Image and Haptic Guidance for Robot-Assisted Laparoscopic Surgery

by

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Abstract

Surgical removal of the prostate gland using the da Vinci surgical robot is the state of the art treatment option for organ confined prostate cancer. The da Vinci system provides excellent 3D visualization of the surgical site and improved dexterity, but it lacks haptic force feedback and subsurface tissue visualization.

The overall objective of the work done in this thesis is to augment the existing visualization tools of the da Vinci with ones that can identify the prostate boundary, critical structures, and cancerous tissue so that prostate resection can be carried out with minimal damage to the adjacent critical structures, and therefore, with minimal complications.

Towards this objective we designed and implemented a real-time image guidance system based on a robotic transrectal ultrasound (R-TRUS) platform that works in tandem with the da Vinci surgical system and tracks its surgical instruments.

In addition to ultrasound as an intrinsic imaging modality, the system was first used to bring pre-operative magnetic resonance imaging (MRI) to the operating room by registering the pre-operative MRI to the intraoperative ultrasound and displaying the MRI image at the correct physical location based on the real-time ultrasound image. Second, a method of using the R-TRUS system for tissue palpation is proposed by expanding it to be used in conjunction with a real-time strain imaging technique. Third, another system based on the R-TRUS is described for detecting dominant prostate tumors, based on a combination of features extracted from a novel multi-parametric quantitative ultrasound elastography technique.

We tested our systems in an animal study followed by human patient studies involving n = 49 patients undergoing da Vinci prostatectomy. The
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clinical studies were conducted to evaluate the feasibility of using these systems in real human procedures, and also to improve and optimize our imaging systems using patient data.

Finally, a novel force feedback control framework is presented as a solution to the lack of haptic feedback in the current clinically used surgical robots. The framework has been implemented on the da Vinci surgical system using the da Vinci Research Kit controllers and its performance has been evaluated by conducting user studies.
Preface

This thesis is written based on several published manuscripts resulting from the work done by the author and in collaboration with multiple researchers. Clinical research ethics approvals for the clinical studies conducted for this thesis were obtained from the UBC Clinical Research Ethics Board (CREB) (application numbers: H11-02267 and H08-02696).

A modified version of Chapter 2 has been published in the following publications:


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A modified version of Chapter 3 has been published as the following publications:


A modified version of Chapter 4 has been published as the following publications:


Preface


The author’s contribution in the work resulting into the above articles was: integrating the system in terms of both software and hardware components; building and conducting lab experiments; formulating and implementing the automatic registration algorithm; coordinating and conducting one animal study at Intuitive Surgical Inc. research and development labs in Sunnyvale, California; coordinating with Vancouver General Hospital (VGH) and UBC department of Urological Sciences staff to conduct the clinical studies; help writing the study clinical research ethics application; conducting the clinical studies in the robotic operating room (OR) of VGH ($n = 24$ patients); system sterilization for operating room re-use; OR data collection software writing; processing the acquired data and evaluating the results; and writing the manuscripts.

A modified version of Chapter 4 has been published as the following publications:


We are in the process of acquiring more patient data to complete the study presented in the above paper and submit the journal version of this work. The author’s contribution in the above articles was: integrating the system in terms of both software and hardware components; coordinating with Vancouver General Hospital (VGH) and UBC department of Urological Sciences staff to conduct the clinical studies; help writing the study clinical research ethics application; conducting the clinical studies in the robotic operating room (OR) of VGH ($n = 5$ patients); system sterilization for operating room re-use; OR data collection software writing; processing the acquired data and evaluating the results; and writing the manuscript.
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A modified version of Chapter 5 has been published as the following publications:


We are in the process of acquiring more patient data to complete the study presented in the MICCAI 2014 paper and submit the journal version of this work.

The author’s contribution in the above articles was: conducting the clinical studies in the robotic operating room (OR) of VGH \( n = 20 \) patients; data processing using machine learning algorithms; coordinating the research with Vancouver General Hospital (VGH) and UBC department of Urological Sciences staff to conduct the clinical studies; system sterilization for operating room re-use; evaluating the results; designing and building of the internal shaker device; and writing the manuscript.

A modified version of Chapter 6 has been published as the following publications:


The author’s contribution in the above articles was: formulating and implementing the algorithm first in Matlab simulation; implementing the idea on four haptic devices in the lab and conducting experiments with them; establishing the da Vinci research kit (dVRK) system in the lab by integrating all hardware and software components to the da Vinci Standard system; implementing the control method on the da Vinci system; software and hardware debugging and maintenance for the dVRK system; conducting user studies with the system (n = 9 users); data processing and evaluating the results; and writing the manuscript. The control algorithm and infrastructure developed by the author for this work was also used for other projects in the lab which resulted into the following publications:


A modified version of Appendix B has been published as the following publications:
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Dedication

I dedicate this work to my parents, Farzad Mohareri and Maryam Mirahmadi, for their endless love, support and encouragement.
Chapter 1

Introduction

1.1 Clinical Motivation

Prostate cancer (PCa) remains the most common solid organ malignancy in men and is responsible for more deaths than any other cancer except lung cancer. Approximately 220,800 new cases will be diagnosed and 27,540 will die from PCa in the United States in 2015 [2]. Radical prostatectomy (RP), the surgical removal of the prostate gland and surrounding tissue, is the standard-of-care option if the cancer is not thought to have spread outside the gland (stage T1 or T2 cancers). Surgical options include the traditional open RP (ORP), minimally invasive laparoscopic RP (LRP), and robot-assisted laparoscopic RP (RALRP). The RALRP procedure involves the da Vinci surgical system (Intuitive Surgical Inc., Sunnyvale, CA, USA), which provides the surgeon with enhanced three-dimensional (3-D) visualization of the surgical site and improved dexterity over standard laparoscopic instruments. The da Vinci surgical system is now used to perform as many as four out of five RP procedures in the United States[81].

Three important goals in RP are: 1) cancer control, 2) preservation of urinary continence, and 3) preservation of sexual function. Success in these goals is believed to be associated with the accurate delineation of cancerous lesions, prostate boundaries, and periprostatic anatomy such as the urethral sphincter muscle and neurovascular bundles. The difficulty in this procedure remains the fundamental tradeoff between the cancer containment goal (achieving negative margins) and the quality of life goal (sparing of critical structures).

In spite of the excellent, magnified, three-dimensional visualization, improved access and superior surgical dexterity to the operating surgeon dur-
1.2. Background

ing RALRP, there remains a distinct lack of guidance tools available for real time in-field determination of the prostate boundary and of the critical structures adjacent to it. The location of peripheral tumors and their possible extension in the proximity of such critical structures would also help identify the surgical resection planes that would provide the absolute best tradeoff between cancer containment and the sparing of critical structures. Intraoperative medical image guidance is a tool that could potentially overcome this deficiency and improve outcomes from RALRP.

1.2 Background

Transrectal ultrasound (TRUS) is the imaging modality most commonly applied for diagnostic and therapeutic purposes in PCa. Several studies have shown the potential benefits of integrating TRUS in variants of RP, including the potential improvement of positive surgical margin rates and urinary and potency functional outcomes [78, 107, 108, 110]. Ukimura et al. [108] found TRUS useful for identifying the correct plane between the bladder neck and the prostate base, and for providing visualization of any hypoechoic nodules abutting the prostate capsule. They also reported that intraoperative TRUS decreased positive surgical margin rates from 29% to 9% of the patients [110]. Van der Poel et al. [83] reported that intraoperative TRUS during RALRP significantly decreased positive surgical margin rates at the prostate base for an experienced laparoscopic surgeon who was new to the robotic procedure. The most significant limitation of all these studies is that the TRUS imaging was performed by an assistant who manually adjusted the probe during surgery. This is problematic in RALRP, because the da Vinci patient-side cart is generally located adjacent to the operating table between the stirrups that hold the patients legs, limiting the assistants access to the patient. In addition, the surgeon must guide the assistant verbally during the procedure, and their ability to coordinate effectively will strongly affect the usefulness of TRUS.

Recently, robotic TRUS manipulators have been used for real-time guidance during RALRP procedures [38, 41, 58]. Hung et al. used a robotic
1.2. Background

TRUS manipulator (ViKY system, EndoControl medical, Grenoble, France) for real-time monitoring of the prostate and periprostatic anatomy. They showed that using robotic TRUS is feasible and safe, and it provided the surgeon with valuable anatomic information [41]. Long et al. used the same TRUS robot to visualize real-time bladder neck dissection, NVB release and apical dissection [58]. They showed that using robotic TRUS resulted in no positive surgical margins in five patients. Han et al. used their custom-made robotic TRUS manipulator for improved visualization of the NVB. This study demonstrated that the prostate can be safely scanned using the TRUS robot, to reconstruct the 3D images of the prostate gland and adjacent NVB, and the intra-abdominal da Vinci instruments can be clearly visualized in the TRUS images [38].

In previous in-vivo studies, the TRUS manipulators have not been registered to the da Vinci robot or camera, and therefore the ultrasound image could not be presented at the correct location in space relative to the console view or the da Vinci instruments. The control of the TRUS image location from within the da Vinci console has also not been demonstrated before in in-vivo studies.

The work presented in this thesis is towards using a robotic TRUS system that has been integrated to the da Vinci surgical system in order to provide intuitive image guidance to the robotic surgeon. We present the robotic TRUS system and details of its clinical integration and studies.

Our hypothesis is that advanced trans-rectal ultrasound imaging can be deployed and used easily during surgery, can be registered to the robot coordinate systems with high accuracy, and can be controlled from the surgeons console, in order to improve the visualization of the prostate and peri-prostatic anatomy, and in order to produce a cancer probability map that can be used to make decisions on surgical margins. In addition to ultrasound imaging as an intrinsic imaging modality, ultrasound can also be used to bring in pre-operative magnetic resonance imaging (MRI) to the operating room by registering the pre-operative MRI to the intra-operative ultrasound and displaying the MRI image at the correct physical location based on the real-time ultrasound image.
1.3 Thesis Outline and Contributions

This thesis covers the background literature related to ultrasound and haptic guidance systems for robot-assisted surgery, the proposed system design, algorithms, and the validation results on phantom as well as in animal and human subjects. The summary of the thesis outline is illustrated in Figure 1.1. A detailed outline of the thesis is as follows:

Chapter 2: Intraoperative Transrectal Ultrasound Guidance for Robot-Assisted Laparoscopic Prostatectomy  This chapter describes the robotic TRUS guidance system, intraoperative TRUS to da Vinci surgical system registration, system integration for in-vivo animal and human clinical studies, details and protocol of the clinical studies, study outcome data analysis and evaluation of the results.

Chapter 3: A System for MR-Guidance During Robot-Assisted Laparoscopic Radical Prostatectomy  This chapter explains the extension of the robotic TRUS system explained in Chapter 2 to be used for MRI guidance during da Vinci prostatectomy. The outline of the approaches used and our experience with the system in the first two patients are described here.

Chapter 4: Automatic 3-D Transrectal Ultrasound to the da Vinci Surgical System Registration  This chapter describes a technique for automatic instrument localization in 3D TRUS, automatic registration experiments using the proposed method (tissue phantoms, ex-vivo and in-vivo), registration accuracy analysis, system integration, evaluation of the results and discussion of the limitations.

Chapter 5: Tracked Robotic Ultrasound Palpation  This chapter describes a method of using ultrasound imaging for tissue palpation using a robotic ultrasound system that can track a surgical instrument. The method is implemented both on our robotic TRUS system and on the da
1.3. Thesis Outline and Contributions

Vinci system with a robotic drop-in ultrasound system. Details of the proposed remote palpation technique, its implementation, experimental results on phantom, ex-vivo and clinical human studies are explained in this chapter.

Chapter 6: Multi-parametric 3D Quantitative Ultrasound Vibro-Elastography Imaging for Detecting Palpable Prostate Tumors
This chapter describes a system for detecting dominant prostate tumors, based on a combination of features extracted from a novel multi-parametric quantitative ultrasound elastography technique. The quantitative elastography data acquisition system used to perform this study is built on top of the robotic TRUS system explained in chapter 2. This chapter will also explain the details of our data collection in the operating room on 10 patients, as well as a description of a proposed technique to integrate this system into the da Vinci surgical system.

Chapter 7: A Novel Force Feedback Control Structure for Robot-Assisted Laparoscopic Surgery
This chapter describes a novel force feedback control framework to potentially enable haptic force feedback for two-handed tasks in teleoperated robot-assisted surgery. Details of the proposed control framework, the da Vinci Research Kit (dVRK) system integration in UBC RCL lab, implementation of the force feedback control structure on the dVRK system and user studies to evaluate the system.

Chapter 8: Conclusion
This chapter summarizes the goals, results and contribution of the research, discusses potential applications of the results, and also suggests possible future directions for improving the work presented in the thesis.

Appendix A: Semi-Autonomous Ultrasound Guidance During Robot-Assisted Laparoscopic Surgery
This chapter describes a semi-autonomous robotic ultrasound guidance system for robot-assisted laparoscopic surgery,
implemented on the da Vinci® surgical system using the dVRK system and a drop-in robotic ultrasound system.

Appendix B: Clinical Study Protocols  This chapter describes the details of the protocols of the clinical studies performed in this work.
1.3. Thesis Outline and Contributions

Figure 1.1: Thesis outline.
Chapter 2

Intraoperative Transrectal Ultrasound Guidance for Robot-Assisted Laparoscopic Prostatectomy

2.1 Introduction

Robot-assisted laparoscopic radical prostatectomy (RALRP) using the da Vinci Surgical System is now used to perform more than 80% of radical prostatectomies in the United States [81]. While RALRP has enhanced the visualization and dexterity over standard laparoscopic procedures, achievement of the 3 main procedure outcomes of cancer control, urinary control and sexual function is still highly dependent on the surgeons intraoperative knowledge of prostate anatomy. It can be challenging for the surgeon to accurately identify critical structures such as the bladder neck, the neurovascular bundles and the apical prostate solely using visual cues provided by the da Vinci stereo vision system. Intraoperative imaging may aid surgeons in localizing these structures.

Transrectal ultrasound is the most common modality for imaging the prostate and is easy to integrate in a standard operating room. To be useful the TRUS transducer must be positioned and controlled by the surgeon in an intuitive way, and its images should be displayed at the correct location relative to the da Vinci vision system and instruments.

Starting with the pioneering study by Ukimura et al. [108], research has
shown the potential benefits of integrating TRUS into variants of RP, including the potential improvement in positive surgical margin rates, and urinary and potency functional outcomes [78, 83, 107, 110]. Recently robotic TRUS systems have been used for real-time guidance during RALRP [38, 41, 58]. Hung et al. used a TRUS robot (ViKY®) for real-time monitoring of the prostate in a 10-patient trial [41]. Long et al. used the same TRUS robot to visualize real-time bladder neck dissection, NVB release and apical dissection in a 5-patient study [58]. Han et al. used a custom-made robotic TRUS manipulator for improved visualization of the prostate gland, the surgical instruments and the NVB in 3 patients [38]. In all previous studies the TRUS manipulators have required manual readjustment using an additional custom-made device such as a joystick or a foot pedal. Furthermore, 3D TRUS was not registered to the da Vinci surgical system’s coordinate frames and hence, using 3D TRUS was not easy to interpret for the surgeon at the da Vinci console. Methods for registration of 3D ultrasound to the da Vinci surgical system has been previously described by a few research groups focusing on fusion of 3D ultrasound with stereoscopic video. Such methods were mainly based on electromagnetic (EM) or optical tracking systems [19, 98]. Cheng et al also described a method based on photo-acoustic markers to register da Vinci camera to 3D ultrasound [18]. While such previous works show successful and accurate registration methods, there exist no evidence of their clinical feasibility.

In this chapter we describe a robotic TRUS guidance system calibrated to and controlled by the da Vinci Surgical System along with it’s first clinical applications. We also present a rapid and clinically feasible, intraoperative registration technique to calibrate 3D ultrasound to the da Vinci surgical instrument. The clinical study is a phase I-II clinical study showing that registered robotic TRUS imaging can be deployed and used easily and safely during surgery with a short setup time, and that TRUS imaging can be controlled in the registered coordinate system directly from within the surgeon console. (Clinical trial registration: www.ClinicalTrials.gov identifier: NCT02001597.)
2.2. Materials and Methods

2.2.1 TRUS Robot

Our research group recently presented a robotic system for TRUS imaging based on a modified brachytherapy stepper (Micro-Touch® 610-911)\cite{4}. The robot has three degrees of freedom and is designed compact enough to fit under the da Vinci patient side manipulators. This system, shown in Figure \ref{fig:trus_robot}, was used for automatic and remote rotation (angle range $\pm 45$ degrees) of the TRUS transducer during the procedure. The insertion depth of the transducer (insertion range $\pm 60$ mm) was also remotely controlled but only manually, and it was limited to $\pm 20$ mm with a velocity of 0.5 mm per second for safety during the human patient clinical studies. Ultrasound images (2-dimensional) were captured using a Sonix ultrasound machine with a sagittal/transverse biplane TRUS transducer (Ultrasonix Medical Corp., Richmond, British Columbia, Canada). Ultrasound volumes were acquired by rotating the TRUS transducer about its long axis and collecting the 2-dimensional sagittal images at each angle increment. Software running on the ultrasound console was responsible for directing the robot movements, ultrasound data acquisition and image processing.
2.2. Materials and Methods

2.2.2 TRUS Robot Calibration to the da Vinci

We also recently described a method for using the TRUS robot to automatically track the da Vinci surgical instruments with the TRUS imaging plane [3]. This tracking allows the surgeon to control the TRUS imaging plane automatically with the tip of a da Vinci surgical instrument. The tracking method is based on a rigid registration of the kinematic frames of the da Vinci surgical manipulators and the robotic TRUS probe manipulator. This rigid registration can be accomplished by defining points on a tissue surface (i.e., a boundary between air and tissue) in both coordinate frames. This requires the ability to localize surgical tool tips accurately in the 3-D TRUS data, since the da Vinci Application Programming Interface (API) [22] can be used to provide the locations of the tool tips in the da Vinci kinematic frame. A schematic of the approach and the prostate anatomy during RALRP is shown in Figure 2.2. In our implementations of the registration method, da Vinci instrument tips have been localized manually in the 3-D TRUS volumes. The approach requires the surgeon to press the tip of a da Vinci instrument (EndoWrist monopolar curved scissors) against the anterior surface of the prostate at 4 locations (Figure 2.3 and Figure 2.2). At each location the TRUS transducer was manually and remotely rotated, using a hand controller, to find the angle giving the highest intensity tool tip artifact in the B-mode image plane. Then the tool tip axial and lateral coordinates were selected in this ultrasound plane. This process involves scrolling through two-dimensional (2-D) slices of the volume, finding the 2-D slice that appears to contain the tool tip and selecting the approximate tip of each fiducial using a mouse. Chapter 3 will describes a method for automatic da Vinci instrument tip localization in 3-D TRUS which is more clinically realistic, since it would be less disruptive to the surgical workflow.

The transformation relating the da Vinci coordinate system to that of the TRUS was computed by identifying the 4 tool tip locations with respect to the TRUS and da Vinci coordinate systems [65]. The 3-dimensional location of the da Vinci instrument tip was streamed out from the da Vinci system using its Application Programming Interface [22], with a reported accuracy.
2.2. Materials and Methods

Figure 2.2: (a) TRUS to da Vinci instrument calibration concept. (b) automatic instrument tip tracking in action. (c) robotic TRUS to da Vinci instrument calibration and automatic tracking concepts. Registration is performed between da Vinci instrument tip coordinate frame and robotic TRUS coordinate frame. After registration TRUS sagittal image automatically follows da Vinci instrument tip.
2.3. In-vivo Studies

This section describes the initial clinical evaluation of our ultrasound-based guidance system for RALRP procedure. Both the TRUS robot system and the calibration technique were tested and validated in lab experiments using tissue phantoms before starting the clinical tests. Some of the phantom study results were published in [3] and some will be explained in Chapter 3.

better than 2 mm [53]. This 3-dimensional location provided the angle necessary to rotate the TRUS transducer to automatically track the tip of the da Vinci instrument with the sagittal imaging plane (Figure 2.2). Thus, the surgeon at the console controlled the location of the TRUS imaging plane simply by moving the robotic instrument around, as if the TRUS image was dragged to a given angle by the da Vinci instrument tip.

Figure 2.3: (a) da Vinci instrument tip pressed at 4 locations across anterior surface of prostate for TRUS to da Vinci instrument calibration. (c) da Vinci scissor tips visible as hyperechoic focal point in B-mode images. Yellow arrows indicate location of instrument tip.
2.3. In-vivo Studies

2.3.1 Canine Study

Before starting the human patient clinical studies, we validated our methods in a canine study approved by IACUC (Institutional Animal Care and Use Committee) at Intuitive Surgical Inc. clinical research labs in Sunnyvale, California.

Brief Research on the Animal Model

A live anesthetised animal is the most realistic, non-patient environment that has been utilized for decades as a method of educating, developing, and refining complex surgical techniques. Despite some anatomical differences with the urinary tracts of humans, the porcine and canine model are the most often used for various urologic procedures in the kidney, urethra, bladder, prostate and bowel [33]. The canine model is more often used for prostate surgery. The small and narrow pelvis in the canine model is an ideal environment to practice radical prostatectomy and robot-assisted laparoscopic radical prostatectomy and it had been used in various related studies and developments [32, 54, 85]. Canine neurovascular anatomy resembles that of humans and it is a suitable model in which to assess prostatectomy related erectile dysfunction. However, key differences, including the absence of discernible seminal vesicles, lateral placement of the pelvic plexus, the laterally placed dominant cavernous nerves and the circumferential urethral distribution of cavernous nerves at the prostatic apex, must be considered during radical prostatectomy studies using the canine model [33]. According to the above brief review, the canine model seems to be the best model for evaluation of our ultrasound-based image guidance system for da Vinci robot-assisted laparoscopic radical prostatectomy. TRUS imaging of the canine prostate has been done in various studies such as [29, 42]. These previous studies show the feasibility of inserting the TRUS probe into the dogs rectum and imaging its prostate.
2.3. In-vivo Studies

Study Description

A 10-month-old male hound weighing 27 kg was used in this study. Following a lower bowel prep, the live anaesthetized animal was placed on the OR table in a 40-degree Trendelenburg position. Before docking the da Vinci surgical robot, the TRUS robot was attached to the OR table using the MicroTouch Brachytherapy stabilizer passive arm (CIVCO Medical Solutions, Kalona, IA), which was adjusted for the TRUS to provide optimal transversal and sagittal images of the animal’s prostate as done in standard brachytherapy procedures (Figure 2.4). A Sonix TABLET ultrasound machine (Ultrasonix Medical Corp., Richmond, BC) with a bi-plane TRUS transducer was used for imaging. All TRUS volumes were captured using the 128-element 55 mm long linear BPL9-5/55 array with transmit frequency of 6.6 MHz and

Figure 2.4: The clinical setup and TRUS images of the canine’s prostate: (a) TRUS robot attached to the OR table in Trendelenburg position with the da Vinci robot docked to the table and da Vinci ports are placed as in RALRP. (b) Sagittal plane TRUS image of the prostate at elevational depth of 4 cm. (c) Transverse plane TRUS image.
2.3. In-vivo Studies

imaging depth of 4.0 cm. They were acquired using an 80-degree rotary sweep about the probe axis, and contained 220 images at increments of 0.36 degrees. Image capture time was 8.8 seconds per volume. The surgeons placed the da Vinci ports in the recommended pattern for RALRP, taking into consideration the smaller size of the canine model. Three arms were used for the procedure, with a Large Needle Driver, Prograsp and Maryland Bi-polar forceps in the right, left and third arm respectively. A 12 mm 0-degree stereo endoscope (3.8 mm disparity) was used throughout the procedure. TilePro™ was used in order for the surgeon to see the ultrasound image in the da Vinci console while performing the surgery. The surgeon continued with the RALRP procedure, with the TRUS transducer in position, until the anterior surface of the prostate was visible in the stereo camera. A complete description of the animal study protocol is included in Appendix B.

Registration Experiments and Results

The surgeon was asked to press the tool tip of a da Vinci instrument against the prostate surface while a full TRUS volume was being acquired (Figure 2.5). The tool tip is visible as a hyperechoic focal point in the B-Mode image. To manually find the tool tip, first the angle of the TRUS imaging plane is selected. Then the tool tip axial and lateral coordinates are selected in this plane. The tip location relative to the TRUS coordinate system is obtained by transforming these cylindrical coordinates to Cartesian ones. The tool tip location relative to the robot coordinate system is also known from the Research API provided by Intuitive Surgical, providing three constraint equations for the homogeneous transformation relating the da Vinci coordinate system to that of the TRUS. Multiple constraints are obtained by repeating the process. \( N = 12 \) different target locations and corresponding volumes were acquired. For \( n = 100 \) iterations, \( N_f = 4 \) point pairs were picked at random and a least squares problem was solved to find the registration homogeneous transformation. The remaining \( N_t = N - N_f = 8 \)
2.3. In-vivo Studies

Table 2.1: 3D TRUS to da Vinci surgical tool registration accuracy (Manual tool tip localization in 3D TRUS). TRE and FRE are calculated for \((n = 100)\) iterations, \((N_f = 4)\) tool tip points and \((N_t = 8)\) target points with 4 manual tool tip localization trials performed by 4 different users.

