



Official Measures of Negative Ion Emissions of Sports Bands

The bands listed below were ordered independently and anonymously online. Lisa Tully, PhD, founder of Energy Medicine Research Institute, Boulder, CO, conducted measurements on each band using a standardized protocol to ensure accurate test results. Each band was coiled and placed in the meter on its side in the same way for each test to avoid variance in results. The COM SYSTEMS 3010 Pro Negative Ion Tester (the industry standard) was used to measure negative ion emission of each band. Results are given below.

Band	Negative Ion Emission (cc/sec)
Fusion IONZ	3290
Ion Me	2495
Ionic Balance	2390
Ionic Strength	1985
I-ionics	1820
Life Strength	1587
True Power	1167
Ion Loop	1132
Energy Armor	1097
Pro Connect	483
Power Balance	308
EFX	208
Phiten	99
Trionz	60

Lisa Tully, PhD
Signature

7/16/13
Date

Report for Double Blind Placebo Crossover Human Clinical Study of the Efficacy of the Fusion IONZ Band in Improving Flexibility, Strength, Balance and Endurance in Healthy Subjects

July 2, 2013

Submitted by **Energy Medicine Research Institute**, Lisa Tully, PhD, founder

Abstract: A human clinical study examined the efficacy of the Fusion IONZ Band to increase flexibility, strength, balance and endurance in 16 healthy subjects. Results demonstrate that the Fusion IONZ Band significantly increases performance in every test of flexibility, balance, strength and endurance except bicep curl maximum weight. The average increase for all tests was 14.42% and the difference between active and placebo was 20.72%.

Introduction

The Fusion IONZ Band(<http://www.fusionIONZ.com/>) is a silicone band imbedded with a proprietary mineral mixture of black tourmaline, germanium and titanium which is a natural source of negative ions. The wristbands were tested in a temperature and humidity controlled laboratory environment with the COM SYSTEMS 3010 Pro Negative Ion Tester - the industry standard. Fusion IONZ wristbands emit up to 4,000 negative ions (anions) per cm³ per second. To date, over 5000 scientific studies have been conducted on the physiological effects of negative ions.

German and Japanese scientists have discovered that tourmaline can radiate energy of 8-12 Hz or alpha waves. Tourmaline also emits far infrared rays. Black tourmaline is thought to have health benefits, including increase circulation, which may improve athletic performance. The Fusion IONZ Band is designed to restore balance, enabling peak performance and a subsequent improvement in overall well-being. There are no known contra-indications for the Fusion IONZ Band.

In this clinical study, tests were conducted that measure flexibility, strength and endurance in 16 healthy humans. Tests conducted included: stretch and reach, hand strength, maximum sit ups in 30 seconds, maximum push ups in 30 seconds, maximum bicep curl weight, maximum bicep curl repetitions and outcome measures with an ergometer bicycle (peak and average power and watts per kilogram, average and peak speed and speed per kilogram, distance and calories. These results demonstrate that the Fusion IONZ Band improves performance in several different tests of flexibility, strength and endurance in healthy humans.

Methods

Sixteen healthy individuals (12 male and 4 female) ranging from 20-57 years of age with no history of disease, pregnancy, drug or alcohol use, or on any medications were subjects in this study. All subjects were in good general health and did not have a high level of fitness.

Institutional Review Board approval was obtained for this study. A baseline measurement was conducted utilizing flexibility and balance tests and ten different strength and endurance tests, described below. At the baseline testing, subjects were given either the active or placebo band to be worn at the second testing.

Subjects were instructed to begin wearing the band and continue wearing the band for one week. They returned after one week (to allow recovery time) for retesting. After the second testing, subjects were given the band that was not tested at the second visit and asked to begin wearing the band for one week, at which time they were retested. The bands were coded so that neither the subject nor the person administering the tests knew which band was being tested. Half of the subjects wore the placebo bands first and the other half wore the active band first to prevent a “learning effect”. The subjects were instructed to refrain from strenuous exercise for 2 days prior to testing. Before each test, subjects were asked to rate their energy level on a scale of 1 to 10.

