

Transcatheter Closure of Atrial Septal Defects

An update on ASD occlusion devices.

BY VICTOR-XAVIER TADROS, MD, MSc, AND ANITA W. ASGAR, MD, FRCPC, FACC

Atrial septal defects (ASDs) are one of the most common congenital heart defects, with a prevalence estimated to affect 100 of 100,000 live births.¹ ASDs are classified according to location, the most frequent being secundum ASD (75%–80%), primum ASD (15%–20%), sinus venosus (5%–10%), and the less common defect, coronary sinus (< 1%). These defects frequently result in left-to-right shunting. Current indications for closure, according to American and European guidelines, are a ratio of pulmonary over systemic flow > 1.5 and enlargement of the right-sided chambers with or without symptoms, in the absence of significant pulmonary hypertension (class I). Closure may also be reasonable in the setting of paradoxical embolism or documented orthodeoxia-platypnea syndrome (class IIa). Closure may also be considered if the pulmonary vascular resistance is less than two-thirds of the systemic resistance or if the pulmonary arterial pressure is less than two-thirds of the systemic pressure at baseline or responsive to pulmonary vasodilators (class IIb) (Table 1).^{2,3}

Transcatheter closure of ASDs has progressed because of the development of the first stainless steel devices covered by Dacron,⁴ and is now the gold standard for the treatment of secundum ASDs. Patients with defects amenable to transcatheter closure can be divided into simple secundum defects (< 26 mm in diameter) and more complex secundum ASDs, which are larger and may have concomitant rim deficiency.⁵ Patients with defects > 40 mm, or those with multiple deficient rims or coexistent pulmonary venous anomalies, are usually referred for surgical closure.

The procedure is most often performed under transesophageal echocardiographic guidance to evaluate the septal anatomy, size the defect using “stop-flow,” and to confirm device position and the presence of residual shunt. Intracardiac echocardiography can also be used but may have some limitations in the setting of large or complex defects with rim deficiency.^{6,7}

Balloon sizing of the ASD is an important step to provide information of the stretched diameter, the compliance of the septum, and the presence of other previously unrecognized defects. In the case of pulmonary hypertension, evaluation of pulmonary pressure during balloon occlusion can provide additional information on the presence of undiagnosed Eisenmenger syndrome.

We will discuss the most commonly used and newer available devices for the transcatheter closure of ASDs, as well as recent device developments in this field.

ASD CLOSURE DEVICES

Amplatzer Septal Occluder

Available since 1997, the Amplatzer Septal Occluder (ASO) (St. Jude Medical Inc.) is a self-expanding, recapturable prosthesis made of nitinol wire mesh, two round discs with a polyester patch inside, and a connecting short waist (Figure 1). Sizes vary from 4 to 40 mm. Large studies have evaluated the safety and efficacy of the ASO. The pivotal

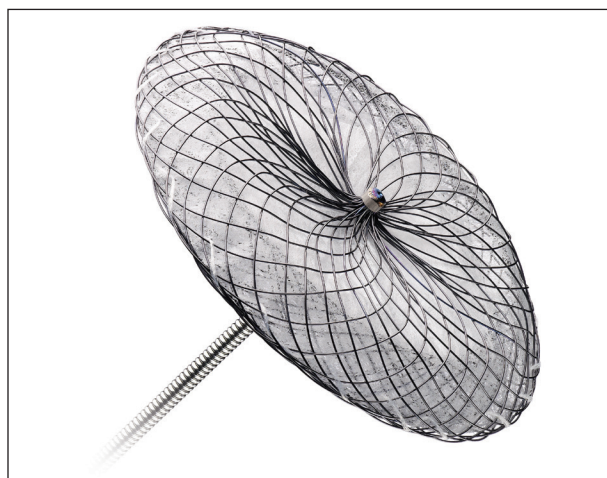


Figure 1. The Amplatzer septal occluder. Reprinted with permission from St. Jude Medical, ©2016. All rights reserved.



