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In-Vitro Thrombogenicity Assessment of Polymer Filament Modified and Native Platinum Embolic Coils

Clinical Paper Review
Prepared by PVH Scientific Communications *for Health Care Professionals*

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Purpose

To evaluate the prothrombogenic effects of platinum embolic coils with filaments and platinum embolic coils without filaments.

Methods

- In-vitro study utilizing a quantitative method that tracks the formation of thrombin upon exposure of the test samples to human platelet rich plasma.
- Thrombin generation was measured via a slow binding fluorogenic substrate. Fluorescence was measured at one-minute intervals and representative thrombograms were generated for each device tested
- Devices: Axium™ MicroFX™ nylon detachable coil system; Axium™ MicroFX™ PGLA detachable coil system; Axium™ detachable coil system (sample size of 2 coils in each of 9 unique batches of human platelet rich plasma = 18 total tests per device type)
- Study endpoints evaluated:
  - Peak Thrombin†
  - Rate of Thrombin Generation‡
  - Endogenous Thrombin Potential (ETP)§

Results

Axium MicroFX coils exhibited significantly higher peak thrombin, rate of thrombin, and Endogenous Thrombin Potential (ETP) as compared to bare platinum Axium MicroFX coils.

Figure 1: Representative thrombograms for Axium, Axium MicroFX PGLA, and Axium MicroFX Nylon samples.

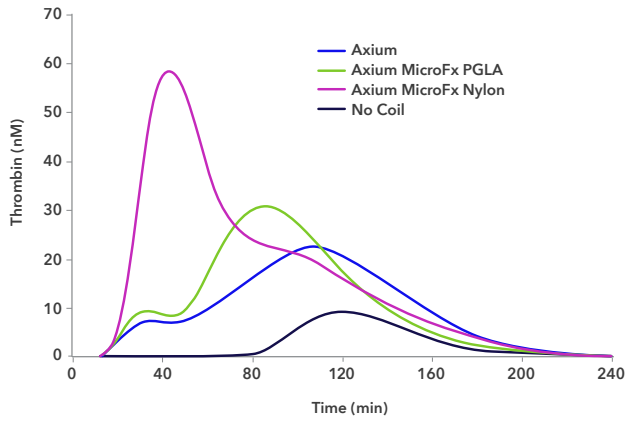
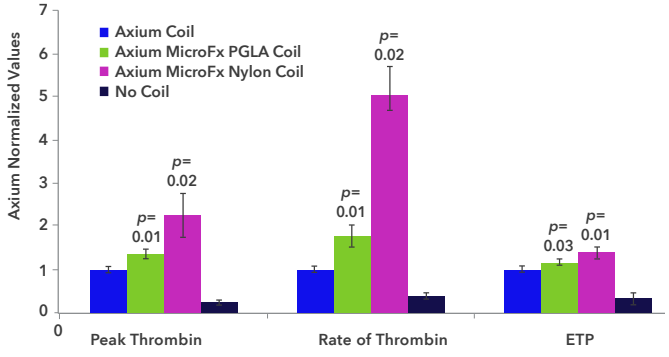


Figure 2: Graphical summary of test result values normalized against bare Axium coil results (mean +/- S.E.) for the three parameters over 18 tests per device type.



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Discussion

- Coils with nylon filaments exhibited significantly higher thrombogenicity than both coils with PGLA filaments and bare platinum coils. Coils with PGLA filaments significantly enhanced thrombogenicity relative to bare platinum coils.
- Because these tests were performed in microplates, the findings provide a quantitative measure of thrombus growth around the coil in the absence of blood flow. This provides a direct thrombogenicity comparison between coils composed of different materials independent of dynamic physiological conditions.
- The only difference between the test sample groups was the presence or absence of microfilaments, and therefore, the improved thrombin generation seen with Axium MicroFX Nylon or Axium MicroFX PGLA is attributed to the presence of the nylon or PGLA fibers.

Author's Conclusions

Coils with added filaments produce a stronger thrombogenic response as compared to bare platinum coils. The impact on thrombogenicity is dependent on the filament material (nylon or PGLA).

Funding Source

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†Peak Thrombin – maximum thrombin generated in the experiment

‡Rate of Thrombin – gradient between the max amount of thrombin generation and the first inflection point

§Total Amount of Thrombin Generated – defined as ETP or endogenous thrombin potenital (area under the curve)