The Role of CardioSEAL and Starflex Devices in Atrial Defect Occlusion

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The CardioSEAL and Starflex implants (Nitinol Medical Technologies, Boston, MA) are self-expanding, double-umbrella septal occluders designed to close small to moderate secundum atrial septal defects (ASDs), the latter having a self-centering mechanism. Overall, successful clinical defect occlusion occurs in more than 90% of patients following implantation. In this article, we discuss the development, design issues, technique of implantation, and clinical results pertinent to these new devices.

Introduction

Atrial septal defects are relatively common cardiac lesions accounting for approximately 10% of all congenital heart lesions [1]. Surgical correction is successful in achieving complete occlusion in the majority of patients, but not without a small but finite risk of mortality and significant morbidity, such as pericardial and pleural effusion, atelectasis, pneumonia, sepsis, and renal failure [2,3]. In addition, sternotomy is associated with pain, disability, and a permanent surgical scar. Because ASDs are easily approached in the catheterization laboratory, there has been a long-standing interest in the development of interventional techniques and devices to close such defects without the need for operation [4-7]. This article reviews the development, technique of implantation, and clinical results of the CardioSEAL and the Starflex implants.

Historical Aspects

The CardioSEAL Occlusion Device was redesigned from the former Bard Clamshell Septal Occluder (C.R. Bard, Billerica, MA) [8•]. This latter double-umbrella device underwent a multicenter clinical trial in both the United States and Canada between 1989 and 1991 with very favorable initial clinical outcomes, although a high rate of supporting arm fracture was noted in follow-up. Despite little or no clinical consequence, these findings prompted discontinuation of elective implantations in 1991. The manufacturing rights and technology for the Clamshell device were subsequently acquired by the Nitinol Medical Technologies in 1995. After re-engineering and modest design modifications, the CardioSEAL Septal Occluder evolved and new clinical trials were begun in late 1996 [8•].

Device Characteristics

The CardioSEAL device consists of two self-expanding umbrellas that affix to the atrial septum by spring tension after implantation. The four metal arms made from the alloy MP35N radiate from the center of the device supporting each umbrella. This metal alloy is far more resistant to fatigue fracture than the original stainless steel formulation used in the Clamshell implant [8•]. The four arms are attached to each other in the center and covered by sewn square Dacron patches. There is also an additional coil joint or hinge in each arm designed to relieve stress forces placed upon the implant during the cardiac cycle, contributing to the improved resistance to fatigue fractures when tested in vitro [8•]. In addition, the spring-back mechanism, which allows the umbrella frame to assume its original shape after deformation during delivery, fixing the implant to the atrial septum, was similarly improved in the new design. The CardioSEAL device is available commercially outside North America in five nominal sizes that correspond to the diagonal length of each umbrella: 17, 23, 28, 33, and 40 mm. It is front loaded into the distal end of the delivery catheter with the aid of a plastic loader through a pin-pin attachment mechanism (Fig. 1). A 10F sheath is required for implantation.

The newer Starflex device has the same basic structure and design of the CardioSEAL Occluder. The major enhancement consists of a flexible self-centering mechanism, resulting from the use of microsprings made from nitinol attached in an alternating fashion between the opposite arms of the umbrellas, crossing the center of the device [9] (Fig. 2). The attachment of the device to the
delivery catheter uses the same pin-pin mechanism as in the CardioSEAL, but also allows the implant to freely pivot against the delivery catheter, reducing tension between the device and the interatrial septum before release [9]. This was achieved by adjusting the attachment mechanism dimensions [9]. The Starflex implant is also available commercially in four nominal sizes: 23, 28, 33, and 40 mm, with the loading system and implantation sheath the same as for the CardioSEAL Occluder.

