

A close-up photograph of a woman's face, showing her eye, nose, and mouth. A vibrant, multi-colored rainbow light effect originates from her eye and extends down her hair, creating a glowing, ethereal glow against a soft, out-of-focus background.

“A multisource
radiofrequency therapy
system allows a volumetric,
homogeneous, targeted, and
controlled dermal heating for
non-ablative radiofrequency
treatments. **”**

MULTISOURCE RF FOR THE TREATMENT OF WRINKLES AND SKIN LAXITY

Liliane Mouyal discusses the use of a non-ablative radiofrequency device and how it contributes to the skin tightening for the aesthetic physician and patient

ABSTRACT

Full title

Multisource phased controlled radiofrequency (3DEEP) for the treatment of face and neck wrinkles and lax skin, using an enhanced treatment protocol

The decrease in quantity and quality of collagen fibres with age and sun exposure is one of the main causes of wrinkles and lax skin. Non-ablative dermal heating to 55–65°C has been shown to trigger the production of new and more effective collagen. A number of studies have also shown that radiofrequency (RF) energy has the ability to volumetrically heat the dermis in a more effective and safe way compared with laser and intense pulsed light (IPL) devices. In this study, a new facial tightening protocol was tested using a novel multisource, phase controlled RF system (EndyMed Pro, EndyMed Medical, Caesarea, Israel) that delivers RF energy to the depth of the dermis and hypodermis, with significantly decreased risk to the epidermis. According to this new treatment protocol,

the face and neck complex was divided into two main, relatively large areas (left and right), rather than the five traditional areas treated using the standard protocol, with high parameters being used in order to compensate for the large treatment area. Thirty patients completed the course of treatment (except for two patients: one who had only five sessions, and one who had eight sessions). The Fitzpatrick wrinkle score decreased from an average of 5.43 at baseline to 4.57 after six treatments, and to 4.28 3 months after the end of treatment. All patients reported a visible improvement after the treatment course, with 54% reporting a cosmetic change greater than 50%, and an additional 32% reporting a cosmetic change of 26–50%. No unexpected adverse events were detected or reported.



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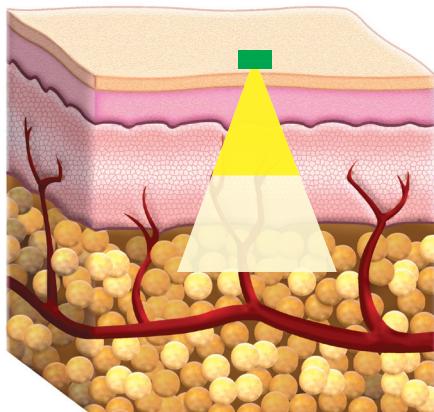
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ONE OF THE MAIN CAUSES OF SKIN LAXITY IS THE decrease in the quantity and functionality of dermal and sub-dermal collagen. This physiologic deterioration leads to skin laxity and wrinkles¹.

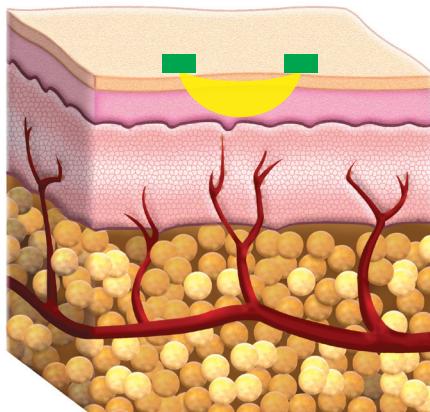
Radiofrequency (RF) energy affects the skin by emitting high-frequency radio waves that interact with the tissue to produce a thermal change. It is well established that heating the dermis for a period of time to 55–65°C triggers a process of collagen remodelling that results in the destruction of ineffective, damaged collagen, and the production of new collagen^{2,3}.

