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TightSculpting®: A Complete Minimally Invasive Body Contouring Solution; Part I: Sculpting with PIANO® technology

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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 first part of a two-article series on TightSculpting®, we describe the principles of the PIANO® laser modality, and provide treatment parameters and guidelines for the fat reduction component of the TightSculpting® body contouring solution.

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

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I. INTRODUCTION

An ideal body has been a long held wish of many people of all ages across the world [1]. Over the past few decades, multiple body contouring treatment modalities have been developed in an attempt to alter the shape of the human body. These modalities include procedures that eliminate or reduce excess skin (i.e., tightening) [2-4], and procedures that reduce excess fat (i.e., sculpting) [5-7].

In the past, body contouring would almost invariably mean a visit to a plastic surgeon. One very effective solution for less invasive body contouring involves laser-assisted lipolysis [6, 8]. However, nowadays, new non-invasive body contouring technologies have been introduced which offer a more favorable alternative to surgery, both in terms of morbidity and financial cost. Most recently, transcutaneous delivery of laser energy to the adipose tissue has attracted significant attention since it offers an even less invasive alternative than traditional laser lipolysis [9-14]. This hyper-thermic laser lipolysis (HTLL) procedure consists of heating the subcutaneous adipose tissue by externally irradiating the skin with a deeply penetrating 1.06 μm laser light. The goal is to heat the adipocytes to hyper-thermic temperatures in the range of 42 – 47 °C for a prolonged time, which has been found to lead to programmed adipocyte cell death [11-13]. Clinical results demonstrated average fat thickness reductions of 14%, 18%, and 18% at 2, 3, and 6 months, respectively. Average fat volume reductions measured by MRI at 3 and 6 months were 24% and 21%, respectively [13].

It should be noted that effects of the HTLL procedure on the body contour are not visible immediately. The programed adipocyte death starts approximately 2 weeks after the treatment, with the evacuation of cellular debris being fully complete after approximately 6 months. Additionally, the reduction of fat can cause loosening of the skin, similarly to what happens following a significant weight loss. For these reasons, it is desirable that a sculpting treatment is combined with a skin tightening treatment, so that results of the treatment also become visible in a shorter time.

Recently, a TightSculpting® aesthetic solution has been introduced [15], which fulfills the above requirements by combining two different laser wavelength treatments to achieve deep fat reduction together with more superficial skin tightening, with both effects achieved during a single procedure and with a single device (See Fig. 1) [15-19].

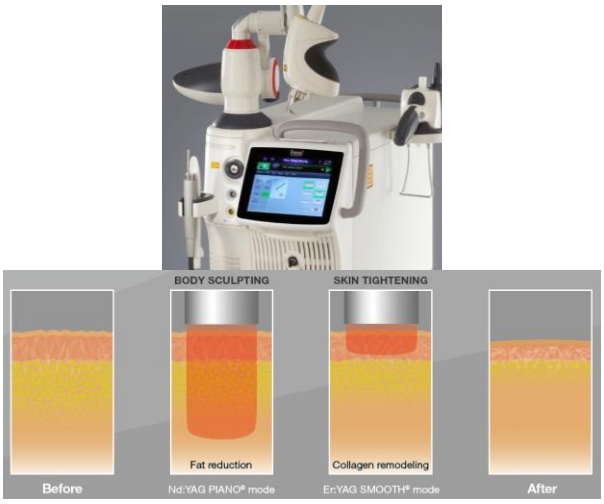

Fig. 1: TightSculpting® is a dual-wavelength, minimally invasive body contouring laser treatment concept available with the Dynamis Nd:YAG/Er:YAG aesthetic laser system (top image) for Nd:YAG laser PIANO® sculpting and Er:YAG laser FotonaSmooth® skin tightening on all body areas (bottom image).

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 either <u>individually</u> [2-5, 20, 21] or <u>in concert</u> [15-19] as a combined dual-wavelength procedure.

The TightSculpting® solution involves the deeply penetrating Nd:YAG laser (λ = 1.06 μm) operating in the PIANO® mode for thermic adipocyte destruction (i.e., "sculpting") and the superficially absorbed Er:YAG laser (λ = 2.94 μm) operating in the FotonaSmooth® mode for collagen remodeling and tightening for improved body contouring results (See Figs. 2 and 3).

