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ORIGINAL INVESTIGATION

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First-in-human experience of left atrial appendage occlusion with the steerable FuStar sheath

Caroline Kleinecke MD[1] | Omar Gomez Monterrosas MD[2] | Giancarla Scalone MD[2] | Yat-Yin Lam[3] | Eun-Seok Shin MD[2] | Barbara Bellmann MD[4] | Johannes Brachmann MD[1] | Jai-Wun Park MD[1,2,3]

[1] Department of Cardiology, Klinikum Coburg, Coburg, Germany

[2] Department of Cardiology, Dietrich-Bonhoeffer-Klinikum, Neubrandenburg, Germany

[3] Department of Medicine and Therapeutics, Prince of Wales Hospital, Hong Kong

[4] Department of Cardiology, Charité Berlin – University Medicine, Campus Benjamin Franklin, Berlin, Germany

Correspondence
Caroline Kleinecke, MD, Department of Cardiology, Coburg Hospital, Ketschendorfer Straße 33, 96450 Coburg, Germany.
Email: carolinekleinecke@web.de

Background: Due the wide variability of left atrial appendage morphology left atrial appendage occlusion (LAAO) remains a challenging procedure. The steerable FuStar delivery sheath was designed to allow both, transseptal access and delivery of percutaneous devices. We here report the first-in-human experience of LAAO with the FuStar sheath.

Methods: Twenty patients (76.6 ± 8.4 years; 12 (60%) males; CHA_2DS_2-VASc score: 5.0 ± 2) with non-valvular fibrillation and contraindications to oral anticoagulation underwent LAAO with the LAmbre device using the FuStar steerable sheath (Lifetech Scientific Corp., Shenzhen, China) at two german centers.

Results: Successful device implantation was achieved in all patients (100%). No periprocedural complications were observed. Procedure time, fluoroscopy time, contrast media, and radiation dose were 23.4 min ± 9.2, 11.9 min ± 4.1, 96.2 mL ± 45.7, and 2718.4 cG*cm^2 ± 3835.3, respectively.

Conclusion: This study demonstrates the feasibility and safety of the steerable FuStar sheath for LAAO.

KEYWORDS
atrial fibrillation, left atrial appendage occlusion, steerable FuStar sheath, stroke prophylaxis

1 | INTRODUCTION

Left atrial appendage (LAA) occlusion (LAAO) is an established alternative to oral anticoagulation (OAC) for stroke prevention in patients with high stroke risk and contraindications to long-term oral anticoagulation. Two randomized trials have shown non-inferiority and a significant reduction of bleeding events of LAAO compared to warfarin.[1–3] Large real-world, multi-centre studies reported high implant success and low periprocedural complication rates for the contemporary Watchman (Boston Scientific, Marlborough, MA)[4,5] and Amulet device (St. Jude Medical, Saint Paul, MN).[6] The LAmbre LAA occluder (Lifetech Scientific Corp., Shenzhen, China) was recently introduced into clinical practice. In two registries of 152[7] and 30[8] patients safety and efficacy of this device was demonstrated up to 12-months. Due to the wide variability of left atrial appendage morphology LAAO is still a challenging procedure and strategies to simplify and streamline the procedure are required.

The steerable FuStar sheath (Lifetech Scientific Corp.) was designed to allow and facilitate both, transseptal access and delivery of percutaneous devices.

Abbreviations: ASD, atrial septum defect; AF, atrial fibrillation; LA, left atrium; LAA, left atrial appendage; LAAO, left atrial appendage occlusion; OAC, oral anticoagulation; PFO, persistent patent foramen ovale; TEE, transesophageal echocardiography; TIA, transient ischaemic attack; TTE, transthoracic echocardiography.

Relationships with industry: Lecture and proctoring honorarium provided by Lifetech Scientific Corp., Shenzhen, China to J.-W. Park.

With use of the FuStar sheath for LAAC, exchange of the transseptal puncture set and the delivery sheath is not necessary any more. This is of potential benefit in reducing procedure time, radiation exposure, air embolisation, pericardial tamponade, or LAA perforation.

