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Pain reducing effect of three types of transcutaneous electrical nerve stimulation in patients with chronic pain: a randomized crossover trial

Albère J.A. Köke[a,b,*], Jan S.A.G. Schouten[d], Myriam J.H. Lamerichs-Geelen[c], Jos S.M. Lipsch[c], Ed M.H. Waltje[c], Maarten van Kleef[a], Jacob Patijn[a]

[a]*Pain Management and Research Center, University Hospital Maastricht, P.O. Box 5800, 6202 AZ Maastricht, The Netherlands*
[b]*Hoensbroeck Rehabilitation Center, Hoensbroek, The Netherlands*
[c]*Department of Physical Therapy, University Hospital Maastricht, Maastricht, The Netherlands*
[d]*Department Epidemiology, University Maastricht, Maastricht, The Netherlands*

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Abstract

Transcutaneous electrical nerve stimulation (TENS) is a frequently applied therapy in chronic pain although evidence for effectiveness is inconclusive. Several types of TENS, based on different combinations of frequency, pulse duration and intensity, exist. The precise mechanism of action and the relevance of combinations of stimulus parameters are still unclear.

To compare the effectiveness of three types of TENS we conducted a randomized, single blinded crossover trial. Patients received two times a 2-week period of daily TENS treatment, separated by a washout period of 2 weeks. In total, 180 chronic pain patients were randomized into three groups. In group 1, high frequency, low intensity TENS (HFT) was compared with high frequency, high intensity TENS (HIT). In groups 2 and 3, HFT and HIT were compared with a control TENS (COT). The order of applying the different modalities of TENS in each group was also randomized.

Primary outcome was the patient's overall assessment of effectiveness and pain reduction (VAS). No differences were found in patient's assessment or pain reducing effect between the three groups, indicating no superiority of one type of TENS. In total, 56% continued TENS after the 2-week treatment period. At 6 months, 42% of all patients still used TENS.

We concluded that there were no differences in effectiveness for the three types of TENS used in this study. Because no placebo group was included, no definite conclusions on effectiveness of TENS in general in the treatment of chronic pain could be made.

Keywords: Transcutaneous electrical nerve stimulation; Chronic pain; Randomized trial; Crossover design; Effectiveness; Patients judgment

1. Introduction

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive therapy mainly used for pain relief for a variety of pain syndromes. Despite its frequent use and theoretical rationale the evidence from RCTs for treatment of chronic pain with TENS is still inconclusive (Carroll et al., 2003).

Theoretically, high frequency and low intensity TENS (HFT) are assumed to work through segmental pain inhibition processes (gate control theory). In contrast, low frequency and high intensity TENS (LFT) are assumed to be effective by the release of endogenous opioids (supra-segmental effect; Walsh, 1997).

Although the frequency of TENS may be the decisive factor in the above-mentioned working mechanism, the results of studies are still inconclusive. Five studies comparing HFT and LFT found no differences in pain reducing effect (Grimmer, 1992; Hseuh, 1997; Jensen et al., 1991; Nash et al., 1990; Tulgar et al., 1991a). Only one study reported a difference in favor of HFT (Mannheimer and Carlsson, 1979) and one in favor of LFT (Tulgar et al., 1991b).

Pulse duration and stimulus intensity differ in HFT and LFT and could also be a decisive factor for efficacy. Animal and human studies have shown higher analgesic effects by increasing the stimulus intensity (Garrison and Foreman,

* Corresponding author. Tel.: +31-43-387-5463; fax: +31-43-387-5457.
E-mail address: ako@sane.azm.nl (A.J.A. Köke).

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1996; Sjolund, 1985, 1988; Wang et al., 1997; Woolf, 1979) or longer pulse duration (Garrison and Foreman, 1996; Walsh et al., 1995, 1998). Combining the stimulus parameters of both working mechanisms increases the hypoalgesic effect of TENS (Walsh et al., 1995).

The precise mechanism of action and the precise relevance of stimulus parameters to hypoalgesic effects are therefore still unclear. As a consequence, the most effective combination of stimulus parameters (frequency, pulse duration, intensity) is still unknown (Chesterton et al., 2002).

