

## **Absence of effects of dimethicone- and non-dimethicone-containing shampoos on daily hair loss rates**

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### **Synopsis**

Shampoos are designed for cleansing and conditioning hair. During normal use, these products come in contact with hair and skin in very diluted concentrations for very short periods of time and are generally recognized as safe by dermatologists (1). Despite the above, when consumers change hair care products, they have a tendency to be more attentive to the conditions of their hair and scalp and to attribute any perceived change, especially any seen as negative, to the new product. One issue that is always of concern is hair loss or, in consumer terms, hair fall occurring shortly after switching to a new shampoo.

To understand why consumers associate hair fall to the use of shampoo, a clinical study was conducted to examine daily hair loss rates in a large population of 404 healthy Thai females using either a dimethicone- or non-dimethicone-containing cosmetic shampoo for a period of six weeks. In addition, perceptual information was obtained on hair fall, hair health, and causes of hair shedding and hair loss.

While published estimates of average daily hair loss rates range from 34.8 to 180 hairs (2–7), this study found mean hair loss rates ranging from 28 to 35 per day in a population of 404 healthy Thai females over a period of six weeks. These daily hair loss rates are consistent with reported findings in the normal population (2–3,8). There were no significant differences in the total, telogen, anagen, and broken hair loss rates between the three different shampoo groups. As expected, significantly higher hair loss rates were noted on shampoo versus non-shampoo days. No differences were noted in the perception of hair fall in subjects using the three different shampoos.

In this study, we determined why consumers associate hair fall with the use of shampoo. While subjects perceived hair fall as a natural process in hair regrowth and therefore unrelated to hair thinning or balding, they attributed any increased hair fall from grooming to the use of unsuitable shampoos, more so than to the grooming processes of combing/brushing or to chemical modification. Other factors known to contribute to abnormal hair loss were not perceived by the subjects as likely causes of hair fall.

## INTRODUCTION

It has long been recognized that cyclic hair growth activity occurs in a random mosaic pattern in which each hair enters anagen (active growing phase), catagen (involutional phase), and telogen (resting phase) independent of other hairs. This results in a daily shedding process in which telogen hairs are shed and replaced by new anagen hairs (2–7,9–10). Since 85% to 90% of the hair is in the anagen phase and there are approximately 100,000 hairs on the head, the reported average daily telogen hair loss ranges anywhere from 34.8 hairs (2), 40–100 hairs (3), 100 hairs (4,7), 100–150 hairs (5), to 100–180 hairs (6). In general, the anagen phase is longer in women than in men (5). During pregnancy, the proportion of hairs in anagen phase may increase to greater than 95%, thereby decreasing the average shedding rate to 15–20 hairs per day (5).

Many factors can lead to increased, abnormal hair loss (4,7,9–22). These include hormonal changes (3,7,9–22), acute and chronic illness (4,7,9–14), scalp infections (3,7,9–14), trauma (3,7,9–15), medication (3,7,9–22), nutritional deficiency (9–22), endocrine disorders (3,7,9–14), and hereditary predilection (3,7,9–14). Although incorrectly used perms and hair colorants can lead to hair breakage as a result of overprocessing during chemical modification (1), shampoos have long been recognized as safe for use on hair (1).

Most traditional shampoos contain anionic surfactants to cleanse the hair. Conditioners contain fatty alcohols and cationic surfactants to lubricate and neutralize the negative charges on the hair. Since anionic surfactants are negatively charged and cationic surfactants are positively charged, the cleansing and conditioning functions from traditional shampoos and conditioners have to be separated in a two-step process because they cannot exist together in one product.

Dimethicone shampoos differ from traditional shampoos in that they clean and condition hair in a single step. This is achieved by the deposition of non-charged hydrophobic dimethicone droplets to condition hair without interfering with the cleaning ability of the anionic surfactants (23).

## MATERIALS AND METHODS

### GENERAL OUTLINE

A total of 460 Thai females between the ages of 18 and 60 years were screened for eligibility to participate in the study. Prior to participation, they were questioned by dermatologists regarding their medical history and medication intake. The subjects then underwent scalp and hair examinations to assess the severity of scalp flaking and inflammation, the presence or absence of scalp diseases, the degree of hair dryness and hair damage, and abnormal hair loss.

