TightSculpting®: A Complete Minimally Invasive Body Contouring Solution; Part II: Tightening with FotonaSmooth® Technology

Matjaz Lukac1, Anze Zorman2, Franci Bajd3
1Institut Jozef Stefan, Jamova 39, 1000 Ljubljana, Slovenia
2Medilase Dermatology & Laser Center, Tbilisijeka 59, 1000 Ljubljana, Slovenia
3University of Ljubljana, Faculty of Physics and Mathematics, Jadranska 19, 1000 Ljubljana, Slovenia

ABSTRACT

Body contouring is a procedure that alters the shape of the human body by eliminating or reducing excess skin and fat. When most people hear the word “body contouring,” they automatically think of surgery and liposuction. However, with the introduction of TightSculpting® and its advancements in laser technology, an effective form of non-invasive body contouring has finally become available. By combining two different laser wavelength treatments, fat-dissolving and skin-tightening can be both achieved during a single TightSculpting® procedure with just a single laser device. The TightSculpting® solution involves a deeply penetrating Nd:YAG laser operating in the PIANO® mode for thermic adipocyte destruction (i.e., “sculpting”) and a superficially absorbed Er:YAG laser operating in the FotonaSmooth® mode for improved skin laxity, collagen remodeling and tightening. The FotonaSmooth® and PIANO® components of TightSculpting® represent a complete body contouring solution, which can be, depending on the type of patient and the goal of the treatment, used individually or in concert, during a single procedure and with a single laser device. The combined procedure can be thus used to treat a variety of conditions, including temporary reduction in the appearance of cellulite.

In this second part of a two-article series on TightSculpting®, we describe the principles of the FotonaSmooth® laser modality and provide treatment parameters and guidelines for improving skin laxity, collagen remodeling and tightening.

Key words: laser sculpting, laser tightening, fat reduction, PIANO sculpting, Smooth tightening, TightSculpting, hyper-thermic laser lipolysis.


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I. INTRODUCTION

In recent years noninvasive body contouring techniques have become some of the most widely used procedures and are growing rapidly in areas of aesthetic medicine [1, 2]. This is because many people are not ready for and will not consider an invasive surgical procedure. Consequently, various non-invasive “cellulite treatments” have been used for many years, including based on topical agents and massage [1].

Laser-assisted lipolysis has been the most widely accepted solution for effective less invasive body contouring [3]. However, with recent advancements in laser technology, even less invasive body contouring options have become available [4-7].

The latest non-invasive body contouring technologies involve FotonaSmooth® Er:YAG laser skin tightening [8-10] and PIANO® Nd:YAG laser body sculpting [11-14]. These two technologies address two complementary body contouring issues. While the FotonaSmooth® tightening focuses on the epidermis and dermis with a goal to reduce skin laxity and improve overall skin structure and texture, the PIANO® sculpting targets unwanted subcutaneous fat by thermally triggering the programmed death of fat cells and the subsequent natural removal of fat cells from the body (See Fig. 1).

Fig. 1: The dual-wavelength TightSculpting® procedure combines PIANO® Nd:YAG laser technology for heating the subcutis, and FotonaSmooth® Er:YAG laser technology for non-ablative superficial heating of the epidermis and dermis.
II. MATERIALS AND METHODS

a) FotonaSmooth® Er:YAG laser modality and technology

The laser used for skin tightening was the Er:YAG laser available in the SP Dynamis and XS Dynamis laser systems (manufactured by Fotona d.o.o.). The treatment is based on the phenomena of non-ablative skin resurfacing with the Er:YAG laser’s extremely long FotonaSmooth® mode (See Fig. 4) [23-30].

The FotonaSmooth® mode can be delivered to the treatment area either with the R11 or R04 manual handpiece, or with a scanning T-Runner handpiece, with T standing for “tightening” (see Fig. 5).

The Er:YAG laser is generally considered to be an ablative laser due to its very high absorption and the resulting very short optical penetration depth into human tissues ($\delta_{opt} \approx \delta_{irr} \approx 1 \mu m$). However, it is not only the optical penetration depth ($\delta_{opt}$) but also the depth of thermal diffusion ($\delta_{thermal}$) that takes place during a laser pulse of duration $t_{puls}$ that determines the thermal penetration depth ($\delta$) of a laser pulse, $\delta = \delta_{opt} + \delta_{thermal}$. The longer the laser pulse duration $t_{puls}$, the longer the thermal diffusion depth ($\delta_{thermal}$), and consequently also the longer the over-all thermal penetration depth ($\delta$).

