

# A History of ASD Closure

A review of atrial septal closure, including the surgical evolution and the subsequent progression of transcatheter device closure.

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The interatrial septum has been of medical interest since the 1800s. The first reported paradoxical embolus through an atrial septal defect (ASD) is attributed to Julius Cohnheim, as translated from the *Handbook for Practitioners and Students* (Second German Ed.) by Alexander McKee in 1889.<sup>1</sup> Since that time, the literature is rich with subsequent reports of paradoxical embolism, as well as other indications for ASD closure.

## SURGICAL INTERVENTION

Surgical intervention progressed through the years, first to successfully close a defect and later to perfect minimally invasive techniques. Initial experimental attempts to surgically close ASDs are credited to Blakemore in 1939, who discussed his interest and work with simple inversion of the atrial appendage.<sup>2</sup> Cohn reported his attempts with atrial wall invagination for experimental ASD closure in dogs in 1947.<sup>3</sup> In 1948, Murray reported extracardiac closure in a 12-year-old girl; however, subsequent catheterization revealed the defect was only partially closed.<sup>2,4</sup> Also in 1949, Santy et al performed the first successful clinical operation using inversion of the right atrial appendage (intussusceptions) to close the ASD in Lyon, France.<sup>5</sup>

Throughout the early 1950s, several attempts were made to surgically close ASDs using various techniques. Swan et al reported using stiff polythene buttons to invaginate the atrial appendages via transatrial sutures to close the ASD, and Bailey et al used that same technique on a series of five patients, reporting three operative deaths and incomplete closures in the remaining two patients.<sup>6,7</sup> In the same article, the atrioseptopexy is described by Bailey, and six operative cases are reported in which there were two operative deaths. Hufnagel and

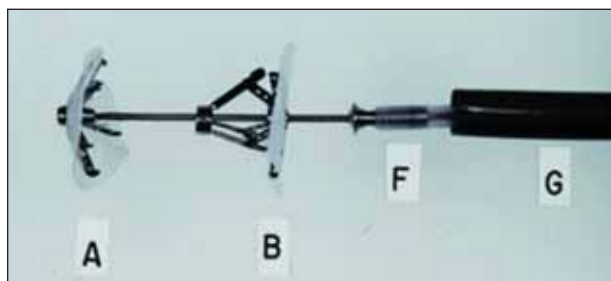
Gillespie reported their experience using two nylon buttons through a right atriotomy for experimental ASD closure in dogs.<sup>8</sup> This technique was later applied in three patients, with 100% mortality.<sup>4</sup> Dennis et al performed ASD closure under direct vision with a pump oxygenator in a 6-year-old girl. At surgery, she was found to have a primum ASD and ultimately died due to “extraneous factors.”<sup>9</sup> Cookson et al attempted ASD closure using hypothermia, but the patient died due to ventricular fibrillation. Hypothermia was attempted in four additional non-ASD patients, with only one survivor who was not repaired using direct vision.<sup>10</sup>

In 1952, Lewis and Taufic reported ASD repair in a 5-year-old girl using hypothermia and inflow occlusion. This was the first successful open heart repair under direct vision and marked the onset of the open heart surgical era.<sup>11</sup> That same year, Gross et al reported the “well technique” repair of ASDs in six patients, with only two survivors.<sup>12</sup>

Dr. John Gibbon opened the modern era of open-heart surgery on May 6, 1953, using the heart-lung machine, or cardiopulmonary bypass (CPB), when he successfully repaired an ASD in an 18-year-old woman.<sup>13</sup> She was the second and only survivor of four attempted surgeries. He reported that he believed the deaths were attributable to human error and not the heart-lung machine. He was so disappointed in the results that he never again attempted CPB for open-heart surgery.<sup>4</sup>

In 1955, Derra et al reported the first successful closure of an ASD in Europe using surface hypothermia and inflow occlusion in eight patients. There was one late death 12 days after the procedure secondary to cerebral embolus.<sup>14</sup>

Surgical closure of ASDs using CPB gained increasing success throughout the 1950s and would become the



