Assessment of Treatment Efficacy and Sebosuppressive Effect of Fractional Radiofrequency Microneedle on Acne Vulgaris

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Background and Objective: A minimally invasive fractional radiofrequency microneedle (FRM) device has been used in skin rejuvenation and acne scars, and a recent pilot study demonstrated the positive therapeutic effect on acne. We evaluated the efficacy of FRM device for acne vulgaris in Asians and conducted objective measurement to assess its effect on sebum production.

Patients and Methods: Twenty Korean patients with acne vulgaris received a single full-face FRM treatment. Outcome assessments included standardized photography, physician’s global assessment, patient’s satisfaction scores, acne lesion count, and objective measurements of casual sebum level (CSL) and sebum excretion rate (SER). They were evaluated at baseline and 2, 4, 8 weeks after the treatment.

Results: After a single FRM treatment, the CSL and the SER showed 30–60% and 70–80% reduction, respectively, at week 2 (P < 0.01), and remained below the baseline level until week 8. Physician's global improvement scores for acne severity and acne lesion count also revealed clinical improvement with maximum efficacy at week 2, but returned to the baseline in most patients by week 8. Patients' satisfaction scores (0–4) were above 2 on average, and adverse effects were minimal.

Conclusion: This prospective study demonstrated the sebosuppressive effect from a single FRM treatment, but its therapeutic efficacy in acne requires further evaluation.

Key words: acne vulgaris; fractional radiofrequency microneedle; sebum excretion

INTRODUCTION

Acne vulgaris is a disorder of the pilosebaceous unit [1]. The putative pathogenic factors of acne are sebum overproduction, follicular epidermal hyperproliferation, Propionibacterium acnes colonization and inflammation [1]. As the relationship between the sebum secretion and acne has been mentioned, a recent meta-analysis study revealed a linear correlation between the sebum excretion rate and the acne severity [2]. Choi et al. [3] also showed that the casual sebum level had positive correlation with the number of acne lesions.

Systemic retinoids and hormones are two pronounced acne medications that reduce sebum secretion [2]. Especially, oral isotretinoin is known to have the greatest effect on sebum reduction among other modalities, and is effective in moderate to severe inflammatory acne. However, due to its teratogenicity and adverse events profile, some patients are unwilling to take it and also some doctors might hesitate to prescribe it [2,4].

A recently introduced minimally invasive fractional radiofrequency microneedle (FRM) device has been used in skin rejuvenation and scars [5,6]. Because the insulated microneedles make it possible to control treatment depth more accurately while sparing the epidermis, it has a more favorable side effect profile than the conventional ablative treatment modalities. At the appropriate depth setting, it creates radiofrequency thermal zones in the deeper reticular dermis and thus induces long-term dermal remodeling which includes neocollagenesis [5–7].

Concerning treatment of acne and its consequences, many studies with a FRM device have been conducted to evaluate its effect on acne scars. Recently, Lee et al. [8] demonstrated a positive therapeutic effect of FRM on inflammatory acne vulgaris and related scars. The authors suggested that FRM might have a thermal inhibitory effect on sebaceous gland, but objective data regarding sebum excretion were lacking. In addition, the duration of clinical improvement from a single treatment as well as the adequate treatment interval for maintenance therapy also needs to be elicited.
This present study was undertaken to evaluate the efficacy of FRM device for acne vulgaris in Asians. Furthermore, this study sought to demonstrate the sebosuppressive effect of FRM through the objective measurement of sebum excretion, and the duration of clinical improvement from a single treatment.

**METHODS**

**Patients**

Twenty patients (10 male, 10 female; mean age: 26.5, range: 21–34; Fitzpatrick skin type: III–IV) suffering from moderate to severe acne vulgaris were recruited in this prospective clinical study approved by the CHA University Institutional Review Board. Informed consent was obtained from each subject prior to enrollment. The Investigator's Global Assessment (IGA) was applied to the patients for the evaluation of acne severity at baseline (Table 1) [9]. At entry, each patient had more than 10 inflamed lesions (papules, pustules, nodules, and cysts). The exclusion criteria were: (1) patients who had taken any medication known to affect sebum secretion such as isotretinoin, or had received chemical peeling or any surgical treatment for acne within 6 months, (2) those who had been treated with topical/oral antibiotics or topical retinoids within 4 weeks, and (3) those with concurrent systemic diseases, pregnancy, previous history of frequent herpes simplex facialis, and active infection. No concomitant therapy for acne vulgaris was permitted during the study. This clinical study started in November 2012 and concluded in January 2013. There were no control groups in this study.

