

**CLINICAL SUMMARY
OLAY RIBBONS BODY WASH
ATOPIC DERMATITIS HOME USE STUDY**

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2006**

SUBMITTED FOR PUBLICATION

Background

Topical corticosteroid cream or ointment with proper washing is recognized as a primary treatment approach for atopic dermatitis (AD), but soap bars may be a potential source of irritation. Non-soap or synthetic detergent (syndet) cleaning bars are widely used by patients with a variety of skin conditions, including AD.¹ However, clinical evidence suggests that petrolatum-depositing body washes can provide an even greater skin benefit to individuals with AD.²

Objective

The objective of this study was to obtain a dermatologist's assessment of the skin effects and tolerance of Olay Ribbons Body Wash (Body Butter version) and a benchmark syndet bar (Dove Bar) during a four week period of home use by subjects undergoing topical corticosteroid therapy for mild to moderate atopic dermatitis. Treatment effects were also assessed by questionnaires administered to subjects, including self-assessment and the Dermatology Life Quality Index (DLQI).³

Methodology

- This was a four-week double blind study conducted at Dermatology Consulting Services in High Point, North Carolina.
- Sixty females between the ages of 18 and 65 with mild to moderate active atopic dermatitis (AD) and from 5% to 30% disease involvement on their bodies were randomized to one of two treatment groups. Group assignments were balanced by disease severity.
- All subjects received triamcinolone acetonide 0.1% cream to apply twice daily to their AD lesions.
- One group of subjects used Olay Ribbons Body Wash for daily showering; the remaining subjects used the syndet bar. Appropriate bathing implements were provided with each cleanser.
- The investigator performed a global assessment of disease status, considering extent of total body involvement, and scored AD signs and symptoms at baseline and after two and four weeks of using the topical corticosteroid and assigned personal cleanser using the SCORAD index.⁴
- The investigator judged subjects' progress against the criteria of condition improvement at 2 weeks and condition clearing at 4 weeks. The investigator also judged on how well each subject tolerated her assigned personal cleanser at the 4 week evaluation.
- Subjects completed a self-assessment questionnaire and a questionnaire based on the dermatology life quality index (DLQI) at each evaluation (Table I).³

Results

- **Global AD assessments showed a shift in the disease severity distribution over the four week course of topical corticosteroid treatment.** Both personal cleanser groups showed improvement, but subjects assigned to use Olay Ribbons Body Wash and the topical corticosteroid showed a greater tendency towards improvement than subjects assigned to use the syndet bar and the topical corticosteroid (Figure 1).
- **SCORAD was a useful tool for tracking changes in subjects' AD disease condition.** Baseline SCORAD values for both treatments were consistent with the requirement of mild to moderate disease severity (Table II), and mean SCORAD values for both personal cleanser groups decreased over the course of treatment. However, after 2 and 4 weeks the SCORAD values for subjects who used Olay Ribbons Body Wash and the topical corticosteroid were significantly less ($P < 0.01$) than those for subjects who used syndet bar and the topical corticosteroid.

