CT HEALTHCARE TRADING AS NIAGARA THERAPY

CYCLOID VIBRATION THERAPY CLINICAL EVALUATION SUMMARY

SUMMARY FOR DISTRIBUTORS

1. Contents

2. Introduction

This is the summary document of the Clinical Evaluation, QD191, Vibration Therapy, A Critical Review of the Evidence with an Emphasis on Post 2006, done by Professor Neil B Piller, Ms Rachel Dawson and Ms Emily Richardson from the Department of Surgery, School of Medicine of the Faculty of Health Sciences at Flinders University in South Australia. This summary has been prepared for Niagara Therapy distributors.

3. The Medical Devices

The Niagara Therapy devices provide a therapeutic massage using Cycloid Vibration Therapy (CVT) technology. The following claims have been demonstrated in Australia and accepted by the Therapeutic Goods Administration (TGA).

Claims demonstrated in Australia - The devices may reduce excess interstitial oedema fluid whether the cause is lymphatic or vascular; may assist in the reduction of musculoskeletal pain; may increase local area blood flow; and may assist in the treatment of wounds, cellulitis and pressure ulcers where an improvement in local circulation is a factor and may assist in joint mobilisation.

The devices are:

3.1. Niagara Therapy Hand Unit

The Hand Unit is a hand held cylindrical therapeutic massage device.

3.2. Niagara Therapy Thermo Cyclopad

The Thermo Cyclopad is a cycloid vibration therapy massage device. A heating element is also contained within the pad.

3.3. Niagara Therapy Adjustable Bed

The adjustable massage bed has raise/lower functions on both the head and foot areas.

3.4. Niagara Therapy Reclining Chair

There are two base models in the Cycloid Therapy Reclining Chair range. Both models incorporate massage motors, thermo heating in the back, massage motor modes, pre-set favourite positions, battery backup and automatic recline and raise.

4. Product Claims

- Reduces excess tissue fluid (swelling) associated with oedema whether the cause is vascular or lymphatic.
- May assist in the treatment of wounds where an improvement in local circulation is a factor
- May assist in the treatment of pressure ulcers and cellulitis where an improvement in local circulation is a factor
- May assist in joint mobilisation
- May assist in the reduction of musculoskeletal pain
- May increase local area blood flow

5. Evidence

The Clinical Evaluation (QD191) includes scientific papers that evaluated the use of externally applied vibration for therapeutic use. The data was compiled and ranked based on the National Health and Medical Research Council (NHMRC) guidelines as described in Appendix 1.

5.1. Lymphoedema and Oedema

Lymphoedema refers to the accumulation of protein rich fluid in the interstitium. This occurs when the flow of lymph fluid is disturbed or where the lymphatic load exceeds the transport capacity (Armer et al. 2009). Oedema refers to accumulation of protein deficient fluid in the interstitum, generally a result of increased capillary filtration or venous insufficiency (Thaler et al. 2010). Lymphoedema and oedema similarly manifests as swelling, most commonly in the periphery, however their aetiology and pathophysiology are considerably different. Both conditions have substantial negative effects on quality of life and are associated with numerous sequelae; impaired limb function, pain, skin changes, propensity to infection and disfigurement (Morgan et al. 2005).

Oedema is frequent in the elderly population with the prevalence peaking at 60% in patients over 80 years of age (Thaler et al. 2010).

Vibration therapy is proposed to stimulate lymph and blood flow when applied to the skin, significantly reducing lymphoedema and oedema by (Jahr et al. 2008). Moseley (2009) states the application of vibration therapy may be effective in reducing limb volume, improving symptoms and wellbeing in lymphoedema patients.

Five studies were found for vibration therapy as an intervention for lymphoedema/edema (Table 1). These studies included a total of 136 participants. One study was of Level II evidence (Jahr et al. 2008) and four studies were Level III-2 evidence (Moseley et al. 2009; Ohkuma 2002; Piller & Merrit 2004; Stewart et al. 2005).

Study	Level of evidence	General conclusion
Jahr et al. 2008	II	Treatment with low intensity and extremely low frequency electrostatic field therapy supplemented with MLD can significantly enhance pain alleviation and swelling reduction in patients with BCRL compared with MLD alone.
Moseley et al. 2009	III-2	Vibrational massage via a handheld unit may help women manage arm lymphoedema at home.
Ohkuma 2002	III-2	Concomitant application of magnetic fields, vibration and hyperthermia were effective in this preliminary trial and this combined modality therapy for lymphoedema treatment should be explored further.
Piller et al. 2004	III-2	CVT can significantly lower limb volume in lymphoedema and edema patients, reduce diastolic blood pressure and improve quality of life and activities of daily living.
Stewart et al. 2005	III-2	Plantar vibration serves to significantly enhance peripheral and systemic blood flow, peripheral lymphatic flow, and venous drainage.

Table 1: Vibration therapy as an intervention for lymphoedema and edema search results

The level II study, under the NHMRC guidelines (Evidence obtained from at least one properly designed Randomised Control Trial, RCT), by Jahr et al. (2008) used an RCT to investigate the effects of vibration as an adjunct to Manual Lymphatic Drainage (MLD) in 21 women with established Breast Cancer Related Lymphoedema (BCRL). Treatment with low intensity and extremely low frequency electrostatic fields supplemented with MLD was found to significantly reduce patients self-reported pain scores and to

significantly decrease limb volume after four weeks of treatment, compared to the control group who were treated with MLD alone.

Four studies were classified as Level III-2 evidence (Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies, or interrupted time series with a control group). Moseley et al. 2009; Ohkuma 2002; Piller & Merrit 2004; Stewart et al. 2005.

