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CONSTANT FORCE APPLICATION ON A BEATING SWINE HEART: ROBOTIC ASSISTANCE FOR MAPPING AND ABLATION PROCEDURES

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ABSTRACT

Robot assisted surgery has been widely accepted by the medical community. Surgeons utilize robots in many different procedures worldwide. However, cardiothoracic surgeons do not regularly use robotic tools to aid them in performing even simple, catheter based procedures such as cardiac ablation or mapping. Some cardiac Monophasic Action Potentials (MAPs) and ablation catheters require a specific window of force to either effectively characterize or scar cardiac tissue. This is challenging to maintain through the cardiac cycle, so the application of a constant force is not a trivial task for surgeons. Robotic assistance to control the force applied to a catheter through ablation and mapping procedures is needed to improve the outcome for patients. The purpose of this work is to develop a single degree of freedom robot that controls the force applied to a beating swine heart. Rather than trying to predict the motion and timing of the heartbeat, or tracking its movement this robot senses and reacts to the force produced by the myocardium. Through the cardiac cycle, the robot applies a constant force to the surface of a beating heart. The kinematics of the cardiac tissue were characterized by utilizing piezoelectric transducers. Hardware to control the catheter motion was designed to fit most commercially available devices. The controller was designed by first building a mathematical model using measured data, and then a control law was implemented considering the heartbeat as disturbances to the system. Finally, testing was completed with dry runs, and in situ and ex-vivo testing in the Visible Heart® Laboratory.

Keywords: Robot Assisted Surgery, MAPs, Ablation, PID, ex-vivo, in-situ.

1 Introduction

Heart disease, stroke and other cardiovascular diseases account for nearly one of every three deaths in the US. About 92.1 million American adults are living with some form of cardiovascular disease or the after-effects of stroke [1]. In 2013, cardiovascular deaths represented 31% of all global deaths. Between 2013 and 2014, the estimated global cost of cardiovascular disease was $204.8 billion, and it is estimated to increase 100% by 2030 [1]. Among these cardiovascular conditions are cardiac arrhythmias, suffered by as many as 2.2 million Americans. [2] They occur when the electrical impulses that coordinate the heartbeats do not conduct properly, causing the heart to beat too fast, too slow or irregularly.

Robot assisted minimally invasive surgery has been widely accepted by the medical community. Surgeons utilize robots in a variety of procedures and applications worldwide. However, robot assisted cardiac surgery has not been adopted for cardiothoracic procedures widely due to the complexity of access during a procedure on a beating heart and breathing lungs. Several control algorithms have been developed to accommodate for this motion. Among these algorithms, beating heart motion synchronization is often accompanied by a high speed camera or a different form of optic system for synchronization [3][4][5]. Beating heart compensation is then achieved for the application of minimally invasive direct coronary artery bypass surgery [3][4] and mitral valve repair surgery [5]. Algorithms that utilize non-optic tracking systems are often applied to the visualization system for laparoscopic surgical robots to supply a stable view to the operating surgeon [5].

Currently, cardiac movement compensation is not implemented for simple procedures such as cardiac mapping and ablation without the use of visual synchronization. Cardiac mapping, which provides MAPs, is highly desirable in order to monitor or identify arrhythmias in patients. In clinical procedures, ablation is the gold standard and its precision and efficacy are key to the quality of life of patients. However, both improved and more efficient MAP recordings and ablation

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procedures are currently limited by the inability to apply constant pressure to cardiac tissue through the cardiac cycle [6] [7].

1.1 Related Work in Literature

A surgical robot system that compensates for motions of organs during an operation is presented in Nakamura et. Al. [3] showing promise but reporting a large tracking error due to camera feedback system problems. An active relative motion canceling algorithm employing electrocardiograms to achieve effective motion cancellation is proposed in Bebek et. Al. [4]. Groeger et al. [9] used a two-camera computer vision system to measure local motion of heart and performed analysis of measured trajectories. These examples of previous work conclude that motion compensation is achievable. Additionally, other work like the one presented in Trejos et. al. [10] demonstrated the ability to complete tasks on targets while motion cancellation is in progress.

