Development of a new polyurethane catheter for peripheral intravenous catheterization to reduce phlebitis risk: an *ex vivo* study

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INTRODUCTION

Peripheral intravenous catheter (PIVC) failure occurs frequently, and phlebitis is a major contributing factor. Endothelial cell loss is considered a key event in phlebitis, and mechanical contact between the catheter and vessel wall is a recognized cause of endothelial injury.

To minimize endothelial injury, catheter materials have undergone continuous refinement over the past several decades, with a trend toward reduced rigidity[1]. Polyurethane is widely used in PIVCs owing to its low rigidity; however, a recent study has shown that the rigidity of commercially available polyurethane catheters varies substantially, which may influence phlebitis incidence[2]. This observation suggests that reducing catheter rigidity may mitigate endothelial damage and lower the risk of phlebitis.

Cox regression analysis of phlebitis by catheter material

(Shinzato *et al.*, *J. Crit. Care Med*, 2026)

Variable	Multivariable analysis	
	HR (95%CI)	p-value
PEU-Vialon	1.45 (0.75-2.8)	0.21
SuperCath	2.60 (1.35-5.00)	<0.01
Other polyurethanes	Ref	-

SuperCath showed a higher risk of phlebitis among polyurethane catheters.

OBJECTIVES

A novel polyurethane catheter with lower rigidity than existing devices was developed and evaluated for its performance through *ex vivo* experiments.

CONCLUSIONS

This finding supports catheter mechanical optimization as a potential strategy to reduce insertion-related complications. Further *in vivo* and clinical studies are warranted to clarify the impact on phlebitis incidence and catheter longevity.

REFERENCES

1. Lynn S. Evolution of Transvascular Catheter From Material, Construction, and Technological Perspectives. *Arterial Treatment of Neurological Diseases: Current Status and Future Directions*. 2025:267–297.
2. Shinzato Y *et al*., Influence of different short peripheral cannula materials on the incidence of phlebitis in intensive care units: A post-hoc analysis of the AMOR-VENUS study. *J. Crit. Care Med*, 2026;12(1).3
3. Sharp R *et al*., The effect of oral hydration and localised heat on peripheral vein diameter and depth: A randomised controlled trial. *Appl Nurs Res*. 2018;42:83–88.
4. Suzuki T *et al*., Differences in penetration force of intravenous catheters: effect of grinding methods on inner needles of intravenous catheters. *Tokai J Exp Clin Med*. 2004;29(4):175–81.
5. Bahl A et al., Evaluating the impact of external forces on peripheral intravenous catheter movement using ultrasound: A randomized pilot study. *J Vasc Access*. 2025;26(1):102–108.

