Abstract O-004 Table 3 Aneurysm occlusion by WEB width in aneurysms with adequate WEB LC

	4mm WEB: (N=16)	5mm WEB: (N=13)	6-7mm WEB: (N=14)	8-11mm WEB:(N=8)	p-value:
Complete Occlusion, %:	100	100	36	38	<0.0001
Adequate Occlusion, %:	100	100	93	63	0.007
Retreatment, %:	0	0	7	13	0.37

nificant lower rate of complete and adequate aneurysm occlusion for larger WEB widths (table 2), even in aneurysms with adequate WEB LC (table 3). Further, there was a statistically-significant lower rate of retreatment in aneurysms treated with 4mm and 5mm WEBs (3%) compared to 6 to 11mm WEBs (18%, p-value 0.04).

Conclusion The efficacy of aneurysm occlusion with WEB decreases with increasing WEB width despite attaining adequate WEB LC. Although attaining greater WEB LC when using larger WEBs, when technically-feasible, may increase the likelihood of complete and adequate aneurysm occlusion at follow-up, proper operator and patient expectations should be set prior to treatment.

Disclosures J. Delgado Almandoz: 2; C; Microvention/Terumo. Y. Kayan: 2; C; Microvention/Terumo. A. Copelan: None. J. Scholz: None.

O-005

COMPARISON OF ON-LABEL VERSUS OFF-LABEL TREATMENT OF INTRACRANIAL ANEURYSMS WITH THE PIPELINE EMBOLIZATION DEVICES

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Background and Purpose The Pipeline Embolization Device (PED) is widely used for treatment of intracranial aneurysms, including in off-label applications. The performance of PED in off-label applications is not well understood. In this work, we quantify real-world efficacy and safety of PEDs in on-label and off-label aneurysm treatments.

Materials and Methods Clinical and angiographic data of patients who underwent PED placement at a high volume academic medical center were retrospectively obtained. Treatments were classified as on-label if they fell within the applications approved by the United States Food and Drug Administration as of 2020. Reasons for off-label classification included aneurysm location outside of approved internal carotid artery segments, size less than 4 mm, recent rupture, and prior stent placement at the site of PED deployment. Recorded outcomes included aneurysm occlusion, procedural complications, ischemic events, in-stent stenosis, intracranial hemorrhage, post-procedural functional status, and mortality.

Results 416 aneurysms in 330 patients were treated with PED, comprising 234 on-label and 182 off-label aneurysms. Overall rate of complete aneurysm occlusion was 76.0% for on-label aneurysms and 76.3% for off-label aneurysms (p=1.000). The risk of ischemic stroke in patients undergoing off-label treatments was 9.1%, higher than the 4.0% in patients undergoing on-label treatment (p=0.047). Procedural complications

Abstract O-005 Figure 1

including thrombus formation, vasospasm, device malfunction, access site complications, and anesthesia related complications occurred in 11.7% of on-label procedures and 11.3% of off-label procedures (p=1.000). Clinical outcomes such as intracranial hemorrhage, death, and long-term functional status were comparable between on-label and off-label groups.

Conclusion In real-world practice, off-label uses of PED can achieve similar safety and efficacy to on-label uses, though there may be a slightly higher rate of ischemic complications in off-label uses. Expert judgment is a useful supplement to official guidelines when assessing reasonable PED use beyond its approved indications.

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O-006

PROTOTYPING A BALLOON STENT FOR MINIMALLY INVASIVE TEMPORARY ANEURYSM OCCLUSION AND EMBOLIZATION

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Introduction Intracranial aneurysm claim 15,000 American lives annually, resulting in an additional 9,000 neurological deficits. While neuro-interventional devices rapidly advance, the use of temporary balloon occlusion to improve aneurysm sac remodeling can increase downstream ischemic risk. Balloons ensure that the aneurysm sac remains occluded during embolization, but also disrupts flow temporarily in the parent vessel.

Methods We propose an alternative to temporary balloon occlusion call the balloon-stent: an ultra-compliant urethane balloon (20 mm length, 2.5-3F diameter) encasing a self-expandable nitinol stent that allows parent artery flow through a hollow central canal (1.5-3mm expanded diameter). The balloon-stent is deployable and retrievable, from a large primary lumen (~0.018" ID - figure 1a). **Abstract 6 Figure 1** Left - CAD rendering of the balloon stent microcatheter device and cross-sectional view (upper right). **Right** - Results of a Computational Fluid Dynamic (CFD) simulation rendering velocity streamlines of an ICA aneurysm Fractional Pressure Ratio (FPR) - pressure drop (ΔP) across neurovascular stenosis, is