Smartlipo MultiPlex – An Advanced System for Laser Lipolysis

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Introduction

In October of 2006, the United States Food and Drug Administration approved Smartlipo (Cynosure Inc. Westford, Ma), a medium pulsed 1064 nanometer Neodymium-doped yttrium aluminum garnet (Nd:YAG) laser for the surgical incision, excision, vaporization, ablation, and coagulation of all soft tissues. Laser-assisted lipolysis is now an exciting, effective and safe option for patients and physicians who wish to improve local adiposities while minimizing downtime.

Doctors, patients and the media are excited about this procedure because for the first time, one modality both liquefies adipose tissue and coagulates tissue resulting in tightening of the skin. Patients are pleased with results and the safety record of Smartlipo has been impressive in our experience. However, clinicians continue to search for ways to enhance the efficacy and safety of laser lipolysis even further.

The Smartlipo MultiPlex is the newest generation of laser-assisted lipolysis devices. This technology incorporates two wavelengths, a 1064 nm and a 1320 nm, that fire sequentially in MultiPlex mode to maximize removal of adipose tissue and skin tightening. The 1064 nm wavelength disrupts a broad region of adipose tissue while heating the treated areas evenly. It also mediates blood vessel coagulation enhancing hemostasis. In contrast, the 1320 nm wavelength scatters minimally and is robustly absorbed by water in the tissue located near the laser tip. The combination of the two wavelengths creates a blended thermal and photomechanical effect that effectively liquefies fat and heats collagen.

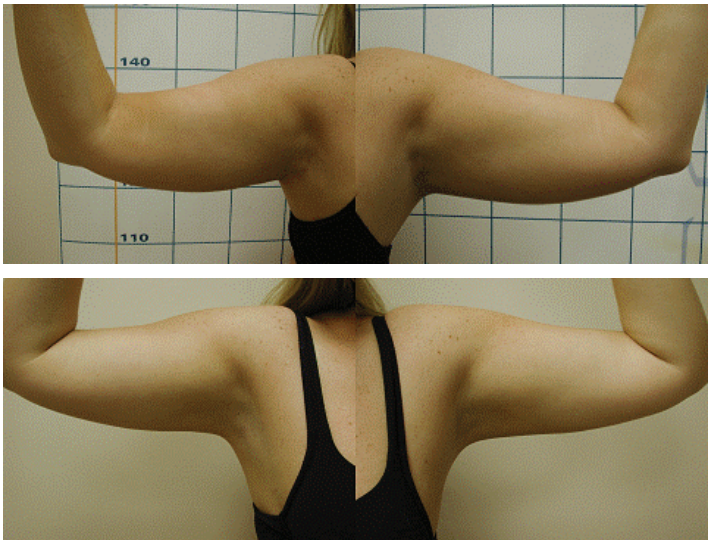
As a result of this latest design, the system provides unique flexibility for the surgeon allowing the use of the 1064 nm or 1320 nm wavelengths alone or in succession. Additionally, the Smartlipo MultiPlex is equipped with a unique delivery system that contains an advanced microchip called the Accelerometer inserted into the intelligent handpiece – SmartSense. SmartSense reduces the energy output of the laser as the handpiece movement slows.

Smartlipo MultiPlex can be used to treat all areas of the body where local adiposities are identified. These areas include the submental area (*see Figure 1*), axillae, arms (*see Figure 2*), abdomen, hips, breasts, back, outer thighs, inner thighs, knees and ankles. In this study, we evaluated the Smartlipo MultiPlex for the treatment of unwanted fatty tissue and tissue tightening.

Figure 1

Before Tx (top) and after Tx (bottom)

Figure 2



Before Tx (top) and after Tx (bottom)

Methods

Twenty patients requesting removal of unwanted fat were enrolled at our center based on the inclusion and exclusion criteria by the Institutional Review Board (IRB).

In order to measure skin tightening, India ink alliquots measuring 4.0 cm squared were tattooed on five of these patients. The purpose of the tattoos was to measure the change in length between corners as well as diagonally between points of the square one month after the procedure. Biopsies were taken from these 5 patients at baseline, 3 days and 1 month after the procedure.

Patients were marked with a surgical marker into several quadrants of equal size prior to the procedure. The sizes of the quadrants varied depending on the treatment locations. Tumescent anesthesia was administered using the Klein infiltration method.

The laser beam is guided through the fat by a 600 micron optical fiber within a 1.0 mm diameter micro-cannula which is attached to the handpiece. The optic fiber is extended 2.0-3.0 mm beyond the cannula tip and the energy from the laser is limited to this site. Transillumination of a red helium:neon (He:Ne) beam allows the surgeon to identify the subcutaneous location of the laser tip. The SmartSense is attached to a groove at the base of the handpiece prior to turning on the laser. The Accelerometer can be set to one of 3 different modes: low, medium or high. Each mode correlates with a different level of sensitivity to the handpiece motion.

