

## New Protocol: EndoliftX Laser and Hyaluronic Ac+ Calcium Hydroxiapaptite as an Effective Approach for Facial Rejuvenation- Case Series of 7 Patients

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Submitted: 2023, Oct04; Accepted: 2023, Nov01; Published: 2023, Nov 24

**Citation:** Ilaria, P., Dybala, A. E., Garori, M., Potenza, C. (2023). New Protocol: EndoliftX<sup>®</sup> Laser and Hyaluronic Ac+ Calcium Hydroxiapaptite as an Effective Approach for Facial Rejuvenation- Case Series of 7 Patients. *Dearma J Cosmetic Laser Therapy*, 2(3), 39-48.

### Abstract

**Background:** Excessive submental fat and tissue laxity can significantly impact an individual's aesthetic appearance, leading to cosmetic dissatisfaction and concerns about aging. Non-invasive and minimally invasive treatments have gained popularity as alternatives to surgical interventions. Laser lipolysis, such as EndoliftX<sup>®</sup>, has emerged as a promising approach for submental fat reduction, and hybrid fillers, like HArmonyCa, have shown potential for enhancing tissue laxity.

**Objective:** This study aimed to evaluate the efficacy and long-term outcomes of a novel combined treatment protocol utilizing laser lipolysis and hybrid filler injection for submental fat reduction and tissue tightening.

**Methods and Materials:** A single-center, prospective, quasi-experimental controlled study was conducted, enrolling seven patients aged between 49 and 67 years. The protocol EndoliftX<sup>®</sup>, involved a 1470nm diode laser (LASEmaR 1500<sup>®</sup> Eufoton<sup>®</sup> Trieste, Italy) treatment (Endolift) followed by hybrid filler (HArmonyCa) injection. Various assessments, including clinical examination, Glogau Scale scoring, and 3D imaging, were performed at baseline and follow-up visits.

**Results:** The results demonstrated significant reductions in submental fat, improved cutaneous elasticity, and reduced wrinkle severity according to the Glogau Scale. Notably, these improvements were visible almost immediately post-procedure and continued to enhance over time, remaining prominent even after 12 months of observation. The treatment was associated with minimal discomfort and downtime.

**Conclusion:** The study highlights the effectiveness and longevity of the combined treatment protocol, making it a valuable option for individuals seeking non-surgical solutions for submental fat reduction and tissue tightening. While further research with control groups is warranted, laser lipolysis with EndoliftX<sup>®</sup>, and hybrid filler injection with HArmonyCa offer a minimally invasive and well-tolerated approach to address submental concerns and achieve favorable aesthetic outcomes, particularly in patients looking to avoid more invasive techniques.

**Keywords:** Aesthetic Medicine, Filler, Rejuvenation, Calcium Hydroxyapatite, EndoliftX<sup>®</sup>

### 1. Introduction

Excessive submental fat, often called submental adiposity, is the buildup of fat beneath the chin and upper neck. It results in a full or sagging appearance in this area, causing cosmetic dissatisfaction, especially when viewed from the side, which can make an individual appear older or overweight. Additionally, laxity of the subcutaneous tissues and the platysma muscle in the lower face can exacerbate the aging and fat accumulation effects. Aging leads to a loss of skin and tissue firmness, causing sagging and the development of jowls, further impacting facial

aesthetics. The increasing concern regarding these issues has driven interest in non-invasive and minimally invasive treatments for submental fat and tissue laxity. Patients now have various treatment options, including injectable treatments, non-surgical energy-based methods, and surgical procedures [1-10]. One minimally invasive option is laser lipolysis. This technique employs laser heat to rupture adipocytes and promote the reformation of the reticular dermis, stimulating neocollagenesis [11-15]. Another approach involves using injectable fillers like hyaluronic acid and calcium hydroxyapatite (CaHA) to induce

collagen formation, improving skin texture and laxity [16]. Our study introduces a novel protocol for addressing excess fat and laxity in the lower third of the face. It combines a 1470nm diode laser treatment (Endolift®) with subsequent injection of a CaHA filler (HarmonyCa®) for the middle third of the face. Remarkably, all patients achieved highly satisfactory and long-lasting results with this approach.

