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MRI-Guided Lumbar Spine Injections with a Body-Mounted Robotic System: Cadaver Studies

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Introduction: This paper reports the system integration and cadaveric assessment of a body-mounted robotic system for MRI-guided lumbar spine injections. The system is developed to enable MR-guided interventions in close bore magnet and avoid problems due to patient movement during cannula guidance.

Material and methods: The robot is comprised by a lightweight and compact structure so that it can be mounted directly onto the lower back of a patient using straps. Therefore, it can minimize the influence of patient movement by moving with the patient. The MR-Conditional robot is integrated with an image-guided surgical planning workstation. A dedicated clinical workflow is created for the robot-assisted procedure to improve the conventional freehand MRI-guided procedure.

Results: Cadaver studies were performed with both freehand and robot-assisted approaches to validate the feasibility of the clinical workflow and to assess the positioning accuracy of the robotic system. The experiment results demonstrate that the root mean square (RMS) error of the target position to be 2.57±1.09mm and of the insertion angle to be 2.17±0.89°.

Conclusion: The robot-assisted approach is able to provide more accurate and reproducible cannula placements than the freehand procedure, as well as reduce the number of insertion attempts.

Keywords: MR image-guided therapy; lumbar spine injections; body-mounted robot; MRI-guided robot.

Introduction

Lower back pain is a prevalent symptom in both children and adults. Around 80% of adults and 10% to 30% of young children experience lower back pain at some point in their lifetimes [1,2]. Lumbar spine injections are a common treatment for chronic pain, which are usually carried out in the pelvis area and lower back, and involve delivery of pain-relief medications to narrow anatomical spaces, small nerves, and tight muscular compartments [3,4]. Traditional lumbar spine injections involve the use of X-ray, i.e.

fluoroscopy or computed tomography, to guide the interventions, which has limited visualization of the nerve anatomy. Moreover, X-ray can cause significant ionizing radiation exposure to both patients and radiologists, which should be avoided as much as possible. MRI is an excellent imaging modality for lumbar spine injections with its capability to offer incomparable soft tissue contrast, exquisite anatomical details, and arbitrary slice orientation without exposing patients or radiologists to ionizing radiation. Current MRI-guided lumbar spine injections are performed by freehand, which is not always accurate and may require multiple insertion attempts to place the cannula [5]. Therefore, there may be a role for robotic assistance to guide the cannula. However, the high-field-strength (1.5-3 Tesla) and tightly constrained closed-bore scanner (diameter 60-70 cm and length around 1 m) are significant challenges to develop robotic systems that can work within the MRI environment.

To overcome these challenges, robotic assistants that are compatible with the MRI environment have been studied over the last two decades [6][7]. From the perspective of mounting mechanisms, MRI-guided robots can be categorized as table-mounted and body-mounted systems. A table-mounted robot is installed on the scanner table with a supporting base or frame, which entails a relative bulky structure profile. In addition, the patient is required to keep still during a procedure to maintain a steady position with respect to the robot. However, patient movement is unavoidable, particularly for procedures that require longer times. Hence, mechanical fixtures, such as the Leksell frame used in stereotactic neurosurgery, are typically used to restrain the patient movement. Table-mounted robotic systems have been investigated for MRI-guided procedures of various applications, such as prostate cancer therapy [8-12], stereotactic neurosurgery [13-16], facet joint treatment [17], breast tissue biopsy [18], and in-room ultrasound fusion [19]. In comparison, a body-mounted robot is mounted directly to a patient using straps or other methods, minimizing the effect of patient movement by moving with him/her. Because supporting bases or frames are not required, they can be devised with compact and lightweight structures. Hata et al. developed a 2-DOF body-mounted robotic cannula guide with a double ring mechanism to orient the probe for MRI-guided cryotherapy of renal cancer [20]. Ghelfi et al. designed a 5-DOF cable-driven body-mounted light puncture robot for abdominal interventions under CT or MRI guidance [21]. He et al. developed a 2-DOF body-mounted MRI-guided cannula placement robot with a soft fluid-driven actuator [22]. These robotic systems have shown encouraging results, nevertheless, they are designed for dedicated applications. In addition, most of them are proof-of-concept prototypes. Further technical improvements and thorough evaluation of the systems are required to facilitate clinical trials.

In our previous study, we have developed a 4-DOF body-mounted robotic assistant for low back injections under intraoperative MRI guidance [23]. The mechanical design, robot kinematics and registration were reported, and the system positioning accuracy was assessed in free space and with an MRI-guided phantom study. In this paper, we extended the study towards clinical system integration and pre-clinical evaluation to prepare for future clinical trials. The main contributions of this paper are: 1) integrating the system towards clinical studies, 2) creating a dedicated clinical workflow of robot-assisted lumbar spine injections under intraoperative MRI guidance on the basis of freehand procedures, and 3) validating the clinical workflow and evaluating system targeting accuracy through cadaver studies of freehand and robot-assisted procedures.