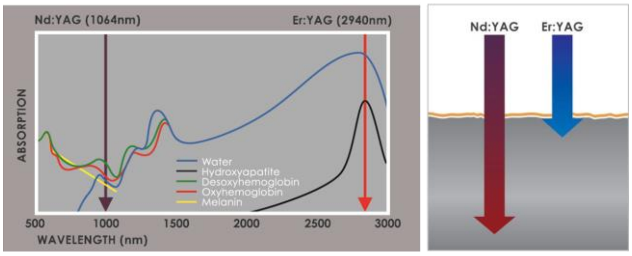

Fig. 2: Left: absorption coefficient in human skin as a function of laser wavelength. Right: TightSculpting® combines the effects of two uniquely positioned laser wavelengths: the most homogeneously penetrating Nd:YAG laser wavelength (1.06 μm), and the most superficially absorbed Er:YAG laser wavelength (2.94 μm).

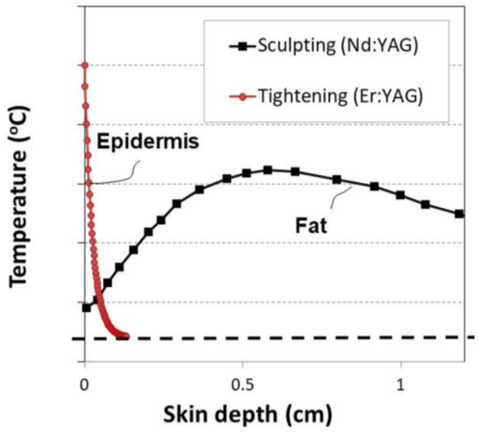

Fig. 3: The dual-wavelength TightSculpting® procedure combines PIANO® Nd:YAG laser technology for heating of deeper lying skin layers, and FotonaSmooth® Er:YAG laser technology for non-ablative superficial heating of the epidermis. The optical penetration depth of the Er:YAG laser in human tissue is extremely short ($\delta_{Er} \approx 1$ μm), while the penetration of the Nd:YAG laser is extremely long ($\delta_{Nd} \approx 1$ cm).

In a two-paper series titled "TightSculpting®: A Complete Minimally Invasive Body Contouring Solution" [22, 23], we describe the science and protocols behind the combined dual-wavelength TightSculpting® treatment concept. In this first part of the series ("Part I: Sculpting with PIANO® Technology"), we focus on the PIANO® laser modality, and provide treatment parameters and guidelines for the fat reduction component of the TightSculpting® body contouring solution.

II. MATERIALS AND METHODS

The PIANO® Nd:YAG laser pulse modality was developed specifically for deep photo-thermolysis treatments [7]. This modality extends the conventional range of Nd:YAG pulse durations to the seconds regime (0.3 - 60 s) and reduces treatment pulse powers to levels which are minimally invasive to the epidermis (See Fig. 4).

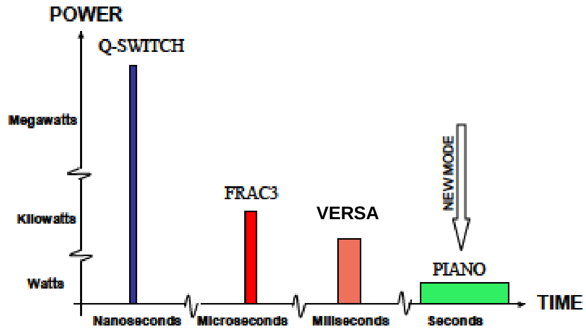

Fig. 4: The "super long pulse" PIANO® mode enables pulse durations in the seconds regime, and delivers high energies with less intensive pulse powers of several Watts [7].

The duration of the PIANO® mode is much longer than the thermal relaxation time of the epidermis. This feature makes this mode safe for reaching deeper-lying skin tissues, with minimal thermal effect on the epidermis. The PIANO® mode pulse durations are also longer than the relaxation times of any other skin structures, such as hair follicles or blood vessels. The PIANO® modality is thus indicated for overall homogeneous, bulk heating of the deeper skin layers (dermis and subcutis), justifying its name (piano: symbolizing soft or smooth).

