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Laser acupuncture for myofascial pain of the masticatory muscles

A controlled pilot study

Key words: Laser acupuncture, myofascial pain, myoarthropathy, Traditional Chinese Medicine (TCM)

Summary *Purpose:* The purpose of this investigation was to evaluate the effectiveness of laser acupuncture within the scope of a pilot study.
Methods: 108 adult patients were examined and of those eleven patients were included in the prospective pilot study. These patients took part voluntarily and were diagnosed with tendomyopathy of the masticatory musculature with maximum face and jaw pain on a visual analogous scale VAS ⩾30 in the last 14 days. Four patients wanted to be sure not to be assigned to the placebo group and were treated with the laser (group1, verum open, N=4). The remaining seven were split by means of block randomisation into groups 2 (verum blind, N=3) and 3 (placebo blind, N=4). Two local points (ST 6, SI 18) and two distant points (SI 3, LI 4) on both sides of the body were stimulated (groups 1 and 2) or placebo-stimulated (group 3) with the LASER-needle® machine for 15 minutes twice a week for three weeks (6 sessions). After three months a clinical follow-up was carried out, which included a standardised questionnaire as to the maximum pain intensity (VAS and verbal scale) and on the need for further treatment. A pain reduction (VAS) of about 50% was evaluated as a success.
Results: Pain decreased on average 40 VAS points for ten of eleven patients. The pain reduction on the VAS in group 1 (verum open) was more than 50% for all four patients, in group 3 (placebo blind) for three of four patients, and in group 2 (verum blind) all remained under 50%. The evaluation on the verbal scale showed a pain reduction from moderate to very strong pains initially, to moderate, light and no pain after three months for all three groups.
Discussion: The range of application of the laser was limited by the narrow inclusion criteria of the pilot study. The laser acupuncture (open and blinded) did not show a negative effect in any group. The pain reduction was strongest with the blinded patients of the placebo group. The worst performance was in the blinded group with laser acupuncture.
Conclusion: Due to the low number of participants, no clear conclusion can be drawn. Laser needle acupuncture may be a treatment option for patients with an interest in a non-invasive, complementary therapy. But clarification and treatment planning on an individual basis must take place first.

Introduction

Myoarthropathies (MAP) of the masticatory system are disturbances which are characterised by pain or malfunction of the masticatory muscles and/or the temporomandibular joints (Palla 2002). Forms of MAP with strong and constant pain require therapy in most cases. Different reversible and irreversible measures are used for this purpose. Current data supports the use of non-invasive measures (Türp et al. 2007). The effect of complementary therapies, for example acupuncture, is controversial (Tough et al. 2009). However, there are only a few controlled studies on the effect of acupuncture with painful MAP. The readiness of patients to take part in randomised studies on complementary medical procedures is low and depends strongly on the general conditions (Schneider et al. 2003).

Traditional Chinese medicine (TCM) is an independent medical concept, which was developed in China over a period of 3,000 years. This natural philosophical concept comprises five interconnected subdisciplines (herbal medicine, acupuncture/moxibustion, nutrition, Qi gong/Tai Chi/AnMo-TuiNa massage, lifestyle counselling) (Institute of complementary medicine KIKOM, University of Bern, www.kikom.unibe.ch). These therapies are thought to use different approaches to influence the energetic state of the body and therefore the patients' well-being (Stux & Pomerantz 1998). The indications for TCM are varied and were last summarized at the turn of the millennium by the World Health Organization (WHO) (2000). In the west, acupuncture (body, ear and skull acupuncture) has established itself as the most frequently applied TCM method and consists of the specific therapeutic influencing of bodily functions according to specific points on the body surface. According to TCM the life energy Qi flows in energy pathways, the so-called meridians, under the body surface (Langevin & Yandow 2002). It is thought that pain and tension result when the Qi flow is disrupted. Specifically stimulating a few (of the more than 360) acupuncture points is thought to alleviate these blockages (Prance et al. 1988). Laser acupuncture (soft laser), also called low level laser Therapy (LLLT), is a therapy method equivalent to needle acupuncture (Schikora 2004). Various appliances with different power ranges are now available and are used both in private practice and hospitals (Mettraux 2004a, b). The stimulation of an acupuncture point with the laser is not only painless, it cannot be felt by the patient at all (Valchinov & Pallikarakis 2005). Using the laser instead of needles therefore allows a blinded study design. Previous investigations (of different study quality) with LLLT reported good to no pain relief for MAP (Mazzetto et al. 2007, Schmid-Schwap et al. 2006, Cetiner et al. 2006, Kulekcioglu et al. 2003, Conti 1997, Hansen & Thoroe 1990).

