Robotics in MRI-Guided Interventions

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Abstract: Robots have been found to be a useful tool in magnetic resonance imaging (MRI)-guided intervention. The utility of robots in MRI-guided therapy ranges from aid for precision targeting to high-dexterity surgical tools to improve or even enable new MRI-guided therapy options. The objective of this article is to review the technical aspects of robotics in MRI-guided interventions, highlight the role of MRI robots in prostate interventions, and finally discuss the future contribution of emerging robotics technology useful in MRI-guided intervention.

Key Words: autonomy, MRI compatibility, MRI-guided interventions, navigation, robotics

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INCREASING INTEREST TO APPLY ROBOTICS IN MAGNETIC RESONANCE IMAGING-GUIDED INTERVENTIONS

Historically, medical robotics research used metal and electromagnetic components, precluding such robots to be used for in-bore procedures. The first modification to these procedures began when Masamune et al[1] at the University of Tokyo used acrylic plastic for the frame and an ultrasonic motor as the actuator. The change in this material created an magnetic resonance imaging (MRI)-compatible motorized stereotactic frame for neurosurgery purposes. The research on MRI-guided robotics continued to evolve to include other stereotactic devices such as the 0.5T open-configuration scanner for prostate interventions,[2] and the closed-bore scanner for breast interventions.[3] According to Taylor and Stoianovici,[4] these robots are classified as surgical computer-aided design and computer-aided manufacturing (CAD/CAM) robots. This is distinct from the class of robots referred to as "surgical assistant systems." Unlike surgical assistant systems such as the da Vinci surgical system master-slave robot (Intuitive Surgical, Sunnyvale, CA), the primary goal of a CAD/CAM robot is the high precision guidance of surgical tools, such as biopsy needles where final placement of needle is still performed by the physician.

Since Masamune's work,[1] many engineering prototypes of MRI-compatible robots have been presented for different MRI-guided interventions, such as for liver,[5] kidney,[6] prostate,[7–13] brain,[14,15] breast,[3,16] and general percutaneous procedures.[17]

For instance, with growing interest in MRI-guided robotics and neurosurgical interventions, a group at the University of Calgary, Calgary, Canada developed the NeuroArm, a clinically realistic robot which is MRI-compatible using materials such as titanium, polyetheretherketone, and polymethylene.[15] As attested in[15] the robot is equipped with an MRI-compatible force/torque sensor for haptics feedback. So far, there has not been an MRI-compatibility test nor a clinical report using the robot in an MRI scanner's bore while patients are in the scanner. If this device has such a capability, it will be a significant first step toward enabling MRI-compatible robots to perform high-dexterity surgical maneuvers using a master-slave mechanism. Similar effort is under way by a group at Worcester Polytechnic Institute[14] as is shown in Figure 1.[14]

A few researchers continue to explore the use of MRI-guided robots for breast intervention. Developed by researchers at the Karlsruhe Institute of Technology,[3] [3]ROBITOM is an MRI-compatible robot for breast intervention. This robot is able to place a needle guide in 2 Cartesian directions using ultrasonic motors while the needle insertion is manually controlled. As of 2005, a second version of the ROBITOM robot[18] [18]a[18] presented. More recently, researchers at the University of Twente presented a pneumatic-driven robot targeting breast interventions.[16] Their robot is still in the development stage and patient studies have not been performed yet.

In our research team, we are proposing a physician-controlled guidance device and for orienting cryotherapy probes in image-guided cryotherapy of renal cancers[19] as is seen in Figure 2.[19] Keeping the device's minimal footprint in mind, we developed a body-mounted tool guidance device. The device comprises 2 ring-shaped motion stages stacked on each other, with the top ring stage holding the cryotherapy probe. The rotation stages can orient the

