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Non-Invasive Radiofrequency Deep-Tissue Heating: Computational Model and Facial Wrinkles Reduction Pilot Clinical Study

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ABSTRACT

Non-invasive facial wrinkle reduction by means of radiofrequency tissue heating is frequently used as an alternative to invasive procedures. Despite its widespread use, there is a lack of published numerical models that would allow an in-depth understanding of tissue heating in specific layers of the body. We constructed a numerical model of non-invasive radiofrequency tissue heating using a CryoDerm device and evaluated the use of the device on facial wrinkles in a pilot clinical study. Our numerical model showed pronounced heating of the deeper tissue layers, with only partial heating of upper layers. The clinical study showed immediate periorbital and nasolabial wrinkle improvement, and great patient satisfaction with a painless therapy.

Key words: rhytid, wrinkle, non-invasive procedure.

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I. INTRODUCTION

Non-invasive treatment for wrinkle reduction is an attractive, frequently used alternative for patients unwilling to undergo invasive procedures (i.e. surgery). For non-invasive skin resurfacing, either optical or electromagnetic (radiofrequency) heating techniques can be used [1–5]. The aim of these techniques is to heat dermis and subcutaneous tissue while minimizing heating of the epidermis and consequently reducing damage to the superficial skin layers [4,6]. The observed tissue contraction immediately after the therapy is hypothesized to result from modifications in the collagen structure due to temperature increase in the dermal layer. Subsequent formation of new collagen fibers then ensures a long-term tissue remodeling, which is beneficial for cosmetic purposes [4,5].

Even though RF tissue heating has been used in wrinkle reduction for many years and is approved by the FDA, only partial computational evaluation of the RF therapy is available in the literature [7,8]. In this paper we present calculations using a finite element model describing RF heating of different tissue layers. The RF field is modeled using parameters obtained from a CryoDerm (Iskra Medical d.o.o., Slovenia) device applicator. A subsequent pilot study on RF facial wrinkle reduction at the nasolabial and periorbital regions using the same device is reported.

II. MATERIALS AND METHODS

a) Numerical modeling

A three-dimensional numerical model of tissue, heated by radiofrequency (RF) energy, was constructed in Comsol Multiphysics 4.3 (Comsol, Burlington, MA, USA). The model consisted of a cylinder with approximate diameter of the arm [9]. The cylinder was further divided into four concentrically arranged layers, each representing one of the tissues: skin, adipose tissue, muscle, and bone. Due to symmetry, only a quarter of the model was considered in order to reduce the calculation time (Fig. 1a). On top of the cylinder, a model of an RF applicator was placed. Since the applicator was flat, the upper part of the cylinder was also flattened, but the thicknesses of the skin and adipose tissue layers was maintained (Fig. 1b).

The applicator consisted of two layers of insulating dielectrics, as shown in Fig. 1c. The active electrode was modeled by assigning an electric potential of either 600 V or 1000 V to a part of the upper boundary of the applicator, which is represented with gray areas in Fig. 1. The neutral electrode was placed on the bottom of the cylinder (see Fig. 1a), however, it was separated from the cylinder with a 0.35 mm thick layer of insulating dielectric. The geometry of the RF applicator and the neutral electrode was built according to the CryoDerm device (Fig. 2).

