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Intracardiac Ultrasound Guided Systems for Transcatheter Cardiac Interventions

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Abstract

Transcatheter cardiac interventions are characterized by their percutaneous nature, increased patient safety, and low hospitalization times. Transcatheter procedures involve two major stages: navigation towards the target site and the positioning of tools to deliver the therapy, during which the interventionalists face the challenge of visualizing the anatomy and the relative position of the tools such as a guidewire. Fluoroscopic and transesophageal ultrasound (TEE) imaging are the most used techniques in cardiac procedures; however, they possess the disadvantage of radiation exposure and suboptimal imaging. This work explores the potential of intracardiac ultrasound (ICE) within an image guidance system (IGS) to facilitate the two stages of cardiac interventions.

First, a novel 2.5D side-firing, conical Foresight ICE probe (Conavi Medical Inc., Toronto) is characterized, calibrated, and tracked using an electromagnetic sensor. A point-to-line registration technique is employed to perform the calibration, which is validated using two geometric phantoms. The results indicate an acceptable tracking accuracy within some limitations. A texture mapping-based 3D Slicer module is also developed to visualize the unique conical geometry of the Foresight ICE probe.

Next, an IGS is developed for navigating the vessels without fluoroscopy. A forward-looking, tracked ICE probe is used to reconstruct the vessel on a phantom which mimics the ultrasound imaging of an animal vena cava. Deep learning methods are employed to segment the complex vessel geometry from ICE imaging for the first time. The ICE-reconstructed vessel was compared to the CT-segmented version of the vessel, which showed a clinically acceptable range of accuracy. The average surface distance error was recorded to be less than a millimeter.

Finally, a guidance system was developed to facilitate the positioning of guidewire and tools during a TriClip procedure which is performed to repair the tricuspid valve by reducing the amount of regurgitation as seen in Doppler ultrasound imaging. The designed system potentially facilitates the positioning of the TriClip at the coaptation gap by pre-mapping the corresponding site of regurgitation in 3D tracking space. A user-friendly Slicer module was developed to automatically segment the vena contracta of the regurgitant jet from Doppler ICE and place it in 3D space.

Summary for Lay Audience

Heart surgeries have evolved from high-risk open-heart surgeries to much safer minimally invasive procedures. Transcatheter interventions often involve repairing a structural heart disease by accessing the heart through veins and arteries. Thin, wire-like tools such as a guidewire are inserted in the body via limbs and are then used to traverse the vessels using live x-ray technology called fluoroscopy. Once the tools reach the heart, they are then positioned at the pathological, target site and deployed to deliver therapy. This positioning of tools is often facilitated using an external ultrasound probe. In this work, we explore the potential of using a novel intracardiac ultrasound probe (ICE) to assist transcatheter procedures in an image-guided system (IGS). We augment a Foresight ICE probe (Conavi Medical Inc.) with an electromagnetic tracking sensor so the probe's position can be always tracked in 3D space. Calibration methods to track the exact location of the ICE image are described as well. The second objective is to demonstrate the feasibility of using a tracked ICE probe in order to generate a vascular roadmap which can then be followed by a tracked guidewire to navigate the vessels. We designed an ultrasound-realistic vessel phantom and reconstructed the vessel in real-time using deep learning methods. The results indicate that ultrasound technology can be used instead of fluoroscopy to visualize and traverse the vessels. The third objective is to develop an IGS to assist the positioning of a therapeutic device during tricuspid valve repair surgery. Current imaging standards produce suboptimal imaging of the tricuspid valve and it can be challenging to identify the site of tricuspid valve regurgitation. We designed an algorithm to automatically detect the location of the regurgitation site from the color Doppler imaging on a tracked ICE probe. This method helps pre-map the location the clinicians have to target with the therapeutic device. This work demonstrates some of the ways an ICE ultrasound technology can improve and assist the existing procedural workflows by providing more information to the clinicians safely and accurately.