Materials and Methods

MR-Conditional Cannula Placement Manipulator

The robot is designed to provide 4-DOF cannula alignment on the patient's lower back, a 2-DOF translational motion and a 2-DOF rotational motion, as shown in Fig. 1. A fiducial frame consisting of four MRI-visible, high-contrast markers (MRSpots, Beekley Medical, Bristol, CT, USA) is installed on the robot for registration purposes. A mounting frame is devised to mount the robot directly to a patient via straps, facilitating the mounting location on the anatomy region of interest. A brass insert will be sterilized before each clinical procedure and inserted inside the cannula guide to create a sterile environment and guide the cannula insertion. The body of the robot is built with MR-Safe (defined in ASTM F2503 [24]) ABS plastic. MR-Conditional aluminium is used for components that require high structural stiffness, such as the cannula guide, universal joint, linear guides, and lead screws. MR-Conditional nonmagnetic piezoelectric actuators (USR30-S4N, Shinsei Corp., Tokyo, Japan, and Piezo LEGS LR5012D, PiezoMotor, Uppsala, Sweden) and optical encoders (ET4-500, US Digital, Vancouver, WA, USA) are used to provide actuation and positioning sensing, respectively. Hence, this system is considered to be an MRI-Conditional system. A detailed description of the mechanical design is reported in [23].

Clinical System Integration

The system consists of five main modules, as illustrated in Fig. 2: 1) MRI scanner and control console, 2) surgical planning workstation, 3) control software, 4) embedded robot controller, and 5) MR-Conditional cannula placement manipulator. The open source platform 3D Slicer [25] is used as the surgical planning workstation to visualize the patient anatomy and perform surgical planning. The robot control software is developed using a MATLAB (MathWorks, Natick, MA, USA) application, which includes a custom graphical user interface (GUI), to manage the high level control information and solve the robot kinematics. An embedded robot controller is developed based on a real-time, industrial grade Galil Motion controller (Galil Motion Control, Rocklin, CA, USA) to generate high-precision closed-loop control of the MR-Conditional cannula placement manipulator with positioning feedback.

The desired target and entry points are determined by the radiologist on the surgical planning workstation and transmitted to the robot control software through the OpenIGTLink communication protocol [26]. Based on that, the robot control software solves the kinematics [23] and generates motion commands for each axis, which are transferred to the robot controller to move the robot and align the cannula to the planned pose. Once the cannula is aligned, the radiologist will insert the cannula manually. Data exchange between the robot control software and the robot controller is connected through optical fiber cables, which run through the waveguide on the shielded patch panel, to minimize electromagnetic interference (EMI) that can cause image degradation. The diagnostic MR images of the cannula trajectory will be acquired and visualized on the surgical planning workstation for verification by the clinician.

Clinical Workflow

As described in the “Introduction” section, current lumbar spine injections typically use X-ray for image guidance, which leads to ionizing radiation exposure to both patients and radiologists. As radiation exposure concerns continue to rise, the use of MRI for procedure guidance is increasing, however, it is not yet routine clinical practice. As currently performed, freehand MRI-guided interventions use an advance and check strategy, which can be challenging and consists of several contiguous steps: 1) visualizing the anatomy of interest with initial MRI scan; 2) path planning based on the images; 3) moving the patient out of the scanner bore and placing the cannula manually; 4) moving the patient back into the scanner bore and verifying cannula placement with repeat imaging, and 5) taking a sample or injecting a drug. The typical workflow of freehand MRI-guided lumbar spine inject is demonstrated in Fig. 3a.

During this freehand procedure, there are many points where errors can be introduced. These errors are categorized into two main divisions: 1) those associated with planning, and 2) those associated with execution of the procedure. The cannula trajectory planning is performed based on an inaccurate and unsteady anatomy landmark on the images, which can shift during the procedure, due to the patient movement or respiratory motion. The cannula is typically aligned with the laser light of the scanner, which can result in alignment errors. Consequently, the cannula placement and verification steps may require multiple attempts using an advance and check strategy. These steps take time, especially moving the patient in and out of the scanner bore and re-imaging with each cannula advance, while the patient must remain still inside the scanner, thereby increasing patient discomfort and anesthesia duration when used. Such multi-step MRI-guided procedures increase the MRI room time and overall procedure cost and can also cause logistical problems in scanner usage and physician scheduling.

To enable MRI-guided interventions using a body-mounted robot, we have developed the following 8-step workflow through consultation with our clinical collaborators on the basis of freehand MRI-guided procedures [27, 28], as demonstrated in Fig. 3b.

(1) Position the patient on the MRI table and create a sterile environment.
(2) Initialize and secure the robot on the patient using straps.
(3) Scan the anatomy of interest and register the robot with fiducial markers.

(4) Plan the cannula trajectory on the planning workstation.

(5) Align the cannula with the robotic assistant.

(6) Insert the cannula manually and acquire confirmation images for verification.

(7) Inject contrast medication and acquire diagnostic images.

