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A COMPARATIVE STUDY BETWEEN THREE CONSERVATIVE TECHNIQUES IN MANAGEMENT OF RECURRENT TEMPOROMANDIBULAR JOINT DISLOCATION- ONE YEAR RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Introduction: The most widely used proliferant in prolotherapy is hypertonic dextrose, which comes in concentrations between 10% and 50%. Its evaluation produced remarkable results in management of patients who had hypermobility in diseased TMJ.

Aim: The aim of the current study was to analyze results obtained after use of injectable TMJ prolotherapy by dextrose versus inter maxillary fixation and combination between the two methods in management of diseased patients by TMJ chronic recurrent dislocation.

Materials and methods: 36 diseased candidates (4 males and 32 females) suffering from long standing recurrent TMJ dislocation were divided randomly to 3 equally sized groups. Diseased candidates in group A were addressed with TMJ dextrose injection only to five Injection sites: (1- stylomandibular ligament; 2- posterior meniscal attachement; 3- upper capsular attachement; 4- upper joint space; 5- lower capsular attachement) .Group B diseased candidates were addressed only with inter maxillary fixation (IMF) for 14 days, and similar ones in group C were cured by use of joint injectable dextrose combined with IMF in the first 14 days. Maximum mouth opening distance, Condylar translation, Muscle Tenderness and TMJ ache were assessed preoperative, and post interference at 1 month, and 1 year.

Results : There was significant decrease in pain, Muscle Tenderness, Maximal Inter-Incisal Mouth Opening, and Condylar translation in 3D and sagittal views.

Conclusion: Prolotherapy should be the primary line of treatment for recurrent TMJ dislocation. Multiple dextrose injection may overcome recurrence of disease; however, the most favorable clinical results were attained by use of dextrose injection combined with IMF.

KEYWORDS: IMF, Dextrose, Pain, TMJ Dislocation, Maximal Inter-Incisal Mouth Opening Running

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INTRODUCTION

The dislocation of the temporomandibular joint (TMJ) happens when the condyle exceeds articular eminence crest and moves far anteriorly during opening. The surrounding joint ligaments are thus frequently strained by an intra-articular synovial fluid effusion, resulting in joint pain and muscular spasms that cause extreme discomfort and make it difficult to eat and speak. [1,2]

Muscle spasm, a significant bony protuberance, and flaccidity of both ligaments mandibular and capsular ones can all result from TMJ dislocation. Such dislocations have been classified in a number of ways [3,4]. However, according to Adekeye et al. [1] and Rowe and Killey [5], the most common appears to be acute, chronic, and recurrent.

Acute, chronic recurrent, and chronic are the three categories for nontraumatic TMJ dislocations. Anterior TMJ dislocation can happen on its own when the Patient chew, kiss, sing, throw up, or yawn—any movement that causes the mouth to open wide. Seizures, neurodegenerative diseases (like multiple sclerosis and Huntington's disease), Drugs has dystonic reactions as (haloperidol, and prochlorperazine), oral general anesthesia intubation, endoscopy), and pathological diseases that leads to flaccid ligaments (like Ehlers-Danlos and Marfan syndrome) are risk factors. [6,7]

The causes of acute TMJ dislocations range in intensity from acute trauma and epileptic seizures to minor anxiety (yawning, extended dental procedures). Recurrent TMJ dislocation, on the other hand, has a very bad effect on personal life quality in addition to its complicated genesis. Chronic dislocation of TMJ can be caused by a variety of internal and external disturbances, including disease (osteoporotic bone loss, systemic disorders), habit (prolonged abnormal mastication), facial architecture (flattening of articular crest, ligamentous flaccidity, abnormal growth of jaws), and bone structure (e.g., capsular weakness, internal derangement). Reduction of the mandible, which involves pushing the displaced jaw downward and backward to its proper position, can be the conventional therapy to TMJ acute dislocation. Reduction of displaced condyle is commonly performed under general anesthesia or sedation in emergency rooms. [8]

Chronic recurrent (habitual) dislocation refers to recurrent episodic dislocations. Cases of recurrent dislocation lasting longer than one month are referred to as "chronic recurrent" [9]. The pathophysiology related to habitual TMJ recurrent dislocation appears to involve trauma, inappropriate chewing habits, TMJ ligament capsule flaccidity, as well chewing muscles abnormalities. TMJ dislocation is known to be significantly impacted by certain medications, such as phenothiazine, or neurological conditions that cause hyperactivity in the muscles, such as Parkinson's disease [10].

Recent modalities are relay on Hippocrates' (500 BC) technique of being the first one to reduce TMJ acute dislocation [11]. Conservative treatment is an option for chronic recurrent TMJ dislocation, and there are two types of treatment for chronic recurrent TMJ dislocation: surgical and non-surgical methods [12].

Conservative treatment of chronic recurrent dislocation may include IMF, deposition of sclerosing solution intracapsular (alcohol), botulinum toxin deposition in affected muscles, use of personal blood to be injected intra-articular as well dextrose prolotherapy injection were among the conservative treatment methods [13–17]. By encouraging collagen proliferation at the fibro-cartilaginous joint, dextrose prolotherapy—also referred to as a medication of collagen regeneration and a tonic for growth factors excitement in intra joint therapy as well support chronic ligament repair, capsular strengthening, and tendons healing to fasten soft tissue healing and alleviate discomfort. [18].

Usually defined as a straightforward, natural, and minimally intrusive method that promotes the

self-healing process to treat affected areas. In order to stimulate the ligament's proliferative response, dextrose is injected into it. These injections are intended to reduce discomfort and strengthen the ligaments. It is a promising strategy for treating TMDs, particularly when other conservative therapy has failed, and the condition is refractory [19].

Prolotherapy by dextrose may attain injections through and around the joint, in fibro-cartilaginous attachment of the ligamentous tissues and capsule adhesions to the arch of zygoma and mandibular condyle. It is obvious that the main objective of this treatment is to increase the TMJ's stability by strengthening the ligaments and capsular tissue [20–22].

Before undergoing surgery or long-term narcotic medication, prolotherapy can be a fantastic substitute. By restoring joint ligaments and capsules, it offers a better long-term solution to the TMJ's recurrent and persistent issues [23, 24].