Keywords: Intracardiac echocardiography (ICE), Image-guided system (IGS), Transcatheter interventions, Tricuspid valve repair, Vessel reconstruction, Fluoro-free navigation.

Co-Authorship Statement

This thesis integrates several publications that are published or in preparation for submission. Details regarding the author's contributions to these manuscripts are provided below.

Chapter 2

Reference: Hareem Nisar, John Moore, Natasha Alves, Germain Hwang, Terry M. Peters, Elvis C. S. Chen. "Ultrasound calibration for unique 2.5D conical images", Proc. SPIE 10951, Medical Imaging 2019: Image-Guided Procedures, Robotic Interventions, and Modeling, 1095126 (8 March 2019).

Contributions: This chapter contains work beyond the above-mentioned publication. It also includes an extensive report on the characterization of the Foresight^{TM} ICE probe. My contributions towrads the report include experimental setup and design, data acquisition, data analysis and writing of the report. Elvis C.S. Chen assisted with the study design. Terry Peters and Brian Courtney reviewed and edited the report. For the manuscript, my contributions include study design, performing experiments, data collection and manuscript preparation. Natasha Alves and Germain Hwang provided their expertise on the probe design during all stages. Elvis C.S. Chen extended his technical expertise during the calibration process. All authors helped in reviewing and editing the manuscript.

Chapter 3

Reference: Hareem Nisar, John Moore, Roberta Piazza, Efthymios Maneas, Elvis C. S. Chen, and Terry M. Peters. "A simple, realistic walled phantom for intravascular and intracardiac applications", Int J CARS 15, 1513–1523 (2020).

Contributions: My contributions to this study include phantom design, preparation of raw materials, imaging data collection, image analysis, and manuscript preparation. John Moore assisted with phantom making and CAD designs. Roberta Piazza helped with the preparation of materials for the phantoms. Efthymios Maneas extended his expertise in phantom making and editing the manuscript. All authors helped in reviewing and editing the manuscript.

Chapter 4

References: Hareem Nisar, Leah Groves, Leandro Cardarelli-Leite, Terry M. Peters, and Elvis C.S. Chen. "Toward Fluoro-Free Interventions: Using Radial Intracardiac Ultrasound for Vascular Navigation", Ultrasound in Medicine and Biology (UMB), (2022)

Hareem Nisar, Patrick K. Carnahan, Djalal Fakim, Humayon Akhuanzada, David Hocking, Terry M. Peters, and Elvis C. S. Chen. "Towards ultrasound-based navigation: deep learning based IVC lumen segmentation from intracardiac echocardiography," Proc. SPIE 12034, Med-

ical Imaging 2022: Image-Guided Procedures, Robotic Interventions, and Modeling, 1203422 (4 April 2022)

Contributions: My contributions include the study design, software development, data collection and analysis, and manuscript writing. Leah Groves assited with the ultrasound reconstruction pipeline and manuscript editing. Leandro Cardarelli-Leite provided his expertise in designing the study and structuring the manuscript. Patrick Carnahan assisted during the software development stage involving deep learning. Djalal Fakim and Humayon Akhuanzada established the ground truth segmentation. David Hocking supervised the process of defining ground truth and made corrections. All authors helped in reviewing and editing the manuscript.

Chapter 5

Reference: Hareem Nisar, Djalal Fakim, Daniel Bainbridge, Elvis C. S. Chen, and Terry Peters. "3D localization of vena contracta using Doppler ICE imaging in tricuspid valve interventions", Int J CARS (2022).

Contributions: My contributions to this work includes study design, data collection, development of the methods, data analysis, and writing. Djalal Fakim was responsible for the manufacturing of the patient-specific valve models and imaging the beating heart phantom for data acquisition. He also contributed towards the writing of the final manuscript. Daniel Bainbridge provided clinical expertise in designing the research question and establishing the clinical need. All authors helped in reviewing and editing the manuscript.