METHODS

Catheter devices

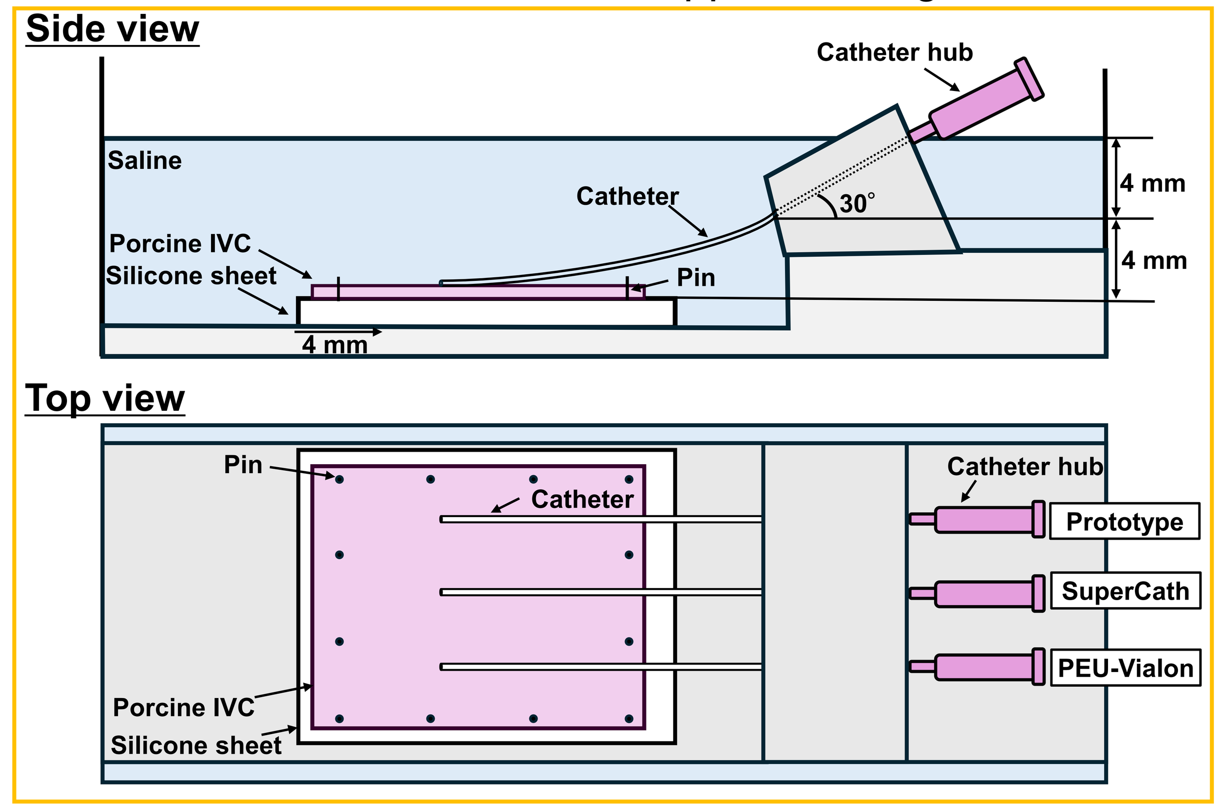
The prototype was evaluated in comparison with materials for which differences in phlebitis incidence related to rigidity have been reported[2]. The following products were selected as representative devices for each material: Insyte Autoguard BC Pro (PEU-Vialon: Nippon Becton Dickinson Company, Ltd, Tokyo, Japan) and SuperCath 5 (SuperCath: Medikit Co., Ltd., Tokyo, Japan). All tested PIVCs were 20-gauge catheters.

Three-point bending test

Catheter rigidity was evaluated using a three-point bending test, simulating physiological conditions (37ºC). The center of the catheter was vertically displaced using a plunger attached to a micro-force testing machine (EZ-LX, Shimadzu Corporation, Kyoto, Japan) and applied load was recorded.

***Ex vivo* porcine vein abrasion model**

The porcine inferior vena cava was opened and secured flat onto a silicone sheet. The catheter tip was positioned to reflect reported diameters of the human forearm cephalic vein and the catheter hub fixation length simulated subcutaneous thickness at the puncture site[3]. The catheter insertion angle was set to 30º, consistent with previously report[5]. Venous abrasion was induced by laterally displacing the vein bring it into controlled contact with the catheter. The displacement distance was determined based on reported catheter movement under external forces applied during clinical use[6].