It is unclear exactly how prolotherapy works. Nonetheless, Usually is postulated as to function through inducing transient, low-degree of inflammatory reaction at targeted site, which stimulates local fibroblast synthesis, which subsequently produce precursors for collagen maturation, hence strengthen affected fibrous tissue. stimulus of Prolotherapy inflammation raises growth factor concentrations, which can either restart or start a new connective tissue repair cycle that was either prematurely stopped or never began [25].

With doses ranging from 10% to 50%, dextrose hypertonic solution was the highly often used prolotherapy in tissue proliferation [25-27]. Its evaluation in management of joint hypermobility produced remarkable results.

AIM

The current trial compared between using injectable prolotherapy of dextrose through TMJ versus inter maxillary fixation and combination between the two methods to cure affected individuals by chronic recurrent TMJ dislocation.

MATERIALS AND METHODS

This prospective randomized controlled clinical trial with a 1:1 allocation ratio that was carried out after ethical approval from Delta University, Faculty of Dentistry.

Patients

Thirty-six patients were selected from outpatient clinic at Naser Institute Hospital, Oral and Maxillofacial Surgery department at Faculty of dentistry, Delta University for Science and Technology. Informed written consent was obtained from each participant sharing through the current research. Diseased inclusion candidates are subdivided into 3 groups, Group A (n=12), patients were managed by injection of dextrose only through the upper joint space and neighboring pericapsular tissues. Group B (n=12), patients were cured by inter maxillary fixation (IMF) only. Group C (n=12). patients were managed by dextrose and IMF for 14 days.

Inclusion criteria were Adult male and female diseased participants from twenty to sixty years of old, suffering from chronic recurrent dislocation of TMJ causing unilateral or bilateral joint ache and/or Clicking. History of dislocation episodes with yawning was usually Patho gnomic during history taking of affected individuals either self-reducible or require specialist assistance. Episodic dislocated rate exceeds 3 times in the last 6 months' time, causing hypermobility of mandible, and during palpation examination depression had noticed in front of auricle area, and maximum mouth opening (MMO) greater than 50 mm. Radiographic assistance was done using Computerized Tomography in limited and extreme positions of mouth opening.

Patients who had any surgical procedures on TMJ, who had undergone orthognathic surgery,

who had history of TMJ pathology ex. (ankylosis, internal derangements), with rheumatoid arthritis, with neurological conditions, Allergy to articaine hydrochloride and/or dextrose, syndrome of Ehler Danlos, Patients taking anticoagulant therapy and/or with hematologic disease were excluded from the study.

MATERIALS

Syringes with 30-gauge needles, Dextrose solution 25%, Amide local anesthetic Articaine Hydrochloride 4% with vasoconstrictor of 1: 200,000 epinephrine (manufactured by ArtPharmaDent), IMF (IMF screws), and Caliper Electronic Digital LCD Screen Micrometer.

METHODS

Pre-operative assessment and examinations

Clinical examination

After medical history was taken, intraoral assessment was done for dental, soft tissue, maximum mouth opening, and shift at mid incisal line. Examination for masticatory muscles tenderness was done, and sounds produced in TMJ were heard by stethoscope.

Radiographic evaluation

Computer Tomography (CT) on both sides of temporomandibular joint was done preoperative and one year postoperative.

Treatment protocol

Dextrose injection technique

In group A : The pre-auricular skin surface was disinfected using povidone-iodine* solution. From the ear tragus to the orbital outer canthus, a line was illustrated on the skin of face. The sketched line showed a spot that was drawn 1 cm anterior to tragus of the ear. Another spot was demarkated on the skin ten millimeters beneath this one. Local anesthesia was applied at this location. Two millilitres of 4% articaine were injected into the posterior periarticular region to induce cutaneous anesthesia using the infiltration technique.

Each diseased candidate was given six sessions of injections through articular and surrounding capsular tissues, (2 sessions of injection per week successively). Two syringes of injection with a gauge of 30 were utilized in each visit, as each single syringe is utilized for each injection side (right and left sides). Each injecting syringe of 5 ml was filled with 2.5 ml solution of 25% dextrose and 2.5 ml (Articaine hydrochloride of concentration 4 %, with vasoconstrictor of epinephrine 1: 200,000 manufactured by company of ArtPharmaDent). local anesthetic solution. one ml of the injection solution was deposited at each of five precised sites of injection. Injection points include ligamentous stylomandibular, attachment of posterior disk, upper attachment of capsule, upper joint space, and lower attachment of capsule. Point of needle entrance for injection at ligamentous stylomandibular was located at 10mm below the ear lobule and 10mm behind the mandibular ramus, so 2/3 of the needle shaft was introduced within tissues from posterior-anterior direction. For injection of upper joint space, needle entrance was perpendicular through the point that was drawn at 10mm anterior to ear tragus and 5mm below canthus-tragus line. The needle was introduced from downward-upward 45degrees at a point of 2mm above the previous point to reach upper attachment of the capsule, and introduced upward-downward 45degrees at another point of 2mm below point of upper joint space to reach lower attachment of capsule. To reach attachment of the posterior disk, the needle was introduced antero-posterior 45degrees at a point was drawn at 2mm behind the point for upper joint space. For all preauricular injections 1/2 of needle shaft was introduced through tissues.

* 10%, Mundidone Betadine: manufactured by company of Nile, for Chemical Industry & Pharmaceuticals, A.R.E.

Fig (1) (A, B, C, D): A: Show maximum mouth opening via digital caliper Pre-operative dextrose injection. B: Identifying the points that will be injected. C: 3D Show Rt condyle anterior to glenoid fossa. D: 3D cuts Show Lt condyle anterior to glenoid fossa.

