Original Article

Effect of "Ionized" Wrist Bracelets on Musculoskeletal Pain: A Randomized, Double-Blind, Placebo-Controlled Trial

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• *Objective*: To assess objectively the perceived benefits of wearing an "ionized" wrist bracelet to treat muscle or joint pain.

• *Subjects and Methods*: This study was performed at the Mayo Clinic in Jacksonville, Fla, in 2000 and 2001. In a randomized, double-blind design, 305 participants wore an ionized bracelet and 305 wore a placebo bracelet for 4 weeks. For each location where pain was present at baseline, participants rated the intensity of pain. Follow-up ratings were made after 1, 3, 7, 14, 21, and 28 days of wearing the bracelet. Two primary end points were defined for evaluating efficacy. The first was the change at 4-week follow-up (day 28) in the pain score at the location with the highest baseline value (maximum pain score). The second was the change at 4-week follow-up in the sum of the pain scores for all locations.

• *Results*: Analysis of the data showed significant improvement in pain scores in both groups, but no differences were observed between the group wearing the placebo bracelet and the group wearing the ionized bracelet.

• *Conclusion*: The finding that subjective improvement in pain scores was equivalent with ionized and placebo bracelet use questions the benefit of using an ionized bracelet. New treatments in alternative medical therapy must be shown to be effective through vigorous, unbiased, objective testing before physicians acknowledge potential benefits or recommend these treatments to patients.

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Treating pain involves multiple modalities. From medications to physical therapy and acupuncture, the options are numerous and varied. However, despite physicians' best efforts to provide pain relief, many patients continue to have pain. Increasingly, patients are trying unconventional treatments in place of traditional, evidence-based medical treatments. In fact, the interest in alternative medicine has grown considerably in recent years.[1,2] A population-based survey[3] indicated that 4 of 10 Americans used complementary and alternative medicine for chronic conditions in 1997 and made an estimated 629 million visits to practitioners of alternative medicine, far exceeding the 388 million visits that were made to primary care physicians during the same year. In addition, the total out-of-pocket expenditures related to the use of complementary and alternative medicine in 1997 were estimated at $27 billion, which is comparable to out-of-pocket expenditures for all physician services.[3,4]

Many methods used in alternative medicine are insufficiently tested or not tested at all.[5] Despite the enormous interest of the general public in alternative medical treatments, little evidence-based research supports claims about the efficacy of such methods. The reasons include lack of interest by the academic community, lack of financial support by corporate sponsors to fund research because the medications are already available, and difficulties in applying current regulatory criteria to alternative medicine.[1]

One alternative method previously untested in the United States is the use of "ionized" wrist bracelets for pain relief. Promotional information from the manufacturer states that the ionized bracelet can "energize the whole body," "relieve pain the natural way," and balance "Yin & Yang (positive and negative ions)." According to the Yin-Yang theory, a relationship exists among acupuncture points, meridians, and the electric currents of the body. An electric current is generated by an interaction of positively and negatively charged ions. If the flow of energy called "chi" remains unimpeded and in balance, individuals are believed to remain physically and mentally balanced and therefore in peak health.[6] According to the company's promotional information, the bracelets were invented by Dr Manuel Polo in 1973 in Spain. The "natural series" brace-

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lets used for this study were 85% copper and 15% zinc, and the cost was approximately $50 each. More expensive models (up to $179) are available from the manufacturer. The ionization process is a secret process not revealed by the manufacturer. A small study (50 patients) from China (not found in a review of the literature) reported benefit with use of the ionized bracelet for headache and for back, hip, leg, and hand pain over a 6-week period.[6] Although numerous professional athletes such as golfers, basketball stars, weight lifters, and hockey players have given testimonials regarding the benefits, questions remain about the effectiveness of these bracelets in relieving pain. We performed a randomized double-blind trial to assess objectively the effects of these ionized wrist bracelets on musculoskeletal pain.

SUBJECTS AND METHODS

Volunteers were recruited from advertisements posted at the Mayo Clinic in Jacksonville, Fla, in 2000 and 2001. Participants included 610 men and women, 18 years of age or older, who had self-reported pain at the beginning of the study in at least 1 of the following areas: neck, shoulders, elbows, wrists, hands, upper back, mid back, lower back, hips, knees, ankles, or feet.

Both ionized and placebo bracelets were provided by the manufacturer. The appearance of each bracelet was identical. The identity of each bracelet was blinded to the manufacturer, participants, and researchers until the study was completed. Specific instructions were given to each participant for correct placement of the bracelets according to the manufacturer's recommendations. This study was approved by the Mayo Foundation Institutional Review Board, and participants gave informed consent.

