

Treating Facial Acne In Adolescents And Young Adults With Auriculoacupuncture And Auriculotherapy: A Pilot Study

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ABSTRACT

Background Potential advantages of using auriculoacupuncture or auriculotherapy to treat facial acne vulgaris include reduced cost of therapy, lack of significant adverse effects, and better patient adherence and acceptance.

Objective To examine the efficacy of using auriculoacupuncture and auriculotherapy for 20 weeks to treat acne in teenagers and young adults.

Design, Setting, and Patients Male and female volunteers (aged 13-25 years) with grade I or II mild to moderate nonscarring facial acne were randomized to 1 of 4 groups: treatment needle (TN), control needle (CN), treatment electrical (TE), or control electrical (CE). Bilateral auricular points used for the 2 treatment groups (TN and TE) were Face Point, Skin Disorder Point F, Genital Control Point, Lung 1, Lung 2, Point Zero, Shen Men, Allergy Point, and Endocrine Point. Nine sham points on the fleshy portion of the auricular ridge were used for CN and CE groups.

Main Outcome Measure Papule count change from baseline.

Results On average, baseline papule counts of males (range, 32-50) were larger than those of females (range, 12-18). The mean changes in papules for males were relatively greater. For females, the CN group had the highest mean baseline count and showed worsening over time as evidenced by an increase in the mean count over time, and mean change values generally below zero, i.e., counts were more than baseline. The other 3 groups continuously improved as shown by the downward trend in the mean papule counts, with the TN group showing the most improvement followed by the CE group. For males, all treatment groups showed improvement over time. The CE and TN groups had the highest baseline counts, but the CE group showed more improvement than did the TN. The CN group had the lowest mean count at the end of the study, but it also had the lowest baseline count. The TE group had a baseline count slightly lower than that of CE and TN, but finished with the most improvement.

Conclusions Both auriculoacupuncture and auriculotherapy appear to provide some promising therapeutic results in the treatment of adolescent mild to moderate acne vulgaris. Differences observed in therapeutic effect of the electrical stimulation vs needle stimulation may result from differences in the amount of energy delivered. Further study of this alternate treatment for acne is warranted.

KEY WORDS

Acupuncture, Electrical Stimulation, Alternative Medicine, Acne

INTRODUCTION

Acne vulgaris is one of the most common dermatological diseases. The prevalence may be as high as 83%-95% in adolescents. While acne affects similar numbers of males and females, males tend to have greater degrees of severity. A substantial percentage of adults are also affected, either as a continuation of their teenage acne or its first appearance in the 3rd or 4th decade. Acne is a disease of the pilosebaceous unit, consisting of sebaceous glands and small hair follicles, and is caused by obstruction of the pilosebaceous canal. The factors leading to acne include sebum overproduction and bacterial infection from *Propionibacterium acnes*, the organism active in inflammatory acne. Acne varies in severity from mild (few comedones and papules) to severe (scarring, highly inflamed pustules, nodules, i.e., acne conglobata).¹⁻³ Acne is often dismissed as an affliction the patient will outgrow, resulting in the postponement of treatment.

While it is true that most cases of acne subside and involute spontaneously and completely within a few years of onset, a small percentage remains active. Acne carries significant psychosocial implications and may cause considerable temporary emotional distress during the acute phase of active outbreak as well as permanent distress when facial scarring results. The psychosocial impact on teenagers may be especially devastating. Low self-esteem, affected personal appearance, peer taunting, and ridicule all demoralize the teen plagued with acne, creating embarrassment and frustration. As acne is successfully treated, peer acceptance improves, resulting in patients feeling less socially isolated.⁴

Accepted Western medical treatment of acne includes tretinoin, topical or oral antibiotics, benzoyl peroxide, salicylic acid, sulfur preparations, azelaic acid, adapalene, tazarotene, birth control pills in women, antiandrogen therapy (low-dose corticosteroids, spironolactone), and isotretinoin as a last resort.⁵ While effective in clearing acne, many of these treatments have significant adverse effects. Tretinoin may cause photosensitivity, excessive skin dryness and cracking, and is contraindicated in pregnancy.

Adverse effects of antibiotics include vaginal yeast infections, allergic reactions, diarrhea, anaphylaxis, and potential for development of antibiotic resistance. Birth control pills may cause hypertension, nausea, weight gain, migraines, depression, and blood clots. Isotretinoin is particularly dangerous and expensive; the adverse effects include elevated lipid profiles, hepatotoxicity, and fetal teratogenicity, thus limiting its use in sexually active females of childbearing age. In addition, the cost for drug therapy may be daunting, ranging from \$10 per month for tetracycline to \$210 per month for isotretinoin.^{1,2}

Given these problems with traditional treatments, patients with acne could benefit from new therapies.⁶ Several studies have reported positive therapeutic effects of auriculoacupuncture and auriculotherapy in the treatment of mild to moderate facial acne vulgaris.⁷⁻¹⁵ The potential advantages of using auriculoacupuncture and auriculotherapy to treat facial acne vulgaris include reduced cost of therapy, lack of significant adverse effects, and better patient adherence and acceptance.

