Carola Gianni ORCID iD: 0000-0002-8174-7207

Closure of the left atrial appendage using percutaneous transcatheter occlusion devices

Carola Gianni[1] MD, Alisara Anannab[1,2] MD, Anu Sahore Salwan[1] MD, Domenico G Della Rocca[1] MD, Andrea Natale[1,3-5] MD, Rodney P Horton[1,6] MD

1. Texas Cardiac Arrhythmia Institute, St. David's Medical Center, Austin, TX, USA
2. Electrophysiology Unit, Department of Cardiovascular Interventions, Central Chest Institute of Thailand, Nonthaburi, Thailand
3. HCA National Medical Director of Cardiac Electrophysiology, USA
4. Interventional Electrophysiology, Scripps Clinic, La Jolla, CA, USA
5. MetroHealth Medical Center, Case Western Reserve University School of Medicine, Cleveland, OH, USA
6. Department of Biomedical Engineering, University of Texas, Austin, TX, USA

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Corresponding Author

Carola Gianni

Texas Cardiac Arrhythmia Institute, St. David's Medical Center

3000 N. IH-35, Suite 720; Austin, TX 78705

E-mail: carola.gianni@gmail.com

Abstract

Closure of the left atrial appendage using percutaneous transcatheter occlusion devices is used for stroke prevention as an alternative for patients with a high risk and contraindications for long-term oral anticoagulation use. In this chapter, we will discuss the practical aspects of four among the available devices that provide percutaneous intravascular closure of the left atrial appendage: Watchman, Amulet, WaveCrest, and LAmbre.

The most worrisome and ominous consequence of atrial fibrillation (AF) remains thromboembolism, most importantly stroke.[1] The left atrial appendage (LAA) remains a focus of thrombus formation in patients with non-valvular AF.[2] Case reports from the 1950s have described surgical amputation of the LAA during open chest procedures for the explicit purpose of reducing stroke risk in AF patients.[3,4] While this approach was initially sporadic, surgical closure of the LAA has become widely accepted and is now included in the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines for

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management of patients with valvular heart disease undergoing heart surgery.[5] Moreover, ACC/AHA/Heart Rhythm Society (HRS) guidelines for cardiac surgery patients with a history of AF include surgical LAA closure whenever possible.[6] Historically, stroke prevention has been focused on systemic pharmacologic anti-thrombotic strategies. Aspirin, clopidogrel, warfarin and various combinations of these agents have been studied. Up until 2005, the oral anticoagulation (OAC) drug warfarin became the agent of choice for reducing stroke risk in patients with higher risk factors based on various risk scores ($CHADS_2$, CHA_2DS_2-VASc), while aspirin was the recommended agent for the lowest risk patients. Since 2005, newer anti-thrombotic agents (novel oral anticoagulants – NOACs) became available in the form of direct thrombin inhibitors (dabigatran) or factor Xa inhibitors (apixaban, edoxaban, rivaroxaban).[7–10] From an efficacy standpoint, warfarin's primary weakness has been difficulty in maintaining the drug in a therapeutic range. From a patient satisfaction standpoint, the need for regular blood tests to establish efficacy and the drug's impact on diet and other prescribed medications remain common complaints. Because the serum concentration of NAOCs is primarily impacted by renal clearance, the dosing is more predictable thereby avoiding blood testing of efficacy. However, the cost remains a barrier to some patients and they share with warfarin the same issues of major bleeding and non-compliance. Therefore, non-pharmacologic options have remained attractive alternatives for patients with a high stroke risk and contraindications for long-term OAC use. Among these, LAA occlusion using percutaneous implanted devices should be considered in this cohort, as recommended by the current AHA/ACC/HRS and European Heart Rhythm Association (EHRA)/European Association of Percutaneous Cardiovascular Interventions (EAPCI) guidelines.[11,12] These recommendations derive from numerous prospective observational registries that have shown the feasibility and relative safety of this approach utilizing different devices, as well as two randomized controlled trials that have shown non-inferiority of LAA occlusion with Watchman when compared to chronic warfarin in terms of stroke, systemic embolism, or death (cardiovascular/unexplained).[13,14]

In this chapter, we will discuss the practical aspects of four among the available devices that provide percutaneous, intravascular closure of the LAA (Table 1; Figure 1): Watchman, Amulet, WaveCrest, and LAmbre. Their main clinical studies are summarized in Table 2, with a focus on peri-procedural complications and feasibility of complete LAA occlusion.