Procedures

Participants were randomly assigned to receive either an ionized wrist bracelet (Q-Ray, QT, Inc, Elk Grove Village, Ill) (n=305) or a placebo wrist bracelet of identical appearance (n=305).

Demographic information, collected on all 610 participants in an initial questionnaire, included age, sex, ethnic background, whether the participant had ever seen or used an ionized bracelet, and whether the participant believed that such a bracelet would reduce joint or muscle pain. Participants were asked to indicate the area in which they had pain and whether they had had a serious injury at that site. For each location where pain was present, participants rated the intensity of the pain on a scale of 1 to 10, with 1 indicating "very little pain" and 10 indicating "pain as bad as it could be." A follow-up questionnaire was given to evaluate pain at these locations after participants wore the bracelets for 1, 3, 7, 14, 21, and 28 days. In this questionnaire, pain was rated on a scale from 0 to 10, with 0 indicating "no pain," 1 indicating "very little pain," and 10 indicating "pain as bad as it could be."

Primary End Points

For each location where pain was present at baseline, changes in pain score were calculated by subtracting the baseline score from the follow-up score at each time point. The percentage of patients whose pain score had improved was also calculated for each time point.

Two primary end points were defined for evaluating efficacy. The first was the change at 4-week follow-up (day 28) in the pain score at the location with the highest baseline value (maximum pain score). The second was the change at 4-week follow-up in the sum of the pain scores for all locations.

Statistical Analysis

Comparisons between groups were based on rank sum tests for quantitative variables and χ^2 tests for dichotomous variables. Tests about whether the percentage of patients with improvement exceeded 50% within each group were conducted at each time point with the use of a normal approximation to the binomial distribution.

All tests for efficacy were 1-sided because they addressed a 1-sided question. All other tests were 2-sided.

Stepwise linear regression was then applied to determine whether group allocation would become significant after adjusting for other factors. The end points used were the 4-week changes in the following scores: maximum pain score, sum of pain scores for all locations, and pain scores for the individual locations where pain had been reported at baseline. The possible confounding variables considered were participants' age, sex, racial origin, whether they had seen the bracelets before, whether they had used the bracelets before, whether they believed that the bracelets could reduce joint or muscle pain, whether they were taking medication for pain, and the magnitude of the baseline score. The significance level used as a criterion for entering and staying in the model was $P<.10$. "Group" was then added as a variable in the final model to determine whether there was a difference between those who wore the placebo bracelet and those who wore the ionized bracelet, after adjusting for all significant factors.

RESULTS

The mean age of the 609 participants who gave their age on the questionnaire was 48.27 years (SD, 13.46 years; range, 18-88 years). Of 608 participants who gave information on sex, 157 (25.8%) were male and 451 (74.2%) were female. Of 607 participants who gave information on racial origin,

Table 1. **Baseline Demographic Variables and Previous Experience With Ionized Bracelets**

Variable	Placebo* (n=305)	Ionized* (n=305)
Mean age (SD) (y)	48.4 (12.9)†	48.1 (14.0)†
Male	75/304 (24.7)	82/304 (27.0)
Racial origin other than white	41/303 (13.5)	33/304 (10.9)
Seen bracelets before	141/305 (46.2)	147/305 (48.2)
Used bracelets before	13/304 (4.3)	14/305 (4.6)
Believe bracelets work	163/195 (83.6)	164/214 (76.6)

*No. of subjects/no. of respondents (percentage).
†Of 305 placebo bracelet respondents and 304 ionized bracelet respondents.

533 (87.8%) were white and 74 (12.2%) were of other racial origin. Of 409 participants who answered the question about whether they believed the bracelets can reduce joint or muscle pain, 327 (80.0%) gave a positive and 82 (20.0%) a negative answer.

Comparisons at baseline between those who wore the placebo bracelet and those who wore the ionized wrist bracelet are summarized in Tables 1 through 3. The groups did not differ significantly from each other at baseline for any variable except elbow injury (Table 3). In view of the large number of statistical tests undertaken, some comparisons might have been expected to differ significantly by chance.

No significant differences were seen between groups for either of the primary end points, ie, change at 4-week follow-up in maximum pain score and in sum of pain scores for all locations. The groups did not differ in the magnitude of change in these variables at any time point during the study, although statistically significant decreases from baseline were observed within each group at all time points (Figures 1 and 2). Similarly, no significant differences were seen between groups in the mean change from baseline after 4 weeks at any site where pain had been present at baseline, although significant decreases from baseline were observed within each group at each site (Table 4).