The PIANO® mode was developed for the Dynamis laser system (manufactured by Fotona d.o.o.) and can be delivered to the patient with either the manual R33 and R34 handpieces, or with the scanning L-Runner handpiece (with L standing for "lipo"), all of which are equipped with the MatrixView skin temperature detection system and a forced cold air nozzle (see Fig. 5).

Fig. 5: The L- Runner: an advanced Nd:YAG laser scanner with MatrixView camera sensor for on-line skin temperature measurement.

Due to the special design of the L-Runner scanning pattern and of the scanner's cooling air nozzle, a homogeneous irradiation and cooling of large skin areas up to 7.6 x 8.4 cm² can be achieved (See Fig. 6).

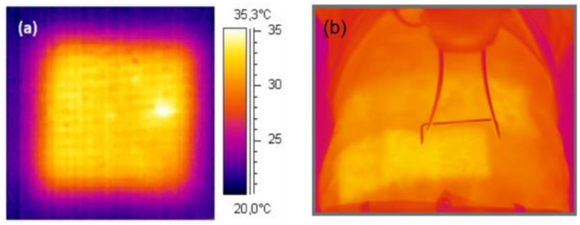

Fig. 6: Thermal camera image of an irradiated skin area.

When a manual (R33 or R34) handpiece is used, the handpiece needs to be moved in a continuous manner as shown in Fig. 7, in order that an approximately homogeneous heating of larger skin areas is achieved.

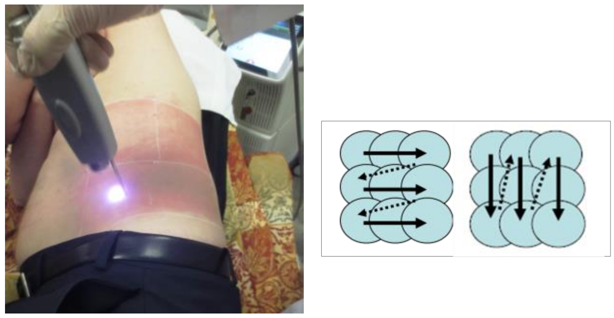

Fig. 7: Manual scanning technique for the R33 or R34 Nd:YAG handpiece.

The MatrixView consists of a special built-in miniature advanced thermal camera, which measures the skin surface temperature within the scanned area and detects the highest skin surface temperature (T_s) achieved anywhere within the laser irradiated area. This skin temperature is continuously displayed on the Dynamis laser system interface. Additionally, the operator can set the treatment minimal (T_{min}) and treatment maximal (T_{max}) temperatures on the Dynamis display, and the MatrixView's indicator light automatically informs the operator of the skin's temperature by changing the color of the temperature indicator from green to yellow whenever the skin surface temperature exceeds the minimal treatment temperature ($T_s \geq T_{min}$), and from yellow to red whenever the skin surface temperature exceeds the maximal treatment temperature ($T_s \geq T_{max}$) (See Fig. 8). This enables the operator to conveniently monitor the skin temperature and to keep the skin surface temperature during a treatment within the selected temperature range of T_{min} - T_{max}.

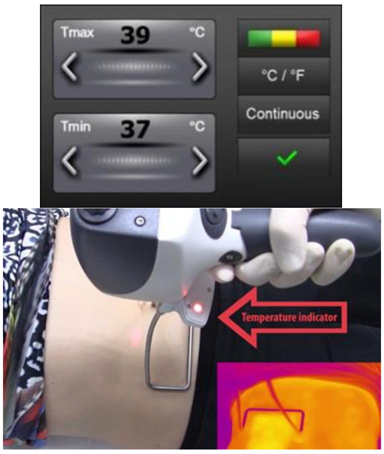

Fig. 8: MatrixView allows the operator to select a low level (T_{min}) and a high level (T_{max}) temperature on the Dynamis laser system interface (above); MatrixView informs the operator of the treated skin temperature by changing the color of the temperature indicator from green to yellow, or from yellow to red whenever the low or the high level temperature threshold is exceeded.

