

# Complex transcatheter left atrial appendage closure using a tailored trans-jugular approach simulated by 3D printing: a case report

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| Background     | Transcatheter left atrial appendage (LAA) closure (LAAc) is less feasible in patients with unusual LAA anatomy.   |
|----------------|---|
| Case summary   | A 65-year-old woman with persistent atrial fibrillation was referred for LAAc. Transesophageal echocardiography (TEE) revealed spontaneous contrast in the LAA without formation of a thrombus; the LAA shape was tortuous and difficult to assess. A first LAAc procedure was unsuccessful given the unsuitable sheath position. Therefore, a soft three-dimensional (3D) model printing was performed by laser sintering and revealed excessive sheath kinking with an inferior approach, but successful deployment would be feasible using a superior approach. Successful trans-jugular implantation of a Watchman FLX 31 device in stable position without residual leakage was achieved during the subsequent procedure. At 3-month follow-up, and after cessation of oral anticoagulation, the patient's symptoms improved. Imaging demonstrated complete LAA occlusion and correct placement of the device along the LAA superior axis. |
| Discussion     | This is the first-reported clinical case of a complex transcatheter LAAc through a trans-jugular approach. Simulating the patient's anatomy with a laser sintering 3D-printed model showed why the transfemoral approach failed, validated the trans-jugular proced-<br>ure, enabled selection of the simple curve access sheath that had the most direct trajectory towards the LAA, confirmed that trans-<br>septal puncture was possible, allowed determination of the angle of puncture, enabled selection of the most appropriate LAA<br>device and had a very low cost compared with planning software or other printing methods.   |
| Keywords       | 3D printing • Left atrial appendage • Trans-jugular • Percutaneous closure • Transseptal puncture • Preprocedural planning and simulation • Case report   |
| ESC Curriculum | 2.1 Imaging modalities • 7.5 Cardiac surgery  |

#### Learning points

- Preprocedural planning is mandatory in complex LAA procedures and 3D printing of the patient's anatomy can assist with pre-operative decisions, including selection of the appropriate route, wires, and closure devices and is relatively low cost.
- In the longer-term, this approach has the potential to save costs by reducing the number of failed procedures for patients with complex anatomy and by reducing procedural patient time.

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#### Introduction

The European Society for Cardiology (ESC) recommendations classify left atrial appendage (LAA) closure (LAAc) as class IIb evidence B,<sup>1</sup> based on two randomized trials of non-inferiority over vitamin K antagonists (VKAs)<sup>2</sup> and several registries that have confirmed a high implantation success rate, with an acceptable rate of procedure-related complications.<sup>3</sup> Transcatheter LAAc has emerged as a valuable option in patients who have a contraindication for anticoagulants. Procedure failure is a rare situation but is more prevalent in patients with unusual and atypical LAA morphology. We present a case of transcatheter LAAc using a tailored trans-jugular approach, supported by threedimensional printing to prepare and simulate the procedure.

# Timeline

| Day 1   | Patient presents with persistent atrial fibrillation and is referred |
|---------|--|
|         | for LAA closure  |
| Day 15  | TEE reveals spontaneous contrast in the LAA without the              |
|         | formation of a thrombus  |
| Day 30  | First (unsuccessful) LAA closure procedure performed via the         |
|         | standard femoral approach  |
| Day 45  | 3D printing of the patient's anatomy and review of possible          |
|         | procedures and approach to enable a successful LAA                   |
|         | closure  |
| Day 90  | Second (successful) LAA closure procedure using a transseptal        |
|         | puncture via a right jugular venous approach under TEE               |
|         | guidance   |
| Day 180 | 3-month patient follow-up by CT and TEE confirming                   |

Day 180 3-month patient follow-up by CT and TEE confirming successful LAA closure

### Case presentation

A 65-year-old woman with persistent atrial fibrillation was referred for LAAc. The patient underwent mechanical aortic and mitral valve replacement in 1995 for rheumatic valvular disease and required a redo surgery due to an extensive pannus with two biological prostheses in January 2020; she also required a single-chamber pacemaker. Her current medical therapy included oral anticoagulation (apixaban 5 mg twice daily) in addition to diuretics and iron supplementation. She developed chronic anaemia due to active intestinal angiodysplasia with recurrent transfusion requirements once or twice each month. Her  $CHA_2DS_2$ -VASc score was 3 and HAS-BLED score was 3. Investigations ruled out other causes of anaemia, including haemolytic anaemia and paravalvular leak. The patient presented with two biologic-al protheses (VHD) without active rheumatic valve disease and, as a result, may be a candidate for LAAc.