RF systems have continually gained in popularity for the treatment of wrinkles and skin laxity over the last decade. This is in part owing to the ability of RF energy to penetrate deep into the tissue without the limitation of skin colour, as seen with optical-based energies. Within the skin, RF energy triggers a significant thermal effect at a particular depth based on different parameters, such as the technology used and electrode configuration. The use of monopolar RF (first generation) ▶

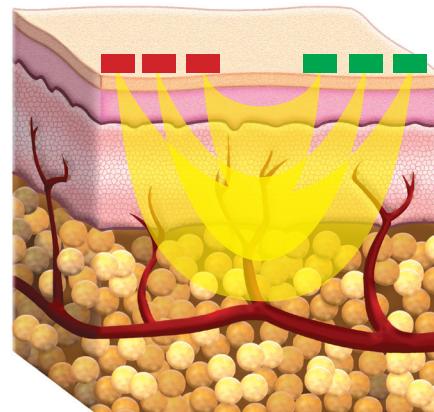
KEYWORDS
skin tightening, radiofrequency,
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Figure 1 Radiofrequency technology comparison

A Monopolar configuration Energy is dispersed through the skin to the whole body, requiring intensive cooling to prevent epidermal damage (blue electrode).



B Bipolar configuration Energy flows superficially between the electrodes, cooling is needed to prevent overheating of the epidermis in the contact areas.



C Non-ablative 3DEEP configuration with phase-controlled electrodes (Green/red electrodes denote electrical polarity) Energy is mostly focused into the dermis and hypodermis, hence no cooling is needed.

systems that use one RF electrode require a higher level of user expertise owing to the higher energy density on the electrode^{4,5}. The use of this type of system is frequently associated with pain and requires intense active cooling to protect the epidermis. Furthermore, much of the energy is being wasted, as the energy flows uncontrolled throughout the body^{6,7}. The use of bipolar (second generation RF) or multipolar RF (third generation RF) has been limited because of the superficial nature of energy flow between the two or more bipolar electrodes connected to a single RF generator⁸. Despite high expectations, the improvements offered by first, second, and third generation RF systems are usually limited, owing to the small volume of dermal heat produced⁹.

A new generation of RF technology (fourth generation) uses multiple RF generators for optimal control of the thermal effect. A multisource RF therapy system

“A new generation of RF technology (fourth generation) uses multiple RF generators for optimal control of the thermal effect.”

(EndyMed Pro, EndyMed Medical, Caesarea, Israel) allows a volumetric, homogeneous, targeted, and controlled dermal heating for non-ablative RF treatments. The Food and Drug Administration (FDA)-cleared EndyMed Pro, powered by 3DEEP technology, has six RF generators that enable full control of the phase of the current flowing between each pair of electrodes. The multiple electrical fields created repel/attract each other, providing the ideal combination of energy directed to a deeper skin layer with minimal surface heating. The repelling forces between adjacent electromagnetic fields drive energy vertically into the target tissue, reducing the amount of energy flowing through the skin surface. In addition, the multiple generators enable better distribution of the energy on the electrodes, reducing the energy density on each electrode, which in turn makes the treatment more comfortable and safe for the patient. The comparison between the different RF modalities is schematically represented in Figure 1.

In the current study, the author tested a new treatment protocol for full-face non-ablative skin tightening. The treatment was performed using the EndyMed Pro multisource RF system. The system forces the energy to penetrate into the deep dermis, causing a non-ablative deep dermal heating effect that results in painless skin tightening.

Materials and methods

A total of 30 patients (all female, aged 38–76 years, average age 55.96 years) were treated using the EndyMed Pro 3DEEP system. The patients were randomly recruited to the study after they had been given a thorough evaluation and had expressed an interest in joining the study—only after fulfilling the inclusion criteria. The ▷

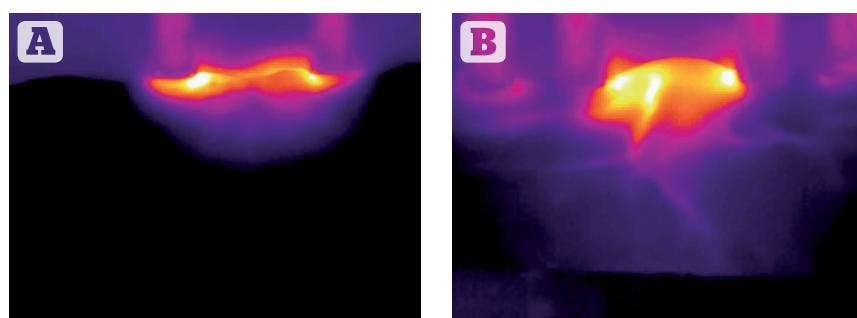


Figure 2 Thermal imaging (ThermaCAM SC 640, FLIR Systems) of bipolar radiofrequency pulse (A) and 3DEEP radiofrequency pulse (B). In both cases, the same energy and pulse duration were used. The comparison shows superficial flow of energy with the bipolar technology, while with the 3DEEP technology a much deeper penetration can be seen. This advantage enables the 3DEEP technology to reduce risks for epidermis and increase efficacy in the deep dermis

