

Clinical Evaluation of Baby Oil as a Dermal Moisturizer

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Synopsis—A population of 106 adult females who exhibited roughened, cracked, and inflamed skins of the elbows, knees, shins, and heels were selected for the evaluation of the SKIN MOISTURIZING ACTIONS of BABY OIL. The baby oil was applied at least twice daily during a 4-week study period to the specified sites on one side of the body. The contralateral sites served as untreated controls. Rating of the skin sites at the outset of the study, during a 2-week interim examination, and at the end of 4 weeks defined a marked and progressive improvement of sites treated with the baby oil. Conversely, untreated sites tended to worsen during the study period.

A statistical analysis of the data revealed that the moisturizing actions were highly significant at both the 2- and 4-week examination times. All ratings were made without foreknowledge of which side of the body had been treated. Photographs obtained in 10 subjects clearly illustrated the differences between skin of treated versus nontreated sites. Following discontinuation of the baby oil application, skins of the treated sites tended to become drier within the first 48 hours. These data suggest that the skin moisturizing actions of the baby oil are not protracted.

INTRODUCTION

According to Blank (1), primary therapy for prophylaxis or correction of dry, scaly, eroded, and inflamed skin should be directed toward maintenance of optimum hydration of stratum corneum. Studies have shown (2, 3) that natural skin lipids are not very effective in preventing water loss under conditions of low environmental humidity. Nor can passage of water through the stratum lucidum and stratum granulosum, the preservers of body water and electrolytes, compensate for enhanced evaporation.

Jellinek (4) points out that removal of surface lipids through frequent use of detergents or exposure to organic solvents also facilitates skin drying. He stresses that moisture in the stratum corneum is bound by hydrophilic components including amino acids, pentoses, and phospholipids. If the skin is

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stripped of lipids, then these hydrophilic modules are readily washed out. In addition, when the fat layer is removed, the surface of the stratum corneum becomes roughened, exposing greater areas of skin, and speeding the evaporation process.

Powers and Fox (5) report that emollient products, formulated to maintain skin integrity under conditions of excessive water loss, vary markedly in effectiveness. Utilizing silica gel dessicators, these investigators studied a series of materials for effectiveness in retarding skin dehydration. Many of the formulations, labeled as skin softeners, actually increased water loss, one as much as 56%. Petrolatum United States Pharmacopoeia (USP) was the most effective barrier material tested for maintenance of dermal hydration.

Anhydrous lanolin, mineral oil, and cold cream also proved to be effective barriers. Spruitt (6) also quantitated water loss from the skin following application of a variety of materials. Flow of water was decreased from 500- to 1000-fold by aliphatic products (mineral-oil based). Unsaturated vegetable oils provided only slight protection, whereas saturated fats were intermediate in activity. Emulsions tended to increase evaporation. Eisner's (7) results support those of Fox and Powers and of Spruitt. Ointments or lotions containing humectants and surfactants again proved ineffective barriers; in this case, with regard to the penetration of an experimental film model by a series of noxious materials including urine, fecal suspensions, acids, and bases. Conversely, baby oil and petrolatum prevented passage of the noxiants.

Baby oil with a mineral oil base remains perhaps the most widely employed skin emollient or softener. In spite of its hydrophobic properties, assuming that the principles of therapy expressed by Blank and other investigators are valid, baby oil can also be properly termed a skin moisturizer. Published data suggest that baby oil as a liquid hydrocarbon, that is capable of providing an effective barrier against water loss, would provide superior moisturizing actions, and that its utility in protecting the vulnerable skin of infants would be equally apparent after application to adults who exhibit sequelae to the variety of skin trauma induced by mechanical and environmental assaults.

The present study was designed to clinically define the moisturizing actions of a commercially-available baby oil* when applied to the roughened, cracked, and inflamed skins of the elbows, knees, heels, and shins of adults.

EXPERIMENTAL METHODS

The study was conducted using a single-blind design with the subjects serving as their own controls. The study group was composed of 111 females with an age range of 13 to 72 years and an average age of approximately 31 years. Treatment sides and contralateral control areas (elbows, knees, heels,

*Supplied by Baby Products Company, Johnson & Johnson, New Brunswick, N.J.

and shins) were randomized according to a schedule developed prior to initiation of the study. To be eligible for participation, candidates were required to be free of any dermatological pathology related to systemic diseases and to exhibit severity of symptoms conforming to a rating of 2 or higher on a 5-point rating scale for at least 2 of the 4 specified skin sites as follows.

