Design of a Robotic System for Ultrasound-Guided Central Line Placement

Background Readings Summary Report
EN.601.656 Computer-Integrated Surgery II
Team 22

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Contents

1 Introduction

Central line placement is a critical procedure that is commonly performed for a reliable, short-term or long-term intravenous vascular access. A central venous catheter is a type of catheter that is inserted into a large vein in the body, typically in the chest or neck, to provide easy access for medical treatment, monitoring, hemodialysis, emergency venous access, blood draws etc. The objective of our project is to design and develop a robotic system for ultrasound-guided central line catheter placement system that can enhance the accuracy and safety of central line placement.
The goals of this project are as follows:

1. Develop a prototype of a robotic system for untunnelled central line catheter placement through the subclavian. The system would automate the following procedures:
    - Needle insertion
    - Guidewire insertion
    - Catheter insertion
2. Test the accuracy and safety of the system by comparing the outcomes of central line placement using the proposed system to the outcomes of traditional central line placement methods.
3. Provide documentation and support for the system to ensure that it can be integrated into clinical practice and used effectively by healthcare providers.

Overall, the proposed system aims to improve patient safety and outcomes by providing a more accurate and reliable method for central line placement. By achieving the goals outlined above, we believe that the system will be a valuable addition to clinical practice and will have a significant impact on patient care.

2 Paper#1: AI-Enabled, Ultrasound-Guided Handheld Robotic Device for Femoral Vascular Access

In this section, the paper "AI-Enabled, Ultrasound-Guided Handheld Robotic Device for Femoral Vascular Access" (see [1]) is discussed.

2.1 Introduction

The use of ultrasound-guided techniques for femoral vascular access has become increasingly popular due to their accuracy and safety. However, the procedure still requires significant skill and experience, and even experienced operators can encounter difficulty in certain cases. The development of AI-enabled robotic devices for femoral vascular access can improve accuracy and efficiency. The system can also reduce the operator fatigue and error. In this paper, the team presents a novel handheld robotic device that utilizes AI algorithms and ultrasound guidance to perform the needle and guidewire insertion for the femoral vascular access.

2.2 Technical Summary

2.2.1 Clinical Workflow

Central line placement traditionally involves multiple steps, including needle puncture, coaxial guidewire insertion, iterative puncture-site dilation, catheter insertion, and guidewire removal. Using a robotic system such as AI-GUIDE simplifies the process. The operator positions the device using a dot-and-crosshairs display, which guides them to the correct vessel position. The system then deploys the needle to the AI-calculated target coordinates and confirms successful placement. The operator then advances the preloaded guidewire and inserts the catheter over it. Using a robotic system can reduce the risk of error in central line placement.

2.2.2 Design of the robotic system

The robotic system consists of several components, including a handheld robotic arm, an ultrasound probe, a needle insertion system and a control console, as shown in Fig.1.

