DENSITY HIGH

Facial and body rejuvenation using new non-microneedle radiofrequency device (DENSITY®)

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[Introduction]

As the skin undergoes natural aging, several visible changes become evident, including a significant decrease in skin elasticity, alterations in facial contours, sagging, and rapid development of fine wrinkles and pores. These facial anatomical changes result from various reasons, including not only photoaging of the skin but also subcutaneous fat volume loss, gravity-induced sagging, and bone density reduction. Hence, treatment modalities have been extensively developed to address the above factors, encompassing a broad spectrum of surgical and non-surgical approaches. The surgical facial lifting demonstrates effectiveness, but it accompanies the drawback of visible scarring and the necessity of an extended recovery time. Conversely, non-surgical treatments like fillers and botulinum toxin injections are relatively straightforward and yield rapid results with minimal downtime; yet, some patients display doubts about the introduction of foreign substances into the body and the potential side effects like vascular complications that could lead to tissue necrosis or eyelid ptosis.

The treatments that generate heat in delivering energy to the deep layer of the skin in a non-invasive and non-surgical way synthesize collagen and elastic fibers, gradually improving skin texture. Such non-invasive methods typically utilize radiofrequency (RF), High-Intensity Focused Ultrasound (HIFU), and non-ablative laser. Thermage® FLX is a representative anti-aging treatment device that employs non-invasive and non-microneedle via monopolar mode RF with capacitive coupling. Thermage® FLX delivers RF energy to the skin tissue using the reverse thermal gradient principle. It generates heat in the dermis while cooling the epidermis, resulting in collagen fibers denaturation and contraction, and collagen regeneration through volumetric heating. Compared to its previous third-generation, Thermage® FLX has higher energy output, a larger tip (4 cm^2) that reduces the treatment time (by approx. 25%) and incorporates pulse tuning for each shot's consistent energy delivery.

DENSITY® HIGH is an exceptional innovation in the field, having recently obtained MFDS approval in Korea and achieving a significant milestone with its bimodal in a single RF irradiation. This cutting-edge device harnesses the strengths of both monopolar and bipolar approaches within one electrode, offering the potential for a synergistic effect in a single-session treatment. DENSTIY® HIGH is the premium DENSITY line, which employs non-invasive monopolar RF treatment with the Classic

DENSITY® HIGH has a unique capability to deliver both monopolar and bipolar RF irradiation through a single electrode. Thus, this bimodal functionality allows it to leverage the strengths of both monopolar and bipolar treatment, anticipating achieving a synergistic effect in an all-in-one treatment.

tips. As such, DENSITY® HIGH accommodates both the Classic and High tips, where each type is available in three sorts: Face, Eye, and Body.

In this article, DENSITY® HIGH treatment cases will be explored using the following tips: High Face, Classic Face, and High Body.

[Methods]

Treatment consent was obtained from every patient before the treatment, and patients who had received RF, HIFU, or laser therapy within the last six months were excluded. For facial treatments, three patients underwent the procedure using the Classic-F tip while another three with the High-F tip. One patient was subjected to a body treatment on the posterior upper arm using the High-B tip. In all cases, prior to procedures, an anesthetic ointment was applied for 30-40 minutes.

Facial treatments:
600 shots were distributed across the entire face: specifically, 500-550 shots to the cheeks and jawline, and 50-100 shots to the forehead. The Classic and High tip sizes were standardized (4 cm^2), and the treatments were performed with 20% surface overlap of each shot. Treatment commenced with a 3.0 energy level and was adjusted to 2.0 depending on the patient's pain tolerance. The total delivered energy ranged from 50 to 55 KJ.

Posterior upper arm treatment:
150 shots were allocated to each arm. The initiate energy level was 4.0 and gradually adjusted to 3.0.

To objectively assess the treatment effects, photographs were taken from the same angle using digital cameras: EOS R6, Canon, Tokyo.
To capture detailed images of skin texture, redness (rosacea), and wrinkles, DermaVision® was additionally employed.

On the fourth week post-treatment, patients were asked to evaluate their satisfaction level subjectively using a scale: 0 (no improvement), 1 (slightly satisfied), 2 (satisfied), and 3 (very satisfied).
Likewise, patients' perceived pain during the treatment was measured with the Visual Analogue Scale (VAS), where they selected from 0 (no pain) to 10 (the most severe pain they had ever experienced).

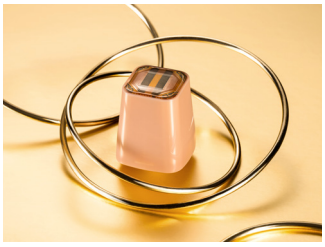
[Results]

Classic-F Tip:
On average, patients experienced improved facial texture and elasticity along with reduced rosacea, noticing the results around two weeks after the treatment and gradually enhancing pronunciation in the fourth week (Fig 1). Treatment satisfaction among the three patients was 2, 2 and 3, indicating high satisfaction overall. On average, the VAS discomfort indicator was 7 at an energy level of 3.0, and it decreased to 4.5 when the energy level was adjusted to 2.0.

High-F Tip:
The High-F tip treatment displayed a significant face-lifting and faster result than

The High tip incorporates the bipolar RF in addition to the Classic tip's monopolar RF within a single electrode, allowing one shot to deliver four monopolar and one bipolar irradiation.

