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RESEARCH PAPER

Development, Formulation, and Effectiveness Testing of a Silicone-Based Barrier-Type Hand Cream

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ABSTRACT

We report the development, design, and results of effectiveness and acceptability testing of a hydrating, nutritive, barrier-type hand cream designed for severely damaged skin (including skin damaged by dermatological problems). We tested different silicone derivatives and a water-in-oil (W/O) silicone emulsifier to produce organoleptic qualities that would increase consumer acceptance of this type of W/O emulsion. Pharmacotechnical and effectiveness tests were done to check the stability and preservation of the formulas, their usefulness in improving dry skin, and acceptance by users. The results of pharmacotechnical testing were optimal. Although no active principle aimed specifically at dermatological problems was present in the final formulas, users reported notable subjective improvements in cracking and scaling.

INTRODUCTION

The skin of the hands is subjected daily to multiple types of physical, environmental, and chemical attack. In some persons, these attacks are intensified because of working conditions that oblige the handling of agents that are highly damaging to the skin (e.g., in paint and cleaning product industries). Latex gloves are the solution in some cases, but drawbacks include allergic dermatitis, incompatibility with the type of task to be performed, or maceration and chafing with prolonged use.

Many specialized products are commercially available to treat this problem; some are aimed at specific types of chemical aggression. However, silicone, as an ingredient in topical formulations, offers a number of advantages (1), and we designed a new formulation for a silicone-based hand cream to investigate a number of potential benefits. The oily product was designed for external use,

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especially for dry skin (2). The water-in-oil (W/O) emulsion was not greasy to the touch and thus was acceptable to users (3). Silicone-containing products are visually attractive and easily spreadable, and the presence of cyclosilicones provides a refreshing sensation. Because silicone-based formulations can contain up to 70% water, their hydrating capacity is high. These products are not toxic to skin and are very stable with time, and the viscosity of the final product is easily modified. Silicones are highly compatible with other ingredients commonly used in cosmetics (4).

In view of these potential advantages of silicone, we report here the development, design, and results of effectiveness and acceptability testing of a hydrating, nutritive, barrier-type hand cream designed for severely damaged skin (including skin damaged by dermatological problems).

MATERIALS AND METHODS

pH Measurement

The pH was measured with a direct method using a Crison micropH 2001 meter (Alella, Barcelona, Spain) (5). In addition, we used phase separation with *n*-butanol and trichloromethane (6).

Rheological Study

Shear stress was measured against increasing shear rate, and viscosity was measured against time at a speed of 100 rpm and constant temperature (20°C). We used a Brookfield DV II+ viscosimeter (Brookfield Engineering Laboratories, Inc., Stoughton, MA) with WinGather VI.I software (7).

Microscopic Appearance

Samples were observed 24 hr after preparation with and without centrifugation for 30 min at 15,000 rpm (Hermle Z252M Microlitre centrifuge, Wehingen, Germany) or after storage for 4 months at 22°C. They were photographed at different magnifications with an Olympus SC35 camera coupled to an Olympus BX40 light microscope (Olympus Optical Co., Hamburg, Germany) at different magnifications. The images were compared with micrographs of freshly prepared creams (8).

Stability

Stability was tested after storage for 4 months at 22°C, 40°C, or 60°C and after centrifugation for 15, 30, 45, or 60 min at 3500 rpm.

Effectiveness Testing

The effectiveness of the formulation as a barrier to damaging agents was tested with wash-off tests and with a household detergent solution at 25°C after shaking at

Table 1

Composition (%) of the Starting Formulations

	Formulation (%)		
Component	1	2	3
Abil WE 09	5	5	5
Abil K	15	5	10
Cocoa butter	3	2	2
Karité butter	3	2	2
Silicone oil	2	3	3
Sodium chloride	0.7	0.5	1
Preservative	0.2	0.2	0.2
Glycerine	3	4	2
Urea	10	10	5
Antioxidant	0.5	0.5	0.5
Glyceryl linoleate (115,000 US hL/g)	2	2	2
Distilled water	To 100	To 100	To 100

Table 2

Appearance of Mixtures Containing Different Proportions of Components Used in the Oily Phase

