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ENDOLIFT® and multi-wavelength laser photobiomodulation: a randomized controlled trial study on 96 subjects, treating skin laxity of the lower third of the face

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ABSTRACT

Background and aims: Many patients look for procedures that can achieve similar results to surgical lift avoiding the risks and possible complications of surgery. Endolift® and multi-wavelength (MW) Laser photobiomodulation (PBM) are considered two of the most effective procedures in the treatment of skin laxity and superficial wrinkles.
We aimed to investigate the reduction of skin laxity of the lower third of the face treated with the Endolift® technique alone or in combination with MW Laser PBM.
Materials and Methods: From June 2016 to June 2018, 96 subjects (18 M; 78 F) were included in this randomized controlled trial (RCT) conducted in two Italian institutions. The area treated was the lower third of the face. The subjects were classified using the Ptosis Scale (grade I-V) at T0, with a Pinch Test <1.9mm. We selected only subjects' grade 4, both males and females, 45-55-years old. Thirty-two subjects (6M; 26F) (group 1) were treated with the Endolift® procedure followed by a session of MW Laser PBM using a simultaneous nonsurgical laser therapy emission of three different wavelengths (532nm, 808nm, 1064nm). The MW Laser PBM was repeated after 7, 14 and 21 days. Thirty-two subjects (6M; 26F) (group 2) underwent only the Endolift® session. 32 subjects (6M; 26F) (group 3) received only MW Laser PBM. Follow up visits were performed at days 60 (T60), 120 (T120) and 540 (T540) after the treatments. The study ended in December 2019 when all the subjects had been followed for 18 months.
Results: The results of the three groups were evaluated using the Ptosis Scale at T0, T60, T120 and T540. The combination of the two treatments (group 1) achieved more rapid effects, while MW Laser PBM alone treatment (group 3) achieved the slowest effect. The median test for independent samples showed that all the differences between groups are statistically significant at each follow-up (p=0.000).
Conclusions: The Endolift® laser in the last 15 years allows to achieve exceptional results in the treatment of skin laxity reaching the desired 'soft' rejuvenation model which is increasingly desired.

[*] ***Running title:***
Enfolift® and treatment of face skin laxity

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MW Laser PBM, in combination with Endolift®, obtains better results. Although significant at T540, the effects of MW Laser PBM alone are slower to reach.

Key words: Endolift, laser therapy, skin laxity, face

Introduction

Endolift® represents the most innovative interstitial connective remodelling technique based on a laser micro-fiber 1470nm. However, best results are obtained in several months, although lasting for more than two years.

Multi-wavelength (MW) Laser photobiomodulation (PBM) is a non-invasive, non-thermal trans-dermal therapy which stimulates cells to generate more energy and undergo self-repair through the use of visible and near infrared light (NIR) with no side effects. MW Laser PBM is not as efficacious as Endolift® in deeper layers and takes longer to attain best results.

Until the beginning of the millennium good cosmetic results needed surgery, but techniques such as botulinum toxin, thread lifts, radiofrequency or more recently the micro-focalized ultrasound have proved to be breakthrough treatments in achieving 'soft' lifting and rejuvenation. Indeed, only the introduction of recent generation fiber lasers, have allowed to achieve excellent results. The mechanism of action of the subcutaneous laser is twofold; both acoustic/mechanical and selective photothermolysis of the targeted tissue. Over the last 20 years various studies [1] have published on laser liposculpture and in 2006 the FDA demonstrated that approximately 50% of 2200 subjects reported superior 'skin tightening' after laser liposuction than patients treated with traditional liposuction [2]. Indeed, it is well established in the literature that it is possible to obtain excellent results with the primary aim of achieving skin remodelling and retraction [3].

Following this trend of success, Dr. Dell'Avanzato developed the Endolift® technique in 2005, which gained popularity in the global market largely since it is a relatively simple and safe procedure, producing immediately visible results whilst also being reproducible and repeatable [4], [5], [6].

Endolift® technique represents nowadays one of the most innovative procedures using a micro-fiber connected to a diode laser 1470nm. The name Endolift® reflects the basic distinctive concept of the methodology; ENDO meaning 'internal' and LIFT 'to raise'. In such a way, the technique aims to lift tissues from deeper layers using an optical fiber as thin as a human hair inserted under the skin in the superficial-middle hypodermis. Here it delivers the laser energy, without the need to cross the superficial layers of the skin (epidermis and dermis). This is one of the many advantages that Endolift® has over its counterparts such as radiofrequency which deliver targeted energy through the superficial cutaneous layer and therefore undergo dispersion as well as causing more pain. Moreover, it uses a naked fibre avoiding any additional cannulas.

MW Laser PBM is also known as low-level laser therapy (LLLT) and seems still highly appreciated in the scientific community. MW Laser PBM could be performed also with non-coherent sources, as LED or IPL, but these sources do not allow a precise dosage of radiation.

