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ORIGINAL RESEARCH

Genicular Nerve Radiofrequency Ablation for Chronic Knee Joint Pain Using a V-Shaped Active Tip Needle: A Single-Center Retrospective Observational Study

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Background: Chronic knee pain from osteoarthritis (OA) affects a significant proportion of adults over 40. Total knee arthroplasty (TKA) remains the standard for advanced OA, yet up to 20% of patients experience chronic postsurgical pain (CPSP). Genicular nerve radiofrequency ablation (GNRFA) can alleviate pain in those unresponsive to conservative treatments or TKA. However, anatomical variability of the genicular nerves may limit treatment durability. This retrospective, single-center observational study investigated whether using a novel V-shaped active tip needle—which creates larger lesions—could improve outcomes.

Methods: Fifty patients with symptomatic knee OA or CPSP, who had a ≥50% reduction in pain after diagnostic genicular nerve blocks, underwent GNRFA with a V-shaped active tip needle between September 2020 and January 2022. Pain and function were assessed using the visual analogue scale (VAS) at rest and during movement, Western Ontario and McMaster Universities Arthritis Index (WOMAC), Douleur Neuropathique en 4 Questions (DN4), and EuroQol-5 Dimensions (EQ-5D) at baseline and 1, 3, 6, and 9 months post-procedure.

Results: By 6 months, 64% of patients showed ≥50% reduction in VAS pain scores, sustained at 9 months ($p<0.0001$). Median WOMAC scores improved from 62.0 at baseline to 40.0 at 6 months ($p<0.0001$). DN4 scores declined from a median of 4.0 at baseline to 2.0 at 6 months and 1.0 at 9 months ($p<0.001$). EQ-5D scores demonstrated significant enhancement in quality of life ($p<0.01$). Pain intensity differences at rest and during movement remained substantially improved at 9 months ($p<0.0001$).

Conclusion: GNRFA using a V-shaped active tip needle is a promising intervention for chronic knee pain, offering significant and sustained pain relief and functional improvement. Larger lesions created by the novel needle may overcome anatomical challenges, though further randomized studies are warranted to validate efficacy and safety.

Keywords: chronic knee pain, chronic knee osteoarthritis, genicular nerve, pain management, radiofrequency ablation, neuromodulation

Introduction

Chronic knee pain from degenerative osteoarthritis (OA) affects 22.9% of adults worldwide over the age of 40.[1] Total knee arthroplasty (TKA) is an effective surgical procedure for treating refractory knee pain and improving patient quality of life. Despite advancements in joint replacement techniques and high success rates achieved with TKAs, a significant proportion of

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patients experience chronic postsurgical pain (CPSP). CPSP is widely accepted to be pain of at least 3–6 months duration that develops or increases in intensity following surgery and significantly affects health-related quality of life.[2]

The number of TKAs has been increasing exponentially and will continue to grow with the progression of a rapidly aging society in the developed world. Along with an increase in TKAs, the number of patients experiencing CPSP following TKA is expected to rise. CPSP following TKA has been strongly associated with negative surgical outcomes and patient satisfaction.[3] A recent systematic review demonstrated that approximately 20% of patients complained of long-term pain following TKA.[4] Observational studies suggest that factors such as female gender, younger age, higher preoperative pain, and psychological distress are associated with higher risks of chronic pain post-TKA.[5–8] These factors can influence patient outcomes and the likelihood of developing CPSP following TKA.

Genicular nerve radiofrequency ablation (GNRFA) is a minimally invasive procedure used to manage chronic knee pain due to OA when conservative and surgical treatments have failed to provide adequate relief of persistent pain following knee replacement surgery.[9,10]

The GNRFA procedure involves the application of targeted thermal radiofrequency to the genicular nerves (superolateral, superomedial, and inferomedial) innervating the knee joint. These sensory nerves are temporarily disabled, resulting in a reduction in pain transmission.

While GNRFA has yielded promising results for many patients, it is essential to note that individual responses to this procedure may vary. The effectiveness of GNRFA may depend on the underlying cause of knee pain and the patient's specific condition. Furthermore, the anatomic variability and small diameter of the genicular nerves are often attributed as causal to the inconsistent efficacy and durability of GNRFA (Figure 1).[11,12]

Therefore, the success of RFA is contingent upon creating a sufficiently large lesion that overlaps the sensory nerve supplying the affected knee joint. Given this variability, a larger lesion should increase the probability of capturing the target nerve. Additionally, this could obviate the need to produce numerous lesions, thereby reducing procedure times

