TECHNIQUES, TECHNOLOGY, AND INNOVATIONS
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Left Atrial Appendage Closure Guided by 3D Printed Cardiac Reconstruction: Emerging Directions and Future Trends

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Emerging Directions and Future Trends. ***Introduction:*** **Percutaneous left atrial appendage (LAA) occlusion has emerged as an alternative therapeutic approach to medical therapy for stroke prevention in patients with atrial fibrillation. 3D printing is a novel technology able to create a patient specific model of any given anatomical portion of the heart.**

Results: **Herein we report the first 2 cases of LAA occlusion procedure with 2 different systems, the Wave Crest device (Coherex Medical, Inc., USA) and the Amplatzer Amulet device (St. Jude Medical, St. Paul, MN, USA), in which a 3D printed LAA model (Care Tronik, Prato, Italy) was used in a rehearse phase. Both patients had history of paroxysmal AF and previous transient ischemic attack (TIA) occurred during oral anticoagulation with correct INR. In the first patient the occlusive device was positioned within the LAA after a rehearse occlusion using the 3D printed LAA plus a 27 mm Coherex Wavecrest device, demonstrating a good compression and sealing, particularly considering a proximal lobe of the appendage. In the second patient an attempt with the 27 mm Amulet device delivered within the 3D printed LAA, based on angiography and transesophageal echocardiographic (TEE), revealed insufficient covering of the proximal part of LAA vestibule; the device was released only after a second test with the 31 mm Amulet demonstrating a good sealing.**

Conclusion: **These 2 cases demonstrated that 3D model could help in finding the correct position within LAA, sizing the device and guiding the choice of the closure device despite the measurements provided by angiography and TEE.** *(J Cardiovasc Electrophysiol, Vol. 27, pp. 768-771, June 2016)*

atrial fibrillation, left atrial appendage closure, 3D printed heart

Introduction

Atrial fibrillation is the most common cardiac arrhythmia, with prevalence in the general population of approximately 1% and an incidence of 0.2% per year.[1,2] Catheter ablation of AF is recommended for patients with drug refractory symptomatic paroxysmal AF. Pulmonary vein isolation (PVI) still remains the cornerstone of AF ablation procedures. AF is a major cause of morbidity and mortality, increasing risks for death, congestive heart failure, and embolic phenomena, including stroke.[3,4] The annual risk of AF-related stroke increases in elderly patients, rising from 1.5% for those aged 50–59 years to 23.5% for those aged 80–89 years.[5] Catheter ablation of AF by means of pulmonary vein isolation (PVI) is the recommended therapeutic option in most cases.

Since echocardiographic and autoptical studies have shown that in up to 90% of the cases the thrombus is located in the left atrial appendage (LAA),[6] percutaneous LAA occlusion has been introduced into clinical practice as a valuable alternative to oral anticoagulation for patients who cannot tolerate anticoagulants or in case anticoagulants are ineffective. Two randomized controlled trials (PROTECT AF study and PREVAIL study) and some initial registry reports for the Amplatzer Cardiac Plug (ACP) demonstrated the non-inferiority of LAA exclusion compared to VKa, and the follow-up publication showed superiority of LAA exclusion over warfarin therapy.[7-10] LAA occlusion was included in the latest ESC guidelines for the management of patients with AF (class of recommendation IIb, level of evidence B).[11] The LAA occlusion procedure is typically guided by TEE, fluoroscopy, and CT scan; however, the correct sizing of the device remains a challenging phase of the process, and any additional tool increasing the overall efficacy would be highly welcomed.

3D printing is a novel technology able to create a patient-specific model of any given anatomical portion of the heart. A virtual model is created from any DICOM file (from cardiac tomography) processed with a customized software, and then printed as high-resolution (200 μm) functional resins.

Herein we describe the first 2 cases of LAA occlusion procedure using 2 different systems, the WaveCrest device (Coherex Medical, Inc., USA) and the Amplatzer Amulet device (St. Jude Medical, St. Paul, MN, USA), in which a

Disclosures: None.

