Treatment of chronic back pain using indirect vibroacoustic therapy: A pilot study

Einly Lim\textsuperscript{a,}\textsuperscript{*}, Renly Lim\textsuperscript{b}, Anwar Suhaimi\textsuperscript{c}, Bee Ting Chan\textsuperscript{a} and Ahmad Khairi Abdul Wahab\textsuperscript{a}

\textsuperscript{a}Department of Biomedical Engineering, Faculty of Engineering, University Malaya, Kuala Lumpur, Malaysia
\textsuperscript{b}Quality Use of Medicines and Pharmacy Research Centre, School of Pharmacy and Medical Sciences, University of South Australia, Adelaide, Australia
\textsuperscript{c}Department of Rehabilitation Medicine, Faculty of Medicine, University Malaya, Kuala Lumpur, Malaysia

Abstract. Background: Low frequency sound wave stimulation therapy has become increasingly popular in the rehabilitation fields, due to its ease, less fatiguing and time efficient application.

Objective: This 12-week pilot study examines the efficacy of applying low frequency sound wave stimulation (between 16–160 Hz) through both hands and feet on relieving pain and improving functional ability in patients with chronic back pain.

Methods: Twenty-three participants with chronic shoulder (eleven participants) or low back pain (twelve participants) underwent a 12-week vibration therapy program of three sessions per week. A low frequency sound wave device comprising four piezoelectric vibration-type tactile transducers enclosed in separate 5-cm diameter circular plates, which generate sinusoidal vibratory stimuli at a frequency of 16–160 Hz, was used in this study. Primary outcome measure was pain sensation measured using the Visual Analogue Scale (P-VAS). The secondary outcome measures were pain-related disability measured using the pain disability index (PDI) and quality of life measured using the SF-12.

Results: At week 12, significant reductions in pain sensation and pain-related disability were observed, with mean reductions of 3.5 points in P-VAS and 13.5 points in the PDI scores. Sixty-five percent of the participants had a reduction of at least 3 points on the P-VAS score, while 52% participants showed a decrease of at least 10 points in the PDI score. Significant improvement was observed in the SF-12 physical composite score but not the mental composite score.

Conclusions: The preliminary findings showed that passive application of low frequency sound wave stimulation therapy through both hands and feet was effective in alleviating pain and improving functional ability in patients with chronic back pain.

Keywords: Chronic pain, rehabilitation, spinal degeneration, vibroacoustic therapy

1. Introduction

Spinal degeneration involves the loss of its normal structure and function due to age-related wear and tear associated with repeated strains, sprains and overuse of the back [1]. Spinal degeneration is the most common cause of back pain, a musculoskeletal disorder defined as pain and soreness, muscle tension, or stiffness in different regions along the spine. It is believed that the pathophysiological process of chronic back pain often starts with different forms of initial muscle damages, which cause an abnormal increase in the muscle tone, impaired circulation and pain [2]. This pain-related fear leads to decreased movement, remodeling of the connective tissue, inflammation, sensitization of the nervous system and a further reduction in the mobility [3,4]. The prevalence of chronic back pain is high and affects many adults in the productive phase of their lives, causing significant disability and loss of daily activities, with relevant social and economic costs. The common treatment options include medications, bracing, postural control, physical therapy/exercise focus-
ing on muscle strengthening and improving flexibility/range of motion [5], as well as surgery in more severe pain circumstances when patients do not respond to non-surgical measures.

Over the past few decades, vibration technology has become a popular treatment strategy in the medical, clinical, sports medicine and rehabilitation fields, due to its ease, less fatiguing and time efficient application. Several categories of vibration therapy devices are available in the market: (i) direct vibration, where vibration devices are applied locally on the affected body parts [6]; (ii) whole body vibration applied through a vibrating platform, with mechanical vibration transmitted from the feet to the rest of the body of a standing/squatting subject performing simultaneous exercises [7]; and (iii) vibroacoustic devices, which use speakers or transducers placed within mats, mattresses, chairs or tables, to apply low frequency (approximately between 20 and 135 Hz) sound wave stimulation to the subjects [8].

