Portable Robot for Autonomous Venipuncture using 3D Near Infrared and Ultrasound Guidance

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Introduction: Performed over 1 billion times each year, venipuncture is the most common invasive procedure in the U.S. While a routine step in most clinical procedures, complications often arise in pediatric, geriatric, obese, and chronically-ill patients, for whom visualizing the veins, accurately inserting the needle, or successfully drawing blood may be challenging. In these difficult cases, the safety and success rate of venipuncture is highly dependent on patient physiology and practitioner experience, and failures have been estimated to incur a $4.7B annual cost to the U.S. healthcare system. These problems have recently driven the development of commercial imaging devices aimed at enhancing vein visibility; however, these devices leave the needle insertion – the ultimate determinant of safety and success – to the clinician. Image-guided robotic systems have demonstrated clinical efficacy for many invasive surgical routines, but have yet to be translated for venipuncture. Here we aim to develop a portable, automated, robotic device that ensures rapid, single-stick venous access while completely removing human contact with the needle.

Materials and Methods: The device aims to mitigate patient and practitioner variability by autonomously drawing blood and delivering intravenous fluids. To do this, the device combines real-time vein imaging, computer vision software, and a miniaturized 7 degrees-of-freedom (DOF) robot that controls the needle. The device operates by computing the 3D position of an autonomously selected peripheral vein and precisely directing a needle into the vein. The main components of the device include: 1) a 3D near infrared imaging system; 2) image analysis software for vein segmentation and stereo reconstruction; 3) a vein selection algorithm built on skeletal graph matching; 4) a USB ultrasound probe to confirm blood flow; 5) a 3 DOF gantry system that positions the ultrasound probe and the needle manipulator; and 6) the 4 DOF manipulator arm to guide the needle into the desired injection site. The current prototype has been miniaturized substantially (measuring ~12 cubic inches) and can be placed on a bench top or transported to the patient's bedside. A touchscreen user interface, on-board blood collection unit, and automated needle loading/disposal system are currently being developed.

Results and Discussion: Proof-of-concept for the device has been demonstrated *in vitro* and in human imaging studies, summarized here[35]. In the human study, we evaluated the near infrared and ultrasound imaging system on 101 patients and observed a two-fold increase in the percentage of detected forearm veins compared to traditional visualization by a trained phlebotomist. We next tested the device on a commercial phlebotomy training arm and observed 100% first-stick accuracy in 100 trials with a mean needle tip position error of 0.35 mm. Finally, we assessed the full automated procedure on customized phantoms that combine to model the optical, acoustic and mechanical properties of human skin over a broad demographic range. Across 288 different phantoms, the device demonstrated 98% first-stick accuracy and a mean completion time of 52 sec, compared to 79% accuracy and 135 sec mean completion time by the phlebotomist. In addition to the above studies, *in vivo* animal trials and IRB-approved first-in-human testing have been initiated at Rutgers University.

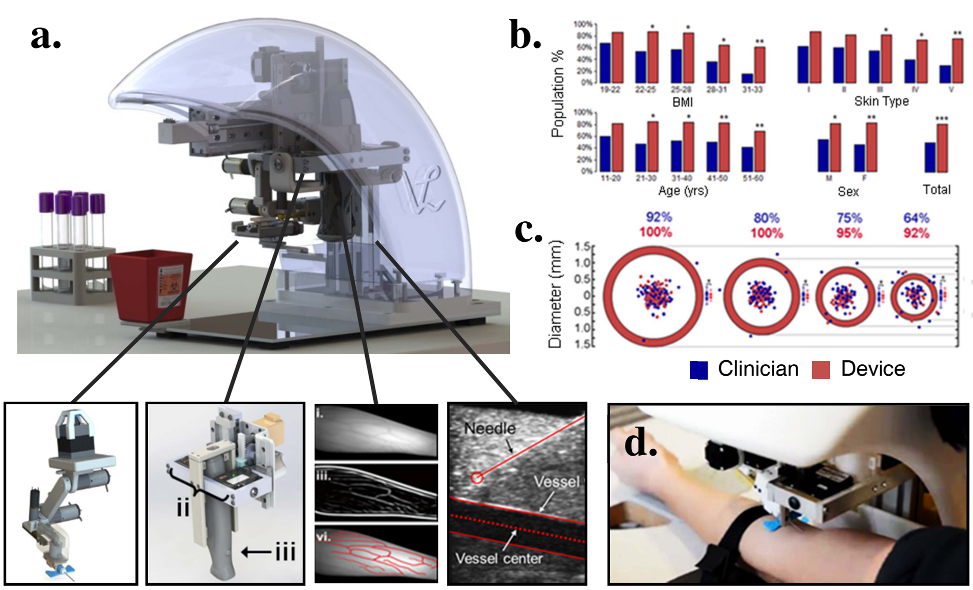

Figure 1. (a) *Top:* Computer render of device subsystems. *Bottom: i,* 4 DOF articulated manipulator arm; *ii,* near IR imaging system; *iii,* portable ultrasound system; *iv,* vein image segmentation; *v,* B-mode needle, vein, and blood flow detection. **(b)** Improved vein detection in 101 patients compared to a phlebotomist. **(c)** Improved accuracy on 288 customized tissue phantoms compared to a phlebotomist. **(d)** IRB-approved first-in-human device testing initiated at Rutgers University.

Conclusions: This work demonstrates progress toward developing a device that performs blood draws and other IV procedures in situations where medical professionals are unable to successfully access the veins. Our goal is to complete animal and human testing, aiming to bring the device through FDA approval and to market in 2017. Once translated, the device has the potential to improve the accuracy, safety, and speed of venous access in major hospitals and diagnostic facilities, as well as in emergency and military use.