

Transcutaneous Electrical Nerve Stimulation (TENS) Treatment Outcome in Long-term Users

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Abstract:

Objective: Previous reviewers of the literature on transcutaneous electrical nerve stimulation (TENS) outcome have concluded the following: (a) there are few long-term TENS follow-up studies, and (b) fewer studies have addressed the effect of long-term TENS use on outcome variables other than pain (e.g., function).

Design/Setting/Participants/Outcome Measures: From a population of 2,003 chronic pain patients (CPPs) who bought a TENS device for pain management, 506 patients were randomly selected and interviewed by telephone long enough after purchase to allow at least 6 months of TENS use. The interview process used a structured "skip" questionnaire designed to assess the CPPs' perceptions regarding the effectiveness of TENS for a variety of outcome variables. Of the 506 CPPs interviewed, 376 (74.3%) had used their TENS device for 6 months or longer and were defined as *long-term users*. The responses of this group of CPPs to the telephone questionnaire were then subjected to statistical analysis.

Results: Paired *t*-tests, correlated *z*-tests, SS Wilks, and chi-square tests demonstrated statistically significant change or improvement ($p < 0.05$) that paralleled the introduction of TENS use in the following outcome variables: less pain interference with work, home, and social activities; increased activity level and pain management; decreased use of other therapies (e.g., physical therapy, occupational therapy, chiropractic); decreased use of narcotics, tranquilizers, muscle relaxants, nonsteroidal anti-inflammatory drugs and steroids.

Conclusions: The results suggest that TENS is associated with improvement on multiple outcome variables in addition to pain relief for CPPs who are long-term users. Also, for some CPPs, long-term TENS use continues to be effective.

Key Words: TENS—Long-term users—Treatment—Outcome—Effectiveness—Chronic pain.

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Transcutaneous electrical nerve stimulation (TENS) is a method of applying low-voltage electrical current through the skin at various placement sites using surface electrodes. It was originally de-

veloped in the early 1970s as a screening technique for predicting which chronic pain patients (CPPs) would respond to implantable stimulators with good pain relief (1). In using TENS for this purpose, it became apparent that a significant percentage of CPPs attained pain relief, mitigating the necessity for implantable stimulators (2). Since that early era, the efficacy of TENS for the treatment of pain has been widely studied in more than 600 publications existing in this area of research (3).

The issue of TENS pain relief efficacy has also been discussed in review articles. In a 1975 review, Long and Hagfors concluded that TENS is a satisfactory treatment for a large number of CPPs and that at least 25% of TENS treated patients can be treated by this technique alone, not requiring more extensive therapy (2). About 10 years later, in another review, Melzack and Wall, two pioneers in the study of pain, concluded that "there was no longer any doubt that TENS is an effective way to treat chronic pain" (4). In a later review, Gersh and Wolf concluded that the literature evidence indicates that TENS is efficacious for the treatment of acute pain; however, in reference to chronic pain, they noted that the weakest part of the TENS research literature was its sole reliance on the CPPs' reports of pain to establish TENS efficacy rather than using other measures of treatment outcome, such as functional activities or socialization. They suggested that researchers concentrate on the long-term effectiveness of TENS in CPPs (5). In 1991 Long again reviewed the TENS literature and concluded the following: (a) nearly all studies indicate that TENS has a beneficial effect on patients suffering from pain of diverse origins; (b) in chronic pain intractable to other treatments, TENS has a short-term benefit in about 50% of patients, and for about 25% TENS is the only therapy necessary for years after treatment begins; (c) the effect of stimulation is beyond that which can be explained by placebo; and (d) there are few long-term follow-up studies available (6).

The authors of this article also reviewed the TENS literature in reference to the effectiveness of long-term treatment with TENS in CPPs and on other measures of treatment outcome besides pain. The TENS studies can be broken down into two categories: those studies that simply report on the percentages of CPPs benefiting from TENS after a long interval and those studies reporting some sort of outcome measure besides pain in this patient population. For the first category, we were able to

find 20 studies (7-27) reporting on more than 7,600 CPPs. The data reported in these studies generally indicate that initially from 48 to 72% of CPPs perceive a positive effect in terms of pain relief from TENS (13,15,18,21,23). At 4 to 5 weeks, 46 to 72% of the original CPPs perceive a positive effect (7,10,11,16,19); at 3 months, 55% perceive a positive effect (20); and at 6 months, 13 to 74% are reported to perceive a positive effect (7-12,14-16,18,22-24). At 12 months after beginning TENS treatment, 20 to 66% of CPPs are reported still to perceive a positive effect for pain reduction (10,11,13,19,20,27). Two years after beginning TENS treatment, 20 to 32% of the original CPPs still are reported to perceive a positive effect from TENS treatment for their pain (11,16,20,26). Finally, at 3 and 4 years, 43 and 25% (respectively) of the original CPPs still report benefit from TENS for their pain (11,21). One study (25) reported that 93% of the CPPs benefited from TENS for pain reduction at a mean of 6.6 months. It is difficult to compare this last study to those above, as here only CPPs with facial pain were included, and these CPPs may represent a special group. Of these 20 studies, only one (23) had used a non-TENS treatment control group (sham TENS). Here it was found that the placebo analgesic effect occurred in 32% of trials versus 48% for actual TENS stimulation. Within these long-term follow-up TENS efficacy studies, we were unable to find any studies reporting that none of the original patients were benefiting from TENS for pain relief at some follow-up time. The lowest benefit results were 20% (26,27).

We were able to find only six studies (20,21,24,25,28,29) that addressed the effect of long-term TENS use on other outcome variables besides pain reduction. Here five studies (20,21,24,25,29) reported that long-term TENS use helped the CPP reduce medication intake. Only one study reported on an associated increase in socialization (20), and one study reported an associated increase in sleep (24). One study (28) in this group used a non-TENS treatment control group. This study demonstrated a significant increase in activity level in the group of CPPs using TENS versus those not using TENS; however, there was no difference in analgesic intake between the two groups at 1-year follow-up.

From the above review of the literature, one can conclude the following: (a) initially a large percentage of CPPs will perceive a positive effect on pain from TENS use; (b) a smaller but significant percentage of patients will continue perceiving a posi-

tive effect over a long time and can be classified as *long-term users* (LTU); (c) there are few long-term follow-up studies in the literature; (d) according to the literature, the LTU group is identified as using TENS for at least 3 months; (e) although the literature indicates that the LTU group benefits in terms of perceived pain reduction, only a limited number of studies have reported whether this translates into changes in other treatment outcome variables (e.g., increased function), and; (f) only one (28) of the reviewed studies (20,21,24,25,28,29) that address outcome variables besides pain reduction employed statistical methods in reporting the efficacy of TENS on changes in pain and other outcome variables in CPPs classified as LTUs. The study described in the following section addresses the perceived efficacy of TENS treatment for pain reduction and other outcome variables in an identified group of CPPs who are LTUs of TENS.

