Left Atrial Appendage Occlusion

The Current Device Landscape and Future Perspectives

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KEYWORDS

• Atrial fibrillation • Stroke prevention • Left atrial appendage occlusion • Stroke

KEY POINTS

- Left atrial appendage occlusion is a safe and effective therapy for stroke prevention in atrial fibrillation patients.
- Different devices have been used for left atrial appendage occlusion.
- Several devices for left atrial appendage occlusion are under development or in the initial clinical experience.

Since the earliest designs of left atrial appendage occlusion (LAAO) devices, technological evolution has undergone a continuous advance resulting in significant improvements in the currently available devices.

In this article, the latest design improvements and clinical data regarding the most widely used devices, the Amplatzer Amulet (Abbott Vascular, Abbott Park, IL, USA) and Watchman (Boston Scientific, Marlborough, MA, USA), are discussed. Recently introduced devices, such as the LAmbre (Lifetech Scientific Co, Ltd, Shenzhen, China) or the Ultraseal (Cardia, Eagan, MN), are also reviewed, and finally, the new prototypes in preclinical or in the initial clinical stage are summarized[1,2] (**Table 1**).

ENDOCARDIAL APPROACH

Amplatzer Cardiac Plug and Amplatzer Amulet

The Amplatzer devices (Amulet and Amplatzer Cardiac Plug) are self-expanding devices with a distal lobe and a proximal disc connected by an articulated waist. The devices are made of a nitinol mesh with 2 polyester patches sewn onto the 2 components. The devices are retrievable and repositionable, and they are implanted from the femoral vein using a transeptal approach.

The Amulet device is an evolution of the Amplatzer Cardiac Plug, and it was introduced in 2012 and obtained the CE mark in January 2013. Despite the similarity in design compared with the Amplatzer Cardiac Plug,[3–6] the Amulet had several novelties, including

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Table 1
Descriptive summary of the main devices of closure of left appendage

	Amplatzer Amulet	Watchman	LAmbre	Ultraseal	Coherex WaveCrest	Lariat
Design	Distal lobe and proximal disc	Parachute-shaped device	Umbrella and a cover connected with a short central waist	Proximal disc and a distal lobe	Umbrella shape and distal anchoring	Percutaneous epicardial LAA ligation guided by an endocardial magnet tipped wire placed in the LAA
Sizes lobe	8 sizes (16, 18, 20, 22, 25, 28, 31, and 34 mm)	5 sizes (21, 24, 27, 30, and 33 mm)	11 sizes (16, 18, 20, 22, 24, 26, 28, 30, 32, 34, and 36 mm)	9 sizes (16, 18, 20, 22, 24, 26, 28, 30, and 32 mm)	3 sizes (22, 27, and 32 mm)	Maximum target size: W 40 × H 20 × L 70 (Lariat+: W 45)
Sheaths	12–14F	14F	8–10F	10–12F	12F	12F Lariat suture delivery device
Device selection	3–6 mm longer than LAA neck diameter	10%–20% longer than LAA neck diameter	3–8 mm longer than the measured LAA orifice	Bulb diameter at least 25% to 33% greater than the largest diameter of the landing zone	The smaller device size is chosen so that the longest measured diameter does not exceed the nominal device size and the average of the longest and shortest diameters is at least 3 mm below the nominal device size	Not applicable

(*Courtesy of* Amulet image courtesy of Abbott Vascular, IL; Watchman image courtesy of Boston Scientific, Burlington, MA; LAmbre image courtesy Lifetech Scientific Co, Ltd, Shenzhen, China; Ultraseal image courtesy of Cardia, Eagan, MN; Coherex WaveCrest System image courtesy of Coherex Medical, Biosense Webster, Johnson & Johnson, Salt Lake City, UT; LARIAT device image courtesy of SentreHEART, Redwood City, CA; with permission.)

the following: (1) device preloaded system, (2) increased number of stabilizing wires (6–10 pairs), (3) inverted attaching end-screw on the disc, (4) larger available sizes (31 mm and 34 mm), (5) longer lobe length (7.5–10 mm), (6) longer connecting waist (5.5–8 mm), and (7) the proximal disc diameter, which is 6 or 7 mm larger than that of the lobe (compared with 4 or 6 mm with Amplatzer Cardiac Plug) depending on the size of the device (Fig. 1).

Amulet devices are usually implanted using the double curved TorqVue 45° x 45° sheath. Twelve-French sheaths are used for devices with sizes 16, 18, 20, 22, and 25 mm. Fourteen-French sheaths are selected for devices with sizes 28, 31, and 34 mm. Amulet sizing is based on the maximum left atrial appendage (LAA) landing zone (between 10 and 12 mm from the ostium), and this should be ≥11 mm and less than 31 mm.

Device deployment technique and signs of stability have been previously described[7,8] (Fig. 2).

Initially, most of the data for the Amplatzer Cardiac Plug device was derived from small registries maintained at centers outside the United States. However, a pooled analysis of 1047 procedures performed in 22 centers outside the United States[9] was published in 2016. The complication rate was 4.97%. Death, stroke, transient ischemic attack, cardiac tamponade, major bleeding, and device embolization were 0.76%, 0.86%, 0.38%, 1.24%, 1.24%, and 0.77%, respectively.

