, little is known about the long-term complications of this extensively used device. We describe the safety and efficacy of percutaneous ASD closure in adults using the OFSO after more than 5 years of follow-up.

2. Methods

2.1. Population. All consecutive adult patients, ≥18 years of age, that underwent percutaneous ASD closure with the Occlutech Figulla ASD Flex I or Flex II device (Occlutech®) in St. Antonius Hospital, Nieuwegein, Netherlands, between 2008 and 2015 were included. The local ethics committee approved the study (registration number R&D/Z16.054).

2.2. Closing Procedure. Percutaneous closure was performed under general anaesthesia using transesophageal echocardiography (TEE) and balloon sizing as reported earlier [6].

Depending on the size and morphology of the ASD, device size was chosen by the interventional cardiologist. The initial success rate was defined as successful implantation.

2.3. Follow-Up. All complications were registered. All patients were discharged on antiplatelet therapy: clopidogrel (75 mg) for 4 weeks and aspirin (80–100 mg) for at least 6 months. If a patient was under anticoagulation therapy, only clopidogrel was associated for 4 weeks. Routine follow-up after closure was scheduled at 1, 6, 12, and 24 months using color-Doppler echocardiography to determine the presence of a residual LRS. Bubble contrast, at rest and after Valsalva, was used to identify a right-to-left shunt (RLS). The size of the RLS was classified by the number of bubbles in the left ventricle on a still frame and graded as minimal (<30 bubbles), moderate (30–100 bubbles), and large (>100 bubbles) [7]. Successful closure was defined as no residual LRS shunt using color-Doppler. Firstly, the electronic patient file was studied to find out whether the patient had a recent follow-up (within 6 months). If not, the patient was asked to participate in an interview by phone. A questionnaire was created together with the interventional and congenital cardiologists with standard follow-up questions. Besides the complaints that were mentioned by the patient, questions were asked about cerebral ischemic events (TIAs or stroke), presence of supraventricular tachycardias, and hospital admissions. If a patient was admitted to another hospital, that hospital was contacted to retrieve the necessary information. When it was unable to get in contact with the patient, the general practitioner was contacted. The questions were standardized to create complete and uniform data.

2.4. Statistical Analysis. Descriptive statistics were used for patients' characteristics. Continuous variables with normal distribution are presented as mean ± standard deviation. All statistical analyses were performed using the SPSS software (version 24.0 for Windows).

3. Results

3.1. Patient Characteristics. In total, 166 adult patients (62% women; mean age 56.7 ± 16.1 years) underwent percutaneous ASD closure using the Occlutech Figulla device between 2008 and 2015. During that study period, no other closure device had been used. The Occlutech Figulla Flex I was implanted in 116 patients (69.9%) and the Occlutech Figulla Flex II in 50 patients (30.1%). There were no differences in baseline characteristics between patients who received the different devices. Patient characteristics of the whole group are summarized in Table 1.

3.2. In-Hospital Complications. Device implantation (mean diameter 24 mm; range 10–40 mm) was initially successful in all patients. However, device embolization occurred in three patients (1.8%) within 24 hours after implantation. After a failed attempt to retrieve the devices percutaneously, they were extracted surgically followed by closure of the ASD. Balloon sizing (using the Amplatzer sizing balloon II, 34 mm (Abbott)) was performed in almost all of the patients. However, another sizing balloon (NuMED PTS-X 40 mm/5 cm-sizing balloon (NuMED Inc.)) had been used, in 2 out of the 3 device embolizations, leading to an inappropriate sizing due to inadequate calibration. In the other patient, a deficient aortic rim was present.

One patient (0.6%) suffered a significant amount of pericardial effusion (PE) a few hours after closure and needed percutaneous drainage. The next day, a second TTE showed no PE. The drain was retrieved, and the TTE was repeated a couple of hours thereafter. Again the TTE showed no PE. The patient was discharged, and after one and four weeks, no recurrent PE was found by TTE.

Table 1: Baseline characteristics.

