Electrical tinnitus suppression: A double-blind crossover study

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A wearable device for transcutaneous electrical tinnitus suppression (ETS) has recently been reported to be effective for relief of tinnitus. Twenty patients with sensorineural hearing loss and tinnitus participated in a double-blind crossover study. Both active devices and internally disconnected placebo devices, supplied by the manufacturer, were used. Reduction in severity of tinnitus was reported by 2 of 20 patients (10%) with the active device and by 4 of 20 (20%) with the placebo device. Fifteen of 20 (75%) had no relief with either device. Those who preferred the placebo device, however, reported only minimal relief, while one of the two who preferred the active device stated it had reduced tinnitus severity by 70% to 80%. This patient was recalled for a series of one-hour test sessions, during which either an active or placebo device was used, according to a random schedule. On each of four *on* trials, the score for severity of tinnitus for each ear decreased by at least 50% (median = 70%), while in three *off* trials, the severity of tinnitus was unchanged or decreased by up to 30% (median = 16%). We conclude that the Theraband headset is effective for a small proportion of patients with sensorineural hearing loss and tinnitus. (OTOLARYNGOL HEAD NECK SURG 1986;95:319)

Tinnitus, like any other symptom, should be vulnerable to two general types of therapeutic attack. First, consideration is given to treatment of the underlying disorder, but no medical or surgical remedies are available for most patients with tinnitus. The second option is symptomatic treatment; unfortunately, this is also unsuccessful in most cases. When there is sufficient hearing loss, a hearing aid will often relieve tinnitus, as well as improve hearing.[1] Biofeedback, acoustic masking, and various drugs have been recommended, but all of these approaches taken together still leave a large proportion of individuals who have tinnitus without relief.[2,3]

Suppression of tinnitus by electrical current applied to the scala tympani[4] or round window[5] has been reported. In addition, electrical stimulation to other sites—including the ear canal,[6] the promontory,[7,8] and the mastoid[9-11]—has been tried in an effort to achieve suppression of tinnitus. Recently, a wearable device for transcutaneous electrical tinnitus suppression has been developed (Theraband headset, Audimax, Inc., Hackensack, N. J.). A 60 kHz carrier frequency is amplitude modulated (90%) by a continuously swept signal (200 Hz to 20 kHz) and applied to surface electrodes on the two mastoid processes. This device showed considerable promise in preliminary testing;[11] however, placebo effects can be substantial in tinnitus studies.[12] Fortunately, the electrical stimulation of the Audimax unit can neither be felt nor heard, making it ideally suited to a double-blind, placebo-controlled study. We undertook this study, hoping to replicate the initial success reported with this device.

METHODS AND MATERIALS

Design. This was a prospective, randomized, double-blind crossover trial, in which each subject used both an active device and a placebo device (for 1 week each), with a 2-week rest period interposed. Half the subjects used an active device during week 1 and a placebo device during week 4; the other subjects used a placebo during week 1 and an active device during week 4. During weeks 1 and 4, subjects were asked to wear their devices for 1 hour the first day, 2 hours the second day, and so on, up to 5 hours' daily use for the fifth, sixth, and seventh days. This study was designed in collaboration with Audimax, Inc. and its scientific advisors; the schedule of device use and the 2-week

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Table 1. Pure-tone audiometry (dB HL)

Frequency (Hz)	250	500	1000	2000	3000	4000	6000	8000
Right ear:								
Mean	14.12	15.88	17.94	23.82	44.12	51.47	53.53	54.41
Std. Dev.	12.40	14.50	13.70	17.00	24.0	27.20	28.71	32.01
Range	0-35	0-40	0-50	5-60	0-85	0-90	5-100	-5-105
Left ear:								
Mean	15.79	15.53	16.32	28.16	48.68	55.79	52.89	53.95
Std. Dev.	14.65	18.48	13.93	22.31	27.28	26.21	26.58	25.53
Range	0-60	-5-75	-5-55	0-80	5-85	5-95	10-95	15-90

Table 2.