Flexibility Test

Subjects sat on the floor against a wall with feet against the stretch and reach measuring device (<http://www.fitnessgiant.com/noname16.html>) and reach as far forward as they can. The distance reached was measured three times and the highest value recorded

Balance Test

Participants stood on one foot with eyes closed and arms outstretched. They touched their nose with each index finger. The length of time until their other foot touched the floor was recorded.

Strength Tests

A) Digital Hydraulic Hand Grip Dynamometer

Subjects squeezed the hand grip dynamometer (<http://www.topendsports.com/testing/store-strength.htm>) as hard as they can in each hand. tested, with the arm at right angles and the elbow by the side of the body. The handle of the dynamometer was adjusted if required - the base should rest on first metacarpal (heel of palm), while the handle should rest on middle of four fingers. The subject squeezed the dynamometer with maximum isometric effort, which is maintained for about 5 seconds. No other body movement is allowed. The subject should be strongly encouraged to give a maximum effort. Two measurements with each hand were recorded and the highest score was recorded.

B) One Repetition Maximum Test to Measure Maximum Strength of the Bicep.

Bicep Curl maximum weight was determined by having the subject perform a bicep curl with a five pound free weight using the dominant arm. The weight was increased by five pounds until the subject could no longer lift the weight with proper form. If the subject was unable to lift the weight, 2.5 pound weights were used as increments to determine the maximum weight that can be lifted and this weight was recorded.

C) Maximum Sit Ups and Push Ups in 30 Seconds

Subjects did as many sit ups as they could in 30 seconds with their feet held down and knees

bent. The number was recorded. This was repeated after a 5 minute rest with push ups, either leaning against the wall, on knees or on toes. The same posture was used for all tests and the maximum number performed in 30 seconds was recorded.

D) Five Minute Road Course Ergometer Measurements: Peak Speed, Watts and Peak Speed and Watts per Kilogram

Subjects were asked to pedal on a stationary bike with an ergometer at their peak performance for five minutes. Peak speed and watts and peak speed and watts per kilogram were recorded.

Endurance

A) Bicep Curl Repetition to Failure

This test was done last to allow recovery time. The dominant arm was used to curl 70% of the maximum weight to failure and this number was recorded.

B) Maximum Sit Ups and Push Ups in 30 Seconds

Subjects did as many sit ups as they could in 30 seconds with their feet held down and knees bent. The number was recorded. This was repeated after a 5 minute rest with push ups, either leaning against the wall, on knees or on toes. The same posture was used for all tests and the maximum number performed in 30 seconds was recorded.

C) Five Minute Road Course Ergometer Measurements: Average Speed and Watts, Average Speed and Watts per Kilogram, Calories and Distance

Subjects were asked to pedal on a stationary bike at their peak performance for five minutes. Distance, average speed, calories and peak watts per kilogram were recorded.

Statistical Methods:

Descriptive statistics were generated to summarize clinical outcomes. Specifically, all outcome measures were summarized in terms of number of means, standard deviations, and ranges (minimum, maximum), stratified by group (placebo vs. active). Absolute changes from baseline were computed for all outcome variables. A paired t-test was used to evaluate changes from baseline within each group. The comparison of changes from baseline between groups was performed using the Grizzle model for cross over studies. A p values are two-tailed and $P < 0.05$ indicates statistical significant differences. Data analysis was performed using SAS[®] version 9.2 software (SAS Corp., Cary, NC). The Grizzle model for 2 X 2 cross over study design was used to evaluate the carry over or learning effect.

Results

Table 1 shows the results for absolute change from baseline for all outcome measures of those wearing the active Fusion IONZ Band. As shown in Table 1, the active Fusion IONZ Band produced increased absolute changes from baseline values for all outcome measures and the p-value¹ column shows that these changes were highly significant ($p < 0.001$ for all except balance, $p = 0.003$) and maximum bicep curls was not significant ($p = 0.188$). Reported energy levels were significantly increased from baseline ($p = 0.041$).

Table 1. Summary statistics for absolute change from baseline for outcome measures with the active Fusion IONZ Band.