Indications for Atrial Septal Defect Closure
The indications for transcatheter closure are basically the same as those for surgical closure. A secundum-type defect, which is clinically detectable and results in volume overload of the right atrium and ventricle (with a pulmonary to systemic flow ratio of > 1.5:1), is considered for treatment in children and young adults [2]. In the very young and in the very elderly patient, indications are less clear. It does not seem to be advantageous to close atrial defects in children less than 3 to 5 years [2], unless they fail to thrive or are extremely symptomatic, which is unusual in clinical practice [2]. In elderly patients, surgical closure has improved symptoms of exercise intolerance and possibly mortality over the short term. However, closure does not seem to have any impact on the late appearance of atrial arrhythmias and stroke if compared with medically treated patients [2].

It has been suggested that the incidence of a patent foramen ovale or a small atrial defect is much higher in young patients with an unexplained history of cerebral vascular accidents, which are considered secondary to presumed paradoxical embolization, than in the general population [10]. Although not thought causal, these small holes are considered the anatomic substrate for the occurrence of paradoxical embolism. It is interesting to speculate, however, that the flap-valve mechanism of the oval foramen may be the nidus for thrombus formation in selected individuals. As such, closure of these defects can eliminate the source of, or pathway for, paradoxical embo-
lization, and their closure by transcatheter techniques has been shown to reduce, but not eliminate, the recurrence rate of possible embolic episodes resulting in stroke [11]. Whereas placement of a device is an attractive alternative for its technical simplicity, and avoids cardiopulmonary bypass and periods of postoperative immobilization, no prospective and randomized studies comparing the effects of anticoagulation therapy versus transcatheter treatment and surgery have been published. Although such studies are underway, per-catheter closure may be cost-effective in selected patients who may be at the highest risk for stroke recurrence, if they could be clearly identified [2].

Patients with secundum atrial defects are screened by transthoracic two-dimensional Doppler echocardiography using standard multiple views. Criteria for transcatheter closure with the CardioSEAL Occluder are listed in Table 1. In addition, another option of transcatheter closure is a patent foramen ovale or small atrial defect is offered to all patients with an unexplained history of recurrent cerebral ischemic attacks or stroke, presumed to be due to paradoxical embolization.

After initial screening with a transthoracic echocardiogram, the selected patients are taken to the cardiac catheterization laboratory and are further evaluated by transesophageal echocardiography (TEE) under general anesthesia prior to catheterization. The TEE reassesses the size and location of the defect, extent of surrounding muscular rims, and the length of the atrial septum and pulmonary venous connections. Generally, patients who do not fulfill the above criteria are referred for surgical intervention. Improvements in the catheter techniques, however, and a better understanding of the interatrial septal anatomy have broadened the selection criteria, allowing effective closure in patients with partial deficiency of rims and multiple, irregularly shaped or unusually located defects [12]. Due to the self-centering properties of the Starflex implant, larger defects, up to 25 mm of stretched diameter, can be closed.

Technique of Implantation
As with any other percutaneous technique for atrial defect occlusion, the procedure is almost always performed under general endotracheal anesthesia with TEE guidance to help in positioning the device [13]. After percutaneous entry of the femoral vein, a complete hemodynamic evaluation is performed. Early in the experience, to delineate the positional anatomy of the defect, a left atrialogram was obtained in the right upper pulmonary vein in a hepatocaval projection (30° cranial and 30° left anterior oblique). This portion of the procedure has now been bypassed, relying entirely on TEE evaluation.

Subsequently, an end-hole catheter is passed through the defect and contrast is used to outline the catheter (hand injection), for later use as a marker for magnification correction. An exchange 260-cm, extra stiff Amplatz guidewire (AGA Medical Corp., Golden Valley, MN) is then placed in the left upper pulmonary vein and the catheter removed. Over this wire, a round occlusion balloon catheter (Meditech, Watertown, MA) is advanced into the left atrium, and inflated with a mixture of contrast and saline (3:1) and pulled toward the atrial septum under fluoroscopic and TEE guidance. After confirmation of complete occlusion of the defect by the balloon, the presence of any additional defect within the atrial septum is interrogated by color Doppler. If there are any defects, their size, location, and distance from the central defect are defined. A cineangiogram is obtained of the balloon being pulled gently and steadily against the septum causing its deformation as it passes through the defect. This deformation, the so-called stretched diameter, is then measured using the catheter as magnification correction.

