White Paper

The Significance of Shallow Thermal Effects from a 1064nm/1320nm Laser on Collagenous Fibrous Septae and Reticular Dermis: Implications for Remodeling and Tissue Tightening through Coagulation

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Introduction

Currently, internal laser-assisted lipolysis (iLAL)[1-7] represents an evolving innovative technique that enhances the results over standard liposuction by providing selective thermo-lipolysis and thermo-denaturation of structural proteins in collagen-containing fibrous septae and reticular dermis. Of the two effects, the singular advantage of iLAL resides its ability to deliver sufficient and controlled thermal energy in a dose-response manner for collagen denaturation (water), collagenesis, remodeling and promotion of tissue tightening through coagulation[8-10]. To date there have been no objective studies that quantify the relationship of lower dermal temperatures to surface skin temperatures that results in measurable shrinkage of tissue areas. This limited clinical study attempts to correlate changes in abdominal skin contraction achieved as a consequence of laser heating from a 1064nm/1320nm device during each phase of the procedure to delineate what contribution, if any, each heated layer provides to skin contraction. The objective observations were correlated to histological findings.

Smartlipo MPX™ System

The Smartlipo MPX™ laser workstation (Cynosure, Inc., Westford, MA, USA) emits 1064nm and 1320nm Nd:YAG wavelengths from a 600µm fiber, protruding 2mm from the tip of a microcannula. In this study, the emission of these two wavelengths was blended either in Multiplex™ Blend 3 (20watts 1064nm:10watts 1320nm) for deeper bulk lipolysis 10-30mm below the dermis or in Multiplex™ Blend 1 (10watts 1064nm: 10watts 1320nm) for shallow heating of collagen fibers (water) within the lower reticular dermis and septae. The 1064nm wavelength possesses a 3-5 times greater absorption profile for methemoglobin than for hemoglobin (higher probability of vessel coagulation), has less affinity to water, but exhibits a relatively greater depth of penetration and more diffuse distribution of energy than the 1320nm wavelength. In contrast, the 1320nm wavelength results in a higher absorption profile in fat and collagen (water) with significantly more localized and concentrated heating than that observed by the 1064 nm wavelength. When these two wavelengths are blended, an augmentation of both profiles was observed than that measured from each alone.

To better control and distribute thermal injury within the deeper fatty tissue and shallower subdermal layer, the Smartlipo MPX™ for this study incorporated three sensing devices:

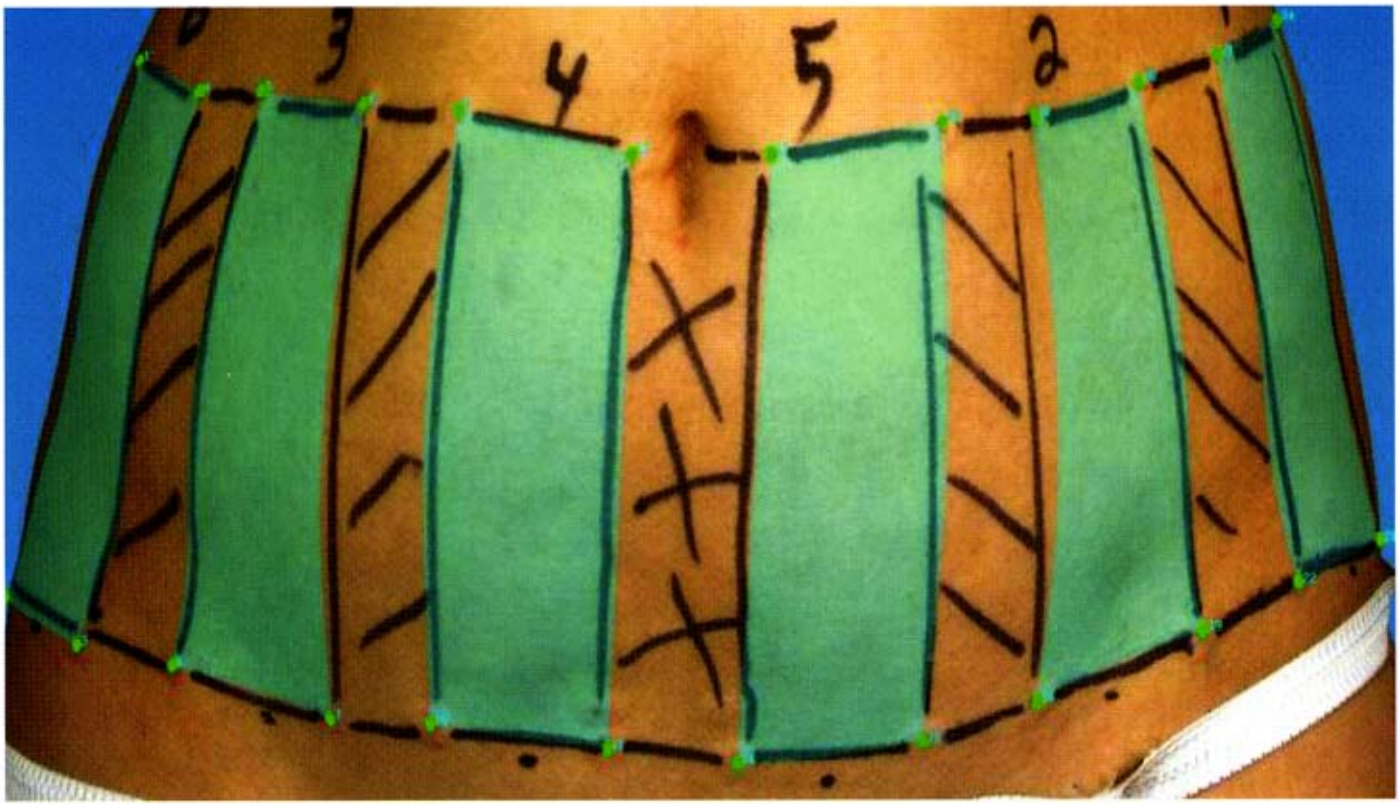

Figure 1. Six Target Fields Randomized amongst Three Subjects for Vectra 3D Analyses of Tattooed Landmarks.

1. An accelerometer delivery system (SmartSense™) was inserted into the handpiece as a motion sensing device to prevent excessive thermal deposition by regulating energy deliverance based on a feedback microchip technology. When the handpiece was motionless, the laser system discontinued within 0.2 seconds to avoid focal overheating.

2. A thermal sensing cannula (ThermaGuide™) continually recorded subdermal temperature fluctuations about 1 cm from its tip. Within the deep tissue (10-30mm), the ThermaGuide™ was at set at a 55°C threshold level. When temperatures exceeded 60°C, the laser stopped and resumed when the tissue temperature decreased below 55°C or when the ThermaGuide™ found cooler tissue.

   When the sensing cannula was used in the shallow subdermal tissue (5mm below the dermis), the ThermaGuide™ was preset to record temperatures below 45°C. The achievement of 45°C at the shallow subdermal level registered a surface skin temperature between 40-42°C.

3. An infrared thermal camera (ThermaView) monitored real-time skin surface temperatures to attain levels between 40-42°C and ensure uniformity of heat distribution by orange-red coloration within the treatment site.

Study Design

A randomized, controlled study measured skin tightening (contraction) in 3 nulliparous volunteers with localized lower abdominal adiposity and minimal-moderate skin laxity. Standardized digital photography, weight, body fat analysis (Futrex 5500, Futrex Inc., Hagerstown, MD) waist and hip circumferences were obtained at baseline, 3 months and 6 months after treatments. Skin contraction was assessed by using the Vectra 3D System (Canfield Scientific, Fairfield, NJ). The lower abdomen was marked into six target zones of 4x10cm rectangles each separated by 2x10cm partitions. The corners of each treated zone were tattooed with India ink. Software analysis identified the permanent markers around each targeted site and calculated the changes in horizontal, vertical, diagonal and perimeter baseline measurements compared to findings at 3 and 6 months (Figure 1). At the completion of the study, total abdominal liposuction was performed to achieve an aesthetic result in each patient. Informed consents were obtained with IRB and HIPPA-approved protocols.

Surgical Procedure

Patients were offered preoperative pain medication and received oral antibiotics. Team members and the subject were protected by special eyeglasses. A 2mm incision below each zone permitted access for treatment. Each of the six 4x10cm target zones was treated randomly by one of the following assignments (Table 1).

Regardless of assigned treatment, deep and shallow subdermal temperatures, as well as surface skin temperatures, were recorded simultaneously in each panel by the ThermaGuide™ and the ThermaView camera. Immediately after treatment one of 1mm punch biopsy was obtained 5mm below the skin of each treated rectangle. After the surgical procedure was completed, each incision was approximated with a single suture. Subjects were dressed with sponge inserts and a compression garment for at least 2-3 weeks. Postoperative antibiotic and pain medications were prescribed.

