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3M™ Cavilon™ Advanced Skin Protectant

Durability of Cavilon Advanced Skin Protectant compared to three commercially available film barriers in healthy human subjects

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Data on file (Study EM 05-013924)

Background

A new differentiated skin protectant with extended durability and ability to adhere to wet, weepy denuded skin has been developed. This product is intended to manage Category 2 Incontinence-associated Dermatitis (IAD) and other types of moderate to severe skin damage. It may also be used to protect intact skin at high risk for breakdown. The objective of this controlled, randomized, prospective open-label study was to determine the durability of this new protectant when applied to intact skin in 21 healthy human volunteers, and compare it to three other products used for similar clinical indications.

Methods

Eight ¾-inch circles of black carbon pigment were applied to the forearms (4 on each arm to allow for duplicates) and covered with the various products. Subjects conducted normal routine activities over 7 days. Photographs were taken and a test site assessment was completed before and after application of the products on Day 0, and at Days 1, 2, 3, 4, and 7 to evaluate pigment loss over time. Carbon Integrated Optical Density (CIOD) was measured, under the assumption that a loss of pigment correlated with a loss of the protective product.

Results

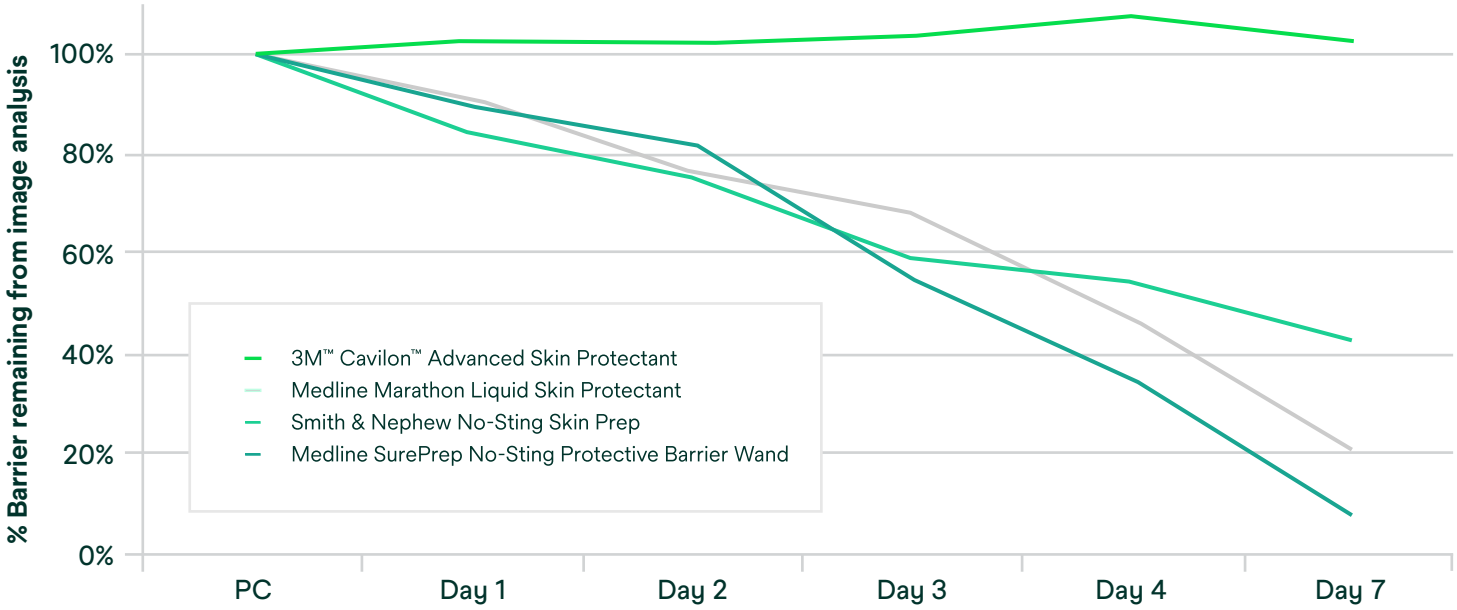
The percent of intact barrier was significantly greater ($p<0.05$) for the new skin protectant than for the other three products at all time points following Day 0. The new skin protectant showed no significant change in CIOD ($p=0.46$) from Day 1 through 7, indicating no meaningful wear over time. The other three products showed significant changes in CIOD ($p<0.01$) beginning at Day 2 or 3.

