

Atrial Septal Defect Device Closure in the Pediatric Population: A Current Review

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Abstract Atrial septal defects are the most common congenital cardiac defects. The natural history of an uncorrected atrial septal defect causes a shortened life expectancy due to right ventricular volume overload and associated congestive heart failure, atrial arrhythmias, and/or pulmonary vascular disease. Surgical closure of the atrial septal defect is a procedure with a long-standing history, and the maturing field of percutaneous closure of atrial septal defects by device implantation has established itself to be a feasible, minimally invasive, and safe procedure. Inherent limitations in device designs have resulted in rare, but serious complications, through subsequent changes in the technical aspects of transcatheter atrial septal defect closure that have minimized the number of patients with an adverse event. Recent Food and Drug Administration re-evaluation of the safety of atrial septal defect closure by device has brought to light some of the acute and long-term issues related to device occlusion. This paper summarizes the history of atrial septal defects, surgical and transcatheter device closure, and the most current outcomes of percutaneous atrial septal defect device occlusion in the pediatric population.

Keywords Atrial septal defect · Device occlusion · Percutaneous · Congenital cardiovascular interventions · Pediatric

Introduction

Anatomy/Diagnosis

An atrial septal defect (ASD) or interatrial communication is defined as any malformation of the atrial septum that allows mixing of blood between the atria. An ASD is one of the most common congenital heart defects (approximately 5/10,000 live births and 7–10 % of all congenital heart defects) and as such, has a long-standing history of intervention [1, 2]. In the truest sense, an ASD is defined as a defect within the oval fossa itself, referred to as a secundum ASD [3]. Other locations of an interatrial communication include a primum ASD, sinus venosus defect, or coronary sinus defect. The size of the defect, the compliance of the ventricles, and the resistance of the downstream vascular bed determine the degree of shunting across an ASD. Congestive heart failure symptoms associated with pulmonary over-circulation are dependent on the above factors, and are rarely present before adulthood. Most patients less than 10 years of age are asymptomatic, whereas those older than 40 years are rarely symptom-free (less than 5 %) [4]. The main complications of an untreated ASD include right ventricular volume overload leading to congestive right heart failure, atrial arrhythmias, or pulmonary arterial hypertension, and are the impetus for closure of all types of ASD [5, 6]. There are reports of transcatheter closure of sinus venosus and coronary sinus ASDs, but the scope of this review will be to outline the

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devices designed exclusively for closure of a secundum ASD.

Indications for Intervention

In 2011, the American Heart Association published guidelines to outline the indications for multiple interventional catheterization procedures, including ASD closure [5]. Determining which patients will benefit from intervention and when closure is indicated are the initial requirements. ASD devices that are currently available with FDA approval, can be implanted successfully in children less than 2 years of age, although common practice standards suggest that a weight greater than 15 kg may offer some technical advantages and simplify the procedure. The usual practice for elective closure of an ASD in a child is between the ages of 3–5 and greater than 15 kg. The recommendations for closure include patients with a hemodynamically significant defect (generally considered to be greater than or equal to 1.5:1 left-to-right shunt or right ventricular volume overload), demonstrable on echocardiogram, with suitable ASD and septal anatomy. It felt to be reasonable to close defects in patients with transient right-to-left shunting at the atrial level who have either experienced sequelae such as paradoxical emboli leading to stroke or transient ischemic attack or are symptomatic secondary to the cyanosis caused by the right-to-left shunt (assuming there is no reliance on this communication to maintain cardiac output). Finally, patients with a small ASD who may be at risk for a paradoxical embolus secondary to other causes (transvenous pacing wires, long-standing indwelling catheter, or a hypercoagulable state) were to be considered for closure [5].

Anatomic location and proximity to other cardiac structures, defect size, and the status of the rims of tissue that border the ASD play a large role in determining the appropriateness of device occlusion.

Sinus venosus defects (superior and inferior), primum ASDs, and coronary sinus defects are not a candidate for device closure in the catheterization laboratory with currently available ASD occlusion devices. All of these types of ASD will require surgical closure with very few exceptions being reported using different closure technologies and devices [7]. The outcomes from surgery have withstood the test of time, and are excellent with low complication rates, but this approach is more invasive than transcatheter techniques and requires cardiopulmonary bypass. In spite of the increased invasiveness, with respect to the non-secundum ASDs, the decision to avoid transcatheter closure is straight forward and without controversy. Determining whether a secundum ASD is appropriate for device occlusion is not always a simple decision, and the debates are mostly related to the inherent

limitations of current device technology and the impact they have on adjacent cardiac structures. Patients with a small, hemodynamically insignificant ASD without other risks should not undergo defect closure. Percutaneous ASD closure is contraindicated in those patients with advanced pulmonary vascular disease due to the potential reliance on a right-to-left shunt to maintain cardiac output during a pulmonary hypertensive crisis [5].