In terms of pain relief, vibration therapy has been shown to help decrease pain in patients with fibromyalgia [9,10], rheumatoid arthritis [11], osteoarthritis [12], low back pain [13], degenerative knee joint disease [14], postoperative gynecological pain [15] and cancer [16]. It has been postulated that vibration therapy stimulates mechanoreceptors in the subcutaneous and connective tissues surrounding visceral organs and joints [17], thereby inhibits pain transmission to the brain. In addition, vibration therapy has also been reported to improve functional ability in various cohorts, which includes an increase in mobility in elderly frail adults [18], reduced muscle tone and increased range of motion/flexibility in patients with cerebral palsy [19], osteoarthritis [20] and chronic low back pain [13]. Enhanced cell metabolism, reflex-activated vasodilation, as well as muscular contraction caused by the tonic vibration reflex mechanism [7] has been accounted for these beneficial effects.

While vibration therapy has normally been applied locally on the affected areas or through whole body vibration (using a vibrating platform or vibroacoustic equipment), passive application of low frequency sound wave stimulation on both hands and feet has been claimed to provide comparable benefits and is widely used in China. According to the principle of Reflexology, hands and feet contain a large amount of reflex points, which may alleviate pain and improve circulation of specific regions in the body when being stimulated [21]. It is believed that low frequency sound, applied through both hands and feet, could penetrate deep into tissues from the skin surface, thus causing resonance in various parts of the body [8]. This in turn leads to an increase in the blood circulation and cell metabolism [8]. Despite its beneficial claims, we are unaware of any study which has investigated the efficacy of these devices.

Therefore, the aim of this pilot study is to evaluate the efficacy of indirect (applied through both hands and feet), low frequency sound wave stimulation (scanning between 16–160 Hz) on alleviating pain and improving functional ability in patients with chronic back pain. Specifically, we have focused on patients with shoulder and low back pain, which form the two major categories of back pain.

2. Methodology
2.1. Subject recruitment

Twenty-three participants with chronic shoulder (eleven participants) or low back pain (twelve participants) were recruited from University of Malaya, Malaysia as well as from among the general population through advertisements in newspapers and websites between May and June 2017. The inclusion criteria were 25 years or older, with continuous shoulder or low back pain without any specific underlying disease for more than 6 months, and a pain score above 3 (based on the Visual Analogue Scale). Clinical examination based on symptom assessment or, if required, magnetic resonance imaging was performed by a rehabilitation specialist to differentiate between mechanical, radicular, or specific causes of back pain. Subjects who meet any of the following criteria were excluded from the study: vertebral osteoporosis, spinal tumors or metastases, recent fractures of the spinal column, acute severe infections, severe cardiac arrhythmia, progressive neurologic condition, pregnant, taking regular pain medication, any surgery for less than three weeks before the start of the trial, or have previously received any form of vibration treatment related to their back pain problem. Participants were asked not to engage in any other treatment program for their back pain throughout the study period. The research was approved by the medical ethics committee of the University Malaya Medical Centre. Written informed consent was obtained from each participant.

2.2. Vibration therapy program

A low frequency sound wave device (Sonic Oxyxygenic Device, Meriwell Sdn Bhd), which comprises four piezoelectric vibration-type tactile transducers en-
closed in separate 5-cm diameter circular plates and a control panel, was used in this study. The device transmitted sinusoidal vibratory stimuli at a frequency of 16–160 Hz (scanning of frequency within this range was done according to a fixed pattern) to the skin of both palms and feet (bottom of the midfoot region). During the treatment, participants were asked to lie in a supine position on a bed in a relaxed manner. Each participant was required to complete a 12-week vibration therapy program, which required them to attend 3 sessions of therapy per week, with a duration of 30 minutes per session. Several participants who requested to attend more sessions were allowed to come up to five sessions per week.

