ClearTouch™ Lite (CTL) Home-Based Acne Treatment Study: Summary and Clinical Results

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April 2006

Introduction

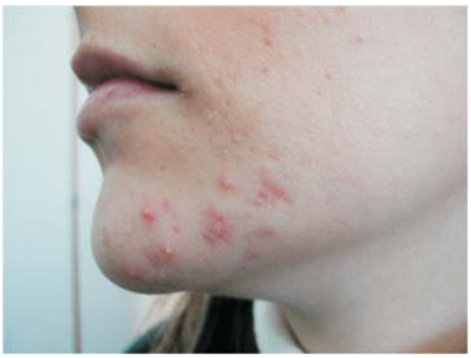
Phototherapy has long been known to have a beneficial effect on acne vulgaris. With the widespread use of lasers and light based devices for a plethora of dermatological and aesthetic applications, the quest for a light based acne treatment modality has led to the recent introduction of several different devices all aimed to allow safe, rapid treatment of inflammatory acne without the risks associated with exposure to antibiotic acne medications.

The objective of this study was to evaluate the safety and effectiveness of the ClearTouch™ Lite (CTL), a smaller version of Radiancy's FDA cleared professional Light and Heat Energy (LHE™) acne treatment system for the treatment of mild to moderate acne. Intended for daily self-use by acne patients, patient compliance with the CTL treatment protocol was also tested as part of this study.

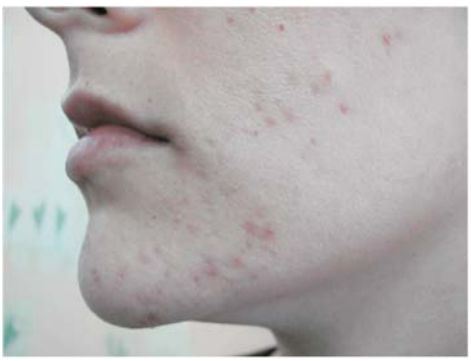
Materials & Methods

The CTL is a small portable device (2.2lbs, 7.5X8.3X4in) technically similar to the FDA cleared Radiancy Acne System (K032205). It consists of a base, a handpiece and a light unit assembly (LUA), which has a spot size of 14X27mm and produces an output wavelength spectrum of 430 – 1100nm. The CTL emits light in a cycle of 6 seconds composed of eight 1 msec pulses with a total fluence of 6J/cm^2 per cycle. The LUA is fitted with a disposable hygiene ring.

To start the CTL the user has to plug the unit into any electrical wall outlet, press the power switch and wait until the "ready" indicator turns on. Once the handpiece is correctly applied to the skin, an audio signal indicates that the user can trigger a sequence of therapeutic pulses by pressing the pulse switch. The handpiece should then be removed from the skin for about 10 seconds to allow cooling of the LUA lamp. The next sequence of pulses may be applied only when the "ready" indictor turns on.

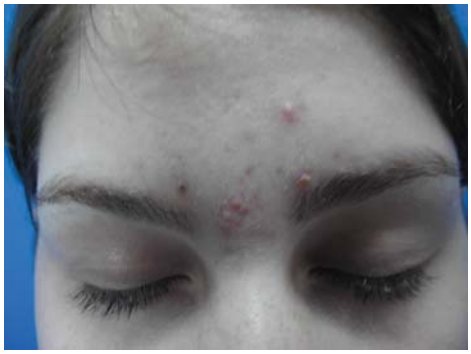


Before Treatment

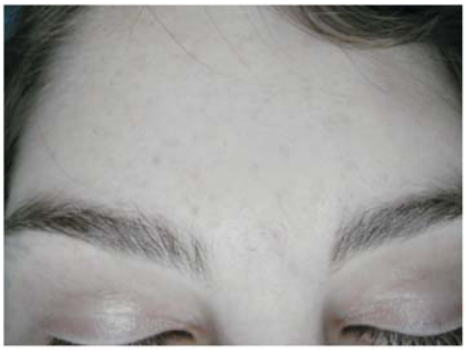


After 6 weeks of treatments
71.5% improvement

The pulses should be administered onto the treatment area with no more than 20% overlap between pulse positions. After covering the entire treatment area, the user should wait 5-10 minutes to allow the skin to cool down before performing a second "pass" over the same area.