Studies by Ginhoux et al. [11] and Rotella [12] demonstrated motion canceling through prediction of future heart motion with predictive controllers and measured heart motion data obtained from a tracking camera as a baseline. The error reported in pixels is equivalent to a maximum of approximately 1.75mm which is too large to use in surgery. In Rotella [12], a 1-DOF test bed system showed accuracy very close to the desired error specifications for heart surgery but it was concluded that further and more descriptive motion was needed and desired.

A recent and simple approach to motion compensation is presented in Yang et. Al. [13]. Here, a novel prediction algorithm is proposed to track the motion of the heart utilizing Dual Time-Varying Fourier Series (DTVFS) modeling the motion and optimal sine filtering is used to accurately measure the instantaneous frequencies of a breathing cycle and heart beating from the motion curves of points of interest.

1.2 System Concept for Robotic Platform

The work discussed previously, implemented varying methods of tracking and prediction for cardiothoracic motion. The work presented in this paper aims to apply simple control and feedback algorithms to maintain the force on cardiothoracic organs.

This work aims to enhance the understanding of MAPs and improve outcomes of patients undergoing cardiac catheter ablation through investigating a simple one Degree of Freedom (1-DOF) robotic platform. This robotic platform utilizes proportional–integral–derivative (PID) control loop to provide a constant contact force through a force-sensing catheter on a beating swine heart model.

2 Methods

The proposed architecture is grounded on a 1-DOF system implemented as a platform for use with commercially available MAP or ablation catheters. The platform aims to control the uni-axial movement of the catheter in response to the movement of tissue. The response of the system compensates for this movement in space and provides a constant contact force over a determined period, allowing the physician to perform the procedure with accuracy. In order to achieve this goal, the heart motion needed to be characterized, a custom robot platform around commercially available MAP and ablation catheters realized, and an algorithm to pair the two systems developed, integrated and implemented.

2.1 Heartbeat Kinematics Characterization

To obtain the requirements for the robotic system, characterization of the beating heart motion was needed. Using piezoelectric transducers and sensors, ventricle displacements were obtained and integrated to acquire displacement, velocity, and acceleration of a swine heartbeat. Force was calculated using acceleration and mass of the piezoelectric transducer. From the full characterization of a swine heartbeat, the force amplitude and period of force oscillation were deduced.

It should be noted that both motors were compensated in the same manner. This was achievable because of the unique direct drive system outlined in the following section.

2.2 Robotic Platform Design

The concept of the robotic platform is summarized in Figure 1. A force sensing catheter (Abbott's TactiCathTM Quartz), connected to a suite (Abbott's TactiSysTM Quartz) enters the robotic platform. The catheter shaft is paired with two motors actuated in such a way that they work together to achieve smooth motion over small distances and quick, precise motions based on the response of the system.

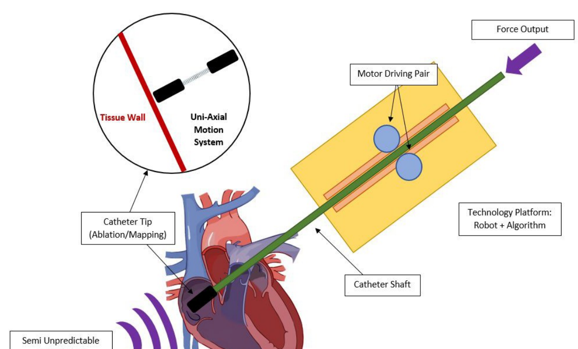

Figure 1: Schematic of Robotic Platform Concept

A key design decision was the use of direct drive motors to reduce undesirable effects from other types of drivers. Primarily, this reduced the need for gears which are notorious for backlash and reduce performance.

2.3 Controller Design

Control of the platform was achieved through PID compensation of the system error signal. Output error is calculated as the difference between the target force and the force sensed at the tip of the catheter. Since both speed and low error are desired in this system, a compensator consisting of integral and derivative terms provided the ideal response. This is shown visually in Figure 2. The calculation is outlined in equation (1).

