In-tunnel closure of patent foramen ovale with a FlatStent EF™

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Abstract

Background: Devices for percutaneous closure of patent foramen ovale (PFO) are traditionally based on two opposing discs, leaving significant surface areas exposed in the left and right atrium. The FlatStent EF™ PFO Closure System (Coherex Inc., Salt Lake City, USA) represents a major departure from these devices because it is designed to focus primarily on the PFO tunnel, leaving minimal foreign material behind.

Aim: To investigate the patient selection, effectiveness, and safety of in-tunnel closure with a FlatStent EF™ in patients with PFO of ≥ 4 mm tunnel length and < 12 mm diameter at preprocedural transoesophageal echocardiography (TEE).

Results: Among 46 consecutive patients undergoing PFO closure, a FlatStent EF™ could be implanted and resulted in initial successful closure (< 5 bubbles during Valsalva manoeuvre) in 21 (46%) patients. TEE at 162 ± 40 and 317 ± 162 days after implantation demonstrated functional closure in 90% and 95% of cases, respectively. No device or air embolisation, pericardial effusion, or thrombus formation was documented. Small in-tunnel peri-device colour Doppler left to right flow was documented in 10% and 2–6 mm protrusion of FlatStent EF™ along right atrial septum without any residual flow/bubble shunting in 14%. Patients with suboptimal closure (> 5 bubbles during Valsalva manoeuvre and/or in-tunnel colour flow) had shorter tunnel on preprocedural TEE (5.3 ± 1.5 vs. 10.8 ± 3.5 mm; p = 0.003). There was no difference in TEE diameter (1.8 ± 0.5 vs. 2.0 ± 0.5 mm; p = 0.38) and stretched diameter by sizing balloon (6.3 ± 2.5 vs. 6.3 ± 1.0 mm; p = 1.00).

Conclusions: In-tunnel PFO closure with a FlatStent EF™ represents an effective and safe option only in carefully selected patients with long tunnel (> 4 mm) regardless of the diameter if it is < 12 mm. These criteria are fulfilled in < 50% of consecutive candidates for PFO closure. The new phenomenon of in-tunnel peri-device flow and FlatStent EF™ protrusion along the right atrial septum were documented during systematic TEE follow up.

Key words: patent foramen ovale, in-tunnel closure

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INTRODUCTION

Devices for percutaneous closure of patent foramen ovale (PFO) are traditionally based on two opposing discs, leaving significant surface areas exposed in the left and right atrium. While these devices have been demonstrated to be effective, they have potential complications including atrial arrhythmia, thrombus formation and erosion of the atrial or aortic wall resulting in perforation and tamponade [1, 2]. The FlatStent EF™ PFO Closure System (Coherex Inc, Salt Lake City, USA) represents a major departure from these devices because it is designed to focus primarily on the PFO tunnel, leaving minimal foreign material behind [3, 4]. The device is composed of a radiopaque planar self-expanding nitinol lattice framework onto which polyurethane foam is attached (Fig. 1). The centre section of the implant with attached foam resides in the tunnel and serves as a nidus for occlusion and tissue ingrowth. The implant has micro-tines on both the left and right atrial anchors, which engage the apical junction of
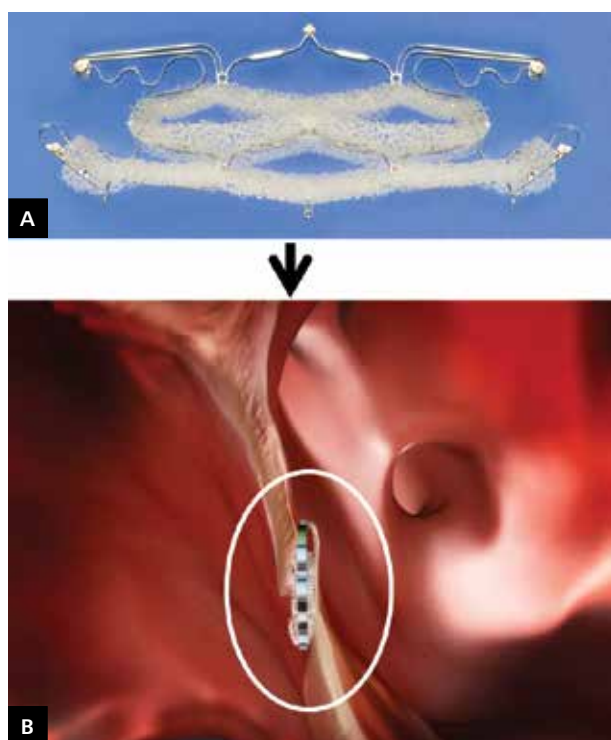
Figure 1. Coherex FlatStent EF™ PFO closure device (**A**) and schematic presentation of device position within the patent foramen ovale tunnel (**B**). The pictures were kindly provided by Coherex Inc, Salt Lake City, USA

