August 2015

Magnetic Resonance Imaging Compatible Remote Catheter Navigation System

Mohammad Ali Tavallaei
The University of Western Ontario

Supervisor
Maria Drangova
The University of Western Ontario

Graduate Program in Biomedical Engineering

A thesis submitted in partial fulfillment of the requirements for the degree in Doctor of Philosophy

© Mohammad Ali Tavallaei 2015

Follow this and additional works at: https://ir.lib.uwo.ca/etd

Part of the Biomedical Commons, Biomedical Devices and Instrumentation Commons, Cardiovascular Diseases Commons, Controls and Control Theory Commons, Electrical and Electronics Commons, Radiology Commons, and the Systems and Integrative Engineering Commons

Recommended Citation
https://ir.lib.uwo.ca/etd/3024

This Dissertation/Thesis is brought to you for free and open access by Scholarship@Western. It has been accepted for inclusion in Electronic Thesis and Dissertation Repository by an authorized administrator of Scholarship@Western. For more information, please contact tadam@uwo.ca.
MAGNETIC RESONANCE IMAGING COMPATIBLE REMOTE CATHETER
NAVIGATION SYSTEM

(Thesis format: Integrated Article)

by

Mohammad Ali Tavallaei

Graduate Program in Biomedical Engineering

A thesis submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy

The School of Graduate and Postdoctoral Studies
The University of Western Ontario
London, Ontario, Canada

© Mohammad Ali Tavallaei 2015
Abstract

Many vascular and cardiac diseases are diagnosed and treated using a medical technique known as percutaneous transluminal catheter intervention (PTC). In PTC, the interventionalist inserts a catheter into the vasculature, and using the vessel as the guiding passageway, the catheter is navigated to desired anatomical targets where it would be used for various purposes such as catheter ablation for the treatment/management of cardiac arrhythmias. The catheterization procedure is conventionally guided with x-ray fluoroscopic imaging and more recently, but rarely, with Magnetic Resonance Imaging (MRI). X-ray imaging irradiates the patient directly during the procedure, and the staff and interventionalists indirectly through scattered radiation at lower dose levels, but on a daily basis. Furthermore, fluoroscopic x-ray imaging only provides 2 dimensional projection images with low anatomical soft tissue contrast. Contrary to fluoroscopy, MRI is not a source of ionizing radiation, allows 3 dimensional visualization and localization, and provides very high soft tissue contrast. However, the closed bore of conventional MRI scanners limits patient access and hinders catheter manipulation by the interventionalist.

This thesis presents the design, development and validation of an MRI-compatible master-slave catheter navigation system that allows the interventionalist to perform the catheterization procedure remotely using the guidance of MRI or x-ray fluoroscopic imaging. For MRI compatibility the robot was actuated with non-magnetic Ultrasonic motors. To permit dynamic control of the robot, a robust control servomechanism was designed and developed to allow for robust motion control of ultrasonic motors for
prolonged periods. A non-magnetic sterilizable robot was designed and developed that allowed for manipulation of conventional steerable catheters, of various gauges, with 3 degrees of freedom. The interventionalist interacts with the remote catheter navigation system (RCNS) using a user-friendly master unit. The motions imparted by the user on the master are measured by the control servomechanism and used to control the robot such that the catheter follows the user’s intended motion.

Evaluation of the system, *ex vivo*, under real-time MRI guidance showed that the system is fully MRI-compatible and allows accurate remote motion control of the catheter tip without degrading the MR image quality. *In vivo* experiments in porcine models showed that the proposed RCNS is safe and allows remote navigation under fluoroscopic imaging, with high accuracy, and without significantly affecting the navigation time or fluoroscopy time. The system was successfully used to remotely deliver effective ablation lesions to desired anatomical targets within the subject’s heart. The presented RCNS takes advantage of the interventionalist’s existing dexterous skills, and does not require any prior training. This system alleviates the work hazards of fluoroscopically guided catheterization, and facilitates MRI-guided catheterization in conventional closed bore scanners.

**Keywords**

Catheter navigation, magnetic resonance imaging, radiofrequency ablation, image-guidance, tele-robotics, fluoroscopy, robust control, embedded systems, master-slave.
Co-Authorship Statement

This thesis is presented in an integrated article format, the chapters of which are based on the following publications that are either published or under review:


My contributions to this work included defining the research questions; formulating the experimental design; deriving the mathematical model of the system as well as deriving the equations for the control signal; design and development of the embedded control system; implementation and experiment execution for validation. Farrokh Atashzar helped in identifying the appropriate control methodology and helped in the edit of the submitted paper.


My contributions to this work included defining the research questions; designing and developing the Ultrasonic motor sercomechanism used for master-slave control of the robot; designing the necessary electronic hardware needed for using the system in MRI; development of experiment protocols and adaptation of existing test standards for evaluation of MRI compatibility; coordinating and executing the experiments as well as analysis of the data. Dr. Yogesh Thakur, designed the system architecture, the slave robot unit and the master unit. Syed Haider, helped in modifying the robot design for MRI compatibility; machined the required parts and assembled the slave robot.

My contributions to this work included defining the research questions; designing the catheter manipulator, machining and assembling the catheter manipulator; assisting the development of the control system as well as implementation and tuning; assisting the design of the catheter manipulator and its manufacturing; developing the experiment protocols and coordinating the in vivo experiments. Daniel Gelman designed and developed the master unit with the assistance of Michael Lavdas; and designed and developed the embedded control system for the DC motor servomechanism and also assisted in preparation of the paper. Michael Lavdas designed the catheter handle manipulator and helped in the manufacturing of the master unit. Dr. Jeffrey Bax proposed the use of a differential gear mechanism for the catheter manipulator. Dr. Doug Jones and Dr. Maria Drangova assisted in the coordination and execution of the in vivo experiments. Dr. Allan Skanes contributed to defining the research questions and executed the in vivo interventions.


My contributions to this work included defining the research questions; designing, developing and assembling the robot and the control system (USM servomechanism),
formulating the experiment protocols; developing the phantom; developing the MRI compatible catheter; execution of the experiments and analysis of the data. Michael Lavdas designed and helped develop the catheter handle manipulator. D. Gelman assisted in the execution of the experiments.


My contributions to this work included defining the research questions; designing, developing and assembling the control unit and the user interface, designing and developing the motion stage; designing the experiment protocols and coordinating experiments; execution of the experiments and analysis of the data. P. Johnson contributed to the experiments and helped quantify the stage motion within the scanner by utilizing spherical navigator echoes. Dr. J. Liu helped quantify the variation in the main magnetic field in presence of the stage.

All of the above work was performed under the guidance and supervision of Dr. Maria Drangova.
Acknowledgments

The work presented in this thesis would not have been possible without the mentorship, friendship and support of many people.

My deep and sincere gratitude goes to Dr. Maria Drangova who has been more than a supervisor; indeed she has been a true friend. She has mentored, motivated and supported me, helping me uncover new and exciting paths that have created great opportunities for me. She has helped me grow so that I can create more opportunities for myself.

I would like to thank Dr. Aaron Fenster, whose greatest gift to me, apart from being an amazing inspiration, was at the start of this journey when he responded to my E-mail and invited me to visit the Robarts Research Institute for the first time. I would like to thank Dr. David Holdsworth, for his insightful and captivating discussions, and highly beneficial feedback throughout the course of my project. I want to thank the clinical member of my advisory committee Dr. Allan Skanes who has been a patient mentor and has offered me insights into the clinical aspect of my work; he vividly helped me maintain a pragmatic perspective.

I would also like to thank Dr. Doug Jones, Dr. Terry Peters, Dr. James Lacefield, Dr. Rajni Patel, Dr. Ting Lee, Dr. Grace Parraga, Dr. Blaine Chronik, Dr. Timothy Scholl, and Dr. Junmin Liu for all their teaching and their generous support when it was needed. Special thanks goes to Dr. Jiro Inoue for reading several chapters of this thesis and providing very useful feedback. I would also like to thank the staff and student members of the Imaging Laboratories as well as many others at the Robarts
Research Institute who provided an incredibly warm and welcoming environment that made Robarts my second home.

My greatest appreciation goes to my parents, who have provided me with infinite and unconditional love. Their continuous support has provided me with the energy and motivation to work hard and confront new challenges, constantly reminding me that travelling on the correct path is itself the true destination.

To my beloved wife Ayda Bashiri, words cannot express the impact you have had on my life. I will always be grateful for your love and support. I love and cherish you with all my heart.

Many sources of funding have supported this work, including the Canadian Institutes of Health Research, the Ontario Research Fund, the National Sciences and Engineering Research Council of Thesis through the Computer Assisted Medical Interventions CREATE Award, the Ontario Graduate Scholarship, and the Western Graduate Research Scholarship.
# Table of Contents

Abstract ................................................................. ii  
Co-Authorship Statement ....................................... iv  
Acknowledgments .................................................. vii  
Table of Contents ................................................... ix  
List of Tables ........................................................ xii  
List of Figures ......................................................... xiii  
List of Abbreviations .............................................. xviii  

Chapter 1. Introduction ............................................ 1  
1.1 Catheterization .................................................. 4  
1.1.1 Cardiac Arrhythmias ........................................ 5  
1.2 Catheter Ablation: Current State of the Art .......... 5  
1.2.1 Electroanatomical Mapping Systems .................... 5  
1.2.2 Remote Catheter Navigation Systems ................. 7  
1.3 MRI Guided Interventions ..................................... 8  
1.3.1 MRI Guided Catheterization .............................. 8  
1.3.2 MRI Compatible Mechatronics ......................... 11  
1.4 Design Approach: MRI Compatible Tele-robotic Catheter Navigation System ... 15  
1.5 Thesis Scope ..................................................... 18  
1.6 Thesis Outline ................................................... 19  
1.7 References ....................................................... 21  

Chapter 2. Robust Motion Control of Ultrasonic Motors Under Temperature Disturbance† ........................................ 30  
2.1 Introduction ...................................................... 30  
2.2 Model Identification ............................................ 33  
2.3 Robust Controller Design .................................... 40  
2.4 Hardware Design and Controller Implementation .... 44  
2.5 Experiment Results .......................................... 45  
2.6 Discussion and Conclusion ................................. 51  
2.7 References ....................................................... 52  

3.1 Introduction ...................................................... 55  
3.2 System Description ............................................ 58  
3.2.1 Catheter Sensor - master ................................. 59  
3.2.2 Catheter Manipulator - slave ......................... 60  
3.2.3 Ultrasonic Motor Servomechanism .................... 62  

ix
3.3 Evaluation ................................................................. 63
  3.3.1 Evaluation of the Servomechanism ............................... 63
  3.3.2 Evaluation of the MR-RCNS ...................................... 64
  3.3.3 Evaluation of the effects of the RCNS on image SNR ........ 66
  3.3.4 Evaluation of the effect of RCNS on in vivo images .......... 67
3.4 Results ........................................................................ 68
  3.4.1 Evaluation of Servomechanism .................................... 68
  3.4.2 Evaluation of the MR-RCNS ....................................... 70
  3.4.3 Evaluation of the effects of the RCNS on image SNR ....... 71
  3.4.4 Evaluation of the effect of RCNS on in vivo images ........ 71
3.5 Discussion .................................................................... 72
3.6 Conclusion ..................................................................... 75
3.7 References ..................................................................... 76

Chapter 4. Design, Development and Evaluation of Compact Tele-Robotic Catheter Navigation System† ........................................ 80
  4.1 Introduction ................................................................. 80
  4.2 System Description ....................................................... 82
    4.2.1 Master Unit .......................................................... 84
    4.2.2 Robot-Slave .......................................................... 85
    4.2.3 Control Unit .......................................................... 89
  4.3 System Evaluation ........................................................ 90
    4.3.1 Evaluation in Laboratory Setting ............................... 90
    4.3.2 Evaluation in vivo .................................................. 91
  4.4 Results ........................................................................ 95
    4.4.1 Evaluations in Laboratory Setting .............................. 95
    4.4.2 Evaluations in vivo .................................................. 97
  4.5 Discussion .................................................................... 99
  4.6 Conclusion ................................................................... 101
  4.7 References .................................................................. 102

  5.1 Introduction ................................................................. 104
  5.2 System Description ....................................................... 106
    5.2.1 User Interface- Master ............................................. 108
    5.2.2 Robot-Slave .......................................................... 109
    5.2.3 Multi-Axis Ultrasonic Motor Servomechanism ............ 110
  5.3 Evaluation ................................................................... 112
    5.3.1 MRI-Compatibility Evaluations ................................. 112
    5.3.2 Evaluation of Remote MRI Guided Navigation ............. 113
    5.3.3 Evaluation of Axial Motion ....................................... 115
    5.3.4 Evaluation of Rotational Motion ............................... 116
    5.3.5 Evaluation of Distal End Deflection ......................... 117
  5.4 Results ........................................................................ 117
    5.4.1 MRI-Compatibility Evaluations ................................. 117
    5.4.2 Evaluation of Remote MRI Guided Navigation ............. 118
List of Tables

Table 2.1: Identified parameters of non-linear model ......................................................38
Table 2.2: Identified parameters of linear model.............................................................39
Table 2.3: Controller parameters. .....................................................................................43
List of Figures

**Figure 1.1:** a) Tracked EP catheter (blue) having three micro-coils fused with EP recordings (red), a prior cine MR and associated endocardial surface contours (white). b) Tissue classification map from delayed enhancement-MRI fused with prior cine MR volume showing blood (red), healthy myocardium (blue), infarct (green) and heterogeneous tissue (yellow). Points are EP catheter recording locations with separate colour coding by activation time. (Reprinted from Radau et al. 2012, permission in Appendix B.1) .......................................................... 11

**Figure 1.2:** The basic components and driving principle of a travelling wave-type USM is shown. The periodic expansion and contraction of the piezoelectric material, results in sinusoidally propagating surface points that have an elliptical trajectory. The friction between the elastic layer and the contact points, result in the rotation of the rotor in the direction of the propagating wave. .......................................................... 14

**Figure 1.3:** The MRI-compatible RCNS architecture. The interventionalist stands behind the console of the desired imaging modality, possibly in the control room, and applies the conventional push, pull and knob actuation on the catheter and its handle; the applied motion is measured by the master unit and transferred as the desired reference motion to the servomechanism. The servomechanism controls the positions of the motors of the catheter manipulator such that the patient catheter replicates the reference motion. The interventionalist uses the obtained MRI or Fluoroscopy images as feedback to complete the navigation procedure .......................................................... 17

**Figure 2.1:** Illustration of the USM/driver system and controller. The USM together with the USM driver circuitry is considered as the system to be modeled and controlled ......................................................................................................................... 34

**Figure 2.2:** Curve illustrating the relationship between control effort, motor temperature and motor speed. The surface is obtained by fitting (1) to experimental data (symbols). The RMSE of the fitted surface was 10.32 rpm. .......................................................... 37

**Figure 2.3:** Temperature variations of simulation vs. experimental results for different prescribed voltages of control signal U. Both experimental results (solid) and simulations (dotted) are plotted. ........................................................................................................ 38

**Figure 2.4:** Experiments (solid) and simulated (dashed) speed variations for different prescribed voltages of control signal U ........................................................................................................ 40

**Figure 2.5:** Robust controller block diagram ......................................................................................................................... 43

**Figure 2.6:** Circuit block diagram ........................................................................................................................................ 45

**Figure 2.7:** Step responses of the system are shown: a) The performance of the controlled system in following a set of inclining and declining step inputs is illustrated; b) a zoomed in step response is illustrated. .................................................................. 46

**Figure 2.8:** Demonstration of Method A – control incorporating temperature feedback. The motor angle with respect to a prescribed sinusoidal reference (with a frequency of 0.5Hz and amplitude of 1 rad) is plotted alongside the control effort.
Signals are plotted from a 5 minute experiment, where a) shows the performance during the initial 10 seconds and b) shows the performance during the last 10 seconds.

**Figure 2.9:** Demonstration of Method B – control does not incorporate temperature feedback. The motor angle with respect to a prescribed sinusoidal reference (with a frequency of 0.5 Hz and amplitude of 1 rad) is plotted alongside the control effort. Signals are plotted from a 5 minute experiment, where a) shows the performance during the initial 10 seconds and b) shows the performance during the last 10 seconds.

**Figure 2.10:** The absolute error in tracking a reference with a frequency of 0.5 Hz and amplitude of 1 rad over 10 seconds. This error is calculated by directly subtracting the reference and encoder value at each sample point.

**Figure 2.11:** The absolute mean error for sinusoidal references with an amplitude 1 rad and four different frequencies; the means are calculated over 5 minutes of operation for each reference. This error is calculated after compensation for the delay.

**Figure 3.1:** The components of the MR-RCNS.

**Figure 3.2:** The MR-RCNS is shown. The interventionalist applies conventional motion on the input catheter in the sensory system shown on the left and the MRI compatible manipulator shown on the right of the image replicates that motion on a patient catheter.

**Figure 3.3:** Schematic diagram of the MRI-compatible manipulator. The patient catheter is held by a set of active and idle rollers. The two active rollers (coupled with a chain) actuate the catheter axially while the idle rollers grip the catheter. The adjustable platform allows adjustment of the position of the idle rollers and allows for accommodation of different gauges of catheters.

**Figure 3.4:** Step response of the servomechanism for a reference value of 90° with no load (a) and a load of 0.11 Nm in (b).

**Figure 3.5:** Example manual motion profiles (angular position) of the master and slave are plotted as a function of time: a) with no load b) with a load of 0.11 Nm c) and d) are zoomed-in versions of the first 500 ms of profiles in a) and b), respectively, plotted to demonstrate the small delay in response.

**Figure 3.6:** Four-chamber cardiac images at diastole acquired without the RCNS present (a) and with the RCNS being manipulated (b). Note that there is no perceived increase in noise or artifact level while the RCNS is being manipulated.

**Figure 4.1:** Schematic diagram of the system, displaying the workflow and interactions of the different components.

**Figure 4.2:** Schematic diagram of the master system is shown. The master unit allows for measurement of the user’s input for axial motion, rotational motion and tip steering (for manipulation of plunger or knob).

**Figure 4.3:** The slave robot is shown. In the example setup, the catheter manipulator is positioned over the patient and the handle manipulator between the patient legs.
Figure 4.4: The internal mechanism of the catheter manipulator and the motions it can impart on the catheter are illustrated. The external components in the center of the manipulator are hidden to better illustrate the differential gear and adjustable roller mechanism. ................................................................. 87

Figure 4.5: Mount of the catheter manipulator is shown. The manually adjustable positions are indicated by the arrows. ................................................................. 88

Figure 4.6: The handle manipulator and its controllable motions are shown. One motor controls the position of the plunger knob via a string, winch, and a series of gears; the other rotates the catheter handle. ................................................................. 89

Figure 4.7: The system setup at the experimental operating suite at CSTAR, London, Ontario. The robot is setup on the animal bed (on the left). By manipulating the master unit, the interventionalist (on the right) remotely controls the robot under fluoroscopic guidance. ........................................................................................................... 93

Figure 4.8: Example manual motion profiles of the master and slave are shown as a function of time: The catheter’s rotational and axial motion, calculated from encoder counts are shown in a) and b) respectively; c) and d) are magnified versions of the first second of the profiles in a) and b), respectively, to illustrate the small delay in the response. ................................................................................................................................. 96

Figure 4.9: Radiographs of the catheter and lead in the animal heart. a) image obtained at 45° right anterior oblique (RAO) angle b) image obtained at 45° left anterior oblique angle (LAO). Both perpendicular images clearly show the contact between the catheter tip and the lead. ........................................................................................................... 97

Figure 4.10: Navigation time to four targets using both the manual and robotic method. No statistically significant difference between the two methods was observed (p=0.705). ........................................................................................................................................ 98

Figure 4.11: Visual confirmation of the created RF lesions. Lesions created on the HL-RA, RAA, RAS, and RV-LW are shown (arrows). ........................................................................................................... 98

Figure 5.1: Components of the MRI-compatible remote catheter navigation system. .......................................................................................................................................................... 107

Figure 5.2: The master and slave units are shown side by side. ........................................................................................................................................................................... 108

Figure 5.3: Block diagram of the USM servomechanism. Three microcontrollers (Micro 1-3) are used to remotely control the robot’s four motors (USM 1-4) using each motor’s shaft position – measured with optical encoders (Enc.1-4) – as feedback. ........................................................................................................................................ 111

Figure 5.4: The designed phantom setup for observation of the catheter’s position in MRI. a) shows the setup for observation of the axial position, b) shows the setup for observation of the catheter’s rotational angle. ........................................................................................................................................ 115

Figure 5.5: Artifact images for GRE sequences obtained from the spherical phantom in the presence of the robot: a) with readout in the AP direction, and for b) in the LR direction. As it can be seen the robot does not create any artifacts. .................................................................................. 118

Figure 5.6: Selected frames from the real-time image streams during remote catheter manipulation in each degree-of-freedom. a.1-3, show the catheter’s axial position with 1 cm of axial catheter motion between the presented consecutive figures; the
arrows point to the catheter’s tip. b.1-3 show the catheter’s rotational angle with 90° of counterclockwise catheter rotation between the presented consecutive figures; the arrow points to the tip of the indicator dial that is connected to the catheter. c.1-3 show the bending of the catheter’s distal end at 3 different bending states.

**Figure 6.1**: A simple structure of an actively trackable MRI compatible and steerable catheter is proposed. Two coils at the distal end act as micro imaging coils permitting the localization of the distal end and detection of its orientation. To allow for bending of the distal end, a non-magnetic pull wire (e.g. fishing line) can be used; the pull wire can be retracted using a plunger on the catheter handle. Non-magnetic body material must be used (e.g. PEEK braided Pebax with stiffness of D30 and D72 for the catheter distal end and body correspondingly). Non-magnetic copper coax cables must be used to deliver signal from the coils to the impedance matching and frequency tuning circuits.

**Figure 6.2**: The proposed rapidly prototyped cardiac phantom is shown. The phantom consists of four cardiac chambers, including: interatrial septum opening, four pulmonary vein openings in the left atrium, the inferior vena cava and the femoral veins. To allow visualization of the phantom in MR images, the container can be filled with saline.

**Figure A.1**: Schematic diagram of the stage. An ultrasonic motor (USM) is used to drive a carriage mounted on a lead screw.

**Figure A.2**: The MRI compatible motion stage shown as it would be set up within the MRI scanner. The controller is positioned in the control room and the connections are passed through low pass filters installed within the RF shield of the scanner room.

**Figure A.3**: Sinusoidal profiles with amplitudes of between 2 and 10 mm (rows) at frequencies of 1 to 0.2 Hz (columns) are shown. In each subplot contains cycles from 5 minutes of the execution of the profile are shown. The worst case NRMSE was lower than 7% for all motion profiles with frequencies less than 0.33 Hz.

**Figure A.4**: b) Representative sinusoidal waveform (7 mm amplitude, 0.25 Hz) – the mean and 95% confidence interval of 75 continuous cycles are plotted. b) The power spectrum of the measured 75 cycles is plotted vs. that of the prescribed reference. c) the confidence interval of executed motion vs. prescription of respiratory motion.

**Figure A.5**: Sinusoidal motion of a phantom traveling within the MRI scanner (prescribed amplitude /frequency: 10 mm, 0.33 Hz). The measurements (dashed line) were made using spherical navigator echoes.

**Figure A.6**: a) Selected frames from a FIESTA cine sequence of a tangerine undergoing 0.33-Hz sinusoidal motion with 5-mm amplitude. b) Schematic representation of the experimental set up, where the tangerine was mounted on an extension rod away from the carriage of the stage.

