LIQUIDS

New materials and development

Vincent VIDAL

LIIE Laboratoire d'Imagerie Interventionnelle Expérimentale

AP-HM

Aix*Marseille université

New materials

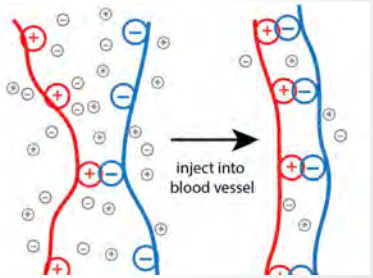
Lava 

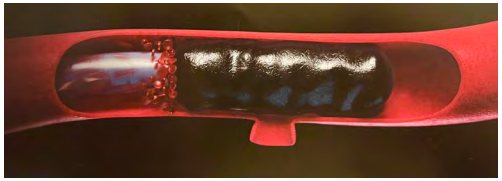
Blackswan

Easyx Q Medics 

Embrace 

Instylla Med

GPX GPX Embolics 

Obsidio 

Obsidio Inc

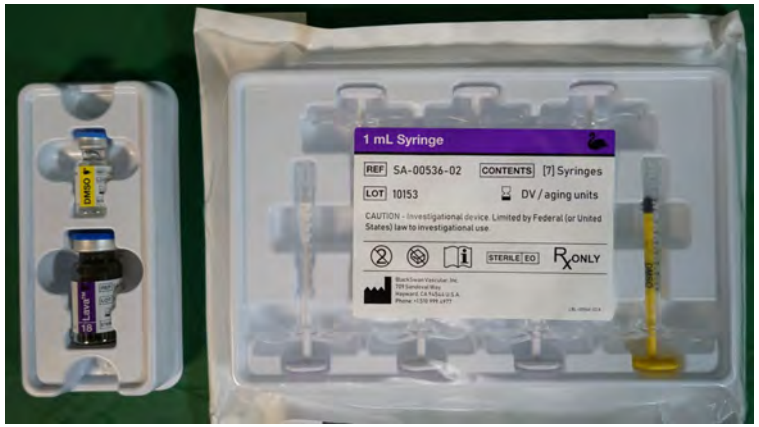
EVOH based + Tantalum

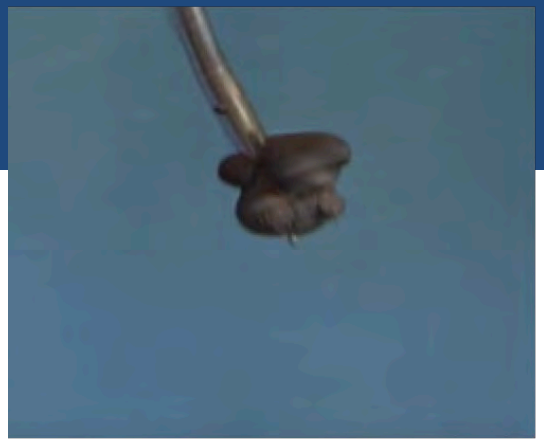
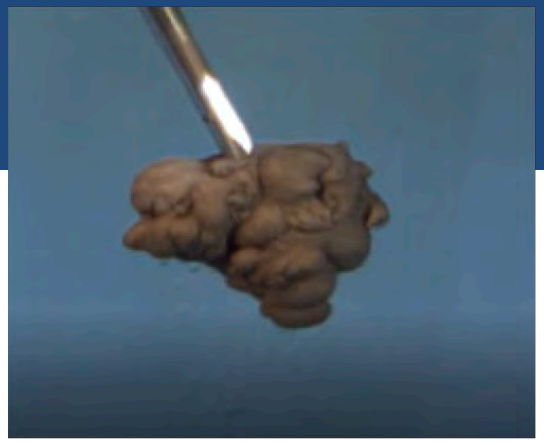
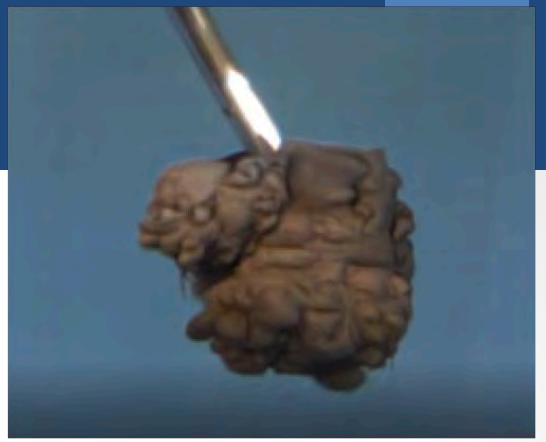
- Onyx

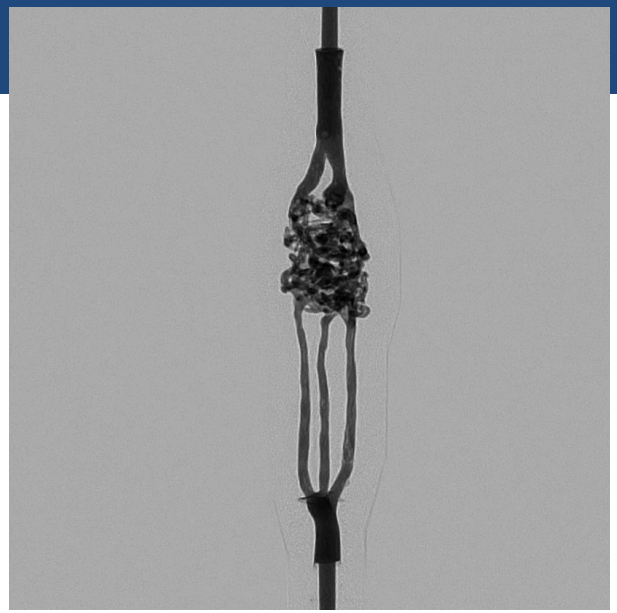
- Squid

- Lava

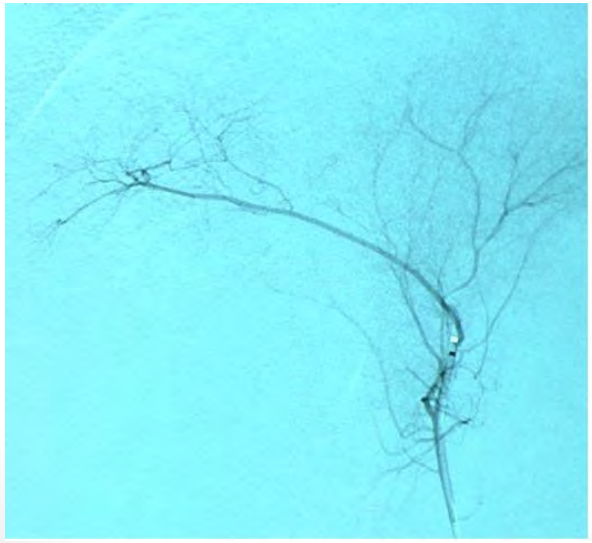
- For US Market
- Lava™ LES is a cohesive material
  - two viscosity (Lava-18 and Lava-34)
  - available in two volumes (2mL and 6mL)
- Lava™ LES system contains an **instant mixing kit to expedite the preparation of material prior to its use**