(8) Retract the cannula, remove the robot and patient.

Our approach can address the aforementioned two main error sources associated with the freehand approach. First, the fiducial frame based registration method can provide accurate registration between the images and the patient anatomy. Second, error due to the patient movement can be minimized through the use of a body-mounted mechanism. Third, closed-loop controlled robotic cannula alignment is able to provide high-precise motion control in contrast to manual alignment. In addition, the procedure time may be reduced by minimizing the number of attempts associated with the freehand approach, which using an advance and check strategy. Therefore, by attenuating the aforementioned error sources, the advantages enabled by the robotic system can potentially improve the accuracy and outcomes of the procedure.

Results

As depicted in the “Clinical Workflow” section, current lumbar spine injections are carried out under X-ray guidance, and the use of MRI is not yet routine clinical practice. Therefore, it is essential to validate the procedure with freehand techniques first for comparison with the robot-assisted procedure. Cadaveric experiments were performed to validate the proposed clinical workflow and evaluate the system targeting accuracy by comparing the results of freehand and robot-assisted lumbar spine injections under intraoperative MRI guidance. The injections were performed on two Thiel soft embalmed cadavers [29], one female (freehand) and one male (robot-assisted). The injections in both studies were performed by the same radiologist. The experiments were performed inside a 1.5T scanner (Signa HDx, GE, Boston, MA, USA) with two DuoFlex coils and imaged with 3D fast imaging employing steady-state acquisition (FIESTA) sequence (TE: 1.46ms, TR: 5.464ms, flip angle: 75°, slice thickness: 3mm, pixel spacing: 0.78mm x 0.78mm) for robot registration, cannula trajectory confirmation, and contrast agent diagnosis.

Freehand Lumbar Spine Injections

Freehand lumbar spine injections were performed on a female Thiel embalmed cadaver with an 18G MRI-Conditional bevel-tipped cannula (InVivo, Philips, The Netherlands). During the freehand procedure, the targets were defined using guiding lines ("line/distance" function of the MRI) with position and angle offsets with respect to the reference point on the intraoperative MR images, as illustrated in Fig. 4a. Since the guiding lines and manual cannula placement are not precise, corrections of cannula placement are usually required after the initial insertion attempt using guiding lines with respect to the previous cannula trajectory, as shown in Fig. 4b. Using the intraoperative MR images, the radiologist landmarked the entry point with respect to the laser reference (see Fig. 4c) and then inserted the cannula according to the guiding lines (see Fig. 4d). Six target locations were defined on the facet joints at various levels (L2 to L5) and on both sides (left and right) of the spine. The results are summarized in Table 1. The RMS errors of the initial attempts were target position error 10.64±6.32mm, entry point error 10.63±5.08mm, and insertion angle error 6.56±3.30°, which were not able to provide sufficient accuracy to place the cannula inside the gap of facet joints. Hence, corrections of cannula trajectories were performed on five out of the six target locations, which reduced the target position error to be 2.61±1.05mm. However, the entry point and insertion angle errors were increased to 11.34±5.40mm and 17.89±7.78°, respectively. After the corrections, the contrast agent (3ml distilled water with 1% gadolinium based Magnevist, Schering AG, Berlin, Germany) was injected into the facet joints to prove the desired intra-articular distribution of the injection.

Robot-Assisted Lumbar Spine Injections

Robot-assisted lumbar spine injections were performed on a male Thiel embalmed cadaver with a 20G MRI-Conditional bevel-tipped cannula (MReye, Cook Medical LLC, Bloomington, IN, USA), following the proposed clinical workflow. The experiment setup is demonstrated in Fig. 5. The mounting frame, as depicted in the "MR-Conditional Cannula Placement Manipulator" section, was attached to the lower back of the cadaver using straps (see Fig. 5a), and then the robot was locked onto the mounting frame (see Fig. 5b). Once the cannula was aligned with the assistance of the robot, the radiologist inserted the cannula manually through the cannula guide and injected the contrast agent (see Fig. 5c). Ten targets in total were defined on the facet joints at various levels (L1 to L5) and on both sides (left and right) of the spine. The first five targets were selected on the lower levels of the lumbar spine and then defined on the upper levels by adjusting the mounting location of the robot manipulator. The experiment results are summarized in Table 1, indicating the RMS errors of the target position to be 2.57±1.09mm, entry point to be 1.69±0.76mm, and insertion angle to be 2.17±0.89°. A representative MR image of the actual cannula trajectory and injected contrast agent is shown in Fig. 5d.

