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

EN.601.656 Computer-Integrated Surgery II
Project Proposal
Team 22

Team Members: Kesi Liang, Pranathi Golla, Xuanning Liu
Team Mentors: Dr. Axel Krieger, Lidia Al-Zogbi, Dr. Vinciya Pandian
Dr. Mathias Unberath, Wenhao Gu

Contents

1 Introduction

In this project proposal, we present our plan for the design of a robotic system for ultrasound guided central line placement. The system's hardware and software components are outlined, along with the technical approach for the design of the system. Finally, a plan for testing and evaluating the system's effectiveness is proposed.

1.1 Background

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. There are several types of central venous catheters, including Centrally Inserted Central line Catheters (CICCs), which are inserted into a central vein and then threaded through the vein until the tip of the catheter is located near the heart. The procedure has 4 standard access points (refer to [1], [2]) as depicted in Fig. 1: jugular, subclavian, femoral and arm veins. The different kinds of CICCs (see [3], [4]) may be listed as follows (refer to Fig. 2):

1. Non-tunneled CICC: This is the most common type of CICC and is inserted through the skin into the jugular, subclavian, or femoral vein. It is typically used for short-term access, such as for administration of medication, fluid replacement, or for drawing blood.

2. Tunneled CICC: This type of CICC is similar to a non-tunneled catheter but has an additional tunnel created under the skin from the insertion site to the exit site. The tunnel helps to anchor the catheter and reduce the risk of infection. Tunneled catheters are commonly used for patients who require long-term access, such as for chemotherapy or dialysis.

3. Peripherally Inserted Central Catheter (PICC): A PICC is a type of CICC that is inserted through a peripheral vein in the arm and threaded through the vein until the tip reaches the central veins. PICCs can be used for long-term access and are often used in patients who require frequent blood draws or administration of medications that may irritate peripheral veins.

4. Implanted Port: An implanted port is a type of CICC that is surgically implanted under the skin, typically in the chest or arm. The port has a small chamber with a septum that is accessed with a special needle for the administration of medication, chemotherapy, or blood draws. Implanted ports are often used for long-term access and can remain in place for months or years.

The choice of CICC depends on the individual patient's needs and medical condition. The medical team will work with the patient to determine the most appropriate type of catheter for their specific situation.

The following is a general outline of the workflow for central line catheter placement (refer to [1], [5]):

- Preparation: Before the procedure, the patient will be prepared by cleaning the skin over the intended insertion site with chlorhexidine solution and administering any necessary medications, such as antibiotics or sedatives. The clinician and the workspace will also be sterilized.

- Prepare ultrasound: Insert the ultrasound probe into a sterile sheath, and use sterile ultrasound gel during the procedure. Identify the jugular vein and carotid artery to ensure a proper entry site.

- Anesthesia: Local anesthesia is administered to numb the area where the needle will be inserted.

- Needle insertion: The clinician will insert a needle and follow the needle trajectory with ultrasound until the vein is entered and blood enters the syringe.

- Guidewire insertion: Remove the syringe and advance the guidewire through the needle. Let the guidewire go along the blood flow. Once the guidewire is ready, the needle is removed. It is essential to always maintain a grip on the wire throughout the procedure.

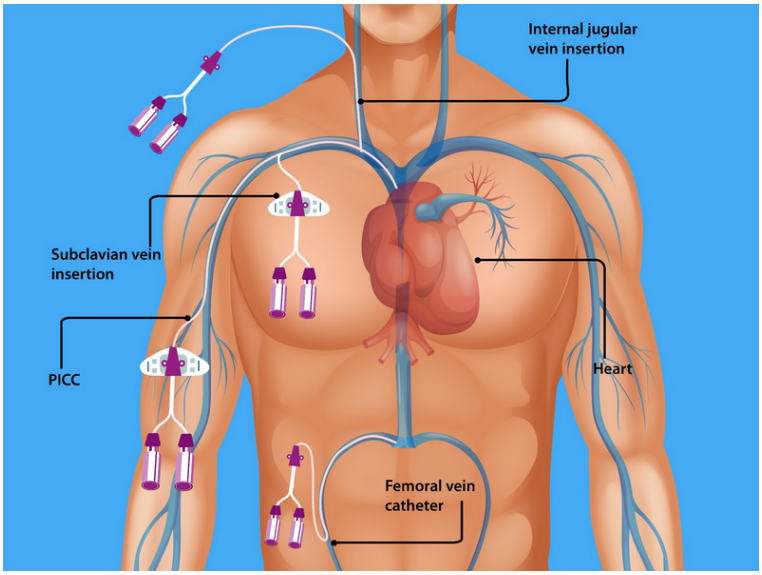

Figure 1: Different access points for CICCs ([2])