Combining high frequency with high stimulus intensity might act both on segmental as well as on supra-spinal levels of pain inhibition systems and therefore can prohibit larger hypoalgesic effects.

To test this hypothesis, we conducted a randomized crossover trial to compare the hypoalgesic effects of high frequency conventional TENS (HFT) and a combination high frequency high intensity TENS (HIT).

However, not only neurophysiological stimuli influence the endogenous pain inhibition system, but also psychological processes such as perceived control over pain or self-efficacy beliefs on coping with chronic pain influence levels of catecholamines and endogenous opioids (Lackner and Carosella, 1999). It can be hypothesized that hypoalgesic effects of TENS are also due to enhanced feelings of control over pain by using TENS.

To test this second hypothesis, we also conducted a randomized crossover trial in groups to compare the hypoalgesic effects of high frequency conventional TENS (HFT) and a combination type high frequency high intensity TENS (HIT) with a 'control' TENS (COT), in which patients were free to use TENS as they preferred. We hypothesized that the HIT has greater hypoalgesic effects than HFT, and that both HFT and HIT are more effective than COT.

2. Methods

Out-patients from the Pain Clinic at the University Hospital of Maastricht were screened for eligibility. Inclusion criteria were (a) patients referred for TENS treatment by pain physicians, (b) duration of pain >6 months, (c) age above 18, (d) no current other treatment for pain. Exclusion criteria were (a) pain due to cancer, (b) the use of a cardiac pacemaker, (c) pregnancy, (d) neurological sensory deficits, (e) language and/or cognitive inability to complete the health assessment questionnaires, and (f) previous TENS for pain relief. After providing an informed consent the patient was included in the study. The ethical committee approved the research protocol. Three different methods of TENS were compared in a randomized, single blinded crossover design. Patients received two times a 2-week period of daily TENS treatment, separated by a washout period of 2 weeks. The subjects were randomly assigned to one of the three groups (group 1, HFT–HIT; group 2, HIT–COT; group 3, HFT–COT). Random assignment was performed by means of a table of random numbers prepared independently by computer. Therapy assignment was drawn from sealed opaque envelops by an independent person.

2.1. Intervention

Three physical therapists, experienced with TENS, conducted the treatment. Patients received their TENS-unit after verbal and written instruction. Based on diagnosis, medical history and physical examination the physical therapist located for each patient three potential sites for stimulation; (a) in the area of painful sensation, (b) in the region of the peripheral nerve innervating the painful area, and (c) according to the segmental innervation of the painful area. Patients were instructed to experiment with electrode positions (stimulation sites), as instructed by the therapist in order to discover the optimal site for pain relief. Self-adhering, reusable electrodes type PALS Platinum 895220 (5×5 cm^2) were used.

Patients kept a daily record of stimulation site used and severity of pain. No co-interventions, besides existing pain medication, were allowed.

In the high frequency conventional TENS group (HFT; frequency 80 Hz, pulse duration 80 μs), patients were instructed to use TENS 4–6 times a day for 1-h periods at sensory threshold intensity. In the high frequency high-intense TENS group (HIT; frequency 80 Hz, pulse duration 250 μs), patients were instructed to use TENS 4–6 times a day for 30-min periods at maximum tolerated intensity level. In the control TENS group (COT; frequency 30 Hz, pulse duration 250 μs) patients were free to choose stimulus duration and stimulus intensity as they preferred. Two TENS-devices were used: TWIN-STAR (van Lent Systems B.V. Netherlands), TENStem (Schwa Medico Netherlands).

2.2. Outcome measurement

Primary outcome variables were patients' global assessment of overall result (positive or negative) and reduction in severity of pain. Global assessment is based on a patient's decision to continue TENS in the future. It can be regarded as an index of the patient's assessment of the benefits (efficacy) of the treatment versus its side effects (risks, problems in handling), providing a patient-based evaluation of the effect of treatment (Farrar, 2000).