Historical Perspective

Surgical closure of an ASD was first reported by Dr. Murray who described ASD closure using an external suture technique [8]. After the introduction of the pump oxygenator in 1953, an open approach to ASD closure became the standard of care until Mills and King reported the first percutaneous (transcatheter) closure of an atrial septal defect in 1976 using a “double umbrella” device [9, 10]. This device was challenging to deploy and required a very large delivery system (22 French) making its widespread use impractical. The long-term success with the initial use of this device (4/5 patients alive and asymptomatic without a residual shunt almost 3 decades later) laid the foundation for innovation and the creation of many different devices to close secundum ASDs without surgery [11].

Many devices have been created and tested in the hopes of creating an ideal percutaneous or transcatheter ASD closure device. The features of the ideal ASD device include a low profile, a flexible frame that conforms to the variability of defect shapes and sizes, a material that is strong enough to maintain closure without distorting or injuring surrounding tissues or structures, the potential to cross the closed ASD in the future in order to gain access to the left atrium, an inert material that is neither immunogenic nor a possible allergen, is available in an array of sizes, and if possible, a device that is bioabsorbable. As there is no device that meets all of these criteria, it is important to understand the benefits and drawbacks of the devices currently available. The early devices, such as the Clamshell Septal Occluder were used extensively with good outcomes and few major complications [12]. However, with follow-up assessments, the Clamshell Septal Occluder was found to have wire frame fractures commonly, and even though none of these were found to be clinically relevant, the device was withdrawn from use. It was modified to become the CardioSEAL Septal Occluder (Nitinal Medical Technology, Inc. Boston, MA) and finally by adding a nitinol self-centering mechanism became the STARflex device [13]. Other devices such as the Sideris Button were created to reduce the footprint of the device by reducing substantially the amount of metal and rigidity, and the BioSTAR device limited the tissue that remains

using a bioabsorbable matrix [14, 15]. Neither of these devices has achieved widespread use, but they are part of the continued drive to achieve the ideal device.

At the time of the writing of this article, there are only two approved and available devices in the United States. The Amplatzer Septal Occluder™ (St. Jude Medical, Plymouth, MN) and the HELEX Septal Occluder™ (WL Gore and Associates, Flagstaff, AZ) have received approval for secundum ASD closure from the United States Food and Drug Administration (FDA) in 2001 and 2006, respectively, with extensive use for many years worldwide (Refer to Fig. 1 for images of the devices). Both devices were studied as a prospective clinical trial and demonstrated similar outcomes when compared with standard surgical closure [16•, 17•]. The Amplatzer septal occluder is composed of a nitinol (nickel titanium alloy) wire mesh encasing Dacron fabric. The device is available in a wide range of sizes and features left and right atrial disks that are contiguous with a self-centering waist. This device is suitable for all subtypes of secundum ASD and has sizes available to close defects as large as 40 mm in diameter internationally, though the largest device in the United States is 38 mm with a left atrial disk measuring 54 mm. Before getting released from the delivery cable, the device can be repositioned, re-deployed, or removed easily. The HELEX occluder is made of a single strand of nitinol attached to a piece of microporous expanded polytetrafluoroethylene (ePTFE). When deployed, the device forms 2 equal-sized opposing helical disks that are “locked” into place through the ASD, across the atrial septum. The HELEX occluder is suitable for closure of small to moderate-sized defects (less than 18 mm in diameter) and is easily repositionable or removable even after release from the catheter delivery system. The next generation device from WL Gore and Associates is a modification of the Helex device design that includes a nitinol strand that is bonded to ePTFE, but uses a flower-petal type of design for the disk instead of a helical form [18]. This *GORE CARDIOFORM Septal Occluder* received approval from the Food and Drug Administration in May 2015, but this newer device is not yet available for clinical implementation in the United States, and is planned to come to the U.S. market before the end of 2015.

