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Research Article

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Combining P (LA/CL) Thread Lifting with Focused-Ultrasound Treatment for a Holistic Lower Face Contouring and Rejuvenation

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Key Abbreviations

PLA- Polylactic acid
PCA- Polycaprolactone
P (LA/CL)) - Poly-L-lactic acid and caprolactone
IFUS- Intense Focused Ultrasound

Introduction

The aging neck undergoes multiple changes, including degenerative changes due to aging as well as actinic damage [1]. The hallmark features of an aging neck include platysma ptosis and banding, uneven ptosis of tissues and development of multiple horizontal rhytides. These changes may or may not be accompanied by bone resorption of the mandible which may exacerbate an 'aged look'[2]. This development of a hypoplastic mentum and subsequent loss of definition of chin and jawline and may give the appearance of the characteristic "turkey neck" look.

Until recently, cosmetic improvement of neck was limited to surgical interventions. However, now patients are opting for more and more minimally invasive "lunch-time" procedures that involve minimal recovery time [3]. Some other attractive features of these 'quick fixes' are related to the high-risks involved with surgical procedures themselves. Some reasons which may prevent individuals from opting for surgical interventions include those who are not mentally unprepared for surgery, those whose medical history prevents them from further surgeries, patients who are unable to carve out post-surgery recovery time as well as younger patients who suffer from early degenerative changes of the face and neck [1]. There is also the standard risk which is associated with all invasive surgical procedures such as infection, skin necrosis, hematoma, seroma, and injury to frontal and marginal mandibular facial nerve branches, in addition to the associated risks involving general anesthesia or other forms of conscious sedation [3].

Aesthetic treatments for rejuvenating the aging lower face have evolved from skin tension–based procedures such as the mini face-lift, to a variety of newer techniques such as chemical peels, laser resurfacing, dermal fillers and neurotoxins injections. Patients are also seeking minimally invasive procedures like thread lifting in combination treatments for a holistic approach to total neck and lower face rejuvenation [3]. Thread lifting has quickly become a mainstay in the aesthetic dermal industry since its inception by Sulamanidze and colleagues [4]. Since then, several studies using various techniques and thread materials have shown optimal lifting results of ameliorating skin and tissue laxity in the aging skin.

Another notable feature of the aging lower face and neck is loss of elasticity and generalized skin laxity. To combat this, Intense focused ultrasound (IFUS) can now be used as a treatment modality. Non-ablative heating devices which emit IFUS energy that can propagate through tissues. This results in selective thermal coagulative changes within the focal region of the beam while leaving the remaining regions unaffected [5]. Lee and colleagues demonstrated the efficacy of a multiple pass protocol in which they used a 4.5mm and a 3mm probe that resulted in 80% of patients (8 out of 10) showing clinical improvements 90 days after treatment with an IFUS device (Ulthera System; Ulthera, Inc., Mesa, AZ). This was confirmed with ultrasound imaging [6].

The purpose of this case study report is to evaluate the synergistic lifting, rejuvenating and anti-aging effects of two common, minimally invasive, lifting and tightening treatments administered in the aesthetic dermal industry and at Everlast Wellness Medical Center. We wanted to determine the combined contouring and lifting effects of an IFU treatment followed by P (LA/CL) threads after a 2 week interval, and its patient satisfaction levels in lower face and neck rejuvenation.

Materials and Methods

Patients

5 patients (All female) with a considerable degree of lower face skin laxity were enrolled in this study. The patients were otherwise in good health but desired a more defined jawline and/or a lifted and tightened lower face with decreased submental skin laxity. Informed consent was taken from these patients. The median age for these patients was 45.2 (range 35-55) and most patients had Fitzpatrick skin type IV. The average BMI of these patients was 25.78 kg/m^2. The demographics for these patients are given in Table 1.