- **AD disease resolution was influenced by the personal cleansing product used.** The expectation is that subjects' AD disease will show improvement after 2 weeks and clearing after 4 weeks when treated with triamcinolone acetonide 0.1% cream. Results from the investigator's assessments are summarized in Figure 2. After 2 weeks, 79.3% of subjects assigned to use Olay Ribbons Body Wash and the topical corticosteroid showed improvement, compared to 26.7% of subjects assigned to use the syndet bar and the topical corticosteroid. After four weeks, 92.9% of subjects assigned to use Olay Ribbons Body Wash and the topical corticosteroid showed clearing, compared to 24.1% of subjects assigned to use syndet bar and the topical corticosteroid.
- **Olay Ribbons Body Wash was well tolerated by the subjects with AD.** At study end, the investigator judged that 92.9% of subjects assigned to use Olay Ribbons Body Wash for daily showering tolerated the product well, compared to 24.1% of subjects assigned to use the syndet bar. This difference is significant at $P < 0.01$. Fifty-seven subjects completed the study. There were no adverse events.
- **Subjects' self-assessment ratings of visual and tactile skin attributes were consistent with the investigator's assessments.** The investigator's assessments showed an improvement in subjects' skin condition over course of treatment; subjects also perceived improvement in their skin condition. The self-assessment results are summarized in Figure 3. Subjects assigned to use Olay Ribbons Body Wash for cleansing perceived significantly ($P < 0.01$) greater improvement in skin dryness, itching, smoothness, softness, and tightness than did subjects assigned to use the syndet bar.
- **The DLQI results showed an impact of personal cleanser on subjects' perceptions of symptoms, feelings, and treatment.** Results for DLQI questions 1, 2, and 10 are summarized in Table III. Responses for both personal cleanser groups trended downward over the course of the study, which is consistent with improvement in AD disease condition. By study end, responses to these questions by the subjects assigned to use Olay Ribbons Body Wash were significantly lower ($P < 0.05$) than from the subjects assigned to use the syndet bar, indicating that Olay Ribbons Body Wash provided greater improvement in these aspects of subjects' life quality.

References

1. Solodkin G; Chaudhari U; Subramanyan K; Johnson AW; Yan X; Gottlieb A. Benefits of mild cleansing: synthetic surfactant based (syndet) bars for patients with atopic dermatitis. *Cutis* 2006;77:317-24.
2. Draelos ZD; Ertel KD; Hartwig PM; Rains GY. The effect of two skin cleansing systems on moderate xerotic eczema. *J Am Acad Dermatol* 2004;50:883-8.
3. Finlay AY, Khan GK. Dermatology life quality index (DLQI) – a simple practical measure for routine clinical use. *Clin Exp Dermatol* 1994;19:210-6.
4. Severity scoring of atopic dermatitis: the SCORAD index. *Dermatology* 1993;186:23-31.

Table I: Questionnaire based on the DLQI and suggested groupings.³ Subjects scored these questions from 0 (not relevant, not at all) to 3 (very much) at each evaluation visit.

Question	Grouping
1. Over the last week, how itchy, sore, painful or stinging has your skin disease been?	symptoms, feelings
2. Over the last week, how embarrassed or self-conscious have you been because of your skin?	symptoms, feelings
3. Over the last week, how much has your skin interfered with you going shopping or looking after your home and garden?	daily activities
4. Over the last week, how much has your skin influenced the clothes you wear?	daily activities
5. Over the last week, how much has your skin affected any social or leisure activities?	leisure
6. Over the last week, how much has your skin made it difficult for you to do any sport?	leisure
7. Over the last week, has your skin prevented you from working or studying?	work/school
8. Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	personal relationships
9. Over the last week, how much has your skin caused any physical problems with relationships?	personal relationships
10. Over the last week, how much of a problem has the treatment for your skin been?	treatment

Table II: SCORAD results for the three study visits. Values were compared with a mixed-model analysis.

SCORAD Results Summary

Evaluation	Topical Corticosteroid Plus:	Mean	Std Err	P-value
Baseline	Olay Ribbons Body Butter	29.5	1.85	0.52
	Syndet bar	27.8	1.85	
Week 2	Olay Ribbons Body Butter	12.8	1.34	< 0.01
	Syndet bar	23.6	1.34	
Week 4	Olay Ribbons Body Butter	7.3	1.82	< 0.01
	Syndet bar	21.4	1.76	

Table III: Dermatology Life Quality Index (DLQI) results for questions 1, 2, and 10. Values shown are the mean (median) responses. *P*-values were calculated using an exact test. No significant differences were