The results of the global, prospective Amplatzer Amulet observational study have been recently published.[10] This registry documents real-world periprocedural, transesophageal echocardiogram (TEE), and clinical outcomes using the Amplatzer Amulet device (n = 1088 patients). Successful device implantation was achieved in 99.0% of patients. During the procedure and index hospitalization, major adverse events occurred in 3.2% of patients, and TEE follow-up after the procedure showed adequate (<3-mm jet) occlusion of the appendage in 98.2% of patients.

The Amplatzer Amulet LAA Occluder trial (Amulet IDE) started enrolling patients in August 2016, randomizing patients in a 1:1 fashion to either the Amulet device or the Watchman device. The purpose is that the Amule device will be evaluated for safety and efficacy by demonstrating its performance is noninferior to Watchman in patients with nonvalvular atrial fibrillation in order to obtain US Food and Drug Administration (FDA) approval. The primary safety endpoint is a composite of procedure-related complications or all-cause death or major bleeding through 12 months, and the primary efficacy endpoint is a composite of ischemic stroke or systemic embolism through 18 months.

From the authors' experience, the Amulet device is versatile and a complete device that can fit in almost any LAA anatomy. It can cover from ≥11 mm to less than 31 mm (landing zone), and only 10- to 12-mm minimum depth is needed to deploy the device. It can be especially useful in chicken-wing anatomies and in the presence of thrombus.[8,11]

Watchman Left Atrial Appendage Device

The current Watchman LAA Closure Technology consists of a parachute-shaped device with a

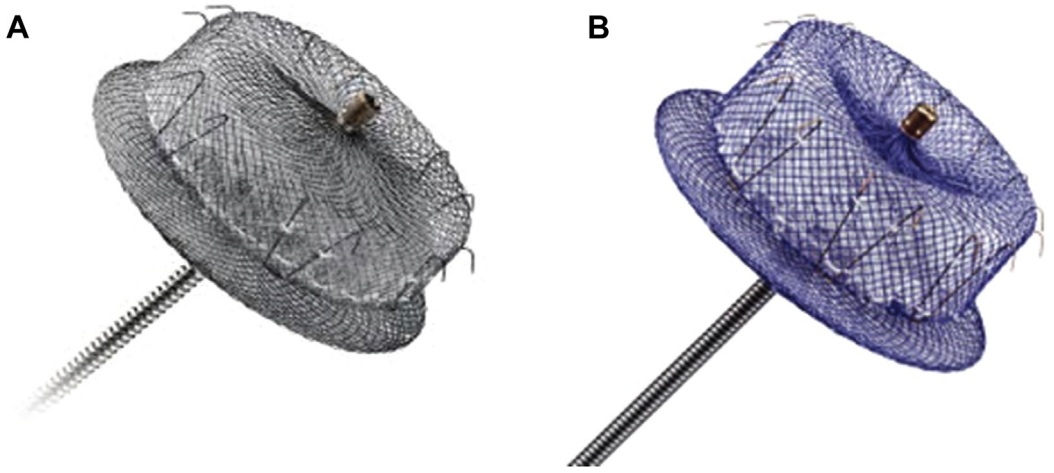

Fig. 1. (*A*) Amplatzer Cardiac Plug. (*B*) Amplatzer Amulet. (*Courtesy of* Abbott, Abbott Park, IL; with permission.)

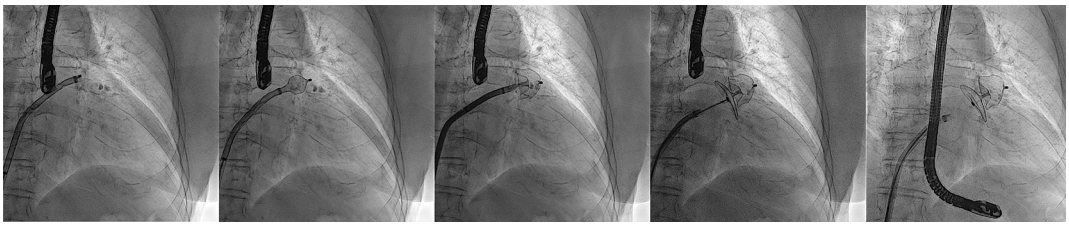

Fig. 2. Amulet device (Abbott Vascular) deployment (see text for a detailed explanation). (*Courtesy of* Abbott, Abbott Park, IL; with permission.)

self-expanding nitinol frame structure with a permeable polyester membrane (polyethylene terephthalate [PET]) over the left atrial surface. There are 10 active fixation anchors at the nitinol frame perimeter, designed to engage LAA tissue for device stability (Fig. 3A).

The device is available in 5 sizes (21, 24, 27, 30, and 33 mm) and is delivered through dedicated 14F sheaths with 12F inner diameter and 75-cm working length. Watchman sizing is based on the maximum LAA ostium diameter, which should be 17 to 31 mm to accommodate available devices. Oversizing is recommended by 9% to 25% based on the widest measurement (Fig. 4).