**Description of Devices**

We used a FRM device (Infini™, Lutronic Co., Goyang-si, Korea), which has a disposable single-use treatment tip consisting of 49 insulated microneedle electrodes in an area of 1 cm². These microneedle electrodes are nonconductive except for the final 300 µm of the distal tip to prevent superficial thermal injury at the insertion site. The depth of the inserted tips can be adjusted from 0.1 to 3.5 mm (0.1, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5 mm) below the skin surface. Bipolar radiofrequency energy is delivered to the dermis at 1 MHz. Adjustable radiofrequency power up to a maximum of 50 W can be delivered, in relation to the levels 1–20 with various exposure times (10–1,000 milliseconds).

**TABLE 1. The Investigator’s Global Assessment (IGA) of Acne Severity**

| Grade 0 | Clear | No inflammatory or noninflammatory lesions |
| Grade 1 | Almost clear | Rare noninflammatory lesions with no more than one papule/pustule |
| Grade 2 | Mild | Some noninflammatory lesions, no more than a few papules/pustules, but no nodules |
| Grade 3 | Moderate | Up to many noninflammatory lesions, may have some inflammatory lesions, but no more than one small nodule |
| Grade 4 | Severe | Numerous noninflammatory and inflammatory lesions, and few nodules and cysts |

**Treatment Protocols**

Patients received a single non-overlapping full-face treatment per the manufacturer’s recommendation after baseline measurements. The face was anesthetized using topical 4% lidocaine cream (LMX4, Ferndale Laboratories, Inc., Ferndale, MI) about 30–60 minutes before the procedure. Then it was cleaned with facial foam cleanser and 70% alcohol. The treatment settings were as follows: 1.0- or 1.5-mm microneedle penetrating depth (periorbital area and forehead, 1.0 mm; all other areas, 1.5 mm); level 5; and a RF exposure time of 50 or 100 milliseconds (forehead, chin, and left cheek, 50 milliseconds; nose and right cheek, 100 milliseconds). We treated each cheek with different exposure times, keeping all other parameters the same. An epidermal cooling device (Caresys, Danil SMC, Seoul, Korea) was used to relieve pain and erythema after the treatment. Subjects were allowed to apply sunscreen or emollients according to their usage but prohibited from using any kinds of retinoids or antibiotics before the study entry and during the study period.

**Clinical Assessments**

Patients were assessed at baseline and 2, 4, 8 weeks after the treatment. Five standard clinical photographs (i.e., an anterior view of the entire face, both oblique views, and both lateral views) were taken using a digital camera (Nikon D90, Nikon, Inc., Tokyo, Japan). Counting of inflammatory acne lesions (including erythematosus papules, pustules, nodules and cysts) was conducted using a photo editing software program (ACDSee Pro Photo Manager, Chilkat Software, Inc., Wheaton, IL). Lesions in the forehead, nose and chin were counted using en face photographs. Those in the cheeks were counted using the oblique and lateral profile photographs. Lesions on the nasal root and upper lip were not counted because these areas were not treated. Investigators’ clinical assessments were performed by two dermatologists comparing before and after photos using a global improvement scale (grade 0 = no improvement; grade 1, 1–25% = minimal improvement; grade 2, 26–50% = moderate improvement; grade 3, 51–75% = marked improvement; and grade 4, 75–100% = near total improvement). Global improvement scores regarding the acne severity and the facial greasiness were recorded separately. The former was primarily based on the number of inflammatory and noninflammatory acne lesions. For the latter, the degree of the gloss and pores visible to the naked eye as well as the tactile assessment of the skin’s oiliness were taken into consideration.
For patients’ satisfaction scores, patients answered questionnaires about efficacy and side effects at every follow-up visit. The degrees of perceived acne improvement and greasiness were categorized using a 5-point scale: 0 = worsened, 1 = no improvement, 2 = somewhat improved, 3 = fairly improved, 4 = noticeably improved. In addition, they were asked to report any adverse effects during the study.