Number of patients	166
Age (years)	56.7 ± 16.1
Female, *n* (%)	103 (62.0)
BMI (kg/m^2)	25.6 ± 4.5
Systolic blood pressure (mmHg)	129.3 ± 17.0
Diastolic blood pressure (mmHg)	79.2 ± 9.3
Risk factors and comorbidities, *n* (%)	
Smoking	23 (13.9)
Diabetes	11 (6.6)
Arterial hypertension	50 (30.1)
Hypercholesterolemia	39 (23.5)
CAD	10 (6.0)
History of AF or AFl	19 (11.4)
Indication for closure, *n* (%)	
RV volume overload	104 (62.7%)
Cryptogenic stroke/TIA	47 (28.3%)
Others	15 (9.0%)
Echocardiography	
RVSP (mmHg)	25.4 ± 7.8
Peak TRV (m/sec)	2.5 ± 0.4
Peak TRV (2.9–3.4 m/sec), *n* (%)	24 (14.5)
Peak TRV (>3.4 m/sec), *n* (%)	4 (2.4)
Mean follow-up (years)	5.9 ± 2.6

Data are presented as mean ± SD or number (percentage). BMI, body mass index; CAD, coronary artery disease; AF, atrial fibrillation; AFl, atrial flutter; RV, right ventricle; TIA, transient ischemic attack; RVSP, right ventricular systolic pressure.

3.3. Follow-Up. At 6-month follow-up, device thrombosis occurred in one patient (0.6%) who was noncompliant for oral anticoagulation therapy prescribed for recurrent idiopathic deep venous thrombosis. The device was extracted surgically, followed by closure of the ASD. All patients in whom a complication occurred recovered well. There were no significant differences in complications between both devices. In-hospital complications are shown in Table 2.

In total, new-onset AF occurred in 9.8% of the patients during the overall follow-up. Recurrent thrombo-embolic

Table 2: Periprocedural characteristics.

General anaesthesia, *n* (%)	166 (100)
TEE guiding, *n* (%)	166 (100)
ASD diameter on TEE (mm)$^{+}$	15.6 ± 6.1
ASD balloon sizing (mm)$^{+}$	20.9 ± 6.7
Device	
Occlutech Flex I, *n* (%)	116 (69.9)
Occlutech Flex II, *n* (%)	50 (30.1)
Device diameter (mm)*	24 (10–40)
In-hospital complication	
Device embolization	3 (1.8%)
Pericardial effusion	1 (0.6%)
New-onset AF	3 (1.8%)
Groin hematoma	13 (7.8%)
TTE shunt, *n* (%)	
Color-Doppler	23 (14.1%)

*Data are presented as median (range). $^{+}$Data are presented as mean ± standard deviation. TEE, transesophageal echocardiogram; ASD, atrial septal defect; AF, atrial fibrillation; TTE, transthoracic echocardiogram.

events occurred in seven patients (3 stroke, 2.1%; 4 TIA, 2.8%) during the total follow-up of almost 6 years. Details of these patients are summarized in Table 3.

Six patients died during follow-up. Three patients died in 15 months, two in 18 months, and one in 33 months after closure, respectively. One patient died due to the complications of liver cirrhosis. This patient had no evidence of pulmonary hypertension on TTE prior to closure. Another patient died because of systemic inflammatory response syndrome due to orbital cellulitis. He had a slightly elevated right ventricular systolic pressure (RVSP 40 mmHg) prior to closure. The third patient died after a tuberculosis infection. Before closure, this patient had an elevated RVSP (46 mmHg), which decreased after closure to 34 mmHg. A 70-year-old male, with a history of arterial hypertension and coronary artery disease, died due to sever systolic heart failure after myocardial infarction. There was no thrombus on the device and no elevated RVSP or secondary signs of pulmonary hypertension prior to closure. The cause of dead of the other two patients is unknown. No device-related cause was suspected after interviewing the families and general practitioners. One of these patients had a RVSP of 43 mmHg without secondary signs of pulmonary hypertension, and the other patient had normal pressures and no signs of pulmonary hypertension either. However, no autopsy was performed. Therefore, a device-related cause could not be excluded.

TTE was performed in 71 patients (49.3%) at 12-month follow-up. Follow-up information was available for 144 patients at long-term follow-up (mean 5.9 ± 2.6 years); data (interview or TTE) could not be retrieved for 22 patients. There was no recurrent LRS at the latest follow-up. There were no significant differences between both devices at long-term follow-up. Long-term follow-up data are presented in Table 4.