Table 1: Summary of baseline demographics of patients (N = 5)

Patient No	Sex	Age	BMI	Fitzpatrick skin type
1	F	55	21.2	IV
3	F	42	25.6	IV
4	F	41	27.5	IV
5	F	36	30.3	IV
5	F	36	30.3	IV

Exclusion criteria were any active systemic or local infections, any local skin disease that might alter wound healing, scarring in the test areas, any diagnosed psychiatric illness, a history of smoking, and insertion of soft-tissue augmentation materials or application of ablative or non-ablative laser procedures within the previous 6 months, pregnancy and those patients with excessive skin laxity.

Materials

Ultrasound Equipment

For the delivery of HIFUS we used the Ulthera device (Ulthera System; Ulthera, Inc., Mesa, AZ). With this device it is possible to simultaneously visualize the skin to deliver focused ultrasound to confined zones under the skin at specific depths to cause localized thermal coagulation. The device allows us to change the depth and size of the thermal lesions by changing the probes. The Ulthera device probes have three presets with a fixed focal depth and frequency: 4 MHz, 4.5-mm focal depth (source energy 0.75–1.2 J); 7 MHz, 4.5-mm focal depth (source energy 0.75–1.05 J); and 7 MHz, 3.0-mm focal depth (source energy 0.4–0.63 J).

Each probe, when activated, delivers a series of ultrasound pulses along a 25-mm exposure line. The depth the ultrasound reaches is 4.5 mm (when the two 4-Mhz, 4.5 mm and 7-Mhz, 4.5 mm-focal depth transducers are used) and 1.1 mm (when the 7-MHz, 3.0-mm focal-depth transducer is used).

Suture threads

We used double blind threads (Aptos Light 2G) for the jawline and neck lifting without anchoring which are a type absorbable thread made from a copolymer of L-lactide with ε-caprolactone. These threads are double-edged traditional trihedral needles with thread fastening in the center of the needle which allow the absorbable thread with notches to be drawn along any desired contour (figure 1) [7]. For the neck lifting with double needle 2G, we used Aptos P (LA/CL)) threads, which are a type of thread made of PLA (Polylactic acid) in combination with PCA (Polycaprolactone). The threads consist of L-Polylactic acid with Σ- caprolactone in a 3:1 ratio. The design of these thread is such that each subsequent barb is located on the opposite direction from the previous one that allows stronger hypodermic fixation and supports grouping the tissues on every micro-section of the thread. The thread is preinstalled in special atraumatic cannula with the rounded tip and a hole aside to minimize tissue injury.

These threads can safely be indicated for lifting and reinforcement of the middle and lower thirds of the face and neck [7]. The two ingredients in these thread play two different roles for rejuvenation. It is been observed that the main component, L- polylactic acid, is responsible for a subtle rejuvenating effect as it stimulates natural revitalization. During thread biodegradation, L-lactic acid is released into surrounding tissues, stimulating neocollagenesis and tissue rehydration. The Σ-caprolactone, the other main component of the thread, works synergistically to slow down PLA biodegradation, increasing the duration of its tightening effect, and serves as a lactic acid delivery system to surrounding tissues [7].

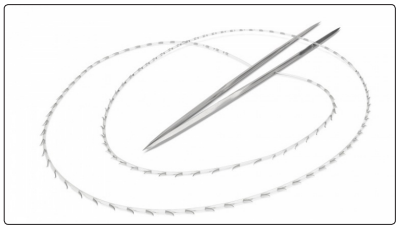


Figure 1: Light Lift Needle 2g (Lln2g)

The tissues reactions that are initiated which result in this tightening effect are due to the formation of collagen type I and type III, and due to the development of a fibrous capsule around the length of the thread. After complete hydrolysis of the thread itself, the fibrous capsule can continue to hold soft tissue for up to 5 months [7].

Assessment

For qualitative assessment, we used the Vectra H1 3D Imaging System (Canfield Scientific, New Jersey, USA) for digital imaging. These images were taken in the following protocol through the treatment program: before Ulthera treatment, 2 weeks after Ulthera (before thread lifting), right after thread lifting, 2 weeks after thread lifting, 1 month after the thread lifting and 3 months after thread lifting. One session of digital assessment comprised of taking 3 digital images: 1 frontal and two at a 45-degree (left and right) following the recommended Vectra H1 System protocol. These images were then prepared using the Canfield Digital Software (Canfield Imaging Systems, Fairfield, New Jersey).

