A Novel Embolic with Minimal Catheter Adhesion Properties: GPX by Fluidx Medical Technology

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Introduction

GPX by Fluidx Medical Technology is a biomimetic embolization device comprised of a proprietary blend of polyelectrolytes. This agent solidifies in response to a decrease in ionic strength upon entering blood vessels and does not utilize toxic organic solvents and *in situ* polymerizing components. Furthermore, the material is non-cytotoxic, non-hemolytic, and has been shown to embolize down to the capillary level in animal models of embolization (Fig. 1) [1].

Catheter entrapment is a serious problem that occurs with many clinical embolization agents [2,3]. Because of this common problem, we sought to investigate the risk of catheter entrapment in GPX. The force required to remove a microcatheter from GPX was measured 2 minutes and 24 hours after exposure to balanced salt solution (BSS) and the beginning of solidification. These timepoints were chosen to represent a clinical scenario (2 min) and to test the worst-case scenario (24 h).

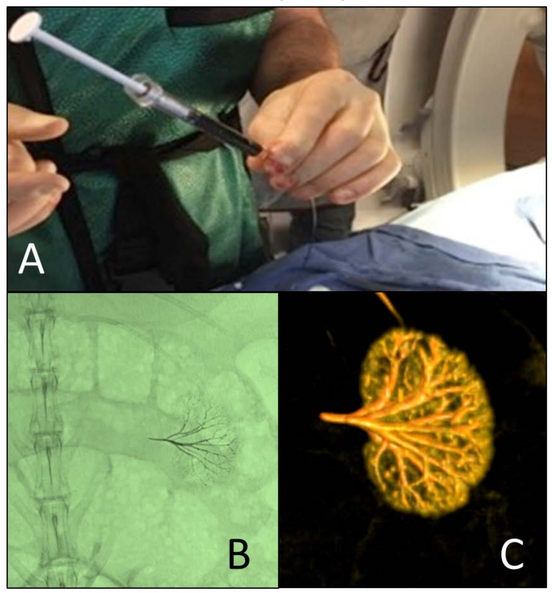

Fig. 1. Rabbit Kidney Embolization with GPX by Fluidx Medical Technology. (A) GPX is ready to use in a premixed, prepackaged syringe. (B) Kidney 90 minutes after GPX injection. (C) Postmortem dorsal 3D image showing complete arterial occlusion down to capillary bed.

Materials & Methods

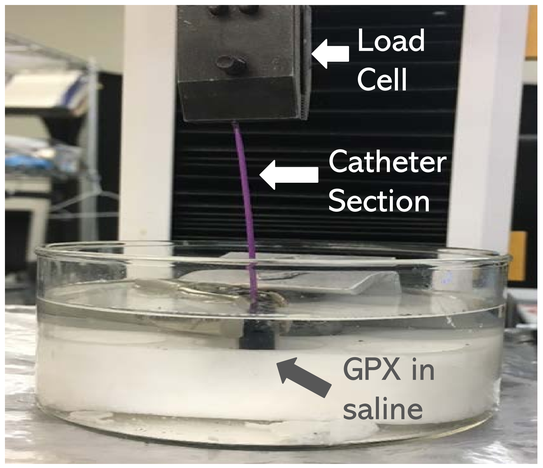

Fig. 2. Photo showing experimental setup on Instron materials tester, measuring catheter removal force.

1. GPX was injected into filtration tubes (Supelco, Inc.; cat #57240-U) to a height of 1 cm (~300 µL of GPX).
2. Cut sections (~10 cm in length) of a 3 F mircocatheter (Renegade HI-FLO, Boston Scientific Inc.) were placed in the center of each GPX-filled tube.
3. The filtration tubes were completely submerged in a dish containing BSS and allowed to incubate.
4. At predetermined intervals of 2 minutes and 24 hours, the force required to remove the catheter from the solidified GPX was measured on an Instron 3342 materials tester (Instron, Inc.) equipped with a 10 N load cell and controlled with Bluehill 3 software (Fig. 2). The catheter was removed in extension mode with a strain rate of 600 mm/minute (1 cm/s).

Results & Discussion

- All values reported represent an average of three runs +/- standard deviation. Student's t-test was used to compare means with significance set at p=0.05.
- The catheters cleanly detached from GPX at both timepoints (2 min and 24 h), with no fragmentation.
- At 2 minutes, the force required to remove the catheter at 1 cm/second was 16.7 mN (+/- 5.8 mN) (Fig. 3).
- Even in the worst-case scenario (24 hours), the force required to remove the embolic was only 384 mN (+/- 107 mN). (Fig 3.)

