

Efficacy of baby shampoo and commercial eyelid cleanser in patients with meibomian gland dysfunction

A randomized controlled trial

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Abstract

Background: To compare the efficacy between Johnson's baby shampoo top-to-toe (No More Tears formula) and OCuSOFT Lid Scrub Original Foaming Eyelid Cleanser (OSO) in patients with grade 2 meibomian gland dysfunction (MGD).

Methods: Sixty participants with grade 2 MGD were enrolled and analyzed based on intention to treat basis in a prospective, randomized, single-blind trial for eye scrub using either diluted baby shampoo or OSO. The data collection included the Ocular Surface Disease Index (OSDI) questionnaire, compliance, and complications. The eye examinations were according to the Tear Film and Ocular Surface Society at baseline and at post-treatment weeks 4 and 12.

Results: The mean (\pm SD) age of the 60 patients who presented with grade 2 MGD was 48.0 ± 13.8 years and 75.0% were females. The OSDI scores of these participants between pre-treatment and post-treatment weeks 4 and 12 improved significantly in both groups (all $P < .001$). The mean (\pm SD) differences of the improvement of OSDI score from baseline were not statistically significantly different between the baby shampoo and OSO groups at post-treatment weeks 4 and 12 ($P = .57$ and $P = .54$, respectively). The compliance and complications were also not statistically significant between the 2 groups.

Conclusions: Eyelid scrub using either baby shampoo or OSO and warm compresses could significantly reduce eye irritability and uncomfortable symptoms in grade 2 MGD patients. In this study, the efficacy, compliance, and complications between the 2 groups were not statistically significantly different.

Abbreviations: MGD = meibomian gland dysfunction, OSDI = Ocular Surface Disease Index, OSO = OCuSOFT Lid Scrub Original Foaming Eyelid Cleanser.

Keywords: baby shampoo, dry eye, meibomian gland dysfunction, OCuSOFT lid scrub original

1. Introduction

Meibomian glands are a special kind of sebaceous gland located in the tarsal plate of the upper and lower eyelids. Lipids are produced by the meibomian glands, which are the main components of the superficial lipid layer of the tear film that protects against evaporation of the aqueous phase and stabilizes the tear film. Hence, meibomian lipids are essential for the

maintenance of ocular surface health and integrity.^[1] Meibomian gland dysfunction (MGD) is an extremely important condition and is one of the most common causes of dry eye.^[2-4] Previous studies reported that the prevalence of MGD among Caucasians varied from 3.5% to 19.9%.^[5,6] In the Asian population, the prevalence of MGD was higher and varied between 46.2% and 69.3%.^[7-10] A Bangkok population-based study reported that

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Ethics approval was provided by the Ethics Committee, Faculty of Medicine, Prince of Songkla University (The Thai Clinical Trials Registry Number was TCTR20160726001).

Informed consent was obtained from all individual participants included in the study.

The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are publicly available.

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46.2% of Thais had MGD and 63.6% of people with dry eye had MGD.^[17]

According to the Tear Film and Ocular Surface Society (TFOS) grading system, the treatment guideline depends on the severity of the MGD. These guidelines consider symptoms and clinical signs of gland expression, meibum quality, ocular surface staining, and lid margin. The management of MGD according to the International Workshop on MGD reached a consensus that eyelid hygiene is the mainstay of clinical treatment of MGD, which consists of 2 components: warm compresses and lid hygiene, including scrubs and mechanical expression.^[11] A published study showed that the use of hypoallergenic bar soap, diluted baby shampoo, and commercial eyelid cleanser were useful in the treatment of MGD.^[12] However, the efficacy of baby shampoo in the management of MGD is controversial. The current literature shows a lack of standard treatment of lid hygiene and no data are available on patient compliance with MGD. The efficacy of hypoallergenic bar soap was not investigated in our study because it is available only at drug stores, additionally; it is not a commercial product for eyelid scrub. Although, baby shampoo is not a special substance for eyelid scrub, it is widely available. The efficacy of baby shampoo is possibly equivalent to OCuSOFT Lid Scrub Original Foaming Eyelid Cleanser (OSO) in grade 2 MGD treatment.

