Feasibility and safety of left atrial appendage closure in a patient with previous foramen ovale occlusion: a case report

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Background
Left atrial appendage (LAA) closure is an alternative to chronic oral anticoagulation for stroke prevention in patients with atrial fibrillation (AF) at high bleeding risk. Patients with a previous percutaneous closure of a patent foramen ovale (PFO) present an increased risk for developing AF during their life, and the presence of an atrial septal device renders future percutaneous left atrial access more challenging. Very few cases of LAA occlusion in patients with a preexisting PFO closure device have been previously reported.

Case summary
A 74-years old woman was admitted to our hospital for symptomatic severe anaemia during direct oral anticoagulant treatment. Her past medical history reported an ischaemic stroke at the age of 55, at that time a PFO was diagnosed and a STARFlex™ PFO occluder (NMT Medical, Boston, MA, USA) was implanted. During the current hospitalization, the patient underwent a colonoscopy that showed colonic angiodysplasias unsuitable for endoscopic treatment and LAA closure was indicated for stroke prevention. After a multimodality pre-procedural planning that included a transoesophageal echocardiogram, a cardiac computed tomography scan and a three-dimensional cardiac model printing, the procedure was planned and the LAA successfully occluded.

Discussion
LAA closure can be performed safely and effectively in patients carrying a previously implanted PFO occlusion device. In complex settings, a pre-procedural multimodality imaging is critical for improving the procedural safety and success rate. We describe the first case of percutaneous LAA closure in a patient with a prior PFO occlusion with the implantation of a STARFlex™ septal occlusion device.

Keywords
Left atrial appendage occlusion • Transseptal catheterization • Patent foramen ovale • 3D printing • Case report

Learning points
• Feasibility and safety of left atrial appendage (LAA) closure in a patient with a previous percutaneous occlusion of a patent foramen ovale.
• Pre-procedural multimodality imaging and choice of the correct device is of utmost importance when planning a challenging procedure.
• Role of LAA occlusion for stroke prevention in patients with atrial fibrillation, high thrombotic risk and contraindications to oral anticoagulation.

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**Introduction**

In patients with atrial fibrillation (AF), left atrial appendage (LAA) closure has emerged as an alternative to chronic oral anticoagulation (OAC) therapy for stroke prevention in patients at high bleeding risk or with contraindications to OAC. LAA closure shows a significant reduction in major bleeding events with a similar stroke rate, compared to OAC. Paradoxical embolism is the main indication for the closure of a patent foramen ovale (PFO) or a small atrial septal defect (ASD). Percutaneous closure of ASD/PFO renders future percutaneous left atrial access more challenging. Cases of combined closure of LAA and interatrial communication have been described, and usually the LAA closure is followed by that of the ASD. To the best of our knowledge, only three cases of PFO closure followed in a second time by LAA occlusion have been reported; of these, two patients received the Amplatzer Cardiac Plug™ (Abbott, Santa Clara, CA, USA) and one the Helex™ (Gore Medical, Flagstaff, AZ, USA) as septal occlusion devices. Here is reported the first case of percutaneous LAA closure in a patient with a prior implantation of a STARflex™ (NMT Medical, Boston, MA, USA) septal occluder.

**Timeline**

| Date       | Event                                                                 |
|------------|-----------------------------------------------------------------------|
| 19 years   | Transcatheter patent foramen ovale (PFO) occlusion with a STARflex device for a cryptogenic ischaemic stroke |
| 4 years    | Diagnosis of atrial fibrillation and start of direct oral anticoagulation |
| Day 1      | Admission for symptomatic anaemia                                      |
| Day 5      | Colonoscopy: multiple colonic angiodysplasias deemed unsuitable for endoscopic invasive treatment |
| Day 7      | Transoesophageal echocardiogram (TOE): single-lobe left atrial appendage (LAA) free from thrombi; PFO occluder regularly in site |
| Day 8      | Cardiac computed tomography                                           |
| Day 12     | Three-dimensional printing and simulation of the procedure with a demo model of the selected device |
| Day 16     | LAA occlusion                                                         |
| Day 18     | Discharge                                                             |
| 40-day follow-up | TOE: LAA and PFO occlusion devices regularly in site without leaks or thrombi. Patient asymptomatic with stable haemoglobin levels. |

**Case presentation**

A 74-year-old woman was admitted to our hospital for symptomatic anaemia during direct oral anticoagulant treatment. Her past medical history reported an ischaemic stroke at the age of 55, at that time significant carotid artery disease and AF were excluded. A transoesophageal echocardiogram (TOE) showed a PFO presenting significant left-to-right interatrial shunt, inverted by Valsalva manœuvre. A successful transcatheter PFO occlusion was performed, with the implantation of a device available at that time (STARflex™ 23 mm, NMT Medical, Boston, MA, USA). At the age of 70 paroxysmal AF was diagnosed and OAC with rivaroxaban 20 mg was commenced due to a CHA₂DS₂-VASc score of 5. After several and ineffective pharmacological attempts of rate and rhythm control, an ablate and pace strategy was carried out 2 years later.

