

HEAT Trial

Randomized, controlled, postmarket study of new generation hydrogel coils in the treatment of intracranial aneurysms across 46 centers in the United States and Canada.

Study Purpose

To compare the clinical and angiographic outcomes in patients treated with **hydrogel coils** versus patients treated with **bare platinum coils**.

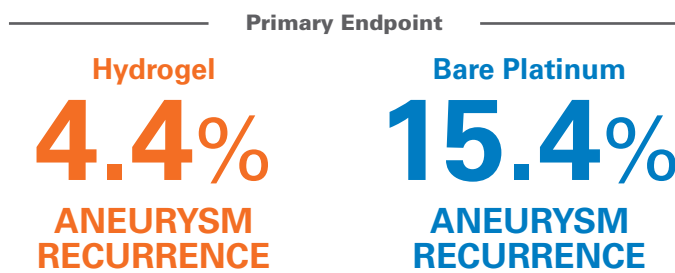
Primary endpoint

Aneurysm recurrence at any point during follow-up (through 24 months) defined as any progression on the Raymond-Roy Occlusion Classification.

Study Results Demonstrated:

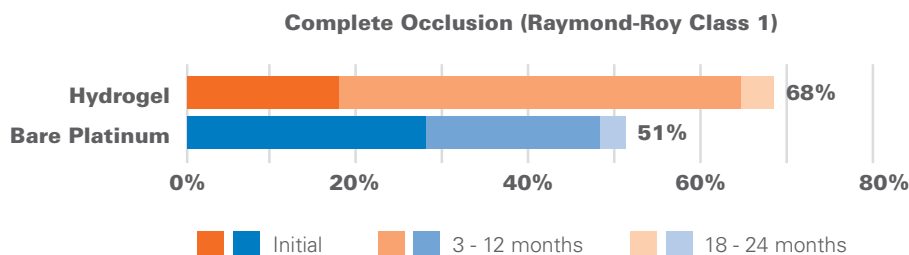
Greater efficacy¹

Hydrogel coils significantly reduced recurrence for aneurysms 3 to 14 mm in size. ($p < .001$)



More progressive occlusion^{1,2}

In the HEAT Trial, hydrogel coils achieved more progressive occlusion at 18-24-month follow-up than bare platinum coils.



Higher efficiency¹

Hydrogel coils were shown to provide a higher average packing density with fewer coils used.

	Average Packing Density	Average Number of Coils	Average Length of Coils Used
Hydrogel	33.0%	5.3	51.1 cm
Platinum	24.8%	6.0	56.2 cm

Comparable safety¹

Hydrogel coils showed no significant difference in adverse events compared to bare platinum. ($p = .498$)

Study Design

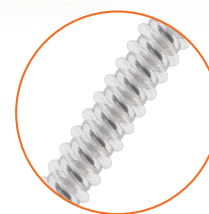
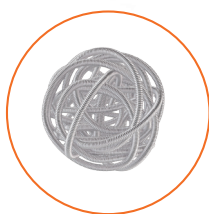
600 patients randomized to receive either¹:

1. Coil embolization with hydrogel coils ($\geq 90\%$ hydrogel by length)
2. Coil embolization with any bare platinum coils

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Untreated, ruptured, or unruptured aneurysms • 18–75 years of age • Aneurysms 3–14 mm in size 	<ul style="list-style-type: none"> • Hunt and Hess 4 and 5 • Concurrent intracranial pathology • Acute or uncontrolled comorbidities

Hydrogel coils in the trial¹

- HydroFrame® Coils
- HydroFill® Coils
- HydroSoft® Coils



Patient Population

	Hydrogel Coils	Bare Platinum Coils
Number of patients analyzed	297	303
Average patient age	56.5	56.9
Mean aneurysm size	7.3 mm	7.5 mm

PI: Bernard Bendok
Sponsor: Northwestern
Funded: MicroVention

References:

1. Bendok BR. New Generation Hydrogel Endovascular Aneurysm Treatment Trial. The HEAT study. Presented at: 15th Annual Society of NeuroInterventional Surgery Meeting; July 23–26, 2018; San Francisco, CA.
2. Dabus G. New Generation Hydrogel Endovascular Aneurysm Treatment Trial. The HEAT Study. Presented at: 10th Congress of the European Society of Minimally Invasive Neurological Therapy; September 6-8, 2018; Nice, France.

RX Only: Federal (USA) law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE: The HydroCoil® Embolic System (HES) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The HES is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature. The HydroCoil® Embolic System should only be used by physicians who have undergone pre-clinical training in all aspects of HES procedures as prescribed by MicroVention and are trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. For complete indications, contraindications, potential complications, warnings, precautions, and instructions, see instructions for use (IFU provided with the device).

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