METHODS

In 1994, the Clinical Research Department at Empi, Inc., a manufacturer of TENS devices, undertook a scientific telephone treatment outcome survey of CPPs who would be identified as LTUs of TENS. To control for potential industry bias, Empi contracted with Winona MRB, Inc., an independent research firm located in Phoenix, Arizona, to collaborate in the survey design and to conduct the study independently. Winona specializes in quantitative methodologies, particularly those involving large-scale data collection and processing.

To assess TENS use and various outcome parameters, a telephone questionnaire was devised using a structured "skip" pattern to identify those CPPs who were nonusers and LTUs of TENS and to ascertain responses for the LTU group. The "skip" questionnaire is a method used routinely in survey research that allows the survey to address follow-up questions to the appropriate populations (i.e., if yes, go to question 3; if no, skip to question x). Survey questions pertinent to this report (i.e., outcome variables) are reproduced in the Appendix. For several of the outcome variables (questions 5A, 6A, 6B, and 10B) (Appendix), 10-point rating scales were used. This type of rating scale is patterned after the numeric pain rating scale (NPRS), which is claimed to perform better than both a 4-point simple descriptive scale or a continuous scale (visual analogue scale) (30). Within the NPRS, the subject is asked to select a number from 0 to 10; therefore, the

scale can be administered over the telephone. The NPRS is reported to have high content validity and high correlation with the visual analogue scale (30). Test-retest reliability has not been reported.

For sampling purposes, Empi provided Winona with the names and telephone numbers of all pain patients who had bought (either through self-pay or insurance purchase) an Epix XL (Model 989, Empi, Inc., Minneapolis, MN, U.S.A.) TENS device during October 1993 (n = 2259). The Winona telephone interviews were conducted between May 19 and May 31, 1994, allowing at least 6 months of potential TENS use and hereby potentially identifying CPPs. Before sampling, Winona removed from the list of potential interview candidates any patient with auto-insurance payer status (n = 256, 11.3%). This step was done because future analyses of the data may include a comparison of worker-compensation and non-worker-compensation payer groups. It was believed that auto insurance patients would not logically fit into either payer category, as a confounding factor influencing their outcome would be related to economic gain. In the worker-compensation group, in addition to economic gain, there could be work-related factors influencing outcome that would not be applicable to the auto group. The sub-categories were then identified as worker-compensation and non-worker-compensation (private, self-pay) subjects. This left a sampling list of 2,003 patients.

All interviewing was conducted at Winona's computer-assisted telephone interviewing facility in Phoenix, Arizona. Before interviewing, all interviewers were trained on sampling techniques and on conducting an efficient, quality interview. The competence of the interviewers for flow and clarity of questions was then tested on a subsample (n = 20) of the population. As a result, minor adjustments were made to several survey questions to enhance clarity before onset of the study.

Worker-compensation patients and non-worker-compensation patients were sorted into equal groups. Names for interviewing were then randomly selected from each group according to the *replicates* method, a method commonly used in survey research to avoid sample bias. Calls were made to the selected patients until a minimum quota of 400 TENS patients who reported using their device in the last 2 months and 100 TENS patients who reported not using their device in the last 2 months was met. In fulfilling these stated quotas, Winona interviewers registered the following information:

of 2,003 potential respondents, 1,822 telephone numbers were dialed; of 1,328 answered calls, 723 patients had either died, moved, there was no such person, or it was a business number; of the remaining 605 patients with whom contact was established, 34 refused to be interviewed, and nine were unavailable on callback; all of the remaining 562 patients were screened for use of the device in the last 2 months; of the 562 screened patients, 506 received the full-skip questionnaire interview as the quotas were filled. At completion of the 506 interviews, Winona registered 405 patients who had used their device in the last 2 months and 101 patients who had not.

The collected data were then tabulated by Winona MRB, Inc., and a report was sent to Empi. Empi then provided the report and the data on computer disk to the senior author in efforts to collaborate on publication.

STATISTICAL ANALYSES

For purposes of statistical analysis, the LTU patient group was defined as patients who used TENS for 6 or more months. Of the 405 patients who reported TENS use in the past 2 months, 29 were removed because of a self-report of less than 6 months of TENS use, thus leaving 376 patients for analysis in what henceforth will be referred to as the *LTU group*. The nonuser (NU) patient group was defined as patients who had not used TENS in the 2 months presurvey and who had used TENS for less than 6 months prediscontinuation. Of the patients who reported not using TENS in the last 2 months ($n = 101$), 26 were removed because of their self-report of TENS use of 6 months or more prediscontinuation, thus leaving 75 patients for analysis in what henceforth will be referred to as the *NU group*.

As a preliminary statistical procedure, the reliability and validity of questionnaire items were tested. Internal consistency reliability was tested using Cronbach's alpha coefficient (31,32). This statistic is appropriate for determining the reliability of a scale (total score created by summing questions together) (33). Construct validity was tested using Pearson's correlation coefficient (31). Test-retest reliability data were gathered 11 months after the original survey for 30 of the original LTU of TENS. Six questions were tested using the following statistical tests: Questions 1, 5a-1, 5a-2, and 6a, Pearson's correlation coefficient; questions 5b and 9, Kendall's Tau-b; and question 5f, kappa statistic.

Analyses were conducted using the SAS System (SAS Institute, Cary, NC, U.S.A.) (34). Descriptive statistics (mean, standard deviation, standard error, and frequency distribution) were calculated for all variables. Paired *t* tests and correlated z-tests (35,36) were used to evaluate quantitative and proportional prescores and postscores scores, respectively. For non-prescore or postscore proportional variables, SS Wilks (37) was used to test for differences between correlated proportions, and a chi-square (33) was used to test for differences between independent proportions.

The correlated z-test was used because it takes into account that the two percentages are correlated and that the same people are included in both percentages, but that the correlation between the percentages can vary (36). SS Wilks for correlated proportions was used because it takes into account that two percentages are perfectly correlated and that the same people are included in both percentages (37).