Table 3. **Baseline Pain Scores for Locations Where Participants Reported Pain***

	Placebo (n=305)		Ionized (n=305)	
Site	No.†	Mean (SD) pain score	No.†	Mean (SD) pain score
Neck	174	4.9 (2.2)	166	4.7 (2.3)
Shoulders	182	5.0 (2.2)	177	5.1 (2.4)
Elbows	65	4.3 (2.2)	67	4.2 (2.3)
Wrists	109	4.8 (2.3)	103	4.5 (2.4)
Hands	118	5.1 (2.5)	116	4.8 (2.6)
Upper back	90	5.1 (2.1)	81	5.0 (2.5)
Mid back	86	4.9 (2.0)	89	5.3 (2.4)
Lower back	191	5.5 (2.2)	186	5.8 (2.3)
Hips	123	5.6 (2.3)	104	5.7 (2.5)
Knees	157	5.4 (2.4)	158	5.1 (2.6)
Ankles	65	5.0 (2.7)	70	5.0 (2.5)
Feet‡	123	5.7 (2.4)	122	5.0 (2.6)

*For each location where pain was present, participants rated the intensity of the pain on a scale of 1 to 10 (1 = very little pain; 10 = pain as bad as it could be).
†Number of participants reporting pain at an individual location.
‡Pain scores in ionized and placebo bracelet groups did not differ significantly from each other at any sites (P>.05) except feet (P=.04).

Table 2. **Percentage of Participants Reporting Baseline Pain or Injury**

	Placebo (%) (n=305)		Ionized (%) (n=305)	
Site	Pain	Injury	Pain	Injury
Neck	57.1	9.5	54.4	9.8
Shoulders	59.7	9.5	58.0	8.2
Elbows	21.6	3.6*	22.0	0.7*
Wrists	35.7	2.6	33.8	2.3
Hands	39.0	1.6	38.0	2.0
Upper back	29.5	3.6	26.6	2.3
Mid back	28.2	3.6	28.8	3.0
Lower back	62.3	11.5	61.0	10.2
Hips	40.3	2.0	34.4	2.3
Knees	51.8	9.5	51.8	6.9
Ankles	21.3	3.6	23.0	4.6
Feet	40.3	4.6	40.0	4.3

*Differences between ionized and placebo bracelet groups were not statistically significant (P>.05) except for elbow injury (P=.01).

When the percentages of patients with improvement in maximum pain score or sum of pain scores for all locations were evaluated at each time point, we again saw no significant difference between groups, although within-group improvement rates were significantly greater than 50% in most instances (Table 5).

Analyses were also undertaken in which comparisons were made between groups after adjusting for other factors that may influence change in pain (eg, age). The results of regression analysis taking such factors into account are listed in Table 6. For each end point, the factors that were significantly (P<.10, see Subjects and Methods section) associated with change in pain scores were identified, and then treatment group was added to the regression model. In each case, no significant association with treatment was identified. This indicates that the failure to identify an effect from the ionized wrist bracelet beyond the effect available from placebo cannot be ascribed to other factors.

DISCUSSION

The results of this study suggest that the use of ionized bracelets for treating muscle and joint pain was no more effective for relieving musculoskeletal pain than was the use of placebo bracelets. However, both groups showed subjective improvement in pain scores.

Up to 30% to 40% of patients with a wide range of clinical conditions, such as pain, asthma, high blood pressure, and even myocardial infarction, have reported subjec-

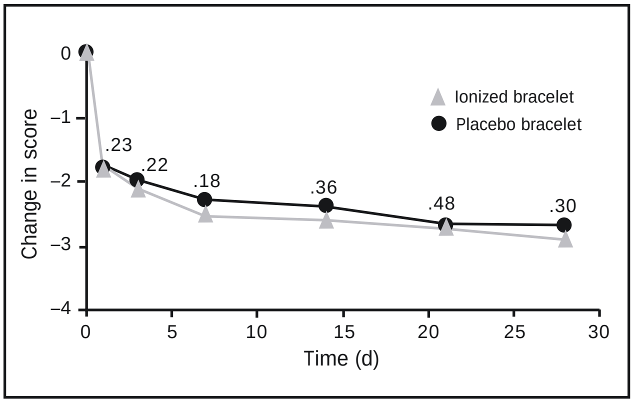

Figure 1. Changes in maximum pain score during 4 weeks of treatment with an ionized bracelet (triangles) or a placebo bracelet (circles). Numbers at data points represent *P* values of the differences between ionized and placebo bracelets.

