J. Cosmet. Sci., 57, 95–105 (March/April 2006)

A pilot study on efficacy treatment of acne vulgaris using a new method: Results of a randomized double-blind trial with Acne Dressing®

CHAO-MING CHAO, WEI-YU LAI, BAI-YAO WU, HUNG-CHIA CHANG, WEI-SHUAN HUANG, and YU-FEI CHEN, *Department Of Dermatology, Tri-Service General Hospital, 325 Cheng-Kung Road Section 2, Taipei 114, Taiwan, Republic of China.*

Accepted for publication October 31, 2005.

Synopsis

For many years the positive effect of hydrocolloid dressings on skin-related conditions attracted the attention of the medical scientific community. The use of Acne Dressing®, a tape of hydrocolloid dressing, for the treatment of acne has not been reported previously. The aim of this study was to evaluate the clinical efficacy and beneficial effect of Acne Dressing® on the marker for sebum output evaluations. We also determined the cosmetic outcome of this application during the treatment of acne and whether the material could prevent hand touching and UVB light from reaching the skin surface. The objective of this study was to assess improvement in acne vulgaris and tolerability during one week of short contact treatment with Acne Dressing® compared to skin tapes. Efficacy data specific to treatment of acne vulgaris with Acne Dressing® (3M Health Care) from a double-blind, randomized, skin types-controlled study is reported. A total of 20 patients with mild-to-moderate acne vulgaris applied the skin tapes or Acne Dressing® every two days for up to one week. Twenty patients were enrolled in this study: ten patients received Acne Dressing® and ten patients received skin tapes. Both groups showed decreases from baseline to the end of treatment in the mean of the overall severity scale (decrease of 1.37 from 1.8 to 0.43 with Acne Dressing® and 0.28 from 1.08 to 0.8 with skin tapes). A statistically significant greater reduction was observed over a period of three to seven days in the overall severity of acne and inflammation in the Acne Dressing group compared with the mono-therapy (skin tapes) group. Similarly, Acne Dressing® resulted in a significantly greater improvement in the redness, oiliness, dark pigmentation, and sebum casual level at days 3, 5, and 7. The ratio of transmission of UVB light with Acne Dressing® was 7.4%, and 38% with skin tapes, which shows less UVB light reaching the skin surface with the Acne Dressing®. No significant adverse events were identified in either group. The pilot study shows the benefit of treatment with Acne Dressing® in improving mild-to-moderate inflammatory acne vulgaris. A future study will investigate a large set of patients in longer followup periods.

INTRODUCTION

Acne vulgaris is an extremely common skin disorder, which in cases of extreme disfiguration can have severe consequences in the personality development of people and

Address all correspondence to Chao-Ming Chao.

which is associated with significant medical, social, and psychological problems (1–3). In recent years, advances in the understanding of the pathophysiology of acne and acne inflammation have led to the development of new therapeutic agents and new management methods. However, many patients hope to negotiate adolescence with fewer of the embarrassing stigmata of acne that impact so unfavorably on the quality of life in this age group. Furthermore, there is the potential to prevent the lasting sequela (e.g. scarring, post-inflammatory hyperpigmentation) of this disease in many of patients.

Acne vulgaris is a multifactorial disease that essentially involves the pilosebaceous unit, composed of the hair follicle and adjacent sebaceous glands. Although the etiology of acne involves multi-related factors, a large amount of evidence implicates an increased rate of sebum production, which is mainly controlled by hormones. Sebum is a lipid-rich secretion product of the sebaceous glands, which has an important role in the pathogenesis of acne and provides a growth medium for *Propionibacteria acnes* (*P. acnes*), which lead to the production of inflammatory mediators that engender the papules, pustules, and later nodulocystic lesions typical of inflammatory acne. However, inflammation, which is a characteristic reaction of tissue to disease or injury and is marked by four signs, i.e., swelling, redness, heat, and pain, is a direct or indirect result of the proliferation of *P. acnes.* Sebaceous follicles containing microcomedones provide an anaerobic, lipid-rich environment in which these bacteria flourish (3). Moreover, the study of Pochi and Strauss (4) indicated that the severity of acne is generally related to the amount of sebum production. The characteristic localization of acne to the face and upper trunk is a result of the distribution of oil-secreting structures known as sebaceous glands within the hair follicles.