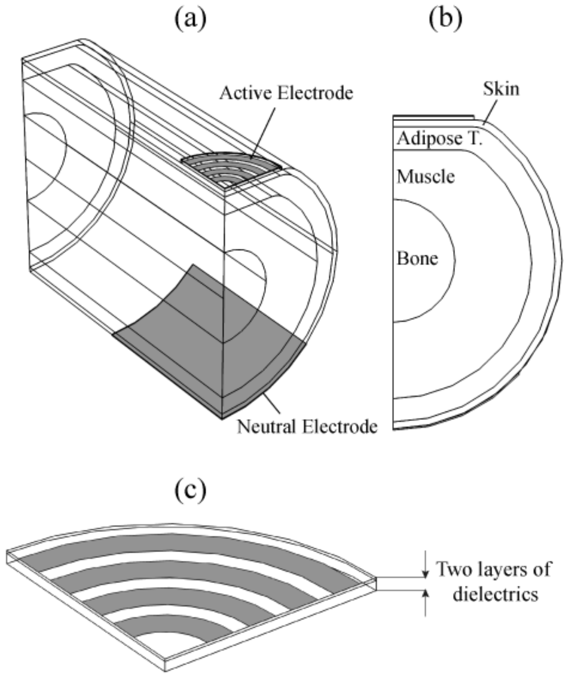


Fig. 1: Tissue model. (a) 3D view. (b) Front view. (c) Model of RF applicator. The surfaces modeling the electrodes are colored in gray.

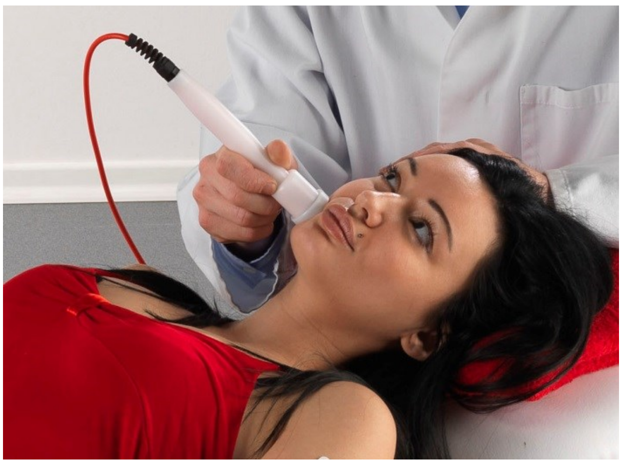


Fig. 2: Radiofrequency tissue heating using the CryoDerm device.

Electric potential V inside the tissue was calculated using the equation

$$\nabla\left(-\sigma\nabla V - j2\pi f\varepsilon\nabla V\right) = 0\,, \tag{1}$$

where σ and ε denote the conductivity and permittivity of a given tissue layer, respectively, f is the frequency of the applied RF signal and j is $\sqrt{-1}$.

The tissue electrical properties (i.e. conductivity and permittivity) vary with frequency of the applied electric field. In our calculations we, therefore, incorporated a model describing the frequency dependency of each tissue layer's electrical properties according to Gabriel et al. [10]. This model is based on measurements on various human and animal tissue samples over a wide frequency range.

To calculate the temperature T inside the tissue, we used Pennes' bioheat equation [11] with an additional term Q_{el} to account for RF induced heating:

$$\rho C\frac{\partial T}{\partial t} = \nabla(k\nabla T) + \rho_b C_b \omega_b (T_b - T) + Q_{met} + Q_{el}\,. \tag{2}$$

In the above expression, the first term on the right accounts for heat transfer due to heat conduction from warmer to colder tissue regions and the second term models the heat convection due to blood perfusion. Q_{met} accounts for the heat generated by metabolism, and $Q_{el} = \sigma\left|\nabla V\right|^2$ is the power dissipation density induced by the applied RF signal. Symbols ρ, C, and k denote the density, specific heat, and thermal conductivity of a given tissue layer, respectively. Symbols ρ_b, C_b, ω_b and T_b denote the density of blood, specific heat of blood, blood perfusion rate, and the temperature of blood, respectively.

The heat exchange from the skin to the environment was modeled with a boundary condition on the skin surface [12]:

$$-k\nabla T\boldsymbol{n} = 8.3\frac{\mathrm{W}}{\mathrm{m^2K}}\cdot(T - T_{air}) + 4\frac{\mathrm{W}}{\mathrm{m^2}}\cdot 2^{0.1(T-T_0)} \tag{3}$$

where $\boldsymbol{n}$ is a unit vector, normal to the skin surface, T_{air} is air temperature, and T_0 is the surface temperature in stationary conditions (no heating), when the air temperature is ~30 °C. The first term on the right side accounts for heat losses due to convection and radiation, whereas the second term accounts for heat losses due to sweating [12].

