Left Atrial Appendage Occlusion

Pilot Study of a Fourth-Generation, Minimally Invasive Device

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Objective: Exclusion of the left atrial appendage is proposed to reduce the risk of stroke in patients with atrial fibrillation. The aim of this study was to evaluate the feasibility and efficacy of a fourth-generation atrial exclusion device developed for minimally invasive applications.

Methods: The novel atrial exclusion device consists of two polymer beams and two elastomeric bands that connect the two beams at either end. Fifteen mongrel dogs were implanted with the device at the base of the left atrial appendage through a median sternotomy and were evaluated at 30 (n = 7), 90 (n = 6), and 180 (n = 2) days after implantation by epicardial echocardiography, left atrial and coronary angiography, gross pathology, and histology.

Results: Left atrial appendage exclusion was completed without hemodynamic instability. Coronary angiography revealed that the left circumflex artery was patent in all cases. A new endothelial tissue layer developed, as expected, on the occluded orifice of the left atrium.

Conclusions: This novel atrial exclusion device achieved easy, reliable, and safe exclusion of the left atrial appendage, with favorable histological results in a canine model for up to 6 months. Clinical application could provide a new therapeutic option for reducing the risk of stroke in patients with atrial fibrillation.

Key Words: Atrial fibrillation, Flutter, Atrium, Minimally invasive surgery, Stroke.

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In the Framingham Study, patients with atrial fibrillation (AF) were up to five times more likely than other patients to experience a stroke.[1] One third of all AF patients may experience a stroke in their lifetime; one Italian study found that of those with a "first-ever ischemic stroke," the "case-fatality rate" was nearly 50% at 1 year.[2] Thrombi were localized to or were present in the left atrial appendage (LAA) in 57% of patients with rheumatic AF and in 91% of patients with nonrheumatic AF.[3] One cause may be the low flow velocities within the LAA experienced during AF.[3] Anticoagulation therapy with warfarin is among the most common therapies to prevent stroke, but warfarin carries risks of major bleeding (2.3% per year) and intracranial hemorrhage (0.9% per year).[4] Many patients cannot tolerate or choose not to take the drug, and it is estimated that only 15% of patients stay within the recommended therapeutic dose even when managed in a primary care setting.[5]

Many investigators have documented that a reduction in stroke risk can be achieved by surgical occlusion of the LAA as well as by percutaneous occlusion.[3,6–8] A second finding in these reports, and one most recently reported by the Cleveland Clinic, is that current techniques are successful only 40% of the time because of recanalization of the LAA or the creation of a clinically significant remnant. In these patients, LAA thrombus was present in 41% patients with unsuccessful LAA exclusion.[9] Katz et al[10] reported incomplete LAA ligation in 36% patients who underwent LAA ligation. Improving the efficacy and repeatability of LAA exclusion, as well as reducing the size of the exclusion device, has been the "holy grail" sought by surgeons. Several investigators have reported novel techniques for LAA occlusion through thoracoscopic or percutaneous approaches.[11–17] We have also previously reported on a novel atrial exclusion device (AED),[18–20] which has been developed for epicardial LAA exclusion on either a beating or arrested heart. The safety and efficacy of this AED have been demonstrated in our previous studies, and AtriCure, Inc, has received clearance from the US Food and Drug Administration for the use of this AED in patients.

Recently, the number of mitral valve surgeries performed via thoracoscopic or robotic facilitated means has been increasing.[21] When LAA occlusion is performed via a thoracoscopic or robotic procedure, a specific device small enough to be introduced into the chest cavity through working ports is

required. Once in the chest, the device must open to full aperture to allow for rapid and safe maneuvering over the LAA apex and down to the LAA orifice. In consideration of these new requirements, we have developed a fourth-generation AED for transthoracic and trans-subxyphoid approaches. This novel device would enable a port access insertion and, once in the body, would open to full aperture. The purpose of this study was to evaluate, by two-dimensional (2D) epicardial echocardiography (EE), left atrial and coronary angiography, gross pathology, and histology, a prototype of the fourth-generation AED developed for use in minimally invasive surgery.

