Society of Interventional Radiology Position Statement on Genicular Artery Embolization for Symptomatic Knee Osteoarthritis

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ABSTRACT

Knee osteoarthritis (KOA) is a prevalent musculoskeletal condition characterized by a significant therapeutic gap between the failure of conservative medical therapies and surgical arthroplasty. Contemporary evidence supports a model in which chronic synovitis and pathologic neoangiogenesis, closely coupled to perivascular nociceptive nerve growth, serve as significant contributors of pain and peripheral sensitization in KOA. Genicular artery embolization has emerged as a targeted, joint-preserving vascular intervention performed by interventional radiologists that directly addresses the inflammatory and neurovascular components of KOA. The purpose of this societal-endorsed position statement is to synthesize the current knowledge base for genicular artery embolization and review its biologic rationale, clinical evidence, technical considerations, safety profile, and evolving regulatory landscape.

ABBREVIATIONS

CT = computed tomography, DSA = digital subtraction angiography, FDA = U.S. Food and Drug Administration, GAE = genicular artery embolization, IDE = investigational device exemption, KL = Kellgren–Lawrence, KOA = knee osteoarthritis, KOOS = Knee Injury and Osteoarthritis Outcome Score, MCID = minimal clinically important difference, MSK = musculoskeletal, OA = osteoarthritis, RCT = randomized controlled trial, SCB = substantial clinical benefit, SIR = Society of Interventional Radiology, TKA = total knee arthroplasty, VAS = visual analog scale, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index

Knee osteoarthritis (KOA) is a highly prevalent and disabling musculoskeletal (MSK) condition with an increasing clinical and economic impact driven by aging populations and increasing metabolic disease (1). Despite the substantial societal burden, a significant therapeutic gap remains between the failure of conservative medical therapies and definitive surgical arthroplasty. Many symptomatic patients are ineligible for total knee arthroplasty (TKA) or elect to defer surgery due to comorbidities, psychosocial factors, access barriers, long recovery periods, or uncertainty over surgical risks and benefits (2). Up to 30% of patients who are advised to undergo TKA ultimately decline surgery; even among patients who proceed with arthroplasty, up to 20% remain dissatisfied with postoperative outcomes (3,4).

First described by Okuno et al (5) in 2014 for KOA refractory to conservative treatment, genicular artery embolization (GAE) has evolved from managing postarthroplasty hemarthrosis to targeting osteoarthritis-associated inflammation. Over the past decade, GAE has seen rapid global adoption within interventional radiology, supported by accumulating clinical evidence demonstrating a favorable safety profile and meaningful improvements in pain, function, and quality of life across diverse patient populations (6). This evidence has supported its integration into specialized MSK embolization programs and culminated in European Conformity mark approval in Europe in 2025 (7).

As MSK embolization (including GAE) technique has advanced, research has shifted from feasibility and short-term effectiveness toward defining best practices, demonstrating effectiveness in placebo controlled trials, and establishing an effect size. Key methodological questions focus on optimal patient selection across the spectrum of

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MSK diseases using imaging and clinical biomarkers, as well as on tailoring technical variables—such as the use of cone-beam computed tomography (CT), embolic material selection, and embolization end points—to individual patient characteristics and disease severity. Important debates also continue regarding the durability of benefit, repeatability of treatment, and comparative effectiveness versus other minimally invasive interventions such as genicular nerve ablation and intra-articular injections (8).

The evidentiary basis for GAE is also evolving from early single-center retrospective experiences and observational studies to randomized controlled trials (RCTs; with or without sham controls), multicenter registries, and larger institutional experiences with longer-term outcomes. These efforts aim to address prior methodological limitations, clarify the magnitude and durability of clinical benefit, and establish GAE's role in KOA treatment algorithms. The outcomes of these studies are expected to further influence guideline incorporation, payer coverage, and broader adoption across interventional radiology and multidisciplinary MSK care pathways.

In 2021, the Society of Interventional Radiology (SIR) convened a multidisciplinary consensus panel to identify key research gaps and priorities related to GAE (9). In 2024, SIR published reporting standards to enhance data harmonization and strengthen the evidence base (10). This article summarizes the progress to date and describes SIR's position regarding the use of GAE for symptomatic KOA.

