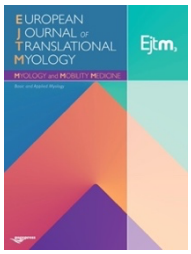
European Journal of Translational Myology



pISSN: 2037-7452 eISSN: 2037-7460

https://www.pagepressjournals.org/index.php/bam/index

Eur J Transl Myol 2026 [Online ahead of print]

To cite this Article:

Meccariello L, Grubor P, Bosco F, et al. **Crack Dol® *vs.* cryotherapy in postoperative pain treatment after patellar fracture fixation.** *Eur J Transl Myol* doi: 10.4081/ejtm.2026.15868

Submitted: 24 June 2026

Accepted: 14 August 2026

Early access: 11 September 2026.

Crack Dol® *vs.* cryotherapy in postoperative pain treatment after patellar fracture fixation

Luigi Meccariello,[1] Predrag Grubor,[2] Francesco Bosco,[3,4] Claudio Domenico Cobisi,[3,4] Lara Cristiano,[5,6] Giuseppina Casolaro,[7] Jacopo Conteduca,[8] Giuseppe Rollo,[8] Dimitra Melissaridou,[9] Michele Mercurio,[10] Lawrence Camarda,[3] Fernando De Maio,[11] Giuseppe Rovere[11,12]

[1]Department of Orthopedics and Traumatology, AORN San Pio Hospital, Benevento, Italy; [2]CEO, School of Medicine and Surgery, University of Doboj, Bosnia and Herzegovina; [3]Department of Precision Medicine in Medical, Surgical and Critical Care (Me.Pre.C.C.), University of Palermo, Palermo, Italy; [4]Department of Orthopaedics and Traumatology, G.F. Ingrassia Hospital Unit, ASP 6, Palermo, Italy; [5]Diagnostic Imaging Unit, Studio Radiologico S. Domenico, A. Cristiano Co. S.r.l., Lamezia Terme, Italy; [6]Department of Radiology, Paideia International Hospital, Rome, Italy; [7]Financial and Management Department, Azienda Sanitaria Locale (ASL) Benevento, Italy; [8]Department of Orthopaedic and Traumatology, Vito Fazzi Hospital, Lecce, Italy; [9]First department of orthopaedics,National and Kapodistrian University of Athens, Attikon University General Hospital, Greece; [10]Department of Orthopedic and Trauma Surgery, "Magna Graecia" University, "Mater Domini" University Hospital, Catanzaro, Italy; [11]Department of Clinical Sciences and Translational Medicine, Section of Orthopaedic and Traumatology, University of Rome Tor Vergata, Roma, Italy; [12]Department of Surgical Sciences, Policlinico Tor Vergata University Hospital, Rome, taly

Abstract

Postoperative pain following patellar fracture surgery may delay rehabilitation and impair functional recovery. While cryotherapy is commonly used, concerns exist regarding its effects on local blood flow. Alternative topical cooling formulations may offer analgesic benefits without prolonged vasoconstriction. In this study, we compared postoperative pain, functional recovery, quality of life, and rescue analgesic consumption among patients receiving traditional ice therapy, ice spray, or Crack Dol® Foam Spray following surgical fixation of patellar fractures. Ninety patients undergoing surgical fixation for patellar fracture were prospectively enrolled in this non-randomized comparative cohort study and allocated into three groups (n = 30 each) based on patient preference and clinical contraindications: ice therapy, ice spray, and Crack Dol® Foam Spray. Pain intensity (Visual Analogue Scale, VAS), health-related quality of life (SF-12), knee function (KOOS), and rescue analgesic consumption were assessed during postoperative follow-up. Patients

in the Crack Dol® Foam Spray group had significantly lower VAS scores at 7, 30, and 90 days compared with the ice and ice spray groups ($p = 0.012$, $p = 0.006$, and $p = 0.004$, respectively). At 90 days, SF-12 Physical and Mental Component Scores were significantly higher in the Crack Dol® group ($p = 0.009$ and $p = 0.014$, respectively). KOOS total scores were also significantly higher at 30 and 90 days ($p = 0.018$ and $p = 0.007$, respectively). Rescue analgesic consumption was significantly lower in the Crack Dol® group ($p = 0.011$). In this prospective, non-randomized comparative cohort study, the use of Crack Dol® Foam Spray was associated with lower postoperative pain scores, lower rescue analgesic consumption, and better patient-reported functional and quality-of-life outcomes compared with traditional ice therapy and ice spray. Given the non-randomized treatment allocation, these findings should be interpreted as associations rather than evidence of a causal treatment effect. Further randomized controlled trials are needed to confirm these preliminary findings.

Key words: ice; patella; fracture; outcomes; pain; management.

Patellar fractures are complex injuries involving the knee extensor mechanism and account for approximately 1% of all skeletal fractures.[1] When displacement or articular incongruity is present, surgical fixation is generally required to restore joint anatomy, ensure extensor mechanism continuity, and allow early mobilization.[2] Despite advances in surgical techniques and postoperative rehabilitation protocols, postoperative pain remains a significant challenge during the early recovery phase and may negatively affect functional outcomes.[3]

Adequate postoperative pain management is essential to facilitate early knee motion, prevent joint stiffness, and improve patient compliance with rehabilitation programs.[4] Among non-pharmacological strategies, cryotherapy is widely adopted in orthopedic postoperative care because of its analgesic, anti-inflammatory, and anti-edematous properties.[5] However, recent evidence suggests that prolonged or repeated application of ice may induce sustained vasoconstriction, potentially reducing peri-incisional blood flow and impairing local tissue oxygenation, which could negatively influence wound healing.[6,7]

In recent years, topical cooling sprays and foams have been proposed as alternatives to traditional ice therapy. These formulations provide a rapid and transient cooling effect, potentially minimizing prolonged tissue ischemia while maintaining analgesic benefits.[8] Crack Dol® Foam Spray is a topical cooling formulation that combines a short-lasting cryogenic effect with functional and botanical components, including menthol, arnica, harpagophytum, escin, and dimethyl sulfone. These ingredients are commonly used for their analgesic, anti-inflammatory, and anti-edematous properties and may support local microcirculation without sustained vasoconstriction.[9,10]

To date, limited clinical evidence is available comparing traditional cryotherapy modalities with topical cooling agents in the postoperative management of patellar fracture surgery. In particular, no prospective studies have directly compared ice therapy, ice spray, and Crack Dol® Foam Spray in this specific clinical setting. The purpose of the present study was therefore to prospectively evaluate and compare these three postoperative pain management strategies in patients undergoing surgical fixation of patellar fractures, focusing on pain control, functional recovery, quality of life, and postoperative analgesic consumption.