Table 1 Scale of clinical improvement

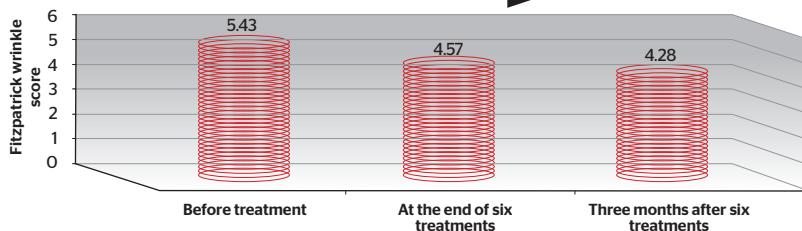
DEGREE	DESCRIPTION
0	No improvement
1	1-25% improvement
2	26-50% improvement
3	51-75% improvement
4	76-100% improvement

► patients were enrolled in the study after meeting all inclusion/exclusion criteria and providing signed informed consent forms. Patients' Fitzpatrick skin types varied between 1 and 4. The main inclusion criteria were healthy patients over 21 years of age with facial conditions as required by the evaluation protocol. It was also necessary for the patient to be able to comprehend and sign informed consent for participation in this study, and commit to all treatments and follow-up visits.

The main exclusion criteria were based on the medical/clinical condition and history of the patient. For example, electrical device implant, metal implants in the treatment area, pregnant or lactating women, patients who underwent any other surgical or cosmetic procedure in the recent past, patients with any skin problem or suspicious lesions in the treatment area, and subjects with clotting disorders or any other medical condition that may affect treatment were causes for exclusion from the study.

Treatment

During each treatment session, patients received a full-face and neck 3DEEP non-ablative facial tightening treatment, while the recommended protocol by the company is to divide the cheeks and the neck into two treatment areas. The first four treatment sessions were

Figure 3 Change in average Fitzpatrick score

performed at 2-week intervals, with an additional two treatment sessions performed at 4-week intervals (i.e. patients received six treatment sessions). Patients returned at 1 and 3 months after the sessions for follow-up.

The RF device used was an EndyMed Pro, a phase-controlled, multisource RF system that emits RF energy at 1MHz of up to 65 watts. All patients were treated with the small (facial) handpiece.

The non-ablative deep dermal heating mode is painless and therefore, does not require any kind of anaesthesia or post-treatment care.

Before commencing the non-ablative procedure, the skin was cleaned with soap and water in order to remove make-up or other lotions. The treatment area (face and neck) was divided into two sections (two sides, approximately 25x10cm). As the treatment area was more than twice the size of the recommended treatment area—according to the treatment protocol of the company—the treatment energy used was the maximum (65W). Using the maximum energy allowed the operator to maintain the desired skin surface temperature in order to reach the endpoint and trigger collagen remodelling through an effective treatment. Each treatment area was heated for up to 10-15 minutes, during which, skin surface temperature was maintained at