4. Discussion

Percutaneous ASD closure using the Occlutech device is safe and effective during a long-term follow-up of more than 800 patient-years.

4.1. Complications. In the current literature, an overall initial successful device implantation using the Occlutech device had been described between 94% and 99% of the procedures [2–4, 8, 9]. Complications that are described are related to the invasive procedure itself, such as groin hematoma and pericardial effusion. Other complications are related to the specific procedure using a device. Firstly, a device embolization is described between 0% and 2.6% for which percutaneous or surgical retrieval was necessary [2–4, 6, 9–13]. Haas et al. described that 1291 patients underwent successful percutaneous ASD closure with the Occlutech device. A device embolization occurred in 20 patients (1.6%) during hospitalization. There were another five embolizations during a mean follow-up of 2.7 years. Predictors for embolization are the absence of balloon sizing and the use of larger devices [9]. Kim et al. studied both the Occlutech and Amplatzer devices in ASD closure and found an embolization in one patient (1.0%) using the Amplatzer device and none in the Occlutech group [14]. More recently, Kenny et al. described a randomized controlled multicenter trial comparing the Occlutech and Amplatzer devices in 176 patients (both children and adults). They found a more successful device placement (99% vs. 90%) and early efficacy (94% vs. 90%) and less in-hospital major complications (5.6% versus 9.8%) using the Occlutech versus the Amplatzer device [12]. Secondly, an atrioventricular block occurs between 0% and 3.4%, mostly caused by oversizing the device [2, 3, 6, 8, 9]. This complication was often resolved after extraction of the device. An atrioventricular block occurred in seven patients (0.5%) during hospitalization in the study by Haas et al., of which five needed a smaller device. Thirdly and less common is device thrombosis; this occurred between 0% and 1% [3–5, 7, 8]. There was no device thrombosis in the study by Haas et al. Fourthly, pericardial effusion after percutaneous ASD is found in about 1.9%. The etiology of the pericardial effusion is unclear, but predictors are older age and higher body surface area at closure [13].

In our study, implantation was successful in 98%. Embolization occurred in 1.8%, which is similar when compared to the other studies. All three devices were extracted surgically, and the ASD had been closed without complications. There was one patient, noncompliant for Coumadin, who suffered a device thrombosis (0.6%). One patient suffered pericardial effusion without evidence of device perforation. As mentioned above, there were no significant differences in complications between the second- and third-generation devices. As mentioned earlier, Haas et al. described a large patient group of both children and adults. The median age was 26 years (range 0.3 to 83 years), which is significantly lower than our population. Furthermore, the first-generation Occlutech septal occluder (OSO) was used in 42% of patients. In our study, only second- and third-generation devices were used. Though, our results are similar to those described by Haas et al., cautiousness is necessary when comparing both studies.

4.2. Cerebrovascular Events. In the literature, cerebrovascular events after closure are rare and occur between 0% and 2.3% [3–5, 8–11]. None of the patients described in the four

Table 3: Thrombo-embolic events during follow-up.

Patient, n	Age, years	Sex	Stroke/TIA	History of stroke/TIA	Time after closure	AF history	RLS	Device thrombus
1	46	Male	Stroke	Stroke	<12 months	No	Minimal	No
2	74	Female	Stroke	No	<12 months	No	No	No
3	26	Female	TIA	Stroke	<12 months	No	Moderate	No
4	71	Female	Stroke	TIA	>12 months	No	No	No
5	79	Female	TIA	No	>12 months	No	No	No
6	46	Female	TIA	TIA	>12 months	No	No	No
7	58	Female	TIA	TIA	>12 months	No	No	No

TIA, transient ischemic attack; AF, atrial fibrillation; RLS, right-to-left shunt.

Table 4: Efficacy and safety during follow-up.