Transesophageal echocardiography (TEE) revealed spontaneous contrast in the LAA without formation of a thrombus (see Supplementary material online, *Video S1*). The ridge diameter was 28 mm. One centimetre inside the LAA, the maximum landing zone diameter was 22 mm. The shape of the LAA was tortuous and difficult to assess. Although the LAA had an initial angle like a chicken wing, preoperative computed tomography (CT) revealed an unusual LAA morphology that was horn-like in shape (due to a vertical upward axis) (see Supplementary material online, *Video S2*) with an inferior implantation and a superior axis, with the ostium close to the mitral prosthesis ring (*Figure 1*).

After written informed consent, a first procedure was performed using a standard left femoral venous approach. The transseptal puncture was performed postero-inferiorly as recommended under TEE guidance. Nevertheless, despite multiple attempts, it was not possible to advance the sheath beyond the first centimetre of the ostium, even with the use of both double-curve and single-curve sheaths and a pigtail probe with an extra-stiff guide (see Supplementary material online, *Figure S1*). The deployment of a 31 mm Watchman FLX (Boston Scientific, Marlborough, Massachusetts, USA) was attempted but was unsuccessful given the unsuitable sheath position (see Supplementary material online, *Videos S3* and 4).

As a result of the unusual LAA morphology, a 3D printing model was prepared using SLS laser sintering technology (www.3Dheartmodeling. com and IMT Mines Alès) using Flexible TPU (Thermoplastic Polyurethane, EOS TPU 1301).

A volume file (IntelliSpace Portal version 12, Philips Healthcare, Best, The Netherlands), segmented to depict the entire left atrium and LAA, a part of the right atrium, superior and inferior vena cava, and aortic and mitral prosthesis (*Figure 1B*), and then reprocessed offline in preparation for 3D printing (*Figure 1C*). Simulation was then performed from inferior and superior access points (*Figure 2*), and with different LAA occlusion devices (see Supplementary material online, *Figures S2E* and *F*). Excessive sheath kinking was demonstrated with an inferior approach, but successful deployment was feasible using a superior approach (see Supplementary material online, *Figures S2C* and *D*).

Transseptal puncture (second procedure) (see Supplementary material online, Video S5) was performed using a right jugular venous approach under TEE guidance (see Supplementary material online, Figure S3). Apixaban was discontinued 72 h before the procedure and 2000 IU unfractionated heparin was administered after jugular puncture and reduced to 100 IU/kg after transseptal puncture with monitoring of activated clotting time to achieve >250 s during the procedure. A Swartz SLO sheath (Abbott, Illinois, USA) and a BRK-1 XS Series transseptal needle (Abbott) were used. Safe access to the left atrium was achieved by advancing a 0.014 stiff coronary wire Iron Man (Abbott) through the BRK-1 XS needle and placed in contact with inter atrial septum connected to radiofrequency. The sheath was then advanced in the left atrium over the needle and Iron Man wire. The SLO was exchanged for the single-curve 14Fr delivery sheath over an Amplatz Super Stiff guidewire placed into the LAA. Deep and safe advancement of the delivery sheath was performed over a pigtail catheter and the Amplatz Super Stiff guidewire until proper depth was achieved. Proper sheath alignment (see Supplementary material online, Videos S6 and 7) without kinking was obtained allowing successful implantation of a Watchman FLX 31 device in stable position without residual leakage (see Supplementary material online, Videos S8, 9 and 10). The position was as predicted during the simulation on the 3D-printed model. No complications occurred during the first or second procedures.