Zone	Treatment
1	100ml tumescent solution (500mg plain Lidocaine, 1mg epinephrine, 20ml of 8.4% sodium bicarbonate in 1000ml normal saline).
2	100ml tumescent solution + 500 passages of laser 1mm cannula at deep (1-2cm below dermis) and shallow (1-5mm below dermis) fat levels.
3	100ml tumescent solution + PAL*, 500 strokes in fan-shape pattern from deep to shallow fat levels, 4.0mm helixed triport 3 cannula, negative pressure below 500mm Hg, aspiration volume = 50ml.
4	100ml tumescent solution + Smartlipo MPX™ Blend 3 (20W 1064nm:10W 1320nm), 2000 Joules 1-2cm below dermis + PAL*, 500 strokes in fan-shape pattern from deep to shallow fat layers, 4.0mm helixed triport 3 cannula, aspiration volume = 50ml.
5	100ml tumescent solution + Smartlipo MPX™ Blend 1 (8W 1064nm: 8W 1320nm), 2500 Joules at 1-5mm below dermis, skin temperature 40-42°C+ PAL*, 500 strokes in fan-shape pattern from deep to shallow fat layers, 4.0mm helixed triport 3 cannula, aspiration volume = 50ml.
6	100ml tumescent solution + Smartlipo MPX™ Blend 3 (20W 1064nm:10W 1320nm), 2000 joules, 1-2cm below dermis + PAL*, 500 strokes in fan-shape pattern from deep to shallow fat layers, 4.0mm helixed triport 3 cannula, aspiration volume = 50ml + Smartlipo MPX™ Blend 1 (8W 1064nm:8W 1320nm), 2500J at 1-5mm below dermis, skin temperatures between 39-40°C.

Table I. Assigned Treatment per Target Zone
*MicroAire Surgical Instruments, Inc. Charlottesville, VA, USA

Patient	Zone 1 Tumsc.	Zone 2 Tumsc. + Cannulation	Zone 3 Tumsc + PAL	Zone 4 Tumsc + Smartlipo MPX Blend 3 + PAL	Zone 5 Tumsc + Smartlipo MPX Blend 1 + PAL	Zone 6 Tumsc. + Smartlipo MPX Blend 3 + PAL + Blend 1
1	T_D 31°C	30.5°C	31°C	53 °C	47 °C	54 °C
	T_S 27° C	27°C	28 °C	32 °C	42 °C	40 °C
2	T_D 32°C	31.5°C	30 °C	55 °C	46 °C	54 °C
	T_S 27° C	27°C	28 °C	33 °C	41 °C	39 °C
3	T_D 29°C	29.5°C	29 °C	53 °C	45 °C	53 °C
	T_S 26° C	26.5°C	27 °C	30 °C	40 °C	39 °C

Table 2 Deep and Surface Skin Temperatures During Phases of Treatment
T_D= Deep Temperature T_S= Shallow Temperature

RESULTS

Subdermal and Surface Skin Temperatures (Table 2)

The average oral temperature for the three subjects before surgery was recorded at 36.3°C (range 36.5-37°C). In Zones 1-3, the deep subdermal temperatures, determined by the ThermaGuide, at 10-20mm in the tumesced subcutaneous fatty tissue ranged between 30.5-31°C after their assigned treatments, and remained slightly higher than simultaneous surface skin temperature recordings between 27-28°C by the ThermaView and MiniTemp® handheld scanner. Zones 1-3 were not exposed to thermal energy. In contrast, Blend 3 treatments in Zone 4 successfully elevated temperatures in the deep fatty layers between 53-55°C, which increased skin surface temperatures minimally to 30-32°C. However, when the immediate subdermal tissue (1-5mm) is thermally challenged during Blend 1 treatments to temperatures between 45-47°C, as assigned to Zone 5, the surface skin temperatures rose to levels between 40-42°C. After by-layer treatments with Blend 3 and Blend 1, as recorded in Zone 6, the corresponding surface temperature recordings were slightly lower (39-40°C) than those observed in Zone 5, receiving only Blend 1 treatments.

Vectra 3D Analysis for Skin Contraction

Table 3 summarizes the results of surface area changes within the six isolated rectangles as determined by 3-Dimensional Analysis using the Vectra 3D system over 3 months. Each targeted zone received a component of the standard treatment protocol for Smartlipo MPX™. A positive change in percentage of surface area within a tattooed treated rectangle reflected percent contraction of the target site over its baseline value. In contrast, a negative percent value in the surface area indicated a larger area after treatment compared to its baseline measurement. Outcomes were tested for significance with a paired t test, using $p<0.05$ as the cutoff value.

Average 3 -Dimensional Abdomnial Surface Area Shrinkage in Three Patients by Canfield Vector 3D Analyses at Three Months

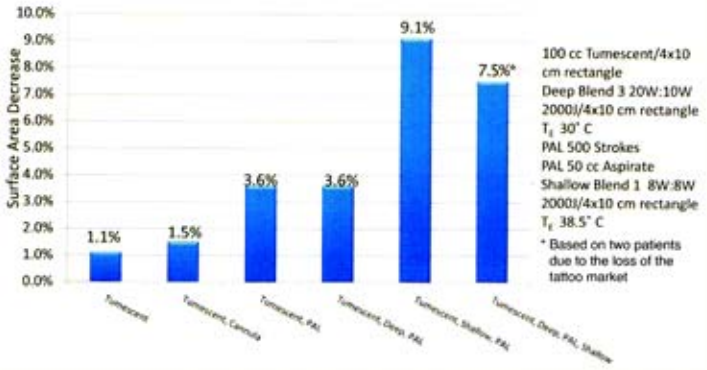

Table 3. Contraction in Tattoo Surface Areas(%)

