Spiral Coated Guglielmi Detachable Coils for Intracranial Aneurysms: Optimizing Mechanical Properties with Biological Activity

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Statement of Purpose: Guglielmi Detachable Coils (GDCs) remain the gold standard for the treatment of intra-cranial aneurysms. However, since platinum-based GDCs are biologically inert, coating GDCs with polymer to illicit an inflammatory response has proved to be beneficial for enhanced aneurysm healing.[1] In addition, direct contact between the aneurysm wall and an acute inflammatory inducing bioactive coil hold potential for accelerated healing. Despite these improvements, current polymer coated coils lack the mechanical strength to serve as primary framing coils. We developed a novel coating technique to confer continuous spiral coating along selected regions of coiled structures. The choice of coating material[2] determines bioactivity, while the coating geometry allows the coating of large framing coils to preserve flexibility to conform to the interior of the aneurysm, and the mechanical integrity to withstand inherent hemodynamic forces after implantation. The purpose of this study is to evaluate the mechanical integrity, flexibility, and efficacy in vivo of these novel, spiral coated coils.

Methods: GDC coils were subjected to (a) no coating, (b) spiral coating, and (c) simple dip coating. For spiral-coating, coils were drawn from aqueous polymer solutions to cover the contact grooves between each coil, and then drawn from an acidic poly-lactic-co-glycolic acid (aPLGA) (Lakeshore Biomaterials) solution. After drying, the coils are immersed in water to remove the aqueous polymer from the grooves. To asses polymer stability on the platinum surface, simple dip coated coils were coated as previously described and passed through an Echelon14™ microcatheter with saline flush and imaged under SEM (Nova 230, FEI) for gross particle loss. The mechanical properties of spiral coated coils, simple dip coated coils, and uncoated coils were tested using a fixed 3-point bending system (Instron 5567) as shown in Figure 1. Young's modulus was calculated for each coil type at an angular deflection of 5.7° and then normalized to uncoated coils. To confirm biological activity of the polymer layer, simple dip coated coils were implanted in an artificially created carotid artery swine model as previously described.[1] Aneurysms were harvested 2 weeks later to determine gross appearance as well as subsequent histological characteristic.

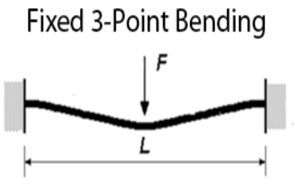

Figure 1. Schematic of the GDC coil flexure mechanical testing.

Results: The simple dip coating technique produced a smooth confluent layer of aPLGA on the surface of the coil as well as the interior volume (Figure 2a). The spiral coating technique produced a thin discontinuous layer of aPLGA on the exterior surface of the coil only (Figure 2b). The polymer layer increased the total diameter by 4um in both simple dip coated and spiral coated coils. SEM images after passing through a microcatheter did not show gross polymer loss (data not shown).

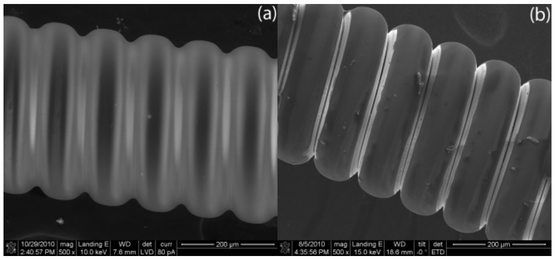

Figure 2. SEM images of GDC coated coils (500x) (a) simple dip coated coil, (b) spiral coated coil.

Mechanical testing showed that spiral coated coils have a significant improvement in flexibility when compared to simple dip coated coils (Figure 3). Gross inspection of implanted coils showed mostly firm opaque tissue, indicating organized thrombus and granulation tissue formation. In addition, histological analysis showed macrophage aggregation around the polymer surface with dense organized connective tissue. Uncoated coils showed little organization, with fresh thrombus (data not shown).

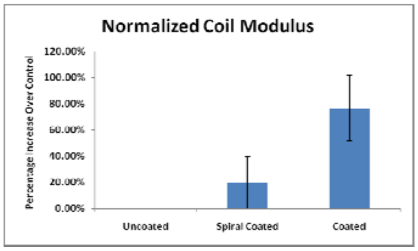

Figure 3 Normalized coil modulus to uncoated coils

Conclusion: We have successfully developed a mechanical strong yet flexible bioactive coil. The thin aPLGA provides a beneficial pro-inflammatory environment with limited impedance to flexibility. The acidic polymer coated coil with preserved mechanical properties may be applied for potentially successful therapeutic treatment through acute inflammation induced wound healing.

References: 1)Yuki, I. J Neurosurg. 2007; 107:109-120. 2) Desai, NP. Hubbell JA. Biomaterials. 1992; 13;505-510