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Original paper

Fully automated MRI-guided robotics for prostate brachytherapy

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*The uncertainties encountered in the deployment of brachytherapy seeds are related to the commonly used ultrasound imager and the basic instrumentation used for the implant. An alternative solution is under development in which a fully automated robot is used to place the seeds according to the dosimetry plan under direct MRI-guidance. Incorporation of MRI-guidance creates potential for physiological and molecular image-guided therapies. Moreover, MRI-guided brachytherapy is also enabling for re-estimating dosimetry during the procedure, because with the MRI the seeds already implanted can be localised. An MRI compatible robot (*MrBot*) was developed. The robot is designed for transperineal percutaneous prostate interventions, and customised for fully automated MRI-guided brachytherapy. With different end-effectors, the robot applies to other image-guided interventions of the prostate. The robot is constructed of non-magnetic and dielectric materials and is electricity free using pneumatic actuation and optic sensing. A new motor (*PneuStep*) was purposely developed to set this robot in motion. The robot fits alongside the patient in closed-bore MRI scanners. It is able to stay fully operational during MR imaging without deteriorating the quality of the scan. In vitro, cadaver, and animal tests showed millimetre needle targeting accuracy, and very precise seed placement. The robot tested without any interference up to 7T. The robot is the first fully automated robot to function in MRI scanners. Its first application is MRI-guided seed brachytherapy. It is capable of automated, highly accurate needle placement. Extensive testing is in progress prior to clinical trials. Preliminary results show that the robot may become a useful image-guided intervention instrument.*

Key words: robotics, magnetic resonance imaging, prostate brachytherapy

Introduction

Prostate cancer is the cancer with the highest incidence of detection in males. It was estimated that prostate cancer was responsible for 10% of cancer related deaths in the male population of the USA [1]. Radical surgery or radiotherapy are the most commonly used curative treatment options for prostate cancer [2], with radiotherapy delivered via external beam irradiation or via brachytherapy. The latter techniques include HDR brachytherapy with an ^{192}Iridium source and an afterloading machine (a temporary implant) or by LDR brachytherapy with ^{125}Iodine of ^{103}Palladium seeds (a permanent implant).

A permanent prostate brachytherapy implant with seeds is one of the most frequently chosen treatment options for patients with clinically localised prostate cancer. Permanent prostate brachytherapy owes its low intervention-related morbidity to a rapid dose fall-off effect, which allows for the delivery of high doses of radiation to the target volume while sparing healthy adjacent structures as much as possible. The procedure of prostate brachytherapy is usually performed under transrectal ultrasound (TRUS) image-guidance [3] with the seeds implanted through transperineally inserted needles guided by a template according to a specified treatment plan [4-6]. Long-term oncological results indicate that brachytherapy is a good treatment option for properly selected patients [7-9].

The success of image-guided interventions such as prostate seed brachytherapy depends on two factors, (**1**) the quality of the image used for the visualisation of the target as well as on (**2**) the ability to deploy the guide needles/probes accurately to the desired target. These factors are related to the imager and to the instrumentation used in the procedure.

Imaging modalities

Modern medicine relies heavily on technical equipment and current technology is evolving very rapidly. This progress allows for existing diagnostic and therapeutic interventions to become more efficient and also helps in the development of new treatment modalities. Due to its good perineal and transrectal accessibility, the prostate is a good target for image-guided interventions.

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As such, ultrasound-guided prostate biopsy and prostate seed brachytherapy are common procedures in modern urological practice. The advantages of ultrasound are its widespread availability and easy to use technology as well as its real-time imaging capability. MRI is however superior to ultrasound with regard to visualisation of the prostate and its surrounding anatomy [10], which should make it the imaging modality of choice to guide brachytherapy seed placement.

Perhaps the most important technical disadvantage of the ultrasound-guidance in prostate seed brachytherapy is its minimal sensitivity in delineating the implanted seeds. This impedes the monitoring of the procedure in its performance. Commonly X-ray imagers are employed during the intervention for visualising the seeds. However, fusing the two image sets is prone to registration errors, and requires significant instrumentation [11, 12].

Also besides its superior imaging, the MRI may also delineate the seeds. In addition to direct monitoring of the procedure, this can be used to make intraoperative adjustments to the dosimetry plan, permitting the deployment of additional radioactive sources in accidentally under-dosed areas [13].

The principal limitation to its routine use in prostate seed brachytheray and image-guided intervention in general, is the complex and challenging environment [14] inherent to MRI technology and the constrained ergonomics of closed-bore scanners.

