

ORIGINAL ARTICLE

Saccharide isomerate ameliorates cosmetic scalp conditions in a Chinese study population

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Email: remo.campiche@dsm.com**Abstract**

Background: Scalp conditions such as flaky or oily scalp affect people across ethnicities and age groups. In addition to flaking, increased sebum secretion, itching, and compromised scalp barrier function were described. Scalp conditions are aesthetically disturbing and may cause psychological distress in affected individuals who are looking for mild and effective treatment at the same time. Saccharide isomerate has a long history as a skin moisturizer, and it was found to improve skin barrier function, also suggesting possible beneficial effects on scalp.

Aims: To provide relevant claim substantiation to introduce saccharide isomerate as a new scalp care active against scalp flaking condition.

Material and Methods: We conducted a placebo-controlled clinical study in an adult Chinese population affected by dandruff scalp as assessed by an adherent scalp flaking score. We monitored transepidermal water loss (TEWL), sebum secretion, and scalp flaking during 28 days.

Results: Formulations containing Saccharide isomerate significantly improved all parameters both over time as well as compared to the placebo formulation.

Conclusion: We propose Saccharide isomerate for cosmetic formulations directed toward improving scalp conditions such as dandruff or oily scalp.

KEYWORDS

flaking, saccharide isomerate, scalp, sebum, TEWL

1 | INTRODUCTION

Scalp health is paramount to people's wellbeing and quality of life.^{1,2} However, scalp disorders are common and affect individuals across ethnicities and age groups with peaks right after birth, during adolescence, and between 30 and 60 years of age.³ Scalp issues are, for example, oily scalp, scalp flaking or dandruff, itchy scalp, and up to more severe conditions like seborrheic dermatitis (SD)⁴ and can also affect hair quality.⁵⁻⁷ Studies show such conditions were associated with dysbiosis of the scalp microbiome, specifically of the

various *Malassezia* species. In particular, *M. furfur* was believed to have a major role in the development of dandruff.⁸ Nevertheless, other *Malassezia* species such as *M. globosa* and *M. restricta* have taken the place of *M. furfur* and were shown to be closely associated with scalp dandruff.⁹⁻¹¹ While the contribution of *Malassezia* to scalp conditions is well established, it is also recognized that dandruff and seborrheic dermatitis have more complicated pathologies than *Malassezia*.³ Various factors are described to contribute to SD such as sebaceous gland activity, scalp microflora metabolism, or individual susceptibility.¹² In addition, scalp skin barrier integrity has

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evolved as an important factor associated with a healthy scalp,¹³ and dandruff and stratum corneum dysfunction are connected.¹⁴ It was also suggested that flaking in dandruff is due to hyperproliferation of scalp skin epidermis.¹⁵ A disturbed scalp barrier is linked to scalp inflammation causing erythema, itch and a burning and stinging sensation, derailed desquamation leading to scalp flaking, as well as a dry and tight scalp due to increased transepidermal water loss (TEWL).¹³ A study on Korean subjects showed increased sebum and TEWL in dandruff sufferers compared to a control group.¹⁶ It could be assumed that increasing or repairing scalp barrier integrity at the same time improves other scalp conditions like oily or flaky scalp simply because homeostasis is reinstalled. Indeed, in a study exploring the circadian rhythm of scalp skin, it was found that skin redness and sebum secretion oscillate during the day, also barrier integrity as measured by TEWL oscillated and was found lowest when redness and sebum were highest.¹⁷ Nevertheless, causal relationship between these parameters has still to be investigated.

Saccharide isomerate¹⁸ is a natural, bioactive, sustainably produced sugar isomerization technology. It is made by transforming edible kernel corn sugars (mostly glucose) into a unique, skin-identical carbohydrate complex, similar to the natural moisturizing factor found in the human stratum corneum. It binds water and was previously shown to have beneficial effects on skin barrier,^{19,20} skin hydration,²¹ and skin microbiota.²² In this study, we aimed at investigating the effects of saccharide isomerate on scalp condition properties. We conducted a clinical study on Chinese subjects suffering from flaky scalp and monitored TEWL, sebum level, and scalp flaking over a period of 28 days.

2 | MATERIALS AND METHODS

2.1 | Shampoo formulations

Rinse-off shampoo formulations as described in Table 1 were used.