septum primum and septum secundum, and serve to hold the device securely in place.

Favourable closure rates and safety of the first and particularly of the second generation of the device have recently been documented [5] and the Certificate of eligibility mark has been obtained. We hereby report our single-centre experience with the second generation of the device named the FlatStent EF™, which contains a larger volume of polyurethane foam to enhance tissue ingrowth and is available in two sizes, 13 mm and 19 mm. The focus of our study was on the patient selection, effectiveness, and safety of the closure assessed by systematic use of transoesophageal echocardiography (TEE) during the follow up.

METHODS

The study was part of a prospective PFO registry in MC Medicor Izola approved by the Slovenian National Ethics Committee. All procedures were in accordance with the Declaration of Helsinki, and patients gave written informed consent.

Patient selection

In our institution, percutaneous PFO closure is always discussed by the "PFO team", consisting of an echocardiographer, interventional cardiologist, and vascular neurologist who is responsible for the final qualification. Patients are eligible for percutaneous closure if they are between 18 and 60 years old, have had ischaemic cerebrovascular insult (CVI), transient ischaemic attack (TIA) associated with cerebral infarct on computed tomography or magnetic resonance imaging (MRI) or peripheral thromboembolism, and have PFO documented by TEE. Patients are routinely screened for other possible causes of CVI/TIA, including large vessel disease such as aortic/carotid atherosclerosis, hypercoagulable state, and paroxysmal atrial fibrillation with 24-h Holter if such event is suspected. If mechanisms other than paradoxical embolisation or lacunar infarct due to intrinsic small-vessel disease are identified, PFO closure is not attempted.

Consecutive patients with PFO as the presumed culprit for paradoxical embolism were screened. FlatStent EF™ implantation was considered in any patient with ≥ 4 mm tunnel length and < 12 mm diameter on TEE [5]. The degree of right-to-left shunting was assessed by TEE during Valsalva manoeuvre and graded according to the appearance of saline bubbles in the left atrium within six cardiac cycles of right atrial opacification as large (> 20 bubbles), moderate (5–20 bubbles), or small (< 5 bubbles) [5, 6].

FlatStent EF™ implantation

Conscious sedation without endotracheal intubation was used and the procedure was guided by simultaneous fluoroscopy and TEE, which was performed by the same echocardiographer. All procedures were performed by the same operator, who was initially assisted by the same second operator. After femoral vein access was achieved, a 6 Fr multipurpose catheter (Cordis, Johnson & Johnson, Warren NJ, USA) was advanced over a J-tipped 0.035-inch guidewire (Cook Medical, Bloomington, IN, USA) into the right atrium and through the PFO into the left upper pulmonary vein. After crossing a PFO, a bolus of unfractionated heparin (5000–7000 IE) was administered and the J-tipped wire exchanged for a long extra-stiff Amplatz wire (AGA Medical Corporation, Plymouth, MN, USA). Balloon sizing (NMT Medical Inc, Boston, MA, USA) was routinely performed to confirm a stretched tunnel diameter of < 12 mm, to observe tunnel shape during balloon expansion, and to select the size of the device (Fig. 2). A 13-mm device was attempted for stretched diameters up to 8 mm, and a 19 mm device for diameters from 9 to 12 mm.

