Abstracts

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

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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® (Anevus Technologies, Inc. (ATI) - Flagstaff, AZ). NeuroCURE® is a non-adhesive, elastic polymer gel (a form of polypropylene diacrylate – 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 (≥ 4mm 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.

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Abstract P-056 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 (*)

P-056 IMPROVED FLUID DYNAMICS SIMULATIONS OF COILED CEREBRAL ANEURYSMS USING MICROTOMOGRAPHY AND HOMOGENIZATION TECHNIQUES

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Hemodynamic changes after aneurysm coiling can be simulated using computational fluid dynamics (CFD) to better predict treatment outcomes. Since the geometry of the coil mass is not visible using conventional imaging, most CFD simulations represent coils as a simplified, uniform porous medium. This
simplification introduces error into CFD simulations that may affect accuracy. We developed an improved method of representing the porous spatial distribution of the coil mass in CFD simulations to reduce such error. This method characterizes the porous spatial distribution of the coil mass using 3D-printed PDMA models of seven patient-specific aneurysms treated with commercially-available coils and scanned using synchrotron microtomography. This provides high-resolution, 3D images of the coil mass geometry (figure 1). Images were segmented to analyze the porosity distribution along the aneurysm radius. Permeability and inertial factor parameters were used to construct a mathematical representation of the coil mass that did not require microtomographic scanning. This was then incorporated into CFD simulations and compared to simulations of the same aneurysms which incorporated the actual microtomographic coil geometry (figure 2). The results show that porous distribution (varying between 0.6 and 0.95) leads to improved permeability gradients, which reduced the error in the mean velocity within the aneurysm dome to lower than 15%, substantially better than those seen with traditional homogenous porous media approaches. Our method thus better represents the effect of the coil mass on intraaneurysmal hemodynamics as compared to the standard approach used in many CFD simulations. Our method could be applied to future CFD studies of coiled aneurysms, without microtomographic scanning, to improve the accuracy of hemodynamic calculations and predict treatment outcome.

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P-058 TARGET ULTRASOFT AND NANO COILS FOR THE TREATMENT OF SMALL BRAIN ANEURYSMS


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Introduction The Q’Apel Medical Wahoo guide catheter is a 7 French guide catheter approved by the FDA in September 2018 with an 0.072" inner diameter and the ability to alternate between tracking and support modes. Tracking mode allows the catheter to navigate distally, and once in support mode, catheter positioning remains extremely stable, mitigating the need for a tri-axial 8 French system. We report our experiences with the Wahoo guide catheter in a variety of embolization procedures.

Methods A retrospective chart review was performed of cases in which the Wahoo catheter was used as a guide from February 2020 to January 2021. Patient demographics, lesions treated, side of lesion, treatment technique, access site, vessel characteristics, devices used, and peri and post procedural complications were collected.

Results 46 consecutive cases were identified. 32 patients were female (69%), and average age was 55 (± 13, range 17-83) years. 41 cases were aneurysm embolizations (89.1%), 3 were MMA embolizations for cSDH (6.5%), and there was one case of an AVM rupture (2.2%) and one case of balloon angioplasty for ICAD (2.2%). 20 cases were treated from the left (43.5%), 24 were treated from the right (52.2%), and in 2 MMA embolizations both sides were treated (4.3%). 33 cases were performed with femoral access (71.7%), 12 via radial access (26.1%). In 14 cases, there was vessel tortuosity (30%); 4 severe (8.7%), 3 moderate (6.5%), and 7 mild (15%). Of the 39 cases in which the guide was placed in the ICA (84.8%), 33 were placed in the petrous ICA or distal to it (84.6%).

There were no instances of guide prolapse from the segment in which it was placed. A variety of treatment modalities were employed. 15 coil (33.6%), 2 coil plus flow diversion (4.3%), 2 coil plus stenting (4.3%), 19 flow diversion (41.3%), 2 WEB (4.3%), 4 Onyx embolizations (8.7%), and 1 balloon angioplasty (2.2%) were performed.

There were two procedural complications: one dissection due to wire navigation and unrelated to the Wahoo guide catheter (2.2%), and one dissection which in which the causal relationship was undetermined (2.2%). There were no long-term neurological sequelae in either case. There were no access site complications. All procedures were successfully completed with no need to change to another guide.

Conclusion The Wahoo catheter is an effective guide catheter than can accommodate a diversity of devices, can be safely navigated into distal vasculature, and be used in a variety of embolizations in lieu of an 8 French based tri-axial system.

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P-058 TARGET ULTRASOFT AND NANO COILS FOR THE TREATMENT OF SMALL BRAIN ANEURYSMS

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Purpose The ULTRA Registry is an multicenter, national, prospective study designed to assess aneurysm occlusion rates and safety profile of the Target™ UltraSoft and Nano coils (Stryker