To date only a limited number of centres have reported their experience with MRI-guided prostatic interventions [15-18]. Promising results in prostate cancer imaging using MR spectroscopy were also shown [19] and the availability of higher field strength scanners make MRI an increasingly attractive imaging modality for targeting prostate cancer [20-22].

Seed placement

Another important factor that influences the outcome of the brachytherapy treatment is the accuracy of seed placement [23]. If even a small part of the target volume does not receive the adequate irradiation, this may lead to relapse of the disease. Conversely, overdosed regions can increase side effects. Accurate seed placement requires a good intraoperative image as well as a good delivery method.

Currently, the standard prostate seed brachytherapy procedure is a manual needle insertion guided by a template that is secured to the perineum. In general, this is an effective means with which to achieve the desired seed distribution. However, seed placement error is a well recognised problem [24-27]. As a result, a loss of dosimetric coverage from treatment plan to post-implant dosimetry has been reported [28]. Nevertheless, post-implant dosimetry is one of the best predictors of treatment success [23] and has been found to be correlated to the quality of life of patients who have undergone prostate seed brachytherapy [29]. Seed placement precision has also been recognised as the limiting factor for the improvement of dose distributions [30].

These problems may be overcome by replacing the needle template with a robotic device for manipulating the needle. A review of published papers in the medical literature on the subject of robots reveals that the impact of medical robotics has exponentially grown since its inception in late 1980s. Robots do not only augment a physician's manipulation capabilities, but also establish a digital platform for integrating medical information [31, 32]. Medical imaging data, in particular, gives robots abilities unattainable to humans, because, unlike humans, robots and imagers are digital devices. Image-guided interventions expand radiology practice above and beyond traditional diagnosis [33] and do so with the use of modern tools.

Image-guided medical robots

Image-guided intervention robotic systems rely on the development of special imager interfaces, image registration, image-guided control algorithms, and also impose stringent requirements on the robotic hardware for imager compatibility, precision, sterility, safety, and size and ergonomics. A robot's compatibility with a medical imager refers to the capability of the robot to safely operate within the confined space of the imager while performing its clinical function, without interfering with the functionality of the imager.

The systems reported for robotic assisted prostate interventions can be classified by the imaging modality used for guidance: ultrasound-guided and MR-guided.

An example of an ultrasound-guided system is the one developed by Wei et al [34]. Their system uses an industrial robot, and a TRUS probe with automated scanning motion. The coordinates of the ultrasound probe with respect to the robot are computed using a calibration procedure. This allows for orienting the robot to any target specified in the ultrasound image. In the first reported prototype the robot was used only as a needle holder, with the physician being responsible for needle insertion and seed deployment.

In a previous report [35], we have collected a set of imager compatibility prescriptions from scientific papers and imager technical notes and assembled a global definition of concurrent compatibility with multiple types of imagers: multi-imager compatibility. The study also derives a compatibility measure for individual imagers and, as expected, found the compatibility with MR imagers to be most demanding.

On the other hand, the potential of MR image-guided interventions is significant for the reason that MRI is the method of choice for imaging soft tissue, and, with spectroscopy and special markers, is the most promising imaging modality for tumour detection [20, 36]. It is therefore conceivable that an MRI-guided robot could improve the accuracy of brachytherapy seed placement.

Ideally, MR image-guidance would be combined with the precision of robotic manipulation. Robots are capable of working more accurately than humans, and as digital devices, can easily be programmed to navigate in a 3D coordinate system. In the case of prostate seed brachytherapy, this means that a robot could very accurately place all of its planned seeds through one or two tiny perineal skin incisions without the need for a template [37]. This is an advantage because a template constrains the possible trajectories of the needle and in some cases may even leave parts of the prostate inaccessible for seed placement [38].

Improvements in the placement of the radioactive seeds are likely to translate into better cancer control as well as reduced irradiation of healthy tissue [23, 29]. Limited accessibility of the patient within the MRI scanner as well as the incompatibility of most components commonly used in robotics, particularly their electromagnetic motors, make the development of an MRI-guided robot a very difficult engineering task. The use of electricity and some electronic devices in the magnet room may be possible, under certain specifications and shielding.

Several electrically actuated systems for MRI-guided brachytherapy have been reported. Chinzei et al developed a MR compatible manipulator for prostate needle interventions [39]. This system automatically positions a needle guide allowing for prostate biopsies and radioactive seed placement under MR guidance in an open MRI scanner. The system is actuated using piezoelectric motors located outside the MR field.

