

A Cohort Study Using a Facial Cleansing Brush With Acne Cleansing Brush Head and a Gel Cleanser in Subjects With Mild-to-Moderate Acne and Acne-Prone Skin

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ABSTRACT

Introduction: Acne vulgaris is a highly prevalent skin condition that can adversely affect the quality of life. Acne-predisposed skin is in a state of subclinical inflammation leading to skin barrier dysfunction. A multi-center cohort study was designed to evaluate clinical efficacy and safety of twice daily facial cleansing using an oscillatory sonic brush, acne brush head, and cleansing gel for 4 weeks.

Methods: Subjects with mild-to-moderate acne and acne-prone skin used the cleansing regime after which they applied the skin care products they routinely used. Physician-assessed skin condition comparing baseline versus week 4 using the FDA/IGA scale and subject satisfaction with cleansing efficacy and handling properties of the regime were scored during the last visit.

Results: Forty-six subjects completed the study. Physician-scored skin condition showed a statistically significant improvement in FDA/IGA scores and a significant reduction of inflammatory and non-inflammatory lesions comparing baseline versus 4 weeks. Thirty-five (76.0%) subjects had cleared or almost cleared. Subjects similarly assessed their skin to be improved.

Conclusion: Both the physician and subject scores revealed the gentle cleansing routine using the sonic brush to be effective reducing the number of acne lesions, improving skin condition. No adverse events were reported during the study period. The cleansing regime may offer an attractive, safe option for maintenance and treatment of subjects with mild-to-moderate acne and acne-prone skin.

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INTRODUCTION

Acne vulgaris is a highly prevalent skin condition.¹ The common onset of acne is in early adolescence, about 85% of those affected have the condition between the ages 8 and 17 years.¹ Acne affects a substantial number of adults, particularly women, who are more likely to view it as a disorder that requires treatment even when the condition is mild.¹⁻³ Compared to adolescent acne, adult acne tends to be more inflammatory³ with the involvement of the cheeks and lower half of the face.³ The presence of comedones in adult acne is uncommon.³

Acne can adversely affect the quality of life due to psychological and emotional distress, including poor self-esteem, social anxiety, depression, and suicidal ideation.⁴ There is an unmet

need for acne information, education, and treatments that provide the best patient outcomes.⁴

Acne has a complex, multifactorial pathophysiology.⁵ Acne-predisposed skin is in a state of subclinical inflammation, which may be linked to changes in skin surface pH and disturbances of the stratum corneum.⁵ Inflammatory events trigger acne lesions and correlate to skin barrier dysfunction.⁵

The impaired skin barrier in acne may benefit from a gentle cleanser used along with other therapeutic measures. Twice daily use of a gentle cleanser in patients with mild-to-moderate acne demonstrated a reduction in acne lesion counts in clinical studies^{6,7} without damage to the skin barrier or sebum overcompensation.

An oscillatory sonic brush uses the skin's elastic properties by applying an optimal amplitude and frequency range.⁸ The sonic brush has been shown to be safe and effective at cleansing the skin for various dermatologic conditions.⁸ Effective cleansing clears pores of debris, allowing sebum to leave the skin surface unimpeded. Cleansing and moisturizing help to manage pH levels of the skin, enabling sufficient water retention.⁹

METHODS

Cohort Population

A multi-center cohort study evaluated the efficacy and safety of a facial cleansing regimen when used twice daily by subjects with mild-to-moderate acne and acne-prone skin as part of a daily skin care routine. Subjects were included in the cohort study with mild-to-moderate facial acne (score 2-3 on the FDA Investigator Global Acne Assessment scale (FDA/IGA), 5-10 inflammatory acne lesions (papules, pustules) and 10 or more non-inflammatory acne lesions (open and closed comedones) (Table 1). Fifty subjects were recruited from 10 centers in the USA, each of the five participating physicians aimed to recruit five subjects.

Regional/local ethical committee approval was obtained for the study. Prior to subject inclusion, the physician informed the subject about the study and obtained the subject's written consent for participation.

