The Efficacy of Farabloc™ in the Treatment of Phantom Limb Pain

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Farabloc is a product promoted for the relief (not cure) of intermittent phantom limb pain. It is a linen fabric with ultrathin steel threads to be worn over the stump and claimed to shield nerve endings from external electrical and magnetic fields. In a double blind, cross-over design, 34 subjects reported their pain relief level on a Visual Analogue Scale during a pretreatment period, Farabloc or placebo treatment period, a no-treatment or "washout" period for the control of any carry-over effect, and an alteration of treatment period. The results were statistically significant ($p < .001$) in favour of the Farabloc period. Of the 34 subjects, 21 reported their greatest pain relief during Farabloc intervention. However, the clinical significance of the findings may be questioned since only two subjects reported complete or near complete pain relief with Farabloc, and the number of potential users is limited. Nevertheless, Farabloc is a relatively inexpensive alternative compared to other therapeutic measures currently available.

Phantom limb pain is one of the most distressful sequela of amputation, affecting a majority of persons with healed stumps, often persisting for years or decades (Jensen, Krebs, Neilson, & Rasmussen, 1985; Sherman, Sherman & Parker, 1984). It is commonly described as a sensation of a twisted absent limb, hyperflexed absent fingers or toes digging into the palm or plantar surface, or as burning, cramping, crushing, shooting, or stabbing sensation in a missing body part. The pain may last for a few minutes, hours or days, occasionally or continuously over a long period. The episode in some persons may be triggered or intensified by unrelated pain (e.g., back pain) or by gentle pressure of the stump, other limb, or head. Urination, defecation, sexual intercourse, or approaching low pressure weather systems could also act as triggers. Although research suggests a physiological basis for the pain, the etiology of phantom limb pain is unknown. Its incidence has not been associated with the reason for the amputation, location of amputation, age, gender, socioeconomic status, or a psychological disorder.

In a 1980 report more than 50 unrelated treatments for phantom limb pain were identified by Sherman, Sherman, and Gall. These include surgical interventions (e.g., sympathectomy, rhizotomy), pharmacological approaches (e.g., nerve blocks, local anaesthetics), physical therapy (e.g., ultrasound, TENS), and psychological treatments (e.g., psychotherapy, biofeedback, hypnosis). Unfortunately, none of the described

methods has been successful for more than a year's treatment duration with more than one third of patients, the same as placebo use in pain management (Evans, 1974).

In recent years, FarablocTM, a proprietary product (Farabloc Development Corporation, Port Coquitlam, B.C.), has been widely promoted in Europe and North America for the relief of intermittent (not constant) phantom limb pain. Farabloc is made of a series of ultrathin steel threads woven, in a specific pattern, into a linen fabric which can be sewn into a garment (e.g., a sleeve/glove, sock, vest) to be worn over the amputation site as soon as the pain is felt. It is based on the same principle as the "Farady Cage" to block external magnetic influences.

No control trials have been reported in the literature of its efficacy. In late 1990, the British Columbia Ministry of Health requested that we evaluate Farabloc. It was hypothesized that the use of Farabloc would have no statistically significant effect on the intensity of the phantom limb pain experienced by persons with limb amputations ($p < .05$).

METHOD

Materials

For the purpose of this study, the manufacturer produced a placebo fabric, identical to Farabloc in colour, thickness, and texture but without the wire mesh which is not visible. Garments were fashioned from each fabric as appropriate for the individual subject.

The manufacturer recommends that Farabloc be used for episodic (not constant) pain. The garment is worn for four or more hours, as soon as the pain begins, in two or three layers over the stump and extending 10 to 15 cm beyond the amputation scar. If other scar tissue or unrelated painful parts exist (e.g., burn scars, arthritic joints) these areas, too, should be covered by the material. For this study, additional garments were made for the subjects as needed to cover other scars or painful body parts. The garments made from Farabloc or placebo fabrics were coded.

Farabloc is non-irritant to the skin. Normal machine washing and drying may be safely used.

Subjects

The subjects were consenting adults with upper or lower extremity amputations and healed stumps, experiencing episodes of phantom limb pain (not constant pain) who were referred to the study by their physicians, prosthetists, or rehabilitation therapists. None of the subjects were associated with the authors as their patients.

To qualify for the study, subjects had to be (a) 19 years of age or older; and (b) able to comprehend English, grant informed consent, and understand the use of a Visual Analogue Scale (VAS) to report pain relief (Huskisson, 1983); and (c) able to keep a log for recording each pain episode (i.e., date, time, and duration of pain, and time when garment applied, duration of wear). Subjects were excluded if they: (a) had stump complications (e.g., skin irritation); (b) were undergoing new treatments; (c) were involved in a compensation claim; (d) had problems with their prosthesis; (e) had changed their normal use of the prosthesis or obtained a new prosthesis; or (f) had a diagnosis of neurological or psychological disorder.