Clinical research has shown that many factors, such as hormones, sebaceous gland hyperplasia with seborrhea, bacteria, food, genetics, drugs, occupation, and stress, are related to the pathogenesis of acne. Moreover, environmental factors, including climate and ultraviolet light, are also thought to be important in the aggravation of acne. Many researchers indicated that acne is aggravated in hot and humid weather (2). The weather in Taiwan is hot and windless, which make peoples' sebaceous glands become hyperplasic with seborrhea. The expectancy of many acne patients is to improve or cover the inflamed acne and reduce the severity of inflammation. Gfesser and Worret (5) indicated that sunbathing may be beneficial for psychological reasons and may produce euphoric effects, but they do not see any reason to treat acne with ultraviolet radiation because of its negative effects on the skin. The dispute about the effect of sunlight on acne was further complicated by Hjorth *et al.* (6). "Acne aestivalis" is named for the acne patients who complained of the aggravation of acne lesions in summer. They considered that the main causative factor is sunlight. However, the precise role of ultraviolet light in the development and irritation of acne lesions is not certain.

Additionally, the eastern female likes to use artistically irregular tapes (e.g., surgical tapes) on ugly and inflamed acne in order to make their appearance more beautiful. However, the unsterilized artistic tapes easily induce an occlusion wound, which can increase the level of inflammation. Most Taiwanese believe that squeezing and pinching can decrease the inflammation of acne; however, the frequent rubbing and touching of acne lesions leads to infection and the risk of developing scars. Some patients with mild acne consider their condition does not warrant a trip to the doctor and instead prefer a fast, safe and side-effect-free novel therapy. A safe and rapidly effective alternative to current therapy options for acne vulgaris is particularly desirable. Therefore, there is a

need for a well-tolerated local therapy that is more effective, cheaper, and without the risk of side effects. Furthermore, it appears that a new method can offer faster resolution, less scarring, and fewer side effects, resulting in greater patient satisfaction.

Acne Dressing® (3M Health Care), a hydrocolloid dressing containing gel-forming agents such as sodium carboxymethylcellulose (NaCMC) and gelatin embedded in an adhesive matrix covered by polyurethane film, has a high absorptive capacity. It is ventilated and waterproof to provide an environment that leads to wound closure and protection of the wound from infection. Hydrocolloid sheets are widely used as a primary dressing in the management of different types of wounds including acute and chronic wounds, pressure sores, donor sites, and burns. Hydrocolloid dressings have been shown to be effective in treating psoriasis vulgaris (7), lichen amyloidosus (8), and venous leg ulcers (9). Zeegelaar *et al.* (9) indicate that hydrocolloid dressings might function well in the extremely humid conditions of tropical climates. Van Vlijmen-Willems *et al.* (7) confirm the anti-psoriatic effect of hydrocolloid dressings and demonstrate that their effect upon inflammation is modest. The characteristics of high absorptive capacity, ventilation, and being waterproof allow Acne Dressing® to absorb sebum production in order to decrease inflammation and avoid contamination from hand touching or air pollution.

MATERIAL AND METHODS

PATIENTS

A total of 20 patients, aged 11 to 35 years, with facial acne, who met all study inclusion and exclusion criteria were enrolled in the study (Table I). These patients presented to the Department of Dermatology at Tri-Service General Hospital over a one-week study period. Inclusion criteria required patients to be ten years or older and to have mild-to-moderate facial acne. Medication-free periods were required before study entry, except for oral antibiotics. Patients were required to understand and follow the study protocol, and written informed consent was obtained from all the participants in the study.

This study was a randomized, double-blind study, with an active and a control group. The control group was given a treatment identical to the base of Acne Dressing®. To maintain investigator masking, clinical assistants collected and recorded data according to facial skin signs and symptoms, and investigators assessed efficacy measures. Patients

Table I
Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Patients who reported mild-to-moderate inflamed acne with lesion size < 1 cm	Patients who have any facial skin disease (apart from acne vulgaris) such as psoriasis or eczema that may interfere with the study procedures
The only form of acne treatment allowed for an eligible patient is an oral antibiotic	Patients using facial topical medicine or receiving any hormone therapy
Reliable and cooperative patients able to follow all study procedures	Allergy or hypersensitivity to hydrocolloids
Patients who understand and sign the informed consent form	

were randomly assigned to two treatment groups, each having ten enrollees: (a) patients in group I received Acne Dressing® as a treatment application and (b) patients in group II received skin tapes as a treatment application. Each group used Acne Dressing® or skin tapes on days 1 (baseline), 3, 5, and 7. The application size was determined by the size of the patient's acne lesions.

