The technique for percutaneous patent foramen ovale (PFO) closure has dramatically evolved during the past decade. Proper patient preparation including pretreatment with antiplatelet, antithrombotic, and antibiotic therapy is important. Informed patient consent and device selection can largely be made from preprocedure transesophageal echocardiography. This review highlights the technical aspects of PFO closure using the Amplatzer (AGA Medical Corporation, Plymouth, MN) and Helex devices (W.L. Gore & Associates, Flagstaff, AZ). Additionally, fluoroscopic-only guidance without intraprocedural echocardiography, and postprocedure surveillance for complications are highlighted. When using these techniques in experienced hands and with appropriate preprocedural cardiac imaging, the technical success rate should be 100%, with a complication rate of < 0.2%.

**PATIENT PREPARATION**

Before implantation, patients should be pretreated with antiplatelet therapy, typically with both aspirin (81 mg) and clopidogrel (75 mg) daily. In patients with an indication for chronic antithrombotic therapy (i.e., those with deep venous thrombosis, pulmonary embolism, or atrial fibrillation), warfarin therapy alone may be used, using bridging with low-molecular-weight heparin before and after PFO closure.

Patients should not undergo PFO closure if they have a current or recent bacterial or fungal infection. Patients should receive a single intravenous antibiotic dose within 1 hour of percutaneous access, typically with 1 g of cefazolin or vancomycin if they are allergic to penicillin. For uncomplicated cases, subsequent intravenous or oral antibiotics are unnecessary.

The peripheral intravenous line should have an air-eliminating filter in position (1.2 Micron filter, Baxter Healthcare Corporation, Deerfield, IL). Patients should receive intravenous normal saline at 1 mL/kg/hour before and during the procedure to avoid left atrial hypovolemia.

**DEVICE SELECTION**

In the vast majority of cases, device selection can be based on preprocedure transesophageal echocardiography. Although some operators only perform transthoracic echocardiography and/or transcranial Doppler studies before bringing the patient to the cardiac catheterization laboratory, a transesophageal echocardiogram is critical in defining the septal anatomy to (1) properly consent a patient for PFO closure, as opposed to atrial septal defect closure or pulmonary arteriovenous fistula closure, (2) exclude other congenital heart abnormalities, such as anomalous pulmonary venous drainage, and (3) select devices and technical strategies likely for success in advance of the procedure.

Although the StarFlex and CardioSeal devices (NMT Medical, Inc., Boston, MA) are available in the United States for septal closure, the author’s preferred devices for PFO closure include the Amplatzer Cribriform and PFO occluders (AGA Medical Corporation) and the Helex device because of their lower rates of device fracture,1 thrombosis,2 and residual shunt.3 For these reasons, technical considerations for implantation of the StarFlex and CardioSeal devices will not be discussed in detail in this review. It is noteworthy that NMT Medical has completed enrollment for CLOSURE I, the randomized, multicenter trial that is testing the StarFlex device in patients with cryptogenic stroke and PFO. Data analysis for this study has not yet been completed.

For small PFOs without associated interatrial septal aneurysm, the 25-mm size Cribriform, PFO occluder, or Helex is preferred. Using devices smaller than 25 mm in adults is not required and may increase the risk for device embolization. For patients with a large atrial septal aneurysm and/or large tunnel diameter of 2 to 4 mm, the 30-mm devices are preferred. The 35-mm devices are reserved for severely mobile septal aneurysms and large tunnel diameters (> 4 mm). In some patients with a very large tunnel diameter with brisk interatrial shunting, the
Amplatzer atrial septal occluder is a good choice. This device’s central disc may perform well when there is a gaping tunnel that is functionally closer to an atrial septal defect. In patients with a thickened septum secundum > 1.5 cm, the Cribriform is preferred because the Helex requires a compressed tunnel length < 12 mm.

Nickel allergy is a poorly defined syndrome. There have been several case reports of severe nickel allergy after implantation of an Amplatzer occluder device.4,5 The one case report of nickel allergy in a patient with the Helex device6 is difficult to interpret because the patient also had sternal wires containing nickel. In two case series of patients with nickel allergy, device-allergic syndrome was reported in the majority of Amplatzer patients,7 and in none of the Helex patients.8 Given the absence of data, the author prefers to use the Helex device in patients with nickel allergy, which is documented by skin patch and/or scratch testing before implantation.

**Implantation Technique**

Closing the PFO from the femoral venous site is far easier than attempting closure from either the internal jugular,9 axillary,10 or hepatic vein11 because of the vertically angled PFO from the inferior right atrium to the superior left atrium. After femoral venous sheath insertion, a 60-U/kg heparin bolus is administered, with additional heparin as needed to maintain an activated clotting time > 225 seconds. Nasal cannula oxygen at 6 L/min is administered for hyperoxygenation, in case of an air embolus while catheterizing the left atrium.

