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DESIGN OF A MOTION COMPENSATED TISSUE RESECTION CATHETER FOR BEATING HEART CARDIAC SURGERY

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ABSTRACT

Cardiac catheters allow clinicians to minimally invasively interact with the beating heart without stopping the heart or opening the chest. However, the fast motion of the intracardiac structures makes it difficult to modify and repair the tissue in a controlled and safe manner. To enable surgical procedures on the inside of the beating heart, we have developed an ultrasound-guided catheter system that virtually freezes the heart by compensating for the fast cardiac motions. The device presented in this paper is a resection tool that allows the catheter system to cut moving tissue, a key surgical task required for many intracardiac procedures including valve and leaflet repair. The motion tracking system is demonstrated in vivo and the tissue resection tool is evaluated by resecting tissue mounted on a cardiac motion simulator. The motion compensated catheter is shown to greatly improve the resection cut quality on the moving tissue target while reducing the forces experienced by the tissue by almost 80%.

INTRODUCTION

Physicians and engineers are developing a range of new procedures, drugs, and technologies to treat ailments that can affect the health and function of the human heart. One of the most significant advances in cardiac therapies is the use of cardiac catheters to give clinicians minimally invasive access to the heart via the vascular system. Cardiac catheters are long and thin flexible tubes and wires that are inserted into the vascular system and passed into the heart. Procedures that are now performed using catheters include measuring cardiac physiological function, dilating vessels and valves, and implanting prosthetics and devices [1].

While catheters can perform many tasks inside the heart, they do not yet allow clinicians to interact with heart tissue with the same level of skill as in open heart surgery. A primary reason for this limitation is that current catheters do not have the dexterity, speed, and force capabilities to perform complex tissue modifications on moving cardiac tissue. One such tissue modification that is required to perform many procedures inside the heart, such as mitral valve repair, is tissue resection [2].

Robotic and actuated catheters are a potential solution to the limitations of conventional catheters. Current robotic cardiac catheters, such as the commercially available Artisan Control Catheter (Hansen Medical, Mountain View CA, USA) or CorPath Vascular Robotic System (Corindus Vascular Robotics, Natick MA, USA), allow for teleoperated guidance of a catheter tool inside the heart [3,4]. These devices permit a human operator to control the positioning of a catheter in vivo. However, these actuated catheter technologies do not provide sufficient speeds to allow the catheters end effectors to keep up with the fast motion of intracardiac structures nor do they attempt to directly modify or resect the cardiac tissue [5,6].

Advances have also been made in the area of tissue resection technology. Robot tissue resection is now possible in laparoscopic procedures with the daVinci surgical robotic system (Intuitive Surgical, Sunnyvale, CA, USA). This device allows for the laparoscopic resection of a large range of tissues and organs, including the prostate, lungs, and gastrointestional system [7,8,9].

Tissue resection is also performed minimally invasively without the use of robotics. For example, the transurethral resection of the prostate (TURP) procedure utilizes a restroscope device, such as the Karl Storz Bipolar Restroscope System (Karl Storz Endoscopy-America Inc., El Segundo, CA, USA), to remove tissue from the prostate via the urethra using electrocautary [10]. Another example of minimally invasive tissue resection is atherectomy, a procedure where plaque or tissue is percutaneously removed from a large blood vessel using a catheter device such as the SilverHawk Plaque Excision System (Foxhollow Technologies, Redwood City, CA USA) [11,12]. Although these devices have demonstrated clinical
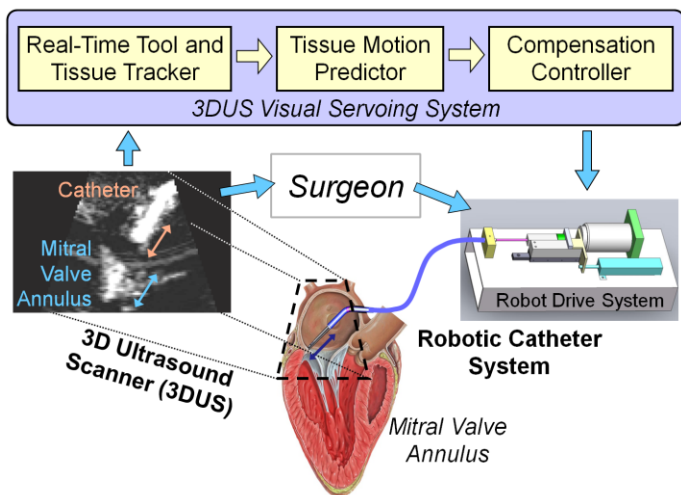
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Figure 1: Motion Compensated Catheter System.