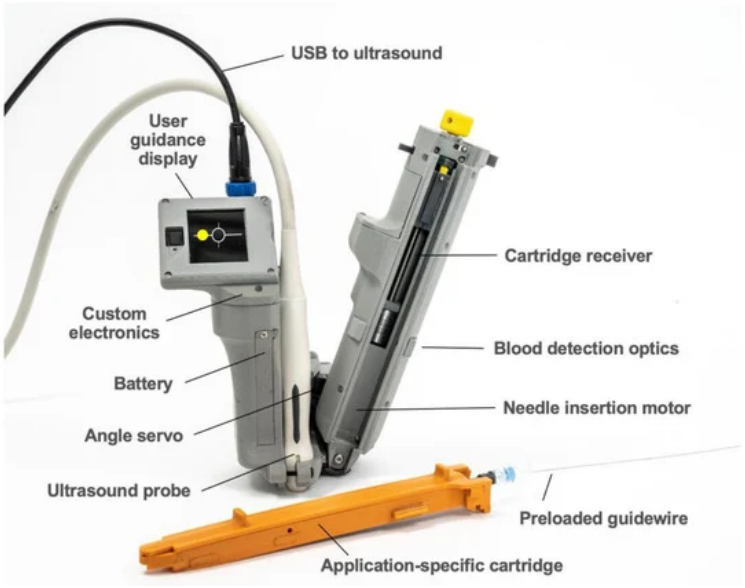

Figure 1: The detailed design of the ultrasound-guided handheld robot

- Robotic arm
  The robotic arm is designed to hold and position the ultrasound probe, which is used to locate the femoral artery. The arm is capable of rotating and tilting the probe to provide a clear image of the artery.
- Needle insertion system
  The system is composed of a linear actuator, a flexible shaft, and a needle advancement mechanism, as shown in Fig.2. The linear actuator is responsible for providing the force necessary to advance the needle into the patient's body, and the flexible shaft is designed to allow for a degree of flexibility and adaptability in the insertion process.
- Control console
  The control console is used to control the movements of the robotic arm and to display the ultrasound image. The console also contains an AI algorithm that analyzes the ultrasound image and provides guidance to the clinician on where to insert the needle.

2.2.3 Performance Evaluation

The AI subsystem is tested for the accuracy of vessel detection and classification. Performance was tested on a validation data set of 930 ultrasound images from a pig. Then the system testing was performed on a phantom. Lab administrators with no prior experience are trained for 2 min to use the system and then perform the task. The team also performs porcine tests to evaluate the performance of the device in the real clinical procedure. The results show that the device was able to successfully perform femoral vascular access with a high rate of success. The results indicates improved efficiency and safety compared to the traditional manual approach, especially for operators with less experience.

2.3 Discussions

2.3.1 Takeaways from the work

- The proposed robotic system is capable of autonomously inserting a needle into the femoral vein while minimizing the risk of complications associated with traditional manual techniques.

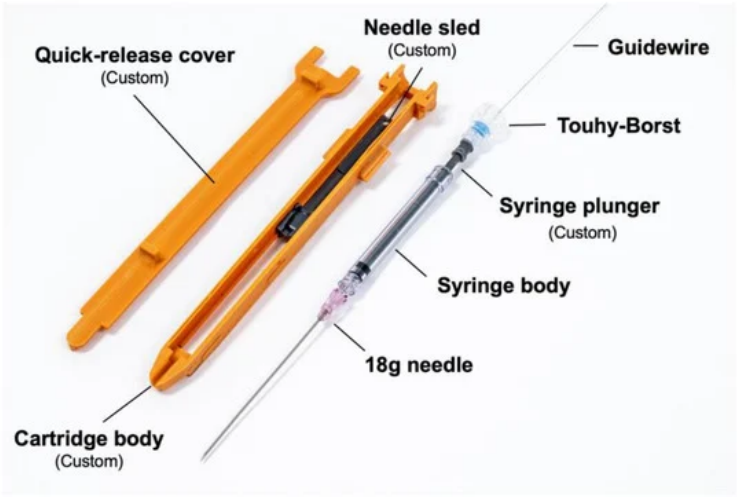

Figure 2: The detailed design of the cartridge

- The system utilizes artificial intelligence algorithms to track the needle and provide feedback to the operator in real-time.
- The proposed system was tested on a phantom model and demonstrated a high success rate and lower complication rates compared to traditional manual techniques.

2.3.2 Relevance to our project

The paper provides a blueprint for designing a robotic system for ultrasound-guided central line placement. While the specific application in this paper is femoral vascular access, the principles and techniques presented in the paper can be adapted to other central line placements such as subclavian and jugular vein access.

2.3.3 Limitations of the work

The main limitation is that it was tested on a phantom model and not in a clinical setting. Further studies are needed to evaluate the efficacy and safety of the proposed system in a clinical setting. Additionally, the cost and feasibility of implementing such a system in a clinical setting need to be evaluated.

3 Paper#2: Body-Mounted Robotic System for MRI-Guided Shoulder Arthrography: Cadaver and Clinical Workflow Studies

In this section, the paper "Body-Mounted Robotic System for MRI-Guided Shoulder Arthrography: Cadaver and Clinical Workflow Studies" (see [2]) is discussed.

3.1 Introduction

Shoulder arthrography is a diagnostic technique that uses contrast agents injected into the joint to visualize the internal structures of the shoulder. The technique can be used to diagnose conditions such as rotator cuff tears, labral tears, and shoulder instability. Magnetic resonance imaging (MRI) is often used to guide the injection of the contrast agent, as it provides high-resolution images of the internal structures of the shoulder. However, the procedure can be challenging and time-consuming, requiring a skilled operator to hold the needle steady while avoiding critical structures. Hence, the

authors propose a body-mounted robotic system to assist operators with the procedure of MRI-Guided shoulder arthrography.