ACTIVE FUSION IONZ BAND					
Parameter	Mean	SD	Min	Max	p-value¹
Stretch and Reach	0.97	0.37	0.50	1.75	<0.001***
Balance	2.63	2.94	0.29	10.67	0.003**
L Hand Strength	6.50	4.20	2.00	17.00	<0.001***
R Hand Strength	7.31	3.50	2.00	13.00	<0.001***
Max Sit Ups	1.94	9.31	1	3.00	<0.001***
Max Push Ups	3.06	1.06	2.00	5.00	<0.001***
Max Bicep Curl	0.47	1.36	0.00	5.00	0.188
Reps to Failure	3.44	3.98	-6.00	10.00	0.004**
Ave Speed	0.99	0.35	0.60	1.91	<0.001***
Peak Speed	1.17	0.87	0.20	3.15	<0.001***
Ave Watts	5.81	6.43	-1.00	20.80	0.003**
Peak Watts	15.49	11.71	5.00	49.00	<0.001***
Ave WPKG	0.39	0.22	0.10	0.80	<0.001***
Peak WPKG	0.43	0.33	-0.10	1.10	<0.001***
Calories	5.25	2.96	2.00	13.00	<0.001***
Distance	0.13	0.09	0.07	0.44	<0.001***
Energy Level	0.50	0.89	-1.00	2.00	0.041*

¹ p-value for evaluating changes from baseline within active group

² p-value for comparison of changes from baseline between placebo band vs. active band

* p<0.05

** p<0.01

*** p<0.001

Definition of statistical term in tables:

Mean=average values for all subjects

SD-Standard Deviation, how much the data varies from the mean (average of all the data)

Min-minimum or lowest value

Max-maximum or highest value

p-value-the probability that the data is different than the comparison (baseline or placebo) value. A p-value of less than 0.05 indicates that the data is significantly different from the comparison measure. The lower the p-value, the more different the test value is from the comparison test value.

In contrast, Table 2 shows that for the placebo band there were decreases from baseline for nine of the performance measures (balance, left and right hand strength, maximum sit ups and push ups, bicep curl repetitions to failure, average watts, watts per kilogram and calories) and no change for distance. The only test that demonstrated a significant difference from baseline (p=0.023) was a negative change (-0.94). There was not a significant difference in reported energy levels.

The p-value² column of Table 2 shows the comparison of changes produced by the active and placebo bands. As shown, there were highly significant (p<0.001) increases for the active band compared to the placebo band for all outcome measures, and maximum sit ups (p=0.042) and average watts (p<0.033), which had lower significance levels.

Table 2. Summary statistics for change from baseline for outcome measures with the placebo band.

PLACEBO FUSION IONZ BAND						
Parameter	Mean	SD	Min	Max	p-value²	p-value³
Stretch and Reach	0.04	0.23	-0.42	0.42	0.539	0.001***
Balance	-0.63	1.43	-3.33	1.33	0.100	0.002**
L Hand Strength	-0.63	1.31	-4.00	1.00	0.076	<0.001***
R Hand Strength	-0.94	1.48	-4.00	2.00	0.023	<0.001***
Max Sit Ups	-0.13	0.34	-1.00	0.00	0.164	0.042*
Max Push Ups	-0.13	0.34	-1.00	0.00	0.164	<0.001***
Max Bicep Curl	0.00	0.00	0.00	0.00	NA	NA
Reps to Failure	-0.31	0.60	-1.00	1.00	0.055	0.002**
Ave Speed	0.00	0.18	-0.30	0.30	1.000	<0.001***
Peak Speed	0.08	0.20	-0.10	0.50	0.131	<0.001***
Ave Watts	-0.19	1.28	-3.00	2.70	0.568	0.033*
Peak Watts	0.34	1.94	-2.30	4.60	0.488	<0.001***
Ave WPKG	-0.01	0.07	-0.10	0.20	0.718	<0.001***
Peak WPKG	0.04	0.24	-0.10	0.90	0.535	0.001**
Calories	-0.38	1.09	-2.00	2.00	0.188	<0.001***
Distance	0.00	0.02	-0.03	0.05	0.999	<0.001***
Energy Level	0.19	0.83	-2.00	2.00	0.383	0.172

¹ p-value for evaluating changes from baseline within active group

² p-value for comparison of changes from baseline between placebo band vs. active band

* p<0.05

** p<0.01

*** p<0.001

Table 3 shows results for all outcome measures with the active Fusion IONZ when expressed as percent change from baseline. The active band produced a positive percentage increase for every outcome measure, with the mean value for each outcome measure ranging from 2.5% to 27.7%. The average percentage increase for all measures was 14.42%.