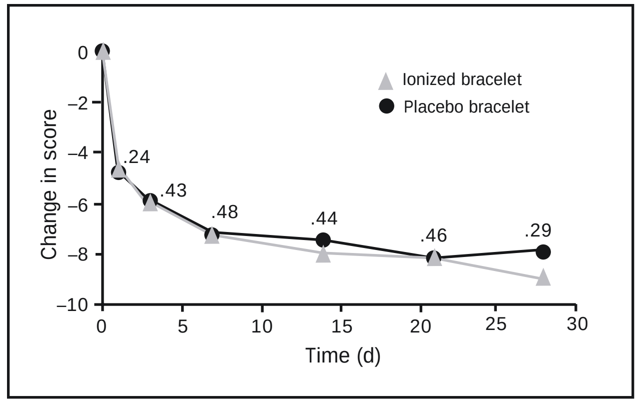

Figure 2. Changes in sum of pain scores during 4 weeks of treatment with an ionized bracelet (triangles) or a placebo bracelet (circles). Numbers at data points represent *P* values of the differences between ionized and placebo bracelets.

tive improvement with the use of placebos. However, the effectiveness of placebos has been questioned recently. In an analysis of clinical trials comparing placebo with no treatment, Hróbjartsson and Gøtzsche[7] found little evidence that placebos had powerful clinical effects except for "possible small benefits in studies with continuous subjective outcomes and for the treatment of pain." Additionally, therapeutic patterns that heighten placebo effects are especially prominent in unconventional healing, and this form of healing may have "enhanced" placebo effects in particular conditions.[8] Although the goal of our study was not to assess the effectiveness of placebos, our results supported the benefits of using placebos to treat pain. The participants in both the ionized and the placebo bracelet group showed a subjective improvement in pain scores. This study did not include participants who received no bracelet. Such a group would have allowed us to study pain in an untreated group during the same period and could have strengthened the results of this study. Accordingly, it is unclear whether pain would have improved in similar

Table 4. **Changes in Pain Scores at Individual Locations After 4 Weeks of Wearing Ionized or Placebo Bracelet***

Site	Placebo (n=305) No.†	Placebo (n=305) Mean‡ (SD) change in pain score	Ionized (n=305) No.†	Ionized (n=305) Mean‡ (SD) change in pain score
Neck	159	–1.4 (2.5)	158	–1.7 (2.4)
Shoulders	164	–1.5 (2.6)	167	–2.0 (2.6)
Elbows	57	–1.3 (2.6)	64	–1.7 (2.5)
Wrists	98	–1.9 (2.4)	95	–2.1 (2.5)
Hands	108	–1.8 (2.4)	111	–2.1 (2.6)
Upper back	80	–1.6 (2.9)	76	–1.7 (2.7)
Mid back	70	–1.4 (2.8)	79	–2.0 (2.6)
Lower back	175	–2.1 (2.6)	177	–2.3 (2.7)
Hips	110	–2.2 (2.7)	94	–2.2 (3.1)
Knees	137	–2.1 (2.4)	150	–1.9 (2.6)
Ankles	59	–2.5 (2.9)	64	–2.6 (2.7)
Feet	114	–2.3 (2.6)	116	–2.2 (2.8)

*For each location where pain was present, participants rated the intensity of the pain on a scale of 0 to 10 (0 = no pain; 10 = pain as bad as it could be).
†Number of participants reporting pain at an individual site.
‡Differences between ionized and placebo bracelet groups were not statistically significant (*P*>.05). Mean changes within each group were significantly different from 0 at all time points (*P*<.05).

Table 5. **Participants With Improved Maximum Pain Score and Sum of Pain Scores for All Locations During 4 Weeks of Treatment With Ionized or Placebo Bracelet**

Time	Placebo (n=305) No.* (%)†	Ionized (n=305) No.* (%)†
Patients with improved maximum pain score		
Day 1	209 (68.5)	193 (63.3)
Day 3	219 (71.8)	228 (74.8)
Day 7	229 (75.1)	231 (75.7)
Day 14	237 (77.7)	234 (76.7)
Day 21	236 (77.4)	230 (75.4)
Day 28	234 (76.7)	236 (77.4)
Patients with improved sum of pain scores		
Day 1	210 (68.8)	188 (61.6)
Day 3	212 (69.5)	217 (71.2)
Day 7	232 (76.1)	228 (74.8)
Day 14	235 (77.0)	226 (74.1)
Day 21	234 (76.7)	229 (75.1)
Day 28	227 (74.4)	237 (77.7)

*Number of participants who reported improvements.
†Differences between ionized and placebo groups were not statistically significant (*P*>.05). Response rates within each group were significantly greater than 50% (*P*<.05) except for the maximum pain score on day 1 with both ionized and placebo bracelets and for the sum of pain scores on day 1 with the ionized bracelet.