Mixture	Appearance After 24 hr
5 g karité butter + 5 g isopropyl myristate	Poor, with very thick, grainy precipitate
5 g karité butter + 5 g liquid vaseline	Poor, with grainy precipitate
2 g karité butter + 4 g liquid vaseline	Poor, with thick, nongrainy precipitate
2 g karité butter + 4 g wheat germ oil	Poor, with thick, very grainy precipitate
1 g karité butter + 3 g liquid vaseline	Fair, with nongrainy, smooth precipitate
1 g karité butter + 3 g sweet almond oil	Fair, with nongrainy, smooth precipitate
1 g karité butter + 3 g carrot oil	Fair, with nongrainy, smooth precipitate
1 g karité butter + 5 g liquid vaseline	Good, homogeneous cream

Table 3

Final Formulas with Different Amounts of Isopropyl Myristate and Lactic Acid

Component	Formulation A (%)	Formulation B (%)
Abil WE 09	5	5
Abil K	15	15
Karité butter	1	1
Silicone oil	3	3
Liquid vaseline	2.5	2.5
Isopropyl myristate	0	1
Sodium chloride	1	1
Preservative	0.2	0.2
Glycerine	3	3
Urea	5	5
Antioxidant	0.5	0.5
Glyceryl linoleate (115,000 US hL/g)	2	2
Natural moisturizing factor	5	5
Lactic acid	0.2	0
Perfume	0.2	0.2
Distilled water	To 100	To 100

60 rpm for a maximum of 2 hr. The amount of product that was washed off was measured gravimetrically (9).

Effectiveness and acceptability were tested in human subjects (10). Nine volunteers with hand skin damaged by external agents, dermatitis, or allergy participated. Four had dermatitis with or without excessive exposure to external agents, and five had dry skin, scaling, or cracking despite the absence of any know disease. The cream was applied for at least 15 days, and at the end of the test period, each participant responded to a four-part, 50-item written questionnaire that recorded information about the subject's usual activities and exposure to damaging agents, subject's perception of the cream immediately after application, effectiveness of the product, and subject's intention to use or buy the product.

RESULTS AND DISCUSSION

Design and Preparation of the Formula

Three starting formulas were prepared (Table 1) by adding the oily phase to the heated aqueous phase and mixing. The resulting products initially had an excellent appearance and adequate viscosity. However, the appear-

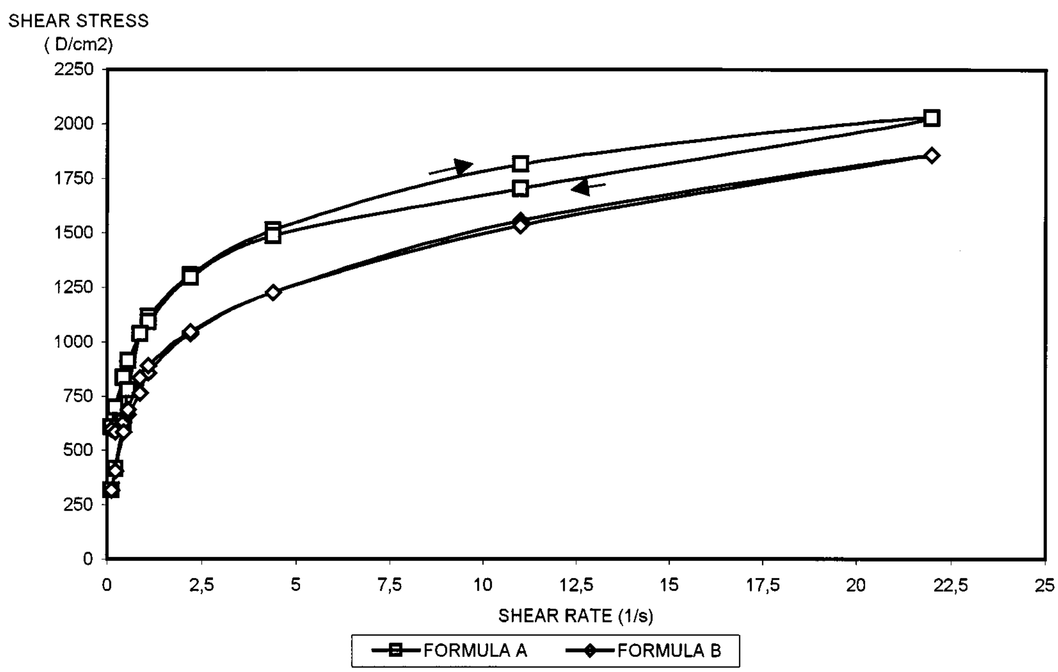

Figure 1. Changes in shear stress with increasing shear rate in the two final formulas, showing a weak hysteresis cycle for formula A.

