Retrospective Evaluation of the Long-term Effects of BroadBand Light (BBL™) Therapy

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INTRODUCTION

BroadBand Light (BBL) delivers infra-red light (400-1400nm) as phototherapy, a non-ablative revitalization of skin on the face, chest, neck, forearms, legs, and hands. To confirm its long-term efficacy, we designed a retrospective study of 15 regular BBL recipients over a period of 5 to 11 years. Our primary objective was to determine whether their skin appeared noticeably younger than their actual ages posttreatment. Such assessments were made by blinded evaluators (n=491) who estimated the pre-treatment and post-treatment ages of participants via clinical photographs pre- and post-study.

Participants ranged in age from 38 to 69 years (median age= 46 years), and had Fitzpatrick skin types I to IV. Each received at least 1 full-face treatment per year with a BBL device (BBL, Sciton, Inc.) during the study period. Before treatment, the median estimated age of participants was slightly lower than the median actual age, but this difference was not significant. However, the median estimated age at the end of the study period was significantly lower than the corresponding median actual age (P=.0084). So, while the treated skin of our study participants actually aged a median of 9 years, it appeared to have waged a median of -2 years.

This paper details our study, which indicates that patients who maintain a regular annual or bi-annual regimen of BBL treatments over 5 to 11 years can reduce and/or delay the long-term signs of skin aging, including sun damage, telangiectases, and poor skin texture in a natural-looking way.

ADVANTAGES OF BBL

Long-term exposure to the sun's ultra-violet (UV) radiation can damage human. Such damage includes reduced epidermal and dermal thickness, wrinkles, dyspigmentation, telangiectases, coarse skin texture, and in some cases actinic keratosis, and epidermal malignancies. Ablative treatments can be effective in treating sun damage, but their long recovery periods and inherent risk of scarring offer a suboptimal choice for many patients.

BBL offers a gentler option for patients seeking younger-looking skin. Its efficacy was previously established during its nearly 2 decades of use, as patients appeared to look younger than their actual age following long-term treatment and routine maintenance with BBL. Our retrospective study further confirms long-term efficacy, based on blinded evaluator (eg, physicians, non-physicians with aesthetic experience, and laypersons) assessments of clinical pre-treatment and post-treatment photographs.

BBL devices, using non-coherent, filtered, multi-wavelength light source, were originally marketed to treat telangiectases of the legs. Unlike pulsed dye lasers, BBL caused minimal purpura, so users soon realized that phototherapy with BBL (visible and infra-red light, 400-1400 nm) could target and revitalize many skin types and conditions, including skin on the face, chest, neck, forearms, legs, and hands. BBL also has been shown to improve coarseness, pigmentation abnormalities, and pore size, with minimal downtime and virtually no scarring. And unlike laser devices, BBL can accommodate large spot sizes, allowing

physicians to treat broader areas, such as extremities, with relatively rapid results and minimal patient discomfort.

BBL has been widely used for skin revitalization in Asian countries, as treatment is typically effective and does not typically result in persistent hyperemia, hyperpigmentation, scarring, or other complications commonly associated with ablative lasers. Recommendations for physician training, indications, patient information, documentation, diagnosis, and test treatment have been reported.

STUDY OBJECTIVES

- To determine whether regular maintenance treatments with BBL over 5 to 11 years can result in sustained improvements in skin quality
- To access a noticeable effect in the actual vs estimated ages of participants, as determined by a panel of blinded evaluators

STUDY DESIGN

Our retrospective study included 15 participants (3 males, 12 females) aged 38 to 69 years (median, 46.0 years, interquartile range, 19.7 years), with Fitzpatrick skin types I to IV. Participants presented with varying degrees of sun damage.

Participants received a series of full-face treatments with a BBL device (BBL, Sciton, Inc.) during the 5 to 11-year study period, with at least 1 BBL per year after the initial series. Photographs were taken before and after the final treatment, then analyzed by 491 blinded evaluators representing the 5 groups shown in Figure 1.