	<12-month follow-up	≥12-month follow-up
Number (*n*)	166	144
Complications, *n* (%)		
TIA	1 (0.6%)	3 (2.1%)
Stroke	2 (1.2%)	1 (0.7%)
AF	9 (5.4%)	6 (4.4%)
Death	0 (0%)	6 (4.4%)
TTE available (*n*)	163 (98.2%)	71 (49.3%)
LRS, *n* (%)	0 (0%)	0 (0%)
RLS, *n* (%)		
No shunt	113 (69.3%)	49 (69.0%)
Minimal	30 (18.5%)	16 (22.5%)
Moderate	15 (9.2%)	5 (7.1%)
Severe	5 (3.0%)	1 (1.4%)

TIA, transient ischemic attack; AF, atrial fibrillation; TTE, transthoracic echocardiography; RLS, right-to-left shunt.

studies with a total number of 501 patients suffered a TIA or stroke after closure [3–5, 8]. The study by Haas et al. described four patients (0.3%) who suffered a TIA or minor stroke [9]. Takaya et al. and Wang et al. described a stroke rate after closure between 1.2% and 2.2%, which is higher when compared to other studies. Though it is unclear what causes this higher cerebrovascular event rate, the age of the patients in both studies is significantly higher when compared to the other studies and might be the reason for this difference [10, 11]. In our study, a stroke rate of 2.1% was found during the long-term follow-up without a device-related cause. One patient had a minimal RLS at follow-up; however, the clinical relevance of this small RLS is unclear. Patient characteristics such as age and the presence of cardiovascular risk factors together with the longer follow-up duration could be the explanation. As described above, the age and cerebrovascular rate in the study by Takaya et al. and Wang et al. were high as well. A higher age is a predictor for cerebrovascular events after closure and in the overall population as well [15]. The cerebrovascular event rates were similar between both devices.

4.3. Arrhythmias. New-onset AF or atrial flutter is a known complication after percutaneous ASD closure and varies in studies between 0% and 4.7%. Supraventricular tachycardias (SVT) occurred in 4.7% in the study by Haas et al. [9]. There was no new onset of SVTs reported during the follow-up in the study by Pedra et al. and Roymanee et al. In 1% of the patients from the study of Aytemir et al., an SVT was diagnosed [4, 5, 8].

In our study, new-onset AF occurred in 5.4% during the first year and in 4.4% at long-term follow-up, which is slightly higher when compared to the literature. A possible explanation is the higher age of our patients when compared to the other studies. There were new-onset SVTs in 11.7% in the study by Wang et al., which is much higher than the other studies [11]. This study also included patients with a higher age. Literature showed a higher incidence of AF in older patients and this might be the explanation [16]. There were no significant differences between both devices which were used. In most studies, new-onset SVTs were diagnosed according to symptoms or coincidental findings on ECG during regular outpatient visits. Therefore, it is difficult to know the exact incidence of new-onset SVTs after closure.

4.4. Residual Shunting. Successful closure using the Occlutech device varies between 90% and 100% at different follow-up times [2, 3, 8, 9]. In our study, successful closure was achieved in all patients that underwent TTE at 12-month follow-up. Though TTE was only performed in 49% of patients, the success rate might be overestimated. Secondly, the LRS rate could be higher if TEE had been used instead of TTE. However, a small residual LRS found by TEE would probably have no clinical importance.

5. Limitations

Our study was an observational, single-center study describing the Occlutech device without comparison to other devices. Further, TTE was used at follow-up, making it possible to underestimate the residual LRS rate. However, it is unclear whether such a small LRS would be of clinical importance. There are no data about residual LRS at long-term follow-up, but TTE at discharge or one-year follow-up showed no LRS, making it unlikely that it would be found at long-term follow-up. We used telephone interviews for obtaining long-term data. This might be insufficient, and data about TTE are therefore not available.

6. Conclusion

Percutaneous ASD closure using the Occlutech device has a high successful closure rate at 12 months and appears to be safe at long-term follow-up with a low complication rate.

