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Face Tight and Bright treatment with 3D IPL 530nm PROTOCOL REVIEW

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Background:
Intense Pulsed Light (IPL) therapy has been widely used for dermatological and cosmetic purposes.
The mechanism of IPL action is based on selective photothermolysis, which involves the use of polychromatic incoherent high-intensity pulsed light of determined wavelength spectrum, fluence, and pulse duration
(Babilas et al., 2010; Ash et al., 2017).
The effect of IPL on the vasculature of the skin of the face is influenced by factors such as wavelength, illumination geometry, and skin tone, which affect the energy density distribution within the tissue (Negishi et al., 2002).
IPL has been indicated as effective for treating superficial lesions such as pigmentation and telangiectasia, as well as more profound cosmetic disorders, including fine wrinkles and large pores in skin Type I-III patients (Ali et al., 2013).
Additionally, IPL has been shown to enhance the expression
of transforming growth factor beta1/Smad3 signaling in acne-prone skin, indicating its potential in treating acne-related conditions (Mahmoud et al., 2010).
The impact of IPL on the vasculature of the skin is also influenced by the absorption of visible light by chromophores in the skin, which is the principle for its use in laser therapy, intense pulse light therapy, and photodynamic therapy
(Gao et al., 2019). IPL was also proposed to induce thermal injury to the dermis, triggering a subclinical wound-healing process that results in fibroblast activation, neocollagenesis, and dermal remodeling (Huang et al., 2020).

Additionally, IPL therapy causes denaturation of melanin caps- containing cells, leading to accelerated differentiation of basal keratinocytes (Yamashita et al., 2006). Furthermore, the bidirectional regulation of matrix metalloproteinase-1 (MMP-1) and transforming growth factor-β1 (TGF-β1) mediated by MAPKs in fibroblasts is suggested as a potential mechanism for IPL's skin rejuvenation effect (Huang et al., 2010). Moreover, regulating aquaporin 3 (AQP3) protein expression in the skin is implicated as a functional mechanism of IPL (Wu et al., 2015). The dilation of tissue vasculature due to the electromagnetic character of IPL is also proposed as a possible mechanism (Minh et al., 2015). In summary, these processes collectively contribute to the stimulation of fibroblast activity, neocollagenesis, and dermal remodelling, ultimately leading to neogenesis. Even with all the independent research on IPL scientific and technological benefits on animal models and patients, we still lack a non-invasive simplified clinical protocol that simultaneously promotes color correction, texture, vascular, pigmentation, wrinkles, and neocollagenesis, achieving younger and healthier-looking skin.

Objective:
This work evaluated the safety, pain, patient comfort, and efficacy of Tight and Bright 3D IPL-530nm non-invasive treatment protocol on the face with the Alpha System (by Formatk System Ltd, Tirat Carmel, Israel). The Tight & Bright protocol treatment aims to improve the abovementioned areas simultaneously. The hypothesis is that in the protocol of Tight and Bright, the rapid release of pulses will lead to a significant scattering effect that, as a result, gradually heats the skin's surface temperature to around 40°C during the treatment but not higher than 42°C. We hypothesize that at a skin surface temperature of around 40°C, we will be able to induce neocollagenesis and elastogenesis, which will address both color correction and texture, vascularity, pigmentation, and wrinkles, thereby, achieving younger and healthier-looking skin.

Methods:
This prospective, single-center case study (Forma-TK Systems, clinical department, Tirat Carmel, Israel) included four female patients, Fitzpatrick skin type from 1-3, ages ranging from
58 to 77 years old (mean 62 years old) that demonstrated signs of skin aging, facial wrinkles, and visible pigmentation. The patients were selected during the period from June 2023 Until December 2023.
All patients signed informed consent before treatment.
Both the patient and the operator used appropriate protective goggles during treatment.
In all the treatments, we used protective ultrasound Parker Gel. To assess the patient's skin Fitzpatrick level, which determines the treatment parameter for each patient, we used Mini-Two (“Milo”), an optical sensor for measuring melanin levels from 1 to 100. The reading method is based on the absorption/ reflection principle at two defined wavelengths (875nm and 660nm). The probe sensor contains two LEDs emitting in the visible (660nm) and IR (875nm) spectrum by a photodetector. The wavelengths correspond to different absorption rates by the skin's pigments (Manufactured by Callegari company, Via Luigi Natale Vernazzi, 13/A 43122 Parma, Italy).