This document presents a position statement developed by interventional radiologists with published expertise in MSK embolization, informed by multidisciplinary consensus among experts in the management of KOA. The statement has been formally reviewed and approved by the Executive Council and the Pain Management Council of SIR.

MECHANISM OF ACTION AND RATIONALE FOR TREATMENT

KOA is increasingly recognized as a heterogeneous disease with distinct structural and inflammatory phenotypes. Although cartilage degeneration is a defining feature, accumulating evidence supports a role for neuroplastic changes along with chronic, low-grade synovitis as causes of pain generation and functional limitation. Imaging and histopathologic studies demonstrate synovial lining hyperplasia, inflammatory cell infiltration, and upregulation of proinflammatory cytokines within the osteoarthritic joint, supporting synovial inflammation as a therapeutic target (11–13).

Cartilage degradation products and catabolic mediators (eg, tumor necrosis factor α, interleukin 1β, and matrix metalloproteinases) enter the synovial space and begin a self-sustaining inflammatory cascade (14). This positive feedback cycle promotes pathologic neoangiogenesis within the synovium and is closely coupled to perivascular nociceptive nerve ingrowth and peripheral sensitization into regions that are normally aneural (15). Importantly, these pathologic neurovascular changes are not uniformly distributed throughout the joint and likely contribute to heterogeneity in symptoms and response to targeted embolization.

GAE is hypothesized to reduce hypervascular synovial perfusion, thereby disrupting angiogenic signaling and perivascular nerve proliferation while preserving global joint perfusion. Preclinical models to date support this concept. Talaie et al (16) reported a study using micro-CT that demonstrated pathologic neovascularization and vascular remodeling in arthritic limbs compared with normal control limbs in a rabbit model of KOA. In a controlled study design, animals treated with GAE exhibited significantly reduced synovial proliferation, villous hypertrophy, and stromal hyperplasia compared with sham controls (17). Additionally, $CD3^+$ inflammatory cell density was substantially lower in the embolization group, supporting a direct anti-inflammatory effect at the synovial level. In a rat model of KOA, Matsuyama et al (18) demonstrated that intra-arterial administration of imipenem/cilastatin reduced pain behaviors and dorsal horn spinal nociceptive signaling, further supporting a localized neuromodulatory effect.

Human imaging studies further reinforce an inflammatory mechanism of action. Contrast-enhanced magnetic resonance (MR) imaging demonstrated significant reductions in synovial enhancement following GAE, consistent with decreased synovitis (19). Studies (20,21) using 2-dimensional (2D) angiographic-perfusion techniques demonstrated selective reduction in perfusion of pathologic hypervascular regions after GAE, with preservation of flow in parent genicular arteries. Importantly, available imaging studies (19,22–24) have not shown a negative impact on subchondral bone perfusion or evidence of osteonecrosis, addressing a key theoretical safety concern.

Emerging biomarker data also suggest that the effects of GAE may modulate inflammatory pathways beyond the immediate vascular target. Reductions in circulating angiogenic and inflammatory mediators following GAE have been reported in association with sustained clinical improvement (25). This supports a plausible biologic link between suppression of synovial angiogenesis and downstream pain modulation (25).

TECHNIQUE

Angiographic techniques for GAE have been described in extensive detail (26). Ongoing refinement of embolic selection, target definition, and imaging adjuncts may further optimize outcomes.

Embolic Selection

Permanent microspheres, resorbable particles, and temporary liquid embolic agents have been used for GAE (**Table 1**). Preclinical imaging studies demonstrate that

Table 1. Embolic Summary

Name	Manufacturer	Resorption time	Initial study
Imipenem/cilastatin	Several	—	Okuno et al (23)
Embozene	Varian	Permanent	Bagla et al (27)
Embosphere	Merit	Permanent	Little et al (28)
Ethiodized oil	Guerbet	Temporary	Sapoval et al (29)
Sakurabead	Crannmed	Temporary	Little et al (24)
Nexsphere	NEXT Biomedical	Temporary	Amin et al (30)

temporary embolic agents may preferentially occlude pathologic inflammatory neovessels while allowing rapid recanalization of normal vessels, providing a biologic rationale for resorbable materials (21).

