

COMPARISON OF EFFICACY OF TOPICAL APPLICATION OF GLUCOSAMINE AND CHONDROITIN SULFATE GEL WITH PHONOPHORESIS USING THE SAME GEL IN TREATING TEMPOROMANDIBULAR JOINT DISORDERS — A RANDOMIZED CONTROL TRIAL

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ABSTRACT:

BACKGROUND—Disorders of the temporomandibular joint (TMD) can be arthrogenous or myogenous. Topical and oral glucosamine and chondroitin sulfate have been reported to be effective for joint disorders, but there is no research on their phonophoretic application for TMD. This study compared the efficacy of topical glucosamine-chondroitin gel versus phonophoresis using the same gel in the treatment of TMD.

METHODOLOGY: A randomized control trial was conducted in 52 patients with TMJ disorders, allocated to study and control groups, wherein the study group receiving phonophoresis with glucosamine-chondroitin gel, and control group receiving topical application of glucosamine-chondroitin gel, and divided equally with 26 patients in each arm.. Pain, mouth opening, clicking, deviation, jaw functional limitation, and masticatory efficiency were assessed. Patients were assessed at two weeks and one month after treatment. Levels of the salivary alpha-amylase stress biomarker were assessed before the treatment and two weeks after the treatment.

RESULTS: Reduction in pain ($p=0.001$) and clicking was noted in the study and control groups ($p=0.001$) after 1-month post-treatment. Mouth opening improved significantly more in the control group ($p = 0.001$) than in the study group ($p \text{ value} = 0.002$) at 1-month post-treatment. A statistically significant improvement in masticatory efficiency was observed in the study group than the control group ($p=0.013$). Jaw functional limitation decreased in both the groups post-treatment ($p=0.001$). The levels of salivary alpha amylase were significantly decreased in the study group ($p=0.001$) compared to the control group.

CONCLUSION: Phonophoresis effectively decreased pain, clicking, and jaw functional limitation, and improved mouth opening and masticatory efficiency. Glucosamine and chondroitin sulfate gel phonophoresis offered superior therapeutic benefits to application of gel alone and can be considered as a non-surgical management of TMD.

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INTRODUCTION:

The term "temporomandibular joint disorders" (TMD) refers to a broad range of temporomandibular joint (TMJ) conditions, which may have a muscle/myogenous (extracapsular) origin, a

joint/arthrogenous (intracapsular) origin, or a combination of both. Although conservative measures are first used to treat TMD in general, the success of these methods differs depending on the severity and chronicity of the disorder.¹ Arthrocentesis,

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arthroscopy, and intra-articular injections are examples of minimally invasive procedures.² Surgical options for treating TMD include discectomy, condylotomy, eminectomy, discopexy, and total joint replacement.³ Oral glucosamine and chondroitin sulfate have been used extensively to treat joint problems, which are primarily knee-related, and also TMJ pain. In a review article, which analysed the efficacy of oral administration of glucosamine versus Ibuprofen showed no statistical difference between these two medications in pain relief.⁴ Glucosamine and chondroitin sulfate, being the structural elements of joint cartilage and articular disc, play an essential role in the cartilage's repair. Glucosamine is a precursor that is crucial for the production of glycosylated proteins and lipids and is naturally generated in the human body. Similar to glucosamine, chondroitin sulfate in cartilage and connective tissue is a glycosaminoglycan with a high molecular weight that is hydrophilic and soluble in water, creating a viscous fluid that is comparable to sodium hyaluronate. Chondroitin supports joint viscosity, promotes cartilage healing, and prevents the action of cartilage-degrading enzymes. Phonophoresis is the use of ultrasound to improve the absorption of medications or other substances through the skin. Through cavitation and alteration of structural lipids in the stratum corneum, it enhances medication penetration through the skin, both during and after the treatment.⁵ It is hypothesized that glucosamine and chondroitin sulfate gel with phonophoresis would be effective in managing TMDs by lowering the severity of the disease and slowing the disease's progression so that more invasive procedures can be avoided. Given that, from previous literature, glucosamine and chondroitin sulfate have demonstrated satisfactory results in other joints of the body with increased efficacy and superiority over other topical drugs.⁶ Even though the oral forms of glucosamine have been used routinely to treat other joints and also for TMD, no literature has been documented using phonophoresis to deliver glucosamine chondroitin sulfate gel in patients with TMDs. The hypothesis of this study would be that phonophoresis is more effective in reducing TMD compared to topical application alone.

This study aimed to evaluate and compare the effectiveness of topical application of glucosamine chondroitin gel and phonophoresis with the same gel in patients with TMD.

Materials and Methods—Ethical Approval-

Institutional review board approval was obtained for this study (SRMDC/IRB/2022/MDS/NO.402).