MATERIAL AND METHODS

Structure and Design of the AED

For purposes of minimally invasive thoracic surgery, the AED needs to be inserted into a small working space with limited handling, but then, it must open fully so that the AED can be optimally placed onto the LAA. The AED's structure is shown in Figure 1. The skeleton of the AED is composed of two polymer beams connected with two elastomeric bands at both ends. The bands at one end of the AED act as a hinge; the other end can be widely opened so that the LAA can easily be placed between the beams, even in thoracoscopic surgeries (Fig. 2A). Before the application, the elastomeric bands at the open end are temporarily connected to the other beam's end with a deployment suture passed through the bands (Fig. 2A). The open end thus creates a wide aperture during application. Once the AED is properly positioned at the base of the LAA and the tissue is clamped under controlled pressure, the deployment suture connected to the elastomeric bands is pulled, extending the band and locking the beams together, approximately parallel, using a radiopaque locking pin (Fig. 2B). The deployment suture is then cut and removed (Fig. 2C). The resulting force profile, controlled by the elastomeric bands, is consistent with those in previous successful animal series (the calculated pressures, a function of the tissue's thickness, range from 100 to 400 mm Hg). As in previous successful animal series, the design of the AED includes a braided knit polyester sheath, intended to promote rapid ingrowth of fibrous tissue.

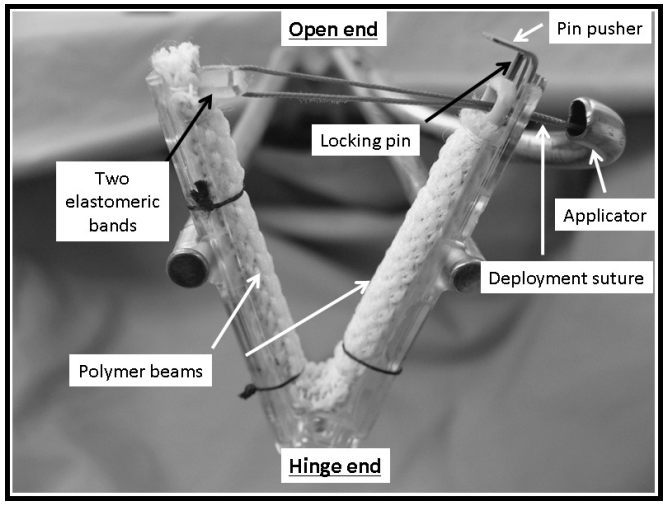

FIGURE 1. The structure of the atrial exclusion device.

Study Design

Fifteen mongrel dogs (mean weight, 27.4 ± 3.6 kg) were used in the present study, which was approved by the Cleveland Clinic's Institutional Animal Care and Use Committee. All animals received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals" prepared by the Institute of Laboratory Animal Resources, National Research Council, and published by the National Academy Press (revised 1996).

Application of the AED

General anesthesia was induced with intravenous thiopental (20 mg/kg) and maintained with isoflurane (0.5%–2.5%). Each dog was laid supine, and the LAA was exposed through a median sternotomy. A single Millar catheter (SPC350; Millar Instruments, Houston, TX USA) was inserted into the pulmonary vein to monitor left atrial pressure, and a 14-gauge angiocatheter was placed into the pulmonary vein for left atrial angiography. Another single Millar catheter (SPC350, Millar Instruments) was inserted into the left ventricle to monitor left ventricular end-diastolic pressure. Hemodynamic parameters, including heart rate, arterial pressure, left ventricular end-diastolic pressure, and left atrial pressure, were collected before (pre-LAA occlusion) and after (post-LAA occlusion) implantation. Ventilatory support was transiently halted during data acquisition. Hemodynamic parameters were digitized in real time at a sampling rate of 200 Hz with a data-acquisition system (PowerLab, ADInstruments, Inc, Mountain View, CA USA) and stored on a hard disk for subsequent analysis by a custom-made visual basic program on Excel software (Excel 2000; Microsoft Corp, Redmond, WA USA). Two-dimensional EE and Doppler EE were performed before and after LAA occlusion. Left atrial volume was also assessed using a biplane area-length method from the apical four- and two-chamber views. Left ventricular end-diastolic (EDV) and end-systolic (ESV) volumes were measured by a single-plane Simpson's rule. Left ventricular ejection fraction was calculated by the equation $100 \times (EDV - ESV)/EDV$. Left ventricular stroke volume was calculated as EDV minus ESV. Angiography of the left atrial and left circumflex (LCX) arteries was performed in the 60-degree left anterior oblique and 30-degree right anterior oblique planes both before and after AED application.