In patients fulfilling criteria for FlatStent EF™ implantation, a 12 Fr sheath (Cook Medical, Bloomington, IN, USA) was advanced to the left atrium in a left anterior oblique view. The device, pre-attached to a monorail delivery system by three tethers, was advanced to the tip of the sheath and the left atrial anchors deployed. The cameras were then rotated to the contralateral right anterior oblique "en-face" view and the system was gently retracted until the left atrial anchors engaged the left atrial outlet of the PFO. This was readily recognised by the anchors flexing on engagement. Once the left atrial anchors were engaged against the septum, the
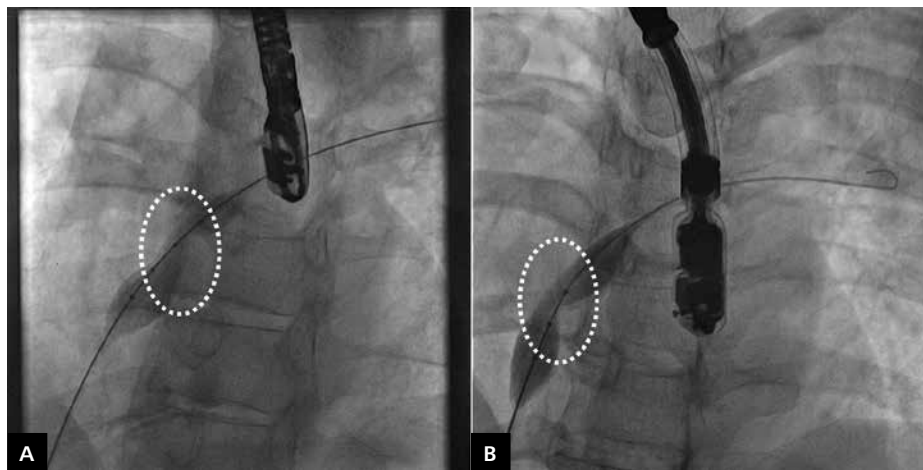
Figure 2. Evaluation of patent foramen ovale tunnel during expansion of the sizing balloon (left anterior oblique view). Sizing balloon expansion may reveal either obvious tunnel shape (**A**) or significant tunnel shortening or disappearance (**B**)
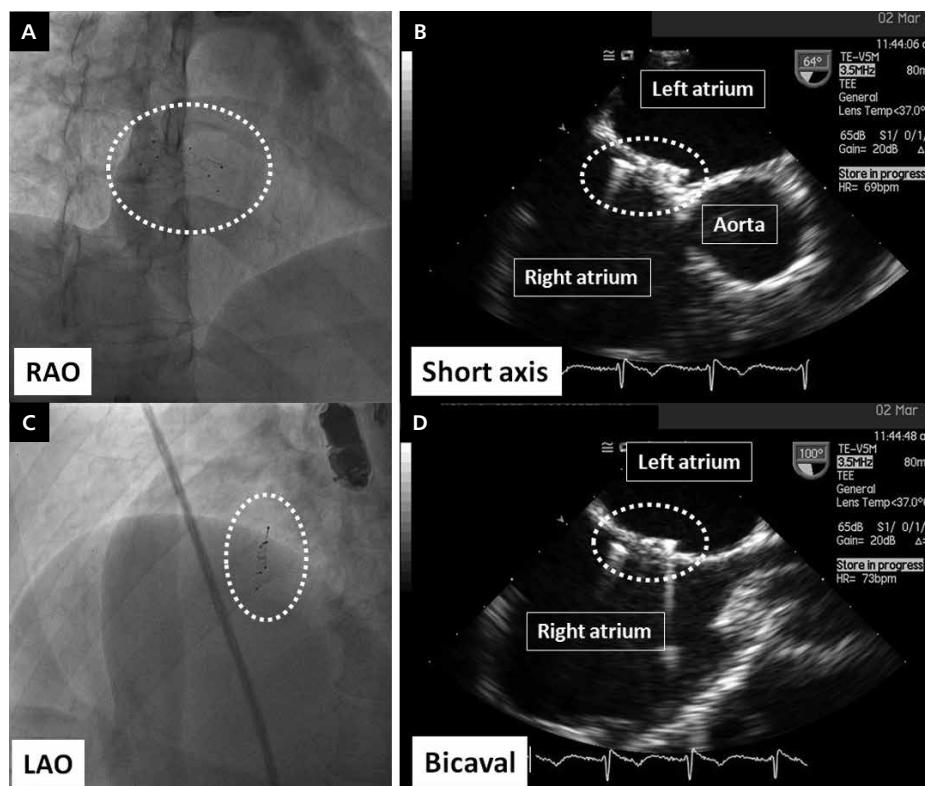