However, more follow-up data are needed to make a reliable conclusion.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request after the author gets approval of the ethics committee.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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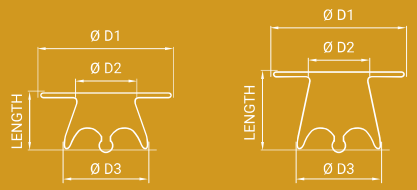
Product specifications

PDA



Article No.	Length [mm]	Ø D1 [mm]	Ø D2 [mm]	Ø D3 [mm]	Sheath Size* [F]	Pusher Article No. Occlutech Occlusion Pusher
Standard Shank						
42PDA05	4.25	9	3.5	5	6	50OP120
42PDA06	5.00	10	4	6	6	50OP120
42PDA07	6.05	11	5	7	6	50OP120
42PDA08	6.30	13	6	8	6	50OP120
42PDA10	7.00	16	8	10	7	50OP020
42PDA12	12.00	18	10	12	7	50OP020
42PDA15	14.00	20	12	15	8	50OP020
42PDA18	16.00	24	14	18	9	50OP020
Long Shank						
43PDA05L	7.00	9	3.5	5	6	50OP120
43PDA06L	7.50	10	4	6	6	50OP120
43PDA07L	8.50	11	5	7	6	50OP120
43PDA08L	9.00	13	6	8	6	50OP120
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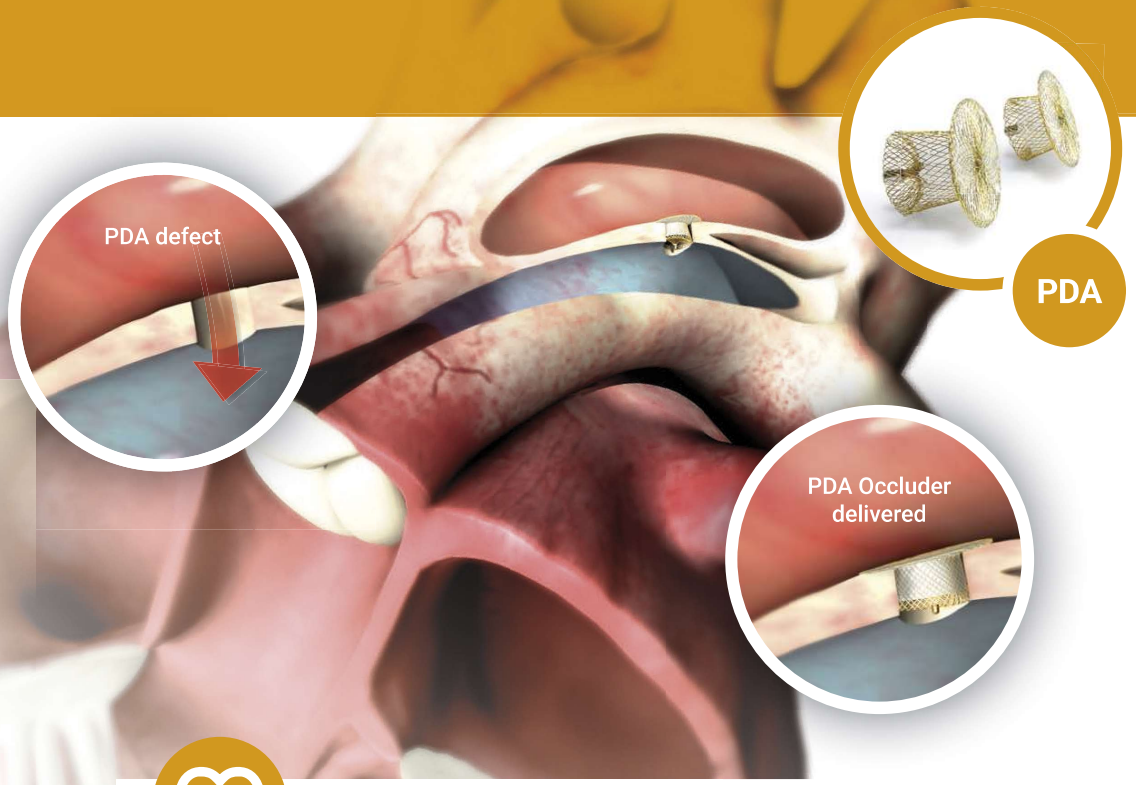

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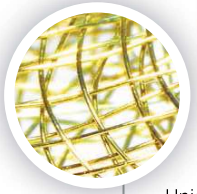
Standard & Long shank lengths

The Occlutech PDA Occluder is available in standard and long shank lengths.



Unique braiding structure

Long

Standard

CLINICAL BENEFITS

The design of the Occlutech PDA Occluder allows rapid occlusion of the defect without any distal clamp.