Figure 2: Catheter Drive System.

efficacy for minimally invasively resecting tissue, none of the existing technologies are capable of safely resecting tissue from the fast moving cardiac structures.

Motion compensation is required when operating on the inside the beating heart because it enables more dexterous interactions and limits the risk of injury from catheter collisions with fast moving tissue structures. Researchers have developed robotic approaches to compensating for the motion of the beating heart [13,14,15], but these techniques are directed at procedures that repair coronary arteries on the external surface of the heart. In previous work, we have developed robotic devices that compensate for the motion of internal heart structures in vivo with a handheld robotic instrument inserted through incisions in the heart wall [6, 16, 17]. This work has been extended to motion compensation with an actuated catheter system [18]. The motion of the tissue target is tracked in real time using 3D ultrasound (3DUS) imaging [16]. This work shows that single degree of freedom (DOF) servoing is sufficient to accurately track the motion of certain cardiac structures, including the human mitral valve annulus [5, 17].

To enable resection of moving tissue inside the beating heart, we have developed a resection end effector for the image-guided motion compensating catheter system described in [18]. To the best of the authors' knowledge, the device presented here is the first tool that is able to apply low, controllable forces while resecting fast moving cardiac tissue. The following paper describes the design of the catheter system and resection end effector. The motion tracking system is evaluated in vivo and the resection tool is evaluated with a simulated cardiac tissue resection task. The results demonstrate that motion compensation enables the successful resection of tissue and reduces the forces applied by the device by almost 80%.

DEVICE DESIGN

Catheter System Design

The catheter system presented here is designed to compensate for the motion of the outer annulus of the mitral valve, the major valve between the left atrium and ventricle. This valve exhibits some of the largest motions and greatest
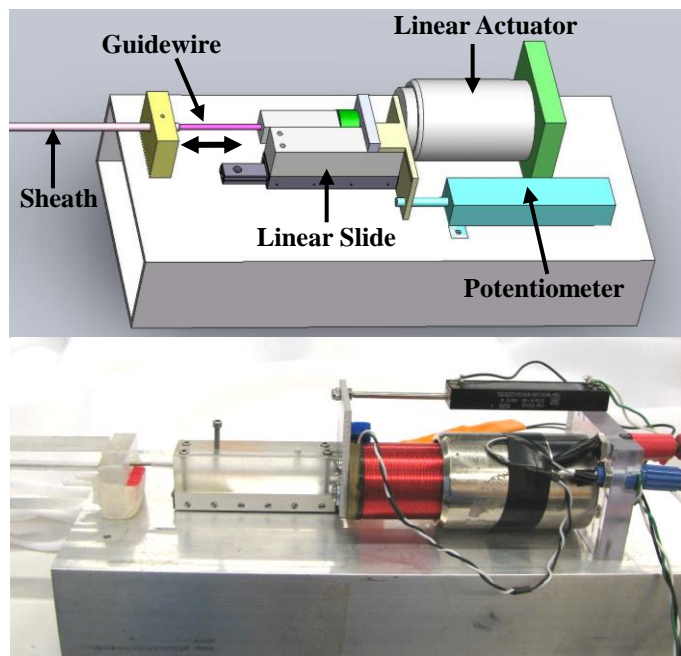
velocities of any structure inside the heart and moves primarily along one axis of motion [5]. Thus, a single DOF system can be used to sufficiently compensate for the valve motion.

