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A Pilot Study for the Safety and Efficacy of Using the Venus Viva Nano-Fractional Device for the Treatment of Wrinkles and Rhytides

ABSTRACT

Fine wrinkles and deep facial wrinkles, referred to as elastosis, are common skin conditions. For many individuals, especially women, facial wrinkles cause significant concern or psychological distress. This pilot study describes the use of nano-fractional radiofrequency to effectively reduce the occurrence of facial wrinkles and elastosis in 10 subjects who underwent a series of three treatments during a 4-week interval. Moderate improvements were observed for >90% of the subjects and no serious adverse events were reported.

INTRODUCTION

Skin laxity, facial texture irregularities such as post acne scars, and facial wrinkles, clinically referred to as rhytides, are common skin conditions in both men and women. The appearance of these types of facial irregularities can result in distress for people of all ages, causing them to turn to cosmetic treatments such as surgical procedures (e.g., face lifts) as well as non-surgical procedures including chemical or laser peels, non-ablative laser resurfacing, or dermabrasion [1]. These procedures are usually associated with prolonged recovery times as well as arduous side effects. To circumvent these issues, the use of non-invasive, nonsurgical approaches that do not require downtime are becoming the preferred method of choice for patients seeking cosmetic improvements. An innovative technique that was introduced to reduce facial wrinkles and rhytides is known as radiofrequency (RF).

One of the earliest procedures entailed using mono-polar RF [2], although bipolar and multi-polar RF devices have also been developed. The premise behind RF technology is dermal heating, which initiates the denaturation of collagen and the stimulation of neocollagenesis through the induction of inflammation that leads to the production of fibroblasts at the heated area and the subsequent development of new collagen [3, 4]. RF energy produces an oscillating electrical current that can penetrate the dermis and hypodermal tissues without disturbing the epidermal-dermal barrier. The generation of the heat energy is the result of the natural resistance that dermal tissue has to the movement of ions with an electromagnetic field. Accordingly, the oscillating electrical current causes collisions between charged ions that are transformed into heat energy [3, 5]. The production of heat energy through RF typically results in ablation, coagulation, and skin resurfacing.

Mono-polar RF devices were used initially for facial treatments, and although the results appeared to be promising, this approach was associated with serious pain as well as the high incidence of adverse events including second-degree burns that are caused by the deeply penetrating heat production of the single electrode [6]. Bipolar and multi-polar RF devices allow the heat energy to be distributed more evenly with less depth-penetration, thereby resulting in less pain and improved safety profiles [7, 8] but concerns remained regarding the ability to precisely control the degree of ablation and coagulation that is required depending on a patient's skin type. Moreover, a randomized, blinded, split-face study comparing the use of mono-polar and bipolar RF devices for the treatment of skin laxity and wrinkles indicated that there was no difference in pain, side effects, or efficacy between mono-polar and bipolar devices [9]. Therefore, RF techniques that improve the ability to control the ablation and

coagulation of the skin can result in treatment consistency that will provide more flexibility to treat a wider variety of skin conditions.

The objective of this study was therefore to evaluate the safety and efficacy of using a nano-fractional RF device to reduce facial wrinkles, rhytides, and elastosis. Nano-fractional RF technology offers more precise depth penetration and consistent selection dermal heating as well as controlled coagulation and ablation ability in comparison to other RF devices. The technology is delivered through 160 pins per tip with 62mj per pin and a smaller footprint per pin (150x20 Microns), which results in micro wounds, efficient skin resurfacing, and minimal downtime.

MATERIALS AND METHODS

Ten subjects (9 females, 1 male) between the ages of 34 and 67 (mean age=42.30 years, SD=10.023) with facial wrinkles and rhytides participated in this pilot study. The inclusion criteria included having 3 to 9 degrees of elastosis on the Fitzpatrick Wrinkle and Elastosis Scale as well as providing written consent. Exclusion criteria were: implanted pacemakers, arrhythmias, or any other known severe heart disorder, implantable metal devices (excluding metal dental devices), medication that affects the skin or hormones, malignant skin cancer in the treatment area, a history of keloid formations or hypertrophic scarring, pregnant or lactating subjects, autoimmune disorders, diabetes, clotting disorders, epilepsy or severe migraines, permanent makeup, tattoos, or body piercings in the treatment area, extreme general weakness, subjects with psychiatric disorders being treated with psychiatric medications, and skin therapy in the past 6 months.

Each subject had a screening assessment, a pretreatment photograph, three treatment visits over a 4-week interval with photographs of the treated areas, and two post-treatment visits (1 month and 3 months post-treatment). Each subject received three RF scan treatments with the use of the 160-pin tip (per area of 8x20 mm). The treatment area was cleaned thoroughly with soap and water; then dried prior to the treatment. The treatment parameters such as the pick power (180 to 280 Volts-V) and the duration of pulses (5 to 25 milliseconds-ms) was determined based on subject skin type and the area of treatment. Biopsies were also performed at varying times after treatment and the tissue was stained with hematoxylin and eosin (H&E) for histological evaluation of the depth of ablation and coagulation.

Before each treatment, every subject was photographed in a standardized way. Subjects were assessed for discomfort during each treatment. Immediately after each treatment, the treated area was assessed for skin responses including hemorrhage, burn, erythema, edema, hyperpigmentation or hypopigmentation, pain, scarring, or infection. In addition, subjects were asked to rate the perceived pain level during the treatment through the use of a visual analog scale (VAS). The Global Aesthetic Improvement (GAI) Scale was used to assess treatment efficacy: 4-Improved significantly; 3-Improved moderately; 2-No difference; 1-Worsedned slightly; 0-Worsened significantly. All of the patient observations were based on comparisons to the baseline and the scale criteria were as follows: 4- marked visual improvement in texture, fine lines, and wrinkles after treatment; 3- visual improvement was noted after treatment, but not dramatic in relation to texture, fine lines, and wrinkles; 2- treated area was the same as the baseline; 1- texture, wrinkles, and fine lines were slightly more apparent than at baseline; 0- dramatic visible increase in texture, fine lines, and wrinkles were apparent after treatment.

RESULTS

All 10 subjects enrolled in the study completed the treatment, including the 1-month and 3-month follow-up visits. Clinical and histological improvements of the treated facial areas were observed for all of the parameters that were evaluated, which included: laxity grade, wrinkles, acne scars, pore appearance, skin elasticity, and pigmentation. At the post-treatment follow-ups, a GAI score of 3 was recorded for >90% of the subjects, indicating that moderate visual improvement in the facial areas that were treated was observed, but dramatic differences in wrinkles and elastosis were not.

The treatments resulted in RF thermal zones within the papillary and reticular dermis. There were no serious complications or adverse events such as burning, scarring, hemorrhage, or infection during the treatments or at post-treatment follow-ups. In the moderate RF energy group (pick power: ≥245 V, pulses: 5 to 30 ms), transient swelling, erythema, and ecchymosis were observed. In the low RF energy group (pick power: 180 V, pulses: 5 to 25 ms), itching, erythema, and skin pins marks that remained for up to 72 hours were reported. All events resolved without sequelae.

DISCUSSION AND CONLCUSION

Skin laxity and deep facial wrinkles are typical signs of skin aging, while dyschromia, elastosis, fine wrinkles, telangiectasia and keratoses are usually attributed to photo-aging. Post acne scars are especially problematic for individuals who suffer from life-long acne. Each of these types of skin conditions is common among both men and women of all ages. The demand for non-invasive facial treatment approaches has increased dramatically as it affords patients with advantages such as marked cosmetic improvements, minimal risks, and rapid recovery periods, but in order to achieve such results safely and consistently it is important that factors such as the degree of ablation and coagulation of the skin can be controlled through the use of the RF device. The present study demonstrates that a nano-fractional RF device is a minimally invasive treatment approach that offers efficient standardization. Furthermore, the current findings indicate that the Venus Viva system resulted in sufficient ablation and coagulation that initiated skin resurfacing in the treated areas. These results also provide implications for marked changes in texture, fine lines, and wrinkles in addition to visual improvement with treatment periods that are longer than 4 weeks.

All 10 of the subjects that participated in this pilot study reported a fair level of comfort during the treatments and no serious adverse events or complications were recorded throughout the duration of the study. Minimal side effects that developed as a result of the treatment resolved without sequelae. Furthermore, subjects with various skin types were treated with varying degrees of RF output energy (maximum of 280 V) and pulse times (max. of 25 ms) and no serious adverse events were observed or reported. These results support the safety of nano-fractional RF scan treatments.

In addition, the GAI scale as well as the subject improvement questionnaire ratings showed that the majority of the patients experienced moderate improvements in all of the parameters that were measured, indicating that the RF treatments resulted in efficient ablation and skin resurfacing. Although some of the subjects reported that they were unsure regarding whether improvements had occurred, none of the subjects reported being dissatisfied with the RF scan treatment results. Therefore, the clinical and histological improvements that were measured for the facial areas that were treated support the efficacy of nano-fractional RF treatment at

reducing the appearance of facial wrinkles, rhytides, and elastosis. Due to the positive clinical outcomes of nano-fractional RF scan devices as well as the minimal risks and side effects; this approach is becoming the gold standard treatment method for patients with skin laxity, deep facial wrinkles, photo-aging, and post acne scars.

LIMITATIONS

Although the results of nano-fractional RF scan treatments are promising, the long-term sustainability of reduced facial wrinkles and elastosis is currently unknown. Therefore, further investigation is required. Furthermore, the formation of areas of encrustation (< 0.5 mm) for 24-72 hours post-treatment must be discussed with patients prior to RF treatment. This is an essential part of skin resurfacing, but may be viewed as cosmetically disadvantageous for some patients as the use of make-up to conceal such formations must be avoided for at least 24 hours after each treatment. In addition, patients may experience noticeable or moderate improvement after RF treatment, but to date, the complete elimination of skin wrinkles and elastosis has not been achieved through this method.

References

1. O'Daniel TG. Multimodal management of atrophic acne scarring in the aging face. Aesthetic Plast Surg. 2011; 35(6):1143-50.
2. Ruiz-Esparza J, Gomez JB. The medical face lift: a noninvasive, nonsurgical approach to tissue tightening in facial skin using nonablative radiofrequency. Dermatol Surg. 2003; 29(4):325-32.
3. Zelickson BD, Kist D, Bernstein E, et al. Histological and ultrastructural evaluation of the effects of a radiofrequency-based nonablative dermal remodeling device: a pilot study. Arch Dermatol. 2004;140(2):204-209.
4. Drew PJ, Watkins A, McGregor AD, Kiernan MN, Clement M. The effects of temperature and time on thermal bond strength in tendons. Lasers Med Sci. 2001;16(4):291-298.
5. Alster TS, Lupton JR. Nonablative cutaneous remodeling using radiofrequency devices. Clin Dermatol. 2007; 25:487-491.
6. de Felipe I, Del Cueto SR, Pérez E, Redondo P. Adverse reactions after nonablative radiofrequency: follow-up of 290 patients. J Cosmet Dermatol. 2007;6(3):163-166.
7. Gold MH, Goldman MP, Rao J, Carcamo AS, Ehrlich M. Treatment of wrinkles and elastosis using vacuum-assisted bipolar radiofrequency heating of the dermis. Dermatol Surg. 2007;33(3):300-309.
8. Royo de la Torre J, Moreno-Moraga J, Muñoz E, Cornejo Navarro P. Multisource, Phase-controlled Radiofrequency for Treatment of Skin Laxity: Correlation Between Clinical and In-vivo Confocal Microscopy Results and Real-Time Thermal Changes. J Clin Aesthet Dermatol. 2011;4(1):28-35.
9. Alexiades-Armenakas M, Dover JS, Arndt KA. Unipolar versus bipolar radiofrequency treatment of rhytides and laxity using a mobile painless delivery method. Lasers Surg Med. 2008;40(7):446-453.

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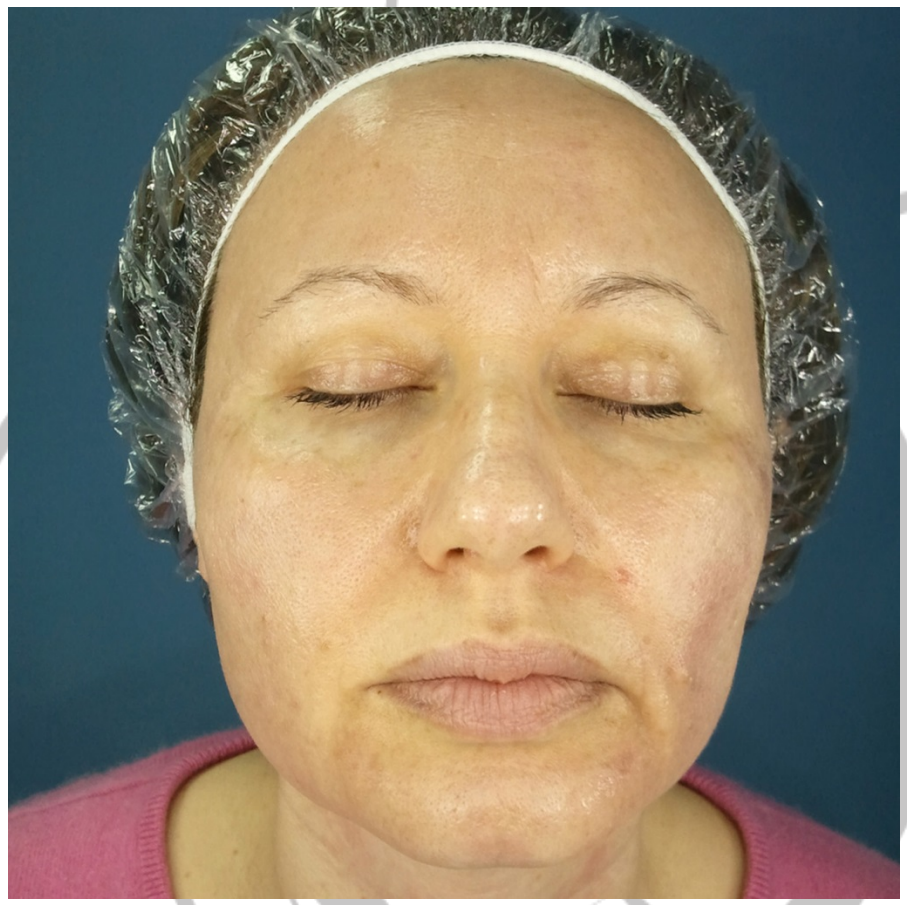

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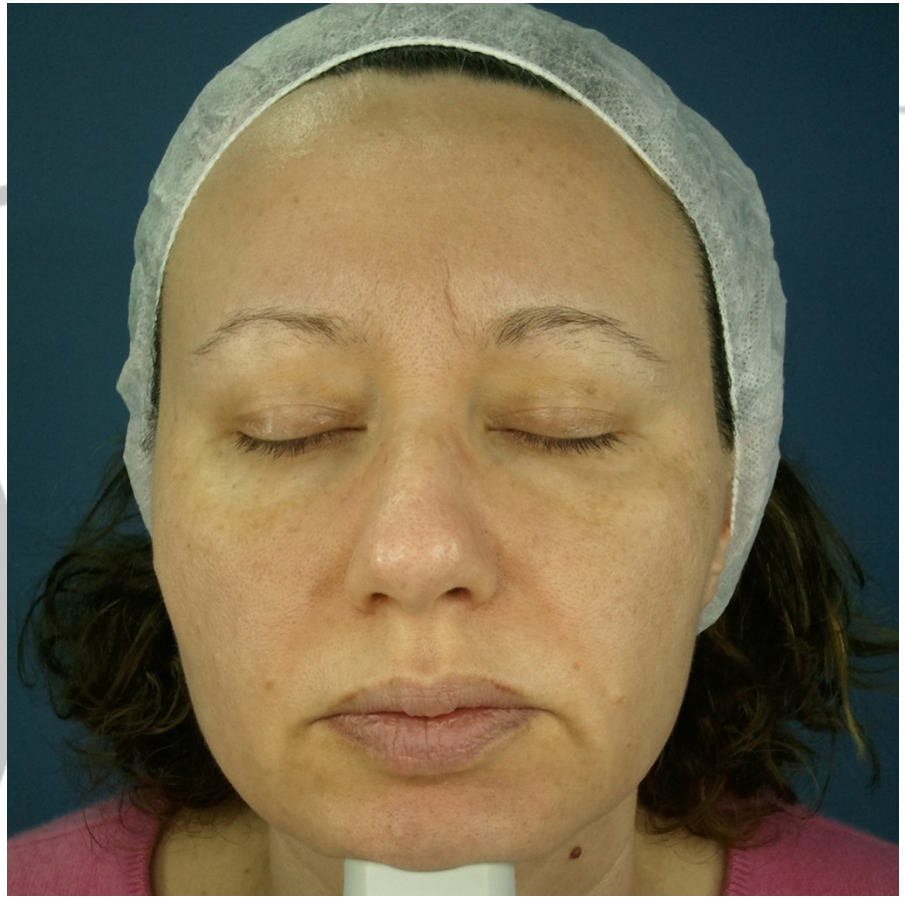

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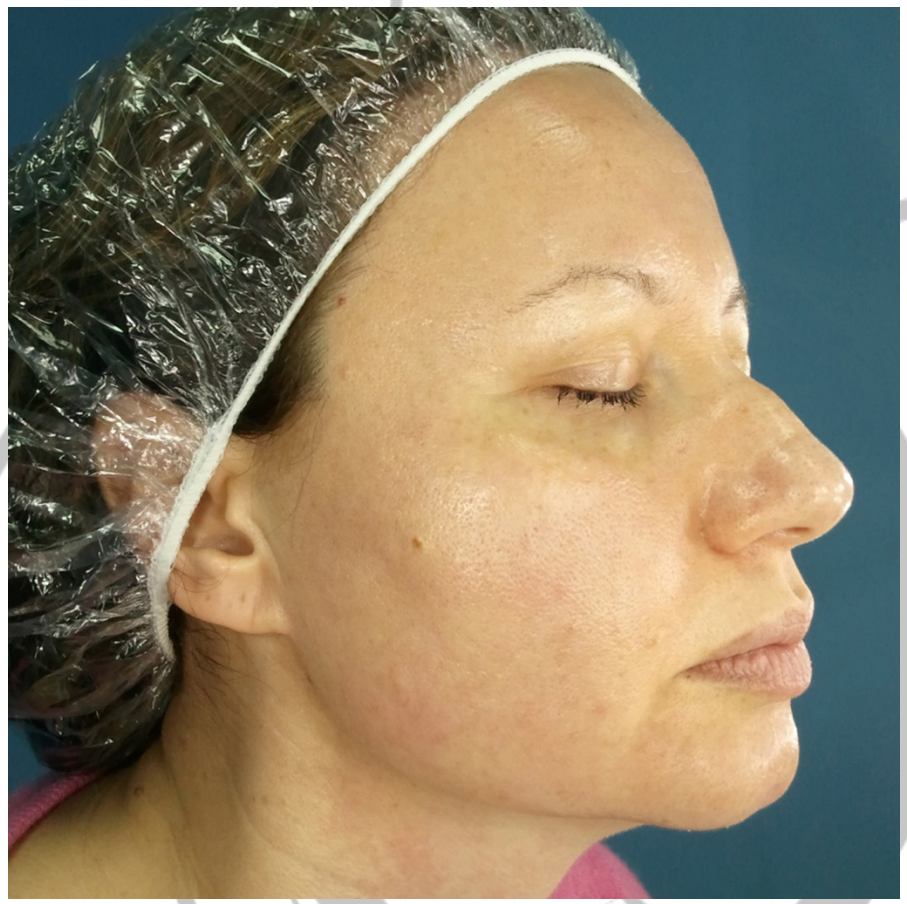