TABLE 1 Composition of shampoo formulations used in this study

Ingredient	Placebo	Shampoo A	Shampoo B
INCI	% w/w	% w/w	% w/w
Aqua	51.1	50.9	50.6
Sodium laureth sulfate	38.0	38.0	38.0
Coco-betaine	4.0	4.0	4.0
Sodium cocoamphoacetate, lauryl glucoside, glycerin, sodium cocoyl glutamate, sodium lauryl glucose carboxylate (PLANTAPON® SF, BASF)	5.0	5.0	5.0
Saccharide isomerate, aqua, citric acid, sodium citrate (PENTAVITIN®, DSM)	--	0.2	0.5
Lactic acid, aqua	0.4	0.4	0.4
Phenoxyethanol, benzyl alcohol, potassium sorbate, tocopherol, aqua (euxyl™ k 700, Ashland)	0.8	0.8	0.8
Sodium chloride	0.7	0.7	0.7

2.2 | Clinical study

This was a randomized, mono-center, placebo-controlled, single-blind study conducted at the contract research organization Guangzhou Landproof Testing Technology Co. Ltd., Guangzhou, Guangdong, P. R. China. Volunteers signed an informed consent to participate in the study. This study was reviewed and approved by the Ethics Committee of Guangdong Daily Chemical Industry (reference: GDIRB [2020] 12-1) prior to initiation. Study volunteers consisted of healthy Chinese women and men as outlined in Table 2.

Inclusion criteria were healthy Chinese men or women between 18 and 50 years of age. Need to have some degree of dandruff as assessed by a dermatologist with a total adherence scalp flaking score (ASFS) greater or equal than 24 and less or equal than 40. Two weeks before the start of the study, volunteers in all three groups were willing to stop using anti-dandruff products and only use the placebo shampoo for at least three times per week in the evening. At the beginning of the study, volunteers in each group started using their respective shampoo formulation. Of note, one day before coming to the study site for measurements, volunteers in all three groups were asked not to wash their hair.

Exclusion criteria were as follows: general exclusion criteria applied, for example, pregnant, breast feeding or planning to become pregnant. Having diseases, particularly of the skin and more so of the scalp.

2.3 | Adverse effects were monitored during the study

Application of products: Foamed shampoos were applied once every other day for the whole study period on the hairs by stroking the hair repeatedly from top to bottom, and to the scalp by gently massaging the entire scalp with fingertips for 3–5 min. Hair and scalp were then gently and thoroughly rinsed with warm water.

Group	Number of volunteers	Min. age [years]	Max. age [years]	Mean age [years]	SD [years]
Placebo	30 (18f / 12m)	22	50	40.73	7.04
Shampoo A	30 (19f / 11m)	20	50	38.50	9.06
Shampoo B	30 (19f / 11m)	23	49	39.30	6.36

TABLE 2 Demographics of study volunteers

Abbreviations: f, female; m, male; SD, standard deviation.

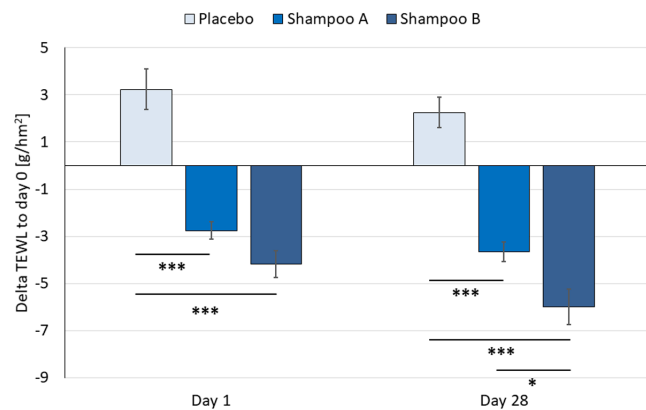


FIGURE 1 Change in TEWL over time in the three study groups. TEWL is displayed as water loss in gram per hours per square meter of skin. * p 0.05, *** p 0.001 by ANCOVA with Tukey adjusted p -value

Measurements had taken place at the study site at controlled environmental conditions which were $21 \pm 1^\circ\text{C}$ temperature and $50\% \pm 5\%$ relative humidity. The study ran between December 21, 2020, and February 3, 2021.

Transepidermal water loss was measured by Tewameter™ nano (Courage & Khazaka), and sebum was measured by Meibometer MB560 (Courage & Khazaka). Adherence scalp flaking score (ASFS) was performed by a trained dermatologist according to previously published reports.²³ Images of the scalp were taken using a dermatoscope (VEOS HD2, Canfield Scientific) at the top of the head (site with the highest ASFS score). At this same site, also the TEWL and sebum measurements were done.

2.4 | Statistical analysis

Intra-group statistical interpretation was done with ANOVA test.

Inter-group statistical interpretation was done with ANCOVA test.