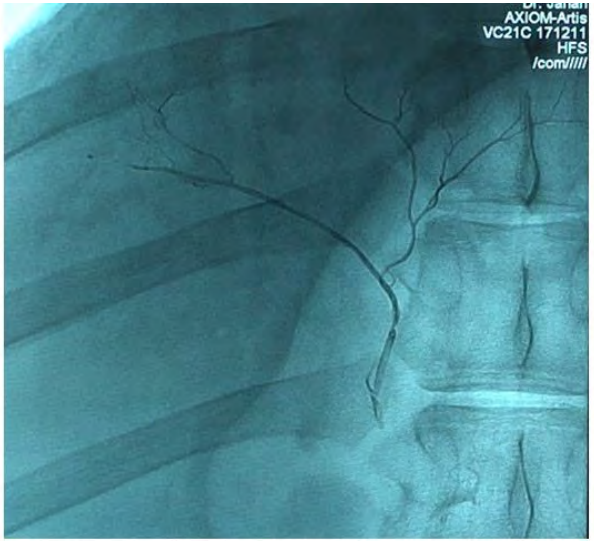




Extensive Chronic GLP Survival (3, 28, 90 and 180 day) Animal Testing Conducted Prior to Human Use





Treatment of Peripheral Arterial Hemorrhage With Lava LES (The LAVA Study)

Overview

Status	Recruiting
Phase	N/A
Sponsor	BlackSwan Vascular, Inc.
Start date	April 2021
Enrollment	113 participants
Identifiers	NCT04649255, TPR-00913-01.A

Conditions
Peripheral Arterial Hemorrhage

Treatments
Liquid Embolic

Summary

To evaluate the safety and effectiveness of the Lava LES for the embolic treatment of arterial hemorrhage in the peripheral vasculature.

- The primary safety endpoint is a composite of freedom from 30-day Major Adverse Events (MAEs). MAEs include the following events as adjudicated by an independent the CEC:
  - Ischemia or infarction of the target territory;
  - Non-target embolization;
  - Allergic reactions to Lava;
  - Catheter breakage;
  - Catheter entrapment
- The primary effectiveness endpoint is Clinical Success, defined as absence of bleeding from the target lesion after embolization with the Lava LES, without the need for emergency surgery, re-embolization, or other target lesion reinterventions within 30 days of the index procedure.

EASYX

- PVA ether polymer + DMSO + Io

CLINICAL STUDY

Safety and Efficacy of Peripheral Embolization with EASYX Liquid Embolic Agent: A Multicenter Prospective Study

Marc Sapoval, MD, PhD, Vincent Vidal, MD, PhD, Carole Déan, PhD, Costantino Del Giudice, MD, PhD, Farouk Tradi, MD, Olivier Chevallier, MD, Anaïs Charles-Nelson, PhD, Oliver Pellerin, MD, PhD, and Romaric Loffroy, MD, PhD

