

Intelligent Systems Application Studies:

Robotics and Automation for Medical Applications

Robotics-Assisted Intervention Final Report

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Intelligent Systems. Thinking Technology.

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TECHNOLOGY MANAGEMENT,
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In association with:


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Robotics-Assisted Intervention

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Executive Summary

This paper was sponsored by Precarn, a national, industry-led, not-for-profit consortium that supports collaborative research and development in intelligent systems. It examines the use of robotics in medical interventions. The results will be used by Precarn to guide their business planning and to inform members of the medical robotics and automation community.

The information in this paper was obtained from a review of the literature, interviews with representatives from industry, academia, and government in Canada and the United States, and a workshop attended by robotics-assisted intervention stakeholders.

The Commission on the Future of Health Care in Canada (The Romanow Report) concluded that Canada's health care system has served Canadians well and is as sustainable. However, it expressed concerns about a number of health care issues, including cost and access. These are two areas where robotics-assisted intervention has the potential to make significant contributions.

The main element of a robotic system is a computer that performs high-level analysis, including: image and sensor processing, anatomical modelling, surgical planning, and control of surgical tools. The system inputs and outputs come from interfaces with medical personnel, the patient, surgical tools, and various imaging and sensing devices.

The use of robotic devices and manipulators enhance the ability of the user in many ways, including: increased accuracy and perception, increased reliability and safety, improved record keeping and logging, and improved performance.

However, robotic systems have intrinsic disadvantages that limit the ways in which they can be used, including: inability to make judgements, poor overall dexterity, limited haptic sensation, and high cost.

The robotic procedure is formed by a series of steps that can be classified into three main areas: preoperative, intraoperative, and postoperative.

There are many different medical procedures and interventions that can benefit from the use of robotic systems, including minimally invasive procedures, procedures requiring much greater accuracy than is achievable by the human hand, and telemedicine that provides medical services to patients located far from the physician.

Key components of robotic intervention technologies include: imaging, augmenting devices and systems (hand-held tools, cooperatively-controlled tools, teleoperated tools, and autonomous tools), supporting devices (positioning, stabilization, dexterity, and autonomy), devices for diagnosis, user interfaces, and networking.

Despite all of the benefits that can be attained through the use of robotics in medical procedures and all the recent and expected developments, very few systems are currently available commercially. Many experts agree that academic research and development are far from commercialization. There is a belief, however, that continuous growth in the market will occur over the next five to ten years. Issues that have been identified as limiting factors in this growth, include:

- Development of evaluation methods – The lack of properly defined indices for success in the use of robotics in a medical setting has caused the medical community to evaluate the use of such systems very critically.
- High cost – The cost of purchasing and maintaining robotic technology has been a limiting factor in its widespread introduction in the clinical field.
- Safety – There is still no consensus as to what the next direction should be in order to ensure safety when robots are used in a clinical setting.
- Regulations – The process of obtaining approvals from regulating organizations needs optimization.
- Interaction between academia and industry – Academia and industry must collaborate more effectively to accelerate the commercialization of new technologies.

Canada is considered to be a strong player in robotic intervention due to its top researchers and a number of strong companies. Canadian universities and research laboratories have world-class expertise in robotics, imaging, and human-computer interfaces. Canada's broadband network infrastructure and skills in video compression and simulation provide an excellent foundation for telemedicine. Our unified healthcare system and efficient approval process is seen as an advantage compared to the United States. Opportunities for Canada in robotics-assisted intervention include its use in remote areas, training, and space.

Although technological advances have been significant in the previous decades, the widespread application of robotics in medicine will depend on future advances. Experts participating in this study have identified of recommended directions in robotics systems, system inputs and outputs, instruments and devices, networks, and training. This will require cooperation among industry, academics, hospitals, and government. Precarn has a role to play in developing a network of centres of excellence in robotic-assisted intervention, facilitating the involvement of the other stakeholders, and working to develop consensus and an implementation plan.

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1. Introduction

1.1 Background

Precarn is a national, industry-led, not-for-profit consortium that supports collaborative research and development in intelligent systems. Precarn's mission is to make Canadian firms more globally competitive by promoting the development and use of intelligent system technologies and expertise.

Intelligent systems emulate the human ability to perceive, reason, make decisions, and act. They enable machines and devices to anticipate requirements and deal with environments that are complex, unknown, and unpredictable. The broad range of intelligent technologies includes robotics, sensors, knowledge-based software, and human-machine interfaces [Precarn 2004].

Precarn commissioned studies of the application of intelligent systems in six priority application areas. The objective of the studies was to determine future market and technology trends in order to identify directions for further research, development, and commercialization of technologies.

One of these application areas was Robotics and Automation for Medical Applications; Hickling Arthurs Low (HAL) Corporation and CSTAR (Canadian Surgical Technologies & Advanced Robotics) were given the responsibility for the investigation of this area. The results are being used by Precarn to guide their business planning, and to inform members of the medical robotics and automation community.

There are many ways in which robotics and automation can be used in medical applications. This project concentrated on two sub-areas: robotics-assisted intervention (covering areas such as robotics-assisted surgery and therapy, tele-surgery, robotic tools in diagnosis, and robotic delivery systems) and laboratory automation (covering areas such as genomics, proteomics, drug discovery, and diagnostics). The focus of this paper is on robotics-assisted intervention.

1.2 The Future of Health Care

The Canadian health care system is in an era of reform and restructuring. Economic and political forces, changes in licensing and education, as well as public expectations, all influence change in the evolving health care delivery system. The Commission on the Future of Health Care in Canada (The Romanow Report) concluded that Canada's health care system has served

Canadians well and is as sustainable as Canadians want it to be. However, it expressed concerns about a number of health care issues, including cost and access.

The Romanow Report points out that meeting the needs of an aging population will add costs to our system. Also, promising advances in medical technology are occurring almost daily; but while they have the potential to provide better treatments and cures, their costs are often substantial. With these increasing costs, is a broad consensus on the need to ensure that the publicly funded system delivers value for money and that the outcomes have a positive impact on the health of the population – an increasingly knowledgeable, sophisticated and litigious public is much less accepting of anything less than excellent care and results. Robotic-assisted interventions have the potential to make cost-effective and safe contributions to health care.

The Romanow Report identified the issues of timely access to services, particularly in rural and remote areas, and the serious disparities in both access to care and health outcomes in some parts of the country, particularly for Aboriginal peoples and in the north. One of the biggest challenges smaller communities face is attracting and retaining health professionals. The issue is less about the sheer numbers of health care providers and more about the preferences of many professionals to live in major urban centres. Telehealth uses information technologies to link patients and health care providers to a wide variety of services outside their community. People in rural and remote locations can be linked to family physicians, specialists and other health services in other centres where health care providers can diagnose, treat and provide consultations at a distance. Robotic-assisted interventions can help provide surgical services to rural and remote areas of Canada. In addition, this access to specialists in urban centres can also make mentoring and training available to physicians that do choose to locate in these locations.

The Romanow Report found that Canada has a solid base of research organizations but there are gaps in the applied research agenda. One such area is rural and remote health. It recommended that funds should be used to ensure that people in smaller communities across the country have access to an appropriate mix of skilled providers. Robotics-assisted intervention is one area of research that will contribute to this need.

1.3 Approach

Information in this paper was obtained from three sources. The foundation for the paper is a review of the literature on robotics-assisted intervention. This was augmented by interviews with representatives from industry, academia, and government in Canada and the United States. Finally, the literature review and interview results were used as the basis for a workshop attended by robotics-assisted intervention stakeholders. Four questions were considered at the workshop:

- What are the major issues in robotics-assisted intervention?
- What are the most important areas for research and commercialization in robotics-assisted intervention?
- What are Canada's strengths and opportunities in these areas?