**Objective Assessment of the Sebum**

The amount of surface sebum is dependent on the amount of excreted sebum from the sebaceous glands and the amount of washed-out sebum from the surface. In this study, the casual sebum level (CSL) and the sebum excretion rate (SER) were measured using a sebumeter (Sebumeter SM815; C-K Electronics, Cologne, Germany), as previously described [10]. The CSL, expressed in mg/cm², represents the spontaneous lipid film covering the skin surface which is mostly derived from sebum. The SER is the speed of production of sebum expressed in mg/cm²/hour, which is an indicator and quantifier of the activity of the sebaceous glands [10]. The sebumeter readings were performed before treatment, and at the follow-up visits (weeks 2, 4, and 8). Three different sites were measured: the forehead (2 cm above the mid-glabella) and the right and left cheeks (the most prominent area of both zygomata). Non-overlapping three spots on each site were measured by the same investigator, and the mean of three measurements was recorded.

**Casual sebum level (CSL).** For the CSL, every subject was asked to wash the face and refrain from putting on any cosmetics for at least 4 hours prior to the measurement. The measurements were conducted in a room with a controlled environment (constant temperature of 21.5 ± 2.5°C and an average humidity of 48 ± 2%), as recommended by European Group for Efficacy Measurements on Cosmetics and Other Topical Products (EEMCO) [11].

**Sebum excretion rate (SER).** We evaluated the amount of facial sebum excretion during 60 minutes to obtain the SER after measuring the CSL. To ensure high measurement reproducibility, we followed the protocol similar to that suggested by Rode et al. [10] The baseline sebum level (at time 0) was measured using the same sebumeter right after the face was cleaned with facial foam cleanser and 70% alcohol wipes. The subjects then stayed in the same controlled environment room for a waiting period of 60 minutes to allow sufficient sebum to be excreted onto the skin surface. After the second sebum level (at 60 minutes) was measured again, the investigator calculated the difference between the sebum levels during 60 minutes.

**Statistical Analysis**

We used a repeated measures analysis of variance followed by post hoc comparisons using Bonferroni to compare data obtained at each follow-up visit to the baseline data. This was performed for the acne lesion count, the CSL, and the SER. Also, the differences between the right cheek and left cheek were validated with independent T-test. Data were analyzed using SPSS software (version 19.0.0, SPSS, Inc., Chicago, IL). P-values of <0.05 were considered statistically significant.

**RESULTS**

**Clinical Assessments**

All 20 patients completed the study, and their demographic data with acne grade are summarized in Table 2. None of the patients had taken any oral antibiotics for acne in the past 2 years or used any topical anti-acne agents within 2 months prior to the study. The global improvement scores for the acne severity (Table 2) and the facial oiliness (Table 3) were assessed at every follow-up visit (weeks 2, 4, and 8) using a quartile scale. The scores for both categories revealed the highest scores at week 2 and declined afterwards (Fig. 1). The mean scores for the facial oiliness were 2.2, 1.9, and 1.7 at the 2-, 4-, and 8-week follow-ups, respectively. Those for the acne severity were 1.8, 1.3, and 0.6, respectively, at the same follow-up assessments, which were lower than those for the oiliness.

In fact, more than half of the patients were graded at 0 for the acne improvement scores at week 8.

For the acne lesion count, the mean of the total number of inflammatory acne lesions decreased from 18.0 at baseline to 14.1 at week 2. However, it increased to 19.6 at week 4, and then decreased to 17.0 at the end of the 8-week follow-up (Fig. 2). The same pattern was observed when the acne lesions in the subdivided zones (i.e., the forehead, right cheek, and left cheek) were counted separately (Fig. 2). The number of the lesions was not significantly different between the right and left cheeks.

Representative photographs which were taken at baseline and at the 2-, 4-, and 8-week follow-ups also reflected a similar tendency: maximum improvement at week 2 followed by the gradual flare-up (Fig. 3).

Patients’ satisfaction scores for clinical improvement were also assessed at every follow-up visit using a 5-point scale. The mean satisfaction scores for the acne severity were 2.1, 2.0, and 2.0 at the 2-, 4-, and 8-week follow-ups, respectively (Table 2). Those for the facial oiliness were 2.1, 2.2, and 2.1, respectively, at the same follow-up assessments (Table 3). Only one patient graded 0 (worsened) on both criteria. Patients showed relatively high overall satisfaction even though the global improvement scores by physicians diminished at later follow-up visits (Fig. 1).