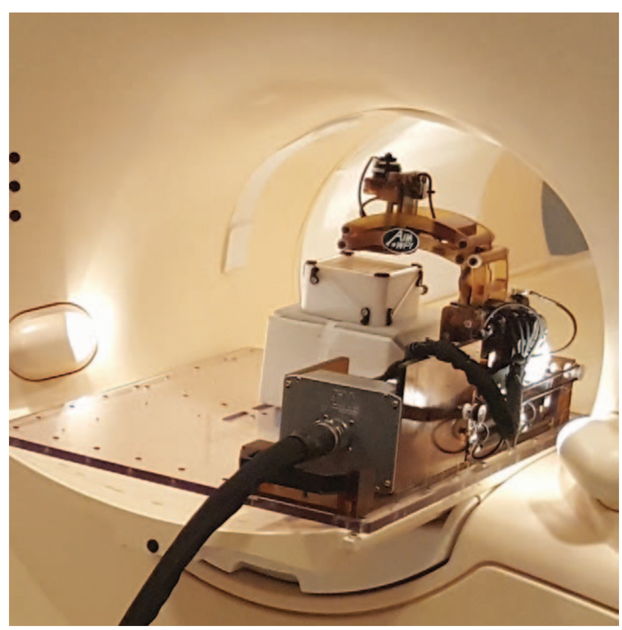

FIGURE 1. MRI-compatible piezoelectrically actuated 7-DOF stereotactic neurosurgery robot intended for MR image-guided conformal ultrasonic interstitial thermal ablation of brain tumors.[14] 7-DOF, 7-degree-of-freedom.

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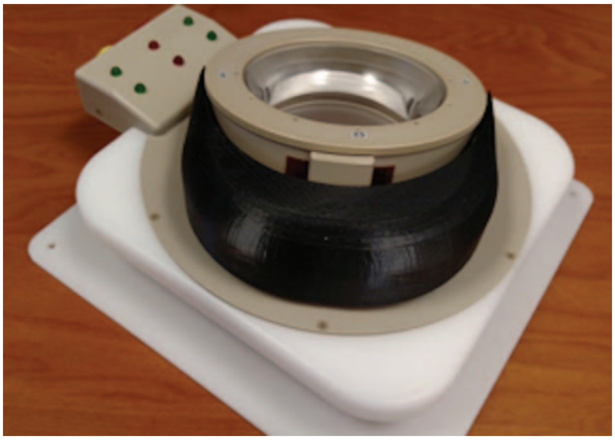

FIGURE 2. Body-mounted robot for MRI-guided cryoablation of abdominal organs.[19]

cryoprobe with the skin incision point as the remote-center-of-motion. The phantom test indicated that the accuracy of probe placement is significantly better with the robotic instrument guide (4.05 mm) than without the robotic instrument guide (6.25 mm, $P < 0.001$), even in the presence of body motion. With the robotic instrument guide, the number of attempts and total procedure time to complete the cryotherapy probe placement reduced regardless of the presence of organ motions.

PROSTATE INTERVENTIONS

One of the most active areas of research in MRI-guided robotics is prostate intervention. Several MRI-compatible robots have been developed for MRI-guided prostate interventions in the past decade.[7–13] An example of such research prototype is shown in Figure 3.[7] Those robots vary from simple devices to fully autonomous systems, and were evaluated in clinical and preclinical tests.

The first clinical trial using a robot to access the prostate was developed by van den Bosch et al.[20] The robot was used to transperineally implant gold seeds in 1 patient. Krieger et al[21] also reported the first clinical trial of an MRI-compatible robot for transrectal prostate access, named APT II. That system is an improvement over their first prototype[22] and combines manipulator mechanics, using a steerable needle channel and a hybrid tracking method. A comparison between robot-assisted and manual transrectal in-bore prostate biopsy was reported by Schouten et al.[23] The clinical trials were performed with a pneumatic robot controlled in an open loop. The findings indicated that there was no significant

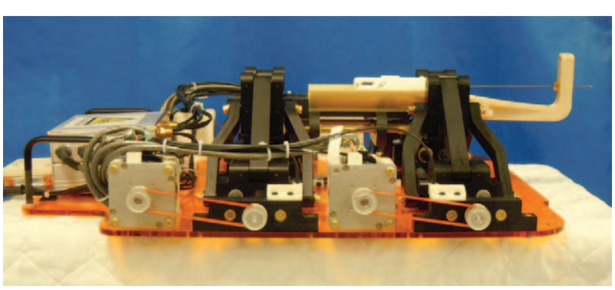

FIGURE 3. MRI-guided 4-DOF parallel manipulator for in-bore prostate transperineal interventions.[7] Courtesy of Dr Iulian Iordachita, Johns Hopkins University.