EVOH based + Iodine

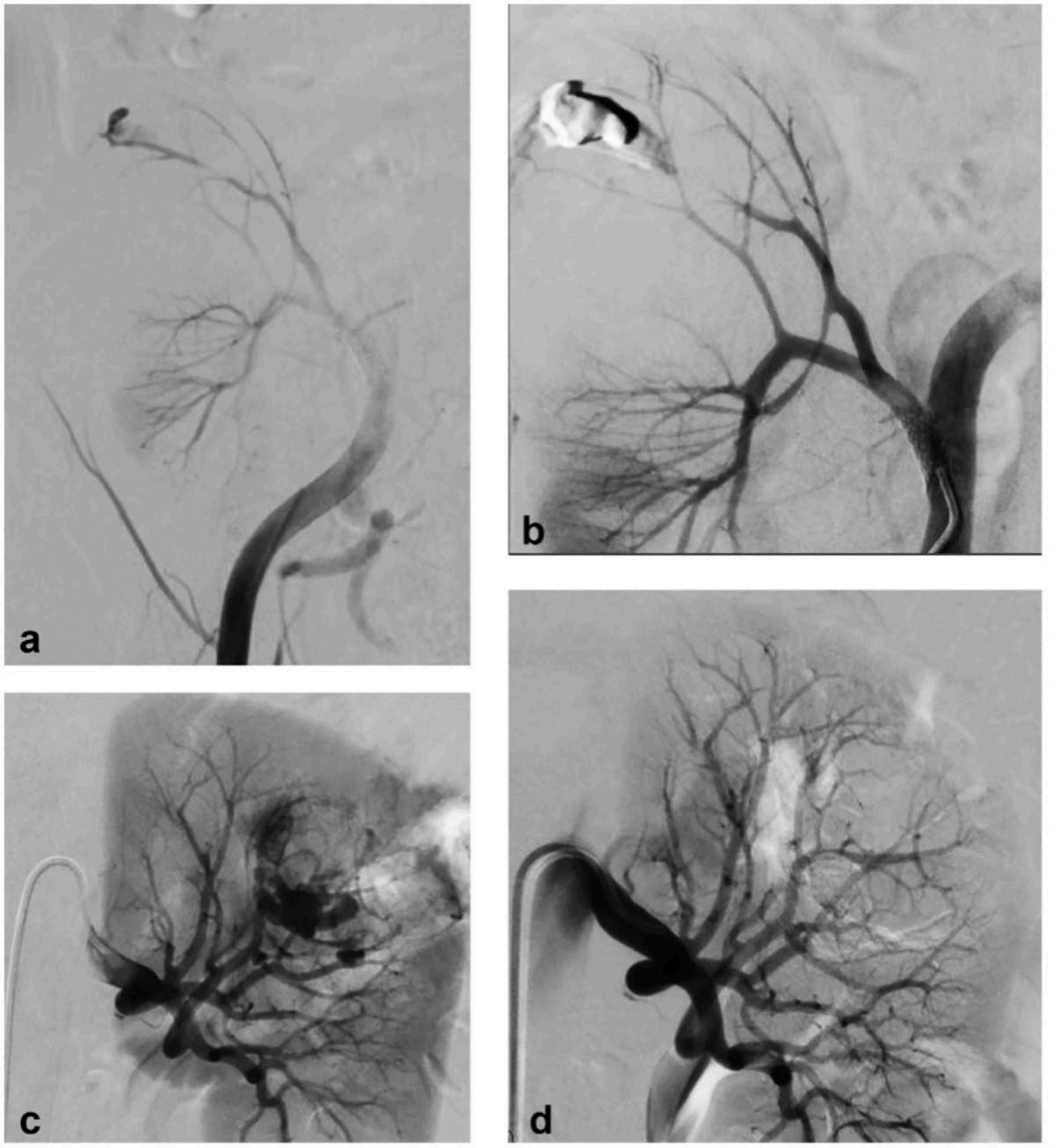
ABSTRACT

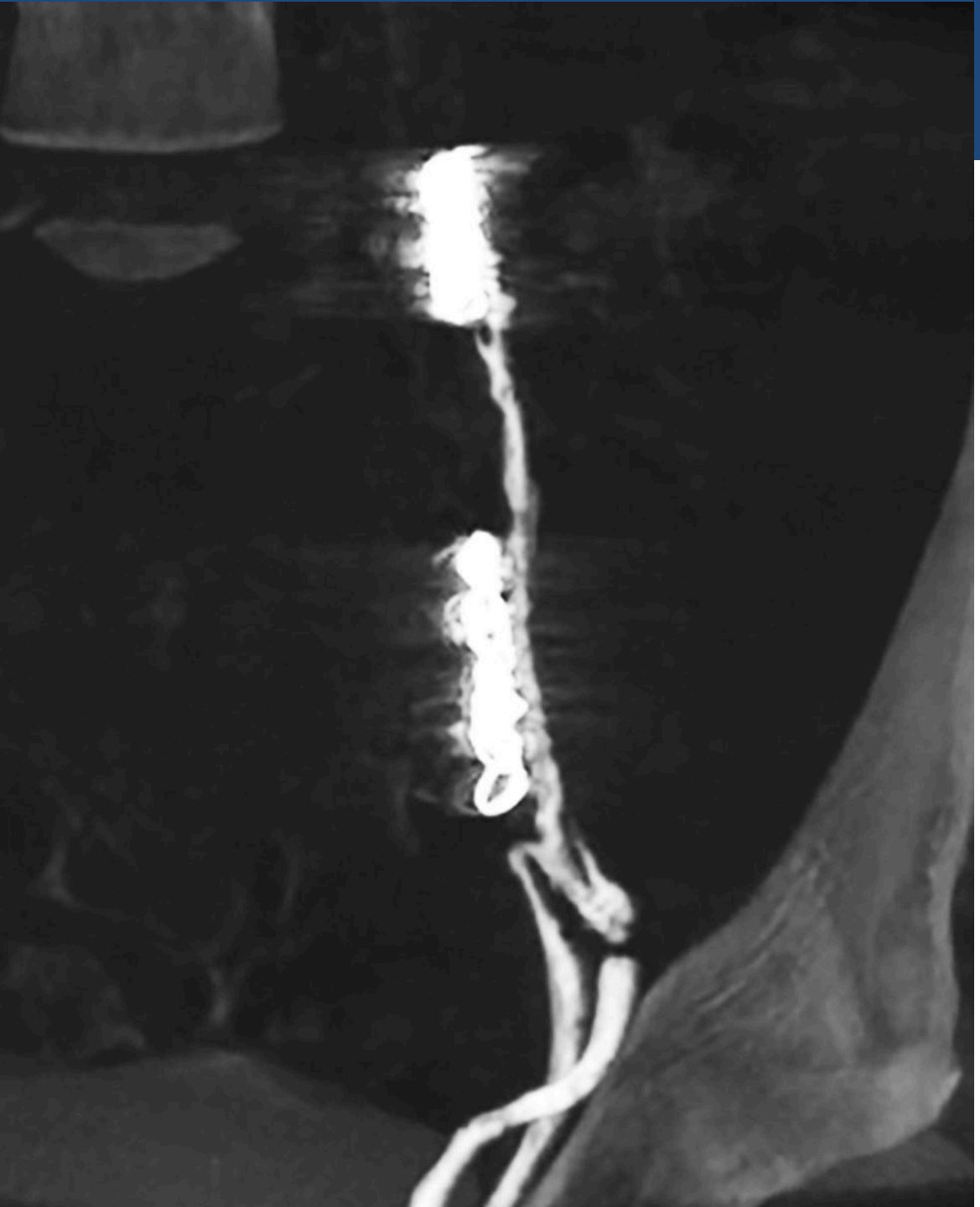
Purpose: To evaluate the clinical safety and efficacy of EASYX, a new nonadhesive precipitating liquid embolic agent based on a polyvinyl alcohol ether polymer labeled with iodine molecules, for peripheral embolization.

Materials and Methods: This open-label prospective multicenter study was conducted on 50 consecutive patients treated with embolization using EASYX in 3 academic hospitals from April 2018 to July 2019. Indications for embolization were symptomatic varicocele (n = 15), type II endoleak (n = 8), acute hemorrhage (n = 16), portal vein embolization (PVE; n = 9), or angiomyolipoma (AML; n = 2). Patient characteristics, technical and clinical success rates, pain at injection, and satisfaction of the interventional radiologists were assessed. Follow-up imaging was performed using ultrasound for varicoceles (at 1 month) and computed tomography (CT) for the other indications (at 3 or 6 months).

Results: The immediate technical success rate was 98%. The clinical success rates were 100% for acute hemorrhage and type II endoleaks, 89% for PVE, 86% for varicoceles, and 50% for AMLs. Patients who underwent PVE showed significant hypertrophy of the future liver remnant at follow-up ($P < .001$), and 55.6% of patients proceeded to hepatectomy. The absence of artifacts on imaging allowed improved monitoring of the aneurysmal sac in patients with type II endoleaks. The satisfaction rate of the interventional radiologists was >90% for 5 of 7 items.

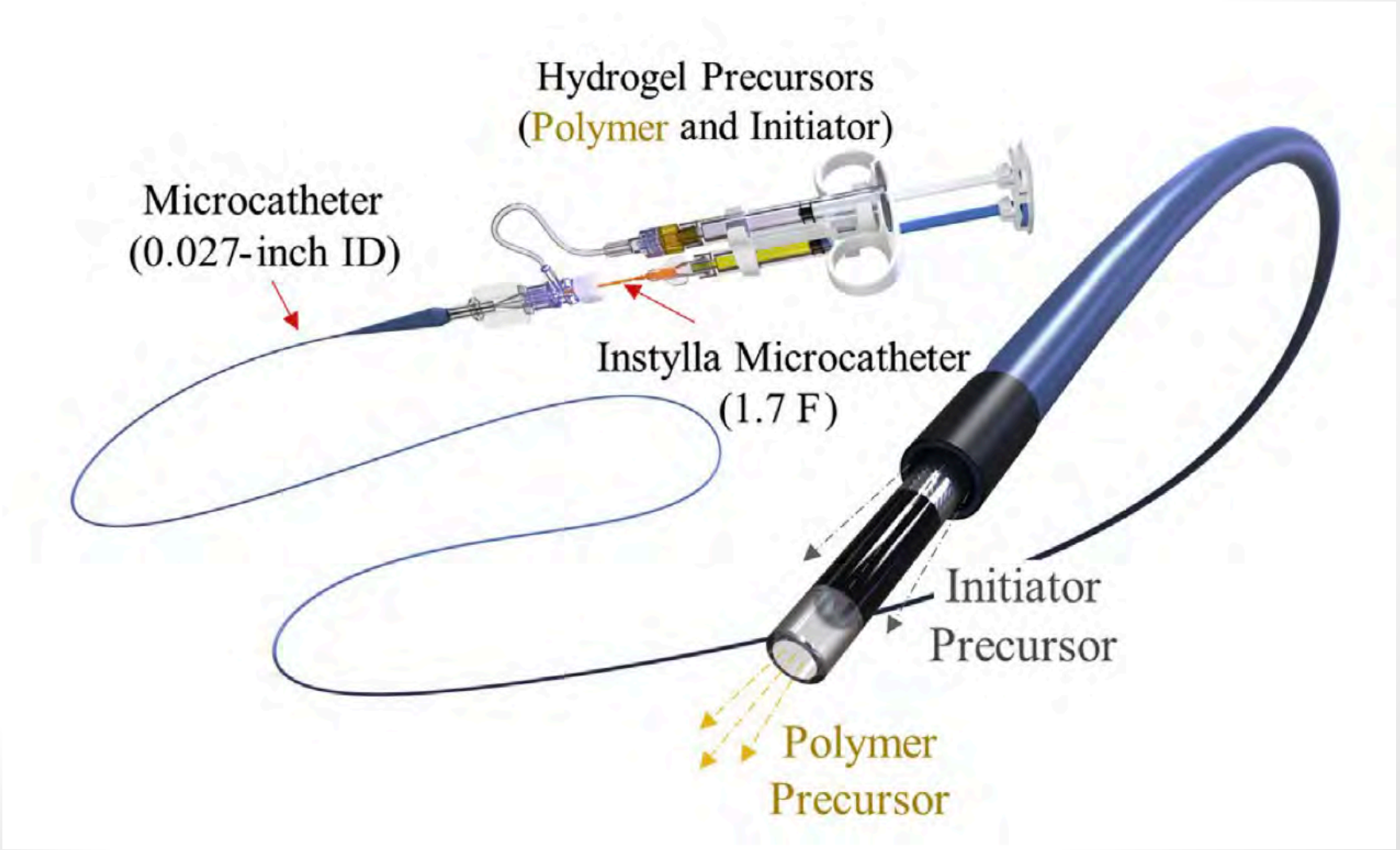
Conclusions: EASYX as a novel copolymer liquid embolic agent was safe and efficient for peripheral embolization. The absence of tantalum allowed reduced CT artifacts on imaging follow-up, which was especially useful in patients with type II endoleaks.


