3.1 OTHER – Innovation

029/279 CLINICAL VALIDATION TRIAL OF BRAIN20(R), A MEDICAL DEVICE TO PREDICT FUNCTIONAL RECOVERY IN PATIENTS WITH ACUTE ISCHEMIC STROKE UNDERGOING ENDOVASCULAR THROMBECTOMY. PROMISE20 STUDY PROTOCOL

1,2Alicia Martínez-Piñeiro*, 3Jordi Cortés, 4Monica Millan, 5Natalia Pérez de la Ossa, 6Marc Ribo Jacobi, 7Joaquín Serena, 8Jaume Colli, 9Gisela Ruiz, 10Antoni Davalos. Hospital Germans Trias i Pujol, Neurosciences, Badalona, Spain; 1,3Time is Brain, Badalona, Spain; 2Universitat Politècnica de Catalunya · Barcelona Tech – UPC, Statistics and Operations Research, Barcelona, Spain; 6Vall d’Hebron University Hospital, Neurology, Barcelona, Spain; 5Hospital Universitari de Girona Doctor Josep Trueta, Neurology, Girona, Spain; 1,7Time is Brain S.L., Badalona, Spain

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Introduction N20 somatosensory evoked potential (SEP) response shows high predictive accuracy of functional recovery in patients with acute ischemic stroke (AIS) undergoing endovascular thrombectomy (EVT) (https://www.clinicaltrials.gov/ct2/show/NCT04099615). This capacity is independent and higher than clinical and advanced imaging variables.

Aim of Study To validate BraiN20®, a portable, non-invasive, AI-based device to monitor in real-time the presence and characteristics of N20 in AIS.

Methods 65 patients with AIS undergoing EVT within 24 hours from onset are included in three comprehensive stroke centers. Eligibility criteria are no significant pre-stroke functional dependence, baseline NIHSS score ≥ 6 points, occlusion (mTICI 0–1) of the intracranial ICA, MCA-M1 or M2 suitable for EVT per local protocols, without infarct volume restrictions measured by ASPECT score or by CTP/DWI-MRI prior to EVT. The primary objective is to confirm an optimal good reliability of N20 registration before EVT higher than 75% by two blind expert neurophysiologists, assuming a true proportion equal to 87.5%. Secondary endpoints are the predictive accuracy of N20 response recorded by BraiN20® before and after EVT on functional outcome evaluated by the mRS at 7 and 90 days and analyzed by using ROC curves. A futility interim analysis is planned after the inclusion of 25% of the sample.

Results The trial is sponsored by Time is Brain S.L. and will start early July 2023. Primary endpoint results are expected by the end of this year.

Conclusion BraiN20® could be a useful medical device to predict salvageable brain and functional recovery of patients along the stroke chain.

Disclosure of Interest Co-Founder and CEO of Time is Brain S.L.

030/301 INTERACTION FORCES BETWEEN A GUIDEWIRE AND A CLOT ANALOGUE – NEW PERSPECTIVES FOR MECHANICAL THROMBECTOMY

1Evgenia Roussinova*, 2Olivier Brina, 3Philippe Reymond, 4Silvestro Micera, 5Mohamed Bouri, 6Paolo Machi. 1Federal Institute of Technology of Lausanne (EPFL), Translational Neural Engineering Lab (TNE), Lausanne, Switzerland; 2Geneva University Hospitals, Division of Neuroradiology, Geneva, Switzerland; 3Scuola Superiore Sant’Anna, The Biorobotics Institute and Department of Excellence in Robotics and AI, Pisa, Italy; 4Federal Institute of Technology of Lausanne (EPFL), Biorobotics laboratory (BioRob), Lausanne, Switzerland

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Introduction In the treatment of acute ischemic stroke, localising the clot and identifying its mechanical characteristics are two of the main highlighted challenges for the choice of the extraction technique.

Aim of Study This study aims to: 1) explore the interaction forces between a guidewire and a synthetic clot for different occlusion conditions in a simplified arterial model; 2) develop algorithms to identify the beginning and the end of the clot and therefore deduce its length.

Methods Clot analogues of different stiffnesses and sizes were injected with a controlled pressure in a silicone conical arterial phantom. A robotic device instrumented with a force sensor controlled the movement of a guidewire at 1 mm/s both in crossing the lesion and in retracting the guidewire after clot penetration.

Results For a given pressure and clot volume, a rigid clot produces higher forces than a soft clot. However, at the same location, we can have a softer clot inserted at a high pressure or a stiffer clot inserted at a low pressure, resulting in similar forces. Based on the slope of the measured force during penetration, the beginning of the clot can be successfully detected. The clot’s end can be identified through the force measurement while retracting the guidewire.

Conclusion This in vitro study shows that multiple factors influence the lodgement of the clot and the corresponding forces that the guidewire encounters. Through a proximal force measurement, the extremities of the clot can be detected.

Disclosure of Interest Nothing to disclose.

4.1 CASE PROPOSAL – Aneurysms

031/303 THREE STORIES ON ECLIPS

Jan-Hendrik Buhk*. Asklepios Hospital St. georg, Neuroradiology, Hamburg, Germany

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Introduction Wide-neck shallow bifurcation aneurysms remain challenging for endovascular treatment and often demand complex combinations of implants.

Aim of Study Here, we present 3 cases, in which the eCLIPS device facilitated treatment of possible wide-necked aneurysms with encouraging results and relatively low procedural complexity.

Methods 3 female patients are presented.

Pat. #1: 52 year-old with history of almost full recovery after severe SAH from tiny basilar tip aneurysm and early relapse. Scheduled treatment with eCLIPS and coils.

Pat. #2: 68 year old with complex ICA terminus aneurysm. Treatment with eCLIPS and coils.

Pat. #3: 76 year old with very wide-neck basilar tip aneurysm, no comorbidities, urgent treatment wish. Individual decision pro treatment with eCLIPS. In this case, the eCLIPS flow diverter was used, no additional coils.

Results All treatments were successful, no periprocedural infarcts.

Pat. #1: 1.5 year follow up shows stable complete occlusion. Clinical status is stable.

Pat. #2: Stable small residual filling after 6 months. Minor late infarction in possible relation to implants noted, as consequence dual platelet inhibition reinstalled.