- What should be the role of stakeholders in advancing robotics-assisted intervention in Canada?

The following chapters use the information obtained from the literature review, interviews, and workshop to discuss robotics-assisted intervention applications, technologies, trends, limiting factors, Canadian strengths and opportunities, and recommended directions.

2. *Robotics-Assisted Intervention Applications*

The term *medical robot* has now been used for over a decade to refer to those mechatronic devices (mechanical devices that use electronics for their control and manipulation) that assist physicians and the rest of the medical community to perform surgical, therapeutic or diagnostic procedures. In this paper, the terms *robotic device* or *medical robot* will be used to indicate surgical manipulators, instruments or devices that employ electronic components for their manipulation and control.

The main element of a robotic system is a computer system, which performs high-level analysis including: image and sensor processing, anatomical modeling, surgical planning and control of surgical devices [Joskowicz, 2001]. The system inputs and outputs come in the form of interfaces as outlined below (Figure 1):

- From the medical personnel to the computer: commands through foot pedals, voice, screens, joysticks or other user interface tools.
- From the computer to the patient: surgical, diagnostic or therapeutic procedure performed through surgical devices and manipulators.
- From the patient to the computer: includes images and force or torque measurements obtained from sensors located on the surgical devices.
- From the computer to the medical personnel: force feedback, visual displays of processed images, and audible alarms and notifications, Section 3.3.

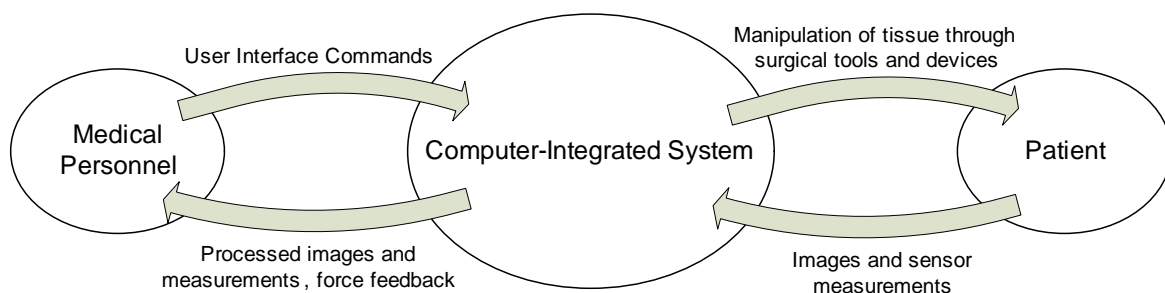


Figure 1: Interfaces to and from the computer-integrated system (CIS).

2.1 The Need for Robotic Systems

Many medical procedures that could not be done in the past are now possible thanks to surgical robots and tele-manipulators. Their advantages and disadvantages are reviewed here.

2.1.1 Advantages

The use of robotic devices and manipulators enhance the ability of the user in many different ways, including the following [Howe, 1999], [Cleary, 2001], [Joskowicz, 2001], [Carrozza, 2003], [Lanfranco, 2004], [Korb, 2004], [Academic Interviews], [Clinician Interviews]:

Increased accuracy and perception

- Robotic devices can improve accuracy in manipulation to different degrees: from filtering hand tremor in hand held devices, to master-slave systems where motion scaling and miniaturized instruments are used to accurately perform small movements.
- Instrument location accuracy is improved by the use of imaging and automated devices that ensure accurate positioning of critical tools.
- Sensorized instruments can enhance the physician's perception by using accurate sensors to provide critical feedback. This allows avoidance of undesired forces, torques or geometrical deviations which are too small to be detected by the surgeon.

Increased reliability and safety

- Instruments can be thoroughly sterilized, providing an advantage over hand washing methods that can be affected by human error or carelessness.
- Instruments are resistant to radiation, infection or other dangers, providing a safer environment for medical personnel.
- Robotic systems can support training through surgical simulation systems.

Improved record keeping and logging

- Robotic systems are capable of using and recording copious, detailed, quantitative information.
- Recording of information allows documentation of the behaviour of the robotic devices for use in evaluation and training. Review of this data allows planning and treatment processes to be detailed in order to improve the quality of the services provided to patients.
- Recording of information also allows detecting sources of error in order to reduce overall error rates.

Improved performance

- Robotic manipulators can be used to improve accessibility during minimally invasive procedures where surgical instruments enter the patient's body through incisions of approximately 1cm diameter.
- Robotic systems can improve dexterity under reduced access conditions as well as compensate for the natural motion of the patient's organs.
- Remotely controlled manipulators allow medical care to be provided to areas where medical access is difficult or impossible, e.g., inside an MRI machine, combat areas, outer space or areas subject to nuclear, chemical or biological contamination.
- The increased performance achieved through the use of robotic systems has allowed surgeons to perform interventions that were not possible in the past.

Other

- Robotic systems allow access to remote areas through telesurgery, which is especially beneficial in Canada where the unified health care system extends over a large area with many remote locations.
- Robotic systems generally have a positive psychological impact on patients.

Regardless of these advantages, new technologies can only extend human capabilities, not replace surgeons [Howe, 1999]. The reason for this is clear when the disadvantages presented in the following section are taken into account.

2.1.2 Disadvantages

Robotic systems and manipulators have a series of intrinsic disadvantages that limit the ways in which they can be used in the operating field. Some of these are as follows [Howe, 1999], [Lanfranco, 2004]:

- Inability to make judgments and limited use of qualitative information: humans are superior at integrating diverse sources of information, using qualitative information and exercising judgment.
- Poor overall dexterity and hand-eye coordination: humans have better dexterity and hand-eye coordination, as well as a finely developed sense of touch.
- Limited to simple procedures or require highly sophisticated instructions: humans on the other hand, are easy to interact with and instruct.

Other disadvantages that are currently present in these systems, which could potentially be addressed in the future, are as follows [Howe, 1999], [Taylor, 2003], [Lanfranco, 2004], [Marohn, 2004]:

- Absence of or very limited haptic sensation.
- Large footprints and cumbersome arms. There is a tradeoff between the manipulator interfering with other equipment and personnel and its ability to reach the desired sites or hold an adequate number of instruments with the necessary dexterity.
- High cost.
- Technology still under development: this makes their dependability still questionable [Troccaz, 2002].
- Recording of actions performed during robotics-assisted surgery could have an impact in liability cases.

2.2 The Robotic Procedure

The robotic procedure is formed by a series of steps which can be classified into three main areas: preoperative, intraoperative and postoperative [Davies, 2000], [Joskowicz, 2001], [Rembold, 2001]. The following sections describe these steps.

2.2.1 Preoperative

Two and/or three dimensional images and information about the patient are obtained using methods such as computer tomography (CT), magnetic resonance imaging (MRI) and ultrasound tomography [Rembold, 2001]. The images are processed to evaluate and convert the data such that essential structures are revealed and presented to the clinician in a suitable form [Howe, 1999]. For example, three dimensional representations can be obtained from a series of two dimensional images. In some cases it is necessary to fuse information from two or three different imaging methods which requires registering points on the different image modalities.

