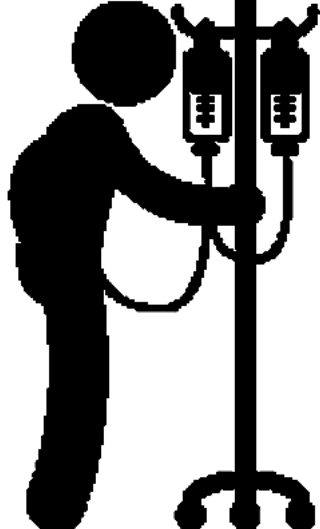


A novel peripheral intravenous catheter aimed at reducing early failure rates: from computer simulations to animal study

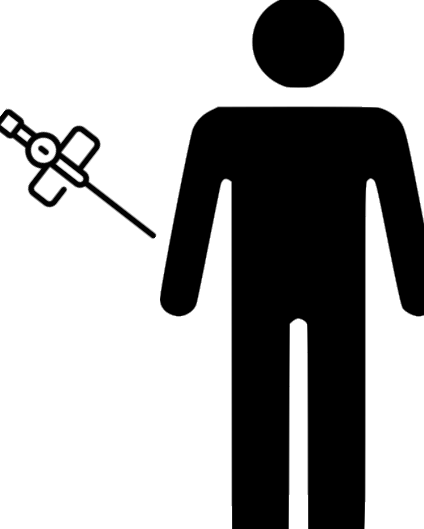
BARRY DOYLE, Lachlan Kelsey, Caroline Shelverton, Gabriella Abbate, Carmen Ainola, Noriko Sato, Samantha Livingstone, Mahe Bouquet, Margaret Passmore, Emily Wilson, Kei Sato, Keibun Liu, Silver Heinsar, Karin Wildi, Peter Carr, Jacky Suen, John Fraser, Gianluigi Li Bassi and Samantha Keogh

INTRODUCTION



90%

of hospitalised patients receive an IV catheter, the majority of which are peripheral IV catheters (PIVC)¹



34%

of PIVCs failed after insertion (excluding dislodgement) despite concentrated efforts to reduce failure (control group = 40% failure)²



50%

of PIVCs experience a complication after being successfully inserted into the vein, resulting in early failure / occlusion¹



\$70

is the cost of reinsertion³ despite the device only costing a few dollars - a \$700 million burden in Australia alone

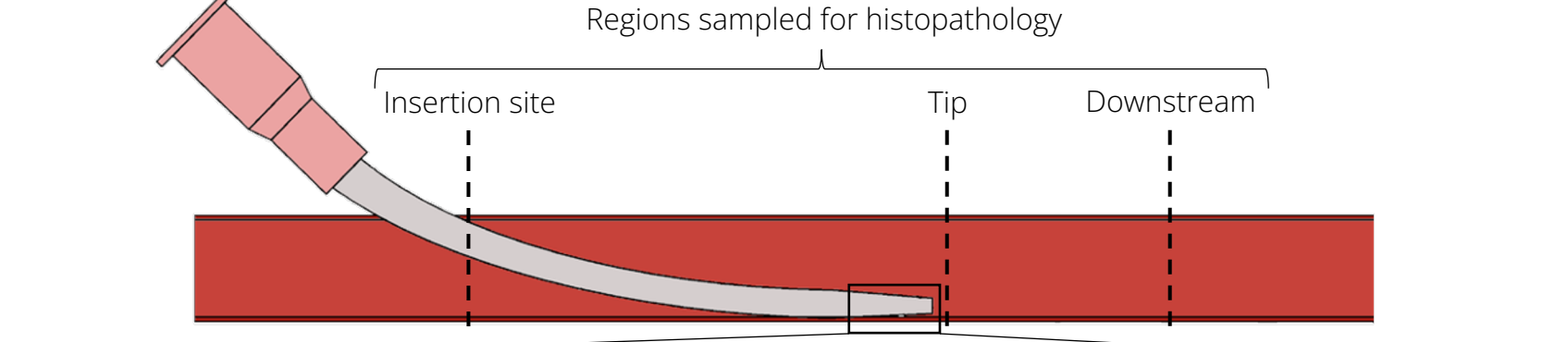
HYPOTHESIS & AIM OF STUDY

Our hypothesis is that a PIVC designed to mitigate the controllable factors of Virchow's Triad will result in reduced early failure rates of the PIVC.

