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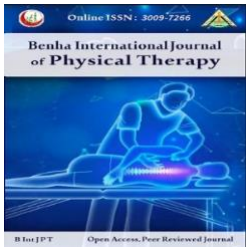


Original research

# Effect of Glucosamine, Chondroitin and Some Herbs Extract Phonophoresis in the Treatment of Grade I and II Knee Meniscal Injuries: a Randomized Placebo-controlled Clinical Trial

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## Abstract

**Background:** Among knee pathologies managed within musculoskeletal medicine, meniscal injuries are notably prevalent. **objective:** to determine the effects of glucosamine, chondroitin, and some herb extracts administered through phonophoresis (PH) as a therapeutic modality for knee meniscal lesions of diagnosed severity of both Grade I and II. **Methods:** A single-blind, randomized controlled trial incorporating a placebo arm was conducted. (allocation ratio 1:1:1) was implemented at the physiotherapy outpatient department of Alahrar Teaching Hospital, Egypt. Fifteen patients (group A) received phonophoresis using glucosamine, chondroitin, and herbal extracts (1 W/cm², 1 MHz, 5 minutes continuous, 5 minutes pulsed). Fifteen patients (group B) received therapeutic ultrasound with the same parameters. Fifteen patients (group C) received sham ultrasound (massage using the head of the ultrasound). Treatment was conducted over twelve successive sessions. The Numeric Rating Scale (NRS) was employed to measure the intensity of pain. Knee functional impairments were evaluated using the WOMAC scale. **Results:** A statistically significant relief was observed in pain and knee functional disabilities for all groups. There was no statistically significant difference between groups A and B regarding the examined parameters. Statistically significant differences in pain and knee functional disabilities were noted between groups A and C, in addition to those between groups B and C. **Conclusion**: The study results propose that the application of ultrasound, using a gel containing glucosamine, chondroitin, and some herbal extracts, or using raw gel significantly improves pain and knee function compared to placebo in managing Grade I and II tears of the knee meniscus.

**Keywords:**Meniscal degeneration,Physiotherapy,Rehabilitation,Ultrasound.

## Introduction

Meniscal injuries of the knee are among the most frequently encountered intra-articular knee pathologies encountered by clinicians treating musculoskeletal diseases. As an intra-articular fibrocartilage entity, the meniscus includes both medial and lateral portions. [1]

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The meniscus is a structurally complex tissue formed by cellular elements and specialized extracellular matrix constituents, with glycosaminoglycans (GAGs) representing the predominant molecular components. The glycosaminoglycans (GAGs) present in meniscal tissue primarily 60% of comprise chondroitin 6-sulfate, 20-30% of dermatan sulfate, 10-20% of chondroitin 4-sulfate, and 15% of keratan sulfate. Consequently, glucosamine (GL) and chondroitin (CH) are considered key biochemical constituents of the meniscus. [2]

Recent scientific research has revealed the significant role of menisci in various anatomical and biomechanical functions, such as lubrication, load distribution, stabilization, proprioception and shock absorption. [1]

Meniscal tears are categorizedby MRI according to T2-weighted signal intensity into four grades. Grade I is characterized by presence of focal T2-weighted hyperintensity which does not include the articular surface. Grade 2 involves linear T2-weighted hyperintensity without articular surface extension. Grade 3 is identified by presence of focal/linear T2-weighted hyperintensity with articular surface extension. Grade 4 is marked by fragmentation of the meniscus. [3]

Meniscus may heal slowly after injury depending on the blood supply, sufficient nutrition, type and grade of injury. [4]

Ultrasound (US), a type of mechanical sound energy, is widely employed in physiotherapeutic interventions. Upon transmission into bodily tissues, US exerts its effects through both thermal and non-thermal processes. Phonophoresis (PH) involves delivering the molecules of drugs in gel form transdermally using a US transducer during treatment. Its primary benefits include the localized delivery of medication without skin penetration and the combined effects of US and drugs without relying on systemic circulation.[5]

Considering that GL and CH, as key cartilage constituents, are recommended in clinical guidelines for modifying both clinical and radiological outcomes of cartilage pathology, their application during PH) may offer enhanced therapeutic benefits in the management of knee meniscal injuries. The principal purpose of this research was to evaluate the effects of GL and CH administered via PH on knee pain as well as functional disabilities for therapeutic intervention in Grade I and II knee meniscus lesions. The secondary purpose of the current research was to examine the efficacy of US application on the same examined parameters.

