Efficacy of Pulsed Radio Frequency Energy Therapy in Temporomandibular Joint Pain and Dysfunction

Emad A. Al-Badawi, B.D.S., M.S.; Noshir Mehta, D.M.D., M.D.S., M.S.; Albert G. Forgione, Ph.D.; Silvia Lobo Lobo, D.D.S., M.S.; Khalid H. Zawawi, B.D.S.

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Address for reprint requests:
Dr. Emad A. Al-Badawi
Dept. of Pediatric Dentistry
Tufts University School of Dental Medicine
8th Floor
One Kneeland St.
Boston, MA 02111
E-mail: ealbadawi@aol.com

ABSTRACT: This randomized double-blind study evaluated the effectiveness of pulsed radio frequency energy therapy (PRFE) in patients with temporomandibular joint arthralgia. Forty subjects (age range 22 to 55 yrs.) were assigned randomly into two equal groups: (1) Experimental group received PRFE using the Energex unit (Energex, Inc. Emerson, New Jersey) and (2) Control group received PRFE placebo treatment using a sham device. Both groups received six applications to the TMJ area over two weeks. Data were analyzed for the following times: baseline, first and second follow-up visits. Numerical Rating Scale scores for TMJ pain showed a significant reduction over time for the experimental group (mean = 6.13 to 3.05, p<0.001). There was also a significant effect for the controls (mean = 5.35 to 4.20, p=0.01). The effect for experimental subjects was a mean reduction of 3.07 versus 1.15 for controls. The significant reduction in controls was attributed to the placebo effect. The experimental group showed a significant increase in mouth opening (mean = 34.95 to 41.70 mm, p=0.002), right lateral movement (mean = 7.85 to 10.80 mm, p=0.001) and left lateral movement (mean = 7.65 to 10.85 mm, p<0.0001). No significant (p>0.1) change in the control group occurred for mouth opening (mean = 38.50 to 39.65 mm), right lateral movement (mean = 8.60 to 8.75 mm) and left lateral movement (mean = 8.50 to 8.80 mm). No side effects were reported during the treatment and the two week follow-up. These results suggest strongly that PRFE is a safe and effective treatment for TMJ arthralgia as well as for increasing mandibular range of motion.

Dr. Emad A. Al-Badawi *received his B.D.S. degree at King Abdulaziz University, Faculty of Dentistry in Jeddah, Saudi Arabia in 1995. He spent the next three years as an oral surgery resident at King Fahad Hospital, Jeddah, Saudi Arabia. In 1998 he joined the TMD and Orofacial Pain program at the Craniofacial Pain Center at Tufts University School of Dential Medicine and was awarded the Master of Science Degree in 2001. Currently, Dr. Al-Badawi is a senior resident at the Pediatric Dentistry De-partment, Tufts University School of Dental Medicine.*

The major objectives in the treatment of temporomandibular joint disorder (TMD) are to reduce or eliminate pain, joint noises and to restore normal mandibular function. It is well established that the majority of patients with TMD achieve relief of symptoms with conservative measures.[1-5] There are numerous nonsurgical treatments for TMD, each reflecting the treating clinician's training and working hypotheses about its etiology. The conservative approach for nonsurgical treatment may range from a dentist working alone to a multidisciplinary team consisting of a dentist, neurologist, physiotherapist, occupational therapist, and chiropractor. The treatment may include one or any combination of medication, occlusal splint therapy, physiotherapy, behavioral therapy and psychotherapy.

One important modality is physiotherapy which is considered by many as one of the established methods of alleviating TMD symptoms.[6] The aim of physiotherapy in the treatment of TMD is to relieve pain, reduce muscle spasm, improve joint mobility, and restore functions.[7,8] The most commonly employed methods of electro-

physiotherapy have been: transcutaneous electrical neural stimulation,[9-11] short wave diathermy,[12-16] megapulse,[17-20] ultrasound,[21-23] laser,[9,24] and interferential current stimulation.[25] Although physiotherapy may be used as the sole treatment, it may be combined with occlusal splint therapy and pharmacological management. The combination approach has been reported to result in more rapid symptom relief, decreased treatment time and overall superior therapeutic outcome.[26]

Pulsed Radio Frequency Energy (PRFE) is one type of physiotherapy used to eliminate pain associated with joint arthritis. Energex (Energex, Inc. Emerson, New Jersey) is a noninvasive therapeutic device that generates radio frequency audio energy in the form of a combined visible/audible corona discharge beam. The pulsed corona discharge energy is generated by an AC power source. The discharge ionizes the air within the applicator tube. This discharged energy is ground seeking and will be directed towards the affected joint. The output frequency of the device is in the 250 kHz range, and the energy is pulsed on and off at 600 Hz.

Munglani, et al.[27] treated four patients with pulsed radio frequency. The patients demonstrated neuropathic pain and poor response to prior treatment. He found significant results, but the placebo effect was not controlled. Crawford, et al.[28] conducted an animal study with induced arthritis to find out if PRFE therapy could be used for treatment of arthritis and to inhibit the progression of inflammation. He also evaluated the application of two different dosages of PRFE (two and four 11-seconds bursts) in a healthy joint to determine any unwanted effects. They concluded that significant effects were obtained when PRFE was used. The changes occurred in range of motion, degree of swelling, and radiographic changes. Reduced severity and duration of lameness, reduced swelling of the carpus and reduced severity of gross pathological and radiographic signs of inflammation, were observed. No detectable harmful effects were present in normal joints exposed to PRFE.