The highest elevation in collagen and elastic fibers occurred when monopolar was followed by bipolar irradiation, as preheating the skin tissue with monopolar RF reduced resistance in the dermal layer and created optimal conditions for bipolar RF delivery.



DENSITY® High-F tip yielded rapid and substantial response, delivering noticeable improvement as early as the second day, while the Classic-F tip required one week for visible results, with ongoing enhancement observed through the fourth week.

the Classic tip; the application with the High tip brought results from the second day, whereas the Classic tip required one week; the improvement progressed to the fourth week (Fig 2). Treatment satisfaction for the three patients was 2,3 and 3, again indicating high satisfaction. The VAS average perceived pain was slightly less than the Classic tip: 6.5 at energy level 3.0, which also decreased to 4 on the energy level lowering to 2.0.

High-B Tip for Posterior Upper Arm:
The treatment energy level commenced at 4.0 and gradually tapered down to 3.0. After four weeks, the skin texture improvements and reduced wrinkles in the upper arm's elbow area (Fig 3) were noticeably visible. The treatment satisfaction was recorded as 2, and the VAS was 4.

Post-Treatment Observations:
Immediately after the treatments, partial erythema was observed for 2-3 hours and disappeared naturally. No blisters, scabs, or other side effects were reported.

[Discussion]

DENSITY® HIGH stands out as a remarkable advancement in the realm of RF devices to be considered a perfect replacement for Thermage® FLX. **DENSTIY® HIGH not only parallels but improves upon the capacity of Thermage® FLX 's advantages, including operational mechanisms, real-time tissue impedance monitoring for precise and consistent energy delivery (constant power), colling gas application and the Face tip dimensions.** In the Classic tip clinical trials, the doctor and patients reported similar outcomes and treatment experiences to Thermage® FLX.

DENSITY® HIGH utilizes 6.78 MHz RF and pulses for 1000ms in each shot; these pulses are divided into five sub-pulses (200ms each), with cooling gas released once at the initiation of the second and fourth sub-pulses. **This division into five sub-pulses accords with the *gate control theory*, resulting in the *TENS-like* effect that elevates treatment intensity while minimizing receivers' discomfort.**
The exclusive feature that distinguishes DENSITY® HIGH from other RF devices is its High tip. **While employing the Classic tip replicates almost identical effects to Thermage® FLX, the High tip transcends its effects through the bimodal function within an electrode, incorporating four monopolar irradiations, followed by one bipolar irradiation.** During the device development phase in animal experiments, **it was determined that administering monopolar RF prior to delivering bipolar RF produces the most robust increase in collagen and elastic fiber production.** Herein, an assumption is made that monopolar RF preconditions the skin tissue by heat and reduces the resistance in the dermis, creating optimal conditions for bipolar RF transmission.

Monopolar RF provides not only immediate effects but also has lasting effects beyond six months through volumetric heating to the deep dermal, fat layers and even fibrous septa in targeting deep wrinkles, nasolabial folds, and under-eye sagging for facial skin lifting and remodelling. In contrast, **bipolar RF transmits higher energy to the papillary dermis, addressing skin elasticity loss, fine wrinkles, and rosacea and enhancing overall skin texture, with much greater immediate effects.**

Utilizing cooling control with 5 levels as a parameter function, the treatment can be tailored to specific treatment areas, depth, and the patient's comfort level.

DENSITY® HIGH has other distinctive features: **Auto On recognizes specific pressure on the handpiece and delivers the energy without the need to press hand or foot switches.** The function not only streamlines the treatment process but also reduces operator fatigue for convenience. Additionally, real-time skin surface temperature is displayed on the handpiece, enabling precise energy adjustment and monitoring to increase treatment effectiveness and decrease the risk of thermal burns.

DENSITY® HIGH employs a cooling approach akin to Thermage® FLX, leveraging contact cooling with Hydrofluoroolefin (HFO) as the cooling gas. **HFO is an eco-friendly gas boasting a Global Warming Potential (GWP) index of less than one and designed to provide intense cooling in less time than other commercial products**. It also has the advantage of adjusting the level of cooling from 1 to 5, facilitating pain management and personalized treatments based on the patient's pain tolerance, treatment area, and depth.

Through numerous case studies, the immediate effectiveness and safety of high-frequency facial and body treatments using DENSITY® HIGH have been evident. As experiences accumulate to find optimal energy combinations for more effective treatments, **it is anticipated that DENSITY® HIGH will outperform traditional non-microneedle monopolar RF devices in terms of lifting and enhancing elasticity**. In conclusion, DENSITY® High is a noteworthy advancement amongst RF devices, demonstrating a significant technological advancement surpassing the capabilities of current monopolar RF devices, including Thermage® FLX.

DENSITY® HIGH is an excellent substitute for Thermage® FLX, a conventional monopolar RF device. It offers comparable features to Thermage® FLX advantages, including operational mechanisms, real-time tissue impedance monitoring for precise and consistent energy delivery (constant power), colling gas application and the Face tip dimensions.

DENSITY® HIGH is anticipated to deliver superior firming and lifting results than conventional non-microneedle monopolar RF devices.

Figures & Legends

Fig. 1. Density Class-F tip / 600 shots

Before | After 4 weeks

Fig2. Density High-F tip / 600 shots

Before | After 4 weeks

Fig3. Density High-B tip / 300 shots

Before | After 4 weeks

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