Each patient was photographed in a room with a constant temperature of 20°C and a constant relative humidity of 40–50%. Photographs of the front and bilateral facial views of each patient were taken at each visit. After five minutes, the Acne Dressing® or skin tapes were applied to inflamed papules (0.5 cm to 1.0 cm). The tapes were changed every two days by the same investigator.

CLINICAL ASSESSMENT

Patients were seen at baseline, defined as the visit when treatment was initiated, and again at 3, 5, and 7 days of treatment. The physician used three methods to assess acne at each visit. First, the "overall acne severity grade" was assessed by using Dr. Cunliffe's (11) grading system before and after treatment. According to this system, the grading scale was 0 (no acne whatsoever) to 10 (the most severe acne). The scale for the depth and width of acne lesions is: 0.25, a few small inflamed lesions; 0.5, small inflammatory lesions over a wider area; 1.0, more intensely inflamed lesions; 1.5, intensely inflamed lesions over a wider area; 2.0, deeper but non-nodular lesions; 2.5, lesions similar to those in grade 2.0 but over a greater area; and 3.0, much of the face involved with intensely inflamed but non-nodular lesions. Second, comparing the patients' condition with baseline photographs, the physician and the patients assessed responses to the treatment questionnaire. The questionnaire included demographic data (age and gender) and assessment of dryness, redness, oiliness, and dark pigmentation. Most questions used a five-point Likert scale with responses from "strongly disagree" to "strongly agree." At the followup visit the physician and patients assessed clinical efficacy and beneficial effects. Third, biometrological assessments were made each time after washing the face in the morning. The participants had not been allowed to wash their faces or apply cosmetics or any other topical products during the previous 15 hours. They were asked not to drink any fluids and to refrain from touching the area under investigation. At each evaluation time, the Sebumeter SM810R (C + K Electronic, Cologne, Germany) was used to assess the sebum casual level (CL, $\mu g/cm^2$) before application of Acne Dressing® or skin tapes.

ULTRAVIOLET B PENETRATION TEST

Lambda 800 UV/VIS Spectrometer, a double mono-chromator optical system capable of doing classical transmission, absorption, and reflectance measurements in the range of 180 nm < λ < 3300 nm, was used to test the penetration of UVB light through Acne Dressing® and skin tapes. Measuring the transmission through both types of tape can enable us to understand the properties of the materials and is useful in avoiding UVB damage to the skin.

STATISTICAL ANALYSIS

The mean of the values of each biometrological parameter collected at each of the measurements was calculated for each patient. The data were analyzed using SPSS 11.0

computer software (SPSS Inc, Chicago). Analysis of variance was used to compare all measures, including the overall acne severity grade, the questionnaire, and the sebum casual level. Differences before and after treatment were computed using a paired *t*-test. Comparisons between the two groups were computed using a nonparametic test, and comparisons were considered significant at $p \leq 0.05$ and p values were two-tailed.

RESULTS

CLINICAL ASSESSMENT

The patients ranged in age from 11 years to 35 years, with the mean being 20.7 years. There were nine males (45%) and 11 females (55%). There were no significant differences in the demographic characteristics between the two treatment groups (Table II). The mean overall severity scale at baseline of patients in group I for Acne Dressing® (mean = 1.175) was higher than that of group II (mean = 1.08) ($p \leq 0.05$). The average number of inflammatory lesion healing days in groups I and II were 3.2 ± 0.79 and 4.3 ± 0.83 days, respectively.

At day 7, the severity of acne, assessed by patients and the physician, was significantly reduced in the treatment group compared with the skin tapes group, as demonstrated by the mean ± SD change from baseline: 0.43 ± 0.21, 0.80 ± 0.23, 0.16 ± 0.07, and 0.41 ± 0.25, respectively ($p \leq 0.05$) (Table II). In the improvement of the overall acne severity grade, redness, oiliness, and the dark pigmentation of acne, the Acne Dressing®

Table II
Comparability of Demographic Data, Overall Severity Acne Scale, and Acne Questionnaire (n = 20)