Due to the special design of the T-Runner scanner, and its V-FotonaSmooth® capability (with V standing for “variable”), the duration of the FotonaSmooth® mode ($t_{smooth}$) can be varied over a range of...
durations: 125 ms, 250 ms, 375 ms, 500 and 625 ms. For the manual handpieces, the FotonaSmooth® pulse duration is fixed to $\delta_{\text{SMOOTH}} = 250$ ms.

The FotonaSmooth® mode, with its super long pulse duration and resulting unique “dual tissue remodeling” mechanism of action [31, 32], thus represents an extremely effective and safe solution for non-ablative tissue regeneration and tightening. The Er:YAG laser in the FotonaSmooth® mode has been found to stimulate neo-collagenesis, improve elasticity and shrink treated soft tissues, and has been used very successfully not only in aesthetics and dermatology [24-27], but also in gynecology for vaginal tightening [28, 29] and in otolaryngology for shrinking of oral mucosa when treating snoring and sleep apnea [30].

The patented technique [24] employed in generating very long FotonaSmooth® Er:YAG laser pulses consists of delivering laser energy in an optimally spaced sequence of consecutively delivered sub-ablative laser micro-pulses within the overall FotonaSmooth® macro-pulse of several hundred milliseconds (Fig. 6).

Fig.6: The Er:YAG laser's FotonaSmooth® mode consists of a series of sub-ablative micro pulses, effectively “pumping” the heat away from the surface deeper into the tissue.

The FotonaSmooth® micro-pulse sequence effectively “pumps” the laser generated heat by means of heat diffusion away from the skin surface, several hundred microns deep into the epidermal and dermal tissue (see Fig. 7) [24, 29, 33-35].

Fig. 7: With the FotonaSmooth® Er:YAG mode, the tissue is heated up to the depth of $\delta \approx 600$ μm. It is not the optical penetration depth $\delta_{\text{opt}}$, but the heat penetration depth $\delta_{\text{SMOOTH}}$ which determines the depth of the thermally affected tissue.

b) FotonaSmooth® dual tissue remodeling

The advantage of the FotonaSmooth® Er:YAG modality as compared to other more deeply penetrating energy sources (such as CO2, diode or RF) is in its ability to generate very intense heat shocks of very short (< 1 ms) duration near the skin surface (starting within $\delta_{\text{Er}} \approx 1 \mu m$), in addition to the slower heating of the deeper lying skin tissues ($\delta_{\text{SMOOTH}} \approx$ up to 600 μm). FotonaSmooth® treatment thus combines the actions of two regenerative mechanisms involving both a short-exposure and a long-exposure biochemical process [31]. The two mechanisms involved in this Dual Tissue-Remodeling mechanism (DTR) are (see Fig. 8) [32]:

i) Fast heat shocking of the superficial epidermis involving the short-exposure biochemical process, and subsequent triggering of the regeneration of deeper lying tissues.

ii) Relatively slow regeneration following thermal injury to the deeper lying tissues involving the long-exposure biochemical process;

The epidermal heat shock triggering is produced by the FotonaSmooth® micro-pulses, while the slow thermal injury of the connective tissue represents a cumulative effect of the over-all FotonaSmooth® macro-pulse (See Fig. 9).
The extremely short duration of the heat shocks generated by the micro-pulses within the FotonaSmooth® macro-pulse provide significant additional safety and efficacy. This is because the threshold temperature for tissue damage is much higher when the exposure of tissue to elevated temperatures is extremely short. Here, it should be noted that it is not only the duration of the laser pulse but also the duration of the cooling phase following laser irradiation which determines the duration of a heat shock. It is in this regime that the advantage of the Er:YAG laser’s short penetration depth becomes most evident. Namely, in order for the cooling phase of a heat shock thermal pulse to be short, there must be large temperature gradients present within the epidermis in order to result in fast conduction cooling. At the tissue surface, the amplitude of the temperature gradient is inversely proportional to the optical penetration depth ($\delta_{opt}$). Therefore, the shorter the optical penetration depth, the faster the heat conduction and the shorter the ramp-down cooling phase. Consequently, the Er:YAG laser, with the highest absorption in tissue and therefore the lowest optical penetration depth, is most advantageous since it is capable of generating the shortest duration exposure times. This characteristic can be seen in Fig. 10, which shows the dependence of the duration of a temperature pulse at the tissue surface on the optical penetration depth for a laser (energy) pulse duration of $t_{pulse} = 100 \mu s$ [31, 32].