With its 0-180 degree deflectable distal end, it facilitates coaxial alignment between sheath and LAA for easy delivery of the occluder.

This study is the first to investigate feasibility and safety of the steerable FuStar sheath in patients with non-valvular atrial fibrillation undergoing LAAO.

2 | METHODS

Twenty consecutive patients who underwent LAAO with the LAmbre device (Lifetech Scientific Corp.) using the dedicated FuStar sheath (Lifetech Scientific Corp.) were retrospectively enrolled in the study. The LAmbre LAA occluder is described in detail elsewhere.[9] Thirteen patients underwent LAAO at the Department of Cardiology, Klinikum Coburg, Germany between January and July 2014 and seven at the Department of Cardiology, Dietrich-Bonhoeffer-Klinikum, Neubrandenburg, Germany between July and August 2017. Patient characteristics, procedural and adverse events were collected in a dedicated database. Eligibility criteria for LAAO were non-valvular atrial fibrillation (paroxysmal, persistent, or permanent) with a CHA_2DS_2-VASc score ≥ 1 and a contraindication for anticoagulation or the patient's explicit request for LAAO as alternative to OAC. Exclusion criteria were thrombus in the LAA, planned cardiac surgery, previous closure of the interatrial septum by surgery or device implantation, active endocarditis or other serious infections. All patients provided written informed consent before the procedure. The present study is investigator driven and was not sponsored by any company.

2.1 | FuStar sheath

The steerable FuStar introducer (Lifetech Scientific Corp.) was designed to deliver percutaneous devices like persistent foramen ovale (PFO), atrial septum defect (ASD) or LAA occluders and vascular plugs. It comprises the deflectable sheath, a dilator, a loader, and a delivery cable (Figure 1). It is available in eight sizes (inner lumen 5, 6, 7, 8, 9, 10, 12, and 14 French) and four lengths (550, 700, 800, or 900 mm). The deflectable distal end is available in 3 or 5 cm. During fluoroscopy, the it is visible through a radiopaque marker band. The distal end of the sheath can be deflected from 0 to 180 degrees (5-10 French) or from 0 to 90 degrees (12-14 French) by rolling a knob at the handle clockwise and anticlockwise (Figure 2). The LAmbre device can be screwed onto the delivery cable and retracted into the loader.

In the present study all sizes of the LAmbre device were delivered by a 10 French sheath with a length of 80 cm.

2.2 | Procedural details

All procedures were performed by a single operator (Jai-Wun Park, >500 procedures).

Transesophageal echocardiography (TEE) was done before and during the procedure to rule out LAA thrombus formation and pericardial effusion, to determine LAA dimensions, to guide transseptal puncture, and to ensure device success.

The 10 French FuStar sheath with a length of 80 cm was advanced with the introducer via a soft J-tipped 0.035 inch wire from the right femoral vein into the right atrium. Transseptal puncture was performed under fluoroscopic and TEE guidance using a BRK-1 needle (St. Jude Medical) with a length of 98 cm. After successful puncture, heparin was administered to achieve an activated clotting time >250 s. The

