A novel method for real-time skin impedance measurement during radiofrequency skin tightening treatments

Yoram Harth, MD[1,2] & Daniel Lischinsky, BSc[2]

[1]*O.R. Medical Center, Herzlya, Israel*
[2]*EndyMed Ltd., Cesarea, Israel*

Summary

The thermal effects of monopolar and bipolar radiofrequency (RF) have been proven to be beneficial in skin tightening. Nevertheless, these effects were frequently partial or unpredictable because of the uncontrolled nature of monopolar or unipolar RF and the superficial nature of energy flow for bipolar or tripolar configurations. One of the hypotheses for lack or predictability of efficacy of the first-generation RF therapy skin tightening systems is lack of adaptation of delivered power to differences in individual skin impedance. A novel multisource phase–controlled system was used (1 MHz, power range 0–65 W) for treatment and real-time skin impedance measurements in 24 patients (EndyMed PRO™; EndyMed, Cesarea, Israel). This system allows continuous real-time measurement of skin impedance delivering constant energy to the patient skin independent of changes in its impedance. More than 6000 unique skin impedance measurements on 22 patients showed an average session impedance range was 215–584 Ohm with an average of 369 Ohm (standard deviation of 49 Ohm). Analyzing individual pulses (total of 600 readings) showed a significant decrease in impedance during the pulse. These findings validate the expected differences in skin impedance between individual patients and in the same patients during the treatment pulse. Clinical study on 30 patients with facial skin aging using the device has shown high predictability of efficacy (86.7% of patients had good results or better at 3 months' follow-up [decrease of 2 or more grades in Fitzpatrick's wrinkle scale]). The real-time customization of energy according to skin impedance allows a significantly more accurate and safe method of nonablative skin tightening with more consistent and predictable results.

Keywords: EndyMed Pro, multisource RF, radiofrequency, radiosurgery, wrinkles, 3DEEP

Introduction

The use of radiofrequency (RF) for aesthetic and dermatological purposes is becoming one of the more popular applications.[1,2] The thermal effects of RF have been proven to be beneficial in skin tightening by immediate collagen contraction and the delayed collagen remodeling process. The effective use of the first-generation RF devices is restricted by the uncontrolled nature of monopolar or unipolar RF and superficial nature of energy flow for bipolar or tripolar configurations. Although first-generation monopolar RF and bipolar RF have been found to be useful on some of the patients, the effects were frequently partial or unpredictable. One of the hypotheses for lack or predictability of efficacy of first-generation RF systems

Correspondence: Yoram Harth, MD, O.R. Medical Center, Ramat Hayam 60, Herzlya 46851, Israel. E-mail: yhart@netvision.net.il

Accepted for publication June 29, 2010

 © 2011 Wiley Periodicals, Inc.

is related to the fact that differences in individual skin impedance are unacounted for during the treatment with these systems.

Energy is delivered to the tissue according to Ohm's law: E (energy in joules) = I (current in amps) × Z (impedance in Ohm) × T (time). This law demonstrates that the energy delivered is directly proportional to the product of impedance, current, and time. Thus, if impedance decreases, the current must increase to maintain the same delivery of energy. Conversely, if impedance increases, the current must decrease for the same reason.

This impedance is known to vary between individuals (according to gender, race, age, etc.) and in the same patients according to body area and current skin humidity. The impedance is shown to vary by site and can be changed by manipulation of the tissue, such as by topical application of moisturizing agents or local anesthesia. Natural or induced alteration of the individual skin impedance may have an effect on the uniform delivery of the effective energy delivered into the tissue.[3–5]

The geometry of the electrode has a major impact on the impedance value. There is a nonlinear inverse relation between the contact area of the electrode with the skin and the measured impedance. For bigger contact area, the impedance will be smaller and *vice versa*.

