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).

Materials & Methods

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 microcatheter (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).

Conclusion

- 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.

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.

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

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.

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.