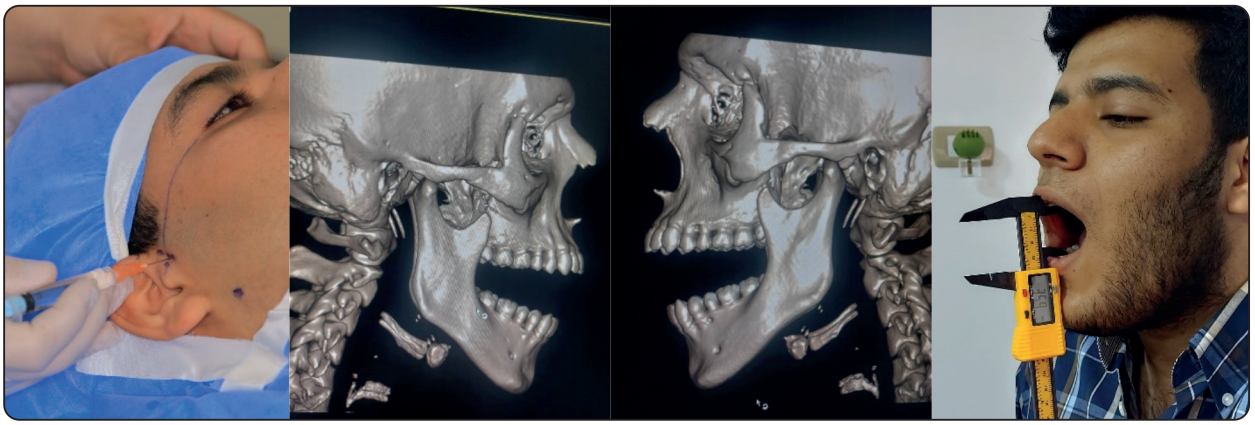

Fig (2) (E, F, G, H): E: During Dextrose injection at marked points. F: 3D cuts show Rt Condyle in normal position during translation movement after six sessions dextrose injection. G: 3D cuts show Lt Condyle in normal position during translation movement after six sessions dextrose injection.H: Show maximum mouth opening via digital caliper post operative dextrose injection.

Group B : Intermaxillary fixation with IMF screws technique

In group B: local anesthesia administration (Articaine hydrochloride of concentration 4 %, with vasoconstrictor of epinephrine 1: 200,000 manufactured by company of ArtPharmaDent) was done bilaterally for maxillary and mandibular anesthesia, then semi closed mouth by IMF was achieved with (0.5mm) stainless steel wires were applied into four IMF intra-bony screws* for 2 weeks. These screws were advanced perpendicular intra-bony through a point located midway at the intermediate space between the neighboring two premolar teeth at the level of attached gingiva and 5mm apical to the cervical line of both teeth. This maneuver was done to avoid any injury for neighboring teeth roots.

(Intra-bony screws using mini screw drive and 0.5 stainless steel wire as all manufactured by Arab Engineers company, Cairo, Egypt.)

Group C: Inter-maxillary fixation (with IMF screws technique) and dextrose injection used in combined group: group 3

Local anesthesia administration (Articaine hydrochloride of concentration 4%, with vasoconstrictor of epinephrine 1: 200,000 manufactured by company of ArtPharmaDent) was done bilaterally for maxillary and mandibular anesthesia,

then closed mouth by IMF was achieved with wires applied into IMF screws for 2 weeks (the same as in group 2). In those patients, just limitation of mouth opening to be of not more than 3cm was applied to allow use of mouth for mastication and speech properly. The patients were given an easy chewing food for 14 days and prescribed analgesic non-steroidal as well antibiotic drugs to a week depending to their allergic status. (Postoperative drugs include use of chlorhexidine digluconate with concentration of (0.2%) as mouthwash, antibiotics as (625mg amoxicillin combined with 125 mg clavulanic acid, (1 gm Augmentin tablets -GSK pharmaceutical company, Egypt) to be taken 2 times per day for one week. In addition, analgesic drug paracetamol with acetaminophen 500 mg (Panadol tablets -GSK pharmaceutical company, Egypt), was prescribed and restricted to times of pain only.

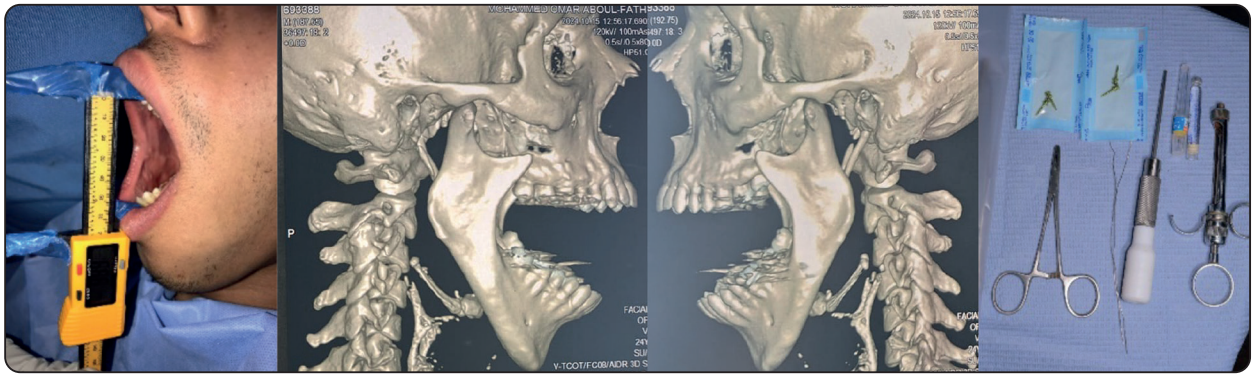

Fig. (3) (A, B, C, D) A: Show maximum mouth opening via digital caliper Pre operative. B: 3D cuts Show Rt condyle anterior to glenoid fossa. C: 3D cuts Show Lt condyle anterior to glenoid fossa. D: Show materials and instruments were used during the procedure (IMF SCROW, SCROW Driver, Steel Wires, Wire Twister, Local Anesthesia, Anesthesia Syringe) .

