CRITICALLY APPRAISED PAPER (CAP)

FOCUSED QUESTION

What is the impact of noninvasive limb cover on chronic phantom limb pain and frequency and general quality of life in a veteran amputee population?


CLINICAL BOTTOM LINE:

Occupational therapists need to be aware of how phantom limb pain (PLP) affects a patient’s mental health and motivation to participate in activities. Through the use of interventions, a patient may decrease PLP and increase daily life occupational performance. This study is valuable because it examined one intervention (noninvasive limb cover) as a possible solution for treating chronic PLP. The findings from this study do not support the use of noninvasive limb covers as an intervention to decrease PLP, especially for individuals who have amputations as a result of diabetes and peripheral vascular disease.

RESEARCH OBJECTIVE(S)

List study objectives.

Assess the efficacy of a noninvasive limb cover for treating chronic PLP, frequency, and quality of life (QOL).

DESIGN TYPE AND LEVEL OF EVIDENCE:

1. Level I evidence--randomized controlled trial (RCT) is the strongest level of evidence in research studies. In a RCT, subjects are randomly assigned to either the intervention or control group; each group is treated equally. The purpose of using a RCT is to test if the intervention has significant results compared to the control group (or placebo group).

2. Double blind--Double-blind studies are used to protect against experimenter and placebo bias. In double-blind experiments, neither the subjects nor researchers know which group receives the intervention or placebo.

Limitations (appropriateness of study design):

Was the study design type appropriate for the knowledge level about this topic? Circle yes or no, and if no, explain.
SAMPLE SELECTION
How were subjects selected to participate? Please describe.

The subjects for this study were randomly selected from a prosthetic/amputee clinic at the VA Long Beach Healthcare System. These subjects were routinely treated at this clinic.

Inclusion Criteria
Inclusion criteria included subjects presenting with an upper- or lower-extremity amputation with a healed residual limb who experienced intermittent PLP, has had 3 or more episodes of PLP during the previous 6 weeks, and had not used Farabloc within the past 6 months. Farabloc is a patented, light-wearing cloth designed to assist with pain management and is worn over affected areas of the body.

Exclusion Criteria
Subjects were excluded from the study if they had residual limb complications, such as cellulitis and residual limb pain caused by a new bone spur within the past 12 months, had previously used Farabloc within 6 months, or were pregnant.

SAMPLE CHARACTERISTICS $N = 57$.

| % Dropouts | 10 |
| #/ (%) Male | 56 |
| #/ (%) Female | 1 |
| Ethnicity | NR |

Disease/disability diagnosis: Upper- or lower-extremity amputation

Check appropriate group:

<table>
<thead>
<tr>
<th>&lt;20/study group</th>
<th>20–50/study group</th>
<th>51–100/study group</th>
<th>101–149/study group</th>
<th>150–200/study group</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

INTERVENTION(S) AND CONTROL GROUPS
Add groups if necessary.

Group 1

Brief Description: Individuals were measured and fitted for the true Farabloc limb cover during the screening phase. Surveys were administered and data were collected 3 times: baseline, 6 weeks’ follow-up, and 12 weeks’ follow-up. Subjects were asked to indicate the point on the line that represented their pain during an episode of PLP.

Setting: NR
<table>
<thead>
<tr>
<th>Who Delivered?</th>
<th>NR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency?</td>
<td>Subjects were asked to wear the cover 24 hours/7 days a week during the duration of the study.</td>
</tr>
<tr>
<td>Duration?</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

**Group 2**

<table>
<thead>
<tr>
<th>Brief Description</th>
<th>Individuals were measured and fitted for the sham Farabloc limb cover during the screening phase. Surveys were administered and data were collected 3 times: baseline, 6 weeks’ follow-up, and 12 weeks’ follow-up. Subjects were asked to indicate the point on the line that represented their pain during an episode of PLP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>NR</td>
</tr>
<tr>
<td>Who Delivered?</td>
<td>NR</td>
</tr>
<tr>
<td>Frequency?</td>
<td>Subjects were asked to wear the cover 24 hours/7 days a week during the duration of the study.</td>
</tr>
<tr>
<td>Duration?</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

