Study To Investigate If Embody's Retinol Gummies Improve The Early Signs Of Skin Aging And Overall Skin Health

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Abstract:

Retinol has been found to have positive effects on overall skin health, skin texture, and even potentially brightening effects of the skin. The effect of orally administered retinol on the skin was studied in 31 women who consumed two retinol gummies daily. Effects of overall skin appearance, skin hydration, reduction in dark spots, and skin sensitivity were measured through study questionnaires at the four-week and eight-week mark. Over the course of the retinol gummy intervention, there was a significant improvement in skin appearance, hydration, fine lines, texture, and dark spots after the eight-week study period as perceived by the study participants. In conclusion, this study suggests that regular intake of Embody's retinol gummy improves the skin's hydration and induces skin changes that can be described as anti-aging.

1. Background and purpose

The skin is the human's largest organ. The aging of the skin is a biological process consisting of two types: 1) intrinsic/chronological aging, the aging process in the body that is inevitable; and 2) photoaging, which is the premature aging process due to exposure to ultraviolet radiation. As humans age, the skin becomes drier, less elastic, and thinner, as the skin's natural rejuvenation process slows down with age [1]. To combat and slow down the aging of the skin, many different retinoids - natural and synthetic - have been tested and explored in a clinical setting for the treatment of aging. In fact, many of these treatments have shown an improvement in skin aging [2], and as a result, many individuals take retinoids for healthier, younger-looking skin, as retinol may reduce fine lines and wrinkles. This happens as retinoids increase the production of collagen, and also stimulate the production of new blood vessels in the skin, which improves skin color [3].

The first retinoid, tretinoin (brand name Retin-A), was initially used as an acne treatment in the 1970s. Researchers then discovered that it also evens pigmentation, fades actinic keratosis spots, age spots, and speeds the turnover of the superficial skin cells [3].

Embody has developed a retinol gummy with the aim to improve the appearance of early signs of aging, such as fine lines, dark spots, and sagging. At the same time, Embody's retinol gummy has also the goal to reduce the overall frequency of adult acne and an improvement of overall skin health by promoting hydrated, brightened skin. In this phase, Embody planned to collect self-reported outcomes and photographic images to understand the assessment of the efficacy of treatment from the participant's perspective, and if participants would see an improvement in their fine lines, wrinkles, dark spots, and sagging. Embody also wanted to find out if their gummy helps to reduce the overall frequency and intensity of adult acne. Based on a review of existing literature and previous studies, retinol has been found to have positive effects, however, due to study limitations, there are also conflicting results. Therefore, in this study, participants received Embody's retinol gummy to understand if the Embody retinol gummy has an impact on the participant's skin, and even potentially reduces fine lines, dark spots, and sagging of the skin, as well as help to reduce the overall frequency of adult acne, and also to understand concepts considered essential by individuals taking retinol products.

2. Study Objectives

- The primary objective of this study was to understand if Embody's retinol gummy is capable of improving the appearance of early signs of aging such as fine lines, dark spots, and sagging, and to determine if it helps to improve the overall skin health by promoting hydrated, brightened skin for study participants.
- The secondary objective was to examine the interpretation and understanding of items in the Embody questionnaires/surveys by participants, and the relevance of these questions to the participants

3. Participant Definition

A total of thirty-five (35) individuals were recruited for this study. Enrolled participants were either male or female, between 18-45 years old, and generally in good health. Participants were also included when they experienced adult acne, as well as early-stage wrinkles that were not treated with topical or oral prescription drugs.

4. Study Design

This was a single group, non-randomized, non-controlled interventional treatment study to evaluate the efficacy of Embody's retinol gummy, an oral supplement in healthy male and female individuals with normal skin that shows signs of early aging such as early wrinkles, and currently don't use any prescription products that are treating their skin. It was hypothesized that the test product, which is specifically designed as retinol gummy to fight early signs of aging and reduce the overall frequency of adult acne, will present a favorable result to fine lines and wrinkles, as well as adult acne. The study was conducted fully virtual and a technology platform was utilized to screen, enroll, and capture study data of the participants. The study duration was eight weeks. The study was also utilizing "before and after pictures" through standardized digital photographs.