The principal objective of the investigation was to assess and compare the effects of eyelid cleaning using either a dedicated eyelid cleanser (OSO, Rosenberg, TX) or Johnson's baby shampoo top-to-toe (No More Tears formula, Johnson & Johnson, Thailand)^[13] to decrease the symptomatology of dry eye sufferers with grade 2 MGD (Table 1).

2. Methods

2.1. Study design

This prospective study was conducted at Songklanagarind Hospital, Prince of Songkla University, Thailand. The study adhered to the tenets of the Declaration of Helsinki and was approved by the Human Research Ethics Committee of the Faculty of Medicine, Prince of Songkla University. The Thai Clinical Trials Registry Number was TCTR20160726001.

Table 1

Ingredients of Johnson's baby shampoo top-to-toe (No More Tears™ formula) and a commercial eyelid cleanser, OCuSOFT lid scrub original foaming eyelid cleanser (OSO).

Baby shampoo	OSO
Water	Water
PEG-80 sorbitan laurate	PEG-80 sorbitan laurate
Ethylhexylglycerin	Sodium trideceth sulfate
Sodium methyl cocoyl taurate	Polyaminopropyl biguanide
Sodium benzoate	PEG-150 distearate
Decyl glucoside	Sodium lauroamphoacetate
Phenoxyethanol	Sodium laureth-13 carboxylate
PEG-150 pentaerythrityl tetrastearate	Odium chloride
PPG-2 hydroxyethyl cocamide	1,2 hexanediol
Glycerin	Caprylyl Glyco
Cocamidopropyl betaine	Cocamidopropyl betaine
Citric acid	Potassium sorbate
Fragrance	PEG-15 cocopolyamine

OSO = OCuSOFT Lid Scrub Original Foaming Eyelid Cleanser; PEG = polyethylene glycol.

Informed consent was obtained from the subjects after explanation of the nature and possible consequences of the study.

2.2. Subject eligibility

The study enrolled participants from 25 to 70 years of age from the out-patient eye clinic in Songklanagarind Hospital from July 2016 to September 2017. All participants were diagnosed with grade 2 MGD according to the TFOS guideline because we could eliminate the confounding factors (e.g., oral tetracycline derivative and anti-inflammatory therapy) affecting the MGD treatment outcome. The participants were able to follow a scheduled visit and use a microwave at home. Informed consent was taken from all participants before participation. The subjects were excluded if any of the following presented in the study: cicatricial eyelid diseases or conjunctival diseases that affect ocular signs and symptoms (for example, pterygium), recent ocular trauma, any corneal lesions or other meibomian gland diseases (for example, meibomian seborrhea or meibomian sicca), following eye or periocular surgery, current use of facial topical antibiotics, history of allergy to cosmetics, any composition of cosmetics or history of allergy to baby shampoo, or any composition of shampoo.

2.3. Study protocol

After classification into the level of severity, all 60 participants with grade 2 MGD were randomized for eyelid scrub using baby shampoo or OSO by block-of-four computer randomizations. The allocation ratio was 1:1, and the randomization was performed per subject and the sequence of randomization was concealed from all investigators by sealed envelopes. The participants in the baby shampoo group were instructed to use a 1:1 mixture of baby shampoo^[12] and clean water to scrub into the eyelid for 30 to 60 seconds and then rinse. The participants in the OSO group were instructed to use OCuSOFT lid scrub original foaming eyelid cleanser to scrub the eyelid for 30 to 60 seconds and then rinse. Product applications were demonstrated by the same investigator at the enrollment visit. All participants in both groups received written instructions and also a heated rice bag delivered 40 to 42°C heat to the eyelids for 5 minutes before performing the eyelid scrub (application 2 times/day).

2.4. Outcome measures and follow-up evaluations

The primary outcome measure was to compare the mean (\pm SD) differences of the improvement of Ocular Surface Disease Index (OSDI) score from baseline to weeks 4 and weeks 12 post-treatment, between baby shampoo and OSO. The secondary outcome measures were lid margin signs according to the TFOS guideline, times of compliance, and the percentage of complications.

