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Case Study - Facial Tight and Bright treatment protocol with the Alpha System 3D IPL 530nm

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Background:
Intense Pulsed Light (IPL) therapy uses selective photothermolysis, a process where targeted tissues in the skin absorb specific wavelengths of light. This targeted absorption leads to a controlled thermal injury that can stimulate various skin rejuvenation processes, including neocollagenesis (new collagen formation) and dermal remodelling in the following ways:

1. Mechanism of Selective Photothermolysis (Selective Absorption): IPL devices emit broad-spectrum light that can be filtered to specific wavelengths. These wavelengths are chosen based on their ability to target chromophores (melanin, haemoglobin, and water) in the skin. Thermal Injury: When the IPL light is absorbed by the target chromophores, it generates heat. This localized heat causes controlled thermal damage to the target tissues without significantly affecting the surrounding tissues.

2. Neocollagenesis (Stimulation of Collagen Production): The thermal injury caused by IPL leads to a wound-healing response in the skin. This response involves the activation of fibroblasts, the cells responsible for producing collagen. The initial thermal injury breaks down old, damaged collagen fibers. The subsequent wound-healing process stimulates the production of new collagen fibers, improving the skin's structure and elasticity over time.

3. Dermal Remodelling (Reorganization of Dermal Matrix): The thermal effects of IPL not only stimulate new collagen production and promote the reorganization and remodelling of the existing dermal matrix. This process enhances the overall integrity and appearance of the skin. As new collagen forms and the dermal matrix remodels, the skin becomes firmer and smoother. This can lead to a reduction in fine lines, wrinkles, and other signs of aging. IPL can also reduce hyperpigmentation and visible blood vessels by targeting melanin and haemoglobin, contributing to a more even skin tone.

4. Clinical Outcomes (Visible Improvements): Patients undergoing IPL treatments typically see improvements in skin texture, tone, and overall appearance. Fine lines, wrinkles, and pigmentation issues are often diminished. The effects of neocollagenesis and dermal remodelling continue to improve for several months post-treatment as new collagen forms and matures.

5. Safety and Efficacy: IPL's selective nature allows targeted treatment with minimal risk to surrounding tissues, making it a relatively safe option for various skin types and conditions. IPL devices can be adjusted in terms of wavelength, pulse duration, and energy level to suit the specific needs of the patient's skin type and the condition being treated.

Nevertheless, 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 530nm non-invasive IPL treatment protocol on the face with the Alpha System (Manufactured 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 was performed by Nina Talib and Amal Raoud, dermal clinicians from the Skincosmediq clinic in the Netherlands. The study included seven patients (five females and two males) with Fitzpatrick skin type 2, ages 32 to 68 (mean 55 years old), demonstrating signs of skin aging, facial wrinkles, and visible pigmentation. The patients were selected from 01.01.2024 to 31.05.2024.

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 22-25, 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 – Each Cheek or forehead received three passes of up to 25 pulses. 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 nine 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 one treatment session and followed up for one month after treatment.

Dr. Nadav Pam, clinical director of Forma-TK Systems Ltd, evaluated clinical photographic images obtained before and after.

Inclusion criteria:

1. The patient's face has significant signs of aging skin, visible pigmentation, and wrinkles.
2. Above the age of 18 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 breastfeedin
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

Number	Age	Gender	Fitzpatrick skin type
Patient 1	62	Female	2
Patient 2	52	Female	2
Patient 3	64	Male	2
Patient 4	34	Female	2
Patient 5	62	Female	2
Patient 6	68	Female	2
Patient 7	45	Male	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	6
2	6
3	6
4	7
5	6
6	6
7	6

Upon evaluation of the VAS score in our case study, the average pain was 6.7, meaning the patients felt moderate transient pain.
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	90%	N/A
2	1	85%	N/A
3	1	81%	N/A
4	1	95%	N/A
5	1	83%	N/A
6	1	87%	N/A
7	1	80%	N/A

Discussion:
All seven patient reached their clinical endpoint with an overall clinical improvement of at least 80% using the 3DIPL with the Alpha System while using the current treatment protocol, without using any additional topical cream or use of oral drugs.

Conclusions:
In conclusion, the Tight and Bright facial treatment using the 3D IPL 530nm with the Alpha System is non-invasive, safe, comfortable, and effective. Seven patients (five females and two males) had an overall visual improvement above 85.8% after the first 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.

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Supplements:

Patient 1 - Female, 62 years old

Before **After 1 Treatment**


Patient 4 - Female, 34 years old

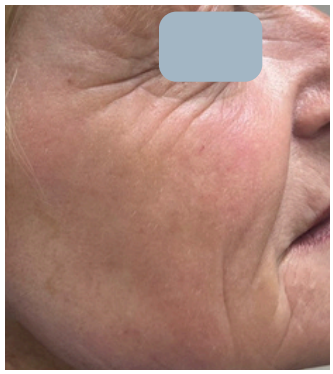
Before **After 1 Treatment**


Patient 2 – Female, 52 years old

Before **After 1 Treatment**


Patient 5 – Female, 62 years old

Before **After 1 Treatment**

Patient 3 – Male, 64 years old

Before **After 1 Treatment**


Patient 6 – Female, 68 years old

Before **After 1 Treatment**


Patient 3 – Male, 45 years old

Before **After 2 Treatments**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