

Original Research

Facial Rejuvenation and Patients Satisfaction with the Fourth Generation of Aptos P(LA/CL)-Hyaluronic Acid Threads: A 12-Month Study

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E-mail: dr.kajaia@tcc.ge; dr.kajaia@tcc.ge**Article information****Received:** April 17th, 2024; **Revised:** May 21st, 2024; **Accepted:** May 30th, 2024; **Published:** May 31st, 2024**Cite this article**Kajaia A. Facial rejuvenation and patients satisfaction with the fourth generation of aptos P(LA/CL)-hyaluronic acid threads: A 12-month study. [In press]. *Trichol Cosmetol Open J.* 2023-2024; 6(1): 7-15. doi: [10.17140/TCOJ-6-120](https://doi.org/10.17140/TCOJ-6-120)**ABSTRACT****Objective**

New generation of biodegradable thread: polycaprolactone (P(LA/CL) copolymer monofilament thread coated by the shell composed of nano- and microparticles of hyaluronic acid (HA) encapsulated into polycaprolactone (P(LA/CL) copolymer shell has been lately introduced by Aptos company as the NAnoMicroCapsules (NAMICA) technology. NAMICA, which utilizes particles consisting of unstabilized (non-cross-linked) HA surrounded by P(LA/CL) nanofibers, securely fixed to lifting threads, is thought to provide long-lasting biostimulating and rejuvenation effects. This study evaluates the 12 month-long skin quality improvement, and lifting effects of the P(LA/CL)-HA threads produced with NAMICA technology on the middle and lower third of the face.

Research Design and Methods

Twenty-six (26) patients, women and men aged 30 to 65-years underwent a mid and lower face lifting using the 4th generation of Aptos P(LA/CL)-HA threads created with NAMICA technology. The threads were applied on the right and left sides symmetrically per 5 threads on each side of the face. Patients' satisfaction and facelift were assessed at study follow-ups.

Main Outcome Measures

Skin quality improvement, midface lift, and patients' satisfaction with the procedure outcome overall, and specifically, satisfaction with facial appearance, skin, cheekbones and cheeks, lower face, and jawline were explored at 4, 9 and 12 months after the procedure and compared with the scores given at the enrolment.

Results

Our results demonstrate that the NAMICA technology provides a significant skin quality improvement, and facial lift which is preserved for 12 months from treatment. The skin quality parameters as wrinkles, evenness and redness improvement were observed during 12 months after new generation threads implantation. The procedure is well-tolerated in all studied subjects with no adverse effects or undesirable symptoms at later follow-ups. Patients' satisfaction scores are kept significantly high for all measured parameters.

Conclusion

This study supports the use of 4th generation of P(LA/CL)-HA threads with NAMICA technology to achieve and preserve an improvement in skin quality, meaningful facial lift, and patients' satisfaction for at least 12^omonths post-treatment.

Keywords

Facelift; Midface lifting; Aptos threads; P(LA/CL)-HA threads; NAMICA technology; Face rejuvenation.

INTRODUCTION

The process of facial aging is manifested as the structural deformities of the skin and hypodermis.¹ Main visual markers of facial aging, such as wrinkle formation, sagging of facial soft tissue,

and distortion of oval contour, are more sharply exteriorized in the middle zone of the face.² Midface rejuvenation is a hastily developing field in aesthetic medicine. Huge demands come towards minimally invasive treatments having a short recovery period, quicker functioning time, and long-lasting satisfactory effects.³

Nowadays in majority of cases, the aesthetic treatment methods are combined to receive desirable combined rejuvenating effects as eliminating sagging skin through mechanical lifting and repositioning of skin and subcutaneous tissue and skin quality improvement. For such goals, aesthetic medicine professionals combine the methods of thread lifting and hyaluronic acid injections. Face-lifting with barbed threads has gained great popularity in the last few years. Various face-lifting threads are present on the market nowadays. Polydioxanone (PDO) threads, poly-L-lactic acid (PLLA) threads, PLLA/polycaprolactone (PCL) threads are predominantly used. New generations of threads are thought to reduce side effects, extend the functioning time, improve satisfaction, and promote skin surface reparation.^{4,5} Threads developed by Aptos LLC (Aptos, Tbilisi, Georgia) are composed of the copolymer poly-L-lactic acid (PLLA) and polycaprolactone (PCL) providing this product-P(LA/CL) with a long-lasting biostimulating effect by the slow and gradual release of PLLA—a potent stimulator of collagen production.^{5,6} As a result, the patient not only has an instant improvement in the shape of their face but also a faster rejuvenating and long-lasting biostimulation effect with thicker, glowing skin.