The Watchman FLX was the newest generation of Watchman device[12,13] introduced on November 2015 in Europe. The Watchman FLX device was similarly a self-expanding nitinol frame structure with fixation anchors and a PET fabric cover. It had several new features compared with the previous generation: (1) it was available in 5 sizes (20, 24, 27, 31, and 35 mm) for ostia measuring from 15 mm to 32 mm in width, (2) it had a reduced device length, (3) the proximal face was flat, (4) the nitinol 18-strut frame (compared with the 10-strut frame in the previous version) provided 80% more contact points at the LAA ostium, (5) atraumatic closed distal end had a fluoroscopic marker, (6) 12 "J"-shaped fixation anchors in 2 rows created a proximal and distal line to aid in device stabilization, (7) a greater range of compression was allowed, ranging from 10% to 27% (Fig. 3B).

However, at the end of March 2016, Boston Scientific decided to withdraw Watchman FLX devices because of a higher-than-anticipated device embolization rate.

From the authors' personal experience (not reported), the Watchman FLX was a very interesting device with a few new features that made its manipulation, deployment, and release easier than the old versions of Watchman. The high rate of embolization could be a combination of deployment technique and technical aspects of the device itself (distribution and angulation of anchors, range of compression permitted, and so on). A new version of the FLX is expected for 2018.

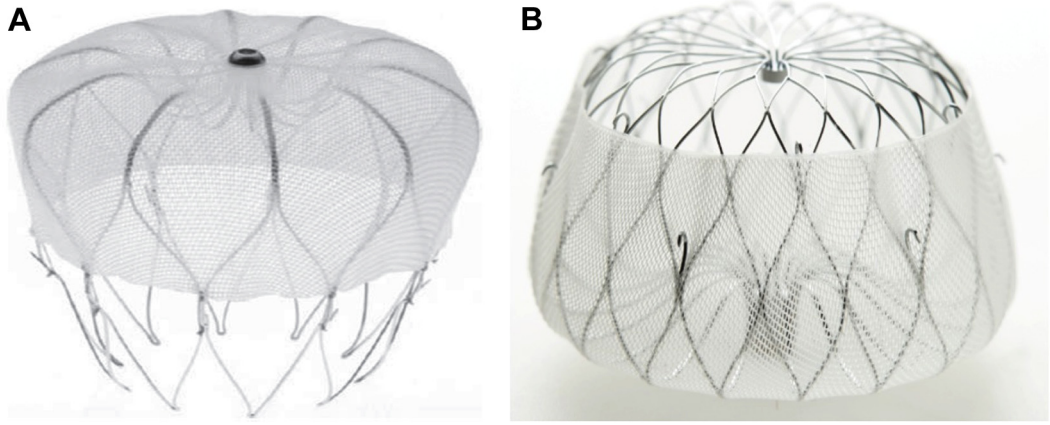

Fig. 3. (*A*) Watchman device. (*B*) Watchman FLX occluder. (Image provided *courtesy of* Boston Scientific. ©2018 Boston Scientific Corporation or its affiliates. All rights reserved.)

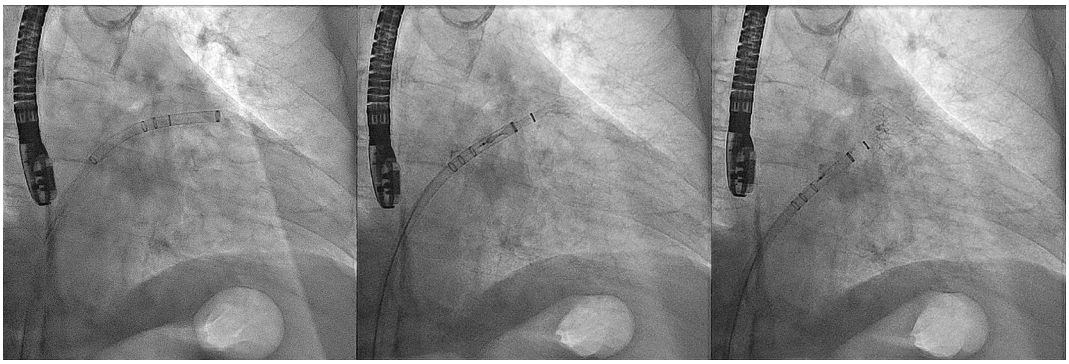

Fig. 4. Watchman device (Boston Scientific) implantation (see text for a detailed explanation). (Image provided *courtesy of* Boston Scientific. ©2018 Boston Scientific Corporation or its affiliates. All rights reserved.)