Variable	Group 1[1] (Mean ± SD)	Group 2[2] (Mean ± SD)	*p*-Value
Age (mean ± SD)	20.7 ± 3.8	21 ± 4.8	.88
Sex			.68
Male	5	4	
Female	5	6	
Overall acne severity scale			
Baseline: Patients	1.18 ± 0.43	1.08 ± 0.41	.60
Physician	0.90 ± 0.33	0.65 ± 0.27	.09
Day3: Patients	0.80 ± 0.34	1.12 ± 0.36	.06
Physician	0.53 ± 0.25	0.68 ± 0.30	.23
Day5: Patients	0.53 ± 0.22	0.93 ± 0.24	.01*
Physician	0.27 ± 0.14	0.68 ± 0.24	.00*
Day7: Patients	0.43 ± 0.21	0.80 ± 0.23	.00*
Physician	0.16 ± 0.08	0.41 ± 0.25	.00*
Questionnaire (day 7)			
Redness	1.2 ± 0.53	2.7 ± 0.84	.00*
Oiliness	1.5 ± 0.53	2.4 ± 0.84	.01*
Dark pigmentation	1.8 ± 0.42	2.3 ± 0.48	.02*
Improvement days of inflammatory lesion healing	2.10 ± 0.57	4.20 ± 0.79	.00*
	3.20 ± 0.79	4.30 ± 0.83	.00*

[1] Group I: Acne Dressing®.
[2] Group 2: Skin tapes.
* $p \leq 0.05$.

was consistently more effective than skin tapes at day 7 (Figure 1), and these differences were statistically significant with p values of <0.05 for the overall acne severity grade, <0.05 for redness, 0.01 for oiliness, and 0.02 for dark pigmentation.

After treatment with Acne Dressing®, the results showed there was significant improvement over the pre-treatment state of acne conditions (including redness, oiliness, and pigmentation) ($p \leq 0.05$) (Table III). Improvement in acne conditions as assessed by the patients was significantly reduced in the treatment group compared with the skin tapes group, as demonstrated by the mean ± SD change: 2.1 ± 0.57 and 4.2 ± 0.79, respectively ($p \leq 0.05$) (Figure 2). All treatment-group patients considered that there was moderate improvement or better. However, only 20% of the skin tapes patients considered there was a moderate improvement in treatment.

SEBUM CASUAL LEVEL EVALUATIONS

There were significant differences between the two groups in the sebum casual level at day 7, as demonstrated by the mean ± SD change from baseline: 186.9 ± 53.04 and 241.8 ± 62.93 ($p \leq 0.05$) (Figure 3). However, there were no significant differences at baseline, on day 3 and, on day 5 in the sebum casual level. Comparing the before and after treatment with Acne Dressing®, the results showed there was significant improvement in acne conditions (including redness, oiliness, and pigmentation) ($p \leq 0.05$) (Table III). However, there were no significant differences between the pre- and post-treatment states in the skin tapes group.

ULTRAVIOLET PENETRATION TEST

As shown in Figure 4, it is clear that the ratio of transmission in Acne Dressing® during the period of UVB exposure (280 nm–320 nm) is less than 7.4%, indicating that Acne Dressing® is a useful material to block UVB from sunlight from reaching the skin

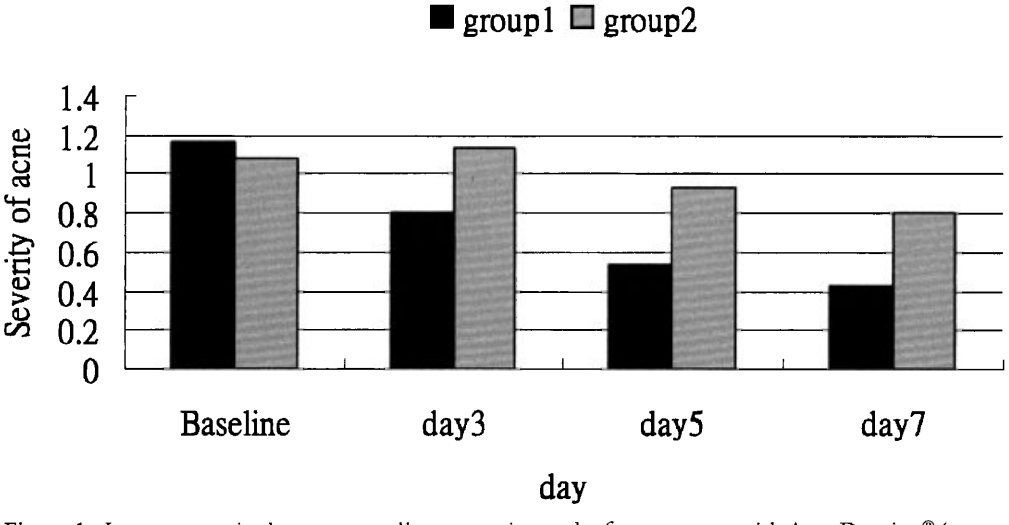

Figure 1. Improvement in the mean overall acne severity grade after treatment with Acne Dressing® (group 1) or skin tapes (group 2).