Figure 3. Appropriate shape and position of the deployed FlatStent EF™ on fluoroscopy (**A**) and transoesophageal echocardiography (**B**) in different views after detachment of the device; RAO — right anterior oblique; LAO — left anterior oblique

implant was held steady and the delivery system retracted completely off the implant. This allows the centre body section to expand laterally to its fully deployed position, and the right atrial anchors to deploy and engage on the right side of the tunnel. Appropriate placement was documented by confirming the expected device shape and position by fluoroscopy and TEE (Fig. 3). If the device position was appropriate and stable during a 'push-pull' manoeuvre and functional closure documented (< 5 bubbles in left atrium during Valsalva), the procedure was considered successful and the device was released via a simple button mechanism on the delivery system handle. If the above criteria were not met, the device was not released but retrieved and repositioned. If the result was still unsatisfactory, either BioSTAR (NMT Medical Inc.,

Boston, MA, USA) or Amplatzer PFO Occluder (AGA Medical Corporation, Plymouth, MN, USA) was used.

Follow up

Patients received one month of clopidogrel 75 mg per day and lifelong Aspirin 100 mg per day. Endocarditis prophylaxis was recommended for 6 months after device implantation. First follow up TEE was performed in all patients after 3–6 months and was repeated within the next 3–6 months if suboptimal PFO closure was documented. Patients were advised to contact us in case of new neurological symptoms, suspected peripheral embolism, and/or unexplained fever.

Study endpoints

The primary endpoint was the proportion of consecutive PFO patients in whom a FlatStent EF™ could be implanted and in whom it resulted in effective closure. Secondary endpoints were closure rate at follow-up TEE and device safety assessed by the incidence of device/air embolisation, pericardial effusion, thrombus formation, and vascular access complication during procedure and at follow up.

Statistical analysis

Numerical variables are expressed as mean $\pm$ standard deviation and categorical as percentages. Unpaired t-test was used for comparisons of tunnel diameter and length between the patients with optimal and suboptimal TEE closure during follow up. For comparison of categorical variables, Fischer exact test was used. $p < 0.05$ was considered as significant.

RESULTS

Among 46 consecutive patients undergoing PFO closure between December 5, 2009 and June 15, 2012, FlatStent EF™ implantation was attempted in 26 (57%) patients (Fig. 4). Because of suboptimal closure according to the protocol definition, the FlatStent EF™ had to be removed in five patients and replaced with an alternative device. Accordingly, a FlatStent™ was implanted and resulted in successful initial closure in 21 of 46 consecutive patients (46%). Unsuccessful closure attempts were equally distributed during the study period. Fluoroscopy time ranged from 6.3 to 17.0 min (9.3 $\pm$ 3.5 min) and there was no obvious impact of learning curve on duration of fluoroscopy.

