Innovation of a Neonatal Peritoneal Dialysis Catheter to Expand Dialysis Capabilities for Critically Ill Neonates in Low- and Middle-Income Countries
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Abstract

The lack of peritoneal dialysis (PD) catheters designed explicitly for neonates creates significant challenges in the provision of neonatal peritoneal dialysis. High resource settings can circumvent this limitation by resorting to alternative extracorporeal dialysis methods. However, low resource settings (LRCs), PD remains the preferred dialysis modality, and the use of off-label catheters for PD results in complications such as omental wrapping and occlusion. This study introduces a novel catheter design featuring a multi-diameter side port configuration and a helical geometry. Through numerical simulations, we found an optimal multi-diameter side port configuration and experimentally evaluated the catheter performance to mitigate occlusion and omental wrapping. We demonstrated that our catheter outperforms a commonly utilized pigtail catheter with same-sized diameter side ports. The catheter is intended to be placed at the bedside to perform renal replacement therapy (RRT) for neonates in low resourced settings.

Computational Fluid Dynamics Analysis

We compared the fluid flow through each side port of a commercially available catheter used at bedside for temporary PD with our novel multi-diameter side port configuration as shown in **fig. 1a**.

Benefit:

Our multi-diameter side port configuration aims to reduce the high-pressure zone created at the two proximal side ports **(fig. 1b)** by redistributing the volumetric flow equivalently across all side ports **(fig. 1c)** to minimize occlusion.

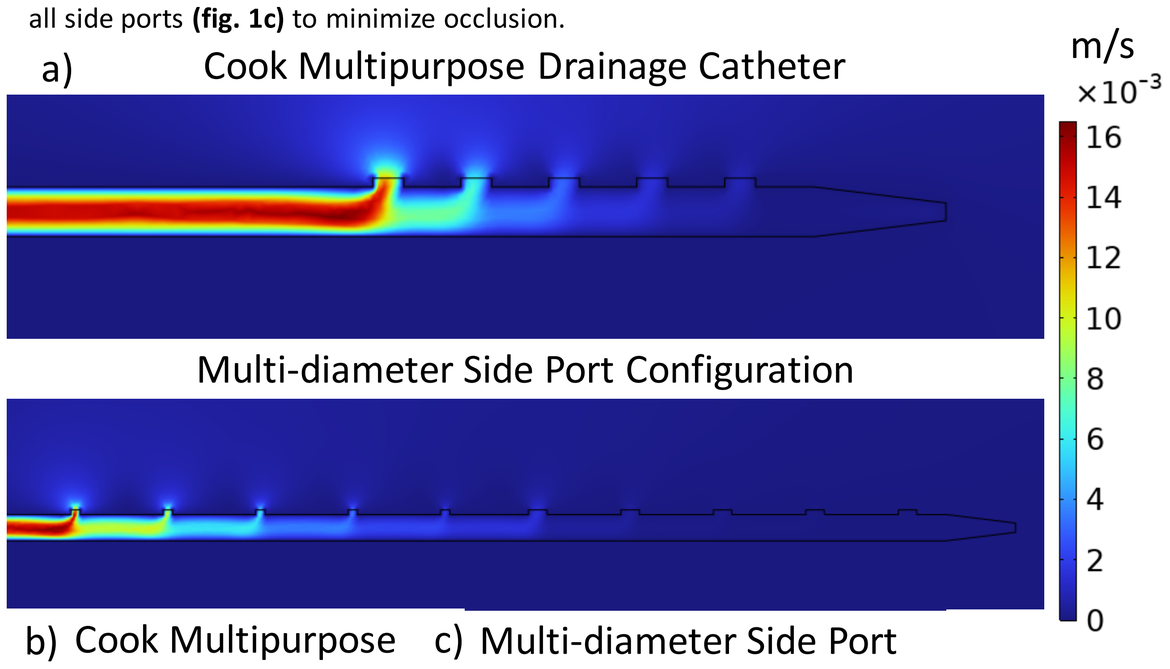


Figure 1. a) Numerical simulation of flow through side ports in control and experimental catheters. b) Percent of volume drained through each side port of control catheter. c) Percent of volume drained through each side port of experimental catheter.

Catheter Manufacturing

Our novel catheter used in this study was manufactured following the procedure in **fig. 2** using a custom-made mold to shape the distal end of the catheter into a helical geometry.

The Cook Multipurpose Drainage catheter and our novel multi-diameter side port configuration and helical shaped catheter were evaluated in two experimental setups to test for two common occlusion complication during PD; fibrin clot occlusion and omental wrapping.