Conclusion

The new skin protectant was more durable than the other products tested. It remained in place for up to 7 days for all subjects, whereas the other products had less than 50% remaining on the skin by that time point.

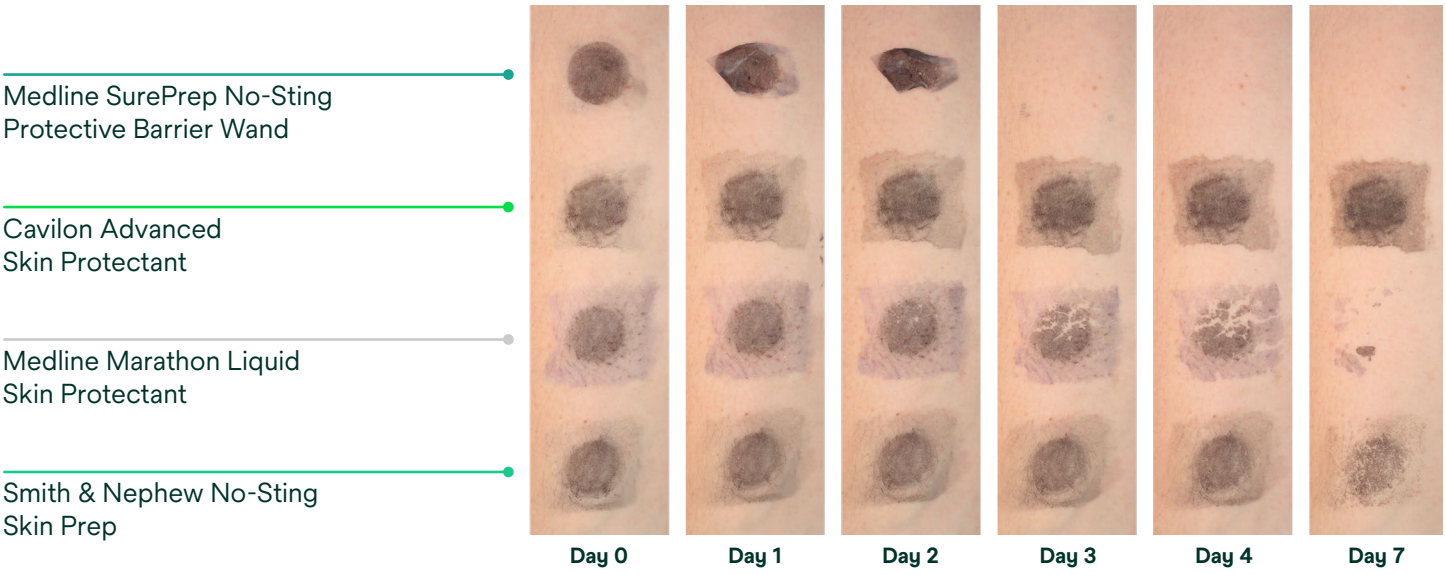
Survival curve:

Percent product remaining over time, based on carbon integrated optical density measurements



Example of one subject:

Volar forearm with tested formulations at days 0, 1, 2, 3, 4, and 7



Volar forearm of a healthy subject with 4 dots of activated carbon covered by various skin protectants over time. As the skin protectant films wear off, the carbon also wears off. The amount of black carbon remaining over time reflects the durability of the skin protectant product.

Adapted from Mathisen M, Grove G, Houser T, Bernatchez SF. Durability of an advanced skin protectant compared with other commercially available products in healthy human volunteers. Wounds 30(9):269-274, 2018.

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