Patent foramen ovale closure with the Occlutech Figulla Flex II device: A long-term (up to 10-years) Follow-up

Daniela Trabattoni, MD, FACC[1]; Giuseppe Calligaris, MD[1]; Giovanni Teruzzi, MD[1]; Sebastiano Gili, MD[1]; Giulia Santagostino Baldi, MD[1]; Sarah Troiano, MD[1]; Paolo Ravagnani, MD[1]; Piero Montorsi, MD[1,2]

Centro Cardiologico Monzino, IRCCS, Milan[1]; Department of Cardiovascular Sciences and Community Health, University of Milan[2] - ITALY

BACKGROUND

Scarce data report the long-term outcomes of patients undergoing PFO closure with the Figulla Flex II device (Occlutech, Germany).

OBJECTIVES

Primary: To investigate the safety and efficacy of Figulla Flex II PFO Occluder on a long-term follow-up (FU)

Secondary:

- Rate of all-cause mortality after 1, 3, 5 and > 5 years following implantation of the Occlutech PFO Occluder
- Proportion of patients with new onset of AF within 1and 45 days, and 6 months after implantation of the Occlutech PFO Occluder
- Proportion of patients with new onset of AF persisting for >6 months after implantation of Occlutech PFO Occluder
- Proportion of patients with recurrence of cryptogenic stroke after 1, 3, 5 and > 5 years following PFO Occluder implantation
- Proportion of patients with technical and procedural successful implantation of the Occlutech PFO Occluder.

METHODS

Consecutive pts undergoing PFO closure at a single, high-volume center, were included. Baseline clinical and procedural features were collected and pts were followed for up to 10 years. The device's long-term safety was assessed, as well as mortality, recurrent cerebrovascular events, new-onset atrial fibrillation (AF), and residual shunt (RLS).

INCLUSION CRITERIA

Each patient must fulfill all of the following criteria and details:

1. Age ≥ 18 years and ≤ 65 years.
2. At least one event of cryptogenic ischemic stroke in the last 12 months.
3. Presence of a PFO indicated for device-assisted closure (in compliance with the Instruction for Use) confirmed by common practice procedures.
4. A large PFO (maximum separation of the septum primum from the secundum) ≥2 mm confirmed by common practice procedures, or an ASA (atrial septal aneurysm) defined by common practice procedures as septum primum excursion ≥10 mm.
5. Life expectancy of at least 1 year.
6. Ability to understand the explanation of the procedure by the physician.
7. Written, informed consent by the patient for participation in the study and agreement to comply with the follow-up schedule.

SCREENING

Patients were carefully screened with transesophageal echocardiography (TEE), contrast transcranial Doppler (TCD) to assess microembolic signals (MES), coagulation analysis and a complete laboratory screening for thrombophilia (antithrombin III, anticardiolipin and antiphospholipid autoantibodies, lupus anticoagulant, protein C and S, homocysteine, genetic tests for factor V and II mutations).
Thrombophilia was defined when ≥1 of these tests were abnormal.
A neurologic evaluation after brain magnetic resonance (MR) or computed tomography (CT) scan assessment was routinely performed in all patients.
Moreover, all patients underwent arrhythmia screening with 24-h Holter monitoring or loop recorder implantation, before indication to PFO closure

BASELINE AND PROCEDURAL CHARACTERISTICS

Medical condition	Total ($N = 442$)*
Medical history	Number (%) of patients
Diabetes mellitus	18 (4%)
Hypertension	106 (24%)
Hypercholesterolemia	124 (28.1%)
Coronary artery disease	3 (0.7%)
Myocardial infarction	1 (0.2%)
Peripheral vascular disease	0 (0%)
Previous TIA	230 (52.1%)
Previous stroke of undetermined origin	59 (13.3%)
Family history of stroke	48 (10.9%)
Migraine	96 (21.7%)
Deep vein thrombosis	18 (4%)
Congestive Heart Failure	0 (0%)
COPD	1 (0.2%)
Birth Control or HRT	3 (0.7%)
Coagulation disorder	42 (9.5%)
Atrial Fibrillation	
Paroxysmal	3 (0.7%)
Persistent	0 (0%)
Permanent	0 (0%)

Baseline PFO characteristics.