The actuated catheter system performance parameters were derived from human mitral valve physiology values [5, 17]. The principal functional requirements are a single actuated linear degree of freedom with at least 20 mm of travel and velocity and acceleration of at least 210 mm/s and 3800 mm/s^2, respectively. The catheter components should have the same dimensions and materials as current clinical cardiac catheters. Finally, the system should be able to apply a sufficient force to modify cardiac tissue, found to be approximately 4 N from preliminary tissue experiments [16].

The system can be divided into three main modules: The drive system that actuates the catheter, the catheter module that is inserted into the heart, and the 3D ultrasound visual servoing system that tracks the tissue and commands the catheter to follow the motion. Figure 1 presents a diagram of the system.

Drive System

The drive system used in this study (Figure 2) is composed of a linear voice coil actuator (NCC20-18-02-1X, H2W Technologies Inc, Valencia CA; 50.8 mm travel, 26.7 N peak force), a linear ball bearing slide (BX3-3, Tusk Direct, Inc., Bethel CT), a linear potentiometer position sensor (CLP13, P3 America, San Diego, CA, USA).

Catheter Module

The catheter module consists of a sheath, a guidewire, and the end effectors required for each specific procedure. The sheath is an 85 cm long section of flexible Teflon tubing (ID 2.4 mm) that encloses the guidewire, a close-wound stainless steel spring (OD 2.2 mm). The guidewire is easily bendable but can apply significant compressive forces without buckling. During the procedure, the sheath is inserted from a peripheral blood vessel (typically the femoral vein) into the heart, and then fixed

Figure 3: Spinning blade resection tool design.

Figure 4: The tissue resection tool concept is actuated by a pull wire that buckles the guidewire, causing it to bend and slice through the tissue.

in place while the drive system servos the guidewire inside the sheath to compensate for the heart motion.

3D Ultrasound Visual Servoing System

The ultrasound servoing system streams 3D image volumes from the ultrasound scanner to an image processing computer via Ethernet (Figure 1). A GPU-based Radon transform algorithm finds the catheter axis in real-time. The target tissue is then located by projecting the axis forward through the image volume until tissue is encountered. This allows the clinician to designate the target to be tracked by simply pointing at it with the catheter. To compensate for the 50-100 ms delay in image acquisition and processing, an extended Kalman filter estimates the current tissue location based on a Fourier decomposition of the cardiac cycle. See [16,17] for a detailed description of the 3DUS visual servoing system.

A PID control system running at 1 kHz controls the position of the linear actuator in the drive system. Commands to the linear actuator are amplified by a linear power supply (QPA-L2-E Current, Quanser Inc., Markham, Ontario, Canada).

Clinician Controls

The catheter device automatically compensates for the fast motion of the cardiac tissue, thus allowing the clinician to operate on a virtual stationary tissue structure. In the case of the single DOF mitral valve repair, catheter motions in lateral directions (i.e. not in the direction of fast tissue motion) are manually controlled by using conventional catheter controls to bend or rotate the catheter and sheath. Commands from a linear joystick are superimposed on the motion compensation trajectory to allow the clinician to adjust the end effector position relative to the fast moving tissue.

Resection Tool Design

The functional requirements of the resection tool are that it cleanly cuts tissue, applies minimal and controllable forces on the moving tissue, and can be accurately manipulated to perform resection procedures inside the intracardiac environment.