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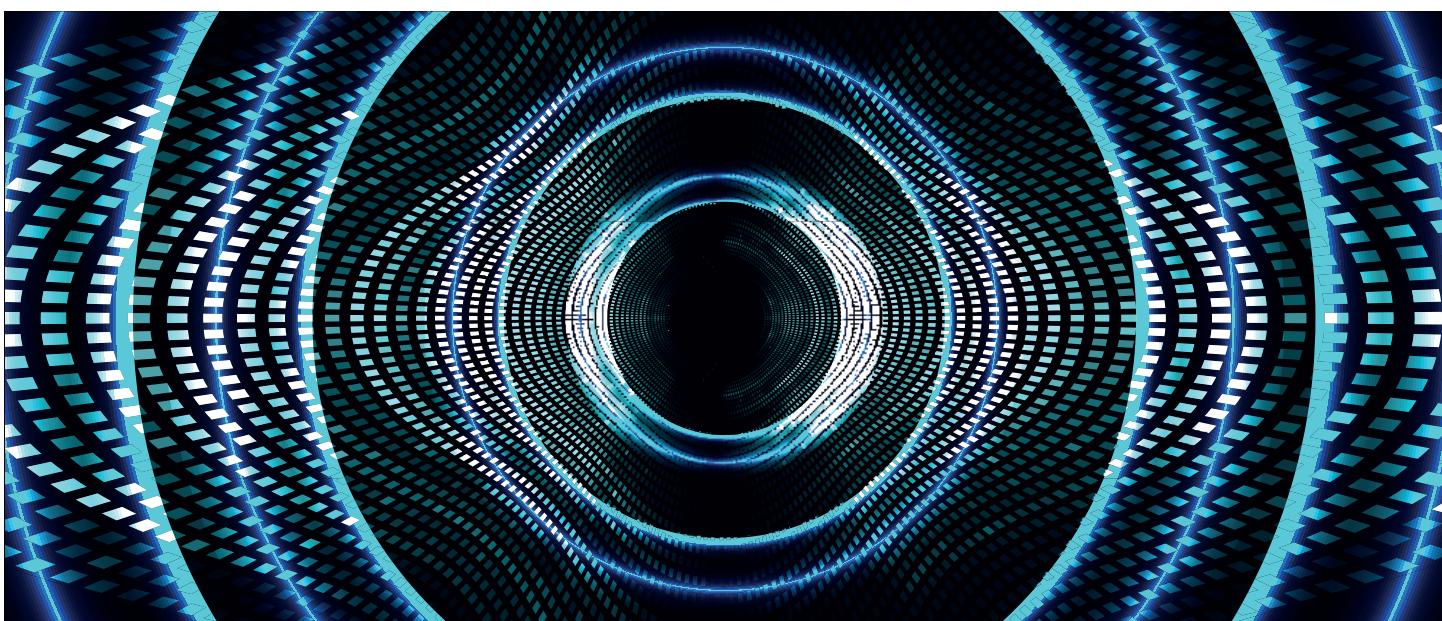


Figure 4 61-year-old female. (A) before treatment and (B) after three treatment sessions. A significant wrinkle reduction can be seen in the perioral and chin area



> 40–42°C. Treated areas were visually assessed for skin responses, including oedema, erythema, and textural changes following the treatment.

Dedicated questionnaires were used for both doctor and patients in order to grade different parameters, such as efficacy, safety, and comfort of treatment, in addition to subjective satisfaction of the patients. The patient answered the questionnaires at the end of the six sessions, at 1-month and 3-month follow-up. In addition, the physician answered a dedicated questionnaire for each patient.

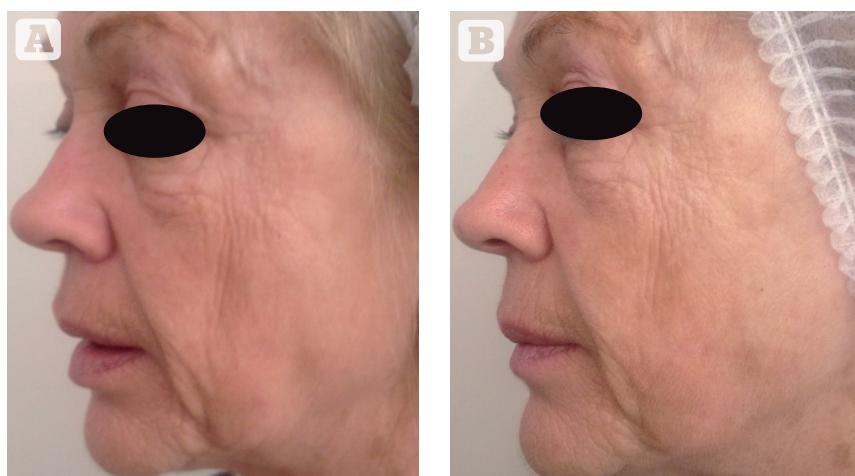
Clinical improvement in skin laxity and texture was evaluated by the physician. Evaluation of the clinical improvement was based on a scale of improvement (*Table 1*).

Results

All patients completed six treatment sessions, except for two patients: one who had only five sessions, and one who had eight sessions. The patient who had only five sessions did not attend the sixth appointment owing to personal reasons. The patient who received eight treatments had two shorter than usual sessions (of the standard six), so the physician decided to administer two further treatments for this patient. Fitzpatrick Wrinkle and elastosis Scale (FWS) scores before the treatment sessions ranged between 3 and 8, while FWS after six treatment sessions ranged between 2 and 7. Three months after the end of treatment, the average Fitzpatrick scale decreased by more than one level. All patients except for two had a decrease in Fitzpatrick scale of at least one level (*Figure 3*). Before and after images can be seen in *Figures 4* and *5*.

