Background and Purpose The Pipeline Flex Embolization Device with Shield Technology (PEDS) is an updated version of the Pipeline Flex Embolization Device (PED) which has been modified to include a surface phosphorylcholine biocompatible polymer. It was already reported PED was less effective in recurrent previously stented cerebral aneurysms using Neuroform stent or Enterprise stent than in nonstented aneurysms. However there is no data regarding PEDS for recurrent previously stented cerebral aneurysms using LVIS stent. The aim of this study was to evaluate the efficacy and safety of the PEDS in the treatment of recurrent previously stented aneurysms using LVIS stent.

Materials and Methods We retrospectively analyzed four consecutive patients (mean age, 52.0 years; all female) who underwent PEDS placement for recurrent previously stented cerebral aneurysms using LVIS stent between January 2020 and February 2021. Two aneurysms were located in the internal carotid artery, two aneurysms in the vertebral artery. The mean size of the aneurysms was 18.7 mm (range, 14-23). Technical success rates, symptomatic stroke within 30 days, occlusion at the latest follow-up angiogram and late adverse events (recurrence and retreatment rates, and strokes or neurologic deaths) were analyzed.

Results The technical success rate was 100%. No symptomatic stroke developed within 30 days. During a mean follow-up period of 5.3 months, complete occlusion was achieved in 3/3 (100%) and no late adverse events occurred.

Conclusions The PEDS may become treatment option for recurrent previously LVIS stented cerebral aneurysms.

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E-125

IMPACT OF COVID RELATED RESTRICTIONS ON CLINICAL TRIALS – INSIGHTS FROM THE STERLING REGISTRY

¹R De Leacy*, ²A Puri, ³R Starke, ⁴B Jankowitz, ⁵A Yoo, ⁶G Pero, ⁷C Chivot, ⁸T Yao, ⁹O Zaidat. ¹Cerebrovascular Center at Mount Sinai, Mount Sinai Health System, New York, NY; ²Radiology, Neurological Surgery, and Neurosurgery, UMass Memorial Health Care, Boston, MA; ³Neurosurgery, UMass Memorial Health Care, Boston, MA; ⁴Neurological Institute, Neurological Surgery, and Stroke Program, Cooper University Health Care, Pittsburgh, PA; ⁵Neurological Surgery, Texas Stroke Institute, Plano, TX; ⁶Neuroradiology, Ospedale Niguarda, Milan, Italy; ⁷Radiology, CHU Amiens Picardie, Amiens, FRANCE; ⁸Neuroscience Institute, Norton Neuroscience Institute, Norton Healthcare, Louisville, KY; ⁹Neuroscience Institute, Mercy St. Vincent Hospital, Toledo, OH

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Introduction The STERLING registry is a prospective collection of aneurysms treated with endovascular techniques. The primary intention is to assess the efficacy and safety of Galaxy and MicrusFrame coils (Cerenovus, Irvine, CA). The Covid pandemic has the potential to alter the delivery of medical care or trial enrollment. Changes to regional or hospital specific research infrastructure will likely affect trials for the worse.

Methods A retrospective review of STERLING sites and patients was undertaken to better understand regional variation in adapting to the pandemic and how enrollment was affected.

Results 45 global sites currently take part in the STERLING registry. 28 sites began enrolling pre-Covid. 34% of U.S. sites were required to halt research, enrollment or elective surgery, whereas only 8% of EU and none of the Japanese sites were

Abstract E-125 Table 1 Post-COVID differences in actual vs. projected monthly enrollment rates by region

Region	Actual (mean $\pm$ SD)	Projected (mean $\pm$ SD)	Mean Diff.	95% CI
US	5.92 $\pm$ 3.53	9.58 $\pm$ 0.51	3.67	1.53; 5.80
EU	3.83 $\pm$ 2.04	5.83 $\pm$ 1.34	2.00	0.54; 3.46
Japan	1.25 $\pm$ 1.60	2.17 $\pm$ 0.39	0.92	-0.07; 1.90
Global	3.67 $\pm$ 1.61	5.86 $\pm$ 0.67	2.19	1.15; 3.24

required to significantly change their research protocols respectively. At the 10 (9 US, 1 EU) sites required to put a hold on research, rates of enrollment dropped from an average of 0.6 subjects/month in the US (0.5 in EU) to 0 in the first month and 0.1 subjects/month in the second month of Covid-related restrictions. At the time of this analysis (1/2021), the average rate of enrollment across those sites partially recovered to 0.2 subjects/month in the US and 0.2 in EU, although 5 of the 10 sites (all US) had not enrolled any subjects post Covid. Overall, mean actual vs. projected enrollment rates decreased more in the U.S. than in the EU and Japan. The percent of ruptured aneurysms in the per-protocol analysis increased from 23% to 40%, while the percent of unruptured aneurysms decreased from 76% to 60%. There were no significant changes to occlusion rates or adverse events pre/post Covid.

Conclusion The Covid pandemic has the potential to dramatically alter how research is conducted worldwide. U.S. sites faced tougher restrictions than their EU and Japan counterparts. Particularly within the U.S., moratoriums on research and elective surgery may be the driving factor in reducing overall enrollment and increasing the percentage of ruptured aneurysm enrollment. Fortunately, these changes did not appear to negatively affect occlusion rates or adverse events.