Table 3. Percentage change from baseline for outcome measures with the active band.

Parameter	Mean	SD	Min	Max
Stretch and Reach	9.0%	3.8%	3.8%	15.9%
Balance	27.7%	20.3%	6.2%	66.7%
L Hand Strength	10.3%	6.1%	2.0%	27.4%
R Hand Strength	11.0%	6.1%	4.8%	25.6%
Max Sit Ups	11.4%	5.7%	16.7%	16.7%
Max Push Ups	14.3%	5.8%	4.2%	29.4%
Max Bicep Curl	2.5%	8.4%	0.0%	33.3%
Reps to Failure	24.2%	21.8%	-30.8%	66.7%
Ave Speed	8.2%	3.3%	4.5%	17.1%
Peak Speed	8.6%	6.7%	1.3%	23.7%
Ave Watts	7.3%	26.1%	4.7%	32.3%
Peak Watts	12.1%	7.7%	3.2%	30.4%
Ave WPKG	30.5%	16.6%	5.3%	50.0%
Peak WPKG	25.4%	16.8%	-3.8%	55.6%
Calories	22.0%	10.1%	6.9%	41.9%
Distance	12.5%	7.8%	6.4%	36.4%
Energy Level	8.2%	15.0%	-16.7%	40.0%

In contrast, nine out of 16 outcome measures were negative percentage changes from baseline, two had no change and five were increases from baseline with placebo. The values ranged from -11.5 to 4.6% and the average was -6.3% .

Table 4. Percentage change from baseline for outcome measures with the placebo band.

Parameter	Mean	SD	Min	Max
Stretch and Reach	0.4%	2.2%	-4.5%	3.6%
Balance	-11.5%	29.2%	-100.0%	38.4%
L Hand Strength	-1.3%	2.6%	-8.9%	2.3%
R Hand Strength	-1.3%	2.2%	-5.0%	3.2%
Max Sit Ups	-0.5%	1.3%	-4.8%	0.0%
Max Push Ups	-0.4%	1.2%	-4.3%	0.0%
Max Bicep Curl	0.0%	0.0%	0.0%	0.0%
Reps to Failure	-1.7%	3.7%	-8.3%	6.7%
Ave Speed	0.0%	1.4%	-2.3%	2.0%
Peak Speed	0.6%	1.4%	-0.9%	3.8%
Ave Watts	-0.2%	1.1%	-2.6%	1.7%
Peak Watts	0.4%	1.6%	-1.7%	3.7%
Ave WPKG	-0.6%	3.2%	-6.3%	7.7%
Peak WPKG	4.6%	23.0%	-7.1%	90.0%
Calories	-1.2%	4.5%	-5.3%	6.7%
Distance	0.0%	1.7%	-2.3%	4.1%
Energy Level	3.1%	12.0%	-25.0%	33.3%

There is no evidence for “carryover effect”, which occurs when learning occurs as a result of repeating the tests for all tests except stretch and reach, which had a lower level of significance (p=0.033). There is no significant difference in the comparison between active band followed by placebo band versus placebo band differences between the treatment arms (whether the active or placebo band was worn first). This demonstrates that there was no learning effect from repeating the measures. The p-values for the comparison for carryover effect are given in the p-value column of Table 5. There were no significant differences in outcome measures resulting from the order of band.

Table 5. Analysis of learning effect with the Fusion IONZ Band.

Outcome	p-value for carry-over effect
Stretch and Reach	0.033*
Balance	0.944
L Hand Strength	0.762
R Hand Strength	0.695
Max Sit Ups	0.244
Max Push Ups	0.826
Max Bicep Curl	0.783
Reps to Failure	0.376
Ave Speed	0.798
Peak Speed	0.959
Ave Watts	0.417
Peak Watts	0.477
Ave WPKG	0.362
Peak WPKG	0.859
Calories	0.984
Distance	0.942

* p<0.05

Flexibility Test

The Fusion IONZ Band increased the stretch and reach measure by a mean value of 0.97 inches (Table 1, p=0.001), a highly significant improvement. The change produced by the placebo band was 0.04 inches and not significantly different from baseline (Table 3, p=0.539). There was a highly significant difference between the active and placebo bands (Table 1, P=0.001).