Additionally, the swine heartbeat was modeled as output disturbances during design and tuning, which allowed for sensitivity transfer function based design. The control was implemented on a Teensy 3.5 microcontroller with gains derived from models including simulated heartbeats and results from the system identification.

$$u = e * K_p + \left(\sum e\right) * K_i + \frac{\Delta e}{\Delta t} * K_d \qquad (1)$$

Where, u is the plant input, e is the output errors, K_p is the proportional gain, K_i is the integral gain, and K_d is the derivative gain.

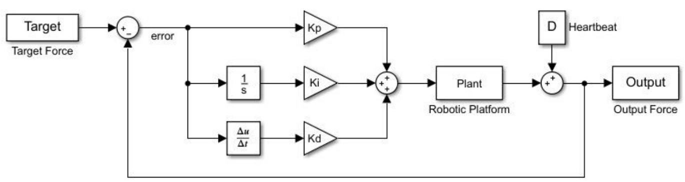

Figure 2: Block diagram of the robotic platform with PID control and disturbance

To interface with the catheter, rubber wheels with a custom guide were used to ensure smooth motion. Additionally, the motors were mounted in a custom housing, shown in Figure 3, which includes adjustable motor mounts for adequate preloading on the catheter. A result of many iterations, this setup provides the best contact with the catheter without damaging sensors.

It is important to note that during the design process of the housing, the most challenging element to finalize was the wheels' contact area with the catheter. The system required the wheels to be light enough that the motor could drive them with relative ease so that they did not add unnecessary resistance or added torque. The surface of the wheels needed to provide a surface to allow the catheter to move with low force inputs, but provide enough friction to prevent slip when the wheels changed direction to compensate for the input motion. At the same time, the system had to be able to break static friction. This delicate balance was achieved after several iterations of materials, wheel profiles and diameters, distance between motor pairs and variations in the gap the catheter fills. This trial and error approach resulted in a system that met all the needs demanded by the algorithm controlling the movement, torque and speed of the motors.

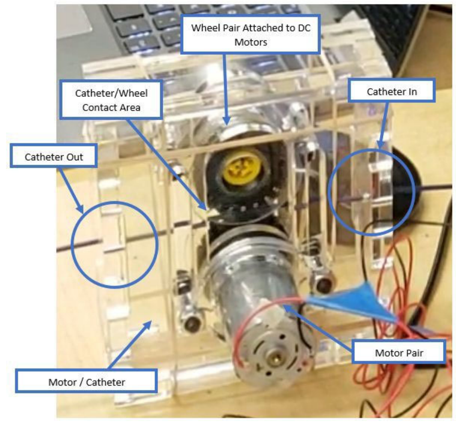

Figure 3: Custom housing

A bench top power supply was connected to a box that housed the system circuitry. Said circuitry box has an umbilical cord connected to the main robotic platform which was designed to be small to fit the space needs of an operating room (OR) or pre-clinical study laboratory. Four of the six surfaces of the box are free of wires and ports such that it could be clamped in place by any means necessary and oriented as needed when tested. The force sensing catheter was threaded through the front and back openings laser cut to reduce the effects of friction, and minimize error as well as prevent damage to the catheter shaft and avoid generating foreign material that could be shed. The TactiCathTM Quartz catheter was connected to the TactiSysTM Quartz suite which generates light that travels through the fiber optics along the shaft and bounces back and forth generating force and direction signals from the tip. The force applied on the catheter tip sensor is constrained to one direction through the robotic platform design and proper subject heart placement. The information gathered in real time by the suite was obtained via an analog output cable that is directly connected to the circuitry box and used in the PID loop to generate an output signal to the motors which in turn move the shaft forward or backward in a uniaxial fashion, providing a constant force application to the tissue, constantly compensating for its movement.