The success of each treatment period (TENS-type) was rated by the patient indicating his/her willingness to continue treatment with specific TENS-type (positive) or not (negative).

Average severity of pain during the past week was measured on a 100 mm visual analogue scale (VAS), which is a valid and reliable measurement (Bolton, 1999).

Baseline measurements consisted of demographic data such as age, gender, marital status, education, employment, pain location, medical diagnosis, and severity of pain (VAS). Following each 2-week treatment period, and at the start of the second treatment period, severity of pain (VAS) was measured by a blinded observer. Also patient assessment was recorded at the end of each treatment period. At 6 months follow-up, patients received a postal questionnaire, containing questions about continuation of TENS and severity of pain (VAS).

2.3. Statistical analyses

The prognostic similarity of the TENS groups at baseline was determined for all baseline characteristics. Therefore, measures of central tendency and dispersion were calculated.

Patients' assessments of outcome were described and compared per group by means of χ^2 tests. A difference in severity of pain within groups was analyzed by paired *t*-test. Severity of pain (VAS) was also analyzed using a mixed linear regression model to compare the effects of all three types of TENS. The outcome measures in the short term (periods 1 and 2) were dependent variables. The intervention allocation (TENS-type) was a dichotomous independent (dummy) variable and the baseline values of the outcome measures were incorporated in the mixed model as covariates. Because of the crossover design, the treatment periods also are incorporated in the model as a fixed factor. In case of differences in baseline characteristic ($P > 0.05$), these variables were also incorporated in the model in order to control for possible confounding. All patients were entered in the analysis, according to the intention-to-treat principle. Analysis was performed using SPSS 11.0 for windows.

3. Results

In the period of April 2000 until March 2001, 228 patients were referred for TENS treatment. A total of 180 were randomized over the three groups. After the first treatment period, there were nine dropouts, who refused further treatment. A total of 171 patients completed both treatment periods. At 6 months follow-up, 151 patients returned their questionnaires (see Fig. 1). Baseline characteristics of all baseline measurements are presented in Table 1. No statistical differences were found at baseline.

3.1. Washout period

Severity of pain was comparable at the start of both treatment periods in all groups. The mean difference between the pain score (VAS)) measured at the start of period 1 and that measured at the start of period 2 was 3.6 mm (SD = 19.9, $P = 0.19$) in group 1 (HFT–HIT), 0.4 mm (SD = 15, $P = 0.84$) in group 2 (HIT–COT) and 2.5 mm (SD = 16.8, $P = 0.26$) in group 3 (HFT–COT).

3.2. Compliance

Eighty-nine percent of the patients filled in their pain diary adequately (at least 10 of 14 days). Only 12 patients (6%) stopped during a treatment period due to lack of effect, worsening of pain or skin irritation. Reports of hours TENS per week for HFT, 36.7 (8.6) h; HIT, 19 (10) h; and COT, 40.6 (19.8) h; were as expected according to instructions. No differences were found in and between groups.

3.3. Electrode placement

Most patients (97%) reported electrode placement directly over the site of pain or in the area of pain as the most favorable stimulus site.

3.4. Adverse effects

During the first period, skin irritation occurred in 9.4% (17/180) of all patients, adherence problems of electrodes in 12.2% (22/180) and problems attaching electrodes in 2.2% (4/180). In four patients, the adverse effects resulted in withdrawal from the study (skin-irritation 2 ×, problems attaching electrodes 2 ×). During the second period, skin-irritation was reported by 5.8% (10/171), adherence problems of electrodes 4.7% (8/171), and problems attaching electrodes body 2.9% (5/171). No significant differences in adverse effects were found between groups. At 6 months follow-up, 6 patients (3 in HFT–COT group and 3 in HIT–COT group) reported skin irritation due to TENS, but still could use TENS regularly.