The adverse event rates for GAE are overall low (31). Adverse events following GAE have been seen with higher frequency with the use of small-particle permanent embolic agents (<100 μm) (27). Most contemporary series report low adverse event rates and skin discoloration (frequently observed with permanent embolic agents) that should not be regarded as a true adverse event, as it is transient and resolves completely in the majority of cases within 1 month (32). While reported rates of adverse events with resorbable embolic agents have been lower than permanent, the durability of treatment could theoretically be shorter owing to their temporary effect. Comparative trials are still pending, and there is no current recommendation for the ideal embolic device for GAE (23,31).

Target Vessel Strategy

The optimal number of arteries to be embolized remains undefined. Early approaches targeted vessels corresponding to focal pain, whereas more recent studies target any artery that demonstrates synovial hypervascularity. Subgroup analysis in a sham-controlled trial (33) suggested improved outcomes when complete embolization of angiographically abnormal vessels was achieved. A recent trial (30) using multivessel resorbable embolic embolization show consistent symptom improvement with an acceptable safety profile in patients undergoing GAE.

The extensive periarticular anastomotic network of the knee joint results in a high degree of collateralization (34,35). Consequently, individual genicular arteries are components of an integrated vascular network that are variable across individuals and should be addressed as a whole rather than as isolated compartments. Failure to recognize this aspect in early clinical experience likely contributed to limited therapeutic success (35). However, clinical trials (24,36,37) using permanent embolic agents—including sham-controlled studies—demonstrated clinical benefit for patients with mild to moderate KOA, even when only 1 compartment corresponding to the pain was targeted.

Lack of recognition of the periarticular anastomotic network in some early experiences may have led to treatment-limiting adverse events and early treatment failures (35). There are many instances where multiartery embolization is not feasible or even necessary, particularly in cases where collateral supply necessitates only 1 artery to be treated. This is most commonly seen in the medial knee, where embolization of the descending genicular artery may obviate the need to embolize the superior medial genicular artery. In a report (21), retrograde embolization of the superior medial genicular artery via anastomoses was technically successful in up to 31% of patients.

Imaging Adjuncts

Cone-beam CT during contrast injection may serve as a valuable adjunct to GAE (38). Cone-beam CT has been shown to identify more potential targets for embolization for 3 reasons. First, variant anatomy is easy to delineate with 3D reconstruction of cone-beam CT images (39). Second, analysis of maximum intensity projection images can facilitate optimal fluoroscopy angle for successful arterial catheterization. Third, higher contrast volume and prolonged acquisition time of cone-beam CT than those of digital subtraction angiography (DSA) allow all genicular arteries to be optimally opacified allowing for easier identification (38). Although not universally available, cone-beam CT can therefore serve as an important equalizer for operators earlier in their learning curve or in anatomically complex cases, whereas high-volume centers may rely more heavily on iterative 2D angiography and pattern recognition to achieve similar target identification and end point assessment. Hybrid angio-CT suites may further improve upon cone-beam CT.

PATIENT SELECTION

Across most prospective studies (24,25,27,31,32,36,40,41), the majority of patients treated by GAE report meaningful clinical improvement and overall satisfaction following the procedure. As the procedure expands into broader practice, refinement of patient selection will likely be the most important determinant of sustained effectiveness. Most trials have included a common core of inclusion and exclusion criteria (**Table 2**) typically requiring symptomatic KOA refractory to conservative therapy and excluding inflammatory arthropathies, infection, and advanced vascular compromise. However, several controversial factors remain.

Radiographic Severity

A central debate concerns the appropriateness of treating patients with Kellgren–Lawrence (KL) Grade 4 disease. The KL grading system is a radiographic classification of osteoarthritis severity, ranging from Grade 0 (no OA) to Grade 4 (severe OA). KL Grade 4 represents advanced radiographic disease characterized by marked joint space narrowing (bone on bone), large osteophytes, subchondral sclerosis, and definite bony deformity.