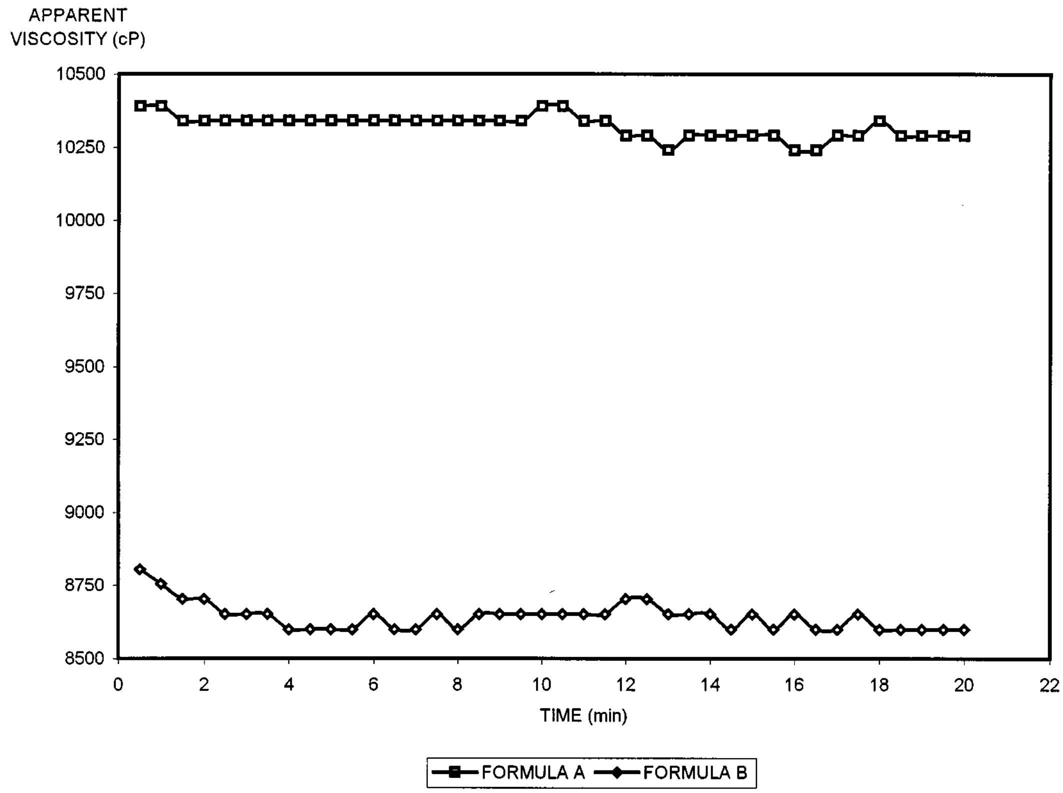

Figure 2. Changes in viscosity of the two final formulas. The operating conditions were 100 rpm at 20°C; readings recorded every 30 sec.

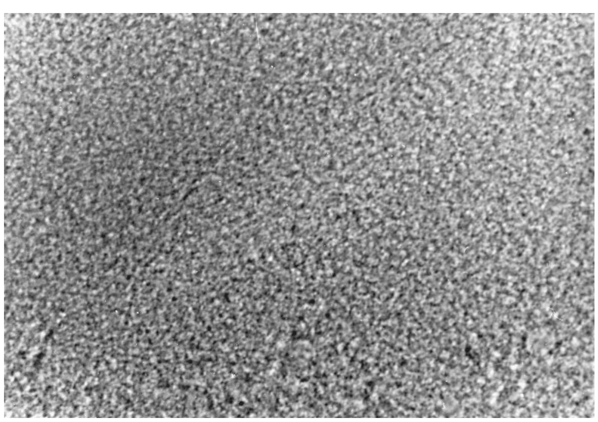

Figure 3. Immersion objective (×100), formula prepared 24 hr previously.