<table>
<thead>
<tr>
<th></th>
<th>(TRE_{A-P}) (mm)</th>
<th>(TRE_{S-I}) (mm)</th>
<th>(TRE_{M-L}) (mm)</th>
<th>Mean TRE (mm)</th>
<th>Mean FRE (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S 1</td>
<td>1.96 ± 1.04</td>
<td>1.66 ± 0.54</td>
<td>1.78 ± 0.85</td>
<td>1.86 ± 0.80</td>
<td>0.86 ± 0.44</td>
</tr>
<tr>
<td>S 2</td>
<td>1.93 ± 0.52</td>
<td>1.62 ± 0.58</td>
<td>1.72 ± 0.70</td>
<td>1.76 ± 0.61</td>
<td>0.97 ± 0.97</td>
</tr>
<tr>
<td>S 3</td>
<td>1.94 ± 1.09</td>
<td>1.67 ± 0.99</td>
<td>1.80 ± 0.92</td>
<td>1.81 ± 0.99</td>
<td>0.91 ± 0.35</td>
</tr>
<tr>
<td>S 4</td>
<td>2.19 ± 1.31</td>
<td>2.07 ± 1.17</td>
<td>2.07 ± 0.97</td>
<td>2.11 ± 1.15</td>
<td>1.02 ± 0.38</td>
</tr>
<tr>
<td>Average</td>
<td>2.01 ± 0.99</td>
<td>1.75 ± 0.82</td>
<td>1.84 ± 0.86</td>
<td>1.88 ± 0.88</td>
<td>0.94 ± 0.54</td>
</tr>
</tbody>
</table>

Target locations were used to calculate the TRE, defined as the error between the location of the tool tips and the transformed points from the ultrasound volumes. To determine the inter-subject variation (ISV) in fiducial localization and analyze its effect on TRE, four different ultrasound users were asked to localize the tool tip in each of the \(N = 12\) B-mode TRUS volumes we acquired. The TRE and Fiducial Registration Errors (FRE) in all three anatomical directions and RMS values for each user, as well as the mean over all users, are reported in Table 2.1.

Table 2.1 lists the mean values for TRE and FRE during TRUS robot to da Vinci instrument registration. A total of 12 TRUS volumes and da Vinci API point-pairs were collected. Errors are represented in the anatomical frame of the patient (Anterior-Posterior (AP), Superior-Inferior (SI), Medial-Lateral (ML)). Mean values of FRE and TRE and their standard deviations were calculated for each combination of \((N_t,N_f)\) for 100 itera-
2.3. In-vivo Studies

Figure 2.5: (a) Camera image of the surgical site through the da Vinci console and spatial locations of the instrument tips scattered on the surface of the prostate. (b) The da Vinci instrument tip locations were spread on the surface of the prostate to achieve an accurate registration across the entire prostate gland. (c) US images of the da Vinci instrument tip pressed on the anterior prostate surface at different points.
2.3. In-vivo Studies

Figure 2.6: TRE and FRE values for different number of tool tip points used for registration. As the number of fiducials increase, TRE decreases. We suggest using 6 fiducials in clinical applications.

Table 2.2: Automatic da Vinci tool tip tracking accuracy.

<table>
<thead>
<tr>
<th></th>
<th>Tracking error (deg)</th>
<th>Mean TRE (mm)</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration Trial 1</td>
<td>1.47 ± 0.83</td>
<td>1.78 ± 0.65</td>
<td>120s</td>
</tr>
<tr>
<td>Registration Trial 2</td>
<td>1.63 ± 1.22</td>
<td>2.00 ± 1.04</td>
<td>90s</td>
</tr>
<tr>
<td>Registration Trial 3</td>
<td>1.95 ± 1.28</td>
<td>2.11 ± 1.17</td>
<td>111s</td>
</tr>
<tr>
<td>Registration Trial 4</td>
<td>1.58 ± 1.63</td>
<td>1.83 ± 0.76</td>
<td>64s</td>
</tr>
<tr>
<td>Average</td>
<td>1.65 ± 1.24</td>
<td>1.93 ± 0.90</td>
<td>96s</td>
</tr>
</tbody>
</table>

As can be seen from this figure, as $N_f$ increases, both the mean and the standard deviation of the TRE decreases. Based on this analysis, the number of fiducials suggested for this registration is $N_f = 6$.

Registration Timing:

To determine the ease with which the above registrations can be performed, we asked the surgeon to perform four timed registrations using four registration points each. For each registration point, the tool tip location was
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found manually in the ultrasound volume. Often the surgeon would gently
move the tool tip to confirm the correct tool tip location. After each regis-
tration, the automatic tracking was activated and the surgeon was asked to
move the tool tip to an additional 10 points on the surface of the prostate.
For each location, the corresponding TRUS angle was recorded, then the
tracking was temporarily deactivated and the points were located manually
by adjusting the TRUS angle. The error in this measurement is shown in
Table 2.2.

The tracking accuracy for the four timed registration trials are reported
in Table 2.2. TRE values were also calculated for each registration. All
registrations were completed in under 2 minutes with an average registra-
tion time of 96 seconds. Throughout the registration experiments and the
surgery, TRUS images were streamed into the da Vinci console for real-time
guidance. Figure 2.7 shows the TilePro™and camera images inside the da
Vinci console, when the automatic tool tracking is activated and the TRUS
image follows the da Vinci tool tip.

2.3.2 Discussion of the Results

In this set of experiments, we tested and validated the intraoperative use of
a robotic TRUS manipulator for RALRP procedures. The TRUS robot is

![Figure 2.7: TilePro™images inside the surgeon console while the automatic
tool tracking is activated. The da Vinci instrument tip is visible in both
camera and ultrasound images.](image-url)
based on a small modification to a standard brachytherapy stabilizer which is available in almost any hospital where brachytherapy is performed. Hospital staff are familiar with the set-up and positioning of the transducer on the stabilizer with respect to the patient.

During the TRUS to da Vinci tool registration, a TRE of $1.88 \pm 0.88$ mm was achieved. This is on par with the results from [5] when using a PVC prostate phantom. It is pointed out by Ukimura et al. [109] that the mean distance between the NVB and the lateral edge of the prostate ranged from $1.9 \pm 0.8$ mm at the prostate apex, to $2.5 \pm 0.8$ mm at the base. This is suggestive of the required accuracy of a guidance system since one major aspect of the system is to accurately localize the NVB. Currently the error in our TRUS to camera registration is slightly larger, but the error between the da Vinci tools and the TRUS is within the range reported in [109].

For this registration approach, some of the registration error may also be due to the limited localization accuracy of the fiducials within the US images. While subjects were instructed on the best way of picking the fiducial edges as described in [36], they had higher variance in localizing the fiducials than the automatic method. The use of an automated algorithm would also mean that no additional personnel would be needed in the OR in order for the tracking to be activated. For the TRUS to da Vinci tool registration error, another contributing factor is the tool tip localization error from the da Vinci API, which has been reported to be within 2mm. Another source of error is instrument shaft deflection, as pointed out in [100].

Timing results have shown that the da Vinci instrument to TRUS registration could be completed very quickly and would be valid throughout the surgery since neither the TRUS nor the da Vinci coordinate systems will be moving. We determined that using six tool tip positions gives the best TRE with minimal added benefit derived from further measurements. This would increase registration time by approximately 20 seconds. Camera to TRUS registration tools should be similar, not counting the time required for camera calibration.

Although the canine model was chosen, there are key differences from humans which actually made the study somewhat more difficult. Positioning
with a human patient does not usually put extensive pressure on the distal end of the transducer, but in the canine case, there was a larger amount of force on the transducer which could cause errors in TRUS rotation during TRUS volume acquisition and also in fiducial localization in TRUS images.

2.3.3 Animal Study Conclusions

We have presented the validation of our intraoperative registration method that can be used during RALRP for image guidance and surgical navigation. Using the kinematics of the robot, we were able to register the da Vinci coordinate system with that of the TRUS robot. This was achieved quickly and efficiently with surgeons new to this concept. All registration errors were within the scope of the clinical setting and the constraints of the ultrasound imaging system. Surgeons even suggested approaches on how to distribute the registration points (2 points at the prostate base, 2 points at mid-gland and 2 points at the apex) to make the process more efficient and maintain registration accuracy across the prostate. We have demonstrated that these registration methods work effectively in an in-vivo environment. The da Vinci kinematic registration was ready for clinical testing after this set of experiments and we submitted our application to human ethics and started patient studies.

2.4 Human Patient Studies

After an evaluation in a canine model and approval of our clinical research ethics application (H11-02267), 20 patients were enrolled in a clinical study.

2.4.1 Patient Population

A total of 20 patients with clinically organ confined prostate cancer undergoing RALRP at our institution agreed to participate in this study between March and November 2013. Median patient age was 63 years (range 52 to 70) and median baseline prostate specific antigen was 5.9 ng/ml (range 0.84 to 36.4). Patient demographic and preoperative data are listed in Table 2.3.
2.4. Human Patient Studies

The study was approved by the University of British Columbia Clinical Research Ethics Board.

Table 2.3: Demographic and preoperative data.

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years ; median (range)</td>
<td>63 (52-67)</td>
</tr>
<tr>
<td>Preoperative PSA, ng/ml ; median (range)</td>
<td>5.9 (0.84-36.4)</td>
</tr>
<tr>
<td>Preoperative Gleason score (index lesion), no. (%)</td>
<td></td>
</tr>
<tr>
<td>3+3=6</td>
<td>5 (25)</td>
</tr>
<tr>
<td>3+4=7</td>
<td>8 (40)</td>
</tr>
<tr>
<td>4+3=7</td>
<td>2 (10)</td>
</tr>
<tr>
<td>4+4=8</td>
<td>2 (10)</td>
</tr>
<tr>
<td>3+5=8</td>
<td>1 (5)</td>
</tr>
<tr>
<td>4+5=9</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Clinical stage, no. (%)</td>
<td></td>
</tr>
<tr>
<td>T1c</td>
<td>8 (40)</td>
</tr>
<tr>
<td>T2a</td>
<td>5 (25)</td>
</tr>
<tr>
<td>T2b</td>
<td>3 (15)</td>
</tr>
<tr>
<td>T3a</td>
<td>3 (15)</td>
</tr>
<tr>
<td>T3b</td>
<td>1 (5)</td>
</tr>
<tr>
<td>IPSS value ; median (range)</td>
<td>7 (1-24)</td>
</tr>
<tr>
<td>Prostate volume, cc ; median (range)</td>
<td>33.5 (11-55)</td>
</tr>
<tr>
<td>Nerve sparing plan, no. (%)</td>
<td></td>
</tr>
<tr>
<td>Bilateral nerve sparing</td>
<td>10 (50)</td>
</tr>
<tr>
<td>Unilateral nerve sparing</td>
<td>8 (40)</td>
</tr>
<tr>
<td>No nerve sparing</td>
<td>2 (10)</td>
</tr>
</tbody>
</table>

PSA: Prostate-Specific Antigen ; IPSS: International Prostate Symptom Score

2.4.2 Procedure Description

Two surgeons performed the procedures for this study using a da Vinci S system. All patients undergoing robotic prostatectomy received a Fleet (R) enema the evening before the surgery. Our robotic TRUS system was attached to the foot of the operating table and was placed to provide optimal transverse/sagittal images of the prostate as in standard brachytherapy.
2.4. Human Patient Studies

prostate volume studies. The TRUS sagittal plane was placed underneath the prostate midline so that the prostate could be imaged from the base to the apex. The system configuration setup inside the OR and during the procedure are shown in Figure 2.9 and Figure 2.8. In the majority of cases, standard dissection of the retropubic space was performed until the anterior surface of the prostate was visible to the surgeon and the endopelvic fascia incised. In a few early cases the Montsouris approach (initial posterior dissection of the prostate and seminal vesicles) was used, with some negative effects on subsequent TRUS image quality due to insufflation gas posterior to the prostate.

The calibration procedure was performed at this stage with the 4 in-
2.4. Human Patient Studies

Instrument tip locations spread across both sides of the dorsal prostate. The automatic TRUS tracking of the da Vinci working instrument tip was enabled and used during several points of the procedure, including transecting the anterior and posterior bladder neck, lifting the prostate off the rectum and dissecting the prostatic apex. In selected cases the TRUS robot was also used for placement of the suture through the DVC, and for identification of the NVBs and seminal vesicles. As in the canine study we used TilePro™ to display real-time TRUS images on the da Vinci console.

The primary aim of this study was to investigate the feasibility and safety of real-time TRUS tracking and imaging in RALRP. The secondary aim was to investigate whether the surgeons found this technology useful at critical stages of RALRP.

2.4.3 Results

Intraoperative TRUS with automatic tracking was performed successfully in all 20 patients and there were no complications related to the addition of this procedure. We did not note any postoperative complications, including infection. Specifically, patients did not complain of anal pain or bleeding. The TRUS transducer was in a condom with ultrasound coupling gel and it was free to rotate without resistance.

The set-up of the TRUS robot at the foot of the bed was performed in a median of 7 minutes (range 5 to 14) with minimal delay to the start of surgery. Indeed the TRUS robot could be positioned while the anesthesiologists gained additional vascular access and the patient was secured to the table with arms tucked. The calibration process was performed after incision of the endopelvic fascia and could be completed in approximately 2 minutes. Table 2.4 lists the critical steps in RALRP where we judged the TRUS images to be useful. At each step it was noted whether the surgeon used or commented on the real-time TRUS images.

At the anterior bladder neck TRUS images can be helpful in confirming the plane of dissection between the bladder and the prostate (Figure 2.10). Experienced surgeons use the shape of the prostate and the distinctive ap-
2.4. Human Patient Studies

Figure 2.9: (a) TRUS robot attached to operating table in Trendelenburg position. (b) TRUS transducer and robot attached to foot of operating table using Micro-Touch brachytherapy stabilizer passive arm. (c) OR setup of TRUS robot and da Vinci system.
2.4. Human Patient Studies

Table 2.4: Intraoperative TRUS results.

<table>
<thead>
<tr>
<th>Task</th>
<th>Count/Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setup time for TRUS robot, min; median (range)</td>
<td>7 (5-14)</td>
</tr>
<tr>
<td>TRUS to da Vinci calibration time, sec; median (range)</td>
<td>120 (110-214)</td>
</tr>
<tr>
<td>No. of cases in which TRUS was found helpful in:</td>
<td></td>
</tr>
<tr>
<td>DVC suture</td>
<td>2 of 20 (10%)</td>
</tr>
<tr>
<td>Anterior bladder-neck dissection</td>
<td>15 of 20 (75%)</td>
</tr>
<tr>
<td>Posterior bladder-neck dissection</td>
<td>13 of 20 (65%)</td>
</tr>
<tr>
<td>Seminal vesicle removal</td>
<td>9 of 20 (45%)</td>
</tr>
<tr>
<td>Close to rectal wall</td>
<td>10 of 20 (50%)</td>
</tr>
<tr>
<td>NVB preservation</td>
<td>1 of 20 (5%)</td>
</tr>
<tr>
<td>Apical dissection</td>
<td>13 of 20 (65%)</td>
</tr>
<tr>
<td>No. of intraoperative complications</td>
<td>0</td>
</tr>
<tr>
<td>Surgical margins¹, no. (%)</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>17 (85)</td>
</tr>
<tr>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td>2mm left anterior</td>
<td>1 (5)</td>
</tr>
<tr>
<td>2mm right posterior</td>
<td>1 (5)</td>
</tr>
<tr>
<td>2.3mm right inferior and apex</td>
<td>1 (5)</td>
</tr>
</tbody>
</table>

¹TRUS was used for all of the listed tasks during each case, but it was noted useful by the surgeon in the specified number of cases.

Appearance of the relatively bloodless plane as the detrusor muscle fibers dissect off the prostate. This is one of the key steps in the learning curve of this procedure that may be accelerated with TRUS images. The TRUS robot also facilitates bladder neck transection by allowing early recognition of an intravesical median lobe.

The posterior bladder neck is a common site of positive margins as it can be difficult to accurately dissect a plane that stays out of the prostate and avoids buttonholing the bladder [9]. In Figure 2.10b, the base of the prostate is clearly delineated and the surgeon can be seen dissecting toward the seminal vesicles.

TRUS imaging may be helpful in ascertaining the extent of the dissection required to reach the tips of the seminal vesicles (Figure 2.11). If the seminal vesicles are dissected out from a posterior access before dropping the bladder.
2.4. Human Patient Studies

Figure 2.10: TRUS use at anterior (A) and posterior (B) bladder neck dissection. Yellow arrows indicate location of instrument tip.
from the anterior abdominal wall, the insufflation gas space that is created impairs subsequent TRUS imaging of the bladder neck.

One of the rare but major potential complications of RP is rectal injury that is usually the result of a difficult posterior dissection. If there is residual inflammation or there are adhesions from the prostate biopsy, for example, the anterior wall of the rectum can easily be drawn up with the anterior retraction of the prostate. With the TRUS robot automatically tracking the tip of the surgeons operating instrument, the rectal wall can be easily visualized. In Figure 2.12(a) the rectum can be seen being tented up, and the plane between the rectum and the prostate is clearly demarcated.

In open RP and RALRP it can be difficult to assess the distal-most extent of the prostatic apex, especially posteriorly, and this is a common site of positive surgical margins [95]. TRUS imaging seems promising in delineating the prostatic apex. For example, in Figure 2.12(b) the hyperechoic tip of the scissors can be seen dissecting just beyond the prostatic apex while preserving the maximal amount of urethra.
2.4. Human Patient Studies

Figure 2.12: TRUS use in dissection at rectal wall (A) and DVC suture (B). Yellow arrows indicate location of instrument tip.
2.4. Human Patient Studies

Figure 2.13(a) shows the NVBs running along the posterior lateral aspect of the prostate close to the rectum, visualized by TRUS in color Doppler mode. After removal of the specimen, preservation of the NVBs could be verified using color Doppler in appropriate cases (Figure 2.13(b)).

2.4.4 Discussion

We have demonstrated for the first time in patients an intraoperative robotic TRUS system that precisely tracks the movements of the da Vinci instruments with an accuracy of the same order as the da Vinci robot instrument positioning. This system takes little time to install, is easy to use and is potentially helpful to surgeons in completing specific steps of the surgery, as noted in Table 2.4.

A concern before the study was that the TRUS probe would push the rectum anteriorly and into the surgical field, thereby narrowing the space around the prostate and compromising instrument maneuverability, as well as increasing the risk of rectal injury. However, by keeping the TRUS probe parallel to the operating bed, the presence of the TRUS probe in the rectum was not even noticeable to the surgeon and did not interfere with any part of the prostatectomy.

Some surgeons use the Montsouris approach to RALRP, which involves posterior dissection of the prostate and seminal vesicles before dissecting the space of Retzius and the prostate anteriorly [35]. We found that this technique introduced gas into the space posterior to the prostate and interfered with optimal TRUS image quality for subsequent stages of the procedure. However, we found it particularly easy with ultrasound guidance to make the transition from routinely using the Montsouris approach to an anterior approach, as the ultrasound clearly delineated the bladder neck and the underlying seminal vesicles.

While the use of the TilePro™ feature did reduce the main video image size, it only needed to be on during brief TRUS imaging sessions, at points in the procedure when the anatomy needed to be confirmed.

The TRUS robot is based on a small modification to a standard brachyther-
Figure 2.13: TRUS use in dissection at prostatic apex (A) and Doppler evaluation of NVBs (B). Yellow arrows indicate location of instrument tip.
apy stabilizer that is widely available and familiar to hospital staff. The TRUS automatic positioning approach has safety features built into it. Indeed, if the TRUS tracking is working with the required accuracy, touching the tissue with the da Vinci tool tip will provide a confirmatory imaging artefact.

While high volume surgeons are less likely to benefit from the use of TRUS, the majority of RALRPs in the United States are performed by surgeons who do fewer than 12 such procedures a year [27]. These surgeons, as well as surgeons in training and those early in their learning curve, may benefit from the added information provided by the TRUS robot. Our qualitative evaluation indicates that the greatest benefit would be expected for dissection of the bladder neck, the prostatic apex and the plane posterior to the prostate with the aim of reducing positive margins, optimizing postoperative continence and reducing the risk of rare but potentially serious rectal injuries, respectively. With higher resolution ultrasound systems and the use of flow imaging, the localization of the NVB may become possible. Thus, intraoperative TRUS might be able to contribute to all 3 aspects of the trifecta of prostate cancer surgery, namely cancer control, continence and potency.

In the future we anticipate enhancing the usefulness of our system. In particular, we believe that image overlay with TRUS to preoperative magnetic resonance imaging registration will be advantageous as it will allow the surgeon to be guided intraoperatively by the preoperative magnetic resonance imaging. While there is currently debate about the true advantages of RALRP compared to other RP approaches, such technological advancements with integration of imaging into the robotic surgeons repertoire have the potential to clearly delineate the superiority of robotic surgery in the future.
Chapter 3

A System for MR-Guidance During Robot-Assisted Laparoscopic Radical Prostatectomy

In this chapter, we describe a new ultrasound and magnetic resonance image guidance system for robot assisted radical prostatectomy and its first use in patients. This system integrates previously developed and new components and presents to the surgeon preoperative magnetic resonance images (MRI) registered to real-time 2D ultrasound to inform the surgeon of anatomy and cancer location. At the start of surgery, a trans-rectal ultrasound (TRUS) is manually positioned for prostate imaging using a standard brachytherapy stepper. When the anterior prostate surface is exposed, the TRUS, which can be rotated under computer control, is registered to one of the da Vinci patient-side manipulators by recognizing the tip of the da Vinci instrument at multiple locations on the tissue surface. A 3D TRUS volume is then taken, which is segmented semi-automatically. A segmentation-based, biomechanically regularized deformable registration algorithm is used to register the 3D TRUS image to preoperatively acquired and annotated T2-weighted images, which are deformed to the patient. MRI and TRUS images can then be pointed at and examined by the surgeon at the da Vinci console. We outline the approaches used and present our experience with the system in the first two patients. While this work is preliminary, the feasibility of fused MRI and TRUS during radical prostatectomy has not been demonstrated
before. Given the significant rates of positive surgical margins still reported in the literature, such a system has potentially significant clinical benefits.

3.1 Introduction

A standard treatment of prostate cancer is radical prostatectomy, or the surgical removal of the prostate gland, via open, laparoscopic or robot assisted surgery. Studies seem to indicate that robot-assisted RP has the best outcomes, yet the rates of positive surgical margins (cancer left behind after surgery) still range between 9% and 30%, depending on the center [26]. The goal of the surgery to remove all the prostate and the cancer within it and extending from it, while attempting to spare as much as possible the adjacent critical structure responsible for continence (sphincter muscle) and potency (neurovascular bundles and the cavernosal nerves). The main reason why the best trade off between achieving oncological success (cancer removal) and functional success (continence and potency) cannot be achieved is the inability to localiz, intra-opratively, the location and extent of cancer. Advances in magnetic resonance imaging (MRI) may provide spatially localized information to fill this void and aid surgical planning, particularly for robotic surgeons [99]. The combination of conventional anatomical MRI and functional MR sequences, known as multiparametric MRI (mp-MRI), is emerging as an accurate tool for identifying clinically relevant tumours. This is due to the additional information provided by functional MRI sequences, such as diffusion-weighted (DW) MRI, dynamic contrast-enhanced (DCE) MRI, which significantly improve the ability of mp-MRI to predict the behaviour of tumours [43]. mp-MRI is becoming an integral diagnostic tool in pre-operative planning of RALRP; specifically for prediction of pathologic stage in extracapsular extension (ECE), neuro-vascular bundle (NVB) and seminal vesicle invasion. This capability of mp-MRI to generate the most accurate characterization of prostate cancer [50], has led to the development of methods for MRI-guided treatment, mainly biopsy and brachytherapy [102].

Direct MRI-guided methods have been reported for prostate biopsy and
3.1. Introduction

brachytherapy [96], but intraoperative MRI is still cumbersome, time consuming, resource costly and not widely used. Cognitive fusion, in which the clinician estimates the lesion’s location in the intraoperative TRUS based on a preoperative MRI, varies greatly with expertise. A more feasible approach to allow integration of MRI data in the operating room involves registration of the preoperative MRI to the intraoperative TRUS, and visualization of the corresponding images to assist the clinician during treatment. Previously, such an approach was successfully demonstrated for prostate biopsy [37, 61, 63, 82, 106], and for prostate brachytherapy [87]. However, there exists no report on integration of such an approach for real-time surgical guidance using the da Vinci surgical system which is currently being used to perform more than 80% of radical prostatectomies in North America.