For the assessment and comparison of results, we used two techniques; a blind evaluation was done by 2 physicians using the Global Aesthetic Improvement Scale as a reference parameter (Table 2) and a direct side-by-side randomized comparison was also done. These two physicians were independently practicing estheticians not employed by Everlast Wellness Medical Center. These physicians were not involved in the any of the recruitment, the treatment, or post-procedure follow-up stages, and only served as independent blinded reviewers. For the procedure regarding direct comparisons, the following was done: the pre-treatment images were presented alongside the corresponding posttreatment images side-by-side for each case. However, the sides of placement of both pictures varied so that reviewers would be unaware which image was pre-treatment and which was post-treatment. The reviewers were also provided with printed versions of the pre- and post-treatment photographs.

The evaluators were informed of the randomization of the left/right positioning of the pre and post treatment images. For each patient, they were asked to observe and report the images as ‘changed’ or ‘unchanged’. If they observed a change, they we asked to identify which image they perceived to be the changed one. This was then recorded in a data sheet. Based on each evaluators result, the changes were then determined to be ‘improved’, ‘unchanged or ‘worsened’. If the correct posttreatment image was identified based on the reference key, the patient’s result was considered improved. If the reviewer did not observe a change, the result was considered unchanged. If the reviewer identified the wrong photograph as the posttreatment image, the result was considered worsened. All results were then collated

on a Microsoft Excel spreadsheet (Microsoft Corp, Redmond, Washington), and trends were analyzed.

Internal Patient Satisfaction Scale through self-reporting was also done. The patients were asked to choose from options 1-4, 1 being extremely satisfied and 4 being not satisfied (Table 3). These results were also collated on a Microsoft Excel spreadsheet and trends were analyzed.

Table 2: Global Aesthetic Improvement Scale

Global Aesthetic Improvement Scale		
	Degree	**Description**
1	Exceptional improvement	Excellent corrective result
2	Very improved patient	Marked improvement of the appearance, but not completely optimal
3	Improved patient	Improvement of the appearance, better compared with the initial condition, but a touch-up is advised
4	Unaltered patient	The appearance substantially remains the same compared with the original condition
5	Worsened patient	The appearance has worsened compared with the original condition

Table 3: Patient Satisfaction Scale

Degree	Description
1	Extremely Satisfied
2	Satisfied
3	Somewhat Satisfied
4	Not Satisfied

General treatment protocol

Ulthera treatment and after care

For anesthesia, J-Cain (South Korea) anesthetic cream was applied to the neck and lower face treatment area 15-20 minutes before the Ulthera procedure. The anesthetic was wiped off with gauze before energy delivery. Areas treated included the submental, mandibular region and neck. The dermis and subcutaneous tissue were targeted using the 4-MHz, 4.5-mm-focal-depth and 7 MHz, 3.0-mm-focal depth probes. For treatment, the 4-MHz, 4.5-mm probe was used first, followed by the 7-MHz, 3.0-mm probe.

Ultrasound gel was applied to the skin before beginning the treatment. The handheld probe was then placed firmly on the targeted skin surface to achieve uniform coupling with the skin surface. The probe was moved in parallel to the first exposure line, placing the successive rows of ultrasound exposures 3 to 5 mm from the previous exposure line. Ultrasound imaging confirmed that the probe was acoustically coupled to the skin tissue and that the focal depth required for therapy was in achieved. On average, 235 exposure lines were placed on the treated areas of each subject using the 4-MHz, 4.5-mm probe and the 7-MHz, 3.0- mm probe of the focused ultrasound system. The total number of lines in each area for each patient was adjusted to accommodate variations in facial size, degree of skin laxity of each area and desired level of effect. A gap of approximately 3 mm between the exposure lines was considered appropriate to achieve good treatment efficacy. The energy setting was 1.2 J for the 4-MHz, 4.5- mm-focal-depth probe and 0.63 J for the 7-MHz, 3.0-mm-focal-depth probe. Complete treatment of the face and neck required 45 minutes per patient. Upon completion of treatment, patients were asked to follow post treatment instructions and were advised to resume their normal skincare regimens. Patient was told to come back in 2 weeks for thread lift.