At the initial visit, history and demographic information of all participants were collected that included age, sex, underlying disease, medication profile, history of drug, or any cosmetic ingredient allergy. The participants were evaluated by best-corrected visual acuity (BCVA) measured by the early treatment diabetic retinopathy study chart and later converted to LogMAR (logarithm of the minimum angle of resolution), OSDI questionnaire developed by the Outcomes Research Group at Allergan (Irvine, CA), and MGD grading under slit lamp biomicroscopy. Other evaluations were meibum quality, expressibility of the glands, corneal staining with fluorescein, and lid

margin according to the TFOS guideline at enrollment. One investigator (OA), who was masked to the treatment and randomization, performed the follow-up at 4 and 12 weeks after starting the treatment. Compliance was measured at 4 and 12 weeks by filling out a self-reported form. The participants were instructed to sign the form every day in the morning and evening (2 times/day) and return the form to the investigator at the follow-up visit.

2.5. Sample size

Based on a previous study,^[14] as an 80% power was used to show non-inferiority ($\delta=11$) of baby shampoo against OSO as significant (for the 2-sided 5% level) given an SD of 16 and no difference expected in mean scores of the 2 treatments at 2 times, a sample size of 27 patients per group was required. Allowing for unexpected 10% dropout rate, we enrolled 30 patients per group in this study.

2.6. Statistical analysis

Data were analyzed using Stata Statistic Software (STATA MP 14.1. StataCorp LP). Data analysis was based on intention to treat basis. Descriptive statistics using mean and standard deviation were reported at each visit. The repeated measures of OSDI scores were evaluated. For the primary outcome, the total scores of the OSDI questionnaire were compared between the 2 groups using the independent samples test. The mean OSDI score in baby shampoo and OSO by week was evaluated using mixed model linear regression. The times of compliance were compared between the 2 groups using the independent samples test. The differences between the 2 treatments in lid margin signs according to the TFOS guideline were compared using the Pearson chi-square test. A P value $<.025$ was considered statistically significant.

3. Results

3.1. Study selection

A total of 60 participants diagnosed with grade 2 MGD were enrolled and completed the analysis. Sixty-five percent of the participants had a Bachelor's degree or higher and 75.0% were females. The mean (\pm SD) age was 48.0 ± 13.8 years (range 25–70 years). The participants were randomized into either the baby shampoo group (50%) or the OSO group (50%) (Table 2). Figure 1 illustrates the flow of participants through the study according to the Consolidated Standards of Reporting Trials (CONSORT) requirements.

3.2. OSDI and treatment outcome in 2 groups

The OSDI scores in the baby shampoo group and OSO group prior to treatment were 42.6 ± 16.1 and 42.1 ± 14.0 , respectively. The OSDI scores, BCVA, and compliance of all participants were recorded. Three participants per group were lost to follow-up, prior to week 4, post-treatment follow-up. According to the TFOS international workshop on MGD, 54 participants were examined under slit lamp biomicroscopy and the parameters at weeks 4 and weeks 12 post-treatment are presented in Table 3.

There was a significant improvement in the OSDI score at post-treatment week 4 (20.3 ± 10.3 [95% confidence interval 16.1,

Table 2

Baseline clinical characteristics of 60 participants.

Variables	Baby shampoo (n = 30)	OSO (n = 30)
Age, mean (\pm SD)	49.8 \pm 12.4	46.2 \pm 15.1
Gender		
Male	4 (13.3%)	11 (36.7%)
Female	26 (86.7%)	19 (63.3%)
OSDI score, mean (\pm SD)*	42.6 \pm 16.1	42.1 \pm 14.0
LogMAR VA, mean (\pm SD)	0.1 \pm 0.1	0.1 \pm 0.1
Compliance (times)	–	–
<i>Lid margin signs according to TFOS guideline</i>		
Lid margin, n (%)		
Normal	0	0
Scattered	30 (100.0%)	30 (100.0%)
Plugging	0	0
Drop out	0	0
Meibum quality, n (%)		
$\geq 2-4$	0	0
4-7	30 (100.0%)	30 (100.0%)
8-12	0	0
≥ 13	0	0
Expressibility, n (%)		
5 glands	1 (3.3%)	1 (3.3%)
3-4 glands	29 (96.7%)	29 (96.7%)
1-2 glands	0	0
No gland	0	0
Ocular staining, n (%)		
No staining	0	1 (3.3%)
None to limited	30 (100.0%)	29 (96.7%)
Mild to moderate	0	0
Increased staining	0	0

OSDI = Ocular Surface Disease Index; OSO = OCuSOFT Lid Scrub Original Foaming Eyelid Cleanser.
* P value = .89.

