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Calf Muscle Pump Stimulation as a Means to Reduce Symptoms of Fibromyalgia Syndrome

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Abstract

Fibromyalgia (FM) is a debilitating chronic condition that often affects women in midlife with widespread pain that interrupts attempts to exercise. The purpose of this pilot study was to test the efficacy of calf muscle pump (CMP) stimulation as an adjuvant therapy for FM by (1) assessing the correlation of the level of symptoms, as measured by the revised Fibromyalgia Impact Questionnaire (FIQR), and blood pressure (BP), (2) measuring change in mean FIQR scores for subjects who use a CMP-stimulation device for 12 weeks, and (3) measuring the correlation of total device usage and the level of symptoms as measured by the FIQR. The 29 male and female participants (mean age = 47.3 years) were screened using the Widespread Pain Index (WPI), Symptom Severity (SS) score, and the FIQR. Participants were contacted weekly, and progress was assessed using the WPI, SS score, and the FIQR as well as general questions regarding responses to CMP stimulation. The attrition rate was high, which is not uncommon in studies of patients with FM. We found that diastolic BP was significantly inversely correlated with baseline FIQR scores during quiet sitting. Further, 12 weeks of CMP stimulation was associated with significant improvement in average FIQR scores at a rate of approximately −1.5 points per week ($R^2 = .9$; $p \leq .0001$). Total device usage was strongly and inversely correlated with baseline FIQR scores ($R^2 = .43$; $p = .02$). These findings suggest that CMP stimulation may provide an additional treatment option for individuals with FM who are challenged to perform traditional forms of exercise.

Keywords

fibromyalgia, hypotension, soleus muscle, vibration

Fibromyalgia (FM) is a debilitating chronic condition with a prevalence of 2–4% in adults, affecting up to 10 million adults in the United States alone. Of those afflicted, 75% are women who are diagnosed between the age of 20 and 50 years (National Fibromyalgia and Chronic Pain Association [NFMCPA], 2013). Individuals with FM typically experience widespread and exaggerated pain as well as cognitive difficulties, sleep disturbances, fatigue, headaches, dizziness, depression, and impaired coordination. These individuals often report comorbidities such as irritable bowel syndrome, interstitial cystitis, migraines, and restless leg syndrome (NFMCPA, 2013). The direct and indirect costs associated with FM are considerable, with an average annual direct medical cost per FM patient of US$3,500 (Sanchez et al., 2011). Moreover, working adults with FM had an average of 17 days of missed work per year, as compared to 6 days for individuals without FM (Kleinman et al., 2009). Because there is no agreement on the underlying mechanism of FM and no specific diagnostic test, diagnosis and treatment can be challenging. In 2010, the American College of Rheumatology (ACR) proposed the use of the Widespread Pain Index (WPI) and the Symptom Severity (SS) scale when making the preliminary diagnosis (Wolfe et al., 2010). In addition, the Revised Fibromyalgia Impact Questionnaire (FIQR) is useful in assessing the functional impact and severity of symptoms of FM (Bennett et al., 2009).

Management of FM usually involves a multifaceted treatment plan incorporating nonpharmacologic strategies such as exercise. A recent meta-analysis showed that exercise should be included as a critical component of a comprehensive treatment plan (Mist, Firestone, & Jones, 2013). While the exact mechanism whereby exercise improves FM symptoms remains unclear, well-controlled studies have confirmed its efficacy