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Figure 1. *3D printed LAA model plus a 27 mm Coherex WaveCrest device showing a good compression and sealing.*

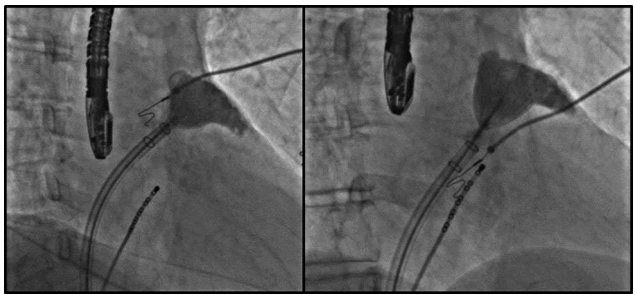

Figure 2. *The first position (left) of the occluder device revealed an uncovered proximal lobe of LAA. After careful retraction (right) a more proximal position was obtained, allowing a complete covering of the proximal lobe.*

3D printed LAA model (CareTronik, Prato, Italy) was used in a rehearse phase for the correct device sizing and for the identification of the ideal position within the LAA vestibule.

Case Presentation 1

A 69-year-old woman with paroxysmal atrial fibrillation was admitted for PVI and concomitant LAA occlusion, due to a transient ischemic attack occurred during oral anticoagulation with correct INR despite a high CHA2DS2Vasc score of 5 points.

The patient had a history of hypertension, previous atrial fibrillation ablation, and subsequent recurrences of arrhythmia despite antiarrhythmic drugs. A brain MRI showed small embolic infarcts at subcortical bilaterally. An ECG showed sinus rhythm with normal atrioventricular and intraventricular conduction time. An echocardiogram showed a slight enlargement of the left atrium, moderate mitral regurgitation with multiple jet and a normal systolic left ventricular function. A transesophageal echocardiogram showed the absence of thrombus in the atrium and left atrial appendage, mild spontaneous echo-contrast, low LAA flow velocities (25-30 cm/s). A cryo-ablation with the third-generation cryoballoon (Arctic Front Advance ST, Medtronic Inc., Minneapolis, MN, USA) and LAA occlusion with the Wave Crest device were planned.

Transseptal access was achieved via the right femoral vein, using a SL0 sheath and a BRK-1 needle (St. Jude Medical). Before crossing the atrial septum, an initial intravenous bolus of heparin 100 IU/kg was administered, followed by continuous infusion of 1,000 IU/h in order

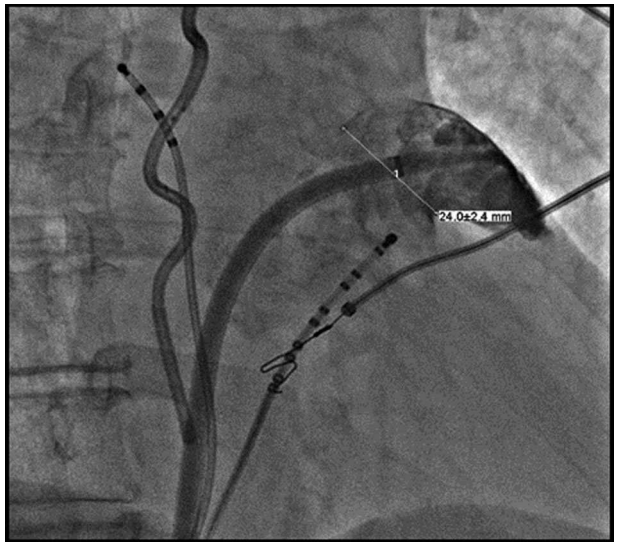

Figure 3. *LAA angiogram evaluating the diameter of the "neck" at the landing zone.*