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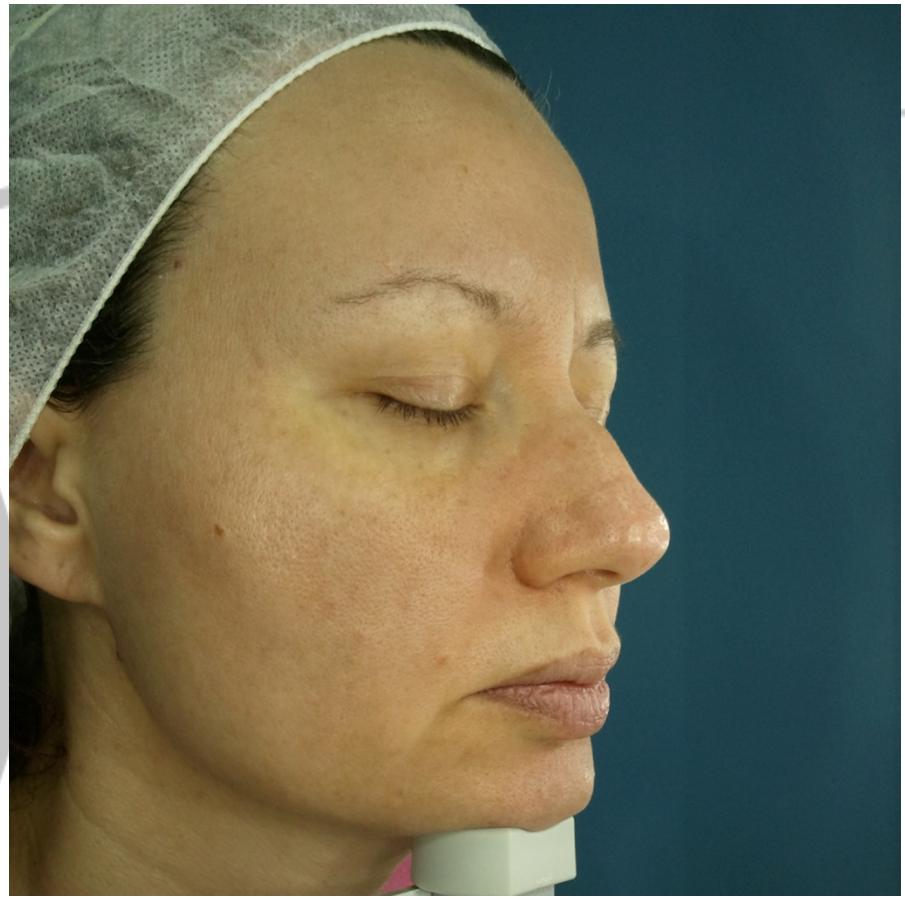

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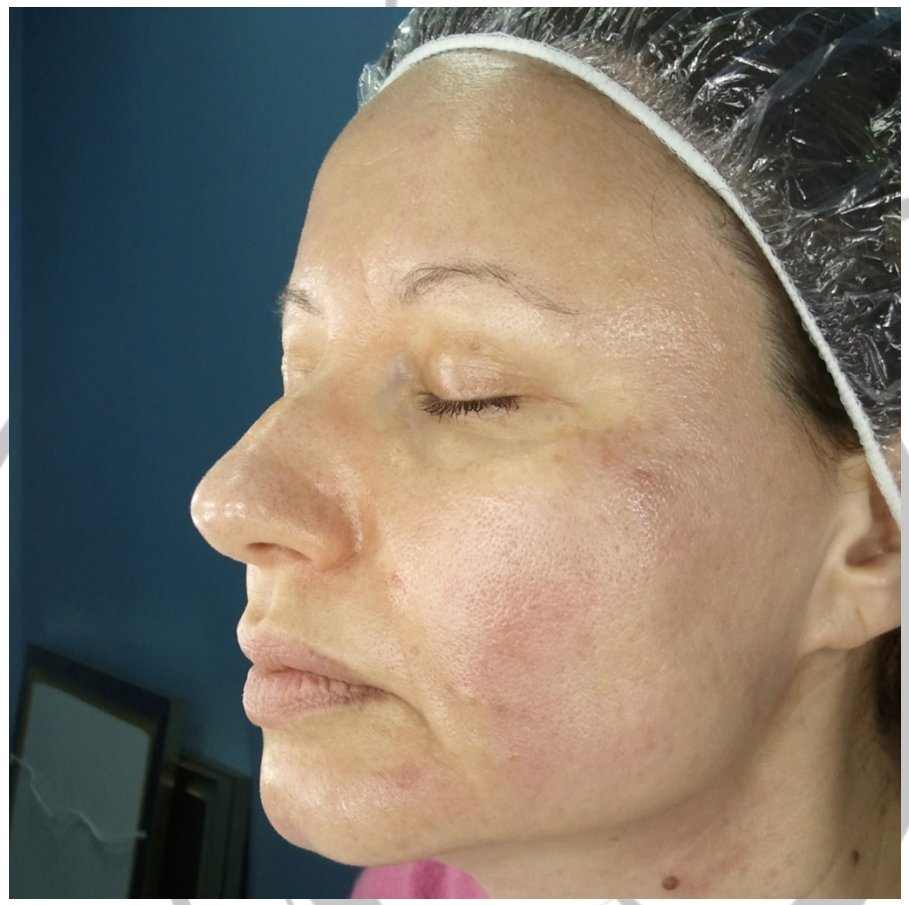

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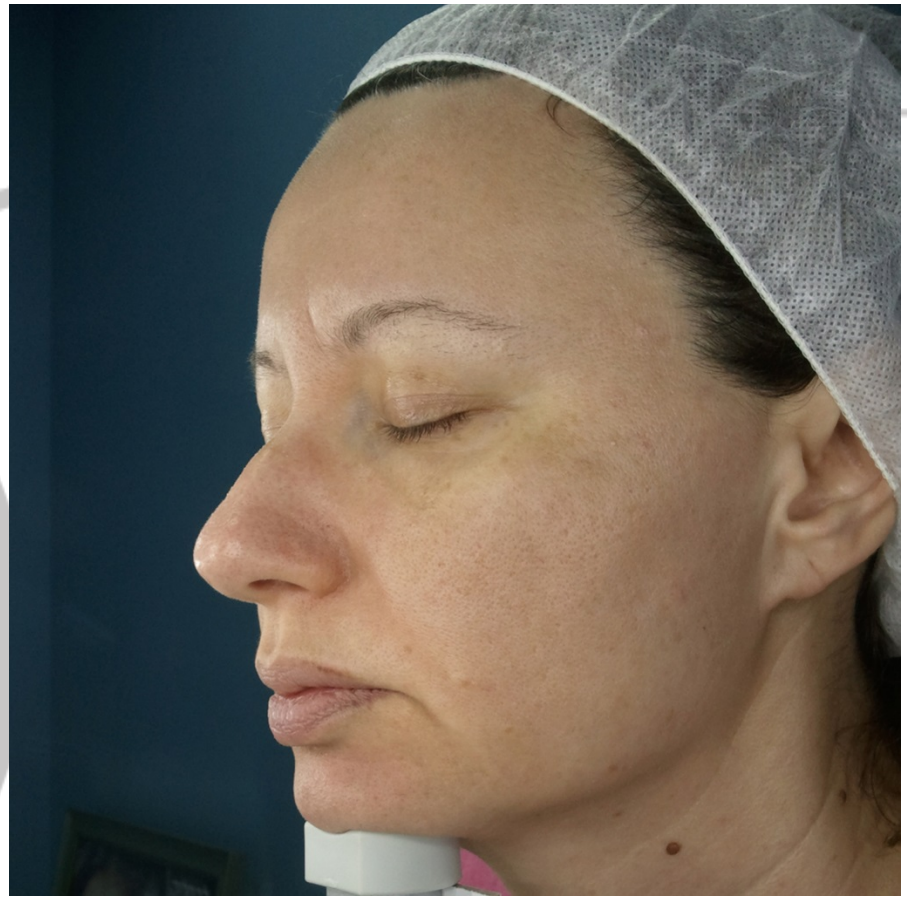

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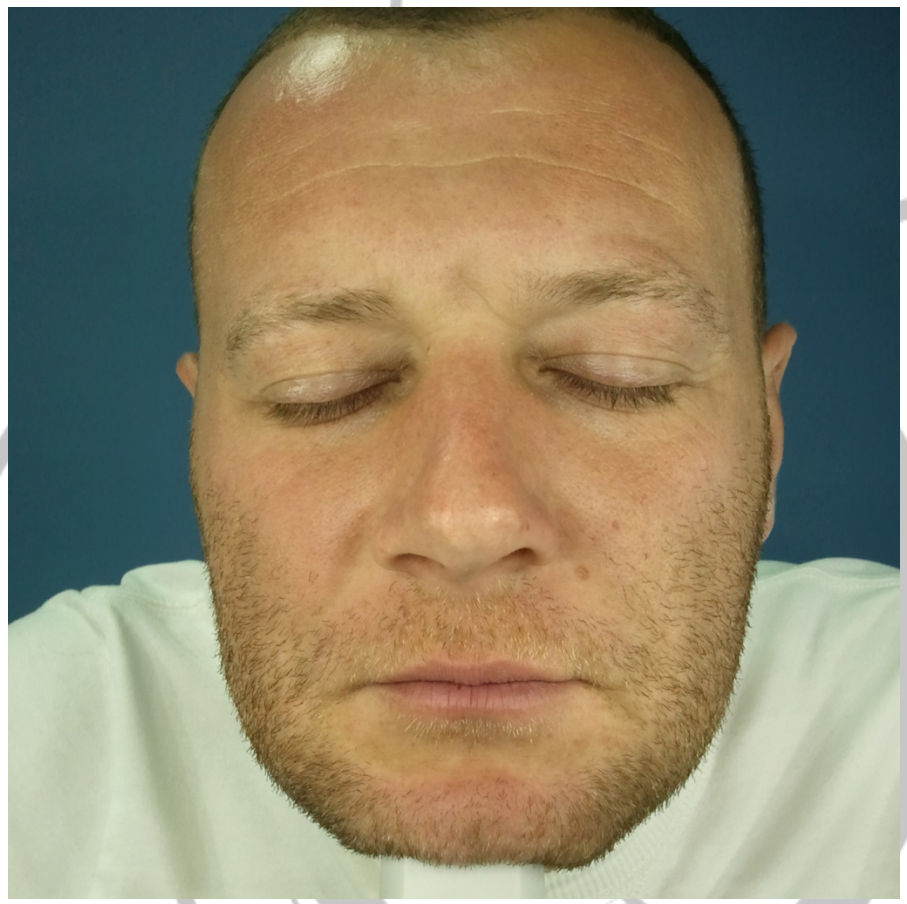

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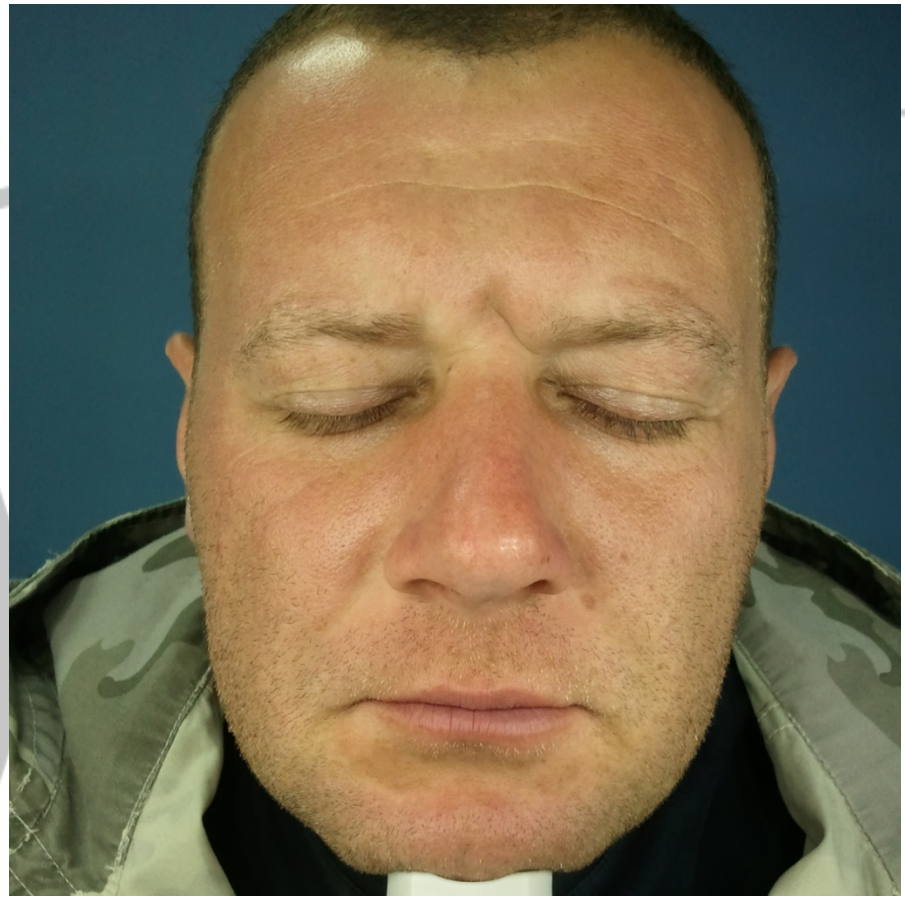

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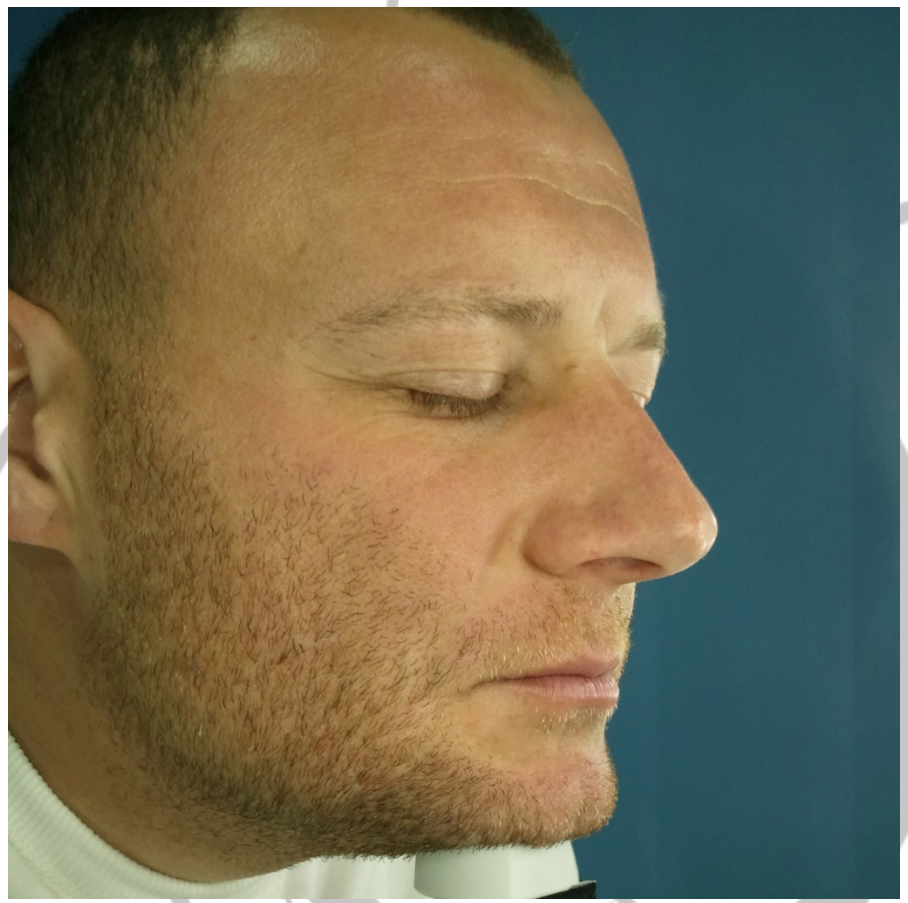