The surgeon then uses these processed images to plan preoperatively every step of the surgical procedure. The planning stage is very much dependent on the type of surgery to be performed. Some examples of surgical planning processes are as follows:

- In minimally invasive cardiac surgery, the planning stage includes determining the location of the entry ports for the instruments and the best location and positioning of the surgical manipulator or cameras [Adhami, 2003], [Lehmann, 2001].
- In maxillofacial surgery planning involves a reconstruction of a three dimensional model of the patient, which the surgeon uses to develop a treatment plan [Bohner, 1997].
- In orthopedic surgery, planning includes the selection of adequate implants, definition of manipulator motion trajectories, actions, cutting forces and placement of markers for imaging; see e.g., [Taylor, 1994].

Although preoperative planning can take considerable time [Korb, 2004], it is especially important when dealing with robotic equipment. The nature of robotic systems allows precise preplanning operations and the ability to transfer these plans to the operating room. Reaching the desired goal can be verified by simulating the surgical outcome in advance and making any necessary changes to the procedures [Korb, 2004].

The biggest problem present in preoperative planning refers to tissue and organs shifting between imaging and surgery. The severity of these shifts depends on the type of surgery, e.g., in cardiac surgery there are distinct shifts and deformations of organs and rib cage due to gas insufflation and collapsing of one lung during minimally invasive cardiac surgery [Schwarz, 2003]; in craniomaxillofacial surgery, location of skin markers creates an average application accuracy of 2-7 mm [Zinser, 2004]. Research is ongoing into reducing the effects of tissue shift especially in neurosurgical applications; see for example [Rexilius, 2002].

2.2.2 *Intraoperative*

At the time of the surgical procedure, the process of registration refers to matching the image data with the patient's anatomy in order to implement the preoperative plan determined at the planning stage. The process of registration links points in the preoperative images with the corresponding points on the patient's body at the time of surgery. Two general approaches have been developed and are explained below [Howe, 1999]:

- **Marker-based schemes:** Markers are placed on specific locations on the patient's body prior to imaging. The markers are exposed during surgery and the computer control system knows the exact correspondence between the markers on the patient's body and the markers in the images. The robotic manipulator then contacts each of the markers such that the complete spatial transformation between the image and the patient can be found. The limitation of this method is that the placement of the markers can be very invasive and complex.
- **Shape-based schemes:** These systems fit the shape of anatomical structures from intraoperative measurements to preoperative image data. The anatomical structures are measured to obtain a description of the shape of the anatomical structure in the patient's coordinates. A computational algorithm is then used to determine the spatial transformation that minimizes the error between the sensed shape and the shape segmented from the image data.

After registration, the model and/or the plan can be updated to match the current location of organs and tissues in the body.

The computer uses one or more interface devices to help the surgeon execute the surgical plan. The interface devices can have different levels of autonomy as outlined below [Korb, 2004], [Davies, 2000], [Troccaz, 2002]:

- **Master-slave systems** present the least level of autonomy, since all the surgeon's actions are imitated by the slave manipulator. Medical procedures that deal with soft tissue require the use of master-slave systems since large deformations of the tissue demand that the surgeon be

in absolute control of the movements [Howe, 1999]. An example of a master-slave system is the da Vinci Surgical Manipulator [Guthart, 2000].

- Semi-autonomous systems provide an intermediate level of control, where both the surgeon and the computer system share the control of the device. The surgeon uses his or her judgment and experience to directly control the procedure, while the computer constrains the motion to avoid high risk areas or forces.
- Autonomous systems are those where the robot carries out a preoperative plan without immediate human interaction. These types of systems can only be used in medical procedures that have narrowly specified tasks and those where the environment is predictable [Howe, 1999], e.g., orthopedic surgery. With these systems, the surgeon is still in control of the procedure by defining the preoperative plan and having the ability to stop the device at any time. For example the ROBODOC system [Taylor, 2003] performs the cutting and shaping of the bone during knee replacement surgery, checking for forces and bone motion, and following a predefined path.

However, since each patient and each surgical procedure have individual characteristics, the pre-programming of a robot can only be done for one patient and one procedure at a time. It is unlikely that total automation of surgical robots will ever be possible. Robots must work in cooperation with the surgeon, not as substitutes for them [Korb, 2004]. Regardless of the level of autonomy, if an emergency presents itself, all surgical manipulators must allow the completion of the procedure manually or through more traditional methods [Davies, 2000].

The verification stage includes the use of feedback (e.g., intra-operative imaging) to ensure that the procedure has been accomplished successfully. The computer system can be used to identify and record important information about the procedure.

2.2.3 *Postoperative*

Postoperative images similar to those obtained preoperatively are used to perform short and long term evaluations of the success of the procedures [Rembold, 2001], [Taylor, 2003]. For this purpose, all markers placed for the purpose of registration must remain in place throughout the procedure, which means that they must be placed such that they will not be removed (machined or taken out as part of tissue removal) by the surgical procedure itself [Davies, 2000]. Postoperative tasks also include the analysis of information recorded during surgery to be used for documentation, evaluation and training [Korb, 2004]. It should be noted that not all computer-integrated systems (CIS) require all the steps outlined above. The systems shown in the following section will show examples of how the different steps can be integrated to form a complete system.

2.3 *Robotic Applications*

There are many different medical procedures and interventions that benefit from the use of robotic systems. These applications are outlined below and have been categorized based on the applicability of robotics.

2.3.1 *Minimally Invasive Procedures*

Minimally invasive is a general term referring to all those modifications to traditional procedures that aim to reduce damage to the patient. These include using blood vessels to move instruments (intravascular), making smaller incisions on the tissue or using natural openings in the body (endoscopic), or operating on a beating heart and moving lungs. Although these modifications greatly decrease trauma to the patient and reduce recovery time, they also significantly increase the difficulty of the procedure by reducing dexterity, limiting perception, and increasing strain and procedure time [Tendick, 1998].

The use of robotics in minimally invasive procedures has addressed many of the difficulties caused by the less than ideal conditions from the surgeon's point of view, as outlined below:

- In endoscopic procedures (including laparoscopy, thoracoscopy, arthroscopy), the use of master-slave systems (e.g., see [Guthart, 2000]) improves dexterity in comparison to standard 4 DOF instruments, compensates for motion reversal caused by the entry point (fulcrum effect), and reduces hand muscle fatigue by compensating for the higher manipulation forces required due to instrument drag [Kypson, 2003].
- In endoscopic procedures where advantage is taken of the natural openings in the human body (e.g., the gastrointestinal tract), smart instruments can help guide the endoscope through, in order to avoid the pain and discomfort experienced by the patient. These smart instruments use the inchworm locomotion principle in order to autonomously maneuver in small places [Phee, 2002].
- In cardiac surgery done on the beating heart or thoracic surgery affected by the movement of the lungs, robotic systems under development track the movement of the organs and cancel the relative motion between them and the surgical tools, e.g., [Ginhoux, 2004].
- Intravascular procedures require aid in navigation and positioning of the instruments. This can be achieved through computer-assisted equipment by means of adding sensors to the tip of the instrument such that it can assist in the advancement and selection of the direction of movement. In these cases, locomotion is still controlled by the surgeon and is assisted by external imaging [Dario, 2003].

