An Investigation Into the Analgesic Effects of Interferential Currents and Transcutaneous Electrical Nerve Stimulation on Experimentally Induced Ischemic Pain in Otherwise Pain-Free Volunteers

Background and Purpose. Interferential currents (IFC) and transcutaneous electrical nerve stimulation (TENS) are used for pain management. This study compared the analgesic effects of IFC and TENS on experimentally induced ischemic pain in otherwise pain-free subjects using a modified version of the submaximal-effort tourniquet technique. Subjects. The subjects were 30 volunteers (18 male, 12 female) without known pathology that could cause pain. Their mean age was 33.5 years (SD=9.9, range=21–54). Method. A single-blind, sham-controlled, parallel-group method was used. The primary outcome measure was the change in the self-report of pain intensity during 1 of 3 possible interventions: (1) IFC, (2) TENS, or (3) sham electrotherapy. The IFC and TENS were administered on the forearm, and the sham electrotherapy group received no current output via a dummy stimulator. Results. A 2-way repeated-measures analysis of variance revealed that there was no change in pain intensity during treatment when all 3 groups were considered together. Further analysis revealed that IFC reduced pain intensity when compared with sham electrotherapy but not when compared only with TENS. Discussion and Conclusion. There were no differences in the magnitude of analgesia between IFC and TENS. Interferential currents reduced pain intensity to a greater extent than sham electrotherapy. [Johnson MI, Tabasam G. An investigation into the analgesic effects of interferential currents and transcutaneous electrical nerve stimulation on experimentally induced ischemic pain in otherwise pain-free volunteers. Phys Ther. 2003;83:208–223.]

Key Words: Analgesia, Experimentally induced pain, Interferential currents, Submaximal effort tourniquet test, Transcutaneous electrical nerve stimulation.

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Transcutaneous electrical nerve stimulation (TENS) and interferential currents (IFC) are noninvasive, analgesic techniques that are claimed to have an effect.\textsuperscript{1–5} There is widespread use of TENS throughout health care, and some patients report satisfaction with treatment outcome.\textsuperscript{1–5} There is an extensive but confusing body of literature on TENS, and systematic reviews have questioned its effectiveness for postoperative pain and labor pain.\textsuperscript{6–9} There is some evidence that TENS is beneficial for some forms of chronic pain.\textsuperscript{9,10} Inadequacies in systematic reviews and in the quality of and appropriateness of randomized controlled trials (RCTs) included in reviews may have contributed, in part, to the negative findings.\textsuperscript{11–13}

Interferential currents are similar to TENS, although the use of IFC appears to be primarily by physical therapists. Surveys have shown that physical therapists report that they use TENS and IFC regularly.\textsuperscript{14–16} The most common use of IFC, we believe, is to relieve pain, although some therapists also report using IFC for the reduction of swelling, the healing of wounds and fractures, and the restoration of function associated with muscle weakness.\textsuperscript{17,18} These indications mirror information provided in key textbooks on the clinical use of IFC.\textsuperscript{19–21} Acceptance of IFC into practice is not based on evidence of effects. Literature on IFC is anecdotal, and some researchers, including ourselves, have questioned the effects of IFC.\textsuperscript{22–24}

Some authors, in nonrefereed publications,\textsuperscript{19–21} claim that the mechanism of action is different between IFC and TENS. The active element of TENS is biphasic pulsed currents.\textsuperscript{25–28} In its conventional form, TENS has been shown to selectively activate large-diameter A\textsubscript{β} fibers without concurrently activating small-diameter A\textsubscript{δ} and C-fibers or muscle efferents, which leads to inhibition of ongoing activity in second-order nociceptive neurons.\textsuperscript{25,26,29,30} In theory, high-frequency (1–250 pulses per second [pps]), low-intensity (non-noxious) pulsed currents should be most efficient at the selective activation of large-diameter fibers.\textsuperscript{26} In practice, however, a trial-and-error approach is used to determine TENS settings. The TENS settings are based on the patients’ titration of current amplitude, frequency, and duration to produce a strong but comfortable electrical paresthesia, because this sensation indicates activity in large-diameter afferents.\textsuperscript{31} The trial-and-error approach, using patients’ self-reports of sensations produced by electrical currents, in our view is justified because we
content it is difficult to predict the exact nature and distribution of currents due to the complex and nonhomogeneous impedance of the tissue underlying TENS electrodes.