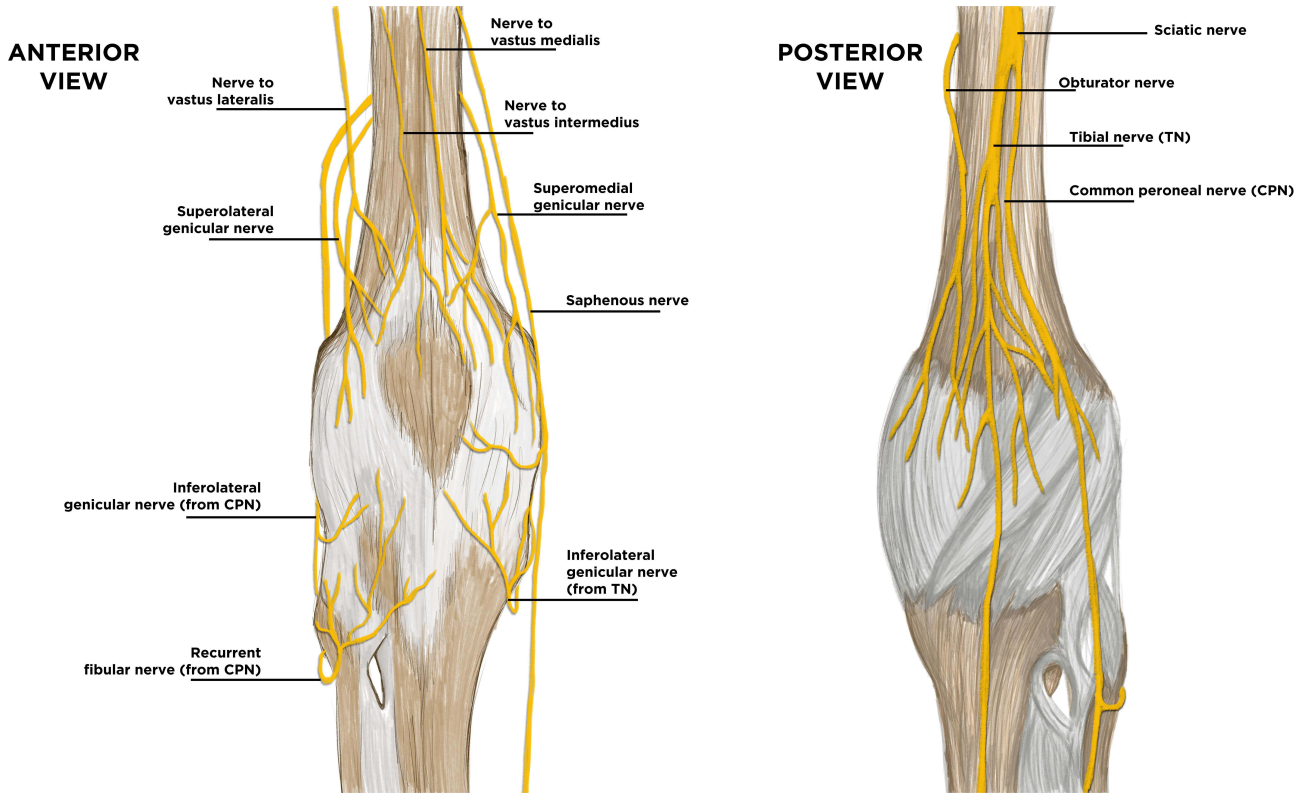

Figure 1 Nerve anatomy of the knee (anterior and posterior views). Illustration demonstrating the nerve anatomy of the knee in both the anterior and posterior view. Anterior view highlights the superolateral genicular nerve, inferolateral genicular nerve (from the common peroneal nerve (CPN)), saphenous nerve, and recurrent fibular nerve. Posterior view highlights the tibial nerve (TN), obturator nerve, CPN, and sciatic nerve.

and potential iatrogenesis.[13] Monopolar RFA is the most used ablation technology, employing a single electrode probe inserted under fluoroscopic guidance adjacent to the target nerve. The use of a V-shaped needle, in which the electrode forks off from the active tip, or cooled-radiofrequency, have been demonstrated to result in increased lesion size, thus having the potential to compensate for the anatomical variability of the genicular nerves.[14]

Amidst the increasing demand to maintain high quality of life in the global aging population, TKA remains the preferred treatment for end-stage knee OA unresponsive to conservative management.[15–17] While most patients report satisfaction, with success rates between 80–85%,[17,18] dissatisfaction due to inadequate functional improvement or CPSP remains high, approximately 15–30% at three months post-surgery.[19–22] These outcomes, exacerbated by the expected surge in TKAs, represent a significant concern.

GNRFA, therefore, offers a viable alternative for those with symptomatic knee OA, improving pain, function, and quality of life.[23–26] A favorable response to a diagnostic genicular block, defined as a 50% reduction in baseline pain, often predicts success.[25] However, the efficacy of GNRFA is not solely determined by diagnostic blocks, as lesion size plays a crucial role in ensuring the treatment's success. Larger lesions, which increase the likelihood of capturing the target nerve despite anatomical variability, have been demonstrated to enhance outcomes.[27] This highlights the importance of selecting a needle capable of creating sufficiently large lesions for optimal nerve capture and sustained pain relief.