Tight and Bright protocol treatment
uses two (2) passes over the treatment area:
First Pass – Full facial treatment in which we used a medium energy level with a 530nm 3D IPL applicator on an Alpha System (produced by Fromatk Systems Ltd). The energy parameters were adjusted according to the Fitzpatrick type of each patient. Fluence (J/Cm2) ranged from 14-16, Mode: single (stamping), Frequency: 1 Hertz and pulse duration (ms) 10-15. The First pass aims to “break down” superficial pigmentation, making the area and the lesions more susceptive to energy absorption.

Second Pass – we divided each cheek into three vertical anatomical lines. Each Cheek received 3 vertical passes of up to 25 pulses (up and down vertical motion). We used the same applicator and system but with different parameters. In the second pass, we used the fluence of 10 J/Cm2, Mode: Triple continues; this is a rapid mode that releases 9 pulses per second ultra-short pulses (pulse duration of 5ms) that pick up on the pigmentation and allows reaching the desired results. The use of ultra-short pulses ensures that the energy absorption is more selective. We measured the skin surface temperature in the treated area before, during, and after each vertical pass. The skin surface temperature measurement was made using an infrared thermometer no-contact, "temperature gun" (Manufactured by NORM company, model: TS400, temperature measurement ranges from -50°C up to 400°C

All patients received a session every at least two treatment sessions and followed up for one month after treatment. Clinical photographic images were taken with the Observe 520X skin analysis system (manufactured by Inno Faith Beauty Sciences B.V., The Netherlands). The Observe 520x system uses patented skin fluorescence and polarized light illumination technology to reveal those conditions. The Observe Skin Analysis scans the skin and generates six images that examine wrinkles & fine lines, surface texture, vascularity, and pigmentation. Clinical photographic images obtained before and after the Observe 520x were evaluated by Dr. Nadav Pam, Forma-TK Systems Ltd, Clinical director.

Inclusion Criteria:

1. The patient's face has significant signs of aging skin, visible pigmentation, and wrinkles.
2. Above the age of 40 years old.
3. Patients without previous facial injections (with active chemical compounds), dermal fillers, or facial cosmetic surgery.
4. Patients who accepted to be included in this study and signed a written informed consent.

Exclusion criteria:

1. Drug-induced photosensitivity (e.g., Isotretinoin, Retin A)
2. Pregnancy and breastfeeding
3. Cancer
4. Epilepsy
5. Severe diseases
6. Auto-immune diseases
7. Frequent episodes of labial Herpes Simplex in case of face Treatment
8. Immunosuppressive pharmacologic therapy
9. Any other medical condition considered contraindicated to the treatment by the investigator

Results:

Regarding skin phototyping for patients according to Fitzpatrick classification based on optical sensor reading.

Fitzpatrick skin type	Number of patients
1	1
2	1
3	2

The Visual Analogue Scale (VAS) measures pain intensity. Using a ruler, the score is determined by measuring the distance (mm) on the 10-cm line between the "no pain" anchor and the patient's mark, providing a range of scores from 0–100. A higher score indicates greater pain intensity. Correlation between Visual and verbal scale: 1-3 = mild pain; minimal impact on the patient. 4-6 = moderate pain; moderate impact on the patient. 7-10 = severe pain; major impact on the patient

Patient number	VAS score
1	4
2	3
3	3
4	4

Upon evaluation of the VAS score in our case study, the average pain was 3.5, meaning the patients felt minimal momentary transient pain and comfort during the treatment and afterward. No side effects were recorded except for transient pain/erythema, which resolved within an hour of the end of the treatment.