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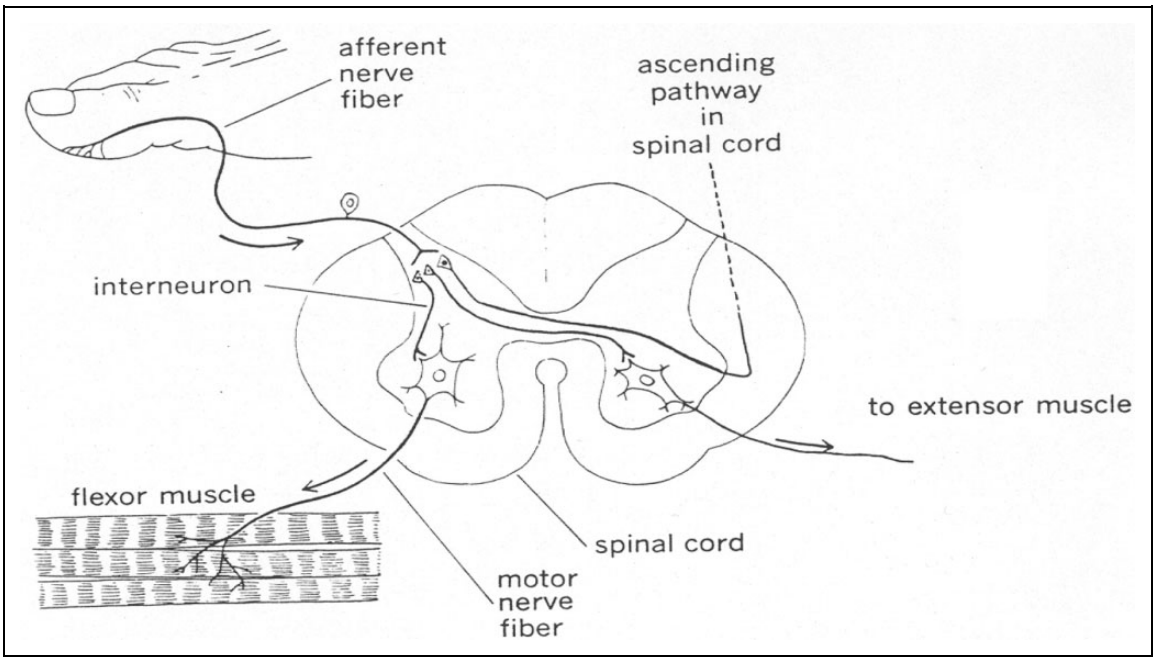

Figure 1. Calf muscle pump (CMP) activation pathway. CMP stimulation activates the soleus muscle through a postural reflex arc originating in the Meissner corpuscles (mechanoreceptors) on the plantar surface of the foot.

(Alentorn-Geli, Padilla, Moras, Haro, & Fernandez-Sola, 2008; Arnold, 2009; Carson, Carson, Jones, & Bennett, 2010). However, individuals diagnosed with FM often have low exercise tolerance due to ongoing pain and fatigue, making exercise impractical (Arnold, 2009).

For those persons with FM and exercise intolerance, exercise can be accomplished through activation of the calf (soleus) muscle pump (CMP) via plantar stimulation (Stewart, Karman, Montgomery, & McLeod, 2005). As shown in Figure 1, plantar stimulation activates the soleus muscle through a postural reflex arc originating in the Meissner's corpuscles on the plantar surface of the foot, which serves to return both pooled venous blood and interstitial fluid to the central circulatory system (Madhavan, Stewart, & McLeod, 2005). Our research has shown that over 40% of women in the general population experience insufficient CMP activity (Goddard, Pierce, & McLeod, 2008). Because 75% of diagnosed FM patients are women, and exercise has been shown to reduce the symptoms of FM, we propose that inadequate CMP activity and the resulting fluid pooling and hypoperfusion may be playing a critical role in the development of FM symptoms. The purpose of this research was to measure (1) the correlation of the level of symptoms, as measured by the FIQR, and blood pressure (BP), (2) the change in mean FIQR scores for subjects who use a CMP-stimulation device for 12 weeks, and (3)the correlation of total device usage and the level of symptoms as measured by the FIQR.

Method

The Institutional Review Boards at Binghamton University and Our Lady of Lourdes Hospital in Binghamton, NY, approved the study protocol. We performed the intake assessment in the Clinical Science and Engineering Research Center (CSERC) at Binghamton University from November 2011 through September 2012.