Instruments

The subject was asked to describe the degree of pain relief that was experienced after each episode of phantom limb pain by marking the VAS. This instrument uses a 10 cm line with "stops" at each end and a description written "no pain relief" on one extreme and "complete pain relief" on the other (Huskisson, 1983). The subject marks a point on the line to correspond with the magnitude of his pain relief. The distance of the mark from the endpoint is measured for a quantitative measurement of pain. The VAS was chosen because it is simple to use, its validity has been established based on high correlations with other standard measures of pain and medication usage, and its reproducibility is as high as 0.99 (Scott & Huskisson, 1979; Jensen, Karoly, & Bravor, 1986; Wall, Novotny-Joseph, & MacNamara, 1985).

To estimate pain relief, the subjects were also asked to record the time, date and duration of each pain episode, and the time and duration of the use of the garment provided to them.

Procedures

This study was a sequential, double blind, crossover design composed of a pretreatment period, random assignment to the use of Farabloc or placebo treatment period, a "wash-out" or no treatment period for the control of any possible carry-over effect of treatment, and a crossover period involving the alteration of treatment. Each of these segments covered a duration of three to five consecutive episodes of pain.

One of the authors (CH) screened the referred candidates for the inclusion/exclusion criteria. Another author (TAC) obtained the informed consent, explained the procedures, and assessed the ability of the subjects to use the VAS and the log. Following the pre-treatment period and based on a predetermined randomized schedule, a departmental secretary provided the subject with a Farabloc garment, or a placebo garment with verbal and written instructions for use. Additional garments were provided, as needed, for other pain or scar sites.

The subject was unaware of the sequence of the presentation of the materials. A research assistant, also blind to the material in use, periodically followed up each subject to ensure compliance with the protocol, to monitor the rotation patterns for each period, and to collect the data which were then forwarded to an independent statistician for analysis. The subjects were instructed to feel free to use their usual medications or analgesics at any time during the trial as prescribed by their physicians, and to continue any other method of pain control to which they were accustomed (e.g., relaxation, removal of the prosthesis, use of a heating pad, or tapping the stump).

RESULTS

Fifty-two persons with amputations who met the criteria were referred to the study. Of these, 34 completed the trial. The others (18) were not included, or were removed from the study, because they: experienced pain too infrequently (less than 15 episodes per year) to participate within the study's time frame (6), found the garment uncomfortable (6), were unable to maintain the log or wear the garment as soon as pain was experienced (4), had a new prosthesis (1), or had an unrelated surgery (1).

Of the 34 sequentially randomized participants, 18 began the treatment with Farabloc (Group 1) and 16 with the placebo (Group 2). The characteristics of the two groups were quite similar (see Table 1). None of the subjects was addicted or used narcotics, antidepressants, anticonvulsants, neuroleptics, or other prescription agents for pain relief. During the trial, none reported any allergic or other problems associated with the use of Farabloc.

Table 1.

Characteristics of the 34 subjects who completed the trial.

Characteristics	Group 1 Farabloc - Placebo (N=18)	Group 2 Placebo - Farabloc (N=16)
Sex: male / female	15 / 3	13 / 3
Age	46 years (sd =8.2)	43 years (sd=8.9)
Education	8 years (sd=4.0)	8 years (sd=3.5)
Time since amputation	1 to 40 years	2 to 31 years
Location of amputation:		
Above knee	4	6
Below knee	8	6
Above elbow	2	3
Below elbow	2	1
Index and thumb	0	0
Shoulder disarticulation	1	1
Reason for amputation		
Trauma	12	10
Vascular	5	4
Cancer	1	2
Description of pre-dominant pain:		
Burning	5	4
Cramping	4	4
Electric shock	2	2

Stabbing	3	2
Shooting	1	1
Pins and needles	1	2
Ants crawling	1	0
Unnatural position	1	1

Table 2 shows each subject's averaged pain relief scores for three to five episodes of pain during each period. In all, 21 subjects reported their greatest pain relief during Farabloc intervention (11 or 61% in Group 1; 10 or 62% in Group 2). However only one of these subjects in each group shows complete (VAS = 10) or near complete (VAS = 9.8) pain relief with Farabloc. One subject in Group 2, subject #5, appears to have had greater pain with both placebo and Farabloc.

Table 2.

Pain relief rating scores using the Visual Analogue Scale by 18 subjects in the Farabloc-Placebo (Group 1)
alteration of treatment and by 16 subjects in the Placebo-Farabloc (Group 2) alteration of treatments.

