Next-Generation Liquid Embolic, NeoCast™, Successfully Occludes Distal Middle Meningeal Artery Branches of Chronic Subdural Hematoma Patients in Initial Cohort of First-In-Human Study

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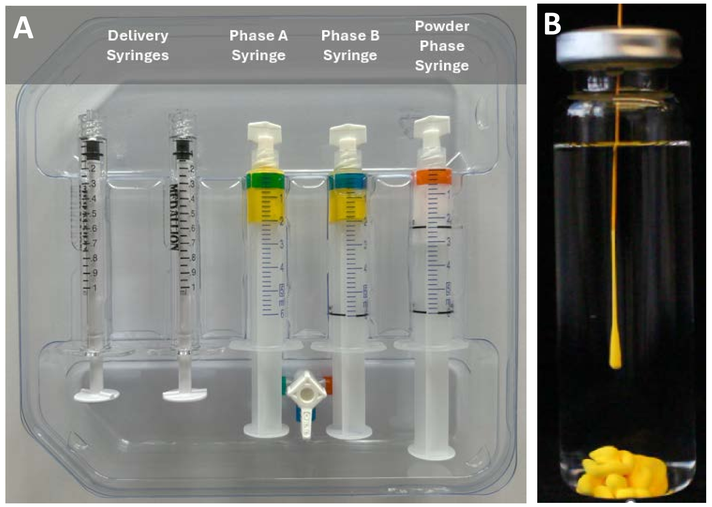
INTRODUCTION

- NeoCast™ is a solvent-free, non-adhesive, and shear-responsive embolic designed for occlusion at the level of the microvasculature
- EMBO-02 Study Objective: Evaluate initial safety and feasibility of embolization with NeoCast in patients with symptomatic chronic subdural hematomas (cSDH)



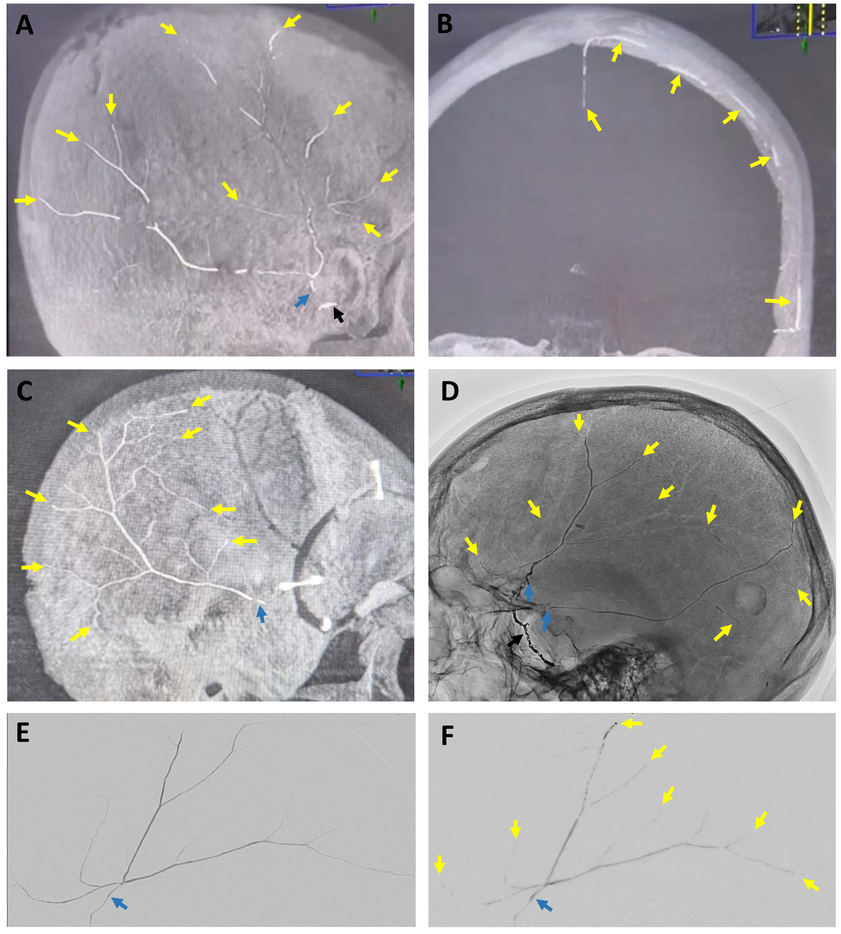
(A) NeoCast System Kit – three components are combined prior to injection with simple syringe to syringe homogenization. **(B)** Injection of NeoCast into a vial, note the fluid-like behavior when injected; structured when at rest (bottom of the vial)