The skin offers high impedance at pulse frequencies used with TENS, so it is likely that currents will remain superficial.\(^27\) The purpose of IFC therapy is to deliver currents to deep-seated tissue.\(^{19,20,22,28}\) Currents with a kilohertz cycle duration are used in an effort to overcome skin impedance and penetrate deep into the body. However, some authors\(^{19–21}\) claim that kilohertz currents are not suitable stimuli to excite nerve fibers, so 2 out-of-phase kilohertz currents are used, which clash deep within tissue to produce an interference wave that is modulated in its amplitude (Fig. 1). Some authors\(^{22,28,32,33}\) claim that the amplitude-modulated interference wave is what makes IFC potentially effective and that by delivering it at frequencies between 1 and 250 Hz, IFC will elicit a physiological response that leads to pain relief. Whether there is pain relief is not certain because of a lack of experimental research. In addition, the potential mechanism by which pain relief occurs is obscure.

With a variety of electroanalgesic devices available, we believe it is important to establish relative effectiveness. Transcutaneous electrical nerve stimulation machines are usually relatively inexpensive, portable, battery-operated devices, whereas IFC machines tend to be more expensive, are not portable, and require an electrical source. Patients can be trained to deliver TENS themselves and often borrow TENS devices from pain clinics or buy their own stimulator so that they can self-administer TENS. In contrast, IFC usually requires a therapist and is administered in clinics. We have previously shown that in treatment with IFC in Britain usually lasts no more than 30 minutes and that patients attend clinics for a course of treatments.\(^18\) The continued use of both IFC and TENS has been justified to some extent by claims that the mechanism of action and analgesic profile of TENS and IFC differ.\(^{19–21}\) Evidence to support these claims is lacking.\(^{22,23,28}\)

Studies on individuals without pain due to pathology take advantage of the ability of humans to evaluate the perceptual magnitude of a precisely controlled noxious stimulus. Interventions, and particularly drugs, are sometimes assessed using subjects who are pain-free but in
whom pain can be induced in the laboratory to monitor interventions and side effects. Studies on subjects using cold-induced pain in our laboratory showed that IFC delivered at a strong but comfortable level elevated pain threshold when compared with sham or “mock” electrotherapy where no electrical current was delivered. However, there were no differences in the analgesic effects of IFC and TENS, suggesting that the output characteristics of the devices did not influence the magnitude of analgesic effects. These findings raise questions about the continued use of both IFC and TENS for relief of pain.

We believe it is important to replicate these findings using a different pain model because the analgesic response to TENS has been shown to be dependent on the sensory modality used to induce pain experimentally. Experimentally induced ischemic pain using the submaximal-effort tourniquet test (SETT) has been used for the assessment of analgesic efficacy of drugs and electrotherapy. Blood flow is arrested in the arm by a tourniquet, and the subject exercises the hand by isometric or isotonic contraction. The resulting deep aching pain closely simulates the sensation of pain due to some pathologies. Pain with this technique is believed to be caused by the accumulation of algesic metabolites (pain-producing chemicals such as potassium, histamine, acetylcholine, bradykinin, serotonin, and adenosine) resulting from occlusion of blood vessels below the inflated cuff and from the mechanical pressure of the cuff, which, theoretically, directly activates mechanosensitive nociceptors. This physiological mechanism differs from that of cold-induced pain where direct activation of high-threshold thermo-sensitive nociceptors produces the pain. The aim of our single-blind sham-controlled study was to compare the analgesic effects of IFC and TENS on experimentally induced ischemic pain using the SETT. The change in subjects’ ratings of pain during intervention from the pretreatment baseline will be used as a measure of response. Effects associated with the delivery of electrical currents will be isolated by comparing the pain measured for the active treatment (TENS and IFC) groups and the sham electrotherapy group. Effects of the electrical currents generated by the devices will be determined by comparing TENS and IFC pain ratings.

Methods

Subjects

The subjects were 30 university student volunteers (18 male, 12 female) without known pathology that could cause pain who were recruited via notice board advertisements. Their mean age was 33.5 years (SD = 9.9, range = 21–54). All potential subjects who expressed interest in participating in the study were briefed on the experimental procedure (both verbally and in written form) and were screened for contraindications to the experimental procedure or electrotherapy. These contraindications included any illness or pathology such as peripheral vascular abnormalities, hypertension and hypotension, peripheral neuropathies, recent trauma, and menstruation problems. Subjects who were taking any medication or who were likely to take any medication during the period of study were excluded.