Materials and Methods

Study design

This was a prospective, non-randomized, controlled comparative cohort study conducted at a single tertiary orthopedic trauma center between January 2021 and December 2024. The study aimed to compare short-term postoperative outcomes associated with three different cooling-based pain management strategies following surgical fixation of acute patellar fractures. No random allocation sequence was used, and the study was not designed as a randomized controlled trial.[11,12]

Study population

Ninety consecutive adult patients undergoing surgical fixation for acute patellar fractures were screened for eligibility. All eligible patients who met the inclusion criteria and provided written informed consent were enrolled and completed the study protocol. The study population was considered representative of typical clinical practice for operatively treated patellar fractures.[13]

Inclusion criteria

Patients were included if they met all of the following criteria: i) age between 18 and 75 years; ii) moderate to severe postoperative pain (Visual Analog Scale [VAS] ≥ 5); iii) intact periarticular skin at the site of topical treatment application; iv) ability to understand the study protocol and provide written informed consent.

Eligibility criteria were defined in accordance with previous clinical studies on postoperative pain management and patellar fracture outcomes.[14,15]

Exclusion criteria

Patients were excluded in the presence of any of the following conditions: i) previous surgery on the affected knee; ii) open fractures or active local or systemic infection; iii) pathological fractures or history of oncological disease; iv) chronic inflammatory, autoimmune, or rheumatologic disorders; v) chronic use of opioids, analgesics, or systemic corticosteroids; vi) known hypersensitivity to topical cooling agents or excipients; vii) severe hepatic or renal impairment; viii) pregnancy or breastfeeding; ix) inability or refusal to provide informed consent

These criteria were selected to minimize confounding factors influencing pain perception, wound healing, and functional recovery.[16]

Group allocation

The final study population consisted of 90 patients divided into three treatment groups (n = 30 per group). Treatment allocation was non-randomized and was based on patient preference together with the presence of relative or absolute contraindications to the individual cooling modalities (Figure 1). No random allocation sequence or allocation concealment procedure was used. Because treatment preference may be associated with patient expectations, adherence, pain perception, and patient-reported outcomes, the possibility of selection bias and residual confounding related to the allocation process cannot be excluded.[17]

Surgical technique and postoperative care

All patients underwent surgical fixation of the patellar fracture according to the fracture pattern and the treating surgeon's clinical assessment. Surgical management followed the institutional principles routinely adopted for patellar fracture fixation and was performed by experienced orthopedic surgeons. Postoperatively, all patients followed an identical rehabilitation protocol including early knee mobilization, progressive range-of-motion exercises, and graduated weight-bearing according to fracture stability. Standardization of postoperative rehabilitation was implemented to reduce treatment-related variability among the study groups.[18,19]

Interventions

All cryotherapy interventions were initiated on the first postoperative day and continued according to the assigned protocol:

Group A: ice therapy

Application of traditional ice packs for 20 minutes, three times daily. Ice packs were applied to the periarticular area, avoiding direct contact with the surgical incision, in accordance with established postoperative cryotherapy protocols.[20]

Group B: ice spray

Application of a commercially available cryotherapy spray to the periarticular knee region twice daily, avoiding the surgical wound. This modality provides rapid skin cooling without prolonged exposure.[21]

Group C: Crack Dol® Foam Spray

Application of Crack Dol® Foam Spray (150 mL) to intact periarticular skin surrounding the knee. The product was applied one to three times daily according to clinical need and patient-reported pain, following manufacturer instructions.

The formulation produces a rapid and transient cooling effect combined with functional and botanical ingredients commonly used in musculoskeletal pain management. The product was not applied directly on the surgical incision, in line with safety recommendations for topical agents in the postoperative setting.[22,23] The frequency and duration of application differed among the three groups because each modality was administered according to its routine clinical use and recommended application protocol rather than according to an experimentally standardized equivalent cooling exposure. Therefore, the interventions were not designed to provide equivalent treatment doses or cooling durations. Individual application-level adherence and the exact number of applications actually performed per day were not prospectively recorded. Consequently, differences in treatment frequency, duration, adherence, and patient-driven use may have contributed to the observed between-group differences and should be considered when interpreting the finding.

Outcome measures

Clinical assessments were performed at 7, 30, and 90 days postoperatively. The following validated outcome measures were used: i) pain intensity assessed using the Visual Analog Scale (VAS, 0–10), a reliable and widely used tool for postoperative pain evaluation;[24] postoperative pain intensity assessed using the VAS represented the primary outcome of the study and was evaluated at the predefined postoperative time points of 7, 30, and 90 days; no single time point was prespecified as the primary endpoint; rather, the primary outcome was assessed across the three predefined postoperative follow-up evaluations; SF-12, KOOS, and rescue analgesic consumption were considered secondary outcomes; ii) health-related quality of life assessed using the Short Form-12 (SF-12), including Physical Component Score (PCS) and Mental Component Score (MCS), validated for orthopedic trauma populations;[25] iii) knee-specific functional outcomes assessed using the Knee Injury and Osteoarthritis Outcome Score (KOOS), including Pain, Symptoms, Activities of Daily Living, Sport and Recreation, and Quality of Life subscales;[26] iv) rescue analgesic consumption, recorded as the mean number of additional analgesic doses per week.

Ethical considerations

No formal Ethics Committee review was obtained for this study. The postoperative cooling modalities evaluated in the study were already used as part of routine clinical care and were not introduced specifically for research purposes. Treatment selection was based on patient preference and clinical contraindications and did not involve experimental procedures or additional diagnostic or therapeutic interventions beyond routine clinical practice. All participants provided written informed consent before enrollment and consented to the use of their clinical data for scientific purposes. Patient data were handled in anonymized form. The study was conducted in accordance with the principles of the Declaration of Helsinki and applicable institutional requirements for research involving human participants.[27]

Statistical analysis

Data were collected and entered into an electronic database for statistical analysis. Descriptive statistics were used to summarize demographic and clinical characteristics. Continuous variables were expressed as mean ± standard deviation (range), whereas categorical variables were reported as frequencies and percentages.

Between-group comparisons of continuous variables were performed using one-way Analysis Of Variance (ANOVA), followed by Tukey's post-hoc test when appropriate. The primary analytical objective was to compare the three treatment groups at each predefined postoperative assessment rather than to model within-patient longitudinal trajectories. Accordingly, between-group comparisons were performed separately at each time point. No repeated-measures ANOVA or mixed-effects model was performed, and group-by-time interactions were not formally evaluated. Therefore, changes observed across follow-up assessments should be interpreted descriptively and exploratorily rather than as evidence of differential longitudinal treatment trajectories.

Categorical variables were analyzed using the Chi-square test or Fisher's exact test, as appropriate. Correlations between pain scores, functional outcomes, health-related quality-of-life measures, and rescue analgesic consumption were assessed using Pearson's correlation coefficient. Statistical significance was set at $p < 0.05$.

No formal a priori sample-size calculation was performed, as the sample size was determined by the number of eligible patients prospectively enrolled during the predefined study period. Effect sizes and confidence intervals were not systematically incorporated into the original analytical

framework. Consequently, the statistical findings should be regarded as exploratory and hypothesis-generating, and their interpretation should primarily consider the magnitude and consistency of the observed between-group differences rather than p-values alone. Future confirmatory studies should incorporate an a priori sample-size calculation, predefined clinically meaningful effect estimates with confidence intervals, and appropriate longitudinal statistical modeling.

