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Cosmetic benefits of a novel biomimetic lamellar formulation containing niacinamide in healthy females with oily, blemish-prone skin in a randomized proof-of-concept study

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Abstract

OBJECTIVE: A randomized study was designed to evaluate the potential cosmetic benefit of a biomimetic, niacinamide-containing moisturizing cream in oily, blemish-prone skin.

METHODS: Healthy adult women with oily, blemish-prone skin were randomized to one of three treatment groups: test, control, or positive control. In the test group, subjects used the test product (containing 4% niacinamide), plus the standard cleanser (Simple® Kind to Skin Moisturizing Facial Wash). In the control group, subjects received no moisturizer but used the standard cleanser. In the positive control group, subjects used Vivatinell Acnecinamide® Gel Cream (containing 4% niacinamide) as a moisturizer and Neutrogena Visibly Clear® Spot Clearing Facial Wash (containing 2% salicylic acid) as a cleanser. The positive control regimen was included to provide a comparison for estimates of effect size. The primary objective was to evaluate skin moisturization as a change from baseline in corneometer values at 8 h for the test regimen vs. the control regimen. Analysis of covariance was applied for the primary efficacy analysis.

RESULTS: A total of 132 subjects were randomized with 44 included in each treatment group. A significant difference was observed in the primary endpoint for the test regimen compared with the control regimen (least-squares mean difference [95% CI]: 3.12 [0.68, 5.56], $P = 0.0128$). A trend was observed in favour of the positive control regimen compared with the control regimen. Secondary measurements of moisturization supported the primary efficacy outcome. Assessment of blemishes showed a significant difference between the test regimen vs. the control regimen for change from baseline in mean total blemish count at Week 8 (least-squares mean difference [95% CI]: −1.80 [−3.41, −0.19], $P = 0.0290$). No statistical comparisons between the positive control group and the test group were performed.

CONCLUSION: This study provides proof-of-concept evidence that a novel lamellar lipid moisturizer containing niacinamide, in combination with a standard cleanser, can help moisturize the skin and provide an overall improvement in the complexion appearance of people with blemish-prone skin. Study registration: NCT03093181.

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Résumé

OBJECTIF: Une étude randomisée a été conçue pour évaluer le bénéfice cosmétique potentiel d'une crème hydratante biomimétique contenant du niacinamide sur une peau grasse sujette aux imperfections.

MÉTHODES: Des femmes adultes en bonne santé, à peau grasse sujette aux imperfections, ont été randomisées dans l'un des trois groupes de traitement : test, témoin ou témoin positif. Dans le groupe test, les sujets ont utilisé le produit testé (contenant 4 % de niacinamide), plus le nettoyant standard (Nettoyant visage Simple® doux pour la peau). Dans le groupe témoin, les sujets n'ont reçu aucune crème hydratante mais ont utilisé le nettoyant standard. Dans le groupe témoin positif, les sujets ont utilisé le gel crème Vivatinell Acnecinamide® (contenant 4 % de niacinamide) comme crème hydratante et le nettoyant visage pour réduire les imperfections Neutrogena Visibly Clear® (contenant 2 % d'acide salicylique) comme nettoyant. Le schéma de traitement du groupe témoin positif était inclus pour fournir une comparaison des estimations de la taille de l'effet. L'objectif principal était d'évaluer l'hydratation de la peau par le changement par rapport à la référence des valeurs du cornéomètre à 8 h pour le schéma de traitement testé par rapport au schéma de traitement témoin. Une analyse de covariance a été appliquée pour l'analyse de l'efficacité primaire.

RÉSULTATS: Un total de 132 sujets ont été randomisés, dont 44 inclus dans chaque groupe de traitement. Une différence significative a été observée dans le critère d'évaluation principal en faveur du schéma de traitement testé par rapport au schéma de traitement témoin (différence moyenne des moindres carrés [IC à 95 %] : 3,12 [0,68, 5,56], P = 0,0128). Une tendance a été observée en faveur du schéma de traitement témoin positif par rapport au schéma de traitement témoin. Les mesures secondaires de l'hydratation ont appuyé le résultat principal d'efficacité. L'évaluation des imperfections a montré une différence significative entre le schéma de traitement testé par rapport au schéma de traitement témoin en ce qui concerne le changement par rapport à la référence dans le nombre moyen total d'imperfections à la semaine 8 (différence moyenne des moindres carrés [IC à 95 %] : _1,80 [_3,41, _0,19], P = 0,0290). Aucune comparaison statistique entre le groupe témoin positif et le groupe test n'a été réalisée.

