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Combining the Absence of Electromagnetic Fields and Mirror Therapy to Improve Outcomes for Persons with Lower-Limb Vascular Amputation

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ABSTRACT

Objective: The objective of this pilot study was to explore whether or not the combination of using a residual limb cover to eliminate electromagnetic fields and a mirror therapy exercise program facilitates healing and decreases pain for individuals with lower-limb vascular amputation.

Materials and Methods: A cross-sectional repeated measures design compared two groups based on the time of amputation. Participants in the acute group (n = 11) began treatment within 48 hrs of their amputation, and those who had surgery at least 6 weeks before starting the study comprised the chronic group (n = 5). Effectiveness was measured by physical factors (e.g., edema, temperature) and perception of phantom limb pain (e.g., intensity, frequency, bothersomeness) at three times: pretreatment, posttreatment at 4 weeks, and maintenance after 8 weeks (interval of 4 weeks of no treatment).

Results: For acute participants, edema, temperature, frequency, and bothersomeness demonstrated significant differences, whereas for the chronic group, temperature, pain intensity, frequency, and bothersomeness were significantly different. Unanticipated results were that the residual limb incisions of the individuals with acute amputations were sufficiently healed to begin prosthetic fitting a month earlier than the typical protocol—a decrease from 12 weeks to 8 weeks—and that wearing tolerance increased from 0 to 2 hrs to 8 to 12 hrs for the individuals with chronic amputations after completion of this treatment intervention.

Conclusions: Results suggest that this combined treatment may improve outcomes for individuals with vascular lower-limb amputations and should be investigated further. (*J Prosthet Orthot*. 2016;28:154–164.)

KEY INDEXING TERMS: amputation, phantom limb pain, mirror therapy, Farabloc, occupational therapy, electromagnetic fields

Although there are declining rates of hospitalization for older adults with nontraumatic lower-limb amputations, hospitalization is still higher in the diabetic population.[1,2] More alarming is the significant variation in the number of lower-limb amputations in specific regions of the country.[3] Specifically, Margolis et al. found higher rates of amputation for Medicare beneficiaries in areas of the country associated with lower socioeconomic status, a prevalence of African Americans, increased age, and diabetes, among other factors. Persons with diabetes have a 30 times greater chance of an amputation than a person without diabetes, which is one of the most devastating complications of this disease.[4] With the increasing numbers of individuals developing diabetes with its associated complications,[5,6] amputation will continue to be a health care issue complicated with slow healing and pain as a result.

Associated with lower-limb amputation, phantom limb pain (PLP) is a potentially debilitating phenomenon limiting an individual's function. Studies suggest that 90% of individuals undergoing amputation will experience some degree of PLP.[7] In one large study, 44% of persons with an amputation reported that their PLP had not diminished over a 30-year period.[8] In a 2005 national study of individuals with amputation,[9] researchers found that persistent chronic pain, rather than the loss of limb, impaired the individual's function. Systematic reviews found no evidence of effectiveness for pharmacologic interventions—the most frequently used intervention[10]—or transcutaneous electrical nerve stimulation.[11] Two newer therapies have emerged: Farabloc technology[12] and mirror therapy.[13] The objective of this pilot study was to determine if combining the two therapies, Farabloc technology and mirror therapy, would improve physical outcome measures as well as reduce PLP for individuals with acute or chronic unilateral lower-limb vascular amputations.

Based on the theoretical concept that electromagnetic fields (EMFs) can affect an individual's nervous system resulting in adverse consequences,[14] Farabloc technology uses a linen-like

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fabric that is woven with metal fibers (e.g., iron, nickel, chromium), which have external electromagnetic shielding properties.[15] Farabloc was developed to shield sensitive tissue from immediate shifts in EMF to calm damaged nerve endings and stimulate blood circulation. It was developed based on the Faraday cage principle, developed by Michael Faraday in 1836.[16] Although the exact mechanism of action for Farabloc is unknown, it is theorized that the absence of high-frequency EMF has a positive effect on damaged cells and subsequently reduces pain.[17] Specifically, it shields high-frequency EMF but does not shield low-frequency EMF that have been shown to facilitate healing.[18,19] Further, it has been shown to block EMF four times more effectively than placebo fabric.[17] When a cell phone is surrounded by the Farabloc fabric, it is no longer able to receive wireless internet signals.

