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Clinical trial

Selective sebaceous gland electrothermolysis as a treatment for acne: a prospective pilot study

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Abstract

Although many therapeutic options exist for acne, relapse often occurs after treatment is stopped. Some preliminary evidence suggests that selective electrothermolysis of the sebaceous glands may represent a novel therapeutic intervention. This trial was conducted to evaluate the efficacy and tolerability of selective sebaceous gland electrothermolysis for the treatment of facial acne. Twelve patients with facial acne were enrolled, all of whom underwent three sessions of therapy. During each session, a 1.5-mm long needle with 0.45-mm of base insulation was inserted into pores of acne lesions. Upon insertion, a high-frequency electrical current was applied for 0.25–0.50 seconds, for a total output of 40 W. Each treatment session took approximately 30–60 minutes. Subject response to therapy was evaluated at one month and 12 months after the final treatment. All the enrolled subjects completed the study and all reported satisfaction with treatment results. In all cases, a reduction in inflammatory and noninflammatory lesion counts was observed after three sessions of selective electrothermolysis, although a few small papules and comedones persisted in several areas of untreated facial skin. Mean lesion reduction at one month after the final treatment was 98.14% for inflammatory lesions and 83.09% for noninflammatory lesions. Clinical success was achieved in the majority of patients (seven of 12 patients) at one month after the second treatment and in all patients at one month after the final treatment. All patients reported transient post-treatment erythema, which faded after a few days. Clinically evident relapse occurred in two of 12 patients (16.7%) one year after the final treatment session. Selective sebaceous gland electrothermolysis can be a safe and effective method of achieving consistent remission in acne.

Introduction

Acne vulgaris is a chronic inflammatory disease of the pilosebaceous units, which is characterized by comedones, papules, pustules, and nodules, and often results in significant facial scarring. Epidemiologic studies estimate that as many as 80% of individuals between the ages of 11 years and 30 years are affected by this common condition. The pathogenesis of acne is deceptively complex: seborrhea, abnormal pilosebaceous duct cornification, ductal colonization with *Propionibacterium acnes*, and secondary inflammatory processes are all implicated in the underlying etiology. As well as the obvious facial disfigurement, acne is also associated with significant psychological morbidity, including emotional debilitation, embarrassment, poor self esteem, and social isolation. Accordingly, an ongoing need for quality medical resources and treatments exists.[1] Although there are many therapeutic options for acne vulgaris, relapse is common after treatments are stopped, although relapse rates after isotretinoin treatment are relatively low if the drug is administered at the correct dose for the correct period. However, because of side effects such as mild cheilitis (dryness of lips), mild xerosis, epistaxis, as well as elevation of serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), cholesterol, and triglycerides, some patients have difficulty complying with isotretinoin treatment.[2]

Preliminary evidence suggests that selective electrothermolysis of the sebaceous glands using the method proposed by Kobayashi and Tamada[3] may represent an additional therapeutic option for facial acne. We undertook this study to evaluate the efficacy and tolerability of this modality. In a one-year follow-up evaluation, we also attempted to quantify the rate of recurrence in treated individuals.

Materials and methods

Patient population

This was a prospective pilot study. Twelve Korean patients with moderate to severe facial acne [according to Investigator's Global Assessment (IGA) scores[4]] (Table 1) were enrolled. All subjects had Fitzpatrick skin types III–V. Exclusion criteria included any use of oral antibiotics or isotretinoin for the treatment of acne within the previous six months, use of topical or systemic antibiotics within the previous two weeks, and pregnancy or lactation in female subjects. Additionally, women using hormonal forms of contraception with anti-androgenic properties for <12 weeks were precluded from enrolling. The mean age of the subjects was 24.6 ± 3.4 years (range: 20–32 years). The group consisted of six women and six men. Table 2 summarizes participant demographics. The study was approved by the Institutional Review Board of Chung-Ang University Hospital. Written informed consent was obtained from all patients prior to treatment.