Table III
Acne Dressing® or Skin Tapes Used to Examine the Effect on Acne Conditions (n = 20)

	Acne Dressing®		Skin tapes		
	Baseline	Day 7	Baseline	Day 7	Significance
Severity of acne by patients[1]	1.18	0.43	1.08	0.80	.000*
Severity of acne by physician[1]	0.90	0.16	0.65	0.41	.000*
Scale of redness[2]	4.1	1.2	4.4	2.7	.000*
Scale of oiliness[2]	3.9	1.5	4.0	2.4	.000*
Scale of dark pigmentation[2]	3.9	1.8	3.7	2.3	.000*
Sebum casual level ($\mu g/cm^2$)	217.6	186.9	240.8	241.8	.000*

* $p \leq 0.05$.
[1] Severity of acne was assessed and performed by using Dr. Cunliffe's grading system.
[2] Scales of redness, oiliness, and dark pigmentation were assessed by five-point Likert scale.

surface covered by the dressing. However, the ratio of transmission in skin tapes during the period of UVB exposure (280 mm–320 mm) is 38%.

DISCUSSION

Acne vulgaris is a common skin disorder that poses significant social and psychological problems to the patient (10). It is most prevalent during adolescence, which is a time of significant physical, emotional, and interpersonal relational development (11). Negative self-perceptions of one's face can have a lifelong consequence. Therefore, the development of a safer, more convenient, and more effective treatment for acne is highly desirable.

Results from clinical assessments show that Acne Dressing® compared with skin tapes was more effective in improving local mild and moderately inflamed acne. Most patients have reported improvement (a reduction in size and redness and less oily skin) after seven days of treatment with Acne Dressing®. The mean percentage decrease in severity of acne after seven days of Acne Dressing® treatment was 82.2% compared with 37% for skin tapes. Ninety percent of patients in the treatment group indicated that the Acne Dressing® absorbed the secretions from the acne, and then reduced the inflammation and pain. Moreover, 95% of patients indicated that the color of this kind of Acne Dressing® was similar to that of skin and that the circular formulary form was very easy to use and enhanced cosmetic appearance.

Many studies of acne emphasize that treatment of acne is needed to reduce inflammation and avoid scarring (1,3,12,13). Measures of efficacy in the study show that the mean percentage decrease in redness after seven days of Acne Dressing® treatment was 71%, as compared with 38.6% for skin tapes. It is also clear that comparison of the pre- and post-Acne Dressing® states shows a significant reduction in redness. All patients treated by Acne Dressing® felt their inflamed acne was much better, and there was a decrease in the number of days of healing (mean = 3.20 ± 0.79) over the skin tapes group (mean = 4.30 ± 0.79). From this viewpoint, Acne Dressing® therapy was more effective in alleviating the acne. All patients treated by Acne Dressing® reported moderate or good improvement. Moreover, there were no adverse effects or patient discomfort noted in any of the patients.