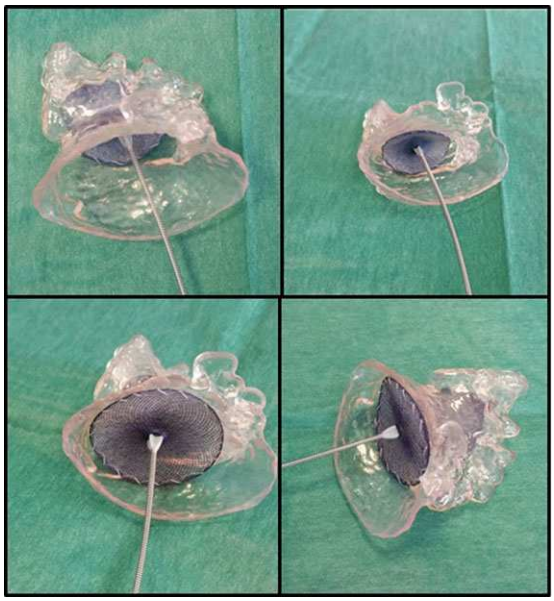

Figure 4. *The images at the top show sufficient covering of the proximal part of LAA vestibule with 27 mm Amulet device; the images at the bottom show a good sealing with the 31 mm Amulet device.*

to maintain the activated clotting time of at least 350 seconds. After transseptal puncture, the long transseptal introducer was replaced with a 15 Fr deflectable introducer Flexcath Medtronic, in which both the circular mapping catheter of the pulmonary veins Achieve and a balloon catheter to cryo-energy (balloon Artic Front 28 mm Advance ST) were advanced the pulmonary veins—upper left, lower left, and upper right—were reconnected. After ablation, a complete occlusion, with bidirectional conduction block, was observed, confirmed by pacing maneuvers.

LAA occlusion was performed with the patient under general anesthesia and with transesophageal echocardiographic (TEE) and fluoroscopic guidance. An LAA angiogram was recorded (right anterior oblique 30°, cranial and caudal 10° view). The diameter of the LAA "neck" was 23 mm on angiography while the diameter on TEE was 25 mm. At this

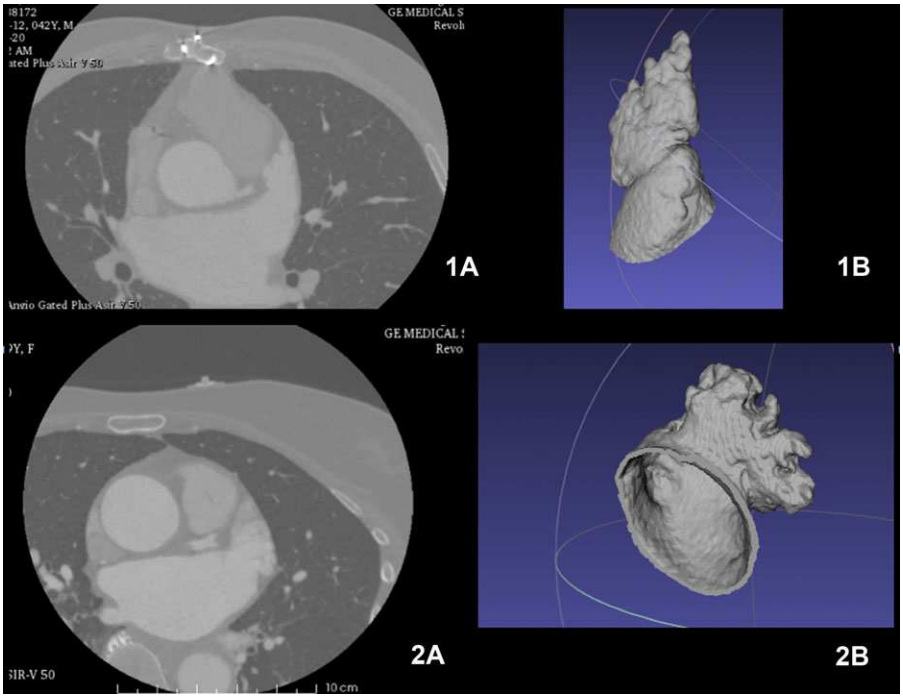

Figure 5. *The perfect reconstruction of LAA from CCT scan images provided by the 3D printer software.*

point a rehearse occlusion using the 3D printed LAA plus a 27 mm Coherex Wave Crest device demonstrated a good compression and sealing, particularly considering a proximal lobe of the appendage (Fig. 1). Throughout the dedicated delivery system the occlusive device was positioned within the left atrial appendage. The first position (Fig. 2) revealed an uncovered proximal lobe; after careful retraction, a more proximal position was obtained, replying the one obtained during the rehearse phase, and allowing a complete covering of the proximal lobe as well. Complete LAA occlusion was confirmed by color-Doppler TEE and, after careful stability testing, the device was released. No pericardial effusion or any other complication occurred. The patient was extubated in the catheterization laboratory and was discharged—2 days later on apixaban 5 mg bid for 3 months.