**Figure A.7**: Representative images acquired with and without the stage present and working. The artifact images (right column) represent variations greater than 30% from baseline. Spin echo (a) and gradient recalled echo (b) images with phase
encoding in the left/right direction are shown; similar results were obtained with phase encoding in the anterior/posterior direction. ...............................................................150

**Figure A.8:** The sagittal view of the $\Delta B0$ map due to the stage is shown. The dashed yellow line indicates the location of the carriage at home position. The figure also illustrates where the stage was positioned with respect to the phantom. ..........................151
**List of Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D</td>
<td>Two-dimensional</td>
</tr>
<tr>
<td>3D</td>
<td>Three-dimensional</td>
</tr>
<tr>
<td>AF</td>
<td>Atrial fibrillation</td>
</tr>
<tr>
<td>AP</td>
<td>Anterior-posterior</td>
</tr>
<tr>
<td>ASTM</td>
<td>American society for testing and materials</td>
</tr>
<tr>
<td>$B_0$</td>
<td>Net magnetization</td>
</tr>
<tr>
<td>BW</td>
<td>Bandwidth</td>
</tr>
<tr>
<td>CM</td>
<td>Catheter manipulator</td>
</tr>
<tr>
<td>CNS</td>
<td>Coronary sinus</td>
</tr>
<tr>
<td>CS</td>
<td>Catheter sensor</td>
</tr>
<tr>
<td>DAC</td>
<td>Digital to analogue converter</td>
</tr>
<tr>
<td>DC</td>
<td>Direct current</td>
</tr>
<tr>
<td>DOF</td>
<td>Degree of freedom</td>
</tr>
<tr>
<td>EAM</td>
<td>Electro anatomical mapping</td>
</tr>
<tr>
<td>FIESTA</td>
<td>Fast imaging employing steady state acquisition</td>
</tr>
<tr>
<td>FGRET</td>
<td>Fast gradient-echo echo train</td>
</tr>
<tr>
<td>FOV</td>
<td>Field of view</td>
</tr>
<tr>
<td>GRE</td>
<td>Gradient recalled echo</td>
</tr>
<tr>
<td>HD</td>
<td>Head</td>
</tr>
<tr>
<td>HM</td>
<td>Handle manipulator</td>
</tr>
<tr>
<td>HL-RA</td>
<td>High lateral right atrium</td>
</tr>
<tr>
<td>LR</td>
<td>Left right</td>
</tr>
<tr>
<td>LFR</td>
<td>Lyapunov function redesign</td>
</tr>
<tr>
<td>MO-Cath</td>
<td>Manually operated catheter</td>
</tr>
<tr>
<td>MR</td>
<td>Magnetic resonance</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
</tr>
<tr>
<td>MR-RCNS</td>
<td>Magnetic resonance imaging compatible remote catheter navigation system</td>
</tr>
<tr>
<td>NEMA</td>
<td>National electrical manufacturer’s association</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>NEX</td>
<td>Number of excitations</td>
</tr>
<tr>
<td>NRMSE</td>
<td>Normalized root mean square error</td>
</tr>
<tr>
<td>PET</td>
<td>Positron emission tomography</td>
</tr>
<tr>
<td>PCI</td>
<td>Percutaneous coronary intervention</td>
</tr>
<tr>
<td>PID</td>
<td>Proportional integral derivative</td>
</tr>
<tr>
<td>PS</td>
<td>Plunger sensor</td>
</tr>
<tr>
<td>PTC</td>
<td>Percutaneous transluminal catheterization</td>
</tr>
<tr>
<td>RAA</td>
<td>Right atrial appendage</td>
</tr>
<tr>
<td>RA-LS</td>
<td>Right atrial low septum</td>
</tr>
<tr>
<td>RAS</td>
<td>Right atrial septum</td>
</tr>
<tr>
<td>RCNS</td>
<td>Remote catheter navigation system</td>
</tr>
<tr>
<td>RF</td>
<td>Radio frequency</td>
</tr>
<tr>
<td>RMSE</td>
<td>Root mean square error</td>
</tr>
<tr>
<td>ROI</td>
<td>Regions of interest</td>
</tr>
<tr>
<td>RV-LW</td>
<td>Right ventricular lateral wall</td>
</tr>
<tr>
<td>RV-OT</td>
<td>Right ventricular outflow track</td>
</tr>
<tr>
<td>SE</td>
<td>Spin echo</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>SNAV</td>
<td>Spherical navigator</td>
</tr>
<tr>
<td>SNR</td>
<td>Signal to noise ratio</td>
</tr>
<tr>
<td>T1</td>
<td>Longitudinal relaxation constant</td>
</tr>
<tr>
<td>T2</td>
<td>Transverse relaxation constant</td>
</tr>
<tr>
<td>TE</td>
<td>Echo time</td>
</tr>
<tr>
<td>TR</td>
<td>Repetition time</td>
</tr>
<tr>
<td>T/R</td>
<td>Transmit and receive</td>
</tr>
<tr>
<td>USM</td>
<td>Ultrasonic motor</td>
</tr>
</tbody>
</table>
Chapter 1.

Introduction

Catheterization is the procedure of inserting a catheter into the body. Applications for this procedure include: obtaining measurements and diagnoses, injection of imaging contrast agents or therapeutic drugs, fluid drainage, delivery of medical devices such as cardiac valves, placement of stents and balloons, and ablating tissue using radiofrequency (RF) alternating current.

Catheterization has become an essential tool in the management of cardiovascular diseases. Cardiac catheterization was first introduced by Werner Forssmann in 1929 [1]. He inserted a uretic catheter into his own antecubital vein and, using x-ray imaging, was able to navigate the catheter and visually confirm that the catheter had indeed reached the right side of his heart. Since then, this method has evolved significantly and it has been widely adapted, to the point that there are now more than 1 million cardiac catheterization procedures being performed annually in North America alone [2]. A general upward trend has been observed in the incidence of cardiac diseases requiring catheterization-based treatments. For example, the number of patients with atrial fibrillation or atrial flutter, which are often treated using RF ablation, is expected to increase three-fold during the next 50 years [3-6].

Fluoroscopy continues to be the main imaging modality for guiding catheterization procedures. Fluoroscopic imaging uses x-rays to image the internal structures of the patient’s body in real-time. This imaging modality provides real-time 2-dimensional (2D) projection images of the desired anatomy. However, x-rays are a type
of ionizing radiation. Therefore, x-ray fluoroscopic imaging irradiates the patient directly [7-9] during the procedure, and the staff and interventionalists indirectly through scattered radiation [10, 11] at lower dose levels, but on a daily basis.

Various studies have been performed that measure radiation exposure levels to the patient during fluoroscopically guided interventional cardiology and the results indicate that patient radiation doses vary significantly depending on the type of procedure as well as among similar studies. However, it can be concluded that in general, interventional cardiology procedures expose the patient to considerable amount of radiation and therefore, caution must be taken to reduce the exposure levels to as low as reasonably achievable. This is of significant importance in the case of children due to their high sensitivity to ionizing radiation [12, 13].

There are other studies that focus on the amount of radiation dose received by the staff and interventionalists, as they are exposed to the scattered radiation on a daily basis. Outcomes of these studies are mixed. While some studies indicate that the amount of radiation exposure and associated risk levels to staff are low and safe, others indicate that cumulative radiological exposure of the staff is associated with a non-negligible lifetime attributable risk of cancer [14].

In conventional fluoroscopically guided catheterization, the staff and interventionalists must wear heavy lead aprons to protect themselves from the scattered radiation. However, studies suggest that these aprons only provide partial protection [11, 15, 16]. Furthermore, the prolonged use of these heavy aprons result in orthopedic complications such as chronic neck and back pain [10, 17].
A further limitation of fluoroscopic imaging is that it only provides 2D projection images of the anatomical structure. As a result, much of the 3 dimensional (3D) information – essential to the catheter navigation procedure – may be lost. Furthermore, this imaging modality provides very low soft tissue contrast. These limitations have motivated the use of other imaging modalities to guide the catheterization procedures.

Magnetic Resonance Imaging (MRI) provides 3D visualization, accurate spatial localization, is safe (no ionizing radiation), and provides extremely high soft tissue contrast. MRI offers further advantages such as the ability to differentiate between ischemic, infarcted, and arrhythmogenic tissue in the heart [18, 19]. As a result, MRI has recently been adopted for interventional cardiac catheterization, with the first clinical experience in 2003 [20].

Although initial MRI-guided catheterization methods have shown promise [21], practical implementation requires the modification of most equipment peripheral to the image acquisition (e.g., magnetically shielded monitors/controls within the scanner room, and specialized noise suppressing headsets to permit communication during the procedure). The narrow bore of conventional closed-bore scanners imposes a physical constraint for the interventionalist during MRI-guided procedures and can limit access to the catheter manipulation site on the patient. Catheterization can be especially challenging with unfavorable entry sites and angles. Although open-bore and wide-bore scanners may partially alleviate some of these problems, their availability is limited and it is unlikely that unobstructed access to the patient will be possible in the foreseeable future. Furthermore, closed bore cylindrical scanners are preferred, as they offer superior field homogeneity and signal strength.
This thesis discusses the design, development, and evaluation of a remote catheter navigation system (RCNS) that is also MRI compatible. These developments aim to facilitate MRI-guided catheter navigation and also allow remote catheter navigation under guidance of conventional fluoroscopic imaging as well as MRI.

1.1 Catheterization

While catheterization is used for a large number of applications, the general focus of this thesis is on percutaneous transluminal catheterization (PTC). In PTC, the patient’s vessels act as the guiding lumina through which the catheter travels. Across all medical specialties, similar techniques are used for intravascular catheter navigation. Using the Seldinger technique [22], a catheter is introduced to the vasculature through an introducing sheath. Using fluoroscopic images, in which the catheter tip is clearly visible, the catheter is navigated through the vasculature using push/pull and rotation. Some catheters also allow for the deflection of the distal end of the catheter through manipulation of a knob/plunger on the catheter handle, providing further maneuverability in catheter steering.

PTC interventions may be used in various applications. For example, the catheter may be used to inject contrast at desired locations (vascular angiography) to help enhance blood/vessel visualization and to facilitate catheter navigation; or an angioplasty balloon catheter, in combination with stents, can be guided to atherosclerotic plaque and expanded to open diseased arteries (vessel stenosis and dilation); or catheters may be introduced in to the cardiac chambers for diagnosis and treatments of cardiac arrhythmias.
1.1.1 Cardiac Arrhythmias

In this thesis, we specifically focus on catheter interventions for the treatment of cardiac arrhythmia. A cardiac arrhythmia occurs when abnormal electrical activity of the heart results in asynchrony and rhythm disturbance of the cardiac chambers. Treatments of cardiac arrhythmia include: drug therapy, surgery and catheter-based RF ablation/cryoablation. High success rates of catheter-based ablation, alongside its minimal invasive nature, has led to wide adaptation of this treatment method as the therapy of choice for the management of many cardiac arrhythmias.

The most commonly encountered type of arrhythmia is atrial fibrillation (AF). Approximately 1% of the population in North America suffers from AF and this number is rapidly growing [3, 4]. In catheter-based ablation therapy of AF, the objective is to use ablation to electrically isolate the arrhythmogenic tissue, located in the pulmonary veins (PV), from the rest of the myocardium [23, 24]. This procedure has been traditionally guided with fluoroscopic imaging.

1.2 Catheter Ablation: Current State of the Art

1.2.1 Electroanatomical Mapping Systems

Since fluoroscopic imaging only provides 2D projection images, 3D information about the relative position of the catheter tip to the cardiac anatomy – essential for accurate navigation – may be lost. To address this limitation, 3D electroanatomical mapping (EAM) systems have been developed that allow 3D visualization of the catheter tip with respect to a static electroanatomical map during complex ablation procedures.
EAM systems provide various features such as: chamber reconstruction, tagging of important anatomical landmarks/ablation lesions, activation and voltage mapping, and display and tracking of diagnostic catheters. The appropriate use of such systems allows the identification of the arrhythmogenic focus as well as visualization of the cardiac chamber geometry.

The two main EAM systems currently in use are the CARTO [25, 26] (Biosense Webster Inc., CA, USA) and the EnSite NavX [27, 28] (St. Jude Medical Inc., MN, USA). The CARTO system incorporates external magnetic field sources, and electromagnetic sensors embedded in the catheter’s distal end to allow tracking of the catheter’s position and orientation. A mapping catheter (with proximal and distal electrode pairs) can be moved along a chamber’s surface to record local endocardial activation times as well as the 3D location – relative to a reference catheter – to allow for simultaneous 3D geometric and electroanatomic mapping. Throughout a catheterization procedure, the ablation catheter can be tracked with respect to the reference catheter position and can be visualized relative to the created EAM, greatly facilitating navigation and reducing the need for fluoroscopy guidance. Studies show that the CARTO system can significantly reduce exposure time while obtaining similar clinical outcomes to conventional methods without prolongation of overall procedure time [29-31]. The major disadvantages of this system are the need for specialized and more expensive catheters [30, 32], sensitivity to reference catheter dislocation [32], and the possibility of electromagnetic interference between the CARTO magnetic field sources and patient implants [33].
The EnSite NavX system incorporates an externally applied electric current to create a gradient voltage across tissue. Using three such fields, the catheter leads can be used to measure the voltage and impedance at any given point, and along each generated field, allowing for estimation of the catheter position. In the EnSite NavX system, the tracked catheter can be moved along the desired chamber’s surface to create an electroanatomical map, similar to the CARTO system. This system has also been proven to reduce exposure and patient dose without degrading the clinical outcome or prolonging the overall procedure time [31, 34, 35]. Some of the limitations of this system are inaccurate rendering of complex anatomical structures and limited application for non-sustained arrhythmias [32].

While EAM systems are used for a variety of cardiac catheterization applications, the literature suggests that these systems are particularly effective in facilitating electric isolation of the pulmonary veins in the treatment of AF, where they have shown to reduce radiation dose and procedure time [32, 34, 36, 37]. Despite these benefits, studies show that the failure rate of catheterization with the aid of EAM systems, for the treatment of AF, remains high at approximately 30% [38]. Furthermore, EAMs have not fully eliminated the need for fluoroscopic imaging and guidance is still subject to low anatomical contrast (inability to visualize soft tissues) and static geometrical maps with high inaccuracies [39].

1.2.2 Remote Catheter Navigation Systems

Some of the limitations of fluoroscopically guided catheter intervention procedures can be overcome by providing the interventionalist with the tools to remotely
perform the catheterization directly from the control room. Several remote catheter navigation systems (master-slave) have been developed and are now commercially available: Niobe (Stereotaxis Inc., MO, USA) [40, 41], Sensei (Hansen Medical, CA, USA) [42, 43], Corpath (Corindus Vascular Robotics, MA, USA) [44], and Amigo (Catheter Robotics Inc., NJ, USA) [45]. The user interacts with the Niobe system through a graphical user interface; this system then uses controlled magnetic fields to move and navigate a magnet connected to the tip of a catheter with 3 degrees of freedom (DOF) to follow the motion prescribed by the user. The Sensei system incorporates custom designed steerable catheters and sheaths to allow the remote manipulation of the catheters/sheaths using a 3-DOF joystick. The Corpath system uses sets of rollers mounted on a rotating gantry to grip on to the catheter and rotate it, allowing for only 2-DOF control of catheters for vascular applications. The Amigo system allows for 3-DOF in manipulation of standard-tip steerable catheters, which utilize rotary knobs mounted on the catheter handle for tip deflection, using a remote controller with push buttons.

All of the mentioned systems are intended for use with fluoroscopy guidance and none are MRI compatible. In general the uptake of these systems has been limited due to their high cost, bulkiness, requirement of specialized (and expensive) catheters and long training periods (due to non-intuitive user interfaces).

1.3 MRI Guided Interventions

1.3.1 MRI Guided Catheterization

High soft tissue contrast, 3D visualization and accurate spatial localization have motivated the use of MRI for diagnostic and therapeutic interventions. Applications such
as MRI-guided biopsy and neurosurgery emerged as early as the 1980s [46, 47]. The adoption of MRI for cardiac interventions has been slower, mainly due to the difficulty of acquiring rapid images from fast-moving cardiac anatomy. Recent technological developments have helped overcome this limitation by providing rapid-acquisition pulse sequences [48, 49]. For the specific application of cardiac catheterization, MRI also offers the unique ability to characterize tissue. For example, MRI offers the ability to visualize infarct, ischemic and arrhythmogenic tissue [50, 51], ablation lesions [52, 53], hemorrhages[54], and detailed information about soft tissue deformation and morphology during catheter/soft-tissue contact [55]. Furthermore, during ablation, MRI offers valuable information on temperature variation of the target tissue. These benefits offer the potential to improve the plan of therapy, prevent complications and enhance procedure efficiency and outcome [51, 56-59].

In 2003, Razavi et al. [20] reported the first diagnostic and interventional MRI-guided catheterization in patients with congenital heart disease, and demonstrated the feasibility and safety of MRI-guided catheterization in humans. Since then, many more human studies have been performed for various applications: peripheral artery angioplasty and stenting [60], balloon pulmonary valvuloplasty [61], vena cava filter deployment (or retraction and retrieval) [62, 63], and electrophysiology catheterization and ablation [64, 65].

Despite proofs of concept and the potential benefit of MRI guided catheterization, various challenges exist on the path towards wide adoption of MRI for interventional cardiac catheterization. A primary challenge is the scarcity of MRI-compatible catheters, guide wires and stents. For the specific case of ablation catheters, there are currently no
clinically approved and commercially available products. However, this limitation can be expected to change, considering the significant amount of promising research aimed at development of new MRI-compatible catheters together with clinical trials for their validation [66-69]. Another challenge is the integration of real-time MRI data into EAM software with the capability of identifying the image plane that contains the catheter. Radau et al. have developed an open source system (VURTIGO) for this application that allows for automatic acquisition, plane prescription, as well as visualization and registration of previously obtained images with the real-time MRI stream images [51]. Figure 1.1 illustrates some of the features of the VURTIGO platform.

There are challenging issues associated with the use of conventional closed-bore scanners for MRI-guided interventions. For example, there is a need for magnetically shielded display monitors and MRI-compatible control within the scanner room. Also, due to the loud acoustic noise during imaging, specialized sound suppressing headphones are required [70]. Another major constraint imposed during MRI guided procedures, in a conventional closed bore scanner, is that the interventionalists are required to reach within the MRI bore to gain access to the catheter manipulation site and depending on the point of entry this may cause significant complications in the procedure. These problems continue to limit the wide adoption of MRI-guided catheterization despite its clear benefits. Similar limitations in other MRI-guided procedures such as neurosurgery, prostate interventions have motivated the design and development of MRI-compatible robots for these applications. However, outside the scope of this thesis and to the best knowledge of the author, no MRI-compatible robot has been proposed for MR-guided catheterization.
1.3.2 MRI Compatible Mechatronics

One of the challenges of developing mechatronics systems, such as surgical robots, for use inside an MRI system is MRI compatibility. The complex topic of MRI compatibility has been central to many research and development applications for MRI. Shellock studies the topic extensively and provides a guidebook on the topic [71]. Shneck comprehensively studied and defined the magnetic compatibility aspect of MRI compatibility [72]. General Electric (GE) Healthcare Systems provided a guideline for interventional MRI device design in 1997 which was then developed further by Chinzei et al., who provided the general design criteria for mechatronics devices intended for use within the MRI bore [73]. Based on the guidelines provided in the latter study, a device is...
MRI compatible if it is MR safe, does not degrade the image quality and can perform its intended task inside the MR environment.

While the possible interactions of MRI on mechatronic devices are complex, they can be generally categorized as: the effect of the magnetic field on mechanical devices (e.g. force); RF pulse effects on conductors (e.g. induced disturbance on sensors or RF heating); disturbance of the magnetic field due to the presence of foreign objects (e.g. induced field inhomogeneity resulting in image artifact); effect of foreign objects on receive RF coil (e.g. coil detuning); noise introduced through wiring from outside the magnet room (e.g. added noise resulting in reduced image signal to noise ratio (SNR)); and effect of foreign resonant objects on the gain controller (e.g. detuning of receiver). These interactions add stringent requirements on the type of material, actuators, sensors and wiring connections used in devices for MRI applications.

The problem of material selection for structural elements or passive components for the assembly can be easily addressed by selecting the right type of materials (preferably nonmagnetic), that have been proven to have limited or acceptable interaction with the MRI system [71, 74]. The greater challenge is the selection of active components, specifically actuators, as most conventional active components are made of magnetic material (e.g. DC motors).

Presently, there are three main actuation techniques available for MRI. These options are: piezoelectric actuators, pneumatic actuators and hydraulic actuators. For MRI-compatible robotic actuation, different research groups have used different actuation options depending on the application and design requirements [75-81]. The MRI compatibility of different actuation options has been compared by Fischer et al. [82].
Among these options, piezoelectric actuators in general and travelling-wave-rotary-ultrasonic motors (USMs) in particular are an extremely attractive choice for the actuation of surgical robots within the MRI environment. The key advantages of USMs in comparison to other techniques are their high torque-to-size ratio, auto-brake at no power, fast dynamics, cleanness (no risk of spills as with hydraulic actuators) and limited electromagnetic interference.

USMs use the piezoelectric effect to generate motion. Conventional USMs consist of piezoelectric material, rigidly connected to a motion amplifier (stator) firmly pressed against an elastic body mounted on the rotor that supports the motor shaft. The piezoelectric material is excited with oscillatory electrical signals (provided by a driver circuit) with frequency close to the mechanical resonance frequency of the assembly. Applying sinusoidal waveforms – that are offset in phase with respect to each other – to the piezoelectric material can create a propagating wave in the material. The motion of this propagating wave is transferred to the rotor as a result of the large friction between the elastic body and the stator [83, 84]. The propagating wave is proportional to the frequency, amplitude, and phase of the applied sinusoidal voltages. The basic components and principles of operation of a travelling wave rotary USM are shown in Figure 1.2.
Figure 1.2: The basic components and driving principle of a travelling wave-type USM is shown. The periodic expansion and contraction of the piezoelectric material, results in sinusoidally propagating surface points that have an elliptical trajectory. The friction between the elastic layer and the contact points, result in the rotation of the rotor in the direction of the propagating wave.

The benefits of USMs – specifically that they can be made of non-magnetic material – have made USMs a highly attractive actuation option for use in MRI compatible mechatronic devices [76, 85, 86]. However, a challenge associated with
ultrasonic motors is the existence of several sources of power loss, including friction, structure damping, and dielectric power loss [87, 88], which result in heating of the motor and response inconsistency. The temperature variations significantly affect the dynamic characteristics of the motor and change the resonance frequency of the piezoelectric material [87, 89, 90]. This phenomenon makes USMs highly nonlinear and time-variant and makes accurate control of these motors challenging – a problem that must be addressed for prolonged use of these motors in dynamic robot motion control.

Addressing the limitations of USMs, and in an attempt to overcome hurdles of both MRI-guided catheterization and fluoroscopically-guided catheterization, in this thesis I focus on the design, development, control and validation of a remote MRI compatible catheter navigation system that can utilize both USMs and DC motors as actuators. Due to the increased prevalence of AF, and its catheter based treatment procedures, this thesis is confined to applications of catheterization for the treatment of AF.

