



Effects of Biofreeze and chiropractic adjustments on acute low back pain: a pilot study[☆]

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Abstract

Objective: This randomized controlled study was designed to determine the pain-relieving effect of Biofreeze (Performance Health Inc., Export, PA) body surface application and chiropractic adjustments on subjects with acute low back pain (LBP).

Methods: The data were collected at the baseline, 2 weeks after treatment, and 4 weeks after treatment for final analyses. Diversified manual adjustments were provided by licensed chiropractors twice a week for 4 weeks to both control and experimental groups. Biofreeze was applied to the lower back area 3 times a day for 4 weeks in the experimental group. Outcome assessments included visual analog scale, Roland Morris Disability Questionnaire, heart rate variability for stress, and electromyography for low back muscle activity.

Results: A total of 36 subjects were recruited in the study (25 male). The average age was 34 years. Significant pain reduction was found after each week of treatment in the experimental group ($P < .05$). The Roland Morris Disability Questionnaire did not show significant changes in both groups. There were no significant differences for pain reduction in the control group. Heart rate variability analysis showed no significant change ($P > .05$) in the experimental group after 4 weeks of Biofreeze and chiropractic adjustments. There were no statistically significant changes in the electromyography readings between the 2 groups.

Conclusion: Biofreeze combined with chiropractic adjustment showed significant reduction in LBP.
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Introduction

In the United States, low back pain (LBP) costs the workers' compensation system an estimated \$8.8 billion each year; and the rate of filing LBP claims is 1.8 per 100 workers.¹ Low back pain is also the second most common symptom leading patients to seek medical care,² with estimated direct and indirect costs of more than \$50 billion per year.³ Low back pain symptoms are extremely common, affecting as many as 80% of the population at some time in their lives.⁴ Diversified chiropractic adjustment is one of the most frequently used adjusting techniques in the chiropractic management of LBP. There is sufficient evidence that diversified adjustment may reduce LBP.

Recent research on LBP has indicated that psychosocial factors play an important role in LBP.⁵ Papageorgiou et al⁶ reported that dissatisfaction with work status doubles the risk of reporting a new LBP in both the employed and nonemployed subjects. Individuals perceiving their income as inadequate were at a 3-fold risk of consulting for the LBP symptom regardless of their employment status. Despite the high costs of chronic LBP, research on the effectiveness of objective measures for LBP is rare.⁷ Low back pain patients with greater body consciousness and anxiety report greater pain symptoms.⁸

Heart rate variability (HRV) has been associated with pain in recent research studies.⁹⁻¹² Heart rate variability has been used in studies to determine the autonomic nervous system activity as an indicator of the stress and anxiety of subjects in pain.^{9,10} It has been reported that chiropractic adjustments improved HRV in a multiclinic study.¹³ Tousignant-Laflamme and Marchand reported that patients with LBP had significant increase in heart rate and sympathetic activity.¹⁴ Electromyogram (EMG) was used in the study to determine muscle activity in the LBP area. Although it has been used widely in LBP research, its value is unproven.¹⁵⁻¹⁷

Biofreeze (Performance Health Inc., Export, PA) is a unique analgesic formulated to provide local pain relief.¹⁸ The purpose of this study was, using randomized controlled design, to determine whether Biofreeze has significant pain-reducing effect when added to the treatment protocol of chiropractic adjustments in patients with LBP.¹⁸⁻²¹ The pain-reducing effect of Biofreeze, in conjunction with chiropractic treatment, has not been studied. There are reported healing effects from cooling the skin and relaxing muscles and joints.^{22,23} Biofreeze uses the principle of cryotherapy. The use of cryotherapy (ie, the application of cold for the treatment of injury or