4.1. Study Procedures - intervention/treatment

Individuals with normal skin but early signs of aging (fine lines or wrinkles) or adult acne were chosen to participate in the study. Participants were advised to discontinue any other oral supplement prior to beginning with the Embody retinol gummy ("washout phase"). Each day for the duration of the study, the participant took two gummies, either in the morning or at night. Participants took photographs of their faces to monitor progression and to serve as a comparison to the baseline photograph that they took before the study started. These photographs were taken at week four and week eight. However, these images were not clinically graded. At baseline and at weeks four and eight, the participants completed a survey to determine the impact that Embody's retinol gummy has on their fine lines, wrinkles, adult acne (if applicable), as well as overall skin health and feel.

5. Purpose

The goal when creating the oral retinol gummy was to use proformed vitamin A esters because they are more bioavailable and bioefficient than proformed carotenoids. Higher efficiency and bioavailability meant better results. The other ingredients in the gummy are known to support cell metabolism. B vitamins, in particular, are important for cell health and cell growth. Vitamin C is a mandatory cofactor for the production of collagen, which retinoids encourage. Assessing the most important ingredient (Vitamin A) individually, the study team expected several key benefits when it came to the overall skin health of the study participants.

Isotretinoin (Vitamin A derivative) for the Treatment of Acne

Isotretinoin (brand name Accutane) has been used to treat cystic acne since its FDA approval in 1982 [5]. Isotretinoin, also known as 13-cis-retinoic acid, is a vitamin A derivative that has been proven to be effective as a treatment for severe cystic acne that has not responded to other treatments. While a successful treatment, oral isotretinoin has been linked to a long list of side effects ranging from mild to life-threatening [4]. Prescription doses of oral isotretinoin are calculated based on body weight and typically start at 0.5 mg/kg/day [5]. For a 170 lb woman (the average American woman according to the CDC), this translates to 38.55 mg/day or 38,550 mcg daily. Treatments are usually completed within 4-6 months to prevent chronic hypervitaminosis A. Patients receiving oral

isotretinoin must remain under careful doctor supervision. Oral isotretinoin is known to cause birth defects and increase the likelihood of miscarriage; it is important for female patients to prevent pregnancy while taking oral isotretinoin and for 1-2 months after discontinuing use [6]. At only 2.5% of the concentration, the Retinol Gummy produces a diluted version of the results of oral isotretinoin. Studies have shown that low-dose oral isotretinoin was effective at reducing the symptoms of cystic acne [7]. Retinyl acetate, being structurally similar to isotretinoin, would logically produce a similar result.

Vitamin A Supplementation for the Treatment of Photoaging

Topical retinoids have been well documented as treatments for symptoms of photoaging including uneven pigmentation, loss of dermal structure, damage to collagen and elastin production, and wrinkles [8] . Oral retinoids such as isotretinoin have similarly been studied for their role in preventing and reducing photoaging symptoms [9]. In a 2015 study, researchers observed an increase in collagen and elastin fiber densities in 65% of patients after a 12-week course of treatment with 20 mg isotretinoin [5]. The results are visible in both histological analysis and photographic comparisons. In addition to its role in stimulating cell turnover, vitamin A also contributes to free radical neutralization through its role as an antioxidant. Studies have linked increased antioxidant levels in the skin to a reduction in the appearance of aging [9,10].