a
b
c
d

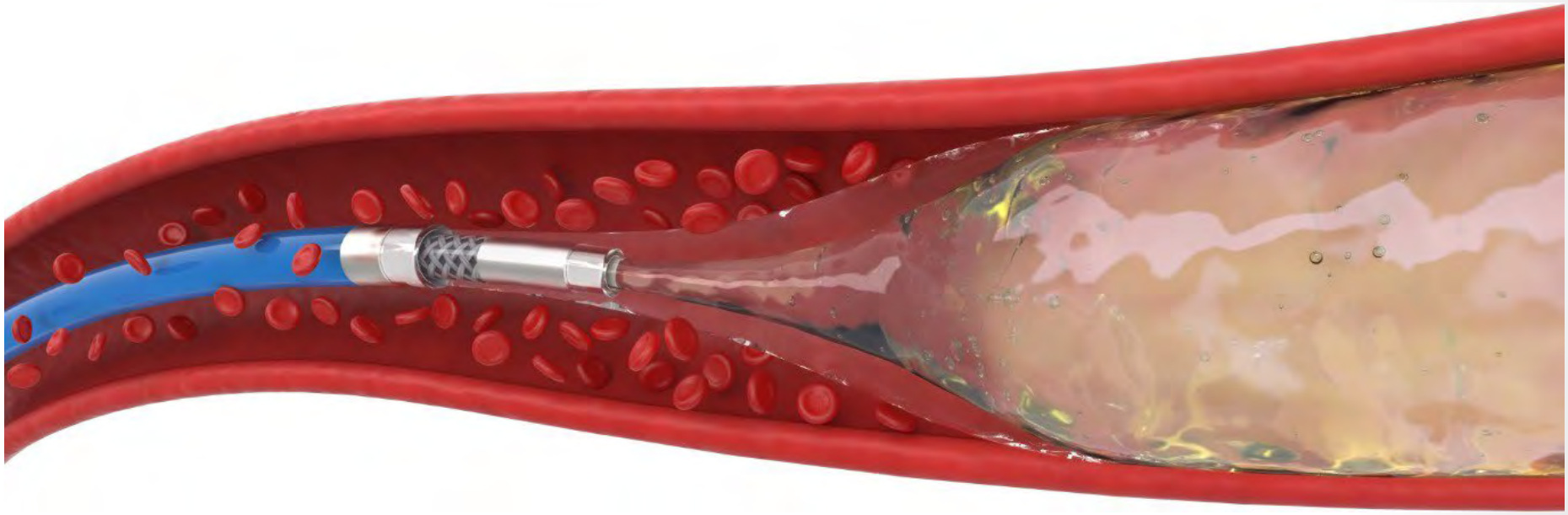


Embrace Hydrogel

- **Polyethyl glycol (polymer + initiator)+ Io**



Embrace : Hydrogel Embolic System



A Pilot First-in-Human Study of Embrace, a Polyethylene Glycol-Based Liquid Embolic Agent, in the Embolization of Malignant and Benign Hypervascular Tumors

Gerard S. Goh, MBBS, Mark D. Goodwin, BM, BCh, Jee-Fu Huang, MD, PhD, Helen Kavnoudias, BAppSc, PhD, and Andrew Holden, MB, ChB

