

P07

Pre-clinical assessment of the oval sutureless Excimer Laser-Assisted Non-occlusive Anastomosis (ELANA) Clip technique for cerebral bypass surgery

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Introduction: Complex cerebral aneurysms that cannot be treated with clip- or coil treatment can be treated with a high-flow bypass using the non-occlusive ELANA-technique. Thus far this technique is limited to the large cerebral arteries (>2.5mm diameter) and the technique remains technically challenging even for trained vascular neurosurgeons. An oval ELANA Clip technique has been developed for non-occlusive anastomoses on smaller arteries (1.8-2.5mm). Can we extend the applicability of the ELANA technique and develop an easier non-occlusive bypass method for treatment of aneurysms on medium-sized cerebral arteries?

Aim is to test feasibility of the developed oval sELANA Clip technique in pre-clinical in vitro models.

Materials and methods: The oval sELANA Clip device was tested in two previously validated in vitro models. 160 rabbit aortas (thoracic and abdominal, mean vessel wall thickness 0.2mm, SD 0.02mm) were used for selection of optimal laser-catheter conformation (n=1125 experiments) and for testing of the full device (laser-catheter, oval clip, donorgraft) with recipient vessel under pressure resembling the clinical operative setting (n=198). Results were measured in flap (punched-out disc of recipient vessel wall) retrieval rate, important to ensure a patent ELANA bypass. Burst Pressure (BuP) testing of the oval sELANA Clip anastomosis were performed to test its safety.

Results: Comparison of the 8 best laser-catheter conformations showed an optimal grid-depth of 0.8mm and push-in depth of 1.2mm with a flap retrieval rate of 91% (RR= 1.30 (CI 1.09-1.56) compared to 2nd best conformation; and RR 1.82 (CI 1.41-2.34) compared to lowest with 50% flap retrieval). Full device testing in a realistic operative model gave 82% flap retrieval vs. 84% of the classic ELANA technique in clinic. Thus, equalling the results of the current clinically used ELANA technique. Burst pressure (BuP) testing of the anastomosis showed all oval sELANA Clip anastomosis sustained a pressure > 250 mmHg without leakage.

Conclusion: The oval sELANA Clip technique was proven feasible by extensive pre-clinical in vitro and ex vivo testing. Long term in vivo validation is the next step before clinical applicability.

Figure 1:

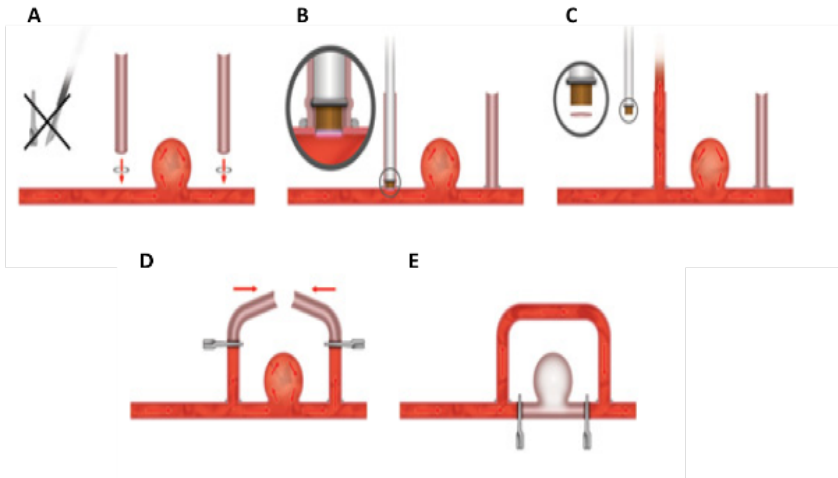


Figure 1: The ELANA Technique illustrated A. Anastomosis with donor attached to recipient vessel. B and C. Laser-assisted arteriotomy. D. End-to-end anastomosis two donorgrafts. E. Aneurysm taken out of circulation with the non-occlusive bypass technique