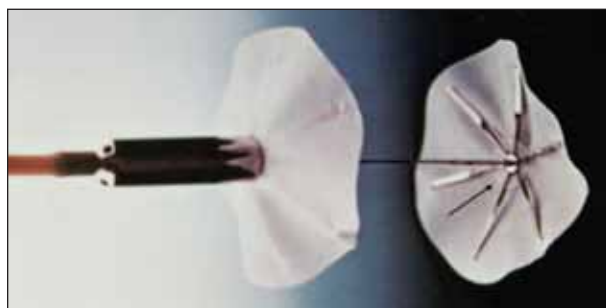
**Figure 1.** Cardiac umbrella used for the first experimental ASD closure: left atrial umbrella (A), right atrial umbrella (B), locking catheter and cone (F), and an outer catheter (G).

gold standard for ASD repair. Although surgical repair of ASDs continues to enjoy tremendous success, variations in techniques to close ASDs continue to be developed. Hybrid techniques, such as surgical repair of coarctation of the aorta and simultaneous use of a device to close an ASD, were suggested by Mills and King in 1976.<sup>15</sup> Suematsu et al reported three-dimensional echocardiography-guided repair of ASDs in an in vitro study.<sup>16</sup> Vasilyev et al reported experimental ASD patch closure in piglets using three-dimensional echocardiography in the beating heart using a 9-F introducer sheath to deliver a polyester patch attached to a 0.1-mm nitinol frame into the right atrium. The patch is then attached to the atrial septum using nitinol minianchors deployed using a pistol-type fixation device. After fixation of the patch, the wire frame is removed leaving behind only the polyester patch and nitinol anchors.<sup>17,18</sup> These attempts may be intermediate to the development of new advances in image-guided intracardiac beating-heart repairs.

## TRANSCATHETER DEVICE INTERVENTION King-Mills Cardiac Umbrella

King and Mills performed the initial experimental transcatheter closure of ASDs in dogs in December 1972.<sup>19</sup> The device (Figure 1), used experimentally, had evolved to consist of six stainless steel struts with barbs at the end of each strut. The paired opposing umbrellas were covered with Dacron, the umbrella had to be opened mechanically, and there was a snap lock mechanism to secure the umbrellas together. A total of 13 animals underwent cardiac catheterization with the intent to close the experimentally punched ASDs, with successful closure in five animals.<sup>19,20</sup>

Balloon-sizing techniques were developed to ascertain ASD sizes. Varying amounts of fluid were instilled in hundreds of Fogarty balloon catheters and measured using calibrated aluminum plates with circular holes starting at 3 mm and graduated every 1 mm to 50 mm. ASDs were then sized in experimentally punched ASDs in dogs and



**Figure 2.** Edward's modification of the King-Mills Umbrella showing the left atrial umbrella, right atrial umbrella, obturator wire, and distal capsule. Both umbrellas had silicone rings (arrow) to allow self-opening.

in patients with ASDs during heart catheterization and compared to the ASD at subsequent surgical repair.<sup>19,21</sup> These comparisons yielded excellent accuracy.

The results of the canine research were very encouraging and led to an improved prototype. The new prototype (Figure 2), created with the assistance of Edwards Laboratories, had the same double-umbrella configuration, covered with Dacron. There were still six stainless-steel struts; however, the barbs were omitted in the new prototype. Again, the snap lock mechanism was used to lock the umbrellas together. On the intersurface of both umbrellas was a silicone ring that allowed the umbrella to be self-opening.

The initial patient to undergo device closure with the King-Mills umbrella was a 17-year-old girl. She was opposed to surgical repair because she was averse to a scar on her chest. Cineangiography and balloon sizing of her defect showed a 2.53-cm secundum ASD with a 2:1 shunt. Her ASD was closed using a 35-mm King-Mills umbrella without difficulty on April 8, 1975, at the Ochsner Clinic in New Orleans, Louisiana.<sup>22</sup>

Initially, seven patients underwent cardiac catheterization with the intent to close their secundum ASD. The first five attempts were successful, but in the last two patients the device would not seat properly, and surgical repair yielded excellent results.<sup>23</sup> Long-term follow-up of four survivors has been well chronicled.<sup>24</sup> The deceased patient died from Hodgkin's disease and a cerebral vascular accident 9 years after device closure.

The King-Mills device lacked centering capabilities and was nonretrievable; thus, suboptimal position on deployment required surgical removal and ASD closure. Large device sizes and large delivery capsules (23 F) minimized its overall use for greater numbers of patients; however, the device and technique established that ASDs could be closed transvenously, thus opening the door for further research and devices.

