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SimCardioTest - Simulation of Cardiac Devices & Drugs for in-silico Testing and Certification

Technical Report

D 2.2: Demonstration of several catheters simulated and real ones

Work Package 2 (WP 2)

Pacing leads and catheters

Task Lead: Inria & Microport
WP Lead: Université Bordeaux, France

PUBLIC

DELIVERABLE INFORMATION

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EXECUTIVE SUMMARY

This report describes the deliverable due at M18, concerning WP2 and specifically UC1 (pacing devices and leads). The deliverable D2.2 has been met by producing a video demonstrating two different scenarios:

1. Impact of plasticity and tip curvature on navigation in a static anatomy
2. Impact of cardiac motion on navigation, with dedicated robot

Methodological requirements and techniques are detailed in the dedicated section.

1- Introduction

Use case 1 (UC1), aims to quantify mechanical and electrical properties of cardiac stimulation devices using computer models and simulation. The computer model credibility in this context of use will be assessed by means of verification and validation, and it will be implemented on the SimCardioTest cloud-based platform for in-silico trials.

UC1 focuses on bradycardia leads, and aims to design a numerical workflow that may be later extended to other implantable devices. It consists of two computational pipelines, which aim at addressing questions on: the pacing and sensing performances of the lead on one side, and its navigation possibilities, and long-term mechanical fatigue on the other side. The mechanical model is implemented inside the SOFA (www.sofa-framework.org) simulation framework, and consists of solving equations of motion, deformation and interaction using standard finite element methods. While the behavior of the lead is explicitly modeled, in order to estimate strain/stress quantities inside it, the anatomy is approximated by a simple compliant behavior. The electrical pacing model will run on simplified geometries, whereas the mechanical and the electrical sensing ones will run at first on a small set of cardiac geometries and vessel trees (access path) obtained from clinical images. This set is expected to enlarge with time in order to be more representative for in-silico trials.

2- Objectives

This report focuses on the first proof of concept (POC) of the numerical approach that we conceived to assess the mechanical performances of the device (namely, the pacemaker lead).

After having presented the draft design of the numerical tool within the deliverable D2.1 on standardization, we have been working on its technical implementation since the beginning of this year (2022). This document explains how the simulations visible on the demo video were actually designed. They aim at reproducing a quasi-realistic case of insertion, both in a numerical model, and in a 3D printed accessory phantom.

The actual nature of the simulation model, and experimental phantom is explained in the video interviews created by two experts working on this specific topic:

- Camille Krewcun, Post-Doctoral researcher at Inria Lille – Northern Europe (team DEFROST), working on the implementation of the numerical simulations (https://www.youtube.com/watch?v=wSj6KdsO9RA);
- Stefan Escaida Navarro, Research Engineer at Inria Lille – Northern Europe (team DEFROST), working on the development of 3D printed replicas of the anatomical parts, using soft robotics and numerical simulation to replicate anatomical motion (https://www.youtube.com/watch?v=jZ7ERc7qtZQ).

Of course, tool design has just started. Improvement and refinement are certainly needed and ongoing.

3- Methodologies

This section describes the material and methods adopted, and details the simulation and real experimental approaches for each of the two scenarios.

The mechanical model for the lead and a supporting stylet, as well as the simulation scenarios, are implemented inside the simulation software SOFA (Simulation Open Framework Architecture), under the terms of GNU LGPLv3 open source license (https://github.com/sofa-framework/sofa/). The software provides a set of classic Finite Element Method (FEM) tools used for different aspects of the simulation (equation solving, collision detection and handling, rendering, etc).

The main features of the simulation video attached to this report are described below. Note that most features are common to both the static geometry and the beating geometry scenarios.

a. Scenario 1: Static model

Simulation

- *Simulated scenario*

  The demonstration simulation represents the navigation of a bradycardia lead inside an artificial heart phantom. In real interventions, a metallic stylet is inserted inside the lead body to aid its navigation, and removed once the lead has reached its target location. In the simulation, we use a single instrument model, representing a homogenized version of the lead and stylet assembly. The mechanical behavior of this virtual instrument is set to approximate the composite behavior of both the lead and the stylet. The video illustrates the different models used in the simulation in order to compute mechanics, quantify contact forces with the compliant anatomy, and handle collisions.

  In the case of the static geometry, two scenarios are simulated. The first one corresponds to a lead navigation for which the stylet is not given a curved shape beforehand. In this scenario, the available navigation actions (push, pull, and rotate) are not sufficient to make the instrument enter the right ventricle. In the second scenario, the instrument is pre-shaped with a slight curvature, similarly to what a physician would do with a stylet in practice. Thanks to this initial curvature, it is now possible to navigate the instrument all the way to the right ventricle. These two simulations reproduce qualitatively the same phenomenon when they are observed by navigating a lead inside a 3D printed silicon phantom with the same geometry. The corresponding experiment is described in the experiment section below. These comparisons also highlight the importance of the plastic deformation applied on the stylet during navigation.