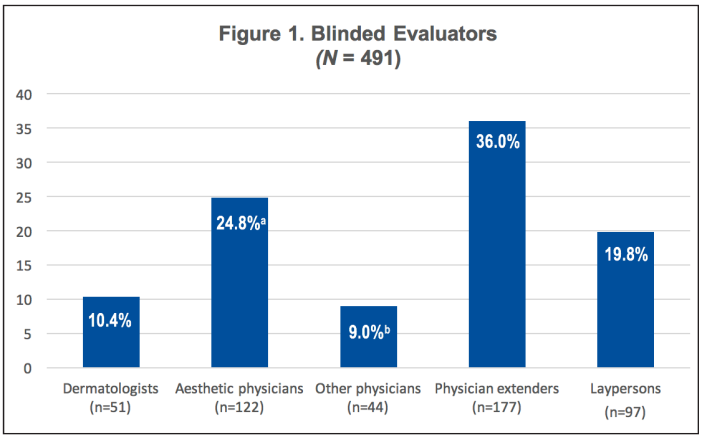
INCLUSION CRITERIA

- Previous BBL treatments for > 5 years
- Informed, signed consent to continued BBL treatment
- Consent to medical photography

EXCLUSION CRITERIA

- Pregnancy
- Current use of retinoids
- Current use of photosensitizing medication

Use of tretinoin and individual skin care regimens were permitted during the study period, but cosmetic surgery, laser resurfacing or treatment, and chemical peels were not. All treatments were administered by the investigators.



[a] Aesthetic physicians: Plastic surgeons and other non-dermatologists who considered aesthetic medicine their primary focus.

[b] Other physicians: Non-dermatologists who did not consider aesthetic medicine their primary focus.

METHODOLOGY

Pre-treatment photographs were taken with a Polaroid Macro 5 SLR (Polaroid Corporation), then stored away from heat and light for subsequent digital scanning. Post-treatment photographs were taken with the Canon EOS Rebel T3i digital SLR (Canon USA, Inc.)

Pre-treatment and post-treatment photographs were taken from standardized medical photography positions. Our survey asked evaluators to estimate the ages of the study participants before and after BBL treatment. As a control, photographs of non-sun exposed and untreated skin from the participants were also included.

PROCEDURES

Treatment protocols for BBL therapy usually followed manufacturer recommendations for skin type. Cooling gel was used in all treatments, while contact cooling was used only in later treatments, as the technology advanced.

- Pre-treatment care was limited to application of a topical anesthetic and sunscreen
- Filter selection varied per skin type and the severity of sun damage

No other aesthetic procedures were performed over the duration of the study period. Post-treatment care included regular use of sunblock and the participants' skin care regimen.

Table 1. Treatment Parameters						
BBL passes	**Filter Wavelength (nm)**	**Fluence (J/cm2)**	**Pulse Width (ms)**	**Cooling Temperature (°C)**	**Spot Size Finesse Adaptors™**	**Notes**
1 to 2	515-, 560-, or 590-nm filter	8 to 12 J/cm2	10 to 20	10 to 20	Square 15x15 mm	Adaptor for forehead, with 1 to 2 J higher fluence
3 to 4	560- or 590-nm filter	15 to 18 J/cm2	15 to 20	TBD	Square 15x15 mm	Localized to the cheeks, chin, nose, and perioral areas

DATA COLLECTION

Photographs of treated patients' skin were presented randomly via Survey Monkey for evaluators to estimate the pre-treatment and post-treatment ages of each participant.

- Photographs were cropped to hide non-skin signs of aging (eg, gray hair), so blinded evaluators could focus solely on treated skin
- Post-treatment photographs show the appearance of patients' skin 5 to 11 years following initial BBL treatment
- Actual ages of participants — before and after treatment — were compared with the blinded evaluators' estimate of ages at these same time points

DATA ANALYSIS PROCESS

The Shapiro-Wilk test showed study were data not continuous or normally distributed, so non-parametric statistics were used. Median estimated ages before and after treatment were calculated and compared to median actual ages, per the Wilcoxon signed rank test. The difference between median estimated post-treatment age and median actual pre-treatment age was also calculated and tested to determine statistical significance.