2.4 System Identification

System identification is a process in which statistical methods and optimal Design Of Experiments (DOE) conditions are used to build mathematical models and describe dynamical systems. During this process, descriptive and informative data from measurements is generated in order to fit the constructed model. A soft pad made from mixing PlatSil® Gel-OO and PlatSil® Deadener LV (Polytek® Development Corp., Williams Township, PA) in equal parts was used in this system identification testing. The chosen material mimics stable tissue. A ramp motor Pulse-Width Modulation (PWM) input was used for the system identification. The range of the ramp PWM input was varied from 25 to 60, linearly increasing over a course of 20 seconds. These values were chosen because the motors broke free and started moving the catheter shaft when the PWM reached 25. A value above 60 would result in higher catheter force output than the targeted range. The PWM input and the force output were recorded.

2.5 The Visible Heart® Laboratories: Test Methods

To test the robotic platform on a beating swine heart, two approaches were taken; one method tested on an in situ preparation, shown in Figure 4 (a), and the other tested on an ex vivo preparation, shown in Figure 4 (b). All testing was performed in the Visible Heart® Laboratory. In all tests, the robot housing was secured to a base on which the heart was resting. The catheter was pushed onto the surface of the heart to provide an initial force. During this time, the force profile of the heartbeat was recorded both to ensure the catheter was set up properly, and to validate the heartbeat characterization performed earlier in this project. The control program was then initialized by providing power to the microcontroller. Force and video data were recorded.

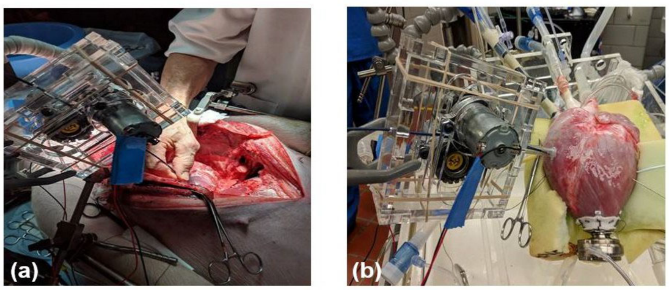

Figure 4: (a) The robot housing with the catheter placed on the surface of the pericardium of a beating swine heart. (b) The robot housing with the catheter placed on the surface of the myocardium of a beating swine heart.

2.5.1 *In Situ* Testing

During the *in situ* testing, the pericardium was surrounding the heart and provided a barrier between the myocardium and the catheter tip. The robot housing was also secured at about a 45 degree angle between the tangential surface of the heart and the vector of the catheter. Stabilization of the catheter was provided by the surgeons hand for this test method. The in situ preparation is shown in Figure 4 (a).

2.5.2 *Ex Vivo* Testing

The *ex vivo* preparation provided a more ideal test preparation, as shown in Figure 4 (b). The catheter had direct contact with the swine heart myocardium. The robotic platform was secured with almost a 90 degree angle between the tangential surface of the heart and the vector of the catheter. The catheter was stabilized to 1-DOF by a tube affixed to the myocardium surface.

3 Results

The *in situ* preparation allowed the catheter to slip easily off the surface of the pericardium even with a surgical hand trying to stabilize the catheter. This led to force data with an increased range and pretty unstable results. The *ex vivo* preparation allowed the catheter to compensate for motion. Gains were tuned and several runs of data were collected. The heartbeat was characterized using both the piezoelectric crystals and the force sensing catheter.

3.1 Heartbeat Kinematics Characterization

Figures 5 through 8 show the characterization of the right ventricle of a single swine heart through the use of piezoelectric transducers.

The heartbeat was also characterized through a force sensing catheter placed on the heart with an applied initial force. Figure 9 shows this characterization.

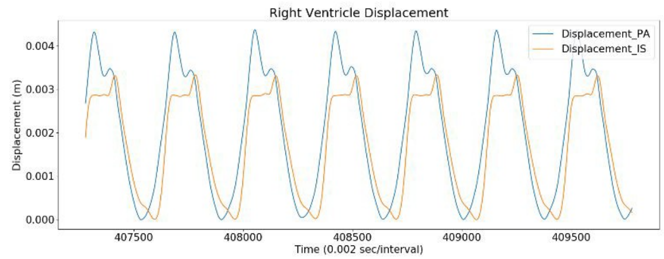

Figure 5: Right ventricle movements in meters vs time. Displacement_PA represents the displacement between the Posterior and Anterior walls of the right ventricle. Displacement_IS represents the displacement between the Inferior and Superior walls of the right ventricle.