**Objective Assessment of Casual Sebum Level (CSL)**

The CSL measured by the sebumeter decreased the most at 2 weeks after the treatment (P < 0.01) and was maintained below the initial level throughout the 8-week follow-up period (Fig. 4). The mean values for the CSL on the forehead were 197, 136, 135, 165 (mg/cm²) [100%, 70%, 70%, 80%; compared to the baseline value] at baseline and the 2-, 4-, and 8-week follow-ups, respectively. On the right cheek, it measured 170, 73.4, 88.3, 155 (mg/cm²) [100%, 40%, 50%, 90%; compared to the baseline value],
respectively, at the same follow-up assessments, whereas it measured 168, 73.7, 81.4, 132 (mg/cm$^2$) [100%, 40%, 50%, 80%], respectively, on the left cheek. There was no statistically significant difference in the CSL between the right and left cheeks. All the measured values during the follow-up period were below the initial level, and were statistically significant ($P < 0.05$) except for those on the right cheek at week 8.

Objective Assessment of Sebum Excretion Rate (SER)

The SER measured by the sebumeter decreased dramatically at 2 and 4 weeks after the treatment ($P < 0.01$) and was sustained below the initial level throughout the 8-week follow-up period ($P < 0.05$) (Fig. 5). The mean SER of the forehead was 128.0, 55.4, 43.8, 99.2 (mg/cm$^2$/hour) [100%, 40%, 30%, 80%; compared to the baseline value] at baseline and the 2-, 4-, and 8-week follow-ups, respectively. On the right cheek, it measured 92.2, 18.8, 19.8, 74.9 (mg/cm$^2$/hour) [100%, 20%, 20%, 80%; compared to the baseline value], respectively, at the same follow-up assessments, whereas it measured 84.6, 27.3, 24.0, 65.4 (mg/cm$^2$/hour) [100%, 30%, 30%, 80%], respectively, on the left cheek. The SER was not significantly different between the right and left cheeks.

Correlation of the Acne Lesion Count and Objective Sebum Assessment

We could not find a direct correlation between acne lesion count and sebum production status (both CSL and SER). Although the acne lesion count and the values of both the CSL and SER showed prominent declines at week 2, the increase in the acne lesion count was more marked than that of sebum production after 4 weeks of follow-up. While the CSL and SER readings during the follow-up remained below the baseline, the acne lesion count at week 4 outnumbered the baseline. The forehead, right cheek and left cheek all showed similar patterns (Fig. 6).

Adverse Events

Patients experienced mild pain during the FRM treatment, but it was well tolerated. Post-therapy bleeding,
erythema, and edema were often encountered, but all were temporary and improved spontaneously within a week. Neither serious nor other possible adverse events including secondary infection, scarring, and hyper/hypo-pigmentation were noticed. Multiple pin-head sized pustular eruptions were observed in two patients, one of whom had a past history of atopic dermatitis, but these lesions were mild, and did not persist longer than 1 week without any additional medication.

**DISCUSSION**

Although there are several kinds of effective systemic agents for acne vulgaris including antibiotics, retinoids, and hormones, some patients want to avoid medication which requires long-term administration and has possible adverse events. Recently, diode laser devices and non-ablative radiofrequency (RF) devices targeting the sebaceous glands have been applied for the treatment of acne [6,8,12,13]. Two studies using a 1,450 nm diode laser revealed a decreased SER after the treatment, and the authors supposed that diode laser devices could lead to secondary functional impairment of the sebaceous glands in addition to direct destruction [12,13]. Other laser treatments have shown to improve acne clinically, but their mechanism of action is not fully understood, and their influence on sebum secretion is not consistent [14].

Another recent study introduced Kobayashi’s method which uses selective electrothermolysis with insulated needles targeting hair follicles [4]. This electrothermolysis method illustrated a mean sebum reduction rate of 31.5% at the 6-month follow-up. The authors explained that its prolonged reduction of sebum might be attributable to the accurate, irreversible electrothermal destruction of the sebaceous glands which are located at depths of 0.3–1.7 mm below the skin surface. The histological evaluation also revealed that the sebaceous glands were replaced by fibrosis [4].

