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OTC acne devices

Home-use technology expands to offer better options for patients

Acne affects up to 90 percent of teenagers at some point during their impressionable adolescent years. Considering this high prevalence and the considerable psychosocial impact of acne, it is not surprising that the search for more convenient, safe and effective treatment options continues.

Home-use devices purportedly possess these attributes. Well-controlled trials using these devices are limited, however, and treatment specifications are not well defined.

Therapeutic options for acne are abundant, including both topical and systemic prescription agents. In addition, an even more plentiful array of over-the-counter (OTC) and cosmeceutical options exist, rendering treatment decisions confusing for both physicians and patients. In most cases, continuous therapy for months, or even years, is needed to prevent recurrence.

Topicals, systemic antibiotics and oral retinoids remain the mainstay of therapy for acne, but alternative options are gaining popularity. In-office laser and light procedures, including photodynamic therapy (PDT), intense pulsed light with vacuum suction, pulsed dye laser and infrared devices have all shown some short-term efficacy. These procedures are still in the infancy of their development and responses are generally short-lived, necessitating multiple office visits.

In-office procedures can also be inconvenient and costly, as few (if any) are covered by insurance. For those acne sufferers who do not wish to have the downtime associated with in-office procedures and whose schedules preclude frequent visits to the dermatologist, home-use devices may provide the answer they're seeking.

Home-use devices are becoming mainstream as the idea of "self-treatment" becomes more acceptable. While these devices are easy to use, convenient, safe and affordable, questions remain regarding their efficacy.

These devices are not subject to the same stringent Food and Drug Administration (FDA) regulations as prescription drugs. Many devices come to market with little to no efficacy data, as companies focus on demonstrating safety. Some OTC devices do not have FDA clearance, as their claims do not designate them as medical devices, thus eliminating this requirement.

LED options

The in-office light-emitting diodes (LED), including red and blue wavelengths, provide at least some improvement of acne (Elman M, Slatkine M, Harth Y. *J Cosmet Laser Ther.* 2003;5(2):111-117). Light-emitting diode treatments are painless, quick, safe and easy to administer, making them a logical choice for the OTC device industry.

Light-emitting diode units are currently the most popular OTC devices for the treatment of acne. Blue light's effectiveness for inflammatory acne may be related to its ability to activate endogenous porphyrins produced by *Propionibacterium acnes*, stimulating the formation of reactive oxygen species and ultimately resulting in bacterial cell death. The range of visible blue light used in these devices is generally 405 nm to 420 nm. Blue light may also be effective for acne due to its anti-inflammatory effects via reduction of interleukin-1 (IL-1; Shnitkind E, Yaping E, Geen S, et al. *J Drug Dermatol.* 2006;5(7):605-611).

Red light (628 nm to 635 nm) penetrates more deeply than blue light, reaching the sebaceous glands, but it is not as effective at activating porphyrins. Red light's activity in treating acne is thought to be due to its anti-inflammatory properties, as it has been shown *in vitro* to downregulate genes encoding pro-inflammatory cytokines such as IL-1 (Whelan HT, Buchmann EV, Dhokalia A, et al. *J Clin Laser Med Surg.* 2003; 21(2):67-74).

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Safety features

Many of the home-use devices include safety features, such as the requirement for skin contact prior to light activation, thus preventing direct eye exposure. This is important, as blue light has been associated with age-related macular degeneration (Kernt M, Walch A, Neubauer AS, et al. *Clin Experiment Ophthalmol.* 2011. Epub Aug 18). Accidental chronic exposure with these lights is still possible, however, and patients should be instructed to avoid the periocular area and to keep their eyes closed during treatments. Unfortunately, some of the devices do not come with eye shields.

Requiring contact with the skin also allows standardization of the distance from the lights. Increasing the distance from the light source to the treatment area will decrease total treatment fluence, compromising efficacy.

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Examining efficacy

Most efficacy data of home-use light devices is based on studies using the in-office versions. Blue light alone (BLU-U, DUSA) has been shown to be effective for treating inflammatory acne and less efficacious at reducing noninflammatory lesions (data accessed from www.clinicaltrials.gov). The total fluence per treatment used in this unpublished study was 10 J/cm^2 (1,000 seconds on a 10 mW/cm^2 device).

Red light and blue light combination has the best clinical data for acne, with inflammatory lesions responding more consistently than noninflammatory (Papageorgiou P, Katsambas A, Chu A. *Br J Dermatol.* 2000; 142(5):973-978). Consistent data for noncoherent infrared light alone does not exist for acne.