The severity of scalp flaking was assessed on a 5-point scale ranging from no flaking (0) to severe flaking (5). Scalp erythema, if present, was assessed on a 4-point scale ranging from slight (1) to severe (4). Scalp disease was assessed on a 5-point scale where 1 represented non-diseased scalp, 2 represented dandruff, 3 represented seborrheic dermatitis, 4 represented psoriasis, and 5 represented eczema. Hair dryness was assessed on

a 4-point scale where 1 represented oily hair and 4 represented dry hair. Hair damage was assessed in a similar manner on a 4-point scale where 1 represented undamaged hair and 4 represented severely damaged hair. The hair dryness and hair damage scores were totalled and used as a stratification criterion for the balance and assignment of subjects in the study. Subjects were assessed for abnormal hair loss using the following criteria: the pull test (3), the evaluation of short hairs at the hair part for tapered and blunt hair characteristics, and the assessment of the width of the hair part for hair thinning. Other means of assessing abnormal hair loss, such as the pluck test (3) were considered, but the pluck test was not implemented since this procedure entailed significant pain and some hair loss from plucking in a group of healthy normals not in a hair growth study.

Subjects deemed healthy, not on chronic medication with the exception of oral contraceptives, not having scalp diseases (including psoriasis, seborrheic dermatitis, and eczema), and not having scalp inflammation or any abnormal hair loss, were enrolled in the study.

A total of 440 females were enrolled. Prior to participation, these subjects were carefully instructed how to collect all shed hair. Special drains were installed in the bathrooms and sinks of each home to aid the complete collection of shed hair. Subjects were requested to maintain their normal routine hair care regimen for two weeks. During this period, they were supervised by field workers on how to collect all shed hair from the sinks, drains, towels, combs, brushes, and pillows on a daily basis. Premarked envelopes were distributed to the subjects to retain the daily collected hair. Field workers visited each subject's home every two to three days to collect the envelopes of hair, redistribute new envelopes for the next set of collections, supervise the hair collection, distribute products, and answer any questions the subject may have had on hair collection and the study.

After the two-week baseline period, subjects were assigned to the following shampoo treatments, using random permutations of three after being stratified on total hair dryness and damage scores of 0 to 6 and 7 to 8, and as to whether they used shampoo products only, used shampoo and conditioner products, or used a 2-in-1 dimethicone-containing shampoo as their normal hair care regimen.

Group	Treatment	Number of subjects
I	Dimethicone-containing 2-in-1 shampoo	145
II	Non-dimethicone-containing shampoo	145
III	Dimethicone-containing shampoo	145

This was a double-blind study. To ensure blindness, the three shampoo products were packaged in identical containers without identification and were distributed by field personnel from Deemar Survey Research Group. The evaluation team from the Thai Institute of Dermatology had no knowledge of what each subject used.

Subjects used the assigned test product *ad libitum*, at least three times a week for a period of four weeks. The frequency of test product use was recorded on both the envelopes of daily hair collection and the product use diaries. Product consumption was determined pre- and posttreatment. During the treatment phase, the subjects collected all shed hair from the sinks, drains, towels, combs, brushes, and pillows for a period of four weeks.

All daily shed hair collections during the two-week baseline and four-week treatment phases were placed in premarked envelopes and sealed daily. The subjects recorded whether they shampooed their hair or not. To ensure compliance in hair collections, field workers visited each subject's home very two to three days throughout the study to collect the envelopes of hair and distribute new envelopes for the next set of hair collections.

All envelopes of hair were taken to the Thai Institute of Dermatology for evaluation. A team of eleven nurses, supervised by four dermatologists, counted and typed all the hair collected from the study. Each day's hair collections were counted, examined, and categorized as telogen, anagen, and broken hairs. During the study, it was noted that some of the hair collections contained small pieces of hair resulting from haircuts. The cut hair was recorded separately from the broken hair and not included in the analyses of total hair loss count. At the termination of the treatment period, the subjects underwent a final scalp and hair examination.

In addition to the hair and scalp evaluations at the baseline and posttreatment periods, subjects were requested to complete self-assessment questionnaires designed to obtain information regarding their perception of hair fall and hair health. The perceptual questions pertaining to hair fall and hair health were based on a 0-to-7-point scale where 0 represented the absence of a particular hair condition, 4 represented that they perceived a moderate condition, and 7 represented that they perceived a severe condition. Subjects were requested to describe the state of their hair health, amount of damage, manageability, thickness, coarseness, fluffiness/fly away, weight of hair, and dryness/oiliness. In addition, they were requested to assess the state of their scalp health, dandruff severity, hair fall severity, scalp itch, scalp dryness, and scalp irritation.