Sample description:

The audit was conducted on 52 patients who were diagnosed with TMD, equally divided into study and control groups. Phonophoresis with topical application

of glucosamine chondroitin gel was given to the study group, whereas only glucosamine chondroitin gel applied to control group. The inclusion criteria were patients aged 15 to 65 years, diagnosed with TMD (both muscle and joint disorders) based on diagnostic criteria for temporomandibular joint disorders (DC-TMD). Patients who are having coagulopathy, cardiovascular disease, under anticoagulant therapy, acute infection of the TMJ region, underwent prior TMJ surgery and not consenting to treatment met the exclusion criteria and were not enrolled in the study. All patients were recruited from the Department of Oral and Maxillofacial Surgery, and informed consent was obtained.

The software used to calculate sample size was GPower version 3.1.9.2.

Study group—phonophoresis using Jointace gel

The affected region was scrubbed with spirit gauze, and The transducer head was applied on the region in a circular motion using a 5 mm of Jointace gel. Electroson 608 (Figure 1), a single-headed therapeutic ultrasound device with a maximum output power of 2.5 watts/cm², was used to administer phonophoresis at continuous waveforms at 1 MHz frequency with 1.5 w/cm² intensity for 10 mins. (Figures 2 &3) Phonophoresis was given on alternate days for three times within a week.

Control group – Topical application of Jointace gel.

Patients were asked to apply 3-4 mm of Jointace gel on the affected site using the index finger for 5 mins twice daily for 2 weeks.

ASSESSMENT PARAMETERS:

CLINICAL

The findings for the treatment were assessed by clinical parameters. The modified HELKIMO DYSFUNCTION INDEX (HDI) was used to evaluate the severity of TMD. The parameters evaluated were joint clicking, jaw deviation following mouth opening, jaw function, and masticatory efficiency, joint pain and maximum mouth opening. TMJ pain was evaluated on a scale of 0–10 by visual analog scale, which was graded by the patient. If the patient responded to a score of 0, it corresponds to nil pain, and if they had responded to a score of 10, it corresponds to severe pain. Mouth opening was assessed from the upper incisor tip to the lower incisor tip, and deviation was measured from the upper to the lower midline on maximum mouth opening using a ruler in millimetres. The presence of clicking was noted on the affected site by auscultating using a stethoscope. If sound was present, a score of 1 was given, whereas if the joint sound was absent, it corresponded to a score of 0. Jaw function was determined by the jaw functional limitation scale (JFLS), a questionnaire with a set of 20 questions. Patients were asked to grade their respective jaw functions from 0 to 10. Masticatory

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efficiency was based on the Likert scale: score 0 - solid hard food, score 1- fibrous food, score 2 - soft food, score 3 - semi-solid food, and score 4 - liquid diet. These clinical parameters were evaluated at intervals before and after treatment: 2 weeks and 1 month of follow-up period.

BIO-CHEMICAL—Salivary Alpha-amylase colorimetric test.

2 ml of the patient's saliva was collected in a test tube. On the same day, the samples were brought to the lab on ice and centrifuged for five minutes at 3500 rpm. and stored at -80°C until analysis. Saliva was collected pre-treatment and at two weeks post-treatment. A double-blinding procedure was conducted where investigator 1, who evaluated the parameters, and investigator 2, who analyzed the data, were blinded.

STATISTICAL TESTS

The normality tests such as Kolmogorov-Smirnov and Shapiro-Wilks tests had revealed results that only mouth opening follows normal distribution, and all other variables (pain score, deviation (mm), JFLS score, masticatory efficiency, and phonophoresis level (IU/L)) does not follow the normal distribution. Hence, both the parametric and non-parametric methods were applied to analyze the data. The mean values were compared between the study and the control groups, using an independent samples t-test was applied. For the comparison of proportions between both the groups the chi-square test was used; then Fisher's exact test was used when any expected cell frequency was less than five. For the comparison of values of study and control group in which the variables do not follow a normal distribution, Mann-Whitney U test and the independent-samples test was applied. For comparison of mean mouth opening values at three time points, repeated measures ANOVA (General Linear Model) followed by post hoc tests was performed in multiple pairwise comparisons. For non-normal variables to compare values between three different time intervals, for repeated measures the Friedman test was applied, and for pairwise comparisons Bonferroni-corrected p-values was measured. For comparison of values at two time points, Wilcoxon signed-rank test was used. SPSS (IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp.

Released 2019) was applied to analyze this data.. The level of significance was fixed as 5% ($\alpha = 0.05$).