24.5] in baby shampoo and 17.9 ± 9.8 [95% confidence interval 13.7, 22.1] in OSO) compared with baseline (both $P < .001$). This improvement was significant at post-treatment week 12 in both the baby shampoo and OSO groups (12.0 ± 6.6 [95% confidence interval 7.8, 16.2] and 9.5 ± 4.7 [95% confidence interval 5.3, 13.7], respectively, both $P < .001$) (Fig. 2). However, no difference was found between the 2 groups at either post-treatment week 4 ($P = .57$) or post-treatment week 12 ($P = .54$) using mixed model linear regression. The mean (\pm SD) compliance results of eyelid scrub for the total of 12 weeks were 125.1 ± 20.8 and 124.6 ± 16.8 times (from a total of 168 times at 2 times/day in 84 days) in the baby shampoo and OSO groups, respectively ($P = .93$). The baseline OSDI scores were not correlated with compliance at week 4 in the baby shampoo and OSO groups ($P = .68$ and $P = .29$, respectively).

3.3. Complications

Complications in both treatments are shown in Table 4. There were no differences at 4 and 12 weeks between the 2 groups in complications that included eye irritation, burning sensation, tearing, photophobia, blurred vision, red eye, and skin or eyelid erythema (all $P \geq .05$).

4. Discussion

Dry eye is a multifactorial disease of tears and the ocular surface which is associated with MGD that results in symptoms of discomfort, visual disturbance, and an unstable tear film with