## 2. Methods

This research comprised a single-center, prospective, quasi-experimental controlled investigation carried out at the Dermatological Ambulatory of Dr. Ilaria Proietti in Latina, within the province of Rome. The study was conducted over the period spanning from April 2022 to December 2022, with patient assessments performed 12 months. Our primary objective was to evaluate alterations in cutaneous laxity and excessive submental fat using an innovative treatment protocol combining laser lipolysis and subsequent injection of a hybrid soft-tissue filler. The study group encompassed seven participants, consisting of one male and six females aged between 47 and 63, with a median age of 58 years. These individuals represented a range of skin phototypes classified as falling within categories II to III according to the Fitzpatrick Skin Phototype Classification. We assessed facial ptosis, wrinkles, and the extent of photoaging using standardized scales before and after the intervention. Participants who met any of the following exclusion criteria were not included: presence of chronic or acute inflammation or infection near the injection site; known hypersensitivity to any of the injectable or topical components utilized in the study; pregnancy or lactation; previous facial aesthetic surgery within the preceding six months; prior facial aesthetic procedures performed within six months before the study; preexisting autoimmune conditions; history of severe allergies or anaphylactic reactions, and an age below 18 years. This study adhered strictly to ethical guidelines as outlined in the Declaration of Helsinki, ensuring the safety, rights, and well-being of every participant. Prior to treatment, all subjects underwent comprehensive clinical evaluations by a specialist, and written as well as verbal informed consent were obtained from each patient.

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### 2.1 Technical Procedures

Following an initial patient evaluation and a comprehensive discussion of the potential risks associated with each procedure, the subsequent protocol was consistently implemented for all interventions. The treatment regimen commenced with the administration of a 1470nm diode laser, followed by the injection of a hybrid filler, specifically calcium hydroxyapatite (CaHA), occurring 30 days post-laser treatment. Preceding each procedure, the targeted skin area underwent thorough antisepsis using 0.5% alcoholic chlorhexidine. Subsequently, a local anesthetic cream, containing 5% lidocaine, was applied to the treatment site, with a 30-minute interval before the procedure's initiation. This anesthetic cream was completely removed immediately prior to the commencement of the treatment. **Table 1** provides a comprehensive overview of each patient's primary dermatological concerns, the quantities of anesthetic agents administered, as well as details regarding laser settings and the

energy levels applied during the procedures.

### 2.2 Laser Treatment-EndoliftX®

A meticulous clinical assessment was conducted to precisely determine the volume and location of submental fat tissue. Prior to introducing the laser fiber, a solution consisting of 5ml of lidocaine and 15ml of saline was injected into the subcutaneous tissue through a 22 G x 4.5 cm microcannula. The same skin puncture site was utilized for the insertion of the laser fiber. The laser procedure employed a 1470nm diode laser (LASEmaR 1500® Eufoton® Trieste, Italy) equipped with an optical fiber ranging from 300 to 400 microns (Eufoton®, FTF Linear Fiber). Laser power output ranged between 2-2.5 W, with parameters set at a T-on of 35-50 and a T-off of 55. On average, approximately 350 Joules were delivered per treated area.

The laser energy, when converted into heat, initiated a series of physiological responses, including:

- Disruption of adipocytes
- Immediate contraction of connective septa, resulting in tissue compaction
- Regeneration of elastic fibers
- Neocollagenesis, leading to the production of Type I and Type III collagen (in the subsequent months)
- Deep skin rejuvenation, with old collagen fibers gradually being replaced by newly formed ones

Following the laser treatment, patients were instructed to wear a lower face patch for a minimum of three hours and to perform manual massages of the treated area for at least seven days. Additionally, all patients were prescribed a course of antibiotic therapy, consisting of azithromycin 500mg administered once daily for three days.