## Methods

The practical part of the study was carried out at outpatient clinic of physical therapy at Al-ahrar Teaching Hospital in Zagazig, Egypt, between October 2022 and May 2024. Ethical approval for this study was granted by the Ethical Review Committee of the General Organization of Teaching Hospitals and Institutes (Approval ID: HAH00014). The trial was registered with ClinicalTrials.gov under the registration number NCT06798428. A total of 45 patients referred from an orthopedic outpatient clinic, with a clinical diagnosis of knee meniscal tears of Grade I or II severity, based on MRI findings and a positive McMurray's test conducted by a qualified physiotherapist were enrolled in this study. Participants with additional knee injuries, systemic disorders involving the musculoskeletal system (such as rheumatoid arthritis), or a body mass index above the threshold of 30 kg/m² were excluded.

### *Study design:*

This study employed a randomized controlled design with parallel group allocation (1:1:1) placebo-controlled, single-blind study. All of the patients were examined by the same physical therapist before beginning treatment and two days after completing the 12-session treatment.

### *Sample size calculation:*

A comprehensive literature review was done to get the most relevant study that informs the sample size estimation [6], which reported a mean pain score (after treatment) of 5.25 ± 1.90 for the treatment group and 6.67 ± 1.78 for the control group. Using G*power (3.1) to calculate the sample size (power = 0.8, alpha error = 0.05 and beta 0.2), we determined that we needed 15 patients for each group (a total of 45 patients for the three groups).

### *Intervention:*

Patients were examined by a single physical therapist-researcher to determine

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suitability for inclusion in the study. Randomized blocks were used to ensure a 1:1:1 blocked randomization. The Numeric Rating Scale (NRS) was employed to measure the intensity of pain. Patients were instructed to specify his/her knee pain intensity during normal movement, with zero point in the scale indicates minimum pain and 10 indicates maximum pain. Functional impairments of the knee were evaluated using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), which is a valid outcome measure assessing three core dimensions: pain, joint stiffness, and physical functioning. Demographic and anthropometric data, including age, weight, and height, were also documented. Each patient was assessed at the beginning of the study and again two days after the last session. For Group A (15 patients), Phonophoresis (PH) was applied using a 4 cm gel containing 5% of GL and CH along with some natural herbs.

The patients were positioned supine with a small pillow under their knee to make slight knee flexion (figure1). The duration of the ultrasound application was 10 minutes. The US was administered at an intensity of 1 W/cm² and a frequency of 1 MHz, consisting of 5 minutes in continuous mode followed by 5 minutes in pulsed mode. The ultrasound device type used for treatment was the ProSound ULS-1000-Medserve (England) (figure 2). For Group B (15 patients), ultrasound insonation was performed using the same parameters as Group A, but with a topical gel that contained no drugs. For Group C (15 patients), A topical gel was administered using the ultrasound transducer for a duration of 10 minutes, with the device powered off, simulating a manual massage technique. All patients did not take any musculoskeletal medication while undergoing physical therapy. The physical therapy was conducted every day over twelve successive sessions (excluding weekly holidays), all performed by the same physical therapist.

**Figure 1:** Ultrasound application

**Figure 2 :**Ultrasound device

***Statistical analysis:***

The underlying assumptions of data normality and variance homogeneity were evaluated. Assessment of normality was conducted using the Shapiro–Wilk test, which indicated a significant departure from a normal distribution ($P < 0.05$), even after the exclusion of outliers revealed through box-and-whisker plot analysis. Furthermore, Levene's test confirmed a significant violation of the homogeneity of variance assumption ($P < 0.05$). Since the data are not normally distributed, non-parametric analysis was performed. The statistical analysis was conducted using the statistical package for social sciences SPSS software version 25 for Windows (SPSS, Inc., Chicago, IL).

Quantitative variables, including demographic characteristics (age, weight, height, and BMI), as well as WOMAC and NRS scores, were reported as means with corresponding standard deviations, but WOMAC and NRS scores were reported as median and interquartile range. Within-group comparisons of pre- and post-treatment scores for the WOMAC and NRS were conducted using the Wilcoxon signed-rank test. Between-group differences across the three study arms were assessed using the Kruskal–Wallis H test. Post-hoc-test used to compare between pairwise of groups conducted by Bonferroni correction test. All statistical analyses were employed using a predetermined significance threshold of $P \leq 0.05$.