There is evidence to support the absence of EMF as a treatment for PLP. Two systematic reviews found evidence to support Farabloc as an effective treatment for management of PLP.[20,21] In another study, 21 of the 34 patients reported their greatest PLP relief during Farabloc intervention, with no adverse effects.[22] Other studies demonstrate evidence of Farabloc's effectiveness with muscle soreness[23] and primary fibromyalgia.[24]

Mirror-box therapy was introduced in the 1990s and has been shown to significantly reduce PLP in individuals with an amputation.[7,13,25,26] Theoretically, mirror therapy is based on the belief that PLP is associated with expansion of the amputated limb's sensory or motor cortex map onto nearby cortical structures. Mirror therapy is thought to reverse cortical remapping and thereby alleviate pain[27] because the visual feedback matches the proprioceptive/motor feedback of a phantom sensation, which corrects the mismatch between visual and proprioceptive/motor cues.[28] Using a mirror placed between the amputated and the nonamputated limb, the concept is that when the individual performs an exercise with the nonamputated limb, it appears as if both limbs are intact. Specifically, executing movements in the mirror suggests that the unaffected hemisphere may generate movements that transfer to the affected hemisphere if the motor system is provided with visual information that can replace or bypass the disturbance of kinesthesis.[29] Thus, it is theorized that intentional movement normalizes the cortical reorganization in the brain.[30] This visual-kinesthetic feedback combined with observation and motor imagery has been shown to be beneficial to individuals with amputation experiencing PLP.[31]

The majority of studies with mirror therapy have involved individuals with upper-limb amputations or lower-limb amputations secondary to trauma. For example, Chan et al.[7] compared mirror therapy and motor imagery therapy and found pain intensity, number, and duration of pain episodes decreased with mirror therapy. In other studies, mirror therapy as a home program has proven effective in decreasing PLP.[26,32]

In summary, there is emerging evidence that Farabloc therapy contributes to the healing process of amputations and subsequently to PLP. In addition, if PLP is induced by a conflict between visual feedback and proprioceptive representation, using the mirror with exercise may correct the mismatch between visual, proprioceptive, and motor cues, thereby reducing the symptoms of PLP.[28]

METHODS

PARTICIPANTS

This study consisted of 16 participants with a unilateral transfemoral or transtibial vascular amputation. Inclusion criteria consisted of adults who 1) spoke English, 2) were able to use a residual limb cover, and 3) had complaints of PLP. The primary exclusion was individuals with medical complications (e.g., cancer, bilateral amputation, neurological disorder, substance abuse) with the exception of diabetes, which was the underlying systemic disorder of all the participants.

The participants were divided into two groups based on the time since their amputation. Participants in the acute group were recruited before their surgery and started the study within 48 hrs of their surgery. Participants in the chronic group had surgery more than 6 weeks previously and were recruited from the Eastern North Carolina Amputee Support Group as they were reporting significant PLP. There were initially 11 acute participants, but 2 participants had medical complications that forced their elimination from the study. The University and Medical Center Institution Review Board of East Carolina University and Vidant Medical Center approved the study, and each participant signed consent before starting the study.

Table 1 displays the demographics of the participants. There was no significant difference between the two groups in terms of ages ($t = 0.216$, $P = 0.83$) with a fairly equal distribution of other demographics.

Table 1. Demographics of participants

	Acute	Chronic
	n = 9	n = 5
Sex	5	3
Male	4	2
Female		
Transtibial	8	3
Transfemoral	1	2
Ethnic	6	2
White	2	2
African American	1	1
Hispanic		
Education	5	3
High school	4	2
College		
Age, y		
Mean (SD)	58.2 (11.2)	61.6 (7.9)
Range	48–78	51–73
Mean time since surgery	35.5 hrs	18.2 mo
Range	26–48 hrs	8–28 mo

SD, standard deviation.

DESIGN

This was a cross-sectional repeated measures design comparing the two groups, with all dependent variables measured on each participant at three time intervals. All the participants received the traditional and experimental protocol for 4 weeks. The traditional protocol included residual limb care (e.g., wound care, application of dry dressings, daily use of a stump shrinker), desensitization techniques, and positioning. The experimental protocol consisted of the combined Farabloc and mirror therapies. Measurement of the dependent variables occurred at pretreatment, posttreatment after 4 weeks of treatment, and maintenance after 4 weeks of no treatment. The dependent variables were physical measurements (e.g., edema, temperature of residual limb) and perception of PLP (e.g., intensity, frequency, duration, bothersomeness).

INSTRUMENTATION

PHYSICAL MEASURES

There were four instruments used. A flexible fabric metric tape measure was used to measure the edema of the residual limb as an indicator of wound healing. Measurements were obtained in millimeters (mm) by measuring the circumference of the distal residual limb at its widest point. The length from the end of the residual limb to the widest point of the residual limb was recorded to ensure that the same circumferential measurement was documented each time. A Hubbard Scientific 6083 Liquid Crystal Temperature Strip was used to measure the skin temperature of the residual limb while wearing the Farabloc residual-limb cover, using the contralateral limb temperature as a baseline measurement.

