Reduction of Chronic Posttraumatic Hand Edema: A Comparison of High Voltage Pulsed Current, Intermittent Pneumatic Compression, and Placebo Treatments

The purpose of this study was to compare the efficacy of intermittent pneumatic compression (IPC) and high voltage pulsed current (HVPC) in reducing chronic posttraumatic hand edema. Thirty patients with posttraumatic hand edema were randomly assigned to IPC, HVPC, or placebo-HVPC groups (10 patients in each group). Patients received a single application of the respective treatment for 30 minutes. Measurements were made before and after a 10-minute rest period and after the 30-minute treatment. A volumetric method was used to quantify edema reduction. Reduction in hand edema was significant between the IPC and placebo-HVPC groups (p = .01). Differences in edema reduction between the HVPC and placebo-HVPC groups did not reach statistical significance (p = .04), but were considered clinically significant. There was no significant difference between the IPC and HVPC groups. A single 30-minute administration of IPC produced a significant reduction in band edema. Additional clinical studies are needed to delineate maximally effective treatment protocols for reduction of chronic posttraumatic hand edema. [Griffin JW, Newsome LS, Stralka SW, et al: Reduction of chronic posttraumatic hand edema: A comparison of high voltage pulsed current, intermittent pneumatic compression, and placebo treatments. Phys Ther 70:279–286, 1990]

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Key Words: Edema; Electrotherapy, electrical stimulation; Hand injuries; Wound bealing.

Hand edema that persists for weeks after upper extremity trauma such as fracture, soft tissue injury, or surgery is a problem in rehabilitation. Chronic hand edema contributes to pain, decreased active motion, and further edema. Serofibrinous exudate accumulates between various soft tissue layers of the hand, with resultant tis-

sue fibrosis and adhesions.^{2,3} The ultimate result can be hand stiffness, which is only partially reversible even with intensive therapy. Thus, reduction of hand edema is a primary treatment goal in the management of patients who have suffered upper extremity trauma.^{1,4} Identification of maximally effective methods for

reducing chronic posttraumatic hand edema should result in faster recovery of hand function and reduced costs of rehabilitation.

Traditional methods of minimizing edema immediately following trauma include elevation, use of external compression wraps, cold application, and active motion of adjacent unaffected parts.^{2,5} Adjunctive methods such as high voltage pulsed current (HVPC) stimulation^{6–9} and application of intermittent pneumatic compression (IPC)^{5,10–12} are also commonly used for edema reduction. A literature search, however, failed to yield reports of any controlled studies of the effect of these modalities on chronic posttraumatic hand edema.

This article was submitted March 27, 1989; was with the authors for revision for 13 weeks; and was accepted December 28, 1989.

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Review of the Literature

Physiologic mechanisms by which reduction of edema can be accomplished include increased lymphatic flow, increased venous drainage, and improved limb blood flow.13 Considerable scientific evidence from animal and human investigations indicates that both IPC and electrical stimulation can produce these physiologic effects.14-24 For example, lymphatic flow has been reported to increase during application of IPC to legs of patients with edema^{14,15} and during electrically stimulated muscle contractions in animal experiments.19-21 Changes in venous blood flow, similar to those produced by voluntary calf muscle contraction, have been documented in patients using both IPC16,18 and electrical stimulation of calf muscles.22,23

Controlled clinical trials investigating the efficacy of HVPC for edema reduction have rarely been reported. In a brief report of a pilot study, Newton compared changes in edema and range of motion in patients with posttraumatic hand edema when HVPC was combined with placement of the affected hand in cool water.25 Edema was not reduced, but ROM improved after HVPC treatment. Numbers of patients, type of hand trauma, and amount of time since injury were not reported. In a study of subjects with acutely sprained ankles, Michlovitz et al found that the addition of HVPC to a treatment program of elevation and ice did not result in significantly greater edema reduction.26 Using an animal model, Mohr et al found that HVPC applied to rat paws immediately after trauma did not produce significant edema reductions.13

