

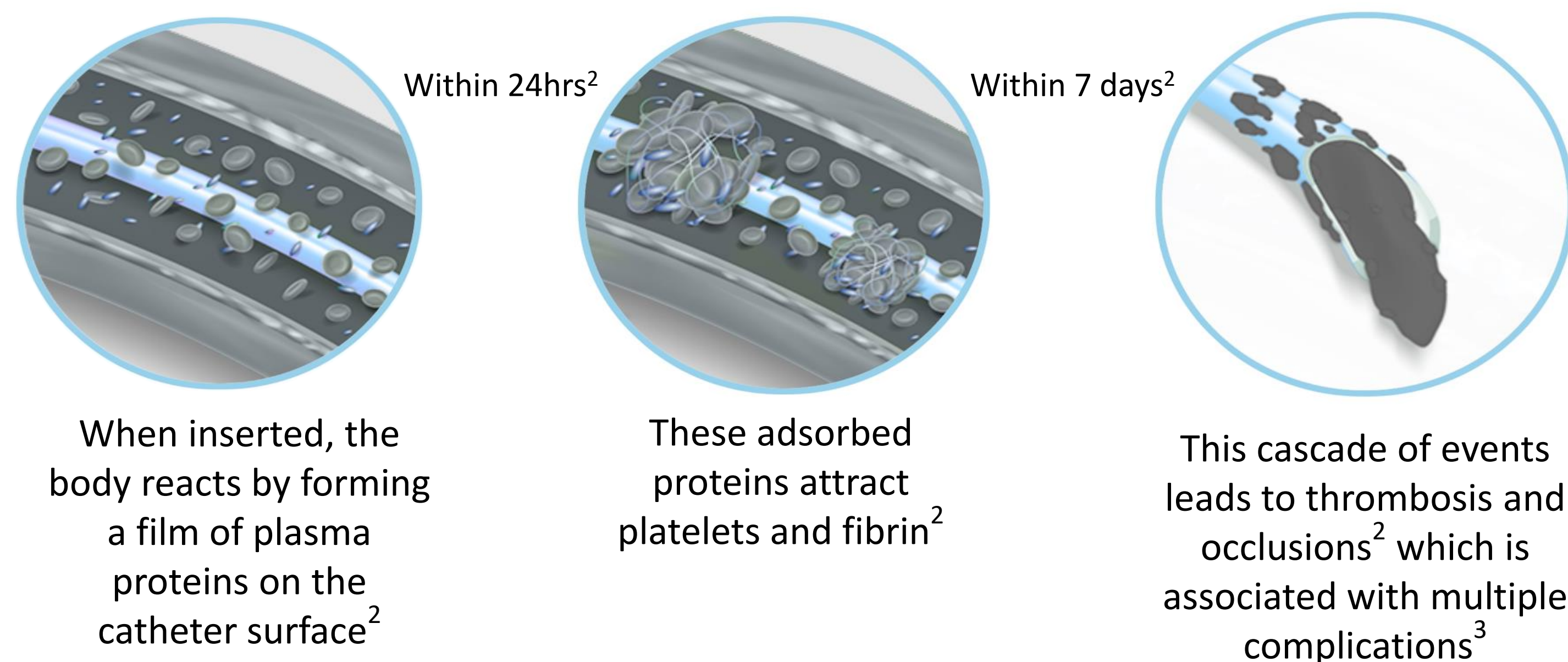
Evolution and Development of Hydrogel Catheter Material for Complication Reduction in PICCs and Midline Catheters

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Background

- PICCs and Midline catheters are primarily composed of polyurethane (PU), coated, and impregnated materials
- These materials have varying degrees hydrophobicity, leading to protein and cellular adherence²

Insertion of venous catheters triggers a foreign body response. This response begins immediately after catheter insertion, which may lead to thrombotic complications and symptomatic issues within the first few days