4-point scale evaluation based on photographic Images from the Observe 520x System:

Patient Number	Number of Treatments	Overall, 4 point Scale Improvement	Side Effects
1	2	82%	N/A
2	4	87%	N/A
3	2	81%	N/A
4	3	84%	N/A

Discussion: (refer to supplements)
The Observe 520x system uses patented skin fluorescence and polarized light illumination technology to assess the Skin. The Observe scans the skin and generates six images that examine wrinkles & fine lines, surface texture, vascularity, and pigmentation

Patient 1	Markedly improved texture and wrinkles after only two treatments.
Patient 2	Had a marked Improvement in visible pigmentation from the first treatment, which gradually improved up to the 4th treatment.
Patient 3	Had marked improvement in vasculature after two treatments.
Patient 4	Had marked improvement after three treatments in all of the camera filters: Visible light, Pigmentation, Texture, Tone, Wrinkles, and Vascular

Patient 1 - Improvement in both texture and wrinkles

Before

After 2 Treatments

Patient 2 - marked Improvement in visible pigmentation

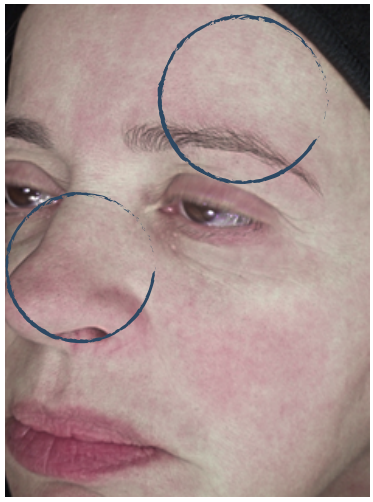
Before

After 4 Treatments

Patient 3 – had marked improvement in vasculature

Before

After 2 Treatments



Patient 4 – had marked improvement in overall improvement in Visible light, Pigmentation, Texture, Tone, Wrinkles, and Vascular

Before

After 3 Treatments

Conclusions:

In conclusion, the Tight and Bright 3D IPL 530nm is a non-invasive, safe, comfortable, and effective treatment. Four female patients had an overall visual improvement above 80% after the second treatment. Further therapies have led to a gradual increase in total improvement over time. There were no side effects during the treatment protocol. The Tight and Bright treatment protocol improves skin tone and texture, color correction, and vascularity and promotes neocollagenesis. The limitations of this study were the lack of a control group, a relatively small number of patients, and a short follow-up period. However, the results were encouraging. Well-designated randomized controlled studies are required with a more significant number of patients and additional sessions to confirm the efficacy further.

References:

[[1] (2023). Hyperspectral assessment of acne skin exposed to intense pulsed light (ipl) intense pulsed light in acne treatment. Skin research and technology, 29(6). https://doi.org/10.1111/srt.13338

[2] (2017). Effect of wavelength and beam width on penetration in light-tissue interaction using computational methods. lasers in medical science, 32(8), 1909-1918. https://doi.org/10.1007/s10103-017-2317-4

[3] (2010). Impact of long-wavelength uva and visible light on melanocompetent skin. journal of investigative dermatology, 130(8), 2092-2097. https://doi.org/10.1038/jid.2010.95

[4] (2014). Differences in visible light-induced pigmentation according to wavelengths: a clinical and histological study in comparison with uvb exposure. pigment cell & melanoma research, 27(5), 822-826. https://doi.org/10.1111/pcmr.12273

[5] (2010). Intense pulsed light (ipl): a review. lasers in surgery and medicine, 42(2), 93-104. https://doi.org/10.1002/lsm.20877

[6] (2007). Evaluation of procollagen i deposition after intense pulsed light treatments at varying parameters in a porcine model. journal of cosmetic and laser therapy, 9(2), 75-78. https://doi.org/10.1080/14764170701299313

[7] (2019). A retrospective analysis for facial telangiectasia treatment using pulsed dye laser and intense pulsed light configured with different wavelength bands. journal of cosmetic dermatology, 19(1), 88-92. https://doi.org/10.1111/jocd.13179

[8] (2022). Visible light and the skin. photochemistry and photobiology, 98(6), 1264-1269. https://doi.org/10.1111/php.13634

[9] (2015). Effect of intense pulsed light on the expression of aquaporin 3 in rat skin. lasers in medical science, 30(7), 1959-1965. https://doi.org/10.1007/s10103-015-1788-4