Staff or students at the university who had not previously used a TENS-like device and had not reported having a painful medical condition within the previous 2 weeks were included in the study. Subjects who had previously heard of the use of TENS devices in health care and for pain relief were allowed to participate in the study provided that they did not express definite beliefs about how TENS worked or whether different types of TENS had different treatment effects. This was ascertained through a dialogue between the investigator (GT) and the subjects prompted by a series of standard questions. The investigator also checked each subject’s nondominant arm for signs of previous trauma and recorded blood pressure from the nondominant arm (because the effectiveness of TENS and IFC is dependent on normally functioning nerves in the skin) using a sphygmomanometer. Outcome measurements were recorded from the nondominant arm so that subjects could use the dominant arm when completing visual analog scales (VASs). All subjects who expressed an interest in the study met the criteria and subsequently agreed to participate. Subjects were required to sign a consent form and were reminded that they had the right to withdraw from the experiment at any time.

Procedure

Each subject attended our research laboratory on 2 separate occasions with a 24- to 48-hour interval between the 2 visits. The first visit was used to record pretreatment data, and the second visit was used to record data from 1 of 3 treatments: (1) IFC, (2) TENS, or (3) sham electrotherapy. During each visit, ischemic pain was induced over a 12-minute period using the SETT (Fig. 2). The self report of pain intensity was recorded at 1-minute intervals during the ischemic pain test using a VAS where 0 cm represented “no pain” and 10 cm represented “worst pain imaginable.”

A posttest short-form McGill Pain Questionnaire (MPQ) was completed by all subjects, because it has been shown to provide sensitive measurements of change in pain brought about by TENS. At the end of the ischemic pain test, subjects ranked 15 MPQ descriptors according to intensity (ie, 0 = “none,” 1 = “mild,” 2 = “moderate,” or 3 = “severe”). Pain scores were derived for sensory components, affective components, Pain Rating Index (PRI),
and Pain Intensity Index (PPI) using the sum of the intensity rank values of the words chosen. The change in MPQ scores during treatment was calculated by subtracting scores for visit 2 (during treatment) from the scores for visit 1 (pretreatment) and used as the outcome measure for the intervention.

**Ischemic Pain Test**

During the SETT, a sphygmomanometer cuff is usually applied above the subject’s elbow and inflated to 200 mm Hg. During pilot studies in our laboratory, we found that most subjects experienced widespread paresthesia within the arm rather than pain. Thus, we modified the SETT by applying the sphygmomanometer cuff to the forearm 5 cm below the elbow crease, because this placement of the sphygmomanometer cuff produced a dull aching pain that was localized to the area of the cuff in all subjects (Fig. 3).

Before the start of the experiment, maximal grip force was determined using a dynamometer (Martin Vigorimeter*) fitted with a medium bulb. Seventy-five percent of maximal grip force was calculated and identified on the dynamometer scale. Ischemic pain was induced in the following manner. Subjects raised their nondominant arm vertically above their head for 1 minute to desanguinate the limb. The sphygmomanometer cuff (15 cm in length) was then inflated to above 200 mm Hg at a rate of 40 mm Hg per second. Full cuff inflation was taken as time 0, and subjects rated the intensity of the pain in their raised arm using the VAS. The forearm was then returned to rest in the horizontal position on a polystyrene box that was designed to support the forearm and hand without applying pressure on the sphygmomanometer cuff. This was done in an effort to ensure that there was an even distribution of pressure throughout the cuff. Subjects then performed 20 hand-gripping exercises at 75% of their maximal grip force for a period of 1 minute (squeeze for 2 seconds and rest for 2 seconds). Pain intensity was recorded on completion of these exercises and at 1-minute intervals for the remainder of the experiment. The cuff was deflated over a period of 2 minutes to allow the limb to resanguinate, and the final pain intensity rating was taken 1 minute after cuff deflation. No signs of any trauma were observed in the arms of any subjects following the ischemic pain test.

**Treatment Groups**

On the second visit to the laboratory, subjects were randomly allocated to one of 3 treatment groups: (1) IFC, (2) TENS, or (3) sham electrotherapy. All subjects received 22 minutes of uninterrupted treatment, and a single-blind experimental approach was

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*Nomeq, Worcestershire, United Kingdom.*