The programmed adipocyte cell death at elevated temperatures is quantified with an Arrhenius kinetic model based on the first-order rate process. The commonly used metric for tissue damage, or in our case the apoptosis efficacy (Ω), is 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 τ (C_τ). The Arrhenius equation parameters A and E_0 depend on the tissue type and the relevant biochemical process. For apoptosis, the Arrhenius parameters were reported by Franco *et al.* [11], to be $A = 1.15 \cdot 10^{28}$ s^{-1} and $E_0 = 187.54$ kJ/mol.

Recently, two multi-institutional studies have been carried out [9, 14] that combined skin surface temperature measurements during procedures with physical model calculations of hyper-thermic laser lipolysis (HTLL) using the L-Runner scanner operating in PIANO® mode. The results of these studies are used in the present analysis with a goal to provide treatment guidelines for the PIANO® sculpting treatment.

III. RESULTS

a) Influence of skin surface cooling

An in-vivo examination of adipocyte viability showed that the adipocyte cell viability decreased significantly at 43-45 ^{o}C after 15-minute exposures [11]. Similarly, it has been shown that significant adipocyte damage can be created with a 25-minute exposure to temperatures in the range of 42–47 ^{o}C [13].

It is important to note that in order to obtain the above elevated temperatures within subcutis in the range of 42 – 47 ^{0}C without patient discomfort or damage to the epidermis, the skin surface needs to be cooled. Without cooling, the temperature maximum is located at the skin surface, thereby limiting the attainable temperature elevations deeper within the tissue, which are in the absence of cooling always lower than at the surface. On the other hand, with effective cooling of the skin surface, the temperature maximum can be moved away from epidermis and deeper into subcutis. This is demonstrated in Fig. 9, which shows measured temperature depth distributions with and without skin surface cooling during a PIANO® mode Nd:YAG laser irradiation [9].

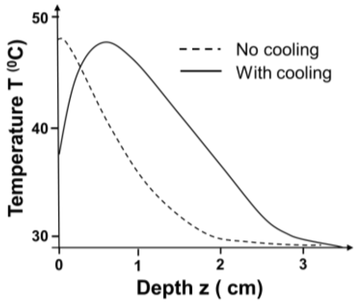

Fig. 9: Temperature depth distribution within a porcine fatty tissue sample following PIANO® Nd:YAG laser irradiation showing i) without cooling of the surface (dashed line), and ii) with forced cold air cooling of the sample surface [3, 11]. When cooling is applied, the temperature maximum shifts to deeper within the tissue.

As can be seen from Fig. 9, without surface cooling, the subcutis temperature is too low for apoptosis, in spite of the epidermal temperature being elevated to an uncomfortable level. With surface cooling, the epidermal temperature is kept below 40 ^{0}C while the subcutis temperatures are at levels required for apoptosis.

<u>b) Single area PIANO® sculpting protocol</u>

During a PIANO® sculpting procedure, the irradiation is delivered to the skin surface until the adipocyte cells deeper within the tissue are heated to temperatures in the range of 42-47 ^{0}C, after which the irradiation is stopped in order to prevent over-heating. Since apoptosis requires the adipocyte cells to be exposed to elevated temperatures for a prolonged time of about 20 minutes, irradiation is re-started when the temperature of the adipocyte cells drops below 42 ^{0}C. This cycle is repeated multiple times until adequate damage to the adipocyte cells is made.

Since during clinical procedures it is not possible to non-invasively and directly measure temperatures within subcutis, an innovative approach is used whereby these temperatures are determined from the skin surface temperatures (T_s) that can be measured during a procedure. In this order, a physical model was developed [9, 14] that has been used in this study to develop clinical protocols to enable practitioners to control temperatures within subcutis by monitoring the measured skin surface temperature evolution.

We first consider that a single L-Runner scan area (up to 10x10 cm²) is to be treated (Fig. 10).

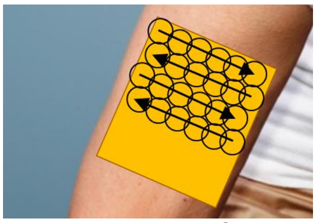

Fig. 10: Single scan area for PIANO® sculpting treatment.