Another animal study using a rabbit model[29] was designed to assess and evaluate soft tissue and cartilage damage that might occur during application of PRFE. Two areas of the rabbit were selected: the ear and the knee joints. The author used three treatment modes of six, twelve, and 18 fifteen-second applications. Histologic assessment of the tissues showed no evidence of cellular damage or disruption in the ligaments or articular cartilage and no vascular disruption. No noticeable changes were observed in treated tissues compared to the opposite side.

A human study[30] was conducted by Dupuis to evaluate the safety and effficacy of the PRFE in subjects with chronic musculoskeletal, joint, ligament, and tendon pain of inflammatory origin (excluding rheumatoid arthritis). Treatment consisted of ten sessions (four 15-seconds each) on successive days, with an optional five additional sessions after one week. A Visual Analog Scale (VAS) was used to assess the pain level. No skin complications were found and no subjects were made worse with treatment. Either pain relief or significant improvement occurred in 62.59% of the subjects while no change occurred in 37.5% of the subjects. The study did not address how long the treatment effect lasted.

These preliminary findings indicate that there is promise in using PRFE therapy in the treatment of TMJ arthralgia. To the authors' knowledge, there have been no studies to date that evaluated the effect of PRFE therapy on temporomandibular joint arthralgia.

Therefore, the primary purpose of this study was to evaluate the effect of PRFE in patients presenting with temporomandibular joint arthralgia. The signs of TMJ arthralgia are: 1. pain and tenderness in the joint capsule and/or the synovial lining of the TMJ; 2. pain in one or both joint sites (lateral pole and/or posterior attachment) during palpation; and 3. one or more of the following self reports of pain: pain in the region of the joint, pain in the joint during maximum unassisted opening, pain in the joint during assisted opening, pain in the joint during lateral excursion.

A secondary purpose of this study was to evaluate the safety and tolerance of PRFE over a two-week period of multiple administrations.

Materials and Methods

Subject Selection

Forty subjects, nine males and 31 females (ages 22-55 years) were selected in order of appearance from people either responding to posted ads or patients seeking treatment at the Craniofacial Pain Center at Tufts University School of Dental Medicine. The inclusion criteria were: 1. ambulatory, age greater than 21; 2. have a clinical diagnosis of temporomandibular joint arthralgia as defined by the research diagnostic criteria[31]; 3. suffer from no systemic illnesses, no cardiac disease, no pacemaker, or other conditions that could be affected by radio frequency discharge beams; 4. have no prosthetic joint replacement or placement of any metallic surgical device in or around the area of treatment; 5. have had no intra-articular steroid injection in the past three months; 6. not currently taking any constant dose of nonsteroidal anti-inflammatory or narcotic analgesic drugs; and 7. be engaged in no other therapeutic modality during the period of the study. Subjects were excluded if they

required medication and/or physiotherapy that might confound study results.

The study was approved by the Human Investigation Research Committee at Tufts University Health Sciences. Informed consent was obtained from each subject, and the study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki.

Subjects were assigned randomly to two equal groups: 1. the Experimental Group, received the PRFE treatment to the affected joint area using the Energex unit; and 2. the Control Group, received PRFE placebo treatment to the affected joint area. The sham device had identical sound, light, and appearance as the experimental unit but did not emit radio frequency waves.

Measuring Instruments

Pain level was assessed using the 10-point Numerical Rating Scale (NRS) where zero = *no pain* and 10 = *pain as bad as it can be.* The NRS was found to be statistically sensitive when measuring pain and discomfort.[32] Also it is sensitive to pharmacologic and nonpharmacologic procedures that alter the experience of pain, and it correlates highly with pain levels.[33-38]

The Therabite Range of Motion Device (Therabite Corp., Newton Square, Pennsylvania) was used to measure mandibular movements (maximal interincisal opening, right and left lateral excursion in millimeters).

The safety of PRFE therapy using the Energex (Energex, Inc. Emerson, New Jersey) device was evaluated by a questionnaire which assessed all anticipated and unanticipated adverse events that might occur to each subject during study participation.

Blinding Procedure

A nonresearch team member assigned subjects randomly into two equal groups without the researchers' awareness. Code numbers were kept in the control of this independent person and were not disclosed to any of the researchers until the experiment was completed. Each subject received a code number followed by the letter "A" or "B". These letters were used to inform the clinician as to which device was to be used (PRFE or placebo). One researcher administered the treatment, another researcher measured and recorded the pain level and the mandibular range of motion, unaware of which treatment device was used. His only role was to measure the pain and record the mandibular range of motion pre- and post-treatment.

PRFE Application Sequence

Both groups received treatment once every other day for two weeks for a total of six treatments. At each visit, treatment was composed of six treatment units of 15 seconds each separated by a seven second interval. Three treatment units were applied in a closed mouth position and three units in an open position. A total of 90 seconds of exposure occurred at each visit, resulting in a total of 540 seconds of exposure for the entire study.

At each visit, before and after application of the Energex device, subjects were assessed for the following: a) pain level using the NRS; b) mandibular range of motion using Therabite measuring tool (Therabite Corp., Newton Square, Pennsylvania); and c) determination of side effects.

