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MicroVention TERUMO

GREAT Study

Second-Generation Hydrogel Coils for the Endovascular Treatment of Intracranial Aneurysms – **A Randomized Controlled Trial**

"The GREAT trial results showed significant benefits of Hydrogel technology."

Professor Christian Taschner, University of Freiburg, Germany
Principal Investigator for the GREAT Study

AIM OF THE STUDY[1]

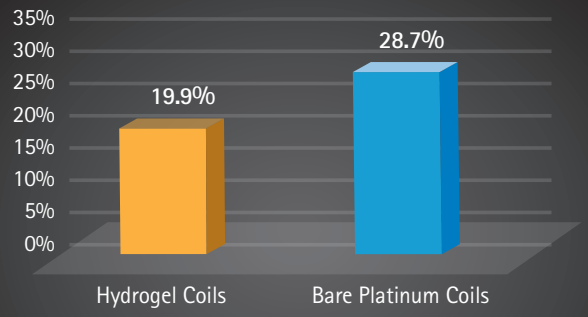
To assess the efficacy of softer, second generation hydrogel coils for the treatment of ruptured and unruptured intracranial aneurysms when compared with the use of bare platinum coils.

GREAT Study results demonstrate that:

- Second-generation hydrogel coils contribute to the reduction of unfavorable composite (angiographic/clinical) outcomes.
- Hydrogel coils appear to be as safe as platinum coils.
- Hydrogel coils achieved statistically significant higher packing density with less coil length.

Unfavorable Composite Angiographic and Clinical Outcomes

p value < 0.05

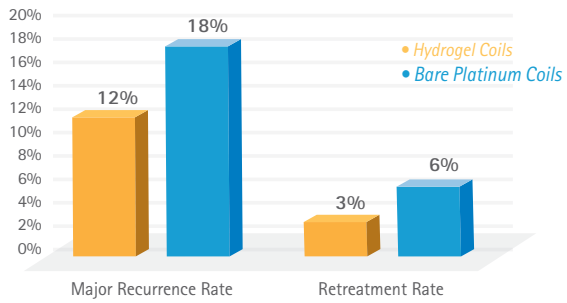


Statistically significant reduction in the proportion of unfavorable composite primary outcome with hydrogel coils.*

45 out of 226 (19.9%) patients in the hydrogel group and 66 out of 230 (28.7%) in the control group had an unfavorable composite primary outcome.
**Adjusted for rupture status.*

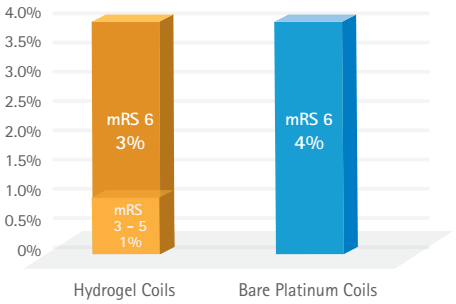
ANGIOGRAPHIC OUTCOMES[1]

Measured by 3-Class Raymond Scale



CLINICAL OUTCOMES[1]

Measured by Modified Rankin Scale (mRS)



	HYDROGEL	BARE PLATINUM
Morbidity mRS 3–5 (Prevented angiographic follow-up)	1%	0%
Mortality mRS 6 (Any death)	3%	4%

CONCLUSION[1]

Coil embolization with second generation hydrogel coils may reduce the rate of unfavorable outcome events in patients with medium sized (4–12 mm) intracranial aneurysms.

STUDY DESIGN[1,2]

A total of 513 patients were randomly assigned to two treatment arms:

1. Coil embolization with HydroSoft®/HydroFrame® coils (≥50% of the administered coil length).
2. Coil embolization with any bare platinum coils.

PRIMARY ENDPOINT[1-3]

Composite outcome of major aneurysm recurrence on follow-up angiography and clinical outcome within 18 months

1. Major aneurysm recurrence on follow-up at 18 month
2. Retreatment for major recurrences within 18 months
3. Morbidity (mRS 3 - 5) that prevented angiographic follow-up
4. Any death (mRS 6)

SECONDARY ENDPOINTS[1-3]

- Clinical outcome at 6 and 18 months measured by mRS
- Total coil length deployed
- Packing density

INCLUSION CRITERIA[1-3]

- Aneurysm size 4mm to 12mm (ruptured/unruptured)
- Patients aged between 18 and 75 years old
- WFNS grade 0–3

EXCLUSION CRITERIA[1-3]

- Bioactive coils (PGA/PGLA)
- Flow diverter
- Previously treated by coiling or clipping

PATIENT POPULATION[1]

No significant difference in patient population.

	HYDROGEL	BARE PLATINUM
# of Patients Analyzed	243	241
Ruptured Aneurysms	42%	44%
Mean Aneurysm Size	6.8mm	7.1mm
Anterior Circulation	74%	76%

PACKING DENSITY[1,3]

	HYDROGEL	BARE PLATINUM
Mean Packing Density*	39%	31%
Coil Volume	0.041cm^3	0.038cm^3
Coil Length	51.2cm	61.6cm

*** Greater aneurysm packing density was achieved in the hydrogel group when compared to the bare platinum group.**

This difference was statistically significant (p=0.001)

The results of the GREAT Study showed that the risk of meeting the unfavorable composite primary endpoint of major angiographic recurrence and poor clinical outcome at long term follow-up was significantly lower in patients treated with softer second-generation hydrogel coils compared to platinum coils.[1]

Study limitations are outlined in the full article, available free via Open Access: http://stroke.ahajournals.org/content/49/3/667

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REFERENCES:

1. Taschner CA., Chapot R., Costalat V., et al. Second-Generation Hydrogel Coils for the Endovascular Treatment of Intracranial Aneurysms - A Randomized Controlled Trial. Stroke 2018; 49: 667-674.
2. Taschner CA., Chapot R., Costalat V., et al. GREAT - a randomized aneurysm trial. Design of a randomized controlled multicenter study comparing HydroSoft/HydroFrame and bare platinum coils for endovascular aneurysm treatment. Neuroradiology 2015; 57: 599-604.
3. Taschner CA., Chapot R., Costalat V., et al. GREAT - a randomized controlled trial comparing HydroSoft/HydroFrame and bare platinum coils for endovascular aneurysm treatment: procedural safety and core-lab-assessed angiographic results. Neuroradiology 2016; 58: 777-786.

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 device should only be used by physicians who have undergone pre-clinical training in all aspects of HES procedures as prescribed by MicroVention.

RX Only: Federal (USA) law restricts this device to sale by or on the order of a physician. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. The HydroCoil® Embolic System should only be used by physicians who have received appropriate training for the device.

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