After data collection was completed as described above, the chest was closed, with a chest tube left in place for drainage. The animals were carefully monitored for 30 (n = 7), 90 (n = 6), or 180 (n = 2) days in their regular housing. Neither anticoagulants nor antiplatelet drugs were given postoperatively.

Explantation of the AED

All animals were monitored for the planned durations. For the terminal studies, each animal was placed under general anesthesia, the heart was reexposed through a median sternotomy, and hemodynamic assessment, left atrial angiography, 2D EE, and Doppler EE were performed in the same manner as for the implantation study. After all data were collected, the

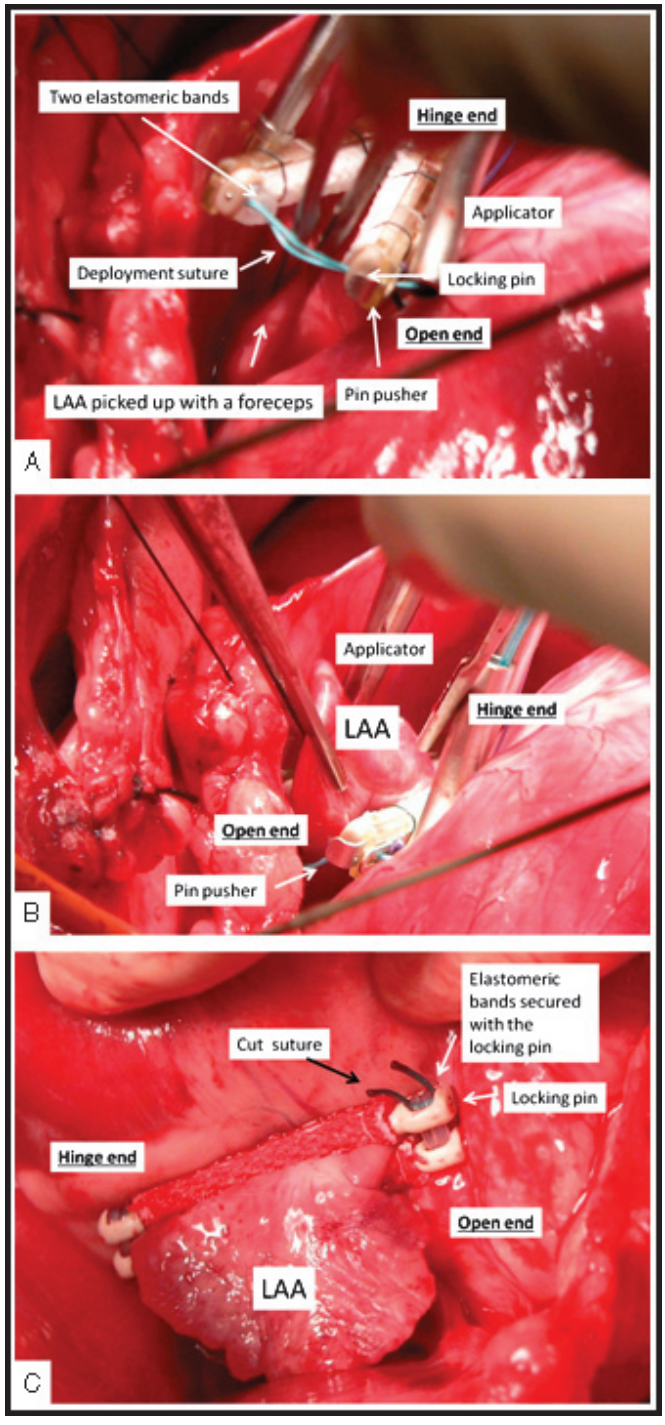

FIGURE 2. Procedure for the AED application. A, The LAA is held by a forceps through the AED. B, The AED is placed at the base of the LAA. The two polymer beams are closed with the applicator. C, The LAA is occluded, and the elastomeric bands pulled with the suture are secured with the locking pin. The deployment suture is cut and removed. AED indicates atrial exclusion device; LAA, left atrial appendage.

dogs were killed under full heparinization (500 U/kg) by rapid intravenous injection of sodium pentobarbital (50 mg/kg) and potassium chloride (120 mEq).