Before applying an RF signal, the model was equilibrated to a room temperature of 25 °C. The values of the tissue geometrical parameters were taken from [9], electrical parameters from [10], and thermal parameters from [12].

b) Facial wrinkle reduction: pilot clinical study

A pilot study has been conducted to show efficacy of the non-invasive CryoDerm device (Fig. 2) for facial wrinkles reduction at the nasolabial and periorbital regions.

In the pilot study, four Caucasian females aged 45–75, and exhibiting light to modest wrinkle development, were enrolled. All subjects reported good general health. Contraindications checked at the time of enrolment were pacemaker, pregnancy, and epilepsy. None of the subjects had records of surgical procedures on the face, collagen implants or administration of botulinum toxin. One patient's treatment was postponed for a week, due to sun induced erythema clearly visible on arrival to the office.

The CryoDerm device (Iskra Medica d.o.o., Slovenia) uses upgraded capacitive radiofrequency technology to maximize subdermal heating while minimizing the surface heating temperature. The used CryoDerm device methodology consists of four procedures: microdermabrasion, endodermal vacuum therapy, radiofrequency therapy, and subsequent rapid skin cooling.

To maximize the deep heating effect, the therapy begins with gentle diamond microdermabrasion, which reduces the thickness of the less conductive epidermal layers of the skin. Endodermal vacuum therapy is then performed to increase liquid content in the treated tissue. Next, radiofrequency therapy begins with the 3 second automatic tune-up where the radiofrequency parameters are adjusted individually for every patient. No superficial cooling or anesthetics are required during the treatment. Before the treatment, the patient's face is divided into five independent regions. In each region the radiofrequency applicator is slowly moved over the treated region until the surface skin temperature reaches 41 °C, and it is kept at this temperature in the whole region for 3 minutes before moving on to the adjacent region. Immediately after the radiofrequency treatment, the heated tissue is cooled down using a specialized applicator preset to 5 °C, which cools down the treated skin.

On average the whole procedure lasts 60 minutes, with 10 minutes for microdermabrasion, 15 minutes for endodermal vacuum therapy, 30 minutes for radiofrequency heating, and 5 minutes for subsequent rapid skin cooling.

Evaluation methods used in the study consisted of expert evaluation of photographs, patient's visual improvement self-reports, and patient satisfaction and pain assessment questionnaires. Photos were taken using a digital camera (model D90, Nikon, Japan) before and immediately after the CryoDerm procedures in standardized ambient light conditions. Two independent experts were asked to evaluate the response in the nasolabial and periorbital regions based on the photographed material using the Fitzpatrick standard wrinkle scale [13], utilizing wrinkle reference photographs for main wrinkle classes [14]. The Fitzpatrick wrinkle scoring system defines three classes of wrinkles: I. mild, II. moderate, and III. severe. Each of the three classes provides an additional three sub scores for an overall scale from 1 to 9 (Table 1).

Table 1: Fitzpatrick wrinkle scale [13]

Class	Wrinkling	Score	Degree of Elastosis
I	Fine wrinkles	1-3	Mild (fine textural changes with subtly accentuated skin lines)
II	Fine to moderate depth wrinkles Moderate number of lines	4-6	Moderate (distinct popular elastosis - distinct papules with yellow translucency under direct lightening - and dyschromia)
III	Fine to deep wrinkles Numerous lines With or without redundant skin folds	7-9	Severe (multipapular and confluent elastosis – thickened yellow and pallid – approaching or consistent with cutis rhomboidalis)

After the treatment patients were asked to fill a questionnaire to self-assess improvement in the nasolabial and periorbital regions on a scale from 1 (no improvement) to 10 (great improvement). Additionally, they assessed overall result & treatment satisfaction on a scale from 1 (not satisfied) to 10 (very satisfied). During the treatment, patients were specifically asked to immediately report any pain to the operator, allowing the operator to modify the treatment parameters. To evaluate the pain during the procedure, patients were asked to grade the pain using a 5-point descriptive scale (1-"nil," 2-"mild," 3-

"moderate," 4-"severe," and 5-"very severe") [15]. The pain was separately graded for each therapy procedure: microdermabrasion, endodermal vacuum therapy, radiofrequency and rapid skin cooling.