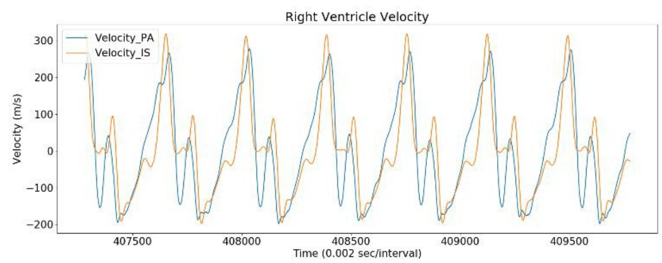

Figure 6: Right ventricle velocity in meters per second. Velocity_PA represents the velocity between the Posterior and Anterior walls of the right ventricle. Velocity_IS represents the velocity between the Inferior and Superior walls of the right ventricle.

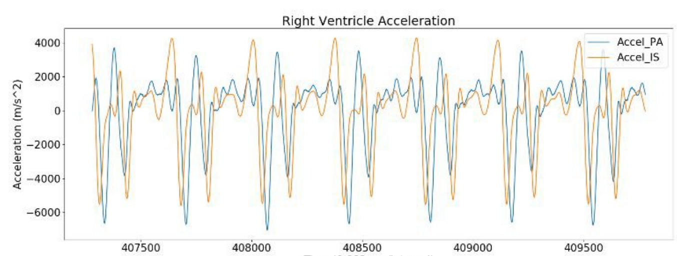

Figure 7: Right ventricle acceleration in meters per second squared. Accel_PA represents the acceleration between the Posterior and Anterior walls of the right ventricle. Accel_IS represents the acceleration between the Inferior and Superior walls of the right ventricle.

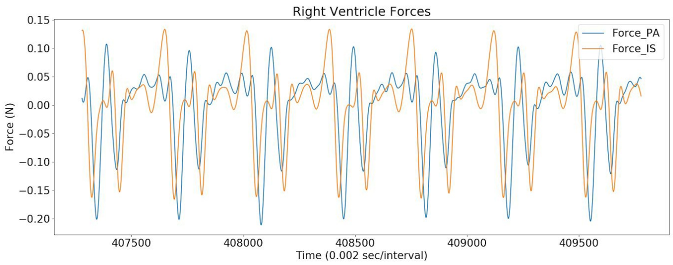

Figure 8: Right ventricle forces in Newtons. Force_PA represents the force applied by the Posterior and Anterior walls of the right ventricle. Force_IS represents the force applied by the Inferior and Superior walls of the right ventricle.

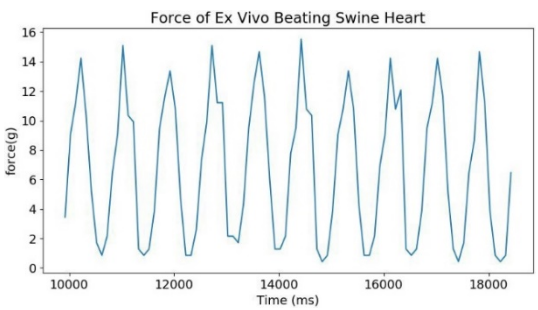

Figure 9: Right ventricle forces in grams from the force sensing catheter (TactiCath^{TM} Quartz).

3.2 System Identification

System identification was performed in order to map the relationship between the motor PWM and the catheter sensed force. The force data was recorded and then fitted through both linear function and nonlinear function respectively, as shown in Figure 10. The function then used to convert force input to PWM output to the motors.