3.2 Techincal Summary

3.2.1 Clinical Workflow

The body-mounted robotic system for MRI-guided shoulder arthrography consists of a lightweight, wearable robotic system that is mounted on the patient's torso. The system includes a four-degrees-of-freedom robot arm that is controlled by the clinician using a joystick. The robot arm positions and orients the injection needle, while the clinician performs the needle insertion and rotation. The clincian wears a head-mounted display that shows real-time MRI images and the position of the robot arm. The system was tested on cadavers and in clinical studies.

3.2.2 Design of the system

The system consists of several components, including a body-mounted robot, a custom-made shoulder brace, a fluid injection system, and a computer interface for controlling the robot (refer to Fig. 3).

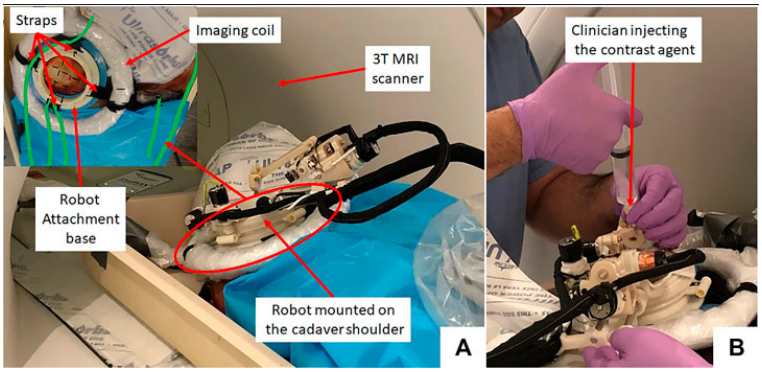

Figure 3: The different components of the robotic system for shoulder arthroplasty

- Body-mounted robot
  This is a foour-degrees-of-freedom manipulator designed to be mounted on the patient, as demostrated in Fig.
- Shoulder brace
  The arms are connected to the shoulder brace, which is custom-made for each patient and designed to hold the arm in a specific position during the procedure. The robot's arms can be adjusted to ensure accurate positioning of the fluid injection system.
- Fluid injection system
  The system consists of a syringe holder, tubing, and a needle that can be inserted into the patient's shoulder joint. The needle is guided by the robot's arms and can be adjusted to ensure accurate placement of the needle tip.
- Computer interface
  The interface allows the operator to control the robot's arms and the fluid injection system using a graphical user interface. The operator can also monitor the progress of the procedure using real-time MRI images displayed on the computer screen.

3.2.3 Performance Evaluation

The cadaver study showed that the system was able to accurately and safely inject contrast agents into the shoulder joint. The system was also able to avoid critical structures such as nerves and blood vessels. The clinical study showed that the system reduced procedure time by approximately 50% compared to manual injections. The system was also rated favorably by both operators and patients.

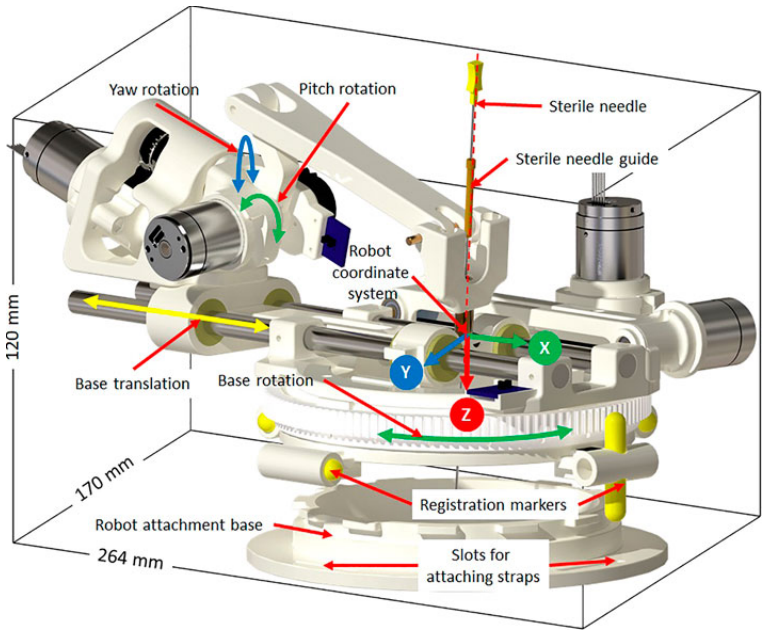

Figure 4: The detailed design of the robot for shoulder arthroplasty

3.3 Discussions

3.3.1 Takeaways from the work

- The body-mounted robotic system for MRI-guided shoulder arthrography has the potential to improve the accuracy, safety, and efficiency of shoulder arthrography procedures.
- The system can assist operators in holding the needle steadily, which would otherwise be challenging.
- Additionally, the system can reduce procedure time, which can lead to a more efficient workflow and improved patient outcomes.