The details of the model are described in [36], and will not be repeated here.

c) Physical model of FotonaSmooth® tightening

In our study, we applied a numerical model of the physical process of tissue resurfacing as originally developed to study thermo-mechanical ablation with mid-IR lasers. The details of the model are described in [36], and will not be repeated here.

In the model, a single wavelength ($\lambda = 2940$ nm) of pulsed laser radiation is delivered to the surface of the treated tissue with a total pulse fluence $F$ (in J/cm$^2$). We modelled the tissue as a water-containing homogeneous media characterized by a single absorption coefficient of $k = 1/\delta_{opt}$ for the delivered Er:YAG laser wavelength $\lambda$. Since the main focus of our study was on the Er:YAG laser wavelength with its extremely short penetration depth, the effects of the scattering of the laser light within the tissue were not included. Similarly, it was taken that the laser spot size is much larger than the penetration depth ($\delta_{opt}$) and therefore the diffusion of dissipated heat was treated in one dimension using a finite-difference scheme.

The model enabled the calculation of the temporal evolution of the tissue temperature during and following Er:YAG laser irradiation of different pulse modalities for different depths $z$ within the tissue.

Based on the obtained temporal evolutions of temperature distributions within the irradiated tissue, we were then able to also calculate Arrhenius integrals as a function of tissue depth for different clinical protocols. The Arrhenius integral, or the tissue injury parameter ($Q$), is a measure of thermally induced tissue injury, subsequently leading to tissue regeneration and tightening. The tissue injury parameter ($Q$) represents the ratio of the concentration of native (undamaged) tissue before
thermal exposure \( (C_0) \) to the concentration of native tissue at the end of the exposure time \( \tau \) \( (C_\tau) \). The Arrhenius parameters used in our study were \( A = 4.76 \times 10^{40} \text{s}^{-1} \) and \( E_0 = 5.67 \times 10^{8} \text{J/mol} \) [31, 32]. In our analysis we calculated the tissue regeneration depth \( (\delta_{\text{reg}}) \) as the depth above which the cell injury required to stimulate tissue regeneration is above \( \Omega = 0.15 \).

III. RESULTS

a) Dependence of thermal penetration depth on Er:YAG laser modality

Figure 11 shows the calculated thermal penetration depths \( (\delta) \) for different Dynamis Er:YAG laser modalities at sub-ablative laser fluences.

![Fig. 11: Thermal penetration depth \( (\delta) \) for different Dynamis Er:YAG laser modalities.](image)

As can be seen from Fig. 11, the thermal penetration depths of “standard” Er:YAG modalities are in the range of 7 \( \mu \text{m} \) for the shortest (MSP) standard mode to 16 \( \mu \text{m} \) for the longest (XLP) standard mode. These modalities are therefore more suited for ablative treatments. On the other hand, the thermal penetration depths of the super long FotonaSmooth® pulses extend from 100 \( \mu \text{m} \) for the shortest (125 ms) FotonaSmooth® mode to 250 \( \mu \text{m} \) for the longest (625 ms) FotonaSmooth® mode.

By varying the FotonaSmooth® mode duration, the operator can vary the ratio between the actions of the direct and indirect regeneration processes. When deep penetration depths are desired, with the most pronounced slow deep thermal regeneration based on the long-exposure biochemical process, it is most advantageous to use the longest duration FotonaSmooth® mode (625 ms). On the other hand, when the operator wants to enhance the heat shock triggering component based on the short-exposure biochemical process, then it is more advantageous to use the shortest FotonaSmooth® mode (125 ms). This can be seen in Fig. 12, which shows the dependence of maximal heat shock temperatures (fast temperature peaks \( T_{p2} \)) on the FotonaSmooth® pulse duration. The shorter the Smooth mode pulse, the higher the fast temperature peaks \( T_{p2} \).

