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Atrial Septal Defects

A Retrospective of Atrial Septal Defect Closure Devices

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[*Rev Cardiovasc Med.* 2007;8(1):49-52]

Device Closure Rates of Simple Atrial Septal Defects Optimized by the STARFlex Device

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J Am Coll Cardiol. 2006;48(3):538-544

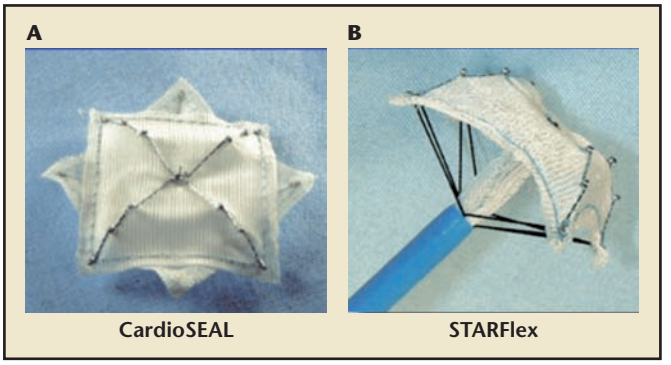
Percutaneous closure of atrial septal defects (ASDs) has been a goal for 30 years.[1] Nugent and colleagues[2] present an historical retrospective of the effectiveness of a particular ASD occluder design championed by the group at Boston Children's Hospital and led by James Lock, MD.

The original model, the Clamshell (C.R. Bard Inc., Murray Hill, NJ), was known as the "double-umbrella" device. It consisted of 2 opposing squares of knitted Dacron® (Invista, Wichita, KS) stretched open by 4 metallic (stainless steel) arms with a single joint in the middle of each outstretched arm. The device was delivered through a sheath positioned across the secundum defect. The left atrial (LA) side was opened first, with care to keep all the "legs" of the device on the LA side of the septum, then the device was pulled into the septum, and the right side was allowed to spring open. A narrow metallic connector was present between the 2 umbrellas. This model was used from 1989 to 1991.

Because of concern regarding arm fractures that were observed in the follow-up period, the device was redesigned using a newer and thicker metal alloy with 2 joints in each arm. The new device was named the CardioSEAL® occluder (NMT Medical Inc., Boston, MA) (Figure 1A). It still had a narrow metallic connector between the 2 discs that potentially allowed movement within the ASD orifice. The CardioSEAL was used from 1997 to 1999, when it was replaced by a self-centering device, the STARFlex® (NMT Medical Inc., Boston, MA). This device had strings between the tips of the disc squares that forced the umbrellas to remain centered within the ASD when deployed (Figure 1B), and it utilized nitinol metal.

Devices were all measured according to the "stretched" diameter of the ASD. This standard measurement is determined by placing a sizing balloon across the atrial septum and noting the maximal balloon diameter that does not demonstrate any residual Doppler color-flow around the balloon when viewed on a transesophageal echocardiogram (TEE) or an intracardiac echocardiogram (Figure 2). Intracardiac echo/Doppler has been increasingly used to deploy these devices, but in the authors' series, all patients had the device deployed while under general anesthesia with TEE guidance. The TEE is

Figure 1. *The evolution of the "umbrella" ASD occluder.* **(A)** *The CardioSEAL device with 2 arm joints.* **(B)** *The STARFlex device with self-centering mechanism. ASD, atrial septal defect.*



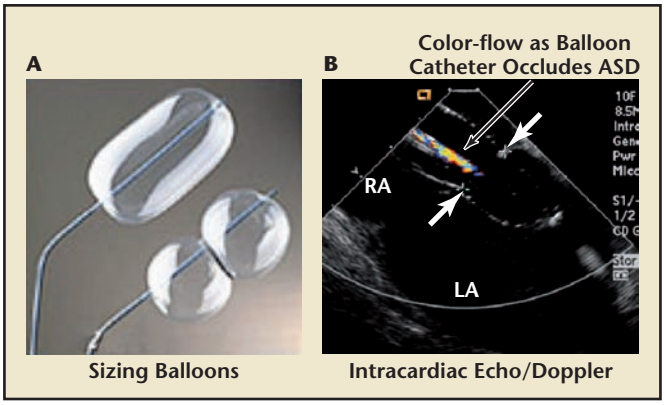


Figure 2. *Use of the sizing balloon for determining the stretched ASD size.* **(A)** *The soft sizing balloons.* **(B)** *Intracardiac echo of gradual inflation of the balloon. Loss of the peri-balloon Color-flow determines when the balloon totally occludes the ASD (black arrow). The diameter of the ASD at that point determines stretched ASD size (white arrows). ASD, atrial septal defect; RA, right atrium; LA, left atrium.*

used to define the defect size, note the amount of rim around the defect, assess the mobility of the atrial septum, and determine the positioning of the device (especially, for this particular device, whether any legs are on the wrong side of the septum).

The authors implanted the Clamshell device in a total of 72 patients: 30 with the CardioSEAL and 42 with the STARFlex. Mean length of follow-up was 7.1 years for the Clamshell, 2.1 years for the CardioSEAL, and 2.0 years for the STARFlex. The largest STARFlex device (40 mm) was taken off the market after 2001 due to embolization concerns. The ASDs that were closed were actually fairly small, with a median stretched size of 14 mm to 16 mm. In general, a maximal device disc diameter twice the maximal stretched defect size was used.