RESULTS

In this study, 52 patients aged 18-55 (36 female, 19 male) were enrolled into both control and study groups receiving topical application of gel alone and glucosamine and chondroitin gel with phonophoresis, respectively, with 26 patients in each group. The mean pain score decreased from 6.19 to 3.14 among the

study group compared to the control group, the mean pre-treatment pain score was 3.81 and 2.77 at one-month post-treatment period. A statistically insignificant decrease in pain was noted between the control and study groups at the 1-month post-treatment period ($p=0.787$). On intra-group comparison at two time periods, pain reduction that was statistically significant ($p=0.001$) was noted in both groups. (Figure-4, Tables-1 and 2) The mean mouth opening score in the pre- and post-treatment periods was found to be 32.77 and 40.54, respectively, among the study group. The mean pre-treatment mouth opening in control group was 36.31 and 45.69 in the post-treatment period. At one month after therapy, the control group showed a statistically significant improvement in mouth opening ($p=0.003$) when compared to the study group. Additionally, a statistically significant improvement in mouth opening was observed within the study ($p=0.02$) and control group ($p=0.001$). (Figure-5, Tables-1 and 2)

Joint clicking was found to be present in 34.6% of patients in the pre-treatment period and in the study group was 26.9% of patients to be present. In the control group, clicking was present in 57.7 percent of patients in the pre-treatment period, which was reduced to 53.8% after one month. A statistically significant reduction in clicking was seen throughout the one-month follow-up period in the study group as opposed to the control group ($p=0.048$). (Figure-6, Tables-1 and 2)

The mean deviation score was noted to be 1.46 among the study group during the pre-treatment period and 1.46 in the post-treatment phase, while after a month it was 1.58 and 1.50 in the pre- and post-treatment phases, respectively, in the control group. At the one-month follow-up period, a statistically insignificant difference in deviation was seen in both the study ($p=0.999$) and control groups ($p=0.135$). (Tables-1 and 2)

In the study group, the mean pretreatment functional limitation score was 4.96, and 2.42 during the post-treatment period. Among the control group it was 4.77 and 2.48 during the pretreatment and post-treatment time intervals, respectively. A statistically insignificant difference of functional limitation ($p=0.999$) between both the groups in the 1-month post-treatment period was noted. However, within the 2 groups, a decrease in statistical significance functional limitation ($p=0.001$) was observed. (Figure-7, Tables-1 and 2)

The mean masticatory efficiency score was noted to be 2.62 and 1.17 in the study group in the pre-treatment and post-treatment periods, respectively; compared to the control group, it was 1.84 in the pre-treatment and 1.19 in the one-month post-treatment period. A statistically significant improvement in masticatory efficiency ($p=0.013$) was noted in the study group

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compared to the control group in all post-treatment periods. Whereas, on intra-group comparison, both study and control groups showed statistically significant improvement in masticatory efficiency ($p=0.001$). (Tables-1 and 2)

The mean levels of salivary alpha amylase exhibited a significant decrease among the study group ($p=0.001$) in after treatment levels compared to before treatment levels compared to the control group ($p=0.218$). (Figure-8, Tables 1 and 2)

DISCUSSION-

TMD include a range of disorders involving the joint, muscles, or both. Treatment options vary widely, from non-invasive methods to surgical procedures. Conservative measures include heat application, soft diet, physical therapy, splints, medications, phonophoresis, and iontophoresis; minimally invasive procedures like arthrocentesis and intra-articular medications can be given; surgical options such as discectomy, discopexy, and arthroscopic procedures may also be performed.

Glucosamine and chondroitin sulfate are commonly used supplements for joint conditions such as knee osteoarthritis, and TMJ disorders.⁶ Glucosamine and chondroitin sulfate gel, when delivered via phonophoresis, could delay TMD progression and reduce the need for invasive interventions.

Jointace gel contains glucosamine and chondroitin sulfate along with the additional active ingredients camphor, menthol, eucalyptus oil, and aloe vera. These compounds are essential for cartilage repair and provide analgesic and anti-inflammatory effects.⁷

Glucosamine is a natural component of the TMJ that supports proteoglycan synthesis in cartilage and exhibits anti-inflammatory effects by inhibition of cytokines like IL-1 and TNF- α . Chondroitin sulfate, a hydrophilic glycosaminoglycan, functions by inhibiting cartilage-degrading enzymes and promoting joint lubrication.⁷ These properties help relieve symptoms and improve functioning of the joint in patients with degenerative joint conditions.

Phonophoresis is a technique used to increase skin permeability, enhance drug absorption, and potentially deliver higher drug concentrations to deeper tissues using ultrasound. The advantages of phonophoresis include bypassing first-pass metabolism, lowering systemic side effects, and improving patient compliance.⁸ Compared to topically applied gel, phonophoresis offers quicker and longer-lasting relief and raises drug concentrations at the target site. In a study by Cagnie et al., higher ketoprofen levels in synovial tissue and plasma were found after phonophoresis, showing detectable plasma levels compared to sham groups.⁹ In our study, the phonophoresis group demonstrated significant improvements in mouth opening, masticatory

efficiency, and reduction in joint clicking compared to the topical application group. Pain decreased more compared to the control group in the study group when compared between the groups, demonstration that the use of phonophoresis was efficacious in reducing pain scores.