2.3.2 *Accurate Procedures*

Procedures that require accuracy much greater than that achievable by the human hand greatly benefit from the use of robotic systems. These applications include the following:

- Microsurgery, in which the microscopes and miniaturized precision instruments are used to perform intricate procedures on very small structures. Master-slave systems can provide the motion scaling and tremor filtering required to achieve the necessary accuracy when manipulating these small structures, e.g., [Ikuta, 2003].
- Neurosurgery requires a high level of accuracy as any damage to the brain tissue affects the patient's behavior and abilities [Rembold, 2001]. Computer-integrated systems allow surgeons to achieve the required accuracy by guiding the instruments and/or scaling down the surgeon's movements [Louw, 2004].
- Orthopedic surgery has benefited from the development of semi-autonomous robotic systems that are directly guided by the surgeon while the robot provides geometric accuracy and increases safety through predefined motion constraints [Jakopec, 2003]. Other tasks performed by robots include accurate drilling, positioning of guides, milling, and placement of screws or nails.
- Maxillofacial, craniofacial or plastic reconstructive surgery in which it is extremely important to achieve the desired accuracy when shaping, placing and orienting the bones in the skull and the face in order to meet the esthetic requirements of patients. Robots or smart instruments can provide the guidance and restrict the position and orientation of the cuts, as well as the magnitude of the applied forces and torques [Lueth, 1998].
- Biosurgery, in which lasers and optical forceps are used by cell biologists to manipulate microscopic cells. Robotic systems must be used to achieve the precision and control necessary to perform the manoeuvres [Satava, 2003].

2.3.3 *Telemedicine*

Telemedicine refers to the provision of medical services to a patient located far away from the physician by means of computer-integrated systems. These systems provide the surgeon with real-time images of the patient, enable direct communication between personnel for the exchange of medical advice, and in some cases allow the surgeon to remotely manipulate surgical tools. These methods have the advantage of allowing medical care to be provided to areas where medical access is difficult or impossible, e.g., remote regions, combat areas, outer space or areas subject to nuclear, chemical or biological contamination [Marohn, 2004].

The consensus from expert clinicians across Canada, the United States and Europe is that advantages brought forth by telemedicine are vast in scope and that telemedicine is an area of sincere interest to the medical profession. Although remote surgical manipulation is the area most often discussed, telemedicine in the long term is much more; it is what one expert describes as an ideologic shift in our approach to healthcare. Telemedicine brings expert mentoring for both surgical applications and expert opinions for diagnostic discrepancies to the most remote centres instantaneously. Regional healthcare centres with all their expertise are brought to the patient instead of vice-versa. Such parameters open the door to what one expert describes as 'hospitals without borders,' a true pancontinental or transglobal approach to healthcare through telenetworks and imaging modalities.

2.3.4 *Other Applications*

- Stable and tiring tasks like endoscope pointing, organ retraction or holding a heart stabilizer [Howe, 1999].
- Exposure to hazardous environments, where radiation or dangerous substances are present, e.g., in handling radiopharmaceuticals [Wilson, 1998].

The list presented above includes only a general overview of how robotics are useful in medical applications and is by no means exhaustive. The extent to which robotic systems are applicable in the medical field is expanding rapidly into many different disciplines [Lanfranco, 2004].

2.4 *Issues*

The workshop of sector representatives was asked to identify major issues in robotics-assisted intervention. They created the following list:

- Need for a national strategy vision: what are the roles of stakeholders, what will we be able to do with this technology, and what impact will it have?
- Cultural acceptance and clinical applicability: superiority over existing technologies, utility still to be proven for most surgical applications, time taken for a procedure currently longer than standard approach, standard of care.
- Flexibility: ability to perform a variety of applications (i.e., ‘Swiss Army knife’). Specialized device development and integration on platforms.
- Funding: Both in development and deployment. Return on investment (for developers and users). Small, underfinanced companies.
- Costs: capital and operating/maintenance costs. Need to make a case for the utilization of these systems.
- Regulatory issues.
- Community: sense of commitment among all stakeholders, critical mass and motivation of receptors and alignment of motivated customers. Need for champions.
- Usability: visualization, interface, learnability.
- Development of surgical simulators (both for training and preoperative procedural practice).
- Existing hospital infrastructure: most hospitals do not have resources to implement/deploy robotics-assisted intervention.

3. *Technologies*

Some of the key research and development areas for CIS for surgery and therapy were identified through interviews with experts from both the academic and the clinical sectors. They are as follows:

- Modeling and analysis of the anatomy (including soft-tissue modeling) and fusing of all the available information about a patient into a unified representation.
- Imaging (including segmentation, registration and interpolation) in real time for autonomous interventions.
- Human/machine interfacing (for teleoperation and haptic interaction), visualization and development of training environments, study of human factors.
- Tracking of both tools and organs in real time (including tracking of tool and organ deformations).
- Miniaturization, improving dexterity and sensing capability of instruments and tools, development of special purpose devices for assisting surgical procedures.
- Developing mechanisms and actuators including electric motors.
- The integration of automation in certain task specific surgical procedures such as suturing and vein harvesting.
- Clinicians noted a need for a greater variety of surgical tools to employ with the current first generation surgical robots while second and third generation robots are being developed. This will optimize present day technology in the midst of continued technological advancements.

At a system level, some experts also identified a need for integration of imaging with surgical/therapeutic devices (so that images can be fed in real time to these devices to enable planning, monitoring and guidance during the intervention) as well as a need for generating test plans for deployment of surgical systems in clinical use. Others stressed the need for standardization of interfaces and the development of various components and devices that feature modularity and robust predictable behaviours, capable of working together in a very systematic and controlled way. In the following, the state of the art in some of the above key technological areas is surveyed.

3.1 *Imaging*

Image-guided surgery relies on a powerful computer system, which assists the surgeon in localizing a lesion, in planning an operative procedure via a 3D organ or tissue model, and in calculating the ideal port placement during the preoperative phase. The diagnostic images, the 3D organ model, and the plan information are registered to the specific patient in relation to landmark structures during the intra-operative phase. In addition, the patient anatomy and surgical instruments can be tracked accurately in three dimensions. Finally, postoperative images and tests are taken to verify the procedure's technical results and to assess the clinical results for the patient [Joskowicz, 2001].

Image guided surgery requires image acquisition, image reconstruction, image registration, image fusion, visualization, surgical planning and navigation. The objective of image-guided surgery is the seamless creation, visualization, manipulation and application of images in the surgical environment with fast availability, reliability, accuracy and minimal additional cost [Haller, 2001].

Advances in image-guided surgery techniques have made it possible to acquire images of a patient while the surgery is taking place, to align these images with high resolution 3D models of the patient acquired preoperatively and to merge intra-operative images from multiple imaging modalities. Image-guided surgery has many applications, including neurosurgery, sinus surgery and bone surgery, and the number is increasing rapidly.

3.2 *Medical Devices*

3.2.1 *Augmenting Devices and Systems*

An augmenting device is used directly by the surgeon to perform surgery or therapy and, as the name implies, augments the surgeon's ability in doing so. In addition to extending the capabilities of the surgeon, the use of such devices and systems may benefit the patient through reducing morbidity, traumas, errors and operation times. Depending on the modes of interaction of these devices and systems with the surgeon, we categorize them into four groups as follows:

Hand-held tools – One advantage of using hand-held tools is that they do not constrain the surgeon and involve minimal changes to the operating room. The down side is that with purely hand-held instruments, a robot cannot be used to physically support heavier instruments. Also without any robotic arms, instruments cannot be locked in position and precisely controlled maneuvers (e.g. as required during microsurgery) are not possible [Taylor, 2003]. The hand-held devices that we are talking about are mostly sensorized.

Cooperatively-controlled tools – In cooperative manipulation, the surgeon and the robot both hold the surgical device – the surgeon provides control and the robot provides precision, sensitivity and guidance. Such devices act as guidance systems with which the surgeon's

motions are constrained. Cooperatively-controlled devices can be active (force controlled) or passive mechanisms.

Teleoperated tools – The idea of performing surgery in a teleoperated (or master-slave) mode, where the movements of a surgical robot (slave) are controlled via a surgeon’s console (master), takes robot-assisted surgery into a new era in which robots are given a more significant role. Master-slave robotic operations can solve many of the problems encountered in conventional surgery in terms of ergonomics, dexterity, fine manipulation capability, and haptic feedback capability for the surgeon.

