The Relevance of High SPF Products: High SPF Sunscreens Help Compensate Under-Application

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BACKGROUND

Label SPF values of sunscreens are determined in labs following a validated protocol with 2mg/cm^2 application density. In practice, most people only apply 0.5 to 1 mg/cm^2 of sunscreen lotions.[1] Several studies have shown that the protection level of a sunscreen at 0.5 or 1 mg/cm^2 application density is much less than the protection level shown on the label.[2-4] In this study, we tested the SPF levels of sunscreen (label SPF>30) at application densities typical of consumer usage.

MATERIALS & METHODS

Materials

Six marketed sunscreens were tested: 4 lotions of SPF 30, 50, 70 and 100 and 2 sprays of SPF 50 and 100. The four lotions were selected because they have similar vehicles and active ingredients. The two tested sprays also contain similar active ingredients. **Table 1** lists the active ingredients of these sunscreens.

In vivo SPF Determination

- The first study was a controlled, randomized, evaluator-blinded, single-center SPF evaluation of 6 sunscreen formulations at application doses of 0.5, 1, 1.5 and 2 mg/cm^2. Total of 341 subjects with skin type I–III were enrolled for the study (N=20 for each test). The evaluator was not aware of application dose density.
- The second study consisted of three side-by-side tests to compare the SPF levels of different formulations when they were applied at the same density and on the same subject panel. A total of 64 subjects were included in this study (N=20 for each test).
- The first test compared the SPF of 4 lotions applied at 0.5 mg/cm^2.
- The second test compared the SPF of 4 lotions applied at 1.0 mg/cm^2.
- The last test compared the SPF of the two sprays applied both at 0.5 and 1.0 mg/cm^2.
- Both studies were approved by an independent investigational review board and conducted according to the protocol detailed in the 1999 FDA sunscreen monograph.[5]

Statistical Analysis

ANOVA with general linear model was used to compare the mean SPF results by the dose, the label SPF or the combination of the two variables. Tukey-Kramer tests were conducted to measure the statistical significance between each possible pair of test results.

Table 1. Active ingredients of tested sunscreens

Active Ingredients	SPF 100 (wt%)	SPF 70 (wt%)	SPF 50 (wt%)	SPF 30 (wt%)	SPF 100 Spray (wt%)	SPF 50 Spray (wt%)
Avobenzone	3.0	3.0	3.0	2.0	3.0	3.0
Homosalate	15.0	15.0	13.0	10.0	15.0	15.0
Octisalate	5.0	5.0	5.0	5.0	5.0	5.0
Octocrylene	10.0	10.0	5.0	4.0	10.0	~
Oxybenzone	6.0	6.0	6.0	5.0	6.0	6.0

RESULTS

Table 2. SPF values of different application densities

Application Dosage (mg/cm2)	SPF 30 Lotion	SPF 50 Lotion	SPF 70 Lotion	SPF 100 Lotion	SPF 50 Spray	SPF 100 Spray
0.5	8.8	13.9	19.3	27.1	12.6	22.4
1.0	16.0	26.0	37.1	55.9	25.7	50.1
1.5	21.8	41.3	54.4	79.3	38.6	75.0
2.0	31.0	52.8	70.6	104.6	50.7	105.3

Measured SPF values are statistically different for different label SPF when tested at the same application density (within row) and are statistically different for the same product when tested at different application densities (within column)

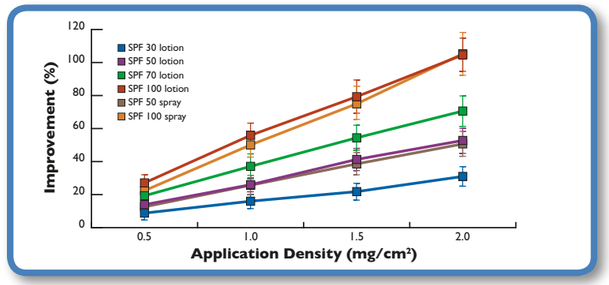

Figure 1 and **Table 2** show the *in vivo* SPF levels at different application densities for the 4 lotions and 2 sprays used in the first study. It is noteworthy that for all these high SPF sunscreens, the actual SPF levels increase approximately linearly with increasing dosage from 0.5 to 2 mg/cm^2 and there is no significant difference between lotion and sprays at either SPF 50 or SPF 100 level.

The second study compared the protection levels of different SPF products at 0.5 and 1 mg/cm^2 application density side-by-side. It confirmed and validated the first study and demonstrated that at relevant application dosage, the high SPF products maintain their superior protection vs. the lower SPF products, supporting that they can help compensate under-application of sunscreen.

Table 3. SPF levels at lower application densities

Label SPF	0.5 mg/cm^2	1 mg/cm^2
SPF 30 lotion	9.1	15.2
SPF 50 lotion	14.3	26.7
SPF 70 lotion	19.3	34.8
SPF 100 lotion	27.8	51.8
SPF 50 spray	13.3	25.4
SPF 100 spray	25.8	49.7

SPF values were statistically different between each adjacent pairs of SPF levels in the table for both 0.5 mg/cm^2 and 1mg/cm^2 application densities (within column)

DISCUSSION & CONCLUSIONS

This is the first report to investigate the dose-dependent behavior of high SPF sunscreens (SPF>30). Consistent with previous results,[2-4] we showed that high SPF products also demonstrated linear correlation with application density in the range of 0.5-2 mg/cm^2. This is not surprising because in the application typical of consumer behavior, the applied film uniformity is probably more important than the overall film thickness, causing the dose behavior of SPF deviates from Beer's law.[6] This study also supports that high SPF sunscreens can help compensate for under-application, because they provide statistically superior protection vs. low SPF sunscreens even when patients under-apply the products.

References

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