In an attempt to understand why consumers associate hair fall with the use of shampoos, a series of questions was posed to the subjects in this study to determine their perception of the possible causes of hair fall, hair thinning, and hair loss tendencies.

#### DATA ANALYSES

Wilcoxon rank sum tests were performed on the mean total, telogen, anagen, and broken hair loss rates at the baseline and treatment periods, and on the differences in total, telogen, anagen, and broken hair loss rates from the baseline to the treatment periods on a daily basis and on shampoo and non-shampoo days. In addition, regression analyses were performed on the differences in the mean total, telogen, anagen, and broken hair loss rates on shampoo versus non-shampoo days. The subjects' perceptions of hair and scalp health were assessed using Wilcoxon rank sum tests on the differences in ratings given by the subjects on the hair and scalp attributes during the baseline and treatment periods. Wilcoxon rank sum tests were performed on the mean number of uses of test product and product consumption. Comparisons with  $p$  values of  $\leq 0.05$  were considered statistically significant. Frequency analyses were performed on the subjects' perceptions of possible causes of hair fall, hair thinning, and hair loss tendencies.

#### RESULTS

Of the 460 subjects screened for potential participation in the study, 440 subjects were

accepted to participate and 404 subjects completed the study. Of the 36 subjects who did not complete the study, 29 subjects (6.6%) discontinued participation in the study prior to termination on their own initiative. The hair loss data from another six subjects (1.4%) were eliminated because of missing hair collections at the baseline and/or the treatment phases of the study.

In this study, three subjects reported that they experienced adverse reactions during the product use phase of the study. These subjects were examined by the investigators, and their reactions were deemed to be unassociated with treatment. One subject claimed that she had hair loss. She was examined and no evidence of abnormal shedding was found. This subject continued to participate in the study uneventfully until termination. However, the hair loss information was not included in the data analyses because the subject switched from using the treatment shampoo to her own shampoo temporarily after she thought she experienced hair loss. A second subject discontinued participation after reporting that she developed a rash while using the product. Examination showed her scalp to be normal, and no rash was present. A third subject discontinued participation after reporting that she had an itchy and sore scalp. She was found to have dandruff. Each of the three subjects was on a different shampoo treatment.

Statistical analyses conducted on the mean total, telogen, anagen, and broken daily hair loss rates at baseline and treatment, and differences in the total, telogen, anagen, and broken daily hair loss rates from baseline to treatment periods indicate no significant differences in the mean daily hair loss rates between the three shampoos tested in this study (Table I). The mean total hairs lost ranged from 28 to 35 hairs per day. These daily hair loss rates are consistent with reported findings in the normal population (2–3,8).

No significant differences were noted in the mean daily hair loss rates during the baseline and treatment periods between the three treatment groups (Figures 1, 2, 3, 4).

Statistical analyses conducted on the mean total, telogen, anagen, and broken daily hair loss rates on shampoo versus non-shampoo days indicate no significant differences in the hair loss rates between the three shampoos (Table II). However, as expected, significantly more total, telogen, and broken hairs were lost during the shampoo days as a result of the hair grooming process (Table II).

Assessment of abnormal hair loss pre- to posttreatment using the pull test (3) indicate that there was no abnormal hair loss at pretreatment. Overall, less than one hair was obtained per subject in each trial of the pull test (3). There were no differences between the number of hairs lost from the pull test during the baseline or posttreatment examination periods.

Evaluations of the short hairs at the hair parts confirmed that subjects had tapered rather than blunt distal hair tips pre- and posttreatment, indicating normal hair regrowth rather than broken hairs. No abnormal hair loss was evident in these subjects at baseline and posttreatment. The subjects' medical and dermatologic history profiles were unremarkable.

Scalp examinations performed during the baseline and posttreatment periods showed no significant differences in scalp flaking. No scalp erythema was observed in the pre- or posttreatment examinations.

