Low-level laser therapy for treatment of temporomandibular joint pain: a double-blind and placebo-controlled trial

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Objective. The objective of this study was to assess the effectiveness of low-level laser therapy (LLLT) in the management of temporomandibular joint (TMJ) pain in a random and double-blind research design.
Study design. TMJ pain patients, randomly assigned, received 2 to 3 treatments per week for 8 weeks of active LLLT (Helium Neon, 632.8 nm, 30 mW) (n = 26) or sham LLLT (n = 26). Measures of TMJ pain during function were evaluated at baseline and weeks 2, 4, and 8 after the first laser therapy.
Results. At the 8-week point, within-group improvements were present for TMJ pain during function, for both the active and sham LLLT groups (P = .000). Between-group differences were not highly evident (P > .05).
Conclusion. The study suggests that LLLT is not better than placebo at reducing TMJ pain during function. **(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2008;105:452-6)**

Temporomandibular joint (TMJ) pain is recognized as an important source of disability that leads to considerable socioeconomic costs as a result of medical treatments, surgical interventions, and frequent absences from work.[1,2] Arthroscopic studies have confirmed the concept that inflammatory processes of the synovium, capsule, or retrodiscal tissues are the underlying mechanisms for the occurrence of TMJ pain.[3,4] Mechanical disturbances were regarded as etiologic in the production of an imbalance between anabolic and catabolic processes, progressive cartilage degradation, and secondary inflammatory components,[5,6] while therapeutic procedures such as splint therapy[7,8] and arthrocentesis[9,10] were described to correct the dysfunctional state by decreasing TMJ loading and promote healthy synovial fluid production.

A potential noninvasive treatment for TMJ pain is low-level laser treatment (LLLT). In recent studies, many authors have reported significant pain reduction with LLLT in acute and chronic musculoskeletal pain conditions such as rheumatoid arthritis,[11] cervical osteoarthritis,[12] knee osteoarthritis,[13] fibromyalgia,[14] and low-back pain.[15]

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The relative clinical efficacy of LLLT for the treatment of temporomandibular disorders (TMD) is controversial. Some authors reported the efficacy of LLLT to be superior to placebo therapy,[16] while others found no significant differences between LLLT and placebo for measures of TMJ pain.[17] In view of the fact that outcomes in LLLT studies may depend on patient samples, treatment procedures, and trial design,[18] the purpose of this study was to assess the effectiveness of LLLT in the management of TMJ pain during function in a random and double-blind research design.

MATERIAL AND METHODS

Subjects

The study group, selected over a period of approximately 1 year, consisted of 52 consecutive patients with unilateral TMJ pain; they were referred from medical practitioners and dentists in the community to the Orofacial Pain and TMD Clinic in the Department of Oral and Maxillofacial Surgery at the University of Innsbruck. This clinic is the primary referral center for TMD at the institution as both conservative and surgical treatments are offered. Patients were referred to the center for treatment with reported pain of the temporomandibular region as the primary problem. Of the total of 156 TMJ pain patients referred for the first assessment, 89 did not meet the inclusion criteria and 15 subjects refused to participate; 52 subjects were included in this study (Fig. 1). The patients ranged in age from 18 to 58 years (mean, 42.9 years). All had failed to obtain satisfactory pain relief after an initial treatment protocol, including self-care (soft diet, cold/hot packs,) and topical 3% diclofenac gel (Voltaren, Novartis, Vienna, Austria), 3 times a day, plus occlusal appliance (hard acrylic, full-arch maxillary stabilization–type

