O-010

FIVE-YEAR AUSTRALIAN EXPERIENCE WITH PIPELINE™ FLEX EMBOLIZATION DEVICES WITH SHIELD TECHNOLOGY™: REAL WORLD EVIDENCE (SCOPE-AUS)

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Objective The Pipeline™ Flex Embolization Device with Shield Technology™ has been available in Australia for 4 years to treat intracranial aneurysms of the anterior and posterior circulation in both elective and ruptured presentations. There is the potential for Shield Technology™ device surface modification to reduce platelet adhesion and platelet specific thrombogenicity. The SCOPE-AUS retrospective multicenter observational cohort study will report risk-adjusted safety and effectiveness outcomes in real-world patient populations treated with the Pipeline™ Flex Embolization Device with Shield Technology at four major centers in Australia.

Methods Real-world outcome analysis of 500 consecutive cases performed between 01 April 2015 - 30 June 2018 at four major centers in Gold Coast, Sydney and Perth will be presented. Pre-defined data variables are collated in a databank of patient socio-demographics, aneurysm and device characteristics, safety and clinical outcomes. Independent neurointerventionist assessments will determine the effectiveness of intracranial aneurysm treatment using validated grading scales to report complete aneurysm occlusion. Safety endpoints will be adjudicated by an independent neurointerventionalist to classify the aetiology of a neurological adverse event. Data abstraction metrics reporting interrater reliability (κ +0.80) and intrarater reliability (ICC 0.75–0.90) will be presented.

Results Comprehensive statistical analysis of the data will report total prevalence, morbidity, mortality and time-to-event analyses at post procedural timepoints (30 days, 6 months and 12 months) using descriptive statistics, Kaplan Meier curves and logistic regression models. Both crude and adjusted estimations of association and risk for confounding or predictive factors in the patient population will be reported. Both relative risk and odds ratios with 95% confidence intervals and p-values will be presented.

Conclusion The findings from this study will present real world safety and efficacy outcomes of high volume centers in Australia using the Pipeline™ Flex Embolization Device incorporating surface modification with Shield Technology™ in contemporary practice.

Human Research Ethics approval number HREC/17/QGC/331; **clinicaltrial.gov registration** NCT03815149; **Grant funding:** Medtronic External Research Program, Medtronic Australasia Pty Ltd, Australia.

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Disclosures H. Rice: 1; C; Medtronic External Research Program, ISR-2017-10909. 2; C; Medtronic, Stryker. 5; C; Queensland Health, QScan Radiology Clinics. L. de Villiers: 2; C; Medtronic, Stryker. 5; C; Queensland Health, QScan Radiology Clinics. M. Owusu: None. J. Wenderoth: 2; C; Medtronic. 5; C; NSW Health, Sydney Neurointerventionalist Specialists. A. Chiu: None. N. Manning: None. A. Cheung: None. T. Phillips: None. C. Rapier: None. S. Gatty: None. L. Ninnes: None. I. Hughes: None. T. Green: None.

O-011

THE SURPASS™ INTRACRANIAL ANEURYSM EMBOLIZATION SYSTEM PIVOTAL TRIAL TO TREAT LARGE OR GIANT WIDE NECK ANEURYSMS – SCENT TRIAL: 3-YEAR OUTCOMES

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Introduction The Surpass™ Flow Diverter (FD) was developed to treat large or giant wide-neck intracranial (IC) aneurysms not amenable to surgical or current standard endovascular treatment due to location, morphology or known treatment challenges. Compared to commercially available flow diversion technology in the US, the Surpass FD offers additional treatment options that fulfill an unmet clinical need as currently available flow diverter technology is limited to IC aneurysms within the ICA from the petrous to the superior hypophyseal segments. The Surpass FD's Indications for Use allow for placement in the ICA up to the terminus. The Surpass FD is available in diameters from 3 to 5 mm and lengths of 15 to 50 mm, therefore allowing fewer Surpass FD use in the treatment of large and giant aneurysms. The goal of the present study is to present 3-year outcomes of SCENT Trial in special safety and efficacy of this large prospective cohort.