The tissue cutting approaches explored in the development of this device include a spinning cutting disk, a slicing approach that replicated the motion of a manual scalpel, and high-frequency electric current electrosurgery. The cutting disk approach involved adding a fast spinning curricular disk blade to the tip of the catheter (Figure 3). Possible actuation approaches include a cable drive system, distal actuation via
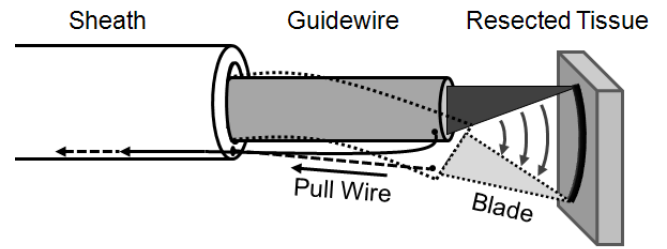
miniature motors, or hydraulic actuation using pressurized saline, as shown in Figure 3. The cutting disk approach was not selected because of the risk of entraining tissue in the spinning disk, size limitations placed on the cutting disk by the catheter sheath, and the challenge of transferring sufficient power to the tip of the catheter. The electrosurgery approach, while desirable in terms of precision and controllability, is not compatible with the intracardaic environment. The amount of heat and vapor produced by applying large mounts of current to the tissue is not safe or feasible in the blood pool inside the heart.

As a result of this analysis and bench top prototypes of the possible approaches, the scalpel-based cutting method was selected. This approach has the benefits that it mimics standard cardiac surgery clinical practice, can be miniaturized to fit almost any size catheter, and the only actuation it requires is the positioning of the guidewire tip relative to the tissue.

The scalpel resection tool operates by slicing in the lateral direction perpendicular to the plane of the tissue surface. One possible method for generating the slicing motion is by buckling the guidewire via a pull wire, a wire running along the outside of the guidewire that can be tensioned to apply a bending moment to the tip of the guidewire. Figure 4 shows a diagram of this actuation strategy with the pull wire running through a channel along the length of the sheath.

Resection Tool Analysis

One challenge of the proposed device is that it requires applying a lateral force on a guidewire. Catheter guidewires are design to be rigid in compression but compliant in bending so that they can navigate the vessels to reach the heart. Figure 5 presents a diagram of the catheter resection process. The guidewire inside the sheath is pressed into the tissue with normal force F_N, resulting in a reaction force from the tissue F_{RN}. In order to cut the tissue, the blade must be forced downwards using a pull wire mechanism with force F_{pull} applied either to the guidewire *(a)* or the blade *(b)*. The location of the pull wire force impacts the cutting efficacy of the device because the force may cause the guidewire to bend away from the tissue due to its low bending compliance, K_{gw}.

The resection catheter system can be modeled as a cantilever beam with two different material properties, as shown in Figure 6. The bending stiffness of the cutting blade is much greater than the stiffness of the guidewire in the direction of the applied force and can therefore be approximated as a rigid segment. Experimental investigation has shown that applying the pull force (F_{pull}) to the sheath ($l_a < 0$) or at any point between
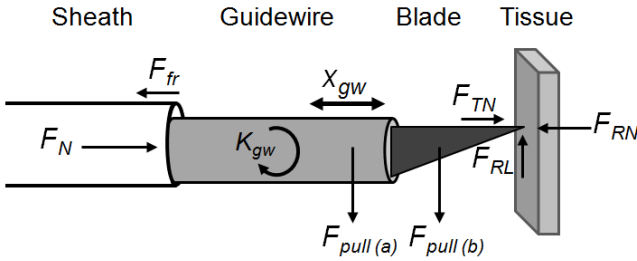
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Figure 5: Model of the tissue resection device. The pulling force F_{pull} provided by the pull wire can be applied to either the guidewire (a) or the blade (b).

the sheath and the cutting blade tip $(0<l_a<l_b)$ causes the guidewire to buckle and the blade tip to tilt upwards, thus losing contact with the tissue. This is because a pull force not aligned with the tissue reaction force (l_b) causes a torque about the reaction force location, which acts as a pivot relative to the tissue and causes the more compliant guidewire to tilt away from the tissue. As a result of this behavior, the pull wire location should be as close to the cutting tip as possible $(l_a \rightarrow l_b)$. Therefore, in this design the pull wire was located in the middle of the cutting blade to prevent tilting of the guidewire while still not interfering with the tissue-blade interaction.