Table 2. Inclusion and Exclusion Criteria

General inclusion criteria	General exclusion criteria
Diagnosis of knee osteoarthritis	Evidence of significant peripheral arterial disease
Age >40 y	Contraindication to angiography (eg, renal insufficiency and contrast allergy)
Ineligibility for or refusal of surgery	Radicular or lumbar spine etiology of knee pain
Pain with VAS >4 (of 10)	Fibromyalgia
Resistant/failed conservative treatment (eg, NSAIDs, PT, or joint injection) for at least 3 mo	First-line therapy for inflammatory arthritis

NSAID = nonsteroidal anti-inflammatory drug; PT = physical therapy; VAS = visual analog scale.

Several studies (42,43) demonstrated lower effectiveness in patients with KL Grade 4 disease compared with that in other grades, while others have shown equivalent success rates in KL Grade 4 versus KL Grade 2 or 3 disease. While it remains the most commonly accepted quantitative method to assess the degree of KOA, the KL scale has numerous deficiencies. Slight changes in radiographic projection may change the categorization (44). Furthermore, the scale does not represent a continuous scale. One can have severe OA with KL Grade 4 with joint space narrowing and mild bony deformity or can have end-stage destruction of the joint with KL Grade 4. Therefore, if patients with KL Grade disease are considered for GAE, further refinement of patient selection may help to exclude those with a predominantly structural phenotype and less pronounced inflammatory activity.

One example for refinement would be to consider exclusion of patients with significant varus or valgus angulation, which suggests marked bony deformity, as GAE may not benefit this patient cohort. As such, radiographic severity alone is an inadequate discriminator; patients with KL Grade 4 disease but preserved alignment, maintained joint congruity, and clear evidence of synovitis may still derive clinically meaningful benefit, whereas those with end-stage mechanical failure or gross deformity are unlikely to respond despite technically successful embolization. For this reason, patients with severe OA should not be automatically excluded from GAE. Ideally, these patients should undergo evaluation with contrast-enhanced MR imaging to assess for synovitis, which will be targeted at embolization. From the current evidence, it is likely that clinical benefit in those with advanced disease will be shorter than in patients with mild to moderate OA (43,45). Patient expectations and alternative therapies must therefore be thoroughly assessed during the patient consultation.

Role of MR Imaging in Patient Stratification

MR imaging is not routinely used in preoperative assessment prior to TKA but may serve as a valuable predictive tool for GAE patient selection in the future. The overall complexity of the knee joint and numerous findings seen in advanced OA make specific MR findings challenging to correlate with clinical success. At the very least, specific MR features can be used to potentially exclude poor GAE candidates. van Zadelhoff et al (46) assessed 54 MR images prior to GAE and correlated them to clinical response, using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at 6 months. They found that those who were less likely to improve were those with higher cartilage full-thickness defects, bone marrow lesions, Grades 2–3 effusion synovitis, and osteophytes (46). However, these findings conflict with those of other studies, which suggest that baseline synovitis was not predictive of response at 3 months (47).

Emerging Imaging Analytics

Given the high complexity and exhaustive findings on MR imaging seen in knee OA, an artificial intelligence methodology may improve patient stratification. In a machine learning analysis of MR images of 72 knees, predictive modeling demonstrated encouraging discrimination for treatment response, with reported accuracy of 81.8% (47). Large data sets of MR imaging prior to GAE with clinical outcomes may eventually demonstrate possible baseline imaging signals that would predispose one to success or failure after GAE.

OUTCOME ASSESSMENT AND ADVERSE EVENT EVALUATION

Accurate evaluation depends on consistent use of validated outcome measures that capture symptom severity and functional limitation in KOA. The SIR Research Reporting Standards identify the WOMAC, the Knee Injury and Osteoarthritis Outcome Score (KOOS), and the visual analog scale (VAS) as the core instruments for assessing treatment response in GAE trials (10). WOMAC remains the most widely used disease-specific instrument across prospective GAE studies, reflecting its utility in quantifying pain, stiffness, and functional impairment in osteoarthritis (25,29,36,40,41,48). Many trials (25,41,48) rely specifically on the WOMAC pain subscale (0–20) as the primary

end point. In parallel, KOOS incorporates WOMAC into and provides a broader functional assessment across domains such as daily living, sports, and quality of life and has been used in several contemporary GAE trials. In contrast to WOMAC, KOOS is in the public domain, making it free to use by clinicians and researchers (24,33,45,49). VAS, scored on a 0- to 100-mm scale, remains a useful measure and has served as the primary end point in prospective single-arm and randomized studies of GAE, often combined with WOMAC score (27,36).