On initial assessment, the patient showed dyspnoea and mild hypoxia with pulse oxygen saturation of 90%. The blood pressure was 100/65 mmHg, physical examination showed normal cardiac murmurs and no signs of congestion. The electrocardiogram showed paced ventricular rhythm. Blood tests revealed severe microcytic hypochromic anaemia (haemoglobin 7 g/dL). Following anticoagulation discontinuation and red blood cell transfusion, gastrointestinal endoscopic examination was planned. Colonoscopy showed multiple colonic angiodysplasias carrying signs of recent bleeding, deemed unsuitable for endoscopic invasive treatment. At this stage, the patient was referred to our division for an evaluation focused to the feasibility of LAA occlusion. A TOE showed a single-lobe ‘chicken-wing’ LAA morphology, free from thrombi. The PFO occluder was regularly in site, without residual leaks nor thrombi. The interatrial septum had a small free residual portion suitable for transseptal catheterization, just posteriorly to the interatrial device.

A pre-procedural cardiac computed tomography (CT) scan was performed in order to comprehensively assess the anatomical relationship between the atria, the septal occlusion device, the residual device-free interatrial septum and the aortic root. Based on the CT scan images, a three-dimensional (3D) accurate model of patient’s atria was printed. In this case, we selected the LAmbre™ (Lifetech, Shenzhen, China) as LAA occluder device, for the smaller diameter of its delivery sheath (10 F) compared to other devices. The procedure was then simulated with the printed patient’s cardiac 3D model and a demo model of the LAmbre™ (Figures 1 and 2), confirming its technical feasibility.

Under general anaesthesia and continuous TOE monitoring, transseptal puncturing was performed at the posterior-inferior edge of the STARflex™ device, in the small free residual portion of the interatrial septum (Figure 3). Following successful access in the left atrium, an LAA closure device (LAmbre™ 22/28 mm, Lifetech, Shenzhen, China) was successfully delivered, resulting in optimal LAA closure without acute complications or residual leaks (Figures 4 and 5). The patient was successfully discharged two days after the procedure, with single antiplatelet therapy with acetylsalicylic acid for the high bleeding risk. At 40-days of follow-up, a TOE was repeated, showing a correctly positioned device at the LAA ostium without leaks or thrombi. No residual shunt was observed in the interatrial septum and the PFO device was correctly positioned. The patient is currently asymptomatic, and haemoglobin levels are stable around 10 g/dL.

**Discussion**

This case highlights the technical feasibility of transseptal puncture and LAA closure in patients with a previously implanted septal PFO occluder. The STARflex™ device has not been investigated in this
setting before and has a larger dimension compared to more recent septal devices. Chronic OAC has been proven to effectively prevent thromboembolic risk related to AF, but side effects and contraindications limit its use in patients at high bleeding risk. In this kind of patients, LAA closure is a safe and effective alternative for both stroke and bleeding prevention. Additionally, AF and the subsequent need for OAC is expected to occur with a certain frequency on the long-term follow-up of patients with a previous PFO closure. Of note, the incidence of AF is reported to be higher with the STARflex™ than other devices, probably due to its larger dimension. Such a large device, may render transseptal left atrial access more challenging or even impossible, as the residual space for transseptal puncture becomes very limited. In this case, after carrying out a pre-procedural TOE, we chose to perform a CT scan and a 3D printing of the atria to assess the feasibility of a transseptal approach, aiming to overcome potential issues that could have occurred during the procedure. Simulation through 3D models has recently emerged as a useful tool for complex procedures with anatomical concerns. LAA closure is an elective procedure, so safety should be focused first. Other approaches including an anterior puncture or crossing through the device are also possible and have been demonstrated with other devices. However, due to the absence of data with the STARflex™, we chose a more conservative approach.

The smaller dimension of the device delivery system that has been selected for this procedure compared to other available ones, is another relevant point considering the tiny portion of free interatrial

Figure 1 Three-dimensional model based on cardiac computed tomography scans.

Figure 2 (A) Cardiac computed tomography. (B) Simulation of the procedure with the three-dimensional model and a demo model of the selected device.
The possibility of having different devices in the cath lab and to choose among them the one that best matches the patient’s anatomical characteristics is a very important feature in a challenging setting like this.

**Conclusion**

LAA closure can be performed safely and effectively in patients carrying a previously implanted PFO occlusion device. Transseptal puncture can be performed even in patients with the older and larger STARflex\textsuperscript{TM} devices. In complex settings, a pre-procedural multimodality imaging is of utmost importance for improving the procedural safety and success rate.

**Lead author biography**

Dr Mario Matta works in the Electrophysiology Lab at Cardiology Division, Sant’Andrea Hospital, Vercelli, Italy since 2018. Following graduation in Medicine, he attended Cardiology School at University of Turin, working subsequently as Electrophysiology Fellow at ‘Città della Salute e della Scienza’ Hospital, University of Turin, including an internal fellowship at Arrhythmology Division, San Raffaele Hospital, Milan, Italy. He is experienced in Interventional Electrophysiology, pacemaker and defibrillator
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**Supplementary material**

Supplementary material is available at European Heart Journal - Case Reports online.

**Slide sets:** A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

**Consent:** All authors confirm that written consent for submission and publication of this case report including images and associated text has been obtained from the patient.

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