A UNIQUE EMBOLIC AGENT: SOLVENT-FREE, SHEAR- RESPONSIVE BIOMATERIAL FOR MICROVASCULAR PENETRATION

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Introduction
The Distally Penetrating Embolic (DPE) is a purpose-built, solvent-free, shear-responsive, silicone-based biomaterial designed for embolization applications where complete casting and occlusion of fine vessel branches is desired (e.g., embolization of the middle meningeal artery for meningiomas and chronic subdural hematoma). The DPE is supplied as a three-part system in small-volume syringes that are mixed prior to use, forming an injectable, shear-thinning paste that preferentially drives into distal vessels where shear is highest; ultimately, the DPE cures in situ into an elastomeric solid. Here, we report on DPE usability and embolization performance in vivo.

Methods
Usability: Six neurointerventional radiologists assessed device preparation and injection using a Likert scale (1-very difficult to 5-very easy). Embolization: A total of 57 injections in 20 swine at two sites were performed to acutely evaluate distal penetration and occlusion performance; injections were performed using a 0.017" microcatheter (n=52) or with dual-lumen balloon occlusion (n=5). Seven and thirty-day studies were conducted against commercially-available controls to evaluate embolization and safety performance in kidney vasculature (n=8 per timepoint). Occlusion via angiography, distal penetration via micro-computed tomography (µCT), and biocompatibility via histopathology were assessed.

Results
Average device preparation time by clinicians was 2.3 ± 0.4 minutes. Usability was acceptable, and all clinicians were able to hand-inject the material through a 150 cm long, 0.017" microcatheter. When injected into vessels with blood flow, the DPE shear-thinned and was carried distally into small branches; thereafter, it proceeded proximally to fill larger vessels. After injection was stopped, proximal blood pressure continued to 'pack' the material further into the distal vasculature and capillary bed until the material completely cured (~10 minutes from initial mixing). With balloon occlusion, the pressure from injection progressively advanced the DPE proximally to distally, whereupon it shear-thinned and evenly penetrated into small vessel branches. At follow-up, angiography showed effective occlusion of target vasculature without evidence of recanalization. µCT radiographs indicated complete casting of millimeter to micron-sized vessels. Histological sections confirmed full luminal occlusion in vessels down to 30-micron diameter (material was not detected in the venous vasculature). Vessel injury and necrosis were both absent while inflammation was only minimal. No hemorrhage occurred when DPE-embolized kidney tissue was surgically incised.

Conclusion
The solvent-free, shear-responsive DPE is an easily prepared, hand-injectable agent that penetrates deeply into distal vessels to provide complete casting and occlusion of target vasculature with favorable biocompatibility. These promising outcomes warrant further study in human subjects.

Disclosures
D. Fiorella: 1; C. National Cancer Institute – R44CA257802, Penumbra, Stryker, Balt USA, Siemens. 2; C.
Abstract O-042 Table 1

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Access</th>
<th>Vessels catheterized</th>
<th>Catheter used</th>
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<th>Contrast</th>
<th>Fluoro Time</th>
<th>Platelet Count</th>
<th>INR</th>
<th>GFR Status</th>
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Abstract O-043

**TRANSUMBILICAL ACCESS FOR VEIN OF GALEN MALFORMATION AND DURAL/PIAL ARTERIOVENOUS FISTULA EMBOLIZATION: A CASE SERIES**

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**Introduction** Vein of Galen Malformation (VOGM), in infants, presents with congestive heart failure, developmental delay, or other serious neurological impairment. Pial arteriovenous-fistulas (pAVF) are distinct from VOGM, but present similarly. In the neonatal period, transfemoral access may be complicated by sheath size needed for embolization, especially if retreatment is required. Here, we report 15 cases of transumbilical access for VOGM/pAVF embolization between January 2014 and September 2021.

**Methods** A retrospective review of our clinical database for patients with pAVF/VOGM treated between January 2014 and September 2021 was performed. Prior to 2014, some data was inaccessible following record loss after administrative changes in the hospital system. Out of 15 cases selected for detailed analysis, five continued treatments beyond this record loss and are reported to the fullest extent available.

**Results** Out of 15 trans-umbilically accessed VOGM/pAVF embolizations, 10 (66.6%) were female. 13/15 demonstrated choroidal VOGM angioarchitecture (86.7%) with one mural VOGM and one pial dAVF. The median treatments performed trans-umbilically was two (Range:1–4). The median age at first treatment was 3 days (Range:1–13). The patient treated at 13 days was catheterized immediately after birth at an outside hospital, then flown to our facility. Of the 15, seven (46.7%) were diagnosed antenatally. One patient presented with mild respiratory failure alone (pAVF). 14 presented with heart failure. In four cases, this heart failure was accompanied by either seizure, mass-effect/respiratory failure, pulmonary hypertension, or hydrocephalus. Line placement in the umbilical artery (UAC) was successful (1UA in 8, both in 7). The median catheter-use time (before exchange for a 4F-sheath or removal) was 6.5-days (Range:1–13). A 4F-sheath was placed intra-procedurally in all cases. In cases where the sheath was maintained post-procedurally, the median time of use was 4-days with a (Range:1–7), monitored daily. While one patient experienced post-UAC fever, no patients presented with thrombosis or inflammation. Intraprocedural complications included a case of pulmonary hemorrhage, which resolved, a case of left PCA micro-guidewire perforation which led to a short but spontaneously resolved bleed, and a subarachnoid hemorrhage. While one of these patients passed away, it was importantly not due to the intervention, but due to the severity of the VOGM. Three (20%) members of our cohort passed away due to the severity of their illness. Five (33.3%) have achieved complete obliteration, six (40%) remain in treatment, and one patient was lost to follow-up. Of the 12...