Several investigators have documented the efficacy of IPC for the treatment of acute posttraumatic edema.^{27–30} Melrose et al reported IPC applied after surgical stripping of varicose veins produced significant reductions in postoperative leg edema and pain in a controlled study.²⁷ Two controlled studies investigated postoperative use of IPC after fasciectomy for Dupuytren's contracture.^{28,29} Hobby

applied IPC for three postoperative days and found that edema was eliminated by the 10th postoperative day in the IPC group, whereas edema was still detectable at the 28th postoperative day in the control group.28 Hazarika et al reported a significant difference in edema between IPC and control groups at the seventh postoperative day, with the IPC group also having less postoperative pain.²⁹ Salisbury studied the effect of IPC on postburn edema in eight patients with bilateral symmetrical burns.30 Intermittent pneumatic compression was applied to one of each patient's burned upper extremities for 48 hours, beginning 24 hours postburn. Significant decreases in edema were apparent in the arm receiving IPC compared with the contralateral arm. Few controlled studies have investigated the efficacy of IPC for the treatment of chronic posttraumatic edema. Airaksinen and colleagues, studying patients with edema persisting two weeks after cast removal following immobilization for lower leg fractures, found patients receiving IPC demonstrated significant edema reduction compared with control patients.31,32

High voltage pulsed current and IPC are widely used in clinical practice to reduce posttraumatic edema. Some theoretical bases exist for use of these modalities, but further controlled studies are needed to substantiate clinical reports of efficacy in specific patient populations. No controlled studies are available comparing the use of HVPC and IPC in patients with chronic posttraumatic hand edema.

The primary objective of this study was to compare the effectiveness of a single 30-minute treatment of IPC, HVPC, and placebo-HVPC in reducing chronic posttraumatic hand edema. The null hypothesis was that no difference in edema reduction would exist among the three treatment groups. The secondary purpose was to assess the need in the research protocol for a 10-minute rest period prior to treatment. The null hypothesis was that no change in edema would be noted in patients after a 10-minute rest period.

Method

Subjects

Thirty patients with chronic posttraumatic hand edema participated in the study. Chronic hand edema was defined as edema persisting for 14 to 21 days following injury.33 Criteria for inclusion were that the patient had suffered trauma to one upper extremity at least two weeks before study participation and that the patient was judged to have clinically significant hand edema by one physical therapist (LSN) at the initial patient evaluation. Clinically significant band edema was defined as a visually detectable swelling of the wrist, dorsum of the hand, and fingers of sufficient magnitude to be considered a problem addressed in the treatment plan. Patients were excluded if they had open wounds, severe pain, or a dystrophic component.

All subjects signed an informed consent form following a description of the purposes and the potential benefits and risks of the study. This study protocol was approved by the Chief of Staff of Campbell Clinic (Memphis, Tenn) and the participating hand surgeon (PEW), which is the customary review process for research proposals at Campbell Clinic. The subjects participated in the study during their first or second outpatient visit. There was no charge for participation in the study, nor was any remuneration given.

Procedure

Subjects were randomly assigned to IPC, HVPC, and placebo-HVPC groups using a table of random digits, with 10 subjects in each group. The subjects received the respective treatment for one 30-minute period on one treatment day only. The same physical therapist (LSN) administered all treatments and conducted all measurements.

Before treatment was begun, volumetric measurements of both affected and unaffected hands were obtained for each subject (prerest measurement).

Each subject then sat for 10 minutes with the affected arm resting on a table adjusted to support the arm with the hand at the level of the fourth intercostal space (heart level). The purpose of this rest period was to minimize the effect on treatment outcome of the subject's hand positioning and activity prior to arrival in the physical therapy department. Following the rest period, a second volumetric measurement was made of the affected hand (postrest measurement). The affected arm was then repositioned and maintained at heart level for the 30-minute treatment period. The purpose of positioning the arm at heart level was to control for the effect of elevation on edema. Immediately after treatment, a third volumetric measurement was made of the affected hand (posttreatment measurement). Subjects were encouraged to relax during the 10 minutes of rest and during the 30 minutes of treatment.

Treatment protocols. During HVPC treatment, one active (negative polarity) electrode was placed over the median nerve in the antecubital fossa. with another over the ulnar nerve at the medial epicondyle; the dispersive electrode was placed on the dorsolumbar region of the back. The active carbon electrodes were 1.5×1.5 in* in size and were secured with a square of paper tape slightly larger than the electrode. Karaya was used as a conductive medium between the electrodes and the subject's skin. The dispersive electrode was 8 × 10 in, and a watersoaked sponge was placed between the electrode and the subject's skin. The HVPC stimulator (Intelect® 550[†]) frequency was set at 8 (twin) pulses per second (pps), with a reciprocal mode of stimulation alternating between five seconds of ulnar nerve stimulation and five seconds of median nerve stimulation. The intensity of stimulation was adjusted to produce minimal observable muscle contractions, and intensity was readjusted during the 30-minute treatment session to maintain slight movements of thumb flexion and finger abduction.

