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NON-INVASIVE EYE REJUVENATION OF ASIAN SKIN USING A NOVEL MULTI-SOURCE, PHASE CONTROLLED RADIOFREQUENCY DEVICE

Amy Patdu discusses the use of a third generation radiofrequency device for periorbital rejuvenation, particularly lines and wrinkles, and skin laxity

ABSTRACT

Over the past decade, aesthetic professionals have witnessed an increasing demand for non-ablative facial treatments with minimal to no downtime. One of the non-ablative treatments available today uses radiofrequency (RF), which has the advantage of volumetric heating with no epidermal damage. In this study, the author focused on eye rejuvenation treatment using a novel non-invasive multi-source, phase-controlled RF device. Nineteen patients participated in the study, which encompassed six treatment sessions over 2 months. An average Fitzpatrick wrinkle score of 5.1 decreased to 2.8 after the six sessions. All patients reported a visible improvement after the treatment course, with 79% reporting a cosmetic change greater than 50%, and 16% reporting a cosmetic change of 26-50%. No unexpected adverse effects were detected or reported. All patients reported the treatment to be comfortable.

FACIAL TREATMENTS FOR SKIN REJUVENATION AND wrinkle reduction have been used in the aesthetic industry for a number of years. Over the past decade, there has been a growing demand for non-invasive treatments with minimal to no downtime or discomfort. The need for effective and safe rejuvenation treatments is especially important when considering treatment to the periorbital area.

From the age of 30 years, human body collagen production is reduced by 1-2%. The decrease in quantity and function of collagen in the dermal and sub-dermal layers causes skin laxity and the appearance of wrinkles^{1,2}. One of the most common and effective methods for collagen remodelling and wrinkle reduction is through the use of radiofrequency (RF). Skin resurfacing and RF energy has been used for medical and aesthetic purposes for more than 100 years. Non-ablative RF devices generate heat as a result of tissue resistance to the movement of electrons within the RF field. ▷