Figure 2. The Amplatzer Cribiform septal occluder.

study evaluated 442 nonrandomized, mostly pediatric, patients and compared them to 153 patients treated with surgery. The mean diameter of ASDs was 13.3 mm in the device group and 14.2 mm in the surgical group, with a procedural success rate of 95.7% in the device group. Furthermore, patients treated with the ASO had a lower rate of major complications, including pericardial effusion with tamponade and surgical wound complication, than patients treated by surgical repair (1.6% vs 5.2%; $P = .03$). The rate of minor complications, such as pericardial effusion and transfusion (6.1 vs 18.8%; $P < .001$), was also lower in those treated with transcatheter closure.⁸

However, serious complications, although rare, have come to light with its wide utilization. Registry data have demonstrated that ASD device embolization is an additional potential complication of transcatheter closure. The incidence is low, with 21 device embolizations described in 3,824 device placements (~0.55%). In those cases, device retrieval was achieved by percutaneous access in the majority of cases, but a surgical approach may be required.⁹ Device erosion is one of the main concerns of transcatheter closure due to its unpredictability and potential for fatal complications. The erosion rate was determined to be 0.1% to 0.28%, depending on the registry.^{10,11} Expert panels examined the risk factors for erosion after reviewing 14 cases of confirmed erosion over 9,000 implantations performed in the United States¹² and found that occurrence is more likely in the days after implantation, but it is possible to be delayed by years. Factors related to erosion include the absence of an aortic rim with an oversized prosthesis, which protrudes against the aortic root, and motion of the device against the adjacent

cardiac structures.¹¹ Other rare complications have been described, such as infection (0.8%), thrombus embolism (2.5%), and arrhythmias (5%).¹³

The Amplatzer Septal Occluder “Cribiform” (St. Jude Medical, Inc.) shown in Figure 2 is specially made for multifenestrated secundum septal defects. It is a double disc made of nitinol wire mesh with polyester fabric and a narrow waist. Its diameter size varies from 18 to 40 mm. The shape is designed to center the device in the primary defect, while also occluding the adjacent fenestrations.

Figulla Flexible Occlutech Septal Occluder

The Figulla Flexible Occlutech Septal Occluder (FSO) (Occlutech International AB) is very similar in its shape to the ASO. It is a self-expanding, recapturable, double round disk made of nitinol wire mesh, with a ceramic titanium oxide surface and polyester patch with only one central pin in the right atrial side. The two discs are separated by a 3- to 4-mm waist with a variety of sizes ranging from 4 to 40 mm. Experience with this device is less than with the ASO; however, it seems to have similar safety and efficacy when compared to the ASO. In a recent publication, the clinical success rate was high and no different from that of the ASO, with full occlusion achieved in more than 90% of the cases at late follow-up.¹⁴ The major complication rate was comparable (2.8% for the ASO and 2.6% in the FSO group), with a median follow-up of 3.6 years (149 patients). Although erosion did not occur in the FSO group, large registries with this device are currently lacking.¹⁵

Gore Helex Septal Occluder

The Gore Helex Septal Occluder (Gore & Associates) has been available since 2006 and consists of a corkscrew-type nitinol wire frame covered by expanded polytetrafluoroethylene to reduce friction with the cardiac adjacent structures; thereby reducing the risk of erosion (Figure 3). It was developed to treat both ASDs and patent foramen ovale. Its size varies from 15 to 30 mm, but it is not recommended for ASDs > 18 mm. In the pivotal study, 119 patients treated with the Gore Helex Occluder closure were compared to

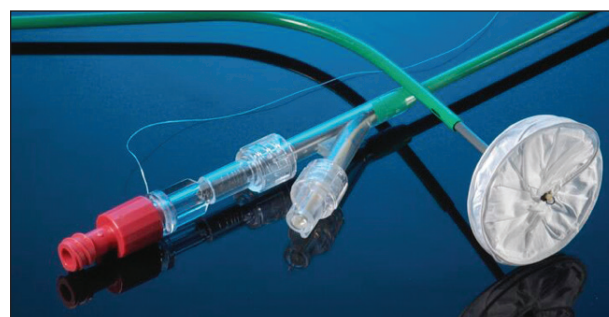


Figure 3. The Gore Helex septal occluder.

Courtesy of W.L. Gore & Associates, Inc.