At the 3 month evaluation period, fifteen of eighteen targeted zones demonstrated either no change or a reduction in surface areas. Although these values ranged from 0% up to 13%, the maximum amount of contraction occurred predominantly within Zone 5 with an average of 9.1% from shallow thermal subdermal injury producing skin surface temperatures between 40-42°C after Blend 1 treatments($p<0.05$). Zone 6, which received both deep (Blend 3) and shallow (Blend 1) heating, resulted in the second highest amount of average area contraction (7.5%). Since no dermal heating occurred from treatments such as tumescent solution, cannulation, pulse-assisted lipolysis and deep lasing, these maneuvers were not expected to result in any statistically significant skin contraction over their baseline values. Three of the eighteen treated zones demonstrated an increase in their areas (negative values) that could not be accounted for by the demographic weight fluctuations in these subjects at the three month evaluation period. At the 6 month evaluation period, Zone 5 (7.6%) continued to exhibit the highest average amount of surface area contraction ($p<0.05$) over all other zones, whose average surface area contraction ranged between a -1.0% (expansion) to 4.0% (contraction).

Histology

The punch biopsies from the bases of Zones 1, 2, 3 and 4 demonstrated an absence of thermal changes to the collagen fibers in the lower reticular dermis and septae. The microscopic examinations of tissues below the skin of Zones 5 and 6, however, revealed marked denaturation of collagen both in the reticular dermis and septal architecture, as shown in Figure 2.

Discussion

This study demonstrates for the first time the direct relationship between precisely treated tissues and tissue contraction. The delivery of sufficient thermal energy within the shallow (1-5mm) subdermal tissue at 45°C produces surface skin temperatures between 40-42°C, that lead to denaturation of collagen fibers within the dermis and septae. Progressive skin shrinkage at 3 and 6 months follow up were observed when

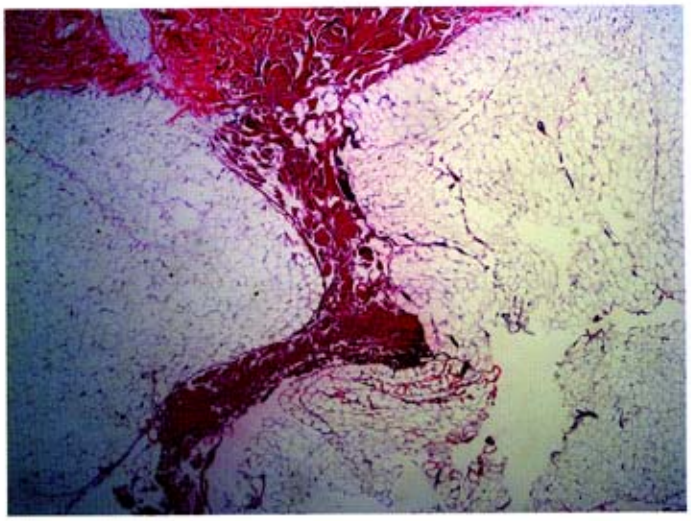

Figure 2. Photomicrograph of tissue exposed to Smartlipo MPX shallow treatment at the base of Zone 5 that demonstrated denaturation of collagen within the reticular dermis and septae along with lipolysis.

these conditions existed. It is of interest that an identical average amount of skin contraction (3.6%) was observed after "Liposuction only" and "Deep MPX Lipolysis and Liposuction". Since both treatments result in volumetric fat reduction without denaturation of collagen fibers, skin shrinkage may reflect skin accommodation and retraction rather than active contraction. As anticipated, tumescent infiltration and cannulation had minimal effects on tissue contraction since no thermal injury or volume loss occurred

Conclusion

An extramural volumetric assessment by Vectra 3D analyses observed skin shrinkage at 3 and 6 months only under conditions when sufficient thermal injury of 45°C was delivered within the immediate subdermis, resulting in surface temperatures between 40-42°C. At these precise thermal ranges, microscopic findings corroborated the clinical and Vectra 3D measurements. When treatments did not result in volume reductions within the subcutaneous fat or did not elicit enough thermal injury to septae and dermal collagen, minimal skin contraction was measured. Further studies are needed to validate these early findings.

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Acknowledgement

The author wishes to thank Dennis DaSilva, Canfield Scientific, Fairfield, NJ for Vectra 3D Analysis and Margaret Gaston for statistics and computer assistance.

Conflict of Interest Statement

Dr. Sasaki is a consultant for MicroAire Surgical Instruments and received limited funding under an unrestricted research grant for the Vectra 3D measurements/analysis by Canfield Scientific and histological studies.