High-SPF sunscreens (SPF $\geq$ 70) may provide ultraviolet protection above minimal recommended levels by adequately compensating for lower sunscreen user application amounts

Hao Ou-Yang, PhD,[a] Joseph Stanfield, MS,[b] Curtis Cole, PhD,[c] Yohini Appa, PhD,[a] and Darrell Rigel, MD[d]
Los Angeles, California; Winston Salem, North Carolina; Skillman, New Jersey; and New York, New York

Background: The manner in which consumers apply sunscreens is often inadequate for ultraviolet protection according to the labeled sun protection factor (SPF). Although sunscreen SPFs are labeled by testing at an application density of 2 mg/cm^2, the actual protection received is often substantially less because of consumer application densities ranging from 0.5 to 1 mg/cm^2. High-SPF sunscreens may provide more adequate protection even when applied by consumers at inadequate amounts.

Objective: We sought to measure the actual SPF values of various sunscreens (labeled SPF 30-100) applied in amounts typical of those used by consumers.

Methods: Actual SPF values were measured on human volunteers for 6 sunscreen products with labeled SPF values ranging from 30 to 100, applied at 0.5, 1.0, 1.5, and 2.0 mg/cm^2.

Results: There was a linear relationship between application density and the actual SPF; sunscreens with labeled SPF values of 70 and above provided significant protection, even at the low application densities typically applied by consumers. Sunscreens labeled SPF 70 and 100 applied at 0.5 mg/cm^2 provided an actual SPF value of, respectively, 19 and 27.

Limitations: The study was conducted in a laboratory setting under standardized conditions and results are extrapolated to actual in-use situations.

Conclusion: Sunscreens with SPF 70 and above add additional clinical benefits when applied by consumers at typically used amounts, by delivering an actual SPF that meets the minimum SPF levels recommended for skin cancer and photodamage prevention. In contrast, sunscreens with SPF 30 or 50 may not produce sufficient protection at actual consumer usage levels. (J Am Acad Dermatol 2012;67:1220-7.)

Key words: minimal erythema dose; sun protection; sunburn; sunburn protection factor; sunscreens; ultraviolet protection.

The harmful effects of ultraviolet (UV) radiation on the skin have been known for quite some time. Exposure to UV radiation leads not only to skin photodamage[1] but, more importantly, to immunosuppression[2] and skin cancers[3] such as squamous cell carcinoma,[4] basal cell carcinoma,[5] and melanoma.[6,7] To reduce the incidence of UV-related skin cancers, the American

From Neutrogena Corp, Los Angeles[a]; Suncare Research Laboratories LLC, Winston Salem[b]; Johnson and Johnson Consumer Companies, Skillman[c]; and New York University Medical Center.[d]

Funded in full by Neutrogena Corp; the preparation of this manuscript was sponsored in full by Johnson and Johnson Consumer Companies.

Disclosure: Drs Ou-Yang and Appa are employees of Neutrogena Corp, the manufacturer of two of the sunscreens tested. Dr Cole is an employee of Johnson and Johnson Consumer Companies, a sister company of Neutrogena Corp. Mr Stanfield is an employee of Suncare Research Laboratories, the independent testing laboratory that received compensation for conducting this study, and he is currently a consultant to Galderma Laboratories LP. Dr Rigel is a consultant for Neutrogena Corp, Johnson and Johnson Consumer Companies, Beiersdorf, and P&G.

Previously presented as a poster at the 69th American Academy of Dermatology Annual Meeting, New Orleans, Feb. 4-8, 2011.

Accepted for publication February 17, 2012.

Reprint requests: Hao Ou-Yang, PhD, Neutrogena Corp, 5760 W 96 St, Los Angeles, CA 90045. E-mail: houyan4@its.jnj.com.

Published online April 1, 2012.