According to the principles of Traditional Chinese Medicine (TCM), acne vulgaris is treated by stimulating ear points that clear heat, dispel wind and damp, cool blood,

and reduce stagnation. Metaphorical Chinese medical acupuncture logic indicates how systemic disease can be reflected in the external ear as a self-contained microsystem that affects the whole body.

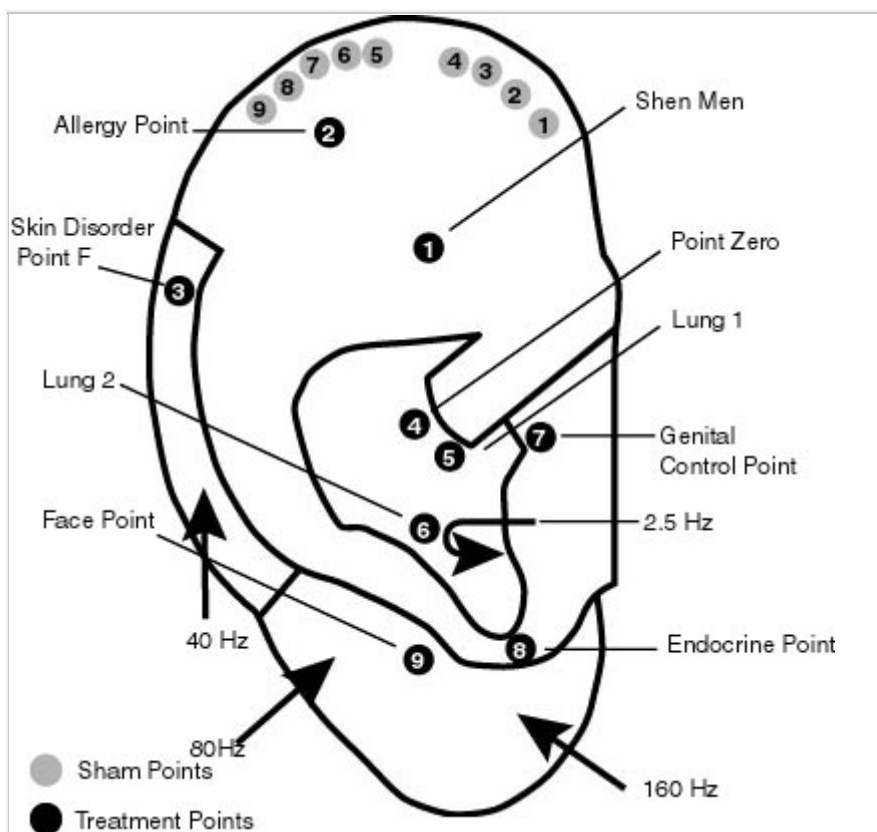


Figure 1. Treatment and Sham Points and Frequencies Used

There is now an accumulation of scientific studies examining electrophysiological data obtained from animals and humans that provide neurohumeral support for these clinical findings.¹⁶ Both forms of ear stimulation do not simply reduce pain or temporarily "cure" the problem but, rather, facilitate the natural bodily healing processes and affect deeper physiologic changes. Starwynn states that the human body generates electrical energy that can migrate long distances through semiconduction. Imbalances in ionic positive and negative charges are associated with pain and injury. Thus the therapeutic effects of acupuncture are due to its ability to discharge (locally and distally) these ionic charges.¹⁷ In traditional Chinese therapy, skin is under the domain of influence of the Lung meridian and therefore, auricular Lung points are logical to use in the treatment of acne vulgaris. There are other logical reasons in selection of all the rest of the ear points in the treatment of acne vulgaris.⁷ Research demonstrating release of endorphins by stimulation of auricular acupuncture points provides a neurohumeral basis for the clinical actions of auricular acupuncture.¹⁸

This pilot study was designed to examine the efficacy of alternative approaches to treat mild to moderate acne in teens and young adults, using auriculoacupuncture and auriculotherapy. Specifically, we sought to determine whether stimulation of ear points by needles or by electrical microcurrent would be effective in 20 weekly

sessions. Specific outcomes examined included changes in number and severity of lesions, presence of adverse effects, and duration of treatment needed to achieve therapeutic success.

METHODS

Male and female volunteers between the ages of 13 and 25 years with mild to moderate facial acne were recruited using a variety of methods, including fliers posted around campus, articles in campus and local newspapers, letters and fliers sent to community physicians, word-of-mouth, and television coverage. The majority of subjects were recruited as a result of coverage by local print and television media.