Balance Test

The length of time balancing on one foot with eyes closed and arms outstretched significantly increased by a mean value of 2.83 seconds (Table 1, p=0.003) for the active band, versus a decrease of -0.63 seconds (Table 2, p=0.1) for the placebo band. There was a significant difference between the active and placebo bands (p=0.002).

Strength Tests

As seen in Table 1, all of the strength tests resulted in highly significant absolute changes from baseline with the active Fusion IONZ Band compared to the placebo band, except maximum bicep curl (p=0.188). The increase in left and right hand strength, bicep curl

repetitions to failure, peak speed, peak power and peak watts per kilogram with the Fusion IONZ Band were highly significant ($p < 0.001$).

Endurance Tests

Table 1 shows that there was a highly significant ($p < 0.001$) increase from baseline for all of the endurance measures with the active band (maximum sit ups in 30 seconds, maximum push ups in 30 seconds, average speed and watts. average speed and watts per kilogram, calories and distance, except bicep curl repetition to failure, which had a slightly less significance value ($p = 0.004$). There also was a highly significant ($p < 0.001$) increase from baseline between the active and placebo bands.

Table 6 demonstrates that the groups were properly randomized. There were no significant differences at baseline detected between subjects who were randomized to the Active-Placebo sequence versus placebo-active sequence.

Table 6. Comparison of outcome measures at baseline between subjects who were randomized to the active-placebo sequence vs. placebo-active sequence

Outcome Measure	Active-Placebo Sequence (N=9)				Placebo-Active Sequence (N=7)				p-value
	Mean	SD	Min	Max	Mean	SD	Min	Max	
Stretch and Reach	11.25	1.48	9.42	13.66	10.79	1.21	9.00	12.42	0.514
Balance	5.75	4.65	0.00	14.11	13.38	14.10	0.00	33.44	0.148
L Hand Strength	66.44	18.45	44.00	98.00	63.00	20.62	44.00	100.00	0.730
R Hand Strength	69.56	20.76	39.00	105.00	72.00	29.15	31.00	121.00	0.847
Max Sit Ups	21.00	5.20	15.00	31.00	20.57	9.00	10.00	39.00	0.906
Max Push Ups	23.00	6.82	17.00	40.00	23.43	11.63	12.00	48.00	0.928
Max Bicep Curl	26.11	11.12	15.00	50.00	26.43	13.45	10.00	50.00	0.959
Reps to Failure	16.56	4.45	10.00	26.00	14.57	3.10	10.00	20.00	0.333
Ave Speed	12.57	1.66	10.60	16.10	12.04	2.21	10.10	16.10	0.596
Peak Speed	14.34	2.12	11.24	18.30	13.64	2.71	11.10	18.20	0.573
Ave Watts	117.07	19.31	96.70	154.60	104.49	26.41	76.40	144.10	0.288
Peak Watts	134.02	34.88	101.20	210.30	121.66	32.46	83.00	161.30	0.481
Ave WPKG	1.59	0.55	0.80	2.60	1.31	0.66	0.60	2.10	0.379
Peak WPKG	1.91	0.60	1.00	3.00	1.83	1.04	0.80	3.60	0.844
Calories	23.78	4.71	19.00	31.00	24.14	7.60	15.00	38.00	0.907
Distance	1.07	0.10	0.88	1.21	1.02	0.17	0.80	1.28	0.501

Discussion

Results of this double blind crossover pilot study demonstrate that the Fusion IONZ Band produces a significant increase in performance for all of the tests of flexibility, strength and endurance that were conducted (stretch and reach, left and right hand strength, bicep curl repetitions to failure, maximum sit ups in 30 seconds, maximum push ups in 30 seconds, maximum peak and average speed, peak and average watts, peak and average watts per kilogram, and distance) except bicep curl maximum weight. There was a high level of

significance for most of the outcome measures, indicating a dramatic improvement in athletic performance.

Interestingly, nearly every subject had an increase in the change from baseline with the active Fusion IONZ for every outcome measure. The average percent change from baseline was as high as 27.7%, which the average being 14.42%. This consistent effect across all subjects demonstrates that the Fusion IONZ has a positive action on nearly everyone that wears it.