The aim of the present study was to evaluate the effectiveness of laser acupuncture using optimum study design. Taking into account the feasibility as well as the demand for a treatment with laser acupuncture in a university dental medical clinic, a pilot project with a few patients was carried out.

Materials and methods

Patients and study design

The clinical outcome of different treatments was documented and compared in the present prospective placebo-controlled pilot study, with the written consent of the patients. All patients were questioned and examined clinically at the initial appointment and three months after treatment. The pilot study was carried out in the prosthodontics clinic at the university dental school in Bern. The following inclusion criteria were fulfilled:

- Voluntary participation (signed informed consent form).
- Diagnosis of tendomyopathy of the masticatory musculature (at least three tender mandiblular muscles, Dworkin & LeResche 1992).
- Maximum pain intensity on the visual analogous scale (VAS) $\geqslant 30$ (mandiblular pain and facial pain) during the last 14 days.
- No other therapy one month before and during the study (a total of four months).
- Age between 18 and 70 years.

Exclusion criteria were diagnosis of arthropathy of the temperomandibular joint with arthralgia or reduced mobility of the mandible, temperomandibular joint arthritis or any recent cranial or facial fractures or acute dental problems. Patients who were suffering a lot from their pain and expressed an immediate demand for treatment were not recruited in this pilot project. Other exclusion criteria were history of ear, nose or throat illnesses, general medical complications requiring treatment, psychological illness, clinical diagnosis of rheumatoid arthritis, current pregnancy, abuse of antipsychotic medication, drugs or alcohol or ongoing other treatment of MAP problems outside the prosthodontics clinic. In total, 108 patients (women 74%, men 26%, average age 39 years) with MAP problems were interviewed over twelve months. The majority, 97 patients, had to be excluded from the study. The most frequent reason was that treatment had already been started by the referring doctor in patients who were suffering a lot from their pain (N=48), as well as not having time to participate in the acupuncture meetings on the part of the patient (N=28). 19 patients complained about joint noise or restricted movement of the mandible without pain. Two patients did not attend the agreed appointment. Therefore eleven patients (ten women, one man) who fulfilled the inclusion criteria took part in the investigation. After consenting to take part, the patients were divided into three groups. The patients who did not want to be blinded and wanted to be certain that they had laser acupuncture treatment were assigned to the verum group 1 (verum open, N=4). The remaining patients who agreed to the random and blinded assignment were split by means of block randomisation to a verum group 2 (verum blind, N=3) and placebo group 3 (placebo blind, N=4) (fig. 1). The average age for all patients was 33 years (22–61 years), and 38 years (30–61 years) for group 1, 34 years (30–38 years) for group 2 and 28 years (22–41 years) for group 3.

The findings were recorded at the beginning (week 0) and at the end (week 16) according to Dworkin & LeResche (1992). The examining dentists were blinded as to the group assignment of the group 2 and 3 patients. The patients wore special protective glasses during the therapy so they could not see whether the laser appliance was switched on or not. In addition, the glasses were stuck to the cheek with adhesive tape. To make sure that the patients did not remove the protective glasses, the dental assistant sat behind the treatment chair (where the patient could not see them) and did not leave the room. The study design for the group 1 patients was therefore "prospective, not blind", for groups 2 and 3 "prospective, randomised, double blind". The patients and operators were given the key of the randomisation in the16th week.