3.3.2 Relevance to our project

This research proposes a compelling design for a body-mounted robotic system for shoulder arthroplasty. Our team hopes to take inspiration from the light-weight design proposed to come up with a body-mounted robotic system for ultrasound-guided central line placement.

3.3.3 Limitations of the work

- Dependence on MRI technology
  The system is dependent on MRI technology, which may not be readily available in all clinical settings.
- Limited clinical experience
  While the system has shown promising results in cadaver and clinical studies, further research is needed to evaluate the long-term outcomes and cost-effectiveness of the system.

4 Paper#3: An MRI Coil-Mounted Multi-Probe Robotic Positioner for Cryoablation

In this section, the paper "An MRI Coil-Mounted Multi-Probe Robotic Positioner for Cryoablation" ([3]) is discussed.

4.1 Introduction

Cryoablation is a procedure to freeze and destroy abnormal tissue by using a needle-like instrument called cryoprobe. The procedure can be used to treat soft tissue cancer in the lung, liver, breast, or kidney. Cryoablation is often performed with MRI to track the position of the probe. Traditionally, the patient need to be slide in and out of the bore each time when the clinician adjusts the intervention probe. Sometimes multiple probes need to be inserted to improve the efficiency of the treatment. And making sure the insertion angle is always corrected is also challenging and time consuming. To solve the problem, the team proposes a compact and patient mountable robotics system to insert multiple probes under the monitor of MRI.

4.2 Technical Summary

4.2.1 Clinical workflow

During a cryoablation procedure, MRI is used to track the position of the probes and visualize the formation of the ice ball. The process begins with an initial scan to locate the area of interest, then an approximation of the entry site for the probe is located. Then an insertion is made at the entry site. And the imaging data form MR is used to estimate the desired entry angle. The probe is inserted in an iterative manner, a few centimeters at a time, with each insertion checked with MR scans until it reaches the desired target point inside the patient.
When including the robot system in the procedure, the clinician does not need to find the correct insertion angles manually. They mount the device on the area of interest, then select the target locations through the user interface. Then the system will automatically adjust the probed to the correct angle. Then the clinician will manually insert the probe following the guide of system. Three probes will be placed and inserted one by one in the order of clockwise rotation.

4.2.2 Mechanical design

The system contains following parts, the patient mountable base, the arc structure, and the carriage on the arc.

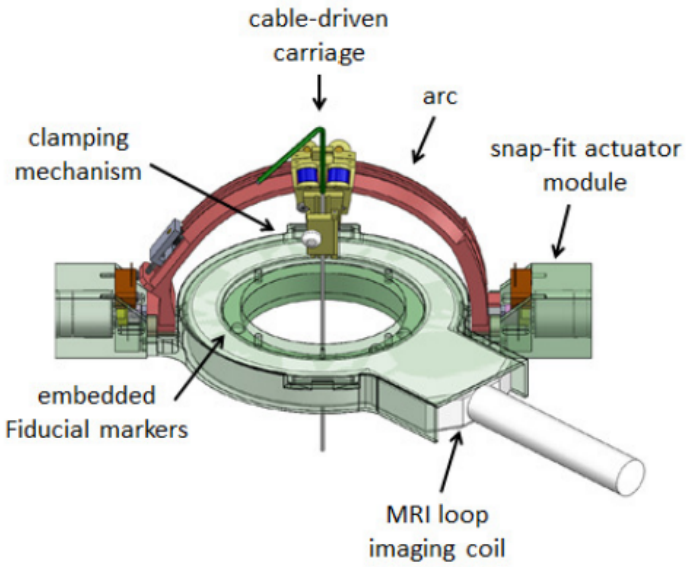

Figure 5: The full design of the robot including the mounting base, the arc, and the carriage