EMBO-02 STUDY DESIGN (ACTRN12624000659505)

- Primary safety endpoint: freedom from device related disabling stroke or neurological death within 30 days of embolization.
- Primary feasibility endpoint: successful injection of NeoCast into the middle meningeal artery (MMA), resulting in complete occlusion at or distal to the point of injection.
- Key inclusion criteria included a confirmed diagnosis of a symptomatic cSDH (>50% hypo or isodense) ≥10mm in greatest thickness and a pre-morbid mRS ≤2.
- Follow-up timepoints include 42d, 90d, and 180d

PRELIMINARY RESULTS (data not cleaned, monitored, or corelab reviewed)

Representative Images



NeoCast, yellow arrows; location of catheter tip during injection, blue arrows; coils, black arrows. *Single injection proximal to the bifurcation:* **(A)** NeoCast penetration into both MMA branches and **(B)** the falx. *Catheter in a wedged position:* **(C)** Complete cast of posterior branch with NeoCast. *Sub-selection of each MMA branch:* **(D)** Resulting cast of anterior and posterior branches with NeoCast. *NeoCast flow behavior, catheter proximal to trifurcation:* **(E)** shows the pre-embo angiography and **(F)** corresponding NeoCast injection showing uniform flow into distal branches.

Demographics (10 subjects enrolled)

- A total of 10 patients have been enrolled, 8 males and 2 females, with an average cSDH thickness of 12.5 ± 2.6mm; 3 (30%) patients presented with bilateral hematomas
- One patient (66M with bilateral cSDH) had planned surgical evacuation 4 days post embolization; remaining patients (90%) were treated with standalone embolization

Embolization Performance

- NeoCast injection was successfully completed in all subjects resulting in occlusion of distal vessels and no non-target embolization
- 1-2 kits of NeoCast were used per patient
- Physicians were satisfied or very satisfied with NeoCast performance

Usability Questions (n=10 cases, 4 operators)	Score (Ave ± SD)
Force required for injection was acceptable	**4.6 ± 0.5**
Control (predictability) during injection was acceptable	**4.8 ± 0.4**
Working time to complete embolization was acceptable	**4.5 ± 0.5**
Visibility on fluoroscopy during injection was acceptable	**4.5 ± 1.0**
Catheter removal after injection was acceptable	**4.9 ± 0.3**
Overall, how satisfied were you with NeoCast performance*	**4.7 ± 0.5**

Scale: 1- Strongly disagree to 5 – Strongly agree *Scale: 1 – Very dissatisfied to 5 – Very satisfied

Safety

- mRS was unchanged between baseline and post embolization (one subject 2→1, one subject 1→2 which improved to a 0 at follow-up)
- All 10 enrolled patients have passed 30 day primary safety endpoint with no device related SAEs

CONCLUSIONS

- NeoCast, a next-generation liquid embolic, has demonstrated vessel occlusion and distal penetration in subjects with symptomatic cSDH
- Investigators were satisfied or very satisfied with NeoCast acute performance and usability in all cases highlighting NeoCast's ease of use
- All 10 subjects have satisfied 30d primary safety endpoint and will continue to be followed out to 180d; clinical outcomes including change in hematoma volume will be captured and reported