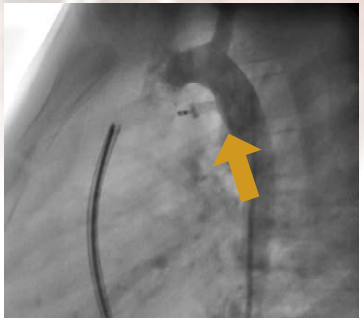
- High procedural success.[1]
- 100 % closure rate at 30 days.[2]
- No or very low major cardiac event rate.[3]

Content references:

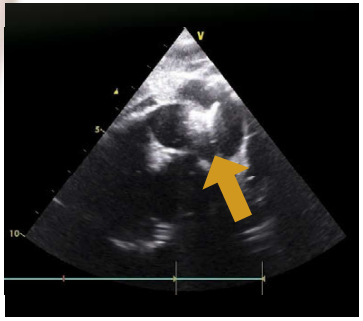
1. M. Bilici et al. Transcatheter Closure of Patent Ductus Arteriosus in Children with the Occlutech Duct Occluder. Pediatr Cardiol, Online 21 August 2017, DOI 10.1007/s00246-017-1702-x.

2. N. Hanna et al. The Occlutech Duct Occluder for Patent Ductus Arteriosus - A Retrospective Case Series. Journal of Structural Heart Disease, February 2017, Volume 3, Issue 1:1-7. DOI: http://dx.doi.org/10.12945/j.jshd.2017.16.002.

3. V. Kudumula et al. The New Occlutech Duct Occluder: Immediate Results · Procedural Challenges and Short-Term Follow-Up. CONGENITAL HEART DISEASE. VOL 27, EPUB 2015 APRIL 15.



PDA Occluder (42PDA06) in place.



PDA Occluder (42PDA06) in place.

Perfecting Performance

Figulla® Flex II Ordering information

Figulla® Flex II PFO Occluder (Single LA Disc)

Article No.	Product Name	Disc Ø (mm)	Defect Size (mm)
18PFO25S	Figulla® Flex II PFO	23/25	8<D≤13

Figulla® Flex II PFO Occluder

Article No.	Product Name	Disc Ø (mm)	Defect Size (mm)
19PFO18D	Figulla® Flex II PFO	16/18	D≤8
19PFO25D	Figulla® Flex II PFO	23/25	8<D≤13
19PFO30D	Figulla® Flex II PFO	27/30	13<D≤15
19PFO35D	Figulla® Flex II PFO	31/35	D≥15

Figulla® Flex II ASD Occluder

Article No.	Product Name	Waist Ø (mm)	Defect Size (mm)
29ASD04	Figulla® Flex II ASD	Size 4	D≤4
29ASD05	Figulla® Flex II ASD	Size 5	4<D≤5
29ASD06	Figulla® Flex II ASD	Size 6	5<D≤6
29ASD07	Figulla® Flex II ASD	Size 7.5	6<D≤7.5
29ASD09	Figulla® Flex II ASD	Size 9	7.5<D≤9
29ASD10	Figulla® Flex II ASD	Size 10.5	9<D≤10.5
29ASD12	Figulla® Flex II ASD	Size 12	10.5<D≤12
29ASD13	Figulla® Flex II ASD	Size 13.5	12<D≤13.5
29ASD15	Figulla® Flex II ASD	Size 15	12<D≤15
29ASD16	Figulla® Flex II ASD	Size 16.5	15<D≤16.5
29ASD18	Figulla® Flex II ASD	Size 18	15<D≤18
29ASD21	Figulla® Flex II ASD	Size 21	18<D≤21
29ASD24	Figulla® Flex II ASD	Size 24	21<D≤24
29ASD27	Figulla® Flex II ASD	Size 27	24<D≤27
29ASD30	Figulla® Flex II ASD	Size 30	27<D≤30
29ASD33	Figulla® Flex II ASD	Size 33	30<D≤33
29ASD36	Figulla® Flex II ASD	Size 36	33<D≤36
29ASD39	Figulla® Flex II ASD	Size 39	36<D≤39
29ASD40	Figulla® Flex II ASD	Size 40	39<D≤40