Recently, we have also employed other catheter balloons to estimate the size of the defect (NuMed, Nicholville, NY, and AGA Medical, Golden Valley, MN). They have radiopaque markers at the distal end and an oblong shape similar to a valvuloplasty balloon catheter. As this balloon is made from a highly compliant material, its deformation is easily observed when it is inflated across the defect, with no need to pull it against the septum. The two methods of defect sizing are not comparable; with one stretching the defect margins, and the other not deforming the defect as much as filling the defect. Similarly, the former places tension on the lower margins of the defect (septum primum) and may not truly stretch the full circumference of the lesion. Additionally, the effect of either sizing technique on oblong, noncircular lesions is not fully understood in relation to choosing device size. Each technique is applied to direct device size choice, and may be device-type specific (plug vs disc).

Although the final selection of the device size is based primarily on balloon sizing of the defect, one must also be aware of the potential sources of error of these methods. Depending on the texture and thickness of the interatrial septum, distension and overestimation of the defect size may occur [12]. Additionally, passage of the balloon catheter through an unappreciated smaller second defect may result in measurement of the defect as considerably smaller.

<table>
<thead>
<tr>
<th>Table 1. Criteria for Transcatheter Atrial Defect Closure</th>
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<tr>
<td>The presence of an ostium secundum defect</td>
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<td>Left-to-right shunting across the septum</td>
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<td>Maximal defect diameter of 20 mm</td>
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<td>Dilated right ventricle with evidence of volume overload</td>
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<td>A safe distance (usually 4 to 5 mm) from the margins of</td>
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<td>the defect to intracardiac structures (atrioventricular</td>
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<td>valves, superior caval vein, upper right pulmonary vein,</td>
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<td>and coronary sinus)</td>
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<td>Adequate rim of tissue around at least 75% of the defect</td>
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<td>circumference: the size of the patient large enough to</td>
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<tr>
<td>accommodate a 10F sheath (usually &gt; 10 kg or &gt; 2 y</td>
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<td>of age)</td>
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than expected. For the CardioSEAL Occluder, the device diameter is selected to be twice the size of the stretched diameter. Note that this device diameter is taken from the diagonal of the disc.

In order to avoid implanting an oversized device, particularly in small patients with large defects, the total diameter of the atrial septum is also measured and compared with the size of the selected device. When multiple defects are present, a single device is implanted only if it is felt that it would cover all the defects. It may be necessary to pass the sheath through the more central defect in order to achieve this goal. Two distant defects can be treated using two occluders implanted through two different sheaths [12]. In this situation, the two devices may overlap slightly after implantation.

After sizing of the defect, a 10F long sheath and dilator (Cook) are advanced over the guidewire into the left atrium. There are several ways to avoid air entry in the system. In our hands, a continuous infusion of heparinized saline is maintained through a side arm attached to the dilator of the long sheath starting before the system is introduced through the skin. The sheath and dilator are passed to the level of the hepatic portion of the inferior caval vein, and the sheath guided over the guidewire into the left atrium toward the pulmonary vein (Jean-Francois Piechaud, Personal communication). This eliminates air from inadvertently entering the left heart due to the left-to-right blood flow. Fluid under pressure is continually passed through the dilator during this maneuver. No attempt to withdraw blood from the sheath is made once in position. After crossing the defect with the sheath, the dilator and the wire are carefully removed attempting to maintain the end of the dilator below the level of the heart on withdrawal. The chosen device is loaded into the delivery catheter and advanced through the long sheath into the inferior caval vein and to the right atrial junction. Pushing the delivery wire on the delivery catheter, the device is advanced out of the distal pod into the sheath until the distal arms are fully opened into the left atrial cavity. Care is taken to avoid entrapment of the device within the left atrial appendage or pulmonary veins. Under TEE guidance, the entire system is pulled back gently until the left atrial umbrella approaches or slightly touches the left atrial side of the septum. This is generally in the region of the anterosuperior portion of the septum and care is taken not to pull an arm through into the right atrium. Indeed, to achieve this position, the center of the implant tends to be on the left atrial side of the defect prior to opening the right atrial arms. If the orientation of the device is perpendicular to the plane of the atrial septum, the device can prolapse through the defect. Attempts should be made to bring the device into a more parallel position by rotation of the system (sheath and delivery catheter) or recapturing it (refolding the device by retracting the delivery wire) into the sheath with redeployment of the left atrial disc.