3.5. Patients' global assessment of effect

No differences in the proportion of patients reporting positive results of the 2-week treatment periods were found between the types of TENS within each group (Table 2). Patients had to assess the two treatment periods (TENS-types). In group 1 (HFT–HIT), 29 patients continued TENS after the initial treatment period. Of these, 14 patients reported success in both types of TENS, 7 patients reported only success with HFT and 8 reported only success with HIT. In group 2 (HIT–COT), 37 patients continued TENS. A positive outcome in both types of TENS in this group occurred in 24 patients, while 6 patients rated only HIT or only COT as positive. In group 3 (HFT–COT), 36 patients continued TENS. Of these, 24 patients judged both TENS-types as positive, 6 reported only positive outcome with HFT and 7 had only a positive result with COT.

A large number of patients ($n = 62$) had a positive outcome in treatment with both types of TENS. A total of

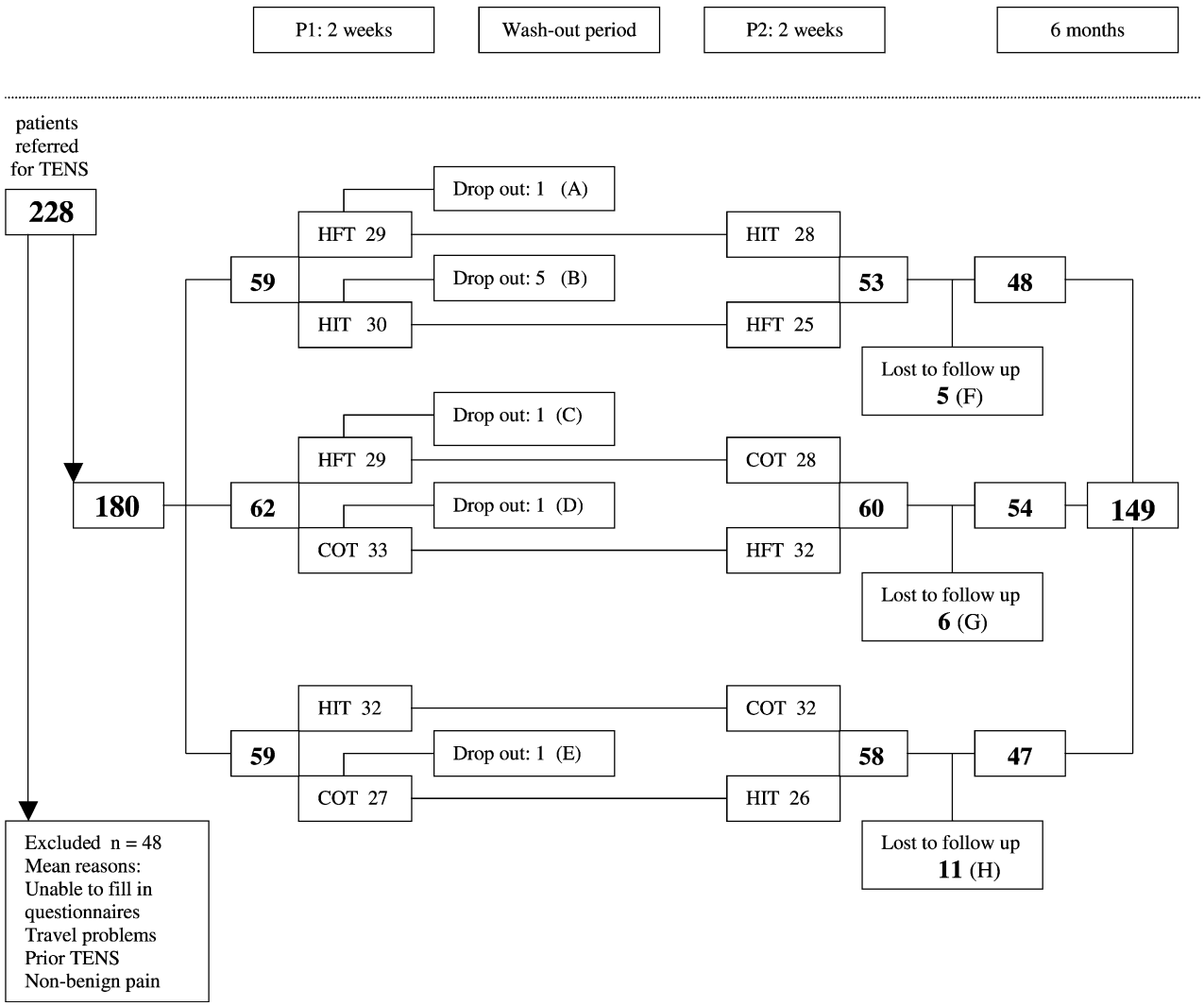

Fig. 1. Flow diagram summarizing the formation of the study group and the number and group membership of dropouts or lost to follow-up throughout course of the study. Reasons for dropout: (A) more pain (1 ×); (B) more pain (1 ×), skin irritation (1 ×), problems handling TENS (2 ×), positive effect (1 ×); (C) more pain (1 ×), problems handling TENS (1 ×) and (D) skin irritation (1 ×). Reasons lost to follow up: (F) one patient died, unknown (4 ×), (G) unknown (6 ×), and (H) one patient died, unknown (10 ×).

102 patients (56%) reported a post-treatment positive result and continued to use TENS.

3.6. Pain

Pain severity decreased between baseline and post-treatment within all groups and types of TENS. In group 1, pain reduction (VAS) was on an average 13.3 mm; in group 2, the reduction was 12.6 mm; and in group 3, the result was 14 mm. No significant difference in size of effect was found between types of TENS within groups (Table 3). The results of the linear mixed model also indicated no statistical difference in pain reducing effect by type of TENS (HFT compared to HIT and COT ($P = 0.729$), HIT compared to HFT and COT ($P = 0.503$), COT compared to HFT and HIT ($P = 0.753$)). Use of pain medication after TENS treatment also did not differ between three groups or type of TENS.

