Dermatology Practical & Conceptual

Keep an Eye on At-Home Devices: Energy-Based Acne and Anti-Aging Devices are Associated with Ocular Adverse Events in a Retrospective Analysis Using the MAUDE Database

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Introduction

Non-pharmacologic therapies, including at-home energy-based devices, are popular treatment options for acne and photoaging [1]. In a 2022 survey study of 1,571 outpatient dermatology patients, 74.41% reported treating their acne with non-pharmacologic, complementary and alternative medicine treatments, with 41.86% using them because they are natural, safe, and without side effects [2]. Energy-based devices are available over-the-counter following 510 (k) premarket notification approval by the US Food and Drug Administration (FDA) [3]. Since these devices undergo much less stringent safety and efficacy endpoints than prescription medications, but are often sought out by patients and dermatologist recommended, we aimed to characterize adverse events (AEs) associated with at-home acne and anti-aging energy-based devices [4].

Methods

We analyzed medical device reports (MDRs) detailing at-home acne and anti-aging devices submitted to the FDA Manufacturer and User Facility Device Experience (MAUDE) Database, which collects AE reports submitted to the FDA related to medical devices, 2013-2023.

Results and Discussion

There was a total of 87 at-home acne and anti-aging energy-based devices MDRs, and mean patient age was 41.3 years, with 52% females. Most MDRs related to injuries (N = 75, 86%), with fewer due to device malfunction (N = 12, 14%). Fifty-four MDRs required a medical visit (N = 54, 62%), and 70% (N = 61) of MDRs required

Table 1. Characteristics of Adverse Event Reports Secondary to At-Home Acne and Anti-Aging Devices 2013-2023

Adverse Event Information	N (%)
# of Events	87
Device Type:	
Light-based device targeting acne	49 (56%)
Transcutaneous electrical stimulator device targeting photoaging	18 (21%)
Light-based device targeting photoaging	11 (13%)
Radiofrequency coagulation device targeting photoaging	3 (3%)
Light-based device targeting both acne and photoaging	3 (3%)
Other[a]	3 (3%)
Medical Complication[b]	
Ocular injury	28 (32%)
Rash[c]	23 (26%)
Headache/migraine	16 (18%)
Dyspigmentation	11 (13%)
Burn	8 (9%)
Pain	8 (9%)
Arrhythmia	6 (7%)
Dizziness	5 (6%)
Burning/tingling sensation	4 (5%)
Light sensitivity	4 (5%)
Swelling/edema	4 (5%)
Other[d]	41 (47%)
Outcome:	
Required medical visit	54 (62%)
No medical visit required	3 (3%)
Need for medical visit not reported	30 (34%)
Management/Treatment:[b]	
Non-antibiotic prescription medications	16 (18%)
Hospitalization/disability	9 (10%)
Over-the-counter treatment	8 (9%)
Surgery/invasive procedure	7 (8%)
Advanced imaging	6 (7%)
Antibiotics	5 (6%)
Cardiac/blood pressure monitoring	4 (5%)
Laboratory tests	2 (2%)
Glasses/eye patch	2 (2%)
None	2 (2%)
Not listed	47 (54%)

[a]Other includes electrically powered dermabrasion brush, microcurrent facial device, electrically powered muscle stimulator, all (N = 1); [b]Could be classified into >1 category. [c]Rash includes skin irritation/inflammation/peeling (N = 10, 11%), erythema (N = 7, 8%), rash (N = 2, 2%), dry skin (N = 2, 2%), hypersensitivity/allergic reaction (N = 2, 2%). [d]Other includes: cyst, electric shock, laceration, scarring, pruritus (all N = 3), dysphagia/odynophagia, seizures, hemorrhage/bleeding (all N = 2), hair loss/hair thinning, miscarriage, physical asymmetry, tooth fracture, dehydration, bradycardia/hypotension, palpitations, irregular heartbeat, muscle/tendon damage, acne, ulcer, loss of consciousness, insomnia, dyspnea, chest pain, anxiety, syncope, nausea, gum and teeth sensitivity, fatigue (all N = 1).

Table 2. List of device technology

Device technology
Red light
Blue light
Orange light
Light-emitting diode
Near infrared and infrared light
Deep thermal heating
Fractional non-ablative diode laser
Microcurrent
Radiofrequency
Radiofrequency assisted microneedling
Muscle stimulation
Topical heating
Cryotherapy/cryothermal
Deep thermal heating
Dermabrasion

management. Ocular injury (N = 28, 32%), rash (N = 23, 26%), headache/migraine (N = 16, 18%), and dyspigmentation (N = 11, 13%) were the most common AEs. Four ocular injury cases (14%) required hospitalization, 3 eye surgery (11%), and 3 an antibiotic (11%).

We found that ocular injury, rash, headache/migraine, and dyspigmentation were the most common AEs associated with at-home energy-based devices targeting acne and photoaging, with most patients requiring medical attention. While 22/28 MDRs reported ocular injuries that were associated with a device recalled in 07/2019, 16/22 followed the recall date, and 6/28 were associated with devices that are still on the market.

While the total number of patients using these devices is unknown, AEs associated with these devices were previously thought to be relatively uncommon. In a systematic review on safety and efficacy of home-use dermatologic devices including 3 randomized controlled trials specific to light emitting acne devices (N = 12), AEs were reported in only 3 patients (2.3%), including xerosis (N = 2) and erythema with desquamation (n=1) [4]. Similarly, in an unblinded, non-controlled trial of 22 patients using an LED device to treat photoaging, no AEs were reported during or after therapy [5].

Limitations include sample size, missing information in MDRs, and unknown number of total patients using these devices.

Conclusion

In summary, the most common AEs reported in patients using at-home acne and anti-aging energy-based devices were ocular injury, rash, headache/migraine, and dyspigmentation. As consumer demand for at-home devices increases with interest in alternative medicine, awareness of such AEs among dermatologists is critical to educate patients who may opt to purchase them. Patients may be counseled on ocular AE risk with such devices, particularly those with pre-existing eye disease or who take medications associated with ocular photosensitivity. Dermatologists are important advocates for patient safety and can encourage patients to report AEs associated with the use of such devices to the FDA.

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