Methods The SCENT Trial is an international, multi-center, prospective, single arm trial designed to evaluate the safety and efficacy of the Surpass™ FD in treatment of large or giant wide-neck (≥ 4 mm) IC aneurysms ≥ 10 mm in size. We present 36-month outcome data. Secondary effectiveness endpoints measured post-index procedure through 60 months: the percent of aneurysm rupture, Surpass implant stenosis ($\geq 50\%$ stenosis), Parent artery occlusion at the target aneurysm location, change in mRS compared to baseline, Surpass delivered to cover the aneurysm neck, Raymond Class and complete occlusion at 36 months, Surpass successfully delivered and implanted, Incidence of retreatment at 36 months.

Results From October 2012 through November 2015, 180 subjects were treated at 26 sites. 36-month follow up, 94.8% (127/134) completed clinical follow-up, 76.9% (103/134) completed clinical and angiogram follow-up. The functional mRS scores remained unchanged or improved in most subjects at 36 months (85.0%, 108/127) when compared to the same measure at baseline. The rate of Raymond 1 total occlusion continued to improve at 36-month follow up compared to 12-month scores; 79.0% (83/105) of subjects demonstrated Raymond 1 occlusion at 36 months vs. 66.1% (119/180) at 12 months. Raymond 2 occlusion at 36 months was 20.0% (21/105), compared to 9.4% (17/180) of subjects with Raymond 2 at 12 months. The Raymond 3 occlusion rate decreased to 1.0% (1/105) of subjects at 36 months compared to 15.0% (27/180) 12-months post procedure. The proportion of subjects experiencing new or worsening major ipsilateral stroke, as adjudicated by the CEC, was 8.3% (15/180) at 12 months and increased to 8.8% (16/180) and 9.4% (17/180) subjects at 24, and 36 months respectively. Four (2.2%, 4/180) experienced aneurysm rupture by 12 months, all within the first-week post target aneurysm treatment. No additional late aneurysm ruptures occurred through 36 months. Four subjects who received retreatment beyond 12 months had a residual aneurysm. The 60-month occlusion durability and safety endpoint results will be the subject of a future presentation.

Disclosures R. Hanel: 1; C; Stryker, Medtronic, MicroVention, Balt. 2; C; Stryker, Medtronic, Balt, MicroVention, Phenox, Three Rivers Medical, Elum, Corindus, Shape Medical. 4; C; elum, Three Rivers Medical, Corindus, Cerebrotech, Synchron,

BlinkTBI, Scientia, RIST, InNeuroCo. A. Coon: 2; C; stryker, medtronic, microvention, inneuroco. P. Kan: 2; C; Inneuroco. A. Wakhloo: 1; C; Phillips. 2; C; Stryker, Phenox. 4; C; Inneuroco, EPIEP, Neural Analytics. P. Meyers: 2; C; Stryker.

0-012 ANTI-THROMBOGENIC COATING FOR FLOW DIVERTERS: USING HIGH-FREQUENCY OPTICAL COHERENCE TOMOGRAPHY TO IMAGE ACUTE THROMBUS BURDEN

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Introduction The use of stents in the treatment of wide neck aneurysms, and more recently the adoption of flow diverters, are important tools for the treatment of aneurysms.¹ One major complication of such implants is thromboembolism, requiring the use of dual anti-platelet therapy (DAPT). However, due to variable response and inherent risks of DAPT, new stents are being developed with anti-thrombogenic coatings with the goal to reduce or eliminate the need for DAPT. **Methods** A novel hydrophilic polymer coating (HPC) applied to a nitinol substrate has been shown to resist platelet aggregation in vitro.² We sought to demonstrate preliminary evidence to confirm this observation in vivo. Three pigs were used with different regimens: no antiplatelet medication (NAPT), 81 mg aspirin (SAPT), and 81 mg aspirin with 75 mg Clopidogrel (DAPT). Two control and two coated devices were implanted in each animal.

Abstract 0-012 Figure 1 HF-OCT cross-sectional imaging from each animal. Metallic flow-diverter struts are visualized by HF-OCT as small bright objects followed by a shadow. Top row (A-C) shows the coated device, with NAPT (A), SAPT (B) and DAPT (C). There is a small amount of clot (white arrow, A), but once SAPT is added, there is almost none left. Bottom row (D-F) shows the control device, with a large amount of clot with NAPT (white arrow D), requiring DAPT to remove all clot. In image (D), blood residuals due to incomplete artery clearance by contrast injection are visible approximately between 5 and 9 o'clock