If PFO closure is performed with fluoroscopic guidance only, right atrial angiography is performed with a 7-F Berman balloon-tipped angiographic catheter (Arrow International, Inc., Reading, PA) or a pigtail catheter in the left anterior oblique projection, with low osmolar or isomolar contrast at 24 mL/s for a total of 30 mL. Levo phase cineangiography demonstrates the left atrial anatomy. The PFO and atrial septal aneurysm are typically demonstrated by right atrial angiography (Figure 1). A 6-F multipurpose catheter is advanced over a 0.035-inch J-tipped guidewire into the superior vena cava. In the left anterior oblique projection, the catheter is positioned posteriorly and withdrawn to the fossa ovalis. Once the catheter is in the fossa ovalis, the guidewire is advanced across the PFO into the left superior pulmonary vein. The multipurpose catheter is then advanced into this pulmonary vein, and its position is confirmed by hemodynamic measurement of left atrial pressure.

In cases in which it is difficult to advance a guidewire into the left atrium, a JR4, hockey stick, or XB 3.5 guide (Cordis Corporation, Bridgewater, NJ) may be used. Occasionally, a Glidewire (Terumo Interventional Systems, Somerset, NJ) is helpful in crossing a small PFO. If there are fenestrations within the PFO that prohibit advancement of the catheter across the PFO, a 4- or 5-F catheter may be used. Hand-injection contrast angiography through the catheter can help identify the entry point for a small PFO. Transseptal puncture for the closure of very small PFOs is not generally recommended; very small PFOs would not pose a significant risk for paradoxical embolization.12

The multipurpose catheter is then exchanged over a
260-cm, 0.035-inch Amplatz extra-stiff straight tetrafluoroethylene-coated stainless steel guidewire (Cook Medical, Bloomington, IN) for the Amplatzer guide (for Amplatzer closure) or a 10-F, 65-cm Flex sheath (Arrow International, Inc., for fluoroscopically guided Helex closure) placed in the left atrium. Sheathless technique is used with removal of both the multipurpose catheter and the femoral venous sheath. Attaching a Check-Flo Performer accessory adapter (Cook Medical) to the guiding catheter allows continuous saline hand flushing while advancing the guide to the left atrium. There should be no risk of air embolization when using these techniques properly.

In cases in which assessment of tunnel length is important, gentle balloon sizing of the PFO may be performed. Another technique to assess compressible tunnel length is inflating a balloon-tipped pulmonary capillary wedge catheter in the left atrium, withdrawing the balloon against the septum, and performing a hand-injection of contrast through the guiding catheter in the right atrium. After choosing the proper device type and size, the left atrial disc is opened in the left atrium. The sheath and device are then withdrawn until the left atrial disc opposes the left atrial septum. With gentle continued tension against the left atrial septum, the right atrial side of the device is deployed. Contrast hand-injection through the sheath next to the right atrial disc is used to confirm proper device position (Figure 2). In the left anterior oblique projection, the two discs are seen in profile. The splay and distance between the two discs superiorly reflects the thickness of the septum secundum. After device release, final right atrial angiography may be performed.

Debate continues about whether intracardiac or transesophageal echocardiographic guidance is required for PFO closure, as opposed to fluoroscopic guidance alone. There are risks and increased time and costs associated with balloon sizing. In experienced hands, PFO closure with the Amplatzer14,15 or Helex devices appears safe with fluoroscopic guidance only and without routine balloon sizing. Transesophageal echocardiography is uncomfortable for the supine patient under conscious sedation, and general anesthesia adds expense and anesthesia requirements to this procedure. Other approaches to improve the tolerability of transesophageal echocardiography have included nasal probe passage.16 The cost of an intracardiac echocardiographic catheter is roughly $2,000 and requires additional femoral venous catheterization. Rare complications include arteriovenous fistula and iliac vein perforation. In the author’s experience of more than 150 fluoroscopically guided PFO closure cases without balloon sizing, the need to summon echocardiography for any assistance during the procedure has not arisen. Fluoroscopic guidance alone for PFO closure in experienced hands appears to be the most straightforward approach. For most implanters without a high-volume experience, intraprocedural transesophageal or intracardiac ultrasound imaging is recommended for percutaneous PFO closure.

POSTPROCEDURE CARE

Transthoracic echocardiography with bubble study is used within 1 day to confirm proper device position and assess for residual shunting. A 12-lead electrocardiogram and chest radiography are useful for a baseline postprocedure. Antiplatelet or antithrombotic therapy should be continued for 6 months until the device is re-endothelialized to prevent device thrombosis. Elective dental work should be deferred for 6 months. If dental work is required, antibiotic prophylaxis to prevent device endocarditis should be done for 6 months. Clinical follow-up with transthoracic echocardiography is performed at 1 and 6 months. Long-term cardiology follow-up is not required. Patients may note occasional sharp chest pain, lasting 1 to 3 seconds after the procedure. If the chest pain and/or palpitations persist for more than 10 minutes, cardiac evaluation with a 12-lead electrocardiogram and transthoracic echocardiogram is indicated.

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