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Design, Fabrication and Initial Examination of a Vein Visualizing Novel Ultrasound Prototype Device for Use in Cannulation Assistance

New Technology and Applications in Vascular Access

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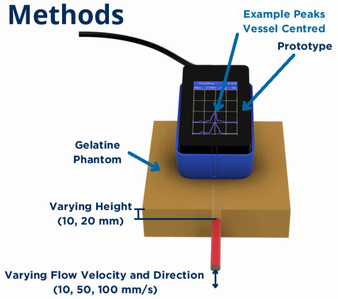
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Introduction

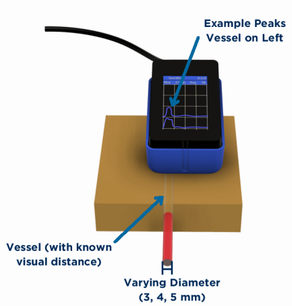
Cannulation is one of the fundamental procedures underpinning modern medical care, with **60-90% of inpatients requiring a cannula** (1). Clinicians typically identify suitable veins for cannulation through visualization and palpation, leading to a **high failure rate of up to 40%**,(2,3) with **>84%** of these failures due to an **inability to visualize or palpate the vessel** (4). Effective technology (ultrasound) has significant adoption barriers such as high training requirements, poor usability and accessibility. We have developed a novel ultraportable, low-cost and easy-to-use ultrasound-based vein visualization device, detecting well-perfused veins at depth and providing coronal visualization of vein pathways to aid in cannulation. This study aims to demonstrate usability, *in vitro* and *in vivo* performance of a prototype in finding veins compared to standard techniques.

In vitro Accuracy Methods

Methods



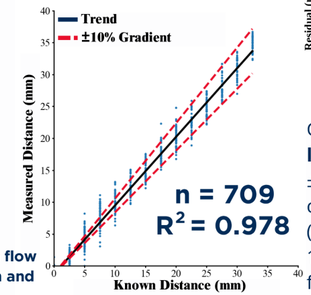
Measurements were performed on 18 differing tissue-mimicking blood flow phantoms



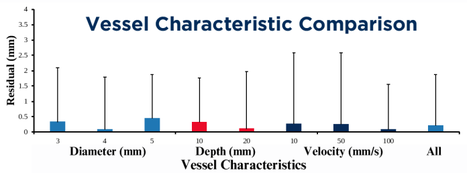
The prototype was translated across a flow phantom with a known vessel location and direction

Results

Average Difference



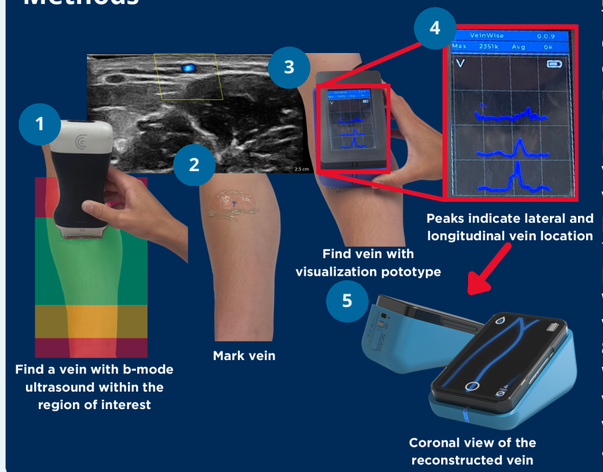
Vessel Characteristic Comparison



Our phantom experiments showed the **prototype's locational accuracy** to be **-0.160mm** (STD ±1.627mm) (97.8% agreement to the known distance, p<.001), across variations of vein diameter (3-5mm), depth (10-20 mm), and velocity (10-100mm/s) to typically cannulated veins in the forearm.