Prototype Design

Based on this analysis, the design presented in Figure 7 was selected. A number 10 size surgical blade was attached to a 2.2 mm diameter guidewire. The guidewire was actuated in the axial direction via the drive system (Figure 2). Lateral direction actuation was provided by a steel pull wire attached to the center of the blade. In the case of this prototype, the pull wire was manually actuated, but in the clinical version the pull wire could either be manually actuated or actuated by a servo-controlled motor on the drive system module. A retractable cover will also be required for the clinical version to prevent unintentional puncture of tissue while positioning the device.

EVALUATION

To evaluate the efficacy of the motion compensated resection device, the system was examined in two ways. First, the motion tracking system was evaluated in vivo to demonstrate its ability to track moving cardiac tissue. Next, the resection tool was evaluated by examining its ability to resect tissue attached to a cardiac motion simulator.

In Vivo Motion Tracking

To investigate the clinical feasibility of image-based catheter control, we integrated the actuated catheter system with the ultrasound visual servoing system developed in previous work [5, 16,17] and evaluated it in vivo. Controlling a catheter to follow the motion of internal cardiac structures requires real-time sensing of both the catheter tip and tissue target positions. 3D ultrasound must be used for guidance because it is currently the only real-time volumetric imaging technique that can image tissue through blood.

The image guidance system was evaluated in vivo on a 75 Kg porcine animal model. For this initial study, the actuated catheter was inserted into the beating heart via the top of the left
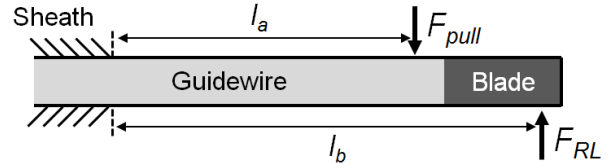

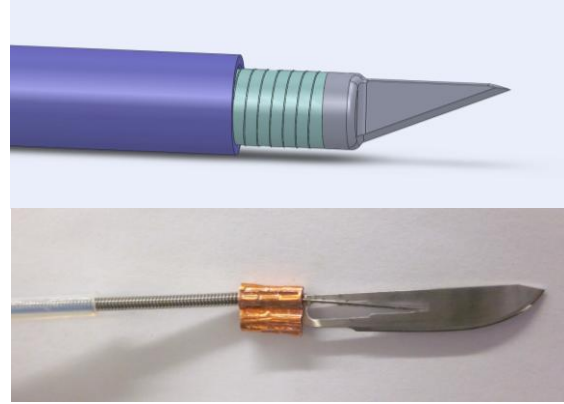**Figure 6: A simplified model of the resection tool mechanics**

Figure 7: (Top) Solid model of the resection tool design and (bottom) the evaluation prototype.

atrium rather than the vasculature to give the surgeon easy access to the mitral valve. The 3D ultrasound scanner probe (SONOS 7500, Philips Healthcare, Andover, MA, USA) was placed epicardially. After the catheter was introduced into the heart, the surgeon used the ultrasound image to aim the catheter at the mitral valve annulus. The imaging system was then initialized and tracked the valve motion. See Figure 8 for a 3DUS image of the catheter device inserted into the porcine left atrium and pointed at the mitral annulus.

The catheter module consisted of a sheath with 1.6 mm inner diameter and a guidewire with a 1.5 mm outer diameter. During the experimental trials, the sheath was configured external to the heart with two 90° bends that correspond to the path from the femoral vein into the left atrium. The catheter was positioned inside the left atrium so that the tip was 1-2 cm from mitral annulus. The catheter controller then performed a calibration routine that estimates the magnitude of the friction force in the system. Next, the image processing routines located the catheter using the Radon transform algorithm and then projected forward to find the target. The catheter was then servoed to maintain a constant distance between the catheter tip and the target.