### 2.3 Hyaluronic Acid+Calcium Hydroxyapatite- HARmonyCa®

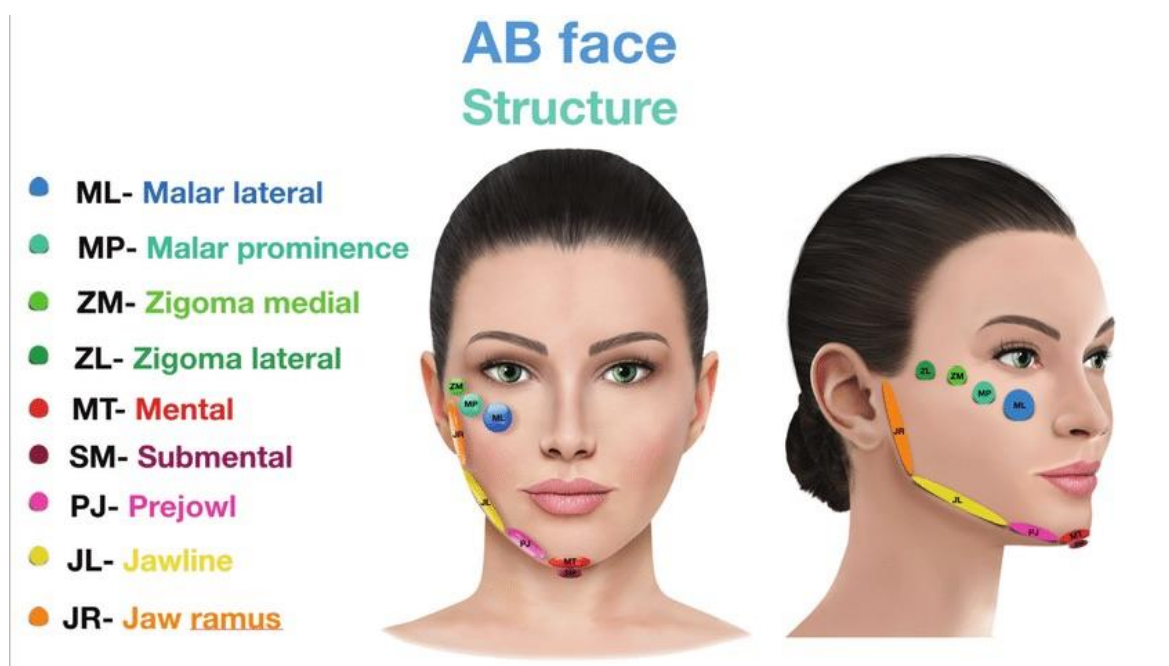
Each patient was positioned comfortably in a supine orientation at a 45-degree angle. The product employed was a combination of HARmonyCa (20 mg/mL hyaluronic acid, cross-linked with BDDE <2ppm), calcium hydroxyapatite (55.7%), and 0.3 ml of lidocaine. It was administered sequentially through a skin puncture in the subzygomatic region and along the anterior edge of the masseter muscle overlying the mandibular body. The injection was directed into the superficial subcutaneous layer in the posterior zygomatic area, utilizing a retrograde linear fanning technique with cannula advancement. Gentle massage and compression of the punctured skin area were applied. In total, 2.5 mL of HARmonyCa was administered per patient, with the application involving two 1.25 mL syringes, one for each hemiface, targeting AB Face Structure points, specifically JR and ZL (as shown in Figure. 1).

Hyaluronic acid contributes to the formation of a supportive extracellular matrix that regulates fibroblast proliferation. Simultaneously, calcium hydroxyapatite microspheres stimulate collagen production. Hyaluronic acid binds to fibrin, facilitating the creation of this supportive extracellular matrix. This process leads to the development of a "hyaline cartilage-like" structure by prompting the differentiation of fibroblast cells into chondroblasts, which deposit endogenous collagen-nature's natural skin lifting agent. The gel gradually degrades in concert

