

# PERCUTANEOUS CLOSURE OF ATRIAL SEPTAL DEFECTS

Clement A. DeFelice

*From Methodist DeBakey Heart Center and Baylor College of Medicine, Houston, Texas*

## INTRODUCTION

The earliest recorded account of an atrial septal defect (ASD) was in the 15th century, when Leonardo da Vinci described a "perforating channel" in the atrial septum during post-mortem evaluation of a heart.<sup>1</sup> Clinical diagnosis in a living patient would not occur until the early 20th century.

In 1953, Dr. Gibbon at the Jefferson Medical College in Philadelphia performed the first ASD repair on cardiopulmonary bypass, and two decades later Drs. King and Mills performed the first transcatheter closure of secundum ASDs.<sup>2,3</sup> The device was deployed in only half of their carefully selected patients, however, since the delivery sheaths were large and the devices bulky and difficult to deploy. Now, due to dramatic advances in device design and cardiac imaging, percutaneous transcatheter techniques can safely and reliably close secundum ASDs and patent foramen ovale (PFO).

### BASICS OF THE SECUNDUM ATRIAL SEPTAL DEFECT

Atrial septal defects account for 10% of all congenital heart disease and 30-40% of congenital heart disease in adults. The most common type is the ostium secundum ASD, a deficiency of tissue at the fossa ovalis level involving the

septum primum. The left-to-right shunting and increased right-sided flow leads to right atrial and ventricular dilatation and eventually to pulmonary hypertension and right ventricular hypertrophy. Symptoms usually take 30-40 years to surface. The clinical consequences of a hemodynamically significant secundum ASD are exercise

intolerance and supraventricular tachyarrhythmias. Ultimately, chronic left-to-right shunting leads to fixed pulmonary hypertension and, eventually, reversed shunting (Eisenmenger Syndrome).

### BASICS OF PATENT FORAMEN OVALE

In utero, the PFO allows oxygenated maternal blood returning from the placenta to cross from the inferior vena cava and right atrium directly through the foramen and into the left atrium, left ventricle, aorta and systemic circulation. The patent foramen is not a hole or defect but more of a tunnel through the atrial septum. At birth, blood flow to the lungs and a rise in left atrial pressure cause approximation and, over time, fusing of the two flaps into a single structure. In 10-30% of the population, the two flaps will not seal and will remain patent.

Two other PFO-related defects are atrial septal aneurysms and fenestrations. An atrial septal aneurysm (ASA) is a congenital defect of highly redundant floppy tissue that oscillates with respiration in the foramen region. The ASA may also contain multiple fenestrations that



**Figure 1**  
LATZER® Septal Occluder

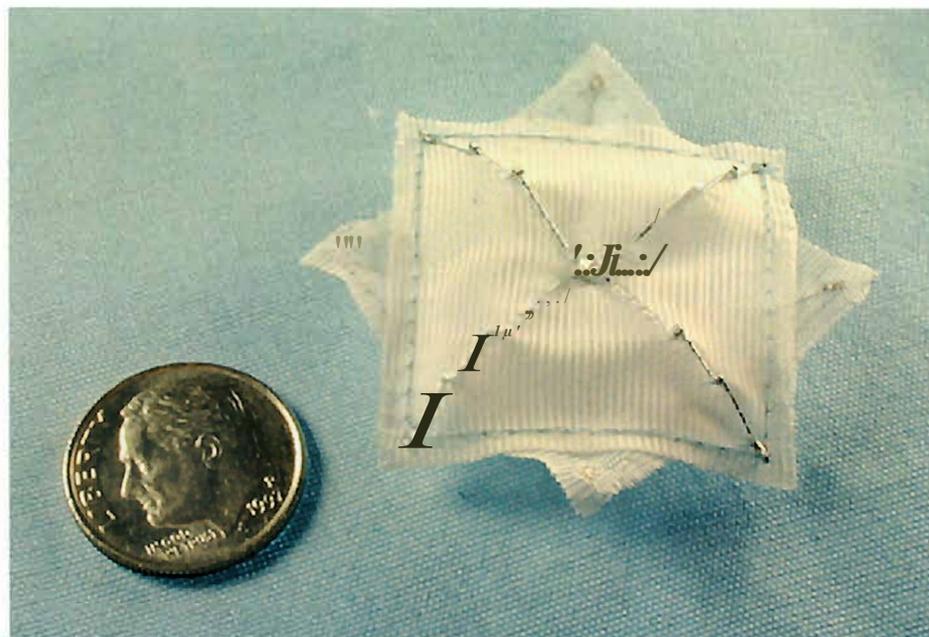
give the septum a "Swiss cheese" appearance. The patent foramen acts as a route for right-to-left shunting of paradoxical emboli or in situ thrombotic debris and has been implicated in cryptogenic stroke. Patients with a PFO plus an ASA are at higher risk for stroke than patients with only a PFO. The aneurysm may facilitate embolic events by increasing shunt volume due to increased septum mobility, directing flow from the inferior vena cava towards the PFO, or acting as a nidus for local thrombosis and subsequent embolization. Patients with cryptogenic strokes have a 44-66% incidence of PFO - twice that of the normal population.