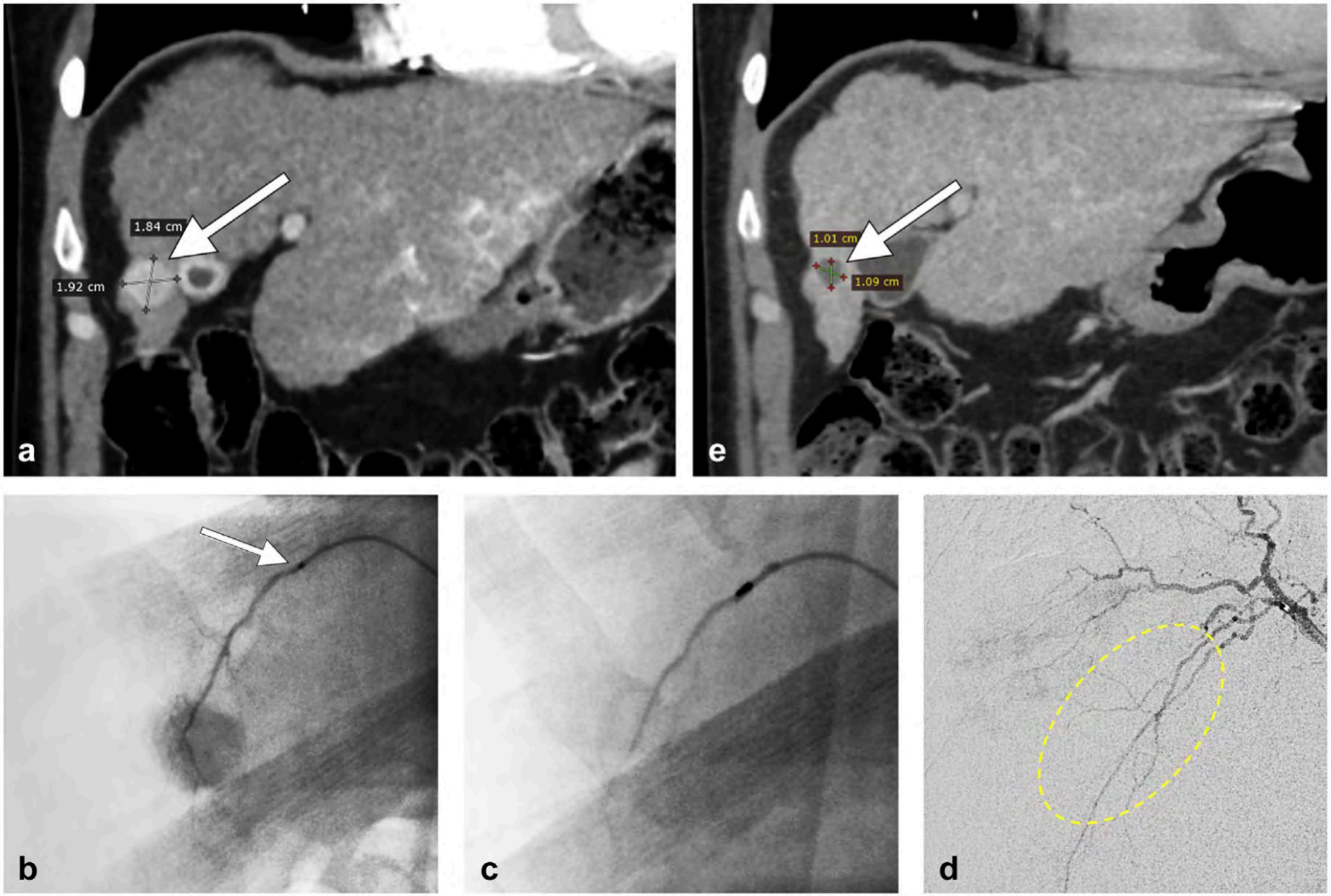
ABSTRACT

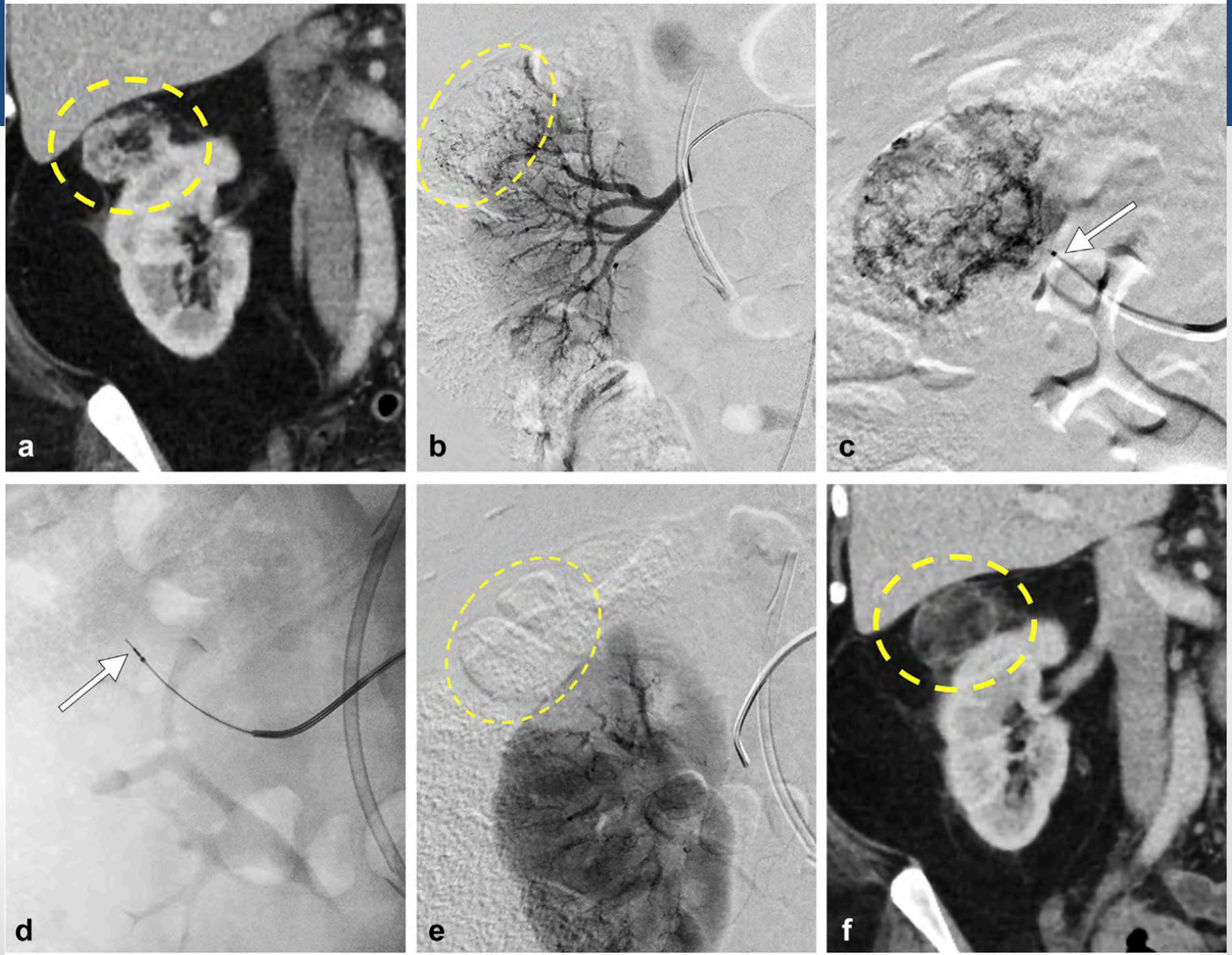
Purpose: To investigate the safety and efficacy of an aqueous polyethylene glycol-based liquid embolic agent, Embrace Hydrogel Embolic System (HES), in the treatment of benign and malignant hypervascular tumors.

Materials and Methods: A prospective, single-arm, multicenter study included 8 patients, 5 males and 3 females, with a median age of 58.5 years (30–85 years), who underwent embolization in 8 tumors between October 2019 and May 2020. Technical success was defined as successful delivery of HES to the index vessel, with disappearance of >90% of the targeted vascular enhancement or, for portal vein embolization, occlusion of the portal branches to the liver segments for future resection. The volume of HES administered, ease of use (5 point Likert scale), administration time, and adverse events (AEs) were recorded. Evaluation was performed at 7, 30, and 90 days via clinical assessment and blood testing, and follow-up imaging was performed at 30 days.

Results: Eight patients were enrolled, and 10 embolizations were performed in 8 lesions. Tumors included hepatocellular carcinoma (n = 4), renal angiomyolipoma (n = 3), and intrahepatic cholangiocarcinoma (n = 1). Technical success was 100%, and the average ease of use was 3.3 ± 1.0 SD. The HES delivery time was 1–28 minutes (median, 16.5 minutes), and the HES volume injected was 0.4–4.0 mL (median, 1.3 mL). All patients reached 30-day follow-up with imaging, and 6 patients reached 90-day follow-up. There were 3 serious AEs in 2 patients that were unrelated to the embolic agent.

Conclusion: HES resulted in a 100% embolization technical success rate. The product ease of use was acceptable, and no target vessel recanalization was noted on follow-up imaging at 30 days.


