

A randomized, controlled, cross-over study of the safety and efficacy of super-absorbent diaper for babies with mild-to-moderate diaper rash

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ABSTRACT

BACKGROUND Super-absorbent diaper is a disposable diaper with new technology which has a soft-airy structure, breathable sheet, and rich absorbent core. This study aimed to compare the safety and efficacy of super-absorbent diaper with standard absorbent diaper.

METHODS A single-blinded, randomized, controlled, cross-over study was performed in 3–24 months babies. A safety study was performed in 113 babies without diaper rash (group A: super-absorbent to standard and B: standard to super-absorbent) and efficacy study in 59 babies with mild-to-moderate diaper rash (group C: super-absorbent to standard and D: standard to super-absorbent). Each group used super-absorbent or standard diaper for 2 weeks. Skin assessment scores (SAS) were recorded at baseline, week-2, and week-4. Non-parametric tests were used to analyze the data.

RESULTS In the safety study, there was no significant increase of SAS in group A at week-2 and -4, but in group B there was a significant increase of SAS (1.9 to 4.1, $p = 0.001$) at week-2 with a significant reduction at week-4 (4.1 to 2.2, $p < 0.001$). In the efficacy study, there was a reduction of SAS at week-2 in group C ($p = 0.07$) and D ($p = 0.05$). However, SAS increased in group C (6.4 to 8.3, $p = 0.2$) and decreased in group D (8.6 to 6.1, $p = 0.13$) at week-4. Super-absorbent diaper showed a significant reduction of SAS in the pubic areas (1.43 to 0.73, $p < 0.011$).

CONCLUSIONS The new super-absorbent diaper is safe to use and may have efficacy in the improvement of skin conditions and diaper rash, especially in the pubic areas.

KEYWORDS efficacy, safety, super-absorbent diaper

Diaper rash is one of the most common dermatologic conditions in babies.^{1–4} The etiology of diaper rash is multifactorial.^{1,5} Its initiating factors are prolonged contact with feces (proteolytic and lipolytic digestive enzymes) together with increased wetness of the skin by urine.² This leads to an increased frictional damage, decreased barrier functions, and increased reactivity to irritants. Other interrelated etiologic factors include an increased skin pH and superinfection with *Candida* and less commonly, with bacteria.^{1–5}

There has been a high reduction in the prevalence and severity of diaper rash during the last several decades. Specifically, the frequency of severe rash has decreased because of the technological advances in the Western cloth diapering practices such as the initial use of cellulose disposable diapers that was subsequently followed by the introduction of disposable diapers with super-absorbent cores and breathable covers.^{5–7}

Super-absorbent diaper was designed using a novel technology to provide a soft-fit structure; more

breathable structure at the waistband, pubic area and buttock; with slit and rich absorbent core in the front to provide increased dryness. This study was aimed to evaluate the safety and efficacy of the super-absorbent diaper with newly improved technological features compared with the standard diaper, for mild-to-moderate diaper rash.

METHODS

This study was single-blinded, randomized, controlled, and cross-over. The investigators were blinded for the type of diapers used by the subjects. The investigation group consisted of babies aged 3–24 months. The inclusion criteria were as follows: 3–24 months old babies using disposable diapers only, diaper rash score was 3–4 in any area (mild-to-moderate diaper rash) or 0–1 in each area (without diaper rash) according to skin assessment scores (SAS) in Table 1, and the willingness of the parent to provide written informed consent to participate in the study. The exclusion criteria included any kind of dermatoses, babies with atopic dermatitis, presence of systemic illness, and babies receiving treatment for

dermatoses. During the study, all babies were equally treated with the same baby soap for the diaper area and mothers were instructed to change the diaper at least every 6 hours.

The safety study included 113 healthy babies, who were divided into 2 groups (A and B). Group A used the super-absorbent diaper for 2 weeks, and then switched to the standard diaper for another 2 weeks. Group B used the standard diaper for 2 weeks and then switched to the super-absorbent diaper for another 2 weeks.

The efficacy study included 59 babies with mild-to-moderate diaper rash, who were also divided into 2 groups (C and D). Group C used the super-absorbent diaper in the first 2 weeks and then switched to the standard diaper for another 2 weeks. Group D used the standard diaper in the first 2 weeks and then switched to the super-absorbent diaper for another 2 weeks. The drop-out criteria was worsening of the diaper rash.