### INDICATIONS FOR CLOSURE

Elective closure has routinely been advised for all ASDs with a significant left-to-right shunt. This is generally determined by Qp:Qs > 1.5:1 or signs of right ventricular volume overload on echocardiography. While most children with an ASD are asymptomatic, those who experience a paradoxical embolus or heart failure should be offered closure at any age.

Indications for closure of PFO are not as clear cut. Currently the indications for closure include the following:

- 1) A second cryptogenic stroke in patients on appropriate anticoagulation or antiplatelet drugs and a documented PFO. These patients are closed with either the NMT CardioSEAL device or the Amplatzer PFO Occluder (Figure 1) under an IRB-approved humanitarian device exemption protocol.
- 2) Randomized clinical trials comparing best medical therapy with device closure in patients with a first-time cryptogenic stroke or TIA and a documented PFO. Currently, the Mechodisc



**Figure 2**

CardioSEAL® Septal Occlusion System depicted at actual size next to a dime

DeBakey Heart Center is actively enrolling patients in the NMT CLOSURE I randomized clinical trial.

There appears to be a strong correlation between PFOs and migraine headaches, and research into percutaneous closure for migraine relief is under way in Europe.<sup>10</sup> Other possible indications for closure are so rare that controlled studies to evaluate superiority are not feasible.

### DEVICES

AGA Medical makes the Amplatzer Septa! Occluder, a self-expanding, double-disc wire mesh device made from nickel-titanium. The two discs are linked together by a short connecting waist. The discs and waist are filled with a polyester fabric to increase thrombogenicity and tissue ingrowth.

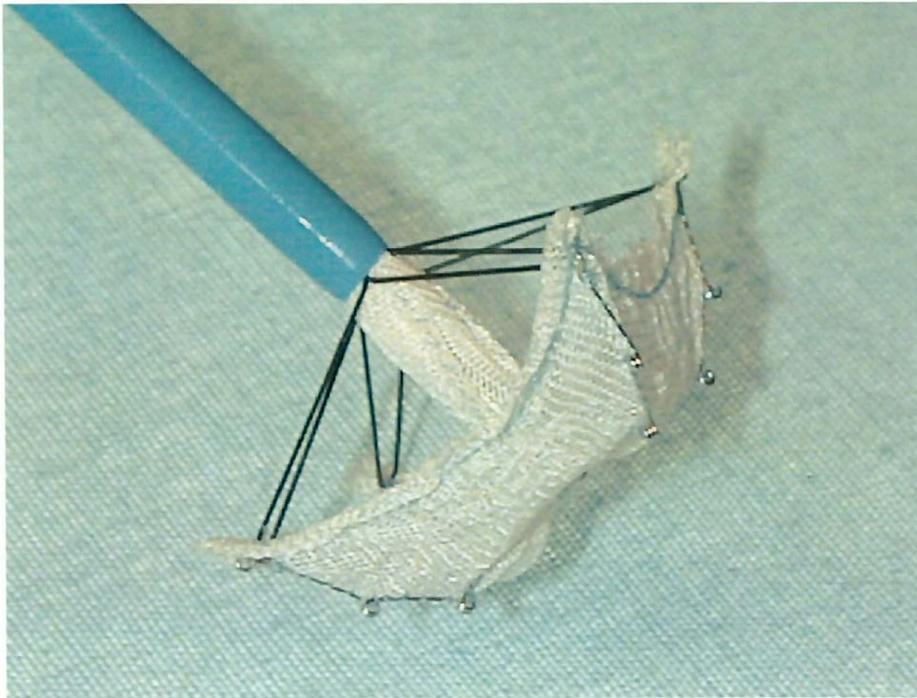
NMT Medical makes both the CardioSEAL and STARFlex devices (Figures 2 and 3) consisting of two self-expanding umbrellas made of Dacron fabric on a

framework of metal alloy. The STARFlex device has a spring-back characteristic that improves septal conformability, displaces stress during atrial contraction and improves fracture resistance.