CONCLUSION: Cette étude fournit des éléments de preuve de concept qu'une nouvelle crème hydratante lipidique lamellaire à base de niacinamide, en association avec un nettoyant standard, peut permettre d'hydrater la peau et fournir une amélioration globale de l'aspect du teint chez des personnes dont la peau est sujette aux imperfections. Numéro d'enregistrement de l'étude : NCT03093181.

Introduction

Most of the skin barrier function resides in the epidermis and particularly, in its outermost layer – the stratum corneum (SC), consisting of corneocytes and intercellular lamellar lipid bilayers [1]. Topical moisturizers that are optimised to restore the skin's barrier properties should mimic the physical and structural attributes of SC lipids; ideally, the lipids should be arranged in conformationally ordered lamellar arrays and have the ability to form repeating bilayers [2].

The development of next-generation biomimetic lamellar lipid topical formulations to improve skin health has been a recent focus of our research, and we have previously discussed the development and use of biophysical methods to measure, characterize and demonstrate the molecular organisation and *in vitro* barrier efficacy of our topical formulations containing biomimetic technology [2,3]. Subsequently, modifications to the composition and relative concentration of long-chain mono- and di-acyl lipids (based on our research knowledge and insights from *in silico* molecular simulations) have informed development of additional novel biomimetic lamellar lipid formulations, including a new topical formulation which contains niacinamide as an additional key functional ingredient. This formulation and variants of it have been assessed in proof-of-concept clinical studies focussed on barrier recovery and ageing skin where it has shown desirable effects on skin barrier function [4].

Blemishes and pimples form as a result of obstruction of the pilosebaceous follicles, with or without inflammation. Increased sebaceous secretion and an abnormal keratinisation form a mass inside the follicle, resulting in a comedone, commonly referred to as a blackhead or whitehead. The environment inside the blocked follicle is anaerobic, which promotes the propagation of anaerobic bacteria. The presence of bacteria and biologically active mediators can trigger the inflammation associated with the appearance of blemishes, commonly referred to as papules and pustules [5].

Pre-clinical published studies have shown that niacinamide has the potential for topical application in cosmetic preparations [6], where it can increase the levels of ceramides, free fatty acids and cholesterol in the SC [7], and decrease sebum production [8]. In clinical studies, topical preparations with niacinamide were shown to reduce sebum production [9], to be effective in subjects with oily skin [10], and to return the altered skin barrier to normal levels in subjects with acne [11]. In addition, Soma and colleagues [12] showed the desquamation index increases in response to moisturization after niacinamide treatment.

We hypothesized that our new niacinamide-containing next-generation biomimetic lamellar lipid formulation could help promote efficient desquamation through improved moisturization and help prevent follicles from becoming blocked, thereby reducing the opportunity for new blemishes to form. This was expected to translate to an overall cosmetic improvement in the appearance of the complexion of people with blemish-prone skin. Accordingly, we undertook a proof-of-concept study to test this new formulation for the first time in humans with oily, blemish-prone skin.

Methods

We report on a randomized, parallel-group, evaluator-blind, controlled, proof-of-concept clinical study. The study was undertaken at a single site in Brazil and was designed to evaluate the cosmetic benefit of a developmental moisturizer formulated with niacinamide and a lamellar lipid base cream (MFC40284; GSK, Brentford, UK) in subjects with oily, blemish-prone skin.

This study was performed in full compliance with International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and all applicable local Good Clinical Practice (GCP) guidelines [13].

Investigators obtained written informed consent from all subjects before enrolment. Summarised study protocols are available at www.gsk-clinicalstudyregister.com.