1.4 Design Approach: MRI Compatible Tele-robotic Catheter Navigation System

The tele-robotic system proposed in this thesis is intended for use with both conventional fluoroscopic guidance as well as MRI guidance. At present, the available tele-robotic solutions for fluoroscopically guided catheterization provide similar performance to that of manual catheterization in terms of patient outcome [91, 92]. Therefore, the main benefit of such systems is the reduction of background radiation to the staff and interventionalist and mitigation of their work environment hazards such as
the risks for chronic musculoskeletal injuries. In conventional diagnostic MRI suites, the scanner bore severely limits patient access by the interventionalist and makes catheter manipulation very challenging for MRI-guided catheterization. Therefore the major contribution of a MRI-compatible RCNS will be to facilitate MRI-guided catheterization and help pave the path for its wider adoption.

The architecture of the tele-robotic system proposed in this thesis is inspired by the design approach of the earlier work by Thakur et al. [93] where a master-slave catheter navigation system, with 2-DOF, was built for fluoroscopically-guided catheterization. Thakur et al.’s design took advantage of the interventionalist’s dexterous skills by using an input catheter in a master unit as the user interface. The master unit sensed and measured the user’s applied motion on the input catheter. The sensed motion was communicated to a computer that sent corresponding control commands to the actuator’s control circuitry to manipulate the robot and replicate the sensed catheter motion on a patient catheter. While this former work was validated in vivo and provided a proof of concept, it had several limitations: it was not MRI compatible, only provided 2-DOF in catheter motion, was not sterilizable and had a large motion delay (up to 300ms) [93]. This thesis aims to overcome the limitations of the aforementioned work but maintains a similar approach.

The RCNS proposed in this thesis is designed as a master-slave system where the interventionalist is directly in the procedure loop and in control of the navigation procedure. An overview of the proposed architecture is illustrated in Figure 1.3. By allowing the interventionalist to directly manipulate a catheter body or handle in the master unit, the system utilizes the dexterous skills and hand-eye coordination of a
trained interventionalist during the navigation. The approach has been that the interventionalist directly manipulates a catheter or catheter handle in a master unit to remotely control the patient catheter. An embedded real-time control system (servomechanism) is used to capture the reference motion from the master unit, as well as the robot’s (slave’s) motion, to create a proportional control signal to appropriately control the robot’s actuators such that the patient catheter’s motion replicates that of the input catheter. Using a desired imaging modality such as fluoroscopy or real-time MRI, the interventionalist obtains the needed visual feedback to guide the navigation and adjust their manipulation on the input catheter in the master unit.

Figure 1.3: The MRI-compatible RCNS architecture. The interventionalist stands behind the console of the desired imaging modality, possibly in the control room, and applies the conventional push, pull and knob actuation on the catheter and its handle; the applied motion is measured by the master unit and transferred as the desired reference motion to the servomechanism. The servomechanism controls the positions of the motors of the catheter manipulator such that the patient catheter replicates the reference motion. The interventionalist uses the obtained MRI or Fluoroscopy images as feedback to complete the navigation procedure.
1.5 Thesis Scope

In this thesis the design, development and evaluation of a MRI-compatible RCNS is presented. Many PTC procedures require both a guide wire and a catheter and some catheter navigation procedures also require a sheath. The tele-robotic system presented in this thesis will focus on remote catheter navigation procedures that only require a steerable catheter, particularly the manipulation of RF ablation catheters for electrophysiology applications in the treatment of atrial fibrillation. These procedures typically do not require a guide wire and therefore manipulation is simplified to the actuation of a tip-steerable catheter.

This thesis presents a RCNS that can be used with multiple imaging modalities (fluoroscopy and MRI). While safety, accuracy and feasibility of remote navigation and ablation are shown in vivo for fluoroscopic guided remote catheterization, a proof of concept for remote MRI-guided catheter manipulation is provided in phantoms using the same robotic design (with Ultrasonic motors instead of DC motors).

In parallel to the development of the presented RCNS, actively tracked electrophysiology catheters are being developed that would allow for fast localization of the catheter’s distal end (e.g. IMRICOR Medical Systems, MN, USA). This would permit automatic plane prescription such that the imaging plane would fully contain the catheter’s distal end. This thesis focuses on the manipulation of conventional tip steerable catheters that are passively tracked. The catheter is navigated under real-time MRI guidance with manual image-plane prescription.
1.6 Thesis Outline

This thesis is divided into six chapters. This introductory chapter introduced the limitations of conventional catheterization approaches, the state of the art in catheterization guidance, as well as the benefits and limitations of MRI guided catheterization.

Chapter 2 presents a robust control method for prolonged motion control of USMs. A version of this chapter, entitled: “Robust Motion Control of Ultrasonic Motors Under Temperature Disturbance” has been submitted to the Journal of Industrial Electronics (Submission No.: 15-TIE-1240). The developments presented in this chapter, allow for dynamic control of MRI compatible mechatronics. Therefore, apart from control of the RCNS, this technology has other important applications, such as dynamic motion control of imaging phantoms for quality assessment of MRI and MRI guided therapy. This is application is further discussed in appendix A; a version of this appendix, entitled: “MRI compatible dynamic motion stage” is submitted to Medical Physics (submission # 15-900).

Chapter 3 discusses the design, development and ex vivo evaluations of an MRI-compatible RCNS with two degrees of freedom in catheter steering. A version of this chapter, entitled “A Magnetic Resonance Imaging Compatible Remote Catheter Navigation System” has been published in a special issue of the IEEE Transactions on Biomedical Engineering on surgical robotics (vol.60 (4): 899-905, 2013).

The limitations of the robotic system presented in chapter 3 are addressed with a new robot design. The details on the upgraded design, as well as development, and in vivo evaluation under fluoroscopic guidance, are presented in chapter 4. A version of this


The final chapter of this thesis summarizes the contributions and limitations of this project and provides suggestions and guidelines for future work.
1.7 References


[33] A. Buiatti, H. Pavaci, I. Deisenhofer, and C. Kolb, "Electromagnetic interference between a three-dimensional cardiac mapping system and an implantable


[53] R. Ranjan, E. G. Kholmovski, J. Blauer, S. Vijayakumar, N. A. Volland, M. E. Salama, et al., "Identification and acute targeting of gaps in atrial ablation lesion
sets using a real-time magnetic resonance imaging system," *Circulation: Arrhythmia and electrophysiology*, vol. 5, pp. 1130-5, 2012.


Chapter 2.

Robust Motion Control of Ultrasonic Motors Under Temperature Disturbance†

2.1 Introduction

Travelling wave rotary ultrasonic motors, also known as ultrasonic motors (USM), use the piezoelectric effect to generate motion. Conventional USMs consist of piezoelectric material connected to an elastic body (stator) and a rotor that is firmly pressed against the elastic body. The piezoelectric material is activated with oscillatory electrical signals (provided by a driver circuit) with frequency close to the mechanical resonance frequency of the assembly. Applying sinusoidal waveforms – that are offset in phase with respect to each other – to the piezoelectric material creates a propagating wave in the piezoelectric material and consequently in the elastic body. This motion is transferred to the rotor as a result of the large friction between the elastic body and rotor [1, 2]. The propagating wave is proportional to the frequency, amplitude, and phase of the applied sinusoidal voltages. Conventional USM driver circuits typically allow the user to manipulate an input control signal, which results in adjustment of the frequency of the sinusoidal waves. The frequency of these waves consequently sets the motor’s speed [3].

†A version of this chapter has been submitted as manuscript to the IEEE Transactions on Industrial Electronics: M. A. Tavallaei, S.F. Atashzar and M. Drangova, “Robust Motion Control of Ultrasonic Motors under Temperature Disturbance”, 2015.
The high torque-to-size ratio, quietness, stall at no power, fast dynamics, non-magnetic properties and small electromagnetic interference have made USMs an attractive choice for numerous applications, including lens drive mechanisms[4], magnetic resonance imaging (MRI) compatible surgical robots and devices [5-7], aerospace applications [8-10] etc.

A challenge specific to ultrasonic motors, which this chapter addresses, is the existence of several sources of power loss, including friction, structural damping, and dielectric power loss [11-13], resulting in heating of the motor and substantial performance degradation and response inconsistency. The temperature variations significantly affect the dynamic characteristics of the motor and change the resonance frequency of the piezoelectric material [14-16]. This phenomenon makes USMs highly nonlinear and time-variant and makes accurate control of these motors challenging.

Specifically addressing the problem of temperature rise in USMs, a recent paper [16] described the redesign of the motor by embedding a water-cooling method directly into the motor assembly. While such a design does overcome the heating problem, it is not yet commercially available and would have potential complications of requiring water pumps and connections as well presenting a risk of leakage. Other attempts to address the problem have primarily focused on developing control methods that allow for improved control of existing USMs. Bekiroglu [17] designed and implemented a control and driver system to control a USM by adjusting the frequency and voltage amplitude of the applied drive signals – the custom developed drive circuitry allows for simultaneous manipulation of these parameters. Chung et al. [18] developed a mathematical model intended for USM control, but their model did not include the effects of temperature rise.
Addressing the challenges in speed control of USMs by only using proportional-integral-derivative (PID) control, Senjyu et al. [19] developed a neural network controller by approximating the nonlinear input-output map and incorporating the inverse model to adjust the control signal. However this method requires training of the neural network and faces the complexities of convergence in the used back-propagation algorithms. Furthermore, Senjyu’s method also requires retraining for different USM motors and was evaluated over durations of only 20 seconds, which may be insufficient for the manifestation of temperature related nonlinearities. The shortcomings of only using a PID controller to control a USM is also illustrated in [14], where a fuzzy self-tuning PI controller that relied on temperature feedback to mitigate temperature effects was introduced; controller performance was validated under no-load conditions and also for only 20 seconds. In [20] a model reference adaptive control technique is used to overcome the non-linearity of USMs, particularly those associated with dead-zone; however, temperature effects are not considered in the modeling/design phase or experiments. In [21], a mathematical model relating the motor’s speed to the phase and frequency of the applied sinusoidal signals is presented while the effect of temperature is neglected. A model-based robust controller was also presented in [3], but temperature effects were not considered in their modeling and control scheme/performance; the experimental results (6 seconds) were obtained using a custom designed driver circuitry. In another work, Maas et al. [22] developed a model-based control system that compensated for nonlinearities and temperature effects by simultaneously manipulating the frequency, amplitude and phase of the applied sinusoidal signals applied to the motor.
This approach also required the development of a custom designed driver circuitry that would allow the user to simultaneously manipulate all three variables.

The problem of temperature dependence and time varying dynamic characteristics of USMs remains a challenge – particularly for prolonged control of off-the-shelf USMs and driver circuits that have a single user-controllable input. Therefore the purpose of this study is to model a single control input USMs/driver system, and to design, implement, and evaluate a robust controller that enables prolonged motion control of such a system. We will demonstrate that accurate and robust control performance is achieved, despite the effects of temperature variations during prolonged motor operation of several minutes. Two robust control architectures are considered – one for the case when temperature feedback is available and the other when it is not.

This chapter is organized as follows. Identification of the system model is presented in section 2.2. The robust control design – based on a linear system model – is presented in section 2.3. Section 2.4 discusses the hardware design for the control system circuitry and further elaborates on the hardware implementation of the controller. Section 2.5 provides experimental results of our proposed control system showing the system robustness over 5 minutes of operation. The chapter concludes with section 2.6– a discussion on the achieved system performance.

2.2 Model Identification

In our modeling approach, the USM and driver combination is considered as the system to be modeled. We model the system as a single-input-multi-output system, where the input voltage to the driver is considered as the single control input. The motor
temperature, shaft position and shaft speed are considered as outputs. Figure 2.1 illustrates the system that is to be modeled and controlled. The USM used in this study was the USR-60NM, which was used with its driver circuit D2060 (Shinsei-Fukoku, Japan). The driver circuit accepts an analogue voltage as the control input. Using a voltage-controlled oscillator, the driver adjusts the frequency of the applied sinusoidal drive voltages to the USM (proportional to the value of the analogue control input) that finally results in speed modifications of the motor [3].

Prior to model identification, experiments were performed to measure the system outputs: temperature, speed, and position as a function of the applied control input signal. The motor’s temperature was considered as an output because it has been shown to have significant effects on the performance characteristics of ultrasonic motors [14, 15, 19]. A

---

**Figure 2.1**: Illustration of the USM/driver system and controller. The USM together with the USM driver circuitry is considered as the system to be modeled and controlled.
temperature sensor (MAX6576, Maxim, USA) was attached to the body of the motor close to the shaft, where the USM is expected to be the hottest [11]. The temperature sensor was read using a digital oscilloscope (MS0 3014, Tektronix, USA) and logged to a personal computer. The experiments were performed at an ambient temperature of 24 °C; no additional ventilation was used to cool the motor during testing. The USM’s internal optical incremental encoder (Shinsei-Fukoku, ME-30-1000PC J3, 1000 counts per revolution) was used for measuring the speed and position of the motor shaft. For each experiment a fixed voltage was considered to the motor driver circuitry and the temperature and position of the motor were simultaneously logged. The tests were stopped once the temperature reached 45 °C (this maximum temperature was selected to represent the practical range of temperatures; see below). For each voltage setting the test was repeated with a load of 0, 5 Ncm, and 10 Ncm. The direction of travel was randomly changed for each loading condition. The tests were repeated for 13 voltage settings ranging from 0.1 –1.4 V with approximate increments of 0.1 V. Using the trust-region method [23] within MATLAB’s curve fitting toolbox, the following equation was fit to the obtained data (RMSE:10.32 rpm):

\[ \dot{\theta} = (1 - e^{-b_0 t})g(T, u), \]  

where \( \dot{\theta} \) is the motors speed, \( t \) is time, \( T \) is the temperature, \( u \) the control voltage and \( g(T, u) \) is a nonlinear relation which can be described as follows:

\[ g(T, u) = \left( b_2 e^{b_3 u} \right) (a_4 u^4 + a_3 u^3 + a_2 u^2 + a_1 u + a_0). \]  

The model equation was considered following a trial and error approach; this form was finally selected as it allowed for a relatively accurate system description–small RMSE– while using a simple fourth order polynomial equation form. In the above
equations $a_{0.4}$ and $b_{0.3}$ are fitting parameters. By taking the derivative of Eq. 2.1, the following nonlinear equation is obtained to describe the dynamics of the motor speed:

$$\dot{\theta} = -b_0 \dot{\theta} + b_0 g(T, u) + \alpha(T, u, t),$$  \hspace{1cm} 2.3

in which $\alpha(T, u, t) = (1 + e^{-b_0 t}) \left( \frac{\partial g(T, u)}{\partial t} \right) + \vartheta(t)$, where $\vartheta(t)$ is random Gaussian noise. The Gaussian noise term was added to account for the unpredictable variations of speed due to the “sticking/ slipping” behavior at the contact interface between the stator and rotor [12, 24].

The effects of temperature and control voltage on the motor’s speed (independent of time) are illustrated in Figure 2.2. It can be seen that an increase of the control voltage results in an increase of the motor’s speed. However, as temperature increases the motor’s speed drops dramatically. The torque load on the motor had a much smaller effect than the temperature – e.g. at 1.4 V the range of speed variation at different loads of 0, 5 and 10 Ncm was 9 rpm compared to a variation range of 55 rpm as temperature increased from 24 °C to 45°C; therefore in the mathematical model we assumed no dependence on the applied torque. This simplifying assumption will be further addressed in the controller design.
In [14], Yano et al. model the temperature dynamics of the USM as follows:

\[
\dot{T} = \frac{-\beta S}{C} T + \frac{\beta S}{C} \left( T_{air} + \frac{q}{\beta S} \right)
\]

where \( q \) is the heat value per unit time \([J/s]\), \( \beta \) is the thermal conductivity at the surface of the motor \([J/m^2Ks]\), \( S \) is the surface area of the motor \([m^2]\), and \( C \) is the motor’s heat capacitance \([J/K]\). While Yano et al. [14] assumed a constant term \( q \), our experimental results, showing the variation of temperature at different control voltages (Figure 2.3), suggest that the term \( q \) varies proportionally with the applied control signal; therefore we assume \( q = c_4 u \). With these assumptions, Eq. 2.3 and Eq. 2.4 represent a nonlinear model of the USM-driver dynamics; the identified parameters for this model are listed in Table 2.1.
Figure 2.3: Temperature variations of simulation vs. experimental results for different prescribed voltages of control signal U. Both experimental results (solid) and simulations (dotted) are plotted.

Table 2.1: Identified parameters of non-linear model

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Value</th>
<th>Symbol</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$a_0$</td>
<td>0.38</td>
<td>$b_0$</td>
<td>-40 $s^{-1}$</td>
</tr>
<tr>
<td>$a_1$</td>
<td>1.02 $V^{-1}$</td>
<td>$b_1$</td>
<td>19.69 $K$</td>
</tr>
<tr>
<td>$a_2$</td>
<td>-5.78 $V^{-2}$</td>
<td>$b_2$</td>
<td>2.06 $rad/s$</td>
</tr>
<tr>
<td>$a_3$</td>
<td>9.51 $V^{-3}$</td>
<td>$b_3$</td>
<td>3.19 $K$</td>
</tr>
<tr>
<td>$a_4$</td>
<td>-3.36 $V^{-4}$</td>
<td>$\beta S$</td>
<td>0.5 $J/Ks$</td>
</tr>
<tr>
<td>$C$</td>
<td></td>
<td></td>
<td>280 $J/K$</td>
</tr>
</tbody>
</table>

While this nonlinear model describes the measured variations of speed with applied control voltage and temperature, we also propose a linear model, which is more
practical – both for parameter identification and for reduced computational cost during control. Therefore, the following linear dynamics model was chosen for use in the design of the robust controller (the difference between the nonlinear behavior and the linear modeling will be addressed by the robustness of the designed controller in this chapter):

\[
\begin{align*}
\dot{\theta} &= -c_0 \dot{\theta} + c_1 T + c_2 u + c_3 \\
\dot{T} &= \frac{-H}{C} T + \frac{H}{C} \left( T_{air} + \frac{c_4 u}{H} \right)
\end{align*}
\]

In Eq. 2.5, \(c_0 \ldots c_4\) are found by linearizing the model described by Eq. 2.4 (e.g. using the first-order Taylor approximation) or by directly fitting the experimental data to this model. The second equation shown in Eq. 2.5 is equivalent to Eq. 2.4, where \(H = \beta S\); the equation was repeated for completeness. The linear model parameters for Eq. 2.4 and 2.5 are provided Table 2.2.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Value</th>
<th>Symbol</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>(c_0)</td>
<td>-40 (s^{-1})</td>
<td>(c_3)</td>
<td>114.56 (rad/s^2)</td>
</tr>
<tr>
<td>(c_1)</td>
<td>-3.91 (K^{-1}s^{-2})</td>
<td>(c_4)</td>
<td>0.2 (J/Vs^2)</td>
</tr>
<tr>
<td>(c_2)</td>
<td>263.35 (V^{-1}s^{-2})</td>
<td>(H)</td>
<td>0.5 (J/Ks)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(C)</td>
<td>280 (J/K)</td>
</tr>
</tbody>
</table>

Simulation of the non-linear model vs. experiments

To validate the non-linear mathematical model identified above, we compared model simulation with experimental results. The motor dynamics obtained by Eq. 2.3 and Eq. 2.4 were simulated using MATLAB-Simulink (The MathWorks, USA) for the
investigated range of input control signals. **Figure 2.3** compares simulated and measured temperature variation over time for several control signal values, while **Figure 2.4** shows simulation and experimental results of motor speed variation with time for the same control signals. Both figures demonstrate good agreement between simulation and experimental results, confirming that Eq. 2.3 and Eq. 2.4 can be used to model the USM-driver dynamics for simulation purposes and/or controller design.

![Graph showing speed variation with time for different prescribed voltages](image)

**Figure 2.4**: Experiments (solid) and simulated (dashed) speed variations for different prescribed voltages of control signal U.

### 2.3 Robust Controller Design

In this section the linear model of Eq. 2.5 that describes the dynamics of the USM and driver circuitry combination is used to implement a robust controller. In comparison to Eq. 2.1 the linear model Eq. 2.5 facilitates motor parameter identification and reduces
the required amount of computation for implementation of the controller. However, the linear model contains uncertainties due to linearization, loading, unmodeled dynamics and time-varying nature of the system. In order to deal with the uncertainties of the system while ensuring an acceptable performance and system stability, the Lyapunov Function Redesign (LFR) robust controller were utilized. The details of the LFR controller and its stability proof are given in [25, 26].

We propose two control methods: the first technique (Method A) overcomes temperature effects by using temperature as a feedback utilized in the controller, while in the second technique (Method B) the effects of temperature variation are treated as increased system uncertainty. To design these control methods, Eq. 2.5 can be rewritten as follows:

\[ B\ddot{\theta} + n(T, \dot{\theta}) = u, \]  

where \( B = \frac{1}{c_2} \) and \( n = \frac{1}{c_2} (c_0 \dot{\theta} - c_1 T - c_3 - \dot{\theta}(t)) \). In Eq. 2.6 \( B \) and \( n(T, \dot{\theta}) \) can be uncertain. The identification procedure provides us with estimation of \( B \) and \( n(T, \dot{\theta}) \) namely \( \hat{B} \) and \( \hat{n}(T, \dot{\theta}) \) correspondingly. Consequently, we can write the identified dynamics of the system as:

\[ \hat{B}\ddot{\theta} + \hat{n}(T, \dot{\theta}) = u. \]  

Based on the LFT technique, the control signal is defined as:

\[ u = \hat{B} y + \hat{n}(T, \dot{\theta}), \]  

where

\[ y = \ddot{\theta}_d + K_D \dot{\theta} + K_p \theta + w. \]  

In Eq. 2.9 \( \theta_d \) is the desired reference trajectory and \( \theta = \theta - \theta_d \). \( K_D \) and \( K_P \) are the feedback gains and \( w \) is described as:
\[ w = \begin{cases} \frac{z}{\|z\|} & \|z\| \geq \varepsilon \\ \frac{z}{\varepsilon} & \|z\| \leq \varepsilon \end{cases} \]  \hspace{1cm} (2.10)

where \( z = D^T Q \xi \), \( \xi = [\bar{\theta} \ \tilde{\theta}]^T \), \( Q \) is a positive definite 2x2 matrix and \( \varepsilon \) is an arbitrarily selected constant tuned to minimize the chattering phenomenon. Based on the stability proof of LFR controllers [25, 26] and assuming:

\[
\begin{align*}
\alpha &= \frac{b_{\text{max}} - b_{\text{min}}}{b_{\text{max}} + b_{\text{min}}} \\
\bar{n} &= n - \hat{n} \\
\|\bar{n}\| &\leq \varphi < \infty \\
\hat{\theta}_d &< Q_M
\end{align*}
\]  \hspace{1cm} (2.11)

the following condition for \( \rho \) guarantees stability of the system:

\[
\rho \geq \frac{1}{1-\alpha} (\alpha Q_M + \alpha \|K\| \|\xi\| + B_M \varphi),
\]  \hspace{1cm} (2.12)

where \( K = [K_P + K_D]^T \) and \( D = [0 \ 1]^T \).

The block diagram of the designed robust controller is shown in Figure 2.5 and the parameters are presented in Table 2.3. The upper bound of \( \varphi \) is adjusted to account for the uncertainty in \( \hat{n} \). As mentioned before, two alternatives for the control implementation are possible. In the proposed controller for Method A (with temperature feedback), \( \varphi \) is considered equal to 0.2 and in Method B (without temperature feedback) we consider \( \varphi = 0.5 \). It should be mentioned that \( \varphi \) is the tuning factor and higher \( \varphi \) will result in a more conservative design and higher control input. Based on the performed experiments, and considering the accuracy of the model described in the previous section, the considered values for \( \varphi \) show an acceptable performance for the system as shown in the rest of this chapter. It is important to note that in the proposed control methods the temperature is not being controlled. Therefore, if possible, the temperature must be monitored periodically to ensure it does not exceed safety limits. It must be noted that
for certain applications such as use within an MRI system, appropriate temperature sensors (e.g. MRI-compatible temperature sensors) may not be readily available or they may be unreliable (e.g. due to possible RF disturbance). Therefore, for such applications, control Method B can be used as it does not rely on temperature feedback.