In parallel to facelifts, the application of dermal fillers is becoming increasingly popular for skin rejuvenation purposes. Hyaluronic acid (HA) as it is known to be involved in foremost biological functions, such as the regulation of cell adhesion and motility, the manipulation of cell differentiation, and cell proliferation and becomes degrade as body ages, has been lately successfully administered as filler. HA-based fillers have launched quickly and widely because of its biocompatibility, non-teratogenicity, safety, durability, ease of application, and good cost/benefit ratio.

Because of its hydration and bio-stimulative effect, hyaluronic acid injections are widely used in aesthetic medicine for skin rejuvenation purposes. However, there are challenges that are faced in aesthetic medicine for hyaluronic acid treatments methods. *In vivo*, HA rapidly degrades by enzymes and radicals existing in the human body.⁷ HA in dermal fillers must therefore be modified to increase its resistance to degradation once injected.⁸ The modification includes Cross-linking of HA polymers—chemically stabilizing the HA molecules. The cross-linking is preventing it from fast degradation. However, the chemical stabilization of HA molecules have its disadvantages and causes complications in HA injections.⁹

Both non-cross-linked and cross-linked HA-fillers have been utilized in aesthetic centers, nevertheless, hygroscopicity and overall effectiveness is more preserved in unstabilized i.e. non-cross-linked molecules of HA.¹⁰

Recently, Aptos LLC has introduced a new generation of threads, in which P(LA/CL) copolymer thread is surrounded with coating consisting of unstabilized (non-cross-linked) HA molecules encapsulated into P(LA/CL) copolymer shell embedded in the net of P(LA/CL) nanofibers around the core P(LA/CL) monofilament thread. This technology named NAnoMIcroCApsules (NAMICA) is believed to provide a long-lasting skin rejuvenation and tissue lift-

ing. The goal of this study was to evaluate the 12 month rejuvenating, skin quality improvement and midface lifting effects of Aptos threads produced with NAMICA technology.

PATIENTS AND METHODS

Patients

Twenty-six (26) subjects undergoing midface thread lifting procedure in the Aesthetic Clinic “TotalCharmVake”, Tbilisi, Georgia, from April 2022 to December 2022 were involved in this prospective study. The study was carried out in accordance with the guidelines laid down in the Declaration of Helsinki and the study protocol approved by the local Ethics committee. Informed consent was obtained from every study subject. The selected patients had aging facial appearance graded with 10-100 points according to the visual scales. All included patients had Fitzpatrick skin phototype I-VI. The age of included women and men was 30 to 65-years. Exclusion criteria were: any previous use of facial threads or previous facial esthetic surgery, use of permanent fillers or hydroxylapatite fillers, pregnancy, allergy, and autoimmune diseases, complicated chronic illnesses, and skin infections. Collected demographic data included age, gender, race, weight (kg), height (m). Other baseline/screening data included general medical history.

Description of the Technique

After clinical examination, all patients underwent thread-lifting procedures in accordance to the Manufacturer’s Instructions for Use. Five threads were applied to each of two sides of the face (1 package of the product - 10 threads were used in total for one patient) with the entry point in the line from the lateral canthus to the tragus; at 1-1.5 cm from the hairline. This point will be in the projection of a cluster of strong fibrous cords linked with the periosteum of the zygomatic arch (Figure 1).

Once areas to be treated were disinfected and cleaned with an antiseptic solution, local anesthesia was applied. Anesthesia was performed symmetrically on each side of the face. Firstly, entry points were injected with 1% lidocaine mixed with epinephrine. Skin was punctured so that anesthetic solution was infiltrated along the pre-marked location for each thread placement. 190 mm absorbable threads with multidirectional barbs comprised of P(LA/CL)-HA (NAMICA Technology) were pre-loaded into 21G round tip cannula (Figures 2).

Cannulas were pulled through so that the threads were placed in subcutaneous tissue. Both sides of the face were treated with five P(LA/CL)-HA threads. Three threads were implanted in the midface area and two threads in the lower face area. (Figure 3). Implanted threads were compressed, cannulas were removed, and the puncture was closed using a medical strip. Patients were provided with post-treatment recommendations.