Before Treatment

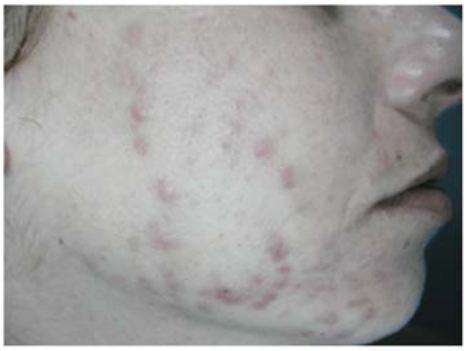


End of treatment – (3 months later)

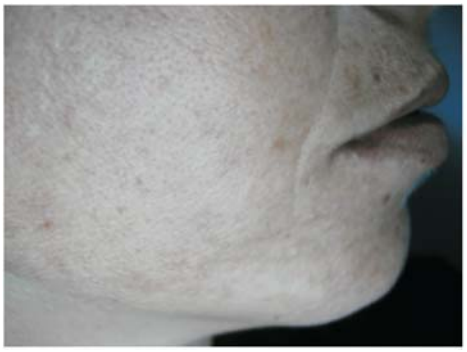
Study Design

The CTL study was conducted at two sites following approval of the study protocol by the Helsinki committee of the Kaplan Medical Center, Rehovot, Israel. Twenty (20) subjects with mild to moderate acne were recruited for the study and were asked to forego any other method of acne treatment for the entire period of the study. Subjects were recruited according to the standard inclusion/exclusion criteria for light based acne treatment systems. All participants signed an informed consent form. Subjects were then instructed on the operation of the CTL system and self-treatment protocol.

Each participant was given a CTL to use daily for a period of 3 months. Participants were scheduled to return to the investigator's office for bi-monthly visits during the treatment period and for monthly follow-up visits, up to 3 months, following the end of the treatment period. At these visits the investigator photographed the treatment areas, evaluated safety and effectiveness of the treatment, documented any adverse effects, registered patients' assessment and satisfaction and responded to any questions



Before Treatment

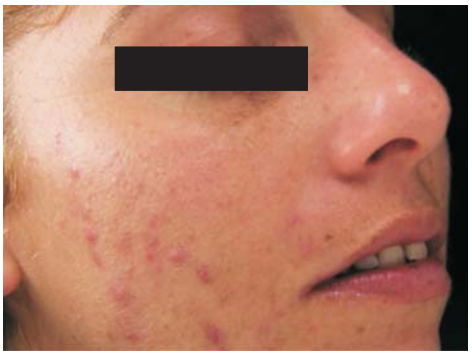


After 3 months of follow up

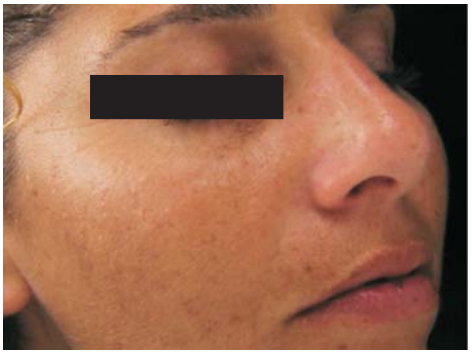
relating to the study. At the final follow-up visit, the subjects were asked to complete a user questionnaire.

Study Population

Twenty subjects (13 females, 7 males) were enrolled in the study. Age range was 14-50 years old with an average age of 21.5.



