Design and Validation of a Soft Robotic Simulator for Transseptal Puncture Training

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Abstract*—*Objective: **Transseptal puncture (TP) is the technique used to access the left atrium of the heart from the right atrium during cardiac catheterization procedures. Through repetition, electrophysiologists and interventional cardiologists experienced in TP develop manual skills to navigate the transseptal catheter assembly to their target on the fossa ovalis (FO). Cardiology fellows and cardiologists that are new to TP currently train on patients to develop this skill, resulting in increased risk of complications. The goal of this work was to create low-risk training opportunities for new TP operators.** ***Methods:*** **We developed a Soft Active Transseptal Puncture Simulator (SATPS), designed to match the dynamics, static response, and visualization of the heart during TP. The SATPS includes three subsystems: (i) A soft robotic right atrium with pneumatic actuators mimics the dynamics of a beating heart. (ii) A fossa ovalis insert simulates cardiac tissue properties. (iii) A simulated intracardiac echocardiography environment provides live visual feedback. Subsystem performance was verified with benchtop tests. Face and content validity were evaluated by experienced clinicians.** ***Results:*** **Subsystems accurately represented atrial volume displacement, tenting and puncture force, and FO deformation. Passive and active actuation states were deemed suitable for simulating different cardiac conditions. Participants rated the SATPS as realistic and useful for training cardiology fellows in TP.** ***Conclusion:*** **The SATPS can help improve catheterization skills of novice TP operators.** ***Significance:*** **The SATPS could provide novice TP operators the opportunity to improve their TP skills before operating on a patient for the first time, reducing the likelihood of complications.**

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***Index Terms*—Cardiology, catheterization, echocardiography, medical simulation, pneumatic actuators, soft robotics.**

I. Introduction

TRANSSEPTAL puncture (TP) is a common procedure used by cardiac electrophysiologists and interventional cardiologists, 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. The most prevalent treatment that uses TP is atrial fibrillation (AF) ablation. AF cases are rising, expected to affect 6–12 million people in the US by 2050 [1]. Thus, the use of AF ablation is expected to also increase and more TP operators will need to be trained. TP is also used in an increasing number of other cardiac procedures, such as left atrial appendage occlusion and mitral valve repair [2].

New operators, i.e., electrophysiology fellows, interventional cardiology fellows, and cardiologists without TP experience, train in TP on live patients under the careful observation of experienced mentors. 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]. These training procedures also carry a greater risk of dangerous complications such as cardiac tamponade due to misplacement of the TP needle during puncture or overextension through the left atrial wall [5], [6]. Skilled operators, i.e. electrophysiologists and interventional cardiologists experienced in TP, develop the ability to navigate the atrium by judging the force felt through their catheters when in contact with the atrial wall and interatrial septum [7]. 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-patient 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 [8]. 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 to standardize the training process.

Realistic simulators for training and surgical planning must be equivalent to their biological counterparts in terms of (i)

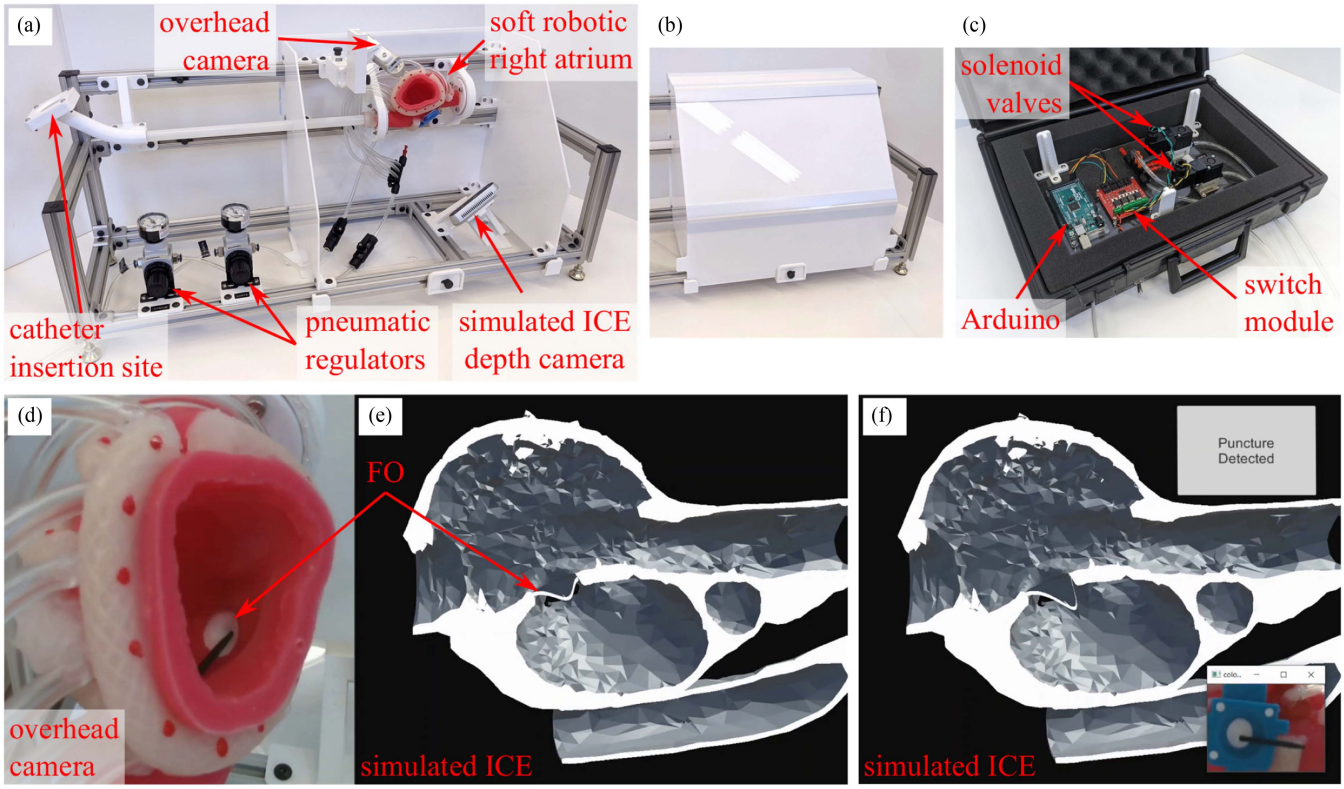

Fig. 1. (a) Soft Active Transseptal Puncture Simulator (SATPS). (b) SATPS with its shroud in the closed position. (c) Pneumatic control board in insulated case. The pneumatic compressor is not shown. (d) A real-time interior view of the atrium from the overhead camera is displayed to the user on an accompanying laptop (not shown). (e) A simulated ICE environment displayed next to the overhead view in (d) shows deformation of the fossa ovalis (FO) during tenting and (f) notifies the user after puncture has been detected.

dynamics, (ii) static response, and (iii) visualization. Dynamic equivalence requires matching the time-varying muscle forces and their effect on the walls of the organ. Static response equivalence requires accurate surface-level force responses that are functions of geometry and material properties. Finally, visualization equivalence entails mimicking real-time imaging such as fluoroscopy or ultrasound that help guide the operator during a procedure. Existing TP simulators from literature range from a virtual reality training environment to static anatomically correct designs with simulated transesophageal echocardiography and fluoroscopy images [9], [10], [11]. Commercial endovascular simulators such as the ANGIO Mentor and the Mentice VIST offer simulated haptic feedback and visualization for a variety of catheter-based procedures, including transseptal puncture [12], [13]. These devices have reported significant levels of realism, but none incorporate actuation and tailored material properties in a single device.