TABLE 1. ATRIAL SEPTAL CLOSURE DEVICES AND SYSTEMS

| Device                                       | Frame                          | Covering                                        | Company                        |
|----------------------------------------------|--------------------------------|-------------------------------------------------|--------------------------------|
| King-Mills Umbrella                          | Stainless steel                | Dacron                                          | Custom made                    |
| King-Mills Umbrella                          | Stainless steel                | Dacron                                          | Edwards Laboratories           |
| Rashkind Single Disk                         | Stainless steel                | Foam                                            | USCI                           |
| Lock Clamshell Device                        | Stainless steel                | Dacron                                          | USCI Angiographic Systems      |
| Sideris "Buttoned" device                    | Teflon-coated stainless steel  | Teflon-covered polyurethane foam                | Custom made                    |
| Atrial Septal Defect Occluder System (ASDOS) | Stainless steel                | Homologous pericardium (preserved)              | Custom made                    |
| Angel Wing/Guardian Angel                    | Nitinol                        | Dacron                                          | Formerly Microvena Corporation |
| Pavānik Monodisk                             | Stainless steel                | Nylon mesh                                      | Custom made                    |
| ASDOS                                        | Nitinol                        | Thin polyurethane layer                         | Osypka Corporation GmbH        |
| CardioSeal                                   | MP35N                          | Dacron                                          | NMT Medical                    |
| Amplatzer Septal Occluder                    | Nitinol                        | Dacron augmentation                             | AGA Medical                    |
| StarFlex                                     | MP35N and nitinol              | Polyester fabric                                | NMT Medical                    |
| Helex Septal Occluder                        | Nitinol                        | Polytetrafluoroethylene (ePTFE)                 | W. L. Gore & Associates        |
| Sideris Detachable Balloon Device            | Latex balloon                  | Polyurethane foam                               | Custom made                    |
| Sideris' Transcatheter Patch                 | None                           | Polyurethane foam                               | Custom Medical Devices         |
| Cardia Devices                               | Nitinol with titanium end caps | PVA (Ivalon polyvinyl alcohol)                  | Cardia, Inc.                   |
| Occlutech Septal Occluder/                   | Nitinol                        | Mesh                                            | Occlutech GmbH                 |
| Occlutech PFO Flex                           |                                |                                                 | Occlutech AB                   |
| Premere PFO Closure System                   | Nitinol                        | Knitted polyester                               | St. Jude Medical, Inc.         |
| Solysafe Septal Occluder                     | Phynox                         | Polyester patches                               | Swissimplant AG                |
| BioStar                                      | Nitinol                        | Bioabsorbable porcine intestinal collagen layer | NMT Medical                    |
| SeptRx IPO                                   | Nitinol with tantalum markers  | Polyester                                       | Secant Medical                 |
| Coherex Flat Stent EF                        | Nitinol with tantalum markers  | Polyurethane foam                               | Coherex Medical, Inc.          |
| PFO Closure System                           |                                |                                                 |                                |
| pfm Device                                   | Nitinol                        | Mesh                                            | pfm Medical AG                 |
| Pfx-15                                       | N/A                            | N/A                                             | Cierra, Inc.                   |
| Sideris Immediate Release Patch (IRP)        | Latex balloon                  | Polyurethane foam with surgical adhesive        | Custom Medical Devices         |
| BioTrek                                      | Poly-4-Hydroxybutyrate (P4HB)  | Poly-4-Hydroxybutyrate (P4HB)                   | NMT Medical                    |

## SUBSEQUENT DEVELOPMENTS

### The Rashkind Single Umbrella Device

Variations in the cardiac umbrella approach to ASD closure were attempted by a number of investigators

and, over time, new materials that improved ASD devices were introduced (Table 1). In 1983, Rashkind reported using a single foam-covered, six-ribbed device (USCI Angiographic Systems, Tewksbury, MA) with

hooks on three alternate ribs.<sup>25</sup> This device was abandoned because of embolization and inadvertent barb “hooking” on undesired surfaces. He did develop a patent ductus closure device that ultimately received Food and Drug Administration approval but was never marketed in the United States.<sup>1</sup> Rashkind also mentioned a double-disk device implanted in a cow septum and that clinical trials were pending; however, further information was not available.<sup>25</sup> Drs. Lock, Hellenbrand, Latson, and Benson modified the Rashkind ASD device in 1985 and initial human use was begun in 1987 by Dr. Hellenbrand at Yale. This was followed by six more cases at Yale or Omaha’s Children’s Hospital.<sup>1</sup> Hellenbrand and Mullins reported their experience in three cases. One case had a significant complication requiring surgery, at which time the device was found to be attached to the left atrial posterior wall. The modified Rashkind ASD device was abandoned as well. The consensus was the device had two major problems: first, when opened, it could not be removed because of the hooks and thus required surgical removal; second, exact positioning was a must and this would limit the number of patients for this approach. After their experience with the Rashkind single-disk device, Drs. Hellenbrand and Mullins and Dr. Lock recommended a double-disc approach to ASD closure.<sup>26,27</sup>