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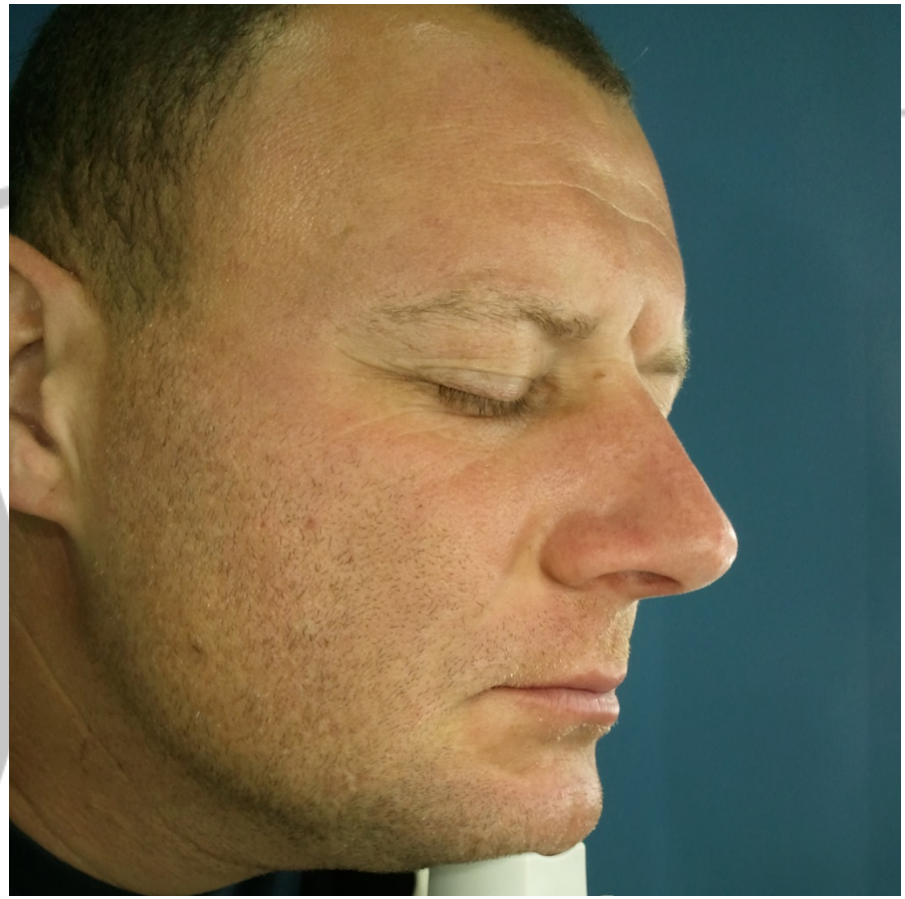

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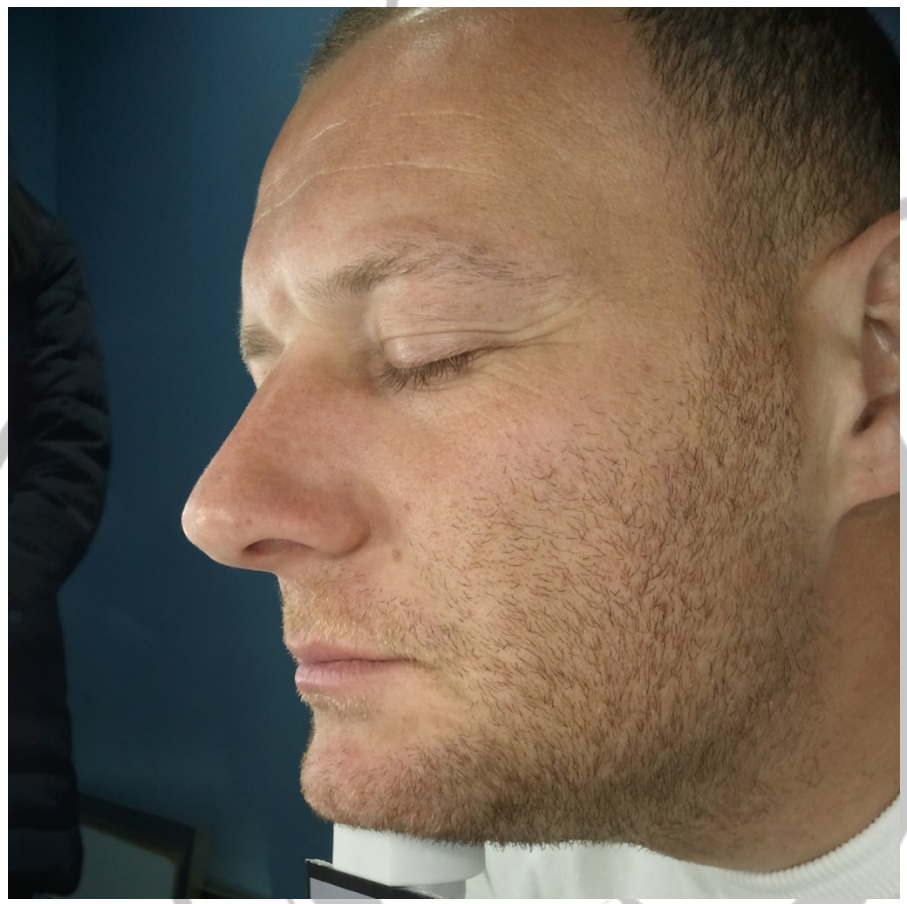

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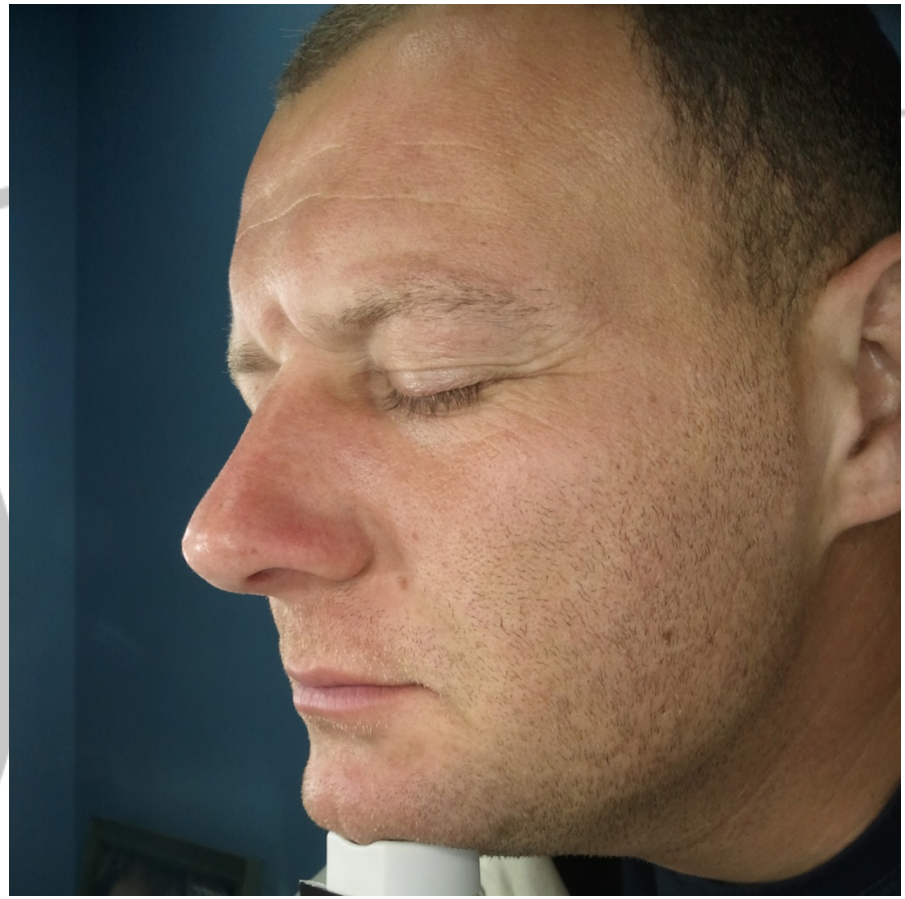

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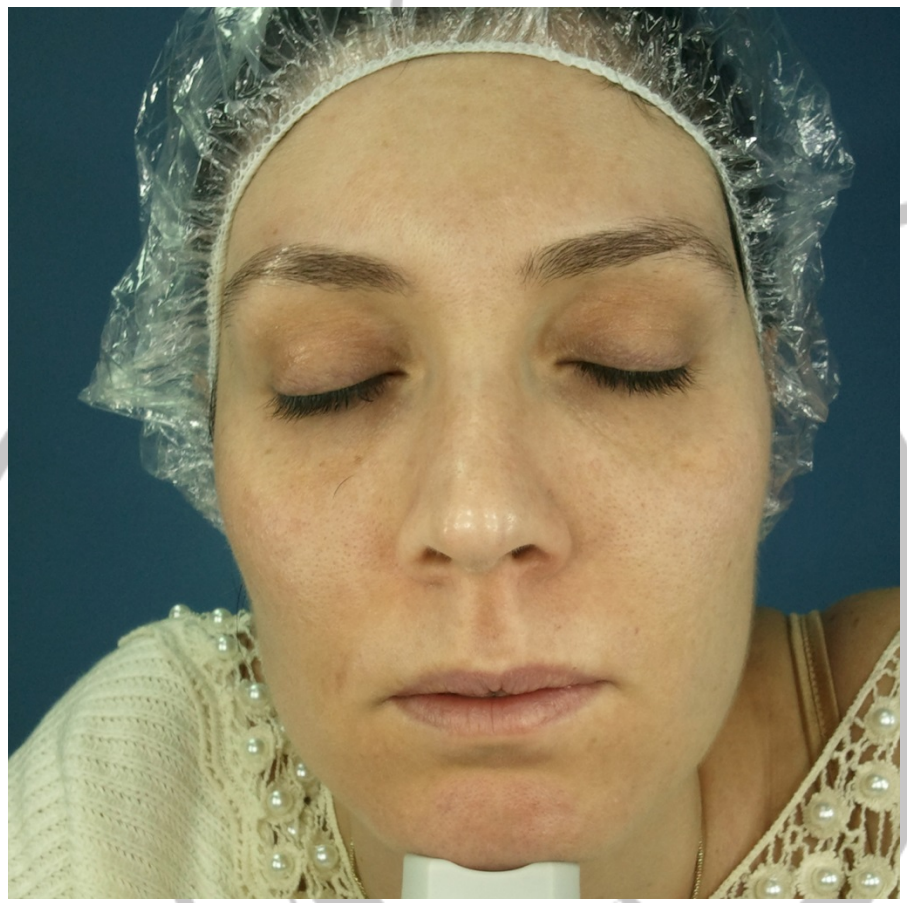

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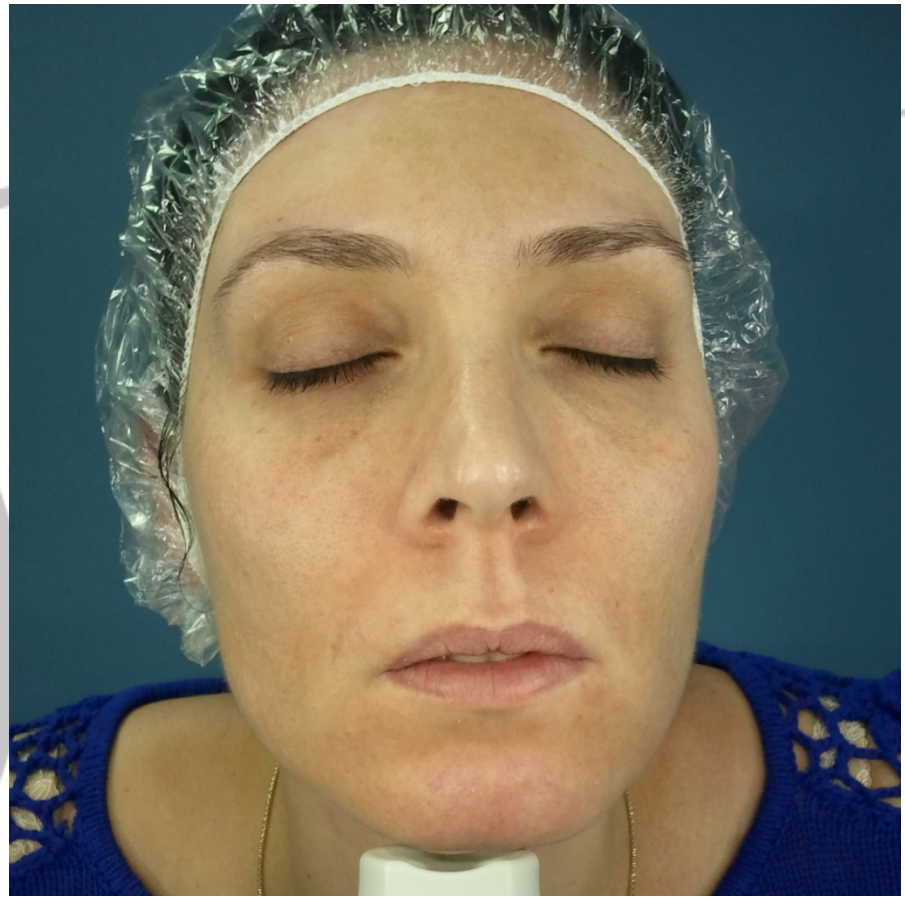

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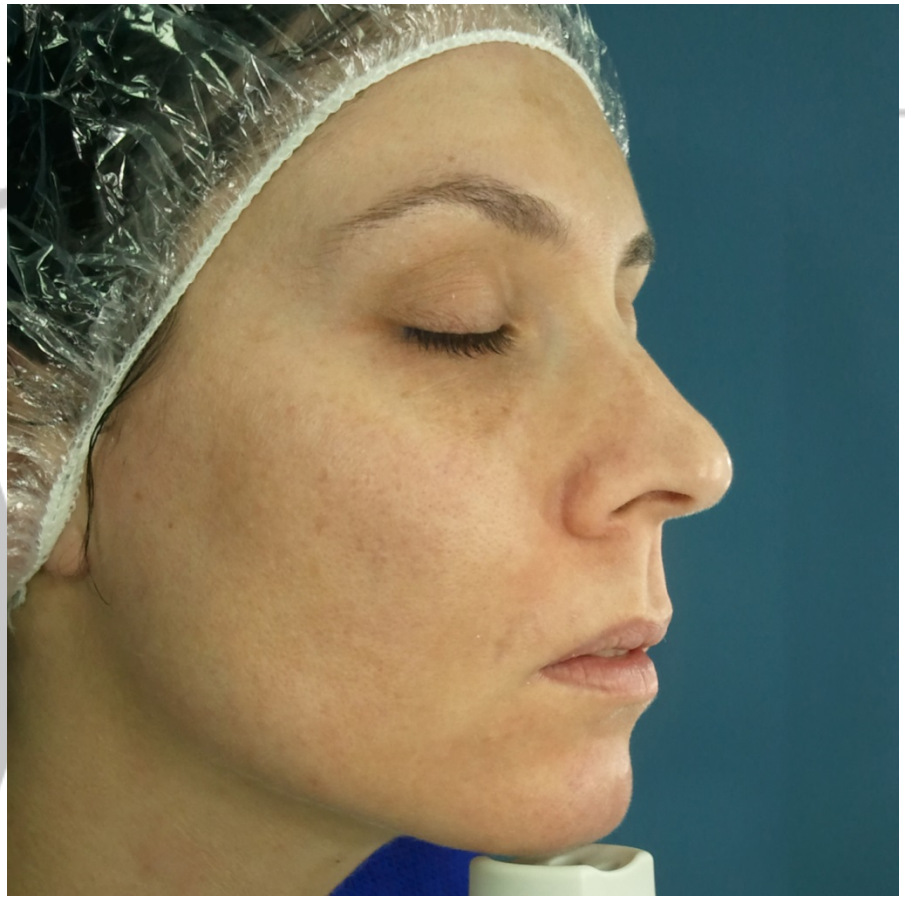

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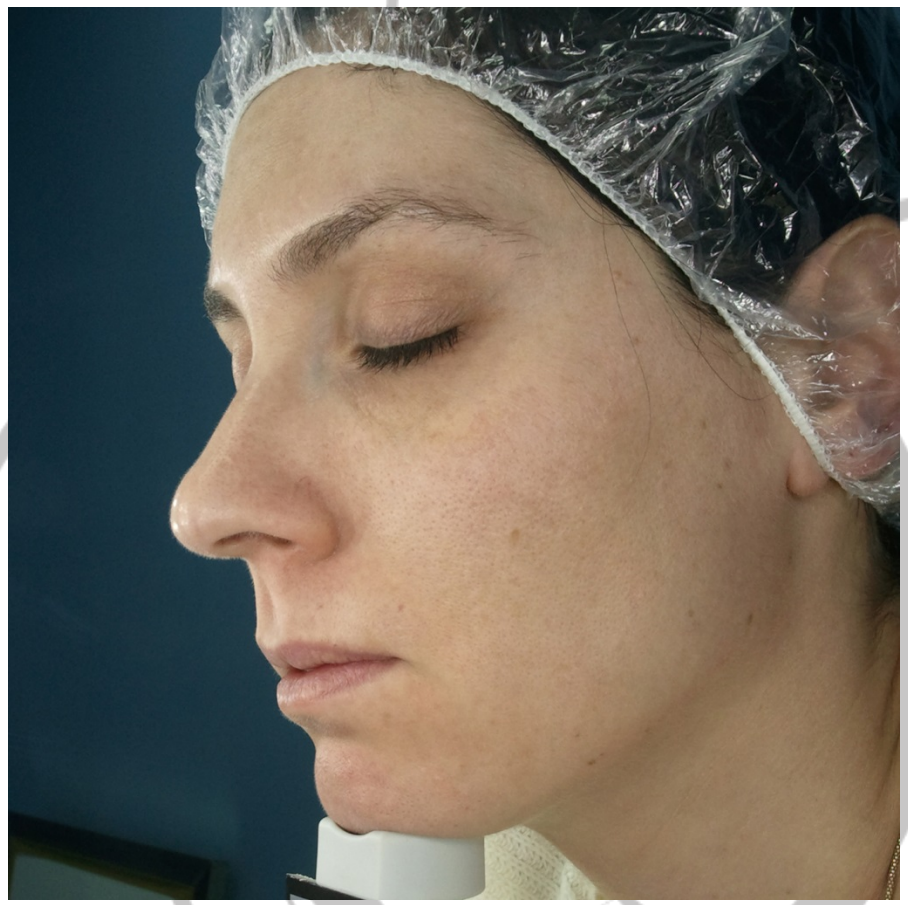