Acupuncture and laser appliance

The verum group 1 and 2 patients received (two 15 min sessions per week, total 6 sessions over 3 weeks) "real" laser needle

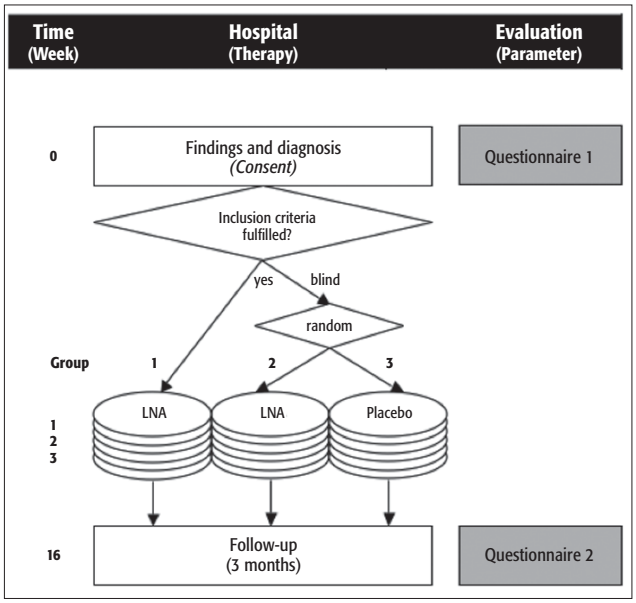

Fig. 1 Design and course of the pilot study (LNA=laser needle acupuncture) with group 1 (N=4), group 2 (N=3) and group 3 (N=4).

acupuncture (LNA). For this purpose, the laser needle was attached, the appliance was switched on and the lasers were *activated*. With the placebo group 3 patients, the laser needle was attached and the laser appliance was switched on, however, the lasers were *not activated*. One person who was trained to use the appliance but who had no information about the respective patient apart from the group assignment carried out all treatment sessions. The choice of acupuncture points was based on TCM guidelines and acupuncture studies (Rosted 2001). The following four points (chosen after consultation with KIKOM) were used in a standardised way with all patients on both sides in the body (fig. 2a, b): local points ST 6 (*stomach* 6, jiache; relation mandiblular) and SI 18 (*small intestine 18,* quanliao; relation maxilla), distant points SI 3 (*small intestine 3,* houxi, spasmolytic) and LI 4 (*large intestine 4,* hegu; analgesic).

All eight of the acupuncture points mentioned above were treated at the same time with the laser device (LASERneedle®-Medical, Ronbar AG, Basel), which switched itself off after 15 min automatically. This device allows double blind studies because patients are not able to feel whether a laser needle is turned on or not. When the laser is activated, a red light is visible at the tip of the needle, which neither generates warmth nor vibrates perceptibly (Schikora 2004). The laser "needles" are based on optic fibres, which carry light along their length. 40 mW optical power is available at the tip of the laser needle. The optical power density (approx. 1 W/cm), which is decisive for the physiological stimulus effect on the acupuncture point, is the quotient of the optical performance and the contact surface. The actual radiation reaching the skin during a treatment is 40–60 J. At 690 nm, which is the wavelength emitted by the laser needle, the radiation absorption in the tissue is minimal. Therefore, it can be ensured that the absorption of photons in tissue is negligible and thermal skin damage can be avoided. Protective glasses should be worn to prevent retinal damage.

Pain assessment

The maximum pain intensity (PI) over the previous 14 days was assessed in each case. The results were recorded at the initial visit (week 0) and after the acupuncture/placebo phase