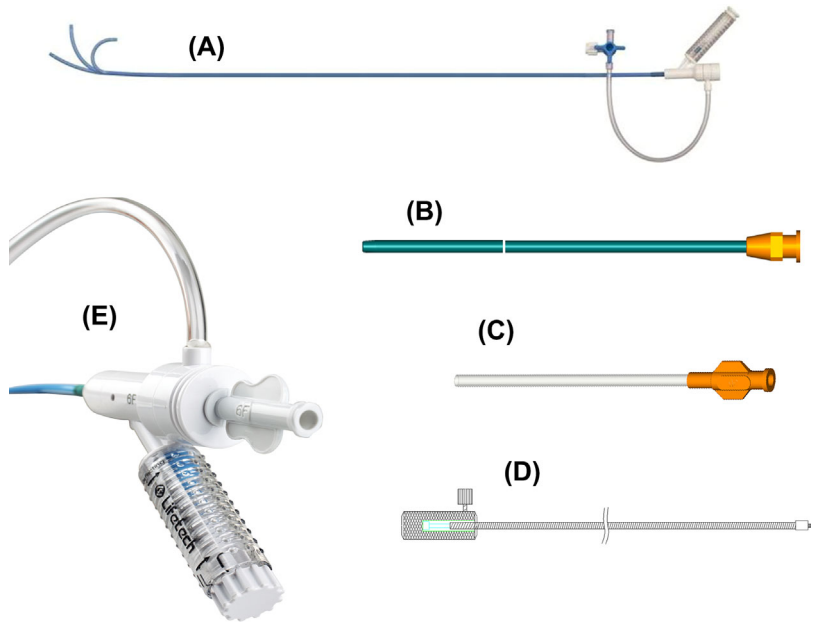

FIGURE 1 Steerable FuStar introducer. Schematic drawings of the steerable sheath (A), dilator (B), loader (C) and delivery cable (D). (E) Handle of the sheath with knob and dilator

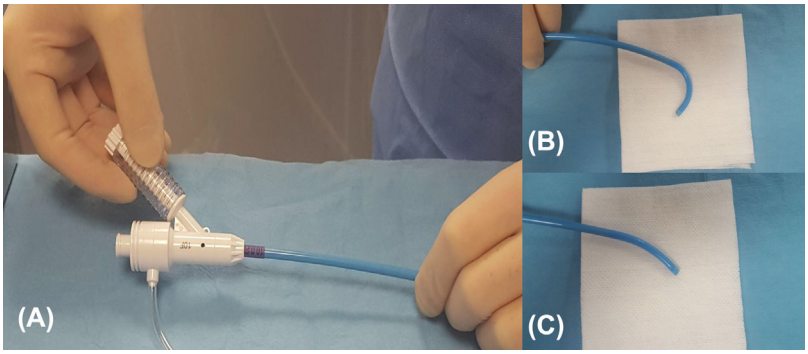

FIGURE 2 Rolling the knob at the handle clockwise and anticlockwise (A) deflects the distal end of the sheath (B and C)

transseptal needle and dilator were removed and exchanged for a 5F pigtail catheter. The FuStar sheath was then advanced to the LAA ostium and the pigtail catheter positioned into the LAA. For device sizing, LAA angiography was performed in right anterior oblique caudal and cranial projections, and both angiographic and echocardiographic measurements were taken into account for choosing the correct device size. The appropriately-sized LAmbre device (usually 4 to 8 mm larger than the measured LAA ostium) was attached to the delivery cable and retracted into the loader. The hole system was flushed carefully.

Next, the FuStar sheath was placed into the opening zone of the LAA. For optimal device positioning the end of the sheath was deflected until an coaxial alignment between sheath and LAA was achieved. Then, the loader with the LAmbre device was advanced through the FuStar sheath. The device was positioned into the landing zone and deployed. To ensure an adequate device stability, a tug test was performed under fluoroscopy. Finally, the device was released (Figure 3).

After the procedure, all patients received dual antiplatelet therapy with aspirin and clopidogrel for 3 months, followed by aspirin alone.

2.3 | Definitions

Implantation success was defined as correct placement of the LAmbre occluder in the LAA.

Periprocedural adverse events included death (<72 h after the index procedure), stroke/TIA, device embolisation, cardiac tamponade or pericardial effusion, fatal or major bleeding, myocardial infarction, systemic embolism, pericarditis, and other relevant complications leading to prolonged hospital stay.