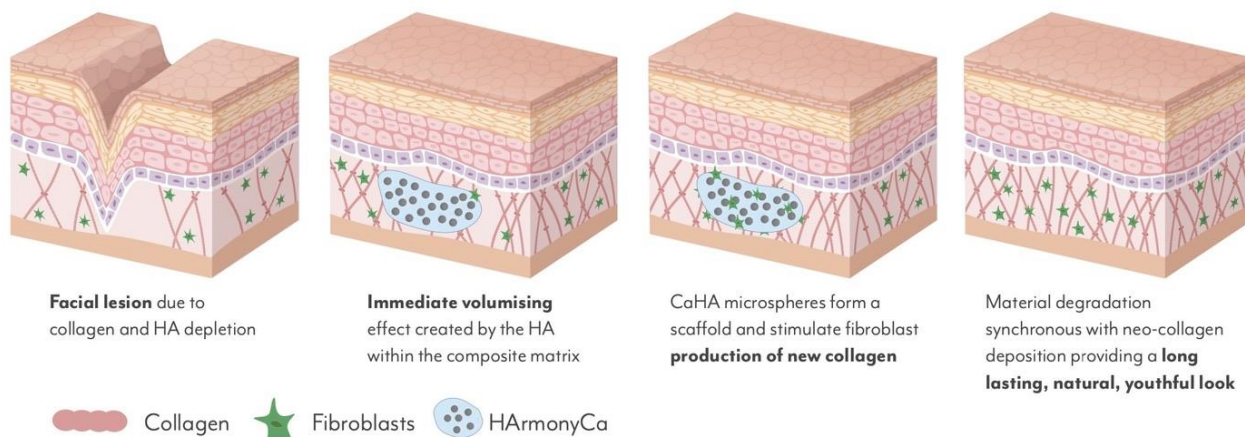
with neocollagen production, resulting in a naturally rejuvenated appearance that is both youthful and long-lasting (Figure. 2).

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
Lower third problematics	Filler complications, Change in neck-chin corner	Subcutaneous fat in the submental area, Smoothed neck-chin corner, Ptosis of the lower third of the face, Change in the contour of the lower jaw	Loose jowls, Pronounced change in the contour of the lower jaw, Local excess of subcutaneous fat in the submental area, Neck skin laxity, Decreased platysma tone	Moderate jowls Ptosis of the lower third	Moderate jowls Ptosis lower third Subcutaneous fat submental area	Early jowls Submental fat Smoothed neck-chin corner	Moderate jowl Ptosis lower third
Anesthetics (quantity)	10CC	15CC	20CC	13cc	20cc	20cc	15cc
Fiber	300	400	400	300	300	400	300
Power	2.2	2.5	2.5	2.2	2.2	2.5-3	2.3
Ton	35	35-45	40-50	30	30	40-55	35
Toff	50	55	55	55	55	50	50
Joules	900	1200	1350	1000	950	1300	1200
Middle third injection area	JR, ZL	JR, ZL	JR, ZL	JR,ZL	JR, JL ZL	JR, ML ZL	JR, JL, ZL
Quantity	3ml	3ml	3ml	3ml	3ml	3ml	3ml

**Table 1. Patients’ Principal Cutaneous Concerns, Volume of Anesthetics, laser settings and applied energies.**



**Figure 1:** The Areas of Injection According to Ab Face Structure. One syringe Containing 1.25 ml of Harmonyca was Injected in each Side.