Tracking Results

The catheter system successfully tracked the mitral annulus tissue target. Figure 8 shows a cross section through a typical ultrasound image volume containing the catheter, mitral valve annulus, and edge of the valve leaflet. Figure 9 shows a plot of the typical catheter tip trajectory and the position of the mitral valve annulus. This plot was generated by manually segmenting the position of the catheter tip and valve structure from the 3DUS volumes three times and then averaging the values. The standard deviations of the segmented tip positions were less than 0.22 mm and the standard deviations of the segmented mitral valve annulus positions were less than 0.32 mm.
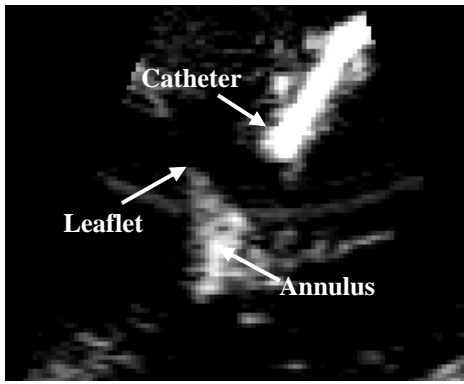
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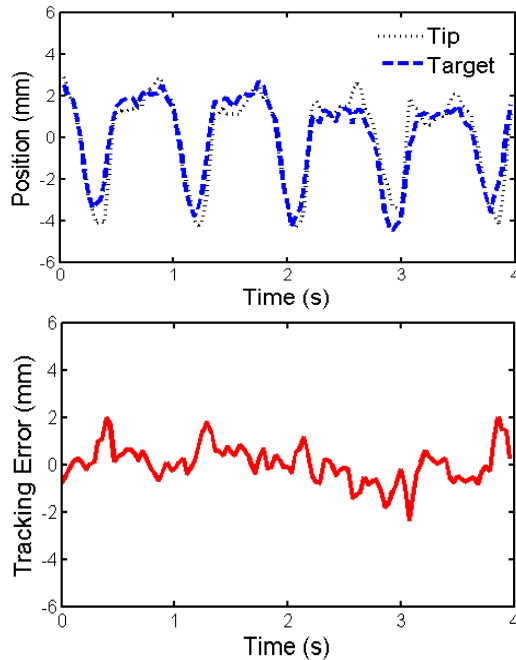**Figure 8: 3DUS image of the catheter in vivo.**

Figure 9: (Top) Trajectory of the catheter tip and the mitral valve annulus. (Bottom) The catheter trajectory tracking error. RMS tracking error was 0.77 mm.

The image guided catheter tracked the valve motion with RMS errors less that 1.0 mm in all experimental trials. The RMS error for the trial presented in Figure 9 is 0.77 mm. The tracking error, shown in Figure 9, was caused by respiration motion not captured in the tissue tracking system, performance limitations of the actuated catheter caused by backlash and friction, and the small beat-to-beat variations in the valve motion not compensated by the image tracking system.

Moving Tissue Resection

The resection device was evaluated with the task of resecting a piece of tissue on a moving target. In this experiment, a piece of bovine muscle tissue was attached to a single DOF motion simulator that followed a human mitral valve annulus trajectory segmented from human ultrasound data [5]. The trajectory simulates the large motion of the human mitral valve moving at 60 beats per minute (Figure 11).

The task called for the user to use the joystick input to approach the moving tissue with the resection tool, apply a normal force to the tissue, and then use the pull wire to move
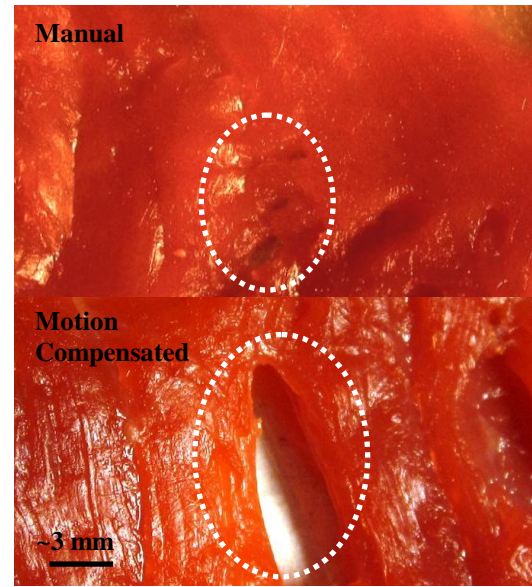