Choosing the Appropriate Device

Prior to cardiac catheterization, the transthoracic echocardiogram (TTE) is the standard of care for diagnosis of an ASD and assessment of the atrial septal rims. A number of different nomenclatures exist for naming the different rims based on the location relative to the defect or the associated anatomical structures. In our opinion, the simplest nomenclature system refers to the associated structures and

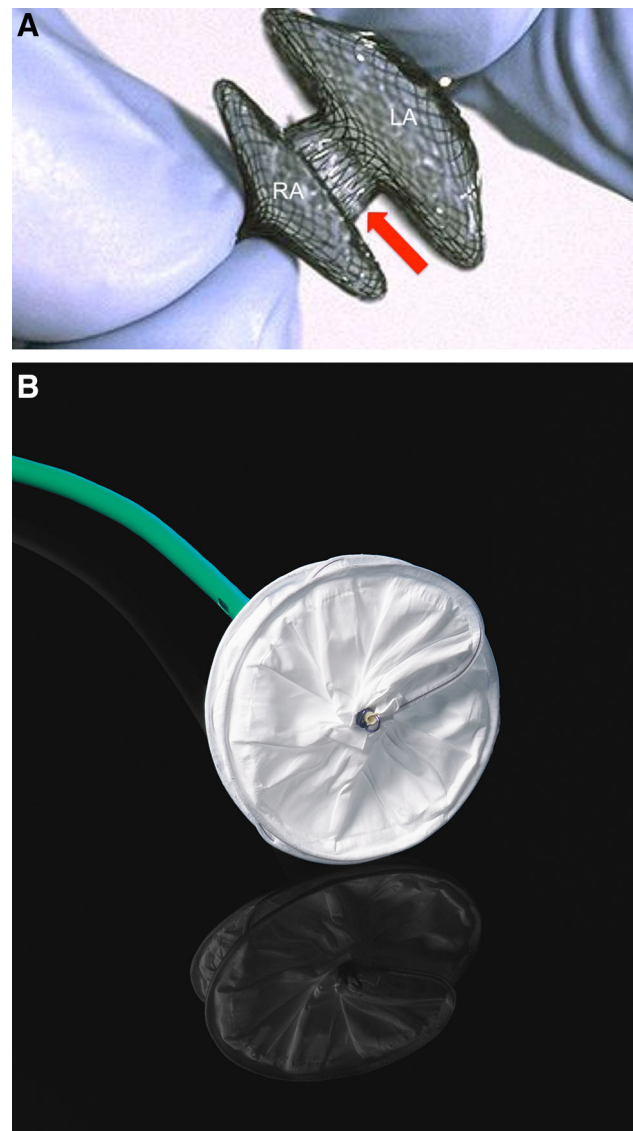


Fig. 1 a A photograph of the Amplatzer Septal Occluder [nitinol mesh with central self-centering waist (*arrow*) that attaches the left (LA) and right atrial (RA) disks]. b The ePTFE covering on the single nitinol wire with the helical pattern of the Gore Helex Occluder as seen from the LA disk while still attached to the delivery cable

includes the superior vena cava rim, inferior vena cava rim, atrioventricular septal rim, retroaortic rim, and posterior atrium rim. The TTE imaging can be used to rule out non-secundum defects that require surgery, as well as assist in planning the interventional approach to device closure of a secundum defect. Specifically, the TTE quantifies the overall size of the ASD in multiple views and is able to assess the associated rims. In the pivotal studies of both the Amplatzer Septal Occluder and the Helex Septal Occluder, all rims were required to be greater than 5 mm in order to meet inclusion criteria [16•, 17•]. Since that time, a number of studies have demonstrated the feasibility of ASD closure with a single deficient (less than 5 mm) or

absent rim, given that all other rims are intact. In the presence of a deficient SVC rim or aortic rim, an increased risk of device erosion may occur [19•]. Deficiency of the atrioventricular septum may cause the device to come into contact with the atrioventricular valves and has been implicated in resultant tricuspid or mitral regurgitation and, in rare circumstances, an atrioventricular valve injury that requires repair [20]. A deficiency of the ASD rims may be implicated in higher rates of device embolization [21]. There are no established criteria for one device versus another, and many interventionists have their own preferences based on the anatomy of the individual ASD. With current devices, some advocate using the Helex device when possible preferentially, due to the lack of a reported erosion, but there is no specific data proving that this strategy will improve outcomes.