Gross Necropsy and Histological Evaluation

After the hearts were harvested, the AED with the LAA and the surrounding left atrial and left ventricular tissue was excised from the heart. A cross-section of the occlusion site of the LAA was made with only polyester fabric left on the appendages. A middle portion of the entire LAA, perpendicular to the AED, with the polyester fabric was taken for cross-sectioning. The cross-sectioned tissue samples were fixed in 10% formalin for 48 hours and embedded in paraffin. Sections were cut from each block at 4 μm and collected onto glass slides. All sections were then dried for 60 minutes at 60°C and stained with hematoxylin and eosin. The connective tissue underneath the AED and the LAA was assessed in cross-sections of the specimens.

Data Analysis

All values are expressed as mean ± SD. Repeated-measures analysis of variance trials were used to assess the differences between values obtained before and after LAA occlusion and at the terminal study.

RESULTS

Implantation and Postoperative Results

The AED was swiftly applied onto the beating heart of all animals without any complications. Application of the AED required approximately 1 minute once the LAA was exposed. In all cases, 2D EE, Doppler EE, and left atrial angiography revealed no communication between the LAA and left atrium after implantation. Angiography revealed no stenosis in the LCX in any case. All animals survived for the planned durations without device-related complications, and their postoperative courses were uneventful.

Explantation Study

The AED on the LAA did not migrate or erode adjacent structures, including the pericardium, left atrium, LCX, great cardiac vein, or pulmonary artery. Doppler EE and left atrial angiography showed no blood flow in the LAA at the time of the explantation study. Angiography demonstrated that none of the AEDs interfered with the blood flow of the LCX or great cardiac vein. The AED and LAA became completely covered with translucent fibrous tissue, with no adhesions to the chest wall or other noncardiac structures. Regarding the excluded LAA, the occluded orifice of the LAA was covered with a white tissue. These findings were consistent with the finding in our previous study using titanium beams and nitinol springs.[20] No thrombus formation in the left atrium was found in any case. In 14 of 15 animals (including 8/8 at ≥90 days), a fibrous tissue between the two beams was too firm to be detached from either beam when pulled by hand. In the excluded appendage, well-organized thrombus was present but contained there. Over time, the appendage decreased in size as a function of study duration (Fig. 3); thus, at 180 days, little to none of the appendage remained, a finding consistent with those of previous AED studies.[8–10]