## Results

Pronounced statistically insignificant variations were identified among all groups concerning demographic data (Table 1). There was a statistically significant improvement in all groups regarding pain intensity measured by the NRS and

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knee functional disabilities measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) after treatment (Table 2) (Figure 3,4). Pronounced significant differences were noticed across all groups with respect to pain as assessed by the NRS and knee functional disabilities assessed by the WOMAC after treatment (Table 2) (Figure 3,4).

There was a statistically insignificant difference in pain and knee functional disabilities between groups A and B. However, statistically marked variations were shown in pain and knee functional disabilities between groups A and C, as well as between Groups B and C (Table 3).

**Table 1:** Clinical general characteristics of patients among groups

| Items | Group A (n=15) | Group B (n=15) | Group C (n=15) | *P*-value |
|---|---|---|---|---|
| Age (year) | 50.40 ±12.29 | 51.00 ±5.45 | 51.33 ±6.12 | 0.967 |
| Weight (kg) | 77.07 ±4.92 | 80.13 ±4.67 | 79.60 ±4.53 | 0.176 |
| Height (cm) | 163.53 ±1.80 | 163.27 ±1.16 | 163.20 ±1.14 | 0.791 |
| BMI (kg/m$^2$) | 28.83 ±1.99 | 30.07 ±2.02 | 29.90 ±1.99 | 0.193 |

P-value>0.05: non-significant probability value

**Table 2:** Within and between-group comparisons for WOMAC and NRS variables

| Variables | Items | Groups (Mean ±SD) | | | *P*-value[2] |
|---|---|---|---|---|---|
| | | Group A (n=15) | Group B (n=15) | Group C (n=15) | |
| NRS | Before-treatment | 7 (6, 8) | 7 (6, 8) | 7 (6, 7) | 0.457 |
| | After-treatment | 2 (2, 4) | 3 (2, 4) | 5 (3, 5) | 0.004* |
| | Change | 5.00 | 4.00 | 2.00 | |
| | Improvement % | 71.43% | 57.14% | 28.57% | |
| | *P*-value[1] | 0.0001* | 0.001* | 0.001* | |
| WOMAC | Before-treatment | 46 (46, 50) | 48 (42, 50) | 48 (46, 50) | 0.628 |
| | After-treatment | 26 (12, 32) | 30 (18, 34) | 44 (40, 46) | 0.0001* |
| | Change | 20.00 | 18.00 | 4.00 | |
| | Improvement % | 43.487% | 37.50% | 8.33% | |
| | *P*-value[1] | 0.0001* | 0.0001* | 0.001* | |

P-value: probability value, * Significant (P<0.05)
P-value[1]: Probability value within each group by Wilcoxon signed-rank test.
P-value[2]: probability value among groups by Kruskal –Wallis H test.

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**Table 3:** Post-hoc test for WOMAC and NRS after-treatment

| Variables | Items | Pairwise groups after-treatment (Post hoc-test) | | |
|---|---|---|---|---|
| | | Group A *vs.* Group B | Group A *vs.* Group C | Group B *vs.* Group C |
| NRS | Change | 1.00 | 3.00 | 2.00 |
| | *P*-value | 0.427 | 0.001* | 0.016* |
| WOMAC | Change | 4.00 | 18.00 | 14.00 |
| | *P*-value | 0.391 | 0.0001* | 0.0001* |

P-value: probability value between pairwise groups (post-hoc test) by Bonferroni correction test. * Significant (P<0.05)