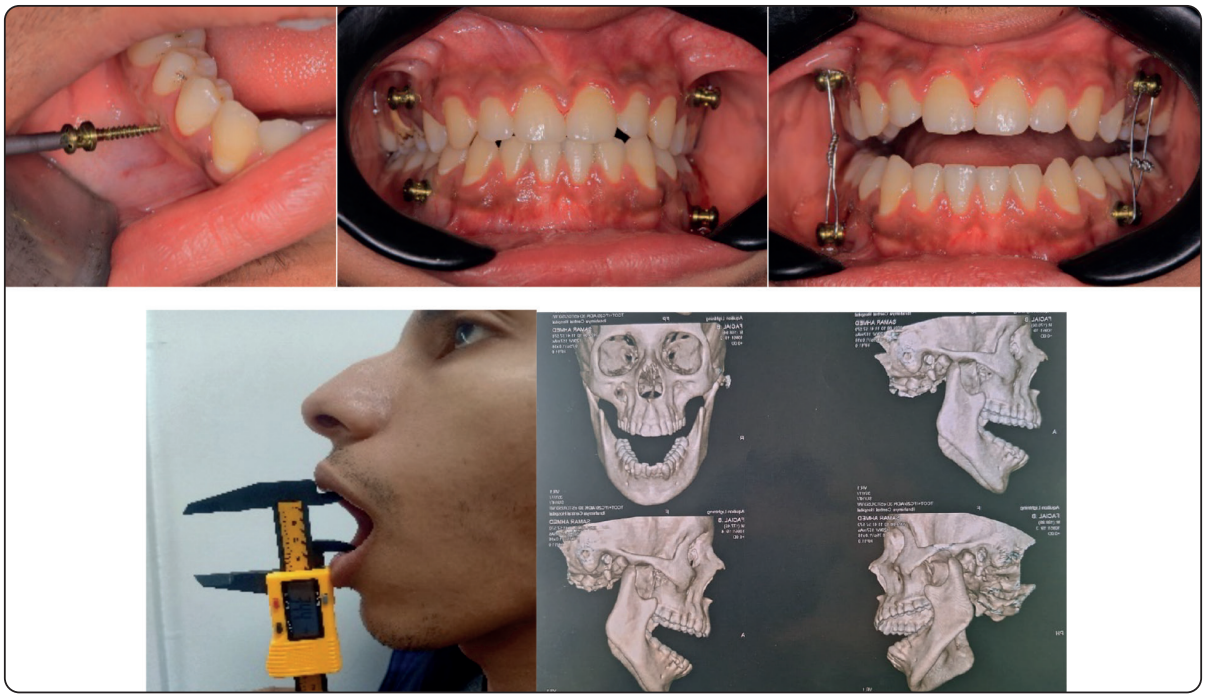

Fig. (4) (E, F, G, H. I)E: During IMF screw placement in premolar area between 4, 5 (the 2 neighboring premolars) in attached gingiva area. F: After IMF screws placement. G: Semi-closed mouth by steel wires. H: Maximum inter incisal opening via digital caliper post operative dextrose injection. I: 3D cuts show RT, LT condyle in normal position during translation movement after 2-weeks of IMF.

Dextrose injection in combination group with IMF: Group C

In this group both Dextrose and IMF were done, and the same injection protocol was used accompanied by IMF for 2 weeks that started at the 1st dextrose injection session.

Postoperative phase

All patients were followed weekly postoperatively at first month then at 3 months and one year. All post-operative records are registered for one month, and one year for all groups.

Post-operative instructions and medications

In post injection period the patients received Panadol (paracetamol combined with acetaminophen of concentration 500 mg - GSK pharmaceutical company, Egypt), single tablet each four hours if there was a need for pain control. Patients are instructed to be away from use of other anti-inflammatory and analgesic medications during treatment to eliminate possible negative effects on prolotherapy proliferation (as Ibuprofen, Diclofenac compounds, Ketolac and other potential non-steroidal drugs inhibit forcibly fibroblasts proliferation so affect negatively fibril synthesis that is in high demand for prolotherapy treatment, but Panadol is slightly analgesic weak non-steroidal mainly it is anti-pyretic drug). Candidates were also given instructions to use a soft diet for succeeding 14 days, avoid massive mouth opening, ice application after injection, and to apply counter pressure against opening under the area of chin region during activities as yawning,

Clinical evaluation

Pain

Visual Analogue Scale (VAS) was used for analyzing pain. Graduated from zero up to ten (from 0 to 1 equals None, from 2 to 4 equals Mild, from 5 to 7 equals Moderate, from 8 to 10 equals Severe). Scale was used and patients were asked to rate degree of pain and discomfort preoperative, 1 month, and one year postoperative.

Muscle tenderness:

Tenderness of masticatory muscles That comprise **external and internal pterygoids, temporalis and masseter muscles in addition to neck sternocleidomastoid and trapezius muscles were assisted by** Visual Analogue Scale (VAS) at preoperative, 1 month, and one year postoperative.

Maximum Mouth opening: by measuring space between upper and lower incisal edges at midline. Maximum mouth opening was measured by Calliper Electronic Digital LCD Screen Micrometer preoperative, 1 month, and one year postoperative.

Joint Sound : was evaluated clinically for each patient in all study stations.

Shift of mid incisal mandibular line : during opening and closing was Registered in relation to sagittal plan.

Radiographic assessment

Condylar translation was measured by Computer Tomography (CT) on both side of temporomandibular joint, and this is done by calculating the difference in condylar translation preoperative and postoperative on sagittal and 3-D computerized tomography using Mimics Medical 19.0 software.

Analysis of statistics

The data had been analyzed by use of SPSS® software version 25 (SPSS Inc., Chicago, IL, USA). tests of Shapiro Wilk were utilized to diagnose normality through data distribution in all different variables. The pain and muscle tenderness data were nonparametric and break the normal distribution. Consequently, descriptive statistics were presented using median, minimum and maximum. Comparison of pain and muscle tenderness between different groups had done by use of the Kruskal Wallis test succeeded by test of Mann Whitney post hoc, and between observations was made using the test of Freidman succeeded by tes of Wilcoxon signed

ranks for multiple comparisons. The mouth opening, condylar translation and shift as data gathered had been parametric and so fulfilled the normal distribution. Consequently, descriptive statistics were presented using mean, and standard deviation. Comparison of mouth opening, condylar translation and shift between groups and observations had made Repeated measures ANOVA succeeded by test of Bonferroni for multiple comparisons. Graphical presentation to data was made using clustered bar charts. Significance of P-values were to be considered if lower than 0.05.

RESULTS

Biodata

Thirty-six patients were included in the current study (4 men and 32 women), their age was in a range of twenty to sixty of years and had a mean of 34.91±9.47 years for group A (study group), 27.41±8.58 for group B (control group), and group C (study group) 30.33± 8.07 . Throughout the study, all the patients in all groups were presented with chronic recurrent TMJ dislocation.