MEDIAN ACTUAL AGES

The actual ages of all participants before and after BBL treatment are presented in Table 2.

- Median actual posttreatment age (55 years) was significantly higher vs the median actual pretreatment age (46 years). The median difference was 8 years (P<.0001)
- The median estimated pretreatment age of 45 years was slightly lower vs the actual pretreatment age of 46 years (NS[a]) (Table 3)

Table 2. Participant Actual Ages and Differences Before & After Treatment[a]

	Actual Age, y		
Participant No.	Pretreatment	Posttreatment	Difference[b]
1	46	51	5
2	60	67	7
3	65	75	10
4	46	54	8
5	47	57	10
6	61	71	10
7	46	56	10
8	38	49	11
9	39	50	11
10	39	49	10
11	53	61	8
12	69	75	6
13	38	46	8
14	50	55	5
15	40	48	8

[a] Median (interquartile range): pretreatment, 46.0 (19.7) years; posttreatment, 55.0 (16.8) years; difference = 8.0 (2.8) years (P<.0001). The interquartile range is a measure of dispersion (75th to 25th percentile).

[b] Posttreatment age – pretreatment age.

POST-TREATMENT: SIGNIFICANTLY LOWER MEDIAN ESTIMATED AGE VS MEDIAN ACTUAL AGE

As Figure 2 and Table 3 show, the median estimated age at the end of the study period (45 years) was significantly lower vs the corresponding median actual age (55 years) (P=.0084). And while participants' skin actually aged a median of 9 years during the study period, evaluators determined that treated skin appeared to have aged a median of -2 years.

Photographs of non-sun-exposed and untreated skin of all subjects were also included in the blinded evaluation, and evaluators estimated ages correctly.[b] Before and after clinical photographs are shown in Figures 3 through 6.

Figure 2. Posttreatment Age, y (IQR)

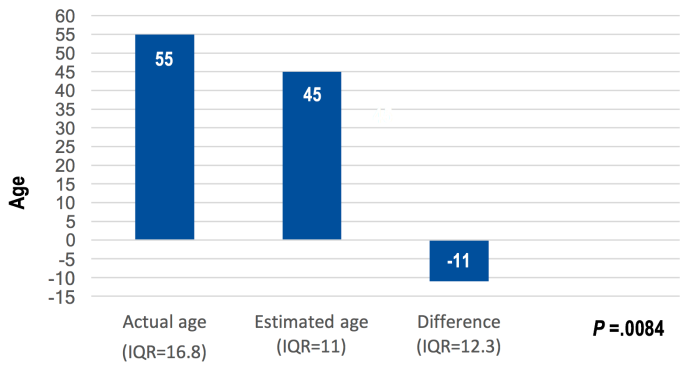


Table 3. Median Ages and *P* Values

Pretreatment Age, y (IQR)				Posttreatment Age, y (IQR)				Final Difference, y (IQR)[c]	P Value[d]
Actual	Estimated	Difference[a]	P Value[b]	Actual	Estimated	Difference[a]	*P* Value[b]		
46.0 (19.7)	45.0 (11.0)	−1.0 (10.7)	.5416[e]	55.0 (16.8)	45.0 (11.0)	−11.0 (12.3)	.0084[f]	−2.0 (13.7)	.4361[e]

Abbreviation: IQR, interquartile range.
[a]Estimated age − actual age.
[b]Estimated age vs actual age (Wilcoxon signed rank test).
[c]Estimated posttreatment age − actual pretreatment age.
[d]Estimated posttreatment age vs actual pretreatment age.
[e]Not significant.
[f]Significant.