3.7. Results of follow-up at 6 months

In total, 151 (84%) of 180 (see Fig. 1) patients initially entered in the study responded to the postal questionnaire at 6 months. After the first treatment period, nine patients withdrew from the study. Another 21 patients did not return their questionnaire, despite reminders. As two patients died before follow-up, the results of 149 patients were analyzed at 6 months.

3.8. Continuing TENS

At 6 months, 75 of the 102 patients who continued using TENS after the treatment period still used TENS regularly

Table 1
Prognostic variables and baseline values of outcome measure for three groups

	HFT–HIT ($N = 59$)	HFT–COT ($N = 62$)	HIT–COT ($N = 59$)	P-value
Age (mean, SD)	52 (14.7)	50 (13.7)	49 (12.8)	0.683
Sex (%male)	34	42	31	0.286
Education (%)				
Low	52.5	61	51	0.464
Middle	44	31	37	0.314
High	3.5	8	12	0.229
Duration pain (months, SD)	81 (92)	66 (96)	78 (89)	0.231
Having a job (%)	34	32	34	0.165
Partner (%yes)	90	82	76	0.116
Pain (mm VAS, SD)	65 (17)	64 (20)	63 (21)	0.961
Medical diagnosis (%)				
CLBP	20.3	21	22	0.974
CPS	13.6	9.7	10.2	0.765
CRPS II	5.1	12.9	8.5	0.319
Failed back surgery	11.9	6.5	11.9	0.518
Thoracic spinal pain	8.5	8.1	3.4	0.469
Neuropathic pain	15.3	14.5	11.9	0.855
Cervical spinal pain	11.9	12.9	10.2	0.895
IBS	0	1.6	5.1	0.161
Cervicogenic headache	6.8	8.1	6.8	0.951
Miscellaneous	6.8	4.8	10.2	0.522

CLBP, chronic low back pain; CPS, chronic pain syndrome; CRPS II, complex regional pain syndrome; IBS, irritable bowel syndrome.

and 18 had stopped. Nine patients, who continued TENS after the treatment period did not return the postal questionnaire after 6 months, were counted as non-users. In total, 27 patients had stopped using TENS. Therefore, 75 (42%) of all 180 patients initially entered in this study still used TENS at 6 months. Reasons for discontinuing TENS in the group with short-term positive outcome were (a) decrease of sufficient hypoalgesic effect (10 patients), (b) development of other illness complaints (3 patients), (c) pregnancy (2 patients), and (d) unknown (9 patients). Three patients (one in each group) stopped because they were totally pain-free.