Alhayek et al. analyzed the efficacy of topical glucosamine and chondroitin gel in adolescents using functional appliances for skeletal Class II malocclusion, and found that there were no significant changes in TMJ pain or discomfort. In contrast, our study observed significant improvements in pain and function in both topical and phonophoresis groups.¹⁰ Previous studies, such as those by RezkAllah et al. and Hedyati et al., support the use of glucosamine, chondroitin, and methylsulfonylmethane phonophoresis in managing osteoarthritis of the knee.^{11,12} These studies showed superior outcomes in pain relief, function, and joint mobility compared to topical applications alone. Our findings align with this study, highlighting the benefits of phonophoresis in improving TMJ symptoms, including pain reduction in mouth opening and jaw function.

A systematic review by Derwich et al. evaluated the efficacy of oral glucosamine in treating TMJ osteoarthritis, in which eight randomized clinical trials were analyzed. Oral glucosamine, at dosages ranging from 240 mg to 1500 mg, was associated with reduced TMJ pain and improved mouth opening when used for more than 3 months.¹³

Another systematic review by Xuan et al. assessed the effectiveness and safety of oral glucosamine in treating knee osteoarthritis. Fourteen randomized controlled trials were included into the study. Glucosamine revealed a modest but statistically significant reduction in pain on the Visual Analog Scale versus placebo, with an overall difference of -7.41 and a 95% confidence interval. It was concluded that glucosamine sulfate at 1500 mg/day was generally well-tolerated, with no serious adverse events or major drug interactions, such as abdominal pain, diarrhoea, and dyspepsia.¹⁴

A randomized control trial conducted by Uygulanan et al. evaluated the efficacy of topical glucosamine-chondroitin sulfate in patients with knee osteoarthritis. Forty-nine patients were divided into two groups: one received topical glucosamine and physical therapy, while the other received a placebo and physical therapy. Both groups showed notable improvement in stiffness, physical function and pain. The patients were evaluated before treatment and at 1, 4, and 12 weeks following treatment. The study concluded that no significant difference was found between the two groups at any point using WOMAC scores, and topical glucosamine-chondroitin sulfate offered no benefit over placebo when combined with physical therapy

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($P>0.05$). In contrast to their study results, our study showed decrease in pain and improved mouth opening, jaw function, and masticatory efficiency in the topical group.¹⁵

The sympathetic nervous-adrenomedullary activity may be assessed using salivary alpha-amylase (sAA). It is a non-invasive biomarker of pain and stress. The autonomic nervous system is activated when the body is stressed, which results in catecholamine release and sympathomimetic symptoms such as increased salivation and salivary alpha-amylase production.¹⁶ Research suggests that salivary alpha-amylase can be used as an objective, non-invasive method of assessing pain, making it a valuable instrument for determining the efficacy of therapy provided to TMD patients.

A cross-sectional study by Morita et al. investigated the link between salivary alpha-amylase and oral parafunctions in 319 elderly individuals. were categorized into different stress groups of patients having TMJ noise, tooth attrition, and bruxism. While there was a substantial positive correlation between salivary a-amylase and TMJ noise and tooth attrition, there was a significant negative correlation ($p < 0.05$) between salivary a-amylase and bruxism. In our study, post-treatment amylase levels significantly decreased among the study group than the control group.¹⁷

The positives of this study are that it is the first of its kind to compare phonophoresis and topical application using glucosamine and chondroitin sulfate on patients with TMD; as since it is a topically applied medicament. The drawbacks were the smaller sample size and the fact that patients were followed up only for one month.

CONCLUSION-

In conclusion, both topical application alone and phonophoresis using chondroitin sulfate and glucosamine gel are efficacious in treating TMD in relevance to reduction of pain, improved mouth opening, and functional limitation. However, phonophoresis was successful in decreasing pain and improving masticatory efficiency, offering superior therapeutic benefits, making it a promising treatment option as a non-surgical management of TMD.

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LEGENDS:

Figure 1: Ultrasound device

Figure 2: Application of jointace gel on the right side of the joint

Figure 3: Phonophoresis with ultrasound device

Figure 4: Mean difference to assess pain score within study and control groups

Figure 5: Mean difference to assess mouth opening between study and Control groups

Figure 6: Mean difference to assess clicking between study and Control groups

Figure 7: Mean difference to assess jaw function within study and control groups

Figure 8: Mean difference to assess salivary amylase levels within study and control groups

TABLE -1 : Mean with standard deviation of all the parameters at pre op and post op 2 weeks and 1 month intervals

TABLE-2 : p-values of parameters within and between the groups at 1 month intervals