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מחקרים קליניים בתחום אנטי אייג'ינג - מכשיר Silk'n FaceFX

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אודות הרופאים שערכו את המחקר

Dr. Michael H. Gold, MD – FAAD

מייסד Gold Skin Care Center, הספא הרפואי לאסתטיקה מתקדמת, מרכז הלייזר וההתחדשות, ומרכז המחקר הקליני של טנסי הממוקם בנשוויל. ד"ר גולד קיבל תואר M.D בבית הספר לרפואה בשיקגו, והשלים את השתלמות הדרמטולוגיה באוניברסיטת נורת'ווסטרן.

Julie A. Biron, BSc

מנהלת מחקר במרכז המחקר הקליני בטנסי מאז ינואר 2004. מאז הפכה למנהלת המחקר ב-TCRC, ג'ולי פיתחה קשרי עבודה חזקים וצברה מוניטין יוצא מן הכלל אצל רופאים, חברות תרופות וארגוני מחקר חוזים.

Whitney Sensing, LPN, CCRP

בוגרת המרכז הטכנולוגי בטנסי בנאשוויל, וויטני עבדה אצל רופא משפחה בקבלת חולים וביצוע הערכות, וכן סייעה לרופא בביצוע פרוצדורות טיפול פרטניות, וכעת היא לומדת לקראת תואר ראשון בסיעוד ועוסקת הן בקוסמטיקה והן בביצוע ניסויים מחקריים מבוססי תרופות.

Liora Levi, Ph.D

ליאורה היא בוגרת הטכניון - המכון הישראלי לטכנולוגיה, שם קיבלה את התואר השני באמנויות, תואר שני במדעים (MSc) בהנדסה ביו-רפואית, דוקטור לפילוסופיה (PhD) ולהנדסה כימית. ליאורה היא כיום מנהלת הנושאים הקליניים והרגולציה של הום סקינובייישן בע"מ (Silk'n).

Original Contribution

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Safety, efficacy, and usage compliance of home-use device utilizing RF and light energies for treating periorbital wrinkles

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Summary

Background The aging process is often associated with undesirable effects on facial skin such as skin redundancy, reduction of elasticity, and increased wrinkling. Radiofrequency (RF) and light-emitting diodes (LEDs) are widely used, clinically proven technologies for skin rejuvenation.

Study Objective This study aimed to evaluate the safety, efficacy, and usage compliance of the home-use device, utilizing RF and LED energies, for self-treatment of periorbital wrinkles and improvement of skin appearance.

Study design Thirty-three subjects performed 21 treatment sessions every other day, over 6 weeks on the periorbital areas. In addition, two maintenance treatments were conducted 1 and 2 months following treatment end. Each subject served as his/her own control, comparing results before treatment, and 3 months following treatment end.

Results Thirty subjects completed the study. A blinded, independent photographs assessment of three dermatologists demonstrated an average reduction of 1.49 Fitzpatrick scores ($P < 0.001$). Analysis revealed improvement (downgrade of at least 1 score) in almost all subjects.

No unexpected adverse events were reported. Post-treatment erythema was seen in all subjects and disappeared within 1 h. In some subjects, post-treatment edema was detected and resolved within 24 h. High satisfaction with the device operation, ease of treatments, safety, and wrinkle reduction was reported.

Conclusions The Silk'n Home Skin Tightening (HST) device offers a safe and effective in-home noninvasive technique to improve the appearance of age-related periorbital wrinkles.

Keywords: aging skin, periorbital wrinkles, radiofrequency

Introduction

The aging process is often associated with undesirable effects on facial skin such as thinning of the epidermis and the subcutaneous layer, which leads to skin redundancy and laxity, reduction of skin strength and elasticity (elastosis), and increased wrinkling.[1]

Patient demand for nonsurgical, noninvasive and no-downtime wrinkle and laxity reduction procedures has grown dramatically over the past decade. This increased demand has fueled the growth of new technologies that deliver these noninvasive and nonablative, anti-aging outcomes. The disadvantages of

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in-office based treatments are availability, inconvenience of travel to the clinic for multiple sessions, cost of the treatments, discomfort with the high fluency devices, and risks of pigmentation issues and scars. Using a small low-energy home-use system can alleviate these disadvantages.