6. Study population

Variable	*Single study arm (n=35)*
Study completed by participant	*31*
Study dropouts	*4*
Age	
Average	*35.9*
Median	*36*
Sex	
Men	*5 (16.13%)*
Women	*26 (83.87%)*
Level of skincare knowledge (0-5 scale) with 0 being the lowest possible score	
Average	*2.3*
Median	*3*
Use of topical retinol skincare product before study start	
Yes	*1 (3.23%)*
No	*30 (96.77%)*

Table 1. Demographic Characteristics of 35 Volunteers Receiving Embody's Retinol Oral Product

7. Data Analysis/Methods

To document and elicit the key concepts, all recorded surveys were analyzed using qualitative analysis software. No statistical testing was performed, as this study is qualitative in nature with a primary purpose of understanding the key treatment attributes and impact on individuals through several surveys and skin image capture. After adjusting for missing/invalid data, thirty-one participants were included in the analysis. Outcomes were analyzed using descriptive statistics and stratified by exposure time on a scale from 0-5 with 0 being the lowest and 5 being the highest possible score:

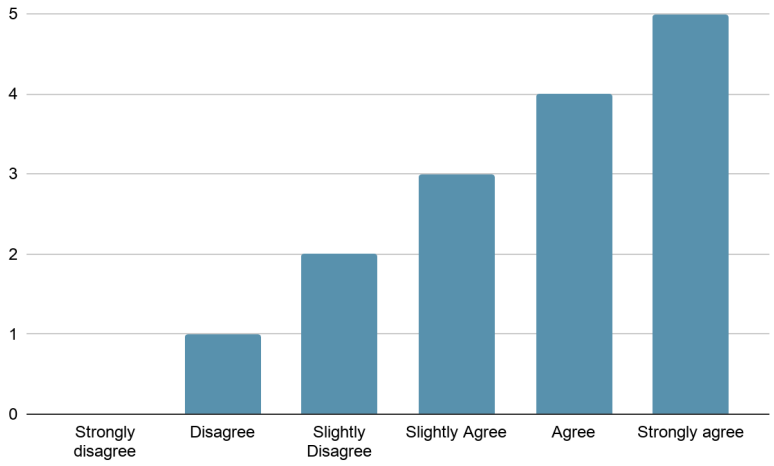

Table 2: Rating scale for participant-reported outcomes survey

8. Results

The use of Embody's retinol gummy was associated with an overall healthier-looking skin and reduction in dark spots through participant self-reported data after the eight-week study period. Participants also reported increased hydration of the skin and an improvement in the appearance of fine lines. After the eight-week intervention period, 93.33% of participants reported that they enjoyed Embody's retinol gummy results. In addition, the following benefits were reported by the study cohort:

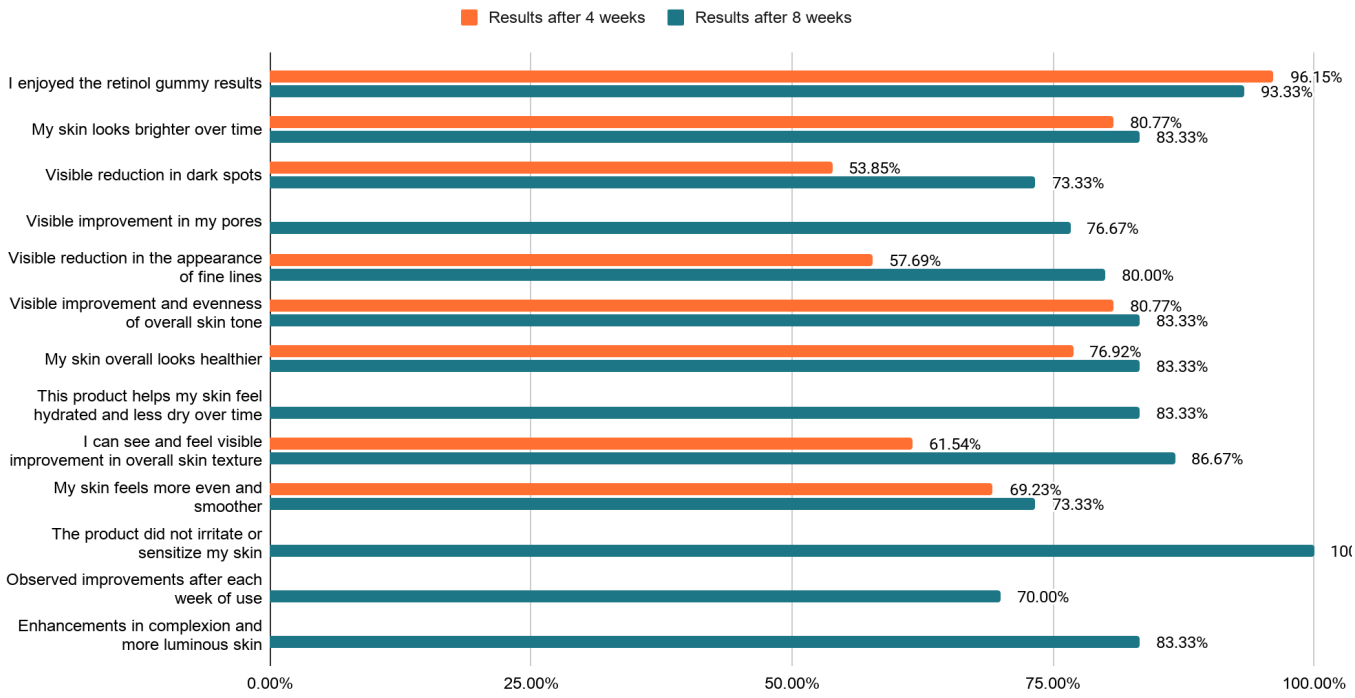

Table 3: Study results after four weeks and eight weeks

In addition to the four-week and eight-week results, a first impression survey was collected to evaluate the texture and taste of the retinol gummy. Results have been very strong with 32 out of 33 participants reporting that they enjoyed the texture and taste of the gummy.

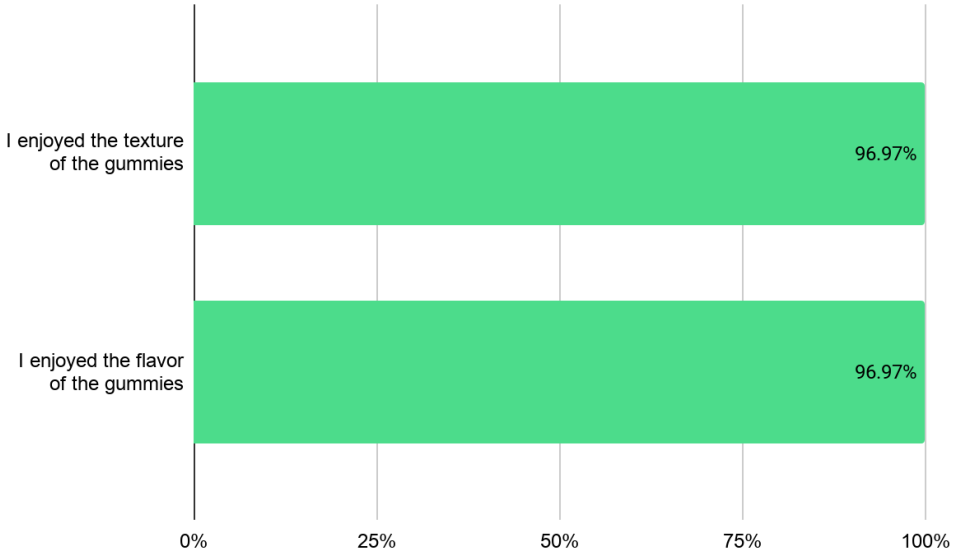

Table 4: Participant impression after the first use of the retinol gummy.

9. Adverse effects

One study participant reported a higher sensitivity to UV light and a related sunburn of the arm. The participant had a pre-existing condition, which in addition to the retinol gummy intake, might have caused an even higher sensitivity to UV light. After consulting with the Investigator of the study, the participant decided to discontinue the study. No other study participant reported a higher level of UV light sensitivity or a related concern.

10. Conclusion

The results of this study indicate that regular intake of a retinol gummy can provide improvement in skin tone and texture, improvements in the lightening of aging-related dark spots, and improved appearance of healthy-looking and less dull skin. Regular intake of oral retinol was found to be effective and tolerated well by the participants in the study. These findings show promise for the use of a retinol gummy as part of a healthy skincare routine.

11. References

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