A FRM device may exert similar effects on sebaceous glands as Kobayashi’s method. They both target dermal structures using insulated needles. Similar to Kobayashi’s method which uses electrothermal energy, the FRM device releases RF which is converted into a thermal effect. Other previous studies have also shown that RF thermal zones containing denatured collagen were maintained in the reticular dermis for longer than 28 days after treatment.

**TABLE 3. Clinical Outcomes Regarding Facial Oiliness at Follow-Ups (Weeks 2, 4, and 8)**

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New dermal tissue partially replaced the zones, and tropoelastin and procollagen steadily increased until 28 days after the procedure [6,7]. These changes were considered as possible mechanism behind clinical improvement in acne scars when treated with FRM devices. While the efficacy of FRM treatment on acne scars has been more actively investigated, there have only been a limited number of reports regarding its efficacy on active acne vulgaris. Recently, Lee et al. [8] demonstrated a positive therapeutic effect of FRM on inflammatory acne vulgaris and related scars after two sessions. The authors suggested that FRM might have a thermal inhibitory effect on sebaceous gland, but objective data regarding sebum excretion were lacking.

Our prospective study demonstrated the sebosuppressive effect from a single FRM treatment in acne vulgaris. The study results revealed that FRM treatment reduced both the CSL and the SER. It produced the maximum sebosuppressive effect at 2 weeks after the treatment ($P < 0.01$). At week 2, the measured areas showed 30–60% reduction in the CSL and 70–80% reduction in the SER. The measurements remained under the baseline values in most of the treated areas throughout the 8-week follow-up period ($P < 0.05$, except for the CSL of the right cheek at week 8) although they increased toward the end (Figs. 4 and 5). The CSL and the SER of the forehead and both cheeks followed a similar pattern, but the reductions in the CSL and the SER were more prominent on the cheeks than the forehead. It seems that sebum production in the cheeks was impacted more than the forehead by the FRM treatment. This difference might result from the difference in treatment depth (1.0 mm on the forehead vs. 1.5 mm on the cheeks).

Fig. 1. Global improvement scores by the investigators and patients’ satisfaction scores regarding the acne severity and the facial oiliness respectively at the follow-up visits (weeks 2, 4, and 8). (Global improvement scores: grade 0 = no improvement; grade 1, 1–25% = minimal improvement; grade 2, 26–50% = moderate improvement; grade 3, 51–75% = marked improvement; and grade 4, 75–100% = near total improvement. Patients’ satisfaction scores: 0 = worsened, 1 = no improvement, 2 = somewhat improved, 3 = fairly improved, 4 = noticeably improved.)

Fig. 2. The average of the total number of inflammatory acne lesions, either when counted in total or in each subdivided zone, decreased at 2 weeks after the treatment but increased at week 4, and then decreased to around baseline at the end of the 8-week follow-up. The lesions on the nasal root and upper lip were not included.
Another hypothesis is that more sebaceous glands might have remained unaffected on the forehead after the FRM treatment because of the higher baseline density. Another thing to mention about the CSL and the SER is that the SER data may reflect the sebosuppressive effect more accurately than the CSL because the period of 4 hours prior to the CSL measurement was not as strictly controlled as to the SER measurement.

In comparison to the sebosuppressive effect, the therapeutic effect of a single session of FRM treatment on inflammatory acne lesions was relatively temporary and rather modest. There was a decrease in the acne lesion

![Image of acne lesions before and after treatment](image)

**Fig. 3.** Moderate acne vulgaris in a 25-year-old woman (A) before the FRM treatment. Clinical improvement was observed most prominently at week 2: (B) 2 weeks, (C) 4 weeks, and (D) 8 weeks after the treatment.

![Casual sebum level chart](image)

**Fig. 4.** The casual sebum level (CSL) measured by the sebumeter before the treatment, and at the follow-up visits (weeks 2, 4, and 8) (*P < 0.05, **P < 0.01).
count at week 2 (Fig. 2), but this did not reach statistical significance \( (P = 0.09) \). By the end of the 8-week follow-up, clinical acne severity returned to the baseline in most patients. To confirm the therapeutic effect of FRM on acne lesions, another study of repeated FRM treatment with a 3-week interval will be needed.