**Table I**  
Mean Daily Total, Telogen, Anagen, and Broken Hair Loss Rates During Baseline and Treatment Periods

Treatment	No. of subjects	Mean hair loss/day (baseline period)		Mean hair loss/day (treatment period)		Difference in hair loss/day (treatment to baseline period)	
		Mean	Standard error of means	Mean	Standard error of means	Mean	Standard error of means
<b>I. Total hair loss</b>							
Shampoo I*	129	35.43	1.97	29.35	1.57	-6.09	1.12
Shampoo II**	138	29.93	1.86	27.60	1.77	-2.33	0.98
Shampoo III***	137	31.62	1.96	27.77	1.65	-3.85	1.21
<b>II. Telogen hair loss</b>							
Shampoo I*	129	30.27	1.74	25.55	1.39	-4.72	0.99
Shampoo II**	138	24.90	1.64	23.35	1.54	-1.56	0.81
Shampoo III***	137	27.07	1.76	24.14	1.44	-2.93	1.18
<b>III. Anagen hair loss</b>							
Shampoo I*	129	0.06	0.02	0.02	0.01	-0.04	0.02
Shampoo II**	138	0.06	0.02	0.09	0.07	+0.03	0.07
Shampoo III***	137	0.05	0.02	0.01	0.002	-0.05	0.02
<b>IV. Broken hair loss</b>							
Shampoo I*	129	5.10	0.60	3.77	0.44	-1.32	0.35
Shampoo II**	138	4.96	0.53	4.16	0.58	-0.80	0.49
Shampoo III***	137	4.60	0.50	3.62	0.42	-0.88	0.34

\* Shampoo I is a dimethicone-containing 2-in-1 shampoo. \*\*Shampoo II is a non-dimethicone-containing shampoo. \*\*\*Shampoo III is a dimethicone-containing shampoo.

Information obtained on shampoo frequencies and product consumption from the hair collection envelopes and product use diaries indicated no significant differences in the mean number of uses of test product over the four-week treatment period for the three treatment groups (Table III). However, significantly less dimethicone-containing 2-in-1 shampoo was consumed during the study in comparison to the non-dimethicone-containing shampoo and the dimethicone-containing shampoo (Table III). Since the test products were distributed in identical packages to maintain product blindness, product characteristics, particularly product thickness, may have accounted for the decreased consumption of dimethicone-containing 2-in-1 shampoo versus the other shampoos. The dimethicone-containing 2-in-1 shampoo is a more viscous product, and this may have provided better control in dispensing.

Consistent with the clinical findings of the absence of effects of shampoos on daily hair loss rates, no significant differences were noted in the subjects' perceptions of the severity of hair fall from the baseline and posttreatment periods with the three different shampoos. However, subjects using the dimethicone-containing 2-in-1 shampoo perceived that they had significantly healthier hair than subjects using the second dimethicone-containing shampoo, and that they had more controlled and less flyaway hair than subjects using the non-dimethicone-containing shampoo (Table IV).

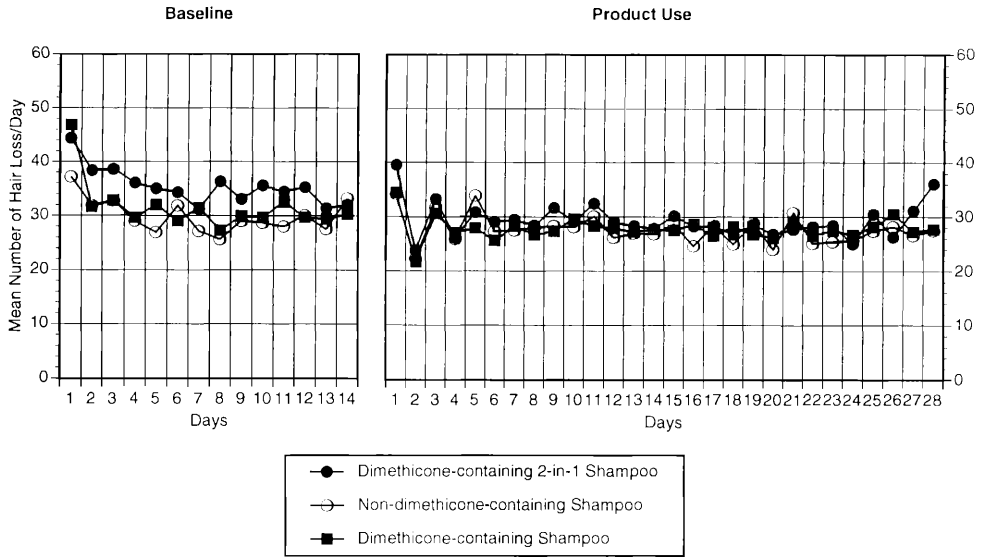


Figure 1. Mean daily total hair loss during baseline and product use periods.