In this work, we present a novel MR-guidance system for the da Vinci which involves an intraoperative segmentation-based MR-TRUS registration method that is integrated into a clinically used robotic TRUS imaging system which in turn can be registered to the da Vinci system’s coordinate frame. In this way a 3D MR volume and the preoperative surgical plan can be mapped to the da Vinci coordinate frame. The surgical instrument can then be visualized, in real-time, with respect to the pre-operative MR volume. In addition, since the TRUS imaging system is robotic, it can track the tip of a da Vinci surgical instrument automatically, and is registered to the pre-operative MR volume, the surgical instrument itself can be used as an intuitive and easy to use control device for the surgeon to manipulate both MR and TRUS images in real-time during the procedure. The system was initially tested and validated on a prostate phantom in a lab setting. Next, it was used with a clinical da Vinci surgical system inside a robotic operating room and tested on two patients undergoing RALRP using the da Vinci. Both patients have undergone clinical pre-operative MR imaging for diagnosis. The description of the system components and methods along with the clinical study results and discussions are presented in this chapter.
3.2 Materials and Methods

The components of our image-guided system are illustrated in Figure 3.1. The system comprises an ultrasound system with a motorized TRUS transducer mounted on a brachytherapy setup, an external PC used for image registration and display on the da Vinci console, and registration and tracking software. These components will be described next.

3.2.1 TRUS Imaging System

A previously designed and clinically used robotic TRUS manipulator [64] was used for automatic and remote rotation (angle range $\pm 45$ degrees) of the TRUS transducer during the procedure [64]. The sagittal TRUS imaging plane is automatically repositioned using the robot so that a 2D ultrasound image continuously contains the tip of a specified da Vinci surgical manipulator. Automatic instrument tracking is achieved by means of a rapid and clinically feasible intraoperative registration technique that solves for the rigid homogeneous transformation between the da vinci and the TRUS robot coordinate systems (Figure 3.1). The registration involves defining points on tissue surface using the da Vinci instrument tip and accurate and automatic localization of the points in both da Vinci and Robotic TRUS coordinate frames [3]. This tracking method allows the surgeon at the console to control the TRUS imaging plane automatically with the tip of a da Vinci surgical instrument with an accuracy of less than 2 mm [65].

A BK ultrasound machine (BK Medical, Herlev, Denmark) with a 8848 4-12 MHz biplane transducer was used for imaging the prostate. Raw in phase quadrature (IQ) data was captured at 43.07 Hz sampling rate and saved into an external PC through a DALSA Xcelera-CL PX4 Full frame grabber card (Teledyne DALSA, Waterloo, ON). The TRUS robot was used for 3D TRUS volume acquisition by automatically controlling the rotation angle of the TRUS transducer and saving the location information of each image. All TRUS volumes were captured using the 214-element 6 cm long sagittal array with a transmit frequency of 9 MHz and an imaging depth of 5.6 cm. Volumes were obtained using a 90-degree rotary sweep about the
3.2. Materials and Methods

probe axis with images acquired at increments of 0.2 degrees. The image capture time was 45 seconds per volume.

Figure 3.1: A schematic of the system. da Vinci $\{O_{dV}, C_{dV}\}$ and Robotic-TRUS $\{O_{RT}, C_{RT}\}$ coordinate frames are registered in order to enable automatic tracking of the instrument with ultrasound. $\{O_{RT}, C_{RT}\}$ and $\{O_{US}, C_{US}\}$ is computed using ultrasound calibration. Images are then converted from cylindrical coordinates to cartesian spatial coordinates for MR-TRUS registration.
3.2. Materials and Methods

3.2.2 TRUS-MR Registration

The prostate gland on each transverse slice in the preoperative T2w MR volume is segmented manually by an expert radiologist before surgery. After interpolating the intraoperative TRUS B-mode images into a 3D grid in order to obtain transverse slices from the sagittal volume, we employed a real-time semi-automatic algorithm for 3-D segmentation of the prostate in the ultrasound volume. This algorithm, described in [59], has been routinely employed during brachytherapy, and found to be a fast, consistent and accurate tool for the delineation of the prostate gland in TRUS images.

Based on the segmented surfaces of the prostate in the TRUS and MR volumes, we construct the binary volumes. We may then register the two binary volumes and apply the resulting displacement map back to the MR volume. First, the two binary volumes are rigidly aligned (and scaled) using the principal axes transformation. This is a fast, one-step registration that was found to provide a good initial alignment for the followed deformable registration. To this end, the binary volumes are treated as pdfs, and the corresponding centers of mass, and covariances are calculated. The aligned MR binary volume can be then computed using a linear coordinate transformation. Next we do the deformable registration using a method developed in our lab [70].

The proposed method was tested on $n = 6$ data sets of RALRP patients who underwent preoperative MR and intra-operative US. The MR volumes were acquired by a 3-Tesla system (Achieva 3.0T, Philips, The Netherlands) using a standard 6-channel cardiac coil with acceleration factor (SENSE) 2. Both of the MR and TRUS transverse volumes were segmented and the surfaces of the prostate were generated with medium resolution and smoothing strength settings. The urethra on both modalities was segmented manually for evaluation as well. In order to maintain consistent processing times, we ran the deformable registration algorithm a fixed number of 30 iterations that takes about 184 sec, and was found to converge sufficiently. Including the times for the semi-automated segmentation ($46 \pm 15$ sec), the total run-time of the entire segmentation-based registration process is about
4 minutes. We evaluated the registration performance using the volume overlap (VO), in the sense of Dice’s coefficient between the MR and the TRUS volumes after rigid and deformable registrations. The mean distance between splines on both modalities that were fitted through the center points of the urethra was also measured for the rigid and deformable registered volumes. The mean VO was computed to be (97.7 ± 0.3\%) and mean error was computed to be (1.44 ± 0.42\text{mm}).

3.2.3 In-vivo Patient Studies and Results

Two patients (ages 55 and 72; prostate specific antigen 13.5 and 28.5 ng/ml) with clinically organ confined prostate cancer undergoing RALRP agreed to participate in this institutional review board approved study. The main components and configuration of our system during this clinical study inside the operating room are shown in Figure 3.2. Both patients underwent preoperative mp-MR and a radiologist was asked to examine their MR volume and segment the prostate and the lesions. The lesions were identified in DCE-MR images and then marked on T2w images.

Once the patient is placed on the operating table and before docking the da Vinci robot, we attached the Robotic-TRUS system to the foot of the operating table and placed the TRUS transducer to provide optimal transverse/sagittal images of the patient’s prostate as performed in standard brachytherapy volume studies. After docking the da Vinci system and start of the procedure, once the anterior surface of the prostate is visible to the surgeon, we performed the TRUS to da Vinci calibration to enable automatic tracking of the surgical instrument with ultrasound. The calibration process was performed after incision of the endopelvic fascia with 4 instrument tip locations spread across both sides of the dorsal prostate and could be completed in approximately 2 minutes. Before activating the automatic instrument tracking control mode, we acquired 3D TRUS volumes (45 seconds each) to be used by the MR-TRUS registration algorithm. The TRUS volume used for the registration was the one that was acquired right before the part of the procedure when the surgeon wanted to use MR
3.2. Materials and Methods

Figure 3.2: (a) MR-guidance system components, (b) The operating room scenario.
3.2. Materials and Methods

Table 3.1: Table of patient study results. $t_{\text{reg}}$ is the duration of each registration process, $N_r$ is the number of times registration was repeated for that patient, $N_f$ is the number of fiducial points selected for instrument registration, and $t_T$ is the total duration of TilePro usage during each case.

<table>
<thead>
<tr>
<th></th>
<th>MR-TRUS reg.</th>
<th>TRUS-dV reg.</th>
<th>$t_T$ (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VO (%)</td>
<td>$e_{\text{reg}}$ (mm)</td>
<td>$t_{\text{reg}}$ (s)</td>
</tr>
<tr>
<td>P1</td>
<td>97.7 ± 0.3</td>
<td>1.5 ± 0.3</td>
<td>240</td>
</tr>
<tr>
<td>p2</td>
<td>96.6 ± 0.2</td>
<td>1.8 ± 0.3</td>
<td>235</td>
</tr>
</tbody>
</table>

Images to localize tumors. This was done to make sure that prostate deformations were minimal and to achieve a more accurate registration results and deformation field.

After the tracking was activated, the surgeon could examine the prostate anatomy and tumor locations by moving the registered surgical instrument around, slightly placing it on the tissue surface in the area of interest and localizing the instrument tip with respect to anatomy seen in real-time TRUS images and then use it’s corresponding MR slice. As it is shown in Figure 3.3, both real-time TRUS and the corresponding MR images are being sent to the da Vinci console and displayed to the surgeon using the TilePro™ feature of the da Vinci system. The surgical view is divided into three tiles with adjustable sizes, one for endoscopic view, one for real-time TRUS and one for corresponding deformed MR slice. Our graphical user interface for MR imaging display (shown in Figure 3.3) shows instrument tip location in cylindrical coordinate frame of the TRUS system (roll angle) with a superimposed red cursor line on the 2D deformed MR slice. This cursor line was used by the surgeon for localization of the registered surgical instrument with respect to the segmented and annotated lesions displayed in MR images. Snapshots of the surgeon console images at the stages when the MR-guidance system was being used to localize tumors are shown in Figure 6.6. A summary of the registration results for both patients is listed in Table 3.1.
3.3 Discussions and Conclusions

The performed surgical procedures were the first in which a surgeon was able to see registered MR images while performing the operation and refining the surgical planes to achieve a better surgical margin and functional outcome. During the first case, a lesion on the right side, stretching from the mid-gland stretching anteriorly and superiorly was seen on MR imaging system (shown in Figure 6.6). Based on this information, the surgeon attempted to leave as much of the nerves intact on the left (“high” or more anterior dissection approach in order to get closer to the prostate) and on the right, forget about sparing or try to get closer to the prostate only posteriorly. The surgeon decided to perform a bilateral nerve sparing but more conservatively because of the anterior lesion on the right seen in MR images. If the lesion was posterior, then he would not have done nerve sparing on that side. During the second case, a lesion on left posterior side was seen on MR images and surgeon avoided sparing the nerve on that side. The intra-operative MR imaging allows surgeons to fine tune based on anatomy. Without MRI, they would just have a certain number and proportion of cores involved on one
side or the other, but no other info on location - hence a guessing game at best. Given the number of papers on the “best” surgical approach, this MR-guidance system could be a powerful tool to trade off positive surgical margins against potency.

Intraoperative TRUS to da Vinci and TRUS-MR registrations were performed successfully for 2 patients. The imaging was examined at the anterior surface of the prostate, after the surgeon placed the dorsal venus complex (DVC) suture at the prostate apex, and before bladder-neck dissection for localization of the tumor and for finding the best surgical plane to achieve both better oncological and functional outcomes before performing NVB release. TRUS volume acquisition and MR-TRUS registration processes were redone before any stage of the surgery when the surgeon wanted to use the system. The mean volume acquisition and registration time was 235 seconds. A fresh TRUS volume would deform the preoperative MR images based on the current deformation state of prostate gland.

It is important and intuitive to the surgeon to have control over the imaging system. Previous work showed that surgeon-assistant coordination is inefficient. The other proposed method to interact with the imaging system would be adding another control device to the daVinci console. Devices such as another foot-pedal or a hand controller was added to the daVinci console. Input device such as the concept of “master as mice on da Vinci platform to change viewpoints” was also presented. The advantage of our system is that once we perform our 2 minutes intraoperative calibration, the surgeon can use the daVinci surgical instrument to move through the 3D volume of both TRUS and MRI and manipulate 3D data. The registration moves the 3D images coordinates to the davinci coordinate system. Hence, surgeon could easily move the tool tip around and find the location of the instrument tip with respect to 3D vision, 3D TRUS and 3D MRI.

This chapter demonstrates a preliminary study on a framework based on a combination of an MR-TRUS registration and TRUS to da Vinci registration. We believe that the MR-TRUS registration approach could be improved in future to better deal with deformations in the prostate gland during the procedure. Furthermore, in order to achieve more consistent and
3.3. Discussions and Conclusions

Figure 3.4: Clinical study results. Both deformed MR and realtime TRUS are shown to the surgeon at the console along with the surgical endoscopic imaging.

To obtain thorough registration accuracy results, target registration error should be computed for all regions of the prostate gland. Such an study requires identification of common anatomical landmarks in both 3D TRUS and 3D MR volumes of the prostate. Another alternative to perform such an analysis is to perform an animal study during which clearly visible fiducials could be injected into the prostate gland and imaged in both modalities.
3.3. Discussions and Conclusions

Figure 3.5: Surgical tool motion in medial-lateral direction and the corresponding TRUS and MR images.

Figure 3.6: View of the surgical console when both MRI and TRUS are in use.
Chapter 4

Automatic 3-D Transrectal Ultrasound to the da Vinci Surgical System Registration

4.1 Introduction

Given the limited field of view of the surgical site in RALRP, several groups have proposed the integration of transrectal ultrasound (TRUS) imaging in the surgical workflow to assist with accurate resection of the prostate and the sparing of the neurovascular bundles (NVBs). In chapter 2, we introduced a robotic TRUS manipulator and a method for automatically tracking da Vinci surgical instruments with the TRUS imaging plane, in order to facilitate the integration of intraoperative TRUS in RALRP. Rapid and automatic registration of the kinematic frames of the daVinci surgical system and the robotic TRUS probe manipulator is a critical component of the instrument tracking system. In this chapter, we describe a fully automatic registration technique based on automatic 3-D TRUS localization of robot instrument tips pressed against the airtissue boundary anterior to the prostate.

In the manual implementations of the registration method, da Vinci instrument tips or other surface fiducials have been localized manually in the 3-D TRUS volumes. This process involves scrolling through two-dimensional (2-D) slices of the volume, finding the 2-D slice that appears to contain the tool tip and selecting the approximate tip of each fiducial using a mouse. While the overall registration method has been shown to work well [3], the
4.1. Introduction

manual fiducial selection procedure is time consuming and the interpretation of the fiducial centers in a sequence of 2-D TRUS images in the volume is subjective and varies from one user to another. A method for automatically localizing the surface fiducials is more clinically realistic, since it would be less disruptive to the surgical workflow. This chapter describes a method for automatic da Vinci instrument tip localization in 3-D TRUS. The detection algorithm could also be applied to other types of surface fiducials, such as the steel spherical fiducials we previously used for registration of 3-D ultrasound to the da Vinci stereoscopic camera [114].

Localization and real-time tracking of surgical tools in 3-D ultrasound has been addressed in previous studies [24, 30, 45]. In our work, da Vinci surgical instruments are working within the carbon dioxide filled abdominal cavity, as depicted in Figure 4.1 and are not generally visible by ultrasound. As a result, the instrument tip must be pressed against the tissue surface to become visible, and allow the registration to occur. Previous work has demonstrated real-time intraoperative registration of 3-D US to surgical robot coordinate frames, but in these cases, the instruments were constantly visible in the ultrasound [72, 73]. To the best of our knowledge, there are no reports of automatic instrument tip or surface fiducial localization in 3-D ultrasound.

Figure 4.1: da Vinci surgical instruments and the prostate surface in a clinical scenario during the RALRP procedure.
4.1. Introduction

The localization problem can be divided into two sub-problems: 1) automatically detecting the presence of the instrument tip in the ultrasound volume and finding the 2-D plane that best contains it, and 2) automatically locating the (x, y) coordinate of the center of each detected tool tip in the 2-D frame. Poon and Rohling [84], in research on calibration of 3-D ultrasound probes, used the centroid of an image region around a user supplied location to semi-automatically detect the center of each fiducial. This method solves the second subproblem, but not the first. In this study, our aim was to create a method for solving both of the problems mentioned earlier, making da Vinci instrument tip localization fully automatic, while achieving registration accuracy comparable to the $0.95 \pm 0.38$ mm that we previously achieved using manual fiducial localization [5].

We propose a multi-scale filtering technique for this 3-D TRUS instrument tip localization problem, which is a combination of a second-order Gaussian derivative, a circular Hough transform, and a hierarchical clustering technique. A 3-D mask is first created based on a background ultrasound volume (a volume that is acquired before pressing the instrument tip on the tissue surface) and is applied to the ultrasound volume that includes the instrument tip. Next, the masked ultrasound volume is further filtered to find the edges representing the candidate tip locations in the remaining part of the image.

Finally, the tip of the instrument is found using a circular Hough transform. Hence, the tool location is both identified in the 3-D volume and inside its corresponding 2-D frame. The same technique could also potentially be used to localize any surface fiducial pressed against the airtissue boundary for registration or other purposes.

As described in this section, we have tested our automatic fiducial localization method in experiments using several tissue models and also in a clinical scenario where the RALRP surgical procedure was performed on an anesthetized dog using a da Vinci Si surgical system. In each case, the fiducial localization error (FLE) and the target registration error (TRE) were evaluated and compared with the manual method. Complete details of the methods, further analysis of the results and discussions and in vivo
validations are presented in this chapter.

4.2 Materials and Methods

Several key factors have to be considered in the selection of a detection algorithm for this problem. Using our TRUS probe manipulator, 3-D TRUS data are acquired as a series of 2-D images during the motion of the probe. While this produces 3-D ultrasound data, actual volumes are constructed by an off-line scan conversion algorithm. The detection algorithm must thus be applied to the raw sequence of 2-D images if it is to run in real time. The appearance of the target fiducials is fairly consistent. As depicted in Figure 4.2, ultrasound images of the da Vinci instrument tips pressed against tissue surface all contain similar features: strong horizontal lines showing the airtissue boundary, approximately circular areas of high-intensity and vertical reflection lines from the instrument tips themselves. The scale of the ultrasound volumes is fixed by the spatial resolution of the ultrasound transducer, so scale invariance is not required. The RALRP procedure involves fairly consistent relative orientations of the TRUS transducer and da Vinci instruments, so rotational invariance is likewise not required. Finally, the detection must be very rapid and a detection algorithm that can scan an entire volume in a few seconds is necessary to avoid disrupting the surgical workflow.

Figure 4.2: (a) Example of an airtissue boundary in an \textit{ex vivo} liver tissue. (b) da Vinci instrument tip pressed against an airtissue boundary.
4.2. Materials and Methods

4.2.1 Automatic Detection Algorithm

Figure 4.2 shows an example image of da Vinci instrument tip pressed against the airtissue boundary of *ex vivo* liver tissue. In our method, the automatic localization of da Vinci instrument tips is performed in four steps: masking, filtering, circle detection, and removal of false positives. A schematic of the process is shown in Figure 4.3.

We first apply a 3-D mask, primarily to remove ultrasound data that lies beyond the airtissue boundary. To create the 3-D mask, series of 2-D images of the background volume have been filtered first using a Hessian-based Frangi vesselness filter [28]. This vessel-enhancing diffusion filter is chosen to find the airtissue boundary lines that are shaped similar to vessels in lung and cardiac images [16, 20]. In this filtering approach, the principal directions in which the maximum changes occur in the gradient vector of the underlying intensity in a small neighborhood are identified. Eigenvalue decomposition of the Hessian matrix is used to calculate these directions. Hence, the Hessian matrix at each pixel of the image for a particular scale (σ) of the Gaussian derivative operator is computed.

Then, the eigenvalue decomposition is applied to extract two orthonormal directions. Based on the computed eigenvalues (λ₁, λ₂) at each scale (Σ = 1, 3, 5), a measure is defined as follows:

\[ S = \max_{\sigma \in \Sigma} S(\sigma) = \begin{cases} 0 & \text{if } \lambda_2 > 0 \\ \exp\left(\frac{R_b^2}{2\sigma^2}\right)(1 - \exp(-\frac{R_n^2}{2\sigma^2})) & \text{if } \lambda_2 < 0 \end{cases} \quad (4.1) \]

\[ R_b = \frac{\lambda_1}{\lambda_2} \] is the blobness measure in 2-D and and \( R_n = \sqrt{\lambda_1^2 + \lambda_2^2} \) is a background or noise reduction term. \( R_b \) shows deviation from blob-like structures and \( R_n \) shows the presence of the structure using the fact that the magnitude of the derivatives (eigen values) is small in the background pixels. In this equation β is chosen as 0.5 and c is chosen to be the max_x,y R_n. Such values are chosen according to the application of the Frangi filter in vessel detection in cardiac US images [28]. Further image processing is done to remove the small areas of high intensity, which are randomly scattered.
in the filtered images due to speckles. Each image is first thresholded by a value obtained from the mean of the intensities of pixels in the images.

Figure 4.3: Automatic tool detection framework. The background ultrasound volume and the volume with the tool inside are the inputs. Slice number and the \((x, y)\) position of the tool tip in the detected slice are the outputs.
Next, parts that have less than \( M \) connected components are removed. The value \( M = 10 \) is obtained by a trial-and-error process for our TRUS images.

The remaining components, which represent the high intensity and relatively large areas corresponding to the tissue structures in the image, are dilated using morphological operators. To find the airtissue boundary, a line detection algorithm using a Hough transform is applied to the images. Lines with the minimum length of 30 pixels and minimum gap of 15 pixels between them are extracted in 260–180 pixel images. As it can be seen from Fig. 3, the airtissue boundary region is shaped like a line which could be straight or curved depending on the tissue surface shape. The line detection algorithm detects lines which construct this region regardless of its curvature. A mask is created using the detected airtissue boundary and artifact and is applied to remove regions corresponding to the artifacts and regions outside the tissue boundary.

After applying the mask to the image set, the Frangi filter is applied to the series of 2-D images and the relatively large components are extracted. A circular Hough transform is applied to the obtained components to find circles with radius of approximately 5 pixels and minimum pixel count of 20. The mean location of these circles (the circular Hough transform finds a number of circles in the vicinity of the tool tip region) in each 2-D image is computed as a candidate for the tool location. Next, a hierarchical clustering algorithm [44] is performed to find the group of candidates that are in adjacent slices, considering the fact that the tool tip can be seen in a multiple consecutive slices. Candidates that are close to each other (Euclidean distance) are linked into the same cluster. The linkage function continues until an inconsistency coefficient reaches a threshold. This approach removes false positive detections that do not necessarily occur in adjacent slices. Once the clusters of 2-D images that have the tool inside them are found, the slice containing the maximum tool tip intensity inside the largest cluster is chosen to be the output slice for the detection algorithm. Results shown in Figure 4.5 and Figure 4.6 clearly demonstrate the earlier methodology implemented in different experiments.
4.2.2 Experimental Setup for TRUS Data Collection

The robotic system shown in Figure 2.1 (a), which is designed for intra-operative TRUS imaging during RALRP, was used for image acquisition in this study. This system consists of a robotic ultrasound probe manipulator (robot), a Sonix TABLET ultrasound machine (Ultrasonix Medical Corp., Richmond, VA, Canada) with a parasagittal/transverse biplane TRUS probe, and control and image processing software. A standard brachytherapy stabilizer arm (Micro-Touch 610-911; CIVCO Medical Solutions, Kalona, IA, USA) was mounted to the operating table, and the robot was installed on the stabilizer, as shown in Figure 2.1 (a). Volumes of 3-D TRUS data were acquired by rotating the 2-D imaging planes and automatically recording the encoder positions for each image. Software running on the ultrasound console is responsible for controlling the robot movements and the ultrasound data acquisition.

4.2.3 System Interface

A simple graphical user interface (GUI) was designed for the surgical team to allow the user to position the probe, automatically collect 2-D B-mode images and radio-frequency (RF) data while rotating from $-40^\circ$ to $+40^\circ$, and perform this automatic registration during RALRP procedure. The registration workflow during this surgical procedure is explained in the diagram depicted in Figure 4.4. The surgeon or his/her assistant will use the GUI installed on the Sonix TABLET ultrasound machine to perform the registration.

4.3 Experimental Results

4.3.1 Phantom and Ex-vivo Results

The proposed automatic detection method has been initially tested on three different tissue models: a custom-made polyvinyl chloride (PVC) prostate phantom of appropriate size and shape to model the imaging conditions
4.3. Experimental Results

Figure 4.4: TRUS to da Vinci registration workflow during RALRP procedure.
4.3. Experimental Results

Figure 4.5: Sample detection results and their corresponding imaging setups. The da Vinci large needle driver is pressed against the tissue surface on different locations and the location of its tip is found using our detection algorithm in 3-D.

during RARLP, an *ex vivo* liver and *ex vivo* bovine tissue. A surgical manipulator commonly used in RARLP (Large Needle Driver, Intuitive Surgical Inc.) was used to perform the registration. Sample results of the tool detection algorithm along with the testing configuration for each of the datasets are depicted in Figure 4.5.

Instrument tip intensity in the US images versus probe roll angle is plotted for TRUS volumes in each dataset and sample results are shown in Figure 4.6. As seen in these figures, the detection algorithm looks at the area under the tool intensity versus probe roll angle curves, selects the cluster as the group with maximum area, removes all false positives, and finally, selects the point with the maximum intensity inside the cluster as the final detection. Scatter plots of the candidate detected points along with
the selected cluster, false positive detections, and the selected 2-D slices are also depicted in Figure 4.6 to further clarify the robustness of the proposed algorithm. The rigid point registration technique proposed by Umeyama [111] was used in this study to evaluate the automatic detection algorithms performance.