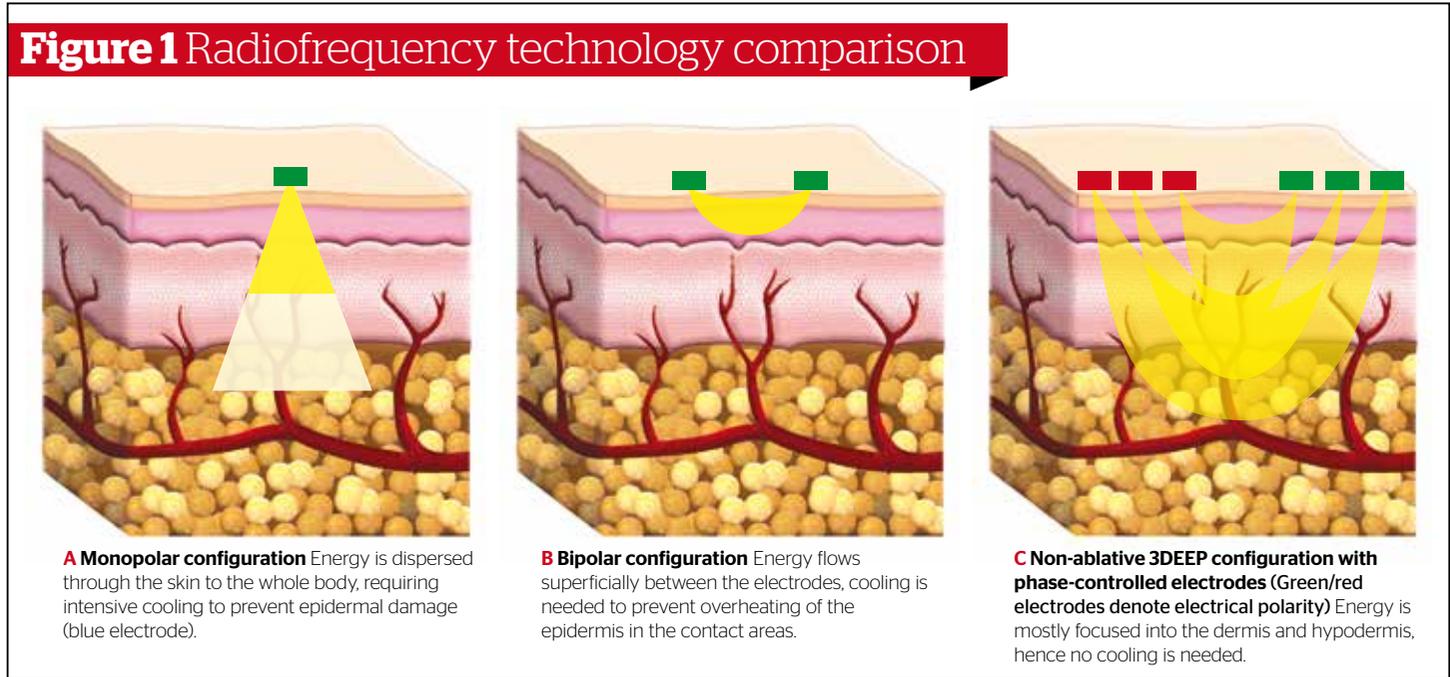


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KEYWORDS

facial tightening, skin rejuvenation, radiofrequency, EndyMed, 3DEEP®, iFine, periorbital



Heat is generated through resistance of the tissue to the RF current, causing a biochemical cascade that influences collagen remodelling and triggers production of new collagen. RF waves penetrate the skin much more efficiently than light energy and are independent of skin colour, offering a clinical benefit in deep dermal heating in darker or Asian skin types.

Heating mechanisms

Current RF devices use two basic mechanisms of heating. The first generation, also called monopolar (or unipolar), uses a single generator, which delivers energy to a single electrode that emits energy onto the skin. RF current is dispersed in the tissue, flowing towards a grounding pad, or grounded through the body. In order to achieve enough heat at the desired targeted depth, high energy and intense cooling are needed, frequently associated with significant patient discomfort³⁻⁵.

With the second generation, bipolar, the RF current flows between two electrodes, which are placed on the skin's surface. Most of the thermal energy is concentrated very superficially along the shortest path between the electrodes, making the treatment less effective for the deep dermis and hypodermis. This technology usually uses an active cooling system for the electrodes in

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order to prevent adverse events, such as burns^{6,7}.

Another type of bipolar system is called multipolar RF, which use more than two electrodes (most commonly, between three and eight electrodes). However, since these systems use only one RF generator, only two electrodes can be controlled at one time, making the flow of energy the same as standard bipolar⁸. A further disadvantage of most existing RF devices is the size of the handpiece. Most handpieces today are relatively bulky and big, and therefore make it difficult to treat hard-to-reach small wrinkles around the eyes.

The third generation of RF—3DEEP[®] technology (EndyMed Medical Ltd, Caesarea, Israel)—uses multi-source phase-controlled RF. This multi-source system (EndyMed PRO[™]; EndyMed Medical Ltd) uses six RF generators with a sophisticated algorithm to control the electrodes' polarity, diverting RF energy from passing along the epidermis, and forcing it to take a longer and deeper route focused in the dermis and hypodermis. This technology enables the reduction of the amount of energy flowing on the skin's surface, making the need for electrode cooling unnecessary. The 3DEEP technology allows a volumetric, focused, homogeneous dermal heating for non-ablative safe and comfortable treatment.

Figure 1 shows the different RF technologies^{9,10}. >

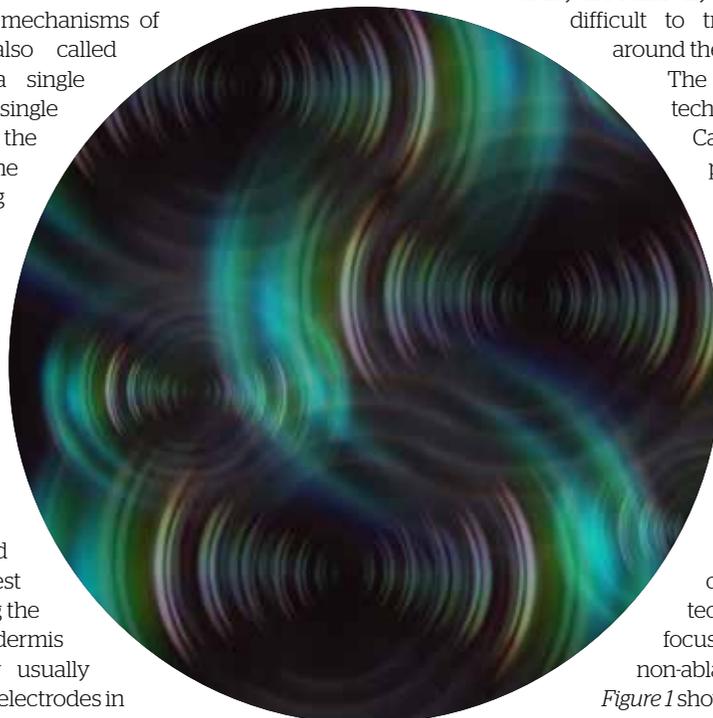


Figure 2
The iFine
handpiece



▷ The 3DEEP by EndyMed Medical Ltd is a US Food and Drug Administration (FDA) approved RF technology for the reduction of mild to moderate facial wrinkles, using multiple generator RF technology to safely heat the deeper levels of the skin for effective collagen remodelling, wrinkle reduction, and eyebrow lifting.