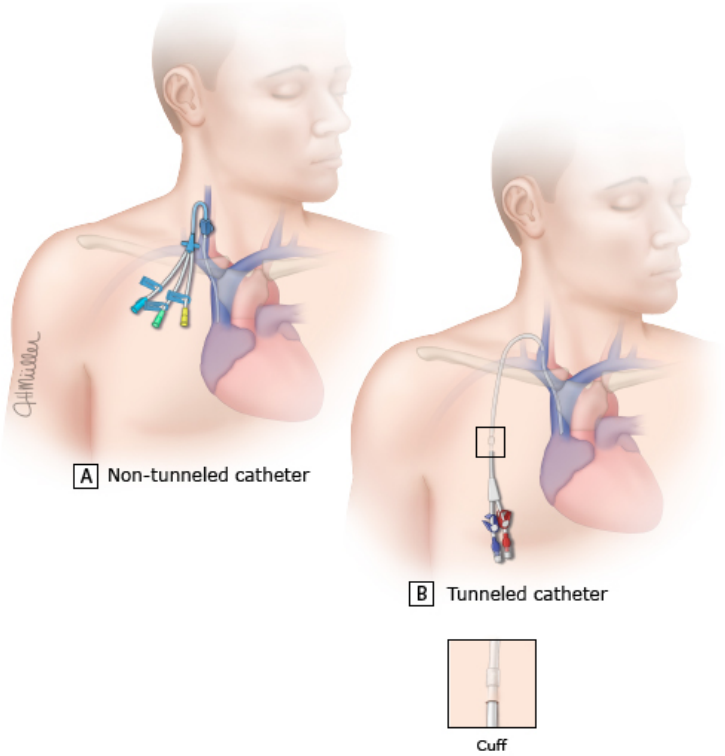

Figure 2: Tunnelled and non-tunnelled catheters ([3])

- Dilation: Insert a dilator and then remove it to extend the entry hole to the width of the catheter.
- Catheter insertion: The catheter is then threaded over the guide wire and advanced into the vein. Once the catheter is in the proper position, the guide wire is removed.
- Secure placement: Flush all ports with saline. The catheter is secured in place with sutures or

adhesive, and a dressing is applied over the insertion site.

- X-ray confirmation: In some cases, an X-ray may be used to confirm that the catheter is properly positioned.
- Post-procedure care: The patient will be monitored for any complications, such as bleeding, infection, or pneumothorax (collapsed lung). The catheter will also be flushed with saline or heparin to prevent clotting.

Overall, central line catheter placement is a complex procedure that requires careful preparation, skill, and attention to detail to ensure successful placement and minimize the risk of complications.

1.2 Motivation

The central line catheter placement procedure may involve the following complications, that may occur during catheter placement or post the procedure:

1. Pulmonary complications including pneumothorax, air embolism.
2. Cardiac complications including arrhythmia and cardiac arrest.
3. Vascular complications including arterial puncture, venipuncture and hematoma.
4. Delayed complications may include catheter-related bloodstream infections, device dysfunction and central vein stenosis.

Central line infections are a serious concern in healthcare settings. While the central lines are used to administer medication, nutrition, and fluids directly into a patient's bloodstream, they can also introduce bacteria and other microorganisms that can cause infections. According to the Centers for Disease Control and Prevention (see [2]), central line-associated bloodstream infections (CLABSIs) can result in prolonged hospital stays, increased healthcare costs, and even death. Therefore, a robotic system for central line placement can minimise the risk of infection, help improve patient outcomes and reduce healthcare costs.

Furthermore, the procedure of central line placement can be physically and mentally demanding for clinicians. Performing the procedure requires a steady hand, precise movements, and the ability to maintain focus over a prolonged period of time. Clinicians may experience physical fatigue and discomfort, as well as mental fatigue and burnout. Hence, a robotic system can assist clinicians with these tasks, not only helping alleviate their burden but also improving the efficiency and safety of the procedure.