The da Vinci instrument tip was pressed against the airtissue boundary at 12 locations in each of the three collected datasets ($N_t = 12$) and its position ($x^0$) in the ultrasound robot frame $\{O_0, C_0\}$ is calculated using our automatic detection algorithm. The da Vinci API was used to provide the location of the tool tip ($x^1$) in the da Vinci frame $\{O_1, C_1\}$. There is a 9 mm offset between the visible edge of the instrument tip in US and the distal element of the kinematic chain provided by the da Vinci API. This distance was added to the vertical component of the point locations in ultrasound images before matching the point pairs in the two frames and calculating the registration transformation. This offset distance might contribute to some of the registration error, since the tool tip might be slightly angled when it is pressed against the tissue.

For each registration experiment, $N_f \geq 3$ points were randomly picked from the total points collected for each tissue type (3 is the minimum number of points for finding the transformation), and the rigid point registration method was used to compute the transformation between the frames $T_{0}^{1}$ to minimize the fiducial registration error (FRE). FRE is computed as the root mean square of the distance between corresponding fiducials after the registration. Next, the remaining points in each dataset were assumed to be the target points and the calculated transformation was used to transform them from the TRUS robot frame to the da Vinci frame and the TRE is estimated. Estimated TRE includes the real TRE and the target localization error (TLE).

TRE is defined as the root mean square of distances between corresponding fiducials after registration (i.e., the distance between the localized position of each tool tip as transformed from the ultrasound robot space to da Vinci space and the position of that corresponding tool tip localized in the da Vinci space provided by the API).
4.3. Experimental Results

Figure 4.6: Sample results of tool intensity-probe angle, detected points in the TRUS volume, and 2-D slide and tool tip inside for (a) liver dataset, (b) PVC phantom dataset, and (c) Bovine tissue dataset. Each group of figures is associated with one experiment in each dataset.
4.3. Experimental Results

Values of FRE and TRE were computed for different number of fiducials $N_f$ chosen between the total points for each dataset $N_t$. Mean values of FRE and TRE and their standard deviations were then calculated for each combination of $(N_f, N_t)$ for 100 iterations ($n = 100$) and the results are plotted for each dataset in Figure 2.6.

As it can be seen from Figure 4.7, as $N_f$ increases, both mean and standard deviation of TRE decreases. Based on this analysis, the number of fiducials suggested for this registration is $(N_f = 6)$. The mean and standard deviation of the TRE for this number of fiducials and 100 iterations are reported in the anatomical frames of the patient in Table 4.1.

Tool tip segmentation error (FLE) was also calculated in $(x, y, \theta)$ directions to further show the accuracy of the method. Three human subjects were asked to independently identify the location of $(n = 10)$ fiducial points in the TRUS volumes and their detections were considered to be the gold standard detections. The manual tool detection method involved scrolling through 2-D slices of the volume, finding the 2-D slice with the tool tip inside and selecting the approximate center of each fiducial. The difference between the average user-defined locations and the result of our algorithm, in addition to the inter-subject variations (ISVs) were calculated and are reported in Table 4.2.

Table 4.1: Mean errors ($n = 100$) between tool tip location and predicted location based on registration. Errors are presented in the anatomical frame of the patient, along the superior-inferior ($e_{S-I}$), medial-lateral ($e_{M-L}$) and anterior-posterior ($e_{A-P}$) axes.

<table>
<thead>
<tr>
<th></th>
<th>$TRE_{A-P}$ (mm)</th>
<th>$TRE_{S-I}$ (mm)</th>
<th>$TRE_{M-L}$ (mm)</th>
<th>Mean TRE (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phantom</td>
<td>0.62 ± 0.31</td>
<td>1.29 ± 0.22</td>
<td>0.82 ± 0.24</td>
<td>1.80 ± 0.32</td>
</tr>
<tr>
<td>Liver</td>
<td>0.72 ± 0.83</td>
<td>2.65 ± 0.51</td>
<td>1.18 ± 0.54</td>
<td>3.33 ± 0.81</td>
</tr>
<tr>
<td>Bovine</td>
<td>1.90 ± 0.79</td>
<td>1.24 ± 0.34</td>
<td>3.51 ± 0.70</td>
<td>4.54 ± 0.88</td>
</tr>
</tbody>
</table>
Figure 4.7: FRE and TRE and their standard deviations for different number of fiducials ($N_f$) and target points ($N_t$) for (a) Steak dataset, (b)Liver dataset and (c)Phantom dataset. As the number of fiducials increases, TRE decreases. We suggest using six fiducials in clinical applications.
4.3. Experimental Results

4.3.2 In-vivo Results

In order to show the clinical feasibility of the proposed methods, we further tested the algorithm on datasets collected during our in vivo canine study. The surgeon was asked to press the tool tip of the da Vinci instrument against the prostate surface while a full TRUS volume was acquired. The tool tip was visible as a hyperechoic point with strong vertical reflection lines in the B-mode images, as shown in Figure 2.5. \((N = 12)\) different target locations on the prostate surface (also shown in Figure 2.5) and corresponding volumes were acquired. Tool tips were automatically located in each volume, and for \(n = 100\) iterations, \(N_f = 4\) point pairs were picked at random and a least squares problem was solved to find the registration homogeneous transformation. The remaining \(N_t = N - N_f = 8\) target locations were used to calculate the TRE. To determine the ISVs in fiducial localization and analyze its effect on TRE, four different ultrasound users were asked to localize the tool tip in each of the \(N = 12\) TRUS volumes. Manual fiducial localizations were compared with the automatic detections to calculate FLE.

The TRE, FRE, FLE, and ISV obtained with the automatic localization method compared to manual localization are listed in Table III. The table includes the TRUS imaging plane \(\theta\) localization error, and the localization error \((x,y)\)=\((\text{lateral,axial})\), in the plane at \(\theta\).

Table 4.2: Mean errors \((n = 10)\) between manual tool tip location and automatic tool tip location \((x,y,\theta)\) directions and inter-subject variations in \((x,y,\theta)\) directions.

<table>
<thead>
<tr>
<th></th>
<th>(FLE_{(x,y)}) (mm)</th>
<th>(FLE_{(\theta)}) (deg)</th>
<th>(ISV_{(x,y)}) (mm)</th>
<th>(ISV_{(\theta)}) (deg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phantom</td>
<td>2.13 ± 0.97</td>
<td>0.67 ± 0.34</td>
<td>3.65 ± 0.88</td>
<td>1.55 ± 0.39</td>
</tr>
<tr>
<td>Liver</td>
<td>3.11 ± 0.88</td>
<td>0.79 ± 0.39</td>
<td>4.25 ± 1.45</td>
<td>2.05 ± 0.8</td>
</tr>
<tr>
<td>Bovine</td>
<td>2.42 ± 1.19</td>
<td>0.68 ± 0.48</td>
<td>3.13 ± 0.88</td>
<td>1.43 ± 0.44</td>
</tr>
</tbody>
</table>
4.4 Discussion of Results

The overall average TRE previously reported in [5] using the manual localization of three fiducials on the PVC tissue phantom was 0.95 ± 0.38 mm. The average TRE using the automatic detection technique in this study is 1.80±0.32 mm for the recommended number of fiducial points \(N_f = 5\) on the PVC tissue phantom. This error could be further reduced to 1.61 ± 0.39 mm by increasing the number of fiducial points to 9. To further evaluate the algorithm robustness before clinical applications, experiments have been done on different tissue types (ex vivo liver and bovine tissue), which are more similar to the human tissue. The minimum calculated TRE value is 2.86±1.40 mm for the liver tissue and 4.15 ± 0.61 mm for the bovine tissue, for picking nine fiducials on the airtissue boundary. Our initial clinical study shows the algorithms accuracy and applicability in a real surgical scenario with average TRE of 2.68 ± 0.98 mm, while four points were chosen to calculate the TRE. The overall average TRE using the manual localization of four points is 1.88±0.88 mm. Using more fiducial points will further decrease the registration error, as shown in Figure 4.7. We propose choosing six tool positions on the tissue surface, \(N_f = 6\), both to achieve an acceptable registration error and to have a reasonable number of tissue indentation repetitions during the surgical procedure. It is pointed out by Ukimura et al. [108] that the mean distance between the neurovascular bundles (NVBs) and the lateral edge of the prostate ranged between 2 and 3 mm from apex to base. This is suggestive of the required accuracy of a guidance system since one major aspect of the system is to accurately localize the NVB. According to these results, the automatic detection algorithm could yield comparable registration accuracy with the manual detection method. It could also compensate for errors resulting from misinterpretation of tool locations in the TRUS volume. The goal of instrument tracking is to have the TRUS parasagittal imaging plane contain the tip of the da Vinci instrument at all times. Hence, TRE values in the axial and lateral ultrasound directions are irrelevant as long as the tool tips are within the image boundaries. Because the thickness of the TRUS beam at the anterior surface of the prostate is on the order
4.4. Discussion of Results

of millimeters at moderate imaging depths, small errors in the elevational direction are not critical. The appearance of surface fiducials in TRUS images, while regular, is not necessarily exactly that of a spheres outline (or the outline of another shape in the case of da Vinci tools).

It is possible that reverberation artifacts, or other issues, might introduce constant offsets in the fiducial localization that would make our registration less accurate. This inaccuracy would not be revealed in the testing described in this work, since we use the same surface fiducials as targets to validate the registration. While this could theoretically be a factor in the validation presented here, we believe it is not significant for two reasons. First, previous work on ultrasound surface fiducials [36] has shown that at worst the artifacts result in a small constant offset. Second, we have performed validation on a related method for 3-D TRUS to camera registration that did not use surface fiducials for validation, resulting in roughly equivalent accuracy [5].

Our focus for this registration technique is the RARLP procedure, and we believe it would be effective to choose two points on the prostate apex, two points on the midgland, and two points on the prostate base. As it is also shown in Figure 4.7, choosing six fiducials results in satisfactory registration error in our in vivo study. In this process, the da Vinci instrument tip is slightly pressed on the surface of the tissue at different locations. The da Vinci instruments should not be deflected during the registration process. This is because we rely upon the joint angle measurements and the tool tip positions, computed via the da Vinci API by solving the robot kinematics, to localize the tool tip relative to the base of the da Vinci patient side cart.

The bending deflection of the da Vinci instrument is not taken into account by the robot API, and is not measured in this work. Such deflections could be estimated by methods explained in [100]. We assume that the bending stress on the instrument resulting from careful soft tissue indentation in this application is negligible and will not affect da Vinci API read outs. Furthermore, the actual TRUS transducer remains fixed relative to the da Vinci during the entire surgery. It is in a fixed correspondence with respect to the robot and held so by a brachytherapy stepper as shown in
4.4. Discussion of Results

Figure 6.1(a). Brachytherapy steppers have been used in many procedures and do not move.

Replacing the process of manual detection of tool tips in the TRUS volume with the proposed automatic technique will accelerate the registration and reduce the disruption to surgical workflow. The processing of each US volume consisting of 150 2-D US images takes approximately 55 seconds. The algorithm is currently implemented in MATLAB, but future implementations of the algorithm in GPU will further accelerate the processing. As previously mentioned in [3], performing a registration by manually identifying three common points takes an experienced operator approximately 2 min, although a surgeon working with actual tissues would likely take longer. Using the automatic method will approximately take the same amount of time; while there will be no need for a sonographer to attend the surgery to manually find the tool tip in the US volume. In addition, the results will not be user-dependent, as is the case in the manual detection. Comparison between the ISV results and automatic localization errors reported in Table 4.2 further proves the consistency and accuracy of the proposed automatic method with respect to the manual method.

The overall goal of this work is to provide an easy to use TRUS guidance system to the surgeons. The images will be streamed to the surgeon console and will be displayed side-by-side to the camera view of the surgical site using the TilePro™ feature of the robot. Because the surgical tool itself is used to point to the ultrasound plane, if the pointing is correct, touching the tissue will provide an ultrasound image of the tool. This in itself is a reasonable check of the tool tracking accuracy. If more than two noncollinear touches are performed, then the problem is constrained fully. Thus, there is a certain safety built in the method that identifies if the tracking is working within the required accuracy. At critical stages of the procedure such as the bladder neck and NVB dissections, the surgeon could use the TRUS images at the desired locations by easily placing the tool at that spot. In case of algorithm failure, the manual registration method could be performed instead. Even if the manual registration fails in this process, manual remote manipulation of the TRUS robot will be used by the operator to provide TRUS guidance to
4.5 Conclusions

In this study, we have addressed the problem of detecting da Vinci instrument tips pressed against an airtissue boundary, in 3-D TRUS data. A method based on multiscale filtering and circle detection has been proposed. The tool tip localization accuracy is evaluated by analyzing the registration error between the TRUS robot frame and the da Vinci frame. Overall, the method decreases the complexity of the registration procedure while keeping its accuracy at the same order of the manual method. The proposed tech-
4.5. Conclusions

The technique will further facilitate integration of TRUS in RALRP with minimum interruption to the surgical procedure. After an automatic registration, which could be completed in less than 5 min using a simple GUI, the surgeon can use TRUS imaging in many steps of the RALRP procedure by easily moving the surgical tool around to control the TRUS imaging plane. Future work will include clinical human trials to verify the accuracy and reliability of the proposed technique. Furthermore, GPU implementation of the algorithm to reduce the processing time to approximately 2 min is also planned in the future work.
Chapter 5

Tracked Robotic Ultrasound Palpation

In this chapter, we propose a method of using ultrasound imaging for tissue palpation using a robotic ultrasound system that can track a surgical instrument. When the surgical instrument presses against the tissue thus causing an indentation, the resulting sub-surface strain image is computed and displayed to the user. The sub-surface strain is indicative of tissue stiffness, and could be used as a contrast mechanism to better outline boundaries of palpable tumors. The automatic tracking of the instrument tip by the ultrasound transducer can be used to regain a sense of palpation by displaying, along or instead of the conventional ultrasound image, the strain field produced by the compression of tissue by the instrument tip near or adjacent to the tip.

We implemented the method on two robotic ultrasound platforms, each designed for specific clinical applications: (i) a robotic transrectal ultrasound (R-TRUS) system (explained in Chapter 2) for robot-assisted Prostatectomy procedure, and (ii) da Vinci surgical system auxiliary patient-side manipulator (PSM) used with a robotic ultrasound transducer for robot-assisted Nephrectomy procedure. Implementation on the da Vinci surgical system (fully explained in Appendix A) was done using the da Vinci research kit (dVRK) controllers that enable complete access to all control levels of the da Vinci manipulators. Initially, experiments have been performed on tissue phantom and ex-vivo models in a lab setting and promising results have been obtained across $n = 5$ users testing the system. Furthermore, we tested the R-TRUS system in a clinical study involving $n = 5$ patients undergoing the
da Vinci Prostatectomy procedure. The clinical study, being the first of its kind, was conducted to first evaluate the feasibility of using this palpation system in a real human procedure, and second, to evaluate whether such an imaging system would provide surgeons with useful information during the procedure.

5.1 Introduction

Robotic surgical systems provide a platform for integrating surgical guidance with imaging and automation of particular tasks, while enhancing the ability of surgeons to perform delicate and precise minimally invasive surgery. One limitation of many robotic surgical systems is the inability of the operating surgeon to feel the tissues on which they are operating. During open surgery, surgeons are able to physically palpate the tissue and feel for stiff tumors under the surface, which enables them to tailor their resection margins to remove only the cancerous tissue and preserve as much healthy tissue as possible. Unfortunately during minimally invasive or robot-assisted procedures, the physical cues provided by open surgery “hands in” palpation are lost. This is because either the surgeon needs to manipulate long laparoscopic instruments through small incisions, with palpation becoming equivalent with probing tissue with a long stick, or because the robotic system that copies the surgeons hand motion at the master console to the instruments within the body provides limited haptic feedback. The loss of haptic feedback during surgery has been lamented by surgeons \[8, 34, 60, 76, 79\]. Procedures such as radical Prostatectomy or partial Nephrectomy could become less invasive if the precise location of the tumors could be found through palpation of sub-surface tissue not seen with the normal laparoscopic camera.

Mechanical properties of tissue that are felt by palpation are important indicators of disease potential. Indeed, palpation techniques are commonly used by medical doctors to determine the potential for disease, for example, stiffer tissue regions that can be felt as harder objects can indicate the presence of cancer. This is the basis for a number of clinical examinations such as the digital rectal examination for prostate cancer.
5.1. Introduction

5.1.1 Background Review

Several techniques have been proposed to enable medical robots to detect lumps in soft tissue. Howe et al. introduced a teleoperation method with haptic force feedback to convey the biomechanics of a palpated artificial tissue. They found that use of their tactile display resulted in increased success of tumor identification and localization \[40\]. Trejos et al. showed that autonomous robotic tumor localization resulted in increased tumor detection accuracy and a significant decrease in the maximum force applied compared to teleoperated human palpation \[104\]. Ahn and Kim teleoperated a robot that mimicked the geometry and motions of a doctors hand; allowing a robotic finger to sweep across the prostate and use the resultant force profile to assess the likelihood of tumors \[7\]. Sangpradit et al. observed discrepancies between a finite element model approximating a wheel-tissue interaction and force data taken during rolling contact experimentation to identify simulated tumors of diverse shapes and depths \[57\]. Liu et al. used a force-sensitive wheeled probe to gather what they referred to as a “rolling mechanical image” and found the continuous measurement approach to be sensitive to differences in force profiles caused by simulated tumors \[57\].

The imaging of mechanical properties of tissue is called elastography. One approach to elastography for medical imaging is strain imaging, which involves the acquisition of tissue images under different states of compression, and computing the relative tissue displacement field using speckle tracking \[115\]. Relative tissue displacement or strain is indicative of tissue elasticity. Indeed, stiffer tissue will undergo less strain than soft tissue, so a strain image of tissue provides elasticity or tissue stiffness contrast. The underlying assumption is that the strain is linearly related to the stress and that this relationship is described mathematically by a linear scale factor called the Young’s modulus, or simply elasticity. Ultrasound is a common imaging modality for this method because it is ubiquitous, non-invasive, safe, inexpensive and portable.

We propose a method of using ultrasound for tissue palpation. The method employs a motorized or beam-steered ultrasound beam that can
track a surgical instrument. When the surgical instrument presses against the tissue thus causing an indentation, the resulting sub-surface strain image is displayed. The sub-surface strain is indicative of tissue stiffness, works at the depth of the ultrasound beam and can be used as a more objective form of palpation. Compared with manual palpation, this method has the advantage of evaluating deeper lying lesions, and furthermore it is semi-quantifiable.

A competitive approach would be to use a laparoscopic ultrasound to probe tissue depth by strain imaging, using the ultrasound transducer itself to compress the tissue [10]. This approach has the disadvantage that a transducer has to be picked up and used, which slows down the procedure and is much more cumbersome than using the instrument for compression. Using the instrument for compression requires a mechanical movement of the transducer, preferably rotation, or electronic beam steering.

In this chapter, we describe systems and methods for creating high-quality real-time strain images using registered robotic ultrasound and manual surgical instrument indentation.

5.2 Materials and Methods

Two experimental systems were used to validate instrument-based strain imaging for robotic radical prostatectomy and partial nephrectomy using the da Vinci surgical system. In both cases, the ultrasound transducers were robotically controlled and 3D ultrasound was registered to the da Vinci surgical instrument. In our proposed method for control of the robotic ultrasound, the ultrasound imaging plane is automatically repositioned using the robot so that a 2D ultrasound image continuously contains the tip of a specified da Vinci surgical manipulatoras demonstrated in Figure 5.1. The automatic instrument tracking is achieved using an air-tissue boundary registration method explained in Chapter 2 and 3. The details of the method implementation for the pick-up ultrasound with the dVRK system is explained in Appendix A and [66].
5.2. Materials and Methods

Figure 5.1: (a) Instrument-based strain concept with robotic registered transrectal ultrasound for radical prostatectomy procedure, (b) Instrument-based strain concept with a pick-up ultrasound transducer grasped by the da Vinci auxiliary manipulator for partial nephrectomy procedure.
5.2. Materials and Methods

5.2.1 Real-Time Strain Imaging System

Real-time strain imaging is achieved using a speckle tracking motion estimation method based on a time domain cross correlation with prior estimates (TDPE) technique [115]. We implemented TDPE on a SonixTablet ultrasound machine (Analogic Ultrasound, Richmond, Canada) and it runs at 25 fps for strain images of 16 000 pixels. 40% of the CPU is used by the main ultrasound program and R-TRUS control software and the remaining 60% of the CPU is used for RF data acquisition, motion tracking, least-square strain estimation and display. 3D ultrasound images were captured using a sagittal/transverse biplane TRUS transducer (Transrectal Biplane Curved BPL9-5/55, 9-5 MHz) by rotating the TRUS transducer about its long axis and collecting the 2-dimensional sagittal images at each angle increment. Software running on the ultrasound console is capable of computing high frame rate strain images which are tracked in the coordinate frame of R-TRUS (Figure 5.1), controlling the robot movements in real-time and ultrasound data acquisition. Mechanical excitation is applied to the tissue manually using the surgical instruments. A sequence of \( n_f \) frames of RF-data is acquired for each 2D plane, processed using TDPE to create a series of real-time displacements per pixel, and then processed by a least-square strain estimation. Temporal averaging of the displacements is performed to reduce the noise-to-signal ratio. Histogram equalization is also performed to unify the scale and intensity of the strain images. In order to evaluate the quality of the strain images in real-time, average correlation coefficient (ACC) is being computed and shown in the imaging interface. The strain images are displayed to the surgeon within the console using the TilePro™ feature of the da Vinci S surgical system to provide real time guidance.

While it does not provide an absolute value of elasticity, strain imaging provides an idea of tissue compliance. If in response to an excitation, a certain region of interest exhibits higher strain than the background, it is likely to be softer.

For validation of the method in the case of radical prostatectomy, a CIRS
5.3 Phantom and Ex-vivo User Study and Results

A prostate phantom (Model 066) was used with a parasagittal/transverse bi-plane TRUS transducer shown in Figure 5.3. This phantom contains the prostate, along with structures simulating the rectal wall, seminal vesicles and urethra in a 11.5 x 7.0 x 9.5 cm clear plastic enclosure. A 5mm thick simulated perineal membrane enables various probes and surgical tools to be inserted into the prostate. This phantom contains 2 isoechoic randomly placed lesions that are at least two times stiffer than the simulated prostate tissue. The ProGrasp robotic instrument was used to touch the surface of the simulated perineal membrane gently to produce the strain images.

When considering the case of partial nephrectomy, a different set-up was used as shown in Figure 5.4. An ex-vivo kidney was implanted with stiff PVC inclusions. These inclusions were then imaged using a robotically held ultrasound transducer [92].

5.3 Phantom and Ex-vivo User Study and Results

Initial validation of our palpation method was performed on a CIRS prostate phantom (Model 066). The phantom contains the prostate anatomy and two isoechoic randomly placed lesions that are at least two times stiffer than the simulated prostate tissue. The ProGrasp™ robotic surgical instrument was used to excite the surface of the phantom’s simulated perineal membrane gently to produce the strain images. In the first set of experiments performed, high-quality strain images were produced in the prostate phantom. The light pressure of the robotic tool on the phantom surface was enough to create a strain image of the entire phantom. The lesions within the phantom could easily be located along with the other anatomical features, such as the simulated urethra (Figure 5.3).

Next, a user study was conducted in which \( n = 6 \) users (2 Urology surgeons, 4 training residents) tested the system in a mock up operating room with a da Vinci Si surgical robot and the R-TRUS system. The users were asked to sit at the da Vinci surgical console and use the system to
5.3. Phantom and Ex-vivo User Study and Results

Figure 5.2: User study imaging interface using the da Vinci Si system, TilePro™ and a CIRS 066 prostate phantom. Under normal B-Mode ultrasound the stiff inclusions cannot be detected but are readily visible on strain images.

palpate the prostate phantom and localize the two stiff inclusions. The real-time strain and TRUS images were being relayed to the surgeon console and visualized to the users using the TilePro™ feature of the da Vinci Si system as depicted in Figure 5.2. R-TRUS to da Vinci surgical instrument registration was performed before users start testing the system. All six users could successfully localize the stiff inclusions inside the phantom with the results listed in Table 5.1. In this set of experiments, we have shown the feasibility and potential use of our system in a scenario identical to a real robotic surgical operation and with only the tools that would be normally available to a robotic surgeon.