In this study, the author evaluated a treatment protocol for non-invasive periorbital skin tightening and wrinkle reduction. The treatment was performed using the 3DEEP iFine handpiece of the EndyMed PRO multisource RF system (Figure 2). The iFine handpiece was specifically designed to treat the hard-to-reach, delicate areas around the eyes, and fine lines and wrinkles found in other delicate and small areas.

Materials and methods

Nineteen patients (14 female, five male), aged 25-77 years (average 51.9 years) were enrolled in this study, which used the iFine handpiece by EndyMed. The patients were recruited after meeting all inclusion/exclusion criteria and signing an informed consent form. The criteria were decided on with consideration to the safety of the patient and the efficacy of the treatment. The main inclusion criteria were healthy patients over 21 years of age, understanding the course of treatment, and having the needed indications for treatment. The main exclusion criteria were patients

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with implants in the treatment area or electrical implants in the body, pregnant or lactating women, patients with known sensitivity, and other common safety contraindications.

The patients' skin wrinkles were classified according to the Fitzpatrick Wrinkle Scale (FWS)[®]. All 19 patients were treated for facial wrinkle reduction at the periorbital area (Figures 3 and 4). Patients received six treatments, where the first four treatments were administered every week, and the last two treatments were administered every 2 weeks. Patients were scheduled for follow-up visits at 1 month and 3 months after the final treatment, which all attended.

Prior to the RF treatment, patients were photographed to allow for comparison and assessment of wrinkle appearance improvement following the treatment. Photos were taken before each treatment session.

The treated area was cleaned thoroughly with soap and water in order to remove any make-up and lotions, and the skin surface was then dried. The treatment

power was set to 5 Watts for all patients. Following two passes of 30 seconds each, the skin surface temperature reached the optimal range of 40-42°C. Temperature was evaluated using an infrared thermometer. After the optimal temperature range was achieved, six passes were performed on each treatment

zone (Figure 4). Immediately after the treatment, the treated area was visually assessed for skin responses, oedema and erythema.

The EndyMed PRO system uses safety features in order to prevent adverse effects. RF energy is not emitted if the handpiece is not in full contact or not in motion, preventing RF spikes of high heating, static shock and surface burns. The treatment is performed in circular motions, while the treated area is covered with ▷

Figure 3 Thermal images. (A) baseline, maximum of 35.9°C under the eye. (B) After two passes of 30 seconds under the eye, power 3 Watts. Maximum temperature is 41.1°C. (Image scale 22-48°C)