Study Interventions

The Clarisonic Mia 2 facial sonic cleansing brush with acne cleansing brush head (Clarisonic Redmond, WA) and Pore and Blemish Gel Cleanser, were used by subjects with mild-to-moderate acne as part of a daily skin care routine.

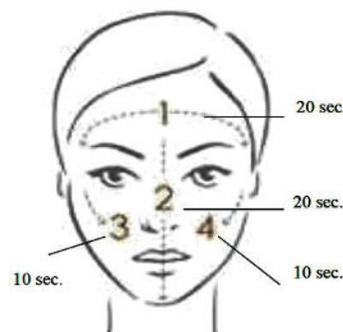
Depending on the severity of the condition, once/twice daily (morning and bedtime) facial cleansing using the sonic brush and gel was performed by the subject over a 4-week (+/- 5 days) period. After cleansing, subjects applied the skin care products they routinely used. The sonic brush, brush head, and cleansing gel were provided at the start of the study and were to be used according to the instructions of the manufacturer (Figure 1). Before starting the cohort, the physician demonstrated the use of the sonic brush and cleansing gel to each subject.

Subjects were allowed to use acne medication (topical and systemic) and/or the over-the-counter products they were using at the time of inclusion in the study, except the cleanser. Subjects who have been using acne medication and/or the over-the-counter products for at least two weeks prior to the study start were instructed to continue the same acne medication and/or the over-the-counter products until the end of the study (week 4 (+/- 5 days)).

TABLE 1.

FDA Investigator Global Acne (IGA) Assessment	
Acne Grade	Description of Facial Condition
0 = none	Clear skin with no inflammatory or non-inflammatory lesions
1 = minimal	Almost clear; rare non-inflammatory lesions with no more than one small inflammatory lesion
2 = mild	Mild severity; greater than Grade 1; some non-inflammatory lesions with no more than a few inflammatory lesions (papules/pustules only, no nodular lesions)
3 = moderate	Moderate severity; greater than Grade 2; up to many non-inflammatory lesions and may have some inflammatory lesions, but no more than one small nodular lesion
4 = severe	Severe; greater than Grade 3; up to many non-inflammatory and inflammatory lesions, but no more than a few nodular lesions

FIGURE 1. Use of the sonic brush and cleansing gel. Prior to the first use, charge the facial cleansing brush handle for 24 hours. Remove the eye makeup by hand. Apply quarter-size amount of the gel cleanser directly to moistened skin or to a wet acne cleansing brush head. Push the on/off button to turn on your sonic brush. Select the desired speed. Follow T-Timer prompts while gently moving the brush head in small circular motions. It is recommended: 1) 20 seconds on forehead; 2) 20 seconds on nose and chin; 3) 10 seconds on one cheek; 4) 10 seconds on the other cheek. NOTE: Keep the brush head flush to the skin. Pressing too hard will impede the motion and reduce effectiveness.



Outcomes

The purpose of the cohort study was to evaluate clinical efficacy and safety of twice daily facial cleansing using a sonic brush, acne brush head and cleansing gel by subjects with mild-to-moderate acne as part of a daily skin care routine.

The primary objective was physician-assessed skin condition comparing baseline versus day 28 (+/- 5 days) (end) using the FDA/IGA scale (Clear (0), Almost clear/minimal (1), Mild (2), Moderate (3), Severe (4)).

TABLE 2.

Visits and Activities		
Visit # Timeline	Visit 1: Week 0 (Baseline)*	Visit 2: Week 4 (+/- 5 days) end of study
Informed Consent	X	--
Medical history on facial acne	X	--
Demographics	X	--
Physician assessment of facial skin area using a clinical scale	X	X
Eligibility Assessment	X	--
Twice-daily treatment with a sonic brush, acne brush head and cleansing gel and use of routine skin care regime	X	X
Patient Satisfaction Questionnaire	--	X
Concomitant facial medications	X	X
Assess AEs/SAEs	X	X
End of evaluation	--	X

AE: Adverse event; SAE: Serious adverse event
*Can be the same day as screening

Secondary objectives were subject satisfaction with cleansing efficacy and handling properties of the sonic brush, cleansing head and cleansing gel scored at day 28 (+/- 5 days) during the last visit. The subjects scored their findings on a 5-Point Likert scale: Strongly disagree (1), Disagree (2), Neutral (3), Agree (4), Strongly agree (5).