PROSTHETIC EVALUATION QUESTIONNAIRE

The Prosthetic Evaluation Questionnaire (PEQ),[33] a comprehensive self-report instrument for individuals with limb loss, was used to measure the three dependent measures of pain duration, frequency, and bothersomeness. The PEQ is a self-administered questionnaire consisting of 82 items with a linear analog scale response format. Although divided into seven sections, it has nine validated scales that are each composed of multiple questions. Because the scales are not dependent on each other, only scales pertinent to this study were used. The linear visual analog scale (VAS) format consists of a continuous numerical variable measuring 100 mm. Measurements increase from left to right and are scored from 0 to 100 with all questions worded with the higher number indicating a more positive response. To calculate the scale scores, the arithmetic mean is computed of all the questions on that scale. A minimum of half the questions of a scale has to be answered to be valid. The measures of pain frequency and endurance were measured on a six-point scale. Psychometric analysis supported the reliability and validity of the PEQ for evaluating the function of the residual limb cover and the major health-related quality of life domains.[33] Questions on the PEQ are phrased *within the past month*; support from a recent study demonstrated the validity of that time frame.[34]

BRIEF PAIN INVENTORY

The measure of pain intensity was measured with the Brief Pain Inventory (BPI).[35] It is a 17-item patient self-rating scale, modeled after the McGill Pain Questionnaire,[36] that uses a 10-point scale to rate perceived pain at the present time as well as its worst, least, and average over the last week. Pain ratings are performed daily as a more accurate record of pain compared with scales with recall periods of 3 days or longer.[34] The area on the body that the pain is perceived is indicated on a body diagram, which distinguishes the pain as being residual limb pain as opposed to PLP.

DAILY LOG

Each participant was required to complete a daily log over the 8 weeks to 1) ensure adherence to protocols and 2) track PLP. The daily log did not have any standardized validity and reliability. However, such logs have been used elsewhere in research.[37] In review of the daily logs at each time interval, all participants met the adherence standards.

PROCEDURE

Each participant had two residual limb covers fabricated for their residual limb that were made from Farabloc fabric.[11] Farabloc is a washable, linen-like fabric with 9.5% steel wire fibers (i.e., iron, nickel, chromium, and nylon) woven throughout to shield the effects of high-frequency EMF.[24] It is individually tailored for the residual limb[24] to be placed over the residual limb dressing and elastic shrinker. Participants were instructed to wear one of the two covers 23 hrs/d for the acute group and whenever their prosthesis was removed for the chronic group. A certified prosthetist tested the integrity and quality of the limb cover material to ensure conduction using a continuity multimeter tester to test for conductivity of voltage at each time interval. The integrity of the fabric remained intact throughout the study.

Participants were also instructed to place a Plexiglas mirror lengthwise between their amputated and contralateral leg while seated, with the reflective side facing toward the nonamputated leg, so that it appeared as though they had two intact limbs. They were instructed to perform mirror therapy exercises with bilateral lower limbs simultaneously, while looking at the reflection of the nonamputated limb in the mirror. These exercises included 1 set of 15 repetitions within available range of motion from proximal to distal joints (hip, knee, ankle, and toes). These exercises were to be performed once a day.

Occupational therapy and physical therapy evaluations and interventions were included in the traditional protocol for all participants, although these interventions occurred at different times for the two groups (i.e., the chronic group received therapy interventions after their surgery). All the participants met or exceed standards of care.

The principal investigator (PI) completed all measurements. The acute participants' measurements (pretreatment)

were completed within 48 hrs after amputation. The chronic participants' measurements were collected in their home, at the Amputee Support Group, or at the prosthetic clinic. After the first measurements, participants then received the Farabloc limb covers and a 27 × 15-in Plexiglas mirror for the mirror therapy intervention.

For the acute participants, intervention was done by their regular occupational therapist, trained by the PI. The PI monitored the interventions for consistency. For the chronic group, the PI educated the participants, as well as family members, on the protocols and monitored the interventions by telephone once per week to ensure the appropriate protocols were followed. All participants were asked to demonstrate their understanding of the protocols.

For the posttreatment measurements, the acute participants were measured during their vascular clinic appointment which was scheduled 4 weeks postsurgery. Each participant was required to bring the mirror, study documentation, and residual limb covers. Testing of the Farabloc limb cover material ensured that the integrity of the fabric had remained intact. For the chronic participants, measurements were done at a scheduled time convenient for the participant and PI. During the last visit, both acute and chronic participants were instructed to continue with their documentation and the standard treatment protocol (but not the mirror therapy or use of the Farabloc residual limb cover) and had to return the Farabloc residual limb covers and mirror to the PI. Four weeks later, the maintenance measurements were completed. At that time, the study materials were returned to participants who requested them.

DATA ANALYSIS

For each phase, the mean and standard deviation was calculated for each variable, for all participants. A complete block design analysis of variance (ANOVA) was conducted for each variable, with a 0.05 significance level with time as the main effect and the individual as the blocking effect. All dependent variables were measured, and the Farabloc residual limb cover material was tested to ensure its integrity. The analysis was repeated for each group (acute and chronic) separately. A least significant difference (LSD) post hoc analysis was performed on all significant variables to compare the mean difference and standard error between periods (pretreatment to posttreatment, pretreatment to maintenance, and posttreatment to maintenance) using a significance level of 0.05 and 95% confidence intervals.

