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A SOFT ROBOTIC SIMULATOR FOR TRANSSEPTAL PUNCTURE TRAINING

Nicholas A. Thompson
Mechanical Science and Engineering
University of Illinois at Urbana-Champaign
Urbana, IL, USA

Abraham G. Kocheril
OSF HealthCare Cardiovascular Institute
Carle Illinois College of Medicine
University of Illinois at Urbana-Champaign
Urbana, IL, USA

Elizabeth T. Hsiao-Wecksler
Mechanical Science and Engineering
Carle Illinois College of Medicine
University of Illinois at Urbana-Champaign
Urbana, IL, USA

Girish Krishnan
Industrial & Enterprise Systems Engineering
University of Illinois at Urbana-Champaign
Urbana, IL, USA

ABSTRACT

Transseptal puncture (TP) is the technique used to access the left atrium of the heart from the right atrium via the interatrial septum in increasingly common catheter-based procedures such as atrial fibrillation ablation. Through repetition, experienced TP operators develop manual skills to manipulate the transseptal catheter assembly inside the right atrium to their target on the fossa ovalis. New operators currently train on actual patients to develop this skill, resulting in increased risk of dangerous complications. To create low-risk training opportunities for new TP operators, we are developing a Soft Active Transseptal Puncture Simulator (SATPS), designed to match the dynamics, kinetostatics, and visualization of the heart during TP. The SATPS includes three main subsystems: (i) An anatomically accurate soft right atrium, fitted with pneumatic artificial muscles, mimics the dynamics of the heart felt by the operator through the catheter assembly. (ii) A replaceable, puncturable fossa ovalis simulates the tissue properties of the real fossa to provide accurate kinetostatic force feedback during tenting and puncture. (iii) A simulated intracardiac echocardiography environment gives the user live visual feedback representative of an ultrasound monitor during an actual TP procedure. The SATPS is an ongoing project, with validation and design improvements forthcoming.

Keywords: Soft robotics, pneumatic artificial muscles, arrhythmia, catheter ablation, surgical training simulator

NOMENCLATURE

AF	Atrial fibrillation
CT	Computed tomography
FREE	Fiber-reinforced elastomeric enclosure
ICE	Intracardiac echocardiography
IVC	Inferior vena cava
PAM	Pneumatic artificial muscle
TP	Transseptal puncture
SATPS	Soft Active Transseptal Puncture Simulator
SVC	Superior vena cava

1. BACKGROUND

Atrial fibrillation (AF) cases are rising, expected to affect 6–12 million people in the US by 2050 [1]. AF ablation, a procedure used by interventional cardiologists to treat AF, includes a technique known as transseptal puncture (TP), wherein the left atrium of the heart is accessed by puncturing the interatrial septum from the right atrium. The procedure is conducted using a catheter assembly consisting of a sheath, dilator, and Brockenbrough needle inserted into the femoral vein and passed through the inferior vena cava into the right atrium. TP is used in an increasing number of other cardiac procedures, such as left atrial appendage occlusion and mitral valve repair [2].

New operators train in TP on live patients under the careful observation of experienced mentors, but it takes around 30 attempts to pass the steepest portion of the learning curve [3]. Until they can perform with the efficiency and accuracy of veteran operators, trainees conduct TP with higher failure rates and increased procedural time [3,4]. Skilled operators develop the ability to navigate the atrium by judging the force felt through their catheters when in contact with the septum [5]. Prior to live patient training, new operators can review relevant fluoroscopy or ultrasound images, but this preparation provides no haptic feedback, leaving them to rely on mentors and live training for crucial haptic skill development. The cardiovascular workforce is aging and retiring, leaving a shortage of experienced guiding hands to pass this skill to the next generation [6]. Thus, there is a clear need for the development of a training simulator to revolutionize the way TP training is conducted to reduce the need for actual patient training and standardize the training process.

Realistic simulators for training and surgical planning must be equivalent to their biological counterparts in terms of (i) dynamics, (ii) kinetostatics, and (iii) visualization. Dynamic equivalence requires matching the time-varying muscle forces and their effect on the walls of the organ. Kinetostatic equivalence requires establishing accurate stiffness and other static surface-level responses that are functions of geometry and material properties. Finally, visualization entails near-equivalent imaging such as fluoroscopy or ultrasound that help guide the operator during a procedure. Existing TP simulators do not incorporate all three aspects, ranging from training in a virtual reality environment to static anatomically correct designs with simulated transesophageal echocardiography images [7,8]. Both devices have reported significant levels of realism, but lack actuation and tailored material properties.