SAS were calculated in both healthy babies and babies with mild-to-moderate rash, which consisted of scoring for erythema, papules, erosion, and desquamation, done in 6 areas (waist front and

Table 1. Skin assessment scores (SAS)

Score	Erythema/edema	Papule/pustule	Immerse/erosion	Desquamation
0	Absent	Absent	Absent	Absent
1	Very slightly erythema, area <2%	Only one site	Slight immerse, area <2%	Slight desquamation, area <2%
2	Very slightly erythema, area (2–10%) or slight erythema, area <2%	Discrete papule, 2–5 sites	Slight immerse, area (2–10%)	Slight desquamation, area (2–10%)
3	Very slightly erythema, area >10% or slightly erythema, area (2–10%) or obvious erythema <2%	Discrete papule, area <10%	Slight to moderate immerse, area >10% or slight erosion, area <2%	Slight to moderate desquamation, area >10%
4	Slight erythema, area (10–50%) or obvious erythema, area <2% with edema	Moderate papule, area (10–50%) or pustule (0–5 sites)	Moderate immerse, area (10–50%) or slight erosion, area (2–10%)	Moderate desquamation, area (10–50%)
5	Obvious erythema, area >50% or obvious erythema, area (2–10%) with edema	Moderate to severe papule, area >50% or pustule (>5 sites)	Moderate to severe immerse, area >50% or moderate erosion, area >10%	Moderate to severe desquamation, area >50%
6	Obvious erythema, area >10% with edema	Large area confluent papule or large pustule/blister	Severe erosion, area >50% or ulcer, necrosis	Severe desquamation

Reproduced from: Yuan C, Takagi R, Yao XQ, Xu YF, Ishida K, Toyoshima H. Comparison of the effectiveness of new material diapers versus standard diapers for the prevention of diaper rash in Chinese babies: a double-blinded, randomized, controlled, cross-over study. *Biomed Res Int.* 2018;2018:5874184. Under the Creative Commons Attribution License (CC BY 4.0) <https://creativecommons.org/licenses/by/4.0/>

back, buttock, pubic region, anal region, and root of thigh) at baseline, week-2, and week-4 (Table 1). This assessment was performed by dermatologists. The same baby soap was used in all the babies and the mothers were instructed on when to change the diapers and clean with wet cotton balls. Other skincare products such as baby wipes or baby creams were not allowed during the study. The babies used at least 2 diapers within 24 hours.

Prior to the study, written informed consent from the parents or legal guardians of the participants were obtained and the study received ethics approval from the Health Research Ethics Committee, Faculty of Medicine Universitas Indonesia, Cipto Mangunkusumo Hospital (No: 411/H2.F1/ETIK/2014). The trial was conducted at PT Equilab International, Jakarta, Indonesia.

Descriptive statistics were done for tabulated raw data only (mean, minimum, maximum, and standard deviation). Wilcoxon signed-rank test and

Mann-Whitney U test were used to analyze the SAS data of within and between the treatment groups, respectively.

RESULTS

Figure 1 shows the flowchart of the study. A total of 195 babies were assessed and only 177 were eligible for the study, 117 of them were allocated for safety study and 60 babies were allocated for efficacy study.

Demographics

The demographic data of the subjects were similar in terms of age, sex, skin lesions, and total numbers of babies for the safety and efficacy studies (Table 2).

Safety study

A safety study was done on 113 healthy babies without any skin lesions on the diaper area or any