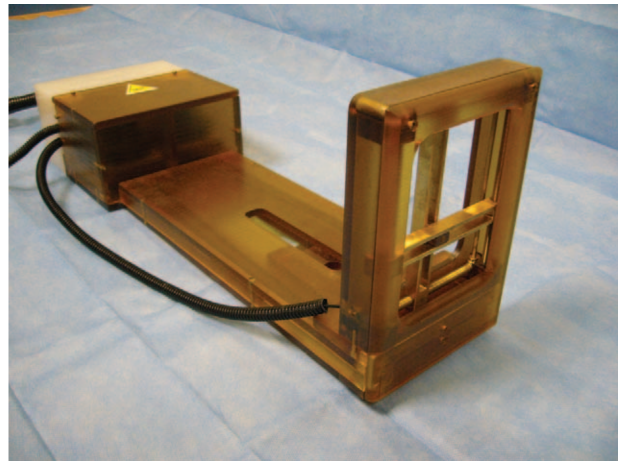

FIGURE 4. Smart template device to place needle-guidance hole robotically, overcoming the coarse needle placement resolution in transperineal template with limited number of needle guide holes.[25]

reduction in the biopsy error or the procedure time. A group from Johns Hopkins University also report 2 cases of prostate interventions using their robot.[24]

One of the authors of this article (N.H.) reported clinical deployment of another robotic needle-guidance template for in-bore 3T transperineal MRI-guided prostate biopsy[25] but in larger cohorts (Fig. 4).[25] That study reports on the utility of a robotic needle-guidance template for in-bore 3T transperineal MRI-guided prostate biopsy. Specifically, it compares manual and robotic biopsies through a 2-arm mixed retrospective-prospective study. A 3T wide-bore MRI scanner (MAGNETOM Verio 3T; Siemens AG, Erlangen, Germany) was used to perform all biopsy procedures. The manual approach used a manual needle-guidance template, which comprises a grid of holes 1.3 mm in diameter spaced 5 mm apart. 3D Slicer (www.slicer.org), a planning and navigation software, was used to plan which guide hole would be used for needle insertion and how deep to insert the needle for each core sample collection. The robotic approach used a motorized robotic needle-guidance template, which is able to set the needle insertion hole with a control resolution of 0.001 mm. During the robotic approach, the 3D Slicer software was modified to issue a motion control command to the robotic needle-guidance template to align the needle insertion hole to the transperineal needle placement trajectory. A confirmation image was taken using axial 2D multislice Turbo Spin Echo images after clinicians inserted the needle, as well.

Two ultrasonic motors with integrated optical encoders are used in the robot. The motor rotations are transmitted to vertical and horizontal prismatic motion of each cross bar by a lead screw-and-nut mechanism. A needle insertion position is created on the axial plane of the template by the cross point of the bars. The structural body of the motorized template is made of brass alloy screws and ultem resin. Timing belts, pulleys, and a miter-gear set compose the nonferrous transmission parts.

Tilak et al's study was conducted with 96 patients in 99 cases; 43 of these cases were performed using the robotic template and the remaining 56 cases were performed using the conventional needle guide template. A significant statistical difference existed in the log of accuracy when the best attempts of needle placement data were observed; the robotic approach 2.39 mm had statistically higher accuracy compared with the manual approach 3.71 mm by $P < 0.027$. Furthermore, the mean core procedure time for the

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manual group was 100.63 minutes, whereas the robotic group's core procedure time was only 90.82 minutes. In comparing the record of diagnosis per subject, no statistical difference existed between the manual and robotic groups; positive cancer was confirmed in 30 of 56 cases in the manual group (53.57%) and 25 of 43 cases in the robotic group (58.13%). In studying the diagnosis per core, however, cancer was detected in 174 of 541 cores (32.16%) from patients in the manual group, whereas 137 of 310 cores (44.19%) from the robotic group were cancer positive. This suggests that the robotic approach has a greater chance of providing a positive cancer core than the manual approach ($P = 0.018$).