Moseley et al. (2009) used a non-randomised experiment to investigate the effects of using a Niagara Therapy Hand Unit on 30 established BCRL patients, in their own home. The results showed significant reductions in arm fluid volume and improvement in range of movement. Participants provided feedback regarding feeling empowered by being able to use the vibration unit in their own home.

Ohkuma (2002) used a combination of magnetic fields, vibration and hyperthermia for 3 hours per day (60 minutes for each therapy) for 20 days in 10 patients with secondary unilateral limb lymphoedema in the leg. In 6 patients, their leg became nearly the same size as that of the contralateral leg. One patient experienced no effect of the treatment. Ohkuma (2002) concluded that this combined modality therapy for lymphoedema treatment has merit and should be explored further.

Stewart et al. (2005) investigated the effect of plantar vibration at 0, 15 and 45 Hz on lymphatic and blood flow in 18 women aged between 46-63 years. It was found that at 45Hz plantar vibration could significantly enhance peripheral and systemic blood flow, peripheral lymphatic flow, and venous drainage.

Piller et al. (2004) assessed the Niagara Therapy Thermo Cyclopad on patients with chronic secondary lymphoedema (n=27), venous oedema (n=14) and no edema (n=20). Participants used the Niagara Therapy Thermo Cyclopad at home for 3 weeks. Fibrotic induration, extracellular and intracellular fluids and limb volume were assessed. Patients with lymphoedema experienced a significant reduction in lower limb volume after 3 weeks of use with the Niagara Therapy Thermo Cyclopad, with reductions of over 230 mL of oedema fluid initially being recorded culminating in a total loss of over 500 mL in the affected leg. Patients with venous oedema also experienced a significant reduction in lower limb volume after 3 weeks of Niagara Therapy Thermo Cyclopad. These mirrored those of the lymphoedema results. Patients in both the lymphoedema and venous oedema groups initially experienced an increase in limb volume (due to mild hyperaemia) with a subsequent clinically significant reduction in volume in the following weeks of treatment. Patients with lymphoedema or venous oedema had significant improvements in quality of life and activities of daily livings as assessed by the Quality of Life and Activities of Daily Living Questionnaire.

It is important to note that Jahr et al. (2008) found that 14 weeks after the vibration therapy was ceased, pain and limb volume had returned to their baseline measurements and there was no longer a difference between the intervention and control groups. This is consistent with the study by Moseley et al. (2009) who found that after a significant decrease in limb volume using a Niagara Therapy Hand Unit, after four weeks of not using the Niagara Therapy Hand Unit their affected arm had returned to its initial state of lymphoedema. This is also consistent with Piller et al. (2004). This highlights that vibration therapy may well be an effective management for lymohoedema however it may not be a permanent cure, and continued use of vibration therapy is required to maintain results.

5.1.1. Conclusion

These 5 studies which provide Level II Evidence (Jahr et al. 2008) and Level III-2 Evidence (Moseley et al. 2009; Ohkuma 2002; Piller et al. 2004; Stewart et al. 2005) support the use of vibration therapy as a non-invasive adjunctive technique that can reduce lymphoedema and edema by enhancing lymphatic and blood flow. These studies are related to the use of the Niagara Therapy Hand Unit as well as the Niagara Therapy Thermo Cyclopad. A common weakness of the studies was small sample size (it's unlikely however that there will ever be any large-scale studies in the area of large sample size due to the nature of the area and funding support

availability from Industry and associated sources), however lymphoedema and oedema were measured objectively and the results were consistent across all studies.

This highlights the need for more thorough investigation into the use of vibration therapy for these conditions however indicates that there is an established potential for this as a therapy.

The studies also illustrate that patients can self-manage chronic conditions in a home environment with minimal input from health professionals once the appropriate treatment is indicated.

5.1.2. Clinical Evaluation of Claims

5.1.2.1. Reduces excess tissue fluid (swelling) associated with oedema whether the cause is vascular or lymphatic.

Wisham et al. (1956) demonstrated increased clearance of radioactive sodium which was injected into the extracellular fluid intracutaneously. Carati, Grillet and Piller (2004) demonstrated that CVT can increase tissue fluid drainage from sub dermal tissues in a pig secondary lymphoedema model.

The impact of low frequency externally applied vibration on extracellular fluid movement is also demonstrated in studies that show that vibration reduces lymphoedema (Jahr et al. 2008; Piller et al. 2004; Stewart et al. 2005), and studies that show vibration assists in wound healing (Arashi et al. 2002; Johnson et al. 2007; Tyer and Thornally) – as enhanced extracellular fluid movement is essential for this to take place.

Leduc, Lievens, and Dewald (1981) found that CVT of a healing surgical incision in mice resulted in significantly greater regeneration of lymph vessels and veins compared to controls. Carati et al. (2004) found evidence of lymphangiogenesis and possible angiogenesis across and near wound sites in pigs massaged with cycloid vibration.

5.2. Circulation

Poor circulation can be associated with poorer health and slower wound healing. Enhanced blood circulation results in increased delivery of oxygen and nutrients to the tissues as well as faster removal of waste products. As discussed previously, enhancing the lymphatic circulation also has a significant benefit for individuals with lymphoedema. The use of vibration to enhance circulation is very useful, as is a CVT device that the patient can use in their own home at their own convenience.