- Robot base
  Because of the limit space inside the bore, the device is mounted on a MRI loop imaging coil. The base is mounted onto the patient body by using adhesive pad or tapes. On the inner wall

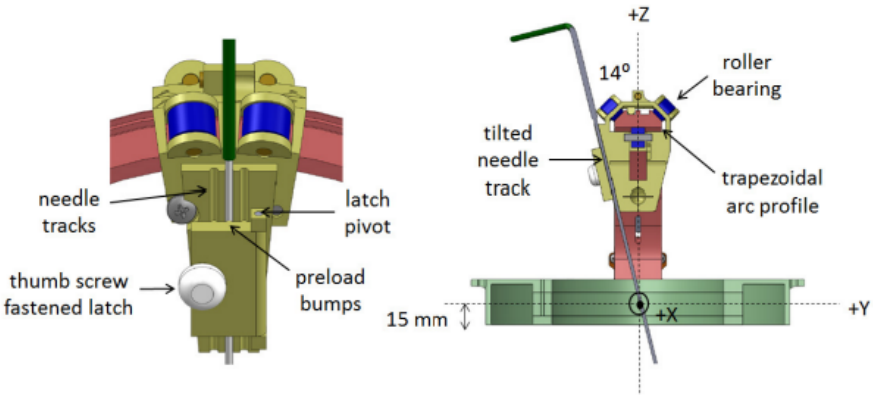

Figure 6: Details of the carriage in front view (left) and side view(right)

of the base, fiducials are positioned uniquely to be used for frame registration. As shown in the Fig.5, there are two motors attached to the round base. One motor is used to control the angle of arc, the other motor is used to control the driving pulley. The pulley will be explained in the Arc structure part. Because the motors are not easy to be sterilized, two motors are enclosed in a removable case, which snaps into the remaining parts of the device.

- Arc structure
  As shown in the Fig.5, the arc is a semicircle frame supporting the carriage. The angle of the arc can be controlled by a motor. The cable driven carriage can slide on the arc, which is controlled by the driving pulley mentioned above. The closed loop cable begins from the driving pulley, attaches to two sides of the carriage, then wraps around a tensioning pulley, and comes back to the driving pulley. So that the carriage can slide back and forth to control the angle of the probe.

- Carriage
  The carriage is the part directly contact with the probes. The contacting parts between the carriage and the arc are five roller bearings which can decrease the friction and backlash. The rubber rollers are small and wide so that the stress is decreased. The probes are latch fastened on the side of the carriage by using thumb screw. There are three tracks designed for three probes. The probes do not share the track to prevent intersecting in the center of the arc.

4.2.3 Inverse Kinematics

The driving angles of the arc and the carriage can be computed from the desired target location. After finishing the straight forward geometry implementation, the angles need to be adjusted because of the special design of the system. The angle of arc need to be adjusted by 14 degrees because the probe does not parallel to the plane of arc as shown in Fig.6. And the angle of carriage also needs to be adjusted because three probes have their own track.

4.2.4 Validation and evaluation

After having CAD model, the team uses Finite Element Analysis (FEA) to ensure the structural integrity during probe orientation and insertion. For each part of the system, the team analysis the force in the boundary conditions separately to ensure the deformation is always acceptable. Then the team uses MATLAB to check the Kinematics equations. The minimum distance between each probe is calculated to ensure there is no intersection. The team also checked the impact of the system to the MRI quality by calculating the Signal to Noise Ratio (SNR). After having a prototype in Fig.7, a bench level test is firstly implemented to evaluate the angular accuracy of the arc and carriage. Then the repeatability of the system is checked by moving the arc and carriage independently from either direction. Lastly, the accuracy of driving probe to the target location is validated. As a result,