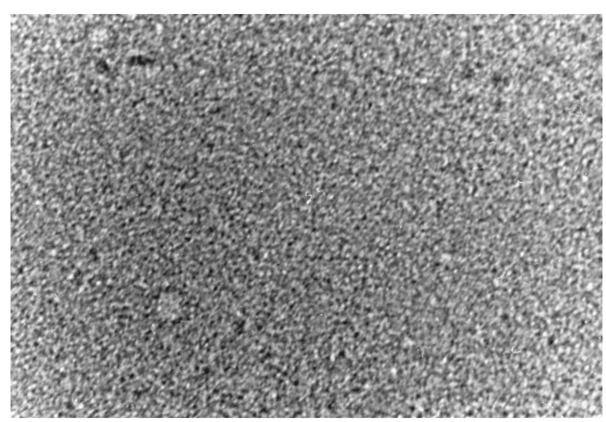

Figure 4. Immersion objective (×100), formula prepared 24 hr previously and centrifuged for 30 min at 15,000 rpm.

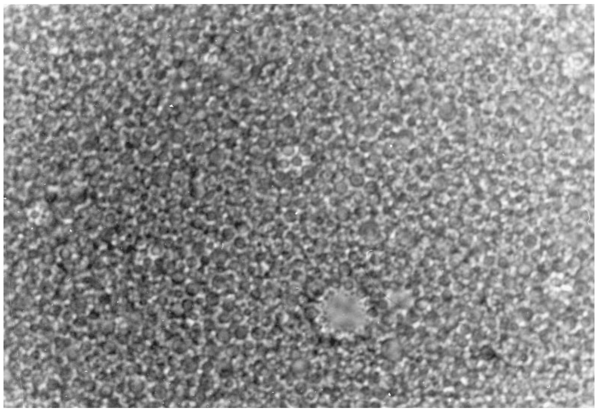

Figure 5. Immersion objective (×100), formula stored for 4 months at 22°C.

ance of small granules within 24 hr, probably because of excessive levels of urea, led us to prepare a series of samples with lower concentrations of urea and without this ingredient and with pH adjusted from 4 to 8 by the addition of lactic acid or triethanolamine.

Granules also appeared in these formulations 24 hr after preparation, and we therefore modified the percentages of the oily phase components (e.g., cocoa butter, karité butter, silicone oil, and Abil K [TH. Goldschmidt AG, Essen, Germany]). We found that the lower the content of oily ingredients, the less frequently granules appeared. This finding suggested that the granules consisted of fatty components that precipitated at low temperatures because of the low melting points of these ingredients (e.g., cocoa butter at 34°C–36°C, karité butter at 29°C–33°C). Although these ingredients do not dissolve in silicones, they are compatible with them and were therefore present in the formulations in melted, but not dissolved, form.

We then searched for an oily phase solvent that would prevent solidification of the melted oily components and that was compatible with the silicones used (11). Isopropyl myristate yielded an acceptably substantive and spreadable cream. We tested a formula similar to those shown in Table 1, except that it contained 2% cocoa butter, 2% karité butter, 2% isopropyl myristate, and lactic acid to 100% at pH values ranging from 4.5 to 6.0. Smaller, easily spreadable granules appeared after 48 hr; however, the cream still did not have the desired visual homogeneity.

In the next step, we omitted cocoa butter to increase the proportion of the watery phase and therefore increase the hydrating capacity of the cream. We also tested different solvents, such as liquid vaseline, which is compatible with silicones, and other oils that are used widely in cosmetics, such as wheat germ oil, carrot oil, and sweet almond oil.

We mixed 1, 2, or 5 g of karité butter with several solvents. Precipitates appeared in many of these mixtures, and the only ones judged to have a satisfactory appearance were those that contained liquid vaseline, carrot oil, or sweet almond oil at a proportion of 5:1 or 3:1 with karité butter (Table 2).