Statistical analyses were performed using MedCalc Statistical Software (version 14.8.1; MedCalc Software bvba, Ostend, Belgium), in accordance with recommended statistical standards for clinical research.[28-34]

Results

Baseline characteristics

Baseline demographic and clinical characteristics are summarized in Table 1. No statistically significant differences were observed among the three groups (Ice, Ice Spray, and Crack Dol® Foam Spray) with respect to the baseline variables assessed, including age, sex distribution, body mass index (BMI), side of injury, and time from trauma to surgery (all $p > 0.05$).

Mean age was 52.4 ± 11.2 years in the Ice group, 50.9 ± 10.8 years in the Ice Spray group, and 51.7 ± 12.1 years in the Crack Dol® group ($p = 0.88$). BMI and sex distribution also showed no statistically significant between-group differences (Table 1).

The baseline characteristics reported in the present study were limited to the variables prospectively and consistently available for all participants. Other potentially relevant fracture-, patient-, and treatment-related variables were not included in the comparative analysis and are therefore considered among the potential sources of residual confounding.

Primary outcome: pain intensity

Postoperative pain intensity assessed using the Visual Analog Scale (VAS), which represented the primary outcome of the study, is reported in Table 2. VAS scores were assessed at 7, 30, and 90 days postoperatively (Figure 2).

At 7 days, mean VAS scores were 6.8 ± 1.1 in the Ice group, 6.2 ± 1.0 in the Ice Spray group, and 4.9 ± 1.0 in the Crack Dol® group. The between-group difference was statistically significant ($p = 0.012$).

At 30 days, mean VAS scores decreased in all three groups and were 4.9 ± 1.0 in the Ice group, 4.5 ± 0.9 in the Ice Spray group, and 3.1 ± 0.9 in the Crack Dol® group, with a statistically significant between-group difference ($p = 0.006$).

At 90 days, mean VAS scores were 3.2 ± 0.8 in the Ice group, 3.0 ± 0.7 in the Ice Spray group, and 1.9 ± 0.7 in the Crack Dol® group, with a statistically significant between-group difference ($p = 0.004$) (Table 2).

Thus, lower mean VAS scores were observed in the Crack Dol® group at each of the three predefined postoperative assessments. Given the non-randomized treatment allocation, these findings represent between-group associations and should not be interpreted as evidence of a causal treatment effect.

Secondary outcome: quality of life

Health-related quality of life assessed using the SF-12 questionnaire represented a secondary outcome and was evaluated at 90 days postoperatively. Results are summarized in Table 3 and Figure 3.

The mean Physical Component Score (PCS) was 41.8 ± 5.6 in the Ice group, 44.1 ± 5.2 in the Ice Spray group, and 48.9 ± 5.1 in the Crack Dol® group. A statistically significant between-group difference was observed ($p = 0.009$).

The mean Mental Component Score (MCS) was 45.3 ± 6.1 in the Ice group, 46.7 ± 5.9 in the Ice Spray group, and 50.6 ± 5.4 in the Crack Dol® group, with a statistically significant between-group difference ($p = 0.014$) (Table 3).

Accordingly, higher mean PCS and MCS values were observed in the Crack Dol® group at the 90-day assessment. These findings should be interpreted in the context of the non-randomized study design and the subjective, patient-reported nature of the SF-12.

Secondary outcome: functional recovery

Functional recovery assessed using the Knee Injury and Osteoarthritis Outcome Score (KOOS) represented a secondary outcome and was evaluated at 30 and 90 days postoperatively. Results are reported in Table 4 and Figure 4.

At 30 days, mean KOOS total scores were 58.2 ± 8.9 in the Ice group, 61.4 ± 8.1 in the Ice Spray group, and 67.9 ± 7.8 in the Crack Dol® group. The between-group difference was statistically significant ($p = 0.018$).

At 90 days, mean KOOS total scores were 67.6 ± 7.8 in the Ice group, 69.9 ± 7.4 in the Ice Spray group, and 76.8 ± 7.2 in the Crack Dol® group, with a statistically significant between-group difference ($p = 0.007$).

The KOOS subdomains showed a similar overall pattern, with higher mean values in the Crack Dol® group, particularly for the Pain and Activities of Daily Living (ADL) domains (Table 4). These results represent observed between-group differences and should not be interpreted as demonstrating a causal effect of the cooling modality on functional recovery.

Secondary outcome: rescue analgesic consumption

Weekly rescue analgesic consumption was evaluated as a secondary outcome and is summarized in Table 5 and Figure 5.

The mean number of additional analgesic doses per week was 5.6 ± 1.4 (range, 3–8) in the Ice group, 4.9 ± 1.3 (range, 2–7) in the Ice Spray group, and 3.2 ± 1.2 (range, 1–6) in the Crack Dol® group. The between-group difference was statistically significant ($p = 0.011$) (Table 5).

Thus, lower rescue analgesic consumption was observed in the Crack Dol® group. Given the non-randomized design and the potential influence of treatment expectations, adherence, and differences in application frequency, this association should not be interpreted as evidence that the intervention itself caused the reduction in rescue analgesic use.

Discussion

The present prospective, non-randomized comparative cohort study found that the use of Crack Dol® Foam Spray following surgical fixation of patellar fractures was associated with lower postoperative pain scores compared with traditional ice therapy and ice spray. Lower rescue analgesic consumption and higher patient-reported functional and health-related quality-of-life scores were also observed in the Crack Dol® group. However, given the non-randomized treatment allocation and the potential influence of selection bias, differences in treatment exposure, adherence, and patient expectations, these findings should be interpreted as associations and not as evidence of a causal treatment effect.

Cryotherapy remains one of the most widely adopted non-pharmacological strategies in orthopedic postoperative care because of its analgesic, anti-inflammatory, and anti-edematous effects. Previous systematic reviews and meta-analyses have reported reductions in postoperative pain with cryotherapy across different orthopedic procedures, although the optimal modality, duration, frequency, and intensity of cooling remain controversial.[1-5] Within this context, the between-group differences observed in the present study suggest that different postoperative cooling modalities may be associated with different short-term clinical outcomes following patellar fracture fixation. However, the present study was not designed to establish the comparative efficacy of the three modalities under equivalent treatment-exposure conditions.

Patients treated with Crack Dol® Foam Spray reported lower VAS pain scores at the postoperative follow-up assessments compared with patients receiving traditional ice therapy or ice spray. This finding was accompanied by lower rescue analgesic consumption. Reduced reliance on systemic analgesics may be clinically relevant in orthopedic postoperative care because of the potential adverse effects associated with prolonged or inappropriate use of nonsteroidal anti-inflammatory drugs and opioids.[16] Previous studies of topical cooling formulations in musculoskeletal conditions have also described analgesic effects without the prolonged tissue cooling associated with conventional ice application.[10] Nevertheless, the present findings should not be interpreted as demonstrating an intrinsic analgesic superiority of the topical foam, because the interventions differed in frequency, duration, and mode of application.