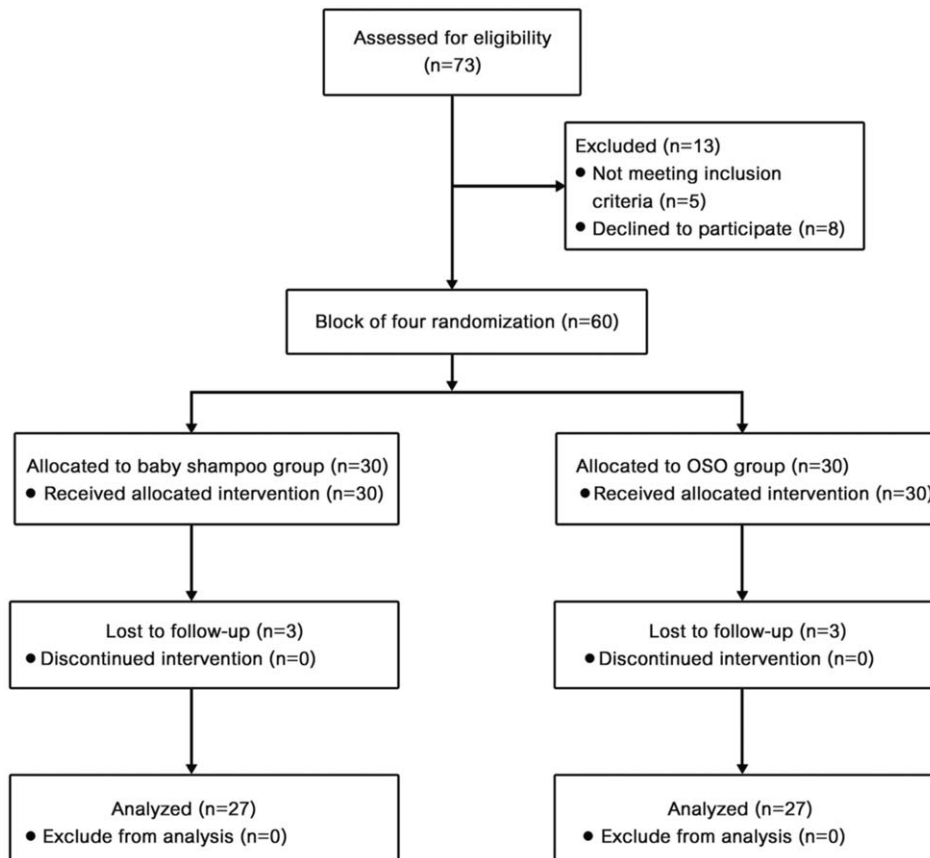


Figure 1. Flow diagram according to the Consolidated Standards of Reporting Trials (CONSORT) statement, showing recruitment, randomization, and patient flow in this study. OSO, OCuSOFT Lid Scrub Original Foaming Eyelid Cleanser.

Table 3

OSDI score, visual acuity, and parameters according to the TFOS guideline at 4wk, and at 12wk post-treatment.

Variables	Week 4		Week 12	
	Baby shampoo (n=27)	OSO (n=27)	Baby shampoo (n=27)	OSO (n=27)
OSDI score, mean (\pm SD) ^{*†}	20.3 \pm 10.3	17.9 \pm 9.8	12.0 \pm 6.6	9.5 \pm 4.7
LogMAR VA, mean (\pm SD)	0.1 \pm 0.1	0.1 \pm 0.1	0.1 \pm 0.7	0.1 \pm 0.1
Compliance (times)	41.0 \pm 8.9	40.7 \pm 8.0	84.2 \pm 15.8	83.9 \pm 13.7
<i>Lid margin signs according to TFOS guideline</i>				
Lid margin, n (%)				
Normal	0	0	0	0
Scattered	27 (100.0%)	27 (100.0%)	27 (100.0%)	27 (100.0%)
Plugging	0	0	0	0
Drop out	0	0	0	0
Meibum quality, n (%)				
\geq 2–4	5 (18.5%)	5 (18.5%)	6 (22.2%)	10 (37.0%)
4–7	22 (81.5%)	22 (81.5%)	21 (77.8%)	17 (63.0%)
8–12	0	0	0	0
\geq 13	0	0	0	0
Expressibility, n (%)				
5 glands	6 (22.2%)	4 (14.8%)	8 (29.6%)	8 (29.6%)
3–4 glands	21 (77.8%)	23 (85.2%)	19 (70.4%)	19 (70.4%)
1–2 glands	0	0	0	0
No gland	0	0	0	0
Ocular staining, n (%)				
No staining	6 (22.2%)	11 (40.7%)	14 (51.9%)	18 (66.7%)
None to limited	21 (77.8%)	16 (59.3%)	13 (48.1%)	9 (33.3%)
Mild to moderate	0	0	0	0
Increased staining	0	0	0	0

OSDI = Ocular Surface Disease Index; OSO = OCuSOFT Lid Scrub Original Foaming Eyelid Cleanser.

^{*} P value at 4 wk = .39.

[†] P value at 12 wk = .12.

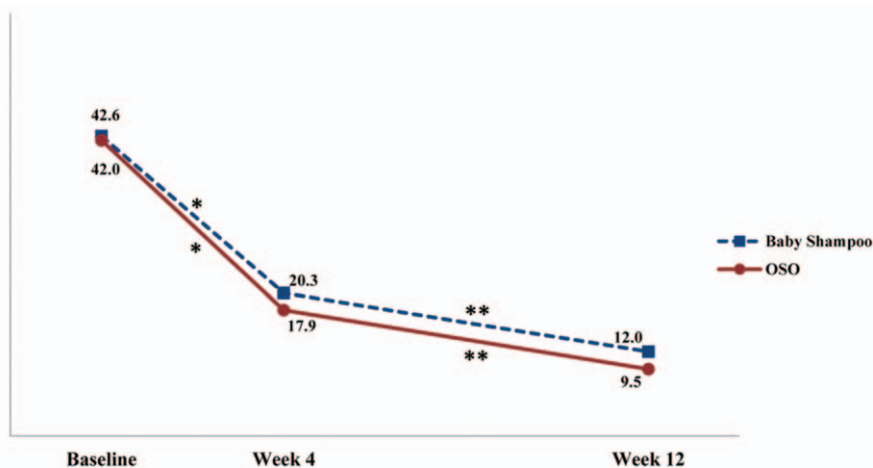


Figure 2. . Mean differences of OSDI scores at baseline, 4wk, and 12wk. * $P < .001$, decrease in the OSDI scores from baseline to 4-wk post-treatment. ** $P < .001$, decrease in the OSDI scores from 4-wk to 12-wk post-treatment. OSO, OCuSOFT Lid Scrub Original Foaming Eyelid Cleanser.