Study Results	Level of evidence	General conclusion
Button et al. (2007)	III-1	Vibration at 65Hz elicited an increase in peripheral blood flow approximately 14% higher than placebo
Kaplan et al. (2002)	III-2	Mild electrical stimulation can significantly increase venous flow
Kerschan-Schindi et al. (2001)	III-2	Low frequency vibration increases muscular and arterial blood flow.
Lohman III et al. (2006)	II	Short duration vibration alone significantly increases skin blood flow
Maloney-Hinds et al. (2008)	III-1	Five minutes of 30 Hz or 50 Hz vibration produced significant increases in skin blood flow
Ryan et al. (2001)	III-2	Vibration applied to the skin increases blood flow and water content of the dermis and epidermis

Table 2: Circulation search results

Six studies were found that pertain to the use of vibration therapy to enhance circulation. One study was Level II evidence (Lohman III et al. 2006), two studies were Level III-1 evidence (Button et al. 2007; Maloney-Hinds et al. 2008) and three studies were Level III-2 evidence (Kaplan et al. 2002; Kerschan-Schindi et al. 2001; Ryan et al. 2001).

Lohman III et al. (2006) found that a short duration of vibration could significantly increase skin blood flow when compared to the group who were administered an exercise regime.

Button et al. (2007) conducted a randomised crossover trial with 20 healthy subjects aged between 40 and 65. The results of the study showed that the group that received vibration had a 26% increase in mean blood flow, which was 12% greater than the group that did not received vibration.

Maloney-Hinds et al. (2008) who conducted 2 randomised experiments in which subjects were randomly allocated to receive either 30 Hz or 50 Hz vibration. The results showed that vibration significantly increased skin blood flow within the first minutes of vibration. No differences between the vibration frequencies administered were found.

In a comparative study Kerschan-Schindi et al. (2001) investigated the effects of low frequency (26Hz) mechanical vibration in 20 healthy subjects. The results showed vibration to significantly increase muscular blood flow, and popliteal artery blood flow.

Ryan et al. (2001) administered 16 subjects with vibration treatment on the heel at 30Hz for 10 minutes. The results showed an increase in blood flow following the vibration as well as an increase of water content of the upper dermis and epidermis.

Kaplan et al. (2002) used mild electrical stimulation of the calf and sole of the feet in 49 healthy subjects aged 51-76. The results showed a significant increase in blood flow velocity in the popliteal and femoral venous blood flow. The authors concluded that mild electrical stimulation could significantly increase venous blood flow.

5.2.1. Conclusion

These studies have shown that externally applied vibration at a low frequency increases venous blood flow, arterial blood flow, and the movement of interstitial fluid. The outcome measures for all studies critiqued were reliable and valid. Although these studies were small they were well designed and provide evidence to support the use of vibration therapy for this purpose. Individuals who wish to improve their circulation could therefore do so in their own home using any of the Niagara Therapy devices. Vibration has enhanced circulation in younger and older participant groups following a short time-period of vibration, ranging from 9 to 60 minutes. The effects of vibration were almost immediately measurable.

5.2.2. Clinical Evaluation of Claims

5.2.2.1. Increases local area blood flow

Studies have shown that externally applied vibration increases local area blood flow. Both venous and arterial blood flow have shown to be increased. Kerschan-Schindi et al. (2001) observed the arterial and muscular blood flow in 20 healthy subjects. The results showed vibration to significantly increase muscular blood flow, and popliteal artery blood flow.

The results of Kaplan et al. (2002) study showed a significant increase in blood flow velocity in the popliteal and femoral venous blood flow.

Maloney-Hinds et al. (2008) study showed vibration produced significant increases in skin blood flow within the first four minutes of vibration. The study found no difference in superiority between the 2 frequencies of vibration administered.

Button et al. (2007) study showed that the group that received vibration had a 26% increase in mean blood flow, which was 12% greater than the group that did not received vibration.

The results on Ryan et al. (2001) study showed an increase in blood flow following vibration therapy.

5.3. Wound Healing, Pressure Ulcers and Cellulitis

Wound healing refers to the body's physiological mechanism to repair damaged tissue. The body's physiological mechanism for wound repair requires additional support for adequate healing when the wound is severe or complicating factors are present (Hunt, 1988). Failure of appropriate therapy and local biochemical events at the site of damaged tissue can lead to poor wound healing, which leaves patients notoriously susceptible to infection (Hunt, 1988).

A pressure ulcer is a localized injury to the skin or underlying tissue, generally resulting from constant pressure on a prominence which obstructs capillary blood flow eventually leading to tissue necrosis. Pressure ulcers represent chronic wounds with impaired healing (Brem et al. 2010). A common problem in the health care setting, pressure ulcers have become an epidemic among bed-bound populations with prevalence as high as 43% in nursing homes (Brem et al. 2010). Brem (2010) highlights that significant costs and morbidities are associated with pressure ulcers, whilst Lyder (2003) states pressure ulcers are associated with increased mortality rates in the elderly.

Cellulitis is defined as inflammation of the skin and subcutaneous tissue, usually due to a Streptococcal infection. Cellulitis is characterized by painful swelling, oedema, erythema, fever and malaise of the affected area (Cox et al. 1998). Progression of this infection and inappropriate treatment can lead to blistering and ulceration requiring hospitalization (Cox, 2002). In 40-60% of cases, patients receiving inadequate or inappropriate initial treatment will have a re-occurrence of cellulitis (Goettsch et al. 2006).

These three conditions can significantly impact quality of life in individuals and compromise the recovery of patients with co-existing health problems. Poor wound healing, pressure ulcers and cellulitis are a burden to the health care system, costing a significant amount in hospital admissions annually and prolonging patient bed days in an already overwhelmed health care system (Brem et al. 2010).

Wound healing refers to the body's physiological mechanism to repair damaged tissue. A pressure ulcer is a localized injury to the skin or underlying tissue, generally resulting from constant pressure on a prominence which obstructs capillary blood flow eventually leading to tissue necrosis. Cellulitis is defined as inflammation of the skin and subcutaneous tissue, usually due to a Streptococcal infection. Cellulitis is characterized by painful swelling, oedema, erythema, fever and malaise of the affected area (Cox et al. 1998).

