

Cosmetic commentary: Is bakuchiol the new "skincare hero"?

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Abstract

Bakuchiol is a new trendy ingredient in cosmetic skincare products, claiming to have similar efficacy to over-the-counter vitamin A derivative products. The manufacturers use clinical trial data to support the claims that bakuchiol has anti-aging properties. This commentary critically appraises these clinical trials. Dermatologists need to be aware of and clinically appraise evidence for these types of cosmetic ingredients in order to provide accurate recommendations to their patients and the consumer. The integrity of our profession and the well-being of our patients depend on it.

KEYWORDS

anti-aging, cosmetic dermatology, facial rejuvenation, Tretinoin

The cosmetic skincare industry is on a seemingly never-ending quest to discover the nonprescription "holy grail" of anti-aging skincare. As dermatologists, we have an obligation to our patients to critically appraise these products to the best of our ability, before we either promote or dismiss their use.

A recent trendy ingredient is bakuchiol. This is the claim: "*Bakuchiol is the gentler yet just as powerful sister to retinol.*"¹ In this context, "retinol" being used to describe over-the-counter vitamin A derivatives found in cosmetic skincare products, not the active, prescription only retinoic acid. Bakuchiol is derived from the seeds and leaves of the plant *psoralea corylifolia*.² It is claimed that it is a "functional analogue of retinol" based on its effects on gene expression profiles of skin cells in vitro.³

Despite its presence in an array of new cosmetic skincare products, coupled with aggressive marketing campaigns and a retail price point implying significant efficacy, there have been only two studies performed looking at bakuchiol 0.5% cream and its effects on the signs of skin aging.

The first one³ had 17 females apply bakuchiol 0.5% cream as a finished skincare product twice daily for 12 weeks. This study has multiple methodological issues but the most important is the lack of a vehicle control. The effect of vehicle or placebo in clinical trials is well recognized and can be relatively high with topical treatments, similar that observed in analgesic or antidepressant trials.⁴ The vehicle used for application of the ingredient studied is almost certainly going to have some occlusive or emollient properties and, hence, will have a temporary as well as potentially longer-term

physiological effect on the skin.⁵ Moisturizing alone could have certainly accounted for the improved smoothness of skin and decrease in the appearance of fine lines seen in the study population over 12 weeks. Robust clinical trial evidence suggests that prescription topical tretinoin treatment improves the clinical appearance of aged skin only after 3 to 6 months of treatment,⁶ with many showing most of the clinically noticeable improvement to occur after 6 months.⁷ Though profilometry is a fairly robust way to monitor topographical skin changes,⁸ it is still hard to believe that significant measurable improvement could be seen after 12 weeks of use of a topical that is almost certainly at least 20 times less efficacious than tretinoin, if one is to believe that bakuchiol is indeed "just as powerful as retinol."⁹ Combined with the small sample size and the lack of reported clinical baseline measurements in the studied parameters, the findings reported in this trial can be viewed as meaningless and do not provide evidence that bakuchiol itself imparts any meaningful effect on the signs of skin aging.

The second paper¹⁰ compares bakuchiol 0.5% cream to retinol 0.5% cream over 12 weeks in 44 patients. This study was published in the BJD which is a reputable journal, and it has many positive aspects to its design (clear primary endpoints, power calculation, correction for multiple comparisons) but there are two major methodological problems which potentially invalidate the findings.

First, this was meant to be a double-blinded study but the protocol is that retinol is used once a day at night and the bakuchiol is used twice daily. How was this blinded? Did the retinol group use a vehicle in the morning and retinol at night to ensure it was indeed

double-blinded? This is not explained and could represent an important source of bias.

Second, and perhaps most important, the study design is that of a superiority study but the hypothesis stated in the paper is that bakuchiol is similar in efficacy to retinol, not that it is better. To show similar efficacy, one would need to do a noninferiority trial. The study did not show that bakuchiol is better than retinol so therefore this is a failed or negative study. The investigators conclude that "*bakuchiol is comparable with retinol in the ability to improve photoaging*" but that is a misleading and incorrect statement because that is not what the study showed; it was designed to show superiority, and it did not show that. In other words, the hypothesis does not agree with the study design. Why would that be? Perhaps the authors knew that bakuchiol would not show superiority so if that had been stated as the hypothesis, they would have been forced to say that this was a negative study. Also, to show similar efficacy one would need to use a noninferiority design and that would necessitate more patients, more time, and potentially more money.

These trials are what I refer to as "marketing" studies: They are performed purely to be used as part of the marketing and sale of a product, not to provide any real, informative scientific data. Is bakuchiol the new "skincare hero"? Not based on these publications. It is concerning to see a handful of dermatologists promoting the use of this ingredient when there is no evidence base for its purported benefits.

It is relevant to add that bakuchiol has already been shown to be a contact allergen² in a case report of a 33-year-old woman with a 1-year history of dermatitis of her face secondary to a 0.1% bakuchiol cosmetic product.

As the billion-dollar skincare industry continues its rapid growth, we must both maintain the integrity of our profession and protect the consumer from being misled by critically appraising products that make significant medical claims.

CONFLICT OF INTEREST

None.

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