Criteria for inclusion in the study were grade I and II mild to moderate nonscarring facial acne vulgaris as determined by a dermatologist blinded to the study. Exclusion criteria were severe acne grades III and IV or any systemic acne therapy (antibiotics, isotretinoin) or retinoid topical treatments (tretinoin) for 1 month prior to the beginning of the study. Different acne grading systems have been used in clinical studies for evaluation of acne treatment. For the purpose of this study, an acne grading system using photographic standards was used in which overall acne was evaluated on a 0 to 8 scale anchored to photographic standards that illustrate grades 0, 2, 6, and 8. Experience with use of this system in large-scale clinical trials has shown to be useful and reliable.²⁰

The study was reviewed and approved by the institutional review board of the University of Nevada, Reno. Potential study volunteers who were younger than 18 years were required to have a parent or guardian present during the orientation to the study and review of the study protocol, risks, and benefits. Parents/guardians were required to sign the informed consent for these younger volunteers, and the teenager was required to sign a "teen" assent form. Volunteers between 18-25 years of age signed their own consent forms.

Subjects were informed that they would be required to present to the Family Medicine Center once weekly for 20 weeks for about 30 minutes each time to receive their treatment, discuss any concerns with the physician, and have 3 photographs (front and each side) taken of their face. Possible adverse effects or risks to the patient of auriculoacupuncture and auriculotherapy (tenderness, inflammation, bleeding, or infection in the ear, feelings of drowsiness, euphoria, relaxation or sedation after a treatment period) were reviewed with each potential volunteer. Rotchford's "Clinical Strategies for Reducing Adverse Events" were followed.¹⁹ (For this study, the most expected adverse effect of drowsiness was addressed by having the subjects wait 30 minutes after the 1st treatment before driving a car, and advising them to be driven to the 1st treatment. Any subject who experienced drowsiness after the 1st treatment was monitored thereafter at every visit.). If, at the end of the study, control group participants desired to have conventional or alternative therapy, it was provided free of charge for up to 20 weekly sessions.

After giving written informed consent, each subject was randomized to 1 of 4 groups and not informed of the assignment to treatment or control group:

1. treatment needle (TN) (auriculoacupuncture)
2. control needle (CN) (auriculoacupuncture)
3. treatment electrical (TE) (auriculotherapy)
4. control electrical (CE) (auriculotherapy).

Prior to beginning the study, the physicians (McKee and Lu) met with each volunteer to take a health history and perform a limited physical examination. Initial numbers of facial lesions were scored by an objective grading method using photographic standards.²⁰ Participants were asked not to use conventional therapies such as tretinoin, isotretinoin, or antibiotics while enrolled in this study. Women taking oral contraceptive pills were allowed to be in the study with the understanding that they neither stop nor start oral contraceptives during the study. A list of standard therapies was given to subjects, in the event they chose to drop out of the study or not adhere to the study protocol. Use of non-prescription topical treatments was monitored during the study.

Treatment

Nine bilateral auricular points from Oleson's Auricular Therapy manual¹⁶ used for the 2 treatment groups (needle and electric) were: Shen Men, Allergy Point, Skin Disorder Point F, Point Zero, Lung 1, Lung 2, Endocrine Point, Genital Control Point, and Face Point. (Treatment points are shown by the solid black dot in Figure 1). Nine sham points (shown by the gray dot in Figure 1) were selected for the 2 control groups (needle and electric) to have no therapeutic effect.

These were located on the fleshy portion of the auricular ridge along the helix rim of the ear, stopping before Darwin's tubercle and avoiding the allergy point. For the needle groups, Tai Ji Acupuncture disposable needles gauge 36 were used. For the control groups, the Electro Medical Stim Flex 400, an FDA-approved device for auricular stimulation with ability to control noise and identify exact point location, was used. Threshold levels in ohms and time current delivery were exact and automatically controlled. Frequencies (also shown in Figure 1) were varied as described by Oleson.

All 4 groups received 20-minute treatments in 20 weekly sessions as follows:

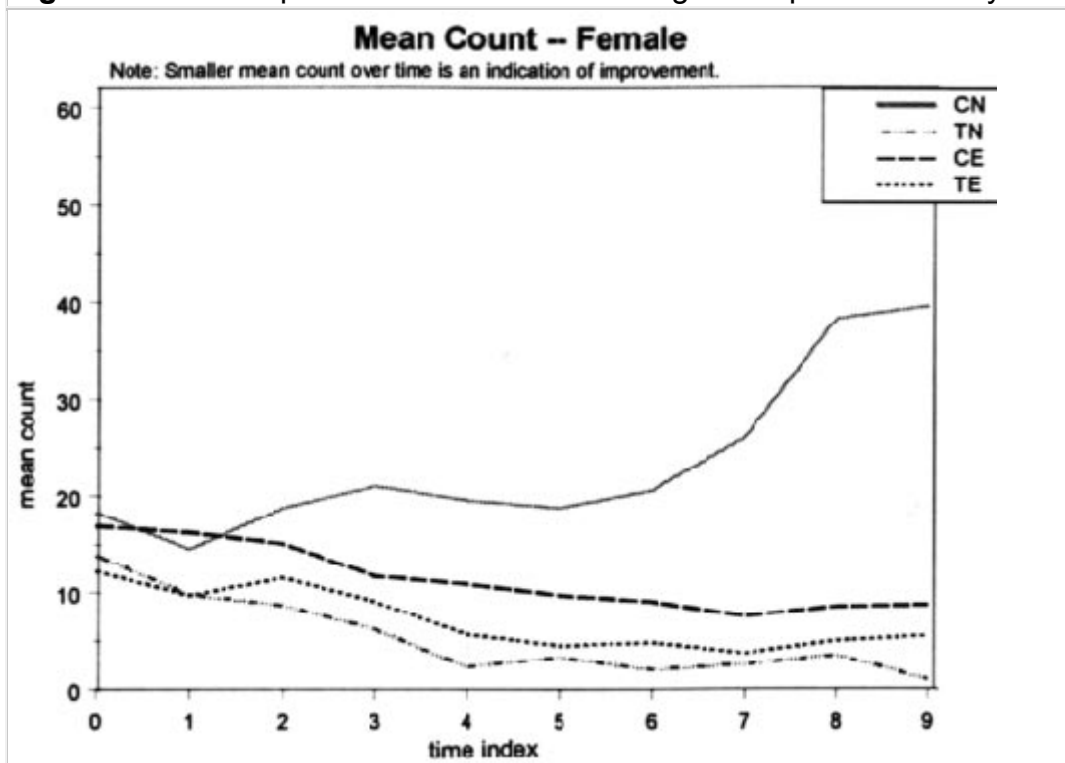
- TN group received auriculoacupuncture in the 9 treatment points listed above, and shown by the black dot in Figure 1.
- CN group received sham acupuncture, the needling at the 9 points described above, and shown by the gray dot in Figure 1.
- TE group received auricular electrotherapy with microcurrent stimulation at each treatment ear point as follows:

Treatment Ear Point	1	2	3	4	5	6	7	8	9
Duration, sec	16	8	8	8	8	8	8	8	16
Frequency, Hz	10	10	40	5	5	5	20	20	80

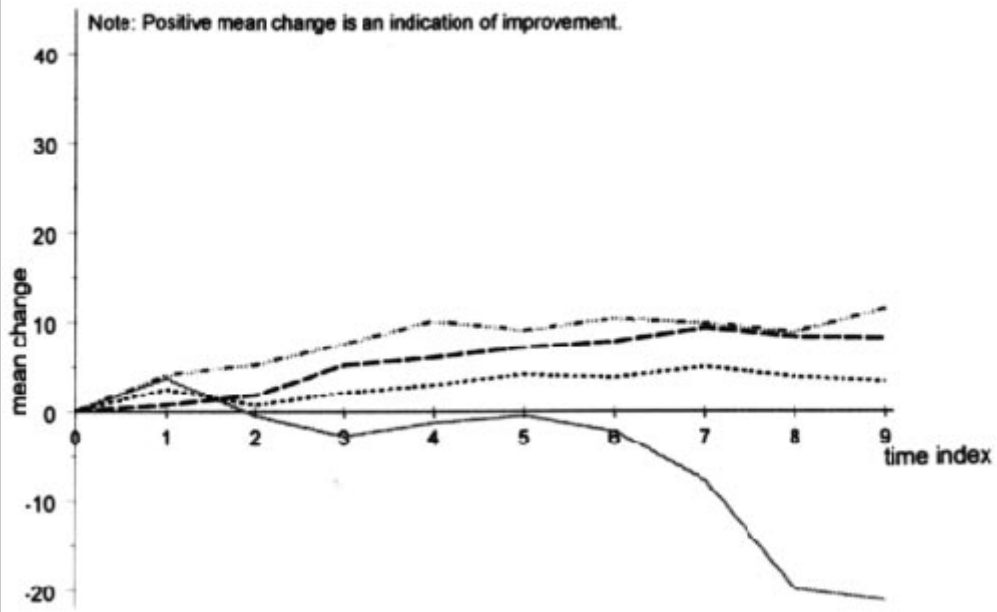
- CE received auriculotherapy with microcurrent stimulation with electricity applied at each sham point for the same duration and at the same frequencies as those used for the corresponding treatment point for the TE group (e.g., sham point #1: duration = 16 sec, frequency = 10 Hz; sham point #2: duration = 8 sec, frequency = 10 Hz; sham point #3: duration = 8 sec, frequency = 40 Hz).