The coupling between the tissue and the measurement electrodes is also an important factor influencing skin impedance and energy delivery. The methods for delivery of RF to the skin can be divided into resistive coupling and capacitive coupling. For resistive coupling, a gel is applied to the skin, reducing the electrical resistance of the stratum-corneum and improving the electrical contact between the electrode and the tissue. In this case, the impedance can be measured using the simple equation of Z (impedance) = V (RF amplitude)/I (RF current). For capacitive coupling, an isolating element is added between that target heating zone and the electrode. In this case, DC currents will be blocked and AC currents will flow through such an isolation element. The combination of the electrodes with the isolation element and the skin create an equivalent to a capacitor. In this case, the equation for a capacitive element is: Z (impedance) = R + 1/JWC (R = real part of the impedance; J = mathematical element to describe imaginary numbers; W = 2 xπxf $\rightarrow$ 2 multiplied by 3.14, multiplied by the frequency of the current flowing through the capacitor; C = capacitance value).

Some of the first-generation RF nonablative tightening devices use impedance measurements. One of these devices (ThermaCool, Thermage; Solta Medical, Thermage, CA, USA) uses a monopolar capacitive configuration for the treatment and impedance measurement. In this device, the impedance is measured between the handpiece contact point on the surface of the skin and a second plate attached to the back of the patient, measuring full body capacitive impedance. In another method used by at least one bipolar device (Aurora; Syneron, Yokneam Illit, Israel), the measurement is between the two electrodes on the surface of the skin (resistive impedance). As the measurement is after the pulse, the operator has to compensate for the impedance manually in the next pulse.

The purpose of this study was to examine the difference in skin impedance during one treatment session over a large number of nonablative treatments. For this purpose, we used the EndyMed PRO (EndyMed) that allows real-time measurement of impedance and customization of energy delivered according to differences in skin impedance.[6] In addition, we looked at the efficacy and predictability of EndyMed PRO treatment in a retrospective analysis of 30 patients treated for facial wrinkles.[7]

Materials and methods

For this study, the large multisource EndyMed PRO™ body contouring handpiece was used (1 MHz, power range 0–65 W). The treatment area was divided into 10 × 10 cm squares. The number of squares depended on the size of the treatment area and was typically 3–4 squares on the abdomen and 2–3 squares on each thigh.

With the EndyMed PRO™, the impedance is measured concomitantly from three pairs of electrodes reflecting data from multiple depths of the treated target skin tissue (Fig. 1).

The skin impedance was automatically measured by the system in real time during treatment and registered through the built in USB port. For the first experiment, 30-s pulses of nonablative RF energy (1 MHz, 40 W; EndyMed) were applied to two different patients. Skin impedance was automatically recorded every 50 ms and registered at the end of each 30-s pulse to the connected USB device.

For the second experiment, we gathered skin impedance data from routine treatment sessions of 22 patients undergoing body and face skin tightening and shaping treatments with EndyMed's 3DEEP™ treatment system.

To test the efficacy and predictability of the EndyMed PRO™ treatment, we analyzed the results of 30 patients treated for facial wrinkles. These patients were treated six times (4 weeks – once a week and two more sessions biweekly). The patients were photographed at baseline, end of six treatments, and 1 and 3 months after the end

Figure 1 Treatment and measurement handpiece showing six electrodes (EndyMed PRO, EndyMed Ltd).

of the treatment sessions. The photographs were evaluated by two blinded dermatologists not involved in the study and graded according to the Fitzpatrick elastosis and wrinkle scale.[8]

Results

Change of skin impedance during one 30-s pulse

Two pulses of 30 s each were applied to the skin, and the raw data were fitted to a linear regression curve to show changes of impedance during a pulse. A total of 600 impedance measurements were performed during each treatment pulse (Fig. 2).

Variability of average skin impedance in a 22-patient group

In this experiment, we gathered skin impedance data from routine treatment sessions of 22 patients undergoing body and face skin tightening and shaping treatments with EndyMed's 3DEEP™ system. We looked at the log file of a total of 6565 impedance measurements, which correspond to 152 treatment sessions (Fig. 3).

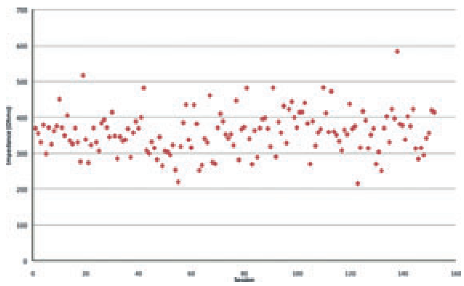


Figure 3 Real-time skin impedance in 152 RF skin tightening sessions. Average session impedance range was 215–584 Ohm. With a median of 356 Ohm. The average was 369 Ohm with a standard deviation of 49 Ohm. Quartiles: 0–25% = 215–318, 25–50% = 318–356, 50–75% = 356–388, 75–100% = 388–584.