Watchman

The Watchman LAA occlusion device is a single lobe device that consists of a self-expanding nitinol 10-strut metal frame covered by a porous (160 μm) polyethylene terephthalate (PET) knit fabric (Figure 1). The PET membrane covers the proximal surface; the portion which remains in contact with the blood of the left atrial (LA) cavity and promotes healing and endothelialization. Opposite to that, across the nitinol frame perimeter, 10 fixation hooks are present to anchor to the LAA and ensure stability, which is also aided by the moderate radial force exerted by the self-expanding frame. The device is packaged in a pre-loaded delivery sheath and is placed in the LAA by means of a 14-F access sheath. The access sheaths are provided in 3 shapes: single curve, double curve and anterior curve. Selection of the access sheath is usually physician reference, although the double-curve and the anterior curve were created to assist in Watchman placement in an LAA with a more superior direction (toward the aortic root). The device is manufactured in 5 sizes (21, 24, 27, 30, and 33 mm) to accommodate most LAA dimensions. It should be mentioned that the larger devices are also longer: as a result, a LAA with a wider ostial diameter would also need a longer body length to provide adequate sheath position prior to device deployment.

Watchman has a new generation, FLX (Figure 1), which is approved in Europe and undergoing approval in the US. Compared to the previous generation, Watchman FLX comes in different sizes (20, 24, 27, 31, and 35 mm), thus is capable to cover smaller and bigger LAA ostia. Another difference is the distal end, which is closed, reducing the risk of trauma within the LAA; in addition, with this design, the device

length is also reduced, making it easier to implant in shallower LAAs. The nitinol frame is composed of 18 struts, with 12 anchors across two lines (vs a 10-struts frame with 10 anchors in a single), improving radial strength and device stability. Finally, the proximal face is flat, with a recessed, tethered insert to reduce the risk of device-related thrombosis.

Procedure

Pre-procedural imaging, by means of transesophageal echocardiography (TEE) or computed tomography (CT) is essential to exclude LAA thrombus and assess LAA anatomy for suitability for LAA closure and to determine appropriate sizing of the device. With TEE, the 4 commonly used views are 0°, 45°, 90° and 135°. In alternative, CT can be employed: its superior spatial resolution allows for 3D reconstructions, and LAA thrombi can be safely ruled out with delayed acquisition imaging.

For Watchman, it is important to obtain two LAA dimensions (Figure 2):

- LAA landing zone width, measured from the circumflex artery to the transition between the smooth LA and the trabeculated LAA (usually 1 to 2 cm distal to the limbus of the LAA-left superior pulmonary vein ridge): between 17 and 31 mm (15 to 32 mm with Watchman FLX)
- LAA depth, measured from the device landing zone line to apex of the LAA: equal or greater than the landing zone width (at least ½ of the device size with Watchman FLX)

Oversizing is recommended by 10 to 20% to ensure stable device positioning. Of note, excessive oversizing may result in compression of the circumflex artery and should be avoided. Oversizing of Watchman FLX might also result in device embolization: with the closed distal end, oversizing leads to reduced anchor/frame-tissue contact, thus affecting the device stability.

The procedure is usually under general anesthesia and guided by fluoroscopy and TEE or intracardiac echocardiography (ICE). Heparin should be administered before transseptal access, to achieve an ACT > 250 sec at the time of LA instrumentation. The transseptal puncture should be low, usually anterior (the LAA should be seen on ICE), to facilitate engagement of the LAA (Figure 3). The latter should be done using the pigtail catheter and contrast, to reduce the risk of LAA trauma and laceration. LAA angiography is then performed to confirm the LAA size, usually using a RAO caudal projection, roughly corresponding to a 135° TEE view. Additional views might be needed for proper sizing and safe sheath positioning (i.e. AP cranial, RAO cranial, and RAO corresponding to a 0°, 45°, and 90° TEE view, respectively). The access sheath is advanced over the pigtail catheter aligning the appropriate radiopaque marker band (according to the device size) at the ostium of the LAA. Device deployment is performed in breath-hold (Figure 4): the device (within its delivery sheath) is advanced until the fluoroscopic marker of the delivery system is aligned to the distal marker of the access sheath; at this point, the access and delivery sheath are slowly withdrawn while maintaining the device in place until it is fully deployed. Before device release, TEE/fluoroscopy are used to confirm:

- proper positioning: the maximum device diameter should be at or just distal to the LAA ostium, not protruding too far into the LA
- stability: assessed with a tug test, i.e. gentle traction until tactile feedback (sensation of heartbeat) and mild device deformity are demonstrated
- correct size (TEE): the device widest diameter should be compressed 10 to 20% of its original size
- proper occlusion: all LAA lobes should be distal to the proximal face of the device, with no peri-device flow seen on contrast injection/color Doppler

If device deployment is too distal, it may be partially recaptured to be repositioned, by maintaining the device in position while advancing the sheath over the device up to (but not beyond) the level of the

fixation hooks. If the device is too proximal, or sizing/position are suboptimal, it is necessary to fully recapture the device (advance the sheath beyond the fixation hooks) and start over with a new device. With Watchman FLX it is possible to correct a proximal deployment by either partial recapture and advance (with the device shaped into an atraumatic ball) or fully recapture and sheath repositioning. Once LAA occlusion is satisfactory, the device can be released by unscrewing the connector wire.

Amulet

The Amulet LAA occlusion device consists of a self-expanding nitinol metal mesh conformed into a distal lobe and a proximal disc connected by a short, central waist (Figure 1). The distal lobe sits within the body of the LAA while the proximal disc covers the LAA ostium from within the LA, thus providing a double sealing system. To reduce device-related thrombosis, both disc and lobe are covered by a sew-in polyester patch membrane, and the proximal end screw is recessed and tethered. The distal lobe has 6 to 10 pairs of stabilizing wires/hooks across its diameter designed anchor to device the LAA and ensure its stability, which is also aided by its mild radial force and proximal disc traction. The device is packaged in a pre-loaded delivery sheath and is placed in the LAA by means of a 12-F to 14-F double-curved access sheath. The device is manufactured in 8 sizes (according to the lobe diameter: 16, 18, 20, 22, 25, 28, 31, and 34 mm). The disc diameter is 6 to 7 mm greater than the distal lobe, with a lobe and waist length of 7.5 to 10 mm and 5.5 to 8 mm, respectively. Thus, the length of the device is shorter than its diameter, accommodating shallower LAAs.

Procedure

Pre-procedural imaging with TEE or CT is essential to exclude LAA thrombus and assess LAA anatomy. Amulet device sizing is based on (Figure 2):

- LAA landing zone width, measured around 1.5 cm distal to the ostial plane: between 11 and 31 mm
- LAA depth, measured from the ostial plane to the back of the LAA, following the axis of the neck: greater than 12 to 15 mm (according to the device size)

An oversizing of 2 to 4 mm is usually recommended for improved device stability. As with Watchman, excessive oversizing should be avoided, as it may result in compression of the circumflex artery and device embolization.

The procedure is usually under general anesthesia and guided by fluoroscopy and TEE or ICE and adequate intraprocedural anticoagulation (heparin administered early on, to achieve an ACT > 250 sec at the time of LA access). The transseptal puncture should be low, usually anterior (Figure 3). After engaging the LAA with a pigtail catheter and confirming the LAA size with angiography, the access sheath is advanced over the pigtail catheter until its tip lies at the level of landing zone. This is best done using a RAO caudal projection, but different views might be used according to the specific anatomy. Device deployment is performed in breath-hold (Figure 5): the device is unsheathed by withdrawing the access sheath until its distal portion forms a ball; the system can be carefully advanced or withdrawn within the LAA to achieve optimal positioning (within the landing zone); at this point, the delivery cable is advanced while further withdrawing the access sheath to uncover the device disc ("push and pull"). Before release, it's important to confirm the following with TEE/fluoroscopy:

- proper positioning: the lobe should be perpendicular to the LAA neck (coaxial to the LAA axis), lying beside the circumflex artery (two thirds of its length distal to it)
- stability: assessed with a tug test (see above)
- correct size: the device widest diameter on TEE should be compressed 2 to 4 mm of its original

size; the lobe should look tire-shaped on fluoroscopy

- proper occlusion: the disc should be adequately separated from the lobe with a concave shape, with no peri-device flow seen on contrast injection/color Doppler