Autonomous tools – In limited applications, such as endoscopic surgery, a robotic system that can perform certain tasks autonomously can reduce the strain on the surgeon and shorten the operation time. A robotic end-effector for autonomous suturing and knot tying is discussed in [Kang, 2001]. In general, however, surgeons are more interested in assistive tools with a degree of intelligence and reaction capability, than in systems that fully automate the surgeons’ role.

3.2.2 *Supporting Devices*

Unlike augmenting devices that are used directly by surgeons to perform interventions, supporting devices perform secondary functions such as holding endoscopes or surgical instruments. It is desirable to improve these systems so that they become more independent of the surgeon and operate with more autonomy.

Positioning and/or stabilization – Positioning stands for tools, camera positioners/stabilizers, ultrasound probe positioners, or stabilizers for the surgeon’s hand.

Increasing dexterity or autonomy of supporting devices – Highly dexterous or autonomous endoscopes.

3.2.3 *Devices for Diagnosis*

With the development of powerful computer systems and advances in robotics and imaging tools and techniques, computer-assisted medical diagnosis and therapy have become common in the last three decades. Robotic systems have been developed with a wide range of applications such as biopsies, online robotic telepathology, blood sampling, medical imaging for diagnosis and navigation systems for path planning. Some research groups have tried to use industrial robots to do the task and some have developed new robotic tools. However to achieve a desired performance and use the robotic tools in everyday operations, several issues have to be addressed such as high cost of teleoperation and robotic tools, consistency and accuracy of operation (e.g. accuracy of needle placement), real-time image guidance, size and complexity of robotic tools, custom designed robots, safety for patient and physician, pre-clinical experiments, accurate interactivity between remote sides, easy to use systems, visualization, path planning to avoid critical structures or organs, etc.

3.3 *User Interfaces*

Computer-based systems working cooperatively with humans must communicate with them, both to provide information and to receive commands. Human-machine interfaces (HMI) play an important role in computed-assisted surgery. Most of common HMI technologies, i.e., speech, computer vision, graphics and haptics are also adopted for surgical use [Taylor, 2003]. However, surgical applications have some special requirements, such as accuracy, reliability, robustness, transparency and real-time response.

A vision system is probably the most important information source during surgery. The endoscopic video camera and television monitor have been the most direct information source during laparoscopic surgery for many years. In many cases, simple computer graphics and text are often added to the video stream [Sim, 2001]. Surgical navigation systems [Haigron, 2004], [Zou, 2001]) provide computer graphic renderings and feedback based on tracked surgical instrument positions. The limited field of view and the lack of depth in mono-display of endoscopic vision are also big challenges to surgeons during the operation procedure. Therefore, endoscopic augmented reality, e.g., color imaging, 3D visualization and stereo vision, have attracted a significant amount of research [Devernay, 2001], [Zou, 2001], [Krupa, 2003]. Methods of overlaying 3D real-time functional models on video vision have been developed to provide intra-operative navigation approaches for surgeons [Hata, 1996], [Blackwell, 2000], [Masamune, 2000]. However, real-time image registration and validation is still a challenge in these applications.

All of the available interactive computer interfaces, e.g., mice, joysticks, touch screens, push buttons and foot switches, can be used to provide inputs and outputs for surgical systems. But they need modifications to meet the special requirements of surgical use, e.g., sterilizability and electrical safety [Taylor, 1996], [Nolte, 1996].

Voice is one of the most natural approaches for human communications. Accordingly, voice recognition devices have been used as a two-way command and control system for surgical applications [Reichenspurner, 1999], [Uecker, 1994].

Haptic devices allow the surgeon to manually interact with the environment. Force and haptic feedback is often important for surgical simulation [Aulignac, 2000], [Sheridan, 1997] and telesurgery applications [Mitsubishi, 1998], [Kumar, 2001], [Berkelmann, 2001], [Kumar, 2000]. Technologies developed for virtual reality and telerobotics applications can be used for surgical applications as well.

3.4 *Networking*

Industry observers noted that a number of technologies would contribute to the viable use of commercial networks for telesurgery. The rollout of Multi Protocol Label Switching (MPLS) as an alternative to ATM and other Quality of Service enabled networks will allow IP data to be transmitted with minimal guaranteed quality and security. Telcos which tout MPLS as an

enabling technology for telemedicine include Bell Canada, Global Crossing, and Sprint. MPLS allows Virtual Private Networks to be created to transmit video, voice and data simultaneously.

Another technology which impacts the networking aspects of telesurgery is video compression algorithms (codecs). It is important that new codecs produce video that is of higher quality, is low latency (< 100 ms) and degrades gracefully.

4. *Robotic Surgery Trends*

4.1 *Teleoperation and Telementoring*

Teleoperation has enjoyed a rich history and has led to many practical applications and a broad vision of interacting with environments far removed from the user. A bilateral telemanipulator enables human interaction with environments that are remote, hazardous or otherwise inaccessible to direct human contact. In teleoperation a human operator moves a master manipulator and a slave manipulator is controlled to follow the motion while manipulating a remote environment.

Telesurgery is one aspect of teleoperation [De Ugarte, 2003]. Although there is not much practical experience with telesurgery at present [Ghodoussi, 2003], [Rovetta, 1993], it is clear that successful telesurgery will require the transfer of robot commands, speech and video signals, as well as stored and real-time medical images [Green, 1995] between master and slave manipulators. To provide more complete interaction, force feedback is often included, since this information can considerably improve the user's ability to perform complex tasks. This allows the operator to be kinesthetically coupled to the environment, and the teleoperation to be controlled bilaterally [Vertut, 1984].

For telesurgery at a distance, a set of provisional network requirements need to be identified. These include reliability, acceptable end-to-end delay, the ability to transfer data from sources with widely differing data rates, and a low data error rate (bit error rate). A major issue in teleoperation systems is the effect of time-delays resulting from communication between local and remote sites. This time delay can destabilize a bilaterally controlled master-slave manipulator system. For example, in one of the earliest works on force feedback [Ferrell, 1966], it was shown that delays of the order of a tenth of a second could destabilize teleoperation.

Other issues that were identified by Industry observers were regulations in the United States which do not allow the use of compressed video for telesurgery. In fact, we were told that in general the regulatory environment in Canada for encouraging sector developments was much more liberal than in the US, where the FDA was seen as slow at providing clearance.

Industry-based interviewees identified a number of additional policy and regulatory issues that need to be addressed before commercial acceptance was likely, including issues of cross border liability and revenue sharing.

4.1.1 Telesurgery

Advanced telecommunications has offered the possibility of transmission of large amounts of information over long distances while reducing transmission time latency. Robotics-assisted telesurgery has made it possible for surgeons to operate on a patient from a considerable distance from the operating table.

With the introduction of modern robotic technology in the operating room (OR), surgeons are now set to progress to performing remote operations routinely. The first step towards the realization of this goal was the development of functional and useful laparoscopic instruments. This facilitated the beginning of minimally invasive surgery. The second step was the incorporation of robotic systems in the OR, with the surgeon being several feet away from the patient [Marescaux, 2001]. Technically, these robotically assisted procedures can be referred to as telesurgery, with the surgeon physically operating at a distance from the patient and interacting via manipulators. However, the real benefit of telesurgery lies in the ability to perform minimally invasive surgery on a patient at a remote location using the connectivity provided by a reliable communication system such as a dedicated network or satellite link. Before this type of surgery can become routine, the effect of issues such as network latency on the efficiency and reliability of remote telesurgery need to be thoroughly investigated both from engineering and clinical perspectives.