3 | RESULTS

3.1 | Scalp TEWL is improved by a shampoo formulation containing saccharide isomerate

Previous studies showed that saccharide isomerate had a positive impact on skin barrier formation as exemplified by improved

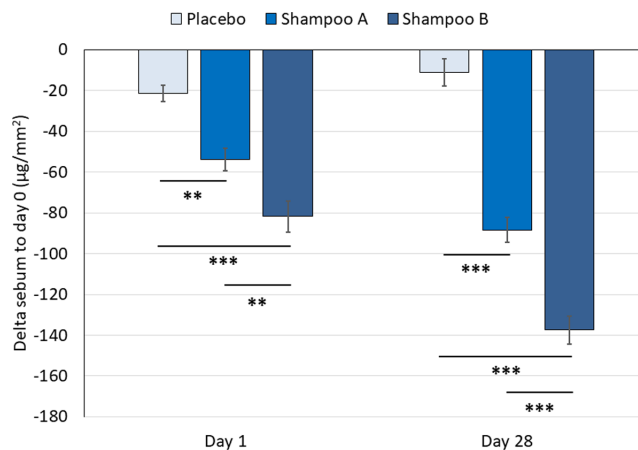


FIGURE 2 Change in scalp sebum over time in all study groups. The change in sebum content is displayed as delta sebum in microgram per square millimeter scalp skin. ** p 0.01, *** p 0.001. by ANCOVA with Tukey adjusted p -value

hydration and induction of genes related to hydration and cornified envelope maturation such as filaggrin and loricrin.²⁰ On the contrary, increased TEWL, indicative for skin barrier disruption, was described in dandruff-affected scalp.¹⁶ While in the group using the placebo shampoo, a slight increase in TEWL was measured (+3.23 g/hm^2 at Day 1 and +2.25 g/hm^2 at Day 28), we found a dose- and time-dependent decrease of TEWL in the groups using the shampoos containing saccharide isomerate. Specifically, we found a change of $-2.75 \text{ g}/\text{hm}^2$ and $-3.65 \text{ g}/\text{hm}^2$ at Days 1 and 28 for the shampoo A group, and of $-4.18 \text{ g}/\text{hm}^2$ and $-5.99 \text{ g}/\text{hm}^2$ for the shampoo B group (Figure 1).

3.2 | Scalp sebum is reduced by a saccharide isomerate containing shampoo over 28 days

As increased sebum content on the scalp was shown to be indicative for dandruff, we measured sebum content on the scalp of the subjects. Similar to what we measured for TEWL (Figure 1), we found a steady decrease of sebum over time for both saccharide isomerate groups while there was no change in the placebo group ($-21.3 \mu\text{g}/\text{mm}^2$ and $-11.1 \mu\text{g}/\text{mm}^2$ at Day 1 and Day 28, respectively) (Figure 2). In particular, we found at Day 1 a change of $-53.7 \mu\text{g}/\text{mm}^2$ for the shampoo A group and of $-81.7 \mu\text{g}/\text{mm}^2$ for the shampoo B group (Figure 2). This reached $-88.4 \mu\text{g}/\text{mm}^2$ at Day 28 in the A group and $-137.4 \mu\text{g}/\text{mm}^2$ in the B group (Figure 2).

3.3 | Visible reduction of scalp flaking over time as assessed by ASFS

Adherence scalp flaking score was found to be reduced similarly in the placebo group (−8.63 units) and the two shampoo groups (−12.63 units for the A group and −12.33 units for the B group) after one day. However, a clear improvement was seen after 28 days in the shampoo groups of −16.9 units for shampoo A and −19.23 units for shampoo B, while the placebo group stayed at baseline level (−4.67 units) (Figure 3A). This improvement in flaking score was visible as documented in Figure 3B.