DLQI Question 1

		Baseline	Week 2	Week 4
During the last week, how itchy, sore, painful, or stinging has your skin been?	Olay Ribbons	2.0 (2.0)	0.8 (1.0)	0.7 (1.0)
	Syndet bar	1.9 (2.0)	1.2 (1.0)	1.2 (1.0)
	<i>P</i> -value	0.45	0.01	0.02

DLQI Question 2

		Baseline	Week 2	Week 4
During the last week, how embarrassed or self conscious have you been because of your skin?	Olay Ribbons	1.5 (1.0)	0.5 (0.0)	0.2 (0.0)
	Syndet bar	1.5 (1.0)	0.9 (1.0)	0.7 (0.0)
	<i>P</i> -value	0.85	0.09	0.03

DLQI Question 10

		Baseline	Week 2	Week 4
During the last week, how much of a problem has the treatment for your skin been?	Olay Ribbons	2.3 (1.0)	0.6 (0.0)	0.1 (0.0)
	Syndet bar	1.8 (1.0)	0.4 (0.0)	0.6 (1.0)
	<i>P</i> -value	0.95	0.41	< 0.01

Figure 1: Change in global AD disease severity over the 4-week course of treatment for subjects assigned to use Olay Ribbons Body Wash or the syndet bar with their topical corticosteroid cream.