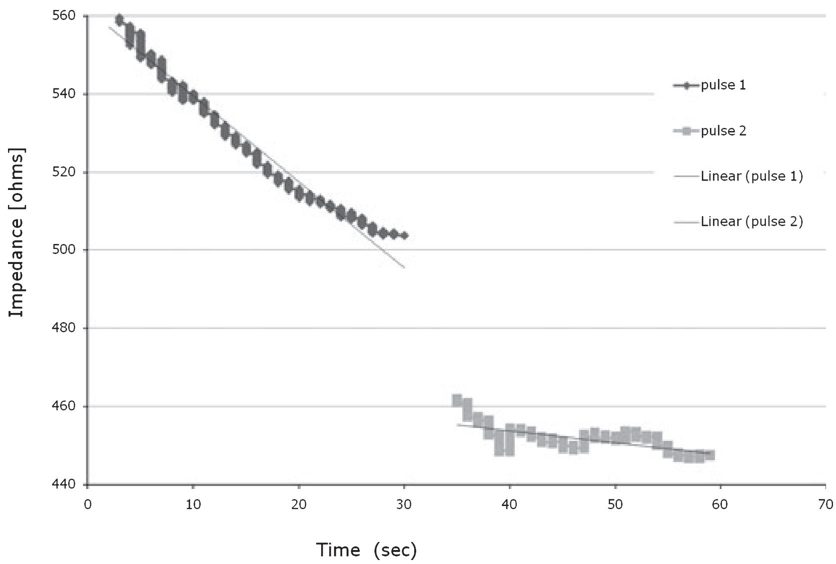


Figure 2 Pulse #1, patient 1, shows a significant decrease in impedance during the treatment pulse, from 560 to 460 Ohm (18%). In the second patient (pulse #2, patient 2), the impedance decreased from 460 to 435 Ohm (5%).

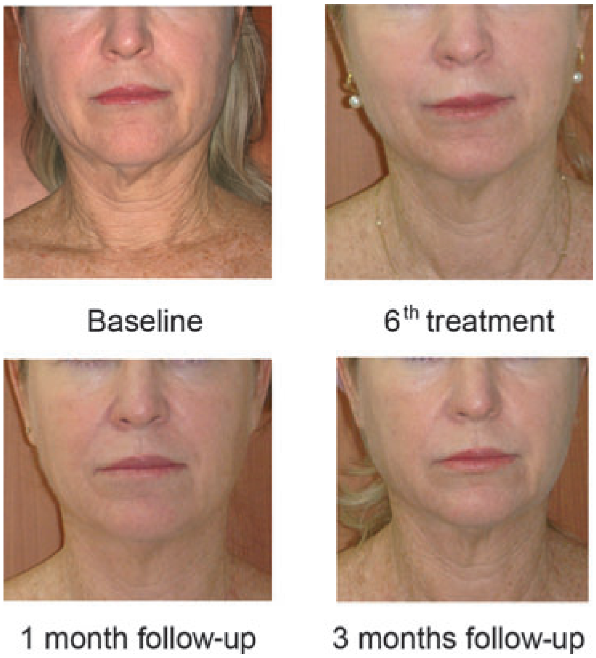


Figure 4 A 57-year-old woman before, at the end of six EndyMed PRO treatment sessions, 1 and 3 months after the end of treatment.

Figure 5 A 71-year-old woman at the end of six EndyMed PRO treatment sessions, 1 and 3 months after the end of treatment.

Figure 6 A 59-year-old man at the end of six EndyMed PRO treatment sessions, 1 and 3 months after the end of treatment.

All 30 patients completed the course of the treatment protocol. All patients have completed the 3-month follow-up. No unexpected adverse side effects were detected or reported. In some patients, post-treatment erythema (hyperemia) was detected. The edema was resolved within 10–30 min. No patients experienced burns, skin breakdown, or scarring. None of the patients has reported pain during the study (Figs 4–6).