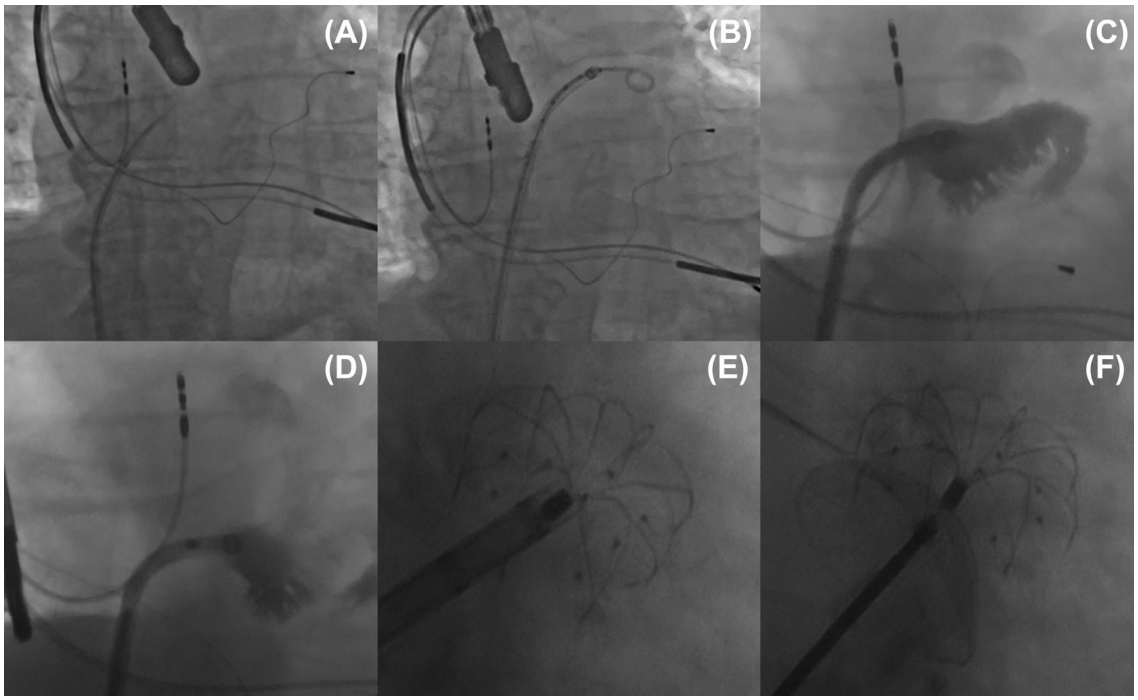

FIGURE 3 Left atrial appendage occlusion procedure with the FuStar sheath. (A) Transseptal puncture via the FuStar sheath using a BRK-1 needle (St. Jude Medical, Minnesota, USA) with a length of 98 cm. (B) Advancement of the FuStar sheath to the LAA ostium and positioning of the pigtail catheter into the LAA. (C) Angiogram of left atrial appendage. (D) Placement of the FuStar sheath into the opening zone of the LAA and advancement of the loader with the LAmbre device through the FuStar sheath. (E) Unsheathing of the umbrella of the LAmbre occluder. (F) Angiogram after fully deployment of the LAmbre device

TABLE 1 Baseline characteristics

	n = 20
Age (years)	76.6 ± 8.4
Male	12 (60%)
BMI (kg/m^2)	30.4 ± 6.9
Permanent atrial fibrillation	11 (55%)
CHA_2DS_2-VASc score	5.0 ± 2
HAS-BLED score	3.7 ± 1.3
Indication for LAAO[a]	
Recent bleeding under OAC	11 (55%)
Increased bleeding risk	5 (25%)
Patients choice	3 (15%)
Stroke under OAC	1 (5%)
Previous stroke/TIA	6 (30%)
Prior myocardial infarction	6 (30%)
Prior PCI/CABG	7 (35%)
Left ventricular ejection fraction (%)	56.4 ±9.2
Arterial hypertension	12 (60%)
Diabetes mellitus 2	6 (46.2%)
GFR (mL/min)	54.7 ± 23.6
Peripheral artery disease	3 (23.1%)
Hyperlipidemia	9 (69.2%)
Patent foramen ovale	None
Atrial septal defect	None

Categorical variables are expressed as frequencies (n) and percentages (%). Continuous data are reported as means and standard deviation.
BMI, body mass index; CABG, coronary artery bypass grafting; LAAO, left atrial appendage occlusion; OAC, oral anticoagulation; TIA, transient ischemic attack; PCI, percutaneous coronary intervention.
[a]Several patients had multiple indications for LAAO.