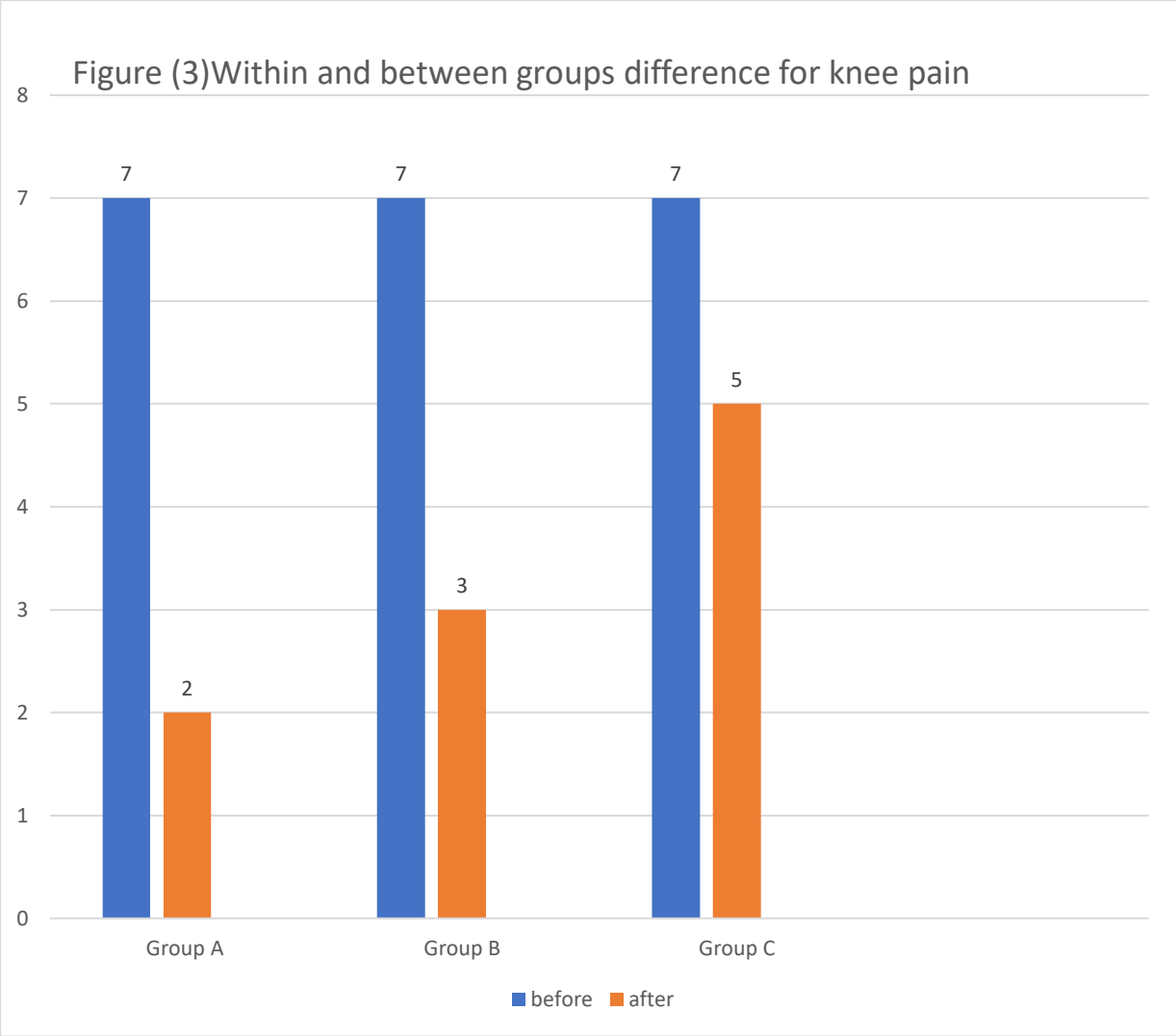


**Figure (3)** Within and between groups difference for knee pain

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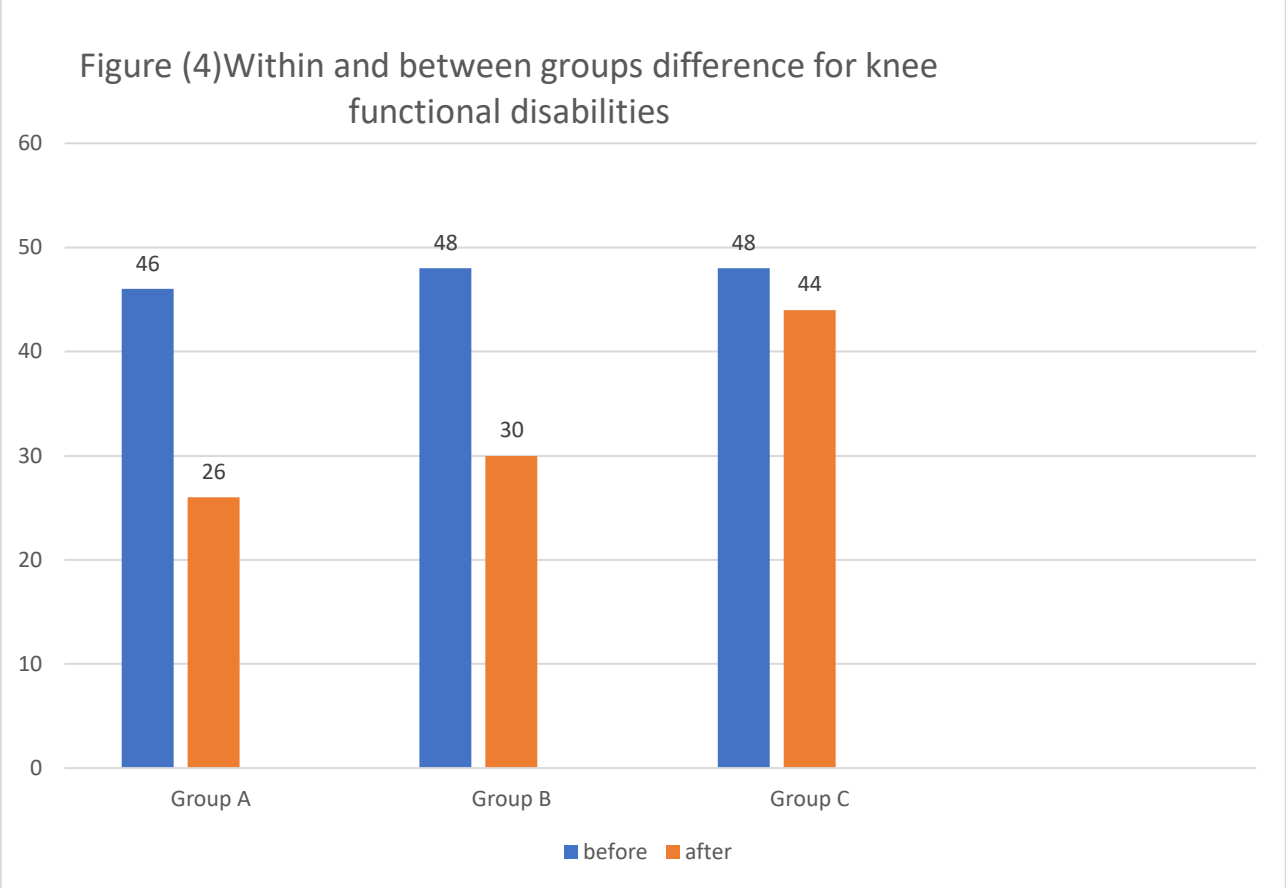


**Figure (4)** Within and between groups difference for knee functional disabilitie

## Discussion

The principal purpose of this research was to explore the efficacy of glucosamine, chondroitin and certain herbs extract (Menthol, Cineol and Camphor) administrated via PH as a therapeutic modality for management of knee meniscal lesions classified as Grade I and II. The secondary purpose was to explore the efficacy of US application on the same parameters. The results demonstrated that application of therapeutic ultrasound (1 W/cm$^2$, 1 MHz and 5 min continuous 5 min pulsed, 12 consecutive sessions), whatever using gel containing glucosamine, chondroitin and some herbal extracts (phonophoresis) or not, significantly improve pain and knee functional disabilities more than placebo.

Meniscal injuries of the knee are among the most frequently observed conditions in clinical musculoskeletal practice.[1] The meniscus may heal slowly after an injury, depending on blood supply, sufficient nutrition, type and grade of injury. Tears occurring in the peripheral, well-vascularized zone of the meniscus are associated with superior healing potential.[4] Conservative treatment is the first line of treatment in cases of undisplaced meniscal tears.

Therapeutic ultrasound (US) is a modality of acoustic energy frequently utilized in physical therapy practice. Emerging evidence supports its application in the management of a range of musculoskeletal conditions. The physiological effects of US on tissues and cells are mediated through both thermal and non-thermal processes.[5]

The application of ultrasonic energy generates vibratory motion in soft tissue molecules as a result of acoustic wave propagation, generating frictional heat and subsequently increasing temperature of tissues. This produced thermal effect, achieved through the continuous mode used in the current study, is thought to lead to increased enzymatic activity, enhanced collagen tissue extensibility, increased local blood flow, and an elevated pain threshold, all of which can help control inflammation and promote healing of soft tissue injuries.[7]