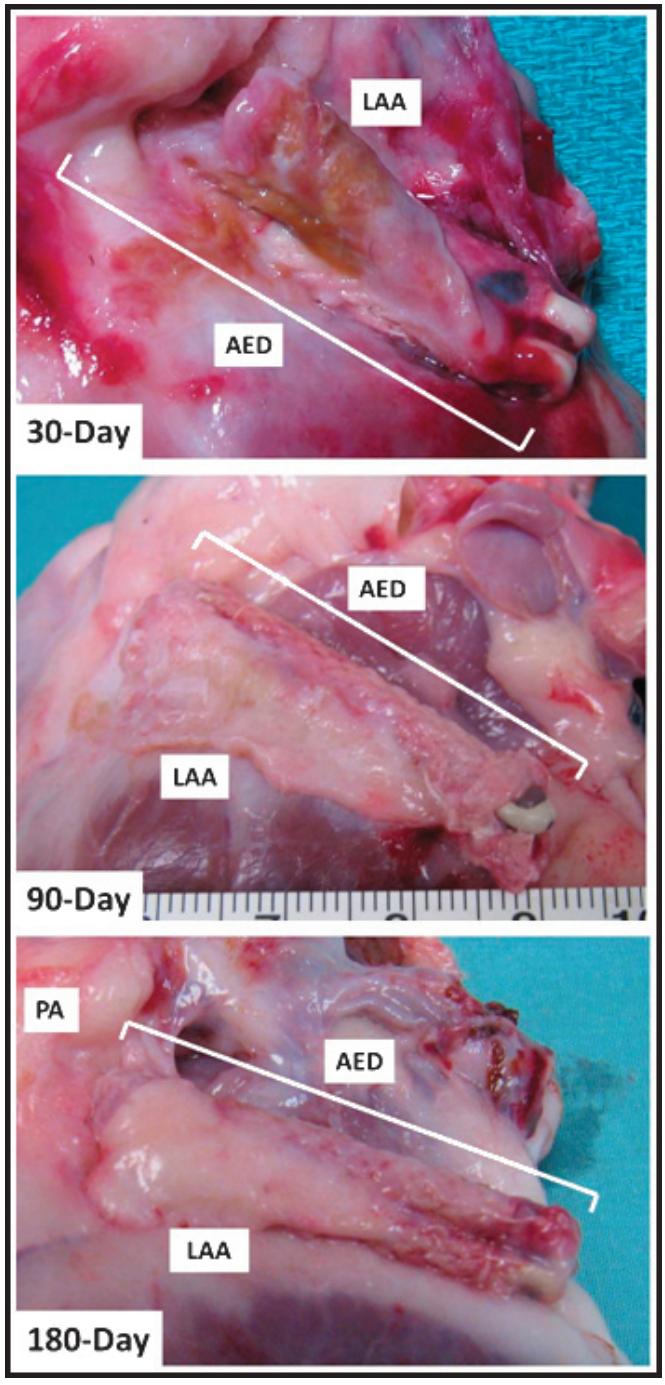

FIGURE 3. The LAA atrophied and decreased in size as a function of the duration of the study. AED indicates atrial exclusion device; LAA, left atrial appendage; PA, pulmonary artery.

Histological Examination of the Appendages

In all studies, the polyester fabric of the AED was infiltrated by fibroblasts that produced fibrous collagen, which implied a very mild inflammatory reaction. The orifice of the LAA was totally closed and healed. In terms of remodeling of the myocardium of the appendage, in the 30-day study, approximately 90% of the LAAs were replaced with fibrous tissue, and in the 90- and 180-day studies, the LAAs were completely replaced with fibrous tissue. These findings were consistent with findings in our previous series.[10]

Hemodynamic, Echocardiographic, and Angiographic Data

Hemodynamic and echocardiographic data are shown in Table 1. There were no statistically significant differences in the hemodynamics or 2D EE parameters among the data points (before and after LAA occlusion and at the terminal study).

COMMENT

The fourth-generation AED enabled the LAA to be excluded successfully without any complications. All appendages excluded by the AED were atrophied. The fibrous tissue in the occluded LAA orifice demonstrated completeness of the exclusion of the LAA. The fourth-generation AED proved to have performance consistent with that of the previous version with titanium beams and nitinol springs as an occlusion device.[20] The AED can open widely, and the LAA was thus easily placed between the two beams. The potential advantage over the previous generation AEDs is that the fourth-generation AED can be easily applied even in limited surgical space, as in the subxyphoid approach or transthoracic approach with thoracoscopy. In the future, it may be possible to combine this implant procedure with other minimally invasive surgery such as transthoracic pulmonary vein isolation with ablation or robotic cardiac surgery.

Atrial fibrillation is the most common cardiac arrhythmia, and the population of AF patients older than 65 years is increasing exponentially.[1,12] Currently, anticoagulation therapy reduces the risk of cardioembolic stroke in AF patients. Such anticoagulation therapy offers many benefits, but there is also an increased risk associated with management of warfarin dosages within desirable ranges, as appropriate per age category.

TABLE 1. Hemodynamics and Echocardiographic Data

	Pre-LAA Occlusion	Post-LAA Occlusion	Terminal Study	*P*
Hemodynamics				
Heart rate, beats/min	99 ± 15	97 ± 14	101 ± 14	0.476
Mean BP, mm Hg	67.2 ± 14	65.7 ± 16	56.9 ± 15	0.055
LVEDP, mm Hg	9.4 ± 5.2	10.7 ± 6.3	12.3 ± 4.0	0.213
Mean LAP, mm Hg	12.3 ± 4.9	12.3 ± 4.9	9.5 ± 3.9	0.088
2D EE				
End-systolic LAV, mL*	25.2 ± 6.9	24.0 ± 7.2	20.1 ± 5.6	0.066
EDV, mL*	61.7 ± 13.9	56.5 ± 14.7	63.8 ± 15.2	0.360
ESV, mL*	31.7 ± 10.0	28.2 ± 10.0	30.4 ± 7.3	0.452
SV, mL*	30.0 ± 7.6	28.3 ± 6.1	33.4 ± 10.2	0.265
EF, %*	49.1 ± 8.8	51.2 ± 7.4	51.8 ± 7.4	0.410

No significant differences were found among the data points. Data are presented as mean ± SD.