Using an ex-vivo porcine kidney, the lesions could also be identified on
5.3. Phantom and Ex-vivo User Study and Results

Table 5.1: Phantom stiff inclusion exploration user study results. Strain imaging parameters: LSE neighbors: 7, Temporal averaging: 90, Frame-rate: 25 Hz

<table>
<thead>
<tr>
<th></th>
<th>Inclusion-I roll angle(deg)</th>
<th>Inclusion-II roll angle(deg)</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>surgeon 1</td>
<td>11.47 ± 1.83</td>
<td>-21.78 ± 1.65</td>
<td>320s</td>
</tr>
<tr>
<td>surgeon 2</td>
<td>12.63 ± 1.22</td>
<td>-22.00 ± 1.04</td>
<td>290s</td>
</tr>
<tr>
<td>resident 1</td>
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<td>311s</td>
</tr>
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<td>12.58 ± 1.63</td>
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<td>resident 4</td>
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<td>320s</td>
</tr>
<tr>
<td>Average</td>
<td>11.65 ± 1.24</td>
<td>-21.93 ± 1.90</td>
<td>291s</td>
</tr>
</tbody>
</table>

the strain and displacement images from the small intraoperative transducer. We touched several different locations around the transducer to estimate the effect on the strain image, but in all cases the strain image clearly depicted the embedded stiffer region (Figure 5.4 and Figure 5.5). In this set of experiments, we have shown the feasibility of creating strain images with only the tools that would be normally available to a robotic surgeon. In the next stage of this study, we have tested the method in real human patient prostatectomy cases. This method is entirely feasible and easy to implement in a real surgical setting with a minimum of added equipment. Although strain imaging is sensitive to boundary conditions and operator technique and, in the absence of measured forces, produces only relative measurements, it is a simple but highly effective method for determining the stiffness under the surgeons tool. Because the proposed integration of strain imaging uses a tool tracking technique, the surgeon can easy and intuitively determine the stiffness directly in the area where they are going to work. This would potentially improve the surgical margins and allow for more precise dissections.
5.4 Human Patient Studies

Figure 5.3: (a) Experimental setup for imaging the CIRS 066 prostate phantom using robotic TRUS and da Vinci ProGrasp instrument, (b) Real-time B-Mode and displacement image example results produced by the users for the phantoms inclusions and urethra. Under normal B-Mode ultrasound the stiff inclusions cannot be detected but are readily visible on strain images.

5.4 Human Patient Studies

After achieving promising results in phantom and ex-vivo studies, 5 patients were enrolled in a clinical study (CREB: H11-02267) similar to the TRUS-guidance study described in Chapter 2. Our main goal in performing this clinical study was: (i) to evaluate the technical feasibility of using such an imaging system in a real da Vinci surgery scenario, (ii) to get some feedback from the surgeons about the intuitiveness of the approach and our imaging user interface and (iii) to evaluate its clinical usefulness to the surgeons (Phase I clinical study).
5.4. Human Patient Studies

Figure 5.4: (a) Experimental setup for imaging the *ex-vivo* kidney, (b) real-time strain and B-mode images produced using instrument-based strain and the pick-up transducer.

Figure 5.5: TilePro™ images from the da Vinci S surgical console. Both strain and B-mode images could be provided to the surgeon at the console in real-time.
5.4. Human Patient Studies

5.4.1 Patient Population

A total of \( n = 5 \) patients with clinically organ confined prostate cancer undergoing RALRP at our institution (Vancouver General Hospital) agreed to participate in this study between November 2014 and February 2015. Median patient age was 63 years (range 52 to 70) and median baseline prostate specific antigen was 5.9 ng/ml (range 0.84 to 36.4). Patient demographic and preoperative data are listed in Table 5.2.

Table 5.2: Demographic and preoperative data.

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years ; median (range)</td>
<td>63 (55-72)</td>
</tr>
<tr>
<td>Preoperative PSA, ng/ml ; median (range)</td>
<td>18.6 (13.5-28.5)</td>
</tr>
<tr>
<td>Preoperative Gleason score (index lesion), no. (%)</td>
<td></td>
</tr>
<tr>
<td>3+4=7</td>
<td>3 (60)</td>
</tr>
<tr>
<td>4+4=8</td>
<td>1 (20)</td>
</tr>
<tr>
<td>4+5=9</td>
<td>1 (20)</td>
</tr>
<tr>
<td>Clinical stage, no. (%)</td>
<td></td>
</tr>
<tr>
<td>T1c</td>
<td>1 (20)</td>
</tr>
<tr>
<td>T2a</td>
<td>1 (20)</td>
</tr>
<tr>
<td>T2b</td>
<td>3 (60)</td>
</tr>
<tr>
<td>IPSS value ; median (range)</td>
<td>5 (2-9)</td>
</tr>
<tr>
<td>Prostate volume, cc ; median (range)</td>
<td>35 (20-46)</td>
</tr>
</tbody>
</table>

PSA: Prostate-Specific Antigen ; IPSS: International Prostate Symptom Score

5.4.2 Procedure Description

The main components and configuration of our system during this clinical study inside the operating room are shown in Figure 5.7 and Figure 5.6.

We usually setup our system in the operating room before the patient is placed on the operating table. This stage of the study includes setting up the video-capture PC with the da Vinci system, setting up and testing the da Vinci research API and TilePro software, and placing the sterile transducer cover (NeoGuard Transducer Cover CV610-843) on the TRUS
5.4. Human Patient Studies

We sterilize the TRUS transducer before doing every clinical study according to the guidelines provided to us by BC cancer agency (included in Appendix B.2). Once the patient is placed on the operating table, after he is anesthetized and while the OR staff are preparing the patient for port placement, we attach our robotic TRUS system to the foot of the operating table. Then we ask the attending Urology fellow to place the TRUS transducer inside patient’s endocavity to provide optimal transverse/sagittal images of the prostate as in standard brachytherapy prostate volume studies. The TRUS sagittal plane was placed underneath the prostate midline so that the prostate could be imaged from the base to the apex. Our robotic TRUS system was draped using sterile disposable drapes (Sterile flat 81.3 X 91.4cm polyethylene drape, CV610-870) to follow reprocessing guidelines set by VCH operation research committee. Once the TRUS system is setup, the OR staff continue with preparing the patient and docking the da Vinci robot.

Once the anterior surface of the prostate is visible to the surgeon, we perform the TRUS to da Vinci calibration (explained in Chapter 2) to enable automatic tracking of the surgical instrument with ultrasound. After the tracking is activated, the surgeon could examine the prostate anatomy and different regions by moving the registered surgical instrument around, pressing on the tissue surface of the area of interest, slightly indent the tissue and look at both TRUS and real-time strain images. As it is shown in Figure 5.10 and Figure 5.8 both real-time strain and TRUS images are being sent to the da Vinci console and visualized to the surgeon using the TilePro® feature of the da Vinci S system. Because the ultrasound images are always underneath the tip of the surgical instrument, using our imaging system was intuitive for the surgeon, especially in terms of 3D spacial orientation. Similar to the case of open surgery where they simply touch and press the surface of tissue in their area of interest and feel the tissue mechanical properties, in this case they touch and press with their surgical instrument and look at the strain image which conveys tissue mechanical properties.
5.4. Human Patient Studies

The calibration process was performed after incision of the endopelvic fascia with the 4 instrument tip locations spread across both sides of the dorsal prostate and could be completed in approximately 2 minutes.

Intraoperative registered TRUS and instrument-based strain imaging was performed successfully for all 5 patients. The strain imaging was examined at the anterior surface of the prostate, after the surgeon placed the dorsal venous complex (DVC) suture at the prostate apex, and before he wanted to start finding the bladder-prostate boundary and dissecting the bladder neck. Strain volumetric data was collected successfully (2D strain imaging).
5.4. Human Patient Studies

Figure 5.7: Operating room configuration during the TRUS+Strain guidance study in OR no. 10 in Vancouver General Hospital.

+ roll angle) for all patients. The software architecture used in this study allowed us to use both automatic tracking control of the TRUS robot and real-time volumetric strain imaging at the same time. Once tool tracking is activated, real-time roll angle of the TRUS sagittal image are streamed from the TRUS control software to the strain imaging software. This allowed us to acquire 3D strain imaging as the surgeon moves the instrument to different locations on the prostate surface to examine. As an example, after the calibration stage and activation of automatic tracking, for two cases we asked the surgeon to start examining the prostate volume by placing his surgical instrument on the surface of the prostate from left-lateral boundary through to the right-lateral boundary. Our goal in collecting volumetric strain images was to collect a 3D strain volume that could be compare to post-operative whole mount whole mount histopathology results. Because of the limitations in the number of whole mount pathology procedures our research group could order at the time of performing this study, we could not get the pathology results for any of the patients in this dataset. Hence, we only relied on qualitative evaluation and feedback from our collaborating clinicians and quantitative evaluation of our strain imaging system. Three different surgical instruments (Prograsp forceps, Large needle driver and
Maryland Bipolar Forceps) were tested to see the effect of instrument tip sharpness, size and shape on the quality of the strain images. Using the sides of the ProGrasp instrument gave us more smooth and consistent images (shown in Figure 5.9). The reason for this is hypothesized to be the larger area over which the displacements are applied on the tissue surface. When the sharp tip of the instrument is used, displacements are applied over a small surface area and would not result in a large and consistent displacement (strain) field.

In order to evaluate the strain image quality in real-time, to make sure that our strain imaging system is working with high quality, we computed the average correlation coefficient (ACC) and showed it inside our imaging graphical user interface. The average correlation coefficient is the index to evaluate how well the tissue motion tracking algorithm is estimating dis-
placement and strain.

Since generating the strain images are being performed by surgical tool motion, and surgical tool motion is in surgeon’s control, there exist a learning curve for the user to produce high ACC strain images. By pressing the tissue surface too hard, the ACC and image quality will drop.

Human-in-the-loop strain palpation is intuitive and easy to use by the surgeons. Instrument based excitation is user subjective and requires some learning. Strain image interpretation by the surgeon requires some experience and learning.

In terms of the evidence for clinical usefulness, there were a few cases that we could detect tissue structures that were not obvious in the endoscope or the BMode TRUS images. Some use cases of instrument-based strain imaging for detecting a clinically proven calcification, and prostate boundary and urethra are shown in Figure 5.12. An imaging sequence inside the da

![Figure 5.9: Three different da Vinci instrument tested for the instrument-based strain imaging. The surgeon was asked to use the longer sides of the instruments to enable applying displacement over a larger area on the tissue surface. All of the above pictures are taken when the instrument is pressed on the anterior surface of the prostate.](image-url)
5.4. Human Patient Studies

Figure 5.10: The imaging system interface inside the daVinci console in two different configurations in two different patient cases using the TilePro™ feature.

Vinci surgeon’s console while the surgeon is trying the system is shown in Figure 5.14.

After testing the system in this pilot clinical study, we concluded that while this imaging system has some potential clinical benefit to augment surgeon’s view of the anatomy with bio-mechanical information, producing high quality and useful strain images required a large amount of learning and...
5.4. Human Patient Studies

![Image of surgical instrument tip palpation](image)

Figure 5.11: Strain imaging using the surgical instrument tip palpation. (a) Instrument tip in pressing motion, (b) instrument tip released.

Training by the surgeon. Because surgical operation time is an extremely important factor for patient health and surgical performance, surgeons are reluctant to spend a huge amount of time practicing with an imaging system to learn how to use it. Furthermore, unlike BMode ultrasound and MRI imaging, which are clinically accepted and practiced imaging modalities, strain imaging is a pretty new imaging modality and lacks evidence for cancer detection.

With further processing to simulate tool-tissue interaction, elastic models can be used to synthesize haptic feedback at the da Vinci masters without compromising system stability. The next step for this system is to estimate...
5.4. Human Patient Studies

Figure 5.12: Strain imaging useful information in different cases and different structures.

Figure 5.13: Detecting blood vessels and pulsatile motion in strain imaging.
5.4. Human Patient Studies

Figure 5.14: Strain imaging on the prostate anterior surface using the needle driver surgical instrument.
In this chapter, we describe a system for detecting dominant prostate tumors, based on a combination of features extracted from a novel multi-parametric quantitative ultrasound elastography technique. The performance of the system was validated on a data-set acquired from $n=10$ patients undergoing radical prostatectomy. Multi-frequency steady-state mechanical excitations were applied to each patient’s prostate through the perineum and prostate tissue displacements were captured by a transrectal ultrasound system. 3D volumetric data including absolute value of tissue elasticity, strain and frequency-response were computed for each patient. Based on the combination of all extracted features, a random forest classification algorithm was used to separate cancerous regions from normal tissue, and to compute a measure of cancer probability. Registered whole mount histopathology images of the excised prostate gland were used as a ground truth of cancer distribution for classifier training. An area under receiver operating characteristic curve of $0.82 \pm 0.01$ was achieved in a leave-one-patient-out cross validation. Our results show the potential of multi-parametric quantitative elastography for prostate cancer detection for
the first time in a clinical setting, and justify further studies to establish whether the approach can have clinical use.

6.1 Introduction

The use of tissue elasticity as a contrast mechanism to detect prostate tumors has been suggested in many previous studies, in the area of elastography imaging [13, 90, 116, 117]. However, most clinical ultrasound elastography systems are based on a quasi-static tissue excitation, with major drawbacks such as dependency on operator skill and lack of reproducibility [6]. Hence, an absolute, quantitative elastography technique is highly desirable. Furthermore, the majority of tested real-time elastography systems are shown to have a high rate of false-positives [13, 14]. One major reason for this poor detection performance is hypothesized to be the fact that the current clinical elastography systems are only capable of producing an image that visualizes a single tissue physical parameter, such as stiffness or compliance, while cancerous tissues are complex and non-uniform and cannot be characterized using only one parameter.

Multi-parametric imaging is an emerging technology that combines information from different techniques, to improve detection rates beyond what can be achieved using any single imaging method. Brock et al. assessed a combination approach of ultrasound elastography and contrast enhanced ultrasound and showed that the multi-parametric approach decreased the false-positive value of real-time elastography alone from 34.9% to 10.3% [14]. Vibro-elastography - the multi-frequency tissue response over a wide excitation bandwidth [90, 105], as well as tissue nonlinear response as a function of applied displacements [117], are also shown to contain additional information that may increase the accuracy of cancer detection based on elastography.

In this work, in vivo 3D volumetric data acquired from multi-frequency quantitative vibro-elastography imaging is analyzed. This is the first report of such clinical data. We propose a novel set of features that combine the B-mode, strain, absolute elasticity, along with the frequency-dependent
parameters that reveal tissue relaxation time and visco-elastic properties. A supervised classification framework is constructed and used to combine the multi-parametric features to separate cancerous and normal tissue and compute a cancer probability map.

6.2 Methods

Absolute Vibro-Elastography:

A multi-frequency steady-state mechanical excitation is applied externally to generate tissue motion. A sequence of $n_f$ frames of RF-data is acquired for each plane in an imaging volume by the ultrasound machine, and processed using a speckle tracking algorithm [115] to create a series of displacements per pixel as a function of time. With a linearity assumption, motion at each pixel has the same temporal frequency content as the input excitation, and therefore the tissue response can be described using complex exponentials (phasor: $p_i = A_i \exp(j\phi_i)$) at each pixel for each frequency $f_i$. A single phasor displacement image is generated from $n_f$ frames for each plane at each frequency and any traveling wave inside the tissue could be revealed from this image at each plane. Tissue strain could also be computed from this phasor image. The waves seen in phasor displacement images are only 2D projections of the actual traveling waves created by the steady state external excitations. Therefore, 2D phasor images are computed for a series of $n_e$ planes creating a 3D volume. The Local Frequency Estimation (LFE) inversion algorithm [68] was used here for elasticity computation. This process is repeated for an entire volume producing $N_E$ elastograms from $N_p$ planes ($N_E = N_p - n_e + 1$).

System Implementation for Prostate Imaging:

The main components of our prostate imaging system are depicted in Figure [6.1]. A BK ultrasound machine (BK Medical, Herlev, Denmark) with a 8848 4-12 MHz biplane transducer was used for imaging the prostate and tissue displacement measurements. Raw In-phase Quadrature (IQ) data was
6.2. Methods

captured at 42.66 Hz sampling rate and saved into an external PC through a DALSA Xcelera-CL PX4 Full frame grabber card (Teledyne DALSA, Waterloo, ON). A previously designed TRUS robot \[4\] was used to automatically control the rotation angle of the TRUS transducer and save location information of each image.

To ensure good wave penetration into the prostate in a noninvasive manner, we used transperineal excitation similar to the approach used in Magnetic Resonance elastography (MRE) \[88\]. An electromagnetic exciter in combination with an Agilent U2761A function generator (Agilent Technologies, Santa Clara, CA) was used to generate desired excitation frequencies. The excitation frequencies used for tissue motion generation in this study varied between 58 Hz to 180 Hz. Since we did not have external access to the image acquisition parameters of the BK ultrasound machine, a band-pass sampling algorithm described in \[25\] was used here for phase and amplitude reconstruction with sampling frequencies that are lower than the excitation

![Figure 6.1: Main components of the quantitative elastography system with transperineal excitations](image-url)
frequencies.

**Patient Data Collection:**

Ten patients with clinically organ-confined prostate cancer (median patient age: 61 years, range: 52-70 and median baseline PSA: 6.4 ng/ml, range: 4.6-36.4) undergoing robotic radical prostatectomy at our institution agreed to participate in this study. Ethics approval for this clinical study was obtained from the UBC Research Ethics Board (H08-02696). For each patient, four to six volumes of multi-parametric data including time displacements, phasor displacement and elasticity data were acquired, for a variety of excitation frequencies. One of the acquired volumes for all patients was at an excitation frequency of 75 Hz and single frequency features were extracted from it. Data from other frequencies were used to compute frequency dependent parameters.

Whole-mount histopathology images of the excised prostate were used as ground truth for cancer detection validation. Depending on the size of the

![Figure 6.2: Clinical setting for data acquisition](image)
6.3 Data Analysis

6.3.1 Registration

To define regions of interests (ROI) for the classifier data, the acquired images should be registered to the pathology images. Bilinear interpolation is performed first to convert the volume in the probe’s curved grid into a 3D Cartesian grid, ensuring that orientation of the axial (transverse) images matches the orientation of the pathology slides (Figure 6.5). A slice-to-surface, particle-filter-based registration technique [71] was used to register the stack of equispaced 2D pathology contours to the 3D surface extracted from the volumetric ultrasound images as depicted in Figure 6.5. To select areas of interest, a re-slicing tool was used which allows the user to select an area on the pathology slides, and using the transformation by which the registration is performed, the corresponding area in the ultrasound volume is identified.
6.3. Data Analysis

**Feature Extraction:**

To define regions of interests (ROI) for the classifier data, the acquired images were registered to the pathology images. A slice-to-surface, particle-filter-based registration technique [71] was used to register the stack of eq-

![Image](image.png)

(a)

![Image](image.png)

(b)

Figure 6.4: (a) Example pathology images, and their corresponding reconstructed B-Mode and absolute elastography, (b) example slices of four types of volumetric images available for feature extraction: B-mode ($B_i$), displacement phasor magnitude ($A_i$) and phase ($\phi_i$), and absolute elasticity ($E_i$). ($f_i = 75Hz$)
6.3. Data Analysis

Figure 6.5: TRUS to pathology registration for comparison to pathology images.

For each plane in each volume, four types of images are available for feature extraction: B-mode ($B_i$), displacement phasor magnitude ($A_i$) and phase ($\phi_i$), and absolute elasticity ($E_i$). To identify ROIs, regions of interest were specified for both Class 1 (malignant cancer) and Class 0 (benign lesion) using the pathology markings which were registered to ultrasound data. A feature vector was created for each ROI corresponding to a whole tumor or a non-cancerous area. For each of the four data types ($B_i$, $A_i$, $\phi_i$, $E_i$), seven statistical parameters of the pixel intensities within the ROI were calculated and used as features. These included the mean, standard deviation, maximum, minimum, median, kurtosis and skewness. Before extracting the features, histogram normalization was performed on the data.
6.3. Data Analysis

Table 6.1: Table of features. Physical meaning of the features: $B_i$: Brightness, $E_i$: Stiffness, $(A_i$ and $\phi_i$): strain, $FR$(FrequencyResponse): Relaxation-time and Viscosity

<table>
<thead>
<tr>
<th>Data type</th>
<th>Features per ROI</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>$B_i$</td>
<td>$\mu_B$ $\sigma_B$ $Max_B$ $Min_B$ $Med_B$ $Kurt_B$ $Skew_B$</td>
<td>1-7</td>
</tr>
<tr>
<td>$E_i$</td>
<td>$\mu_E$ $\sigma_E$ $Max_E$ $Min_E$ $Med_E$ $Kurt_E$ $Skew_E$</td>
<td>8-14</td>
</tr>
<tr>
<td>$A_i$</td>
<td>$\mu_A$ $\sigma_A$ $Max_A$ $Min_A$ $Med_A$ $Kurt_A$ $Skew_A$</td>
<td>15-21</td>
</tr>
<tr>
<td>$\phi_i$</td>
<td>$\mu_\phi$ $\sigma_\phi$ $Max_\phi$ $Min_\phi$ $Med_\phi$ $Kurt_\phi$ $Skew_\phi$</td>
<td>22-28</td>
</tr>
<tr>
<td>$FR$</td>
<td>$m_\phi$</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>$m_E$</td>
<td>30</td>
</tr>
</tbody>
</table>

across the data-set to map the intensities to the same dynamic rage for all cases. A feature vector with $n=28$ components (described in Table 1) was created per ROI, all calculated from images with excitation at 75 Hz.

In order to leverage the multi-frequency data for each patient, two frequency dependent features were computed for each ROI and added to the feature vector. The displacement phasor phase ($\phi_i$) and elasticity ($E_i$) frequency-response were analyzed for the range of frequencies available for each patient.

Assuming linearity, the tissue displacement transfer function could be formulated as: $G(j\omega) \approx \frac{X(j\omega)}{U(j\omega)} = \frac{1}{1+Tj\omega}$, where $X(j\omega)$ is the displacement measured at each pixel, $U(j\omega)$ is the input displacement from external excitation, and $T$ is a time-constant. The phase of this transfer function is $\angle G(j\omega) = \arctan(T\omega)$, which is the same as the computed phasor phase $\phi_i$ at each frequency. Hence, the slope of a line fitted to the $\phi_i$ frequency-response will be $T$, an estimate of the tissue relaxation time. Such analysis was performed for each ROI in our data-set, and the slope of a line fitted to the $\phi_i$ frequency response was computed ($m_\phi$) and added to the feature vector.

Tissue visco-elastic properties are reported to vary with the input excitation frequency [90] and the rate of such variations may yield more information about tissue characteristics. The frequency response of $E_i$ was computed for each ROI and the slope of a line fitted to the curve ($m_E$), rate of change of elasticity with frequency, was included as another feature for
6.3. Data Analysis

each ROI. Using the combination of all described features, we incorporated the texture and intensity features from one common frequency and also used the multi-frequency content of the data.

Classification:

Binary classification between malignant and benign lesions was performed using random forests [12]. To generate the trees, a random feature vector $\theta_k$ is selected from all the available features for each tree $k$. This vector is independent of the feature vectors for the other trees, but has the same distribution. The decision tree is grown using the training set and $\theta_k$; each node in the tree is partitioned using the best binary split. Once grown, each decision tree yields a classifier $h(x; \theta_k)$, where $x$ is the input vector. After all the independent trees have been grown, to classify an input example, each tree casts a unit vote and the final classification is based on the most popular class.

Bootstrapping of features was always performed, and the Gini index was used as the criterion for determining the best binary split. Various other parameters are available for design and a number of these were optimized using a grid-search method: (i) Number of estimators ($N_e$): the number of trees in the forest. (ii) Maximum number of features ($Max_{nf}$): these are the number of features to consider when looking for the best binary split. (iii) Maximum depth of the tree $Max_{nt}$: tested values for this parameter ranged from no limit to a depth of 15. This parameter is also tree-specific.

To perform classifications consistent with the tissue types in the prostate gland, features were extracted twice: (i) only from the peripheral zone (PZ) of the prostate, (ii) from the whole gland (WG), since different regions in the prostate have inherently different elastic properties [62].

In order to demonstrate the performance of each group of features, four classification experiments with different feature vectors were performed: (i) multi-parametric and multi-frequency experiment ($n = 30$, feature index: 1-30 in Table 1), (ii) multi-parametric single-frequency experiment ($n = 28$, feature index: 1-28), (iii) multi-parametric and multi-frequency experiment
6.4 Results

without B-Mode features \((n = 23, \text{feature index: } 8-30)\), (iv) single-frequency single-parametric experiment \((n = 7, \text{feature index: } 8-14)\).

For each combination of these parameters, a leave-one-patient-out cross-validation was performed. Benign lesions were the negative class (class 0) and malignant ones were positive (class 1). The accuracy, sensitivity, specificity, precision and area under the receiver operating characteristic (ROC) curve (AUC) was recorded for each of the ten leave-one-patient-out classifications, and then averaged to find the classifier performance for that particular set of parameters. Further, this grid search was performed three times for each of the three feature vectors described in the Feature Extraction section. A total of three experiments were completed using random forests, with a unique parameter optimization done for each.