RESULTS

The Cronbach's alpha results were acceptable for questions 5a and 6a/6b, both for prescores (0.69) and for change scores (0.76). When global measures of medication and drug use were added, alpha decreased for the prescores to 0.56, possibly because our global measures were less than perfect. For our global reliability analyses of difference scores, we used the previous six variables plus we were able to add questions 5b, 5e, and 9, which resulted in an acceptable estimate of reliability for the global measure of change of 0.69. The Pearson's product correlation indicated that items that were logically related were significantly correlated. For example, we found that question 5b was significantly correlated ($p < 0.0001$) with improvement in questions 5a-1, 5a-2, 5a-3, and 10a. For the test-retest reliability data, correlations ranged from 0.13 to 0.81, most being fairly high with three correlations being statistically significant ($p < 0.01$). We believe greater test-retest correlations were not achieved as a result of the small sample size, the time interval between testing (11 months), and the possibility of the variability of the measurements with time.

The mean age of the NU group was 50.1 ± 16.5 years; 34.7% were men, and 30.7% were worker-compensation patients. They reported using TENS for 3.4 ± 1.7 months prediscontinuation. Of the NU who discontinued using the device because of improvement in their condition ($n = 30$), 96.7%

claimed that they would use TENS again if they were reinjured or if the previous level of pain reoccurred. For 96.7% of this last subgroup, it was also a comfort to know that the device was available if their pain reoccurred. Of the subgroup of nonusers who quit using the device for technical or other reasons ($n = 25$), 88.0% responded that if the reason for discontinuing their TENS device could be resolved, they would use it again. Reasons for discontinuation of TENS use and the mean days of use before discontinuation for these subgroups are presented in Table 1. The most common reason was condition improvement. Before discontinuation, the "condition improved" group used the device for a mean of 114.4 days ($SD \pm 56.7$). The mean length of use for patients who reported no longer finding TENS helpful was 97.3 days ($SD \pm 49.0$).

The mean age of the LTU group was 47.9 ± 14.7 years; 38.3% were men, and 49.7% were worker-compensation patients. Overall, the LTU group had used TENS for a mean period of 12.0 ± 12.4 months. Of the LTU group, 69% reported using the TENS device from 6 months to a year, 27% had used the device for longer than 1 year, and 4% did not remember exactly how long they had used the device. The LTU group reported using TENS for 30.7 ± 21.6 days in the 2 months presurvey and using it for 6.1 ± 5.2 h per day. This group reports having the pain for which the TENS device was being used for 40.4 ± 62.2 months, but 15.5% of the LTU had been reinjured or had experienced an event that caused the pain to worsen in the past 6 months.

Of the 376 LTU surveyed, 68.9% were able to report a diagnosis for which their TENS was prescribed. The most commonly reported diagnostic category was herniated disc/sciatica/SP lumbar laminectomy. The reported diagnoses are presented in Table 2. For the patients in Table 2 who were unable to report their diagnosis, 49.2% reported the

TABLE 1. Reasons for discontinuation of TENS in the Nonusers ($n = 75$) and mean days of use

Reason for discontinuation	No. of patients	Mean days of use		
		(%)	(mo)	SD
Condition improved	30	(40.0)	114.4 (3.8)	56.9
Technical problems	16	(21.3)	109.0 (3.6)	47.5
Little help from start	14	(18.7)	83.7 (2.8)	34.4
Other	9	(12.0)	97.1 (3.2)	56.5
Did not help anymore	6	(8.0)	97.3 (3.2)	49.0

TENS, transcutaneous electrical nerve stimulation.

TABLE 2. Long-term users ($n = 376$): diagnosis TENS prescribed for

Diagnosis	No. of users	(%)
Unknown	117	(31.1)
Herniated disc/sciatica/S/P lumbar laminectomy	79	(21.0)
Lumbar sprain/strain	46	(12.2)
Other	34	(9.0)
Neuralgia	26	(6.9)
Spinal stenosis	20	(5.3)
Carpel tunnel syndrome/tendonitis/rotator cuff tear	16	(4.3)
Rheumatoid arthritis	13	(3.5)
Fibromyalgia/myofascial pain syndrome	10	(2.7)
Degenerative disc disease/spondylolisthesis	8	(2.1)
Fractured vertebrae/ "broken back"	2	(0.5)
RSD/causalgia	3	(0.7)
TMJ	2	(0.5)
Total	376	(100)

TENS, transcutaneous electrical nerve stimulation; SP, status post lumbar laminectomy; RSD, reflex sympathetic dystrophy; TMJ, temporomandibular joint.

location of their pain to be back, hip, tailbone, or buttock. The pain location categories are summarized in Table 3.

Overall, the mean satisfaction rating of TENS was 8.19 among LTU on a 10-point scale, with 10 representing excellent. Additional satisfaction ratings reported by the LTU group for the TENS device are presented in Table 4.

Tables 5, 6, and 7 present the results for the outcome variables for the LTU group. This group reported a statistically significant reduction ($p < 0.001$) in the amount of pain interference with work outside the home, activity inside the home, and social activity. In addition, they reported a significant increase ($p < 0.001$) in the amount of pain relief achieved since using TENS (Table 5) and also reported a significant reduction in the use of narcotic/analgesics ($p < 0.001$), tranquilizers ($p < 0.05$), muscle relaxants ($p < 0.01$), nonsteroidal anti-

TABLE 3. Long-term users who do not know diagnosis ($n = 117$), pain locations with multiple mentions ($n = 238$)

Anatomy	No. of users	(%)
Lower/upper/midback/hip/tailbone/buttock	117	(49.2)
Shoulder/neck/head	66	(27.7)
Leg/knee/foot/ankle/calf	40	(16.8)
Arm/hand	12	(5.0)
Chest/trunk	2	(0.9)
Other	1	(0.4)
Total	238	(100)

TABLE 4. Satisfaction ratings for the TENS device for long-term users ($n = 376$): summary of rating scale means^a

	N ^b	Mean	SD
Overall satisfaction	372	8.19	2.08
Ease of use/convenience	369	7.66	2.44
Effectiveness of pain management	367	7.50	2.20
Quality of device	368	8.86	1.76
Comfort of the stimulation	371	8.35	1.96

TENS, transcutaneous electrical nerve stimulation.

^a 10 = excellent; 1 = poor.