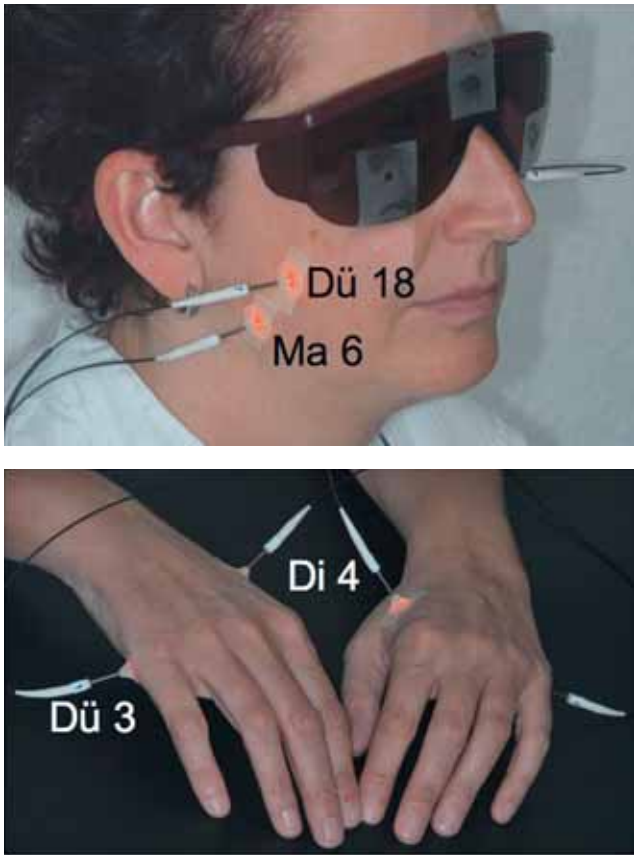

Fig. 2a, b Attached laser needles and the local points in the face (ST 6 – relation mandible, SI 18 – relation maxilla) and the distant points in the hand (SI 3 – spasmolytic, LI 4 – analgesic).

(week 16) by dentists in the department of prosthodontics who were all supervised and calibrated by the same person. The assessments (weeks 0 and 16) as well as the acupuncture sessions (weeks 1, 2, 3) took place in a separate room in the clinic. For the evaluation of the maximum pain intensity a visual analogous scale from 0 (no pain) to 100 (maximum pain) was used. The question was: "If you think of the moments during the last 14 days in which you had facial pain, how would you classify your strongest pain?" A pain reduction (VAS) of about 50% was evaluated as a success. In addition, the patients evaluated their maximum pain on a verbal scale (VERSUS) according to the following classification: none/weak/moderate/strong/very strong pain (Conti et al. 2001).

The patients could leave the study at any time without specification of reasons. Standard therapy (physiotherapy, splint therapy) was carried out if necessary at the final visit in the 16th week.

Results

Visual analogous scale VAS

The average maximum pain intensity for all eleven patients was 66 (±23) VAS points at the first visit (week 0) and 26 (±20) in the week 16. The initial pain intensity was comparable in the three groups (tab. I).

Pain decreased for ten of eleven patients. The VAS value fell about 40 points on average. For groups 1 and 3 the reduction was 51 and 46 VAS points. An average reduction of 16 VAS points was observed in group 2 (verum blind). One of these patients

Tab. I VAS values of the maximum pain intensity at the beginning (week 0) and at the follow-up (week 16).

	N	VAS week 0	VAS week 16	VAS difference
All patients	11	66	26	–40
Group 1 (open verum)	4	67	16	–51
Patient 1		42	1	–41
Patient 2		90	23	–67
Patient 3		54	11	–43
Patient 4		82	30	–52
Group 2 (blind verum)	3	61	45	–16
Patient 5		36	20	–16
Patient 6		48	50	+ 2
Patient 7		98	64	–34
Group 3 (blind placebo)	4	68	22	–46
Patient 8		61	48	–13
Patient 9		87	19	–68
Patient 10		85	5	–80
Patient 11		40	16	–24

reported slightly increased pain intensity from 48 at the beginning to 50 VAS points in week 16. A reduction of at least 50% in VAS values was observed with all patients in group 1 (open verum) and with three of four patients in group 3 (blind placebo) (fig. 3). In group 2 (blind verum) the reduction was less than 50% for all patients.

Verbal scale

The patients also classified their initial pain on a verbal scale as moderate to extremely strong. Treatment led to a reduction of pain in all groups. Figure 4 shows a clear improvement in pain in group 1 (open verum) and group 3 (blind placebo); one patient in each of these groups claimed to be free of pain after the therapy (week 16). In group 2 (blind verum) no patients complained of very strong pain, but neither did anyone claim to be pain free.

