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ENABLING CLOSED-LOOP SURGERY IN MRI

In the field of automation and control, we often interact with rigid, known objects in a well-defined environment. This is especially true in most manufacturing settings where a continuous stream of consistent products passes down an assembly line with fixtures to hold them in a given pose or vision systems to identify part location. This scenario lends itself well to robotics and automation for reliably performing the required task. However, now think about your body... For starters, everyone is different, so the location and shapes of organs and other structures vary from person to person. Now add on top of that the fact that most internal structures are very compliant. Further, these soft structures do not maintain a consistent shape and can deform due to a patient's orientation, interactions with surgical instruments, or swelling causing a change in volume of an organ as it is being operated on. For example in a surgery where the goal is to remove a cancerous tumor, success of the procedure hinges on how precisely a surgeon identifies the tumor boundaries and ensures removal in its entirety while preventing unnecessary collateral damage. To ensure successful removal of cancerous tissue, often excess tissue is removed (aka increased resection margins) which may improve the odds of eliminating the cancer, but possibly at the additional cost of further complications and invasiveness of the procedure. Ideally one would like to track the structures in real-time and use this information to guide the procedure – this is what we refer to as Image-Guided Surgery (IGS). Further improving on this, we can incorporate electro-mechanical assistant devices to ensure that the surgical plan is performed as intended through Robot-Assisted Surgery (RAS).

IMAGE-GUIDED SURGICAL INTERVENTIONS

The fields of IGS and RAS in their present form have existed for approximately three decades, but the concept of stereotaxis in surgical guidance dates back over a century, with the Horsely-Clark stereotactic mechanical alignment frame to align needles for neurological interventions in 1908. The field of IGS has grown significantly in recent years, with such systems becoming more widely accepted by medical professionals because they enable more information available at the surgical site while performing a procedure. A typical procedure requires a clinician to review preoperative medical images, formulate a plan, mentally register the plan to the patient, and then perform the intervention - often without any imaging updates. Typical IGS systems integrate: imaging, spatial tracking, registration, and visualization. However, often the 3D patient information is a previously acquired preoperative CT or MRI registered to the patient during the procedure and the information used to guide the procedure is essentially "stale" by the time it is being used. There is a tremendous need for integrating interactive, real-time, intra-operative imaging into the surgical navigation environment.

Although direct visualization or endoscopic cameras let us see inside the body, they only provide surface information and not inside of structures. Therefore, various medical imaging modalities and methods of presenting information in a timely manner, in an appropriate location, and assisting with interventions have been active areas of research. X-ray fluoroscopy provides inexpensive, convenient imaging but is typically limited to imaging bony structures or vasculature with the introduction of a contrast agent. Computed Tomography (CT) uses x-rays to generate high-resolution, cross-sectional images of the body. However, both of these approaches have poor soft tissue contrast and subject the patient and physician to ionizing radiation if used intraopereatively. Ultrasound is a very convenient and portable imaging system readily available in an operating room (OR), however it often has poor image quality and suffers from artifacts such as shadowing of tissue beyond a rigid structure or a needle that is being inserted under image guidance, for example.

Magnetic resonance imaging (MRI) is an excellent medical imaging modality for detecting and characterizing diseases due to its outstanding soft tissue contrast that allows for accurate delineation of pathologic and surrounding normal structures. Thus, MRI has an unmatched potential for guiding, monitoring and controlling therapy. In needle biopsies, the high sensitivity of MRI in detecting lesions allows excellent visualization of the pathology, and the high tissue contrast helps to avoid critical structures in the puncture route. Advances in magnet design and magnetic resonance (MR) system technology coupled with fast pulse sequences have contributed to the increasing interest in interventional MRI (iMRI).

INCORPORATING ROBOTIC ASSISTANTS

Computer Integrated Surgery (CIS) requires integration of information and action. The IGS systems provide information to the surgeon in a timely manner as the procedure is being performed. The next level of integration is to couple robotic action with that information to physically assist with the procedure. The field of medical robotics was born in the late 1980's and has seen tremendous growth over the years [Taylor 2003]. Often these systems fall into one of two categories, of which there is some cross-over: tele-operated minimally invasive surgical instruments and image-guided semi-autonomous robotic systems. The former acts much like a remote-controlled robotic manipulator, while the latter uses medical images to guide an intervention – often a needle-based percutaneous procedure.

CLOSING THE LOOP WITH MRI

Magnetic resonance imaging is an ideal interventional guidance modality: it can provide real-time high-resolution 3D images or 2D images at arbitrary orientations, and is able to monitor therapeutic agents, surgical tools, tissue biomechanical properties, and physiological function. With continuously improving MRI image quality and acquisition speed, it is now possible to perform interventions under real-time MR image guidance. However, MR brings unique challenges to the implementation of interventional guidance systems, and the benefits can not be readily harnessed for interventional procedures due to difficulties associated with the use of high-field (>=1.5T) MRI and conventional mechatronics approaches.

