

AMPLATZER® Multi-Fenestrated Septal Occluder - “Cribriform” Case Study

Percutaneous Closure of a Multi-Fenestrated Atrial Septal Defect Using the AMPLATZER® Cribriform Occluder

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A four year old boy weighing 17 kg was referred for the evaluation of a heart murmur. He was asymptomatic, however his cardiac examination was abnormal demonstrating a grade 2/6 systolic ejection murmur over the mid precordium radiating to the base with a fixed split second heart sound. An ECG showed normal sinus rhythm with an incomplete right bundle branch block pattern. His transthoracic echocardiogram performed in the outpatient department demonstrated right atrial and ventricular chamber enlargement. An aneurysm of the atrial septum was also noted. Within the aneurysmal atrial septum were multiple fenestrations of the secundum septum. Color Doppler demonstrated that there were multiple small defects distributed across the atrial septum with a significant amount of left to right shunting present. His parents were counseled regarding all the available treatment options to include voluntary enrollment in the clinical trial of the AMPLATZER® Cribriform Occluder. They elected to have their child participate in the Cribriform device study.

Under general endotracheal anesthesia, the patient underwent a complete hemodynamic cardiac catheterization. The right heart pressures were within normal limits. Left heart pressures were normal except the left ventricular end-diastolic pressure was mildly elevated at 12 mmHg. A left to right shunt of 2.2:1 was determined by the Fick method. The pulmonary vascular resistance was normal at 0.6 Woods units with an Rp:Rs ratio of



0.1. A transesophageal echocardiogram (TEE) was then performed which demonstrated right heart chamber enlargement with an atrial septal aneurysm present (figure 1A). Detailed imaging in multiple planes of the atrial septum with color Doppler demonstrated several small closely spaced defects extending from the inferior edge of the aneurysm to the antero-superior edge adjacent to the aorta (figure 1B).

The central most portion of the atrial septal aneurysm was virtually “sieve-like” with several very closely spaced holes (figure 2). Using multi-planar TEE imaging, the central most defect in the aneurysmal septum was crossed using a woven Dacron end-hole catheter (figure 3A). Then, using color Doppler to demonstrate the most peripheral defect, the distance between central most holes and the most peripheral defects was measured (figure 3B). Note that balloon sizing of the defects was not performed. A device size was chosen such that the distance measured from the central-most defect to the most peripheral was slightly more than doubled in order to ensure complete coverage.

Once the device size to be utilized was determined, a 9F delivery sheath was advanced across the defect over a 0.035 J-tip AMPLATZER Guidewire. A 25mm AMPLATZER Cribriform Occluder was easily advanced through the delivery sheath and deployed into the septum. The fluoroscopic appearance of the AMPLATZER Cribriform Occluder deployment

sequence is shown in figure 4. With the device still securely attached to the delivery cable, detailed TEE imaging with color Doppler was then performed. Particular attention was paid to assessing the peripheral aspects of the device/septum to assess for potential uncovered defects. All defects appeared covered without any areas of significant residual shunting by color flow interrogation. The “Minnesota wiggle” was performed to ensure device stability and to enhance the device’s return to its annealed form. The device was then released from the cable into final position and color Doppler imaging confirms excellent position and no residual shunting (Figure 5).

The AMPLATZER Cribriform Occluder implant procedure required only 14 minutes of fluoroscopy and was well tolerated without any complications. The patient was discharged the following morning after a chest x-ray and transthoracic echocardiogram showed the device to be in proper position. Daily aspirin (5mg/kg) was recommended for six months. Follow-up at one year demonstrated the device to be in excellent position with no residual shunting visible by color Doppler (figure 6). Further follow-up three years post implant demonstrated normalization of the heart size on CXR with the device remaining in nominal position (figure 7).