Conversely, the placebo band produced decreases in more than half of the outcome measures, no change in change bicep curl maximum weight and did not produce a significant increase the remaining outcome measures. Furthermore, there was a highly significant difference between the active and placebo bands in all tests of strength, balance, flexibility and endurance.

When expressed as percentage change, the placebo produced mostly negative changes from baseline and the average was -6.25%. The difference between the average values of active and placebo was 20.72%.

In a self report of energy levels, the active Fusion IONZ Band produced a significant increase in energy that was over twice that of placebo. In addition, the placebo band did not produce a significant increase in energy levels.

Although the absolute changes seem small for some of these tests, they are significant changes, especially when one takes into account the importance of lifting a weight that is only a few pounds heavier. The same conclusion is true for the stretch and reach test, using distance as the endpoint rather than weight lifted. Furthermore, the increases observed with the active Fusion IONZ Band had a high level of significance, demonstrating the efficacy of the Fusion IONZ Band in the tests.

Factors that can influence the outcome were analyzed and found to have no effects on the outcomes. All of the subjects were properly randomized, as shown by the lack of difference between baseline measures between the active and placebo groups. Additionally, there was no “learning effect” (that can occur as a result of repeating a test, regardless of the length of the washout period), except for stretch and reach, which had a low level of significance ($p=0.033$). Perhaps people get more limber from repeating this test.

The tests utilized in this pilot study are objective measures of flexibility, balance, strength and endurance that are used in standard athletic testing. They are academically credible and superior to applied kinesiology tests that are commonly used to demonstrate the efficacy of products that increase athletic performance.

Conclusions

This double blind crossover clinical trial shows that the Fusion IONZ Band produces a highly significant increase in all tests of flexibility, balance, strength and endurance in 16 healthy humans when worn for one week, which is correlated with a reported increase in energy.

The average percentage increase with the Fusion IONZ was 14.42% and the difference between active and placebo was 20 72%. It is likely that the Fusion IONZ Band will produce greater or sustained effects when worn for longer periods.

Research Team

Research was conducted by Lisa Tully, PhD, owner of Energy Medicine Research Institute and Ryan Shilling, owner of Watts Up. Both companies are based in Boulder, Colorado.

Dr. Lisa Tully received her PhD in Pharmacology and Toxicology from the Indiana University School of Medicine. Dr. Tully has several publications in peer-reviewed medical journals and has presented her research at international scientific conferences. Following her postdoctoral fellowship, Dr. Tully shifted from academic medical research to pursuits in integrative medicine and has attended many international medical conferences over the past decade, evaluating low cost and effective health care.

Dr. Tully is currently on the Scientific Advisory Board of several companies and non-profit organizations and is founder of the Energy Medicine Research Institute, whose mission is to assess the efficacy of vibrational medicine technologies and therapies.

Ryan Shilling, owner of Watts Up, a company that specializes in athletic training, has professionally tested athletes for a decade. He has performed testing for Athletic Republic, a company that trains athletes. He has conducted field tests on athletes specific to running and cycling. He specializes in testing athletes for strength, flexibility and endurance for training purposes.

Report for Double Blind Placebo Crossover Human Pilot Clinical Study of the Efficacy of the Fusion IONZ Band in Decreasing Pain in Healthy Subjects

July 15, 2013

Submitted by **Energy Medicine Research Institute**
Lisa Tully, PhD, founder

Abstract: A pilot human clinical study examined the efficacy of the Fusion IONZ Band to decrease pain as reported by the Visual Analog Scale (VAS) in 13 healthy subjects with chronic shoulder, elbow and wrist pain from overuse. Results demonstrate that the Fusion IONZ Band significantly decreases pain at 24 hours and one week of wearing the band.

Introduction

The Fusion IONZ Band(<http://www.fusionIONZ.com/>) is a silicone band imbedded with a proprietary mineral mixture of black tourmaline, germanium and titanium which is a natural source of negative ions. The wristbands were tested in a temperature and humidity controlled laboratory environment with the COM SYSTEMS 3010 Pro Negative Ion Tester - the industry standard. Fusion IONZ wristbands emit up to 4,000 negative ions (anions) per cm³ per second. To date, over 5000 scientific studies have been conducted on the physiological effects of negative ions.