potential damage to the ocular surface, which affects quality of life.^[15–17] It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.^[18] Eyelid hygiene and warm compresses are the mainstay treatments for MGD; however, clinicians use a wide range of treatment regimens to manage MGD.^[19,20]

In this randomized trial, significant improvement was observed in the OSDI scores after using either the baby shampoo or the OSO in grade 2 MGD patients at weeks 4 and weeks 12 post-treatment. Although this current study showed an improvement in the number of secondary outcomes including meibum quality,

expressibility, and ocular staining in both groups, there were no statistically significant differences between the 2 groups. To our knowledge, eyelid scrub should statistically significantly improve the symptom scores; however, no significant improvement in the lid margin signs was observed in either treatment because only grade 2 MGD was selected. It was reported that in moderate to advanced MGD patients who were treated with intense pulsed light had significant improvement of eyelid signs.^[21]

These findings are consistent with previous reports which described improvements in MGD or the signs and symptoms of blepharitis following eyelid hygiene regimens with dedicated

Table 4

Complications of both treatments.

Complications	Post-treatment at 4 wk			Post-treatment at 12 wk		
	Total (N=54)	Baby shampoo (n=27)	OSO (n=27)	Total (N=54)	Baby shampoo (n=27)	OSO (n=27)
Eye irritation						
None	29 (53.7)	14 (51.9)	15 (55.6)	45 (83.3)	23 (85.2)	22 (81.5)
Mild	24 (44.4)	13 (48.1)	11 (40.7)	9 (16.7)	4 (14.8)	5 (18.5)
Moderate	1 (1.9)	0 (0.0)	1 (3.7)			
Burning sensation						
None	30 (55.6)	13 (48.1)	17 (63.0)	33 (61.1)	17 (63.0)	16 (59.3)
Mild	22 (40.7)	13 (48.1)	9 (33.3)	21 (38.9)	10 (37.0)	11 (40.7)
Moderate	2 (3.7)	1 (3.7)	1 (3.7)			
Tearing						
None	48 (88.9)	24 (88.9)	24 (88.9)	51 (94.4)	26 (96.3)	25 (92.6)
Mild	6 (11.1)	3 (11.1)	3 (11.1)	3 (5.6)	1 (3.7)	2 (7.4)
Photophobia						
None	48 (88.9)	24 (88.9)	24 (88.9)	50 (92.6)	25 (92.6)	25 (92.6)
Mild	5 (9.3)	3 (11.1)	2 (7.4)	3 (5.6)	1 (3.7)	2 (7.4)
Moderate	1 (1.9)	0 (0.0)	1 (3.7)	1 (1.9)	1 (3.7)	0 (0.0)
Blurred vision						
None	51 (94.4)	25 (92.6)	26 (96.3)	52 (96.3)	26 (96.3)	26 (96.3)
Mild	3 (5.6)	2 (7.4)	1 (3.7)	2 (3.7)	1 (3.7)	1 (3.7)
Red eye						
None	51 (94.4)	25 (92.6)	26 (96.3)	54 (100.0)	27 (100.0)	27 (100.0)
Mild	3 (5.6)	2 (7.4)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)
Skin or eyelid erythema						
None	53 (98.1)	27 (100.0)	26 (96.3)	54 (100.0)	27 (100.0)	27 (100.0)
Mild	1 (1.9)	0 (0.0)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)

OSO=OCuSOFT Lid Scrub Original Foaming Eyelid Cleanser.