Subjects

Female subjects aged 18–45 years (inclusive), who had a minimum of 8 and maximum of 25 blemishes (papules and pustules) at Visit 1 (screening) and a minimum of 8 blemishes at Visit 2 (randomization), a Fitzpatrick skin type I to V, and a sebumeter score greater than 66 μg cm^{-2} at the forehead, were eligible for inclusion in the study. Subjects were not eligible if they had used a medicated acne treatment within the last 12 months, had an active skin disease in the test area, had a medical history of dysplastic nevi or melanoma on the face or had moles, cysts, tattoos, scars, irritated skin, or hairs, in the test area.

Design

The trial consisted of screening, washout and test phases. After screening, eligible subjects underwent a 5- to 7-day washout period to standardize cleansing and skincare regimens prior to entry in the test phase. Subjects were enrolled and placed on washout if they had a minimum of 8 and a maximum of 25 facial blemishes (papules and pustules, excluding those on the nose) and subsequently randomized if they presented a minimum of 8 facial blemishes at the end of washout period. During the washout period, subjects were instructed not to use any skincare or cosmetic product and to cleanse their face twice-daily (morning and night) with the standard cleanser provided (Simple® Kind to Skin Moisturizing Facial Wash [Unilever, Leatherhead, UK]).

Following the washout period, eligible subjects were randomized in a 1 : 1 : 1 ratio, stratified by age (<21 years and ≥21 years), to one of three treatment groups: test, control or positive control. In the test group, subjects used the test product (containing 4% niacinamide), plus the standard cleanser. In the control group, subjects received no moisturizer but used the standard cleanser. In the positive control group, the treatment regimen included a cream based on 4% niacinamide technology (Acnecinamide® Gel Cream; Vivatinell, Wigan, UK), which is reportedly effective at reducing the number of blemishes in subjects with blemish-prone skin. Additionally, the positive control regimen included a cleanser containing 2% salicylic acid (Neutrogena Visibly Clear® Spot Clearing Facial Wash; Johnson & Johnson Pty Ltd, Maidenhead, UK), also marketed for the cosmetic improvement of blemish-prone skin. The combination of a cream clinically proven to reduce blemish counts and a salicylic acid-containing cleanser was chosen as a positive control regimen to provide a maximized clinical benefit.

The standard cleanser, positive control cleanser and positive control moisturizer used in this study are commercially available and

were used in accordance with their respective packaging instructions. The positive control cleanser was chosen because it contains salicylic acid which is considered effective at promoting desquamation [14]. The positive control moisturizer, based on niacinamide, was chosen because it has been reported to be effective at reducing blemish counts with continued use for 8 weeks [15].

Assessments

Assessments included instrumental measurements of skin moisturization with a corneometer (Corneometer CM 865 [Courage + Khazaka, Cologne, Germany]); blinded evaluator assessments of blemish counts (papules and pustules); blinded lay evaluator (i.e. by untrained individuals) assessments of photographs (taken using a Canfield Visia imaging system [Canfield, Parsippany, USA]) and instrumental measurements of casual skin sebum levels and sebum excretion rate with a sebumeter (Sebumeter SM 815 [Courage + Khazaka electronic, Cologne, Germany]). Sebumeter measurements were the last assessment of the day, taken at 5 and 90 min after cleansing with 70% isopropyl alcohol (IPA) [Labour Import, Brazil]; the sebum excretion rate was calculated as the difference in 90- and 5-min sebumeter values. Both corneometer and sebumeter assessments were taken in a temperature (20 ± 1°C) and humidity-controlled (50 ± 10% relative humidity) environment.

Image capture and analysis need to be very carefully controlled to be reliable; in our study, the Canfield Visia imaging system was used to take all photographs, which were calibrated to ensure consistent image illumination and capture. High-resolution colour photographs of the front of each subject's face were taken using polarised and non-polarised lighting. For analysis, the baseline and Week 8 photographs were displayed side-by-side on a high-resolution, colour-calibrated display screen in a room with neutral wall colours and standardized lighting. Both the polarised and non-polarised image pairs were assessed for each subject by every lay person evaluator. Images were judged as either 'left' (i.e. the blemishes in the image on the left were more obvious than those in the image on the right) or 'right' (i.e. the blemishes in the image on the right were more obvious than those in the image on the left). The photographic images that were collected are not appropriate for publication in this manuscript; they are high-resolution, colour-calibrated images that need to be displayed on high-resolution, colour-calibrated screens, in a room with carefully controlled lighting. Reproduction of these images in hard-copy or when displayed electronically will result in a significant loss of colour quality and resolution which will make the blemish benefit difficult to observe.