The overarching goal of this work was to provide low-risk training opportunities to new TP operators, allowing them to develop the haptic awareness and skill of more experienced operators before performing TP on a live patient. To that end, we developed a Soft Active Transseptal Puncture Simulator (SATPS), designed to match the dynamics, static response, and visualization of the heart during TP (Fig. 1). A preliminary version of this work was reported previously [14]. In this manuscript, we present three complete subsystems of the SATPS, along with subsystem and system validation. Subsystems were validated with benchtop tests. System validation of the SATPS by clinicians experienced in TP addressed three key hypotheses:

- *Hypothesis 1:* An active TP simulator is more realistic than a passive simulator.
- *Hypothesis 2:* The SATPS realistically simulates the tactile and visual feedback experienced during TP.
- *Hypothesis 3:* The SATPS is a useful training device for transseptal puncture.

Medical simulators are commonly evaluated through a series of validity assessments, including face, content, construct, and concurrent validity [15], [16], [17], [18], [19]. The scope of this pilot study was limited to face and content validity for the purpose of gathering design feedback for further development of the SATPS. According to McDougall, face validity establishes the realism of the simulator, and content validity is a judgement of the appropriateness of the simulator as a teaching modality [17]. Face and content validity are subjective, and are usually established through input from experienced clinicians [19]. In this study, face validity was represented by Hypothesis 2 and content validity by Hypothesis 3.

II. System Design

A. Design Considerations

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 (FO), an elliptical membrane on the interatrial septum [20]. (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 FO 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 SVC into the right atrium, it encounters the pulsating aortic mound [21], [22]. 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 FO. (iii) The operator applies the correct force on the catheter to produce tenting before advancing the needle to puncture the FO. This last step usually requires force feedback and visual observation of the FO 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. To capture these critical steps, the SATPS required systematic integration of bioinspired actuators on an anatomically accurate atrium, stretchable materials with the same properties as the FO, and visual simulation tools.

B. System Description

The SATPS includes three main subsystems. An anatomically accurate soft right atrium incorporates compliant pneumatic actuators to mimic the dynamics of the heart felt by the operator through the catheter assembly (Fig. 2(a)–(c)). A replaceable, puncturable fossa ovalis simulates the tissue properties of the real fossa to provide accurate force feedback during tenting and puncture (Fig. 2(d)). Lastly, a simulated intracardiac echocardiography environment gives the user live visual feedback of the fossa ovalis that is representative of an ultrasound monitor during the real procedure (Fig. 1(e)).

1) Soft Robotic Right Atrium for Dynamic Equivalence: The soft right atrium was modeled from a CT heart scan (The Lynn & Arnold Irwin Advanced Perioperative Imaging Lab) and cast from silicone rubber (EcoFlex 00-50, Smooth-On Inc.) in a 3D-printed mold with a water-soluble polyvinyl alcohol (PVA) mold core. We modified the digital heart model using 3D modeling software (Blender 2.8, Blender Foundation) 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. All elastomers used in the SATPS were platinum cure silicones that

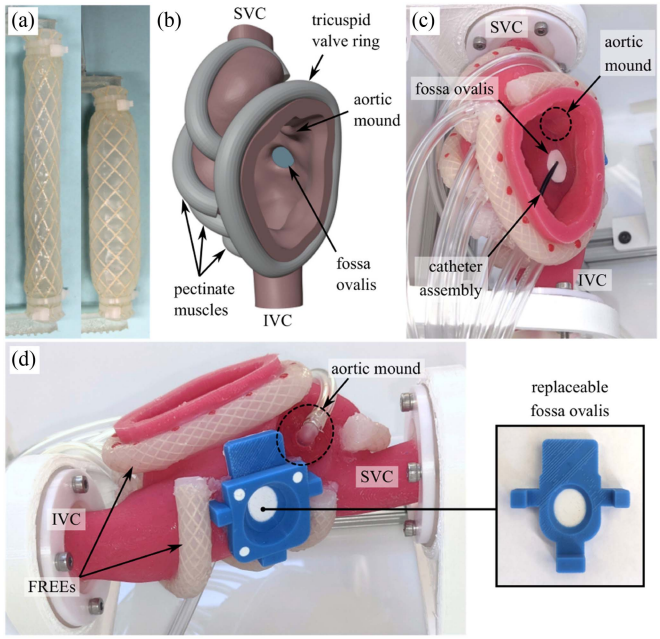

Fig. 2. (a) Unpressurized *(left)* and pressurized *(right)* contracting FREE actuator. (b) CAD rendering of soft right atrium with FREEs representing pectinate muscles and tricuspid valve ring. (c) Cast silicone right atrium with catheter assembly in tenting position. (d) Cast silicone right atrium with replaceable fossa ovalis.

were mixed thoroughly by hand, degassed in a vacuum chamber, and cured at room temperature. After curing, a low friction silicone coating (MED-6670, NuSil) was applied to the interior of the atrium to simulate the lubricity of blood between the catheter assembly and cardiac tissue. Silicone parts were stored at room temperature in plastic zip-top bags up to six months. All parts were stored in an interior lab with no windows, meaning ultraviolet light exposure was minimal. Platinum cure silicone rubbers are generally resistant to degradation from temperature, UV light, and aging [23].

The SATPS simulates atrial contraction using soft pneumatic actuators called fiber-reinforced elastomeric enclosures (FREEs) [24]. 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 have fiber angles of $\pm 30^{\circ}$, causing them to contract axially and expand radially when pressurized, similar to biological muscle (Fig. 2(a)). Contracting FREEs have been used previously to simulate contraction from ventricular muscles in a soft robotic device for ventricular compression [25].

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 were cast in 3D-printed molds from silicone rubber (EcoFlex 00-50, Smooth-On Inc.). This silicone rubber was also used to bond the FREEs to the cast atrium. The axis of each FREE follows a three-dimensional cubic Bézier curve approximating

a muscle path along the surface of the right atrium to produce realistic atrial dynamics. Specifically, our FREEs simulate the pectinate muscles and the tricuspid valve ring (Fig. 2(b)). 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 equal to the pitch of a fiber in a straight FREE with the desired contraction ratio. The fibers used in the SATPS FREEs are cotton thread. We verified the FREEs' ability to produce realistic atrial contraction by measuring the change in volume during actuation, and comparing the results to physiological values (see Section III-A).