Ultimately, by addressing these two key issues, a robotic system for central line placement could reduce the time required for the procedure, increase accuracy, and potentially reduce complications associated with the placement of central lines.

1.3 Prior Work

In [6], Zevallos et al. developed a robotic system for teleoperated needle insertion that enables subsequent guide wire and catheter insertion. The authors utilised a Universal Robots UR3e robotic arm to hold the needle insertion mechanism and the ultrasound probe. However, the robotic setup is bulky and challenging to use, and the process of aligning the robot to the artery in the longitudinal plane is time-consuming. Reuben et. al developed a novel algorithm for identifying the venous bifurcations in infrared images of the hand to determine the needle insertion point for robotic intravenous catheterization in [7]. However, it is difficult to detect closely-spaced bifurcations using this algorithm, and it also has limitations in the tracking strategy. In [8], Alvin et. al developed a robotic system driven by a deep-learning framework using bimodal near-infrared and duplex ultrasound images as inputs for needle and catheter insertion into vessels. Nevertheless, there are limitations in safety and accuracy.

In [9], Brattain et al. have proposed a handheld robotic device that incorporates artificial intelligence and ultrasound guidance to improve the accuracy and success rate of femoral vascular access. The

device automatically finds the insertion point based on the ultrasound image and completes the insertion workflow. The device is designed to be user-friendly so that even less experienced medical providers can achieve high accuracy. However, the device has limitations; it can only address catheter insertion for femoral vascular access and requires specialised equipment as it is not compatible with the common Catheterisation Kit. Additionally, the handheld device is not as accurate and stable as the patient-mounted device. In [10], Reuben proposes the HaemoBot robotic system, which incorporates artificial intelligence and machine learning to improve the accuracy and success rate of intravenous (IV) catheterization. The device significantly increases the success rate of IV insertion, and the author also provides a complete set of steps to establish a framework for robot-assisted insertion. They analyzed the common reasons for insertion failure. However, the article lacks empirical data to support the proposed technology as it is still in the developmental stage.

1.4 Objectives

The objective of this 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 jugular vein. 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 Technical Approach

The robot system is divided into four parts, robot mechanism design, operation workflow design, image guidance program design, and interface design. The details will be introduced in the subsections.

2.1 Robot design

The team begins the process by researching the current literature and identifying existing clinical needs related to central line placement. Combined with the clinician meeting notes provided by one of the group members, we have a better understanding of the operational workflow and the difficulties clinicians encounter during the insertion process. Based on the conversation with the clinician, central line placement can be a physically demanding procedure, and a robotic system can help reduce surgeon fatigue, allowing them to perform the procedure more comfortably and for longer periods.

During the analysis phase, the team categorises the complications that commonly happen during the operation. Some of those could be addressed by a robotic system, and some cannot. For the complications that can be addressed, the team searches for the reasons and brainstorms potential solutions to improve the workflow and discusses them with the clinicians to have their feedback. Infection is a common problem for central line placement operations. The main reason for infection is that clinicians touch equipment without proper sterilisation. If the robotic system can perform some of the tasks, such as the insertion of a needle, guidewire, and catheter, without manual control from clinicians, the

chances of infection will be reduced.

Once the team has a clear understanding of the clinical needs and feasibility of potential solutions, the team will then determine the required device design specifications, including the weight, size, form of interface, and patient-mountable access. The mounting platform needs to be applicable to the patient population in different sizes. The team will start the design for jugular insertion, but the device will be adaptable to fit other insertion locations. The team will then create high-level and low-level designs to address the problem and meet the specifications. The high-level design will include the overall architecture of the system, while the low-level design will include the detailed components and subsystems of the device. The team will also document the step-by-step workflow of the robot-assisted central line placement operation, ensuring that the device is practical and efficient in a real clinical environment.

With high-level and low-level designs in place, the team will synthesise the design by creating computer-aided design (CAD) files that will be used to perform tasks. The team will work iteratively with mentors and clinicians to refine the model until it meets the necessary requirements. At the same time, the controller or encoder will be modified to realise control of the robot hardware.

Once the model is finalised, the team will create a prototype to test its functionality. If time permits, the team will conduct a phantom study to further validate the design. The results of these tests will inform any necessary revisions to the device before it is ready for clinical use.