TABLE 1. RECOMMENDATIONS FOR ASD CLOSURE

Indications	Recommendations for Closure
Qp/Qs > 1.5 with enlargement of right-sided chambers, with or without symptoms	Class I
Paradoxical embolism or orthodeoxia-platypnea syndrome	Class IIa
Significant shunt with PHT PVR < 2/3 SVR or PAP < 2/3 PAS at baseline or with pulmonary vasodilators	Class IIb
Eisenmenger syndrome	Class III
Adapted from ACC/AHA Guidelines. Abbreviations: Qp, pulmonary blood flow; Qs, systemic blood flow; PHT, pulmonary hypertension; PVR, pulmonary vascular resistance; SVR, systemic vascular resistance; PAP, pulmonary artery pressure; PAS, systemic arterial pressure.	

128 patients who underwent surgical closure. The results showed noninferiority of device closure with a clinical success rate of 91.7% and a low rate of major and minor complications, mainly driven by device embolization requiring catheter retrieval.¹⁶ The Food and Drug Administration's continued access trial of the Gore Helex Septal Occluder for secundum ASD showed a high clinical success rate in 137 patients (96.7%–98.3%), with a low major adverse event rate (3.6%–4.8%). No erosion has been recorded with the use of the Gore Helex Septal Occluder.^{17,18}

Gore Cardioform Septal Occluder

The newer-generation Gore Cardioform Septal Occluder (Gore & Associates) improves upon the Helex design. It is a flexible, retrievable, double disc device with a petal design made of a nitinol frame covered by expanded polytetrafluoroethylene to facilitate rapid endothelialization (Figure 4). Initial and further experiences in a small cohort with the Gore Cardioform Septal Occluder showed clinical success rates of 89% to 100%.¹⁹⁻²¹ In comparison to the ASO, the efficacy was similar with a low risk of a major adverse event, such as fracture or embolization, with no difference in procedural time. No erosion has been described yet, even in deficient aortic rims²²; however, large registries are lacking to detect this rare event. The Gore Cardioform Septal Occluder is suitable for secundum ASDs < 18 mm.

The Gore Cardioform ASD Occluder

The Gore Cardioform ASD Occluder (Gore & Associates) is the newest device in the Gore family of septal occluders that is designed to treat larger ASDs. It consists of an implantable occluder and a delivery system (Figure 5). The occluder is configured in nominal outer diameters of 27, 32, 37, 44, and 48 mm to treat a range of defects ranging in size from 8 to 35 mm. These occluders have been engineered to provide unique conformability and the ability to adapt to the dynamic variability of secundum ASDs. Each occluder size has a potentially broad treatment range while maintaining septal apposition and a flat profile. The occluder is

composed of a platinum-filled nitinol wire frame covered with expanded polytetrafluoroethylene. The three smaller devices are constituted of a six-petal helical wire frame, although the two largest are composed of an eight-petal helical wire frame. When fully deployed, the occluder assumes a configuration that includes a left and right atrial disc, as well as an adaptable intradisc region (waist) intended to occupy the defect.

The delivery system consists of an 80-cm working length and a 10- to 14-F outer diameter delivery catheter coupled to a handle that facilitates loading, deployment, and locking of the preloaded occluder. The handle allows repositioning and retrieval of the occluder via the retrieval cord, if necessary. The occluder is delivered using conventional catheter techniques with or without the aid of a ≤ 0.035-inch guide-wire and is deployed using simple push/pull motion on the slider of the handle.

This device is not currently commercially available or approved; however, it has been used under Canada's Special Access Programme.

FOLLOW-UP AND RECOMMENDATIONS

Antiplatelet Therapy

Data to support dual-antiplatelet therapy after ASD closure are lacking, so there are no clear recommendations on



Figure 4. The Gore Cardioform septal occluder.

Courtesy of W.L. Gore & Associates, Inc.



Courtesy of M.L. Gore & Associates, Inc.