Vibration therapy has been proposed to improve the recovery of the aforementioned conditions by enhancing the microcirculation in the affected area (Johnson et al. 2007). Enhanced microcirculation results in increased delivery of oxygen and nutrients to the area, which promotes healing and cellular repair (Hunt, 1988). In addition, increased blood and lymphatic flow will aid removal of cellular debris and waste products away from the affected area.

Five studies were identified which included a total of 120 participants. One study was Level II evidence (Johnson et al. 2007), one study was Level III-1 Evidence (Arashi et al. 2010; Tyer & Thornalley 2008), one study was level III-2 evidence (Stewart et al. 2005) and one study was level III-3 Evidence (Wilson et al. 2002).

Study	Level of evidence	General conclusion
Johnson et al. 2007	II	CVT combined with standard therapy can significantly reduce cellulitis treatment time when compared to standard therapy alone
Arashi et al. 2010	III-1	Vibration may improve stage 1 pressure ulcer healing in older adult patients
Stewart et al. 2005	III-2	Plantar vibration serves to significantly enhance peripheral and systemic blood flow, peripheral lymphatic flow, and venous drainage.
Tyrer & Thornalley (2008)	III-2	Vibration therapy in conjunction with antibiotics resulted in successful recovery of patients with cellulitis that previously required hospital admission for treatment
Wilson et al. 2002	III-3	Gentle CVT combined with standard compression bandaging, enhances the healing rate of venous ulcers and helps to relieve pain

Table 3: Wound and pressure ulcer healing and cellulitis search results

In a thoroughly designed RCT, Johnson et al. (2007), found that CVT for 30 minutes 3 times per day combined with standard therapy (antibiotics) significantly reduced cellulitis treatment time when compared to standard therapy alone.

Arashi et al (2010) used a nonrandomized, blinded, control design to investigate the role of vibration therapy in facilitating the healing of stage 1 pressure ulcers in older adults. The study found that the number of healed ulcers was significantly higher in the group that used vibration compared to the group that didn't use vibration. The results suggest vibration therapy may improve healing of stage 1 pressure ulcers in older patients.

Tyrer and Thornalley (2008) describe the utilisation of CVT in a community medical centre for patients with cellulitis. Over a 10-month period 3 patients were seen with recurrent lower limb cellulitis. Given oral antibiotic therapy and CVT 3 times a day for 30 minutes for a mean of 10.3 days (till resolution of cellulitis), all 3 patients were successfully treated. The study also provides information on cost to the hospital of treating severe cellulitis (2185 British pound) verses treatment in a community setting using CVT (335 British pound). The community centre in the study had previously used similar techniques described above, with 14 patients presenting with cellulitis. Of those patients 13 had cellulitis resolution, while 1 required hospitalization. It should be noted that the strength of this study is low due to the small amount of patients studied, and also that there was lack of a control in terms of treating patients with oral antibiotics and no CVT.

Stewart et al. (2005) investigated the effects of plantar vibration on systemic flow. It was found that with plantar vibration (45Hz), the edema formation threshold was increased by 48%+-12. It should be noted that microcirculation filtration right shifted because of the increased edema formation threshold. The study indicates strongly that plantar vibration increases blood flow peripherally and systemically, as well as reducing edema formation. There is evidence to suggest these factors will assist in wound healing and may indeed help prevent the persistence of wounds.

Wilson et al (2002) investigated healing of venous ulcers in a study of 21 patients (mean age of 74) with a current venous ulceration lasting 1-48 months. The study was classified as a level III-3 evidence. Patients use the Niagara Therapy Thermo Cyclopad under their ulcerated leg which had a compression bandage on, sixty-two percentage of the patients completely healed venous ulcers within 4-12 weeks, with the mean area of healed ulcers being 3.6cm^2. Of the patients with incompletely healed ulcers, 3 had ulcers initially of 10cm^2, which were reduced 63-65% after 12 weeks.

The remaining 5 patients had ulcerations in the range of 2-9cm^2, with a 31-90% reduction in ulcer size at 12 weeks. The results show that vibration treatment is effective at promoting healing of venous ulcers when combined with compression bandaging. It should be noted that this study would have benefited greatly by

being run simultaneously against patients who did not receive vibration therapy and patient receiving vibration therapy, but without compression bandaging.

5.3.1. Conclusion

The evidence for use of vibration therapy in patients at a frequency of 45-50Hz is put forth by the Stewart et al (2005) study in which blood flow was found to be significantly increased both in limbs and systemically. It can be inferred from this study that increases in blood flow and microcirculation, as a result of vibration therapy, will result in reduced recovery time from wound healing, ulcers, and cellulitis by theory only. The studies of Arashi et al (2010) and Johnson et al. (2007) confirm that vibration therapy does appear to reduce recovery time in patients with ulcers and cellulitis.

Wilson et al (2002) showed that venous ulcer healing time was reduced with vibration therapy and compression bandages. The shortcomings in the significance of the results are that there is no control provided to compare those on the treatment plan to those not receiving treatment. In summary, the literature supports clinical application of vibration therapy used in conjunction with other therapies to reduce both the healing time and the progression of wounds, ulcers, and cellulitis.

5.3.2. Clinical Evaluation of Claims

5.3.2.1. Increases tissue healing rates (particularly of venous leg ulcer and cellulitis)

This claim is supported by evidence based literature. Johnson et al. (2007) CVT combined with standard therapy can significantly reduce cellulitis treatment time when compared to standard therapy alone. Arashi et al. (2010) found that vibration may improve stage 1 pressure ulcer healing in older adult patients. Stewart et al. (2005) concluded plantar vibration serves to significantly enhance peripheral and systemic blood flow, peripheral lymphatic flow, and venous drainage. Wilson et al. (2002) found gentle CVT combined with standard compression bandaging, enhances the healing rate of venous ulcers and helps to relieve pain.