Traditional ice therapy produces analgesia primarily through sustained local cooling, with consequent vasoconstriction, decreased nerve conduction velocity, and modulation of local inflammatory activity. Prolonged cooling may also reduce local blood flow and tissue oxygenation, raising theoretical concerns regarding tissue recovery when excessive cooling is applied near a surgical site.[20,21] Topical cooling formulations, in contrast, produce a more rapid and transient

cooling sensation. Differences in cooling dynamics may have contributed to the between-group differences observed in the present study; however, tissue temperature, local perfusion, and microcirculatory changes were not directly measured. Therefore, no mechanistic or causal conclusion regarding differences in local cooling effects can be drawn from the present data.

Beyond its cooling effect, Crack Dol® Foam Spray contains ingredients including menthol, arnica, escin, harpagophytum, and dimethyl sulfone. Menthol has been associated with analgesic effects through activation of transient receptor potential melastatin-8 (TRPM8) channels and modulation of nociceptive pathways,[6,7] while arnica-based formulations have been investigated for potential anti-inflammatory and analgesic effects in postoperative and musculoskeletal settings.[8,9] However, the present study was not designed to evaluate the independent contribution of individual components of the formulation. Consequently, the observed differences in pain scores cannot be attributed to any specific ingredient or mechanism, and dedicated mechanistic studies would be required to investigate these potential effects.

Lower pain scores in the Crack Dol® group were accompanied by higher KOOS scores at both 30 and 90 days postoperatively. Pain control is clinically relevant during rehabilitation after patellar fracture fixation because excessive pain may interfere with knee mobilization, participation in rehabilitation, and recovery of activities of daily living.[18,19] Nevertheless, the association between lower pain scores and higher functional scores observed in the present study does not establish that the cooling intervention itself caused improved functional recovery. Rehabilitation adherence was not quantified in sufficient detail to determine whether differences in participation or other unmeasured factors contributed to the functional outcomes.

Similarly, SF-12 Physical and Mental Component Scores at 90 days were higher in the Crack Dol® group. VAS, KOOS, and SF-12 are established patient-reported outcome measures and provide complementary information regarding pain, knee function, and health-related quality of life.[14,24-26] However, because these outcomes are subjective, they are particularly susceptible to expectation and reporting bias. Blinding of participants and treating clinicians was not feasible because the three interventions differed visibly and sensorially. In particular, the sensory characteristics and commercial presentation of a topical foam formulation may have influenced treatment expectations and patient perceptions. Therefore, expectation and performance bias cannot be excluded when interpreting differences in VAS, KOOS, SF-12, and rescue analgesic consumption.

Several additional limitations should be considered. First, treatment allocation was non-randomized and was based on patient preference and clinical contraindications to the individual cooling

modalities. No random allocation sequence or allocation concealment was used. Consequently, selection bias and residual confounding cannot be excluded, despite the absence of statistically significant differences in the baseline characteristics assessed. Patient preference may have been associated with treatment expectations, adherence, pain perception, and satisfaction, potentially influencing patient-reported outcomes. Moreover, not all potentially relevant fracture-, patient-, and treatment-related variables were available in a sufficiently standardized manner for inclusion in the comparative analysis. Unmeasured differences in fracture characteristics, comorbidities, perioperative factors, or other clinical variables may therefore have contributed to the observed outcomes.

Second, the three interventions were not equivalent in treatment exposure. Traditional ice therapy, ice spray, and Crack Dol® Foam Spray differed in application frequency and duration according to their respective routine clinical protocols. Application-level adherence and the exact number of daily applications actually performed by individual patients were not prospectively quantified. Consequently, differences in treatment frequency, duration, adherence, patient-driven use, and treatment expectations may have contributed to the observed between-group differences. The results therefore cannot be attributed exclusively to the intrinsic characteristics of any individual cooling modality.

Third, the statistical analysis was designed primarily to compare the three treatment groups at predefined clinically relevant postoperative assessment points rather than to model individual longitudinal trajectories. Accordingly, the study did not formally evaluate group-by-time interactions using repeated-measures or mixed-effects modeling. In addition, no formal a priori sample-size calculation was performed. These methodological considerations limit the strength of the statistical inference and further support interpreting the present results as preliminary and hypothesis-generating. Future confirmatory studies should incorporate an a priori sample-size calculation, predefined clinically meaningful effect estimates and confidence intervals, and longitudinal statistical models when appropriate.

Finally, a formal prespecified safety endpoint was not incorporated into the original study protocol. Therefore, the present study cannot provide a comprehensive comparative assessment of skin reactions, hypersensitivity, wound complications, surgical-site infection, delayed wound healing, or treatment discontinuation. Future prospective trials evaluating topical cooling modalities in proximity to surgical wounds should include standardized and systematic safety monitoring.

Despite these limitations, the study has several strengths. The prospective design, standardized surgical and rehabilitation pathways, and use of validated patient-reported outcome measures provide clinically relevant information regarding three cooling strategies used in postoperative orthopedic practice. Furthermore, the pragmatic nature of the treatment protocols reflects their routine clinical application. Nevertheless, these strengths should be considered together with the absence of randomization, lack of blinding, differences in treatment exposure, absence of detailed adherence data, and potential residual confounding. Accordingly, the present findings should be regarded as preliminary evidence supporting further investigation rather than as definitive evidence of comparative treatment efficacy.

Conclusions

In this prospective, non-randomized comparative cohort study, the use of Crack Dol® Foam Spray following surgical fixation of patellar fractures was associated with lower postoperative pain scores and rescue analgesic consumption, as well as higher patient-reported functional and health-related quality-of-life scores, compared with traditional ice therapy and ice spray. However, given the non-randomized treatment allocation and the potential for selection bias and residual confounding, these findings should be interpreted as associations rather than evidence of a causal treatment effect. Further adequately powered, randomized controlled trials with standardized treatment protocols and longer follow-up are needed to confirm these findings and to determine the comparative efficacy of topical cooling formulations in postoperative orthopedic care.

Corresponding Author

Giuseppe Rovere, Department of Clinical Science and Traslational Medicine, Section of Orthopaedics and Traumatology, University of Rome “Tor Vergata”, Viale Oxford 81, 00133 Rome (Italy)

E-mail: rovere292@hotmail.com

Luigi Meccariello
drlordmec@gmail.com

0000-0002-3669-189X

Predrag Grubor
predraggrubor@gmail.com
0000-0001-6826-1790

Francesco Bosco
Francesco.bosco03@unipa.it
0000-0001-8306-1869

Claudio Domenico Cobisi
claudiocob2@gmail.com

Lara Cristiano
laracristiano2811@gmail.com
0000-0001-7594-9446

Giuseppina Casolaro
giusycasolaro1@gmail.com

Jacopo Conteduca
conteduca85@msn.com
0000-0003-0798-2820
Giuseppe Rollo
rollogiuse@gmail.com
0000-0003-1920-1286

Dimitra Melissaridou
dimitramelissaridi@gmail.com
0000-0003-4403-1100

Michele Mercurio
mercuriomi@gmail.com
0000-0002-8742-5612

Lawrence Camarda
lawrence.camarda@unipa.it
0000-0003-0825-0533

Fernando De Maio
demaio@med.uniroma2.it
0000-0002-5201-6755

Contributions

Luigi Meccariello, Francesco Bosco, Claudio Domenico Cobisi conceptualization; Lara Cristiano, Giuseppina Casolaro, methodology, software, formal analysis, data curation; Jacopo Conteduca, Giuseppe Rollo, Dimitra Melissaridou validation, writing – original draft preparation; Michele Mercurio, Lawrence Camarda investigation; Fernando De Maio resources; Giuseppe Rovere, writing – review and editing; Luigi Meccariello, Predrag Grubor visualization; Francesco Bosco, Giuseppe Rovere, Claudio Domenico Cobisi supervision; project administration; all authors have read and agreed to the published version of the manuscript

Conflict of Interest

The authors declare that the study received financial support from Neilos Srl. The funder had no role in the study design, treatment allocation, data collection, data management, statistical analysis, interpretation of the results, preparation or revision of the manuscript, or the decision to submit the manuscript for publication. The authors declare no other conflicts of interest.