2.3. Outcome measures

The primary outcome was change in pain from baseline to week 12, which was assessed on a visual analogue scale (P-VAS) ranging from 0 (pain free) to 10 (maximum pain). Participants were considered treatment responders if they had an improvement of at least 3 points on the P-VAS scale [22]. At the beginning of each week, the patients were asked to rate their average pain intensity in the past one week. The secondary outcome measures were the pain-related limitation and quality of life. Pain-related limitations in everyday life were assessed using two pain disability index (PDI): the Roland-Morris Low Back Pain and Disability Questionnaire for the low back pain patients and the Shoulder Pain and Disability Index for the shoulder pain patients. Since two different questionnaires were used to measure PDI, the maximum score of each questionnaire was scaled to 100-point for standardization and to allow the PDI to be analysed together (0 indicates no pain-related limitation while 100 indicates maximum level of pain-related limitation). Quality of life was assessed using the SF-12 questionnaire which consists of the physical composite score (PCS) and the mental composite score (MCS) (0 indicates the lowest level of health while 100 indicates the highest level of health) [23].

2.4. Statistical analyses

Statistical analyses were conducted with Statistical Package for Social Sciences (SPSS v22.0, SPSS Inc., USA). Changes in P-VAS, PDI and SF-12 from baseline to week 4, 8 and 12 were evaluated with the non-parametric Friedman’s two-way analysis of variance by ranks test. This was followed by the Wilcoxon Signed-Ranks post-hoc test to compare the difference between baseline and week 4, week 8 and week 12, respectively. A priori, a p-value of < 0.05 was considered statistically significant.

3. Results

Of the 23 subjects enrolled, seventeen subjects completed the 12-week trial, while the remaining six dropped out (1 after the 6th week and 5 after the 8th week) for nonspecific reasons. Table 1 shows the baseline data of the study participants.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Baseline data of the study participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (year) ± standard deviation</td>
<td>49.7 ± 13.1</td>
</tr>
<tr>
<td>Gender</td>
<td>6 males, 17 females</td>
</tr>
<tr>
<td>Height (m) ± standard deviation</td>
<td>1.62 ± 0.09</td>
</tr>
<tr>
<td>Weight (kg) ± standard deviation</td>
<td>66.0 ± 15.0</td>
</tr>
<tr>
<td>Body Mass Index (kg/m²) ± standard deviation</td>
<td>25.2 ± 5.8</td>
</tr>
<tr>
<td>Duration of chronic pain (year) ± standard deviation</td>
<td>7.1 ± 7.9</td>
</tr>
</tbody>
</table>

Signed-Ranks post-hoc test to compare the difference between baseline and week 4, week 8 and week 12, respectively. A priori, a p-value of < 0.05 was considered statistically significant.

On average, the baseline value for P-VAS was 5.6 ± 2.1 on a 10-point scale (Table 2). The pain sensation showed a continuous improvement from baseline to week-4, week-8 and week-12, respectively (Fig. 1), with a mean reduction of 1.6, 2.5 and 3.5 points (p < 0.01). Shoulder pain patients showed a mean reduction of 2.9 ± 2.7 points in the P-VAS score from baseline (5.7 ± 2.0 points) to week-12, while lower back pain patients had a mean reduction of 3.7 ± 2.5 points in the P-VAS score (from a baseline value of 5.5 ± 2.3 points). At the end of the treatment period, the proportion of participants improving at least 3 points on the P-VAS scale was 65% (7 out of 11 for shoulder pain patients and 8 out of 12 for low back pain patients).

With regards to the PDI, there was a statistically significant decrease of 7.5-point at week-4 (p < 0.05), from a baseline mean value of 26.5 ± 23.7. The PDI continued to fall significantly at week-8 and week-12 (p < 0.01), with mean reductions of 10.3 and 13.5-point, respectively (Fig. 2). Several improvements (i.e. defined as having at least 3 points reduction in the shoulder disability scale of 0–10) were observed in the shoulder pain patients with regards to their self-assessed difficulties in performing the following activities: washing hair and back (5 out of 11 patients), putting on an undershirt/jumper/pants (4/11), placing an object on a high shelf (4/11), carrying a heavy object of 4.5 kg (4/11) as well as removing something from the back pocket (4/11). Among the low back pain pa-
Table 2