German and Japanese scientists have discovered that tourmaline can radiate energy of 8-12 Hz or alpha waves. Tourmaline also emits far infrared rays. Black tourmaline is thought to have health benefits, including increase circulation, which may improve athletic performance. The Fusion IONZ Band is designed to restore balance, enabling peak performance and a subsequent improvement in overall well-being. There are no known contra-indications for the Fusion IONZ Band.

Several scientific studies have documented the health benefits of negative ions, including increased metabolism, better tissue oxygenation, and respiratory improvements. Anecdotal reports from individuals wearing negative ion emitting bands have indicated pain relief.

In this pilot clinical study, 13 healthy individuals with chronic pain were asked to rate their pain with the VAS for pain before, 15 minutes and 24 hours after wearing the Fusion IONZ band or placebo. These results demonstrate that the Fusion IONZ Band significantly decreases subjective chronic wrist, elbow and shoulder pain levels in healthy humans.

Methods

Thirteen healthy individuals (11 male and 2 female) ranging from 20-57 years of age with chronic shoulder, elbow, or wrist pain that have not had surgery were in the study. The participants of this study had no history of disease, pregnancy, drug or alcohol use, or were on any medications. All subjects were in good general health and did not have a high level of fitness.

Institutional Review Board approval was obtained for this study. Subjects were asked to rate their pain on a 1 to 10 scale (VAS) and then began wearing either the Fusion IONZ band or placebo. They repeated the VAS at 15 minutes and 24 hours.

After the 24-hour time point measure, subjects were asked to stop wearing the band for three days to allow for a washout period. At this time, subjects were asked to rate their pain and given the band that was not tested at the first visit. They were asked to rate their pain at 15 minutes and 14 hours. The bands were coded so that neither the subject nor the person administering the tests knew which band was being tested. Half of the subjects wore the placebo bands first and the other half wore the active band first to prevent a “learning effect”.

After both bands were tested, subjects were instructed to begin wearing the active band and continue wearing the band for one week at which time they were asked to rate their pain.

Statistical Methods:

Descriptive statistics were generated to summarize clinical outcomes. Specifically, all outcome measures were summarized in terms of number of means, standard deviations, and ranges (minimum, maximum), stratified by group (placebo vs. active). Absolute changes from baseline were computed for all outcome variables. A paired t-test was used to evaluate changes from baseline within each group. The comparison of changes from baseline between groups was performed using the Grizzle model for cross over studies. A p values are two-tailed and $P < 0.05$ indicates statistical significant differences. Data analysis was performed using SAS® version 9.2 software (SAS Corp., Cary, NC). The Grizzle model for 2 X 2 cross over study design was used to evaluate the carry over or learning effect.

Results

Table 1 shows the results for absolute change and percentage change from baseline at 15 minutes and 24 hours after wearing either active or placebo Fusion IONZ bands of those wearing the active Fusion IONZ Band. As shown in Table 1, the active Fusion IONZ Band produced significantly decreased absolute changes from baseline values at 24 hours and one week (p-value¹ column under active, $p < 0.01$). In contrast, the placebo band did not produce significant changes in pain levels (p-value¹ column under placebo). The drop in self-reported pain levels with the active Fusion IONZ band at 15 minutes, 24 hours and one week was -8.82, -20.46 and 29.46%, respectively. The p-value² column under placebo of Table 1 shows the comparison of changes produced by the active and placebo bands, which was significant at 24 hours.

Table 1. Self Reported Pain Levels are Decreased with Active but not Placebo Fusion IONZ Band.

	Active				Placebo			
	Time	Mean	SD	p-value ¹	Mean	SD	p-value ¹	p-value ²
Absolute Change	15 min	-0.50	1.19	0.1558	-0.10	0.28	0.2397	0.3031
	24 hrs	-1.00	1.04	0.0047**	0.08	0.28	0.3370	0.0052**
	1 week	-1.00	1.04	0.0047**				
% Change	15 min	-8.82%	22.43%	0.1815	-3.05%	9.26%	0.2589	0.4691
	24 hrs	-20.46%	22.02%	0.0058**	2.56%	9.25%	0.3370	0.0122*
	1 week	-29.46%	22.02%	0.0058**				

¹ p-value for evaluating changes from baseline within active group

² p-value for comparison of changes from baseline between placebo band vs. active band

** p<0.01

Definition of statistical term in tables:

Mean=average values for all subjects

SD-Standard Deviation, how much the data varies from the mean (average of all the data)

Min-minimum or lowest value

Max-maximum or highest value

p-value-the probability that the data is different than the comparison (baseline or placebo) value.