Based on the published physical model, the following single area PIANO® sculpting protocol is recommended for Caucasian patients (melanin volume fraction mvf = 1%):

i) Set the MatrixView threshold temperatures (see Fig. 8) to T_{max} = 38⁰C and T_{min} = 29⁰C. Note that with these settings the MatrixView starting indicator's color will be yellow, indicating that the starting skin surface temperature of about 35⁰C is in the range between T_{max} and T_{min}.

ii) Set the Nd:YAG laser PIANO® power density (G) to G = 1.2 W/cm².

iii) Set the external forced cold air cooling power to h_T = 50 W/m² K (corresponding to Level 1 when using Zimmer Cryo 6), and keep it on during the whole duration of the treatment.

iv) Press the laser footswitch and start to irradiate the scanned skin area until the skin temperature reaches T_{max} and the MatrixView indicator starts blinking red.

v) Stop laser irradiation (release the footswitch) and continue to cool the skin area until the skin temperature drops to below T_{min}, and the MatrixView indicator turns to green.

vi) Press the laser footswitch and start irradiating the skin again.

vii) Repeat the above heating and cooling cycle for N = 5-7 cycles (see Fig. 11).

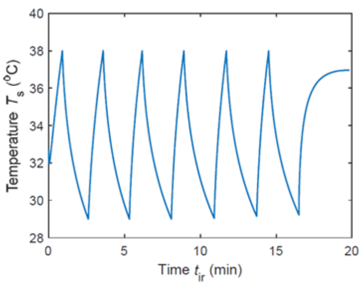

Fig. 11: Cyclic heating and cooling of the skin surface temperature (T_s) during N = 6 cycles of single area PIANO® sculpting. During the treatment cycles the skin surface temperature oscillates between T_{max} = 38 ⁰C and T_{min} = 29 ⁰C.

Figure 12a shows the temperature depth profiles during each cycle immediately after the PIANO® irradiation is stopped (red indicator light is on) and when the PIANO® irradiation is started again (green indicator light is on). The calculated level of damage to adipocytes cells (Ω) following each cycle is shown in Fig. 12b.

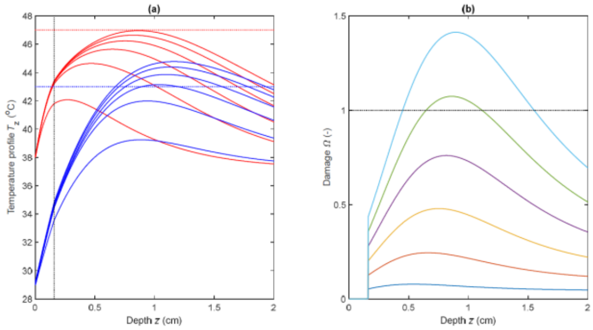

Fig. 12: (a) Temperature depth profiles during N = 1 - 6 cycles immediately after PIANO® irradiation is stopped (red lines) and when PIANO® irradiation is started again (blue lines). (b) The resulting consecutive apoptosis efficacy Ω following each cycle. The depth region between $z \approx 0.5$ and z ≈ 1.7 cm is the region where $\Omega \geq 1$, and therefore where the most effective apoptosis (fat reduction) is expected.

c) Cyclical PIANO® sculpting protocol

Note that during the above single area treatment protocol, the laser is operating only for about 50% of the time. Therefore, the treatment duration is longer than potentially necessary, particularly when treating large body areas. In order to achieve a better utilization of the laser device's output, and a faster treatment of larger body areas, a multiple area "cyclical" PIANO® procedure was developed. During cyclical PIANO® sculpting, a larger skin area to be treated is divided into several (preferably four) equal neighboring skin surface segments, with the size of the segments corresponding to the L-Runner's scanning area (See Fig. 13).

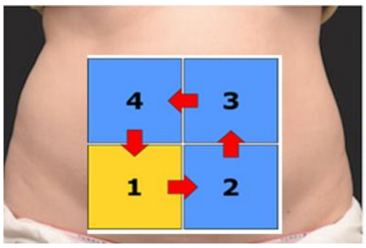

Fig. 13: Cyclical PIANO® irradiation protocol. Four adjacent scan area skin segments are sequentially heated for N consecutive cycles.