![Robust controller block diagram](image)

**Figure 2.5:** Robust controller block diagram.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Value</th>
<th>Symbol</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$B_{\text{max}}$</td>
<td>290</td>
<td>$\varepsilon$</td>
<td>0.1</td>
</tr>
<tr>
<td>$B_{\text{min}}$</td>
<td>250</td>
<td>$K_P$</td>
<td>700</td>
</tr>
<tr>
<td>$\varphi$</td>
<td>0.2, 0.5</td>
<td>$K_D$</td>
<td>50</td>
</tr>
<tr>
<td>$Q_M$</td>
<td>25</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 2.3:** Controller parameters.
2.4 Hardware Design and Controller Implementation

To implement the described control methods, a custom embedded system was designed. At the core of the circuit is an XMEGA microcontroller (ATMEL, USA) running at 32 MHz. The microcontroller obtains motor position and speed by reading an optical encoder coupled to the motor. The microcontroller also reads the temperature data from a temperature sensor. The data of the encoders and the temperature sensors are passed through low pass filters that cut off ambient noise at approximately 30 KHz. Based on the input of a reference trajectory (from an external memory card, computer, or another position sensor), the microcontroller executes one of the presented robust control methods and calculates a control signal. The on-chip 12-bit digital-to-analogue converter (DAC) converts the calculated control signal to an analogue value. To ensure voltage and current compatibility (e.g. to satisfy the driver’s sinking current) with the driver circuitry, the control signal is passed through a current buffer to sustain currents of approximately 200 mA. To eliminate spikes in the signal, the control voltage is passed through a low pass filter with a cut-off frequency of 200 Hz. A single bit determines the direction of travel. The driver circuitry uses this bit to determine which of the sinusoidal drive signals is leading, thereby determining the clockwise or anti-clockwise rotation of the USM. Furthermore, the microcontroller controls the power to the motor driver circuitry by means of a relay circuit. The motor manufacturer recommends that the motor temperature does not exceed 55°C. To ensure safety and maximize the motor’s lifetime, a relay circuit is used to shut off power to the motor when the temperature exceeds the recommended safety limits. By taking advantage of the stall-at-no-power feature of USMs, the relay
may also be used to shut off power to the motor if it is to be kept stationary at a fixed reference point for prolonged periods. The circuit block diagram is shown in Figure 2.6.

![Circuit block diagram](image)

**Figure 2.6:** Circuit block diagram.

### 2.5 Experiment Results

The proposed robust controller was implemented on the designed embedded system. Using serial communication, data from the embedded system were logged to a personal computer at a rate of 25 Hz. The data included the time stamp, the reference value, the encoder value, the temperature and the control-signal value. The tests were performed with the motor under a load of approximately 5 Ncm. Both control Method A and Method B were evaluated.
In the first experiment the motor was prescribed several increasing or decreasing step inputs (step size of 1 rad). As can be seen in Figure 2.7 the controller (Method B) controls the motor position to match the reference position – the position curves overlap (a) except for an acceptable rise time (b); no overshoot or offset were recorded. Similar results were obtained using Method A.

Figure 2.7: Step responses of the system are shown: a) The performance of the controlled system in following a set of inclining and declining step inputs is illustrated; b) a zoomed in step response is illustrated.

A second set of experiments was performed for the two different control methods. For Method B (no temperature feedback) the temperature was assumed to be constant at
$T = 35^\circ\text{C}$ in the developed model and $\varphi$ was set to 0.5 for the controller. The loaded motor was prescribed sinusoidal motion profiles with amplitudes of 1 rad at frequencies of 0.25 Hz, 0.33 Hz, 0.5 Hz, and 1 Hz. Each profile was executed continuously over 5 minutes. This duration was selected because it allowed sufficient time for the motor to heat up (enough to change dynamic characteristics) without exceeding the selected threshold of 45 $^\circ\text{C}$. Figure 2.8 illustrates the reference and encoder values alongside the control effort for the first and last 10-second periods of the 5 minute sequence for a sinusoidal reference with amplitude of 1 rad and frequency of 0.5 Hz. Figure 2.9 shows similar responses for Method A. These figures demonstrate excellent agreement between the reference and measured (encoder) trajectories, which is maintained throughout the 5-minute period, but the figures clearly demonstrate that the control signal has varied greatly throughout this time.

To better illustrate the tracking error, Figure 2.10 shows the absolute error of Method A over the first 10 seconds. This error was calculated by directly subtracting the reference and encoder values at every sample point. Ideally, the reference and motor position would overlap exactly. However, practically there is a delay in the motion control. This delay was calculated using a brute force search approach where we searched for the amount of temporal shift in the signal (1 ms in each step) that resulted in the minimum RMSE between the reference and motor position. The average delay between the encoder and the reference was measured to be 25 ms for the four sinusoidal profiles prescribed. For many applications such a small delay may be acceptable and therefore, after delay compensation by means of shifting the data, the average absolute error in
position tracking was calculated for 4 different frequencies, over 5 minutes for each, and is plotted in Figure 2.11.

Figure 2.8: Demonstration of Method A – control incorporating temperature feedback. The motor angle with respect to a prescribed sinusoidal reference (with a frequency of 0.5Hz and amplitude of 1 rad) is plotted alongside the control effort. Signals are plotted from a 5 minute experiment, where a) shows the performance during the initial 10 seconds and b) shows the performance during the last 10 seconds.
Figure 2.9: Demonstration of Method B – control does not incorporate temperature feedback. The motor angle with respect to a prescribed sinusoidal reference (with a frequency of 0.5Hz and amplitude of 1 rad) is plotted alongside the control effort. Signals are plotted from a 5 minute experiment, where a) shows the performance during the initial 10 seconds and b) shows the performance during the last 10 seconds.
Figure 2.10: The absolute error in tracking a reference with a frequency of 0.5 Hz and amplitude of 1 rad over 10 seconds. This error is calculated by directly subtracting the reference and encoder value at each sample point.

Figure 2.11: The absolute mean error for sinusoidal references with an amplitude 1 rad and four different frequencies; the means are calculated over 5 minutes of operation for each reference. This error is calculated after compensation for the delay.
2.6 Discussion and Conclusion

In this chapter we have successfully designed and implemented a robust control method, that permits robust motion control of USM despite significant temperature dependent disturbances. As a first step, the dynamic model of the system (USM and driver combination) was identified; this model was then approximated with a simpler linear model, which was used to design a robust inverse dynamic controller. The presented control method was implemented on a custom designed embedded system and experiments over prolonged periods showed that the controller is robust to variations in the system dynamics due to disturbances from temperature elevations or modeling uncertainties. We have also demonstrated that the controller is capable of maintaining excellent performance without direct temperature feedback.

While excellent performance can be maintained without temperature observation, it is recommended that the temperature be monitored so that it does not exceed the recommended safety limit of the manufacturer. Alternatively the temperature may be estimated from performance data. In extremely long applications it may be necessary to cool the motor to ensure that its temperature remains in the safety range.
2.7 References


Chapter 3.

A Magnetic Resonance Imaging Compatible Remote Catheter Navigation System with 2-Degrees-of-Freedom†

3.1 Introduction

Cardiac catheterization has become an essential tool in the management of cardiac and vascular diseases, in general, and the treatment of cardiac arrhythmias, in particular. The conventional approach to percutaneous transluminal catheter procedures relies on fluoroscopic x-ray imaging as the main modality for guiding the interventionalist during the procedure. Fluoroscopically guided catheterization provides two-dimensional (2D) projections of the anatomical site in real time and is limited by low tissue contrast, making interpretation of the complex three-dimensional (3D) anatomy difficult. Furthermore, fluoroscopy-guided catheterization exposes both patients and staff [1, 2] to radiation. Interventionalists and staff must wear heavy lead aprons during the long procedures, commonly resulting in physical strain [3]. A large number of cardiac catheterizations (1,059,000 in USA) are performed annually [4] and a general upward trend has been observed in the incidence of cardiac procedures requiring catheterization-based treatments. For example the number of patients with atrial fibrillation is expected

to increase 2.5-fold during the next 50 years [5-7], reflecting the growing proportion of elderly individuals. Paralleling these trends, numerous avenues for improving the procedures – in terms of efficacy and ease of delivery – are being explored.

Significant developments aimed at reducing exposure of the interventionalist and staff while maintaining procedure efficacy, have included a series of robotically guided catheter manipulators [8-12] or magnetically guided navigation systems [13, 14]. For electrophysiological procedures, 3D electrical mapping, using systems such as CARTO (Biosense Webster) or EnSite NavX (St. Jude Medical), has provided the ability to visualize the catheter in relation to a 3D electrical map. However, guidance is still subject to low anatomical contrast, and the inability to visualize soft tissues and lesions limits the efficacy of the treatment.

Magnetic Resonance Imaging (MRI) allows for high contrast visualization of soft tissue in 3D and has been shown to differentiate between ischemic, infarcted, and arrhythmogenic tissue in the heart [15]. These advantages of MRI make it an attractive modality for guiding catheter-based treatments. Recent developments have demonstrated the ability to acquire MR images at high frame rates [16, 17], demonstrating the potential for MRI to become a source of image feedback for image guided minimally invasive interventions, particularly of percutaneous transluminal catheter procedures [18]. MRI-guidance of catheterization has been demonstrated in animals as early as the late 1990’s [19] and Razavi et al. [20] used MRI-guided cardiac catheterization on humans in 2003. Although these MRI methods show promise [21], practical implementation requires modifications to most equipment peripheral to the image acquisition (e.g. magnetically shielded monitors, controls within the scanner room and specialized noise suppressing
headsets to permit communication during the procedure). Another important constraint imposed during an MRI guided procedure is the requirement for the interventionalist to reach within the MRI scanner bore in order to reach the catheter manipulation site on the patient. The catheterization can be specially challenging with unfavorable entry sites and angles. Although open bore and wide bore scanners may partially alleviate some of these problems, their numbers are limited and it is unlikely that clear access to the patient will be possible in the foreseeable future. Therefore the mentioned problems continue to limit the transition from fluoroscopic-guided to MRI-guided catheterization. Similar limitations in other MRI guided procedures such as neurosurgery [22], prostate interventions [23, 24] and other MRI guided procedures [25, 26] have motivated design and building of MRI compatible robots for these applications; many of these have followed the general design criteria for MR compatible robots proposed by Chinzei et al. in the early 1990s [27].

The developments presented in this chapter aim to facilitate MRI guided catheterization by allowing the interventionalist to perform the catheter navigation from a location remote to the MRI scanner. Specifically, a Magnetic Resonance compatible Remote Catheter Navigation System (MR-RCNS) was designed and built. The MR-RCNS allows the interventionalist to apply conventional push/pull and rotate motions on an input catheter and have the motions replicated on a remote patient catheter by an MR compatible slave robot inside the magnet room, thereby freeing the interventionalist from the workspace constraints of the MRI scanner.

This chapter is organized as follows: first the mechatronics design of the master-slave system is described in section 3.2, the methods of evaluating the system’s
performance and its electromagnetic interference are detailed in section 3.3 and the results of evaluation are given in section 3.4. Finally a discussion and conclusions are presented in sections 3.5 and 3.6, respectively.

3.2 System Description

The MR-RCNS is designed as a master-slave system that takes advantage of an interventionalist’s existing dexterous skills – relying on the push/pull and twist motions conventionally imparted on a catheter during manipulation. The design is based on prior developments of a remote catheter navigation system [11, 28] designed and evaluated by our group. Figure 3.1 represents the schematic diagram of the new MR-RCNS and Figure 3.2 is a detailed photograph of the master and slave components of the system. Each component of the system is described below.

Figure 3.1: The components of the MR-RCNS.
3.2.1 Catheter Sensor - master

The sensor, which remains outside the magnet room, does not need to be MR compatible, so the original design was used [29] (note that, with minor modification, the sensor can be made MR-compatible and used within the scanner room if necessary). The role of the catheter sensor (CS) is to enable the measurement of the rotational and axial motions imparted by the interventionalist on an input catheter. As described in detail in [11, 28, 30], the CS utilizes a pair of optical encoders coupled to the input catheter. The angle measurements of the encoders are transmitted directly to the motor servomechanism (see below) and used to determine the motion of the catheter manipulator.
3.2.2 Catheter Manipulator - slave

The catheter manipulator (CM) must replicate the motion imparted on the input catheter and must operate within the environment of a clinical MRI scanner – where it is subjected to strong (up to 3T) and rapidly switching magnetic fields (gradients). The design of the manipulator was based on that described in [11]. The overall principle of operation was maintained – the patient catheter is moved in the axial direction using a set of rollers that grip the catheter and are driven by a motor mounted on a rotating gantry. The rotating gantry provides rotational motion of the entire assembly, including the catheter. A schematic of the new manipulator is shown in Figure 3.3. The main new features of the manipulator are the inclusion of an adjustable platform that holds the spring-compressed idle rollers, which grip the catheter and the use of two active rollers, as opposed to a single one. The adjustable platform is manually positioned, by tightening a large-diameter plastic screw, thereby accommodating various gauge catheters. Easy adjustment of the platform also facilitates the insertion and removal of the catheter, which is achieved with the rollers separated. The addition of a second active roller ensures that the catheter remains straight within the manipulator and minimizes buckling; the two active rollers are coupled via a chain and the axis of one is connected directly to the axial motor. As a requirement in the MRI compatible model all gantry components are manufactured out of Delrin and the urethane rollers are held using stainless-steel springs. A slip ring (AC6438, Moog Inc., East Aurora NY, USA) is used to transfer the electrical control signals to the axial motor, as the gantry is rotated, via a sprocket and non-magnetic chain drive.
Studies of catheter dynamics in conventional catheter navigation [30] showed that the minimum needed force and torque requirements are $0.29 \pm 0.06$ N and $1.15 \pm 0.3$ mNm respectively. Also the peak velocities were measured to be $360 \pm 180$ mm.s$^{-1}$ and $19 \pm 7$ rad.s$^{-1}$ for axial and rotational catheter motion. The previous version of manipulator described in [11, 30] uses DC motors and is not MR-compatible. To satisfy MR-compatibility and the required force torque requirements a pair of ultrasonic motors made of non-ferromagnetic material (USM45 and USM60, Xi’an Ultrasonic Technology Co., LTD., China) with a maximum torque of 0.4 Nm, nominal torque of $\sim 0.1$Nm and peak speed of 320 rpm were used for actuation. Ultrasonic motors were selected because they
produce no backlash, have a hard stop even without power and allow precise positioning [29]. For axial motion, force is applied on the catheter through rollers (radius ~3 mm). Therefore with sufficient friction between the rollers and catheter the nominal torque of the motors can easily provide forces exceeding the peak requirement in catheterization (0.3N).

3.2.3 Ultrasonic Motor Servomechanism

The CM of the MR-RCNS must be able to replicate the motions measured by the CS in near real-time. To achieve this fast response an embedded system was designed and built to control the motors of the CM. The embedded system simultaneously measures the encoder positions of corresponding joints of the master and slave and compares the two values to calculate an error. A control signal proportional to this error is calculated by the embedded system and applied to the ultrasonic motor driver. This implementation differs from the original RCNS [11], as it no longer requires a dedicated workstation.

The embedded system uses an 8-bit microcontroller (ATMEL Inc., San Jose, California USA) with a clock cycle rate of 8 MHz that results in a closed loop control rate of approximately 3 kHz, as implemented. The encoder position of each joint can be logged to a personal computer at a sampling rate 100 times slower than the control rate (30 Hz) through a serial RS-232 port. The microcontroller uses interrupt service routines to perform tasks such as serial communication or measuring the encoder positions. A PID control scheme was implemented to calculate the control signal $u(t)$:
$$u(t) = K_p e(t) + K_i \int_0^t e(\tau) d\tau + K_d \frac{d}{dt} e(t),$$

3.1

where $e(t)$ is the difference between the reference value and the measured motor position at any point in time $t$, $K_p$, $K_i$, and $K_d$ are the proportional, integral, and derivative gains respectively. In the current implementation, the gains were set as follows: $K_p \approx 20$, $K_i \approx 0$, and $K_d \approx 0.33$.

Separate servomechanisms – comprising a sensor encoder, an embedded system, and an ultrasonic motor – were assembled for the axial and rotational motions. To minimize electromagnetic interference from the servomechanism, all wires were shielded and the shields were grounded.

3.3 Evaluation

3.3.1 Evaluation of the Servomechanism

Before evaluating the complete RCNS, the accuracy, robustness, and dynamic performance of the control algorithm used in the servomechanism were tested. For these experiments the response of the motor to defined inputs was evaluated under different loading conditions, as described below.

Accuracy and Robustness

To evaluate the accuracy of the servomechanism and its robustness to increased loading, the step response of the servomechanism was studied. Weights (up to 500 g) were suspended from a pulley of radius 2.25 cm mounted to the shaft of the motor. This provided torques of 0.11 Nm that is close to the motor’s nominal torque (0.1 Nm). The
response of the servomechanism was recorded following a 90° input angle. For each load (torque ranges of 0 – 0.11 Nm), the step response was measured 20 times. These tests were performed both in the laboratory settings and with the motors inside the magnet using the FIESTA and FGRET pulse sequences (full description of the scanner, pulse sequences, and setup is provided in section B, below).

**Dynamic Motion Replication**

To validate the dynamic motion replication capabilities of the servomechanism manual motion profiles were applied to an encoder wheel, acting as a master joint. The encoder positions of this master joint and the motor were logged to a personal computer through the embedded system. Each manual motion profile consisted of 40 revolutions in the clockwise and anticlockwise directions; twenty sets of motion profiles were evaluated. These experiments were performed under the maximum loading conditions – 0.11 Nm. Using the cross-correlation function in MATLAB (MathWorks Inc., Massachusetts USA) the delay between each master and slave profile was determined and an average delay of the 20 motion profiles was calculated.

### 3.3.2 Evaluation of the MR-RCNS

Following the initial evaluation of the servomechanisms, the accuracy and precision of the entire MR-RCNS was evaluated inside the bore of a clinical MRI scanner (3 T, Discovery 750, software revision 22M32, General Electric Healthcare, USA). For the imaging experiments the 32-channel cardiac transmit-receive radiofrequency (RF) coil was used. The CS and the embedded systems were placed in the scanner’s control
room and the wire connections for the motor drive and encoder signals were passed through 1,000 pF RF filters with a 3dB cut-off frequency of 3.2 MHz. These filters were required to minimize the introduction of external RF noise into the MR scanner suite and RF interference with motor controllers and embedded system during image acquisition.

The MR-RCNS slave was placed on the patient bed within the scanner bore at a distance of approximately 60 cm from the magnet isocenter. Ablation catheters (6F-7F, Biosense Webster Inc.) were used for both the input and patient catheters; these were confined to travel within 6-mm diameter Plexiglas tubes for all experiments.

The accuracy tests were performed during an imaging session to evaluate any effects image acquisition may have on the manipulator performance. For these experiments, the effect of two pulse sequences used in cardiac imaging were evaluated: FIESTA – a steady state free precession pulse sequence – (FOV 24 cm, slice thickness 6 mm, TR 4.5 ms, TE 1.7 ms, FA 45°, matrix 256x256, and BW 125 kHz, NEX 4) and FGRET – a real-time multi-echo fast gradient echo pulse sequence – (FOV 24 cm, slice thickness 10 mm, TR 10.5 ms, TE 1.4 ms, FA 12°, matrix 128x96, and BW 125 kHz, echo train length 8). Each sequence was repeated continuously for the duration of the experiments and for the FGRET sequence the imaging plane was continuously altered to simulate a real-time catheter-guidance experiment.

3.3.2.1 Axial Motion Accuracy

To measure axial accuracy the input catheter was moved over a distance of 127 mm from a starting position; the experiment was repeated ten times in each direction. The position of the tip of the input catheter was measured using calipers and that of the
patient catheter was marked on a ruler then measured using calipers; in each case care was taken to avoid parallax.

3.3.2.2 Rotational Motion Accuracy

Rotational accuracy was evaluated using protractors mounted at the distal end of each Plexiglas tube; a pair of pointers mounted on the catheters was used to indicate the angle. The master was rotated 3,600 degrees in the clockwise (and anticlockwise) direction ten times; the angle of the input and output catheters was recorded at the end of each motion for each direction.

3.3.3 Evaluation of the effects of the RCNS on image SNR

A concern when introducing electronic devices within an MRI scanner is that RF noise from the devices can potentially introduce noise and artifacts within the MR images. To determine any detrimental effects of the MR-RCNS on the MR images, we followed the guidelines for measuring signal-to-noise ratio (SNR) outlined by the National Electrical Manufacturer’s Association (NEMA) [31]. Specifically, a 17-cm diameter water phantom (MRS HD sphere, model 2152220; General Electric, Milwaukee, WI, USA), doped with metabolite salts and gadolinium-based contrast agent [32] was used; the $T_1$ and $T_2$ values of the solution were 392 ms and 297 ms, respectively. The Spin Echo (SE) pulse sequence was used (FOV 24 cm, slice thickness 6 mm, TR 1,300 ms, TE 20 ms, matrix 256x256, and BW 15.6 kHz). All geometric corrections and filters were turned off for the experiments. All gain settings were
maintained constant throughout the experiment. The room and phantom temperature were 19.5°C.

The effect of the MR-RCNS on image SNR was evaluated with the CM positioned at approximately 70 cm and 40 cm from the isocenter; these positions were chosen as they represent the expected range of positions during actual catheterization procedures. For both sequences, images were acquired at each position at baseline and during each of the following three states: 1) RCNS connected to the servomechanism via the 1,000 pF filters; 2) all RCNS electronics turned on but no motion applied; and 3) the input catheter (in the console room) was moved thereby actuating the RCNS motors (on the scanner bed).

Noise in the images was calculated using method 1 outlined in the NEMA protocol [31]. Specifically, two consecutively acquired images of the same slice were subtracted and the standard deviation (σ) in an 11x11 pixel region of interest (ROI) in the center of the difference image was calculated; the noise in the region was then calculated as $\sigma/\sqrt{2}$ to correct for the difference operation. Image signal was calculated as the average intensity of a 7x7 pixel ROI in the center of the first image. The signal to noise ratio (SNR) was calculated from the central axial slice of the acquired images, for all four conditions mentioned above.

3.3.4 Evaluation of the effect of RCNS on *in vivo* images

While a complete clinical evaluation of the RCNS is beyond the scope of this study, we performed a series of preliminary tests using *in vivo* imaging. Specifically, cardiac images of a healthy volunteer were acquired using FIESTA and FGRET (“real
(time”) pulse sequences with the RCNS placed at a distance of 40 cm from the isocenter – a distance that is representative of the point of entry of the catheter in clinical use. Images were first acquired without the robot and then while the robot was manipulated as it would be during catheterization. All imaging studies were performed after informed consent was obtained and with the approval of the Human Subjects Research Ethics Board of the University of Western Ontario.

