STUDY SUMMARY

TRACKABILITY OF A HIGH-STRENGTH THROMBORESISTANT HYDROGEL CATHETER: AN IN VITRO ANALYSIS COMPARING VENOUS CATHETER FORCES IN A SIMULATED USE PATHWAY

ACCESS VASCULAR

LeRoy, K. J., & Donahue, D. T. (2023). Trackability of a high strength thromboresistant hydrogel catheter: An In vitro analysis comparing venous catheter forces in a simulated use pathway. Journal of the Mechanical Behavior of Biomedical Materials, 1056070.

Objectives

This study investigated the surface and frictional properties of a HydroPICC® device constructed of a novel, inherently lubricious bulk hydrogel. Investigators posited that these materials would lower the forces required to advance and retract the HydroPICC® devices and that the measured forces are significantly lower than those of two commercially available PICCs made of conventional thermoplastic polyurethane.

Materials & Methods

- The three 4 Fr PICC devices that were evaluated in the in vitro trackability testing were HydroPICC® (Access Vascular, Inc.), PowerPICC™ (Becton Dickinson and Company), and BioFlo™ PICC (AngioDynamics).
- Quantification of the trackability and pushability of the PICC devices were evaluated in an in vitro test tracking pathway in this study.
- The tracking pathway is an established model designed to represent tortuous physiological vasculature.
- Testing was performed at Machine Solutions, Inc. using an established Interventional Device Testing Equipment (IDTE) system to track a catheter through a test fixture constructed according to American Society for Testing and Materials (ASTM) standard F 2394–07.[1]
- Six replications of the experiment were run with a fresh catheter used for each replication. Each device was hydrated with normal saline for 5 min prior to testing.
- A guidewire was positioned through the pathway and clamped distally. The test catheter was then manually advanced to the desired start position.
- The system was then set up for an insertion distance of +45.5 cm, and a retraction distance of −45.5 cm at 100 cm/min.
- The system was also maintained at physiological conditions (deionized water at 37 ± 2 °C) for the duration of the test sequence.

Results

- A statistically **significant decrease in the maximum insertion, maximum retraction, and average force was observed between the PowerPICC™ device and the HydroPICC® device**, as well as between the BioFlo™ PICC and the HydroPICC® device.
- The HydroPICC® device was observed to have a **90% reduction in the average tracking force over BioFlo™ PICC and an 84% reduction in the average tracking force over PowerPICC™.**

	Max Insertion Force	Max Retraction Force	Average Force
HydroPICC®	12.34 (SD 3.51) g	5.696 (SD 0.628) g	0.718 (SD 0.476) g
BioFlo™ PICC	175.0 (SD 47.4) g	80.3 (SD 28.3) g	7.14 (SD 2.47) g
PowerPICC™	104.8 (SD 25.8) g	56.4 (SD 10.1) g	4.47 (SD 1.28) g

*Mean results (n = 6 per device type) of the in vitro trackability testing for three PICC devices (HydroPICC®, PowerPICC™ and BioFlo™ PICC)

1. Ramli et al., 2018. Design of a modular testing platform for the handling and study of endovascular devices. 2018 IEEE-EMBS Conference on Biomedical Engineering and Sciences (IECBES) (2018), pp. 255-258, 10.1109/IECBES.2018.8626628

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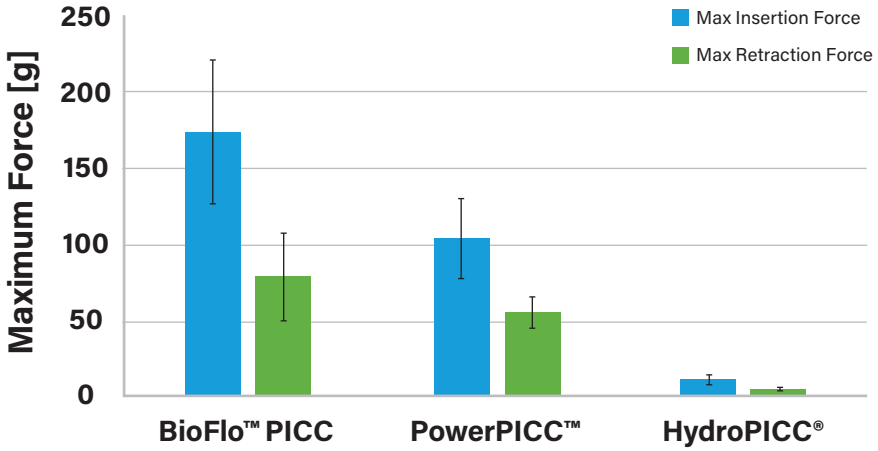
Discussion

- The HydroPICC® is comprised of a unique physically cross-linked PVA hydrogel structure with large extended hydrophilic polymer chains that provide a lubricious super-hydrophilic surface.
- The HydroPICC® device was observed to exhibit a statistically significant lower insertion and retraction force compared to both the PowerPICC™ and BioFlo™ control devices based on an unpaired, two-sided t-test used in commercially available PICC devices.
- The HydroPICC® was also found to exhibit a statistically significant decrease in average force when compared to both PowerPICC ($P < .001$) and BioFlo PICC ($P = .001$).
- Clinical studies are needed to demonstrate how the reduced insertion and retraction forces measured by the HydroPICC® in the simulated use condition translate to 'Ease of Insertion' scores and clinical outcomes such as reduced potential for vessel wall injury.



Plot of the average maximum insertion force and retraction force for BioFlo PICC, PowerPICC, and HydroPICC. Error bars denote one standard deviation.

Conclusion

- The novel lubricious hydrogel material significantly reduces the force required to insert, advance, and remove vascular access devices compared to polyurethane in a simulated vascular model.
- The lower force required to place the hydrogel VADS may reduce vessel damage during insertion and removal events compared to polyurethane-based devices.
- While clinical benefits of these novel devices have been demonstrated,[2,3] additional clinical trials are needed to determine whether the differences in frictional properties between conventional VADs and HydroPICC® devices translate into improved clinical outcomes (ie, Reductions in vascular injury, catheter failure, and decreased rates of infections).

Disclosures: Kristen J. Leroy and Daniel T. Donahue are employees at Access Vascular Inc. Investigation was sponsored by Access Vascular Inc.

2. Bunch, 2022. Retrospective assessment of midline catheter failures focusing on catheter composition. J. Infusion Nurs., 45 (5) (2022), pp. 270-78, 10.1097/NAN.0000000000000484.
3. Moureau, 2022. Integrative review: complications of peripherally inserted central catheters (PICC) and midline catheters with economic analysis of potential impact of hydrophilic catheter material. Int J Nurs Health Care Res, 5 (10) (2022), p. 17, 10.29011/2688-9501.101347.

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