Another MR compatible robotic system was reported by Krieger et al who developed a device for transrectal needle placement in the prostate under MR-guidance [40]. Their device is manually operated but uses special localisation coils to track the real-time position of the device in the MR image space. The system was successfully tested in animal and human studies at the National Institutes of Health.

MrBot robotic system

The MrBot robot is designed for image-guided percutaneous needle interventions of the prostate. The prostate is a gland located directly beneath the bladder and completely surrounding the proximal part of the urethra. The gland is walnut shaped and measures about 40 x 30 x 30 mm^3. Depending on the amount of subcutaneous tissue, in most men the centre of the prostate lies about 70 mm ± 20 mm beneath the perineal skin.

The space in closed-bore MRI scanners along the patient is very limited, because the size of the bore is of the order of 500 mm in diameter. Previous clinical trials [41] revealed that perineal access leg room may be gained if the patient is positioned in the MRI head first in the left lateral decubitus position (on his side). As such, MrBot is designed to operate as represented in

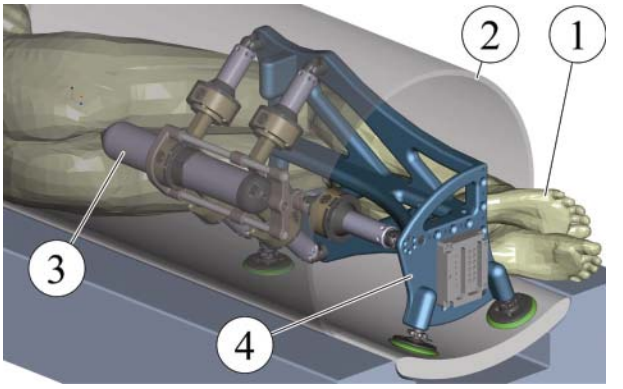

Figure 1. Closed-bore MRI intervention setup

Figure 1, where the patient (**1**) and robot (**4**) are placed within the bore of an MRI scanner (**2**).

Two approaches are used for prostate needle access: transrectal and transperineal, each with its advantages and disadvantages. Traditionally, prostate biopsies are performed transrectally under ultrasound-guidance, and the transperineal access is used for brachytherapy and thermal ablations, also with ultrasound [42].

The main advantage of the transrectal approach is the reduced anaesthetic requirement. The robot was designed for transperineal access because this allows for a wider range of clinical interventions to be performed with the same robot, by simply changing the needle driver. A modular structure comprising a robotic component (**4**) that can be utilised with intervention specific needle drivers (**3**), Figure 1, was sought for different applications such as biopsy, brachytherapy, thermal ablations, or therapeutic injections. The range of motion is similar to the size of the template commonly used in brachytherapy (50 mm x 50 mm) and a slight angulation of the needle (± 10°) is desired. For safety, failsafe non-backdrivable actuation is required along with slow speeds (< 20 mm/s). High velocity needle insertion was allowed to facilitate piercing.

In contrast with the previously reported needle guide systems, our robot is more complex and 'MRI stealth'. It is designed to interact with the patient in a closed-bore MR imager without interfering with the imager and allows for fully automatic needle insertion and seed deployment under MR-guidance. In addition, this fully actuated system is entirely made of non-magnetic and dielectric materials, and is electricity-free exclusively using pneumatics and optics. The system consists of an end-effector mounted on an MR compatible robotic manipulator [43] and it incorporates a new type of pneumatic actuators (PneuStep) developed for fully MR-compatible actuators [44]. The key novelty of the reported system is the automatic seed deployment under MR-guidance.

The MrBot robot, Figure 2, [43] allows for positioning the needle injector end-effector in all directions and its orientation about two directions normal to the needle axis. Its workspace allows the placement and alignment of the needle towards any prostate target,

Figure 2. MR compatible fully automated brachytherapy system

assuming that initially the robot is roughly aimed towards the prostate. The manipulator is pneumatically driven using custom designed MR compatible actuators, PneuStep [44].

The PneuStep is a new type of pneumatic motor, developed especially for MRI compatible robots. Unlike other types of pneumatic motors, this new motor achieves high precision of motion (0.055 mm in the design used here) in a safe and easily controllable manner by using a stepping motor principle. Pressure waves are used to set the motor in motion. These waves are created by a pneumatic distributor remotely located in the controller unit and are transmitted to the robot through air hoses. The actuation is encoded by fibre optics so that the motors use pressure and light but no electricity. These features prevent the robot from creating any interference with the electromagnetic environment inherent to MRI technology. To provide the safety standard required for the use in medical applications, the robot's motors are built for failsafe operation, any form of malfunction leading to a lock.

