Non-Fluoroscopic 3D Image Guidance for PAD Interventions: An Initial Preclinical Study in Five Vascular Phantoms

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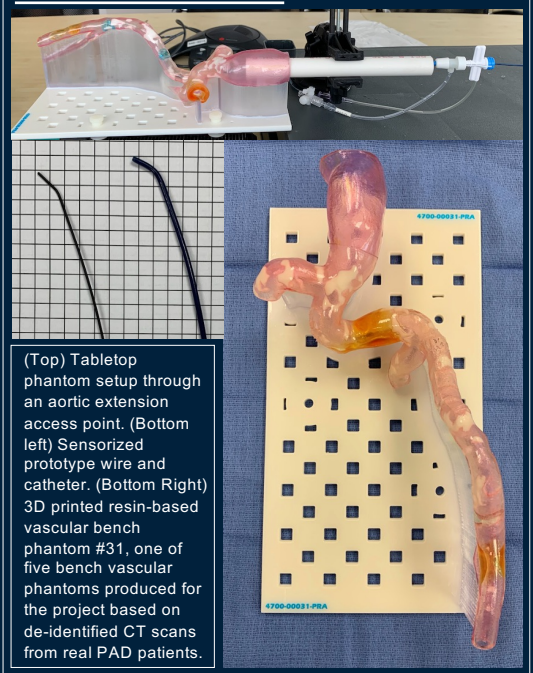
Purpose

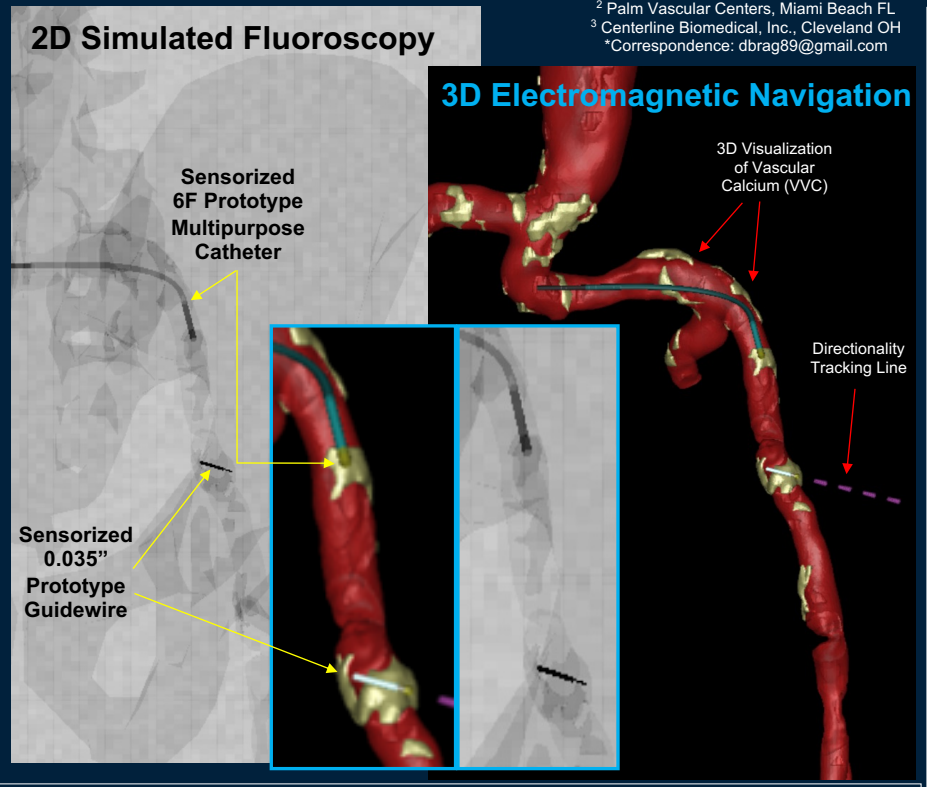
Assess the potential role of utilizing a novel 3D electromagnetic navigational system as an adjunct to conventional 2D fluoroscopy for patients with peripheral arterial disease (PAD).

Materials and Methods



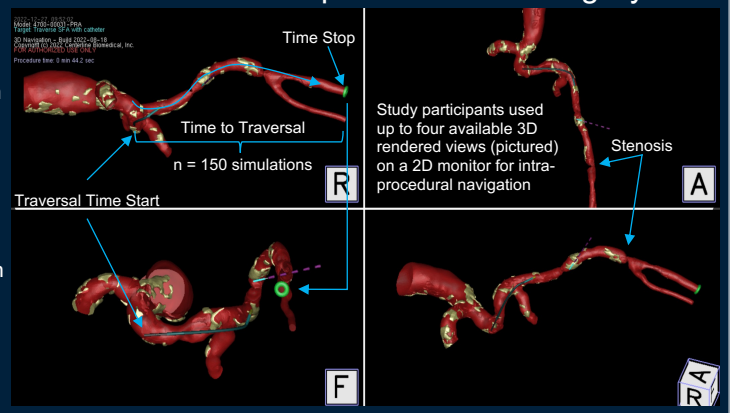
(Top) Tabletop phantom setup through an aortic extension access point. (Bottom left) Sensorized prototype wire and catheter. (Bottom Right) 3D printed resin-based vascular bench phantom #31, one of five bench vascular phantoms produced for the project based on de-identified CT scans from real PAD patients.