The present study examines the effectiveness and feasibility of employing a V-shaped active tip needle in GNRFA to manage chronic knee pain, whether from OA or CPSP. We hypothesize that this needle design, by generating larger and more uniform lesions, can address the limitations posed by the genicular nerves' small diameter and variable anatomy, thereby offering sustained pain relief and improved functionality.

Methods

This study involved a retrospective, single-center, observational review of patient records from a single center, examining those who underwent percutaneous GNRFA using a V-shaped active tip needle (Venom cannula, Stryker®) for chronic knee pain between September 2020 and January 2022. This time frame was chosen to ensure consistent follow-up and complete data collection. Records beyond January 2022 were not included as they did not meet the necessary follow-up period for our analysis.

The study was conducted at Foundation G. Giglio–Cefalù, Palermo, with approval from the Local Ethics Committee and Hospital Scientific Committee and waived the requirement for individual patient consent because all patient information was anonymized and de-identified. This study was performed in accordance with the Declaration of Helsinki.

Study inclusion criteria were participants >18 year of age, symptomatic knee osteoarthritis and/or CPSP, a favorable response (≥ 50% pain relief) to a diagnostic genicular nerve block, and final GNRFA performed using a V-shaped active tip needle. Incomplete records were excluded from the analysis.

Because the primary objective was to assess the feasibility and outcomes of the V-shaped active tip needle, a control group (eg, treated with a standard RFA needle) was not included. While the absence of a comparator group limits direct comparisons, this approach was chosen to explore the potential advantages of the novel V-shaped design in a real-world setting.

Data collected from the medical records included demographic information (age, sex), type of GNRFA procedure, use of oral analgesics (nonsteroidal anti-inflammatory drugs and/or opioids), prior knee replacement surgery, and pain-related measures such as the Visual Analogue Scale (VAS) at rest and during movement, the Douleur Neuropathique en 4 Questions (DN4), the Western Ontario and McMaster Universities Arthritis Index (WOMAC) and the EuroQol-5 Dimension (EQ-5D) at baseline and follow-up (Table 1).

Pain intensity was evaluated using the visual analogue scale (VAS) scored from 0 to 100, both at rest and during movement. The mean pain intensity difference (PID) was calculated as the difference between the VAS scores at each follow-up stage and the baseline score.

The WOMAC score assessed the impact of knee pain on daily activities, DN4 evaluated neuropathic pain severity, and EQ-5D gauged health-related quality of life. Data were collected at baseline and follow-up intervals at 1-, 3-, 6-, and 9-months post-treatment.[28]

Follow-up data were collected through patient records. In the first month, assessments were performed by the treating physician, while subsequent follow-ups were conducted via telephone by an independent investigator to minimize

Table 1 Baseline Demographic and Clinical Characteristics (N = 50)

Variable	Value
Age (years), mean ± SD	69.7 ± 9.6
Sex, n (%)	Female: 30 (60%), Male: 20 (40%)
Prior TKA, n (%)	18 (36%)
Comorbidities, n (%)	Hypertension: 22 (44%) Diabetes Mellitus: 12 (24%) Obesity (BMI ≥30): 15 (30%) Other: 19 (38%)*
Baseline VAS at rest, median [IQR]	60 [40, 90]
Baseline VAS during movement, median [IQR]	50 [40, 80]
Baseline WOMAC, median [IQR]	62 [52, 92]
Baseline DN4, median [IQR]	4 [3, 6]
Baseline EQ-5D, median [IQR]	50 [40, 60]
Analgesic use, n (%)	50 (100%)

Notes: *Other comorbidities include conditions (eg, cardiovascular disease, respiratory disorders) reported by fewer than 20% of patients.
Abbreviations: TKA, total knee arthroplasty; VAS, Visual Analogue Scale; WOMAC, Western Ontario and McMaster Universities Arthritis Index; DN4, Douleur Neuropathique en 4 Questions; EQ-5D, EuroQol-5 Dimensions.

hospital visits.[29–32] Patients were also asked about their resumption of post-procedural analgesic use. Clinical records were screened for early- and late-onset adverse events. All medical records were reviewed by three independent investigators (G.L.B., G.M., and M.P). This study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[33]

Technical Procedures

Diagnostic Genicular Nerve Block

Patients were positioned supine with their knee in slight flexion. The area was cleaned and draped. Local anesthesia was first injected at the entry point, and a 22-gauge spinal needle was inserted at each location targeting the genicular nerves under fluoroscopic guidance. Two milliliters of 1% lidocaine was injected at each of the target sites. Patients who experienced at least ≥ 50% pain reduction within 30–90 minutes and lasting at least 2 hours were considered to have a positive test. Three to four weeks following the diagnostic block with lidocaine, a second diagnostic block with 0.25% bupivacaine was performed. A positive response to the second diagnostic block was defined as a pain reduction of ≥ 50% lasting at least 3 hours. Those who demonstrated positive responses to each diagnostic block were deemed suitable candidates for the GNRFA.