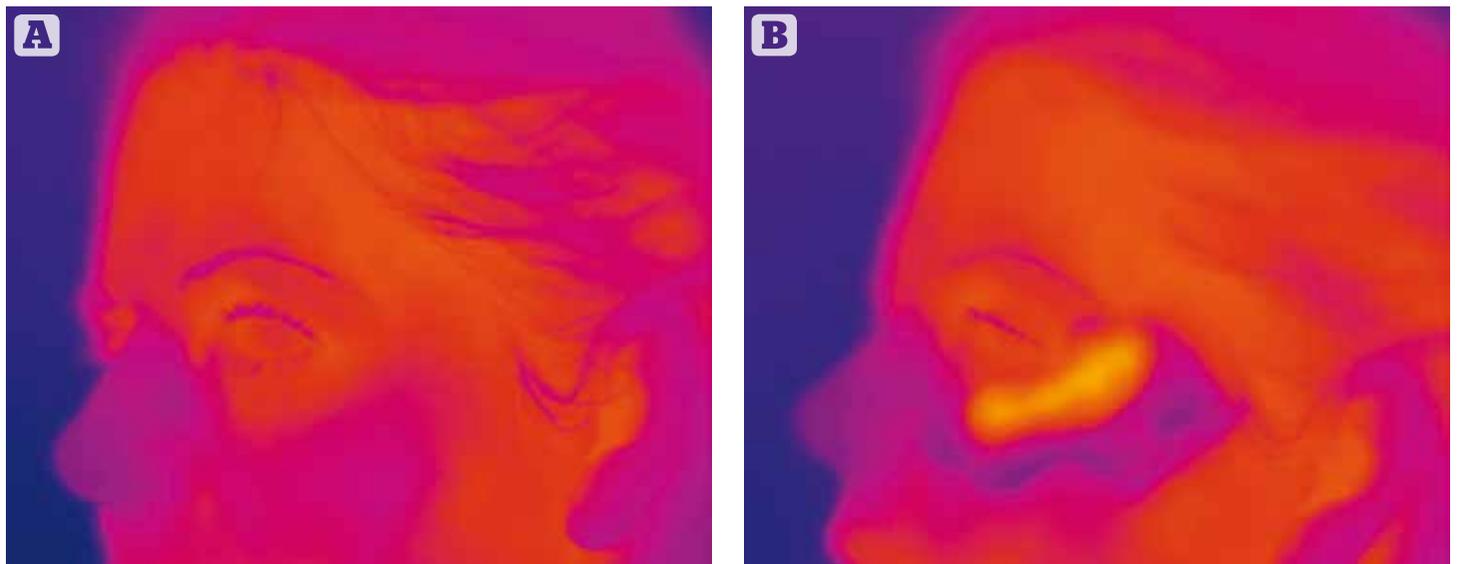
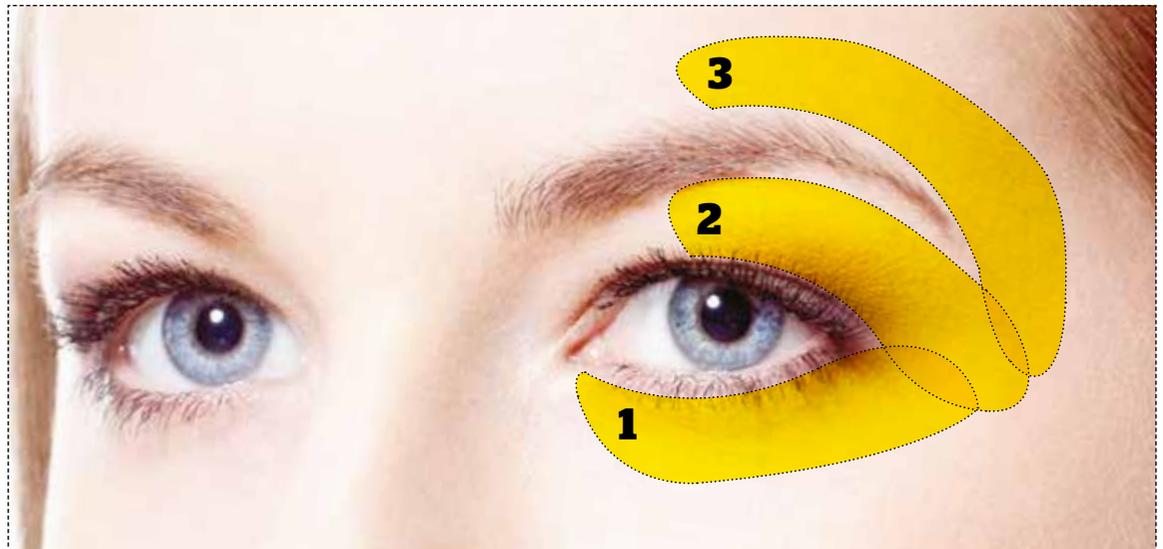


Figure 4 Periorbital treated areas. Each eye has three areas for treatment: (1) under the eye; (2) under the eyebrow; (3) above the eyebrow. When treating these areas, it is important to pull the skin away from the eyeball



ultrasonic gel for smooth movement of the handpiece.

Results

All patients completed a series of six treatments according to the manufacturer's protocol. Six 30-second passes were performed in each area after reaching a temperature of 40-42°C. Two patients had eight passes in each area because the appearance of their wrinkles was of greater significance. All treatments were carried out using a power of 5 Watts. Patients' baseline degree of elastosis varied from 1-9 (average 5.1±2.4) on the Fitzpatrick Elastosis and Wrinkle Scale. All patients, except for one, had a decrease in Fitzpatrick wrinkle score. These results show a very low rate of non-responding patients; approximately 5% compared to the 15-20% non-responding rate usually seen in these types of procedures. Before and after pictures can be seen in Figures 5-7.