Each administration of PRFE used the same energy level, duration and distance from the skin (2.0 cm). Subjects were asked to keep the same appointment times for every visit to assure uniform exposure with respect to the time of day. Following the six initial visits, the subjects returned for two follow-up visits, one week apart. No treatments were applied during these visits, but NRS and mandibular range of motion were reassessed.

Results

Statistical Analyses

TMJ pain, mouth opening, right lateral and left lateral movements were measured over one month at: 1. baseline (first visit, day 1); 2. first follow up (7th visit, day 19); and 3. second follow-up (8th visit, day 26).

A 2x3 analysis of variance (ANOVA) was conducted on mean scores of two groups (experimental vs. control) times three time periods (first visit [baseline], follow-up 1 and follow-up 2). A separate ANOVA was performed for each of the four measured sites. Post hoc multiple comparison *t*-tests were calculated.

I. TMJ Pain: The 2x3 ANOVA showed a significant main effect for visits ($F_{df=2}$= 49.3, $p<0.0001$). The effect for groups was not significant ($F_{df=1}$=0.8, $p>0.1$). The group by visit interaction was significant ($F_{df=2}$=9.3, p=0.0002). It can be seen in **Figure 1** and **Table 1** that the mean TMJ pain reduced significantly from experimental baseline to the first follow-up (mean= 6.13; SD=1.6 to 2.74; SD=2.3, $p<0.001$) and held at that level at the second follow-up (mean=3.05; SD=2.8, $p<0.001$). Mean pain in experimental follow-up 1 was not different from that of follow-up 2 showing a consistency in responding. Baselines for experimental and control groups were marginally significantly different (mean=6.12, SD= 1.6 vs. 5.35, SD= 1.6 $p<0.05>0.02$) and control baseline was found to be significantly different from follow-up 1 (mean=3.96; SD=2.0 $p<0.001$) and follow-up 2 (mean=4.2; SD=1.8, $p<0.01>0.001$). For

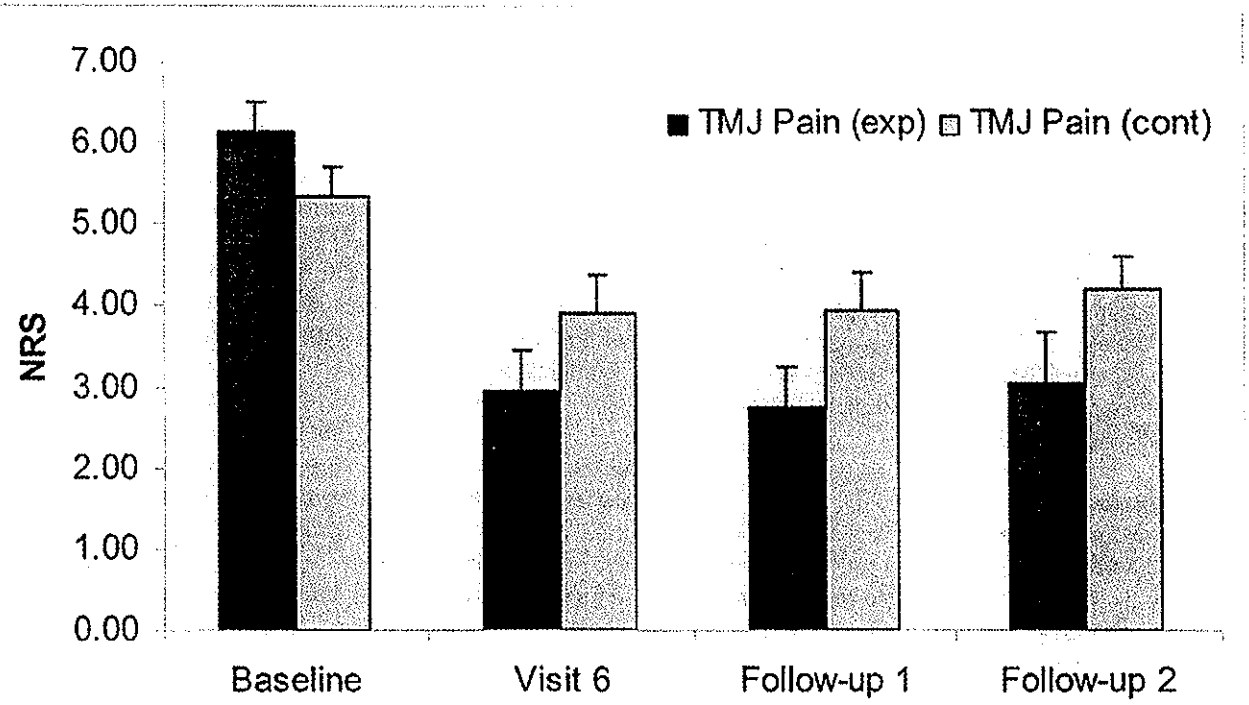

Figure 1
Mean Numerical Rating Scale (NRS) values for TMJ pain: Treatment period at Day 1 through first follow-up and second follow-up.

the control group, follow-up 1 was no different than follow-up 2 showing a consistency in responding over the follow-up periods. Therefore a significant reduction in pain occurred in both experimental and control groups. This obliged a comparison of the size of the reduction in both groups. The mean difference between baseline and second follow-up for both placebo and experimental pain groups was calculated. It was found that the mean difference of both groups was significantly different from baseline. **Figure 2** shows that the mean difference from baseline in the control group is 1.15 and in the experimental group 3.07. The difference between the two means is 1.92, 166.9% greater than the placebo value. Although both groups were found to be significantly different from baseline, the effect size of the control group is much smaller than that of the experimental group. The mean difference of 1.15 for the

