Building an Evidence Base for Genicular Artery Embolization

How the GRAVITY trial is generating data for GAE in knee osteoarthritis.

By The Interventional Oncology Medical Affairs Team, Siemens Healthineers

Knee osteoarthritis (OA) remains one of the most common causes of chronic pain and disability worldwide, and a substantial proportion of patients fall into a difficult treatment gap: Conservative therapy has failed them, but they are not yet ready for or do not wish to undergo total knee arthroplasty. Genicular artery embolization (GAE) has emerged over the past decade as a minimally invasive, joint-preserving option for this population, targeting the abnormal periarticular neovascularity and associated inflammatory signaling that drives OA-related pain.[1]

Interventional radiologists have built the case for GAE through a steady accumulation of prospective feasibility, safety, and single-arm outcome data.[2-4] A University of California, Los Angeles (UCLA)–led, single-arm cohort has since extended that experience to 2 years of follow-up, reinforcing the durability of clinical benefit well beyond the first year.[5] Across these data, GAE has shown a consistent, well-characterized safety profile and a generally low rate of self-limited adverse events.[2-4]

What these single-arm data have not been able to provide is a well-powered, prospective, randomized comparison of GAE against the realistic alternative most patients actually face: continued conservative management. That is the gap the GRAVITY trial (NCT04682652) was designed to close, and its primary endpoint results, recently presented at the 2026 Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Annual Congress, mark a meaningful step forward for the field.[6,7]

GRAVITY: A RANDOMIZED, INVESTIGATOR-LED TRIAL AT UCLA

GRAVITY (Genicular Artery Embolization Versus Observation for the Treatment of Symptomatic Knee Osteoarthritis: A Randomized Controlled Trial) is an investigator-initiated study led by UCLA and conducted under an FDA-approved investigational device exemption (IDE), a regulatory mechanism that permits the clinical evaluation of an investigational use of a device in human subjects. UCLA is serving as study sponsor and the Interventional Oncology business of Siemens Healthineers is providing research grant support.[6,7] The study is a prospective, single-center, randomized controlled trial comparing GAE using Embozene® microspheres (Siemens Healthineers) against observation in patients with symptomatic knee OA who have failed conservative therapy.

Eligible patients were aged 40 to 79 years, had moderate-to-severe knee pain with radiographic disease (Kellgren-Lawrence grade 2-4), and had a documented history of failed or resistant conservative treatment, such as nonsteroidal anti-inflammatory drugs, physical therapy, or joint injection, for at least 3 months. As an open-label comparison against observation, GRAVITY was built with a structured crossover option, allowing patients initially randomized to observation to receive GAE after their 6-month assessment—a design choice that preserves ethical access to the therapy under study while still permitting a clean, randomized primary comparison.

A Multidimensional Endpoint Strategy

The trial's primary endpoint was defined prospectively as the proportion of patients achieving a clinically meaningful reduction in WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) pain and function score at 6 months. Secondary endpoints extend well beyond that single measure and include score change to 24 months, adverse events, quality-of-life measures, and two mechanistic substudies that set GRAVITY



Figure 1. Evolution of the evidence supporting GAE, including the GRAVITY trial and recent regulatory milestones.

apart from most prior GAE research—serial MRI with compositional cartilage mapping and paired plasma and synovial fluid biomarker panels, both collected at baseline and 6 and 24 months. Together, these are designed to help clinicians understand not just whether GAE works but also the biological mechanism by which it does.

A Positive Trial, First Disclosed at CIRSE

GRAVITY met its primary endpoint; at the 6-month analysis, patients randomized to GAE achieved a significantly greater rate of clinically meaningful pain and function improvement than those randomized to observation.[6] These findings were presented for the first time as a scientific abstract at the 2026 CIRSE Congress in September, where the presenting investigators described GRAVITY as among the first randomized trials to demonstrate that GAE outperforms observation-based care for knee OA at this primary timepoint.

It is important to be precise about where the evidence stands today (Figure 1). The detailed efficacy and safety data from GRAVITY, including the full statistical results, have not yet been peer-reviewed. However, what can be said with confidence, based on the investigators' own CIRSE presentation, is that the trial achieved its prospectively defined primary endpoint in a randomized, IDE-regulated design. It is important to note that 24-month clinical follow-up, crossover-arm analysis, imaging, and biomarker results are still to come. A full peer-reviewed publication is anticipated, and this readership will be well served by revisiting GRAVITY once that manuscript is available.