A p-value of

less than 0.05 indicates that the data is significantly different from the comparison measure.

The lower the p-value, the more different the test value is from the comparison test value.

Table 2 demonstrates that the groups were properly randomized. There were no significant differences at baseline detected between subjects who were randomized to the Active-Placebo sequence versus placebo-active sequence.

Table 2. Comparison of outcome measures at baseline between subjects who were randomized to the active-placebo sequence vs. placebo-active sequence.

Sequence: Active-Placebo N=7		Sequence Placebo-Active N=6		p-value
Mean	SD	Mean	SD	
4.71	1.25	5.50	2.51	0.4794

There is no evidence for “carryover effect”, which occurs when learning occurs as a result of repeating the tests. There is no significant difference in the comparison between active band followed by placebo band versus placebo band differences between the treatment arms (whether the active or placebo band was worn first). The p-values for the comparison for carryover effect are given in the p-value column of Table 3. There were no significant differences in outcome measures resulting from the order of band.

Table 3. There is No Learning Effect In the Study.

	Time	p-value
Absolute Change	15 min	0.9395
	23 hrs	0.7943
	1 week	
% Change	15 min	0.9450
	23 hrs	0.7685
	1 week	

Discussion

Results of this double blind crossover pilot study demonstrate that the Fusion IONZ Band produces a significant decrease in subjective pain ratings. The drop in self-reported pain levels with the active Fusion IONZ band at 15 minutes, 24 hours and one week was -8.82, -20.46 and -29.46%, respectively. There was a decrease in pain levels at the 15-minute time-point that was not significant. This is likely a result of variability. However, the pain level ratings at 24 hours and one week were significant. The changes in pain produced by placebo were not significant at 15 minutes and 24 hours. Furthermore, the changes between active and placebo were significant at 24 hours.

Interestingly, at the one week time point, most subjects reported an increase in mood and better workouts. Results of another study showed the Fusion IONZ band significantly increase performance in tests of strength, balance, flexibility and endurance. Therefore, it is likely that the Fusion IONZ band has several positive effects on health.

Factors that can influence the outcome were analyzed and found to have no effects on the outcomes. All of the subjects were properly randomized, as shown by the lack of difference between baseline measures between the active and placebo groups. Additionally, there was no “learning effect” (that can occur as a result of repeating a test, regardless of the length of the washout period).

Conclusions

This double blind crossover pilot clinical trial shows that the Fusion IONZ Band produces a highly significant decrease in subjective pain level ratings at 24 hours and one week and the placebo band did not produce a significant change. The average percentage decrease with the

active Fusion IONZ band was 29 46% one week after wearing the band. It is likely that the Fusion IONZ Band will produce greater or sustained effects when worn for longer periods.

Research Team

Research was conducted by Lisa Tully, PhD, owner of Energy Medicine Research Institute and Ryan Shilling, owner of Watts Up. Both companies are based in Boulder, Colorado.

Dr. Lisa Tully received her PhD in Pharmacology and Toxicology from the Indiana University School of Medicine. Dr. Tully has several publications in peer-reviewed medical journals and has presented her research at international scientific conferences. Following her postdoctoral fellowship, Dr. Tully shifted from academic medical research to pursuits in integrative medicine and has attended many international medical conferences over the past decade, evaluating low cost and effective health care.

Dr. Tully is currently on the Scientific Advisory Board of several companies and non-profit organizations and is founder of the Energy Medicine Research Institute, whose mission is to assess the efficacy of vibrational medicine technologies and therapies.

Ryan Shilling, owner of Watts Up, a company that specializes in athletic training, has professionally tested athletes for a decade. He has performed testing for Athletic Republic, a company that trains athletes. He has conducted field tests on athletes specific to running and cycling. He specializes in testing athletes for strength, flexibility and endurance for training purposes.