Lifestyle interference from tinnitus	
Little or no interference with work or social activities	3
Some interference, but can live with it	13
Takes considerable effort to maintain normal activites	3
Serious interference—can only do simple tasks	1
Unable to perform any work or social activity	0

delay between active and placebo trials were based on their preliminary clinical experience. Subject-selection criteria and data-collection instruments were also submitted to Audimax prior to the beginning of the study and were modified according to their requests in an attempt to maximize the power of the study (i.e., the probability that any genuine therapeutic effect would be detected).

Devices. Audimax, Inc. loaned us 10 Theraband headsets, 5 of which had been internally disconnected so that no electrical signal was present at the mastoid electrodes. Each of these devices was bench-tested in our own laboratory. The placebo devices produced no current, while the active devices produced—as expected—a 60 kHz carrier, amplitude modulated by a signal sweeping between approximately 200 Hz and 20 kHz, at approximately 3V across a 5 kΩ load. The serial numbers of the active and placebo devices were known only to one of us (R.A.D.), who prepared a randomized device-assignment schedule. Another investigator (K.H.) actually handed out and collected the devices and administered questionnaires, thus assuring that neither the subjects nor the individual interacting with them knew whether a given device was functional or not.

Subjects. Twenty subjects were recruited from our own otologic clinics and by referral from community otolaryngologists and speech and hearing clinics. Criteria for inclusion were sensorineural hearing loss of cochlear origin and tinnitus severe enough to justify the patient's expenditure of time. Subjects were not paid for their participation. Criteria for exclusion included tinnitus in a normally-hearing or deaf ear, pregnancy, recent URI, recent psychiatric care, and cardiac pacemakers. All patients had had otologic examination and diagnosis within the 6 months prior to the study. All subjects signed a consent form approved by the University of Washington's Human Subjects Committee.

Fifteen subjects (75%) were men and 5 (25%) were women. The mean age was 50.25 (standard deviation = 12.26, range 30 to 71). Otologic diagnoses were noise-induced hearing loss (14 cases), presbycusis (4 cases), and miscellaneous (6 cases); the sum is greater than 20 because some of the patients had more than one diagnosis. Audiometric characteristics of the subject group (mean thresholds, standard deviations, and total ranges) are shown in Table 1. All subjects complained of continuous tinnitus whenever they were awake; thirteen of 20 reported frequent sleep disturbance from tinnitus. Tinnitus was bilateral in 16 of 20 patients, left-sided in 3, and right-sided in 1.

The duration of tinnitus prior to this study was 10 months to 27 years (mean = 10.25 years). Most patients reported substantial interference with lifestyle on their entry questionnaires (Table 2). Seventeen of 20 reported anxiety or depression, which they blamed on their tinnitus.

Data collection. Pure-tone audiometry (250 Hz to 8 kHz, ANSI-1969) was performed at the first visit and each weekly visit. Tinnitus matching (for pitch and loudness) and acoustic maskability were determined at the initial visit. Table 3 shows the range of frequencies and sensation levels reported by our subjects. Of 36 ears with tinnitus, two ears (one patient) refused the matching test and two ears (two patients) could not find a matching stimulus, leaving 32 ears reported in Table 3. Each subject completed an intake questionnaire, as mentioned previously. In addition, each subject kept a daily diary, in which he or she recorded the number of

Table 3. Tinnitus matching

A.	Frequency (Hz)	2000	3000	4000	5000	6000	8000	10000	
	Pure-tone	1	1	9	3	5	5	3	
	Narrow-band noise	1	0	3	0	0	0	1	
B.	**Sensation level (dB)**	**0**	**1**	**2**	**4**	**5**	**10**	**20**	**40**
		5	1	15	1	3	4	1	2

hours the device provided was actually used, the duration (hours) and severity (on a 0 to 7 scale) of tinnitus during the past 24 hours, any sleep disturbance, and miscellaneous comments. At each weekly visit, another brief questionnaire was completed, in which patients were asked to compare their tinnitus during the past week to the tinnitus during the preceding week with regard to duration, loudness, and severity. If a device had been worn during the past week, the patients were asked whether or not it helped at all and, if so, how much (0 to 100%). Finally, on the fifth and final visit, they were asked to say whether they preferred either of the devices they had been given. Techniques of data analysis and statistical inference will be presented in the *Results* section.