0190-9622/$36.00

doi:10.1016/j.jaad.2012.02.029

Academy of Dermatology recommends, among other measures, the generous application of a "broad-spectrum, water-resistant sunscreen with sun protection factor (SPF) of at least 30 to all exposed skin."[8]

Many studies have shown that sunscreens can protect from UV-induced damage and skin cancer.[9-12] The determination of their SPF value is regulated by the Food and Drug Administration (FDA) and other internationally recognized testing standards, which all dictate that sunscreens be tested at an application density of 2 mg/cm^2.[13,14] However, several investigations have shown that consumers typically apply less than 2 mg/cm^2,[15-20] thus reducing the actual protection of the sunscreen.[21-23] In an open study conducted at the beach on 42 volunteers, Bech-Thomsen and Wulf[15] calculated that the average sunscreen density applied by sunbathers was 0.5 mg/cm^2. Another group assessed the amount of sunscreen applied by 10 women with photosensitive skin conditions, as they would use it during a sunny day; they found that the median application dose was 0.5 mg/cm^2, with site variations from 0 to 1.2 mg/cm^2.[16] Grosick and Tanner[17] reported a study in which 700 women were given free access to various sunscreens SPF 15 and higher to be used over 3 to 6 weeks; the study found that the SPF achieved in actual use was below that of the labeled SPF. Investigations on sunscreen application by beachgoers have further confirmed that consumers rarely apply sunscreens uniformly and usually do not reapply them often enough, particularly after swimming.[18,19]

In 2011, the FDA proposed to cap the labeled SPF at "50+," stating that there is insufficient evidence that SPF values above 50 produce additional clinical benefits.[24] However, a consumer in-use study conducted to compare the efficacy of a sunscreen with SPF 50 versus one with SPF 85 demonstrated that the higher SPF sunscreen provided better sunburn protection.[25] In addition, it is widely presumed that high-SPF sunscreens may deliver an SPF adequate for skin cancer and photodamage prevention even when underapplied by consumers.

The purpose of this study was to test the actual SPFs of sunscreens with labeled SPFs 30 to 100 under the reduced densities that are typically applied by users, to determine if high-SPF products applied per consumer behavior would still yield an SPF adequate for skin cancer prevention,[26] compared with lower SPF products.

CAPSULE SUMMARY

- Consumers typically apply sunscreens unevenly and in amounts lower than recommended, reducing the actual sunburn protection factor.
- Sunscreens with sun protection factor of 70 and above yield significant protection even when underapplied in typical consumer use situations.
- Sunscreens with sun protection factor of 70 and above may deliver the minimal SPF levels for skin cancer and photodamage prevention, even when misused or under-applied.

METHODS

This study evaluated the effects of various application densities on the actual SPF values of 6 sunscreen products, with labeled SPFs ranging from 30 to 100. The investigation was designed with a 2-step approach. An initial study (study A) was conducted on 251 volunteers to determine the SPF value of 6 sunscreens (labeled SPF from 30-100) at 4 different application densities (0.5, 1.0, 1.5, and 2.0 mg/cm^2). The second study (study B), conducted on 76 volunteers after the results of study A were reviewed, was carried out to compare the SPF values of the 6 sunscreens at low application densities (0.5 and 1 mg/cm^2) side by side.

Both studies were single center, controlled, randomized, and evaluator blinded. Subjects were male/female healthy volunteers with Fitzpatrick skin types I, II, and III.[27] To facilitate estimation of the minimal erythema dose (MED), colorimetric measurements of each subject's skin were obtained according to the international SPF method, and the individual typology angle value was computed.[14] Both studies were conducted in accordance to the FDA final monograph on sunscreen products[13,28] and to the Declaration of Helsinki principles; protocols and informed consent were approved by an independent institutional review board.

Test sunscreen formulations and test sites

Six US-marketed sunscreen formulations were tested (4 lotions and two sprays). The 4 lotions were selected based on similar vehicles and types of active ingredients. The two sprays also contained similar types of active ingredients. The test products were:

(A) SPF 30 lotion sunscreen (Coppertone Sport 30, SPF 30, Schering-Plough HealthCare Products Inc, Memphis, TN).

(B) SPF 100 lotion sunscreen (Neutrogena Ultra Sheer Lotion SPF 100, Neutrogena Corp, Los Angeles, CA).