Table 1
Factorial Analysis of Variance for TMJ Pain

	Exp. baseline	Exp. 1st F/U*	Exp. 2nd F/U	Control baseline	Control 1st F/U	Control 2nd F/U
Experimental group baseline	X	<0.001	<0.001	<0.05 >0.02	<0.001	<0.001
Experimental group 1st F/U		X	NS	<0.001	<0.01	<0.001
Experimental group 2nd F/U			X	<0.001	<0.02	<0.01
Control group baseline				X	<0.001	<0.01
Control group 1st F/U					X	NS
Control group 2nd F/U						X

*F/U = follow-up

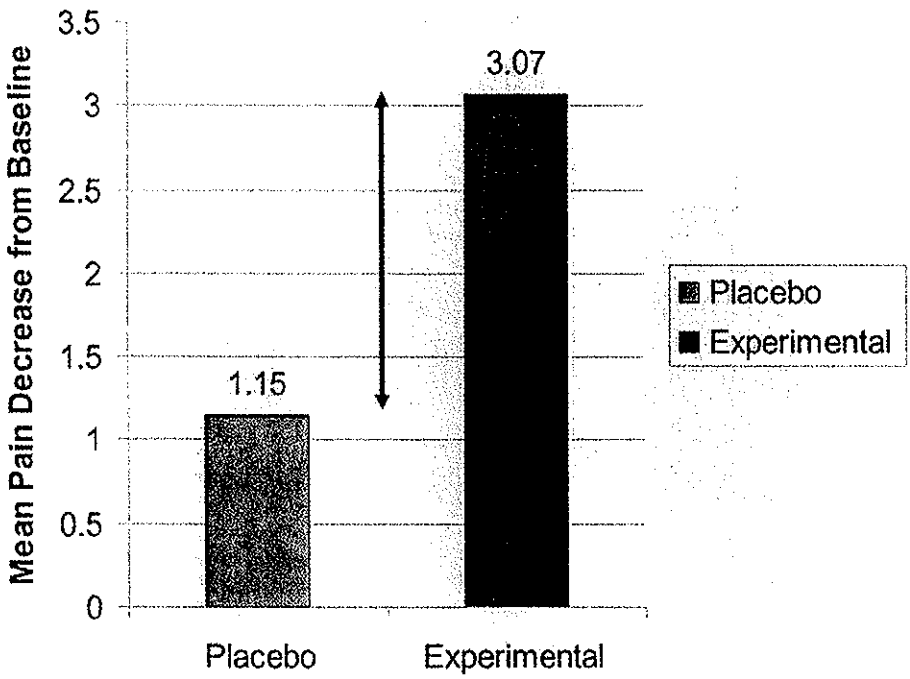

Figure 2
Mean difference between baseline and second follow-up for placebo and experimental groups. Arrow shows that although both groups were significantly greater than baseline, the experimental group's mean of 3.07 is 1.92 points (166.9%) greater than the placebo group.

placebo group indicates that a portion of the experimental response is most likely the contribution of the placebo effect.

Table 1 shows that the experimental baseline is greater than control follow-up 1 and follow-up 2. Experimental follow-up 1 and follow-up 2 are significantly less than all control measures. The mean pain of experimental baseline is greater than all control follow-up 1 and follow-up 2 values, which means there was significant reduction in the control group when compared with experimental baseline.

II. Mandibular Range of Motion:

a. Mouth Opening : A 2x3 ANOVA was conducted to evaluate mouth-opening measurements over the visits for both groups. There was a significant main effect for visits ($F_{df=2}$= 20.3, p=0.0001). The effect for group was not significant ($F_{df=1}$ = 0.02, p>0.1) but group by visit interaction was significant ($F_{df=2}$=10.4, p=0.0001).

The results (**Table 2**) showed that there was a significant increase in mouth opening from experimental baseline to the first follow-up (mean=34.95mm; SD=6.7 to 41.8mm; SD=6.4, p=0.001) and held at that level to the second follow-up (mean=41.7mm; SD= 6.5, p=0.001) (**Figure 3**). The experimental mean of FUl was not different

Table 2
Factorial Analysis of Variance for Mouth Opening

	Control baseline	Control 1st F/U*	Control 2nd F/U	Exp. baseline	Exp. 1st F/U	Exp. 2nd F/U
Control group baseline	X	NS	NS	<0.001	<0.01	<0.01
Control group 1st F/U		X	NS	<0.001	<0.05	<0.05
Control group 2nd F/U			X	<0.001	<0.05	<0.05
Experimental group baseline				X	<0.001	<0.01
Experimental group 1st F/U					X	NS
Experimental group 2nd F/U						X