“ All patients reported the same or better treatment results with the EndyMed PRO system, compared with other skin tightening devices. ”

Patients' feedback was carried out using questionnaires. Following treatment, a mild erythema appeared on the treatment area, which dissipated after 20-90 minutes. Seventy-nine percent of patients reported that the treatment was very comfortable, and 21% reported minimal discomfort. No patient had experienced moderate or higher discomfort during treatment. No

adverse events occurred during the treatments (Figure 8). In addition, patient satisfaction with the treatment results was evaluated. A moderate improvement (51-75%) was achieved for 12 patients, and a significant improvement (>76%) was achieved in three patients (Figure 9).

Meeting expectations

All patients reported the same or better treatment results with the EndyMed PRO system, compared with other skin tightening devices. When asked whether the treatment met expectations, 68% reported 'yes' and >

Figure 5 Periorbital iFine treatment in a 77-year-old female patient. (A) Baseline and (B) immediately after the treatment. There is a noticeable reduction of 'eye bags' and tightening of upper eyelid





Figure 6 Periorbital iFine treatment in a 60-year-old male patient. (A) Baseline and (B) after six treatment sessions. There is a significant reduction of the tear trough

Key points

- The market requires an effective and safe treatment for skin laxity in the periorbital area, owing to its sensitive nature
- The EndyMed iFine handpiece offers a novel approach to non-ablative treatments
- Patients enjoy the treatments unmindful of the necessity for follow-ups. They report that results are achieved quickly, and that they suffer no downtime, pain or discomfort.
- The superiority of the technology makes iFine suitable for all skin types, including darker, Asian skin tones

▷ 32% reported ‘yes to some extent’ (Figure 10). When asked at the end of the last session whether the treatments had met their expectations, all patients answered ‘yes’. All patients also reported that they would recommend the treatment to their friends.

The use of the EndyMed PRO system was pleasing, both for the physician and her patients. The author found the ease of use and the short treatment time needed to complete a full treatment around the eyes to be convenient and cost-effective for the clinic. The overall impression of the author is shown in Figure 11.

The effect of Filipino culture on aesthetic treatments

Cultural bias for youthful looks permeates Filipino society. Mass media plays an important role in perpetuating the pristine, taut and sprightly female in all forms, whether it is the mother cradling her child, the executive closing a business deal, or the teacher giving instructions to her wards in the classroom. In cinema and television, it is not uncommon for the general audience to notice lines around the eyes, on the forehead and around the mouth, and make derogatory remarks. They want their idols—despite their advanced age—to continue to look and act young.

The introduction of iFine in the Philippine market offers an option to the different demographics. The interest was palpable not only among female groups, but also from the male sector, largely owing to aversion to derogatory remarks. Nobody wants to hear that he or she looks 10 or 15 years older than their actual age.

As iFine presents a non-invasive procedure, this further galvanised the initial interest. Many felt comfortable that no needles or other invasive procedures would be used. Skeptics, however, remained, but they were manageable in number. From the initial batch of patients who received iFine treatments, almost all have expressed their pleasure at the ease of application and at the immediacy of results.

“Multi-source RF has been shown as an effective, non-invasive treatment for face and body skin tightening and fractional RF skin resurfacing.”

Discussion and conclusions

Multi-source RF has been shown as an effective, non-invasive treatment for face and body skin tightening and fractional RF skin resurfacing². One of the main challenges is to have an effective treatment while remaining completely safe for the patients. Mayoral et al⁴ reported that some of the risks of treatment may be caused when being too aggressive with other technologies. The 3DEEP technology was reported to



Figure 7 Periorbital iFine treatment in a 60-year-old female patient. (A) Baseline and (B) after six treatment sessions. There is a significant reduction of wrinkles and lifting of upper eyelid

Perioral treatments

In addition to the results described in this article for periorbital wrinkles, more technologies are now dealing with skin rejuvenation and wrinkle reduction in another hard-to-reach area: the perioral area. This is another area defined as problematic to treat owing to its gentle, thin and sensitive skin, and also owing to the small surface

maintain a high level of safety combined with an excellent level of efficacy for wrinkles and lax skin⁹, and also when using the iFine Handpiece¹².

The results obtained in this study demonstrate significant reduction of periorbital wrinkles and skin laxity using a painless, non-invasive treatment technology. The multi-source RF technology (EndyMed PRO) was found to be safe, effective and comfortable both for the therapist and patient.