TABLE 2 Procedural data

	n = 20
Successful implantation	20 (100%)
Transseptal puncture	20 (100%)
Resizing of the device	0
Size of LAmbre device	
16-22 mm	1 (5%)
18-24 mm	1 (5%)
22-28 mm	1 (5%)
22-34 mm	1 (5%)
24-30 mm	2 (10%)
26-32 mm	3 (15%)
28-34 mm	3 (15%)
22-34 mm	1 (5%)
30-26 mm	1 (5%)
30-36 mm	4 (20%)
34-38 mm	1 (5%)
36-40 mm	1 (5%)
LAA diameters	
Orifice (mm)	21.7 ± 6
Landing zone (mm)	21.2 ± 4.7
Depth (mm)	32.9 ± 10.8
Number of LAA lobes	
Single lobe	8 (40%)
Two lobes	6 (30%)
Three lobes	4 (20%)
Four lobes	1 (5%)
Five lobes	1 (5%)
LAA thrombus	None
Procedure time (min)[a]	23.4 ± 9.2
Fluoroscopy time (min)	11.9 ± 4.1
Contrast media (mL)	96.2 ±45.7
Radiation dose (cG*cm^2)	2718 ± 3836

Categorical variables are expressed as frequencies (*n*) and percentages (%). Continuous data are reported as means and standard deviation. LAA, left atrial appendage.
[a]Time from transseptal puncture to delivery of the device.

2.4 | Statistical analysis

Categorical variables are expressed as frequencies and percentages. Continuous data are reported as means and standard deviation. All statistical analyses were performed using IBM-SPSS version 24 (IBM Corp.)

3 | RESULTS

A total of 20 patients (76.6 ± 8.4 years; 12 (60%) males) underwent LAAO using the FuStar sheath. Baseline and procedural characteristics are shown in Tables 1 and 2. A total of 11 (55%) patients had permanent atrial fibrillation, the mean CHA_2DS_2-VASc score was 5.0 ± 2.

Implantation success was achieved in all 20 procedures (100%). Procedure time, fluoroscopy time, contrast media, and radiation dose were 23.4 min ± 9.2, 11.9 min ± 4.1, 96.2 mL ± 45.7, and 2718.4 cG*cm^2 ± 3835.3, respectively. Periprocedural adverse events were not observed.

4 | DISCUSSION

This study is the first to demonstrate the feasibility and safety of the FuStar sheath (Lifetech Scientific Corp.) for LAAO with the LAmbre LAA occluder.

Successful device implantation was achieved in all procedures without periprocedural adverse events.

The LAA is commonly directed anterosuperiorly, or less frequent inferoposteriorly. Depending on its shape with one or more lobes and on its bending, it is classified as chicken wing, cactus, windsock, cauliflower, large double lobe, or cone-shaped lobe.[10,11]

Due to this complex and widely heterogeneous morphology and topography of the LAA, in selected cases like the anterosuperiorly directed chicken wing, LAAO can be a challenging procedure.

Lange et al[12] described a case of successful LAAO with an Amplatzer Amulet device using a 12 French steerable Destino-Guiding-Sheath (OSCOR Inc., Palm Harbor, FL). LAAO of an LAA in a very anterior superior position had been failed in first attempt using the regular 12 French AMPLATZER-TorquVue™-Delivery-Sheath (St. Jude Medical). With the help of the Destino-Guiding-Sheath an optimal coaxial position for device delivery could be achieved.

For most optimal device-, technical and procedural success a coaxial alignment of the delivery sheath into to the LAA is vital.

Usually, this can be achieved by a transseptal puncture at the optimal puncture site—in most of the cases in inferoposterior position of the fossa ovalis. However, sometimes alignment of sheath and LAA is difficult and prolongs the interventions by need of an additional transseptal puncture, change of the delivery sheath or more risky maneuvers like steering the sheath with a stiff wire including the risk of LAA perforation. The 0-180 degree deflectable distal end of the FuStar sheath facilitates coaxial alignment between sheath and LAA for easy delivery of the occluder.

Originally, the steerable FuStar sheath was designed to deliver percutaneous devices like atrial septum defect (ASD) or persistent foramen ovale (PFO) closure devices or vascular plugs.

Lu et al[13] examined feasibility of the FuStar sheath for embolization of peripheral vessels with the Cera vascular plug in a porcine model.