If the device positioning is unsatisfactory, the disc and lobe can be sheathed back into the "ball" configuration, paying attention not to cover the 2 radiopaque markers on the device (location of the stabilizing wires/hooks) do not enter the radiopaque marker band on the sheath. If the size is inadequate or the markers enter beyond the radiopaque marker band, the device must be entirely removed, and the sheath replaced. Once LAA occlusion is satisfactory, the device can be released by unscrewing the connector wire.

WaveCrest

The WaveCrest LAA occlusion device is a single lobe device that consists of a self-expanding nitinol frame covered by a polytetrafluoroethylene (ePTFE; also known as Gore-Tex) knit fabric (Figure 1). The ePTFE membrane covers the proximal surface, including the proximal screw end, to prevent thrombosis on the portion of the device in contact with the systemic circulation. A rim of polyurethane is located at the end of the membrane, where the device is in contact with the myocardium, to promote endothelialization. At the distal end, the frame perimeter is provided with 20 fixation hooks to anchor the device to the LAA and ensure its stability (as opposed to the other devices, WaveCrest has no radial force to aid with stability). Unique to the WaveCrest, the hooks are retractable, which separates positioning of the device from its anchoring. The device is packaged in a pre-loaded delivery sheath and is placed in the LAA by means of a 12-F access sheath. The access sheaths are provided in 4 shapes, which differs in the angle of the curve and orientation of the distal curve: single curve (60°, 75°, and 90°), and anterior curve (90°).To confirm good sealing, contrast can be injected through both sheaths: injection through the delivery sheath, distal to the device, is unique to WaveCrest and allows for leak detection by means of contrast extravasation. The device is manufactured in 3 sizes (22, 27, and 32 mm), which accommodate most LAA dimensions. The length of the device is < 10 mm, which makes it attractive for the smallest LAA anatomies. As with Watchman, selection of the access sheath is usually physician reference, although the anterior curve is preferable for LAAs with a more superior direction (toward the aortic root).

Procedure

Pre-procedural imaging with TEE or CT is performed to exclude LAA thrombus and assess LAA anatomy. WaveCrest device sizing is based on (Figure 2):

- LAA landing zone width, measured from the circumflex artery to the transition between the smooth LA and the trabeculated LAA (usually 1 to 2 cm distal to the limbus of the LAA-left superior pulmonary vein ridge; same as Watchman): between 15 and 29 mm

- LAA depth plays a minor role as the level of the landing zone marks the distal device margin (i.e. should be > 10 mm)

An oversizing of 3 to 8 mm is usually recommended for improved device stability. As with other LAA occlusion devices, excessive oversizing should be avoided as it may result in device embolization.

The procedure is usually under general anesthesia and guided by fluoroscopy and TEE or ICE. As stated above, heparin should be administered early on, to achieve an ACT > 250 sec at the time of LA access. The transseptal puncture should be low, usually anterior. After engaging the LAA and confirming the

LAA size with angiography (see above), the access sheath is carefully advanced over a pigtail catheter until the appropriate radiopaque marker band (according to the device size) lies at the level of landing zone. This is best done using a RAO caudal projection, but different views might be used according to the specific anatomy. Device deployment is performed in breath-hold (Figure 6): the device is fully unsheathed by withdrawing the access sheath; the system can be carefully manipulated within the LAA to achieve optimal positioning (within the landing zone); at this point, the anchoring hooks are deployed for fixation. A radiopaque marker is visible at the level of the hooks and facilitates fluoroscopic assessment of their position. Before release, fluoroscopy/TEE are used to confirm:

- proper positioning: the lobe should lie within the proximal LAA
- stability: assessed with a tug test (see above)
- correct size (TEE): the device widest diameter should be compressed 3 to 8 mm of its original size
- proper occlusion: no peri-device flow seen on proximal contrast injection/color Doppler, with no contrast extravasation with distal contrast injection

If the device positioning is unsatisfactory, the hooks can be retracted, and the device fully recaptured to be repositioned in a better location. Once LAA occlusion is satisfactory, the device can be released by unscrewing the connector wire.