Pneumatics gives outstanding MRI compatibility. It has only been used in two systems, the Innomotion abdominal access robot [45, 46] and the reported MrBot prostate robot. Compared to Innomotion, our system is fully actuated and uses special MRI more precise and controllable motors. The full actuation of the robot is important for remote operation, so that interventions can be performed within the scanner. With manual needle insertion repeated in-and-out of the scanner moves are needed between accessing the patient and imaging.

The MrBot system consists of two major components, Figure 2. The first one is the controller unit, which resides outside the MR room and includes a computer, motion control elements, and a series of electro-pneumatic and electro-optical interfaces. These controller elements are located outside the imager's room and are connected to the robot with several hoses. The second component of the system is the robot itself, which fits into the 50 cm bore of a standard closed MRI scanner and is designed to interact with the patient within the imager.

Experiments show that the robot does not interfere with the MR imaging when it is operated within the magnet [47, 48]. Moreover, the compact design of the device deals with one of the best known difficulties of interventional MRI, namely patient accessibility. By fitting into a standard 50 cm bore along with a man, Figure 1, the MrBot robot allows for interaction with the patient inside the scanner. This obviates the necessity of moving the patient in and out of a closed scanner for imaging and manual needle insertion, respectively.

The needle injector was designed using the observation that high speed needle insertion reduces soft issue deflection. This was experimentally tested *ex vivo* and was also reported by other researchers [49]. At the moment this is the only end-effector that has been developed. However, it is easily detachable from the robot and could be replaced with other end-effectors, allowing the system to engage in different automated image-guided interventios such as biopsy, serum injections, or ablation procedures. In order to achieve full MR compatibility, the entire robot is built of non-magnetic and dielectric materials such as ceramics, plastics and rubbers. The only exception is the MR compatible titanium needle.

In conventional prostate brachytherapy a number of needles preloaded with seeds are inserted into the prostate under ultrasound-guidance. Alternatively, a single needle can be used to place all seeds according to a treatment plan [37]. In this case, the needle is sequentially placed at the desired seed locations and the radioactive seed is deployed through the cannula of the needle. The seeds located on the same needle trajectory can be deployed sequentially in the same needle insertion starting from the deepest location. Therefore, prostate seed placement requires the robotic system to perform the following tasks: needle orientation, needle insertion, and seed deployment.

The overall system diagram is presented in Figure 3. Needle orientation is performed using the MR compatible manipulator, MrBot. Needle insertion and seed deployment are performed by a special brachytherapy end-effector.

Preclinical tests

Several tests have already been completed with the robot as part of its comprehensive preclinical testing to support its verification and validation for clinical trial regulatory protocols.

MRI compatibility tests

In the confined space and the electromagnetic environment of the clinical MRI scanners, no restraint

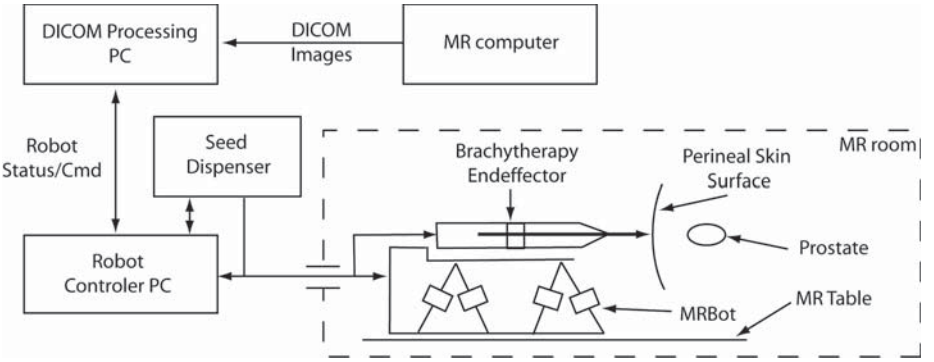

Figure 3. MrBot system diagram

of the robot's action was noted. More importantly, the presence of the robot in the scanner neither caused any interference with the MRI, nor did it deteriorate the quality of the obtained images. Apart from the markers attached to the end-effector the robot was invisible for the MRI. The same observation was made when the brachytherapy end-effector was operated and imaged in the 7T research MRI, within which the pneumatic motor positioned the needle with the same high precision with which it did outside the MRI scanner [47].

Motion accuracy

In the basic motion capability tests the mean value of the error's norm over all the experiments was 0.076 mm with a standard deviation of 0.035 mm. However, after a warm-up phase of several cycles the errors were consistently around 0.050 mm. The respective tests in the 1.5T MRI scanner yielded a mean error value of 0.060 mm with a standard deviation of 0.032 mm. These somewhat better results recorded in the MRI were due to several unrecorded warm-up cycles performed while adjusting the robot within the confined space of the scanner.