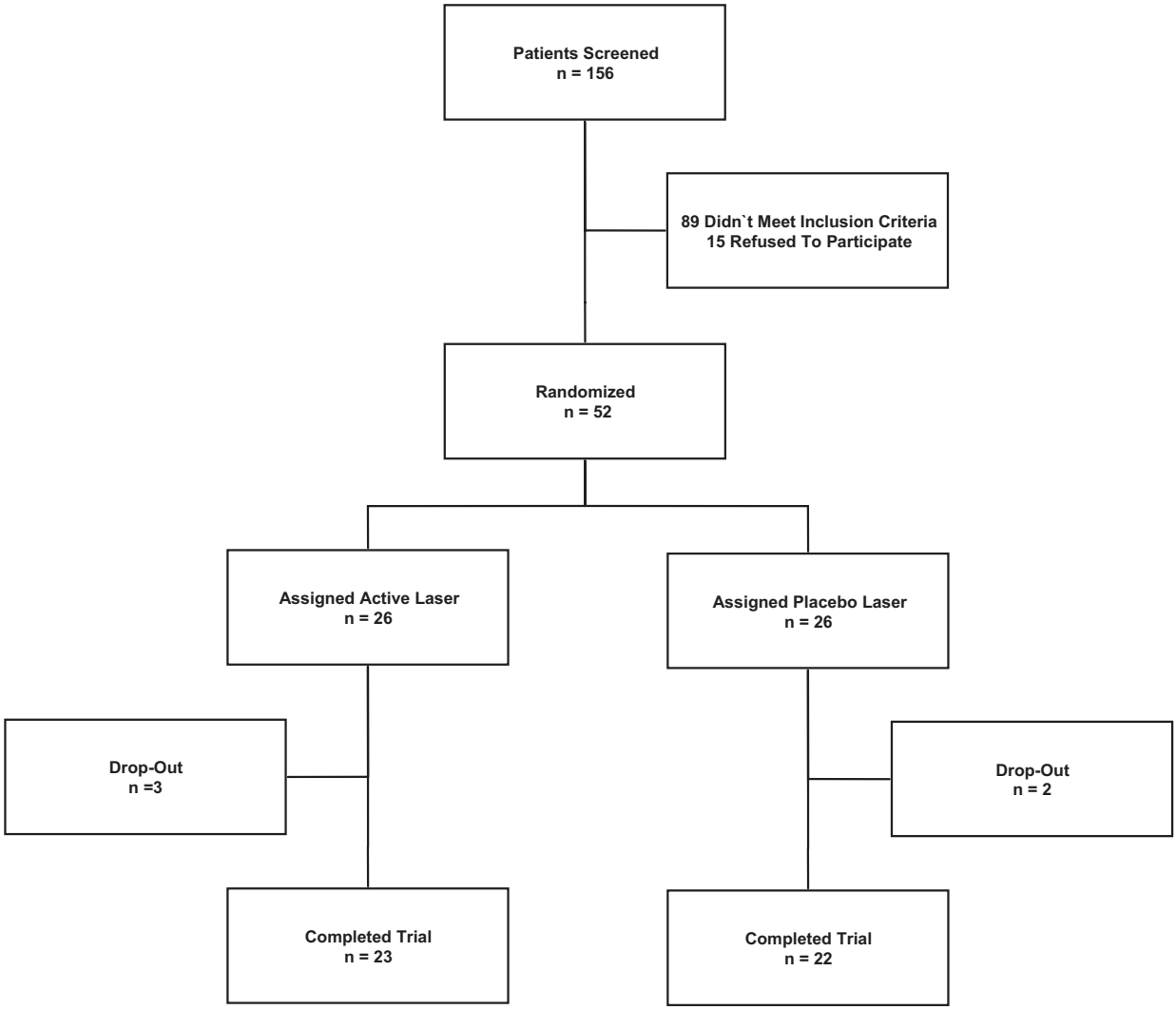

Fig. 1. Trial profile.

splint). Patients were instructed to adhere to this treatment protocol for a period of 6 weeks; they were not subjected to treatment within the last 2 weeks before the trial.

Criteria for including a TMJ pain patient were (1) a report of orofacial pain referred to the TMJ as well as the presence of unilateral TMJ pain during function, (2) absence of a clinical TMJ disorder condition defined according to the Clinical Diagnostic Criteria for Temporomandibular Disorders,[19] (3) a preoperative visual analog scale (VAS) pain level greater than 20 mm and less than 80 mm, (4) recency of pain onset of 2 years or less,[20] (5) be ambulatory and able to be treated as an outpatient, and (6) be available for the study schedule. Patients with a myalgia, collagen vascular disease, or a history of trauma were not included in this study

The Human Studies Research Committee of the Innsbruck Medical University approved all procedures, and written informed consent was obtained from each subject prior to inclusion in the study. No drop out was reported after inclusion and randomization due to complications.

Study design, randomization, and blinding

In this double-blind randomized clinical trial (RCT), patients, research therapists, and investigators were unaware of which treatment the subjects received during both the intervention and follow-up phases. Equipment used for both sham and active groups were identical in appearance except for a hidden code label, known only to the research assistant. The sham emitter was like the HeNe emitter in appearance, but was inactive. The code was kept undisclosed from the investigators until the data were analyzed. Participants were randomly assigned to either the active (26 patients) or sham laser group (26 patients) by one of the nontreating authors.