Air is supplied to the actuators by a pneumatic control system consisting of a small compressor (TC-326 T, Master Airbrush), two pneumatic regulators (PPR2-N02BG-2, PneumaticPlus), two solenoid valves (VT307W-5DZ1-02T-F, SMC Corporation), a MOSFET switch module (IRF540, NOYITO), and a microcontroller board (Mega 2560, Arduino). The regulators are mounted on the frame of the SATPS to allow for pressure adjustment. All other components aside from the compressor are stored in an insulated case to reduce noise from the solenoid valves (Fig. 1(c)). The control system toggles air supply to the FREEs and the aortic mound chamber, both of which are actuated at a typical atrial fibrillation patient heart rate of 75 beats per minute (bpm) [26].

2) Replaceable Fossa Ovalis for Static Response Equivalence: The SATPS atrium is fitted with an enclosure that holds a puncturable insert that simulates the fossa ovalis (Fig. 2(d)). This component allows for continued use of the SATPS without the need to replace the entire right atrium. The fossa region of the insert is cast from soft silicone rubber (Dragon Skin 10 Medium, Smooth-On Inc.), chosen to mimic the tenting stiffness and the puncture force of real fossa tissue during TP (see Section III-B). Matching these properties will help new operators learn the correct force to apply during the final steps of the procedure. Application of excessive force could result in accidental puncture of the left atrial wall due to overextension of the needle into the left atrium. The frame and enclosure for the fossa insert (blue material in Fig. 2(d)) are cast from stiffer silicone rubber (Dragon Skin 30, Smooth-On Inc.) that secures the insert while maintaining the ability to flex with the beating atrium. During operation of the SATPS, the TP catheter assembly only comes into contact with the soft fossa ovalis region of the insert (Fig. 2(c)).

3) Simulated Intracardiac Echocardiography for 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 ovalis (FO) and atrial walls.

To simulate ICE imaging, the SATPS uses a depth camera (RealSense D415, Intel Corporation) to detect the deformation of the simulator's FO as it moves with the beating right atrium. The depth camera data are used to produce real-time simulated ultrasound images in a 3D content development software (Unity 2019, Unity Technologies) displayed on a laptop that is facing

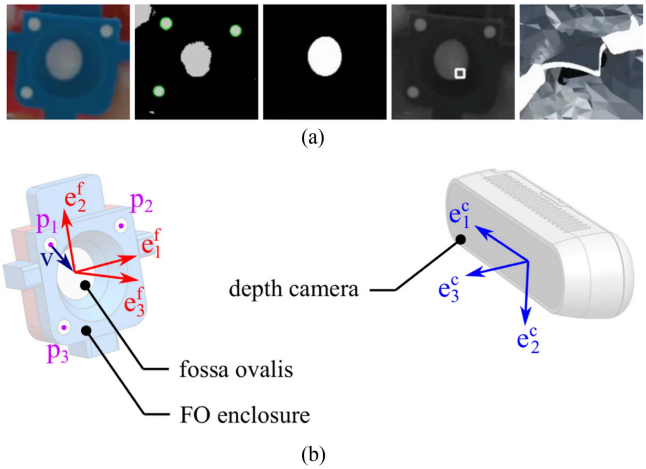

Fig. 3. (a) Computer vision sequence for the simulated ICE subsystem. From left to right: RGB view, location of reference points, isolation of FO pixels, identification of tenting peak, and animation of tenting on the digital FO. (b) Definition of camera and FO orthonormal bases.

the user. The animated simulation shows a deforming virtual FO that is embedded in a CT heart scan model [27]. The digital heart is animated to simulate beating. The simulated heart motions are timed with the signals opening and closing the pneumatic solenoid valves for the soft robotic right atrium. A cross-section through the simulated interatrial septum of the 3D heart is displayed to the user in a configuration representing a typical ICE view during TP (Fig. 1(e)).

The 3D depth camera data of the physical FO are used to create the 2D animation of the virtual FO in real-time (Fig. 3(a)). Each frame of the animation begins by establishing an instantaneous local coordinate system for the physical FO, which is constantly moving due to the actuation of the right atrium. Positions of all pixels detected by the depth camera are represented in the orthonormal camera basis $\{\mathbf{e}^c\}$ positioned on the front face of the camera, and must be converted to an orthonormal basis $\{\mathbf{e}^f\}$ aligned with and centered on the undeformed FO. Colored markers on the exterior of the FO enclosure located at points p_1, p_2, and p_3 are identified using an open source computer vision library (OpenCV) and used to define 3×1 reference vectors $\vec{p}_1$, $\vec{p}_2$, and $\vec{p}_3$ from the camera basis origin (Fig. 3(b)). The 3×1 unit vectors making up $\{\mathbf{e}^f\}$ are then defined as follows:

$$\hat{e}_1^f = \frac{\vec{p}_2 - \vec{p}_1}{||\vec{p}_2 - \vec{p}_1||}, \quad \hat{e}_2^f = \frac{\vec{p}_1 - \vec{p}_3}{||\vec{p}_1 - \vec{p}_3||}, \quad \hat{e}_3^f = \hat{e}_1^f \times \hat{e}_2^f \tag{1}$$

The change of basis for any 3×1 position vector $\vec{r}$ from $\{\mathbf{e}^c\}$ to $\{\mathbf{e}^f\}$ is then:

$$[\vec{r}]_{\mathbf{e}^f} = x\hat{e}_1^f + y\hat{e}_2^f + z\hat{e}_3^f = \mathbf{A}\left([\vec{r}]_{\mathbf{e}^c} - \hat{p}_1 - \vec{v}\right), \tag{2}$$

$$\text{where } \mathbf{A} = \begin{bmatrix} \hat{e}_1^f & \hat{e}_2^f & \hat{e}_3^f \end{bmatrix}^T \tag{3}$$

and $\vec{v}$ is the known vector pointing from p_1 to the center of the undeformed FO, which is constant and determined by the geometry of the FO enclosure.

The last steps in each frame are to identify and transmit the tenting peak location, and to recognize when puncture has been completed. The color boundary between the FO and the edge of the FO insert is identified using OpenCV (Fig. 3(a)). The coordinates with the maximum z value within the FO boundary according to (2) represent the tenting peak. This peak location is sent to Unity, where it is used to position the peak of the virtual FO mesh. The nodes radiating out from the virtual peak are positioned with a second-order polynomial approximation, terminating at the edge of the FO mesh. SATPS users receive an on-screen notification that puncture has occurred if the color of the TP dilator is detected by the depth camera (Fig. 1(f)). The above process repeats for every frame captured by the depth camera, resulting in a real-time ICE-style representation of tenting of the simulator's FO.