disease) is widespread in sports medicine today.^{24,25} It is an established method when treating acute soft tissue injuries, but there is a discrepancy between the scientific basis for cryotherapy and clinical studies.²⁶ The physiological and biological effects are due to the reduction in temperature in the various tissues, together with the neuromuscular action and relaxation of the muscles produced by the application of cold.^{27,28} Cold increases the pain threshold, the viscosity, and the plastic deformation of the tissues but decreases the motor performance.²⁹ However, Biofreeze cooling gel gives rise to the cooling sensation without lower skin temperature because of the unique characteristic of menthol, which is one of the main ingredients.³⁰⁻³² A study on the effect of topical menthol reported that topical menthol on human skin elicits sensation of pain and coldness and an increased cutaneous perfusion.³³ These authors used the highest concentration of menthol (40%) that can be dissolved in 90% ethanol to induce pain.³³ Despite the high concentration of menthol, the skin temperature did not decrease more than the control group with 90% ethanol.³³ It is clear that the cooling effect of Biofreeze is different from the application of cold. It is possible that menthol stimulates the peripheral sensory receptors to inhibit pain through the gate control mechanisms.

The specific aims of the study were to study the effectiveness of Biofreeze combined with chiropractic adjustments on LBP compared with chiropractic care only. The hypothesis was that Biofreeze enhances the effect of chiropractic adjustments on acute LBP.

Methods

One experimental group and one active control group were recruited in the study, and all subjects received chiropractic adjustments. The experimental group received both chiropractic care and Biofreeze treatment. A laboratory technician used a random table of numbers to assign subjects into the 2 groups. Assignment of all subjects was predetermined by the random table. An Excel (Microsoft Corp, Redmond, WA) spreadsheet was used to record the first 40 random numbers for 40 subjects. Subjects with the largest 20 random numbers were assigned in the Biofreeze group, and the lowest 20 numbers were assigned in the active control group. The researcher was blinded from treatment and assignment of subjects. Each new patient was first given a random number and then assigned into treatment group by another researcher who was not the treating doctor. The sample

size was an estimate based on using *t* test, expected difference in mean values of 0.30, expected standard deviation of 0.04, $\alpha_1 = .05$ ($\alpha_2 = .10$), and power of 0.8, which required a sample size of 29 for the study. There were no interim analyses and preset stopping rules, except in case of discomfort that occurred to the subjects. All study procedures were approved by the institutional review board at Logan College of Chiropractic and explained to each subject before testing. All subjects had to sign a written informed consent before their participation in the study. All data collection was conducted at the research department of the college. Newspaper ads and personal contact were used to recruit LBP patients.

Inclusion criteria

Subjects of different age, sex, and racial background were included in the project. *Acute LBP* was defined as onset of pain within 3 months or current episode of LBP from chronic LBP.

Exclusion criteria

Subjects with heart failure and kidney diseases were excluded from the study. Subjects under medical treatment or who had had surgery and trauma, such as a recent car accident, were excluded. Subjects demonstrating radiating symptoms indicative of herniated or degenerative disks or spinal stenosis were also excluded. Subjects with LBP of over 3 month' duration were disqualified from the study unless it had been an acute episode of LBP. Subjects were disqualified if they were taking any type of prescription medication or nonsteroidal anti-inflammatory drug products for LBP.

Outcome measures

The data were collected at the baseline, 2 weeks after commencing treatment, and after 4 weeks of treatment.

1. Visual analog scale (VAS) for LBP: Subjects used a pen marking on a horizontal line to indicate their pain severity on a pain level of 0 to 10.³⁴
2. The Roland Morris Disability Questionnaire: A standard 24-question Roland Morris Disability Questionnaire was used for the assessment of LBP on daily function.³⁵
3. Low back muscle EMG³⁶: Electromyographic data were recorded at 1000 Hz by surface electrodes. The surface electrodes were connected to an amplifier and streamed continuously through an analog-to-digital converter (Biopac Systems, Inc, Goleta, CA)

to an IBM-compatible notebook computer. All data were filtered with a 10-Hz high-pass filter according to the methods described by Tiller et al³⁷ and saved with the use of computer software (Acqknowledge 3.5; Biopac Systems, Inc). Two EMG modules were used for each EMG recording session. Each EMG module had 3 electrodes: positive, negative, and ground. One module's 3 electrodes were placed on the right side of the lower back, and the other modules were placed on the left side of the lower back. All subjects' EMGs were recorded while in standing position. Once resting EMG was recorded, the subject was instructed to bend forward while a dynamic EMG was recorded.