**Figure 2:** The Role of HarmonyCa in Producing New Collagen and Volumizing Effect.

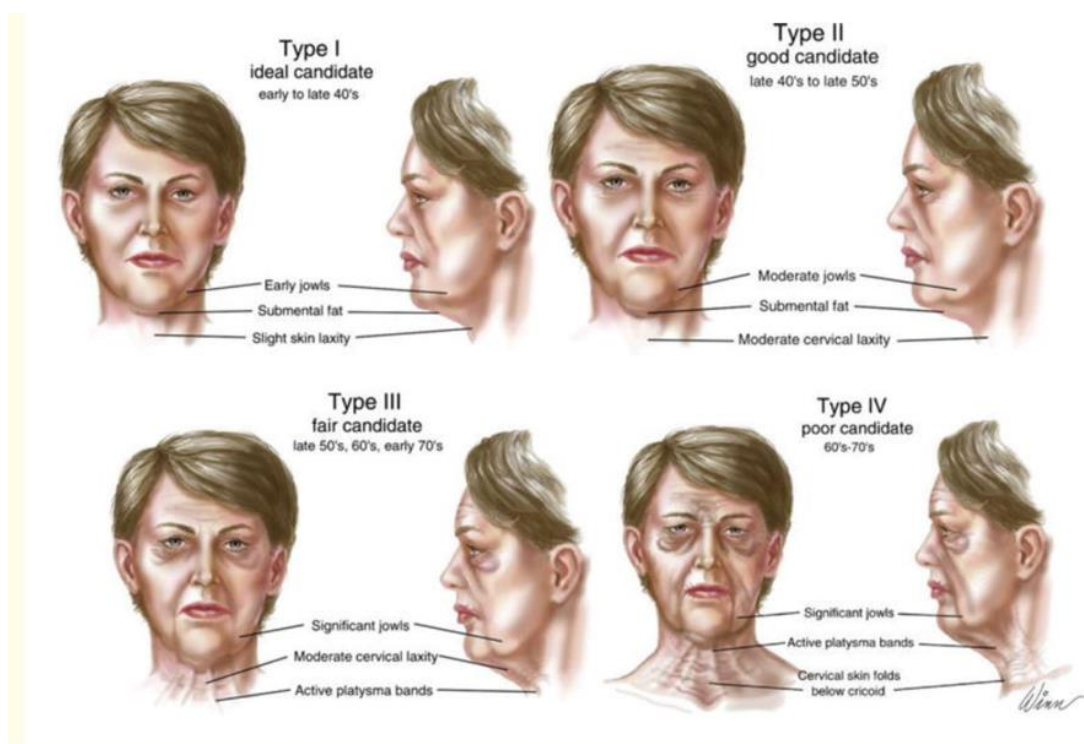
### 3. Data Collection

In this research study, a certified dermatologist was enlisted to compile data and evaluate each patient. During the initial visit, the following data points were recorded:

- a. Patient's age Gender

- b. Phototype classification based on the Fitzpatrick scale  
Classification of facial ptosis in accordance with Baker's Classification (Figure. 3)

Throughout the study, including baseline and subsequent follow-up visits at 30, 60, 90 days, and after a 12-month.



**Figure 3:** Baker's Classification of Face Ptosis

	Description	Skin characteristics
Type 1: "no wrinkles"	Early photoaging	Mild pigment changes No "age spots" Minimal wrinkles
Type 2: "wrinkles in motion"	Early to moderate photoaging	Early brown "age spots" Keratoses palpable but not visible Parallel smile lines begin to appear
Type 3: "wrinkles at rest"	Advanced photoaging	Obvious dyschromia Visible brown "age spots" Visible capillaries (telangiectasias) Wrinkles present at rest
Type 4: "only wrinkles"	Severe photoaging	Yellow-gray skin color Precancerous skin changes and/or prior skin malignancies Wrinkles throughout, at rest or moving

**Figure 4:** Glogau Wrinkles and Photoaging Severity Score

#### 4. Results

Our research involved the participation of seven individuals (1 male and 6 females) with ages ranging from 49 to 67 years, with a median age of 58 years. None of the participants had a significant medical history of note, except for one patient who had experienced a local infection following dental treatment, which had been successfully treated with antibiotic therapy eight weeks prior to the laser procedure. All previous aesthetic treatments had been performed at least six months before their enrollment in this study.

Regarding the patients' phototype, they predominantly fell within the range of Fitzpatrick II and Fitzpatrick III, with 2 patients classified as Fitzpatrick II and 5 patients as Fitzpatrick III. Baker's classification types were distributed as follows: Type I-2, Type II-5, and Type III-IV-0.

The Glogau Scale scores, which evaluate the severity of wrinkles and photoaging, demonstrated noteworthy improvements:

- a. At baseline, 5 patients were classified as G3, and 2 patients as G4.
- b. At the 30-day visit, 6 patients were categorized as G3, with 1 patient as G4.
- c. At the 60-day visit, all patients had G3 scores, with none falling under G4.
- d. At the 90-day visit, 1 patient achieved a G2 score, while

6 patients remained at G3, with none at G4.

- e. Remarkably, at the visit after 12 months, improvements persisted, with patients distributed as follows: G2 (patients), G3 (patients), and G4 (patients).

