Use of RecoveryRx Device for Treatment of Delayed Onset Muscle Soreness – Comparison to Acetaminophen and Control Group

Principal Investigator: Sheena Kong, M.D. (November 2009)

Executive Summary

Study Purposes

The study has two primary purposes. The first is to assess whether patients using RecoveryRx for treatment of Delayed Onset Muscle Soreness (DOMS) realize reduced levels of muscle pain or soreness when the RecoveryRx device is applied after a DOMS inducing exercise regiment. The second is to assess the effectiveness of treatment of DOMS with RecoveryRx versus acetaminophen in the form of Extra Strength Tylenol®.

Design

This was an observational study to evaluate the treatment of Delayed Onset Muscle Soreness (DOMS). After a vigorous resistance training exercise regiment designed to induce DOMS, 102 study participants were placed into one of three groups: 1) a control group, 2) a group that utilized the RecoveryRx device, and 3) a group that received over- the-counter strength acetaminophen in the form of Extra Strength Tylenol.

Each participant was engaged in a vigorous resistance based exercise regiment designed to induce DOMS in the bicep muscles. Upon completion of the exercise regiment, participants selected for the RecoveryRx group were given RecoveryRx devices which were placed on the bicep muscles. These participants wore the devices for the subsequent 48 hour period.

All participants in the study returned 48 hours later. Participants in the control and RecoveryRx groups were then surveyed concerning their levels of DOMS-related muscle pain and soreness. Participants within the acetaminophen group were administered 1 gram of acetaminophen in the form of Extra Strength Tylenol. Ninety minutes after administration of acetaminophen these study participants were also surveyed concerning their levels of DOMS- related muscle pain and soreness.

Study was approved by RCRC Independent Review Board of Austin, Texas and has been registered with The National Institutes of Health (NIH).

Device and Medication Usage

The RecoveryRx device manufactured by BioElectronics Corporation was used by one group of study participants. A different group was given over-the-counter strength of

acetaminophen in the form of Extra Strength Tylenol. The dosage of acetaminophen was 1 gram. The control group used neither the RecoveryRx device nor acetaminophen.

Results

Of the the 102 patients enrolled in the study, 38 used the RecoveryRx device, 38 acted as control, and 26 used acetaminophen in the form of Extra Strength Tylenol. The mean VAS score for the RecoveryRx was 1.500, significantly below the VAS scores of 2.507 for the acetaminophen group and 3.179 for the control group.

Comparison between the RecoveryRx group and the control group was significant at the 0.001 level. Comparison between the RecoveryRx group and the acetaminophen group was significant at the .05 level.

No study related adverse effects were reported by any participant.

Discussion

The data yielded by this study appears to demonstrate that the use of RecoveryRx for the treatment of Delayed Onset Muscle Soreness (DOMS) is both safe and effective. Additionally, the data yielded by the study appears to demonstrate that the continuous use of RecoveryRx will result in significantly less DOMS-related pain and muscle soreness compared to a treatment regiment consisting of an OTC dosage of acetaminophen.

Background

Delayed Onset Muscle Soreness (DOMS) is a condition associated with increased physical exertion. This condition is experienced by all individuals regardless of fitness level as it is a normal physiological response to increased exertion and the introduction of unfamiliar or strenuous physical activities. The pain caused by DOMS can impair physical training and performance, and as a result, it is of great concern to trainers, coaches, and therapists. DOMS affects many more individuals than just athletes. Many ordinary people are developing this condition as a result of excessive physical or out of the ordinary exertion. The pain and discomfort associated with this condition generally peaks at between 36 to 72 hours after an exercise routine and usually resolves within 96 hours.

For several decades DOMS had been attributed to lactic build up in the muscles after exertion. Over the past few years this assumption has been shown to be unrelated to this condition. Several research studies have indicated that lactate levels return to normal within 60 minutes post exercise. Therefore, increased lactate levels cannot cause DOMS.

DOMS is predominately caused by eccentric exercise. Connolly et al. (2003) explains that the injury that results from eccentric exercise causes damage to the muscle cell membrane, which sets off an inflammatory response. The inflammatory response leads to the formation of metabolic waste products, which act as chemical stimulus to the nerve endings that directly cause a sensation of pain and swelling.

W. Stauber et al (2000) used a high-powered microscope to analyze muscle fibers after an intense workout. Based on his research it was clear that cell membranes were ruptured and other structural components were disrupted; however, damage to the muscle fibers is relatively small. This damage is not limited to one area but occurs throughout the muscle fiber. This microscopic muscle damage causes an inflammatory response. It is this inflammatory response that causes muscle soreness due to: 1) the accumulation of fluid (swelling) and 2) chemicals secreted by white blood cells that activate pain receptors (Smith, 1991).