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List of Abbreviations

2D	Two dimensional
2.5D	Two and a half dimensional
3D	Three dimensional
4D	Four dimensional
CT	Computed tomography
ECG	Electrocardiogram
EM	Electromagnetic
FOV	Field of view
ICE	Intracardiac echocardiography
IGI	Image guided intervention
IGS	Image guidance system
IVC	Inferior vena cava
IVUS	Intravascular ultrasound
MRI	Magnetic resonance imaging
MTS	Magnetic tracking system
MV	Mitral valve
PVA-c	Polyvinyl alcohol cryogel
ROI	Region of interest
SVC	Superior vena cava
TAVR	Transcatheter aortic valve repair
TEE	Transesophageal echocardiography

TMM	Tissue-mimicking material
TR	Tricuspid valve regurgitation
TTE	Transthoracic echocardiography
TV	Tricuspid valve
US	Ultrasound
VMM	Vessel-mimicking material

Chapter 1

Introduction: Ultrasound Guidance in Transcatheter Cardiac Interventions

Transcatheter cardiac interventions face the challenges of invisible tool phenomena, not having a line-of-sight with the anatomy, and relying on 2D fluoroscopic imaging, which is known to cause harmful radiation exposure and spinal issues in the interventional team due to the need to wear heavy lead-lined aprons. In this thesis, we address these challenges by designing image guidance systems (IGS) to facilitate the different stages of a transcatheter cardiac procedure using electromagnetic (EM) tracking technology and intracardiac echocardiography (ICE). We first characterize, calibrate, and track a novel Foresight^{TM} ICE probe so it may be used in an IGS. Then, an ICE-generated vessel reconstruction method is developed to facilitate fluoro-free tool navigation. Finally, the tracked ICE probe is used in a Doppler mode to identify the site of tricuspid valve regurgitation in 3D space and facilitate the device positioning step during valve repair interventions. This chapter provides the necessary background information and overview of the state-of-the-art technology relevant to the work performed in this thesis.

1.1 Cardiology

1.1.1 Cardiac Anatomy

The heart is the *heart* of the human body as it supplies and regulates blood flow throughout the circulatory system to keep the rest of the body alive. This complex and dynamic organ continuously beats by means of muscular contractions to maintain the blood flow. It is positioned slightly left to the mediastinum in the chest, and in humans, there are four cardiac chambers – two atria and two ventricles, along with two atrioventricular valves namely the tricuspid valve (TV) and the mitral valve (MV). The right atrium, the tricuspid valve, and the right ventricle

are collectively referred to as the 'right-sided heart'. Similarly, the left atrium, the mitral valve, and the left ventricle are called the 'left-sided heart'. The left and right atria are separated by a thin wall of tissue called the atrial septum, that needs to be punctured when a left-sided transcatheter procedure is performed. From a therapy perspective, there are many differences in the left and right sides of the heart including the anatomy of the atrioventricular valve, the pressures on each side, and the means of access to the desired anatomical structure.

The pressure on the left side of the heart is around three times higher than that on the right side, and by approximately 8mmHg on average and is mainly due to the function each side is performing. The muscles on the left side are stronger as well since they have to pump the oxygenated blood to the entire body including the extremities. On the other hand, the right-sided heart supplies blood to the lungs with fewer vessels and less resistance, thus requiring lower blood pressure and pumped by less powerful heart muscles. For this reason, there is a high risk of perforation during right-sided heart surgery or therapy.

The nature of mitral and tricuspid valve surgeries/therapies differ significantly as these valves differ greatly in their anatomy and positioning. The mitral valve has two leaflets that are connected to the papillary muscles using tendinous chords (chordae tendinae) or "heart strings". Due to its posterior location, close to the esophagus, the MV can be visualized well using standard cardiac ultrasound or transesophageal echocardiography (TEE) views. As such, mitral valve therapies have been well developed and standard protocols exist in clinical practice. Meanwhile, tricuspid valve therapies and imaging protocols are currently underway. As the name suggests, the tricuspid valve has three leaflets that regulate the blood flow between the atrium and the ventricle. It is positioned such that the TEE probe is parallel to the TV annulus and at a significant distance, thus causing signal dropout in the ultrasound (US) imaging. Moreover, the chordae are more complicated in the case of the TV, with the chordae tendinea attaching the leaflets to the papillary muscles as well as directly to the walls of the right ventricle.