RESULTS

The results of the study—based on the weekly questionnaires—are summarized in Table 4. (*Amount of time present* and *loudness* are self-explanatory. *Severity* represents the subject's response to the question "How much did your tinnitus bother you last week, compared to the week before?") These data do not suggest that the active device was more often effective than the placebo in reducing the symptoms of tinnitus (amount of time present, loudness, severity). In fact, most patients reported no change in any of these variables after both active and placebo trials.

In addition to noting any changes in these three symptoms, subjects were asked to indicate (after weeks 1 and 4) whether they found the device they had worn during the previous week helpful. There were six positive responses out of a total of 40 device trials—two indicated that the active device was helpful; four indicated the placebo was helpful.

On the last visit, subjects were asked which device—the one worn in the first week or the one worn in the fourth week had been more helpful. Fifteen indicated no difference between active and placebo, three found the placebo more helpful, and two found the active device more helpful. Of the three who preferred the placebo device, none indicated that it helped more than

Table 4. Tinnitus (re: previous week)

		Less	Same	More
Amount of time present				
	Active	0	19	1
	Placebo	2	17	1
Loudness				
	Active	3	13	4
	Placebo	3	12	5
Severity				
	Active	2	13	5
	Placebo	3	12	5

40%. However, a strikingly positive response was manifested by one of the two subjects who preferred the active device; he maintained that his tinnitus was reduced 70% to 80% after wearing the active device. His response is reflected in his daily tinnitus-severity diary entries, as presented in Fig. 1.

This single case of positive response could have been merely a spontaneous and coincidental abatement of tinnitus during a single week. To exclude this possibility, this subject was recalled for a series of seven 1-hour test sessions, during which an active ETS device was placed on his head. The device had been turned *on* or *off*, according to a previously and randomly arranged schedule, unknown to the patient. The *on-off* switch and indicator lights were taped over, so he could not determine their status. He was asked to rate his tinnitus (0 to 7) in each ear, before and after each of these sessions. The results are shown in Fig. 2. Clearly, he noticed a greater reduction in the severity of his tinnitus with the active device than with the placebo.

After each of these sessions he was also asked to state whether the device had been *on* or *off* during the hour. On each of seven such trials (4 *on*, 3 *off*), he was able to determine the status of the device accurately. The probability of this occurring by chance (analogous to correctly predicting the outcome of 7 tosses of a fair coin) is $(\frac{1}{2})^7 = 0.0078125$. Thus, we are confident that the efficacy of ETS—using the Theraband headset—was demonstrated for this subject.

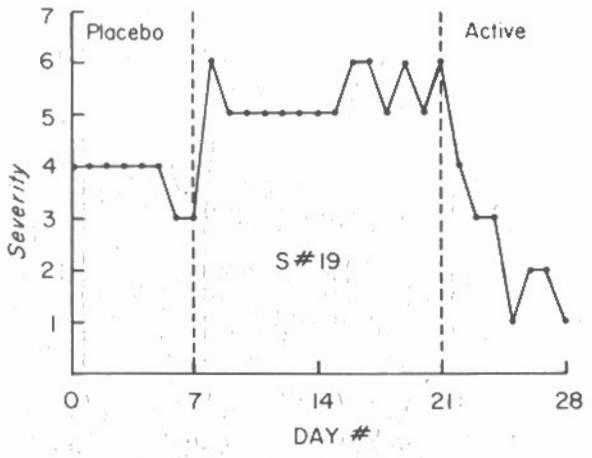

Fig. 1. Daily tinnitus-severity scores for the one subject who responded strongly to ETS, during 1 week of wearing a placebo device, 2 weeks of no device use, and a final week in which he wore an active device.