The Watchman device has been extensively studied, including the randomized, prospective, and multicenter PROTECT-AF (WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation) trial,[14–16] the PREVAIL (Prospective Randomized Evaluation of the WATCHMAN LAA Closure Device in Patients With Atrial Fibrillation vs Long-Term Warfarin Therapy),[17] and the recently published Registry on Watchman Outcomes in Real-Life Utilization (EWOLUTION).[18–20]

LAmbre

The LAmbre device (Lifetech Scientific Co, Ltd, Shenzhen, China) has recently obtained the CE mark on 15 June 2016. It is a nitinol-based, self-expanding device comprising a hook-embedded umbrella and a cover connected with a short central waist (Fig. 5). The waist acts as an articulating, compliant connection between the cover and the umbrella, allowing the cover to self-orient to the cardiac wall. The cover is 4 to 6 mm larger in diameter than the umbrella; however, there are devices available with a cover 12 to 14 mm larger than the umbrella (these devices could be useful for small LAA with wide orifices or for LAA with multiple shallow lobes). The proximal cover is filled with sewn-in PET. The distal umbrella comprises 8 claws with individual stabilizing hooks attaching. The umbrella was specially engineered to allow for complete collapse and repositioning. An additional PET membrane was introduced to the umbrella in the newer version of the implant to ensure LAA sealing (Fig. 6). Several sizes of the implants (16–36 mm) have been developed to accommodate the variation of LAA anatomy, and they are delivered by sheaths that ranged from 8 to 10 French in size.

The size of the implant should be 4 to 8 mm larger than the measured LAA orifice. The delivery sheath containing the implant is placed on the proximal part of the LAA. The umbrella is partially deployed by slowly pushing the device out from the delivery sheath. The whole system is then gently pushed forward to the desired landing zone to allow better flowering of the umbrella and grasping of LAA walls by the retention hooks. The sheath is then withdrawn to expose the disc, allowing it to expand in the left atrium and covering the LAA ostium by gently pushing the delivery cable forward.

Gentle tug test by applying tension to the delivery cable is performed to ensure device stability. The implant can be intentionally recaptured, completely retrieved, and redeployed. The first evidence of its efficacy and safety has been already published.[21–23] Larger trials are currently underway (eg, Study of Safety and Efficacy of a Left Atrial Appendage

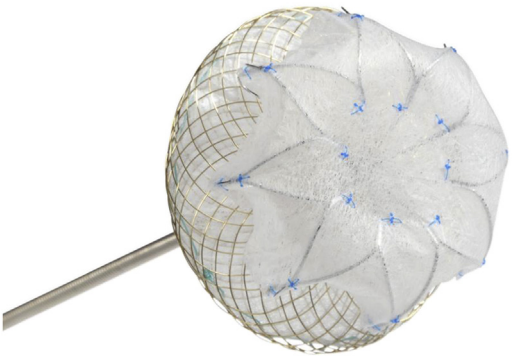

Fig. 5. LAmbre device (Lifetech Scientific Co, Ltd) consisting of a fabric-enriched cover and an umbrella connected by a short central waist. (*Courtesy of* Lifetech Scientific Co, Ltd, Shenzhen, China; with permission.)

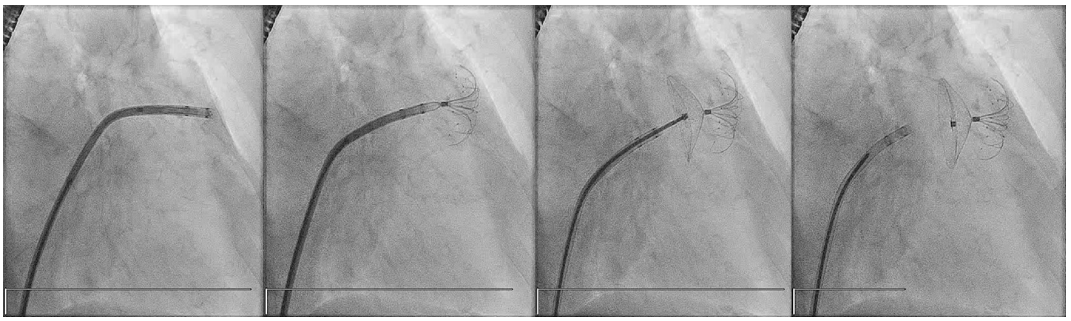

Fig. 6. LAmbre device (Lifetech Scientific Co, Ltd) implantation (see text for a detailed explanation). (*Courtesy of* Lifetech Scientific Co, Ltd, Shenzhen, China; with permission.)

Occluder; NCT02937025), and the launch of a 3-year global postmarket surveillance study has been recently announced. This registry plans to enroll more than 500 patients from about 30 clinical centers in Europe, Asia, and South America.

From the authors' limited personal experience,[22,23] this device is highly adaptable to different LAA morphologies, and it can be very useful in difficult anatomies. The combination of distal hooks and the U-shaped ends and the central waist design may help to achieve complete sealing and to prevent embolization in complex cases. Furthermore, the distal aspect of umbrella is covered by PET membrane, and this characteristic could make this device suitable for LAA occlusion with thrombus (the covered umbrella could potentially prevent thrombus migration).[24]

Ultraseal

The Ultraseal LAA closure device (Cardia, Eagan, MN, USA) obtained the CE mark in 2016; it is a self-expandable device composed of 3 parts (Fig. 7): (1) a distal bulb that anchors the device into the LAA, (2) a proximal sail that occludes the LAA, and (3) an articulating center post that connects those sections at the central portion of the device frame. The struts, which provide the structure of the device, are made of stranded nitinol. The distal bulb has 12 hooks that prevent dislodgment of the device from the appendage. The hooks are held by a radiopaque collar.

The device is available in 9 different bulb sizes ranging from 16 mm to 32 mm. The seal diameter is 6 mm larger than the distal bulb, and delivery sheath sizes range from 10F to 12F.

