Safety and Efficacy of the ReBuilder Electrical System in Treating Peripheral Neuropathy

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Figures.

1. A patient's feet being treated with the split compartment electrode-containing solution
2. Electrolyte impregnated gloves (not used in this trial). Socks also available
3. Close up of the ReBuilder®. Note small size and portable nature
4. Mean pain ratings before and after using the ReBuilder®

Abstract

Context. Millions of Americans have symptoms of peripheral neuropathy(PN)including pain, numbness, burning, or absence of sensation.Standard treatment is pharmacologic. Studies of electrical stimulation demonstrate equivocal results.

Objectives. To evaluated the safety and efficacy of the the ReBuilder® electrical system we evaluated a large series of patients treated with this device.

Methods. A retrospective review of 551 qustionnaires returned by individuals who purchased the ReBuilder® on-line over 18 months was performed. Respondants reported pain or other symptoms and rated pain scores daily on a scale of 1(least) to 10. The ReBuilder delivers one signal to nerves and another to muscles. Signals are pulsed at 7.83 hertz to each foot via electrodes immersed in an electrolyte bath.

Rsults. Incomplete records (20) were excluded. The remaining 531 were analyed. Of the group, 86% reported pain and 14% had other symptoms. The device was used for 9.9±7.2 days (4-120). Of those with pain, 77% were satisfied with their relief. Pain score decreased from 7.31±1.85 to 3.42±1.00($p<0.0001$). ANOVA was used to compare change in pain scores in 3 groups of pts with a)initial pain, b)equivocal pain,and c) no pain. Significant reduction in pain score was seen in group a)(pain) vs the other 2 groups ($p<0.0001$). Overall quality of life improved in 91%. No adverse eventw were reported.

Conclusions. Treatment of PN with the ReBuilder® resulted in sig improvement in pain and quality of life, In randomized trials, will likely prove superior to drug-based therapies.

Introduction

Peripheral neuropathy (PN) is the most common neuromuscular disorder, and usually presents as symmetric distal polyneuropathy. The estimated incidence of PN in the general population is 2.4% and 8% in persons older than 55 (1). Diabetes is the most frequently reported cause of PN; 40%-50% of patients who have had type 2 diabetes for >10 years have PN and 26% of all diabetic patients have painful PN (2,3). Another risk group is cancer patients who receive chemotherapy agents that are neurotoxic to the peripheral nervous system (e.g. platinum analogues, taxanes, vinca alkaloids, thalidomide, bortezomid, and ixabepilone) (4,5). PN also occurs in patients with HIV and may arise in those with amyloidosis, Sjogren's syndrome, or other conditions, and in many cases is idiopathic (6,7,8). Whatever the cause, PN often causes significant morbidity including altered mobility and balance, fatigue, depression and anxiety, and decreased quality of life (9).

PN has an insidious onset, starting in the distal ends of the longest neurons and progressing slowly over months to years. Manifestations originate in the toes and fingers, then gradually progress to the feet and hands (stocking and glove pattern), and rarely to above the knees and the elbows (8). Although PN can affect motor and (rarely) autonomic nerves, large and small afferent sensory neurons are most often involved. Manifestations may include distressing bilateral numbness, paresthesia and impaired temperature, touch, vibratory sense and proprioception, as well as loss of deep tendon reflexes (DTRs) (10). Some individuals also experience difficult to manage neuropathic pain in the affected areas, which arises as a direct consequence of the pathogenic event affecting the peripheral somatosensory system (11). In addition to paresthesias, individuals may experience other symptoms that reflect damage to

small Aδ and C nerve fibers – that is, shooting, electric or shock-like, or stabbing (lancinating or knife-like) pain (9,12). Other persons report allodynia after contact with non-painful stimuli (e.g. clothing or bed sheets against skin), pain when walking that feels like walking on marbles or on hot sand, or feelings of heat, burning, or cold in their feet.