All unexpected adverse events observed by or reported to the investigators were evaluated. The intensity, duration and causal relationship to the treatment were rated for all adverse events.

Study Design

The cohort had an evaluation duration of 28 days (+/- 5 days) during which the cleansing regime was used. Two or three (depending if screening and baseline assessments could be combined during visit 1) visits were planned during the study period (Table 2).

The sample size for the study was calculated at fifty subjects, which was deemed large enough to collect clinically meaningful data and allowed for a dropout rate of 15%. Subjects used the cleansing regime for a period of 28 days (+/- 5 days). Statistical evaluation was performed using IBM SPSS (IBM Corporation Armonk, New York, NY). A paired T-test or ANOVA was applied to analyze skin condition comparing baseline (day 0) versus day 28 (+/- 5 days) (end) per subject and per group. Where appropriate tests were carried out at the 5% significance level and a confidence interval of 95%.

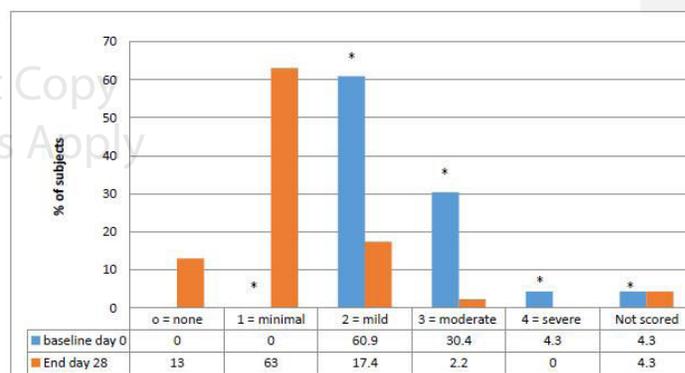
TABLE 3.

Demographics and Physician-Assessed Skin Condition at Baseline						
N = 46 (100%)						
Age (years):	27.55					
Mean: (± SD)	(± SD 8.02)					
Range	30					
Gender:	Male: 4 (8.7%) Female: 42 (91.3%)					
Physician-scored FDA/IGA	0 = none	1 = minimal	2 = mild	3 = moderate	4 = se- vere	Not scored

Baseline: Frequency (%)	0	0	28.0 (60.9%)	14.0 (30.4%)	2.0 (4.3%)	2 (4.3%)
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FDA/IGA scale: 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe
FDA Investigator Global Acne Assessment scale (FDA/IGA), Inflammatory lesions (IL), Non-inflammatory lesions (NIL)

FIGURE 2. Physician-assessed skin condition at baseline and at the end of the study. Mean difference: 1.33 (SD ± 0.68). Two-tailed paired samples test: $t(42) = 12.78$, $P < 0.05^*$



*FDA/IGA scale: 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe. FDA Investigator Global Acne Assessment scale (FDA/IGA)

RESULTS

The multi-center cohort study aimed to include 50 subjects with mild-to-moderate facial acne. Four subjects withdrew consent before the start of the study and forty-six subjects started with the sonic brush cleansing regime after giving informed consent. Subjects had a mean age of 27.55 (± SD 8.02) years, were mainly female: 42 (91.3%) with 4 (8.7%) males.

FDA/IGA acne score at baseline was mild in 28 (60.9%) of the cases, moderate in 14 (30.4%) and severe in 2 (4.3%) of the cases. For 2 (4.3%) cases severity class was not scored (Table 3).

TABLE 4.