These studies ranged from Level II to III-3 and although some weaknesses were found in studies, overall there is enough evidence to conclude that externally applied vibration therapy can be used to reduce healing time required for wound healing and pressure ulcers.

5.4. Osteoporosis and Joint Mobility Limitations

Osteoporosis is a systemic skeletal disease characterized by low bone mineral density and deterioration of bone tissue. This condition leads to an increase in bone fragility rendering patients more susceptible to fractures (Kanis et al. 2002). The clinical significance of osteoporosis is related to the morbidity and mortality related to fractures. Cooper (1997) found a mortality rate 20% greater than expected at 5 year's post hip and vertebral fracture in men over 75 years of age. Further the cost of caring for osteoporotic fractures is enormous and is expected to dramatically rise in the future Gabriel et al. (2002).

It has been postulated that vibration therapy can increase bone mineral density. Animal studies have provided evidence that whole body vibration has anabolic effects on the bone however the exact physiological mechanism of how this occurs is not well understood. There has also been interest in the role of vibration in improving joint mobility and flexibility and in improving arthritic symptoms.

Four studies were included that included the use of vibration therapy for improving bone mineral density or joint mobility. One was Level I evidence (Slatovska et al. 2010), 2 were Level II evidence (Atha et al. 1976; Williams et al. 1961) and 1 was Level III-1 evidence (Lievens et al. 1984).

Study	Level of evidence	General conclusion
Atha et al. 1976	II	CVT and active stretching can temporarily increase joint mobility

Slatkovska et al. 2010	I	WBV can cause significant but small improvements in BMD in postmenopausal women and children and adolescents, but not in young adults
Lievens et al. 1984	III-1	CVT may improve knee flexion and extension movements in older patients with osteoarthritis
Williams et al. 1961	II	CVT can increase trunk flexibility. There was no difference found between the various vibration modalities.

Table 5: Osteoporosis and joint mobility limitations search results

5.4.1. Conclusion

The evidence presented by Slatovksa et al. (2010) provides good evidence that whole body vibration can cause significant but small improvements in bone mineral density in postmenopausal women and children and adolescents, but not in young adults. This is could be an effective alternative to weight bearing exercise to improve and maintain bone mineral density in women at higher risk of falls or osteoporotic fracture.

The evidence relating to joint mobility is not as compelling. Atha et al. (1976) showed improvements in flexibility following vibration however it is not known if these were carry over affects from previous vibration, as all participants were allocated to each group at different stages. Lievens et al. (1984) and Williams et al. (1961) both supported the hypothesis that vibration could improve joint mobility, however considering the weaknesses of these studies it is difficult to make a conclusion. Although the evidence is not compelling it can be inferred that there is a potential for vibration therapy to improve joint mobility. It would be useful to see a more recent well designed RCT to establish the effects of vibration on joint mobility.

5.4.2. Clinical Evaluation of Claims

5.4.2.1. Improves the range of movement of knee joints and trunk and lumbar flexibility

Lievens (1984) demonstrated that knee flexion and extension movements, both active and passive, were significantly improved in patients with osteoarthritis of the knee compared to the control group that did not receive CVT.

Williams, Drury, and Bierman (1961) found that the CVT in the Niagara Therapy Thermo Cyclopad and Niagara Therapy Hand Unit significantly improved standing toe touch and sitting trunk flexibility tests after 30 minutes of vibration to the paravertebral areas of the back and the posterior aspects of the lower extremities. Atha et al. (1976) demonstrated the CVT of the Niagara Therapy Thermo Cyclopad at the thigh and lower back, while sitting, lead to a significant increase in mobility compared to controls and that this increase persists for 24 hours.

These studies indicate CVT can have a therapeutic effect on patients with poor joint mobility or lumbar flexibility. Based on the evidence available it can be concluded that this claim can be supported.

5.5. Pain

Chronic pain is a significant sequale of many health conditions. It has huge psycho-social and economic costs to society and individual. Vibration therapy has been proposed to reduce the experience of pain through the ‘gate theory’. Put simply, mechanical stimuli to the neurons which are sensing pain can cause inhibitory action on these neurons, therefore reducing the sensation of pain.

Three studies were included, 2 studies with level II evidence (Alentorn-Geli et al. 2008; Paice et al. 2000 II) and 1 study with level II-2 evidence (Lundeberg 1984).

Study	Level of evidence	General conclusion

Alentorn-Geli et al. 2008	II	A 6 week traditional exercise program with supplementary whole body vibration safely reduces pain and fatigue, whereas exercise alone fails to induce improvements
Lundeberg 1984	III-2	Vibration therapy may be a valuable measure for symptomatic treatment of chronic pain
Paice et al. 2000	II	Patients who received vibration therapy had higher pain relief scores however this was not statistically significant

Table 6: Pain search results

5.5.1. Conclusion

Alentorn-Geli et al. (2008) found that a 6-week traditional exercise program with supplementary whole body vibration safely reduces pain and fatigue while exercise alone fails to induce improvements. Lundberg (1984) found that vibratory stimulation at 100Hz in patients with symptomatic chronic pain could reduce the symptoms of pain, however it is acknowledged that in this study there is no control group. In conclusion, externally applied vibration can reduce the symptoms of pain in individuals with symptomatic chronic pain however this statement would be more compelling if there were larger well designed RCT's in this field. The results from Paice et al. (2000) also suggest a trend toward vibration therapy being an effective pain relieving modality for HIV patients with distal symmetrical polyneuropathy however these results were not statistically significant.