The landing zone for the anchoring hooks of the device should be measured at a depth of 10 to 12 mm from the intended seal location. The selected device should have a bulb diameter at least 25% to 33% greater than the largest diameter of the landing zone.

The steps for implanting the device are as follows: (1) the distal end of the sheath should be positioned in the LAA at the intended landing zone, (2) holding the sheath in place, the forceps are advanced until the entire bulb section of the device is deployed, (3) the sheath is retracted until the entire seal section of the device is deployed (Fig. 8).

Regueiro and colleagues[25] and Sabiniewicz and colleagues[26] published their experience in 2016 with the Ultraseal device in 12 patients and 6 patients, respectively. The device was successfully implanted in most patients without any major periprocedural complication.

Fig. 7. Ultraseal LAA device (Cardia) consists of proximal disc and a distal lobe connected by a double articulating center for optimal positioning and repositioning within the appendage. (*Courtesy of* Cardia, Eagan, MN; with permission.)

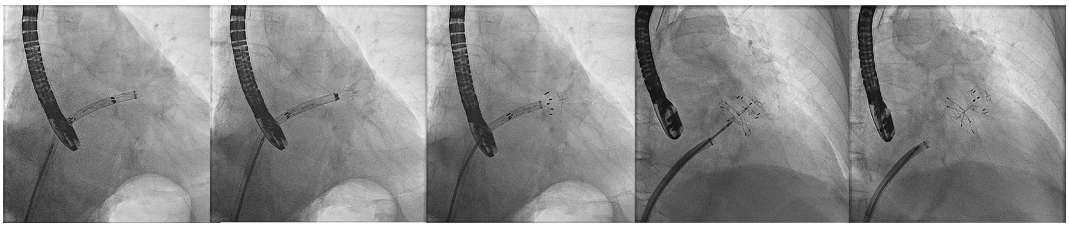

Fig. 8. Ultraseal (Cardia) implantation (see text for a detailed explanation). (*Courtesy of* Cardia, Eagan, MN; with permission.)

From the authors' limited personal experience, the articulating joint of this device allows a significant amount of movement in multiple directions in order to conform to the variations of LAA anatomy. It can be especially useful in LAA with a tight angle at the level of the landing zone or for chicken-wing anatomies.

The Coherex WaveCrest System

The Coherex WaveCrest (Coherex Medical, Biosense Webster, Johnson & Johnson, Salt Lake City, UT, USA) is a device with an umbrella shape. The device is anchored with 20 microtines distributed circumferentially at the distal device margin. The occluder material is expanded polytetrafluoroethylene (ePTFE). It is available in 3 sizes (22 mm, 27 mm, 32 mm). It is deployed similarly to other endovascular devices and has been tested in animals and humans with satisfactory and promising results. The delivery sheath is inserted just distal to the landing zone and rotated in alignment with the neck. Deployment is a 2-step procedure: unsheathing the foamed leading edge cover and then rolling out the distal anchors. At the end of each step, position and orientation of the device are confirmed on contrast angiography and TEE images.

The device was first implanted in June 2012. In 2015, the design was refined as follows (generation 1.3 device): (1) additional and optimized anchors were added, (2) increased ePTFE coverage, (3) redesigned threads and ergonomics improve closure and ease of use (Fig. 9).

The Coherex WAVECREST I Left Atrial Appendage Occlusion Study (NCT02239887) conducted in Europe, Australia, and New Zealand enrolled 73 patients with the current-generation device, and it was completed in 2015. Forty-five-day data showed primary

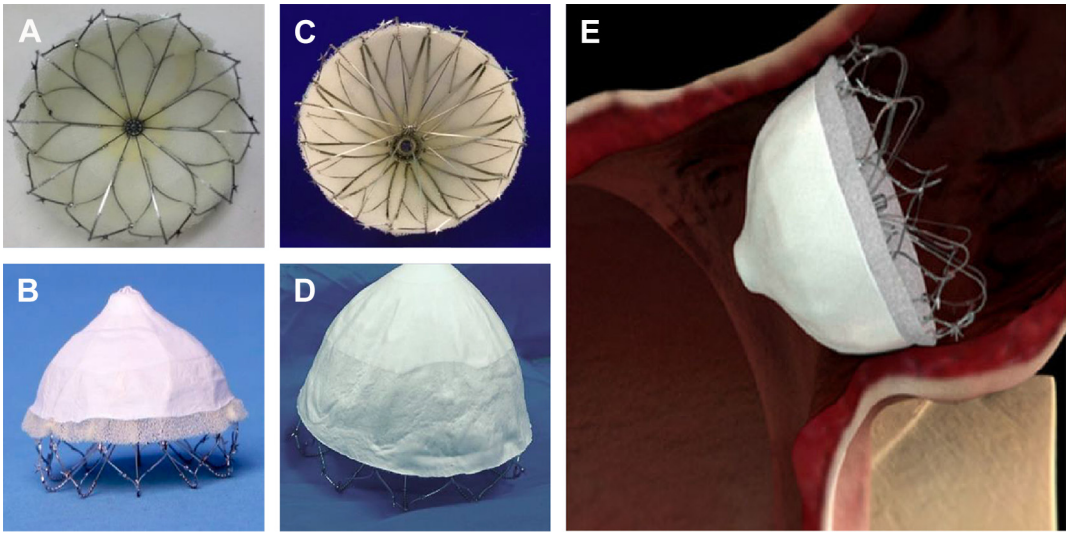

Fig. 9. The Coherex WaveCrest System. (*A*, *B*) First version device. (*C*, *D*) New design (2015 year) with additional anchors and more ePTFE covage. (*E*) Device deployment: sheath is placed in the LAA ostium and retracted to deploy the occluder. Anchors are then advanced to fix the occluder. (*Courtesy of* Coherex Medical, Salt Lake City, UT; with permission.)