Treatment protocols

Before treatment, each subject's face was gently cleansed with a mild cleanser prior to the application of a topical anesthetic cream (EMLA®; AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA). After 30 minutes, the anesthetic was removed, and the subject was asked to adopt a supine position prior to the initiation of treatment. Throughout the duration of the procedure, ×2 to ×3 magnifying lenses were used by study personnel. Acne lesions (comedonal acne lesions and inflammatory acne lesions) were identified, the surrounding skin was stretched, and a 1.5 mm-long needle with a 0.45 mm base insulation was inserted into the center of the lesional follicular pore at an angle of 60–70° (Fig. I). Using an electrosurgical apparatus (IME-HR 5000; IME Co. Ltd., Tokyo, Japan), a high-frequency current was then applied for 0.25–0.50 seconds at an intensity of approximately 40 W. Treatment duration was about 10 minutes per 10 lesions treated. The day after the procedure, the contents of the comedo or inflammatory lesion (e.g. pus) were expressed by applying gentle pressure. All subjects underwent a total of three treatment sessions at one-month intervals. During the second and last treatments, the operator deliberately inserted the needles in directions that differed slightly from those used in the preceding session. Complete lesion counts and subject response rates were assessed one month after the final treatment. Subjects were also evaluated for remission rates one year after the final treatment. All subjects were prohibited from using any anti-acne treatment (except for standard washing and moisturizing procedures) while enrolled in the study.

Efficacy evaluation

The patients were photographed at each visit. On each occasion, subjects were photographed by the same photographer in the same position, using identical camera and lighting settings. To evaluate efficacy, two variables were used: overall success rate (defined as the percentage of patients rated as ''clear'' or ''almost clear'' on the IGA) and net change in the number of facial acne lesions. All lesion counts included both inflammatory (papules, pustules, nodules) and non-inflammatory (open and closed comedones) lesions. Lesions were assessed on the face only. At each visit, a blinded physician counted the number of facial acne lesions on each subject's face. This same blinded physician also assessed the overall success rate before each treatment and one month after the final session and documented any side effects. At the end of the study, subjects were asked to rate their level of satisfaction with the final results of the treatment on a four-point scale (4 = very satisfied, 3 = satisfied, 2 = slightly satisfied, 1 = unsatisfied). One year after the last session, all subjects returned for a final follow-up evaluation at which treatment-specific recurrence was assessed. Specifically, any treated patient in whom acne was rated as ''mild,'' ''moderate,'' ''severe'', or ''very severe'' on the IGA was considered to have suffered a relapse. Treatment effects were determined based on statistical analysis using the Wilcoxon signed rank test to compare lesion counts at each follow-up visit with baseline counts. A P-value of <0.05 was considered to indicate statistical significance.

Results

All subjects completed the study and all showed a reduction in inflammatory and non-inflammatory acne lesions after three selective electrothermolysis treatments. Clinical

Table 1 Investigator's global assessment

Rating	Definition
0 = Clear	Residual hyperpigmentation and erythema may be present
1 = Almost clear	A few scattered comedones and a few (<5) small papules
2 = Mild	Easily recognizable; less than half the face is involved. Many comedones and many papules and pustules
3 = Moderate	More than half of the face is involved. Numerous comedones, papules and pustules
4 = Severe	Entire face is involved. Covered with comedones, numerous papules and pustules and few nodules and cysts
5 = Very severe	Highly inflammatory acne covering the face; nodules and cysts are present

Table 2 Summary of patient demographics

	n	Age, years, range (mean)	Fitzpatrick skin type I	II	III	IV	V	VI
Female	6	20–32 (25.5)	–	–	2	3	1	–
Male	6	21–28 (23.7)	–	–	1	4	1	–
Total	12	20–32 (24.6)	–	–	3	7	2	–

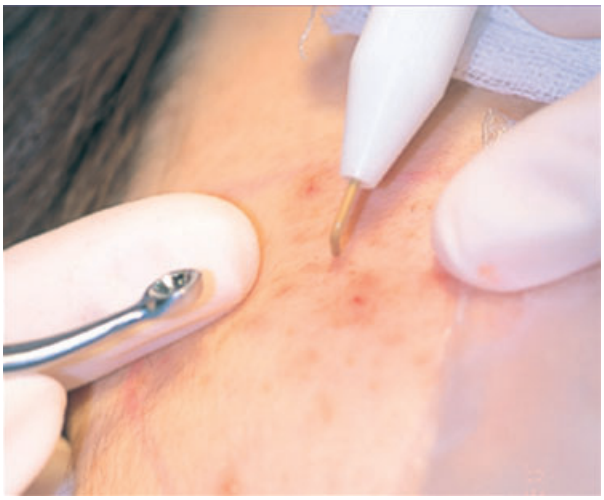

Figure 1 In selective electrothermolysis in the treatment of acne, a fine needle with an insulated coating is inserted into the center of the follicular orifice and used to deliver an electrical current, after which an extractor is used to remove any coagulated sebum from the lesion