Data Assessment

Calibrated and stereoscopic images of the patient’s face were ac-

Figure 1. NAMICA Utilizes Particles Consisting of Unstabilized (Non-cross-linked) HA Surrounded by P(LA/CL) Nanofibers, Securely Fixed to Lifting Threads

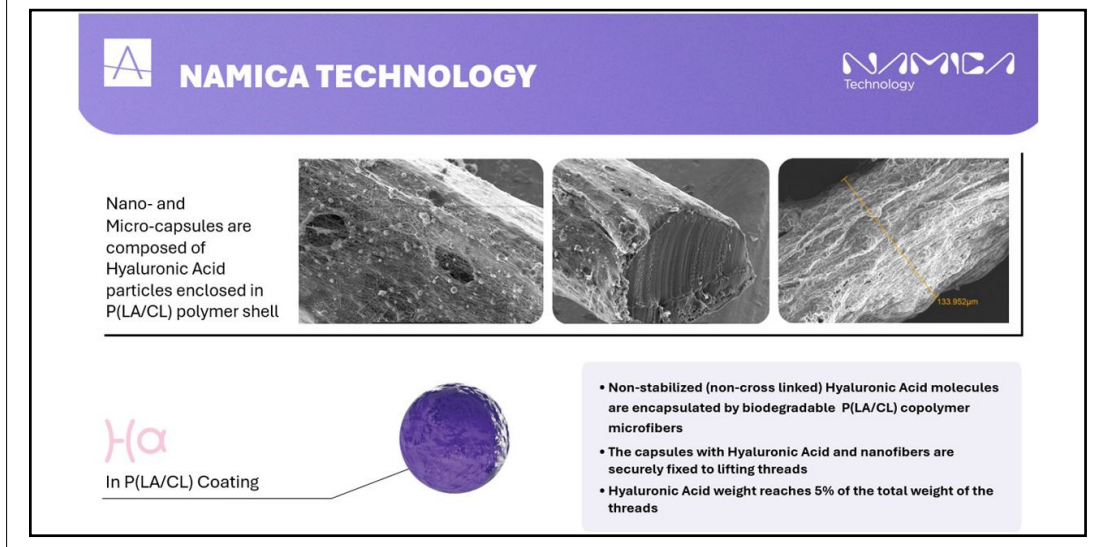


Figure 2. P(LA/CL) – HA View

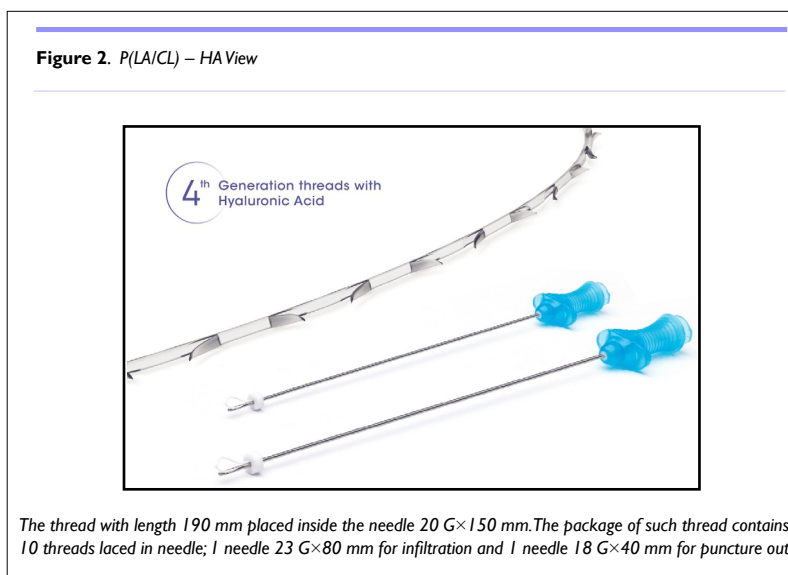
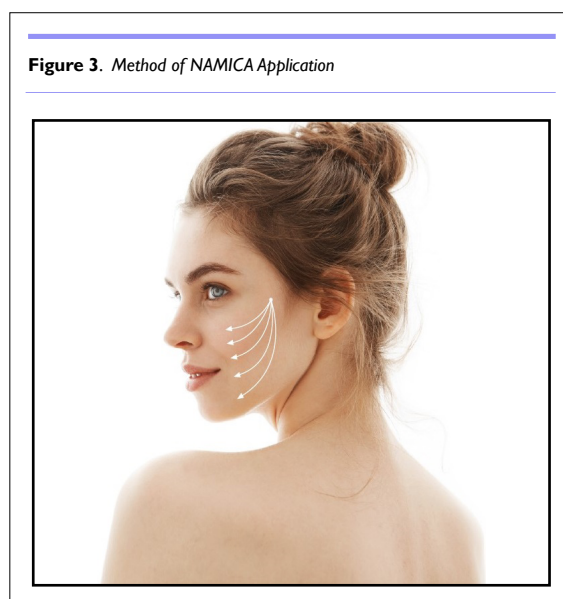


Figure 3. Method of NAMICA Application



quired with a passive stereovision digital camera LifeViz Mini (Quantificare S.A., 06410 Biot, France, version: 3.15.13, Patent US 9,621,875) and its Quantificare 3D Viewer + surface reconstruction and analysis. This equipment was used for skin quality parameters (wrinkles, evenness, oiliness, redness) and lifting level assessment. Skin quality parameters (Wrinkles and evenness) measuring value using this method of assessment is scored from -10 to +10, per which -10 is the worst case (for example for wrinkles it is many deep wrinkles) to +10 is the best case (no wrinkles). Redness improvement was assessed by blinded Physicians' visual assessment of images analyzed by LifeViz® software and compared post-procedure with baseline images. Lifting was measured in mm.