2.2 Workflow design

The team will mostly be following the Seldinger technique, which is a medical procedure used to safely access blood vessels and other hollow organs. The following is a brief description of the technique (refer to [5]):

- The desired vessel is punctured with a needle, with ultrasound guidance if necessary.
- A round-tipped guidewire is then advanced through the needle, and the needle is withdrawn.
- A cannula or catheter can now be passed over the guidewire into the vessel.
- After passing the cannula or catheter, the guidewire is withdrawn.

The preparation and order of the main steps will be the same as the Seldinger technique. The insertion parts will then be modified to include the robot system in the procedure.

First, the clinician sterilises themselves and the patient. The ultrasound probe is then placed on the area of interest, and the ultrasound image is displayed on a screen. The clinician finds the target point and inserts the angle for needle insertion on the image. The angle of insertion is usually 30 degrees, and the depth is around 2-3cm, but this will vary depending on the patient's anatomy. The target point coordinates and insertion angle will be transformed from the image frame to the actuator frame. The actuator will then perform the needle insertion. After ensuring the success of the needle insertion, the robot will insert the guidewire through the needle. The clinician will then remove the needle. Next, the robot will insert the catheter through the guidewire, and the clinician will stop the insertion when the guidewire and catheter reach the correct position. After finishing the insertion, the clinician will remove the guidewire.

By following this process, the clinician will only have to remove the needle and guidewire by hand, which is a much easier task than insertion. Additionally, the possibility of infection will be reduced because the clinician will touch less equipment.

2.3 Image guidance

The robot system will include an actuator to perform the insertion, a platform to connect with the Clarius C3 ultrasound probe, an interface to provide feedback to the clinician, and a mounting platform. The actuator may be either a lightweight robot arm or a motor with a linear driver. The feedback will be based solely on the ultrasound image, as it is the most common and reliable way to detect the

position of the needle. The images will be displayed to the clinician, who will determine the target point and insertion angle in the image coordinate. The coordinates will then be transformed from the image coordinate to the probe coordinate, and the probe coordinate and actuator coordinate will be registered or calibrated. This will enable the actuator to precisely control the movement of the needle to the desired location.

2.4 Interface

The interface could be a user-friendly software that shows real-time ultrasound images. The clinician will be able to virtually place a needle in the vein. The location and angle of the needle can be adjusted by the clinician. After the clinician confirms the location and angle of the needle, the information will be transferred to the actuator as described in Section 2.3. The interface also allows the clinician to pause or stop the insertion when needed

2.5 Possible challenges

The design of the proposed robotic system may be challenging for several reasons. One of the most significant difficulties is ensuring precision and accuracy of the robotic system in needle insertion, guidewire advancement, and catheter insertion procedures. The system would be provided with an emergency stop button for the clinician to take charge in case the robot moves farther than needed. The system must be able to navigate through the complex vascular anatomy of the jugular vein while avoiding possible complications, such as puncturing the carotid artery or the lung. Hence, the robot has to be designed for patients of all anatomy, gender, age, sex etc.

Furthermore, the primary motivation behind the design of the robotic system is to reduce risk of complications like infections by avoiding contact between the clinicians and the parts of the Catheterisation kit. Hence, our main challenge would be to design a robot with minimum mechanisms for the different procedures of needle insertion, guidewire advancement and catheter insertion. Additionally, the guidewire has to be held in place while the catheter is being inserted. In the absence of that, there is a possibility of the patient inhaling the guidewire, causing complications. We plan to keep this in mind while designing the mechanism.

3 Testing

Testing a robot designed for central line placement operation would typically involve several steps, including:

1. Design validation: Before building the robot, the design should be validated using computer simulations or models to ensure that it will be effective in performing the central line placement operation.

2. Functional testing: Once the robot is built, it should undergo functional testing to ensure that it can perform the necessary movements and actions accurately and reliably.

3. Performance testing: The robot should be tested in a laboratory or simulated clinical environment to ensure that it can perform central line placement accurately and consistently, as well as identify and respond to any issues that may arise.

Throughout the testing process, the robot's performance would be measured against established performance metrics, such as accuracy, precision, and speed. Any issues or problems that are identified during testing would be addressed and resolved.