WHY IS IT SO HARD?

The ability to create and deploy a device capable of operating within the scanner bore is still frustrated by the high strength magnetic fields, and extreme sensitivity to electromagnetic interference (EMI). MRI poses formidable engineering challenges with limited access to the patient and a strong magnetic field that prevents the use of many conventional materials and electronics as shown in **Figure 1**. For example, the primary actuator in just about all traditional robotic systems is the DC motor – by its design such a device is just about the worst possible type of device to use in an MRI scanner. An MRI machine contains a strong magnetic field aligned with the scanner's axis (a typical 3 Tesla scanner is about 500 times the earth's magnetic field strength) and time-varying magnetic gradients used for localization. A motor typically comprises a steel can (ferromagnetic posing a projectile risk as well as inducing imaging distortion), permanent magnets (distorting the magnetic field as well as a safety risk), and coils of wires (which can induce eddy current that distort imaging as well as induce heating). Further, an MRI scanner incorporates a highly sensitive antenna that is used to pick up the resonant radio frequency signals of the excited Hydrogen atoms in the body – any electronics in the vicinity of the scanner that emit electrical noise may be picked up by the scanner's receiver and significantly degrade the quality of the images obtained.

With all of the benefits of MRI-guided interventions, there is a clear advantage to using MRI. But, due to these challenges the use of robotic assistants in a scalable, clinically viable fashion has really just started to take off. There are a number of technical aspects and concerns to consider when putting an interventional magnet into operation. The most pertinent ones are: configuration and field strength of the magnet (which necessitates a compromise between access to the patient and signal-to-noise), safety and compatibility of the devices and instruments that will be used in or near the magnetic field, spatial accuracy of imaging for localization and targeting, optimal use of the imaging hardware and software (the dynamic range of gradients, limitation and availability of pulse sequences, radiofrequency coils) and level of integration with guidance methods for accomplishing the procedure.

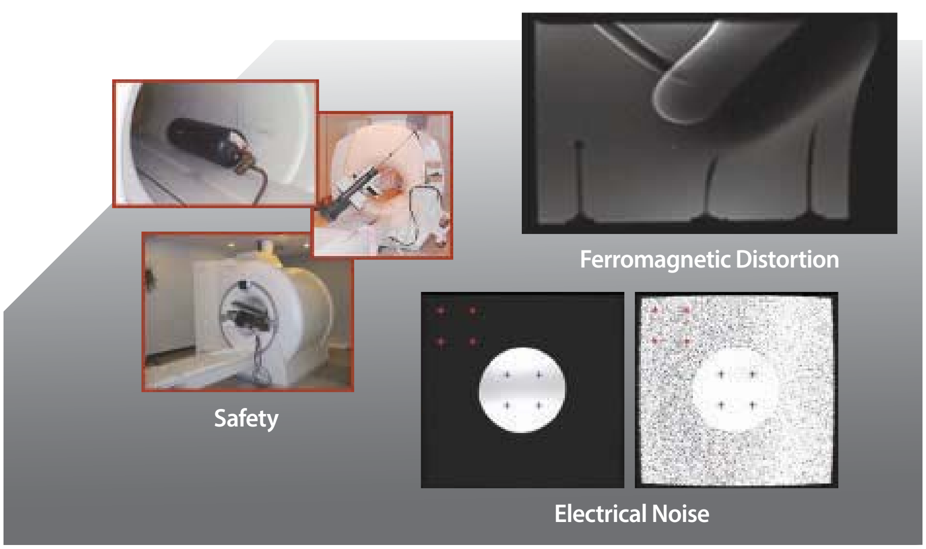

FIGURE 1 Examples of some of the difficulties encountered with robotics introduced into the MRI environment including safety issue due to projectiles, distortion of the magnetic fields, and introducing electrical noise that degrades image quality.

MRI-COMPATIBLE SURGICAL ROBOTS

Robotic assistance has been investigated for guiding instrument placement in MRI, beginning with neurosurgery and later percutaneous interventions with some examples shown in **Figure 2**. One of the first MRI-compatible robotic devices dates back to 1995 by Masamune et al. for stereotactic neurosurgery [Masamune 1995]. DiMaio et al. reported on the use of a robot suspended from a specialized open interventional MRI scanner for MR-guided prostate interventions [DiMaio 2007]. Krieger et al. developed a remotely actuated manipulator for access to prostate tissue under MR guidance in a closed bore diagnostic scanner [Krieger 2005]. Innomotion developed and commercialized a pneumatic robot aimed at performing percutaneous interventions inside the bore of a high field scanner [Melzer 2008]. Fischer et al. also attempted to develop a pneumatically actuated robotic assistant aimed at prostate biopsy and brachytherapy inside the bore of the scanner, with the goal of minimizing interference with the scanner [Fischer 2008]. Attempts at improving the accuracy of served pneumatic devices were attempted in [Wang 2010] and [Yang 2011]. Stoianovici et al. further attempted to improve upon the accuracy problems of pneumatic actuation by developing a robotic assistant for MR image-guided percutaneous prostate interventions based upon novel pneumatic stepping motors [Stoianovici 2007]. Although most systems to date are focused on image-guided percutaneous interventions within the bore of the scanner, Sutherland et al. have developed a dexterous robot for performing neurosurgery beside the bore of the scanner [Sutherland 2008].