Moreover, 3D images captured during the study revealed significant enhancement in all seven patients, with Figures 5-19 illustrating representative examples.

#### Example Patient n.1

57-years-old female, Fitzpatrick 3, Glogau 3, Baker's classification type 1, developed filler complication in the lower third of the face due to a bacterial infection after a dental procedure. After dissolving the filler with hyaluronidase and prescribing oral antibiotic therapy around 8 weeks before, the patient was included in the study. The major concern was to improve residual problematics after hyaluronic acid dissolution such as marked skin laxity. The other goals were the improvement of the submental fat, and smoothening of lower jaw and neck-chin corner. Optical fiber of 300 microns was used for the laser treatment; following settings were applied: Power 2.2W, Ton 35, Toff 55 with a total amount of the energy of 900Joule. One month after the laser treatment two syringes of hybrid filler (one per side) were injected. (Figure 5-7)



**Figure 5:** Example patient n. 1; time 0, no laser treatment, no hybrid filler.



**Figure 6:** Example patient n. 1 three months after laser treatment and two months after hybrid filler. The blue area shows where HarmonyCa was injected.

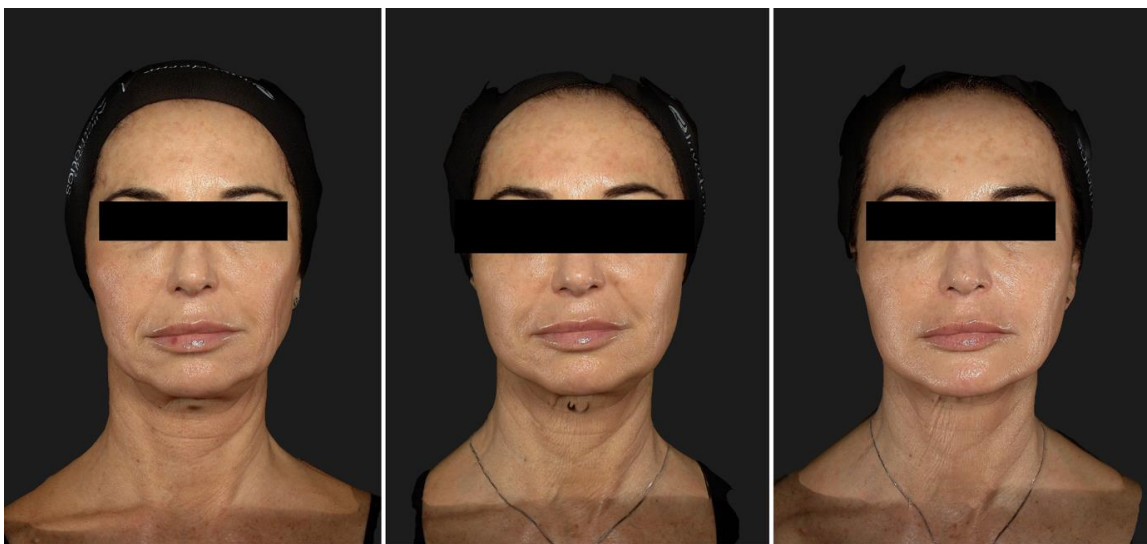


**Figure 7:** Example patient n. 1 before the treatment and after three months.

**Example Patient n.2**

55-years-old female, Fitzpatrick 2, Glogau 3, Baker's classification type 2. Came to our clinic complaining of local excess of subcutaneous fat in the submental area, smoothed neck-chin corner, ptosis of the lower third of the face with a

pronounced change in the contour of the lower jaw. For the laser treatment optical fiber of 400 microns was used, Power 2.5, Ton 45, Toff 55 with a total amount of energy of 1200Joule. Two syringes of hybrid filler (one per side) were injected one month after the laser treatment. (Figure. 8)



BEFORE

AFTER 2 MONTHS

AFTER 3 MONTHS



BEFORE

2 MONTHS AFTER

3 MONTHS AFTER

**Figure 8:** Example patient n.2. From the left: before the treatment; 60 days after the treatment (30 days after laser procedure and 30 days after filler injection); 90 days after the first treatment.