![Fig. 12: Dependence of heat shock temperature peaks \( T_{p2} \) on the FotonaSmooth® pulse duration. The data is for \( F_{\text{SMOOTH}} = 1.8 \text{J/cm}^2 \). Note that for the short duration (< 1 ms) heat shocks generated during the FotonaSmooth® mode micro-pulse sequence, the critical temperature for tissue damage \( (T_{\text{damage}}) \) is very high, above 250 °C [31, 32].](image)

It should be noted that by stacking FotonaSmooth® pulses onto the same skin area, it is possible to further increase the thermal penetration depth. This is demonstrated in Fig. 13, which shows the dependence of \( \delta \) on the number \( (N_{\text{stack}}) \) of stacked FotonaSmooth® pulses.

![Fig. 13: Thermal penetration depth \( (\delta) \) as a function of the number \( (N_{\text{stack}}) \) of stacked FotonaSmooth® pulses for different durations of FotonaSmooth®.](image)

b) STP (Surface Temperature Parameter)

It is to be noted that the amplitude of the fast temperature peaks \( T_{p2} \) (See Fig. 9) is not critical for patient comfort or safety. This is because with the short duration (< 1 ms) heat shocks generated during the Smooth mode micro-pulse sequence, the critical temperature for tissue damage is above the tissue ablation threshold of about 250 °C [31, 32]. Therefore, whenever the tissue temperature reaches the ablation threshold temperature, the onset of tissue ablation keeps the temperature at this limit, thus preventing the
temperature from ever reaching the critical level for tissue damage. This mechanism is similar to the case of boiling water, which keeps its temperature at 100 °C regardless of the heating power.

On the other hand, the amplitude of the long exposure temperature peak $T_{p1}$ (defined as the skin surface temperature $T_s$ at a delay of 20 ms following a FotonaSmooth® pulse sequence) is critical for patient comfort and safety. This is because for the $\approx 0.2$ s long temperature exposure to $T_{p1}$ (see Fig. 9), the temperature threshold for tissue damage is at about $T_{damage} \approx 75$ °C.

For long exposures (several seconds) to elevated temperatures, the reported heat pain thresholds ($T_{p1}$) for different body areas are in the range of $T_{p1} = 41-45$ °C [37, 38]. The heat pain threshold increases logarithmically towards shorter exposures, and is equal to: $T_{p1} \approx 55$ °C for $\approx 0.2$ s and $T_{p1} \approx 70$ °C for $\approx 0.05$ s [39, 40].

In order to determine heat pain thresholds for the FotonaSmooth® treatment, where the exposure to elevated temperatures is a complex function of time, we recorded discomfort of 17 patients during the same number of treatment protocols as calculated for the same treatment parameters, with $STP$ being proportional to the increase in $T_{p1}$ ($STP \propto (T_{p1} - 35°C)$).

The proportionality factor was chosen to give pain threshold values for $STP$ to be at about 100% for treatments without topical anesthesia. Since the heat pain threshold is a complex function of temperature depth distributions, we introduced a Surface Temperature Parameter ($STP$), which correlates the reported heat pain threshold treatment parameters with $T_{p1}$ as calculated for the same treatment parameters, with $STP$ being proportional to the increase in $T_{p1}$ ($STP \propto (T_{p1} - 35°C)$).

The results are shown in Fig. 14.

Note that depending on the individual patient’s pain threshold, these values may vary by approximately 10-15%.

As expected, applying a topical anesthesia improves patient’s tolerance to pain. Our comparison tests on 17 patients treated with and without a prior application of EMLA showed that the STP pain threshold increased by more than 30% when EMLA cream was used.

c) FotonaSmooth® treatment protocol for T-Runner

In our analysis, the FotonaSmooth® tightening treatment protocols were selected from the simulated outcomes of the protocol parameter combinations, taking into account the following criteria: (i) $STP$ (Surface Temperature Parameter) is below or at 100%; ii) for deep tightening treatments the tissue regeneration depth ($\delta_{reg}$) is largest under condition (i), and ii) for superficial skin laxity treatments, the required laser fluence is lowest for the largest heat shocks generated. The resulting recommended FotonaSmooth® protocols are provided in Table 1 below.