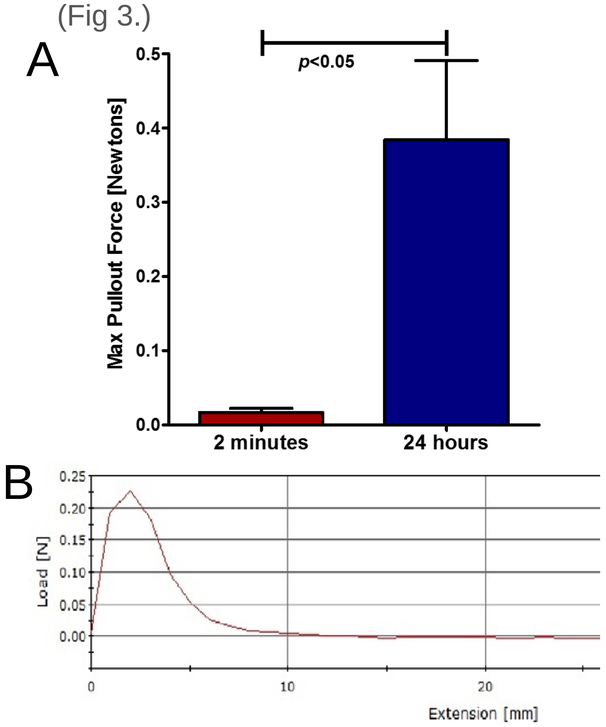

Fig. 3. Catheter pullout force results. (A) Maximum force required to remove a catheter from solidified GPX at selected timepoints (n=3). (B) Representative raw force profile for removing a 3F microcatheter from solidified GPX at 24 hours.

Conclusion

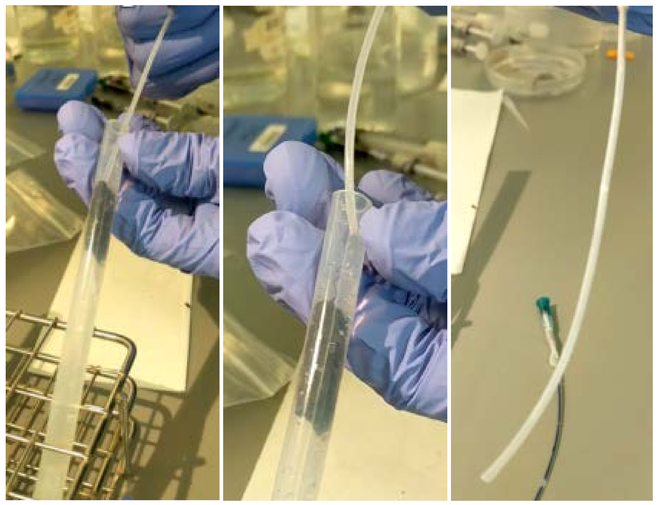

Fig. 4. In both qualitative and quantitative tests, GPX does not significantly adhere to catheters. Catheters removed from GPX at 2 minutes and 24 hours after exposure to BSS showed no evidence of adhesion issues.

- Even when embedded in solidified GPX, catheters only require a minimal amount of force (<0.4 Netwons) to remove with no fragmentation of the embolic observed (Fig. 4).
- Catheter adhesion to GPX is very weak.
- Catheter entrapment should not be a clinical concern with the GPX embolization agent.
- The lack of catheter adhesion with GPX may facilitate development of new embolization techniques.

[1] J.P. Jones, M. Sima, R.G. O'Hara, R.J. Stewart, Water-borne endovascular embolics inspired by the undersea adhesive of marine sandcastle worms, Adv. Healthc. Mater. 5(7) (2016) 795-801.

[2] G.M. Debrun, V.A. Aletich, H. Shownkeen, J. Ausman, Glued catheters during embolisation of brain AVMs with acrylic glue, Interv. Neuroradiol. 3(1) (1997) 13-19.

[3] A.S. Puri, R. Rahbar, J. Dearden, R.J. Graham, C. Lillehei, D.B. Orbach, Stretched and sheared microcatheter retained after Onyx embolization of infantile myofibromatosis, Interv. Neuroradiol. 17(2) (2011) 261-266.