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Innovation

A new left atrial appendage occluder (Lifetech LAmbre™ Device) for stroke prevention in atrial fibrillation☆

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ABSTRACT

Non-valvular atrial fibrillation (AF) is the commonest cardiac arrhythmia which causes ischemic stroke. Percutaneous left atrial appendage (LAA) closure is increasingly performed in AF patients with high stroke and bleeding risks. WATCHMAN and Amplatzer Cardiac Plug are the two mostly implanted devices worldwide with good clinical results. However, the need for relatively large delivery sheaths (9–14 French) and limited recapture and repositioning capabilities remains problematic for both devices. LAmbre™ is a new; self-expanding LAA occluder constructed from a nitinol mesh and polyester membranes. It consists of an umbrella and a cover connected by a short central waist. The device is delivered by an 8-10 French sheath and has full recapture and repositioning capabilities. This report discussed in detail the novel features andprocedural steps for LAmbre™ device.

Warfarin is difficult to be used safely and conveniently to prevent embolic stroke related to atrial fibrillation (AF) [1]. More than 90% of atrial thrombi associated with AF were found in left atrial appendage (LAA) and transcatheter LAA occlusion has been developed as an alternative strategy to warfarin for stroke prophylaxis in AF patients [2–6]. WATCHMAN device (Boston Scientific Inc., US) and Amplatzer Cardiac Plug (St Jude Medical Inc., US) are 2 commercially available devices with reported efficacy in humans [4,5,7–9]. However, both devices have limitations including the need for relatively large delivery sheaths (9–14 French) and limited recapture and repositioning capabilities [10]. LAmbre™ (Lifetech Scientific Corp., Shenzhen, China) is a novel; self-expanding LAA occluder constructed from a nitinol mesh and polyester membranes and consists of an umbrella and a cover connected by a short central waist. The device is delivered by an 8–10 French sheath and has full recapture and repositioning capabilities.

1. LAmbre LAA closure system

The name "LAmbre" is a derivative from "an umbrella in the left atrial appendage". The closure system comprises an implant and its delivery system. The implant is a nitinol-based, self-expanding device comprising a hook-embedded umbrella and a cover connected with a short central waist (Fig. 1). 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, covering the LAA orifice and provides apposition against the chamber wall under gentle tension. The proximal cover is filled with sewn in polyethylene terephthalate (PET) fabric. The distal umbrella comprises 8 claws with individual stabilizing hooks attaching to them to facilitate anchoring to LAA wall. The umbrella was specially engineered to allow for complete collapse and repositioning. An additional PET membrane has been introduced to the umbrella in the newer version of the implant to ensure LAA sealing in case the cover fails to achieve optimal occlusion (Fig. 1). Several sizes of the implants (16–36 mm) have been developed to accommodate the variation of LAA anatomy and they were delivered by sheaths that ranged 8–10 French in size.

The delivery system consists of a sheath, dilator, delivery cable, loader and vise. The delivery sheath allows for contrast injection both in LAA and proximal to the occluding surface to assess sealing and device positioning at the interface of LAA orifice and left atrial wall.

2. Implantation procedure

The procedure is performed via femoral vein approach under fluoroscopic and angiographic guidance. Transseptal puncture is performed using conventional Brockenbrough technique by an 8 Fr transseptal sheath (SL1, St Jude Medical, US) and needle, and the LAA is reached over a guidewire. A heparin bolus of 1800–3000 (80–100 U/kg) is administered after successful transseptal puncture. The diameters of the orifice and length of LAA are measured from LAA angiogram in right anterior oblique (RAO) cranial projection. The size of the implant would be 4–8 mm larger than the measured LAA

☆ Conflict of interest: Yat-Yin Lam is the clinical proctor for LAmbre device.

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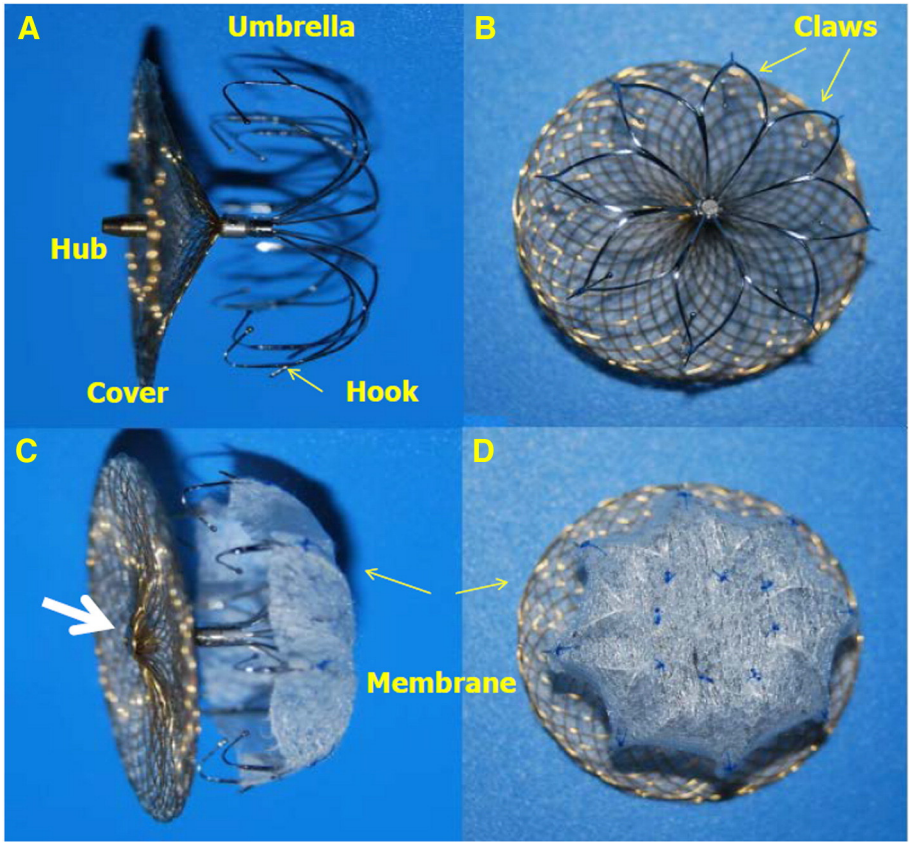