The first non-surgical laser stimulation effect was discovered in 1967 by Endre Mester when trying to repeat an experiment first conducted by Paul McGuff in Boston, who had successfully used the newly discovered ruby laser to cure malignant tumours in rats [7]. Mester's custom-made ruby laser possessed only a very small fraction of the power possessed by McGuff's laser, and despite not curing tumours he observed a heigh rate of hair growth and better wound healing in the rats [8].

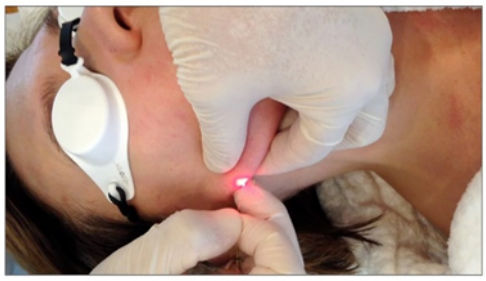
This was the first indication that LLLT could have a beneficial use in medicine [9]. Nowadays, LLLT or MW Laser PBM are continuing to receive consent [10], [11] and represent an effective non-invasive, non-thermal trans-dermal therapy to stimulates cells to generate more energy and undergo self-repair through the use of visible and NIR with no side

effects, as anti-inflammatory and to increase the venous-lymphatic drainage [12].

Materials and Methods

From June 2016 to June 2018, 96 subjects (18 M; 78 F) were included in this randomized controlled trial (RCT) in two different institutions in Italy, the Medical Department of Espace Chenot Health Wellness SPA at L'Albereta Relais and Chateaux and the Institute of Laser Medicine of Florence. The 96 subjects were selected with a Pinch Test <1.9mm, in order to not treat subjects with large amount of extra fat. The area treated was the lower third of the face. The subjects were classified using the Ptosis Scale (grade I-V) at T0. We selected only subjects' grade 4, both sex, age 45-55 years old. Thirty-two subjects (6M; 26F) (group 1) received the Endolift® procedure as first, then underwent a session of MW Laser PBM using a simultaneous nonsurgical laser therapy emission of three different wavelengths (532nm, 808nm, 1064nm). The Laser PBM was repeated after 7, 14 and 21 days. Thirty-two subjects (6M; 26F) (group 2) underwent only an Endolift® session. Further 32 subjects (6M; 26F) (group 3) received only MW Laser PBM. Follow up visits were programmed at days 60 (T60), 120 (T120) and 540 (T540) after treatment. The study was closed in December 2019 when all subjects had been followed for 18 months.
The Endolift® session is performed using a 300micron FTF (fiber -to-fiber) micro-fiber with radial emission, connected to a diode laser 1470nm, inserted, without any incision or anesthetic, directly into the superficial middle-hypodermis **(Fig. 1)**.

Fig.1: The Fiber is easily inserted, without any incision or anaesthetic drug



Once the fiber has been inserted into the correct plane, represented by the superficial and medium hypodermis, the positioning of the fiber is identifiable due to a red aiming beam visible through the skin. The fiber is moved throughout the intervention area in a fan-like manner, delivering energy firstly in a retrograde then anterograde fashion, creating micro-tunnels oriented mainly along the anti-gravitational vectors. During the procedure the skin surface temperature should never exceed 40 °C (measured through an external thermal sensor). Cumulative energy of Endolift® ranging from 500 J to a maximum of 1400 J with a mean of 800 J for the entire area. The session of MW Laser PBM is then performed. The MW Laser PBM energy delivered is around 4J/cm^2 for each emission with a total of 12J/cm^2 considering the overlapping technique in each zone, with a mean total of 360 J/cm^2 for each subject. The dose of each laser irradiation was established following the parameters accepted by the international scientific community regarding the laser biomodulation of the skin and soft tissues [9], [10]. We use more wavelengths because each one has a different penetration in the tissue and a different antiphlogostic activity, anti-oedema and regenerative, increasing the metabolic exchange in each irradiated tissue. The antiphlogistic effect occurs at 808nm and 1064nm, the regenerative effect at 532nm and 808nm [11], [12]. The three different wavelengths have also different penetration, so that they can be absorbed by more tissue layers. The subjects after 7, 14 and 21 days, received the same amount of J/cm^2 as in T0.
After the procedure all subjects were able to immediately resume their daily life activities; there were no cutaneous marks or signs, just a moderate erythema (2% of cases) and oedema (3%) that resolved in a few hours, in all the 3 groups.

Statistical Analysis

In all groups data distribution was non normal as evaluated by the Kolmogorov-Smirnov's single sample test. Thus, changes of median scores between groups were examined using the non-parametric median test for independent samples.

The non-parametric related samples sign test was used to analyse variations of median values in the same group through the follow-ups. The IBM SPSS Statistics for Windows, (version 26.0; IBM Corp, Armonk, NY, USA) was utilized for calculations. The significance level was set at $p<.05$.