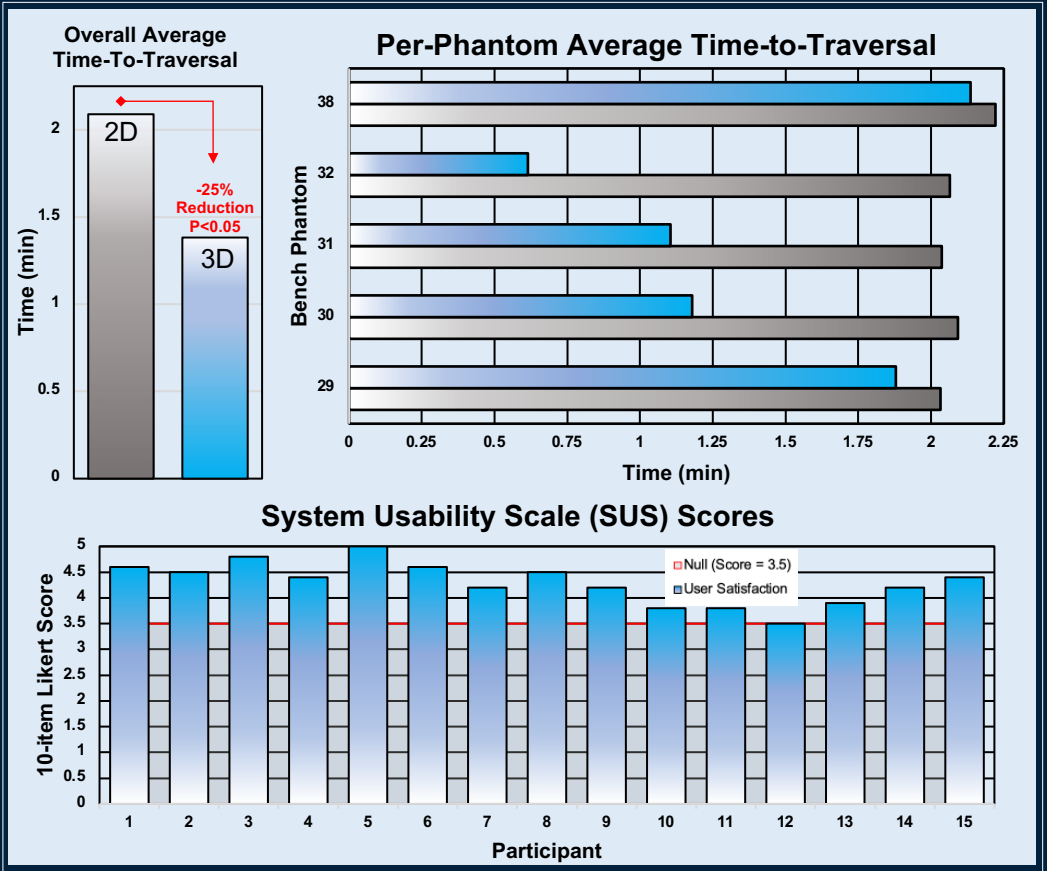
Using a prototype 6Fr catheter and guidewire with integrated tracking sensors, 15 interventionalists individually navigated each of the 5 vascular phantoms to selectively access a predetermined target using both the non-fluoroscopic 3D platform as well as a simulated 2D fluoroscopy-like imaging and the times were recorded. Participants then completed a 10-item standard system usability scale (SUS) Likert questionnaire (score 1-5, 5=strongly agree) evaluating system usability and user satisfaction, which were subsequently compared to a reference mean score >3.5 corresponding to a high degree of user satisfaction. A one-tailed statistical t-test was used to compare mean phantom traversal times and questionnaire scores.



Real-Time Multi-3D Rendered Intraoperative Positioning System

Investigational software was developed based on a commercially-available aortic electromagnetic navigation platform (IOPS, Centerline Biomedical, Inc., Cleveland, OH), with patient-specific structural maps of vessel lumens and calcification.





Results

Study participants demonstrated a statistically significant reduction in the time required to navigate the bench phantoms, performing 0.7min (42sec) faster on average ($p < 0.05$) using the non-fluoroscopic 3D image guidance vs. simulated 2D fluoroscopy, corresponding to a 25% average relative reduction in time to phantom traversal. Participants also reported sufficiently high levels of usability satisfaction with the new platform, with a mean SUS score of 4.29 ($p < 0.05$), exceeding the acceptance criterion of mean SUS ≥ 3.5.

Conclusion

This small preclinical phantom study highlights the future potential of Centerline Biomedical's non-fluoroscopic 3D image guidance technology as a possible adjunct to conventional 2D fluoroscopy for highly precise visualization and navigation of PAD-afflicted vasculature. Future studies are planned to further explore and confirm the proposed benefits of this system over traditional fluoroscopy for PAD interventions including reductions in ionizing radiation usage, iodinated contrast administration, procedure times, and healthcare costs.