1.84 cm
1.92 cm
a
1.01 cm
1.09 cm
e
b
c
d


a
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Study Description

Go to

Brief Summary:

To determine whether Instylla HES has the ability to effectively embolize targeted arterial segments of hypervascular tumors as well as standard of care (SOC) transarterial embolization/conventional transarterial chemoembolization, while resulting in an acceptable risk of device and procedure-related serious adverse events.

Condition or disease	Intervention/treatment	Phase
Hypervascular Tumors	Device: Instylla HES Other: TAE or cTACE	Not Applicable

Study Design

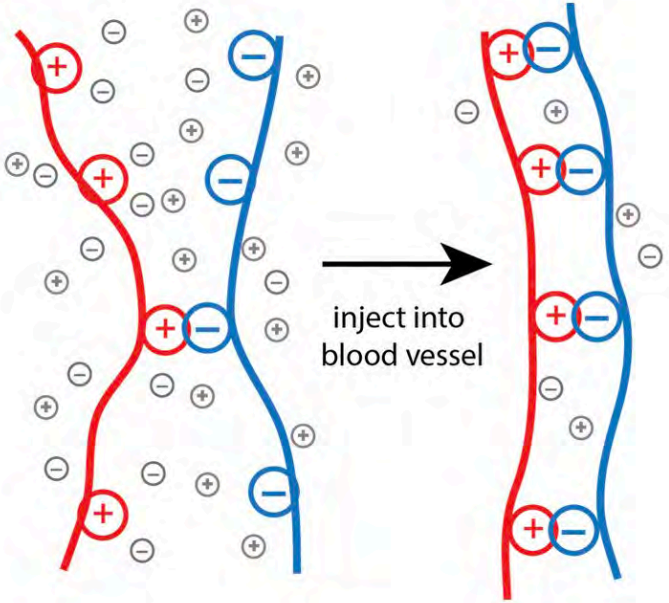
Go to

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	150 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	Randomized Multi-Center, Subject and Evaluator Blinded, Parallel-Group Study to Evaluate the Safety and Effectiveness of the Instylla Hydrogel Embolic System (HES) Compared With Standard of Care Transcatheter Arterial Embolization (TAE) / Transcatheter Arterial Chemoembolization (cTACE) for Vascular Occlusion of Hypervascular Tumors; A Pivotal Study
Actual Study Start Date:	January 4, 2021
Estimated Primary Completion Date:	April 30, 2022
Estimated Study Completion Date:	July 31, 2022

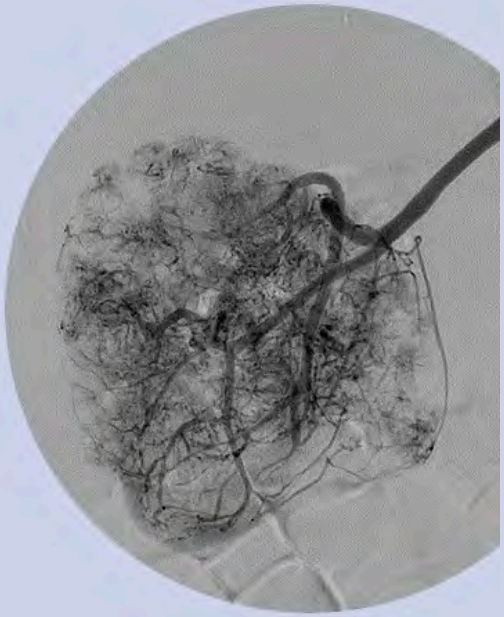
GPX

- **Aqueous-based, low viscosity polymer +Ta**

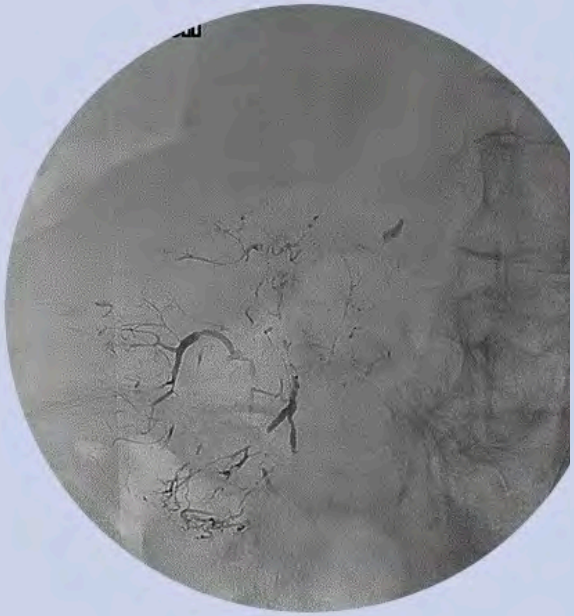
GPX



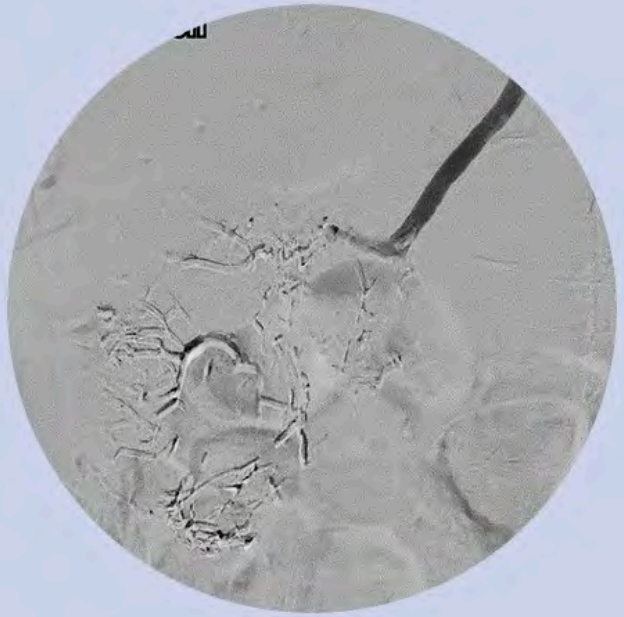
- Aqueous-based, low viscosity polymer solution in the delivery syringe
- Ready-to-use, requires less than 1 minute of tableside preparation by the clinician
- Can be delivered using standard microcatheters and no special solutions required
- Solidifies rapidly upon delivery through an electrostatic mechanism of action without polymerization or dimethyl sulfoxide (DMSO) precipitation associated with other liquid embolics
- Polymers bind upon delivery forming a durable, gel-like solid