Baseline PFO Characteristics	Total (N = 442)
	Number (%) of patients
Atrial Septal Aneurysm	92 (20.8%)
Atrial Septal hypermobility	245 (55.4%)
Other Atrial Septal defects	10 (2.2%)
Eustachian Valve present	40 (9%)
Chiari Network Present	88 (19.9%)
PFO Tunnel	$n = 350$
Tunnel Length	
<2 mm	15 (4.3%)
2–4 mm	100 (28.5%)
5–7 mm	185 (52.8%)
>/= 7 mm	50 (14.2%)
Shunt at rest	
None	73 (16.5%)
Trace (<2 mm)	122 (27.6%)
Moderate (2–5 mm)	205 (46.4%)
Severe (5 mm)	42 (9.5%)
Shunt at Valsalva	
None	22 (4.9%)
Trace (<2 mm)	45 (10.2%)
Moderate (2–5 mm)	180 (40.7%)
Severe (5 mm)	195 (44.1%)
Shunt direction	
Left-to right	8 (1.8%)
Right to left	420 (95%)
Bi-directional	14 (3.1%)

Procedural characteristics.

	Total (N = 442)
Procedure Characteristics	Number (%) of patients
Anesthesia	
Conscious Sedation	442 (100%)
Procedure Time [Minutes]	n = 442
Mean (SD)	26.1 (12.5)
Min, max	9, 61
Fluoroscopy Time [Minutes]	n = 442
Mean (SD)	5.4 (1.97)
Min, max	1, 14.4
Device Size Implanted	
16/18 mm	152/442 (34.4%)
23/25 mm	219/442 (49.5%)
27/30 mm	69/442 (15.6%)
31/35 mm	2/442 (0.5%)
Shunt Status Post Procedure-Day 1*	
None	420/441 (95.2%)
Trace (<2 mm)	16/441 (3.6%)
Moderate (2–5 mm)	5 (1.1%)
Severe (5 mm)	0

* 1 excluded as device embolized into the aorta.

RESULTS

A total of 446 consective pts were screened between December 2011 and February 2017 at Centro Cardiologico Monzino, in Milan. Four patients had a procedure attempted but did not have a device implanted, thus were excluded from the analysis. There were 442 patients enrolled who received Flex II PFO occluder device. Of these, 441 (mean age 45.5 ± 13 years, 57% women) had a successful procedure, defined as an implant with no SAE or large shunt, and one had a procedure failure due to device embolization into the aorta, followed by a successful percutaneous retrieve of the device.
The main indication for closure was TIA or stroke of undetermined origin (65.5%), migraine in 21.7%, positive brain MRI (10.8%), and decompression disease in 2%. Baseline characteristics, PFO characteristics and Procedural details are summarized in Tables above.

The investigational device: the Occlutech PFO Occluder is a self-expanding, sterile, double-disc implant consisting of a Nitinol wire mesh (scaffold) with superelastic properties. It consists of two retention discs connected through a thin flexible ridge. Two very thin polyester patches sewn in the left atrial and right atrial disc ensure instant cessation of blood flow through the defect as well as optimal tissue growth.

Procedural success, defined as no SADE (serious adverse devicer-elated event) or large shunt, was 441/442, resulting in **99.7% success rate** and one procedural failure due to device embolization into the descending aorta immediately after device release.

In-hospital complications occurred **in 15 (3.4%) patients**. In total, 4 patients (0.9%) had an access site hematoma (n = 2) and femoral pseudoaneurysm (n = 2) not requiring surgical correction. Transient de novo supraventricular tachycardias (n = 6) and paroxysmal atrial fibrillation (n = 5) occurred in 11 (2.5%) patients.

Follow-up: 30 subjects have been lost to follow-up and three died of malignancies during the long-term follow-up. Regarding the remaining 408 patients: a **mean follow-up time of 9.2 ± 1.0 years** has been completed **in 268 (65.7%)** subjects and **a follow-up time of 6.8 ± 0.4 years in 140 (34.3%)** subjects.

On the long-term follow-up, minimal ***residual right-to-left shunt*** observed after device implantation persisted in 5 patients and the residual moderate shunts observed pre-discharge became trivial in 2 cases, remained moderate in 2, and became severe in 1 case on the 1-year follow-up without clinical sequelae.

Arrhythmias: Atrial fibrillation, atrial flutter, or SVT recurrences were detected **in 9/408 (2.2%)** patients during the 6-month and 1-year follow-up. After the first year, two patients suffered a TIA (0.5%) without a residual RLS at FU; one was probably due to a hypertensive crisis while the other was associated with migraine with aura onset.

CONCLUSIONS

Our study, which presents to date the largest cohort of patients treated with PFO closure with the implantation of an Occlutech Figulla Flex device, has shown that the investigated device can be used with a high procedural success and a low procedural and long-term rate of adverse events.

Trabattoni D, et al. Int J Cardiol. 2023 Sep 15;387:131116. doi: 10.1016/j.ijcard.2023.06.007. PMID: 37301447.

Products displayed are not approved or available for sale in the United States. Products are not approved or available in all geographies. Please contact your Occlutech representative for questions about the availability of products in your area.

Centro Cardiologico Monzino