IN-SILICO REPLACEMENT OF SINGLE-LUMEN CANNULA BENCH TESTING ACCORDING TO ISO 18193:2021

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Introduction

Cannula systems are essential for extracorporeal membrane oxygenation (ECMO) allowing adequate blood flow. To replace the costly bench testing for single-lumen cannulas (SLCs), we develop a validated in-silico replacement.

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Materials and Methods

The ISO 18193:2021 standard describes three main bench tests for SLCs: pressure drop (PD), blood cell damage, and collapse resistance. We present a computational fluid dynamics (CFD) model of the PD test based on our novel Smoothed Particle Hydrodynamics (SPH) framework able to capture turbulent characteristics like Large Eddy Simulations.

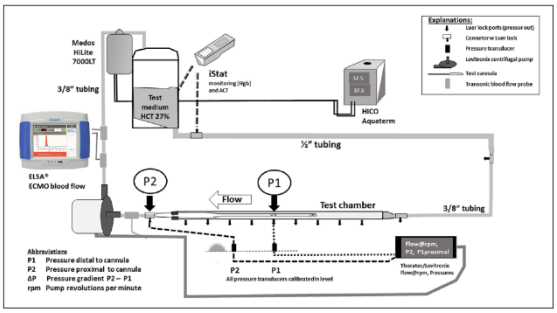

Figure 1: PD test setup [1]

The PD test is conducted according to [1] complying with the ISO 18193:2021 standard (Fig. 1). PD simulations of a selected commercial 19Fr/23cm SLC are performed for multiple operating flow rate range data points.

Results

The PD-flow rate simulation data shows close agreement with the literature reference. The relative error of the pressure drop results is in the range of 3%, indicating the accuracy and regulatory utility of the SPH computations.

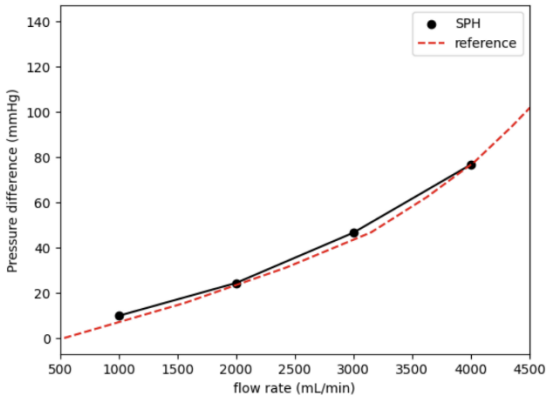

Figure 2: PD under different flow rates for the selected commercial SLC (19Fr/23cm). Red: bench test data from [1] and black: SPH simulation results.

Discussion and Conclusions

We showed that the in-silico model (Fig. 3) provides accurate results to replace the physical bench test, significantly reducing time and cost. Therefore, it allows cannula manufacturers to replace in-vitro tests streamlining development and optimization times. Thanks to thorough validation, the model presents benefits for the regulatory approval process like indicating substantial equivalency to predicate devices.

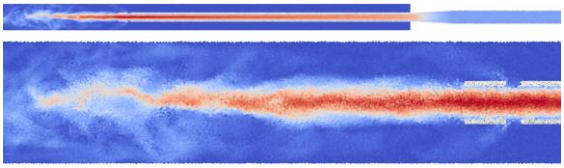

Figure 3: *Velocity distribution in the developed arterial SLC flow field (flow rate: 1 L/min).*
Scale: 0-1.2 m/s from blue to red.

References

1. Broman, L. M., et al. "Pressure and flow properties of cannulae for extracorporeal membrane oxygenation I: return (arterial) cannulae". Perfusion, 2019, Vol. 34(1S) 58–64. DOI: 10.1177/0267659119830521.