4. Heart rate variability analysis was performed using the Biocom HRV device (Biocom, Seattle, WA).
5. Disposable electrodes (silver/silver chloride) were used for all bipolar electrocardiographic measurements. The positive electrode was placed on the left arm, the negative electrode was attached to the right arm, and the ground electrode was placed on the left leg. The spectral analysis of this signal was obtained from a successive discrete series of R-R duration values taken from the electrocardiographic signal sampled at 256 Hz and transformed by the fast Fourier technique. All post analyses, including fast Fourier transforms, power spectral density, and time domain measurements, were performed with digital signal processing software.¹⁹

Treatment

Diversified manual adjustments twice a week for 4 weeks were provided by licensed chiropractors. The treating doctors had training sessions to make sure that they provided consistent care to patients. These discussion and training sessions were designed to reduce variations in the treatment results. All subjects were required to come to the research department to complete the adjustments and testing. Application of Biofreeze was followed by chiropractic adjustments on treatment days.

For at-home care, subjects were instructed to apply Biofreeze 3 times a day as follows: Using a 5-g sample pack, subjects were instructed to apply Biofreeze to the low back once in the morning and 2 times in the afternoon. For evening application, subjects were instructed to apply once in the late afternoon, once in the evening, and once at bedtime. Subjects were to apply Biofreeze until the gel had penetrated—approximately 30 seconds to 1 minute per side,

starting on the low back just above the tailbone in the lumbar region. They were also instructed to apply half of the Biofreeze packet from the hand to the fingers and palms, massaging it in a circular motion to one side of the low back, stopping approximately a few inches above the waistline, and applying the rest of the packet to the other side. If the area was difficult to reach, subjects were advised to ask for assistance to apply the Biofreeze.

All continuous data were expressed in mean and standard deviation and analyzed by Student *t* tests. A *P* value < .05 was considered significant. The SPSS (SPSS, Inc, Chicago, IL) statistical analysis software was used in the analysis.

Results

A total of 36 subjects (25 male, 11 female) with an average age of 34 years were recruited to the study. Eighteen subjects were in the control group, and 18 were in the experimental group. Three adjusting chiropractors provided care. It was not feasible for one doctor to perform all the treatments over the study period. Although the treatment period for each patient was 4 weeks, there was overlapping of patient recruitment and treatment over the study period.

1. Visual analog scales: Significant pain reduction was found after each week of treatment ($P < .05$, from 4.091 ± 2.343 to 1.333 ± 1.732) in the experimental group. There were no significant differences for the control groups (4.428 ± 2.376 to 5.2 ± 2.167 , $P > .05$) (Fig 1).
2. Roland Morris Disability Questionnaire: There were no significant changes in the Roland Morris Disability Questionnaire scores for both groups after 4 weeks of Biofreeze and chiropractic

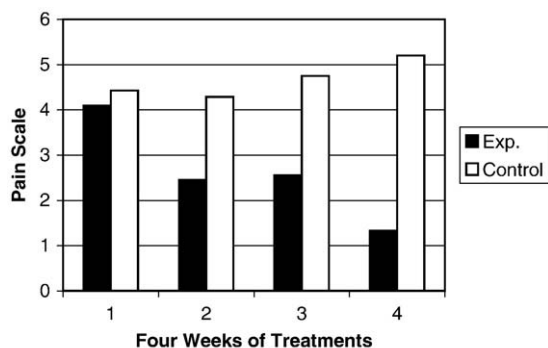


Fig 1. Effect of Biofreeze and chiropractic adjustment for 4 weeks on LBP.