Radiofrequency (RF) energy has been used in medicine for several decades. It is the most widely used technique in dermatology for nonablative skin rejuvenation.[2,3] It produces an electrical current that generates heat through the resistance of the dermal and subcutaneous tissues. These thermal effects stimulate initial collagen contraction and a wound-healing response, which induce the remodeling of dermal collagen and tighten the skin tissues.[4]

Light-emitting diode (LED) sources are unique in that they emit a narrow spectrum of light in a noncoherent manner. The depth of tissue penetration, and therefore the light's target, is primarily dependent upon the wavelength of the light. LEDs appear to affect cellular metabolism by triggering intracellular photo-biochemical reactions, believed to increase tissue energy sources, reduce the oxidative stress, affect collagen synthesis, and stimulate blood flow.[5] Red LEDs specifically have been shown to induce dermal changes such as activating the growth of fibroblast cells, increasing collagen synthesis, and inducing enzymatic activities in the subcutaneous layer of the skin. These effects in turn influence the skin appearance and are correlated with a more vibrant and firm skin texture.[6]

Home Skinovations Ltd. (Yokneam, Israel) has developed Silk'n HST, an innovative over the counter handheld device, intended for noninvasive treatment of mild-to-moderate facial wrinkles and rhytides and skin tightening. The HST system comprises of a wall-mounted AC adaptor and a hand piece. The device delivers thermally regulated RF energy and low-power light spectrum in the red and infrared (IR) range using light-emitting diodes (LEDs). The Silk'n HST treatment surface is comprised of three RF electrodes and an array of eight LEDs. The red and IR LEDs emit optical power of 70 and 55 mW/cm2, respectively; the RF generator provides 1 MHz RF with maximal output power of 10W, reaching a maximal temperature of 43°C. The device is easily operated by a single mode push button located on the user interface board and a set of light indicators informing the user on the device current operation mode (i.e., energy level treatment, standby, or error, see Fig. 1). The device is equipped with a proximity sensor which activates the RF and optical LEDs only upon direct contact with the skin, and a temperature sensor that deactivates power supply when skin temperature over exceeds the maximal allowed skin temperature levels.

This clinical study aimed to evaluate the safety and efficacy of the Silk'n HST device for periorbital wrinkle reduction and skin tightening.

Materials and methods

Subjects

Subjects were enrolled in the study after meeting all inclusion/exclusion criteria and providing a signed inform consent form. Subject's wrinkle and rhytide appearance were classified according to Fitzpatrick Wrinkle Scale.[7,8] Recruited subjects were 35–65 years of age, with Fitzpatrick wrinkle score of II-VI. Exclusion criteria were composed of scarring, inflammation or infection of the area to be treated, history of skin disorders, keloids, abnormal wound healing, pregnancy, or lactating. Subjects with current or history of malignancy, implants, or a pacemaker device were also excluded, as well as subjects with Botox/HA/collagen/fat injections or other augmentation methods with biomaterials during the last 6 months. Exclusion was applied on subjects with poorly controlled endocrine disorders as diabetes or thyroid dysfunction, sever concurrent conditions as cardiac disorders, epilepsy, or uncontrolled hypertension, as well as liver and kidney disorders. Patients with history of diseases stimulated by heat, as recurrent herpes simplex in the treated area, were excluded as well. Facial resurfacing, or deep chemical peeling within the last 3 months, history of bleeding coagulopathies, or use of anticoagulants in the last 10 days were grounds for exclusion.

Figure 1 Silk'n SHT device overview.

Study design

This is a single-arm prospective study of 18 weeks for evaluating the safety and efficiency of the device use on the periorbital areas. Treatments were performed every other day for 6 weeks (treatment phase) and were followed by two monthly maintenance treatments during the next 12 weeks (follow-up phase). The treatment phase included three prescheduled face-to-face visits, during which the participants used the device independently but under supervision. The additional 20 treatments (including two maintenance treatments) were performed at home. The primary end point of the study was an average reduction of at least 1 score in wrinkle appearance according to the Fitzpatrick Wrinkle and Elastosis scale (Table 1), while comparing baseline scores with the ones achieved at the end of follow-up. This evaluation was conducted in a blinded manner, by three independent reviewers according to standardized before-and-after photographs. A subjective impression of improvement in wrinkle appearance was measured as well by questionnaires, assessing the level of satisfaction with the device operation and treatment results.