^b Missing number reflects subjects who answered "don't know."

inflammatory drugs (NSAIDs) ($p = 0.003$), and steroids ($p = 0.014$). A complete list of prescription medication categories reported by the LTU are outlined in Table 5. The LTU group also reported statistically significant reductions ($p < 0.001$) in the use of other therapies since TENS (Table 6). In addition, the number of patients using no other therapies increased significantly for the LTU group since using TENS ($p < 0.001$). Of the LTU group, 65.9% reported an increase in their activity level since treatment with TENS ($p < 0.001$) (Table 7). Among those whose activity level did not increase, 85.5% reported that TENS helped them manage the pain at their current level of activity ($p < 0.001$) (Table 7).

DISCUSSION

The purpose of this study was to identify a group of CPPs who could be classified as "long-term users" of TENS and to report on their perceptions of TENS efficacy for a number of outcome variables including pain reduction. To that end, we defined our LTU group as those who had used TENS for 6 months or longer. Our results identified 74.3% of the interviewed patients ($n = 506$) as belonging to the LTU group. This percentage is slightly higher than the range (13–74%) of patients perceiving a positive effect from TENS use at 6 months as reported in previous literature (7–12,14–16,18,22–24). It is, however, remarkably close. We therefore believe that the way we have defined our LTU group is not at variance with the previous literature, although it is unclear whether such a comparison can be made because of different methodology, sampling, and technology; however, these results demonstrate that, contrary to the popular belief that TENS is valuable only as a short-term treatment, a

long-term effect does exist for certain selected groups of CPPs.

The LTU group is of interest for one major reason: It identifies a group of CPPs who appear to obtain benefit from TENS use over an extended period. In this study, the CPPs had used TENS for a mean period of 12.0 ± 12.4 months, which was surprising as the survey population consisted of patients whose TENS devices were purchased 6 months before implementing the survey. These results may be due to a number of factors, including rental time before purchase or the possibility that the current TENS purchase was a replacement unit for other TENS devices. Typically, the purchase of a TENS device is preceded by a rental period (varying in duration of approximately 1–6 months) during which the effectiveness of the device and the chronicity of the patient's pain is evaluated. The fact that all the patients in the LTU group had bought their TENS unit and some presumably had gone through a rental time period before buying a TENS unit has relevance to the issue of tolerance to TENS. A decline in response to TENS, often termed *tolerance* to TENS analgesia, may occur over time (38,39). The mechanism of this tolerance is not understood but is thought to be due to an adaptive change by the nervous system to regular repetitive stimuli produced by TENS (40). It is expected that patients developing tolerance to TENS analgesia would go through their rental trial of TENS and decide not to buy a TENS unit. Thus, identification of a group of CPPs in which the tolerance effect appears not to occur, despite a mean period of 12.0 ± 12.4 months of use, is of interest for future studies in this area.

Because of the lack of a tolerance effect to TENS in the LTU group, the pattern of TENS use is also of interest. The LTU group had used TENS for 30.7 ± 21.6 days in the 2-month presurvey with 6.1 ± 5.2 h of daily use. One previous study reported that a third of their long-term users had used TENS for 10.3 h per day (38). Their data therefore support our results. Another recent study indirectly supports our results: Marchand et al. (39) determined that TENS treatments given in a laboratory setting for 30 min, twice weekly for 10 weeks produced a cumulative analgesic effect with repeated use. This study's results could thus explain the high frequency of TENS use (almost daily) reported in our LTU group. It is possible that these CPPs were attempting to achieve a cumulative effect. It appears, however, that within the LTU group, tolerance to

TABLE 5. Change in pain interference, actual pain relief, and change in medication use from pre-TENS use to TENS use for long-term users (n = 376)

Question	N	Mean change	SD	df	t-Value	p Value ^a
5a. Pain interference ^b						
With work outside home	296 ^c	2.70 ^d	2.74	295	16.98	0.001
With activity inside	349 ^c	3.03 ^d	2.58	248	21.95	0.001
With social activity	312 ^c	2.79 ^d	2.79	311	17.66	0.001
6a./6b. Pain relief ^b	350 ^c	2.47 ^d	3.91	349	11.81	0.001
8. Medication ^e						
Narcotic/analgic	376	-0.277 ^f	0.736	375	-7.29	0.001
Tranquilizer	376	-0.021 ^f	0.205	375	-2.01	0.05
Muscle relaxant	376	-0.043 ^f	0.332	375	-2.49	0.01
Sedative/hypnotic	376					
NSAID	376	-0.088 ^f	0.561	375	-3.03	0.003
Antidepressant	376	-0.013 ^f	0.171	375	-1.51	0.132
Steroid	376	-0.016 ^f	0.125	375	-2.47	0.014
Other	376	-0.011 ^f	0.103	375	-2.01	0.05

TENS, transcutaneous electrical nerve stimulation; df, degree of freedom; NSAID, nonsteroidal anti-inflammatory drugs.

^a Paired t test analysis.

^b Based on a 10-point scale.

^c Size of N reflects subjects excluded from the analysis for responses "do not know" and "does not apply."

^d Positive value represents decreased pain interference and increased pain relief.

^e Number of medications.

^f Negative value represents decreased medication use.

TENS did not develop despite frequent use. Such a finding is surprising, as one would expect TENS tolerance to be prevented by infrequent use and to develop with frequent use. This issue requires further research to determine the differences between patients who obtain long-term TENS benefit compared with patients in which the effects fade over time.

In reference to outcome variables, the survey data indicated that the LTU group reported that TENS use resulted in a statistically significant increase in pain relief and, as a consequence, de-

creased pain interference with work outside the home, with activity inside the home, and with social activities (Table 5). An often overlooked focus in pain management research is that of the CPPs' quality of life (QOL) (41). It is claimed that researchers often measure discreet outcomes of pain management interventions, e.g., pain. These discreet outcomes may not truly reflect the impact of the interventions of the CPPs' lives; that is, there may not necessarily be a relationship between the measured outcome variable and an impact on the CPPs' QOL (42). The QOL concept is thought to have a mini-

TABLE 6. Change in therapy use for long-term users (n = 376) from pre-TENS use to TENS use

Question	N	% Pre mean	% Post mean	% Mean change	df	Corr	t value	p Value ^a
7a./7b. Other therapies used								
PT/OT	376	81.9	26.1	-55.8 ^b	375	0.106	-19.563	0.001
Chiropractic	376	18.4	5.6	-12.8 ^b	375	0.363	-6.666	0.001
Rx medication	376	77.4	51.3	-26.1 ^b	375	0.275	-9.074	0.001
No therapies	376	3.7	34.6	30.8 ^c	375	0.093	12.084	0.001
Other therapies	376	11.4	8.2	-3.2 ^b	375	0.075	-1.531	0.127

TENS, transcutaneous electrical nerve stimulation; df, degree of freedom; corr, corrected; PT, physical therapy; OT, occupational therapy.