### ECHO GUIDANCE

Echocardiography has become essential in diagnosing ASDs and plays a crucial role during percutaneous closure procedures. Transesophageal echocardiography (TEE) was once the mainstream technique for device sizing, positioning and deployment but caused discomfort and required airway protection and general anesthesia; it has since been replaced by intracardiac echocardiography (ICE).<sup>4</sup>

Currently, the most advanced catheter in use is the AcuNav Catheter (Siemens), a 10 French variable frequency, phased-array transducer with Doppler capabilities and a four-way articulation. The transducer accurately delineates the cardiac anatomy with high-quality images and allows for



**Figure 3**  
STARFlex® Septal Closure System

color Doppler interrogation of the atrial septal defects and shunts.

### PROCEDURAL DETAILS OF TRANSEPTAL CLOSURE

Percutaneous device closure of PFOs and secundum ASDs has many common features. The ICE imaging catheter is placed percutaneously from the femoral vein into the right atrium, where the interatrial septum is viewed with specific attention to contiguous cardiac structures, defect position and size, and possible fenestrations, multiple defects or an atrial septal aneurysm. The catheter is moved from the right atrium through the atrial septal defect, its position in the left atrium confirmed with contrast injection, fluoroscopy and ICE imaging. The catheter is then placed into the left superior pulmonary vein and exchanged with a wire. To determine the correct size of the

Amplatzer atrial septal occluder (ASO) device used for ostium secundum ASD closure, a sizing balloon is inserted over the wire and inflated with saline and contrast to measure the defect's balloon waist. This measurement should match the size of the device's connecting waist between the discs to ensure a complete seal of the defect. The left and right atrial discs keep the device in place, removing the potential for device prolapse to either side of the intra-atrial septum.

To correctly size the CardioSEAL and STARFlex devices used for PFO closures, the device's umbrellas must be twice the size of the balloon waist to completely cover the defect. The device is immersed in saline, attached to its delivery catheter and drawn into the delivery sheath. The sheath must be completely flushed to clear any air from the system since air embolism can lead to stroke and ST segment elevation with chest pain.

After the left and right atrial umbrellas/discs are deployed, the atrial septum is interrogated with the ICE catheter, which documents full deployment of both umbrellas/discs and appropriate conformation of the device against the septum. This also assesses contiguous structures to ensure there is no obstruction of the SVC or IVC or interference with mitral or tricuspid valve structures.

Once the operator is comfortable with the review, the device can be released from its delivery cable or catheter. An injection of agitated saline or contrast in the right atrium and final evaluation with color Doppler is done to look for any residual shunting. A very significant advantage of the Amplatzer ASO device is the ability to retrieve the device into the delivery sheath even after both discs have been deployed. The CardioSEAL/STARFlex devices cannot be retrieved after deployment of the right atrial umbrella without significantly damaging the device?

### OUTCOMES

Transcatheter occlusion of atrial-level defects in experienced hands is very effective and safe. Careful case selection leads to successful implantation rates of greater than 96%. Total occlusion rates of ASD closure with the Amplatzer ASO is 95% initially and 99% at three months. Total occlusion rates of PFO closure with the CardioSEAL/STARFlex devices are 70-80% initially and 85-90% at three months. The STARFlex device has a higher complete closure rate than the CardioSEAL device.<sup>11</sup>

### COMPLICATIONS

Device malposition or embolization varies significantly between devices and is related to operator experience and appropriate case selection. After a significant learning

curve, these two complications should be less than 1%.