## The Lock Clamshell

Lock’s experience and observations lead him to a conceptual variation of the spring-loaded Rashkind patent ductus arteriosus (PDA) device, which culminated in a double-hinged paired umbrella (covered with Dacron) and four arms that could be folded back on themselves.<sup>27</sup> The device was named the Lock Clamshell (USCI Angiographic Systems). The metal components were stainless steel and the folded arms lent some centering capabilities to the device. Between 1987 and 1991, the Lock Clamshell was used successfully in approximately 1,000 patients; however, a significant number of early and late arm fractures lead to elective withdrawal of the device.<sup>24</sup> The Lock Clamshell device further proved the feasibility of transvenous closure of ASDs.

## The Buttoned Device

The Buttoned double-disc device was initially reported in 1990 and underwent several generational changes, culminating in the Center-on-Demand device (COD).<sup>28-30</sup> Approximately 3,000 buttoned devices were implanted (the last implantation was in the late 1990s).<sup>24</sup> The buttoned device has since been abandoned but as of 2009 the COD had limited availability.

## The Atrial Septal Defect Occluder System

The Atrial Septal Defect Occluder System (ASDOS) was reported by Babic in 1990.<sup>31</sup> His device used a long venoarterial wire track and a pair of self-opening umbrellas made of stainless steel and covered with preserved pericardium. It was centered with an Ivalon plug placed between the two umbrellas. The device was later modified and licensed as the ASDOS system in 1994, at which time the device had two self-opening umbrellas composed of a nitinol frame covered with a thin polyurethane membrane. Approximately 600 patients received the ASDOS device but by 2001 it had been abandoned.<sup>24</sup>

Nitinol is a nickel and titanium alloy. Metal alloys with mechanical recoil were first described in 1932 by Ölander and later by Buehler (1962).<sup>32</sup> Buehler named his alloy discovery nitinol. Nitinol is a very pliable, compressible alloy that resumes its original preformed configuration after manipulation. Today, nitinol is usually in a 55% nickel and 45% titanium combination. This and other alloys, such as MP35N (cobalt chromium, molybdenum, and nickel) and Phynox (cobalt, chromium, iron, nickel, and molybdenum), are used in a number of ASD occluding devices and have greatly enhanced transvenous device closure.<sup>24</sup>

## Das Angel Wing

The Das Angel Wing was reported in 1993 (formerly Microvena Corporation). This device had two Dacron-covered square disks or wings and a nitinol frame with midpoint torsion spring eyelets. A circular hole with a diameter equal to one-half of the size of the disk was punched from the right disk with the margins sewn to the left-sided disk forming a conjoined ring, the centering mechanism.<sup>33</sup> Rickers et al reported a multicenter study enrolling 101 patients in 1998 and, in 1999, Banerjee et al reported on a United States multicenter trial in 70 consecutive patients (phase I clinical trial).<sup>34,35</sup> A phase II trial involving 47 patients followed; however, after the phase II trial in the United States and the clinical experience in Europe, it was decided to halt investigation in attempts to reconfigure the device. The new device, named the Guardian Angel, had rounded right and left atrial wings, better retrievability, easier positioning, and a self-centering mechanism.<sup>36</sup> As of 2003, to our knowledge, there has been no further activity of either the Angel Wing or Guardian Angel, and they are therefore presumed to be abandoned.

## The Monodisk

Pavānik et al reported on the Monodisk, which consisted of a single disk of a stainless steel ring covered with a double layer of nylon mesh and three pieces of braided

hollow stainless steel wire sutured to the backside of the circular disk. The device was tested in dogs with reportedly good success and was subsequently successfully implanted in two patients with secundum ASDs in 1993. No further trials were undertaken, and the device has been abandoned.<sup>24,37</sup>