Table 6. **Regression Models Analyzing Contribution of Predictor Variables to Change in Pain Scores After 4 Weeks of Treatment**

Predictors	Coefficient (β)	SE	*P* value	Adjusted R^2
Maximum pain score				0.130
Bracelet type	–0.221	0.216	.31	
Initial maximum score	–0.456	0.051	<.001	
Age	0.025	0.008	.002	
Sum of pain scores				0.182
Bracelet type	–1.380	0.990	.16	
Initial sum score	–0.337	0.030	<.001	
On pain medication	1.843	1.090	.09	
Age	0.115	0.038	.002	
Neck				0.150
Bracelet type	–0.344	0.257	.18	
On pain medication	0.535	0.265	.04	
Initial pain	–0.431	0.058	<.001	
Shoulders				0.184
Bracelet type	–0.300	0.261	.25	
On pain medication	0.734	0.269	.007	
Initial pain	–0.474	0.057	<.001	
Elbows				0.288
Bracelet type	–0.480	0.386	.22	
Age	0.040	0.017	.02	
On pain medication	0.953	0.396	.02	
Initial pain	–0.538	0.085	<.001	
Wrists				0.249
Bracelet type	–0.405	0.308	.19	
Age	0.053	0.013	<.001	
Initial pain	–0.492	0.067	<.001	
Hands				0.204
Bracelet type	–0.528	0.304	.08	
Age	0.022	0.013	.08	
Initial pain	–0.466	0.061	<.001	
Upper back				0.266
Bracelet type	–0.098	0.383	.80	
Age	0.034	0.015	.02	
Initial pain	–0.617	0.083	<.001	
Mid back				0.269
Bracelet type	–0.347	0.386	.37	
Age	0.042	0.014	.003	
Initial pain	–0.592	0.086	<.001	
Lower back				0.173
Bracelet type	–0.075	0.261	.77	
Age	0.030	0.010	.003	
Initial pain	–0.492	0.058	<.001	
Hips				0.211
Bracelet type	–0.030	0.358	.93	
Age	0.037	0.014	.01	
On pain medication	0.507	0.367	.17	
Initial pain	–0.567	0.077	<.001	
Knees				0.159
Bracelet type	0.084	0.273	.76	
Age	0.040	0.011	<.001	
On pain medication	0.289	0.284	.31	
Initial pain	–0.378	0.055	<.001	
Ankles				0.277
Bracelet type	–0.240	0.433	.58	
Age	0.047	0.017	.007	
Initial pain	–0.591	0.086	<.001	
Feet				0.234
Bracelet type	–0.377	0.318	.24	
Age	0.040	0.013	.003	
Female	–0.233	0.387	.55	
Initial pain	–0.501	0.063	<.001	

populations with observation alone. Further studies could help clarify this issue.

CONCLUSION

Alternative medical treatments are increasing in popularity. Although patients may perceive benefits from alternative medical therapies, there is little objective evidence to support the effectiveness of most alternative methods. Our finding that the subjective improvement in pain scores was similar for ionized and placebo bracelets questions the benefit of using an ionized bracelet. As practicing clinicians, we need continued research to test claims made by manufacturers of alternative medical products to ensure that our recommendations are adequately and sufficiently supported by objective, research-based evidence.

REFERENCES

1. Eskinazi DP. Factors that shape alternative medicine. *JAMA*. 1998;280:1621-1623.
2. *Enhancing Accountability of Alternative Medicine*. New York, NY: Milbank Memorial Fund; 1998.
3. Eisenberg DM, Davis RB, Ettner SL, et al. Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey. *JAMA*. 1998;280:1569-1575.
4. Rao JK, Mihaliak K, Kroenke K, Bradley J, Tierney WM, Weinberger M. Use of complementary therapies for arthritis among patients of rheumatologists. *Ann Intern Med*. 1999;131:409-416.
5. Sugerman J, Burk L. Physicians' ethical obligations regarding alternative medicine. *JAMA*. 1998;280:1623-1625.
6. The Q-Ray. Available at: www.q-ray-ionized-bracelet.com. Accessibility verified August 2, 2002.
7. Hróbjartsson A, Gøtzsche PC. Is the placebo powerless? an analysis of clinical trials comparing placebo with no treatment. *N Engl J Med*. 2001;344:1594-1602.
8. Kaptchuk TJ. The placebo effect in alternative medicine: can the performance of a healing ritual have clinical significance? *Ann Intern Med*. 2002;136:817-825.