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**Figure 2.**
Experimental procedure. The subjects raise their arm above their head for 1 minute, and the first pain intensity rating (VAS 1) is taken. The sphygmomanometer cuff is inflated over a period of 20 seconds, and the second pain intensity rating (VAS 2) is taken. The subjects lower their arm to the horizontal position and perform 20 handgrip exercises over a 1-minute period, after which the third pain intensity rating (VAS 3) is taken. The arm remains rested in the horizontal position, and pain intensity ratings are taken at 1-minute intervals (VAS 4–9). The cuff is then deflated over a 2-minute period after the pain intensity rating at 7 minutes (VAS 9) has been taken. VAS=visual analog scale.
used whereby the subjects were not aware of which treatment they were being given. Four self-adhesive electrodes (each electrode = 4.5 cm²) were applied to all subjects before the start of the experiment, and treatment was switched on 10 minutes 40 seconds before the arm was raised above the head (Fig. 2). Electrode sites were chosen to target afferents emerging from the ischemic area. We were concerned that afferents under the cuff might be unable to fire due to pressure block from the cuff. However, all subjects in the IFC and TENS groups reported that they experienced a strong but comfortable electrical paresthesia, suggesting to us that afferents remained active. Electrodes were attached to an EMS model 70 interferential therapy machine,† which could deliver either IFC or TENS.

IFC. Electrodes were applied in a quadripolar manner to the anterior and posterior aspects of the subjects’ forearm so that electrical currents would intersect at the midpoint of the cuff. The distal electrode for channel A was attached to the anterior surface of the forearm 5 cm proximal to the first wrist crease. The distal electrode for channel B was attached to the posterior surface of the forearm directly beneath the distal electrode for channel A. Proximal electrodes were applied directly above the cuff. Subjects in the IFC group were told that in order to produce an effect, the intensity of the stimulator must be maintained at a “strong but comfortable level” at all times. Initially, when the IFC device was switched on for the first time, the “strong but comfortable level” was obtained by increasing current amplitude so that the subjects reported either that the currents were uncomfortable or that motor threshold had been reached.

† Electro Medical Supplies, Greenwich, United Kingdom.
Cold-induced pain.

Therapists and were used in our previous studies on settings we used, in our view, are commonly used by of 100 Hz generated by 4-kHz sinusoidal waves. The IFC was an amplitude-modulated frequency time during the test was 19.2 mA (SD = 10.2, range = 4.0–29.0). The IFC was an amplitude-modulated frequency of 100 Hz generated by 4-kHz sinusoidal waves. The settings we used, in our view, are commonly used by therapists and were used in our previous studies on cold-induced pain.35,36

**TENS.** Transcutaneous electrical nerve stimulation is usually applied using a single-channel device via 2 electrodes. The TENS in our study was delivered via 4 electrodes using a dual-channel device in order to standardize the amount of current administered by the 2 modalities. Electrodes were applied to the anterior and posterior aspects of the subjects’ forearm in an identical manner to that for IFC. To minimize interference of currents from the 2 channels, both distal electrodes were attached to channel A of the TENS device and both proximal electrodes were attached to channel B. Subjects were told that the intensity of the stimulator must be maintained at a “strong but comfortable level” at all times. The “strong but comfortable level” was obtained using the same procedure as that described for IFC. Mean current amplitude for the TENS group recorded as the maximum amplitude reached at any time during the test was 11.3 mA (SD = 2.7, range = 8.0–17.0). Subjects were told that the sensation produced by the current might fade away and that they should adjust the stimulator to maintain a strong but comfortable sensation. The electrical characteristics of TENS were set to deliver 200-microsecond biphasic pulsed currents at a pulse frequency of 100 pps and a “continuous” pulse pattern. These settings were chosen because we believed that they were similar to those used for IFC and that they were consistent with those used in our previous studies on cold-induced pain.35,36

**Sham electrotherapy.** Subjects in the sham electrotherapy group received no current output from the IFC device or the TENS device (TENS, IFC, and sham electrotherapy were all delivered using the same electrotherapy machine). This was achieved using a circuit that prevented currents from reaching subjects in the sham electrotherapy group but that allowed currents to reach subjects in the active IFC group without altering the electrical characteristics (Fig. 3). The output from the IFC device was displayed on a cathode ray oscilloscope during the treatment cycles for both the active treatment groups and the sham electrotherapy group to give the impression to subjects that electrical currents were being delivered to the electrodes. Subjects in the sham electrotherapy group also were told that “the electrotherapeutic device may have effects at subthreshold levels, which you may not be able to feel” and “this means that you may or may not feel a slight tingling sensation beneath the electrodes.” Previous workers57–59 have found that this technique can reduce sham electroanalgesia. No subjects questioned this procedure, and their responses to a posttest question revealed that all subjects in the sham electrotherapy group believed that they were receiving currents.