The recommended cyclical PIANO® procedure consists of the following steps:

i) Set the MatrixView's higher-level temperature T_{max} (see Fig. 8) to the temperature value as recommended in Table 1, depending on the patient's skin type and cold air cooling power. For convenience, set T_{min} to $T_{min} = T_{max} - 1\ ^0$C.

ii) Set the Nd:YAG laser's PIANO® power density (G) to G = 1.2 W/cm² and keep this setting with the footswitch pressed for the whole duration of the treatment.

iii) Set the external forced cold air cooling power to the recommended cooling power h_T (see Table 1), and keep the cooling with this setting on during the whole duration of the treatment.

iv) Start irradiating a first segment (for example, segment 1 in Fig. 13). As the temperature approaches T_{max} the MatrixView indicator light will first turn yellow, which will indicate that the temperature is only one degree below T_{max}.

v) When the MatrixView indicator light starts blinking red, move the irradiation scan area over to the next segment (segment 2).

vi) Repeat the same procedure as for segment 1 on the remaining three segments. Once all four segments have been irradiated in this manner, position the scan area back above the first segment of the cycle, and repeat the irradiation cycle for all four segments. Repeat performing irradiation cycles for the recommended number of cycles, *N* (see Table 1).

In our analysis, the PIANO® sculpting treatment efficacy was studied for different skin types. Temperature evolutions and the resulting expected apoptosis parameter Ω were calculated for a wide range of combinations of T_{max}, h_T, and *N*. The laser power density was fixed to G = 1.2 W/cm². Protocols recommended for specific skin types were selected from the simulated outcomes of the protocol parameter combinations, taking into account the following criteria: i) the skin surface temperature should never exceed the pain threshold temperature of 43 ^{0}C [24, 25]; ii) the maximal subcutis temperature should never exceed 47 ^{0}C; iii) Ω should exceed the adipocytes apoptosis threshold of Ω = 1; and iv) the duration of the PIANO® treatment of each segment (t_{ir}) is shorter than 25 minutes.

The obtained recommended cyclical PIANO® sculpting protocols are shown in Table 1 for skin types with the following epidermal *mvf* (melanine volume fraction) values: *mvf* = 1% (pale Caucasian skin), *mvf* = 2% (tanned Caucasian skin), *mvf* = 5% (Asian skin) and *mvf* = 10% (African skin).

Table 1: Recommended cyclical PIANO® sculpting protocols for skin types with mvf = 1, 2, 5 and 10%. The cooling powers are provided with corresponding approximate cooling levels for Cryo6 (manufactured by Zimmer GmbH).

	Cooling power h_T (W/m²K)	Threshold temperature T_s (°C)	No. cycles *N*	Duration of treatment t_{ir} (min)	Depth of apoptosis (cm)
PALE CAUCASIAN (*mvf* = 1%)	60 (Level 2)	37.5	5	19	0.3-1.9
	70 (Level 3)	36	5	22	0.3-2.1
	100 (Level 5)	32	4	21	0.5-2.2
TANNED CAUCASIAN (*mvf* = 2%)	60 (Level 2)	38	5	19	0.3-1.9
	70 (Level 3)	36 .5	5	22	0.3-2.1
	100 (Level 5)	33	4	21	0.5-2.2
ASIAN (*mvf* = 5%)	100 (Level 5)	34	4	21	0.4-2.2
	130 (Level 9)	31	4	24	0.5 - 2.5
AFRICAN (*mvf* = 10%)	130 (Level 9)	33	4	25	0.5-2.5

For illustration, Figure 14a shows tissue depth temperature profiles, averaged over each consecutive PIANO® cycle, with Fig. 14 b depicting the resulting depth profiles of the injury to adipocytes following each consecutive PIANO® cycle. The data is for the Asian skin type (*mvf* = 5%) with h_T = 100 W/m²K (Zimmer 5) and T_{max} = 34 ^{0}C, as recommended in Table 1.