Table I. Baseline comparison of demographic and standard measures between LLLT study groups

Variable	Study groups		P value
	Active LLLT group (n = 26)	Sham LLLT group (n = 26)	
Subjects			
Age, y	44.1 ± 16.6	41.8 ± 11.2	.559*
Female/Male	22/4	20/6	.482†
TMJ pain			
Pain relief with prior initial treatment protocol,‡ mm	11.2 ± 9.1	7.7 ± 9.3	.176*
VAS pain level during function, mm	38.2 ± 7.6	39.7 ± 12.2	.598*
Time since onset, wks	23.3 ± 7.3	26.7 ± 10.3	.189*
Nonchronic/Chronic§	12/14	10/16	.575†

LLLT, low-level laser therapy; VAS, visual analog scale.
**P* values were assessed by 1-way analyis of variance.
†*P* values were assessed by chi-square analysis.
‡Self-care and topical 3% diclofenac gel plus occlusal appliance.
§Time since pain onset of ≤ 6 months/> 6 months.

The order of subject assignment was based on a sequence of computer-generated random numbers. Assessment of the participants (week 0, 2, 4, and 8) was conducted by an independent investigator who was unaware of the participants' group allocation.

Laser treatment

The therapeutic LLLT application was achieved through light, static, and direct contact of the probe on the skin. The probe was placed perpendicular directly on the skin at the center of the upper joint space, approximately 1 cm in front of the tragus. The laser beam was delivered through a handheld single laser probe. During each session, the treatment was applied for 2 minutes at both the closed mouth and maximum mouth opening position. Each patient received 1 series of 20 treatments. Each series lasted 8 weeks, and patients were treated 2 to 3 times a week.

A red-beam laser (Model 2000; Helbo Medizintechnik, Austria) (632.8 nm HeNe laser, continuous wave, 30 mW output power, 1.5 J/cm^2 energy density) was used. The laser was calibrated before use, and the laser probe was wiped with alcohol before each treatment. The subjects and the clinician were required to wear protective glasses.

Follow-up measures

The baseline (week 0) and follow-up (weeks 2, 4, and 8 after the first laser therapy) evaluation of TMJ pain during function was accomplished by patient self-assessment using a visual analog scale (VAS), i.e., patients registered the mean pain perceived on chewing or eating hard foods in the preceding 7 days.

Data analysis

An intention-to-treat outcome analysis included data from all randomly assigned participants. Two-way repeated-measures analysis of variance was used for assessment of independent variables of "session" (I, II, III, IV), and "study group" (active LLLT, sham LLLT). Statistical analysis of session-related measurements of VAS consisted of univariate analysis of variance. A Bonferroni correction of the alpha-level for session-related data was performed.

The pretreatment data were analyzed by chi-square analysis and 1-way analysis of variance. Significance was set at P less than .05. For all statistical analyses, the SPSS 10.0.7 software program (SPSS Inc., Chicago, IL) was used.

The sample size was calculated to detect a 20% difference between treatment groups in the primary effectiveness measure.[17,21] Using a power of 80% and $\alpha = 0.05$, the required sample size was 26 patients per group. For analysis, the NCSS Power Analysis and Sample Size program (PASS) (NCSS Inc., Kaysville, UT) was applied.

RESULTS

Baseline comparisons between the 2 treatments groups were made based on age, gender, pain relief with prior initial treatment protocol, time since pain onset, and baseline severity of TMJ pain during function. No significant differences were seen in the listed parameters ($P > .05$) (Table I). The results showed that, with time, all 2 study groups had a significant improvement in TMJ pain during function ($P = .000$), and there were no significant group differences ($P > .05$) (Table II).