Preshaping the long sheath under a heat gun, and making a slight curve at its end to direct it posteriorly in the left atrium may also be helpful, as can positioning the sheath into the right upper pulmonary vein at the commencement of the maneuver. Rotation or repositioning of the system may also be necessary to achieve optimal contact between the device and the septum to close multiple or unusually located defects [12]. When a satisfactory position is obtained, the sheath is further retracted over the delivery catheter opening the proximal umbrella within the right atrium. To avoid distortion of the atrial septum by the relatively stiff attachment of the device to the wire, the sheath is fully retracted to the inferior caval vein. While connected to the delivery wire, proper positioning of the device is confirmed by TEE, and if the device is in a stable location the release mechanism is activated and the device detached. TEE is again employed to confirm the final position of the device, evaluate the presence, location, and size of possible residual shunting, and rule out systemic or pulmonary venous obstruction and compromise of the atrioventricular valve function (Fig. 3).

At our institution, three-dimensional echocardiographic reconstruction has also been performed in patients undergoing CardioSEAL implantation, and found helpful in defining unusually shaped defects, and in documenting (retrospectively) device positioning at various stages during implantation [14]. Cefazolin is administered (40 mg/kg, maximum dose 1 g) as well as heparin sulfate (150 UI/kg, maximum 5000 UI) prior to device implantation. After removal of the sheath, hemostasis is achieved by local pressure and the patient allowed to awaken in the catheterization laboratory. A second dose of antibiotics is administered after 8 hours. According to a pre-established protocol approved for the Health Protection Branch, Ministry of Health-Canada, our first 50 patients were discharged home the following morning, but recently the procedure has been performed on a same-day basis. A low dose of aspirin (3 to 5 mg/kg daily; maximum 325 mg) is prescribed for 6 months and endocarditis prophylaxis recommended for the first 6 months after the procedure, even if no residual leak is present.

The Starflex Occluder implant is positioned using a similar approach, although there are some technical differences. Due to its self-centering characteristics, the size of the device is selected such that the ratio of the device to the stretched diameter is slightly less than that for the CardioSEAL, being 1.5 to 1.6:1 [9]. The delivery process follows the same steps as noted previously until the distal arms are opened in the left atrium. At this point, in order to activate the self-centering mechanism, the long sheath is pulled back to a point where the tips of the proximal arms are within the sheath, so that the centering microsprings between the umbrellas are fully uncovered [9] (Fig. 4). Although these springs are not visible on fluoroscopy, they can be seen on echocardiography, resembling a picture of a parachute (Fig. 5). The whole system is then pulled back until the left atrial
umbrella slightly touches the interatrial septum. The proximal umbrella is opened by fully retracting the sheath over the delivery catheter to the inferior caval vein, uncovering the delivery wire. The new pin-pivot attachment system reduces the tension between the device and the atrial septum before release, decreasing the risk of dislocation and improving pre-release septal alignment [9]. If the position appears adequate on TEE, the device is released.