Genicular Nerve Radiofrequency Ablation

The genicular nerves, which are sensory branches supplying the knee joint, include the superior medial, superior lateral, and inferior medial genicular nerves (Figures 2 and 3). Accurate localization of these nerves is essential for effective radiofrequency ablation. The superior medial genicular nerve runs around the femoral shaft, curving over the femoral medial epicondyle and descending 1 cm anterior to the adductor tubercle. The superior lateral genicular nerve is found at the junction between the femoral shaft and the lateral epicondyle, while the inferior medial genicular nerve is located around the tibial medial epicondyle, near the tibial insertion of the medial collateral ligament.

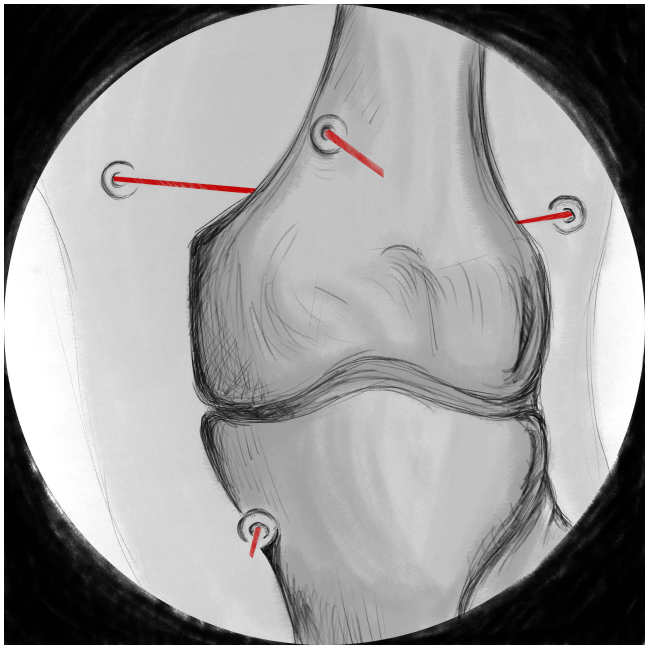

Figure 2 Fluoroscopic anteroposterior view illustrating needle trajectories targeting the genicular nerves. Illustration demonstrating the anteroposterior fluoroscopic view of needle placement in the knee, highlighting needle insertion points targeting various areas of the joint. The red lines represent the trajectory of needles being inserted. The needle insertions are aligned with structures such as the patella and femoral condyle to target specific regions for therapeutic purposes, such as radiofrequency ablation or injections blocks.

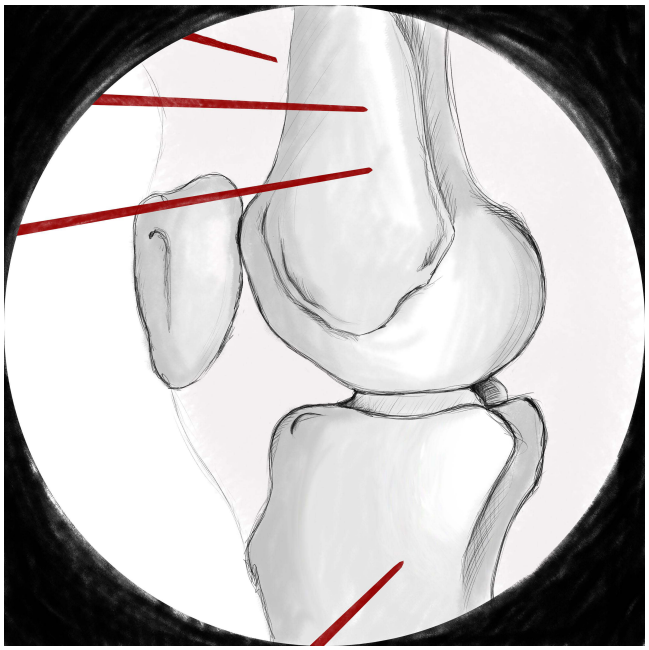

Figure 3 Lateral fluoroscopic view of the knee demonstrating needle placement.