While there has been some research conducted on the treatment of DOMS, no particular treatment option has been proven to be dominant in treating or preventing the condition. The most popular intervention is pharmacological options using non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen. Stretching and warm-up exercises as well as nutritional augmentation via supplements have also been explored with varying degrees of success.

NSAIDs, such as aspirin and ibuprofen, and acetaminophen are popular

treatments for DOMS, but some of the research conducted in this area is inconclusive. Additionally, there are significant concerns associated with negative potential side effects such as gastrointestinal distress, liver toxicity and related coronary issues.

There has been considerable research relative to using nutritional supplementation as a potential treatment for DOMS with particular emphasis on vitamins E and C and other antioxidants, which are thought to reduce the proliferation of free radicals generated during an inflammatory response. These effects are inconclusive as are other investigations into use of L-carnitine.

While neither NSAIDs nor nutritional supplements have been proven to reduce the onset of DOMS, there has been some research suggesting that simple warm-up exercises can meaningfully reduce the onset of the condition. Szymanski (2003) introduced the "repeated-bout effect" as a way to reduce DOMS. The repeated-bout is a progressive adaptation to exercise that has been shown to consistently reduce DOMS and exercise induced damage to muscles.

RecoveryRx is a miniaturized medical device that delivers continuous electromagnetic therapy to restore damaged cells. The device is a Class III medical device that is available only through a licensed health care practitioner in the United States. The device, however, is widely available on an over-the-counter basis outside of the United States.

Significant clinical data shows that RecoveryRx reduces edema, inflammation and pain.

RecoveryRx uses a mild electrical current and radiofrequency waves at a frequency that stops the release of pain and inflammatory mediators, increasing blood flow, and reestablishing normal cell interaction.

Pulsed electromagnetic stimulation (PEMF) in some form has been used or investigated since the early 1930s. There is a large body of clinical experience that has realized its value as an effective treatment for tissue trauma, particularly in the early stages of inflammation. Numerous studies are available that document its effectiveness in orthopedic surgery, arthritis, and even plastic surgery (breast augmentation). While no study has demonstrated the complete elimination of pain, PEMF has shown less dependence on medications and some enhancement of the recovery period. Also, there has not been a single study showing any harmful effects so it is safe to conclude that PEMF is safe for human use.

The precise mechanism by which PEMF works on controlling pain after injury is not known. It is theorized that it may affect pain levels by its effect of nitric oxide (NO) release, a short-lived signaling molecule in the anti-inflammatory cascade. It is also suggested that it has an effect on stabilizing cell membranes such that

the edema phase of an injury is more rapidly resolved.

AtciPatch devices function at a frequency in the 27.1 MHz ISM band and are confined within the field of the patch's loop antenna. The patch induces electric current in human tissue, but it is oscillating at such a high frequency that it cannot be detected by the patient. The high frequency results in a depth of penetration into the tissues of approximately 10 cm. When the patch is used over a 24 hour period, it produces an absorbed energy of 630 mJ/cc which is well within the range of effectiveness for soft tissue injuries. The patch produces a power density at the skin surface between 14 and 73 μW/cm² and induces an electrical field of about 10 milliVolt/cm, resulting in adsorbed power levels in the range of 7.3 μW/cm3. This provides field exposure levels at the target tissue that are five to nine orders of magnitude above the thresholds which have been established for non-thermal electromagnetically induced biological effects at the cell and tissue level.

The RecoveryRx uses proven medical technology to truncate the human body's natural inflammatory response breaking the cycle of chronic inflammation. RecoveryRx does this by delivering pulsed electromagnetic energy directly to the affected area and driving out the edematous fluid along with byproducts of the damaged tissue. The affect is a well documented and a significant overall improvement in the restorative and recovery process following injury resulting in a substantial reduction in the pain associated with soft tissue injury. These statements are supported by multiple studies, but no specific research has been done relative to its effects on DOMS.

RecoveryRx was cleared by FDA in 2002 for the treatment of edema following blepharoplasty. Clinical data presented by BioElectronics to Health Canada resulted in its approval for relief of pain in musculoskeletal complaints, and the product is now available over-the-counter throughout Canada. The product is also cleared for over-the-counter sales in European Union countries and other countries throughout the world.