Discussion

This study reports the system integration and preclinical validation in a human cadaver model of a body-mounted robotic system for lumbar spine injections under intraoperative MRI guidance. The clinical workflow of the robot-assisted approach was proposed based on the freehand procedure, and compared with MRI-guided cadaver studies. Comparing the targeting accuracy results of the robot-assisted and freehand approaches, it indicates that the robot-assisted approach is able to provide more accurate and reproducible cannula placements (total RMS error of target position: 2.57±1.09mm, insertion angle: 2.17±0.89°) than the freehand counterpart (total RMS error of target position: 8.09±5.55mm, insertion angle: 14.07±7.61°). The robotic assistant can also reduce the insertion attempts, as most of the freehand insertions required at least one correction of cannula direction. Hence, the robot may avoid potential complications from multiple insertion attempts and failed injections. Nevertheless, at the current stage, the total procedure time of the robot-assisted approach (50 min) is longer than the freehand counterpart (34 min), which is mainly due to the time required for setting up and removal of the robot, as well as fiducial frame registration. In addition, because it is still at the early stage of development, the clinical team would need a learning period to become acquainted with the robotic system. As the development of the system progresses, the procedure time can be reduced in the future. Furthermore, for future clinical trials, the robot setup will be done in parallel with the patient setup as much as possible to reduce the setup time.

The experiment results indicate four main factors that lead to the cannula placement errors of the robot-assisted approach: (1) mechanism errors, including fabrication/assembly tolerance, backlash of timing belts, deformation of plastic materials, etc., (2) imaging errors, including image resolution, registration accuracy, cannula artifacts, etc., (3) skin elasticity variations at the entry point, and (4) cannula bending. The error sources of the mechanism and imaging factors were analyzed in our previous study on free space evaluation and MRI phantom study with a reported target position error of 1.70±0.21mm and insertion angle error of 0.66±0.43° [23]. Significant skin deformation at the entry point was observed during the initial test insertions into the cadaver, especially as the tissue dried out over the time, which caused bending and deviation of the cannula trajectory and consequently failure of reaching targets. Considering the skin elasticity, the moisturizer was applied to the skin of cadaver, and manual cannula steering was performed by the radiologist to reduce the cannula deviation in the consecutive insertions presented in this study.

The results reported in this study are in accordance with the published study on MRI-guided spine injections using an image overlay system that presented mean target error of 1.9±0.9mm and angle error of 1.6±1.0° in a human lumbar spine phantom [30]. The INNOMOTION system for MRI-guided sciatic pain and facet joint treatments demonstrated the precision of the insertion site in the axial plane was ±1mm, and angular deviation in the transverse plane was ±1.0° in porcine models [17].

In this paper, the robotic system is assessed with human cadaver studies and compared with the freehand approach. Although the results are promising, this study has several limitations. The compact design of the robot manipulator is able to provide accurate alignment for cannula insertions, nevertheless, the access of the fingers to the skin is lost, which can help to hold the skin and prevent skin motion during cannula insertions. Cannulas of different sizes were used for the two cadaver studies, due to the limitation of available cannulas. The difference of artifacts generated by the two cannulas and the consequent influence of accuracy seemed to be minimal, but further repeat trials are necessary to reach more definitive conclusions. Effects of patient motion (e.g. patient movement and respiratory motion) were not taken into account, which may affect the accuracy of cannula placement, although the proposed body-mounted mechanism can minimize the effects. Manual cannula insertions are still time-consuming, since it requires time to move the patient out of the scanner bore to insert the cannula and move back for imaging. In a future study, we plan to integrate this system with a remotely actuated cannula driving device under development [31,32], which would enable a fully actuated system for lumbar spine injections under real-time MRI guidance and thus eliminate the needs of moving patient in and out of the scanner bore. The fully actuated system should further streamline the clinical workflow and reduce the procedure time. In addition, we intend to assess the robotic system with human volunteers to evaluate patient motion and clinical workflow. While the clinical focus of this study is lumbar spine injections, the robot could serve as an enabling platform technology that can be applied to MRI-guided interventions that require a high level of precision, along with real-time image confirmation in future work.

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Conflict of Interest

All authors declared that they have no conflict of interest.

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Table 1. Targeting Accuracy Results Freehand vs Robot-Assisted Approach

Approach	**Remark**	**||Error|| (mm-deg)**		
		Target	**Entry**	**Angle**
Freehand	**Initial Attempt**	**10.64(6.32)**	**10.63(5.08)**	**6.56(3.30)**
	After Correction	**2.61(1.05)**	**11.34(5.40)**	**17.89(7.78)**
	Total	**8.09(5.55)**	**11.47(4.82)**	**14.07(7.61)**
Robot-assisted	**Total**	**2.57(1.09)**	**1.69(0.76)**	**2.17(0.89)**