[10] (2018). Synergistic effects of long-wavelength ultraviolet a1 and visible light on pigmentation and erythema. british journal of dermatology, 178(5), 1173-1180. https://doi.org/10.1111/bjd.15940

[11] (2007). Comparison study of intense pulsed light versus a long-pulse pulsed dye laser in the treatment of facial skin rejuvenation. annals of plastic surgery, 59(5), 479-483. https://doi.org/10.1097/sap.0b013e3180327943

[12] (2002). Full-face photorejuvenation of photodamaged skin by intense pulsed light with integrated contact cooling: initial experiences in asian patients. lasers in surgery and medicine, 30(4), 298-305. https://doi.org/10.1002/lsm.10036

[13] (2013). Intense pulsed light enhances transforming growth factor beta1/smad3 signaling in acne-prone skin. journal of cosmetic dermatology, 12(3), 195-203. https://doi.org/10.1111/jocd.12045

[14] (2020). Intense pulsed light for the treatment of pigmented and vascular disorders and lesions: a review. dermatological reviews, 2(2), 69-81. https://doi.org/10.1002/der2.47

[15] (2022). Treatment of acne fulminans with intense pulsed light: a case report. the journal of cosmetic medicine, 6(2), 99-102. https://doi.org/10.25056/jcm.2022.6.2.99

[16] (2001). Photorejuvenation for asian skin by intense pulsed light. dermatologic surgery, 27(7), 627-632. https://doi.org/10.1046/j.1524-4725.2001.01002.x

[17] (2002). Rejuvenation of photoaged skin: 5 years results with intense pulsed light of the face, neck, and chest. dermatologic surgery, 28(12), 1115-1119. https://doi.org/10.1046/j.1524-4725.2002.02113.x

[18] (2006). Laser versus intense pulsed light: competing technologies in dermatology. lasers in surgery and medicine, 38(4), 261-272. https://doi.org/10.1002/lsm.20326

[19] (2010). A split-face study of intense pulsed light on photoaging skin in chinese population. lasers in surgery and medicine, 42(2), 185-191. https://doi.org/10.1002/lsm.20889

[20] (2007). Intense pulsed light. journal of the american academy of dermatology, 56(3), 466-467. https://doi.org/10.1016/j.jaad.2006.10.031

[21] (2000). Treatment of dark skin (types v and vi) with intense pulsed light source for hair removal. international journal of cosmetic surgery and aesthetic dermatology, 2(1), 35-39. https://doi.org/10.1089/153082000750021268

[22] (2002). Long-term hair removal using the intense pulsed light source: a two-year follow-up study. international journal of cosmetic surgery and aesthetic dermatology, 4(1), 15-18. https://doi.org/10.1089/153082002320007430

[23] (2020). Involvement of aquaporins in the intense pulsed light-enhanced wound healing in diabetic rats. lasers in surgery and medicine, 53(4), 549-556. https://doi.org/10.1002/lsm.23303

[24] (2002). Full-face photorejuvenation of photodamaged skin by intense pulsed light with integrated contact cooling: initial experiences in asian patients. lasers in surgery and medicine, 30(4), 298-305. https://doi.org/10.1002/lsm.10036

[25] (2010). Ipl irradiation rejuvenates skin collagen via the bidirectional regulation of mmp-1 and tgf-β1 mediated by mapks in fibroblasts. lasers in medical science, 26(3), 381-387. https://doi.org/10.1007/s10103-010-0870-1

[26] (2015). Effect of intense pulsed light on the expression of aquaporin 3 in rat skin. lasers in medical science, 30(7), 1959-1965. https://doi.org/10.1007/s10103-015-1788-4

[27] (2015). Effects of intense pulsed light on tissue vascularity and wound healing: a study with mouse island skin flap model. plastic surgery international, 2015, 1-6. https://doi.org/10.1155/2015/429367

[28] (2020). Intense pulsed light for the treatment of pigmented and vascular disorders and lesions: a review. dermatological reviews, 2(2), 69-81. https://doi.org/10.1002/der2.47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