WoCoVA 9th World Congress on Vascular Access | 15-17 APRIL 2026 VALENCIA SPAIN

Translational Blind Spots in Hemocompatibility Assessment of Intravascular Devices

Nisha Gupta, BSc, MSc, PhD

Teleflex Vascular Division Research & Development Department, Wyomissing, PA 19610, USA

Introduction

To assess hemocompatibility and thrombotic risk of intravascular devices, short-term *in vitro* blood flow loop assays are widely used. These assays are also commonly utilized to support preclinical performance assessments[1-2]. However, the ability of these models to predict chronic *in vivo* outcomes remains limited[3-4]. This study evaluates the translational relevance of a commonly used blood flow loop model by directly comparing *in vitro* findings with outcomes from a long-term clinically simulated large animal implantation study.

Methods

Peripherally Inserted Central Catheters (PICCs) with **anti-adherent** (anti-biofouling) or **chlorhexidine-impregnation** (antimicrobial) technology were evaluated against Plain PICCs (Control) using the following experimental set-up:

***In Vitro* Blood Flow Loop**

- Devices were plasma pre-conditioned (14 or 30 days)
- Tested in heparinized (1U/mL) bovine blood + ^{111}In-labeled platelets
- N = 6 /device/timepoint
- Blood circulation for 1–2 hours at 200mL/min
- Gross thrombus photographs
- Thrombus quantification by gamma counting

***In Vivo* Clinically Simulated Ovine Model**

- Jugular vein implantation for 14 or 30 days
- N = 3/device/timepoint
- Explanted and assessed for thrombus and vein pathology (qualitative + quantitative)

Limitations & Disclosure

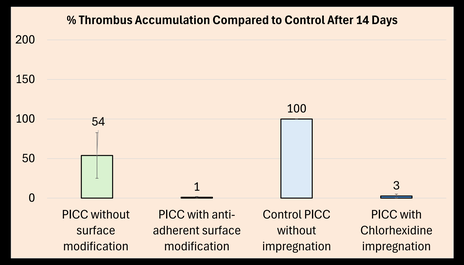
- *In* vitro assay and in *vivo* sheep model results may not reflect clinical outcomes.
- Chlorhexidine-based catheters are manufactured by Teleflex.
- Anti-adherent PICC incorporated a novel technology investigated by Teleflex.
- Author is a Teleflex employee; Study funded by Teleflex; data on file.

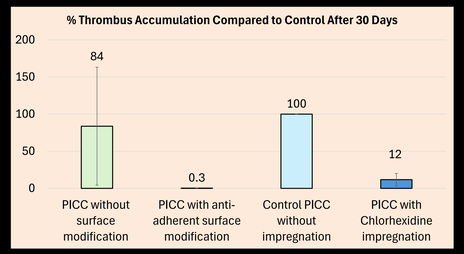
References

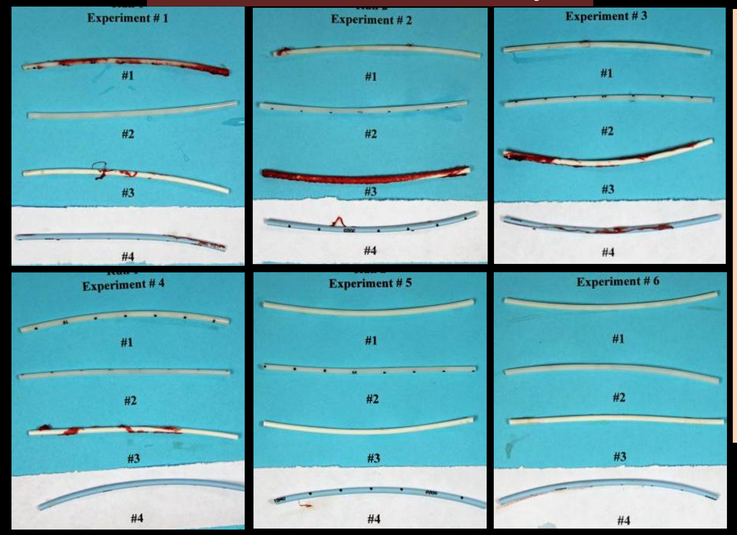
1. Jamiolkowski MA, Hartung MC, Malinauskas RA, Lu Q. An In Vitro Blood Flow Loop System for Evaluating the Thrombogenicity of Medical Devices and Biomaterials. ASAIO J. 2020 Feb;66(2):183-189.
2. Sukavaneshvar S. Device thrombosis and pre-clinical blood flow models for assessing antithrombogenic efficacy of drug-device combinations. Adv Drug Deliv Rev. 2017 Mar;112:24-34.
3. van Oeveren W. Obstacles in hemocompatibility testing. Scientifica (Cairo). 2013;2013:392584.
4. Sylvia CJ Jr, Wagel MA, Giare-Patel K, Spangler TA, Breznock EM, Gupta N. Chlorhexidine-coated peripherally inserted central catheters reduce fibroblastic sleeve formation in an in vivo ovine model. J Vasc Access. 2018 Nov;19(6):644-650.

