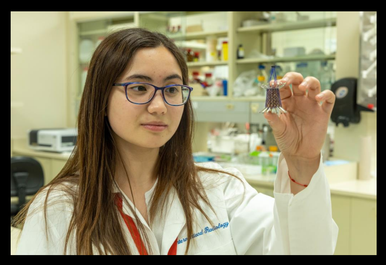

Fabrication of radiopaque, drug loaded resorbable inferior vena cava filters

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Introduction

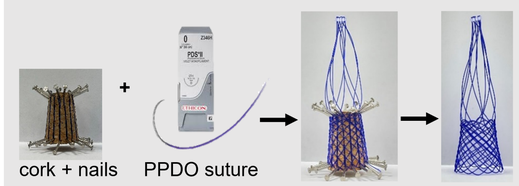
Pulmonary embolism (PE) affects about 10 million individuals annually in the world [1]. The most conventional way to prevent PE is to use metallic inferior vena cava filters (IVCFs) to catch these clots. However, only 35% of metal filters are eventually retrieved [2]. The objective of our study is to infuse *imaging enhancers* made up of nanoparticles and *drugs* unto the *absorbable polymers* to facilitate its imaging over time and to prevent thrombosis.

MEDICAL DEVICE COMPONENTS

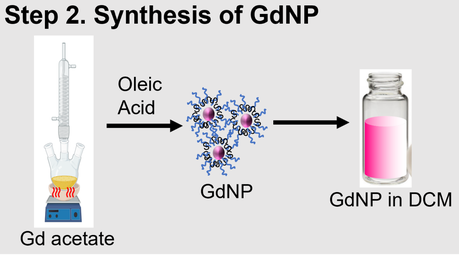
Poly-p-dioxanone (PPDO)	Gadolinium Nanoparticles (GdNP)	Dipyridamole (DPA)
• **Absorbable polymer** • Polyester • Manufactured by J&J as PDS II • Non-antigenic and non-pyrogenic • Degraded by hydrolysis and is completely metabolized in the body	• **Confers radiopacity** • Paramagnetic lanthanide element • Has been used as an MRI, SPECT, and CT contrast agent but is cleared easily • Longer circulation time and evasion of the RES (reticulo-endothelial system)	• **Prevents thrombosis** • Anti-platelet medicine • Works by blocking phosphodiesterase and adenosine deaminase • Off-label for stroke prevention and hemodialysis graft patency

Method

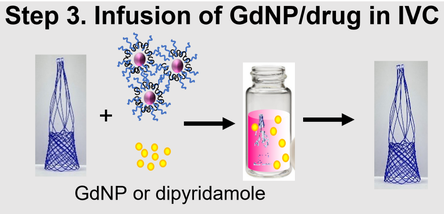
Step 1. Braiding to form the IVC filters



Step 2. Synthesis of GdNP



Step 3. Infusion of GdNP/drug in IVC filters



Results

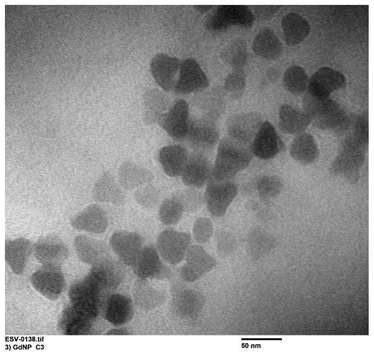


Figure 1. Transmission electron microscopy image of the synthesized Gd nanoparticles showing plate-like structure with average diameter of 35.76 ±3.71 nm.