Some patients who took part in the study were younger than 30 years of age, and therefore their FWS was low. In these cases, physical appearance may be part of their occupation; therefore, their appearance is very important, particularly with regard to improvement in wrinkles around the eyes.

Eye rejuvenation can also be considered as an anti-ageing process, as the use of RF encourages an increase in the quantity and quality of the collagen component of the skin.

All patients but one who participated in this study had a decrease in their FWS, which proves the effectiveness of the 3DEEP technology. The patients seemed to maintain the same results, or even to have an improvement in their wrinkle appearance, at 3-month follow-up.

EndyMed 3DEEP is a safe and effective non-invasive technology leading to skin tightening, and the iFine handpiece is a remarkable breakthrough for periorbital skin rejuvenation. The author believes that the non-invasive facial treatments are gaining popularity and their demand will increase in the future owing to the growing requirement for rapid treatments with no downtime.

► **Declaration of interest** None

► **Figures 1-3** © EndyMed Medical Ltd.

► **Figures 5-11** © Dr Amy Patdu

area. People who smoke for many years tend to develop more wrinkles around the lips. In recent years there has been growing demand to target these problematic wrinkles. The iFine handpiece from EndyMed™ was specifically developed for this area as it fits easily and it is possible to fine-tune the energy required for sensitive skin.

“Eye rejuvenation can also be considered as an anti-ageing process, as the use of RF encourages an increase in the quantity and quality of the collagen component of the skin.”

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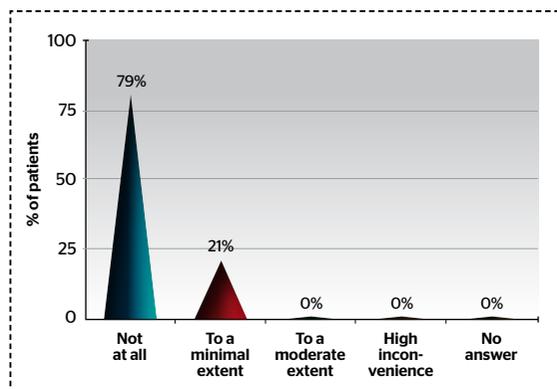


Figure 8 Distribution of patients' discomfort during treatment. Most of the patients found the treatment to be comfortable

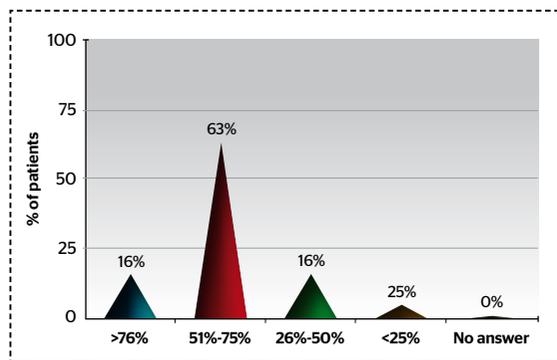


Figure 9 Distribution of patients' opinions on the level of cosmetic change following six treatment sessions

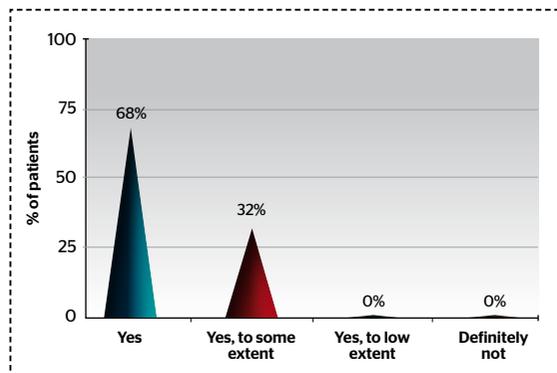


Figure 10 Distribution of patients' satisfaction with the treatment

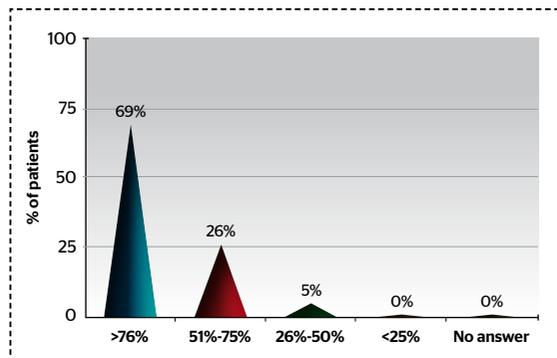


Figure 11 Physician evaluation of overall improvement