Fig. 1. The LAmbre™ is a nitinol-based, self-expanding device consisting of a fabric-enriched cover and an umbrella connected with a short central waist, and 1 attachment hub (A). The umbrella comprises 8 claws with individual stabilizing hooks attaching to them (B). The hub is recessed to the surface of the cover (white arrow) and an additional membrane was introduced to the umbrella in the newer version of LAmbre™ (C and D).

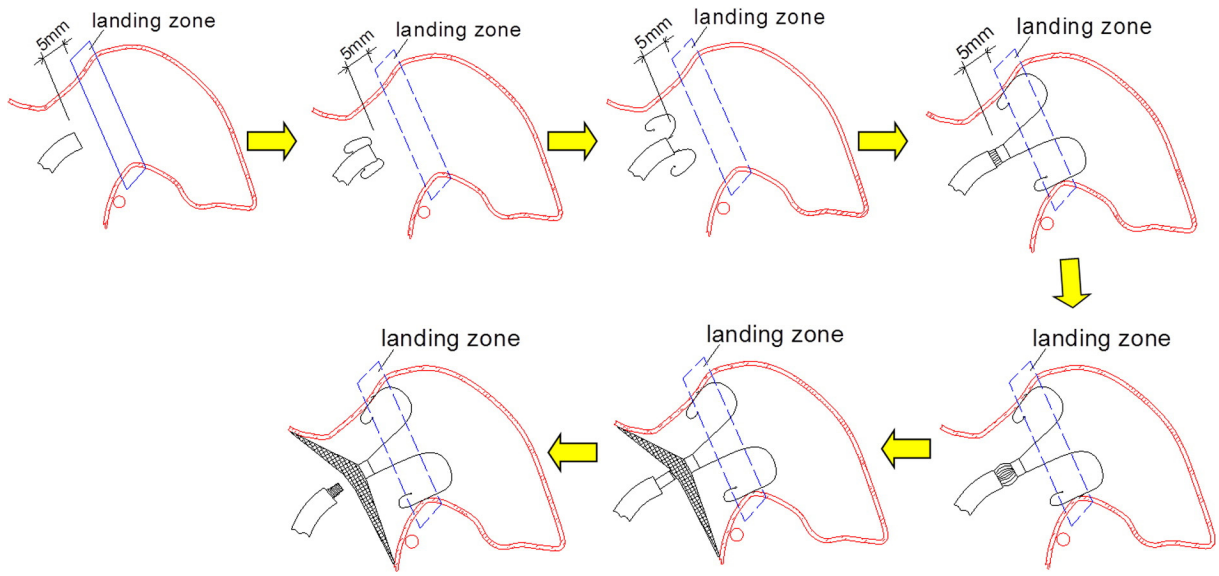

Fig. 2. The delivery sheath is positioned in the proximal portion of the left atrial appendage (LAA) and the umbrella is partially deployed by slowly pushing the device out of the sheath. The whole system is then advanced to the desired landing zone of LAA to allow flowering of the umbrella and engagement of the stabilizing hooks into the LAA walls. The cover is then deployed to seal the LAA ostium by withdrawing the delivery sheath.

orifice, based on the clinical judgment of the implanting physician using other anatomical and procedural considerations.

The delivery sheath containing the implant is placed on the proximal part of LAA. The umbrella of the implant is partially deployed by slowly pushing out the device from the delivery sheath. The whole system is then gently push "en-bloc" forward to the desired landing zone to allow better flowering of the umbrella and grasping of LAA walls by the retention hooks (Fig. 2). 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. Once the implant is placed in LAA, left atrial angiogram was performed to check device positioning, LAA sealing and impingement on surrounding cardiac structures. 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 re-deployed.

The main advantages of LAmbre device include small delivery system and the ability to be fully retrievable and repositionable during implantation. The avoidance of deep seating of the delivery catheter into LAA during deployment can potentially reduce the risk of LAA perforation. Human trials are currently underway.

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