Clinical Evaluation and radiographic evaluation

Pain and muscle tenderness

Effect of group

Comparison of median scores of pain and muscle tenderness between groups for different observations was applied in Table 1. For preoperative observation, there was no significant difference in median scores of pain and muscle tenderness between groups. For T1(scores at 4 weeks postoperative) and T3(scores at 1 year postoperative) observations, Dextrose injection(GroupA) showed the highest pain and muscle tenderness scores followed by Intermaxillary Fixation (Group B) and the lowest scores were noted with Both Dextrose injection and Intermaxillary Fixation (Group C). Multiple (post hoc) comparisons of scores between groups were applied in the same table form. As T1 observation, there was a significant difference to pain values between each 2 groups except between Dextrose injection (group A), and Intermaxillary Fixatio n (group B). Regarding muscle tenderness scores, there was a significant difference through each 2 comparative groups with exception present between Intermaxillary Fixation(group B) as well Both Dextrose injection and Intermaxillary Fixation(group C). For T3 observation, there was a significant difference to pain as well muscle tenderness values between each 2 comparative groups with exception in between Intermaxillary Fixation(group B) and Both Dextrose injection and Intermaxillary Fixation(group C).

Effect of observation

A comparison of median scores of pains and muscle tenderness between observations in different study groups had applied in Table form 1. In all groups, there was a significant difference in the median scores of pain and muscle tenderness scores between observations For all groups, pain and muscle tenderness scores significantly decreased with time. The highest scores were noted with preoperative observation, followed by T1 and the lowest pain scores were noted with T3. Multiple (post hoc) comparisons of scores between observations are presented in the same table. For all groups, pain and muscle tenderness scores significantly decrease from preoperative to T1. However, no significant difference was noted between T1 and T3.

Mouth opening, condylar translation and shift

Effect of group

The mean mouth opening comparison, condylar translation as well shift between groups for different observations is applied in Table forms 2 and 3. In observation of preoperative period, there was no significant difference through mean mouth opening, condylar translation and shift between groups. For T1 and T3 observations, Dextrose injection (group

A) showed the highest mean mouth opening, condylar translation and shift followed by Intermaxillary Fixation(group B) and the lowest scores were noted with Both Dextrose injection and Intermaxillary Fixation(group C). Multiple (post hoc) comparisons of scores between groups were presented in the same table. For T1 and T3 observation, there was a significant difference in mouth opening through every 2 groups. For T1 observation, there was a significant difference in condylar translation through each 2 comparative groups. However, in T3, there was a significant difference in condylar translation between each 2 comparative groups with exception present between Intermaxillary Fixation(group B) as well Both Dextrose injection and Intermaxillary Fixation(group C). For T1 and T3 observation, there had no significant difference through shift a long each 2 comparative groups.

Effect of observation

A comparative analysis of mean mouth opening, condylar translation and shift between observations for different groups was applied in Table forms 2 and 3. In all groups, there was a significant difference to mean mouth opening, condylar translation and shift between observations. For all groups, the highest mouth opening, condylar translation and shift were noted with preoperative observation, followed by T3 (observation at 1 year), and the lowest means were noted with T1 (observation at 4 weeks). Multiple (post hoc) comparisons of means between observations are presented in the same table. For all groups, mouth opening, and condylar translation significantly decreased from preoperative through T1, and hence significantly raised again in T3. There was a significant difference through each 2 comparative observations. For shift, at all groups, there was a significant difference through each comparative 2 observations with exception present between T1 as well T3.

Pain

All diseased candidates were followed up weekly at 1st month,but records were registered at 1 month and 1 year after intervention. pain reduction with Statistic significance through the study course was confirmed in all diseased candidates by use of Visual Analogue scale (VAS). Statistical variation between study groups over the follow-up period was reported; value of p =001* for both comparative groups (Table 1). with age ranged from 20 to 60 years old.

Maximum Mouth opening

The mean maximum mouth opening increased from preoperative to 1 month, and 1 year in all cases. The maximum interincisal mouth opening in the follow up periods was found to be statistically non-significant as P values were (p<.001*) in all groups. Moreover, inter-group comparison showed statistical non-significant difference(p<.001) through each follow-up era.

Muscle tenderness was assessed by the presence or absence of joint tenderness on palpation which significantly decreased in all groups as stated before.Joint sound is decreased in all patients from first session till end of follow up but sorry fully not fully erased.

Radiographique Evaluation

The mean pre-operative condylar translation in Group A was 7.17b±.58, while the mean condylar translation at 1 year for the same group was 7.75c±.62. For Group class B, the post-operative mean 1-month of condylar translation had 6.25b±.45, while the mean condylar translation at 1 year for the same group was 7.00c±.00. In Group C, the mean 1-month post-operative condylar translation was 5.83b±.39, while the mean condylar translation at 1 year for the same group was 7.00c±.00. (Table 3) and as it is highly obvious that massive reduction in condylar translation in all groups but highly pronounced in combination group(group C).

TABLE (1) Comparison of median scores of pain and muscle tenderness between groups and observations

	pre Me (mini-maxi)	T1 Me (mini-maxi)	T3 Me (mini-maxi)	Freidman test P value
		Pain		
Dextrose injection	9.00 A, a (7.00-10.00)	4.50A, b (2.00-8.00)	4.50 A, b (3.00-8.00)	**<.001***
Intermaxillary Fixation	9.00 A, a (7.00-10.00) a	3.00 A, b (0.00-5.00) b	1.00 B, b (0.00-3.00) b	**<.001***
Both Dextrose injection and Intermaxillary Fixation	9.00 A, a (8.00-10.00)	1.00 B, b (0.00-2.00)	.00 B, b (0.00-1.00)	**<.001***
Kruskal Wallis test (P value)	**.641**	**<.001***	**<.001***	
		Muscle tenderness		
Dextrose injection	7.00 A, a (1.00-10.00)	3.50A, b (0.00-5.00)	3.00 A, b (1.00-4.00)	**<.001***
Intermaxillary Fixation	7.50 A, a (0.00-10.00) a	0.00 B, b (0.00-3.00) b	0.00 B, b (0.00-1.00) b	**<.001***
Both Dextrose injection and Intermaxillary Fixation	8.00 A, a (5.00-9.00)	0.00 B, b (0.00-2.00)	.00 B, b (0.00-1.00)	**<.001***
Test of Kruskal Wallis P value				

Me; median, Mini; minimum, Maxi; Maximum; *p had significance to level of 5%. All capital letters at each column showed a difference of significance through each 2 comparative groups (Mann Whitney test, p lower than.05). Similar capital letters at each column showed nondifference of significance among every 2 groups (test of Mann Whitney, p>.05). Different small letters at the raw itself showed a difference significance among each bi-observations (test of Wilcoxon signed ranks, p lower than .05). Similar small letters at each raw showed non- difference of significance through each 2 comparative observations (test of Wilcoxon signed ranks , p more than .05)