BENEFITS OF PRECISION TOOL PLACEMENT IN MRI-GUIDED PROSTATE INTERVENTIONS

Needle placement error can be modeled as a probability distribution, as elegantly described in references26 and 27 Assuming that increased biopsy accuracy is translated into the probability of the needle hitting the tumor, or the ''hit rate,'' we can use this as a measure for MRI-guided prostate interventions. Supposing that needle placement error follows the norm, the hit rate for a tumor with a volume of clinical significance (0.5 mL sphere with a radius of 4.92 mm) is estimated to improve from 63.9% to 98.6%, as the accuracy is improved from our previous clinical study 5.39[25] to 2.0 mm. For next-generation biopsies, there are increasing demands for improved accuracy of prostate sampling (multiple foci within the gland). New research is underway to determine the combined ability of imaging and genomics to further characterize focal prostate cancer (and multiple foci within a single lesion), using a so-called radiogenomics approach. This approach shows early promise for examining possible intratumoral heterogeneity by biopsy and treating accordingly.[28] In practice, the hit rate of aiming for a quadrant of lesion to deal with intratumoral heterogeneity will increase from 35.2% to 78.1%. If the accuracy of needle placement is improved from 5.39[25] to 2.0 mm. For ablations, the clinical impact is measured by the ablation margin rather than the accuracy of needle placement. The needle placement accuracy is translated into an ablation margin to ensure the complete ablation of the tumor. The margin can be roughly estimated by using a simple model consisting of spherical tumor and ablation volume. If one aims to cover the tumor using a single probe with a placement accuracy of 5.39 mm, one would need to add 10.56 mm to the regular ablation margin (typically 5 mm) to achieve complete coverage at a 95% confidence level. The margin would be decreased to 3.92 mm if the needle placement accuracy is 2 mm. The scope of the current proposal is limited to assessing the improved accuracy using the suite of advanced tools. The efficacy of biopsy and ablation, namely, the hit rate and decreased ablation margin, will be assessed in follow-up clinical studies with a large cohort of patient enrollment.

COMMERCIALIZED ROBOTS FOR MRI-GUIDED INTERVENTIONS

Perhaps, the most advanced form of MRI-compatible robot, which has been developed and clinically validated, and commercialized, is INNOMOTION robot developed by Melzer et al,[17] for percutaneous placement of needles in MRI scanner. This robot has a robotic arm attached to a C-shaped outer arm that tightly fits into the 60-cm bore of a standard MR scanner, guiding a biopsy needle. In Leipzig, Germany, Moche et al, performed 2 biopsies in the bone (femur and sacral bone), 3 other biopsies in different regions not subject to organ motion (lesser pelvis, iliac lymph node, lumbar spine abscess), and 1 in a region subject to respiratory motion (liver). The authors stated that a stereotactic device such as INNOMOTION is helping which will assist biopsies of lesions that are either hard to reach, difficult to align by mental mapping of the trajectory, or in regions with few anatomical reference points. The same principle have applies to most of the CAD/CAM robots in MRI-guided therapies. The system, under the commercial name INNOMOTION, was the first commercially available MRI-compatible robot for general percutaneous interventions, and received the Conformite Europeenne mark in 2005. However, the INNOMOTION robot is no longer in the market. Although the system was not specifically designed for prostate interventions, Zangos et al[29] reported a cadaver study for transgluteal access to the prostate.

