

Thread lifting of the midface: A pilot study for quantitative evaluation

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Abstract

Volume restoration remains the principal target to be addressed when approaching midface rejuvenation, and absorbable sutures can create a suspension system that addresses ptotic skin located primarily in the midface. The aim of this pilot study was to investigate the effectiveness in lifting sagging tissue and to determine the outcome of thread lifting procedures of the midface. Six participants were enrolled and treated with suspension threads to correct mild to moderate ptosis of the flabby tissues of the midface. Volumetric changes were calculated at t0 (pretreatment), t1(120 days) and t2 (365 days), with a mean follow-up time of 349.64 days, (range from 304 to 380.5 days). Results showed an overall average improvement of 5.59 mL at 120 days (t0-t1) after thread implantation, up to a mean value of 4.16 mL at the end of the 350 days follow up (t0-t2). A comparison was made in between and statistical analysis was performed with level of significance set at $P < .05$. The records shown suggest that it is possible to achieve volume restoration which lasts up to 12 months as all parameters improved significantly ($P < .05$) at t1 and at t2 with respect to t0. Facial tissues suspension by means of threads is therefore safe and effective, as it is possible to achieve tissue repositioning which lasts up to 12 months for the correction of mild to moderate ptosis of the midface.

KEYWORDS

midface, quantitative evaluation, rejuvenation, threads, volume

1 | INTRODUCTION

Facial aesthetics are mainly dependent on midface features' attractiveness and treatment of its aging is therefore considered as a key component in face rejuvenation.

Adipose volumes' atrophy plays a pivotal role in facial tissues involution, with loss of malar prominence, hollowing of the tear trough and deepening of the naso-labial folds: the consequent skeletonization accounts for the tired appearance of the face.¹

Furthermore, dermatochalasis of superficial soft tissues is responsible for the malar mounding, nasolabial folding and jowling.²

These predictable changes are the result of a full-thickness process which results in subsequent gravitational ptosis of depleted facial volumes, overall covered by an altered skin envelope.

Volume depletion plays a major role in the midface more than in other areas and this has been taken into account in the development of surgical techniques and leads to the descent of the deep and superficial fat compartments.³

Indeed, volume restoration then remains the principal target to be addressed when approaching midface rejuvenation.⁴

Even though moderate and severe cases require rhytidectomy for achieving adequate improvement, thus making midface lift and facelift still the gold standard for facial rejuvenation, there is an ongoing search for less invasive techniques,⁵ as surgical invasiveness, potential complications and prolonged recovery time are always worthy of thoughtful consideration.⁶

Fat, hyaluronic acid and other agents can all restore the lost malar volume but they are generally claimed to lack in structure, durability.⁷

Alloplastic implants have been therefore advocated too for decades, but they are not suitable for every patient.⁸

Absorbable sutures can create a suspension system that addresses ptotic skin located primarily in the midface.

Nevertheless, few parameters are referred to as a reliable suggestion regarding how much to elevate or volumize in order to achieve balanced outcomes in the midface.⁹

Midface suspension with absorbable sutures has been approved by the Food and Drug Administration in 2015 and since then it is a reliable tool to rely on in order to treat mild to moderate ptosis of the facial tissues and, as a non-surgical option, it could be of choice for patient for whom surgery is contraindicated^{3,10}.

Once applied it allows to improve tissue elevation and, with proper thread insertion technique, to restore volume in the sub-malar area.^{11,12}

To the best of the authors' knowledge, published reports about thread lifting efficacy and longevity are merely based on non-standardized photographic assessment and self-related questionnaires addressed to patients, even during long follow-up periods of large patient groups and after a statistical evaluation of the results.^{13,14}

This observational study has been carried out to determine, through standardized photographic analysis, the outcome of thread lifting procedures of the midface.

2 | MATERIALS AND METHODS

2.1 | Patient population

Between December 2018 and January 2020, six participants were enrolled in this study.

Men were aged between 41 and 49 years (mean age 45.3 years), while women were between 48 and 68 years (mean age 64.5 years).

The study protocol followed the ethical guidelines of the Declaration of Helsinki and the participants were asked to give their signed informed consent (ICF) for surgery.

Exclusion criteria included

- facial soft tissue fillers,
- botulinum toxin A injections in the face

in the year prior to baseline and in the following 6 months,

- energy Based Devices application on the face

in the year prior to baseline and in the year following threads insertion.

2.2 | Technique

Enrolled participants were treated with 190 mm bidirectional barbed, poly-lactic/polycaprolactone (PLLA-PCA) 2/0 suspension threads,

(Excellence VisageEV and Excellence VisageHAEVHA, Aptos LLC, Tbilisi, Georgia) to correct mild to moderate ptosis of the flabby tissues of the midface.