LAmbre

The LAmbre is a nitinol LAA occlusion device conformed into a distal lobe and a proximal disc, both covered by a PET membrane, and connected by a short, central waist, thus providing a double sealing system (Figure 1). The proximal disc is a nitinol mesh with a recessed proximal end screw to minimize the risk of device-related thrombosis, while the distal lobe is composed of a nitinol frame with two rows of 8 perimetral anchors to ensure its stability, which is aided by the mild radial force exerted by the frame. Unique to LAmbre, the articulated connecting waist which allows the disc and lobe to lie at different angles without affecting the device stability. The device is packaged in a pre-loaded delivery sheath and is placed in the LAA by means of an 8- to 10-F access sheath. There are 2 different type of manufactured LAmbre devices designed to accommodate single- and double-lobe anatomies. Each type comes in different sizes: 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, and 36 mm for the single-lobe design, and 16, 18, 20, 22, 24, and 26 for the double-lobe design. The disc diameter is 4 to 6 mm greater than the distal lobe in the single-lobe design, and 12 to 14 mm greater in the double-lobe design. As with WaveCrest, the length of the device is < 10 mm, accommodating shallower LAAs. The access sheaths are provided in 2 shapes: single curve and double curve, chosen according to the operator preference.

Procedure

Pre-procedural imaging with TEE or CT is performed to exclude LAA thrombus and assess LAA anatomy. LAmbre device sizing varies according to the design. On single-lobe design devices, sizing is based on (Figure 2):

- LAA landing zone width, measured from the circumflex artery to the transition between the smooth LA and the trabeculated LAA (usually 1 to 2 cm distal to the limbus of the LAA-left superior pulmonary vein ridge; same as Watchman and WaveCrest): between 11 and 28 mm
- LAA depth plays a minor role as the level of the landing zone marks the distal device margin (i.e. should be > 10 mm)

On dual-lobe design devices, sizing is based on:

- LAA lobe landing zone width, measured around 1 cm distal to LAA bifurcation: between 11 and 20 mm
- LAA bifurcation depth, measured from the LAA ostial plane to the LAA lobe opening plane: less than 10 mm
- LAA lobe depth plays a minor role as the level of the landing zone marks the distal device margin (i.e. should be > 10 mm)

An oversizing of 3 to 8 mm is usually recommended for improved device stability. As with other LAA occlusion devices, excessive oversizing should be avoided as it may result in device embolization.

The procedure is usually under general anesthesia and guided by fluoroscopy and TEE or ICE. As with other devices, heparin should be administered to achieve an ACT > 250 sec at the time of LA access. The transseptal puncture should be low, usually anterior (Figure 3). After engaging the LAA and confirming the LAA size with angiography (see above), the access sheath is carefully advanced over a pigtail catheter until distal tip lies at proximal end of the LAA. This is best done using a RAO caudal projection, but different views might be used according to the specific anatomy. Device deployment is performed in breath-hold: the distal lobe is unsheathed by pushing it forward to the landing zone, where the anchoring hooks can grasp the LAA, stabilizing the device; at this point, the delivery sheath is slowly withdrawn to expose the disc, which covers the LAA. Before release, fluoroscopy/TEE are used to confirm:

- proper positioning: the lobe should lie within the proximal LAA/proximal aspect of the chosen lobe
- stability: assessed with a tug test (see above)
- correct size (TEE): the device widest diameter should be compressed 3 to 8 mm of its original size
- proper occlusion: the disc should be adequately separated from the lobe with a concave shape, with no peri-device flow seen on contrast injection/color Doppler

If the device positioning is unsatisfactory, the device can be fully recaptured and repositioned in a better location. Once LAA occlusion is satisfactory, the device can be released by unscrewing the connector wire.

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Figures

Figure 1. Principal devices for left atrial appendage closure

Figure 2.Device sizing on transesophageal echocardiography

Examples of different LAA measurements on a 90° TEE view. Solid and dashed lines represent LAA landing zone and depth, respectively; grey solid line represents the anatomical ostium while the red dashed circle is the left circumflex coronary artery. For a detailed description for each device, see text.