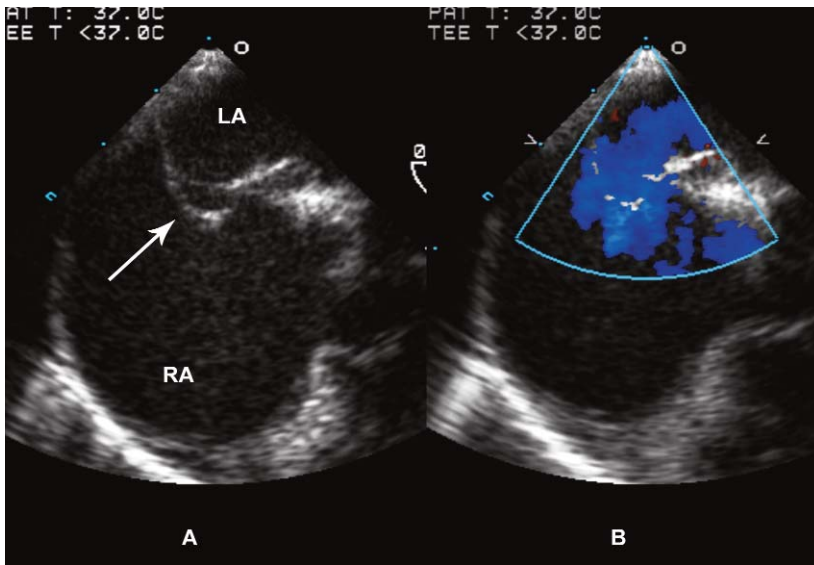


Figure 1. A. Transesophageal echocardiogram demonstrating an aneurysmal atrial septum (arrow) and a dilated right atrium. B. Color Doppler showing multiple openings with left to right shunting.

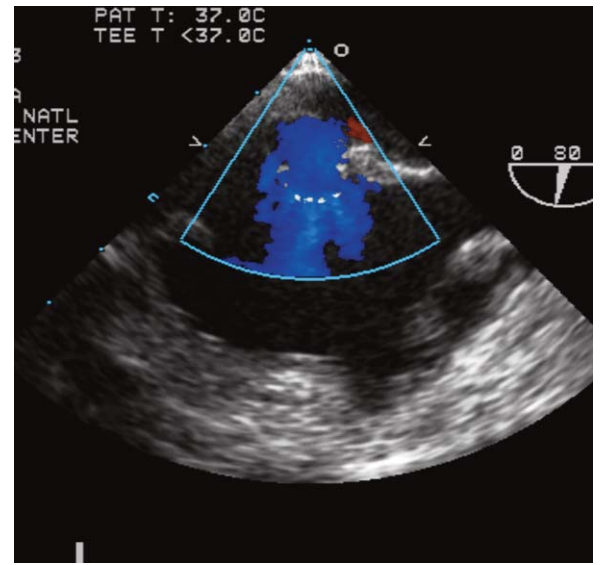


Figure 2. Color Doppler image of the central portion of the atrial septal aneurysm showing multiple “sieve-like” openings consistent with a cribriform atrial septal defect.

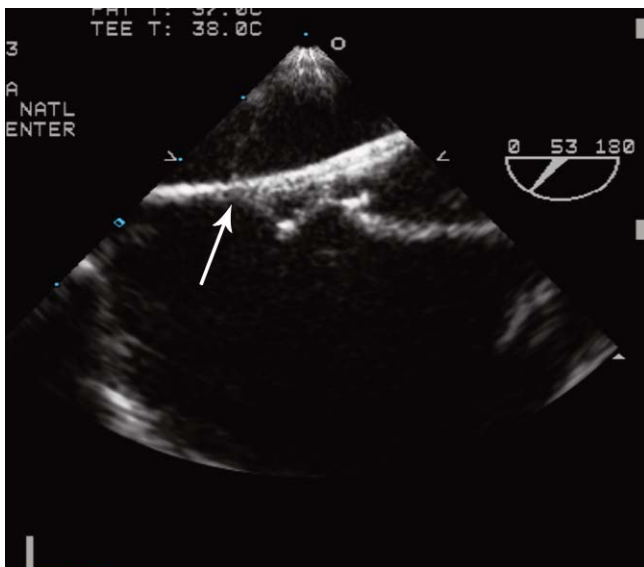


Figure 3A. Intra-procedural echocardiogram used to guide end-hole catheter through central most hole (arrow) in defect.