**Data Analysis**

Data were analyzed by calculating the change in pain intensity rating and MPQ scores during the intervention when compared with the pretreatment measurements. Pretreatment VAS recordings for pain intensity rating were subtracted from the corresponding recordings obtained during treatment for each subject and displayed as the mean change in pain intensity rating for each treatment group. Because the aim of this experiment was to compare the effects of interventions on pain, data points taken during cuff inflation and hand grip exercises (VAS units 1–3) and cuff deflation (VAS units 10–12) when pain was either absent in the pretreatment readings or fluctuating greatly were not used in the analyses (Figs. 2 and 4). The absence of pain in the pretreatment VAS scores would prevent the detection of pain reduction, and subjects would find estimating pain intensity difficult during marked fluctuations, as experienced when the cuff was being inflated and deflated. We defined a meaningful analgesic effect as a reduction of 1 VAS unit or more for the active treatment groups when compared with the sham electrotherapy group. Treatment effects were determined by a 2-way repeated-measures analysis of variance (ANOVA) on the change in pain intensity during treatment for VAS units 4 through 9. The change in MPQ scores were calculated by subtracting the pretreatment measurement from the measurement obtained during treatment for each subject and displayed as the mean change in MPQ for each treatment group. A 1-way ANOVA on the change in MPQ scores was used to determine effects among the treatment groups.

**Results**

**Pain Intensity**

The pain intensity ratings are summarized in Table 1. Pretreatment pain intensity ratings were similar to those previously reported by other groups using the same technique to induce pain.45,47 The repeated-measures
ANOVA on the pretreatment data for the entire VAS data set (ie, VAS units 1–12) indicated there was no effect of treatment group or group × time interaction. These findings suggest to us that subjects in different treatment groups were matched in pretreatment VAS scores. There was an effect of time (P<.01), which we attributed to the onset of pain that occurs during cuff inflation and hand grip exercises (VAS units 1–3) and to the decrease in pain that occurs upon cuff deflation (VAS units 10–12) (Tab. 1).

The repeated-measures ANOVA on the change in pain intensity during treatment for VAS units 4 through 9 there was no effect of time or group × time interaction (Tab. 2). Effects for treatment groups failed to reach statistical significance. Unpaired t tests on the average change in pain intensity during cuff inflation were used to isolate potential effects among the 3 treatment groups (Fig. 5). The unpaired t tests revealed that IFC reduced pain intensity when compared with the sham treatment (P=.05). The apparent reduction in pain intensity during TENS (Figs. 4 and 5) did not reach statistical significance when compared with the sham treatment (P=.06). There were no changes in pain intensity between IFC and TENS.

MPQ Scores
McGill Pain Questionnaire sensory, affective, PRI, and PPI scores were calculated for pretreatment data and data obtained during treatment. One-way analysis of the pretreatment data showed that there were no differences among the groups for any of these measures. The change in each of the MPQ scores during treatment was used as the outcome measure and was calculated for each individual by subtracting the pretreatment values from the corresponding values obtained during treatment (Fig. 6). There were no differences among the groups for any MPQ scores (1-way ANOVA). However, scores for affect suggested that there might have been differences between active treatment groups and the
### Table 1

Pain Intensity Rating for Transcutaneous Electrical Nerve Stimulation (TENS), Interferential Currents (IFC), and Sham Electrotherapy During the Ischemic Pain Test

<table>
<thead>
<tr>
<th></th>
<th>Cuff Inflated</th>
<th>Handgrip Exercises Start</th>
<th>Handgrip Exercises End</th>
<th>Cuff Deflating</th>
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<td>20 s</td>
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<td>2 min</td>
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<td>VAS 1</td>
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<td>VAS 3</td>
<td>VAS 4</td>
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<td>1.7</td>
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<td>1.2-8.1</td>
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<td>3.4</td>
<td>4.0</td>
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<td>-1.4-1.5</td>
<td>-1.9-1.3</td>
<td>-2.0-2.1</td>
<td>-1.6-1.7</td>
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* Pain intensity ratings were scored on a 0- to 10-cm visual analog scale (VAS), where 0 = "no pain" and 10 = "worst pain imaginable."
sham electrotherapy group. The 1-way ANOVA was used to reveal differences across all 3 treatment groups. We set levels of significance at .05. However, we wanted to reveal potential differences among groups (ie, TENS versus sham electrotherapy, IFC versus sham electrotherapy, TENS versus IFC). When the probability value from the 1-way ANOVA for the MPQ scores (and from the 2-way ANOVA for VAS scores) fell between 0.1 and .05, we decided to explore the relationship among groups further. Post hoc analysis revealed a reduction in the score for affect during intervention for the IFC group when compared with the sham electrotherapy group \((P=.03,\) unpaired \(t\) test). However, there were no differences in the change in scores for affect during intervention between the TENS and sham electrotherapy groups or between the IFC and TENS groups.