*F/U = follow-up

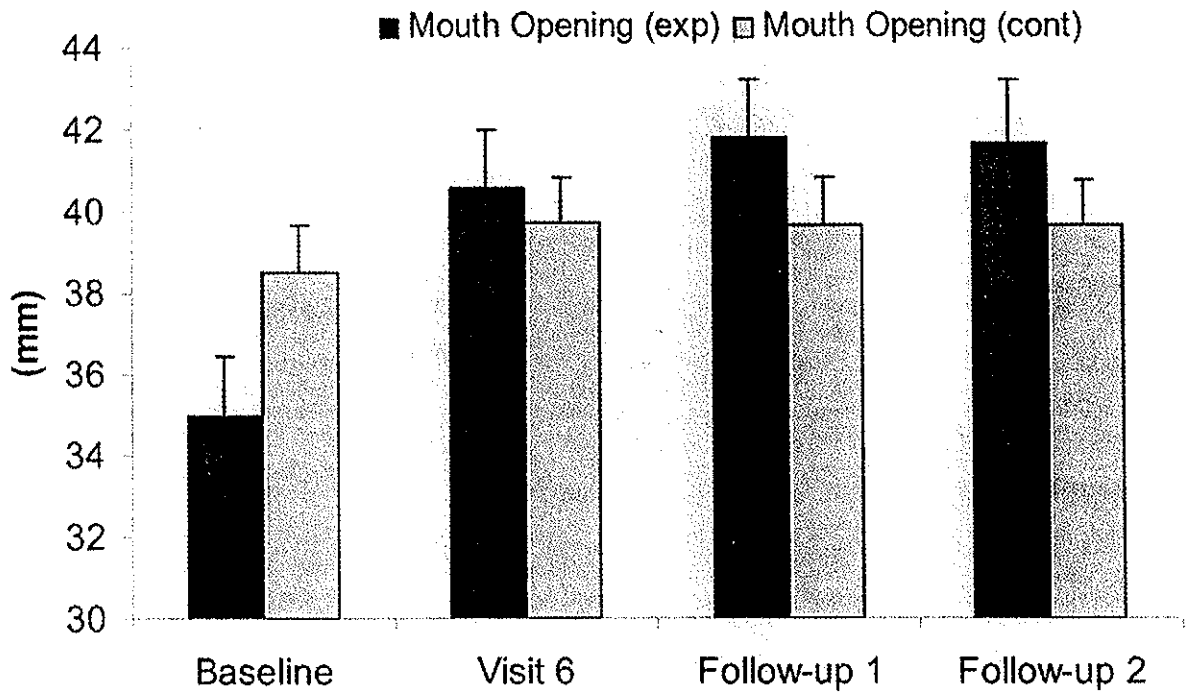

Figure 3
Mean (mm) for mouth opening: Treatment period is Day 1 through first follow-up and second follow-up.

from that of follow-up 2, showing a consistency in responding. Baselines for experimental and control groups were significantly different. The control baseline was not found to be significantly different from control follow-up 1 or follow-up 2. For the control group, follow-up 1 was no different from follow-up 2 showing a consistency in responding over the follow-up periods. The increase in mouth opening was greater in experimental follow-up 1 and follow-up 2 than all control measures.

b. Right Lateral Movement: A 2x3 ANOVA was conducted to evaluate the right lateral movement over the visits for both groups. The ANOVA indicated a significant effect for visits ($F_{df=2}$= 14.4, p=0.0001). The effect for groups was not significant ($F_{df=1}$ = 3.4, p=0.07). The group by visit interaction was also significant ($F_{df=2}$ = 11.7, p=0.0001).

The results showed that there was a significant change from baseline for right lateral movement at the first and second follow-up (mean=10.75 mm; SD=2.5 and 10.8 mm; SD= 2.7, respectively, p=0.001), when compared to baseline (mean =7.85 mm; SD=2.9) (**Figure 4**).

Table 3 shows that the experimental mean of follow-up 1 was not different from that of follow-up 2, showing a consistency in responding. Baselines for experimental and control groups were not significantly different. Control baseline was not found to be significantly different from control follow-up 1 or follow-up 2. For the control group, follow-up 1 was no different from follow-up 2 showing a consistency in responding over the follow-up periods. The increase in right lateral movement was greater in experimental follow-up 1 and follow-up 2 than all control measures.

c. Left Lateral Movement: A 2x3 ANOVA indicated a significant effect for visits ($F_{df=2}$=34.9, p<0.0001). The effect for group approached but did not attain significance ($F_{df=1}$=3.4, p=0.07). The group by visit interaction was also significant ($F_{df=2}$=24.1, p=0.0001).

The results showed that there was a significant increase in left lateral movement from experimental baseline to the first follow-up (mean=7.65mm, SD=2.4 to 10.9 mm; SD=1.9, p<0.001) as well as during the second follow-up (mean=10.85mm, SD=2.2, p<0.001) (**Figure 5**).

The experimental mean of follow-up 1 was not different from that of follow-up 2 showing a consistency in re-sponding. Baselines for experimental and control groups were significantly different. Control baseline was not found to be significantly