Hemocompatibility in an *In Vitro* Blood Flow Loop

Thrombus formation after Day 30







#1 – PICC without surface modification

#2 – PICC with anti-adherent surface modification

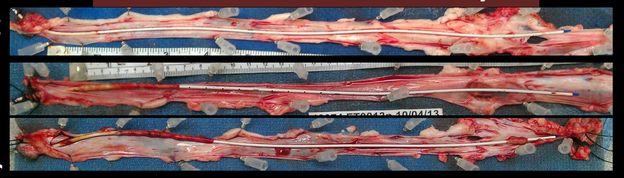
#3 – PICC without impregnation (Control)

#4 – PICC with Chlorhexidine impregnation

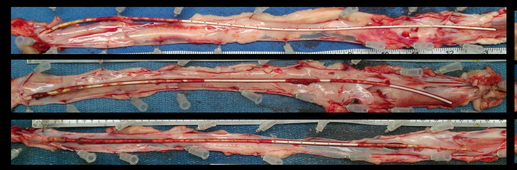
Hemocompatibility in an *In Vivo* Clinically Simulated Ovine Model

Thrombus formation after Day 30

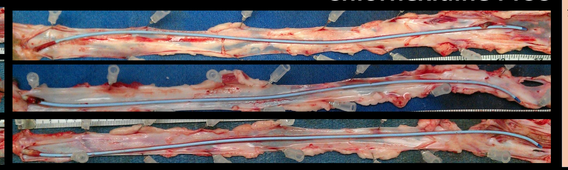
Plain PICC

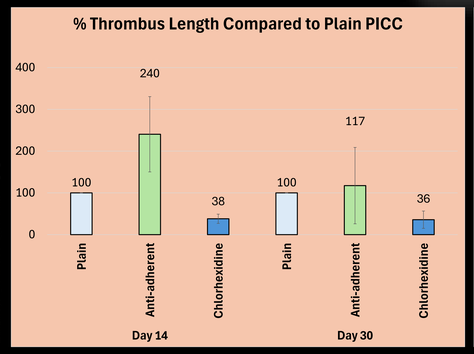


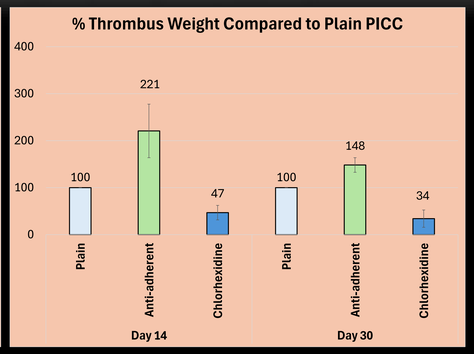
Anti-adherent PICC



Chlorhexidine PICC







Results

- ❑ **No significant difference** in thrombus formation was observed between Anti-adherent and Chlorhexidine PICCs after 30-day simulated use in the *in vitro* blood flow loop model.
- ❑ In contrast, in the clinically simulated ovine model, **clear differentiation between groups emerged**:
  - **Anti-adherent PICCs showed increased thrombus formation** vs. Control (148% weight; 117% length) at 30 days.
  - **Chlorhexidine PICCs demonstrated reduced thrombus formation** vs. Control (34% weight; 36% length) at 30 days.

Conclusions

- **The study demonstrated a clear divergence between *in vitro* and chronic *in vivo* outcomes.**
- **While *in vitro* testing showed no differentiation, the ovine model revealed substantial technology-dependent differences in thrombus formation.**
- **Anti-adherent surface modification alone did not translate to improved *in vivo* thromboresistance.**
- **In contrast, chlorhexidine-impregnated PICCs demonstrated sustained thrombus reduction under chronic *in vivo* conditions.**
- **These findings highlight the translational limitations of short-term blood loop models, which lack endothelial interactions, fibrin sheath development, inflammatory response, and physiologic flow dynamics.**
- **Integrated, longer-term, biologically relevant models may better predict clinical vascular device performance.**