The safety of the procedure was evaluated by monitoring the occurrence of potential procedure-related side effects. Following each treatment, the treated areas were visually assessed for skin response (e.g., edema, erythema, hypopigmentation, hyperpigmentation, and textural changes). The severity of each skin reaction was assessed according to a predefined scale of "no reaction," "mild," "moderate," and "excessive" reaction, which are relative definitions, derived from the clinician's experience. The pain level was determined in view of the patient's response.

Table 1 Fitzpatrick wrinkle scale

	Fitzpatrick Wrinkle and Elastosis Scale		
Class	Wrinkling	Score	
I	Fine wrinkles	1–3	Mild: fine texture changes with subtly accentuated skin lines.
II	Fine-to-moderate depth wrinkles Moderate number of lines	4–6	Moderate: distinct papular elastosis (individual papules with yellow translucency under direct lighting) and dyschromia.
III	Fine-to-deep wrinkles, numerous lines With or without redundant skin folds	7–9	Severe: multipapular and confluent elastosis (thickened, yellow, and pallid) approaching or consistent with cutis rhomboidalis.

Treatment procedure was conducted according to the device user manual and included a 15 min treatment on the periorbital area at each side, corresponding to two treatment zones. During the first visit, the subject was asked to perform an independent treatment under the supervision of a clinical staff member in order to evaluate the device usability. The subject was not guided during this phase unless the he had requested assistance. Usability measures included full ability to complete device-related tasks in a time frame of up to 1 h and with minimal attempts to ask for assistance. Usability was evaluated by post-treatment assessment conducted by the observer, as well as post-treatment questionnaire filled by the subject himself.

Usability questionnaires

Post-treatment usability questionnaires were filled by the subjects immediately following the first treatment to assess their impression on the device instructions for use and ease of operation (see Table 4). Questionnaire items 1–6 were scored on a 5-point scale from 1 to 5 with "1" begin "very hard" (items 1–3 and 6) or "ambiguous" (items 4–5) and "5" being "very easy" (items 1–3 and 6) or "obvious" (items 4–5). Questionnaire item 7 was scored by "Yes" or "No."

Subject satisfaction questionnaires

At the last follow-up visit, participants were asked a series of questions designed to explore the level of satisfaction regarding the device operation and treatment results. Questionnaire items 1 and 3–7 were scored on a 5-point scale from 1 to 5 with "1" begin "very dissatisfied" and "5" being "very satisfied." Questionnaire item 2 was an open question, designed to collect data on device aspects that can be improved in view of the user's experience. Item 7 was scored according to the level of improvement that was achieved by the device in view of the participant's impression.

Data analysis

Efficacy was determined by wrinkle reduction rate as evaluated by three blinded dermatologists, comparing baseline results with the scores achieved at the end of follow-up (3 months after treatment end). The criterion for study success was an average reduction of the

Fitzpatrick score by one unit or more according to at least two of the three reviewers. Statistical analysis of the blinded evaluation was conducted using the paired Wilcoxon test. A sample size of 30 participants was determined as sufficient for detecting the required score reduction, given an SD value of up to 1.8, with confidence of 95% and power of 80%.

The safety analysis set was used for describing subject disposition, which was tabulated; the numbers of enrolled, exposed, prematurely terminated and completed subjects were summarized. A list of dropouts/terminations were prepared including time and reason for discontinuation. In addition, any issues that were raised by the subjects regarding treatment conduct and effects were described and investigated.

Results

Subject

Thirty-three subjects, two males (6%) and 31 females (96%), with an average age of 53.3 ± 7.7 years (range: 39–64 years) were enrolled in the study by a single USA clinical site. Thirty subjects (91%) completed the study course, received all 23 treatments (including two maintenance treatments), and attended the one- and 3-month follow-up visits. Three subjects withdrew from the study because they were not compliant with the treatment protocol.