A. Elbows and knees

0=smooth visually and to the touch

1="snow" visible in creases; slightly rough to the touch

2=scales and "snow" visible; moderately rough to the touch

3=pronounced scaling and roughness to the touch

4=cracking associated with severe roughness to the touch

B. Heels

0=smooth visually and to the touch

1=rough to the touch with "snow" and cracking just visible

2=rough to the touch; cracking and scaling evident

3=quite rough to the touch; scaling and cracking pronounced

4=very rough to the touch; extreme scaling and cracking

C. Tibia

0=smooth visually and to the touch

1=smooth to the touch; "snow" visible in creases

2=scaling and slight glazing

3=pronounced scaling and slightly rough to the touch

4=severe scaling and cracking; very rough to the touch

Following the baseline examination, subjects were instructed to utilize at least 2 drops of the baby oil on the designated areas at least twice daily (on arising and at bedtime) during a 4-week study period. While the oil was to be applied sparingly so that it was not recognizable at the times of clinical assessment, they were requested to use enough to cover the test sites completely. Use of other skin conditioning preparations during the study was prohibited. The subjects were again rated after 2 and 4 weeks. All examinations were conducted in a uniform manner with elbows and knees bent at a 90° angle. Discussions between the investigator and subject were prohibited, and at no time was the investigator made aware of the identity of the treatment side.

Finally, photographic documentation of effectiveness was obtained from 20 of the subjects. These individuals had been selected at random and specified by subject number prior to therapeutic trial. Each of the 4 sites on both the right and left sides of the subjects were photographed at the scheduled examinations and again either 24 or 48 hours following treatment withdrawal to allow a determination of duration of baby oil activity.

RESULTS

Valid data were obtained from 106 of the initial 111 participants. Four subjects were excluded from the final statistical analysis because of insufficient baseline dermatologic involvement and one because of insufficient rating data due to a missed rating session caused by intercurrent illness.

That the initial severity of the dermatological signs were comparable for the treatment sites and contralateral untreated sites among the population can be ascertained by review of Table I. In general, skin of elbows, knees, and heels exhibited a greater degree of drying, scaling, and roughness at the outset of the trials in comparison to shins.

Skin moisturizing activities of the baby oil are illustrated in Fig. 1. Severity of the signs was decreased in comparison to baseline readings to a significant extent at all 4 treatment sites. Conversely, untreated sites tended to become more severely afflicted over the 4-week study period. Actually, tibial areas were significantly worse at the 4-week evaluation ($P=0.01$). Improvement appeared to be progressive with continued treatment. However, even after 2 weeks, the degrees of benefit were clearly demonstrable. A summary of the statistical analyses of the data is presented on Table II.

Results of evaluations of the 10 individuals who returned to the clinic 24 hours after the baby oil applications were terminated and the additional 10 who reported to the clinic 48 hours later are summarized in Table III.

The data suggest that the protectant moisturizing actions of baby oil do not persist for extended periods following termination of therapy, as skin of treated sites tended to return to the pretreatment state during the 24- and 48-hour follow-up periods.

Mean scores calculated from raw data and obtained utilizing the described objective methods prove the thesis that the completely nonpolar liquid hydro-

Table I

Distribution of Sites by Treatment Group and Initial Severity of Dermatologic Signs
Site

Severity ^a	Elbow		Knee		Heel		Tibial Area	
	Treated	Untreated	Treated	Untreated	Treated	Untreated	Treated	Untreated
0	5	3	7	9	4	4	6	7
1	24	27	40	35	20	20	48 ^b	49 ^b
2	53 ^b	52 ^b	48 ^b	50 ^b	62 ^b	59 ^b	43	41
3	20	20	10	11	18	21	9	9
4	4	4	1	1	2	2	0	0
TOTALS:	106	106	106	106	106	106	106	106

^a Median severity.

^b See protocol for definitions.