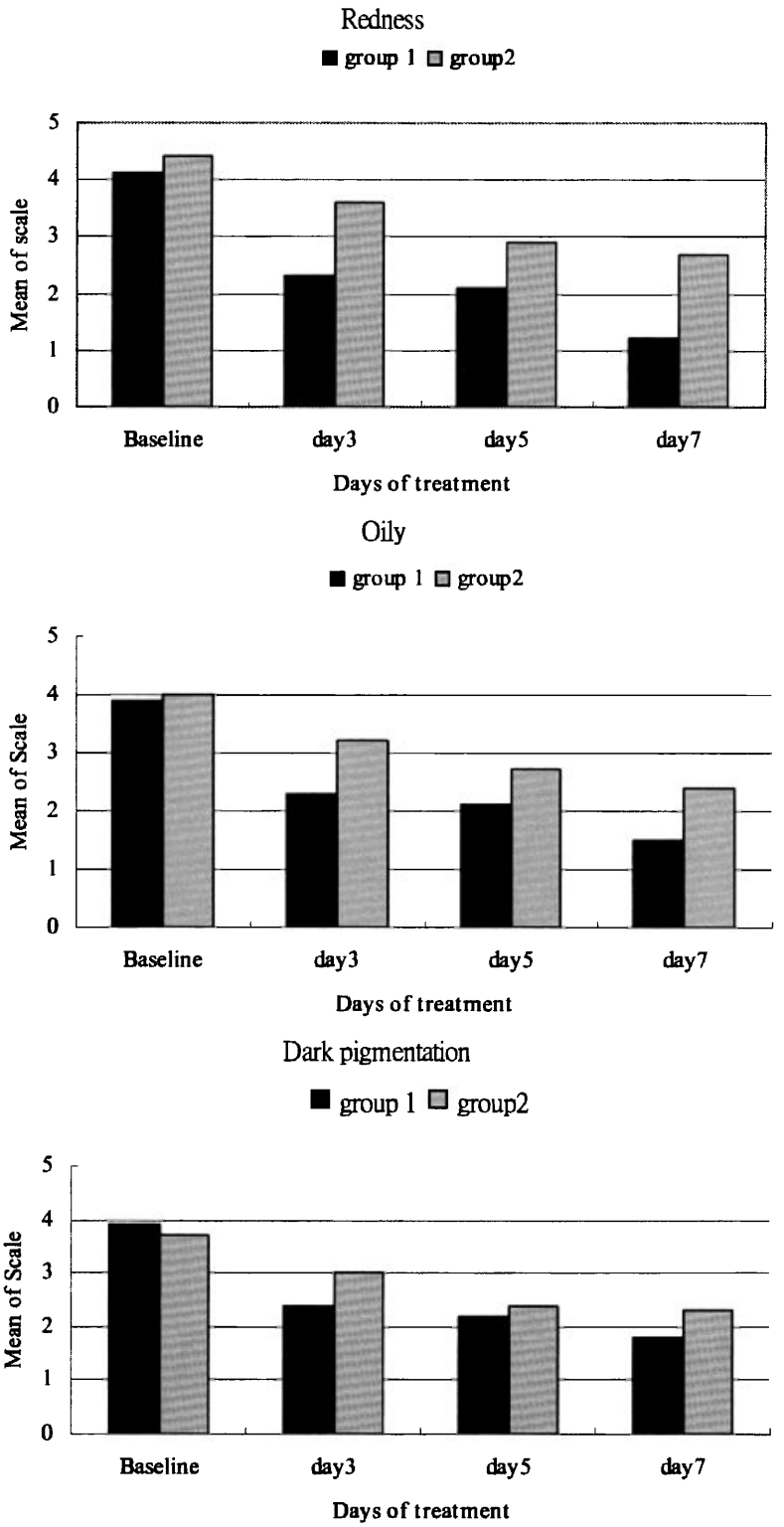

Figure 2. Improvement in the mean of scale assessed by patients after treatment with Acne Dressing® (group 1) or skin tapes (group 2).

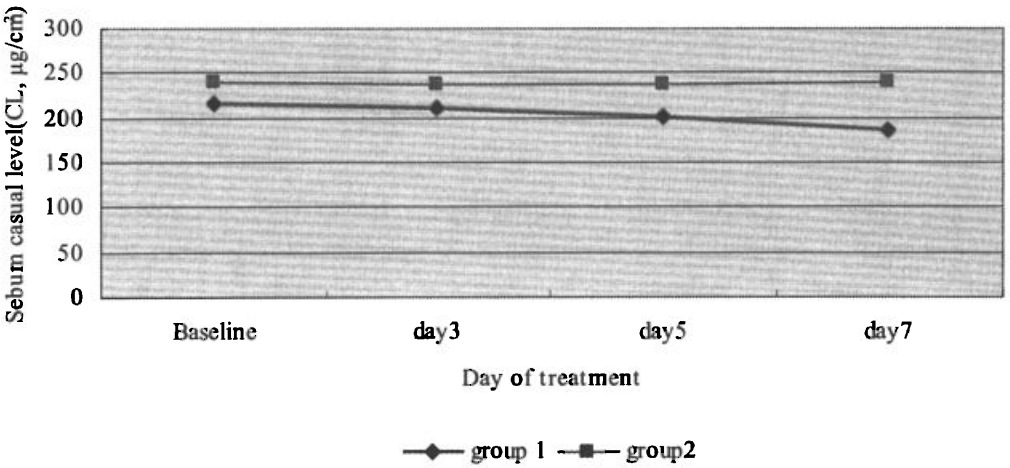

Figure 3. Improvement in assessment of sebum casual level by patients after treatment with Acne Dressing® (group 1) or skin tapes (group 2).