Once proper disinfection with Iodopovidone 10% in water was carried out, local anesthesia was performed by subcutaneous injection of 2% lidocaine with 1:100000 epinephrine with an 80 mm blunt tip 23G cannula from an insertion point open by a 18G 40 mm needle laterally and inferiorly to the lateral canthus. After a 15 minutes lag, threads loaded in a 150 mm blunt tip 20G cannula are implanted in the mentioned insertion point, down to the nasolabial fold.

Cannulas with their inner threads were inserted deep in the subcutaneous fat and along a curvilinear pattern (Figure 1). This would allow, once the threads are tensioned, to embrace the tissue in order to both suspend and also pull the volume back.

The bidirectional barbs allow, once the cannula is removed, to fix the tissues in the planned position ensuring proper midface contouring.

Three to up to five threads were inserted in each side.

2.3 | Image capture and analysis

Calibrated and stereoscopic images of patient's face were acquired with a passive stereovision digital camera LifeViz Mini (Quantificare S.A., 06410 Biot, France) and its Quantificare 3D Viewer + surface reconstruction and analysis software before (t0), 120 days after threads implantation (t1) at a time point in which edema has subsided and changes in facial volume can be properly quantified, and after 365 days (t2).

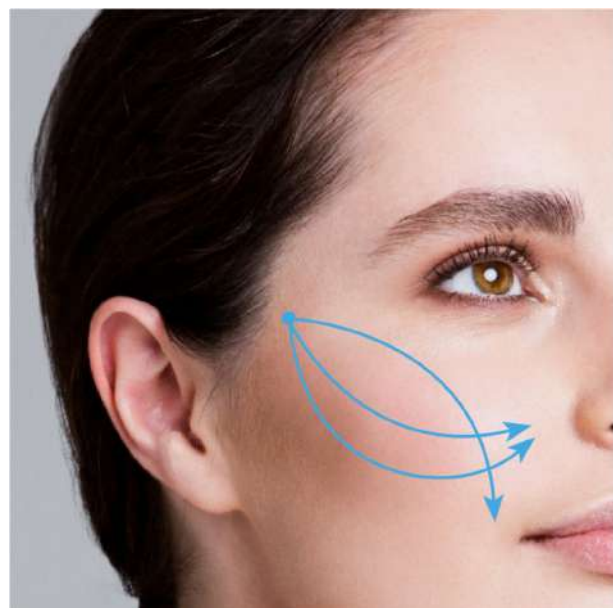


FIGURE 1 Thread insertion pattern

All patients consented to the reproduction of recognizable photographs.

Reference points were taken as described (Figure 2)

- in front of the Tragus (point Ar—Articularis);
- lateral canthus (point Ex—Exocanthon)
- nostril (point Al—Alare)
- oral commissure (point Ch—Cheilon)

in order to outline the midface area.

The stereophotographic system 3D LifeViz Mini (Canon 500D body, Dermapix software, Quantificare S.A., 06410 Biot, France) includes a customized Canon 500D, 15.1 megapixel digital reflex camera with a 39 mm bifurcated lens. Photographs were taken from a fixed distance of 60 cm with the use of two light beams that converge

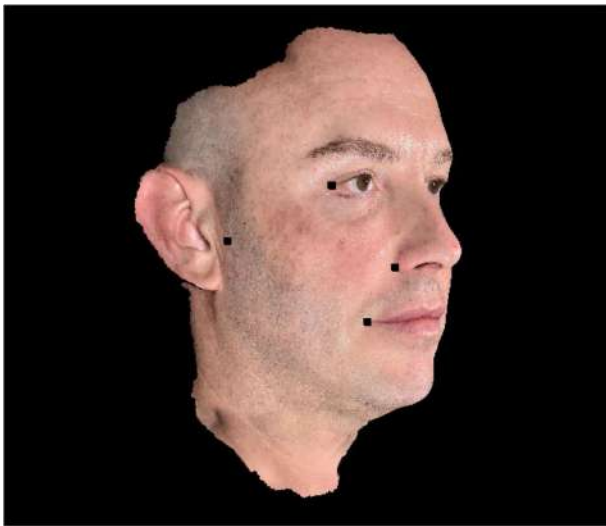


FIGURE 2 Reference points: in front of the tragus (point Ar—Articularis), lateral canthus (point Ex—Exocanthon), nostril (point Al—Alare), oral commissure (point Ch—Cheilon)

at one spot when the camera is held perpendicular at the correct distance from the targeted point.