Among patients with successful implantation of the FlatStent EF™, there were 10 men and 11 women with age between 21 and 60 years (42 $\pm$ 12 years). They had history of CVI (16 patients), TIA (4 patients), or TIA-like symptoms with cerebral ischaemic lesions on MRI (1 patient). Preprocedural TEE demonstrated PFO tunnel length 4–17 mm (10 $\pm$ 4 mm) and diameter 1–3 mm (2.0 $\pm$ 0.5 mm). Atrial septal aneurism was documented in three patients and Eustachian valve with the size 13–18 mm in three (14%) patients. Thickness of septum secundum in excess of 6 mm was seen in four
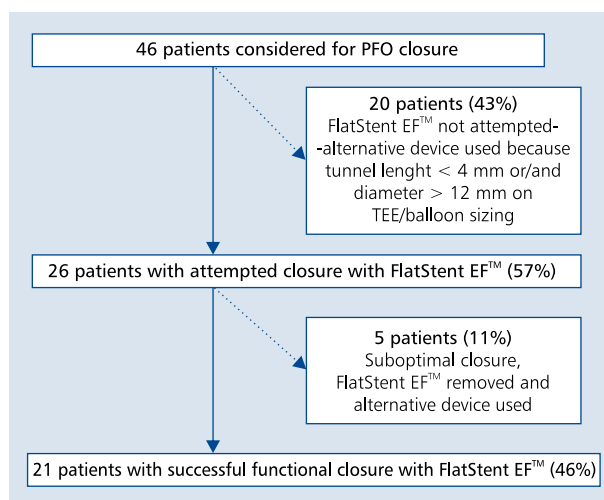

Figure 4. Selection of patients for FlatStent EF™ implantation in our study; PFO — patent foramen ovale; TEE — transoesophageal echocardiography

(19%) patients. Preprocedural bubble study during Valsalva revealed significant shunt (> 20 bubbles) in 11 patients and moderate shunt (5–20 bubbles) in 10 patients. Tunnel diameter measured by sizing balloon ranged from 3 to 10 mm (6.3 $\pm$ 2.3 mm). A 13-mm device was implanted in eight patients and 19-mm device in 13 patients. Immediate postprocedural complete closure was achieved in 17 (81%) patients and small residual shunt (< 5 bubbles) was present in four (19%) patients. Accordingly, all patients had successful functional closure as defined by the protocol.

At the first follow up TEE, 86 to 228 days (162 $\pm$ 40 days) after implantation, the device was within the tunnel in all patients (Fig. 5). Moderate bubble shunting was documented in two patients. Accordingly, complete closure was present in 76% and per protocol defined functional closure (< 5 bubbles) in 90% (Table 1). In two (10%) patients, a small in-tunnel left-to-right colour Doppler flow was documented (Fig. 6). In another three (14%) patients, a 2–6 mm protrusion of FlatStent EF™ along the right atrial septum without in-tunnel Doppler flow and bubble shunting during Valsalva was seen (Fig. 7).

In patients with no residual bubble shunting and/or in-tunnel colour Doppler flow, additional TEE was performed 200–550 days (317 $\pm$ 162 days) after implantation. Moderate (5–20 bubbles) residual shunting disappeared in two patients but appeared in one patient (Table 1). Assuming no shunting in patients with documented complete closure at the first follow up TEE, complete closure was 86% and per protocol defined successful functional closure in 95%. In-tunnel left-to-right colour Doppler flow disappeared in both patients but appeared in two (10%) patients. In a patient with moderate bubble shunting, the third follow-up TEE was performed 1150 days after the implantation and revealed < 5 bubbles on Valsalva and persistence of in-tunnel colour Doppler flow, which was much smaller.

Patients with > 5 bubbles on Valsalva and/or in-tunnel colour Doppler flow documented at the first or second follow up TEE had significantly shorter tunnel length (5.3 vs. 10.8 mm; p = 0.003) at preprocedural TEE. The patients with suboptimal closure were also more likely to have tunnel shortening to < 4 mm or even tunnel disappearance during sizing balloon expansion, although the difference was not significant (4/4 vs. 6/17; p = 0.38) (Fig. 2). There was no difference in tunnel diameter measured by either preprocedural TEE (1.8 ± 0.5 vs. 2.0 ± 0.5 mm; p = 0.38) or intraprocedural