The primary objective of the study was to evaluate skin moisturization (change from baseline) compared with no treatment; the primary endpoint was changed from baseline in corneometer values at 8 h ± 15 min on Day 1.

Secondary endpoints included: change from baseline in corneometer values at 1 h ± 15 min and 3 h ± 15 min on Day 1, and at 1, 4 and 8 weeks; lay person assessment of the improvement from baseline in overall appearance of blemishes by photographic comparisons at 8 weeks; evaluator assessment of change from baseline in blemish count (sum of papules and pustules at the forehead, chin and cheeks) at 1, 4 and 8 weeks; evaluator assessment of change from baseline in individual blemish count (individual count of papules and pustules at the forehead, chin and cheeks) at 1, 4 and 8 weeks; change from baseline in sebumeter values at 1, 4 and 8 weeks and change from baseline in sebum excretion rate at 1, 4 and 8 weeks.

The frequency and severity of any adverse events (AEs) and/or serious AEs (SAEs) were recorded for individuals at each study visit.

Statistical methods

Analysis of covariance (ANCOVA) was applied for the primary efficacy analysis, with treatment as the main effect, and age stratification and baseline measurement as covariates. Least-squares (LS) means and differences between least-squares means for the test group vs. the control group and the positive control vs. the control, together with 95% confidence intervals (CIs) are presented. Because of the exploratory nature of the study, no adjustment to the alpha level for multiple comparisons was made. No statistical comparisons between the positive control regimen and the test product were planned; the positive control regimen was included to support validation of the trial design and to provide a reference point for estimates of effect size.

The change from baseline in secondary endpoints was analysed at each post-baseline time point using the same ANCOVA model as used in the primary analysis as detailed above.

The summary and analysis of lay person image assessment were performed for polarised images and non-polarised images separately. Data from all 24 assessors were pooled, and a repeated-measure logistic regression was applied. Additionally, data from all assessors for each subject were combined into an average rating, and an analysis of variance (ANOVA) was performed.

Results

A total of 205 subjects were screened, and 132 subjects were randomized (44 subjects in each treatment group). A total of 124 subjects completed the study (41 subjects in the test group, 42 subjects in the control group and 41 subjects in the positive control group; Fig. 1 and Table S1).

All subjects who were randomized and received at least one dose of study product (for the control group this included any use of the cleanser post-randomisation) were included in the safety population (132 subjects). All subjects who were in the safety population, and had at least one post-baseline efficacy assessment, were included in the intent-to-treat (ITT) population (132 subjects). One subject randomized to the positive control group was administered the incorrect study product; this subject was included in the control group for the safety population (45 subjects) and the positive control group for the ITT population (44 subjects). No randomized subjects were excluded from the safety population or ITT population. A total of 110 subjects (83.3%) were included in the per-protocol (PP) population.

Demographic and baseline characteristics of the ITT and safety populations were similar (Table S2). All subjects were female; the majority were either White/Caucasian/European (61.4%) or African American/African (31.8%). The overall mean age was 25.3 years, with a range of 18–40 years. Most subjects had Fitzpatrick skin type II (31.1%) or III (34.1%). Stratification by age showed 31 (23.5%) subjects in the <21 years age strata overall and 101 (76.5%) in the ≥21 age strata; this was similar and balanced across all treatment groups.

Primary efficacy

A statistically significant difference was observed for change from baseline in corneometer measurement at 8 h when the test product was compared with the control regimen (Table I). A trend was observed in favour of the positive control regimen when compared