Figure 10: Tissue resection experiment results. (Top) The manual tool punctured the tissue a number of times but did not successfully cut the tissue. (Bottom) The motion compensated tool cleanly resected the tissue.

the blade laterally and slice through the tissue. This task was carried out using the actuated catheter with and without motion compensation. To evaluate the normal forces applied by the catheter on the tissue, a force sensor was integrated into the motion simulator (LCFD-1KG, Omega Engineering, Stamford CT, range: 10 N, accuracy: +/-0.015 N). In this experiment, the target position was taken directly off a potentiometer on the motion simulator instead of the in vivo 3DUS image guidance system.

Resection Results

The motion compensated resection tool successfully resected the tissue. Motion compensation allowed the cutting blade to track the trajectory of the tissue while the pull wire forced the blade through the tissue. The manual resection device, on the other hand, failed to completely or cleanly cut the tissue. Figure 10 illustrates how the two approaches cut the tissue. The manual, non-motion compensated tool was only able to stab into and puncture the tissue because it did not track the motion of the tissue target. When the user advanced the blade towards the tissue, it collided repeatedly but was unable to actually slice the tissue. The motion compensated device was able to cleanly and evenly slice the tissue because the compensation allowed the blade to maintain a constant position relative to the tissue. Once the user advanced the blade to a sufficient cut depth, the pull wire was drawn and the blade cleanly cut through the tissue.

These results are reinforced by the normal forces applied to the tissue during the experiments. As shown in Figure 11, the resection tool without motion compensated applied considerably more force on the tissue than the motion compensated tool. Motion compensation reduced the RMS force value by 77% (0.77 N vs. 3.31 N) and the peak force values by almost 70% (1.82 N vs. 5.81 N).
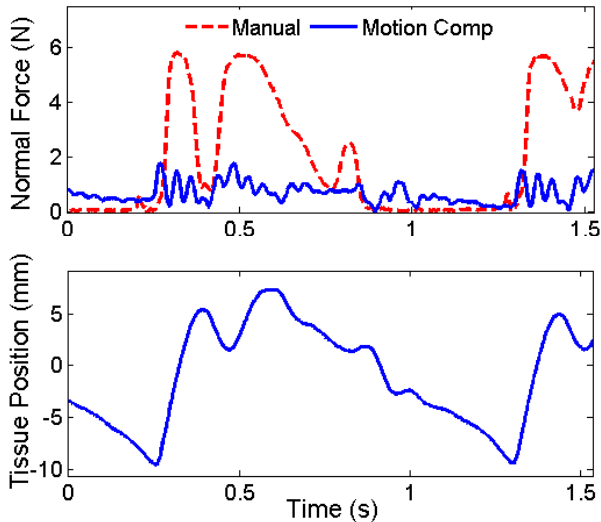
Figure 11: (Top) Normal forces applied to the tissue by the manual catheter and the motion compensated catheter. (Bottom) The trajectory of the cardiac motion simulator.

CONCLUSIONS AND FUTURE WORK

These results show that motion compensation is required to safely and effectively resect the fast moving tissue structures inside the heart. Without the use of motion compensation, the resection blade was unable to make a clean, straight cut in the tissue and the end effector applied quadruple the force on the tissue. The in vivo motion compensation results also show that the actuated catheter system is able to successful track the fast cardiac motion using 3DUS guidance.

This work demonstrates the possibility of resecting tissue inside the beating heart, however a number of technological advances are required to make this device clinically feasibility. One of the biggest remaining challenges is how to provide the clinician with clear real time images of the cardiac structures with enough resolution to allow for accurate repair procedures. In additional to better imaging, more tools will be required to perform complete surgeries. For example, end effectors to approximate and affix tissue will be required to perform annuloplasty procedures [2]. Finally, strategies for safely using these tools in vivo will need to be explored and perfected before clinical trials can proceed.