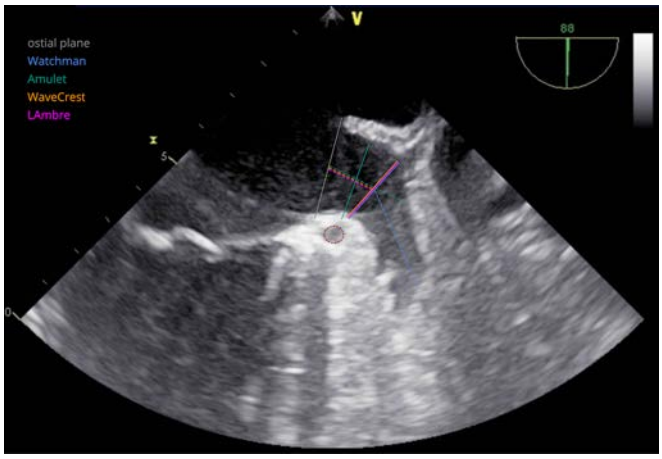


Figure 3.Importance of a low mid-to-anterior transseptal puncture

For LAA occlusion the transseptal puncture should be low, in the mid to anterior septum to facilitate engagement of the LAA. On ICE (rightmost), the LAA and MV should be in view.

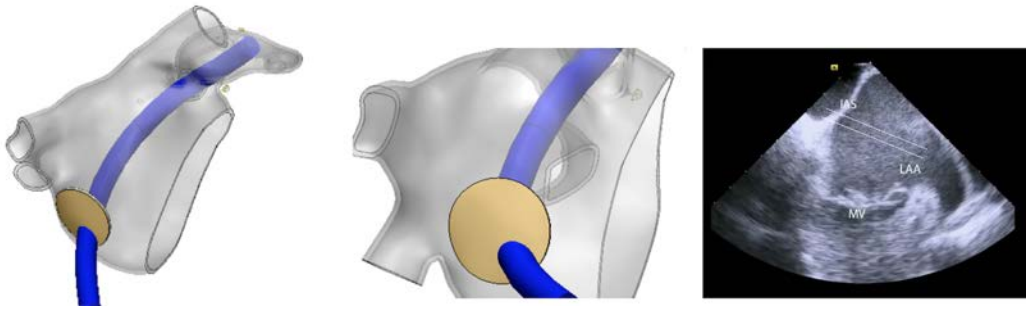


Figure 4.Watchman deployment

Step-by-step procedure as seen on fluoroscopy. See text for description.

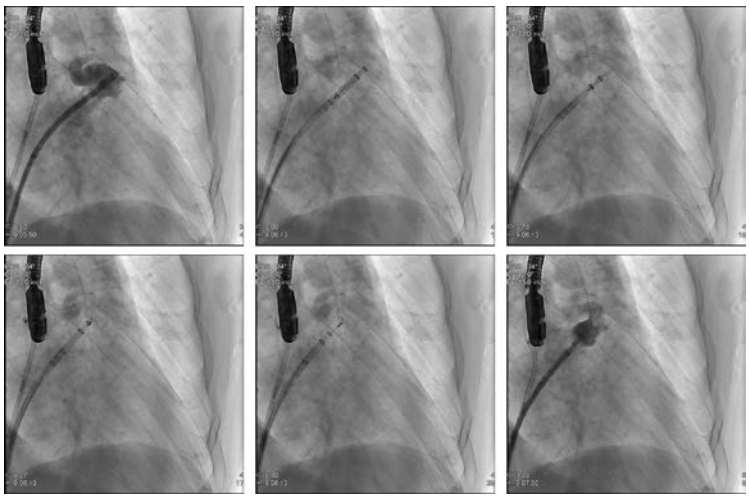


Figure 5. Amulet deployment

Step-by-step procedure as seen on fluoroscopy. See text for description.