WHAT THIS MEANS FOR ADVANCING TREATMENT OPTIONS

The regulatory path for GAE is already advancing on its own track. Embozene microspheres received FDA Breakthrough Device designation for GAE in knee OA in 2021, reflecting the agency's recognition of both the unmet clinical need and the strength of the early evidence base.[8] In September 2025, Embozene received CE Mark approval specifically for GAE in the treatment of knee OA, formally establishing GAE as an approved indication in CE Mark jurisdictions.

Embozene for GAE is also cleared in Australia, Brazil, and Singapore. Currently, GAE is not approved for use in the United States.

GRAVITY adds something the field has been missing: a randomized, controlled comparison conducted under FDA oversight. Alongside the growing single-arm literature and the CE Mark precedent in Europe, GRAVITY's peer-reviewed publication is positioned to potentially advance the treatment landscape globally.

SIEMENS HEALTHINEERS INTERVENTIONAL ONCOLOGY: INVESTING TO MOVE THE FIELD FORWARD

GRAVITY exists because Siemens Healthineers Interventional Oncology made a deliberate choice to invest in independent, investigator-led science rather than wait for evidence to accumulate on its own. The research grant supported a single-center, UCLA-sponsored trial precisely because rigorously designed, randomized data are what the interventional radiology community needs to move GAE toward a defined treatment option. That investment extends beyond funding the trial itself; it extends to its imaging and biomarker substudies, the planned 24-month and crossover-arm analyses, and the physician education that accompanies this evidence as it matures. ■

1. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the management of osteoarthritis of the hand, hip, and knee. Arthritis Rheumatol. 2020;72:220-233. doi: 10.1002/art.41142
2. Okuno Y, Korchi AM, Shinjo T, et al. Midterm clinical outcomes and MR imaging changes after transcatheter arterial embolization as a treatment for mild to moderate radiographic knee osteoarthritis resistant to conservative treatment. J Vasc Interv Radiol. 2017;28:995-1002. doi: 10.1016/j.jvir.2017.02.033
3. Padia SA, Genshaft S, Blumstein G, et al. Genicular artery embolization for the treatment of symptomatic knee osteoarthritis. JB JS Open Access. 2021;6:e21.00085. doi: 10.2106/JBJS.OA.21.00085
4. Little MW, Gibson M, Briggs J, et al. Genicular artery embolization in patients with osteoarthritis of the knee (GENESIS) using permanent microspheres: interim analysis. Cardiovasc Intervent Radiol. 2021;44:931-940. doi: 10.1007/s00270-020-02764-3
5. Cusumano LR, Sparks HD, Masterson KE, et al. Genicular artery embolization for treatment of symptomatic knee osteoarthritis: 2-year outcomes from a prospective IDE trial. J Vasc Interv Radiol. 2024;35:1768-1775. doi: 10.1016/j.jvir.2024.08.028
6. Padia S. GRAVITY: genicular artery embolization versus observation for the treatment of symptomatic knee osteoarthritis–a prospective randomized controlled trial. Presented at: Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Annual Congress; September 7, 2026; Copenhagen, Denmark.
7. Genicular artery embolization vs observation for symptomatic knee osteoarthritis (GRAVITY). Clinicaltrials.gov. Accessed September 25, 2026. https://clinicaltrials.gov/study/NCT04682652
8. Ahmed O, Taslakian B, Okuno Y, et al. Society of Interventional Radiology position statement on genicular artery embolization for symptomatic knee osteoarthritis. J Vasc Interv Radiol. 2026;37:108803. doi: 10.1016/j.jvir.2026.108803

Reference 6 reflects a conference abstract presentation; detailed efficacy and safety results from GRAVITY have not yet appeared in the peer-reviewed literature and are not reported in this article. Regulatory milestones referenced above (FDA Breakthrough Device Designation, 2021; CE Mark for GAE in knee osteoarthritis, 2025) reflect publicly reported designations for Embozene microspheres (Varian Medical Systems, Inc.) and are not themselves peer-reviewed publications.

QR700045245