III. Subsystem Validation

Benchtop tests were used to verify the accurate simulation of the right atrium during TP by the SATPS. Atrial dynamics of the SATPS were evaluated by measuring the volume displacement of the soft robotic right atrium during actuation. Static response of the atrial septum was validated with static force testing of several possible materials for the replaceable fossa ovalis subsystem. Accuracy of the simulated ICE visualization was verified by comparing measured tenting peak locations to known constants in a dynamic test.

A. Atrial Volume Displacement

The aim of this test was to verify the soft actuators' ability to simulate atrial muscle contraction. A soft robotic right atrium was sealed at the entrance to the SVC and the tricuspid valve opening with 3D-printed plugs attached with silicone adhesive (Sil-Poxy, Smooth-On, Inc.). A graduated cylinder was attached to the IVC using a 3D printed adapter. The atrium assembly was mounted on an aluminum frame with the graduated cylinder oriented vertically. The atrium was filled with water and the baseline volume was recorded from the graduated cylinder. Actuator pressure was increased in 10 kPa increments up to 100 kPa, and the change in atrial volume was recorded while maintaining constant pressure at each increment (Fig. 4(a)). The right atrial (RA) ejection or emptying fraction (EF) was calculated as:

$$EF = 100\% \times \frac{\Delta RAV_P}{RAV_0} \tag{4}$$

where ΔRAV_P is the change in RA volume at pressure P and RAV_0 is the volume of the unactuated atrium. RAV_0 was estimated as 90.6 mL using the CAD model for the inner core of the atrium mold. Calculated EF values were compared to physiological RA stroke EF values from literature [28].

The right atrium displaced an anatomically realistic volume of water when actuated. Atrial ejection fraction reached a maximum of 23% at a pressure of 100 kPa. This result is nearly within one standard deviation of mean healthy RA stroke ejection fractions measured by Li et al. ($35 \pm 11\%$, n = 135) (Fig. 4(b)) [28]. Gorter et al. [29] determined that RA EF is reduced in patients with atrial fibrillation, indicating the SATPS could be adjusted to simulate atrial dynamics of AF patients by decreasing pressure to the actuators.

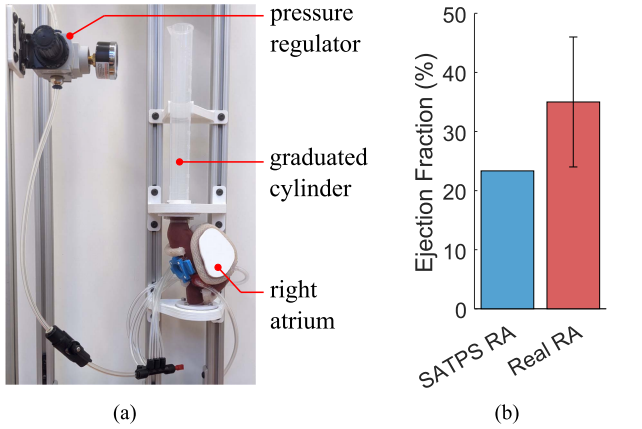

Fig. 4. (a) Atrial volume displacement testing setup. (b) SATPS right atrial ejection fraction at 100 kPA compared to right atrial ejection fraction measurements from healthy adults [28] (mean ± SD).

B. Fossa Ovalis Tenting and Puncture Force

To provide realistic haptic feedback during tenting and puncture, the material used for the replaceable FO subsystem needed to have the same tenting and puncture behavior as real atrial septum tissue. Testing protocol and physiological values for comparison were based on the work of Howard et al., who measured tenting and puncture response of *ex vivo* human atrial septum tissue [30]. We evaluated the potential fossa ovalis materials based on three characteristics. Tenting force, which here is the force needed to tent the fossa ovalis by a distance of 8 mm, provides a measure of the force feedback felt during tenting. Puncture force, or the force required to pass the needle tip, dilator tip, and sheath through the fossa ovalis, represents the force feedback felt during puncture. Needle tenting distance, which is the depth of tenting by the needle before it punctures the fossa ovalis, provides a measure of the required tenting depth before puncture is feasible during TP.

Three types of silicone rubber were tested: Ecoflex 00-30, Dragon Skin 10 Medium, and Dragon Skin 30 (Smooth-On Inc.). Silicone for each sample group was mixed thoroughly by hand and degassed in a vacuum chamber before casting in 3D-printed molds (2 mm × 25 mm × 25 mm). Cured samples were stored under the same conditions as the SATPS parts described in Section II-B1. To approximate the suction device used by Howard et al. to constrain heart tissue, samples were secured with a 3D-printed fixture for testing (Fig. 5(a)) [30]. The fixture compressed a sample between two flat plates secured with a screw and nut. Openings in the top and bottom plates of the fixture represent the mean dimensions of an adult fossa ovalis, 14.1 mm × 12.1 mm [31]. Three samples of each material were fabricated and tested. Sample thicknesses were measured with a caliper. Each sample was

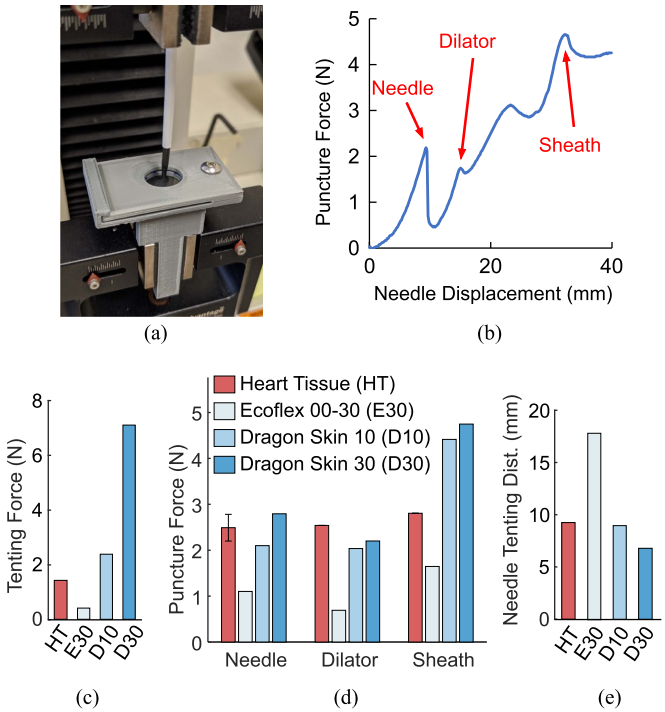

Fig. 5. (a) Fossa ovalis material testing setup. (b) Typical puncture force measurement curve. (c) Force required to tent the fossa ovalis a distance of 8 mm. (d) Force required to pass each component of a TP catheter assembly through the fossa ovalis. (e) Tenting distance by needle before puncture. Human tissue data is from [30]. Bar plots represent mean ± SE with n = 8 for human tissue and mean with n = 3 for each type of silicone.

subjected to one tenting force test followed by one puncture force test.