The purpose of our electrical stimulation protocol was to elicit minimal, nonfatiguing contractions of the hand muscles. We set the frequency of stimulation at 8 pps because we have found it effective in clinical practice for edema reduction. Our choice of frequency was influenced by animal studies concerning effect of electrical stimulation on lymphatic flow. 19,20 Bolter and Critz found a twofold to threefold increase in lymphatic flow using a frequency of 10 pps to elicit repetitive muscle contractions.19 Ladd et al noted lymphatic flow increased more during shivering (ie, during alternate contraction and relaxation of muscles at a frequency of 7-13 cycles per second) than during muscle contractions generated by 60-pps (3 seconds on, 2 seconds off) electrical stimulation of nerve.20 We set the stimulation to alternate between 5 seconds to ulnar nerves and 5 seconds to median nerves to give equal stimulation time to each site and to allow for equal contraction and relaxation times for each set of muscles stimulated. The polarity of active electrodes was set at negative in reference to the dispersive electrode, primarily because in preliminary studies this polarity seemed to produce the desired motor response with least discomfort. According to some authorities, whether electrode polarity for HVPC-generated muscle contractions is negative or positive does not matter.7 We stimulated nerves some distance from the hand itself, so that, if effective, this treatment protocol might be useful when direct access to the hand would not be possible (ie, casted hands).

The placebo-HVPC treatment procedure was the same as the HVPC treat-

ment procedure, except that the dispersive electrode was disconnected without the subject's knowledge. Subjects in both HVPC and placebo-HVPC groups were instructed that there might not be any perceptible sensation during the 30-minute treatment session.

The affected arm of the subjects in the IPC group was covered with a cotton stockinette and placed in an IPC sleeve extending from the fingertips to the elbow. The IPC unit (Presssion[†]) was set on a cycle of 30 seconds of inflation/30 seconds of deflation (on/off times), with an inflation pressure of 40 mm Hg. We selected an inflation pressure of 40 mm Hg for several reasons. This pressure has been found sufficient to empty the venous system of the calf; higher compression pressures did not further increase blood flow.16,18 Other investigators using IPC for reduction of acute posttraumatic hand edema also have used this inflation pressure.28,30 Little clinical evidence exists to indicate optimal on/off times for IPC protocols.

Investigators using IPC for the treatment of posttraumatic edema have used on/off times ranging between 40/20 seconds³⁰ and 120/120 seconds.27,29 During compression with IPC, the tissue under the garment is compressed and blood flow may be reduced.34 Our intention was to give the optimal inflation time for increase of interstitial pressure, without impairing tissue perfusion. In studies investigating the effect of IPC on lower extremity venous flow, the maximal effect was noted when the time interval between compressions was one minute, apparently related to the amount of time required for venous refilling.16 We arbitrarily set the deflation time at 30 seconds to allow time for venous and lymphatic refilling and still allow a reasonable amount of time for compression during the 30minute treatment session.

Measurement of hand edema.

Hand volume was assessed with the Volumeter[®], [‡] which measures water displacement. In clinical practice,

^{*1} in = 2.54 cm.

[†]Chattanooga Corp, PO Box 4287, Chattanooga, TN 37405.

[‡]Volumeters Unlimited, 52421 Double View Dr, PO Box 146, Idyllwild, CA 92349.

hand edema is assessed either by a volumetric method or by circumferential measurements.28 Eccles first reported using measurements of water displacement to assess the effect on hand volume of variables such as ambient temperature, anodal galvanism, vigorous exercise, and dependency.35 Other investigators have since used the volumetric method to measure edema reduction produced by various treatments in patients with postoperative edema,28,29 rheumatoid arthritis,36,37 lymphedema,38,39 and other various upper limb disorders.40 We consider the volumetric method to be a valid measure of hand volume.

Reproducibility of volumetric measurements of the hand has been noted by other investigators, with testretest differences reported to be less than 1%,35,39,41 We conducted a testretest study of the reliability of measurements prior to beginning this study. Volume displacements of the affected hand were recorded for 12 patients with posttraumatic hand edema, and measurements were repeated within a 10-minute period. The mean change between repeated measurements was 0.6 mL (range = -3 to 7). The intraclass correlation coefficient (ICC[3,1])42 was .99. This ICC type applies when each patient is measured by the same set of judges (or judge in this study), who are the only judges of interest.42 We wished to estimate the reliability of measurements from only the one therapist who was going to conduct the experiment. We concluded that this volumetric assessment procedure vielded reliable measurements.