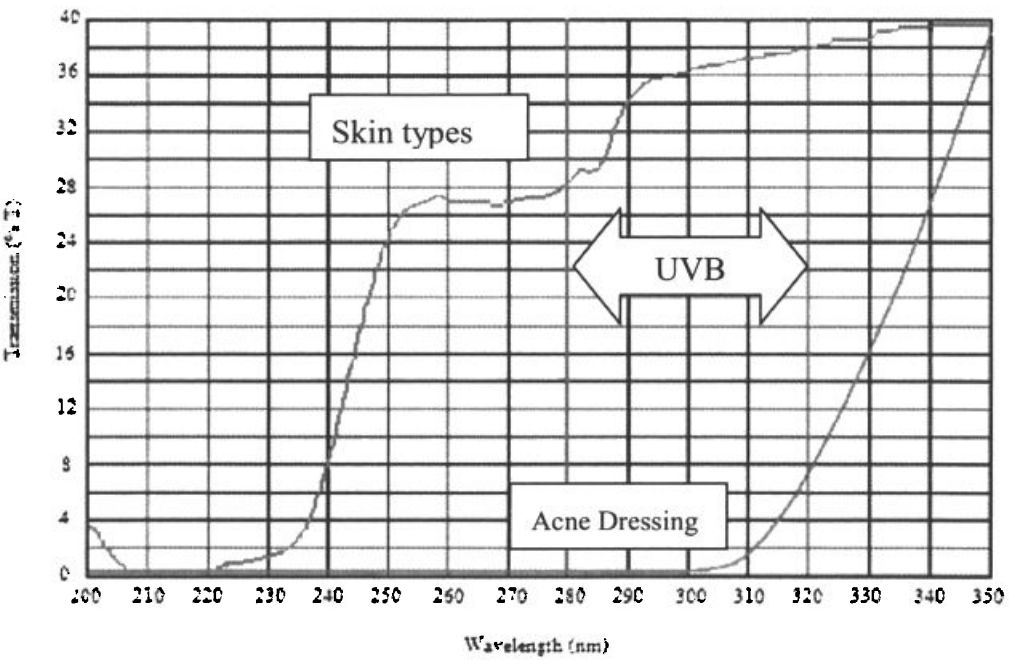

Figure 4. Ultraviolet transmission test of Acne Dressing® and skin tapes.

As Mondon *et al.* (13) point out, the reduction in sebum production, cell proliferation, and anti-inflammation activity leads to a visible improvement of the skin condition, without leaving scars or provoking irritation or other side effects. A significant decrease ($p \leq 0.05$) in the sebum casual level on the treated acne was seen at day 7 after treatment with Acne Dressing®. The resultant effect in sebum absorption and the gradual decrease of sebum was helpful in reducing the inflammation. Some studies have indicated that sebum has a central role in the pathogenesis of acne and that the severity of acne is

generally proportional to the amount of sebum production (1,13). For the absorptive characteristic of Acne Dressing®, this kind of material has shown efficacy in many skin conditions, and is an effective way to absorb sebum production and reduce the oiliness of the skin.

The ratio of transmission in Acne Dressing® during the period of UVB exposure (280 nm–320 nm) is less than 7.4%, which is helpful in reducing the damage from sunlight. Significant efficacy in reducing red pigmentation has been shown during treatment; however, this is not to say that dark pigmentation will not present itself again in the future. Long-term observation and long-term treatment with Acne Dressing® is to be considered for further study.

No studies have ever tried to use Acne Dressing® to treat acne. Therefore, the result of this study is compared with those of similar studies. To our knowledge, this is the first randomized study showing that an Acne Dressing® can produce effects and clinical improvement after exceedingly short periods of skin contact. A possible explanation for the efficacy of short-contact therapy may be found in the Lichen amyloidosus study of Hallel-Halevy and colleagues (8). Their work demonstrated that hydrocolloid dressings achieve an excellent effect in the skin of Lichen amyloidosus after tape periods as short as one day.