eyelid scrub and diluted baby shampoo.^[12,14,22–24] Patients who used a phospholipid–liposome solution specially designed for lid scrub demonstrated a significantly greater clinical improvement than those who used a mild baby shampoo.^[23] Sung et al demonstrated the objective and subjective clinical improvements in blepharitis patients following a 4-week treatment with both a dedicated eyelid cleanser (TheraTears Sterilid) and a diluted baby shampoo at a ratio of 1:10.^[25] The results revealed significant improvement in the Standardized Patient Evaluation of Eye Dryness questionnaire and Symptom Assessment in Dry Eye (SANDE) symptomology scores; however, the SANDE score in eyelid cleanser treatment had significantly greater improvement.^[25] In a previous study, the SANDE questionnaire had a significant correlation and negligible score differences in the OSDI scores.^[26] Interestingly, in this study the baby shampoo group had a non-inferior outcome compared with a previous report.^[25] First, the concentration of baby shampoo and water at a ratio of 1:1 was higher which was possibly more effective in eyelid scrub. Second, the formulation of baby shampoo in our study was without yellow 6 and yellow 10. Third, only participants who had grade 2 MGD without blepharitis were included, which is a low-grade severity of MGD. Sung et al also reported a significant reduction in matrix metalloproteinase 9 expression in the dedicated eyelid cleanser group, in addition to, decreased goblet cells and MUC5AC expression in the baby shampoo group which was possibly from the detergent effects.^[25]

In addition, the comparison between the 2 groups found no statistically significant differences in the improvements of the OSDI scores as well as the clinical signs that included lid margin, meibum quality, expressibility, and ocular staining. The participants in our study understood and followed our instructions to perform the eyelid scrub properly with overall good compliance in both treatment groups. However, the real situation in the outpatient clinic of a self-applied therapy is limited by patient compliance.

Encouraging long-term use of eyelid hygiene and warm compresses presents a challenge for the ophthalmologist. The introduction of eyelid scrubbing methods, such as OSO and diluted baby shampoo, may provide a more consistent solution for compliance. This study showed that the mean (\pm SD) compliances were 125.1 ± 20.8 and 124.6 ± 16.8 times in the baby shampoo and OSO groups, respectively, which had no statistically significant difference between the 2 groups ($P = .93$). Additionally, the effectiveness of any self-applied treatment depends on patient preference, efficacy awareness, convenience, ease of purchase, cost, and any adverse effects. All participants used the baby shampoo for eyelid scrub, which was conducted with unsterile tap water and lathered the foam formulation by on their own. The efficacy, compliance, and complications in the baby shampoo group were not significantly different from the OSO group.

The strong point of this current study is the unique participants who were grade 2 MGD and therefore the confounding factors affecting the MGD treatment outcome could be eliminated. The result revealed that the diluted baby shampoo is one of the options for treatment of eyelid scrub in grade 2 MGD patients. The baby shampoo is available in the convenience store and low price (1 \$/bottle). In contrast, OSO is limited to purchase in some rural area and high price (11–17 \$/bottle). The outcomes from our report can provide more information on eyelid cleaning methods in Thai patients and possibly for the worldwide

population to develop a standardized technique in eyelid cleaning for patients with MGD.

5. Limitations

Our study had some limitations as followings. First, we could not blind the participants because the packages of the 2 eyelid scrubbing methods were different. However, we could blind the investigator who evaluated the clinical parameters of the participants. Second, we did not measure the conjunctival cytology, which might need a further study to prove the results in patients with grade 2 MGD.

6. Conclusions

In summary, this study showed that either OSO or baby shampoo for eyelid scrub can improve the dry eye symptoms scores for patients with grade 2 MGD even though there was no statistically significant difference between the 2 groups. The compliance and complication results were also not statistically significantly difference between the 2 groups and no serious adverse events were reported.

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Author contributions

Study concept and design: OA and YU; Acquisition of data: OA, YU, PS, and OH; Analysis and interpretation of data: OA, YU, PS, and OH; Drafting the manuscript: OA and YU; Revising the manuscript critically for important intellectual content: OA, YU, PS, and OH; Study supervision: OA, PS, and OH. All authors had full access to all of the data in this study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors read and approved the final manuscript.

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