

Cosmeceuticals

Efficacy and Influence on Skin Tone

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KEYWORDS

- Cosmeceuticals • Skin tone • Postinflammatory hyperpigmentation • Topical formulations
- Dyspigmentation

KEY POINTS

- Cosmeceuticals form an important part of the over-the-counter skin treatment market, especially in persons of African descent.
- Some industry forecasters believe that the cosmetics industry has hit a glass ceiling in new cosmeceutical development, largely because of the failure of the US Food and Drug Administration to develop a new classification system.
- It is believed that a new quasidrug category, similar to the Japanese designation, would allow the introduction of more robust active ingredients into cosmeceuticals.
- Although claims are made for various cosmetic ingredients such as vitamin C and E, there is a lack of scientific evidence of their efficacy.
- Dermatology will move the cosmeceutical category forward, and the cosmeceutical category will move dermatology forward.

INTRODUCTION

Cosmeceuticals and the Regulatory Environment

Cosmeceuticals, from a consumer standpoint, are believed to be a category of skin care products that function as active cosmetics going beyond mere adornment and scenting of the skin. Yet, from a regulatory standpoint, cosmeceuticals is an unrecognized term with no meaning, because cosmeceuticals are purely cosmetics and viewed as such in the United States.¹ In dermatology, cosmeceuticals are believed to encompass the topical application of biologically active ingredients, which affect the skin barrier and overall skin health.² The ability of cosmeceuticals to enhance skin functioning depends on the incorporation of ingredients into a topical vehicle that maintains the integrity of the active, delivers the active in a biologically appropriate form, reaches the target site in sufficient quantity to exert an effect, and

properly releases the ingredient from the carrier vehicle. Clinical testing using the scientific method for efficacy assessment must be performed to document the value of the cosmeceutical.

Because cosmeceuticals are considered cosmetics, safety to the consumer is of key importance. Most cosmeceuticals are formulated from ingredients that already have a proven safety record in the marketplace. This situation may be because of their extraction from foods, such as topical lycopene from tomatoes or topical avocadoin from avocados. Alternatively, extensive animal testing may be undertaken by the raw material supplier to determine that the new ingredient is appropriate for human use. In the case of botanicals, most are assumed safe based on their ubiquitous nature. To avoid regulatory issues, most cosmeceuticals use ingredients that are generally recognized as safe, which is how cosmetics are also formulated.

No relevant conflicts of interest.

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Dermatol Clin 32 (2014) 137–143

<http://dx.doi.org/10.1016/j.det.2013.12.002>

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This article discusses cosmeceuticals and their efficacy. It examines available testing methodologies used to better understand how cosmeceuticals affect the skin and the various mechanisms of action cosmeceuticals use to improve skin appearance. The discussion focuses on skin tone and what this term means in persons of African descent and how problems can be avoided when using cosmeceuticals in skin of color.

Development of Scientific Substantiation

Cosmeceutical formulations must be tested for 3 important reasons: (1) to determine that they provide a benefit that is perceived by the consumer; (2) to establish that the formulation is safe and free of adverse reactions; and (3) to support marketing claims. Consumers purchase a new cosmeceutical once based on the name, promises made on the packaging, recommendations from advertising or acquaintances, appearance, and fragrance. However, the consumer does not repurchase a product that is not perceived to work. In many regards, the consumer is the most discriminating grader when it comes to cosmeceutical preparations. Most cosmetic companies carry out extensive consumer testing before a product is released into the marketplace. This testing is then backed up by dermatologist-led testing to determine efficacy but also to ensure that the product does not cause any adverse reactions, such as allergic contact dermatitis, irritant contact dermatitis, comedogenicity, or acneogenicity.³ Testing is sometimes performed in conjunction with an ophthalmologist to ensure that no eye issues arise as a result of accidental eye instillation.

In addition to clinical testing to assess consumer subjective evaluations and dermatologist objective evaluations, noninvasive testing is also performed to confirm the visual and tactile observations. Noninvasive testing is used because it does not enter the body and evaluates skin performance by placing electronic sensors or devices on the skin to gain insight into skin functioning. This type of testing allows product evaluation without the traditional biopsy that is used for medical diagnostic purposes. If a cosmeceutical manufacturer made claims based on biopsy information, such as “this cream increases type III collagen production,” it could be considered a drug. Noninvasive testing avoids this conundrum and allows efficacy evaluations in a scientific manner without entering the skin.

The need for scientific substantiation of cosmeceutical performance has led to the development of skin bioengineering. Skin bioengineering

develops equipment to assess skin functioning before and after product application to detect small changes that might not be visually or tactilely perceived (**Box 1**). Sometimes, clinical studies must be run in 4 to 12 weeks for practical reasons, and it is hoped that small skin improvements might become magnified over time with continued use. Usually, noninvasive results parallel clinical results in an efficacious formulation.

The most common claim for substantiation in cosmeceuticals is skin moisturization. Moisturization can decrease fine lines of dehydration, improve skin smoothness, decrease itching, and increase light reflection from the skin surface. All of these benefits enhance the visual, tactile, and sensory functioning of the skin. Corneometry is the technique used to determine how much water is present in the skin, which is one way of assessing skin moisturization. Corneometry uses a probe that emits and receives low current electricity. The electrical current is transmitted into the skin by the sending portion of the probe and received. This measure is an indication of the electrical conductivity of the skin. Because water is an excellent conductor of electricity, skin water content can be measured. More water in the skin correlates with better skin appearance and functioning, translated to the consumer as better skin moisturization. Thus, corneometry is the noninvasive bioengineering assessment technique used to substantiate claims of enhanced skin moisturization.

Moisturization can also be evaluated by assessing the integrity of the skin barrier. An intact skin barrier prevents water loss and encourages superior skin moisturization, whereas a damaged barrier encourages transepidermal water loss. The noninvasive test to measure transepidermal water loss is evaporimetry.⁴ Evaporimetry uses a probe that senses the humidity of the air directly above the skin. The probe contains 2 humidity meters, which are placed at known distances above the skin. The water vapor passes between the 2 fixed distance humidity meters through an orifice of

Box 1

Bioengineering tests relevant to cosmeceutical testing

- a. Corneometry
- b. Evaporimetry
- c. Silicone replicas
- d. Chromametry
- e. Laser Doppler flowmetry

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