Despite widespread use, the instruments are inherently subjective, are vulnerable to fluctuations based on mood, weather, and seasonal variation in arthritic symptoms, and may not uniformly capture disease burden across diverse patient populations (50–52). Comprehensive instruments such as WOMAC and KOOS can be time consuming for patients to complete and include items that are impractical or irrelevant for older adults or individuals with limited baseline function. These nuances underscore the need for thoughtful interpretation of patient-reported outcome measures and, where possible, the integration of objective biomarkers and imaging correlates when evaluating treatment response to GAE. Longitudinal collection of patient-reported outcome measures through electronic platforms or ePRO systems, rather than isolated in-clinic assessments, may reduce recall bias, better capture the temporal dynamics of pain and function, and facilitate more robust comparative effectiveness analyses between GAE and other interventions.

Interpretation of outcomes should also evolve beyond simple statistical significance to incorporate patient-centered thresholds such as minimal clinically important difference (MCID), substantial clinical benefit (SCB), patient-acceptable symptom state, and responder analyses. MCID for WOMAC pain is typically estimated at approximately 4 points (20% improvement) based on the surgical literature (53). SCB represents a higher threshold, often approximately 6 points (30% improvement), while KOOS improvements of 8–15 points are generally accepted as clinically meaningful (53–55). Patient-acceptable symptom state defines an absolute symptom threshold at which patients consider their disease state acceptable, such as a VAS score of $\leq$3/10 (56). Many GAE studies also categorize patients dichotomously as responders or non-responders, commonly defining response as a $\geq$50% reduction in VAS or WOMAC scores, a standard derived from interventional pain literature and increasingly used in embolization research (32). To improve the reporting of results in symptom-modifying clinical trials, the Outcome Measures in Rheumatology Osteoarthritis Research Society International (OMERACT-OARSI) responder criteria were developed as a simplified, composite index to evaluate individual patient outcomes. This approach permits the presentation of results based on a dichotomous "responder: yes/no" analysis, moving beyond simple group averages to highlight the proportion of patients who achieve clinically meaningful benefit. This validated framework defines a responder as a patient achieving high improvement ($\geq$50% and an absolute change $\geq$20 points) in pain or function, or a moderate improvement ($\geq$20% and an absolute change $\geq$10 points) in at least 2 of the 3 symptomatic domains: pain, physical function, or patient global assessment (57). Using this standardized approach in GAE research ensures international harmonization and allows for more precise comparisons between embolization and other symptomatic OA therapies.

Across published prospective trials and meta-analyses, GAE has demonstrated rapid and durable improvements in pain and function. In an early Japanese experience, Okuno et al (23) reported substantial decreases in VAS and WOMAC scores, which were sustained through 48 months, with a cumulative clinical success rate defined as significant decreases in WOMAC approaching 80% (23). Similar durability was observed in the Genicular Artery Embolization in Patients with Osteoarthritis of the Knee (GENESIS) study using permanent microspheres, where VAS improved from 58.6 at baseline to 37.7 at 2 years ($P <$ .001), with parallel gains in KOOS domains and associated reductions in analgesia usage (24). In addition, 2-year outcomes from a prospective U.S. investigational device exemption (IDE) trial reinforced the durability of the procedure using 100-μm permanent microspheres in patients with moderate-to-severe OA (32). In that study, Cusumano et al (32) reported that among patients who achieved clinical success (defined strictly as a $\geq$50% reduction in WOMAC) at 12 months, 72% maintained this therapeutic benefit at 24 months (32). Notably, this study demonstrated sustained clinical success even in patients with severe radiographic disease (KL Grade 4), with a 42.9% success rate in this subgroup at 2 years. These findings are reinforced by systematic reviews and meta-analyses, showing consistent pain reduction and improvement of functional scores at 6–12 months and high proportions of patients achieving MCID or SCB (6,58).