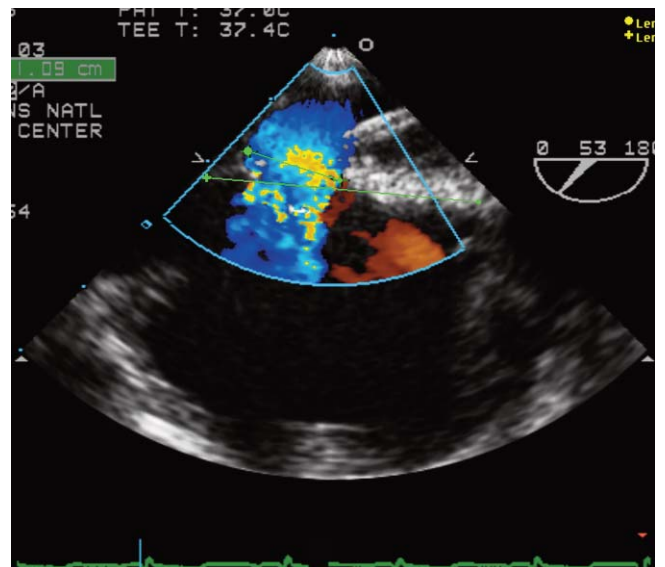


Figure 3B. Sizing protocol for choosing device: measurement is made from edge of catheter (through central most hole) to the peripheral most area of color Doppler shunting (distance A= 10.9 mm). Device size is chosen at least double this distance to ensure that all holes are covered across the entire diameter of the defect (in this case $2 \times 10.9=21.8$, therefore a 25 mm device is chosen.)