All patients remained in the pilot study until the follow-up (3-month recall in week 16). At the follow-up six patients reported a clear relief of pain and did not request further treatment. One patient from the verum group (No. 4) and two patients each from the blind groups (Nos. 5, 7, 8, 11) requested further treatment in the clinic in spite of pain reduction.

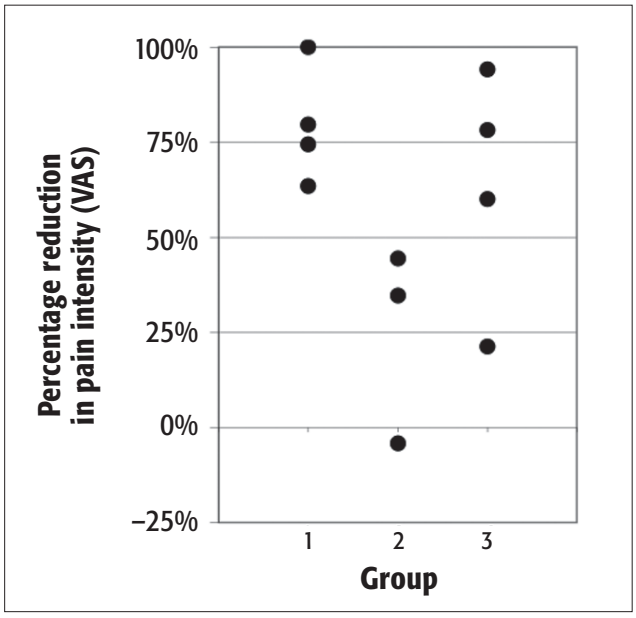

Fig. 3 Percentage reduction in the maximum pain intensity for the patients of the three groups from week 0 (initial visit) and week 16 (after the verum/placebo phase at the follow-up).

Discussion

Laser acupuncture seemed to have the best effect if the patient was informed about the treatment and the appliance was activated (group 1). Surprisingly, the placebo group patients experienced a greater pain reduction on average on the VAS than the verum group. Because the patients were not seen by their dentists during the acupuncture sessions, and because no long discussions with the person who attached the laser needle took place, a placebo effect by the therapist is very unlikely (Benedetti 2002). False acupuncture can serve as a comparison. The needling of points, which are not recognised as acupuncture points, counts as placebo acupuncture or false acupuncture (McNeely et al. 2006, Goddard et al. 2005), even if this induces a painful stimulus. It has been shown that false acupuncture can also have a positive effect on sore masticatory muscles (Goddard et al. 2002), which, again, might cause the patient to be influenced by the therapist (Benedetti 2002). Similarliy, with Kulekcioglu et al. (2003) the test group and control group achieved equally good results, probably because of the LLLT, and also because the patients were instructed to do exercises daily. The advantage of the LLLT is that it is non-invasive and easy to use (Ilbuldu et al. 2004). The analgesic and anti-inflammatory effect of laser therapy was investigated by Fikácková et al. (2006) by measuring temperature at the painful temperomandibular joint. The inflammatory-raised temperature was measurably lowered with LLLT. Whether this effect is clinically relevant, remains open. Núñez et al. (2006) reported a stronger analgesic effect and a greater improvement in oral opening restriction with LLLT than with transcutaneous electrical nervous stimulation (TENS). An increased effect could not be shown for increased laser energy application (wavelength, surface, duration) or for shorter (daily instead of weekly) treatment intervals (Bjordal et al. 2003). The local blood circulation in sensitive areas of the masseters with chronic myofascial pain patients did not increase after treatment with a laser. Interestingly, with healthy test persons the local microcirculation increased after application of the laser and reduced after application of the placebo laser (Tullberg et al. 2003).