examples are shown in Figures 2 and 3. One month after the first treatment, the mean reduction in acne lesions was 59.20% for inflammatory-type lesions ($P < 0.01$) and 48.64% for non-inflammatory lesions ($P < 0.01$). One month after the second treatment, the mean reduction in acne lesions was 82.96% for inflammatory lesions ($P < 0.01$) and 69.79% for non-inflammatory lesions ($P < 0.01$). One month after the final treatment, the mean reduction in acne lesions was 98.14% for inflammatory lesions ($P < 0.01$) and 83.09% for non-inflammatory lesions ($P < 0.01$). In terms of the overall success rate, clinical success was achieved in the majority of patients (seven of 12 patients) one month after the second treatment and in all cases at one month after the final session. Figures 4 and 5 illustrate progressive changes in numbers of inflammatory and non-inflammatory lesions from baseline. Of the 12 patients, one (8%) reported being "slightly satisfied" with the treatment, four (33%) reported being "satisfied", and seven (59%) reported being "very satisfied." The mean score for patient satisfaction was 3.50 ± 0.67 (out of 4). The most common reported side effect was transient erythema at the sites of treated lesions. The inflammatory content (pus) released by gentle pressure spread to the surrounding tissue, inducing erythema and further inflammation. Although this occurred in all subjects, the redness typically faded within several days and seldom persisted for a week. Other severe adverse events – such as pigmentary alterations, scarring, and infections – were not reported. One year after the final treatment, two of 12 patients (16.7%) were found to have relapsed. However, in both cases, the acne was rated as "mild."

Discussion

Lloyd and Mirkov[5] first reported selective sebaceous gland photothermolysis as an effective treatment for acne. These authors employed a long-pulse diode laser with a wavelength of 810 nm to destroy enlarged sebaceous glands preloaded with indocyanine green chromophore.[5] Kobayashi and Tamada[3] demonstrated that selective sebaceous gland electrothermolysis is a safe and effective therapeutic option for facial seborrhea. They also showed that a decreased number of sebaceous glands and the formation of fibrosis were observed after selective sebaceous gland electrothermolysis in a preliminary histologic study.[3] Together, the results from these studies suggest that this technique may represent a new therapeutic modality in the treatment of acne.

Here, we show that selective sebaceous gland electrothermolysis effectively treats acne; all our subjects reported satisfaction with the treatment in their self-assessment surveys. Other than transient erythema and mild dryness, no adverse events were observed in any of the subjects. Our data also indicate a low relapse rate after this specific therapy: only a few tiny papules or comedones were observed in untreated areas of skin in a few patients. We also presume that more than three treatment sessions (probably at least four or five sessions) will be required in very large cystic lesions to completely destroy all associated sebaceous glands as most recurrences occurred in the treatment zones of the largest acne lesions. We attribute our results to the permanent reduction in sebum excretion achieved by selective electrothermolysis through the precise destruction of hyperactive