Participants

One (E.H.) of the investigators invited potential subjects to participate based on a chart review at his medical practice following office appointments. Subjects came to the CSERC where E.H. performed a thorough assessment of the symptoms and impact of FM including the tender-point exam and also collected demographic information. The diagnosis of FM was in accordance with the ACR criteria (Wolfe et al., 2010) as follows: (1) WPI score $\geq$ 7 and total SS score $\geq$ 5 or a WPI score between 3 and 6 and a total SS score $\geq$ 9, (2) symptoms present at a similar level for at least 3 months, and (3) no evidence of a disorder that would otherwise explain the pain. Patients eligible for inclusion were men or nonpregnant women, aged 21–70 years, diagnosed with FM. Additional inclusion criteria included the ability to use the CMP-stimulation device on a daily basis for 30 min/day for 5 days of the week and a willingness to complete a weekly telephone survey expected to take approximately 30 min. Exclusion criteria included a previous diagnosis of hypertension or evidence of hypertension, a history of deep vein thrombosis or ongoing treatment for a venous condition, or a demonstrated rise in systolic BP (SBP) to greater than 140 mmHg or a rise in diastolic BP (DBP) to greater than 90 mmHg during 20 min of CMP stimulation. This exclusion criterion is based on the concern that CMP stimulation may elevate the BP to a hypertensive range.

Protocol

Participants were seated upright in an armchair with their feet placed on the CMP-stimulation device (inactivated) and their beat-to-beat BP was monitored (Porta-Pres; FinaPres Medical Systems BV, Amsterdam, NLD) during 20 min of quiet sitting. The CMP-stimulation device (45 Hz at 50 μm; Juvent, Inc., Somerset, NJ) was then activated and beat-to-beat BP monitoring continued for an additional 20 min. SBP, DBP, and heart rate were recorded (Biopac Model MP35, Biopac Systems, Inc., Galeta, CA). The CMP-stimulation device was installed in the participant's home or workplace for daily use over a 12-week period with instructions on safe use. We suggested using a "ramp-up" schedule of 5–10 min/day with a gradual increase to 1 hr/day to prevent undue muscle tenderness. The CMP-stimulation devices had an internal monitor that recorded the day, time, and duration of device use.

The impact of FM on participants was measured using the FIQR (Bennett et al., 2009), which contains three subscales measuring functional impact, overall impact, and intensity of symptoms. The maximum score for the FIQR is 100; scores between 79 and 100 are considered extreme, between 65 and 79 are considered severe, between 50 and 65 are considered moderate, between 15 and 50 are considered mild, and between 10 and 15 are considered normal. The FIQR was found to be well correlated with the original FIQ ($r = .88$, $p < .001$) and showed good correlation with related domains in the Short Form-36 Health Survey ($r = .45$–$.80$). In addition, the discriminate validity was ascertained by comparing total FIQR scores $\pm SD$ in FM patients (56.6 $\pm$ 19.9) with subjects with rheumatoid arthritis/systemic lupus erythematosus (28.6 $\pm$ 21.1), major depressive disorders (17.3 $\pm$ 11.8), and healthy controls (12.1 $\pm$ 11.6; Bennett et al., 2009).

Scores from the WPI and the total SS scale from the ACR guidelines (Wolfe et al., 2010) and from the FIQR (Bennett et al., 2009) were initially gathered during screening and then weekly by phone call follow-up, with the phone call follow-up surveys all being administered by the same team member (L.M.B.). During these calls, the team member also asked general questions about their responses to CMP stimulation. Following 12 weeks of intervention, the subjects returned to the CSERC to return the device and for repeat testing. Final assessments of FM indicators, including the WPI, total SS score, and FIQR, were obtained and the device usage compliance data were downloaded and tabulated.

Data Analysis

Descriptive statistics were computed and *t*-tests performed using Origin 8.6 (OriginLab Corp, Northampton, MA). The association between DBP and baseline FIQR was obtained using univariate linear regression. The lowest sustained (minimum of 1 min) BP (mmHg) values recorded during 20 min of quiet sitting were used for analysis. In addition, FIQR scores obtained through weekly telephone interviews were averaged for participants who completed the 12-week trial. The time-dependent effect and total device usage were plotted against FIQR scores and analyzed using univariate linear regression.

Table 1. Characteristics of Participants at Baseline.