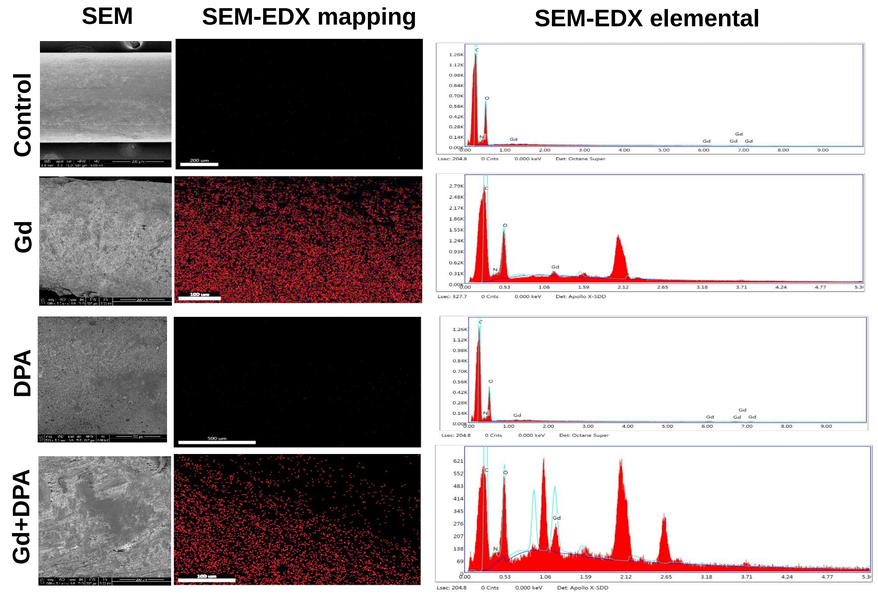


Figure 2. Scanning electron microscopy (SEM) and Gd mapping using energy-dispersive X-ray spectroscopy (EDX). Control PPDO sutures had a smooth surface, and addition of Gd and/or DPA increased the roughness of the surface of the PPDO sutures. The peak at 1.185 keV confirms the presence of Gd. A platinum (Pt) peak at 2.05 keV is also evident due to the sputter coat used for SEM.

Table 1. Physico-chemical Properties of Gd- and/or drug-loaded PPDO sutures

	Suture Thickness (cm)	Melting Temperature (°C)	Load-at-break (kg)	Radiopacity (HU)
Control	0.39 ± 0.00	105.90 ± 0.30	5.24 ± 0.12	-130 ± 38
Gd	0.49 ± 0.05	103.32 ± 0.68	4.39 ± 0.87	2713 ± 105
DPA	0.41 ± 0.00	104.13 ± 0.20	4.60 ± 0.64	-135 ± 172
Gd+DPA	0.42 ± 0.03	103.61 ± 0.08	5.38 ± 0.65	1516 ± 281

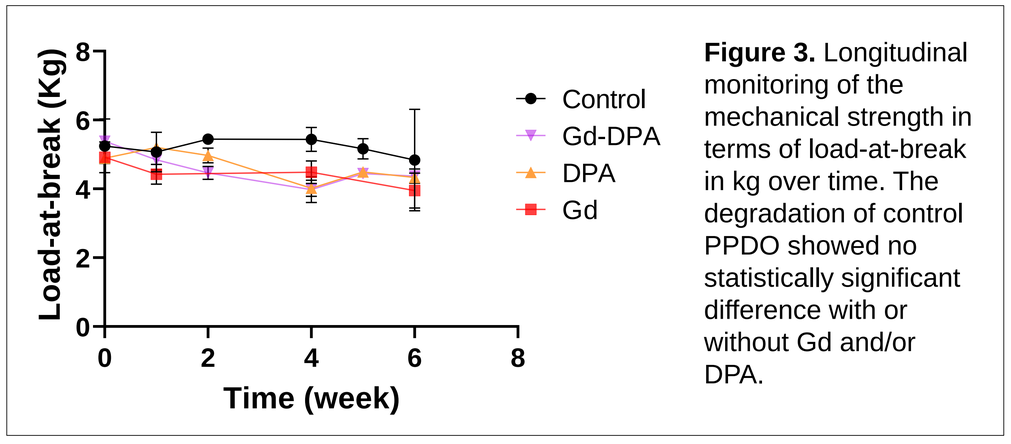


Figure 3. Longitudinal monitoring of the mechanical strength in terms of load-at-break in kg over time. The degradation of control PPDO showed no statistically significant difference with or without Gd and/or DPA.