Figure 5. The Gore Cardioform ASD occluder.

the optimal regimen and duration of antiplatelet therapy; however, there is a consensus among experts (based on the experience of a septal closure device on a patent foramen ovale patient with cryptogenic stroke) to prescribe low-dose aspirin for 6 months and clopidogrel for 1 to 6 months after implantation.^{23,24} New-onset migraine attacks have been reported in approximately 15% of patients during follow-up after transcatheter ASD closure. A recent Canadian multicenter randomized trial evaluated the efficacy of clopidogrel in prevention of migraine compared to placebo in 171 patients. Results showed a reduced mean number of monthly migraine days within the 3 months after the procedure in the clopidogrel group (0.4 vs 1.4; incidence risk ratio, 0.61 [95% confidence interval, 0.41–0.91]; $P = .04$) and a lower incidence of migraine attacks in the clopidogrel group (9.5% vs 21.8%; odds ratio, 0.38 [95% confidence interval, 0.15–0.89]; $P = .03$). Less severe migraines were also described in the clopidogrel group.²⁵

Imaging

Clinical and echocardiographic follow-up are recommended at day 1 after implantation to rule out possible procedural complications, pericardial effusion, or device embolization. An additional transthoracic echocardiogram is recommended at 3 months to evaluate the presence of a residual shunt, or a possible early procedure-related complication, such as migration or erosion. Yearly follow-up is recommended if the ASD was closed as an adult with pulmonary hypertension, atrial arrhythmias, right ventricle or left ventricle dysfunction, or coexisting cardiac lesion. Any chest pain, rapid onset of shortness of breath, or syncope, which may be the

result of a cardiac erosion, requires urgent evaluation.³ Endocarditis prophylaxis is recommended for the first 6 months after transcatheter ASD closure.²

Magnetic Resonance Imaging

Both ASO and the Gore Cardioform Septal Occluder have been determined to be compatible with magnetic resonance imaging under certain conditions, which are a magnetic field of ≤ 3 Tesla, a maximal spatial gradient magnetic field of ≤ 720 G/cm, and a whole body average absorption rate of 3.0 W/kg for 15 minutes of scanning.

CONCLUSION

Transcatheter closure of isolated secundum ASDs has proven safety and efficacy and is the standard of care. The Amplatzer Septal Occluder is the most commonly used and known closure device; however, long-term risks of device erosion have stimulated interest in the development of newer devices. Given the evolution of structural heart disease interventions for atrial fibrillation and valvular heart disease, preserving access to the left atrium may be paramount, and the choice of which device to use will likely have important future effects on patient care. ■

1. Botto LD, Correa A, Erickson JD. Racial and temporal variations in the prevalence of heart defects. *Pediatrics*. 2001;107:E32.
2. Baumgartner H, Bonhoeffer P, De Groot NM, et al. ESC Guidelines for the management of grown-up congenital heart disease (new version 2010). *Eur Heart J*. 2010;31:2915–2957.
3. Warnes CA, Williams RG, Bashore TM, et al. ACC/AHA 2008 guidelines for the management of adults with congenital heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Develop Guidelines on the Management of Adults With Congenital Heart Disease). Developed in collaboration with the American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2008;52:e143–e263.
4. Auslander M, Beekman RH 3rd, Lloyd TR. Transcatheter closure of atrial septal defects. *J Interv Cardiol*. 1995;8:533–542.
5. Butera G, Romagnoli E, Carminati M, et al. Treatment of isolated secundum atrial septal defects: impact of age and defect morphology in 1,013 consecutive patients. *Am Heart J*. 2008;156:706–712.