Echocardiography, either intracardiac (ICE) or transesophageal (TEE), with or without 3-D capabilities has become a crucial tool for the interventional cardiologist and plays a significant role in the guidance of these procedures and in the assessment of the acute closure result [5]. The role of the procedural echo is to first confirm the size of the defect, absence of additional congenital heart defects that would necessitate surgical repair, and finally a confirmatory reassessment of the associated ASD rims. Additional information, such as ASD size relative to the total atrial septum length, can assist in the decision-making process, such that the overall device size can be determined to “fit” within the confines of the atria, or be a potential reason that the procedure should be aborted and the patient referred for surgical repair. There is no absolute ASD size that is defined to be too large, and many informal surveys of interventional cardiologists continue to demonstrate the differences in opinion, within the overall community, about whether there exists an ASD that is “too large” to close percutaneously.

Balloon Sizing (Stop-Flow Versus Stretch)

There are many different approaches that have been utilized and documented in determining the most effective approach to device implantation and a thorough review of these techniques is beyond the scope of this paper. As mentioned earlier, a systematic and thorough approach, individualized to each patient, will allow for the best result possible. Attention to detail is a very important key in optimizing success with minimal complications. This refers to a thorough hemodynamic and imaging assessment at baseline, through device positioning, device release, and post-deployment prior to sheath removal. As part of the assessment of defect size, the original “stretch diameter” of the ASD used a compliant balloon for inflation across the defect until it demonstrated a proper waist. The

recommended strategy was then to add a few millimeters to the waist diameter to choose the device size. This “oversizing” was recommended to avoid device embolization, but was eventually noted to be associated with device “erosion” through the adjacent structures and related to life-threatening scenarios of bloody pericardial effusion and tamponade either acutely or remote from the time of procedure [19•]. Recommendations for defect sizing and device selection subsequently changed and a transition to the “stop-flow” technique took place, whereby the compliant sizing balloon was inflated slowly, under echo guidance, until there was no visible shunt identified by color Doppler interrogation. The balloon waist was then measured on echo and cineangiogram and defined the defect size. Based on this measurement, the device was sized according to either the measured diameter of the balloon or slightly larger per individual operator’s discretion [19•]. The newest reported strategy involves ASD sizing and device selection based on TEE or ICE imaging only without balloon sizing. Operators who utilize this technique measure the absolute defect size, assess the thickness of the tissue rims and, if felt to be substantial enough to be supportive of the device, a size that either measures from thick septal rim to thick septal rim, uses color flow diameter or a pre-determined size larger than the defect is selected [22, 23]. The stop-flow technique and the above strategy of using echo imaging are the two only standard techniques of device sizing that are currently utilized for device closure.

Results

Post-surgical outcomes are excellent with low morbidity and have substantially modified the natural history of patients with an ASD. Follow-up of 135 patients in the long-term have confirmed appropriate closure of an ASD by surgical means. Additionally, it was found to be advantageous in those with a younger age compared with those patients who were older [24]. Device closure of secundum ASD is associated with low complication rates, short anesthetic times, and short hospitalizations. When conditions are favorable, transcatheter secundum ASD closure has become the treatment of choice rather than surgery in many institutions. Several studies have shown outcomes from transcatheter device closure of secundum ASD to be comparable to surgical outcomes in appropriately selected patients [25–27]. Presence of any residual shunt at long-term follow-up is reported in approximately 1 % of patients with almost complete resolution of right heart volume overload [28]. Since the era of the pivotal trial of the Amplatzer Septal Occluder, device occlusion of an ASD was noted to have a similarly very low, and in

some studies, a slightly lower, mortality when compared with surgical closure [16•, 17•, 29]. There are studies that have demonstrated a difference in the developmental outcomes of patients undergoing an open ASD closure with cardiopulmonary bypass, as compared with device closure without the need for bypass [30]. It is, as yet unclear if this is a true finding or an unidentified bias from the studies, which needs to be assessed by a randomized control trial, as it has not been identified in all studies. At the present time, it is unlikely that a randomized trial would be feasible for financial and patient-preference considerations.

As mentioned, the usual practice for elective closure of an ASD in a child is between the ages of 3–5 and greater than 15 kg. Reports have demonstrated the feasibility for closure in smaller children who were referred for issues of poor growth and/or right heart volume overload. There was no identified improvement in growth in asymptomatic patients and the complication rate was higher than the published standards as classified [31]. Successful occlusion was noted in small children and those that were unsuccessful were unrelated to an absolute age or size. The predictor for successful transcatheter ASD closure was an ASD size-to-weight ratio that was less than 1.2 mm/kg [32]. With the current devices, it is no longer necessary to have a septal rim present along the entire margin of the defect with safe and successful closure of secundum ASD with deficiencies of the inferior, posterior, and superior rims [33].