*These measurements were obtained from available data in 13 animals.

2D EE indicates two-dimensional epicardial echocardiography; BP, blood pressure; EF, ejection fraction; EDV, end-diastolic volume; ESV, end-systolic volume; LAA, left atrial appendage; LAP, left atrial pressure; LAV, left atrial volume; LVEDP, left ventricular end-diastolic pressure; SV, stroke volume.

Dabigatran (Pradaxa) is an alternative drug to prevent stroke in patients with AF. Dabigatran given at a dose of 110 mg was associated with rates of stroke and systemic embolism that were similar to those associated with warfarin (relative risk with dabigatran, 0.91; 95% confidence interval, 0.74–1.11; $P < 0.001$ for noninferiority), as well as lower rates of major hemorrhage.[21] As compared with warfarin, dabigatran administered at a dose of 150 mg was associated with lower rates of stroke and systemic embolism (relative risk, 0.66; 95% confidence interval, 0.53–0.82; $P < 0.001$ for superiority) but similar rates of major hemorrhage.[21] A potential alternative therapy for stroke prevention in AF patients is percutaneous exclusion of the LAA from the circulatory system. It is reported that residual peridevice flow into the LAA after percutaneous closure with the Watchman device was common (32.0% of implanted patients) and was not associated with an increased risk of thromboembolism.[22] Catheter-based surgical suture ligation of the LAA (LARIAT snare device) is feasible in humans with a successful closed-chest LAA ligation procedure in 12 of 13 patients.[23] Because thrombi commonly originate in the LAA of AF patients, surgical LAA occlusion theoretically decreases the rate of strokes. As of now, however, according to guidelines of the American College of Cardiology and the American Heart Association, LAA occlusion is recommended only during mitral valve surgery.[24] Recently, the number of mitral valve surgeries in which thoracoscopy or robotic machines are used has been increasing.[25] A specific device that can be widely opened even in a small space is necessary to make AED placement readily accomplishable in such thoracoscopic procedures.

The fourth-generation AED demonstrated good performance, comparable with that of the previous version constructed of titanium beams and nitinol springs, as an occlusion device. The new growth of fibrous tissue found in the occluded orifice showed that the LAA exclusion was complete. Incomplete exclusion of the LAA after surgery can actually increase the risk of stroke rather than prevent stroke.[9,10] The occluded endocardial surface was covered with a new endothelial layer in all studies. The new endothelial layer of the occluded orifice to the left atrium was found in both the present and previous studies.

There are limitations to this preclinical study. The study series was small (n = 15), and the follow-up period was only a maximum of 180 days. It is possible that there would be device failures and/or deployment complications with a longer follow-up or with application in patients whose tissues are less resilient than those of the healthy canines used in our study. In addition, the experimental animals started out in sinus rhythm rather than AF.

CONCLUSIONS

The fourth-generation AED for minimally invasive surgeries achieved easy, reliable, and safe exclusion of the LAA with favorable histological results. Clinical application could provide a new therapeutic option for reducing the risk of stroke in patients with AF.

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CLINICAL PERSPECTIVE

This is a pilot study from Dr Fumoto and his group at the Cleveland Clinic looking at a fourth-generation atrial exclusion device (AED). The device was able to be applied safely without any collateral injury in 15 dogs and the animals were evaluated at 30, 90, and 180 days. In each animal evaluated, the orifice of the left atrial appendage was closed and healed.

The potential advantage of this AED over previous devices is that it can be applied easily in a limited surgical space. Although this study does not rule out complications that may occur with longer term follow-up, it does suggest that this fourth-generation AED reliably excludes the left atrial appendage.