4.1.2 Telementoring

Telementoring is defined as a remote surgeon acting as a preceptor to provide guidance through difficult operations. In telementoring the mentor has some ability to control the proceedings that occur at the operating table [Docimo, 1996]. Since the last decade, laparoscopic surgery has been rising in demand, with an increasing number of surgeons learning and incorporating this technique into their practice. Widespread mentoring is required for this demand to learn laparoscopic techniques. Telementoring may also be useful because it allows surgeons to teach their colleagues without inconveniences such as traveling and scheduling teaching seminars [Rosser, 2001], [Link, 2001]. Successful early telementoring experiences have encouraged extensive and wider applications [Schulam, 1997]. Rosser and colleagues believe that the concept of telementoring, if properly utilized, can be a powerful tool for the delivery of healthcare in underserved communities [Rosser, 2001].

4.2 Research and Commercialization

The workshop of sector representatives was asked to identify the most important areas for research and commercialization in robotics-assisted intervention. They created the following list:

- Focus on end-user research. Systematic benefit assessment studies and focus groups with clinicians to find clinically oriented solutions.
- User interfaces: human factors and perception, surgeon-robot interfaces, haptics.

- Design of electro-mechanical tools: miniaturization, system size, ergonomics, and human factors. Self contained *mm* scale robotics requiring minimal intervention.
- Real-time imaging in the operating room.
- Visualization and data/sensor fusion in 3D.
- Integration of patient-specific information and models into systems.
- Techniques to reliably navigate to targets
- Tissue modeling and simulation
- Training Simulators
- Modularity in designs, standardization, and software interfaces to support modularity.

5. Current Limiting Factors

The overall objective of the healthcare profession is to optimize patient care by all means practical and fiscally possible. Quality of care in surgery is often graded on patient outcomes with four overriding variables (1) success rate of the surgical intervention, (2) complications incurred from surgical interventions, (3) length of hospital stay, (4) re-admission rates to hospital. Guided by these principles, the concept of minimally invasive surgery and increased surgical precision by way of robotic technology becomes appealing as it has the potential to maintain or improve surgical success rates in certain settings, while limiting patient morbidity incurred from the act of surgery itself. While long-term follow-up is needed to gain insight into such ideals, initial feasibility studies and a progression to routine surgical procedures with robotic technology is the initial step forward.

Despite all the benefits that can be attained through the use of robotics in medical procedures and all the recent and expected developments, very few systems are currently available commercially. Many experts agree that academic research and development are far from marketing and commercialization. This concerns the medical and engineering communities at large. There is a belief however, that a continuous growth in the market will occur over five to ten years from now. The following sections provide an overview of some of the issues that have been identified as limiting factors in the widespread acceptance of robotic technology in surgery and therapy.

5.1 Development of Evaluative Methods

The lack of properly defined indices for success in the use of robotics in a medical setting has caused the medical community to evaluate the use of such systems very critically. Some authors encourage surgeons to be careful since critical measures like operative safety, speed of recovery, level of discomfort, procedural cost, and long operative quality have no standard way of being defined [Kypson, 2003]. This is aggravated by the fact that the success of using CIS over traditional methods might not be fully assessable until many years after the intervention [Howe, 1999]. The ability of CIS to record, document and analyze data will help to assess the success more effectively. However, a method for figuring out how to apply these capabilities still needs to be developed [Joskowicz, 2001]. What must be kept in mind by the medical community at large, is that the ultimate payoff will be improved and more cost-effective health care. They must work toward a better definition of how to assess success.

5.2 *High Cost*

The high cost of purchasing and maintaining robotic technology has been a limiting factor in its widespread introduction into the clinical field. This high cost is driven by the cost of developing the systems being very high due to the large technical effort required to ensure safety and reliability [Korb, 2004]. Most hospitals cannot afford the technology, and those that can usually have research capabilities and would prefer to have two systems: one for research and training, and one for clinical use [Marohn, 2004]. The cost of the technology can be somewhat justified by the cost savings caused by reduced patient recovery time, and fewer repeat surgeries due to better surgical outcomes [Joskowicz, 2001]. However, more effort needs to be put into developing more cost effective systems from the point of view of the initial investment and the cost of running and maintaining the equipment.

Some industry interviewees indicated that the cost of systems would only drop once a set of standards for electronic and mechanical interoperability have emerged. In fact, cost of existing systems was seen as the major roadblock to increased acceptance of CIS surgery. MedMarket Diligence, LLC [2004] predicted that the cost of a telesurgery in Canada would drop from US\$9,000 in 2006 to US \$2,000 by 2011, with cost reductions coming primarily from robots, not networking. The same study predicted that the number of telesurgeries in Canada would increase from 1000 to 5000 per year over the same period.

5.3 *Safety*

Although the question of safety in the use of medical robots has been a subject of discussion for many years [Davies, 1996], [Duchemin, 2004], [Ellenby, 1994], [Dowler, 1995], [Fei, 2001], there is still no consensus as to what the next direction should be in order to ensure safety when robots are used in a clinical setting. Many safety guidelines have been developed for industrial robots, which mainly consist of isolating the robot and preventing its operation while people are in its workspace [Davies, 1996]. However these guidelines for industrial robots cannot apply to those used in the medical field, since medical systems have the inherent requirement of interacting with humans. Although regulatory agencies require that safety be addressed for all medical devices [Howe, 1999], thus far the absence of a clearly defined legal norm to govern medical robots has caused a delay in the development of standard safety guidelines [Duchemin, 2004]. This lack of guidelines has slowed the development of medical robots and has limited the functionality and performance of the existing systems in order to control risk [Ellenby, 1994].

Attempts have been made to develop systems and methodologies for evaluating safety during the use of robotic devices in medical applications. Examples include a systematic methodology for analyzing, controlling and evaluating safety when using medical robots [Fei, 2001] and a multi-criteria approach that proposes the interaction of safety components in hardware and software, in order to achieve the required level of safety [Duchemin, 2004].

Many researches have developed safety features that are built into different medical devices; see [Fei, 2001] for a good review. Examples include: the design of a manipulator such that it is impossible to exert force in directions that are dangerous to the patient [AESOP, 2004], limiting

the size of the robot workspace to eliminate the possibility of tissue damage away from the intended surgical site [Howe, 1999], or reducing the impact loads associated with uncontrolled manipulator collisions [Zinn, 2004]. However, the causes of safety problems are so diverse (human error when manipulating or instructing the device, system error caused by hardware failure, software failure or a combination thereof [Fei, 2001]) and dependent on the characteristics of each device, that considerable effort needs to be placed to ensure its safe operation during its development, raising the development cost and time and potentially pricing the device out of the market [Davies, 1996].

The development of safety guidelines must consider that the benefits that can be obtained from medical robots are such that a small amount of risk is inherent in their use, while taking every effort to ensure that the system is as safe as possible [Davies, 1996]. Up to now, the applications of medical robots have been such that a system failure would not result in a life-threatening situation as long as the equipment can be removed and the procedure completed using more traditional methods. However, as technology continues to advance and some medical procedures that could not be performed before become possible, this might no longer be the case [Camarillo, 2004]. Therefore, acceptable safety levels will depend on how critical the procedure is [Davies, 1996].