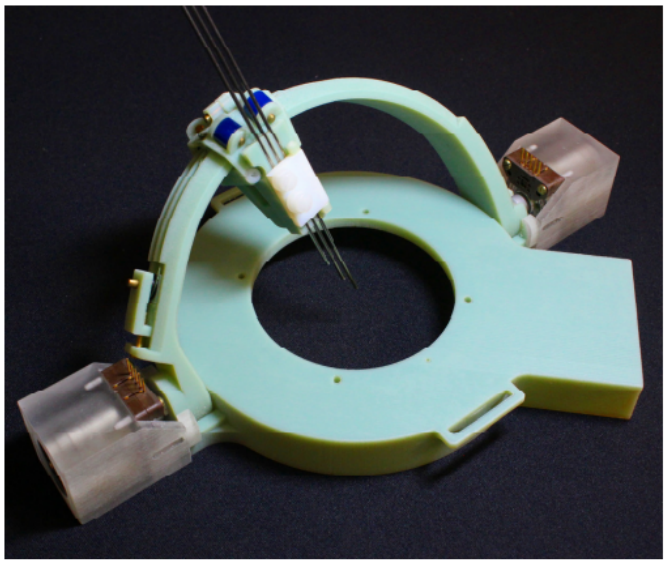

Figure 7: Prototype of the robot with three probes installed

the system can perform the angle adjustment during the Cryoablation procedure accurately without effecting the MRI quality.

4.3 Discussions

4.3.1 Takeaways from the work

- The paper describes a new robotic probe positioner that can be used for MRI-guided cryoablation operations. The system can adjust the orientation of the probes based on the clinician inputs to assist the procedure.
- The team tested the system in both in simulations and in real experiments and found that it is able to accurately perform the placement task. Therefore this new robotic positioner could potentially improve the accuracy and efficiency of MRI-guided cryoablation procedures, leading to better outcomes for patients.
- The main contributions of the system comparing to prior works are the minimal size and the multiple probes insertion feature.

4.3.2 Relevance to our project

- The paper introduced a compact and patient mountable device to perform an insertion task, which is similar to the main goal of our project. The design architecture help us divid our peoblem into subtasks.
- Our project needs to insert needle, catheter, and guidewire. The paper is inspiring in the way of performing multiple objects insertion. However, unlike inserting three identical probes, catheter and guidewire have different stiffness and dimension to the needle.
- The arc design and the sliding design of the carriage are also inspiring to our project.
- The ease of sterilization problem is also being addressed in the paper, which is a problem to be solved in our project.

4.3.3 Limitations of the work

- The limitation of the design is that it only performs the adjustments of the orientation of the probes. The clinicians still need to insert the probes manually after the adjustment. Our project will cover all the angle adjustments and insertions procedures.
- In addition, the device is designed for MRI guided insertion, while our project uses ultrasound imaging. Our project does not use coil, so the shape of the base does not have to be limited to round. And the base will probably be able to hold ultrasound probe.
- The design only has two degree of freedom for the orientation adjustment. For our project, we will add more degree of freedom to make the process more automatically.
- And the structure is only suitable for the flat body. The round base can not be mounted stably for the complex part such as the subclavian. We will figure out a better design for subclavian in our project.

5 Paper#4: Design of a Percutaneous MRI-Guided Needle Robot With Soft Fluid-Driven Actuator

In this section, the paper "Design of a Percutaneous MRI-Guided Needle Robot With Soft Fluid-Driven Actuator" ([4]) is discussed.

5.1 Introduction

The paper presents a novel design for a percutaneous needle robot that can be guided by magnetic resonance imaging (MRI). The robot is intended for use in minimally invasive medical procedures, such as biopsy and brachytherapy, where high accuracy and precision are required to minimize damage to surrounding tissue. It presents the design and implementation of the robot, along with experimental results demonstrating its performance in a simulated surgical scenario.

5.2 Technical Summary

5.2.1 Clinical workflow

The authors proposed a 4-stage clinical workflow for MRI-guided percutaneous intervention using their robotic system. Firstly, in the preparation stage, the target position is found by reviewing the pre-operative MRI images and the patient is positioned. Secondly, perform MR scans, complete the interventional planning based on the data, attach the robot, perform MR scans again, and complete robot registration in the planning stage. Thirdly, the targeting stage includes coarse adjustment, manual locking, fine adjustment, and granular jamming locking. Finally, the interventional procedures.

5.2.2 Mechanical design

The design and clinical considerations of the proposed system are dexterity, size and weight, positioning accuracy, and MR safety. The detailed design is shown as Fig.8.

- Robotic Platform
  The robotic platform is mounted directly on the patient or on a loop coil. There are three adhesive attaching pads and a fasten belt serving as anchorage.
- Soft Fluid-Driven Actuator
  It is used for fine adjustment of the needle guide and can generate 2-DoF planar motion by three soft chambers.
- Passive Needle Holder
  The surgeon grips the robot by the passive needle holder during coarse adjustment. It is nested between the outer and inner cover which works with the constraint ring to both constrain its axial motion and act as a friction lock.