Most research has focused on diabetic neuropathy, but there are few adequately powered, well designed studies to firmly establish optimal pharmacologic treatment (Bril, et al, 2011)(13). Research regarding management of PN from other causes lags behind. At this time the mainstay of management is symptomatic control of neuropathic pain and tingling with anticonvulsants (e.g. gabapentin, pregabalin, topiramate), tricyclic antidepressants (e.g. nortriptyline, imipramine), serotonin-norepinephrine reuptake inhibitor antidepressants (e.g. duloxetine, venlafaxine), NMDA antagonists, and opioid analgesics (8,9,13,14). Opioids may effectively treat neuropathic pain, but analgesia may not be satisfactory because dose-limiting adverse effects occur before adequate pain relief. Combination analgesic therapy with an anticonvulsant and opioid is likely to be more effective than either single agent (8). Other pharmacologic agents are being studied for PN. For instance, increasing knowledge about the endocannabinoid system has led to studies of smoked cannabis for neuropathic pain, which have shown efficacy that is counterbalanced by a narrow therapeutic index (15,16).

There is little data supporting the use of nonpharmacologic measures. However, there is some intriguing data regarding transcutaneous nerve stimulation (TENS) and related technologies. For instance, Jin and colleagues (2010) (17) reviewed the literature to identify studies comparing TENS to sham treatment for symptomatic diabetic PN. They identified only three small studies that met inclusion criteria, but these confirmed that active TENS (alone or

with amitriptyline) used for 30 minutes once a day for 4-12 weeks was significantly superior to placebo in reducing pain and subjective symptoms of PN . Similarly, Pieber and others (2010) (18) reviewed 15 studies of TENS and other forms of external electrotherapy (e.g. pulsed dose electrical stimulation, high frequency muscle stimulation, frequency-modulated electromagnetic neural stimulation) and concluded these methods are continued benefits for patients with painful diabetic PN – although four of the studies reviewed suffered from small sample sizes, most lacked a placebo or control group, and follow up was inconsistent across studies. Interestingly, there was some evidence that the electrical stimulation methods might be more effective than TENS. Hypotheses for these therapies is that they may act by supraspinal mechanisms, modulate descending inhibitory pathways, increase pain threshold, influence calcitonin, reduce windup, or reduce nerve impulse transmission from damaged neurons.

Three studies examined Scrambler therapy (ST), in which electrical stimulation of superficial areas for neuropathic pain was evaluated. The first study included 226 patients with neuropathies from various etiologies accompanied by severe unrelieved pain (Sabato 2005) (19). The majority of patients (81%) experienced >50% pain relief, while 10% had partial relief (25% to 49%) and 9.8% had no relief (f<24% or visual analog scale [VAS]>3). The author concluded that Scrambler therapy led to statistically significant (P<0.0001) pain relief in all treated neuropathies.

Two other studies (21,24) have used a later version of the Scrambler, the ST5 (MC5-A Calmare). The ST5 has a multiprocessor and five channels that can simultaneously stimulate ‘artificial neurons’ in up to five painful areas the patient identifies in order to modulate pain

responses. An 'operator' in the clinic applies ST5, which is contraindicated for patients with a pacemaker, an implanted defibribillator, or surgical clips in an arterial aneursym or the vena cava. The ST5 is purported to interfere with pain transmission, and an 'operator' uses the device to administer one to six 30-minute painless treatments in the clinic.

Ricci and others (20) reported the results of open-label study in Europe using the ST5 in 73 patients with cancer or non-cancer related pain unrelieved by analgesics. Patients were treated twice a week for a total of 10 treatments. Before treatment, mean pain scores for cancer patients were 5.4 (±2.5 SD (standard deviation) and 7.0 (±2.3) for non-cancer patients. By the end of the second week, pain scores averaged 1.4 (±1.8) and 1.8 (±2.2) 1.6 (±2.0). All values were statistically significant ($p<0.0001$), and pain relief persisted for 30 days – the study period.

Another similar open label pilot study to evaluate the efficacy of the ST5 was done in the US. In this study 16 evaluable patients experiencing chemotherapy-induced PN had electrodes placed over the painful areas and the treatment intensity was increased to maximum bearable without pain and continued for 60 minutes on each of 10 subsequent days (Smith et al, 2010) (21). Fifteen of 16 patients met the primary endpoint variable – ≥20% reduction in pain score from baseline ($p <0.0001$). Mean pain scores were 5.81 (± 1.11) before and 2.38 (± 1.82) after day 10 ($p <0.0001$).