Characteristic	All participants ($N = 23$)	Participants completing the protocol ($n = 10$)	p
Age, years	47.3 $\pm$ 2.0	48.5 $\pm$ 2.8	.72
Percentage of women (%)	91.3	90	n/a
Height (m)	1.6 $\pm$ 0.5	1.6 $\pm$ 0.8	.90
Weight (kg)	77.3 $\pm$ 8.4	75.7 $\pm$ 8.7	.79
Body mass index (kg/m^2)	28.6 $\pm$ 1.3	28.1 $\pm$ 1.6	.86
Systolic blood pressure	102.4 $\pm$ 3.1	105.0 $\pm$ 2.7	.61
Diastolic blood pressure	58.0 $\pm$ 3.2	61.0 $\pm$ 3.9	.59
Tender-point exam score	12.3 $\pm$ 0.7	12.4 $\pm$ 1.2	.92
Widespread Pain Index score	11.9 $\pm$ 0.7	11.7 $\pm$ 0.9	.85
Symptom Severity total score	8.1 $\pm$ 0.5	7.8 $\pm$ 0.6	.69
FIQR score (initial)	52.8 $\pm$ 4.5	53.5 $\pm$ 7.6	.94

Note. FIQR = Fibromyalgia Impact Questionnaire Revised. Values are expressed as mean $\pm$ standard error, unless otherwise indicated. p values are the results of Student's *t*-test.

Results

We screened 29 patients for inclusion into the study. During lab screening, we excluded 6 (5 due to SBP > 140 and 1 due to pregnancy concerns), so that a total 23 individuals, 21 women and 2 men, all White, with a mean age of 47.3 years ($\pm$ 2.0), started the study protocol (Table 1). All participants were on average overweight, with a mean body mass index (BMI) of 28.6 kg/m^2 and 9 in the obese (BMI > 30 kg/m^2) category. In addition, all participants were, on average, hypotensive, with an initial DBP of 58.0 ($\pm$ 3.2) mmHg. The mean baseline FIQR score was 52.82 ($\pm$4.46), which is in the moderate range (Bennett et al., 2009). The mean WPI score for all participants (possible range 0–19) was 11.91 ($\pm$ 0.65), the mean total SS score (possible range 0–12) was 8.14 ($\pm$ 0.48); and the tender-point exam (possible range 0–18) resulted in a mean score of 12.26 ($\pm$0.69).

After starting the intervention phase of the study, 13 participants dropped out due to the following reasons: 6 experienced increased pain after device usage, 4 claimed insufficient time, and 3 experienced unrelated health issues. The remaining 10 participants, 9 females and 1 male, completed 3 months of CMP stimulation. We observed no significant differences between the baseline demographic data of all participants and those of the subgroup of participants who completed the study (Table 1). While six participants dropped out due to increased pain, the remaining participants reported no other adverse effects during the intervention period. In response to general

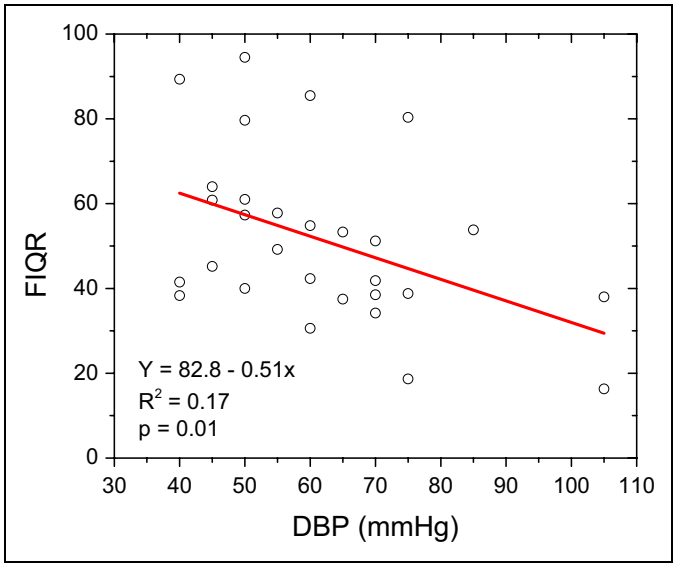

Figure 2. Relationship between diastolic blood pressure (DBP) and baseline Fibromyalgia Impact Questionnaire Revised (FIQR) score. Linear regression analysis on baseline FIQR scores for the starting group ($N = 23$) indicated a significant negative correlation with DBP (lowest value sustained for 1 min or more during 20 min of quiet sitting).