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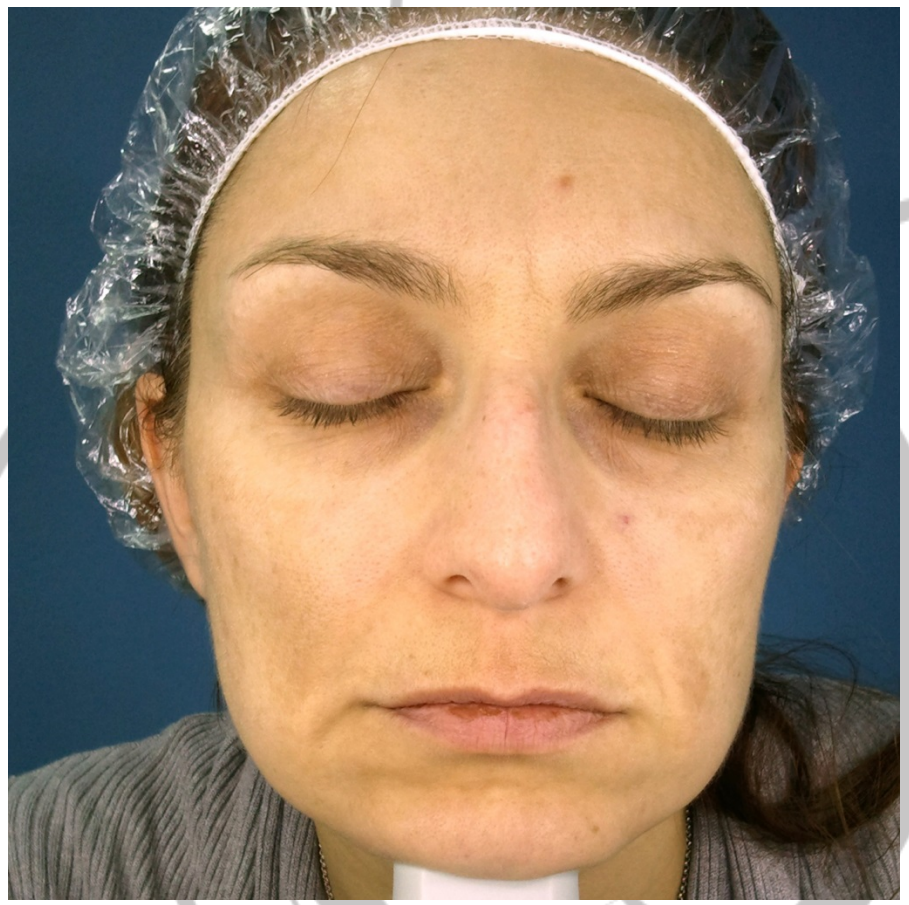

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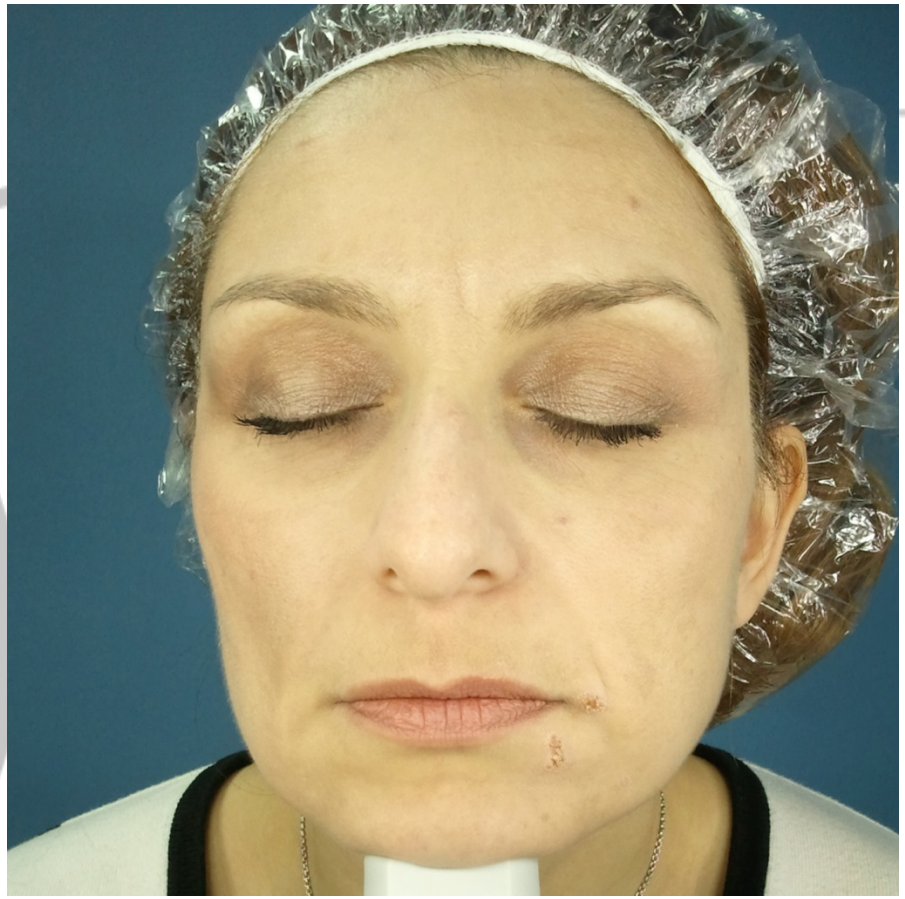

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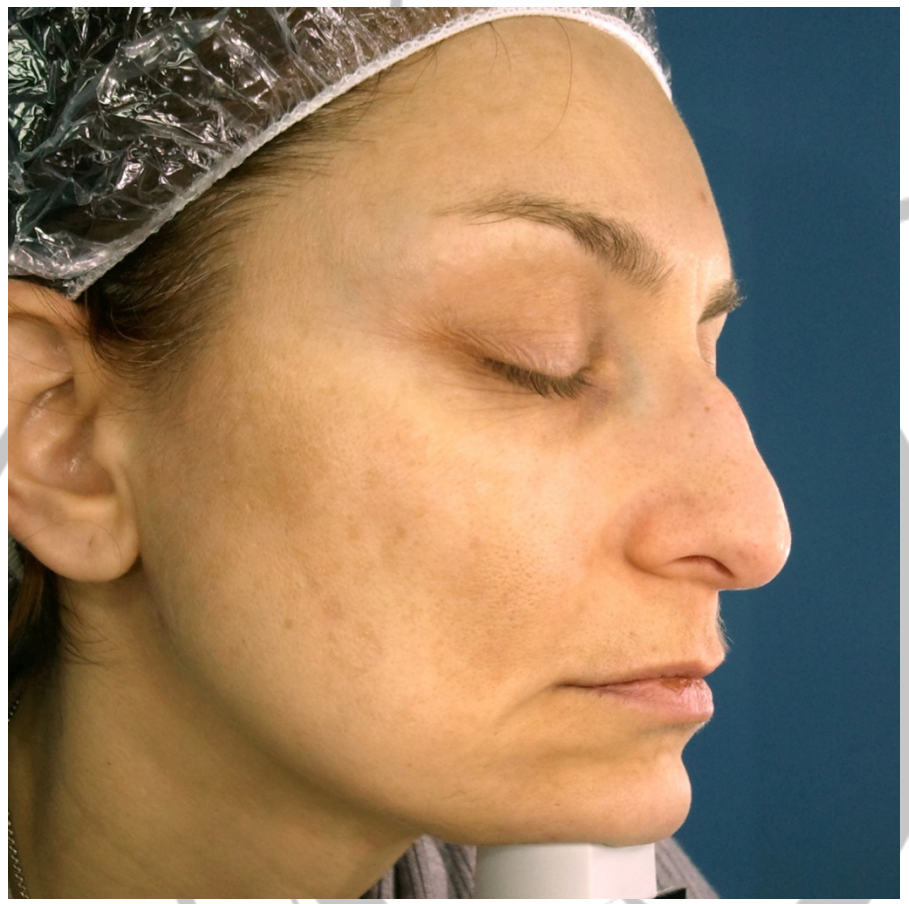

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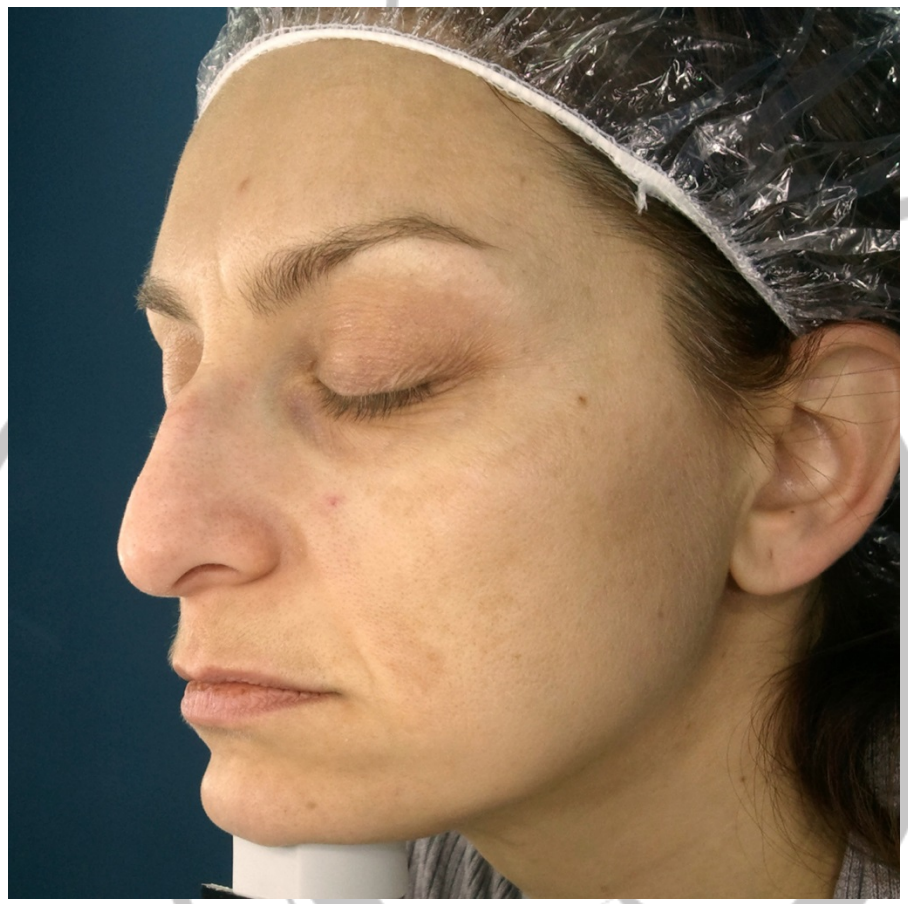

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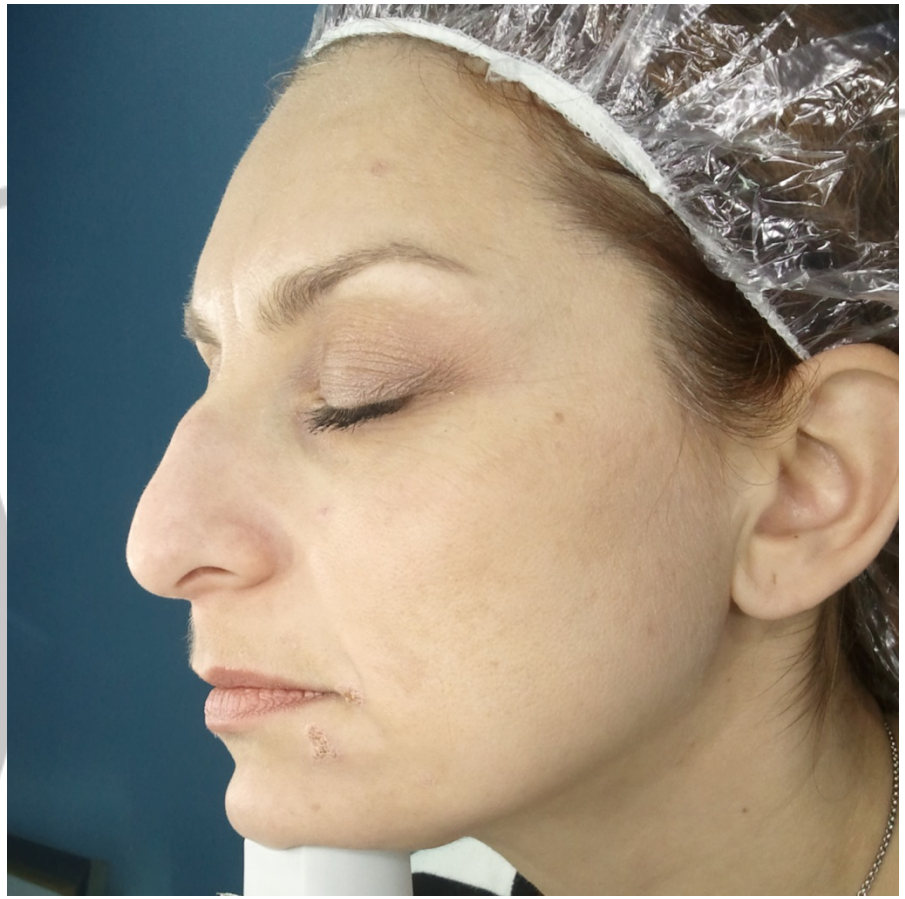

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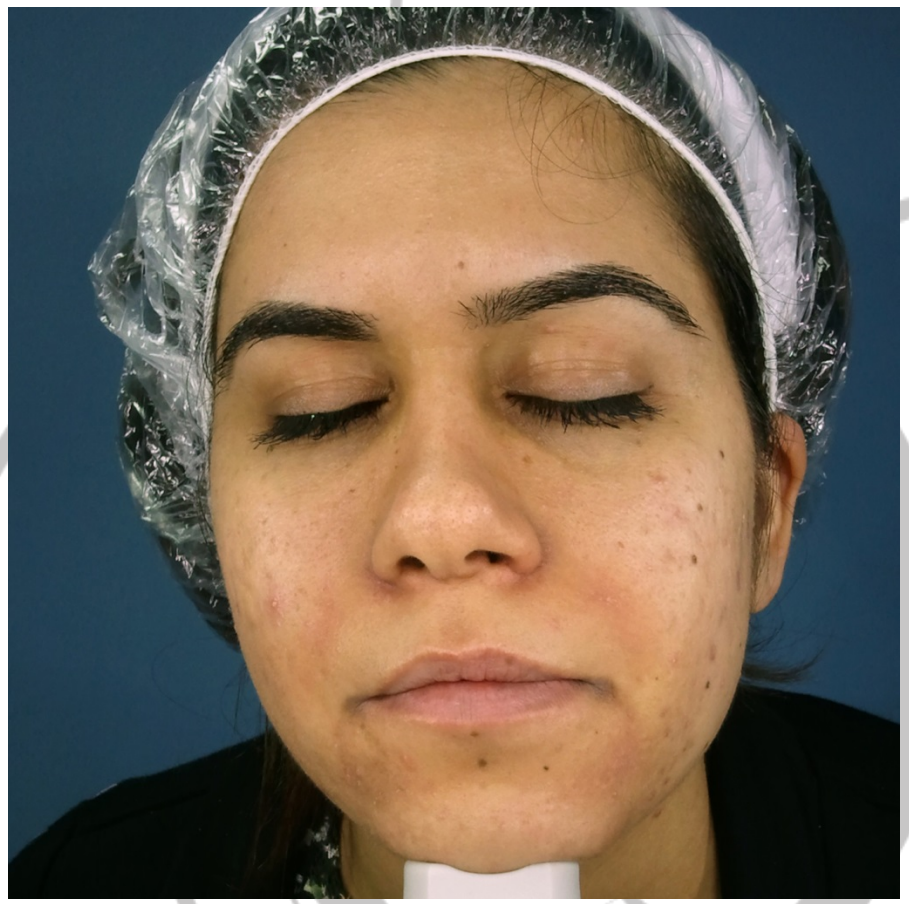

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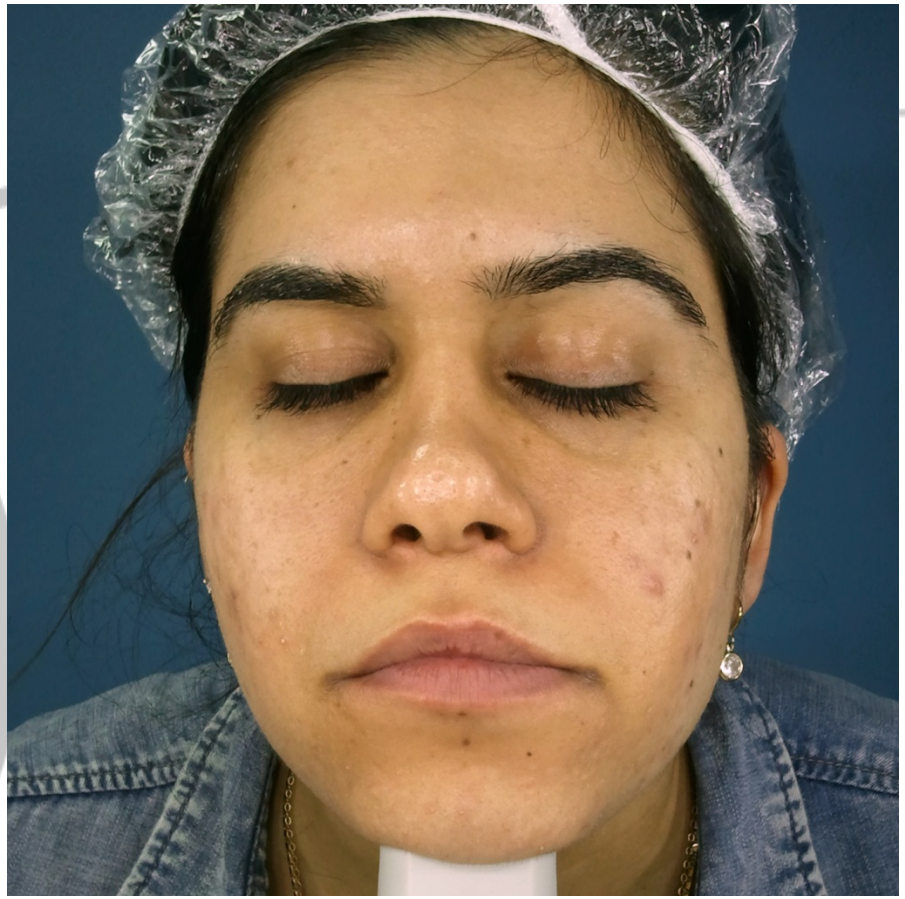