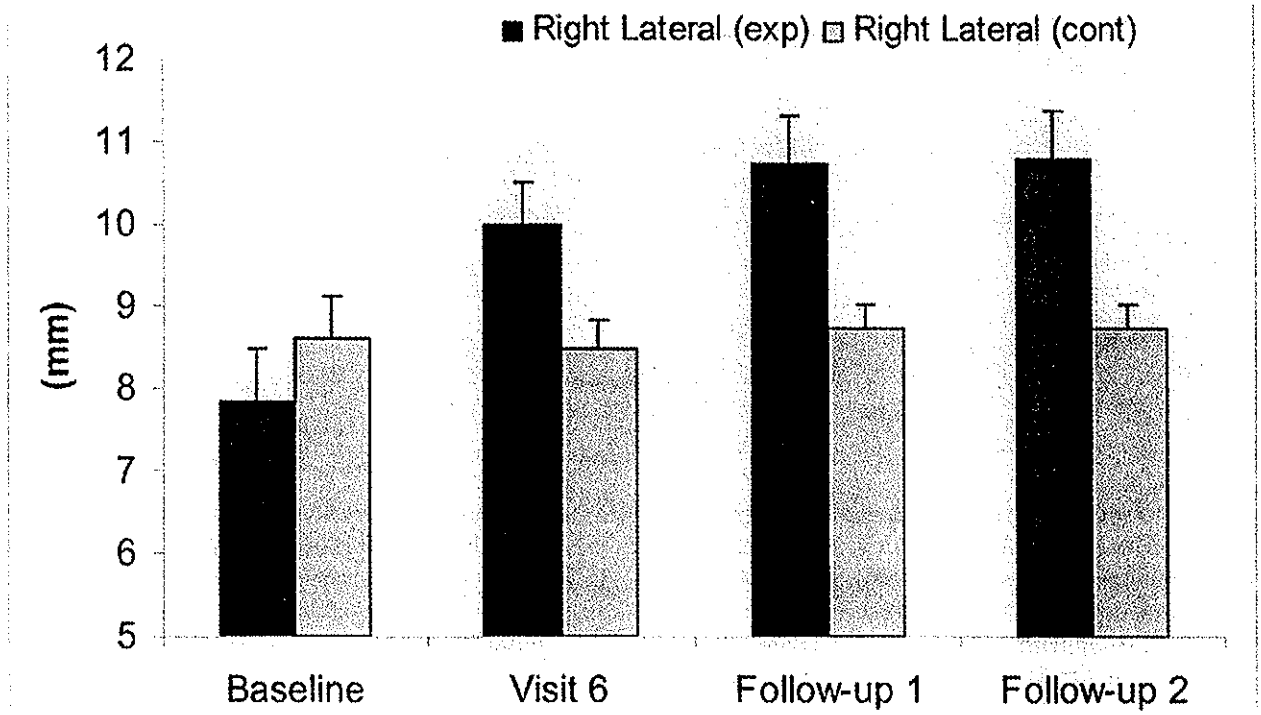

Figure 4
Mean (mm) values for right lateral movement: Treatment period is Day 1 through first follow-up and second follow-up.

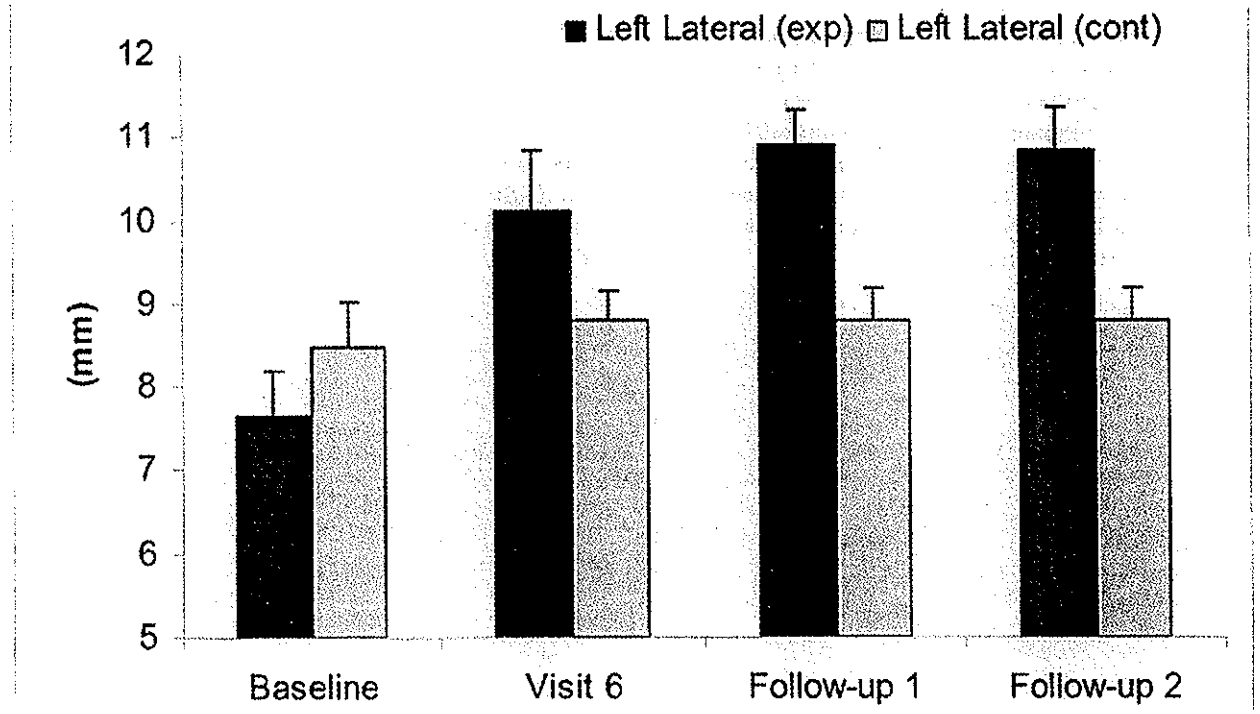

Figure 5
Mean (mm) values for left lateral movement: Treatment period is Day 1 through first follow-up and second follow-up.