Funding

This study received financial support from Neilos Srl. The funder had no role in the study design, treatment allocation, data collection, data management, statistical analysis, interpretation of the

results, preparation or revision of the manuscript, or the decision to submit the manuscript for publication.

Ethics approval

Formal Ethics Committee review was not obtained because all cooling modalities evaluated in this study were already used as part of routine clinical care, treatment selection was based on patient preference and clinical contraindications, and no experimental procedures or additional diagnostic or therapeutic interventions were introduced for research purposes. The study was conducted in accordance with the Declaration of Helsinki and applicable institutional requirements. Patient data were analyzed in anonymized form.

Informed consent

Written informed consent to participate and to use anonymized clinical data for scientific purposes was obtained from all participants before enrollment.

Patient consent for publication

Written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

Availability of data and materials

The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to applicable privacy and institutional requirements.

References

1. Muaddi H, Lillie E, Silva S, et al. The effect of cryotherapy application on postoperative pain: a systematic review and meta-analysis. Ann Surg 2023;277:e257-65.

2. Karam KM, Moussa MK, Noailles T, et al. Postoperative cryotherapy in joints other than the knee: a systematic review of pain, edema, analgesic use, and blood loss in the shoulder, hand, hip, and ankle joints. Orthop J Sports Med 2025;13:23259671251320132.
3. Chareancholvanich K, Keesukpunt W, Pornrattanamaneewong C, et al. Comparison of three cryotherapy techniques for early post-TKA pain control and patient satisfaction: a randomized controlled trial. Arthroplasty 2025;7:5.
4. Yao Y, Xie W, Opoku M, et al. Cryotherapy and thermotherapy in the management of osteoarthritis and rheumatoid arthritis: A comprehensive review. Fundam Res 2024;5:2409-31.
5. Kunkle BF, Kothandaraman V, Goodloe JB, et al. Orthopaedic application of cryotherapy: mechanisms and clinical outcomes. JBJS Rev 2021;9:e20.00016.
6. Li Z, Zhang H, Wang Y, et al. The distinctive role of menthol in pain and analgesia: Mechanisms, practices, and advances. Front Mol Neurosci 2022 Oct 5;15:1006908.
7. Makibuchi T, Yamashiro K, Anazawa S, et al. Assessing the effects of the topical application of L-menthol on pain-related somatosensory-evoked potentials: a human study. Brain Sci 2023;13:918.
8. Toma C-C, Marrelli M, Puticiu M, et al. Effects of Arnica phytotherapeutic formulations on pain and inflammatory conditions: a systematic review. Plants 2024;13:3112.
9. Iannitti T, Morales-Medina JC, Bellavite P, et al. Effectiveness and safety of arnica montana in post-surgical setting, pain and inflammation. Am J Ther 2016;23:e184-97.
10. Ballester Herrera MA, Muñoz Vives JM, Marti A. Clinical evolution and safety of a cryotherapy - based spray for mild to moderate joint and muscle pain: a descriptive observational study. Int J Sports Phys Ther 2025;20:243-52.
11. Lazaro LE, Wellman DS, Pardee NC, et al. Effect of computerized tomography on classification and treatment planning for patellar fractures. J Orthop Trauma 2013;27:336–44.
12. Boström A, Ekelund A, Möller M. Epidemiology of patellar fractures in adults. Knee Surg Sports Traumatol Arthrosc 2018;26:3715–21.
13. Wild M, Eichler C, Thelen S, et al. Fixed-angle plate osteosynthesis of patella fractures. Injury 2016;47:1215–20.
14. Breivik H, Borchgrevink PC, Allen SM, et al. Assessment of pain. Br J Anaesth 2008;101:17–24.
15. Bijur PE, Silver W, Gallagher EJ. Reliability of the visual analog scale for measurement of acute pain. Acad Emerg Med 2001;8:1153–7.

16. McQuay HJ, Moore RA. An evidence-based resource for pain relief. Oxford University Press; 2018.
17. Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med 2000;342:1887–92.
18. van der Heijden RA, Gaskill T, van Erp JHJ, et al. Early mobilization after operative fixation of patella fractures. Arch Orthop Trauma Surg 2017;137:189–95.
19. Kasten P, Schewe B, Maurer F, Gösling T, Krettek C. Patella fractures: operative management and long-term results. Injury 2019;50:S71–7.
20. Raynor MC, Pietrobon R, Guller U, Higgins LD. Cryotherapy after ACL reconstruction. Am J Sports Med 2005;33:683–91.
21. Costello JT, Culligan K, Selfe J, Donnelly AE. Muscle, skin and core temperature after cryotherapy. J Athl Train 2012;47:632–9.
22. Derry S, Moore RA, Rabbie R. Topical NSAIDs for acute musculoskeletal pain. Cochrane Database Syst Rev 2015;6:CD007402.
23. Mason L, Moore RA, Edwards JE, et al. Topical analgesics for acute and chronic pain. BMJ 2004;328:995.
24. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain. Arthritis Care Res 2011;63:S240–252.
25. Ware J Jr, Kosinski M, Keller SD. A 12-item short-form health survey. Med Care 1996;34:220–33.
26. Roos EM, Toksvig-Larsen S. Knee Injury and Osteoarthritis Outcome Score (KOOS). Health Qual Life Outcomes 2003;1:64.
27. World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013;310:2191–4.
28. Altman DG. Practical statistics for medical research. Chapman & Hall/CRC; 2018
29. Rovere G, Bosco F, Cuttaia C, et al. Infection prevention in total knee arthroplasty: current concepts, controversies, and a clinical algorithm. Eur J Transl Myol 2026; doi:10.4081/ejtm.2026.15177.

30. Bosco F, Rovere G, Burgio C, et al. Accuracy and learning curve of imageless robotic-assisted total knee arthroplasty. J Orthop 2025;66:77-83.

31. De Marco D, Messina F, Meschini C, et al. Periprosthetic knee fractures in an elderly population: open reduction and internal fixation vs distal femur megaprostheses. Orthop Rev (Pavia) 2022;14:33772.

32. Rovere G, Bosco F, Miceli A, et al. Adoption of blockchain as a step forward in orthopedic practice. Eur J Transl Myol 2024;34:12197.

33. Pavan D, Morello F, Monachino F, et al. Similar biomechanical properties of four tripled tendon graft models for ACL reconstruction. Arch Orthop Trauma Surg 2022;142:1155-65.