Before volumetric measurement of the hand in this study, the Volumeter® was filled with tap water and allowed to stabilize until water stopped overflowing into the catch receptacle. The catch receptacle was then emptied, dried, and replaced under the drainage spout. The subject's hand was slowly immersed in the water until the stop dowel inside the Volumeter® rested between the web spaces of the middle and ring fingers. The arm

remained immersed at this depth until water stopped overflowing from the drainage spout of the Volumeter® into the catch receptacle. The catch receptacle was moved so as not to fill further during removal of the arm. The subject's arm was then removed from the Volumeter® and dried. The water displaced into the catch receptacle was carefully poured into a graduated cylinder and measured to the nearest milliliter.

Data Reduction and Analysis

The volume of water displaced during the measurement of hand edema was recorded for prerest, postrest, and posttreatment measurements. Volume changes after treatment for each affected hand were determined by subtracting posttreatment from postrest volume displacements. Edema reduction was defined as a decrease in water displacement (in milliliters) from postrest to posttreatment measurements. Means and standard deviations for volume displacements and for volume changes were calculated for each of the three treatment groups.

Nonparametric statistical tests were used to analyze the significance of differences between prerest and postrest volumes in all subjects and of differences in volume changes from postrest to posttreatment measurements among treatment groups. This approach was preferable to parametric methods, which require assumption of normality and homogeneity of variance. We used the Wilcoxon matched-pairs signed-rank test to assess differences in prerest and postrest volumes of the affected hand. The Kruskal-Wallis ordered-scale test was used for overall comparison to test the hypothesis of equal change in all three treatment groups; Wilcoxon's rank-sum test was used for multiple comparisons. A probability level of .05 was used for the overall test of equality of the three groups. A probability level of .017 (p < .05/3) was used for multiple-comparison tests.

Results

Characteristics of the 30 subjects are presented in Table 1. Subjects' ages ranged from 21 to 84 years, and amount of time postinjury ranged from 3 to 20 weeks. Most subjects had undergone some type of surgical procedure following trauma, such as amputation, skin grafting, soft tissue repair, or pin fixation. Etiologies of injury varied and included crush and laceration injuries involving machinery, falls, and motor vehicle accidents; one subject had a palmar fasciectomy for Dupuytren's contracture (surgical trauma only). Forty-seven percent of the subjects had suffered trauma to the wrist or hand, with the remainder suffering injury proximal to the carpus (Tab. 2). There were no significant differences among groups in characteristics or in prerest hand volumes.

Hand volume measurements by treatment group are presented in Table 3. Prerest and postrest hand volumes in the 30 subjects were not significantly different, as assessed by the Wilcoxon test (p = .761). The mean change between prerest and postrest was 0.13 mL (range = -3 to 8 mL).

Concerning posttreatment volume changes (Tab. 4), the Kruskal-Wallis test revealed significant differences between the placebo-HVPC, HVPC, and IPC groups (p = .011) Multiple comparisons by the Wilcoxon's ranksum test revealed a significant difference between the IPC and placebo-HVPC groups (p = .004), with no significant difference between HVPC and IPC (p = .446). The difference between the HVPC and placebo-HVPC groups did not quite reach statistical significance (p = .036). Wide variability existed in the HVPC and IPC groups in the amount of posttreatment change, ranging from no change to decreases of 15 mL (Tab. 4, Figure).

Discussion

In this study, we found no significant difference between prerest and postrest hand volume measurements. We

had included the 10-minute rest period in the study protocol as a control for the effect of patient activity prior to treatment. Because no change occurred following the rest period, we concluded that patient activity prior to the treatment session did not affect volume measurements. We plan to eliminate this rest period as a protocol component in future studies. The small differences between prerest and postrest measurements (\overline{X} change = 0.13 mL, range = -3 to 8 mL) are similar to the findings from our preliminary reliability study of 12 patients $(\overline{X} \text{ change} = 0.6 \text{ mL}, \text{ range} = -3 \text{ to } 7$ mL). On the basis of these findings, we now consider in our facility that a reduction in hand volume after a single treatment must be at least 8 mL to be greater than measurement error.