Study Execution

Study Design

- This was an observational study to evaluate the treatment of delayed onset muscle soreness.
- Study participants were placed randomly into one of three groups 1) a control group, 2) a group that utilized RecoveryRx, and 3) a group that received over-the- counter strength acetaminophen
- 102 participants in total - 38 used the RecoveryRx, 38 acting as control, and 26 used acetaminophen
- Sample size for acetaminophen group was smaller due to resistance from participants to consume acetaminophen

- Age range from 18 to 35, subjects were healthy collegiate athletes and trainers who exercise regularly and participate in team sports
- Interventions were approximately 20 sets of 10 repetitions of bicep resistance exercises using free weights to induce DOMS in the bicep muscles of both arms
- Approximately 48 hours post exercise, participants returned to study site and were given a Pain Recording Scale (Visual Analogue Scale) sheet to record their perceived level of DOMS pain in their bicep muscles.

Exclusion Criteria

- Anyone who is unable to give consent or document written consent in English
- Anyone who is confirmed or who could possibly be pregnant
- Anyone with allergy or intolerance to acetaminophen
- Anyone with known active liver disease

Recruitment of Participants

Participants were recruited from collegiate athletic teams and athletic training personnel.

Randomization

After the DOMS inducing resistance exercise regiment was completed, each study participant was randomly assigned to one of the three participating groups. Study participants assembled randomly in a straight line. The number of participants in the line was divided by three. Starting left to right of the line the three groups were selected with the first third becoming the RecoveryRx group, second third becoming the control group and the final third becoming the acetaminophen group.

Adverse Events Reporting

As described in the informed consent forms, all adverse events were to be reported to the investigating physician or the collegiate athletic training personnel. Participants were given the direct phone number to the principal investigator. No adverse events were reported to either the principal investigator for the collegiate athletic training personnel.

Data Collection

Measurements of DOMS-related muscle pain assessments were done by the participants who completed a simple form that recorded pain and muscle soreness levels on the VAS line. The data was collected by the athletic training personnel under the supervision of the principal investigator. The principal investigator transferred the data to a spreadsheet from which statistical analysis was performed.

Statistical Analysis

Data was collected from the participants approximately 48 hours after the administration of the DOMS inducing resistance exercise regiment using a VAS (Visual Analogue Score) pain assessment.

Statistical Analysis

Data were collected at the end of the study. The monitor copied the data from the individual sheets and placed in a spreadsheet with one entry per participant depending on the participant's particular group, i.e., Tylenol, Control or RecoveryRx. Thus there were three columns, one for each group. At the end of the study, the data were provided for analysis.

The data were analyzed using Excel macro's. Means, variances and standard deviations for the VAS scores were calculated for each subsample. The difference between cell means was tested using t-tests with the following formula:

$$t = \frac{\bar{X}_T - \bar{X}_C}{\sqrt{\frac{var_T}{n_T} + \frac{var_C}{n_C}}}$$

where X is the mean for the group, VAR is the variance of the observations, n is the sample size and the subscripts T and C represent the two different groups being compared, e.g. "treatment" and "control" group.

Acceptance Criteria

This study used two tailed tests and significance levels of .05, .025 and .001 to determine the significant differences in sample means.

Results

102 patients were enrolled in this study, 38 using the RecoveryRx, 38 acting as control, and 26 using Tylenol. Table 1 shows the mean VAS scores for each subsample along with the variances for these means, i.e., var/n .

Table 1: Group Means and Variances

	Tylenol	Control	RecoveryRx
Means	2.507	3.179	1.500

Means Variance	.1315	.1678	.0620

Table 2 presents the results of the individual t-tests. Comparisons were made between RecoveryRx and the control group and RecoveryRx and the Tylenol group. The former comparison was significant at the .001 level; the latter was significant at the .05 level.

Table 2: t-test statistics

	t-statistic	degrees of freedom	significance level
RecoveryRx vs. Control	3.504	78	.001
RecoveryRx vs. Tylenol	2.290	64	.05

Discussion

The data from this study demonstrates the RecoveryRx device manufactured by BioElectronics Corporation had a significant effect on reducing DOMS-related symptoms of muscle pain and soreness when compared to both a control group that received no treatment and a group that was treated with 1 gram of acetaminophen in the form of Extra Strength Tylenol. Based on this data, the principal investigator concludes that RecoveryRx is safe and effective treatment for DOMS.

The use of RecoveryRx seems to be a convenient, safe and effective new treatment for muscle pain and soreness, especially when compared to currently FDA approved over the counter treatments, such as acetaminophen, NSAIDs and other pain medications that may have questionable safety profiles.