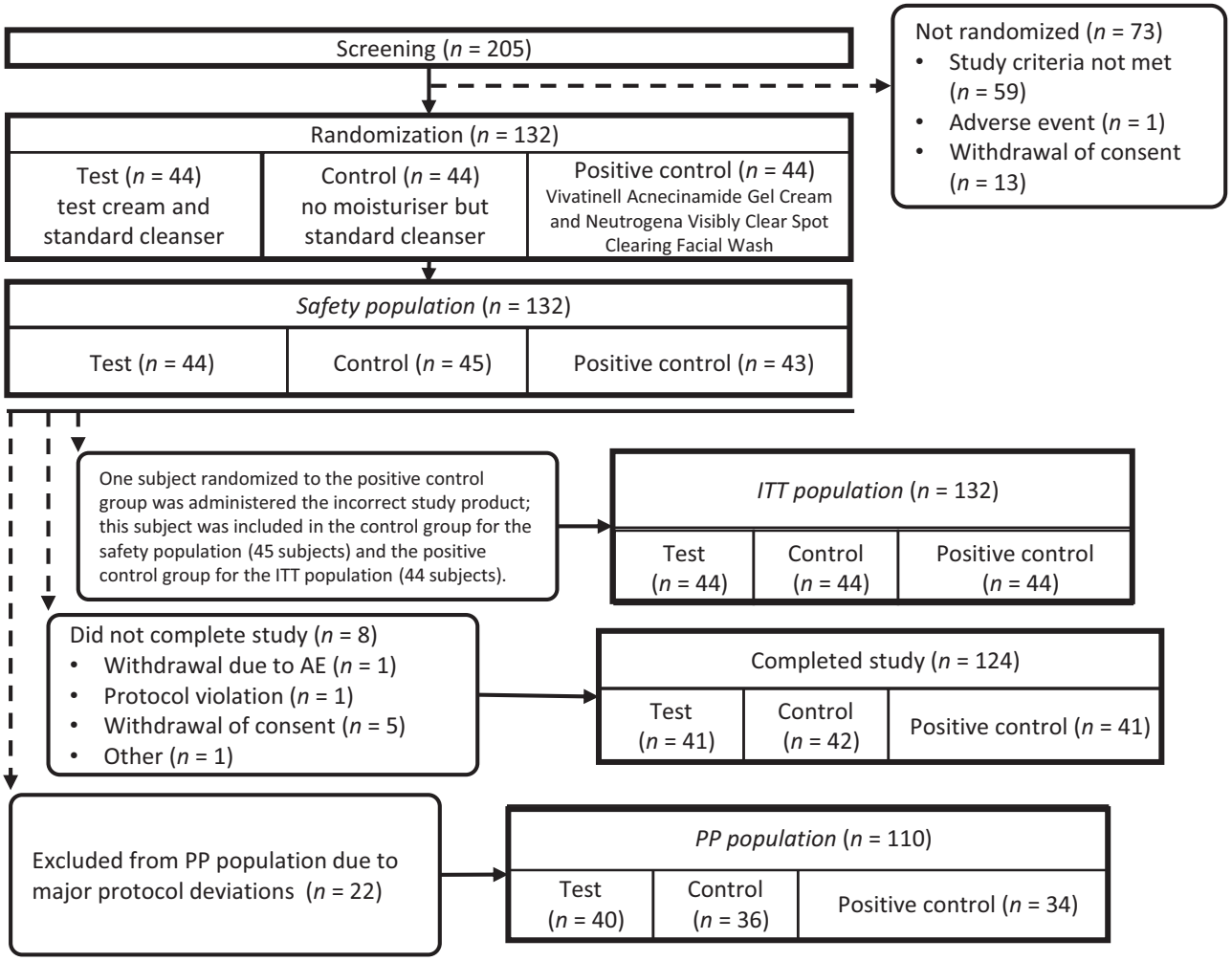

Figure 1 Subject flow. Screening and randomization of study subjects. PP, per-protocol; ITT, intent-to-treat.

with the control regimen, supporting model validity. Within treatment groups, the mean change from baseline in corneometer measurements at 8 h was similar across the two age strata. The PP analysis was similar to the ITT analysis.

Secondary efficacy

Within-group changes from baseline in corneometer measurements were statistically significant in subjects in the test group at all time points (1 h, 3 h, 1 week, 4 weeks and 8 weeks), indicating increased moisturization with time. In the control group, changes from baseline (indicative of increased moisturization) were statistically significant at 1 h and 4 weeks only, and in the positive control group, similar positive statistically significant changes were observed at 1 h, 3 h, 1 week and 8 weeks (Fig. 2).