RESULTS

Table 2 shows the results of the ANOVA for all participants with five of the seven variables demonstrating a significant difference. Only the measures of duration of pain and temperature without residual limb cover did not reach significance. This latter nonsignificance is expected because it was a control measurement of the residual limb skin temperature.

To examine further, the two groups were separated for individual ANOVAs, which affected the results (see Table 3). For the acute participants, intensity ($P = 0.098$) was not significant, whereas for the chronic group, edema ($P = 0.983$) and residual limb temperature without residual limb cover ($P = 0.672$) were not significant. Duration was not significant for either group.

Table 4 illustrates the post hoc analyses across the three periods for both groups. Different patterns emerged depending on the outcomes measured. For the acute group, there was a significant difference between the pretreatment and posttreatment as well as pretreatment and maintenance (i.e., the treatment period) for edema, frequency, and bothersomeness, but not between the posttreatment and maintenance (i.e., during

Table 2. Mean, SD, and ANOVA between periods for all participants

	All Participants (n = 14)				
	Pretreatment	Posttreatment	Maintenance	ANOVA	
Variable (n = 14)	Mean (SD)	Mean (SD)	Mean (SD)	F (2,26)	*P*
Residual limb effects					
Edema, cm	40.6 (5.5)	38.7 (5.8)	37.8 (6.2)	5.86	0.008
Temperature with residual limb cover	31.3°C (1.6°C)	31.0°C (1.5°C)	32.1°C (1.5°C)	11.75	0.001
Temperature without cover	31.8°C (1.3°C)	31.5°C (1.4°C)	30.8°C (1.4°C)	3.04	0.065
PLP					
Intensity (0–100)	71.5 (7.4)	30.86 (7.4)	12.79 (7.4)	16.64	0.001
Frequency (0–6)	4.8 (1.5)	1.71 (1.9)	2.0 (1.8)	25.74	0.001
Duration (0–6)	2.4 (1.6)	1.9 (1.2)	1.6 (1.5)	1.53	0.235
Bothersomeness (0–100)	18.4 (28.8)	69.6 (34.8)	87.0 (28.4)	25.06	0.001

Edema: measured in centimeters (cm) around the widest part of the residual limb. Temperature with Farabloc limb cover: measured in Celsius with Farabloc limb cover on the residual limb. Temperature without Farabloc cover: measured in Celsius without Farabloc limb cover on the residual limb. Intensity: worst PLP daily, averaged over 4 weeks on a VAS in millimeters from 0 (no pain) to 100 (pain as bad as you can imagine). Frequency: how often person experiences PLP over 4 weeks from 0 (never) to 6 (all the time). Duration: how long each PLP episode lasts on a VAS in millimeters from 0 (I have none) to 6 (more than 2 days). Bothersomeness: how bothersome PLP was over 4 weeks on a VAS in millimeters from 0 (extremely bothersome) to 100 (extremely mild).

The figures in bold indicate $P = 0.001$.

ANOVA, analysis of variance; PLP, phantom limb pain; SD, standard deviation.

Table 3. Mean, SD, and ANOVA for separate acute and chronic groups between three periods

	Acute					Chronic				
	n = 9	n = 5								
	Pretreatment	Posttreatment	Maintenance	ANOVA		Pretreatment	Posttreatment	Maintenance	ANOVA	
Groups	Mean (SD)	Mean (SD)	Mean (SD)	F (2,16)	*P*	Mean (SD)	Mean (SD)	Mean (SD)	F (2,8)	*P*
Residual limb										
Edema, cm	40.7 (6.1)	37.8 (6.2)	36.2 (5.7)	10.23	**0.001**	40.4 (4.8)	40.3 (5.4)	40.5 (6.6)	0.17	0.983
Temperature residual limb cover	31.7°C (1.5°C)	31.6°C (1.3°C)	32.7°C (1.3°C)	6.18	**0.010**	30.6°C (1.6°C)	30.0°C (1.4°C)	31.0°C (1.4°C)	21.71	**0.001**
Temperature without cover	32.3°C (0.5°C)	32.0°C (1.3°C)	30.8°C (1.5°C)	4.15	**0.035**	30.8°C (1.8°C)	30.5°C (1.1°C)	30.8°C (1.3°C)	0.42	0.672
PLP										
Intensity (0–10)	6.3 (1.5)	2.4 (2.6)	1.2 (1.9)	2.69	0.098	6.4 (2.1)	4.1 (1.8)	0.9 (0.7)	5.70	**0.029**
Frequency (0–6)	4.6 (1.8)	1.4 (1.9)	1.8 (1.8)	14.93	**0.001**	5.2 (.8)	2.2 (1.9)	2.4 (2.1)	8.98	**0.009**
Duration (0–6)	2.7 (1.7)	1.9 (1.3)	1.9 (1.7)	0.86	0.441	2.0 (1.2)	2.0 (1.2)	1.2 (1.1)	3.37	0.087
Bothersomeness (0–100)	20.4 (33.3)	67.0 (40.8)	82.3 (34.8)	9.65	**0.002**	14.8 (21.4)	74.2 (23.6)	95.4 (8.1)	29.51	**0.001**