The aim of this study was to design a new PIVC that reduces endothelial injury and blood stasis, and then perform a proof-of-concept study in a porcine model of IV access.

METHODS

1

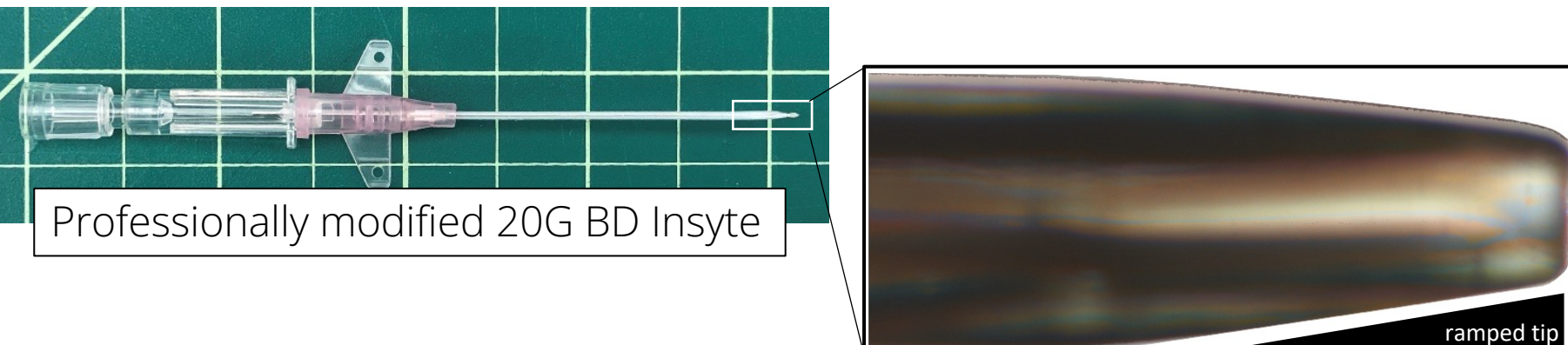


FloRamp asymmetric tip

Conventional symmetric tip

We used computer-aided design and previously reported computational fluid dynamics (CFD)^{4,5} to design a PIVC with a ramped tip geometry, which directs the infused fluid away from the vein wall, reducing endothelial shear stress and injury; we called the design the **FloRamp™**