efficacy of 92% and 97% with an intention-to-treat and as-treated protocol, respectively. There were no procedural strokes, device embolization, or device-associated thrombus, and only 2.7% had major adverse events (2 pericardial effusions requiring percutaneous drainage and 1 major bleeding event). As a result of this study, it obtained the CE mark.

Recently, the recruitment phase of the WAVECREST PMCF Study (NCT03204695) has started. It is a prospective, nonrandomized, multicenter study to confirm safety and performance of the Coherex WaveCrest in the current medical practice setting. The primary outcome measures are the incidence of all-cause deaths and device- and/or procedure-related events (45 days) and the secondary outcome measures: rate of successful device release within LAA, technical success at implant, and procedural.

OTHER ENDOCARDIAL DEVICES

There are more devices in development with limited clinical experience so far.

The LAA Occluder Occlutech (Occlutech International, Helsingborg, Sweden) consists of a self-expanding, flexible nitinol mesh. It has a tapered cylindrical shape that adapts to the shape of the LAA (Fig. 10). The proximal part has a larger diameter to seal the orifice. The loops at the distal rim aid in keeping the implanted device in position. The outer surface of the occluder is covered with a nonwoven, biostable poly(carbonate) urethane layer.

Fig. 10. Occlutech LAA (Occlutech International) occlusion device is a flexible nitinol-based, self-expanding device consisting of an outer surface covered with a nonwoven, biostable poly(carbonate) urethane layer. (*Courtesy of* Occlutech International, Helsingborg, Sweden; with permission.)

The size of the LAA closure device was chosen according to the LAA landing zone with a device size (diameter of distal part) about 3 to 5 mm oversized.

The distal end of the device has an inverted floor to reduce elongation during deployment and enhance anchoring stability.[27]

Occlutech won CE mark approval in the European Union for its LAA occluder device in June 2016. However, during both the LAA trial and commercial use, 4 dislocations were reported, so that the company has suspended for the moment shipping and selling of the occluder.

The Sideris Patch or The Transcatheter Patch (Custom Medical Devices, Athens, Greece) is a frameless, balloon-deliverable device used for the occlusion of heart defects. This device is bioabsorbable and can be adjusted for the shape and size of the LAA. The patches are tailored from polyurethane foam. The supporting balloon is made from latex and is inflated to diameters of 15 to 25 mm by diluted contrast. A 2-mm nylon loop is sutured at the bottom of the patch, to which a double nylon thread is connected for retrieval purposes. It is attached by a 2-stage polyethylene glycol surgical adhesive that is applied to the distal half of the device. Activation of the adhesive is achieved by direct injection of alkaline solution.

The device complex is advanced through the long sheath over the guidewire into the LAA. The balloon is inflated with dilute contrast until it stretches the LAA (3–10 mL of injectable volume corresponds to 14- to 25-mm patch diameter). Subsequently, alkaline solution is injected through the central lumen of the catheter. The balloon/patch position is confirmed by fluoroscopy and TEE. The supportive balloon catheter is removed 45 minutes after surgical adhesive activation according to the following procedure: the balloon is deflated, and the catheter assembly is retracted through the introducing sheath with the tip of the sheath held against the patch; the position and stability of the patch are confirmed by pulling lightly on the retrieval thread under echocardiography. If the result is satisfactory, the patch is released by removing the double nylon thread.

This device was studied in 20 patients showing successful placement in 17 cases.[28] There was 1 complication related to the procedure; namely, thrombus was released from the long sheath in the left atrium upon withdrawal and required treatment to be dissolved. No

recurrent strokes were reported. The Transcatheter Patch has CE mark approval for the use of occlusion of heart defects in general.

An improved version of the Sideris Patch is the Prolipsis device, tested in 10 patients with good acute outcomes (full occlusion, no embolization, no pericardial effusion, no thrombosis) and long-term follow-up (full occlusions, no new strokes or stroke-related deaths).