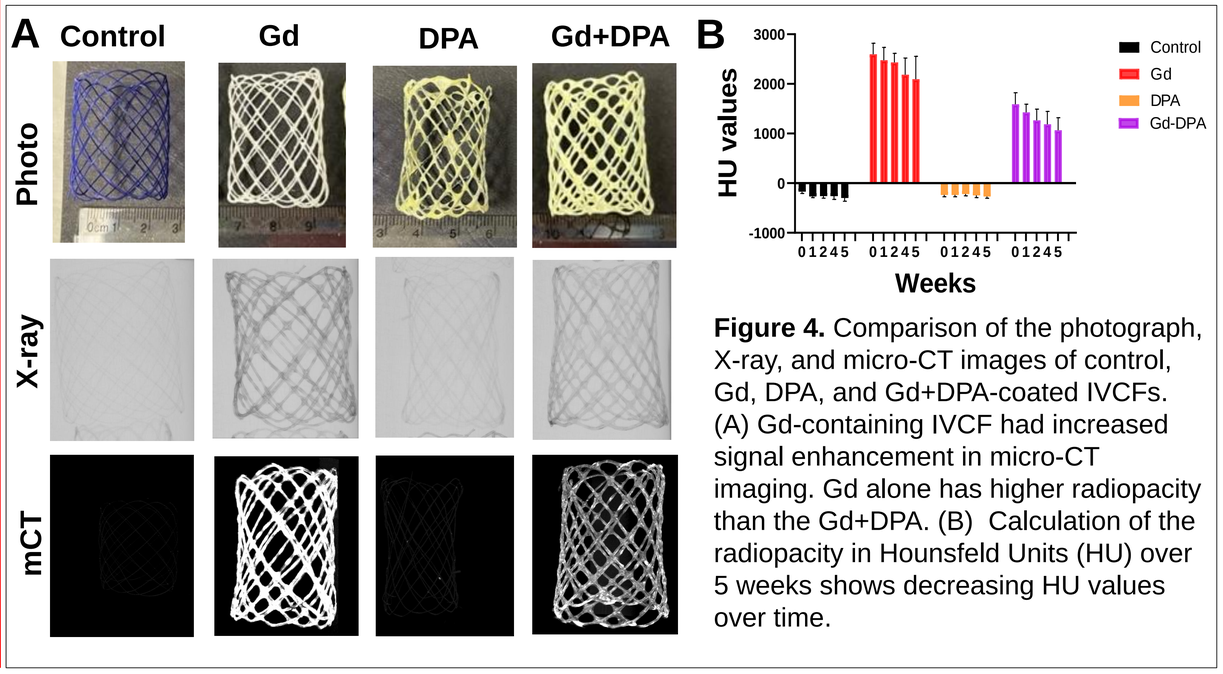


Figure 4. Comparison of the photograph, X-ray, and micro-CT images of control, Gd, DPA, and Gd+DPA-coated IVCFs. (A) Gd-containing IVCF had increased signal enhancement in micro-CT imaging. Gd alone has higher radiopacity than the Gd+DPA. (B) Calculation of the radiopacity in Hounsfeld Units (HU) over 5 weeks shows decreasing HU values over time.

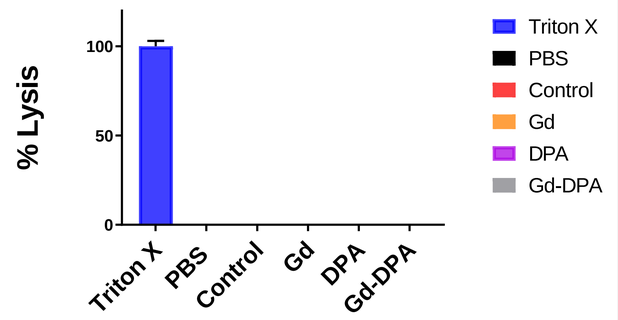


Figure 5. Hemolysis assay shows no significant differences among the various groups tested.

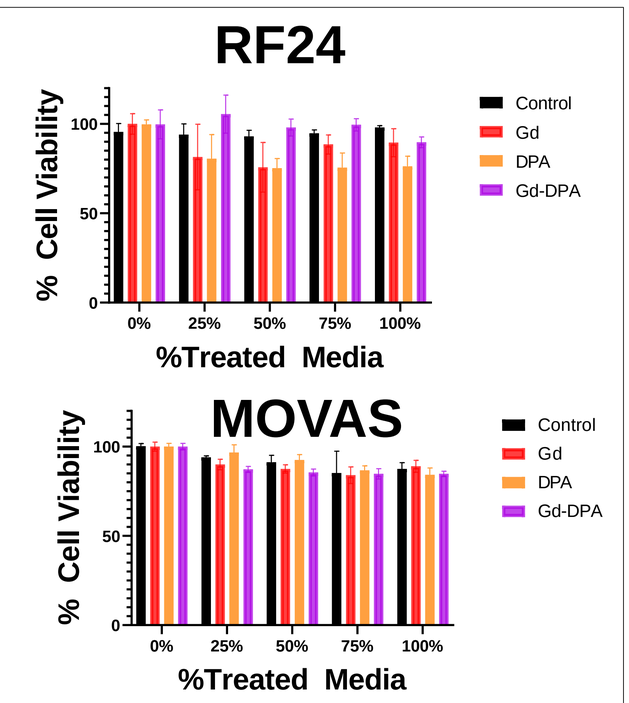


Figure 6. Treatment of MOVAS (mouse vascular smooth muscle) and EC-RF24 (immortalized human vascular endothelial) with varying concentrations of treated cell media with control, Gd, DPA, or Gd+DPA did not show significant cytotoxicity ($p < 0.05$). Cells were incubated in treated media for 24h before cytotoxicity assay with 10% alamarBlue.

Conclusions

A novel radiopaque, resorbable IVCF made up of PPDO infused with GdNP and DPA was successfully fabricated. By incorporating GdNP, routine imaging would be possible and the addition of drugs could prevent thrombosis.

Innovations:

1. Using low-cost cork and nails, fabrication of different sizes, shapes and type of medical devices becomes possible.
2. GdNP has never been used as a CT contrast agent for absorbable medical device.
3. Combination of Gd and DPA affords the synergistic effects of imaging and local therapy.

References

[1] Quencer KB., et al. CVIR Endovascular 2020.
[2] Weinberg AS, et al. Endovascular Today 2019.