Our clinical observations and reports from patients experiencing painful PN that support the potential value of a new device, the ReBuilder® (22) designed to deliver dual electrical stimulation to muscle and nerve tissues (ReBuilder Medical Inc.). We were encouraged to develop a more rigorous rationale for using or recommending this device after discussions with

several or our patients and their physicians, who expressed extreme frustration at the lack of effective therapeutic options. Some patients even expressed suicidal thoughts because of unrelieved PN and pain. These findings form the basis for this preliminary study, a review and analysis of patient-generated data collected by ReBuilder Medical Inc.

Methods

The ReBuilder® device is registered with and approved by the FDA as a 510K pre-amendment version TENS (transcutaneous electrical stimulator) and an electronic muscle stimulator (EMS)(24). The ReBuilder® delivers energy via cutaneous electrodes to each foot (and hand, if indicated) that is placed in one compartment of an electrically isolated split compartment bath containing a salt mixture (newer versions offer the alternative of electrolyte impregnated socks and gloves) (figure 1). According to the manufacture, the ReBuilder®'s individualizes its outputs based of the physical mass and digital impedance of the individual using it (http://rebuildermedical.com). Impulses are designed to imitate the natural waveform of healthy peripheral neurons, with a small amount of current under the curve and a relatively high transient voltage of 40-90 volts. The resultant current is below that commonly produced by traditional TENS units. The device delivers a second, simultaneous, lower voltage (5-20 volts), wider waveform signal designed to stimulate muscle tissue. This signal causes the muscles of the feet, calves, and thighs and buttocks to intermittently contract and relax. The dual stimulation electric signal is pulsed at a frequency of 7.83 cycles per second, which theoretically allows afferent neurons time to repolarize between pulses. The dual stimulation is hypothesized to travel from the distal end of the ascending sensory neuron, across the spinal

interneuron, and down to the distal end of the motor neuron in the contralateral limb (http://www.rebuildermedical.ca/monograph.php).

Sample

The convenience sample was comprised of 551 individuals who purchased the ReBuilder® between December, 2002 and May, 2004 in response to an Internet advertisement offering financial incentive for trying a new treatment for peripheral neuropathy. Along with the device, the package included a simple survey questionnaire which they were requested to return within three months. They were also asked to record their reason for using the device (pain or other symptom) and to rate their pain, if applicable, on a numerical rating scale (NRS) of 1 (least) to 10 (worst) before and after using the device. The survey questionnaire also asked about perceived quality of life at the beginning and the end of the study period, and also provided space in which to record any personal comments. Individuals who returned the enclosed patient questionnaire within three months of purchase were included for analysis. Because the gold standard for pain assessment is an individual's own report, outcomes were determined by comparing respondents' pain scores at the beginning and end of the trial period.

Statistical Analysis

Statistical tests were performed using the SPSS software version 20 (IBM, Armonk, N.Y.), and included calculation of descriptive statistics, means and frequencies for categorical variables. A paired t-test was done to examine any differences in beginning and end of trial pain ratings in persons who reported initially reported pain. In addition, a one way analysis of variance (ANOVA) was performed to compare the differences in pain score changes in the 3 groups of respondents; a) those who reported an improvement in pain b) those who were

unsure whether their pain improved, and c) those who stated that there pain had not improved.

Results

Twenty records were excluded from analysis because of confusing or conflicting data. The remaining 531 records formed the basis of this report. Eighty-eight percent of respondents reported the cause of their PN was not known. Only 7% reported their neuropathy was due to diabetes, 3% reported it was anatomic, and 1% each reported toxic or vascular causes. No other demographic data were asked for or provided.

The duration that individuals in this sample used the ReBuilder® on a daily basis ranged from four to 120 days (mean, 9.9 day, ± 7.2 days). Four hundred fifty-six (85.9%) of the sample reported pain at the beginning of their trial with the ReBuilder®, and of these, 405 (76.6%) reported satisfaction with their degree of pain relief at the end of the trial. The mean pain rating of those who reported pain before using the ReBuilder® was 7.31 (± 1.85) and 3.42 (± 1.99) at their end report (paired t test, $p<0.0001$). Conversely, for individuals who had pain before using the device but reported equivocal (n = 57) or no pain relief (n = 53), their mean pain scores were 3.98 (± 1.92) and 4.17 (± 1.97) respectively (fig 3). One way ANOVA revealed a significantly greater reduction in pain score in 'yes' responders, as compared to the 'equivocal' and 'no' responders ($p<0.0001$). In addition, 91% of respondents reported improved quality of life after using the ReBuilder®. A greater number of individuals reported on their satisfaction with pain relief (n = 515) than initially reported pain (n = 456). This discrepancy is explain by individuals who initially reported severe numbness or tingling in their feet but still reported an improvement in pain score.