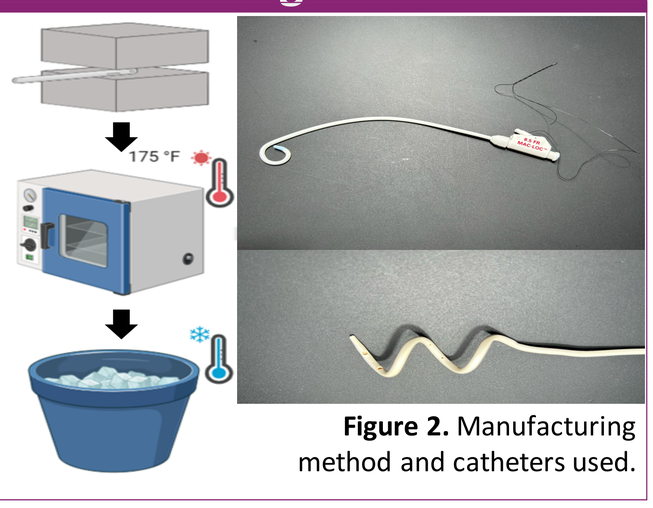
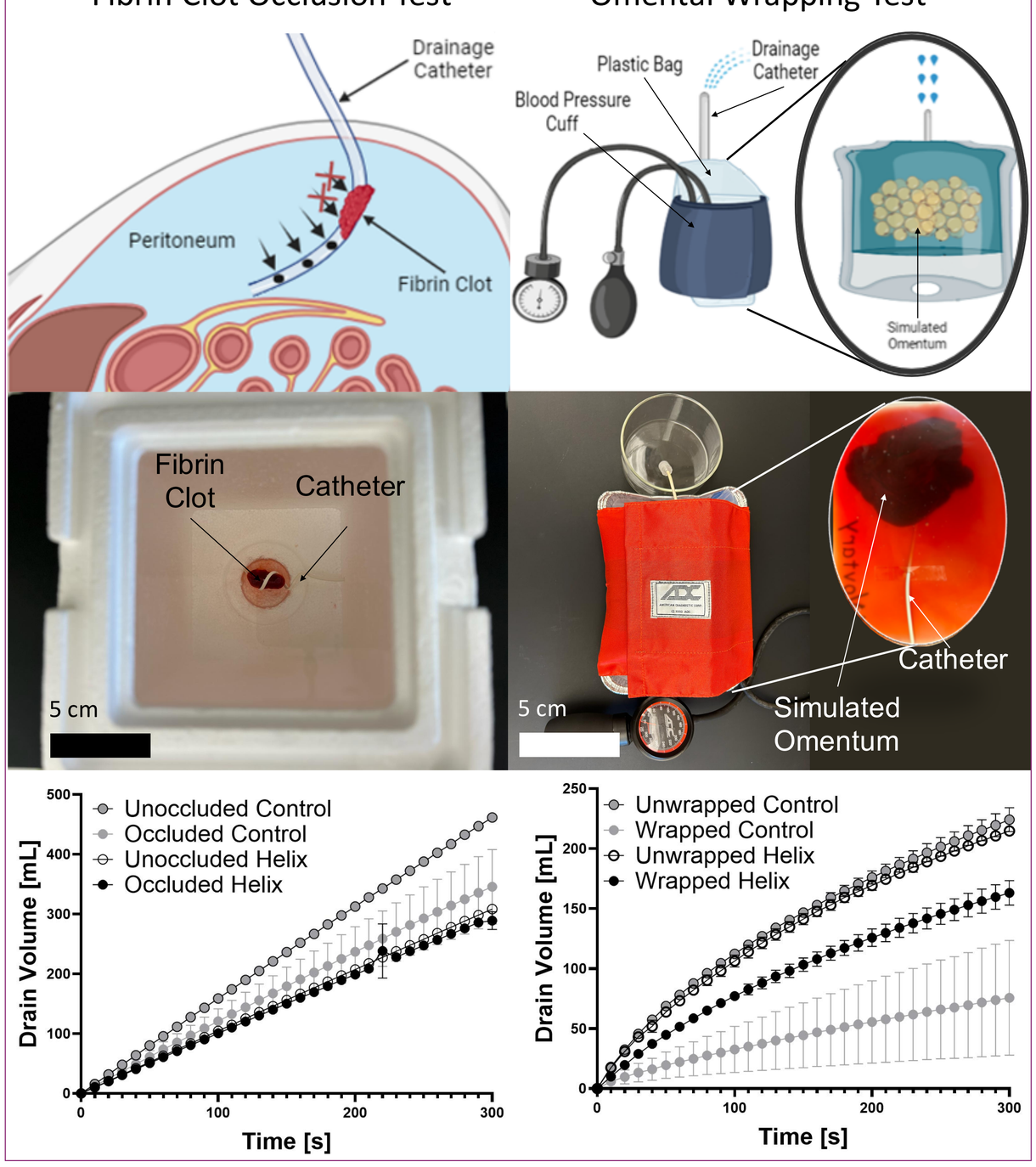


Figure 2. Manufacturing method and catheters used.

Experimental Evaluation

We evaluated the test catheter's ability to prevent fibrin clot occlusion and omental wrapping. Each experiment schematic, experimental setup, and result is presented in its corresponding column in the figure below. A fibrin clot analog was placed proximal to the catheter side port to induce occlusion and a simulated omentum was wrapped around the catheter to simulate wrapping. The drain volume was measured and presented in the line graphs below.

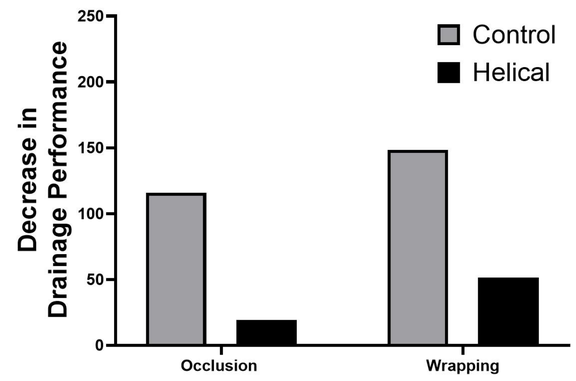


Discussion

The difference between the occluded and unoccluded test catheter indicates the impact of occlusion on the catheter.

The data in the bar graph show there was a great difference for the control catheter in both situations while our novel helical catheter was barely affected in both situations.

The experimental data confirms that our proposed design effectively avoids fibrin clot occlusion and omental wrapping.



Conclusion

In conclusion, the innovative design featuring helical geometry and 10 side ports in the neonatal PD catheter demonstrates promising potential to address common mechanical malfunctions, such as occlusion and omental wrapping. Our experimental findings underscore the importance of this design in mitigating complications, paving the way for enhanced peritoneal dialysis outcomes in neonates. Further studies and clinical validations are warranted to validate the practical application of this novel catheter design.

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