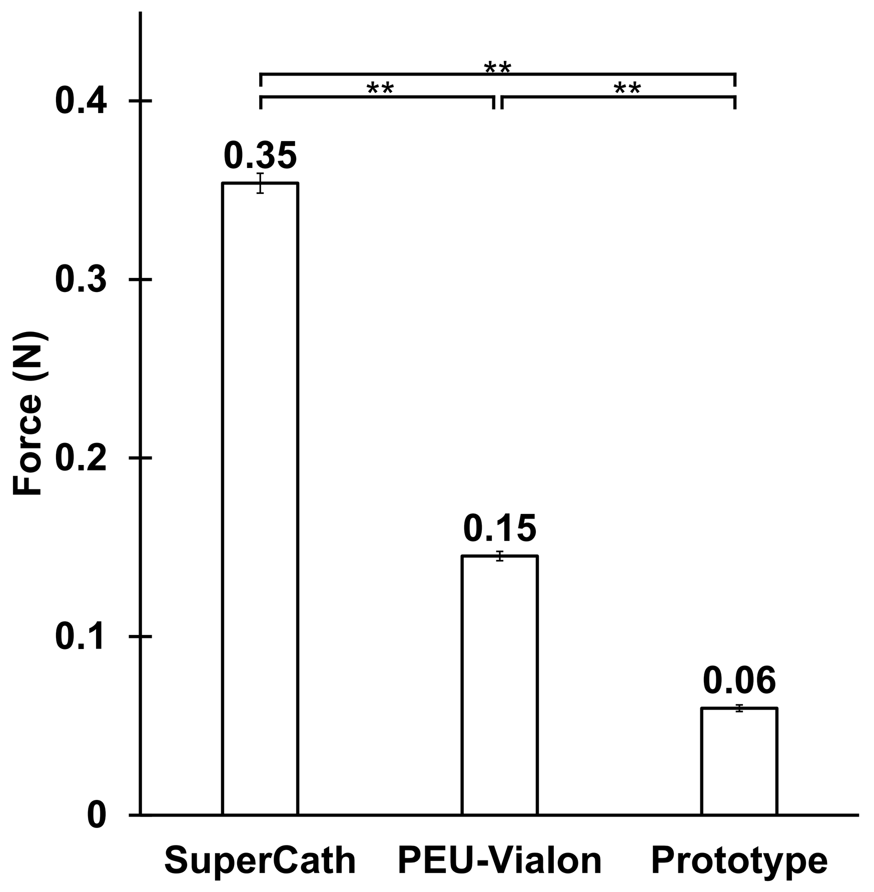
Venous injury evaluation

For venous injury evaluation, Evans Blue (EB) staining, SEM observation and histological analysis using H&E staining were performed. The EB-positive area was quantitatively analyzed using ImageJ software (National Institute of Health, Bethesda Maryland, USA). In the histological analysis, areas of endothelial cell detachment or degeneration were defined as endothelial injury area.

RESULTS

Fig.1 Rigidity of Catheter

Average ± SD (N=3) ** p< 0.01



The prototype exhibited significantly lower rigidity than both comparators.