Safety assessment

Post-treatment skin reaction was assessed by the principle investigator. No unexpected adverse events were detected or reported during the study. All patients participating in the study reported no significant pain during the treatment. Post-treatment mild-to-moderate erythema was detected in all subjects. The erythema disappeared within 1 h without any intervention. In some subjects, post-treatment edema (hyperemia) was detected. All cases of edema were resolved within 24 h, and no treatment was needed (see Table 2 for post-treatment assessment of skin reactions).

Table 2 Post-treatment skin reaction evaluation

	No reaction		Mild		Moderate		Total
	N	%	N	%	N	%	N
Pain							
Visit 1	33	100.0	0	0	0	0	33
Visit 2	33	100.0	0	0	0	0	33
Visit 3	29	96.6	1	3.3	0	0	30
Erythema							
Visit 1	1	3.0	19	57.6	13	39.4	33
Visit 2	0	0	26	78.8	7	21.2	33
Visit 3	5	16.6	24	80.0	1	3.3	30
Edema							
Visit 1	27	81.8	6	18.2	0	0	33
Visit 2	32	97.0	1	3.0	0	0	33
Visit 3	30	100.0	0	0	0	0	30

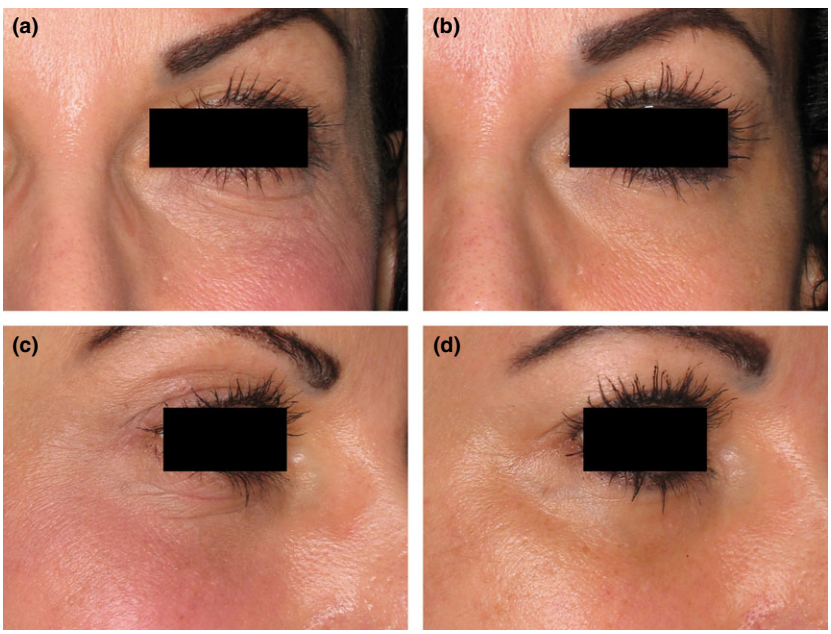

Figure 2 A 55-year-old woman. Front and side view prior to study initiation (a) and at 3-month follow-up (b).

Treatment efficacy assessment

Blinded evaluation

Analysis of pre- and post-treatment digital images was conducted by three blinded independent physicians. Figures 2–5 exemplify representative before-and-after photographs of four female patients, showing a notable change in skin appearance following 23 treatment sessions.

Table 3 summarizes averages (±STDV) of Fitzpatrick scores given by the three reviewers at baseline and at 3-month follow-up, along with percentage grade reduction and statistical evaluation of the change. Results show a statistically significant improvement of 1.49 ± 0.51 scores (31.3%±9.2%) when averaging the evaluations of all three reviewers ($P < 0.001$). Results of each reviewer separately indicate on a statistically significant improvement that is greater than 1 score (improvement range of 26.6–32.7%), indicating the success criterion of the study was met. There was no correlation (rs = 0.115, $P = 0.546$) between rhytide reduction and skin type; all skin types showed improvement. Responders analysis revealed an improvement (downgrade of 1 score or more) in at least 90% of the subjects according to each of the reviewers (96.7%, 90.0%, 93.3% for reviewers 1, 2, and 3, respectively) as well as according to their average scoring (90.0%).