Results

The results of the three groups were evaluated using the Ptosis Scale at T0, T60, T120 and T540. The majority of subjects shifted from grade 4 to grade 2 and 1 **(Fig. 2)**.

Fig 2: Endolift® + MW Laser PBM

The median value comparison within groups showed a strong modification in group 1 between T0 (4) and T60 (1, p=0.000) while no modification was observed through the other follow-up visits at T120 and T540 (p=0.157).
However statistical significance was observed in the T0-T540 difference (p=0.000) **(Table 1a)**.

Table 1a: Kolmogorov-Smirnov's single sample test was used

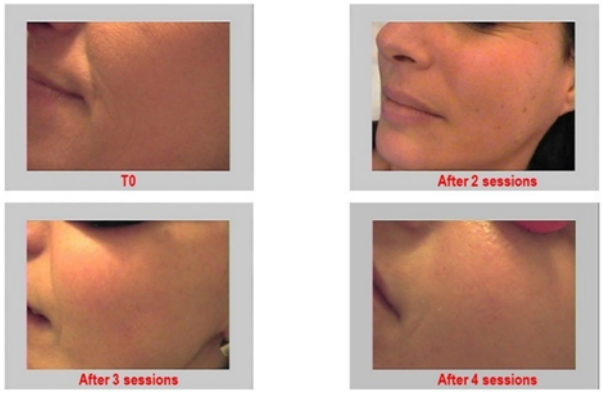
	T0	T60 (p in groups T0-T1)	T120 (p in groups T1-T2)	T540 (p in groups T2-T3)	p in groups T0-T3
Group 1	4	1 p=0,000	1 p=0,157	1 p=0,157	0,000
Group 2	4	2 p=0,000	1 p=0,008	1 p=0,180	0,000
Group 3	4	4 p=1	2 p=0,000	2 p=0,157	0,000
p between the groups	0,000	0,000	0,000	0,000	

In group 2 **(Fig. 3)** this value changed from 4 to 2 at T60 (p=0.000), and from 2 to 1 at T120 (p=0.008).

Fig 3: Endolift®

At T540 it remained the same but did not reach any statistical significance (p=0.180). However, the difference between values at T0 the baseline and at T540 are equally significant (p=0.000).
In group 3 **(Fig. 4)** values are equal at T60 (4, p=1) while a significant change was found between T60 and T120 (median value from 4 to 2, p=0.000). No statistically significant difference was found through T120 and T540 (p=0.157). The difference T0-T540 was significant (p=0.000).

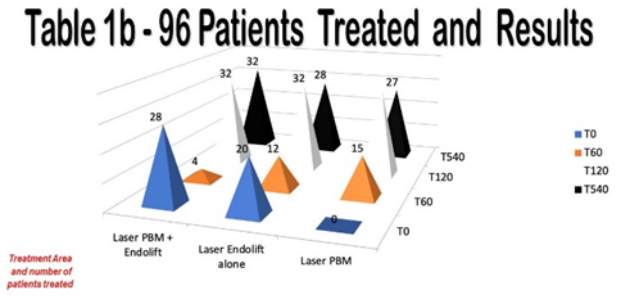
Fig 4: MW Laser PBM



The median test for independent samples showed that all the differences between groups are equally statistically significant at each follow-up (p=0.000).

Discussion

Follow-up was excellent in all groups **(Table 1b)**.



The procedure causes remodelling of collagen and connective tissue photobiomodulation, resulting in the 'skin tightening' effect. Skin laxity is reduced, and superficial wrinkles are smoothed resulting in an overall compacting of the skin which is immediately visible and continues to progress over the following period. The laser acts simultaneously on the collagenous fibrous septa, resulting in further skin retraction and tissue compaction.
As in many other procedures evaluating symmetries can be difficult with the naked eye, i.e., for the mandibular contours, due the natural physiological differences between the body sides. Thus, while skin changes visibly appreciated by the operator are the main endpoint, the amount of laser energy emitted during the Endolift® treatment represents a secondary clinical end point. The combination of the 2 procedures Endolift® and MW Laser PBM allows to obtain the best results in a faster time.

Conclusions

In recent years, laser has become one of the most important innovations in medicine and surgery, of similar importance than laparoscopic or robotic-assisted surgery. It has several clinical indications including aesthetic thanks to devices and techniques which are now more easily reproducible, safer and minimally invasive. We consider the use of Endolift® laser technology a breakthrough treatment aimed at lifting tissues directly within the skin. The use of MW Laser PBM alone could be useful in patients with early lesions. The use of MW Laser PBM in combination with Endolift® showed a significant role in achieving the desired 'soft' rejuvenation model which is increasingly required but needs the concomitant use of different cosmetic techniques to achieve the best results in a shorter time, longer duration of the effects and conservation of the natural expression of the face.

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