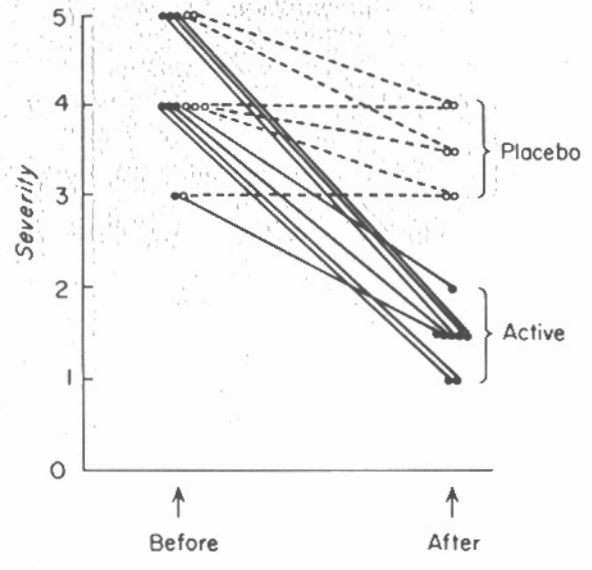

Fig. 2. Tinnitus-severity scores for subject 19, before and after a series of 1-hour test sessions, with either active device *(solid lines)* or placebo *(dashed lines)*. Each line represents one ear.

This subject is not markedly different from the overall subject pool: he is male, 37 years of age, has had tinnitus for 16 years in both ears (left > right), and has a mildly asymmetric, noise-induced hearing loss. His tinnitus was matched at 8000 Hz in one ear (0 dB SL) and 4000 Hz in the other ear (+2 dB SL), and was acoustically maskable without residual inhibition.

None of our subjects could feel or hear anything when the device was turned on. No changes in pure-tone audiometric thresholds exceeding 5 dB were seen on serial testing. Even our "star patient" required about 30 minutes of stimulation before he could tell the device was *on* (by the effect on his tinnitus). He now wears the device for 30 to 60 minutes twice a day and claims 2 to 3 hours of relief from each session.

DISCUSSION

The purpose of the present study was to investigate the efficacy of external electrical stimulation—as provided by the Theraband headset—for the suppression of tinnitus. Electrical stimulation for tinnitus suppression has been reported by many authors and has had varying degrees of success. It appears that the closer the active electrode is to the neural and sensory elements of the cochlea, the better the results are. Success rates are ranked as follows: scala tympani (80%),[4] round window (60%),[5] promontory (43%),[8] transcutaneous (4% to 62%).[10,11]

Shulman et al.[11] found that the Theraband headset was effective in suppression of tinnitus for 13 of 21 patients (62%). Our study, however, did not confirm this success rate. Only two of 20 patients (10%) experienced any apparent success with the device. Furthermore, reductions in tinnitus loudness and severity were at least as frequent with the placebo devices as with the active units.

If we set a criterion for success of greater than 50% reduction in tinnitus severity, one subject was successfully treated with the active device (1/20 = 5%), compared to 0/20 successful placebo trials. Even if this observation were not invalidated by the use of a *post hoc* criterion, it would fall far short of statistical significance. However, it *did* prompt us to study this single subject further (using a repeated-measures design), and we were able to demonstrate that—*for him*—active stimulation with the Theraband device was more effective than placebo, at a statistically significant level ($p < 0.01$). We are comfortable with two conclusions: First, the Theraband headset did work on one of our 20 subjects; second, the response rate in a relatively unselected group of patients is very low. For clinical populations similar to ours, we can estimate a 5% response rate, although the confidence limits of this estimate are rather wide because of the small sample size. The true response rate could be as high as 24%; this is the upper confidence limit ($p < 0.05$) for the proportion 1/20.[13]

This patient's success warrants future study with the headset. It may be that undiscovered etiologic and/or demographic variables will allow prediction of which patients will experience suppression of tinnitus through

external electrical stimulation. Future double-blind studies with the Theraband headset are currently being planned. However, the low success rate found in this study—in which there was no preselection of patients—indicates that future studies might incorporate a screening procedure, in which patients use a functioning headset for a short-term trial. If success is reported, the subjects could then be enrolled in a double-blind study similar to the one employed in this study.

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