TABLE (2) Comparison of mean mouth opening, condylar translation and shift between groups and observations

	Pre X1±SDe	T1 X1±SDe	T3 X1±SDe	Repeated Measures ANOVA P value
		Mouth opening		
Dextrose injection	57.08±4.42A,a	43.08±3.15A,b	48.83±2.62A,c	**<.001***
Intermaxillary Fixation	57.67±4.89A,a	31.92±2.23B,b	41.33±2.90B,c	**<.001***
Both Dextrose injection and Intermaxillary Fixation	60.58±3.70A,a	29.00±2.86C,b	36.42±1.83C,c	**<.001***
Repeated Measures ANOVA (P value)	**.125**	**<.001***	**<.001***	
		Shift		
Dextrose injection	1.83±1.19A,a	.42±.51A,b	.58±.67A,b	<.001*
Intermaxillary Fixation	2.50±1.17A,a	.17±.39A,b	.25±.45A,b	<.001*
Both Dextrose injection and Intermaxillary Fixation	1.92±.90A,a	.25±.45A,b	.08±.29A,b	<.001*
Repeated Measures ANOVA (P value)	.281	.401	.055	

X1; mean, SDe; Standard deviation; *p has significance at level of5%. Different capital letters through each column showed a significant difference through each 2 comparative groups (Bonferroni test, p lower than 05). Similar capital letters through each column showed non- significant difference through each 2 comparative groups (Bonferroni test, p more than .05). Different small letters through each raw showed a significant difference between each 2 observations (Bonferroni test, p<.05). Similar lower letters in the same row showed non- significant difference through each comparative 2 observations (test of Bonferroni, p more than.05)

TABLE (3) Comparison of condylar translation between groups and observations :

	Pre X1±SDe	T1 X1±SDe	T3 X1±SDe	Repeated Measures ANOVA P value
		Condylar translation		
Dextrose injection	9.17±1.03A,a	7.17±.58A,b	7.75±.63A,c	<.001*
Intermaxillary Fixation	9.50±1.17A,a	6.25±.45B,b	7.00±.00B,c	<.001*
Both Dextrose injection and Intermaxillary Fixation	9.83±.1.19A,a	5.83±.39C,b	7.00±.00B,c	<.001*
Repeated Measures ANOVA (P value)	.365	<.001*	<.001*	

X1; mean, SDe; Standard deviation; *p has significance at level of5%. Different capital letters through each column showed a significant difference through each 2 comparative groups (Bonferroni test, p lower than 05). Similar capital letters through each column showed non- significant difference through each 2 comparative groups (Bonferroni test, p more than .05). Different small letters through each raw showed a significant difference between each 2 observations (Bonferroni test, p<.05). Similar lower letters in the same row showed non- significant difference through each comparative 2 observations (test of Bonferroni, p more than.05)

DISCUSSION

The current study reported patients suffering from Recuurent TMJ hypermobility that were treated by dextrose 25% prolotherapy in multiple sessions , IMF for short-term therapy, or combined treatment of both modalities.The primary findings were joint dislocation, pain, and sound of clicking or crepitus, in addition to masticatory muscles tenderness, mid-line mandibular shift, maximum mouth opening, and condylar translation.That were improved through follow period but with difference in between groups towards favour side of combied treament group (Gruop C), so these outcomes suggested favourable therapeutic results of the study with short-term treatment in all groups. Results of prolotherapy, and IMF varried widely in literature, as some stated inconsistent results[21,42] others said non-significant outcomes were gained either clinically or radiographically through short-term treatment[26]. Some other researches mentioned that progressive improvement was attained which was in agreement to outcomes obtained in the current study [19,31,34,35]. In addition most of previous studies used short-term acting local anaesthetics during prolotherapy or IMF as lignocaine that was effective only for 5-10minutes[37], in contrast to the current study that Articaine long acting local anaesthetic was used during tratment and its effect was lasting efficiently for suffient longer period of time. All procedures of the current study were done in out-clinic which were simple,easy,time saving and economic. Other studies stated different concentrations of prolotherapy use in addition to varible injection sessions from single to multiple [37,38,39,43,44,45].The current study used dextrose 25% for six sessions and in (group C) IMF was applied for 2 weeks .

Pain was evaluated using VAS scores on a scale of 0–10 for follow up period in all groups. For group A median score prior to the treatment was 9.00a, Median score of pain after 1 month was 4.50b, while after 1-year Median score of pain was 4.50b. There was a significant difference in median scores in aching pain among observations, which was similar to clinical outcomes obtained from multiple other researches [16,17,19,20,21,24]. For group B median score prior to the treatment was 9.00a, Median score of pain after 1 month was 3.00b, while after 1-year Median score of pain was 1.00b. There was a significant difference also through median scores in aching pain among observations. Which was in

a line with studies of other researches [38,44,45]. For group C: median score prior to the treatment was 9.00a, Median score of pain after 1 month was, Median score of pain after I month was 1.00b, while after 1-year Median score of pain was. 00b. There was too significant difference in median scores of pain between observations. Results in the current study were more superior to that obtained in other studies and this may be due to number of prolotherapy injections and/or drug concentration that was combined with IMF. [38,44,45].

For all groups, pain scores significantly decreased with time. The highest pain scores were noted with preoperative observation, followed by 1 month and the lowest pain scores were noted 1 year postoperatively. Pain significantly decreased from preoperative to 1 month postoperatively. However, no significant difference was noted between 4 weeks and 12 months after the interference period. So, there was a significant difference between each 3 observations except between 1 month and 1 year postoperatively, which in agreement with other multiple previous studies, that showed progress in pain reduction after using conservative, and minimal invasive procedures as used in the current study.[37-39] It was noticed that at 1year three cases were suffering from moderate pain, and all are related to group of prolotherapy injection alone (group A), and this may be attributed to heavy mouth use or psychological stresses led to masticatory muscles spasm that led to moderate pain but not relapse of these cases.

Ungor et al. [42] noticed a significant decrease at TMJ aching after dextrose prolotherapy of concentration 10%, which had in a consistence with the findings of the current investigation.

Additionally, the study by **Refai et al.**[31] revealed as mean pain prior treatment had 6.72±2.78, but after 10% dextrose prolotherapy, it decreased to 0.61±1.57 at the final follow-up visit. This had in line with our study, but the difference may be attributed to sample size and follow up period or prolotherapy concentration.