### Discussion

Physical therapists need information about the absolute and relative effects of TENS-like devices. In our single-blind, sham-controlled investigation into the analgesic effects of IFC and TENS in pain-free volunteers who had ischemic pain induced, we found that IFC reduced the intensity of experimentally induced ischemic pain when compared with sham electrotherapy. However, the analgesic effects produced by IFC were similar in magnitude to those observed for TENS. The IFC, but not TENS, produced a reduction in the affective components of pain when compared with sham electrotherapy.

Our findings for TENS are similar to the results of previous studies by other workers using comparable methods.\(^{37,40,47,60}\) Transcutaneous electrical nerve stimulation at non-noxious intensities has been found to reduce ischemic pain to a greater extent that sham TENS in otherwise pain-free subjects using SETT.\(^{37}\) Roche et al\(^{46}\) reported that TENS produced a greater response to induced ischemic pain in otherwise pain-free volunteers when compared with no stimulation and that the effect was dependent on the time course of the pain and the intensity and time duration of TENS. High-intensity continuous TENS increased endurance of pain, whereas low-intensity trains of stimulation raised pain thresholds but did not increase endurance. Greater reductions in pain intensity have been found for TENS when compared with sham TENS on experimentally induced ischemic pain under double-blind, sham-controlled conditions in 32 otherwise pain-free volunteers,\(^{47}\) although those researchers were unable to replicate their findings in a subsequent study using similar methods.\(^{45}\) In addition, researchers\(^{60}\) have reported that TENS did not influence the duration of ischemia tolerated or the intensity of pain when delivered proximal to the tourniquet.

One reason for the conflicting results may be that TENS effects depend on the sensory modality used for to induce pain experimentally.\(^{37}\) We have repeatedly demonstrated in otherwise pain-free volunteers that TENS elevates cold-induced pain threshold when compared with sham TENS.\(^{36,58,61,62}\) In these studies, TENS was administered in a conventional manner by delivering currents at a strong but comfortable intensity within or immediately proximal to the site of pain. Transcutaneous electrical nerve stimulation has also been shown to produce analgesic effects in otherwise pain-free subjects when pain was induced thermally,\(^{63–65}\) although researchers using other experimental pain models have found conflicting results. Some researchers\(^{66}\) have reported that TENS increases the mechanical pain threshold in otherwise pain-free subjects, whereas other researchers\(^{57}\) have reported that TENS has no effect on mechanical pain threshold in otherwise pain-free subjects. Reports that TENS reduces delayed-onset muscle soreness (DOMS)\(^ {67,68}\) or electrically induced pain\(^{69,70}\) are countered by reports that it does not.\(^{71,72}\) There are reports that TENS does not alter pain associated with RIII nociceptive reflexes in otherwise pain-free subjects.\(^{73,74}\) Inconsistencies in findings may be due to variations in TENS application procedures, inadequate doses of TENS, and outcome measurements taken at inappropriate times.\(^{75}\) Our findings add to the conflicting nature of existing evidence because the apparent reduction in experimentally induced pain by TENS did not reach statistical significance \((P=.06)\) when levels were set at .05.

Experimental work on the analgesic effects of IFC is sparse. We have previously reported that IFC delivered at a “strong but comfortable” level produced a greater reduction in pain intensity ratings for experimentally induced ischemic pain than sham electrotherapy and no treatment control in volunteers who were pain-free.\(^{76}\) We have reported that IFC elevates pain threshold when compared with no treatment and with sham electrotherapy using cold-induced pain in otherwise pain-free subjects.\(^{36,77}\) However, the analgesic effects of IFC on pain induced experimentally under placebo-controlled conditions is yet to be confirmed by other researchers.

Proving that technique-based interventions such as TENS and IFC produce effects that are greater than

### Table 2.

<table>
<thead>
<tr>
<th>Source of Variance</th>
<th>df</th>
<th>SS</th>
<th>F</th>
<th>P</th>
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<td>Treatment group</td>
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<td>2.9</td>
<td>.07</td>
</tr>
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<td>1.6</td>
<td>0.5</td>
<td>.75</td>
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<td>1.0</td>
<td>0.13</td>
<td>1.00</td>
</tr>
</tbody>
</table>
those produced by placebo, in our view, is difficult. There is disagreement on what constitutes a TENS placebo, due in part to difficulties in defining the active element of the technique. Because some authors believe that electrical currents are the critical variable of all electrotherapeutic devices, they have used devices that deliver no current (ie, sham electrotherapy) as placebo controls because they enable researchers to isolate effects associated with the electrical currents themselves. In our study, sham electrotherapy was achieved using an electronic circuit to gate the output of the stimulator so that no current was delivered to the subjects. This ensured that there were no differences in the appearance of the stimulator to subjects in different treatment groups. We also used the verbal suggestion that “IFC may have effects at subthreshold levels, which you may not be able to feel” and a waveform displayed on a cathode ray oscilloscope. Subjects were instructed to alter the intensity of the currents using a dial on the stimulator in order to “prevent the body from adapting to the currents,” and this was accompanied by changes in the size of the electrical wave on the cathode ray oscilloscope. No subjects questioned the lack of sensation from the stimulating device.