3.4 Results

3.4.1 Evaluation of Servomechanism

*Accuracy and Robustness*

Representative curves for the step response of the servomechanism system for a reference value of 90° is shown in Figure 3.4 for no load and a maximum load of 0.11 Nm. In all cases – multiple repetitions and different loading conditions – overshoot of 0±0° and offset of 0±0° were observed, at the 30 Hz sampling rate used to record the angular position. (Note that a faster sampling rate could not be utilized because logging the encoder data competes for CPU resources with the control algorithm, and would have resulted in compromised performance.) The same results were obtained when the motors were inside the magnet during the FIESTA and FGRET imaging.
**Figure 3.4:** Step response of the servomechanism for a reference value of 90° with no load (a) and a load of 0.11 Nm in (b).

*Dynamic Motion*

All motion profiles executed during the characterization of the ability of the servomechanism to replicate motion were successfully executed; these profiles contained velocities up to $20.6 \pm 4 \text{ rad.s}^{-1}$. Sections from representative manual motion profiles recorded with a load of 0.11 Nm and with no load are shown in **Figure 3.5**. Under maximum loading conditions the delay in replicating the master encoder’s motion was $41\pm21 \text{ ms}$. 
Figure 3.5: Example manual motion profiles (angular position) of the master and slave are plotted as a function of time: a) with no load b) with a load of 0.11 Nm c) and d) are zoomed-in versions of the first 500 ms of profiles in a) and b), respectively, plotted to demonstrate the small delay in response.

3.4.2 Evaluation of the MR-RCNS

3.4.2.1 Axial and Rotational Motion Accuracy

When replicating motion within the MRI scanner, an absolute error of 1.0 ± 0.8 mm with a peak absolute error of 2.8 mm was measured when replicating axial motion over 100 mm. The rotational motion accuracy tests showed an absolute value error of 2±2° with a peak absolute error of 6° for rotational catheter motion replication over 360°. The type of pulse sequence, including the real-time acquisition, did not affect the axial nor rotational accuracy of the system.
3.4.3 Evaluation of the effects of the RCNS on image SNR

As expected, the SNR evaluation results showed that the worst-case SNR drop occurred when the RCNS was connected and the motors were moving (state 3). The SNR at this state was 130.6 dB for the SE images, which represented a drop of 2.5% from the baseline SNR.

3.4.4 Evaluation of the effect of RCNS on *in vivo* images

During the evaluation of the effect of the RCNS on *in vivo* images, no additional noise or artifacts were observed in any of the images, independent of the image orientation or pulse sequence used. The images in Figure 3.6 are two representative FIESTA images from the acquired series, qualitatively demonstrating that the RCNS does not impact image quality detrimentally.

![Figure 3.6](image)

**Figure 3.6**: Four-chamber cardiac images at diastole acquired without the RCNS present (a) and with the RCNS being manipulated (b). Note that there is no perceived increase in noise or artifact level while the RCNS is being manipulated.
3.5 Discussion

We have presented an MR compatible master-slave catheter manipulator that captures the interventionalist’s conventional motion on an input catheter and replicates that motion on a catheter within the bore of an MRI scanner. This MR-RCNS enables MR guided catheterization in a conventional MRI suite, removing the need to modify the conventional MRI facilities to accommodate in-suite image monitors and removing the ergonomic burden on the interventionalist. The MR-RCNS met all pertinent requirements for MR compatibility – performing robustly within the MRI environment, being safe, and not affecting the images during operation (both in terms of noise and artifact). During operation within the MRI environment, the master-slave system was shown to have an error of 1.0 ± 0.8 mm when replicating axial motions over 100 mm and an error of 2±2° for rotational motion over 360°. The measurement of the rotational motion replication accuracy is dependent on the catheter’s flexibility – a more rigid catheter would be less prone to twisting and would provide more accurate replication readings. It should be noted that the method used to evaluate the errors in motion replication (calipers and protractors with accuracies of ±0.02 mm and ±1° respectively), might have added some uncertainty to the measurements.

Overall, the errors in replication of the motion are acceptable for the majority of catheterization procedures – especially taking into account the fact that position verification and catheter tip guidance is commonly performed using visual feedback. The interventionalist is simply using the master to drive the slave catheter and small errors in position do not represent a problem, as has been demonstrated in the previous non-MRI compatible RCNS implementation. Since the evaluation of the servomechanism
demonstrated no offset or overshoot in the controller’s response, we can assume that any error in the position of the catheter is mechanical and caused by slippage between the catheter and the rollers. The extent of the slippage will depend on the catheter material, environmental conditions, and speed. Further reduction of the errors in motion replication can be achieved by either eliminating sources of slippage in the catheter manipulation or by utilizing direct feedback of the actual catheter position.

The time delay of motion replication using the RCNS was 41±21 ms which is significantly smaller than the earlier non MR-compatible version which had a delay of approximate 300 ms [11]. The shortening of the time delay is attributed to the use of an embedded system with a real-time control capability and an independent controller for each joint. The kinematics of the motions applied on the input catheter in our evaluations were very similar to the previous study [30]. Given the success in using the previous version of the RCNS (non-MRI compatible) during in-vivo cardiac ablation studies [33], we anticipate that the MR-RCNS described here will be at least equally successful as the delay in motion replication is smaller and therefore the new system is better capable of replicating dynamic motion [11].

An important aspect of introducing any mechanically driven system within an MRI suite is to ensure that the operation of such a device does not introduce undesirable RF noise in the MRI images. The presented results demonstrate a very small decrease in SNR during SE image acquisition, but no artifacts were observed. It must be noted that the type of MRI-compatible catheter used will dominate any local image artifacts and therefore local analysis was not covered in this study. Overall, the use of the MR-RCNS
did not adversely affect the image quality and can be used during interventional procedures.

Our implementation does not include haptics feedback for the interventionalist. Force information from the tip of the catheter interacting with the tissue or between the catheter and vessel wall would be beneficial in some catheterization procedures, e.g. ablation [34]. Obtaining such feedback from the tip of the catheter would require designing an MRI compatible catheter with a force sensor at the tip, which can ultimately be integrated with the RCNS.

Further updates to this system require the miniaturization of the manipulator, which will enable the manipulation of multiple catheters and sheaths required during many catheterization procedures. The present design is compatible both with MRI and x-ray guidance and will represent an ideal solution for interventional suites that combine x-ray and MRI guidance (XMR). Before implementation in the clinic is possible, the designed prototype will have to be modified to ensure that all components are both MR-compatible and sterilizable. Materials such as polyaryletherketone resins (PEEK), stainless steel or titanium will be appropriate and are able to withstand sterilization procedures such as autoclaving. Minor modifications may also need to be made to ensure that the motors can be separated from the device easily prior to sterilization. Alternative sterilization methods such as gaseous chemicals may be considered to reduce the required modifications.

Further studies, evaluating the performance of the MR-RCNS during real-time MRI guidance of procedures in vivo are also required.
3.6 Conclusion

We have introduced a magnetic-resonance-compatible remote catheter navigation system that observes the interventionalist’s conventional motion on an input catheter in a master setup and replicates that motion through an MR compatible slave manipulator on a patient catheter. This system facilitates MRI-guided catheterization in conventional MRI scanners without the requirement of modifying the conventional MRI suite. The presented system also frees the interventionalist from the requirement to work within the constraining physical workspace of an MRI scanner.
3.7 References


Chapter 4.

Design, Development and Evaluation of Compact Tele-Robotic Catheter Navigation System†

4.1 Introduction

Cardiac catheterization is a widely accepted tool for the treatment and diagnosis of many cardiovascular diseases. These procedures are conventionally guided with fluoroscopic imaging. However, fluoroscopic imaging is a source of radiation that exposes the interventionalists and staff to scattered radiation on a daily basis, necessitating the use of leaded aprons for protection. These heavy radiation protection garments provide only partial protection [1-3] and their prolonged use is known to cause chronic neck and back pain [4, 5]. While proper training, improved imaging technology, and safety equipment have resulted in reduced exposure levels, scattered radiation exposure of staff continues to be a major safety concern; studies suggest that cumulative radiation exposure of staff is associated with a non-negligible lifetime risk of cancer [6, 7] attributed to the excess radiation. Some of the safety measures aimed at reducing the exposure of staff to radiation – such as the separation of the control and procedure room in conventional catheterization labs [8] – can potentially disrupt the flow of an intervention and reduce the efficiency of the procedure by physically separating staff and patients.

hindering communication among them. These limitations of fluoroscopically guided catheter intervention procedures can be overcome by providing the interventionalist with the tools to remotely perform the catheterization directly from the control room.

Several remote catheter navigation systems (master-slave) have been developed and are now commercially available: Niobe (Stereotaxis Inc.) [9, 10], Sensei (Hansen Medical) [11, 12], Corpath (Corindus Vascular Robotics) [13], and Amigo (Catheter Robotics Inc.) [14]. The user interacts with the Niobe system through a graphical user interface; this system then uses controlled magnetic fields to move and navigate a magnet connected to the tip of a catheter with 3 degrees of freedom (DOF) to follow the motion prescribed by the user. The Sensei system incorporates custom designed steerable catheters and sheaths to allow the remote manipulation of the catheters/sheaths using a 3 DOF joystick. The Corpath system uses sets of rollers mounted on a rotating gantry to grip on to the catheter and rotate it, allowing for only 2 DOF to control catheters for vascular applications. The Amigo system allows for 3 DOF for the manipulation of standard-tip steerable catheters, which utilize rotary knobs mounted on the catheter handle for tip deflection, using a remote controller with push buttons.

Developments by Thakur et al. [15-17] have taken advantage of the interventionalist’s dexterous skills in remote manipulation of conventional commercial catheters; in this design approach the interventionalist directly applies push/pull and rotatory motions to a catheter traveling within a motion-sensing device. As a result, the system in [16, 17] required minimal operator training and allowed for remote navigation using conventional and commercially available catheters. However, the former design
only enabled catheter manipulation with 2 DOF and lacked the means to manipulate the catheter handle plunger for steering of the distal end.

In this work, we addressed the limitations of [15-17] and developed a remote catheter navigation system (RCNS) that allows full 3 DOF manipulation of conventional steerable catheters – specifically catheters of various diameters, with a plunger mechanism for distal tip deflection. The new master-slave system design continues to take advantage of the user’s existing dexterity: the user pushes/pulls and rotates a catheter handle and rotates a knob similar to the manipulation of a conventional catheter handle. Another improvement in the presented system is that it allows for sterilization/replacement of components that come into contact with the catheter and also greatly facilitates catheter exchange. The developed system can potentially reduce the amount of radiation to the interventionalist, and facilitate procedure flow, by allowing the interventionalist to perform the navigation remotely (possibly directly from the control room). Furthermore, the proposed system can potentially increase catheter stability, motion precision and accuracy.

In this chapter the RCNS is described. The mechanical design of the user interface (master unit), the robot (slave unit) and controller are explained in the following section. Evaluations of the robot that include experiments in both the laboratory settings and in vivo are described in section 4.3. The results are presented in section 4.4 followed by the Discussion and Conclusion sections.

4.2 System Description

The RCNS is designed as a tele-robotic system. The robot (the slave unit) is composed of two sections: the handle manipulator (HM) and the catheter manipulator
These two components work together to provide 3 DOF in catheter navigation. The interventionalist manually interacts with a master unit that takes advantage of their existing dexterous skills – relying on the push/pull, twist, and knob manipulations conventionally imparted on a catheter handle during navigation. The control system captures the motion imparted by the interventionalist on the master unit and, using the motor’s encoder signal as feedback, controls the motors of the robot such that the user’s applied input motions are replicated on the patient catheter. Using image guidance (such as fluoroscopic imaging) the interventionalist tracks the catheter position and remotely navigates it to the desired anatomical target. Figure 4.1 is a schematic diagram describing the interactions of the system components. The master unit, the slave robot and the control unit are explained in this section.

Figure 4.1: Schematic diagram of the system, displaying the workflow and interactions of the different components.
Figure 4.2: Schematic diagram of the master system is shown. The master unit allows for measurement of the user’s input for axial motion, rotational motion and tip steering (for manipulation of plunger or knob).

4.2.1 Master Unit

The role of the master unit, Figure 4.2, is to enable the measurement of the interventionalist’s imposed rotational, axial and catheter tip deflection manipulations on a standard interventional catheter. The master unit utilizes a catheter handle mounted on a linear slide. A rack and pinion mechanism coupled to a quadrature optical encoder (HEDS 5600, Avago Technologies, USA), with 1,000 counts per revolution, measures the relative axial position of the linear slide with respect to the base of the assembly. The handle and the deflection mechanisms of the catheter (knob) are both free to rotate independently along the axis that supports them. The position of the handle and knob are both measured using two additional optical quadrature encoders (HEDS 5600, Avago...
Technologies, USA). A Teensy 3.1 development board (PJRC, OR, USA) that incorporates a 32 bit ARM-architecture micro controller (MK20DX256VLH7, Freescale Semiconductor, Bermuda) is used for real-time quadrature decoding and streaming of the position data to the main control unit. A simple user interface on the master unit allows for deactivation/activation of tracking. This feature permits readjustment of the handle position when the range of motion on the slide has been exceeded.

4.2.2 Robot-Slave

The slave unit, shown schematically in Figure 4.3, is composed of the handle manipulator and catheter manipulator. The HM sits between the patient’s legs, while the CM is positioned over the patient. The CM and HM are described below.

![Handle Manipulator and Catheter Manipulator](image)

**Figure 4.3**: The slave robot is shown. In the example setup, the catheter manipulator is positioned over the patient and the handle manipulator between the patient legs.
4.2.2.1 Catheter Manipulator

The CM is designed to manipulate the catheter body directly. The design of the CM makes use of a differential gear mechanism to allow for rotational and axial manipulation of the catheter with the source of actuation (two brushed-12V-DC motors) fixed. This design greatly reduces the size and inertia of the manipulator and permits easy disengagement of the manipulator from the body for sterilization or repair. Inside the structure is a set of parallel rollers that grip on to the catheter (active rollers); these rollers are pulled towards the catheter using two elastic bands and allow constant pressure on the catheter. These rollers are coupled to the differential gear mechanism through miter gears: the rotation of the rollers (with urethane coating) results in axial motion of the catheter, while the rotation of the base of the structure, results in the rotation of the entire assembly, and therefore provides rotation of the catheter body. To ensure future compatibility with use within an MRI scanner, the body of the CM was manufactured from Delrin®; and all gears were stainless steel or brass. Figure 4.4 illustrates the internal components of the CM (exterior housing hidden) and shows how the gears engage to achieve the desired function. With appropriate actuation of the differential gear mechanism (using two motors), one can control the rotational and axial motion of the catheter arbitrarily. A further advantage of this design is that because adjustable shafts support the rollers, various catheter gauges can be accommodated without the need for any adjustment. Furthermore, the differential gear mechanism can easily be disengaged from the base (that supports the motors) for replacement or sterilization purposes.
Figure 4.4: The internal mechanism of the catheter manipulator and the motions it can impart on the catheter are illustrated. The external components in the center of the manipulator are hidden to better illustrate the differential gear and adjustable roller mechanism.

4.2.2.2 Mount

To enable arbitrary positioning of the CM, with respect to the patient, and to allow for access to various entry points, a Mount was developed. The mount, illustrated in Figure 4.5, is a simple stand, manufactured from Delrin® and PEEK, that supports the CM and allows the user to adjust the height and lateral position, as well as the roll and yaw angles of the manipulator.
4.2.2.3 Handle Manipulator

Conventional steerable catheters have a plunger (or knob) on their handle that is used to deflect the catheter’s distal end. The HM was designed to allow for the manipulation of this plunger. The designed HM, shown in Figure 4.6, has a rotating gantry (coupled to a 12V brushed DC motor) on which the catheter is mounted. A winch and spring mechanism is used to push and pull the catheter plunger. The winch (actuated with a second DC motor) rolls a string that is connected to one end of a lever; the other end of the lever applies pressure to one side of the plunger. The other side of the plunger is supported by a spring. The spring stiffness is selected such that it allows for pushing
back the plunger when the lever relaxes. This design allows both motors to remain stationary during operation. Most of the HM components are made of plastic using a 3D printer (Objet30 Pro, Stratsys, MN USA).

![Diagram of handle manipulator](image)

**Figure 4.6**: The handle manipulator and its controllable motions are shown. One motor controls the position of the plunger knob via a string, winch, and a series of gears; the other rotates the catheter handle.

### 4.2.3 Control Unit

The control unit is responsible for real-time control of the DC motors of the robot. This unit comprises an Arduino Due development platform (Smart Projects, Strambino, Italy) that incorporates a 32-bit ARM-architecture microcontroller (SAM3X8E, ATMEL, California USA) together with a custom developed daughter printed circuit board that contains the DC motor driver integrated circuits (VNH5019, STMicroelectronics, Geneva Switzerland). The control unit communicates with the master unit to obtain the desired reference positions, and simultaneously measures the positions of quadrature incremental Hall-effect encoders mounted on each motor (3200 counts per revolution). Using a
proportional-integral-derivative control method, the processor calculates the appropriate control signal to reduce the error between the desired reference motion profile and the motor position, ultimately allowing for master-slave control of the robot.

4.3 System Evaluation

4.3.1 Evaluation in Laboratory Setting

Evaluation experiments were first performed in the laboratory setting to determine the accuracy of the RCNS to replicate prescribed axial in rotational catheter motions. For these experiments, the patient catheter (7 F, Biosense Webster Inc., CA, USA) was confined to a 6-mm diameter acrylic tube that had a ruler aligned and attached to it.

4.3.1.1 Axial Motion

Axial motion of ±100 mm was imparted on the master’s input handle to provide a reference position. The corresponding starting and stopping position of the patient catheter with respect to the ruler were recorded. Measurements were repeated 10 times for each direction.

4.3.1.2 Rotational Motion

To measure the accuracy of rotational motion, a protractor was mounted on the end of the acrylic tube such that the catheter passed through its center. A mechanical “arrow” was connected to the tip of a catheter to enable measurement of the catheter angle with respect to the protractor. The input handle was rotated to ±360º and the corresponding angle of the patient catheter was measured. Measurements were repeated 10 times for each direction.
4.3.1.3 Plunger Motion

To validate that the robot can provide a full range of motion for the plunger, the user rotated the plunger input of the master unit until the robot handle manipulator reached the maximum motion range and fully deflected the catheter tip. This was repeated multiple times.

4.3.1.4 Dynamic Motion

Master and slave motion profiles were streamed to a personal computer at a rate of 30 Hz during 6 manual maneuvers, each approximately 1 minute in duration. Upon completion of the experiments the master and slave profiles were cross-correlated (using the \texttt{xcorr} function in MATLAB, MathWorks Inc., Massachusetts USA) to determine the delay between each master and corresponding slave profile. The average delay for the 6 maneuvers was calculated for each DOF (axial and rotational).

4.3.2 Evaluation \textit{in vivo}

4.3.2.1 Objective

The objective of the \textit{in vivo} experiments was to demonstrate the safety and feasibility of remote catheter navigation and RF-lesion generation, using the described RCNS.

4.3.2.2 Animal Preparation

All animal studies were performed in accordance with institutional and national guidelines and approved by The University of Western Ontario Animal Use and Care Subcommittee. Three male pigs, weighing 30-40 kg, were used in this study; while a single animal would have been sufficient to demonstrate the \textit{in vivo} feasibility of the
RCNS, malfunction of equipment not related to the RCNS (RF generator, animal 1) and RCNS miscalibration (animal 2) required the use of additional animals.

Each animal was given an intramuscular injection of atropine (0.04 mg/kg) and Acepromazine (0.2 mg/kg) and premedicated with Telazol, reconstituted with 2.5 ml Xylazine (100 mg/ml) and 2.5 ml sterile saline administered at a dose of 0.03 ml/kg. Throughout the intervention, each animal was intubated and maintained under general anesthesia (1–2% isoflurane in O₂ and NO mixture). Anaesthetic and analgesia were monitored throughout the study. To access the vasculature, using the Seldinger technique, a 9 F introducer sheath (Fast-Cath, St. Jude Medical, St. Paul, MN, USA) was inserted into the right external jugular vein for the insertion of a 52 cm Active-Fixation pacing lead (5067, Medtronic, Republic of Ireland), which, when positioned into set locations, provided a navigation target. Two additional introducers were inserted into the right and left femoral veins. If the vessels could not be accessed percutaneously, a cut down was performed. The right femoral insertion point was prepared for use with the robotically operated catheter (RO_Cath) and the left femoral vein was prepared for use with a manually operated catheter (MO_Cath).

4.3.2.3 Experimental Setup

The RCNS was transported to the operating suite and positioned on the operating table. After the animal was prepared and positioned on the bed, the catheter mount was manually adjusted for the preferred entry position and orientation angle. The system was then turned on. The experimental setup is depicted in Figure 4.7. All navigations were performed under fluoroscopic guidance using a portable x-ray system (OEC Elite 9900, GE HealthCare, Waukesha, WI, USA). The catheters used in this study were deflectable,
7 F, non-irrigated, D-type curvature catheters (BioSense Webster Inc., Diamond Bar, CA, USA). The RO_Cath was passed through the manipulator without engagement of the rollers in the CM or fixation of the handle in the HM unit so that it could be manually operated.

Both RO_Cath and MO_Cath were inserted manually into the right and left femoral veins, respectively, and guided up the inferior Vena Cava to be aligned with the apex of the heart, just above the diaphragm. The RO_Cath was then mounted on the robot.

**Figure 4.7:** The system setup at the experimental operating suite at CSTAR, London, Ontario. The robot is setup on the animal bed (on the left). By manipulating the master unit, the interventionalist (on the right) remotely controls the robot under fluoroscopic guidance.
4.3.2.4 Procedure and Data Collection

The *in vivo* experiments were performed by an interventionalist with more than 15 years of experience in catheterization. The interventionalist had not used the RCNS previously and was provided training instructions just prior to the start of the first animal experiments.

The first animal was used to evaluate navigation feasibility and compare navigation time between the RO_Cath and MO_Cath. To provide a target for catheter navigation, the pacemaker lead was inserted via the external jugular vein and navigated to 4 different locations during the experiment. These positions were in close proximity to the following anatomical landmarks: right atrial appendage (RAA), right ventricular lateral wall (RV-LW), right atrial low septum (RA-LS) and right ventricular outflow track (RV-OT).

Using fluoroscopic guidance, and when necessary verifying catheter tip position by repositioning the fluoroscopy unit between the left anterior oblique and right anterior oblique views), the interventionalist navigated the tip of the MO_Cath or RO_Cath towards the tip electrode of the pacemaker lead. Orthogonally positioned images were acquired and recorded to confirm the catheter tip had reached the target lead. The time to reach the target, as well as the radiation exposure and exposure time were also recorded. Following each manipulation, the RO_Cath/ MO_Cath was pulled back to the starting location above the diaphragm, the time was reset and the catheter was again navigated to the target. This experiment was repeated 4 times for each target for both manual and robotic modes of operation. The order sequence of robotic and manual navigation was randomly changed for navigation to each target, to prevent bias.
Time of navigation and exposure time for each anatomical target location were compared between the two modes of navigation (manual and robotic). For this comparison two-way repeated measures analysis of variance was used for data obtained from the same animal. All statistical analyses were performed using Prism\textsuperscript{TM} (GraphPad Software Inc., San Diego, CA, USA) and $p < 0.05$ was considered significant.

The feasibility of RF lesion generation was evaluated in animal 3. For this experiment the interventionalist navigated the RO_Cath to 5 targets in the right side: high lateral right atrium, (HL-RA), right atrial appendage (RAA), right atrial septum (RAS), coronary sinus (CS), and the right ventricular lateral wall (RV-LW) and delivered 50 watts of RF power for 60 s. The right ventricle was selected as the final target as it is well known to be highly susceptible to RF-induced ventricular fibrillation in pigs. After the experiment, the pig was euthanized and the heart excised for validation of successful lesion creation.