Following the successful second procedure, the patient continued to receive apixaban (2.5 mg twice daily) until the control CT scan at month 2. Between the two interventions, the patient continued to need transfusions. At the patient's 3-month follow-up visit, and after cessation of oral anticoagulation, an improvement in symptoms was seen with no need for additional transfusions. Imaging demonstrated complete LAA occlusion and correct placement of the device along the LAA superior axis as predicted by the simulation procedure, with an adequate compression and no residual leak (Figure 3 and Supplementary material online, Figure S4). TEE follow-up confirmed there was no leakage around the device. After 9 months' follow-up, there was no need for further transfusions, the patient's pulmonary pressure and functional class had improved, which was attributed to the withdrawal of blood transfusion-related volume loading, as well as the cessation of repeated post-transfusion inflammatory responses and the favourable effect of normalized iron stores.



**Figure 1** Pre-procedure imaging. (A) Biplane TEE view showing a large LAA(\*) ostium close to the mitral prosthesis ring (M). Owing to the low position, the usual landmarks (such as the circumflex artery) are absent. (B) Pre-procedure CT scan: volume rendering of the left atrium in purple, right atrium in transparency green shell, including inferior (IVC) and superior vena cava (SVC). Note that mitral (M) and aortic (A) prosthesis are superimposed in using volume rendering filled to remark the horn-like shape of the LAA with basal insertion and directed upwards (blue arrow). (C) SLS 3D-printed model with exact representation of the left atrium, right atrium which is sectioned in order to see the orifice corresponding to the thin inter atrial septum (red arrow). Note the aortic and mitral bioprostheses.

# Discussion

To the best of our knowledge, we present the first-reported clinical case of a 65-year-old female with atrial fibrillation who underwent a complex transcatheter LAAc through a trans-jugular approach after failure through the transfemoral approach. Although pre-operative planning revealed a rare type of LAA with a low insertion, it did not provide sufficient information to predict the failure of the first attempted procedure. However, using the novel approach of simulating the patient's anatomy with a 3D-printed model had many advantages including enabling an understanding of why the transfemoral approach failed, validation of the trans-jugular procedure, selection of the simple curve that had the most direct trajectory towards the LAA, confirmation that transseptal puncture was possible, determination of the angle of puncture and its anterior-superior location, selection of the most appropriate LAA device and had a very low cost compared with other printing methods. Transcatheter LAAc has emerged as valuable option in patients with atrial fibrillation and who have a contraindication for anticoagulants with bleeding requiring iterative transfusions (recommendations class IIb, level of evidence B),<sup>4</sup> as observed in this case study.

Procedure failure is a rare situation, but is more prevalent in patients with unusual and atypical LAA morphology. In this case study, the first attempted procedure failed because of the misalignment of the delivery sheath.<sup>5</sup>

The success rate of LAAc procedures improves from 88% in the original PROTECT AF trial<sup>2</sup> to 99% in the latest registries,<sup>6</sup> with higher event rates also being reported in real-world analyses.<sup>7</sup> Furthermore, some patients with unsuitable anatomy were excluded from these different trials.<sup>8</sup> It is important to note that the procedural success is dependent on the learning curve through precise, preprocedural planning, which includes the use of more widely available 3D CT guidance and 3D printing.<sup>5</sup>

To date, 3D printing has demonstrated the ability to guide prosthesis selection and device sizing, reduce procedure time and procedure



**Figure 2** Simulation using 3D-printed model. (A and B) Anterior and posterior view through a window cut in the posterior wall of the left atrium. Successful testing of the simple curve access sheath via the jugular vein and the superior vena cava (SVC). Note the perfect alignment with the LAA (blue arrow). (*C*) Appropriate deployment of a Watchman Flex prosthesis; good apposition without leak or bulging, in line with the LAA axis.