Patients were positioned supine for the procedure, and continuous monitoring of vital signs was ensured. Under C-arm fluoroscopy in an anteroposterior view, along with ultrasound guidance, topographical localization of the superior medial, superior lateral, and inferior medial genicular nerves was performed. Sedation was achieved using short-acting intravenous agents, typically midazolam at a dose of 0.05 mg/kg. Two milliliters of 2% lidocaine was injected at the entry points for needle insertion. An 18-gauge, 100 mm needle with a V-shaped active tip was introduced to the predetermined

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anatomical locations of the genicular nerves, using ultrasound guidance when the patient's body habitus allowed. A single fluoroscopic shot in anteroposterior (AP) and lateral (LL) views was taken to confirm the correct positioning. This combined approach leverages the real-time visualization of soft tissues and nerves via ultrasound, while fluoroscopy provides precise alignment with bony landmarks, enhancing accuracy, minimizing vascular injury risk, and ensuring optimal needle placement for effective nerve ablation.

Nerve localization was confirmed using sensory stimulation at ≤ 0.4 mV, 50 hz, ensuring accurate targeting of the nerve responsible for pain transmission. Motor stimulation was performed to rule out unintended ablation of nearby motor nerves, with acceptable thresholds between 0.9 and 3 V at 2 hz. The presence of paresthesia at the site of the patient's usual pain indicated a successful sensory response, while the absence of muscle contraction confirmed an appropriate motor test.

Radiofrequency ablation was then performed at 85°C for 90 seconds at each targeted nerve location. Following the ablation, 2 mg of dexamethasone and 1 mL of ropivacaine (0.25%) were injected at each treated level to minimize post-procedural inflammation and provide additional analgesia.

Statistical Analysis

Quantitative variables are represented with means ± standard deviations (SDs) or as the median and interquartile range (IQR), where appropriate. Categorical variables are expressed as proportions (frequencies and percentages). A 95% confidence interval (CI) for the statistics of selected variables was also calculated. The normality of data distribution was verified through the Shapiro–Wilk normality test. A non-parametric Friedman test with a pairwise Wilcoxon signed-rank test for post-hoc analysis was used to determine whether there was a statistically significant difference between dependent variables at follow-up time points. DN4 and EQ-5D scores were similarly analyzed to evaluate changes in neuropathic pain and quality of life over time. P-values were adjusted according to the Bonferroni multiple-testing correction method. P-values < 0.05 were statistically significant. The statistical analysis was performed using GraphPad Prism.

Results

We initially reviewed a total of 65 patient records during the study period. Of these, 15 patients were excluded due to either incomplete follow-up data (n = 8) or withdrawal of consent (n = 7). The remaining 50 patient records met the criteria for inclusion in the final analysis, ensuring full data collection over the required follow-up period (Table 1).

All 50 patients included in the analysis used analgesics prior to the procedure. The median baseline VAS score at rest was 60.0 [IQR 40.0, 90.0], while during movement, it was 50.0 [IQR 40.0, 80.0]. The median baseline WOMAC score was 62.0 [IQR 52.0, 92.0], indicating a substantial impact on daily life due to knee pain. Additionally, the median DN4 score was 4.0 [IQR 3.0, 6.0], suggesting the presence of neuropathic pain in a significant proportion of patients. The baseline EQ-5D index yielded a median value of 50 [IQR 40.0, 60.0], reflecting moderate impairment in quality of life.

At 1 month, VAS scores reflected significant reductions both at rest and during movement, with the median pain intensity difference (PID) at rest being −20.0 [IQR −40.0, 0.0], and during movement, −30.0 [IQR −50.0, −10.0]. The WOMAC score demonstrated early improvements, and DN4 scores also decreased, reflecting initial reductions in neuropathic pain. Quality of life, as measured by the EQ-5D index, began to improve at this point.

By 3 months, further reductions were observed in VAS at rest and during movement, with PIDs of −30.0 [IQR −50.0, −10.0] and −35.0 [IQR −60.0, −20.0], respectively. WOMAC scores continued to improve, and the EQ-5D index demonstrated noticeable gains in patient quality of life. Neuropathic pain, as indicated by DN4 scores, evidenced further declines, suggesting sustained relief.

At 6 months, the median PID at rest was −35.0 [IQR −55.0, −15.0], and during movement, −40.0 [IQR −70.0, −25.0]. WOMAC scores demonstrated a further decrease, signifying ongoing functional improvements. DN4 scores continued to indicate reductions, suggesting sustained relief from neuropathic pain, while EQ-5D indices reflected continued improvement in quality of life.