4.4 Results

4.4.1 Evaluations in Laboratory Setting

4.4.1.1 Axial, Rotational and Plunger motion

Our measurements indicate that the error in axial positioning of the catheter is $0.1\pm0.1$ mm over 100 mm of manipulation. The rotational error was $7\pm6^\circ$ over $360^\circ$ of motion. The handle manipulator was capable of controlling the position of the plunger allowing for arbitrary deflection of the catheter tip; note that quantitative evaluation of the accuracy of catheter tip deflection is not possible because the amount of deflection is
dependent on many variables, including catheter, catheter age, ambient temperature etc. – what is important is similar tip curvature can be achieved when using the robot compared to manual knob manipulation. Overall, the proposed tele-robot allows for accurate remote position control of the catheter tip with 3-DOF.

4.4.1.2 Dynamic Motion

Representative profiles of dynamic motion profiles of the master and slave are presented in Figure 4.8. Excellent agreement can be seen between the master and slave positions, both in the axial and rotational directions. The average delay between the master and slave profiles was 35±15 ms.

**Figure 4.8:** Example manual motion profiles of the master and slave are shown as a function of time: The catheter’s rotational and axial motion, calculated from encoder counts are shown in a) and b) respectively; c) and d) are magnified versions of the first second of the profiles in a) and b), respectively, to illustrate the small delay in the response.
4.4.2 Evaluations in vivo

All 4 pacing lead targets were successfully reached with both the MO_Cath and the RO_Cath. Successful navigation was confirmed by obtaining two orthogonal fluoroscopic images, that both showed the catheter tip immediately adjacent to the target lead tip; Figure 4.9 shows a representative set of these images. Figure 4.10 shows the navigation time of each method to each of the four targets. Statistical analysis showed that the method of navigation had no effect overall on navigation time (p=0.705) or exposure time (p=0.806). Navigation attempts in the second animal failed as the misalignment of the mount resulted in excessive force on the catheter, therefore, limiting its proper actuation. Ablation was not attempted in the second animal due to technical failure of the RF generator. Ablation lesions were successfully delivered to all anatomical target sites in the third animal. The lesions were clearly visible after the heart was excised and inspected as is illustrated in Figure 4.11.

Figure 4.9: Radiographs of the catheter and lead in the animal heart. a) image obtained at 45° right anterior oblique (RAO) angle b) image obtained at 45° left anterior oblique angle (LAO). Both perpendicular images clearly show the contact between the catheter tip and the lead.
Figure 4.10: Navigation time to four targets using both the manual and robotic method. No statistically significant difference between the two methods was observed (p=0.705).

Figure 4.11: Visual confirmation of the created RF lesions. Lesions created on the HL-RA, RAA, RAS, and RV-LW are shown (arrows).
4.5 Discussion

In this chapter we have presented a tele-robotic system that allows for remote navigation of a conventional tip steerable tip catheter with 3 degrees of freedom. This study demonstrated, the feasibility and safety of the presented RCNS for remote catheter navigation and RF lesion generation in vivo. Without any prior training sessions, the interventionalist successfully navigated the RO_Cath to 4 different targets (4 times to each target for a total of 16 RO_Cath navigations) in the right side of the animal’s heart. Statistical analysis showed no significant difference between the navigation times of manual vs. remote navigation. The interventionalist was also successful in creating ablation lesions with the RO_Cath at intended anatomical targets. Laboratory experiments showed the robot to be accurate with an axial error of 0.1±0.1 mm over 100 mm of motion and a rotational error of 7±6° over 360° of motion. Dynamic motion evaluation demonstrated that the robotic system has a very rapid response, with a delay of 35±15 ms.

The presented robotic system is compact and easily accommodates conventional steerable catheters of varying external diameter. The unique design of the system allows for arbitrary positioning of the catheter manipulator at the desired point of entry, preventing buckling of the patient catheter between the robot and the introducer sheath. The system design also allows for catheter exchange in less than 2 minutes.

Since the presented compact RCNS uses the same general approach as that described in [16, 17], the overall design continues to take advantage of the user’s dexterous skills in the master unit. Furthermore, the addition of a handle deflection sensor/manipulator allows the interventionalist to directly manipulate a catheter handle in
the master unit. Therefore, the currently presented RCNS has a negligible learning curve – interventionalists were able to operate the system without any prior training. The new robotic system also allows for simple disengagement of the differential gear mechanism (which comes in direct contact with the patient catheter) allowing for its replacement or sterilization; this was not feasible with the earlier system design.

Apart from the DC motors, all components of the presented robot are made of non-magnetic material. By replacing the DC motors with non-magnetic Ultrasonic motors (also non-magnetic) it is expected that the presented robot will be fully compatible with Magnetic Resonance Imaging (MRI), as has been shown with an earlier mechanical design [15]. Therefore the presented robot design can also be potentially used for remote catheter navigation under MRI guidance, as well as fluoroscopic imaging.

During in vivo navigation experiments with the second animal, the robot faced a calibration issue. Due to poor adjustment of the mount, the sharp angle of entry into the pig’s right femoral vein was not fully compensated. As a result the catheter was pulled towards the introducer at a sharp angle at the point where it exited the manipulator. This in turn had forced the catheter to slip out of the roller’s grip. Readjustment of the catheter and the mount fixed this issue. While such a sharp entry angle is unique to porcine models, and is unexpected for human subjects, the catheter has to be confined to the center of the manipulator (e.g. with a narrow tube), to prevent any such slippage or complications in the future. Alternatively, a more versatile mount can be developed that accommodates a larger range of motion in the orientation of the CM.

The presented robot manipulates conventional steerable catheters of various gauges and with a plunger steering mechanism. The robot can potentially facilitate the
operation flow of an electrophysiology lab, by allowing the interventionalist to be with the staff in the control room, facilitating communication and eliminating the need for continuous wear of heavy lead protection, as well as allowing the interventionalist to remain seated during the navigation procedure. Although, the presented robotic system must undergo further preclinical and clinical studies to validate its efficacy, the initial results, presented in this chapter, are highly promising.

4.6 Conclusion

We have introduced a tele-robotic system that allows 3-DOF for remote navigation of conventional steerable catheters of different gauges. *In vivo* evaluation of the tele-robotic system demonstrated feasibility of remote catheter navigation and ablation and showed that the navigation method had no significant effect on navigation time. The presented system facilitates catheterization and allows the interventionalists to remotely perform the navigation procedure from a safe distance, minimizing exposure to radiation.
4.7 References


Chapter 5.

Magnetic Resonance Imaging Compatible Remote Catheter Navigation System with 3-Degrees-of-Freedom†

5.1 Introduction

Catheter based interventions are an essential tool for the therapy and diagnosis of many cardiovascular diseases. Fluoroscopic imaging is the main modality used for guiding catheterization procedures, but this modality only provides low-contrast 2-dimensional (2D) projection images. X-ray fluoroscopic imaging irradiates the patient directly [1-3] during the procedure, and the staff and interventionalists indirectly through scattered radiation [4, 5] at lower dose levels, but on a daily basis. The exposure of interventionalists and staff to scattered radiation has motivated the development of remote catheter navigation systems that allow the interventionalist to remotely perform the catheterization procedure: Niobe (Stereotaxis Inc., MO, USA) [6, 7], Sensei (Hansen Medical, CA, USA) [8, 9], Corpath (Corindus Vascular Robotics, MA, USA) [10], and Amigo (Catheter Robotics Inc., NJ, USA) [11]. However, while these systems have eliminated the exposure of the interventionalist to scattered radiation, they have not improved the efficiency of the catheterization procedure and require the use of fluoroscopic imaging for procedure guidance.

Contrary to fluoroscopic imaging, Magnetic Resonance Imaging (MRI), offers high soft tissue contrast, provides 3D anatomical visualization and permits the visualization of infarct, ischemic and arrhythmogenic tissue [12, 13] ablation lesions [14, 15] hemorrhages [16], and detailed information about soft tissue deformation and morphology during catheter/soft-tissue contact. Furthermore, during ablation, MRI offers valuable information on temperature variation of the target tissue. These benefits offer the potential to improve the plan of therapy, prevent complications and enhance procedure efficiency and outcome [13, 17-20]. With recent developments permitting real-time MRI acquisition of rapidly moving cardiac anatomy [21, 22], there is great motivation to use MRI for guiding cardiac catheterization procedures.

Several challenges are associated with the use of conventional closed-bore scanners for MRI-guided interventions. For example, there is a need for magnetically shielded display monitors and MRI-compatible control within the scanner room. Also, due to the loud acoustic noise during imaging, specialized sound suppressing headphones are required [23]. Another major constraint imposed during MRI guided procedures, in a conventional closed bore scanner, is that the interventionalists are required to reach within the MRI bore to gain access to the catheter manipulation site and depending on the point of entry this may cause significant complications in the procedure. These problems continue to limit the wide adoption of MRI-guided catheterization despite its clear benefits.

An MRI compatible remote catheter navigation system (MR-RCNS) was previously developed by our group that allowed remote manipulation of a conventional catheter with 2 degrees-of-freedom (DOF) [24]. This work was a first prototype of its
kind that demonstrated the feasibility of remote catheter navigation inside an MRI system. Before further developments toward clinical applications, an MRI compatible robot must be capable of manipulating the catheter handle (plunger/knob), for tip steerable catheters, to provide full 3-DOF-motion control. Furthermore, the robot must be compact enough so that it can be oriented and positioned arbitrarily depending on the desired catheter insertion point; also, the robot must be sterilizable. To address these needs a redesign of the aforementioned prototype is required.

In this chapter we propose a second generation of the MR-RCNS, to overcome the limitations of [24] by allowing the manipulation of a conventional catheter (with a steerable distal end) with 3-DOF. The robot is compact and can be oriented arbitrarily at the point of entry. Furthermore, the robot allows for sterilization/replacement of robot components that come in contact with the catheter. A non MRI-compatible version of this system has been successfully evaluated in vivo for fluoroscopically guided catheterization and is fully described in Chapter 4.

This chapter is organized as follows: the system is fully described in section 5.2. In section 5.3 the evaluation experiments are explained in detail, followed by the results in section 5.4. Finally, the discussions and conclusions are presented in sections 5.5 and 5.6 correspondingly.

5.2 System Description

The presented MR-RCNS is a master-slave system that allows for remote navigation of a conventional steerable catheter with 3-DOF. The interventionalist, utilizing their dexterous skills, manipulates an input catheter in a master unit by applying
conventional push/pull, rotation, and plunger actuation motions. A custom-developed
servomechanism captures the motion from the master unit and controls the robot such
that it replicates the user’s motion, on a patient catheter inside the magnet. This robot is
an MRI-compatible version of its predecessor that utilized conventional DC motors and
has been thoroughly described in Chapter 4. The schematic of the MR-RCNS in Figure
5.1 shows the components of the system in use. This section describes each system
component, with Figure 5.2 showing a photograph of the master and slave components.

![Schematic of the MR-RCNS](image)

**Figure 5.1**: Components of the MRI-compatible remote catheter navigation system.
5.2.1 User Interface- Master

The master unit captures the interventionalist’s applied input motion. In our experimental setup this unit is positioned in the scanner’s control room and therefore does not need to be MRI compatible. The master unit consists of the catheter sensor (CS) and the plunger sensor (PS). To sense the user’s rotational and axial motions exerted on the input catheter, the CS uses two optical encoders coupled to the catheter; this unit is fully described in [25, 26]. The PS uses a third optical encoder coupled to a knob, to measure the user’s input for the desired position of the plunger. The positions of these 3 encoders are captured by the USM servomechanism, as reference motion, and used to control the robot.
5.2.2 Robot-Slave

As described previously in Chapter 4, the robot (slave) consists of two sections: The Catheter manipulator (CM) and the catheter handle manipulator (HM). The CM is actuated with two motors and incorporates a differential gear mechanism. Inside the CM, a set of parallel rollers grip on to the catheter. These rollers are actuated with the differential gear mechanism to allow for axial and rotational manipulation of the catheter. A mount allows for manual adjustment of the position and orientation of the CM depending on the catheter point of entry. The use of the differential gear mechanism allows for the position of the motors to be stationary and therefore facilitates the disconnection of the CM from the mount for sterilization/replacement purposes.

In the HM the catheter handle is mounted on a rotating gantry and a winch-spring mechanism is used to push/pull the catheter plunger. The rotation of the winch retracts a string that is connected to one end of a lever. The other end of the lever pushes on the catheter plunger, therefore, moving it forward. A spring on the other side of the plunger counteracts the force of the lever on the plunger. As soon as the winch relaxes the string, the lever is relaxed and the spring pushes back the plunger to its initial position. The third and forth actuators of the robot are used in the HM to allow for the rotation of the catheter handle and the push/pull of the catheter plunger (actuation of the winch). The mechanical design of the robot is thoroughly described in Chapter 4.

The slave robotic system must be fully MRI compatible to safely and accurately manipulate a patient catheter inside the scanner without affecting the image quality. Some mechanical components of the robot, such as the CM, were precision machined from fully non-magnetic material including: brass, Delrin, Aluminum, stainless steel.
The remaining parts were made using additive manufacturing from stainless steel/titanium using a selective laser melting machine (AM125, Renishaw, Canada), or poly methyl methacrylate (PMMA) and polypropylene using a plastics 3D printer (Objet 30 pro, Stratasys, Israel). The actuators chosen for the robot were non-magnetic Ultrasonic motors (USM45, Xi’an Ultrasonic Technology Co., China; USR60-NM, Fukoku-Shinsei, Japan). The suitability of USMs for MRI-compatible tele-robotic systems has been previously demonstrated [24].

5.2.3 Multi-Axis Ultrasonic Motor Servomechanism

To dynamically control the non-magnetic USMs of the robot in real-time, a custom embedded system was developed. The proposed electrical system follows the design architecture and control algorithm described in Chapter 2 but is enhanced to control 4 motors simultaneously. This system incorporates 3 microcontrollers (XMEGA256A3B, ATMEL Inc., USA), as shown in the block diagram of Figure 5.3. Measuring the applied reference inputs and comparing them with the corresponding motor’s measured positions, an analogue control signal is generated based on the control algorithm described in Chapter 2 and supplied to the corresponding motor’s driver circuitry.

Because the CM incorporates a differential gear mechanism, the two USMs driving the CM have to be manipulated in synchrony to achieve accurate axial and rotational manipulation of the catheter. Therefore, one microcontroller is used to control both motors of the CM. This microcontroller captures the axial and radial positions of the CS and – by using feedback from quadrature optical encoders connected to the USM shafts – controls the USMs of the CM unit to allow axial and rotational motion control of
the catheter. A second microcontroller also measures the rotational reference position from the CS and controls the third USM in the HM to rotate the HM gantry such that the catheter handle and catheter body rotate synchronously. Finally, the third microcontroller measures the reference position of the PS and controls the USM that actuates the winch (consecutively the catheter’s plunger) such that steering of the patient catheter’s distal end is achieved.

To prevent RF interference between the scanner and the control unit and also to block penetration of RF noise into the magnet room (through the signal and power lines), low pass RF filters with a cutoff frequency of 3 MHz –grounded to the magnet’s RF shield– were used on all the electrical connections between the master (in control room) and slave (in the magnet room) as depicted in **Figure 5.1**.

**Figure 5.3**: Block diagram of the USM servomechanism. Three microcontrollers (Micro 1-3) are used to remotely control the robot’s four motors (USM 1-4) using each motor’s shaft position – measured with optical encoders (Enc.1-4) – as feedback.
5.3 Evaluation

5.3.1 MRI-Compatibility Evaluations

From the perspective of MRI-compatibility we are primarily concerned with the safety and performance of the robotic system during imaging, and the quality of the obtained MR images. The safety and performance of the system was evaluated as part of a remote MRI guided navigation evaluation (described next). The effect of the system on the images was evaluated based on variations in image SNR and image artifact. All evaluations were performed inside the bore of a clinical MRI scanner (3T, Discovery 750, General Electric Healthcare, Waukesha, WI).

5.3.1.1 Image Signal to Noise Ratio (SNR)

The National Electrical Manufacturer’s Association (NEMA) [27] provides standard guidelines for the measurement of signal-to-noise ratio (SNR) in MR images. These guidelines were followed to evaluate the effect of the MR-RCNS on image SNR. Using a 16 channel cardiac coil, a Spin echo (SE) pulse sequence was used (FOV 24 cm, slice thickness 6 mm, TR/TE= 1,300/20 ms, matrix 256 × 256, and BW 15.6 kHz) to obtain images of a 17-cm-diameter water-based phantom (MRS HD sphere, model 2152220; General Electric, Milwaukee, WI), doped with metabolite salts and gadolinium-based contrast agent (T1/T2 = 392/297 ms). All gain settings were maintained constant throughout the experiment. Experiments were performed at a room and phantom temperature of 20 °C. For this experiment, two sets of images were obtained: one with the robot active, and the other with the robot completely removed and disconnected. Following the NEMA guidelines, the subtraction of the two consecutive images in each set was used to calculate the image SNR.
5.3.1.2 Image Artifacts

In order to quantify image artifacts caused by the presence of the robot, the ASTM standard test method for the evaluation of MR image artifacts from passive implants [28] was followed as a guideline. The robot was placed at a distance of 40 cm from isocenter, representing the typical distance of the robot from the imaging field of view during cardiac interventions. The previously mentioned spherical phantom and cardiac coil were used for this experiment as well. Spin echo (FOV 24 cm, slice thickness 6 mm, TR/TE= 1,300/20 ms, matrix 256 × 256, and BW 15.6 kHz) and GRE (FOV 24 cm, slice thickness 5 mm TR/TE=500/10 ms, flip angle 60°, matrix 256x160, and BW 15.6 kHz) pulse sequences were first applied with the readout and phase encode directions in the left/right (LR) direction and then repeated with readout directions reversed to anterior/posterior (AP), for a total of 4 images. After the 4 acquisitions, the robot was removed – without moving the phantom – and the four pulse sequences were repeated. Following the guidelines in [24], the corresponding slices of each sequence were compared between the two states (robot present or absent). Pixel intensities that varied by 30% or more were considered as artifact.

5.3.2 Evaluation of Remote MRI Guided Navigation

To evaluate the performance of the presented robot in remote motion control of the catheter in each degree of freedom, a custom phantom was developed. The phantom was designed such that it would confine the catheter and allow visualization of the catheter position/angle with respect to the phantom. For evaluation of the robot’s control of the catheter’s axial motion a Plexiglas tube was used; multiple O-rings spaced 1-cm apart were placed on the surface of the tube, as illustrated in Figure 5.4.a. To evaluate the
robot’s control of the catheter’s rotational motion, a plate was connected to the end of the Plexiglas tube and four plastic extrusions on a circle concentric to the tube, each $90^\circ$ apart, were created as depicted in Figure 5.4b. The phantom was then put inside a saline-based phantom, with a volume of $70 \times 30 \times 10$ cm, filled with $12.5 \text{ g/L polyacrylic acid (PAA)}$ and $1 \text{ mL/L Gadovist (gadobutrol 604.72 mg/L)}$.

In all the navigation experiments, a conventional steerable 7 F, non-irrigated, D-type curvature catheter (BioSense Webster Inc., Diamond Bar, CA, USA) was used. However, for MRI-compatibility and visualization, the catheter was slightly modified: the leads at the distal end were clipped; the metal pull-wire was replaced with a fishing line; the metal spring inside the catheter was removed; and hot glue was applied to the tip of the catheter to create a spherical marker, with a diameter of $\sim 4$ mm, so that the catheter tip could be visualized in real-time MR images.

For all real-time MR imaging, a 16-channel cardiac coil (GE Healthcare, USA) was used to obtain real-time MR-Echo sequences (slice thickness of 3 mm, frequency and phase FOV of 18 cm and temporal resolution of $\sim 85$ ms).
Figure 5.4: The designed phantom setup for observation of the catheter’s position in MRI. a) shows the setup for observation of the axial position, b) shows the setup for observation of the catheter’s rotational angle.

5.3.3 Evaluation of Axial Motion

The input catheter, in the CS, was confined to a tube that allowed measurement of the input catheter’s axial position. The patient catheter (manipulated by the robot) was
positioned inside the Plexiglas tube of the phantom (Figure 5.4.a) and was then mounted on the robot. The imaging plane was adjusted to contain the catheter along the tube.

Based on visual feedback from the real-time MR image stream, the user manipulated the master unit to remotely navigated the patient catheter tip to positions of ±10, ±20 and ±30 mm with respect to the visible markings on the images (from the intersection of the image plane with the plastic O-rings on the Plexiglas tube). At the end of each navigation attempt, the corresponding position of the input catheter was recorded and each attempt was repeated 5 times in each direction.

5.3.4 Evaluation of Rotational Motion

The body of the input catheter in the CS was confined to a tube and an arrow was connected to one end of the catheter so that the input catheter’s angle could be read with respect to a protractor. The patient catheter was positioned inside the phantom and an indicator dial was connected to the distal end of the catheter. The imaging plane was prescribed such that the indicator dial and the four plastic extrusions of the phantom (refer to Figure 5.4.b) could be seen. This allowed visualization of the catheter’s angular position relative to the four extrusions.

Based on visual feedback from the real-time MR image stream, and using the master unit, the user remotely rotated the patient catheter indicator dial to angles of ±90° and ±180° relative to the visible extrusions (from the intersection of the image plane with the 4 plastic extrusions) in the MR images. At the end of each rotation, the corresponding angle of the input catheter was recorded and each attempt was repeated 5 times in each direction.
5.3.5 Evaluation of Distal End Deflection

To evaluate the robot’s ability in actuation of the catheter’s plunger, the image plane was adjusted such that it contained the catheter’s distal end. Using the PS the user remotely actuated the plunger to obtain full deflection of the distal end. Remote deflection and straightening of the distal end was repeated 3 times.

5.4 Results

5.4.1 MRI-Compatibility Evaluations

The robot was safely positioned inside the scanner bore. We did not experience any force or torque on the robot. There were no signs of RF heating on the robot body.

5.4.1.1 Image Signal to Noise Ratio (SNR)

Evaluation showed that the SNR of the images was preserved and the SNR dropped less than only 3 dB from a baseline SNR of 108 dB when the robot was introduced and manipulated.

5.4.1.2 Image Artifacts

Based on the metrics presented in the ASTM [28] guidelines, the robot did not introduce any artifacts in the obtained images. Figure 5.5 shows the GRE artifact images of the spherical phantom for the two readout directions (AP and LR). Any artifact would appear as a white pixel in the binary artifact images. As can be seen in the figure, no artifacts were detected and changing the direction of phase encoding did not affect the results. Similar results were obtained for the SE pulse sequences.
Figure 5.5: Artifact images for GRE sequences obtained from the spherical phantom in the presence of the robot: a) with readout in the AP direction, and for b) in the LR direction. As it can be seen the robot does not create any artifacts.

5.4.2 Evaluation of Remote MRI Guided Navigation

The MR-RCNS allowed successful remote navigation of the catheter tip to all targets that were specified in the real-time image stream, for both axial and rotational motions. The system also allowed full remote control of the deflection of the catheter’s distal end. Figure 5.6 presents visual confirmation of the system’s performance in remote motion control of the catheter, based on the real-time image stream feedback, independently in each degree of freedom.

Quantitative measurements, showed the mean absolute difference between the master and slave positions during image guided navigation to be $0.2 \pm 0.1$ mm in the axial direction and $22 \pm 16^\circ$ in the rotational direction.
Figure 5.6: Selected frames from the real-time image streams during remote catheter manipulation in each degree-of-freedom. a.1-3, show the catheter’s axial position with 1 cm of axial catheter motion between the presented consecutive figures; the arrows point to the catheter’s tip. b.1-3 show the catheter’s rotational angle with 90° of counterclockwise catheter rotation between the presented consecutive figures; the arrow points to the tip of the indicator dial that is connected to the catheter. c.1-3 show the bending of the catheter’s distal end at 3 different bending states.