34.Burgio C, Bosco F, Rovere G. et al. Early and delayed periprosthetic joint infection in robot-assisted total knee arthroplasty: a multicenter study. Eur J Orthop Surg Traumatol 2024;34:3155–62.

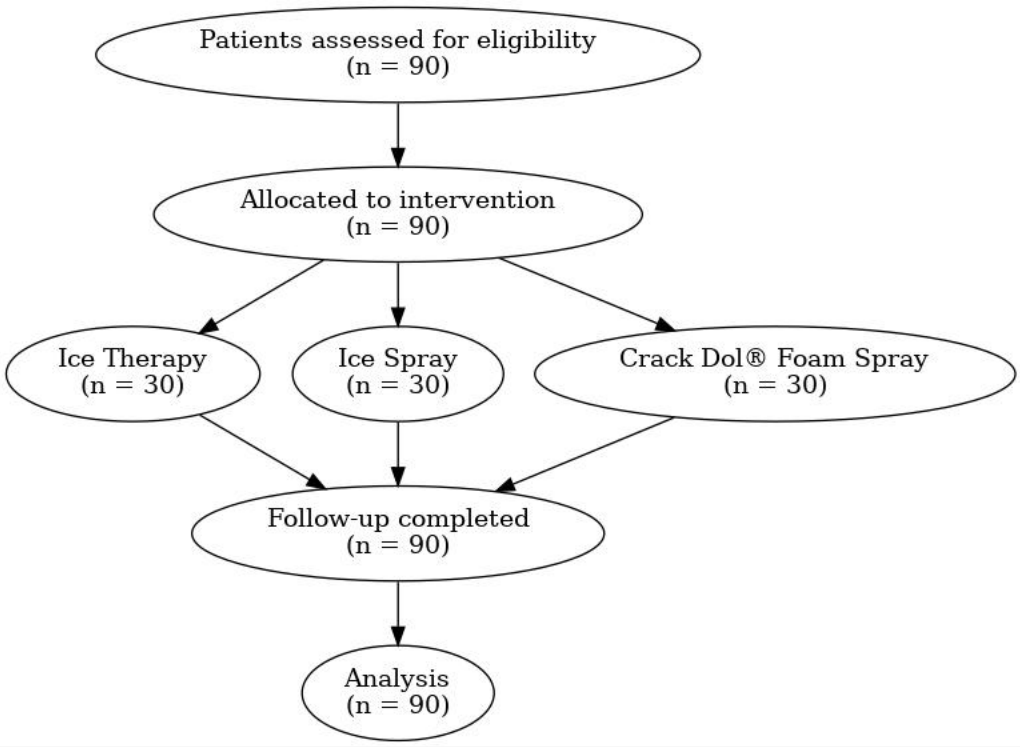


Figure 1. Patient flow diagram showing enrollment and assignment to the three postoperative cooling groups. Treatment assignment was non-randomized and was based on patient preference and clinical contraindications. Thirty patients were included in each treatment group (Ice, Ice Spray, and Crack Dol® Foam Spray), and all participants completed the scheduled follow-up assessments.

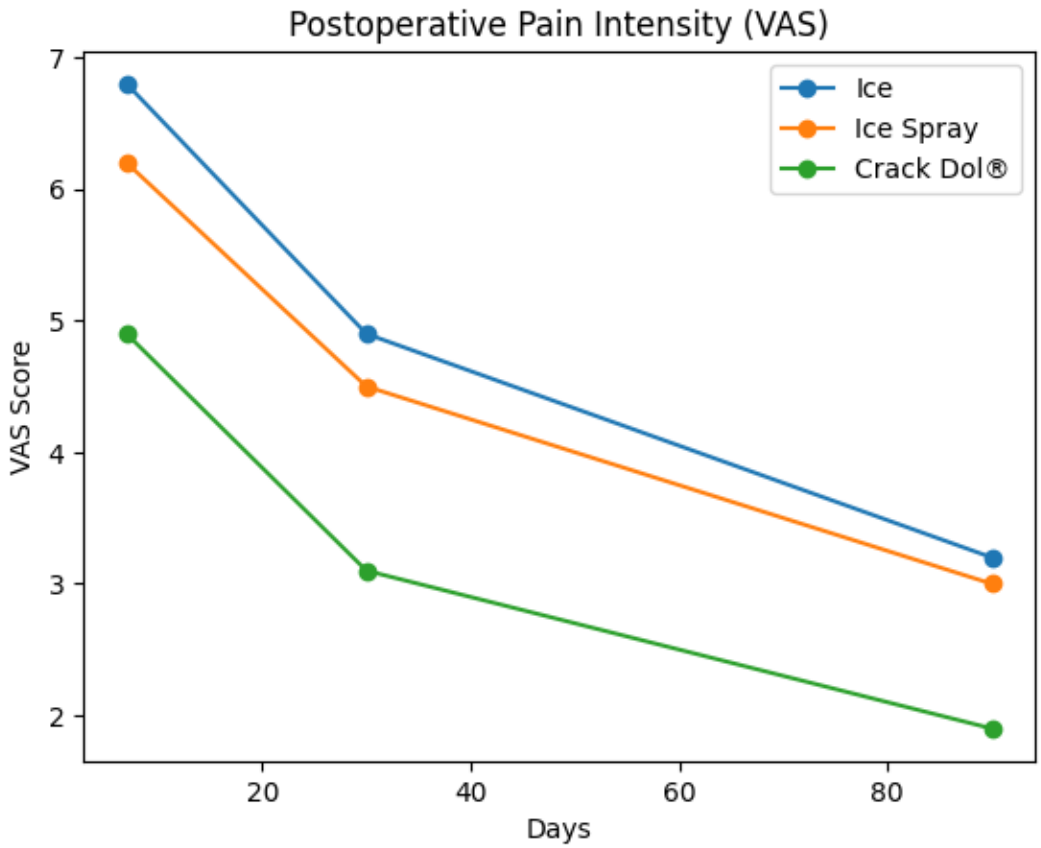
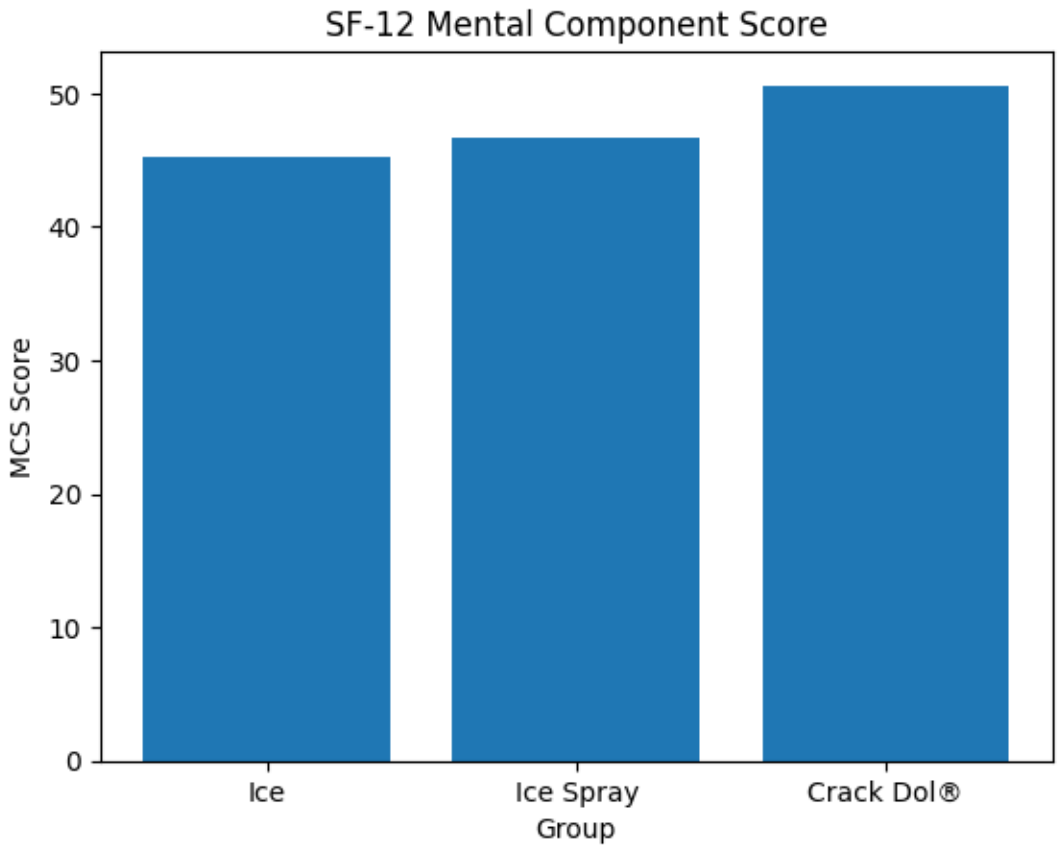