Three medical quality photographs (front, left, and right sides) were taken at each visit with a digital camera to create a permanent record of each subject's clinical status throughout the course of treatment that could then be re-evaluated by a second dermatologist later if necessary. A dermatologist who was blinded to each subject's treatment group assignment and week of treatment counted the number of papules (small, circumscribed solid elevation of the skin) and pustules (small elevation of the skin filled with pus), and these numbers were entered into a database using Microsoft Excel (Microsoft, Redmond, WA).

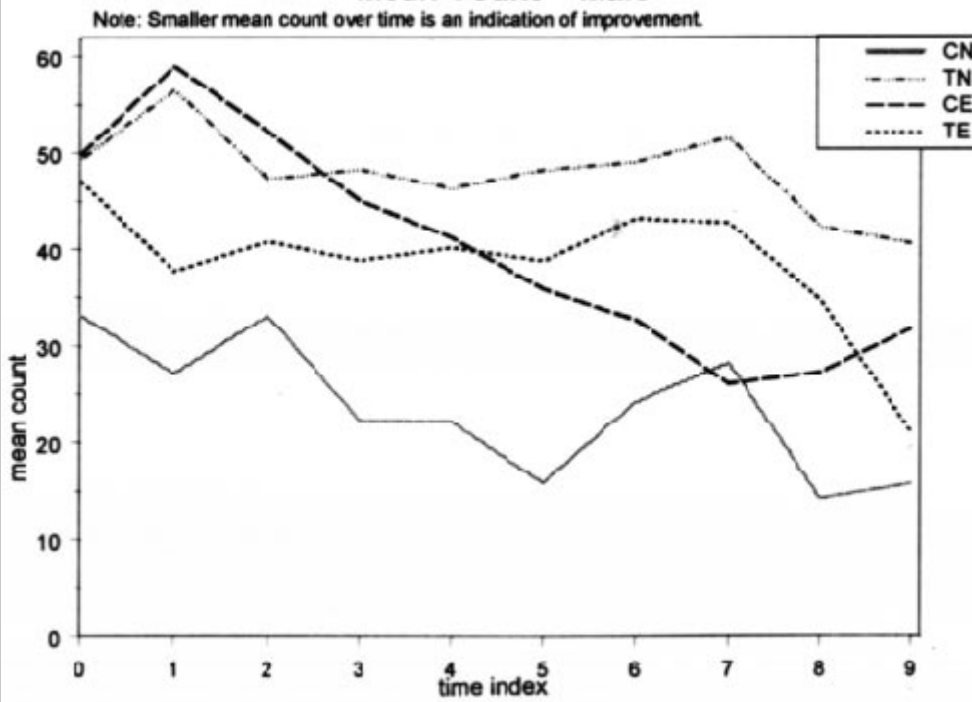
Figure 2. Mean Papule Count and Mean Change in Papule Counts by Sex