The cannula is directed under the skin and a foot-pedal controls the laser firing. The cannula is passed through the subcutaneous layer in a fanning pattern until the endpoint of reduced adipose tissue thickness is reached.

The laser was applied to each outlined quadrant until the surgeon achieved the desired clinical endpoint. The surgeon's endpoints are clinically determined by palpation and creation of the optimal contour, and shaping. A thermal camera was also employed to monitor the surface temperature as the laser was applied more superficially in order to promote skin tightening. The thermal camera was connected to a color monitor, which enables the surgeon to identify temperature rise within a particular quadrant. Blue-green signifies cooler areas while red signifies optimally heated areas.

The temperature range (determined by previous abdominoplasty studies and published literature) that correlated with safety and efficacy of lipolysis was about 40 degrees Celsius. Based on previous studies, temperatures of 47 degrees Celcius and higher resulted in epidermolysis *(see Table 1)*. Typically, a superficial temperature rise to 38-40 degrees was employed as an endpoint. We found that the surface temperature may continue to rise several degrees post lasing as the heat accumulated in subdermally.

In order to provide objective endpoints/guidelines, the amount of energy measured in kilojoules was recorded for each quadrant. Specific protocols and treatment settings are being established and will vary depending on patient and treatment areas. The following case details our experience with this new Smartlipo MultiPlex laser system.

Case

A 33 year-old female with excess adipose tissue involving her bilateral hips wished to improve her shape. She had no previous medical history and no prior liposuction to the hips.

After an informed consent was obtained, she was photographed, marked with a surgical marker (including quadrants for the purpose of the study), and prepped in sterile fashion. Pre-operative medications were administered. One liter of tumescent anesthesia was infused to each hip.

Once properly anesthetized, a baseline temperature was obtained. Laser-lipolysis was then administered to quadrant #1 with 20 Watts of 1064 nm and 15 Watts of 1320 nm used

Temperature of onset: ranges ºC	**Heating times**	**Histopathologic effect**
Low 40 ºC +	hours to minutes	Edema and hyperemia*
45 ºC +	minutes to seconds	Thermal denaturation of structural proteins in fresh tissue *
50 ºC +	minutes to seconds	Damage model prediction of skin damage (epidermal necrosis)**
50 ºC - 90 ºC	minutes to seconds	Change of collagen *

Table 1: Epidermal necrosis and collagen change based on temperature. (Model prediction based on previous studies and literature finding) [3,4,5]

with the MultiPlex setting to the deep subcutaneous tissue until the tissue was pliable. An end deep temperature was recorded. Subsequently, the laser was administered superficially to quadrant #1 with 10 Watts of the 1064 nm and 10 Watts of the 1320 nm. An end temperature range between 38 and 40 degrees Celsius was obtained. The treatment was continued in a similar fashion though all quadrants. The lipolyzed adipose tissue was then removed by a power suction cannula.

Results

Patient post-op follow-up time at the time of this manuscript varies from 4 weeks to 6 weeks. Several enrolled patients are nearing the study completion and preliminary results are so far excellent. In the presented case, one month after the procedure, a reduction in fatty tissue volume and improved skin laxity has been observed (*see Figure 3*). The diagonal measurement of the opposite corners of the tattooed square decreased from 6.0 cm to 5.0 cm one month after the procedure. On average, we have seen 15% tightening of the overall area after 1 month. Early biopsies demonstrate significant disruption of adipocyte membranes. The patient graded her level of satisfaction a 5 out of a possible 5 and would recommend the procedure to friends or family. Additionally, most patients have minimal bruising and pain and return to work in 1 to 2 days.

Figure 3

Before Tx (top) and after Tx (bottom)

Discussion

Laser lipolysis technology continues to improve as clinicians search for faster, more effective and safer ways to remove fat. Laser lipolysis performed with the Smartlipo MPX has demonstrated efficacy and faster recovery time as compared to traditional liposuction.

One potential adverse reaction of laser-assisted lipolysis is excess concentration of laser energy within the irradiated tissue leading to carbonization and thermal burns. We have found that when lipolyzing deep areas laser energies can be maximized to 20 Watts for the 1064 nm and 15 Watts for the 1320 nm wavelengths without adverse sequelae. However, when treating more superficially, decreasing the energy output to 10 Watts for the 1064 nm and 10 Watts for the 1320 nm provides excellent results and added safety. By blending the two wavelengths in the Multiplex mode, we are able to generate higher temperatures that heat a broader area while distributing the laser energy more evenly. This results in more efficient lipolysis and safer, more efficient heating of the collagen bundles in the dermis.

For patients at risk for skin laxity after removal of adipose tissue, Smartlipo MultiPlex provides satisfying results. In this study we demonstrated through tattoos that skin tightening is a key contribution of laser lipolysis.

Smartlipo MPX is a relatively new technology that has demonstrated efficacy in skin tightening and laser lipolysis. Additional studies are recommended to expand the use and knowledge of this system.

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