This temporary improvement of acne by the FRM treatment could have resulted from either thermal damage to the sebaceous glands by RF or physical disruption of hyperkeratotic plugs in the follicular infundibula by the microneedles, or both. Although the decreased level of sebum production was maintained for a longer period of time, the improvement of active acne seemed short-lasting (Fig. 6). This discrepancy may be due to the multiple etiologic factors of acne. Control of sebum overproduction may not be sufficient for overall acne improvement. Nevertheless, there was an interesting finding about the patients’ satisfaction scores. They remained high even after the global improvement score and the acne lesion count implied the declined therapeutic effect. Patients might have regarded the decreased sebum or improvement in overall skin texture as a clinical improvement in their acne.

Our study focused on the sebum overproduction because previous studies supported the connection between acne and high rates of sebum secretion [15]. Also earlier studies using bioengineering methods revealed that the facial sebum secretion was increased in patients with acne [1,16,17]. Recently, Janiczek-Dolphin et al. [2] conducted a meta-analysis to seek the relevance of the sebum reduction and the acne treatment outcome. The reduced sebum production was related to clinical acne improvement regardless of the treatment modalities which included oral retinoids and oral contraceptives.

However, there are some difficulties when studying the relationship between sebum secretion and acne. For one thing, objective sebum measurement methods have been adopted in clinical studies only recently [10]. Besides, there are many factors which can affect facial sebum secretion, such as topographic differences, environmental factors, demographic profiles, inherited factors, and hormonal factors [18–20]. There are also diurnal and seasonal changes in facial sebum. Youn et al. [18] demonstrated that day-to-day variations in sebum secretion can be cyclic, and these variations may have different patterns for different ethnicities.

Fig. 5. The sebum excretion rate (SER) measured by the sebumeter before the treatment, and at the follow-up visits (weeks 2, 4, and 8) (* \( P < 0.05 \), ** \( P < 0.01 \)).

Fig. 6. The acne lesion count, CSL, and SER of the forehead, right cheek, and left cheek assessed at baseline and 2, 4, and 8 weeks after the treatment.
underlying mechanism of acne treatment. In an effort to minimize the confounding variables in sebum measurement, our study was carried out in the afternoon hours (from 1 PM to 5 PM) and during the winter months (from November to January). Most importantly, we conducted the measurement in a controlled environment room with constant temperature and humidity.

There are two more aspects to consider regarding obtaining high measuring reproducibility: the measuring device and the parameters. First, we used the Sebumeter® and the changes in sebum level can be analyzed quasi-quantitatively. It is based on the photometric method and utilizes the fact that the special film becomes transparent as it absorbs sebum. Although there are other non-invasive methods [10,11], the Sebumeter® is more universally used because of its convenience. Its measurement is independent of skin water content and a zero calibration before each measurement allows high accuracy. Second, as for the sebum parameters, quantitative parameters include the CSL, the SER, the sebum replacement time, the instant sebum delivery, the follicular excretion rate, and the density in sebum-enriched reservoirs [11]. We adopted the CSL and the SER because they are the most widely used parameters in previous works [1,3,4,12–18,21] and can be measured by the sebumeter®.

In conclusion, this study demonstrated a significant sebosuppressive effect of a single FRM treatment through objective assessment of sebum levels. Although there was a temporary decrease in the acne lesion count after the treatment, the overall clinical improvement in acne during the follow-up was not significant. The limitations of this study are the small number of patients, the lack of a control group, the single treatment session, and the lack of histological assessment. We only performed a single FRM treatment and thus the results reflect the duration of the FRM effect after one session. Perhaps multiple sessions with adequate intervals may yield better outcomes. Also, different device settings may induce different clinical outcomes. As part of comparing the effects of different parameters, we treated the right cheek with a longer RF exposure time than the left side. However the sebum level and clinical improvement were not significantly different while patients mentioned more pain and post-treatment crusting on their right cheeks. Different results might have been obtained if we had changed the power levels instead of the exposure time. Therefore, further investigations are required regarding the number of sessions, the interval between sessions, and treatment parameters. Nonetheless, these preliminary study results call for the need for further clinical trials to evaluate the possible therapeutic efficacy of FRM on acne and suggest the usefulness of noninvasive measurement devices for studying the underlying mechanism of acne treatment.

REFERENCES