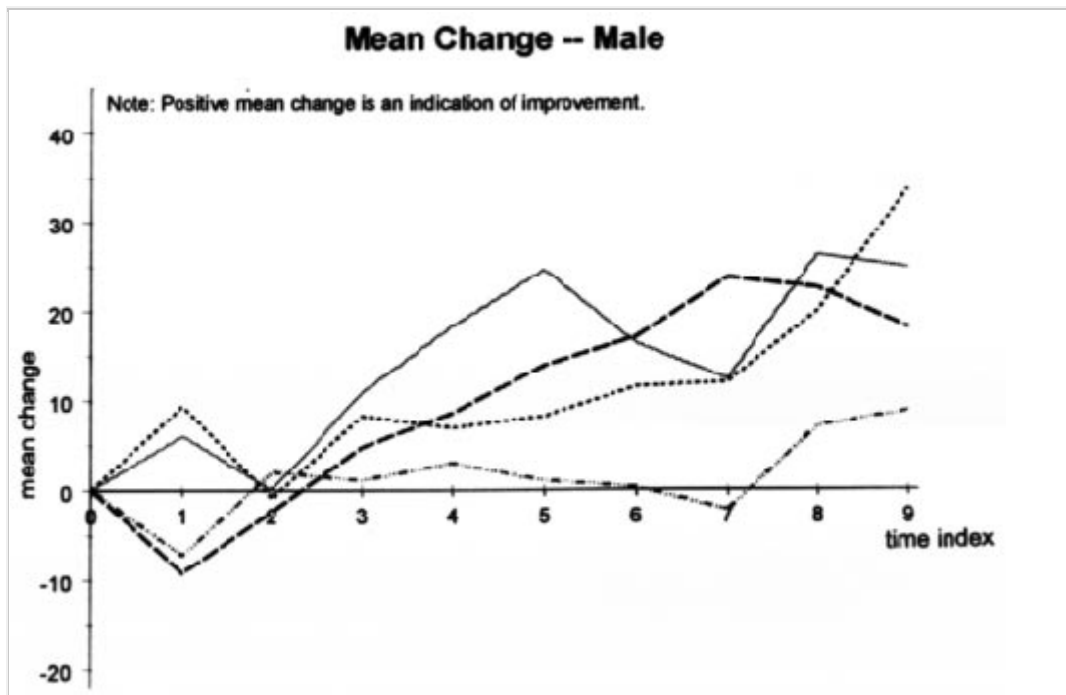


Mean Change -- Female



Mean Count -- Male





Statistical Analysis

To test our hypotheses, the changes in the number (baseline count minus current count) of papules and pustules were modelled, separately, over time using repeated measures analyses. Results and conclusions of the analyses were obtained using SAS PROC MIXED (SAS Institute Inc, Cary, NC) with an unstructured covariance based on 5% significance level. There were several missing values in the 1st few weeks of treatment due to missing or unreadable photos. Some subjects did not have initial assessment photos, some subjects had missing photos of the 1st or 2nd treatment week, and 2 of the 29 subjects had their 1st available photo only on the 3rd week of treatment. As a consequence, "baseline count" for each subject was obtained by taking the average of all available readings up to the 3rd treatment week. Because some subjects were unable to appear every week and some subjects withdrew from the study before the last treatment, these resulted in more missing data values. In order to maximize the use of available information, "current count" for each subject was obtained by taking the average of available data values of 2 consecutive treatment weeks. A "time index" for the modified data that was used in the analyses was defined to represent sequential time periods as follows:

Time Index	0	1	2	3	4	5	6	7	8	9
Treatment Week	0-3	4-5	6-7	8-9	10-11	12-13	14-15	16-17	18-19	20

The predictor variables in the model were sex, treatment, time index (1-9), and all 2- and 3-factor interaction terms of these variables. Baseline count (i.e., count at time index 0) was included in the model as a covariate. Time index was treated as

a categorical variable instead of a continuous variable to avoid assuming a particular form of the mathematical relationship between mean change in counts and time. The decision was made to use this modeling strategy even though degrees of freedom were lost and the power of the statistical tests was lowered in order to avoid the possibility of obtaining misleading results due to fitting an inappropriate model.

RESULTS

A total of 29 subjects participated in the study (15 female and 14 male); 60% of the females and 79.6% of males completed all 20 weeks of treatment. Table 1 summarizes the distribution of the subjects by their last week of treatment, sex, and treatment group. The means and SDs of subjects' ages are shown in Table 2. Male subjects were significantly younger on average than female subjects. We noted that, on the average, subjects assigned to the TN group tended to be younger relative to subjects in the other treatment groups, particularly among females.

To better assess the possible therapeutic effects of the treatments, graphs of the mean counts, and mean change in counts of papules and pustules per sex and treatment group over time are presented; Figure 2 illustrates the mean and mean change in papule counts.

- On the average, baseline papule counts of male subjects (range, 32-50) were larger than those of female subjects (range, 12-18). Consequently, the mean changes in papules for males were relatively larger. Also, papule counts of female subjects were less variable than those of the male subjects as indicated by smoother curves for females.
- For female subjects, the CN group had the highest mean baseline count and showed worsening condition over time as supported by an increase in the mean count over time, and mean change values generally below zero, i.e., counts were more than baseline. The other 3 groups continuously improved as shown by the downward trend in the mean papule counts, with the TN group showing the most improvement, since it had the highest mean change curve over time, followed by the CE group.
- For male subjects, all treatment groups showed improvement over time. The CE and TN groups had the highest baseline counts, but the CE group showed more improvement than did the TN group. The CN group had the lowest mean count at the end of the study, but it also had the lowest baseline. The TE group had a baseline count slightly lower than that of the CE and TN groups, but finished with the most improvement as evidenced by the largest mean change at the end of the study.

Figure 3 displays graphs of mean and mean change in pustule counts.