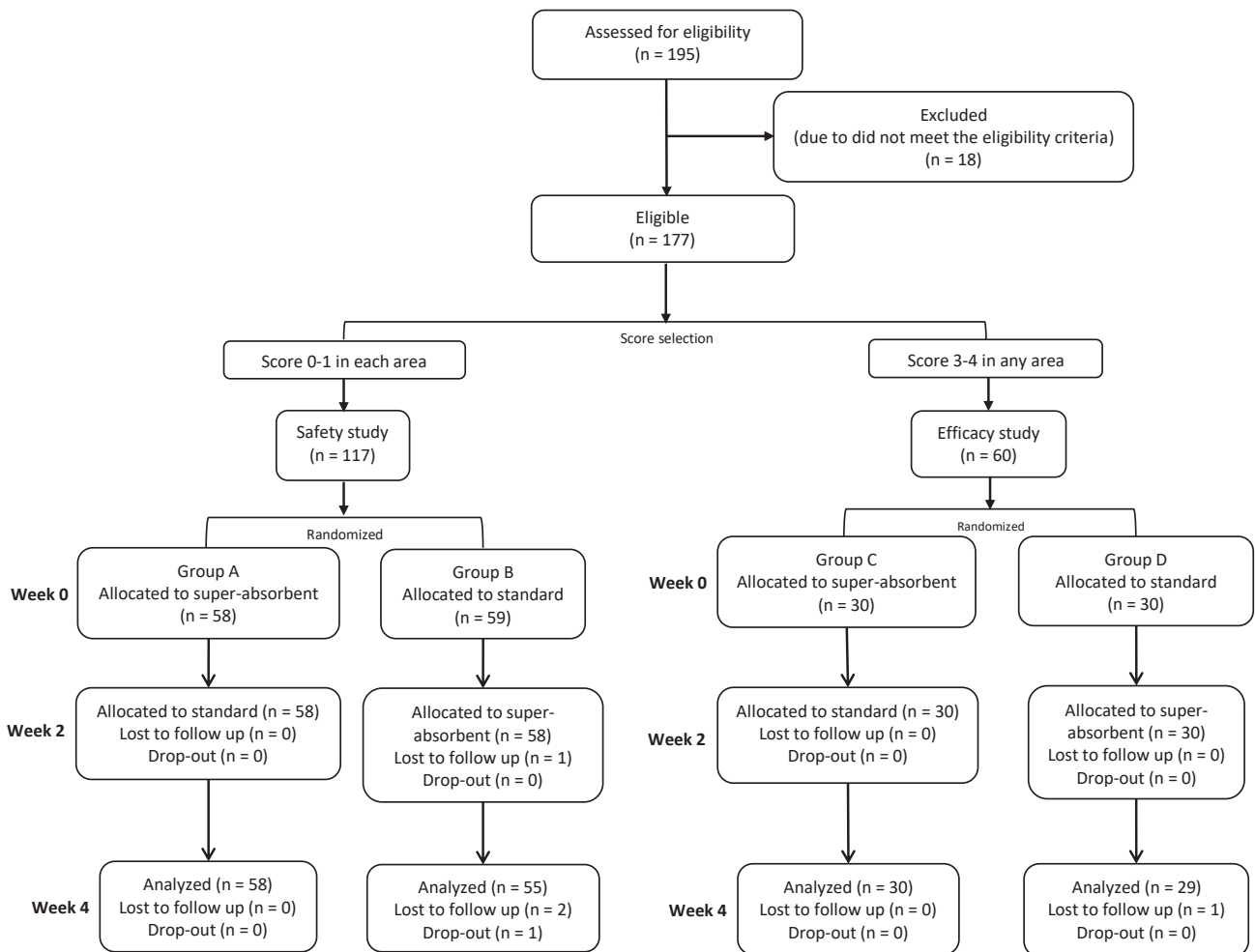


Figure 1. Study flowchart. Drop-out=worsening of the diaper rash or non compliance; lost to follow up=subjects did not come for the evaluation visit

Table 2. Demographic characteristics of the subjects

Variable	Group A, n (%) (N = 58)	Group B, n (%) (N = 55)	Group C, n (%) (N= 30)	Group D, n (%) (N= 29)
Male sex	30 (51.7)	30 (54.5)	17 (56.7)	15 (51.7)
Age (months)	3–24	3–24	3–24	4–24
Skin conditions	Healthy	Healthy	Mild–moderate diaper rash	Mild–moderate diaper rash
Skin assessment score				
Week-0	20 (34.5)	14 (25.5)	14 (46.7)	17 (58.6)
Week-2	24 (41.4)	16 (29.1)	20 (66.7)	16 (55.2)
Week-4	23 (39.7)	19 (34.5)	12 (40.0)	19 (65.2)

Group A=super-absorbent to standard; group B=standard to super-absorbent; group C=super-absorbent to standard; group D=standard to super-absorbent

Table 3. Total diaper changes and baby soap using per day of safety and efficacy study

		Safety study		Efficacy study	
		Group A (N = 58)	Group B (N = 55)	Group C (N = 30)	Group D (N = 29)
Diaper (pc/day)	Week-0 to week-2	4.7	4.7	5.1	4.9
	Week-2 to week-4	4.9	5.0	5.1	4.9
Soap (ml/day)	Week-0 to week-2	10.1	9.9	9.2	9.0
	Week-2 to week-4	10.8	10.2	10.7	10.0

Group A=super-absorbent to standard; group B=standard to super-absorbent; group C=super-absorbent to standard; group D=standard to super-absorbent

other skin lesion, which could influence the skin conditions in the diaper area. SAS was used to evaluate the safety. Skin care in the diaper area, in this case, total daily diaper changes, and the amount of baby soap used daily were equal in both groups. The total diaper changes per day (average: 4.7–5.0 pieces/day) and the total amount of baby soap used per day (average: 9.9–10.8 ml/day) were same in groups A and B (Table 3).