ACKNOWLEDGMENTS

REFERENCES

[1] D. S. Baim, *Grossman's Cardiac Catheterization, Angiography, and Intervention*. Lippincott Williams & Wilkins, 2005, pp. 992.

[2] W. R. Chitwood, "Robotic mitral valve repair: Trapezoidal resection and prosthetic annuloplasty with the da Vinci Surgical System", *J Thorac Cardiovasc Surg*, vol 120, 2000, pp. 1171-1172.

[3] D. B. Camarillo, et al, "Mechanics Modeling of Tendon-Driven Continuum Manipulators," *IEEE Trans. Robotics*, vol. 24, 2008, pp. 1262-1273.

[4] R. Beyar, "Navigation within the heart and vessels in clinical practice," *Annals of NY Academy of Sciences*, vol. 1188, 2010, pp. 207-218.

[5] D.T. Kettler, et al., "An active motion compensation instrument for beating heart mitral valve surgery," in *Proc. of Int. Conf. Intelligent Robots and Systems*, 2007.

[6] S. G. Yuen, S. B. Kesner, N. V. Vasilyev, P. J. del Nido and R. D. Howe, "3D ultrasound-guided motion compensation system for beating heart mitral valve repair," in *Medical Image Computing and Computer-Assisted Intervention*, LCNS vol. 5241, 2008, pp. 711-719.

[7] J. Bodner, H. Wykypiel, G. Wetscher, T. Schmid, "First experiences with the da VinciTM operating robot in thoracic surgery", *Eur J Cardiothorac Surg*, vol 25, 2004, pp. 844-851.

[8] P. C. Giulianotti, N. C. Buchs, G. Caravaglios, and F. M. Bianco, "Robot-assisted lung resection: outcomes and technical details", *Interactive CardioVascular and Thoracic Surgery*, vol 11, 2010, pp. 388 - 392.

[9] T. A. D'Amico, "Robotics in thoracic surgery: Applications and outcomes", *J. Thorac. Cardiovasc.* Surg., vol 131, 2006, pp. 19 - 20.

[10] V. Malhotra, "Transurethral Resection of the Prostate", *Anesthesiology Clinics of North America*, vol 18, Issue 4, 2000, pp. 883-897.

[11] K. N. Garratt, et al, "Safety of percutaneous coronary atherectomy with deep arterial resection" *The American Journal of Cardiology*, vol 64, 1989, pp. 538-540.

[12] F. Ikeno, et al, "Early experience with a novel plaque excision system for the treatment of complex coronary lesions", *Cath. and Cardio. Interventions*, vol 61, 2004.

[13] O. Bebek and M. Cavusoglu, "Intelligent control algorithms for robotic assisted beating heart surgery," *IEEE Trans. Robotics*, vol. 23, 2007, pp. 468–480.

[14] R. Ginhoux, et al., "Active filtering of physiological motion in robotized surgery using predictive control," *IEEE Trans. Robotics*, vol. 21, 2005, pp. 67–79.

[15] Y. Nakamura, K. Kishi and H. Kawakami, "Heartbeat synchronization for robotic cardiac surgery," *Proc. IEEE Int. Conf. Robotics and Automation*, 2001, pp. 2014–19.

[16] S. G. Yuen, N. V. Vasilyev, P. J. del Nido , R. D. Howe, "Robotic Tissue Tracking for Beating Heart Mitral Valve Surgery," *Medical Image Analysis*, 2010, In Press.

[17] S. G. Yuen, D. T. Kettler, P. M. Novotny, R. D. Plowes, and R. D. Howe, Robotic "Robotic Motion Compensation for Beating Heart Intracardiac Surgery," *Int. J. Robotics Research*, vol. 28, no. 10, 2009, pp. 1355-1372.

[18] S. B. Kesner, R. D. Howe, "Design and Control of Motion Compensation Cardiac Catheters," in *Proc. of IEEE Int. Conf. Robotics and Automation*, 2010, pp. 1059-1065.