“ All subjects experienced mild to moderate oedema and erythema as an immediate response to the treatment. Both oedema and erythema were resolved after one hour post-treatment. **”**

Figure 5 62-year-old female (A) before treatment and (B) after six treatment sessions. A significant improvement in skin laxity in the lower face and a reduction of wrinkles can be seen



Patient experience

The patient experience was evaluated using multiple choice questionnaires.

All subjects experienced mild to moderate oedema and erythema as an immediate response to the treatment. Both oedema and erythema were resolved after one hour post-treatment. No unexpected adverse events were detected or reported. Eighty percent of patients reported the treatment as comfortable (no discomfort at all) and 17% reported minimal discomfort during the treatment. None of the patients experienced burns, skin breakdown, or scarring. No patients reported any pain during the study (*Figure 6*).

When asked at the end of the last session whether treatment met expectations, 67% of patients responded 'yes', and 27% responded 'yes to some extent' (*Figure 7*).

When asked at the end of the last session their subjective opinion of the cosmetic change they experienced, 54% reported an improvement greater than 50% (NB. two patients did not answer this question) (*Figure 8*).

When asked whether they would recommend the skin tightening treatment to their colleagues and friends, 67% of patients answered 'definitely yes' and 20% answered 'yes' (*Figure 9*).

All but one patient believed that the treatment had a noticeable tightening effect (one patient did not answer this question as she could not evaluate), with 55% of patients experiencing a noticeable wrinkle reduction (three patients did not answer this question). All but one patient believed the treatment had a noticeable improvement in skin texture (one patient did not answer this question), and that the treatment improved the contour of their face and neck (one patient did not answer this question).

Physician evaluation

No complications were recorded during the treatment sessions.

Eighteen patients had undergone a skin tightening treatment with a different technology in the past; 82% of these patients reported the same or better result with the EndyMed Pro system (this question was not answered by one of the patients).

The author was satisfied with the safety of the EndyMed Pro system, both with the ease of performing the skin tightening treatment procedure and with the duration of the treatment procedure while using the EndyMed Pro system.

Overall, the author was satisfied with the skin tightening improvement obtained in 29 of the patients. When evaluated 3 months after the last session, all patients showed significant improvement in skin laxity; 14% of the patients showed more than a 76% improvement in skin laxity; 38% of patients showed a 51-75% improvement; and 45% of patients showed a 26-50% improvement (Figure 10).

Discussion

Energy-based devices—specifically RF devices—have rapidly evolved over the last decade and are now taking a central role in the treatment of multiple aesthetic and medical skin conditions¹⁰. One unique and important feature of RF-based systems is their ability to heat large volumes of dermal and hypodermal tissue, regardless of skin type or colour.

The intrinsic disadvantage of current RF systems is the low volume of dermal heating in bipolar systems or the painful treatment in monopolar systems. Monopolar and bipolar RF systems must be used at a higher power in order to increase volumetric heating in the dermis.

Skin temperature is dependent on the energy in use and the size of the treatment area. The aim of this study was to evaluate the safety and efficacy of an alternative protocol from the standard recommended by the manufacturer. In this alternative protocol, the author used higher energy on a larger area so that the proportions remained. ▶

Figure 6 Discomfort during treatment according to patients

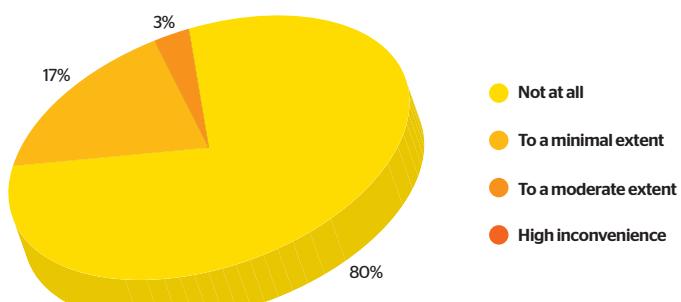
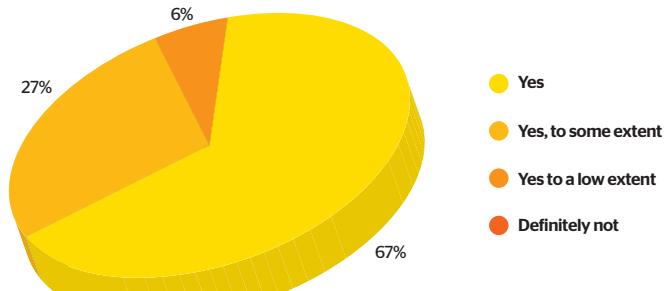


Figure 7 Patients were asked whether the treatment fulfilled expectations



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The results show that the protocol suggested in this article provides an alternative treatment, using higher energies and a larger treatment area. This protocol was both time-saving for both physician and patient, and also showed very good skin improvement and a high satisfaction rate.