**Follow-Up**

In our first 50 patients undergoing transcatheter closure with the CardioSEAL implant under a pre-established protocol, a chest radiograph and a transthoracic color Doppler echocardiogram were obtained prior to discharge. Clinical assessment with chest radiograph and electrocardiogram was performed at 1, 6, and 12 months of follow-up. Transesophageal echocardiography (TEE) was repeated 6 and 12 months after the procedure. The location and size of residual shunting were classified on echocardiography according to our previous published experience [13]. Right ventricular end diastolic dimension was measured and normalized against predicted values for age [15]. A fluoroscopic evaluation was also performed at the 6-month review. Arm fractures, when present, were identified on chest radiograph or fluoroscopy. A 24-hour ambulatory electrocardiogram was obtained, if there was evidence of arrhythmias on standard electrocardiogram or symptoms suggesting a rhythm disturbance. Recently, this protocol has been simplified with TTEs being performed at 6-month intervals.

**Results**

Results from the United States Food and Drug Administration multicenter and Canadian trials for this device are not as yet available. Under these protocols, a core laboratory independently evaluated the clinical, echocardiographic, angiographic, and radiologic data from the centers participating in the study. However, preliminary data from single and multiple institutions in North America and Europe are available.

The European multicenter experience with both occluders was presented at the Adult with Congenital Heart Disease meeting in June 1999 in Frankfurt, Germany, and at the third Pediatric Interventional Cardiology Symposium in September 1999 in Chicago, by Dr Marco Carminati from the Ospedale G. Pasquini, in Massa, Italy. Between October 1996 and April 1999, the procedure was attempted in 334 patients at a mean age of 12 years and with a mean weight of 44 kg. A total of 245 patients (73%) had isolated secundum defects, with 21 (6%) having multiple defects, 15 (5%) an atrial defect with a septal aneurysm, 44 (13%) a patent foramen ovale,
and 9 (3%) having a fenestrated Fontan. The mean defect size was 11.5 mm by TTE, 12 mm by TEE, and 15 mm by stretched diameter. The mean ratio of the device used to the stretched defect was 2.16 (1.4 to 7). Implantation was achieved in 325 patients (97.3%) with a mean fluoroscopy time of 18 minutes. Device embolization occurring within a few minutes to a few hours was observed in 13 patients (4%); 12 to the pulmonary artery, and 1 to the left ventricle. Ten patients underwent uncomplicated surgical repair and three had catheter retrieval and successful implantation of a second device. The device to defect ratio for the embolized devices was 1.8 (1.5 to 2.2). One patient had hemiplegia noted 4 hours after implantation. A residual leak was detected in 41% immediately after the procedure, decreasing to 31% at discharge, 24% at 1 month, 21% at 6 months, and 20.5% at 12 months. During follow-up two patients underwent elective surgical repair at 6 months: one for device malposition and one for late device embolization. Arm fractures were seen in 19 of 309 patients (6.1%), most commonly with the larger devices (23 mm: n = 1; 28 mm: n = 1; 33 mm: n = 7 [8%]; 40 mm: n = 10 [25%]). All patients were asymptomatic and no clinical complications related to fractures were observed. There were no arrhythmias, endocarditis, valvular distortion, thromboembolic events, or other complications. At 1-year follow-up, clinical success, defined as complete closure of the defect or presence of a trivial leak, was observed in 99 out of 107 patients (92.5%).

At our institution, between December 1996 and July 1998, 50 patients (median age 9.7 years) underwent attempted percutaneous occlusion with the CardioSEAL device. The mean defect diameter estimated by TEE was 11.9 ± 2.9 mm (range 7 to 18 mm; median 12 mm) and by stretched diameter 13.7 ± 3.2 mm (range: 7.5 to 20 mm; median 14 mm). Two defects were found in 10 patients (20%) and a fenestrated septum in 1 (2%). Partial deficiency of septal rims (< 4 mm) was present in 19 patients (38%). The Qp:Qs was 1.9 ± 0.7 (range: 1 to 4) and fluoroscopy time ranged from 7 to 32 minutes (mean 15.5 ± 5.4 minutes). The ratio device to the stretched diameter was 2.5 ± 0.4 (range 1.9 to 3.6).