Complications

Risks are associated with all types of transcatheter ASD closure techniques; including, but not limited to, device migration, embolization or malposition; cardiac erosion or perforation leading to pericardial effusion, tamponade or death; arrhythmia; atrioventricular conduction delay or complete heart block; thrombus formation on the device leading to embolic sequelae such as stroke, myocardial infarction, or pulmonary embolus; infection of the device/bacterial endocarditis, atrioventricular valve impingement/regurgitation [5, 34]. From the pivotal study, the overall complication rate from implantation of an Amplatzer Septal Occluder was approximately 7 % (1.6 % major complication) compared with complications after surgical closure of 24 % (5.2 % major complication) with no mortality [16•]. The conclusion from this study was device closure with the Amplatzer device resulted in a lower adverse event rate, both major and overall. With the Helex Septal Occluder, major complications noted from its pivotal study were 5.9 %, compared with surgical outcomes of 10.9 % major complications [17•]. Additional inherent risks from any cardiac catheterization including hematoma,

vascular injury, and myocardial injury, bleeding or air embolism are also present. After the pivotal trial of the Amplatzer Septal Occluder, post-market monitoring of the device and the FDA adverse events database, Manufacturer and User Facility Device Experience database (MAUDE), were established and identified the rare and potentially life-threatening risk of device erosion through the confines of the atrial wall. In 2004 Amin et al. reviewed all cases of hemodynamic compromise after Amplatzer Septal Occluder implantation in order to identify causes of device erosion. At the time of publication, there were estimated to be approximately 30,000 devices implanted worldwide, with a rate of approximately 0.1–0.3 % of implantations resulting in erosion [19•]. No identifying cause was definitively proven, but patients with an over-sized device and deficiency of the retroaortic rim were associated with erosion and recommendations and were made to update the indications/technical aspects of device implantation. Transition to stop-flow technique from balloon stretch diameter, application of gentle stability testing, and identification of patients at higher risk (Amplatzer Septal Occluder >1.5 times the native ASD diameter, small pericardial effusion at 24 h, deformation of the device at the aorta, minimal aortic and superior vena cava rims) were recommended from this review.

With device erosion in mind, the U.S. FDA convened a panel meeting in May 2012 to systematically review the literature, interventional cardiology and congenital cardiac surgery experiences, including representation from St. Jude Medical, Plymouth, MN (Amplatzer Septal Occluder) and W. L. Gore and Associates, Flagstaff, AZ (Helex Septal Occluder), members of cardiac surgical societies and interventional cardiology societies. A thorough review of the literature by the panel, combined with expert opinion, determined that an absent retroaortic rim should be stated as a warning and not as a contraindication in the indications for use of the Amplatzer Septal Occluder. Additionally, a standardized post-device monitoring regimen was established, recommendations were made to consider expansive data collection (such as a national outcomes registry) and re-examination of the pivotal study and post-market approval studies. Lastly, the panel emphasized the importance of patient education about the signs and symptoms of device erosion, and the necessary urgent assessment for anyone with an Amplatzer Septal Occluder in the setting.

The key data reviewed by the FDA panel started with the initial report by Amin et al. that noted a total of 28 cases of device erosion with almost 90 % of the cases having a deficiency of the aortic rim. A follow-up review by Amin in 2014 reported an additional 12 cases of device erosion in spite of adherence to the 2004 recommendations [35•]. Factors identified to significantly increase the risk of erosion with respect to the ASD rims were the absence of

the retroaortic rim in multiple views and an absent or thin posterior rim consistency. Additionally, atrial septum malalignment or a dynamic ASD were also risk factors. A thorough interrogation of the device placement to rule out impingement on the transverse sinus between the aorta and the atrial wall was recommended to identify patients with tenting of the atrial free wall in this location. In follow-up of these ASD devices by echocardiography, if atrial free wall tenting is present, and a pericardial effusion is noted, Amin recommended that this finding should be a strong indicator for device removal [35]. Due to the potential for late onset of erosion (greater than 5 years), all patients should be properly informed of the potential complication, signs and symptoms, and appropriate precautions to take under appropriate circumstances [36]. To date, there have been no incidences of device erosion associated with the Helex device, however there have been numerous cases of wire frame fracture (5–7 %), though rarely resulting in cardiac injury or complication [5].