This thesis deals primarily with transcatheter interventions which are often performed to repair structural heart diseases. During these interventions, the heart is accessed using either the inferior vena cava (IVC) or the superior vena cava (SVC) which opens directly into the right atrium. The tricuspid valve can be accessed by entering in the right atrium and bending the catheter at roughly 90 degrees. To access the left atrium or the mitral valve, the catheter first needs to enter the right atrium and then puncture the atrial septum to be advanced into the left atrium. Transseptal puncture is a meticulous procedure with an associated risk of aortic valve puncture or pericardial perforation.

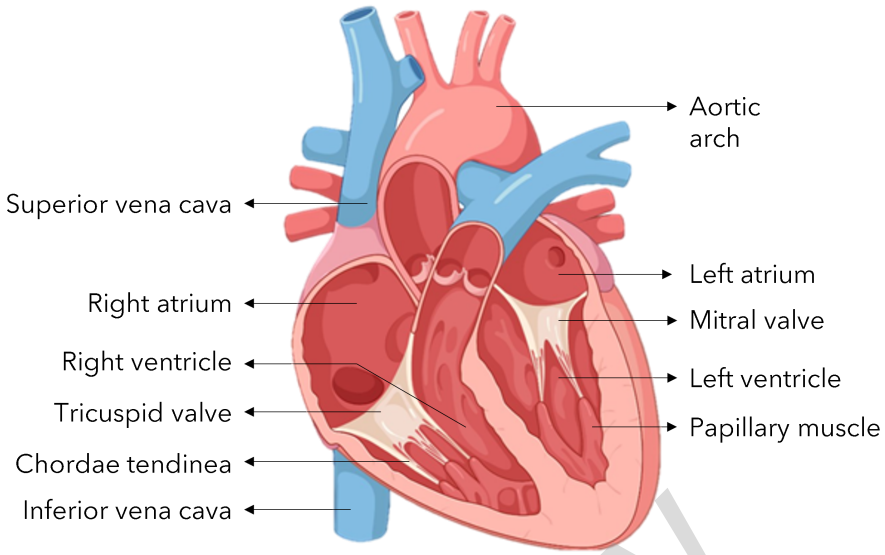

Figure 1.1: Illustration of the cross-sectional view of the heart with common anatomical features [157]

1.2 (R)evolution of Cardiac Therapy

This thesis strongly advocates for percutaneous, transcatheter, cardiovascular interventions as opposed to open-heart surgeries. We, as humankind, have come a long way towards simplifying the surgical procedures for the heart and are still progressing. From the first successful heart surgery by Dr. Ludwig Rehn in 1896 to repair a stab wound, to the revolutionary invention of the cardiopulmonary by-pass machine and the development of Cath labs and interventional suites – surgery has continuously improved with technological advances [39, 69]. Today, well-established techniques in cardiac surgery can further benefit from modern technology to enhance patient safety, minimize the concerns of the medical staff, and reduce the time for hospitalization. This section looks at the different categories of cardiac surgery and therapy i.e., the evolution of open-heart surgery, to minimally invasive cardiac surgeries and transcatheter procedures. A comparison of these major surgical categories can be seen in figure 2.

1.2.1 Open-Heart Surgeries

Cardiac surgery was clinically initiated in the early 1940s when only a few procedures, including the closure of a patent ductus to separate the two merged blood vessels, repair of aortic coarctation or narrowing, the Blalock-Taussig shunt to increase the blood flow to the lungs, and the mitral commissurotomy to repair mitral valve stenosis could be performed [189]. Atrial septal defect closure was tried using techniques such as hypothermia and the Gross well [58],