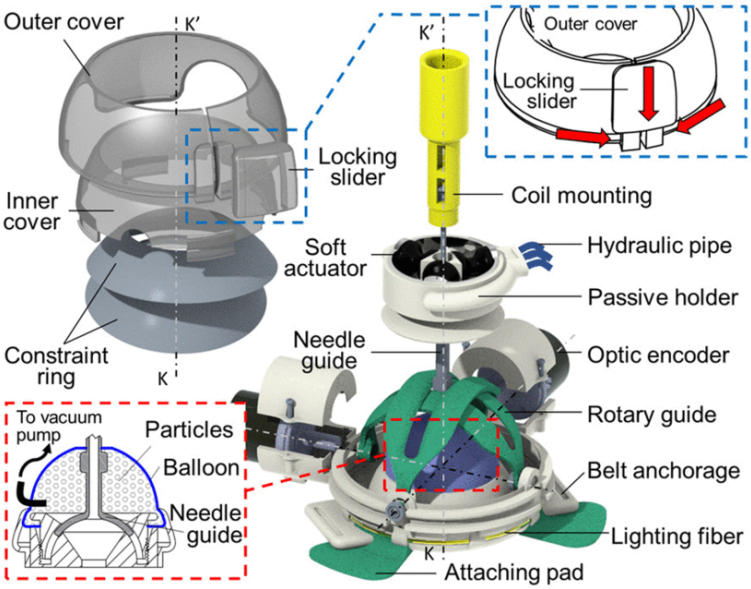

Figure 8: The detailed design of the robot with soft fluid -driven actuator

- Granular Jamming Locking of Needle Guide
  It provides a second level of locking once fine adjustment with the soft actuator is complete.

5.2.3 Targeting Kinematics

To solve the inverse kinematics based on the desired tip position, co-registration between image co-ordinate system and the robot is executed first. Then obtain the desired coordinate of the actuation block using the equation set and constraint. In the end, solve the desired inputs of each chamber and the desired encoder angles based on the needle orientation.

5.2.4 Performance evaluation

The performance of the robotic system was experimentally evaluated in terms of transmission stiffness, feedback control of the fluid-driven actuator, needle targeting accuracy, positional frequency response, MR-based tracking test, and MR compatibility test.

5.3 Discussions

5.3.1 Takeaways from the work

- The use of a soft, fluid-driven actuator can provide several advantages over traditional rigid actuators, such as improved safety and the ability to navigate through complex anatomical structures.
- The system is designed to be compatible with MRI guidance, allowing for real-time imaging and feedback during needle placement.
- The system includes a closed-loop control algorithm to ensure accurate needle placement.

5.3.2 Relevance to our project

This paper describes a robotic system for needle insertion that uses a soft, flexible actuator. While the specific application of the system is different (MRI-guided needle placement versus ultrasound-guided central line placement), the use of a flexible actuator could provide similar benefits in terms of safety and navigational capabilities.

5.3.3 Limitations of the work

- The system was developed specifically for MRI-guided needle placement, so it may not be directly applicable to other imaging modalities or procedures.
- The study only evaluated the system in a simulation and ex vivo model, so further testing in live animals or human subjects would be needed to validate its efficacy and safety.
- The system was designed for percutaneous needle insertion, so it may not be suitable for other types of procedures or interventions.

6 Conclusion

To conclude, the past decade has witnessed research on compact, i.e., hand-held or body-mounted, robots for needle insertion for various medical applications. In this literature review, the most relevant papers have been summarised, along with the limitations and takeaways of each of them. While the first paper "Body-Mounted Robotic System for MRI-Guided Shoulder Arthrography: Cadaver and Clinical Workflow Studies" emphasises the need for a robotic system for ultrasound-guided needle insertion, the system is bulky and tackles only femoral access. The rest of the papers have discussed designs of various body-mounted robotic systems. However, they were all MRI-guided procedures. The robot proposed in "An MRI Coil-Mounted Multi-Probe Robotic Positioner for Cryoablation" has an ideal design for the necessary degrees of freedom for the needle insertion to size ratio.

Hence, we propose the design of a lightweight body-mountable robotic system for automating the needle insertion, guidewire and catheter advancement procedures of central line placement, thereby bridging the research gap in design and applications.

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