Table 1 Changes in Roland Morris Disability Questionnaire scores across 4 weeks of treatments

	Adjustment	Adjustment + Biofreeze
Baseline	5.000 ± 6.049	5.000 ± 4.314
Week 2	3.909 ± 6.347	4.643 ± 4.106
Week 3	5.000 ± 7.433	5.000 ± 4.513
Week 4	3.600 ± 5.412	8.000 ± 3.807
<i>P</i> Value (Within Group)	>.05	>.05

adjustments ($P > .05$) (Table 1). The scores improved in the second week as shown in Table 1, but it bounced back in the third week to the baseline level.

3. Heart rate variability analysis: There were no significant changes in HRV analysis for both groups after 4 weeks of Biofreeze and chiropractic adjustments ($P > .05$) (Tables 2, 3).
4. Surface EMG analysis: The surface EMG in the experimental group showed consistent resting potentials over the 4-week study period, whereas the control group had more variations in resting EMG readings. However, there were no statistically significant changes in the EMG readings between the 2 groups (Tables 4, 5).

Discussion

The major component of Biofreeze is menthol, which is the world's most widely used food-flavoring compound, with an annual production of more than 3500 tons.³⁸ Menthol is an alcohol derivative and is naturally found in plants of the *Mentha* species that have the typical mint smell and flavor. Menthol is a highly lipid-soluble substance and metabolizes into glucuronide compounds, which are much more water soluble and more readily excreted in the urine.

The major effect of menthol when applied to the skin is to cause a sensation of coolness or warmth, attributed to the stimulation of thermoreceptors recognized by Goldscheider in 1886.³⁹ The mechanism of action is believed to be on specific sensory nerve endings and thermoreceptors in the skin.²⁷ Menthol exerts its effects on cold receptors by interfering with the movement of calcium across the cell membrane. Menthol caused an increase in calcium concentration in the nasal area of the cat; it also caused a marked increase in the frequency of warm-receptor discharge and a depression in the discharge of cold receptors.^{40,41}

Table 2 Heart rate variability analysis of the experimental group over a 4-week period

	Mean NN	Mean HRT	SDNN	RMSSD	Total Power	VLF	LF	HF	LFNorm	HFNorm	LF/HF
Baseline											
Mean	777.317	78.0799	56.9948	44.94924	1072.053	334.4977	517.5409	220.0145	76.04153	23.95848	4.580123
SD	83.32889	9.069486	27.97229	27.16118	880.0112	251.287	439.3095	283.4354	13.14943	13.14943	3.174537
Fourth week											
Mean	759.3806	80.63403	63.39133	57.64812	1509.88	571.5804	573.9766	364.3227	67.23875	32.76124	3.450067
SD	113.3062	11.89603	36.0342	42.825	1881.797	766.9527	700.687	764.5625	20.62019	20.62019	2.732027
<i>t</i> Test	0.527654	0.386982	0.286636	0.093633	0.272592	0.255567	0.696424	0.404808	0.167124	0.167125	0.362522

Mean NN, normal to normal; HRT, heart rate; SDNN, standard deviation of normal to normal interval; RMSSD, square root of the mean squared differences of successive NN interval; VLF, very low frequency; LF, low frequency; HF, high frequency; LFNorm, normalized low frequency; HFNorm, normalized high frequency.

Table 3 Heart rate variability analysis of the chiropractic adjustment–only group over a 4-week period

	Mean NN	Mean HRT	SDNN	RMSSD	Total Power	VLF	LF	HF	LFNorm	HFNorm	LF/HF
Baseline											
Mean	851.8375	72.88225	139.6731	150.7414	272457.2	230832.7	34890.45	6733.984	71.91562	28.08438	4.524799
SD	177.0228	12.82346	254.3074	321.5155	1048830	892005	132306.6	24523.06	20.62763	20.62764	3.463004
Fourth week											
Mean	796.0744	77.09393	63.21569	54.80205	1743.116	806.7853	583.3312	352.9991	67.8913	32.10872	3.571344
SD	120.2323	12.77549	41.44921	40.62335	2537.489	1557.976	604.0656	504.6002	17.3477	17.34768	3.688321
<i>t</i> Test	0.13467	0.176416	0.237125	0.258253	0.338139	0.338501	0.337384	0.329042	0.796787	0.796787	0.659978