Tenting and puncture force tests were conducted using a modified Brockenbrough needle (EP003994S, Medtronic, Inc.) and Mullins sheath and dilator assembly (EP008591, Medtronic, Inc.). The outside diameters of the needle tip, dilator, and sheath were 0.8 mm, 2.6 mm, and 3.0 mm, respectively. The needle was straightened and trimmed to a length of 130 mm, measured from the needle tip. The sheath was been trimmed to 95 mm, and the dilator to 110 mm. The sheath and dilator were bonded together at the trimmed base to prevent relative displacement during testing, leaving 15 mm of dilator extended past the tip of the sheath. The needle was allowed to slide inside the dilator so it could be retracted for tenting tests or extended and fixed in place for puncture tests. Material testing was conducted on an electromechanical force testing machine (Insight 1, MTS) fitted with clamp-style grips (Advantage Screw Action Grips, MTS) to secure the sample fixture and modified catheter assembly (Fig. 5(a)).

Tenting tests measured the force response as the dilator was advanced into the sample without puncture. The sample fixture was held in the lower grip of the testing machine and the catheter assembly was held in the upper grip, centered on and perpendicular to the material sample with the needle tip retracted into the dilator. The tool head was positioned such that the dilator tip was just above the top surface of the material sample. Force and displacement data were then collected while advancing the dilator tip into the sample to a depth of 8 mm. The tool head was advanced at a rate of 254 mm / min for the purpose of direct comparison to the tissue measurements by Howard et al. [30]. Tenting force was recorded as the force measurement at the final 8 mm depth.

Puncture tests measured the force response as the needle, dilator, and sheath were advanced through the sample. The sample fixture and catheter assembly were positioned in the testing machine grips in the same manner as for tenting force testing. However, for puncture force testing, the needle was extended and constrained to prevent retraction into the dilator during testing. The tool head was positioned such that the needle tip was just above the top surface of the material sample. Force and displacement data were collected while advancing the needle through the sample at a rate of 254 mm / min to a depth of 40 mm. Local maxima in the force-displacement plots indicated the puncture force for each of the TP catheter assembly components (Fig. 5(b)). The displacement value at the peak representing needle puncture force was recorded as the needle tenting distance.

Fossa ovalis material evaluation indicated Dragon Skin 10 Medium was the closest analog to real human fossa ovalis tissue in terms of static response. Although human tissue samples in [30] were found to have mean thickness 0.68 ± 0.27 mm (mean ± SD, n = 8), due to fabrication limitations of ± 0.3 mm the simulated tissue samples were thicker. Silicone samples had mean thickness 1.87 ± 0.18 mm (mean ± SD, n = 9). Mean tenting force for Dragon Skin 30 was four times greater than that of human tissue (Fig. 5(c)). Mean needle puncture force for Ecoflex 00-30 was 56% less than that of human tissue. Dragon Skin 10 and Dragon Skin 30 samples had mean needle puncture forces just 16% less and 11% greater, respectively, than that of human tissue. Standard deviations were not published for human tissue puncture force for the dilator tip and sheath insertion, but mean values suggest a closer match to Dragon Skin 10 and Dragon Skin 30 compared to Ecoflex 00-30 (Fig. 5(d)). Mean needle tenting distances for Ecoflex 00-30, Dragon Skin 10, and Dragon Skin 30 were 92% greater, 4% less, and 27% less, respectively, than that of human tissue (Fig. 5(e)). Based on its relative similarity to human tissue in all measured properties compared to the other two silicone types, Dragon Skin 10 was selected for the replaceable fossa ovalis insert.

C. Simulated ICE Measurements

For the simulated ICE subsystem to provide accurate visual feedback, the location of the tenting peak displayed on-screen must match the location of the physical tenting peak relative to the dynamic right atrium. The simulated ICE algorithm locates and measures the position of the tenting peak on the moving fossa ovalis, and converts the position to a local basis centered on the FO (Section II-B3). To evaluate the accuracy of the algorithm's output, a validation study was performed using 3D-printed test cones attached to the exterior surface of fossa ovalis inserts. The cones were designed to simulate the shape of the tented FO with peaks in 2 mm increments and centered at $x = y = 0$

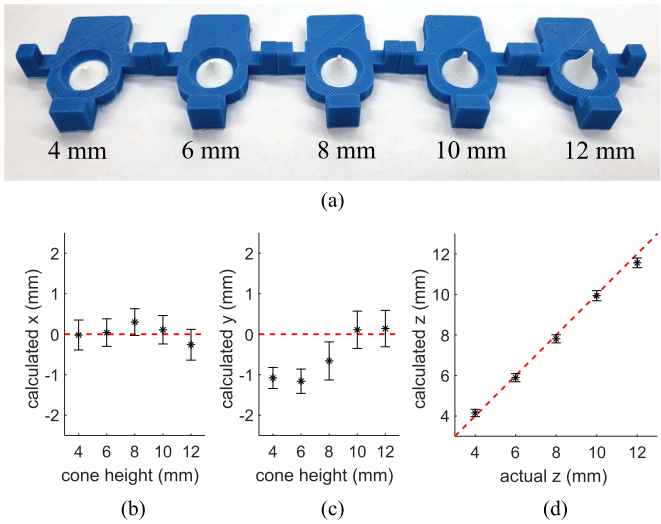

Fig. 6. (a) Test cones with varying heights attached to FO inserts. Calculated (b) x, (c) y, and (d) z peak coordinates (mean $\pm$ SD, n = 3000 for each cone). Red dashed lines represent perfect accuracy.

(Fig. 6(a)). Each assembled test insert was installed in the soft robotic atrium and the calculated x, y, and z coordinates of the tenting peak, as defined in (2), were recorded. The right atrium was actuated by the FREEs for the duration of each test to verify accurate motion tracking of the FO. Each test cone was measured for 3000 frames, or approximately 30 seconds. The calculated coordinates were then compared to the known actual coordinates, which were determined by the test cone geometry.

Results of the simulated ICE validation test showed that the depth camera algorithm accurately measures the three-dimensional position of the physical FO tenting peak relative to the local basis on the moving atrium. Mean calculated x coordinates were within 0.5 mm of the true value for all test cones (Fig. 6(b)). The least accurate coordinates were in the y direction, with a maximum mean discrepancy of 1.16 mm (Fig. 6(c)). Mean tenting distance, represented by the z coordinate was within 0.5 mm of the true value for all test cones (Fig. 6(d)). A possible source of error in mean x and y coordinates is misalignment during attachment of the cones to the FO inserts. Variance in the data is mostly due to noise in the raw camera measurements. The demonstrated accuracy from the simulated ICE algorithm is sufficient to allow users to position the needle in the desired region of the FO and unambiguously confirm tenting before puncturing the FO.

IV. System Validation

The purpose of system validation was to test the three hypotheses presented in Section I through hands-on evaluation by experienced clinicians.