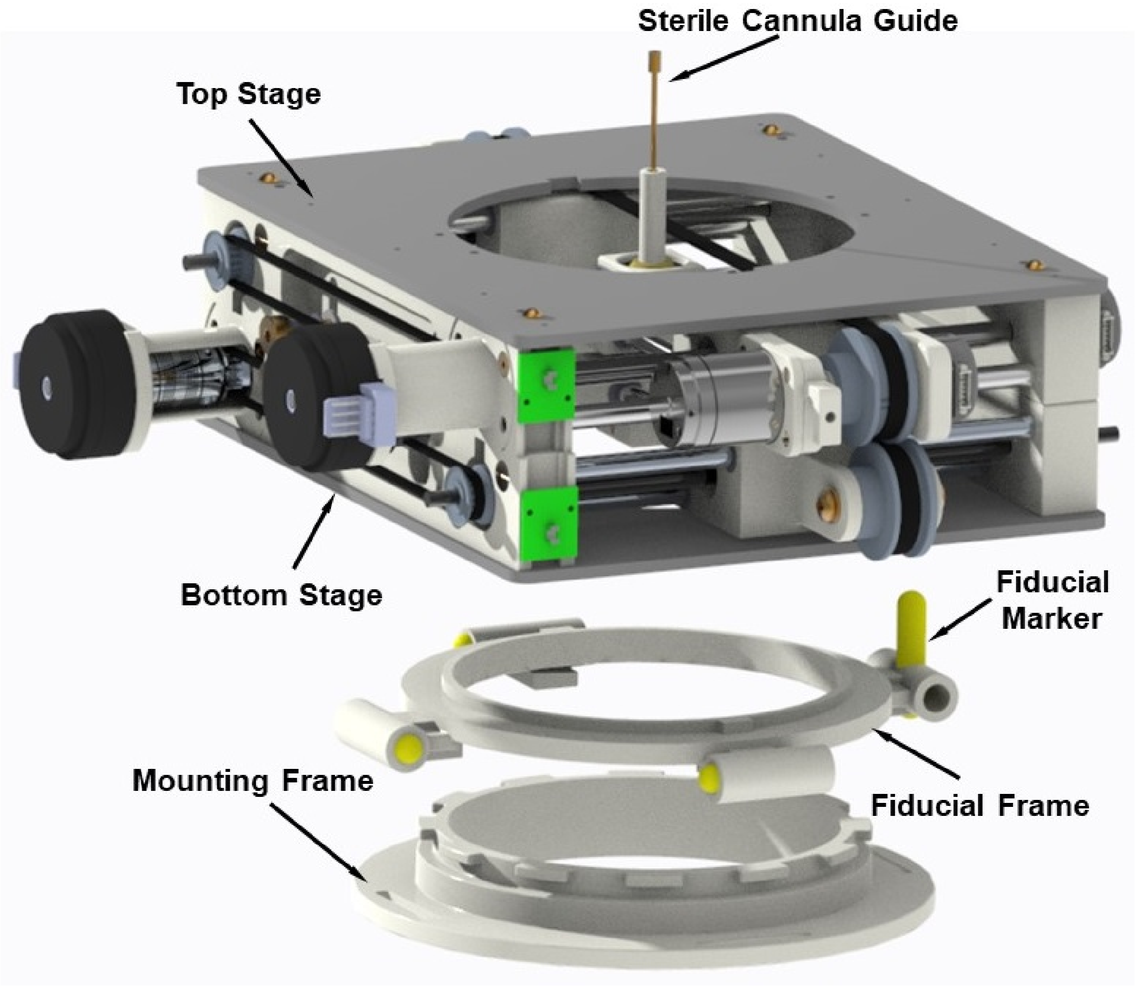
Figure 1. CAD model of the MR-Conditional body-mounted cannula placement manipulator, consisted of two stages, a fiducial frame and a mounting frame.

Figure 2. Clinical system integration of the robotic system for MRI-guided lumbar spine injections, showing the system architecture, dataflow and the role of radiologist.

Figure 3. Workflow comparison of the freehand approach (top) and robot-assisted approach (bottom) for MRI-guided lumbar spine injection, with average time per step recorded in the “Results” section.

Figure 4. Freehand lumbar spine injection under intraoperative MRI guidance. (a) Cannula trajectory planning with guiding lines and parameters, defined with respect to the reference point on the image, (b) defined with respect to the previous cannula trajectory. (c) Radiologist landmarked the entry point with respect to the laser reference, and (d) then inserted the cannula according to the guiding parameters.