Industry observers noted an apparent mismatch between the reliability required of data networks (typically 99.9999%) and the usual success rate of conventional surgery, which they quoted at being between 90%-94%,

5.4 Regulations

The process of obtaining approvals with regard to safety and regulatory issues from regulating organizations is a process that needs urgent optimization [Camarillo, 2004]. Regulatory agencies are present in most countries [WHO, 2004] and include the United States Food and Drug Administration (FDA), the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom and the Therapeutic Products Directorate (TPD) under the authority of the Food and Drugs Act in Canada. One of the biggest challenges for robot manufacturers has been to prove to these organizations the safety of robotics-assisted surgical systems. Most of the development time and cost is related to obtaining these regulatory approvals [Taylor, 2003]. Some experts from academia mentioned that, at this point, regulatory hurdles are almost insurmountable. Industry observers noted that the FDA was much less willing to allow the use of these technologies, compared to Health Canada or authorities in the EU.

5.5 Interaction between Academia and Industry

Academic Interviewees commented on how academia and industry must collaborate to accelerate the commercialization of new technologies. Their comments are summarized below:

5.5.1 *Role of Researchers*

- Develop proof of concepts and demonstrate the potential of applications
- Brainstorm with clinicians and develop good ideas prior to selecting the best company to collaborate with. Companies should not need to be convinced that the technology is a good idea.

5.5.2 *Role of Industry*

- Provide understanding and expertise to do the transition between the development of a product and its clinical deployment.
- Determine what is clinically practical from all the research that is done.
- Collaborate with researchers to provide infrastructure and tools so that researchers can be more efficient.

5.5.3 *Other comments about collaboration*

- Small companies do not have the money and the manpower, so academia needs to provide funding for them. However, some experts mentioned that although small companies are difficult to find, they are the ideal vehicle to put instruments in the hands of the clinicians. They are more open and in that context are able to interact with clinicians more easily.
- In collaborations with large companies, one researcher noted that success comes down to establishing relationships with a small number of people within the organization.
- Intellectual property is a big issue. At the start of the process, both parties must be very specific about which ideas belong to whom and what each collaborator gets.

5.6 *Market Monopoly*

The few industries currently involved in the progressive advancement of robotic surgery are to be commended for their efforts. However most clinicians interviewed agree that the lack of competition in surgical robotics significantly impedes the advancement of such technologies or, at the very least, stagnates progress.

6. Canadian Strengths and Opportunities

6.1 Canadian Industry

The worlds leading developers of robotic-assisted intervention technologies are based in the United States – particularly Intuitive Surgical and EndoVia Medical. These companies are supported by a range of companies that specialize in navigation, haptics, integrated operating rooms, and surgical tools and devices.

In Canada, MD Robotics is working on a robotic arm for neurosurgery, MPB Technologies and Handshake VR are working on haptic devices, Northern Digital and ORTHOsoft provide navigation capabilities, and Telesat and Bell provide data communications that support telehealth.

MD Robotics and the Seaman Family MR Research Centre at the University of Calgary /Foothills Hospital in Calgary are developing the neuroArm, a robotic tool for neurosurgery. The neuroArm robotic system comprises two robotic arms, each with at least 6 degrees-of-freedom, and a third arm equipped with two cameras providing 3-D stereoscopic views. The system will function under the direct control of a surgeon at the robotic workstation. The workstation incorporates a computer processor, hand controllers to manipulate each arm, a joystick controller for positioning the camera and lights, three types of display and data/video recorders. Working with a specialized set of tools, neuroArm will be designed to perform soft tissue manipulation, needle insertion, blunt dissection, suturing, rasping of tissue, cauterizing, cutting, manipulation of a retractor, tool cleaning, suction, and irrigation. Eventually, the use of the neuroArm will be extended to other types of surgery. In particular, operations that require image guidance and precise motion. Future applications include spinal surgery, where intra-operative images can be used to guide tools to precise targets while avoiding critical structures.

MPB Technologies produces the Freedom 6S - a high fidelity force feedback device operating in 6 degrees of freedom - provides the user with a realistic sense of touch in both virtual and real-world applications. The device is a well-balanced, low friction, high-resolution tool ideally suited to medical robotics and master/slave robotics. It provides robotic master/slave control for robotic surgery, medical mentoring, telehealth, and teaching.

Handshake VR Inc. provides the tools necessary to design and develop haptic-enabled (sense of touch) teleoperation applications. Handshake's underlying core technology is time delay compensation (TiDe), the only commercially available solution for haptic teleoperations. Handshake's proSENSE Virtual Touch Toolbox provides rapid prototyping development.

Northern Digital provides optical localizer technology for use in computer-assisted therapy. Their technology guides the intricate and subtle manoeuvres in numerous, highly specialized medical applications, delivering real-time, precise measurement. Products include the Polaris and Optotrak Certus optical tracking systems and the Aurora electromagnetic system.

ORTHOsoft develops and markets medical navigation software for the global orthopedics market. They have a complete line of applications, instruments and equipment for orthopedic surgery. ORTHOsoft has developed instruments and software for the following surgical procedures: total hip replacement, total knee replacement, pedicle screw placement (spine), and anterior cruciate ligament reconstruction. They have also developed their own internal navigation computer language. The Navitrack platform includes an ergonomically designed Navitrack Station and Optical Stand manufactured by ORTHOsoft.

The academic interviewees indicated that most of their funding comes from government agencies (NIH and NSF in the U.S.; CFI and NSERC in Canada) or from their respective universities. There is little private foundation donation (e.g. Whitaker foundation). Some experts stated that the funding from industry is comparatively minuscule. One of them said that normally about 10% of the funding comes directly from industry itself while the rest is supplemented by government agencies. The suggested solution was to collaborate with clinicians because companies are inclined to give grants more for clinical work and far less for engineering research and development. Another interviewee mentioned that some areas of medical robotics research (such as haptics) that are also common to other areas of engineering can and do receive funding from industry as well as military sources.

6.2 *Strengths*

The academic experts who were interviewed believed that Canada has certain strengths due to its many researchers at the very top in medical robotics. Image guided surgery, surgical simulators, and development of special-purpose devices for medical applications were pointed out as some examples in which Canada has been a leader. One interviewee believes that Canada needs to define its place, which is probably imaging and robotics, and link with the world from that perspective. The other strength that Canada has is the presence of a number of good companies in this area in Canada, for example, Northern Digital, Orthosoft, etc. Moreover, at the moment, there are a couple of significant medical robotics projects in progress in Canada. For instance, the NeuroArm robot (University of Calgary) is a very large-scale system with a budget of \$30 M. This is quite significant when compared with the Computer Motion investment of \$100 M for its robotic MIS work.

The academics and clinicians interviewed pointed out that the socialized healthcare system in Canada allows Canadians to look at the effectiveness of methods rather than worrying too much about the market. Moreover, unlike the health care system in the U.S. that is very fragmented, the

unified healthcare in Canada allows for meaningful deployment of tele-surgical systems providing service to remote areas.

The workshop of sector representatives was asked to identify Canadian strengths in robotics-assisted intervention. They mentioned the following:

Universities: world-class expertise in robotics, imaging, and human computer interfaces. Research support programs (e.g. IRIS/Precarn, ORDCE, NSERC Industrial Postgrad Fellowship) and collaboration with companies.

Network infrastructure and skills: broadband, video compression, simulation (e.g. CANARIE, SHARCNET)

Medical communities: smaller, easier for national collaboration. Higher ratio of highly trained residents in Canada than in US.

NRC: ability to prototype miniature mechanical devices (e.g. IMTI)

Single payer system: larger regional conglomeration of hospitals. Companies only have to make their case once (i.e. to a teaching centre of a hospital) and then deploy across many hospitals.

Approval process: more streamlined and efficient compared to the US.

Visualization: ATI Technologies, Canadian Microelectronics expertise (CMC).