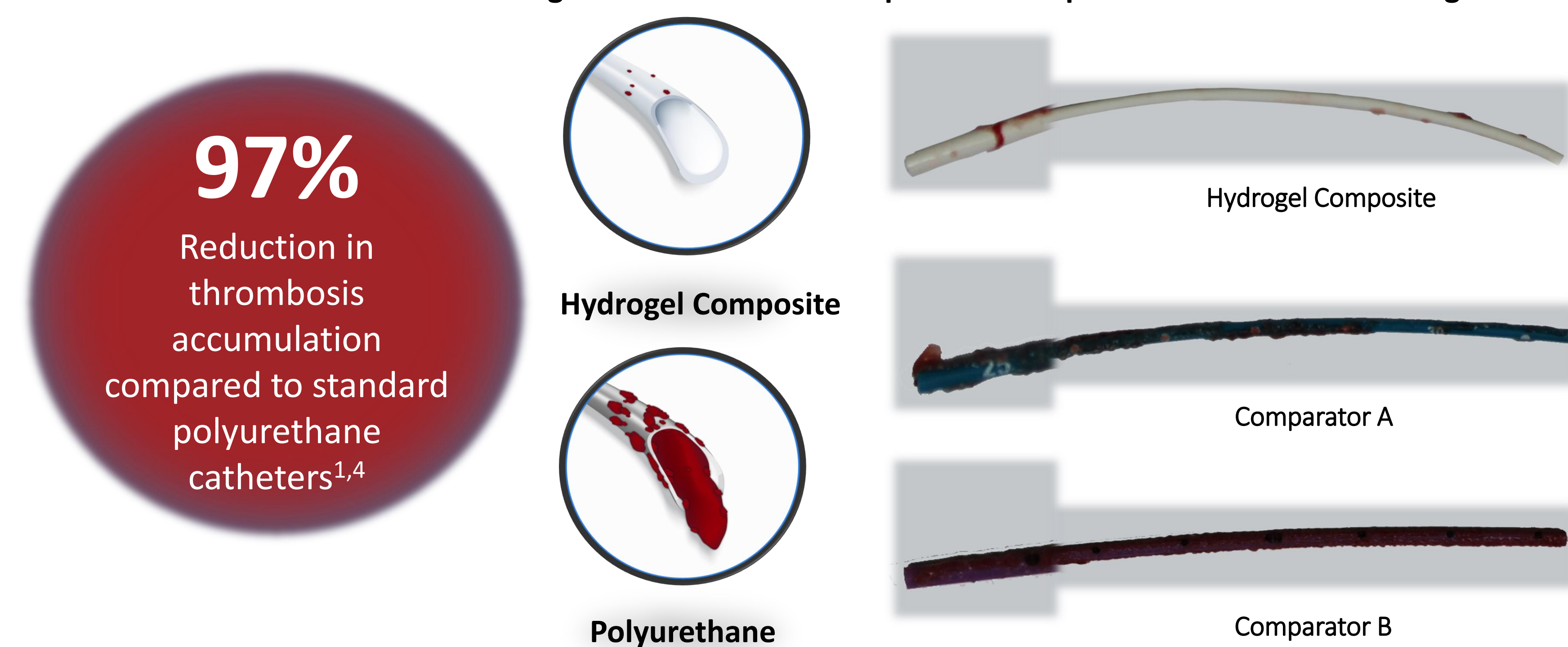


Methods¹

- A new bulk hydrophilic, hydrogel composite catheter material was evaluated for biocompatibility, and reduced foreign body response
- The catheter material consisted of polyvinyl alcohol (PVA), extruded, then heat treated to establish cross-linked high-strength hydrogel
- Testing was performed for tensile strength, hydration and hydrophilic characteristics, extended durability, and blood cell adherence

Results

120 minutes in an US FDA-recognized in vitro blood loop model compared with a market-leading controls¹



Designed to reflected a super-lubricious and hydrophilic surface making it less likely for bacterial and cellular adherence

- In-vitro testing confirmed the antithrombogenic properties of HBM¹, clinical results show reduction in failures⁵
- US FDA cleared PICCs and midline catheter, specifications below⁶

Hydrogel Composite PICC Catheter (K193015)	
Size:	4 French – Single Lumen
Usable Length:	55 cm
Outer Diameter:	1.35 mm (4 Fr)
Inner Diameter:	1.00 mm
Max. Guide Wire Compatibility:	0.018 in. (0.46 mm)
Max. Power Injection Flow Rate:	3.5 mL/s at 11.8 cP
Reverse Taper:	6 cm
Outer Diameter at Suture Wing:	1.8 mm (5.5 Fr)

Hydrogel Composite Dual Lumen PICC Catheter (K213550)	
Size:	5 French – Dual Lumen
Usable Length:	55 cm
Outer Diameter:	1.67 mm (5 Fr)
Inner Diameter:	20 gauge
Max. Guide Wire Compatibility:	0.018 in. (0.46 mm)
Max. Power Injection Flow Rate:	3.5 mL/s at 11.8 cP
Reverse Taper:	6 cm
Outer Diameter at Suture Wing:	2.3 mm (7 Fr)

Hydrogel Composite Midline Catheter (K203069)	
Size:	4 French – Single Lumen
Usable Length:	20 cm
Outer Diameter:	1.35 mm (4Fr)
Inner Diameter:	1.00 mm
Max. Guide Wire Compatibility:	0.018 in. (0.46 mm)
Max. Power Injection Flow Rate:	6 mL/s at 11.8 cP
Reverse Taper:	6 cm
Outer Diameter at Suture Wing:	1.8 mm (5.5 Fr)

Discussion and Conclusions

- These results are promising for the reduction and prevention of these common complications
- With the high surface lubricity, low cellular adhesion, thromboresistance, durability, and functionality these PICC and Midline catheters may herald a new age of improved outcomes for patients and cost savings for healthcare facilities
- A recent retrospective clinical study on midline lines (n=205) showed 6x fewer complications with HBM compared to standard polyurethane catheters (3.8% vs. 23.8%)⁵

	Hydrogel (N=104)	Polyurethane (N=101)	P Value ^a
Subject had at least 1 midline failure, n (%)			<.001
Yes	4 (3.8%)	24 (23.8%)	
No	100 (96.2%)	77 (76.2%)	
Subject had midline replaced, n (%)			<.001
Yes	4 (3.8%)	22 (21.8%)	
No	100 (96.2%)	79 (78.2%)	
Subject had upper extremity venous thrombosis, n (%)			<.001
Yes	0 (0.0%)	7 (6.9%)	
No	104 (100.0%)	93 (92.1%)	
Unknown	0 (0.0%)	1 (1.0%)	
Subject had midline occlusion, n (%)			.003
Yes	4 (3.8%)	17 (16.8%)	
No	100 (96.2%)	84 (83.2%)	
Subject had phlebitis, n (%)			.001
Yes	1 (1.0%)	14 (13.9%)	
No	103 (99.0%)	87 (86.1%)	
Subject had leaking, n (%)			>.001
Yes	1 (1.0%)	20 (19.8%)	
No	103 (99.0%)	81 (80.2%)	

^a P-value for Likelihood Ratio Chi-square Test. P<.05 considered statistically significant

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