The camera captures two images simultaneously by taking a photograph from different angles. The Dermapix software then automatically integrates the stereo images and produces a three-dimensional reconstruction in the “fine analysis” mode that the 3D Viewer app converts to visualization of 3D pictures.

The software provides alignment of pre- and postoperative images along Frankfurt Horizontal Plane, and then proceed with their comparison.

The “volume assessment” tool allows to calculate volumetric changes of the outlined area by an algorithm which compares surfaces prior to and after thread insertion thus estimating the difference in tissue suspension achieved with the inserted threads. This gradient is further converted in milliliters (ml), and then translated onto a colorimetric scale thus depicting the relative distance from images after registration (Figure 3).

Midface volumetric changes in between the mentioned points were calculated by the “Quantificare Analysis 3D Viewer +” dedicated software on the patient images at t0 (pretreatment), t1 (120 days) and t2 (365 days), with a mean follow-up time of 349.64 days, (range from 304 to 380.5 days).

3 | RESULTS

Six out of the six patients completed the study, with no dropouts during the follow-up period (Table 1).

The mean age of the examined population is 54.1 years.

Descriptive statistics showed that all analyzed parameters improved significantly ($P < .05$) at t1 and t2 with respect to t0.

All the mentioned volumetric changes were measured and retrieved by Quantificare 3D Viewer + (Quantificare S.A., 06410 Biot, France) software from patient images.

Results showed an overall average improvement of 5.59 mL at 120 days (t0-t1) after thread implantation, up to a mean value

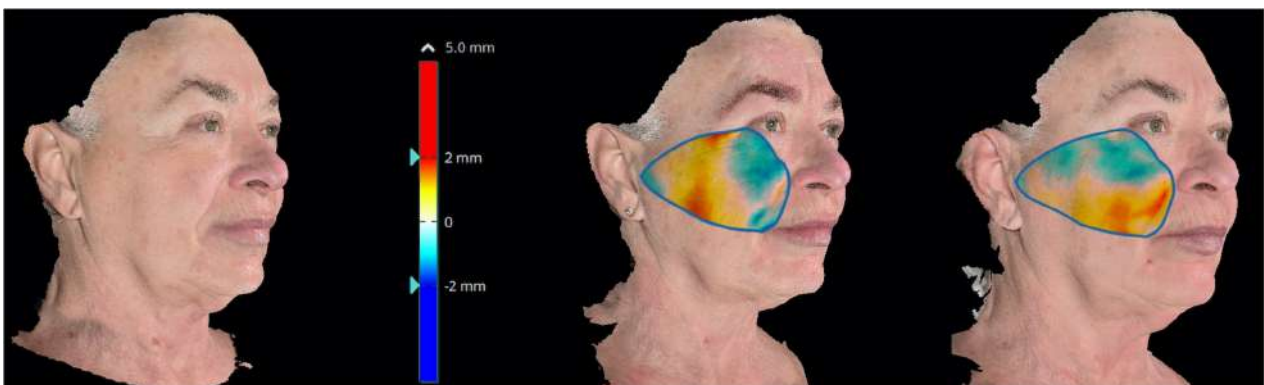


FIGURE 3 Volumetric changes of the outlined area prior to (left), 3 months (center) and 1 year (right) after thread insertion translated onto a colorimetric scale

of 4.16 mL at the end of the 350 days follow up (t0-t2) (Figures 4-6).

No adverse event was reported neither during thread insertion nor later, except for a slight aching sensation at the insertion points, which underwent spontaneous resolution in all cases.

Patient discomfort was considered mild and mainly related to thread perception and this ended up with spontaneous resolution as well in all treated cases.

3.1 | STATISTICAL ANALYSIS

The outcome to be evaluated was volume change of the suspended midface tissue in the postoperative image relative to the preoperative image.

A comparison was made between the immediate (t0-t1) and the late (t0-t2) postoperative period.

Statistical analysis was performed by using GraphPad PRISM[®] Software. D'Agostino-Pearson normality test was performed to verify data distribution. Dunn's multiple comparison test and Friedman test for repeated measures were both performed to compare

TABLE 1 Summary of patients treated in the study (measurements are in ml)

PZ		t1(120)			T2(365)		
		dx	sx	tot	dx	sx	tot
1	f	4.37	1.92	6.29	3.75	1.96	5.71
2	m	0.66	1.60	2.26	2.05	1.18	3.23
3	f	0.80	2.54	3.34	1.12	1.74	2.86
4	m	2.75	4.34	7.09	1.85	0.72	2.57
5	f	6.42	4.89	11.31	1.64	3.67	5.31
6	m	1.30	1.97	3.27	2.23	3.10	5.33

results on right and left side, and on the entire face at different time points. The level of significance for statistical analysis was set at $P < .05$.