Figulla® Flex II Uniform Occluder

Article No.	Product Name	Disc Ø (mm)	Defect Size (mm)
16UNI17	Figulla® Flex II UNI	17/17	D≤8.4
16UNI24	Figulla® Flex II UNI	24/24	D≤11.9
16UNI28	Figulla® Flex II UNI	28.5/28.5	D≤13.9
16UNI33	Figulla® Flex II UNI	33/33	D≤16.4
16UNI40	Figulla® Flex II UNI	40/40	D≤19.5

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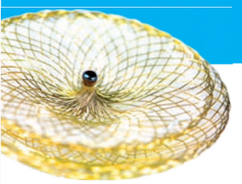
Occlutech®

Perfecting Performance

Occlutech®

Figulla® Flex II The Third Generation ASD and PFO Occluders

Figulla® Flex II The Third Generation ASD and PFO Occluders



A track record of innovation, performance and safety

Since developing the first unique Occlutech occluder in 2003, over 20,000 ASD and PFO occluders have been delivered to over 50 countries around the world. Occlutech's track record regarding performance and safety is excellent while we are still dedicated to innovating and constantly improving our products. The very flexible technology allows our products to adjust and fit a wide variety of geometries. Flex II, the third generation occluder, is now launched following what likely is already one of the best performing range of products available.

Unique new features

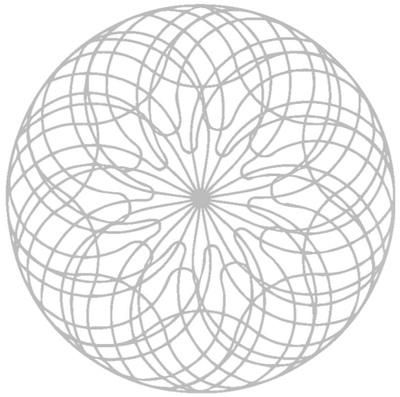
The Flex II range of occluders has been developed in order to fulfil Occlutech's strive for constant innovation and improvement and incorporates several new features:

- New braiding - minimizing the amount of material on the left atrial disc
- Improving delivery sheath compatibility
- New shapeable delivery system tip – allows a pre-set configuration for the advanced procedure
- Flexible delivery system allowing to-the-point placement while minimizing any unwanted drag or pull on the implant

Superior design

The new Figulla Flex II uses Occlutech's unique design capability of individually braiding the occluder with different patterns along the occluder. The distal disc has a different pattern than the proximal disc, giving the product a lower profile while advanced in the delivery catheter.

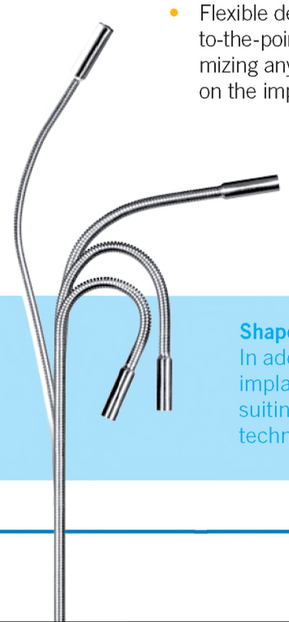
The unique Flex II braid minimizes the amount of material in the distal disc while significantly reducing diameter sizes during insertion



Delivery System

The delivery system of the Figulla Flex II range of products has been further improved. The occluder can now be angled some 50 degrees without any major drag on the product. This supports the placement under difficult conditions, especially in defects with less significant rims and where the angle of the desired placement is different from the angle of delivery system.

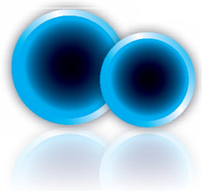
The delivery system allows a tilt of up to 50° giving perfect placement prior to release



Shapeable tip
In addition to the optimal angulation potential between the delivery system and implant, the actual tip of the delivery system can be shaped to the desired angle suiting any implantation technique. Occlutech's especially developed "Kinza" technology allows the pre-implantation shaping of the tip.

Reducing sheath diameters

The unique Occlutech braiding technology has allowed Occlutech to reduce the required size of the delivery sheath by 1-3 F. On average the required diamateter has been reduced by 20 % an important feature, especially in small children.