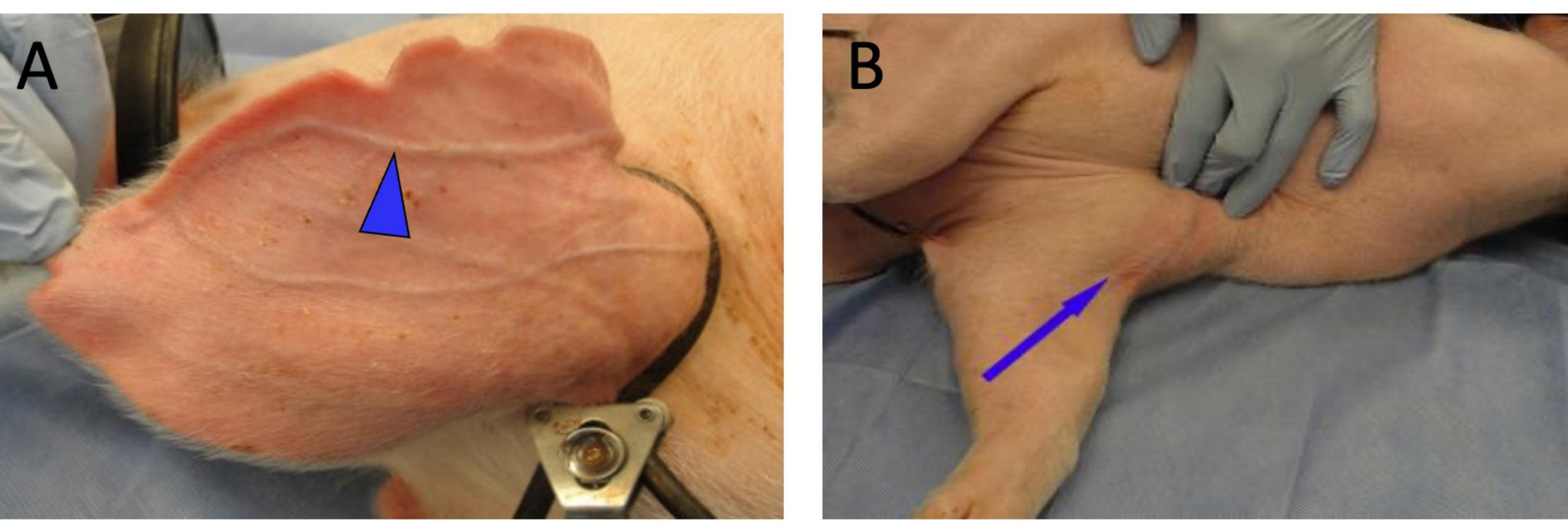
2



Professionally modified 20G BD Insyte

To test the impact of the FloRamp tip alone, we modified a 48mm 20G winged BD Insyte device to incorporate the novel asymmetric tip. This was performed by a specialist IV catheter manufacturer (Medical Murray, USA).