4 | DISCUSSION

Midface aging has been extensively described: the Maxilla undergoes a reduction that follows an inferoposterior vector, and this underlies mid-facial tissue malposition.¹⁵

Furthermore, there is a late increase in volume in superficial fat pads, whereas the deep ones decrease earlier.¹⁶

The progressive weakening of the ligamentous net that tethers superficial tissues to the underlying bony scaffold leads to early sagging until hollowing of the infraorbital rim occurs, deepening of nasolabial and marionette folds, and jowls formation.^{17,18}

Furthermore, midface aging evolves as a full-thickness process, affected by both involuntional and gravitational changes.

Multiple techniques have been used to rejuvenate the midface, ranging from open surgery with extensive dissection, to minimal access, and closed, procedures with barbed sutures and no dissection.^{10,19-21}

Midface rejuvenation definitely is a demanding procedure in both volumizing and lifting aspects.

Any tissue suspension technique which does not include midface volume restoration by submalar augmentation or fat grafting, will end up in a skeletonized appearance without any balanced rejuvenation.²²

Non-surgical midface rejuvenation must achieve an adequate contouring, whether through volume injection or volume suspension, as the smooth transition between different facial regions provides for the harmony of areas of concavity and convexity within the subject's frame.^{23,24}

Unfortunately the inappropriate placement and the excessive amounts of injected fillers have led to face distortion and lack of



FIGURE 4 Frontal view, before (t0) and 120 days (t1) post treatment



FIGURE 5 Oblique view, before (t0) and 120 days (t1) post treatment



FIGURE 6 Lateral view, before (t0) and 120 days (t1) post treatment

results; this is mainly due to insufficient knowledge of the anatomy of deep fat compartments and ligaments, which always grants prompt explanation for the unmet results.²⁵

As an additive technique it may result in simply increased facial volumes with unnatural contours, visibly shifting the gravity center of the face to its lower third,¹² especially considering the lost volumes compared to the injected ones.^{26,27}

Finally, to expand facial tissue by volume injection achieves no skin-lifting effect more than a perceived improvement.²⁸

The first Author to ever mention the aesthetic applications of tissue suspension with barbed sutures, was Georgian author Sulamanidze.^{22,29,30}

The search for the best vector when placing sutures keeps evolving toward optimum tissue elevation along with improved treatment outcomes.^{12,30}

Thread lifts generally involve inserting a uni- or bi-directional suture with cones or barbs subcutaneously.¹⁰ Effectiveness of thread

lifting is related to the focal nature of soft tissues ptosis³¹ and to the way that threads works histologically.³²

It is nevertheless mandatory to state that “thread face-lifts” should instead be seen only as a temporary procedure until patient aging requires further approaches.

Thread lifting techniques must be addressed to treat moderate cutaneous falling requiring a relatively modest degree of lifting³³ and should be considered for the improvement of the entire face rather than a single fold.³⁴

Therefore proper evaluation cannot be carried on bidimensionally, as the degree of tissue suspension performed by threads cannot be considered just as a linear modification of fixed landmarks on the skin, as rejuvenation of the midface is especially obtained at its best by restoring convexities and fullness rather than pulling the skin.

To outline landmarks on the skin and to measure linear length modification in order to assess the degree of thread-lifting effect has already been done by Authors in reference to jawline rejuvenation,

where restoring the flat and regular appearance of the mandibular contour is the preferred outcome to be achieved.³⁵

The vectors of surgical facelift are of course to be considered when threads are inserted, but volume restoration cannot be missed, as in the surgical setting it is necessary to harvest a SMAS flap or to carry on fat-grafting, or even to insert prosthesis. When threads are placed to rejuvenate the midface, proper curvilinear insertion patterns have to be respected in order to collect volume in the deep subcutaneous fat layer and to pull it up to restore midface projection.

Therefore, in this case the Authors have chosen to consider the volume measured in mL as the parameter of choice, rather than by millimeter of skin lifting.

While the morphologic changes which occur with aging have been extensively and objectively characterized with conventional imaging techniques such as MRI,^{16,36,37} laser scanning,^{38,39} computed tomography and cone-beam computed tomography,^{40,41} little or no parameters exist nowadays to suggest how much to elevate or to volumize the midface with respect to desirable outcomes. The assessment of facial aesthetic outcomes therefore largely remains a subjective evaluation lacking in objective means of measurement.⁹

The introduction of tridimensional stereophotogrammetry to make reliable measurements on photographs by using simultaneously captured coordinates coming from two or more configured cameras allows us to objectively compare outcomes and their longevity.