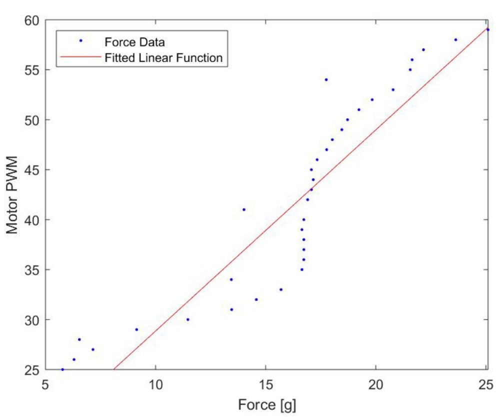

Figure 10: System identification data that showed the PWM-force relationship and a linear fit of the data.

3.3 Disturbance Simulations

Before testing *in situ*, the heartbeat characterization was used to tune and simulate the robotic platform. As previously mentioned, characteristics such as heartbeat amplitude and frequency were used to drive a mathematical system model. The aim of this model was to determine if disturbance rejection was possible from a theoretical standpoint. While achieving a constant force on a stationary object was considered intuitively achievable, modeling was required to ensure feasibility of disturbance rejection.

3.4 The Visible Heart® Laboratory: Testing Results

During testing, the force catheter was placed on the beating heart in a location that caused minimal fibrillation. A baseline force was applied to the heart and 10 seconds of heartbeat data was collected. The control program was then initiated and force compensation was attempted. The control program was ended and heartbeat data was collected to verify continuous heart contact. The method is illustrated in Figure 11.

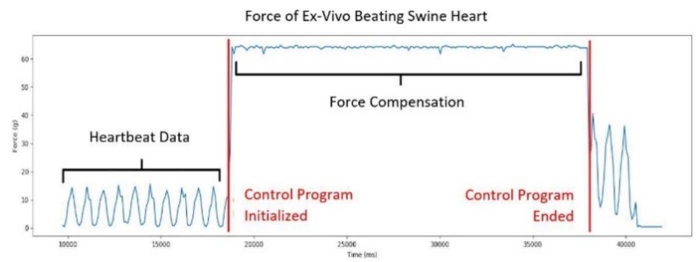

Figure 11: The data collection method for robot testing

3.4.1 *In Situ* Testing

The force data for the in situ testing is shown in Figure 12. During the testing, the catheter was not perpendicular to the surface of the heart at all times and it was secured with the surgeon's hand to prevent it from slipping off the pericardium. The heart was in fibrillation during the data collection.

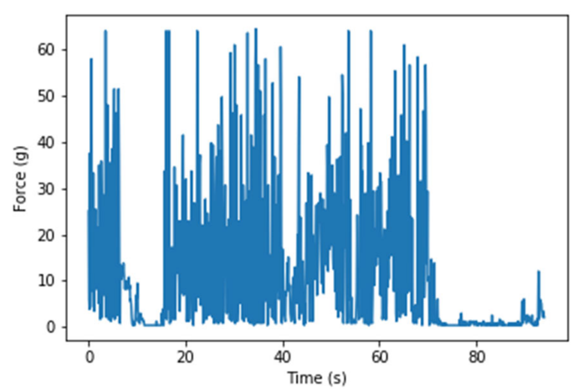

Figure 12: *In situ* testing: force data over the course of 85 seconds with a target force of 20 grams.

3.4.2 *Ex Vivo* Testing

The robotic platform achieved force compensation and allowed the force to be maintained near a target force. The error of the system drastically changed, which indicated force compensation. The force data and the error for the PID controller is shown in Figure 13.