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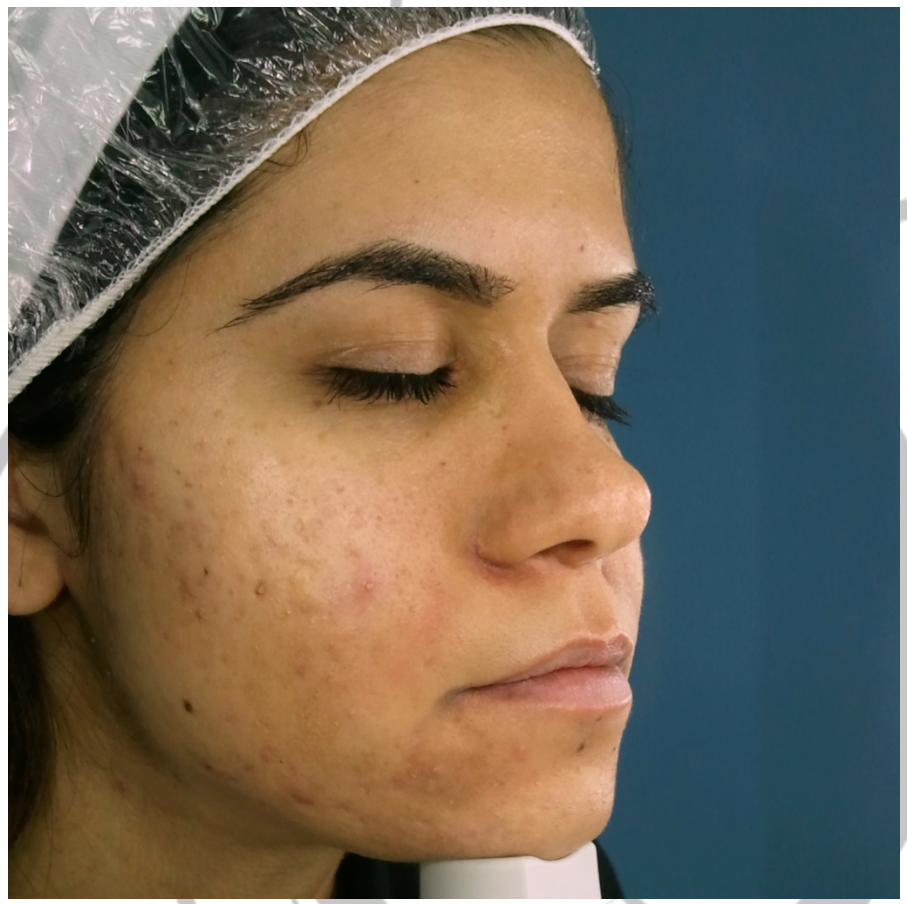

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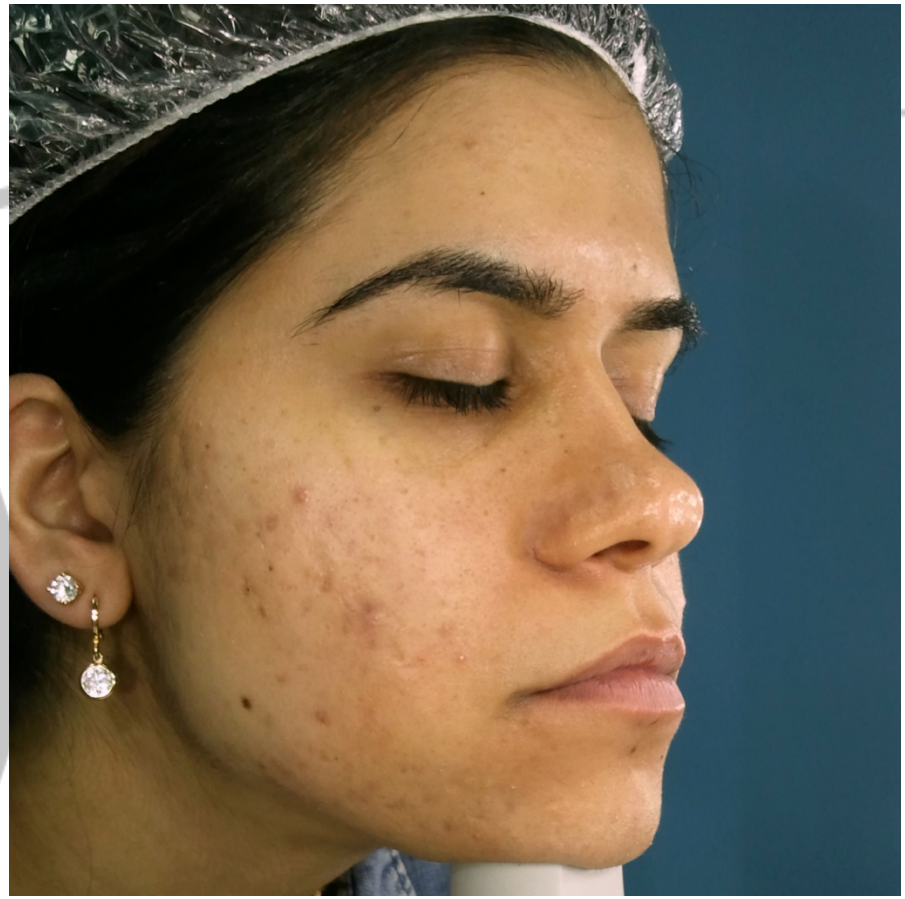

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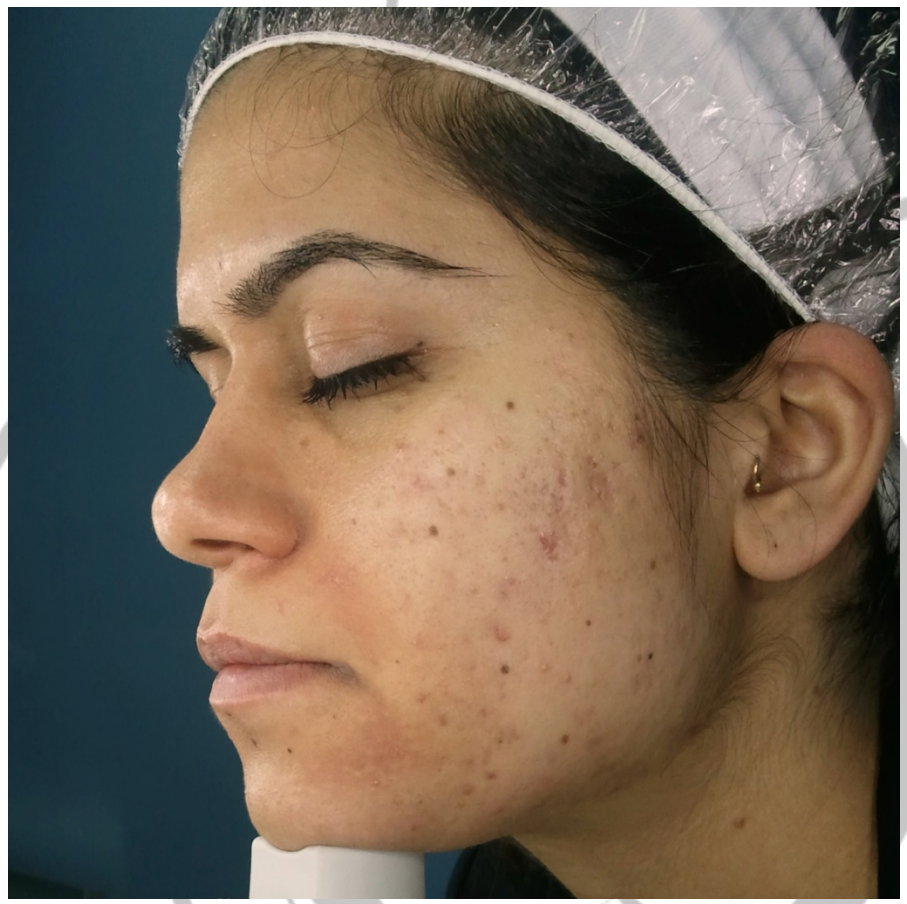

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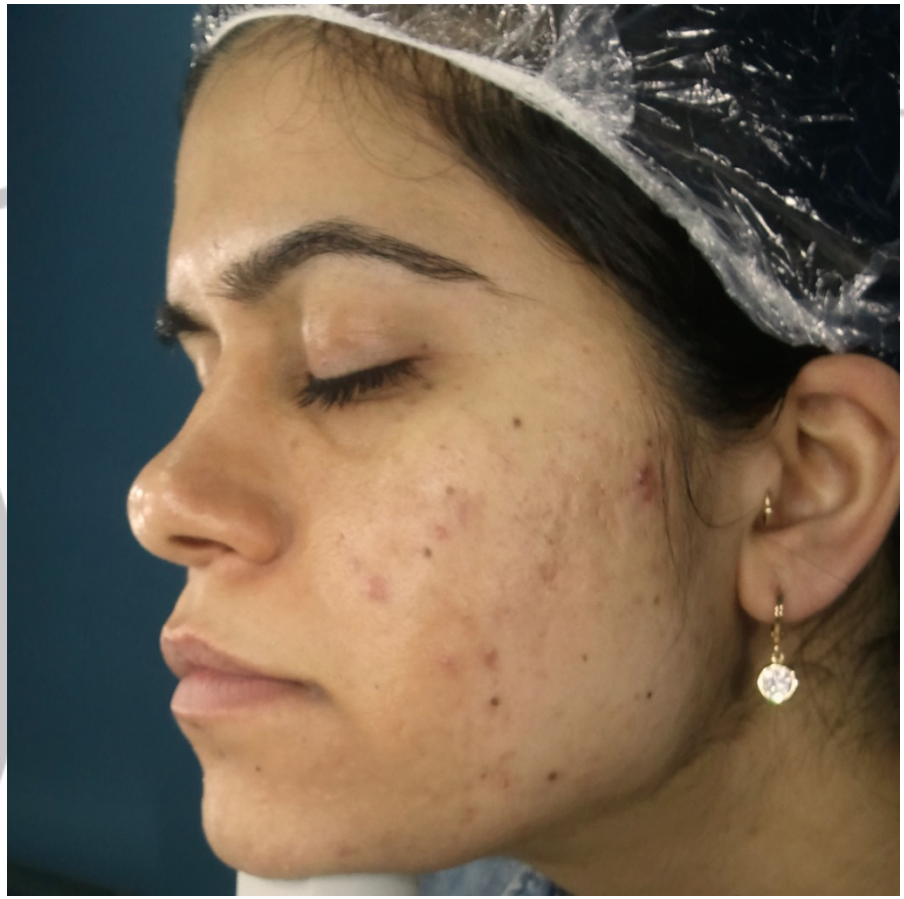

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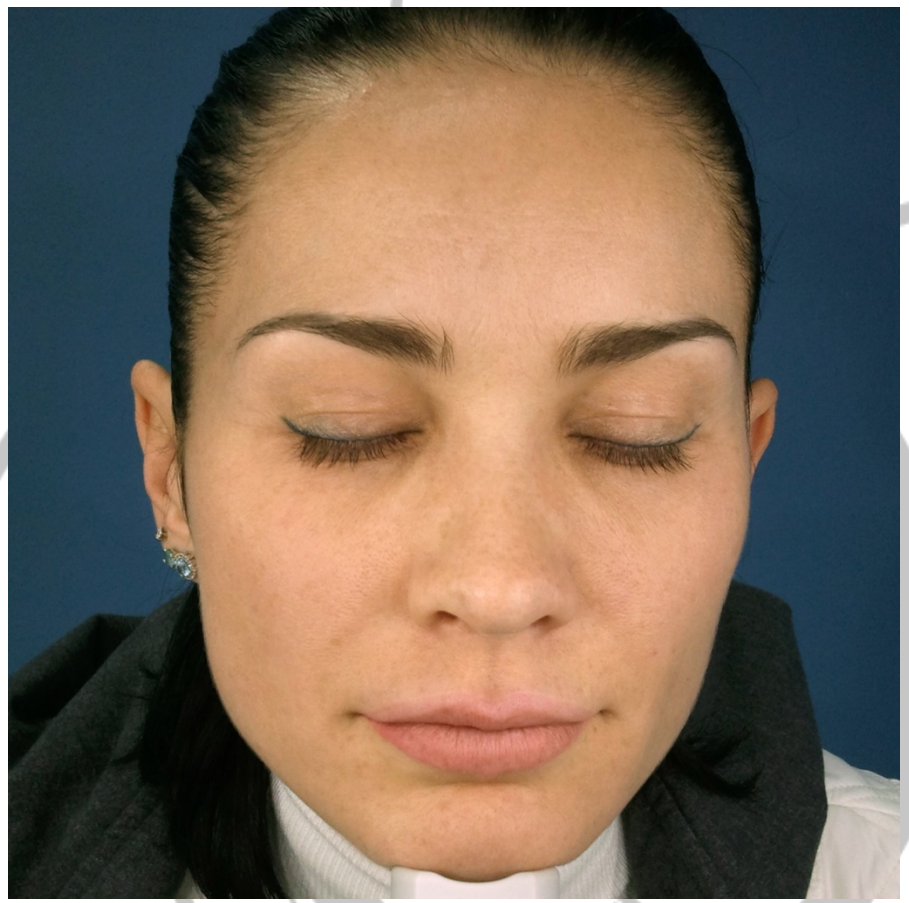

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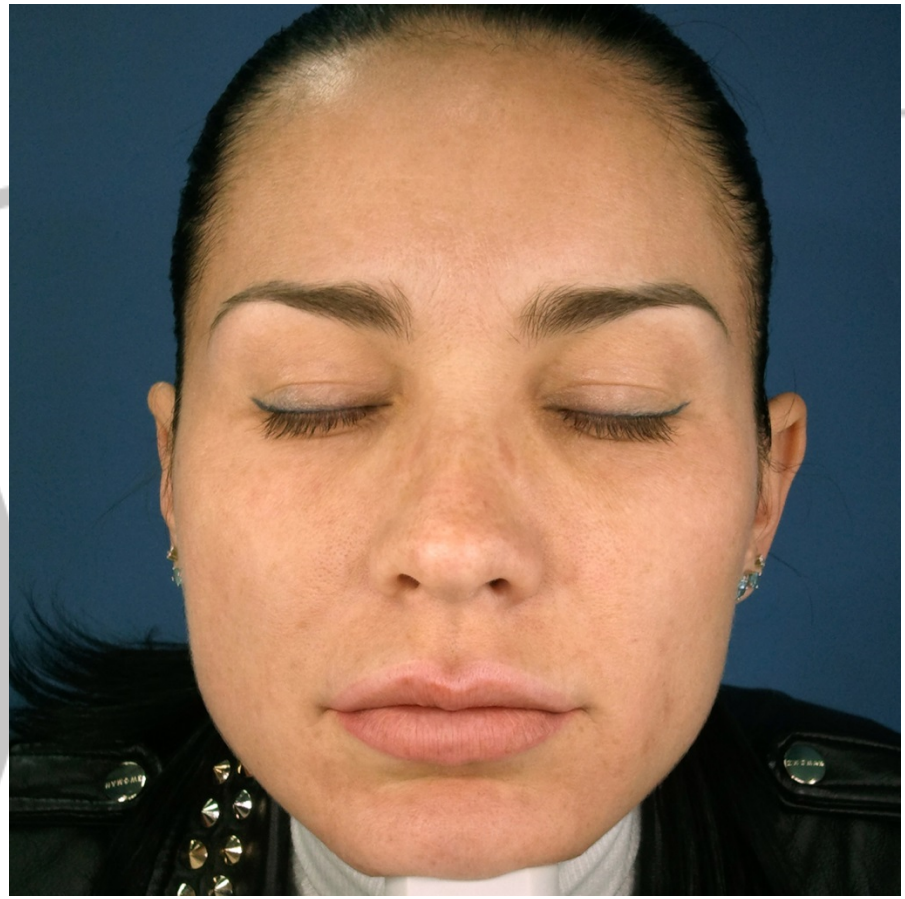

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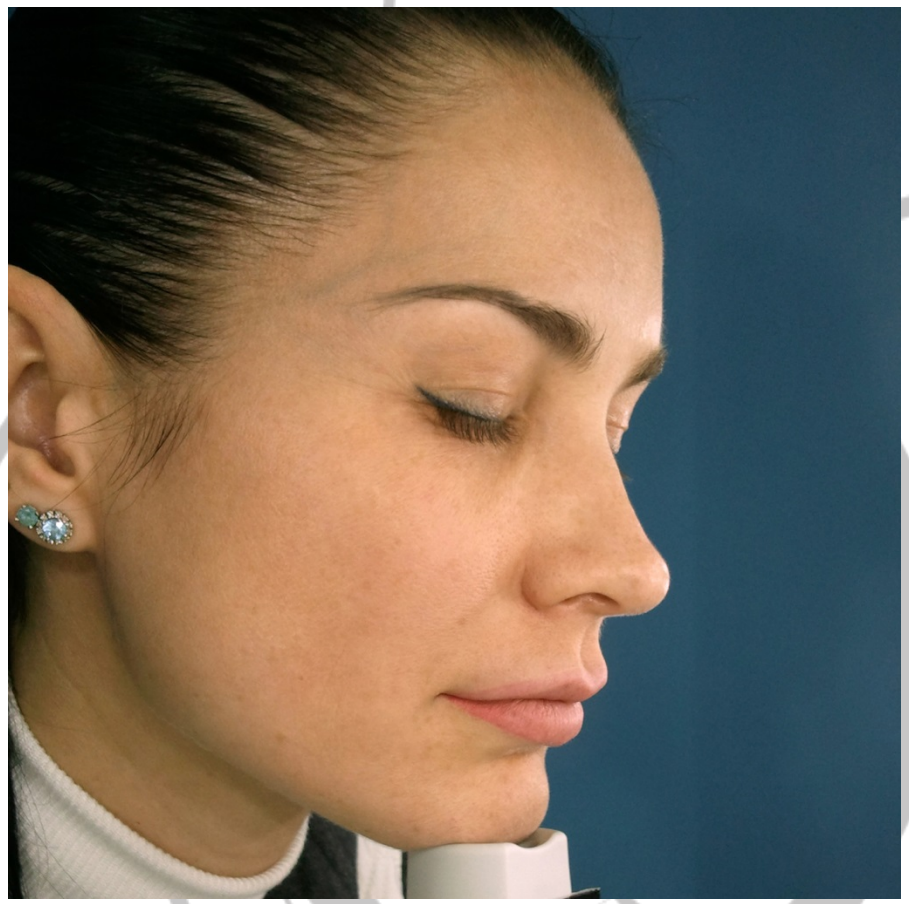