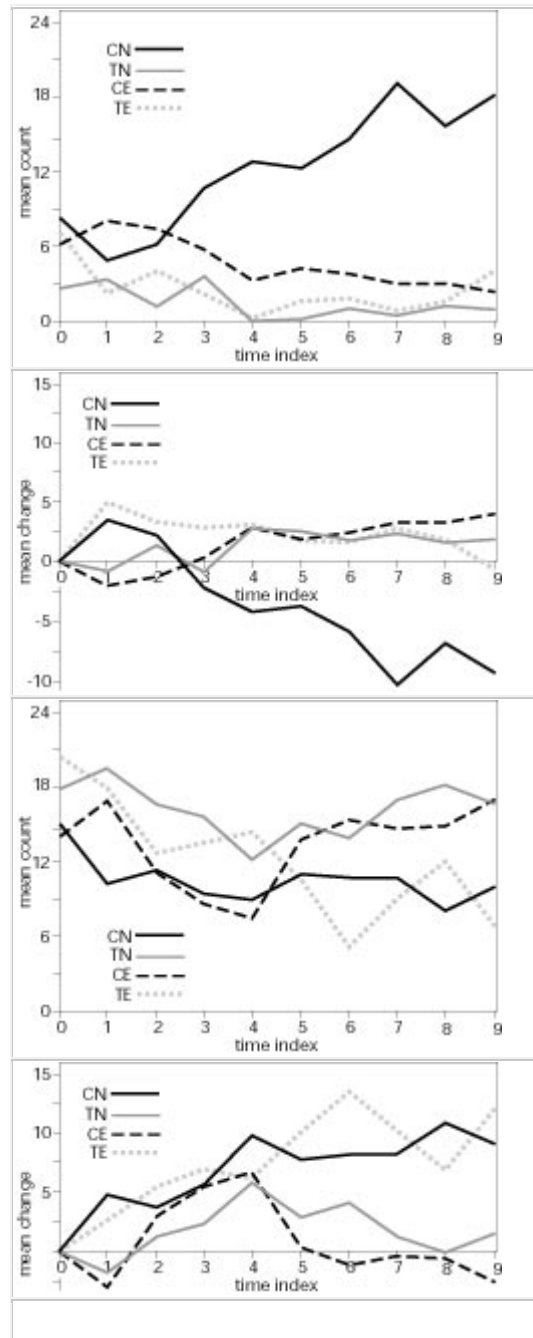
- As in papule counts, male subjects had significantly higher baseline counts, more variable curves, and larger changes in pustule counts on average than did female subjects.
- For females, the CN group worsened over time as shown by mean change values below zero, although there is evidence of some improvement at Time Index 1 and 2. The TN and CE groups worsened at first, but showed improvement past time index 4, with the CE group showing the most

improvement, especially since it started with a relatively high mean baseline pustule count. The TE group showed marked improvement (large positive mean changes) early on, but decreased over time as indicated by smaller positive mean changes and a below-zero value (i.e., worse condition relative to baseline count) at Time Index 20.

- For males, the TE group improved the most because it had the highest baseline count and ended up with the largest mean change at the end of the study. The CN group, which had the lowest baseline count, also improved over time. The CE group improved early in the study but worsened toward the end, while the TN group showed only moderate improvement over time.

Modeling the change in counts as described in the previous section is a way to determine if the above observations are statistically significant or are simply due to chance. Since baseline count could possibly affect the amount of change in the papule and pustule counts, this was included as a covariate in the modeling. Results showed significant 3-factor "sex-treatment-time" interaction for papules ($P < .001$) and pustules ($P = .003$). Hence, there were significant therapeutic effects, but these effects depended jointly on treatment, sex, and time. As expected, it was also found that the baseline count was a significant covariate ($P < .001$). The treatment groups were then compared with each other to determine which group differed from another after adjusting for the baseline count for each time index.

Table 3 summarizes the results of these comparisons of the treatment groups by sex and time after adjusting for baseline counts. No significant differences among the treatment groups for female subjects were observed until the 18th week of treatment. As seen in Figure 2, the significant results were mainly due to the CN group getting worse while the other groups continued to improve, particularly the CE and TN groups. For male subjects, significant differences were observed in the early part of the treatment period, where the TE and CN groups both showed significant improvement over the CE and TN groups. However, at the 20th week of the treatment period, only the TE and TN groups were significantly different from each other, with the TE subjects improving significantly compared with the TN group. The CE and



CN groups also showed improvement at the end of the treatment period as seen in Figure 2, but these improvements were not significantly different from those of the TN or TE groups.

On pustule counts, the CN group was significantly worse than the other groups for females as early as treatment week 14 and continued until the end of treatment. Conversely, there was an increasing trend in the mean change in pustule counts for males and hence, evidence of improvement for both the CN and TE groups. From Table 3, the improvement in the TE group was significantly higher than that of the TN and CE groups, but not with the CN group. The CN female group significantly worsened (papule and pustule) while the other 3 treatment groups improved. TE and CN groups appeared to indicate some positive therapeutic effects on papule and pustule counts.

DISCUSSION

The design of this study was sound and statistical modeling was well-conducted. Even though the sample size was small, some significant results were obtained. Electroacupuncture using the points described appeared to provide some promising positive therapeutic results in the treatment of adolescent mild to moderate acne vulgaris. Differences observed in therapeutic effect of the electrical stimulation vs needle stimulation may result from differences in amount of energy delivered and may also warrant further investigation.