In the group of patients still using TENS, 10 patients (13%) reported an increased hypoalgesic effect. In 51 patients (67%), the effect was stable over time and in 14 patients (18%), the hypoalgesic effect decreased.

We compared pain ratings of patients still using TENS versus patients who did not continue TENS at the beginning or stopped during the past 6 months. At 6 months, pain ratings on VAS in the group of TENS-users dropped compared to baseline (62 mm (SD = 20) versus 45 mm (SD = 23)). In the group of non-users, the pain ratings on VAS at 6 months were also lesser compared to baseline (64 mm (SD = 20) versus 60 mm (SD = 20). The mean pain reduction in the users group was greater than in the non-users group. This difference was statistically significant (Table 4).

Table 2
Total patients assessments for periods 1 and 2 together (% positive results)

	Group I	Group II	Group III
HFT	21/59, 36%	30/62, 48%	
HIT	22/59, 37%	–	30/59, 51%
COT	–	31/62, 50%	30/59, 51%

4. Discussion

A total of 102 patients (56%) reported the results of TENS treatment as positive and continued using TENS direct after the trial. Yet, no differences in success rate or reduction in severity of pain per type of TENS were found in this study. Patients reported an equal reduction of severity of pain in all type of TENS. Therefore, there is no evidence of superiority of one type of TENS in treatment of patients with chronic pain.

Compared to reported relative difference in percentage change in pain severity from baseline as outcome ranged from 11 to 38% (Milne, 2003), our reduction in pain of 19% for the total study group is average. A minimal reduction between 30 and 50% in VAS score is considered as clinically relevant (Farrar et al., 2000). Using the 50% reduction outcome parameter, only 20% of all test periods would have been positive in our study. Comparing this result to the proportion of patients judged, TENS (56%) as positive indicates that 36% had less than 50% reduction of pain. Apparently, 50% reduction is too high to serve as a clinically relevant outcome. Recommendation for pain relief of 30% in VAS scores is probably more appropriate as in our population, patients with a positive assessment had on an average 33.5% (range 25–43) pain reduction on VAS.

The fact that all TENS types displayed equal effect questions the supposed different working mechanisms. In COT, the frequency of 30 Hz was chosen as a frequency in between the low (1–10 Hz) and high (50–100 Hz) range, to diminish optimal neurophysiological working mechanism. The combination with used pulse duration (250 μs) was based on feelings of comfort. Patients were allowed to use the TENS as often and as long as they thought would be effective. Patients were also free to choose the intensity they preferred. Although we cannot rule out the physiological effects of this type of TENS, according to the theoretical assumptions described above, it should be less effective neurophysiologically. The fact that COT is equally effective might indicate that a patient's personal preferences might be important. Johnson et al. (1991a) already mentioned that patient's preference for specific pulse frequencies and patterns is more related to reasons of comfort than to the cause and site of pain. Psychological mechanisms, such as increasing the feeling of control and enhancing coping with pain by TENS should be taken into consideration for

Table 3
Comparison of pain reduction in mm VAS per type of TENS

	Pain reduction (mm VAS), mean (SD)		Mean difference	SE, mean	95% CI		*P*-value
					Lower	Upper	
Group I	HFT	HIT					
$N = 53$	13.4 (21.9)	13.5 (21.9)	−0.1	3.5	−7.09	7.02	0.991
Group II	HIT	COT					
$N = 58$	12 (21)	13 (19.3)	−1.0	3.1	−7.21	5.18	0.744
Group III	HFT	COT					
$N = 60$	13.3 (19.7)	15 (23.6)	−1.7	3.5	−8.61	5.24	0.629

explaining effects of TENS, as these factors influence pain severity in general (Jensen and Karoly, 1991). But definite conclusions on evidence for effectiveness of TENS or proposed working mechanisms cannot be made in this study, because a placebo group was not included.