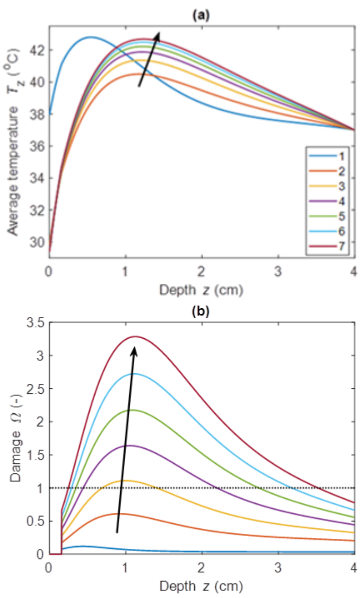

Fig. 14: (a) Temperature depth profiles averaged over each consecutive PIANO® cycle (*N* = 1-7), and (b) corresponding apoptosis depth profiles following each PIANO® cycle. The skin was an Asian-skinned patient with melanin volume fraction *mvf* = 5%. The treatment parameters are taken from Table 1 for this skin type: laser power density *G* = 1.2 W/cm², forced-air cooling level h_T = 100 W/m²K. The horizontal dotted line in (b) represents Ω = 1, the adipocytes damage threshold. The arrows show the direction of the change following each cycle.

When in doubt about whether the skin type is appropriately diagnosed, or about the cooling power of the external cold air cooler, the following simple test can be made. Monitor the duration of the first heating phase for the first segment (i.e., the time required for the first segment to reach T_{max} during the first cycle). This duration should be in the range of 60-70 s. If the heating phase is significantly shorter, then either the skin type is darker than estimated or the cooling power is too low. Try increasing T_{max} or the cooling power. And, if the heating phase is significantly longer, then either the skin type is lighter than estimated or the cooling power is too high. Try decreasing T_{max} or the cooling power. Observe also the patient's comfort during the first cycle. If the patient reports significant discomfort, reduce T_{max}. Similarly, increase T_{max} if the patient can handle a higher temperature.

IV. DISCUSSION

In what follows we provide examples of clinical results following the TightSculpting® procedure. As can be seen from examples, the TightSculpting® procedure can be performed on almost all body areas (See Fig. 15).

Fig. 15: Most common areas treated with TightSculpting® are: flanks, back fat, upper abdomen, lower abdomen, thighs (outer, inner, front, back), love handles, muffin top and upper arm.

Fig. 16: Thighs: before and after TightSculpting® (3 Tx). Courtesy of Dr. Pham Huu Nghi, MD.PhD, Vietnam.

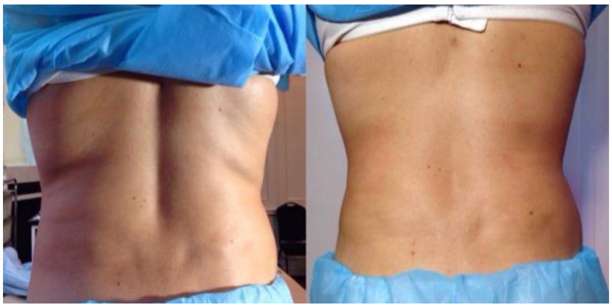

Fig. 17: Flanks: before and after TightSculpting® (1 Tx). Courtesy of Dr. Adrian Gaspar, Argentina.

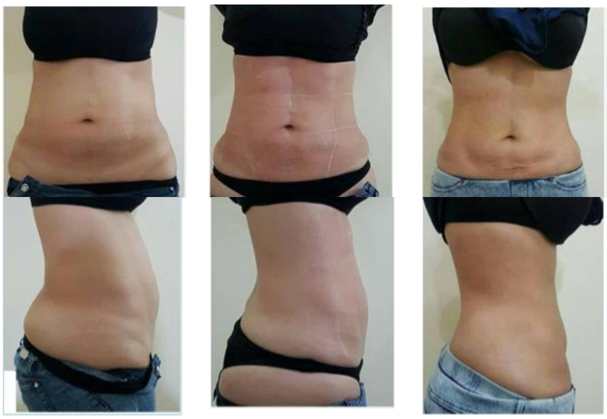

Fig. 18: Abdomen: before, immediately after and after TightSculpting®. Courtesy of Dr. Liliana Fernandez, Colombia.