Despite confidence in the authenticity of our sham intervention, this type of control does not establish the nature of the effects. Thus, we cannot discount the possibility that treatment effects were produced by distraction associated with sensations generated by the electrical currents. Researchers have attempted to account for nonspecific distraction effects produced by TENS currents by monitoring the effect of TENS on visual stimuli. In order to isolate the effects of electrical currents on specific physiological processes such as segmental inhibition of antinociceptive transmission, which could be considered the critical element of TENS from a physiological perspective, researchers would need to compare the effects of currents delivered at segmental and remote body sites. This was beyond the scope of our study.

Despite our confidence in sham electrotherapy, there are still problems in achieving and maintaining blinding.
in studies of technique-based interventions. Treatment effects due to the use of placebos may be up to 17%. Double blinding is considered the “gold standard” in clinical trials for isolating this effect. Reports on TENS that claim to have achieved double blinding rarely provide details on how blinding was maintained or monitored throughout the trial. In drug trials, the investigator can administer the treatment and record outcome measurements while remaining blinded. In technique-based interventions, such as many of the interventions used in physical therapy, including TENS and IFC, this is not necessarily possible because the investigator (or therapist) needs to be aware of the treatment in order to administer treatment appropriately. Investigators (or therapists) who administer treatments are likely to have prior knowledge and expectations about treatment outcome, and this may influence the way in which treatment is given and thus bias the outcome.

In studies of technique-based interventions, we believe what we consider a triple-blind method should be the “gold-standard.” Subject membership in a treatment group is concealed from the subject, the investigator recording outcomes, and the investigator (or therapist) administering the treatment. Blinding the investigator (or therapist) administering the treatment is problematic, if not impossible. One approach could be to train an investigator who was naive to the therapeutic strategy and outcome to administer treatment using a standard protocol. We used a single-blind experimental approach in our study because of the lack of additional investigators. We attempted to reduce bias associated with the experimenter’s expectation of treatment outcome by using standardized cue cards. In summary, our findings suggest that electrical currents produced changes in pain intensity, but it was not possible to determine whether the effects were due to distraction or to a segmental inhibition of nociceptive input.

Figure 6. Mean (±SD) (n=10 per group) change in McGill Pain Questionnaire (MPQ) scores during the treatment intervention when compared with the pretreatment value for sensory and affective dimensions and for Pain Rating Index (PRI) and Present Pain Intensity (PPI). Probability values represent 1-way analysis of variance across groups.
With a variety of electroanalgesic devices available, we believe it is important for the therapist to know whether one electroanalgesic device can be used to deliver an intervention that is more effective than another. The comparison between TENS and IFC could provide some evidence of the treatment effects of each modality. By standardizing current intensity across subjects using the report of a strong but comfortable intensity, we contend that we were able to discount putative effects associated with differences in the subjects' perceptions of the strength of stimulation. The finding that there were no differences in pain relief between TENS and IFC suggests that the different output characteristics had no effect on the magnitude of pain relief. This finding is consistent with our previous work.36 We reported that there were no differences in the magnitude of the increase in pain threshold or ratings between IFC and TENS on cold-induced pain.36 Another group71 also reported no differences in the effects of TENS or IFC on the rating of pain associated with RIII nociceptive reflexes. However, their findings differ from ours because they did not find TENS and IFC effects when compared with sham electrotherapy, although they did not record outcome measurements during stimulation.

Because TENS effects are believed to be maximal while the stimulator is switched on and are short-lived when the device is switched off, it is possible that treatment effects were missed.36,58,62,86 Work in our laboratory suggests that IFC also has short post-stimulation effects when delivered at non-noxious intensities.35,36 Most therapists, we believe, deliver IFC at non-noxious levels when managing people with painful conditions.18 Interferential current machines are relatively expensive and require an electrical supply other than batteries, so treatment usually takes place in a clinic under therapist supervision. Treatment sessions generally last no more than 30 minutes, and patients are often required to attend the clinic for a course of treatments. If the analgesic effects of IFC are no different than those of TENS, then the practice of short-duration treatment sessions may be of little value. Most TENS machines are portable, and patients can self-administer treatment throughout the day. Thus, the use of TENS may be a more appropriate treatment strategy to control an ongoing pain problem.