Figure 2. Postoperative pain intensity measured by the Visual Analog Scale (VAS).
Mean VAS scores at 7, 30, and 90 days postoperatively for the Ice, Ice Spray, and Crack Dol® groups. Patients treated with Crack Dol® Foam Spray showed significantly lower pain scores at all time points compared with the other groups.


SF-12 Mental Component Score
MCS Score
0
10
20
30
40
50
Ice
Ice Spray
Crack Dol®
Group

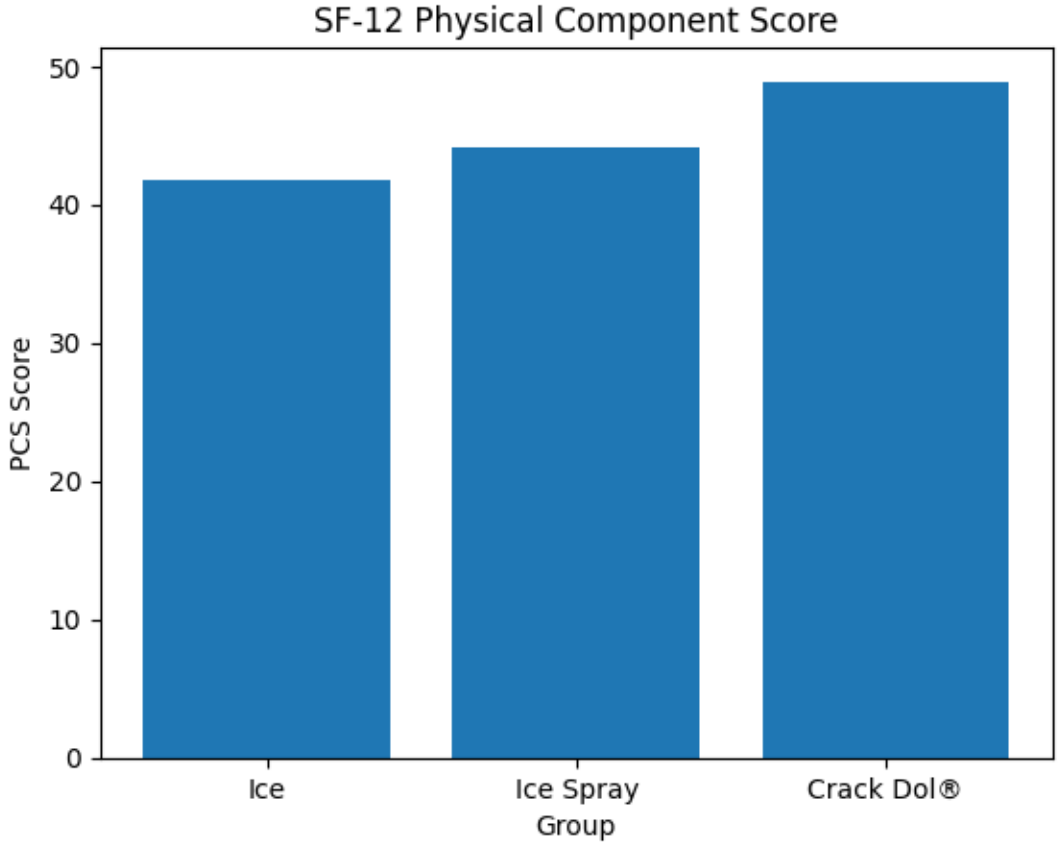

SF-12 Physical Component Score
PCS Score
0
10
20
30
40
50
Ice
Ice Spray
Crack Dol®
Group

Figure 3. Health-related quality of life assessed by the Short Form-12 (SF-12) at 90 days. Comparison of Physical Component Score (PCS) and Mental Component Score (MCS) among the three treatment groups. Higher scores indicate better perceived physical and mental health.