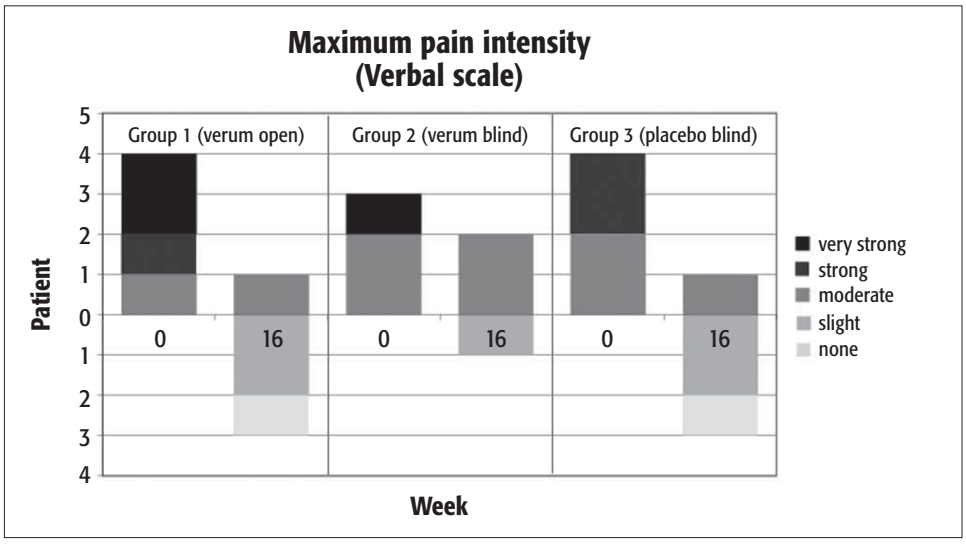

Fig. 4 Maximum pain intensity (verbal scale) at the beginning (week 0) and after the verum/placebo phase at the follow-up (week 16) for groups 1–3.

The pilot project with the LASERneedle® appliance, which has been used for some years in medical centres and private practices (Stähler 2004, Stähler 2003, Litscher 2003; Litscher & Schikora 2002a–c), should yield information not only on the effect, but also on the general handling and patient acceptance in dental medicine. Because the clinic sees many referred patients who have already been treated (seasonally up to 80% of all MAP patients), these had to be excluded from the pilot study. The investigation was not publicly advertised and no compensation was paid to attract a big number of patients. This would have falsified the range of patients and might possibly have drawn a more special, acupuncture-sensitised type of patient. At the same time it was difficult to find patients who only had masticatory muscle pain without symptomatic or etiological participation of the mandiblular joints. Patients with high pain intensity and who were suffering a lot from their pain (Dworkin & LeResche 1992) were allocated to Axis II because they needed quick intervention (medication, psychological support) and, therefore, could not be recruited for the pilot project. Venancio et al. (2005) reported similar problems with patient selection for subjects with isolated mandibular joint pain. Interestingly, the pain reduction experienced by these 30 patients resembles the course of the present investigation. In a double blind study Conti (1997) compared the therapy success of joint and muscle groups with each other, also with only 20 patients. LLLT was more effective for patients with muscular problems.

In the short-term, tendomyopathy shows a fluctuating course with phases of increased painfulness and phases of complete freedom from pain. This could be another explanation for the different results. In the mid to long-term, i.e. over several years, the prognosis is good if allowed to progress naturally without therapeutic intervention. In the present pilot study, a follow-up was carried out after three months. Cetiner et al. (2006) had an even shorter observation period (one month), which is why a definitive effect for the LLLT is contestable.

In the present investigation the same acupuncture points were used for all patients. This choice is inadequate according to TCM, because the points to be treated should be determined on an individual basis. Without preliminary TCM diagnostics, interference fields and infection foci may remain unrecognized and hinder therapy success. Therefore, we tried to choose a combination of local points related to the upper and lower jaw (SI 18, ST 6) and to incorporate distant points with spasmolytic (SI 3) and analgesic effects (LI 4). The effect of acupuncture can be explained from a conventional scientific medical point of view by the stimulation of neighbouring free nerve cells which send signals to the spinal cord and the brain stimulating the release of pain-reducing substances there (Irnich & Beyer 2002, Carlsson 2002, Ernst & Lee 1987). How quickly the effect appears and how long the analgesic effect lasts, depends on the kind of stimulation (Staud 2007).