The LeFort device (Shape Memory Alloy Co, Shangai, China) is a new-design dedicated LAA device, consisting of a self-expanding nitinol frame covered with permeable PET membrane and 10 active fixation anchors. LeFort LAA occlusion plug was designed as an umbrella-shaped device with a size of 21 mm to 33 mm consisting of nickel titanium alloy metal stent outside and the flow-barrier inside. The metal stent was covered by a polyester synthetic fiber membrane on the upper part and a protruding barbule on the lower part.[29]

SeaLA LAA Occluder (Hangzhou Nuomao Medtech Co, Zhejiang, China) is a new occluder device designed as an umbrella shaped device. It consists of one seal disc and one anchor disc and a flexible connection between them. It has a nitinol braiding mesh for the whole device that helps to adapt different LAA anatomic structures. The seal disc consists of one plate and one waist, and 3 PET membranes are sutured inside. There are 9 hooks around the outer surface of the anchor disc. The device is delivered through an 8F to 10F sheath. Preclinical studies have revealed the SeaLA LAA Occluders' safety and feasibility in canines. The China FDA and CE Clinical Studying will be used to further evaluate its safety and feasibility.

Numerous next-generation LAA closure technologies are in various stages of development and clinical testing as is PFM device (PFM Medical, Köln, Germany).

EPICARDIAL APPROACH

Epicardial approaches offer advantages of avoiding the need for transeptal puncture, risk of acute procedure-related thromboembolism, and device embolism.[30]

Sierra Ligation System or AEGIS system (Aegis Medical, Vancouver, British Columbia, Canada) permits LAA closure via epicardial approach and has 3 major components: a deflectable sheath, a deflectable grabber, and the hollow suture stiffened with a preloaded 0.25-mm wire (Fig. 11). This device introduces an appendage grabber, via percutaneous subxiphoid pericardial access, with embedded electrodes within the jaws permitting electrical navigation onto the appendage via bipolar electrograms that identify the electrical activity of the tissue captured by the jaws. A hollow suture preloaded with a support wire to permit remote suture loop manipulation and fluoroscopic visualization is advanced to the appendage base and looped around the appendage. The loop can be variably sized to accommodate multiple LAA lobes and shapes. Following loop closure, the wire is removed leaving only suture behind, which is remotely locked with a clip to maintain closure.[31] A small series has demonstrated feasibility in humans.[32]

Recently, Aegis Medical Innovations Inc has received Investigational Testing Authorization approval from Health Canada to initiate a clinical trial called LASSO-AF in Canada for this device.

The AtriClip LAA Occlusion System (AtriCure, Mason, OH, USA) is a clip made of 2 parallel rigid titanium tubes with elastic nitinol springs covered with a knit-braided polyester sheath (Fig. 12) and is placed epicardially at the base of the appendage. For human use, the clip is available in 4 sizes (35 mm, 40 mm, 45 mm, and 50 mm). When closed, the clip applies uniform pressure over the length of the 2 parallel branches to ensure occlusion of the LAA.

There are several published series of its use in humans,[33,34] the largest included 71 patients undergoing open cardiac surgery at 7 US centers. The left atrial appendage in 1 patient was too small and did not meet eligibility criteria; the remaining 70 patients had successful placement of the device. Intraprocedural successful left atrial appendage exclusion was confirmed in 67 of 70 patients (95.7%). Although significant adverse events occurred in 34 of 70 patients (48.6%), there were no adverse events related to the device and no perioperative mortality. At 3-month follow-up, 1 patient died and 65 of 70 patients (92.9%) were available for assessment. Of the patients who underwent imaging, 60 of 61 patients (98.4%) had successful LAA exclusion by computed tomography angiography or TEE imaging.[35] The Atriclip is the only FDA-approved surgical device for LAAO.

HYBRID APPROACH

The *LARIAT system* (SentreHEART, Redwood City, CA, USA) uses percutaneous epicardial LAA ligation guided by an endocardial magnet-