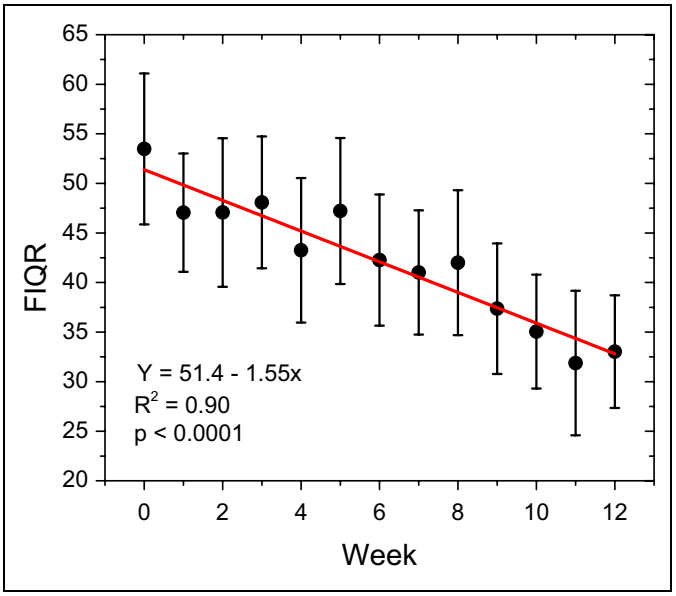

Figure 3. Effect of 12 weeks of plantar stimulation on Fibromyalgia Impact Questionnaire Revised (FIQR) scores for the 10 participants who completed the protocol. Calf muscle pump (CMP) stimulation was associated with a significant change in average weekly FIQR scores at a rate of approximately −1.5 points/week, resulting in the average FIQR score decreasing from 53 to 33.

questions regarding CMP stimulation, all 10 participants who completed the protocol reported that utilization of the device was a positive addition to their daily lives.

Linear regression analysis performed on baseline FIQR scores for all participants ($N = 23$) indicated a significant ($R^2 = .17$; $p = .01$) negative correlation with DBP (lowest value sustained for 1 min or more during 20 min of quiet sitting; see Figure 2). Baseline FIQR scores were not correlated with SBP. Daily use of CMP stimulation over 12 weeks was associated with a significant change in mean FIQR scores at a rate of approximately −1.5 points/week ($R^2 = .9$; $p < .0001$). At this rate, the mean FIQR score for the 10 participants who completed the protocol decreased from 53 to 33, representing a 33% improvement in symptoms, or a decrease from the moderate to the mild range (Bennett et al., 2009; see Figure 3). Usage data downloaded from the devices demonstrated that compliance varied from an average daily use of approximately 5 min to 2.5 hr. Total device usage (minutes) rate was found to be strongly and inversely correlated to the average 12-week FIQR scores ($R^2 = .43$; $p = 0.02$; see Figure 4). Individuals who were more severely affected by FM, as indicated by a higher FIQR score, on average used the device less throughout the intervention period.

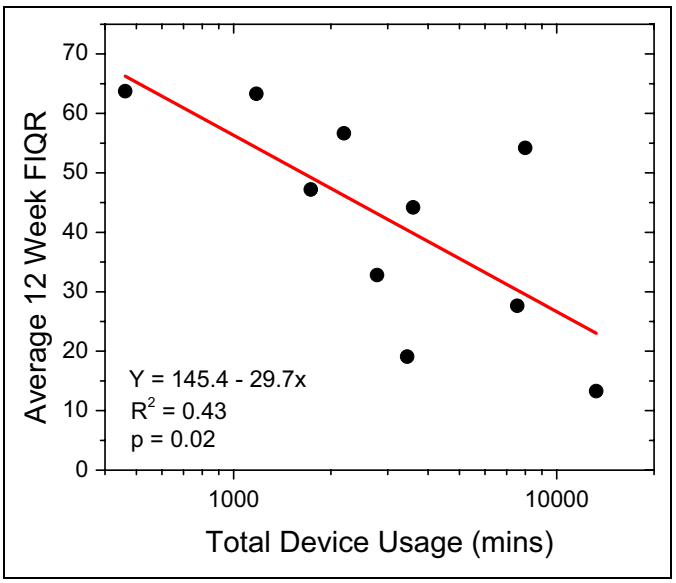

Figure 4. Relationship between total device usage of calf muscle pump (CMP)-stimulation device and average Fibromyalgia Impact Questionnaire Revised (FIQR) score over the 12-week study period. Total device usage was strongly and inversely correlated with the 12-week average FIQR scores.

