

A CHALLENGING LEFT ATRIAL APPENDAGE OCCLUSION GUIDED BY 3D-PRINTED HEART MODEL AND TRANS SEPTAL PUNCTURE SIMULATION USING THE BIOMODEX BIOREALISTIC HAPTIC SIMULATORS.

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Background:

Structural cardiology is booming. More and more innovative and complex procedures are being performed every day. At the same time, the era of 3D printing and procedural simulation is upon us.¹⁻³

We faced a left atrial appendage occlusion (LAAO) failure, related to complex anatomy. The LAA presented in reverse chicken wing (Figure 1A) and the left atrium was extremely dilated. We used preprocedural imaging analysis, including multi-slice computed tomography (MSCT) to prepare the case and analyze the catheter trajectory. Despite several (4) different transseptal punctures under transesophageal echocardiography (TEE) and the use of an Amplatzer steerable delivery catheter (Abbott Vascular) we were unable to bring the Abbott sheath to the LAA ostium.

Therefore, we decided to use a patient-specific 3D printed model, created from the patient's MSCT, inclusive of the initial transeptal punctures, in order to rehearsal the specific case in conjunction with two of the Biomodex Biorealistic Haptic Simulators. We used the **Biomodex® LAACS™** Station to rehearse the femoral approach and the pre-determined optimal transseptal puncture sites. We also used the **Biomodex® TRACS™** Station to rehearse the transjugular approach on the same anatomy. This allowed us to choose the best option and be fully prepared for both case scenarios.

<u>Methods</u>:

The objectives of the rehearsal were to simulate and identify the 1) best trans-septal puncture, 2) the positioning of the delivery catheter, 3) the implantation and 4) sizing of the Amulet device (Abbott Vascular).



The 3D model reproduces the anatomy from the patient's MSCT images (Figure 1B) which allows to tackle the anatomical challenges we encountered during the initial patient case. This specific BIOMODEX cartridge includes unique technologies implementing biomechanical (Invivotech® Materials) and acoustic properties (Echotech[™] Imagery) to the model, making it clearly visible under TEE

imaging and providing impressive tactile feedback to the operator.⁴

The **Biomodex® LAACS™** (Left Atrial Appendage Closure Solution) is a platform designed by BIOMODEX (Paris, France) for simulation-based rehearsal of transcatheter left atrial appendage occlusion, using the 3D model, via femoral approach.

The **Biomodex® TRACS™** (TRAnscatheter Cardiac Solution) is the new evolution of the LAACS system, allowing the simulation via jugular approach.

We therefore planned 3 simulations, the first one to choose the best trans septal puncture area, the second one to simulate all the steps of a real procedure using the femoral route and the last one to rehearse the procedure using the jugular route. All these simulations were thoroughly guided with TEE imaging, to visualize the different key views necessary to obtain the optimal transseptal puncture for a successful LAA Occlusion.

<u>Results</u>:

The first simulation allowed us to test several trans-septal puncture areas, in order to obtain an optimal alignment of the delivery catheter and the ostium of the LAA. We previously identified 4 possible transseptal puncture areas on this very large inter atrial septum (Figure 1B). We found out that the puncture should be performed low and slightly anterior.

The second simulation was performed in the cath lab, at the Paris Centre Cardiologique du Nord, to reproduce all the steps of the real procedure, using the femoral approach, under TEE and fluoroscopic guidance. (Figure 1C).

We used an SL1 sheath and a standard transeptal puncture needle. We immediately tested the low and slightly anterior transeptal puncture, identified during the first simulation. This puncture allowed us to wire the LAA, then align the standard delivery catheter (Abbott Vascular) to the LAA ostium (Figure 1E) and finally implant a 31mm Amulet device (Abbott Vascular) without difficulty and with optimal sizing and positioning (Figure 1F).

The third simulation was performed at Biomodex's headquarters in Paris with the support of the new Biomodex platform (TRACS) using TEE guidance, via the jugular approach. We used the same equipment as for the second simulation. The trans-septal puncture was performed quite low and allowed us to go directly into the LAA by leaning on the bottom of the left atrium (Figure 1D). We could observe, looking directly at the model, that the sheath was naturally



oriented towards the orifice of the LAA. We also managed to position successfully the 31mm device easily.

Based on the success of the three simulations, we rescheduled the procedure. We planned to perform the transseptal puncture using a dedicated radiofrequency (RF) guidewire (0.035" VersaCross RF System, Baylis Medical) to maximize our chances of performing it at the desired location identified during the simulations. Finally, the procedure was performed via the femoral route, the very low, slightly anterior transeptal puncture was spotted on TEE and done easily using the Versacross guide. The standard delivery catheter was placed immediately in front of the LAA ostium (Figure 1G) and the 31mm Amulet device was optimally deployed on first attempt (Figure 1H).

Comparing the first patient LAAO procedure with the second procedure after simulation, the second procedure lasted about twenty minutes (versus two hours the first attempt), only one transeptal puncture was necessary (versus four the first time), the Amulet prosthesis was successfully implanted, and the patient outcome is good.

Discussion:

In this short report we present a complex case of LAAO made possible by procedural simulation with a patient-specific 3D printed model.

The different simulations of the procedure allowed us to verify our hypotheses regarding the best transseptal puncture zone. Thus, we obtained the best possible alignment of the delivery catheter with the ostium of the LAA, with both, trans femoral and trans jugular approaches. Thanks to the BIOMODEX® BIOREALISTIC HAPTIC SIMULATORSTM and their unique combination of patient specification and echogenicity, we were also able to identify the TEE views and proper angles, which were necessary to locate this unusual transseptal puncture. In the end, we were able to perform the procedure with a single transseptal puncture and device deployment, drastically reducing the procedural risks.

Conclusion:

Procedural rehearsal using BIOMODEX® BIOREALISTIC HAPTIC SIMULATORSTM coupled with patient-specific 3D printed model derived from the computed tomography and guided with realistic TEE and fluoroscopic imaging, allowed us to easily perform a complex LAA occlusion.