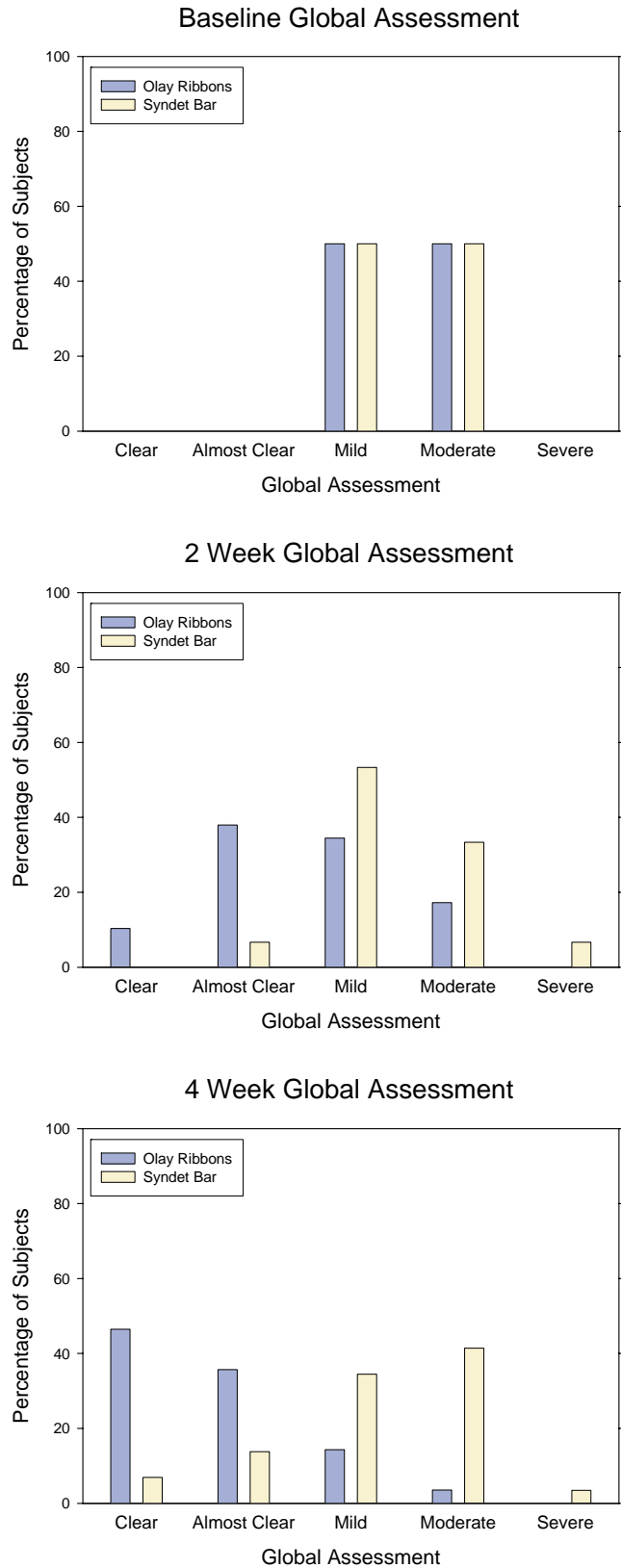


Figure 2: Comparison of disease resolution for subjects in each personal cleanser group.

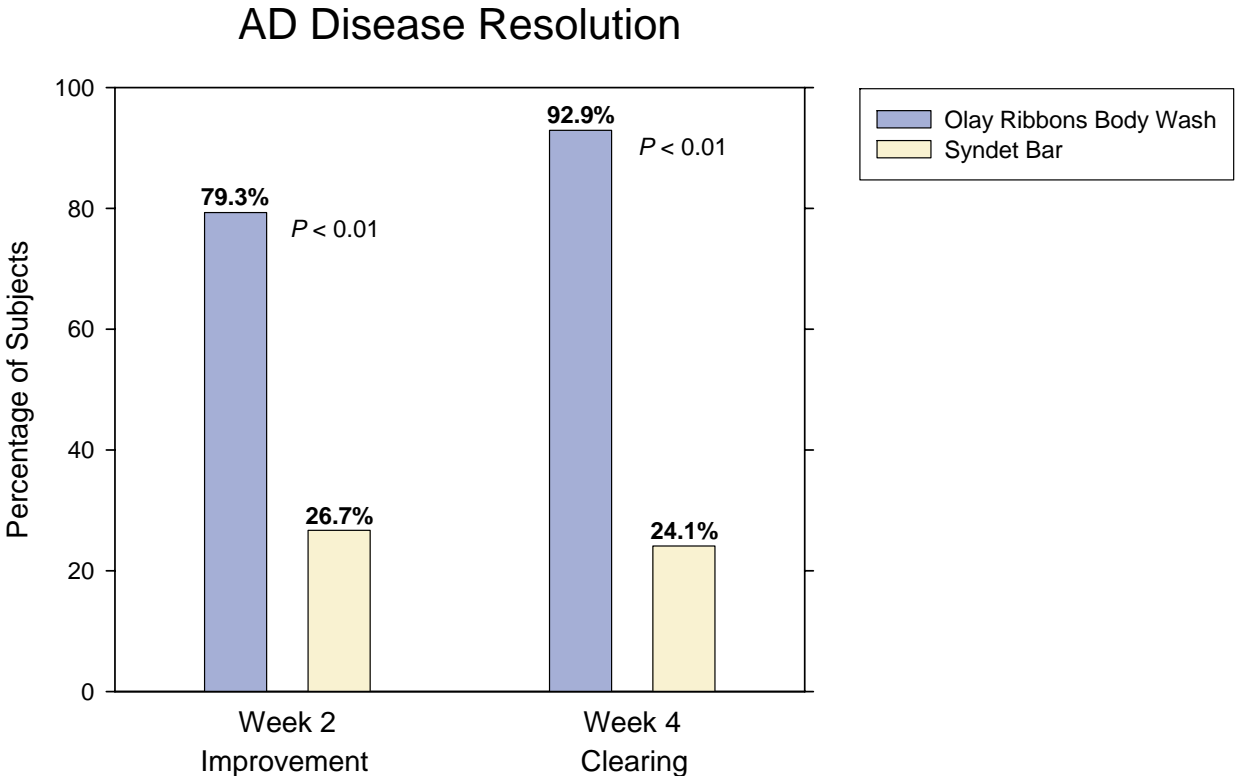


Figure 3: Change (improvement) in subject self-assessment responses over the course of treatment.

