Use of a digital event logger to assess and enhance compliance

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STUDY METHODS

Eighty-eight female subjects of Fitzpatrick skin type II- IV age 30- 65 years of age were enrolled in an IRB approved, double blinded, 12-week clinical study of a dyspigmentation cosmetic treatment topical. Protocol compliance with the twice daily application of the topical to each of 4 specified face and body locations was recorded via a digital event logger. The topical dispenser (Fig.1) contained a digital event logging/reporting topical and an internal data logging function connection to a database where study compliance could be monitored for outcome. Completion of diaries and verbal subject questioning may not produce accurate compliance assessment. Devices are currently available for assessing the opening and closing of pill bottles (1), but no such compliance device exists for the dispensing of topical products.

RESULTS

After 1 week, 16% of subjects did not use the topical or used it less frequently than instructed. Two noncompliant subjects discontinued study participation and were replaced. The remaining non-compliant subjects were contacted to correct product compliance.

With continued compliance monitoring during 4 weeks of product use, 93% of subjects correctly applied the topical twice daily as directed. In Figure 4 the percentage of subjects that were compliant is shown using four compliance targets (percentage of total prescribed doses). Fifty-two percent of the subjects exhibited compliance with the study protocol.

REFERENCES

1. Mehta SJ, Asch DA, Troxel AB, Lim R, Lewey J, Wang W, Zhu J, Norton L, Marcus N, Volpp KG. Comparison of subjects’ actions during a prescribed activity can yield a significant amount of data that can be used to improve the ability of a study to discriminate between arms of the study and interpret results.

FINANCIAL DISCLOSURES

This study was funded by Nu Skin Enterprises, Inc. DK, MR, TD, MB and HK are employees of Nu Skin Enterprises. ZD is employed by Dermatology Consulting Services.