Fig.2 EB-stained images

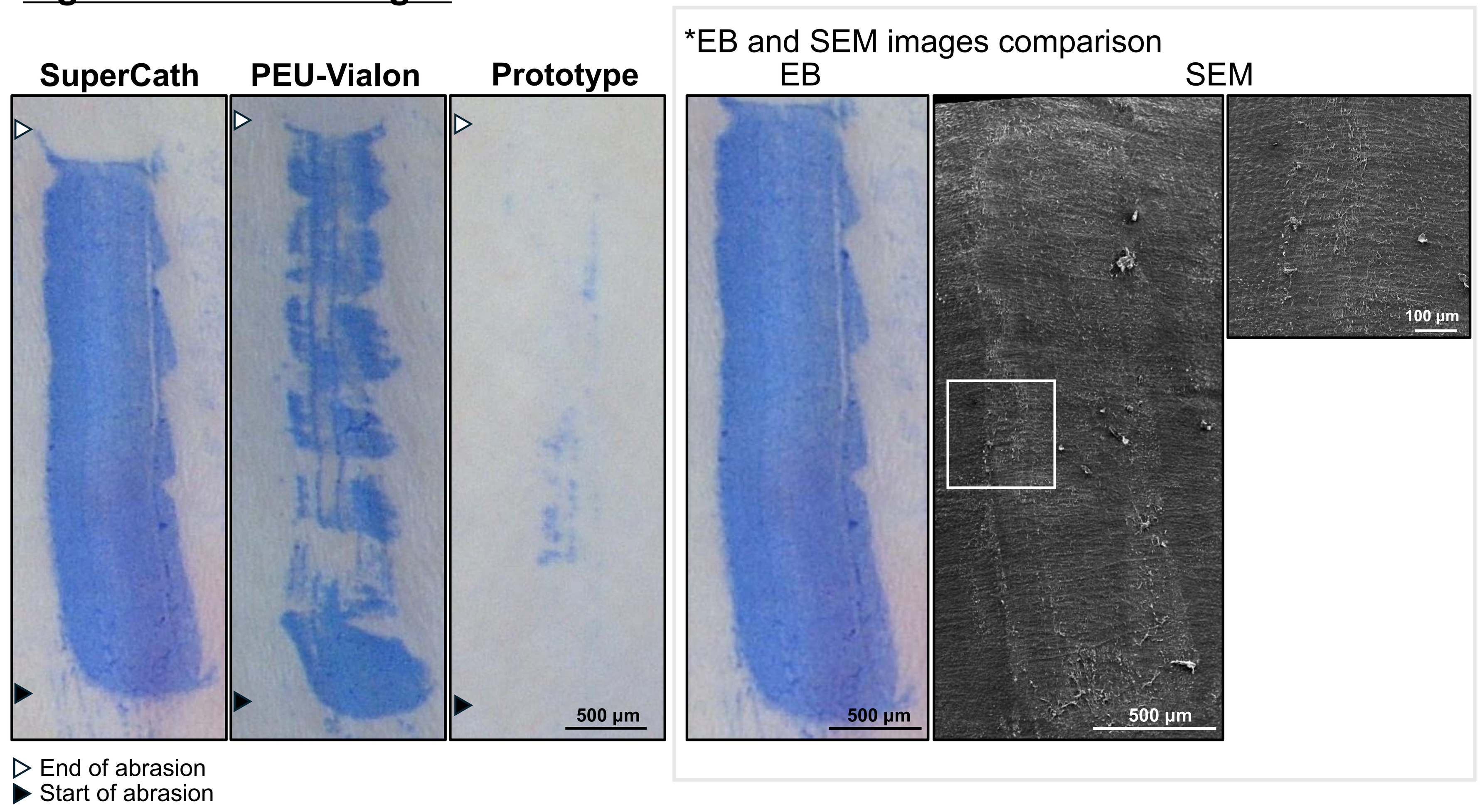
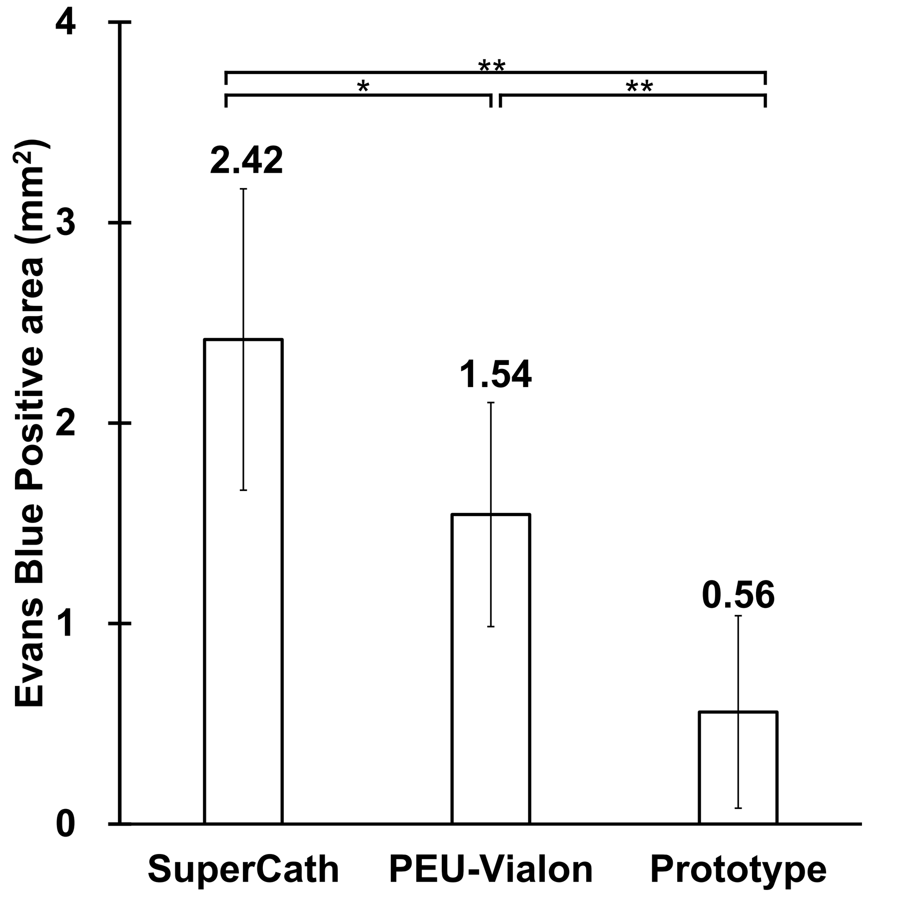