^a Correlated z test analysis.

^b Negative value represents decrease in therapy use.

^c Positive value represents increased nonuse of therapies.

TABLE 7. Patient perceptions for change in activity level, pain management, help in return to work, and medication use for long-term users (n = 376) with TENS use

Question	N	% Yes	% No	% Diff	df	t Value	p Value ^a
5b. Increased activity	370	65.9	34.1	31.8	369	6.439	0.001
5c. TENS helps manage pain	131	85.5	14.5	71.0	130	11.510	0.001
5f. TENS helped return to work ^b	29	86.2	13.8	72.4	28	5.658	0.001
9. Medication decrease	189	50.8	49.2	1.6	188	0.220	0.826

TENS, transcutaneous electrical nerve stimulation; diff, difference; df, degree of freedom.

^a SS Wilks for correlated proportions analysis.

^b Question includes patients who were candidates for return to work (patients working before TENS purchase and those who never stopped working were excluded).

num of four core dimensions identified by factor analyses: functional status, including ability to work; psychological well-being; physical symptoms, for example, pain; and social relations (43). Our study results on pain interference therefore appear to address some aspect of all these core dimensions except that of psychological well-being. These results are also supported by some additional results of this study that addressed some of these QOL issues. The proportion of CPPs in the LTU group reporting increased activity, increased help in returning to work, and increased pain management was significantly greater than the proportion of CPPs reporting no increase for each of these items (Table 7). Finally, these results also support the results of a previous study that found an increase in socialization in association with pain reduction in long-term TENS users (1).

Patient satisfaction was recently recognized as an important treatment outcome variable in all types of medical treatment situations. For pain, the Quality Assurance Committee of the American Pain Society recently recommended that an evaluation of patient satisfaction should be one of the components of a total quality assurance program on pain management (44). In the LTU group, the satisfaction variable was assessed as satisfaction with the device for overall satisfaction, ease of use, effectiveness of pain management, quality, and comfort. For all these items, mean satisfaction scores were very high: all 7.5 or above (Table 4).

In addition to the high satisfaction with the device in the LTU group, there also appear to be some indications of high satisfaction with the device in the NU group. For example, of those in the NU group who discontinued using their device because of improvement, 96.7% claimed they would use the device again if they were reinjured or the previous level of pain recurred, and 96.7% were comforted that the device was available. Even of those in the

NU group who quit for technical reasons, 88% claimed they would use the device again if the technical reason for discontinuation was resolved. Although these last results in the NU group do not address satisfaction directly, it appears that these indirect data point to significant satisfaction for the device, even in the NU group.

The LTU group data indicate that the initiation of TENS appeared to be associated with a statistically significant reduction in the use of most medication groups and the reduction in the use of various types of therapies (Tables 5 and 6). Specifically, TENS use was associated with a reduction in the use of narcotics, tranquilizers, muscle relaxants, NSAIDs, steroids, other drugs, physical and occupational therapy, chiropractic care, overall medication use, and an increase in patients not using any therapies. The demonstrated reduction in medication utilization upon TENS introduction supports the results of previous studies (20,21,24,25,29). The reduction in the use of other therapies on the introduction of TENS has not been demonstrated previously. This reduction in the use of medications and therapies after TENS introduction has three possible explanations. It is possible that the decreased use was a function of the LTU group having reached "chronic" patient status, at which point it would be expected that their use of medical care would naturally decrease over time. We were not able to find any naturalistic studies supporting or disproving this possibility in which a group of CPPs were monitored for an extensive period without aggressive treatment, such as a pain center, while their medical use was being monitored. We did, however, find several studies in which nontreated chronic pain patients were used as controls, and their medical use was monitored during the study period (45-47). Two studies (45,46) reported no decrease (45) or a nonsignificant decrease (46) in the use of addictive medications in the CPP control group on follow-up;

another study (47) reported noticeable reduction in the average number of medications at follow-up. Additionally, we were able to find one naturalistic study (48) in which 38 CPPs with nonmalignant pain were treated with opioid maintenance, with 24 CPPs monitored for at least 6 months. Although this was a highly selected group, none of the CPPs reduced their medication intake. Finally, we were unable to find studies addressing other forms of medical treatments besides medications used in an attempt to explore this issue. Another possibility for the reduction in medications and therapies after TENS introduction is that the changes were actually attributable to a TENS effect. Although the design of the questions for Tables 5 and 6 did not allow for a definitive "yes" here, one other question within the questionnaire supports the notion that the reduction in medications and therapies after TENS introduction is attributable to a TENS effect; this is question 6A/6B (Table 7). The results of this question indicate that the CPPs had a significant decrease in their level of chronic pain after TENS introduction. As medications and therapies are usually prescribed for pain, it would follow that the reduction in medications and therapies should be attributable to decreased pain, which in turn was a function of TENS use. A third possibility for the reduction in medications and other therapies is that it is both a TENS effect and a natural decrease of use over time. We currently cannot address this last possibility.

Our study has demonstrated that a group of CPPs appear to gain therapeutic benefit from long-term TENS treatment with resultant improvement for several QOL variables and an associated decrease in the use of medication and therapy. Another issue is whether the CPP's perceived effects of TENS treatment are secondary to a placebo response. The placebo response to TENS treatment has been a major issue in the TENS literature (39,49). In the current study, the therapeutic benefit reported by the LTU group from TENS treatment is unlikely to be a placebo response for two reasons: First, the placebo response extinguishes with time, as non-specific effects do not exist over a long period (50). Therefore, if the therapeutic response was a placebo effect, it is unlikely that it could have lasted for over 6 months as was the case in the LTU group. Although the duration of response to placebo has not been studied extensively (51), there are more data in the literature indicating that the placebo response is of short duration (<2 months)

(15,52,53,54) compared with opposing data (>2 months) (55). Second, CPPs usually experience multiple unsuccessful attempts at treatment from a variety of sources. As such, they are likely to have "placebo sag" or, in conditioning terms, extinction of their placebo response, which in turn makes success from future treatment (even powerful nonplacebos) less likely (56). As presented, the LTU group had suffered from chronic pain for a mean period of 40.4 ± 62.2 months. Thus, it is likely that this group had received and failed multiple pain treatments. It is also likely, as already pointed out, that the LTU group would have received a trial period of TENS use before buying a TENS unit. This group would be expected to be candidates for the "placebo sag" phenomena, making the placebo response less probable. Thus, the likely presence of this phenomenon in this group of CPPs makes their perceived response to TENS treatment quite significant. The only way to ensure that a treatment is not related to a placebo effect, however, is to compare it with a placebo treatment. Despite the fact that this study does not permit elimination of a placebo component, the persisting effect found is sufficient to conclude a clinically desired effect from TENS.