Testimonials from the questionnaires were not analyzed statistically. The most common comments were “miraculous relief,” “I can feel my feet again, “ I am no longer suicidal,” and “I have a life again.” Unexpected comments included ulcer-healing in 3 patients, resolution of fungal nail infection in one, and improved sexual function in 3 patients.

Discussion

A potential advantage of the ReBuilder® over other technologies including ST5 or TENS is its simplicity of use. In particular, the ST5 treatment must be administered in the clinic and ideally by a specially trained clinician. The inventor of the ST5 now requires that physicians attend a three day training course because of the critical need to correctly place electrodes for optimal pain relief (23). On the other hand, there are two versions of the ReBuilder®, one that patients can use at home and one that can be used in the clinic. In addition, it is registered with DCA and generally paid for by Medicare and other third party insurers.

In an unpublished study, 134 adult patients experiencing neuropathic pain related to diabetes, peripheral vascular disease (PVD) , alcoholism, and/or chemotherapy-related neuropathy used the ReBuilder once a day at home for one month (Karlock & Phillips; data on file, ReBuilder Medical, Inc.) About a third of patients returned their devices because of ineffective relief, but the others experienced relief and continued to use the device. Patients with two conditions causing PN, such as diabetes and PVD or diabetes and alcoholism seemed to get the least relief. This study was done before Medicare started to reimburse for the ReBuilder, so patients paid for the device themselves (if they could afford it) and continued to

use it daily for six or more months – despite having to use the cumbersome twin compartment footbath that has been replaced with conductive socks and gloves.

There are numerous causes of peripheral neuropathies, which are thought to result from axonal degeneration that occurs secondary to accumulation of toxins or neurotoxic agents, vitamin deficiencies, inherited genetic abnormalities, hyperglycemia and glucose accumulation within neurons, or other causes (25). In addition, factors in the external environment of neurons, such as vascular compromise or ischemia, inflammation, and oxidative stress may lead to secondary demyelination and axonal dysfunction (2). Involvement of small and large sensory neurons often leads to manifestations such as numbness tingling, dysesthesia and burning, as well as change in temperature sensation and proprioception, and loss of DTRs. Resulting neuropathies may lead to severe pain, disability, erectile dysfunction, impaired ability to walk and drive safely, and decreased quality of life (23).

There is no known cure for peripheral neuropathy and except in the case of diabetes mellitus, where tight glucose control has been reported to effect improvement (26,27). Treatment has been directed largely at relieving symptoms rather than treating the underlying cause. TENS is a simple, non-invasive treatment for neuropathic pain based on the gate control theory *(28*). that proposes stimulation of large myelinated A fibers inhibits transmission of painful afferent impulses from A δ and C fibers to the dorsal horn of the spinal cord, thereby closing the gate. This hypothesis may be too simplistic, as central mechanisms may be involved and TENS therapy may not change C or Aδ mediated thresholds or perceptions (e.g. cold, warmth, cold or heat pain, vibration or touch (29). TENS may be useful for neuropathic pain related to diabetes and other conditions, and often leads to improvement of pain that

diminishes with cessation of TENS use (17,18,29) was overall improvement in PN pain at twelve weeks of treatment. Current evidence-based guidelines conclude TENS is “probably effective in lessening the pain of painful diabetic neuropathy and improving quality of life” (Bril et al (13).

The data regarding electrical stimulation of superficial areas using scrambler therapy (ST5) for neuropathic pain is also promising and may be effective for analgesic-resistant pain. The ST5 is also designed to interfere with pain transmission, and use led to >50% pain relief in 181 or 226 patients (80.09%) in one study (Sabato) (19). Similarly, a later version of this technology was effective to reduce mean pain scores by 74% after ten days of treatment in 73 patients in whom relief persisted up to 30 days (Ricci 2011) (20).