- *Hypothesis 1:* An active TP simulator is more realistic than a passive simulator.
- *Hypothesis 2:* The SATPS realistically simulates the tactile and visual feedback experienced during TP.
- *Hypothesis 3:* The SATPS is a useful training device for transseptal puncture.

Hypotheses 1 was tested through blind and disclosed comparison of the simulator in "active" and "passive" states. Hypothesis 2 was tested through face validity assessments of the SATPS that asked participants to rate the simulator's realism. Hypothesis 3 was tested through a content validity assessment that asked participants a series of questions about the training utility of the simulator.

TABLE I
System Validation Participant Background Information

Participant	Primary Field	Years of Practice	TPs per Month	Career TPs
1	EP	6	16	>1000
2	EP	2	6	250
3	EP	10	12	2000
4	EP	18	10	>700
5	EP	>20	9	>1000
6	EP	>20	12	>200
7	IC	7	4	>150

EP = electrophysiology, IC = interventional cardiology

A. Methods

The SATPS system validation study was conducted at the Jump Trading Simulation and Education Center in Peoria, IL and OSF Saint Anthony Medical Center in Rockford, IL, and was approved by the University of Illinois at Urbana-Champaign Institutional Review Board (IRB #21731, April 13, 2021). A convenience sample of seven clinicians with a minimum of 100 career TPs were recruited to perform the system validation assessments (Table I). All participants gave informed consent before beginning their session.

Validation sessions were conducted individually. Each trial in this study consisted of the participant performing a transseptal puncture on the SATPS in one of two states: passive (actuators off) and active (actuators on). Pneumatic control valves were cycled at 75 bpm in both states, but airflow to the actuators could be toggled on or off using ball valves hidden under an opaque shroud. This configuration allowed the pneumatic control valves to cycle and create pneumatic actuation sounds during either actuator state, thus preventing the user from guessing the difference between the two states using auditory cues. Before each trial, research personnel positioned the catheter assembly with the tip of the dilator in the superior vena cava (SVC) with the needle retracted. Participants then navigated the catheter assembly to the fossa ovalis, induced tenting, and punctured through the fossa, completing the trial. Participants were allowed to reset trials at any time.

Participants conducted a practice trial with the SATPS in the passive state to familiarize them with the simulator and mitigate any learning effect in the results. Participants then conducted a blind assessment, followed by a disclosed assessment, and finishing with a content validity questionnaire. For the disclosed assessment, a real-time overhead view from a second depth camera (RealSense D415) was displayed on a laptop next to

TABLE II
SYSTEM VALIDATION QUESTIONS AND RESULTS (N = 7). ALL SCORES EXCEPT C2 ARE GIVEN ON A 5-POINT LIKERT SCALE (1–5)

Questions	Results		
Blind Assessment	Score (mean ± SE)		
B1: How realistic was...	Passive	Active	Average
... the feel of navigating the right atrium with the catheter?	3.7 ± 0.5	3.6 ± 0.2	3.6 ± 0.3*
... the feel of the catheter on the aortic mound?	3.7 ± 0.3	3.1 ± 0.3	3.4 ± 0.3
... the feel of tenting the fossa ovalis?	4.3 ± 0.3	3.7 ± 0.4	4.0 ± 0.3**
... the feel of puncturing the fossa ovalis?	4.4 ± 0.2	3.7 ± 0.4	4.1 ± 0.3**
... the representation of tenting in the simulated ICE imaging?	4.1 ± 0.5	3.6 ± 0.4	3.9 ± 0.4*
... the representation of the rest of the heart in the simulated ICE imaging?	3.1 ± 0.5	3.3 ± 0.5	3.2 ± 0.5
... performing transseptal puncture on the SATPS, overall?	3.6 ± 0.6	3.4 ± 0.3	3.5 ± 0.4
	Score (mean ± SE)		
B2: Which felt more realistic in terms of tactile feedback?	3.2 ± 0.6		
Disclosed Assessment			
D1: Which state was more realistic in terms of...	Score (mean ± SE)		
... the feel of navigating the right atrium with the catheter?	3.7 ± 0.4		
... the feel of the catheter on the aortic mound?[1]	2.8 ± 0.4		
... the feel of tenting the fossa ovalis?	3.1 ± 0.1		
... the feel of puncturing the fossa ovalis?	3.0 ± 0.0		
... performing transseptal puncture on the SATPS, overall?	3.1 ± 0.3		
	Score (mean ± SE)		
D2: Which actuation state do you prefer?	3.3 ± 0.4		
Content Validation			
C1: How useful is the SATPS for training how to...	Score (mean ± SE)		
... correctly locate the fossa ovalis with the catheter?	4.0 ± 0.4*		
... verify catheter position on the fossa ovalis before puncture using ICE?	3.9 ± 0.5		
... puncture the fossa ovalis with appropriate force?	4.1 ± 0.3**		
	YES	NO	
C2: Could the SATPS be useful for training residents?[2]	3	3	
Could the SATPS be useful for training fellows?	6	1	
Could the SATPS be an appropriate training and testing format before catheterization lab experience for residents / fellows?	4	3	
Could the SATPS be used as part of the privileging or certifying process for transseptal puncture?	1	6	
Would you recommend using the SATPS for training in transseptal puncture?	5	2	
Score Key			
B1: 1 = very unrealistic, 2 = somewhat unrealistic, 3 = neutral, 4 = somewhat realistic, 5 = very realistic			
B2: 1 = passive much more realistic, 2 = passive somewhat more realistic, 3 = no difference, 4 = active somewhat more realistic, 5 = active much more realistic			
D1: 1 = passive much more realistic, 2 = passive somewhat more realistic, 3 = no difference, 4 = active somewhat more realistic, 5 = active much more realistic			
D2: 1 = strongly prefer passive, 2 = somewhat prefer passive, 3 = no preference, 4 = somewhat prefer active, 5 = strongly prefer active			
C1: 1 = very useless, 2 = somewhat useless, 3 = neutral, 4 = somewhat useful, 5 = very useful			

[1] n = 5 for this question, since two subjects do not use the aortic mound as a tactile cue during TP.
[2] n = 6 for this question because one participant felt it was not applicable for residents to train in TP.
* $p < 0.05$, ** $p < 0.01$

the simulated ICE view to assist the user during right atrial navigation before tenting (Fig. 1(a) and (d)).

1) Blind Assessment: The first stage of system validation was a blind assessment, in which the actuator state was unknown to the participant. The purpose of the blind assessment was to obtain an unbiased comparison of the system in the passive and active states by blocking the participant's view of the atrium under an opaque shroud (Fig. 1(b)). The overhead camera view was omitted from the blind assessment trials to prevent participants from visually identifying the difference between the two states. To prevent the number of completed trials from skewing participant responses due to a learning effect, presentation of the passive or active test condition was randomized, and a new fossa ovalis insert was installed before the start of each test condition. A blind assessment questionnaire included questions evaluating each step of conducting TP on the SATPS for realism on a five-point Likert scale (Table II). Participants completed the questionnaire after each test condition. After completing both test conditions, participants were given the option to retry their first test condition and modify their questionnaire answers for the first test condition based on the experience of both conditions. After finishing the blind trials, participants answered one additional question asking which test condition felt more realistic in terms of tactile feedback.