4 Management Plan

The management plan is divided into five parts: a brief introduction of the mentors, team members and their responsibilities, deliverables, dependencies, and the timeline of the tasks.

4.1 Mentors

The mentors consist of:

- Dr. Axel Krieger (axel@jhu.edu)
- Lidia Al-Zogbi(lalzogb1@jhu.edu)
- Dr. Vinciya Pandian (vpandia1@jhu.edu)
- Dr. Mathias Unberath (unberath@jhu.edu)
- Wenhao Gu (wgu11@jhu.edu)

4.2 Team Members and Responsibilities

The team consists of:

- Kesi Liang (kliang19@jhu.edu)
  MSE BME Student, first-year
  Responsible for the registration of the robotic system w.r.t. ultrasound image and calibration of the ultrasound probe, software development, and system integration.
- Pranathi Golla (pgolla1@jhu.edu)
  MSE ME Student, first-year
  Responsible for the Kinematic design of the mechanism, 3D printing of the parts of the mechanism and motor control using Arduino.
- Xuanning Liu (xliu226@jhu.edu)
  MSE ME Student, first-year
  Responsible for the CAD model design of the robotic system, and the workflow development.

The team will also have some shared responsibilities, which are the design specifications, the prototype assembly, and testing.

4.3 Deliverables

The deliverables of the project are shown below in Fig. 3.

	Deliverables
Minimum	• Design document with the high-level and low-level specifications of the robotic central line placement system, which can perform needle insertion, guidewire advancement, and catheter advancement through the jugular vein. • CAD model of the robotic system.
Expected	• Prototype and functionality demonstration of the system, which can perform central line placement automatically with image guidance. • Documentation of the functioning of the system. • GUI for insertion site selection from the ultrasound images.
Maximum	• Experimental evaluation of the accuracy and safety of the system on phantoms. • Submission of the work to a peer-reviewed venue.

Figure 3: The minimum, expected and maximum deliverables of the project

4.4 Dependencies

The dependencies of the project are shown below in Fig. 4.

Dependency		Need	Status	Follow-up	Contingency Plan	Deadline
Prototyping/ Fabrication	3D printer and laser cutting	To do model prototype	Resolved	N/A	N/A	3/25/2023
	Ultrasound probe	Used as the sensor of the system	Resolved	Will be provided by Lidia	N/A	3/15/2023
	Hardware (Arduino board, motors, screws, and nuts)	To assemble the system	Partially resolved	Few parts already available; will purchase rest soon	Purchase new ones if necessary, or borrow from Prof. Axel Krieger's lab	3/25/2023
Software	Arduino IDE	For communication with the Arduino board	Resolved	N/A	Other team members' laptop	3/25/2023
	SolidWorks	To build CAD model	Resolved	N/A	Other team members' laptop	3/15/2023
	ROS	Simulate and control the robot system	Resolved	N/A	Other team members' laptop	3/07/2023
Testing	Lab space (B08G)	For testing	Partially resolved	Two team members have access; other member will request Ashley soon	Other team members' access	3/07/2023
	Testing equipment (catheter kits and phantom)	For testing	Partially resolved	Will request Dr. Vinciya Pandian soon	N/A	4/11/2023
Financial support		To purchase necessary hardware	Resolved	N/A	If insufficient, need to borrow hardware from other labs	3/25/2023

Figure 4: Dependencies

4.5 Timeline

The timeline is shown in Fig. 5.