Statistically significant differences in favour of the test product vs. the control regimen, for change from baseline in corneometer values at 1 and 3 h, were observed (LS mean difference [95% CI]; 1 h: 14.84 [11.88, 17.80], $P < 0.0001$; 3 h: 8.68 [6.17, 11.20], $P < 0.0001$). Furthermore, trends in corneometer values in favour of the test product vs. the control regimen were seen at 1, 4 and 8 weeks, although differences between groups were not statistically significant.

Similarly, a statistically significant difference in favour of the positive control group compared with the control group for change from baseline in corneometer measurement was observed at 1 h, 3 h and 1 week (LS mean difference [95% CI]; 1 h: 8.68 [5.72, 11.64], $P < 0.0001$; 3 h: 4.04 [1.53, 6.55], $P = 0.0018$; and 1 week: 4.03 [0.06, 7.99], $P = 0.0466$). At 4 weeks, the comparison favoured the control regimen, and at 8 weeks, no difference was observed. Within-group mean changes in corneometer values from baseline by age group (ITT population) were observed at 1 week for both the test group and the positive control group. This trend was also observed for the test group at 4 and 8 weeks. These outcomes are unlikely to be of clinical relevance.

The mean total blemish count showed statistically significant within-group changes from baseline for subjects in the test group and positive control group at 4 and 8 weeks only. At 8 weeks, there was a statistically significant difference in favour of the test regimen vs. the control regimen for change in blemish count from baseline

Table I Primary efficacy results (ITT population)

	Test*n* = 44	Control*n* = 44	Positive control*n* = 44
Baseline *n*	44	44	44
Mean (SD)	62.18 (8.20)	63.13 (7.91)	64.36 (8.25)
8 h *n*	44	44	43
Mean (SD)	68.32 (6.73)	65.76 (8.08)	67.99 (7.33)
8 h change from baseline *n*	44	44	43
Mean (SD)	6.14 (6.44)	2.63 (5.60)	3.60 (7.86)
Median	6.23	2.85	3.70
Minimum to maximum	−6.20 to 17.03	−10.17 to 18.87	−12.93 to 28.37
LS mean (SE), *P*-value[1]	5.70 (0.87), <0.0001	2.59 (0.87), 0.0035	4.10 (0.88), <0.0001

Comparisons[†,‡]

	Difference	95% CI	*P*-value
Test vs. control	3.12	(0.68, 5.56)	0.0128
Positive control vs. control	1.51	(−0.95, 3.96)	0.2262

Higher corneometer values are indicative of improved skin moisturization.
ITT, Intent-to-Treat; ANCOVA, analysis of covariance; LS, least-squares; SD, standard deviation; SE, standard error.
[†]From ANCOVA with treatment main effect, age stratum and baseline as covariates.
[‡]Difference is first named treatment minus second named treatment such that a positive value favours the first named treatment.

(LS mean difference [95% CI]; −1.80 [−3.41, −0.19]; $P = 0.0290$) (Fig. 3). At 1 and 4 weeks, no significant differences were observed. No significant differences were observed for positive control regimen vs. the control regimen; however, at 4 and 8 weeks, a trend was observed in favour of the positive control regimen, supporting model validity (LS mean difference [95% CI]; 4 weeks: −0.80 [−2.43, 0.84], $P = 0.3351$; 8 weeks: −0.83 [−2.45, 0.80], $P = 0.3159$). There were no apparent trends in terms of age group.

Lay person assessment of photographs showed statistically significant improvements in blemish appearance, for both polarised and non-polarised images at 8 weeks, in favour of the test regimen vs. the control regimen (polarised images, $P = 0.0243$ and non-polarised images, $P = 0.0181$). No difference between the positive control and control regimen was observed (polarised images, $P = 0.8931$ and non-polarised images, $P = 0.8319$). Additional ANOVA analysis also showed a statistically significant improvement in the overall appearance of blemishes in favour of the test product vs. control when analysed via polarised images ($P = 0.0279$) and non-polarised images ($P = 0.0224$) at Week 8.

A statistically significant within-group decline in casual sebum levels and sebum excretion rates were observed in within-group changes from baseline for the test regimen. However, no statistically significant differences between the test group and the control group, or between the positive control and the control group, were seen at any time point.