**Intervention Biases:** *Circle yes or no and explain, if needed.*

<table>
<thead>
<tr>
<th>Contamination</th>
<th>YES/NO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NR</td>
</tr>
<tr>
<td>Co-intervention</td>
<td>YES/NO</td>
</tr>
<tr>
<td></td>
<td>NR</td>
</tr>
<tr>
<td>Timing</td>
<td>YES/NO</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Site</td>
<td>YES/NO</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

**Use of different therapists to provide intervention**

<table>
<thead>
<tr>
<th>YES/NO</th>
<th>No</th>
</tr>
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</table>

**MEASURES AND OUTCOMES**

Complete for each relevant measure when answering the evidence-based question:

Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article--yes/no/NR [not reported]), and how frequently the measure was used.

**NPRS:** Overall bodily pain was measured using a numerical pain rating scale (NPRS). This scale consists of a 10-cm line with numbers ranging from 0 (*no pain*) to 10 (*worst pain possible*). Subjects were asked to indicate the point on the line that represented their pain during an episode of PLP. Reliability and validity were not reported. Measurements were taken 3
different times: baseline, 6-weeks’ follow-up, and 12-weeks’ follow-up. PLP was measured by frequency per week and per month.

Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article--yes/no/NR [not reported]), and how frequently the measure was used.

The Veteran RAND 12-Item Health Survey (VR–12) measures general health-related QOL. This measure was used 3 times: baseline, 6-weeks’ follow-up, and 12-weeks’ follow-up. Reliability and validity were not reported.

Measurement Biases
Were the evaluators blind to treatment status? Circle yes or no, and if no, explain.

**YES/NO**
Both participants and researchers were blind to the assignment of interventions.

Recall or memory bias. Circle yes or no, and if yes, explain.

**YES/NO**
A numerical pain rating scale was used. Subjects were to self-report and indicate the point on the line that represented their pain. Therefore, it is possible that they may have recalled the past scores.

Others (list and explain):

The effect of the true Farabloc group may have been biased due to the investigators choosing not to use intent-to-treat analysis, which is used to analyze participants in the group to which they were randomly assigned. It avoids the effects of dropout rates and group crossover effects. Not using this analysis may indicate a potential bias due to researchers not adhering or addressing randomization protocol.

RESULTS
List results of outcomes relevant to answering the focused question.

Include statistical significance where appropriate ($p < 0.05$).
Include effect size if reported.

No statistical significance found between the true and sham Farabloc.
At the baseline measurement, the true and sham Farabloc groups had similar levels of PLP and overall body pain.
At the 6-week measurement, the sham Farabloc group had lower PLP levels than did the true Farabloc group. However, at the 12-week measurement, the true Farabloc group had lower levels of PLP than did the sham Farabloc group.

Effect size NR.

Was this study adequately powered (large enough to show a difference)? Circle yes or no, and if no, explain.

**YES/NO**
It was reported that with an $n$ at least equal to 30 in each group ($N = 60$), there would be at least an 80% power to detect a difference between the two groups, with a 2-sided $\alpha$ equal to .05.
Were appropriate analytic methods used? *Circle yes or no, and if no, explain.*

**YES/NO**

Investigators chose not to use an intent-to-treat analysis, which may have caused the effect of the true Farabloc group to be biased.

Were statistics appropriately reported (in written or table format)? *Circle yes or no, and if no, explain.*

**YES/NO**

**CONCLUSIONS**

State the authors’ conclusions that are applicable to answering the evidence-based question.

The true Farabloc and sham Farabloc did not significantly decrease PLP levels, overall pain levels, and the frequency of PLP episodes per week. Farabloc does not appear to be an efficacious, adjunctive therapy for chronic PLP in amputees whose main cause of amputation is diabetes or peripheral vascular disease. To appropriately address whether Farabloc is efficacious in treating chronic PLP caused by trauma, a new study needs to be conducted focusing on the amputee population with trauma as the cause of amputation.

This work is based on the evidence-based literature review completed by Erin M. Livingston, OTS, and Rochelle Mendonca, PhD, OTR/L, Faculty Advisor, University of the Sciences.


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