Usability evaluation

Results of a post-treatment assessment, which was conducted during the first visit by the study staff, indicate that 100% of the subjects operated the device correctly and performed the treatment well according to the instructions. All subjects completed the treatment tasks within 30 min with zero requests for assistance during the process.

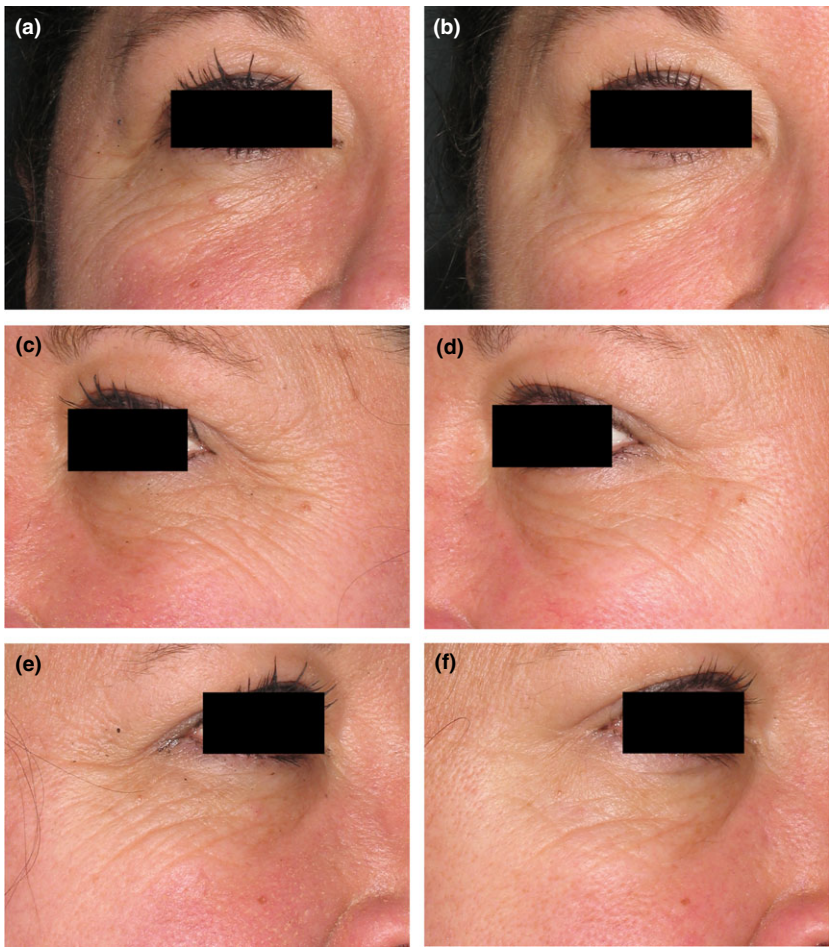

Figure 3 A 53-year-old woman. Front and side view prior to study initiation (a) and at 3-month follow-up (b).

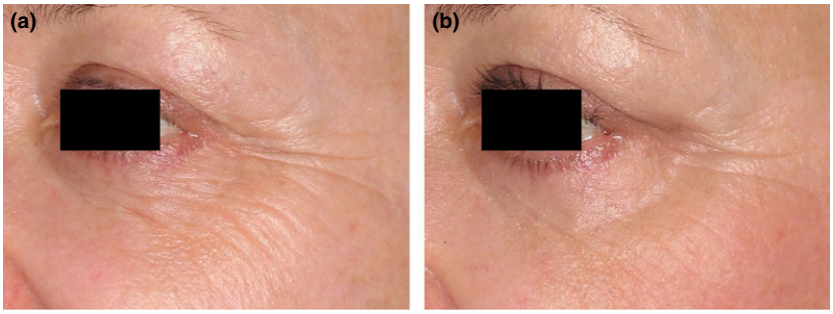

Figure 4 A 63-year-old woman. (a) prior to study initiation; (b) at 3-month follow-up.

