LARGE, WIDE-NECK ANEURYSM CANINE MODEL TREATED WITH NEUROCURE® LIQUID EMBOLIC – 12-MONTH SURVIVAL

Introduction
High recanalization rates of large aneurysms embolized with current devices can be attributed in part to limited modeling of larger aneurysms during preliminary device testing in animal models. We developed a clinically-relevant in vivo canine model of large, wide-neck aneurysms to study aneurysms with traditionally high recanalization rates post-treatment. This model was then treated with a new liquid embolic device under development: NeuroCURE® (Aneuvas Technologies, Inc. (ATI) - Flagstaff, AZ). NeuroCURE® is a non-adhesive, elastic polymer gel (a form of polypropylene diacylate – PPODA) that self-coalesces and completely fills the aneurysms sac in less than 10 minutes.

Materials and Methods
The canine large aneurysm model was developed by the Neurosurgery Research Center at Barrow Neurological Institute (BNI – Phoenix, AZ) and completed as a GLP study at American Preclinical Services (APS – Minneapolis, MN). The study included 10 canines (4 – 3-month, 4 – 6 month, and 2 – 12 month survivals post-embolization) A lateral wall aneurysm was surgically created by anastomosis of the external jugular vein (EJV) segment onto the common carotid artery (RCCA) in the neck. The EJV segment was sewn to the RCCA to form a wide-neck aneurysm (5 – 7 mm diameter). The distal EJV was tied off at a dome height ≥ 10 mm. The animals were survived at least 2 weeks pre-embolization to allow for aneurysm maturation, stabilization, and vessel model healing. NeuroCURE® was then delivered under balloon protection using a single 10 minute inflation.

Results
Pre-treatment angiographic imaging verified a patent aneurysm with large dome height (>10 mm) and wide-neck morphology (>4 mm neck diameter and midline Dome: Neck (D:N) ratio 1.1:1 to 2:1, figure 1A). Post-treatment histology verified healing of the aneurysm neck (full endothelialization and neointimal formation, figure 1A and B). Due to the near complete aneurysm filling, GLP histology verified no thrombus formation, no clot reorganization, no neo-angiogenesis, and minimal inflammation across all survival timepoints.

Conclusion
The canine model was adopted over other models (i.e. rabbit-elastase) because of comparable healing responses to humans, representative blood-flow, similar blood pressure, and vessel sizes that accommodate both large aneurysms and multiple microcatheters. The model and survival timepoints have been approved by the Food and Drug Administration (FDA) for clinical assessment of NeuroCURE®, for which an Investigational Device Exemption (IDE) application is underway.

Disclosures
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Improved fluid dynamics simulations of coiled cerebral aneurysms using microtomography and homogenization techniques

Abstract P-055 Figure 1

A) continuous neointimal growth across the neck of a canine aneurysm (12-month survival); B) H&E stain showing neck neointimal formation (**) at the dimple created by balloon protection, > 90% aneurysm fill (white intrasaccular area is NeuroCURE), and a stabilized remnant of a microcatheter track inside the NeuroCURE gel (*)

Abstract P-056

Method of obtaining high-resolution coil geometry

Abstract P-056 Figure 1

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