CONCLUSION

We concluded that there was positive improvement of facial acne vulgaris by auriculoacupuncture and auriculotherapy. The results of this pilot study appear promising, suggesting that further study of this alternate treatment for acne is warranted. Apparent sex differences associated with time to treatment effectiveness may affect subject retention and point to a shorter time frame needed to treat males. Although the improvement in facial acne did not always reach statistical significance for the treatment groups, there was improvement that may indicate clinical efficacy.

Many lessons were learned from this pilot study in this rapidly evolving field. Based on our lessons and on advances in the field of auriculotherapy, we recommend that future studies consider:

- Recruiting a larger number of subjects
- Including funds for recruitment and subject remuneration in budget request
- Broadening inclusion criteria to include participants with severe acne vulgaris
- Controlling more rigorously for cofactors or potential confounders such as diet and exercise
- Limiting intervention to only 1 type of treatment (electrical stimulation or acupuncture) at a time
- Considering acne in all 3 phases; and
- Treating the selected active points with a multifrequency probe to allow each point to maximally utilize the appropriate frequency for its stage.

This study used a recipe approach to point selection and took into account only 1 phase of disease process as reflected in the external ear. When disease is

considered in all 3 phases of energetic expression, this necessitates changes in point selection and frequency of optimal electricity delivered to the ear. A multisequence probe would deliver all frequencies to the ear in auriculotherapy, allowing each point to only absorb the frequency that corresponded to its energetic phase. Furthermore, because each subject has unique reasons and energetic imbalances responsible for physical disease expression, a more individualized study design would seem prudent if it could be adequately controlled. For example, more accurate point scanning for electrically active points prior to needling or probe placement to individualize the treatment may result in better outcomes, with some points producing a specific localized effect and others producing a more systemic effect.

Table 1. Distribution of Subjects by Last Week of Treatment, Sex, and Treatment Group

Treatment	Sex	Last Week of Treatment							Total
		6	7	8	12	13	16	20	
CN	F							2	2
	M			1				3	4
TN	F		1	1				2	4
	M							2	2
CE	F							3	3
	M							3	3
TE	F	1	1	1			1	2	6
	M				1	1		3	5
Total		1	2	3	1	1	1	20	29

Abbreviations: TN, treatment needle (auriculoacupuncture); CN, control needle (auriculoacupuncture); TE, treatment electrical (auriculotherapy); CE, control electrical (auriculotherapy).

Table 2. Subjects's Ages

Treatment Group	Age, Mean, (SD), y	
	Female	Male
CN	19(4.2)	17(1.9)
TN	16(2.1)	15(.7)
CE	21(1.5)	15(1.2)
TE	21(3.4)	16(3.6)

Table 3. Results of Comparing Treatment Groups *

Time	Papules		Pustules	
	Female	Male	Female	Male
1 (weeks 4-5)	TE>TN (P=.04) TE>CE (P=.01) CN>TN (P=.02) CN>CE (P=.005)			
5 (weeks 12-13)	CN>TN (P=.02) CN>TE (P=.04)			TE>CE (P=.03)
6 (weeks 14-15)			TE>CN (P=.01) TN>CN (P=.02) CE>CN(P=.01)	TE>TN (P=.03) TE>CE (P=.001) CN>CE (P=.02)
7 (weeks 16-17)			TE>CN (P=.001) TN>CN (P=.003) CE>CN (P=.002)	
8 (weeks 18-19)	TE>CN (P=.04) TN>CN (P=.03) CE>CN (P=.03)		TE>CN (P=.04) TN>CN (P=.03) CE>CN (P=.03)	CN>TN (P=.008) CN>CE (P=.008)
9 (week 20)	TE>CN (P=.02) TN>CN (P=.003) CE>CN (P=.009)	TE>TN (P=.04)	TE>CN (P=.008) TN>CN (P=.003) CE>CN (P=.001)	TE>TN (P=.02) TE>CE (P=.002) CN>CE (P=.01)

*Only comparisons with P<.05 were included in this table.

Further investigation is needed to determine if differences in therapeutic effect between electrical and needle stimulation result from higher energetic input from electrical stimulation. More studies are also needed to better understand the apparent effectiveness of sham therapy from both electrical and needle sham therapy. One possibility is that there may be a strong placebo effect, while it is also possible that the points selected to be sham may actually have therapeutic effects.

On a more holistic level, this study addressed solely physical symptom manifestation even though our being is much more complex, encompassing spiritual, mental, emotional, and energetic parts of our vital force. We believe that all these other aspects of our being affect the root of the disease process. It is possible that a more complex treatment protocol taking these issues into account would yield better results.

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