At follow-up, residual peri-device flow was not a significant issue and appeared less often with the newer designs (it occurred in only 1 patient out of 42 in the STARFlex group). Table 1 outlines the results and the incidence of reported complications. The results are impressive and demonstrate the continued improvement in the use of this particular device.

The authors also note the favorable comparison of their device with other percutaneous ASD devices and with surgical ASD closure (Table 2). This is particularly relevant, since only the Amplatzer® device (AGA Medical Corp., Golden Valley, MN) is currently on the market and approved for use in the United States. The Amplatzer is a self-expandable double disc device (the larger disc is on the LA side) with no legs or metal struts. It is self-centering, with the connector between the discs fully occluding the ASD orifice. The excellent results, the ease of use, and the availability of the Amplatzer device have currently made it the most commonly used device for ASD closure. The Helex™ device (Gore Medical Associates, Newark, DE) (Figure 3A) is a nitinol wire frame "coil" covered with Dacron that springs open from the catheter sheath into revolving disc shapes, trapping the septal defect between the discs. It is made by the company that produces

Table 1
ASD Closure With Clamshell, CardioSEAL, and STARFlex Devices

	Clamshell	CardioSEAL	STARFlex
Surgery for device complication	4 (6%)	1 (3%)	0
Surgery for residual shunt	6 (8%)	0	0
Second device	3 (4%)	1 (3%)	0
Unrepaired shunt	3 (4%)	0	1 (2%)
Severe complication	5 (7%)	1 (3%)	0
Embolization and surgery	2	1	0
Embolization fractured arm	1	0	0
AV valve interference	1	0	0
Device thrombus	1	0	0
Moderate complication	19 (26%)	9 (30%)	11 (26%)
Minor complication	17 (24%)	2 (7%)	7 (17%)
Successful procedure	57/72 (79%)	28/30 (93%)	41/42 (98%)

ASD, atrial septal defects; AV, atrial ventricle. Data extracted from Nugent AW et al.[2]

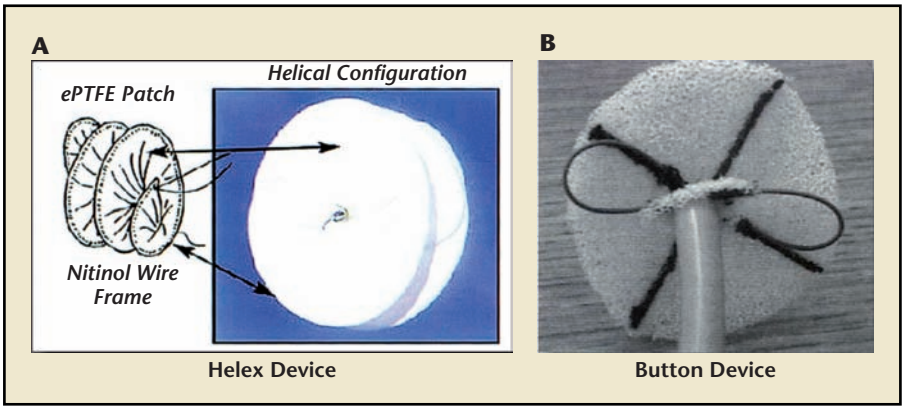


Figure 3. *Other ASD occluder devices.* **(A)** *The Helex device.* **(B)** *The Sideris "button" device. ePTFE, expanded polytetrafluoroethylene.*

Table 2
Comparative Results of Uncomplicated ASD Closure

	Number of Patients	Closure Rates	Severe Complications
Other ASD Devices			
Amplatzer[3]	442	99%	1.1%
Helex[4]	14	92%	7.1%
Sideris[5]	423	90%	6.4%
Das Angel Wings[6]	14	86%	7.1%
Surgical Results			
Du ZD et al[3]	154	100%	5.2%
Berger F et al[7]	61	98%	3.3%
Galal MO et al[8]	232	NR	6.0%
Pastorek JS et al[9]	58	92%	3.4%

ASD, atrial septal defect; NR, not reported.

Gore-Tex®. The Sideris™ button device (Custom Medical Devices, Amarillo, TX) (Figure 3B) deploys an LA disc that is locked into place with a "button" or opposing clip on the RA side to hold it onto the atrial septum. The Das Angel Wings™ (Microvena Corp., White Bear Lake, MN) initially consisted of self-expanding nitinol squares for each side of the septum that were covered with Dacron and connected by material the size of the ASD. It later was changed to a circular shape and called the Guardian Angel™. It is no longer in use.

As for all ASDs that might be closed percutaneously, the device selection criteria are critical. Complications do arise when the defects are inappropriately sized, when there is inadequate rim to hold the device in place, when there are structures (such as the mitral valve or pulmonary vein) that might be interfered with by the discs, or if there are multiple fenestrations within the atrial septum. Devices that are too large can erode cardiac structures, especially the aorta adjacent to the LA superior wall. Atrial arrhythmias were a more significant problem with early devices compared to current ones, but they still do occur. Devices that are too small can result in residual shunts or embolization. In some institutions, not only is TEE used to help define the septal anatomy, but cardiac magnetic resonance imaging has demonstrated excellent images of the shape of the defect (frequently, they are oddly shaped) along with the other structural concerns noted above.

Conclusion

The authors have shown that the current generation of the classic double umbrella device still compares favorably with other devices being deployed for the percutaneous closure of uncomplicated ASDs. This is a new era in the closure of ASDs, and as the bugs are now almost entirely worked out of most of these devices, percutaneous closure of uncomplicated secundum ASDs should now be considered standard of care. ■

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