DISCUSSION

This study used a specific type of LLLT treatment (HeNe, continuous wave, 632.8 nm, 30 mW) involving direct irradiation on painful TMJs, applied 2 to 3 times a week over 8 consecutive weeks. Participants with TMJ pain did benefit throughout the treatment period from the LLLT protocol used in this study. The variable of VAS pain during function improved significantly in

Table II. Comparison of mean VAS pain levels between LLLT study groups

	VAS level, mm				P value*		
Study group	Session I (0 week)	Session II (2 weeks)	Session III (4 weeks)	Session IV (8 weeks)	Group difference	Time course	Interaction
LLL treatment group (n = 26)	38.2 ± 7.6	27.4 ± 17.5	20.9 ± 17.7	12.3 ± 16.1	.534	.000	.751
LLL placebo group (n = 26)	39.7 ± 12.2	25.2 ± 12.7	16.5 ± 15.0	11.8 ± 16.8			
P value† for group difference	.598	.618	.384	.961			

VAS, visual analog scale; *LLLT,* low-level laser therapy.
**P* valuea for the main effects and interaction were assessed by 2-way repeated-measures analysis of variance.
†*P* value for the group differences in each observation time point were assessed by 1-way analysis of variance.

both groups, and the active LLLT treatment group failed to show any tendency for greater beneficial changes compared with the placebo group. This finding is most likely related to the placebo effect. Psychological factors, such as the desire to feel better, may have influenced physiological processes thereby resulting in the desired outcome.[22]

There is insufficient evidence either for or against the use of LLLT for the treatment of TMJ disorders. Findings from a controlled, short-term study of TMJ patients specific to arthralgic degenerative joint disease suggested that the use of mid-laser treatment (904 nm, 27 W, applied for 9 minutes, 3 treatments per week for 3 weeks) may be beneficial for reducing pain severity, when compared to a control appliance.[16] These observations are inconsistent with those of a randomized, double-blind, controlled evaluation of LLLT treatment (gallium-aluminum-arsenide, 780 nm, 30 mW, applied for 30 seconds, twice a week for 6 weeks) for TMJ capsulitis/synovitis and painful disk displacement with reduction, which showed no significant difference in the effectiveness of active LLLT treatment in reducing pain intensity compared with a control condition.[17] However, the results may be not directly comparable, as the populations were not described in a comparable manner and also did not match for signs and symptoms. Further randomized clinical trials that pay attention to method of allocation, outcome assessment, sample size, and duration of follow-up are necessary to assess the therapeutic efficacy of specific LLLT treatments, and the diagnostic validity of specific clinical TMJ disorder variables.

The physiologic mechanisms underlying significant decreases in pain of musculoskeletal disorders after LLLT are unknown. LLLT is often used for individuals with arthritic hands,[11,23-25] while LLLT application seems to have more beneficial effects on knees[13,26] than on hands.[25,27] Further, LLLT seems to be more effective in the management of rheumatoid arthritis, an inflammatory condition, than for osteoarthritis.[28] Some possible mechanisms associated with LLLT include changes on the cellular level with increased ATP production by the mitochondria[29] and improved cellular respiration,[30] increased serotonin[26] and endorphins,[31] decreased inflammation,[32,33] and improved local blood circulation.[34,35]

The findings of this study are restricted to a specific set of parameters; however, optimal treatment parameters (e.g., wavelength, dosage, number of treatment sessions) have not been agreed on.[36] Nevertheless, the approach was appropriate in that the study used a laser found successful in the treatment of musculoskeletal pain.[26,37] One may also question the use of a 632.8-nm wavelength rather than the more typical choices in the 830-nm[11-13,25] or 904-nm[13-16] region. However, as beneficial results have been achieved at this wavelength in earlier studies,[26,37] a 632.8-nm wavelength penetrates more deeply into musculoskeletal tissues than shorter wavelengths,[38] and a trend for improved pain outcome with the 632 nm compared to 820 nm has been reported[28]; the choice in this study may have been appropriate. Further, the number of treatment sessions could be debated. Using 20 sessions was arbitrary, but represents a clinically reasonable number of treatments and reflects a consensus among laser therapy clinicians and researchers that successful treatment typically requires multiple treatments.[25,26,39]

LLLT is a noninvasive, quick and safe, nonpharmaceutical intervention that may be beneficial for patients with TMJ pain disorders. However, the efficacy of LLLT in the management of TMJ pain has not been demonstrated in this study to produce positive patient outcomes. It may be assumed that a more tailored application of LLLT should be developed to take into account the multifactorial aspects of the disorder.

CONCLUSIONS

This randomized clinical trial found no significant difference between LLLT and placebo in the outcome measure of TMJ pain during function. It suggests that LLLT is not better than placebo at reducing TMJ pain.

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