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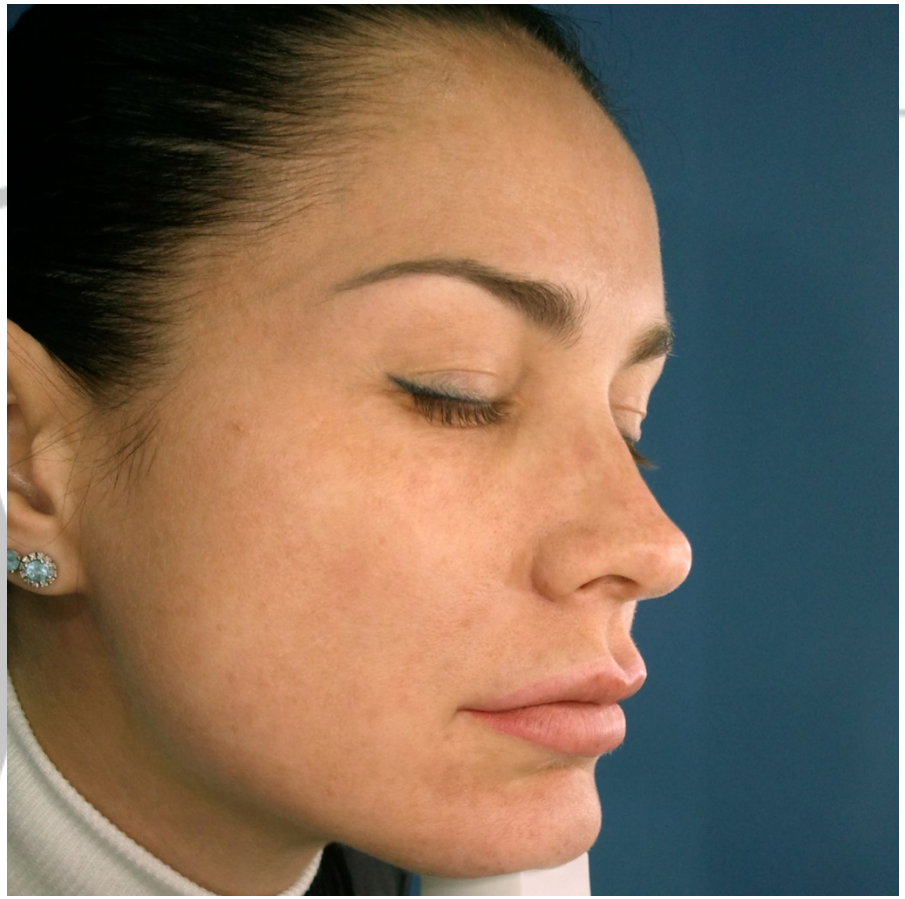

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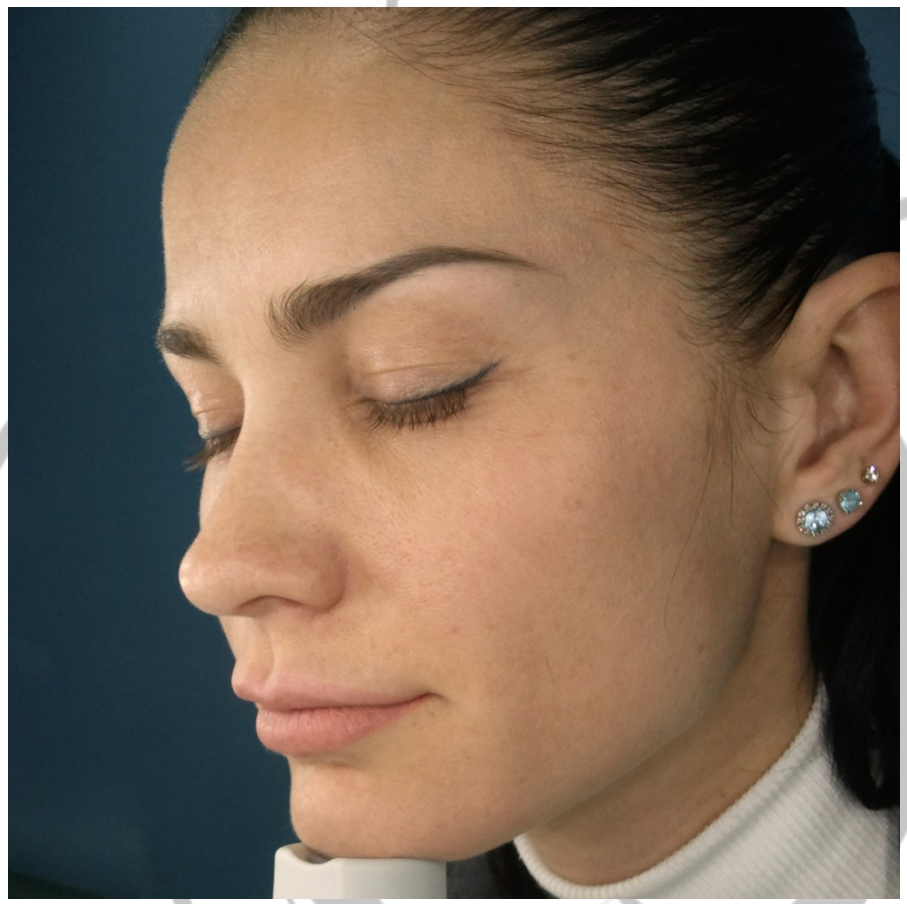

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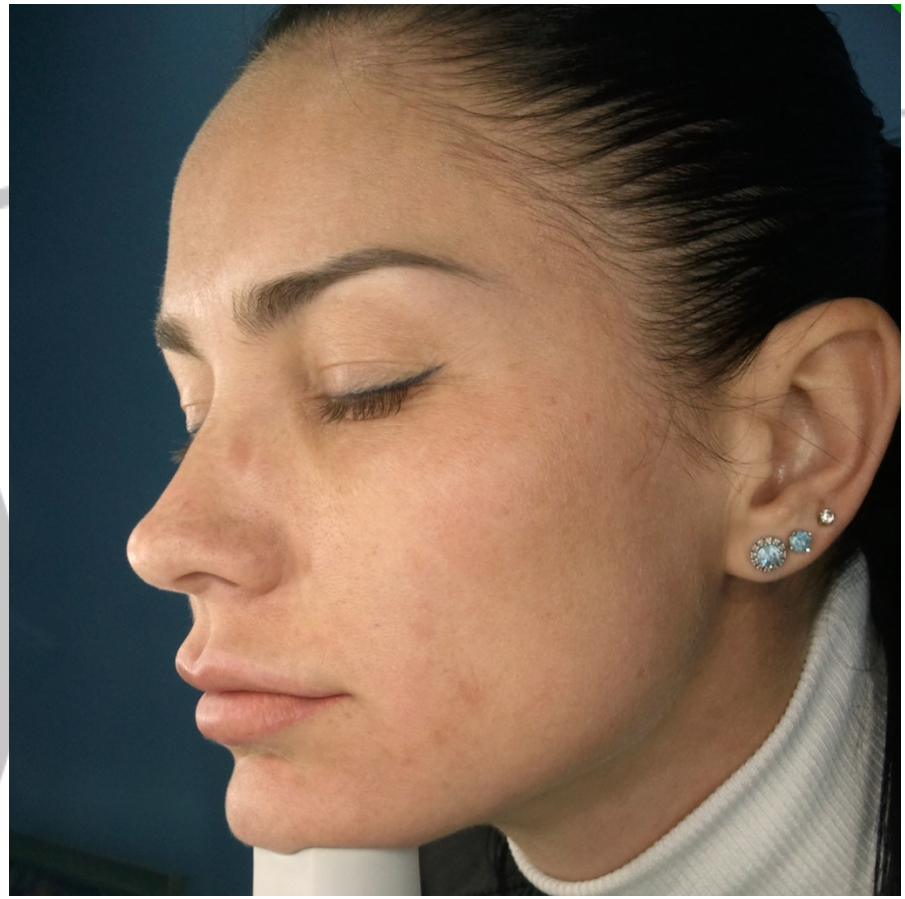

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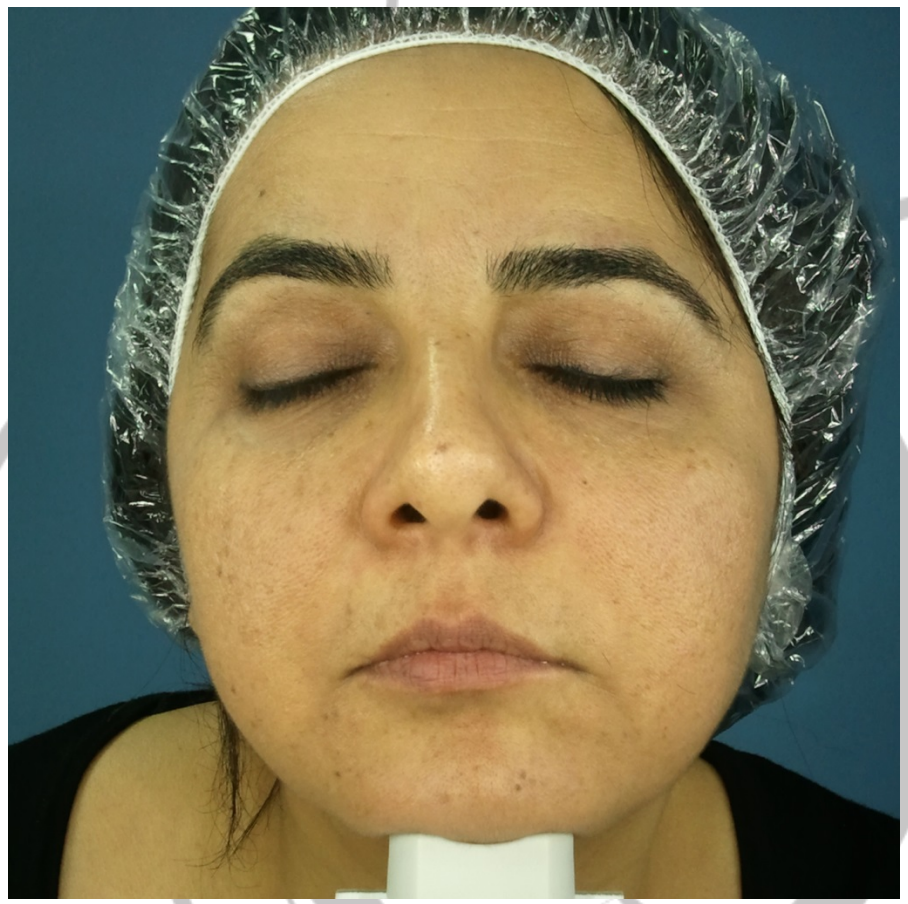

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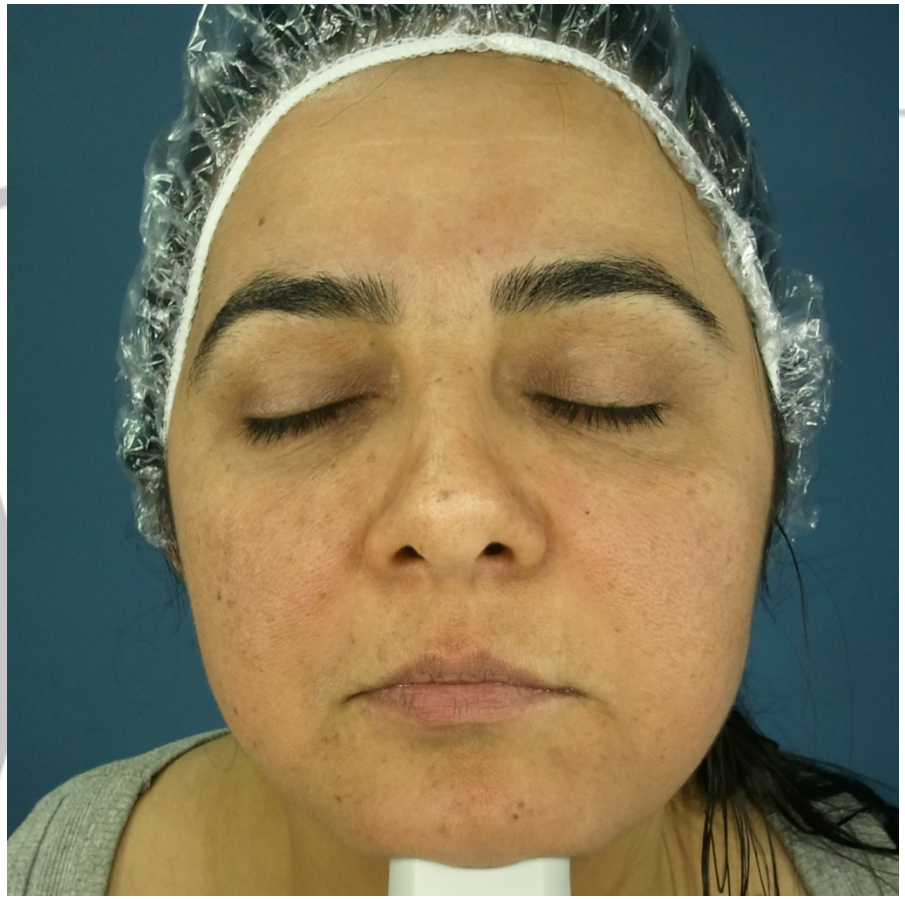

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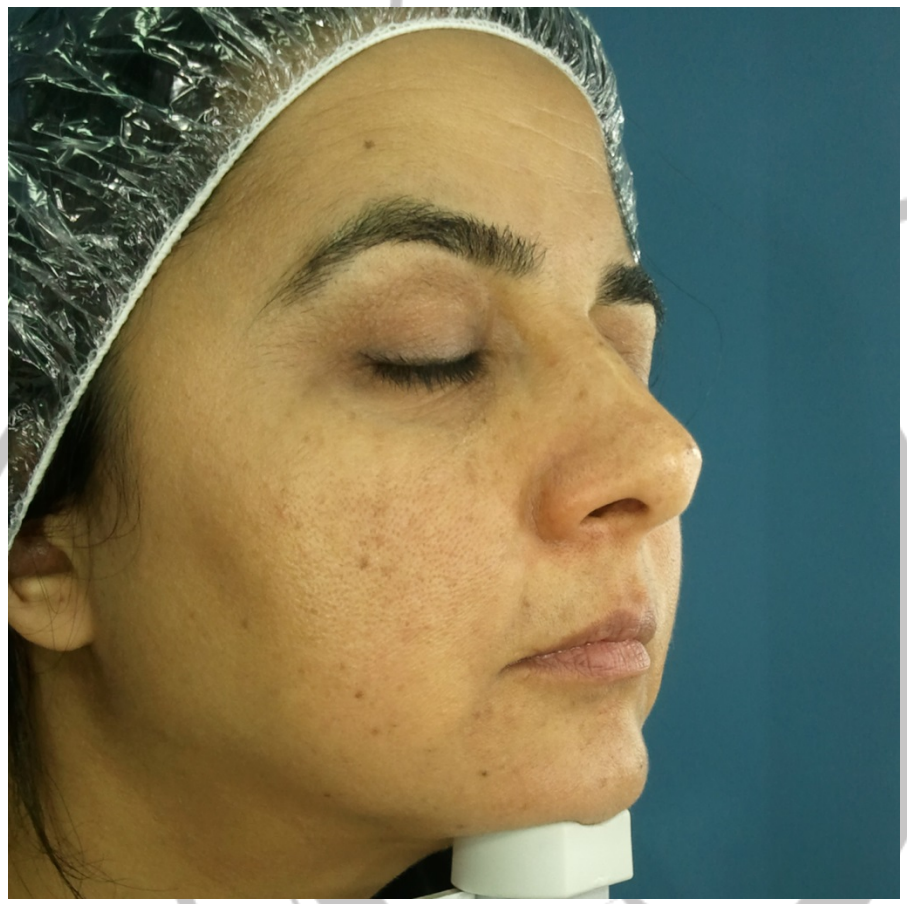

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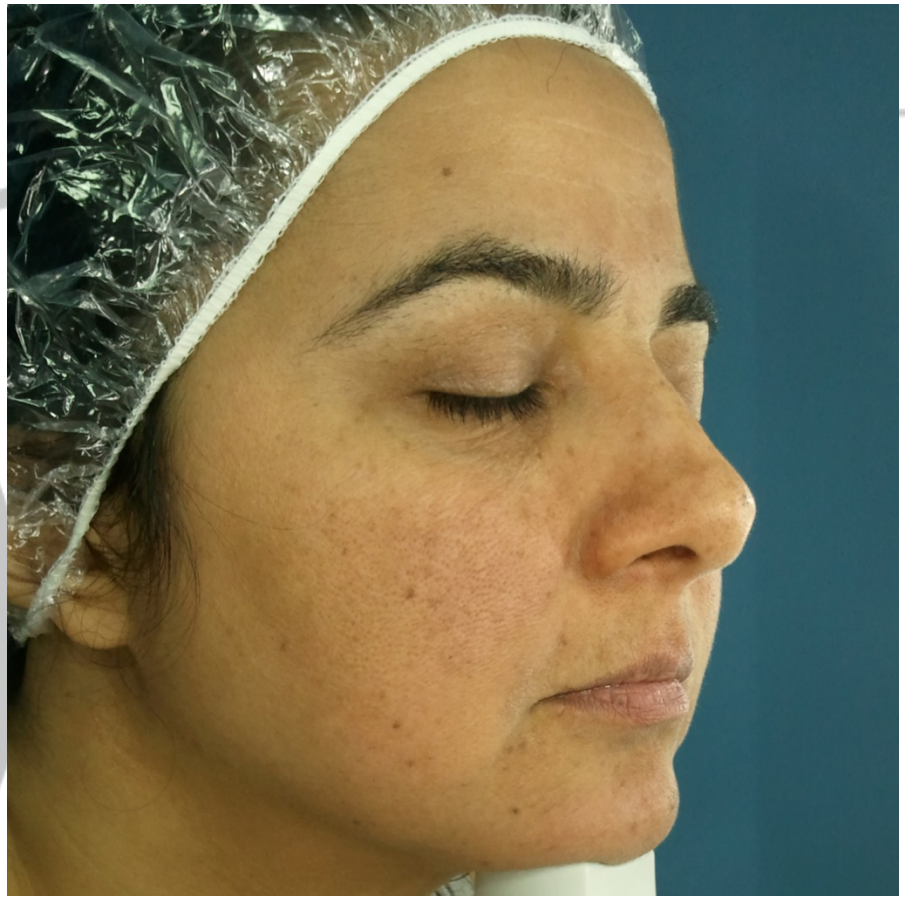