The two subjective pain scales evaluated the complaints differently. The VERSUS pain evaluation cannot be equated with the VAS assessment. The general pain relief is more readily reflected by VERSUS and does not correlate with VAS (Fine et al. 1998). While the definition of therapy success used here (an improvement of at least 50% on the VAS) indicates a significant pain reduction, it is not to be equated with complete freedom from pain.

Regular practitioner-patient contact, as was the case in this pilot study, seems to positively affect the course of the MAP regardless of the applied therapy. The patients regularly had the opportunity to comment, and, therefore, probably felt they were in good hands. One shortcoming in this study design is that there was no control group, with splint therapy or physiotherapy and the same weekly support. MAP is known to have a good chance of healing by itself and splint therapy can also be successful (Al-Ani et al. 2005). Similarly good results have been shown for muscle exercises taught as a home program with re-examination and reinstruction (Katsoulis & Richter 2008, Mulet et al. 2007, Michelotti et al. 2004). The effectiveness of LLLT seems to be comparable to that of splint therapy, however it is less costly and less time consuming. This method may be suitable for patients with a high demand for medical treatment. Despite the restrictions mentioned at the start of this pilot study, the patients were happy with the therapy, even if it did not lead to complete freedom from pain. Most patients (nine of eleven) would also have laser needle acupuncture treatment for another painful problem, even if they had to pay for the treatment themselves.

Conclusion

To what extent the laser acupuncture influenced the success of the therapy, cannot be concluded from the present data. The number of patients treated was too small to allow generalised conclusions. It can at least be concluded that this ther-

apy had no detrimental effect on the patients' complaints. Laser acupuncture is an option for patients interested in a non-invasive, complementary therapy. Diagnosis and treatment planning should take place for each patient before laser acupuncture treatment.

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Résumé

But: Cette étude pilote avait pour but d'évaluer cliniquement l'efficacité de l'acuponcture laser sur un petit nombre de patients.
Matériel et méthode: De 108 patients adultes examinés onze patients avec une dysfonction douloureuse de la musculature masticatoire sans participation articulaire ont participé à cette étude bénévolement. L'intensité maximale des douleurs chroniques sur l'échelle visuelle analogique (EVA) devait être ⩾30 durant 14 jours avant le début de l'étude. Quatre des onze patients ne voulaient pas être classés au groupe placebo et ont été traités au laser (groupe 1, verum ouvert, N=4). Les autres ont été randomisés et divisés dans le groupe 2 (verum non-voyant, N=3) et groupe 3 (placebo non-voyant, N=4). Les points locaux ST 6/SI 18 et points distants SI 3/LI 4 ont été stimulés pendant 15 minutes avec le LASERneedle® deux fois par semaine pendant trois semaines (total 6 séances). Après trois mois, les patients ont eu un contrôle clinique et ont rempli un questionnaire standardisé sur la douleur (EVA et échelle verbale) et sur la nécessité d'un traitement supplémentaire. Une réduction de 50% sur l'EVA était estimée comme succès.
Résultats: La douleur maximale était réduite en moyenne de 40 points sur l'EVA pour dix des onze patients. Dans le groupe 1 (verum ouvert) la réduction était de plus de 50% pour les quatre patients, dans le groupe 3 (placebo non-voyant) pour trois des quatre patients, et dans le groupe 2 (verum non-voyant) tous les patients sont restés sous 50%. L'évaluation sur l'échelle verbale montrait pour tous les patients une nette amélioration après trois mois.
Discussion: Les critères d'inclusion stricts ont limité l'indication du laser. L'application de l'acuponcture laser (non-voyant et ouvert) n'avait pas d'effet négatif. La réduction des douleurs était plus forte chez les patients non-voyants du groupe placebo. L'acuponcture laser était la pire chez les patients du groupe ouvert.
Conclusions: Le petit nombre de participants ne permet pas de faire des conclusions générales. L'acuponcture laser pourrait être une thérapie optionale chez les patients intéressés aux thérapies complémentaires et non invasives. Une information et planification individuelle du traitement doit être faite au préalable.

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