Figure 5. Robot-assisted lumbar spine injection under intraoperative MRI guidance, showing (a) mounting frame attached to the cadaver’s lower back, (b) robot locked onto the mounting frame, (c) radiologist manually inserts the cannula and injects the contrast agent with the assistance of robot, and (d) representative MR images showing actual cannula trajectory and injected contrast agent within the gap of the facet joint.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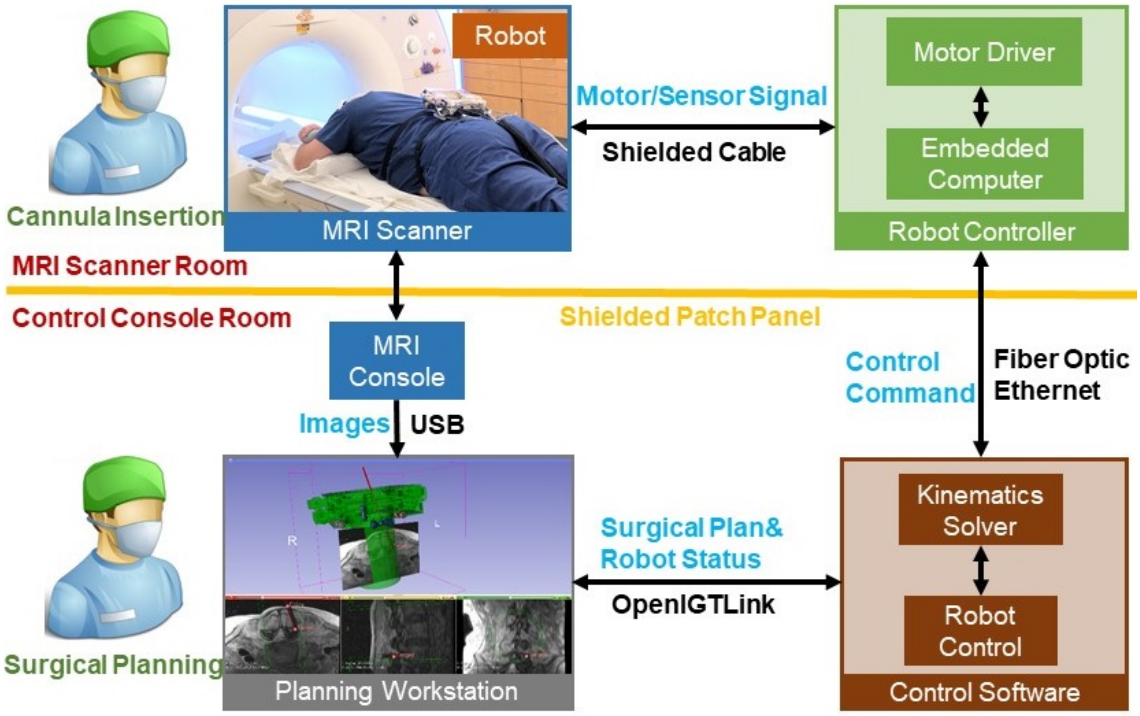
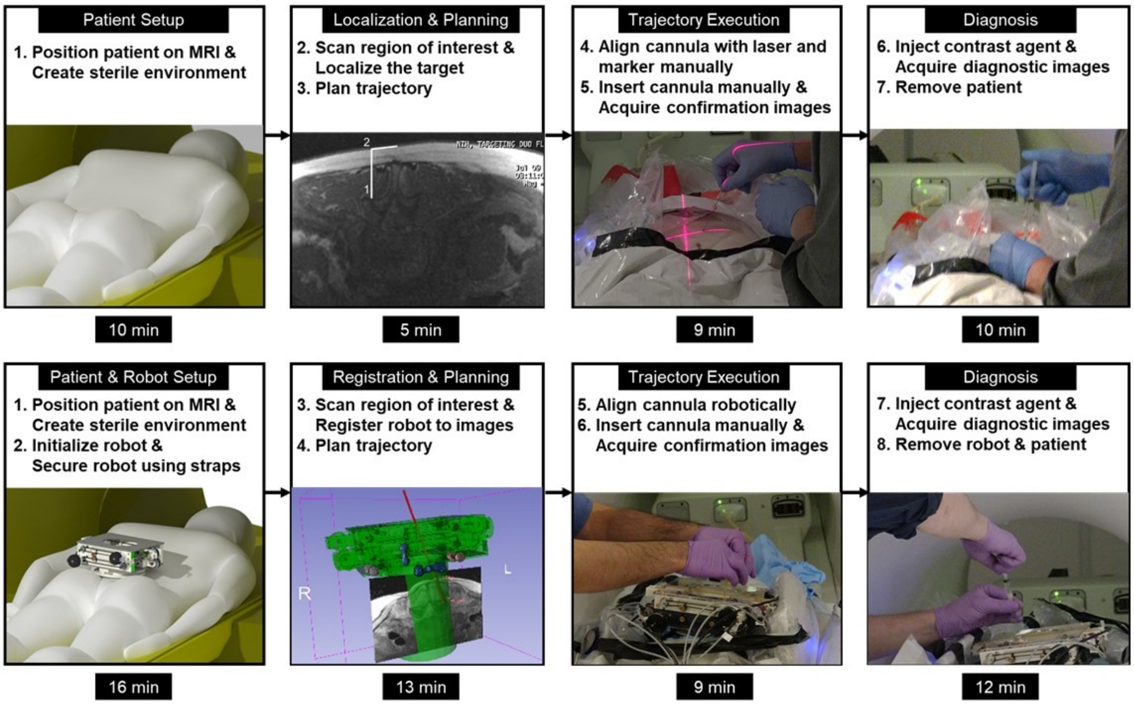
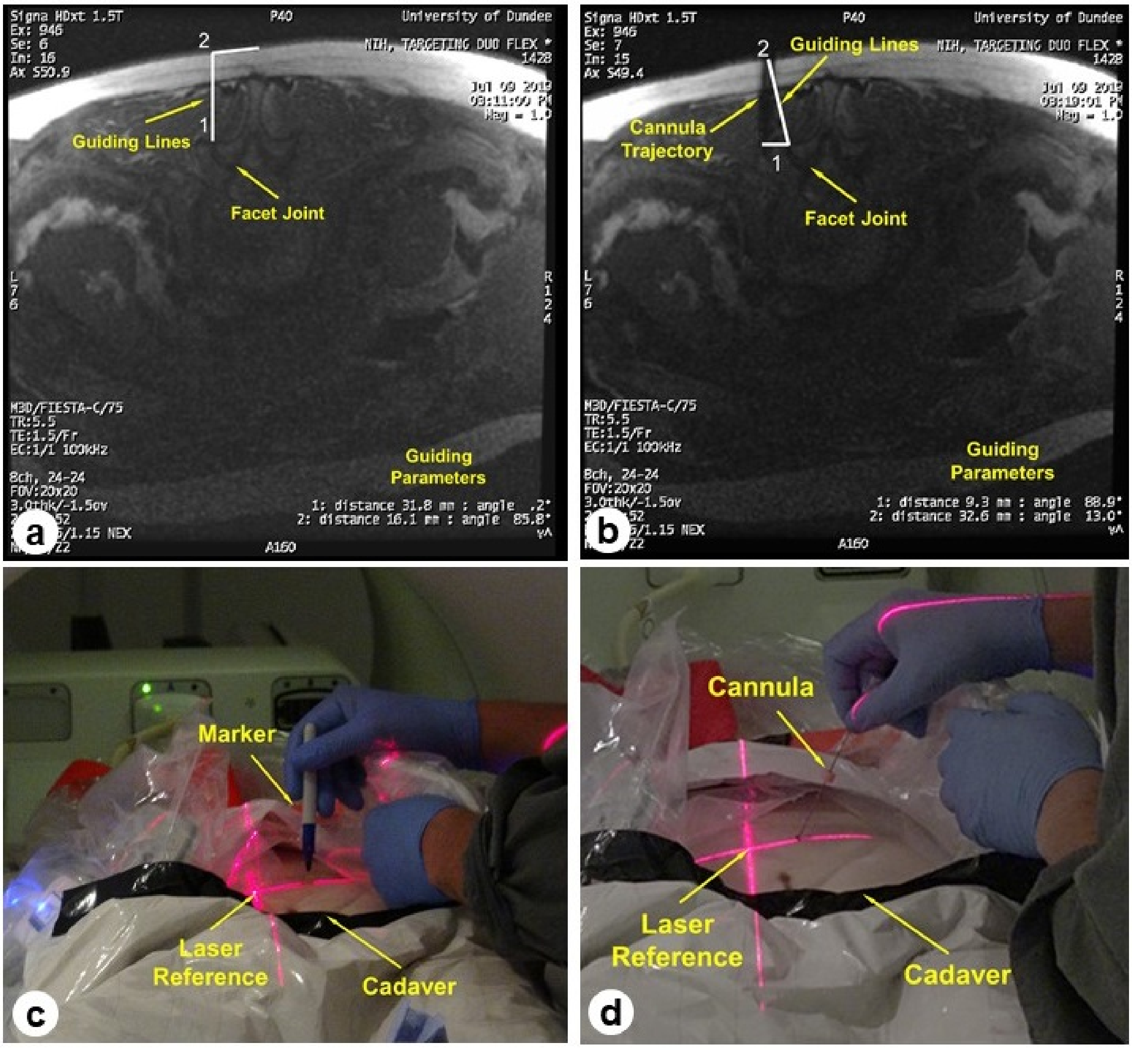
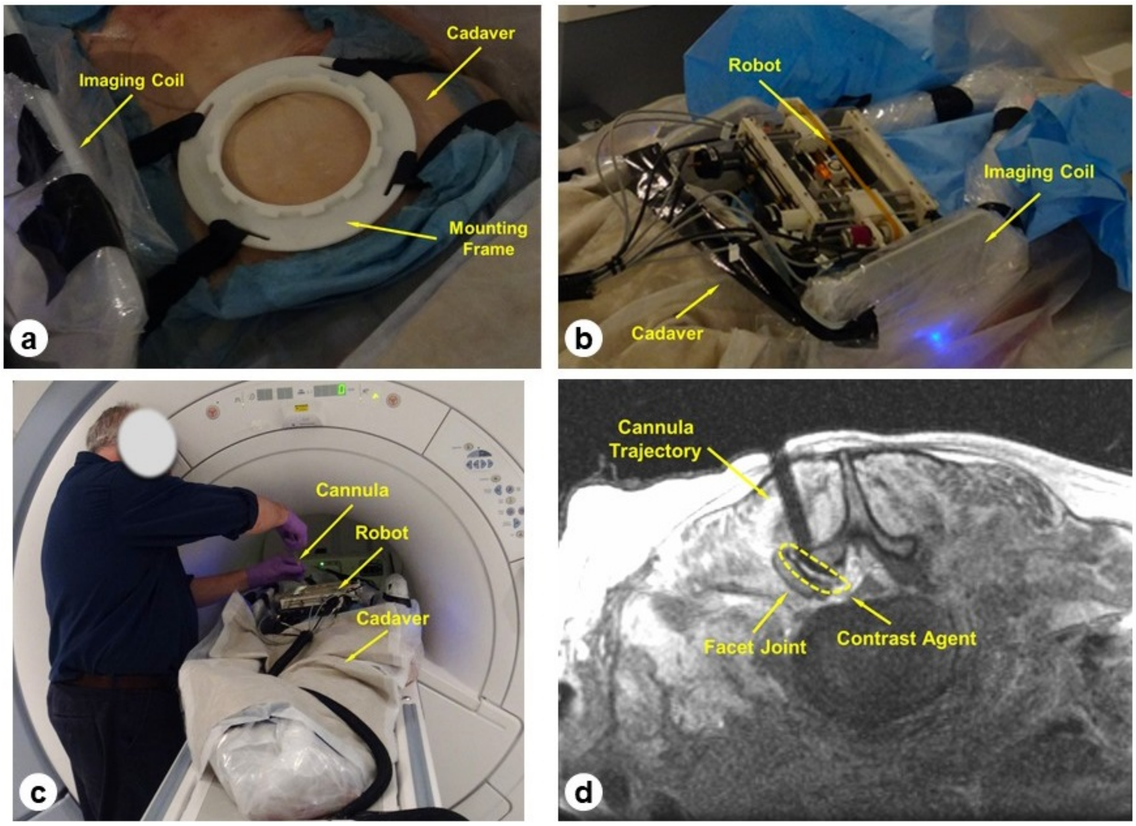
Bottom Stage
Fiducial Marker
Mounting Frame
Fiducial Frame