III. RESULTS

a) Numerical model

The rise in temperature of a given tissue layer due to RF heating depends on the power dissipated in this tissue layer. Since the electrical properties of tissues vary with frequency of the electric field, it can also be expected that at different frequencies, different tissues will be heated to a different degree.

We investigated how the power dissipation density Q_{el} in each tissue layer changes with the frequency of the applied RF signal. We performed calculations on our tissue model for a frequency range from 1 kHz to 1 GHz and determined the maximum Q_{el} in the skin, adipose tissue, muscle, and bone. Results are presented in Fig. 3. In the low and high frequency range, the highest amount of power is dissipated in the skin layer. However, between the frequencies of 68 kHz and 6.5 MHz, the maximum Q_{el} is observed in the adipose tissue. This suggests that with an appropriate frequency of the applied RF signal, it is possible to heat the adipose tissue to a greater extent than other tissues. Note also that the power is dissipated in the tissue despite the fact that electrodes are not in direct contact with the skin. This is due to capacitive coupling between the applied RF signal and the tissue's electrical properties.

We next calculated the time course of the increase in tissue temperature due to RF heating. Fig. 4 presents the maximum obtained temperature in each tissue layer during the first 300 s after the RF applicator is applied to the skin. The frequency of the RF signal was set to 1 MHz, and the voltage on the active electrode was either 600 V (Fig. 4a) or 1000 V (Fig. 4b). Note that the initial maximum temperature varies for each tissue layer since the outermost layers (skin and fat) have a slightly lower temperature due heat loss in the ambient air (25 °C).

In Fig. 4 one can observe that the highest temperature is indeed achieved in the adipose tissue. Both the maximum temperature in the skin and in the muscle are lower, whereas the temperature in the bone practically does not change for the time considered. The increase in the temperature, however, depends on the value of the applied voltage. The highest temperature in the adipose tissue, achieved after 300 s of heating, is 39.4 °C when the applied voltage is 600 V, and 45 °C when the applied voltage is 1000 V.

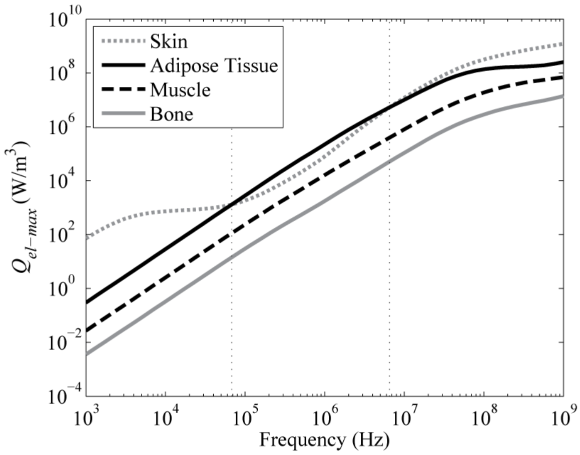
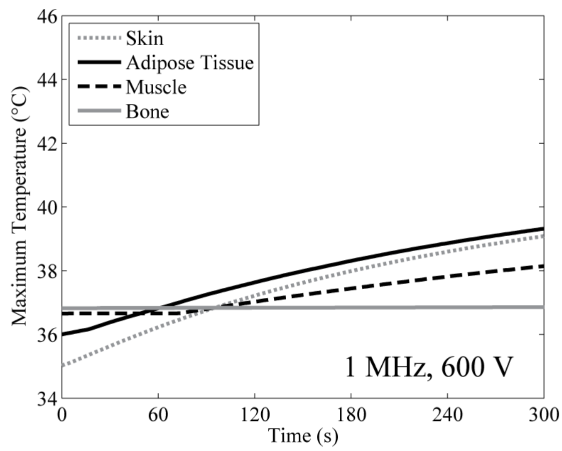


Fig. 3: Frequency dependency of the maximum power dissipation Q_{el_max} density in each tissue layer of the model. Vertical lines mark the frequencies for which Q_{el_max} in the adipose tissue exceeds Q_{el_max} in other tissues.