**Figure 3** Second procedure. (A) Fluoroscopy view: the single-curve sheath is correctly placed into the ostium of the LAA(\*) and fits its curvature as predicted by the testing on the 3D model. (B) TEE 3D view shows the same orientation of the sheath into the LAA. (C) TEE biplane view: Delivery of the Watchman Flex prosthesis (red arrow) in the axis of the LAA, resulting in an optimal position, without impairment of the mitral prosthesis (M).

failures, as well as the number of devices used per patient,<sup>9</sup> thus, it may be considered as a safety net in procedural planning awareness, particularly to assess procedural risk in patients with unusual anatomy.<sup>10</sup> Moreover, it accelerates the learning curve and predicts prosthesis implantation difficulties.<sup>11</sup> Therefore, a pre-operative approach based on a 3D-printed simulation in LAAc procedures was tested in a large national multicentric prospective registry—the LAA-Print French Registry (ClinicalTrials.gov; NCT03330210)—and defined a risk score that pre-identified a group of high-risk patients comprising patients with failed procedures, inappropriate implantation, and high complication rates.<sup>12</sup>

The 3D model has the challenge of mimicking the flexibility of tissues and creating a realistic model of the anatomy, not only of the LAA, but of the whole LA and surrounding structures. The SLS technology, which was used in this case study, has the advantage of a very high resolution (50 µm) and the capability to create a hollow structure without tissue support. The use of a TPU material resulted in a soft model that mimicked the *in vivo* LAA distensibility properties for a proper simulation of device positioning. An alternative occluder—an Amplatzer Amulet device (Abbott)—was considered. Simulation and device implantation testing on the 3D-printed model demonstrated an abnormal prosthetic disc overflow extending beyond the mitral prosthetic ring, contraindicating this option (see Supplementary material online, *Figure S2*).

In this case, the surgical approach was judged impossible because of significant pericardial and mediastinal adhesions already noted during previous open-heart surgery.

An alternative approach through a trans-jugular vein was considered. It has not been previously described for LAAc but has been a useful alternative in various transcatheter interventions on the atrial septum.<sup>13</sup> Simulation on the 3D-printed model showed that a single curved access sheath would align and make it easier to enter the LAA. However, transseptal puncture through the jugular approach access was another challenging step. The transseptal puncture was simulated accurately, therefore, due to the tangential angle (see Supplementary material online, *Figure S3*). It was successfully achieved using radiofrequency (RF) on the BRK needle with an activated RF catheter (wire connected to RF). The needle was protected by the SLO and was pulled out only for the tenting, meaning there was no risk during the jugular crossing.

## Conclusion

Transcatheter LAAc using a tailored trans-jugular approach is an option for unusual LAA morphology. Simulation with a 3D-printed models was highly useful to prepare and simulate this complex transcatheter procedure. The use of 3D printing could be recommended for LAAc for anticipated difficult cases (e.g. unusual anatomy or inappropriate orientation for delivering the sheath) or if there are questions about the best choice of prosthesis.

## Lead author biography



Dr Vlad Ciobotaru, MD, PhD is a formal resident medical student at the University Paris Descartes and researcher at the National Medical Research Unit, Inserm450 Paris, France. Dr Ciobotaru is a Clinical Fellow at the University Hospital of Paris; Clinical chief—Assistant MD at the Hospital of Paris European Hospital Georges Pompidou Paris and a cardiovascular specialist in cardiac imaging. He is the CEO of 3DHeartModeling, which provides 3D printing solutions on heart structures. He has received awards for his work from the ESC (2017) and the French Society of Cardiology (2019).

## Supplementary material

Supplementary material is available at European Heart Journal – Case Reports online.

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**Slide sets:** A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementarydata.

**Consent:** The authors confirm that written consent for submission and publication of this case report, including the use of images and associated text, has been obtain from the patient in line with COPE guidance. For supplemental videos, please see the online version of this article.

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#### Data availability

All data are incorporated into the article and its online supplementary material.