Subject-reported outcomes were assessed using the validated FACE-Q® questionnaires (Satisfaction with the procedure; Satisfaction with facial appearance, Satisfaction with skin).

All patients accepted the reproduction of their recognizable photographs.

All included patients were asked to fill the correspondent FACE-Q® – patient-reported outcome questionnaire (FACE-Q®

2020 Memorial Sloan-Kettering Cancer Center, all rights reserved) at D0 and 4 months, 9 months, and 12 months after the procedure. The domains reported in the FACE-Q® are Satisfaction with facial appearance, satisfaction with skin, adverse effects: skin, appraisal of lines: overall, satisfaction with cheeks, satisfaction with cheekbones, appraisal of lines: nasolabial folds, appraisal of lines: marionette, adverse effects: cheeks, lower face and jawline.

GraphPad Prism software was applied for the statistical analyses. Chi-squared test was used to evaluate facial lift, and the Wilcoxon signed-rank test was employed to evaluate differences in the total mean surface area of facial lift. The scale questions were summed up based on the FACE-Q® recommendations. Differences at three time intervals were compared using a non-parametric Wilcoxon Sign Rank test. The normal approximation has been applied and a *p*-value of less than 0.05 was considered statistically significant.

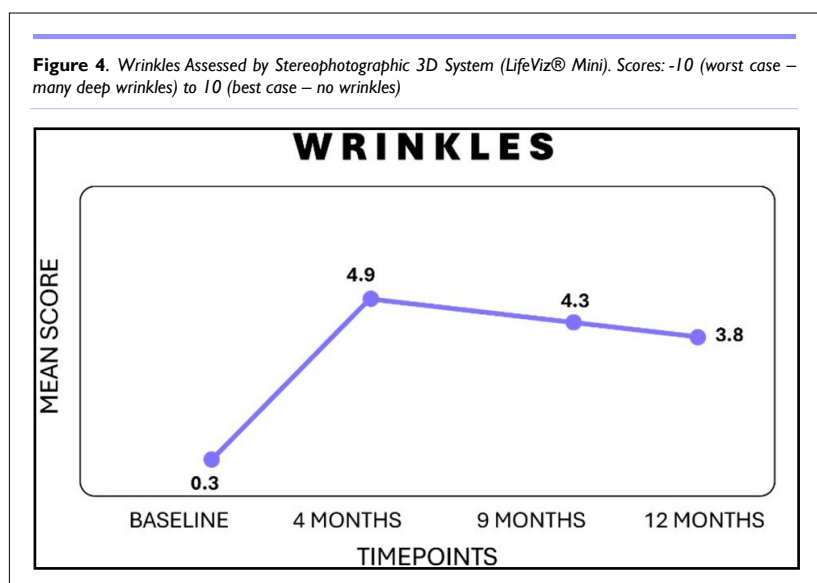
RESULTS

Skin quality parameters wrinkles, and evenness score was improved significantly at each timepoint 4, 9, and 12 months (Table 1).

Skin quality parameters	4 Months			9 Months			12 Months		
	Improved % (n)	No Change	Worsened	Improved % (n)	No Change	Worsened	Improved % (n)	No Change	Worsened
Wrinkles	100% (26)	0	0	100% (26)	0	0	96.2% (25)	3.8%(1)	0
Evenness	92.4% (24)	7.6% (2)	0	92.4%(24)	7.6%(2)	0	96.2% (25)	3.8%(1)	0
Red spots(redness)	100%(26)	0	0	96.2 (25)	3.8% (1)	0	92.4%(24)	7.6%(2)	0

Wrinkles improved in 100% (26) at 4 and 9 months and in 96.2% (24) at month 12. The mean baseline score calculated as 0.3

score increased to 4.8 at month 4, 4.2 at month 9, and 3.8 at month 12 (Figure 4).



The mean baseline score for evenness calculated for baseline as 1.15 score increased to 4.0 at month 4, 4.42 at month 9, and 5.46 at month 12 (Figure 5). Redness improvement assessed

by 3 blinded evaluators was assessed as improved in 100% (26) of patients at month 4, in 96.2% (25) at month 9, and in 92.6% (24) at 12 months (Figure 6).