All patients had successful implantations, although in four (8%) a second device was implanted after removal of a malpositioned initial implant. There were no significant immediate complications. All patients, except one, were discharged within 24 hours, and at discharge 40% had complete closure. Mean follow-up was 9.9 ± 3.2 months (range 6 to 12 months), and at the latest follow-up, persistent shunting was identified in 23 patients (46%), measuring less than 2 mm in 13 patients (26%), between 2 and 4 mm in 4 patients (8%), and greater than 4 mm in 6 patients (12%). Interestingly, out of the 6 patients with leaks measuring greater than 4 mm by color flow Doppler, 4 had normal right ventricular sizes and septal motion. In a univariate analysis, defects with little or no rim, particularly in the anterosuperior portion of the septum, were associated with a higher incidence of residual leaking due to the prolapse of one arm through the defect. However, in a multivariate analysis, no risk factor was predictive of residual shunting. The right ventricular end diastolic dimension corrected for age decreased from 137% ± 29% to 105% ± 17% and septal motion abnormalities normalized in all but one patient. Fractures were detected in 7 patients (14%) and prolapse of one arm of the device through the defect in 16 patients (32%), the latter being more common in those with partial deficiency of rims (Fig. 6). No untoward effects resulted from fractures or prolapse. Five patients (10%) experienced transient headaches. There were no episodes of device embolization, endocarditis, stroke, or cardiac-related hospital admissions [16].

After completion of this study, approximately 60 additional patients have undergone transcatheter defect closure using a similar technique with similar immediate outcomes. A significant complication occurred during follow-up in one patient: a 9-year-old boy, weighing 32 kg, who had a 28-mm CardioSEAL device implanted to a central 9.5-mm (stretched diameter) secundum defect. TEE demonstrated good device position with no protrusion and no residual leak 20 minutes after the implantation. These findings were subsequently confirmed by TTE the following morning and at the first-month follow-up appointment. At 6 months, he developed a small perforation in the roof of the left atrium caused by one of the device arms, which required surgical intervention. The explanted device was almost fully endothelialized and the manufacturer found no abnormality in its structure after extensive assessment.

Comments

The clinical experience described previously shows that the implantation of the CardioSEAL device corrects the hemodynamic disturbances secondary to the right ventricular volume overload, although small residual leaks are commonly detected in follow-up of little, if any clinical significance. Although noting residual shunts with color Doppler is important, it is the septal motion and right heart internal dimensions that reflect the hemodynamic burden to the right ventricle, noting that the size or even the presence of a leak can be affected by turbulent flow patterns near the device. Although little data is available, preliminary results suggest that the rate of residual leaks is lower with the Starflex device (Dr. Mario Carminati, Personal communication).

The potential risk of paradoxical emboli in patients with residual defects after transcatheter closure remains speculative, probably being a rare event. Prewitt et al. [17] have reported one patient who developed a transient ischemic attack 6 months after a Clamshell implant, in the setting of residual bidirectional atrial shunting. Incomplete device endothelialization was demonstrated after device explantation and surgical repair. In contrast, previous animal studies have shown complete endothelialization 3 months after Clamshell implantation [18].
The low profile of the CardioSEAL and the Starflex devices facilitates endothelialization and minimizes the risks of thrombus formation in the atrium. In our experience, defects with little or no rim, particularly in the anterosuperior portion of the septum, have been associated with the prolapse of one arm of the device through the defect. Three-dimensional echocardiographic studies have identified possible causes of such an event (Figs. 6 to 8) [14•]. Underestimation of the longest dimension of an elliptical defect, by deforming its contour at the time of balloon sizing, and malalignment between the device and the plane of the atrial septum, accentuated by the tension on the delivery system at the time of deployment, may result in such positional anomalies. Additionally, acute angulation of the anterosuperior left atrial arm to the long axis of the ascending aorta when the anterior rim is deficient may also lead to arm prolapse after placement [14•].