Safety

The products tested in this study were generally well tolerated. Eight subjects (6.1%) reported 11 treatment-emergent AEs (TEAEs) during the study: 1 subject (2.3%) in the test group reported 1 TEAE, 2 subjects (4.4%) in the control group reported 1 TEAE each and 5 subjects (11.6%) in the positive control group together reported 8 TEAEs (Table S3). The most common TEAEs were nervous system disorders, which occurred in five subjects (6 events of headache and 1 event of hyperaesthesia). All other AEs occurred once in 1 subject each. All TEAEs were of mild or moderate severity. All TEAEs were resolved at the end of the study. Only 1 TEAE was considered treatment-related: 1 subject in the control group had 2 events of contact dermatitis, with 1 event considered to be treatment-related (standard cleanser), which was mild in severity. The subject withdrew from the study as a result of this AE, which resolved without treatment. There were no deaths or other SAEs among subjects who participated in the study.

Discussion

In this proof-of-concept study, we had expected that the developmental moisturizing cream, with niacinamide and next-generation biomimetic technology, would moisturize the skin and help promote desquamation and prevent follicles from becoming blocked, thereby preventing the formation of new blemishes. This would translate to an overall improvement in the complexion of subjects with sensitive, oily, blemish-prone skin.

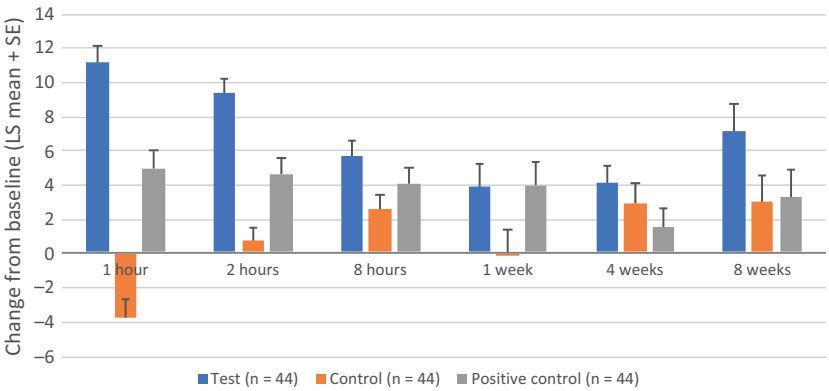

Figure 2 Secondary efficacy corneometer measures; change from baseline (ITT population). ITT, Intent-to-treat; LS, least-squares; SE, standard error.

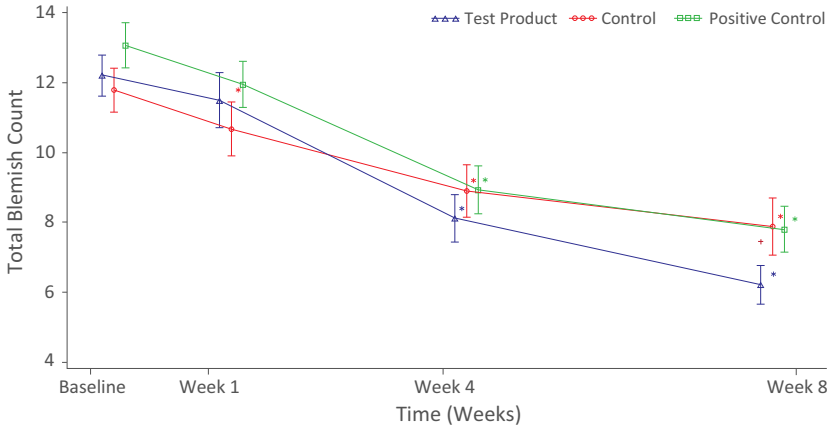

Figure 3 Total blemish count over time by treatment regimen group (ITT population). Total blemish count = mean (±SE). *Significant within-group change from baseline ($P < 0.05$). +Significant treatment difference on change from baseline vs. control ($P < 0.05$). ITT, Intent-to-treat.

The study was considered a success as the primary endpoint was met with a significant difference in change from baseline in corneometer values at 8 h in favour of the test group vs. the control group. This result was supported by secondary efficacy corneometer endpoints, which demonstrated significant differences in favour of the test regimen compared with the control regimen (at early time points [1 and 3 h]).