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Baseline Mean ± SD (n = 23)</th>
<th>Week 4 Mean ± SD (n = 23)</th>
<th>Week 8 Mean ± SD (n = 22)</th>
<th>Week 12, Mean ± SD (n = 17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain (Visual Analogue Scale, 0–10)</td>
<td>5.6 ± 2.1</td>
<td>4.0 ± 2.3 (p = 0.004*)</td>
<td>3.1 ± 2.3 (p = 0.001*)</td>
<td>2.1 ± 1.6 (p = 0.001*)</td>
</tr>
<tr>
<td>Physical function (Pain Disability Index, 0–100)</td>
<td>26.5 ± 23.7</td>
<td>19.0 ± 18.4 (p = 0.042*)</td>
<td>16.2 ± 18.1 (p = 0.008*)</td>
<td>13.0 ± 14.3 (p = 0.008*)</td>
</tr>
<tr>
<td>Quality of Life (SF-12 Physical Component Score, 0–100)</td>
<td>38.9 ± 8.7</td>
<td>42.0 ± 8.9 (p = 0.036*)</td>
<td>41.7 ± 9.5 (p = 0.072)</td>
<td>42.9 ± 7.3 (p = 0.009*)</td>
</tr>
<tr>
<td>Quality of Life (SF-12 Mental Component Score, 0–100)</td>
<td>53.0 ± 9.5</td>
<td>54.7 ± 6.7 (p = 0.236)</td>
<td>54.9 ± 9.4 (p = 0.123)</td>
<td>55.2 ± 8.3 (p = 0.381)</td>
</tr>
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</table>

*Statistically significant difference (p < 0.05): baseline to week-4, week-8 and week-12.

Fig. 1. Pain sensation as measured by the Visual Analogue Scale at baseline, week-4, week-8 and week-12 (P-VAS: visual analogue scale for pain).

Fig. 2. Pain-related disability as measured by the pain disability index at baseline, week-4, week-8 and week-12 (PDI: pain disability index).

While vibroacoustic therapy has commonly been applied locally on the affected regions or through whole body vibration (with vibration transducers placed in a mat/chair), this is the first study to investigate the efficacy of applying low frequency sound wave stimulation on patients with chronic back pain through both hands and feet. Treatment of diseases or symptoms through the hands and feet (e.g. by applying pressure) has its root from Reflexology, which suggested that each of the organ, structure and gland in the body has its corresponding reflex point on the hands and feet [21]. To date, reflexology is a well established form of complementary medicine, and has been shown to reduce blood pressure/heart rate, vary autonomic nervous modulation [24] and induce relaxation [25] in different cohort studies.

Our 12-week pilot study showed that the device was effective in relieving back pain in two-thirds of the participants (Table 2 and Fig. 1). Even though the vibratory stimulus was not applied in close proximity to the painful regions, our preliminary results were compa-
rable to that reported by Lundenberg et al. on chronic pain patients, which found a reduction of pain in 69% of patients when applied on the best pain reducing site [6]. In that study, they found that the area of pain, the affected muscle or tendon, the antagonistic muscle and a trigger point outside the painful area were the best pain reducing site. Among other sites which were tested in their experiments included regions along the spine, humerus and tibia.

Our results may be explained by the presence of a large amount of cutaneous mechanoreceptors on both hands and feet [17], which acted to inhibit the nerve fibers from transmitting pain signal to the brain when being stimulated by the vibration signal. The frequency range of the device used in our study was between 16–160 Hz, which is within the range of the best pain reducing frequencies found in Lundenberg et al.’s study on chronic pain patients (i.e. 50–200 Hz) [6]. A significant reduction in pain sensation has also been observed in chronic lower back pain patients in another study after undergoing whole body vibration exercise on a vibration platform [13]. In comparison to whole body vibration exercises, the current therapy program has the advantage of allowing patients to adopt a relaxed lying position during the treatment session instead of standing on a vibration platform. Consequently, this therapy program can be used by and would appeal to patients with limited stability and mobility, who would not normally be able to undergo whole body vibration exercises.