(a)



(b)

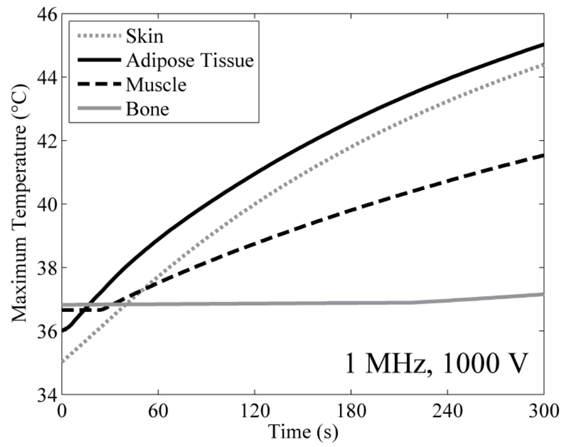


Fig. 4: Time course of maximum temperature in each tissue layer, when the voltage on the active electrode is either (a) 600 V or (b) 1000 V. The frequency of the RF signal is 1 MHz.

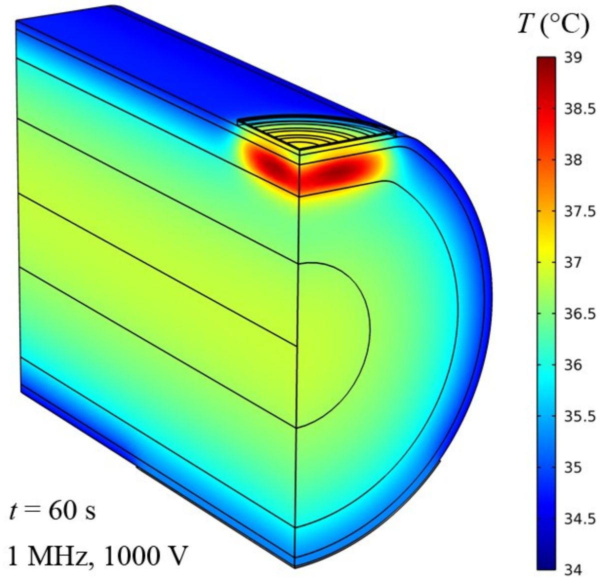


Fig. 5: Spatial distribution of tissue temperature after 60 s of RF heating (1 MHz, 1000 V).

Fig. 5 demonstrates the spatial distribution of temperature in the entire tissue after 60 s of RF heating (1 MHz, 1000 V). Most of the heat is generated in the adipose tissue, locally beneath the RF applicator. On the opposite side, where the neutral electrode is placed, the tissue temperature is practically unaffected. This is due to the large area of the neutral electrode, which reduces the electric current density and consequently minimizes heating.

b) Facial wrinkle reduction: pilot clinical study

Clinical improvements on both evaluated areas were assessed by two independent experts. The experts' baseline wrinkle assessments were in all three major wrinkle classes: mild, moderate and severe. Average wrinkle reduction was 1.8±1.0 point in the periorbital and 1.3±0.7 point in the nasolabial region on the Fitzpatrick wrinkle scale. The maximum improvement of 3 points was seen in one patient in the periorbital region. One patient had limited response in the nasolabial region. Except for this single case, both experts observed at least one degree of improvement immediately after the therapy in comparison to the baseline score for all the subjects.

All patients self-graded their wrinkle improvement with scores of 9–10; the treatment satisfaction was also exceptionally high with all grades at 9 or 10.