Objective biomarkers and imaging end points are increasingly incorporated into modern GAE trials. Taslakian et al (25) demonstrated significant reductions in serum vascular endothelial growth factor and interleukin 1 receptor antagonist levels at 12 months following embolization with permanent microspheres. Early data also suggest reductions in nerve growth factor, supporting a mechanistic effect on nociceptive sensitization, although further confirmation is required (41). Integration of molecular and imaging biomarkers may further refine patient selection and improve mechanistic understanding.

GAE maintains a strong safety profile across >1,000 reported cases worldwide. The incidence of major adverse events is low, with most reports indicating no occurrences of permanent neurologic injury, septic arthritis, or osteonecrosis. Minor procedure-specific adverse events are

Table 3. FDA Breakthrough Device Designations for GAE

Date granted	Device name	Manufacturer	Agent type
October 2021	Embozene microspheres	Varian (Siemens Healthineers, Palo Alto, California)	Permanent embolic (hydrogel core with Polyzene-F coating microspheres)
May 2021	Sakurabead	CrannMed (Dublin, Ireland)	Resorbable embolic particles
March 2022	Embosphere microspheres	Merit Medical Systems (South Jordan, Utah)	Permanent (trisacryl gelatin microspheres)
February 2025	Lipiojoint	Guerbet (Villepinte, France)	Transient liquid embolic (ethiodized oil emulsion)
March 2025	Nexsphere-F	Next Biomedical (Seoul, South Korea)	Resorbable (bioresorbable spheres for temporary occlusion)

FDA = Food and Drug Administration; GAE = genicular artery embolization.

typically transient and self-limiting, the most prevalent being cutaneous changes such as transient skin discoloration or erythema, which is observed in 10%–30% of patients (6,58). Other localized adverse events include focal skin ulcers occurring in approximately 0.3% (6). While more significant concerns such as focal bone infarcts have been identified on postprocedural MR imaging, these remain clinically rare (<0.1%) and generally asymptomatic. Crucially, GAE has not been found to negatively impact the technical execution or outcomes of subsequent total knee replacement, supporting its safety as an interim therapeutic option (59).

THE FUTURE OF GAE: REGULATORY MILESTONES AND THE PATH TO LEVEL 1 EVIDENCE

The body of literature to date on GAE has not only established the safety and technical feasibility of GAE but also consistently demonstrated its clinical effectiveness, with significant and durable reductions in pain scores and tangible improvements in functional status for patients with symptomatic KOA (24,25,29,32,36,41,48). However, broader adoption of GAE and consideration for inclusion in multispecialty clinical guidelines will be informed by the continued generation of high-quality clinical evidence, including randomized studies, as part of the natural evolution of evidence-based practice. The current research landscape is characterized by this pivotal shift from single-arm observational studies to large-scale, multicenter, RCTs with or without sham procedures. These studies are essential to definitively isolate the physiological treatment effect from the placebo response and to establish comparative effectiveness against existing conservative therapies, such as intra-articular corticosteroid injections. Concurrently, regulatory bodies, including the U.S. Food and Drug Administration (FDA), have used specific pathways to facilitate the investigation of these devices for this emerging indication.

Regulatory Momentum

The FDA Breakthrough Devices Program is designed to expedite the development and review of medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating conditions. In the context of KOA, where effective nonsurgical options are limited, the FDA has granted this designation to 5 distinct embolic platforms (Table 3), prioritizing the regulatory review process for upcoming IDE trials. Despite this momentum, it is important to note that none of these embolic agents currently hold a formal FDA indication for MSK procedures; in the United States, their use for knee pain remains off-label.

While the U.S. market continues its clinical trial phase, the European and Canadian regulatory landscapes have already reached a formal turning point. As of late 2025, both Embozene (Varian) and Embosphere (Merit Medical) secured the CE mark specifically for GAE to treat KOA, transitioning the procedure from off-label to a recognized therapeutic indication in the EU. Paralleling this progress, Nexsphere-F (NextBiomedical) is the only resorbable embolic microsphere certified under European Conformity marking under the Medical Devices Directive and recently secured Health Canada approval for MSK pain embolization.