Edema: measured in centimeters (cm) around the widest part of the residual limb. Temperature with Farabloc limb cover: measured in Celsius with Farabloc limb cover on the residual limb. Temperature without Farabloc cover: measured in Celsius without Farabloc limb cover on the residual limb. Intensity: worst PLP daily, averaged over 4 weeks on a VAS in millimeters from 0 (no pain) to 10 (pain as bad as you can imagine). Frequency: how often person experiences PLP over 4 weeks from 0 (never) to 6 (all the time). Duration: how long each PLP episode lasts on a VAS in millimeters from 0 (I have none) to 6 (more than 2 days). Bothersomeness: how bothersome PLP was over 4 weeks on a VAS in millimeters from 0 (extremely bothersome) to 100 (extremely mild).

The figures in bold indicate $P = 0.001$.

ANOVA, analysis of variance; PLP, phantom limb pain; SD, standard deviation.

Table 4. LSD post hoc analysis for separate acute and chronic groups between the three periods

		Acute			Chronic		
		n = 9			n = 5		
Variable	I to J	Mean Difference (SE) (I-J)	*P*	95% CI	Mean Difference (SE) (I-J)	*P*	95% CI
Residual limb							
Edema, cm	Pretreatment to Posttreatment	2.89 (1.00)	**0.011**	0.77–5			
	Pretreatment to Maintenance	4.44 (1.00)	**0.001**	2.33–6.56			
	Posttreatment to Maintenance	1.56 (1.00)	0.138	−0.56 to 3.67			
Temperature with Farabloc limb cover	Pretreatment to Posttreatment	0.17°C (0.34°C)	0.632	−0.56 to 0.89	0.60°C (0.15°C)	**0.004**	0.25–0.95
	Pretreatment to Maintenance	−0.94°C (0.34°C)	**0.014**	−1.67 to −0.22	−0.40°C (0.15°C)	**0.031**	−0.75 to −0.05
	Posttreatment to Maintenance	−1.11°C (0.34°C)	**0.005**	−1.83 to −0.39	−1.00°C (0.15°C)	**0.001**	−1.35 to −0.65
Temperature without Farabloc cover	Pretreatment to Posttreatment	0.33°C (0.57°C)	0.566	−0.87 to 1.54			
	Pretreatment to Maintenance	1.56°C (0.57°C)	**0.015**	0.35 to 2.76			
	Posttreatment to Maintenance	1.22°C (0.57°C)	**0.047**	0.02–2.43			
PLP							
Intensity (0–10)	Pretreatment to Posttreatment				2.28 (1.13)	0.079	−0.33 to 4.9
	Pretreatment to Maintenance				5.25 (1.13)	**0.001**	2.93 to 8.16
	Posttreatment to Maintenance				1.92 (1.13)	**0.021**	0.64 to 5.87
Frequency (0–6)	Pretreatment to Posttreatment	3.11 (0.63)	0.001	1.79–4.44	3.00 (0.80)	**0.005**	1.17-4.83
	Pretreatment to Maintenance	2.78 (0.63)	0.001	−0.46 to 4.06	2.80 (0.80)	**0.008**	0.97 to 4.63
	Posttreatment to Maintenance	−0.33 (0.63)	0.601	−7.94 to 30.39	−0.20 (0.80)	0.807	−2.03 to 1.63
Bothersomeness (0–100)	Pretreatment to Posttreatment	−46.58 (14.67)	**0.006**	−77.68 to −15.47	−59.40 (10.88)	**0.001**	−84.48 to −34.32
	Pretreatment to Maintenance	−61.89 (14.67)	**0.001**	−92.99 to −30.78	−80.60 (10.88)	**0.001**	−105.68 to −55.52
	Posttreatment to Maintenance	−15.31 (14.67)	0.312	−46.42 to 15.79	−21.20 (10.88)	0.087	−46.28 to 3.88

Edema: measured in centimeters (cm) around the widest part of the residual limb. Temperature with Farabloc limb cover: measured in Celsius with Farabloc limb cover on the residual limb. Temperature without Farabloc cover: measured in Celsius without Farabloc limb cover on the residual limb. Intensity: worst PLP daily, averaged over 4 weeks on a VAS in millimeters from 0 (no pain) to 10 (pain as bad as you can imagine). Frequency: how often person experiences PLP over 4 weeks from 0 (never) to 6 (all the time). Duration: how long each PLP episode lasts on a VAS in millimeters from 0 (I have none) to 6 (more than 2 days). Bothersomeness: how bothersome PLP was over 4 weeks on a VAS in millimeters from 0 (extremely bothersome) to 100 (extremely mild).

The figures in bold indicate $P = 0.001$.