Figure 5. Evenness Assessed by Stereophotographic 3D System (LifeViz® Mini). Scores: -10 (worst case—rough skin) to 10(best case—smooth skin)

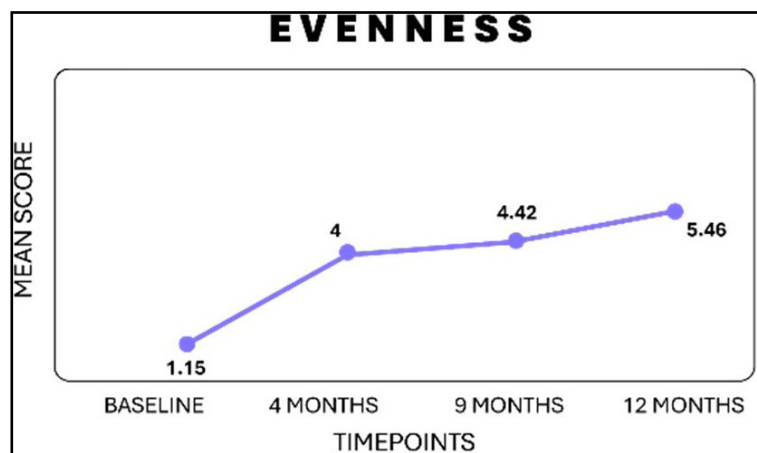
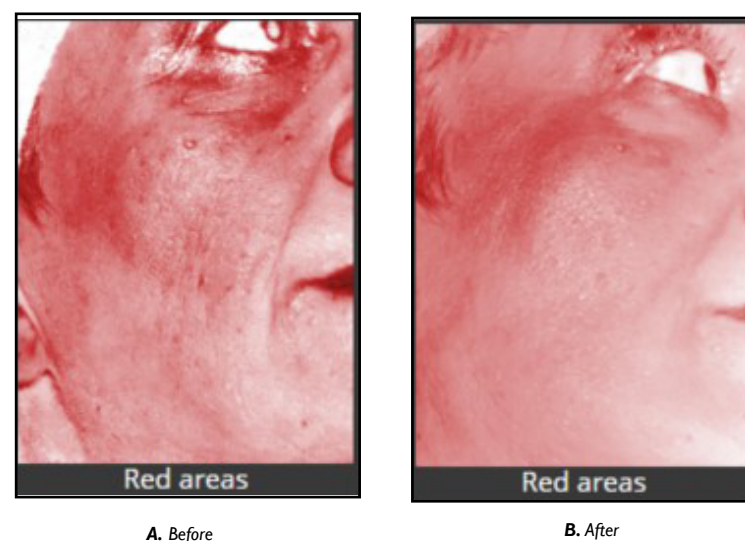


Figure 6. Blinded Physicians' Visual Assessment of Images Analyzed by LifeViz® Software for Redness and Comparison of Post-procedure Images with Baseline



Meaningful changes in facial lifting were effectively measured using 3D surface imaging techniques at 4, 9, and 12 months post-treatment separately on the right and left side of the face.

Measurement results are summarized in Table 2. The lifting effect was maximal at month 4 and maintained till month 12.

Table 2. Changes in Facial Lift (mm) on the Right and Left Side 4, 9 and 12 months post Treatment

Amount of Facial Lift	4 months post-treatment subjects, % Right/Left	9 months post-treatment subjects, % Right/Left	12 months post-treatment subjects, % Right/Left
≥0.5mm	100/100	100/100	100/100
≥1.0mm	100/100	100/100	42/50
≥1.5mm	83/79	50/62.5	0/0
≥2.0mm	54/58	8.5/4	0/0

Subject-reported outcomes were assessed using the validated FACE-Q[®] questionnaire Satisfaction with the procedure, Satisfaction with skin, and Satisfaction with facial appearance. Subjects completed the questionnaire at the time of enrollment and at 4, 9 and 12 months post-treatment. Mean scores are based on a satisfaction scale: 1=very dissatisfied, 2=somewhat dissatisfied, 3=somewhat satisfied, and 4=very satisfied. All questions were scored between 3 (somewhat satisfied) to 4 (very satisfied) by all patients and there was no significant differences between 4 months, 9 months and 12 months measurements meaning that 100% of patients expressed meaningful satisfaction with the procedure through 12 months. To note, were no adverse effects or undesirable symptoms noted at any follow-ups.