Discussion

We found that DBP was significantly inversely correlated with baseline FIQR scores during quiet sitting. Daily usage of CMP stimulation over a 12-week period was associated with a significant decrease in FIQR score. Finally, total device usage was inversely correlated with mean FIQR score over the 12-week study period.

We believe that the negative correlation between DBP and the baseline FIQR score is an important finding. If cardiac output is consistently low, there is a decrease in perfusion to all tissues, but in particular to the brain, which can put an individual at risk for the type of cognitive symptoms that are often

exhibited in the FM population. This association, therefore, may help to explain the commonalities between symptoms of FM and those of hypotension such as syncope, dizziness, headaches, fatigue, chronic pain, depression, and anxiety (Hagen, Zwart, Holmen, & Svebak, 2005; Hildrum et al., 2007; Ng, Feng, Niti, & Yap, 2010). Interstitial fluid pooling into the lower limbs commonly results in venoconstriction, reduced venous return, reduced cardiac output, and, correspondingly, reduced tissue perfusion. CMP stimulation was likely useful in increasing DBP and, resultantly, in decreasing FIQR scores.

Compliance results showed that the individuals who were more severely affected by FM used the device less during the intervention period. One possible explanation is that the individuals who experience more severe symptoms are more sensitive to external stimuli, such as vibration through the plantar surface, and are thus reluctant to use the CMP-stimulation device due to concern about symptom exacerbation. We set the device to operate at 50 μ of displacement, an intensity sufficiently high to ensure that the mechanoreceptors of the plantar surface would sense the stimulus independent of the participant's age. However, younger individuals are capable of detecting plantar stimulation of less than 10 μ of displacement, and so the intensity of the stimulation may well have been irritating to many of our participants. Subsequent work should provide a range of appropriate stimulus intensities.

While the observed improvements in FIQR scores are encouraging, this study did have several limitations. One was the lack of control for various confounding aspects of the study protocol that could have contributed to the positive outcomes we observed. The presence of the CMP device in the home or office could have produced a placebo-type response. In addition, the weekly phone calls may have produced a positive socialization effect that might have elicited different responses than if the participants had completed the questionnaires unassisted. Use of the FIQR as the only tool to capture potential change in symptoms is also a limitation.

Another limitation includes the small portion of the sample that completed the study, reflecting a relatively high drop-out rate (60%) in comparison to other pilot studies we have undertaken in our laboratory. High attrition rates have plagued many studies involving exercise in FM. The average attrition rate for studies involving aerobic exercise interventions in FM included in a recent Cochrane review was 27% (Busch, Barber, Overend, Peloso, & Schachter, 2007). Likewise, programs testing running, calisthenics, and fast dancing in patients with FM have reported up to 67% attrition rates (Jones & Liptan, 2009). Other factors that may have contributed to our higher attrition rates are that the subjects were not compensated, they may have viewed the weekly phone call to complete the questionnaires as a burden, and some may have found the study requirement of daily CMP stimulation to be inconvenient. It is important to note, though, that the drop-out rate we observed, while high, is not unexpected based on those reported in other studies.

In summary, exercise has been increasingly viewed as an important first-line intervention for FM. However, individuals with FM often find exercise difficult to accomplish. The results of this pilot study suggest that CMP activation via plantar micromechanical stimulation may be capable of achieving a significant reduction in FM symptoms by increasing DBP and, consequently, tissue perfusion. CMP stimulation thus has the potential to become an effective tool for health care providers to use in their repertoire of interventions aimed at improving the quality of life in persons with FM.

Authors' Note

Additional study data or information about CMP stimulation can be obtained from the corresponding author of this article.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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