Group 1	Pre-treatment	Farabloc	Washout	Placebo
1	0.0	0.8	2.0	1.0
2	0.0	4.8	0.0	2.8
3	1.1	0.4	0.5	1.5
4	2.0	2.0	2.1	3.1
5	1.0	3.6	2.0	2.2
6	2.3	7.0	2.0	3.1
7	0.2	8.1	0.5	3.1
8	2.0	4.7	1.9	4.0
9	0.3	5.8	0.0	2.4
10	3.2	9.8	2.9	4.8
11	1.2	0.3	0.5	0.4
12	1.1	3.5	2.0	0.0

13	2.8	1.8	3.0	2.1
14	0.3	3.2	3.0	3.2
15	2.5	6.0	1.2	2.5
16	0.0	3.8	0.0	1.5
17	2.0	5.2	2.2	3.8
18	0.0	0.5	2.0	1.0
Group 1	Pre-treatment	Placebo	Washout	Farabloc
1	1.1	0.8	2.0	1.0
2	0.8	1.0	1.0	3.0
3	1.8	2.0	2.0	0.6
4	0.9	3.8	4.9	6.0
5	1.2	0.0	2.0	0.0
6	2.1	7.0	3.0	6.7
7	3.2	3.0	2.9	4.7
8	1.0	0.0	0.0	1.5
9	0.0	5.2	2.9	7.3
10	0.0	3.5	0.6	8.1
11	2.2	2.2	3.2	6.2
12	1.7	1.0	0.9	2.6
13	0.0	1.0	0.2	0.5
14	1.0	1.3	1.2	1.9
15	2.2	3.8	2.9	10.0
16	1.8	3.0	2.2	7.1

Table 3 presents the mean and standard deviation values for each group per period. The mean pain relief scores are the greatest during the second period (P2) for Group 1 and P4 for Group 2 (i.e., when using Farabloc). These period means differ by only 2 or 3 points on the VAS (scale of 10) as compared to other period means.

The standard deviation values (Table 3) are slightly higher in the placebo periods than in the pretreatment or washout periods, indicating the placebo effect was operating on some subjects. The intervention (Farabloc) standard deviation values are the largest, as Farabloc apparently worked on some but not on others.

Pain relief rating scores using the Visual Analogue Scale by 18 subjects in the Farabloc-Placebo (Group 1) alteration of treatments and by 16 subjects in the Placebo-Farabloc (Group 2) alteration of treatments.

Table 3.

The mean and standard deviation values for the VAS scores for the four periods: (1) pretreatment, (2) Farabloc-Placebo Group 1, Placebo-Farabloc Group 2, (3) washout, and (4) alteration of treatment.

Group	Period			
	1 Mean (sd)	2 Mean (sd)	3 Mean (sd)	4 Mean (sd)
Group 1	1.22 (1.08)	3.96 (2.75)	1.54 (1.04)	2.36 (1.28)
Group 2	1.31 (0.90)	2.43 (1.93)	1.99 (1.30)	4.27 (3.12)

The results of the repeated measures analysis of variance in Table 4 indicate the statistical significance of the group-by-period interactions ($p < .001$). There is a main effect for periods, and no main effect for groups; both of which are in keeping with the pattern of the Farabloc effect.

Table 4.

The result of the repeated measures analysis of variance comparing the difference in the VAS mean scores for each period by the two groups.

Source	D.F	Sum of Squares	F-Value	p
Group	1	1.76	0.25	0.6237
Period	3	106.54	16.17	0.0000
Group x period	3	50.83	7.69	0.0001
Subjects	32	222.17		
Error	96	211.46		
TOTAL	135	593.06		

Tukey's multiple pairwise comparison range test ($p < .05$) showed no difference between groups in the pretreatment/washout periods (i.e., the means 1.2,1.5,1.3,1.9 in Table 3).

The two placebo means (2.4 and 2.4) are the same and not significantly different from pretreatment/washout means. The two intervention means (4.0 and 4.3) are quite similar but significantly greater than the pretreatment/washout means.

Ideally in such a cross-over design, comparing the intervention with placebo means, the two intervention means would be significantly different than the placebo means (at least within the group). In this study, the intervention mean in Group 1 is significantly greater than Group 1 placebo mean, but is not greater than Group 2 placebo mean. However, Group 2 intervention mean is significantly greater than the Group 2 and Group 1 placebo means. It is likely that with a few more subjects in each group, the results would have come out consistent with the ideal pattern.

In summary, the results indicate that the subjects reported significantly greater pain relief on the VAS scale when they were using the Farabloc garment as compared to their pretreatment, washout or placebo pain relief ratings.

DISCUSSION

The results of this study do not support the hypothesis that the use of Farabloc would have no statistically significant effect on the intensity of the phantom limb pain. While only few subjects in this study obtained complete, or near complete pain relief with Farabloc, most of them reported their greatest pain relief when using the garment, as compared to other periods. The differences in pain relief scores between periods were, on the average, about three points on the Visual Analogue Scale in favour of Farabloc intervention and statistically significant ($p < .001$).