Patients' satisfaction with facial appearance was analyzed scoring symmetrical, balanced, well-proportional, fresh, and rested look of it, as well as morning and night-time satisfaction with its appearance, profile look, and looks in photos. The scores were

statistically significantly elevated at all follow-up time points (4, 9, and 12 months) compared to the baseline and kept similar through 12 months. Importantly, the skin rejuvenation effect is the added value of the facelift. Evaluation of patients' satisfaction with their skin looks was high at all follow-up time points (Figures 7, 8 and 9)

The results for FACE-Q[®] Satisfaction with the procedure showed that 100% of patients were pleased with the results at all time points by 12 months. The results turned great for 92.31% at 4 months and 100% at 9 and 12 months. The results for FACE-Q[®] Satisfaction with skin, 100 % of patients were very satisfied at 4,9, and 12 months for below skin characteristics (e.g. Skin look at the end of the day, skin refreshed look, skin smoothness, skin hydration, skin even colored). For FACE-Q[®] satisfaction with skin appearance, 100% of patients were satisfied with facial appearance (e.g. symmetry, look at the end of the day, fresh look, rested look). Photographs of the patients before the procedure and 12 months after treatment with NAMICA are shown in Figures 10 and 11.

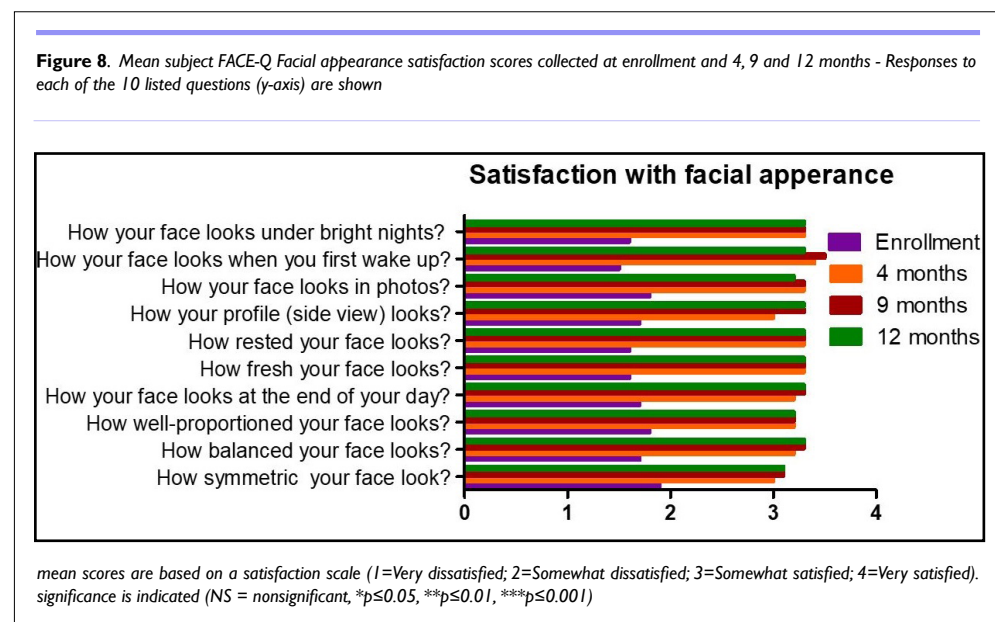
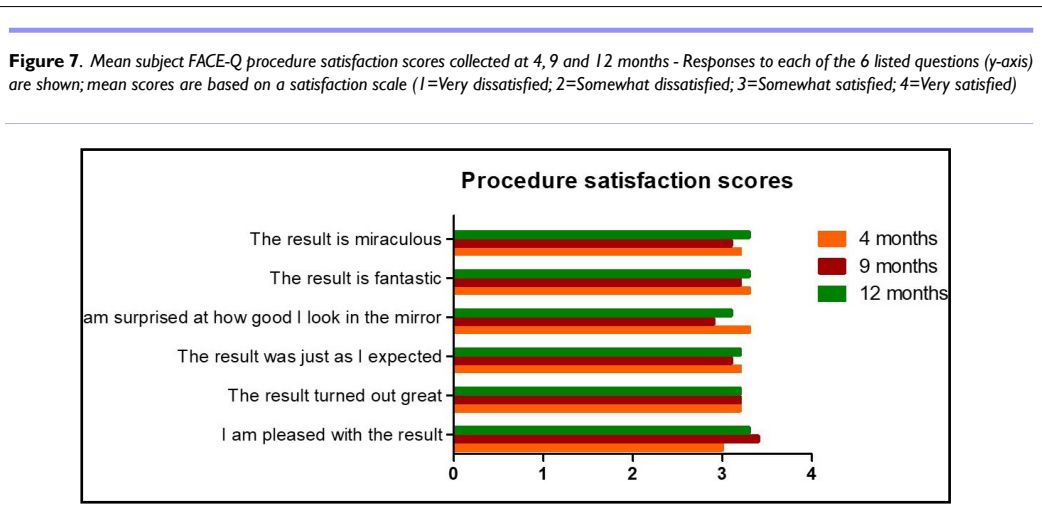
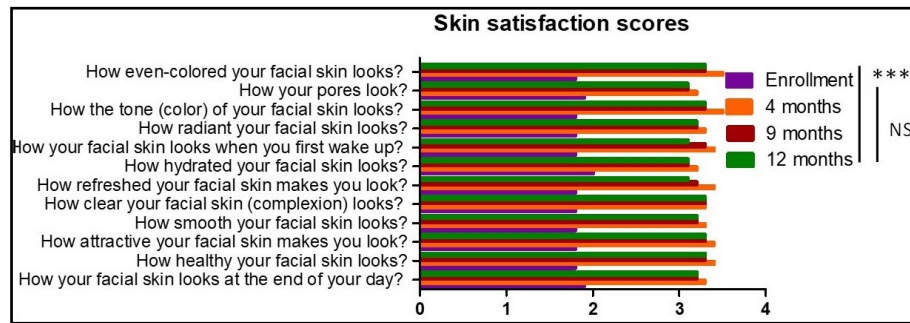
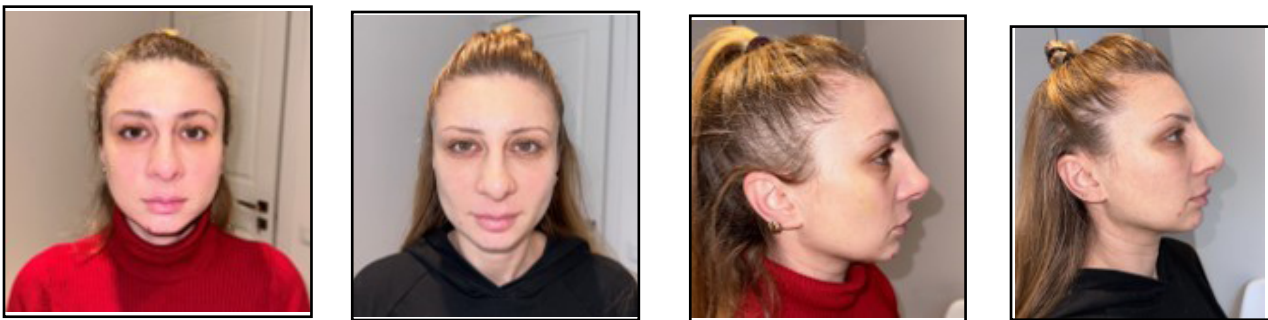