Perceptual research aimed at understanding why consumers relate hair fall to the use of shampoos indicates that while subjects perceived hair fall as a natural process in hair regrowth (37.1%) and therefore unrelated to hair fall in hair thinning or balding, they associated any increased hair loss during grooming to the use of unsuitable shampoos (39.1%) more so than to the grooming process of combing/brushing itself (27.7%) or to chemical modification, such as perming (14.6%). Other factors known to contribute to abnormal hair loss, such as childbirth (5.7%), medication (4.2%), nutritional defi-

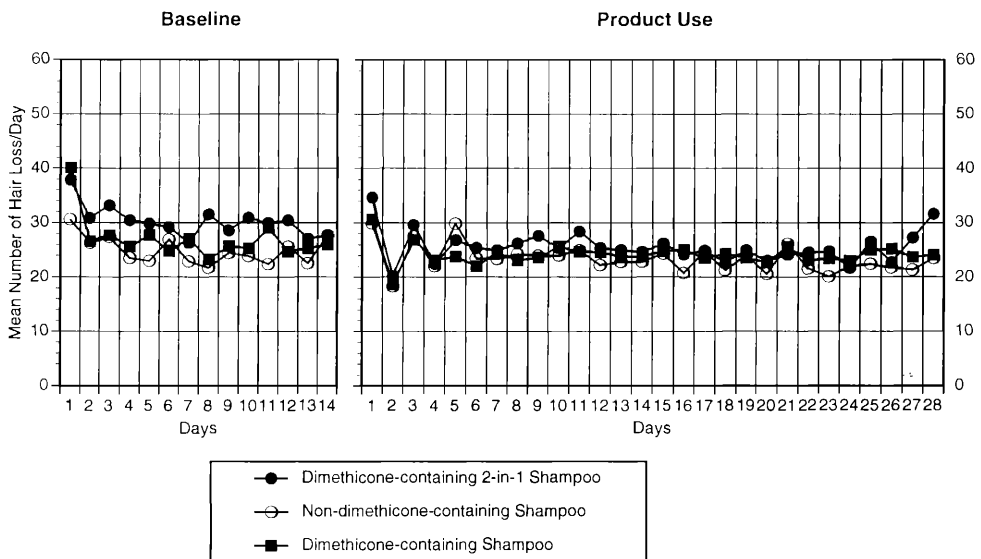


Figure 2. Mean daily telogen hair loss during baseline and product use periods.

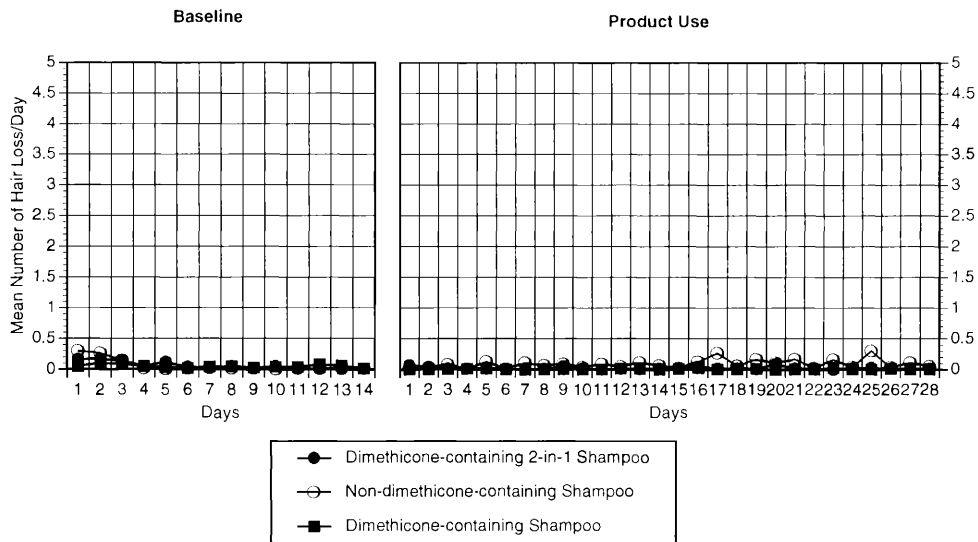


Figure 3. Mean daily anagen hair loss during baseline and product use periods.

ciency (1.2%), hereditary predilection (1.7%), and acute or chronic illness (2.7%) were not perceived as likely causes of hair fall.