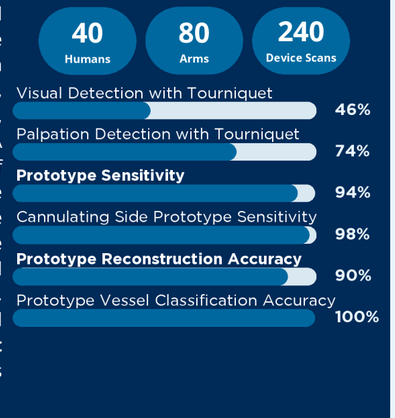
In vivo Human Sensitivity

Methods



Results

There was a **high overall detection sensitivity**, and **coronal view localization** and **reconstruction sensitivity**. The prototype **detected** veins with poor naked eye visibility **(91%)**, veins with no palpability **(83%)**, veins of self-identified DIVA patients **(87%)**, and veins of tanned-to-dark skin tone participants **(95%)**. The prototype was able to reconstruct these veins with an **88%, 80%, 94%,** and **86% accuracy**, respectively. Within successfully reconstructed veins, the sensitivity to **correct vessel classification** (vein vs artery vs tissue noise) was **100%.**

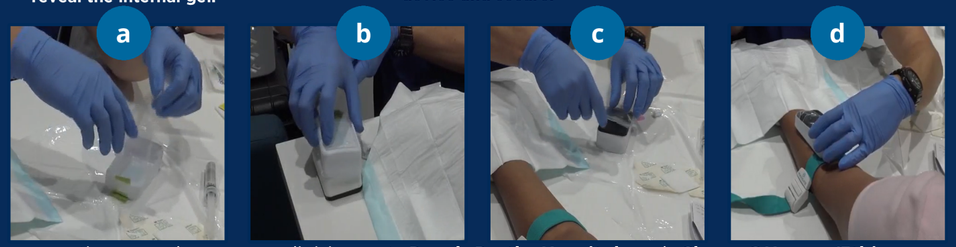


Usability Protocol

Place all sterile objects onto the sterile field. Clean hands and don gloves. Peel back the internal layer #1 to reveal the internal gel.

Pick up the device with the sheath and place it into the sterile field. Pull the top layer, tab #2, over the device and secure.

Peel tab #3 to reveal the external sterile gel. You are now ready to use the device for vascular access assistance.



Nine consenting vascular access clinicians at **Royal Perth Hospital** and **Chemo@Home (Ethics approval: RGS0000005480)** were recruited for usability evaluations, focusing on the ease of use of our device and adherence to the proposed sterile workflow. The usability study found that **100% of users completed the device workflow in a sterile manner** with minimal assistance and training and **90% agreed the user interface (coronal visualization) would aid** in improving first pass cannulation.

Limitations

There are **limitations** in the study procedures as the sensitivity was recorded after finding a suitable vein with ultrasound, introducing bias. The ultrasound operator was a product engineer, not a trained clinician. The device is currently in prototype phase and not at a design freeze with further optimisation to improve accuracy, form factor, user-interface and sensitivity underway.

Conclusion

We anticipate that as our device continues to be developed, it will be an extremely useful tool for clinicians to use, giving the ability to **detect and view well-perfused veins** at **depth**, providing the **coronal view of vein pathways** in an **ultraportable** and **easy to use user-interface**. The results illustrate a **104% and 25% increase** in ability to detect veins compared to **visualization and palpation**, respectively. We have demonstrated preliminary data suggesting **high sensitivity and specificity of vein finding** and the feasibility of developing this **simplified** and **low-cost solution**. Future work will focus on **larger clinical validation** and **usability studies** to demonstrate how the **functional performance, intuitive user interface** and **sterile workflow** of the device can facilitate **ease of use**, **widespread adoption** and **reduced first pass insertion failure.**

References

1. Platt V, Osenkarski S. Improving Vascular Access Outcomes and Enhancing Practice. J Infus Nurs. 2018 Nov;41(6):375–82.
2. Keogh S, Mathew S. Peripheral intravenous catheters: A review of guidelines and research. Sydney: Australian Commission on Safety and Quality in Health Care; 2019.
3. Kleidon TM, et al. Implementation of a paediatric peripheral intravenous catheter care bundle: A quality improvement initiative. J Paediatr Child Health. 2019 Oct;55(10):1214–23.
4. van Loon FHJ, et al. The Modified A-DIVA Scale as a Predictive Tool for Prospective Identification of Adult Patients at Risk of a Difficult Intravenous Access: A Multicenter Validation Study. J Clin Med. 2019 Jan 26;8(2).