In-human Evaluation of a Robotic Venipuncture Device for Performing Blood Draw Procedures

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Introduction: Venipuncture, the process of using a medical needle to obtain venous access for either blood draw or intravenous (IV) therapy, is one of the most ubiquitous medical procedures performed worldwide. However, difficulties in obtaining venous access can cause even simple venipuncture procedures such as blood draws to become prolonged and costly to healthcare facilities, requiring additional personal or alternative rescue pathways. Our lab is involved with developing a robotic hand-held device that is capable of both autonomously identifying and cannulating suitable vessels for venous access quickly and accurately, eliminating the possibility of human error and alternatives venous pathways [1]. Here, we present the robotic needle placement accuracy results of an IRB approved human study of a semi hand-held robotic venipuncture device tasked with drawing blood from patient's peripheral forearm veins.

Materials and Methods: This IRB approved human study involved tasking the venipuncture device to robotically insert an attached 25G needle into a patient's peripheral forearm vessel and draw 5ml of blood for point-of-care blood analyzing. A total of 33 random patients over 18 years of age were recruited for this study. An attending physician prepped patients for blood draw and visually identified suitable vessels in the upper forearm area for needle insertion by the device. The device featured a Telemed linear 2D ultrasound imaging probe in short-axis orientation to determine the vessel depth and alignment relative to the device's needle trajectory path.

Results and Discussion: The results in figure 1 depict the venipuncture device's needle tip placement accuracy. Figure 1.A shows the venipuncture device positioned over the patient's upper forearm with blood being drawn into a blood collection tube. The needle tip placement accuracy (Figure 1.B) is the difference between the actual and desired position of the needle tip in the patient's vessel. Needle tip final position was determined visually from the ultrasound image stream. The needle tip placement was considerably low, with an RMS error 0.23±0.17mm. Force feedback profiles were also recorded along the needle axis during insertion, with average an average puncture force of 1.048 N.

A B

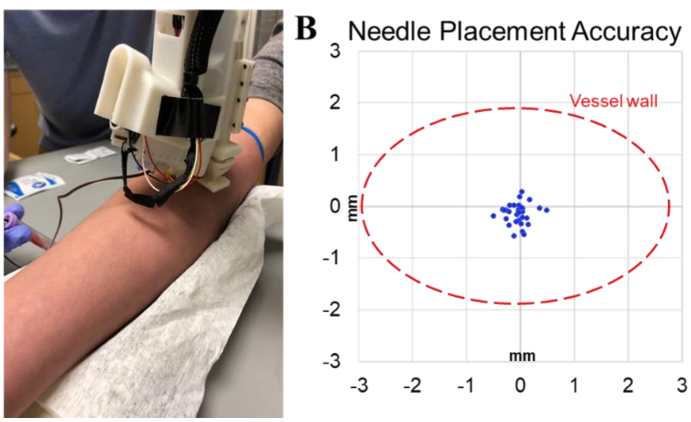

Figure 1: Device and placement error from human study. (A) Device set-up over patients' upper forearm and blood flow into blood collection tube. (B) Needle tip position (blue dots) versus desired position (0,0) during human study (n=27). Average patient vessel major and minor axis size was 5.79 and 3.77 mm, respectively (shown as red ellipse).

Conclusions: An IRB approved human study was conducted to evaluate the efficacy and accuracy of a robotic venipuncture device for drawing blood from peripheral forearm veins. The device demonstrated a high needle tip placement accuracy when inserting a 25G needle towards the target vessel center, with an RMS error of 0.23±0.17mm. Future work will be involved with further miniaturization, developing additional features for true hand-held use, and implementing machine learning algorithms to optimize device automation and improve use for difficult venous access patients.

Acknowledgements: Biotechnology Training Program: NIH T32 GM008339 & NIH R01 EB020036R01 EB020036.

References: [1] M. Balter, J. Leipheimer, A. Chen, A. Shrirao, T. Maguire and M. Yarmush, "Automated end-to-end blood testing at the point-of-care: Integration of robotic phlebotomy with downstream sample processing," Technology (Singap World Sci), vol. 6, no. 2, pp. 59-65, 2018.