Figure 9. Mean subject FACE-Q Facial appearance satisfaction scores collected at enrollment and 4, 9 and 12 months - Responses to each of the 12 listed questions (y-axis) are shown



mean scores are based on a satisfaction scale (1=Very dissatisfied; 2=Somewhat dissatisfied; 3=Somewhat satisfied; 4=Very satisfied). significance is indicated (NS = nonsignificant, *p<0.05, **p<0.01, ***p<0.001)

Figure 10. Female, 35 Years Old Patient, Underwent Midface Lifting using the Aptos 4th Generation of Barbed P(LA/CL) – HA threads (NAMICA Technology)



Photos for following timelines: A, C—before the procedure; B, D—12 months after procedure

Figure 11. Female, 59-Years-Old Patient, Underwent Midface Lifting Using the Aptos 4th Generation of Barbed P(LA/CL)–HA Threads (NAMICA Technology)



Photos for following timelines: A, C—before the procedure; B, D—12 months after procedure

DISCUSSION

The allure of human beauty is intricately linked to the state of one’s skin, with flawless skin emerging as a universally appreciated trait. Underscoring the significance of maintaining healthy and high-quality skin is a key focus in our discourse on aesthetic medicine.

Numerous studies underscore the substantial influence of skin quality on emotional well-being, general quality of life, self-perception, and interpersonal relationships, highlighting the pivotal role of healthy skin in our narrative of well-being within the realm of aesthetic medicine. Data from this study supports the use of P(LA/CL)-HA threads produced with NAMICA technology

to achieve and preserve a meaningful skin quality improvement combined with facial lift, an overall rejuvenating effect, and patient satisfaction for a sufficient period of time post-treatment. In our study all subjects were treated on the right and left side symmetrically applying 5 threads per side: 1st thread till the lower jaw on the border of the jowl fat compartment, 2nd thread till the projection of mandibular cutaneous ligament, 3rd thread till the mouth angle, 4th till the middle part of nasolabial fold not crossing it and 5th till the nose alar angle. While similar studies describe the treatment of patients with 3 to 4 sutures in the midface, accumulating evidence suggests that optimal results are achieved with a holistic approach that most often includes four sutures in the midface, 1 to 2 sutures in the jowls or jawline, and two sutures in the upper neck, per side. Various studies describe the implantation of up to 8 sutures per side.¹¹⁻¹³ Thus, the selection of adequate number of sutures is critical for ensuring that there is sufficient support for repositioned tissue and abundant volumization for providing recontouring.