The study by **Cömerte Kilik et al.** [34] found that the preoperative mean of aching pain had 4.30 ± 2.57, but following 12.5% dextrose prolotherapy, it decreased to 0.89 ± 1.45 at the conclusion of the follow-up. which is consistent with the findings of the current investigation with minimal difference may be due to data distribution in other study or drug concentration.

Similarly, **Pandey et al.,** [11] reported that at all follow-up visits, 25% dextrose prolotherapy produced superior outcomes than autologous blood prolotherapy in terms of lowering pain intensity (VAS scale). In group A, intensity of aching pain decreased as start 5.1±1.52 and descend to 1.7±0.48, but at group B, it decreased from 5.4±1.26 to 0.8±0.79 which in agreement with results of this study and slight difference may be attributed to number of injections given for each patient. So multiple injection in the current study gained superior results than that collected after single injection in other studies.

There was statistic non-significant difference at the severity to discomfort among the two comparative groups (dextrose prolotherapy and IMF), according to Adam et al. [38]. This outcome is in line as the findings of Alderman et al. [40] and Refai et al.[39]. Similarly, Mustafa et al. [41] found no intergroup difference but a statistically significant difference in pain reduction between the dextrose and placebo groups. So results gained from the current study were compatible with that of multiple other studies.

Muscle tenderness was assessed by presence or absence of masticatory muscles tenderness on palpation. For (group A) median score prior to the treatment for muscle tenderness was 7.00a, Median score of muscle tenderness after I month was 3.50b, while after 1-year Median score of muscle tenderness was 3.00b. There was a significant difference to median scores in muscles pain among observations, which was in agreement with results obtained from multiple other researches. [37,39,42,43] For (group B) median score prior to the treatment was 7.50a, Median score of muscle tenderness after

1 month was.00b, while after I year median score of muscle tenderness was .00b. There was a significant difference to median scores in muscles aching among observations, which was in a line with results obtained from other researchers[38,44,45]. For (group C) median score prior to the treatment was 8.00a,Median score of muscle tenderness after 1 month was, Median score of muscle tenderness after 1 month was 0 .00b, while after 1 year median score of muscle tenderness was 0. 00b. Here there was a significant difference also to median scores in muscles pain among observations, which was similar to results gained from other studies. [44,45]

For all groups, there was a significant difference at median scores in muscle tenderness among different observations, and muscle tenderness scores significantly decreased with time. The highest muscle tenderness scores were noted with preoperative observation, followed by 1 month postoperatively and the lowest muscle tenderness scores were noted with 1 year postoperatively, also for all groups, muscle tenderness significantly decreased from preoperative to 1 month postoperatively. However, no significant difference was noted between 4 weeks and 12 months at the post-interference period. There was a significant difference between each 2 observations except between 1 month and 1 year postoperatively. this was in agreement with results gained in other multiple studies[16,19,20,21,24,26,27,34,38,44,45].It was noticed that three cases were suffering from muscle tenderness and all are related to (group A) and this was at 1 year, that may be attributed to heavy mouth use or psychological stresses led to muscle spasm, and so to relapse of these cases but with notice that all were related to group of prolotherapy injection alone (group A).

Maximal Mouth Opening was assessed through the average intrinsic vertical mouth opening (between the upper and lower central incisors) measured by Caliper Electronic Digital LCD Screen Micrometer at preoperative, 1 month, and 12 months postoperative. In (group A): mean± SD of maximum mouth opening prior to the treatment was 57.08a ± 4.42, mean± SD of pain after 1 month was 43.08b±3.15, while after 12 months mean± SD of mouth opening was 48.83c± 2.62. There was a significant mean difference in mouth opening between observations. The obtained results here were similar to results of other studies[37,39,42,43]

In (group B): mean± SD of maximum mouth opening prior to the treatment was 57.67a ± 4.89, mean± SD of pain after 1 month was 31.92b ±2.23, while after 12 months mean± SD of mouth opening was 41.33c± 2.90. There was too a significance of mean difference at mouth opening among observations. Results of this group were coherent with results of other studies. [38,44,45]

In (group C): mean±SD of maximum mouth opening prior to the treatment was 60.58a±3.70, mean± SD of pain after 1month was 29.00b ±2.86, while after 12 months mean±SD of mouth opening was 36.42c± 1.83. There was a significance of mean difference at mouth opening among observations. Gained results of this group were in a line with results of other researchers[38,44,45]

For all groups, the highest maximum mouth opening was noted with preoperative observation, followed by 12 months postoperatively, and the lowest mouth opening were noted after 1month postoperatively. So maximum opening of mouth had decreased significantly from pre- interference to 1month post-interference, then significantly increased again at 1year post-interference. There was a significant difference among each 2 observations. Which may be attributed to inflammatory reaction succeeded with each prolotherapy injection till a lot of micro-collagenous fibrils strengthen joint capsule and ligaments (groups 1,3),and in (group 2) that had IMF may be due to relaxation and hypoactivity of the joint and associated muscles that gave chance for tissue repair and decrease of inflammatory mediators within affected tissues, and so significant decrease in opening occur at 1 month but with time and mouth function return slightly to its pre-operative state. That may be due to muscle tris-

mus from psychological stresses or any other else as inflammatory mediators re-accumulation. This may explain the gained increase again in mouth opening in all groups at one-year post-operative but still lower than the base line scores, but maximum increase in mouth opening, as well mid line mandibular shift was noticed in group A at 1 year. Noticeably this group show semi relapse to 3 patients as deterioration in their records return near baseline and explanation was attributed to heavy occlusal load, repeated cycles of spastic muscles pull, and/or psychological stresses that led to moderate deterioration in those patients.

In line with the findings of the current investigation, **Pandey et al.,** [11] reported that, MMO decrease was commencing in the second week following prolotherapy and continuing during the six-month follow-up, a statistic significant difference in MMO had observed among prolotherapy of autologous blood and prolotherapy with dextrose concentration of 25%. When it came to reducing the maximal mouth opening, autologous blood prolotherapy outperformed 25% dextrose prolotherapy.

These findings were also similar to those of a study by **Hegab AF** [44], where the MMO decreased from 49.76 ± 0.90 mm to reach 42.96 ± 0.97 mm after conclusion that autologous blood injection is a medication. In the current study, groups (A, C) MMO decreased nearly in a similar manner which is in line with the previous research results.