We decided to use liquid vaseline in the test formulas for several reasons (12): its compatibility with the soluble silicones we used, the absence of undesired coloring (in contrast with carrot and sweet almond oil), and its added barrier effect, which would reinforce that of the silicone in the final formulation.

The hydrating capacity of the cream was increased by adding 5% natural moisturizing factor (NMF) (Roig Pharma, SA, Barcelona, Spain). We prepared the two formulas listed in Table 3. To adjust the pH, isopropyl myristate was added to formula B but not to formula A, and lactic acid was added to formula A but not to formula B.

Pharmacotechnical Testing

pH Measurement

The pH was measured directly as the mean of five determinations and was 4 ± 0.2 for formula A and 4.7 ± 0.2 for formula B. We also measured pH in the aqueous phase after separation from the formula; these tests yielded mean values (five determinations) of 4.2 ± 0.1 for formula A and 4.8 ± 0.1 for formula B.

Rheological Testing

Shear stress was tested at increasing shear rates (Fig. 1), and viscosity was measured at 100 rpm (Fig. 2). Figure 1 illustrates pseudoplastic behavior with a very short hysteresis cycle in formula A and no hysteresis in formula B. The corresponding equations (according to the power law) are $\tau = 1039.5 \times \gamma^{0.2347}$ for formula A, and $\tau = 846.83 \times \gamma^{0.24}$ for formula B, where τ is shear stress in D/cm^2, and γ is shear rate in 1/s.

Figure 2 shows no change in viscosity in either formula at a constant rate of 100 rpm. This explains the absence of significant hysteresis in Fig. 1.

Microscopic Appearance

Figures 3, 4, and 5 show that droplet size was homogeneous, suggesting that these silicone-based creams were stable. Figures 3 and 4 show that centrifugation had little

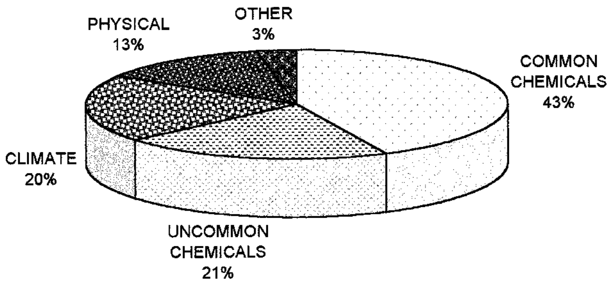

Figure 6. Main causes of damage to hand skin in our study group.

discernible effect on droplet size and homogeneity. After storage for 4 months (Fig. 5), small, homogeneous droplets were visible.

Stability

At room temperature, both formulas were stable for 6 months, with no significant changes. During storage at 40°C, the creams became discolored after 25 days. At 60°C, darkening was first evident after 10 days. In centrifugation, tests neither of the formulas showed symptoms of destabilization.

Effectiveness Tests

After 30 min, there was no significant wash off of any of the samples with plain water or soapy water. After 2 hr, there was no loss with plain water, but soapy water removed approximately 30% of the cream.

Demographic items in the survey were used to obtain general information on the participants (age, sex, occupation) and to determine the main sources of damage to the skin of their hands (Fig. 6). Frequency of exposure was very high in 33% of the participants, high in 56%, and low or nonexistent in 11%. Figure 7 shows the main types of damage to the skin reported by the participants.

The participants were generally very satisfied with the cream. All participants found the organoleptic qualities of the creams pleasing regardless of which formula they tested.

Figure 8 illustrates the participants' opinions regarding the long-term effect of using the hand cream. The cream eliminated the main skin problem (cracking and dry skin) in 33% of the participants; the remaining 67% reported significant improvement in the problem. This second group included the participants with dermatitis.

In comparison with other products for hand skin care, our formulas were rated ''much better'' by 22% of the respondents, ''better'' by 67%, and ''as effective'' by 11%.

When asked about their overall opinion of the formula, all participants responded favorably: 78% ''liked'' the cream, and 22% liked the cream ''very much.'' When asked if they would buy the cream if it were available commercially, 22% of the participants answered that they would ''definitely'' buy it, and 78% responded that they would ''probably'' buy it.