NEW EMERGING TECHNOLOGIES TO ENHANCE MRI-COMPATIBLE ROBOT

Cooperative Control

When cooperative robotic control becomes available, the clinician maintains ultimate control through a hands-on interface and the instrument moves only on the clinician's command; however, the motion will be autonomously directed to ensure that the desired path is followed to the intended target. We believe this is a sensible and safe next step in image-guided robotics to improve precision tool placement by taking advantage of novel robotic vision and automation technologies. Only limited investigation has been conducted on automated (actuated) needle insertion in surgical robotics, and even the published report on robotic needle insertion does not use imaging as feedback[20,30] or was validated only in phantom studies.[9] In our view as well as experts' view in *Nature Robotics* article,[31] the automation in medical robotics shall be introduced with significant attention to safety. The proposed technique leverages the capabilities of novel tele-operated semiautonomous needle placement in a clinically viable and safe way, as our approach integrates with a traditional workflow whereas the clinician maintains direct control of the intervention for safety. The other key innovation for safe and successful deployment of cooperative robot in this proposal is haptic sensing and display, which otherwise will be lost in teleoperation robots. Anecdotally, radiologists remark that haptic feedback is valuable during manual needle procedures, and there is some evidence that haptic display is useful in robot-assisted needle insertion.[32] Also, in our initial patient studies where the robot acted as an automated guide for manual insertions, we noted that tactile sensation is critical (and should not be lost when going to actuated insertion). In other applications, haptic feedback in robot-assisted minimally invasive procedures has increased the physician's sense of presence and led to faster and more accurate task execution.[33–36] In the past, frontiers of medical robotics have proposed an hands-on robotics for open surgeries. However, the solution to use hands-on cooperative robotics in real-time image-guided therapy is unprecedented, new, and in increasing demand in the dawn of precision medicine.

Full Autonomy

The autonomous medical robots are expected to be introduced to physicians with careful control by governmental regulatory bodies such as United States Food and Drug Administration (FDA). Most of the FDA-cleared medical robot today uses some form of artificial intelligence including image segmentation or motion control that automates part of physician's task to reduce their cognitive load. FDA however seems to be more comfortable to put physicians as ultimate decision maker by mandating them to review and approve the decision made by computers. The summary statements of FDA-cleared medical robots often say that devices are intended to ''assist the surgeons'' (MAKO Surgical Corporation, The Robotic Arm Interactive Orthopedic System, K093425) or ''assist in the accurate control'' of devices (Intuitive Surgical, da Vinci Endoscopic

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Instrument Control System, K040237), thus limiting the role of medical robots as assistant, not replacement to physicians. As role of robots evolves and autonomies are introduced, regulatory body will have to define how physicians are involved in more detail acknowledging the fact computers are in fact making part of medical decision.

In reality, the role of robot in decision-making process is substantial for instance in external radiation therapy.[37] In external radiotherapies, a robotic eye can autonomously track the motion of moving cancer target and emit the radiation beam to the cancer target using 6 degree-of-freedom robotic arm (Accuray, Synchrony Reparatory Tracking System, K120233). The motion of the cancer is often induced by respiratory and cardiac motion or any involuntary movement by patients undergoing radiation therapy. By automatically recognizing the artificial fiducial marker placed in organs in real-time x-ray images, the robot can be controlled to aim the moving target to increase the effectiveness of the radiation treatment.[38] This image-based detection and motion control is fully autonomous and does not involve physician intervention, thus considered a primitive form of robotic automation.

Open Data in Clinical Research

Industry researchers rarely share their results of safety and accuracy validation used for FDA market clearance for medical device. Regulatory body such as FDA is certainly involved to monitor these testings, but not required to share the data with public. For instance, the summary statement available for public about the aforementioned radiotherapy device simply states that a test was performed, without further detail. As autonomous robotics evolves, and is applied to medical devices and delivered to patient, public perception of robot should be carefully managed to avoid anxiety or confusion about autonomous technology. Therefore, transparency of safety assurance process in FDA, and sharing of the test data submitted for clearance may help public to understand the autonomous medical robotics better. Added value of this increased transparency of data submitted to FDA is accelerated development and increased safety of autonomous medical robots in development. Collectively, public will be benefited from open data policy of the government in particular FDA.

CONCLUSIONS

The robotics in MRI-guided intervention has been an active area of investigation. As the growing number of articles report engineering prototype of the robot, paucity of material is available to investigate the utility of the robots from clinical studies. There are, however, opportunities to further explore the potential benefit of robots through application of emerging technology such as autonomous control.

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