Our data show significant improvement in skin quality and lifting effect through the 12 month period indicating on the elements of tissue repositioning events around the treated area. Of importance, tissue repositioning and skin quality improvement have a crucial role along with hyperkinetic muscle relaxation, skin resurfacing, and tissue revolumization to achieve durable rejuvenation results. Most often patients demand for skin quality improvement along with thread lifting is supported by their desire for face recontouring together with rejuvenation with the notably impressive visual effects than other treatment modalities such as fillers, toxins, or energy-based devices can provide. In our study, skin quality improvement was assessed based on score changes before and after the procedure and the amount of lift was calculated based on changes in the projection of the skin's surface in comparison with the baseline project of the skin surface with is an important supplement to the subjective data from the patients' satisfaction with procedure overall, facial appearance and skin. Numerous reports now address it as one of the key criteria for the selection between different rejuvenating treatment options. Our data, reporting the dynamics of skin quality parameters and facial lift up to 12 months post-treatment, that provides and important information for aesthetic practitioners about the window where retreatment might be considered. Importantly, some authors even suggest that there is no need for patients to completely loose the lifting effects, rather additional sutures can be placed at certain timeframes to maintain and/or further improve results.¹¹

P(LA/CL)-HA threads used in our study were demonstrated to provide facial skin quality improvement and facial lift preserved through the study duration of 12 months. Noteworthy though, that the procedure was well-tolerated in all studied subjects and no adverse effects or undesirable symptoms were noted at later follow-ups. In addition, vast majority of subjects have given satisfactory responses to all questions evaluating their satisfaction with the procedure. These findings suggest that 4th generation of P(LA/CL)-HA threads with NAMICA technology is an unique, adaptable, safe, and minimally invasive approach to combined effect of skin quality improvement and tissue lifting and repositioning.

Besides skin quality improvement and face lift, assess-

ment of subject-reported outcomes indicates on the meaningful rejuvenating effects from P(LA/CL)-HA threads. Patients have mostly given "somewhat satisfied" or "very satisfied" responses to the questions measuring their satisfaction with facial appearance and skin. As demonstrated for the rage of various absorbable suspension sutures, they provide a unique result of repositioning, and lift with recontouring. While 4th generation of P(LA/CL)-HA threads showed along with above mentioned effects provides wrinkles and evenness improvement. Consistent with the inclusion and exclusion criteria for this study, the ideal patient has string bony projections and skin that is mobile and pliable and of a sufficient thickness to avoid palpability of the sutures. However, most often, the patients have facial skin redundancy and a visible nasolabial fold and/or marionette lines. These patients, although not being ideal candidates, might still benefit from such treatment. Moreover, while before it was only possible to gain the combination of effects of skin quality improvement and facial lift with thread lifting with additional procedures and other methods and treatment modalities of rejuvenation. Several reports strongly argue that the best aesthetic result is reached by combining fillers and threadlifting.¹⁴⁻¹⁶ Other studies underline the benefits of either treatment depending on clinical indications and demands and suggest rather to avoid application of multiple procedures, each having notable side effects during a recovery period. The recent comparative study by El-Mesidy et al¹⁴ evaluated the efficacy of filler injection *vs.* thread lifting reporting statistically significant improvement in GAIS favoring the filler. Importantly however an argument about the benefits of threads for patients desiring an oval, less wide face shape is also proven.¹⁴ Now with the 4th generation of P(LA/CL)-HA threads the suspension suture technique can be easily considered as the method providing the combined effect of facelift and rejuvenation through skin quality improvement. In order to better explore the elements of the combined effect of lifting and skin quality improvement, longer-scale studies with larger populations are warranted.

CONCLUSION

NAMICA technology ensures a meaningful facial rejuvenation expressed by a well-preserved improvement in skin quality, a significant mid and lower face laxity, and uttermost patients satisfaction with the procedure at least for 12 months.

CONSENT

Written consent to reproduce their recognizable photographs, use anonymized clinical data for analysis, and consent for publication were obtained from every study subject.

ETHICAL STATEMENT

Study protocol and consent form used for the study were approved by the Ethics committee of the Clinic of Plastic and Aesthetic Surgery and Cosmetology "Total Charm Vake", Tbilisi, Georgia.

AUTHORS' CONTRIBUTIONS

Albina Kajaia conceived the idea, conducted the study, collected

and analyzed the data, and wrote the manuscript.

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