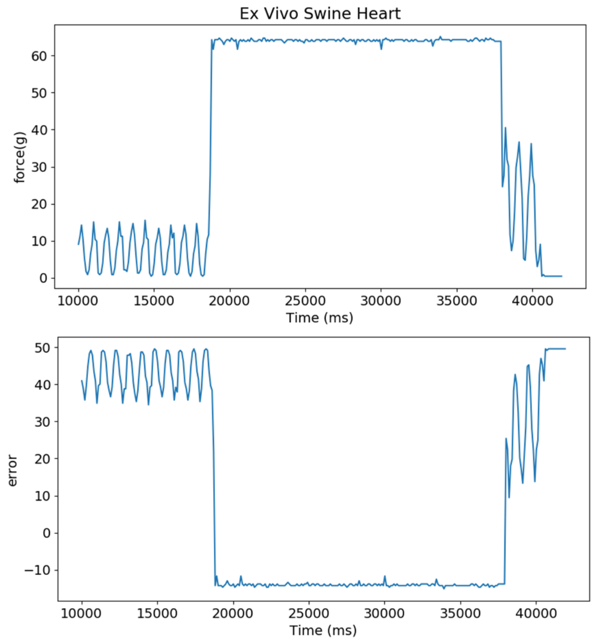

Figure 13: Ex-vivo testing: force data and the error over the course of one run with a target force of 50 grams.

4 Discussion

During the *in situ* testing, the force sensing catheter shaft was too flexible to be constrained to a single degree of freedom. Some stabilization systems were quickly designed to allow for ex-vivo testing. The force data during *in situ* testing suffered from lack of stabilization as shown in Figure 16. In future iterations, a more reliable stabilization system is needed along with factors in the system dynamics that account for the flexibility of the catheter.

Another effect on the catheter force output was heart fibrillation. The catheter itself applied enough force to depolarize the myocardium, as is intended for MAPs readings. This caused the heart to fail to conduct properly and go into fibrillation. During testing, this was remedied by moving the catheter to another location where fibrillation was minimized. A potential solution to this is to increase the surface area of the catheter tip, or a different tip geometry to allow the force to distribute over a greater area. It is important to note this issue is only present when both the catheter and the system are working to compensate the motion of the target area, as a slight increase in force will be magnified when the catheter comes into contact with a small area of tissue. Due to the heart fibrillation, the controller and gains fell out of the ideal range of operation for the system to properly work. More studies should be done in order to determine and implement properly tuned gains to account for fibrillation of the heart, should this occur.

The control loop was designed to reach a force threshold and then compensate as fast as possible. In Figure 13, it is apparent that the controller has a steady state error of about 10 to 15 grams. This is likely due to the linear approximation of the system dynamics. A non-linear model could improve the performance and error. In addition to a non-linear approach, thresholds for acceleration and velocity of the catheter to allow the control loop to compensate more efficiently with minimal overcorrection.

5 Conclusion

The large error reported in use of timing and movement tracking via optics and motion prediction algorithms continues to cause problems in cardiothoracic surgical robotics. This work aims to address this problem by presenting a platform that can achieve a constant contact force by sensing and reacting, in real time, to the force produced by the myocardium.

The use of a force controlled robotic platform provides a base system to enable improvements in both cardiac mapping and ablation procedure outcomes. The system, using a control law and system identification based models as well as real time force data processing and reaction, proves to facilitate further advances both in the fields of cardiac electrophysiology and robotics.

The ever changing and evolving medical device industry has the responsibility to keep innovating and finding ways to make procedures less harmful for patients and reduce the risk undergone. Minimally invasive mapping and ablation are examples of exemplary technology development over the last two to three decades. Automating these principles and procedures is critical to improve patient outcomes, reduce therapy costs, reduce risk, and ultimately reduce the impact of heart disease to improve lives.

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REFERENCES

[1] Benjamin, J., Emelia, Virani, S., Salim, Callaway, W., Clifton, Chamberlain, M., Alanna, Chang, R., Alexander, Cheng, E., Susan, Chiuve, N., Stephanie, Cushman, D., Mary, Delling, F., Francesca, Deo, R., Rajat, De Ferranti, C., Sarah, Ferguson, Chaffin, Jane, Fornage, E., Myriam, Gillespie, H., Cathleen, Isasi, T., Carmen, Jiménez, L., Monik, Jordan, S., Lori, Judd,

[2] B., Suzanne, Lackland, E., Daniel, Lichtman, P., Judith, Lisabeth, K., Lynda, Liu, J., Simin, Longenecker, D.,