Case Presentation 2

A 42-year-old man with 2 previous AF episodes treated with electrical cardioversion and controlled with antiarrhythmic drugs was admitted for LAA occlusion due to a TIA despite warfarin therapy. The patient had a history of Marfan syndrome and previous mitral annuloplasty intervention in 1996.

An echocardiogram showed a mild enlargement of the left atrium (55 mm), slight mitral regurgitation, and a normal systolic left ventricular function. A TEE showed the absence of thrombus in the atrium and left atrial appendage, mild spontaneous echo-contrast, and remarkable LAA diameter, ranging from 25 mm (90°) to 30 mm (130°).

LAA occlusion was performed with the patient under general anesthesia. An LAA angiogram was recorded (right anterior oblique 30°, cranial and caudal 10° view). The diameter of the LAA "neck" was 23–25 mm at the landing zone and 28 mm at the ostium (Fig. 3); a good concordance with TEE measurement was observed (23 mm and 27 mm, respectively). An attempt with the 27 mm Amulet device, delivered within the 3D printed LAA, revealed insufficient covering of the proximal part of LAA vestibule; a second test with the 31 mm Amulet demonstrated a good sealing (Fig. 4): complete LAA occlusion was confirmed by color-Doppler TEE and, after careful stability testing, the device was released. No pericardial effusion or any other complication occurred. The patient was extubated in the catheterization laboratory and was discharged after 2 days on warfarin therapy.

Discussion

In this report we describe 2 cases of LAA occlusion (1 of which following cryo-ablation of atrial fibrillation) using 2 different systems guided by fluoroscopy, TEE and, in addition, a 3D printed, patient-specific LAA model, guided by CCT scan images (Fig. 5), as a proof of correct positioning and sealing.

The complexity and variability of LAA structure[12] crash against a fixed shaped device, which is supposed to perfectly fit the contracting structure and to completely seal the vestibule.

The LAA is a complex multiform structure with contracting properties. Many variables need to be considered to accurately select the device which best fits the LAA size and morphology.

The 3D printing of a patient's left atrium/LAA is quickly obtained, although requiring an adequate knowledge of the software. All the processes take about 4 hours from the file DICOM upload to 3D printing. The print takes 2 hours if done at the highest resolution. Just one biomedical engineer is required to follow all the steps. The material cost of the 3D print is almost $200 although there are software and other costs for a total amount of about $300. The method is potentially suitable even for epicardial reconstruction for a sub-xiphoid approach.

Moreover, a study by Budge *et al.*[13] demonstrated that assessment of the LAA orifice diameter showed poor correlation between computed CCT and TEE, implying the need

for an additional tool, i.e., LAA angiography, to provide a trusty estimate of the appendage measures.

The potential risks related to the device under or oversizing are migration or embolization of the device, cardiac perforation, LAA tear, air or clot emboli, and pericardial effusion. In all the clinical trials focused on LAA closure devices, these complications ranged from 2.2% to 9.9%[14] and were reduced with increasing number of procedures, suggesting a significant role of the learning curve.

To date, a single case of LAA occluder device driven by a 3D printed model[15] has been described. Using data from the CCT scan, a 3D model made up of a resin material to simulate atrial mechanical properties of the left atrium and LAA was printed. Then 3 different sizes of Watchman devices, the 21-mm, 24-mm, and 27-mm, were tested. The correct device was chosen after analyzing the anatomic deformation for each device and after the identification of the areas and extent of the device engagement on the flexible atrial model. In our report, we extend this concept, including 2 different devices: in the first case the 3D model helped in finding the correct position to cover a proximal LAA lobe, while in the second case this technique contributed in sizing the device, guiding the choice of the largest Amulet (31 mm) despite the measurements provided by angiography and TEE.

Our experience confirmed that LAA angiography and TEE may under- or overestimate LAA measurements: printed LAA model is an additional tool for the correct device sizing and for a reliable rehearse of the vestibule sealing and proximal lobes covering.

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