Successive application of Acne Dressing® gives a dramatic effect in active acne over a short period of time. This result fits in with Webster's suggestion of treating acne: "Treatment regimens should be simple" (14). In addition, Acne Dressing® is self-adhesive and can be left on the skin for two days or more. This kind of tape is waterproof, thus permitting face washing, and is protective in addition to being cosmetically acceptable. Moreover, the circular and thin formulary form and skin color tapes not only cover the redness to improve the cosmetic outcome, but also allow ventilation, which in turn leads to no increase in the level of inflammation.

Based on this pilot study, it may be an evident that Acne Dressing® is a new option by itself or in conjunction with oral antibiotics for treating acne, and can result in improvement in mildly and moderately inflamed papules. Despite much interest and a rigorous prospective, randomized and controlled trials in this area are limited. In order to establish its recognition, more clinical studies are needed to elucidate the treatment's efficacy in different acne symptoms in a large set of patients and in longer followup periods.

ACHNOWLEDGMENT

We thank Mr. Edison Chen, who provided the material for study. As research assistant, he assisted with data entry, data analysis, and the production of the figures and tables.

REFERENCES

(1) U. Jappe, Pathological mechanisms of acne with special emphasis on Propionibacterium acnes and related therapy, *Acta Derm. Venereol.*, **83**, 241–248 (2003).
(2) H. Gollnick, Current concepts of the pathogenesis of acne: Implications for drug treatment, *Drugs*, **63**, 1579–1596 (2003).
(3) S. K. Brown and A. R. Shalita, Acne vulgaris, *Lancet*, **351**, 1871–1876 (1998).

(4) P. E. Pochi and J. S. Strauss, Endocrinologic control of the development and activity of the human sebaceous gland. *J. Invest. Dermatol.,* **43,** 383–388 (1964).
(5) M. Gfesser and W. I. Worret, Seasonal variations in the severity of acne vulgaris, *Int. J. Dermatol.,* **35,** 116–117 (1996).
(6) N. Hjorth, K. E. Sjolin, B. Sylvest, and K. Thomsen, Acne aestivalis-Mallorca acne, *Acta Derm. Venereol.,* **52,** 61–63 (1972).
(7) I. M. J. J. van Vlijmen-Willems, A. Chang, J. B. Boezeman, and P. C. van de Kerkhof, The immunohistochemical effect of a hydrocolloid occlusive dressing (DuoDERM E) in psoriasis vulgaris, *Dermatology,* **187,** 257–262 (1993).
(8) D. Hallel-Halevy, E. Finklstein, M. H. Grunwald, and S. Halevy, Lichen amyloidosus treated by hydrocolloid dressing, *JEADV,* **18,** 691–692 (2004).
(9) J. E. Zeegelaar, W. Langenberg, R. Hu, F. M. Lai, A. Fat, and W. R. Faber, Tolerability and efficacy of hydrocolloid dressings in the treatment of venous leg ulcers under tropical conditions: An open prospective study, *J. Eur. Acad. Dermatol. Venereol.,* **15,** 234–237 (2001).
(10) S. J. Orringer, S. Kang, T. Hamilton, W. Schumacher, S. Cho, C. Hammerberg, J. G. Fisher, J. D. Karimpour, M. T. Johnson, and J. J. Voorhees, Treatment of acne vulgaris with a pulsed dye laser, *JAMA,* **291,** 2834–2839 (2004).
(11) J. Cunliffe, *Acne* (Martin Dunitz Ltd, London, 1997).
(12) M. M. S. Mulder, V. Sigurdsson, E. J. van Zurren, E. J. Klaassen, J. A. J. Faber, J. B. F. de Wit, and W. A. van Vloten, Psychosocial impact of acne vulgaris, *Dermatology,* **203,** 124–130 (2001).
(13) P. Mondon, K. Lintner, F. Girard, and C. Gibaud, The effect of a synthetic ceramide-2 on transepidermal water loss after stripping or sodium lauryl sulfate treatment: An *in vivo* study, *Int. J. Cosmet. Sci.,* **19,** 15–25 (1997).
(14) G. Y. Webster, Acne vulgaris, *BMJ,* **325,** 475–478 (2002).