The key secondary endpoint, reduction in blemish count, was also considered to be met as a significant reduction from baseline was observed in favour of the test regimen vs. the control regimen at Week 8. These data were further supported by the lay evaluation of blemishes by photographic assessment, which indicated that subjects in the test group were more likely to show an improvement in overall blemish appearance at Week 8 compared with subjects in the control group. Such lay grader assessment is valuable as it is more representative of the wider population and indicates that the numerical improvement in blemish count was visible. Interestingly, the change from baseline in total blemish count was significant for the control group at all time points, illustrating the favourable effects provided by twice-daily cleansing which can remove surface oils, bacteria and dead skin cells which can cause blemishes to form [5].

The focus of the data presented in this manuscript is to support the primary endpoint, which was dermatologists visual grading of the full-face and did not involve an assessment of photographs. The secondary lay grader assessments of photographs were included to support the clinical assessments to build confidence that the dermatologists-reported benefits are consumer relevant. Given the reasons specified in the methods section, the scientific value to the reader of including a sub-set of images in support of secondary endpoints is minimal and would likely result in confusion where quality becomes compromised.

The positive control group was included to support validation of the clinical study and to provide a reference point for estimates of effect size. The regimen in this group consisted of a cosmetic moisturizing cream with niacinamide, which has been reported as efficacious in subjects with blemish-prone skin [14,16] and a cosmetic cleanser containing 2% salicylic acid for exfoliation. At 1 h, 3 h and 1 week, a significant difference in change from baseline in corneometer values was observed for the comparison between the positive control group and the control group, in favour of the positive control group. However, at 8 h, 4 weeks and 8 weeks, these differences were not seen. These data indicate that the clinical model was sufficiently sensitive to detect a significant difference in skin moisturization but that the regimen used in the positive control group did not exhibit sustained efficacy. Similarly, significant reductions in the blemish count at Week 4 and Week 8 were seen within the positive control group but there were no significant differences between this group and the control group. Previous studies have demonstrated a significant reduction in total blemish count (comedones, papules and pustules) at 8 and 12 weeks with twice-daily use of Acnecinamide® Gel Cream [14,16], but these studies did not include a control arm. In the present study, blemish appearance was evaluated as being similar for the positive control group and the control group; this finding may benefit from further investigation.

Given the significant improvements seen in skin moisturization, blemish count and overall blemish appearance in favour of the test regimen, it was surprising that the test regimen did not provide additional benefit to skin oiliness. It is noteworthy that while niacinamide-containing moisturizers are reportedly effective at reducing sebum levels, a recent study in Japanese and Caucasian subjects found no improvement in Caucasian subjects [9], highlighting potential population differences. Therefore, it is possible that there may also be a difference in how blemish-prone skin vs. non-blemish-prone skin responds to similar products. Indeed, it may prove beneficial to undertake future studies that are designed to evaluate the use of niacinamide in subjects with different skin types.

In conclusion, the primary objective of this study was met with a significant difference in moisturization between the test product and the control regimen at 8 h. Additionally, the key secondary objective was met and showed a significant difference in favour of the test regimen in total blemish count at 8 weeks. All study treatments were generally well tolerated.

Overall, these results indicate that the next-generation biomimetic lamellar skincare formulation containing niacinamide, in combination with a standard cleanser, can help moisturize the skin and provide an overall improvement in the appearance of the complexion of people with blemish-prone skin. These clinical data warrant further research into the role of topical biomimetic technologies in blemish-prone skin.

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Conflict of interest

JC, CFG, HM, MC, MT, DM and RV are all employees of GSK Consumer Healthcare. RD is an employee of Azidus Brasil, a Contract Research Organization that has received funding from GSK Consumer Healthcare.

Author contributions

All authors have been involved in drafting the manuscript or revising it critically for important intellectual content and have read and given final approval of the version to be published.

Data sharing

Anonymised individual participant data and study documents can be requested for further research from www.clinicalstudydatarequest.com

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Subject disposition.
Table S2. Demographics (safety population).
Table S3. Treatment emergent adverse events (safety population).