Chris, Lutsey, J., Pamela, Mackey, A., Jason, Matchar, D., David, Matsushita, K.A., Kunihiro, Mussolino, M., Michael, Nasir, H., Khurram, O'flaherty, L., Martin, Palaniappan, L., Latha, Pandey, W., Ambarish, Pandey, H., Dilip, Reeves, Z., Mathew, Ritchey, T., Matthew, Rodriguez, Hy., Carlos, Roth, M., Gregory, Rosamond, S., Wayne, Sampson, S., Uchechukwu, Satou, S., Gary, Shah, S., Svati, Spartano, S., Nicole, Tirschwell, S., David, Tsao, S., Connie, Voeks, S., Jenifer, Willey, S., Joshua, Wilkins, S., John, Wu, S., Jason, Alger, S., Heather, Wong, S., Sally, and Muntner, S., Paul. "Heart Disease and Stroke Statistics—2018 Update: A Report From the American Heart Association." *Circulation 137*, no. 12 (2018): E67-492.

[3] W. M. Feinberg, "Prevalence, age distribution, and gender of patients with atrial fibrillation. Analysis and implications," *Archives of Internal Medicine*, vol. 155, no. 5, pp. 469–473, 1995.

[4] Y. Nakamura, K. Kishi, and H. Kawakami, "Heartbeat synchronization for robotic cardiac surgery," *Proceedings 2001 ICRA. IEEE International Conference on Robotics and Automation (Cat. No.01CH37164)*.

[5] Bebek, O., and M.C. Cavusoglu. "Intelligent Control Algorithms for Robotic-assisted Beating Heart Surgery." *Robotics, IEEE Transactions* on 23, no. 3 (2007): 468-80.

[6] L. Cheng, M. Sharifi, and M. Tavakoli, "Towards robot-assisted anchor deployment in beating-heart mitral valve surgery," *The International Journal of Medical Robotics and Computer Assisted Surgery*, vol. 14, no. 3, 2018.

[7] Hosseini, Rozen, Saleh, Vaid, Biton, Moazzami, Heist, Mansour, Kaadan, Vangel, and Ruskin. "Catheter Ablation for Cardiac Arrhythmias: Utilization and In-Hospital Complications, 2000 to 2013: Utilization and In-Hospital Complications, 2000 to 2013." *JACC: Clinical Electrophysiology* 3, no. 11 (2017): 1240-248.

[8] A. Thiagalingam, A. D'Avila, L. Foley, J. L. Guerrero, H. Lambert, G. Leo, J. N. Ruskin, and V. Y. Reddy, "Importance of Catheter Contact Force during Irrigated Radiofrequency Ablation: Evaluation in a PorcineEx VivoModel Using a Force-Sensing Catheter,"*Journal of Cardiovascular Electrophysiology*, 2010

[9] Schmidt, M.. "Utility of Monophasic Action Potentials in the Diagnosis and Treatment of Cardiac Arrhythmias" PhD Dissertation, University of Minnesota (2018).

[10] M. Groeger, T. Ortmaier, W. Sepp, G. Hirzinger, *"Tracking local motion on the beating heart"*, Proc. SPIE Med. Imaging Conf., vol. 4681, pp. 233-241, Feb. 2002.

[11] A. Trejos, S. Salcudean, F. Sassani, S. Lichtenstein, *"On the feasibility of a moving support for surgery on the beating heart"*, Proc. Med. Image Comput. Comput.-Assisted Interventions, pp. 1088-1097, 1999.

[12] R. Ginhoux, J. A. Gangloff, M. F. DeMathelin, L. Soler, J. Leroy, M. M. A. Sanchez, J. Marescaux, *"Active filtering of physiological motion in robotized surgery using predictive control"*, IEEE Trans. Robot., vol. 21, no. 1, pp. 67-79, Feb. 2005.

[13] J. Rotella, *"Predictive tracking of quasi periodic signals for active relative motion cancellation in robotic assisted coronary artery bypass graft surgery",* Aug. 2004.

[14] Bo Yang, Tingting Cao, Wenfeng Zheng, *"Beating heart motion prediction using iterative optimal sine filtering"*, Image and Signal Processing BioMedical Engineering and Informatics (CISP-BMEI) 2017 10th International Congress on, pp. 1-5, 2017