Table 3
Factorial Analysis of Variance for Right Lateral Movement

	Control baseline	Control 1st F/U*	Control 2nd F/U	Exp. baseline	Exp. 1st F/U	Exp. 2nd F/U
Control group baseline	X	NS	NS	NS	<0.01	<0.01
Control group 1st F/U		X	NS	<0.001	<0.05	<0.05
Control group 2nd F/U			X	<0.001	<0.05	<0.05
Experimental group baseline				X	<0.001	<0.001
Experimental group 1st F/U					X	NS
Experimental group 2nd F/U						X

*F/U = follow-up

different from control follow-up 1 or follow-up 2. For the control group, follow-up 1 was no different from follow-up 2 showing a consistency in responding over the follow-up periods. The increase in left lateral movement was greater in experimental follow-up 1 and follow-up 2 than all control measures (**Table 4**).

Placebo Effect

Figure 6 shows the results of an overall analysis of the four measures using percent change from baseline. For ROM, the change in the percentage from baseline in the control group was minimal (approximately 2.75% compared to approximately 33% for the experimental group). In contrast, pain measure of the percent change (reduction) from baseline in the control group was 22%. The percent change for the experimental group was 50%. This level of reduction in the control group prompted another analysis of the pain data as it appeared that the pain measures were being affected by a variable (variables) not found in the ROM data (**Figure 2**).

III. Side Effects: The only unwanted effect was the high pitch sound of the device during application. In the treatment group one subject experienced slight redness and three subjects experienced a slight burning sensation at the treatment site only during PRFE application. One subject in the placebo group reported a tingling sensation over the application area. This sensation disappeared when stimulation stopped. These patients continued in the experiment to completion.

Discussion

There have been no previous studies on the effect of PRFE in the treatment of TMD. The present data indicate that a significant beneficial effect results from using PRFE in the treatment of joint pain. While both experimental and control groups started out at almost equal pain levels, both groups decreased significantly to a level, which was maintained over both follow-up sessions, **Figure 1**. The experimental group showed a significant

Table 4
Factorial Analysis of Variance for Left Lateral Movement

	Control baseline	Control 1st F/U	Control 2nd F/U	Exp. baseline	Exp. 1st F/U	Exp. 2nd F/U
Control group baseline	X	NS	NS	<0.02	<0.001	<0.001
Control group 1st follow-up		X	NS	<0.01	<0.001	<0.001
Control group 2nd follow-up			X	<0.01	<0.001	<0.001
Experimental group baseline				X	<0.001	<0.001
Experimental group 1st follow-up					X	NS
Experimental group 2nd follow-up						X

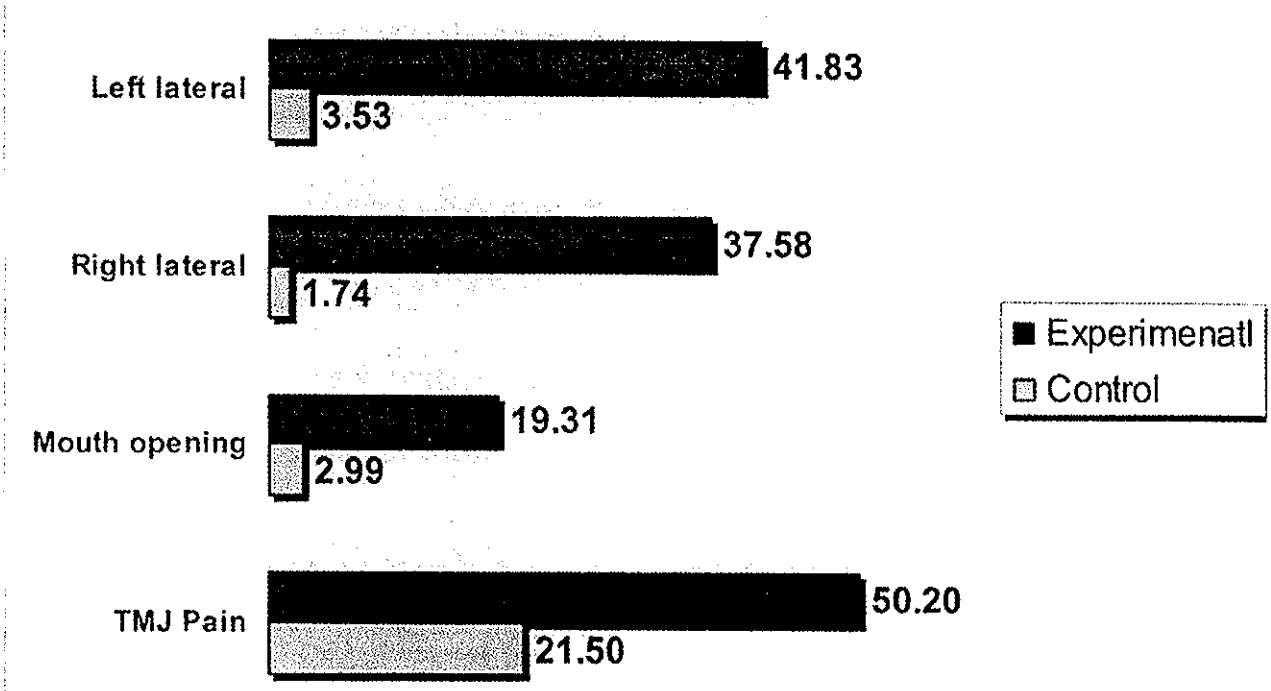

Figure 6
Percentage of change from baseline to two week follow-up. TMJ pain, mouth opening, right and left lateral movement N=20 (baseline value - second week follow-up/baseline value) x100.