Upcoming Clinical Trials and IDE Studies: Bridging the Evidence Gap

GAE research has progressed from single-arm feasibility studies to multicenter RCTs designed to address 3 key questions: (*a*) the magnitude of the placebo effect, (*b*) the comparative effectiveness of GAE versus primary medical therapies (specifically intra-articular corticosteroids), and (*c*) the utility of resorbable versus permanent embolic agents. A summary of active trials is provided in Table 4.

Sham-Controlled Investigations. Several double-blind, sham-controlled trials are underway to isolate the physiologic effect of embolization from placebo response. GENESIS II (NCT05423587) has completed enrollment (n = 110) and randomized patients with mild to moderate OA to GAE with permanent microspheres versus sham, with crossover permitted after 6 months. LipioJoint-2 (NCT06497140) is a phase 3 trial (target n = 130) comparing ethiodized oil–based emulsion with sham procedure, with a primary end point of VAS pain reduction at 3 months. The National Institutes of Health (NIH)-funded Genicular Artery Embolization for Reducing

Table 4. Summary of Ongoing and Upcoming GAE Clinical Trials

NCT number	Study name/acronym	Principal investigator/sponsor	Location/institution	Study design	Primary agent/comparison
NCT05423587	GENESIS II	Mark Little, MBBS (Varian)	Reading, UK (Multicenter)	RCT (double-blind, sham-controlled)	Embozene vs sham (saline)
NCT06497140	LipioJoint-2	Marc Sapoval, MD, PhD (Assistance Publique, Hôpitaux de Paris)	Paris, France	RCT (sham-controlled)	Lipiojoint (oil emulsion) vs sham
NCT04682652	GRAVITY	Siddharth Padia, MD (UCLA/Varian)	UCLA (Los Angeles, California)	RCT (open label)	Embozene vs observation
NCT06166628	GENI	David Clinkard, MD	Queen's University (Kingston, Canada)	RCT (3 arms)	GAE vs phenol nerve ablation vs sham
NCT06550024	SURE	CrannMed	Multicenter	RCT (open label)	Sakurabead (resorbable) vs corticosteroid
NCT06872567	RESORB	North American Science Associates	Multicenter	RCT (open label)	Nexsphere-F (resorbable) vs corticosteroid
NCT07380906	GAE registry	Joint & Vascular Institute	Libertyville, Illinois	Prospective registry	WOMAC score tracking
NCT06940479	GAE-KOA	NA (Based on title)	NA	Mechanistic cohort	Synovial fluid analysis
NCT06859164	SHAM-PAIN	Osman Ahmed	University of Utah	Sham-controlled	GAE vs sham

GAE = genicular artery embolization; GAE-KOA = Evaluating Changes in Synovial Fluid Before and After GAE for Knee Osteoarthritis; GAE Registry = GAE Prospective Registry; GENESIS II = Genicular Artery Embolisation for Knee Osteoarthritis II; GENI = Genicular Artery Embolization vs Nerve Ablation Intervention; Gravity = Genicular Artery Embolization Versus Observation for the Treatment of Symptomatic Knee Osteoarthritis: a Randomized Controlled; Lipiojoint-2 = Effect of Genicular Arteries Embolization in Symptomatic Knee Osteoarthritis LipioJoint-2; NA = not available; RCT = randomized controlled trial; RESORB = Randomized Controlled Study Evaluating Genicular Artery Embolization Against Intra-Articular Corticosteroid Knee Injection for Osteoarthritic Knee Pain; SHAM-PAIN = Genicular Artery Embolization for Reducing Pain in Medically Refractory Symptomatic Knee Osteoarthritis-A Randomized Sham-Controlled Pilot Study; SURE = SakuraBead Used as Resorbable Embolic for Genicular Artery Embolization; UCLA = University of California, Los Angeles; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