Fractures have not been completely eliminated with the CardioSEAL Occluder, although the incidence was significantly lower when compared with the Clamshell implant [19,20]. Their presence has not resulted in an increased rate of residual shunting, device embolization, or other clinical complication, and clinical significance of such fractures remains to be determined with longer follow-up. Recently some variables have been associated with fractures, including larger device size, manufacturing wire lot, and difficult device placement [21]. Based on the previous reports on the intermediate-term outcome (up to 10-years follow-up) of the Clamshell device [8•,19,20], it is unlikely that these fractures will cause untoward events.

The relatively high incidence of headaches detected in follow-up after device closure is an interesting observation with an unknown etiology. We speculate that the release of vasoactive mediators from platelets during the early process of endothelialization and vasoactive hormones due to increased left atrial pressure and chamber distension after defect closure may play a role in the genesis of these symptoms.

As to the patient who had a perforation of the left atrium, we were unable to find a reasonable explanation for this occurrence. No cases of cardiac perforation secondary to CardioSEAL implantation for treatment of a variety of lesions, including secundum and muscular ventricular septal defects, have been reported in the international experience thus far. Likewise, not a case of perforation has been reported after more than 1000 Clamshell implantations. One may speculate that the occurrence of fractures in the Clamshell device may have had a protective role preventing wall perforation in the beating heart. Although the device implanted in this patient was slightly oversized for the stretched diameter (ratio almost 3:1), there was ample room in the left atrium to accommodate the occluder. Marked thickening of the atrial wall adjacent to the device with subsequent spontaneous resolution was also reported after Clamshell implantation [19]. Progression of this type of lesion to the point of wall erosion and eventual perforation is also speculative, although no focal thickening was observed on repeat echocardiograms.

Although no large series of patients undergoing Starflex implantations have been published, initial results suggest several advantages, which may improve results regarding rate of complete closure, incidence of arm prolapse through the defect, prevalence of fractures, and risk of cardiac perforation. The "soft" microspring centering mechanism does not distort the atrial septum and will likely adjust to variations in defect shape, size, and morphology [9]. The spring coil design allows for an individual positioning of each arm, and reduces the stresses between the device and the heart [9]. Due to the self-centering mechanism, smaller devices (compared to the CardioSEAL design) can be used to close similar sized defects and additionally, larger defects, up to 25 mm (stretched diameter), can be addressed with this implant. Finally, the issue of the surrounding rim also becomes less critical for implantation [9].

Conclusions
The CardioSEAL and the Starflex occluders are self-expanding, double-umbrella devices designed to close small to moderate secundum atrial defects, the latter having a soft
self-centering mechanism. Better understanding of atrial septal anatomy, modifications in implantation technique, and design refinements have extended the limits of transcatheter closure. Defects that are unusually located, double or multi-perforated, and with partial rim deficiency can be addressed with these devices, with good results. Significant immediate- and long-term morbidity resulting from the procedure is uncommon. Overall, successful clinical defect occlusion occurs in more than 90% of patients, although small residual leaks are commonly seen with the CardioSEAL device. These leaks tend to resolve or decrease over time, with little if not any hemodynamic burden to the right ventricle. The newer Starflex Occluder offers several advantages due to its soft self-centering mechanism, which will improve results in regard to closure rate, arm prolapse, prevalence of fractures, and risk of cardiac perforation.

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References and Recommended Reading
Recently published papers of particular interest are highlighted as:
- Of importance
- Of major importance


An excellent, timely review of the development of transcatheter devices in atrial defect closure.


An early study of the three-dimensional appearance of the CardioSEAL implant after implantation, and a discussion of the impact of anatomy on device stability and positioning.


