

Introduction: The field of medical robotics has seen rapid growth in the past decade and is causing a major shift in clinical therapy. In particular, robots have made a significant impact in laparoscopy, orthopedic surgery, and neurosurgery. However, the most ubiquitous clinical procedure in the US, venipuncture, lacks a robotic solution, and phlebotomists continue to rely on manual techniques to access the venous bloodstream. These techniques require complex visuomotor coordination, and the success rate is highly dependent on clinician skill and experience. The challenges of venipuncture are also compounded in pediatric, geriatric, and obese populations where the success rate is highly dependent on patient physiology. Consequently, venipuncture is the leading cause of hospital complications in the US, where 200 million failed procedures are reported to occur each year. This high failure rate incurs an annual cost of \$4.7 billion to the US healthcare system. To combat these problems, we have developed an automated image-guided venipuncture robot with >95% first-stick accuracy, that performs the procedure in <90 sec. The device couples optical and acoustic imaging with a 3 degree-of-freedom (DOF) gantry system and a 4 DOF manipulator arm to guide the needle into the desired injection site. This paper focuses on the robotics of the device, in particular, the kinematics and control system architecture of the needle manipulator.

Methods: Considering several design requirements for the robotic arm, including size (<12 cubic cm), weight (<0.4 kg), and precision to cannulate 1-3 mm diameter veins, we designed a 2 link, 4 DOF manipulator arm. Direct drive actuation was selected for 3 DOF, and a rack and pinion gearing system was chosen for the linear injection motion. Using a desktop 3D printer, all custom designed linkage parts were printed using acrylonitrile butadiene styrene (ABS). The full venipuncture robot is illustrated in Fig. 1, with the manipulator arm highlighted in the top left. Power and torque calculations governed the motor selection, and the derived open loop transfer functions served as plant models for the closed loop control system. Employing, custom motor drivers, encoder-based PID position control was used to minimize errors between the desired and actual joint positions. Manipulator joint kinematics allowed us to correlate the joint angles with the 3D Cartesian coordinates of the needle tip in real-time.

Results and Discussion: To validate the controllability and repeatability of each joint in the robot arm, simulation and experimental frequency response testing was performed at various sine wave frequencies (22.5, 30, 45, 90, 180 deg/s). Simulations were done in Simulink (MatLab), while real-time experiments were conducted in LabVIEW (National Instruments). The resulting experimental root mean square errors for 45 deg/s frequency (corresponding to 7.5 rpm—our desired joint rotation speed) were 0.989 ± 0.053 , 0.893 ± 0.043 , and 1.153 ± 0.001 deg for each link in the arm – M1, M2, and M3 (as labeled in Fig. 1) respectively. Simulations yielded slightly better results; however, the computational model did not incorporate friction or changing inertias. The corresponding simulation root mean square errors were 0.018, 0.002, and 0.001 deg for M1, M2, and M3 respectively. These results demonstrated that the robot arm is sufficiently precise to cannulate 1-3 mm target veins.

Conclusions: In conclusion, a novel robotic manipulator arm was designed, implemented, and programmed for use in an automated venipuncture device. The control architecture of the arm was validated computationally and experimentally, demonstrating that this sub-system of the device is robust, controllable, and repeatable. Future studies will focus on integrating the robotic and imaging controls to perform *in vitro* tests on customizable tissue phantom arm models, as well as *in vivo* experiments on rat tail veins. Our next goal is to refine the current prototype for first-in-human clinical testing, aiming to bring the venipuncture device to market within the next 3 years. Once translated, this technology has the potential to improve the standard of care in pediatrics, geriatrics, diagnostic facilities, as well as emergency and military use.

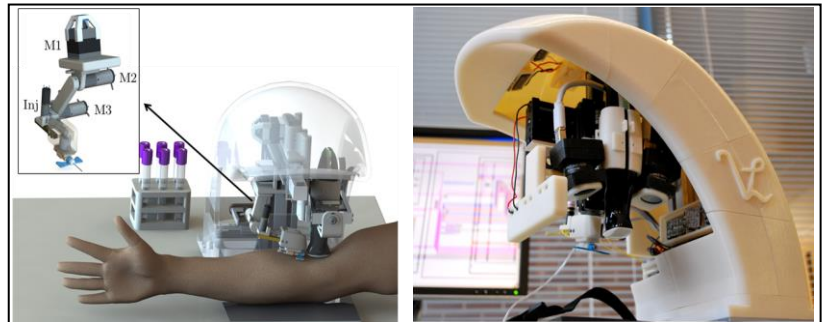


Figure 1: Left) Design of a blood draw procedure using the venipuncture robot with the manipulator arm highlighted in the top left (labels correspond to each motor). Right) Physical prototype