Our retrospective analysis included 532 individuals who had purchased the ReBuilder device - possibly in desperation because other medical treatments had failed to relieve their or had caused intolerable adverse effects. Many expressed suicidal thoughts because they were told there was “nothing else that could be done for them “and they would have to “live with their pain.” After searching the Internet or hearing of the device by word of mouth, they purchased the ReBuilder and agreed to complete a follow up questionnaire within three months of purchase. Compliance was high: more than 90% returned the questionnaire within three months of purchase and only 19 of the 551 questionnaires were excluded from the analysis because of confusing or conflicting data. Of note, the opportunity for these individuals to add comments provided us with compelling qualitative, subjective information .

The ReBuilder is distinctly different from traditional TENS units, and from “scrambling” types of electrical stimulation in that it is designed to improve the microcirculation and to re-polarize and re-educate the nerves to follow the correct pathways rather than to confuse the

nerve fibers. It was also designed to be simple to use in the home setting. Recent versions include silver impregnated gloves and stockings for home use, to avoid the electrolyte bath, further simplifying the treatment process and making it portable.

Limitations

The limitations of this study must be recognized. There is little information about the self-selected sample, particularly in terms of etiology and duration of PN, and other medical data. We also did not observe a 'standard' treatment duration, and there is no follow up data regarding continued use and duration of pain relief in the yes responders. Correspondingly, we cannot say whether those whose responses were 'equivocal' or 'no' would respond with further use of the ReBuilder®; that is we do not know the time frame in which the onset of and maximal pain relief occur.

Conclusion

To our knowledge, there is no published data or information that includes the large number of individuals (more than 500) experiencing painful neuropathy detailed in our report. Despite the limitations identified, we believe this provides compelling information that should drive larger prospective studies. Other questions remain to be answered in future studies: 1) can use of the ReBuilder return some degree of peripheral normal sensation 2) is pain reduction lasting or not 3) can the ReBuilder delay the onset of PN in patients with diabetes or those who are prescribed neurotoxic chemotherapy? Other investigators mayalso be interested in elucidating the mechanisms of pain relief of the ReBuilder. Our hypothesis is that the electric stimuli promote healing of the microcirculation and re-direct the small neurons into an appropriate arrangement. Finally, nerve conduction velocity (NCV) studies are considered the

gold standard of diagnosing PN, and should be included in future studies pre- and post-treatment to determine whether velocity improves.

Legends

Figure 1. A patient being treated with the split compartment, electrolyte-containing solution

Figure 2. Use of the electrolyte-impregnated gloves (not used in this trial). Socks also available

Figure 2. Close up of the ReBuilder®. Note small size and portable nature

Figure3. Mean Pain Ratings Before and After Using the ReBuilder
Legend: Four hundred fifty-six respondents reported pain before using the ReBuilder. After a mean duration of 9.9 days of using the device, mean pain ratings varied among those satisfied with, equivocal, or not satisfied with their pain relief.