The results of the safety study are shown in Figure 2a. Group A showed no significant changes in the total SAS from baseline to week-2 ($p = 0.09$) and from week-2 to week-4 ($p = 0.35$). Group B showed a significant increase in the total SAS from 1.9 at baseline to 4.1 at week-2 ($p < 0.001$). However, after using super-absorbent diaper, there was a significant decrease in the total SAS from 4.1 to 2.2 ($p < 0.001$) from week-2 to week-4.

Efficacy study

An efficacy study conducted in 59 babies with a mild-to-moderate diaper rash. SAS was used to evaluate the efficacy. Skin care on the diaper area, in this case, total daily diaper changes, and the amount of baby soap used daily were equal in both groups C

and D. The total number of diaper changes per day (average: 4.9–5.1 pieces/day) and the total amount of baby soap used daily (average: 9.0–10.7 ml/day) were same in groups C and D (Table 3).

The results of the efficacy study are shown in Figure 2b. Group C and D both showed a decreasing tendency in the total SAS from baseline to week-2 ($p = 0.07$ and $p = 0.05$). However, group C showed an increase in the total SAS, 6.4 to 8.3 ($p = 0.2$) from week-2 to week-4, whereas group D showed a continuous decrease in the total SAS, 8.6 to 6.1 ($p = 0.13$) in the same period.

SAS of specific areas

The SAS of all the 6 areas evaluated are shown in Figure 2, c–e. Evaluation on the waistband area in group C showed a decrease in the SAS from 2.63 at baseline to 1.73 at week-2. From week-2 to week-4, this group showed a significant increase in the SAS from 1.73 to 2.57 ($p = 0.043$). While group D showed no change in the SAS from baseline to week-2, it did show a slight decrease in the score from 2.54 at week-2 to 2.19 at week-4 ($p = 0.108$).

In the pubic area, group C showed a significant decrease in the SAS at baseline to week-2 (1.43 to