For embolization of peripheral vessels the use of the FuStar sheath was feasible and safe. Furthermore, compared with the standard introducer, plug embolization through the FuStar steerable sheath was associated with shorter fluoroscopy times and less contrast medium.

In this study the average procedure time, fluoroscopy time, contrast media and radiation dose were 23.4 min ± 9.2, 11.9 min ± 4.1, 96.2 mL ± 45.7 and 2718.4 cG*cm^2 ± 3835.3, respectively. A potential bias comparing those procedural results with other registry studies may be the highly experienced single operator. Procedure time in our registry was shorter than in other series using the LAmbre occluder and a double-curve delivery sheath. These series with 153[7] and 30[8] patients reported a procedure time of 66.0 ± 24.0 and 29.0 ± 10.1 min. Nevertheless, in the registry of 153 patients less contrast media (84 mL) was needed, and in the registry of 30 patients fluoroscopy time was shorter (3.5 ± 1.9 min). In comparison the Watchman post-approval U.S. registry[5] with 3653 patients reported a median procedure time of 50 min and Kosikas et al[14] a fluoroscopy time of 20.1 min for LAAO with Amplatzer devices. A series of LAAO with 25 patients[15] using the Amulet device and the dedicated Amplatzer sheath reported an average fluoroscopy time of 19.8 ± 8.7 min, although in three procedures a combined procedure with atrial septal defect closure was performed. Performance of the FuStar sheath compared to other delivery sheaths for LAAO has to be evaluated in randomised trials.

Another potential benefit to obviate the exchange of transseptal and delivery sheath is to avoid adverse events like air embolism, pericardial effusion, or tamponade and LAA perforation although this risk is minimized if change of the sheath is performed over a stiff wire in the left upper pulmonary vein. Air embolization leading to stroke, pericardial perfusion or tamponade and LAA perforation are dreaded periprocedural complications, although recent published real-world registries with 3822 patients and 1088 patients reported low complication rates for the Watchman device[5] (1.7%) and for the Amulet device[16] (3.2%). As a purely preventive treatment without immediate benefit for the patient, it is mandatory to develop strategies to simplify the LAAO procedure and keep the rate of complications as low as possible.

4.1 | Limitations

The results of the present study must be interpreted cautiously. Sample size was small and the retrospective and observational character of the study design does not exclude selection bias.

On the other hand, it reflects an unselected real-world cohort. High operator experience in this study may not reflect clinical practice in other catheterizations laboratories with multiple operators being partly on their learning curves. Since this study is observational and has a non-randomized design comparison cannot be drawn to other delivery sheaths for LAAO.

Furthermore, the use of the FuStar sheath was confined to the LAmbre device only. The usefulness of a steerable sheath for established LAAO devices has to be evaluated in future studies.

5 | CONCLUSIONS

This study represents our initial experience with the steerable FuStar sheath for LAAO with the LAmbre LAA occluder. It demonstrates its feasibility and safety. Further studies with larger numbers of patients and randomised-controlled trials will be needed to confirm the usefulness of the FuStar sheath for LAAO in patients with non-valvular atrial fibrillation.

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Drs Kleinecke, Monterrosas, Scalone, Lam, Shin, Bellmann, Brachmann and Park took part in the data evaluation and in the planning, writing, revising, and reviewing the final draft of this manuscript. All co-authors contributed fully in terms of the design of the study, the evaluation of data, the actual manuscript preparation, and the revision and approval of the final submitted manuscript. As the corresponding author, Dr Kleinecke confirms that all authors have seen and approved the final text.

AUTHORSHIP DECLARATION

All authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors. All authors are in agreement with the manuscript.

CONFLICTS OF INTEREST

Jai-Wun Park and Yat-Yin Lam received personal fees (honorarium for lecture and proctoring) from LifeTechScientific Corporation, outside the submitted work. The other authors have no conflicts of interest to declare.

ORCID

Caroline Kleinecke http://orcid.org/0000-0002-6814-5236
Omar Gomez Monterrosas http://orcid.org/0000-0001-8166-8296

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