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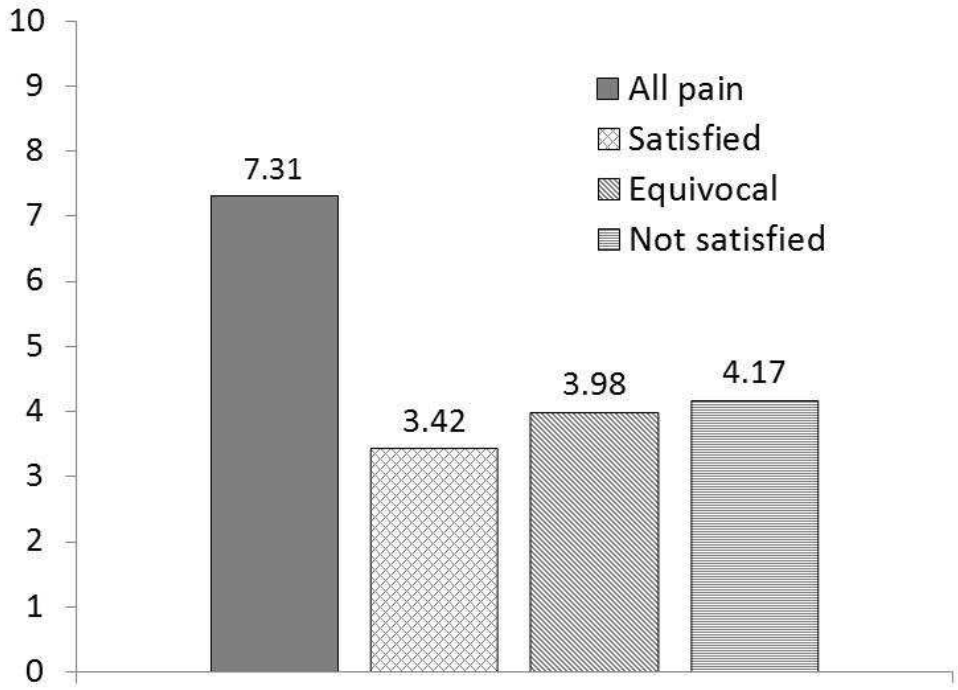
Figure 3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Figure(1)
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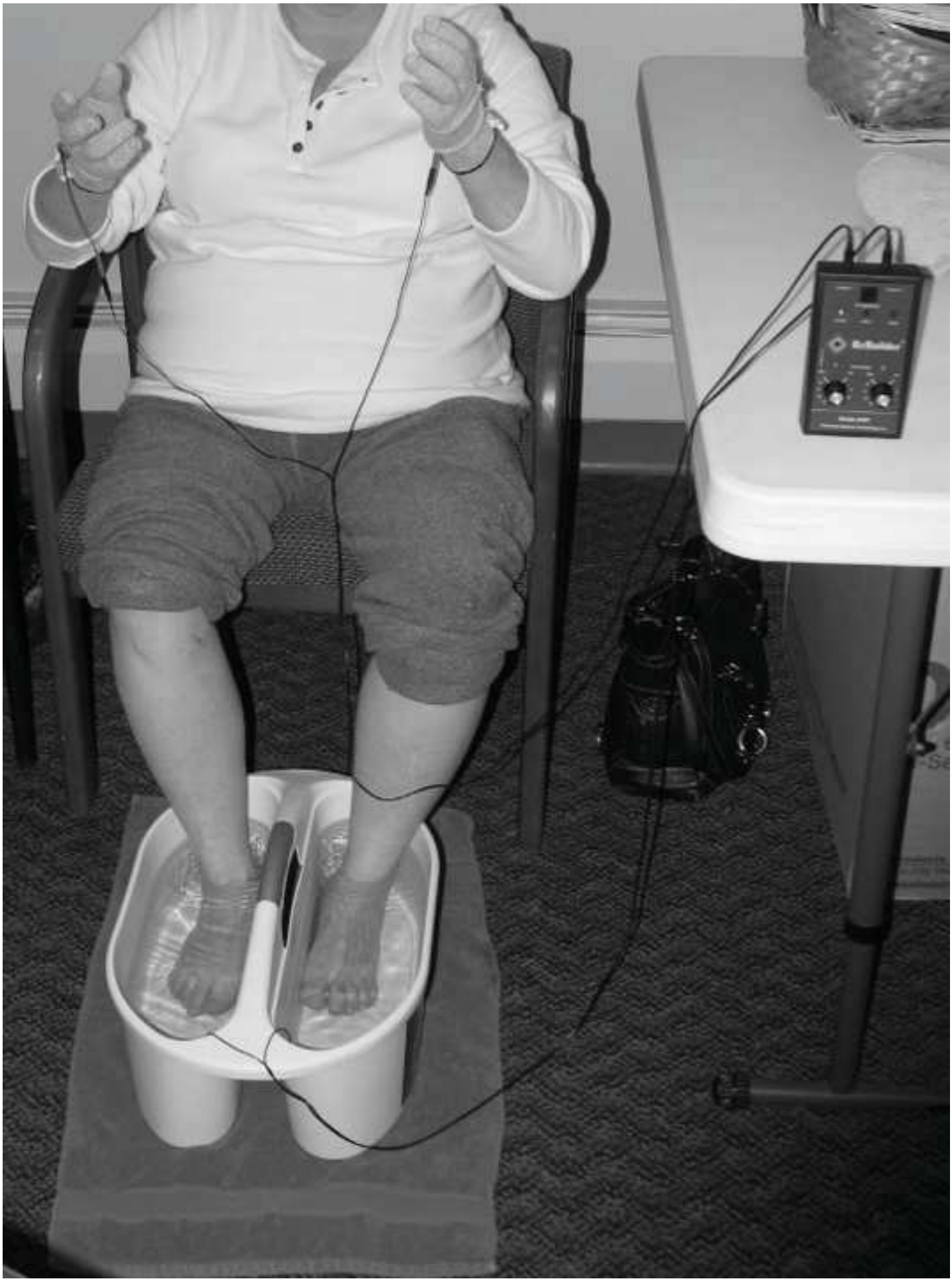