Marking for thread lift

At the 2-week marks, the 3D pre-treatment pictures of the patient were taken using the outlined Vectra technique. Then the marking was done for thread insertion using a dermographic pen. The procedure for this was as follows: for redefining the jawline, lines were marked starting 1 cm in front of tragus going towards the ramus of the lower jaw (4-5 cm) (Figure 2). For a subtle neck lift with an anchoring point, two lines were then marked starting from retro auricular area going towards the mandible in an open "V" fashion (Figure 3). The exit points where marked in near the midline. The last two lines were marked starting from the retroauricular going towards the midline on both sides of the neck (figure 4) for lower neck lift using an anchoring point.

Anesthesia

The procedure was performed with the patient under local anesthesia. We marked the skin preoperatively to determine the appropriate vector of the thread with a dotted line using a dermographic pen. Patients received a total of 5 ml of local anesthesia comprising 9:1 ratio of 2% lidocaine with epinephrine (1:200,000) and 8.4% sodium bicarbonate was infiltrated on the entry and exit point parallel to the jawline.

Thread lifting protocol

Technique for redefinition of the mandibular contour

The technique used for the redefinition of the mandibular contour involves the use of a thread introduced through a double needle in correspondence to the mandibular angle through two adjacent inlet holes. Two needles are inserted which go across the cheek towards the jaw for 4–5 cm (figure 2). The threads should draw a "V" open towards the outside. The ends were then pulled and the excess thread was trimmed. No sutures were necessary here. A total of 2 threads were used for each patient on each side.

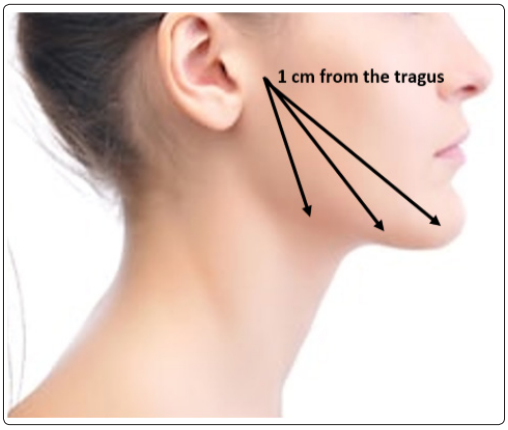


Figure 2: Redefinition of the mandibular contour with two threads

Technique for neck lifting without anchoring

For the treatment of the neck, the double needle is introduced with anchoring just near the retro auricular area, and advanced under the

deep dermis following the marked line until it exits at the marked exit point under the mandible. The ends of the thread are then pulled lightly and the excess is trimmed (figure 3). No sutures are necessary here.

Figure 3: Neck lift with anchoring

Technique for neck lifting with straight needle with anchoring point

A one cm incision was made in the retroauricular area. Then a knot was tied in the thread to fashion the anchoring point. The needle was then inserted and the thread was laced medially till it exited at the midline of the neck (figure 4). The same was repeated on the other side of the neck. One thread was utilized per side of each patient.

When all planned threads have been placed and anchored, the patient was returned to the seated position. Careful pressure was applied along the threads so that barbs catch on the fibrous septae of the subcutis preventing retrograde movement. The patient was cleaned and post-treatment 3D digital images were taken using Vectra. Then patient was then educated about post-procedural care and asked to return to the clinic after 2 weeks, 1 month and 3 months for follow up and imaging. Similar treatment was done for all patients.

At the end of the 3 months, baseline pre-Ulthera 3D images were compared and analyzed to the corresponding 3 month post Ulthera treatment 3D images for each patient using blind evaluators. The degree of change was also measured using the GAIS by the blind evaluators. Also at the final 3 month follow up, patients were asked to report their level of satisfaction with the overall treatment results using the Patient Satisfaction Scale.