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COMPARISON OF STENT RETRIEVER THROMBECTOMY USING 3D PATIENT SPECIFIC MODELS OF INTRACRANIAL CIRCULATION WITH ACTUAL MIDDLE CEREBRAL ARTERY OCCLUSION THROMBECTOMY CASES

¹M Mokin*, ¹E Pressman, ²K Sommer, ²C Ionita. ¹University of South Florida, Tampa, FL; ²University at Buffalo, Buffalo, NY

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Background Stent retriever (SR) thrombectomy is commonly used for the treatment of emergent large vessel occlusion (ELVO) in acute ischemic stroke (AIS). Clot imaging parameters such as clot length, diameter, distance to the internal carotid artery (ICA) terminus and vessel angle where the SR is deployed may predict the likelihood of achieving first-pass effect (FPE). Most of the proposed factors that seem to affect recanalization success have been studied individually, and conflicting data derived from clinical versus in vitro studies using 3D printed models of intracranial circulation currently exist.

Methods Using patient-specific 3D phantoms of the cervical and intracranial circulation, we simulated MCA M1 and M2 occlusions treated with SR thrombectomy using Solitaire (Medtronic) or Trevo (Styker). Our primary outcome was first-pass effect, defined as Thrombolysis in Cerebral Infarction score of 2c-3 achieved after a single thrombectomy attempt. We also performed retrospective analysis of same clot imaging characteristics of consecutive cases of MCA occlusion and its association with FPE matching the 3D in vitro experiments. Analysis was conducted using IBM SPSS Statistics Version 25 (IBM Corp., Armonk, NY). Chi-square tests, and bivariate logistic regressions were the main statistical tests used in analysis. A p-value of less than 0.05 was considered to indicate statistical significance. 95% confidence intervals (95CI) were generated.

Results We compared 42 thrombectomy experiments performed using patient-specific 3D in vitro models with a retrospective cohort of 42 patients treated with SR thrombectomy. We found that in the in vitro cohort, higher MCA angulation was associated with a lower likelihood of FPE (Odds ratio (OR) = 0.967 95CI = 0.944-0.991, $p = 0.008$). Meanwhile in the in vivo cohort, higher MCA angulation was associated with a higher likelihood of FPE (OR = 1.039 95CI = 1.003-1.077, $p = 0.033$). Neither clot length nor location of clot (M1 vs M2) was associated with a difference in FPE rates in either cohort.

Discussion Comparison of SR thrombectomy performed during actual MCA occlusion cases versus patient specific 3D replicas revealed MCA angulation as an independent predictor of procedure success or failure. However, the opposite direction of effect was observed between the two studied environments, indicating potential limitations of studying SR thrombectomy using 3D models of LVO.

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E-127

COMBINED MIVI-Q™ ASPIRATION CATHETER-STENT RETRIEVER APPROACH TO STROKE THROMBECTOMY: PRELIMINARY CLINICAL EXPERIENCE

S Remollo*. *Interventional Neuroradiology, Hospital Universitari Germans Trias i Pujol, Badalona, Spain*

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Background Large-bore aspiration catheters enabling greater flow rates and suction force for mechanical thrombectomy might improve outcomes in patients with stroke secondary to large-vessel occlusion. Complete or near-complete recanalization after a single thrombectomy pass (first-pass effect) is associated with improved clinical outcomes. We assessed the efficacy and safety of novel MIVI Q™ aspiration catheters in combination with stent-retriever devices.

Methods We retrospectively analyzed demographics, procedure characteristics, and clinical data from consecutive patients with acute anterior large-vessel occlusion treated with a combined approach using MIVI Q™ aspiration catheters and stent retrievers. Reperfusion was defined according to the Modified Thrombolysis in Cerebral Infarction (mTICI) score. Clinical outcomes were measured by the National Institute of Health Stroke Scale (NIHSS) and modified Rankin Scale (mRS) scores.

Results We included 52 patients [median age, 75 y (IQR:64-83); 31 (59.6%) women; 14 (26.9%) with occlusions in the terminal internal carotid artery, 26 (50%) in middle cerebral artery (MCA) segment M1, and 12 (23.1%) in MCA segment M2; median NIHSS score at admission, 19 (IQR:13-22)]. After the first pass, 25 (48%) patients had mTICI $\geq$ 2c. At the

Abstract E-127 Table 1 Angiographic outcomes and clinical efficacy

Groin-puncture-to-revascularization [min], median (IQR)	42 (22-66)
Q™ tFPE, n (%)	22 (42.3)
Q™ FPE, n (%)	25 (48)
mTICI 3, n (%)	28 (53.8)
mTICI 2c-3, n (%)	35 (67.3)
mTICI $\geq$ 2b, n (%)	47 (90.4)
mRS 0-2 at 90 days, n (%)	24 (46.2)
sICH, n (%)	1 (1.9)
Serious device-related adverse events, n (%)	0 (0)
Serious procedure related adverse events, n (%)	1 (1.9)

Abstract E-127 Figure 1 LEFT Illustration of the Q™ and stent retriever combined approach during the thrombus wedging maneuver. After removing the microcatheter, the stent retriever has been slightly retracted and the Q™ catheter carefully advanced under pump aspiration to ensure better engagement of the thrombus. The flared proximal tip of the Q™ catheter (magnified inset) ensures a tight seal between its outer surface and the Super 90 guiding catheter's inner surface, enabling increased suction power (curved black dashed arrow) directly through the guide catheter. RIGHT Q6 aspiration catheter and Stent Retriever with a "pinned" thrombus