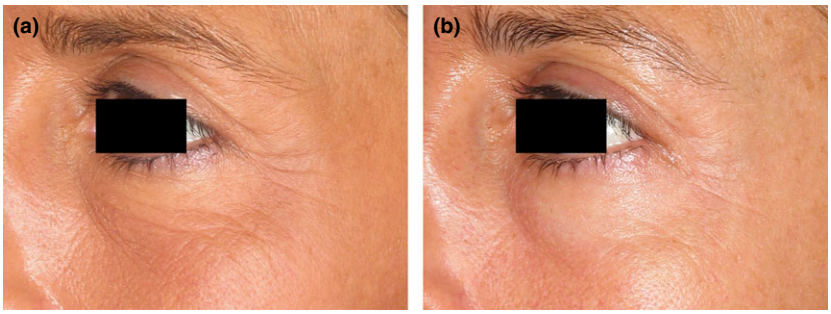

Figure 5 A 49-year-old woman. (a)—prior to study initiation; (b) at 3-month follow-up.

Post-treatment usability questionnaires indicated on an average score of 4.88 for items 1–6, indicating the device was easy to operate and that the user manual was comprehensible (see Table 4). The vast majority of participants (29 of 30, 97%) reported that it was very easy to accomplished the tasks associated with the device use. Positioning the device on the treatment area, adjusting the energy level, and understanding the user manual content were "easy" or "very easy" according to all the participants, who also indicated the device status and energy level were obvious.

Subjects' satisfaction evaluation

Table 5 summarizes descriptive statistics of the subjects' satisfaction scores. The average score of all items was 4.04, indicating the participants were satisfied with the treatment performance and results. All study participants were (very or somewhat) satisfied with the ease of learning to use the Silk'n HST device. Most participants were satisfied with the safety of performing the treatment (26 of 30, 87%) and with the ease of treatment (27 of 30, 90%). The vast majority of participants (29 of 30, 97%) indicated that there was some improvement in their wrinkle status.

Discussion and conclusions

In the current study, we report for the first time on the effect of a novel home-use device for wrinkle reduction, utilizing a combination of RF and light energies. Thirty subjects were treated on the periorbital areas and followed for 3 months after the final treatment. To assess the device efficacy, pre- and post-treatment standardized digital photographs were evaluated in a blinded manner. Analysis of study results has revealed statistical significance, while comparing baseline scores to the scores obtained at 3-month follow-up. The improvement in wrinkle status has also reached significance when analyzing the evaluation of each reviewer separately, which indicates the study success criterion was met.

The clinical results of nonablative RF antiwrinkle effects in the periorbital area were first reported by Fitzpatrick and his colleagues,[9] who demonstrated clinical improvement in periorbital rhytides in 80% of the subjects. In a different study, 24 patients underwent a single RF treatment to improve the upper third of the face; only 36% of the patients reported improvement in a self-assessment evaluation.[10]

Wunsch *et al.* [6] demonstrated the effect of broadband polychromatic light energy on wrinkle status in 113

Table 3 blinded evaluation average (±STDV) of Fitzpatrick scores at baseline and 3-month follow-up (following 21 treatment sessions and two maintenance treatments), and grade reduction, comparing to baseline

# reviewer	Scoring time	Fitzpatrick score		Grade reduction		% grade reduction		*P value
		Average	SD	Average	SD	Average	SD	
Reviewer 1	Baseline	5.1	1.0	1.67	0.61	32.7	11.5	$P < 0.001$
	Three-month follow-up	3.4	0.9					
Reviewer 2	Baseline	4.0	1.1	1.43	0.68	34.7	15.3	$P < 0.001$
	Three-month follow-up	2.5	0.8					
Reviewer 3	Baseline	5.0	1.0	1.37	0.61	26.6	11.4	$P < 0.001$
	Three-month follow-up	3.6	0.7					
Average Score	Baseline	4.7	0.9	1.49	0.51	31.3	9.2	$P < 0.001$
	Three-month follow-up	3.2	0.6					

*Paired Wilcoxon test.