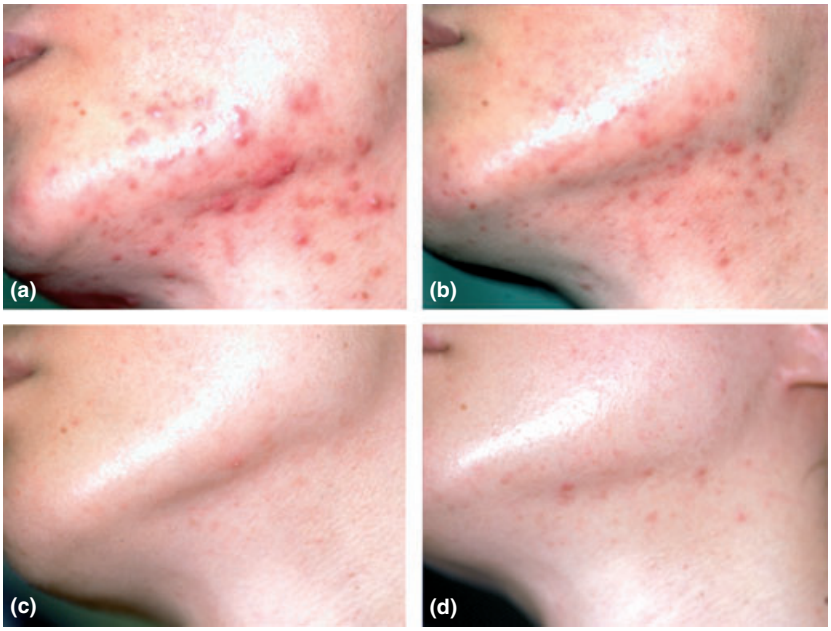

Figure 2 Facial acne in a 23-year-old man (a) before the initiation of treatment, (b) at 1 month after the first treatment, (c) at 1 month after the final treatment, and (d) at 1 year after the last treatment

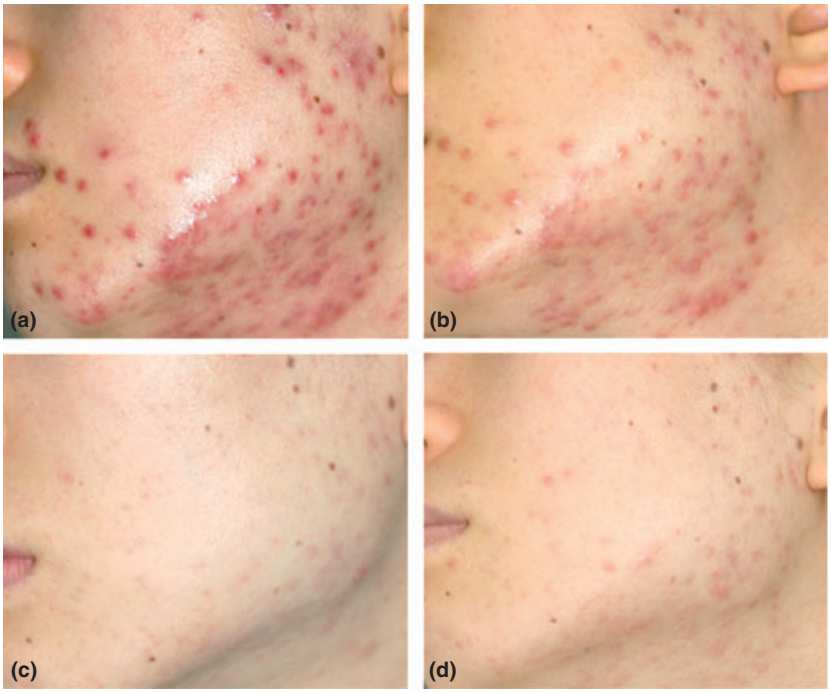

Figure 3 Facial acne in a 25-year-old man (a) before the initiation of treatment, (b) at 1 month after the first treatment, (c) at 1 month after the final treatment, and (d) at 1 year after the last treatment

sebaceous glands by electrical heat.[3] Reducing the production of sebum, which is a medium for bacteria growth, is helpful for normalizing *Propionibacterium acnes* hypercolonization. It is also possible that this intervention-induced heat extended to the thermal destruction of bacteria.[5] Moreover, the development of new technology, which allowed for very tight adhesion between the short, thin needle and insulating material, was critical to our study. This reliable, strong insulation permitted us to use electrical power at a voltage sufficiently high to eliminate the target tissue without damaging the surface of the skin.