At the 9-month follow-up, the median PID at rest was −40.0 [IQR −60.0, −2.5], and during movement, it was −40.0 [IQR −80.0, 0], indicating sustained pain relief. The analysis of repeated measures over different time points revealed statistically significant changes in VAS at rest (Friedman chi-squared = 131.96, df = 4, $p < 0.05$), VAS during

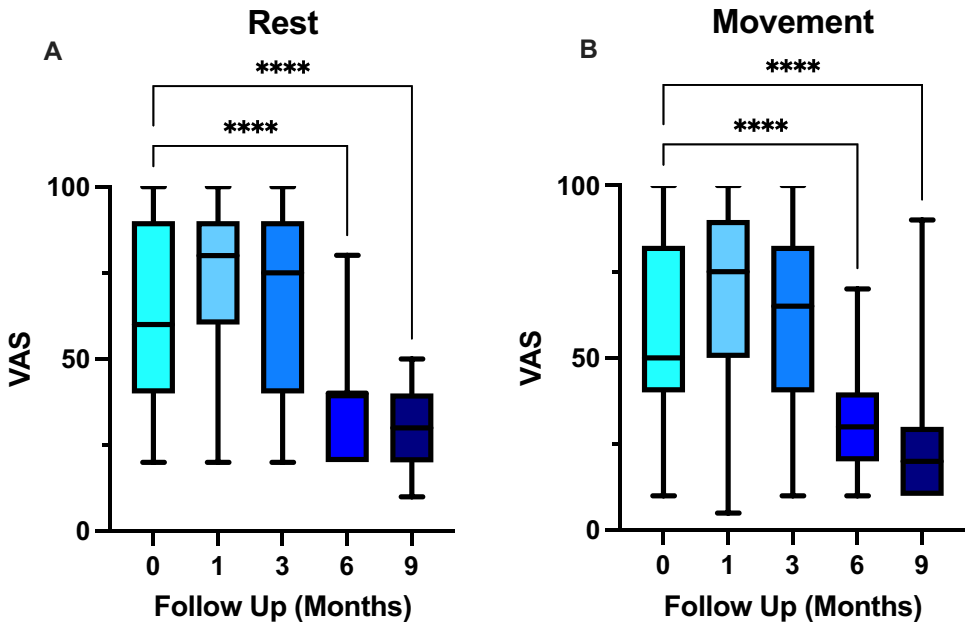

Figure 4 Changes in VAS (Visual Analog Scale) Scores at Rest and During Movement. This figure shows the progression of VAS scores at rest (**A**) and during movement (**B**) across the 9-month follow-up period. At baseline (0 months), the median VAS scores were significantly higher compared to the follow-up periods. A substantial reduction in pain intensity was observed at 1, 3, 6, and 9 months, with the greatest improvements seen after the 1-month follow-up. The reduction in VAS scores at both rest and during movement was statistically significant, with p-values showing **** ($p < 0.0001$) at all time points compared to baseline. This indicates a continuous and significant improvement in pain relief following GNRFA. Number of participants: 50. Statistical significance: **** $p < 0.0001$ for all follow-up points.

movement (Friedman chi-squared = 119.86, df = 4, $p < 0.05$), and WOMAC scores (Friedman chi-squared = 93.122, df = 4, $p < 0.05$). Significant improvements were also observed in DN4 scores (Friedman chi-squared = 55.78, df = 4, $p < 0.05$) and the EQ-5D index (Friedman chi-squared = 44.25, df = 4, $p < 0.05$), indicating ongoing reductions in neuropathic pain and improvements in quality of life. The trends in VAS, WOMAC, DN4, EQ-5D and PID scores over the 9-month follow-ups are visually represented in Figures 4–8.

Discussion

Our results suggest that GNRFA using a V-shaped active tip needle may be an effective treatment for managing chronic knee pain, resulting in significant improvements in VAS scores at rest and during movement, as well as in WOMAC scores up to 9 months post-procedure (Figures 4 and 5). These findings align with previous research indicating the efficacy of GNRFA in reducing knee pain and enhancing functional outcomes for patients with osteoarthritis.[23–26]

The use of a V-shaped active tip needle, a method not extensively explored in earlier studies, likely contributes to the sustained pain relief observed. This innovative approach may be beneficial due to the larger lesion size it creates, which could more effectively cover the anatomical variability of the genicular nerves.[11,12,27] Mechanistically, the V-shaped needle may generate a broader and more uniform lesion footprint; anatomical investigations suggest that this expanded ablative field increases the likelihood of capturing small and variably positioned genicular nerve branches, thereby enhancing analgesic durability.[11,12] The increased precision provided by the V-shaped needle may explain the differences observed between our findings and those of other studies, particularly in addressing the challenges of achieving adequate nerve ablation given the small size and variable anatomy of the genicular nerves.[11,12,27]

Our findings also demonstrate a significant increase in the percentage of patients reporting a ≥ 50% reduction in VAS scores at 6 and 9 months (Figure 4), indicating a trend of progressive symptom improvement.

Although the results are inherently predictable in the absence of a control group, they remain clinically meaningful, as validated by improvements across multiple outcome measures (VAS, WOMAC, DN4, and EQ-5D). Patient comorbidities, prior treatments, and any standard rehabilitation protocols, (Table 1) may have influenced these clinical outcomes, highlighting the multifactorial nature of chronic knee pain and the need for careful patient selection.