**Example Patient n. 3**

49-years-old female, Fitzpatrick 2, Glogau 2, Baker's classification type 3. Came into our clinic complaining of loose jowls, pronounced change in the contour of the lower jaw, local excess of subcutaneous fat in the submental area, smoothed neck-chin corner, neck skin laxity, and decreased platysma tone. She had

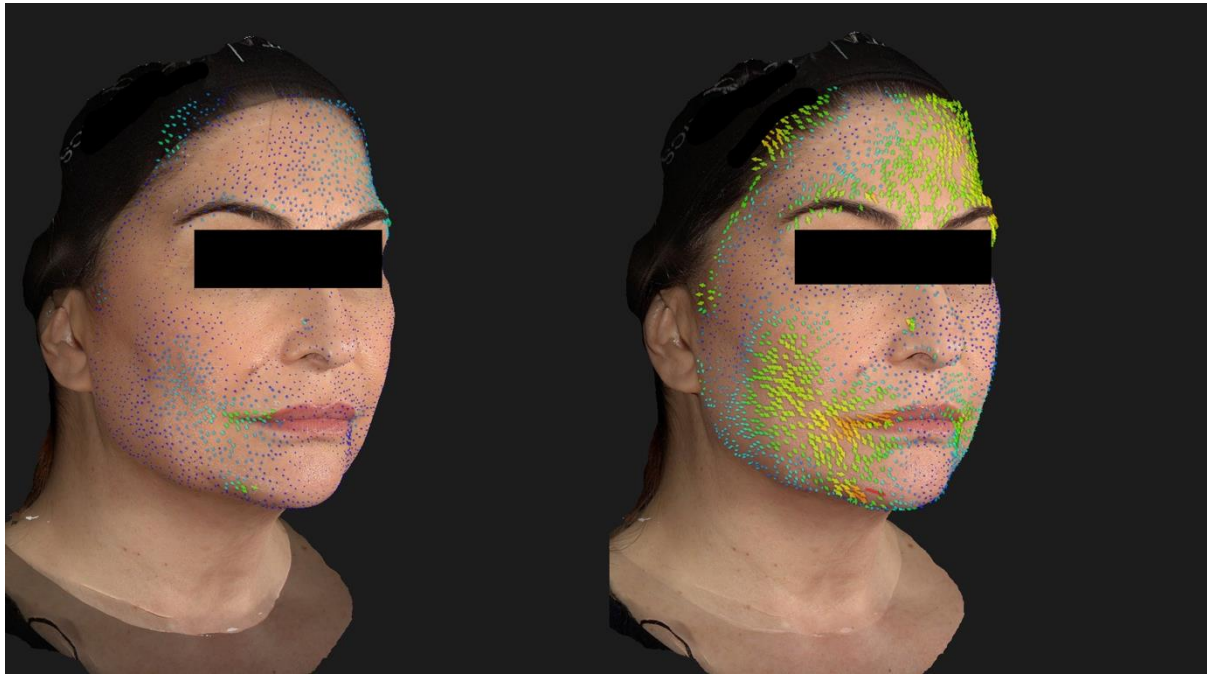
done o previous treatments in these areas. For the laser treatment an optical fiber of 400 microns was used, Power 2.5, Ton 40-50, Toff 55 with a total amount of applied energy of 1350Joule. Two syringes of hybrid filler (one per side) were injected one month after the laser treatment. (Figure. 9)



Before

30 days after filler treatment





**Figure 9:** Example Patient n. 3; on the left- patient after laser procedure and before filler injection, on the right- 30 days after filler treatment and 60 days after laser procedure.

Importantly, localized and self-limiting side effects, such as mild edema, pain, and ecchymosis, were infrequently reported. Notably, no instances of vascular occlusive events or infections were observed following the procedure. The results demonstrated that both the laser treatment and filler injection led to increased skin thickness, density, and elasticity. The combination of these procedures effectively addressed deficiencies in adipose tissue by promoting the natural generation of endogenous collagen, yielding enduring improvements that persisted even after 12 months.