The Flex II braid allows on average 20 % less diameter in the delivery sheath

Superior surface treatment technology

The Occlutech surface technology was developed in order to obtain the highest possible biocompatibility of the implant. A special oxidation process that creates a layer of titanium oxide gives the Occlutech occluders their characteristic golden colour.

A layer of titanium oxide provides the Occlutech implants with their characteristic golden colour

Quality made in Europe

Occlutech adheres to the highest quality standards. We never compromise on quality. Our dedication to patients and the medical community is the main driver of our vision.

We want to be in the forefront of developing technologies and products that matter, that make a difference and that will help our customers to be at the forefront when it comes to better treating structural heart disease.

Before expansion, the distal tip of the Occlutech occluder take a soft round shape, minimizing risk of damage

Soft atraumatic tip

The outstanding soft, atraumatic tip of the occluder allows implantation unde the most difficult conditions. Occlutech's unique patented braiding technology allows the occluder to be manufactured without a distal clamp, minimizing both the risk of thrombus formation and of damaging the distal wall of the left atrium.

Perfecting Performance

Occlutech®

ASD comparative study: Occlutech outperforms Amplatzer and Gore

Early to Mid-Term Follow-Up Outcomes of Percutaneous Closure of ASDs Using Recent Generation Devices: a Single-Center Experience by Kim proves safety and comparability between all three devices in a highly skilled Korean interventional center with a procedural success of 100%.

- **267 patients**: 152 FSO / 98 ASO / 17 GSO including very small children (39 children <15 kg) with a mean FU of 2 years
- **FSO performs excellently** while its group consisted of significantly more challenging anatomies and sicker patients:
  - **28 small children (<15 kg)**
  - Biggest mean defect size vs. GSO and ASO (21,2 mm)
  - 92% NYHA-Class I-III
  - 29 multiple ASDs
  - **127 deficient retro-aoritic rims (<5mm)**
  - Procedural success: 100%
- **Sizing of the GSO is not standardized**. Due to the missing selfcentering waist, it is **not feasible for big anatomies** (>15mm)
- **ASO-complications: One embolization** has been observed for ASO (1%), **Cardiac erosion** is discussed broadly as a serious complication **in up to 0.3% of the ASO-treated patients**

- **Low profile** of LA disc is "indispensable" in small children
- **Recapturablity** and **ballconnector** helps procedural success
- **unparalleled adaptability** and **minimization of implant material quantity**, greater **flexibility** reduces trauma risk
- usage of FSO is the **hospital standard for ASDs in small children**
- **The FSO is safe, effective and reliable with great practical value.**

Occlutech

Early to Mid-Term Follow-Up Outcomes of Percutaneous Closure of Atrial Septal Defects Using Recent Generation Devices: a Single-Center Experience

Ah Young Kim, MD1, Se Yong Jung, MD1, Jenny Yeonsoo Chang2, Jo Won Jung, MD, PhD1, and Jae Young Choi, MD, PhD, SCAI1

Abstract

Background and Objectives:

This study aimed to describe our early to mid-term experience with transcatheter atrial septal defect (ASD) closure using the Occlutech Figulla® Flex II device (FSO), Gore® Cardioform septal occluder (GSO), and Amplatzer® septal occluder (ASO) after they were first approved in Korea in 2014, and to compare the three aforementioned kinds of ASD closure devices.

Methods:

Between September 2014 and August 2016, 267 patients underwent transcatheter ASD closure in our institution. Baseline characteristics, hemodynamic features, comorbidities, and procedural success and complication rates were analyzed retrospectively. The unpaired Student t-test or variance analysis was used in the statistical analysis.

Results:

The FSO was most commonly used (n=152, 56.9%), followed by the ASO (n=98, 36.7%) and GSO (n=17, 6.4%). Baseline characteristics and hemodynamic features were similar between the devices, except that the defect size and pulmonary flow-to-systemic flow ratio were lower in the GSO group than in the other groups. Overall, the procedural success rate remained at 100%, and major complication rate was <1%. No late complication occurred during the follow-up.

Conclusions:

The FSO and GSO are feasible, safe options for use in transcatheter ASD closure, and they are comparable to the ASO.

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https://doi.org/10.4070/kcj.2018.0278