decrease in pain level of 50% while the control group also exhibited a significant decrease of only 22%. The mean difference from baseline to second follow-up was shown to be greater in the experimental than in the control group by 166.9%. Likewise, the experimental group showed a significant increase in ROM. Mouth opening increased 19%, right lateral 38%, and left lateral 42% compared to the control group's 3% increase in mouth opening, 2% right lateral, and 4% left lateral. The control group differences were not significant, **Figure 6**.

Gray, et al.[9] conducted a similar study using short wave diathermy and megapules devices. That study found that there was 70-74% improvement in pain compared to the control group. But the study used two direction responses, *improved* or *not improved*. Using this method of measurement, the study yields a 100% improvement.

The difference between the devices they used and the present device is that the PRFE causes an increase in the oxygenated hemoglobin blood flow to the area[39] while the short wave diathermy may emit either a constant or pulsed output. Constant output is used to achieve deep heating effect whereas the pulsed output allows cooling between pulses, heats less and enhances the non-thermal effects. It is known that the energy delivery from the device comes from high voltage caused ionization of the contiguous air, producing a visible corona discharge. Engineers at Tufts University are currently researching the mechanism.

We have also observed that the control group also exhibited a reduction in pain. The control group pain decreased 22% from baseline to two-week follow-up with no treatment. The experimental group, on the other hand, showed a 50% reduction from baseline pain. In contrast, the percent change of mouth opening and right and left lateral movement responses do not show any remarkable difference from baseline (**Figure 6**). The absence of the placebo-like response in the mandibular range of motion groups is probably due to the fact that the movement was measured objectively in ROM. In the TMJ pain, the levels were assessed subjectively. Pain reports are subjective and may be inflated by the placebo effect.[23-25] The placebo effect is usually present when subjective assessments are made. The decrease in pain found in the experimental group is approximately 30% greater than the placebo response obtained in this experiment. The overall beneficial effect of PRFE on TMJ reported pain is a combination of a placebo effect and the true

effect of PRFE. Such an observation should not be ignored.[40]

There was evidence of minor side effects and skin irritation or color changes at the site of application during the treatment. One subject experienced slight redness and three subjects experienced a slight burning sensation at the treatment site only during PRFE application. These patients continued in the experiment and reported disappearance of these phenomena. One subject in the placebo group reported a tingling sensation over the application area. This subject also continued the experiment to completion. The only unwanted effect to the device was the high pitch sound, which required the use of earplugs during the treatment session. There is no explanation presently for the mechanism of action by which the PRFE provides the beneficial effects noted in this study. Whether the PRFE effect is dependent on the wavelength of visible energy or audible energy is still unclear. The effectiveness of a given radio frequency source must lie in its ability to penetrate biological tissues. The depth of penetration of PRFE using the Energex unit has yet to be determined.

In conclusion, the Energex treatment for subjects enrolled in this study appeared to be safe and effective in reducing and eliminating TMJ pain and restoring function.

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Dr. Noshir R. Mehta *is Professor and Chairman of General Dentistry and Director of the Craniofacial Pain Center at Tufts University School of Dental Medicine. He holds a Diplomate from the American Board of Orofacial Pain and is a Fellow of the International College of Dentists and a Fellow of the American College of Dentists. Since receiving his D.M.D. degree and his M.S. in periodontics at Tufts University, he has been involved in occlusion research. Dr. Mehta has lectured internationally on TMD/MPD and has published numerous scientific papers.*

Dr. Albert G. Forgione *is Chief Clinical Consultant of the Craniofacial Pain Center at Tufts University School of Dental Medicine. He received a Ph.D. in psychology from Boston University and then joined Tufts University and lectured in Behavioral Medicine. Dr. Forgione established the TMJ Center at Tufts University School of Dental Medicine with Dr. Mehta in 1978.*

Dr. Silvia Lobo Lobo *received her D.D.S. degree at Universidad Latinoamericana de Ciencia y Technologia in San Jose, Costa Rica in 1999. In 2002, she completed the TMD and Orofacial Pain program at the Craniofacial Pain Center at Tufts University School of Dental Medicine. She received a Master of Science degree from Tufts University in 2002. Dr. Lobo is currently working as a clinical instructor at the Craniofacial Pain Center.*

Dr. Khalid H. Zawawi *received his B.D.S. at Punjab University, de'Montmorency College of Dentistry, Pakistan in 1992. He spent six years as a clinical instructor in the Department of Oral Surgery at King Abdulaziz University, Faculty of Dentistry in Jeddah, Saudi Arabia. In 2001, he completed the certification program in TMD and Orofacial Pain at the Craniofacial Pain Center at Tufts University School of Dental Medicine. Dr. Zawawi is currently a Research Associate at the Gelb Center and is working on a Doctor of Science degree in oral biology at Boston University School of Dental Medicine.*