CI, confidence interval; SE, standard error.

the nontreatment period). For the variable of temperature with residual limb cover and temperature without residual limb cover, significant differences were noted between the pretreatment and maintenance as well as posttreatment and maintenance measures. Temperatures of the residual limb with the Farabloc residual limb cover were lower than temperatures of the residual limb without the residual limb cover.

For the chronic participants, the temperature of the residual limb without the Farabloc residual limb cover showed no significant difference. However, the temperature of the residual limb with the Farabloc cover on was significantly different at all three measurement times—decreasing during the treatment phase and increasing during the nontreatment phase to a higher temperature than before treatment. In terms of PLP, frequency and bothersomeness were significantly different between pretreatment and posttreatment as well as pretreatment and maintenance (i.e., during the treatment phase), but not posttreatment to maintenance (i.e., during the nontreatment phase), suggesting treatment was effective. Phantom limb pain intensity approached significance ($P < 0.079$) between pretreatment and posttreatment, reaching significance between pretreatment and maintenance as well as posttreatment and maintenance.

There was an unexpected outcome for the participants in the acute group. While all participants (both groups) had their surgery in the same setting and were seen postsurgically by the same physician and rehabilitation staff, there was a significant change in the time until the residual limb incision was sufficiently healed, so that prosthetic fitting could begin. Whereas all of the chronic participants were fitted for their prosthesis at 12 weeks postsurgery (the typical period for vascular patients at this facility), seven of the nine acute participants began prosthetic fitting at 8 weeks, 4 weeks earlier. Two of the nine were delayed due to medical complications (i.e., dehiscence of the incision and chronic obstructive pulmonary disease complications). For participants in the chronic group, the wearing tolerance of prostheses increased significantly as a result of participation in the study. Specifically, wearing time increased from 2 to 12 hrs for two participants (n = 2), 2 to 10 (n = 1), 0 to 8 (n = 1), and from 0 to 12 (n = 1). With the exception of the two with medical complications, all participants were able to use their prostheses after the intervention on either a part-time (five participants) or full-time basis with three of the acute participants returning to work after the 12 weeks.

DISCUSSION

The purpose of this pilot study was to investigate the effectiveness of combining two PLP treatments for persons with vascular amputations, specifically, the absence of EMFs using Farabloc technology (external source) and implementing mirror therapy as a method of sensory cortex reorganization (internal source) to improve healing and reduce PLP. The results of this pilot study suggest that the combination of the two therapies may improve physical outcomes and reduce PLP for individuals with acute and chronic vascular amputations. For all 14 participants, there were significant differences in frequency, bothersomeness, and temperature between pretreatment and posttreatment and, in some cases, even after treatment stopped. When analyzed as separate groups, there were interesting differences. Individuals with acute amputations had greater gains in residual limb healing, whereas those with chronic amputations had decreases in pain intensity.

An unexpected result of this study was the decrease in time from surgery until individuals with acute amputations were ready for prosthetic fitting. In accordance with typical vascular amputation protocols for this facility, fitting of a prosthesis occurs around 12 weeks after amputation and this was true for the five chronic participants who had their prosthesis fitted before the study was started. However, the participants with acute amputations appeared to have reduced edema and accelerated residual limb wound healing, so that seven of the nine participants with acute amputations (78%) were ready for prosthetic fitting 4 weeks early (8 weeks after amputation). The implications of this finding are considerable for individual health outcomes, as well as for society, in terms of cost savings. Using a more effective treatment protocol to improve residual limb healing for acute amputations would decrease the waiting time required for the individual to become a functional prosthetic user. More importantly, early prosthesis use has been shown to reduce PLP,[38] which will increase mobility and quality of life satisfaction. In fact, a clear relationship has been found between mobility success and mobility satisfaction as well as satisfaction with life; those individuals who achieved mobility were 36% more likely to be satisfied with their mobility and 28% more likely to be satisfied with life than those who were not successful.[39]

Equally unexpected was the impact of the treatment protocol on the chronic group—individuals with amputations who had been fitted with a prosthesis but who were not wearing them because of discomfort and pain. In addition to the mobility issues of not using the prosthesis, individuals who do not use their prosthesis may be at even greater risk for contralateral amputation[40] because persons who rely solely on their contralateral limb after a major amputation make that limb more susceptible to trauma due to excessive forces on this limb. In all five cases, the increase in prosthetic wearing times averaged from 2 hrs before intervention to 12 hrs after intervention. The majority of persons with chronic amputations were able to increase their participation in active, rather than sedentary (and in one case bed-bound), lifestyles.

PHYSICAL FACTORS

Edema decreased significantly for the acute group in the treatment period, with no significant difference between posttreatment and maintenance. It is not surprising that edema would decrease as part of the healing process after surgery. However, the marked decrease in edema that allowed earlier prosthetic wear by 4 weeks suggests a significant finding, as standard therapy had been the same (12 weeks) for previous individuals with amputation. It is possible that the active motion of the residual limb with mirror therapy exercises may explain some of the decreased edema, as edema has been shown to

decrease with active motion.[41] However, an alternative explanation may be due to the combination treatment protocol—increased active motion in addition to the high-frequency EMF shielding effects of the residual limb cover. High-frequency EMF increases cell permeability,[24] so the absence of high-frequency EMF provided by the residual limb cover may mean that the cells are less permeable with a reduction in cell membrane fluidity and an increase in superoxide dismutase, which has anti-inflammatory properties.[18] Coupled with the increased exercise, the combination of these two therapies may have important implications for treatment that need further consideration.