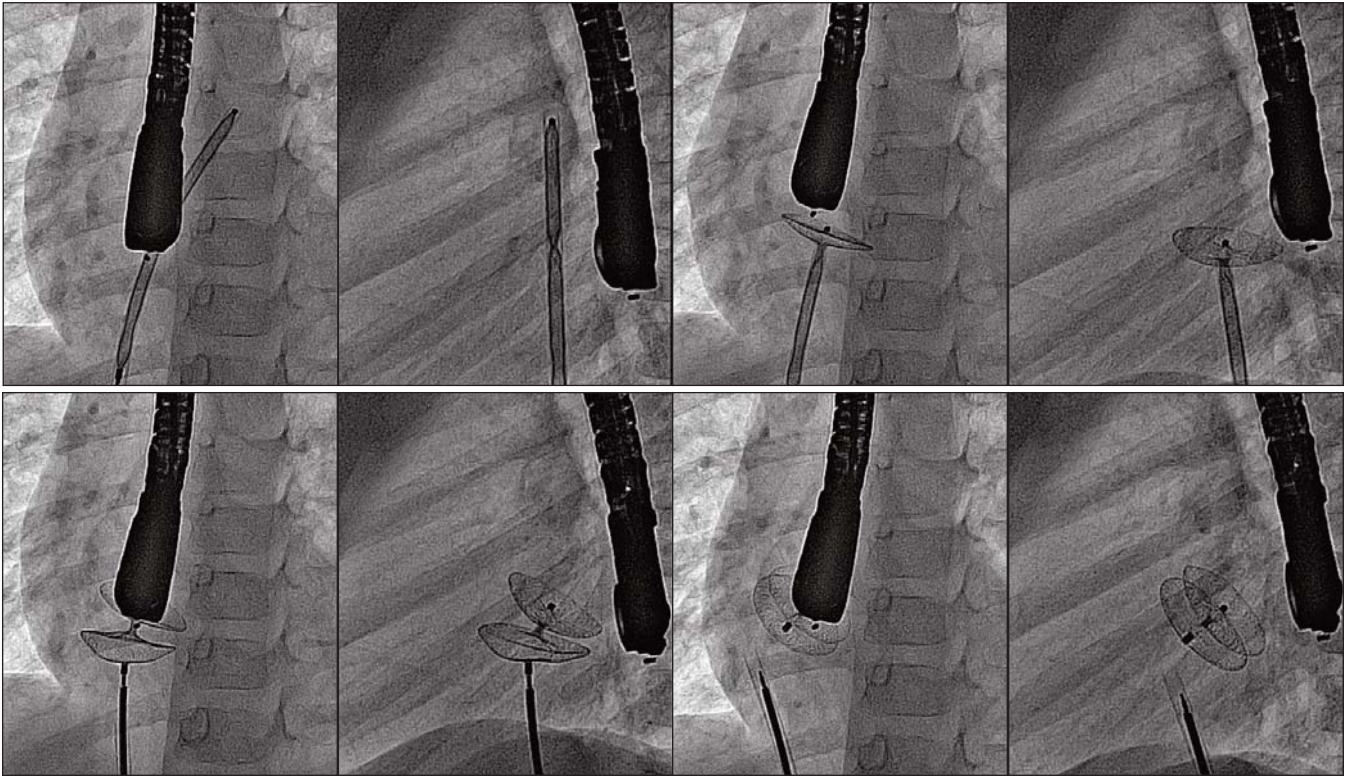


Figure 4

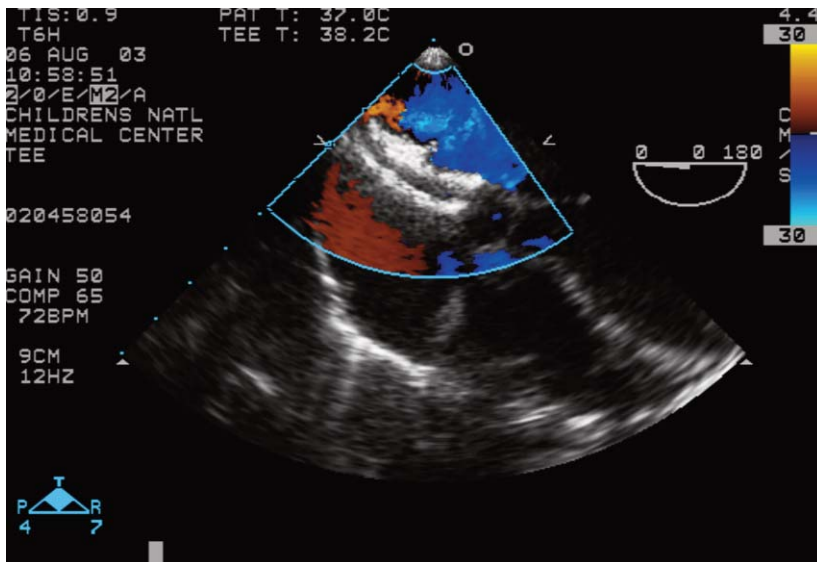


Figure 5. Transesophageal echocardiogram image showing the final position of the 25 mm AMPLATZER Cribriform device immediately after release. Note device covers all holes and no color Doppler shunting is seen.