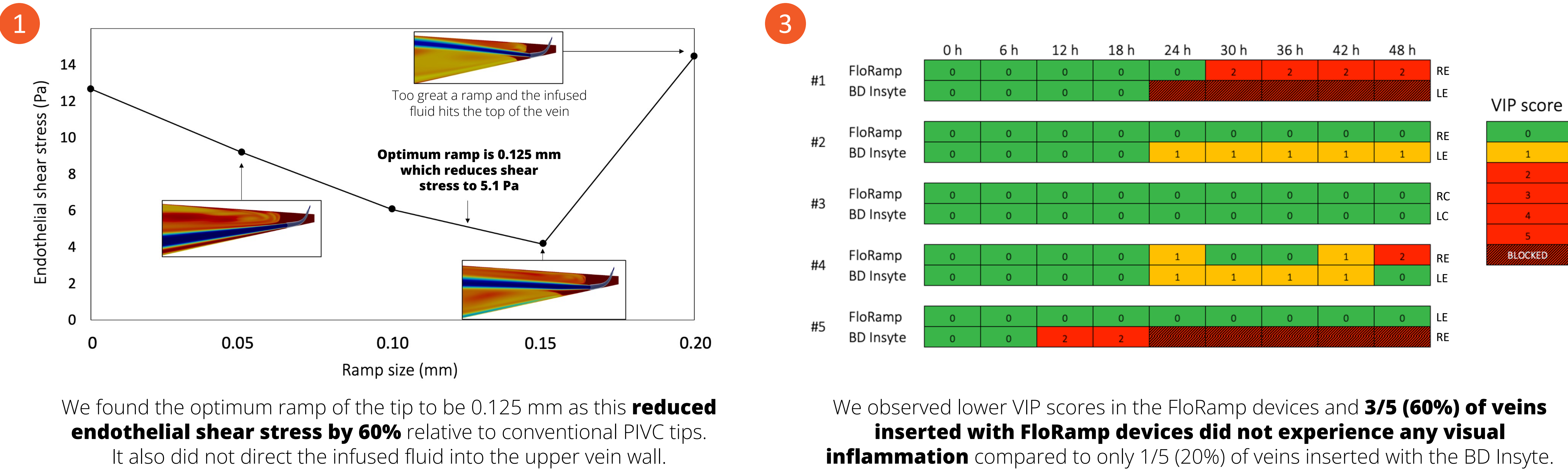
3



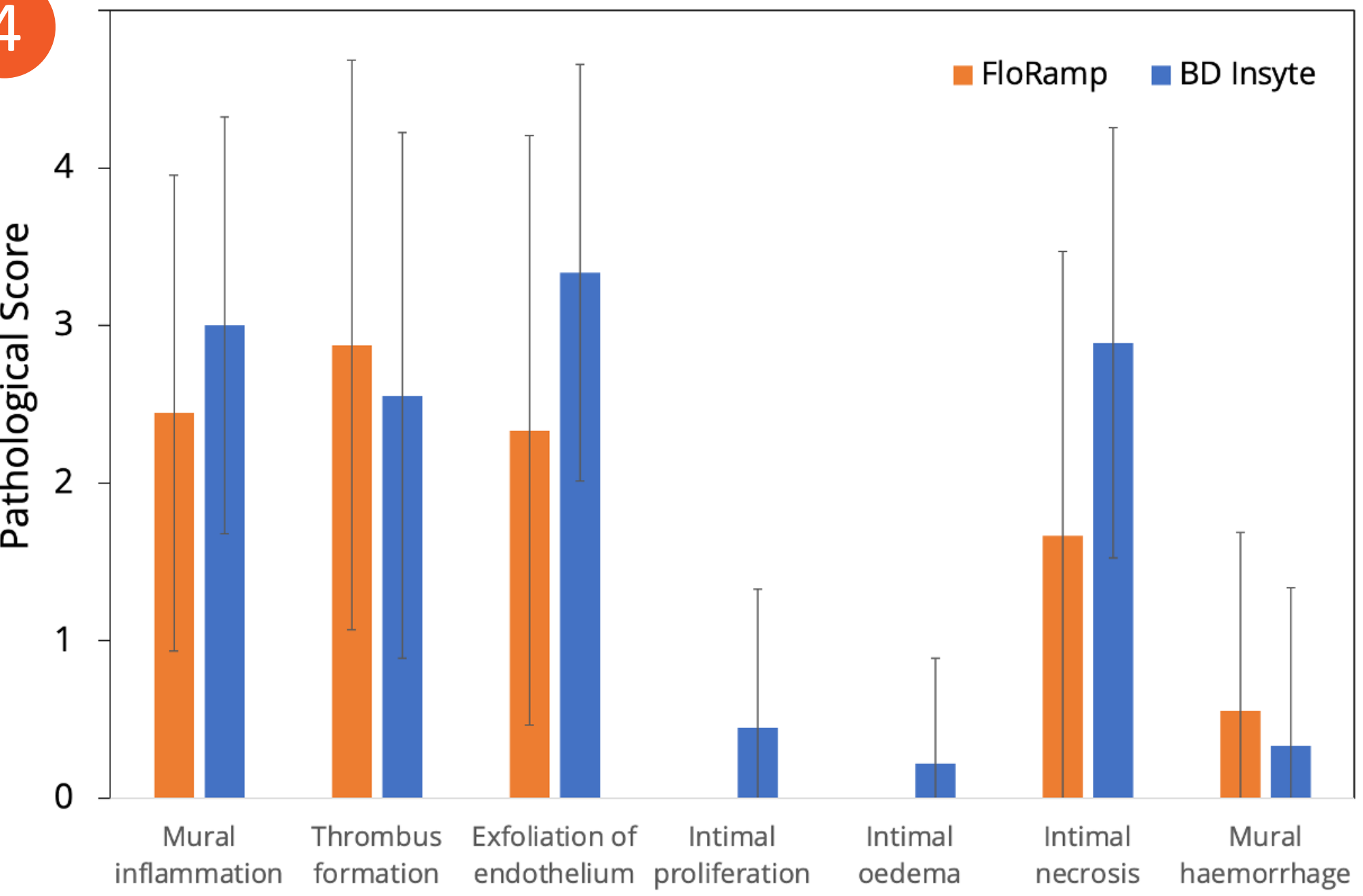
A B

- We used 4 white female pigs that were sedated and monitored for the entire experiment.
- On commencement, trained nurses randomly inserted either a FloRamp or an BD Insyte at ~20° into the marginal ear veins (*Fig. 3A*) and cephalic veins (*Fig. 3B*); inserters were blinded to the device as the FloRamp had no noticeable visual or tactile difference during insertion.
- After insertion, PIVCs were secured using tissue adhesive and covered with sterile dressing.
- Every 6h we paused the continuous background TKVO infusion⁵, assessed the insertion site using the VIP score (score 0 - 5)⁶, and infused saline at 1 mL/s while measuring resistance to infusion (score 0 - 2; 2 = occlusion).
- After 48h, we stopped the experiment, euthanised the pigs and harvested the relevant veins for histopathology.
- We sampled sections from the insertion site, the tip and the distal region of the vein (*Fig. 1*), and performed independent, blinded, quantitative histopathology.
- We followed previous methods⁷ and tested for 7 biomarkers, scoring each from 0 - 4 (4 = severe).

RESULTS: 5 comparative insertion sites in 4 pigs (5 FloRamp vs. 5 BD Insyte)



4



Pathological Score

Legend: FloRamp (orange), BD Insyte (blue)

Markers: Mural inflammation, Thrombus formation, Exfoliation of endothelium, Intimal proliferation, Intimal oedema, Intimal necrosis, Mural haemorrhage

Veins inserted with the **FloRamp exhibited lower pathological scores in 5/7 (70%)** of the markers assessed.

CONCLUSION

Despite best efforts from end users, premature failure of PIVCs remains a significant healthcare problem.

Here we report a new PIVC distal tip with an asymmetric ramp, the FloRamp, that appears to hold promise, outperforming a market-leading device in a well-controlled study using a porcine animal model of IV access.