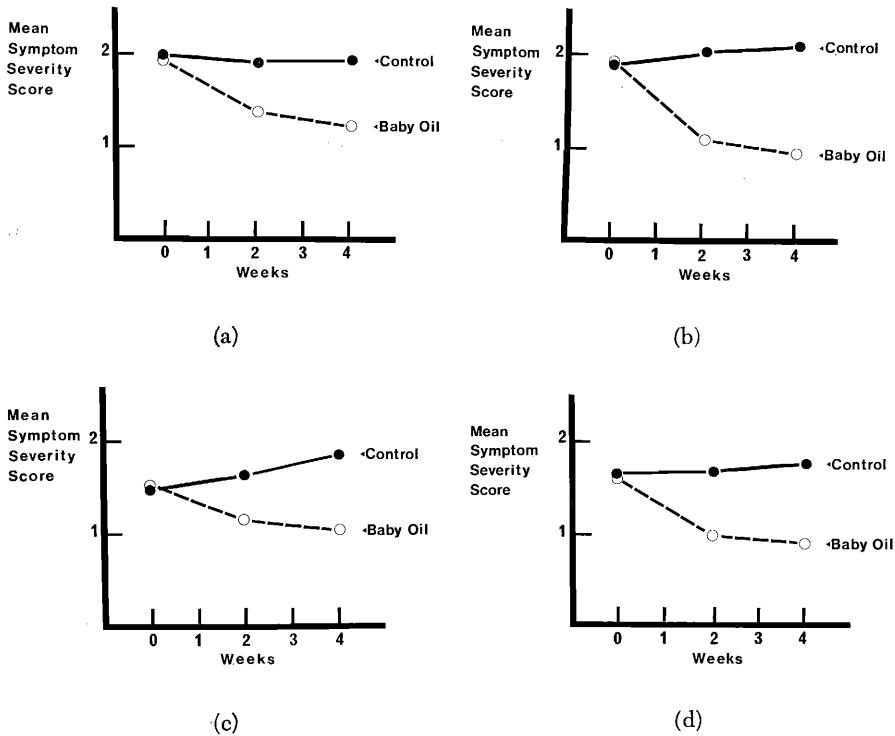


Figure 1. Reduction in mean symptom scores following application of baby oil to various anatomical sites: (a) heels; (b) elbows; (c) shins; (d) knees

Table II
 Mean Dermatologic Severity
 (Scores By Weeks)

	Baseline Score	Week 2		Week 4	
		Mean	Statistical Significance ^a	Mean	Statistical Significance ^a
Elbows					
treated	1.9	1.1	0.001	1.0	0.001
untreated	2.0	2.0	0.311	2.1	0.066
Knees					
treated	1.6	1.0	0.001	0.9	0.001
untreated	1.6	1.7	0.543	1.7	0.245
Heels					
treated	1.9	1.4	0.001	1.2	0.001
untreated	2.0	1.9	0.538	1.9	0.588
Tibial Areas					
treated	1.5	1.2	0.001	1.1	0.001
untreated	1.5	1.6	0.213	1.7	0.001

^a Statistical significance of change from baseline—Wilcoxon Matched-Pair Signed Ranks.

Table III

Mean Severity Ratings 24 and 48 Hours After Treatment as Compared to the Ratings for the Last Treatment Day^a

	Mean Severity of Treated Sites				Mean Severity of Untreated Sites			
	Last day of treatment	24 hours after	Last day of treatment	48 hours after	Last day of treatment	24 hours after	Last day of treatment	48 hours after
Elbows	1.4	2.1	0.9	1.8	2.6	2.6	2.3	2.2
Knees	0.7	1.8	0.7	0.9	2.6	2.5	1.2	1.4
Heels	1.2	1.8	1.3	1.9	2.7	2.8	2.2	2.4
Shins	1.0	1.9	0.9	1.6	2.4	2.4	1.7	1.7

^a Two separate treatment groups composed of 10 subjects each were evaluated at 24 and 48 hours, respectively.

carbon, as represented by the baby oil, can exert clearly demonstrable skin moisturizing action. This anomaly was even more impressively demonstrated photographically. Figures 2 and 3 illustrate contrasts between treated and untreated sites.