Therapeutic ultrasound exerts non-thermal effects primarily through mechanisms such as

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acoustic streaming and cavitation. Acoustic streaming is defined as the steady, unidirectional flow of fluid induced by the propagation of ultrasound waves, which facilitates the displacement of ions and small molecules. Cavitation involves the interaction of sound waves with gas bubbles in the tissue fluids, generating mechanical forces within the microenvironment. Although the phenomena of cavitation and microstreaming have been predominantly observed under in vitro conditions, these phenomena are associated with enhanced fibroblast activity, promotion of collagen synthesis, and facilitation of tissue regeneration.[8]

To the best of the authors' knowledge, this is the first randomized, placebo-controlled trial that explores the therapeutic effects of phonophoresis using a combination of glucosamine, chondroitin, and herbal extracts, alongside ultrasound application, in the management of knee meniscal lesions classified as Grade I and II.

In a case report, Muche´ 2003 reported a case suffering from a Grade II tear localized to medial meniscus posterior horn. The patient received three sessions of continuous therapeutic ultrasound, administered at an intensity of 1.0 W/cm² and a frequency of 1 MHz for 15 minutes per session. By the third session, the patient's pain score on the Visual Analog Scale (VAS) had decreased from 9/10 to 4/10 .[9,10]

Two published studies investigated the efficacy of GL phonophoresis in the management of knee osteoarthritis. Hedayati et al., detected a significant enhancement in osteoarthritis (OA) criteria in the intervention group (GL phonophoresis, US was at continuous mode, frequency of 1 MHz, 0.3 watt/cm$^2$ ,5 min) compared to placebo.[11] RezkAllah also noticed a significant improvement in pain, range of motion (ROM), and functional disability between GL sulfate, CH sulfate and Methylsulfonylmethane phonophoresis group (pulsed US,1 MHZ, 1.5 w/cm$^2$, 5 min) compared to control or topical application.[12]

While theses previous two studied investigated the effect of GL PH in the treatment of knee OA , this current study investigated the effect of GL , CH added to some herbal extracts phonophoresis in the treatment of knee meniscal injuries, this current study found a significant improvement in pain and functional disability (compared to control) as previous two studies , but in this current study there was no significant difference between PH and US , as these two studies didn't compare between PH and US. While Hedayati et al., used a continuous mode for PH, RezkAllah used pulsed mode, in this current study, pulsed US was used to take advantage of its non-thermal effect of US (5min), while continuous US was employed to benefit from its thermal effect of US (5min). Some researchers consider pulsed US to be better for PH application, while others suggest continuous US; therefore, both modes were used to ensure optimal application for PH. Continuous US was used before pulsed US, as some researchers recommended that deep heat should be applied prior to pulsed US for better drug penetration.[13]

According to many trials, 5 minutes is not enough for US application, so 10 minutes application was utilized in this current study.[8,14-16] While the treatment in the current study was administered over 12 consecutive sessions, the other two studies employed a more extended treatment duration.

A large-scale study with an extended follow-up period is needed to investigate the effects of US and PH in the treatment of knee meniscal degeneration.

One notable limitation of this study is the absence of blinding for the treating physiotherapist, who also served as the primary investigator responsible for patient assessment and data collection. This lack of blinding may introduce detection and performance bias, as the therapist's awareness of group allocation could unintentionally influence treatment delivery or outcome evaluation. The second limitation is that assessment was conducted before treatment and two days after the last session, with no follow-up thereafter. Additionally, the available commercial GL and CH topical gels also contain certain herbal extracts (Menthol, Cineol and Camphor), so we could not use gels containing only GL and CH.

## Conclusion

This parallel randomized (1:1:1) placebo-controlled, single-blind study demonstrated that the application of therapeutic ultrasound (1 W/ cm$^2$, 1 MHz for, for 5 min continuous mode followed by 5 min pulsed mode, for 12 successive sessions) whatever, using gel containing

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glucosamine, chondroitin and certain herbal extracts (phonophoresis) or using raw gel, significantly improve pain and knee functional disabilities compared to placebo in the management of Grade I and II knee meniscal tears.

***List of abbreviations:***

Glycosaminoglycans (GAGS), glucosamine (GL),chondroitin (CH) Ultrasound (US), Phonophoresis (PH), body mass index (BMI) numeric rating scale (NRS),Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Visual Analog Scale (VAS), range of motion (ROM).

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