ENABLING TECHNOLOGIES FOR MRI-GUIDED INTERVENTIONAL SYSTEMS

In order for a system to compatible with the MRI environment, it should: be safe in the MRI environment, preserve the image quality, and be able to operate unaffected by the scanner's electric and magnetic fields. The latest 2013 American Society for Testing and Materials (ASTM) made a detailed classification for the MRI-compatibility of devices environment [ASTM 2013]. The generally accepted classifications are: *MRI-Safe*: An item that poses no known hazards resulting from exposure to any MRI environment; *MRI-Conditional*: An item with demonstrated safety in the MRI environment within defined conditions; and *MRI-Unsafe*: An item which poses unacceptable risks to the patient, medical staff, or other persons within the MRI environment. Ferromagnetic materials must be avoided entirely because they cause image artifacts and distortion due to field inhomogeneities, and they pose a dangerous projectile risk. Non-ferromagnetic metals such as aluminum, brass, titanium, high-strength plastic, and composite materials are typically permissible with appropriate design considerations. However, the use of any conductive materials in the vicinity of the scanner's isocenter must be limited because of the potential for induced eddy currents to locally deform the magnetic field homogeneity. Electrical systems must be properly shielded and filtered, designed to limit noise emission. Care must also be taken to avoid resonance and heating.

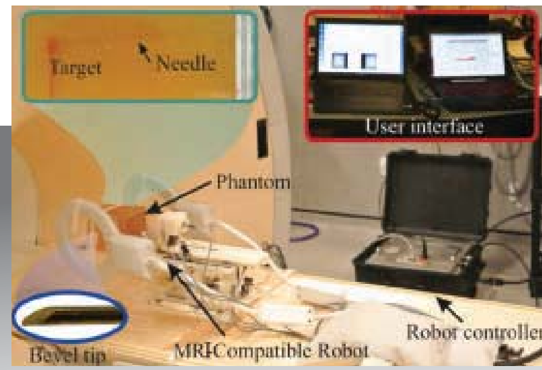

FIGURE 2 Samples of various MRI-compatible robotic approaches: Clockwise from left: A dexterous neurosurgical robot [Sutherland 2008], A percutaneous needle insertion robot [Stoianovici 2007],and an autonomous image-guided needle steering system [Patel 2015].

Actuation Technologies: As previously noted, traditional DC motors are contraindicated for use in MRI. Although in some circumstances they may be able to be shielded and kept a distance away from the scanner, they are non-ideal and not able to be used within the confines of an MRI scanner's bore. Therefore, the most common approaches taken to actuating a robot designed to be compatible with the MRI environment are: pneumatics (either servo-controlled or more recently with air powered stepper motors), hydraulics (often using water or saline), cable-driven (with remote actuation units), and ceramic piezoelectric actuators (resonant ultrasonic motors and non-resonant low frequency variants). However, it should be kept in mind that often even with these inherently compatible technologies, often commercially available solutions are not practical. For example, most pneumatic cylinders still use steel enclosures, most fittings contain ferrous components, and drive or control electronics often are not configured to minimize the induced electrical noise. Some recent innovations or advancements in the field include pneumatic stepping motors, high precision servo control of pneumatic cylinders, cable-driven actuators, and piezoelectric actuation.

Sensing Technologies: Closed loop control requires multiple levels of feedback. At the joint level, we need a way to detect the position of each linear or rotary joint. This is often done using potentiometers or encoder. In MRI, these technologies can be used with special design considerations. As long as potentiometer housing are nonferrous, then the trick lies on effectively filtering the electrical signals. Optical encoders have proven to be successful for position sensing inside the scanner bore during imaging when coupled with differential line drivers (to eliminate false counts and increase signal robustness), filtering appropriate electrical lines, and thoroughly shielding cables to minimize EMI. Fiberoptic sensing has also been investigated, with available devices available now for absolute and incremental position sensing without direct electrical connections.