Fig. 19: Thighs: Before and after TightSculpting®. Courtesy of Dr. Adrian Gaspar, Argentina.

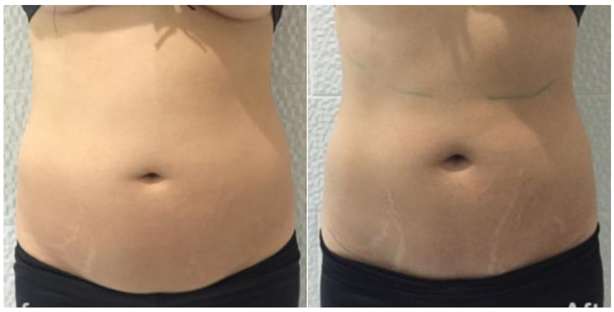

Fig. 20: Abdomen: before and after TightSculpting®. Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 21: Abdomen: before and after TightSculpting®. Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 22: Arms: before and after TightSculpting®. Courtesy of Dr. Mark Taylor, USA.

Fig. 23: Abdomen: before and after TightSculpting®. Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 24: Before and after TightSculpting®. The procedure was performed in conjunction with PRP. Courtesy of Michelle Watson-Strickland, USA.

Fig. 25: Flanks: before and immediately after TightSculpting® (2 Tx). Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 26: Flanks: before and immediately after TightSculpting® (2 Tx). Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 27: Abdomen and thighs: before and after TightSculpting®. Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 28: Buttocks and thighs: before and after TightSculpting®. Courtesy of Dr. Adrian Gaspar, Argentina.

Fig. 29: Thighs: before and after TightSculpting® (8 Tx). Courtesy of Dr. Adrian Gaspar, Argentina.

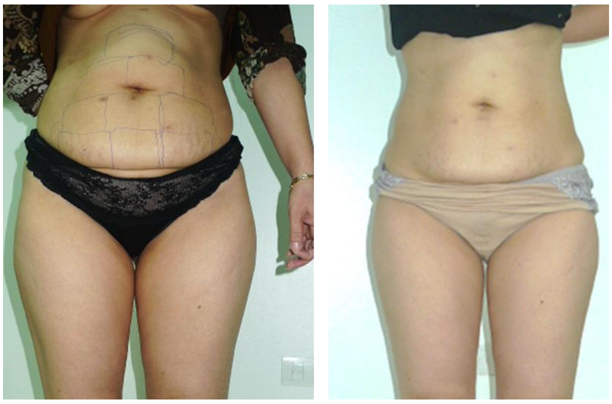

Fig. 30: Abdomen: before and after TightSculpting® (6 Tx). Courtesy of Dr. Pham Huu Nghi, MD.PhD, Vietnam.

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

V. CONCLUSIONS

FotonaSmooth® and PIANO® represent a complete TightSculpting® body contouring solution, which can be, depending on the type of patient and the goal of the treatment, used either individually or in concert as a combined dual-wavelength procedure.

During the combined Er:YAG and Nd:YAG laser TightSculpting® treatment, superficial tightening is combined with deep heating of the skin using thermal pulses. For the purpose of deep bulk heating of the skin, 1064 nm Nd:YAG is used in a super-long PIANO® pulse modality. This seconds-long pulse regime enables sufficient time for the epidermis to share the absorbed heat with the dermis through heat diffusion, thus sparing the epidermis from potential injury. During the treatment, the generated heat is transmitted through the skin, increasing local vascularization and accelerating organic chemical reactions, including fat metabolism, as well as causing the tightening of deep connective structures (reticular dermis, retinaculum cutis, fasciae).

The 2940 nm Er:YAG laser in the non-ablative FotonaSmooth® regime acts to deliver energy onto the skin to produce controlled surface-tissue heating without ablation, as well as subsequent collagen remodeling, with the purpose of improving skin thickness, elasticity and firmness. Superficial tightening using FotonaSmooth® Er:YAG thermal pulses works to improve flaccidity and the surface appearance of the area.

In conclusion, the TightSculpting® body sculpting procedure represents a comfortable, safe and effective non-invasive alternative to surgical liposuction. 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.

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