The treatments were completely painless, with all but one patient reporting "nil" (1) pain. A single patient reported "mild" (2) pain during the dermabrasion procedure and "nil" (1) during other procedures. Immediately after the treatment mild erythema was observed, resolving within hours. No other side effects were noted in the duration of the study.

IV. DISCUSSION

In this paper we present numerical results for a model of RF tissue heating and the results of a pilot clinical study demonstrating the applicability of RF heating for wrinkle reduction. The numerical model provides important data on the dynamics of the temperature increase in different tissue layers, which demonstrate that the heating effects are more pronounced in deeper layers, i.e. below the skin surface. Therefore, radiofrequency seems more suitable for lower dermal and subcutaneous tissue heating than other techniques e.g. optical, where the energy dissipation is strongly observed in the upper layers of the skin.

Our calculations demonstrate that the maximum temperature of the skin is lower compared to the maximum temperature of the adipose tissue. However, the maximum temperature in the skin layer is observed at the border between the adipose tissue layer and the skin layer, whereas other skin regions are heated to a lesser extent (see Fig. 5). In other words, thermal conduction from the adipose tissue layer considerably contributes to the observed increase in the skin temperature and could thus play an important role in heating of the target dermal layer.

Our numerical model currently does not distinguish between the epidermal and dermal layer of the skin, possibly overscoring the energy dissipation in epidermal tissue and underscoring the heat buildup in the viable dermis. Further division of the skin layer into epidermal and dermal layers is a subject of future work and improvement of our numerical model.

The observed frequency dependence of the power dissipation in separate tissue layers and the strong influence of the applied voltage on the extent of tissue heating predicted by numerical modeling (Figs. 3 and 4) further enable room for technology improvement. Due to inter-patient variance in skin properties, the optimal working parameters cannot be pre-determined. Therefore, the CryoDerm device uses a built-in module to measure and determine patient- and area-specific therapy parameters in the 3-second calibration phase of the therapy. Because the tissue parameters are temperature dependent, it is wise to perform automatic parameter tuning during the treatment, to ensure optimal parameters for the duration of the therapy.

Fig. 6: A baseline photo (left) and immediately after the treatment (right) of a 58 year old patient.

Fig. 7: A baseline photo (left) and immediately after the treatment (right) of a 45 year old patient.

The expert evaluation of the periorbital and nasolabial regions shows immediate improvement, on average more than one point on the Fitzpatrick scale. Even though the visual improvement of facial texture (seen in wrinkle reduction and improved skin tone) was impressive, it was still unexpected for patients to self-grade it with the highest available grades. Since all the patients were very satisfied with the treatment, part of this somehow unrealistic score can also be attributed to the fact that the study enrolment provided them with a rather costly therapy pro-bono.

The CryoDerm device used in this study is an improved version of the Iskra Medical radiofrequency device Green IRF. The latter device was previously used in a 46-subject study, where facial wrinkle reduction was observed with no additional treatment modalities to Green IRF radiofrequency heating [16]. Five radiofrequency treatments were administered in two week intervals, with the results clearly visible three months after the final radiofrequency treatment. Due to a small sample size in our study it is impossible to directly compare the results; but from the personal experience of the author (A.C.M.) after a 1 year use of the device in the practice, the wrinkle reduction and skin tone enhancement with the compound CryoDerm therapy are superior to the results obtained with the radiofrequency therapy alone. Aside from the expected erythema, no side effects were observed during this study.

In future work our numerical model will be modified from the currently used geometry to better suit facial geometry and tissue properties. Such a model will allow us to gain additional knowledge of the spatial and temporal dependence of tissue temperature increase due to RF heating.

V. CONCLUSIONS

The non-invasive radiofrequency therapy using CryoDerm compound therapy modalities is an efficient and painless treatment for facial wrinkles. The computational model confirmed that the device delivers radiofrequency heating to lower layers of tissue, with only partial heating of the superficial layers. In the pilot clinical study, we report immediate improvement of facial wrinkles.

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