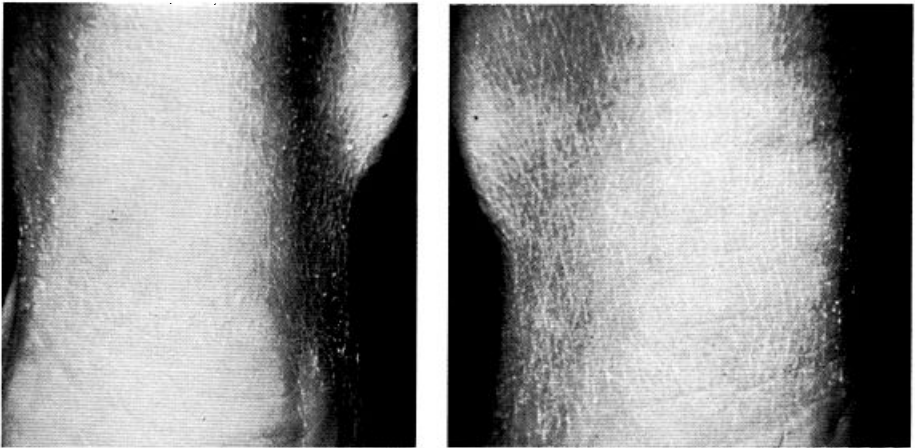
Review of photographs from all 20 subjects allowed definition of similar degrees of benefit. Conversely, the follow-up photographs taken at 24 and 48 hours later exhibited less remarkable differences. The photographs, like the ratings, indicate that deterioration is relatively rapid when applications of the baby oil are stopped.

DISCUSSION

An occlusive film of a liquid hydrocarbon as afforded by the baby oil, according to available evidence, provides a highly effective mechanism for retarding water loss even under extremes of low humidity in the environment. Such a product, then, can appropriately be termed a skin moisturizer despite its hydrophobic properties. In fact, occluding the skin may be a more effective mechanism for maintaining moisture and protecting the stratum corneum than attempts to promote penetration and skin retention of hydrophilic substances (e.g., amino acids and polypeptides) and/or oleaceous materials.

The data obtained in the present study are clearly the most impressive that we have obtained in our clinic, although we have had the opportunity to evaluate many "moisturizers," of which several were apparently effective.

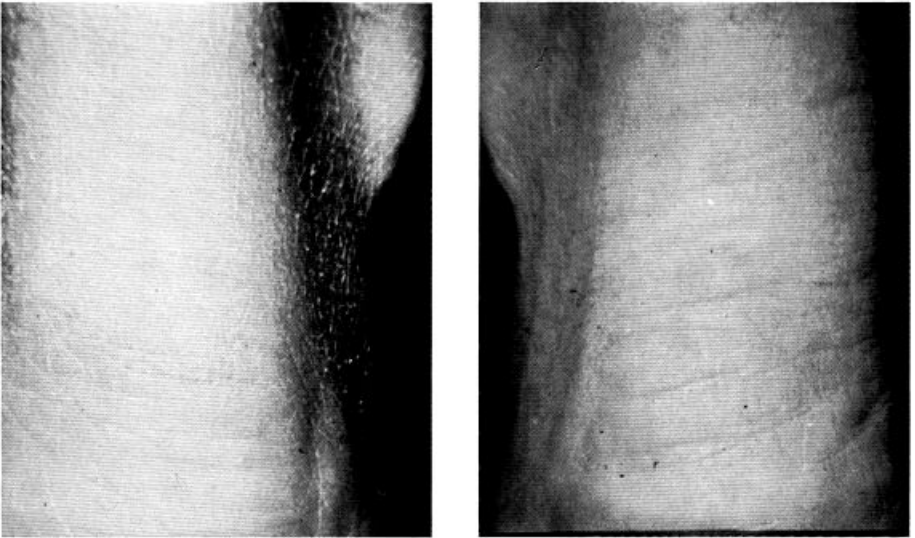
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(a)

(b)

Figure 2. Comparison of (a) right and (b) left heels prior to treatment



(a)

(b)

Figure 3. Comparison of (a) right and (b) left heels following 4 weeks of baby oil treatment of left side

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