#### References

- 1. Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomström-Lundqvist C, Boriani G, Castella M, Dan GA, Dilaveris PE, Fauchier L, Filippatos G, Kalman JM, La Meir M, Lane DA, Lebeau JP, Lettino M, Lip GYH, Pinto FJ, Thomas GN, Valgimigli M, Van Gelder IC, Van Putte BP, Watkins CL; ESC Scientific Document Group. 2020 ESC guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): the task force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. *Eur Heart J* 2021;**42**:373–498.
- Reddy VY, Doshi SK, Sievert H, Buchbinder M, Neuzil P, Huber K, Halperin JL, Holmes D; PROTECT AF Investigators. Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-year follow-up of the PROTECT AF (Watchman left atrial appendage system for embolic protection in patients with atrial fibrillation) trial. *Circulation* 2013;**127**:720–729.
- Reddy VY, Gibson DN, Kar S, O'Neill W, Doshi SK, Horton RP, Buchbinder M, Gordon NT, Holmes DR. Post-Approval U.S. Experience with left atrial appendage closure for stroke prevention in atrial fibrillation. J Am Coll Cardiol 2017;69:253–261.
- 4. January CT, Wann LS, Calkins H, Chen LY, Cigarroa JE, Cleveland JC, Ellinor PT, Ezekowitz MD, Field ME, Furie KL, Heidenreich PA, Murray KT, Shea JB, Tracy CM, Yancy CW. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guide-line for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association task force on clinical practice guide-lines and the Heart Rhythm Society. J Am Coll Cardiol 2019;**74**:104–132.
- Glikson M, Wolff R, Hindricks G, Mandrola J, Camm AJ, Lip GYH, Fauchier L, Betts TR, Lewalter T, Saw J, Tzikas A, Sternik L, Nietlispach F, Berti S, Sievert H, Bertog S, Meier B. EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion—an update. *EuroIntervention* 2020;**15**:1133–1180.
- Landmesser U, Schmidt B, Nielsen-Kudsk JE, Lam SCC, Park JW, Tarantini G, Cruz-Gonzalez I, Geist V, Della Bella P, Colombo A, Zeus T, Omran H, Piorkowski C, Lund J, Tondo C, Hildick-Smith D. Left atrial appendage occlusion with the AMPLATZER amulet device: periprocedural and early clinical/echocardiographic data from a global prospective observational study. *EuroIntervention* 2017;**13**:867–876.

- Pison L, Potpara TS, Chen J, Larsen TB, Bongiorni MG, Blomström-Lundqvist C; Scientific Initiative Committee, European Heart Rhythm Association. Left atrial appendage closure-indications, techniques, and outcomes: results of the European Heart Rhythm Association Survey. *Europace* 2015;**17**:642–646.
- Lakkireddy D, Thaler D, Ellis CR, Swarup V, Sondergaard L, Carroll J, Gold MR, Hermiller J, Diener HC, Schmidt B, MacDonald L, Mansour M, Maini B, O'Brien L, Windecker S. Amplatzer amulet left atrial appendage occluder versus Watchman device for stroke prophylaxis (amulet IDE): a randomized, controlled trial. *Circulation* 2021; 144:1543–1552.
- Ciobotaru V, Combes N, Martin CA, Marijon E, Maupas E, Bortone A, Bruguière E, Thambo JB, Teiger E, Pujadas-Berthault P, Ternacle J, Iriart X. Left atrial appendage occlusion simulation based on three-dimensional printing: new insights into outcome and technique. *EuroIntervention* 2018;**14**:176–184.
- Ciobotaru V, Elsan HPLF, France N. Impact of a new access sheath shape in improving LAAC procedures: a study based on 3D printing simulation. J Am Coll Cardiol 2021;77:1143–1143.
- Wang DD, Qian Z, Vukicevic M, Engelhardt S, Kheradvar A, Zhang C, Little SH, Verjans J, Comaniciu D, O'Neill WW, Vannan MA. 3D Printing, computational modeling, and artificial intelligence for structural heart disease. JACC Cardiovasc Imaging 2021;14:41–60.
- Ciobotaru V, Combes N, Iriart X, Marijon E, Hascoet S, Nguyen A, Ternacle J, Defaye P, Jacon P, Lepillier A, Thambo JB, Teiger E, Cheneau E, Commeau P, Elbaz M. P2436 preliminary data from "LAA-print French registry": a large national multi-centric prospective registry evaluating a new preoperative approach based on 3Dprinted simulation in LAAC procedures. *Eur Heart J* 2019;40: ehz748.0768.
- Hascoet S, Fraisse A, Elbaz M. Successful percutaneous transcatheter patent foramen ovale closure through the right internal jugular vein using a steerable catheter. *Catheter Cardiovasc Interv* 2013;82:E598–E602.