6. Bartakian S, El-Said HG, Printz B, Moore JW. Prospective randomized trial of transthoracic echocardiography versus transesophageal echocardiography for assessment and guidance of transcatheter closure of atrial septal defects in children using the Amplatzer septal occluder. *JACC Cardiovasc Interv.* 2013;6:974-980.
7. Kim NK, Park SJ, Shin JJ, Choi JY. Eight-French intracardiac echocardiography - safe and effective guidance for transcatheter closure in atrial septal defects. *Circ J.* 2012;76:2119-2123.
8. Du ZD, Hijazi ZM, Kleinman CS, et al. Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults: results of a multicenter nonrandomized trial. *J Am Coll Cardiol.* 2002;39:1836-1844.
9. Levi DS, Moore JW. Embolization and retrieval of the Amplatzer septal occluder. *Catheter Cardiovasc Interv.* 2004;61:543-547.
10. Moore J, Hegde S, El-Said H, et al. Transcatheter device closure of atrial septal defects: a safety review. *JACC Cardiovasc Interv.* 2013;6:433-442.
11. El-Said HG, Moore JW. Erosion by the Amplatzer septal occluder: experienced operator opinions at odds with manufacturer recommendations? *Catheter Cardiovasc Interv.* 2009;73:925-930.
12. Amin Z, Hijazi ZM, Bass JL, et al. Erosion of Amplatzer septal occluder device after closure of secundum atrial septal defects: review of registry of complications and recommendations to minimize future risk. *Catheter Cardiovasc Interv.* 2004;63:496-502.
13. United States Food and Drug Administration. FDA Executive Summary Memorandum. Paper presented at Circulatory System Devices Advisory Panel; May 24, 2012; Gaithersburg, MD.
14. Godart F, Houeijeh A, Recher M, et al. Transcatheter closure of atrial septal defect with the Figulla ASD Occluder: a comparative study with the Amplatzer Septal Occluder. *Arch Cardiovasc Dis.* 2015;108:57-63.
15. Roymane S, Promphan W, Tonklang N, Wongwaitawee Wong K. Comparison of the Occlutech Figulla septal occluder and Amplatzer septal occluder for atrial septal defect device closure. *Pediatr Cardiol.* 2015;36:935-941.
16. Jones TK, Latson LA, Zahn E, et al. Results of the U.S. multicenter pivotal study of the HELEX septal occluder for percutaneous closure of secundum atrial septal defects. *J Am Coll Cardiol.* 2007;49:2215-2221.
17. Javois AJ, Rome JJ, Jones TK, et al. Results of the U.S. Food and Drug Administration continued access clinical trial of the GORE HELEX septal occluder for secundum atrial septal defect. *JACC Cardiovasc Interv.* 2014;7:905-912.
18. Rhodes JF Jr, Goble J. Combined prospective United States clinical study data for the GORE HELEX septal occluder device. *Catheter Cardiovasc Interv.* 2014;83:944-952.
19. Freixa X, Ibrahim R, Chan J, et al. Initial clinical experience with the GORE septal occluder for the treatment of atrial septal defects and patent foramen ovale. *EuroIntervention.* 2013;9:629-635.
20. Lombardi M, Tagliente MR, Pirolo T, et al. Feasibility and safety of a new generation of gore septal occluder device in children [published online ahead of print April 9, 2014]. *J Cardiovasc Med (Hagerstown).*
21. Nyboe C, Hjortdal VE, Nielsen-Kudsk JE. First experiences with the GORE Septal Occluder in children and adults with atrial septal defects. *Catheter Cardiovasc Interv.* 2013;82:929-934.
22. Smith B, Thomson J, Crossland D, et al. UK multicenter experience using the Gore septal occluder (GSO) for atrial septal defect closure in children and adults. *Catheter Cardiovasc Interv.* 2014;83:581-586.
23. Meier B, Kalesan B, Mattle HP, et al. Percutaneous closure of patent foramen ovale in cryptogenic embolism. *N Engl J Med.* 2013;368:1083-1091.
24. Carroll JD, Saver JL, Thaler DE, et al. Closure of patent foramen ovale versus medical therapy after cryptogenic stroke. *N Engl J Med.* 2013;368:1092-1100.
25. Rodes-Cabau J, Horlick E, Ibrahim R, et al. Effect of clopidogrel and aspirin vs aspirin alone on migraine headaches after transcatheter atrial septal defect closure: the CANOA randomized clinical trial. *JAMA.* 2015;314:2147-2154.

Victor-Xavier Tadros, MD, MSc

Interventional Cardiology
Department of Medicine
Montreal Heart Institute
Université de Montréal
Montréal, QC, Canada

Disclosures: Supported by a grant from the Montreal Heart Institute.

Anita W. Asgar, MD, FRCPC, FACC

Interventional Cardiology
Department of Medicine
Montreal Heart Institute
Université de Montréal
Montréal, QC, Canada

(514) 376-3330; anita.asgar@umontreal.ca

Disclosures: Consultant for Gore & Associates.