- *Geometries*

  The instrument geometry is modeled using beam finite elements, characterized by their length and cross-section shape (in this case, circular).

  In the case of the static geometry, the simulation is run with the CAD design used initially to 3D-print the heart phantom. Starting from this CAD design, an opening was created at the location of the phantom where the lead and stylet are introduced. Only the internal surface is used in the computations (*cf* next paragraph for details).

- *Mechanical models*

  The instrument is simulated with a Cosserat beam mechanical model (see [1] for details), associated with a plasticity model to represent the stylet behavior. The plasticity model is still under development, and expected to be published in a journal article.

The anatomy is represented by its inner surface, meshed with triangles, and used for collisions. This surface is deformable, but with an approximated, stiff, piecewise linear compliance, so that we are able to deduce the forces acting on the anatomical wall during lead navigation.

- *Interactivity*

  In the simulation, the navigation is performed interactively by a non-specialist user. The user uses a keyboard to run a sequence of actions chosen among: push or pull the instrument, rotate it clockwise, or counterclockwise. These actions are similar to the available options for the physician during a real intervention.

Experiment

The experiment corresponding to that scenario makes use of the following tools:

- A 3D printed static silicon anatomy (**Figure 1**) consisting of:
  - left and right subclavian veins (LSCV and RSCV),
  - left external jugular vein (LEJV),
  - left internal jugular vein (LIJV),
  - superior and inferior vena cava (SVC and IVC),
  - right atrium (RA),
  - right ventricle (RV),
  - pulmonary trunk with left and right pulmonary arteries (LPA and RPA).

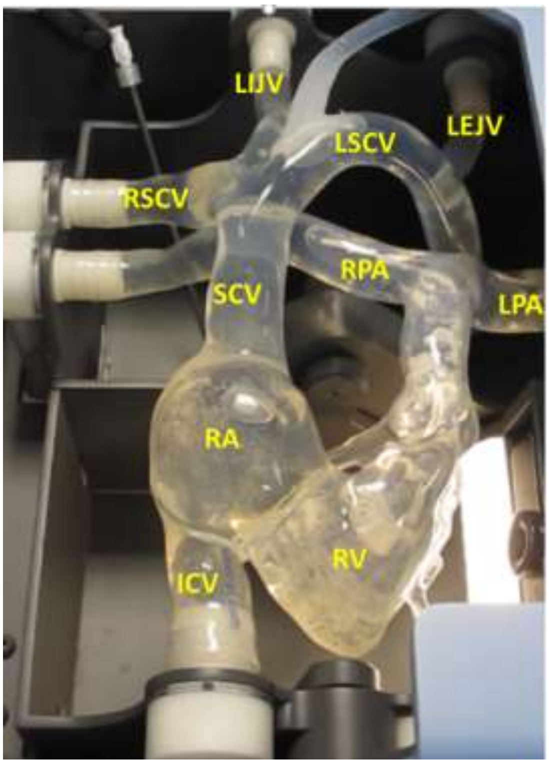

Figure 1: 3D printed static anatomical model, made of silicone.

The phantom is placed within a sealed mock-loop circulation bench test, with water filling the model. This phantom was developed as part of the European Union's Horizon 2020 innovation action under the Fast Track to Innovation Pilot grant agreement AXONE No 737817. Commercial lead: model VEGA™ (**Figure 2**), model reference Vega52 TRF563099

Figure 2: MicroPort commercial lead (VEGA™).

- Stylet: model soft 0.35 L52 tampered, SO-82-030Z-B
- Camera: model CANON PowerShot G12, PC1564, NO. 2820503010855

The video shows the insertion and navigation of the lead within the silicone phantom, while water is filling the model. One operator manipulates the lead; another one records all the steps from the lead access to its arrival at the RV apex. Lead fixation is not being performed so as not to harm the wall with the screw.

Multiple views are being provided to better appreciate the lead behavior within the vascular path.

b. Scenario 2: Dynamic model

Simulation

- *Simulated scenario*

In this scenario, the lead model is the same as in the static anatomy case. However, the anatomical geometry is the one of a beating heart phantom prototype, developed by the DEFROST team at Inria Lille, also in the context of the SimCardioTest project.