Data calculated from a collection of points along a three axis-coordinate system enable us to obtain, once elaborated by the dedicated software, reliable measurements as well as tridimensional images and their comparison with the facial aesthetics prior to treatment.⁴²

Compared⁴¹ while it employs compact and portable equipment which is user-friendly and quick to use.⁴³

The method is, therefore, well suited to clinical settings when monitoring the pre and postoperative course.^{43,44}

Cosmetic procedures and their outcomes are assessed very subjectively, and quantitative evaluations move beyond the mere judgment of patients and clinicians, and are therefore strongly recommended in order to fill the gap in facial aging treatment and evaluation.^{45,46}

This is why the Authors measured using a standardized tridimensional stereophotogrammetry device among objective (anthropometric) landmarks in the presented paper.

The aim of this pilot study was to quantitatively investigate the effectiveness in lifting sagging tissue in the correction of mild to moderate ptosis of the midface.

The Authors checked on changes in facial volume, and although a certain degree of ptosis recurrence has to be taken into account, the follow-up time allowed to assess the longevity of the results, largely assured by the histological reaction of the tissue around the implanted threads,⁴⁷ as the effects of face rejuvenation performed by thread insertion and tissue suspension are claimed to persist up to 1 to 1.5 years thanks to the collagen stimulation provided by the PLLA.⁴⁸

The results shown in this work suggest that it is possible to achieve volume restoration with the outlined operative protocol that can therefore be considered safe and reliable.

This study comes however with at least some limitations that require thoughtful consideration.

The mean age of the study population is quite advanced (54.1 years), as this rejuvenating technique is usually addressed to younger patients.

As this is a pilot study, the limited number of treated subjects urges the Authors to consider the presented outcomes as preliminary, although statistically validated, since it was not possible to carry out an age-related analysis.

Furthermore, the follow-up duration is somewhat limited, with respect to PLLA-PCA thread result longevity, which is claimed to be between 12 and 18 months. The Authors agree with this judgment and consider that the here mentioned follow-up variability (12 months) is coherent with a pilot study, and it is reliable for the presented statistical evaluation.

Indeed, future investigations with longer follow-ups are strongly advised.

The statistical evaluation has been conducted for the purpose of validating the quantitatively assessed volume variations; this leads to two considerations around the analysis and results.

First, with the ANOVA test the initial volume has been assumed to be 0, and the change in volume was quantified and plotted after 3 months and 1 year. One could argue that any variation against 0 could be considered as significant. Nevertheless, as the focus of the investigation is the effect of thread action on facial volumes, then the entity of variation rather than its clinical relevance are the important points.

Finally, the aging process will not come to a halt after a rejuvenating treatment, and changes occurred along the 1 year-follow-up have to be looked upon from this perspective.

The level of evidence with respect to the Levels of Evidence classification of the Oxford Centre for Evidence-based Medicine (OCEBM),⁴⁹ is 4. Nevertheless, to the best of our knowledge, this is the first objective, standardized photographic analysis of midface suspension by barbed, resorbable threads.

The shown quantitative measurements require some training. Even though the software use is intuitive, once one is familiar with it the process gets more user-friendly and not excessively time consuming since, as already mentioned, it can be difficult to incorporate it in the daily practice.

This is still a unique tool for non-invasively collecting and comparing reliable measurements of facial aesthetics.

Absorbable sutures have been shown to have an improved safety and efficacy profile in case of minimally invasive treatments for ptotic facial skin, and they should be considered a workhorse in nonsurgical lifting of such.¹⁰

This study has been carried out to overcome subjectivity of cosmetic procedures assessment in evaluating thread lifting, thus providing detailed and reliable results, along with their statistical evaluation up to 12 months. The Authors strongly believe that evidence has to be incorporated in clinical practice⁵⁰ and longer follow-up, larger patient groups and studies on different facial areas are indeed needed to further investigate the reliability of outcomes evaluation done by

stereophotogrammetry and to objectively assess the effectiveness of thread lifting in treating facial ptosis given these positive preliminary results.

5 | CONCLUSIONS

The results of this pilot study suggest that facial tissues suspension by means of PLLA-PCA threads is safe and effective, and with a proper technique it is possible to achieve tissue repositioning which lasts up to 12 months for the correction of mild to moderate ptosis of the midface by shifting volumes (as quantitatively evaluated at 1 year-follow up).

No side effect was reported, and no complication occurred: the operative protocol and the chosen thread lifting method were both proved to be safe and reliable.

Threads action in suspending facial tissues is immediate, effective and reliably long-lived.

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CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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