Central to the analysis of the results is the consideration of the clinical (not statistical) significance of the findings. It may be argued that even if Farabloc works, a difference of three VAS points (Table 3), on the average, is not a significant pain relief. Of our 34 subjects, only nine (26%) reported, five or greater, VAS points on pain relief with Farabloc as compared to their individual pretreatment or washout periods.

On the question of clinical significance, we can only offer the study's findings and the observation that the material was found to be harmless. It is reusable, obtainable without a prescription, and inexpensive (about $400.00) as compared to other dubious therapeutic measures in use. Many individuals will find the garment uncomfortable to wear in bed, or impractical when at work or in public. Discomfort with the garment may explain the response of Subject 5 in Group 2 who reported to be in greater pain with the garments (placebo and Farabloc) than during the periods without them. In this study, only people with episodic pain were involved. The manufacturer does not recommend Farabloc if the pain is constant. Thus, these limitations further restrict the number of potential users.

At present there is no widely successful method for treating phantom limb pain. Based on exhaustive literature reviews, authors (Sherman, Sherman & Gall, 1980; Sherman, Ernst, Barja, & Bruno, 1988) have concluded that the reports of beneficial interventions have been generally supported by small research samples, flawed research designs, transient effects, or with below the expected rate of placebo response. Yet, many treatment methods continue to be used. Some work for some individuals. Plausible scientific explanations have been offered for a few interventions based on a variety of theoretical concepts of cause and pathophysiology. Unfortunately, phantom limb pain remains elusive even with

the most diligent medical management. Experts have recommended that the elements of patient's complaints (e.g., burning or cramping; pain at night or pain with decreased atmospheric pressure; or a combination of these) be delineated to help in the selection of a specific therapy (Iacono, Linford, Sandyk, 1987; Sherman, 1989). We are unable to explain our results based on any of the current etiologic theories. We attempted to distinguish the characteristics of those who benefited from Farabloc from those who did not. They were similar in history, symptoms experienced, and personal variables.

According to the manufacturer, phantom limb pain is caused by external electrical and magnetic fields irritating the severed nerve endings of the stump. The assumption is made that the human nervous system is analogous to a complex set of electrical receptors and conductors, with the brain acting as a central receiving station. In this system, protection from external electrical and magnetic fields is thought to be normally provided by the surface layers of body tissue, which is lacking over the scar of an amputation site. Therefore, when the severed nerve endings are exposed to external electric and magnetic fields, the brain perceives the irritation as pain. It is reasoned that the Farabloc garment would repel the external forces and protect the nerve endings through the shielding effect of its wire mesh.

This study was concluded in late 1991. Ideally at the end of a subject's participation, we would have allowed the subject to select one of the two garments (Farabloc or placebo) for a follow-up after six months or a year. The realities of funding limitations and the difficulties of maintaining an intact group prevented us from pursuing the study. A replication of our results is recommended.

REFERENCES

Evans, F. J. (1974) . The placebo response in pain reduction. Advances in Neurology, 4, 289-296.

Huskisson, E. C. (1983). Visual analogue scales. In Ronald Melzak (ed.), Pain Measurement and Assessment. New York, NY: Raven Press.

Iacono, R. P., Linford, J., & Sandyk, R. (1987). Pain management after lower extremity amputation. Neurosurgery, 20, 496-500.

Jensen, M. P., Karoly, P., & Bravor, S. (1986). The measurement of clinical pain intensity: A comparison of six methods. Pain, 27, 117-126.

Jensen, T. S., Krebs, B., Nielsen, J., & Rasmussen, P. (1985). Immediate and long-term phantom limb pain in amputees: Incidence, clinical characteristics and relationship to pre-amputation limb-pain. Pain, 18, 267278.

Scott, J., & Huskisson, E. C. (1979). Accuracy of subjective measurements made with or without previous scores: An important source of error in serial measurements of subjective states. Annals of Rheumatic Diseases, 38, 558-559.

Sherman, R. A., Sherman, C. J. & Gall, N.G. (1980). A Survey of current phantom limb pain treatment in the United States. Pain, 8, 85-99.

Sherman, R. A. (1989). Stump and phantom limb pain. Neurologic Clinics, 7, 249-264.

Sherman, R. A., Ernst, J. L., Barja, R. H., & Bruno, G. M. (1988). Phantom pain: A lesson in the necessity for careful clinical research in chronic pain problems. Journal of Rehabilitation Research, 25:VII-X.

Sherman, R. A. Sherman, C. J., & Parker, L. (1984). Chronic phantom and stump pain among American veterans: Results of a survey. Pain, 18, 83-94.

Wall, R., Novotny-Joseph, P., & MacNamara, T. E. (1985). Does amputation pain influence phantom limb pain in cancer patients? Southern Medical Journal, 78, 35-36.

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