In addition to the issue of the placebo response, there are a number of other potential confounding issues in this study. First, it is possible that during the period of TENS use the LTU group developed the perception of improvement for pain and the other outcome variables simply because of spontaneous improvement in their chronic pain condition. This is called *regression to the mean* (51). Although possible, it seems unlikely because of the chronicity of LTU group's pain condition. Second, at the time of TENS initiation, a certain percentage of the LTU group was receiving medications, other therapies, or both. Thus, the perceived improvement in the outcome variables could have been a function of these treatments rather than TENS or these treatments plus TENS. This is also possible but unlikely, as the LTU group was able to decrease their use of both medications and other therapies while using TENS. This would speak to the perceived improvement being related to TENS. Third, the design of the study did not allow for an actual pre-TENS measurement of the outcome variables for that time point. As such, the LTU group was asked to remember their pain and functional status pre-TENS introduction at a time when they had already been using TENS for some time. The accuracy of CPPs' memory of pain may be questionable; CPPs

have been shown to remember significantly more pain than they actually rate during a baseline period (57), although discrepancies between prebaseline estimates of pain and remembered ratings were found to be smaller than the discrepancies between actual baseline ratings and remembered pain ratings (58). In some CPPs, present pain level has been shown to influence recall of chronic pain and medication use (59). These discrepancies in remembering pain may be related to the presence of self-referential selective memory disturbances (60), that is *recall bias*. Difficulties in remembering post-health status may not be unique to CPPs. Other groups of patients have demonstrated different recollections of their health status during their hospital stay versus recollection 3 months later (61). It is therefore possible that selective memory issues in the LTU could have affected their perceptions in reference to the outcome variables studied in this survey. As pointed out, however, this problem may not be unique to pain research but to all health research using retrospective patient recollections of health status. Fourth, the presented results on pain improvement, decreased use of various therapies, decreased medication use, and other measures of patient function are based on patient's impressions rather than on factual information. As such, this information would not be as accurate as factual data. Fifth, our definition of the LTU group was formulated by selecting a group of CPPs who would benefit from TENS use; otherwise, they would not be users of TENS. This is true, but it does not detract from the finding that such a group is present within the CPP population and perceives significant benefit from TENS use.

Three issues arise as to the degree that the results of this study data can be generalized to the general population of TENS users. First, this study involved only one type of TENS device, which has design characteristics (waveform, and so on) that may or may not have influenced the outcome. The results, therefore, may or may not be generalized to other types of TENS devices. The second problem relates to the concepts of efficacy versus effectiveness (62). Efficacy research protocols offer the therapy only to patients meeting specific criteria, follow explicit protocols, take place in academic settings, compare test product to a placebo, and seek a specific physiological outcome. Effectiveness trials dif-

fer by testing the treatment on a "typical" patient population using routine medical care in an ordinary setting, which will compare the product to generally available care and patient-perceived outcomes. It is claimed that the information from effectiveness trials can be generalized to broad populations, whereas controlled clinical trial information is useful only in demonstrating a limited effect (62). Because efficacy trials offer therapy to patients meeting specific criteria and because patients are recruited for these trials in limited fashion, for example via newspaper ads, the selected population for these trials may not be truly representative of the problem population at large (63). Although this study used survey methods to assess patient responses, it can best be characterized as an effectiveness study. As such, the data presented here may be generalizable to a subgroup of the general population of patients exposed to TENS. The third problem relates to specific parameters of stimulation. We do not know the specific parameters of stimulation used by the LTU group. It is possible that this LTU group received better instructions on how to use their TENS and found parameters of stimulation that were more conducive to a long-term effect. This is possible as we know that parameter selection is very individualized. Therefore, future studies identifying an LTU group may wish to investigate this issue.

CONCLUSIONS

The results of this long-term treatment outcome survey indicate that within a CPP population, there is a subgroup of patients who use and benefit from TENS for extremely long periods, in contradiction with the popular belief that TENS is valuable only as a short-term treatment. In addition, long-term TENS use by this group is associated with improved function and quality of life and reduced use of adjunctive treatments and medications (i.e., improvement for these outcome variables). Future longitudinal TENS research will need to define and characterize this group of chronic pain patients more fully and to measure outcomes of treatment repeatedly on different occasions.

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APPENDIX

5a. On a scale of 1 to 10 with 1 meaning "Does Not Interfere At All" and 10 meaning "Interferes A Great Deal," how much would you say your pain interfered with the following situations **before** and **after** using your TENS device. How much would you say your pain interfered with your . . . (READ LIST)? (RECORD ONE RESPONSE FOR EACH—REPEAT SCALE AS NECESSARY)

DO NOT READ

↓

	<i>Does not interfere at all</i>					<i>Interferes a great deal</i>					<i>Does not apply</i>	<i>Don't know</i>	
Ability to work outside the home													
Before	1	2	3	4	5	6	7	8	9	10	11	X	
After	1	2	3	4	5	6	7	8	9	10	11	X	
Daily activity within the home													
Before	1	2	3	4	5	6	7	8	9	10	11	X	
After	1	2	3	4	5	6	7	8	9	10	11	X	
Social activities outside the home													
Before	1	2	3	4	5	6	7	8	9	10	11	X	
After	1	2	3	4	5	6	7	8	9	10	11	X	

5b. In general, has your use of the TENS device allowed your activity level to . . . (READ LIST)? (RECORD ONE RESPONSE ONLY)

- Increase 1
- Stay the same 2
- Decrease 3

5c. At your current activity level, has the TENS device helped you manage your pain?

- Yes 1
- No 2

5f. Has using the TENS device helped you return to work?

- Yes 1
- No 2
- Never stopped working 3

6a. On a scale of 1 to 10, with 1 being "Not At All Effective" and 10 being "Extremely Effective," please rate how effectively your pain was relieved before you started using the TENS device. (RECORD ONE RESPONSE ONLY—REPEAT SCALE AS NECESSARY)

DO NOT READ

Not at all effective
Extremely effective
Don't know

1 2 3 4 5 6 7 8 9 10 X

6b. Using the same 1 to 10 scale, please rate how effective the TENS device is in relieving your pain. (RECORD ONE RESPONSE ONLY—REPEAT SCALE AS NECESSARY)

DO NOT READ

Not at all effective
Extremely effective
Don't know

1 2 3 4 5 6 7 8 9 10 X

7a. What treatments or therapies were you using to manage your pain prior to using the TENS device? (READ LIST—RECORD ALL MENTIONS UNDER Q.7a) (PROBE) Anything else?