<table>
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<th>Table 1: Basic FotonaSmooth® treatment parameters for T-Runner</th>
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<tr>
<td>Deep tightening</td>
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<td>Superficial laxity</td>
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It is recommended that the operator selects the parameters depending on the individual patient’s skin type and sensitivity to discomfort, with the parameters shown in Table 1 serving only as the basic guidelines. For any combination of the selected treatment parameters, the system calculates and displays the corresponding ablation depth, regeneration depth ($\delta_{reg}$) and Surface Temperature Parameter ($STP$) (See Fig. 15).
Note that the regeneration depth is larger for larger STP (See Fig. 16). When larger regeneration depths are desired, the pain threshold can be increased to about $STP = 125\%$ by applying topical anesthesia. When exceeding the STP threshold values of 100%, first perform a small test area/spot treatment.

Fig. 16: Dependence of regeneration depth on surface temperature parameter ($STP$) for the FotonaSmooth duration of 625 ms and $N_{stack} = 6$.

IV. DISCUSSION

In what follows we provide examples of clinical results following the TightSculpting® procedure. As can be seen from the examples, the TightSculpting® procedure can be performed on almost all body areas (See Fig. 17).

Fig. 17: Most commonly treated body areas with TightSculpting® are: flanks, back fat, upper abdomen, lower abdomen, thighs (outer, inner, front, back), love handles, muffin top and upper arm.

Fig. 18: Before and after TightSculpting®. Waist (-6 cm), umbilicus (-8 cm), hip (-7 cm), SF belly (-14 mm). Courtesy of Dr. Pham Huu Nghi, MD.PhD, Vietnam.

Fig. 19: Flanks: before and after TightSculpting®. Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 20: Abdomen: before and after TightSculpting® (5 Tx). Courtesy of Dr. Anil Sharma, Canada.

Fig. 21: Abdomen: before and after TightSculpting® (8 Tx). Courtesy of Dr. Adrian Gaspar, Argentina.
Fig. 22: Flanks: before and 3 months after TightSculpting® (2 Tx). Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 23: Before and after TightSculpting®. Courtesy of Dr. Hakan Yurteri, Turkey.

Fig. 24: Abdomen: before, immediately after and after TightSculpting®. Courtesy Dr. Liliana Fernandez, Colombia.

Fig. 25: Flanks: before and immediately after TightSculpting® (1 Tx). Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 26: Abdomen: before and after TightSculpting®. Courtesy of Dr. Liliana Fernandez, Colombia.

Fig. 27: Thighs: before and after TightSculpting®. Courtesy of Dr. Pham Huu Nghi, MD.PhD, Vietnam.

Fig. 28: Flanks: before and immediately after TightSculpting® (1 Tx). Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 29: Abdomen: before and after TightSculpting®. Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 30: Abdomen: before and 6 weeks after TightSculpting® (1 Tx). Courtesy of Dr. Tamara Meissnitzer.

Fig. 31: Abdomen: before and after TightSculpting® (4 Tx). Courtesy of Dr. Layos Kemeny, Hungary.
V. CONCLUSIONS

Combined Er:YAG and Nd:YAG laser treatment for body contouring has proven to be a comfortable, safe and effective treatment for trans-dermal skin tightening and reduction of adipose tissue. In combination with a healthy lifestyle, this technology, which has been developed into the TightSculpting® body sculpting procedure, represents a very promising non-invasive alternative to laser lipolysis.

Although laser lipolysis has been described as a “lunchtime treatment”, it is nevertheless classified as a surgical procedure associated with certain risks due to surgical incisions and the use of anesthetics, as well as with subsequently reduced skin firmness and lack of skin ability to conform to the reduced body size. The TightSculpting® procedure represents a safe and effective alternative that addresses both excess body fat as well as the surface appearance of the skin on the selected body areas. The procedure can be used also for temporary reduction in the appearance of cellulite.

NOTES

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The Fotona Dynamis laser and the indications described in this paper are cleared for sale and use in the EU. For countries where specific national approvals or clearances are required, some of the indications described in this paper may not have been cleared yet. For example, in the United States the Fotona PIANO® and Fotona SMOOTH® modalities of the Fotona Dynamis laser system have been cleared by the FDA for laser-assisted lipolysis and treatment of wrinkles, and for non-ablative skin resurfacing, correspondingly. In view of these clearances, the term “sculpting” should be understood to mean the treatment of wrinkles, and the term “tightening” should be understood to mean the non-ablative resurfacing. For other countries, please check with Fotona or the applicable local national regulatory body to find out whether the Fotona Dynamis and its described indications are available for promotion and sale in your country.

REFERENCES

23. FotonaSmooth®, TightSculpting® and PIANO® are registered trademarks of Fotona d.o.o.