Physician-Assessed Skin Condition at Baseline and at Week 4						
Baseline N = 46 (100%); End of study N = 44 (95.7%)						
Physician-scored FDA/IGA	0 = none	1 = minimal	2 = mild	3 = moderate	4 = severe	Not scored
Baseline:						
Frequency (%)	0	0	28.0 (60.9%)	14.0 (30.4%)	2.0 (4.3%)	2 (4.3%)
End of study:						
at 28 days (+/- 5 days):	6.0 (13.0%)	29.0 (63.0%)	8.0 (17.4%)	1.0 (2.2%)	0	2.0 (4.3%)
Frequency (%)						

Comparing baseline versus end results: Mean difference: 1.33 (SD ± 0.68); Two-tailed Paired Samples Test: $t(42) = 12.78, P < 0.05 (0.00)$. FDA/IGA scale: 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe. FDA Investigator Global Acne Assessment scale (FDA/IGA), inflammatory lesions (IL), non-inflammatory lesions (NIL)

Treatments reported at the start of the study that were continued throughout included: benzoyl peroxide and a topical retinoid either alone or in combination (with/without a topical antibiotic) for mild acne and oral antibiotics combined with topical therapy for moderate-to-severe acne. Only two subjects used a non-comedogenic moisturizer to reduce inflammation and/or side effects from treatment, such as skin irritation or dryness.

Forty-four subjects (95.7%) completed the study period and were included in the analysis. Two subjects were lost to follow-up. No adverse events were reported during the study period. At the end of the study physician-scored skin condition revealed that 35 (76.0%) subjects had cleared or almost cleared, 8 (17.4%) had mild acne and 1 (2.2%) had moderate acne (Table 4). The mean improvement in FDA/IGA comparing skin condition at baseline versus 28 days (+/- 5 days) was significant (1.33 (SD ± 0.68)); Two-tailed Paired Samples Test: $t(42) = 12.78, P < 0.05$ as well as the reduction in the number of physician-scored inflammatory and non-inflammatory lesions (Figure 2).

The subject scored skin condition using a 5-Point scale (Strongly disagree (1), Disagree (2), Neutral (3), Agree (4), Strongly agree (5)) at the end of the study revealed comparable results to the physician scores on improvement of skin condition. When asked if the number of skin imperfections had reduced they scored a mean of 4.13 (SD ± 0.99) (Agree/Strongly agree). The subjects further reported that the excess of sebum was removed (4.31 (SD ± 0.82)), visible blackheads had reduced (4.07 (SD ± 1.00)) as well as redness (4.04 (SD ± 0.93)) providing a more even facial skin complexion (4.08 (SD ± 0.87)). The subjects rated the brush and gel as easy (4.89 (SD ± 0.32)), fast and effective to use (4.84 (SD ± 0.43)), and fitted their skin care regimen (4.77 (SD ± 0.57)). The subjects reported that after using the sonic brush and gel for 4 weeks they felt better about their facial skin (4.61 (SD ±

TABLE 5.

End of Study Subject Scores on Skin Condition	
N = 46: Item scored	Mean (± SD)
The number of skin imperfections is reduced	4.13 (0.99)
The pores are deeply cleaned	4.20 (0.81)
The excess of sebum is removed	4.31 (0.82)
The imperfections are dried out	3.91 (1.08)
Blackheads are visibly reduced	4.07 (1.00)
The redness from imperfections is visibly reduced	4.04 (0.93)
The marks left by spots are less visible	3.88 (1.00)
The complexion is more even	4.08 (0.87)
The skin is smoother	4.47 (0.76)
The skin is softer	4.58 (0.81)
The skin is more radiant	4.20 (0.73)
The sonic brush is easy to use	4.89 (0.32)
Cleansing with the sonic brush is fast and effective	4.84 (0.43)
Using the sonic brush fits my skin care regime	4.77 (0.57)
Using the sonic brush gives me the best clean to help fight my breakouts	4.52 (0.82)
The frequency of breakouts is reduced	4.22 (0.96)
The severity of breakouts is reduced	4.34 (0.91)
I feel better about my facial skin after using the brush	4.61 (0.75)
I feel more confident in my personal life after using the brush	4.39 (0.92)
I feel more confident in my professional life after using the brush	4.41 (0.95)

Agree /Strongly Agree

0.75) and more confident in their personal (4.39 (SD ± 0.92)) and professional life (4.41 (SD ± 0.95)) (Table 5).

