The Effect of Biofreeze® on Post Manipulation Soreness in Patients with Mechanical Neck Pain: a randomized double-blinded controlled trial

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Background: In any given year, 30-50% of adults will experience some form of significant neck pain.1 Mechanical neck pain implies the source of pain is in the spine and/or its supporting structure. One treatment option for mechanical neck pain is cervical manipulation. However, post manipulation soreness is one of the most commonly reported complications of manipulation. While soreness is not serious, it is a barrier to receiving manipulation. Biofreeze® is a commonly used topical analgesic and has been reported to be helpful in the treatment of neck pain among other conditions.3 Given the prior research on the effectiveness of Biofreeze® on neck pain, it is possible that the application of Biofreeze® pre-manipulation would reduce the immediate soreness post manipulation.

Purpose: To determine if pre-manipulation addition of Biofreeze® to mechanical neck pain patients is effective at reducing post-manipulation soreness compared with mechanical neck pain patients who receive a placebo.

Hypothesis: Mechanical neck pain participants who receive Biofreeze® prior to manipulation will report significantly lower levels of immediate post-manipulation soreness and increases in cervical range of motion than participants who receive a placebo.

Design: A double blinded randomized clinical trial

Participants: A convenience sample of 20 patients between the ages of 11-59 years old, with a history of non-radicular mechanical neck pain, were recruited from an outpatient chiropractic, physical therapy and rehabilitation clinic. Exclusionary criteria included: no cervical manipulation recommended, current radicular signs and/or symptoms, and history of neck surgery. Each intervention group contained 10 patients.

Intervention: Subjects were randomly assigned, using quasi block randomization, to the control or intervention groups: (1) Control group [C], placebo gel applied 5 minutes before cervical manipulation; (2) Intervention group [BF], Biofreeze® gel applied 5 minutes prior to cervical manipulation. The participants and researchers involved in recording pain scale and cervical range of motion were not informed as to which treatment the participant received. The participants rated their pain on a Visual Analog Scale at the following intervals: (1) 5 minutes before the intervention, (2) 1 minute after the intervention, (3) 10 minutes post intervention, (4) 20 minutes post intervention, and (5) 30 minutes post intervention. Cervical range of motion was also measured at 3 intervals: (A) immediately prior to the application of Biofreeze® or placebo, (B) 1 minute after manipulation, (C) 30 minutes after manipulation. Six cervical range of motion values were recorded: flexion (F), extension (E), left side-bending (LSB), right side-bending (RSB), left rotation (LR), and right rotation (RR) at maximum, average, and variance of degrees.

Main Outcome Measures: Soreness was measured on a 0-10 visual analog pain scale at 5 intervals. Cervical range of motion was measured in degrees at 3 intervals. A repeated measures ANOVA was conducted with pain (VAS score) as the dependent variable and group [BF, C] and interval (pre-manipulation soreness and post-manipulation soreness) as the independent factors. A second repeated measures ANOVA was also conducted with range of motion as the dependent variable [F, E, LSB, RSB, LR, RR] at maximum, average, and variance degrees and group [BF, C] and interval (pre-manipulation soreness and post-manipulation soreness) as the independent factors. Significant main or interaction effects indicated the use of post hoc comparisons to determine specific time by group differences.

Results: Initial descriptive evaluation revealed a significant difference in gender between groups. The

Biofreeze® group had significantly greater female subjects than males (F=8, M=2) compared to the Control group (F= 3, M=7) ($p = 0.025$).

There was a significant main effect ($p \leq 0.001$) of VAS scores over time and a group/time interaction ($p = 0.024$) between VAS scores and intervention groups. Post-hoc analysis revealed that the Biofreeze® group significantly declined in reported VAS scores at all time points except between 20 minutes and 30 minutes. The control group did not significantly change over time.

There was a significant group and time interaction ($p = 0.045$) at average LR. Post-hoc analysis revealed the Control group's average range of motion declined between 1 minute (65.06°±6.08°) and 30 minutes (60.24°±5.85°). Although not a significant main effect, there was also a significant decline ($p = 0.015$) in maximum LR from 1mintue (68.10°±6.09°) to 30 minutes (63.30°±5.76°). For all remaining cervical range of motion maximum, average, and variance there was no significant main effects or interactions.

Conclusion: Initial results of this study suggest the application of Biofreeze® reduces post manipulation soreness up to 20 minutes after manipulation. No significant difference was found between group cervical range of motion, except a decline of degrees in the control group at average left rotation. This may be explained by the small sample size (n=20). Future research will continue with the present protocol until a sample size of n=60 has been reached.