- *Mechanical models*

The mechanical models are mostly identical to the static geometry case. The main difference is that the virtual membrane, representing the reference position for the deformable surface, is assigned successive positions over time, instead of remaining still. These positions correspond to the motion of a simulated phantom, which changes shape according to imaging data (see below). The positions correspond to a discretization of the heart motion during a heartbeat. For this deliverable, the data are extracted from an electro-mechanical simulation of the heart, but in the long term, patient-specific images will be used instead.

Experiment

The corresponding experiments are carried out using an animated phantom, whose motion is controlled in such a way that it deforms according to the motion of a real heart. Such a motion may be acquired from medical imaging, or by computer simulation. After a processing step, the motion of the heart is expressed as a succession of point clouds or meshes. The phantom is based upon one frame of the data. Then, in SOFA, a sequence of actuation can be found such that the deformation of the phantom best matches the data. In the current version of the phantom, the actuation consists of a rigid robot arm, providing 6D motion, and a series of cables attached to the walls, as visible on Figure **3**. The last part of the video shows also the motion of the phantom. **Figure 4** shows a newer version of the phantom that includes vein models (not yet realized in hardware). The (simulated) motion of this phantom is the basis of the lead navigation in the dynamic model. Having the real phantom and its digital twin will allow us to study the mechanical model of the lead by comparing a navigation scenario in the real phantom to the corresponding navigation in simulation.

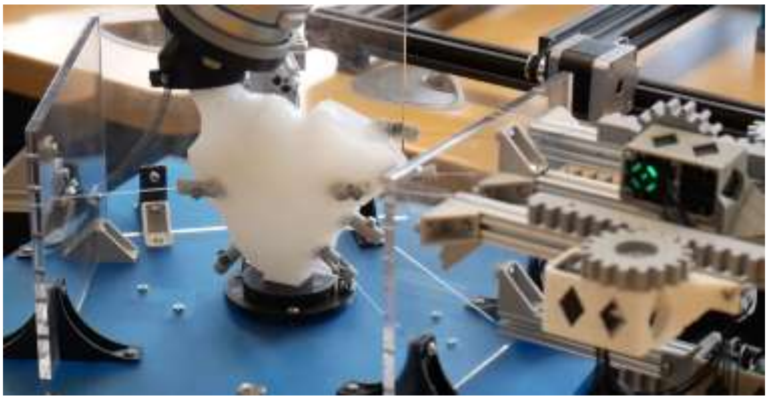

Figure 3: Prototype of a phantom for the right ventricle actuated by a rigid robot arm and cables (see also the corresponding video).

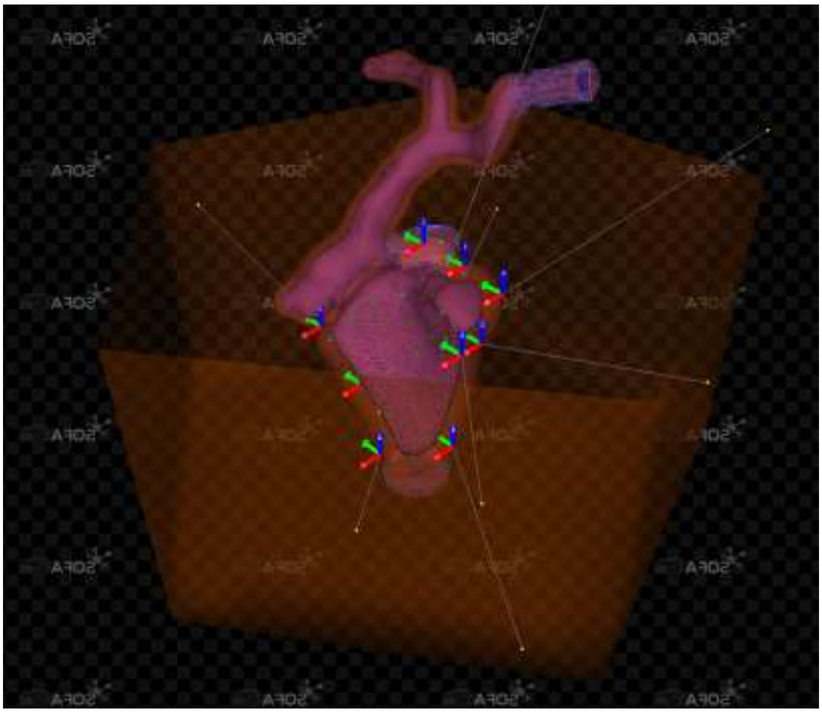

Figure 4: A view of the current phantom design (including vein models) in simulation.

4- Results

The demonstration video described in this report is publicly visible by following the links:

https://youtu.be/auY_qdaOu_w

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This video is divided into four main sequences. The first two sequences refer to a navigation scenario in a static anatomical geometry, whereas the last two sequences correspond to a lead navigation inside an anatomical model which mimics a cyclic heart motion.