The continued use of both IFC and TENS is justified by some therapists who claim that the mechanism of action and analgesic profile of TENS and IFC differ. They lack data, however, to support this and related assumptions (eg, whether TENS or IFC is effective). It is believed that IFC excites deep tissue and TENS excites superficial tissue,19–21 although this remains to be proven experimentally. To our knowledge, there is no experimental evidence available to determine whether TENS and IFC stimulate fiber populations at different depths, resulting in different analgesic profiles. The IFC modulation patterns described in textbooks are unlikely to be faithfully reproduced in biological tissue. Measurements of voltage patterns of IFC within biological tissue (pork) and an isotropic medium (water) have shown that modulation patterns produced in biological tissue are complex and unpredictable.87,88 Measurements of sensory, motor, and pain thresholds to IFC under single-blind conditions have shown no differences in the presence and absence (eg, pure 4-kHz currents) of amplitude-modulated waves, suggesting that pure 4-kHz waves are the main variable in stimulation.89 The only suggestion that there may have been may be differences in the analgesic profiles in our study were found in changes in affective scores of the MPQ following treatment. Interferential currents but not TENS reduced affective components of the pain experience. We found no differences in any MPQ scores between TENS and sham electrotherapy or between IFC and TENS. Other authors47 using similar methods also have reported a lack of difference in MPQ scores between TENS and sham electrotherapy. Further work in this area is needed to confirm the possibility that reductions in effect contribute to pain relief obtained with IFC.

Laboratory studies are often viewed with suspicion by clinical investigators. However, we argue that laboratory studies serve as an essential precursor to clinical trials, providing data from which to determine dose relationships and treatment regimens.34,38–44 Because laboratory studies can be conducted in an environment in which variables can be controlled and modified in a systematic manner, they overcome many of the logistical problems associated with clinical trials. These problems include staff and patient recruitment, nonadherence and withdrawal, ethical considerations associated with placebo intervention, and constraints of time and cost of executing a clinical trial. Models of experimentally induced pain enable investigators to quantify the duration and intensity of the noxious stimulus, which is difficult to control in clinical settings due to larger fluctuations in the intensity and quantity of pain across time. In our study, the deep aching pain associated with SETT remained stable in its intensity during pretreatment recordings once the cuff had been fully inflated, and this enabled measurement of effects on pain sensations that were similar among subjects and repeatable over time.

There are clear differences between experimentally induced pain and clinical pain. Experimentally induced pain produces minimal tissue damage and can be terminated at any point during the test. Consequently, it is less likely to be influenced by affective and cognitive elements that may contribute to the overall report of pain in patient populations. Experimentally inducing pain
also has been criticized because it elicits only one type of pain sensation, whereas a patient’s pain often is more complex. Some models of experimentally induced pain also produce painful sensations that are not normally experienced by patients, such as electrically induced pain. We chose the ischemic model of experimentally induced pain because it produces a deep aching pain sensation that has similar qualities to those found in clinical conditions. In addition, SETT has similarities to ischemia of soft tissue leading to pain, including that experienced by people with angina. Transcutaneous electrical nerve stimulation and TENS-like devices such as IFC have been used in the symptomatic management of ischemic pain.\textsuperscript{19–21,27} Despite our argument about the importance of laboratory-based research, we note that only clinical trials can document an intervention’s effectiveness.

**Conclusion**

Interferential currents reduced the intensity of experimentally induced ischemic pain, although there were no differences in the magnitude of response between TENS and IFC. Comparisons of effects between treatments can provide information about relative effectiveness and can inform decisions about treatment selection. The findings of our study, if they can be replicated in a clinical trial, suggest that IFC is at least as effective as TENS when delivered to produce a strong but comfortable electrical paresthesia within the site of pain, as is most likely used in clinical practice. However, the lack of difference in the analgesic effects of TENS and IFC bring into question the continued use of both modalities when administered in this way. The small amount of experimental evidence that has compared IFC and TENS suggests that it may be more cost-effective to use TENS rather than IFC when therapy is administered at a strong but comfortable level for the symptomatic relief of pain. As it is the output characteristics of electrotherapeutic devices such as TENS and IFC that gives them their identity, and ultimately their place in the commercial market, it is crucial that more well-designed clinical and experimental studies be performed to assess their relative usefulness.

**References**