Figure 6. Small in-tunnel peri-device left-to-right colour Doppler flow (arrow) on transoesophageal echocardiography 177 days after FlatStent EF™ implantation
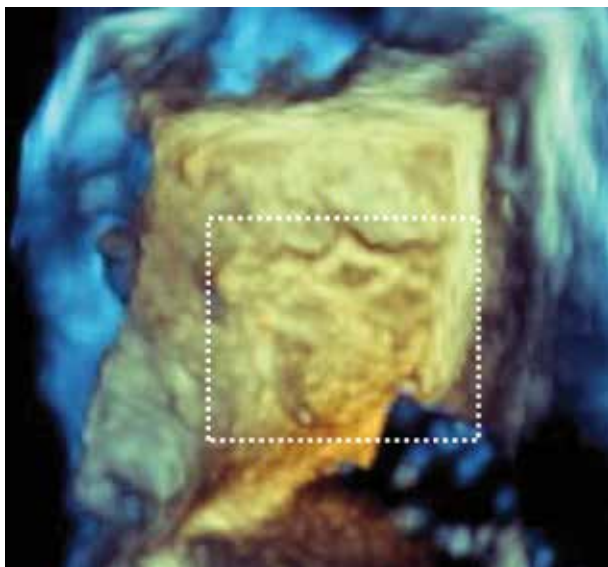

Figure 5. Three-dimensional transoesophageal echocardiographic view from the left atrium, showing left atrial anchors of the FlatStent EF™ at the apical junction of septum primum and secundum with the centre section of the implant residing within the tunnel covered by very thin septum primum
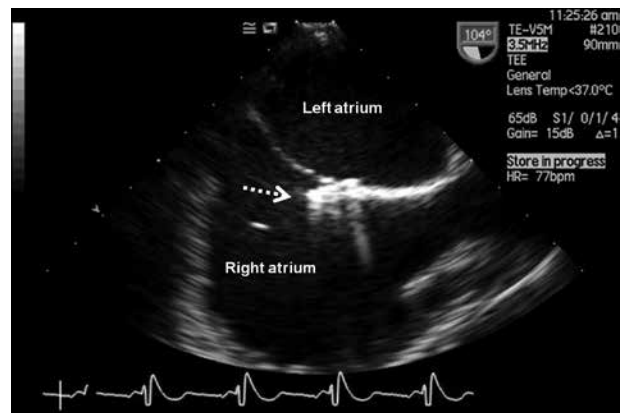

Figure 7. Bicaval transoesophageal view showing protrusion (arrow) of the FlatStent EF™ along the right atrial septum without concomitant peri-device in-tunnel colour Doppler flow

Table 1. Patients with any residual bubble shunting or small in-tunnel peri-device left-to-right colour Doppler (CD) flow on transoesophageal echocardiography (TEE) after FlatStent EF™ implantation. TEE was performed postprocedurally, the first follow up TEE at 162 ± 40 days, and the second follow up TTE at 317 ± 162 days after implantation. Since moderate shunt was present in patient number 2 at second follow up TTE (*), a third TEE was performed after 1150 days and revealed < 5 bubbles with persistence of small in-tunnel CD flow

Patient number	Postprocedural TEE		1st follow-up TEE		2nd follow-up TEE	
	Bubbles	CD flow	Bubbles	CD flow	Bubbles	CD flow
2	0	None	< 5	None	5–20*	Present*
4	< 5	None	0	None	ND	ND
5	< 5	None	< 5	None	0	None
6	0	None	5–20	None	< 5	Present
9	< 5	None	< 5	Present	0	None
11	0	None	5–20	Present	< 5	None
20	< 5	None	0	None	ND	ND

ND — not done because of complete closure during previous control

sizing balloon (6.3 ± 2.5 vs. 6.3 ± 1.0 mm; p = 1.00). Patients with FlatStent EF™ protrusion had significantly shorter tunnel during preprocedural TEE (6.5 ± 3.0 vs. 10.8 ± 3.5 mm; p = 0.036).

There was no device or air embolisation, pericardial effusion, thrombus formation, or vascular access complication during procedure and follow up. Transient atypical chest pain was documented in seven (33%) patients and palpitations in one (5%) patient. One patient with complete closure had transient TIA-like symptoms. Another patient with small residual shunt (< 5 bubbles) and in-tunnel colour Doppler flow at the first follow up TEE also had TIA-like symptoms that disappeared after complete closure was documented on subsequent TEE. Both patients with TIA-like postprocedural symptoms were examined by our neurologist.