Fluence, irradiance

While employing an appropriate laser wavelength is important for home-use acne devices, total fluence delivered is also crucial — but less well-described — in the literature. Total fluence (J/cm^2) is based on the irradiance of the device (W/cm^2) and the duration of treatment (seconds). The lower the irradiance of the device, the longer the treatment time needed to obtain an equivalent total fluence.

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The irradiance of the FDA-cleared OTC LED devices varies significantly, and one cannot judge the irradiance solely based on the number of LEDs. Each LED has its own irradiance, so totals will vary. In addition, the distance of the device from the skin during treatment will also influence the total fluence.

Generally, in-office LED systems for acne deliver 10 J/cm^2 to 70 J/cm^2 per treatment session. Exact dosimetry for PDT and light-alone treatments for acne is still not well delineated (Sakamoto FH, Torezan L, Anderson RR. *J Am Acad Dermatol.* 2010;63(2):195-211). Higher total fluence does not necessarily translate to a better outcome (Horfelt C, Stenquist B, Larkö O, et al. *Acta Derm Venereol.* 2007;87:325-329).

Despite the lack of efficacy data, home-use light devices for acne are garnering increased attention. These devices are safe to use and may afford reduction of inflammatory lesions.

The authors of this column made several attempts to communicate with manufacturers of home-use light devices in the United States, and only a few provided the irradiance and recommended total treatment fluence of their devices. The Tanda Clear (Syneron) consists of 20 LEDs emitting blue light (414 nm) and is to be applied for three minutes twice daily. The 415 nm Baby Blue (Quasar) is to be used two to three times weekly for 15 minutes in acne-prone areas of the face.

The LightStim (LightStim) utilizes 72 LEDs with combination blue, red and infrared wavelengths (450 nm to 850 nm). In unpublished company data, an uncontrolled, nonrandomized trial of 45 patients using the device for five minutes nightly experienced an average lesion count reduction of 61 percent (no distinction inflammatory versus noninflammatory).

The ANSR: BEAM (Oregon Aesthetic Technologies), which is not FDA cleared, employs red (660 nm) and blue (430 nm) light and is intended for 10 minutes of treatment (five minutes each wavelength) twice daily. Additionally, there are home-use LED bulbs that can be purchased for off-label use.

Additional data

Data for OTC acne devices is limited. A recently published, uncontrolled, eight-week study of 28 patients using an in-home blue light LED (410 nm, 40 mW/cm^2; TRIA Clarifying Blue Light, TRIA Beauty) twice daily found that this device resulted in a statistically significant decrease in inflammatory and, to a lesser extent, noninflammatory lesions from baseline, as well as a reduction in number of flares (Wheeland RG, Dhawan S. *J Drugs Dermatol.* 2011;10(6):596-604). Typical doses were 29 J/cm^2 for spot treatment, and 2 J/cm^2 for full face treatment. It should be noted, however, that all study participants were treated concomitantly with a topical regimen including salicylic, glycolic and azelaic acids.

Another study assessed the efficacy of a combination LED home-use device (Omnilux Clear-U, Photo Therapeutics) emitting blue (415 nm, 40 mW/cm^2) and red (633 nm, 70 mW/cm^2) in 19 patients used twice weekly for four weeks, and assessed over 12 weeks (Sadick NS. *J Drugs Dermatol.* 2008;7(4):347-334). This uncontrolled study found a reduction from baseline of 69 percent of inflammatory lesions and 12 percent of noninflammatory lesions. It is important to note that treatment time (20 minutes for blue light and 30 minutes for red) for the study covered an area of 5 cm x 6 cm. Therefore, a considerably longer time would be required for full-face treatment.

This device's irradiance is four times higher than one of the most popular in-office devices. One of the most significant limitations of all home-use devices is the small treatment window, requiring multiple applications to cover the entire face.

Other OTC devices

There are currently two FDA-cleared home-use pulsed-light devices for acne. These device use a combination of intense pulsed light and heat (Claro, Solta Medical, 400 nm to 1,100 nm, 6 J/cm^2 six-second treatment; no!no! Skin, Radiancy, 450 nm to 2,000 nm, 6 J/cm^2 10-second treatment). Other OTC acne devices are based solely on heat, including the Zeno (118°F for 2.5 minutes, Tyrell) and ThermaClear (212°F for 2.5 seconds, Therative) devices.

Despite the lack of efficacy data, home-use light devices for acne are garnering increased attention. These devices are safe to use and may afford reduction of inflammatory lesions. An effective total fluence may be difficult and time-consuming to achieve with lower-powered devices. Therefore, spot treatment is the most useful application of the current technology, as effective dosing can be achieved within a reasonable amount of time. DT