Erosion of the septal occluder devices occurs in approximately 0.1-0.15% implants, most of which were placed in patients with deficient aortic or superior rims and the device to stretch diameter ratio was significantly larger than that of the FDA trial group.<sup>8</sup> While a rare complication, death occurred in 10% of these patients. Recommendations have been made to avoid oversizing the device and to define ASD stretch diameter as the balloon diameter at which flow through the ASD has been eliminated by color Doppler to avoid overstretching the defect. If a pericardial effusion is seen on the pre-discharge echocardiogram, the patient should be followed in-house for an additional 24-48 hours to ensure that follow-up echocardiography does not show any effusion increase.

A recent study of 1,000 patients found an incidence of thrombus formation on ASD devices for ASD closure of 1.2% and an incidence with PFO occluder devices of 2.5%.<sup>5</sup> Thromboembolic events were seen in 20% of this subgroup, and heparin and coumadin anticoagulation resolved the thrombus in 80%. The remaining patients required surgical removal of the device. There are case reports of thrombolytic agents being used successfully to address device thrombosis.<sup>9</sup>

Arrhythmias are seen post-implant in approximately 1-4% and vary from first-degree AV block to complete heart block and atrial fibrillation. They are usually short lived and do not require medical therapy. Patients who develop complete heart block are typically hemodynamically stable and have not required pacing. While rare, complete heart block is more common with the Amplatzer ASD

occluder and it has been transient in all cases. There appears to be a direct correlation between arrhythmia incidence and device size.

## CONCLUSION

Percutaneous transcatheter closure of atrial defects has proven to be safe and effective while having a low complication rate. Patients with hemodynamically significant secundum ASDs that are amenable to percutaneous closure should be referred for this procedure; otherwise, surgical closure would be requested. Percutaneous closure for PFO is indicated in patients with a second cryptogenic stroke while on therapeutic anticoagulation or full antiplatelet therapy. Patients with a first-time cryptogenic stroke or TIA should be referred for inclusion in the NMT STARflex closure trial - currently being conducted at the Methodist DeBakey Heart Center and at sites across the country - and trials testing the AGA Medicals Amplatzer ASD device.

## REFERENCES

1. da Vinci L. Excerpta from Quardemia Anatomica II. In: Rashkind WJ, editor. *Congenital Heart Disease. Philadelphia (PA): Hutchinson Ross; 1982.*
2. Gibbon JH. Application of a Mechanical Heart-Lung apparatus to cardiac surgery. *Minn Med. 1954;37:171-185.*
3. King TD, Mills NL. Secundum Atria/ Septa/ Defects; Non operative closure during cardiac catheterization. *fAMA. 1976;235:2506-9.*
4. Zanchetta M. Intracardiac echocardiography-guided transcatheter closure of secundum atrial septal defects. *f Am Coll Cardiol. 2003; 42:1677-82.*
5. Krumdorf U. Incidence and clinical course of thrombus formation on atrial septal defect and patent foramen ova/e closure devices in

1,000 consecutive patients. *J Am Coll Cardiol. 2004;43:302-309.*

6. Landzberg M. Indications for closure of patent foramen ovale. *Heart. 2004;90:219-224.*
7. Syamasundar R. Summary and comparison of atrial septal defect closure devices. *Curr Interv Cardiol Rep. 2000;2:367-376.*
8. Amin Z, Hijazi ZM, Bass JL, Cheatham JP, Hellenbrand WE, Kleinman CS. Erosion of Amplatzer septal occluder device after closure of secundum atrial septal defects. *Catheter Cardiovasc Interv. 2004 Dec;63(4):496-502.*
9. Anzai H, Child J, Natterson B, Krivokapich J, Fishbein MD, Chan VK et al. Incidence of thrombus formation on the CardioSEAL and the Amplatzer closure devices. *Am J Cardiol. 2004 Feb 15;93(4):426-31.*
10. Azarbal B, Tobis J, Suh W, Chan V, Dao C, Gaster R. Association of interatrial shunts and migraine headaches impact of transcatheter closure. *J Am Coll Cardiol. 2005;45:489-92.*
11. Chessa M, Carminati M, Butera G, Bini RM, Dragu M, Rosti L, et al. Early and late complications of transcatheter occlusion of secundum atrial septal defects. *J Am Coll Cardiol. 2002 Mar 20;39(6):1061-5.*

Clement A. DeFelice is currently enrolling patients with a documented cryptogenic stroke or clinical TIA within the last three months and a PFO with evidence of right-to-left shunting. For more information, contact Dr. DeFelice at the Methodist DeBakey Heart Center, 713-790-9125.