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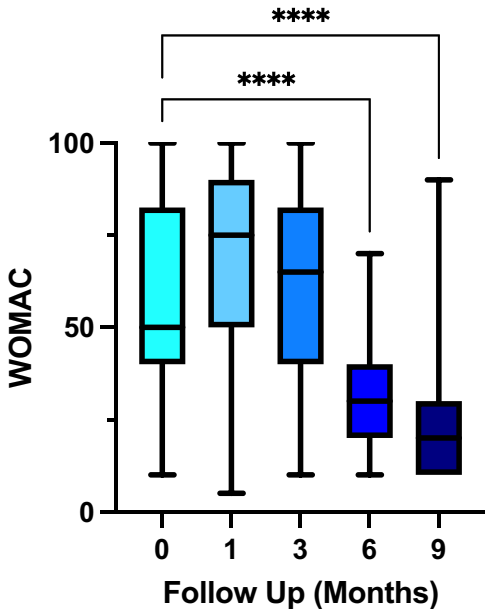

Figure 5 Changes in WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) Scores. The WOMAC scores, reflecting pain, stiffness, and physical function, significantly decreased over the 9-month follow-up period. At baseline, higher scores indicated a greater impact of knee pain on daily life, which progressively decreased at 1-, 3-, 6-, and 9-months post-procedure. This figure demonstrates that the reduction in WOMAC scores were statistically significant, with **** ($p < 0.0001$) at all time points compared to baseline, illustrating improved knee function and reduced discomfort in patients following GNRFA. Number of participants: 50. Statistical significance: **** $p < 0.0001$ for all follow-up points.

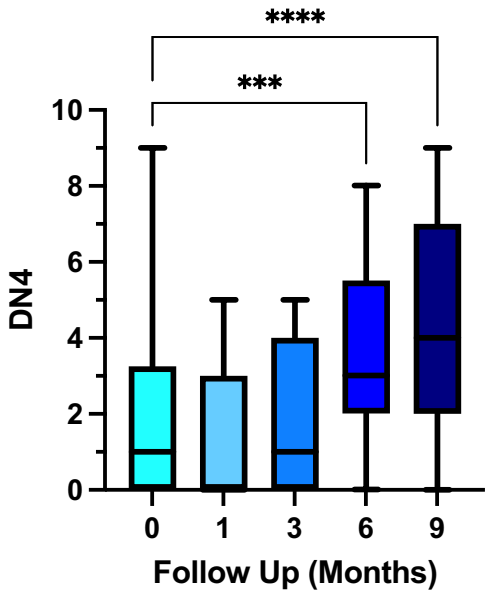

Figure 6 Changes in DN4 (Douleur Neuropathique 4) Scores. This figure tracks the DN4 score, a measure of neuropathic pain, over the 9-month follow-up period. A marked reduction in neuropathic pain symptoms was seen from baseline to 1, 3, 6, and 9 months. The most significant improvements occurred by the 3-month follow-up, and these reductions persisted through to 9 months. The statistical significance of the reductions in DN4 scores was *** ($p < 0.001$) at 1 month and **** ($p < 0.0001$) at subsequent follow-ups. Number of participants: 50. Statistical significance: *** $p < 0.001$ at 1 month, **** $p < 0.0001$ at 3, 6, and 9 months.

Limitations

However, our study is not without limitations. Most notably, the lack of a control group using traditional RFA techniques limits our ability to directly compare the efficacy of the V-shaped needle to more conventional methods. Additionally, the relatively small sample size of 50 participants may limit the generalizability of these findings, as a larger cohort could introduce more

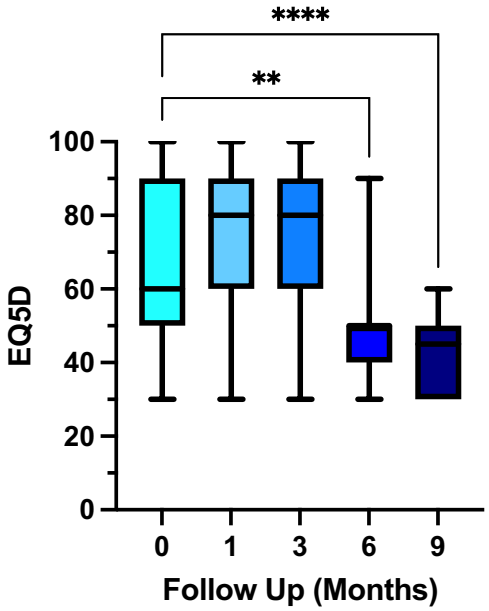

Figure 7 Changes in EQ-5D (EuroQol-5 Dimension) Scores. The EQ-5D scores represent the patients' quality of life related to their health. Over the 9-month follow-up, there was a significant improvement in health-related quality of life, with a substantial increase in EQ-5D scores after the procedure. This improvement was particularly noticeable at 1 and 3 months, and the positive trend continued at 6 and 9 months. The statistical significance of these improvements was ** ($p < 0.01$) at 1 month and **** ($p < 0.0001$) at later follow-ups, indicating robust improvements in patients' quality of life after the GNRFA procedure. Number of participants: 50. Statistical significance: ** $p < 0.01$ at 1 month, **** $p < 0.0001$ at 3, 6, and 9 months.