Figure 8 The level of cosmetic change according to patients' opinions

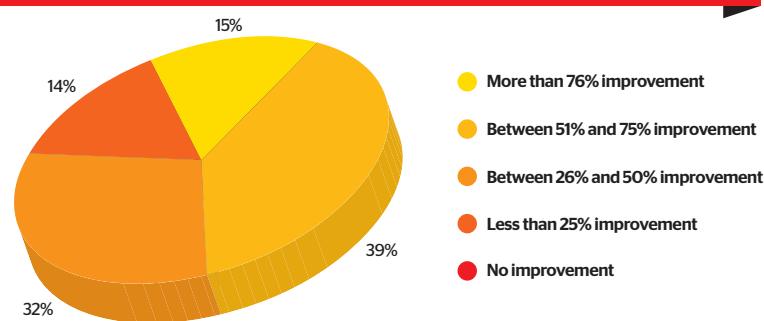


Figure 9 Tendency of patients to recommend the skin tightening treatment to friends and colleagues

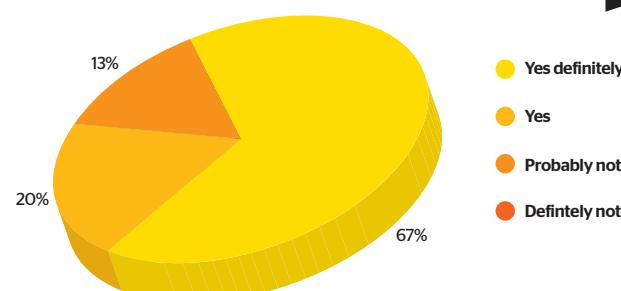
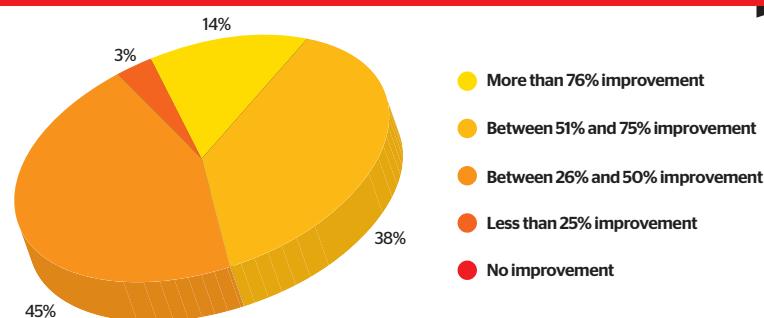


Figure 10 Overall improvement in skin appearance (Physician evaluation)



The EndyMed Pro multisource RF is the latest technology offered for body and face non-ablative skin tightening, and this article presents, for the first time, clinical data from a study using a unique treatment protocol of multisource RF skin tightening. Between 4 and 6 weeks after treatment, dermal changes were noted, including significant improvement in skin texture, and a reduction in wrinkles and skin laxity.

In this study, all treatments were performed without any anaesthesia, and yet were regarded by the majority of patients as pain-free. In fact, no patients considered the procedure intolerable at any point.

Conclusions

Based on the results, the author believes the EndyMed Pro facial tightening treatment protocol, which divides the face into two sections rather than five, using the maximum energy, provides an exciting new option for effective facial skin tightening for skin laxity, without discomfort and downtime. Further study will support the results and conclusions of this article.

► **Declaration of interest** This evaluation was not sponsored by any entity or company and was performed solely by Dr Liliane Mouyal.

► **Figures 2-10** © Liliane Mouyal MD, Medecin Esthetique- DIUE Lasers Médicaux, Paris, France.

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Key points

- Skin temperature is dependent on the energy used and the size of the treatment area
- The protocol used in this study was time-saving and showed very good skin improvement and a high satisfaction rate
- This article describes clinical data from a study using a unique treatment protocol of a multisource radiofrequency skin tightening application
- No patients considered the procedure intolerable at any point
- The alternative protocol described in this article used higher energy on a larger area, and was found to be both safe and effective