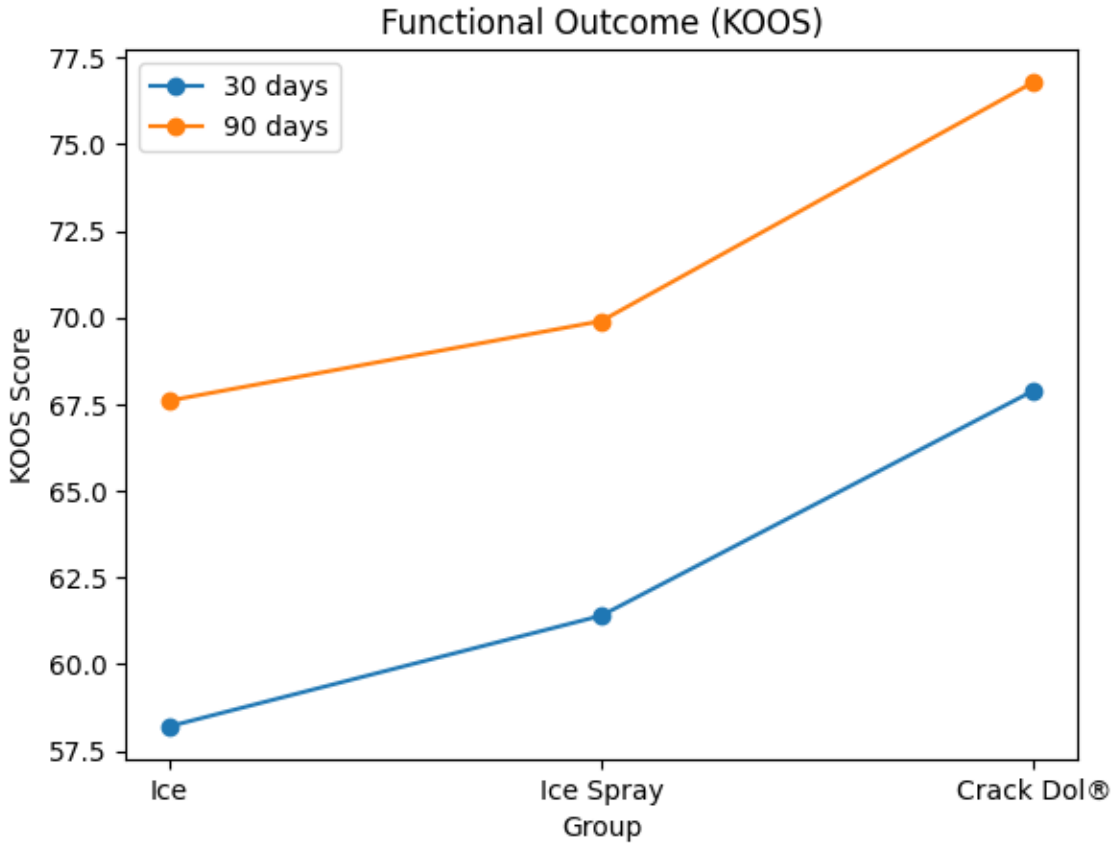


Figure 4. Functional outcomes evaluated using the Knee Injury and Osteoarthritis Outcome Score (KOOS). Mean KOOS total scores at 30 and 90 days postoperatively for the Ice, Ice Spray, and Crack Dol® groups. Higher scores reflect better knee function and recovery.

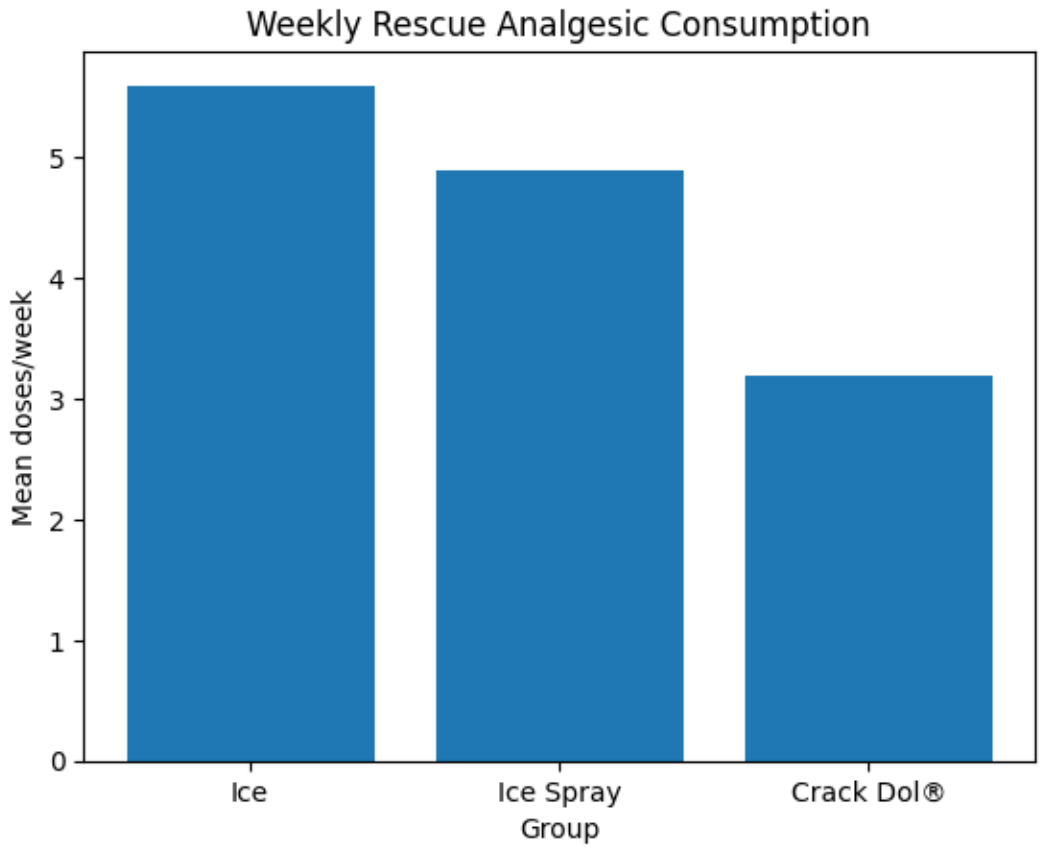


Figure 5. Weekly rescue analgesic consumption during postoperative follow-up.
Mean number of additional analgesic doses per week required by patients in each treatment group. Lower values indicate reduced reliance on systemic analgesics.

Table 1. Demographic and baseline characteristics.

Parameter	Ice (n=30)	Ice Spray (n=30)	Crack Dol® (n=30)	p-value
Mean age (years)	52.4 ± 11.2 (28–72)	50.9 ± 10.8 (26–74)	51.7 ± 12.1 (29–73)	0.88
Gender (M/F)	17 / 13	16 / 14	18 / 12	0.81
BMI (kg/m²)	27.6 ± 3.4	28.1 ± 3.9	27.8 ± 3.6	0.73
Right/Left knee	14 / 16	15 / 15	13 / 17	0.92
Time to surgery (days)	2.1 ± 0.8	2.0 ± 0.7	2.2 ± 0.9	0.67

Table 2. Visual Analogue Scale (VAS**) scores.**

Time Point	Ice	Ice Spray	Crack Dol®	p-value
7 days	6.8 ± 1.1 (5–9)	6.2 ± 1.0 (4–8)	**4.9 ± 1.0 (3–7)**	0.012
30 days	4.9 ± 1.0	4.5 ± 0.9	**3.1 ± 0.9**	0.006
90 days	3.2 ± 0.8	3.0 ± 0.7	**1.9 ± 0.7**	0.004

Table 3. Quality of life (SF-12) scores at 90 days.

Domain	Ice	Ice Spray	Crack Dol®	p-value
PCS	41.8 ± 5.6	44.1 ± 5.2	**48.9 ± 5.1**	0.009
MCS	45.3 ± 6.1	46.7 ± 5.9	**50.6 ± 5.4**	0.014

Table 4. Knee Injury and Osteoarthritis Outcome Score (KOOS) **total score.**

Time Point	Ice	Ice Spray	Crack Dol®	p-value
30 days	58.2 ± 8.9	61.4 ± 8.1	**67.9 ± 7.8**	0.018
90 days	67.6 ± 7.8	69.9 ± 7.4	**76.8 ± 7.2**	0.007

Table 5. Weekly rescue analgesic use.

Group	Mean doses/week	Range	p-value
Ice	5.6 ± 1.4	3–8	—
Ice Spray	4.9 ± 1.3	2–7	—
Crack Dol®	**3.2 ± 1.2**	1–6	0.011