In vitro & ex vivo mock-up tests

In tissue mock-up tests, Figure 4, the mean placement error of 125 stainless steel seeds was 0.72 mm with a standard deviation of 0.36 mm. In the 7T MRI scanner, the end-effector moved the brachytherapy needle with a mean placement error of 0.047 mm and standard deviation 0.053 mm.

Under *ex vivo* conditions, the results of our precision tests compare favourably with the accuracy that has been reported in other MRI-guided prostatic interventions [26, 50]. By utilising online MRI-guidance, it is conceivable that automated, digital seed delivery systems such as MrBot would improve the accuracy of seed placement in PPB and permit a more customised and targeted distribution of the radioactive seed sources.

In vivo tests

Animal tests are in progress with four animal trials already performed on four intact male dogs each weighing between 25 kg and 30 kg, the protocol of this survival study being approved by the animal care and use committee of our institution, Figure 5. All experiments were completed successfully. Apart from the registration markers, the robot was invisible to the MRI and did not produce any noticeable artifacts. There were a total number of 18 implanted seeds in the four dogs. Accordingly, 18 needle positions and 18 seed positions were acquired and compared with the respective target points. All attempted seed placements were successful and the four dogs survived the procedures without complications and continued to do well thereafter.

Advantage of the modular structure of the robot

Due to the modular structure of the robot, it will be easy in the future to exchange the brachytherapy end-effector with one designed for a different procedure. Alternative end-effectors could be designed to take biopsies, inject liquid agents, and insert cryotherapy or radiofrequency probes. In this way the robot could potentially improve the performance of other image-guided interventions and also play an important role in the validation and application of new targeted procedures emerging for diagnosis and therapy of prostatic disease.

Figure 4. Experiment with stainless seeds inserted in mock-up tissue

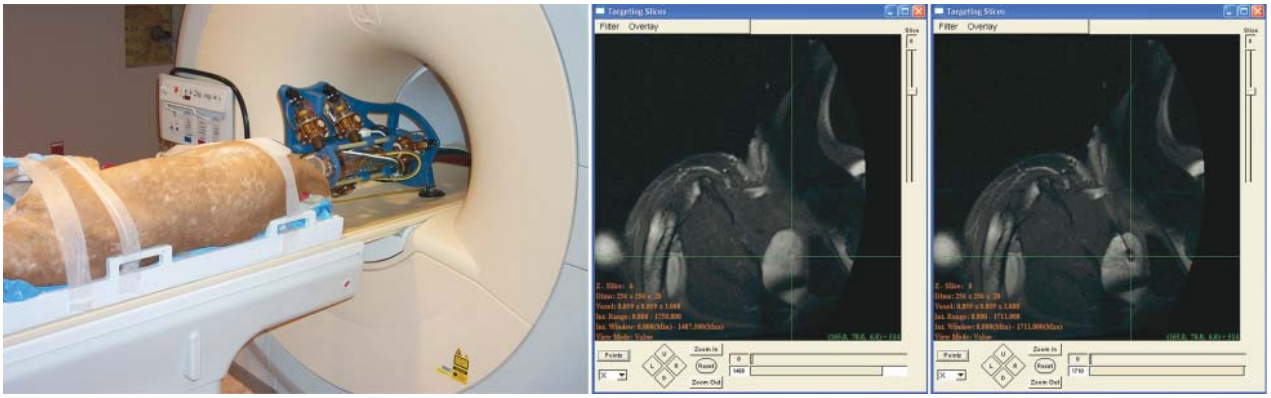

Figure 5. Animal study: MR setup and targeting slices before and after the insertion of the needle

Conclusions

This paper describes a fully-automated robotic system for prostate brachytherapy under MRI-guidance. The system is entirely constructed of non-metallic components and does not use classic actuation methods. It is fully actuated and allows for automated needle manipulation, insertion, and seed deployment within a closed-bore scanner, without deteriorating the quality of MR imaging. The system shows remarkable accuracy and has the potential to improve the precision of radioactive seeds implantation. Currently the system is evaluated in animal studies and prior to any clinical use more extensive testing will be performed. The new brachytherapy system is a significant technology leap. It is the first instrument to implant the seeds without manual intervention, and it does so in the MRI scanner under direct image-guidance. The tests performed thus far prove the feasibility of the MRI robotic concept. With further testing and refinements, this promising technology may become a useful clinical instrument.

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