Over-the-counter light therapy for acne: a cross-sectional retrospective analysis

Divya Seth[1] MPH, Sophie Wang[1] BS, Harib H Ezaldein[2] MD, Miesha Merati[2] DO, Jeffrey F Scott[2] MD

Affiliations: [1]Case Western Reserve University School of Medicine, Cleveland, OH, [2]Department of Dermatology, University Hospitals, Cleveland Medical Center, Cleveland, OH

Corresponding Author: Divya Seth MPH, 2109 Adelbert Road, Cleveland, OH 44106, Email: dxs654@case.edu

Abstract Acne vulgaris affects a large portion of the population and drives many patients to seek over-the-counter (OTC) treatments. Light-emitting diode (LED) therapy has recently emerged as a potential therapeutic option for inflammatory acne. We used the U.S. Food and Drug Administration (FDA) 510(k) premarket submission database to assess the growth in OTC LED therapy devices for treatment of acne. We also used Google Trends data in searches for "acne light therapy mask" to characterize growth in consumer interest in these devices. Overall, 35 LED devices received pre-market approval from 2000 to 2018, with a peak in approvals in 2016. Similarly, there was a dramatic increase in public interest in these devices in 2016. Only two devices were associated with company-approved trials. The current regulatory process requires little evidence to substantiate specified uses and a better understanding of practice guidelines and the efficacy of this treatment modality is required.

Keywords: acne, light therapy, FDA approval, 510(k), Google Trends

Introduction

Acne vulgaris affects 70-87% of the population, and the potential for acne scarring has significant psychosocial impact, driving patients to pursue many over-the-counter (OTC) treatments [1]. Treatments for inflammatory acne vary widely; light-emitting diode (LED) therapy has recently emerged as an accessible option. Absorption of light by *Propionibacterium acnes* results in the porphyrin-dependent production of reactive oxygen species, causing oxidative stress that can kill bacteria and reduce follicular obstruction [2]. However, the evidence for effective OTC blue LED therapy for the treatment of inflammatory acne is limited.

To market a device in the United States (U.S.), manufacturers must first seek prior pre-approval from the U.S. Food and Drug Administration. Through a 510(k) premarket submission, manufacturers must demonstrate that their device is substantially equivalent to a legally marketed predicate. As the device approvals process is not well characterized in the literature, we sought to assess the growth in OTC LED therapy devices for treatment of inflammatory acne.

Methods

In this cross-sectional retrospective analysis, we reviewed all LED light therapy devices (product code "OLP") between January 1, 2000 and July 24, 2018 in a publicly available U.S. FDA database for premarket approval of devices. A literature search for research associated with each device was performed using PubMed. Google Trends search volume index (SVI) for the term "acne light therapy mask" was assessed from 2010 to 2018 through the Google Trends website (trends.google.com) as a proxy for public interest in the light therapy acne devices [3]. Google Trends' SVI provides a normalized search frequency relative to searches for the same term over time that is presented on a scale from 0-100. Descriptive analysis was performed on the following data: number of devices marketed, manufacturing corporations, indicated use, and research studies.

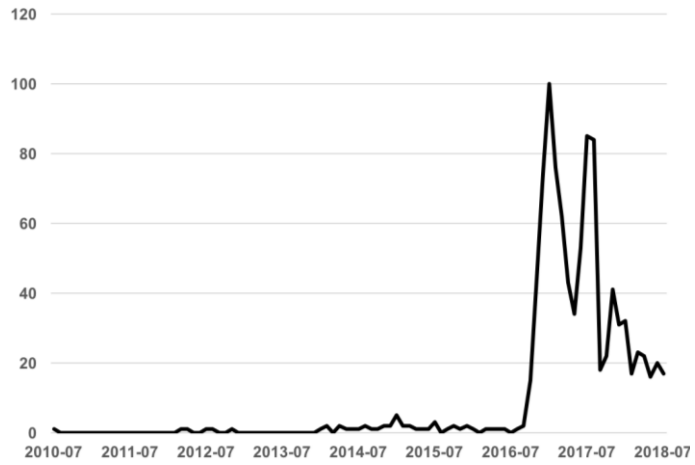

Figure 1*: Google trends search volume index (SVI) for "light therapy mask for acne" increased in 2016. Search volume index is calculated in relation to all searches for the term, with a range of 0 to 100.*

Results

A total of 35 devices received 510(k) pre-market approval from 2000 to 2018, with the first device approved in 2009. There was an increase in device approvals from one in 2009 to seven in 2016. Google search trends for "acne light therapy mask" spiked in 2016 (from SVI=1 in January 2016 to SVI=100 in January 2017, **Figure 1**).

The majority of devices were similar in their methods of action. A total of 24 devices specified the use of blue light (410-465 nm) for mild-to-moderate inflammatory acne. Nine devices did not specify an exact method of action. One device specified "thermal energy" as the method of action and one device emitted both red light and infrared radiation. Fifteen devices additionally specified emission of red light (605-660nm) for treatment of periorbital wrinkles. Only two devices (Illumask and Tanda) were associated with company-sponsored trials showing significant improvement in inflammatory acne lesions following light therapy mask treatment [4, 5].

A growing market of OTC LED light therapy devices for inflammatory acne are available to consumers, with a marked rise in devices from 1 in 2009 to 35 in 2018. Moreover, the public's interest in light therapy devices for acne is increasing, as demonstrated through a dramatic peak in Google searches for such devices in 2016 (**Figure 1**). Although device-specific research remains extremely limited, a few studies indicate efficacy of blue light therapy in reducing inflammatory acne lesions. According to a recent Cochrane review, blue-red light therapy versus placebo for inflammatory acne favored blue-red light based on patient-reported outcomes, as well as a reduction in non-inflammatory lesions compared to topical treatment with 5% benzoyl peroxide [2]. However, these findings were not reproducible and there remains a need for rigorous assessment of OTC LED light therapy devices [2].

Conclusion

The current regulatory process requires little evidence to substantiate specified uses. For example, no evidence was available for any of the devices and their ability to treat periorbital wrinkles. Therefore, adverse effects of these devices may be under-reported and a better understanding of practice guidelines and the efficacy of this treatment modality is required.

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