### DISCUSSION

The results of this clinical study support a prior premise that dimethicone and non-dimethicone-containing shampoos do not affect daily hair loss rates. In this study, we observed mean hair loss rates ranging from 28 to 35 hairs per day. While published estimates of daily hair loss rates range from 38.4 to 180 hairs (2–7), this study provides

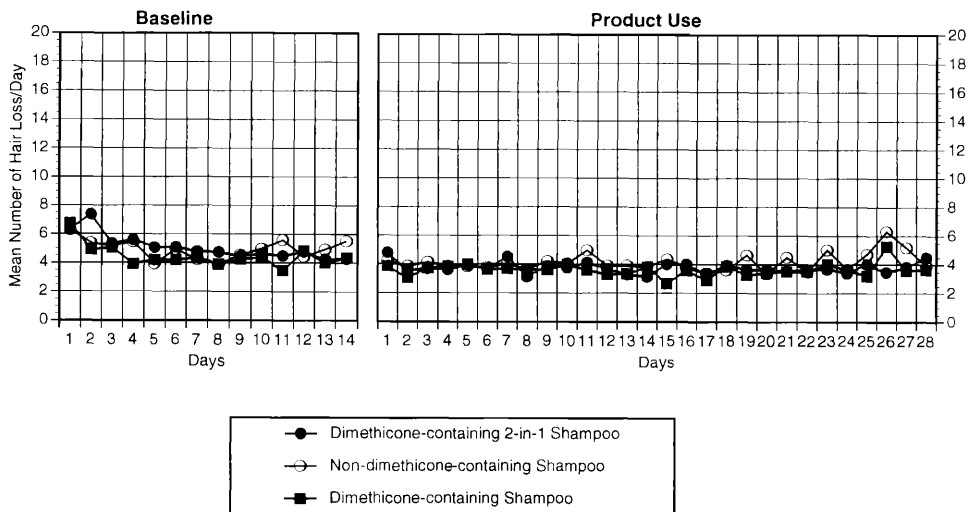


Figure 4. Mean daily broken hair loss during baseline and product use periods.



**Table II**  
Mean Daily Hair Loss Rates on Shampoo and Non-Shampoo Days

	No. of subjects	Mean hair loss/day (baseline period)			Mean hair loss/day (treatment period)				
		Shampoo days (A)†	Standard error	Non-shampoo days (B)†	Standard error	Shampoo days (C)†	Standard error	Non-shampoo days (D)†	
<b>I. Total hair loss</b>									
Shampoo I*	129	46.07B	2.88	26.94	1.67	35.30D	2.15	22.85	1.55
Shampoo II**	138	38.79B	2.91	23.72	1.67	33.14D	2.18	22.89	1.57
Shampoo III***	137	39.96B	2.87	25.85	1.66	33.66D	2.15	22.64	1.54
<b>II. Telogen hair loss</b>									
Shampoo I*	129	39.92B	2.63	22.45	1.43	31.97D	1.94	19.43	1.29
Shampoo II**	138	32.80B	2.66	19.26	1.45	28.18D	1.97	18.84	1.31
Shampoo III***	137	34.50B	2.61	21.87	1.42	29.73D	1.93	19.22	1.29
<b>III. Anagen hair loss</b>									
Shampoo I*	129	0.06B	0.02	0.06	0.03	0.02	0.07	0.03	0.02
Shampoo II**	138	0.05B	0.02	0.07	0.03	0.15D	0.07	0.06	0.02
Shampoo III***	137	0.06B	0.02	0.04	0.03	0.01	0.07	0.00	0.02
<b>IV. Broken hair loss</b>									
Shampoo I*	129	6.07B	0.67	4.44	0.54	4.31D	0.56	3.39	0.52
Shampoo II**	138	5.93B	0.68	4.39	0.54	4.81D	0.57	3.99	0.52
Shampoo III***	137	5.39B	0.67	3.94	0.54	3.93D	0.56	3.40	0.51

\* Shampoo I is a dimethicone-containing 2-in-1 shampoo. \*\*Shampoo II is a non-dimethicone-containing shampoo. \*\*\*Shampoo III is a dimethicone-containing shampoo.