DISCUSSION

Acne affected skin is characterized by inflammation leading to disruption of normal physiological functions of the epidermis, including the stratum corneum.^{5,15,16} Moreover acne therapies can induce alterations in the epidermis. Enhanced trans-epidermal water loss is reported with benzoyl peroxide, tretinoin, tazarotene, and isotretinoin use.⁵ Xerosis and dermatitis commonly result from acne treatment and are very important reasons for non-compliance.⁴

The compromised skin barrier in acne may be improved with a gentle cleansing regime, potentially reducing acne lesion counts and enhancing antimicrobial defenses.^{10,16}

The evaluated oscillatory sonic brush applies an optimal am-

plitude (angular) and frequency (60–90Hz) range to efficiently remove dirt and debris.⁸ Moreover the cyclic mechanical stimulation of the sonic brush was shown to increase expression of certain dermal proteins (such as, collagen 4 and 7, procollagen, laminin 5, fibronectin, fibrillin, and decorin) ex-vivo in human skin.⁸ The mechanical stimulation of the tissue while using the brush may improve skin condition such as wrinkle presentation when using the brush regularly as part of an anti-aging regime. Clinical studies have shown the use of the oscillatory sonic brush is safe (compared to stand-alone use of a cleanser) and does not cause erythema or other clinical signs of irritation.^{10,11} Other investigations demonstrated safety and efficacy of various cleansers and skin care products for acne in combination with the sonic brush.¹²⁻¹⁴

The present study demonstrated a significant (mean difference: 1.33 (SD ± 0.68); Two-tailed Paired Samples Test: $t(42) = 12.78$, $P < 0.05$) improvement in physician scored FDA/IGA scale and subject scored skin condition after 28 days (+/- 5 days) of sonic brush and cleansing gel use. The cleansing regime was easy, fast, and safe, as there were no reported adverse events during the study period.

Four typical cases are shown to illustrate these results (Figures 3–6).

FIGURE 3. Case 1. Female 45-year-old presented with mild acne at baseline. After 28 days of sonic brush use (A) Physician-scored acne lesions had almost cleared. (B) Subject-scored skin condition confirmed this result, improving skin radiance, making her feel more confident about her appearance. Handling of the brush was easy and fast and no skin irritation occurred. *Case and photographs courtesy of Dr. M.H. Gold*

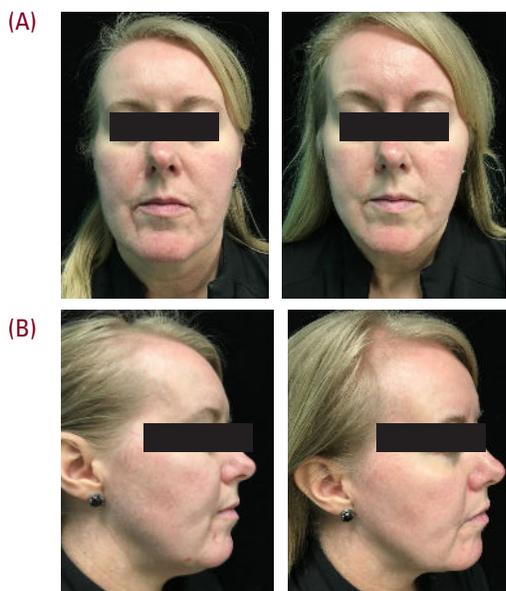


FIGURE 4. Case 2. Female 37-year-old presented with mild acne at baseline. After 28 days of sonic brush use (A) Physician scored acne lesions had almost cleared. (B) Subject scored skin condition confirmed this result, improving all scored aspects, making her feel better and more confident about her appearance. Handling of the brush was easy and fast and no skin irritation occurred. *Case and photographs courtesy of Dr. M.H. Gold*