6.4 Results

The classification results in terms of sensitivity, specificity, accuracy and area under the ROC curve (AUC) for each experiments are presented in Table 6.2. In plotting the receiver operating characteristic (ROC) curve, a value of probability=0.5 was used as the cutoff between classes.

Comparison of Results in Each Prostate Region:

For each of the experiments with different feature groups, the classification algorithms were tested once on ROIs extracted from the PZ, and once on ROIs from the WG. Results suggest that limiting the analysis to the PZ would consistently lead to better results in terms of AUC, specificity and accuracy (AUC changes from 0.79 ± 0.01 to 0.82 ± 0.01 in experiment (i)).

Comparison of Results for Different Feature Groups:

Comparing the results of the multi-frequency multi-parametric experiment with single-frequency single-parameter elasticity imaging shows \(\approx 10\%\) improvement in AUC and specificity in the PZ. Single-frequency single-parameter experiments represent the traditional single parameter elasticity imaging.
Comparison between the results of experiment (i) and (ii) shows 4% improvement in an AUC and 7% improvement in the specificity in the PZ, when multi-frequency features are added to the feature vector. Without using features from B-Mode, the multi-frequency multi-parametric elasticity imaging could yield an AUC of 0.77 (compare the results of experiments (i), (iii)).

### 6.5 Discussions and Conclusions

On the basis of the receiver operating characteristic curve, a value of probability=0.5 was used as the cutoff between benign and malignant.

Table 6.2: Classification results. n: number of features, f-index: feature index, Zone: prostate region features extracted from, \(N_{ROI}\): number of ROIs extracted, Param.: \([N_e, Max_{nf}, Max_{nt}]\) for random forest, AUC: area under ROC curve. Results corresponding to PZ are colored in gray for easier comparison.

<table>
<thead>
<tr>
<th>Ex</th>
<th>n</th>
<th>f-index</th>
<th>Zone</th>
<th>(N_{ROI})</th>
<th>Param.</th>
<th>Acc.</th>
<th>Sens.</th>
<th>Spec.</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>i</td>
<td>30</td>
<td>1-30</td>
<td>PZ</td>
<td>164</td>
<td>[19, 19, 2]</td>
<td>0.72±</td>
<td>0.61±</td>
<td>0.82±</td>
<td>0.82±</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>WG</td>
<td>231</td>
<td>[18, 14, 2]</td>
<td>0.67±</td>
<td>0.63±</td>
<td>0.74±</td>
<td>0.79±</td>
</tr>
<tr>
<td>ii</td>
<td>28</td>
<td>1-28</td>
<td>PZ</td>
<td>164</td>
<td>[17, 18, 2]</td>
<td>0.69±</td>
<td>0.62±</td>
<td>0.75±</td>
<td>0.78±</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>WG</td>
<td>231</td>
<td>[17, 19, 2]</td>
<td>0.66±</td>
<td>0.61±</td>
<td>0.72±</td>
<td>0.77±</td>
</tr>
<tr>
<td>iii</td>
<td>23</td>
<td>8-30</td>
<td>PZ</td>
<td>164</td>
<td>[16, 17, 2]</td>
<td>0.65±</td>
<td>0.61±</td>
<td>0.72±</td>
<td>0.77±</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>WG</td>
<td>231</td>
<td>[13, 4, 7]</td>
<td>0.64±</td>
<td>0.60±</td>
<td>0.68±</td>
<td>0.75±</td>
</tr>
<tr>
<td>iv</td>
<td>7</td>
<td>8-14</td>
<td>PZ</td>
<td>164</td>
<td>[19, 2, 2]</td>
<td>0.64±</td>
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<td>WG</td>
<td>231</td>
<td>[18, 3, 2]</td>
<td>0.64±</td>
<td>0.64±</td>
<td>0.63±</td>
<td>0.70±</td>
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6.5. Discussions and Conclusions

Previous reports on the clinical application of elastography for prostate cancer detection all confirm its usefulness, but also agree on the fact that single parametric elasticity imaging alone is not sufficiently accurate to enable guidance for diagnosis and treatment. In the published clinical studies with whole mount histopathology validation, Brock et al., reported an overall sensitivity and specificity of 49% and 73.6% using shear-wave elastography [13]. Salomon et al. reported sensitivity and specificity of 75.4% and 76.6%, using quasi-static elastography [91]. We show that the combination of all features (experiment (i)) provides sensitivity of 0.61% and specificity of 0.82% and has a more efficient cancer detection performance than each method individually.

Nodular prostatic hyperplasia was observed inside the prostate transition zone for 80% of the cases. It causes changes in the tissue mechanical properties and could contribute to some of the false positive detections outside the PZ. Hence, the elasticity reconstruction is expected to perform better in the PZ region, leading to more accurate results.

Feature importance analysis from random forest classification shows that \(Kurt_\phi\), \(Kurt_A\), \(Kurt_E\) have the highest importance rank in the classification results. Kurtosis is a measure of “peakedness” of the distribution of the parameters in each ROI. Such results reveal that a dominant tumor typically has a consistent intensity contrast with respect to the surrounding healthy
tissue in elasticity and displacement phasor images.

A multi-parametric cancer detection framework based on quantitative vibro-elastography imaging was proposed in this chapter. A unique set of features were computed based on the acquired data from 10 patients in a feasibility clinical study, and their detection performance was compared with traditional single parameter elastography. Promising detection results justify further clinical studies to prove the clinical usability of the system.

According to the pathology reports for each patient, there are varying numbers of small tumor spots detected inside each prostate which were marked by the pathologist. According to [62], minimum tumor diameter for it to be considered as palpable is 7mm. We believe that considering the small tumors inside this data-set contributed to some of the false positive detections in our system.

In most of the cases, symmetrical nodular prostatic hyperplasia (showing secondary cystic atrophy) was observed inside the prostate transition zone. This biological phenomenon causes change in the tissue mechanical properties and could contribute to some of the false positive detections. Also, according to the pathologist, not most of the cancers they marked in the slides were stiffer than the surrounding tissue. They mentioned the soft tumor phenomenon is one of the cases.
Chapter 7

A Novel Force Feedback Control Structure for Robot-Assisted Laparoscopic Surgery

Despite the recent widespread success of robot-assisted minimally invasive surgery, haptic feedback is not yet available in current clinical surgical robotic systems. The absence of haptic feedback is a concern for novice surgeons in the field, especially for execution of force-sensitive surgical tasks. A novel force feedback control framework for two-handed tasks in teleoperated robot-assisted surgery (RAS) is presented in this chapter. In bimanual tasks such as suturing and palpation that involve an action and a reaction force, the applied forces on the environment by the dominant action hand are not transferred back to the same hand, but rather to the non-dominant hand using our proposed asymmetric control framework. Such a technique provides an intuitive way of feeling the force, while avoiding destabilizing effects, since the control loop is not closed from the slave to the master of the same hand. The framework has been initially evaluated on an experimental setup consisting of four force feedback haptic devices, then on the da Vinci surgical system (Standard version) using the da Vinci Research Kit (dVRK) controllers. The da Vinci implementation involves a teleoperation controller based on kinematic correspondence, motion scaling and gravity compensation, as well as torque control for force rendering at the master manipulators. A series of user studies involving a small group of both sur-
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gerons \((n = 3)\) and novices \((n = 6)\) were conducted to evaluate the system in suture knot tying and haptic exploration tasks. The results show that the proposed technique has some promise when implemented on a realistic surgical robot, but further work is necessary to make the system fully usable.

7.1 Introduction

Tele-robotic surgical systems have provided significant contributions to the growth of minimally invasive surgery (MIS), due to their enhanced precision, range of motion, dexterity and 3D endoscopic visualization offered to the surgeon. Clinical advantages such as smaller incisions and minimized tissue trauma translate into reduced wound complications, patient discomfort and recovery times, making these systems also attractive to patients and the healthcare industry [48].

Despite these successes, current commercially available surgical robotic systems have limited haptic (tactile and kinesthetic) feedback. This deficiency is hypothesized to be a limiting factor in the performance of such systems in robot-assisted MIS [77]. Force feedback conveys medically relevant information that could improve the performance of a surgical task in different ways. The surgeon could estimate tissue mechanical properties such as stiffness and texture using a combination of force and motion data, allowing him/her to identify pathologic conditions [60, 76, 113]. Force feedback can also prevent trauma and incidental tissue damage as it provides surgical tool-tissue interaction forces to the operator [34]. In manipulation tasks such as blunt dissection [112] and suturing [86], force feedback is important to prevent excessive retraction forces or puncture of the tissue. Furthermore, force feedback can help to reduce the likelihood of breaking sutures from unintentionally large applied forces. Bethea et al. reported that even experienced surgeons training with robot-assisted surgery often break sutures and damage delicate tissue [8]. This is attributed to the fact that high enough forces could not be applied to create knots that are firm enough without breaking the suture or damaging the tissue. Kitagawa et al., in a study done on the da Vinci surgical system (Intuitive Surgical Inc.,
Sunnyvale, CA) showed that resolved force feedback would improve robot-assisted performance during complex surgical tasks such as knot tying with fine suture [49]. In a work studying the role of haptic feedback in a blunt dissection task using a telerobotic system, Wagner et al. discovered that force feedback reduces the number of errors that damage tissue by a factor of three [112].

Recently, there have been a few studies on the effect of alternative forms of feedback on surgical knot tying practice. Visual sensory substitution is reported to help surgeons apply more consistent, precise, and greater tensions to fine suture materials without breakage during robot-assisted procedures [21, 48, 75, 86]. Audio feedback is also proven to be a valuable sensory substitution method [21]. Furthermore, some groups have reported integration of real-time ultrasound elastography to the da Vinci surgical system, to compensate for the loss of haptic feedback for palpation purposes [15]. However, while such alternative methods are shown to improve the surgical performance of existing robotic systems, they might cause mental or visual overload for surgeons. Providing realistic haptic feedback will make surgical robots more intuitive, would naturally facilitate surgical tasks and would decrease mental workload, leading to better performance. The technical challenges in the application of force feedback in a clinically practical telesurgical system could be divided into three categories: (i) integration of force sensors into surgical instruments (haptic sensing) [31, 34, 47, 79], (ii) techniques to display the sensed force back to the surgeons hands (haptic display) [31, 47, 76, 86] and (iii) stable and robust force feedback control architectures. This work is concerned with offering a novel solution to the third problem. Force feedback teleoperation has been extensively addressed in previous works on bilateral controllers [39], cooperative multi-master multi-slave teleoperation systems [80, 93, 94] and bimanual haptic teleoperation systems [51, 52, 103]. Due to safety and stability requirements for surgical telerobots, most of the previous reports either provide a scaled force feedback or require additional hardware for indirect haptic feedback not to the controlling hand.

This work introduces a new force feedback control solution for a class of
cooperative two-handed tasks in telerobotic surgery. While executing surgical tasks, surgeons commonly use both their hands cooperatively to achieve precise control. Often, tasks are divided between the two hands. As an example, in knot tying and remote palpation tasks, one hand would be used to hold the suture knot or a part of a tissue or an organ, and the other hand is used to exert tensile/compressive forces. A clinical example of such a scenario is robot-assisted knot tying performed with the da Vinci surgical system as depicted in Figure 7.1. The proposed control approach takes advantage of the task division between the right and left hands, suggesting that the human operators use one hand as the action hand and the other as the fixed/reaction hand, only while performing such tasks. Then the controller

Figure 7.1: Two-handed robot-assisted knot tying in da Vinci Radical Prostatectomy, suture ligation of dorsal veins at prostate apex (department of Urological Sciences, University of British Columbia). The division of the tasks between the two hands is demonstrated in this figure.
7.1. Introduction

performs an asymmetric transmission of velocity/force signals from the surgical environment to the operator’s hands. The action hand applies forces to the surgical environment through its corresponding master-slave pair; force/impedance is sensed at the contact point and transmitted back to the other hand, which is holding the fixed master-slave pair. A schematic of this control framework is shown in Figure 7.2. By implementing such an indirect haptic force feedback technique, the action hand will safely perform the sensitive surgical task and is protected from any time-delayed position/force signal, while the operator is able to feel the applied forces on his/her other hand (fixed hand), and adjust them accordingly. Controller instability will not occur because one hand performs the action and the other receives the feedback signal.

There are many ways to implement this basic idea; in this work we present a variable structure controller to implement this concept and test its applicability. The user can switch between three control modes depending on the task: one structure for normal bimanual unilateral control, and the other two for the asymmetric control for tasks in which either the right or left hand could be used as a fixed hand while the other is performing the action.

To illustrate the feasibility and force-reflecting performance of the proposed controller, initial experiments have been performed using a two-master/two-slave setup composed of four 3-DOF haptic devices, and the preliminary results were presented in [4].

In this work, we address a much more realistic scenario, involving a da Vinci surgical system. The da Vinci Research Kit (dVRK) controllers were used to implement this control framework on the first generation of the da Vinci surgical system (da Vinci standard). Such controllers are "open source mechatronics" platforms consisting of hardware, firmware and software components [17, 46] and are being installed at multiple centers for medical robotics research (see dVRK wiki: [I]). We integrated the controllers with the da Vinci classic system in our lab, established a bimanual teleoperation control structure based on the components from the open source cisst/SAW libraries [17] and implemented the asymmetric force feed-
7.1. Introduction

Figure 7.2: The asymmetric control framework schematic described for a two-master two-slave platform performing common two-handed tasks: (a) suture knot tying: tensile force being applied by the action hand and the reaction force being transferred back to the reaction hand, (b) palpation: compressive force being applied by the action hand and the reaction force being transferred back to the reaction hand.

back control framework. Using the dVRK controller with the da Vinci classic enabled us to conduct user studies in a reasonably realistic da Vinci surgery environment, where users sit at the surgeon’s console and work under stereo-vision through a high resolution stereo-viewer, while using our custom control algorithms.

The rest of this chapter is organized as follows. The architecture of the proposed controller in terms of general master-slave network parameters is described in Section II. In Section III, the method implementation on the da Vinci surgical system is described. Description of the user studies, the results and discussions are presented in Section IV.
7.2 Asymmetric Control Architecture

The force feedback teleoperation controller design problem poses stringent requirements for performance, stability and robustness. Figure 7.3(a) and Figure 7.3(b) show a typical control block diagram and two-port network model of a straightforward and commonly used method for creating unilat-

Figure 7.3: (a) Uni-lateral control structure for bimanual teleoperation, analogous to a simplified version of the da Vinci robot control structure, (b) Two-port network model of the uni-lateral bimanual teleoperation control with a shared environment.
eral teleoperation. It is assumed that the operator’s right and left hands are holding the right and left master manipulators, and their corresponding slave robots are in contact with an environment/object that is shared between them. In these block diagrams, the left and right hand dynamics, the environment, and the left and right master and slave dynamics are lumped into linear time-invariant (LTI) impedances $Z_{hL}$, $Z_{hR}$, $Z_e$, $Z_{ML}$, $Z_{MR}$, $Z_{SL}$, $Z_{SR}$, respectively. $F_{hL}$, $F_{hR}$, $F_{SL}$, $F_{SR}$ are the forces at the left and right hands and left and right slave robots, $F'^*_{hR}$ and $F'^*_{hL}$ are the forces applied by the human hand, $F_e$ is the force between the right and left slaves and the environment, $V_{ML}$, $V_{MR}$, $V_{SL}$, $V_{SR}$, $V_{hL}$ and $V_{hR}$ are the velocities of the left and right master and slave robots and hands respectively, all in the Laplace domain. The master devices continually send their positions to their corresponding slaves, and each slave robot uses its local PD controller ($C_{SR}$ and $C_{SL}$) to ensure position/velocity tracking to achieve kinematic correspondence both in free and in contact motions. In such a control structure, energy exchange is only uni-lateral, from human hands to master devices, $E_{(h-m)R}$ and $E_{(h-m)L}$, from master devices to their corresponding slave manipulators, $E_{(m-s)R}$ and $E_{(m-s)L}$, and from slave robots to the environment in contact, $E_{(s-e)R}$ and $E_{(s-e)L}$ (shown in the block diagram of Figure 7.3). Realistic scenarios include sources of energy leaks ($E_{Loss}$) or an out-of-phase energy transfer because of the delayed communication channel. In the unilaterial teleoperation case, since the overall control loop is not closed over the communication channel, there is no energy exchange between master and slave robots, and these manipulators are not subject to instability. If impedance control is used to cause the slave robots to track the masters and vice versa, it will be position exchange (P-P) bilateral control and the human operator will receive haptic force feedback. If the remote slave robots track the masters, but force sensors on the remote robots are used to determine the displayed forces, it will be position forward/force feedback (P-F) control. The P-P control structure is well suited for the master and remote robots that move freely when the user or environment pushes on the end-effector (similar to the da Vinci surgical robot). However, the user might feel some forces during free space motions because of the inertia and fric-
7.2. Asymmetric Control Architecture

tion in the slave robots, especially for large surgical robots. If the dynamic slave forces are too strong, one could suggest lowering the controller gains, but this softens the feel when the slave robot encounters contact surfaces. Nevertheless, due to the cost and fragility issues with force/torque sensing, the P-P controllers are the preferred structure if either the master or the remote robot does not have large friction or inertia (very large or very small robots) [76].

Both the P-P and P-F control structures are also subject to low stability margins in common cooperative surgical tasks, especially when there is scaling involved. This is due to a variety of issues such as unmodeled dynamics, transport or time-delay or changing environment conditions. Hence, they are difficult to integrate in the currently available telerobotic surgical systems. The controller proposed in this work is an alternative and safe approach to enable force feedback for a category of common two-handed surgical tasks such as robotic knot tying and remote palpation (Figure 7.2 and Figure 7.4).

Since human operators use both hands cooperatively to perform such tasks, we suggest using one hand to apply the tensile/compressive forces (action hand) and the other to hold the suture knot or the object under compression/tension (fixed/reaction hand). The control strategy is structured in such a way that the forces applied to the surgical environment by the action hand, through the action master-slave robot pair, get transferred back to the other hand, which is holding the other master-slave robot pair. The control loop is closed through the human operators body, that could isolate the action hand from the forces that are fed back to the fixed hand.

The method is applicable to both position exchange bilateral control and position forward/force feedback control as shown in Figure 7.4(a) and Figure 7.4(b). Both position and force signals could be transferred back asymmetrically using this method. In this work, the asymmetric position exchange strategy (Figure 7.4(a)) is implemented.
7.2. Asymmetric Control Architecture

Figure 7.4: (a) Asymmetric position forward force feedback control structure, (b) Asymmetric position forward position back control structure, (c) Two port network model of the bimanual teleoperation control showing the asymmetric structure.
7.2. Asymmetric Control Architecture

In the case when the left hand is fixed and the right hand is performing the suture/tissue manipulation and applying the force (Figure 7.4(b)), the right (action) master robot’s velocity $V_{MR}$ is transmitted to its corresponding slave robot, and the controller at the slave side $C_{SR}$ ensures velocity/position tracking for this master-slave pair. The velocity tracking error is fed back by the controller of the other master robot to reproduce the same force and mechanical impedance that the moving slave is experiencing in the environment. In addition, the controller at the fixed slave robot is responsible to force this manipulator to stay fixed at the surgeon’s desired position, i.e. the position it was at the time of the controller switching from unilateral to asymmetric. The same scenario happens when the right hand is executing the action and the left hand is fixed.

To ensure position and force tracking and allow asymptotic stability as it is proved in [74], PD controllers with damping injection are used for controllers $C_{SL}$, $C_{SR}$, $C_{MR}$ and $C_{ML}$. The energy exchange between the moving slave robot and the slave environment ($E_{s-e}$) gets transmitted back to the fixed master manipulator, and then back to the fixed hand $E_h$. Hence, the human operators will be able to control the energy/force they exert by one hand through feeling it on their other hand. In many cases, this is a very intuitive approach in which the user feels the reaction as opposed to the action forces. For example, when tying a knot, one hand pulls the suture while the other holds the thread. Tissue could be palpated in the same manner. The metaphor used by the user is that of holding an object with one hand while feeling it being probed by the other hand.

The energy flow and control loop is closed through the human operator’s body; one hand is the energy sink (fixed hand), the other hand is the energy source (action hand), and the human brain acts as the controller of this loop to adjust the energy balance. In addition, the possible out of phase energy loss due to the delay in the communication channel could be compensated by the human operator’s brain. Currently, most expert robot-assisted surgeons only rely on visual cues such as tissue deformation caused by tension/compression forces, and use their brain to correlate forces and deformations. Addition of our indirect force feedback system will poten-
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tially help them perform a more precise and realistic correlation and force reconstruction, leading to better overall performance.

7.2.1 Stability and Transparency

The performance objective in force-feedback teleoperation is to have a high stiffness robot to feel material properties such as surface texture while having low inertia and low friction to reflect small environment forces [76]. The application of our proposed control framework will allow using high gain controllers to achieve the above performance objective without losing stability.

To learn about transparency, the conditions of kinematic correspondence \( (V_h \equiv V_e) \), and impedance matching \( (Z_{th} \equiv Z_e) \) have been examined in [67]. In two-handed teleoperation systems and in cooperative tasks such as knot tying and palpation, the goal would be to match the mechanical impedance between the two slave robots with the mechanical impedance that the human operator is feeling between his/her two hands. As an example, when the operator is pulling the suture to tie the knot, the same tensile force and compliance between the slave robots should be transferred back and felt between the two master devices. Furthermore, when the operator is compressing tissue between the two slave robots to get their mechanical properties, they should perceive the mechanical impedance of the tissue.

7.3 Controller Implementation on the da Vinci Surgical System

An overview of the dVRK platform integrated with the da Vinci classic surgical system is shown in Figure 7.5. Descriptions of the system architecture, various components and their installation on the da Vinci system will be explained in the next sections.
7.3. Controller Implementation on the da Vinci Surgical System

7.3.1 System Components

Hardware

The mechanical hardware is the first-generation da Vinci robot with two 8-DOF Master Tool Manipulators (MTMs), three 7-DOF Patient Side Manipulators (PSMs), one Endoscopic Camera Manipulator (ECM), a high resolution stereo viewer with a stereo endoscope, and a foot pedal tray. The foot pedal tray includes five switches accessed using the foot (Figure 7.5b) and is employed in our custom control architecture as a user-controlled switch between different control modes. Control electronics include four controller boxes (developed at Johns Hopkins University in collaboration with Intuitive Surgical Inc. [17, 46]) each containing two pairs of custom designed boards: (1) an IEEE-1394 FPGA Control board, and (2) a Quad Linear Amplifier (QLA) board. Using FPGAs as the control processing units at the hardware side enables a centralized computation and distributed I/O architecture in which high level control algorithms could be implemented on a Linux PC, while high-speed I/O is performed through an IEEE-1394a serial network (max 400 Mbits/sec). The Quad Linear Amplifier is designed to interface with the FPGA board and provides the ability to control up to four DC motors. Control boxes shown in Figure 7.5c contain two sets of FPGA and QLA boards each, and are capable of controlling up to eight DC servo-motors which makes them suitable to control da Vinci PSM/MTM manipulators. The interface to all the electronics, joint level motion sensors and actuators in MTMs and PSMs is through DL156 pin connectors (Figure 7.5d).

Software Architecture

Based on the centralized computation and distributed I/O architecture [46], all computations including data read/write, joint level servo loop control and high level robot control are implemented on a Linux PC. Interface between the FPGA controllers and high level robot control software (through the IEEE-1394a protocol) is established with a low-level C++ API. For
7.3. Controller Implementation on the da Vinci Surgical System

Figure 7.5: (a) The overview of the da Vinci Research Kit platform installed in UBC RCL Laboratory. (b) The da Vinci classic console with a high resolution stereo viewer, two MTMs and a foot pedal tray. (c) 8-axis controller packages each responsible for controlling one da Vinci MTM or PSM manipulator. (d) The connections from the da Vinci system to the control boxes through zero insertion force DL156 pin connections and break-out boards provided by Intuitive Surgical. Controllers are connected in a daisy-chain structure using IEEE-1394a bus external and internal to the boxes. (e) Two da Vinci PSMs and the Endoscopic Camera Manipulator arm with the stereo endoscope.

the high level robot control and algorithm implementations, a component-
7.3. Controller Implementation on the da Vinci Surgical System

based control architecture using the open-source cisst/SAW libraries was employed [17].

7.3.2 Bimanual Teleoperation Controller Implementation

In order to establish a teleoperation system with one MTM-PSM robot pair, software modules for I/O level data read/write, joint level servo PID control and logical robot control have been defined and a teleoperation component based on kinematic correspondence has been implemented. The I/O level modules communicate with the robot sensors and actuators directly through the IEEE-1394 connection to provide PSM I/O level interface, MTM I/O level interface and an interface for foot pedal events. Upper level control is provided by the PSM/MTM PID servo controllers that connect to the PSM and the MTM I/O level interfaces, respectively. The teleoperation module communicates to each of the arms’ joint level PID control routines as well as to the foot pedal interface for control state switching based on the foot pedal events.