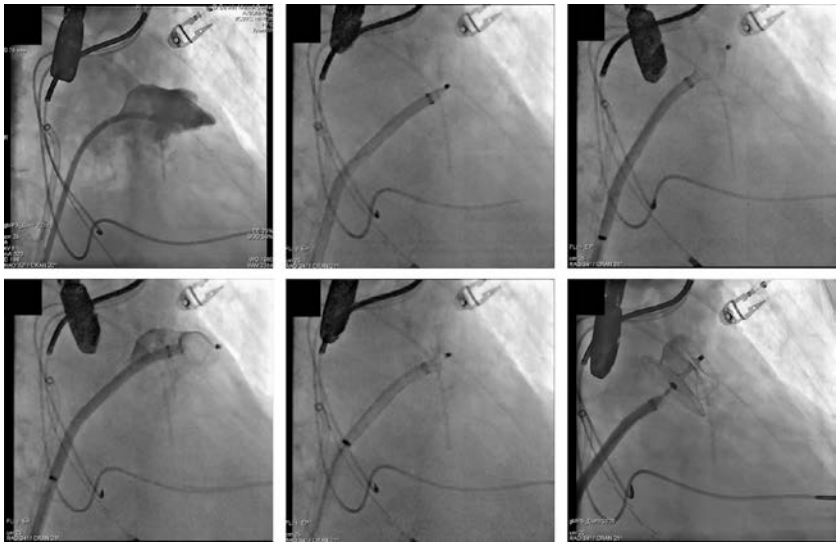
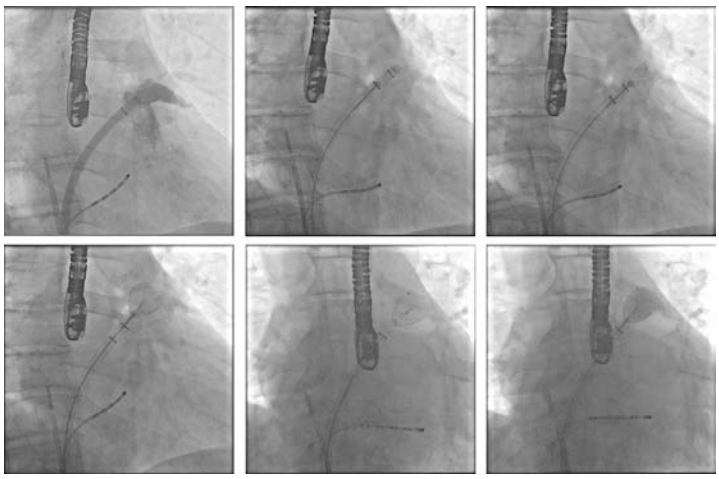


Figure 6. WaveCrest deployment

Step-by-step procedure as seen on fluoroscopy. See text for description.



Tables

Table 1 Left atrial appendage closure devices, main characteristics

Device	Manufacturer	Design	Sizes (mm)	Approval
Watchman	Boston Scientific	Single lobe	5 sizes: 21, 24, 27, 30, 33	CE mark FDA approved
Watchman FLX	Boston Scientific	Single lobe	5 sizes: 20, 24, 27, 31, 35	CE mark ongoing FDA approval trial
Amulet	St. Jude Medical	Distal lobe and proximal disc	8 sizes:	CE mark

			16, 18, 20, 22, 25, 28, 31, 34	ongoing FDA approval trial
WaveCrest	Biosense Webster	Single lobe	3 sizes: 22, 27, 32	CE mark ongoing FDA approval trial
LAmbre	LifeTech	Distal lobe and proximal disc	11 sizes: 16, 18, 30, 22, 24, 26, 28, 30, 32, 34, 36	CE mark FDA approval trial planned

CE, Conformité Européenne; FDA, Food and Drug Administration

Table 2 Left atrial appendage closure devices, main studies (feasibility, safety)

Device	**Author, year (study name)**	**Design**	**N (device)**	**Procedure-related complications***	**Follow-up (average)**	**Incomplete closure***
Watchman	Holmes, 2009[15] (PROTECT-AF)	RCT	463	7%°	18 months	32% at 1 year[16]
	Holmes, 2014[17] (PREVAIL)	RCT	269	5%	18 months	NA
Amulet	Landmesser, 2017[18]	Prospective observational	1078	6%°	11 months	2%
WaveCrest	Stone, 2017[19] (unpublished)	Prospective observational	69	4%	NA	NA
LAmbre	Huang, 2017[20]	Prospective observational	153	6%	12 months	16%

*definition varies among studies

°approximately (reported events include non-periprocedural, device-related events, which might not always be discerned from peri-procedural ones)