### The CardioSeal and StarFlex Devices

The CardioSeal device (NMT Medical, Boston, MA) was reported by Latson in 1996 and evolved from the Lock Clamshell. The CardioSeal is a square, non-self-centering patch covered with polyester made with four MP35N ribs that have two mid-arm coils in tandem.<sup>38</sup> The StarFlex device (NMT Medical, Inc.) further evolved from the CardioSeal to include self-centering capabilities by adding fine nitinol coil springs connected in sequence to the corner of one patch with the adjacent corner of the opposite patch, then back to the next corner and so on. The safety and effectiveness of the CardioSeal and StarFlex devices have been demonstrated through significant clinical trials.<sup>24</sup>

### The Amplatzer Septal Occluder

The Amplatzer Septal Occluder (AGA Medical Corporation, Plymouth, MN), developed by Dr. Kurt Amplatz, is a self-centering device with two circular retaining discs that are made of nitinol wire mesh connected by a short connecting waist. The waist centers the device, as well as occludes the defect. The first clinical trial was reported by Masura et al in 1997, and the device has since been used extensively worldwide.<sup>39</sup>

### The Helex Septal Occluder

The Helex Septal Occluder (W. L. Gore & Associates, Flagstaff, AZ) is made of a single nitinol wire covered with an ultra thin membrane of expanded polytetrafluoroethylene (ePTFE) and, in its occlusive configuration, forms two rounded flexible discs straddling the septum.<sup>40</sup> The first clinical implant was in 1999, and the Food and Drug Administration phase I feasibility trial began in 2000.<sup>41</sup> The Helex occluder has been used extensively worldwide.

### The Sideris Transcatheter Patch

The Sideris Transcatheter Patch (TP) (Custom Medical Devices, Inc.) has improved to the Immediate Release Patch (IRP) (Custom Medical Devices) and is a continuum of the detachable double balloon and transcatheter patch techniques reported in 2000.<sup>42,43</sup> Initially, this device required a double balloon and up to 48 hours for the patch to adhere to the septal wall, an obvious disadvantage of this technique.<sup>24</sup> The IRP uses a single latex

balloon, a safety bioabsorbable thread (Vicryl, Ethicon, a Johnson & Johnson company, Somerville, NJ) and polyurethane patch with surgical adhesive (polyethylene glycol-based adhesive). The addition of the adhesive makes the device release immediate, and attachment to the septum (mediated by fibrin formation) takes place in approximately 48 hours.<sup>44</sup>

### The PFO-Star Device

Cardia, Inc. (Eagan, MN) has developed several generations of devices for patent foramen ovale (PFO) and ASD closure. The PFO-Star began as a double-umbrella, four-arm frame made from two crossing wire struts of solid nitinol with titanium end caps and has progressed to the latest generation, the Ultrasept. The Ultrasept has incorporated all of the previous features of the previous generation devices and added enhanced safety and performance. The Ultrasept device may soon be available for human trial.<sup>45</sup> The initial clinical use of Cardia devices (PFO-Star) was reported by Braun et al in 2002.<sup>46</sup>

### The Occlutech Flex

The Occlutech Flex devices (Occlutech, Helsingborg, Sweden) were further developed from the initial Occlutech devices. These devices are self-expanding, double discs made of nitinol wire mesh. They are self-centering but without a left atrial hub.<sup>47</sup> The first reported clinical use was in 2008 by Halabi and Hijazi in the pediatric setting and by Krizanec et al and Krecki et al in the adult arena.<sup>48-50</sup>

### Premere PFO Closure System

The Premere PFO closure system (St. Jude Medical, Inc., St. Paul, MN) features a right-sided, cross-shaped nitinol anchor positioned between two thin membranes of knitted polyester and an uncovered cross-shaped, left-sided anchor designed specifically for PFO occlusion. The two anchors are connected by a braided flexible tether, allowing the anchors to move independent of each other and therefore easily conform to septal thickness and tunnel length without causing septal distortion. The device has undergone clinical trials.<sup>51</sup>

### The Solysafe Septal Occluder

The Solysafe Septal Occluder (Swissimplant AG, Solothurn, Switzerland) can be used to close ASDs or PFOs. It is a self-centering device with two foldable polyester patches attached to eight Phynox wires. The course of the wires through the patches enables the device to center itself in defects of varying diameters. The maximum diameter is given by the distance the wires are fixed to in the patches. The first clinical implant was reported in 2008.<sup>52</sup>

(Courtesy of NMT Medical, Inc.)