Haptics and Teleoperation: Although robotics provides a way to operate within the bore of an MRI scanner, a side effect is the loss of tactile feedback for the clinician. This is valuable information in many cases, and thus we strive to return haptic feedback for teleoperated approaches. Haptic feedback requires estimating or measuring the integration forces of the instrument (e.g. a needle in an image-guided biopsy or therapy delivery case), and therefore it is necessary to incorporate force sensing. An example is described by Su et al., that describes a robotic device for teleoperated needle insertion, where the slave robot detects needle insertion forces and the teleoperation master reflects those forces back to the user [Su 2013]. Similar to potentiometers, traditional strain gauge based load cells may be able to be used if filtered, shielded, and of nonferrous construction. However, fiberoptic sensors enable high accuracy sensing without imposing such constraints. There are a multitude of approaches that have been investigated for one degree of freedom (DOF) and multi-DOF force/torque sensing. Intensity based approaches measure differences in light intensity returning off a reflective object in the sensor; the problem with many of these approaches is the lack of robustness to various environmental factors (such as flexing of the fiber cables or ambient light). An alternative approach is essentially a fiber optic strain gauge. One technique, known as Fabry-Perot Interferometry (FPI), is based on measuring a change in interference patterns of light passing through a small cavity at the end of an optical fiber. Another technique is the Fiber Bragg Grating (FBG) approach which results in a wavelength shift of light based on the amount of strain in the fiber. Each approach has its strengths and weaknesses with regard to complexity, cost, size, and accuracy.

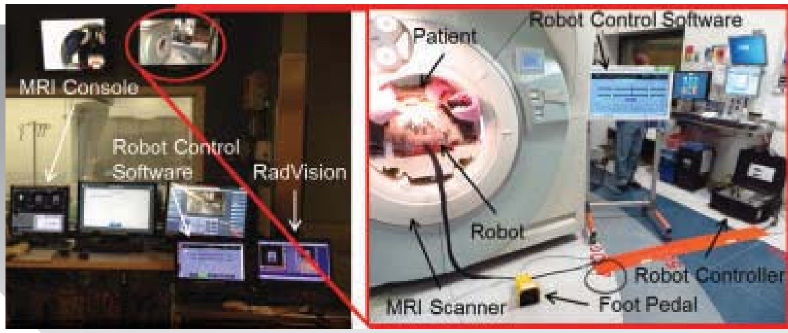

FIGURE 3 An example of a clinical configuration for MR image-guided prostate cancer biopsy using the robot described in [Eslami 2015].

Localization and registration: Not only does the robot need to have proprioceptive feedback, but typically it is required to also have external localization of the robot. Often fiducials are placed on the robot and used to determine the 6-DOF pose of the robot with respect to the MR imaging system, thus enabling targeting of features identified in the MRI images and calculating the corresponding inverse kinematics to move the robot. Various localization approaches have been implemented, including identifying discrete points on the robot as well as localization based on cross-sectional images of various unique patterns. These fiducials are often passive tubes or spheres filled with MR contrast agent, but improvements in imaging may be made with passive self-resonant tracking coils or active tracking coils that directly interface with the MRI scanner. These tracking coils may be integrated into the robot base, its end effector, or in some cases a needle, cannula, or catheter itself.

System Architecture: Various teams have taken different approaches to integrating these technologies into their robotic devices and the corresponding control systems. Often the system design was based upon the requirements of the surgical procedure being addressed. For example, many systems use sensing and actuation technologies that are safe for use in MRI, but are not overly concerned with EMI because the system is designed to iterate between sessions of MR imaging and robotic manipulation rather than manipulation during live imaging. Another design consideration is whether to place the control system (such as the valve controller or motor driver units) inside the scanner room or in the adjacent console room.

Putting a controller outside the MRI scanner's room eases some design considerations, but comes with complicating issues. For pneumatics, this requires long air hoses which significantly reduces bandwidth and control performance. For electrical control of piezoelectric motors, this requires running wires into the scanner room which can act as antennas (bringing in unwanted EMI), or require custom patch panels to route signal in and out of the scanner room (which is practical for a permanently installed system, but less so for a portable compact robotic assistant). The use of well-shielded, low-noise control systems that reside in the MRI scanner room and communicate to an external control system via fiber optics allows for ultra-portable devices that require no modifications or special requirements of the MRI suite.

CLINICAL SYSTEMS

MRI is a highly effective soft tissue imaging system, and the ability to utilize this procedure in-vivo coupled with precision computer controlled motion will prove to be an invaluable asset in the future development of minimally invasive surgery. With all of these challenges, there have been some amazing advances of late. Several systems have successfully performed clinical trials such as those described in [Krieger 2005], [DiMaio 2007], [Stoianovici 2007], [Sutherland 2008], and [Eslami 2015]. One such example of an ongoing clinical trial for MR image-guided prostate biopsy is shown in **Figure 3**. New systems on the horizon promise for further integration of real-time imaging with semi-autonomous robotic control of curved needle paths as instruments are delivered to targets in the body such as those described in [Su 2013] and [Patel 2015]. ■

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