Table 4 post-treatment usability questionnaire

	Question	Average score	SD
1.	How easy/hard was it to accomplish the task(s) assigned to you?	4.97	0.2
2.	Rate the ease of correctly positioning the device on the treatment area	4.69	0.6
3.	Rate the ease of adjusting the energy level of the device to the desired level	4.94	0.2
4.	How apparent was the device status (on/off and indicator lights)?	4.87	0.3
5.	How apparent was the energy level status of the device?	4.91	0.4
6.	How easy/hard was it to understand the User's Manual?	4.88	0.3
	Average for all the above questions	4.88	0.37
7.	Did you encounter any problem with the device?	100%: NO 0%: Yes	

Table 5 satisfaction questionnaire scores

	Question	Average score	SD
1.	Over all, how satisfied are you with the Silk'n HST™ device?	4.2	0.7
2.	What are some aspects of the device that can be improved?*	20%: cordless device 13.33%: gel dries too quickly 10%: too warm 6.7%: not too hot, should be stronger 6.7%: feels good, easy to use	
3.	How satisfied are you with the safety of performing wrinkle reduction treatment with Silk'n HST™ device?	4.5	0.9
4.	How satisfied are you with the ease of treatment with Silk'n HST™ device?	4.2	0.7
5.	How satisfied are you with the ease of learning to use the Silk'n HST™ device?	4.9	0.3
6.	How satisfied are you with the wrinkle reduction obtained by the Silk'n HST™ device?	3.7	0.8
7.	Please describe level of improvement obtained by the Silk'n HST™ device	2.8	0.9
	Average of all questions	4.04	0.99

*Answered by 16 of the 30 subjects (53.3%).

subjects, as assessed by a blinded evaluation of three reviewers. Responders' analysis has shown an improvement in wrinkle status in 69–75% of the treated subjects (depending on the wavelength range used for treatment). In contrast, 14–15% of the subjects exhibited no change, while the wrinkle status got worse in 10–17% of the subjects. In comparison with the aforementioned studies, our analysis revealed a good responders rate of 90% (27 of 30 subjects that responded to the treatment), while no worsening of fine lines or wrinkles was observed in the nonresponders' group.

In a similar device, utilizing RF for the treatment of wrinkles, it has been reported that the use of RF is associated with significant pain and in a small but significant number of cases subcutaneous fat atrophy develops.[11] All subjects participating in this study have reported mild-to-no pain during treatment. No subcutaneous fat atrophy was detected externally, and the observed skin reactions, edema and erythema, were expected and transient. Edema and erythema are common responses following RF treatments, representing a desirable effect and indicate on treatment efficacy. These prolonged skin reactions may indicate that the

treatment initiates a collagen-remodeling process, which remains active after the treatment session is completed. The RF output power of the HST home-device constitutes about less than 10% of the power density emitted by the professional RF devices currently on the market. This low energy does not cause complications and therefore is very safe to the user's skin, with minimal potential risk.

The Silk'n HST combination of low-level RF and light energies achieves a notable effect on wrinkle status via various mechanisms. The thermal RF provides a direct stimulation of collagen-remodeling and wound-healing response for the induction of skin tightening.[4] In addition, the LED light induces collagen construction by affecting the metabolism of Fibroblast cells and other cell types. The LED light also increases the internal tissue energy sources, reduces oxidative stress, and stimulates blood flow.[5,6] We hypothesize that this unique combination of technologies brings forth increased efficacy, while maintaining the safety features of the device.

In addition to the objective safety and efficacy measurements, subjective questionnaires indicated on high satisfaction of the users with the device operation and safety, ease of treatments, and wrinkle reduction results. Usability evaluation concluded that the device is easy to operate and the instructions for use are comprehensible and suitable for the average potential user.

This study has some limitations. First, the open-label, single-arm design might influence the patients' satisfaction results, due to the placebo effect that was not controlled. On the other hand, the primary end point was the blinded evaluation of before-and-after photographs to ensure impartiality and avoid errors arising from bias. An additional limitation would be the relatively small sample size; however, this was found to be statistically justified and appropriate for the primary end point. One more limitation would be the performance of treatments on the periorbital areas only; therefore, additional studies should be conducted to support the device efficacy and safety in other treatment areas.

To our knowledge, this is the first time a home-use device that utilizes RF and LED combination is examined in a well-controlled clinical study. By employing both objective and subjective measures, this study establishes the safety and efficacy of Silk'n HST for improving the appearance of age-related periorbital wrinkles. The HST can also be used to treat rhytide and laxity on other facial areas, such as the perioral, nasolabial, forehead, and neck. Further studies may demonstrate this versatility.

Acknowledgments

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