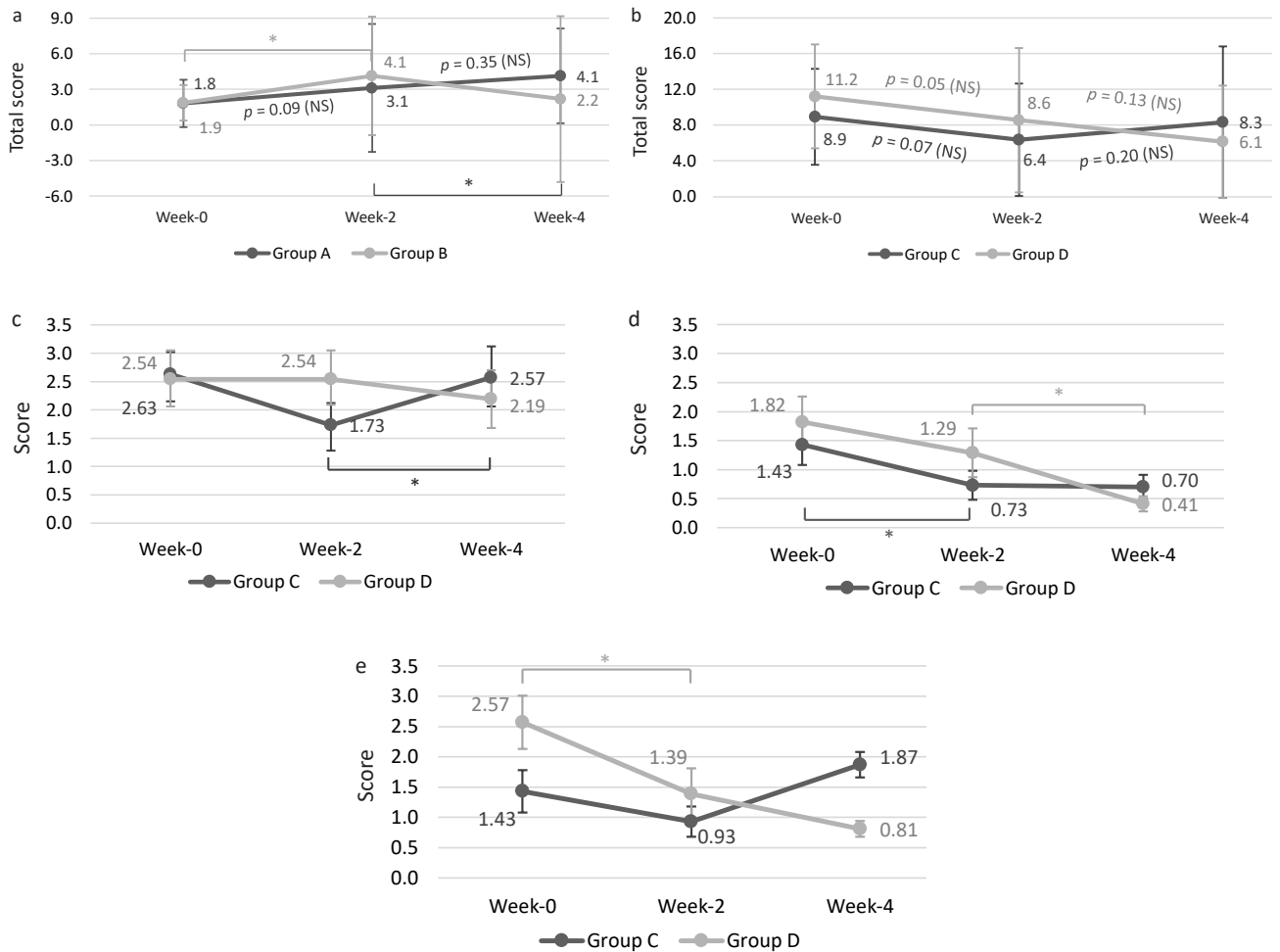


Figure 2. Profiles of the diaper rash severity expressed as the total skin assessment scores (SAS) in both groups: (a) safety study; and (b) efficacy study, assessed at the baseline, week-2, and week-4 of the product use. Profile of the diaper rash severity on the: (c) waist band; (d) pubic; and (e) buttock area expressed as the SAS. Group A=super-absorbent to standard; group B=standard to super-absorbent; group C=super-absorbent to standard; group D=standard to super-absorbent
*Statistically significant different, $p < 0.05$

0.73, $p = 0.011$), and after switching to the standard diaper, there was no significant decrease in the SAS. In group D, the first 2 weeks of using the standard diaper showed a decrease in the SAS (1.82 to 1.29, $p = 0.135$), but it was not significant. However, after switching to super-absorbent diaper, there was a significant decrease in the SAS from 1.29 to 0.41 ($p < 0.049$) from week-2 to week-4.

Evaluation of the buttock area showed that there were no significant differences at baseline, week-2 and week-4 in group C. However, after switching to the standard diaper, there was a slight increase in the SAS from week-2 (0.93) to week-4 (1.87). In group D, the SAS at baseline significantly decreased from 2.57 to 1.39 in week-2 ($p = 0.033$) and continued to decrease to 0.81 after switching to super-absorbent diaper.

DISCUSSION

It is known that the use of disposable diapers can prevent the occurrence of diaper rash. A modern disposable diaper is composed of a top sheet, an absorbent core, gathers, and breathable sheets. However, sometimes even after using a disposable diaper, the skin may still be damped by sweat or pee and thus irritates the skin; resulting in the development of diaper rash.⁸ This condition maybe accentuated in hot and humid environmental conditions, like in Indonesia.⁹ In addition, less frequent diaper changes also have a role in the pathogenesis of diaper rash.

To overcome these issues, a new technology diaper was created called the super-absorbent diaper. The diaper was composed of: (1) soft-fit structure

which consist of soft fit waist gathers and illum gathers; (2) airy-gather structure at waist tip part as a 3D straw shape; (3) a breathable back sheet; and (4) slit and rich absorbent core which has a high and quick absorbance and control liquid diffusion. This super-absorbent diaper design provided a lower humidity in area covered by the diaper.

In this study, the mothers were instructed to change the diaper at least every 6 hours as they were also taught about the initiating factor of diaper rash is prolonged diaper use leading to increased wetness of the skin. Experts generally recommend minimizing the diaper-wearing time by changing diapers frequently; using disposable, super-absorbent, and breathable diapers; bathing at least daily in water with baby oil or water-dispersible creams; cleansing gently and applying protective ointments or pastes that are petrolatum-based or contain substances such as zinc oxide to prevent diaper rash.⁴ All the babies were treated with the same baby soap for the diaper area.