Baseline angiogra

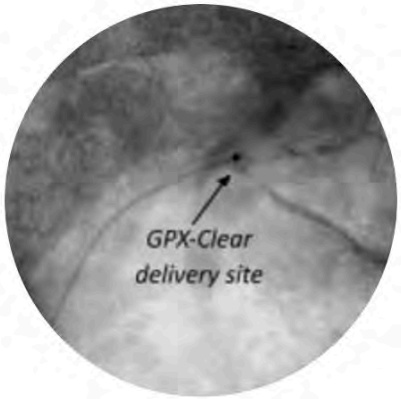


Angiogram post-GPX deliv
through microcatheter



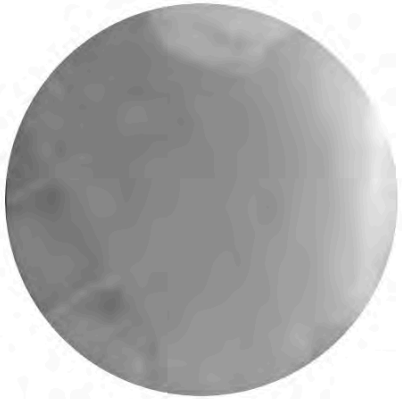
DSA post-GPX delivery

Pretreatment angiogram

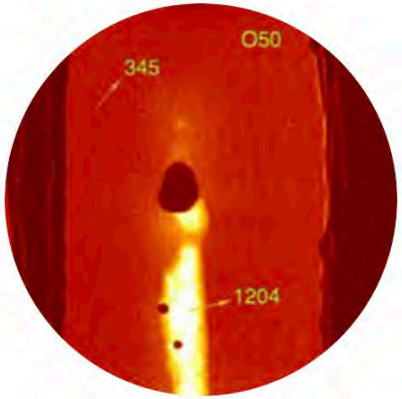


Fluoroscopic image taken immediately after delivery showing GPX-Clear Embolic Device placement

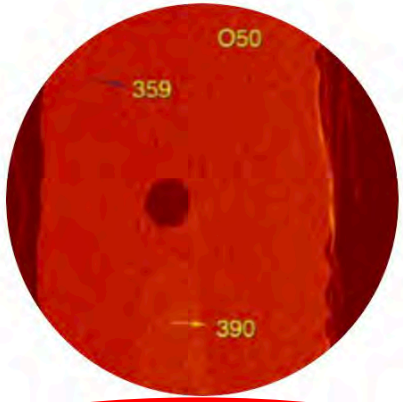
Post-treatment DSA showing complete occlusion of targeted region with GPX-Clear Embolic Device



Fluoroscopic image 1-day post-embolization showing dissipation of radiopacity



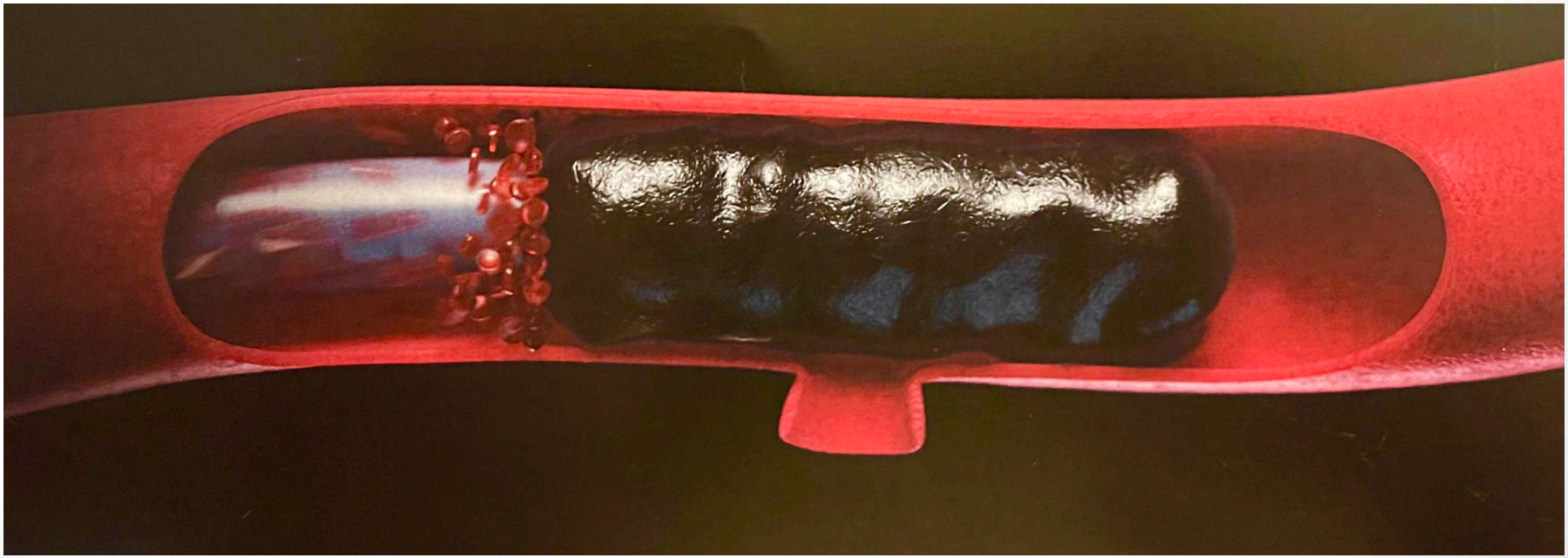
Radiopacity 1-hr post-GPX-Clear Embolic Device delivery



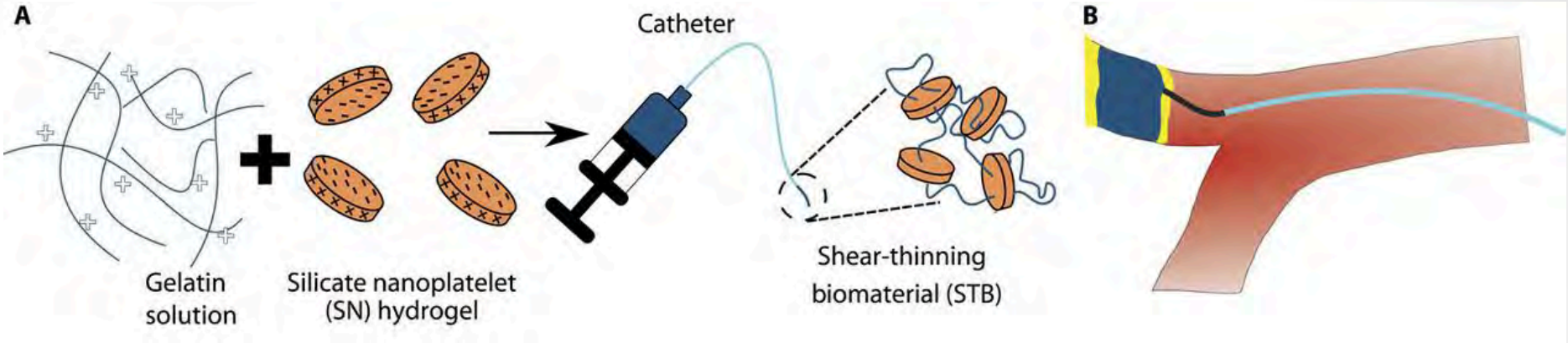
Radiopacity dissipated at 24-hr post-GPX-Clear Embolic Device delivery