As discussed previously in this report, Jahr et al. (2008) found that vibration therapy significantly reduced pain as well as lymphoedema in lymphoedema patients. Johnson et al. (2007) found that vibration therapy could reduce pain in patients being treated for wound healing.

5.5.2. Clinical Evaluation of Claims

5.5.2.1. Reduces pain

Alentorn-Geli et al. (2008) found a significant reduction in pain and fatigue in the exercise and vibration group when compared to the exercise only group and control group. The authors conclude that a 6 -week traditional exercise program with supplementary whole body vibration safely reduces pain and fatigue whereas exercise alone fails to induce improvements. Lundberg (1984) found that vibratory stimulation at 100Hz in patients with symptomatic chronic pain could reduce the symptoms of pain, however it is acknowledged that in this study there is no control group. Jahr et al. (2008) found that vibration therapy significantly reduced pain as well as lymphoedema in lymphoedema patients. Johnson et al. (2007) found that vibration therapy could reduce pain in patients being treated for wound healing.

In conclusion, externally applied vibration can reduce the symptoms of pain in individuals with symptomatic chronic pain.

6. General Discussion

The literature review investigates the use of vibration therapy for the treatment and symptomatic relief of conditions such as lymphoedema, oedema, wound healing, pressure ulcers, cellulitis and musculoskeletal pain.

There is a relative deficiency of quality research into the effects of vibration therapy despite the fact that many health disciplines employ the use of vibration therapy devices. The lack of quality randomised controlled trials to determine the effect of vibration therapy does leave some questions with respect to the strength of evidence based support for the use of vibration devices.

However, evidence from critically reviewed research available demonstrates a potential for the use of this modality to manage some health conditions.

If externally applied vibration can be effectively used in some health conditions it is likely there could be a significant reduction in costs to the health care system, time away from work, work productivity as well as an improvement in the psychosocial environment of the patient.

7. CVT

CVT has been shown to be an effective therapeutic measure for a range of health conditions. CVT has been shown to improve lymphatic function, reduce pain, improve joint mobility and enhance wound healing. CVT is a non-invasive technique that patients can use in their own home at their own convenience.

The CVT devices addressed in this report are the Niagara Therapy Hand Unit, Niagara Therapy Thermo Cyclopad, Niagara Therapy Adjustable Bed and the Niagara Therapy Reclining Chair. Upon consideration of the evidence provided, any of these devices could be used for any of the conditions addressed in the claims. The advantage of having more than one method of delivering CVT is that patients can have a unique CVT treatment program that suits their specific needs. Having CVT available in their own home empowers patients by allowing them to choose when they would like to use the therapy and which delivery method is best for them.

8. Optimum Frequency, Duration and Force of Application

Many different studies have used therapeutic vibrators with mixed results. However, some results are most promising and seem to indicate that at different frequencies different results could be expected. For the purposes of moving tissue fluid, the frequency range of 40-60 Hz was most often successful. However, the quality of many studies was lacking, therefore before conducting human trials animal studies were warranted in order to establish the frequency, force, amplitude, and duration of vibration therapy treatments before testing with patients. Carati, Grillet and Piller (2004) concluded, based on their animal study of the Niagara Therapy Hand Unit, that the optimal vibration protocol is 30 minutes in duration at a low frequency (32-45 Hz) while also applying light pressure in order to reduce the risk of erythema.

9. Additional Literature Review

This section provides the conclusion of the additional literature reviews conducted:

- It has been determined that there is a low risk that a pacemaker could be negatively affected by electronic massage devices. It's recommended that Niagara Therapy devices are not directly placed over the pacemaker and 15cm should be maintained between the Niagara Therapy deice and pacemaker.
- Niagara Therapy does not demonstrate the performance of the devices in treating cancer patient's symptoms; however, it does indicate the use of massage as a widely-accepted form of symptom treatment.

10. Appendix 1

For evidence related to the use of externally applied vibration as a therapeutic use, initially only studies considered to be of NHMRC Level 1 or Level 2 evidence (Table 7) that evaluated the use of externally applied vibration for therapeutic use were considered for inclusion.

Due to the paucity of evidence available, the search was expanded to include lower levels of evidence. While important summary documents, studies reported in systematic reviews already selected for inclusion were not subjected to individual critical appraisal to prevent replication of data.

Level	Description of evidence
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly designed randomised control trial
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case series, either post-test or pre-test and post-test

Table 7. NHMRC levels of evidence for intervention studies (NHMRC 1999)

11. References

Ahmed RL, Prizment A, Lazovich D, Schmitz KH, Folsom AR (2008) Lymphoedema and quality of life in breast cancer survivors: The Iowa Women's Health Study. Journal of Clinical Oncology 26(35):5689-5696

Alentorn-Geli E, Padilla J, Moras G, Haro C, Fernandez-Sola J (2008) Six Weeks of Whole-Body Vibration Exercise Improves Pain and Fatigue in Women with Fibromyalgia. The Journal of Alternative and Complementary Medicine 14(8):975-981

Arashi M, Sugama J, Sanada H, Konya C, Okuwa M, Nakagami G, Inoue A, Tabata K (2010) Vibration Therapy Accelerates Healing of Stage I Pressure Ulcers in Older Adult Patients. Advances in Skin & Wound Care 23(7):321-327

Armer JM, Stewart BR, Shook RP (2009) 30-Month Post-Breast Cancer Lymphoedema. Journal of Lymphoedema 4(1):14-18.