DISCUSSION

We herein report our experience with the second generation Coherex FlatStent EF™, which could be successfully used in less than 50% of consecutive candidates for percutaneous PFO closure. The most important feature predicting successful closure with a FlatStent EF™ appeared to be tunnel length, and not diameter, providing that the length was > 4 mm and diameter < 12 mm, as recommended by the manufacturer [5]. This points to the fact that the FlatStent EF™ may be used only after careful selection of patients. If these rules are respected, functional closure rate in excess of 90% comparable to other devices such as Starflex, Biostar, and Amplatz PFO occluder documented also in our PFO registry [7] may be expected. We do not have any experience with an Amplatz cribriform septal occluder, which, however, does not seem to be superior to a standard PFO occluder [8].

Although not significant because of the small group of patients, tunnel shortening or even disappearance during sizing balloon expansion seems to predict suboptimal closure during the follow-up TEE. This indicates that not only tunnel length but also compliance is important for FlatStent EF™ success. Despite more rigorous definition of residual bubble shunting by us, our closure rate by FlatStent EF™ was better than in the pivotal study [5]. This is most likely a result of less strict patient selection and use of the first generation device in more than half of the patients enrolled in the pivotal study. We think that the second generation of the device represents a significant improvement and believe that possible development in the future should focus on further increase in polyurethane foam volume or utilisation of an alternative substance to accelerate tunnel tissue ingrowth. A larger size device greater then 19 mm would also be beneficial for larger and more compliant tunnels and would be likely to decrease the risk of embolisation, which was not documented in our study but was a problem with the first generation device [5]. Such improvements would allow for more effective closure

also in currently suboptimal candidates who unfortunately represent more than half of the consecutive all-comer population.

Because of the need for careful patient selection, we believe the FlatStent EF™ represents a "niche" rather than "working horse" closure device. A PFO with small-to-moderate diameter and long, less compliant tunnel may be ideal for FlatStent EF™, for which there is no upper limit of tunnel length. The FlatStent EF™ may therefore be particularly useful in the setting when traditional disk devices may not perform well, such as in the case of thick septum secundum, long and non-compliant tunnel, and large Eustachian valve, which may interfere with right atrial disk. While atrial septal aneurism is not a contraindication for FlatStent EF™, careful assessment of PFO tunnel including use of a sizing balloon is necessary before an implantation attempt.

As yet not reported observation is appearance of small in-tunnel peri-device left-to-right colour Doppler flow associated with variable bubble shunting not observed in postprocedural TEE but only at follow up TEE. This phenomenon seemed to be dynamic over time and probably reflects tunnel remodelling and scaring after FlatStent EF™ implantation. We also noticed protrusion of the FlatStent EF™ along the right atrial septum, which seems to be benign but again pointed to a possible shortening of the tunnel during the as yet not well-described process of PFO remodelling and scarring following device implantation.

Our experience with in-tunnel PFO closure with the FlatStent EF™ indicates the complexity and variability of the PFO tunnel [9, 10], which undoubtedly represent the most important anatomic feature determining the success of the FlatStent EF™. Because of the need for careful tunnel assessment with systematic use of a sizing balloon and detailed device evaluation before detachment, the technique is more demanding for interventional cardiologists and echocardiographers. This is reflected also in longer fluoroscopy time compared to Amplatz PFO occluder in our registry [7]. Because systematic use of a sizing balloon is mandatory, at least in our opinion, FlatStent EF™ closure is also more costly compared to traditional disc-based technologies. However, for optimal and least invasive PFO closure, leaving as little as possible foreign material in the heart, "one size may not fit all", and different anatomic features may require specific devices able to adjust to the tunnel length, size, compliance, and variable thickness of septum secundum [10].