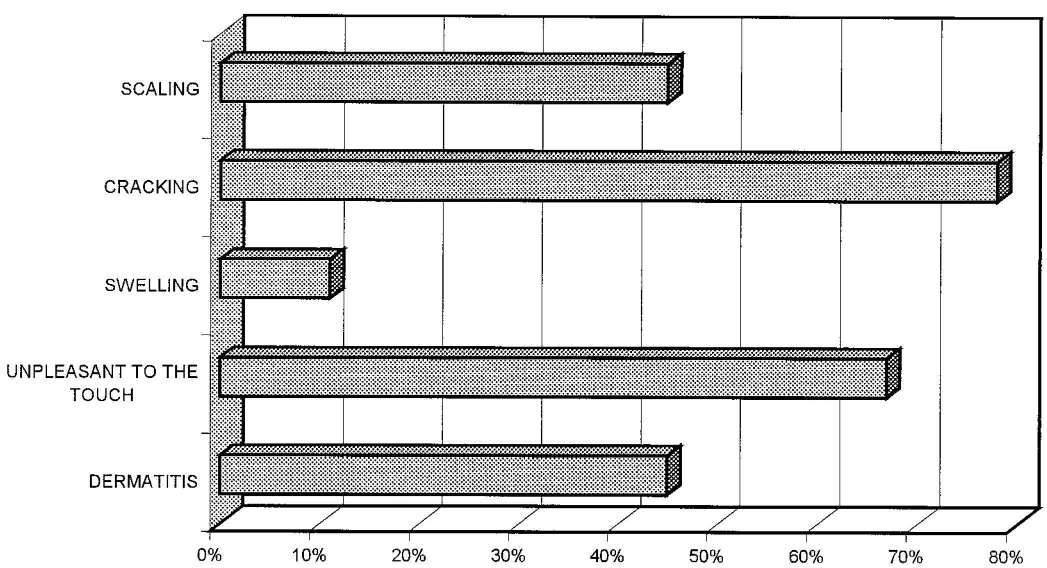

Figure 7. Main dermatological problems in our study group.

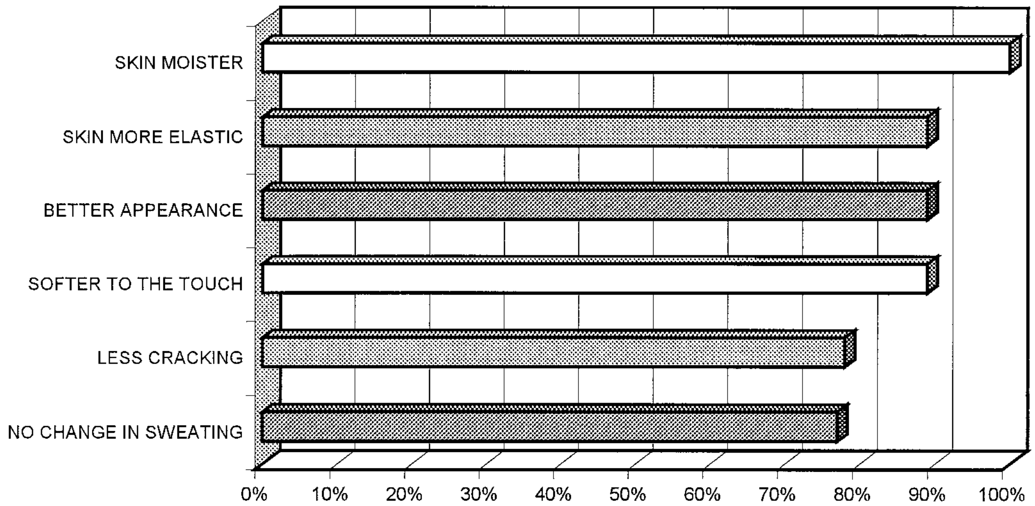

Figure 8. Users' opinions of the effects of the formula.

In conclusion, our silicone-based formulation is stable, shows good organoleptic characteristics, provides an effective barrier to damaging external agents, and has adequate hydrating action. The formulation was found to be effective against dry skin and to ameliorate symptoms of some dermatological pathologies.

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