Analysis of the photographic results at the 3-month follow-up revealed improvement (downgrade of at least 1 score according to the Fitzpatrick scale) in all (100%) patients according to both reviewers. Statistical comparison (using paired *t*-test) was conducted among the pretreatment Fitzpatrick score (baseline) to the following six treatments' Fitzpatrick score, 1-month follow-up and 3-month follow-up Fitzpatrick scores for each reviewer. Statistical analysis was conducted by SAS 9.1 (SAS Institute, Cary, NC, USA). Score differences were found to be statistically significant while comparing baseline score to the scores obtained following six treatments ($P < 0.0001$), 1-month follow-up ($P < 0.0001$), and 3-month follow-up ($P < 0.0001$) for both reviewers, indicating treatment efficacy. Figure 7 represents averages (± STDV) of Fitzpatrick scores given by the two reviewers at baseline, following six treatments, and at 1- and 3-month follow-up. Statistical analysis that was conducted by using one-way ANOVA of the Fitzpatrick scores obtained at following six treatments, and at 1- and 3-month follow-up reveal statistical significance

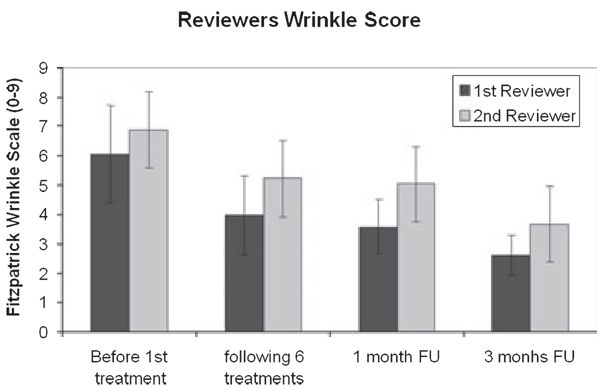


Figure 7 Averages (± STDV) of Fitzpatrick scores given by the two reviewers.

($P < 0.0001$) for both reviewers. Analysis of the percent of improved patients has shown that the majority of patients had good results or better (decrease of 2 or more grades in Fitzpatrick's wrinkle scale.). Fifty-seven percent at the end of treatment sessions, 70% at 1-month follow–up, and 86.7% at the 3-month follow-up (Fig. 8).

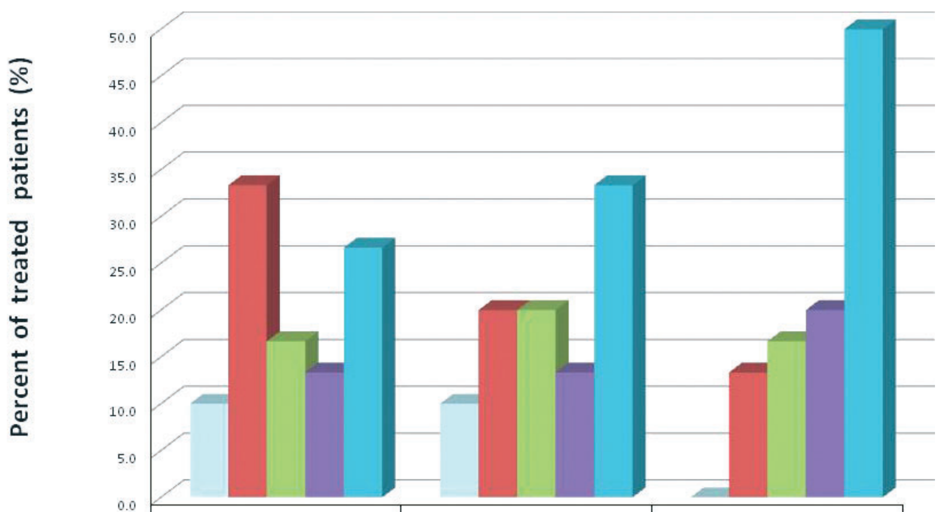
Conclusions

It is well accepted that the energy that enters the treated target tissue relates directly to the tissue impedance in the time of treatment. It is also known that tissue and more specifically skin impedance varies between different individuals and in the same individuals between body sites and according to the real-time skin humidity.