Edema reduction was not anticipated for the chronic group, as wound healing was complete with this group. However, what was significant was the increased tolerance that the chronic group noted in terms of wearing their prostheses. The daily logs of the participants show that four of the five participants reported an increase in their wearing time. One participant was able to wear her prosthesis for the first time since surgery, 17 days after initiating the treatment protocol. Persons with long-term vascular amputations frequently struggle with prosthetic fitting and wearing, due to volume changes in the residual limb.[42] If effective, as suggested in this study, Farabloc could be incorporated into the socket of a prosthesis through lamination, for stabilization of residual limb volume, at the muscle cell membrane level,[17] which may improve the limb volume consistency and thereby increase wearing tolerance of the prosthesis.

Phantom limb treatments are based on the assumption that PLP is due to functional or structural changes in the peripheral and central nervous systems in response to noxious somatosensory input. Amputated nerves have an increased excitability or reduced threshold of stimulus.[43] Thus, an external mechanism to reduce this excitability may be beneficial. A Farabloc residual limb cover might reduce noxious somatosensory input by reducing the high-frequency EMF that overstimulates these nerve pathways. Farabloc may also affect the blood supply of the residual limb. Although the temperature of the residual limb has not been clinically measured in the past, users of the Farabloc fabric report a perceived increase in temperature, which may contribute to its pain-relieving properties.[24] Thus, one of the outcome measures in this study was temperature of the residual limb. The temperature of the residual limb with no cover was the control for each participant to compare the temperature of residual limb with the Farabloc limb cover. Interestingly, the residual limb temperatures were an average of 1.18°C cooler for the combined group of participants when wearing the Farabloc residual limb cover. This reduction could possibly be due to the shielding effects. Despite this decrease in temperature, these users also perceived an increase in temperature while wearing the Farabloc residual limb cover as in the previous study.[24]

When examining the results for the separate groups for the temperature with the cover, although different, the pattern is the same. Both groups demonstrated decreased temperatures during the treatment and maintenance periods as compared with the pretreatment measurement. For the acute group, it can easily be explained as recovery from surgery. The reduced inflammatory response, resulting in a reduction of leukocytes and neutrophils as blood markers for inflammation and cell destruction[17] while wearing the residual limb cover, may be one explanation for the temperature reduction. However, for the chronic group, it would appear that the cover helped lower the temperature of the residual limb while being worn consistently and that this result was maintained after treatment was discontinued. The chronic group's control (i.e., without the cover) temperature showed no differences.

Excessive heat and sweating of the residual limb within the socket of a prosthesis is the primary reason that persons with amputation report decreases in wearing time.[44] These results suggest that lamination of Farabloc fabric within the prosthesis socket could lead to a decrease in temperature, which may increase wearing times with a corresponding increase in participation in life. Unfortunately, temperature readings with the use of the Hubbard Scientific 6083 Liquid Crystal Temperature Strip thermometer are not sufficiently sensitive. Improved accuracy of temperature readings would be required before a clear association could be made between residual limb temperatures and PLP reduction. In addition, wound bed temperature was not measured, which might indicate wound healing. Nevertheless, the initial results here warrant further investigation.

PAIN AND DISCOMFORT MEASURES

In terms of the PLP measures, there were significant decreases in PLP intensity, frequency, and bothersomeness for all participants. For frequency and bothersomeness, the pattern for the separate groups was the same; frequency of pain and how much it bothered them was significantly decreased while wearing the cover and performing the mirror therapy exercises, and remained at the same level during the maintenance period. While this could be easily explained as healing from the surgery for the acute participant group, for the chronic group, it is more suggestive of a treatment effect. The decreased level for frequency and bothersomeness through the maintenance period indicates a continued treatment effect, which warrants further investigation. Individuals with vascular disorders such as diabetes frequently suffer from peripheral neuropathic pains for many months or years before an amputation.[45] Once neuropathic pain is established, it is extremely difficult to eradicate[46]; therefore, a treatment that was able to decrease the neuropathic pain before an amputation may lead to an even greater improvement of PLP after amputation. The shielding properties of a Farabloc garment, such as those used in another study,[24] may be useful in preventing or reducing this neuropathic pain.

Evidence from the measure of intensity may indicate a different process. For the acute group, there were no differences at all, which was not surprising as they were recovering from a recent surgery. However, for the chronic group, intensity differences approached significance from pretreatment to posttreatment ($P = 0.079$) and there was a significant difference noted after the intervention ended. One explanation may be that it took more time to decrease the intensity of the pain (over 8 weeks instead of 4). Alternatively, it may be that wearing prosthesis

consistently with increased activity was the main reason for decreased intensity. Regardless, the combined therapies suggest improvement, so this also needs further investigation.