**Figure 3.** The BioTrek device has eight ribs and circular patches and is completely bioabsorbable.

## BioStar

Mullen et al reported the BioStar (NMT Medical) multicenter study in 2006. The BioStar replaced the StarFlex device, and the Dacron covering the nitinol frame has been replaced with a heparin-coated, acellular, porcine-derived intestinal collagen matrix that allows absorption and replacement with human tissue (95%) within 2 years. The nitinol frame remains in the interatrial septum.<sup>53</sup>

## pfm Closure Devices

The Nit-Occlud PFO pfm closure devices (pfm Medical AG, Cologne, Germany) were developed to occlude PFOs. They are made of nitinol mesh and in its final form have a double-disc configuration. The initial clinical application was in 2007 and is currently scheduled for phase II clinical trials in Argentina.<sup>54</sup>

## SeptRx Intrapocket PFO Occluder

The SeptRx Intrapocket PFO Occluder (SeptRx, Inc., Fremont, CA) was developed in the early 1990s as the first device to target only the PFO tunnel. It is composed of nitinol with tantalum markers and is implanted into the flap of the defect and stretches the defect in the anterior-posterior direction, leading to an opposition of the septa secundum and primum. The potential advantages are less distortion of the atrial septum and minimization of potential thromboembolic nidus in the left atrium. The first successful clinical implant was in 2006, and a clinical trial of 13 patients was reported by Majunke et al in 2008.<sup>55</sup>



(Courtesy of NMT Medical, Inc.)

**Figure 4.** The BioTrek 6 months after ovine implantation, left-sided view. Note encapsulation and partial membrane reabsorption at the device perimeter.

## Coherex FlatStent EF PFO Closure System

The Coherex FlatStent EF PFO closure system (Coherex Medical Inc., Salt Lake City, UT) is a nitinol lattice covered with polyurethane foam and radiopaque markers. It has a distal left atrial wing and a proximal right atrial wing. The center portion of the stent is implanted within the PFO tunnel. Clinical trials were initiated in 2007. Limited published data are available.<sup>56</sup>

## Radiofrequency Technology

In 2007, Sievert et al reported the initial clinical experience (Paradigm I Study) with the use of radiofrequency energy (PFX-15 closure system, Cierra, Inc., Redwood City, CA) to close PFOs in 30 patients who had experienced a cryptogenic stroke or transient ischemic attack. At initiation of the trial, there was no exclusion for ASD size; however, the study was later amended to PFOs with a maximum diameter of 10 mm. The closure rate after a single procedure was only 43% (13 of 30) and increased to only 63% when nine of the 14 unclosed ASD patients agreed to a second study. The remaining three patients had successful device closure.<sup>57</sup> Sievert et al later reported on a series of 144 patients and concluded that the closure rate was less than desired and further technique and device modification would be necessary to achieve a clinically desirable closure rate.<sup>58</sup>

## The BioTrek Device

The BioTrek device (Figures 3 and 4) (NMT Medical) evolved from the BioStar and is designed to be 100%

reabsorbable. The covering discs and support ribs are made of poly-4-hydroxybutyrate. Over time, the patches and the connecting hub disappear, leaving the fibrous septum. As of early 2010, the device was reportedly in preclinical testing.<sup>59</sup> Bailey, one of the early pioneers in surgical ASD closure, suggested the ideal procedure would be one that obliterated the defect without necessitating the introduction of a prosthetic device.<sup>7</sup> Perhaps, a bioabsorbable device might be a compromise?

## SUMMARY

In the realm of congenital heart defects, repair of the atrial septum is considered among those with the least risk. This is in no way to suggest that this is a minor procedure or to discount the incredible talents of the surgeons and cardiologists who perform these procedures. This is more to honor those who have ventured down a lonely path to begin and perfect procedures and devices to improve outcomes in the lives of individuals with congenital heart disease. During the past 70 years, tremendous advances have occurred in the scope of surgical and non-surgical closure of secundum ASDs and PFOs. The surgeons who initially demonstrated tremendous courage and stamina to close these defects, despite significant morbidity and mortality, forged a path for the surgeons today. Their efforts, although difficult, have ultimately led us to achieve surgical survival rates approaching 100%.

Transvenous device closure of these same defects has been undertaken for almost 4 decades and, in the last decade, has achieved overall results comparable to our surgical colleagues.<sup>60-62</sup> Since our initial efforts, many have undertaken the task to develop an optimal device for closure. All of these individuals are to be commended, for without their courage, we would not be able to move forward. However, the history of transvenous device closure of ASDs is not complete and in the years to come, more will be added to this discussion. Many others will work to develop the ultimate occluder system, and we encourage and salute your efforts. ■

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