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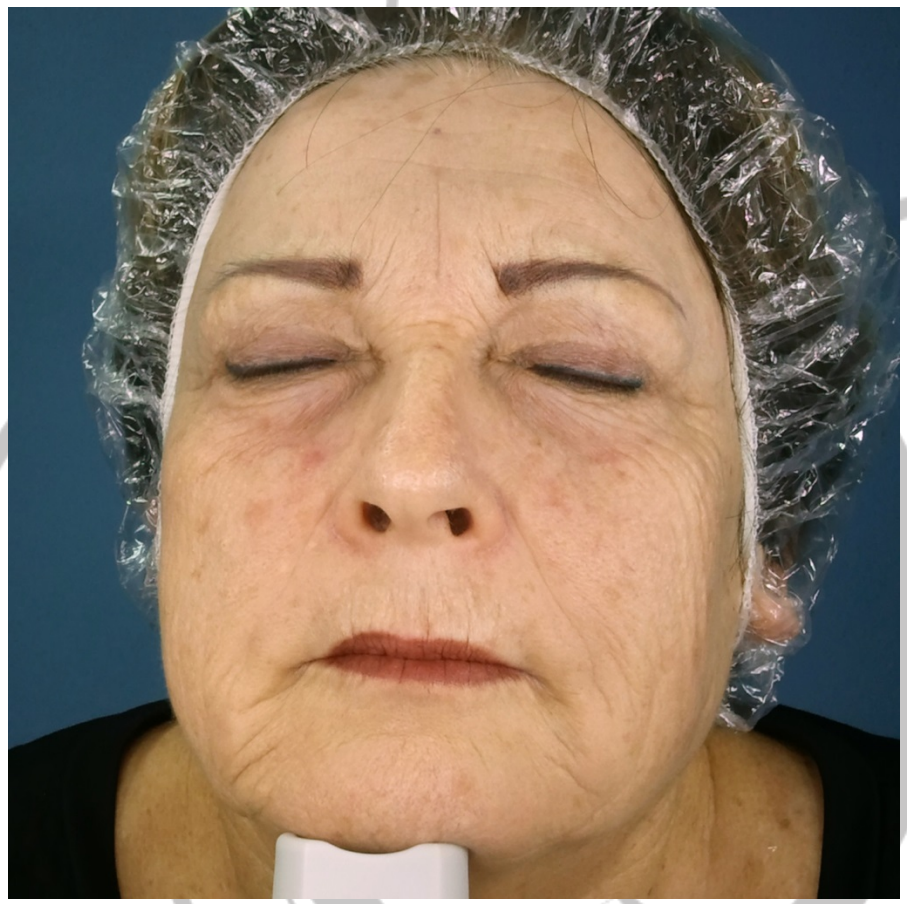

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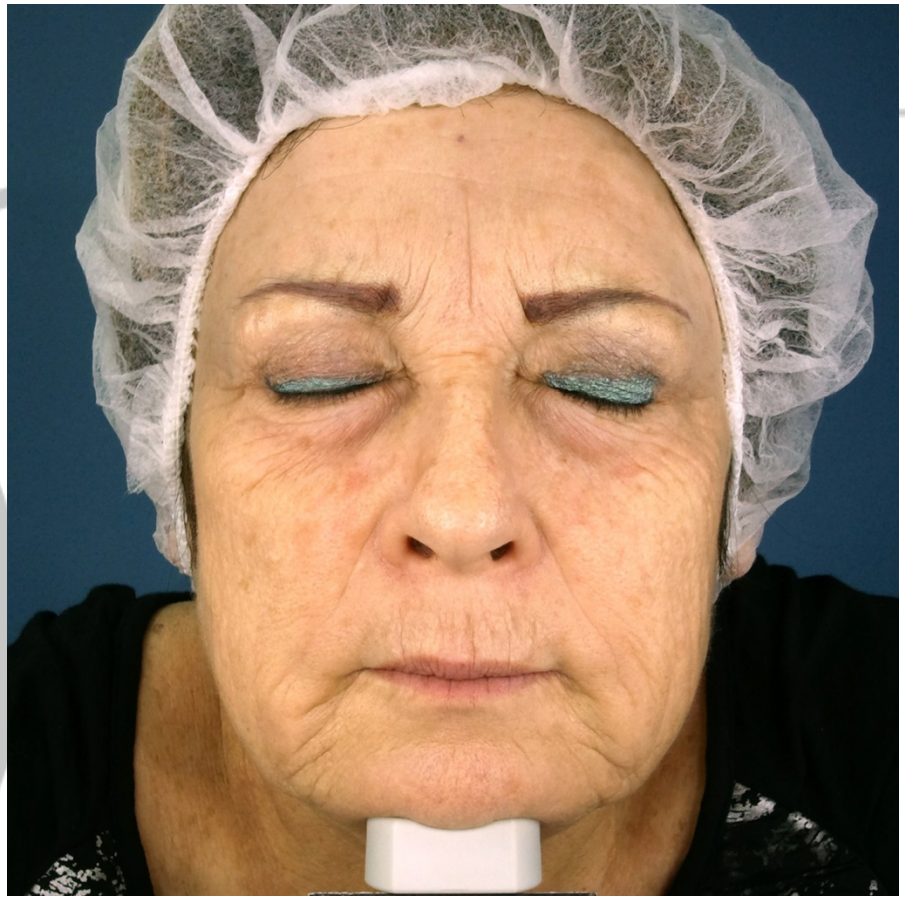

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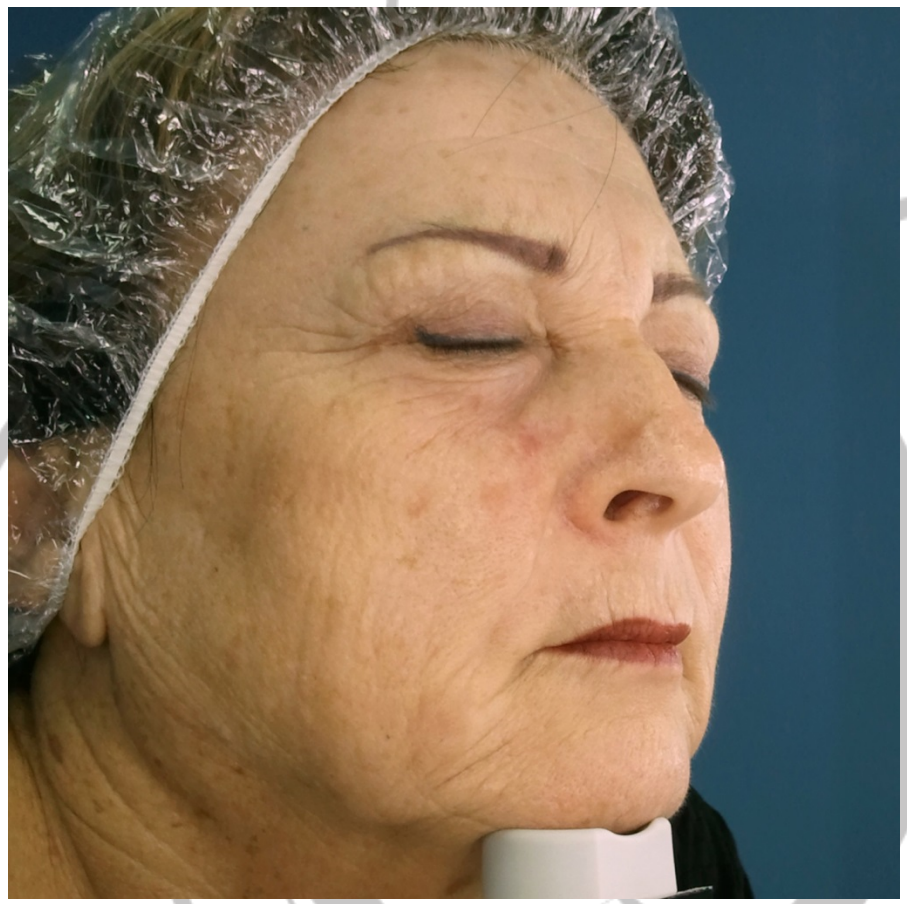

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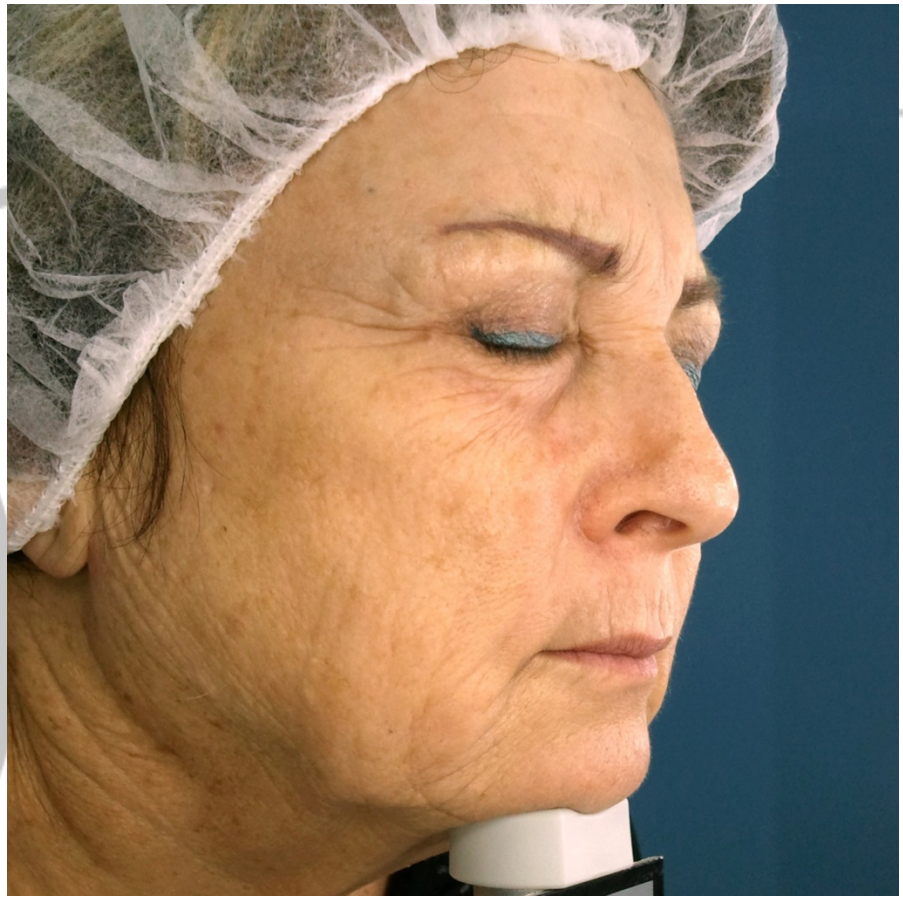

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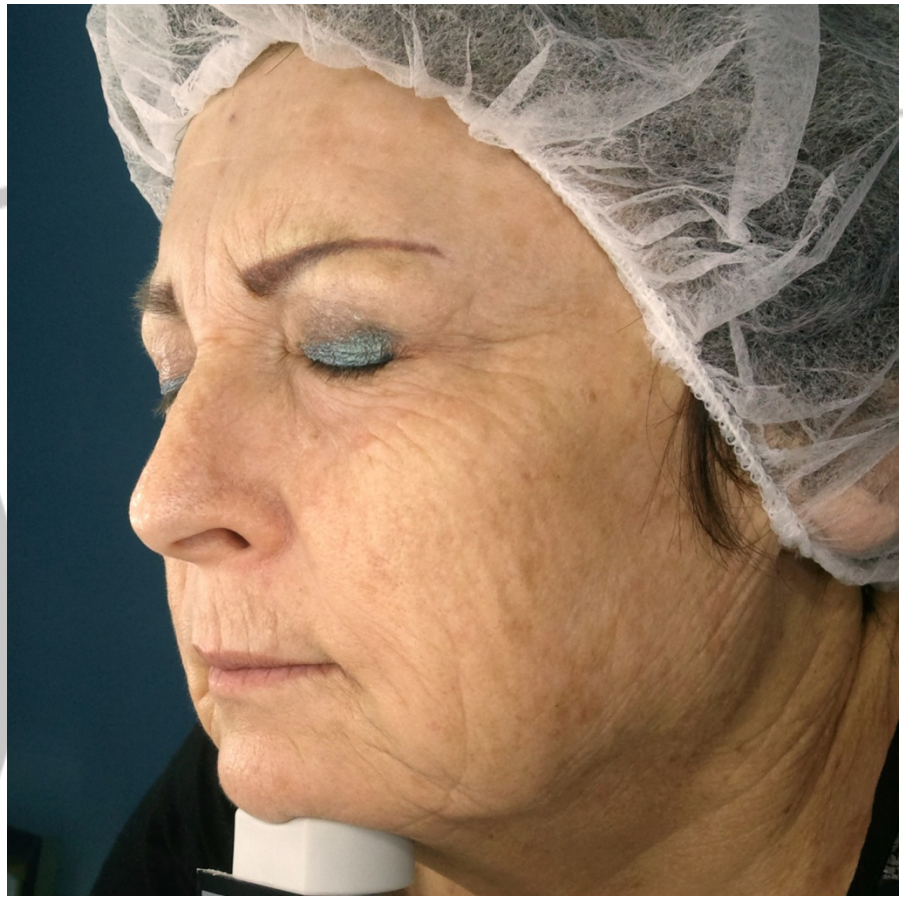

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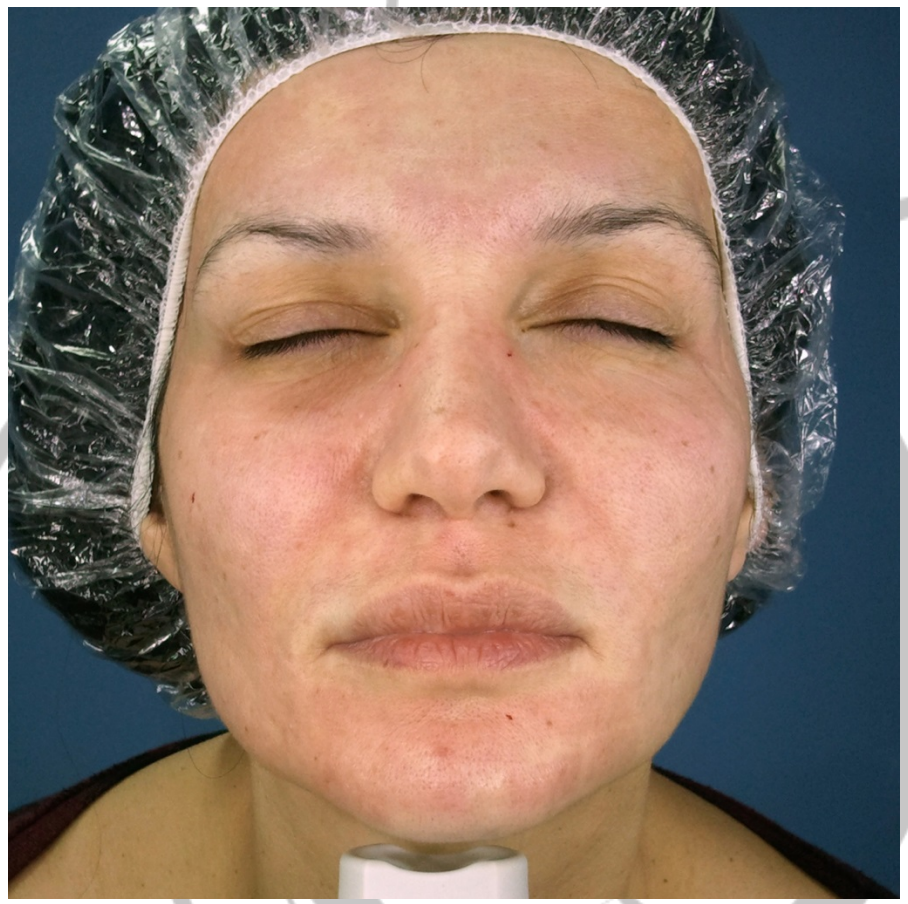

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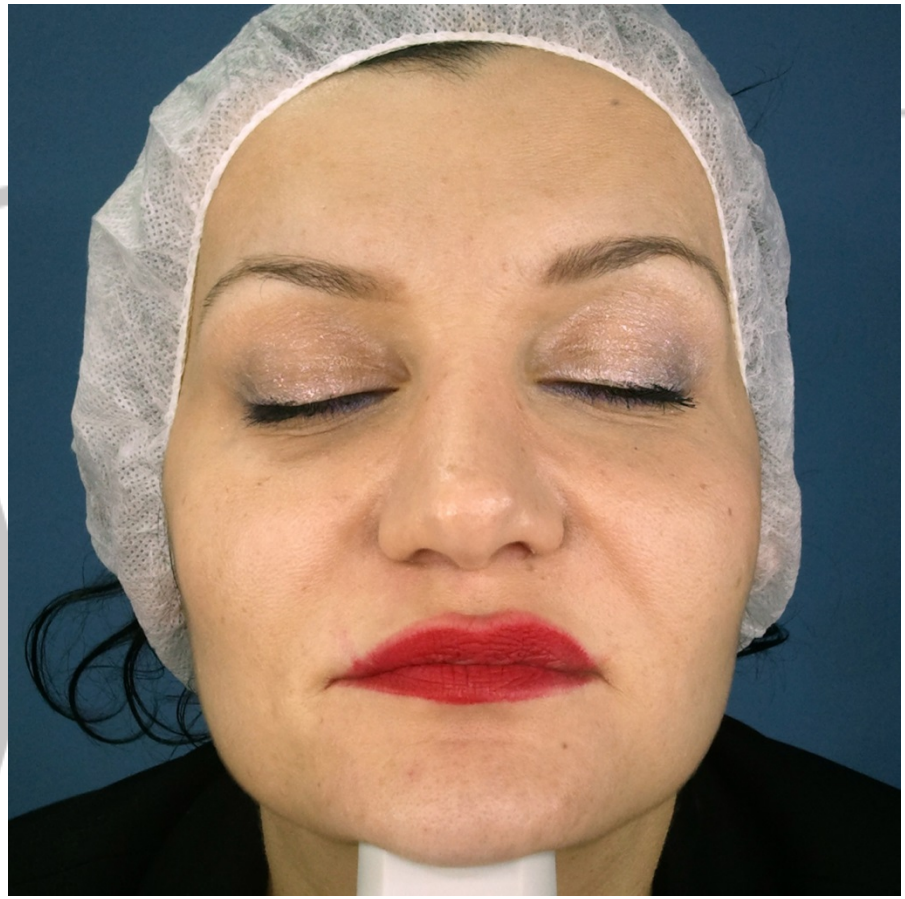