2) Disclosed Assessment: The second stage of system validation was a disclosed assessment, in which the participant knew the state of the actuators. The disclosed assessment provided a direct comparison of the two actuator states while

providing a clear view of the catheter assembly position prior to tenting. First, research personnel explained and demonstrated the difference between the active and passive actuator states. A new fossa ovalis insert was installed, and participants conducted at least one trial each for the passive and active states. The overhead camera provided participants with a view of the interior of the atrium for the entire duration of each trial. After all disclosed trials, participants completed a series of questions directly comparing the passive and active states in terms of realism and user preference on a five-point Likert scale (Table II).

3) Content Validation: After completing all system validation trials, participants completed a questionnaire designed to evaluate the content validity of the SATPS. The questionnaire included a task training assessment to evaluate the utility of the SATPS for training users in each critical step of TP on a five-point Likert scale, and a system assessment with yes/no questions regarding use cases for the SATPS (Table II).

4) Statistical Analysis: Statistical analyses of compiled validation questionnaire scores were used to evaluate each hypothesis. Student's *t*-tests have been shown to be robust even when used with Likert scale data with small sample sizes, non-normal distributions, and unequal variances [32], [33]. To test Hypothesis 1, paired *t*-tests were used to evaluate whether active realism scores were greater than passive realism scores for each participant during the blind assessment. One-sample *t*-tests were used to evaluate if mean scores from the blind and disclosed state comparison questions were greater than the neutral score of 3. Hypothesis 2 was tested using averaged passive and active blind assessment realism scores for each participant. One-sample *t*-tests were used to determine if the mean of all averaged participant scores for each question was greater than the neutral score of 3. Hypothesis 3 was evaluated by using one-sample *t*-tests to compare mean content validation scores to the neutral score of 3 (Table II). All *t*-tests used $p < 0.05$ as the threshold for significance. Statistical analysis was performed using data analysis software (OriginPro 2020, OriginLab). Results are presented as mean $\pm$ standard error (SE) unless otherwise noted.

B. Results and Discussion

Results of system validation generally confirmed the overall realism and training utility of the SATPS. However, results also suggest that Hypothesis 1 did not account for the high variability in patient cardiac conditions. Participant feedback yielded valuable insights for improving the SATPS.

1) Passive and Active State Comparison: Results from the blind assessment found no statistically significant difference in realism scores for the features of the simulator between passive and active states ($p > 0.05$, Table II). Mean scores comparing the realism of the two states after the blind and disclosed assessments were not significantly greater than the neutral score of 3 (3.2 ± 0.6 and 3.3 ± 0.4, respectively). None of the disclosed assessment state comparison scores were significantly greater than 3. Thus, these results led us to reject Hypothesis 1 (*an active TP simulator is more realistic than a passive simulator*).

Comments from participants indicated that the reason for the rejected hypothesis was not due to a lack of perceptible difference in the tactile feedback of the two actuator states. Six of the seven participants were electrophysiologists (EPs), meaning they most commonly performed TP during atrial fibrillation ablation procedures. Multiple participants stated that the active heart felt more like a healthy young heart than that of an AF patient. Patients with atrial fibrillation have reduced atrial ejection fractions [29], [34], implying decreased atrial wall displacement during atrial systole. Therefore, the beating of the right atrium in a patient with atrial fibrillation is less likely to be felt by the operator through the TP catheter assembly compared to patients without AF. For clinicians who primarily operate on AF patients, a passive simulator could then be considered more realistic than an active one.

Results and feedback from the passive and active state comparison suggest that the active state might be considered more realistic by pediatric EPs or interventional cardiologists than the primarily adult EPs included in this study. An expanded validation study with a more diverse participant group would help distinguish the simulation preferences of different specialists. Even within our participant group there was variability in actuator state preference, suggesting that a TP simulator should offer versatile actuation settings to train new users for different TP techniques and applications. The ability of the SATPS actuators to be adjusted via pressure regulation makes it possible for the SATPS to simulate variety of cardiac conditions.

2) Face Validity: Face validity of the SATPS, represented by Hypothesis 2 (*the SATPS realistically simulates the tactile and visual feedback experienced during TP*), was largely supported by the results of this study (Table II). Participants rated the realism of the tactile feedback from the soft robotic atrium and the replaceable fossa ovalis favorably. The feel of navigating the right atrium was significantly more realistic than neutral (3.6 ± 0.3, $p = 0.046$). The realism of the feel of the catheter on the aortic mound was borderline significant (3.4 ± 0.3, $p = 0.086$). The feel of tenting and puncturing the FO received the highest mean realism scores among all subsystems, and both were significantly higher than neutral score of 3 (4.0 ± 0.3, $p = 0.005$ and 4.1 ± 0.3, $p = 0.003$, respectively).

The most common detractors for tactile realism scores were FO position and friction. The FO in the soft robotic atrium was more posterior than expected for most participants, resulting in increased difficulty locating the fossa during the blind assessment. While the position of the fossa was anatomically correct in the atrium model according to mean FO position from literature [31], it is likely that the compliance of the soft robotic atrium caused it to sag, rotating the FO posteriorly. This rotation error was increased during actuation. Adding an additional rotational constraint to the assembly could help maintain correct FO positioning in both actuation states. Although friction between the TP catheter assembly and the walls of the atrium was reduced by the low-friction coating, there was still noticeably more friction between the catheter and the silicone than there would be between the catheter and heart tissue lubricated by blood. This friction caused excessive resistance during axial translation of the catheter and during "clocking", or axial rotation of the

catheter. The rotational resistance exacerbated the perceived FO position error, since participants had to apply extra rotation of the catheter to overcome friction during clocking.

Representation of tenting in the simulated ICE subsystem had a mean realism score that was significantly greater than the neutral score, but representation of the rest of the heart did not (3.9 ± 0.4, $p = 0.031$ and 3.2 ± 0.5, $p = 0.34$, respectively, Table II). Participants felt the on-screen FO deformation during tenting was accurate and useful for confirming the puncture location, but the lack of pre-tenting needle tracking and the static cross-sectional view were regarded as major limitations of the current system. Without the ability to locate the needle inside the atrium with simulated ICE or fluoroscopy, some participants became disoriented during the blind assessment trials. Participants had varying preferences for the orientation of the heart in the simulated ICE. The view of the FO and the surrounding anatomy during real TP is dependent on the ICE technology used (radial or phased-array) and the specific procedure for which the TP is being performed [35]. These results highlight a need for expanded simulated ICE capabilities in the SATPS to improve realism, including a controllable ICE view and pre-tenting needle imaging.