Figure 4: Neck lifting with straight needle with anchoring point

Results

All of the 5 patients completed the 3 month follow up. The mean patient age was 45.2 years (range, 35-55 years), and the mean body mass index (BMI) was 25.78 kg/m2 (range, 21.2-30.3 kg/m2). Details of the patients are given in Table 1.

Assessments by blind evaluators

According to assessments by blind evaluators, improvements in skin laxity of the lower two-thirds of the face and the neck occurred in 4 (80%) of the 5 patients. No change was observed for 1 patient (20%), and the result was worse for none of the patients. An average of the GAIS improvement score given by each evaluator was calculated for each patient. Details for this are given in Table 4 and figure 5.

Patient satisfaction levels

Patient satisfaction was assessed at the end of the 3 month treatment plan using the Patient Satisfaction Scale. One patient related their experience to be extremely satisfactory, two reported satisfied and two reported their final result as somewhat satisfying. Details are given in Table 5.

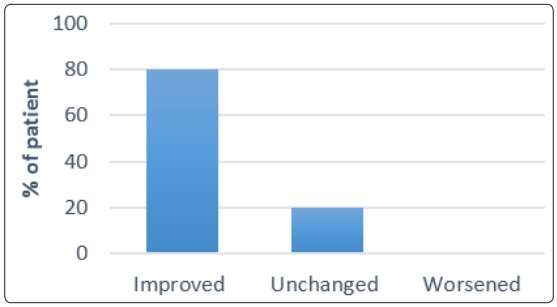


Figure 5: Graph displaying the results from the blind evaluator assessment of 3D photographs

Table 4: Summary of blind evaluator assessment of 3D photographs

Patient No	Age	Blind evaluator assessment	GAIS score given by evaluators
1	55	Changed	2
2	52	Changed	2
3	42	Changed	3
4	41	Changed	2
5	36	No change	4

Table 5: Summary of patient satisfaction scores at 3 month follow up

Patient No	Age	Adverse reaction after thread lifting	Adverse reaction after Ulthera
1	55	Swelling, inflammation, mild pain	Redness, mild pain
2	52	Swelling	Redness, mild pain
3	42	Swelling	Redness, mild pain
4	41	Swelling, inflammation, mild pain	Redness, mild pain
5	36	Mild pain	Redness, mild pain

Adverse Events

During the treatments and in the follow ups, patients were continuously monitored for any systemic side effects, skin surface reactions and other adverse effects. Throughout the treatments, skin

surface remained intact, and there were no reports of acute skin damage or other serious post-procedural side effects like scarring, burns, hypopigmentation, hyperpigmentation, or ulceration.

Adverse reactions to both the treatments were mild and typical to the treatments themselves. Patient related erythema, swelling and mild inflammation post thread lifting and mild erythema and pain post Ulthera. Severe adverse effects like thread migration, induration, bruising and scarring were not noted in any of the patients. Summary of the adverse effects are given in table 6.

Table 6: Summary of the adverse effects seen after each treatment

Patient No	Age	Patient Satisfaction
1	55	1
2	52	3
3	42	2
4	41	2
5	36	3

Discussion

Many patients require a variety of treatments to address the different but concurrent etiologies of their aging face. Each treatment, when applied correctly, can help ameliorate a certain aspect of aging. Hence the question naturally arises, can these treatments be used in combination to exert a synergistic effect? It also becomes imperative that we as estheticians, determine the safety of such combinational treatments.

When considering a combinational approach for anti-aging, the esthetician must assess each different concerns of the patient separately and then integrate it into a treatment plan. This includes considering each area and the extent of each problem separately, the overall desired goals of the patient, the possible side effects of each treatment and the patients tolerance, the timeframe for each treatment and affordability of a combinational approach.

A variety of anti-aging combination treatments have been explored, the most common one being the combination of botulinum toxin A with dermal fillers [8]. Chemical peels can be combined with other nonsurgical cosmetic procedures including BTX and fillers [9]. There exist plenty of studies in literature for the efficacy of IFU and thread lifting treatments separately, however, the author could not find any reports for the proven efficacy of combining thread lifting with IFU in an outpatient setting at the time of writing this paper. Non-ablative ultrasound treatment of skin tightening is performed by heating the dermis and the underlying tissue while threads lift sagging skin by mechanical lifting action and biostimulation [6,7]. When administered individually, the rejuvenating effects of these two treatments are noted in the months following the each treatment, so the reasoning of combining these two treatments so they may elicit tissue reactions in the same time frame as each other to deliver a well-rounded anti-aging treatment for the lower face and neck is the rationale behind administering these two treatments with a short gap of 2 months.