FIGURE 5. Case 3. Female 30-year-old presented with mild acne at baseline. After 28 days of sonic brush use (A) Physician scored acne lesions had almost cleared. (B) Subject scored skin condition confirmed this result, improving skin complexion and texture, making her feel more confident about her appearance. Handling of the brush was easy and fast and no skin irritation occurred. *Case and photographs courtesy of Dr. M.H. Gold*

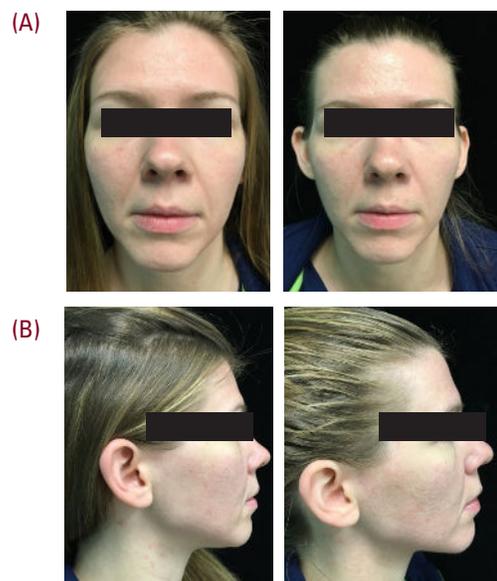
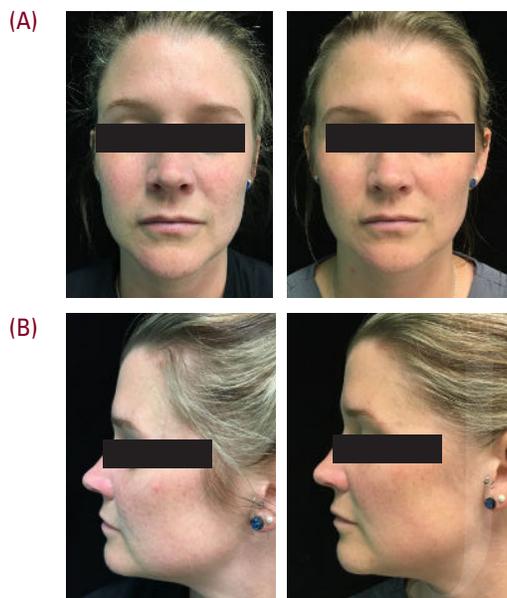


FIGURE 6. Case 4. Female 34-year-old presented with mild acne at baseline. After 28 days of sonic brush use (A) Physician-scored acne lesions had cleared. (B) Subject scored skin condition confirmed this result, improving skin condition and self-confidence significantly. Handling of the brush was easy and fast and no skin irritation occurred. *Case and photographs courtesy of Dr. M.H. Gold*



LIMITATIONS

This study gave a description of practice and did not have a comparator or control group; therefore, cause and effect relationships cannot be inferred. It was beyond the scope of this study to draw any conclusions regarding the possible impact of the evaluated cleansing regime on the underlying disease if it was used as monotherapy; this impact will be explored in future studies. Moreover, the subjects were not on a standardized acne regimen upon entering the trial; therefore, therapeutics added shortly prior to study initiation could represent confounders.

CONCLUSIONS

Cleansing of the face (shown to remove dirt, excess of sebum, and other unwanted debris) may potentially improve skin in mild-to-moderate acne patients. The gentle and effective cleansing routine using the sonic brush reduced significantly ($P < 0.05$) the number of physician-scored inflammatory and non-inflammatory lesions in the treated subjects. Subjects similarly assessed their skin to be improved. No adverse events were reported during the study period. The cleansing regime using the sonic brush may offer an attractive, safe option for maintenance and treatment of subjects with mild-to-moderate acne and acne-prone skin.

DISCLOSURES

Dr. Michael Gold is a consultant and has performed research for Clarisonic. All authors contributed to the development, execution of the study, writing, or critical review of the article. The study products used were provided by Clarisonic, who supported a one-day meeting for study protocol development. All authors are registered in ORCID.

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