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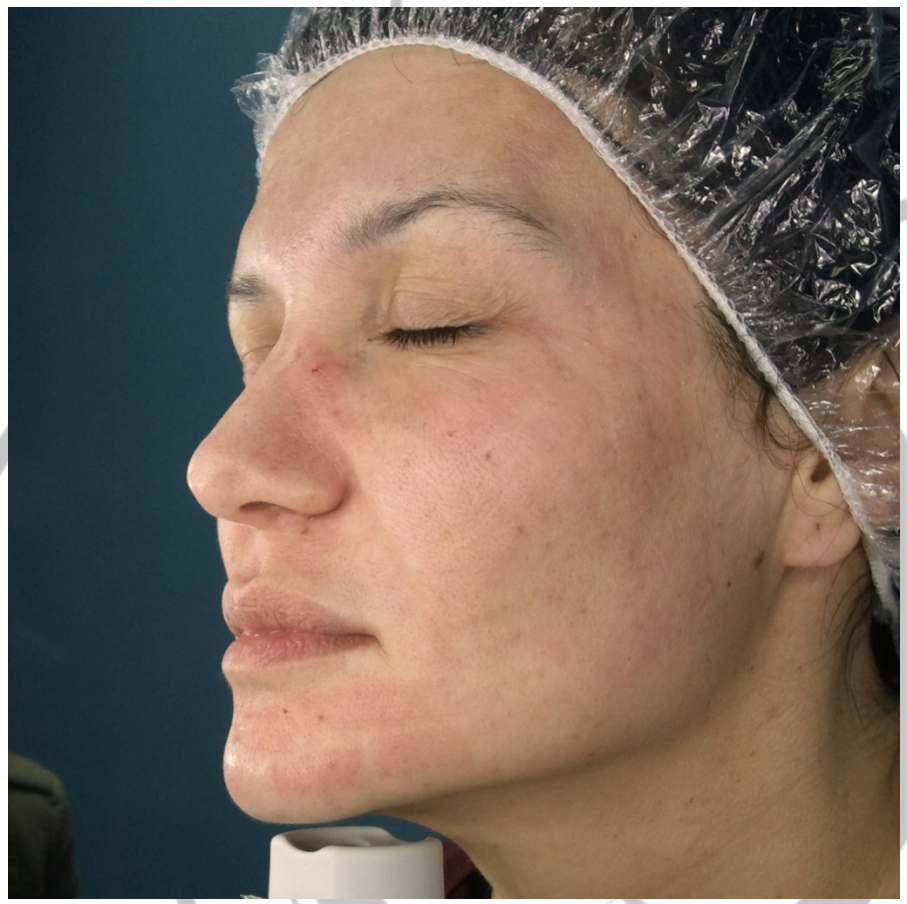

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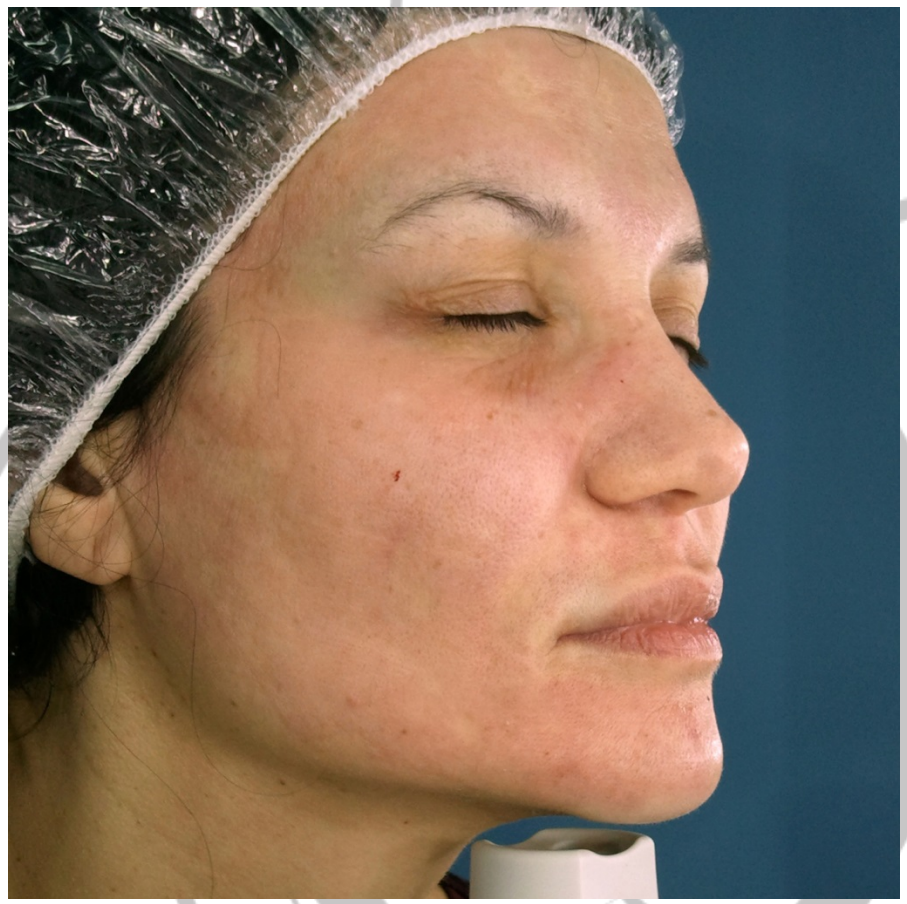

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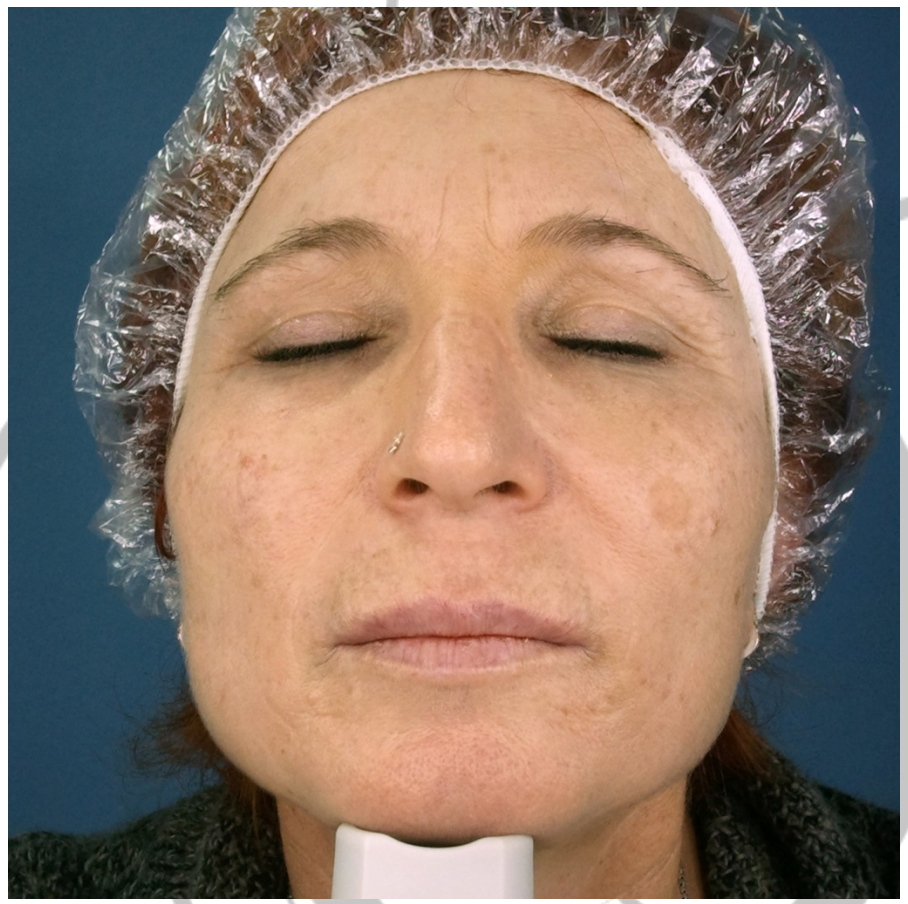

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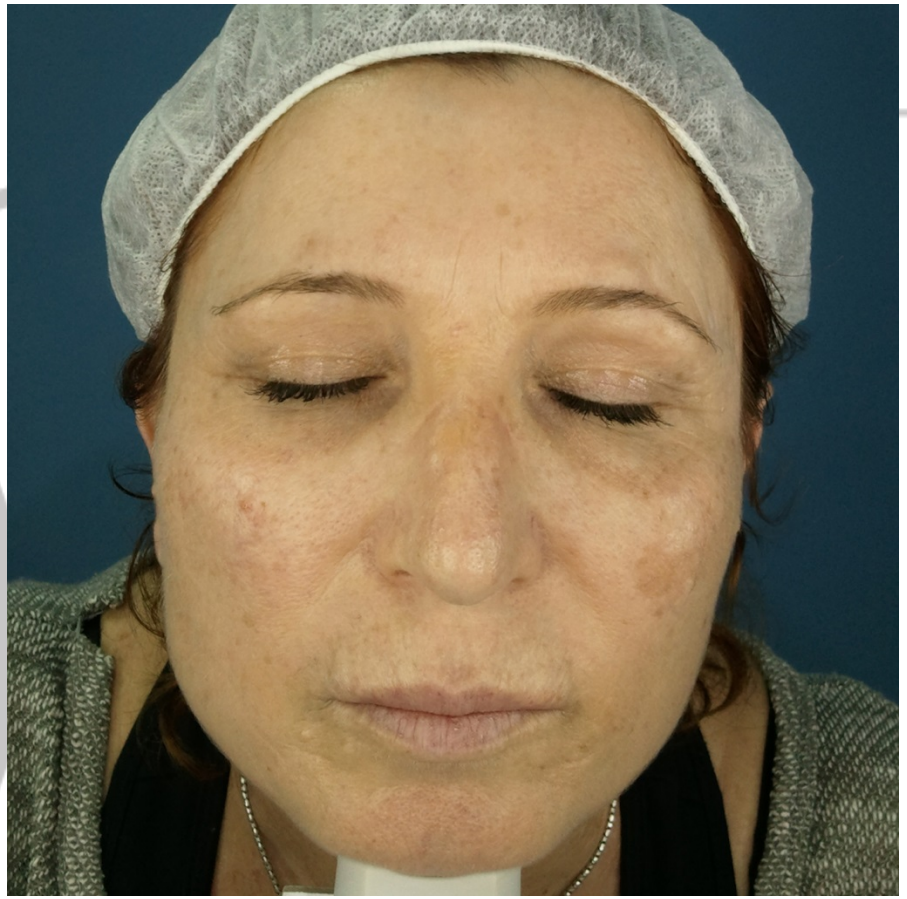

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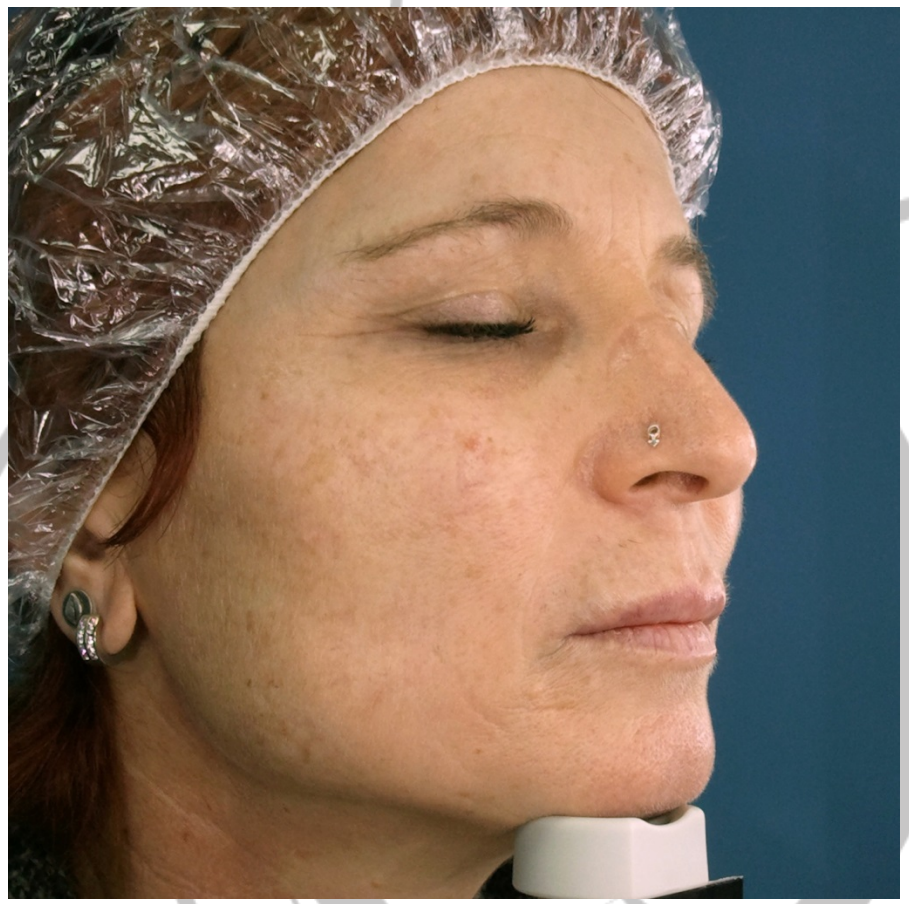

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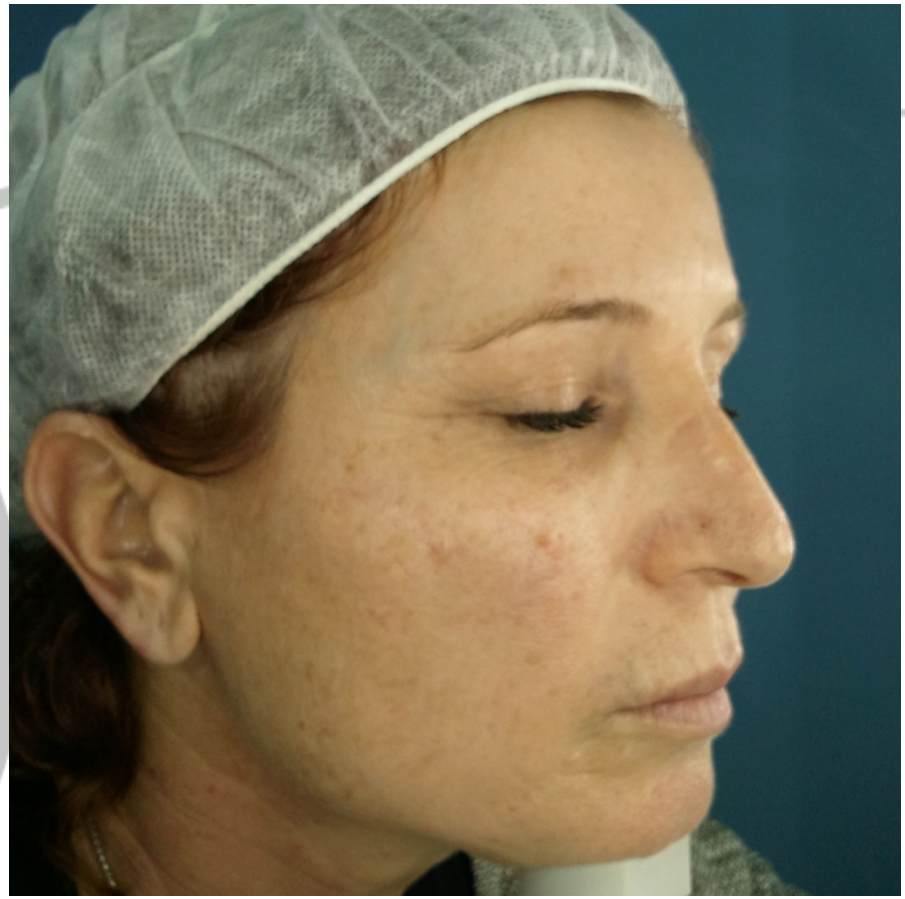

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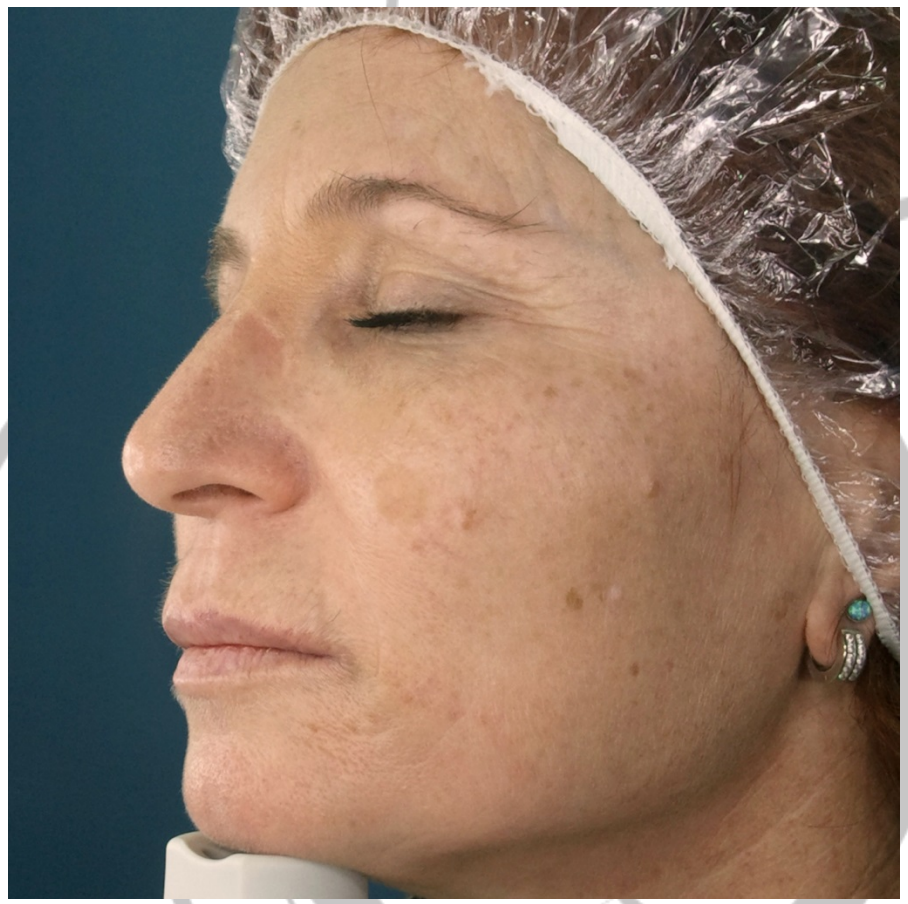

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