We present an ongoing project called the Soft Active Transseptal Puncture Simulator (SATPS), designed to match the dynamics, kinetostatics, and visualization of the heart during TP (Fig. 1). We are developing the SATPS to provide low-risk training opportunities to new operators, allowing them to develop the haptic awareness and skill of more experienced operators before performing TP on a live patient. Our hypothesis is that a dynamic simulator that provides haptic feedback will offer a more effective training experience than a static or purely visual simulator. This paper describes the overall SATPS system and ongoing work in each of the SATPS subsystems, including an overview of our design process.

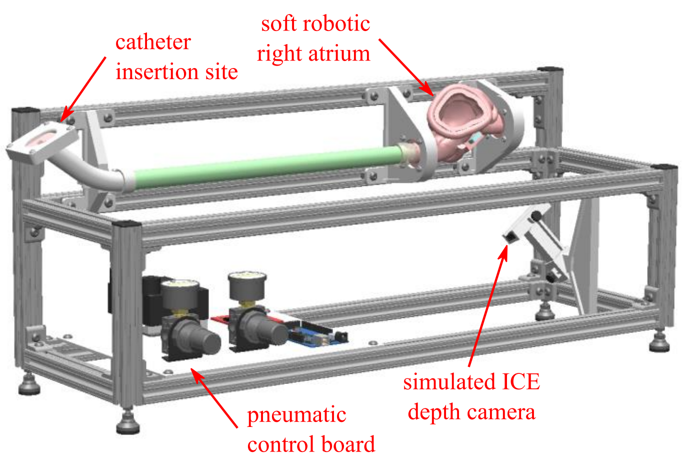

FIGURE 1: CAD rendering of the Soft Active Transseptal Puncture Simulator assembly. Real-time simulated ICE images are displayed on a laptop (not pictured).

2. DESIGN APPROACH

The basic sequence of events during transseptal puncture is as follows: (i) A guidewire is inserted into the femoral vein, through the inferior vena cava (IVC), past the right atrium, and into the superior vena cava (SVC). (ii) A sheath and dilator are advanced over the guidewire into the SVC, the guidewire is removed, and a Brockenbrough needle is inserted into the dilator, stopping short of the dilator tip. (iii) The catheter assembly (sheath, dilator and Brockenbrough needle) is retracted from the SVC, over the aortic mound, and onto the fossa ovalis, an elliptical membrane on the interatrial septum [9] (Fig. 2b). (iv) Once tissue deformation from the applied force (i.e. “tenting”) is verified on an ultrasound monitor, the needle is advanced from the dilator, puncturing through the fossa and into the left atrium. Then the dilator and catheter are advanced over the needle into the left atrium, completing the TP.

Training operators to navigate a patient’s heart with a TP catheter assembly requires consideration of three critical steps during the procedure: (i) As the catheter assembly is retracted back from the superior vena cava into the right atrium, it encounters the pulsating aortic mound. The operator must avoid puncturing the aortic mound, which would lead to excessive blood loss. (ii) The operator uses a combination of visual cues and dynamic force feedback to locate the fossa ovalis. (iii) The operator applies the correct force on the catheter to produce tenting before advancing the needle to puncture the fossa ovalis. This last step usually requires force feedback and visual observation of the fossa tenting using ultrasound via intracardiac echocardiography (ICE). Historically, fluoroscopy has also been used to visualize catheter position before puncture, but reduced radiation exposure and the ability to locate specific puncture sites on the septum make ICE the preferred visualization tool for modern TP procedures.

Thus, a training simulator that captures these critical steps requires a systematic integration of bioinspired actuators, stretchable materials with the same properties as the fossa, and visual simulation tools. In the SATPS, novel soft actuators provide dynamic equivalence to atrial musculature. We achieved anatomical and physiological accuracy by using cardiac CT scans to produce physical and virtual components, matching actuator alignment to that of cardiac muscle fibers, and replicating fossa ovalis tissue properties using novel materials. To incorporate ICE imaging without the need for expensive catheter-based ultrasound equipment, we coupled our physical representation of the beating atrium with a simulated ICE environment. Finally, the entire system is modular and tunable. Each subsystem can be replaced individually, allowing for improvements during development as we receive feedback from expert clinicians. The actuators can be manufactured to produce different degrees of contraction and fine-tuned in real-time via pneumatic pressure.