Participants indicated decreases in the duration of PLP for the combined group, although they were not statistically significant. The brevity of the treatment protocol period (4 weeks) might have influenced this result as well as the low number of participants. Further research is required to ascertain the optimal treatment period, as well as long-term maintenance results of this treatment protocol.

LIMITATIONS

This study was a pilot study and is limited primarily due to the small sample size, which decreases the ability to generalize the findings. The other major limitation was not having a control group of participants without the Farabloc or not using the mirror therapy. This is a significant limitation. It is possible that the participants improved simply because they were getting additional attention and were motivated to improve. However, regardless of the small number and no control group, the physical changes of the residual limb as well as the significant improvements in the quality of life demonstrated in another article,[47] particularly for the chronic group, seem to be more than can be expected from any placebo effect.

The variety of settings (e.g., acute hospital, inpatient rehabilitation, home) in which the participants used the treatment protocol is also a limitation because this increases the number of external influences that may have an effect on these results. The choice to use participants with vascular amputations compared with participants with traumatic amputations also increases the comorbidities involved in this study. However, the positive results of this study on participants with more complex medical conditions than might be typical of a traumatic amputation lead to further support of the outcomes.

An associated limitation with this is the relatively short length of time that individuals with acute amputations tend to remain in acute care and inpatient rehabilitation settings in which the conditions can be closely monitored. Vidant Medical Center as the flagship of Vidant Health serves 29 surrounding counties, therefore monitoring therapy conditions upon discharge from this facility was challenging. However, the PI was diligent about educating therapists in an identical and systematic manner so that those who would directly work with the clients in home health, outpatient, or rehabilitation were educated regarding the identified treatment protocols. Participants were given written instructions, a home exercise program to follow upon discharge, and follow-up calls weekly by the PI, which assisted with compliance to the treatment protocol.

CONCLUSIONS

In summary, this study aimed to ascertain the usefulness of using a combined treatment protocol of Farabloc technology to eliminate external EMFs and the exercise program of mirror therapy to reorganize the sensory motor cortex internally. The main hypothesis was that the combined treatment protocol would have a significant effect on PLP in individuals with acute and chronic amputations. Decreasing edema and the discomfort due to PLP was evident in both groups of individuals with amputations. Results varied between the acute and chronic participants, but overall the changes were maintained (and in some cases improved) even after treatment was terminated, suggesting that the combined intervention of the two treatments has a biological impact that will remain once intervention is over. Further research will be needed to determine the ideal length of intervention.

Overall, the significant decreases during the treatment period of PLP frequency and bothersomeness are important for the acute group to maximize their ability to participate in the rehabilitation process, which occurs within the first month after surgery. With a reduction in PLP, an overall improvement of participation can be anticipated. Similarly, the improvements for the chronic group are promising. All five of these participants agreed to participate in this study because their PLP prevented functional use of their prosthesis and interfered with work, activities of daily life, and quality of life. Despite the time since surgery (an average of 18.2 months), these participants were able to benefit from this treatment protocol in managing their PLP symptoms. This suggests that persons with amputation dealing with chronic PLP symptoms that limit participation in all life tasks can use a combination of Farabloc technology and mirror therapy to improve their quality of life.

Because of the limitations of such a small sample, it will be critical to expand this study to a larger population, using a multi-site study with control groups, which are randomly selected from a variety of geographic areas to increase the reliability and generalizability. In addition, examining the effects of this combined treatment protocol with persons with traumatic amputations and persons with upper-limb amputations would be beneficial. Results of this study could have a far-reaching impact. If research continues to show the same results, an alternative treatment protocol to decrease the debilitating effects of PLP in persons with amputations would be established. This protocol provides a cost-effective, drug-free alternative to current PLP treatments. This combined treatment protocol reduces PLP to the extent to which persons with amputation can increase participation in their activities of everyday life and subsequently improve their quality of life. Further, if the time between amputation and prosthetic fitting can be decreased, as it has in this study, medical costs can be significantly reduced and function and quality of life for our older adults with vascular disorders can be improved.

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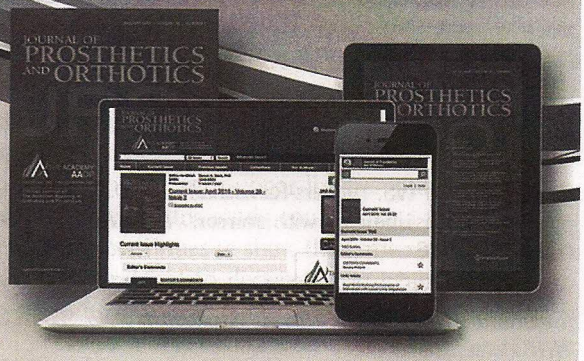

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