The inconclusive results of this study are in line with a recent systematic review on TENS treatment for a variety of chronic pain syndromes (Carroll et al., 2003). Definite conclusions in this review could not be drawn due to methodological flaws (randomization, blinding, sample size) and missing data on factors such as compliance, site of application, treatment duration, optimal frequencies and stimulus intensities. We tried to overcome these flaws in our study design with an appropriate randomization and blinding as well as acceptable sample size. Because of heterogeneity of the chronic pain population, in terms of type and localization of pain and medical diagnosis, a crossover design was chosen. Heterogeneity of study populations is considered to be a factor diminishing treatment effects in randomized clinical trials. In a crossover trial, each participant acts as his or her own control, thereby reducing heterogeneity and increasing power.

Compliance was generally good. Patients reported sufficient use of TENS during the 2-week treatment periods. The total hours of TENS in our study were much higher than reported in other studies (Carroll et al., 2003; Milne, 2003; Osiri, 2003). A period of 2 weeks of daily use of TENS seems appropriate for decision making on continuing TENS-treatment. However, the duration of our treatment period to evaluate effectiveness of TENS might be inadequate. Osiri (2003) stated that TENS benefits are achieved with treatment periods of at least 6 weeks. However, this conclusion was based on only one study. We agree with Osiri that a single treatment period, as used in many TENS studies, is inadequate to test clinical effectiveness. TENS has, as suggested, a direct impact on pain modulating systems, therefore, pain reduction reasonably should appear within 2 weeks when applied on daily basis.

Electrode placement is another important factor, which can influence the effectiveness of TENS (Walsh and Baxter, 1996). During the 2-week test period, patients were allowed to test several electrode placements as recommended by the physical therapist. In general, most patients chose local placements within the painful region. We did not control adequate trial of electrode placements during treatment periods. It is possible that searching for optimal electrode placements was not sufficient in all patients.

Adverse effects are rarely presented in studies of TENS (Carroll et al., 2003). The reported adverse effects in our study are comparable with other reports (Kumar and Marshall, 1997; Nash et al., 1990) although other studies mentioned no adverse effects at all (Moore and Shurman, 1997). Adverse effects of TENS seem rare, indicating TENS to be a safe technique.

A declining effect of TENS with time is suggested (Johnson et al., 1991b). Most studies on TENS, however, did not measure long-term effect (Carroll et al., 2003; Milne, 2003; Osiri, 2003). In our study, about 26% of 102 patients stopped using TENS during the 6 months follow-up. A decline of pain reducing effect was the most reported reason for discontinuing. A much larger group (74%), however, continued TENS where some even reported progression in pain reduction. This results in a positive success rate of 42% of all patients randomized in the study on the long term. The severity of pain at 6 months was in general less compared to baseline levels. Initially pain ratings were high and this might be due to regression to

Table 4
Pain reductions from baseline at 6 months follow-up in TENS-users versus non-users

Pain reduction (mm VAS), mean (SD)		Mean difference	SE difference	95% CI		Significance (2-tailed)
Users ($N = 75$)	Non-users ($N = 74$)			Lower	Upper	
17 (20)	4 (20)	13	3.3	−19	−6	0.0001

the mean. On the other hand, pain ratings of patients still using TENS were lower than patients who did not use TENS at 6 months follow-up. The reduction in pain (rating) might have contributed to the continuation of TENS on the long term. This might be indicative of a pain-reducing effect of TENS in this group of patients. However, other reasons might influence a patient's decision to continue TENS. Since other reasons for continuing TENS were not assessed in this study, definite explanations for long-term use of TENS are lacking.

5. Conclusion

No differences in positive assessment of TENS by chronic pain patients or hypoalgesic effects were found between three different types of TENS. A substantial proportion of patients with chronic pain reported reduction in pain ratings, even after 6 months. Further research to detect specific characteristic of this subgroup is needed. Definite conclusions on effectiveness of TENS in general cannot be made in this study, because a placebo intervention was not included. Considering psychological working mechanisms in future TENS-research seems necessary.

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