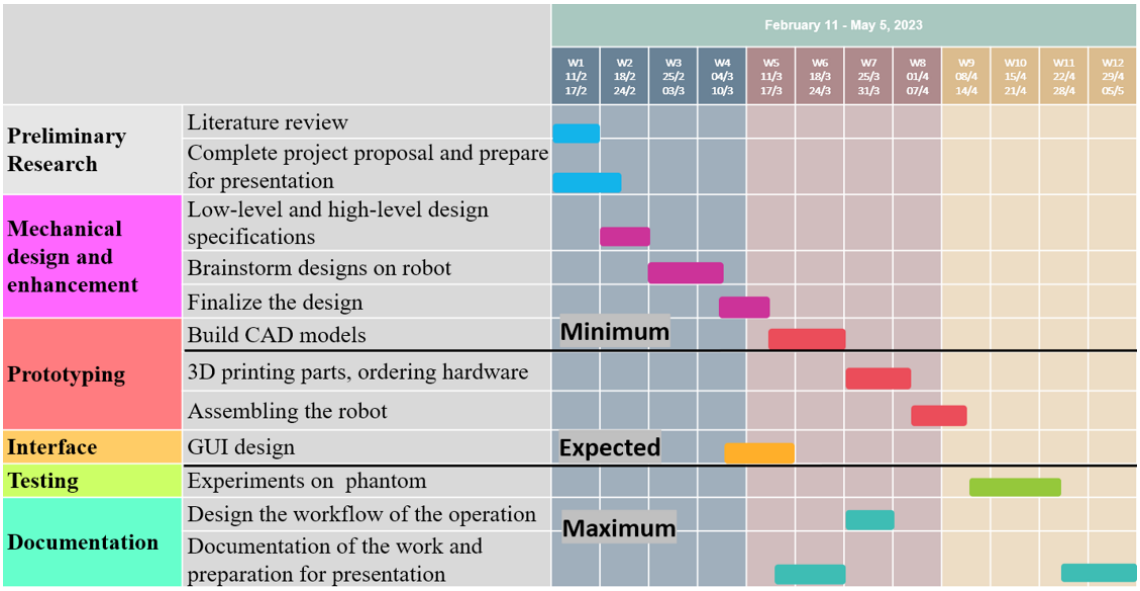

Figure 5: Timeline of the tasks

Backup plan:
The high level and low level design specifications are pre-requisite for all the later parts, so there is no back up plan for that. If the CAD model building is not completed on time, the team can still start to design the GUI and the operation workflow. If the phantom study could not be completed on time, the team can start to document the progress they have made.

4.6 Communication

- Meeting plan

  Mentor meeting:
  Time: Tuesday 10:00 - 11:00
  Location: Zoom or Hackerman 116
  Weekly meeting scheduled with Lidia Al-Zogbi and Wenhao Gu, Dr. Axel Krieger will attend the meeting biweekly

  Group meeting:
  Time: Thursday 10:00 - 11:00
  Location: Zoom or Hackerman 136
  Weekly meeting scheduled for three group members

- Communication platform

  Slack, Zoom, Overleaf, Dropbox, Email

References

[1] A. Tse and M. A. Schick, "Central line placement," in *StatPearls*, StatPearls Publishing, 2022.

[2] Y. Haddadin, P. Annamaraju, and H. Regunath, "Central line associated blood stream infections," in *StatPearls*, StatPearls Publishing, 2017.

[3] V. Chopra and I. Davidson, "Central venous access: Device and site selection in adults," in *UpToDate*, UpToDate Publishing, 2022.

[4] E. Cheung, M. O. Baerlocher, M. Asch, and A. Myers, "Venous access: a practical review for 2009," *Canadian Family Physician*, vol. 55, no. 5, pp. 494–496, 2009.

[5] J. R. Roberts and J. R. Hedges, *Roberts and Hedges' clinical procedures in emergency medicine E-book*. Elsevier Health Sciences, 2013.

[6] N. Zevallos, E. Harber, K. Patel, Y. Gu, K. Sladick, F. Guyette, L. Weiss, M. R. Pinsky, H. Gomez, J. Galeotti, *et al.*, "Toward robotically automated femoral vascular access," in *2021 International Symposium on Medical Robotics (ISMR)*, pp. 1–7, IEEE, 2021.

[7] R. D. Brewer and J. K. Salisbury, "Visual vein-finding for robotic iv insertion," in *2010 IEEE International Conference on Robotics and Automation*, pp. 4597–4602, 2010.

[8] A. I. Chen, M. L. Balter, T. J. Maguire, and M. L. Yarmush, "Deep learning robotic guidance for autonomous vascular access," *Nature Machine Intelligence*, vol. 2, no. 2, pp. 104–115, 2020.

[9] Brattain LJ, Pierce TT, Gjesteby LA, Johnson MR, DeLosa ND, Werblin JS, Gupta JF, Ozturk A, Wang X, Li Q, Telfer BA, Samir AE, "AI-Enabled, Ultrasound-Guided Handheld Robotic Device for Femoral Vascular Access," *Biosensors*, vol. 11, no. 12, 2021.

[10] R. D. Brewer, "Improving peripheral iv catheterization through robotics: From simple assistive devices to a fully-autonomous system," 2015.