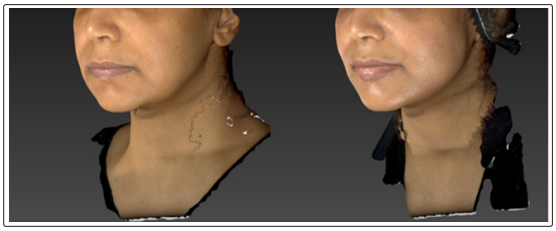
Patient selection is of critical importance here. Patients chosen must be those experiencing mild to moderate skin laxity and must be willing to follow a healthy diet and active lifestyle to maintain the results from their treatments. These factors, the author believes, might be the reason for the unchanged result of Patient 5. Patients with higher BMIs or those with severe skin laxity may not experience the same degree of results as documented here. Also, patients with unhealthy diets, sedentary lifestyle or those with underlying medical conditions may also not have lasting results and may not fully benefit from monotherapy or combined treatments.

Patient expectations must be well-informed and realistic despite being administered two treatments. The practitioner may benefit from informing the patient that these treatments may not benefit each patient in the same way, as shown by Lee and colleagues [6].

In our clinical practice, we found that combining these two minimally invasive treatments presents as a viable alternative to single individual treatments. The synergistic effect of these two treatments spaced out with a short gap to allow for healing and initiation of collagen production allows for the overlap of their individual rejuvenating effects. The results we obtained from this study are in line with other studies done for combinational treatments where patients have reported high levels of satisfaction when two treatments are combined [10].

The outcomes were assessed quantitatively and qualitatively. On the basis of these assessments, 80% of the patients were determined to have "changed" improvement in lower face skin laxity. Improvement from baseline was noted by 4 out of the 5 patients at post-Ulthera 3 month mark.

Patients before and after:

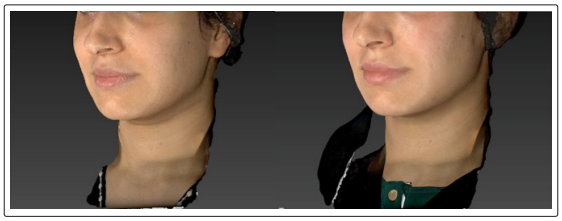


Patient 1

Patient 2

Patient 3

Patient 4



Patient 5

Conclusion

The appeal of noninvasive skin tightening treatments such as the ones the author has used are limited post procedure healing time, ability to return to work or social engagements, and lower risk of adverse events than with ablative or surgical skin resurfacing. A literature search would reveal that it is widely believed that energy delivery to the deeper subcutaneous layers of the face, or even the SMAS, is most effective in inducing skin tightening [11]. It is also evident that IFUS is able to spare the epidermis and avoid damage to the papillary dermis without simultaneous skin cooling while creating a zone of thermal coagulation deep within the reticular dermis and subcutaneous layers [12]. It is also known that absorption of IFUS energy is independent of chromophores such as melanin and hemoglobin and therefore, the use of IFUS may be specifically meritorious in treatment of darker skin types [12].

The lack of severe side effects noted would lead the author to believe that combining these two treatments is safe and poses minimal risk as an outpatient treatment regimen. The author believes that this study should serve as a motivator to encourage the use of combining minimally invasive treatments to treat the lower face and neck safely in an outpatient setting. However, close follow up is recommended and strict treatment protocols outlined by the device manufacturer and those published in literature must be followed.

Further safety and efficacy studies need to be done using different techniques and treatment in combination to the treatments done here to assist in creating safe and effective guidelines for the combination of such treatments. Studies must also be done to include histological analysis of the resulting tissue changes to better understand the effect of combining treatments and better estimate their safety.

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