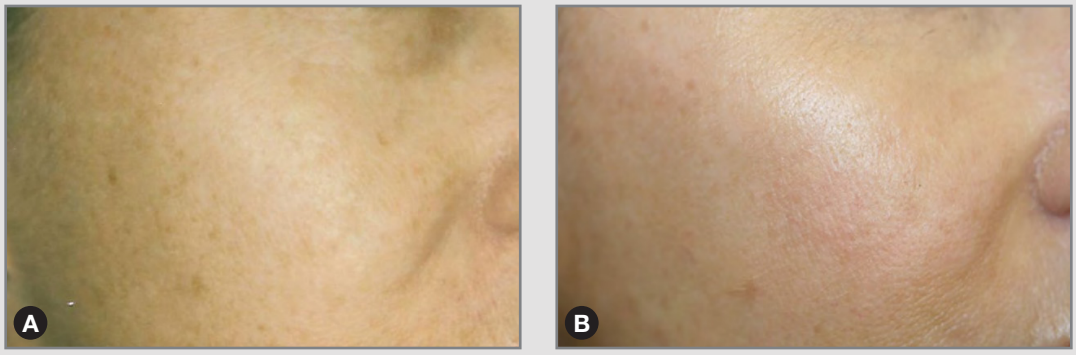


Figure 3. A 46-year-old woman before (A) and 5 years after treatment of her right cheek with BBL at least once per year (B).

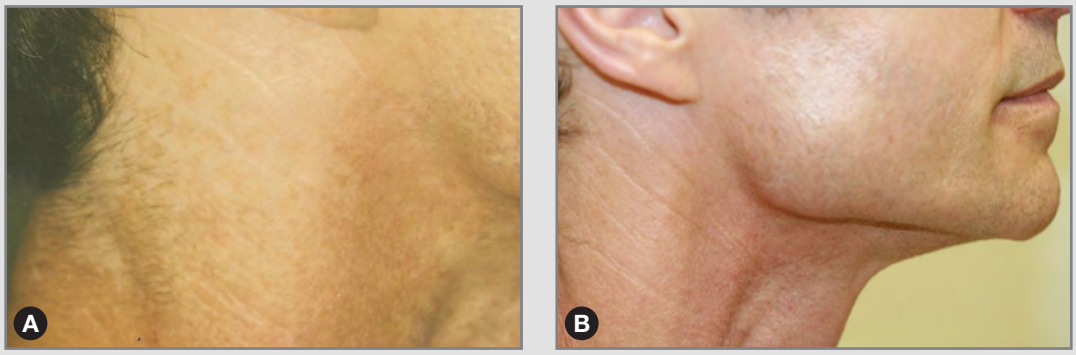


Figure 4. A 43-year-old man before (A) and 11 years after treatment of the right lateral neck an average of four treatments per year. (B) Age 55 in after photo

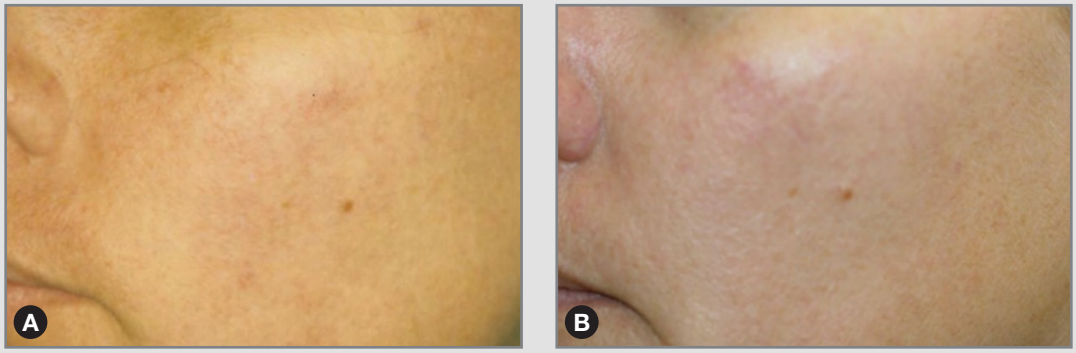


Figure 5. A 38-year-old woman before (A) and 8 years after treatment of the left cheek with BBL at least once per year (B).