Atha J, Wheatley DPE, Wheatley DW (1976) Joint mobility changes due to low frequency vibration and stretching exercise. British Journal of Sports Medicine 10(1): 26-33

Bausewein C, Booth S, Gysels M, Higginson IJ (2011) Non-pharmacological interventions for breathlessness in advanced stages of malignant and non-malignant diseases. Cochrane Database of Systematic Reviews (2) Art. No.: CD005623. DOI:10.1002/14651858.CD005623.pub2.

Brem H, Maggi J, Nierman D, Rolnitzky L, Bell D, Rennert R, Golinko M, Yan A, Lyder C, Vladeck B (2010) High Cost of Stage IV Pressure Ulcers. The American Journal of Surgery 200:473-477

Button C, Anderson N, Bradford C, Cotter JD, Ainslie PN (2007) The effect of multidirectional mechanical vibration on peripheral circulation of humans. Clin Physiol Funct Imaging. Jul(4):211-216

Cooper C (1997) The Crippling Consequences of Fractures and Their Impact on Quality of Life. The American Journal of Medicine 103(2):512-519

Cox NH (2002) Management of Lower Leg Cellulitis. Journal of the Royal College of Physicians 2(1):23-27

Cox NH, Colver GB, Paterson WD (1998) Management and Morbidity of Cellulitis of the Legs. Journal of the Royal Society of Medicine 91:634-637

Cristiano LM, Schwartzstein R (1997) Effect of chest wall vibration on dyspnea during hypercapnia and exercise in chronic obstructive pulmonary disease. American Journal of Respiratory & Critical CareMedicine 155(5):1552–9

Dawes DJ, Meterissian S, Goldberg M, Mayo N (2008) Impact of lymphoedema on arm function and health-related quality of life in women following breast cancer surgery. J Rehabil Med 40:651-658

Dice JP (2004) Physical Urticaria. Immunol Allergy Clin N Am. 24:225-246

Fujie T, Tojo N, Inase N, Nara N, Homma I, Yoshizawa Y (2002) Effect of chest wall vibration on dyspnea during exercise in chronic obstructive pulmonary disease. Respiratory Physiology & Neurobiology 130(3):305–16

Gabriel SE, Tosteson ANA, Leibson CL, Crowson CS, Pond GR, Hammond CS, Melton LJ (2002) Direct Medical Costs Attributable to Osteoporotic Fractures. Osteoporosis International 13:323-330

Gilsanz V, Wren TAL, Sanchez M, Dorey F, Judex S, Rubin C (2006) Low-level, high-frequency mechanical signals enhance musculoskeletal development of young women with low BMD. J Bone Miner Res 21:1464–1474

Goettsch WG, Bouwes Bavinck JN, Herings RMC (2006) Burden of Illness of Bacterial Cellulitis and Erysipelas of the Leg in the Netherlands. Journal of European Academy of Dermatology and Venereology 20:834– 83

Grant AC, Wang N (2004) Carotid dissection associated with a handheld electric massager. Southern Medical Journal 97(12): 1262-1263

Gusi N, Raimundo A, Leal A (2006) Low-frequency vibratory exercise reduces the risk of bone fracture more than walking: a randomized controlled trial. BMC Musculoskelet Disord 7:92

Hunt TK (1988) The Physiology of Wound Healing. Annals of Emergency Medicine 17(12):1265-1273

Iwamoto J, Takeda T, Sato Y, Uzawa M (2005) Effect of wholebody vibration exercise on lumbar bone mineral density, bone turnover, and chronic back pain in post-menopausal osteoporotic women treated with alendronate. Aging Clin Exp Res 17:157–163

Jahr S, Schoppe B, Reisshauer A (2008) Effect of treatment with low-intensity and extremely low-frequency electrostatic fields (Deep Oscillation) on breast tissue and pain in patients with secondary breast lymphoedema. J Rehabil Med 40:645-650

Johnson S, Leak K, Singh S, Tan P, Pillay W, Cuschieri RJ (2007) Can cycloidal vibration plus standard treatment reduce lower limb cellulitis treatment times? Journal of Wound Care 16(4): 166-169

Kanis JA, Black D, Cooper C, Dargent P, Dawson-Hughes B, De Laet C, Delmas P, Eisman J, Johnell O, Jonsson B, Melton L, Papapoulos S, Pols H, Rizzoli R, Silman A, Tenehouse A (2002) A New Approach to the Development of Assessment Guidelines for Osteoporosis. Osteoporosis International 13(7):527-536

Kaplan RE, Czyrny JJ, Fung TS, Unsworth JD, Hirsh J (2002) Electrical foot stimulation and implications for prevention of venous thromboembolic disease. Thromb Haemost 88(2):200-204

Kerschan-Schindi K., Grampp S., Henk C., Resch H., Preisinger E., Fialka-Moser V. and Imhof H. Whole-body vibration exercise leads to alterations in muscle blood volume. Clin Physiol. 2001 May;21(3):377-82

Lange DJ, Lechtzin N, Davey C, David W, Heiman-Patterson T, Gelinas D, et al. (2006) High-frequency chest wall oscillation in ALS. Neurology 67:991–7.