During nonablative RF skin tightening and body contouring, RF energy is delivered into the skin. To allow a constant and consistent energy delivery, there is a need for the power delivered to be normalized for skin impedance. Some of the first-generation RF skin tightening devices offer skin impedance measurements, but these measurements are not optimal. The reliability of monopolar measurement is hampered by their configuration supplying full-body capacitive resistance which is inadequate for accurate target skin impedance assessment. Other systems allow postpulse bipolar impedance measurement reflecting impedance of superficial surface only which is insufficient for effective real-time impedance customization.

In this current study, we used for the first time a novel kind of RF energy delivery system which allows also monitoring of the real-time local skin impedance changes during nonablative RF skin treatment.

In the first experiment measuring the impedance through two 30-s pulses, we noticed the decrease in impedance in parallel to accumulated tissue energy delivery. This can be related, most probably, to the temperature increase during the pulse. We believe that the difference in impedance decrease rates emphasizes differences in skin characteristics between two individual patients.



	End of Tx.	1 Month FU	3 Months FU
No change = 0	10.0	10.0	0.0
Mild improvement = 1	33.3	20.0	13.3
Good improvement = 2	16.7	20.0	16.7
Very good improvement = 3	13.3	13.3	20.0
Excellent improvement = 4+	26.7	33.3	50.0

Figure 8 Improvement (decrease) in Fitzpatrick's wrinkle scale in treated patients.

 © 2011 Wiley Periodicals, Inc.

In our second experiment, we examined impedance variability over multiple sessions in multiple treated individuals. The results show large fluctuation with a maximum impedance measurement of 584 Ohm (58% over the average) and minimum of 215 Ohm (41% under the average).

Our findings validate the expected differences in skin impedance between individual patients and in the same patients during the treatment pulse. These findings pinpoint the importance of reliable real-time impedance measurement and normalization of energy delivered for the impedance changes.

The EndyMed PRO™ that was tested in this study overcomes many of the caveats of previous generation nonablative systems. In contrast to other systems that allow capacitive full body (monopolar) or only superficial measurement (bipolar), the EndyMed PRO™ allows real-time measurement of impedance in the multiple skin levels. As the system incorporates tissue impendance in its multisource RF delivery amplifiers, a constant power delivery is achieved. Clinical study on 30 patients with facial skin aging using the EndyMed PRO™ has shown high predictability of efficacy. At 3 months' follow-up, 86.7% of patients had good results or better (decrease of 2 or more grades in Fitzpatrick's wrinkle scale).

In summary, our data confirm the existence of large fluctuations in skin impedance between individual patients and during nonablative treatment sessions. The real-time customization of energy according to skin impedance as implemented in the tested system allows a significantly more accurate and safe method of nonablative skin tightening with more consistent and predictable results.

References

1 Alster TS, Lupton JR. Nonablative cutaneous remodeling using radiofrequency devices. *Clin Dermatol* 2007; **25**: 487–91.
2 Gold MH. Tissue tightening: a hot topic utilizing deep dermal heating. *J Drugs Dermatol* 2007; **6**: 1238–42.
3 Lack EB, Rachel JD, D'Andrea L, Corres J. Relationship of energy settings and impedance in different anatomic areas using a radiofrequency device. *Dermatol Surg* 2005; **31**: 1668–70.
4 Lukaski HC. Regional bioelectrical impedance analysis: applications in health and medicine. *Acta Diabetol* 2003; **40**(Suppl 1): S196–9.
5 Woo EJ, Hua P, Webster JG *et al.* Skin impedance measurements using simple and compound electrodes. *Med Biol Eng Comput* 1992; **30**: 97–102.
6 Elman M, Vider I, Harth Y *et al.* Non invasive therapy of wrinkles, lax skin using a novel multisource phase controlled radiofrequency system. *J Cosmet Laser Ther*, 2010; **12**: 81–6.
7 Harth Y, Vider I, Elman M *et al.* Long term anti wrinkle reduction using a novel multisource of RF phase controlled radiofrequency treatment system. *Lasers Surg Med*, 2010; **42**: 94–5.
8 Fitzpatrick R, Geronemus R, Goldberg D *et al.* Multicenter study of noninvasive, radiofrequency for periorbital tissue tightening. *Lasers Surg Med* 2003; **33**: 232–42.