The null hypothesis of no difference in edema reduction among treatment groups was rejected. The IPC group exhibited a significant decrease in hand edema compared with the placebo-HVPC group. Our findings support those of others concerning the efficacy of IPC for posttraumatic edema reduction. Other studies of the use of IPC in the treatment of posttraumatic edema differed from ours in the amount of time postinjury IPC was begun, duration of IPC application, and compression intensity used. In studies of postburn and postoperative edema,^{27–30} IPC was begun after injury and patients received IPC treatments fairly continuously over a period of days; some investigators allowed patients to increase the intensity of compression pressure to a maximum comfortable level. In studies of chronic postfracture leg edema,31,32 patients received 75 minutes of IPC a day for five consecutive days, using a compression pressure of 60 mm Hg. Our subjects received a single 30minute application of IPC, with a compression pressure of 40 mm Hg. Perhaps a longer treatment time, different inflation and deflation times, or allowing the subjects to increase the compression pressure to tolerance would have produced even greater edema reductions.

Table 1. Description of Treatment Groups

Variable	Placebo-HVPC ^a (n = 10)	HVPC (n = 10)	IPC ^b (n = 10)	p
Age (yr)		-		
\overline{X}	49.0	43.8	50.4	NS
S	16.7	14.6	18.1	
Weight (lbc)				
X	165.5	158.8	157.0	NS
S	37.0	21.5	17.4	
Time postinjury (wk)				
X	9.1	6.1	8.3	NS
S	6.2	2.3	4.3	
Injury location				
(% proximal to wrist)	70	40	50	NS
Surgery postinjury				
(% yes)	70	70	70	NS
Sex				
(% male)	70	90	60	NS
Hand				
(% dominant)	60	40	50	NS

^aHVPC = high voltage pulsed current.

The reduction in edema between HVPC and placebo-HVPC treatments did not quite reach statistical significance. Edema in half of the HVPC group subjects, however, decreased more than the 8 mL we consider to be measurement error. We therefore consider this change to be clinically significant. The HVPC protocol in our study differed from those in other HVPC studies. 13,25,26 We placed electrodes over motor nerves, whereas Newton²⁵ applied HVPC through a water bath and Mohr et al13 and Michlovitz et al²⁶ applied electrodes over the area of injury. The frequencies used in Mohr et al's13 and Michlovitz et al's26 studies were higher (80 and 28 pps, respectively) than the frequency used in our study, and the intensities were lower (below threshold for muscular contraction). We selected a low pulse rate (8 pps), with intensity high enough to produce minimally visible, repetitive muscle contractions. Perhaps one reason edema reduction was noted in

some subjects is that the HVPC activated a muscle-pumping mechanism, whereas such an effect was not produced in preceding studies with

Table 2. Type and Location of Injury

Injury	Number
Fracture or dislocation within wrist or hand, with or without soft tissue injury	11
Soft tissue injury to wrist or hand, with- out fracture	3
Fracture or dislocation proximal to wrist, with or without soft tissue injury	15
Soft tissue injury prox- imal to wrist, with- out fracture	1

 $^{^{}b}$ IPC = intermittent pneumatic compression.

 $^{^{}c}1 \text{ lb} = 0.4536 \text{ kg}.$

Table 3. Hand Volume Measurements at Prerest, Postrest, and Posttreatment Sessions in Treatment Groups

	Unaffected Hand		Affected Hand					
			Prerest		Postrest		Posttreat	tment
Group	x	s	X	s	X	s	X	s
Placebo-HVPC a (n = 10)	512.2	104.1	573.1	111.2	572.1	109.9	570.8	109.5
HVPC (n = 10)	507.3	54.2	553.7	75.0	553.3	73.8	547.0	73.0
IPC^b (n = 10)	503.8	82.9	557.4	92.4	558.4	92.1	550.7	92.1

[&]quot;HVPC = high voltage pulsed current.

HVPC. A higher intensity of stimulation than we used (ie, to patient tolerance), different electrode placement, or longer stimulation time may have produced larger reductions in edema. We believe our finding of edema reduction with HVPC, although not reaching statistical significance, is sufficient to justify further clinical research using the concept of HVPC-generated muscle contractions to reduce chronic posttraumatic edema.