Before Treatment



After 3 months of follow up

Of the 20 subjects enrolled, 13 completed the study and 7 did not. All seven of those patients who opted out of the study did so within the first four weeks. Reasons for opting out were; the daily regimen was inconvenient for them, they were dissatisfied with the immediate results or they decided to try alternative remedies.

Study Results

Papules and pustules were counted from patient photographs taken at baseline and at 1-month intervals up to and including the 3-month follow up visit. Average lesion count at baseline for the 13 patients who completed the study was 10.8 lesions. This number was reduced throughout the study period as shown in Table 1. Most patients experienced drying of lesions and significant improvement in skin appearance within the first 1-2 weeks of using the CTL device and also reported faster resolution of new lesions that appeared during the treatment phase of the study. Though not counted, patients reported improvement in non-inflammatory lesions (blackheads). Most significant improvement was reported on pustules though no separate lesion count was conducted on papules and pustules.

Daily treatment time was reported to be in the range of 5-20 minutes with most patients able to tolerate the entire 8-pulse sequence. Adverse events were minimal with only 2 patients reporting brief incidents of excessive erythema and superficial crusting.

Daily use of CTL did not arrest the dynamic nature of acne. Patients did experience outbreaks throughout the 6 month study period, though overall these outbreaks seemed milder and patients experienced faster resolution. While some patients experienced only moderate results, others experienced very dramatic and consistent resolution of their acne lesions, which continued to improve throughout the follow-up period.

Physicians' overall assessment of the results was classified as significant and most patients' final evaluation was noted as satisfactory. Of the patients who completed the study, only two were not completely satisfied. Nevertheless, these patients noted in the termination questionnaire that they would recommend the treatment to a friend.

Conclusions

Based on this study, the CTL appears to be a safe and moderately effective technique for the treatment of acne (see before and after photographs). Most participants who completed the study experienced improvement and some experienced significant improvement. A few experienced no improvement.In almost all cases, patients experienced drying of lesions and improvement in skin appearance within 1-2 weeks of using the device. Lack of more significant long-term results may be due to the fact that acne is a dynamic disease,

which can change drastically within the 3 months of treatment and 3 months of follow-up applied in this study.

While patients found the operation of the unit to be simple and the pain tolerable, persistence in daily use for a period of 3 months was problematic for about half the patients initially enrolled in the study. An alternative protocol of 1 month daily treatments or a protocol based on bi-weekly treatments may be more acceptable for these patients and may still offer beneficial clinical results.

A combination of CTL with conventional acne medications may also improve overall results. Alternatively, CTL may be an excellent modality for patients seeking a medication-free acne treatment technique in order to avoid the adverse effects of anti-acne medications and prevent antibiotic resistance.

Initials	Baseline	1 mo.	2 mo.	3 mo.	FU 1	FU 2	FU 3	Comments
Subject 1	13	16	10	15	11	3	10	Satisfied, significant improvement, would recommend
Subject 2	3	5	2	1	2	2	5	Significant improvement, would recommend
Subject 3	2	0	3	2	1	6	3	Satisfied, significant improvement, would recommend
Subject 4	13	14	14		13	16	-	Satisfied, would recommend
Subject 5	16	17	14	10	26	-	-	Not completely satisfied, some improvement, would recommend
Subject 6	41	13	24	25	25	-	27	Significant improvement, would recommend
Subject 7	2	0	3	-	2	-	-	Significant improvement, would recommend
Subject 8	0	0	0	5	0	1	0	Significant improvement
Subject 9	7	4	2	8	5	-	-	Improvement on chin
Subject 10	12	-	6	22	9	-	10	Would recommend
Subject 11	9	1	2	12	-	-	-	-
Subject 12	13	6	3	3	0	0	-	Significant improvement, would recommend
Subject 13	9	7	4	0	1	0	1	Significant improvement, would recommend
Average	**10.8**	**6.9**	**6.7**	**9.4**	**7.9**	**4**	**8**	

Table 1: CTL Study Summary of Data Collection

ClearTouch™ Lite Device

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