## 5. Discussion

The outcomes of our study substantiate the effectiveness and long-term sustainability of an innovative combined treatment protocol, which incorporates laser lipolysis and hybrid filler injection as a comprehensive solution for addressing submental fat and tissue laxity. Notably, the remarkable improvement in patient outcomes was discernible almost immediately post-procedure, and this enhancement continued to progress over time, remaining evident even after a year of observation. Our findings unveiled a substantial reduction in submental fat deposition, coupled with a noticeable enhancement in cutaneous elasticity. The Glogau Scale scores corroborated the discernible improvements in wrinkles severity. Most notably, the majority of patients transitioned from higher Glogau categories to lower ones with time, signifying a marked and sustained benefit over an extended period [17]. This underscores the enduring and long-lasting effects of the treatment, which culminate in a more youthful and aesthetically pleasing appearance that persists beyond the immediate post-treatment period.

It is imperative to acknowledge the limitations inherent in our study, particularly the absence of a control group for comparative assessment. Future research endeavors should diligently integrate control groups to further authenticate and substantiate

the efficacy of our treatment approach. When considering the array of available submental fat reduction procedures, including injectable treatments, non-surgical energy-based methods, and surgical procedures, each approach presents its own set of advantages and disadvantages. Clinicians must carefully select the most suitable treatment for individual patients. Injectable treatments, like deoxycholic acid (e.g., ATX-101 or Belkyra), offer a non-invasive option for submental fat reduction. These treatments are minimally painful and require minimal downtime, making them appealing to many patients. However, they may necessitate multiple sessions, and the results can take time to become noticeable. On the other hand, non-surgical energy-based methods, such as radiofrequency devices and cryolipolysis, can provide more rapid results with a single session but may entail discomfort during treatment and potentially longer recovery times due to swelling and bruising [1-9].

Surgical procedures, like liposuction or platysmaplasty, are invasive and carry more significant risks and recovery periods. They are typically reserved for cases with severe submental fat and laxity. In contrast, laser lipolysis offers a minimally invasive alternative with a shorter recovery period, less discomfort, and the ability to precisely target treatment areas. Laser lipolysis is a particularly suitable choice for patients who prefer non-invasive treatments and wish to avoid more "aggressive" techniques [11,12]. Moreover, it can be applied in areas that are not suitable for traditional liposuction or in cases where additional sculpting is needed after prior liposuction procedures. Furthermore, laser lipolysis stimulates neocollagenesis, enhancing skin texture and elasticity over time, which is a unique advantage not shared by many other methods [11-15]. In summary, our study underscores the robustness of a combined treatment protocol involving laser lipolysis and hybrid filler injection for submental fat reduction and tissue enhancement. The sustained improvements observed in both clinical examination and 3D imaging further underscore

the potential of this approach in addressing submental concerns and achieving highly favorable aesthetic outcomes. Nonetheless, future research endeavors should encompass control groups to bolster the validity of our findings and refine the treatment protocol. Clinicians should also remain attentive to the potential collateral effects of laser lipolysis while considering its advantages in comparison to other submental treatment procedures. Ultimately, the choice of treatment should be tailored to the patient's specific needs and preferences, with laser lipolysis emerging as a compelling option in many cases.

## 6. Conclusions

In conclusion, our study presents an innovative treatment protocol that effectively addresses submental fat accumulation and tissue laxity through the combination of minimally invasive and nearly painless procedures, including laser lipolysis and hybrid filler injection. The outcomes of this research showcase not only immediate and substantial improvements in patient outcomes but also the remarkable longevity of these effects, which persist even after a year of observation. These findings underscore the potential of this combined therapy in delivering enduring aesthetic enhancements with minimal downtime, ultimately contributing to greater patient satisfaction. While our study lacked a control group, the advantages of laser lipolysis, such as its minimally invasive nature and the stimulation of neocollagenesis, position it as a compelling and well-tolerated option for submental rejuvenation. Moreover, the use of hybrid fillers, exemplified by HArmonyCa<sup>®</sup>, provides a holistic solution, promoting natural-looking and long-lasting volume restoration and skin rejuvenation. Future investigations incorporating control groups will further elucidate the efficacy of this treatment approach and refine its clinical application.

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