Great variability in edema reduction in the IPC and HVPC groups existed (Figure), and half of the subjects in each group demonstrated responses no different from those of the placebo-HVPC group. Reasons for such variability are unknown. The three treatment groups were equivalent in amount of time since injury, age, location of injury, and pretreat-

Table 4. Changes in Hand Volume Measurement (in Milliliters) Between Postrest and Posttreatment Sessions in Treatment Groups

	Postrest Posttreat	estrest to esttreatment		
Group	X	s		
Placebo-HVPC ^a	-1.3	1.1		
HVPC	-6.3	5.3		
IPC ^b	-7.7	5.4		

[&]quot;HVPC = high voltage pulsed current.

ment hand volume. The use of human subjects presents difficulties in controlled clinical studies because identical types of trauma are impossible to obtain.13 Nevertheless, we considered this sample to be representative of patients treated in a typical physical therapy clinic. We analyzed the characteristics of the 10 subjects in the IPC and HVPC groups who demonstrated decreases in edema of 8 mL or more after treatment, but we were unable to identify any consistent feature that differentiated them from the other subjects. It is possible that subjects who received no benefit from the HVPC treatment would have benefited from IPC application, and vice versa, although our study was not designed to allow evaluation of this possibility.

The results of this study indicate that significant edema reduction may be obtained in some patients with chronic posttraumatic hand edema after one 30-minute treatment with IPC. The largest edema reductions achieved with IPC represented a decrease of 2% to 3% from postrest volumes. Whether subjects would demonstrate progressively greater edema reductions with repeated treatments is unknown. Greater edema reductions might have been obtained by combining IPC or HVPC treatment with elevation of the hand, as is common in clinical practice. However, we intentionally eliminated the effect of hand elevation in order to establish the treatment effects of IPC and HVPC modalities alone.

We cannot comment on possible mechanisms by which edema reduction was accomplished in this study because neither lymphatic flow nor blood flow was measured. No measurements of muscle strength, joint ROM, or hand functional ability were performed because the purpose of this study was to assess edema reduction only. We therefore cannot conclude whether edema reduction in the IPC and HVPC groups resulted in improved ROM, reduced pain, or increased function. Such issues would

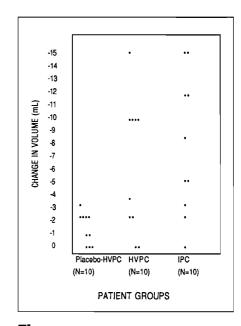


Figure. Frequency distribution of band volume reductions in individual subjects between postrest and posttreatment measurements. (HVPC = bigh voltage pulsed current; IPC = intermittent pneumatic compression.)

 $^{^{}b}$ IPC = intermittent pneumatic compression.

^bIPC = intermittent pneumatic compression.

be important to consider in a more longitudinal study.

Technical considerations noted concerning HVPC and IPC were that, in terms of the amount of time required to set up the subject and equipment for treatment, IPC was simpler and faster to administer than HVPC. A portable IPC unit was frequently sent home for patient use overnight, when edema reduction was achieved with the single treatment. Two subjects were unable to tolerate the 40-mm Hg compression pressure applied by the IPC unit; for such patients, HVPC might be a reasonable treatment alternative. Conversely, several subjects seemed somewhat afraid of electrical stimulation; for such patients, IPC could be used with less treatmentinduced anxiety.

Future Research

Further studies of the efficacy of IPC and HVPC for reduction of posttraumatic hand edema are needed to identify maximally effective treatment protocols, specifically concerning the intensity and frequency of stimulus application, the additive effect by combination with hand elevation, the optimal length of each treatment session, and the number of sessions required for maximum effect. A study design in which each patient receives several types of treatment might identify certain patient characteristics predicting a positive or negative response to HVPC or IPC treatment. Longitudinal studies investigating the relationship of edema reduction to recovery of hand functional ability are essential in documenting the efficacy of IPC and HVPC in the rehabilitation of patients with chronic posttraumatic hand edema.

Conclusion

Results of this controlled study of patients with posttraumatic hand edema indicated that significant edema reductions occurred after one 30-minute treatment with IPC, in comparison with placebo-HVPC treatment. Although edema reduction noted with the HVPC treatment protocol, com-

pared with the placebo-HVPC protocol, did not reach statistical significance, the results were considered clinically significant. Further clinical trials are indicated to explore the efficacy of different IPC and HVPC treatment protocols in similar patient populations.

Acknowledgments

We wish to express our appreciation to Roger VanderZwagg, PhD, and Faten El-Zeky, PhD, for statistical consultation and analysis and to Bland Cannon, MD, and Ken Crispell, MD, for their advice in planning this study. We thank the Chattanooga Corporation for the loan of the IPC and HVPC units used in this study. We thank Kay Daugherty and Margaret Ayers for assistance with manuscript preparation.

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