3. SATPS SUBSYSTEMS

The SATPS includes three main subsystems. An anatomically accurate soft right atrium fitted with pneumatic artificial muscles (PAMs) mimics the dynamics of the heart felt by the operator through the catheter assembly (Fig. 2). A replaceable, puncturable fossa ovalis simulates the tissue properties of the real fossa to provide accurate kinetostatic force feedback during tenting and puncture (Fig. 2). Lastly, a simulated intracardiac echocardiography environment gives the user live visual feedback representative of an ultrasound monitor during the real procedure (Fig. 3).

3.1 Soft Robotic Right Atrium Demonstrating Dynamic Equivalence

The soft right atrium was modeled from a CT heart scan (The Lynn & Arnold Irwin Advanced Perioperative Imaging Lab, Toronto, ON, Canada) and cast from silicone rubber (EcoFlex 00-50, Smooth-On Inc., Macungie, PA, USA) in 3D printed molds. We modified the digital heart model using 3D modeling software (Blender 2.8, Blender Foundation, Amsterdam, Netherlands) to incorporate functional elements such as a pneumatic chamber for an actuated aortic mound, a pocket for inserting a replaceable fossa ovalis, and grooves for the pneumatic actuators.

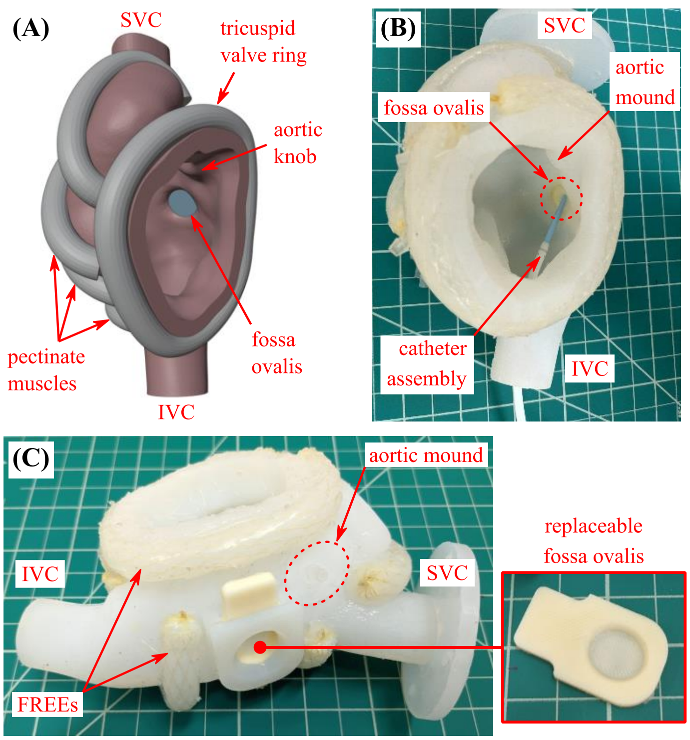

FIGURE 2: (A) CAD rendering of soft right atrium with FREEs representing pectinate muscles and tricuspid valve ring. (B) Cast silicone right atrium with catheter assembly in tenting position. (C) Cast silicone right atrium with replaceable fossa ovalis.

The SATPS simulates atrial contraction using a variation of the established class of PAMs called fiber-reinforced elastomeric enclosures (FREEs) [10]. FREEs consist of an elastomer bladder surrounded by helical networks of inextensible fibers. The angle of these fibers relative to the axis of the FREE determines the FREE's behavior when pressurized. The FREEs used in the SATPS contract axially and expand radially when pressurized, similar to biological muscle. Contracting PAMs have been used previously to simulate contraction from ventricular muscles in a soft robotic device for ventricular compression [11].

Achieving realistic atrial compression in the SATPS demanded FREEs that could be wrapped around the tight radius of the atrium without buckling, necessitating the development of custom pre-curved FREEs. The actuator bladders are cast in 3D printed molds from silicone rubber (EcoFlex 00-50, Smooth-On Inc., Macungie, PA, USA), which was also used to bond the FREEs to the cast atrium. The axis of each FREE follows a Bézier curve approximating a muscle path along the surface of the anatomically accurate right atrium to produce realistic atrial dynamics. Specifically, our FREEs simulate the pectinate muscles and the tricuspid valve ring (Fig. 2a). The FREE bladder castings also include grooves for fibers, which are arranged in helical paths around the curved FREE axis. The pitch of the helical fiber path is determined by the fiber angle of a straight FREE with the desired contraction ratio. The fibers used in the SATPS FREEs are Kevlar thread (H20-7295BS, Fire Mountain Gems and Beads, Inc., Grants Pass, OR, USA).