† Significantly different from the designated group at  $p \leq 0.05$ .

A = baseline hair loss rate on shampoo days.

B = baseline hair loss rate on non-shampoo days.

C = treatment period hair loss rate on shampoo days.

D = treatment period hair loss rate on non-shampoo days.

**Table III**  
Mean Product Use Frequency and Consumption

	Dimethicone- containing 2-in-1 shampoo (129) A†	Non-dimethicone- containing shampoo 138 B†	Dimethicone- containing shampoo (137) C†
Mean number of uses of product over the study during treatment period	15.5	16.1	16.0
Mean frequency of product use per week	3.9	4.0	4.0
Mean total product consumption in gm	212.7	259.9 A	266.8 A
Mean consumption express as gm/use	14.8	17.6 A	18.6 A

† A denotes that significantly less dimethicone 2-in-1 shampoo is consumed ( $p \leq 0.05$ ) in comparison to the other two shampoos.

**Table IV**  
Differences in Hair and Scalp Perception Baseline to Posttreatment Periods

Attribute rated**	Shampoo I (A)*	Shampoo II (B)*	Shampoo III (C)*
<b>A. Hair effects</b>			
Hair health (healthy/not healthy)	0.55 C	0.43	-0.01
Fluffiness of hair (not fluffy/flyaway)	0.35 B	-0.16	-0.04
Damage (not damaged/damaged)	0.25	0.40	0.43
Manageability (not manageable/manageable)	0.08	-0.06	-0.10
Thickness of hair (thin/thick)	0.12	0.26	0.44
Texture of hair (fine/coarse)	0.20	0.14	0.12
Body of hair (no weight/lots of weight)	-0.45	-0.36	-0.38
Dryness/oiliness (dry/oily)	-0.28	-0.26	-0.20
<b>B. Scalp effects</b>			
Scalp health	0.3	0.3	0.2
Hair fall	0.2	0.3	0.06
Dandruff	0.7	0.9 C	0.4
Scalp itch	0.7	0.8	0.6
Scalp dryness	0.2	0.7 C	0.04
Scalp irritation	0.1	0.1	-0.1

\* The notations A, B, C denote that the following treatments, when compared to other treatment regimens, are significantly different at  $p \leq 0.05$ .

A = Dimethicone-containing 2-in-1 shampoo.

B = Non-dimethicone-containing shampoo.

C = Dimethicone-containing shampoo.

\*\* Rating based on a 0-to-7-point scale used both at the baseline and posttreatment evaluations.

Moderately  
healthy

Healthy	1	2	3	4	5	6	7	Not healthy
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A positive difference in score from baseline to posttreatment indicates that the product is rated better at posttreatment as compared to pretreatment.

data on the actual mean daily hair loss rates in a large population of 404 healthy Thai females over a period of six weeks and is consistent with reported findings in the normal population (2–3,8). As expected, significant differences were noted in the hair loss rates from grooming on shampoo versus non-shampoo days. No abnormal hair loss was evident pre- to posttreatment. Scalp examinations conducted to assess the degree of flaking, erythema, and scalp disease pre- to posttreatment indicated no shampoo-related effects.

The subjects in the study answered questionnaires relating to their perception of hair fall and hair health. No differences were noted in the hair fall perceptions of the subjects using the three different shampoos.

In this study, we determined why consumers associate hair loss with the use of shampoos. While subjects on study perceived hair fall as a natural process in hair regrowth (37.1%) and unrelated to hair thinning or balding, they associated any increased hair loss during the hair grooming process to the use of unsuitable shampoo (39.1%), more so than to the grooming process of combing/brushing (27.7%) or to chemical modification (14.6%). Other factors known to contribute to abnormal hair loss such as childbirth (5.7%), medication (4.2%), nutritional deficiency (1.2%), hereditary predilection (1.7%), and acute or chronic illnesses (2.7%) were not perceived by the subjects as likely causes of their hair fall.

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