Two types of robot objects, one for each MTM and one for each PSM, have been defined to handle forward and inverse kinematics, and robot-specific higher level control. Forward and inverse kinematics as well as the robot specific control is achieved through manipulator calibration files (containing DH parameters, joint range and limits, etc.) provided by Intuitive Surgical Inc.

Furthermore, a gravity compensation component has been implemented on the MTMs using the Recursive Newton Euler Algorithm (RNEA) [71]. Given the joint position and velocity variables, RNEA calculates the set of joint torques to produce the required acceleration to compensate for the manipulator dynamics. RNEA is a model-based approach to start with and is subject to modeling uncertainty, especially due to friction in the cable driven mechanisms of the MTMs.

The two-MTM two-PSM teleoperation control structure shown in Figure 7.6 was established by expanding the single pair teleoperation module to interface with I/O and PID level control components of four arms and
implementing one to one kinematic correspondence between each robot pair. In this block diagram, the left and right hand dynamics, the environment, and the left and right master and slave dynamics are lumped into linear time-invariant (LTI) impedances $\mathcal{Z}_L$, $\mathcal{Z}_{LR}$, $\mathcal{Z}_e$, $\mathcal{Z}_{MTML}$, $\mathcal{Z}_{MTMR}$, $\mathcal{Z}_{PSM1}$, $\mathcal{Z}_{PSM2}$, respectively for all seven actuated degrees of freedom of the manipulators (i.e. $\mathcal{Z}_{MTM} = \{ \mathcal{Z}_{J1}, \mathcal{Z}_{J2}, \mathcal{Z}_{J3}, \mathcal{Z}_{J4}, \mathcal{Z}_{J5}, \mathcal{Z}_{J6}, \mathcal{Z}_{J7} \}$). $\tau_{hL}$, $\tau_{hR}$, $\tau_{MTML}$, $\tau_{MTMR}$, $\tau_{PSM1}$, $\tau_{PSM2}$ are torques at the left and right hands, left and right robot arms, $\tau^*_{hR}$ and $\tau^*_{hL}$ are the torques applied by the human hands and $\tau_{GC}$ is the torque on MTMs from the gravity compensation component, all in 7-DOF (i.e. $\tau_{GC} = \{ \tau_{J1}, \tau_{J2}, \tau_{J3}, \tau_{J4}, \tau_{J5}, \tau_{J6}, \tau_{J7} \}$). $V_{MTML}$, $V_{MTMR}$, $V_{PSMR}$ and $V_{PSML}$ are the velocities of each manipulator in 7-DOF computed by joint motion sensors. $C_{GC}$ is the gravity compensation controller at each MTM and $C_{PSM1}$, $C_{PSM2}$ are the joint level PID controllers at each PSM responsible to ensure position (rotation/translation) tracking. All of the joint motions and torques are transmitted to their corresponding local controller through DL156 pin connectors and then to the central control processing unit through the IEEE-1394a bus. All of the controllers are implemented in the centralized computation and distributed I/O architecture as shown in Figure 7.6. Control loop frequencies of 1 kHz for the I/O level, 333 Hz for the kinematics and robot logic control, and 200 Hz for the teleoperation loop could be achieved while having stable data synchronization between various components of a two-MTM two-PSM teleoperation controller.

The foot pedal buttons were employed to switch between various control states. The COAG button is used as a toggle switch to activate and deactivate the teleoperation with gravity compensation mode. Furthermore, the clutch button is used to activate the clutching mode in which MTMs' movements are not reflected to the their PSM side, to reposition the MTMs when needed. Motion scaling (PSM:MTM: 1:5, 1:3, 1:2) for each MTM/PSM pair is also implemented to increase the accuracy of the task performance, similar to the original da Vinci robot controller.

Figures 7.7 shows the Cartesian positions of each MTM/PSM pair in different control states with a motion scaling of 1:5. The master devices
continually send their positions (rotation/translation) to their corresponding slaves, and each slave robot uses its local PID controller $C_{PSM_1}$ and $C_{PSM_2}$ to ensure position/velocity tracking to achieve kinematic correspondence both in free and in-contact motions.

### 7.3.3 Force Feedback Controller Implementation

The asymmetric control framework depicted in Figure 7.2 is implemented using the control structure shown in Figure 7.6. $C_{MTM}$ is the joint level controller at the MTM side that is responsible to produce the feedback torque $\tau_{FB}$ on the MTMs based on the position tracking errors on the PSM side, in

![Diagram showing the bimanual teleoperation framework.](image)

Figure 7.6: The bimanual teleoperation framework. Solid lines show the control structure between the components and the dashed lines show the communication structure for signals transmitted between the local hardware controllers, centralized control unit (Linux PC) and robot manipulators. Red lines and controllers $C_{MTM}$ at each MTM are responsible to generate the feedback torque on each hand according to the control state in the force feedback structure (based on the foot pedal events). The IEEE-1394 daisy-chain configuration between the central PC and four dVRK controllers is also shown in the center boxes.
7.3. Controller Implementation on the da Vinci Surgical System

Figure 7.7: The bimanual teleoperation system performance: (a) Cartesian position tracking for the left MTM-PSM pair, (b) Cartesian position tracking for the right MTM-PSM pair. Different control states (teleoperation, clutched, fixed) based on the foot pedal events could be seen in the specified time intervals. PSM-MTM Kinematic correspondence with motion scaling could be seen in the teleoperation intervals. PSM-fixed MTM-moving control state could be seen in the clutch mode intervals. A tension spring was being manipulated between the surgical tools in the in-contact intervals.
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7-DOF (\(\tau_{FB} = \{\tau_1, \tau_2, \tau_3, \tau_4, \tau_5, \tau_6, \tau_7\}\)). The control strategy is structured in such a way that the forces applied to the surgical environment by the action hand, through the action master-slave robot pair, get transferred back to the other hand, which is holding the other master-slave robot pair. In this work, the asymmetric position exchange strategy (position forward for action MTM-PSM pair, position backward for reaction MTM-PSM pair) is implemented. In the case when the left hand is fixed and the right hand is performing the suture/tissue manipulation and applying the force, the right (action) MTM motion (translation/rotation) is transmitted to its corresponding PSM, and the controller at the PSM side \(C_{PSM}\) ensures position tracking for this MTM-PSM pair. The position tracking error is fed back to the controller of the other master robot to reproduce the same force and mechanical impedance that the moving slave is experiencing in the environment. In addition, the controller at the fixed PSM is responsible to force this manipulator to stay fixed at the surgeon’s desired position, i.e. the position it was at the time of the controller switching from unilateral to asymmetric.

Figures 7.8a and b show Cartesian positions of both MTM/PSM pairs describing the system behavior for the complete force feedback and normal teleoperation scenarios in which the user holds a tension spring with one robot tool (fixed MTM/PSM pair), and applies a pulling action with the other hand (Figure 7.11b) to explore the spring stiffness while receiving force feedback on the fixed hand. Figure 7.8(c) demonstrates the energy exchange in the system for the same spring pulling experiments. The total control effort or energy at each manipulator was computed by a summation of the control efforts at each joint. Three springs were tested in this experiment (\(K_{SP_1} < K_{SP_2} < K_{SP_3}\)). The action and reaction motions and their corresponding control effort on all four arms could be seen in each time interval specified on these figures. Figure (c) shows the proportionality of the control effort generated on the reaction MTM with the spring stiffness at the PSM side. MTML SP1 means that the MTML is the receiver of the force feedback while PSM2 is fixed for holding spring 1 (SP1), and MTMR-PSM1 is performing the pulling action. The same scenario happens for other intervals. The user switches the force feedback control state between right and
left MTMs for each spring in this experiment. The surgeon operators are able to control the energy/force that they exert on the surgical environment.

Figure 7.8: The Cartesian positions of both MTM-PSM pairs and total control effort on each manipulator in a spring stiffness exploration task.
7.3. Controller Implementation on the da Vinci Surgical System

because of the energy transfer from the moving slave gets transferred back
to the fixed master manipulator and thus the fixed hand of the surgeon. The
action and reaction pairing can be intuitive during such tasks as knot tying,
when the action hand pulls the suture and the reaction hold the thread to
feel the strength of the pull. Tissue can be manipulated as well, where the
reaction hand holds the tissue steady and the action hand applies pressure
to gauge the tissue stiffness. With the action (moving) hand as the energy
source and the reaction (fixed) hand as the energy sink, the energy flow and
control loops are closed through the human operators body. This means that
the human brain can be used to adjust the system in order to maintain the
energy balance. Currently, most expert robot-assisted surgeons only rely
on visual cues such as tissue deformation caused by tension/compression
forces, and use their brain to correlate forces and deformations. Addition
of our indirect force feedback system will potentially help them perform a
more precise and realistic correlation and force reconstruction, leading to
better overall performance. The force feedback controller $C_{MTM}$ gain was
adjusted based on the user experience and stiffness of the materials being
manipulated. Higher gains will produce more torque $\tau_{FB}$ on the user’s hands
based on the mechanical impedance at the PSM side. The control structure
switching is implemented using the buttons on the foot pedal tray. Once the
user is in the teleoperation mode, she can use the foot pedal buttons to have
her right or left hand as the receiver of the force feedback while the other
hand is in the normal teleoperation mode performing the pulling/pushing
action. Motion and impedance scaling could be implemented in such a con-
trol structure without instability issues, because the control loops are not
closed from one slave robot to its corresponding master.
Figure 7.9: Four robot manipulator motions and the control effort on each arm in a knot tying experiment.
Figures 7.9a and b show Cartesian positions of both MTM/PSM pairs describing a two handed knot tying experiment in which the users used the normal teleoperation control to manipulate the suture to make the knot and used the force feedback controller to tie the knot (Figure 7.10). The energy exchange plot (Figure 7.8 c) shows the amount and pattern of the energy transferred back to the fixed hand while the other hand is performing the pull action on the knot. Figure 7.8 c shows the knot tying with force feedback section of the experiment, in which MTMR-PSM1 is performing the pulling action, while MTML-PSM2 is being fixed to hold the knot. MTML is receiving the feedback while PSM2 is trying to be fixed but is pulled by the suture between the surgical tools. The same pulling motion pattern in PSM1 (consecutive pull and release motion) could be seen in the feedback pattern on MTML, proving the impedance matching property of the system. MTMR is working under gravity compensation in a very low energy state. Tasks were performed under the stereo endoscope where the location of the arm and ECM setup joints were manually adjusted. Tool to camera registration was using the Read-API of da Vinci system by reading the forward kinematics of the camera tip and each PSM setup joints with respect to the robot base, transforming the PSM tool end frames first to the robot base and then back to the camera tip.

7.4 User Studies

7.4.1 Methods

Two tests were undertaken to test how this new system could be used during surgical tasks. Nine users (3 surgeons and 6 novices) participated in two different tests that utilize the force feedback system developed for the da Vinci system. A variety of users were used such that we could see if the haptic feedback would be useful to an experienced surgeon, and if it would change the way a novice user performed the task. Each user was given instruction on how to use this force feedback system, and given time to become familiar with how the feedback feels when manipulating suture and
7.4. User Studies

All user tests were completed using a motion scaling factor of 1:5 and force feedback gain of 100. Large needle drivers were used during the course of the tests as these instruments are most likely to be used while suturing. This system is independent of the tool type and can be used with any type of da Vinci tool. The first test required the users to differentiate three springs of varying stiffness to simulate a haptic exploration task. The springs were covered such that the users could only see a string tied to each end, minimizing the possible use of visual cues. They were instructed to pull on each spring using the force feedback to determine the relative ranking, from stiffest to weakest. The three springs have constants of 1.2, 0.2 and 0.03 N/m respectively. The springs were then reordered and the users asked to repeat the experiment. Each correct relationship between the springs was given one point, for a total of 12 points.

The second test required the users to tighten the first throw of a suture knot (Figure 7.10). They were first asked to tighten the knots by hand, then using the da Vinci without force feedback and finally using the force feedback system. During each trial, the users were asked to tighten the knot and hold this force for 3 seconds, and this was repeated 5 times. Load cells were attached to the ends of both suture sections, such that the force applied with each hand could be measured during the test. These 5 sections were segmented and used during the data analysis. During the force feedback variant, the left hand was fixed and the right hand moving to tighten the suture.

7.4.2 Results

The average score for all users during the spring differentiation was 98%, 106/108 correct relationships. Only a single user made one mistake during the task. All users felt that they were able to differentiate the springs with confidence.

The standard deviations during the knot tightening exercise were examined, and there is some evidence that tightening with the robot is less consistent than tying by hand. We looked at how consistent the force was
7.4. User Studies

Figure 7.10: Tightening the first throw of a knot. Two load cells at both sides were used to measure the force exerted by each hand/robot. The user study was done under stereo-vision system of da Vinci.

between pulls on the suture, and how well the users could hold a given force. We were interested in seeing if the users force would drift over time if there
7.4. User Studies

was no feedback. Without force feedback, users must rely only on visual cues to determine if the knot is tight, leading to a less consistent force applied since it is difficult to differentiate degrees of force once the knot is reasonably tight.

The difference between hand tying and robot tying shows that the implementation of force feedback system is warranted. Figure 7.13 shows the standard deviation of the average force applied during the five tightening sessions. In all but one user, the force applied by hand had a smaller standard deviation than that applied by the robot. In one case, user #3, using the robot was more consistent than tying by hand, but this user has more hours tying sutures with the robot than by hand.

Figure 7.12 shows the graphs of the one user during each of the three

![Image](image1.png)

(a)

![Image](image2.png)

(b)

Figure 7.11: (a) A user practicing with a spring to get a feel for the force feedback, (b) springs with different stiffness for the haptics exploration test.
7.4. User Studies

Figure 7.12: The forces applied to the suture by the left (red) and right (blue) hand during the the variants of the suture tying task. The consistency of the applied forces were improved in the force feedback variant compared to the robot only variant.

variants, tightening by hand, with only the robot and with the force feedback. The blue is the force applied by the right hand, and the red, that applied by the left hand. During the force feedback variants, the left hand was fixed and the right hand moving to tighten the suture.

7.4.3 Discussion

All users who participated in these tests, especially the surgeons, were excited about the possible inclusion of force feedback into the da Vinci robot. We chose to use two tasks for our experiments that mimic tasks in a surgical environment that would most benefit from the inclusion of force feedback,
7.4. User Studies

Figure 7.13: The standard deviation of the mean forces applied during each tightening of the suture for the hand tying and robot tying tasks. Results demonstrate the decreased consistency of the applied forces in the robot tying vs. hand tying, supporting the need for haptic force feedback.

that of tightening sutures and testing tissue for stiffness. It is sometimes noted that the 3D vision provided by the stereo camera can compensate for the lack of force feedback, but this is not the case when dealing with stiff objects such as needles and suture where excessive forces do not have a visual feedback component.

The force applied during the use of force feedback varied and the correct use of the system depended heavily on the user’s familiarity with the use of the robot and understanding how the force feedback was applied. The users who were able to achieve the most consistent results were those who had both used the da Vinci and had a good understanding of the feedback system. This method of force feedback combines the force felt on one hand and the movement made by the other and it takes some time to understand. We believe that with additional practice with the system the users’ accuracy
7.4. User Studies

and consistency would increase.

We did see some drifting of the force the users applied when using the da Vinci without force feedback but not sufficient to be significant compared to that of a hand tie. We did notice that in some users, the difference in force applied by the two hands when using the da Vinci, in comparison to the hand tie, was very large. This could be due to the fact that once the knot reaches a certain tightness it is hard to discriminate visually further force applied.

During these tests we also became aware of some areas of improvement. The users felt the position of the master was not consistent, even after all force was released. With repeated tests of the force, the master position tended to drift. This could be due to the way that the position is measured.

It was noted from several users during the knot trials that the system changes slightly the manner in which they would tie a knot. Typically the user would pull with both hands with somewhat equal force. This is more natural and also centers the knot as it is pulled tight. Since one hand is fixed during the use of force feedback, the knot needs to be placed in the correct location first, then the feedback only engaged to tighten the knot fully.

Further user testing with a more realistic set up and additional user training will provide a better understanding of how the system can be used during surgical tasks and where additional improvements can be made.

One improvement that we hope to make in the future is the way in which the applied force is measured. Currently, we look at how the position of the end effector changes as the force is applied. But due to the robot impedance, some directions of movement are much easier than others. In the future we plan to adapt the method of force sensing to be more versatile and accurate. The body wall and cannula disturbances could also be simulated in future work to see how that affects force estimation using position tracking errors, as well as the effects of such disturbances on the user.

The other implementation issue was using the foot pedal to change control states. Some users suggest that this would be counter intuitive and a smart switch based on voice control or methods being used for surgical
7.4. User Studies

skill evaluation to extract trajectories and patterns from surgeons’ movements could be used for real-time automatic identification of the action and reaction hands.
Chapter 8

Conclusions

In this thesis we have developed image and haptic guidance systems for robot-assisted laparoscopic surgery. The main focus was to develop systems that could be translated into clinic. We have also spent a huge amount of effort developing protocols and performing clinical studies, to show evidence of clinical benefit and also to use the acquired data to further optimize our systems.

Our conclusion for the TRUS-guidance study is that real-time, robotic TRUS guidance during RALRP is feasible and safe, and it provides the console surgeon with valuable guidance. The results of this study justify follow up studies comparing outcomes of RALRP with and without registered TRUS guidance. In a future clinical study involving high number of patients (between 100 to 500), we can show the real clinical benefit of the system. In addition, performing a multi-center study with different surgeons with different expertise would further clarify the usefulness of our system.

Our conclusion for the MR-guidance study is that it could be a powerful tool to trade-off positive surgical margins against potency. This is the first clinically tested MR-guidance system for surgery. We have received a very positive feedback from surgeons on clinical usability of the system. In future, the system should be tested in a clinical study with minimum 20 patients undergoing da Vinci Prostatectomy and preoperative MR. Such an study would show the clinical usability of the system in different patients with different anatomical challenges and prove it’s usefulness. Furthermore, new and improved MR-TRUS registrations could be tested with the developed framework.

In chapter 4, we have developed an algorithm to automatically localize surface fiducials in 3D ultrasound. This algorithm is used to enable au-
Chapter 8. Conclusions

tomatic registration of coordinate frames based on the air-tissue boundary registration concept. While we used this algorithm for automatic registration of 3D TRUS to the da Vinci surgical system using the da Vinci instrument tips as the fiducials, this algorithm could also be used for other similar applications.

In chapter 5, we described a system for real-time remote palpation based on robotic ultrasound and strain imaging. The system is intuitive and easy to use and has the potential to compensate for the lack of haptic feedback in the current state of the surgical robotic systems. The system has been tested in user study involving 6 users on a prostate phantom and promising results have been obtained. We further tested the system on 5 prostate cancer patients undergoing da Vinci radical prostatectomy. While the system could have some clinical benefit for tumor and calcification detection, it requires some prior learning and training by the surgeons. Such a training would familiarize the surgeon with the system and the images so that they can use it during the operation.

In chapter 6, we described a system for acquisitions of multi-parametric quantitative ultrasound elastography data from patients in the operating room. We further described a framework to evaluate the system’s cancer detection performance using classification algorithms and comparison with post-operative whole-mount histopathology. The system is tested on 10 patients and promising cancer detection results have been obtained. In future, more data should be collected and fed into the classification algorithm in order to increase the accuracy and reliability of the results. Similar to any other classification algorithm, the more data one provides to the algorithm, the better the classifier would be trained and more reliable would be the results.

In chapter 7, we presented a new control framework for force feedback teleoperation. We implemented the algorithm on the da Vinci surgical system using the da Vinci research kit controllers. Development of this algorithm involved establishing the dVRK system in the lab and implementing robust teleoperation, torque control, trajectory tracking and gravity compensation controllers. We used the developed system in a user study involv-
ing 9 users testing the system. While the results showed potential benefits of the proposed approach in standard suturing and palpation tasks, the user interface of the system could be improved in order for it be used more intuitively.
Bibliography


Bibliography


Appendix A

Semi-Autonomous Ultrasound Guidance During Robot-Assisted Laparoscopic Surgery

Robotic surgical systems enable surgeons to perform delicate and precise minimally invasive surgery and also provide a platform for integrating surgical image-guidance and automation of particular tasks. Currently such systems are primarily controlled by the surgeon in a human-in-the-loop master-slave architecture. Introducing autonomy of surgical sub-tasks has the potential to assist surgeons by decreasing the workload and also improved surgical navigation.

This chapter describes a semi-autonomous robotic ultrasound guidance system for robot-assisted laparoscopic surgery, implemented on the da Vinci® surgical system. The da Vinci auxiliary patient side manipulator (PSM) is introduced here as a robotic ultrasound surgical assistant (US-PSM). A robotic pick-up ultrasound transducer is rigidly grasped by the surgeon using the auxiliary PSM, and 3D ultrasound is registered to the tip of the other operating PSMs instrument performing tasks such as tumor resection. Solving a real-time inverse kinematics and ultrasound registration problem enables the auxiliary manipulator to autonomously track the surgical tool in a restricted task-specific workspace and provide real-time ultrasound guidance to the surgeon. Furthermore, the proposed strain imaging technique in Chapter 5 could be used with this system to also provide subsurface images.
to the surgeon at the console. The techniques were implemented on the da Vinci® surgical system (classic version) using the da Vinci research kit (dVRK) controllers that enable complete access to all control levels of the da Vinci manipulators via custom mechatronics and open-source software.

A.1 Introduction

Medical robots have been used clinically for more than two decades in many fields including orthopedics, minimally invasive surgery, and image-guided interventions. As surgeons and engineers strive to make surgical procedures more minimally invasive, challenges arise with regards to workspace limitations, tool ergonomics and cooperation between surgeons and assistants. The introduction of robotic laparoscopic surgery has provided surgeons with a minimally invasive option with improved tool dexterity and high quality stereo-vision. This has increased the number and difficulty of the procedures that can be performed. The robotic platform also provides a platform for integration of surgical guidance with medical imaging and the automation of particular surgical tasks.

Surgical guidance has been used successfully during neurosurgery and orthopedics. The use of image guidance has expanded into abdominal surgery, which is a shifting dynamic and complicated environment. Surgeons cannot rely on pre-operative imaging since significant organ shifts can take place within the abdominal cavities. Ultrasound has become the intra-operative modality of choice for many applications, as it is real-time, non-ionizing and relatively inexpensive.

Though ultrasound has many advantages, it is an operator dependent modality. The quality of the ultrasound is very dependent on the experience of the ultrasound operator. Ultrasound requires a certain amount of hand-eye coordination as well in order to understand the spatial relationship between the anatomy of the image and the location of the ultrasound probe. Intra-operative ultrasound that is used during the robotic surgery is manipulated by the patient side assistant, instead of the operating surgeon, breaking the normal hand-eye coordination.
A.1. Introduction

Despite the challenges, intra-abdominal ultrasound is currently used regularly during robotic partial nephrectomy. This procedure involves the removal of cancerous sections of the kidney, while preserving as many healthy nephrons as possible. This more difficult procedure has been shown to have better patient outcomes. Ultrasound is used during this procedure to identify the resection margins of the tumour, helping to ensure the complete removal of the cancerous tissue.

Certain other procedures, such as liver resection and some cardio-thoracic, have the potential to benefit from the integration of intra-operative ultrasound. Ultrasound is routinely used during open liver surgery to provide real-time guidance but has not penetrated as deeply into the laparoscopic market.

The use of a robotically controlled ultrasound probe would put the control of the ultrasound probe back into the hands of the surgeon, making them independent of their patient side assistants. In addition, the surgeon would now have the precision of motion that the robotic tools provide allowing for more exact placement of the probe on the organ of interest.

In the case of robotic partial nephrectomy, the perioperative outcomes are similar, regardless of whether a laparoscopic or robotic ultrasound probe is used. A robotic probe, however, might provide advantages in terms of surgeon autonomy. Perioperative parameters including time spent in the operating room, blood loss and positive surgical margin rates were comparable between patients who underwent robotic partial nephrectomy with a laparoscopic probe \( n = 72 \) or a robotic probe \( n = 73 \).

The use of the robotic platform also allows for the potential of automated motion in certain situations. Robotic motions can be separated into three main types, (i) direct control, (ii) shared control and (iii) supervisory control. Direct control describes the typical teleoperated robot, where all motion is dictated by the surgeon's motions. In shared control, the robot and the surgeon use the same resources to complete the task, and in supervisory control, the surgeon would direct the robot to complete a task, but the robot is pre-programmed to make the motions without direct surgeon control.

Robots with shared control include those that implement virtual fixtures,
using force feedback to guide the surgeon, who is in control of the tool.

Autonomous motion has been explored in surgical robotics. RoboDoc, for instance, used a pre-programmed plan to drill out femur for hip replacement [101]. Another drilling robot also uses preoperative imaging to drill out the inner ear for cohelear implants. Other robotics are more reactive to their environments, using visual servoing based on a real-time ultrasound image to control the placement of the robot. Research in surgical robotics is moving towards the development of a more autonomous system such as the PAKY-RCM for biopsy [97], Arthrobot in orthopedics [23] and Neuromate in neurosurgery [56]. To make these types of autonomous motions more dynamic, The Language of Surgery is being developed to better understand the motions and actions that make up the complicated task of surgery.