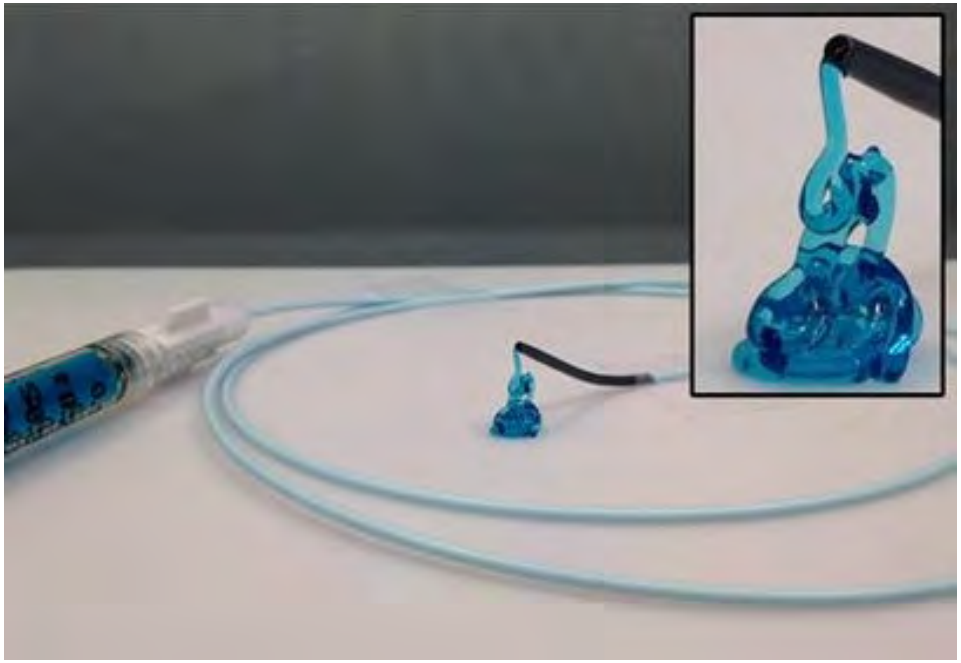
Obsidio

- **Between Liquid and Solid**
- Nanosilicate + gelatin + Ta

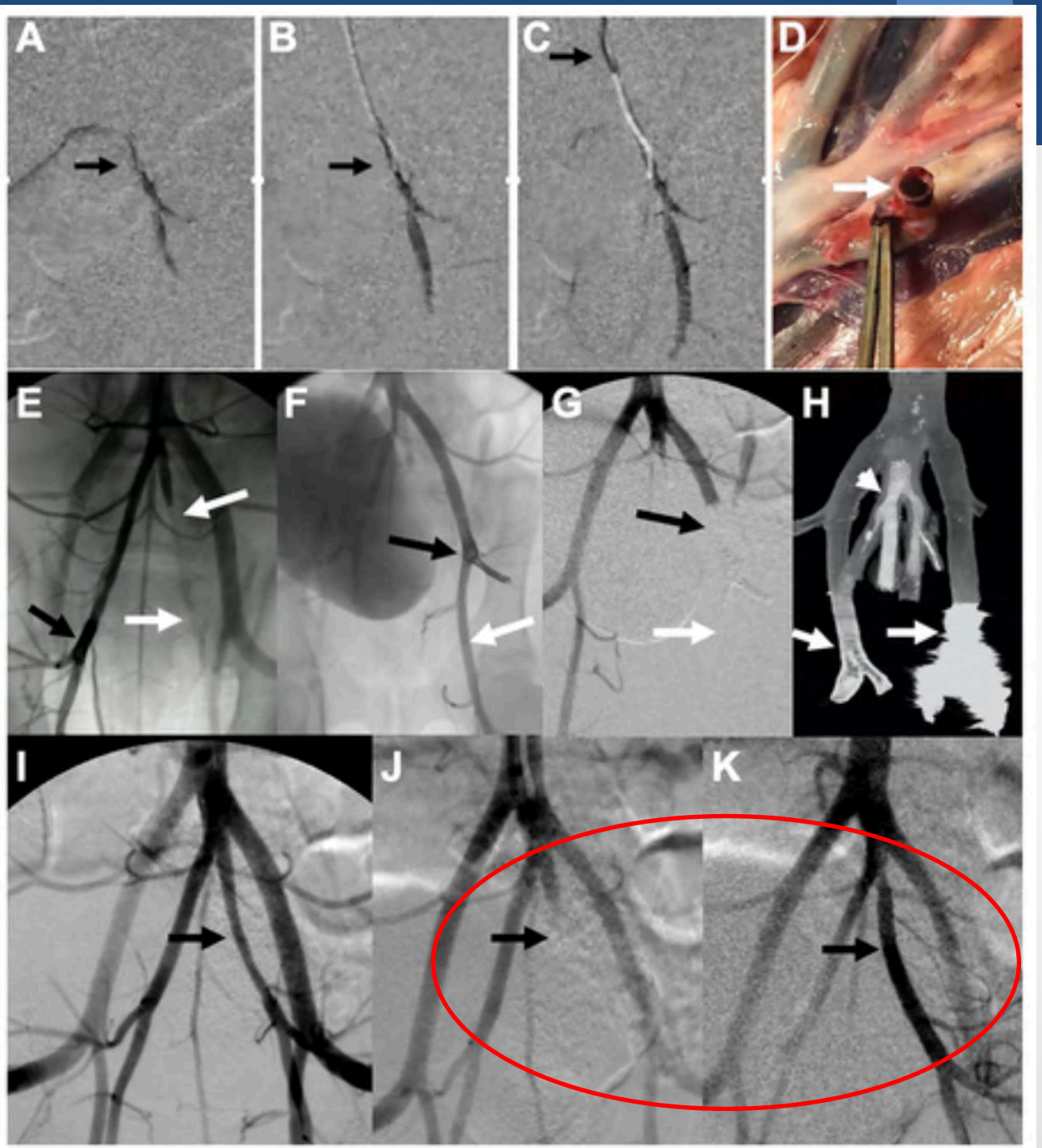


Obsidio


A
Catheter
B
Gelatin solution
Silicate nanoplatelet (SN) hydrogel
Shear-thinning biomaterial (STB)



Obsidio



New material

- **Lava** EVOH + DMSO + Ta
- **Easyx** PVA ether polymer + DMSO + Io
- **Embrace** Polyethyl glycol (polymer + initiator)+ Io
- **GPX** Aqueous-based, low viscosity polymer +Ta
- **Obsidio** Nanosilicate + gelatin + Ta

New material

- **Lava** EVOH + DMSO + Ta
- **Easyx** PVA ether polymer + DMSO + Io
- **Time for treating bleeding with liquids**
- **GPX** Aqueous-based, low viscosity polymer +Ta
- **Obsidio** Nanosilicate + gelatin + Ta

New material

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New material

- **Easyx** PVA ether polymer + DMSO **+ Io**
- **Embrace** Polyethyl glycol (polymer + initiator) **+ Io**

New materials

Lava

Blackswan

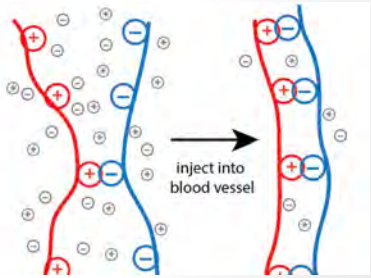
Easyx Q Medics

Ready to use !

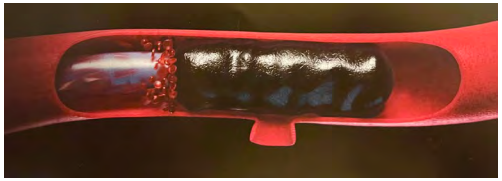
Embrace

Instylla Med

GPX GPX Embolics



Obsidio



Obsidio Inc


FDA
MDR