7b. In addition to your TENS device, what other treatments or therapies are you currently receiving for the pain for which your TENS device was prescribed? (READ LIST—RECORD ALL MENTIONS UNDER Q7.b) Anything else?

	Q.7a Prior	Q.7b Current
Physical or occupational therapy	1	1
Chiropractic treatment	2	2
Prescription pain medication	3	3
No other treatment	4	4
Other	5	5
	(Specify) _____	(Specify) _____
	_____	_____
	_____	_____

8a. Which prescription pain medication(s) did you take before you received your TENS device? (DO NOT READ LIST—RECORD ALL MENTIONS)

8b. Which prescription pain medication(s) are you still taking? (DO NOT READ LIST-RECORD ALL MENTIONS)

(List not reproduced due to space limitations. List included both trade names and generic equivalent.)

9. Since you have been using the TENS device, has your reliance on prescription pain medication . . . (READ LIST)? (RECORD ONE RESPONSE ONLY)

- Increased 1
- Stayed the same 2
- Decreased 3
- Don't know X

DO NOT READ →

10a./b. Using the same scale, how would you rate the TENS device in terms of . . . (READ LIST)? (RECORD ONE RESPONSE FOR EACH-REPEAT SCALE AS NECESSARY)

	Poor										Excellent	Don't know
	1	2	3	4	5	6	7	8	9	10	X	
Overall satisfaction	1	2	3	4	5	6	7	8	9	10	X	
Ease of use/convenience	1	2	3	4	5	6	7	8	9	10	X	
Effectiveness of pain management	1	2	3	4	5	6	7	8	9	10	X	
Quality of device	1	2	3	4	5	6	7	8	9	10	X	
Comfort of stimulation	1	2	3	4	5	6	7	8	9	10	X	

REFERENCES

1. Shealy CN. Transcutaneous electrical stimulation for control of pain. *Clin Neurosurg* 1974;21:269-77.
2. Long DM, Hagfors N. Electrical stimulation in the nervous system: the current status of electrical stimulation of the nervous system for relief of pain. *Pain* 1975;1:109-23.
3. Shealy CN, Mauldin CC Jr. Modern medical electricity in the management of pain. *Clin Podiatr Med Surg* 1994;11:161-75.
4. Melzack R, Wall PD. Acupuncture and transcutaneous electrical nerve stimulation. *Postgrad Med J* 1984;60:893-6.
5. Gersh MR, Wolf SL. Applications of transcutaneous electrical nerve stimulation in the management of patients with pain: state-of-the-art update. *Phys Ther* 1985;65:314-36.
6. Long DM. Fifteen years of transcutaneous electrical stimulation for pain control. *Stereotact Funct Neurosurg* 1991;56:2-19.
7. Ebersold MJ, Laws ER, Stonnington HH, Stillwell GK. Transcutaneous electrical stimulation for treatment of chronic pain: a preliminary report. *Surg Neurol* 1975;4:96-9.
8. Johnson MI, Ashton CH, Thompson JW. Long term use of transcutaneous electrical nerve stimulation at Newcastle Pain Relief Clinic. *J R Soc Med* 1992;85:267-8.
9. Lyons AE. Long-term use of transcutaneous electrical stimulation (letter). *J R Soc Med* 1993;86:492.
10. Hartung E, Buhl R, Goepe R. Experience with transcutaneous electrical nerve stimulation (TENS). *Pain* 1987;S4:S367.
11. Karwetzky C, Ochs G, Struppler A. Specific effectiveness of TENS in chronic pain syndromes: longtime follow-up. *Pain* 1987;S4:S367.
12. Van Doorn JN, Spierdyk J. Transcutaneous electrical nerve stimulation for relief of pain. *Acta Anaesthesiol Belg* 1981;1:21-31.
13. Long DM. External electrical stimulation as a treatment of chronic pain. *Minn Med* 1974;57:195-8.
14. Meyler WJ, de Jongste MJL, Rolf CAM. Clinical evaluation of pain treatment with electrostimulation: a study on TENS in patients with different pain syndromes. *Clin J Pain* 1994;10:22-7.
15. Sylvester K, Kendall GP, Lennard-Jones JE. Treatment of functional abdominal pain by transcutaneous electrical nerve stimulation. *Br Med J* 1986;293:481-2.
16. Bates JAV, Bchir MB, FRCP, Nathan PW. Transcutaneous electrical nerve stimulation for chronic pain. *Anesthesia* 1980;35:817-22.
17. Fox EJ, Melzack R. Comparison of transcutaneous electrical stimulation and acupuncture in the treatment of chronic pain. In: Bonica JJ, Albe-Fessard D eds: *Advances in pain*