- The first sequence shows the navigation of a bradycardia lead inside an anatomical 3D-printed silicone phantom, representing the right cavities of the heart with surrounding vessels. Water (at room temperature) is circulating inside the phantom. As in clinical practice, a metallic stylet is inserted inside the lead to facilitate navigation. This first sequence is composed of two runs: in the first run, the stylet is straight when it is placed inside the lead, which prevents the operator from bringing the lead to the target location. In the second run, the operator manually pre-bends the stylet, giving it an initial curvature. This curvature is transmitted to the lead once the stylet is inserted inside, which gives the operator more maneuverability, and allows him to reach the target location. Two alternative views of similar navigation are also presented, to better illustrate the 3D geometry of the phantom and the lead trajectory.
- The second sequence shows a computer simulation scene, reproducing qualitatively the two runs of the first sequence. The anatomical geometry used in the scene is the one used to 3D-print the phantom of the first sequence. The combination of the lead and stylet is approximated in the simulation by a unique homogenized instrument. This instrument is moved interactively by the user using four keys, to respectively push, pull, rotate clockwise, or rotate counterclockwise the instrument. The models used to handle the different aspects of the simulation (visualization, collision detection, force computation, ...) are shown. Like in the experimental case, two runs of navigation are performed numerically: one in which the instrument is initially straight, and one in which it is given an initial curvature. For each run, three points of view are shown, similar to the three camera angles of the first sequence. We observe qualitatively the same type of outcome: placing the lead inside the ventricle is greatly facilitated with an initial curvature.
- The third sequence also corresponds to a computer simulation scene, but this time involving a moving anatomical geometry reproducing a cyclic heart motion. In this scenario, we use a digital version of a soft beating heart phantom, developed in SimCardioTest for validation purposes. From the full volume of the phantom, displayed at the beginning of the sequence, only the internal surface is used in the simulation. The same models as previously mentioned are associated as well to this surface, and shown in the video. During navigation, the simulation is able to handle the instrument interactions with the moving surface, while computing the resulting stress and strain in the instrument, and the contact forces applied on the anatomy. Once the lead has reached the target location, the simulation is able to retrieve the cyclic stress and strain quantities within the lead resulting from the anatomical motion. For more details on the heart phantom motion and conception, please refer to the dedicated section above.

- The fourth and last sequence is a video illustrating the mechanism of the beating heart phantom. At the moment the current prototype only includes a right ventricle geometry, but the next steps of development will consist of the addition of a venous access, as shown in the simulation video of the third sequence.

5- Conclusion

This deliverable is a video that demonstrates the possibility to compare computer simulations and bench experiments of a pacemaker lead navigation in veins and cardiac geometries. Although it is still a proof of concept, it illustrates our ability to reach more complex scenarios. This demonstration explores the possibility to use bench experiments for validation purpose, and ultimately to replicate key aspects of clinical practice with computer simulations, in view of in-silico trials.

The first scenario, despite being static, proved the computer simulation capable of capturing the crucial steps of the lead manipulation during navigation. Stylet shape and mechanical behavior were found to be essential for the lead to reach the implantation site, exactly as demonstrated by the experiments. Overall, the numerical workflow allows one to simulate the interactive navigation of a lead inside a beating heart anatomy, either corresponding to representative phantoms used for validation, or to actual patient-specific anatomies extracted from imaging data.

It is noteworthy that for the beating heart scenario, the anatomical geometry still needs to be refined, and technical developments are ongoing. On the 3D printed replica side, only the right ventricle is considered within the benchmark when aiming at replicating the heart movement.

Concurrently, retrieving patient data has been delayed due to contract negotiations, as well as latency in identifying suitable data sets. Currently, several dynamic cardiac CTs, and veins CTs were obtained, but for different patients. We are still in the process of constructing complete relevant anatomical models, which amounts to complex segmentation, meshing, and registration tasks, including coherence of meshes along time sequences.

Despite these unexpected issues, the simulation environment is already able to take into account realistic and beating anatomical geometries, which makes it ready both to simulate navigation in patient-specific anatomies, and to enter the validation pipeline as soon as delays on the experimental side are solved. Ongoing work therefore consists of refining the numerical models, while addressing the remaining obstacles for the processing of patient-specific anatomies.

6- Bibliography

[1] F. Renda, V. Cacucciolo, J. Dias and L. Seneviratne, "Discrete Cosserat approach for soft robot dynamics: A new piece-wise constant strain model with torsion and shears," 2016 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS), 2016, pp. 5495-5502, doi: 10.1109/IROS.2016.7759808.

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