Leduc A, Lievens P, Dewald J (1981) The influence of multidirectional vibrations on wound healing and on regeneration of blood- and lymphvessels. Lymphology 14:179-185

Lievens P, Van De Voorde J (1984) The influence of cycloidal vibrations on the knee joint mobility of osteoarthritic patients. Physiotherapy 70(6): 241-243

Lohman EB. 3rd, Petrofsky JS, Maloney-HindsC, Bettas-Schwab H, Thorpe D (2007) The effect of whole-body vibration on lower extremity skin blood flow in normal subjects. Med Sci Monit. Feb;13(2):CR71-6

Lundeberg T (1984) Long-Term Results of Vibratory Stimulation as a Pain Relieving Measure for Chronic Pain. Pain 20:13-23

Lyder CH (2003) Pressure Ulcer Prevention and Management. Journal of the American Medical Association 289(2):223-226

Madhavan, G, Stewart JM, McLeod KJ (2006) Cardiovascular systemic regulation by plantar surface stimulation. Biomedical Instrumentation & Technology 40(1): 78-84

Mahamaneerat WK, Shyu CR, Stewart BR, Armer JM (2008) Breast Cancer Treatment, BMI, Post-op Swelling/Lymphoedema. Journal of Lymphoedema 1;3(2):38-44

Maloney-Hinds C, Petrofsky J, Zimmerman G (2008) The effect of 30Hz vs. 50Hz passive vibration and duration of vibration on skin blood flow in the arm. Med DSci Monit. Mar;14(3):CR112-6

McDonagh D, Wilson, L, Haslam C, Weightman D (2005) Good vibrations: do electrical therapeutic massagers work? Ergonomics 48(6): 680-691

Morgan PA, Franks PJ, Moffatt CJ (2005) Health-related Quality of Life with Lymphoedema: A Review of the Literature. International Wound Journal 2(1):47-62

Moseley A, Piller N, Heidenreich B, Douglass J (2009) Pilot study of a handheld massage unit. Journal of Lymphoedema 4(1):24-28

Nakayama H, Shibuya M, Yamada, Suzuki H, Arakawa M, Homma I (1998) In-phase chest wall vibration decreases dyspnea during arm elevation in chronic obstructive pulmonary disease patients. Internal Medicine 37:831–5

NHMRC (National Health and Medical Research Council) (1999) A guide to the development, implementation and evaluation of clinical practice guidelines. Canberra. NHMRC.

Ohkuma M (2002) Treatment of peripheral lymphoedema by concomitant magnetic fields, vibration and hyperthermia; A preliminary report. Lymphology 35(2): 87-90

Paice JA, Shott S, Oldenburg FB, Zeller J, Swanson B (2000) Efficacy of a vibratory stimulus for the relief of HIV-associated neuropathic pain. Pain 82:291-296

Piller, NB, Merritt, J and Esterman A (2004) Home use of massage pads for secondary leg lymphoedemas – What the patient can expect. Proceedings of the 19th International Congress of Lymphology Sept 2003: Lymphology (suppl) 37

Rubin C, Recker R, Cullen D, Ryaby J, McCabe J, McLeod K (2004) Prevention of postmenopausal bone loss by a lowmagnitude, high-frequency mechanical stimuli: a clinical trial assessing compliance, efficacy, and safety. J Bone Miner Res 19:343–351

Russo CR, Lauretani F, Bandinelli S, Bartali B, Cavazzini C, Guralnik JM, Ferrucci L (2003) High-frequency vibration training increases muscle power in postmenopausal women. Arch Phys Med Rehabil 84:1854–1857

Ryan T, Salter D. The effects of vibration on skin blood flow. 9th Europ. Conf.

Microcirculation, Antweerp. Bibliotheca Anatomica 1976; 16: 180-184

Ryan TJ, Thoolen M, Yang YH (2001) The effect of mechanical forces (vibration or external compression) on the dermal water content of the upper dermis and epidermis, assessed by high frequency ultrasound. Journal of Tissue Viability. 11(3)

Sibuya M, Yamada M, Kanamaru A, Tanaka K, Suzuki H, Noguchi E, et al. (1994) Effect of chest wall vibration on dyspnea in patients with chronic respiratory disease. American Journal Respiratory & Critical Care Medicine 149:1235–1240

Slatkovska L, Alibhai SMH, Beyene J, Cheung AM (2010) Effect of whole-body vibration on BMD: a systematic review and meta-analysis. Osteoporosis International 21:1969-1980

Stewart JM, Karman C, Montgomery LD, McLeod KJ (2005) Plantar vibration improves leg fluid flow in perimenopausal women. Am J Physiol Regul Integr Comp Physiol 288(3):R623-9

Thaler HW, Wirnsberger G, Pienaar S, Roller RE (2010) Bilateral Leg Edema in the Elderly: Clinical Considerations and Treatment Options. European Geriatric Medicine 1:353-355

Torvinen S, Kannus P, Sievanen H, Jarvinen TA, Pasanen M, Kontulainen S, Nenonen A, Jarvinen TL, Paakkala T, Jarvinen M, Vuori I (2003) Effect of 8-month vertical whole body vibration on bone, muscle performance, and body balance: a randomized controlled study. Journal of Bone Mineral Research 18:876–884

Tyrer A, Thornalley C (2008) Cycloidal vibration for the treatment of cellulitis in a community setting. British Journal of Nursing 17(20):S34-37

Verschueren SM, Roelants M, Delecluse C, Swinnen S, Vanderschueren D, Boonen S (2004) Effect of 6-month whole body vibration training on hip density, muscle strength, and postural control in postmenopausal women: a randomized controlled pilot study. Journal of Bone Mineral Research 19:352–359

Ward K, Alsop C, Caulton J, Rubin C, Adams J, Mughal Z (2004) Low magnitude mechanical loading is osteogenic in children with disabling conditions. Journal of Bone Mineral Research 19:360–369

Wilson JM, Arseculeratne YM, Yang Y, Cherry GW (2002) Healing venous ulcers with cycloidal multidirectional vibration therapy. Journal of Wound Care 11(10):395-398

Williams HE, Drury BJ, Bierman W (1961) The influence of cyclo massage on physical activity. Journal of the Association for Physical and Mental Rehabilitation 15(2): 41-45

Wisham LH, Shaanan A, Bierman W (1956) The influence of vibration on temperature and on the clearance of radioactive sodium in human subjects. Archives of Physical Medicine and Rehabilitation Dec 37