Because this study is not a comparison study, it is impossible to directly compare the efficacy of this treatment with that of other treatments. However, selective electrothermolysis has some notable advantages over

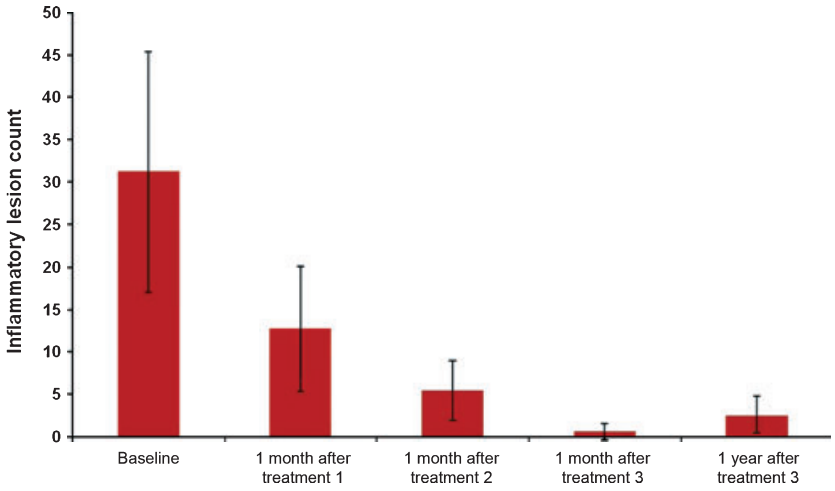

Figure 4 Changes in total mean inflammatory lesion count from baseline

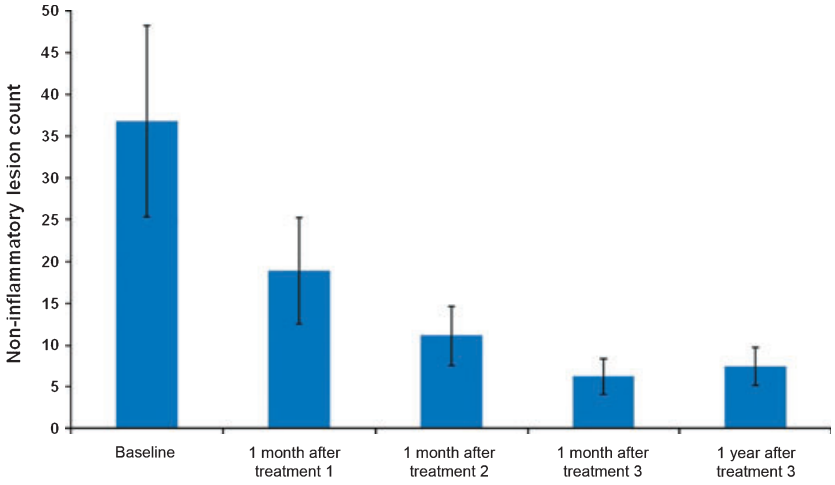

Figure 5 Changes in total mean non-inflammatory lesion count from baseline

other acne treatments. Most conventional topical agents – including antimicrobials, retinoids, and anti-inflammatory agents – must be applied daily for several weeks before any effect is seen, and most are associated with some degree of skin irritation.[2,4,6,7] Similarly, many of the conventional oral medications used in treating acne – including antibiotics, oral contraceptives, and retinoids – have significant portfolios of side effects, including, but not limited to, gastrointestinal upset, antibiotic resistance, thromboembolic events, and teratogenicity.[2,8–10] By contrast, selective electrothermolysis performed by properly trained therapists has not been associated with any severe side effects. As this method is not a systemic treatment, many of the intrinsic problems associated with the current acne regimens (e.g. patient compliance and associated side effects) are not applicable. More recently, optical treatments have been introduced as alternative treatments for acne, including pulsed dye lasers (PDLs), infrared diode lasers, radiofrequency devices, intense pulsed light (IPL), and broad-spectrum blue and red light sources.[11–15] However, the therapeutic efficacy of these modalities is limited, and relapse is common after these treatments are stopped. As selective electrothermolysis results in the permanent destruction of treated sebaceous glands, it is associated with a low relapse rate. Additionally, this intervention achieves therapeutic efficacy in only two or three treatment sessions. Unlike photodynamic therapy, selective electrothermolysis does not require patients to avoid sun exposure for 48 hours after treatment and can be used in photosensitive patients.[16–18]

In conclusion, our results suggest that selective electrothermolysis is clinically effective for the treatment of acne and that it is associated with minimal complications. Although few studies have fully described this treatment, we contend that selective electrothermolysis represents another effective treatment modality that supports consistent remission in acne. However, as this is a small study, additional, larger studies are needed to fully evaluate this technique.

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