The most common complication identified from the MAUDE database is device embolization and required surgical removal in 77 % of patients. A survey of proctors for the Amplatzer Septal Occluder noted an incidence of embolization of 0.55 %, with 71 % undergoing transcatheter retrieval and only a small number referred for surgical removal [29]. Potential risks for embolization include an undersized device, floppy or deficient rims, and overly aggressive stability testing or unintentionally applying excessive force on the delivery cable while releasing the device. Device embolization can occur with both septal occluders and both have established techniques for transcatheter device retrieval that all implanters are expected to be prepared for.

The potential for adverse complications aside from erosion or embolization are certainly present, but much less frequently encountered. Continued aseptic techniques in the catheterization laboratory are effective at minimizing infectious risks and bacterial endocarditis as a cause of device removal is less than 1 %. Arrhythmias (including complete heart block) is reported in less than 0.5 % of implanted devices, with its development at higher risk with larger devices and deficiency of rims [37]. Thromboembolism is of great concern due to the potential for stroke, but the incidence of thrombosis on all ASD devices is reported to only be approximately 1 % with the majority resolving with anticoagulation therapy. The ePTFE membrane of the Helex device seems to be the least thrombogenic of the devices at present [38]. One of the important recommendations to come from the FDA panel meeting was the need to develop a better understanding of the epidemiological, technical, and physical properties of devices that optimize outcomes and lessen the risk profile.

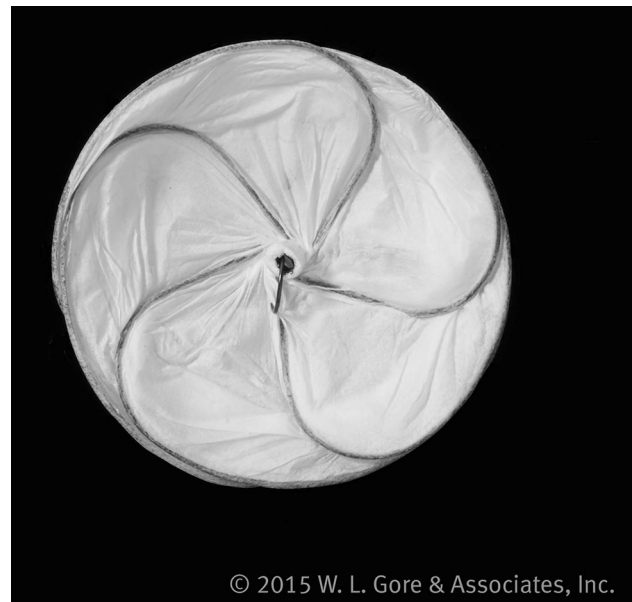


Fig. 2 The new “flower-petal” design of the GORE CARDIOFORM Septal Occluder with a single nitinol wire covered with ePTFE

Future/New Developments

As mentioned, the next generation ASD device from Gore is the GORE CARDIOFORM Septal Occluder (Fig. 2). Post-market approval was granted for this device based on the safety profile and similar characteristics to the Helex device. The new design is more robust with the “flower-petal” type of design for each disk instead of the helical loop, while the single nitinol wire frame maintains its flexibility. This device is not a self-centering device and will not be indicated for closure of large ASDs, similar to the indications for the Helex device [18, 39]. There are currently studies of a new self-centering device from Gore, but these studies are in their infancy and not yet reported. Internationally, there are multiple nitinol wire devices that are similar in design to the Amplatzer septal occluder, but none are currently FDA approved. At the time of writing, there were no additional new devices under investigation that the authors are aware of.

Conclusion

Percutaneous secundum ASD closure has become the standard of care in many institutions worldwide. There are inherent limitations of current technologies that are continually being upgraded to achieve better outcomes with a limited risk profile. At present, with appropriate and careful selection of patients, ASD device closure is a less invasive procedure than surgical ASD closure, with a modestly

lower complication and mortality risk. Recognition of risk factors and a thorough and systematic approach to each individual patient will optimize the acute and long-term results. Utilization of echocardiographic guidance, appropriate sizing of the defect, and technical expertise during device implantation are all key factors that are essential in selecting the best device, limiting complication rates, and optimizing patient outcomes. The introduction of newer devices will need to be investigated carefully to determine which defects can be safely closed percutaneously and the current set of indications, warnings, and contraindications should be reassessed to reflect important technological advances.

Compliance with Ethics Guidelines

Disclosure Matthew A. Crystal and Julie A. Vincent declare they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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