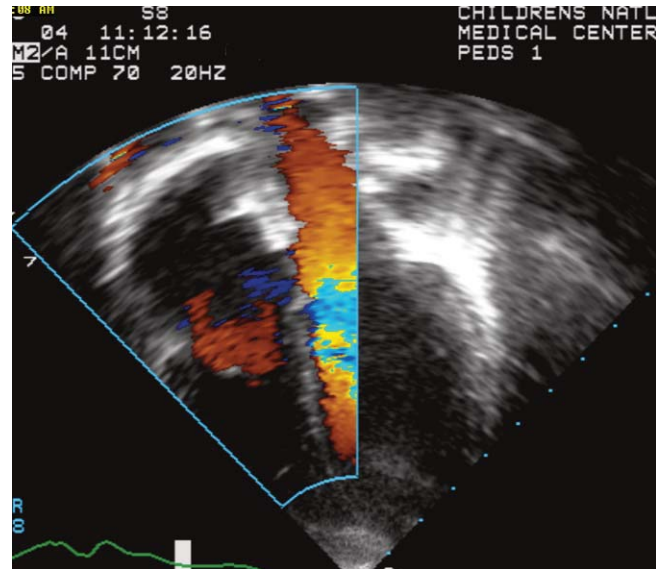
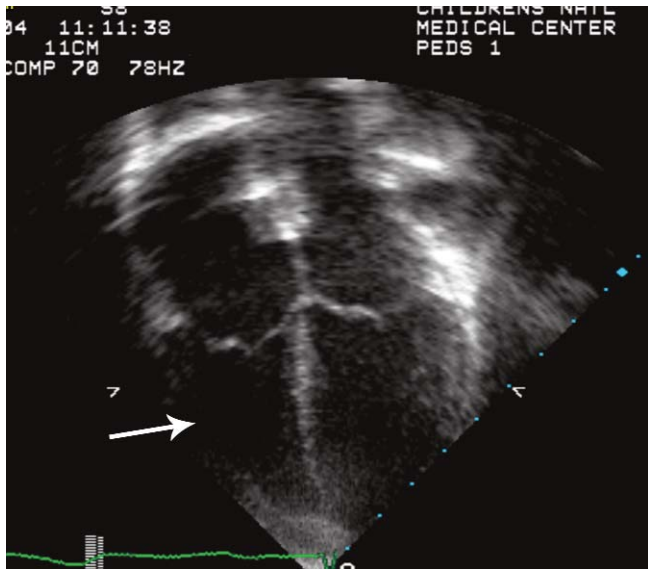


Figure 6. 2-D and color Doppler Transthoracic Echocardiographic images of the 25 mm Cribriform Atrial Septal Occluder at one year follow-up. Note: the right ventricular volume (arrow) has normalized and there is no residual shunting seen by color Doppler.

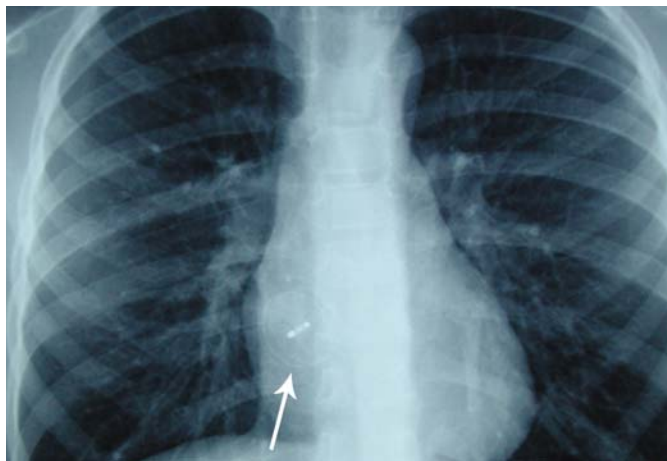


Figure 7A. Plain film chest x-ray in the PA projection showing a 25mm Cribriform Occluder device (arrows) in position at three years post implant (patient age=7 years). Note: the heart size and pulmonary vasculature have normalized.

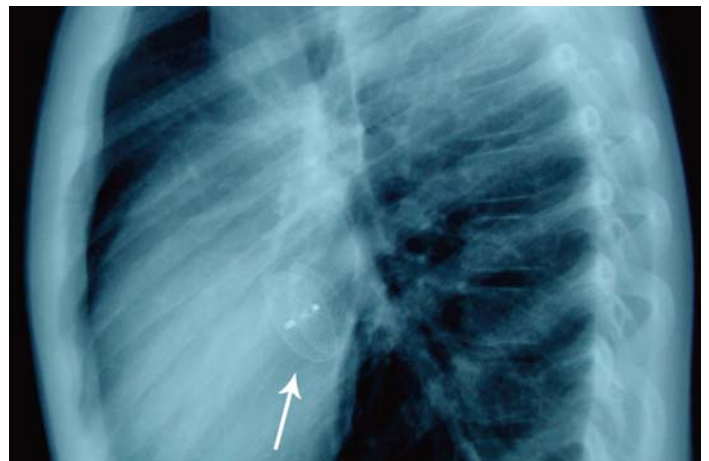


Figure 7B. Lateral chest x-ray companion view of same showing the proper orientation of the Cribriform device in this view.



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