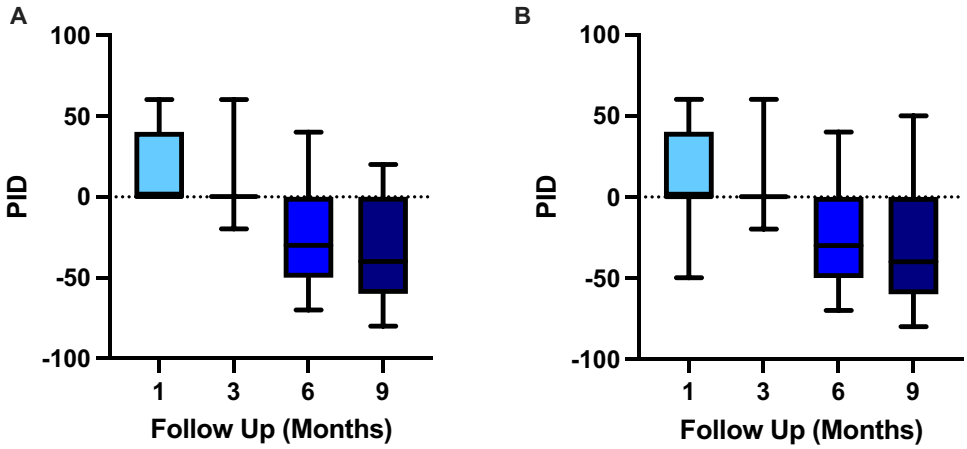

Figure 8 Changes in Pain Intensity Difference (PID) at Rest and During Movement. This figure shows the progression of PID at rest (**A**) and during movement (**B**) over the 9-month follow-up period. At baseline (0 months), the median PID values were significantly higher compared to the follow-up periods. A substantial reduction in pain intensity was observed at 6 and 9 months, with the greatest improvements seen in the initial months. The reduction in PID at both rest and during movement was statistically significant, with p-values showing ($p < 0.0001$) at all time points compared to baseline, indicating a continuous and significant improvement in pain relief. Number of participants: 50. Statistical significance: $p < 0.0001$ for all follow-up points.

variability and strengthen statistical power.[25–34] Moreover, the effectiveness of the diagnostic block, essential for selecting suitable candidates for RFA, depends on a variety of technical and anatomical, and potentially psychological factors, which might lead to false-positive outcomes that could distort the perceived effectiveness of RFA over time.[11,12] Another limitation is that we did not control for other interventions, such as physical therapy, psychological support, or educational programs that participants may have undergone during the study period. These could have influenced the outcomes and potentially confounded the results. While comorbidities and concurrent therapies were noted in Table 1, a more detailed prospective design would better isolate the contribution of the V-shaped needle to clinical improvements. Moving forward, larger, controlled and preferably randomized trials comparing of the V-shaped cannula with conventional RFA needles are warranted.

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Such studies would confirm whether the broader lesion footprint indeed provides significant advantages, clarify the long-term duration of its analgesic effects, and help refine patient selection criteria for optimal outcomes.

Conclusion

GNRFA using a V-shaped active tip needle appears to be a feasible and potentially effective treatment for chronic knee pain, offering meaningful reductions in pain intensity and improvements in function. Notably, the V-shaped cannula design unlike standard single-tip needles has been studied infrequently, and our results suggest that it may provide clinically significant pain relief well beyond the immediate post-procedure period. However, these findings must be interpreted with caution due to the retrospective design, lack of a control group, and relatively small sample size. Larger, prospective randomized trials are needed to compare the V-shaped cannula with conventional RFA techniques, thereby validating its efficacy, identifying optimal patient selection criteria, and clarifying the duration of its analgesic benefits.

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Disclosure

Dr Giuliano Lo Bianco reports consulting for Stryker and Abbott, outside the submitted work. Dr Sean Li reports grants for consulting from Abbott, Avanos, Averitas Pharma, Biotronik, Boston Scientific, Medtronic, Nalu Medical, NeuroOne, Nevro, PainTeq, Presidio, Saluda, SPR Therapeutics, and Vertos, outside the submitted work. Dr. Schatman is the senior medical advisor for Apurano Pharma, outside the submitted work. Dr. Alaa Abd-Elsayed reports consulting for Avanos, outside the submitted work. The authors report no other conflicts of interest in this work.

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