Mean NN, normal to normal; HRT, heart rate; SDNN, standard deviation of normal to normal interval; RMSSD, square root of the mean squared differences of successive NN interval; VLF, very low frequency; LF, low frequency; HF, high frequency; LFNorm, normalized low frequency; HFNorm, normalized high frequency.

Table 4 Electromyogram of the experimental group over a 4 week period

	Baseline			Fourth week		
	Min	Max	Mean	Min	Max	Mean
Mean	-0.05824	0.124512	-0.06949	0.005798	0.084382	0.000347
SD	0.113845	0.10208	0.13693	0.074285	0.084007	0.036602
<i>t</i> Test	0.895805	0.526835	0.227039			

The cooling effect of menthol is used widely in sports medicine to reduce pain in acute injuries.^{28,29} The pain-reducing effect over the 4-week study period was demonstrated using the visual analog scale for LBP. Subjects responded positively in using the pain-relieving gel. Cooling sensation was reported by subjects immediately after applying the gel to the lower back. The significant pain reduction effect was not seen in the chiropractic adjustment-only group. Despite reduction of pain, the Roland Morris Disability Questionnaire did not show significant improvement in function in the treatment group.

It was surprising that the chiropractic adjustment group did not show significant pain relief after 4 weeks of care. The failure to show significant pain relief in the chiropractic group could be a random error due to the small sample size or caused by variations introduced by the treating doctors using different adjustment positions and forces applied. Although a training session was provided for doctors before the study began, it was difficult to maintain the same adjustments throughout the study. This was one of the limitations of the current study. The reason for having 3 doctors for the treatments was the busy schedules of all treating doctors and the scattered patient visits at the treating clinic. It was not feasible for one doctor to complete the entire study, as doctors had other duties to perform. By introducing variables from the treating doctors, the study resulted in less consistent treatment effects. On the other hand, Biofreeze can be applied by patients at home; it was not affected by changing the treating doctors. Therefore, the pain-relieving effect from Biofreeze was more consistent over the 4-week period.

The resting EMG at the standing position showed less variation in the study group with Biofreeze compared with the adjustment-only group. It was not clear why the resting EMG showed these large differences between the 2 groups and whether this reduction of resting EMG played any role in the pain-relieving effect of the Biofreeze. It was noted that the chiropractic adjustment group had a reduction of resting EMG at the fourth week, despite large variations of resting potential changes in the first 3 weeks.

The HRV analysis was used in the study to show the stress levels in patient with acute LBP. If the stress level associated with acute LBP was reduced after effective treatment, the HRV analysis should show an improvement in the total power and standard deviation of normal to normal heartbeats. However, because of the small sample size, there were no significant differences between the treatment and active control groups. It was not clear based on this study whether HRV was associated with the pain reduction. Further study is needed to investigate the relationship of LBP and the autonomic nervous system activity.

Conclusions

Biofreeze combined with chiropractic adjustments significantly reduced acute LBP when compared with an active control group. There were no significant changes in the Roland Morris Disability Questionnaire, HRV, or EMG in both groups. Further studies with larger sample sizes are needed to confirm the findings of the study.

Table 5 Electromyogram of the chiropractic adjustment-only group over a 4-week period

	Baseline			Fourth week		
	Min	Max	Mean	Min	Max	Mean
Mean	-0.0287	0.111846	-0.02045	-0.104	0.135192	-0.01151
SD	0.121715	0.077657	0.063446	0.057561	0.102494	0.054276
<i>t</i> Test	0.200423	0.650108	0.065011			

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