Pain in Medically Refractory Symptomatic Knee Osteoarthritis-A Randomized Sham-Controlled Pilot Study (SHAM-PAIN) trial is a single-center, sham-controlled, randomized pilot study (n = 40) not only evaluating feasibility of patient enrollment and willingness to undergo randomization to a sham intervention in the United States but also generating preliminary effectiveness data for GAE using Lipiojoint (60). The 3-arm Genicular Artery Embolization vs Nerve Ablation Intervention (GENI) for Knee Osteoarthritis trial (NCT06166628) randomizes 150 patients awaiting TKA to GAE, phenol genicular neurolysis, or sham, with WOMAC improvement at 3 months as the primary end point with incorporation of biomarker and imaging correlates (61).

Active-Comparator Trials vs Standard of Care. To establish GAE within the clinical treatment algorithm, ongoing open-label RCTs are comparing embolization directly with intra-articular corticosteroid injections. The SakuraBead Used as Resorbable Embolic for Genicular Artery Embolization (SURE) trial (NCT06550024) will assess resorbable Sakurabead versus corticosteroids in approximately 89 patients, while the Randomized Controlled Study Evaluating Genicular Artery Embolization Against Intra-Articular Corticosteroid Knee Injection for Osteoarthritic Knee Pain (RESORB) trial (NCT06872567) compares Nexsphere-F (a gelatin-based sphere that degrades within 2–6 hours) against steroid injections. These studies are designed to determine whether embolization provides more durable symptom relief than pharmacologic therapy.

Mechanistic and Registry Data. Complementary mechanistic trials and registries aim to refine patient selection and elucidate biologic response. The Genicular Artery Embolization Versus Observation for the Treatment of Symptomatic Knee Osteoarthritis: a Randomized Controlled (GRAVITY) trial (NCT04682652) has completed enrollment (n = 117) and includes imaging and biomarkers end points in addition to clinical outcomes. The GAE-KOA study further evaluates synovial fluid changes before and after embolization to identify molecular markers of response.

CONCLUSIONS

GAE is a minimally invasive treatment performed by interventional radiologists for patients with symptomatic, medically refractory KOA who are not candidates for, or wish to delay, TKA. Preclinical, imaging, and biomarker studies provide a biologically plausible rationale, demonstrating that GAE targets synovial neoangiogenesis and modulates the vascular–inflammatory–neurogenic pathways associated with KOA pain. Clinical studies further support its safety and technical feasibility, with consistent improvements in pain, function, and quality of life. Accordingly, GAE has gained broad international

acceptance as a therapeutic option for patients with KOA refractory to conservative management.

The field is now entering a maturation phase that will define GAE's long-term role in treatment algorithms. Priorities include demonstrating superiority over placebo and other active comparators in high-quality trials, optimizing patient selection, standardizing technique, clarifying embolic selection, and establishing the durability and repeatability of clinical benefit. Ongoing sham-controlled and active-comparator randomized trials, together with large real-world registries and biomarker-driven phenotyping studies, are expected to generate higher-level evidence and inform multidisciplinary consensus guidelines.

In sum, converging clinical data, global adoption, and evolving regulatory frameworks position GAE not as an experimental intervention but as an established treatment option for KOA—one whose role in standard practice will be further defined by the next generation of randomized and registry-based evidence.

SIR POSITION

- Genicular artery embolization (GAE) is supported by a growing body of evidence demonstrating clinically meaningful reductions in pain and improvements in function in appropriately selected patients with symptomatic knee osteoarthritis.
- GAE has a favorable safety profile when performed by interventional specialists with formal training and advanced experience in microcatheter work and embolotherapies.
- GAE should be offered as a minimally invasive treatment option for patients with symptomatic knee osteoarthritis who have failed conservative therapy and/or are either ineligible for, unwilling to undergo, or seeking to delay total knee arthroplasty.
- Ongoing randomized controlled trials aim to quantify potential placebo effects and further define the long-term durability, optimal embolic selection, and comparative effectiveness of GAE.
- GAE should be performed within multidisciplinary care pathways and reported using standardized outcome measures consistent with the SIR Research Reporting Standards.

AUTHOR INFORMATION

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