The safety study results showed that in group A, super-absorbent diapers could maintain the skin condition the same as it was at baseline even after 2 weeks, while in group B, the standard diapers significantly worsened the skin condition after 2 weeks. Between week-2 to -4, in group A, which switched to the standard diaper, the skin condition still did not change significantly. However, in group B, after switching to super-absorbent diaper, the skin condition improved considerably. Therefore, the new technology of this super-absorbent diaper can contribute towards improving the skin condition.

Regarding the efficacy in mild-to-moderate diaper rash, both diapers were shown to improve the skin rash in the first 2 weeks because there was a decrease in the mean total SAS. On the one hand, between week-2 and week-4, there was no further improvement after switching to the standard diaper in group C and the mean total SAS tended to increase, although it was not significant. On the other hand, there was further improvement after switching to the super-absorbent diaper in group D, as indicated by a decrease in the mean total SAS.

In the evaluation of the 6 areas which were scored during this study, pubic areas showed a significant improvement with the use of super-absorbent diaper compared with the standard diaper. There was a significant improvement in the skin rash on the

pubic area from baseline to week-2 in group C (using super-absorbent diaper). The condition remained the same after switching to standard diaper in this group. Group D showed a tendency of improved skin condition during the first 2 weeks. However, it improved significantly after using super-absorbent diaper during week-2 to -4. There was a tendency of improving skin rash on the waistband area from baseline to week-2 in group C, although it was not significant when compared with that in group D, in which there was no improvement at all. However, after using the standard diaper from week-2 to -4, there was a significant worsening of the diaper rash, whereas, in group D, there was a tendency of slight improvement after using the super-absorbent diaper.

The evaluation of the buttock area showed that both diapers could improve diaper rash in the first 2 weeks. The standard diaper showed a significant improvement in group D. However, in the second week, there was no further significant improvement after switching to super-absorbent diaper in group D, whereas there was worsening of the skin rash after switching to the standard diaper in group C. Similarly, Yuan et al⁸ reported more babies had SAS improvement in the buttock and anal region in new material diaper group than in standard diaper group.

Disposable diaper with new technology has breathable outer layers and fit to baby's body contour that can reduce local humidity.¹⁰ The top sheet of the diaper is also designed to rapidly attract fluid and transport it to the next layer so the baby's skin is always dry.¹¹ The inner core of the diaper is made of a super-absorbent material where the fluid is absorbed and locked away.^{5,11} Moreover this super-absorbent diaper has the capability of high and quick absorbance and control liquid diffusion due to its slit and rich absorbent core. Therefore, it can also provide dryness and improve the skin condition in the diaper area.

Clinical evidence supports that modern disposable diaper technology can overcome the negative impacts of overhydration, increased pH, friction, and other factors that can damage the skin integrity as well as decrease the severity of diaper dermatitis.^{5,10} According to several clinical studies, moderate to severe diaper dermatitis was 50% declined after the introduction of modern diaper.⁵

Such an improvement in diaper products is likely to contribute in lowering the incidence of diaper

rash.⁸ Moreover, frequent diaper changes and proper skin care, as instructed to the mothers, also play an essential role in improving the skin condition and thus the diaper rash.

The limitation of this study is that objective parameters such as transepidermal water loss (TEWL) and skin capacitance as well as the temperature and humidity in the subject's environment were not measured. In conclusion, the new super-absorbent diaper is safe to use and can contribute in improving the skin condition. Both diapers showed a tendency to improve diaper rash. The super-absorbent diaper may further improve diaper rash, especially on the waistband and pubic areas. To further elucidate the physiological changes of the skin after diaper usage, other objective parameters such as TEWL, skin capacitance, and environmental temperature and humidity can be measured.

Conflict of Interest

Inne Arline Diana, Srie Prihianti Gondokaryono, Titi Lestari Sugjito, Maya Devita Lokanata, Triana Agustin, Githa Rahmayunita, Indah Maharani, and Nanny Shoraya received grant support through their institution (Indonesian Society of Dermatology and Venereology). Haruko Toyoshima was employee of KAO Corporation Japan and Danang Agung Yunaidi was employee of PT Equilab International Jakarta at the time of the conduct of this study and manuscript preparation.

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