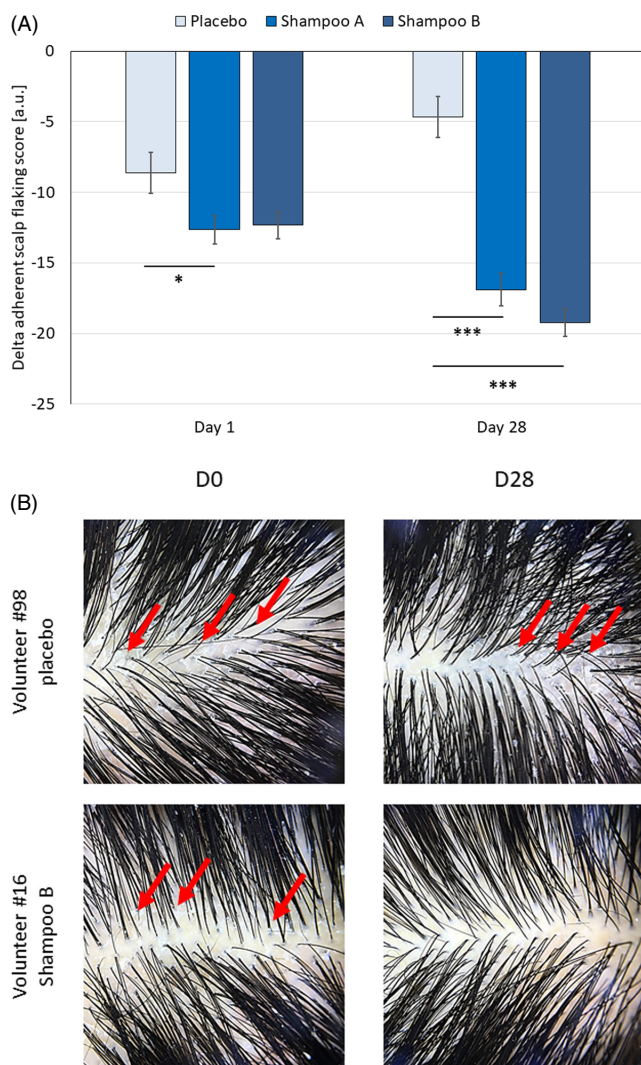


FIGURE 3 (A) Change in ASFS over time in the three study groups. * $p < 0.05$, *** $p < 0.001$ by ANCOVA with Tukey adjusted p -value. (B) Representative scalp images of two volunteers, one using the placebo formulation (#98) and one using the Shampoo B formulation (#16) at the beginning of the study (D0) and at the end of the study (D28). Red arrows point out white flakes on the scalp

4 | DISCUSSION

In this study, we investigated the efficacy of saccharide isomerate present in rinse-off shampoo formulations against dandruff scalp in a Chinese population of healthy adult men and women. We employed representative parameters such as TEWL, sebum content, and ASFS to measure improvements in scalp conditions over time and between groups. Previous reports showed that saccharide isomerate improved skin barrier and suggested better maturation of the cornified envelope.^{20,24} Reminiscent of these findings, we found significantly improved TEWL values on the scalp in the groups using either shampoo A or shampoo B. Moreover, after 28 days, shampoo B was significantly better than shampoo A indicating a dose-dependent effect and suggesting an improved scalp barrier (Figure 1). Furthermore, our results suggest a continuous improvement in TEWL over the whole study period, although we used here a rinse-off formulation. However, previous findings suggest a tight binding of saccharide isomerate to carbohydrate structures of the stratum corneum which persist even after washing of the skin.¹⁸ We assume that this retention capability of saccharide isomerate is the reason for this long-term effect even in a rinse-off formulation.

So far, no reports were found or studies conducted showing an effect of saccharide isomerate on sebum control. Scalp conditions such as dandruff or seborrheic dermatitis are associated with an increased sebum content.¹² Interestingly, we found here a time- and dose-dependent decrease in sebum content in the groups using the formulations containing saccharide isomerate (Figure 2). In addition, we found anti-dandruff or anti-flaking activity for saccharide isomerate (Figure 3). Moreover, dandruff and flaky scalp conditions are associated with increased TEWL and diminished scalp barrier function as well as an irritated and itchy scalp.¹³ As saccharide isomerate improves TEWL and is known to improve skin barrier and hydration,²⁰ we speculate that this contributed to the overall improvement in scalp conditions. Even if we have not investigated in this study the effect of the saccharide isomerate containing formulations on the scalp microbiome, we do have preliminary time-kill study data showing that saccharide isomerate has a growth inhibitory effect on *Malassezia furfur* (not shown). Further investigations are necessary to also look at other *Malassezia* species and microbiota. Nevertheless, as differences in scalp microbiome were reported for healthy and dandruff scalp,^{25,26} one can assume that an improvement in scalp conditions as reported here would have an impact on scalp microbiome composition or distribution.

In conclusion, we provide evidence for a beneficial effect of a rinse-off formulation containing saccharide isomerate on scalp, particularly on scalp TEWL, sebum, and ASFS.

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CONFLICT OF INTEREST

The cosmetic active saccharide isomerate used in this study is marketed and sold by DSM Nutritional Products under the trade name PENTAVITIN®.

ETHICAL APPROVAL

The study protocol and the informed consent form were reviewed and approved by the Ethics Committee of Guangdong Daily Chemical Industry prior to the initiation of the study (ref. GDIRB [2020] 12-1).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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