Robot
Cannula Insertion
MRI Scanner
Motor/Sensor Signal
Shielded Cable
Motor Driver
Embedded Computer
Robot Controller
MRI Scanner Room
Control Console Room
Shielded Patch Panel
MRI Console
Control Command
Fiber Optic Ethernet
Images
USB
Surgical Planning
Planning Workstation
Surgical Plan& Robot Status
OpenIGTLink
Kinematics Solver
Robot Control
Control Software


Patient Setup
1. Position patient on MRI & Create sterile environment
10 min
Localization & Planning
2. Scan region of interest & Localize the target
3. Plan trajectory
5 min
Trajectory Execution
4. Align cannula with laser and marker manually
5. Insert cannula manually & Acquire confirmation images
9 min
Diagnosis
6. Inject contrast agent & Acquire diagnostic images
7. Remove patient
10 min
Patient & Robot Setup
1. Position patient on MRI & Create sterile environment
2. Initialize robot & Secure robot using straps
16 min
Registration & Planning
3. Scan region of interest & Register robot to images
4. Plan trajectory
13 min
Trajectory Execution
5. Align cannula robotically
6. Insert cannula manually & Acquire confirmation images
9 min
Diagnosis
7. Inject contrast agent & Acquire diagnostic images
8. Remove robot & patient
12 min


Signa HDxt 1.5T
Ex: 946
Se: 6
Im: 16
Ax S50.9
P40
University of Dundee
NIH, TARGETING DUO FLEX *
1428
Jul 09 2019
03:11:00 PM
Mag = 1.0
2
1
Guiding Lines
Facet Joint
L
7
6
R
1
2
4
M3D/FIESTA-C/75
TR:5.5
TE:1.5/Fr
EC:1/1 100kHz
8ch, 24-24
FOV:20x20
3.0thk/-1.5sp
1.15 NEX
Guiding Parameters
1: distance 31.8 mm : angle .2°
2: distance 16.1 mm : angle 85.8°
A160
a
Signa HDxt 1.5T
Ex: 946
Se: 7
Im: 15
Ax S49.4
P40
University of Dundee
NIH, TARGETING DUO FLEX *
1428
Jul 09 2019
03:19:01 PM
Mag = 1.0
2
Guiding Lines
Cannula Trajectory
1
Facet Joint
L
7
6
R
1
2
4
M3D/FIESTA-C/75
TR:5.5
TE:1.5/Fr
EC:1/1 100kHz
8ch, 24-24
FOV:20x20
3.0thk/-1.5sp
1.15 NEX
Guiding Parameters
1: distance 9.3 mm : angle 88.9°
2: distance 32.6 mm : angle 13.0°
A160
b
Marker
Laser Reference
Cadaver
c
Cannula
Laser Reference
Cadaver
d


Cadaver
Imaging Coil
Mounting Frame
a
Robot
Imaging Coil
Cadaver
b
Cannula
Robot
Cadaver
c
Cannula Trajectory
Facet Joint
Contrast Agent
d