5.5 Discussion

In this chapter we have presented a fully-MRI compatible remote catheter navigation system that allows for remote navigation of steerable catheters with 3 DOF inside an MRI system. Using the presented system the user was able to remotely navigate
the catheter, in all 3 DOF, to desired targets under the guidance of real-time MRI. This robot design is compact enough to fit inside the bore of the scanner together with the patient and would allow the interventionalist to remotely perform catheterization procedures using conventional closed bore scanners.

Our system evaluation showed that the RCNS is fully MRI compatible. The robot did not experience any force when placed inside the bore and there were no signs of RF heating. Our quantitative evaluations showed that the robot does not degrade the image SNR nor does it introduce any artifacts in the obtained images.

The robot presented in this chapter is a second generation of its type and overcomes the limitations of its predecessor [24] by allowing for 3 DOF in catheter motion control instead of only 2 DOF; also, the present design permits the disconnection of the CM from the supporting mount and motors for sterilization/replacement purposes. The ability to sterilize the robot is a crucial feature that allows for transfer of the presented system to the clinic.

While the user was able to successfully navigate the catheter in each DOF with high accuracy, based on the image feedback, there was a larger than expected discrepancy between the master and slave rotational angles. The source of this error was mostly due to loosening of the motor shaft coupler for the motor that rotated the gantry in the HM. As this part (shaft coupler) was fabricated from 3D printed material, it did not have the material properties required to hold the setscrew that fixed the shaft coupler to the motor shaft. These minor limitations can be overcome in the future (e.g. by machining the shaft coupler from stronger material such as brass, aluminum, or PEEK). However, because the interventionalists navigate using image guidance, it is expected
that a small discrepancy between input and output angular position would not impact the navigation procedure significantly.

In parallel to the development of the presented MR-RCNS, actively tracked electrophysiology catheters are being developed that would allow for fast localization of the catheter’s distal end (e.g. IMRICOR Medical Systems, MN, USA). These catheters would greatly facilitate 3D navigation, as it would permit automatic plane prescription such that the imaging plane would fully contain the catheter’s distal end. Due to unavailability of actively tracked catheters in the market at the time of writing this manuscript, this chapter focused on the manipulation of conventional tip steerable catheters that are passively tracked; therefore the image planes were adjusted and prescribed manually. Further in vivo evaluation of the MR-RCNS would ideally be performed in conjunction with actively tracked MR compatible ablation catheters like the one described above.

In this manuscript we targeted the use of the MR-RCNS for ablation procedures. However, the system can be adapted to facilitate other MRI guided percutaneous interventions, including angioplasty, renal artery sympathetic denervation, and image guided drug delivery

5.6 Conclusion

We have developed an MRI compatible remote catheter navigation system that allows for remote navigation of conventional steerable catheters with 3 degrees of freedom. The presented master-slave system allows replication of the interventionalist’s motion, imparted on an input catheter in a master unit, by the slave robot on a patient catheter. This study demonstrated that the robot was fully MRI compatible and showed it
is feasible to use the proposed system to remotely navigate the tip of a steerable catheter, in 3 degrees of freedom, to pre-defined visual targets in a phantom model using real-time MRI feedback.
5.7 References


Chapter 6.

Conclusion and Future Directions

6.1 Contributions

The goal of this thesis was to design, develop and evaluate a remote catheter navigation system that would allow the interventionalist to perform the catheterization procedure remotely under the guidance of both x-ray fluoroscopy and MRI. A compact RCNS is proposed that is fully MRI compatible and allows for remote navigation of conventional tip steerable catheters with 3 DOF. The proposed system alleviates the occupational risks to interventionalists and staff during conventional fluoroscopically guided catheterization and facilitates MRI guided catheterization in conventional closed-bore MRI scanners.

6.1.1 MRI Compatible Remote Catheter Navigation System

All Chapters of this thesis focus on individual steps required for the design, development and evaluation of a remote MRI compatible catheter navigation system. These steps were:

a) The development of means to dynamically control Ultrasonic motors for prolonged periods despite disturbances due to thermal heating (allowing for dynamic control of an MRI compatible surgical robot) (Chapter 2).
b) Demonstration of the feasibility of remote catheter manipulation inside an MRI system, using a remote MRI compatible catheter navigation system (Chapter 3) without degrading image quality or system performance.

c) Design and development of a sterilizable robot for actuation of conventional steerable catheters with 3 DOF and evaluating the performance of the new design \textit{in vivo} (Chapter 4).

d) Controlling the robot, presented in Chapter 4, with a custom designed 4-axis USM servomechanism and evaluating the system’s MRI compatibility and its performance in real-time MRI guided catheter navigation independently for each degree of freedom (Chapter 5).

As mentioned earlier, USMs are a preferred option for the actuation of MRI compatible mechatronics. However, dynamic motion control of USMs is challenging due to their time varying and temperature dependent characteristics. Therefore, Chapter 2, concerned itself with the robust motion control of these motors for prolonged periods. A robust control algorithm was developed and implemented on a custom designed real-time embedded system. The evaluations showed that, by using the presented control system architecture, it is feasible to control USMs with high accuracy for prolonged periods. This contribution permits accurate and dynamic control of MRI compatible mechatronics for prolonged periods.

In Chapter 3, an MRI compatible remote catheter navigation system was introduced. This system allowed for remote control of conventional catheters with 2 DOF. The robot used in this system was a non-magnetic version of [1]. This robot was remotely actuated by USMs, using a custom designed real-time USM servomechanism. This system provided a first proof of concept and system evaluation showed that it is
feasible to remotely actuate a conventional catheter, with high accuracy, inside an MRI system—during imaging—without degrading the image quality or robot performance.

The first version of the robot, presented in Chapter 3, only allowed for 2 DOF in catheter motion control, was bulky, and did not allow for sterilization of the robot. Addressing these limitations, a second generation of the robot was designed. In Chapter 4, the design and \textit{in vivo} evaluation of the second generation of the robot were presented. The results indicate that the presented compact system is safe and that it was feasible to remotely navigate conventional steerable catheters, under fluoroscopy guidance, to desired anatomical targets and successfully deliver ablations. Statistical analysis showed that the navigation and fluoroscopy times do not differ significantly between manual catheter navigation and robotic catheter navigation. The user interface of the RCNS takes advantage of the interventionalist’s dexterous skills in catheter manipulation and did not require any prior training. The results demonstrate that the presented RCNS is a pragmatic solution that addresses the problem of staff and interventionalist exposure to scattered radiation by allowing the interventionalist to perform the catheterization procedure remote from the radiation source.

In Chapter 5, design and development of a 4 axis USM servomechanism for the control of the robot (described in Chapter 4) was presented. \textit{In vitro} evaluations of the system were also described in this chapter. The presented results showed that the system is fully MRI compatible and can be used to control and maneuver a steerable catheter in all 3 DOF, under real-time MRI guidance and without degrading the image quality. The presented MRI compatible RCNS, is compact enough to fit inside the bore of a conventional scanner together with a patient, and allows the interventionalist to
comfortably guide the catheterization procedure, remotely, from the control room of the MRI suite.

6.1.2 Dynamic Motion Control of Ultrasonic Motors

As discussed earlier, Chapter 2 of this thesis presented the means for robust motion control of USMs. While the prime intention for developing this control method was to robustly control the robot during dynamic catheter manipulations throughout an intervention, it was evident that this development had other important applications. For example, the presented control system could be used to dynamically control an MRI compatible motion stage for quality assessment of motion sensitive MRI applications and MRI guided therapy. To this end, an MRI-compatible motion stage, capable of moving various imaging phantoms, was developed and thoroughly evaluated for MRI compatibility, consistency and accuracy. This system is comprehensively described in Appendix A of this thesis.

6.2 Conclusion

An MRI compatible remote catheter navigation system, capable of manipulation of conventional steerable catheters, with 3 DOF has been presented. The system takes advantage of the interventionalist’s pre-existing skills, is easy to use, and requires no prior training. In vivo studies showed that that the system is safe, and allows for accurate catheter navigation and delivery of ablation lesions without any significant affects on the navigation/fluoroscopy times. The interventionalist was able to use the system immediately and without any prior training.
In vitro evaluations showed that, by utilizing USMs, the system can be made fully MRI compatible and the system allows for accurate remote navigation of a conventional catheter with 3 DOF to targets specified in real-time MR images. The system did not create any artifacts in images nor did it degrade the image SNR.

6.3 Limitations

The RCNS presented in Chapter 3 showed that it was feasible to remotely navigate a catheter inside an MRI bore during imaging without degrading image quality, however, the robotic manipulator only allowed for 2 DOF in catheter motion control. This limitation was addressed by a new compact design that allowed for 3 DOF in catheter motion (presented in Chapter 4). Ex vivo and in vivo experiments demonstrated the accuracy and safety of the design for remote catheter navigation. However, in one of the experiments, due to small mechanical calibrations issues with the mount, the catheter had slipped out of the grip of rollers in the CM resulting in a less reliable control of the catheter position. To ensure robust manipulation of the catheter under all circumstances, this limitation has to be addressed by confining the catheter to the center of the CM (e.g. with a narrow tube). Alternatively, a more versatile mount can be developed that accommodates a larger range of motion in the orientation of the CM.

Another limitation of the system is that the plunger actuation mechanism, is not limited in its range of motion and the interventionalist can attempt to move the plunger beyond its range of motion. As a result the catheter, or the string that pulls the lever, may be damaged. This problem may be addressed by physically adding limits switches to the
plunger actuation mechanism in the HM component of the robot; alternatively limits may be set in the code to limit the range of motion of the motor that actuates the plunger.

The presented RCNS does not include force feedback. Literature suggests that force feedback from the tip of the catheter is beneficial as it is an important determinant of lesion formation [2, 3]; more importantly it is a highly important factor in the safety of catheterization procedures as excessive contact force can result in severe cardiac complications (e.g. perforation) [4, 5]. Suggestions are proposed in section 6.4 on how force feedback can be implemented in the RCNS as part of future work.

During the in vitro experiments for evaluation of remote MRI guided navigation, presented in Chapter 5, the performance of the robot was evaluated independently for each degree of freedom. While this method allowed evaluation of the robot’s performance in control of each DOF, a more comprehensive simulation of catheter navigation could have included remote navigation of the catheter tip to relevant targets inside a 3D cardiac phantom (further described in section 6.4). However, the challenges for targeted catheter navigation in 3D were not due to the limitations of the MR-RCNS, but were due to the difficulty of manually prescribing the imaging plane such that it contained the catheter’s distal end. Even if the plane was successfully prescribed (after several trial and errors), it was difficult for the user to visualize where the catheter was with respect to the target. Therefore, in the presented validation studies the catheter was constrained such that it would maintain in constant imaging planes. The performance in each DOF was then evaluated independently without the need of adjusting the imaging plane to track the catheter.
6.4 Suggestions for Future Work

The proposed future directions of work can be divided into the following: implementation of force feedback; remote MRI guided catheter navigation using actively tracked catheters; clinical validation of the system’s safety and efficacy, and application to other problems (described in section 6.4.4).

6.4.1 Implementing Force Feedback

In conventional cardiac catheterization performed by experienced academic centers, major complication rates can be as high as 6% [6]. Comparison of conventional catheters with catheters that provide force feedback, have shown that force feedback catheters are superior with regards to procedure safety and risk of cardiac perforation [7]. Therefore, regulation of the contact force at the catheter tip, during the ablation procedure would further improve the safety and efficiency of catheter navigation and ablation delivery[8]. However, in conventional manual catheterization, regulation of the contact force is challenging due to the rapid motion of the cardiac anatomy.

Automatic force regulation of the catheter tip has been attempted in several recent publications [9-12]. However, none of these systems incorporate remote catheter navigation in conjunction with automatic force regulation solutions. It is expected that by feeding back the force data to the RCNS control mechanism, an extra control loop may be implemented to allow for automatic regulation of the contact force when needed (e.g. when the interventionalist has reached the target and is delivering ablation). Alternatively, the force-feedback data can be used to provide the user with haptic feedback in the master unit. Furthermore, the force data can be used as a safety mechanism to retract the catheter when the force value exceeds a certain threshold. These
improvements should help improve the safety of catheterization, reduce complication rates and improve the quality of the lesions.

6.4.2 Remote MRI Guided Catheter Navigation Using Actively Tracked Catheters

As mentioned in section 6.3, the MR-RCNS presented in Chapter 5, was evaluated in vitro using passively tracked catheters and by manual adjustment of the image acquisition plane. This limitation significantly hindered navigation to targets in the 3D volume. However, by real-time tracking of the catheter tip, one may automatically detect the catheter tip position and orientation and automatically prescribe an imaging plane that contains the catheter’s distal end [13, 14]. As a first step, actively tracked catheters must be obtained when commercially available (e.g. Vision-MR™ Ablation Catheter, IMRICOR, USA) or developed following available guidelines for catheter prototype development [15]. Figure 6.1 illustrates a possible structure for an actively tracked and steerable catheter. As an alternative to active tracking techniques that rely on coils and MRI, the catheter position and orientation may also be tracked directly by using MRI compatible position sensors (e.g. fiber bragg grating) [16, 17].

Once actively tracked catheters are available, they can be used in combination with the Vurtigo platform [18], to allow catheter tip visualization and automatic plane prescription. In vitro experiments may also be performed using a 3D cardiac phantom. Figure 6.2 presents a prototype of such a phantom. Fiducial markers may be placed arbitrarily at desired locations (using plastic extrusions) to act as targets during catheterization.
Figure 6.1: A simple structure of an actively trackable MRI compatible and steerable catheter is proposed. Two coils at the distal end act as micro imaging coils permitting the localization of the distal end and detection of its orientation. To allow for bending of the distal end, a non-magnetic pull wire (e.g. fishing line) can be used; the pull wire can be retracted using a plunger on the catheter handle. Non-magnetic body material must be used (e.g. PEEK braided Pebax with stiffness of D30 and D72 for the catheter distal end and body correspondingly). Non-magnetic copper coax cables must be used to deliver signal from the coils to the impedance matching and frequency tuning circuits.

Figure 6.2: The proposed rapidly prototyped cardiac phantom is shown. The phantom consists of four cardiac chambers, including: interatrial septum opening, four pulmonary vein openings in the left atrium, the inferior vena cava and the femoral veins. To allow visualization of the phantom in MR images, the container can be filled with saline.
6.4.3 Clinical Validation of the System’s Safety and Efficacy

In Chapter 4 of this thesis, we demonstrated the \textit{in vivo} evaluation of the RCNS by navigating the catheter to pre-specified targets in porcine models and delivering RF energy to create ablation lesions. However, in conventional fluoroscopically guided catheter ablation, the catheter is first swept around the myocardium to make electrical measurements to help create EAMs and to identify the origin of the arrhythmogenesis. This step must be included in a future preclinical study to better simulate a realistic scenario.

For clinical translation of the presented RCNS for fluoroscopically guided catheterization, the system must be validated for remote catheter navigation in human patients for the treatment of cardiac arrhythmia. In such experiments, the general protocol for diagnosis and therapy should remain the same and the only change would be that the interventionalist would use the robot to remotely navigate the catheters. However, it is recommended that the system be used by multiple interventionalists to help determine variability in performance and outcome.

For clinical translation of the proposed MR-RCNS for MRI guided catheterization, \textit{in vivo} experiments should be pursued in preclinical and clinical experiments to show the safety and feasibility of the MR-RCNS for remote real-time MRI guided catheter navigation and ablation in conventional closed bore scanners. However, if the MRI suite in which the experiments are to be performed has not been set up to support an intervention, several important ancillary devices must be purchased,
including: hemodynamic monitoring and recording equipment, anesthesia equipment and intravenous fluid pumps (all must be MRI compatible) [19].

6.4.4 Potential Clinical Applications

The application of interest for the presented RCNS was catheter ablation for the treatment of cardiac arrhythmia. However, the presented system has the potential to be used for various other catheter-based interventions: angiography, vessel stenosis, vessel dilation, renal artery denervation for the treatment of hypertension, cerebrospinal fluid drainage for the management of hydrocephalus, image-guided drug delivery for cancer management/therapy, and endovascular coiling for the treatment of brain aneurysms.
6.5 References


Appendix A. Magnetic Resonance Imaging Compatible Linear Motion Stage†

A.1 Introduction

Anatomical motion in patients is ubiquitous, varies temporally, and is patient specific. Magnetic resonance imaging (MRI) is highly sensitive to motion and developments have been made to both reduce its effects on image quality (ghost artifacts, blurring, and reduction of SNR) [1, 2] as well as to extract physiological information (flow measurement, elastography, strain and deformation analysis, etc.)[3-6]. Recently the use of MRI in hybrid imaging systems (e.g. PET-MRI) has increased interest in using MRI to improve PET image quality (though motion compensation) [7-9]. In MRI guided radiotherapy, anatomical motion impedes accurate targeting and delivery of therapy [10, 11], but also provides an opportunity to monitor and correct for motion [11-13].

During the development and validation stages of motion measurement and correction techniques it is important to be able to simulate physiological motion within the MRI scanner. Several motion phantoms have been described in the literature, addressing the need to move objects within the scanner with a known profile and reproducibly. These motion phantoms actuate motion in one of two ways: using non MRI compatible DC or stepper motors that must be placed at the end of long actuating rods [11, 14-18], or incorporating pneumatic actuators that generally lack accurate positioning and motion control[7, 19]. Further challenges associated with such systems include their

†A version of this chapter has been submitted to Medical Physics: M. A. Tavallaei, P. Johnson, J. Liu and M. Drangova “Magnetic Resonance Imaging Compatible Motion Linear Motion Stage”, 2015.
size and weight, lack of versatility to move arbitrary phantoms in varying orientations and simulating arbitrary motion profiles

Many of these limitations can be addressed through the use of an MRI compatible actuator. Travelling wave rotary ultrasonic motors (USM), can be made of non-magnetic material and can be used as actuators inside the scanner [20-22]. However, a challenge in controlling these motors has been that they are nonlinear and have time-variant and temperature dependent response [23, 24]. Recent developments by our group [20, 25] have allowed for dynamic robust motion control of these motors that overcomes the limitation mentioned above.

Using a USM and a linear motion stage made of nonmagnetic materials we have developed an MRI compatible motion stage that can move any user selected phantom to a defined position or dynamically move the phantom following a user-defined motion profile. In this appendix, the stage’s accuracy in executing dynamic motion profiles – in both laboratory settings and inside the scanner during imaging – is quantified. Furthermore, to test its MRI compatibility, the effect of the stage on image artifacts, SNR and B0 homogeneity is evaluated. Finally an example application of the stage in gated imaging is provided.

A.2 Methods

System Design and Setup

Figure A.1 is a schematic of the design used for the linear motion stage. While, the general design is straightforward, ensuring MRI compatibility demands the use of non-magnetic, readily available materials. An 8-start, 2.54 cm travel-per-turn lead screw was custom fabricated from Polyether ether ketone (PEEK) to drive a Polyoxymethylene
(Delrin) carriage along rails made of Polytetrafluoroethylene (Teflon). All materials were selected for their mechanical properties, while ensuring MRI compatibility. The dimensions of the stage were selected to enable a range of motion of up to 5 cm, while maintaining the device small (13 x 7 x 29 cm overall dimensions) so that it can be as versatile as possible and fit within a variety of scanner/RF coil configurations.

**Figure A.1**: Schematic diagram of the stage. An ultrasonic motor (USM) is used to drive a carriage mounted on a lead screw.

The actuator of the stage is an ultrasonic motor (USR60-NM, Fukoku-Shinsei, Japan), selected for its MRI compatibility, power and torque specifications. Dynamic control of the USM’s position is achieved via a custom-designed embedded system. The control circuit implements the control techniques developed by Tavallaie et al. [20, 25] to allow robust and dynamic control of the USM for prolonged periods. An optical encoder, embedded in the USM, is used during motion control and also for logging the motor/carriage position by means of a serial port on the controller.
The control system, which is a stand-alone unit, was programmed to enable three different modes of operation: 1) translation to a user-defined position, 2) sinusoidal motion with user-defined amplitude and frequency, and 3) execution of a user-defined motion profiles (e.g. one that mimics respiratory motion). Interface with the control unit is achieved either through its display panel or through a serial port. In order to facilitate use with gated applications, the control unit was also programmed to output a 5 V pulse once per cycle for the sinusoidal profiles and at arbitrary times for user-specified dynamic motion profiles.

In a typical setup, the control unit is positioned in the scanner control room beside the console, while the stage is placed within the scanner bore, as illustrated in Figure A.2. To minimize the introduction of external electromagnetic interference into the magnet room and to obtain undistorted feedback from the encoder, the electrical connections for the motor and the encoder signals were passed through low pass capacitive filters (1000 pF) with a 3.2 MHz 3-dB cutoff frequency, mounted on the penetration panel of the scanner room’s RF shield.

Figure A.2: The MRI compatible motion stage shown as it would be set up within the MRI scanner. The controller is positioned in the control room and the connections are passed through low pass filters installed within the RF shield of the scanner room.
Evaluation in Laboratory Setting

Stage performance was evaluated both in the laboratory setting and within the MRI scanner. In the laboratory, the accuracy of the motion stage was evaluated for both fixed positions and dynamic reference profiles. For all laboratory tests the stage was loaded with a weight of 3 kg. The accuracy of the stage in reaching fixed reference positions was evaluated using an optical measuring microscope (STM6, Olympus, Japan). The carriage was taken to its home position (arbitrarily defined at the center of the stage) using the controller and this position was defined on the microscope as the origin for future measurements. Reference positions of ±1, ±5, ±10 and ±20 mm were prescribed and repeated 10 times for each direction. After motion was executed the carriage position was measured using the microscope and the USM encoder (logged through the control unit).

To evaluate the execution of dynamic motion, an optical tracking tool was attached to the carriage and sinusoidal reference profiles, with amplitudes of 2, 5, 7 and 10 mm at frequencies of 1, 0.5, 0.33, 0.25 and 0.2 Hz, were prescribed. The position of the tracking tool was measured using an optical tracker (Vicra, Northern Digital Inc., Canada) and logged at 20 Hz for a period of 5 minutes; the USM encoder logged the carriage motion simultaneously. For each motion profile, individual cycles were superimposed and the absolute error and root-mean-squared errors from the prescribed profile were calculated using MATLAB (MathWorks, USA).

Finally, the ability of the motion stage to execute physiological motion profiles was tested. The respiratory motion profile recorded from a patient over 45 seconds was
programmed into the controller and executed over a period of 5 minutes. The executed profiles, as measured by the optical tracker, were compared to the programmed profile.

**Evaluation Within An MRI Scanner**

*Execution of motion profiles*

Stage performance was evaluated within a 3T scanner (MR750, General Electric, USA). The stage was placed within a birdcage RF head coil and loaded with a skull-sized phantom filled with agarose gel. The phantom was placed on an extension plate (placing the carriage 20 cm away from the isocentre) and sinusoidal motion profiles were executed (amplitude = 5, 10 mm; frequency = 0.33 Hz). Both the static positions and the executed sinusoidal motion were measured using the pre-rotated baseline spherical navigator echoes (SNAV) technique [26], since the technique enables accurate measurement of dynamic motion.