The mean realism score for performing TP on the SATPS overall was not significantly higher than the neutral score (3.5 ± 0.4, $p = 0.14$, Table II)). When discussing their responses, participants who gave low scores for overall realism primarily focused on the absence of sophisticated imaging they typically use during TP. These participants considered tactile feedback secondary to visual feedback, and gave their perception of the simulated ICE realism more weight than the other two subsystems when assigning the overall score.

3) Content Validity: Content validity of the SATPS, represented by Hypothesis 3 (*the SATPS is a useful training device for transseptal puncture*), was supported by the results of this study. In the task training assessment, the utility of the SATPS scored significantly higher than the neutral score of 3 for training users how to locate the FO and puncture it with appropriate force (4.0 ± 0.4, $p = 0.019$ and 4.1 ± 0.3, $p = 0.008$, respectively) (Table II). The utility of the simulator for training how to verify catheter position on the FO using ICE scored greater than neutral with borderline significance (3.9 ± 0.5, $p = 0.056$). The system assessment portion of the validation study also supported Hypothesis 3, with six out of seven participants stating that the SATPS could be useful for training fellows in TP, and five out of seven stating they would recommend the SATPS for training in TP. Participant responses suggest that in its current form, the SATPS is primarily useful as an introduction to TP for fellows before operating on a real patient, and less suitable for use in testing or certification processes.

Suggestions from participants to improve content validity focused on more advanced visual feedback capabilities and representation of a larger variety of patient anatomies and pathologies. While many experienced operators are able to navigate the atrium relying primarily on tactile feedback, most still rely on fluoroscopy or ICE to assess the situation if they encounter unexpected difficulties. Expanding the function of the simulated ICE environment and adding a simulated fluoroscopy environment would help trainees to learn how to troubleshoot with both imaging technologies when the procedure does not go as planned. Participants also pointed out that the SATPS is a good representation of a normal, healthy heart, but that the SATPS could better prepare trainees for difficult TP scenarios if it represented atypical, but not uncommon abnormalities, such as redundant atrial septa and thick or calcified septa. These two example scenarios require a modified technique for puncturing through the septum, and would be safer for trainees to encounter for the first time in a simulator instead of a real patient.

V. Study Limitations and Future Work

A. Design Limitations

System validation highlighted several design limitations of the SATPS (Section IV-B). The current soft robotic right atrium and the replaceable fossa ovalis seem to accurately simulate a typical healthy heart, but the SATPS would be more realistic and a more effective training tool if there were additional atria and FO inserts to represent the high variability in patient heart shape and size, including atypical anatomy known to increase TP difficulty. The simulated ICE subsystem does not currently display the TP catheter assembly until tenting begins, preventing the user from using imaging to troubleshoot issues that arise during navigation of the right atrium. In a training environment, the system is intended to be used with the overhead camera enabled to assist the user with pre-tenting navigation. However, visualization could be improved by using the overhead camera to simulate an ICE view during the whole procedure. The SATPS also lacks simulations of other common feedback tools such as fluoroscopic imaging, pressure feedback, and contrast injection [2].

B. Sample Size Limitations

The system validation study was limited by the effects of using a small convenience sample determined by the availability of local expert TP specialists. This study's participants were predominantly electrophysiologists who operate on adults. Testing with a broader range of cardiac specialists, who perform TP on a variety of patients and conditions, could provide more diverse perspectives on the simulator's design.

Statistical findings of the system validation results were limited by the small participant group. Although small samples of Likert data can yield meaningful results from *t*-tests, smaller sample sizes also tend to reduce statistical power, increasing the likelihood of false negative errors and potentially creating a bias for large effects among the statistically significant results [32], [33]. In our assessment, these potential errors and biases do not substantially change the conclusions presented in this work. In the case of Hypothesis 1, low statistical power increases the likelihood of missing a potential difference in perceived realism between the passive and active SATPS actuation states. Combined with clinician feedback, a statistically significant result with a low effect for Hypothesis 1 leads to the same conclusion as a statistically insignificant result: the passive and active states are approximately equal in terms of realism, but

simulate different cardiac conditions. Similarly, low statistical power for Hypotheses 2 and 3 may have increased the chance of small undetected effects that indicate perceived realism or utility by participants. Combined with verbal feedback, these results would still highlight areas for improvement in future SATPS iteration.

C. Future Work

Design improvements to the SATPS are driven by participant feedback during system validation.

The control system of the SATPS will be upgraded to improve realism and expand simulation capabilities. We will develop an algorithm using data from the overhead depth camera to track the catheter assembly as it travels through the right atrium, providing the necessary input for expanded simulated ICE and simulated fluoroscopy environments. Development of a physical controller for adjusting the simulated ICE view is underway. The SATPS control system can be programmed to produce any heart rate or rhythm within the physical limitations of the soft actuators, which take time to inflate and deflate. This functionality was not included in our pilot study, but could improve realism by more accurately simulating heartbeats of patients with different conditions.

Mechanical upgrades will improve the tactile accuracy of the SATPS and broaden its training utility. Additional soft robotic right atria should be developed to represent different heart shapes, and new fossa inserts should be designed to represent more challenging puncture conditions such as redundant and calcified atrial septa. Realism of fossa ovalis inserts could be further improved with thinner, tougher materials enabled by revised manufacturing methods, including composites or 3D-printed materials with tunable material properties [36], [37]. Conductive FO materials could allow for trainees to practice with increasingly popular radiofrequency TP needles. Further reduction of friction inside the atrium would also improve realism. Expanding the scope of the SATPS to include guidewire placement would give trainees practice in another critical step of TP. Incorporating an adjustable femoral vein insertion angle, a parameter dependent on patient body fat, would provide an opportunity to practice TP with and without the ability to rest one's hands on the patient's leg during atrium navigation and puncture.

Following design changes, the SATPS should be validated with expanded face and content validation with a larger and more diverse sampling of novices and experts. Additional, more objective testing should include construct validity to demonstrate that the SATPS can be used to correctly distinguish between expert and novice TP operators, and concurrent validity to determine if the SATPS improves real-world performance metrics for TP. Parameters for concurrent validity, such needle placement accuracy and extension into the left atrium, could be identified and measured using both cameras on the SATPS.

VI. Conclusion

We designed the SATPS to simulate the right atrium for the purpose of training in three critical steps of transseptal puncture: locating the fossa ovalis, verifying the position of the TP catheter during tenting, and puncturing the FO with appropriate force. The SATPS is novel because it accurately simulates atrial dynamics, FO force feedback, and ICE imaging during tenting. System validation showed that an active TP simulator is not necessarily more realistic than a passive one, but that it is still advantageous to allow for both in order to simulate a variety of cardiac conditions. The SATPS was considered a mostly realistic representation of the right atrium during TP, and a good training tool for beginners before they operate on a real patient for the first time. The realism and training utility of the SATPS will be improved with more advanced imaging simulation and a wider variety of physical atrium and fossa ovalis models.

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