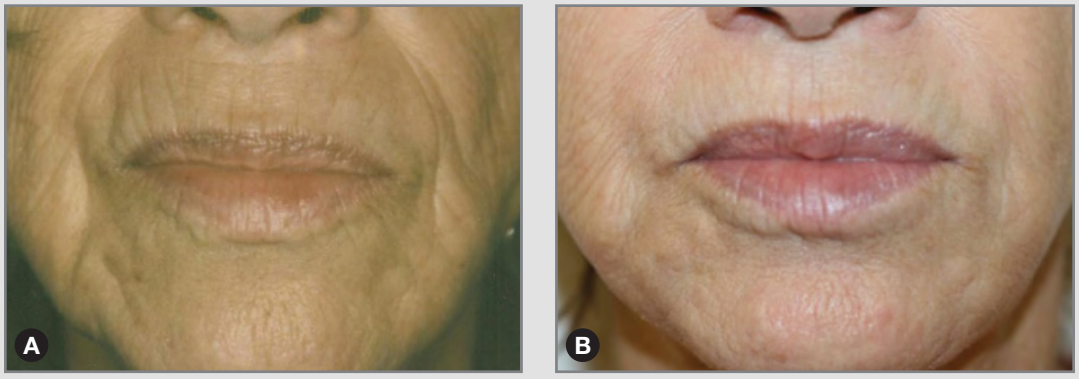


Figure 6. A 61-year-old woman before (A) and 10 year after treatment of the perioral area with BBL at least once per year (B) Age 71 in after photo.

STUDY STRENGTHS

Our study was the longest blinded evaluation of visual skin quality resulting from BBL treatment. Changes in perceived age for up to 11 years were evaluated for patients who had initial treatments and maintenance treatments at least once per year.

One previous study evaluated the effectiveness of light therapy via patients' self-reporting of significant improvements in perceived skin texture, telangiectases, and pigmentation after receiving an average of 3 treatments over 4 years. The prior study was limited by:

- Focusing on the 4-year effect of a series of repeated light treatments
  - o Regular follow up treatments were not studied

In a report published prior to our current study, Dr. Bitter recommended a series of typically gentle BBL treatments, spaced several weeks apart, for optimal, gradual improvement, with minimal adverse effects and downtime for the patient. His guidelines were confirmed when our study participants' BBL treatment effects were maintained after at least one treatment per year for 5 to 11 years.

Another prior light therapy study determined that patients could expect, on average, a 2-year reduction in their perceived age per treatment. Limitations of this study vs ours included:

- Shorter treatment period (3 weeks)
- Solely self-reported estimates of the appearance of reduced age
- Small patient population (n=5)

Although it is not yet known if widely spaced treatments produce progressive improvements, our study's longer treatment intervals vs prior short-term studies suggest that BBL treatment effects persist much longer than previously known.

STUDY LIMITATIONS

- Relatively small number of participants (n=15)
- Non-standardization of before and after photographs
- Lack of specific grading criteria for evaluators

Our study sought to determine whether blinded evaluators could estimate the ages of participants by observing treated and untreated skin. Thus, evaluators' grading criteria did not include improvement in skin texture, pigmentation, or other signs of aging.

Pre-treatment clinical photographs were taken with a Polaroid camera. Although these photographs were stored in ideal conditions, they were formatted differently than the post-treatment photographs taken years later with a digital camera. However, the ability of blinded evaluators to estimate ages correctly via photographs of non-sun-exposed and untreated skin taken pre-treatment and post-treatment [b] suggest that photographic quality did not bias their responses.

CONCLUSION

Our study demonstrates that patients who maintain a regular annual or biannual regimen of BBL treatment can both reduce and delay long-term signs of aging, such as sun damage, telanciectases, freckles, and poor skin texture in a natural looking way. The limitations noted above warrant additional studies with a greater number of patients, histologic evaluation, and assessments of individual skin characteristics to determine whether improvements are progressive with regular BBL treatments.

[a] Not significant.

[b] Data not shown.

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