Stage performance was also evaluated during gated imaging. In this experiment a 5 V signal (provided by the control unit) was used to trigger a pulse-emulating device (MR Finger, Shelly Medical Imaging Technologies Inc., Canada), which simulates peripheral pulse signals and was used as the gating source. Gated images were acquired of a moving tangerine (5 mm amplitude and frequency of 0.33 Hz) using the HD T/R knee phased array coil; gated FIESTA (TR/TE=8/4 ms, flip 20°, slice thickness 5 mm, 25 frames reconstructed) images were acquired in the coronal orientation in order to visualize the moving tangerine.
Evaluation of the effect of the stage on image artifact level, field homogeneity, and noise

Despite the use of MRI-compatible materials for fabricating the stage, it was important to determine whether the stage operation introduced image artifacts, additional noise, or significant magnetic field homogeneity degradation. First, image artifacts were quantified following the methods outlined in the ASTM standard for the evaluation of MR image artifacts from passive implants [27]. Specifically, the motion stage was placed on the patient bed beneath a Nylon support structure on which a 33 x 22 x 13 cm water based phantom (CTL rectangular, model 2406200; General Electric, Milwaukee, WI) was placed. The body RF coil was used to acquire axial spin echo (SE) (TR/TE=800/10 ms, FOV = 24 cm, 32 KHz, 256x160 matrix) and gradient recalled echo (GRE) (TR/TE=500/20 ms, FOV = 24 cm, flip angle 60°, 32 KHz, 256x160 matrix) images. In each case, ten 5-mm thick slices centered over the carriage were acquired. In accordance with the ASTM guidelines, the acquisitions were repeated with flipped phase encode and readout directions. The motion stage was then removed – without moving the phantom – and the four acquisitions were repeated. Following the guidelines in [27], the corresponding slices of each sequence were compared between the two conditions (stage present or absent); a change in intensity of 30% or more at any pixel was considered as artifact.

The same experimental set-up was used to evaluate the effect of the stage on main magnetic field (B₀) homogeneity. Images of the phantom were acquired with and without the motion stage, using a 3-echo GRE pulse sequence (3D IDEAL, TR/TE=7/3ms, FOV/slice thickness = 32 cm /2 cm, acquisition matrix = 156 X 156 X 156). B₀ field maps were calculated using the B₀-NICE technique [28] for each condition and the difference
between the two $B_0$ maps was calculated to represent the inhomogeneity induced by the presence of the stage. A field map was also acquired with the motor turned on but not moving.

Lastly, the guidelines of the National Electrical Manufacturer’s Association (NEMA) for the measurement of signal-to-noise ratio (SNR) in MR images were followed to evaluate the effect of the stage on image SNR [29]. Spin echo images (FOV 24 cm, slice thickness 6 mm, TR/TE= 1,300/20 ms, 256 × 256 matrix, and BW 15.6 kHz) were acquired of 17-cm-diameter water phantom doped gadolinium-based contrast agent (MRS HD sphere, model 2152220; General Electric, Milwaukee, WI; T1/T2 = 392/297 ms). For SNR evaluation, two sets of images were obtained: one with the stage on and moving beneath the phantom and the other with the stage removed and disconnected. The scanner’s gain settings were preserved between the two acquisitions. These experiments were performed at a room temperature of 20 °C.

A.3 Results

Accuracy in the Laboratory Setting

The mean absolute error of the system in taking the stage to fixed positions, measured with the microscope, was $0.025 \pm 0.021$ mm. The measured mean error, indicating bias in the system, was $0.017 \pm 0.028$ mm. The measurement results of the sinusoidal motion profiles are presented in Figure A.3, where each subplot represents an overlay of the measured positions of all cycles tracked for 5 minutes. The worst-case normalized root mean squared error (NRMSE) was below 7% for frequencies below 0.33 Hz and better than 10% for frequencies below 0.5 Hz. A sample sinusoidal profile
(0.5 Hz, 7 mm amplitude) is shown in **Figure A.4.a** with the corresponding 95% confidence interval; **Figure A.4.b** illustrates the corresponding power spectrum for the reference and measured profiles. **Figure A.4.c** depicts the results of the respiratory profile measurements, demonstrating that the motion stage is able to reproduce physiological motion profiles, with a confidence interval similar to that reported for the sinusoidal profiles.

**Figure A.3**: Sinusoidal profiles with amplitudes of between 2 and 10 mm (rows) at frequencies of 1 to 0.2 Hz (columns) are shown. In each subplot contains cycles from 5 minutes of the execution of the profile are shown. The worst case NRMSE was lower than 7% for all motion profiles with frequencies less than 0.33 Hz.
Figure A.4: b) Representative sinusoidal waveform (7 mm amplitude, 0.25 Hz) – the mean and 95% confidence interval of 75 continuous cycles are plotted. b) The power spectrum of the measured 75 cycles is plotted vs. that of the prescribed reference. c) the confidence interval of executed motion vs. prescription of respiratory motion.

Accuracy Inside the MRI Scanner

The sinusoidal profile in Figure A.5 demonstrates the measured motion profile of a phantom being moved within the scanner with a prescribed motion profile with a frequency of 0.33 Hz and amplitude of 10 mm. Similar results were obtained at other frequencies. Representative images of a moving phantom are seen in Figure A.6, where several frames (5 frames apart) from the gated FIESTA cine acquisition of the moving tangerine are shown, demonstrating the feasibility of using the motion stage for applications requiring gating.
Figure A.5: Sinusoidal motion of a phantom traveling within the MRI scanner (prescribed amplitude /frequency: 10 mm, 0.33 Hz). The measurements (dashed line) were made using spherical navigator echoes.

Figure A.6: a) Selected frames from a FIESTA cine sequence of a tangerine undergoing 0.33-Hz sinusoidal motion with 5-mm amplitude. b) Schematic representation of the experimental set up, where the tangerine was mounted on an extension rod away from the carriage of the stage.
Effect of the stage on image artifact, field homogeneity and SNR

The motion stage was shown not to introduce image artifacts. **Figure A.7** shows SE and GRE center-slice images of the phantom both with and without the stage, alongside the corresponding artifact image (representing variations of 30% or more); the sample images were acquired with the read direction set left-right (L/R) but the same results were obtained with the read direction flipped. The SNR measurement experiments showed that the SNR of the SE images were at 91dB and did not change with the stage present and active.

The effect of stage on $B_0$ is illustrated in **Figure A.8**, where a sagittal $\Delta B_0$ map is shown; the relative position of the phantom with respect to the stage when the images were acquired is also shown. As can be seen, the worst-case $B_0$ variation was less than 2 ppm and rapidly trailed off away from the motor.

**Figure A.7**: Representative images acquired with and without the stage present and working. The artifact images (right column) represent variations greater than 30% from baseline. Spin echo (a) and gradient recalled echo (b) images with phase encoding in the left/right direction are shown; similar results were obtained with phase encoding in the anterior/posterior direction.
Figure A.8: The sagittal view of the $\Delta B_0$ map due to the stage is shown. The dashed yellow line indicates the location of the carriage at home position. The figure also illustrates where the stage was positioned with respect to the phantom.

A.4 Discussion

In this appendix we introduced an MRI compatible linear motion stage that is actuated with an ultrasonic motor. Our results show that the motion stage is highly accurate in reaching fixed positions, with an absolute error of $0.025\pm0.021$ mm, and is highly consistent and robust in executing dynamic motion profiles with a worst case NRMSE of 7% for frequencies of 0.33Hz and below. We have also shown that the motion stage does not introduce any artifacts, preserves the $B_0$ field with an induced variation of less than 2 ppm, and maintains the SNR of the obtained images. Evaluation of the stage within a 3T MR scanner during imaging showed that the accuracy of the motion measured within the laboratory setting is maintained when used in the scanner. Cine images also confirmed that the prescribed sinusoidal motion was highly consistent with the expected motion.
The obtained results indicate that the motion stage is fully MRI compatible and can be used to create accurately controlled dynamic motion for prolonged periods directly inside the bore of the scanner. As the executed motion profiles are known a priori, and can be reproduced with high accuracy, the proposed system can be used to validate motion correction techniques and to be incorporated within MR-guided radiotherapy studies evaluating motion compensation strategies. While not specifically demonstrated in this appendix, the materials of the phantom are also fully x-ray, PET, and SPECT compatible and the stage can be used in hybrid scanners or independently.

Due to the bounded speed limits of the USM, the error in motion control increases as the speed requirements pass beyond the USM’s speed limits. As discussed earlier, the NRMSE for a frequency of 1 Hz can be as high as 30% depending on the amplitude of the motion. Therefore, desired motion profiles must be prescribed with consideration of the motor’s capabilities.

Based on the recorded encoder counts, the closed loop control system appears to track the reference signal with high accuracy and consistency. However, as was shown in Fig. 3 the profiles tracked with the optical tracking system demonstrated a small but measurable variability in successive profiles. This inconsistency suggests that the system, as implemented, was missing encoder counts. Modification of the method used to decode the optical encoder or use of an absolute encoder are expected to remove this problem and reduce the variability even further.

Using ultrasonic motors also presents another limitation, namely the maximum operating temperature (~ 45 °C) and the change in operating characteristics as the temperature increases. In the presented implementation of the motion stage, experiments
were performed for a maximum duration of 5 minutes, which is sufficient for the
majority of imaging experiments. The development of improved robust USM control
mechanism (Chapter 2) has resulted in maintenance of the accurate performance of the
device for prolonged periods; including a simple heat sink on the motor further reduces
the temperature and accurate waveforms can be generated for periods of up to an hour.

The carriage of the stage is designed to support adaptors for various applications.
This feature provides the user has the option to place phantoms of various shapes directly
on top of the carriage (e.g. Figure A.1) or carry a phantom remotely possibly inside a
torso or small coil (e.g. Figure A.6.b) or apply push/ pull on flexible phantoms.

One limitation of this system is that when the motor is very close to the isocenter
(<~20cm) it is possible that some pulse sequences (e.g. GRE with large flip angles) may
introduce extensive noise on the encoder signal line. This may result in malfunction of
the device. Addition of appropriate filters on the signal line, or the use of absolute
encoders are expected to remove this limitation. However, in such a scenario, an adapter
can be used to move the stage to a distance of approximately 20 cm from the isocenter
permitting accurate and reliable function of the device.

The presented motion stage provides a means of creating consistent and
accurately controlled motion profiles inside the scanner during imaging. The small
footprint of the stage allows arbitrary positioning and orientation of the stage and allows
moving of conventional phantoms. The system can be used for various applications that
are sensitive to motion. Examples include but are not limited to: evaluation of motion
estimation, evaluation of multimodality image registration, evaluation of tracking
accuracy and evaluation of MRI guided therapy of moving targets.
A.5 Conclusion

We have shown that the presented motion stage is MRI compatible and is capable of producing accurate and consistent motion profiles inside the scanner during imaging without introducing artifacts, inhomogeneities, or additional noise. The system provides an easy means to provide a ground truth of motion for MRI applications that are sensitive to motion.
A.6 References


# Appendix B. Permissions

## B.1 Reprint permission: Chapter 1, Figure 1.1

This is a License Agreement between Mohammad A Tavallaei ("You") and Springer ("Springer") provided by Copyright Clearance Center ("CCC"). The license consists of your order details, the terms and conditions provided by Springer, and the payment terms and conditions.

All payments must be made in full to CCC. For payment instructions, please see information listed at the bottom of this form.

<table>
<thead>
<tr>
<th>License Number</th>
<th>3621981023955</th>
</tr>
</thead>
<tbody>
<tr>
<td>License date</td>
<td>May 04, 2015</td>
</tr>
<tr>
<td>Licensed content publisher</td>
<td>Springer</td>
</tr>
<tr>
<td>Licensed content publication</td>
<td>Springer eBook</td>
</tr>
<tr>
<td>Licensed content title</td>
<td>VURITIGO: Visualization Platform for Real-Time, MRI-Guided Cardiac Electroanatomic Mapping</td>
</tr>
<tr>
<td>Licensed content author</td>
<td>Perry E. Radau</td>
</tr>
<tr>
<td>Licensed content date</td>
<td>Jan 1, 2012</td>
</tr>
<tr>
<td>Type of Use</td>
<td>Thesis/Dissertation</td>
</tr>
<tr>
<td>Portion</td>
<td>Figures</td>
</tr>
<tr>
<td>Author of this Springer article</td>
<td>No</td>
</tr>
<tr>
<td>Order reference number</td>
<td>None</td>
</tr>
<tr>
<td>Original figure numbers</td>
<td>Figure 2</td>
</tr>
<tr>
<td>Title of your thesis / dissertation</td>
<td>MAGNETIC RESONANCE IMAGING COMPATIBLE REMOTE CATHETER NAVIGATION SYSTEM</td>
</tr>
<tr>
<td>Expected completion date</td>
<td>Jul 2015</td>
</tr>
<tr>
<td>Estimated size(pages)</td>
<td>160</td>
</tr>
<tr>
<td>Total</td>
<td>0.00 CAD</td>
</tr>
</tbody>
</table>

**Terms and Conditions**

Introduction

The publisher for this copyrighted material is Springer Science + Business Media. By clicking "accept" in connection with completing this licensing transaction, you agree that the following terms and conditions apply to this transaction (along with the Billing and Payment terms and conditions established by Copyright Clearance Center, Inc. ("CCC"), at the time that you opened your Rightslink account and that are available at any time at http://myaccount.copyright.com).

Limited License

With reference to your request to reprint in your thesis material on which Springer Science and Business Media control the copyright, permission is granted, free of charge, for the use...
indicated in your enquiry.

Licenses are for one-time use only with a maximum distribution equal to the number that you identified in the licensing process.

This License includes use in an electronic form, provided its password protected or on the university's intranet or repository, including UMI (according to the definition at the Sherpa website: http://www.sherpa.ac.uk/romeo/). For any other electronic use, please contact Springer at (permissions.dordrecht@springer.com or permissions.heidelberg@springer.com).

The material can only be used for the purpose of defending your thesis limited to university-use only. If the thesis is going to be published, permission needs to be re-obtained (selecting "book/textbook" as the type of use).

Although Springer holds copyright to the material and is entitled to negotiate on rights, this license is only valid, subject to a courtesy information to the author (address is given with the article/chapter) and provided it concerns original material which does not carry references to other sources (if material in question appears with credit to another source, authorization from that source is required as well).

Permission free of charge on this occasion does not prejudice any rights we might have to charge for reproduction of our copyrighted material in the future.

Altering/Modifying Material: Not Permitted
You may not alter or modify the material in any manner. Abbreviations, additions, deletions and/or any other alterations shall be made only with prior written authorization of the author(s) and/or Springer Science + Business Media. (Please contact Springer at (permissions.dordrecht@springer.com or permissions.heidelberg@springer.com)

Reservation of Rights
Springer Science + Business Media reserves all rights not specifically granted in the combination of (i) the license details provided by you and accepted in the course of this licensing transaction, (ii) these terms and conditions and (iii) CCC's Billing and Payment terms and conditions.

Copyright Notice Disclaimer
You must include the following copyright and permission notice in connection with any reproduction of the licensed material: "Springer and the original publisher/journal title, volume, year of publication, page, chapter/article title, name(s) of author(s), figure number(s), original copyright notice) is given to the publication in which the material was originally published, by adding, with kind permission from Springer Science and Business Media" Warranties: None

Example 1: Springer Science + Business Media makes no representations or warranties with respect to the licensed material.

Example 2: Springer Science + Business Media makes no representations or warranties with respect to the licensed material and adopts on its own behalf the limitations and disclaimers established by CCC on its behalf in its Billing and Payment terms and conditions for this licensing transaction.
Indemnity
You hereby indemnify and agree to hold harmless Springer Science + Business Media and CCC, and their respective officers, directors, employees and agents, from and against any and all claims arising out of your use of the licensed material other than as specifically authorized pursuant to this license.

No Transfer of License
This license is personal to you and may not be sublicensed, assigned, or transferred by you to any other person without Springer Science + Business Media’s written permission.

No Amendment Except in Writing
This license may not be amended except in a writing signed by both parties (or, in the case of Springer Science + Business Media, by CCC on Springer Science + Business Media’s behalf).

Objection to Contrary Terms
Springer Science + Business Media hereby objects to any terms contained in any purchase order, acknowledgment, check endorsement or other writing prepared by you, which terms are inconsistent with these terms and conditions of CCC’s Billing and Payment terms and conditions. These terms and conditions, together with CCC’s Billing and Payment terms and conditions (which are incorporated herein), comprise the entire agreement between you and Springer Science + Business Media (and CCC) concerning this licensing transaction. In the event of any conflict between your obligations established by these terms and conditions and those established by CCC’s Billing and Payment terms and conditions, these terms and conditions shall control.

Jurisdiction
All disputes that may arise in connection with this present License, or the breach thereof, shall be settled exclusively by arbitration, to be held in The Netherlands, in accordance with Dutch law, and to be conducted under the Rules of the Netherlands Arbitrage Instuut (Netherlands Institute of Arbitration). OR:

All disputes that may arise in connection with this present License, or the breach thereof, shall be settled exclusively by arbitration, to be held in the Federal Republic of Germany, in accordance with German law.

Other terms and conditions:

v1.3

Questions? customercare@copyright.com or +1-855-239-3415 (toll free in the US) or +1-978-646-2777.

Gratis licenses (referencing $0 in the Total field) are free. Please retain this printable license for your reference. No payment is required.
B.2 Reprint permission: Chapter 3

Thesis / Dissertation Reuse

The IEEE does not require individuals working on a thesis to obtain a formal reuse license, however, you may print out this statement to be used as a permission grant:

Requirements to be followed when using any portion (e.g., figure, graph, table, or textual material) of an IEEE copyrighted paper in a thesis:

1) In the case of textual material (e.g., using short quotes or referring to the work within these papers) users must give full credit to the original source (author, paper, publication) followed by the IEEE copyright line © 2011 IEEE.
2) In the case of illustrations or tabular material, we require that the copyright line © [Year of original publication] IEEE appear prominently with each reprinted figure and/or table.
3) If a substantial portion of the original paper is to be used, and if you are not the senior author, also obtain the senior author's approval.

Requirements to be followed when using an entire IEEE copyrighted paper in a thesis:

1) The following IEEE copyright/credit notice should be placed prominently in the references: © [year of original publication] IEEE. Reprinted, with permission, from [author names, paper title, IEEE publication title, and month/year of publication]
2) Only the accepted version of an IEEE copyrighted paper can be used when posting the paper or your thesis on-line.
3) In placing the thesis on the author's university website, please display the following message in a prominent place on the website: In reference to IEEE copyrighted material which is used with permission in this thesis, the IEEE does not endorse any of [university/educational entity's name goes here]'s products or services. Internal or personal use of this material is permitted. If interested in reprinting/republishing IEEE copyrighted material for advertising or promotional purposes or for creating new collective works for resale or redistribution, please go to http://www.ieee.org/publications_standards/publications/rights/rights_link.html to learn how to obtain a License from RightsLink.

If applicable, University Microfilms and/or ProQuest Library, or the Archives of Canada may supply single copies of the dissertation.
Appendix C. Animal Ethics Approval

AUP Number: 2013-064
PI Name: Drangova, Maria
AUP Title: Catheter Navigation Using A Remote Navigation System To Ablate Arrhythmic Sites In A Pig Model
Approval Date: 06/02/2014

Official Notice of Animal Use Subcommittee (AUS) Approval: Your new Animal Use Protocol (AUP) entitled "Catheter Navigation Using A Remote Navigation System To Ablate Arrhythmic Sites In A Pig Model" has been APPROVED by the Animal Use Subcommittee of the University Council on Animal Care. This approval, although valid for four years, is subject to annual Protocol Renewal.2013-064::1

1. This AUP number must be indicated when ordering animals for this project.
2. Animals for other projects may not be ordered under this AUP number.
3. Purchases of animals other than through this system must be cleared through the ACVS office. Health certificates will be required.

The holder of this Animal Use Protocol is responsible to ensure that all associated safety components (biosafety, radiation safety, general laboratory safety) comply with institutional safety standards and have received all necessary approvals. Please consult directly with your institutional safety officers.

Submitted by:
on behalf of the Animal Use Subcommittee
University Council on Animal Care

The University of Western Ontario
Animal Use Subcommittee / University Council on Animal Care
Health Sciences Centre, • London, Ontario • CANADA – N6A 5C1
PH: 519-661-2111 ext. 68768 • FL 519-661-2028
Email: ausec@uwo.ca • http://www.uwo.ca/animal/website/
Curriculum Vitae

University Education

2010– Ph.D. Biomedical Engineering (in progress)
Magnetic resonance imaging compatible remote catheter navigation system
Supervisor: Maria Drangova, Ph.D.
Graduate Program in Biomedical Engineering,
Robarts Research Institute, The University of Western Ontario, London, Canada

2005–2008 M.Sc. Electrical-Control Engineering
Modeling of driver decision-making behavior
Supervisor: Sohrab Khanmohammadi, Ph.D.
Department of Control Engineering
Faculty of Electrical and Computer Engineering, Tabriz University, Tabriz, Iran

Department of Electrical Engineering,
Faculty of Engineering, Urmia University, Urmia, Iran

Scholarships, Awards and Grants

2015 13th Annual Imaging Network Ontario (ImNO) Symposium — second place poster award
2014 Regional Advisory Service Fund Award (Vital Biomedical Technologies Inc.), $5,000
2013-2014 Ontario Centres of Excellence’s (OCE’s) Market Readiness Program Grant (Vital Biomedical Technologies Inc.), $25,000
2013-2014 Ontario Graduate Scholarship (OGS), $15,000
2013-2014 Western Graduate Scholarship
2012 Imaging for Cardiovascular Therapeutics (ICT) commercialization award, (Vital Biomedical Technologies Inc.), $20,000
2012 ISMRM Student Travel Award, $600
2012 10th Annual Imaging Network Ontario (ImNO) Symposium — first place poster award
2011-2012 Graduate Thesis Research Fund Award
2011-2012 Collaborative Research and Training Program in Computer Aided Medical Interventions, $27,000
2010-2014 Western Graduate Research Scholarship
2009-2010 Ryerson Graduate Scholarship
2009-2010 Ryerson International Student Scholarship for Engineering Doctoral Students
2004 Urmia University — Merit of Distinctive Academic Achievement

Publications, Presentations and Abstracts

Patent applications

**Articles in refereed journals**


**Invited talks**


2. **M. A. Tavallaei**, M. Drangova, “MRI compatible Surgical Robots”, *Research Center for Science and Technology in Medicine (RCSTIM), Tehran University of Medical Sciences, Tehran, Iran, August 2012*.


**Conference papers and abstracts**


7. M. A. Tavallaei, Maria Drangova, “Fully MRI-Compatible Dynamic Motion stage” the 12th Imaging Network Ontario (ImNO) Symposium, Toronto, March 2014.


Work Experience

2012- ViTAL Biomedical Technologies Inc., London, ON, Canada
President/Co-founder

2011-2015 Robarts Research Institute, London, ON, Canada
Research Assistant

2009-2010 Ryerson University, Toronto, ON, Canada
Research Assistant

2008 Robotsaz, Urmia, Iran
Systems Engineer

Teaching Experience

2010-2011 The University of Western Ontario, London, ON, Canada
BME 9599 – Programming Fundamentals For Engineers– Teaching Assistant

2009-2010 Ryerson University, Toronto, ON, Canada
Mechatronics and Design – Teaching Assistant

2010 Ryerson University, Toronto, ON, Canada
Control Systems – Teaching Assistant

2008 Urmia University, Urmia, Iran
Control Systems and Design – Teaching Assistant

2008 Faragir English Language Institute, Urmia, Iran
IELTS Preparation – Teacher