6.3 *Opportunities*

The workshop of sector representatives was asked to identify Canadian opportunities in robotics-assisted intervention. They mentioned the following:

Remote areas: provide service using telemedicine/telesurgery/telementoring

Exports: use networking capabilities to export medical expertise.

Integration: companies have great products but they don't link together. Strengthen interaction between researchers, companies and users

Training: develop a 'cluster' of advanced robotic assistant trained medical experts.

Space: use of medical (& other) robotic interventions in outer space. Implications for earthly applications (e.g. hazardous waste).

Miniaturization: use advances in other industries (manufacturing, resources, environment etc).

Incubators: for spin-off companies.

7. *Recommended Directions*

The previous sections have presented an overview of the different components and applications of robotic systems. Although technological advances have been significant in the previous decades, the widespread application of robotics in the medical field will depend on future advances. Some researchers from academia argued that research should focus on systems and applications and not on the technology; however, not all experts interviewed agreed with this. The following sections provide an overview of the future work that has been identified by experts in the field. These suggestions have been grouped at the following levels: systems, inputs and outputs, instruments and devices, data networks, and training.

7.1 *Systems*

At the system level, several directions could be taken to change how robotics is used in a medical setting. These directions include the following [Rembold, 2001], [Cleary, 2001], [Pransky, 2001], [Satava, 2004a], [Camarillo, 2004], [Industry interviews], [Academic Interviews] [Clinician Interviews]:

- **Standardization:** Develop hardware and software interfaces that emphasize modularity and promote intra-operability and sharing of information between components. Emphasize the development of systems rather than instruments.
- **Imaging:** Real-time imaging with increased levels of accuracy, rate of data collection/sampling and non-invasiveness; real-time intra-operative information processing and automatic segmentation of images (feature extraction); more emphasis on interventional imaging as opposed to diagnostic; improved visualization of the surgical field.
- **Planning and navigation:** patient specific models that allow for autonomous guidance or for guiding the surgeon; better tissue models.
- **Communication:** Close the data loop among the surgeon, the computer and the patient, i.e., development of true image-guided interventions.
- **Intelligence:** Incorporate supervising sensors and software into the robot that monitor every step of the surgical procedure and ensure safety. Use the principles of artificial intelligence in order to learn, remember and evolve.

7.2 *System Inputs and Outputs*

Future work with respect to system inputs and outputs should include the following directions [Cleary, 2001], [Rembold, 2001], [Satava, 2004b], [Academic Interviews] [Clinician Interviews]:

- Reconstruct three-dimensional data from two-dimensional intraoperative images in order to develop patient specific anatomical models.
- Develop better user-interfaces [Cleary, 2001], which provide the necessary control and information feedback to the surgeon without providing overwhelming information.
- Create open interfaces to imaging scanner environments and to tracking devices.
- Develop real-time tracking mechanisms that do not require markers and that have reduced cost.
- Improve realism in the design of surgical simulators through the development of more robust and accessible user input devices.

7.3 *Instruments and Devices*

Several recommendations have been made in order to improve the design and the technology of medical instruments and devices that form part of CIS for surgery and therapy. Some of these recommendations are as follows [Taylor, 2003], [Cavusoglu, 2003], [Lanfranco, 2004], [Satava, 2004a], [Camarillo, 2004], [Glukhovsky, 2004] [Industry interviews], [Academic Interviews] [Clinician Interviews]:

- Develop actuators and sensors that can stand a common and less expensive sterilization process, i.e., autoclaving. Current practice depends on the use of gas or soak sterilization.
- Improve the dexterity of instruments in general, particularly those used in minimally invasive procedures. Develop technology to detect how the tools and devices are deforming inside the body.
- Incorporate force sensors into robotic devices in order to provide the user with touch sensation (haptic feedback). This technology could be further extended by incorporating high-fidelity sensors to improve force sensation beyond the capabilities of the human hand.
- Create intelligent instruments that provide sensory control and guidance, e.g., limit the forces applied to avoid damage, record hand motions for performance records, or sound alarms when approaching dangerous conditions.
- Develop instruments that can track the motion of organs and tissue.
- Focus on more task-specific instruments and devices, which will lower the size and cost of the equipment. In addition, simpler systems will be easier to introduce into the market.

7.4 *Networks*

For remote operations and telemedicine, the speed, quality, and reliability of the data networks are of vital concern:

- Research should address quality of service issues on commercial data networks, including fast re-routing.
- Network performance in high latency environments needs to be addressed.
- Better video compression algorithms, that simultaneously provide high quality, low latency and graceful degradation, need to be developed.

7.5 *Training*

Recommendations on how to train personnel in order to better introduce and take advantage of technology include the following [Lanfranco, 2004] [Satava, 2004a] [Camarillo, 2004], [Academic Interviews] [Clinician Interviews]:

- Exploit the benefits of using surgical simulators in a training environment.
- Train personnel specific to the use of computer-integrated systems in a medical setting, e.g., groups of engineers that are coming to be known as clinical engineers that could serve as intermediaries between surgeons and other engineers.
- Technology is only adopted when the first generation of practitioners arrives from university or professional schools well versed in the use of those tools. Thus medical schools should be equipped with this technology as a way to hasten its acceptance.

7.6 *Roles*

From the future directions presented above, it is easy to see how robotic technology will transform surgery in the coming years. Robots will undoubtedly become standard tools in many common procedures. However, it is important to keep in mind that there is a need for close collaboration between robotics researchers, imaging and computer scientists, and surgeons in order to better understand the demands of surgical procedures and the culture of surgical practice [Howe, 1999].

The workshop of sector representatives was asked to identify roles for stakeholders in advancing robotics-assisted intervention in Canada. They mentioned the following:

Precarn

- Develop a network of centres of excellence in robotic-assisted intervention.

- Organizer further workshops to design a mutually agreed upon implementation plan.
- Continue to lobby, advocate, and connect key stakeholders and influencers with each other - act as an integrating force. Act as a catalyst to bring industry, academia, and government together in joint projects. Be a bridge between academic researchers and industry. Bring the proof of concept within the reach of industry.
- Ensure a phase 4 for IRIS focused on medical robotics and interventions.

Industry

- Establish a standards body to set open software interface standards for integrated medical systems.
- Discuss long-term research opportunities with universities. Support collaborative research with universities and commercialize new technologies developed by researchers.
- Fund more grad students (e.g. through NSERC IPF and others).
- Think in terms of providing turn-key solutions - infrastructures and clinical practices.
- Communicate more with end users (clinicians and patients).
- Academic experts feel that researchers should not try to reproduce those devices that are already available commercially or even base new research on them.

Academics

- Share results; do not let IP issues stand in the way of collaboration.
- Fundamental research and development. Appropriate mix of pure research and applications oriented research. Increased market-focus in research projects.
- Translate clinical needs into industry-relevant products.
- Train people.

Clinicians

- Tighter collaboration with Canadian-based companies to identify solutions in robotics-assisted intervention.
- Provide input to academics regarding unsolved problems or areas that require improvement.
- Attend networking events, focus groups, keep an open mind to new possibilities.
- Encourage residents to do research.

Government

- Develop a national vision.
- Coordinate policy at different levels.
- Provide appropriate mandate and funding to a multi-disciplinary body such as Precarn.
- Develop incentives for start-ups and SMEs specific to robotics and user interfaces.
- Define regulatory standards that are acceptable world wide, while at the same time making the clearance process efficient and cost effective.
- Promote industry-academic joint projects.
- Provide funding for research, evaluation, and implementation.
- Act as the conduit that brings all the parties together.
- Encourage collaboration and integration of ideas.

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