The MMO descended hence started 50.38 ± 7.63 mm to reach 46.15 ± 7.02 mm in the research of **Refay.** [31], as utilized dextrose prolotherapy of 10% concentration, while MMO descend from 46.14 ± 6.89 mm as reach 43.29 ± 5.92 mm at the finite of medication at the study from **Cömerte Kilik et al.** [34], which had utilized dextrose prolotherapy concentration of 12.5%. Results of the current study were more superior to the gained results of both studies, and this may be explained on the basis of difference in used prolotherapy concentration (25%), and number of injection sessions (6) that led to more better study findings in this research.

In (group A): mean± SD of maximum mouth opening (MMO) prior to the treatment was 57.08a ± 4.42, mean± SD of (MMO) after 1 month was 43.08b±3.15, while after 12 months mean± SD of (MMO) was 48.83c± 2.62. There was a significant difference in mean (MMO) between observations. In (group B): mean± SD of (MMO) prior to the treatment was 57.67a ± 4.89, mean± SD of (MMO) after I month was 31.92b ±2.23, while after 12 months mean± SD of (MMO) was 41.33c± 2.90. There had a significant difference mean mouth opening among observations. In (group C): mean± SD of (MMO) prior to the treatment was 60.58a ± 3.70, mean± SD of (MMO) after 1month was 29.00b ±2.86, while after 3 months mean± SD of (MMO) was 36.42c± 1.83. There was a significant difference in mean mouth opening among observations. The previous results were in a line with multiple previous studies and more superior to some others. [11,31,34,37-39,42-45]

Computerized tomography was used to measure the degree of Condylar translation in sagittal views and 3-D computerized tomography. In (group A): mean±SD of condylar translation prior to the treatment was 9.17a±1.03, mean±SD of condylar translation after 1 month was 7.17b±.58, while after 12 months mean±SD of condylar translation was 7.75c±.62. There was a significant difference in mean condylar translation among observations. This was in agreement with results of other researchers [16,17,19,21,37,39]. Outcomes of this group were more superior to results of other studies that may be due to used prolotherapy type and/or concentration in addition to number of prolotherapy injections as some of other studies used autologous blood, dextrose (10% ,12.5%), as well prolotherapy injections number ranged from single one to multiple injections[31-35]. But current results were in a line with other researchers who used dextrose (25%, or 50%), and multiple injection sessions.[36,37]

In (group B): mean± SD of condylar translation prior to the treatment was 9.50a±1.17, mean±SD of condylar translation after I month was 6.25b±.45, while after 12 months mean± SD of condylar

translation was 7.00c± .00. There was a significant difference in mean condylar translation between observations. These outcomes were compatible with results in other studies. [38,44,45]

In (group C): mean± SD of condylar translation prior to the treatment was 9.83a ±1.19, mean± SD of condylar translation after 1month was 5.83b ±.39, while after 12 months mean± SD of condylar translation was 7.00c± .00. There was a significant difference in mean condylar translation among observations, and the current results were in agreement with results of other researches. [38,44]

In all groups, there was a significant difference in mean condylar translation among observations. The highest condylar translation was noted with preoperative observation, followed by 12 months postoperatively, and the lowest condylar translation was noted with 1 month postoperatively. Hence, condylar translation significantly decreased from preoperative to 1 month postoperatively, then significantly increased again at 1 year postoperatively. There was a significant difference among each two of observations, and this may be attributed to inflammatory response that was initiated to prolotherapy with multiple sessions of injection that led to augment laxity of joint capsule, and ligaments by collagenous microfibrils. Although this collagenous augmentation with time becomes weakened again slightly with muscle activity and mouth functions. In case of (group B) the decrease from preoperative to one month postoperative may be due to limitation of mouth movement and muscular hyperactivity decrease of offending muscles, and so at one year postoperative it was noticed an increase again in condylar translation, as these muscles regained part of its hyperactive muscle tone again although still it was below baseline scores, Which was considered a value of the associated treatment (IMF). It was noticed that best results were seen in (group C), and the explanation may be due to combination of treatment modalities that was used in this group.

In a similar vein, **Pandey et al.,** [11] discovered that while both groups(autologous blood, and 25% dextrose) demonstrated positive outcomes in terms of a decrease in the incidence of dislocation, no statistic significant difference among them was observed to any of follow-up recalls.

According to a study introduced by **Machone et al.,** [43] 20 from 25 patients did not suffer from another aching episode of TMJ dislocation following an injection of autologous blood, and this showed that different materials may be used in prolotherapy for treatment of joint dislocations.

Zhou et al. [37] observed that 50% dextrose prolotherapy significantly reduced the frequency of dislocation episodes in TMJ hypermobility subjects. According to **Refai et al.** [31], 10% dextrose prolotherapy resulted in a considerable decrease in the mean frequency of luxation and no locking occurrences at the end of the research, and this was in line to current study although different concentration of dextrose was used, and this showed that many concentrations are used in researches but this study results were hopeful as this may be attributed to multiple sessions of injection at many sites and results are followed for one year, but still other studies are needed on larger sample size and more follow time and to determine ideal concentration , and sessions number needed in prolotherapy for recurrent dislocation .

IMF could be utilized either alone or in conjunction with other treatments for persistent recurrent dislocation of the TMJ. A (3 - 6) weeks limitation period was advised in the former scenario. [44] Ertaş [45] stated that in order to avoid the risk of ankylosis, a lower limit of three weeks was taken. According to other researches , patients who were kept in IMF for more than six weeks developed fibrous or osseous ankylosis. Furthermore, neither the IMF alone nor in conjunction with sclerosing agents produced any generally desirable results [34-45]. This was in contrary to gained results in the current study that showed progress in all groups and more superior

results were associated with combined treatment group, and hopefully no dislocation episode was recure till the follow-up end with all treatment groups.

CONCLUSION

Within the limitations of this study, for chronic recurrent TMJ dislocation, prolotherapy and IMF should be the primary line of conservative treatment. 25% dextrose prolotherapy was a straightforward, safe, and economical therapeutic option for recurring these TMJ dislocations. It was more helpful for individuals who experience pain from chronic recurrent dislocations, however combination of prolotherapy with IMF of jaws for 2 weeks gave more superior results to prolotherapy only or IMF alone, as this was noticed clinically and radiographically after follow-up of patients for one year. More future studies are needed with more follow-up period and larger sample size.

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