We present a system where the third arm of the da Vinci is used to autonomously track the operating arms. We focus on the application of this system for partial nephrectomy. This is particularly applicable to partial nephrectomy, where the surgeon must cut out a section of the kidney without leaving cancerous tissue behind. Having real-time ultrasound guidance at the time of resection could provide the surgeon with vital information to improve surgical margins and avoid internal kidney anatomy. Unfortunately this has never been previous possible because the tumour resection requires the full attention of both operating arms and an external laparoscopic probe does not have the dexterity to show the surgeon useful information. A custom designed ultrasound probe will be held in the third arm of the da Vinci. Through a calibration method described below, the ultrasound probe will be autonomously adjusted in order to show the surgeon the tip of his tool in relation to critical anatomy.

The da Vinci Research Kit (dVRK) controllers were used to implement this technique on the first generation of the da Vinci surgical system (da Vinci classic).
A.2 Materials and Methods

A.2.1 System Overview

Figure A.1 depicts the main components of our research platform. The dVRK system that has been fully explained in Chapter 7 is used for this experiment. The ultrasound transducer (Figure A.1c) used in this work is a custom-made intra-abdominal transducer that is small enough to fit through a standard laparoscopic incision, and can be picked up and maneuvered by the ProGrasp instrument of the da Vinci [92]. Its unique design allows for it to be easily picked up in a repeatable manner such that the position of the ultrasound image, with respect to the da Vinci instrument can be pre-calibrated. As a high frequency probe (The transducer has 128 elements, is 28 mm long and is operated at 7 to 10 MHz), it allows for high quality imaging of the kidney and can be placed directly on the kidney surface. The transducer is used in combination with a Sonix TABLET ultrasound machine (Ultrasonix Medical Corp., Richmond, VA, Canada).

Bimanual Teleoperation and Auxiliary PSM Control

A component for independent control of the auxiliary PSM is added to the bimanual teleoperation framework established in the work presented in Chapter 7. The foot-pedal buttons are employed in this component to interchange the MTM-PSM teleoperation chain, and to control the auxiliary PSM with the right of left MTM. Normally, the bi-manual teleoperation would work with (MTMR-PSM1, MTML-PSM2) structure. Using the auxiliary control module, the user can control PSM3 with either MTMR or MTML. We used this control component for autonomous control of the auxiliary arm on top of the existing bi-manual teleoperation using the method explained in the next section.

A.2.2 3D Ultrasound and Robot Instrument Registration

In our proposed method for control of the auxiliary PSM with ultrasound (US-PSM), the US imaging plane is automatically repositioned using the
Figure A.1: The overview of the da Vinci Research Kit controllers and the da Vinci classic surgical system in UBC RCL Laboratory. Three da Vinci PSMs, two for bimanual tele-manipulation and the auxiliary arm for ultrasound.

PSM wrist such that a 2D ultrasound image continuously contains the tip of a specified da Vinci surgical manipulator as shown in Figure A.2. Surgeons can then elect to have a real-time ultrasound image that actively tracks their instruments as they work, allowing them to continuously monitor their position relative to sensitive anatomical structures, without pausing to reposition the ultrasound probe. Automatically tracking the tip of a da Vinci instrument with the ultrasound imaging plane requires that the position of the instrument tip relative to the US-PSM be known.

To perform the registration, we define five coordinate systems: da Vinci PSM base coordinate system \{O_1, C_1\}, PSM instrument wrist base coordinate system \{O_{w1}, C_{w1}\}, the US-PSM base coordinate system \{O_2, C_2\}, the
A.2. Materials and Methods

US-PSM instrument (ProGrasp) wrist base coordinate system \( \{O_{w2}, C_{w2}\} \) and the coordinate system of the ultrasound image \( \{O_{us}, C_{us}\} \). \( \{O_1, C_1\} \) and \( \{O_2, C_2\} \) are coordinate systems which is located at the base of each PSM, at the end of the setup joints kinematics chain which is held fixed in the dVRK experimental setup. Based on the coordinate frames introduced in Figure A.2a, we have:

\[
USP = C_{us} \times C_{w2} \times C_{w1} \times \mathcal{C}_1 \times \mathcal{C}_{w1} P \quad (A.1)
\]

Using our established dVRK software platform, Cartesian position of the tip and wrist angles of the da Vinci operating instruments are known in their corresponding coordinate frames \( \{O_1, C_1\} \) and \( \{O_2, C_2\} \) which are located at the base of each PSM as shown in Figure A.2a. Hence, \( C_{w1}, P, \mathcal{C}_1T_{w1} \) and \( C_{w2}T_{C_2} \) transformations are known in real-time. The custom-designed transducer creates a static and repeatable transform between the da Vinci
A.3. Experiments and Results

The relative motion accuracy of the ProGrasp instrument with respect to each arm’s base coordinate frame is measured using the NDI OptoTrak.
A.3. Experiments and Results

Certus motion capture system. A custom-made 3D printed tool with 8 optical markers (shown in Figure A.3) was built so that it can be rigidly picked up and attached to the ProGrasp tool of the da Vinci. First, the tool was moved and rotated around in the OptoTrak field of view to construct a rigid body on the tool using the NDI 6D Architect software. The orientation of the rigid body coordinate frame was manually adjusted to align with Intuitive convention for wrist orientation: Z-axis of the tip frame is aligned with the instrument pointing direction and the Y-axis is aligned with the jaw open/close axis.

The instrument tip was moved to 20 different points \((x,y,z, \text{Roll}, \text{Pitch}, \text{Yaw})\) in the robot work-space and the 6D coordinate of each point was captured in both OptoTrak frame and DVRK frame. The mean Cartesian motion error was calculated to be \(1.8398 \pm 0.4775 \text{ mm}\) and the mean wrist motion error is \(2.6176 \pm 1.2224 \text{ deg}\). These values could vary from tool to tool and arm to arm because of the errors caused by instrument aging and compliance in the cables. Moving the calibration tool with the da Vinci instrument will not mask kinematics errors, because accuracy of building the rigid body depends on the OptoTrak system, and is independent of the accuracy that you move it around.

You might want to test some situations in which there are force loads at the remote center or at the instrument tip. This is where the kinematics will diverge from actual, due to compliance in the drive-train. This may be

![Figure A.3: The custom made calibration tool with 8 optical markers attached to it. The markers are attached to the tool in a way that minimum 3 markers are always visible in the camera field of view.](image)
A.4 Discussions, Future Work and Conclusions

The presented system is particularly applicable to the partial Nephrectomy procedure, where the surgeon must resect a section of the kidney without leaving cancerous tissue behind. Having real-time ultrasound guidance at the time of resection could provide the surgeon with vital information to improve surgical margins and spare internal kidney anatomy. This has never been previously possible because the tumor resection requires the full attention of both operating arms and an external laparoscopic probe does not have the dexterity to show the surgeon useful information.

Figure A.4: Semi-autonomous guidance on ex-vivo kidney.

relevant for your application.

Figure A.5: Ultrasound images of the da Vinci tool pressed on the kidney surface for registration.
A.4. Discussions, Future Work and Conclusions

Figure A.6: The kidney experiment with da Vinci 3 arms, one holding the kidney, one performing the tissue cutting and poking and one holding the US probe autonomously tracking the tool.
Appendix B

Clinical Study Protocols

B.1 Animal Study at Intuitive Surgical Inc (22 October 2012)

B.1.1 Setup Preparation

- 1.1 Initialize the TRUS robot control software (VibroApp), RF imaging software and Ultrasonix software for acquiring Ultrasound B-mode and Doppler images.

- 1.2 Setup the connections between system components:
  - a. Connect the TRUS probe to the PC based Sonix TABLET US machine (Ultrasonix medical corp., Richmond, Canada).
  - b. Connect the Ethernet cable between Sonix TABLET US machine and back of the da Vinci surgeon console for API data streaming.
  - c. Connect motors (Roll, Translate and Vibration) to the control box using their serial connections.
  - d. Connect the control box to the Sonix TABLET US machine using the 3 in 1 USB connection.

- 1.3 After the animal has been placed on the table, sedated and secured in a Trendelenburg position to simulate RALRP procedure, install the TRUS system at the foot of the OR table using the CIVCO stabilizer arm and the bed attachment clamps as it is shown in Fig. 1.

- 1.4 Prepare the TRUS probe for insertion into the animals rectum:
apply ultrasound gel and probe cover from sterile packaging to the probe.

- 1.5 Insert the probe into the animals rectum using the gross positioning clamp on the CIVCO arm. The array on the US probe should be positioned axially so that the Parasagittal array images as much of the prostate as possible.

B.1.2 Pre-Operative Phase:

- 2.1 Transrectal Vibro-Elastography data collection: Capture two to three sweeps of B-mode and RF data with position information by rotating the Parasagittal imaging plane from -40 to 40 degrees and vibrating the TRUS probe with 2-10 Hz frequencies.

- 2.2 Transperineal Vibro-Elastography data collection:
  - a. Install the shaker mechanism for Transperineal vibrations on the CIVCO stabilizer arm.
  - b. Capture two to three sweeps of B-mode and RF data with position information by rotating the Parasagittal imaging plane from -40 to 40 degrees and vibrating animals perineum using the shaker with frequency in the range of 50-200 Hz.

- 2.3 Capture Doppler images of the prostate lateral to evaluate localization of the NVB based on Doppler signals in the vasculature.

B.1.3 Intra-Operative Phase:

- 3.1 The surgeon should start to open up the animal as in the usual RALRP procedure. Insert the da Vinci trocars under vision, dock the da Vinci robot and begin initial dissection.

- 3.2 Once the anterior aspect of the prostate has been identified, we could start registering the TRUS robot to the da Vinci kinematic frame and da Vinci stereo-camera.
3.3 Before starting the registration process:

- a. Capture two to three sweeps of B-mode data with position information by rotating the Parasagittal imaging plane from -40 to 40 degrees to evaluate how the air-tissue boundary (at anterior part of the prostate) looks like in a real intra-op scenario. The US volumes captured at this stage will also be used to further evaluate the automatic tool tip localization algorithm that has been developed for this application [8].

- b. Capture B-mode and Doppler images of NVB (visible at the posterior-lateral prostate border) with position information.

- c. Perform two sweeps of transrectal Vibro-Elastography and capture RF data for further processing.

- d. Perform two sweeps of transperineal Vibro-Elastography and capture RF data for further processing.

3.4 The registration should be done using the air-tissue boundary method reported in [9, 10]. Two different approaches will be tested and registration accuracy will be calculated.

- Registration between TRUS and da Vinci tool:
  * a. Adjust the US machine parameters for optimized imaging.
  * b. Initialize the ISI API kinematic streaming module. Choose the patient side manipulator number that is being used for registration. Start the kinematic streaming.
  * c. Place the da Vinci tool tip against the air-tissue boundary.
  * d. Use the 3D mouse to rotate the Parasagittal TRUS plane until the tip of the tool could be visualized in the Parasagittal image. Typically, after the user locates the tip of the instrument, the image is rotated back and forth in small increments until maximum tool intensity is seen.
  * e. If the location of the tool in the ultrasound image is not clear, it is helpful to gently vibrate the da Vinci manipulator manually, to make its location in the image clearer.
B.1. Animal Study at Intuitive Surgical Inc (22 October 2012)

* f. Initialize the transformation finder software and select the tool tip center in the US image selected in 3.4.d.

* g. Repeat 3.4.b to 3.4.e four more times, and export the transformation between the TRUS robot and da Vinci API frames to the VibroApp software (motor control software) to start tool tracking.

- Registration validation (calculating the tool tracking accuracy after registration):
  In this step, the tracking accuracy will be calculated as the difference between the users defined tool tip location and tool location resulting from automatic tool tracking after registration. Here is the procedure:
  h. Click on begin tracking in VibroApp window. The TRUS probe will automatically rotate to track the registered da Vinci tool tip.
  i. Place the da Vinci tool tip on the surface of prostate in a random location.
  j. Record the probe angle.
  k. Turn off automatic tracking. Take a 5 degrees sweep around the guessed tool location to see the surrounding US images.
  l. Turn on manual tracking and try to find the exact location of the tool tip using the 3D mouse.
  m. Record the probe angle.
  n. Also, record the point coordinates (x, y, z) using the API.
  o. Repeat 3.4.h to 3.4.n for 10 different points on the prostate surface and calculate mean, max and standard deviation of tracking error.
  p. Repeat the registration and validation process for 4 different users and calculate mean and standard deviation of error for all users.

- 3.4.2 Registration between TRUS and da Vinci stereo camera using the registration tool:
  q. Place the registration tool against the air-tissue boundary.
  Use the 3D mouse to rotate the Parasagittal TRUS plane until the spherical fiducial on the registration tool could be visualized
in the Parasagittal image. A 5 degrees volume will be collected around each spherical fiducial.

– s. Adjust the imaging focus depth as necessary on the Ultrasonix console.

– Initialize the transformation finder software and select the tool tip in the collected 5 degrees US volume.

– u. Find the corresponding optical marker in the da Vinci camera frame using the optical tracking software.

– v. Repeat 3.4.r to 3.4.u for all of the fiducials on the registration tool, and record the transformation between the TRUS robot and da Vinci camera frames. Registration validation (calculating image overlay accuracy after registration):

– w. Place the da Vinci tool tip on the tissue

– x. Capture a US volume and record the location of the tool tip in the US volume.

– y. Record the snap shot of the tool tip location in the camera view. Also, record the video of the tool tip placed on the tissue. The tool tip is a common feature in both camera and US frames.

– z. Overlay the US volume on the camera view off-line using the calculated transformation matrix from registration in 3.4.3.

– aa. Find the difference in pixels, between the location of the tool tip in the camera view and in the transformed, overlaid US volume.

– bb. Repeat 3.4.w to 3.4.aa for 10 points.

– cc. Report the mean and standard deviation of the error.

• 3.5 Pick-up ultrasound evaluation:

– a. The drop in probe designed to be used during partial nephrectomy should also be tested in this environment. Tools should be switched to use the Prograsp on PSM2. Video recording will be on.
b. The camera and port should be removed, the transducer placed through the incision and then the port and camera replaced. Additional suture may be required to contain any leaks of abdomen pressure.

c. The surgeon can grasp and drop the transducer multiple times (20). Difficulties and failures will be recorded.

d. The surgeon will use the transducer to locate important structures related to the procedure, such as the prostate base and apex, the NVB and the urethra. Each structure should be identified in both the axial and transverse planes. Images will be saved when the surgeon believes he has found the best orientation possible. US volume acquisitions with da Vinci and TRUS will be compared after this step.

e. New freehand techniques of elastography have been developed using the da Vinci and the pick-up ultrasound transducer.

f. Probe will be left in place throughout the rest of the procedure to be used at the surgeons discretion.

g. Transducer will be removed after the camera at the end of the surgery.

3.6 After the registration, the surgeon should continue the steps of the procedure, while making use of real-time 2D B-mode imaging guidance, with both manual repositioning of the imaging planes using the 3D mouse and automatic tool tracking. The 3D mouse will be placed on or near the da Vinci surgeon console so the operating surgeon can control the position of the arrays. Real-time B-mode images should be examined before dissection of the prostate base and apex, and separation of the NVB.

3.7 Once the prostate has been fully mobilized and placed in a specimen bag, the TRUS transducer should be fully retracted using the remote manual control, in order to avoid negatively affecting the anastomosis.
• 3.8 After the completion of the procedure, remove the probe, stepper and stabilizer arm.

B.1.4 System Evaluation Criterion:

Robot Spacing Issue:

The TRUS robot should be placed at the foot of the OR table, in the space between da Vinci and the table as it is shown in Fig. 1. This configuration has been tested in the OR in Vancouver General Hospital and the TRUS system could be fitted marginally in this spacing. We want to double check this issue during an actual RALRP procedure and make sure that the surgeon could reach the sweet spot for placing the surgical tools and could do the procedure comfortably without any spacing issue.

Procedure Timing Issue:

An estimate of the amount time that will be added to the standard RALRP procedure should be calculated. The extra time added to the procedure is an important factor for evaluation of our image guidance system. Measuring the amount of time needed to perform all of the above steps in an animal study will give us a good estimate for the actual clinical application. In fact, we should time all calibration procedures so we can get an idea of learning time involved.

Imaging Evaluations:

The following factors should be checked in the captured images:

• How well can we see the air-tissue boundary (at anterior part of the prostate) in the B-mode images once the anterior aspect of the prostate has been identified?

• How well can we see the da Vinci tool tip (or the registration tool) pressed against the air-tissue boundary in the B-mode images? Can we localize the tool tip in the B-mode images and use its location for registration?
B.2 Transrectal Probe Disinfection at BC Cancer Agency

- How well can we see the NVB in the Doppler images and where is its location (at what angle in the US volume)?

- Vibro-Elastography images: Cancer detection, prostate boundary detection.

- Comparison between pick-up ultrasound images and TRUS images. Feasibility evaluation of using pick-up ultrasound for RALRP procedure as well.

Registration Accuracy:
Registration validation will be done using the procedures explained in 3.4 and accuracy will be reported to the surgeons.

Drop-In Probe Evaluation:
This new ultrasound probe will be evaluated by the surgeon with respect to image quality and manoeuvrability. Any issues with respect to blocking the camera will be noted. An evaluation sheet will be provided to the surgeon after the procedure. The freehand elastography results will be compared to those collected with the transrectal ultrasound transducer.

B.2 Transrectal Probe Disinfection at BC Cancer Agency

The probe disinfection station has two columns. The right one (blue) is filled with a Cidex disinfectant. The left column is water. Make sure you have gloves during the whole process.

- Put the probe in the Cidex column for 15 minutes (hook the cables to the black plastic on top of the column).

- Carefully, take out and move the probe to the water column for 30 seconds.
B.2. Transrectal Probe Disinfection at BC Cancer Agency

- Rinse for at least 30 seconds and inspect the probe for Cidex residue.
- Wipe the probe with a clean towel or tissue.
- Cover the probe (e.g., using a pillow cover).
- Fill in and sign the disinfection log (in probe case).
Appendix C

Elastography and the da Vinci

The desirability of having haptic or palpation feedback during robot-assisted surgery has been mentioned by many practitioners who use the da Vinci system. The tissue mechanical properties felt through palpation, such as elasticity and viscosity, can be acquired by using ultrasound elastography techniques. Elastography images can then convey the tissue properties visually, and can be helpful in many ways, including by helping determine organ and tumour boundaries and the effect of treatment such as thermal ablation. With further processing to simulate tool-tissue interaction, elastic models can be used to synthesize haptic feedback at the da Vinci masters without compromising system stability. Previous elastography systems developed for the da Vinci involved only strain imaging, which contains limited and subjective information, and is neither repeatable nor quantitative.

The quantitative elastography data-set collected for this part of the work was collected inside the operating room, after the patient is anesthetized on the OR table and before docking the da Vinci robot. Once the da Vinci surgical system and our TRUS system is docked, there is a very limited space to externally reach the patient’s prostate and send mechanical excitation. Hence, we propose using an internal mechanical excitation system that could be integrated with the da Vinci system and used during the procedure and produce absolute elasticity maps of the prostate intraoperatively. The design of our internal excitation system will be explained in the next section.
C.1 Tissue Exciter Design and Building for Intraoperative Elastography

The quantitative elastography method requires that the steady state tissue motion in a volume of tissue be measured. This is because waves can travel in arbitrary directions and measuring the wavelength in a single plane or along a line can produce large errors. This measurement over a volume should be carried out without modifying the wave pattern. Therefore, even though it may be simpler to use, it is not advisable to simply attach an exciter to the ultrasound transducer to induce waves in tissue, because the excitation source would move with the transducer and therefore significantly change the wave pattern in tissue with transducer motion.

Many sources of mechanical excitation have been tested in our group for elastography imaging. These include voice coil actuators coupled to the tissue through a rigid mechanical link [11], vibration motors [4], pneumatic [118] and hydraulic transmission [89] or manual excitation achieved by pushing the ultrasound transducer against the tissue [69]. For an internal excitation system, two actuation options are available, considering the size and biocompatibility issues: miniature vibration motors and moving coil actuators. We propose using a miniature brushless DC motor with an eccentric load on its shaft for the actuation mechanism of the exciter.

Our exciter design (Figure C.1 and Figure C.2) is composed of a small cylinder with no sharp edges for easy insertion through the trocar or directly through the incision between the trocar and tissue, as done with our pick-up ultrasound transducer. The exciter has a diameter of 11 mm. Accurate excitation frequencies are achieved by adding a feedback loop or a phase locked loop. A MEMS-size accelerometer is placed inside the exciter system for excitation frequency measurement and to provide feedback to the controller. Different components of our designed excitation system are listed in Table C.1.

Desirable excitation waves in the frequency range of 50-200 Hz and amplitude of approximately 1 mm could be achieved using such a system. The cylinder and the adapter part will be manufactured from a lightweight, stiff,
C.1. Tissue Exciter Design and Building for Intraoperative Elastography

Figure C.1: Shaker enclosure and motor housing design.

Figure C.2: (a) Motors and the accelerometer, (b) Motor with eccentric mass on its shaft enclosed in the 3D printed enclosing with its cap open, (c) cap fully closed for testing.
### Table C.1: Internal shaker components.

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motor</td>
<td>Brushless Maxon motor, 6 mm diameter, nominal speed 11200.0 rpm,</td>
</tr>
<tr>
<td>Controller</td>
<td>digital 1-Q-EC Amplifier 24 V / 1 A, speed control</td>
</tr>
<tr>
<td>Accelerometer</td>
<td>ADXL 362 3-axis accelerometer</td>
</tr>
</tbody>
</table>

sterilizable material, as discussed below. The actuator and the connecting cable will also be sterilizable, as is the case with intra-operative ultrasound transducer cables. An EM sensor will be integrated with the exciter so that its location can be tracked with external EM tracking systems on the ultrasound machines.

An adapter part is designed at one end of the cylindrical exciter for easy pick-up and maneuverability with the da Vinci ProGrasp forceps. Unlike our pick-up ultrasound probe, the shaker does not need to be calibrated to the da Vinci tool tip. Only an easy and fast grasping technique should be designed for it. Different grasping methods and adaptor shapes have been designed and tested to reach an optimum shape within such size constraints. Three potential designs for the adapter part are illustrated in Figure [C.3]. Methods for fixing the shaker to the tissue during excitation will be explored and include suturing it close to the region of interest (e.g. lateral or superior to the prostate; onto the kidney) or designing a vacuum mechanism that could be remotely controlled. We have been able to test several prototype designs using rapid prototyping on our Objet 3D printers before having the casing manufactured as shown in Figure [C.4].

### C.2 Clinical Integration Plan

Once the design is completed, it will be tested for current leakage and other safety measures by the Biomedical Engineering Department at Vancouver General Hospital (VGH). In addition, in order to use the exciter inside a patient in the OR, the sterilization department at VGH requires that each device have validated manufacturer instructions regarding reprocessing, and
C.2. Clinical Integration Plan

Figure C.3: (a) Three sides design with 120 degree, (b) Two-sided design with 180 degree, (c) One sided design.

Figure C.4: The internal tissue excited graped by the Prograsp instrument of the daVinci system.
be in accordance with CSA standards (CSA Z314.9). Since we are not a manufacturer as recognized by the hospital, we will need to get the device and sterilization process validated by a third party. We have already completed this process for the intra-operative pick-up ultrasound probe and are familiar with the procedures. The completed exciter will be sent to Advanced Sterilization Products (ASP), the manufacturer of the STERRAD®. STERRAD® is a sterilization machine that uses hydrogen peroxide plasma to sterilize operating room equipment. This method is often used on more delicate equipment such as intra-operative ultrasound probes and will be appropriate for our exciter. ASP will create a set of validated instructions such that the exciter can be sent through the sterilization department at VGH as any other device used in the OR. We will also test the device to assure that the sterilization process has not affected its efficacy.

The use of the STERRAD® system does affect our choice in materials, since all materials used in this device need to be compatible with the cleaning method as well as be biocompatible. A plastic that is both bio- and STERRAD® compatible is ULTEM. This plastic is a material originally produced by the General Electric Plastic division and is a thermoplastic that is heat and solvent resistant. It is often used in medical devices, including the casing of intra-operative probes. Other biocompatible plastics include medical grades of PVC and Polyethylene, PEEK, Polycarbonate, Polysulfone, Polypropylene and Polyurethane. In addition, companies such as Tristar, specialize in one-on-one material selection and part manufacturing. If it is determined that the design of the exciter is beyond what we can manufacture in the lab, outside consultation is possible.

An alternative to using plastics would be to use a stainless steel casing. Surgical grade stainless steel is often used for many re-useable medical devices due to its durability and sterilizability. However, steel may interfere with the electromagnetic tracking system, so plastics are preferred.