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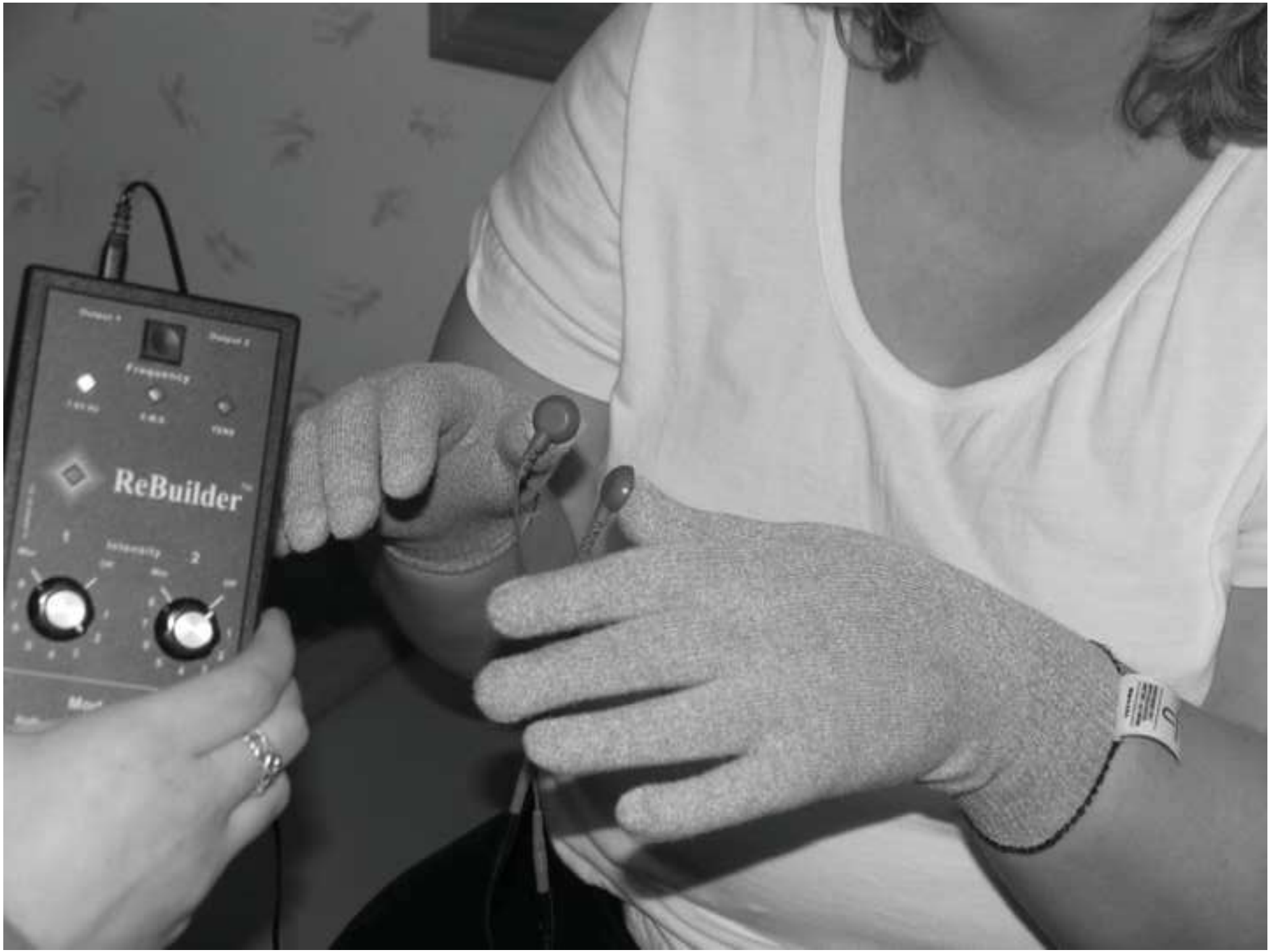

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