CONCLUSIONS

In-tunnel PFO closure with a FlatStent EF™ represents an effective and safe option only in carefully selected patients, which is the case in < 50% of consecutive candidates for PFO closure. As such, the FlatStent EF™ represent a "niche" rather than a "working horse" PFO closure device, which may be suitable in patients with small-to-moderate PFO diameter and

long, less compliant tunnel, and in particular in the setting when traditional disk devices may not perform well, such as in the case of thick septum secundum, long and non-compliant tunnel, and large Eustachian valve that may interfere with right atrial disk. However, important limitations of our study related to the small number of patients, single-centre experience, lack of direct comparison with traditional disk-based closure devices, and no independent TEE core laboratory evaluation have to be taken into account when interpreting our results.

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Śródkanałowe zamknięcie przetrwałego otworu owalnego za pomocą stentu FlatStent EF™

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Streszczenie

Wstęp: Urządzenia do przezskórnego zamknięcia przetrwałego otworu owalnego (PFO) tradycyjnie są zbudowane z dwóch przeciwstawnych dysków o stosunkowo dużej powierzchni, które zakłada się do lewego i prawego przedsionka. System stentu do zamykania PFO FlatStent EF™ (Coherex Inc., Salt Lake City, USA) stanowi zdecydowane odejście od tego typu urządzeń, ponieważ mieści się on głównie w kanale PFO, a ilość obcego materiału znajdująca się poza kanałem jest minimalna.

Cel: Badanie przeprowadzono w celu oceny doboru pacjentów, skuteczności i bezpieczeństwa śródkanałowego zamknięcia PFO przy użyciu stentu FlatStent EF™ u chorych, u których długość kanału, określona na podstawie przeprowadzonej przed zabiegiem echokardiografii przezprzełykowej (TEE), wynosiła ≥ 4 mm, a średnica < 12 mm.

Wyniki: U 21 (46%) spośród 46 kolejnych pacjentów poddanych zabiegowi zamknięcia PFO było możliwe wszczepienie stentu FlatStent EF™; u tych chorych uzyskano wstępne skuteczne zamknięcie PFO (< 5 pęcherzyków kontrastu podczas próby Valsalvy). Wyniki TEE wykonanego po 162 ± 40 i 317 ± 162 dniach po wszczepieniu stentu wykazały czynnościowe zamknięcie PFO u odpowiednio 90% i 95% chorych. Nie stwierdzono zatoru powietrznego ani spowodowanego urządzeniem wysięku osierdziowego, ani też utworzenia się skrzepliny. W badaniu techniką kolorowego doplera u 10% chorych wykryto niewielki śródkanałowy przeciek lewo-prawy wokół urządzenia, a u 14% stwierdzono wysunięcie stentu FlatStent EF™ wzdłuż przegrody prawego przedsionka o 2–6 mm, bez cech przepływu resztkowego/pęcherzyków kontrastu. U chorych z suboptymalnym zamknięciem (> 5 pęcherzyków kontrastu podczas próby Valsalvy i/lub przepływ śródkanałowy w badaniu metodą kolorowego doplera) długość tunelu określona w TEE przed zabiegiem była mniejsza (5,3 ± 1,5 vs. 10,8 ± 3,5 mm; p = 0,003). Nie stwierdzono różnicy pod względem średnicy kanału określonej w TEE (1,8 ± 0,5 vs. 2,0 ± 0,5 mm; p = 0,38) ani średnicy rozciągniętego otworu zmierzonej za pomocą balonu wymiarującego (6,3 ± 2,5 vs. 6,3 ± 1,0 mm; p = 1,00).

Wnioski: Śródkanałowe zamknięcie PFO przy użyciu stentu FlatStent EF™ jest skuteczną i bezpieczną metodą zarezerwowaną dla starannie dobranych pacjentów z długim kanałem (> 4 mm) niezależnie od średnicy kanału, jeśli mieści się ona w zakresie < 12 mm. Kryteria te spełniało < 50% kolejnych pacjentów kwalifikowanych do zamknięcia PFO. W trakcie obserwacji po zabiegu u chorych systematycznie wykonywano TEE, w których stwierdzono nowe zjawisko — śródkanałowy przeciek wokół urządzenia i wysuwanie się stentu FlatStent EF™ wzdłuż przegrody prawego przedsionka.

Słowa kluczowe: przetrwały otwór owalny, zamknięcie śródkanałowe

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