- research and therapy, vol. 1 Proceedings of the First World Congress on Pain: Florence, Italy. New York: Raven Press, 1976:797-801.
18. O'Neal R. Relief of chronic facial pain by transcutaneous electrical nerve stimulation. *Br J Oral Surg* 1981;19:112-5.
 19. Gronow DW, Quinn RJ. Effectiveness of long term use of TENS. *Pain* 1987;S4:S368.
 20. Eriksson MBE, Sjolund BH, Neilzen S. Long term results of peripheral conditioning stimulation as an analgesic measure in chronic pain. *Pain* 1979;6:335-47.
 21. Vielvoye-Kerkmeier APE, Ruigrok NJF, van der Kaaden MN. Transcutaneous electrical nerve stimulation (TENS): a retrospective study of its effect on pain and analgesics consumption. *Pain* 1987;S4:S369.
 22. Loeser JD, Black RG, Christman A. Relief of pain by transcutaneous stimulation. *J Neurosurg* 1975;42:308-14.
 23. Thorsteinsson G, Stonnington HH, Stillwell GK, Elveback LR. The placebo effect of TENS. *Pain* 1978;5:31-41.
 24. Fried T, Johnson R, McCracken W. Transcutaneous electrical nerve stimulation: its role in the control of pain. *Arch Phys Med Rehabil* 1984;65:228-31.
 25. Bremerich A, Wiegel W, Thein T, Dietze T. Transcutaneous electric nerve stimulation (TENS) in the therapy of chronic facial pain. *J Craniofac Surg* 1988;16:379-81.
 26. Central post-stroke pain—the effect of high and low frequency TENS. *Pain* 1989;38:187-91.
 27. Taylor P, Hallett M, Flaherty L. Treatment of osteoarthritis of the knee with transcutaneous electrical nerve stimulation. *Pain* 1981;11:233-40.
 28. Sternbach RA, Ignelzi RJ, Deems LM, Timmermans G. Transcutaneous electrical analgesia: A follow-up analysis. *Pain* 1976;2:35-41.
 29. Nathan PW, Wall PD. Treatment of post-herpetic neuralgia by prolonged electrical stimulation. *Br Med J* 1974;3:645-7.
 30. Downie WW, Leatham PA, Rhind VM, Wright V, Branco JA, Anderson JA. Studies with pain rating scales. *Ann Rheum Dis* 1978;37:378-81.
 31. Carmines EG, Zeller RA. *Reliability and validity assessment*. Newbury Park, CA: Sage Publications, 1979:17:32-47.
 32. Cole B, Finch E, Gowland C, Mayo N. *Physical rehabilitation outcome measures*. Toronto, Ontario: Canadian Physiotherapy Association, 1994:28-9.
 33. Hatcher L, Hatcher S, Edward J. Assessing the scale reliability with coefficient alpha. In: *A step-by-step approach to using the SAS® system for univariate and multivariate statistics*. Cary, NC: SAS Institute, Inc., 1994:155-6, 505-16.
 34. *SAS® Proprietary Software Release 6.08*. Cary, NC: SAS Institute 1989.
 35. Kish L. Special bernoulli case of general formula. In: *Survey sampling*. New York: Wiley, 1965:458.
 36. Devore J, Peck R. *Statistics: the exploration and analysis of data*. St. Paul, MN: West Publishing Co, 1986:385.
 37. Banks S. *Experimentation in marketing*. New York: McGraw Hill, 1965:198.
 38. Johnson RI, Ashton CH, Thompson JW. An in-depth study of long-term users of TENS: implications for clinical use of TENS. *Pain* 1991;44:221-9.
 39. Marchand S, Charest J, Li J, Chenarce J-R, Lavignolle B, Laurencelle L. Is TENS purely a placebo effect? A controlled study on chronic low back pain. *Pain* 1993;54:99-106.
 40. Cheng RSS, Pomeranz B. Electrotherapy of chronic musculoskeletal pain: comparison of electroacupuncture and acupuncture-like transcutaneous electrical nerve stimulation. *Clin J Pain* 1986;2:143-9.
 41. Hitchcock LS, Farrell BR, McCaffery M. The experience of chronic pain. *J Pain Symptom Manage* 1994;9:312-8.
 42. Wells N. Quality of life issues in pain management research. *Am Pain Soc Bull* 1994;July/Aug:6-10.
 43. Cella DF, Tulsky DS. Quality of life in cancer: definition, purpose and method of measurement. *Cancer Invest* 1993;11:327-36.
 44. Miaskowski C, Nichols R, Brody R, Synald T. Assessment of patient satisfaction utilizing the American Pain Society's Quality Assurance Standards on acute and cancer related pain. *J Pain Symptom Manage* 1994;9:5-11.
 45. Nicholas MK, Wilson PH, Goyen J. Comparison of cognitive-behavioral group treatment and an alternative non-psychological treatment for chronic low back pain. *Pain* 1992;48:339-47.
 46. Deardorft WW, Ruben MS, Scott DW. Comprehensive multidisciplinary treatment of chronic pain: a follow-up study of treated and non-treated groups. *Pain* 1991;45:35-43.
 47. Tollison CD, Kriegel ML, Salterthwaite JR, Hunnant DW, Turner KP. Comprehensive pain center treatment of low back worker's compensation injuries. *Orthop Rev* 1989;18:1115-26.
 48. Portenoy RK, Foley KM. Chronic use of opioid analgesics in non-malignant pain: report of 38 cases. *Pain* 1986;25:171-86.
 49. Deyo RA, Walsh NE, Martin DC, Schoenfeld LS, Ramamurthy S. A controlled trial of TENS and exercise in chronic low back pain. *N Engl J Med* 1990;322:1627-34.
 50. Simmonds MJ, Keemar S. Pain and the placebo in rehabilitation using TENS and laser. *Disabil Rehabil* 1994;16:13-20.
 51. Turner JA, Deyo RA, Loeser JD, Von Korff M, Fordyce WE. The importance of placebo effects in pain treatment and research. *JAMA* 1994;271:1609-14.
 52. Berde CB, Glick R. The placebo response: powerful and still puzzling. *IASP Newsletter* 1994;July/Aug:3-4.
 53. Fine PG, Robets WJ, Gillette RG, Child TR. Slowly developing placebo responses confound tests of intravenous phentolamine to determine mechanisms underlying idiopathic chronic low back pain. *Pain* 1994;56:235-42.
 54. Max MB, Culname M, Schafer SC. Amitriptyline relieves diabetic neuropathy pain in patients with normal or depressed mood. *Neurology* 1987;37:589-96.
 55. Diamond EG, Kittie CF, Crockett JE. Comparison of internal mammary ligation and sham operation for angina pectoris. *Am J Cardiol* 1960;5:483-6.
 56. Peck C, Coleman G. Implications of placebo therapy for clinical research and practice in pain management. *Theor Med* 1991;12:247-70.
 57. Linton SJ, Melin L. The accuracy of remembering chronic pain. *Pain* 1982;13:281-5.
 58. Linton SJ, Gunnar Götestam K. A clinical comparison of two pain scales: Correlation, remembering chronic pain, and a measure of compliance. *Pain* 1983;17:57-65.
 59. Smith WB, Safer RA. Effects of present pain level on recall of chronic pain and medication use. *Pain* 1993;55:355-61.
 60. Pincus T, Pearce SA, McClellan A, Turner-Strokes L. Self-referential memory in pain patients. *Br J Clin Psychol* 1994;103:379-82.
 61. Guadagnoli F, Cleary PD. How consistent is patient-reported pre-admission health status when collected during and after hospital stay? *Med Care* 1995;33:106-12.
 62. Wechisler J. View from Washington. *Appl Clin Trials* 1995;4:16-21.
 63. Deyo RA, Bass JE, Schoefeld LS, Ramamurthy S. Prognostic variability among CPPs: implications for study design, interpretation, and reporting. *Arch Phys Med Rehabil* 1988;69:174-8.