In addition to pain sensation, patients with chronic back pain have often complained of increased tissue stiffness, reduced range of motion, flexibility, force production and mobility [2,3]. Based on our preliminary results, a reduction in pain-related disability was observed in more than half of the participants (Table 2 and Fig. 2). Specifically, notable improvements were observed in the shoulder pain patients with regards to their range of motion (e.g. able to reach the back) and muscle strength (e.g. able to carry heavy objects). Meanwhile, our low back pain patients reported a reduction in muscle tension which enabled them to sit/ work for longer hours, as well as quicker pain recovery after exercise or repetitive work (e.g. lab work). Similar improvements with regards to an increased range of motion and reduced muscle tension have been observed in cerebral palsy patients who underwent pulsed 44 Hz vibroacoustic therapy [19]. In addition, both local and whole body vibration have been reported to be beneficial in the management of delayed onset muscle soreness, which involves strength losses, pain, stiffness, reduced range of motion, flexibility and mobility after unaccustomed or strenuous exercise [26].

The beneficial effects demonstrated by our treatment program with regards to functional ability could be explained by the tonic vibration reflex mechanism [7], where mechanical stimuli caused by vibration is transferred from the muscle spindles to the central nervous system, causing reflex peripheral muscular contraction, a reaction leading to an improvement in the muscle strength and blood circulation. Further evidence of peripheral vasodilation and improved local blood circulation in subjects undergoing vibroacoustic treatment have been provided by a study conducted on frail older adults [18], where an increase in average skin surface temperature and a reduction in both systolic and diastolic pressure were observed at the end of their treatment sessions. As both hands and feet are located at the furthest distance from the heart, improving local circulation in these regions through low frequency sound wave stimulation could help returning blood from the upper and lower extremities back to the heart effectively. The effect of low frequency sound wave vibration (16–160 Hz) on local microcirculation has also been demonstrated in recent studies in the field of Traditional Chinese Medicine, where researchers found that different Meridian channels reacted to different frequencies (as indicated by an increase in the local microcirculation measured by a Laser Doppler flowmetry) [27]. They hypothesized that low frequency sound wave could induce a resonance phenomenon, which improves Qi and blood circulation along the pathway of the Meridian channels, thereby enhancing cell metabolism.

Despite improvements in pain sensation and pain-related limitation, the improvement in general well being, as indicated by the physical composite score, was minimal (Fig. 2). Overall, the MCS score increased from 53 to 55.2, which indicates an overall improvement in the mental health. However, the increase was not statistically significant, and this could be due to several factors. Firstly, this study involves a small sample size, and we hypothesize that a larger sample size in our next randomized controlled trial is likely to result in significant improvement in the mental health. Secondly, patients enrolled in the present study did not suffer from any mental health problem to begin with, and therefore their improvement in pain has not led to further improvement in their mental health condition.

There are several limitations in this study. First, there was no control group in this study to isolate the psychological response to treatment which may
overestimate the effects of the vibration therapy. Second, the sample size was small. Nevertheless, this pilot study provides important preliminary data necessary to calculate sample size in future randomized controlled trial evaluating the efficacy of this new set up of equipment.

5. Conclusion

In conclusion, the passive application of low frequency sound wave stimulation therapy through both hands and feet was effective in relieving pain and improving functional ability in patients with chronic back pain. As compared to the most common commercially available vibroacoustic equipment (in the form of chairs/tables/mats/beds), the device used in this study presents a much simpler set up. A large randomized controlled trial is warranted to confirm the efficacy of this device as an alternative treatment option for patients with limited stability and mobility, such as those in the early stages of rehabilitation and older adults who are too frail to perform any form of exercises.

Acknowledgments

We thank Meriwell Sdn Bhd for providing us with the Sonic Oxygenic Device for this pilot study and the subjects for their participation.

Conflict of interest

None to report.

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