Fig.3 Quantification of EB-positive area

Average ± SD (N=9) *p < 0.05, **p < 0.01



The prototype exhibited a significantly smaller EB-positive area.

Fig.4 H&E-stained images

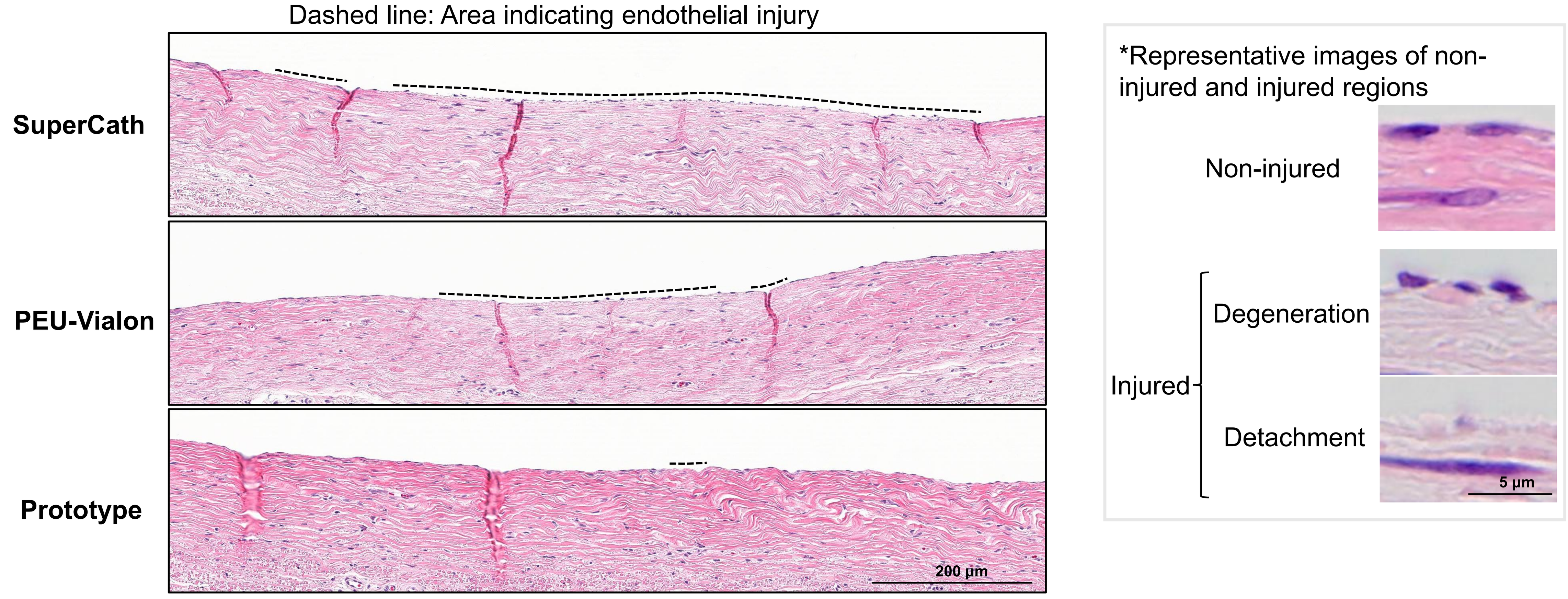
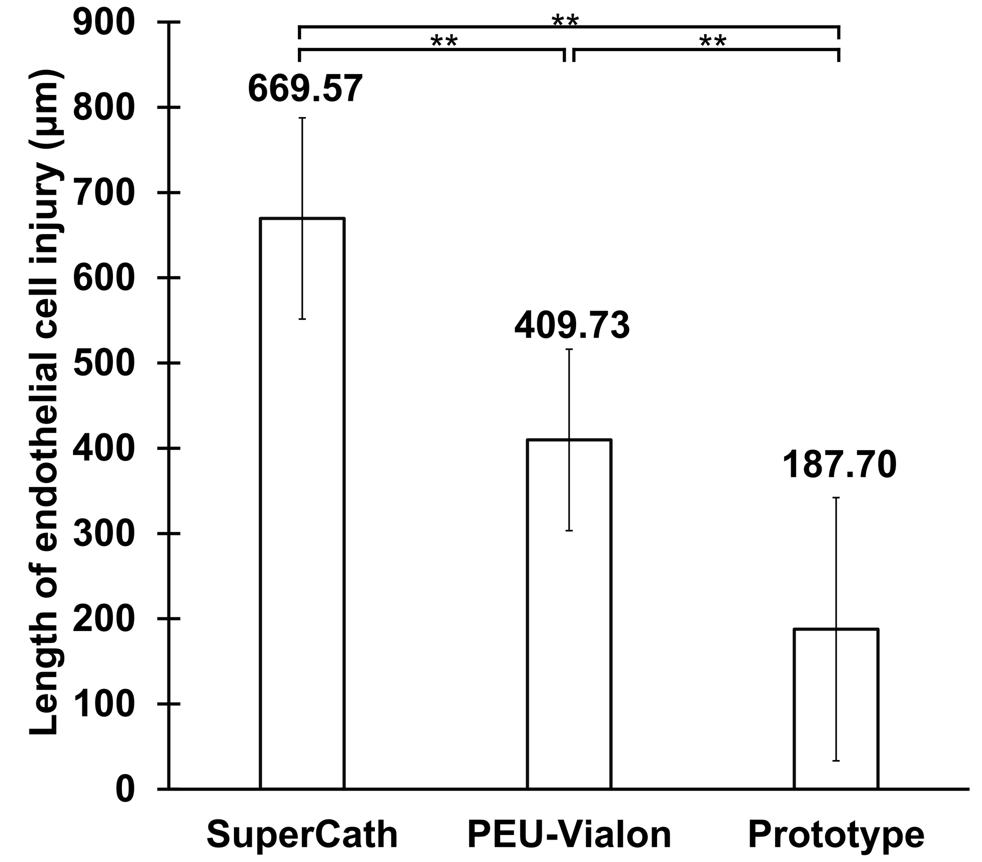


Fig.5 Quantification of endothelial injury

Average ± SD (N=9) **p <0.01



The prototype exhibited significantly less endothelial injury, including endothelial cell detachment and degeneration.

DISCUSSION

1. The newly developed low-rigidity PIVC exhibited suppressed endothelial injury in an *ex vivo* porcine vein abrasion model compared with commercially available catheters.
2. The clinically reported differences in phlebitis incidence were consistent with differences in vascular injury observed in this model.
3. The newly developed PIVC may contribute to a lower risk of phlebitis by reducing vascular injury.
4. As this study was an *ex vivo* study, downstream biological responses were not assessed; instead, the study focused on immediate mechanical injury.