3.2 Replaceable Fossa Ovalis Demonstrating Kinetostatic Equivalence

The SATPS atrium is fitted with a housing that holds a puncturable material that simulates the fossa ovalis (Fig. 2c). This component will allow for continued use of the SATPS without the need to replace the entire right atrium. The fossa will be cast from a highly elastic material designed to mimic the tenting stiffness and the puncture force of real fossa tissue during TP [12]. Identification of an appropriate material is still pending. Matching these properties will help training operators learn the correct force to apply during the final steps of the procedure. Application of too much force could result in accidental puncture of the left atrial wall due to overextension of the needle into the left atrium.

3.3 Simulated Intracardiac Echocardiography (ICE) Demonstrating Visualization Equivalence

Transseptal puncture operators rely on intracardiac echocardiography to verify dilator position on the fossa ovalis during tenting before puncture. ICE uses a probe inserted into the right atrium along the same vascular pathway as the transseptal catheter to create a cross-sectional image of the fossa and atrial walls. To simulate ICE imaging in our TP simulator, we are using a time-of-flight camera (CamBoard pico flexx, PMD Technologies, Siegen, Germany) to detect the deformation of the simulator's fossa ovalis. The depth data are used to produce real-time simulated ultrasound images in a 3D content development software (Unity 2019, Unity Technologies, San Francisco, CA, USA). The animated simulation shows a deforming virtual fossa ovalis that is embedded in a CT heart scan model (Jump Simulation, Peoria, IL, USA) (Fig. 3). The simulated ICE environment will allow users to target specific puncture sites on the fossa ovalis, which is necessary for different catheter-based procedures [2].

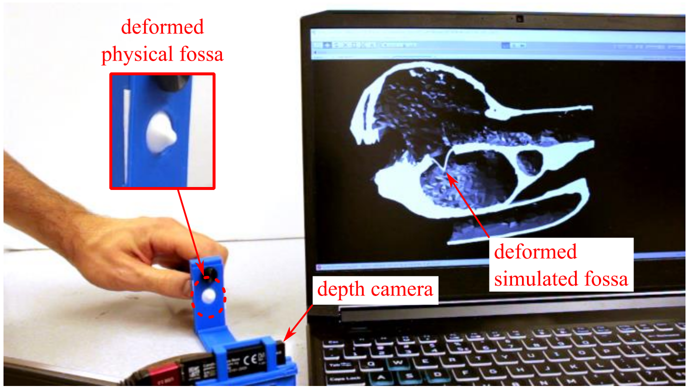

FIGURE 3: Preliminary demonstration of real-time simulated ICE images of an elastomeric fossa during manual tenting with a stationary test apparatus.

4. LIMITATIONS AND FUTURE WORK

The current SATPS prototype is limited by its single right atrium model, which cannot represent the high variability in heart shape and size among different patients. Future models of interchangeable right atria and fossa ovalis inserts could represent distinct pathologies and anatomies for a more diverse training regimen.

Ongoing work for the SATPS includes identification of suitable materials for the replaceable fossa ovalis, including validation with mechanical testing for tenting stiffness and puncture force. We will also validate and tune the FREEs for the simulated right atrium by measuring atrial volume change and comparing the results to physiological values [13]. Following system integration, the SATPS will undergo face and content validation by experienced clinicians. Tuning the FREEs' pneumatic pressure during clinician review will allow for immediate re-evaluation of atrial dynamics. We will incorporate design improvements based on quantitative validation results and clinician feedback.

5. CONCLUSIONS

Transseptal puncture is an increasingly common procedure as a result of the growing need for catheter-based cardiac procedures such as AF ablation. Experienced interventional cardiologists develop haptic skill in navigating the right atrium during TP via force felt through the TP catheter assembly. There is currently no commercially available realistic and dynamic simulator to allow new operators to develop this skill in a risk-free environment. We are developing a Soft Active Transseptal Puncture Simulator that offers dynamic, kinetostatic, and visualization equivalence with a soft robotic right atrium, a realistic replaceable fossa ovalis, and a simulated ICE environment. This ongoing work will be validated through comparison to physiological metrics and evaluation by expert clinicians.

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