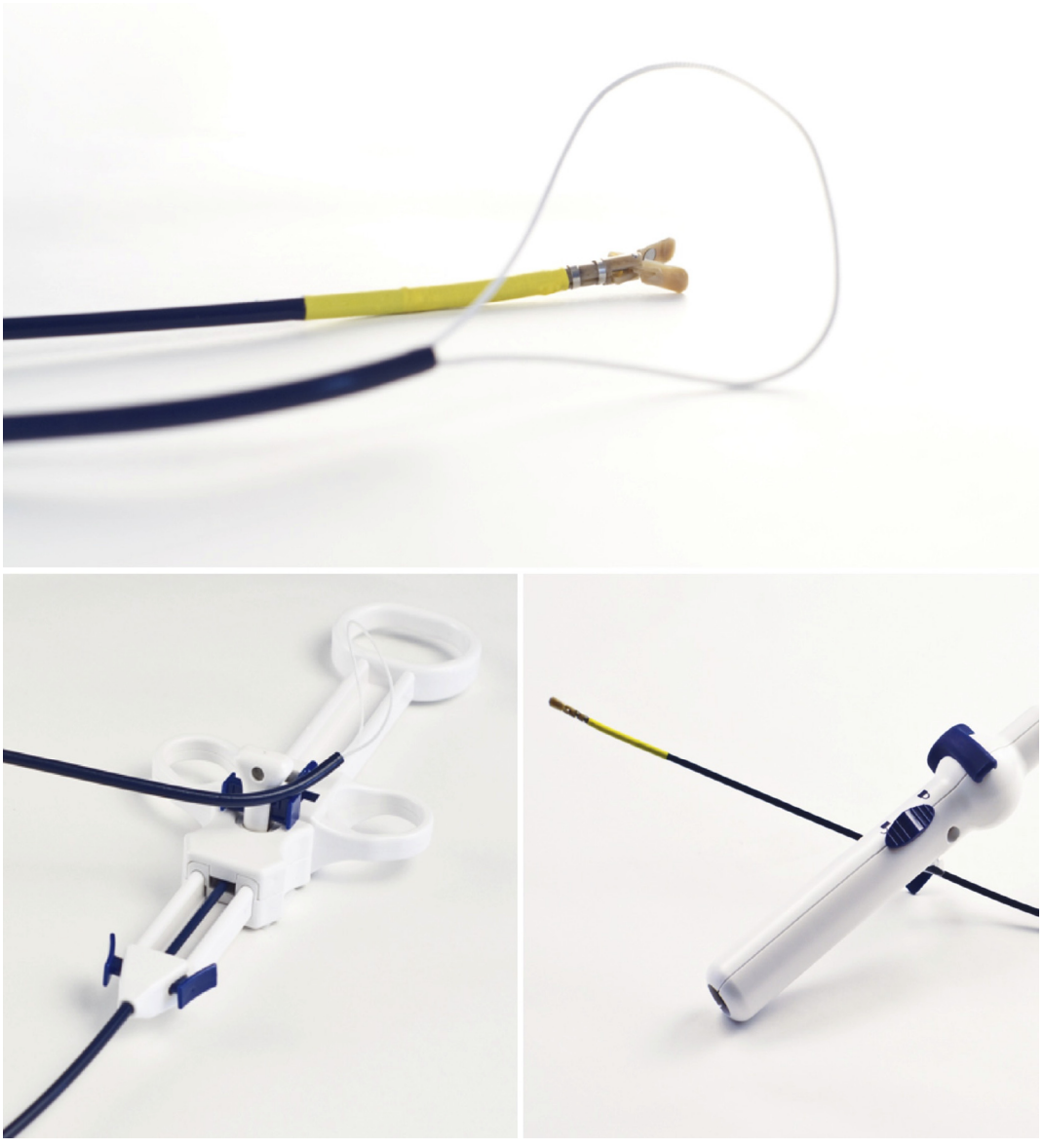

Fig. 11. Sierra ligation system. (*Courtesy of* Aegis Medical, Vancouver, British Columbia, Canada; with permission.)

tipped wire placed in the LAA via the transseptal approach, with a second magnet-tipped wire placed epicardially in union to form a rail over which an epicardial suture loop is advanced and then closed. An endocardial balloon at the LAA ostium defines where the epicardial suture needs to be placed (Fig. 13).

After initial human reports,[36] the experience in a series of 89 patients has been reported with successful closure in 85 patients (96%). A subsequent report of 27 patients with AF and high stroke risk unable to take anticoagulants, acute success was seen in 25 patients with TEE-confirmed persistent closure at 4 months

Fig. 12. The AtriClip device. (*Courtesy of* AtriCure, Mason, OH; with permission.).

Fig. 13. LARIAT device. (*Courtesy of* SentreHEART, Redwood City, CA; with permission.)

in 22 patients.[37] Complications included LAA perforation (n = 1), pericarditis (n = 3), transseptal sheath thrombus causing stroke (n = 1), and late cerebrovascular accident (n = 1). The LARIAT has CE mark approval for commercial use. The LARIAT system device is approved by the FDA for soft tissue closure (approximation) only, but not specifically for prevention of thromboembolism with LAA occlusion. In July 2015, the FDA issued a safety communication stating that cases of death and complications such as perforation of the heart or complete LAA detachment from the heart associated with the use of LARIAT had been reported. These real-world data raised concerns about the procedural safety of this device.

The next-generation Lariat for LAA ligation (The LARIAT+) has already implanted in 58 patients and published the experience recently, with acceptably low periprocedural adverse events.[38] The new design has improved features consisting of the following: (1) expansion of the snare from 40 mm to 45 mm, (2) addition of a platinum-iridium "L" Marker that allows one for easier identification of the correct orientation of the LARIAT + snare loop under fluoroscopy, (3) a stainless steel wire braid on catheter shaft that provides improved "torque-ability" of the catheter with 1:1 torque control for ease of positioning during LAA capture.

FUTURE PERSPECTIVE

Percutaneous LAA occlusion devices represent a safe and effective therapeutic option to reduce the stroke burden in patients with nonvalvular AF.

The current results of LAAO show a high success rate with a low rate of complications. The newer generations of the most used devices and the new devices currently under development seek to be able to adapt to any type of atrial left appendage morphology (eg, small appendages, tight angle at the level of the landing zone, or complex morphologic variants), with high success rates of implantation and a decrease in the rate of major complications during the procedure and in the long-term follow-up, as well as offer a complete coverage of the LAA that translates into a low clinical event. The new materials used for the sealing should allow a rapid endothelialization of the device that translates into a low thrombogenesis on its surface. Clinical studies are needed not only to compare their efficacy against the new oral anticoagulants but also to compare the superiority of one over the other and not to attribute a class effect of closure superiority (percutaneous, surgical, or hybrid) on anticoagulant treatment in the prevention of ischemic stroke.

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